CLINICALTRIALS.GOV PLAYBOOK

Statement of purpose

- In an effort to enhance accountability and transparency, NIH as well as the FDA and the International Committee of Medical Journal Editors requires certain clinical trials to be prospectively registered in Clinicaltrials.gov. This guide is designed to aid that process by provided definitions and guidance for all data elements in Clinicaltrials.gov.

General Q & A

- Who can create a record?
  - The PI can designate anyone to establish a record. That individual will become the "record owner".
  - This task is best left to someone with a strong understanding of the study methodology to ensure data entry is accurate.
  - The record owner can be changed at any time, just contact an administrator

- Who can modify a record?
  - Anyone listed as study owner, PI or on the access list can modify a record

- Who can add individuals to a study record access list?
  - The record owner or an administrator can add individuals to the study record access list

- Who can release a record?
  - **Only the PI can release the record.**

- What happens if the PI leaves the university?
  - If the study will continue at the University of Kentucky, the responsible party will need to be changed in the study record to whom ever is continuing the study at UK.
  - If the study is ongoing, but the PI is taking it to their new institution, contact an administrator to have the study record transferred to the new institution.
  - If the study is complete, the record will remain in UK's CT.gov database even if the PI leaves.

- See the "What happens next" section for information related to study start up, completion, termination and study's being withdrawn
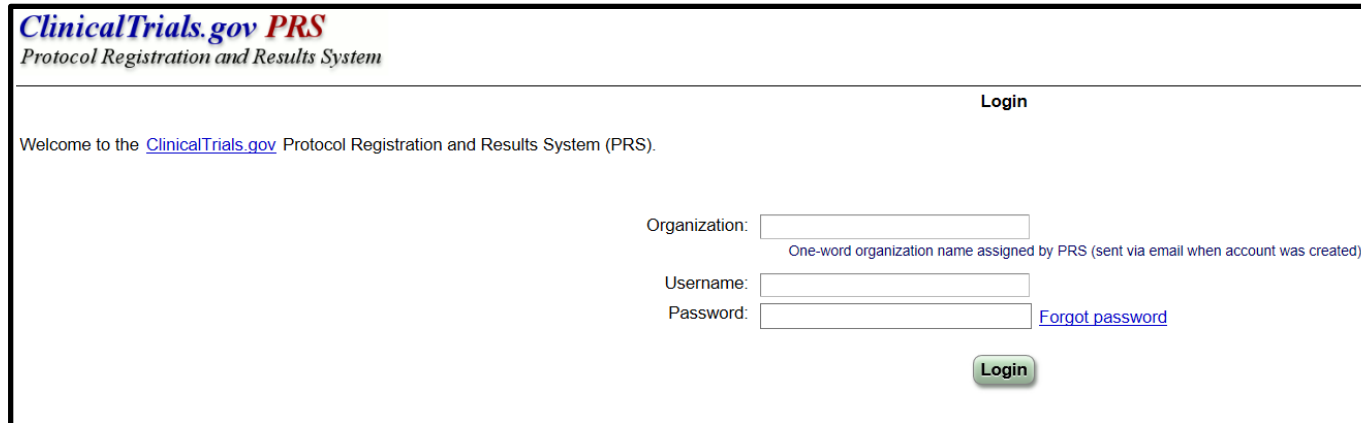
Key dates

For trials initiated after January 18, 2017, the final rule establishes specific reporting dates for certain trial related events and milestones:

Data Element	Deadline for Updating (i.e., not later than the specified date)
Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
Intervention Name(s)	30 calendar days after a nonproprietary name is established.
Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after an NCT number is assigned to a newly created expanded access record. [1]
Expanded Access Status	30 calendar days after a change in the availability of expanded access.
Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
Overall Recruitment Status	30 calendar days after a change in overall recruitment status. [2]
Individual Site Status	30 calendar days after a change in status of any individual site.
Human Subjects Protection Review Board Status	30 calendar days after a change in status.
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
Enrollment	At the time the primary completion date is changed to "actual," the actual number of participants enrolled must be submitted.
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
Responsible Party, by Official Title	30 calendar days after a change in the responsible party or the official title of the responsible party.
Responsible Party Contact Information	30 calendar days after a change in the responsible party or the contact information for the responsible party.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Record Verification Date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

New users
General

- If you are new to Clinicaltrials.gov, email Emily.Bradford@uky.edu (UK CT.gov administrator) to establish a login and password.

- You will receive an automated email message from CT.gov informing you that your credentials have been created. Click the link in that email to login. You will be taken to the following screen:

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

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

Username: _____
Password: _____   Forgot password

Login

- The organization will always be "UKentucky". Enter your login (listed in the email) and the temporary password and select "login"

New users
First time login

- You will now see the following screen upon login:
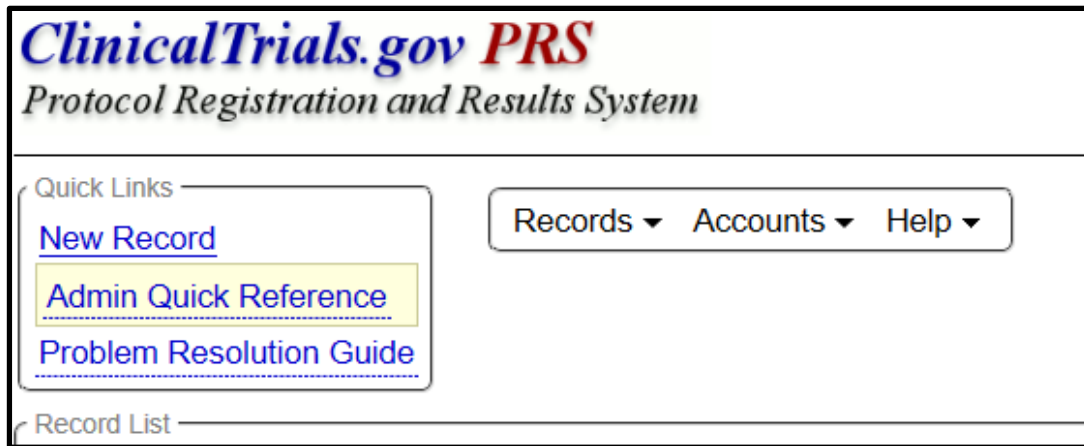
- Select the "Accounts" tab, then "change password" to create your own unique password

- If you forget your password, the system administrator can reset it. Simply email Emily.Bradford@uky.edu

Forgotten password

- In the event that you have forgotten your Clinicaltrials.gov password, simply email the system administrator Emily Bradford at Emily.Bradford@uky.edu to have it reset.

Creating a new record

- To create a new record, select "New Record" in the upper left hand corner of the screen:
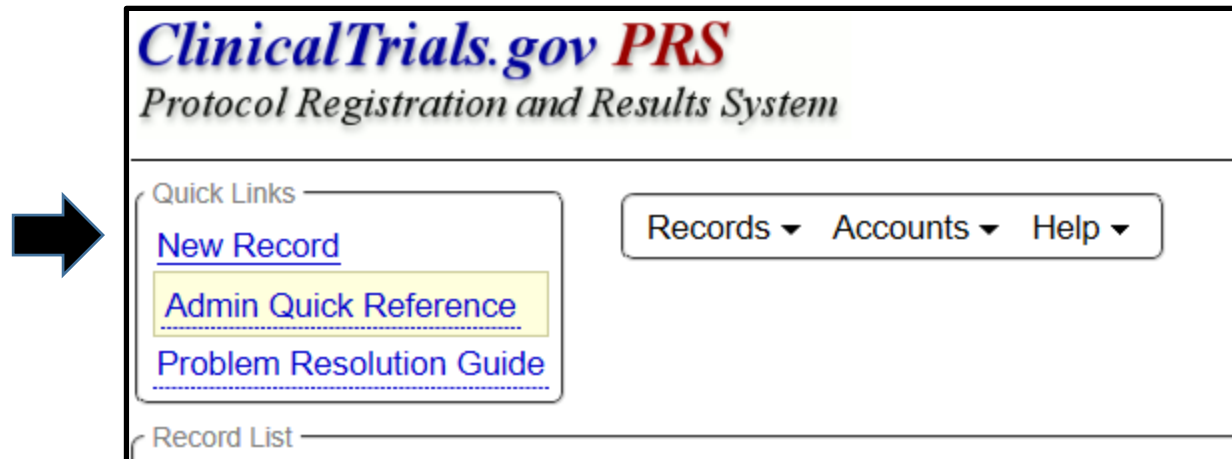
Creating a new record

- Having selected "new Record", you will see the following screen:

- Please use your IRB approval number for the "Organization's Unique Protocol ID".
- Then answer the remaining questions on this page and the system will generate the required data elements and you can continue registering your study.

CT.gov data elements for trial registration

- Study identification
- Study status
- Sponsor/collaborator
- Oversight
- Description
- Conditions
- Study design
- Interventions
- Eligibility
- Contacts/locations
- References

- Basic navigation
  - Select "edit" to enter a data element

  Edit   **Study Status**
  Record Verification:
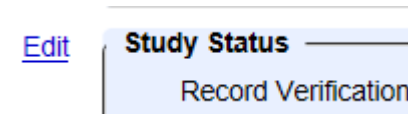
  - Select "Save" at any point to save data entered. Select "cancel" to exit the data element (data will not be saved if you select "cancel").

  Save   Cancel

  - The record can be opened and closed as often as necessary to complete the data entry.

Study Identification

- **Unique Protocol Identification Number ***
  Definition: Any unique identifier assigned to the protocol by the sponsor.

  - This will typically be your study's IRB number unless otherwise stated

- **Brief Title ***
  Definition: A short title of the clinical study written in language intended for the lay public. The title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.
  Limit: 300 characters.

  - This is equivalent to a running title for a manuscript

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

  - Examples include: PROVE-IT, HOPE, ENHANCE

- **Official Title *§**
  Definition: The title of the clinical study, corresponding to the title of the protocol. Limit: 600 characters.

- **Secondary IDs [*]**
  For more on secondary IDs, see the next slide

Study Identification

- **Secondary IDs [*]**
  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 clinical study. This includes any unique clinical study identifiers assigned by other publicly available clinical trial registries. If the clinical study is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID. Limit: 30 characters.

- When you select the "Add secondary ID" tab, the following will appear on screen:

- Simply follow the prompts to complete the secondary ID section.

Study Identification
Issues

- Most likely issues with this data element:

    - Very short "brief titles" will typically result in a "note" flag questioning if the title is descriptive enough. Resolution of this is at the discretion of the investigator

    - "Official title" is very short. This title should describe the study in a very detailed manner. Short titles here will also likely get flagged and will need resolved to submit the record.

    - If you list a collaborator such as NIH in the "Sponsor/Collaborator" element as being a funding agency but have not listed an NIH grant # as a Secondary ID in this section, the PRS review will create and "Error" message and the record cannot be submitted until this error is resolved.

Study Status

Study Status

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

  - You must interact with your study record at least once a year. Any time you open the record, review it and change this date to reflect your interaction with the database.

- **Overall Recruitment Status ***
  Definition: The recruitment status for the clinical study as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical study has an Individual Site Status of "Recruiting," then the Overall Recruitment Status for the study must be "Recruiting." Select one.

  - Not yet recruiting: Participants are not yet being recruited
  - Recruiting: Participants are currently being recruited, whether or not any participants have yet been enrolled
  - Enrolling by invitation: Participants are being (or will be) selected from a predetermined population
  - Active, not recruiting: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled
  - Completed: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred)
  - Suspended: Study halted prematurely but potentially will resume
  - Terminated: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention
  - Withdrawn: Study halted prematurely, prior to enrollment of first participant

    - If a study is withdrawn, the following text box will appear:

      - **Why Study Stopped *§**
        Limit: 160 characters.
        Definition: A brief explanation of the reason(s) why such clinical study was stopped (for a clinical study that is "Suspended," "Terminated," or "Withdrawn" prior to its planned completion as anticipated by the protocol).

Study Status

Help   Definitions

* Record Verification Date: Month: January ▾ Year: 2018

* Overall Recruitment Status: --Select-- ▾
Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: --Select-- ▾ Day: [ ] Year: [ ] Type: --Select-- ▾
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: --Select-- ▾ Day: [ ] Year: [ ] Type: --Select-- ▾
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: --Select-- ▾ Day: [ ] Year: [ ] Type: --Select-- ▾
Final data collection date for study.

Continue   Back   Quit

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

- **Study Start Date *§**
Definition: The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.
  - Note: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

- **Primary Completion Date ***
Definition: The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.
  - Once the clinical study has reached the primary completion date, the responsible party must update the Primary Completion Date to reflect the actual primary completion date.

- **Study Completion Date *§**
Definition: The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant's last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated.
  - Once the clinical study has reached the study completion date, the Responsible Party must update the Study Completion Date to reflect the actual study completion date.

Study Status
Issues

This section will generate 90% of the errors with a study record prior to completion of the recruitment process.

- **The most common issues are:**
  - **Entering an "anticipated" start date and have the study listed as "not yet recruiting" when the study record is created, then having that start date pass. The system will flag the record indicating the "anticipated" start date has past but the study is still listed as "not yet recruiting".**
    - **If you have begun recruiting, make sure to sign in and change the "recruiting status" to "recruiting" and change the anticipated start date to the date the first subject signed their consent. Then change the date "type" to "actual" from "anticipated". You will also need to change the recruiting status in the "Contact/Location" data element to "recruiting".**
    - **If the study still has not started, simply adjust the "anticipated start date" to some point in the future**

- **The same issue can arise at the end of the study were the "primary completion date" will pass; however, the "overall recruiting status" will still be listed as "recruiting".**
  - **If the study is still ongoing, simply move the "primary completion date" and "study completion date" to some new anticipated end point in the future.**
  - **If the study has reached its recruiting goals, change the recruitment status to either "active, no longer recruiting" meaning the last subject has been recruited but data is still being collected, or**
  - **"complete" , meaning the study has collected its final endpoint data and adjust the completion dates from *anticipated* dates to *actual* dates. Once the study is compete, the system will expect data to be enter in one year for Applicable clinical trials.**

Sponsor/Collaborator

Sponsor/Collaborator

- **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
  - The University of Kentucky will *never* be the responsible party. The responsible party will always be the principle investigator or the sponsor-investigator. If the study has an external sponsor (Pharma, etc) the study will be listed under that organization's CT.gov account.

- **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. Must be the University of Kentucky. If the responsible party is not affiliated with UK, the study must be registered with that individual's institutional CT.gov registry, not UK's.

- **Collaborators**
Definition: Other organizations (if any) *OUTSIDE THE UNIVERSITY* providing support. Support may include funding, design, implementation, data analysis or reporting. The responsible party is responsible for confirming all collaborators before listing them. Limit: 160 characters. Any listed collaborator must be included in the "Secondary ID" box in the Study Identification element, otherwise the PRS review will return an error message

Oversight

Oversight
General

The key question to ask regarding the statements : "US FDA-regulated drug" and "US FDA regulated device" is not whether you're using an FDA regulated product but rather are you ***studying*** an FDA regulated product. The answer to either statement is only yes if your outcomes are based on the performance of that substance or device.   Ex: a new device trial requires local anesthesia prior to placement. The answer to "US FDA regulated drug" is no even though your are providing an FDA regulated drug because your outcomes are based on the device performance.

- **Studies a U.S. FDA-regulated Drug Product *§** (*Optional for Observational Studies*)
  Definition: Indication that a clinical study is studying a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act.

- **Studies a U.S. FDA-regulated Device Product *§** (*Optional for Observational Studies*)
  Definition: Indication that a clinical study is studying a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.
  - If you are using an FDA-regulated device product, click here for further information

- **Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information** (*Optional for Observational Studies*)
  Definition: Complete the following information regarding an IND or IDE for the clinical study as defined under U.S. Food and Drug Administration (FDA) regulations in 21 CFR 312.3 or 21 CFR 812, respectively.
  - If you're using an IND/IDE, click here for further information

- **Human Subjects Review ***
  Definition: Studies must have approval (or be exempt, as appropriate) from a Human Subjects Protection Review Board prior to the enrollment of the first participant to be eligible for registration. A study may be submitted for registration prior to approval by the review board so long as the study is not yet recruiting participants.
  - For human subjects review, click here for further information

- **Data Monitoring Committee**
  Definition: Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study. Select Yes/No.

- **FDA Regulated Intervention**
  Definition: Indicate whether this study includes an intervention subject to U.S. Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug, and Cosmetic Act: 505, 510(k), 515, 520(m), and 522. Select Yes/No.
  - **Section 801 Clinical Trial**
    Definition: If this study includes an FDA regulated intervention, indicate whether this is an applicable clinical trial as defined in U.S. Public Law 110-85, Title VIII, Section 801. Select Yes/No.

Oversight
FDA-regulated device product

- **Studies a U.S. FDA-regulated Device Product *§** (*Optional for Observational Studies*)
  Definition: Indication that a clinical study is studying a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.

- **Device Product Not Approved or Cleared by U.S. FDA *§** (*formerly "Delayed Posting"*)
  Definition: Indication that at least one device product studied in the clinical study has not been previously approved or cleared by the U.S. Food and Drug Administration (FDA) for one or more uses. Select one.

  Yes: At least one studied FDA-regulated device product has not been previously approved or cleared by FDA

- No: All studied FDA-regulated device products have been previously approved or cleared by FDA

-
  Note: Full posting of registration information will be delayed if "Yes" is selected and the study is an applicable clinical trial that is required to be registered under 42 CFR 11.22. However, the responsible party may authorize NIH to post the information using the Post Prior to U.S. FDA Approval or Clearance data element.
  Post Prior to U.S. FDA Approval or Clearance
  Definition: Authorize NIH to post publicly clinical trial registration information for a clinical study of a device product that has not been previously approved or cleared (that would otherwise be subject to delayed posting). Select Yes/No.

- **Pediatric Postmarket Surveillance of a Device Product [*]**
  Definition: Indication that a clinical study that includes a U.S. FDA-regulated device product is a pediatric postmarket surveillance of a device product ordered under section 522 of the Federal Food, Drug, and Cosmetic Act. Select Yes/No

Oversight
FDA IND/IDE

- **Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information** (*Optional for Observational Studies*)
Definition: Complete the following information regarding an IND or IDE for the clinical study 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 the clinical study is being conducted under an IND or IDE application filed with the FDA. Select one.
(*Will not be made public - for administrative purposes only*)

  - Yes: Clinical study is conducted under an IND or IDE filed with the FDA.
  - No: Clinical study is not conducted under an IND or IDE filed with the FDA. Includes a clinical study that is "IND exempt" under FDA regulations in 21 CFR 312.2(b), or is for a non-significant risk device subject to FDA-abbreviated IDE requirements in 21 CFR 812.2(b), or is exempt from the IDE filing requirements in 21 CFR 812.

- If there is an IND or IDE filed with the FDA for the clinical study, 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/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 clinical study. (*Will not be made public - for administrative purposes only.*)

Oversight
Expanded access

- **Availability of Expanded Access [*]**
Definition: Whether there is expanded access to the investigational product for patients who do not qualify for enrollment in a clinical trial. Expanded Access for investigational drug products (including biological products) includes all expanded access types under section 561 of the Federal Food, Drug, and Cosmetic Act: (1) for individual participants, including emergency use; (2) for intermediate-size participant populations; and (3) under a treatment IND or treatment protocol. Select one.

- Yes: Investigational product is available through expanded access

- No: Investigational product is not available through expanded access

- Unknown: If the responsible party is not the sponsor of the clinical trial and manufacturer of the investigational product

- **Expanded Access Record NCT Number [*]**
Definition: If expanded access is available, the NCT number of the expanded access record. If there is no existing expanded access record, the responsible party who is both the manufacturer of the investigational drug product (including a biological product) and the sponsor of the ACT is required to create an expanded access record. (For more information on data requirements for this Study Type, see Expanded Access Data Element Definitions).

Oversight
Human subjects protection

- **Human Subjects Review ***
  Definition: Studies must have approval (or be exempt, as appropriate) from a Human Subjects Protection Review Board prior to the enrollment of the first participant to be eligible for registration. A study may be submitted for registration prior to approval by the review board so long as the study is not yet recruiting participants.

- **Human Subjects Protection Review Board Status ***
  Definition: Indicate whether a clinical study has been reviewed and approved by at least one human subjects protection review board or such review is not required per applicable law (for example, 21 CFR Part 56, 45 CFR Part 46, or other applicable regulation). Select one.

  - Request not yet submitted: Review board approval is required but has not yet been requested
  - Submitted, pending: Review board approval has been requested but not yet granted
  - Submitted, approved: Review board approval has been requested and obtained
  - Exempt: An exemption in accord with applicable law and regulation has been granted
  - Submitted, denied: Review board has denied the approval request
  - Submission not required: Review board approval is not required because the study is not subject to laws, regulations, or applicable institutional policies requiring human subjects review

Oversight
Human subjects protection continued

- If the study is not an applicable clinical trial that is required to be registered under 42 CFR Part 11, is not funded in whole or in part by the U.S. Government, and is not conducted under an IND or IDE, then the following information is required:
  - **Board Approval Number [*]**
    Definition: Number assigned by the human subjects review board upon approval of the protocol. May be omitted if status is anything other than approved. (*Will not be made public - for administrative purposes only.*)
  - **Board Name [*]**
    Definition: Full name of the approving human subjects review board. (*Will not be made public - for administrative purposes only.*)
  - **Board Affiliation [*]**
    Definition: Official name of organizational affiliation of the approving human subjects review board. (*Will not be made public - for administrative purposes only.*) Limit: 255 characters.
  - **Board Contact [*]**
    Definition: Contact information for the human subjects review board. (*Will not be made public - for administrative purposes only.*)
    - **Phone** (or Email required): Phone number
    - **Extension**: Phone extension, if needed
    - **Email** (or Phone required): Electronic mail address.
    - **Address**: Mailing address for the board, including street address, city, State or province, postal code, and country.

Oversight
Data monitoring and FDA regulated interventions

- **Data Monitoring Committee**
  Definition: Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study. Select Yes/No.

- **FDA Regulated Intervention**
  Definition: Indicate whether this study includes an intervention subject to U.S. Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug, and Cosmetic Act: 505, 510(k), 515, 520(m), and 522. Select Yes/No.

  - **Section 801 Clinical Trial**
    Definition: If this study includes an FDA regulated intervention, indicate whether this is an applicable clinical trial as defined in U.S. Public Law 110-85, Title VIII, Section 801. Select Yes/No.

Study Description

Study description

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.

Save   Cancel

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

- **Brief Summary ***
  Definition: A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public.
  Limit: 5000 characters.

- **Detailed Description**
  Definition: Extended description of the protocol, including more technical information (as compared to the Brief Summary), if desired. Do not include the entire protocol; do not duplicate information recorded in other data elements, such as Eligibility Criteria or outcome measures.
  Limit: 32,000 characters.
  For Patient Registries: Also describe the applicable registry procedures and other quality factors (for example, third party certification, on-site audit). In particular, summarize any procedures implemented as part of the patient registry, including, but not limited to the following:
  Quality assurance plan that addresses data validation and registry procedures, including any plans for site monitoring and auditing.

- Data checks to compare data entered into the registry against predefined rules for range or consistency with other data fields in the registry.

- Source data verification to assess the accuracy, completeness, or representativeness of registry data by comparing the data to external data sources (for example, medical records, paper or electronic case report forms, or interactive voice response systems).

- Data dictionary that contains detailed descriptions of each variable used by the registry, including the source of the variable, coding information if used (for example, World Health Organization Drug Dictionary, MedDRA), and normal ranges if relevant.

- Standard Operating Procedures to address registry operations and analysis activities, such as patient recruitment, data collection, data management, data analysis, reporting for adverse events, and change management.

- Sample size assessment to specify the number of participants or participant years necessary to demonstrate an effect.

- Plan for missing data to address situations where variables are reported as missing, unavailable, non-reported, uninterpretable, or considered missing because of data inconsistency or out-of-range results.

- Statistical analysis plan describing the analytical principles and statistical techniques to be employed in order to address the primary and secondary objectives, as specified in the study protocol or plan.

Study description

Issues

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.

Save   Cancel

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

- Potential issues:
  - The brief description will get flagged if the system reviewer believes the content is too technical. Use this section to describe your study proposal/design to a non-scientist.
  - The detailed description should not contain:
    - Any mention of compensation
    - Inclusion/exclusion criteria
    - Primary end point details
    - Secondary end point details
    - No personal pronouns, make sure to change "we" to "the investigators" and "you" to "participants". This results in a lot of returned registries.

  - It may be easier to complete the remainder of the registry, then come back to the detailed description. Having filled in the remaining elements, you'll be more aware of any duplication that may be noted in this element.

Conditions/Keywords

Conditions/Keywords

* **Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study ***
Definition: The name(s) of the disease(s) or condition(s) studied in the clinical study, or the focus of the clinical study. 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 Unified Medical Language System (UMLS) Metathesaurus.

  * **For a link to MeSH, click here**
  * **This will be the same information found in FORMS-E, Human Subjects and Clinical Trials Information, Section 2.1 "Conditions or Focus of Study", also derived from a MeSH search**

* **Keywords**
Definition: Words or phrases that best describe the protocol. 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.

  * This section is identical to keywords used when writing a manuscript.

Study Design

Study Design
Interventional studies

Study Design
Interventional

Help Definitions

* Study Type: Interventional
* § Primary Purpose: --Select--
* Study Phase: --Select--
   Use "N/A" for trials that do not involve drug or biologic products.
* § Interventional Study Model: --Select--
Model Description:
* § Number of Arms:
* § Masking:
   ☐ Participant
   ☐ Care Provider
   ☐ Investigator
   ☐ Outcomes Assessor
   ☐ None (Open Label)
   Check all roles that are masked or check None (Open Label).
Masking Description:
* § Allocation: --Select--
   Select N/A for single-arm studies.
* § Enrollment: Number of Subjects: Type: --Select--

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

- **Interventional Study Design * (***For interventional studies only***)**
  Definition: A description of the manner in which the clinical trial will be conducted, including the following information:
  - If your study is not interventional, exit the study design element and select "change" next to intervention prior to selecting "edit" to modify the study design element
  - Instructions for Observational and expanded access study design will be listed after the Intervention Study Design section.

Study Design
Interventional
Primary purpose

* **Primary Purpose *§**
  Definition: The main objective of the intervention(s) being evaluated by the clinical trial. Select one.

  * **Treatment**: One or more interventions are being evaluated for treating a disease, syndrome, or condition.

  * **Prevention**: One or more interventions are being assessed for preventing the development of a specific disease or health condition.

  * **Diagnostic**: One or more interventions are being evaluated for identifying a disease or health condition.

  * **Supportive Care**: One or more interventions are evaluated for maximizing comfort, minimizing side effects, or mitigating against a decline in the participant's health or function.

  * **Screening**: One or more interventions are assessed or examined for identifying a condition, or risk factors for a condition, in people who are not yet known to have the condition or risk factor.

  * **Health Services Research**: One or more interventions for evaluating the delivery, processes, management, organization, or financing of healthcare.

  * **Basic Science**: One or more interventions for examining the basic mechanism of action (for example, physiology or biomechanics of an intervention).

  * **Device Feasibility**: An intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; or a clinical trial to test a prototype device for feasibility and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

  * **Other**: None of the other options applies.

Study Design
Interventional
Study Phase

- **Study Phase** *

  Definition: For a clinical trial of a drug product (including a biological product), the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21 and in 21 CFR 312.85 for phase 4 studies. Select only one.

  - **N/A**: Trials without phases (for example, studies of devices or behavioral interventions).
  - **Early Phase 1 (Formerly listed as "Phase 0")**: Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information.
  - **Phase 1**: Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
  - **Phase 1/Phase 2**: Trials that are a combination of phases 1 and 2.
  - **Phase 2**: Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks.
  - **Phase 2/Phase 3**: Trials that are a combination of phases 2 and 3.
  - **Phase 3**: Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug.
  - **Phase 4**: Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.

Study Design
Interventional
Interventional Study Model

- **Interventional Study Model *§**
  Definition: The strategy for assigning interventions to participants.

  - **Single Group**: Clinical trials with a single arm

  - **Parallel**: Participants are assigned to one of two or more groups in parallel for the duration of the study

  - **Crossover**: Participants receive one of two (or more) alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study

  - **Factorial**: Two or more interventions, each alone and in combination, are evaluated in parallel against a control group

  - **Sequential**: Groups of participants are assigned to receive interventions based on prior milestones being reached in the study, such as in some dose escalation and adaptive design studies

  - **Model Description**
    Definition: Provide details about the Interventional Study Model. Limit: 1000 characters.

Study Design

Interventional
Number of Arms, Masking, Masking description, Allocation

Edit Interventional Study Design

Help Definitions

* Study Type: Interventional
* § Primary Purpose: --Select--
* Study Phase: --Select--
Use "N/A" for trials that do not involve drug or biologic products.
* § Interventional Study Model: --Select--
Model Description:
* § Number of Arms:
* § Masking:
☐ Participant
☐ Care Provider
☐ Investigator
☐ Outcomes Assessor
☐ None (Open Label)
Check all roles that are masked or check None (Open Label).
Masking Description:
* § Allocation: --Select--
Select N/A for single-arm studies.
* § Enrollment: Number of Subjects: Type: --Select--

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

- **Number of Arms *§**
Definition: The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during all periods or phases.Note: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

- **Masking *§**
Definition: The party or parties involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual participants. Select all that apply.
  - Roles, if Masking:
    - Participant
    - Care Provider
    - Investigator
    - Outcomes Assessor: The individual who evaluates the outcome(s) of interest
  - No Masking

- **Masking Description**
Definition: Provide information about other parties who may be masked in the clinical trial, if any.
Limit: 1000 characters.

- **Allocation *§**
Definition: The method by which participants are assigned to arms in a clinical trial.

  - N/A (not applicable): For a single-arm trial
  - Randomized: Participants are assigned to intervention groups by chance
  - Nonrandomized: Participants are expressly assigned to intervention groups through a non-random method, such as physician choice

Arms and interventions

Interventional

Arms and Interventions
Arms

- **Arm Information** * (*For interventional studies only*)
  Definition: A description of each arm of the clinical trial that indicates its role in the clinical trial; provides an informative title; and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

- **Interventions** *
  Definition: Specify the intervention(s) associated with each arm or group; at least one intervention must be specified for interventional studies. For observational studies, specify the intervention(s)/exposure(s) of interest, if any. If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.

- **Arm or Group/Interventional Cross-Reference** *
  Definition: If multiple Arms or Groups have been specified, indicate which Interventions (or exposures) are in each Arm or Group of the study, using the Cross-Reference check boxes.

Arms and Interventions
Arms

A

B

- **Arm Information** * (*For interventional studies only*)
Definition: A description of each arm of the clinical trial that indicates its role in the clinical trial; provides an informative title; and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

  A. This is the view you'll get if you have not assigned any Arms in your Study Design element.

  B. If you've included the number of Arms in your Study Design element your Arms window will look like this (this assumes two arms were indicated in the previous section.

Arms and Interventions

Arms

Help Definitions

Arms:
* Arm Title: [_____]

Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

* Arm Type: [--Select-- ▼]
[*] Arm Description:
[_____]

Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

[× Delete Arm]

* Arm Title: [_____]
* Arm Type: [--Select-- ▼]
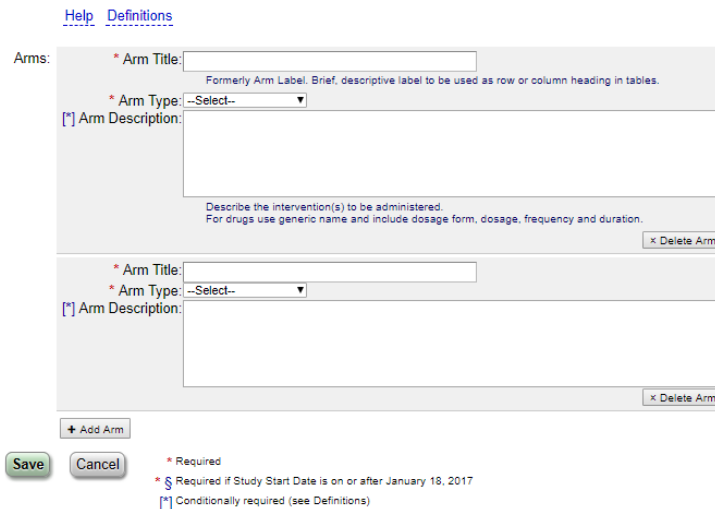[*] Arm Description:
[_____]

[× Delete Arm]

[＋ Add Arm]

[Save] [Cancel]

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

- **Arm Information** * (*For interventional studies only*)
Definition: A description of each arm of the clinical trial that indicates its role in the clinical trial; provides an informative title; and, if necessary, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.

- **Arm Title** *
Definition: The short name used to identify the arm.
Limit: 62 characters.

  - This title should be similar to what you would title the column of this data in a spreadsheet application. Needs to be descriptive, not just "group 1" or "Arm 1"

- **Arm Type** *
Definition: The role of each arm in the clinical trial.

  - Experimental
  - Active Comparator- *Standard of Care falls into this group*
  - Placebo Comparator
  - Sham Comparator
  - No Intervention
  - Other

- **Arm Description [*]**
Definition: If needed, additional descriptive information (including which interventions are administered in each arm) to differentiate each arm from other arms in the clinical trial.
Limit: 999 characters.

  - You must use the exact name of the intervention (drug, device, etc.) from the next section in this text box to prevent a PRS review error message when the system compares your intervention name in the intervention element to the Arms description element.

Arms and Interventions

Intervention
Type

Arms: [No Arms have been specified.]

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: [ ] × Delete
(if any) + 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

Save   Cancel

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

- **Interventions ***
  Definition: Specify the intervention(s) associated with each arm or group; at least one intervention must be specified for interventional studies. For observational studies, specify the intervention(s)/exposure(s) of interest, if any. If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.

- **Intervention Type ***
  Definition: For each intervention studied in the clinical study, the general type of intervention. Select one.

  - **Drug**: Including placebo

  - **Device**: Including sham

  - **Biological/Vaccine**

  - **Procedure/Surger**y

  - **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**

Arms and Interventions
Intervention
Name and Description

- **Intervention Name(s) ***
  Definition: A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study. *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. *Do not use a trade name in this field*
  Limit: 200 characters.

  - **Other Intervention Name(s) [*]**
    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(s), including, but not limited to, past or present names such as brand name(s), or serial numbers. *This is the location to indicate trade names of the intervention such as drug brand name or device brand name.*
    Limit: 200 characters.

  - This is not required if your intervention only has one name. Your protocol entry may include a "note" from the PRS review indicating that the text box is blank. This will not effect your protocol.

- **Intervention Description ***§
  Definition: Details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical study. For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.
  Limit: 1000 characters.

Arms and Interventions

Cross-reference

- **Arm or Group/Interventional Cross-Reference ***
  Definition: If multiple Arms or Groups have been specified, indicate which Interventions (or exposures) are in each Arm or Group of the study, using the Cross-Reference check boxes.

- The system will automatically populate this section based on the arms/intervention data input

- The system will generate a matrix for assigning interventions to specific arms based on the data the user inputs. Simply select the boxes where appropriate in the matrix to match your Arm/intervention details.

Arms and Interventions
Common issues

- The Arms and Interventions element tends to create many *notes, warnings* and *errors* with PRS review.

- Some common issues in this section:
  - The intervention name must appear in the Arm description exactly as it does in the Intervention name section.
  - Arm titles must be descriptive to pass review (don't use group 1 and group 2, etc.)

- Notes and warnings will not prevent the record from being released to the public domain, they simply indicate that the review regards elements as not being clear, and to please correct. Errors are issues that must be fixed prior to be declared complete within the public domain.

Study Design
Observational studies

Study Design

Observational
Study model

- **Observational Study Model** *

  Definition: Primary strategy for participant identification and follow-up. Select one.

  - **Cohort**: Group of individuals, initially defined and composed, with common characteristics (for example, condition, birth year), who are examined or traced over a given time period.

  - **Case-Control**: Group of individuals with specific characteristics (for example, conditions or exposures) compared to group(s) with different characteristics, but otherwise similar.

  - **Case-Only**: Single group of individuals with specific characteristics.

  - **Case-Crossover**: Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (that is, control period).

  - **Ecologic or Community Studies**: Geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (for example, air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (for example, healthcare system, laws or policies median income, average fat intake, disease rate).

  - **Family-Based:** Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment.

  - **Other:** Explain in Detailed Description.

Study Design
Observational
Time perspective and Biospecimens

- **Time Perspective ***
  Definition: Temporal relationship of observation period to time of participant enrollment. Select one.

  - **Retrospective**: Look back using observations collected predominantly prior to subject selection and enrollment

  - **Prospective**: Look forward using periodic observations collected predominantly following subject enrollment

  - **Cross-sectional**: Observations or measurements made at a single point in time, usually at subject enrollment

  - **Other**: Explain in Detailed Description

- **Biospecimen Retention**
  Definition: Indicate whether samples of material from research participants are retained in a biorepository. Select one.

- **Biospecimen Description**
  Definition: Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue).
  Limit: 1000 characters.

Study Design
Observational
Enrollment

- **Enrollment ***
  Definition: The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study.Note: "Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.

- **Target Follow-Up Duration ***
  Definition: For Patient Registries, the anticipated time period over which each participant is to be followed. Provide a number and select a Unit of Time (years, months, weeks, days).

- **Number of Groups/Cohorts ***
  Definition: Number of study groups/cohorts. Enter "1" for a single-group study. Many observational studies have one group/cohort; case control studies typically have two.

- Potential PRS review flag:
  - Once you have enrolled the last subject, you will need to change the study status from "recruiting" to "active, not recruiting" in the study status element. Once this in done, you will need to change the "anticipated" enrollment to the actual number of subjects enrolled and change the type to "actual". The PRS review will generate errors if the number of subjects listed here does not match the total number of subjects in the basic study demographics in the data elements to be completed at the conclusion of the study.

Groups and Interventions
Observational

Groups and Interventions
Observational studies
Group/Cohort information

- **Group/Cohort Information** (*For observational studies only*)
  Definition: Specify the predefined participant groups (cohorts) to be studied, corresponding to Number of Groups specified under Study Design (for single-group studies, the following data elements are optional). Do not use this section to specify strata (Detailed Description can be used for that purpose, if desired).
  Limit: 62 characters.

- **Group/Cohort Label** *
  Definition: The short name used to identify the group.

- **Group/Cohort Description** [*]
  Definition: Explanation of the nature of the study group (for example, those with a condition and those without a condition; those with an exposure and those without an exposure).
  Limit: 1000 characters.Note: The overall study population should be described under Eligibility.

Groups and Interventions
Observational studies
Intervention type

Groups:

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)

+ Add Other Name

× Delete

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

Save   Cancel

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

- **Intervention Type ***
  Definition: For each intervention studied in the clinical study, 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**

Groups and Interventions
Observational studies
Intervention name and description

- **Intervention Name(s) ***
  Definition: A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study. 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) [*]**
    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(s), including, but not limited to, past or present names such as brand name(s), or serial numbers.
    Limit: 200 characters.

- **Intervention Description *§**
  Definition: Details that can be made public about the intervention, other than the Intervention Name(s) and Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions studied in the same or another clinical study. For example, interventions involving drugs may include dosage form, dosage, frequency, and duration.
  Limit: 1000 characters.

Groups and Interventions
Observational studies
Intervention name and description

- **Arm or Group/Interventional Cross-Reference** *
  Definition: If multiple Arms or Groups have been specified, indicate which Interventions (or exposures) are in each Arm or Group of the study, using the Cross-Reference check boxes.

Outcome Measures

Outcome Measures
Primary outcome

- **Primary Outcome Measure Information ***
  Definition: A description of each primary outcome measure (or for observational studies, specific key measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment).

- Note: "Primary outcome measure" means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical studies have one primary outcome measure, but a clinical study may have more than one.

- For each primary outcome measure, include the following information:

- **Title**: * Name of the specific primary outcome measure
  Limit: 254 characters.

- **Description**: [*] Description of the metric used to characterize the specific primary outcome measure, if not included in the primary outcome measure title.
  Limit: 999 characters.

- **Time Frame**: * Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is generally the specific duration of time over which each participant is assessed (not the overall duration of the study).
  Limit: 254 characters.

Outcome Measures
Secondary outcome

- **Secondary Outcome Measure Information [*]**
  Definition: A description of each secondary outcome measure (or for observational studies, specific secondary measurement[s] or observation[s] used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment).Note: "Secondary outcome measure" means an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified analysis plan for evaluating the effects of the intervention or interventions under investigation in a clinical study and is not specified as an exploratory or other measure. A clinical study may have more than one secondary outcome measure.

- For each secondary outcome measure, include the following information:

- **Title**: * Name of the specific secondary outcome measure

- **Description**: [*] Description of the metric used to characterize the specific secondary outcome measure, if not included in the secondary outcome measure title.

- **Time Frame**: * Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is generally the specific duration of time over which each participant is assessed (not the overall duration of the study).

Outcome Measures
Other pre-specified outcomes

Other Pre-specified Outcomes:

+ Add Other Outcome

Save   Cancel

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

- **Other Pre-specified Outcome Measures**
  Definition: Any other measurements, excluding post-hoc measures, that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study.

  - **Title**: * Name of the specific other pre-specified outcome measure

  - **Description**: [*] Description of the metric used to characterize the specific other pre-specified outcome measure, if not included in the other pre-specified outcome measure title.

  - **Time Frame**: * Time point(s) at which the measurement is assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is generally the specific duration of time over which each participant is assessed (not the overall duration of the study).

Outcome Measures
Common issues

- **The outcome title should be succinct and descriptive**
- **If your study will include the use of multiplex analysis or questionnaires with multiple outcomes measured at once, every outcome must be listed separately**
  - **For example, if you are measuring TNF-α, IL1-β and IL-6 from a single plate, all three proteins need to be listed as individual outcome measures.**

- **The time frame must be indicated as specifically as possible. Do not use the study duration as a timeframe. This measure is based on the amount of time a measurement takes to collect in an individual research participant.**
  - **If you're collecting blood at multiple time points throughout the study do not indicate a time point of " duration of study", instead include the specific time points such as: baseline, 1 week, 4 weeks, 26 weeks.**
  - **If you're reporting a change in something over time, include the word change in your outcome time such as " Change in protein x after 1 week". Then your time frame would be "1 week" and the data most likely reported as percent or actual change in protein x levels.**

Eligibility

Eligibility
Sex/ Gender

- **Sex/Gender ***
  Definition: The sex and, if applicable, gender of the participants eligible to participate in the clinical study.

  Sex *
  Definition: The sex of the participants eligible to participate in the clinical study.
  Select one.Note: "Sex" means a person's classification as male or female based on biological distinctions.
  - All: Indicates no limit on eligibility based on the sex of participants
  - Female: Indicates that only female participants are being studied
  - Male: Indicates that only male participants are being studied
- **Gender Based [*]**
  Definition: If applicable, indicate whether participant eligibility is based on gender.
  Select one.Note: "Gender" means a person's self-representation of gender identity.
  - Yes: Eligibility is based on gender
  - No: Eligibility is not based on gender
- **Gender Eligibility Description**
  Definition: If eligibility is based on gender, provide descriptive information about Gender criteria.
  Limit: 1000 characters.

Eligibility
Age Limit

Help   Definitions

* Sex: --Select-- ▼
    Biological sex of eligible participants.

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

* Age Limits: Minimum: --Select-- ▼   Maximum: --Select-- ▼

* § Accepts Healthy Volunteers: --Select-- ▼

* Eligibility Criteria:
Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

Save   Cancel

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

- **Age Limits ***
  Definition: The minimum and maximum age of potential participants eligible for the clinical study, provided in relevant units of time.

  Minimum Age *
  Definition: The numerical value, if any, for the minimum age a potential participant must meet to be eligible for the clinical study.

- **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 potential participant can be to be eligible for the clinical study.

- **Unit of Time ***
  Select one.
  - Years
  - Months
  - Weeks
  - Days
  - Hours
  - Minutes
  - N/A (No limit)

Eligibility
Healthy volunteers and Eligibility criteria

Help   Definitions

* Sex: --Select-- ▾
Biological sex of eligible participants.

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

* Age Limits: Minimum: --Select-- ▾   Maximum: --Select-- ▾

* § Accepts Healthy Volunteers: --Select-- ▾

* Eligibility Criteria:
Inclusion Criteria:
-
Exclusion Criteria:
-

Special Characters

Save   Cancel

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

- **Accepts Healthy Volunteers *§** (*Optional for Observational Studies*)
Definition: Indication that participants who do not have a disease or condition, or related conditions or symptoms, under study in the clinical study are permitted to participate in the clinical study. Select Yes/No.

- **Eligibility Criteria ***
Definition: A limited list of criteria for selection of participants in the clinical study, provided in terms of inclusion and exclusion criteria and suitable for assisting potential participants in identifying clinical studies of interest. *Use a bulleted list for each criterion below the headers "Inclusion Criteria" and "Exclusion Criteria".   IF you use paragraph form to enter your criteria the record will be returned!*
Limit: 15,000 characters.

Eligibility
Observational studies
Study population description & sampling method

Help   Definitions

* Sex: --Select-- ▼
Biological sex of eligible participants.

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

* Age Limits: Minimum: --Select-- ▼   Maximum: --Select-- ▼
* § Accepts Healthy Volunteers: --Select-- ▼

* Eligibility Criteria:
Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

Save   Cancel

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

- **Study Population Description** * (*For observational studies only*)
  Definition: A description of the population from which the groups or cohorts will be selected (for example, primary care clinic, community sample, residents of a certain town).
  Limit: 1000 characters.

- **Sampling Method** * (*For observational studies only*)
  Definition: Indicate the method used for the sampling approach and explain in the Detailed Description. Select one.

  - Probability Sample: Exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive participant sampling

  - Non-Probability Sample: Any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer

Contacts/Location

Contact/Location
Central contact

- **Central Contact Person** * (*or Facility Contact required*)
  Definition: The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed. Include the following information:

  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

Considerations for the "Central Contact":
1. The named individual will be listed as the study contact on the public side of CT.gov and as such needs to be prepared to address inquires from the general public regarding the study
2. This will also be the primary contact for the system administrator when issues arise within the registry. This individual should have considerable knowledge of the project and be accessible when called upon by the system administrator. The study PI is typically not the best person to be the central contact
3. If the listed individual leaves the study/university, please update the record as quickly as possible to maintain accurate information in the CT.gov public domain.

Contact/Location
Central contact backup

Considerations for the "Central Contact Backup":
1. **The named individual will be listed as the study contact backup on the public side of CT.gov and as such needs to be prepared to address inquires from the general public regarding the study in the event that the Primary contact is not reachable**

- **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

Contact/Location
Overall study official

- **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

This is typically the sponsor/investigator for studies at UK

Contact/Location
Facility

- **Facility Information** *
  Definition: For each participating facility in a clinical study, the following information:

- **Facility Name:** *§ Full name of the organization where the clinical study is being conducted. Limit: 254 characters. *Will always be the University of Kentucky*

- **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** *

**For single site studies, this will typically be the "Central Contact" for the study.
If this is a multisite study, the central contact and facilities contact can be different. This person will also be listed on the public side of CT.gov.**

Contact/Location
Site recruitment status

- **Individual Site Status ***
  Definition: The recruitment status of each participating facility in a clinical study.

- **Not yet recruiting**: Participants are not yet being recruited

- **Recruiting**: Participants are currently being recruited, whether or not any participants have yet been enrolled

- **Enrolling by invitation**: Participants are being, or will be selected from a predetermined population

- **Active, not recruiting**: Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled

- **Completed**: The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, the last participant's last visit has occurred)

- **Suspended**: Study halted prematurely but potentially will resume

- **Terminated**: Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention

- **Withdrawn**: Study halted prematurely, prior to enrollment of first participant

For single site studies this section will also be the same as the study status section.

Contact/Location
Facility Contact

Help   Definitions

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

* Site Recruitment Status: --Select--
Recruitment status for this individual location.

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

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

Either Central Contact or Facility Contacts are required.
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 Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

- **Facility Contact * (or Central Contact required)**
  Definition: For each facility participating in a clinical study, including the name or title, telephone number, and email address of a person to whom questions concerning the study and enrollment at that site can be addressed. Include the following information:

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

  Typically the central study contact for UK studies

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

**For single site studies, this will typically be the "Central Contact" for the study.
If this is a multisite study, the central contact and facilities contact can be different. This person will also be listed on the public side of CT.gov.**

Contact/Location
Add Investigators

Help   Definitions

* Facility: Name: [   ]
City: [   ]
State/Province: [Kentucky] ZIP/Postal Code: [   ]
Country: [United States ▼]

* Site Recruitment Status: [--Select-- ▼]
Recruitment status for this individual location.

* Facility Contact: First Name: [   ] MI: [ ] Last Name: [   ] Degree: [   ]
Phone: [   ] Ext: [   ] Email: [   ]

Facility Contact Backup: First Name: [   ] MI: [ ] Last Name: [   ] Degree: [   ]
Phone: [   ] Ext: [   ] Email: [   ]
Either Central Contact or Facility Contacts are required.
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 Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

- **Investigators** (at the facility location). Include the following information:
  - **First Name**
  - **Middle Initial**
  - **Last Name**
  - **Degree**
  - **Role**:
    - 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

List all co-PI's and Sub-investigators in this section. They will all be listed on the public side of CT.gov.

IPD Sharing Statement

IPD Sharing Statement
Plan to share/description

Plan to Share IPD: [Yes ▼]
Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Plan Description:
[   ]
Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

IPD Sharing:

Supporting Information: Check all types of supporting information that will be shared.
☐ Study Protocol
☐ Statistical Analysis Plan (SAP)
☐ Informed Consent Form (ICF)
☐ Clinical Study Report (CSR)
☐ Analytic Code

Time Frame:
[   ]
Describe when the data will become available and for how long.

Access Criteria:
[   ]

URL: [http://   ]
Web address (if any) with additional information about the plan to share IPD.

[Save] [Cancel]

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

- **Plan to Share IPD**
  Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study). Select one.
  - Yes: There is a plan to make IPD and related data dictionaries available.
  - No: There is not a plan to make IPD available.
  - Undecided: It is not yet known if there will be a plan to make IPD available.

- **IPD Sharing Plan Description**
  Definition: If Plan to Share IPD is "Yes," briefly describe what specific individual participant data sets are to be shared (for example, all collected IPD, all IPD that underlie results in a publication). If the Plan to Share IPD is "No" or "Undecided," an explanation may be provided for why IPD will not be shared or why it is not yet decided.
  Limit: 1000 characters.

- If Plan to Share IPD is "Yes," provide the following information

- ***As of July 1, 2018, the International Committee of Medical Journal Editors will require a prospective data sharing plan for publication in one of their member journals***

IPD Sharing Statement
Supporting information, time frame, Access

- **IPD Sharing Supporting Information Type**
  Definition: The type(s) of supporting information that will be shared, in addition to the individual participant data set and data dictionaries for the IPD itself. Select all that apply.
  - Study Protocol
  - Statistical Analysis Plan (SAP)
  - Informed Consent Form (ICF)
  - Clinical Study Report (CSR)
  - Analytic Code

- **IPD Sharing Time Frame**
  Definition: A description of when the IPD and any additional supporting information will become available and for how long, including the start and end dates or period of availability. This may be provided as an absolute date (for example, starting in January 2025) or as a date relative to the time when summary data are published or otherwise made available (for example, starting 6 months after publication).
  Limit: 1000 characters.

- **IPD Sharing Access Criteria**
  Definition: Describe by what access criteria IPD and any additional supporting information will be shared, including with whom, for what types of analyses, and by what mechanism. Information about who will review requests and criteria for reviewing requests may also be provided.
  Limit: 1000 characters.

- **IPD Sharing URL**
  Definition: The web address, if any, used to find additional information about the plan to share IPD.
  Limit: 3999 characters.

References

References
Citations, PubMed, Results

Help   Definitions

Citations:

+ Add Citation

Links:

+ Add Link

Available IPD/Information: References to deidentified individual participant data (IPD) sets and supporting information.

+ Add Data/Information

Save   Cancel

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

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

  - **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 clinical study. Select Yes/No.

This section can be used to list previous studies that created the foundation for the work presented as well as any publications that results from the current study.

References
Citations, PubMed, Results

- **Available IPD and Supporting Information**
  Definition: The individual participant data (IPD) sets and supporting information that are being shared for the study. Provide the following information for each:

  Available IPD/Information Type
  Definition: The type of data set or supporting information being shared.

  - Individual Participant Data Set
  - Study Protocol
  - Statistical Analysis Plan
  - Informed Consent Form
  - Clinical Study Report
  - Analytic Code
  - Other (specify)

- **Available IPD/Information URL**
  Definition: The web address used to request or access the data set or supporting information.
  Limit: 3999 characters.

  Available IPD/Information Identifier
  Definition: The unique identifier used by a data repository for the data set or supporting information.
  Limit: 30 characters.

  Available IPD/Information Comments
  Definition: Additional information including the name of the data repository or other location where the data set or supporting information is available. Provide any additional explanations about the data set or supporting information and instructions for obtaining access, particularly if a URL is not provided.
  Limit: 1000 characters.

Notes, Warnings and Errors

After your record has been reviewed, it may contain "notes, warnings and error" messages. The following pages include some of the more common messages the investigator is likely to receive.

Notes

Issues that will not prevent the release of the record

- **Arm description has not been entered**
  - Please enter an Arm description and release the record

- **No intervention has been included in the Arm Description**
  - The intervention name must be included in the Arm Description exactly as it is written in the intervention name.

- **A title this short may not be sufficiently descriptive**
  - Sometimes a short "Brief" title is more that sufficient, the note is simply asking you to make sure

- **Outcome measure description is shorter than the outcome measure title**
  - Make sure that the outcome description is sufficiently informative for a lay person to understand the intent of the outcome

- **There are many more "Notes" that may arise, most have self-explanatory definitions**

Warning
Issues that are potentially serious and should be reviewed an corrected

- **A record for an active study must be reviewed, updated and verified at least once per year**
  - Once a study has been verified, please update the study verification date in the study status data element and release the record.

- **Start date should not be in the past for a study not yet recruiting**
  - If the study has begun recruiting, change the anticipated start date to the actual date the first subject signed a consent

Errors

Issues that must be resolved before a record can be released

- **Update not released**
  - A change has been made to the record requiring the PI to release it. Please login and release the record

- **Record verification date**
  - You must verify the contents of your record at least annually. Anytime you change your record, review all the elements for accuracy and change the "Record Verification Date" the month and year of those changes. Then RELEASE the record.

- **Recruiting status/anticipated start date**
  - If your study is listed as "not yet recruiting" but your anticipated start date has past the system with generate and error message

- **Recruiting status/primary competition date**
  - If your study is listed as recruiting; however, the listed primary completion data has pasted the system will generate and error. If the study is still ongoing, change the primary completion date to some point in the future

- **Use of pronouns in the detailed description**
  - The system does not allow the use of pronouns in the brief or detailed description. Change all "we" to the investigator, and all "you" to participants.

- **Outcome timeframe**
  - The outcome timeframe should be directly related to the measurement taken (ie. One week post intervention, 1 month, 5 days, etc.). It will likely never be the actual duration of the study

Results

CT.gov data elements for trial results reporting

- Participant Flow Data

- Baseline Characteristics

- Outcome measure and statistical analysis

- Adverse events

- Basic navigation
  - Select "edit" to enter a data element

    Edit
    Participant Flow
    Information is required
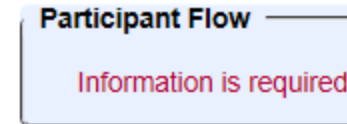
  - Select "save" at any point to save data entered, selecting "cancel" exit the data element. Data not previously saved with the "save" command will be lost

    Save   Cancel

  - The record can be opened and closed as often as necessary to complete the data entry.

Participant flow

Participant flow
General info

- Information to document the progress of research participants through each stage of a study in a tabular format, including the number of participants who started and completed the clinical study. (Identical in purpose to a [CONSORT flow diagram](#), but represented as tables).

- The tabular presentation may be separated into "periods," each of which comprises an interval of study activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.

Below is an example of the participant flow

Participant flow
Recruitment

- **Recruitment Details**
Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (For example, medical clinic), to provide context.
Limit: 350 characters.

  Pre-assignment Details [*]
Definition: Description of significant events in the study (for example, wash out, run-in) that occur after participant enrollment, but prior to assignment of participants to an arm or group, if any. For example, an explanation of why enrolled participants were excluded from the study before assignment to arms or groups.
Limit: 350 characters.

Below is an example of the participant flow

Participant flow
Arm/group(cohort) information

- **Arm/Group Information ***
Definition: Arms or groups for describing the flow of participants through the clinical study. In general, it must include each arm to which participants were assigned.

- **Arm/Group Title ***
Definition: Descriptive label used to identify each arm or group.
Limit: >=4 and <= 62 characters.
  - This is identical to section 8 of the registration component of CT.gov. Cut and paste

- **Arm/Group Description *§**
Definition: Brief description of each arm or group. In general, it must include sufficient details to understand each arm to which participants were assigned and the intervention strategy used in each arm.
Limit: 999 characters.
  - This is identical to section 8 of the registration component of CT.gov. Will be your arm description for an interventional study or your cohort/group description for an observational study

Below is an example of the participant flow

Participant flow
Units and timing

- **Type of Units Assigned [*]**
Definition: If assignment is based on a unit other than participants, a description of the unit of assignment (for example, eyes, lesions, implants).
Limit: 40 characters.

- **Period(s) ***
Definition: Discrete stages of a clinical study during which numbers of participants at specific significant events or points of time are reported.There is no limit to the number of periods that may be used to describe a single study. Each subsequent period represents a study stage following the previous period. That is, participants "flow" from earlier to later periods.

- **Period Title ***
Definition: Title describing a stage of the study. If only one period is defined, the default title is Overall Study. When a study has more than one period, none of the Period Titles should be Overall Study.
Limit: 40 characters.

Started *
Definition: Number of participants initiating the period. In the first period, it is the number of participants assigned to each arm or group. If assignment is based on a unit other than participants, also include the number of units at the beginning of the period.
  - The initial enrollment will be equal to the number of consents signed, you will then identify the number of individuals randomized to the study and describe why they are different if subjects were lost in that period

- **Comments**
Definition: Additional information about the Started milestone or Milestone Data.
Limit: 100 characters.

Below is an example of the participant flow

More details available in the Results Data Element Definitions.   April 2017

Participant Flow Template   *ClinicalTrials.gov*

| Recruitment Details | |
| [*] Pre-assignment Details | |

Period ①

* Period Title	Overall Study	①		
* Arm/Group Title				
*§ Arm/Group Description ②				
		Number of Participants ④	Number of Participants ④	Number of Participants ④
* Started				
[*] Milestone Title ③				
[*] Milestone Title ③				
[*] Milestone Title ③				
* Completed				
Not Completed		*(automatically calculated)*		
Reason Not Completed Type ③				
[*] Adverse Event				
[*] Death				
[*] Lack of Efficacy				
[*] Lost to Follow-up				
[*] Physician Decision				
[*] Pregnancy				
[*] Protocol Violation				
[*] Withdrawal by Subject				
[*] Other Reason				
[*] Other Reason				
[*] Other Reason				

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

① Complete a Period table for each stage of the study. If only one Period, the Title is "Overall Study". For multiple Periods, include descriptive Titles for each Period.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ [Optional] Add as many Milestone Title or Other Reason Not Completed rows as needed. A descriptive title for each row is required.
④ Number and Type of Units Assigned may also be specified.

Participant flow
Completed/not-completed

- **Completed** *
Definition: Number of participants at the end of the period. If assignment is based on a unit other than participants, also include the number of units at the end of the period.

  - **Comments**
Definition: Additional information about the Completed milestone or Milestone Data. Limit: 100 characters.

- **Not Completed** *(calculated automatically)*
Definition: Number of participants (and units, if applicable) that did not complete the study or period. This is calculated automatically by subtracting Completed from Started.

Below is an example of the participant flow

Participant flow
Milestones

- **Additional Milestone(s)**
  Definition: Any specific events or time points in the study when the numbers of participants (and units, if applicable) are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, Started and Completed, within each period.

- **Milestone Title [*]**
  Definition: : Label describing the milestone
  Limit: 40 characters.

- **Milestone Data [*]**
  Definition: Number of participants to reach the milestone, in each arm/group. If assignment is based on a unit other than participants, also include the number of units to reach the milestone.

  - **Comments**
    Definition: Additional information about the milestone or data.
    Limit: 100 characters.

Below is an example of the participant flow

Participant flow
Reason for not completing

- **Reason Not Completed**
  Definition: Additional information about participants who did not complete the study or period. If reasons are provided, the total number of participants listed as Not Completed must be accounted for by all reasons for non-completion.

- **Reason Not Completed Type [*]**
  Definition: Reason why participants did not complete the study or period. Select one.
  - Adverse Event
  - Death
  - Lack of Efficacy
  - Lost to Follow-Up
  - Physician Decision
  - Pregnancy
  - Protocol Violation
  - Withdrawal by Subject
  - Other

- **Other Reason [*]**
  Definition: A brief description of the reason for non-completion, if "Other" Reason Not Completed Type is selected.
  Limit: 40 characters.

- **Reason Not Completed Data [*]**
  Definition: Number of participants in each arm or group that did not complete the study or period, for each Reason Not Completed.

Below is an example of the participant flow

Baseline characteristics

Baseline characteristics
General

- A table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of participants in the clinical study.

Below is an example of the baseline characteristics
More details available in the Results Data Element Definitions.

Baseline characteristics
Arm/group(cohort) information

- **Arm/Group Information ***
Definition: Arms or groups for describing the flow of participants through the clinical study. In general, it must include each arm to which participants were assigned.

- **Arm/Group Title ***
Definition: Descriptive label used to identify each arm or group.
Limit: >=4 and <= 62 characters.
  - This is identical to section 8 of the registration component of CT.gov. Cut and paste

- **Arm/Group Description *§**
Definition: Brief description of each arm or group. In general, it must include sufficient details to understand each arm to which participants were assigned and the intervention strategy used in each arm.
Limit: 999 characters.
  - This is identical to section 8 of the registration component of CT.gov. Will be your arm description for an interventional study or your cohort/group description for an observational study

Below is an example of the baseline characteristics
More details available in the Results Data Element Definitions.

April 2017

Baseline Characteristics Template	Age* (use at least one)			ClinicalTrials.gov
* Arm/Group Title				
*§ Arm/Group Description ①				
* Overall Number of Baseline Participants ②				③
[*] Baseline Analysis Population Description				
Age, Categorical				
<=18 years				③
Between 18 and 65 years				③
>=65 years				③
* Unit of Measure Participants				
Age, Continuous				
* Measure Type	* Measure of Dispersion			
(Select One) Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM	(Select One) Standard Deviation Inter-quartile Range Full Range			
* Unit of Measure				
Age, Customized				
* Measure Type	* Measure of Dispersion			
(Select One) Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	(Select One) Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range			
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤ ③ ④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤ ③ ④⑤
* Unit of Measure				

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

Baseline characteristics
Baseline analysis population information

- **Overall Number of Baseline Participants ***
Definition: Total number of participants for whom baseline characteristics were measured, in each arm/group and overall.

  Overall Number of Units Analyzed [*]
Definition: If the analysis is based on a unit other than participants, the number of units for which baseline measures were measured and analyzed, in each arm/group and overall.

  Type of Units Analyzed [*]
Definition: If the analysis is based on a unit other than participants, a description of the unit of analysis (for example, eyes, lesions, implants).
Limit: 40 characters.

  Baseline Analysis Population Description [*]
Definition: If the Overall Number of Baseline Participants (or units) differs from the number of participants (or units) assigned to the arm or comparison group and overall, a brief description of the reason(s) for the difference such as how the analysis population was determined.
Limit: 350 characters.

- **The analysis population is the number of participant that had data collected. It represents the total enrollment (consents signed) minus the number of subjects lost prior to data collection**

Below is an example of the baseline characteristics

More details available in the Results Data Element Definitions. — April 2017

Baseline Characteristics Template — *Age* (use at least one)* — *ClinicalTrials.gov*

					Total
* Arm/Group Title					
*§ Arm/Group Description ①					
* Overall Number of Baseline Participants ②					③
[*] Baseline Analysis Population Description					
Age, Categorical					
<=18 years					③
Between 18 and 65 years					③
>=65 years					③
* Unit of Measure	Participants				
Age, Continuous					
* Measure Type / * Measure of Dispersion					
(Select One): Mean, Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM / (Select One): Standard Deviation, Inter-quartile Range, Full Range					
* Unit of Measure					
Age, Customized					
* Measure Type / * Measure of Dispersion					
(Select One): Count of Participants ④, Mean, Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM, Number, Count of Units ④ / (Select One): Not Applicable ⑤, Standard Deviation, Inter-Quartile Range, Full Range					
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③ ④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③ ④⑤
* Unit of Measure					

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

Baseline characteristics
Baseline measure information
Age

- **Baseline Measure Title ***
  Definition: The name of the baseline or demographic characteristic measured in the clinical study. Select as many as needed. Study-Specific Measure *§ (Select as many as needed)

- Age * (Select at least one of the following):
  - Age, Continuous: For example - mean or median age
  - Age, Categorical:
    - <=18 years
    - >18 and <65 years
    - >=65 years
  - Age, Customized: Customizable age categories

Below is an example of the baseline characteristics

More details available in the Results Data Element Definitions.   April 2017

Baseline Characteristics Template	*Age* (use at least one)*			ClinicalTrials.gov
* Arm/Group Title				Total
*§ Arm/Group Description ①				
* Overall Number of Baseline Participants ②				③
[*] Baseline Analysis Population Description				

Age, Categorical

<=18 years				③
Between 18 and 65 years				③
>=65 years				③
* Unit of Measure	Participants			

Age, Continuous

* Measure Type	* Measure of Dispersion			
(Select One) Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM	(Select One) Standard Deviation Inter-quartile Range Full Range			
* Unit of Measure				

Age, Customized

* Measure Type	* Measure of Dispersion			
(Select One) Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	(Select One) Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range			
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤ ③ ④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤ ③ ④⑤
* Unit of Measure				

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

Baseline characteristics
Baseline measure information
Sex/Gender

- **Baseline Measure Title ***
  Definition: The name of the baseline or demographic characteristic measured in the clinical study. Select as many as needed.
  Study-Specific Measure *§ *(Select as many as needed)*

- Sex/Gender * *(Select at least one of the following):*
  - Sex: Female, Male
  - Sex/Gender, Customized

Below is an example of the baseline characteristics

Baseline characteristics
Baseline measure information
Race/Ethnicity/Region

- **Baseline Measure Title ***
  Definition: The name of the baseline or demographic characteristic measured in the clinical study. Select as many as needed.
  Study-Specific Measure *§ *(Select as many as needed)*

- Race and Ethnicity *§Race (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories

- Ethnicity (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories

- Race/Ethnicity, Customized

- Race and Ethnicity Not Collected

- Region of Enrollment

Below is an example of the baseline characteristics

More details available in the Results Data Element Definitions.   April 2017

Baseline Characteristics Template	*Race*§, Ethnicity*§, and Region*			*ClinicalTrials.gov*
* Arm/Group Title				Total
*§ Arm/Group Description ①				
* Overall Number of Baseline Participants ②				③
[*] Baseline Analysis Population Description				
Race (NIH/OMB) ④				
American Indian or Alaska Native				③
Asian				③
Native Hawaiian or Pacific Islander				③
Black or African American				③
White				③
More than one race				③
Unknown or Not Reported				③
* Unit of Measure	Participants			
Ethnicity (NIH/OMB) ④				
Hispanic or Latino				③
Not Hispanic or Latino				③
Unknown or Not Reported				③
* Unit of Measure	Participants			
Region of Enrollment				
United States				③
Region/Country Name ⑤				③
Region/Country Name ⑤				③
Region/Country Name ⑤				③
* Unit of Measure	Participants			

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for each Baseline Measure.
④ If not using NIH/OMB categories, use Race/Ethnicity, Customized (not shown); if not collected, use Race and Ethnicity Not Collected (not shown).
⑤ [Optional] Region of Enrollment Baseline Measure is optional, but at least one Region/Country is required if reporting Region of Enrollment. Add as many Regions/Countries as needed.

Baseline characteristics
Baseline measure information
Study specific measure

- **Study-Specific Baseline Measure Title(s) [*]**
  Definition: If "Study-Specific Measure" is chosen, provide the name of the measure.
  Limit: 100 characters.

- **This section can be used to add as many additional baseline measures as are necessary to fully describe all the data collected**

- **Baseline Measure Description**
  Definition: Additional descriptive information about the baseline measure, such as a description of the metric used to characterize the specific baseline measure.
  Limit: 600 characters.

Below is an example of the baseline characteristics

More details available in the Results Data Element Definitions.

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Baseline Characteristics Template	Study-Specific Measure*§				ClinicalTrials.gov
* Arm/Group Title					Total
*§ Arm/Group Description ①					
* Overall Number of Baseline Participants ②					③
[*] Baseline Analysis Population Description					
[*] Study-Specific Baseline Measure Title					
Baseline Measure Description					

* Measure Type	* Measure of Dispersion					
(Select One) Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	(Select One) Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range					
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③	④⑤
[*] Row/Category Title ⑥		④⑤	④⑤	④⑤	③	④⑤
* Unit of Measure						

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Baseline characteristics

Baseline measure information
Measure Type

- **Measure Type ***
  Definition: The type of data for the baseline measure. Select one.
  - Count of Participants
  - Mean
  - Median
  - Least Squares Mean
  - Geometric Mean
  - Geometric Least Squares Mean
  - Number
  - Count of Units

- **Measure of Dispersion ***
  Select one.
  - Not Applicable (only if Measure Type is "Number", "Count of Participants", or "Count of Units")
  - Standard Deviation
  - Inter-Quartile Range
  - Full Range

Below is an example of the baseline characteristics
More details available in the Results Data Element Definitions.

Baseline characteristics
Baseline measure information
Additional information

- **Number of Baseline Participants [*]**
  Definition: The number of participants analyzed for the baseline measure, if different from the Overall Number of Baseline Participants, in each arm/group and overall.

- **Number of Units Analyzed [*]**
  Definition: The number of units analyzed for the baseline measure, if different from the Overall Number of Units Analyzed, in each arm/group and overall.

- **Analysis Population Type [*]**
  Definition: Indicate whether the baseline measure analysis is based on participants or units other than participants. Only applies if Type of Units Analyzed is specified. Select Participants/Other Units.

- **Measure Analysis Population Description [*]**
  Definition: Explanation of how the number of participants (or units) for analysis was determined, if different from the Overall Number of Participants [or Units] Analyzed.
  Limit: 350 characters.

- **Category or Row Title [*]**
  Definition: Name of distinct category or row for a baseline measure, if any. Category Titles are only for mutually exclusive and exhaustive categories summarizing data using the Measure Type of a "Count of Participants" or "Count of Units." Row Titles are for any type of data.
  Limit: 50 characters.

- **Baseline Measure Data ***
  Definition: The value(s) for each baseline measure, for each arm/group and overall.

- **NA (Not Available) Explanation [*]**
  Definition: Explain why baseline measure data are not available, if "NA" is reported for Baseline Measure Data.
  Limit: 250 characters.

- **Unit of Measure ***
  Definition: An explanation of what is quantified by the data (for example, participants, mm Hg), for each baseline measure.
  Limit: 40 characters.

Below is an example of the baseline characteristics

Outcome measures

Outcome measures
General

- A table of data for each primary and secondary outcome measure by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.

- Note: Outcome measure information from the Protocol Section of the record will be copied into the Results Section the first time results are created.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.   April 2017

Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc
Outcome Measure Title	
[*] Outcome Measure Description	
*Outcome Measure Time Frame	

Outcome Measure Template   *ClinicalTrials.gov*

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Outcome Measure Information

- **Outcome Measure Information ***
Definition: A description of each outcome measure.

Note: "Outcome measure" means a pre-specified measurement that is used to determine the effect of an experimental variable on participants in the study. Post-hoc (that is, not pre-specified) outcome measures may also be reported.

Below is an example of the outcome measures

Outcome measures
Outcome Measure Information

- **Outcome Measure Type** *
  Definition: The type of outcome measure. Select one.
  - Primary
  - Secondary
  - Other Pre-specified
  - Post-Hoc

- **Outcome Measure Title** *
  Definition: Name of the specific outcome measure.
  Limit: 255 characters.
  - **Straight from section 9 (Outcome Measures) from the study registration, copy/paste**

- **Outcome Measure Description [*]**
  Definition: Additional information about the outcome measure, including a description of the metric used to characterize the specific outcome measure, if not included in the Outcome Measure Title.
  Limit: 999 characters.
  - **Straight from section 9 (Outcome Measures) from the study registration, copy/paste**

- **Outcome Measure Time Frame** *
  Definition: Time point(s) at which the measurement was assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is generally the specific duration of time over which each participant is assessed (not the overall duration of the study).
  Limit: 255 characters.
  - **Straight from section 9 (Outcome Measures) from the study registration, copy/paste**

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

April 2017

* **Outcome Measure Type**	(Select One)	Primary	Secondary	Other Pre-specified	Post-Hoc		
* **Outcome Measure Title**							
[*] **Outcome Measure Description**							
* **Outcome Measure Time Frame**							

* **Arm/Group Title**			
*§ **Arm/Group Description** ①			
* **Overall Number of Participants Analyzed** ②			
[*] **Analysis Population Description**			

* **Measure Type**	* **Measure of Dispersion/Precision**			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range ___ % Confidence Interval Geometric Coefficient of Variation			
[*] **Row/Category Title** ⑤		③④	③④	③④
[*] **Row/Category Title** ⑤		③④	③④	③④
* **Unit of Measure**				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Outcome Measure Information

- **If you define an outcome in the results section but do not enter data, a text box will appear asking you to provide an anticipated date for data entry**

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.   April 2017

Outcome Measure Template					*ClinicalTrials.gov*

* Outcome Measure Type	(Select One)	Primary	Secondary	Other Pre-specified	Post-Hoc
* Outcome Measure Title					
[*] Outcome Measure Description					
* Outcome Measure Time Frame					

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Arm/group information

- **Arm/Group Information ***
  Definition: Arms or comparison groups in the study, including all arms or comparison groups based on the pre-specified protocol and/or statistical analysis plan.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

- **Arm/Group Title ***
  Definition: Descriptive label used to identify each arm or comparison group.
  Limit: >= 4 and <= 62 characters.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

- **Arm/Group Description *§**
  Definition: Brief description of each arm or comparison group. In general, it must include sufficient detail to understand how the arm(s) or comparison groups were derived from the arm(s) to which participants were assigned in Participant Flow (if different) and the intervention strategy in each arm/group.
  Limit: 999 characters.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

Outcome measures
Analysis population information

- **Overall Number of Participants Analyzed ***
Definition: Number of participants for whom an outcome measure was measured and analyzed, for each outcome measure and each arm/group.

Type of Units Analyzed [*]
Definition: If the analysis is based on a unit other than participants, a description of the unit of analysis (for example, eyes, lesions, implants).
Limit: 40 characters.

Overall Number of Units Analyzed [*]
Definition: If the analysis is based on a unit other than participants, the number of units for which an outcome was measured and analyzed, for each outcome measure and each arm/group.

Analysis Population Description [*]
Definition: If the Number of Participants Analyzed or Number of Units Analyzed differs from the number of participants or units assigned to the arm or comparison group, a brief description of the reason for the difference (such as how the analysis population was determined).
Limit: 350 characters.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

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Outcome Measure Template — *ClinicalTrials.gov*

* Outcome Measure Type	(Select One)	Primary	Secondary	Other Pre-specified	Post-Hoc
* Outcome Measure Title					
[*] Outcome Measure Description					
* Outcome Measure Time Frame					

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Outcome Measure Data Table

- **Measure Type ***
  Definition: The type of data for the outcome measure. Select one.
  - Count of Participants
  - Mean
  - Median
  - Least Squares Mean
  - Geometric Mean
  - Geometric Least Squares Mean
  - Number
  - Count of Units

- **Measure of Dispersion/Precision ***
  Select one.
  - Not Applicable (only if Measure Type is "Number," "Count of Participants," or "Count of Units")
  - Standard Deviation
  - Standard Error
  - Inter-Quartile Range
  - Full Range
  - 80% Confidence Interval
  - 90% Confidence Interval
  - 95% Confidence Interval
  - 97.5% Confidence Interval
  - 99% Confidence Interval
  - Other Confidence Interval Level
  - Geometric Coefficient of Variation (only when Measure Type is "Geometric Mean")

- **Other Confidence Interval Level [*]**
  Definition: The numerical value for the confidence interval level, if "Other Confidence Interval Level" is selected. Provide a rationale for choosing this level in the Outcome Measure Description.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.   April 2017

Outcome Measure Template				*ClinicalTrials.gov*
* Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc			
* Outcome Measure Title				
[*] Outcome Measure Description				
* Outcome Measure Time Frame				

* Arm/Group Title				
*§ Arm/Group Description ①				
Overall Number of Participants Analyzed ②				
[*] Analysis Population Description				
* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Outcome Measure Data Table

- **Category or Row Title [*]**
Definition: Name of distinct category or row for an outcome measure, if any. Category Titles are only for mutually exclusive and exhaustive categories summarizing data using the Measure Type of a "Count of Participants" or "Count of Units". Row Titles are for any type of data.
Limit: 50 characters.

Number of Participants Analyzed [*]
Definition: The number of participants analyzed for the outcome measure in the row and for each arm/group, if different from the overall Number of Participants Analyzed.
Limit: 50 characters.

Number of Units Analyzed [*]
Definition: The number of units analyzed for the outcome measure in the row and for each arm/group, if different from the overall Number of Units Analyzed.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

Outcome measures
Outcome Measure Data Table

- **Outcome Data** *
Definition: The measurement value(s) for each outcome measure, including each category/row and each arm/group.
  - **NA (Not Available) Explanation [*]**
  Definition: Explain why outcome measure data are not available, if "NA" is reported for Outcome Data.
  Limit: 250 characters.

- **Unit of Measure** *
Definition: An explanation of what is quantified by the data (for example, participants, mm Hg), for each outcome measure.
Limit: 40 characters. .

Below is an example of the outcome measures
More details available in the Results Data Element Definitions.

April 2017

Outcome Measure Template						*ClinicalTrials.gov*

* Outcome Measure Type	(Select One)	Primary	Secondary	Other Pre-specified	Post-Hoc
* Outcome Measure Title					
[*] Outcome Measure Description					
* Outcome Measure Time Frame					

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Statistical analysis

- **Definition**: Result(s) of scientifically appropriate tests of statistical significance of the primary and secondary outcome measures, if any. Such analyses include: pre-specified in the protocol and/or statistical analysis plan; made public by the sponsor or responsible party; conducted on a primary outcome measure in response to a request made by FDA.If a statistical analysis is reported "Comparison Group Selection" and "Type of Statistical Test" are required. In addition, one of the following data elements are required with the associated information: "P-Value," "Estimation Parameter," or "Other Statistical Analysis."

The statistical analysis fields will present themselves if the measurement type and measure of dispersion/precision warrants further explanation of the statistical methods performed

- **Statistical Analysis Overview**
  Definition: Summary description of the analysis performed.

- **Comparison Group Selection [*]**
  Definition: The arms or comparison groups involved in the statistical analysis (check all to indicate an "omnibus" analysis).

  - **Comments**
    Definition: Additional details about the statistical analysis, such as null hypothesis and description of power calculation.
    Limit: 500 characters.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.   April 2017

Outcome Measure Template   *ClinicalTrials.gov*

* Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	
[*] Outcome Measure Description	
* Outcome Measure Time Frame	

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Statistical analysis

- **Type of Statistical Test [*]**
  Definition: Identifies the type of analysis.
  Select one.
    - Superiority
    - Non-inferiority
    - Equivalence
    - Other (for example, single group or other descriptive analysis)
    - Non-Inferiority or Equivalence (*legacy selection*)
    - Superiority or Other (*legacy selection*)

    - **Comments [*]**
      Definition: If, "Non-inferiority" or "Equivalence," provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority or equivalence margin, and other key parameters.
      Limit: 500 characters.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

Outcome Measure Template	ClinicalTrials.gov

April 2017

* Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc	
* Outcome Measure Title		
[*] Outcome Measure Description		
* Outcome Measure Time Frame		

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range ____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

* Required   *§ Required if Primary Completion Date is on or after January 18, 2017   [*] Conditionally required
① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Statistical analysis

- **Statistical Test of Hypothesis** (*or Method of Estimation or Other Statistical Analysis required*)
  Definition: Procedure used for statistical analysis of outcome data and the calculated p-value.

  P-Value [*]
  Definition: Calculated p-value given the null-hypothesis

  Comments
  Definition: Additional information, such as whether the p-value is adjusted for multiple comparisons and the *a priori* threshold for statistical significance. Limit: 250 characters.

  Method [*]
  Definition: The statistical test used to calculate the p-value, if a P-Value is reported.

- **Other Method Name [*]**
  Definition: If "Other" is selected, provide name of statistical test.
  Limit: 40 characters.

  Comments
  Definition: Any other relevant information about the statistical test, such as adjustments or degrees of freedom.
  Limit: 150 characters.

Below is an example of the outcome measures

Outcome measures
Statistical analysis

- **Statistical Test of Hypothesis** (*or Method of Estimation or Other Statistical Analysis required*)
  Definition: Procedure used for statistical analysis of outcome data and the calculated p-value.

  P-Value [*]
  Definition: Calculated p-value given the null-hypothesis

  Comments
  Definition: Additional information, such as whether the p-value is adjusted for multiple comparisons and the *a priori* threshold for statistical significance. Limit: 250 characters.

  Method [*]
  Definition: The statistical test used to calculate the p-value, if a P-Value is reported.

- **Other Method Name [*]**
  Definition: If "Other" is selected, provide name of statistical test.
  Limit: 40 characters.

  Comments
  Definition: Any other relevant information about the statistical test, such as adjustments or degrees of freedom.
  Limit: 150 characters.

- **Method of Estimation** (*or Statistical Test of Hypothesis or Other Statistical Analysis required*) Definition: Procedure used to estimate effect of intervention

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

Outcome measures
Statistical analysis

- **Estimated Value [*]**
Definition: The calculated value for the estimation parameter.
- **Confidence Interval** (*If applicable*)
  - **Level [*]**
  Expressed as a percentage.
  - **Number of Sides [*]**
  Select 1-sided or 2-sided.
  - **Lower Limit [*]**
  Definition: Required if confidence interval is "2-sided" or if confidence interval is "1-sided" and no Upper Limit is entered.
  - **Upper Limit [*]**
  Definition: Required if confidence interval is "2-sided" or if confidence interval is "1-sided" and no Lower Limit is entered.
  - **NA (Not Available) Explanation [*]**
  Definition: Explain why the upper limit data are not available, if "NA" is reported as upper-limit of "2-sided" confidence interval. Limit: 250 characters.

Below is an example of the outcome measures

More details available in the Results Data Element Definitions.

April 2017

Outcome Measure Template — *ClinicalTrials.gov*

	(Select One)	Primary	Secondary	Other Pre-specified	Post-Hoc
* Outcome Measure Type					
* Outcome Measure Title					
[*] Outcome Measure Description					
* Outcome Measure Time Frame					

* Arm/Group Title			
*§ Arm/Group Description ①			
* Overall Number of Participants Analyzed ②			
[*] Analysis Population Description			

* Measure Type	* Measure of Dispersion/Precision			
(Select One)	(Select One)			
Count of Participants ③	Not Applicable ④			
Mean	Standard Deviation			
Median	Standard Error			
Least Squares Mean (LSM)	Inter-Quartile Range			
Geometric Mean	Full Range			
Geometric LSM	___ % Confidence Interval			
Number	Geometric Coefficient of Variation			
Count of Units ③				
[*] Row/Category Title ⑤		③④	③④	③④
[*] Row/Category Title ⑤		③④	③④	③④
* Unit of Measure				

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

Outcome measures
Statistical analysis

- **Parameter Dispersion Type**
  Select one.
  - Standard Deviation
  - Standard Error of the Mean

- **Dispersion Value**
  Definition: The calculated value for the dispersion of the estimated parameter.

- **Estimation Comments**
  Definition: Any other relevant estimation information, including the direction of the comparison (for example, describe which arm or comparison group represents the numerator and denominator for relative risk).
  Limit: 250 characters.

- **Other Statistical Analysis**
  Definition: If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of any other scientifically appropriate tests of statistical significance.

Below is an example of the outcome measures

Adverse events

Adverse events
General

- **Definition**: Any untoward or unfavorable medical occurrence in a participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

  Three types of adverse event data are to be reported: "All-Cause Mortality," "Serious," and "Other (Not Including Serious)" Adverse Events.

- **All-Cause Mortality**: The occurrence of death due to any cause.

- **Serious Adverse Events**: Include adverse events that result in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

- **Other** (Not Including Serious) Adverse Events: Adverse events that are not Serious Adverse Events.

More details available in the Results Data Element Definitions.

April 2017

All-Cause Mortality and Serious Adverse Events Template — *ClinicalTrials.gov*

*§ Time Frame							
[*] Adverse Event Reporting Description							
Source Vocabulary Name for Table Default ①							
*§ Collection Approach for Table Default ①	(Select One)	Systematic	Non-Systematic				

* Arm/Group Title				
*§ Arm/Group Description ②				

*§ All-Cause Mortality

	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk
*§ Total						

* Serious Adverse Events

		* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events
	* Total									
* Adverse Event Term	* Organ System									
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		

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

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

Adverse events
Basic table information

- **Time Frame *§**
  Definition: The specific period of time over which adverse event data were collected. Limit: 500 characters.

- **Adverse Event Reporting Description [*]**
  Definition: If the adverse event information collected in the clinical study is collected based on a different definition of adverse event and/or serious adverse event than the Adverse Events definition below, a brief description of how the definitions differ. May also be used to provide any additional relevant information about adverse event collection, including details about the method of systematic assessment (for example, daily questionnaire) or information about how the analysis population was determined (if the Number of Participants at Risk differs from the number of participants assigned to the arm or comparison group). Limit: 500 characters.

- **Source Vocabulary Name for Table Default**
  Definition: Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (for example, SNOMED CT, MedDRA 10.0). Default value for Source Vocabulary Name to be applied to all adverse event terms entered in the "Serious Adverse Event" and "Other (Not Including Serious) Adverse Event" tables. If necessary, Source Vocabulary Name may also be specified for specific Adverse Event Terms. Limit: 20 characters.

More details available in the Results Data Element Definitions.   April 2017

Other (Not Including Serious) Adverse Events Template   *ClinicalTrials.gov*

*§ Time Frame	
[*] Adverse Event Reporting Description	
Source Vocabulary Name for Table Default ①	
*§ Collection Approach for Table Default ①	(Select One) Systematic Non-Systematic

* Arm/Group Title			
*§ Arm/Group Description ②			

* Other (Not Including Serious) Adverse Events

* Frequency Threshold for Reporting Other Adverse Events (0–5%) ____%		* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events
* Total										

* Adverse Event Term	* Organ System									
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		

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

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

Adverse events
Basic table information

- **Collection Approach for Table Default *§** (*or Collection Approach for each Adverse Event Term required*)

  Definition: The type of approach taken to collect adverse event information. Default value for the type of approach taken to collect adverse event information (Systematic or Non-Systematic Assessment) to be applied to all adverse event terms entered in the "Serious Adverse Event" or "Other (Not Including Serious) Adverse Event" tables. If necessary, Collection Approach may also be specified for specific Adverse Event Terms. Select one.
  - **Systematic Assessment**: Any method of routinely determining whether or not certain adverse events have occurred, for example through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method
  - **Non-Systematic Assessment**: Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

Adverse events
Arm/Group Information

- **Arm/Group Information ***
Definition: Arms or comparison groups in the study, including all arms or comparison groups based on the pre-specified protocol and/or statistical analysis plan.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

- **Arm/Group Title ***
Definition: Descriptive label used to identify each arm or comparison group.
Limit: >= 4 and <= 62 characters.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

- **Arm/Group Description *§**
Definition: Brief description of each arm or comparison group. In general, it must include sufficient detail to understand how the arm(s) or comparison groups were derived from the arm(s) to which participants were assigned in Participant Flow (if different) and the intervention strategy in each arm/group.
Limit: 999 characters.
  - **Straight from section 8 (Arm/group and intervention) from the study registration, copy/paste**

More details available in the Results Data Element Definitions.   April 2017

Other (Not Including Serious) Adverse Events Template   *ClinicalTrials.gov*

*§ Time Frame	
[*] Adverse Event Reporting Description	
Source Vocabulary Name for Table Default ①	
*§ Collection Approach for Table Default ①	(Select One) Systematic Non-Systematic

* Arm/Group Title				
*§ Arm/Group Description ②				

* Other (Not Including Serious) Adverse Events

* Frequency Threshold for Reporting Other Adverse Events (0–5%) ____%		* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events
* Total										
* Adverse Event Term	* Organ System									
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		
	③	④[*]			④[*]			④[*]		

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

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

Adverse events
Total Number Effected

- **Total Number Affected by All-Cause Mortality *§**
  Definition: Overall number of participants, in each arm/group, who died due to any cause.

- **Total Number at Risk for All-Cause Mortality *§**
  Definition: Overall number of participants, in each arm/group, included in the assessment of deaths due to any cause (that is, the denominator for calculating frequency of all-cause mortality).

- **Total Number Affected by Any Serious Adverse Event ***
  Definition: Overall number of participants affected by one or more Serious Adverse Events, for each arm/group.

- **Total Number at Risk for Serious Adverse Events *** (*or Number at Risk for each Serious Adverse Event Term required*)
  Definition: Overall number of participants included in the assessment of serious adverse events (that is, the denominator for calculating frequency of serious adverse events), for each arm/group.

- **Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events ***
  Definition: Specify the frequency of occurrence that an Other (Not Including Serious) Adverse Event must exceed, within any arm or comparison group, to be reported in the Other (Not Including Serious) Adverse Event table. The number for the frequency threshold must be less than or equal to the allowed maximum (5%). Do not include symbols (for example, > or %) in the data field, it will be expressed as a percentage. For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.

Adverse events
Total Number Effected

- **Total Number Affected by Any Other (Not Including Serious) Adverse Event Above the Frequency Threshold ***
  Definition: Overall number of participants affected, for each arm/group, by at least one Other (Not Including Serious) Adverse Event(s) reported in the table. Adverse events reported in the table are those that occurred at a frequency exceeding the specified Frequency Threshold (for example, 5%) within at least one arm or comparison group.

- **Total Number at Risk for Other (Not Including Serious) Adverse Events *** (*or Number at Risk for each Other, [Not Including Serious], Adverse Event Term required*)
  Definition: Overall number of participants, for each arm/group, included in the assessment of Other (Not Including Serious) Adverse Events during the study (that is, the denominator for calculating frequency of Other (Not Including Serious) Adverse Events).

Adverse events
Adverse Event Term/Organ System

- **Adverse Event Term ***
  Definition: Descriptive word or phrase for the adverse event.
  Limit: 100 characters.

- **Organ System ***
  Definition: High-level categories used to group adverse event terms by body or organ system. Select one. (Adverse events that affect multiple systems should be classified as "General disorders.")

  - Blood and Lymphatic System Disorders
  - Cardiac Disorders
  - Congenital, Familial and Genetic Disorders
  - Ear and Labyrinth Disorders
  - Endocrine Disorders
  - Eye Disorders
  - Gastrointestinal Disorders
  - General Disorders
  - Hepatobiliary Disorders
  - Immune System Disorders
  - Infections and Infestations
  - Injury, Poisoning and Procedural Complications
  - Investigations
  - Metabolism and Nutrition Disorders
  - Musculoskeletal and Connective Tissue Disorders
  - Neoplasms Benign, Malignant and Unspecified (Including Cysts and Polyps)
  - Nervous System Disorders
  - Pregnancy, Puerperium and Perinatal Conditions
  - Product Issues
  - Psychiatric Disorders
  - Renal and Urinary Disorders
  - Reproductive System and Breast Disorders
  - Respiratory, Thoracic and Mediastinal Disorders
  - Skin and Subcutaneous Tissue Disorders
  - Social Circumstances
  - Surgical and Medical Procedures
  - Vascular Disorders

Other (Not Including Serious) Adverse Events Template — ClinicalTrials.gov — April 2017

More details available in the Results Data Element Definitions.

This data element has the potential to be very lengthy if your intervention has the potential to affect many organs

Adverse events
Additional Description

- **Adverse Event Term Additional Description**
  Definition: Additional relevant information about the adverse event.
  Limit: 250 characters.

- **Source Vocabulary Name**
  Definition: Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (for example, SNOMED CT, MedDRA 10.0). Leave blank to indicate that the value specified as the Source Vocabulary for Table Default should be used.
  Limit: 20 characters.

- **Collection Approach *§** (*or Collection Approach for Table Default required*)
  Definition: The type of approach taken to collect adverse event information. Select one or leave blank to indicate that the value specified as the Assessment Type for Table Default should be used.
  - Systematic Assessment: Any method of routinely determining whether or not certain adverse events have occurred, for example through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method
  - Non-Systematic Assessment: Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

- **Adverse Event Data**

  Number of Participants Affected *
  Definition: Number of participants, in each arm/group, experiencing at least one event being reported.

  Number of Participants at Risk *
  Definition: Number of participants assessed, in each arm/group, for adverse events (that is, the denominator for calculating frequency of adverse events). Leave blank to indicate that the value specified as the total at risk in the arm/group for the table should be used.

  Number of Events
  Definition: Number of occurrences, in each arm/group, of the adverse event being reported.

More details available in the Results Data Element Definitions. April 2017

Other (Not Including Serious) Adverse Events Template ClinicalTrials.gov

Limitations and Caveats
Additional Description

- **Overall Limitations and Caveats**
  Definition: Describe significant limitations of the study. Such limitations may include not reaching the target number of participants needed to achieve target power and statistically reliable results or technical problems with measurements leading to unreliable or uninterpretable data.
  Limit: 250 characters.

Certain Agreements

- Information indicating whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the study, to discuss the results of the study at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the study. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

  Are all PIs Employees of Sponsor? *
  Definition: Indicate whether the principal investigator is an employee of the sponsor. Select one. Yes: The principal investigator is an employee of the sponsor

  - No: The principal investigator is not an employee of the sponsor

  - If "No" the following information is required:

- **Results Disclosure Restriction on PI(s)? [*]**
  Definition: Indicate whether there exists any agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants participating in the clinical study) between the sponsor or its agent and the principal investigator (PI) that restricts in any manner the ability of the PI to discuss the results of the clinical study at a scientific meeting or any other public or private forum or to publish in a scientific or academic journal the results of the clinical study, after the Primary Completion Date. Select Yes/No.

  If there are agreements with multiple PIs who are not employees of the sponsor and there is a disclosure restriction on at least one PI, select "Yes."

Edit

Certain Agreements
[Relationship of Principal Investigator and Sponsor not specified.]

Information is required

Certain Agreements

- **PI Disclosure Restriction Type**
  Definition: Additional information about the results disclosure restriction. If there are varying agreements, choose the type below that represents the most restrictive of the agreements (for example, the agreement with the greatest embargo time period). Select one.
  The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding study results for a period that is **less than or equal to 60 days** from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo.

- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding study results for a period that is **more than 60 days but less than or equal to 180 days** from the date that the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot unilaterally extend the embargo.

- Other disclosure agreement that restricts the right of the PI to disclose, discuss, or publish study results after the study is completed

- **Other Disclosure Restriction Description**
  Definition: If "Other disclosure agreement..." is selected, describe the type of agreement including any provisions allowing the sponsor to require changes, ban the communication, or extend an embargo.
  Limit: 500 characters.

Edit

Certain Agreements
[Relationship of Principal Investigator and Sponsor not specified.]

Information is required

Results Point of Contact

- Point of contact for scientific information about the clinical study results information.

   Name or Official Title *
   Definition: The person who is designated the point of contact. This may be a specific person's name (for example, Dr. Jane Smith) or a position title (for example, Director of Clinical Trials).

   Organization Name *
   Definition: Full name of the designated individual's organizational affiliation.

   Phone: *§ Office phone number of the designated individual. Use the format 12 456-7890 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code.

   Extension (Ext.): Phone extension, if needed

   Email: *§ Electronic mail address of the designated individual.

Edit

Results Point of Contact
Name/Official Title: ---
Organization: ---
Phone: ---
Email: ---

Information is required

Delayed results

Results Section

Results submission is required by FDAAA 801 for certain applicable clinical trials of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies. [Record must have a ClinicalTrials.gov ID (NCT number) before results can be entered.]

Delay Results For applicable clinical trials subject to FDAAA 801, results submission may be delayed (in limited circumstances) with a Certification or Extension Request.

For more information see: When Do I Need to Register and Submit Results?

- A responsible party may delay the deadline for submitting results information if one of the two certification conditions below applies to the clinical study. Alternatively, the responsible party may request an extension of the results submission deadline for good cause. The extension must be granted by the NIH Director. **Delay Results Type [*]** : Select one
    - Certify Initial Approval: Trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed or cleared by FDA for any use before the Primary Completion Date of the trial, and the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study.
    - Certify New Use: Trial studies an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug, product (including a biologic product) or device product) has been filed or will be filed within one year with FDA.
    - Extension: Request, for good cause, an extension of the deadline for submitting results information
    - Note: If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification under "Certify New Use," that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria: (1) the applicable clinical trial is required to be submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; (2) the applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted. [42 U.S.C. 282 (j)(3)(E)(v)(II) and 42 CFR 11.44(b)(3)]

- **Intervention Name(s)**
Definition: Provide the name of one or more drugs, biological products or devices to which the certification applies. For drugs use generic name; for other types of interventions provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol section.

- **FDA Application Number(s)**
Definition: Provide at least one FDA application number (for example, NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."

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

- **Explanation [*]** (*Required when Delay Results Type is "Extension."*)
Definition: Description of the reason(s) why clinical study results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request. Note that "pending publication" and delays in data analysis for unspecified causes are not considered good cause for an extension.
Limit: 999 characters.

FAQ

What happens once my study completes enrollment

- Once you've enrolled the last subject you will need to:
  - Change your study status to "active, not longer recruiting". This is critical to inform the public viewing this study on CT.gov that it is no longer an option for participation.
  - In the study design section, change the enrollment number to the actual number of subjects enrolled and change the enrollment type to "actual" from "anticipated"
  - Change your record verification date to the month and year that enrollment was met and release the record.
  - Change the recruitment status in the Contact/Location element
  - This must be done within 30 days of the change

What happens once my study completes data collection for the primary outcome

- Once you've completed data entry for the primary outcome:
  - Change the study status to "active, no longer recruiting"
  - Change the primary completion date to the date the last data point was collected for the primary outcome.
  - Change the date type from "anticipated" to "actual"
  - Change the verification date to the month and year the last primary outcome data point was collected.
  - Change the recruitment status in the Contact/Location element
  - Release the record
  - This must be done within 30 days of the change

- **Data entry in the results section is required one year from the date of primary outcome completion**

What happens once my study completes all data collection

- Once you've completed data entry for all outcomes:
  - Change the study status to complete
  - Change the study completion date to the date the last data point was collected for all outcomes.
  - Change the date type from "anticipated" to "actual"
  - Change the verification date to the month and year the last outcome data point was collected.
  - Change the recruitment status in the Contact/Location element
  - Release the record
  - This must be done within 30 days of the change

- **Data entry in the results section is required to be complete one year from the date the final outcome data was collected**

What happens if my study is terminated

- If your study terminates for any reason:
    - Change the study status to terminated
    - Provide a reason for the termination in the text box below "overall recruitment status"
    - Change the primary and study completion dates to the date the study terminated and change the date type from "anticipated" to "actual"
    - Change the recruitment status in the Contact/Location element
    - In the Study Design element, change the enrollment number to the actual number of subjects enrolled, then change the number type to "actual" from "anticipated"
    - This must be done within 30 days of the change

- If your study was an applicable clinical trial, data will still need to be entered for your terminated study
    - You will need to complete all data elements even if you only enrolled a single subject
    - If your trial did not enroll enough participants for meaningful data analysis, you can indicate that in the data table elements

What happens if my study is Withdrawn

- If your study is withdrawn for any reason:
    - Change the study status to withdrawn in the study status element
    - Provide a reason why the study was withdrawn in the text box below "overall recruitment status"
    - Change the primary and study completion dates to the date the study was withdrawn and change the date type from "anticipated" to "actual"
    - Change the recruitment status in the Contact/Location element
    - This must be done within 30 days of the change