

## ClinicalTrials.gov PRS

Protocol Registration and Results System

[Help: Protocol Modules](#) > All

### Help: Protocol Modules - All

Protocol module help pages contain an introduction, examples, data entry tips and a review checklist for each module in the protocol section.

#### Study Identification Module

##### Introduction

The Study Identification module contains identifiers and titles that uniquely identify a study within the sponsoring organization.

##### Example

**Study Identification**

Unique Protocol ID: example-1

Brief Title: Tramadol and Acetaminophen for Adults With Migraine Headaches (TAAMH)

Official Title: Placebo-Controlled, Randomized, Double-Blind Trial of Tramadol and Acetaminophen for Adults With Chronic Migraine Headaches

Secondary IDs: ABC123 [National Headache Center]

##### Data Entry Tips

- Unique Protocol ID is an unique identifier assigned by the sponsoring organization, possibly an accession number or a grant number. Multiple studies conducted under the same grant must each have a different ID.
- Brief Title must be unique within the sponsoring organization's PRS account.
- Secondary IDs are identifiers or numbers assigned to the study, including unique identifiers from other registries and NIH grant or contract award numbers, if applicable. Secondary ID types:
  - US NIH Grant/Contract Award Number - include activity code, institute code and 6-digit serial number. Other components of the full award number (type code, support year and suffix, if applicable) are optional. Use the [NIH RePORTER](#) to look up the grant number -- numbers not recognized by RePORTER will not be accepted.
  - Other Grant/Funding Number - also provide name of grantor.
  - Registry Identifier - also provide name of clinical trials registry.
  - EudraCT Number - from European Union Drug Regulatory Authorities Clinical Trial System.
  - Other Identifier - also provide name of issuing organization.

##### Review Checklist

- Brief title is understandable to the lay public.
- All applicable identifiers (e.g., IDs from other registries, NIH grant numbers) for this study have been included in Secondary IDs.
- If the study has an acronym it is listed in the Acronym field, rather than within the Brief Title or Official Title (ClinicalTrials.gov will automatically display the acronym next to Brief Title on the public display).

## Additional Resources

[Tips for Entering Special Characters](#)

[Protocol Review Criteria](#) (PDF)

## Study Status Module

### Introduction

The Study Status module contains key dates and Overall Recruitment Status of a study.

### Example

Study Status
Record Verification: December 2016
Overall Status: Recruiting
Study Start: December 18, 2016 [Actual]
Primary Completion: June 2018 [Anticipated]
Study Completion: January 2019 [Anticipated]

### Data Entry Tips

- Review a record for an Active (not completed or terminated) study and update the Verification Date at least once per year, even if no additional or updated information was submitted during that year. Note: some data elements will need to be updated more frequently.
- When Overall Recruitment Status is Recruiting, the Recruitment Status must be specified for each Location.
- When the final participant has been examined or received an intervention for the purposes of final collection of data for the Primary Outcome Measure, update Primary Completion Date and change Type to Actual.
- When the final participant has been examined or received an intervention for the purposes of final collection of data for the overall study, update Study Completion Date and change Type to Actual.

## Additional Resources

[Protocol Review Criteria](#) (PDF)

## Sponsor/Collaborators Module

### Introduction

The Sponsor/Collaborators module identifies who is responsible for initiating, funding, designing and conducting the study, and for performing the associated data analysis and reporting.

### Examples

<b>Sponsor/Collaborators</b>
Sponsor: National Library of Medicine (NLM)
Responsible Party: Sponsor
Collaborators: National Headache Center

<b>Sponsor/Collaborators</b>
Sponsor: National Library of Medicine (NLM)
Responsible Party: Principal Investigator
Investigator: John Smith, MD [jsmith]
Official Title: Director, Clinical Research
Affiliation: National Library of Medicine (NLM)
Collaborators:

### Data Entry Tips

- Select Sponsor for Responsible Party unless the Principal Investigator has been designated as Responsible Party by the Sponsor or the Principal Investigator is the Sponsor.
- If the Principal Investigator (PI) is designated as Responsible Party, the PI must Release (submit) the record to ClinicalTrials.gov following initial data entry and after each update.
- For IND/IDE studies, the IND holder is the Sponsor or Sponsor-Investigator.
- For multi-site studies, individual sites are not typically listed as Collaborators.
- All funding or supporting organizations other than the Sponsor should be listed as Collaborators.
- Sponsor and Collaborator names should include only the official name of the organization, not department names, addresses or any other extraneous information.

### Additional Resources

[Final rule for Clinical Trials Registration and Results Information Submission \(42 CFR Part 11\)](#)

[About Responsible Party](#)

[Elaboration of Definitions of Responsible Party and Applicable Clinical Trial \(ACT\) \(PDF\)](#)

### Oversight Module

#### Introduction

The Oversight module includes information related to the regulatory status of products studied in the trial, human subjects protections and plans to share individual participants data.

#### Examples

**Oversight**

U.S. FDA-regulated Drug: Yes

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE Study: Yes

IND/IDE Information: FDA Center: CDER  
 IND/IDE Number: 12345  
 IND Serial Number: 123  
 Has Expanded Access No

Human Subjects Review: Board Status: Approved

Data Monitoring: Yes

Plan to Share IPD: Yes

De-identified individual participant data for all primary and secondary outcome measures will be made available within 6 months of study completion.

**Oversight**

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE Study: No

Human Subjects Review: Board Status: Approved Approval Number: 01/13/2017  
 Board Name: Bethesda Institutional Review Board  
 Board Affiliation: Bethesda Hospital  
 Phone: 301-555-5555 Email: example@bethesda.org

Data Monitoring: Yes

Plan to Share IPD: No

**Data Entry Tips**

- For more information on U.S. FDA-regulated Drug and Device Products and Applicable Clinical Trials (ACT) see the [ACT Checklist](#) (PDF).
- Human subjects protection review board information:
  - Provide information for only one review board, even for studies involving multiple boards.
  - Board Approval Number may be omitted if status is anything other than approved. If the board does not assign numbers, enter the date of approval in mm/dd/yyyy format.
- If planning to share individual participant data (IPD), fill in the Description field with a brief description of the data to be shared, availability time frame and instructions for requesting the data. If not sharing IPD, an explanation may be provided in the Plan Description field.

**Additional Resources**

[ACT Checklist](#) (PDF) - Checklist and Elaboration for Evaluating Whether a Clinical Trial is an Applicable Clinical Trial (December 2016)

[Which Trials Must Be Registered and Have Results Submitted to ClinicalTrials.gov?](#)

[Elaboration of Definitions of Responsible Party and Applicable Clinical Trial \(Draft, March 2009\)](#) (PDF)

[Protocol Review Criteria](#) (PDF)

**Description Module****Introduction**

The Study Description module includes the Brief Summary and Detailed Description fields.

## Example

### Description

**Brief Summary:** This study evaluates the addition of tramadol to acetaminophen in the treatment of migraine headaches in adults. Half of participants will receive tramadol and acetaminophen in combination, while the other half will receive a placebo and acetaminophen.

**Detailed Description:** Tramadol and acetaminophen each relieve pain, but they do so by different mechanisms.

Tramadol achieves pain relief in two ways. It binds to the -opioid receptor on nerves (the same mechanism that is responsible for the effectiveness of narcotics, such as morphine), and it also inhibits the reuptake by nerves of two neurotransmitters, serotonin and norepinephrine, that the nerves use to communicate with one another. This inhibition may lead to reduced transmission of pain signals from nerve to nerve in the spinal cord and brain.

Acetaminophen achieves pain relief in the spinal cord and brain by increasing the threshold to pain, that is, by increasing the strength of the painful stimulus that is necessary in order to give rise to the sensation of pain. It does this by inhibiting an enzyme that makes prostaglandins.

## Data Entry Tips

- Brief Summary is a short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.
- Detailed Description is an extended description of the protocol, optionally including more technical information.
- A limited text formatting capability is provided (e.g., paragraphs, bulleted or numbered lists). See [Tips for Formatting Text](#).

## Additional Resources

[Tips for Entering Special Characters](#)

[Protocol Review Criteria](#) (PDF)

## Conditions Module

### Introduction

The Conditions module includes the Conditions and Keywords lists. Conditions include the primary disease (s) or condition(s) being studied. Keywords may optionally be specified to improve search results on the ClinicalTrials.gov public site.

## Example

### Conditions

Conditions: Headache Disorders  
Migraine Disorders

Keywords: aura  
photophobia

### Data Entry Tips

- Condition names should be taken from the National Library of Medicine's Medical Subject Headings (MeSH) vocabulary when possible.
- Use the suggested terms that appear after the first part of the word is entered or select the Search MeSH link on the Conditions page to search for valid condition terms.
- Condition names should include only the name of the condition, excluding any other extraneous information..
- If there are no specific conditions under study, enter a brief description of the primary focus of the study and disregard the NOTE indicating that the Condition is not recognized.
- It is not necessary to specify Keywords for words or phrases that are already included in other fields such as Brief Title, Brief Summary, Conditions or Interventions.

### Additional Resources

[Protocol Review Criteria](#) (PDF)

## Interventional Study Design Module

### Introduction

The Interventional Study Design module describes the primary investigative techniques used for a study in which individuals are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes (i.e., a clinical trial).

### Example

Study Design
Study Type: Interventional [ <a href="#">Change...</a> ]
Primary Purpose: Treatment
Study Phase: Phase 2
Interventional Study Model: Parallel Assignment
Number of Arms: 2
Masking: Participant, Investigator
Allocation: Randomized
Enrollment: 500 [Anticipated]

### Data Entry Tips

- Study Phase is defined by the US FDA for trials of drug products (including biological products). Select "N/A" for trials that do not involve drugs or biological products.
- For active studies, set Enrollment Type to Anticipated and specify the target number of subjects. Update the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.

### Additional Resources

[Help: Study Type](#)

[Protocol Review Criteria](#) (PDF)

## Observational Study Design Module

### Introduction

The Observational Study Design module describes the strategy for the observational research, including participant identification and follow-up.

### Example

**Study Design**

Study Type: Observational [Change Study Type...](#)

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: Samples Without DNA

Biospecimen Description:
 

- tear samples
- contact lenses
- bacteria isolated from contact lenses

Enrollment: 200 [Anticipated]

Number of Groups/Cohorts: 2

### Data Entry Tips

- Select the Change Study Type link on the Protocol Section page if this is not an observational study. In observational studies, the investigator does not assign participants to interventions, but instead observes (for example) patients who have been given interventions in the course of routine clinical care.
- For Biospecimen Description list all types of biospecimens to be retained, if any.
- For active studies, set Enrollment Type to Anticipated and specify the target number of participants. Update the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.
- Some observational studies have one Group/Cohort; case control studies typically have two.

### Additional Resources

[Help: Study Type](#)

[Protocol Review Criteria](#) (PDF)

## Arms/Groups and Interventions Module

### Introduction

The Arms/Groups and Interventions module includes up to three editing pages, depending upon Study Type:

Study Type	Editing Pages
Interventional	Edit Arms Edit Interventions Edit Arm/Intervention Cross-Reference
Observational	Edit Groups Edit Interventions/Exposures Edit Group/Intervention Cross-Reference
Expanded Access	Edit Interventions

### Example

**Arms**

Arm: Experimental: Acetaminophen & Tramadol  
Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth, every 6 hours for 7 days

Arm: Active Comparator: Acetaminophen & Placebo  
Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth, every 6 hours for 7 days

**Interventions**

Intervention: Drug: Acetaminophen  
Other Names:  
Tylenol  
Anacin-3  
Acetaminophen tablet

Intervention: Drug: Tramadol  
Other Names:  
Ultrim  
Rybix  
Tramadol tablet

Intervention: Drug: Placebo  
Other Names:  
Placebo (for Tramadol)  
Sugar pill manufactured to mimic tramadol 50 mg tablet

**Cross-Reference**

Arms	Interventions		
	Drug: Acetaminophen	Drug: Tramadol	Drug: Placebo
Experimental: Acetaminophen & Tramadol Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth, every 6 hours for 7 days	✔	✔	
Active Comparator: Acetaminophen & Placebo Acetaminophen 325 mg tablet and Tramadol 50 mg tablet by mouth, every 6 hours for 7 days	✔		✔

✔ - Intervention is administered to patients in this Arm.

**Data Entry Tips**

- Arm Title (or Group/Cohort Label) should be descriptive enough to distinguish one arm from another, yet concise enough for use as Results column headings. Examples: Acetaminophen, Melatonin 10 mg, Lifestyle counseling, Placebo
- For a multi-arm interventional study set Arm Type to Experimental for the arm(s) involving the drug or device product under study. For other arms select the appropriate Comparator option.
- In Arm (or Group/Cohort) Description, include the intervention name(s), exactly as specified in the Intervention Name field. For drugs, use the generic name if it has been established, and include dosage form, dose, frequency and duration.
- **Do not specify the same intervention multiple times.** Use Arm/Group Descriptions to describe differences in dosage, frequency, etc.
- For Intervention Name enter the generic name of a drug. Include brand names, serial numbers and code names in the Other Intervention Names list.
- For Observational studies use Intervention Name to identify intervention(s) or exposure(s) of interest.

## Additional Resources

[Protocol Review Criteria](#) (PDF)

## Outcome Measures Module

### Introduction

The Outcome Measures module includes primary and secondary outcome measures. Other pre-specified outcome measures may also be provided.

### Example

#### Outcome Measures

Primary Outcome Measure:

1. 4-Item Pain Intensity Measure (P4)

Self reported pain intensity in the morning, afternoon, evening and with activity over the past 2 days. Each item is scored 0-10 (0 = no pain; 10 = pain as bad as can be), yielding a total between 0 and 40.

[Time Frame: 2 days]

Secondary Outcome Measures:

2. Recurrence of Pain

Return of any migraine headache pain during the specified post-dose period, following a pain-free response at 2 hours.

[Time Frame: 24 and 48 hours]

3. Sustained Freedom from Migraine

Pain free, with no migraine associated symptoms (photophobia, phonophobia, nausea) at the time of assessment, following a symptom-free response within 1 day of initial dose.

[Time Frame: 7 days]

### Data Entry Tips

- A study typically has one Primary Outcome Measure.
- Outcome Measure information should describe WHAT is to be measured, not why it is measured.
- Outcome Measure Titles should not be overly general (e.g., "bioequivalence," "safety," "feasibility").
- Make each Outcome Measure Title unique and descriptive, indicating the metric to be used. Examples:
  - Change in Systolic Blood Pressure
  - Area under the plasma concentration versus time curve (AUC) of [DRUG NAME]
  - Peak Plasma Concentration (Cmax) of [DRUG NAME]
- Specify each Outcome Measure separately. The same measurement taken at different time points must be specified as unique Outcome Measures.
- Time Frame is usually a single point in time at which a study participant is assessed for that measure, with these exceptions:
  - Change measures (e.g., "baseline and 8 weeks")
  - Time-to-Event measures (e.g., "up to 100 weeks," "from date of randomization until the date of first documented progression or date of death from any cause, whichever came first, up to 100 months")
  - Pharmacokinetic measures (e.g., "0, 1, 2, 3, 4, 6, 8, 24 hours post-dose")

## Additional Resources

[Protocol Review Criteria](#) (PDF)

## Eligibility Module

## Introduction

The Eligibility module specifies the criteria for determining which people are (or are not) eligible to participate in the study.

## Example

Eligibility
Minimum Age: 18 Years
Maximum Age:
Sex: All
Gender Based: No
Accepts Healthy Volunteers: Yes
Criteria: Inclusion Criteria:
• Subject has migraine headache
• Subject has had 1-8 migraines per month over the previous 3 months
Exclusion Criteria:
• History of heart disease
• History of bleeding disorders
• Pregnant, trying to become pregnant or breast feeding
• Allergic to acetaminophen or tramadol

## Data Entry Tips

- For Age Limits, if there is no minimum or maximum age, select "N/A (No limit)" from the corresponding option menu.
- For Eligibility Criteria include headings for "Inclusion Criteria" and "Exclusion Criteria" with a bulleted list under each heading:

Inclusion Criteria:  
- Clinical diagnosis of Alzheimer's Disease  
- Must be able to swallow tablets

Exclusion Criteria:  
- Insulin dependent diabetes  
- Thyroid disease

## Additional Resources

[Tips for Formatting Text](#)

[Tips for Entering Special Characters](#)

[Protocol Review Criteria](#) (PDF)

## Contacts/Locations Module

### Introduction

The Contacts/Locations module specifies contacts and study officials for the overall study. For each study site the module includes the name and location of the facility, along with facility contacts and site investigators.

### Example

**Contacts/Locations**

Central Contact: John J Smith  
 Telephone: 301-555-5555  
 Email: [jsmith@nlm.gov](mailto:jsmith@nlm.gov)

Central Contact Backup: Mary B Jones  
 Telephone: 301-555-4444  
 Email: [mjones@nlm.gov](mailto:mjones@nlm.gov)

Study Officials: Gregory House, MD  
 Study Principal Investigator  
 National Headache Center

▼ Locations: **United States, Maryland**

NIH Clinical Center Recruiting

Bethesda, Maryland, United States, 20892

Principal Investigator: Lilly C White, MD

Ashton Headache Center Not yet recruiting

Ashton, Maryland, United States, 20861

Principal Investigator: Joseph M Brown, PhD

**United States, Virginia**

Virginia Headache Clinic Recruiting

Reston, Virginia, United States, 20190

**France**

Paris Headache Clinic Active, not recruiting

Paris, France

**Data Entry Tips**

- Overall Study Officials are required by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE).
- If a Central Contact Person is specified, it is not necessary to specify Facility Contact for each location.
- Unless the Overall Recruitment Status of an active study is "Not yet recruiting":
  - At least one location must be specified.
  - At least one location must have status set to "Recruiting".
  - Recruitment Status must be specified for each Location.
  - Either any location that is recruiting must have Facility Contact specified, or Central Contact must be specified.
- If the Overall Recruitment Status of the study is anything other than Recruiting, location Recruitment Status is not shown on ClinicalTrials.gov.  
*Tip: When Overall Recruitment Status changes from Recruiting to anything else, it is not necessary to update each location's Recruitment Status.*
- Update Overall Recruitment Status by editing the Study Status module.
- Contact information is shown on ClinicalTrials.gov only for locations with status set to "Recruiting" or "Not yet recruiting".
- Use the Sort Locations button to sort locations in the same order in which they will appear on the ClinicalTrials.gov public web site: country/state/city order, with US locations first.

**Additional Resources**

[Protocol Review Criteria](#) (PDF)

**References Module****Introduction**

The References module includes Citations for publications and Links to web sites related to the study.

**Example**

**References**

Citations: Murnion BP, Gnjidic D, Hilmer SN. Prescription and administration of opioids to hospital in-patients, and barriers to effective use. *Pain Med.* 2010 Jan;11(1):58-66. doi: 10.1111/j.1526-4637.2009.00747.x. Epub 2009 Nov 17. PubMed ID: 19930113

Lipton RB, Buse DC, Saiers J, Fanning KM, Serrano D, Reed ML. Frequency and burden of headache-related nausea: results from the American Migraine Prevalence and Prevention (AMPP) study. *Headache.* 2013 Jan;53(1):93-103. doi: 10.1111/j.1526-4610.2012.02292.x. Epub 2012 Nov 13. PubMed ID: 23148774

Links: URL: <http://nih.gov>  
Description: test link

Study Data/Documents: Type: Individual Participant Data Set  
URL: <http://bethesda.org/data?id=123>  
Identifier: 123  
De-identified data for primary and secondary outcome measures.

Type: Study Protocol  
To request an electronic copy send email to [protocols@bethesda.org](mailto:protocols@bethesda.org).

**Data Entry Tips**

- Specify Citations using the PubMed Identifier (PMID) from the MEDLINE database when applicable. Use the PubMed Citation Matcher link to search for citations based on journal name, date, author(s), title and other criteria.
- When entering a PMID use the Lookup button to verify that the ID is correct.
- If a publication does not have a PMID use the Enter Citation Text button to enter the full bibliographic citation. All citations not including a PMID are subject to review by ClinicalTrials.gov.
- Alternatively, a PubMed Central ID (e.g., PMC1234567) for a citation from PubMed may be entered in the PubMed ID field. The corresponding PMID will be displayed after successful lookup.
- For Citations, only select "Yes" for Results Reference if the reference is reporting the results of this specific study.
- For Links, the Description field will be used as link text on the ClinicalTrials.gov public web site.
- Links to educational, research, government, and other non-profit web sites are acceptable. Do not include links to sites whose primary goal is to advertise or sell commercial products or services. All links are subject to review by ClinicalTrials.gov.
- For each Available Study Data Set or Document, specify the web address (URL) where the data set or document may be accessed, downloaded or requested. If there is no applicable web address, use the Comments field to provide instructions for requesting the data set or document.

**Additional Resources**

[Protocol Review Criteria](#) (PDF)