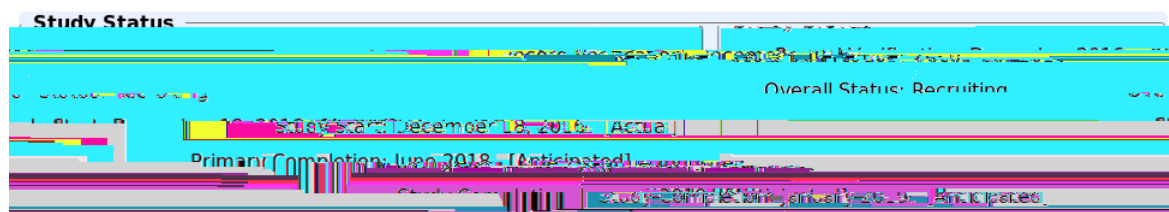




[Tips for Entering Special Characters](#)

[Protocol Review Criteria](#) (PDF)

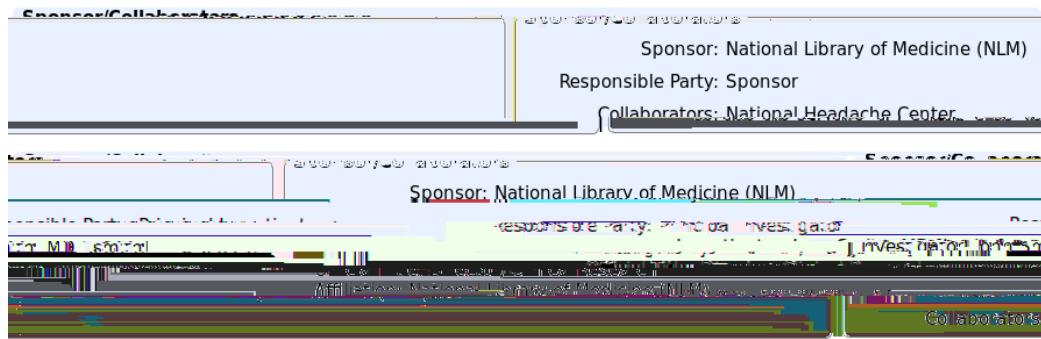
The Study Status module contains key dates and Overall Recruitment Status of a study.



- 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.

[Protocol Review Criteria](#) (PDF)

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.



- 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.

.....



**Oversight**

U.S. FDA-regulated Device 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 AT: 01/13/2017

Board AT: 01/13/2017

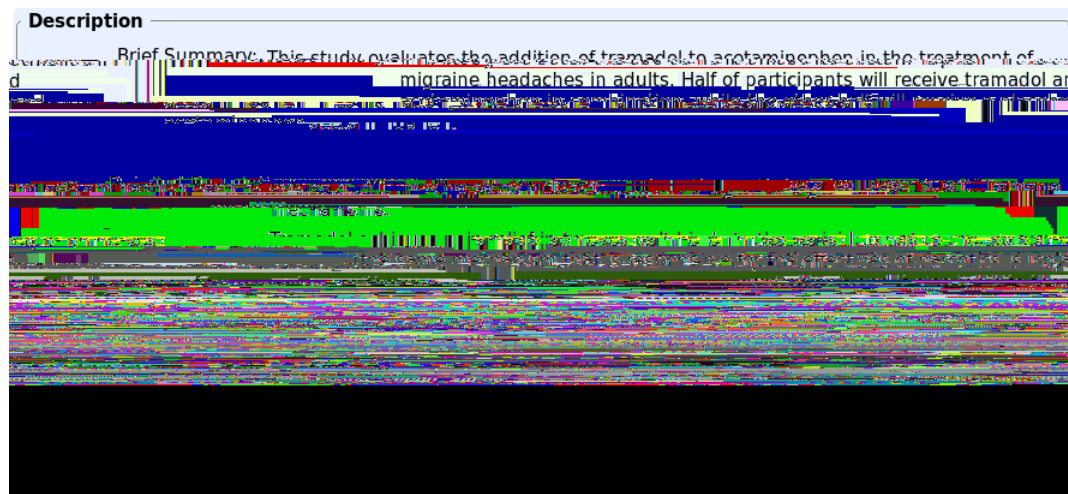
Phone: 301.555.5555 Email: \_\_\_\_\_

ing: Yes

Data M

PD: No

Plan to S

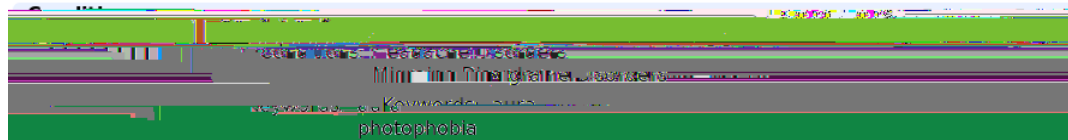


- Brief Summary is a short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.
- Detailed Description is an extended description of the protocol, optionally including more technical information.
- A limited text formatting capability is provided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

[Tips for Entering Special Characters](#)

[Protocol Review Criteria](#) (PDF)

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.



Data Entry Tips

## Observational Study Design Module

### Introduction

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

### Example



### 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:



**Arms**

Arm: Experimental: Acetaminophen & Tramadol

Arm: Active Comparator: Acetaminophen & Placebo

**Interventions**

Acetaminophen

Other Names:  
Tylenol  
Anacin-3

↑ acetaminophen tablet

Intervention: Drug: [ ]

Tramadol

Other Names:  
Ultram  
Prolofen

Information: Drug: Opioid  
Other Names:  
Placebo (for Tramadol)  
Sugar pill manufactured

**Cross-Reference**

Interventions			Arms
Drug:	Drug:	Drug:	
Acetaminophen	Tramadol	Placebo	

▼ 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 Measures:**

1. 4-Item Pain Intensity Measure (P4)  
Self-reported pain intensity in the morning, afternoon, evening and with activity using the measure... Each item is scored 0-10... yielding a total between 0 and 40.  
[Time Frame: 7 days]

**Secondary Outcome Measures:**

2. Recurrence of Pain  
Return of migraine pain during the specified time frame...  
[Time Frame: 24 and 48 hours]
3. Sustained Freedom from Migraine  
Pain free, with no migraine associated symptoms (photophobia, phonophobia, nausea) at time of occurrence...  
[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.
- FT08-- plasmawhy6( co"santred87(2)-6.9).5ue)-isurcurve., AUC) ofred87DRUG NME6.4( Tf0 -49 -2.4-.7c.0007c0 s)TJET010 c1.3643 -2.4

## Introduction

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

## Example

The screenshot shows a form titled "Eligibility" with the following fields and values:

- Minimum Age: 18 Years
- Maximum Age:
- Sex: All
- Gender Based: No
- Accepts Healthy Volunteers: Yes
- Criteria: Inclusion Criteria:
- Exclusion Criteria:

The criteria lists are partially obscured by a blue and green overlay. Visible items include:

- History of heart disease
- History of bleeding disorders
- Pregnant, trying to become pregnant, or breast feeding
- Allergic to acetaminophen or ibuprofen

## 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

#### 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



### 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