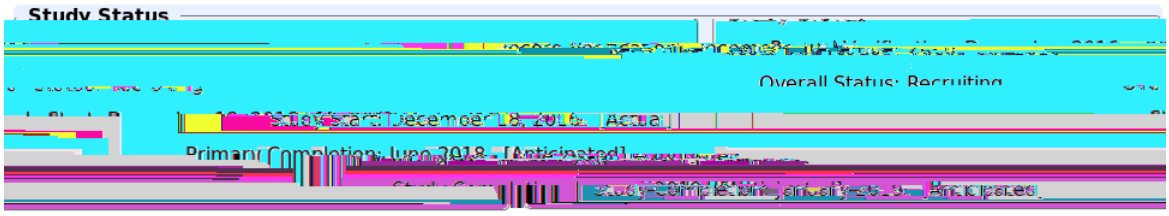
Tips for Entering Special Characters

Protocol Review Criteria (PDF)

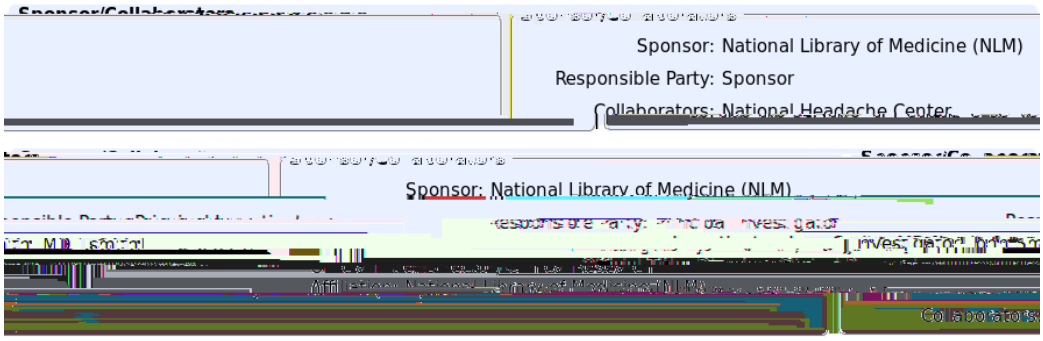
The Study Status module contains key dates and Overall Recruitment Status of a study.



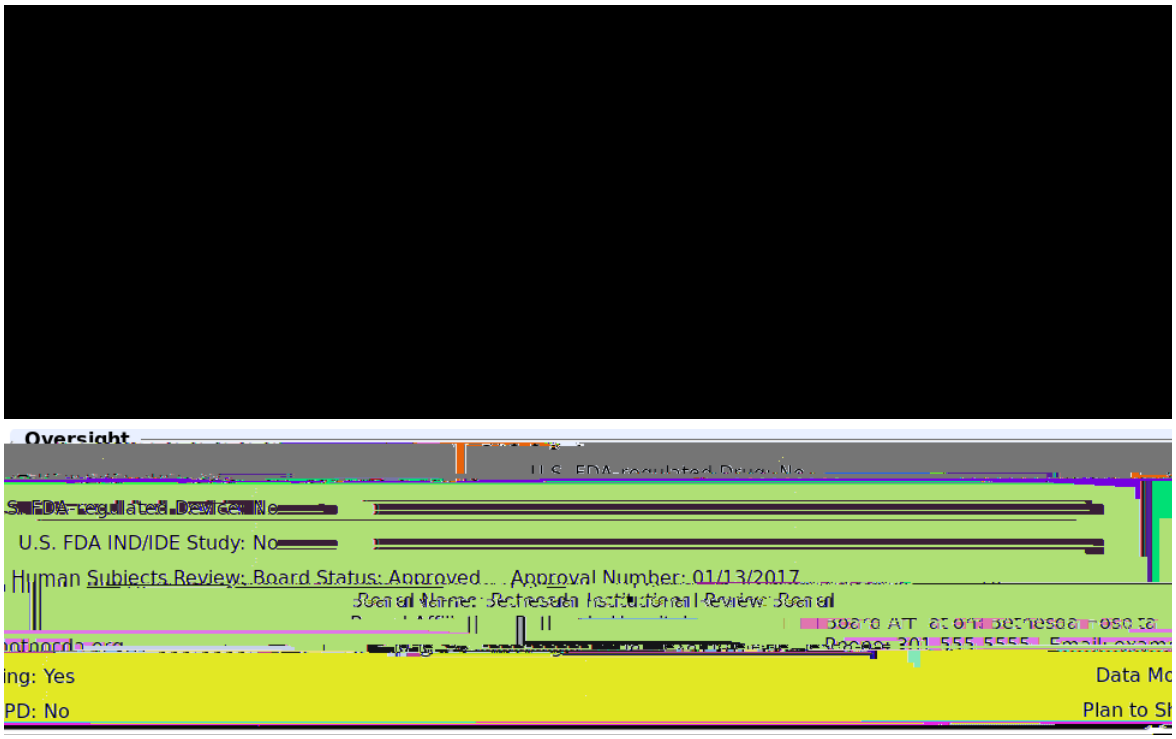
- Review a record for an Active (not completed or terminated) study and update the Verification Date at least once per year, even if no additional or updated information was submitted during that year. Note: some data elements will need to be updated more frequently.
- When Overall Recruitment Status 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)

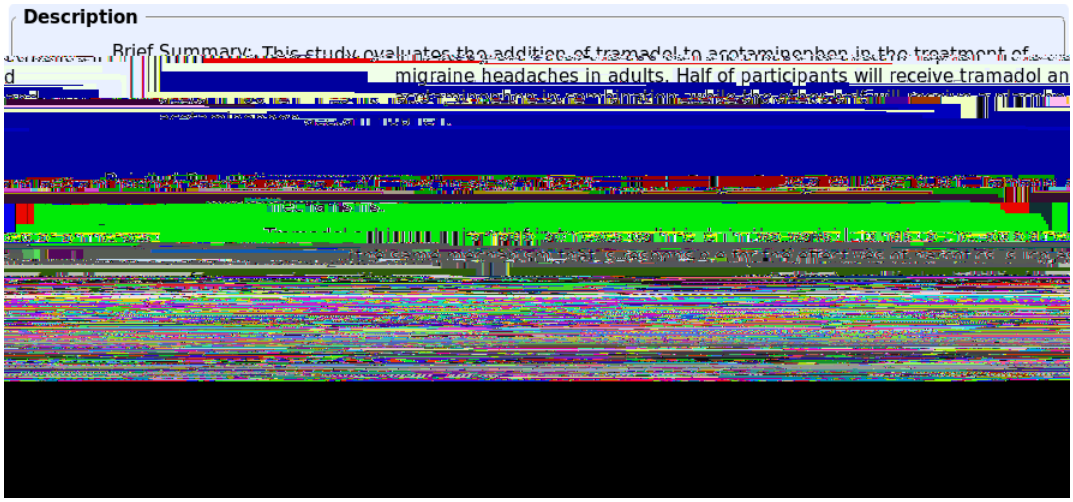
The Sponsor/Collaborators module identifies who is responsible for initiating, funding, designing and conducting the study, and for performing the associated data analysis and reporting.



- 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 Drug: 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
Phone: 301 555 5555
ing: Yes
Data Mo
PD: No
Plan to Sh

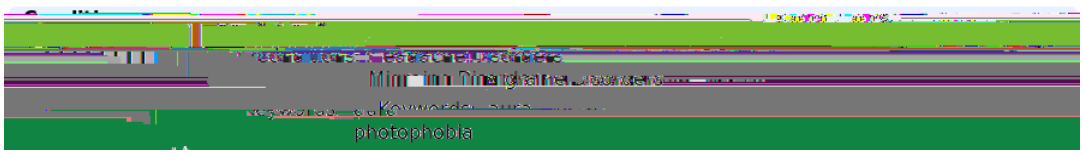


- Brief Summary is a short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis.
- Detailed Description is an extended description of the protocol, optionally including more technical information.
- A limited text formatting capability is provided (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.

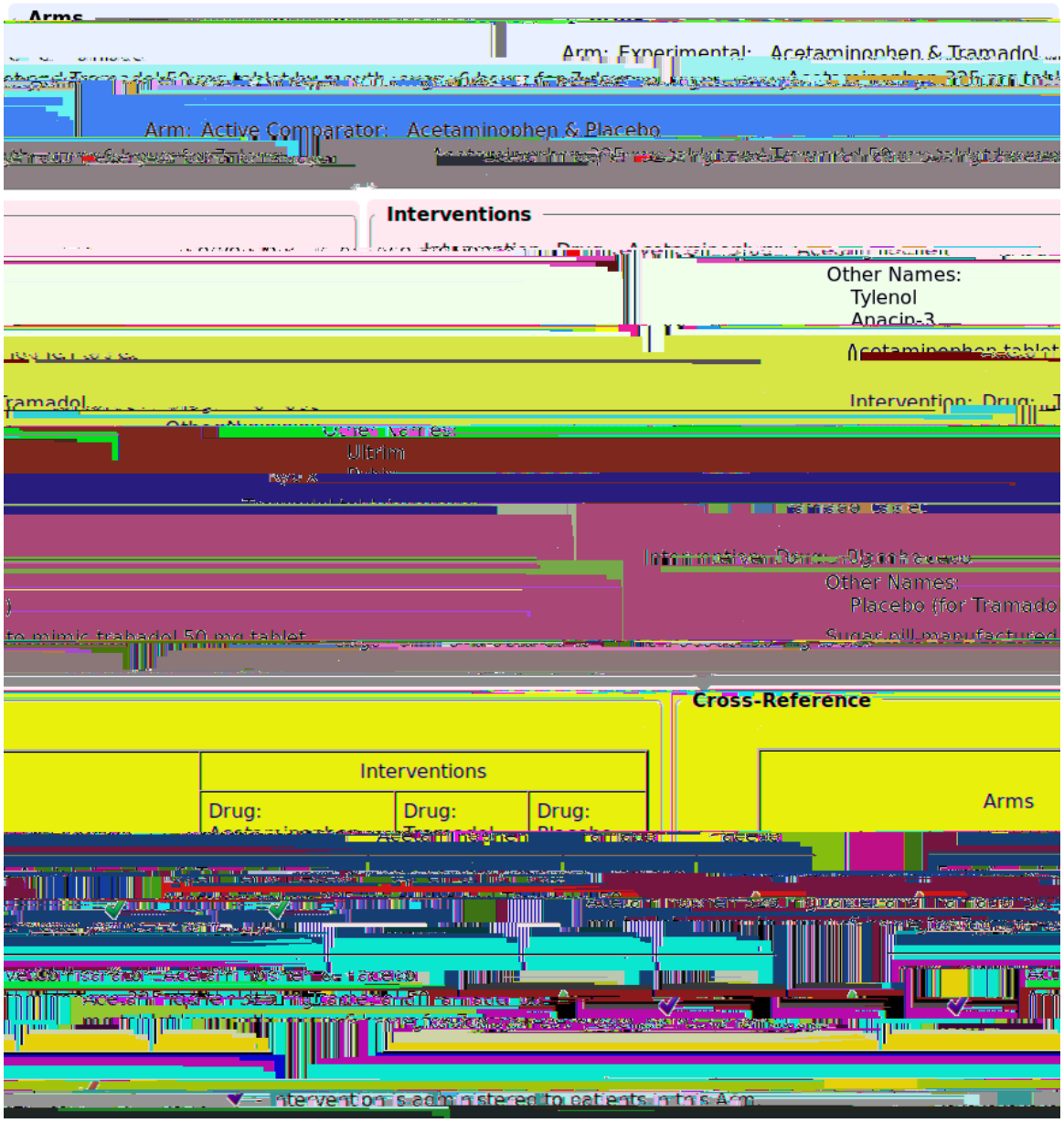
Additional Resources

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:



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

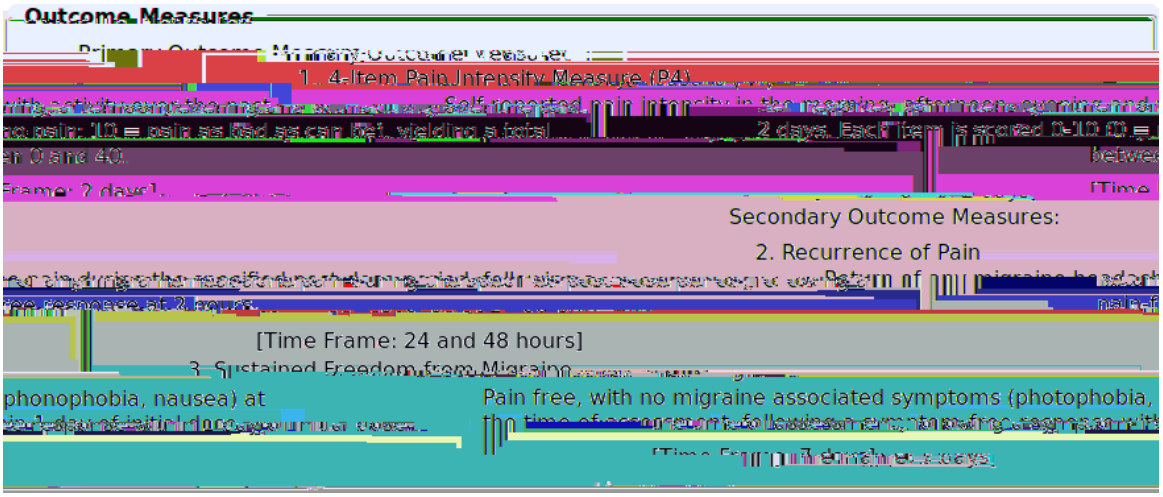
Protocol Review Criteria (PDF)

Outcome Measures Module

Introduction

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

Example



Data Entry Tips

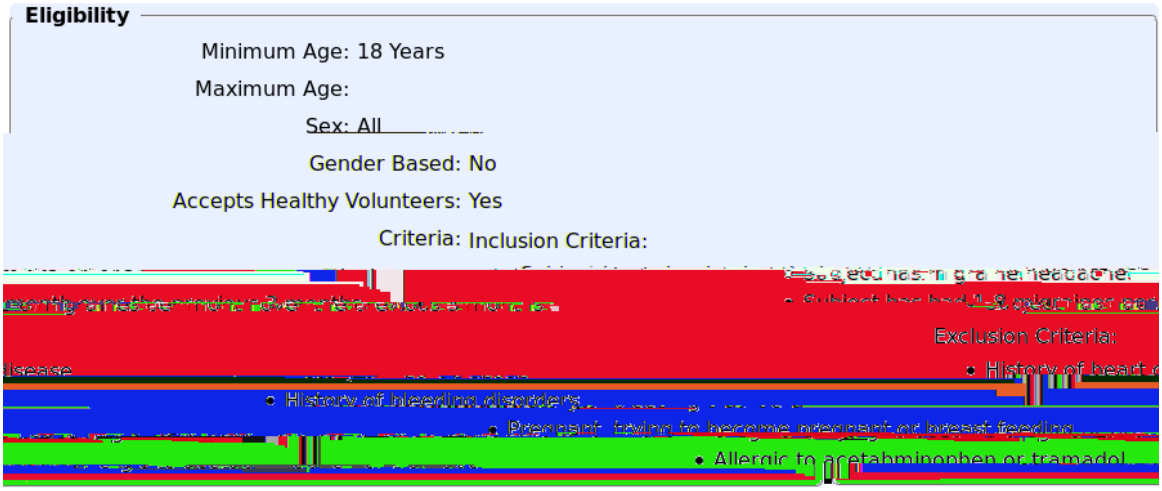
- A study typically has one Primary Outcome Measure.
- Outcome Measure information should describe WHAT is to be measured, not why it is measured.
- Outcome Measure Titles should not be overly general (e.g., "bioequivalence," "safety," "feasibility").
- Make each Outcome Measure Title unique and descriptive, 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

Introduction

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

Example



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