# 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



# 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

# https://register.clinicaltrials.gov/prs/app/template/help%2CHelpProtocolMo... 1/23/2017

Enoncor/Collaboratore.com	า อาชอาวิเออา (สิ่งเอา ซิเอา ซิ
	Sponsor: National Library of Medicine (NLM)
	Responsible Party: Sponsor
	Collaborators: National Headarhe Cepter
Sponsor: Ni	ational Library of Medicine (NLM)
	รองสาร ยาย หลามรูป สาไปปี a Investigator
tin Mile Leõplint	

- 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.

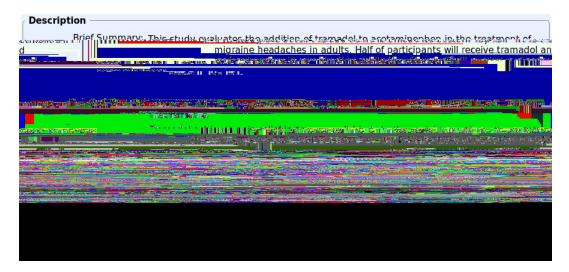
\_\_\_\_\_

# Additional Resources

Oversight.			
	II C EDA-roaulated Drug	. NI 🔿 .	
SNEDA-regulated.Devider.No			
U.S. FDA IND/IDE Study: No=			

Huma	n Subjects Review: Board Status: Approved. Approval Number: 01/13/2017
	Stean an Alarmer: Sectresarian Inschludionean Revnews: Stean an
	Boaro ATT at on Betresoan oso ta
ntrincri	
ng: Yes	s Data Mo
	Plan to S

### Example



# 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

- M 10 W			0000%
		· · · · · · · · · · · · · · · · · · ·	
	enie enc. Nátří hel Laconsteinci		
	-		
<del>negoralag e</del> s Kermedes -			
 photophobia			

#### **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 —			 	
		EA. Mar The		

# 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.

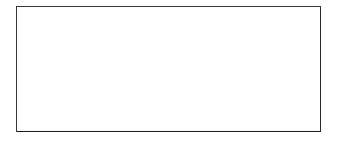
# Additional Resources

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: I	Experimental Acetaminophen & Tramadol
ence and a second s	
The second s	
Arm: Active Comparator: Acetaminophen & Plac	tebo
เราะสมขางสมของสารสารสารสารสารสารสารสารสารสาร	i 👞 z fyże weiter w nich febre odstrigiter eas
	,,
Interventions	
	Other Names: Tylenol
	Anacip_3
	Acotaminonkop tablat
109 ICT 100 C.	
ramadol	Intervention: Drug
Ulbrim	
Page 19 Al	
The survey of the balance of the bal	1997年1997年1997年1997年1997年1997年1997年1997
	Interimetiven Percus Olgan kokeen
	Other Names:
)	Placebo (for Tramado
to mimic trabadol 50 mg tablet	Sugar oil manufactured
	Cross-Reference
Interventions	
Drug: Drug: Drug:	Arms
	ian marana misan miguan serang na marang na paga na pa Na na paga na pa
ntervention is administered to patien	nts in this Arm.

- 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
Contraction C
nite esticitive methor material and a second sec
ro pair: 10 e pair sa 654 a <u>s car 621 vieldiro a brial 10 2 days. EachTi</u> rem is spored 0-10 0 e an 0 and 40. Betwee
Frame: ? rluxc1 [Time
Secondary Outcome Measures:
2. Recurrence of Pain
านการการการการการการการการการการการการการก
nales
[Time Frame: 24 and 48 hours]
3 Sustained Ecedom (Sono Miscain Constant Consta
phonophobia, nausea) at Pain free, with no migraine associated symptoms (photophobia, <u>ion/vdgametisitinInforceage</u> umuua voece
ມີມີ ເມື່ອງ ເພື່ອງ ເ

### 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

Eligibility	
Minimum Age: 18 Years	
Maximum Age:	
Sex: All	
Gender Based: No	
Accepts Healthy Volunteers: Yes	
Criteria: Inclusion Criteria:	
	<u>ini ini ini a</u> etti nasimi <u>gira meth</u> eattathetti
eentig nandebentriche sidverte bestewat antimate an	· Contribute to the board of the spectrum of the second
	Exclusion Criteria:
isease	<ul> <li>History of heart /</li> </ul>
History of bleed build soders.	
• Riemant trying	to become interment of breast feeding.
	Allergic to acetabminophen 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 diabetesThyroid 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

https://register.clinicaltrials.gov/prs/app/template/help%2CHelpProtocolMo... 1/23/2017

- 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
- Ip: 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

at ents; Ct-time C tablerSP Auth briefs (i	ana sa see eeking beer na had aamin sinai oo di oo di disto ndso ta ana sa see eeking beer na maga wata lan. 1040-5055 see i
Sel D: 189360106	INFIDUDINI IN 75-4635-7008-1862-45-58 EPUIS-2008-Nov DATA PUIS
Frequency and burden of headache-	Lipton RB, Buse DC, Saiers J, Fanning KM, Serrano D, Reed N
มาอาศักราชกล่า เช่น Mighania การกลายและการการการการการการการการการการการการการก	STOR Pringesture with that a substance with from the other of read Contracts Contracts
(1): 35-103. doi: 10.1111/ <u>j.1525-4510.2012.02232.x. E</u> p	ulo 2012-Now 13. Fead ache - 2013 jan
	Publiqued 110: 23314537
	Liinkee: WRL: https://inih.gow
	Déscription: test link
<del>adalah kulu</del> ng pertakan <u>pertakan kuluk</u> ing pertakan ku	Mark 201 - 1 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -
	//betreeds.org/data?id=123
	.123
	le bent nëo data rompri many and secore shy outcomeumeasures.
	eparen Ele internationer en l

- 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