

# ClinicalTrials.gov Results Reporting Quick Guide

## Before you begin:

Use [flow chart](#) to determine results reporting is required for your study. In general, FDA regulated Applicable Clinical Trials (ACTs) and NIH founded clinical trials require results reporting

## Penalties for responsible party (PI) who failed to submit results:

- Civil monetary penalty (**\$12,103**) per day, per trial for ACTs ([FDAAA Civil Money Penalties](#))
- Withholding NIH funding

## Instruction:

This quick guide supplements [ClinicalTrials.gov online help](#). Take a few minutes to familiarize yourself with this document, which summarizes requirements and gives results reporting tips.

- **Keep this guide open while you enter information in each section of the results**
- Results for the primary outcome measure(s) are due within **12 months** of the *Primary Completion Date*
- All remaining results are due within 12 months of the *Study Completion Date*
- Enter results in the Results Section

## Tips for Success:

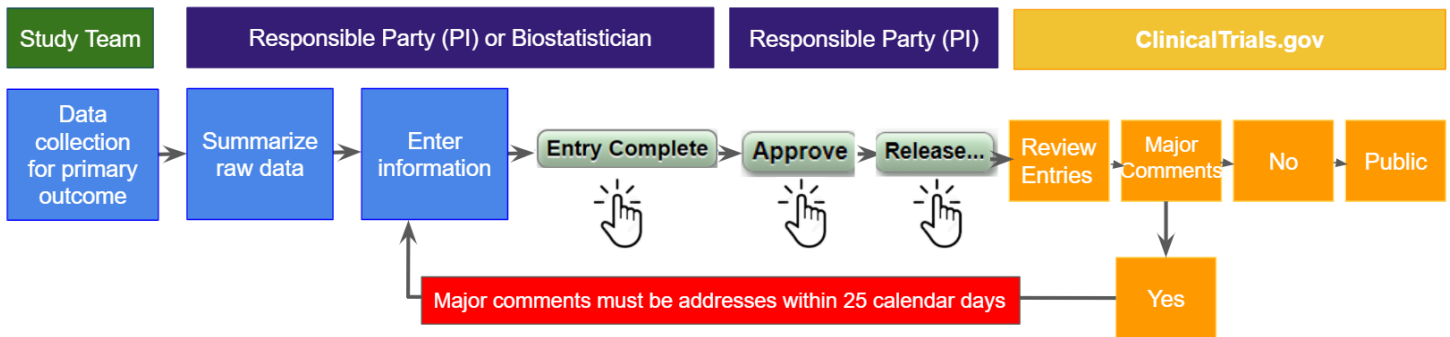
1. Initiate results reporting 3-4 months before the due date because
  - results reporting may take up to **50** hours (depending on the complexities of the trial)
  - average ct.gov review cycle may take up to **30** day
2. PI or Biostatistician to do results reporting as it requires basic biostatistical knowledge and involves summarizing raw data, deriving outcome measures, choosing appropriate unit, type and statistical dispersion for the outcome measures
3. Add biostatistician in the *Access List* to help with results reporting, if available

Record Owner: Test User	Access List: <a href="#">Edit</a>
Last Updated: 12/17/2014 14:08 by Test User	Upload: Allowed <a href="#">Edit</a>
Initial Release: [Not yet released]	PRS Review: [Not yet released]
Results Expected: January 2015	Public Site: [Not yet registered]

4. Use resources in the Protocol Registration and Results System (PRS)

<b>Screen Tips</b>	Look for short definitions in blue text under the data element on the screen
<b>Example</b>	
<b>Data Element Definitions and Help</b> <i>(top of screen)</i>	Click Help for entry tips for the different modules of the <i>Protocol Section</i> (each module has a separate <i>Help</i> page)
<b>Requirements indicators</b> <i>(bottom of screen)</i>	In general, a red asterisk means that entry is required
<b>Validation Messages</b> <i>(throughout the record)</i>	<b>NOTES:</b> Check if there is a problem with the entries – maybe there is, maybe not <b>WARNINGS:</b> It's likely there is a problem (possible there is not), check these carefully <b>ERRORS:</b> Fix these—records cannot be released when they contain errors

5. Always complete the ClinicalTrials.gov submission cycle  
Records can “get stuck” if the responsible party (PI) does not take the steps to **Approve** and **Release**



## Before You Begin Entering Results

1. Look for examples at <https://clinicaltrials.gov/ct2/search/advanced> (Highly recommended for anyone reporting results for the first time!)

Search a study similar to yours with results submitted and accepted by ClinicalTrials.gov

Get familiar with creating tabular format: columns and rows:  
Results must be entered in tables; written results/conclusions are not allowed

- **Table columns** are populated by **arms/comparison groups**
- **Table rows** are populated by **parameters and categories**

[You can see sample records with results information here.](#)

2. Gather **summary data** with appropriate **statistical dispersion** (e.g., mean with standard deviation, median with interquartile range, etc.) for:
  - a. baseline characteristics (e.g., age, sex, race)
  - b. pre-specified outcomes
  - c. adverse events
 If they are not available, ask PI/Biostatistician

## Getting Started:

**Step 1:** Log into PRS at <https://register.clinicaltrials.gov>

Organization: UTexasSouthwestern

Don't have an account? email at [ctgov@utsouthwestern.edu](mailto:ctgov@utsouthwestern.edu)

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

Username:

Password:  [Forgot password](#)

Login

**Step 2:** Review Protocol Section before you being results reporting

[Open](#) **Protocol Section**

Identifiers: NCT03065179 Unique Protocol I  
Brief Title: SBRT in Combination With Nivolu  
Module Status: Study Identification: ✓  
★ Study Status: ✓ → [Edit](#)  
Sponsor/Collaborators: ✓  
Oversight: ✓  
Study Description: ✓  
Conditions: ✓  
Study Design: ✓  
★ Arms and Interventions: ✓ →  
Outcome Measures: ✓  
Eligibility: ✓  
Contacts/Locations: ✓  
IPD Sharing Statement: ✓  
References: ✓

**Verify**  
1. Study Status (Overall Status & Study Dates)  
2. Arms and Interventions

**Study Status**  
Record Verification: March 2020  
Overall Status: Active, not recruiting  
Study Start: November 6, 2014 [Actual]  
Primary Completion: June 5, 2016 [Actual]  
Study Completion: December 18, 2022 [Anticipated]

**Ensure the arm names are descriptive, include dose, formulation, and route of administration  
IMPORTANT to have accurate information here as it automatically be pulled to results section**

**Step 3:** Upload Protocol, Statistical Analysis Plan and Informed Consent Form

**IMPORTANT: MUST be PDF/A format with a cover page including official title, NCT# and document date, otherwise you will NOT pass CT.gov PRS review**

[Open](#) **Document Section**

Documents that may be uploaded include:

- Study Protocol and Statistical Analysis Plan -
- Informed Consent Form - optional under 42 C

Uploaded PDF/A Documents:

**3. Upload IRB approved Protocol with Statistical Analysis Plan and Informed Consent Form on the Document Section, if applicable.**

**Tip 1: Must include cover page with official title, NCT# and document date**  
**Tip 2: Documents must be in PDF Archive (PDF/A format)**

**Step 4:** Click "Enter Results" under Results Section to being results reporting

**Results Section**

[Enter Results](#) Results submission is required by policies.

**4. To begin a new results posting, click Enter Results**

# Results Entry

This section follows the order of the 6 modules of the Results Reporting Section of the study record

[Open](#) **Results Section**

Module Status:	Participant Flow:
	Baseline Characteristics:
	Outcome Measures:
	Adverse Events:
	Certain Agreements:
	Limitations and Caveats:
	Results Point of Contact:

## Module 1 Participant Flow Section (required section)

### Tips

- Watch NIH's Video Tutorial <https://prsinfo.clinicaltrials.gov/webinars/module5/index.html>
- Get your [Consort Flow Diagram](#) (Figure 1 in the manuscript), if available.
- This module documents the “flow” of participants through different stages of the study.

At minimum, you need to report

- Enrolled (# participants consented and determined eligible)
- Started (# participants assigned to a study arm)
- Completed (# participants at the end of the period)

### Step 1: Click “Edit”

[Edit](#) **Participant Flow**

Information is required

**Step 2:** Define the Arms/Groups, copy it from Protocol Section (recommended) or create New. Ensure the arm names are descriptive, include dose, formulation, and route of administration:

Copy from: <b>Protocol Section</b>	Title	Arm/Group
	Description	Nivolumab/Ipilimumab Induction Dual Immur
<b>Select</b>		
Create: <b>New</b>	Define New Arms/Groups	
<b>Select</b>		

### Step 3: Enter Participant Flow Data

This number should match  
 - Actual Enrollment in Protocol Section  
 - All numbers below must add up to this #  
 Any difference must be explained in the Pre-Assigned Details (e.g., 145 participants were screened, 143 were randomized)

**Protocol Enrollment: 143**

**Periods (1)**  
 \* Period Title: Overall Study

	AmphoB standard	AmphoB+Fluc400	AmphoB + Fluc800	Total (Not public)
* Started:	47 47 subjects randomized; 45 subjects treated	48 48 subjects randomized; 2 subjects treated-2 subjects randomized to AmphoB rec'd AmphoB+Fluc400	48 48 subjects randomized; 49 treated-3 subjects randomized to AmphoB+Fluc400 rec'd AmphoB+Fluc800	143
* Completed:	36	33	31	100
Not Completed: (Started - Completed)	11	15	17	

Any differences in the number b/w "Started" and "Completed" must be explained

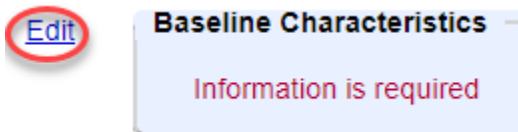
**Reason Not Completed**  
 + Add Reason Not Completed

- Other
- Select Reason Type --
- Adverse Event
- Death
- Lack of Efficacy
- Lost to Follow-up
- Physician Decision
- Pregnancy
- Protocol Violation
- Withdrawal by Subject
- Other

### Module 2 Baseline Characteristics (required section)

- Tips
- Watch NIH's Video Tutorial <https://prsinfo.clinicaltrials.gov/webinars/module6/index.html>
  - Data must be presented **per arm** and for all patients who started the study
  - Arm titles/description should be consistent with other sections
  - Overall number of Baseline Participants should match the number of participants started (from Participant Flow)

#### Step 1: Click "Edit"



#### Step 2: Copy the arms/groups information from Protocol Section or Participant Flow Section, or create new groups

Copy from: <b>Protocol Section</b> <input type="button" value="Select"/>	Title	Drug A 100 mg	Drug A 200 mg
	Description	Drug A 100 mg orally twice daily for 2 weeks Drug A: Drug A administered as 50 mg tablets	Drug A 200 mg orally twice daily for 2 weeks Drug A: Drug A administered as 50 mg tablets
Copy from: <b>Participant Flow</b> <input type="button" value="Select"/>	Title	Drug A 100 mg	Drug A 200 mg
	Description	Drug A 100 mg administered as 50 mg tablets orally twice daily for 2 weeks	Drug A 200 mg administered as 50 mg tablets orally twice daily for 2 weeks
Create: <b>New</b> <input type="button" value="Select"/>	Define New Arms/Groups		

### Step 3: Verify the Arm/Group information and edit if necessary, then click “Save”

Edit Baseline Arms/Groups

[+ Add Arm/Group](#)   [Help](#)   [Definitions](#)

<p>* Arm/Group Title: <input type="text" value="Drug A 100mg"/></p> <p>* § Arm/Group Description: <input type="text" value="Drug A 100 mg orally twice daily for 3 months"/></p> <p style="text-align: right; font-size: small;">Characters remaining: 954</p> <p style="text-align: right;"><input type="button" value="Delete"/> <input type="button" value="Move"/></p>	<p><input type="text" value="Drug B 200 mg"/></p> <p><input type="text" value="Drug B 200 mg orally twice daily for 3 months"/></p> <p style="text-align: right; font-size: small;">Characters remaining: 954</p> <p style="text-align: right;"><input type="button" value="Delete"/> <input type="button" value="Move"/></p>
--	---

\* Required  
 \* § Required if Primary Completion Date is on or after January 18, 2017

### Step 4: Add baseline measures and click “Save”

Minimum: age and gender must be reported

- Age (select one)
  - Age reported as continuous (e.g., mean [Standard Deviation]) or
  - Age reported as categorical (e.g., <18 years, >=18-64 years, >=65 years)
- Gender
  - Generally given as biologically female, male
  - Can be customized (e.g., female, make, transgender [F-M], transgender)

Optional: other demographics and baseline characteristics you wish to report

- Race
- Ethnicity
- Region of enrollment
- Study specific baseline characteristics

[Help](#)   [Definitions](#)

\* Baseline Measure Title:

<p>* <b>Age</b></p> <p style="font-size: x-small;">At least 1 is Required</p>	<input checked="" type="checkbox"/>   <input checked="" type="checkbox"/>  <input type="checkbox"/>	<p>Age, Continuous      <a href="#">Example</a></p> <p>Age, Categorical ≤18 years; 18 to 65 years; ≥65 years      <a href="#">Example</a></p> <p>Age, Customized      <a href="#">Example</a></p>	
<p>* <b>Sex/Gender</b></p> <p style="font-size: x-small;">At least 1 is Required</p>	<input checked="" type="checkbox"/>  <input type="checkbox"/>	<p>Sex: Female, Male      <a href="#">Example</a></p> <p>Sex/Gender, Customized      <a href="#">Example</a></p>	
<p>* § <b>Race and Ethnicity</b></p>	<input type="checkbox"/>   <input type="checkbox"/>  <input type="checkbox"/>  <input type="checkbox"/>	<p>Race (NIH/OMB)      <a href="#">Example</a></p> <p>Ethnicity (NIH/OMB)      <a href="#">Example</a></p> <p>Race/Ethnicity, Customized      <a href="#">Example</a></p> <p>Race and Ethnicity Not Collected      <a href="#">Example</a></p>	
<p><b>Region of Enrollment</b></p> <p style="font-size: x-small;">Pre-filled with countries from Locations in Protocol</p>	<input checked="" type="checkbox"/>	<p>Region of Enrollment      <a href="#">Example</a></p>	
<p>* § <b>Study-Specific Measures</b></p> <p style="font-size: x-small;">Additional Baseline Measures assessed in the study, if any.</p>	<input type="button" value="+ Add"/>	<p><a href="#">Example</a></p>	

\* Required  
 \* § Required if Primary Completion Date is on or after January 18, 2017  
 [?] Conditionally required (see Definitions)

**Step 5:** Click “Edit” and begin data entry

**ERROR : A Race or Ethnicity Baseline Measure has not been entered.**

<a href="#">Edit</a>	Arm/Group Title	Drug A 100mg	Drug B 200 mg	Total
<a href="#">Edit</a>	Arm/Group Description	Drug A 100 mg orally twice daily fo...	Drug B 200 mg orally twice daily fo...	
	<b>Overall Number of Baseline Participants</b> Baseline Measure information is required.			unknown
	▶ Baseline Analysis Population Description			
<a href="#">Edit</a>	Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed --- participants	--- participants	unknown participants
		<=18 years	---	unknown
		Between 18 and 65 years	---	unknown
		>=65 years	---	unknown
<a href="#">Edit</a>	Age, Continuous Baseline Measure information is required. Unit of measure: ---			
<a href="#">Edit</a>	Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed --- participants	--- participants	unknown participants
		Female	---	unknown
		Male	---	unknown
<a href="#">Edit</a>	Region of Enrollment Baseline Measure information is required. Measure Type: Number Unit of measure: participants			
	United States			
<a href="#">Edit</a>	BP Baseline Measure information is required. Unit of measure: ---			



## Baseline Characteristics Table Example

Arm/Group Title		Drug A	Drug B	Total
► Arm/Group Description		Patients will received initial tran...	Patients will receive oral misopros...	
<a href="#">Edit</a>	<b>Overall Number of Baseline Participants</b>	1117	1110	2227
	► Baseline Analysis Population Description			
<a href="#">Edit</a>	Age, Continuous Mean (Standard Deviation)	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: years	26.8 (6.6)	26.6 (6.7)	26.7 (6.6)
<a href="#">Edit</a>	Sex: Female, Male Measure Type: Count of Participants	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: participants			
	Female	1117	1110	2227
	Male	0	0	0
<a href="#">Edit</a>	Race/Ethnicity, Customized Measure Type: Count of Participants	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: participants			
	Black, non-Hispanic	192	186	378
	White, non-Hispanic	41	40	81
	Hispanic	840	860	1700
	Other	44	24	68
<a href="#">Edit</a>	Region of Enrollment Measure Type: Count of Participants	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: participants			
	United States	1117	1110	2227
<a href="#">Edit</a>	Parity Measure Type: Count of Participants	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: participants			
	Parity = 0	591	584	1175
	Parity = 1	219	208	427
	Parity = 2	158	155	313
	Parity = > 2	149	163	312
<a href="#">Edit</a>	Body mass index (kg/m2) Mean (Standard Deviation)	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: kg/m2	29.7 (6.7)	30.1 (7.2)	29.9 (7.0)
<a href="#">Edit</a>	Diabetes Measure Type: Count of Participants	1117 participants	1110 participants	2227 participants
<a href="#">Delete</a>	Unit of measure: participants			
	None	977	952	1929
	Gestational	99	115	214
	Pregestational	41	43	84

### Module 3 Outcome Measures (required section)

#### Tips

- Watch NIH's Video Tutorial <https://prsinfo.clinicaltrials.gov/webinars/module7/index.html>
- **Get PI/Biostatistician involve as this section requires basic statistical knowledge**
- Get your summary data (e.g., Table 1, Table 2 of the manuscript)
- Data must be presented **per arm**
- Search the public site for examples <https://clinicaltrials.gov/ct2/search/advanced>
- Arm titles/description should be consistent with other sections
- Make sure **NO** placeholders within the data tables
- Statistical Analysis is optional!

**Step 1:** Click "Open" and begin data entry

[Open](#)

**Outcome Measures**

Information is required



**Step 2:** Primary outcome/ secondary outcome were copied from the Protocol Section when the results were created. Click “Edit” to being entering data

Outcome Measures copied from Protocol Section Outcome Measure Data is required for at least one primary outcome measure.

**1. Primary Outcome**

[Edit](#) [Delete](#)

Title:	Safety: Number of Participants With Treatment Related Adverse Events of Special Interest Assessed by CTCAE 4.0
Description:	Number of Participants with treatment related adverse events of special interest assessed by CTCAE 4.0
Time Frame:	1 year

Outcome Measure Data Not Reported

**2. Secondary Outcome**

[Edit](#) [Delete](#)

Title:	Efficacy: Objective Response Rate of Slowing Tumor Growth or Decrease in Tumor Size
Description:	Objective Response Rate of slowing tumor growth or decrease in tumor size. NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	1 year

Outcome Measure Data Not Reported

**Step 3:** Edit outcome measure title, description and time frame if necessary (see the list of example below). Click “Enter Outcome Measure Date”

[Help](#) [Definitions](#)

\* Outcome Measure Type: Primary

\* Outcome Measure Title: **A detailed title describing WHAT is being measured** Characters remaining: 145  
Safety: Number of Participants with treatment related adverse events of special interest assessed by CTCAE 4.0

[\*] Outcome Measure Description: **A detailed description of HOW this outcome is being assessed** Characters remaining: 678  
Number of Participants with treatment related adverse events of special interest assessed by CTCAE 4.0 such as:  
• Fatigue  
• Skin reactions: including rash, itching, hives, redness, and dry skin  
• Diarrhea  
• Nausea

Outcome Measure Time Frame: 1 year **Specific time point when data for this outcome will be assessed**

[Save](#) [Validate](#) [Cancel](#) [Enter Outcome Measure Data](#)

<b>Title</b>	Describe <b>WHAT</b> is being measure (parameter) and how (metric) and time points Examples: <ul style="list-style-type: none"> <li>• Safety, as measured by number of subject with at least one adverse event as assessed by CTCAE v4.0</li> <li>• Mean change from baseline in systolic blood pressure at 6 Months</li> <li>• Mean change from baseline in pain scores on the Visual Analog Scale (VAS) at 6 weeks</li> <li>• Mean change from baseline in lesion size at 24 months</li> <li>• Biomarker, as measured by number of participants with XXXXX</li> <li>• Maximum tolerated dose of Drug A in patients with breast cancer</li> <li>• Number of hospitalizations at 24 months</li> </ul>
<b>Description</b>	Describe <b>HOW</b> each outcome measure, quantitative data, will be reported in detail. If scale will be used, include <u>full unabbreviated name of the scale, what it measures, range of possible scores, and meaning of scores</u> Examples: <ul style="list-style-type: none"> <li>• Lesion size in millimeters will be measured by ultrasound, at baseline and week 2</li> <li>• The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression.</li> <li>• Scores are measure on a 100 mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain.</li> <li>• Number of participants who experience adverse events &gt;= Grade 3, as defined by Common Terminology Criteria for Adverse Events by CTCAE v4.0</li> </ul>
<b>Time Frame</b>	Describe <b>WHEN</b> or how long it will take to assess the outcome measure in a participant Examples: <ul style="list-style-type: none"> <li>• Week 12 (for single assessment)</li> <li>• Day 1 post intervention</li> <li>• Changes from baseline to 12 weeks (for change measures, 2 time points)</li> <li>• Through end of study (for change measures, continues)</li> <li>• 0, 1, 2, 3, 4, 6, 8, 24 hours post-dose (for pharmacokinetic measure)</li> <li>• 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 (Time to event measure)</li> </ul>

**Step 4:** Once ready, Click “Enter Outcome Measure Date”



**Step 5:** Enter the number analyzed in each group

If number of participants analyzed is less than number enrolled in each arm, then you must describe the difference in “Analysis Population Description” section. E.g., “Participants with available data were analyzed”

## Step 6: Complete Outcome Measure Data Table

1. Enter the type of data for the outcome measure

### Outcome Measure Data Table

* Measure Type:	Count of Participants	Hide calculated percentage
* Measure of Dispersion/Precision:	-- Select Measure Type -- Count of Participants Mean Median Least Squares Mean Geometric Mean Geometric Least Squares Mean Number	
	+ Add Category	
+ Add Row		
* Unit of Measure:	participants	

2. Enter the Measure of Dispersion/Precision used

- May chose “Not Applicable” if you chose “Number” or “Count of Participants” for Measure Type
- Continuous variable (e.g., mean, median) must report precision. In general, you would chose “Standard Deviation” for mean and “Inter-Quartile Range” or “Full Range” for median. If they are not available, consult with a Biostatistician.

### Outcome Measure Data Table

* Measure Type:	Mean
* Measure of Dispersion/Precision:	Not Applicable -- Select Measure of Dispersion/Precision -- 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 Not Applicable
+ Add Row	
* Unit of Measure:	

3. Enter Unit of Measure

Unit of measure is an explanation of what is quantified by the data (e.g., participants, mm Hg, years, hours, units on scale, score on scale, percentage of XXXX)

*Example of outcome (hours of sleep) measure data table choosing **mean** for measure type*

**Outcome Measure Data Table**

\* Measure Type: Mean

\* Measure of Dispersion/Precision: Standard Deviation

Mean: 20

Standard Deviation: 5.6

+ Add Row

\* Unit of Measure: hours

Commonly reported units: participants | years

Example of outcome (hours of sleep) measure data table choosing **median** for measure type

**Outcome Measure Data Table**

\* Measure Type: Median

\* Measure of Dispersion/Precision: Inter-Quartile Range

Median: 20

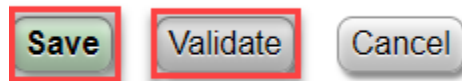
Inter-Quartile Range: 15 to 24

+ Add Row

\* Unit of Measure: hours

Commonly reported units: participants | ye

Once ready, Click “Validate” then “Save”



**Step 7:** Add Statistical Analysis (e.g., p-value, odds ratio, risk ratio, hazard ratio) (**OPTIONAL**)

1. Select “Add Statical Analysis”



2. Complete Analysis Overview Section

a. Select what arms are included in the statistical test, and add details about the test as appropriate

**Statistical Analysis Overview**

[Help](#) [Definitions](#)

\* Comparison Group Selection: Select the Outcome Measure Arms/Groups involved in the statistical analysis.

Drug A 100 mg  Drug A 200 mg

Comments: (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation.

b. Select type of statistical test

\* Type of Statistical Test

-- Please Select --

Superiority

Non-Inferiority

Equivalence

Other

[\*] Comments:



## Method of Estimation

[Help](#) [Definitions](#)

<b>[*]</b> Estimation Parameter:	(If applicable) <input type="text" value="Hazard Ratio (HR)"/> If other, please specify: <input type="text"/>
<b>[*]</b> Estimated Value:	Provide the data for the Estimation Parameter. <input type="text"/>
Confidence Interval:	(If applicable) <input type="text" value="95"/> % Confidence Interval Number of sides: <input type="text" value="2-Sided"/> Lower Limit: <input type="text"/> Upper Limit: <input type="text"/>
Parameter Dispersion Type and Dispersion Value:	(If applicable) <input type="text" value="-- Please Select --"/> <input type="text"/>
Estimation Comments:	<input type="text" value="-- Please Select --"/> <input type="text" value="Standard Deviation"/> <input type="text" value="Standard Error of the Mean"/> <small>Important estimation information, including the direction of and denominator for relative risk).</small>

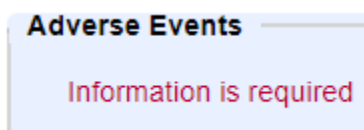
### 5. Complete Other Statistical Analysis Section (Optional)

## ***Module 4 Adverse Events (required section)***

### Tips

- Watch NIH's Video Tutorial <https://prsinfo.clinicaltrials.gov/webinars/module8/index.html>
- Get your adverse events (AEs) data
- ALL AEs must be reported, regardless of whether they are attributed to intervention!
- Two AEs tables must be reported
  - Serious AEs
  - Other AEs
- Must report the number at risk and affected

### Step 1: Click "Edit" and begin data entry



### Step 2: Copy the arms/groups information from Protocol Section or Participant Flow Section, or create new groups

Copy from: <b>Protocol Section</b> <input type="button" value="Select"/>	Title	Arm/Group	Arm/Group
	Description	Drug A 100 mg	Drug A 200 mg
Copy from: <b>Participant Flow</b> <input type="button" value="Select"/>	Title	Drug A 100 mg orally twice daily for 2 weeks	Drug A 200 mg orally twice daily for 2 weeks
	Description	Drug A: Drug A administered as 50 mg tablets	Drug A: Drug A administered as 50 mg tablets
Create: <b>New</b> <input type="button" value="Select"/>	Define New Arms/Groups		

**Step 3:** Verify the Arm/Group information and edit if necessary, then click “Save”

Edit Baseline Arms/Groups

+ Add Arm/Group    [Help](#)    [Definitions](#)

\* Arm/Group Title:    

\* § Arm/Group Description:    

Characters remaining: 954    Characters remaining: 954

\* Required  
\* § Required if Primary Completion Date is on or after January 18, 2017

**Step 4:** Begin adverse events data entry by selecting “Edit”

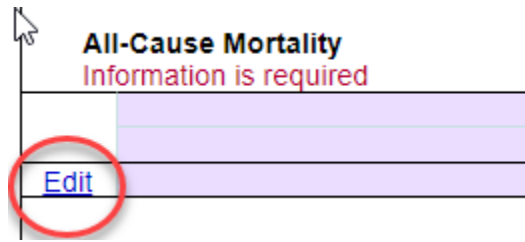
<input type="button" value="Edit"/>	<b>Information is required</b>	
	Time Frame	
	Adverse Event Reporting Description	
	Source Vocabulary Name for Table Default	[Not specified]
	Collection Approach for Table Default	[Not specified]

- Time Frame: Must be specific and indicate when adverse events were reported  
**INCORRECT** - “at study completion”  
**CORRECT** - “Weekly until end of study, an average of up to 1 year”
- Adverse Event Reporting Description: Must indicate if there were any specific criteria/definitions used to report AEs. (e.g., *only serious adverse events were collected according to the study protocol*)
- Source Vocabulary Name (Optional): 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.
- Collection Approach: Choose one
  - Systematic Assessment: AEs were recorded in daily participant diaries



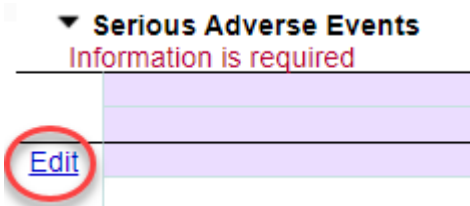
- ii. Non-systematic assessment: AEs were collected in response to spontaneous reports by participant
5. Total Number of Participants “At Risk”

**Step 5:** Select “Edit” in All Cause Mortality Section (Include death from **ANY** cause during the AE reporting time-frame)



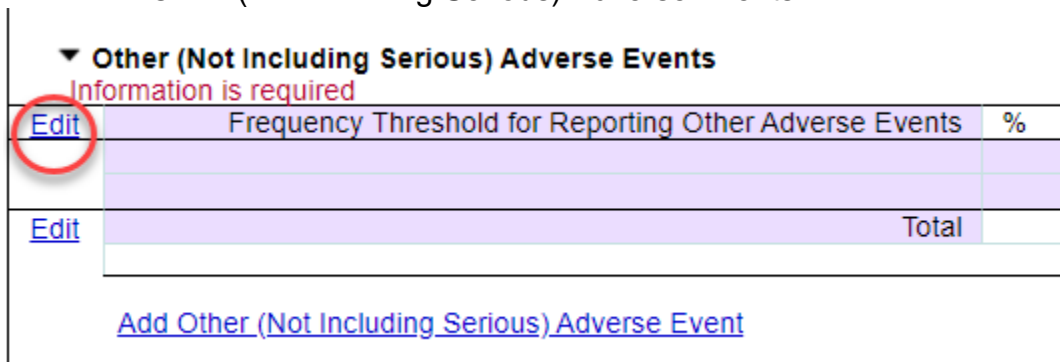
- Total Number Affected: overall number of participants, in each arm/group, who died due to any cause
- Total Number At Risk: must be the number of participants who are assigned to the arm. If there is discrepancy, must be explained within the “Adverse Event Reporting Description” **INCORRECT** - “0”

**Step 6:** Select “Edit” in Serious Adverse Events



- Total Number Affected: overall number of participants affected by one or more Serious Adverse Events, for each arm/group.
- Total Number At Risk: must be the number of participants who are assigned to the arm. If there is discrepancy, must be explained within the “Adverse Event Reporting Description” **INCORRECT** - “0”

**Step 7:** Select “Edit” in Other (Not including Serious) Adverse Events



- Report at a threshold: Enter a number between 0 (no threshold; all events reported) and 5 (only events occurring in greater than 5% of participants in any Arm/Group are reported).

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.

- Total Number Affected: 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: must be the number of participants who are assigned to the arm. If there is discrepancy, must be explained within the “Adverse Event Reporting Description” **INCORRECT** - “0”

### **Module 5 Limitations and Caveats (NOT required section)**

Use this section to describe limitations of the trial

- *“PI for this study is no longer with the institution and the relevant data have been destroyed.”*
- *“The underlying data are not available for accurately reporting the information”*
- *“Early termination leading to small numbers of subjects analyzed”*
- *“Technical problems with measurement leading to unreliable or uninterpretable data”*
- *The study was terminated and the PI has left the institution. Despite exercising all possible efforts to contact the original PI/study team members to obtain the data, the study PI refused to provide the collected data, and no data are available to be reported”*
- *“The study was terminated and the PI has left the institution. Despite exercising all possible efforts to contact the original PI and study team members to obtain the data, the study PI and study team members contact information could not be found, and no data are available to be reported”*



**Limitations and Caveats**  
[Not Specified]

### **Module 6 Certain Agreements and Results Point of Contact (required section)**

This section describes agreements between the sponsor and Principal Investigator(s) on their rights to publish study results

**Step 1:** Click “Open” in the More Information and select “Edit” to open the Certain Agreements Section



**More Information**

**Certain Agreements**

[Relationship of Principal Investigator and Sponsor not specified.]

Information is required



### Certain Agreements

All Principal Investigators ARE employed by the organization sponsoring the study.

- Question 1: Are all PIs Employees of Sponsor?
  - If yes, select “Yes” from the drop-down menu, no further questions
  - If no, select “No” from the drop-down menu, and answer
- Question 2: Results Disclosure Restriction on PI(s)?
  - If no, select “No” from the drop-down menu, no further questions
  - If yes, select “Yes” from the drop-down menu and select the type of agreement from the radio buttons

**Step 2:** Click “Edit” to open the Results Point of Contact Section



### Results Point of Contact

Name/Official Title: ---  
 Organization: ---  
 Phone: ---  
 Email: ---

Enter name of the contact (usually the Responsible Party), organization name (usually UTSW) and contact phone and/or email

The person best able to provide scientific information about the clinical study results information should be entered as the Results Point of Contact.

### Edit Results Point of Contact

[Help](#) [Definitions](#)

* Name or Official Title:	<input type="text"/> Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).
* Organization Name:	<input type="text"/>
* § Phone:	<input type="text"/> Ext. <input type="text"/>
* § Email:	<input type="text"/>

Save


Cancel

\* Required

\* § Required if Primary Completion Date is on or after January 18, 2017

[\*] Conditionally required (see Definitions)

## Finalizing and Submitting Results to CT.gov

- Clear **ALL** red flags , errors **Error**, warnings **Warning**, and notes **Notes**



### Good to Go

Results Section	
Module Status:	Participant Flow: ✓
	Baseline Characteristics: ✓
	Outcome Measures: ✓
	Adverse Events: ✓
	Certain Agreements: ✓
	Limitations and Caveats: ✓
	Results Point of Contact: ✓



### Not Ready to Go

Results Section	
Module Status:	Participant Flow: ❌
	Baseline Characteristics: ✓
	Outcome Measures: ❌
	Adverse Events: ❌ 1 Note
	Certain Agreements: ✓
	Limitations and Caveats: ✓
	Results Point of Contact: ✓

- Perform **spell-check** by clicking on the “Spelling” link on the left top of the page  
Be sure to expand all acronyms within each section the record

[Spelling](#) [Preview](#) [Draft Receipt \(PDF RTF\)](#) [Download XML](#)  
[Open](#) **Protocol Section**

- Click on the green “**Entry Complete**”
- Responsible Party (PI) to review, approve and submit record to CT.gov
  - Click on the green “**Approve**” and “**Release**”

