

OVERVIEW

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing study results records using the PRS. Initial entry of a study (protocol) is the subject of a separate job aid document.

The screen shots provided below for your review and assistance are step by step guidance to enter study results. What appear to be broken images occurred when the original page was greater than one full screen at capture, and in this document the cropped screen images are shown together on one page for continuity.

Due to system limitations, capture of screens was required to occur in edit mode rather than initial entry of data. This resulted in the appearance of summary screens that may differ when initial results entry occurs. The system has provided links to additional information for most fields that require entry; it is suggested they be selected (by double-click) whenever there is need.

The results section of a clinicaltrials.gov file is divided into discrete parts, each of which includes nested series of data entry screens.

1. Results Point of Contact	5. Outcome Measure
2. Certain Agreements	6. Limitations and Caveats
3. Participant Flow	7. Adverse Events
4. Baseline	

You will see these as form section headers across the top of each main screen page, useful for navigation though they are not jump-to links. The ‘where you are now’ marker is yellow highlight on these area labels that is applied by the system.

Color Key Code used on subsequent pages:

-  **Green = Text explanation**
-  **Orange = Highlighted information on form**
-  **RED = Please take note**

This "send message" shows on all screens, however it's better to consult your Organizational contact prior to sending emails to this external group.

Yellow highlight is the where you are marker. The second line of text changes as you travel through screens that are nested from each main screen, to show where in the file you are at any given time.

Results

Results Point of Contact
Edit Results Point of Contact

Certain Agreements Participant Flow Baseline Outcome Measure Limitations and Caveats Adverse Events

Title: Study Title. truncated. appears on all Results entry pages.

Your ClinicalTrials.gov Protocol code ID will appear on all Results entry pages.

Investigator's Name or Official Title:* Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).

Organization Name:* Point of contact for scientific information about the posted clinical trial results.

Phone:* ext.

Email:*

OK saves changes and either advances to a next screen or returns you to the screen you came from. Some screens do not have OK and Cancel in them; see example on page 4.

Red asterisks mark required fields.

Underlined texts in blue are links. Some are navigational, and move you to other screens, especially Add, Create and Edit. Other blue underlined text next to a box for data entry are field labels that take you to helpful descriptions of what it is that the system is looking for.

Results						
Results Point of Contact	Certain Agreements Edit Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Restrictions on PI after Trial is Completed*

*Other than an agreement solely to comply with applicable provisions of law protecting the privacy of human participants.

Are all PIs Employees of Sponsor? *	<p>If all principal investigators are employees of the sponsor, select "Yes" and skip the remaining questions.</p> <p>No <input type="radio"/></p>	Indicate Yes or No, here.
Results Disclosure Restriction on PI(s)?	<p>If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the trial is completed, select "Yes" and select a "Restriction Type." Trial completion is defined as the final date on which data were collected (see Study Completion Date definition).</p> <p>If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes" and answer the remaining question.</p> <p>No <input type="radio"/></p> <p>If "No", skip the following question.</p>	
PI Disclosure Restriction Type:	<p>Indicate which type of restriction applies. If there are varying agreements with multiple PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).</p> <p><input checked="" type="radio"/> None Selected</p> <p><input type="radio"/> The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.</p> <p><input type="radio"/> The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.</p> <p><input type="radio"/> Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.</p> <p>If the restriction type is "Other disclosure agreement ...", please describe the agreement.</p> <p>Maximum allowed content length (500)</p>	

OK Cancel

Information certifying whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

Participant Flow: Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial. (Identical in purpose to a CONSORT flow diagram, but represented as tables.)

The tabular presentation may be separated into "periods," each of which comprises an interval of trial activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

On screens without OK and Cancel buttons, links positioned here on the pages jump back to a higher level screen and from there allow moves to other sections of the file.

[Results Overview](#)

[Edit](#)

Recruitment
Details:

Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context. Limit: 350 characters.

Pre-assignment
Details

Definition: Description of any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups. Limit: 350 characters.

See p. 8.

[Participant Flow main screen continues on page 5]

Create Period **Add Arm/Group**

See p. 6. See p. 7.

Periods **All Participants** **Total**
(=sum per row)

Overall Study
Modify/Delete

STARTED
 Other Milestones:

COMPLETED

Not Completed:
(=Started - Completed)

[Expand All](#)

[Expand Section](#)

[Edit](#)

An example. Overall Study was the Period name given in the source study used to acquire these screen images.

However many milestones you want your study to have, given study structure. Over time you will be returning to edit these fields to advance the milestones from Started to Completed status.

See p. 9.

Note section marker text change from previous page to here, to show where you are now.

[Send message to PRS](#)



Results

Results Point of Contact Certain Agreements **Participant Flow
Add Period** Baseline Outcome Measure Limitations and Caveats Adverse Events

Title: []

When a trial has more than one period, none of the period titles should be "Overall Study"

Period Title: * Overall Study

New Period Title: *

The source study used to acquire these screen images had only one period.

OK Cancel

Once one period is added, there's the ability to add another if there are multiple.
Limit to Period Title: 40 characters

Jumps to page 4, (up one level) from which another link can be selected.

Definition of Period: Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use Overall Study for "Period Title."

There is no limit to the number of periods that may be used to describe a single trial. Each subsequent period represents a trial stage following the previous period. That is, participants "flow" from earlier to later periods. All results sections must cover participant flow from initial assignment to arms/groups to completion of the trial.

This screen is the destination when the “Add Arm/Group” link in the image on p. 5 is selected.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Add Participant Flow Arm/Group	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Arm/Group Title:	Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill	Minimum length for Title is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Maximum 62 characters.
Arm/Group Description:	Maximum allowed content length (999) Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.	
Modify Similar Arm/Groups:	Also add similar group in: Baseline Characteristics <input checked="" type="radio"/> Yes, add similar groups <input type="radio"/> No, add only this group	Baseline Characteristics is the next main results section following this one in the ClinicalTrials.gov study file. Here is opportunity to have some fields there pre-populated for you.

(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

This is the destination screen when the Edit link next to Recruitment Details and Pre-assignment Details in the image on page 4 is selected.



Results						
Results Point of Contact	Certain Agreements	Participant Flow Edit Pre-assignment Description	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Recruitment Details:

Please enter key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context.

Maximum allowed content length (350)

As text is entered it goes off-screen in this small box; use the scroll bar to see all of it.

Pre-assignment Details:

Please describe any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups.

Maximum allowed content length (350)

OK Cancel

This link will jump back to the main Participant Flow screen.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Period	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

[Participant Flow](#)

See the upper part of p. 10.

Add Milestone

Edit	Overall Study	All Participants	Total (=sum per row)
	STARTED	96	96 (Calculated)
	Received Placebo Modify/Delete	93	93 (Calculated)
	Received Low Dosage Modify/Delete	93	93 (Calculated)
	Received Medium Dosage Modify/Delete	93	93 (Calculated)
	Received High Dosage Modify/Delete	93	93 (Calculated)
	COMPLETED	93	93 (Calculated)
	Not Completed: (=Started - Completed)	3 (Calculated)	3 (Calculated)

See p. 11.

Values on this screen are from the study used to source the images.

See the lower part of p. 10.

Add Reason for Not Completed

Edit	Overall Study	All Participants	Total (=sum per row)
	Total (=sum per column)	3 (Calculated)	3 (Calculated)
	Other [REASON] Modify/Delete	3	3 (Calculated)

See p. 12.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Add Milestone in Period	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Milestone Title: *

Name of the Milestone entry screen. Loop through the Milestone screens as many times as there are study milestones to be expressed.

OK Cancel

Milestone Definition: Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Add Reason Not Completed for Period	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title

Reason Not Completed: * Choose "Other" only when an appropriate option is not available in the "Reason Not Completed" pick-list.

-- Please Select --

Other Reason: Please enter "Other Reason" when "Other" is selected as "Reason Not Completed".

OK Cancel

Picklist Selections here are:

- Adverse Event
- Death
- Lack of Efficacy
- Lost to Follow-Up
- Physician Decision
- Pregnancy
- Protocol Violation
- Withdrawal by Subject
- Other

Free text field for when the pick list choices do not fit.

Results						
Results Point of Contact	Certain Agreements	Participant Flow Edit Milestone Data in Period	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Please enter the **number of participants** for each milestone and any related comments

Overall Study All Participants	
STARTED	<input type="text" value="96"/> * [Add Comment]
Received Placebo	<input type="text"/> * [Add Comment]
Received Low Dosage	<input type="text"/> * [Add Comment]
Received Medium Dosage	<input type="text"/> * [Add Comment]
Received High Dosage	<input type="text"/> * [Add Comment]
COMPLETED	<input type="text"/> * [Add Comment]
Comments:	
Prefill Number of Baseline Participants:	Select yes if you would like the number of baseline participants to equal the number of participants who started this period. <input checked="" type="radio"/> Yes, number of baseline participants equals number to start this period. <input type="radio"/> No, change only participant flow

Here is where the numbers of participants in each Group are entered and later, can be edited.) "Started", and "Received" fields here must include any Subjects who started the study and dropped out or were withdrawn before completing it.
Note only numbers of participants are required, comments are optional.

Links in the left-hand blue column on this page take you to informational text.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events
		Edit Reason Not Completed Data for Period				

Title:

Please enter the number of participants to drop or withdraw due to each reason. Include each participant only once. The sum across all reasons in a group should equal the total not completed for the group.

<u>Overall Study</u>	All Participants
	Number Participants
Total Not Completed	3 <i>(Calculated=Started - Completed Milestone)</i>
Other	
[REASON]	<input type="text" value="3"/> *

The system will check your math and return a message if there is discrepancy.

On this page enter number of participants who did not complete the Period of the study for this given reason why not. System copies to here, the name of the reason which was entered on p. 10.

Next part of the Study Results begins here, pgs. 13 and 14 are one screen.

Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Overview	Outcome Measure	Limitations and Caveats	Adverse Events
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Title:

[Results Overview](#) See p. 15. See lower portion of p. 17.

Add Baseline Measure	Add Arm/Group	All Participants <i>All participants received 3 we...</i> Modify/Delete
See p. 18.		
Edit Overall Number of Baseline Participants		96

Mapped in by the system from where it was entered (p. 18).

[Age Categorical](#) *Number (Not Applicable) [Units: participants]*
[Modify/Delete](#)

Edit		<i>All Participants</i>
	<=18 years	--
	Between 18 and 65 years	-
	>=65 years	-

See p. 19. See p.

[Add Baseline Measure](#)

[Age Continuous](#) *Mean ± Standard Deviation [Units: years]*
[Modify/Delete](#)

Edit		<i>All Participants</i>
See p. 21.		---

See p. 15.

[Add Baseline Measure](#)

[Gender, Male/Female](#) *Number (Not Applicable) [Units: participants]*
[Modify/Delete](#)

Edit		<i>All Participants</i>
	Female	--
	Male	--

See p. 23.

[Add Baseline Measure](#)

See p. 15.

Region of Enrollment *Number (Not Applicable) [Units: participants]*

[Modify/Delete](#)

[Edit](#)

All Participants

United States

See p. 25.

Baseline Characteristic : A table of demographic and baseline data for the entire trial population and for each arm or comparison group. Note that only baseline measures for Age and Gender are required; all other baseline measures are optional. The table cells accommodate different types of data:

- Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group
- Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group
- Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group

Overall Number of Baseline Participants (per arm/group) : Overall number of participants for which baseline characteristics were measured for all baseline measures reported. Note that if the participant population differs for a particular baseline measure, the number of participants should be included in the Baseline Measure Description.

Results Point of Contact	Certain Agreements	Participant Flow	Baseline Add Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events
--------------------------	--------------------	------------------	----------------------------------	-----------------	-------------------------	----------------

Title:

Baseline Measure Title: *	-- Please Select --	Pick list choices shown on page 15.
Study-Specific Baseline Measure Title:	If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure.	
Baseline Measure Description:	Additional information such as details about the collection method or participant population, if different from Overall Number of Baseline Participants. Maximum allowed content length (600)	
Measure Type: *	-- Please Select --	Pick list choices shown on page 15.
Measure of Dispersion: *	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.	
Unit of Measure: *	-- Please Select --	Pick list choices shown on page 16
<p>If the Measure Type is "Number", the Unit of Measure is typically "participants".</p>		
<p>Fill in field.</p>		

OK Cancel

Baseline Measure Definition: Name and description of a characteristic measured at the beginning of the trial. Note that baseline measure data for "Age" (at least one of the three types) and "Gender" are required. There is no limit to the number of additional "Study-Specific Measures" that may be provided.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Add Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Baseline Measure Title: *	-- Please Select --	
Study-Specific Baseline Measure Title:	-- Please Select --	Study-Specific", please enter a brief descriptive name for the measure.
Baseline Measure Description:	<ul style="list-style-type: none"> Study Specific Characteristic Age Continuous Age Categorical Age, Customized Gender, Male/Female Gender, Customized Race (NIH/OMB) Ethnicity (NIH/OMB) Race/Ethnicity, Customized Region of Enrollment 	<p>Details about the collection method or participant population, if different from Overall Number of Baseline Participants.</p> <p>1 (600)</p>
Measure Type: *	-- Please Select --	
Measure of Dispersion: *	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.	
Unit of Measure: *	If the Measure Type is "Number", the Unit of Measure is typically "participants".	
<input type="button" value="OK"/> <input type="button" value="Cancel"/>		

Picklist choices shown just below, on this page.

Picklist choices shown below, next page.

Examples: participants, mm Hg . Limit: 40 characters)

Measure Type: *	-- Please Select --	
Measure of Dispersion: *	-- Please Select --	cable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.
Unit of Measure: *	<ul style="list-style-type: none"> Number Mean Median Least Squares Mean Geometric Mean Log Mean 	Number", the Unit of Measure is typically "participants".
<input type="button" value="OK"/> <input type="button" value="Cancel"/>		

Measure of Dispersion:*

Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.

Unit of Measure:*

- Please Select --
- Please Select --
- Not Applicable
- Standard Deviation
- Inter-Quartile Range
- Full Range

Number", the Unit of Measure is typically "participants".

OK Cancel

This is the destination when the "Add Arm/Group" link from p. 13 is selected.

[Send message to PRS](#)



Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline Add Baseline Arm/Group	Outcome Measure	Limitations and Caveats	Adverse Events
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Title:

Arm/Group Title:*

Title should be descriptive, yet concise, to provide context for tabular data.

Examples: Metformin, Lifestyle counseling, Sugar pill

Arm/Group Description:

Maximum allowed content length (999)

Modify Similar Arm/Groups:

Also add similar group in: **Participant Flow**

Yes, add similar groups No, add only this group

Minimum length for Title is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Maximum 62 characters.

OK Cancel

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Edit Baseline Participants	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Number of Participants Started First Participant Flow Period	All Participants	Total <i>(calculated)</i>
	96	96

All Participants	
<u>Overall Number of Baseline Participants *</u>	<input type="text" value="96"/>

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

[Baseline Overview](#)

Age Categorical

Overall Number of Baseline Participants	96	
Age Categorical <i>Number (Not Applicable) [Units: participants]</i>	All Participants <i>All participants received 3 we...</i>	
<=18 years		
Between 18 and 65 years		
>=65 years		
<i>Total (=sum across categories)</i>	<i>96.0 (Calculated)</i>	

[Edit](#)

See p. 20 where data entries may be made.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Edit Baseline Measure Data	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Age Categorical

Overall Number of Baseline Participants	96	
Age Categorical *	All Participants	
	Number	
<=18 years <i>Units: participants</i>	<input type="text"/>	Enter the number of participants in these fields.
Between 18 and 65 years <i>Units: participants</i>	<input type="text"/>	
>=65 years <i>Units: participants</i>	<input type="text"/>	
<i>Total (=sum across categories)</i>	96.0 (Calculated)	

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

[Baseline Overview](#)

See p. 22.

Age Continuous

Create Categories Create Categories if you wish to report categorical data (e.g., low, medium, or high).

Overall Number of Baseline Participants	96
Age Continuous <i>Mean ± Standard Deviation [Units: years]</i>	All Participants <i>All participants received 3 we...</i>

[Edit](#)

See the screen below on this page.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Edit Baseline Measure Data	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Age Continuous

Overall Number of Baseline Participants	96
Age Continuous *	All Participants
Mean	Standard Deviation
<i>Units: years</i>	
<input type="text"/>	<input type="text"/>

Data entry screens here.



Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Add Baseline Measure Category	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Age Continuous

Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen. Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure).

Category Title*

New Category Title*

OK

Cancel

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events

Title

[Baseline Overview](#)

Gender, Male/Female

Overall Number of Baseline Participants	96
Gender, Male/Female <i>Number (Not Applicable) [Units: participants]</i>	All Participants <i>All participants received 3 we...</i>
Female	--
Male	--
<i>Total (=sum across categories)</i>	96.0 (Calculated)

[Edit](#)

See the screen below on the next page.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Edit Baseline Measure Data	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Gender, Male/Female

Overall Number of Baseline Participants	96	
<u>Gender, Male/Female</u> *	All Participants	
	Number	
Female <i>Units: participants</i>	<input type="text"/>	Data entry screens here.
Male <i>Units: participants</i>	<input type="text"/>	
<i>Total (=sum across categories)</i>	96.0 (Calculated)	

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Baseline Measure	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

[Baseline Overview](#)

Region of Enrollment

[Add Country/Region](#)

Overall Number of Baseline Participants	96	
Region of Enrollment <i>Number (Not Applicable) [Units: participants]</i>	All Participants <i>All participants received 3 we...</i>	
United States Modify/Delete	96	
<i>Total (=sum across categories)</i>	<i>96.0 (Calculated)</i>	

[Edit](#)

See the screen below on the next page.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline Edit Baseline Measure Data	Outcome Measure	Limitations and Caveats	Adverse Events

Title:

Region of Enrollment

Overall Number of Baseline Participants	96	
Region of Enrollment *	All Participants	
	Number	
United States <i>Units: participants</i>	<input type="text" value="96"/>	Data entry screen here.
<i>Total (=sum across categories)</i>	96.0 (Calculated)	

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Outcome Overview	Limitations and Caveats	Adverse Events

Title:

[Results Overview](#)

Need help? The [Outcome Measure Simplified Form Examples](#) show the type of information needed to report Results for an Outcome Measure. Also, the webinar on the [Outcome Measures and Statistical Analyses Module](#) provides an overview of the purpose and specific, required data elements.

[Add Outcome Measure](#)

See p. 28 (next page).

The Module is a set of slides at <http://prsinfo.clinicaltrials.gov/webinars/module7/>

[Expand All](#)

1

Posted	<i>Type : Primary Title:</i>
	<i>Time Frame:</i>
	<i>Description:</i>
	<i>Safety Issue?</i>

[Un-Post/Delete](#) [Copy](#)

[Expand Section](#)

[Edit](#) See pp. 28-30.

NOTE : An Arm/Group Description is shorter than the Arm/Group Title.

[Add Statistical Analysis](#) See pp. 31-33.

The blue-circle-i NOTE Information messages won't stop you from proceeding.

Your Administrator will be checking to see that you have provided some information for each note that you have.

If additional information is required, you will receive a notification from PRS.

(Note that primary and secondary outcome measure information from the protocol section of the record will be copied into the results section the first time results are created. After that, "Outcome Measure Type," "Outcome Measure Title," "Outcome Measure Time Frame" and "Outcome Measure Safety Issue? (Y/N)" for primary or secondary outcome measures may only be changed in the results section.)

Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Initial Outcome Measure Arm/Groups	Limitations and Caveats	Adverse Events
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Title: This link is informational, to help text.

Arm/Group*

Select the Arm/Groups for this [Outcome Measure](#). The Arm/Groups define columns for reporting tabular Outcome Measure data. You will be able to edit the Arm/Group Titles and Descriptions later, if desired.

<input type="checkbox"/> Use Arm/Groups (i.e., columns) from Participant Flow	Arm/Group Title	All Participants			
	Arm/Group Description	All participants received 3 weekly doses of: <i>drugname</i> at a low dose (18 mg), medium dosage (27 mg or 36 mg depending on weight) and a high dosage (52 mg or 36 mg depending on weight) and another week of placebo.			
<input type="radio"/> Use Arm/Groups (i.e., columns) from Adverse Events	Arm/Group Title	Placebo	Low dosage	Medium Dosage	High Dosage
	Arm/Group Description		Low dose: 18 mg <i>drugname</i>	Medium Dosage: 36 mg <i>drugname</i>	54 mg <i>drugname</i>
<input type="radio"/> Use Arm/Groups (i.e., columns) from Outcome Measure	Arm/Group Title	Placebo	Low Dosage	Medium Dosage	High Dosage
	Arm/Group Description	placebo	18 mg <i>drugname</i>	36 mg <i>Drugname</i> if >25 kg; 27 mg <i>drugname</i> if < 25 kg.	54 mg <i>Drugname</i> if >25 kg; 36 mg <i>drugname</i> if < 25 kg.
<input checked="" type="radio"/> Define New Arm/Groups (columns)					

Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Outcome Measure Data	Limitations and Caveats	Adverse Events
--------------------------	--------------------	------------------	----------	---	-------------------------	----------------

Title:

<u>Outcome Measure Type*</u>	Primary
<u>Outcome Measure Title*</u>	Maximum allowed content length (255)
<u>Outcome Measure Description</u>	Maximum allowed content length (600)
<u>Outcome Measure Time Frame*</u>	Time point(s) at which outcome measure was assessed. Limit: 255 characters.
<u>Safety Issue</u> <small>(FDAAA)</small>	Is this outcome measure assessing a safety issue? No

Pick list choices are:
 Primary Outcome Measure (from Protocol section)
 Secondary Outcome Measure (from Protocol section)
 Other Pre-specified Outcome Measure
 Post-Hoc Outcome Measure

Time point(s) at which outcome measure was assessed. Limit: 255 characters.

Yes or No

Save and Validate

Enter Outcome Data

[Add Arm/Group](#)

Arm/Group Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill									
<u>Arm/Group Title*</u> and <u>Description*</u>	<table border="1"> <tr> <td style="text-align: right;">Remove Arm/Group</td> <td>Placebo</td> </tr> <tr> <td colspan="2">Maximum allowed content length (999)</td> </tr> <tr> <td colspan="2">placebo</td> </tr> <tr> <td colspan="2">NOTE : An Arm/Group Description is shorter than the Arm/Group Title.</td> </tr> </table>	Remove Arm/Group	Placebo	Maximum allowed content length (999)		placebo		NOTE : An Arm/Group Description is shorter than the Arm/Group Title.	
Remove Arm/Group	Placebo								
Maximum allowed content length (999)									
placebo									
NOTE : An Arm/Group Description is shorter than the Arm/Group Title.									
	<table border="1"> <tr> <td style="text-align: right;">Remove Arm/Group</td> <td>Low Dosage</td> </tr> <tr> <td colspan="2">Maximum allowed content length (999)</td> </tr> <tr> <td colspan="2">18 mg drugname</td> </tr> </table>	Remove Arm/Group	Low Dosage	Maximum allowed content length (999)		18 mg drugname			
Remove Arm/Group	Low Dosage								
Maximum allowed content length (999)									
18 mg drugname									

[In the model study there is a sideways portion to this page that holds data from additional study groups – omitted here.]

Arm/Group Title* and Description*	<input type="checkbox"/> Remove Arm/Group Placebo Maximum allowed content length (999) placebo <input type="button" value="NOTE : An Arm/Group Description is shorter than the Arm/Group Title."/>	<input type="checkbox"/> Remove Arm/Group Low Dosage Maximum allowed content length (999) 18 mg drugname
Number of Participants Analyzed:*	96	96
<input checked="" type="checkbox"/> Report Units Analyzed other than participants (e.g., eyes, lesions, implants) (Not necessary for most studies)		
Analysis Population Description:	Please explain how the number of participants for analysis was determined. Maximum allowed content length (350) Intent to treat with imputation for missing data.	
Measure Type:* Mean Measure of Dispersion/Precision:* Standard Deviation	Pick list choices are: Number (e.g., number of participants) Measure of Central Tendency, if a continuous measure is reported Least Squares Mean • Log Mean Mean Median Geometric Mean	
<input checked="" type="checkbox"/> Add Category		
Unit of Measure*	Score (e.g., mm Hg) <input checked="" type="checkbox"/> use participants <input checked="" type="checkbox"/> use years <input checked="" type="checkbox"/> use units on a scale <input checked="" type="checkbox"/> use percentage of <something> If the Measure Type is "Number", the Unit of Measure is typically "participants".	
<input type="button" value="Save and Validate"/> <input type="button" value="Save and Continue"/> <input type="button" value="Cancel"/>		

Fill-in field, not picklist. Pre-programmed suggestions are provided in smaller blue font to the right (see green check marks).

Pick list choices are:
 Not Applicable (only when Measure Type is "Number")
 Standard Deviation
 Inter-Quartile Range
 Full Range
 Standard Error
 95% Confidence Interval
 90% Confidence Interval
 Geometric Coefficient of Variation (only when Measure Type is "Geometric Mean")

Statistical Analyses - OPTIONAL; if statistical analysis information is provided, then [*]-marked data elements are required.

[Send message to PRS](#)



Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Add Outcome Statistical Analysis	Limitations and Caveats	Adverse Events
--------------------------	--------------------	------------------	----------	---	-------------------------	----------------

Title:

Posted Primary Outcome: ; Units: ;

[Statistical Analysis Overview:](#)

Comparison Group Selection: *

Generally, at least 2 groups should be checked. Check all groups for an "omnibus" analysis.

Placebo Low Dosage Medium Dosage High Dosage

Please provide additional details about the analysis, such as null hypothesis and power calculation.

Maximum allowed content length (500)

Identifies the arms or comparison groups involved in the statistical analysis (check all groups to indicate an "omnibus" analysis).

Yes or No

Is this a non-inferiority or equivalence analysis? *

ERROR : Please enter whether the Statistical Analysis tested for Non-inferiority or Equivalence.

If yes, please describe details of power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.

Maximum allowed content length (500)

Identifies whether the analysis is a test of non-inferiority or equivalence (Choose "Yes") or superiority (Choose "No").

P-Value: (e.g. <0.01)

NOTE : Both P-Value and estimated Confidence Interval have not been entered for a Statistical Analysis.

ERROR : Either P-Value or estimated Confidence Interval or Estimated Value must be entered for a Statistical Analysis.

If desired, provide additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.

Maximum allowed content length (250)

If, "Yes", provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.

[Statistical Test of Hypothesis:](#)

All red Stop sign ERROR: system messages that the system comes back to you with must be resolved before the study record can be finalized.

This screen continues on p. 32 (scroll down when live).

Statistical Test of Hypothesis:

Method: -- Please Select --

Describe any other relevant information, such as adjustments or degrees of freedom.
Maximum allowed content length (150)

What parameter did you estimate (e.g., Odds Ratio)? -- Please Select --

If other, please specify:

Estimated Value:

When the confidence interval is entered, it must be fully specified. A fully specified confidence interval includes percentage and one of the following:

- 1-sided: enter either the lower or upper limit
- 2-sided (default): enter both lower and upper limits

Also, when a confidence interval is entered, an Estimated Value and parameter must be entered.

Method of Estimation:

95 % Confidence Interval:

Number of sides: -- Please Select --

Lower Limit:

Upper Limit:

Parameter Dispersion Type: -- Please Select --

Describe any other relevant estimation information, including the direction of the comparison (e.g., describe which Arm/Group represents the numerator and denominator for relative risk).

Method picklist choices are:

- ANCOVA
- ANOVA
- Chi-square
- Chi-squared, Corrected
- Cochran-Mantel-Haenszel
- Fisher Exact
- Kruskal-
- Log Rank
- Mantel-Haenszel
- McNemar
- Mixed Models Analysis
- Regression, Cox
- Regression, Linear
- Regression, Logistic
- Sign Test
- t-test, 1 sided
- t-test, 2 sided
- Wilcoxon (Mann-Whitney)
- Other

Parameter picklist choices are:

- Cox Proportional Hazard
- Hazard ratio (HR)
- Hazard Ratio, log
- Mean Difference (Final Values)
- Mean Difference (Net)
- Median Difference (Final Values)
- Median Difference (Net)
- Odds ratio (OR)
- Odds Ratio, Log
- Risk Difference (RD)
- Risk Ratio (RR)
- Risk Ratio, log
- Slope
- Other

Screen Image continues below on next page.

When the confidence interval is entered, it must be fully specified. A fully specified confidence interval includes percentage and one of the following:

- 1-sided: enter either the lower or upper limit
- 2-sided (default): enter both lower and upper limits

Also, when a confidence interval is entered, an Estimated Value and parameter must be entered.

Method of Estimation:

95

% Confidence Interval:

Number of sides: -- Please Select --

Lower Limit:

Upper Limit:

Parameter Dispersion Type: -- Please Select --

Confidence Interval # of Sides 1 or 2 sided

Parameter Dispersion Type:

Standard Error of the Mean or Standard Deviation

Describe any other relevant estimation information, including the direction of the comparison (e.g., describe which Arm/Group represents the numerator and denominator for relative risk).

Maximum allowed content length (250)

OK

Cancel

Results

Results Point of Contact

Certain Agreements

Participant Flow

Baseline

Outcome Measure

Limitations and Caveats
Edit Limitations and Caveats

Adverse Events

Title:

Overall Limitations and Caveats:

If appropriate, please describe limitations of the trial.

Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

Maximum allowed content length (250)

OK

Cancel

Next major part of Results.
This example includes only 4 nonserious AEs.

[Send message to PRS](#)



Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events Adverse Event Overview
--------------------------	--------------------	------------------	----------	-----------------	-------------------------	--

Title:

[Results Overview](#)

See p. 37

Edit	Time Frame	<p>(Note that arm information from the protocol section will be copied into the results section the first time results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)</p>
	Additional Description	
	Source Vocabulary for Table Default	
	Assessment Type for Table Default	

See p. 38.

See pp. 39-40

[Sort Adverse Events Alphabetically - a productivity aid to facilitate Adverse Event \(AE\) data entry](#)

Sorts Adverse Event Terms alphabetically within each Table ("Serious" and "Other")

NOTE: Order of AEs displayed within tables in the ClinicalTrials.gov public Web site may differ.

[Add Arm/Group](#)

[Add Serious Adverse Event](#)

List all Serious Adverse Events.

See p. 41

	Placebo <small>Modify/Delete</small>	Low Dosage <small>Low dose: 18 mg Modify/Delete</small>	Medium Dosage <small>Medium Dosage: 36 mg Modify/Delete</small>	High Dosage <small>54 mg Modify/Delete</small>
	NOTE : An entry in Arm/Group Description is recommended.			
Edit Total for Serious Adverse Events	0 Affected out of 96 At Risk (0%)	0 Affected out of 96 At Risk (0%)	1 Affected out of 96 At Risk (1.04%)	0 Affected out of 96 At Risk (0%)
<i>Maximum for a single Event</i>	0 participants Affected by a Serious Adverse Event	0 participants Affected by a Serious Adverse Event	1 participants Affected by a Serious Adverse Event	0 participants Affected by a Serious Adverse Event
<i>Sum for all Events</i>	0 participants Affected by all Serious Adverse Events	0 participants Affected by all Serious Adverse Events	1 participants Affected by all Serious Adverse Events	0 participants Affected by all Serious Adverse Events
Edit Name of SAE				

[Non-Serious AEs are shown below the SAEs on this same screen, image on page 36 immediately below.]

See p. 42

See p. 44.

See p. 46.

[Add Other Adverse Event](#)

List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit	Frequency Threshold for reporting Other Adverse Event	1 %			
Edit	Total for Other Adverse Events	Placebo	Low Dosage	Medium Dosage	High Dosage
		13 <i>Affected out of 96 At Risk (13.54%)</i>	12 <i>Affected out of 96 At Risk (12.5%)</i>	16 <i>Affected out of 96 At Risk (16.67%)</i>	37 <i>Affected out of 96 At Risk (38.54%)</i>
	<i>Maximum for a single Event</i>	<i>4 participants Affected by a Other Adverse Event</i>	<i>3 participants Affected by a Other Adverse Event</i>	<i>5 participants Affected by a Other Adverse Event</i>	<i>9 participants Affected by a Other Adverse Event</i>
	<i>Sum for all Events</i>	<i>13 participants Affected by all Other Adverse Events</i>	<i>12 participants Affected by all Other Adverse Events</i>	<i>16 participants Affected by all Other Adverse Events</i>	<i>37 participants Affected by all Other Adverse Events</i>

See p. 47

[Edit](#) **Names of reportable nonserious AEs are listed here, and are populated into the left-hand column of the next screens, illustrated below.**

NOTE : [12 occurrences] An empty Assessment Type has been entered for an Adverse Event.

See p. 48

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events Edit Adverse Event Report
--------------------------	--------------------	------------------	----------	-----------------	-------------------------	---

Title:

Time Frame for Adverse Event Reporting	Please provide description of period in which adverse event data were collected (e.g., 1 year, 6 months) Maximum allowed content length (255) <input type="text" value="Period in which the reported adverse event data were collected (e.g., 1 year, 6 months)."/>
Additional Description	Maximum allowed content length (350) <input type="text" value="Additional relevant information about adverse event collection, including details about the method of systematic assessment (e.g., daily questionnaire)."/>
Source Vocabulary for Table Default	Please enter the name and version of the source vocabulary, if any, for adverse event terms. Source Vocabulary will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified. (e.g., SNOMED CT, MedDRA 10.0) <input type="text" value="Limit: 20 characters"/>
Assessment Type for Table Default	Assessment type will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified. If systematic, provide explanation of the method in Additional Description. <input type="text" value="-- Please Select --"/>

OK Cancel

Assessment Type for Table Default picklist choices are:
Systematic Assessment
Non-systematic Assessment

Results						Adverse Events
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Add Adverse Event Arm/Group

Title

Arm/Group Title: *	Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill
Arm/Group Description:	Maximum allowed content length (999)

Results						Adverse Events
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Add Serious Adverse Event

Title:

<u>Adverse Event Term:</u> *	Word or phrase describing an adverse event. Limit: 100 characters
<u>Source Vocabulary Name:</u>	Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0). Blank means use table default. No current default source vocabulary
<u>Organ System:</u> *	-- Please Select --
<u>Assessment Type:</u>	Blank means use table default. No current default assessment type -- Please Select --
<u>Additional Description:</u>	Maximum allowed content length (250)

Additional relevant information about the adverse event, including any deviation from the Time Frame for Adverse Event Reporting.

OK Cancel

Source Vocabulary Name: Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (e.g., SNOMED CT, MedDRA 10.0). Leave blank to indicate that the value specified as the Source Vocabulary for Table Default should be used. (Limit: 20 characters)

High-level categories used to group adverse event terms by body or organ system. Select one. Adverse events that affect multiple systems should be classified as "General disorders." Organ System picklist options are shown on the next page (p.40).

Assessment Type : Method used to assess the adverse event. Select one or leave blank to indicate that the value specified as the Assessment Type for Table Default should be used.

- Systematic Assessment:** Any method of routinely determining whether or not certain adverse events have occurred, for example through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method
- Non-systematic Assessment:** Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

Results						Adverse Events Add Serious Adverse Event
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	

Title:

Adverse Event Term:*

Source Vocabulary Name: Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0).
Blank means use table default.
No current default source vocabulary

Organ System:*

Assessment Type:

- Please Select --
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

This is the destination when the Edit link on p. 35 is selected.

[Send message to PRS](#)



Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events
						Edit Serious Adverse Event Total

Title:

Please enter the Total Number of Participants Affected and at Risk as integers.

- The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow.
- The Total Number of Participants Affected in an Arm/Group must be less than or equal to the sum of Participants Affected for All Adverse Events in the Arm/Group.
- The Total Number of Participants Affected in an Arm/Group must be greater than or equal to the Maximum Number of Participants Affected for any Adverse Event in the Arm/Group.

Serious Adverse Event(s)	Placebo		Low dosage <i>Low dose: 18 mg.</i>		Medium Dosage <i>Medium Dosage: 36 mg</i>		High Dosage <i>54 mg</i>	
	# Affected *	# at Risk *	# Affected *	# at Risk *	# Affected *	# at Risk *	# Affected *	# at Risk *
Maximum for a single Serious Adverse Event	0 (Calculated)		0 (Calculated)		1 (Calculated)		0 (Calculated)	
Sum for all Serious Adverse Events	0 (Calculated)		0 (Calculated)		1 (Calculated)		0 (Calculated)	
Total	<input type="text" value="0"/>	<input type="text" value="96"/>	<input type="text" value="0"/>	<input type="text" value="96"/>	<input type="text" value="1"/>	<input type="text" value="96"/>	<input type="text" value="0"/>	<input type="text" value="96"/>

Data entry areas for all study arms (model study had 4).
Table format is preferred.

Results						Adverse Events Adverse Event Subset
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	

Title:

[Adverse Event Overview](#)

	Placebo	Low Dosage	Medium Dosage	High Dosage	
Edit	Total for Serious Adverse Events	0 Affected out of 96 At Risk (0%)	0 Affected out of 96 At Risk (0%)	1 Affected out of 96 At Risk (1.04%)	0 Affected out of 96 At Risk (0%)
	Name of SAE	0 Affected out of 96 At Risk (0%)	0 Affected out of 96 At Risk (0%)	1 Affected out of 96 At Risk (1.04%)	0 Affected out of 96 At Risk (0%)
	Category	0 Events	0 Events	1 Events	0 Events
	Assessment Type				

See p. 43, which is where the entry screens are, for numbers of Subjects who incurred the named SAE.

Results

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events Edit Serious Adverse Event Subset Data
--------------------------	--------------------	------------------	----------	-----------------	-------------------------	--

Title: _____

Please enter the number of participants affected and at risk as integers. Also, if available, enter the number of events as integers

<u>Serious Adverse Event(s)</u>	Placebo			Low dosage <i>Low dose: 18 mg</i>		
	# Affected *	# at Risk *		# Affected *	# at Risk *	
<u>Total</u>	0	96		0	96	
	# Affected *	# Events	# at Risk [blank =Total]	# Affected *	# Events	# at Risk [blank =Total]
SAE Name Assessment Type	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value=""/> [96]	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value=""/> [96]

Next dose groups for studies with more than two, will go off to the right starting on this screen (here). Using the horizontal scroll bar would bring the remaining groups on screen.

Data entry areas for study arms, 2 of 4 shown.

OK Cancel

SAEs are done – now the non-serious AEs. The screens look much alike – the nature of the events is the difference. This screen is the destination when the “Add Other Adverse Event” link on p. 36 is selected.



Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events Add Other (Not Including Serious) Adverse Event

Title:

Adverse Event Term: *

Source Vocabulary Name: Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0).
Blank means use table default.
No current default source vocabulary

Organ System: * -- Please Select --

Assessment Type: Blank means use table default.
No current default assessment type
-- Please Select --

Additional Description: Maximum allowed content length (250)

Same Organ System picklist options as for SAEs, see next page (p. 45).

Assessment Type picklist options are:
Systematic Assessment
Non-Systematic Assessment

OK Cancel

Results						Adverse Events
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Add Other (Not Including Serious) Adverse Event

Title:

Adverse Event Term: *

Source Vocabulary Name: Please enter the name and version for the term's source vocabulary, if any, (e.g., SNOMED CT, MedDRA 10.0).

Blank means use table default.

No current default source vocabulary

Organ System: *

Assessment Type:

Additional Description:

- Please Select --
- Please Select --
- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Investigations
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

Results						Adverse Events
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Edit Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events

Title:

Frequency Threshold for Reporting Other Adverse Event:

Enter a number for the frequency above which Other (Not Including Serious) Adverse Events are reported.
The number must be less than or equal to the allowed maximum (5%) and must not include any symbol (e.g., >=).

%

OK

Cancel

The frequency of Other (Not Including Serious) Adverse Events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups. T

The number must be less than or equal to the allowed maximum (5%), and must not include any symbols (e.g., >= , %).

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.

Screen looks the same for AEs and SAEs; text in the yellow flag and header of left-hand column below will distinguish.

[Send message to PRS](#)



Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events
						Edit Other (Not Including Serious) Adverse Event Total

Title:

Please enter the Total Number of Participants Affected and at Risk as integers.

- The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow.
- The Total Number of Participants Affected in an Arm/Group must be less than or equal to the sum of Participants Affected for All Adverse Events in the Arm/Group.
- The Total Number of Participants Affected in an Arm/Group must be greater than or equal to the Maximum Number of Participants Affected for any Adverse Event in the Arm/Group.

<u>Other Adverse Event(s)</u>	Placebo	Low dosage <i>Low dose: 18 mg.</i>	
Maximum for a single Other Adverse Event	4 <i>(Calculated)</i>	3 <i>(Calculated)</i>	
Sum for all Other Adverse Events	13 <i>(Calculated)</i>	12 <i>(Calculated)</i>	
	# Affected *	# at Risk *	# Affected *
Total	<input type="text" value=".."/>	<input type="text" value="96"/>	<input type="text" value=".."/>

Next Dose Groups/Arms for studies with more than two, would go off to the right here.

Data entry areas for all study arms, 2 of 4 shown.

Results						
Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events Adverse Event Subset

Title:

[Adverse Event Overview](#)

See p. 49 for actual data entry screens.

	Placebo	Low Dosage
Edit Total for Other Adverse Events	13 <i>Affected out of 96 At Risk (13.54%)</i>	12 <i>Affected out of 96 At Risk (12.5%)</i>
Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	0 <i>Affected out of 96 At Risk (0%)</i> 0 <i>Events</i>	1 <i>Affected out of 96 At Risk (1.04%)</i> 1 <i>Events</i>
Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	1 <i>Affected out of 96 At Risk (1.04%)</i> 1 <i>Events</i>	0 <i>Affected out of 96 At Risk (0%)</i> 0 <i>Events</i>
NOTE : An empty Assessment Type has been entered for an Adverse Event.		
Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	3 <i>Affected out of 96 At Risk (3.12%)</i> 3 <i>Events</i>	1 <i>Affected out of 96 At Risk (1.04%)</i> 1 <i>Events</i>
Name of AE Category How Assessed Number rated 4 (severe) Modify/Delete	1 <i>Affected out of 96 At Risk (1.04%)</i> 1 <i>Events</i>	3 <i>Affected out of 96 At Risk (3.12%)</i> 3 <i>Events</i>

For brevity, four AEs from a longer list and only 2 arms of the four that the study had are illustrated here.

Results

Results Point of Contact Certain Agreements Participant Flow Baseline Outcome Measure Limitations and Caveats **Adverse Events**

Edit Other (Not Including Serious) Adverse Event Subset Data

Title:

Please enter the number of participants affected and at risk as integers. Also, if available, enter the number of events as integers.

Other Adverse Event(s)	Placebo			Low dosage <i>Low dose: 18 mg</i>		
	# Affected *	# Events	# at Risk * [blank =Total]	# Affected *	# Events	# at Risk * [blank =Total]
Total	13		96	12		96
AE Name How Assessed	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="96"/> [96]	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="96"/> [96]
AE Name How Assessed	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text"/> [96]	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text"/> [96]
AE Name How Assessed	<input type="text" value="3"/>	<input type="text" value="3"/>	<input type="text"/> [96]	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text"/> [96]
AE Name How Assessed	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text"/> [96]	<input type="text" value="3"/>	<input type="text" value="3"/>	<input type="text"/> [96]

Data Entry is done here, numbers of Subjects who incurred each named AE and total number of Subjects at risk for that AE.

Only with study ownership in the clinicaltrials.gov system are the screens shown in this illustration visible. These illustrations would have not been possible without the kind permission of the model study's PI, who allowed the image extractor temporary ownership of the study in the ClinicalTrials.gov system.