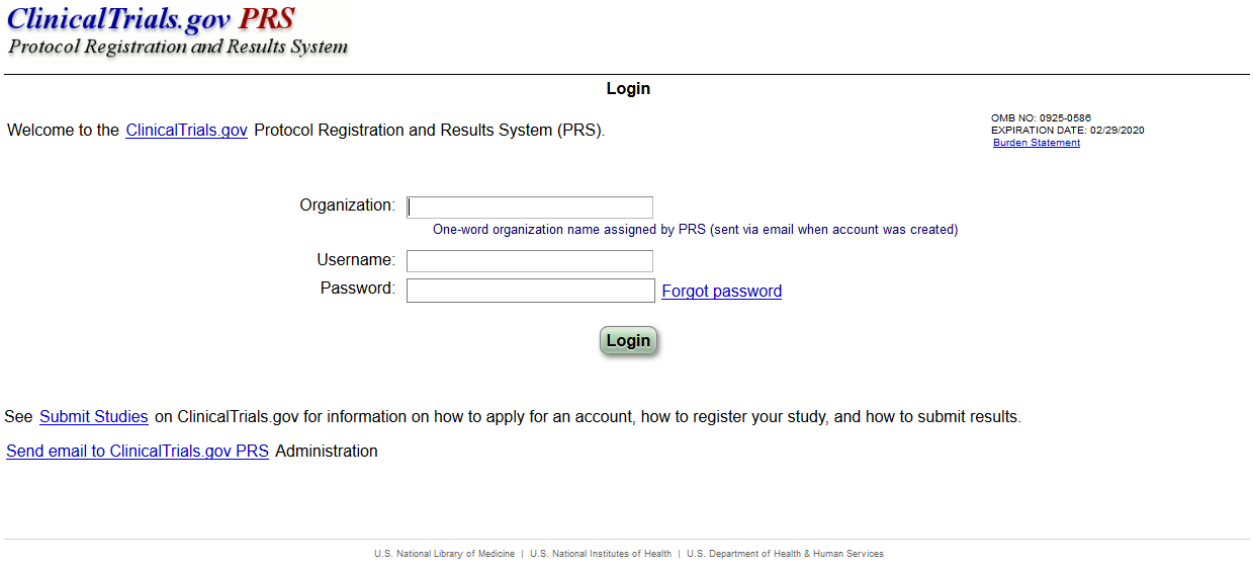
Attachment 5 - ClinicalTrials.gov Results Reporting Data Entry Screen Shots (DRAFT)



OMB NO: 0925-0586
EXPIRATION DATE: 02/29/2020
Burden Statement

Public reporting burden for this collection of information is estimated to vary from 2.0 to 8.0 hours per response for registration, 10.0 to 45.0 hours per response results information submissions, and 15 minutes to 2 hours for other submissions including certifications for delay, extension requests, and expanded access. These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address.

Edit Participant Flow

Help Definitions

Protocol Enrollment:	Enrollment is a Protocol Section data element (Protocol Registration Data Element Definitions). Changing the value here will change the value in the Protocol Section.
Recruitment Details:	Edit
[*] Pre-assignment Details:	Edit

Arms/Groups (2) + Add Arm/Group

	Edit	Edit	
* Arm/Group Title:	**Arm 1**	**Arm 2**	Total (Not public)
* § Arm/Group Description:			
	× Delete Move ▶	× Delete ◀ Move	
[*] Type of Units Assigned:	+ Add Units Assigned (Optional) Use only if assigned units other than participants (e.g., eyes, lesions, implants).		

Periods (1)

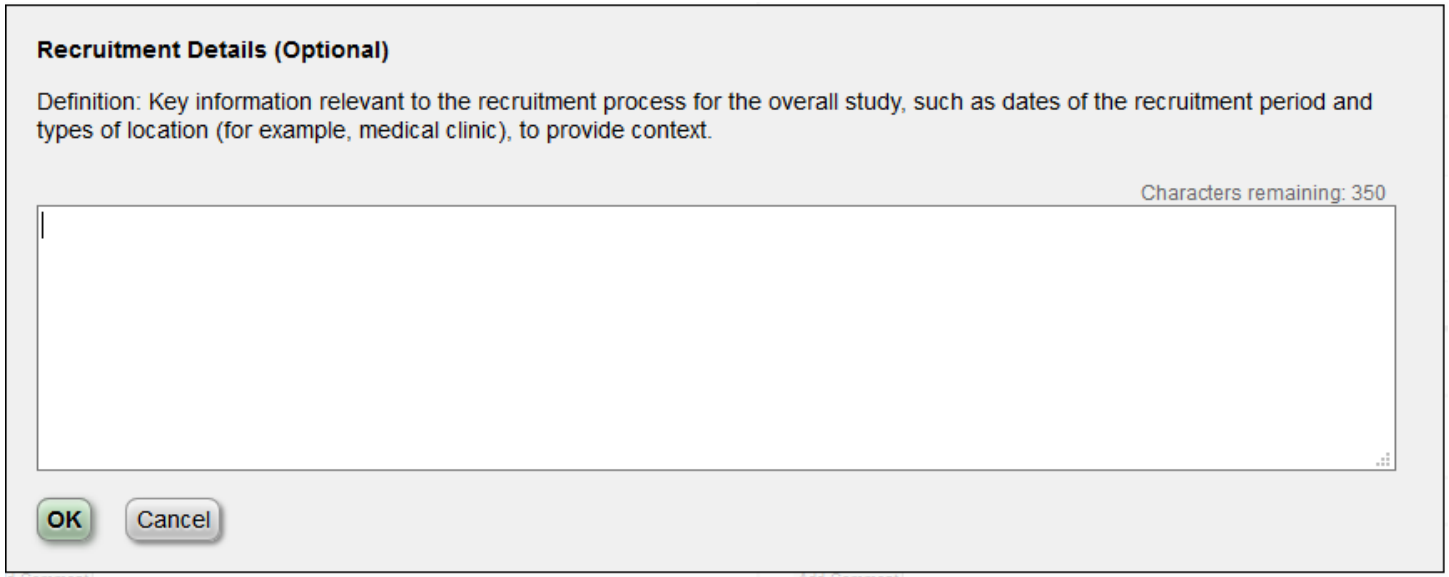
Protocol Enrollment:

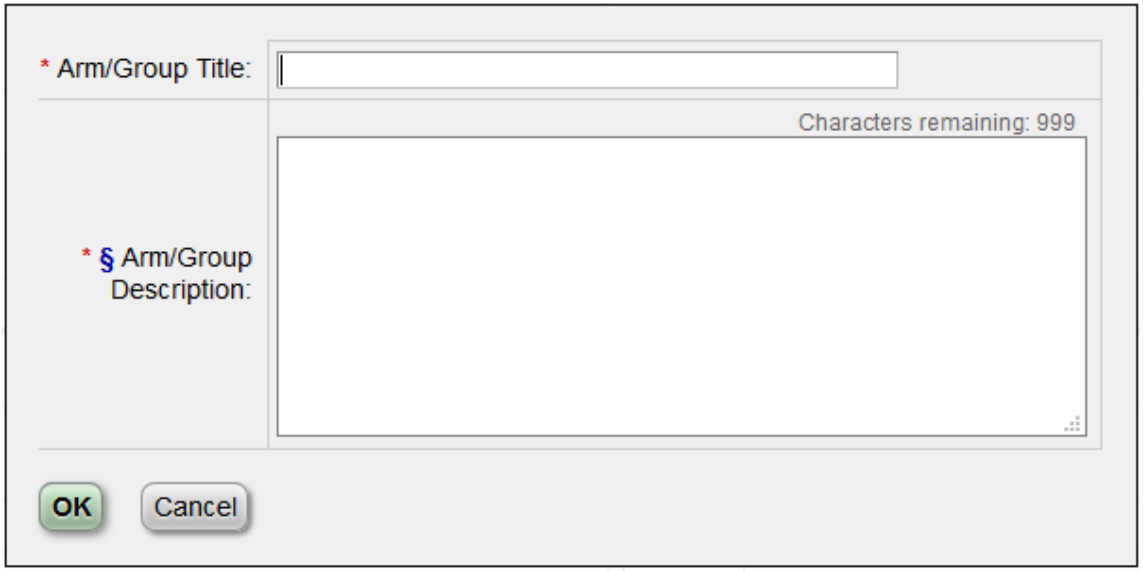
* Period Title:	Overall Study		
	Arm 1	**Arm 2**	Total (Not public)
* Started: Add Comment	Add Comment	Add Comment	unknown
+ Add Milestone			
* Completed: Add Comment	Add Comment	Add Comment	unknown
Not Completed: (Started - Completed)	unknown	unknown	
Reason Not Completed			
+ Add Reason Not Completed			

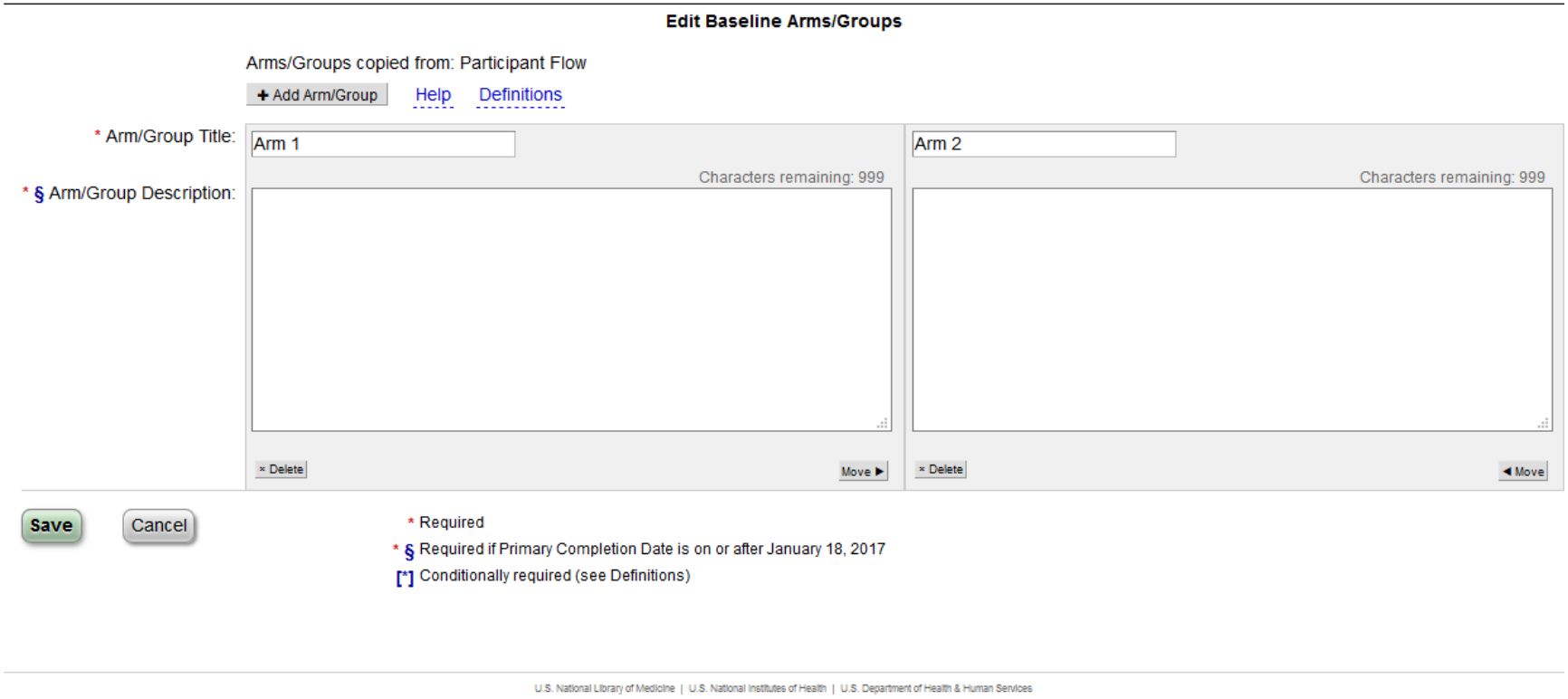
+ Add Period

Save Validate Cancel

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


Recruitment Details (Optional)
Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (for example, medical clinic), to provide context.
Characters remaining: 350
OK
Cancel


* Arm/Group Title:
Characters remaining: 999
* § Arm/Group Description:
OK
Cancel


Edit Baseline Arms/Groups
Arms/Groups copied from: Participant Flow
+ Add Arm/Group
Help
Definitions
* Arm/Group Title:
* § Arm/Group Description:
Arm 1
Characters remaining: 999
Arm 2
Characters remaining: 999
× Delete
Move ▶
× Delete
◀ Move
Save
Cancel
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Add Baseline Measures

Help Definitions

		* Baseline Measure Title:	
* **Age** At least 1 is Required	☑	Age, Continuous	Example
	☑	Age, Categorical ≤18 years; 18 to 65 years; ≥65 years	Example
	☐	Age, Customized	Example
* **Sex/Gender** At least 1 is Required	☑	Sex: Female, Male	Example
	☐	Sex/Gender, Customized	Example
* § **Race and Ethnicity**	☐	Race (NIH/OMB)	Example
	☐	Ethnicity (NIH/OMB)	Example
	☐	Race/Ethnicity, Customized	Example
	☐	Race and Ethnicity Not Collected	Example
Region of Enrollment Pre-filled with countries from Locations in Protocol	☑	Region of Enrollment	Example
* § **Study-Specific Measures** Additional Baseline Measures assessed in the study, if any.	+ Add		Example

Save Cancel

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

Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Age, Categorical
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type:	Count of Participants Hide calculated percentage			
* Measure of Dispersion:	Not Applicable			
	Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
	<=18 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
	Between 18 and 65 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
	>=65 years	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
+ Add Row				
* Unit of Measure:	participants			

Save Validate Cancel

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

Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Sex: Female, Male
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type:	Count of Participants	Hide calculated percentage		
* Measure of Dispersion:	Not Applicable			
	Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
	Female	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
	Male	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
+ Add Row				
* Unit of Measure:	participants			

Save Validate Cancel

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

Edit Baseline Measure

Help Definitions

Information is required

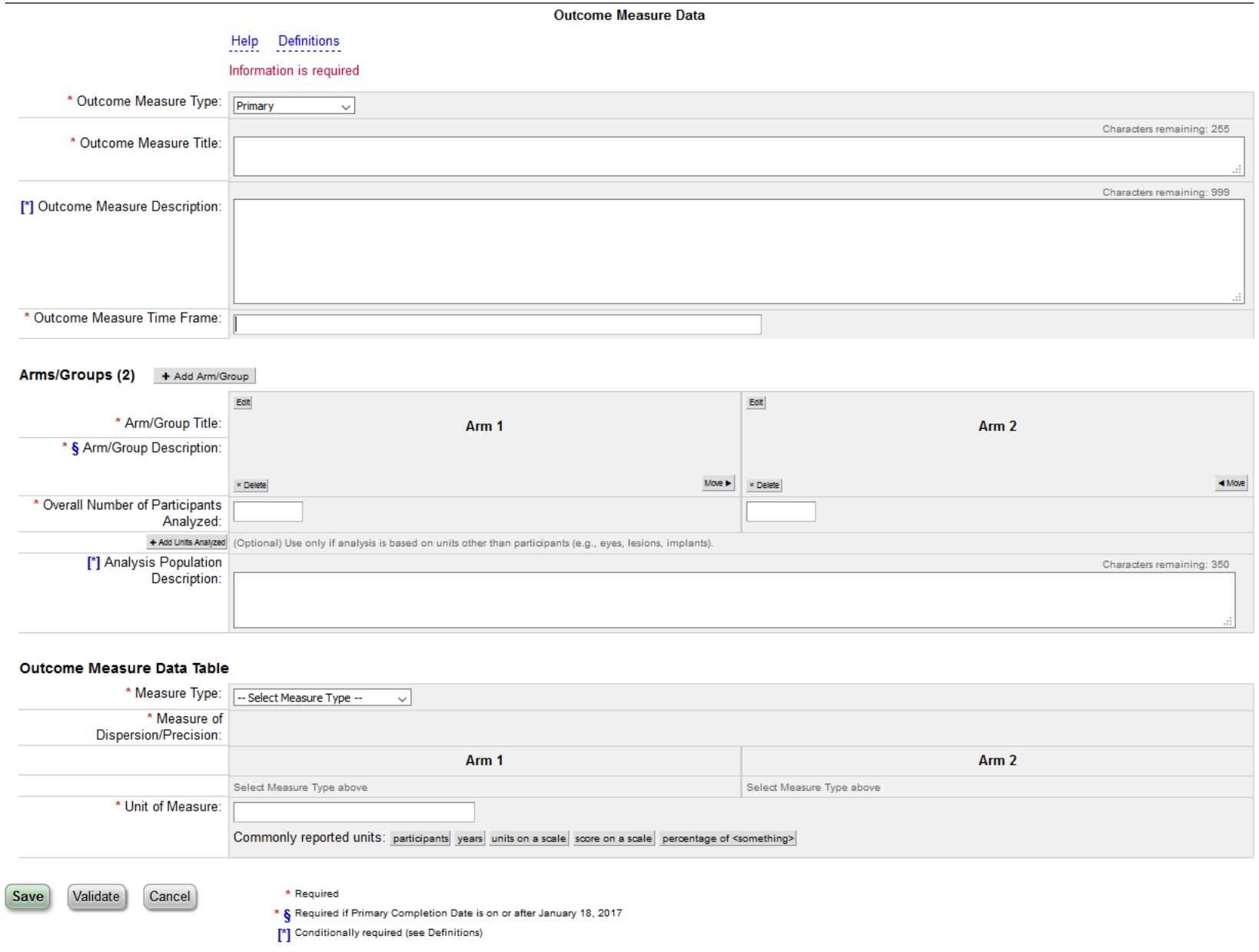
* Study-Specific Baseline Measure Title:	
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Arm 1	Arm 2	Total
Overall Number of Baseline Participants:	---	---	unknown
Baseline Analysis Population Description:			

* Measure Type:	-- Select Measure Type --			
* Measure of Dispersion:	-- Select Measure of Dispersion --			
	Number Analyzed: Participants	--- participants Edit	--- participants Edit	unknown
		Select Measure Type above	Select Measure Type above	Select Measure Type above
+ Add Row				
* Unit of Measure:				
	Commonly reported units: years units on a scale participants			

Save Validate Cancel

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



Outcome Measure Data

Help Definitions

Information is required

* Outcome Measure Type: Primary

* Outcome Measure Title: Characters remaining: 255

[*] Outcome Measure Description: Characters remaining: 999

* Outcome Measure Time Frame:

Arms/Groups (2) + Add Arm/Group

	Arm 1	Arm 2
* Arm/Group Title:	Edit	Edit
* § Arm/Group Description:	Arm 1	Arm 2
	× Delete Move ▶	× Delete ◀ Move
* Overall Number of Participants Analyzed:		

+ Add Units Analyzed (Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).

[*] Analysis Population Description: Characters remaining: 350

Outcome Measure Data Table

* Measure Type: -- Select Measure Type --

* Measure of Dispersion/Precision:

	Arm 1	Arm 2
	Select Measure Type above	Select Measure Type above

* Unit of Measure:

Commonly reported units: participants | years | units on a scale | score on a scale | percentage of <something>

Save Validate Cancel

* Required

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

[*] Conditionally required (see Definitions)

Edit Adverse Event Table Defaults

Help Definitions

* § Time Frame:	Provide a description of the specific period of time over which adverse event data were collected (e.g., 1 year, 6 months) Characters remaining: 500
[*] Adverse Event Reporting Description:	If the definition of adverse event and/or serious adverse event, used to collect adverse event information, differs from the clinicaltrials.gov Definitions, describe how the definitions differ. Also, optionally provide additional relevant information about adverse event collection. Characters remaining: 500
Source Vocabulary Name 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)
* § Collection Approach 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 Adverse Event Reporting Description. -- Please Select --

Save Cancel

* Required

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

[*] Conditionally required (see Definitions)

Edit All-Cause Mortality

Help Definitions

All-Cause Mortality	Arm 1	Arm 2
* § Total Number Affected:	participants	participants
* § Total Number At Risk:	participants	participants

Save Validate Cancel

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

Edit Serious Adverse Event Total

Help Definitions

Serious Adverse Event(s)	Arm 1	Arm 2
* Total Number Affected:	participants	participants
* Total Number At Risk:	participants	participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow

Save Validate Cancel

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

Edit Other (Not Including Serious) Adverse Event Total

Help Definitions

Other Adverse Event(s)	Arm 1	Arm 2
* Total Number Affected:	participants	participants
* Total Number At Risk:	participants	participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow.
Preview Participant Flow

Save Validate Cancel

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

Edit Limitations and Caveats

Definitions

Overall Limitations and Caveats:

Characters remaining: 250

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.

Save Cancel

Edit Certain Agreements

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.

Definitions

* Are all PIs Employees of Sponsor?	If all principal investigators are employees of the sponsor, select "Yes". No
[*] Results Disclosure Restriction on PI(s)?	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 Primary Completion Date, select "Yes." If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes." Yes
PI Disclosure Restriction Type:	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). (•) None Selected ( ) 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. ( ) 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. ( ) Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. If the restriction type is "Other disclosure agreement ...", please describe the agreement. Characters remaining: 500

Save Cancel

* Required

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

Edit Results Point of Contact

Definitions

* 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:	
* § Phone:	Ext.
* § Email:	

Save Cancel

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