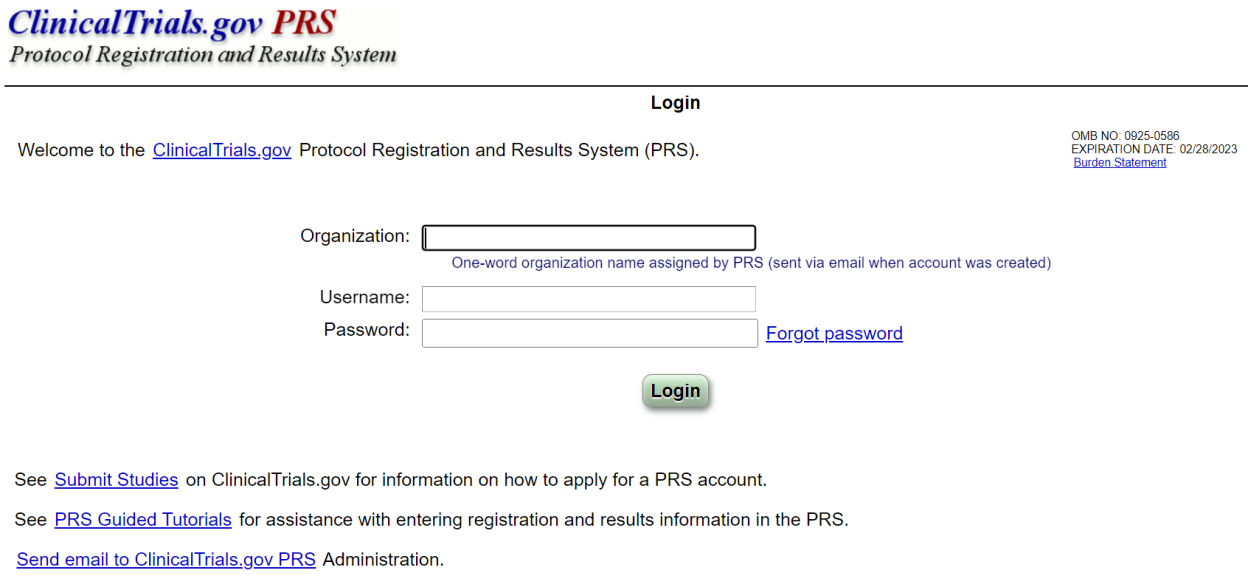
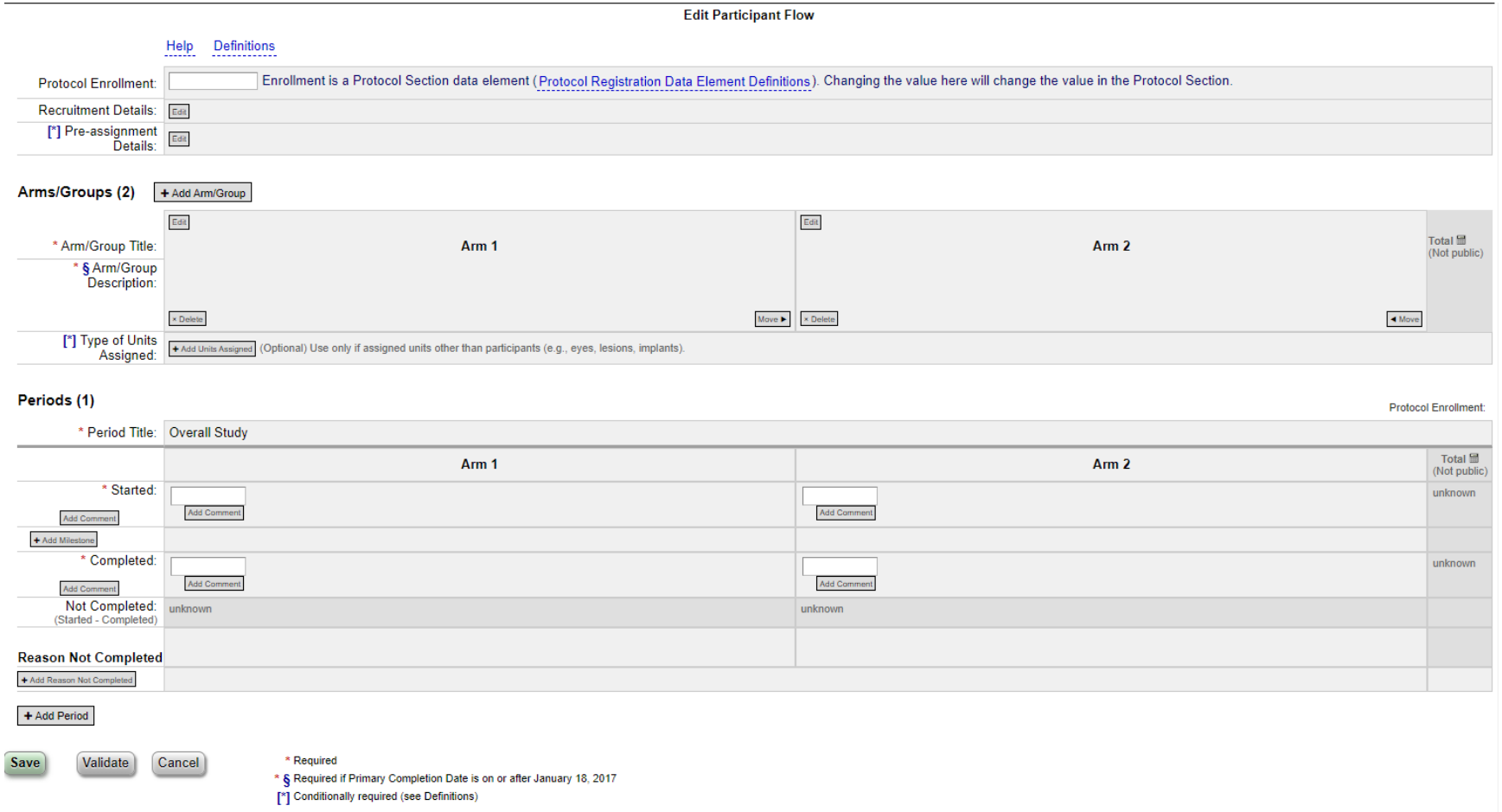
Attachment 5 – Results Information Submission Data Entry Forms



OMB NO: 0925-0586
EXPIRATION DATE: 02/28/2023
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 for 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

	Arm 1	Arm 2	Total (Not public)
* Arm/Group Title:	Edit	Edit	
* § 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)

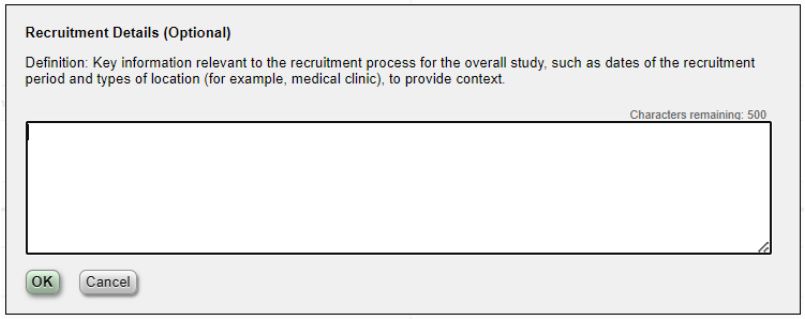
Protocol Enrollment:

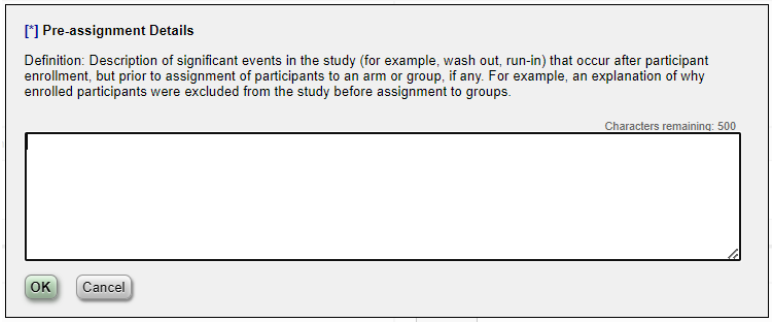
	Arm 1	Arm 2	Total (Not public)
* Period Title:	Overall Study		
* Started: Add Comment	Add Comment	Add Comment	unknown
+ Add Milestone			
* Completed: Add Comment	Add Comment	Add Comment	unknown
Not Completed: (Started - Completed)	unknown	unknown	
Reason Not Completed			
+ Add Reason Not Completed			

+ Add Period

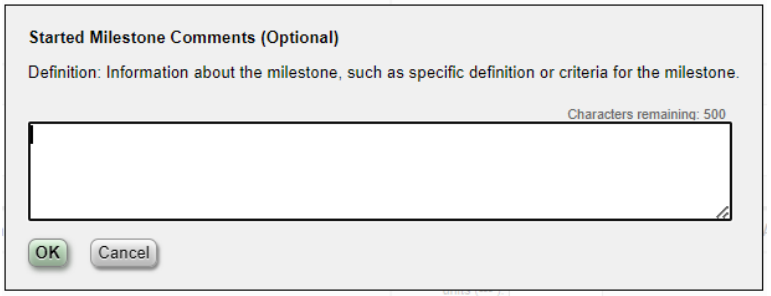
Save Validate Cancel

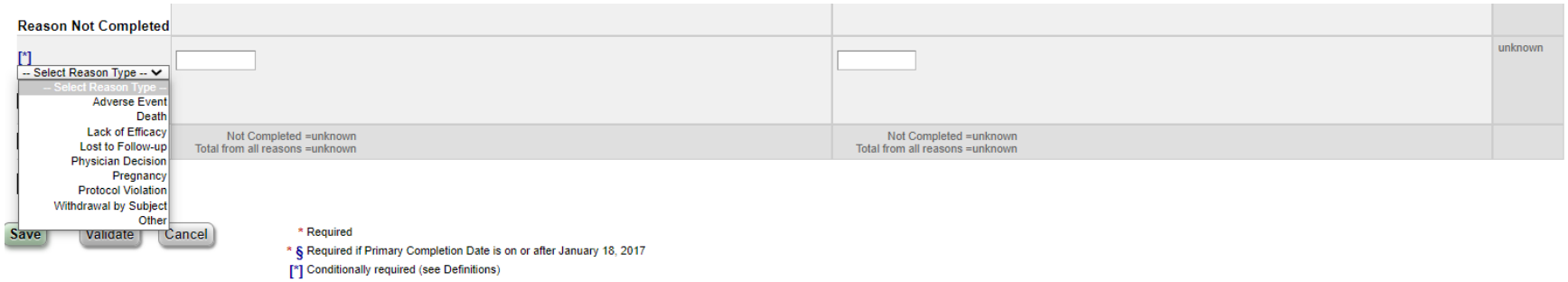
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)


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: 500
OK
Cancel


[*] Pre-assignment Details
Definition: Description of significant events in the study (for example, wash out, run-in) that occur after participant enrollment, but prior to assignment of participants to an arm or group, if any. For example, an explanation of why enrolled participants were excluded from the study before assignment to groups.
Characters remaining: 500
OK
Cancel


* Arm/Group Title:
Characters remaining: 95
Arm 1
Characters remaining: 1500
* § Arm/Group Description:
OK
Cancel


Started Milestone Comments (Optional)
Definition: Information about the milestone, such as specific definition or criteria for the milestone.
Characters remaining: 500
OK
Cancel


Reason Not Completed
[*]
-- Select Reason Type --
-- Select Reason Type --
Adverse Event
Death
Lack of Efficacy
Lost to Follow-up
Physician Decision
Pregnancy
Protocol Violation
Withdrawal by Subject
Other
unknown
Not Completed =unknown
Total from all reasons =unknown
Not Completed =unknown
Total from all reasons =unknown
Save
Validate
Cancel
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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	Study-Specific Baseline Measure Title(s):	Example
		× Delete	

Save Cancel

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

Edit Baseline Analysis Population

Help Definitions

	Arm 1	Arm 2	Total
* Overall Number of Baseline Participants:			24
[*] Overall Number of Units Analyzed:			calculated
[*] Type of Units Analyzed:			
× Delete			

[*] Baseline Analysis Population Description:

Information about the analysis population when it is different from the assignment in Participant Flow or information about how participants contribute units.

Characters remaining: 500

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 Type --		
	Count of Participants Mean Median Least Squares Mean Geometric Mean Geometric Least Squares Mean Number		
	mber 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)

Baseline Measure Description (Optional)

Definition: Additional information about the measure, such as details about the collection method.

Characters remaining: 600

OK Cancel

Arm/Group:	Arm 1
Overall Number of Baseline Participants:	---
Number Participants Analyzed:	

OK Cancel

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:	Characters remaining: 255

Arms/Groups (2) + Add Arm/Group

	Arm 1	Arm 2
	Edit	Edit
* Arm/Group Title:	Arm 1	Arm 2
* § Arm/Group Description:		
	× 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: 500

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)

Outcome Measure Data Table

		Arm 1	Arm 2
* Measure Type:	Count of Participants [Hide calculated percentage] [Convert Categories to Rows]		
* Measure of Dispersion/Precision:	Not Applicable		
* Row Title Characters remaining: 100 [× Delete] [▼ Move]	Number Analyzed	--- participants [Edit]	--- participants [Edit]
	* Category Title Characters remaining: 100 [× Delete]	Count of Participants ____ NA%	Count of Participants ____ NA%
	* Category Title Characters remaining: 100 [× Delete]	Count of Participants ____ NA%	Count of Participants ____ NA%
	[+ Add Category]		
* Row Title Characters remaining: 100 [× Delete] [▲ Move]	Number Analyzed	--- participants [Edit]	--- participants [Edit]
		Count of Participants ____ NA%	Count of Participants ____ NA%
		Count of Participants ____ NA%	Count of Participants ____ 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)

Add Outcome Statistical Analysis

Primary Outcome	
Title:	
Time Frame:	
Unit of Measure:	

Tip: Many of the data elements are optional and may be left blank. "Comparison Group Selection" and "Type of Statistical Test" are required. In addition, one of the following data elements are required with the associated information: "P-Value", "Estimation Parameter", or "Other Statistical Analysis."

Statistical Analysis Overview

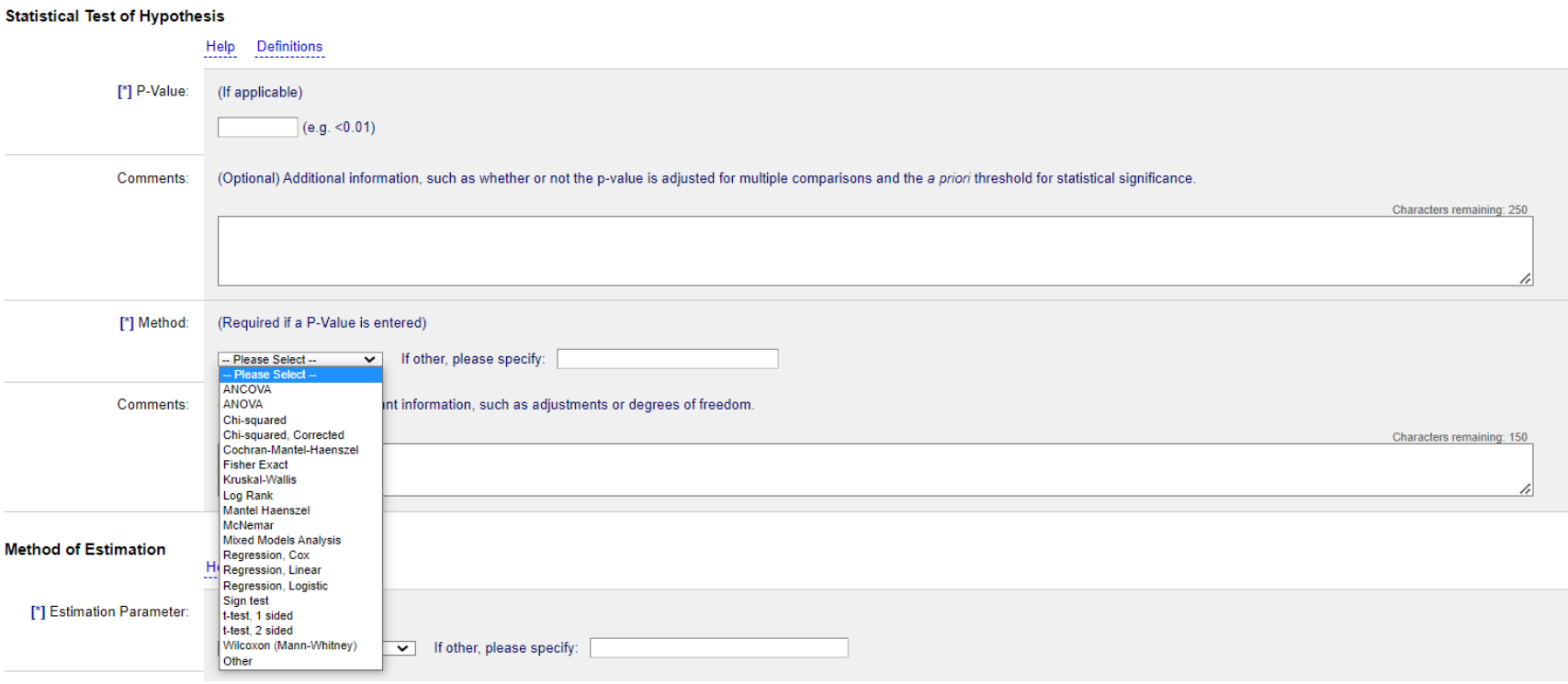
Help Definitions

* Comparison Group Selection: Select the Outcome Measure Arms/Groups involved in the statistical analysis.
☐ Arm 1 ☐ Arm 2

Comments: (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation.
Characters remaining: 500

* Type of Statistical Test: -- Please Select --

[*] Comments: If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required. Also describe any other key parameters and details of the power calculation (if not described elsewhere).
Characters remaining: 500


Statistical Test of Hypothesis
Help
Definitions
[*] P-Value:
(If applicable)
(e.g. <0.01)
Comments:
(Optional) Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.
Characters remaining: 250
[*] Method:
(Required if a P-Value is entered)
-- Please Select --
If other, please specify:
Comments:
nt information, such as adjustments or degrees of freedom.
Characters remaining: 150
-- Please Select --
ANCOVA
ANOVA
Chi-squared
Chi-squared, Corrected
Cochran-Mantel-Haenszel
Fisher Exact
Kruskal-Wallis
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
Method of Estimation
[*] Estimation Parameter:
If other, please specify:

Method of Estimation

Help Definitions

[*] Estimation Parameter: (If applicable)

-- Please Select -- If other, please specify:

[*] Estimated Value: Provide the data for the Estimation Parameter.

Confidence Interval: (If applicable)

% Confidence Interval

Number of sides 2-Sided

Lower Limit:

Upper Limit:

Parameter Dispersion Type and Dispersion Value: (If applicable)

-- Please Select --

Estimation Comments: (Optional) Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk).

Characters remaining: 250

Other Statistical Analysis

Help Definitions

If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of the scientifically appropriate test of statistical significance.

Characters remaining: 999

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)

Results: Add Serious Adverse Event

Help Definitions

* Adverse Event Term:	
* Organ System:	-- Please Select --
Adverse Event Term Additional Description:	Characters remaining: 250
Source Vocabulary Name:	(table default)
* § Collection Approach:	-- Please Select -- (table default)

Save Cancel

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

Existing Serious Adverse Event Terms:

Edit Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events

Help Definitions

* Frequency Threshold for Reporting Other Adverse Events:	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). [ ] %

Save 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)

Results: Add Other (Not Including Serious) Adverse Event

Help Definitions

* Adverse Event Term:	
* Organ System:	-- Please Select --
Adverse Event Term Additional Description:	Characters remaining: 250
Source Vocabulary Name:	(table default)
* § Collection Approach:	-- Please Select -- (table default)

Save Cancel

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

Existing Other Adverse Event Terms:

Edit Limitations and Caveats

Help Definitions

Overall Limitations and Caveats:

Characters remaining: 500

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

Help 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)