

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

PRS TEST SYSTEM

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
[Burden Statement](#)

This is a test version of the Protocol Registration and Results System (PRS). Creating or modifying records in this system will have no effect on the production (operational) PRS or ClinicalTrials.gov.

The data on this system is occasionally replaced entirely with a copy of the latest data from the production system. [Data last copied from production PRS: Feb 4, 2016] If you had an account on the production PRS at that time, the same login information should work on this system.

WARNING: Do not use the PRS Test System to prepare data for the production PRS. This system sometimes runs a software release that is not fully compatible with that of the production system.

If you notice problems or have questions while using this test system, please contact us using the Contact ClinicalTrials.gov PRS link (in the upper right corner, after logging in).

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

Username:

Password:

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results. [Send email to ClinicalTrials.gov PRS Administration](#)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two substantive updates to the results information. 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](#)

Recruitment Details:

Pre-assignment Details:

Arms/Groups (2)

	Experimental Drug	placebo	
* Arm/Group Title:	Experimental Drug	placebo	Total (Not public)
* § Arm/Group Description:	Experimental Drug Description	Placebo Drug Description	
	<input type="button" value="x Delete"/>	<input type="button" value="Move ▶"/>	<input type="button" value="x Delete"/> <input type="button" value="◀ Move"/>
<input type="checkbox"/> Type of Units Assigned:	<input type="button" value="+ Add Units Assigned"/> (Optional) Use only if assigned units other than participants (e.g., eyes, lesions, implants).		

Periods (1) Protocol Enrollment: 200

* Period Title: Overall Study

	Experimental Drug	placebo	
* Started:	100 <input type="button" value="Add Comment"/>	100 <input type="button" value="Add Comment"/>	200
<input type="button" value="+ Add Milestone"/>			
* Completed:	95 <input type="button" value="Add Comment"/>	100 <input type="button" value="Add Comment"/>	195
Not Completed: (Started - Completed)	5	0	
Reason Not Completed			
<input type="checkbox"/> Lost to Follow-up	5 <input type="button" value="Delete"/>	0 <input type="button" value="Delete"/>	5
<input type="button" value="+ Add Reason Not Completed"/>	Not Completed =5 Total from all reasons =5	Not Completed =0 Total from all reasons =0	

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

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: 350

* Arm/Group Title:

Characters remaining: 999

* § Arm/Group Description:

Edit Baseline Arm/Groups

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

* Arm/Group Title:	Experimental Drug	Placebo
* § Arm/Group Description:	Experimental Drug Description Characters remaining: 970	Placebo Drug Description Characters remaining: 975

Edit Baseline Analysis Population

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

* Overall Number of Baseline Participants:	Experimental Drug	Placebo
	100	100

[+ Add Units Anal/250](#) (Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).

Tip: Compare number of baseline participants with numbers in [Participant Flow](#)

[] 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: 350

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

Add Baseline Measure

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

- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)
- [Example](#)

Edit Baseline Measure

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

* Baseline Measure Title: **Race (NIH/OMB)**

Baseline Measure Description: Additional information about the measure (e.g., description of scale)

	Experimental Drug	Placebo	Total
Overall Number of Baseline Participants:	100	100	200
Baseline Analysis Population Description:			

* Measure Type: **Count of Participants**

* Measure of Dispersion: **Not Applicable**

	100 participants <input type="button" value="Edit"/>	100 participants <input type="button" value="Edit"/>	200
Number Analyzed: Participants			
American Indian or Alaska Native	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
Asian	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
Native Hawaiian or Other Pacific Islander	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
Black or African American	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
White	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
More than one race	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%
Unknown or Not Reported	Count of Participants <input type="text"/> NA%	Count of Participants <input type="text"/> NA%	Count of Participants unknown NA%

* Unit of Measure: participants

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

Outcome Measure Data

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

* Outcome Measure Type: **Primary**

* Outcome Measure Title: **Primary Outcome Measure Title 1** Characters remaining: 224

* § Outcome Measure Description: **Primary Outcome Measure Description 1** Characters remaining: 902

* Outcome Measure Time Frame: **Primary Outcome Measure Time Frame 1**

Arms/Groups (2)

	<input type="button" value="Edit"/> Experimental Drug	<input type="button" value="Edit"/> Placebo
* Arm/Group Title:	Experimental Drug	Placebo
* § Arm/Group Description:	Experimental Drug Description	Placebo Drug Description
* Overall Number of Participants Analyzed:	<input type="text" value="100"/>	<input type="text" value="100"/>
<input type="button" value="+ Add Units Analyzed"/>	(Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).	
<input type="checkbox"/> Analysis Population Description:		

Outcome Measure Data Table

* Measure Type: Count of Participants		Hide calculated percentage	Convert Rows to Categories
* Measure of Dispersion/Precision: Not Applicable			
		Experimental Drug	Placebo
* Row Title	Number Analyzed	100 participants Edit	100 participants Edit
Row 1		Count of Participants 50 50%	Count of Participants 20 20%
Delete	Move	Add Category	
* Row Title	Number Analyzed	100 participants Edit	100 participants Edit
Row 2		Count of Participants 50 50%	Count of Participants 80 80%
Delete	Move		
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: Primary Outcome Measure Title 1
Time Frame: Primary Outcome Measure Time Frame 1
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. <input type="checkbox"/> Experimental Drug <input type="checkbox"/> Placebo
Comments:	(Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation. <div style="border: 1px solid gray; height: 40px; width: 100%;"></div> <p style="text-align: right;">Characters remaining: 500</p>
* 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). <div style="border: 1px solid gray; height: 40px; width: 100%;"></div> <p style="text-align: right;">Characters remaining: 500</p>

Statistical Test of Hypothesis

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

<input type="checkbox"/> P-Value:	(If applicable) <input type="text"/> (e.g. <0.01)
Comments:	(Optional) Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the <i>a priori</i> threshold for statistical significance. <div style="text-align: right;">Characters remaining: 250</div> <input type="text"/>
<input type="checkbox"/> Method:	(Required if a P-Value is entered) -- Please Select -- If other, please specify: <input type="text"/>
Comments:	(Optional) Any other relevant information, such as adjustments or degrees of freedom. <div style="text-align: right;">Characters remaining: 150</div> <input type="text"/>

Method of Estimation

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

<input type="checkbox"/> Estimation Parameter:	(If applicable) -- Please Select -- If other, please specify: <input type="text"/>
<input type="checkbox"/> Estimated Value:	Provide the data for the Estimation Parameter. <input type="text"/>
Confidence Interval:	(If applicable) ⓘ <input type="text"/> % Confidence Interval Number of sides: 2-Sided Lower Limit: <input type="text"/> Upper Limit: <input type="text"/>
Parameter Dispersion Type and Dispersion Value:	(If applicable) -- Please Select -- <input type="text"/>
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). <div style="text-align: right;">Characters remaining: 250</div> <input type="text"/>

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. <div style="text-align: right;">Characters remaining: 999</div> <input type="text"/>
--	---

* 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 Additional Description.
 -- Please Select --

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

Edit Adverse Event Arms/Groups

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

* Arm/Group Title: Experimental Drug Placebo

* § Arm/Group Description: Experimental Drug Description Placebo Drug Description
 Characters remaining: 970 Characters remaining: 975

Total for Serious Adverse Events:	0 Affected Participants out of 0 At Risk	0 Affected Participants out of 0 At Risk
Total for Other (Not Including Serious) Adverse Events:	0 Affected Participants out of 0 At Risk	0 Affected Participants out of 0 At Risk

* 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	Experimental Drug	Placebo
* § Total Number Affected:	<input type="text"/> participants	<input type="text"/> participants
* § Total Number At Risk:	<input type="text"/> participants	<input type="text"/> participants

* 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)	Experimental Drug	Placebo
* Total Number Affected:	<input type="text" value="0"/> participants	<input type="text" value="0"/> participants
* Total Number At Risk:	<input type="text" value="0"/> participants	<input type="text" value="0"/> 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](#)

* 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:

Adverse Event Term Additional Description:
Characters remaining: 250

Source Vocabulary Name:

* § Collection Approach: (table default)

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

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

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

* Frequency Threshold for Reporting Other Adverse Events:
 %

* 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)	Experimental Drug	Placebo
* Total Number Affected:	<input type="text"/> participants	<input type="text"/> participants
* Total Number At Risk:	<input type="text"/> participants	<input type="text"/> 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](#)

* 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:

Adverse Event Term Additional Description:
Characters remaining: 250

Source Vocabulary Name:

* § Collection Approach: (table default)

* 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

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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

[] Conditionally required (see Definitions)

Edit Results Point of Contact

Definitions

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

Save

Cancel

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