

Attachment 5 – Results Information Submission Data Entry Forms

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

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

Username:

Password: [Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS account.

See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.

[Send email to ClinicalTrials.gov PRS Administration.](#)

OMB NO: 0925-0586
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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:

Pre-assignment Details:

Arms/Groups (2)

| | | | |
|--|--|---------------------------------------|---|
| <input type="button" value="Edit"/> | <input type="button" value="Edit"/> | <input type="button" value="Edit"/> | <input type="button" value="Total (Not public)"/> |
| * Arm/Group Title: | Arm 1 | Arm 2 | Total (Not public) |
| * § Arm/Group Description: | | | |
| <input type="button" value="Delete"/> | <input type="button" value="Move"/> | <input type="button" value="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:

| | | | |
|---|--|--|--------------------|
| * Period Title: | Overall Study | | |
| | Arm 1 | Arm 2 | Total (Not public) |
| * Started: | <input type="text"/> | <input type="text"/> | unknown |
| <input type="button" value="Add Comment"/> | <input type="button" value="Add Comment"/> | <input type="button" value="Add Comment"/> | |
| <input type="button" value="+ Add Milestone"/> | | | |
| * Completed: | <input type="text"/> | <input type="text"/> | unknown |
| <input type="button" value="Add Comment"/> | <input type="button" value="Add Comment"/> | <input type="button" value="Add Comment"/> | |
| Not Completed: (Started - Completed) | unknown | unknown | |
| Reason Not Completed | | | |
| <input type="button" value="+ Add Reason Not Completed"/> | | | |

* 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/Group Description: Characters remaining: 1500

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 -- | <input type="text"/> | <input type="text"/> | unknown |
| <ul style="list-style-type: none"> -- Select Reason Type -- Adverse Event Death Lack of Efficacy Lost to Follow-up Physician Decision Pregnancy Protocol Violation Withdrawal by Subject Other | Not Completed =unknown Total from all reasons =unknown | Not Completed =unknown Total from all reasons =unknown | |

Save Validate Cancel

* Required
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 [*] Conditionally required (see Definitions)

Add Baseline Measures

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

* Baseline Measure Title:

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

* 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: | <input type="text"/> | <input type="text"/> | <input type="text" value="24"/> |
| <input type="checkbox"/> Overall Number of Units Analyzed: | <input type="text"/> | <input type="text"/> | calculated |
| <input type="checkbox"/> Type of Units Analyzed: | <input type="text"/> | | |

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

- * 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: 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:

* Measure of Dispersion:

| | Arm 1 | Arm 2 | Total |
|-------------------------------|--|--|---------------------------|
| Number Analyzed: Participants | --- participants <input type="button" value="Edit"/> | --- participants <input type="button" value="Edit"/> | unknown |
| | Select Measure Type above | Select Measure Type above | Select Measure Type above |

+ Add Row

* Unit of Measure:

Commonly reported units:

* 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

Arm/Group:

Overall Number of Baseline Participants:

Number Participants Analyzed:

Outcome Measure Data

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

Information is required

| | | |
|----------------------------------|---------|---------------------------|
| * Outcome Measure Type: | Primary | Characters remaining: 255 |
| * Outcome Measure Title: | | Characters remaining: 999 |
| [*] Outcome Measure Description: | | Characters remaining: 255 |
| * Outcome Measure Time Frame: | | |

Arms/Groups (2) [+ Add Arm/Group](#)

| | | |
|--|--|-------|
| * Arm/Group Title: | Arm 1 | Arm 2 |
| * § Arm/Group Description: | | |
| * 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: | | |

Outcome Measure Data Table

| | | |
|------------------------------------|---|---------------------------|
| * Measure Type: | -- Select Measure Type -- | |
| * Measure of Dispersion/Precision: | Arm 1 | Arm 2 |
| * Unit of Measure: | Select Measure Type above | Select Measure Type above |
| | 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

* Measure Type: Count of Participants Hide calculated percentage Convert Categories to Rows

* Measure of Dispersion/Precision: Not Applicable

| | | Arm 1 | Arm 2 |
|---|---|---|---|
| * Row Title Characters remaining: 100 | Number Analyzed --- participants Edit | --- participants Edit | --- participants Edit |
| * Category Title Characters remaining: 100 | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% |
| * Category Title Characters remaining: 100 | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% |
| + Add Category | | | |
| * Row Title Characters remaining: 100 | Number Analyzed --- participants Edit | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% |
| | | Count of Participants <input type="text"/> NA% | Count of Participants <input type="text"/> NA% |
| + Add Row | | | |
| * Unit of Measure: participants | | | |

Save Validate Cancel

* Required
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 [] 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. <input type="checkbox"/> Arm 1 <input type="checkbox"/> Arm 2 |
| Comments: | (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation. <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <div style="text-align: right; font-size: small;">Characters remaining: 500</div> |
| * 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 #ccc; height: 40px; margin-top: 5px;"></div> <div style="text-align: right; font-size: small;">Characters remaining: 500</div> |

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 --

- 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

If other, please specify:

Comments: Additional information, such as adjustments or degrees of freedom.

Characters remaining: 150

Method of Estimation

[*] Estimation Parameter:

If other, please specify:

Method of Estimation

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

| | |
|---|--|
| [*] Estimation Parameter: | (If applicable) <input type="text" value="-- Please Select --"/> If other, please specify: <input type="text"/> |
| [*] Estimated Value: | Provide the data for the Estimation Parameter. <input type="text"/> |
| Confidence Interval: | (If applicable) <input type="text"/> % Confidence Interval Number of sides <input type="text" value="2-Sided"/> Lower Limit: <input type="text"/> Upper Limit: <input type="text"/> |
| Parameter Dispersion Type and Dispersion Value: | (If applicable) <input type="text" value="-- Please Select --"/> <input type="text"/> |
| Estimation Comments: | (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). <input type="text"/> <small>Characters remaining: 250</small> |

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. <input type="text"/> <small>Characters remaining: 999</small> |
|---|

* 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.

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: | <input type="text"/> participants | <input type="text"/> participants |
| * § Total Number At Risk: | <input type="text"/> participants | <input type="text"/> 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: | <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](#)

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: | <input type="text"/> |
| * Organ System: | -- Please Select -- |
| Adverse Event Term Additional Description: | <div style="border: 1px solid gray; height: 60px; width: 100%;"></div> Characters remaining: 250 |
| Source Vocabulary Name: | <input type="text"/> (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: | <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](#)

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: | <input type="text"/> |
| * Organ System: | -- Please Select -- |
| Adverse Event Term Additional Description: | <div style="border: 1px solid gray; height: 60px; width: 100%;"></div> Characters remaining: 250 |
| Source Vocabulary Name: | <input type="text"/> (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](#)

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