ClinicalTrials.gov PRS
Protocol Registration and Results System

Help: Results Module > All

Help: Results Modules - All

Results Participant Flow

▼ Overview

- Participant Flow shows how participants were assigned to intervention(s) and how they progressed through the study. It is a tabular version of a CONSORT flow diagram

- The table columns (Arm/Groups) describe participants' experiences as they progressed through the study.

- The table rows (Milestones) describe the number of participants starting and completing the study in addition to any other significant events.

- Additional tables (Periods) can be used to describe separate stages of the study.

- Units of assignment other than participants (e.g., eyes, lesions, implants) can also be described.

- Example Participant Flow table.
  ▶ show

Resources:

Data you will need:	Participant Flow Data Preparation Checklist (PDF)
1-page data organization tools:	Participant Flow Template (PDF)
Video tutorial:	

Results: Participant Flow Module (17:32)

Review criteria: Results Review Criteria (PDF)

Data Elements

▸ Recruitment & Pre-assignment

▸ Arm/Group

▸ Type and Number of Units Assigned (if other than Participants)

▸ Period

▸ Milestones

▸ Reason Not Completed

Study Design Examples

▸ Parallel

▸ Cross-over

▸ Dose Escalation

▸ Factorial

▸ Multiple Period

▸ Units Other than Participants

Results Baseline Characteristics

▾ Overview

- Baseline Characteristics is a table of demographic and baseline data, similar to Table 1 in a journal article.

- The table columns (Arms/Groups) represent the groups of participants assessed at baseline with an additional column for the entire study population (Total).

- Arm/Group Titles are used as the column headers.

- Arm/Group Descriptions describe participants included in the column and any interventions they received.

- The table rows represent each Baseline Measure and the summary data for participants within each Arm/Group.

  - Age and Sex/Gender must be reported.

  - Race and Ethnicity and any other measure(s) assessed at baseline and used in the analysis of the primary outcome measure(s) must be reported for studies with a Primary Completion Date on or after January 18, 2017.

  - Provide all other baseline measures used to characterize the participant population.

    For example: prior treatment history, disease history/severity, concomitant conditions, measures used to assess outcomes.

  - Customize baseline measures by including additional rows (for any type of data) or categories (for mutually exclusive/non-overlapping and exhaustive categories).

- If units other than participants (e.g., eyes, lesions, implants) were assigned to Arms/Groups, Type and Number of Units Analyzed can be specified overall and for each baseline measure.

Example Baseline Characteristics table.

▶ <u>show</u>

Resources:

Data you will need: <u>Baseline Measure Data Preparation Checklist</u> (PDF)

- <u>Age - Baseline Template</u> (PDF)

1-page data organization tools:	• Gender - Baseline Template (PDF) • Race, Ethnicity, Region - Baseline Template (PDF) • Study Specific Measure - Baseline Template (PDF)
Video tutorial:	Results: Baseline Characteristics Module (12:25)
Review criteria:	Results Review Criteria (PDF)

Study Design Examples

▶ Parallel

▶ Cross-over

▶ Dose Escalation

▶ Factorial

▶ Multiple Period

▶ Units Other than Participants

Results Outcome Measures and Statistical Analysis

Overview

▼ Outcome Measure

- The Outcome Measures module summarizes results data for all measures assessed.

  ○ For Applicable Clinical Trials, all pre-specified primary and secondary outcomes are required.

- Each Outcome Measure presents summary data using a structured tabular format and includes the following:

- ◦ A Title and Description sufficient to allow a reader to understand the reported data, including any relevant elaborations, definitions, and/or criteria

- ◦ A Time Frame specifying when the measurement was assessed for each participant

- ◦ A description of the analysis population evaluated

- ◦ Number of Participants Analyzed, and the option to specify a Type and Number of Units Analyzed other than participants (e.g., eyes, lesions, implants)

- ◦ Description of any rows (for any type of data) or categories (for mutually exclusive and exhaustive categories) used in the data table

- ◦ Summary data for each Arm/Group

- ◦ The Unit of Measure associated with the numerical data (e.g., mg/dL, participants, percentage of participants)

▸ Statistical Analysis

Example Outcome Measure table with Statistical Analysis

▸ **show**

▾ Resources

Data you will need:	Outcome Measure And Statistical Analysis Data Preparation Checklists (PDF)
1-page data organization tools:	• Outcome Measure Template (PDF) • Completed Outcome Measure Example Templates (PDF)

Video tutorial: Results: Outcome Measures and
Statistical Analyses Module (13:03)
Review criteria: Results Review Criteria (PDF)

Study Design Examples

▶ Parallel: Scale and Change from Baseline

▶ Parallel: Response Rate

▶ Cross-over: Change from Baseline

▶ Dose Escalation: Pharmacokinetics - Cmax

▶ Factorial: Kaplan-Meier Cumulative Probability

▶ Multiple Period: Composite Outcome

▶ Multiple Period: Scale and Change from Baseline

▶ Units Other than Participants

Results Adverse Events

▼ Overview

- The Adverse Events Module consists of three tables of summary adverse event data for each group:

  ◦ All-cause Mortality - all deaths, due to any cause, that occurred during the study (required if Primary Completion Date is on or after January 18, 2017)

  ◦ Serious Adverse Events - all serious adverse events that were collected during the study, whether or not they were anticipated or considered to be attributed or associated with the intervention

  ◦ Other (Not Including Serious) Adverse Events - non-serious adverse events that were collected during the study, whether or

not they were anticipated, and that occurred above a specified frequency threshold (0-5%) in any Arm/Group

> Frequency Threshold Example: If the frequency threshold is specified as 5%, then any non-serious adverse event that occurred in more than 5% of participants in any of the arms must be reported

- The table columns (Arms/Groups) represent the groups of participants for which adverse events are reported. The columns are shared between the adverse event tables.

- The table rows represent summary adverse event data for the participants within each Arm/Group:

  - The top row summarizes the total number of participants assessed for and affected by adverse events listed in the table.

  - Additional rows are used in the Serious Adverse Events and Other (Not Including Serious) Adverse Events tables to represent each Adverse Event Term, its System Organ Class, and the number of participants with the event.

- Data for Serious and Other (Not Including Serious) Adverse Events may be reported using direct data entry in the PRS or by using a properly formatted spreadsheet and the Download/Upload feature (see link at top of Adverse Events Overview screen).

Adverse Events Tables Example

▶ <u>show</u>

Resources:

Data you will need: Adverse Event Data Preparation Checklist (PDF)

1-page data organization tools:	• Serious Adverse Events Template (PDF) • Other (Not Including Serious) Adverse Events Template (PDF)
Video tutorial:	Results: Adverse Events Module (12:30)
Review criteria:	Results Review Criteria (PDF)

Study Design Examples

▸ Parallel

▸ Cross-over

▸ Dose Escalation

▸ Factorial

▸ Multiple Period

Spreadsheet Download and Upload

▸ Feature Overview

▸ Download Tips

▸ Data Entry Tips

▸ Upload Tips