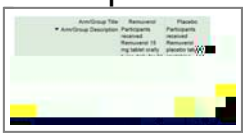
Help: Results Modules - All

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.

▶ 

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 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.

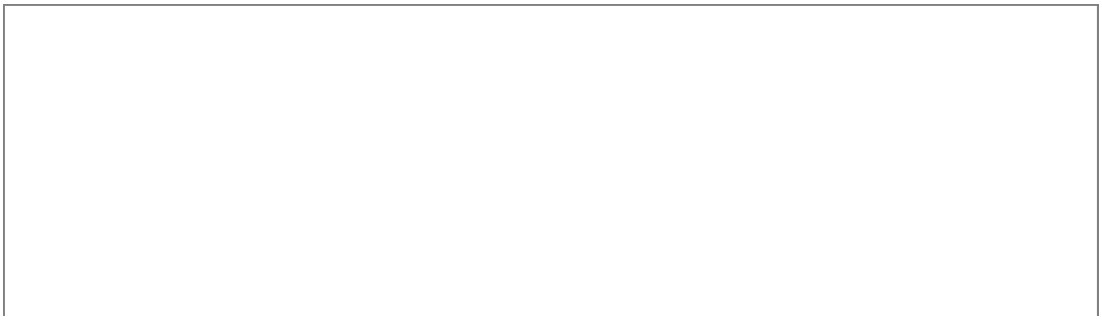
Resources:

Data you will need: Baseline Measure Data Preparation

1-page data organization tools:

- Gender - Baseline Template (PDF)
- Race, Ethnicity, Region - Baseline

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



Video tutorial: Results: Outcome Measures and Statistical Analyses Module (13:03)

Review criteria: Results Review Criteria

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 Othevent tables.