Participant Flow Data Preparation Checklist

Overview: The Participant Flow module is a tabular summary of participants' progress through each stage of a study by assignment group. Use this checklist with the Participant Flow Template and Results Data Element Definitions to complete this module of the results section.

Select	Information to have available for Participant Flow	Data Element
☐	• Conceptual overview of the study design, including the type (e.g., single group, cross-over, parallel) and any distinct stages (e.g., double-blind then open-label) ◦ Tip: Have a CONSORT flow diagram available.	
☐	• Description of any significant study events that occurred after participants were enrolled, but before they were assigned to a study group (e.g., run-in phase or washout)	[*]Pre-assignment Details
☐	• Number of groups that accurately describes the study design from participant assignment to completion ◦ Tip: The number of groups is typically equal to the number of unique paths (participant experiences) in a CONSORT flow diagram, from beginning to end. Each group will be reported as a table column.	*Arm/Group Information
☐	• For each group: ◦ Title—Descriptive label for the group ▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column. ◦ Description—Detailed explanation of the interventions administered or the groups observed during each stage of the study ▪ Tip: Include details about the intervention (e.g., dosage, dosage form, frequency and duration of administration) or observation.	*Arm/Group Title *§Arm/Group Description
☐	• Number of discrete stages or intervals of activity in the study	*Period(s)
☐	• Descriptive title for each period (the default for one Period is "Overall Study") ◦ Tip: A Period Title should describe what happened during that period of the study. For example, "Double-blind (0 to 24 weeks)" and "Open-label (24 to 48 weeks)" are more descriptive than "Period 1" and "Period 2."	*Period Title
☐	• Number of participants that Started and Completed each period: ◦ Started—Participants initiating each period (e.g., the number of participants assigned or randomized to each group for that period) ▪ Tip: If the number of participants starting the first period is different from the total enrolled in the study, explain why in Pre-assignment Details. ◦ Completed—Participants still in the study at the end of the period ◦ Tip: If the unit of assignment is a unit other than participants, specify the name of the unit (e.g., eyes, lesions, implants) and provide the number of units. ◦ Tip: Each unit of assignment (participants or units other than participants) should only be represented in one group. For example, if the unit of assignment is participants, do not count a participant more than once by including them in more than one group. ◦ Tip: Use the Additional Milestone field to record any specific events or time points in the study between the Started and Completed milestones.	*Started *Completed [*]Type of Units Assigned Additional Milestone

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

Select	Information to have available for Participant Flow	Data Element
☐	• Number of participants for each period and group that did not complete and the reasons they did not complete	Not Completed Reason Not Completed

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