

Participant Flow Data Preparation Checklist

Overview: A tabular summary of the participants' progression through each stage of a study by group. Use this checklist with the [Participant Flow Template](#)^Δ and [Results Data Element Definitions](#).

	Information to have available for Participant Flow	Term
<input type="checkbox"/>	<ul style="list-style-type: none"> 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) <u>Tip:</u> Have a CONSORT flow diagram available 	Background
<input type="checkbox"/>	<ul style="list-style-type: none"> A description of any study events that occurred before participants were assigned to a study group (e.g., run-in phase, number of screen failures) 	^Δ Pre-assignment Details
<input type="checkbox"/>	<ul style="list-style-type: none"> Number of groups that accurately describes the study design from participant assignment to completion. Each group will be reported as a table column. <u>Tip:</u> The number of groups is typically equal to the number of unique paths (participant experiences) in a CONSORT flow diagram, from beginning to end. 	Arms/Groups
<input type="checkbox"/>	<ul style="list-style-type: none"> For each group, a detailed explanation of the participants and/or interventions <ul style="list-style-type: none"> Title—A descriptive label for the group (header for the table column). Use informative labels (e.g., “Placebo”), not generic labels (e.g., “Group 1”). Description—A detailed explanation of the interventions administered or the groups observed during each stage of the study. Include details about the intervention and the frequency and time period of administration or observation. 	* ^Δ Arm/Group Title ^Δ Arm/Group Description
<input type="checkbox"/>	<ul style="list-style-type: none"> Number of distinct stages or intervals of activity in the study 	Periods
<input type="checkbox"/>	<ul style="list-style-type: none"> If there is more than one stage (Period), each Period will need a unique Title (the default for one Period is “Overall Study”). <ul style="list-style-type: none"> A Period Title should be a descriptive label. For example, “Double-blind (0 to 24 weeks)” and “Open-label (24 to 48 weeks)” are more descriptive than “Period 1” and “Period 2.” 	* ^Δ Period Title
<input type="checkbox"/>	<ul style="list-style-type: none"> For each Period, the number of participants in each group that: <ul style="list-style-type: none"> Started—Generally, the participants assigned (or randomized) to each group <ul style="list-style-type: none"> Additional Milestone (optional)—Any important event(s) during study Completed—As defined for the study <u>Tip:</u> If the number of participants starting the first Period is different from the total enrolled in the study, explain why in Pre-assignment Details 	* ^Δ Started * ^Δ Completed
<input type="checkbox"/>	<ul style="list-style-type: none"> For each Period, the number of participants in each group that dropped out and the reasons they dropped out 	^Δ Reason(s) Not Completed

*Required
^ΔTemplate Field