

Outcome Measure Template

Outcome Measure Type*	(Circle One) Primary	Secondary	Other Pre-specified	Post-Hoc	Safety Issue?	(Circle One) Yes	No
Outcome Measure Title*							
Outcome Measure Description							
Outcome Measure Time Frame*							
Arm/Group Title*	*	*	*	*	*	*	*
Arm/Group Description ①							
Number of Participants Analyzed*	*	*	*	*	*	*	*
Analysis Population Description							
	Measure Type*	Dispersion/Precision Type *	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type	
	(Circle One) Number Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) ② Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error 95% Confidence Interval 90% Confidence Interval Geometric Coefficient of Variation					
Unit of Measure *	*						
Category Title④	[*]	*	③ *	*	③ *	*	③ *
Category Title④	[*]	[*]	③ [*]	[*]	③ [*]	[*]	③ [*]

*** Required by ClinicalTrials.gov**

[*] Conditionally required by ClinicalTrials.gov

① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".

③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.

④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.