

Outcome Measure Template

* Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	
[*] Outcome Measure Description	
* Outcome Measure Time Frame	

* Arm/Group Title				
*§ Arm/Group Description ①				
* Overall Number of Participants Analyzed ②				
[*] Analysis Population Description				
* Measure Type	* Measure of Dispersion/Precision			
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation			
[*] Row/Category Title ⑤			③ ④	③ ④
[*] Row/Category Title ⑤			③ ④	③ ④
* Unit of Measure				

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

- ① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
- ② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
- ③ If Measure Type is a “count,” percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
- ④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
- ⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.