

Baseline Characteristics Template *Sex/Gender** (use at least one) **ClinicalTrials.gov**

* Arm/Group Title								Total
*§ Arm/Group Description ①								
* Overall Number of Baseline Participants ②								③
[*] Baseline Analysis Population Description								
Sex: Female, Male								
Female								③
Male								③
* Unit of Measure	Participants							
Sex/Gender, Customized								
* Measure Type	* Measure of Dispersion							
(Select One) Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	(Select One) Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range							
[*] Row/Category Title ⑥			④ ⑤		④ ⑤		④ ⑤	③ ④ ⑤
[*] Row/Category Title ⑥			④ ⑤		④ ⑤		④ ⑤	③ ④ ⑤
[*] Row/Category Title ⑥			④ ⑤		④ ⑤		④ ⑤	③ ④ ⑤
* 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 Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.

④ If Measure Type is a “count,” percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).

⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.

⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.