

**Baseline Characteristics Template**      **Study-Specific Measure\*§**      **ClinicalTrials.gov**

<b>* Arm/Group Title</b>								<b>Total</b>	
<b>*§ Arm/Group Description ①</b>									
<b>* Overall Number of Baseline Participants ②</b>									<b>③</b>
<b>[*] Baseline Analysis Population Description</b>									
<b>[*] Study-Specific Baseline Measure Title</b>									
<b>Baseline Measure Description</b>									
<b>* Measure Type</b>	<b>* Measure of Dispersion</b>								
<b>(Select One)</b> Count of Participants ④ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ④	<b>(Select One)</b> Not Applicable ⑤ Standard Deviation Inter-Quartile Range Full Range								
<b>[*] Row/Category Title ⑥</b>			④ ⑤		④ ⑤		④ ⑤	③	④ ⑤
<b>[*] Row/Category Title ⑥</b>			④ ⑤		④ ⑤		④ ⑤	③	④ ⑤
<b>* Unit of Measure</b>									

**\* 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. Row/Category Titles are only required if more than one row.