

Baseline Characteristics Template *Age **

Arm/Group Title *	*	*	*	*	*	*
Arm/Group Description ①						
Overall Number of Baseline Participants *	*	*	*	*	*	*
Age, Categorical ②	Number of Participants		Number of Participants		Number of Participants	
Unit of Measure Participants						
<=18 years	[*]	[*]	[*]	[*]	[*]	[*]
Between 18 and 65 years	[*]	[*]	[*]	[*]	[*]	[*]
>=65 years	[*]	[*]	[*]	[*]	[*]	[*]
Age, Continuous ②	Measure Type [*]	Dispersion/ Precision Type [*]	Measure Type	Dispersion/ Precision Type	Measure Type	Dispersion/ Precision Type
	(Circle One) Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) Standard Deviation Inter-quartile Range Full Range				
Unit of Measure	[*]	③[*]	[*]	③[*]	[*]	③[*]
Age, Customized ②	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) Not Applicable④ Standard Deviation Inter-quartile Range Full Range				
Unit of Measure	[*]	③[*]	[*]	③[*]	[*]	③[*]
Category Title ⑤	[*]	③[*]	[*]	③[*]	[*]	③[*]
Category Title ⑤	[*]	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 At least one Age Baseline Measure (Categorical, Continuous, or Customized) is required by ClinicalTrials.gov

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 "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number".

⑤ [Optional] Add as many Categories as needed. When more than one Category is entered, Category Title and Baseline Measure Data are required for each row.