Baseline Characteristics Template *Race, Ethnicity, Region*

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Arm/Group Title *	*	*	*
Arm/Group Description ①			
Overall Number of Baseline Participants*	*	*	*
Race (NIH/OMB) ②	**Number of Participants**	**Number of Participants**	**Number of Participants**
Unit of Measure Participants			
American Indian or Alaska Native	[*]	[*]	[*]
Asian	[*]	[*]	[*]
Native Hawaiian or Pacific Islander	[*]	[*]	[*]
Black or African American	[*]	[*]	[*]
White	[*]	[*]	[*]
More then one race	[*]	[*]	[*]
Unknown or Not Reported	[*]	[*]	[*]
Ethnicity (NIH/OMB) ②	**Number of Participants**	**Number of Participants**	**Number of Participants**
Unit of Measure Participants			
Hispanic or Latino	[*]	[*]	[*]
Not Hispanic or Latino	[*]	[*]	[*]
Unknown or Not Reported	[*]	[*]	[*]
Region of Enrollment	**Number of Participants**	**Number of Participants**	**Number of Participants**
Unit of Measure Participants			
United States	[*]	[*]	[*]
Region/Country Name ③	[*] [*]	[*]	[*]
Region/Country Name ③	[*] [*]	[*]	[*]
Region/Country Name 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 If not using the NIH/OMB standard categories, you may create customized categories by using "Race, Customized" and/or "Ethnicity, Customized".
③ [Optional] Region of Enrollment Baseline Measure is optional. At least one Region/Country is required when reporting Region of Enrollment. Also, add as many Regions/Countries as needed. Region/Country Name and Baseline Measure Data are required for each reported Region of Enrollment row.