Guidance for Reporting Valid Analysis as Required by the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research (NOT-OD-25-131)

For NIH-funded research meeting the definitions of an applicable clinical trial and an NIH-defined Phase III Clinical trial, NIH requires the reporting of valid analysis results in ClinicalTrials.gov. The valid analyses, or stratified results reporting, should be done *for each primary outcome measure* by sex, and race and/or ethnicity. For additional information, please see the guide notice for the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research policy, NOT-OD-25-131.

Plans for conducting valid analyses by sex and race and/or ethnicity should be indicated at the time of submission of registration information to ClinicalTrials.gov. Outcomes related to valid analyses should be created for each primary outcome and can be added or edited in the Protocol Section of the registration form within the ClinicalTrials.gov Protocol Registration and Results System (PRS). Valid analyses may be submitted as primary outcome measures, secondary outcome measures, or other pre-specified outcome measures. For example, if a previously determined secondary outcome is to investigate differences in main effects by sex, this secondary outcome may already meet the criteria for valid analysis by sex and may be entered as a secondary outcome. If the previously determined outcome measures do not include stratified results for the primary outcome(s), it may be best to enter outcomes for the required analyses as other pre-specified outcome measures. The sponsor or investigator must choose the appropriate type of outcome measure based on the study's protocol.

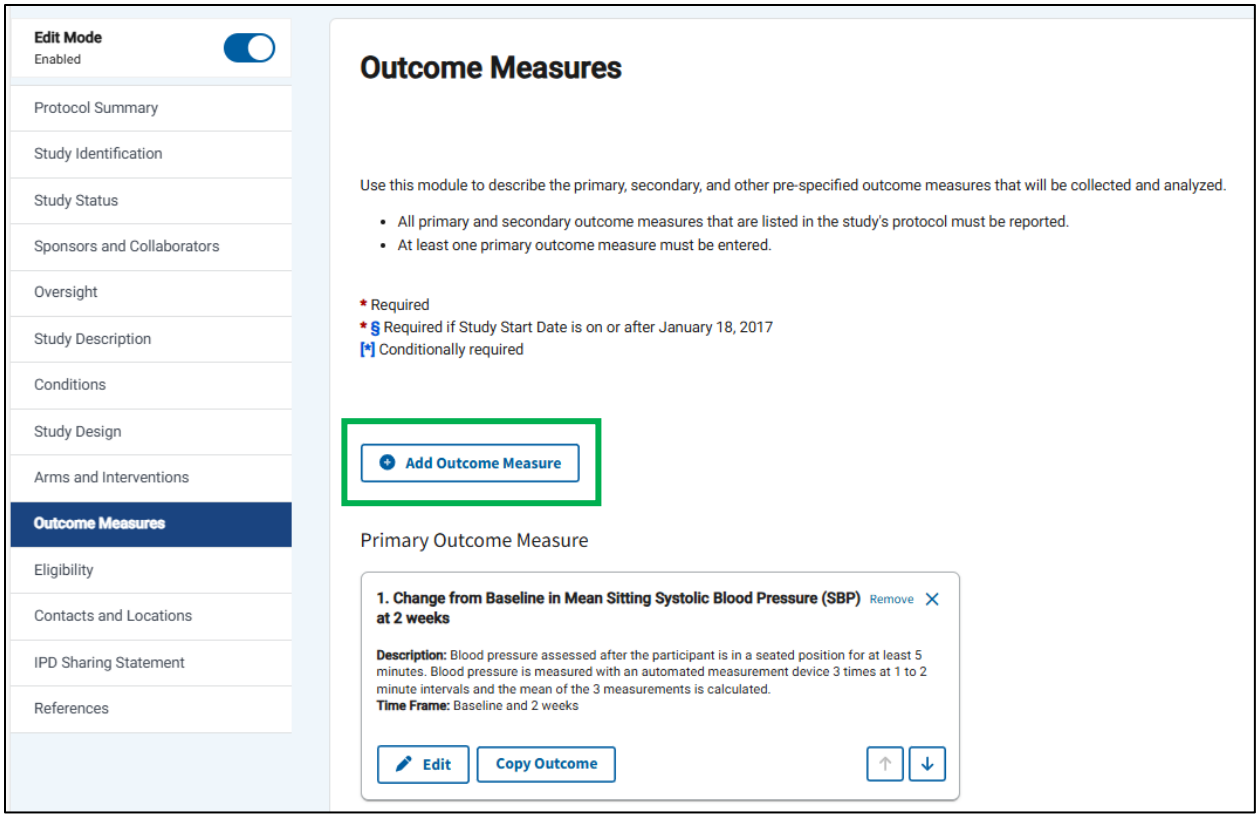
To aid in identifying the required analyses, "NIH-required analysis" should be added to the description of the valid analysis-specific outcome measures.

Examples of How to Report an Analysis by Sex and Race and/or Ethnicity*

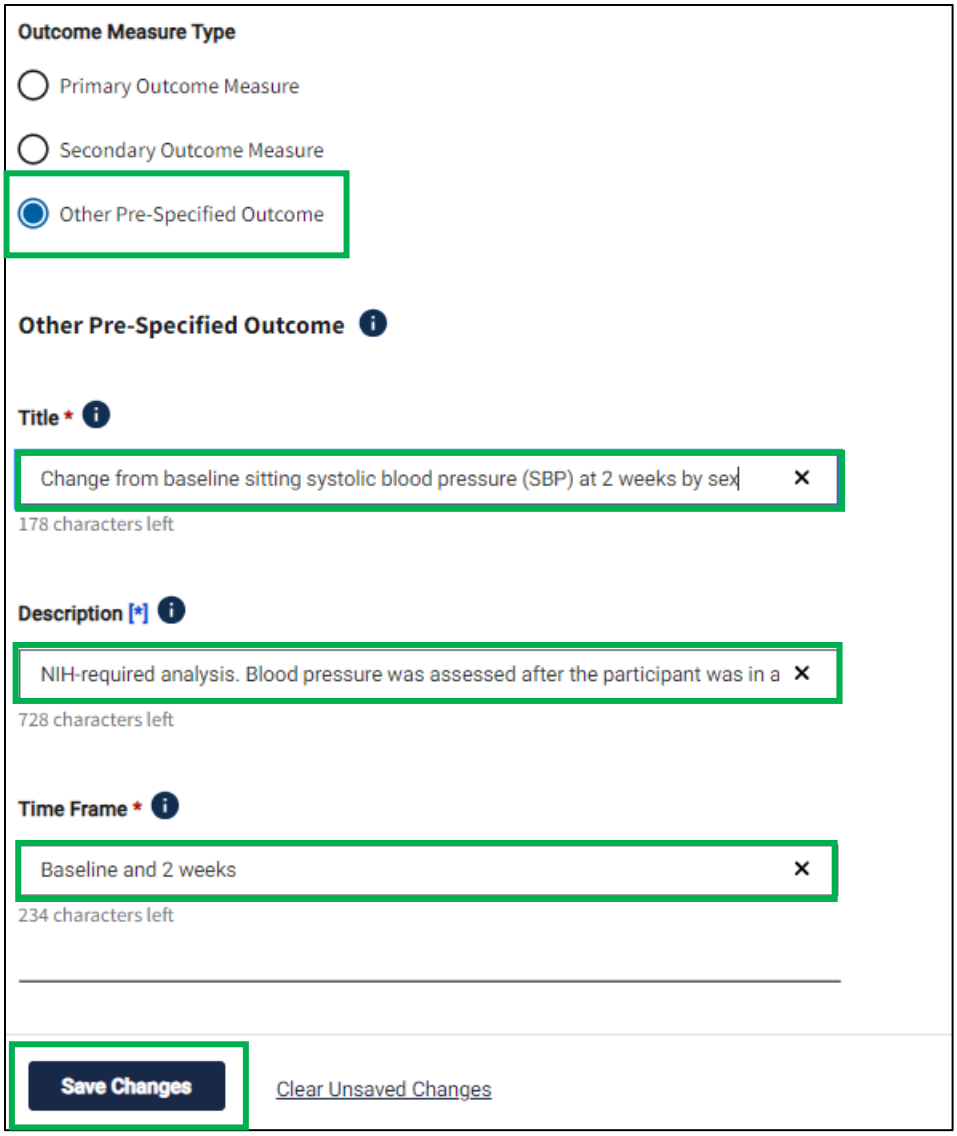
*Note: The examples below describe PRS use as of July 24, 2025. For the most current PRS help resources, visit "PRS Help Resources" under the "Submit Studies" menu on ClinicalTrials.gov.

PRS Protocol Section: Outcome Measures

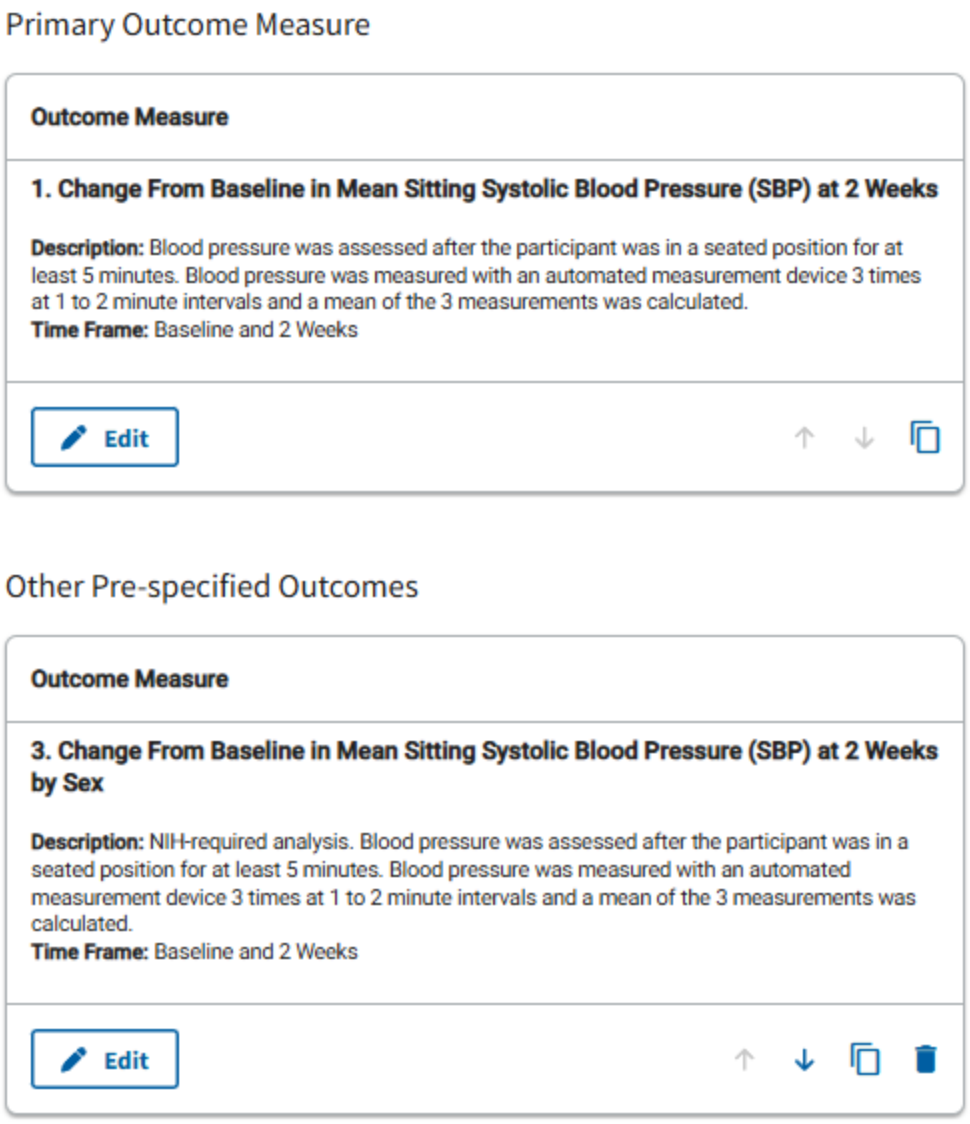
At the point of registration, the Outcome Measures module is used to create or edit outcome measures. It is in this module that outcome measures should be included to describe valid analyses by sex and race and/or ethnicity. As an example, "Other Pre-specified Outcomes" can be added to describe valid analyses for each primary outcome. Select the "Add Outcome Measure" button to create these additional outcome measures.



Select "Other Pre-Specified Outcome" as the Outcome Measure Type and enter the title, description, and time frame in the accompanying text boxes.



After saving changes, the steps above can be repeated to include additional other pre-specified outcome measures. The other pre-specified outcome measures will be displayed in the Outcome Measures module as shown below.



PRS Results Section: Baseline Characteristics

When submitting results for the study, the Baseline Characteristics module is used to provide data that are consistent with the stratified populations used for the valid analyses. Baseline measure information must be provided to describe the age, sex, and race and/or ethnicity of the study participants. Baseline data for the primary outcome measures must be reported and baseline data for any other outcome measures can be presented here as well. In the figure below, which demonstrates how the Baseline Characteristics module is represented on the ClinicalTrials.gov website, preformatted baseline measures provide age, sex, ethnicity, and race data per arm and overall for study participants, and a study specific measure provides the baseline data for the primary outcome measure. Customizable baseline measures are also available for reporting demographic information.

Baseline Characteristics

Arm/Group Title	Hypertena	Placebo	Total
Arm/Group Description	Participants received one 20 mg Hypertena tablet in a fasting state each morning for 4 weeks.	Participants received one Placebo tablet (matching 20 mg Hypertena) in a fasting state each morning for 4 weeks.	Total of all reporting groups
Overall Number of Baseline Participants	101	99	200
Baseline Analysis Population Description	[Not Specified]		

Age, Continuous			
Measure Type: Mean (Standard Deviation) | Unit of measure: years			
Number Analyzed	101 participants	99 participants	200 participants
	34.78 (9.72)	35.34 (10.71)	34.98 (9.89)

Sex: Female, Male			
Measure Type: Count of Participants | Unit of measure: Participants			
Number Analyzed	101 participants	99 participants	200 participants
Female	41 40.6%	36 36.4%	77 38.5%
Male	60 59.4%	63 63.6%	123 61.5%

Ethnicity (NIH/OMB)			
Measure Type: Count of Participants | Unit of measure: Participants			
Number Analyzed	101 participants	99 participants	200 participants
Hispanic or Latino	18 17.8%	17 17.2%	35 17.5%
Not Hispanic or Latino	83 82.2%	82 82.8%	165 82.5%
Unknown or Not Reported	0 0%	0 0%	0 0%

Race (NIH/OMB)			
Measure Type: Count of Participants | Unit of measure: Participants			
Number Analyzed	101 participants	99 participants	200 participants
American Indian or Alaska Native	0 0%	0 0%	0 0%
Asian	6 5.9%	5 5.1%	11 5.5%
Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
Black or African American	13 12.9%	12 12.1%	25 12.5%
White	82 81.2%	82 82.8%	164 82.0%
More than one race	0 0%	0 0%	0 0%
Unknown or Not Reported	0 0%	0 0%	0 0%

Sitting Systolic Blood Pressure (SBP)			
Measure Type: Mean (Standard Deviation) | Unit of measure: mmHg			
Number Analyzed	101 participants	99 participants	200 participants
	148.3 (12.0)	146.4 (8.1)	147.3 (10.3)

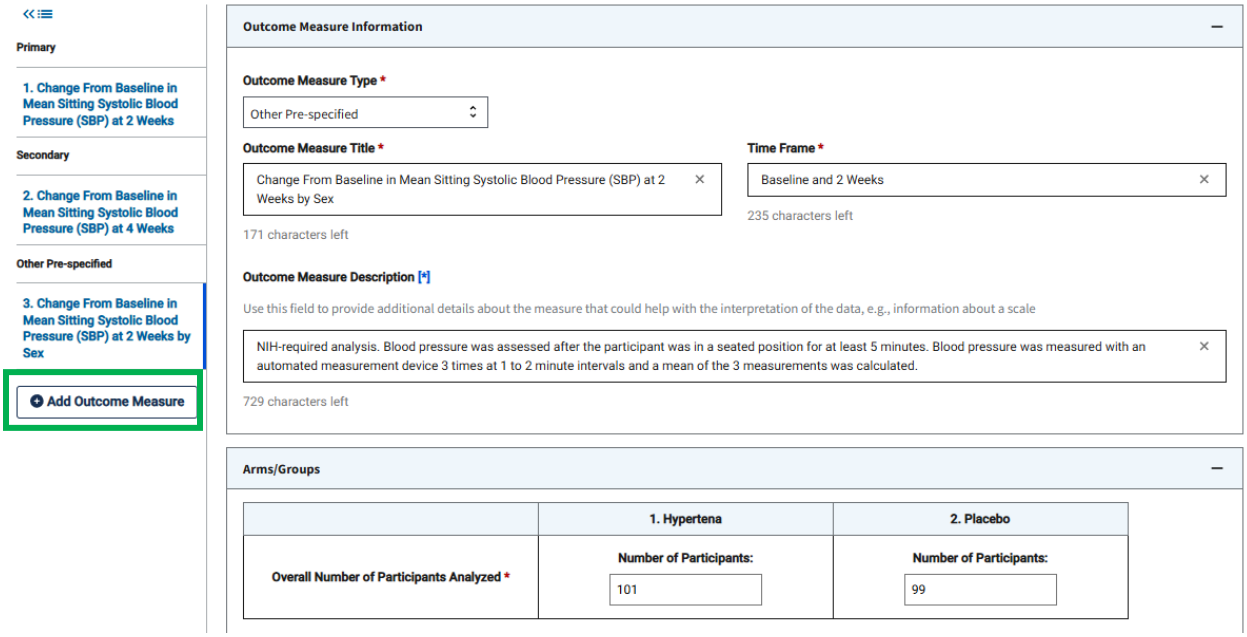
PRS Results Section: Outcome Measures

The Outcome Measures and Statistical Analyses module of the Results Section carries over the information added at the time of registration and provides data tables for report of the results of analyses. Use this module to include the results information for the pre-specified primary outcome measure. The figure below demonstrates how a primary outcome measure is represented on the ClinicalTrials.gov website.

Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks –		
Type: Primary | Time Frame: Baseline and 2 Weeks		
Description	Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.	
Time Frame	Baseline and 2 Weeks	
Analysis Population Description	[Not specified]	
Arm/Group Title	Hypertena	Placebo
Arm/Group Description	Participants received one 20 mg Hypertena tablet in a fasting state each morning for 4 weeks.	Participants received one Placebo tablet (matching 20 mg Hypertena) in a fasting state each morning for 4 weeks.
Overall Number of Participants Analyzed	101	99
Mean (Standard Deviation) | Unit of measure: mmHg	-13.9 (1.7)	-7.2 (1.9)

If the NIH-required analyses were included as primary, secondary, or other pre-specified outcomes, navigate to the appropriate outcome measures to provide the relevant data.

If the NIH-required analyses by sex and race and/or ethnicity were not specified as outcome measures at the time of registration, add additional outcome measures (primary, secondary, other pre-specified, or post hoc) to report the additional analyses. This can be done by clicking on the “Add Outcome Measure” button at the bottom of the list of outcome measures.



When entering outcome measure data for stratified populations in the PRS:

1. Use the “Add Row” button beneath the Outcome Measure data table to add data for subgroups. If a “Count of Participants” is used as the Measure Type and mutually exclusive, exhaustive categorical data will be presented, the “Add Category” button will also be available beneath the Outcome Measure data table and can be used to add categorical data for each subgroup.
2. Use the Analysis Population Description to explain why the numbers analyzed per row differ from the overall numbers analyzed (e.g., sub-group analysis).

Arms/Groups −

	1. Hypertena	2. Placebo
Overall Number of Participants Analyzed *	**Number of Participants:** 101	**Number of Participants:** 99

Units Analyzed +

Analysis Population Description [*]

Use this field to explain any difference between the numbers here and the numbers of participants or units assigned to the arms or groups in the Participant Flow. If multiple rows are used in the data table, explain any difference between the analysis population in any row and the overall analysis population.

Data were stratified by sex

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Outcome Measure Data Table −

Measure Settings

Measure Type * Mean

Measure of Dispersion/Precision * Standard Deviation

Unit of Measure * mmHg

36 characters left

	1. Hypertena	2. Placebo
Number of Participants Analyzed	**Number of Participants**	**Number of Participants**
	Mean **Standard Deviation**	**Mean** **Standard Deviation**

Add Row

The completed data tables should resemble the following examples:

Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks by Sex – Type: Other Pre-specified | Time Frame: Baseline and 2 Weeks		
Description	NIH-required analysis. Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.	
Time Frame	Baseline and 2 Weeks	
Analysis Population Description	Data were stratified by sex	
Arm/Group Title	Hypertena	Placebo
Arm/Group Description	Participants received one 20 mg Hypertena tablet in a fasting state each morning for 4 weeks.	Participants received one Placebo tablet (matching 20 mg Hypertena) in a fasting state each morning for 4 weeks.
Overall Number of Participants Analyzed	101	99
Male		
Number Analyzed	60	63
Mean (Standard Deviation) | Unit of measure: mmHg	-13.9 (1.6)	-7.0 (2.1)
Female		
Number Analyzed	41	36
Mean (Standard Deviation) | Unit of measure: mmHg	-13.8 (1.8)	-7.7 (1.6)

Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks by Race – Type: Other Pre-specified | Time Frame: Baseline and 2 Weeks		
Description	NIH-required analysis. Blood pressure was assessed after the participant was in a seated position for at least 5 minutes. Blood pressure was measured with an automated measurement device 3 times at 1 to 2 minute intervals and a mean of the 3 measurements was calculated.	
Time Frame	Baseline and 2 Weeks	
Analysis Population Description	Data were stratified by race	
Arm/Group Title	Hypertena	Placebo
Arm/Group Description	Participants received one 20 mg Hypertena tablet in a fasting state each morning for 4 weeks.	Participants received one Placebo tablet (matching 20 mg Hypertena) in a fasting state each morning for 4 weeks.
Overall Number of Participants Analyzed	101	99
White		
Number Analyzed	82	82
Mean (Standard Deviation) | Unit of measure: mmHg	-13.9 (1.7)	-7.3 (2.0)
Black or African American		
Number Analyzed	13	12
Mean (Standard Deviation) | Unit of measure: mmHg	-13.1 (1.7)	-6.4 (1.7)
Asian		
Number Analyzed	6	5
Mean (Standard Deviation) | Unit of measure: mmHg	-14.8 (0.8)	-7.4 (1.1)

For questions regarding the NIH valid analysis policy, please contact inclusion@od.nih.gov. For questions regarding ClinicalTrials.gov PRS functionality, please contact register@clinicaltrials.gov.