Guidance for reporting valid analysis as required by the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (NOT-OD-18-014)

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/gender, and race and/or ethnicity. For additional information, please see the guide notice for the Inclusion of Women and Minorities policy, NOT-OD-18-014.

Plans for conducting valid analyses by sex/gender 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/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 or gender, this secondary outcome may already meet the criteria for valid analysis by sex/gender 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.

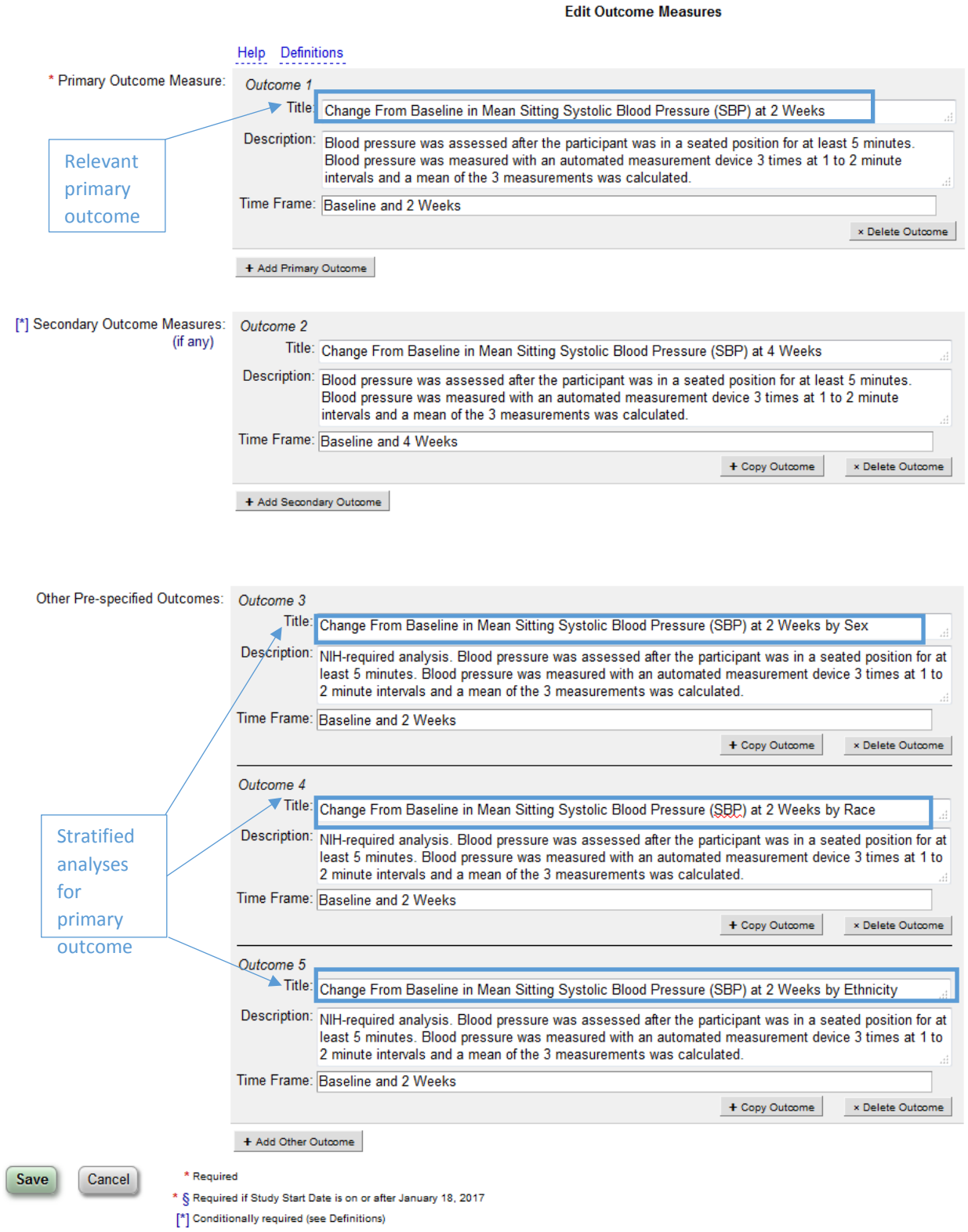
To aid in identifying the required analyses, "NIH-required analysis" should be added to the description of the valid analysis-specific outcomes measures.

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

*Note: The examples below describe system use as of May 4, 2018. For the most current instructions, please visit the resources available on ClinicalTrials.gov.

As an example, for each primary outcome, additional "other pre-specified outcome measures" are added to describe each valid analysis by sex or gender, and race and/or ethnicity.

PRS Protcol Section: Edit Outcome Measures screen



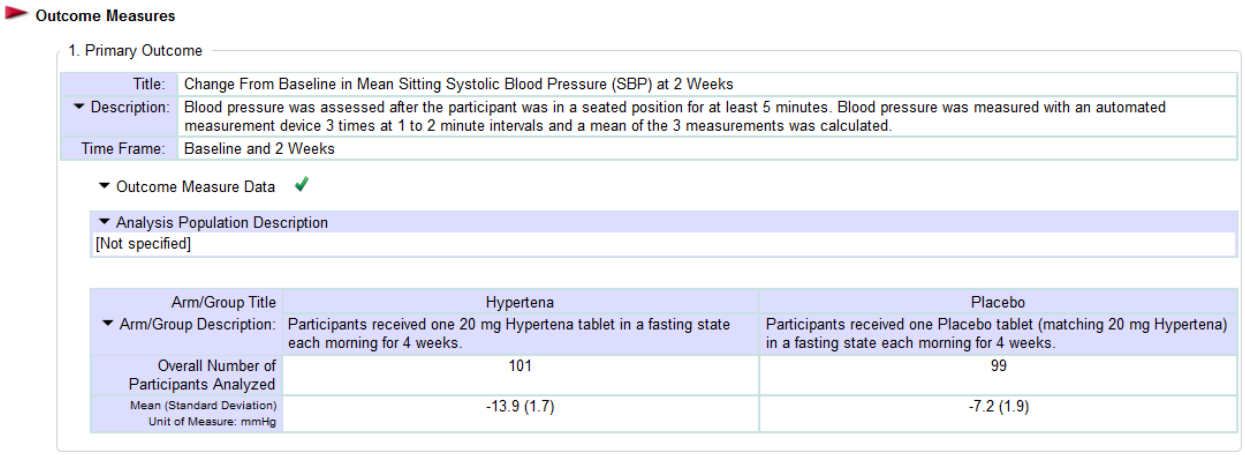
PRS Results Section: Baseline Characteristics

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/gender, and race/ethnicity (if collected) 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.

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.			
Overall Number of Baseline Participants		101		99		200	
▼ Baseline Analysis Population Description [Not specified]							
Age, Continuous 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	40.59%	36	36.36%	77	38.5%
	Male	60	59.41%	63	63.64%	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	17.82%	17	17.17%	35	17.5%
	Not Hispanic or Latino	83	82.18%	82	82.83%	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	5.94%	5	5.05%	11	5.5%
	Native Hawaiian or Other Pacific Islander	0	0%	0	0%	0	0%
	Black or African American	13	12.87%	12	12.12%	25	12.5%
	White	82	81.19%	82	82.83%	164	82%
	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) 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)	

Include the results information for the pre-specified primary outcome measure.



Outcome Measures

1. Primary Outcome

Title:	Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 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

Outcome Measure Data ✓

Analysis Population Description

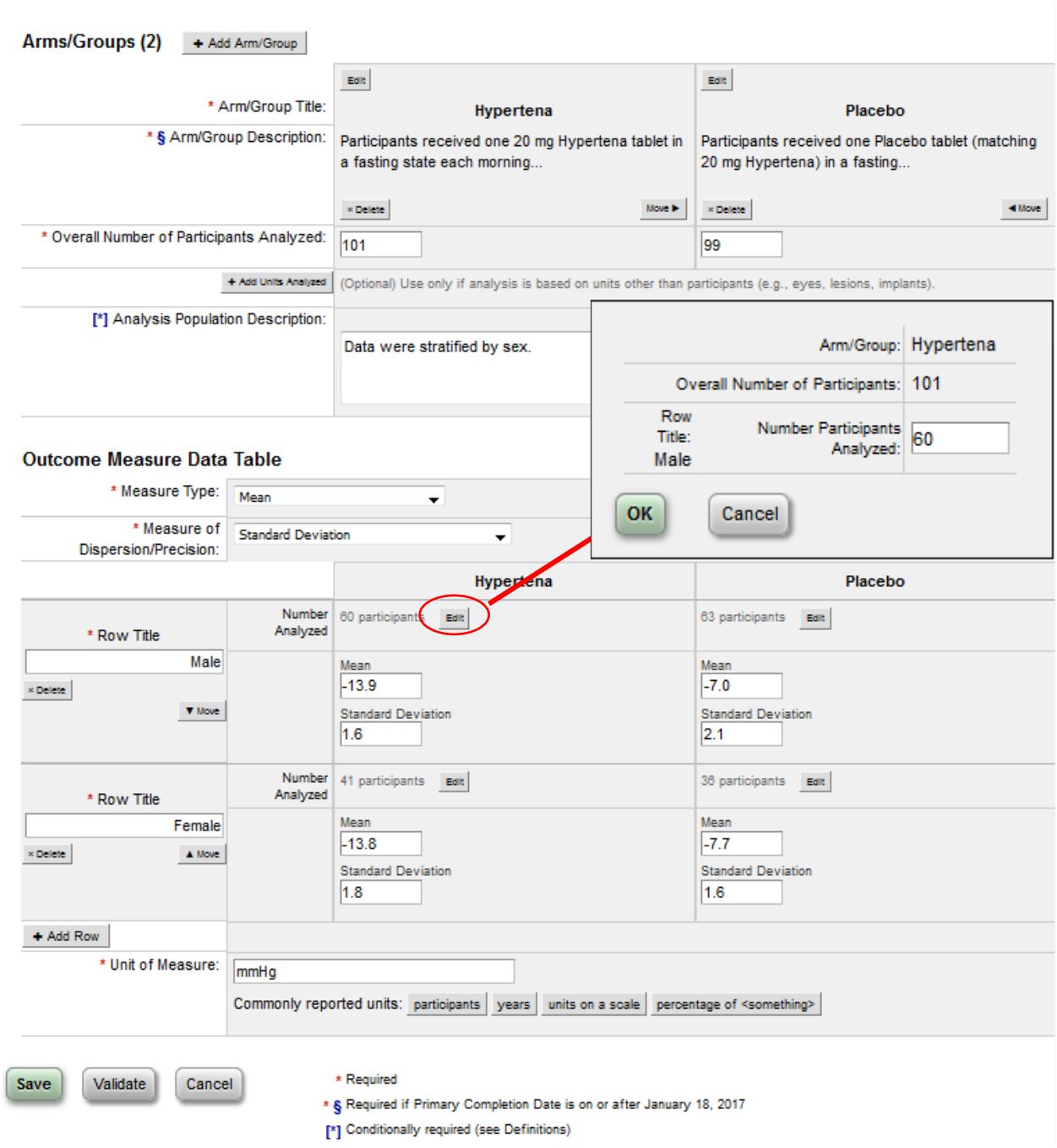
[Not specified]

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 by sex/gender and race/ethnicity were not pre-specified as part of the primary outcome measure, add additional outcome measures (secondary, other pre-specified, or post hoc) to report the additional analysis.

When entering data for stratified populations on the Outcome Measure Data page in the PRS:

1. Select the appropriate Measure Type and Measure of Dispersion/Precision. Once selected, the "Add Row" button will be available and can be used to add data for subgroups. If a Count of Participants is used as Measure Type and mutually exclusive, exhaustive categorical data will be presented, then the "Add Category" button will appear and can be used to add data for subgroups.
2. Use the Edit buttons in the Number Analyzed row to specify, in the pop up window, the subgroups contributing data to each row. Use the Analysis Population Description to explain why the numbers analyzed per row differ from the overall number analyzed (e.g., sub-group analysis).


Arms/Groups (2)
+ Add Arm/Group
* Arm/Group Title:
Hypertena
Placebo
* § Arm/Group Description:
Participants received one 20 mg Hypertena tablet in a fasting state each morning...
Participants received one Placebo tablet (matching 20 mg Hypertena) in a fasting...
* Overall Number of Participants Analyzed:
101
99
+ Add Units Analyzed
(Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).
[*] Analysis Population Description:
Data were stratified by sex.
Arm/Group: Hypertena
Overall Number of Participants: 101
Row Title: Male
Number Participants Analyzed: 60
OK
Cancel
Outcome Measure Data Table
* Measure Type: Mean
* Measure of Dispersion/Precision: Standard Deviation
Hypertena
Placebo
* Row Title
Male
Number Analyzed
60 participants
63 participants
Mean
-13.9
-7.0
Standard Deviation
1.6
2.1
* Row Title
Female
Number Analyzed
41 participants
36 participants
Mean
-13.8
-7.7
Standard Deviation
1.8
1.6
+ Add Row
* Unit of Measure:
mmHg
Commonly reported units: participants years units on a scale percentage of <something>
Save
Validate
Cancel
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

The completed data tables should resemble the following examples:

3. Other Pre-specified Outcome

Title:	Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks by Sex
▼ 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

▼ Outcome Measure Data ✓

▼ 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
		Mean (Standard Deviation) Unit of Measure: mmHg		
Row Title				
Male	Number Analyzed		60 participants	63 participants
			-13.9 (1.6)	-7.0 (2.1)
Female	Number Analyzed		41 participants	36 participants
			-13.8 (1.8)	-7.7 (1.6)

4. Other Pre-specified Outcome

Title:	Change From Baseline in Mean Sitting Systolic Blood Pressure (SBP) at 2 Weeks by Race
▼ 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

▼ Outcome Measure Data ✓

▼ 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
		Mean (Standard Deviation) Unit of Measure: mmHg		
Row Title				
White	Number Analyzed		82 participants	82 participants
			-13.9 (1.7)	-7.3 (2.0)
Black or African American	Number Analyzed		13 participants	12 participants
			-13.1 (1.7)	-6.4 (1.7)
Asian	Number Analyzed		6 participants	5 participants
			-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 functionality, please contact Register@clinicaltrials.gov.