

# 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 Protocol Section: Edit Outcome Measures screen

**Edit Outcome Measures**

[Help](#) [Definitions](#)

\* Primary Outcome Measure:

**Relevant primary outcome**

**Outcome 1**

Title:

Description:

Time Frame:

[\*] Secondary Outcome Measures: (if any)

**Outcome 2**

Title:

Description:

Time Frame:

Other Pre-specified Outcomes:

**Outcome 3**

Title:

Description:

Time Frame:

**Outcome 4**

Title:

Description:

Time Frame:

**Outcome 5**

Title:

Description:

Time Frame:

\* Required

\* § Required if Study Start Date is on or after January 18, 2017

[\*] Conditionally required (see Definitions)

## 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 ▼ Arm/Group Description		Hypertena	Placebo	Total
		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.	
<b>Overall Number of Baseline Participants</b>		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

	Hypertena	Placebo
* Arm/Group Title:		
* § 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.	

## Outcome Measure Data Table

	Hypertena	Placebo
* Measure Type:	Mean	
* Measure of Dispersion/Precision:	Standard Deviation	
* 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	38 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](mailto:inclusion@od.nih.gov). For questions regarding ClinicalTrials.gov functionality, please contact [Register@clinicaltrials.gov](mailto:Register@clinicaltrials.gov).