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Baseline Characteristics Module

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Outline

- Overview of Baseline Characteristics module
- Required data elements
- ClinicalTrials.gov review criteria
- Examples

2

Purpose

The Baseline Characteristics module is designed to summarize important attributes of the participants enrolled at the start of the study.

3

FDAAA* Provision

"A table of the demographic and baseline data collected overall and for each arm of the clinical trial…"

[Sec. 282(j)(3)(C)(i)]

*Food and Drug Administration Amendments Act of 2007

4

Description of Baseline Characteristics Module

- Table of demographic and baseline data for the entire trial population and for each arm or comparison group
- Accommodates different data types:
  - **Continuous**: measure of central tendency (e.g., mean) and measure of dispersion (e.g., standard deviation)
  - **Categorical**: for each category - (1) a count or (2) measure of central tendency and measure of dispersion

5

"Table 1" Journal Article Format

Table 1. Baseline characteristics of the modified intention-to-treat population in a phase II randomized trial of amphotericin B alone or combined with fluconazole in the treatment of human immunodeficiency virus (HIV)–associated cryptococcal meningitis.

Variable	AmB ($n = 46$)	AmB+Fluc400 ($n = 48$)	AmB+Fluc800 ($n = 41$)
Country			
Thailand	32 (69.6)	34 (70.8)	31 (75.6)
United States	14 (30.4)	14 (29.2)	10 (24.4)
Age, mean years $\pm$ SD	36.5 $\pm$ 8.52	36.4 $\pm$ 8.69	35.8 $\pm$ 9.36
Sex			
Male	30 (65.2)	31 (64.6)	26 (63.4)
Female	16 (34.8)	17 (35.4)	15 (36.6)
Race			
Asian/Thai	32 (69.6)	34 (70.8)	31 (75.6)
Black	8 (17.4)	10 (20.8)	3 (7.3)
White	4 (8.7)	4 (8.3)	6 (14.6)
Other	2 (4.4)	0	1 (2.4)
CD4 T cell count, median cells/mm[3] (range)	18 (1–123)	17 (0–80)	15 (0–94)
Viral load, median copies/mL (range)	272,000 (400–1,342,580)	369,000 (50–1,000,000)	169,000 (216–1,000,000)
Opening pressure			
>250 mm CSF	22 (47.8)	26 (54.2)	22 (53.7)
≤250 mm CSF	20 (43.5)	19 (39.6)	17 (41.5)
Not done	4 (8.7)	3 (6.3)	2 (4.9)
CSF cryptococcal antigen titer, median (range)	2048 (4–32768)	1024 (4–71024)	1024 (4–16384)
MMSE, mean score $\pm$ SD	25.5 $\pm$ 5.21	25.3 $\pm$ 5.07	23.4 $\pm$ 7.25
Received prestudy fluconazole and/or flucytosine[a]			
Yes	6 (13.0)	4 (8.3)	2 (4.9)
No	40 (87.0)	44 (91.7)	39 (95.1)
Receipt of antiretroviral therapy			
Yes	5 (10.9)	3 (6.2)	3 (7.3)
No	41 (89.1)	45 (93.8)	38 (92.7)

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Pappas PG, Chetchotisakd P, Larsen RA et al. Clin Infect Dis. 2009

6

ClinicalTrials.gov Format

Baseline Measures

	AmphoB Standard	AmphoB+Fluc400	AmphoB+Fluc800	Total
Number of Participants	45	47	49	141
Age, Categorical **[units: participants]**				
<= 18 years	0	0	1	1
Between 18 and 65 years	45	47	47	139
>=65 years	0	0	1	1
Age, Continuous **[units: years]** **Mean ± Standard Deviation**	37.1 ± 8.47	36.5 ± 8.21	35.9 ± 9.44	36.5 ± 8.69
Gender **[units: participants]**				
Female	16	15	18	49
Male	29	32	31	92
Region of Enrollment **[units: participants]**				
United States	14	14	14	42
Thailand	31	33	35	99

NCT00145249

7

Data Elements

General

- Arm/Group*
  - Title
  - Description
- Overall # of Baseline Participants* (per Arm/Group)

For each Baseline Measure:

- Baseline Measure Title*
- Baseline Measure Description
- Measure Type*
- Measure of Dispersion*
- Unit of Measure*
- Data* (per Arm/Group and Total)

*Required by ClinicalTrials.gov

8

Default Tables Provided

- Age* (Continuous; Categorical; or Customized)
- Gender* (Female, Male; or Customized)
- Race (NIH/OMB; or Customized)
- Ethnicity (NIH/OMB; or Customized)
- Region of Enrollment

*Required by ClinicalTrials.gov   9
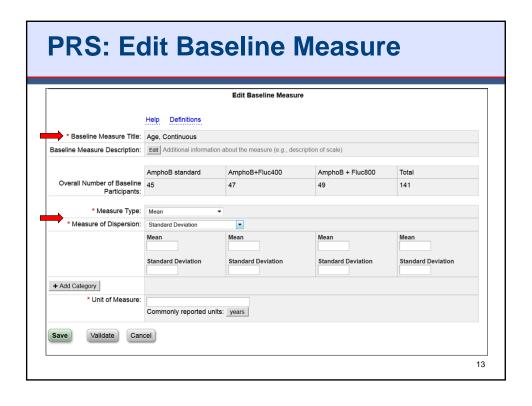
Basic Information Needed

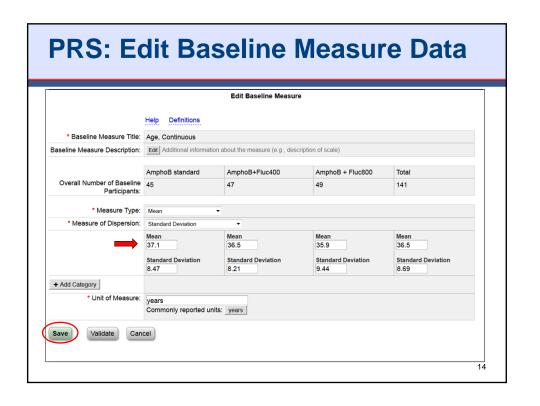|	Arm Title*	Arm Title*	Total
	Arm Description	Arm Description	
Overall Number of Baseline Participants*	# participants	# participants	*[calculated]*
Baseline Measure Title*			
Baseline Measure Description			
Units of Measure*			
Measure Type* (select one)			
Number			
Mean			
Median			
Least Squares Mean			
Geometric Mean			
Log Mean			
Measure of Dispersion* (select one)			
Not Applicable (when Measure Type = Number)			
Standard Deviation			
Interquartile Range (25th, 75th)			
Full Range (low value, high value)			

10

Best Practices

- Minimum requirements
  - Age and Gender
- Region of Enrollment
- Other relevant demographic characteristics
- Clinical measures relevant to study, such as
  - Clinical characteristics, including baseline values of outcome measures
  - Prior and concurrent treatment characteristics

11

PRS: Edit Baseline Participants

12

PRS: Edit Baseline Measure

PRS: Edit Baseline Measure Data

General Review Criteria

- Abbreviations are expanded first time used
- No spelling errors exist
- Arms/Groups
  - Informative Titles ("Arm," "Period," "Milestone")
  - Arm/Group Descriptions are descriptive; contain information about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated
- Information is consistent with other sections of record (or discrepancies explained)
- No written results or conclusions

15

Specific Review Criteria

- Overall Number of Baseline Participants is consistent with the Number STARTED in the Participant Flow module
  - If not consistent, explanatory comments are provided in Baseline Analysis Population Description
- Unit of Measure is consistent with Baseline Measure Title
  - E.g., Baseline Measure Title of "Age" should have Unit of Measure of "Years, Months, etc."
- Data appear valid

16

PRS Review

Arm/Group Title	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800	Total
▸ Arm/Group Description	Amphotericin B 0.7 mg/kg for 14 day...	Amphotericin B 0.7 mg/kg and the ra...	Amphotericin B 0.7 mg/kg and the ra...	
Overall Number of Baseline Participants	45	47	49	**141**
▸ Baseline Analysis Population Description				
Age, Categorical units: participants Measure Type: Number				
<=18 years	0	0	1	1
Between 18 and 65 years	45	47	47	139
>=65 years	0	0	1	1

17

Example – Error

Baseline Measures

	Drug X
Number of Participants	10
Age, Categorical [units: participants]	
<= 18 years	0
Between 18 and 65 years	2
>=65 years	8
Age, Continuous [units: years] Mean ± Standard Deviation	12.5 ± 7.55
Gender [units: participants]	
Female	49
Male	92

Comments:
The Mean Age ("12.5 years") is inconsistent with the data provided for Age, Categorical (0 participants were <=18 years and 8 of 10 participants were 65 years of age or older). Please review and revise as appropriate.

18

Example – Error

	Double-blind Placebo Patch	Double-blind Drug X Patch	Total
Age, Continuous [units: participants] **Mean ± Standard Deviation**	61.2 ± 11.36	59.4 ± 9.56	60.3 ± 10.45

Comments:
Baseline Measure Title (Age, Continuous) and Units of Measure ("participants") are inconsistent. It appears that the units should be "years" instead of "participants". Please review and revise as appropriate.

19

Specific Review Criteria (cont'd)

- Categorical data
  - Categories do not overlap and all possible categories are presented
  - If "Number" is the Measure Type and "participants" are Unit of Measure, the total number of participants in each Arm/Group matches Overall Number of Baseline Participants
    - If not matching, explanatory comments are provided
  - Unit of Measure is specified in the Category Title (e.g., "years" for categories of age)

20

Specific Review Criteria (cont'd)

- Continuous measures (e.g., mean, median)
  - Total column is completed; zeros may not be entered unless the actual value of the measure is zero
- For measures obtained using a scale:
  - Name of scale is provided in Baseline Measure Title
  - Range and direction of scores (0 = worst; 10 = best) are indicated in Baseline Measure Description
  - Unit of Measure is "units on a scale," if no other unit
- Preferred formatting for Unit of Measure of study participants is "participants" (e.g., instead of "number of participants")

21

Example – Error

Baseline Measures

	Drug X
GOG Performance Status [units: participants]	
0	48
1	27
2	4

22

Example – Corrected

Baseline Measures

	Drug X
Gynecological Oncology Group (GOG) Performance Status [1] [units: participants]	
0 – Fully Active	48
1 – Restricted Strenuous Activity, Ambulatory	27
2 – Ambulatory, Difficulty Walking	4
3 – Limited Self-Care, Partly Confined to Bed	0
4 – Completely Disabled, No Self-Care	0

[1] 5-point, ordinal scale specifying patient's ability to perform activities from 0 (fully active) to 4 (completely disabled, no self-care)

23

Additional Information

General ClinicalTrials.gov information:
http://clinicaltrials.gov

FDAAA-related information (see Submit Studies):
http://clinicaltrials.gov/manage-recs/fdaaa

Office of Extramural Research:
http://grants.nih.gov/Clinicaltrials_fdaaa/

Questions?
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