ClinicalTrials.gov
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# Baseline Characteristics Module

**Results Database Train-the-Trainer Workshop**
**September 2015**

http://ClinicalTrials.gov

## FDAAA 801 - Baseline Measures

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

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

FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

2

# Results: Baseline Characteristics

## Publication ("Table 1")

**Table 1.** Baseline demographic and disease characteristics of the patients*

| Characteristic | Placebo (n = 88) | Rituximab (n = 169) |
|---|---|---|
| Female sex | 93.2 | 89.9 |
| Age, mean ± SD years | 40.5 ± 12.8 | 40.2 ± 11.4 |
| Race, % | | |
| White | 55.7 | 56.2 |
| African American | 27.3 | 23.7 |
| Hispanic | 9.1 | 14.2 |
| Asian/Pacific Islander | 5.7 | 3.6 |
| Other | 2.2 | 1.1 |
| Disease duration, mean ± SD years | 8.7 ± 7.6 | 8.5 ± 7.2 |
| Long-term prednisone therapy† | 53.4 | 58.6 |
| Assigned prednisone dosage at screening, mg/kg/day | | |
| 0.5 | 61.4 | 62.7 |
| 0.75 | 29.5 | 32.0 |
| 1.0 | 9.1 | 5.3 |
| Background immunosuppressive drug | | |
| Azathioprine | 36.4 | 32.0 |
| Methotrexate | 27.3 | 27.8 |
| Mycophenolate mofetil | 36.4 | 39.6 |

## ClinicalTrials.gov

**Baseline Measures**

| | Placebo + Prednisone | Rituximab + Prednisone | Total |
|---|---|---|---|
| **Number of Participants** | 88 | 169 | 257 |
| **Age [units: years] Mean ± Standard Deviation** | 40.5 ± 12.8 | 40.2 ± 11.4 | 40.3 ± 11.9 |
| **Gender [units: participants]** | | | |
| **Female** | 82 | 152 | 234 |
| **Male** | 6 | 17 | 23 |
| **Race [units: participants]** | | | |
| **White** | 49 | 95 | 144 |
| **African American** | 24 | 40 | 64 |
| **Hispanic** | 8 | 24 | 32 |
| **Asian/Pacific Islander** | 5 | 6 | 11 |
| **Other** | 2 | 2 | 4 |
| **Disease duration [units: years] Mean ± Standard Deviation** | 8.7 ± 7.6 | 8.5 ± 7.2 | 8.6 ± 7.3 |

3

Adapted from Merrill JT et al. *Arthrit Rheum* 2010 and NCT00137969

# ClinicalTrials.gov Format

| | Placebo + Prednisone | Rituximab + Prednisone | Total |
|---|---|---|---|
| **Number of Participants** | 88 | 169 | 257 |
| **Age [units: years] Mean (Standard Deviation)** | 40.5 (12.8) | 40.2 (11.4) | 40.3 (11.9) |
| **Gender [units: participants]** | | | |
| **Female** | 82 | 152 | 234 |
| **Male** | 6 | 17 | 23 |
| **Race [units: participants]** | | | |
| **White** | 49 | 95 | 144 |
| **African American** | 24 | 40 | 64 |
| **Hispanic** | 8 | 24 | 32 |
| **Asian/Pacific Islander** | 5 | 6 | 11 |
| **Other** | 2 | 2 | 4 |
| **Disease duration [units: years] Mean (Standard Deviation)** | 8.7 (7.6) | 8.5 (7.2) | 8.6 (7.3) |

"Default" Required Measures

"Default" Optional Measure

Study Specific Measure

4

Adapted from NCT00137969

# Baseline Characteristics Template
## Age

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| * Arm/Group Title | | | | | | | Total | |
| Arm/Group Description ① | | | | | | | | |
| * Overall Number of Baseline Participants | | | | | | | ② | |
| Baseline Analysis Population Description | | | | | | | | |
| Age, Categorical ③ | | | | | | | | |
| [*] <=18 years | | | | | | | ② | |
| [*] Between 18 and 65 years | | | | | | | ② | |
| [*] >=65 years | | | | | | | ② | |
| [*] Unit of Measure | Participants | | | | | | | |
| Age, Continuous ③ | | | | | | | | |
| [*] Measure Type | [*] Measure of Dispersion | | | | | | | |
| (Circle One)<br>Mean<br>Median<br>Least Squares Mean<br>Geometric Mean<br>Log Mean | (Circle One)<br>Standard Deviation<br>Inter-quartile Range<br>Full Range | | ④ | | ④ | | ④ | ④ |
| [*] Unit of Measure | | | | | | | | |
| Age, Customized ③ | | | | | | | | |
| [*] Measure Type | [*] Measure of Dispersion | | | | | | | |
| (Circle One)<br>Number<br>Mean<br>Median<br>Least Squares Mean<br>Geometric Mean<br>Log Mean | (Circle One)<br>Not Applicable ⑤<br>Standard Deviation<br>Inter-quartile Range<br>Full Range | | | | | | | |
| [*] Category Title ⑥ | | | ④ | | ④ | | ④ | ② ④ |
| [*] Category Title ⑥ | | | ④ | | ④ | | ④ | ② ④ |
| [*] Unit of Measure | | | | | | | | |

* Required by ClinicalTrials.gov [*] Conditionally required by ClinicalTrials.gov

5

# Baseline Characteristics Template
## Study Specific Measure

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| [*] Study-Specific Baseline Measure Title | | | | | | | | |
| Baseline Measure Description | | | | | | | | |
| * Arm/Group Title | | | | | | | Total | |
| Arm/Group Description ① | | | | | | | | |
| * Overall Number of Baseline Participants | | | | | | | ② | |
| Baseline Analysis Population Description | | | | | | | | |
| [*] Measure Type | [*] Measure of Dispersion | | | | | | | |
| (Circle One)<br>Number<br>Mean<br>Median<br>Least Squares Mean<br>Geometric Mean<br>Log Mean | (Circle One)<br>Not Applicable ③<br>Standard Deviation<br>Inter-quartile Range<br>Full Range | | | | | | | |
| [*] Category Title ⑤ | | | ④ | | ④ | | ④ | ② ④ |
| [*] Category Title ⑤ | | | ④ | | ④ | | ④ | ② ④ |
| [*] Unit of Measure | | | | | | | | |

* Required by ClinicalTrials.gov
[*] Conditionally required by ClinicalTrials.gov

6

# Baseline Characteristics Checklist

http://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html

**Baseline Characteristics Data Preparation Checklist**

**Overview:** A tabular summary of all characteristics measured at baseline for each group and overall. The table is similar to "Table 1" in a journal article. Use this checklist with the Results Data Element Definitions and the Simple Results Templates* for Age; Gender; Race, Ethnicity, Region; and Study Specific Measures.

| | Information to have available for Baseline Characteristics | Term |
|---|---|---|
| ☐ | • Have a list of all baseline characteristics and the corresponding summary-level data (similar to Table 1 in a journal article). Age and Gender must be provided. | Background |
| ☐ | • The number of separate groups for which summary data will be provided.<br>• Tip: Generally equal to the number of groups/intervention strategies to which participants were assigned (randomized) at the beginning of the study | Arm/Groups |
| ☐ | • For each group:<br>o Title—A descriptive label for the group (header for table column). Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1").<br>o Description—A detailed explanation of the participants included in the group and the interventions received. This may include a description of how groups of participants were recombined for analysis purposes. | *^Arm/Group Title<br>^Arm/Group Description |
| ☐ | • Number of participants, in each group and in the entire study population (total), from whom data were collected and summarized. Participants should only be represented in one group and in the total (i.e., do not double-count). | *^Overall Number Baseline Participants |
| ☐ | • An explanation of the criteria used to determine which participants were included in the analysis | ^Baseline Analysis Population Description |
| | **Information to have available for each Baseline Measure** | **Term** |
| ☐ | • Title—Describe specifically what was measured and will be reported as data<br>• Description—Any elaboration needed to understand the measure and the reported data. Information should be written for a public audience (i.e., not specialists in your field, but general readers of the medical literature).<br>o If the measure was based on a scale, explain any numerical categories or provide the range and direction of possible scores (0=no pain; 10=worst possible pain) to allow a reader to properly interpret any reported values. | *^Baseline Measure Title<br>^Baseline Measure Description |
| ☐ | • The method used to summarize baseline data:<br>o Central tendency—E.g., mean, median, geometric mean<br>o Number—E.g., count (of participants) | *^Measure Type |
| ☐ | • For a measure of central tendency, specify a measure that represents "the spread" of the summary data (e.g., standard deviation).<br>o Tip: This is not applicable for a Number (e.g., count of participants) | *^Measure of Dispersion |
| ☐ | • Numerical values for the summary-level data in each group and overall (total) | *Baseline Data |
| ☐ | • The specific unit associated with the numerical data (e.g., mg/dL, participants) | *^Unit of Measure |

7

# Best Practices

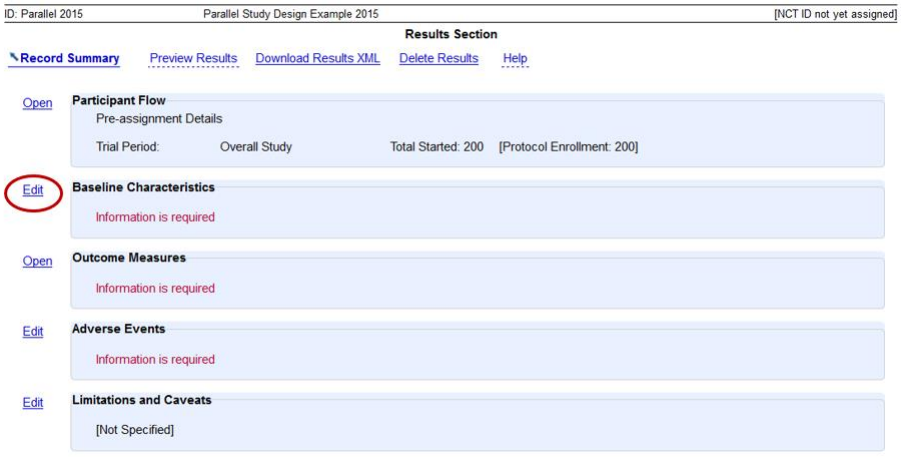
- Minimum requirements
  - Age and Gender
- Region of Enrollment, Race/Ethnicity
- Other relevant demographic characteristics
- Clinical measures relevant to study, such as
  - Clinical characteristics, including baseline values of outcome measures
  - Prior and concurrent treatment characteristics

8

# Baseline Characteristics
## *Tutorial*

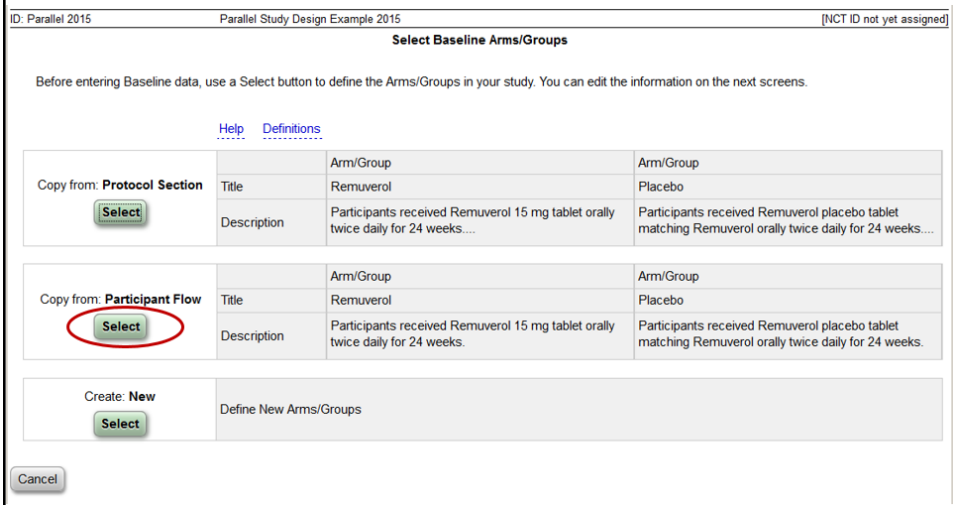
9

# Results Section



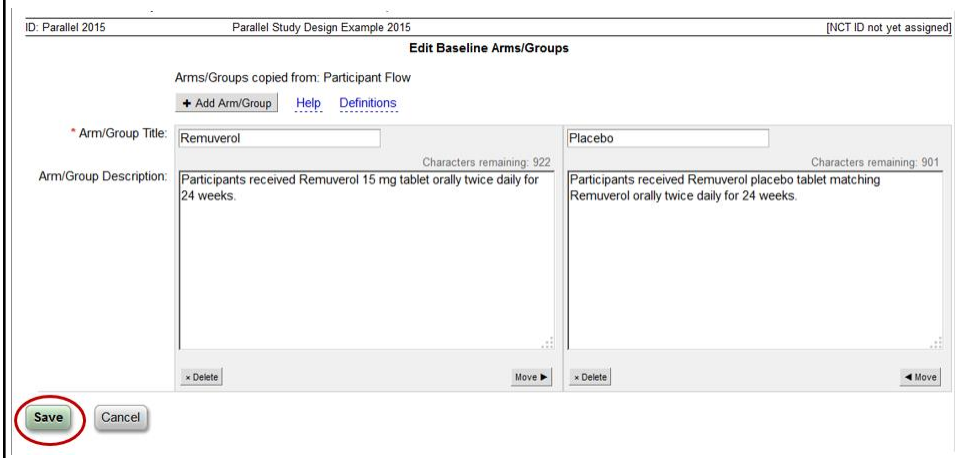

10

# Select Baseline Arms/Groups



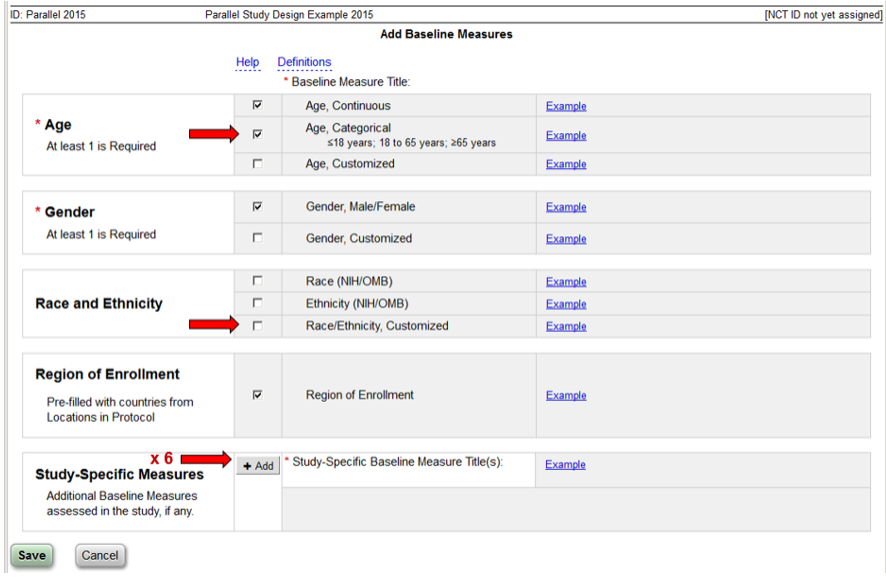

11

# Edit Baseline Arms/Groups



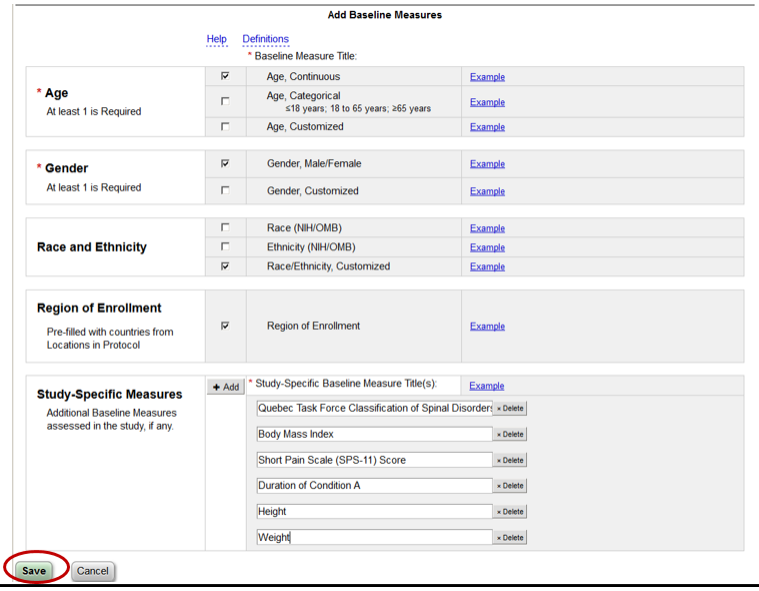

12

# Add Baseline Measures



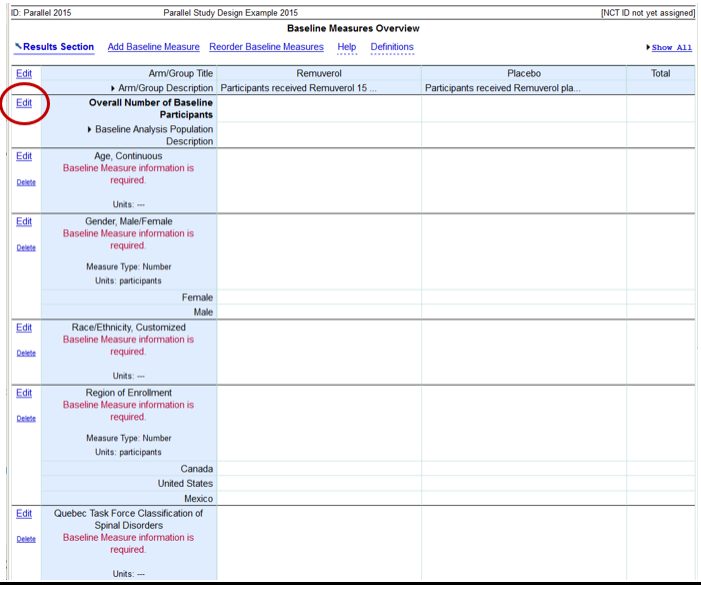

13

# Add Baseline Measures (cont.)




14

# Baseline Measures Overview


ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

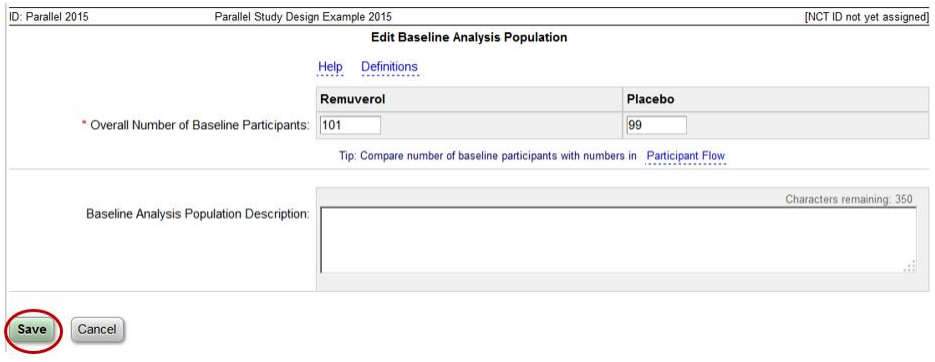
**Baseline Measures Overview**

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

| Edit | Arm/Group Title / Arm/Group Description | Remuverol / Participants received Remuverol 15 ... | Placebo / Participants received Remuverol pla... | Total |
|---|---|---|---|---|
| Edit | **Overall Number of Baseline Participants** / Baseline Analysis Population Description | | | |
| Edit Delete | Age, Continuous — Baseline Measure information is required. — Units: --- | | | |
| Edit Delete | Gender, Male/Female — Baseline Measure information is required. — Measure Type: Number — Units: participants | | | |
| | Female | | | |
| | Male | | | |
| Edit Delete | Race/Ethnicity, Customized — Baseline Measure information is required. — Units: --- | | | |
| Edit Delete | Region of Enrollment — Baseline Measure information is required. — Measure Type: Number — Units: participants | | | |
| | Canada | | | |
| | United States | | | |
| | Mexico | | | |
| Edit Delete | Quebec Task Force Classification of Spinal Disorders — Baseline Measure information is required. — Units: --- | | | |

15

# Edit Baseline Analysis Population


ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

**Edit Baseline Analysis Population**

Help | Definitions

| | Remuverol | Placebo |
|---|---|---|
| * Overall Number of Baseline Participants: | 101 | 99 |

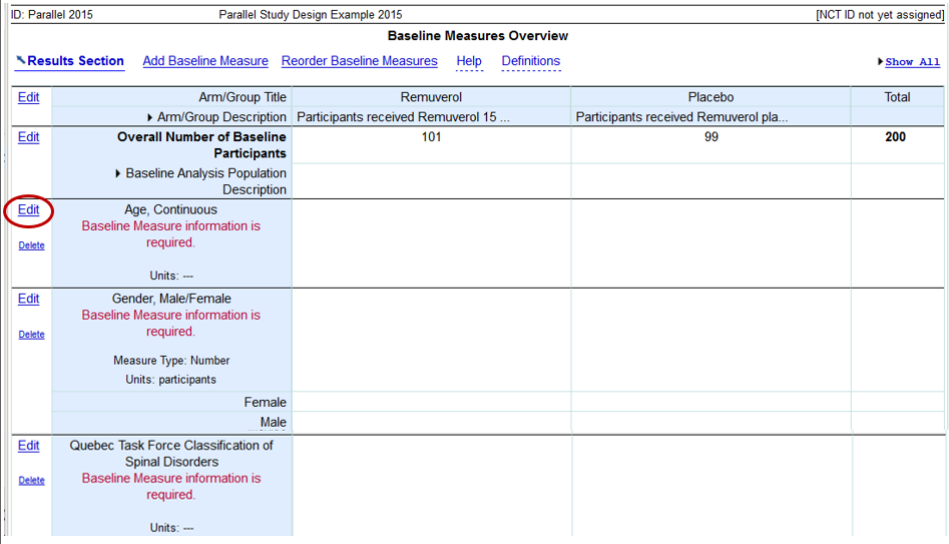
Tip: Compare number of baseline participants with numbers in Participant Flow

Baseline Analysis Population Description: Characters remaining: 350

Save | Cancel

16

# Baseline Measures Overview



ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

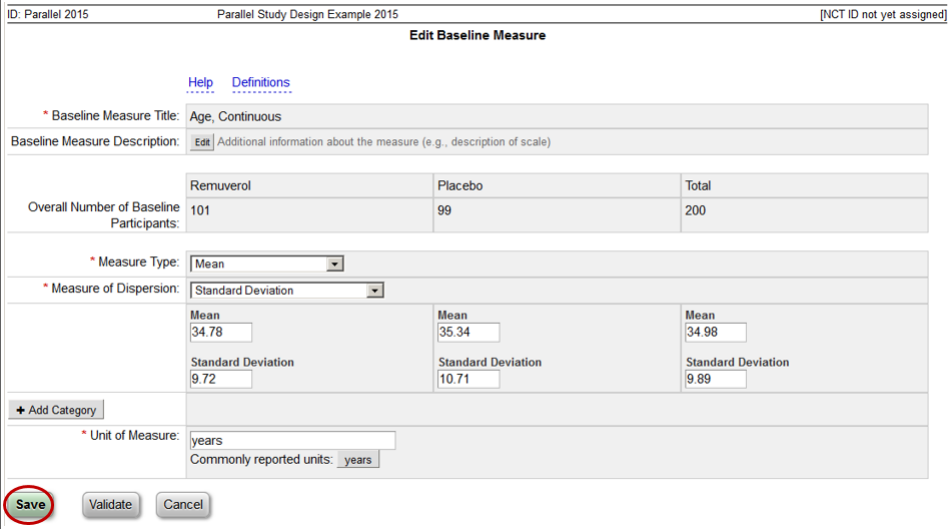
**Baseline Measures Overview**

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

| Edit | Arm/Group Title / Arm/Group Description | Remuverol / Participants received Remuverol 15 ... | Placebo / Participants received Remuverol pla... | Total |
|---|---|---|---|---|
| Edit | **Overall Number of Baseline Participants** | 101 | 99 | **200** |
| | Baseline Analysis Population Description | | | |
| Edit Delete | Age, Continuous<br>Baseline Measure information is required.<br>Units: --- | | | |
| Edit Delete | Gender, Male/Female<br>Baseline Measure information is required.<br>Measure Type: Number<br>Units: participants | | | |
| | Female | | | |
| | Male | | | |
| Edit Delete | Quebec Task Force Classification of Spinal Disorders<br>Baseline Measure information is required.<br>Units: --- | | | |

17

# Edit Baseline Measure
## Age, Continuous



ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

**Edit Baseline Measure**

Help | Definitions

* Baseline Measure Title: Age, Continuous

Baseline Measure Description: Edit | Additional information about the measure (e.g., description of scale)

| Overall Number of Baseline Participants: | Remuverol | Placebo | Total |
|---|---|---|---|
| | 101 | 99 | 200 |

* Measure Type: Mean

* Measure of Dispersion: Standard Deviation

| Remuverol | Placebo | Total |
|---|---|---|
| Mean: 34.78 | Mean: 35.34 | Mean: 34.98 |
| Standard Deviation: 9.72 | Standard Deviation: 10.71 | Standard Deviation: 9.89 |

+ Add Category

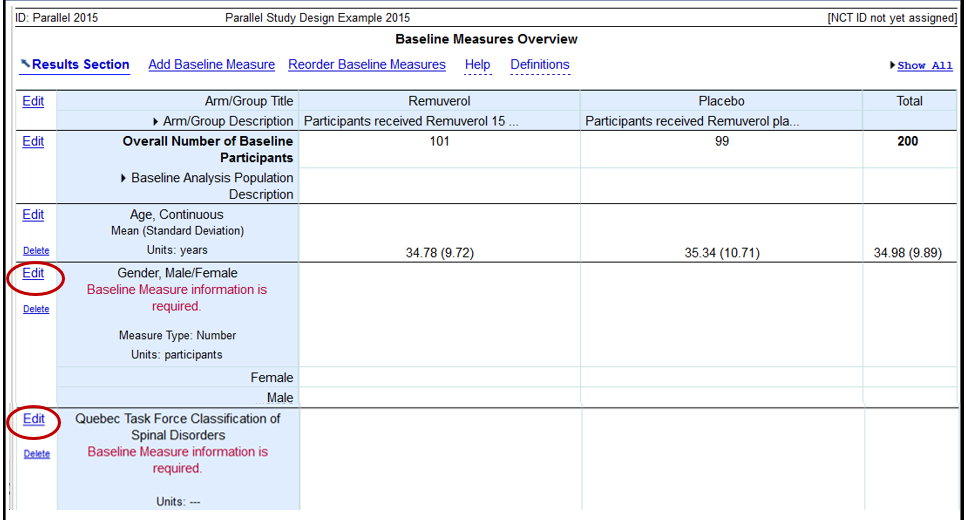
* Unit of Measure: years

Commonly reported units: years

Save | Validate | Cancel

18

# Baseline Measures Overview



ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

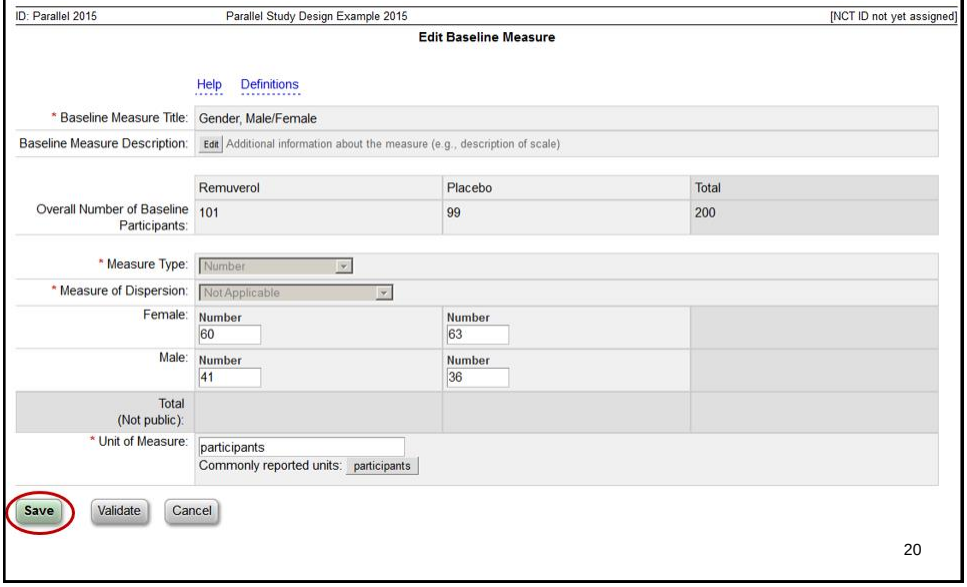
**Baseline Measures Overview**

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

| Edit | Arm/Group Title | Remuverol | Placebo | Total |
|---|---|---|---|---|
| | Arm/Group Description | Participants received Remuverol 15 ... | Participants received Remuverol pla... | |
| Edit | **Overall Number of Baseline Participants** | 101 | 99 | **200** |
| | Baseline Analysis Population Description | | | |
| Edit Delete | Age, Continuous<br>Mean (Standard Deviation)<br>Units: years | 34.78 (9.72) | 35.34 (10.71) | 34.98 (9.89) |
| Edit Delete | Gender, Male/Female<br>Baseline Measure information is required.<br>Measure Type: Number<br>Units: participants | | | |
| | Female | | | |
| | Male | | | |
| Edit Delete | Quebec Task Force Classification of Spinal Disorders<br>Baseline Measure information is required.<br>Units: --- | | | |

19

# Edit Baseline Measure
## Gender, Male/Female



ID: Parallel 2015 Parallel Study Design Example 2015 [NCT ID not yet assigned]

**Edit Baseline Measure**

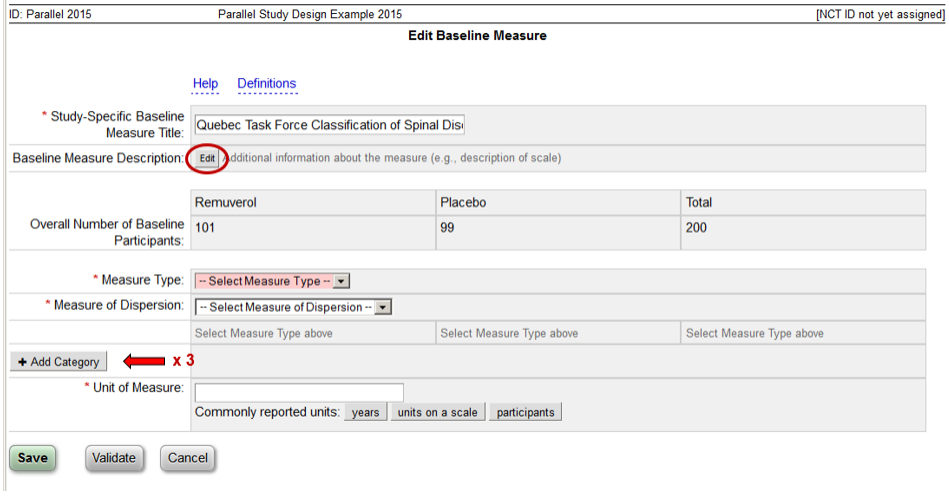
Help | Definitions

| | | | |
|---|---|---|---|
| * Baseline Measure Title: | Gender, Male/Female | | |
| Baseline Measure Description: | Edit Additional information about the measure (e.g., description of scale) | | |
| | Remuverol | Placebo | Total |
| Overall Number of Baseline Participants: | 101 | 99 | 200 |
| * Measure Type: | Number | | |
| * Measure of Dispersion: | Not Applicable | | |
| Female: | Number 60 | Number 63 | |
| Male: | Number 41 | Number 36 | |
| Total (Not public): | | | |
| * Unit of Measure: | participants<br>Commonly reported units: participants | | |

Save | Validate | Cancel

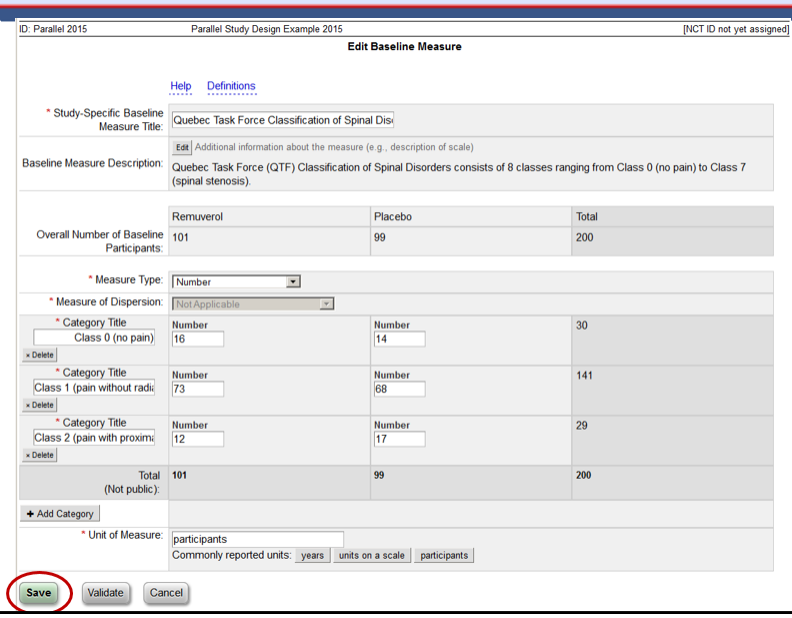
20

# Edit Baseline Measure
## Study Specific






# Edit Baseline Measure (cont.)
## Study Specific



# Baseline Measures Overview

ID: ParallelR 2015 Parallel Study Design Example (With Results) 2015 [NCT ID not yet assigned]

**Baseline Measures Overview**

Results Section | Add Baseline Measure | Reorder Baseline Measures | Help | Definitions | Show All

| | | | | |
|---|---|---|---|---|
| Edit | Arm/Group Title | Remuverol | Placebo | Total |
| | ▸ Arm/Group Description | Participants received Remuverol 15 ... | Participants received Remuverol pla... | |
| Edit | **Overall Number of Baseline Participants** | 101 | 99 | **200** |
| | ▸ Baseline Analysis Population Description | | | |
| Edit | Age, Continuous<br>Mean (Standard Deviation) | | | |
| Delete | Units: years | 34.78 (9.72) | 35.34 (10.71) | 34.98 (9.89) |
| Edit | Gender, Male/Female<br>Measure Type: Number | | | |
| Delete | Units: participants | | | |
| | Female | 60 | 63 | 123 |
| | Male | 41 | 36 | 77 |
| Edit | Quebec Task Force Classification of Spinal Disorders [1]<br>Measure Type: Number | | | |
| Delete | Units: participants | | | |
| | Class 0 (no pain) | 16 | 14 | 30 |
| | Class 1 (pain without radiation) | 73 | 68 | 141 |
| | Class 2 (pain with proximal extremity radiation) | 12 | 17 | 29 |
| | | [1] Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis). | | |

23

# Enter Baseline Characteristics

- Example Study Designs
  - Factorial
  - Crossover
  - Cluster Randomized
  - Dose Escalation
  - Multiple Period

24