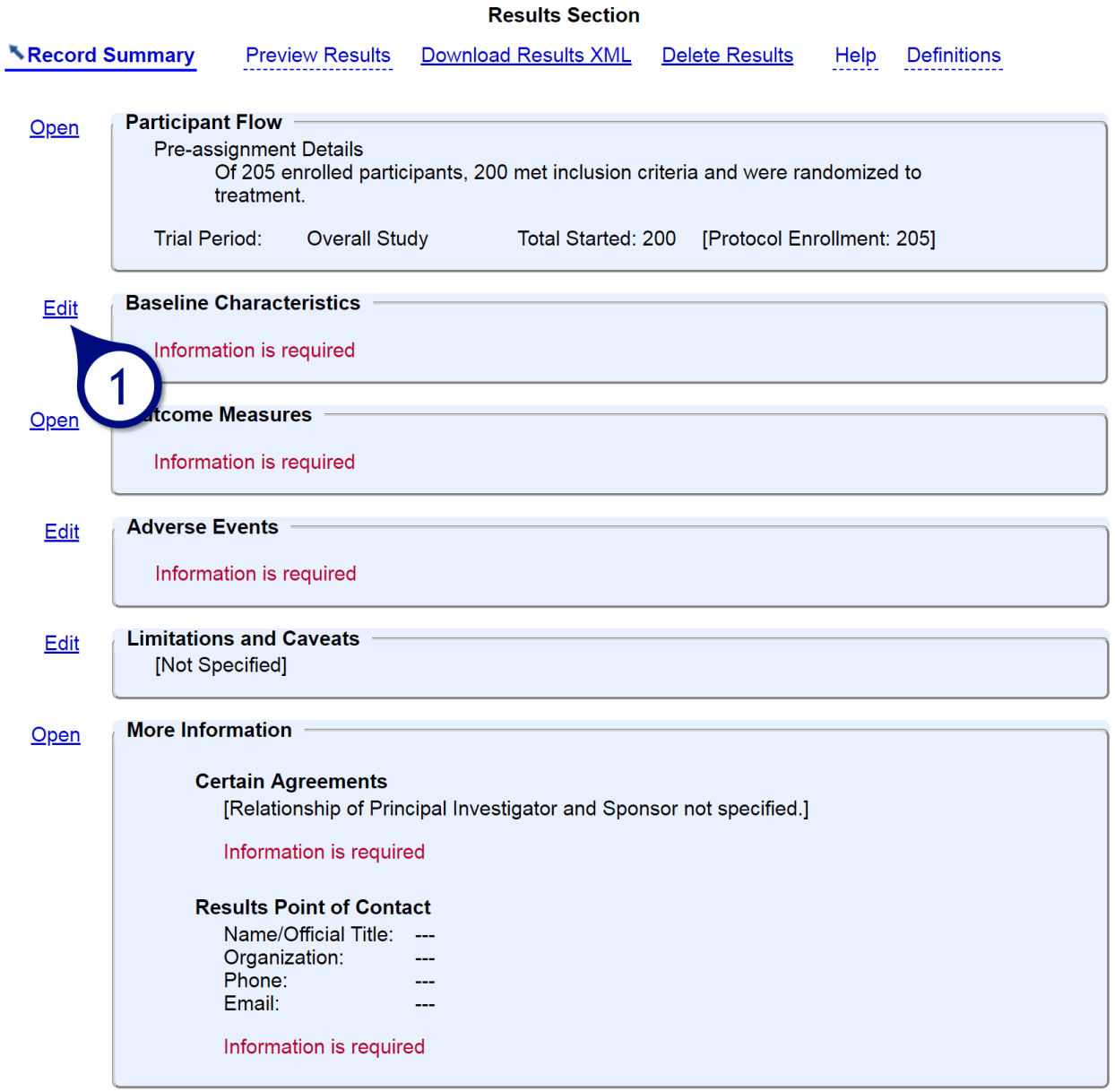
ClinicalTrials.gov PRS

Protocol Registration and Results System

Baseline Characteristics Data Entry Walkthrough

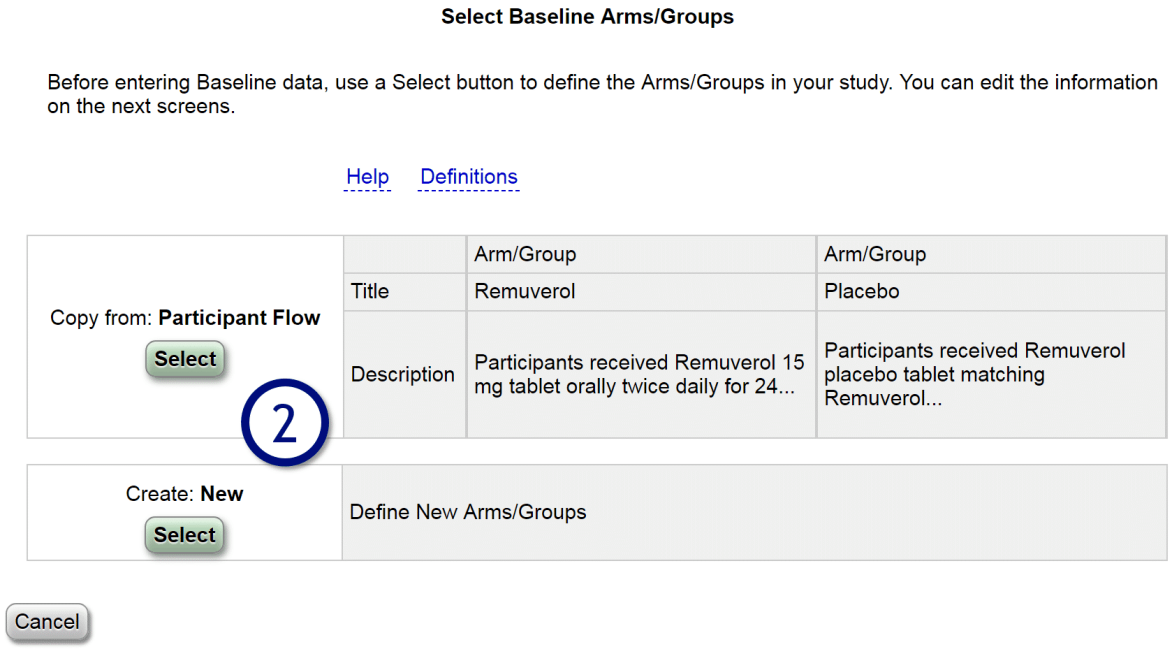
Step 1

On the Results Section page, click on the **Edit** link next to Baseline Characteristics.



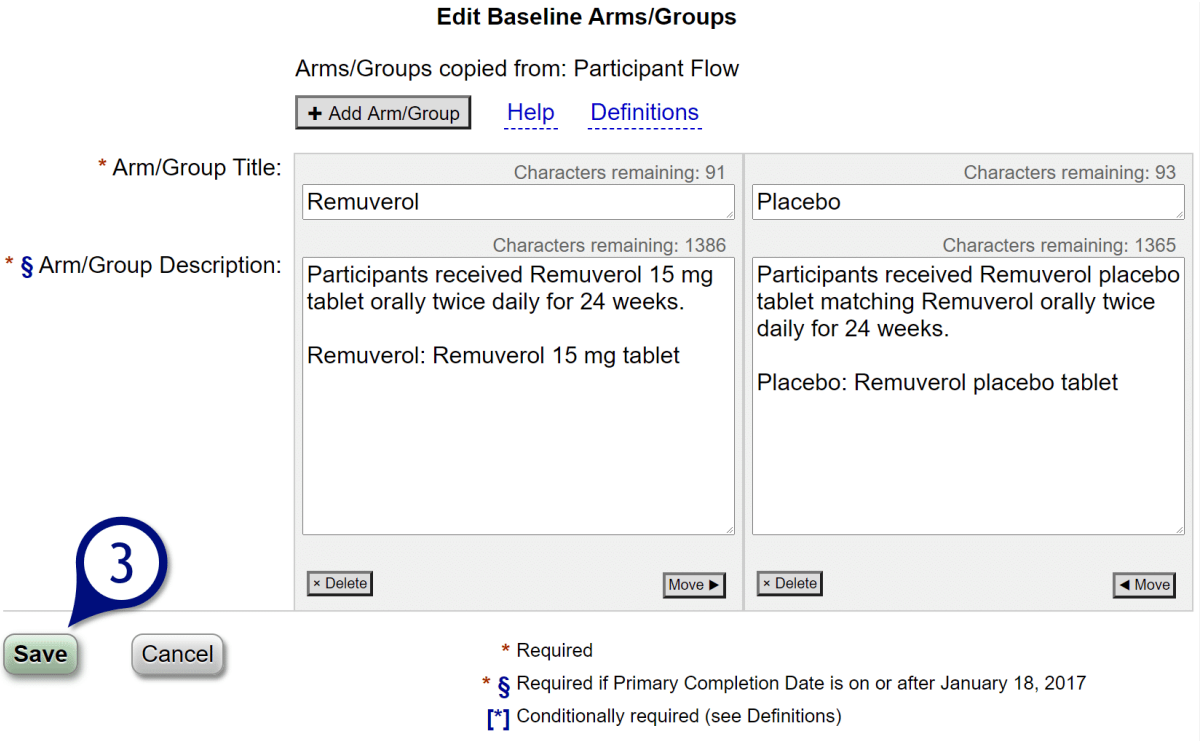
Step 2

Click on the **Select** button for the Copy from: Participant Flow option to copy arms/groups from the Participant Flow module.



Step 3

Review the Arm/Group Information (no edits should be needed), then click on the **Save** button.



Step 4

Locate the baseline measures that were assessed for the study in the Parallel Study Design Example: Figures and Tables document (see table 1; relevant text highlighted in yellow below).

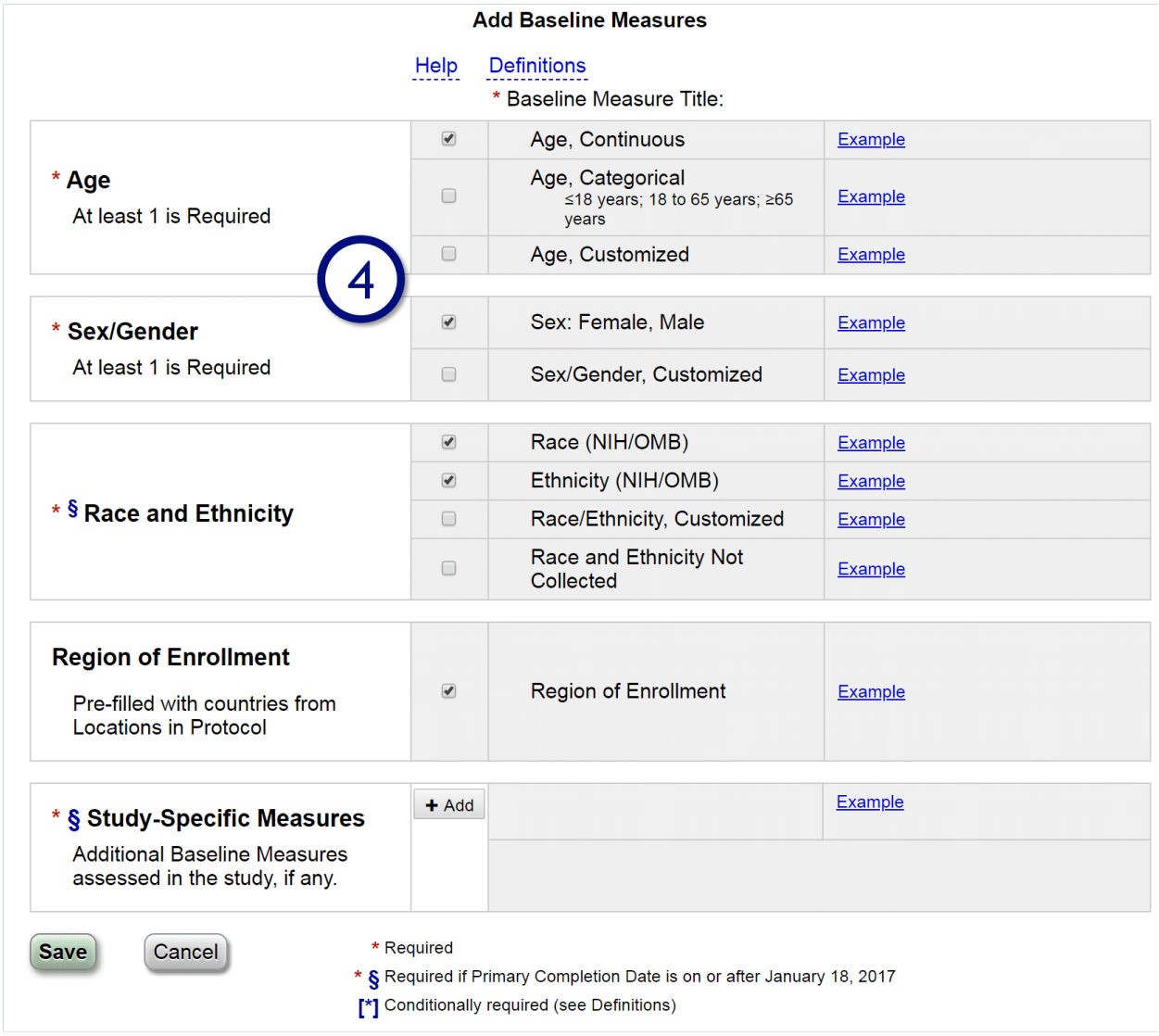
Table 1: Baseline Demographics and Disease Characteristics of Participants

Characteristic	Remuverol N = 101	Placebo N = 99	Total N = 200
Age, years, mean (SD)	34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex, n (%)			
Female	60 (59.4)	63 (63.6)	123 (61.5)
Race, n (%)			
African American	5 (4.95)	4 (4.04)	9 (4.50)
White	95 (94.06)	94 (94.95)	189 (94.50)
American Indian	1 (0.99)	1 (1.01)	2 (1.00)
Ethnicity, n (%)			
Hispanic	5 (4.95)	4 (4.04)	9 (4.50)
Region of Enrollment, n (%)			
United States	44 (43.56)	47 (47.48)	91 (45.50)
Canada	35 (34.65)	35 (35.35)	70 (35.00)
Mexico	22 (21.78)	17 (17.17)	39 (19.50)
QTF Classification of Spinal Disorder*			
Class 0, n (%) – *no pain*	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – *pain without radiation*	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – *pain with proximal extremity radiation*	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m2, mean (SD)	26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score, mean (SD)**	6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
Duration of Disc Herniation, years, mean (SD)	3.82 (3.18)	3.47 (2.95)	3.65 (3.07)
Height, cm, mean (SD)	186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight, kg, mean (SD)	77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

* Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from 0 (no pain) to Class 7 (spinal stenosis).

** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).

Mark the checkboxes for the baseline measures that will be included in the Baseline Characteristics table. Frequently reported baseline measures are preselected for inclusion but can be deselected as needed. Note that preformatted baseline measures (Sex: Female, Male; Race (NIH/OMB); and Ethnicity (NIH/OMB)) should be used to report the Sex, Race, and Ethnicity baseline assessments of the Parallel Study Design Example because the data fit the categories defined for these measures. Customized baseline measures (Age, Customized; Sex/Gender, Customized; or Race/Ethnicity, Customized) should be used only when this is not the case.

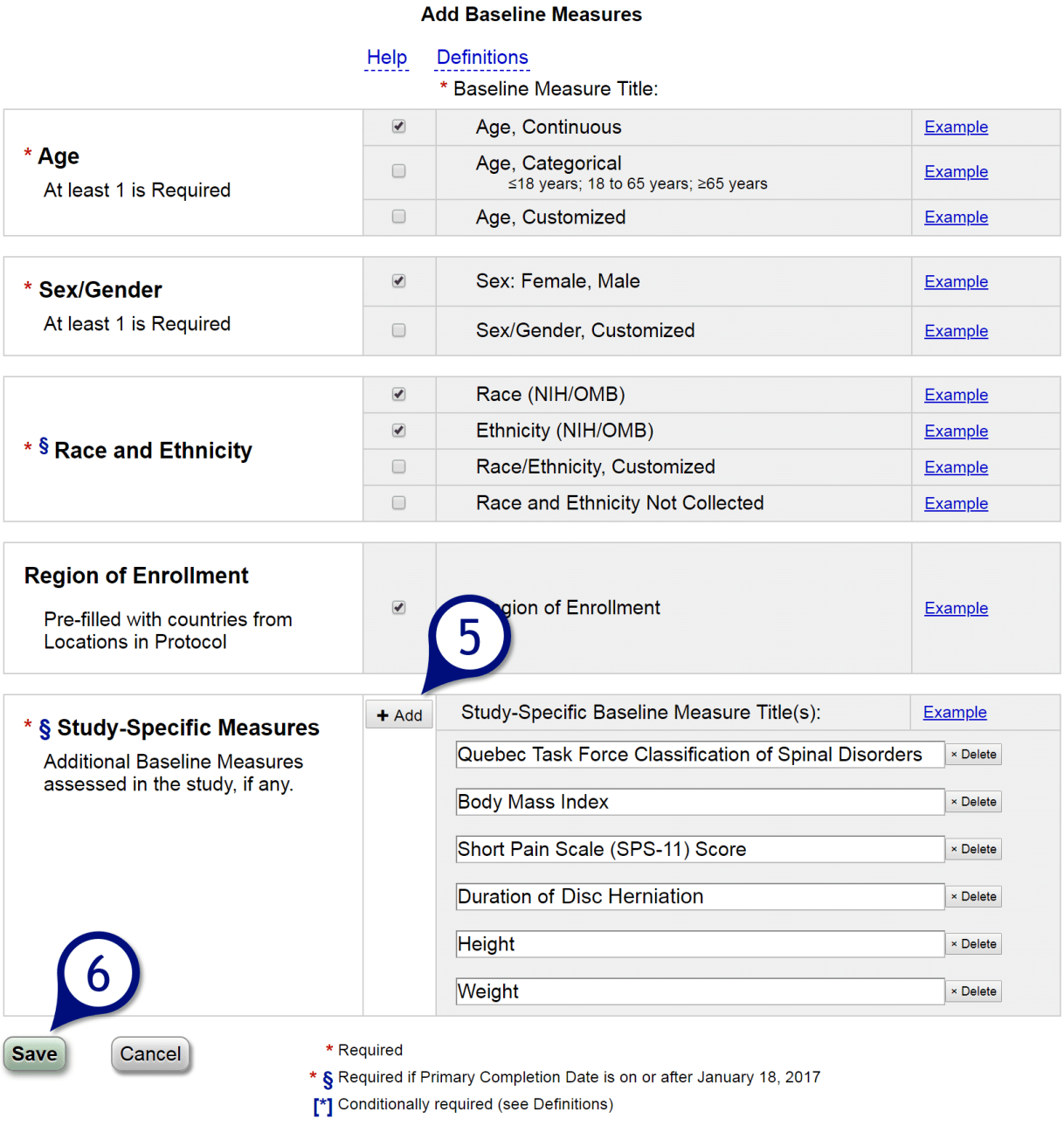

Add Baseline Measures
Help
Definitions
* Baseline Measure Title:
* Age
At least 1 is Required
Age, Continuous
Example
Age, Categorical
≤18 years; 18 to 65 years; ≥65 years
Example
Age, Customized
Example
4
* Sex/Gender
At least 1 is Required
Sex: Female, Male
Example
Sex/Gender, Customized
Example
* § Race and Ethnicity
Race (NIH/OMB)
Example
Ethnicity (NIH/OMB)
Example
Race/Ethnicity, Customized
Example
Race and Ethnicity Not Collected
Example
Region of Enrollment
Pre-filled with countries from Locations in Protocol
Region of Enrollment
Example
* § Study-Specific Measures
Additional Baseline Measures assessed in the study, if any.
+ Add
Example
Save
Cancel
* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Step 5

Click on the **+ Add** button next to Study-Specific Measures as many times as necessary to include all the relevant baseline measures. Then add a descriptive Baseline Measure Title for each Study-Specific Measure.

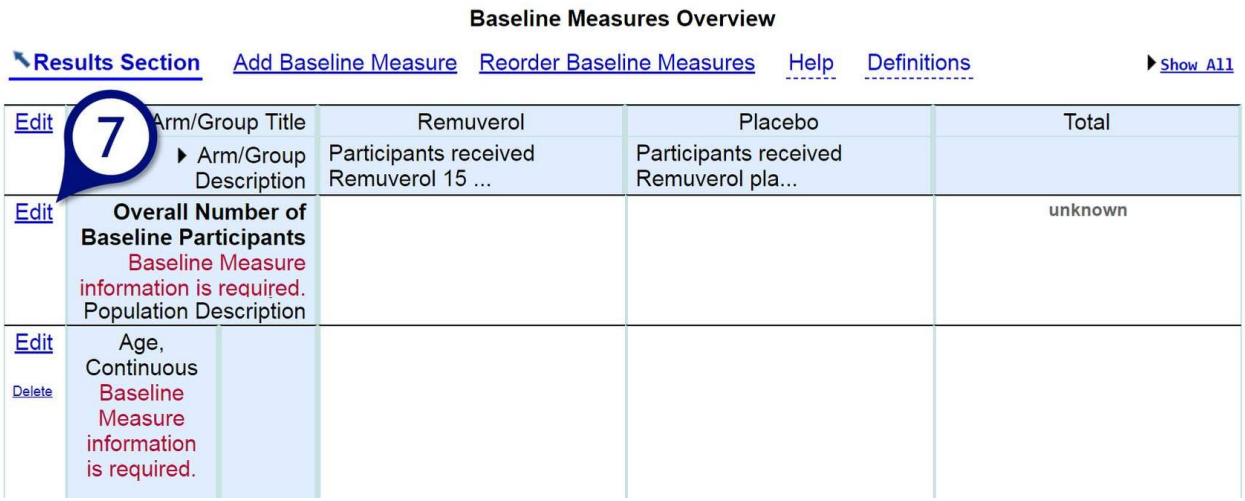
Step 6

Click on the **Save** button.



Step 7

Click on the **Edit** link next to Overall Number of Baseline Participants.



Step 8

Use the Parallel Study Design Example: Figures and Tables document to determine the numbers of participants analyzed at baseline in each arm/group and in total (see table 1; relevant text highlighted in yellow below).

Table 1: Baseline Demographics and Disease Characteristics of Participants

CHARACTERISTIC	REMUVEROL N = 101	PLACEBO N = 99	TOTAL N = 200
Age, years, mean (SD)	34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex, n (%)			
Female	60 (59.4)	63 (63.6)	123 (61.5)
Race, n (%)			
African American	5 (4.95)	4 (4.04)	9 (4.50)
White	95 (94.06)	94 (94.95)	189 (94.50)
American Indian	1 (0.99)	1 (1.01)	2 (1.00)
Ethnicity, n (%)			
Hispanic	5 (4.95)	4 (4.04)	9 (4.50)
Region of Enrollment, n (%)			
United States	44 (43.56)	47 (47.48)	91 (45.50)
Canada	35 (34.65)	35 (35.35)	70 (35.00)
Mexico	22 (21.78)	17 (17.17)	39 (19.50)
QTF Classification of Spinal Disorder*			
Class 0, n (%) – *no pain*	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – *pain without radiation*	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – *pain with proximal extremity radiation*	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m2, mean (SD)	26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score, mean (SD)**	6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
Duration of Disc Herniation, years, mean (SD)	3.82 (3.18)	3.47 (2.95)	3.65 (3.07)
Height, cm, mean (SD)	186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight, kg, mean (SD)	77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

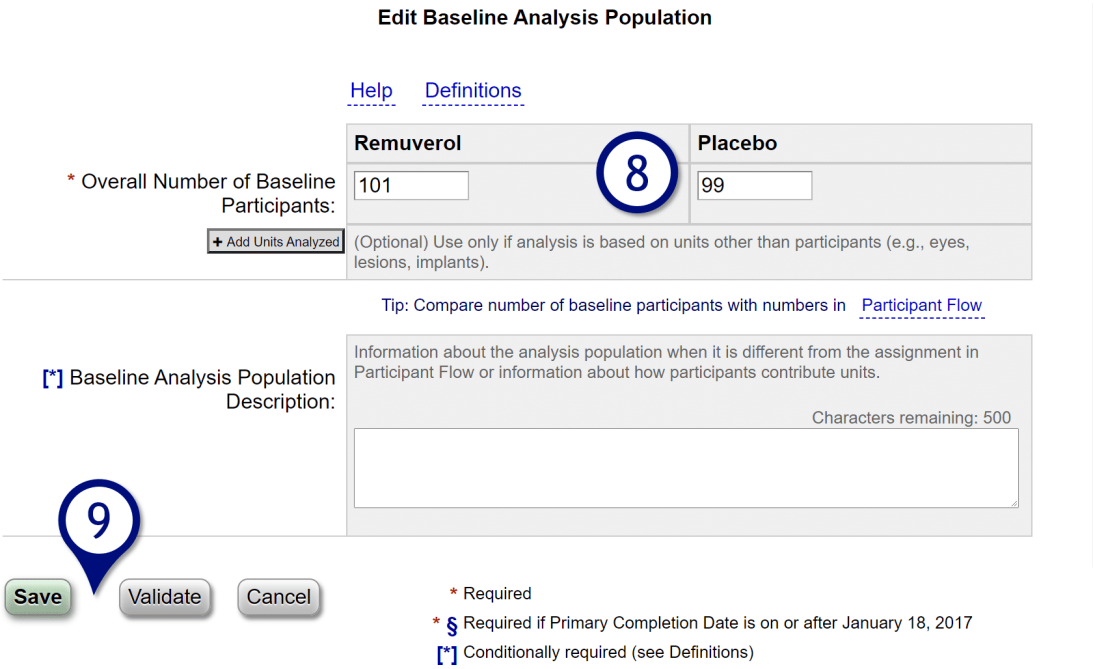
* Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from 0 (no pain) to Class 7 (spinal stenosis).

** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).

Enter the Overall Number of Baseline Participants for each arm/group.

Step 9

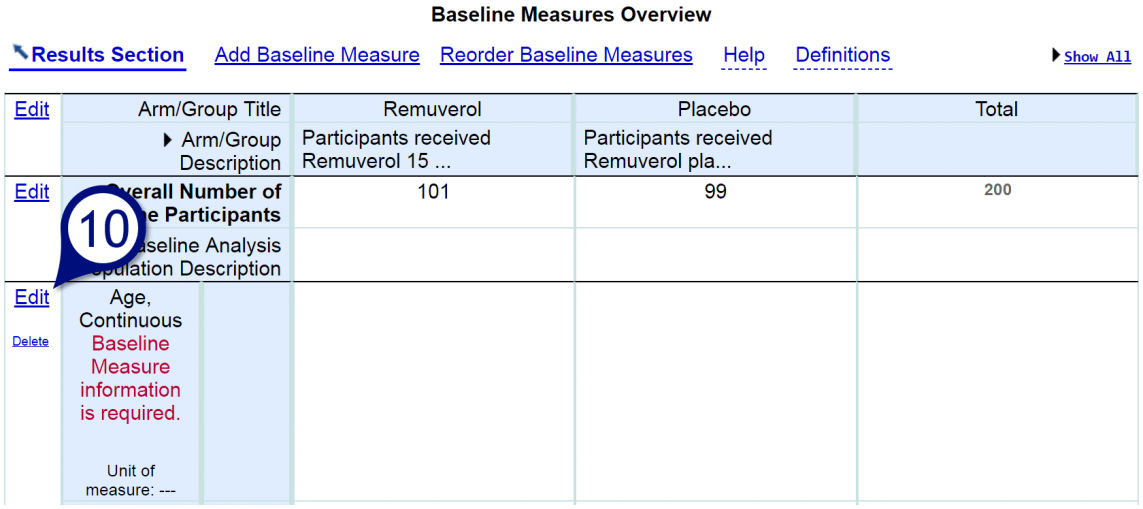
Before leaving the Edit Baseline Analysis Population page, click on the **Validate** button to check for system validation messages that should be addressed. Address any error messages, and review any warnings or notes carefully and address them if necessary. Then click on the **Save** button to save your work and return to the Baseline Measures Overview page.



Step 10

Click on the **Edit** link next to a baseline measure with continuous data. Continuous data can take any value within a continuum for a given assessment (for example, a physiological range of values for weight or heart rate).

The images for steps 10–15 show data entry for the Age, Continuous baseline measure. Once you have added the Age, Continuous measure, you will repeat steps 10–15 to enter data for the remaining continuous baseline measures in the Parallel Study Design Example.



Step 11

Use the Parallel Study Design Example: Figures and Tables document to locate the data for each continuous baseline measure (see table 1; relevant text highlighted in yellow below).

Table 1: Baseline Demographics and Disease Characteristics of Participants

CHARACTERISTIC	REMUVEROL N = 101	PLACEBO N = 99	TOTAL N = 200
Age, years, mean (SD)	34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex, n (%)			
Female	60 (59.4)	63 (63.6)	123 (61.5)
Race, n (%)			
African American	5 (4.95)	4 (4.04)	9 (4.50)
White	95 (94.06)	94 (94.95)	189 (94.50)
American Indian	1 (0.99)	1 (1.01)	2 (1.00)
Ethnicity, n (%)			
Hispanic	5 (4.95)	4 (4.04)	9 (4.50)
Region of Enrollment, n (%)			
United States	44 (43.56)	47 (47.48)	91 (45.50)
Canada	35 (34.65)	35 (35.35)	70 (35.00)
Mexico	22 (21.78)	17 (17.17)	39 (19.50)
QTF Classification of Spinal Disorder*			
Class 0, n (%) – *no pain*	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – *pain without radiation*	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – *pain with proximal extremity radiation*	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m2, mean (SD)	26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score, mean (SD)**	6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
Duration of Disc Herniation, years, mean (SD)	3.82 (3.18)	3.47 (2.95)	3.65 (3.07)
Height, cm, mean (SD)	186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight, kg, mean (SD)	77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

* Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from 0 (no pain) to Class 7 (spinal stenosis).

** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).

Click on the **Edit** button next to the Baseline Measure Description to include additional descriptive information about the measure, if necessary.

- Age, Continuous; Body Mass Index (BMI); Duration of Disc Herniation; Height; and Weight: No additional information is needed for these measures.
- Short Pain Scale (SPS-11) Score: Include the information highlighted in the second footnote for table 1.

Step 12

Select “Mean” as the Measure Type and “Standard Deviation” as the Measure of Dispersion. All of the continuous baseline measures included in table 1 report data with a mean and standard deviation.

Step 13

Enter the summary-level data for each arm/group and for the entire study population (Total column).

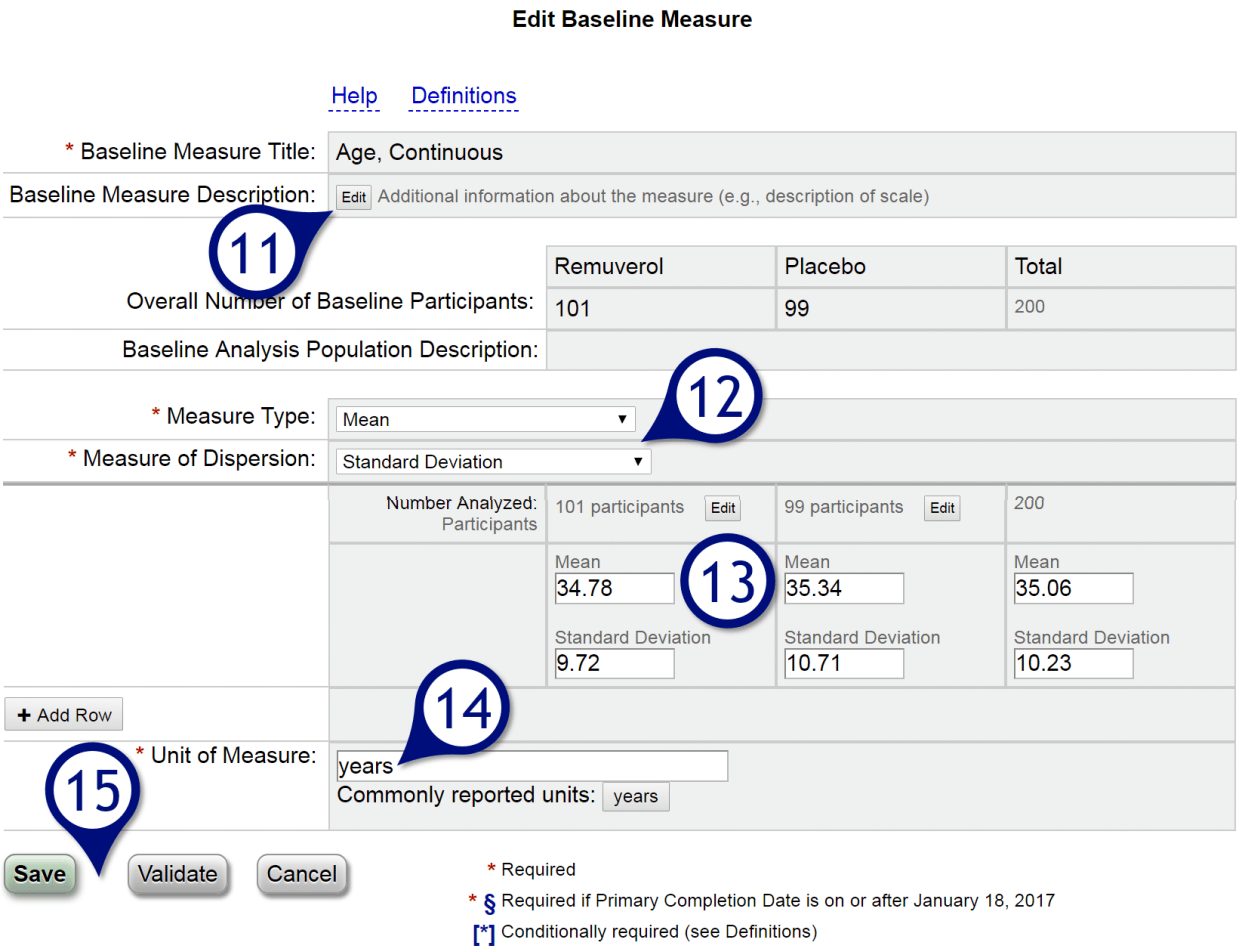
Step 14

Enter the Unit of Measure by clicking on the button for the appropriate Commonly reported units (for example, **years**) to select a predefined unit or by entering your own units in the text field.

- Age, Continuous and Duration of Disc Herniation: Click on **years**.
- Body Mass Index (BMI): Enter “kg/m^2” in the text field.
- Short Pain Scale (SPS-11) Score: Click on **units on a scale**.
- Height: Enter “cm” in the text field.
- Weight: Enter “kg” in the text field.

Step 15

Before leaving the Edit Baseline Measure page, click on the **Validate** button to check for system validation messages that should be addressed. Address any error messages, and review any warnings or notes carefully and address them if necessary. Then click on the **Save** button to save your work and return to the Baseline Measures Overview page.

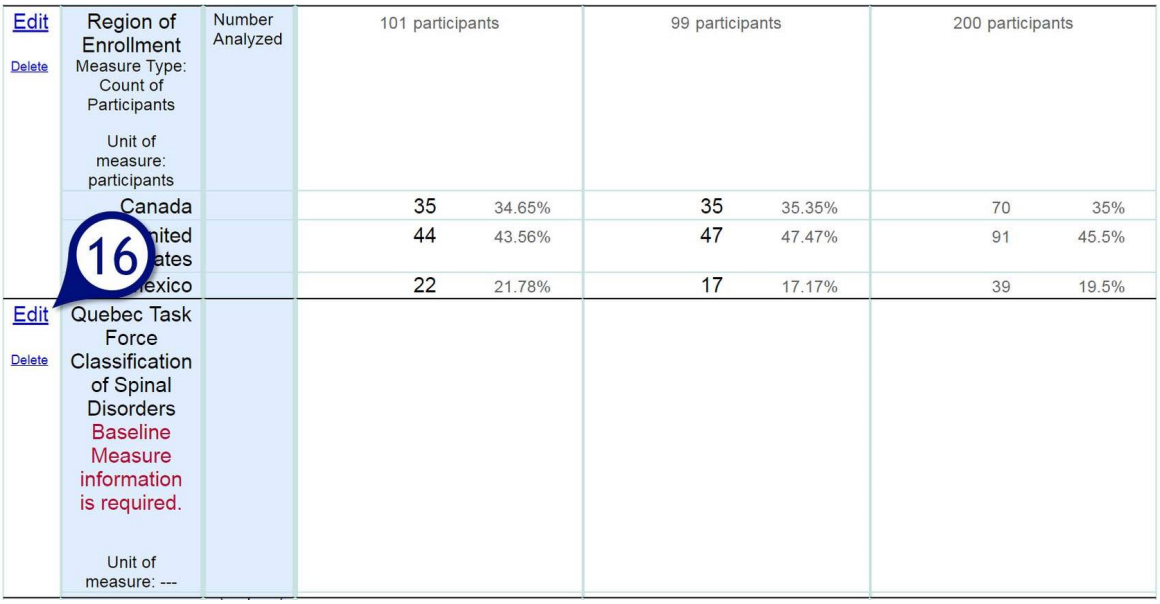


Enter data for the remaining continuous baseline measures by repeating steps 10–15.

Step 16

Click on the **Edit** link next to a baseline measure with discrete data. Discrete data are based on counts and represented by integer values (for example, numbers of participants falling into different classifications on a scale, such as Class 0 (no pain), Class 1 (pain without radiation), etc.).

The images for steps 16–22 show data entry for the study-specific measure Quebec Task Force Classification of Spinal Disorders. Once you have added the Quebec Task Force Classification of Spinal Disorders measure, you will repeat steps 16–22 to enter data for the remaining discrete baseline measures in the Parallel Study Design Example.



Step 17

Use the Parallel Study Design Example: Figures and Tables document to locate the data for each discrete baseline measure (see table 1; relevant text highlighted in yellow below).

Table 1: Baseline Demographics and Disease Characteristics of Participants

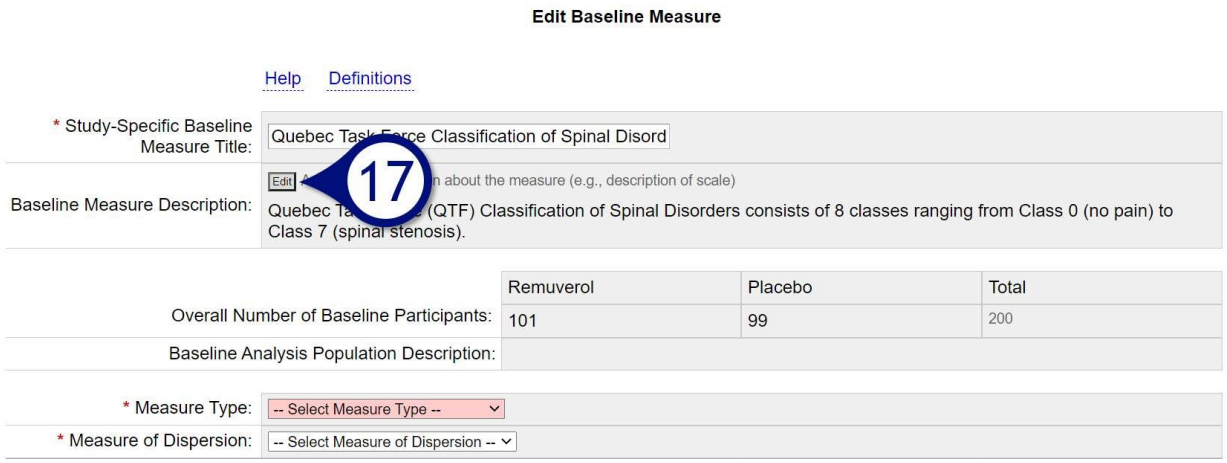
CHARACTERISTIC	REMUVEROL N = 101	PLACEBO N = 99	TOTAL N = 200
Age, years, mean (SD)	34.78 (9.72)	35.34 (10.71)	35.06 (10.23)
Sex, n (%)			
Female	60 (59.4)	63 (63.6)	123 (61.5)
Race, n (%)			
African American	5 (4.95)	4 (4.04)	9 (4.50)
White	95 (94.06)	94 (94.95)	189 (94.50)
American Indian	1 (0.99)	1 (1.01)	2 (1.00)
Ethnicity, n (%)			
Hispanic	5 (4.95)	4 (4.04)	9 (4.50)
Region of Enrollment, n (%)			
United States	44 (43.56)	47 (47.48)	91 (45.50)
Canada	35 (34.65)	35 (35.35)	70 (35.00)
Mexico	22 (21.78)	17 (17.17)	39 (19.50)
QTF Classification of Spinal Disorder*			
Class 0, n (%) – *no pain*	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – *pain without radiation*	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – *pain with proximal extremity radiation*	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m2, mean (SD)	26.65 (4.50)	27.41 (4.72)	27.03 (4.63)
Short Pain Scale (SPS-11) Score, mean (SD)**	6.48 (1.34)	6.57 (1.73)	6.52 (1.55)
Duration of Disc Herniation, years, mean (SD)	3.82 (3.18)	3.47 (2.95)	3.65 (3.07)
Height, cm, mean (SD)	186.42 (9.46)	176.91 (8.28)	181.71 (10.09)
Weight, kg, mean (SD)	77.03 (14.38)	78.53 (13.56)	77.77 (14.00)

* Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from 0 (no pain) to Class 7 (spinal stenosis).

** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain on the SPS-11 ranges from 0 (no pain) to 10 (worst possible pain).

Click on the **Edit** button next to the Baseline Measure Description to include additional descriptive information about the measure, if necessary.

- Quebec Task Force Classification of Spinal Disorders: Include the information highlighted in the first footnote for table 1.
- Sex: Female, Male; Race (NIH/OMB); Ethnicity (NIH/OMB); and Region of Enrollment: No additional information is needed for these measures.



Step 18

Select a Measure Type, if necessary.

- Quebec Task Force Classification of Spinal Disorders: Select “Count of Participants” to most accurately represent the data reported.
- Region of Enrollment: Change from “Number” to “Count of Participants” to allow data in the Total column to be automatically summed for each row.
- Sex: Female, Male; Race (NIH/OMB); and Ethnicity (NIH/OMB): The Measure Type has been preselected.

Step 19

Click on the **+ Add Category** and/or **+ Add Row** buttons as many times as necessary to include all the data assessed as part of the measure. Provide distinct Category or Row Titles.

- Quebec Task Force Classification of Spinal Disorders: Use three categories when reporting these data to allow the automated system validations to check that the sum of participants equals the number analyzed for each arm/group and the total. (Note: “Count of Participants” must be selected as the Unit of Measure for these validations to work.)
- Region of Enrollment: Locations provided in the Protocol Section will be used to automatically populate the table. Other locations can be added by clicking on the **+ Add Region** button, and existing locations can be edited or deleted.
- Sex: Female, Male; Race (NIH/OMB); and Ethnicity (NIH/OMB): Categories for these measures have been predefined.

Step 20

Enter the data for each arm/group. Enter data for the entire study population (Total column) if the totals have not been calculated automatically.

- Quebec Task Force Classification of Spinal Disorders: The totals will be calculated automatically for each category if “Count of Participants” is selected as the Measure Type.

In addition, automated system validations will check that the sum of participants equals the number analyzed for each arm/group and the total.

- Region of Enrollment: The totals will be calculated automatically for each category if "Count of Participants" is selected as the Measure Type. When entering data for this baseline measure, verify that all the participants included in the Number Analyzed row are represented and distributed in a consistent way.
- Sex: Female, Male; Race (NIH/OMB); and Ethnicity (NIH/OMB): The totals will be calculated automatically for each category. Automated system validations will check that the sum of participants equals the number analyzed for each arm/group and the total.

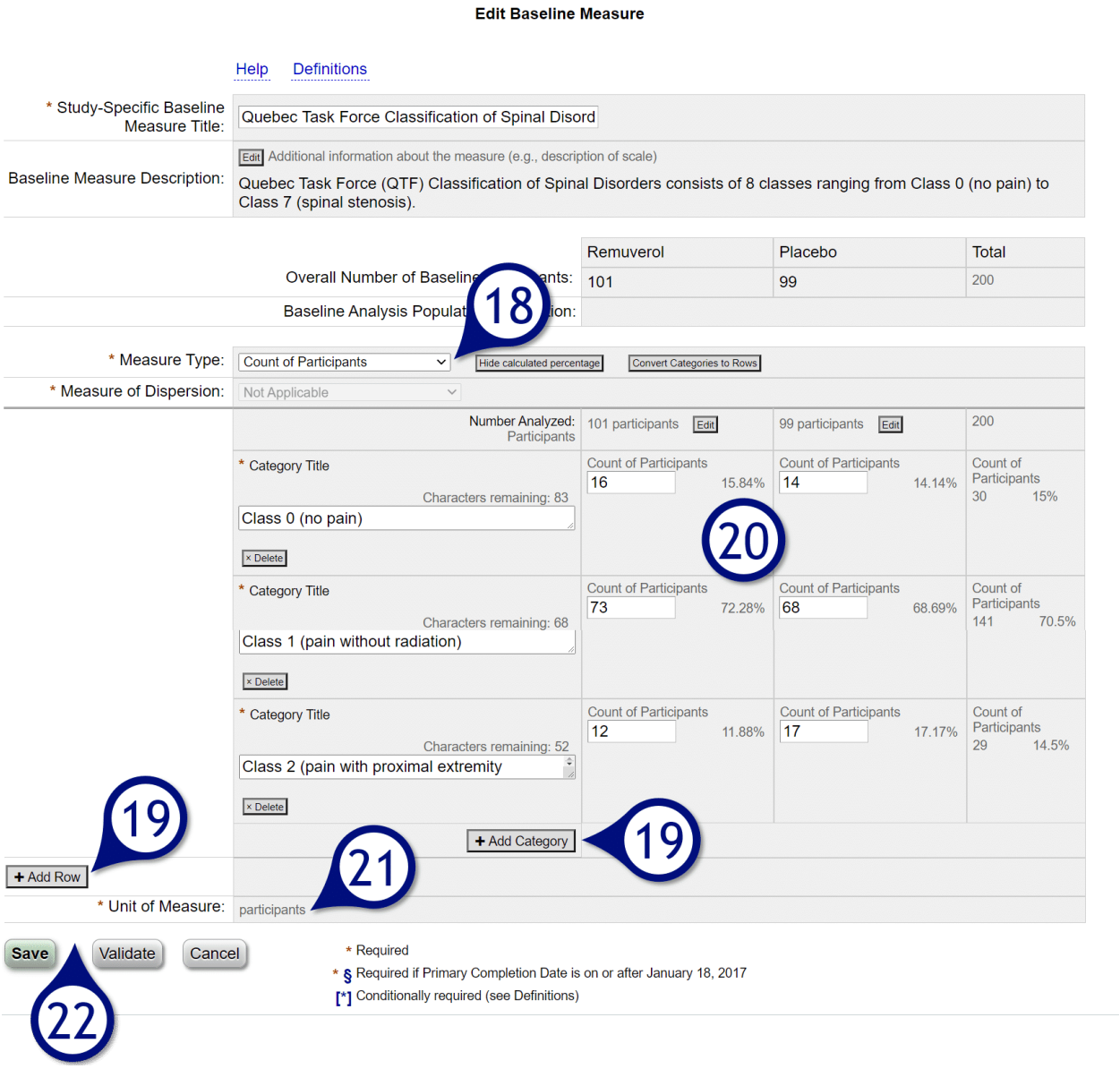
Step 21

Enter a Unit of Measure if one does not appear automatically.

- Quebec Task Force Classification of Spinal Disorders and Region of Enrollment: "Participants" will appear automatically if "Count of Participants" is selected as the Measure Type.
- Sex: Female, Male; Race (NIH/OMB); and Ethnicity (NIH/OMB): "Participants" will appear automatically for these measures.

Step 22

Before leaving the Edit Baseline Measure page, click on the **Validate** button to check for system validation messages that should be addressed. Address any error messages, and review any warnings or notes carefully and address them if necessary. Then click on the **Save** button to save your work and return to the Baseline Measures Overview page.



Enter data for the remaining discrete baseline measures by repeating steps 16–22.

Return to the Results Section page by clicking on the **Results Section** link at the top of the Baseline Measures Overview page.