

Baseline Characteristics Data Entry Walkthrough

Step 1

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

Results Section

[Record Summary](#) [Preview Results](#) [Download Results XML](#) [Delete Results](#) [Help](#) [Definitions](#)

[Open](#) **Participant Flow**
Pre-assignment Details
Of 205 enrolled participants, 200 met inclusion criteria and were randomized to treatment.
Trial Period: Overall Study Total Started: 200 [Protocol Enrollment: 205]

[Edit](#) **Baseline Characteristics**
Information is required

[Open](#) **Outcome Measures**
Information is required

[Edit](#) **Adverse Events**
Information is required

[Edit](#) **Limitations and Caveats**
[Not Specified]

[Open](#) **More Information**
Certain Agreements
[Relationship of Principal Investigator and Sponsor not specified.]
Information is required
Results Point of Contact
Name/Official Title: ---
Organization: ---
Phone: ---
Email: ---
Information is required

Step 2

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

Select Baseline Arms/Groups

Before entering Baseline data, use a Select button to define the Arms/Groups in your study. You can edit the information on the next screens.

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

Copy from: Participant Flow Select		Arm/Group	Arm/Group
	Title	Remuverol	Placebo
	Description	Participants received Remuverol 15 mg tablet orally twice daily for 24...	Participants received Remuverol placebo tablet matching Remuverol...

Create: **New**
Select

Define New Arms/Groups

2

Cancel

Step 3

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

Edit Baseline Arms/Groups

Arms/Groups copied from: Participant Flow

[+ Add Arm/Group](#) [Help](#) [Definitions](#)

	Characters remaining: 91	Characters remaining: 93
* Arm/Group Title:	Remuverol	Placebo
* § Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks. Remuverol: Remuverol 15 mg tablet	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks. Placebo: Remuverol placebo tablet
	x Delete Move ►	x Delete ◀ Move

3

[Save](#) [Cancel](#)

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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	PLACEBO	TOTAL
	N = 101	N = 99	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	<input checked="" type="checkbox"/>	Age, Continuous	Example
	<input type="checkbox"/>	Age, Categorical ≤18 years; 18 to 65 years; ≥65 years	Example
	<input type="checkbox"/>	Age, Customized	Example
* Sex/Gender At least 1 is Required	<input checked="" type="checkbox"/>	Sex: Female, Male	Example
	<input type="checkbox"/>	Sex/Gender, Customized	Example
* § Race and Ethnicity	<input checked="" type="checkbox"/>	Race (NIH/OMB)	Example
	<input checked="" type="checkbox"/>	Ethnicity (NIH/OMB)	Example
	<input type="checkbox"/>	Race/Ethnicity, Customized	Example
	<input type="checkbox"/>	Race and Ethnicity Not Collected	Example
Region of Enrollment Pre-filled with countries from Locations in Protocol	<input checked="" type="checkbox"/>	Region of Enrollment	Example
* § Study-Specific Measures Additional Baseline Measures assessed in the study, if any.	<input type="button" value="+ Add"/>		Example

* 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.

Add Baseline Measures

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

* Baseline Measure Title:

* Age At least 1 is Required	<input checked="" type="checkbox"/>	Age, Continuous	Example
	<input type="checkbox"/>	Age, Categorical ≤18 years; 18 to 65 years; ≥65 years	Example
	<input type="checkbox"/>	Age, Customized	Example
* Sex/Gender At least 1 is Required	<input checked="" type="checkbox"/>	Sex: Female, Male	Example
	<input type="checkbox"/>	Sex/Gender, Customized	Example
* § Race and Ethnicity	<input checked="" type="checkbox"/>	Race (NIH/OMB)	Example
	<input checked="" type="checkbox"/>	Ethnicity (NIH/OMB)	Example
	<input type="checkbox"/>	Race/Ethnicity, Customized	Example
	<input type="checkbox"/>	Race and Ethnicity Not Collected	Example
Region of Enrollment Pre-filled with countries from Locations in Protocol	<input checked="" type="checkbox"/>	Region of Enrollment	Example
* § Study-Specific Measures Additional Baseline Measures assessed in the study, if any.	+ Add	Study-Specific Baseline Measure Title(s):	Example
		Quebec Task Force Classification of Spinal Disorders	x Delete
		Body Mass Index	x Delete
		Short Pain Scale (SPS-11) Score	x Delete
		Duration of Disc Herniation	x Delete
		Height	x Delete
		Weight	x Delete

Save

Cancel

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Step 7

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

Baseline Measures Overview				
Results Section	Add Baseline Measure	Reorder Baseline Measures	Help	Definitions
Show All				
Edit	7 Arm/Group Title	Remuverol	Placebo	Total
	► Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	
Edit	Overall Number of Baseline Participants Baseline Measure information is required. Population Description			unknown
Edit Delete	Age, Continuous Baseline Measure information is required.			

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	PLACEBO	TOTAL
	N = 101	N = 99	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 (%) – <i>no pain</i>	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – <i>pain without radiation</i>	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – <i>pain with proximal extremity radiation</i>	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m ² , 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.

Edit Baseline Analysis Population

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

	Remuverol	Placebo
* Overall Number of Baseline Participants:	101	99
<div style="border: 1px solid black; padding: 2px; display: inline-block;">+ Add Units Analyzed</div> (Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).		

Tip: Compare number of baseline participants with numbers in [Participant Flow](#)

[*] Baseline Analysis Population Description:

Information about the analysis population when it is different from the assignment in Participant Flow or information about how participants contribute units.

Characters remaining: 500

9

Save

Validate

Cancel

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

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.

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 the Participants	101	99	200
	Baseline Analysis Population Description			
Edit Delete	Age, Continuous Baseline Measure information is required. Unit of measure: ---			

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	PLACEBO	TOTAL
	N = 101	N = 99	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 (%) – <i>no pain</i>	16 (15.84)	14 (14.14)	30 (15.00)
Class 1, n (%) – <i>pain without radiation</i>	73 (72.28)	68 (68.69)	141 (70.5)
Class 2, n (%) – <i>pain with proximal extremity radiation</i>	12 (11.88)	17 (17.17)	29 (14.50)
Body Mass Index (BMI), kg/m ² , 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/m²” 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.

Baseline Characteristics Data Entry Walkthrough

Edit Baseline Measure

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

* Baseline Measure Title: Age, Continuous

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

11 Overall Number of Baseline Participants:

Remuverol	Placebo	Total
101	99	200

Baseline Analysis Population Description:

* Measure Type: Mean 12

* Measure of Dispersion: Standard Deviation

Number Analyzed: Participants	101 participants Edit	99 participants Edit	200
Mean	34.78 13	35.34	35.06
Standard Deviation	9.72	10.71	10.23

+ Add Row

14 * Unit of Measure: years

15 Commonly reported units: years

[Save](#) [Validate](#) [Cancel](#)

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

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.

Edit	Region of Enrollment	Number Analyzed	101 participants		99 participants		200 participants	
Delete	Measure Type: Count of Participants							
	Unit of measure: participants							
	Canada		35	34.65%	35	35.35%	70	35%
	United States		44	43.56%	47	47.47%	91	45.5%
	Mexico		22	21.78%	17	17.17%	39	19.5%
Edit	Quebec Task Force Classification of Spinal Disorders							
Delete	Baseline Measure information is required.							
	Unit of measure: ---							

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	PLACEBO	TOTAL
	N = 101	N = 99	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)
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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)
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QTF Classification of Spinal Disorder*			
Class 0, n (%) – no pain	16 (15.84)	14 (14.14)	30 (15.00)
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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)
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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.

Edit Baseline Measure

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

* Study-Specific Baseline Measure Title: Quebec Task Force Classification of Spinal Disord

Baseline Measure Description:  [Edit](#) Learn more about the measure (e.g., description of scale)
 Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).

	Remuverol	Placebo	Total
Overall Number of Baseline Participants:	101	99	200
Baseline Analysis Population Description:			

* Measure Type: -- Select Measure Type --

* Measure of Dispersion: -- Select Measure of Dispersion --

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.

Baseline Characteristics Data Entry Walkthrough

Edit Baseline Measure

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

* Study-Specific Baseline Measure Title: Quebec Task Force Classification of Spinal Disord

Baseline Measure Description: [Edit](#) Additional information about the measure (e.g., description of scale)
Quebec Task Force (QTF) Classification of Spinal Disorders consists of 8 classes ranging from Class 0 (no pain) to Class 7 (spinal stenosis).

	Remuverol	Placebo	Total
Overall Number of Baseline Participants:	101	99	200
Baseline Analysis Population:			

* Measure Type: Count of Participants [Hide calculated percentage](#) [Convert Categories to Rows](#)

* Measure of Dispersion: Not Applicable

	Number Analyzed: 101 participants Edit	99 participants Edit	200
* Category Title Characters remaining: 83 Class 0 (no pain) x Delete	Count of Participants 16 15.84%	Count of Participants 14 14.14%	Count of Participants 30 15%
* Category Title Characters remaining: 68 Class 1 (pain without radiation) x Delete	Count of Participants 73 72.28%	Count of Participants 68 68.69%	Count of Participants 141 70.5%
* Category Title Characters remaining: 52 Class 2 (pain with proximal extremity) x Delete	Count of Participants 12 11.88%	Count of Participants 17 17.17%	Count of Participants 29 14.5%
+ Add Category			

[+ Add Row](#)

* Unit of Measure: participants

[Save](#) [Validate](#) [Cancel](#)

* Required
* § Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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.