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# Outcome Measures Module

Results Database Train-the-Trainer Workshop  
October 2012

<http://ClinicalTrials.gov>

## FDAAA - Outcomes

“...a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial...including the results of scientifically appropriate tests of the statistical significance of such outcome measures.”

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

FDAAA = Food and Drug Administration Amendments Act of 2007

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## Description of Outcome Measures Module

The Outcome Measures module displays the results and associated statistical analyses for each pre-specified primary and secondary outcome measure. Other outcome measures may also be included.

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## Outcome Measures Journal Article Format

**Table 2. Primary safety assessment of the number of patients with severe, life-threatening, or fatal treatment-related toxicities.**

Variable	AmB (n = 47)	AmB+Fluc400 (n = 48)	AmB+Fluc800 (n = 45)
Related to either study drug			
Overall			
Patients with event	19 (40.4)	18 (37.5)	14 (31.1)
90% CI, % <sup>a</sup>	28.3–53.5	25.8–50.4	19.9–44.3
p <sup>b</sup>		.573	.794
By severity <sup>c</sup>			
Severe	13 (27.6)	13 (27.1)	9 (20.0)
Life-threatening	6 (12.8)	5 (10.4)	5 (11.1)
Fatal	0	0	0
By relatedness <sup>c</sup>			
Probably related	16 (34.0)	16 (33.3)	12 (26.7)
Definitely related	3 (6.4)	2 (4.2)	2 (4.4)
Related to fluconazole			
Overall			
Patients with event	0	0	2 (4.4)

© 2009 Infectious Diseases Society of America

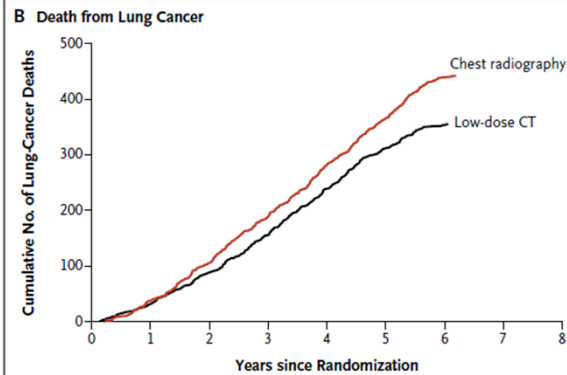
4

<b>ClinicalTrials.gov Format</b>	
<b>Measure Type</b>	Primary
<b>Measure Title</b>	Number of Grade 3-5 Adverse Experiences That Are Definitely or Probably Related to Study Drug
<b>Measure Description</b>	Events are reported by MedDRA Preferred Term. Grade 3 - Severe. Incapacitating; inability to perform usual activities and daily tasks; significantly affects clinical status; requires therapeutic intervention. Grade 4 - Life-threatening. AE is life-threatening. Grade 5 - Death. AE causes death.
<b>Time Frame</b>	Day 100
<b>Safety Issue</b>	Yes
<b>Population Description</b>	
Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.	
The Regulatory Safety population includes all subjects who were randomized, who receive at least 1 dose of study drug, and who have any on-study data.	
NCT00145249	5

<b>ClinicalTrials.gov Format (cont.)</b>			
<b>Measured Values</b>			
	AmphoB Standard	AmphoB+Fluc400	AmphoB + Fluc800
<b>Number of Participants Analyzed</b> [units: participants]	45	47	49
<b>Number of Grade 3-5 Adverse Experiences That Are Definitely or Probably Related to Study Drug</b> [units: Events]			
Hypomagnesaemia	2	1	0
Hypokalaemia	0	0	1
Anaemia	1	1	0
Drug intolerance	1	0	0
Creatinine renal clearance increased	0	0	1
Psychotic disorder	0	0	1
NCT00145249			6

## Outcome Measures Journal Article Format

“ After the accrual of 144,103 person-years in the low-dose CT group and 143,368 person-years in the radiography group, 356 and 443 deaths from lung cancer in the two groups, respectively, had occurred ...”



**Figure 1. Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.**  
The number of lung cancers (Panel A) includes lung cancers that were diagnosed from the date of randomization through December 31, 2009. The number of deaths from lung cancer (Panel B) includes deaths that occurred from the date of randomization through January 15, 2009.

N Engl J Med 365:5 August 2011

## Outcome Measures ClinicalTrials.gov Format

### Measured Values

	LDCT Screening	CXR Screening
<b>Number of Participants Analyzed</b> [units: participants]	26722	26732
<b>Lung Cancer Deaths</b> [units: Participants]	356	443

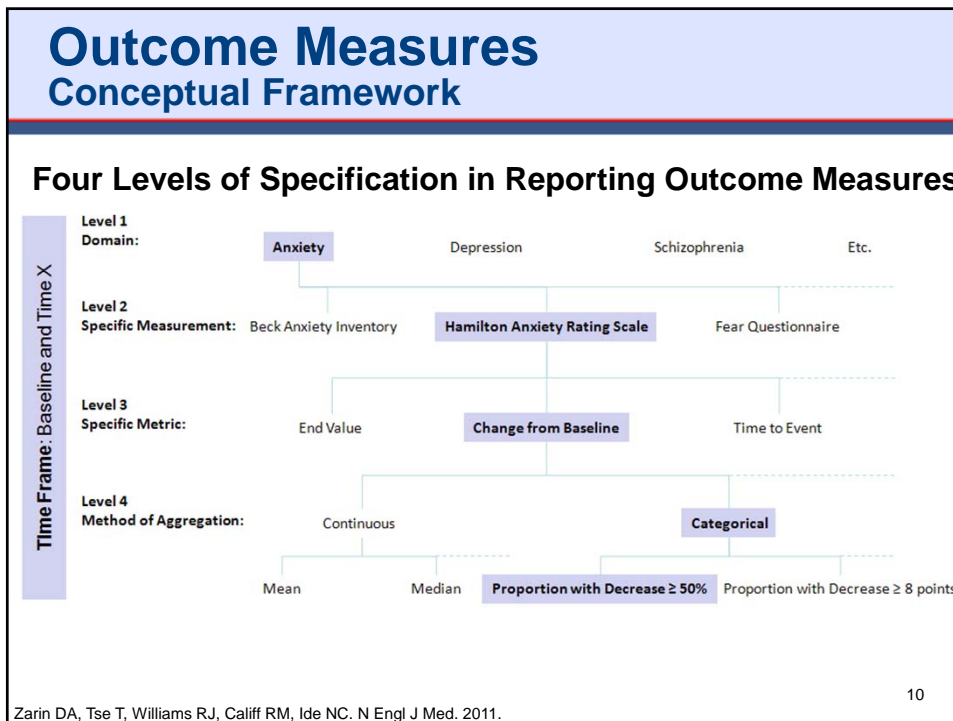
### Statistical Analysis 1 for Lung Cancer Deaths

<b>Groups</b> <sup>[1]</sup>	All groups
<b>Method</b> <sup>[2]</sup>	Weighted log-rank (details below)
<b>P Value</b> <sup>[3]</sup>	0.004
<b>Hazard Ratio (HR)</b> <sup>[4]</sup>	0.800
<b>95% Confidence Interval</b>	( 0.733 to 0.932 )

NCT00047385

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<b>Outcome Measure Template</b>					
<b>Measure Type*</b>	(Circle One) Primary	Secondary	Other Pre-specified	Post-Hoc	<b>Safety Issue?*</b> (Circle One) Yes No
<b>Measure Title*</b>					
<b>Measure Description</b>					
<b>Measure Timeframe*</b>					
<b>Analysis Population Description</b>					
<i>Outcome Data Table</i>		[1]	[2]	[3]	
<b>Unit of Measure*</b>	<b>Arm/Group Title*</b>				
	<b>Arm/Group Description*</b>				
	<b>Number of Participants Analyzed*</b>				
<b>Number / Central Tendency*</b> (Circle One and enter numeric value in each column)	Number Mean Median Least Squares Mean Geometric Mean Log Mean				
<b>Dispersion/Precision*</b> (Circle One and enter values in each column)	Not Applicable Standard Deviation (Use only with Number) (Do NOT use with Number) Inter-quartile Range (Low to High) (Do NOT use with Number) Full Range (Low to High) (Do NOT use with Number) Standard Error (Do NOT use with Number) 95% Confidence Interval (Low to High) 90% Confidence Interval (Low to High)				



## Specification of Outcome Measures in Protocol

Level	Primary OMs (% Total) n=100
1 – Domain (only)	36%
2 – Specific Measurement	25%
3 – Specific Metric	26%
4 – Method of Aggregation	13%
Included Specific Timeframe	63%

Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. N Engl J Med. 2011.

## Best Practices

- If the Number of Participants Analyzed is not the same as a “row” (Started, Completed, Other Milestone) in Participant Flow, describe the population in the Analysis Population Description
- Use multiple Outcome Measures to report results for the same measure at multiple time points
- If the reporting groups are different from Participant Flow Arm/Groups, use Outcome Measure Arm/Group Title/Descriptions to explain and relate to Participant Flow Arm/Group Title/Descriptions

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# Outcome Measures Tutorial

**Results : Overview**

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure	Limitations and Caveats	Adverse Events
Title: Example Parallel Study Design*****			ID: FDXAR -no results			
<a href="#">Edit Protocol</a>	<a href="#">Delete Results</a>	<a href="#">Preview Results</a>				

[Expand All](#)

[Edit](#) **Results Point of Contact:** Name/Official Title:  
 Contact: Organization:  
 Phone:  
 Email:  
 ● ERROR : Neither Phone nor Email was entered for results Point of Contact.  
 ● ERROR : Results Point of Contact Name/Official Title has not been entered.  
 ● ERROR : Results Point of Contact Organization has not been entered.

[Edit](#) **Certain Agreements:** [Relationship of Principal Investigator and Sponsor not specified.]  
 ● ERROR : The Certain Agreement question about PI employment has not been answered.

[Edit](#) [Preview](#) **Participant Flow:** Trial Period: Overall Study [Expand Section](#)

[Edit](#) [Preview](#) **Baseline Characteristics:**

Overall Number of Baseline Participants	<a href="#">Expand Section</a>
Age Continuous	<a href="#">Expand Section</a>
Gender, Male/Female	<a href="#">Expand Section</a>
Race/Ethnicity, Customized	<a href="#">Expand Section</a>
Region of Enrollment	<a href="#">Expand Section</a>
Study Specific Characteristic [Quebec Task Force Classification of Spinal Disorders]	<a href="#">Expand Section</a>
Study Specific Characteristic [Body Mass Index]	<a href="#">Expand Section</a>
Study Specific Characteristic [Short Pain Scale (SPS-11) Score]	<a href="#">Expand Section</a>
Study Specific Characteristic [Duration of Condition A]	<a href="#">Expand Section</a>
Study Specific Characteristic [Height]	<a href="#">Expand Section</a>
Study Specific Characteristic [Weight]	<a href="#">Expand Section</a>

[Edit](#) [Preview](#) **Outcome Measures:**

1 Primary Outcome	Not Posted	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 <i>[Week 24]</i> <i>Safety Issue? Unknown</i>	
2 Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 12 <i>[Week 12]</i> <i>Safety Issue? Unknown</i>	
3 Secondary Outcome	Not Posted	Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 24 <i>[Week 24]</i> <i>Safety Issue? Unknown</i>	

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## Outcome Overview

**Results**

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	<b>Outcome Measure Outcome Overview</b>	Limitations and Caveats	Adverse Events
--------------------------	--------------------	------------------	----------	---	-------------------------	----------------

Title: Example Parallel Study Design\*\*\*\*\* ID: FDXAR -no results

[Results Overview](#)   [Preview Outcome Measures](#)

**Need help?** The [Outcome Measure Simplified Form Examples](#) show the type of information needed to report Results for an Outcome Measure. Also, the webinar on the [Outcome Measures and Statistical Analyses Module](#) provides an overview of the purpose and specific, required data elements.

[Add Outcome Measure](#)   [Reorder Outcome Measures](#)   [Expand All](#)

**ERROR : At least one Primary Outcome Measure must "Post" Results data.**

1

<b>Not Posted</b>	<p>Type : <b>Primary</b> Title: <b>Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24</b></p> <p>Time Frame: Week 24</p> <p>Description:</p> <p>Safety Issue? Unknown</p> <p><a href="#">Post Outcome Measure</a>   <a href="#">Edit Title Fields</a>   <a href="#">Delete</a></p> <p><b>WARNING : Outcome Safety Issue? has not been entered.</b></p>
-------------------	---

2

<b>Not Posted</b>	<p>Type : <b>Secondary</b> Title: <b>Number of Patients With a 50 Percent or Greater Reduction in Pain as Determined by SPS-11 at Week 12</b></p> <p>Time Frame: Week 12</p> <p>Description:</p> <p>Safety Issue? Unknown</p> <p><a href="#">Post Outcome Measure</a>   <a href="#">Edit Title Fields</a>   <a href="#">Delete</a></p> <p><b>WARNING : Outcome Safety Issue? has not been entered.</b></p>
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## Outcome Measure Arm/Groups

**Results**

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	<b>Outcome Measure Initial Outcome Measure Arm/Groups</b>	Limitations and Caveats	Adverse Events
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Title: Example Parallel Study Design\*\*\*\*\* ID: FDXAR -no results

[Arm/Group\\*](#)

Select the Arm/Groups for this [Outcome Measure](#). The Arm/Groups define columns for reporting tabular Outcome Measure data. You will be able to edit the Arm/Group Titles and Descriptions later, if desired.

<input checked="" type="radio"/> <b>Use Arm/Groups (i.e., columns) from</b> 2 Participant Flow	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 15%;">Arm/Group Title</th> <td>Remuverol</td> <td>Placebo</td> </tr> <tr> <th style="width: 15%;">Arm/Group Description</th> <td>Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.</td> <td>Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.</td> </tr> </table>	Arm/Group Title	Remuverol	Placebo	Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.	<input type="radio"/> <b>Define New Arm/Groups (columns)</b>
Arm/Group Title	Remuverol	Placebo						
Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.						

[Continue](#)   [Cancel](#)



## Outcome Measure Data

**Results**

Results Point of Contact    Certain Agreements    Participant Flow    Baseline    **Outcome Measure**    Limitations and Caveats    Adverse Events

Outcome Measure Data

Title: Example Parallel Study Design\*\*\*\*\*    ID: FDXAR -no results

**Outcome Measure Type\*** Primary

**Outcome Measure Title\*** Current length: 21 [Maximum allowed content length: 1011]  
Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24

**Outcome Measure Description** Maximum allowed content length: 999

**Outcome Measure Time Frame\*** Week 24

**Safety Issue (FDAAA)** Is this outcome measure assessing a safety issue?  
No

**Save and Validate**

**Enter Outcome Data**

Arm/Group Title should be descriptive, yet concise, to provide context for tabular data. Examples: Medication, Lifestyle counseling, Placebo

Arm/Group Title and Description*	Primary Arm/Group	Placeholder	Placeholder
<p><b>Number of Participants Analyzed*</b></p> <p><b>Analysis Population Description</b></p> <p><b>Number of Outcome Events*</b></p> <p><b>Number of Outcome Events*</b></p>	<p><b>Maximum allowed content length (999)</b></p> <p>Participants assessed themselves at night weekly using a 11-point Short Pain Scale (SPS-11) at week 24.</p> <p><b>ERROR: The Number of Participants Analyzed has not been entered for an Outcome Measure group.</b></p> <p><b>ERROR: The Number of Participants Analyzed has not been entered for an Outcome Measure group.</b></p> <p><b>ERROR: A Measure Number of Control Treatment Values has not been entered.</b></p> <p><b>ERROR: A Measure Number of Control Treatment Values has not been entered.</b></p>	<p><b>Maximum allowed content length (999)</b></p> <p>Participants assessed themselves at night weekly using a validated instrument weekly using the 24 weeks.</p> <p><b>ERROR: The Number of Participants Analyzed has not been entered for an Outcome Measure group.</b></p> <p><b>ERROR: A Measure Number of Control Treatment Values has not been entered.</b></p>	<p><b>Maximum allowed content length (999)</b></p> <p>Participants assessed themselves at night weekly using a validated instrument weekly using the 24 weeks.</p> <p><b>ERROR: A Measure Number of Control Treatment Values has not been entered.</b></p>

**Unit of Measure\*** (e.g., mm Hg)  per participant  per time point  per both a unit  per percentage of control

**Save and Validate**    **Save and Continue**    **Cancel**

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## Outcome Measure Data (cont.)

**Results**

Results Point of Contact    Certain Agreements    Participant Flow    Baseline    **Outcome Measure**    Limitations and Caveats    Adverse Events

Outcome Measure Data

Title: Example Parallel Study Design\*\*\*\*\*    ID: FDXAR -no results

**Outcome Measure Type\*** Primary

**Outcome Measure Title\*** Maximum allowed content length (255)  
Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24

**Outcome Measure Description** Current length: 202 [Maximum allowed content length: 999]  
SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr period. The severity of pain scores on the SPS-11 range from 0 (no pain) to 10 (worst possible pain).

**Outcome Measure Time Frame\*** Baseline and Week 24

**Safety Issue (FDAAA)** Is this outcome measure assessing a safety issue?  
No

**Save and Validate**

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## Outcome Measure Data (cont.)

**Enter Outcome Data**

Arm/Group Title should be descriptive, yet concise, to provide context for tabular data. Examples: Metformin, Lifestyle counseling, Sugar pill

**+ Add Arm/Group**

<b>Arm/Group Title* and Description*</b>	<input type="button" value="Remove Arm/Group"/> Remuverol <input type="button" value="Move Right"/>	<input type="button" value="Remove Arm/Group"/> Placebo <input type="button" value="Move Left"/>
	Maximum allowed content length (999) Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Maximum allowed content length (999) Participants received Remuverol placebo tablet matching Remuverol orally twice daily for 24 weeks.
<b>Number of Participants Analyzed:*</b>	101 <b>ERROR : The Number of Participants Analyzed has not been entered for an Outcome Measure group.</b>	99 <b>ERROR : The Number of Participants Analyzed has not been entered for an Outcome Measure group.</b>
	<input checked="" type="checkbox"/> Report Units Analyzed other than participants (e.g., eyes, lesions, implants) (Not necessary for most studies)	
<b>Analysis Population Description:</b>	Please explain how the number of participants for analysis was determined. Current length: 152 [Maximum allowed content length: 350] Intent to treat population (all participants who received at least one dose of intervention). Last observation carried forward (LOCF) imputation method.	

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## Outcome Measure Data (cont.)

<b>Measure Type:*</b>	Mean	-3.84
	<b>ERROR : Measure Type (e.g., Number, Mean, etc.) has not been entered.</b>	<b>ERROR : A Measure Number of Central Tendency Value has not been entered.</b>
<b>Measure of Dispersion/Precision:*</b>	Standard Error	0.61
	<b>ERROR : Measure of Dispersion/Precision Type (e.g., Standard Deviation, Full Range, etc.) has not been entered.</b>	<b>ERROR : A Measure Number of Central Tendency Value has not been entered.</b>
		0.51
		-2.08

**+ Add Category**

**Unit of Measure\*** units on a scale (e.g., mm Hg)  use participants  use years  use units on a scale  use percentage of <something>

If the Measure Type is "Number", the Unit of Measure is typically "participants".

**ERROR : An Outcome Measure Unit of Measure has not been entered.**

Save and Validate **Save and Continue** Cancel

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## Outcome Overview

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Outcome Overview	Limitations and Caveats	Adverse Events
Title: Example Parallel Study Design*****			ID: FDXAR -no results			
<div style="border: 1px solid #ccc; padding: 5px;"> <p><b>Posted</b> <span style="float: right;">Type : <b>Primary Title: Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24</b></span></p> <p><i>Time Frame: Baseline and Week 24</i></p> <p><i>Description: SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr...</i></p> <p><i>Safety Issue? No</i></p> <p style="font-size: small;"> <a href="#">Un-Post/Delete</a>    <a href="#">Copy</a> </p> <p style="text-align: right;"><a href="#">Collapse Section</a></p> </div>						
<b>Edit</b>						
	Remuverol <i>Participants received Remuverol...</i>			Placebo <i>Participants received Remuvero...</i>		
<i>Number of Participants Analyzed</i>	101			99		
<i>Number of Units Analyzed</i>	Same as Number of Participants Analyzed					
<i>Analysis Population Description</i>	<i>Intent to treat population (all participants who received at least one dose of intervention). Last observation carried forward (LOCF) imputation method.</i>					
<b>units on a scale</b>	<b>Mean ± Standard Error</b>			<b>Mean ± Standard Error</b>		
	-3.84 ± 0.61			-2.08 ± 0.51		
<a href="#">Add Statistical Analysis</a>						

## Add Outcome Statistical Analysis

Results Point of Contact	Certain Agreements	Participant Flow	Baseline	Outcome Measure Add Outcome Statistical Analysis	Limitations and Caveats	Adverse Events
Title: Example Parallel Study Design*****			ID: FDXAR -no results			
<div style="border: 1px solid #ccc; padding: 5px;"> <p><b>Posted</b>    <b>Primary Outcome: Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24 ; Units: units on a scale [Baseline and Week 24]</b></p> </div>						
<p><b>Comparison Group Selection: *</b> Generally, at least 2 groups should be checked. Check all groups for an "omnibus" analysis.</p> <p><input checked="" type="checkbox"/> Remuverol    <input checked="" type="checkbox"/> Placebo</p> <p>Please provide additional details about the analysis, such as null hypothesis and power calculation. Current length: 272 [Maximum allowed content length: 500]</p> <div style="border: 1px solid #ccc; padding: 5px; font-size: small;"> <p>It was calculated for this study that, approximately 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α = 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.</p> </div> <p><b>Statistical Analysis Overview:</b></p> <p>Is this a non-inferiority or equivalence analysis? * No</p> <p><b>ERROR : Please enter whether the Statistical Analysis tested for Non-inferiority or Equivalence.</b> If yes, please describe details of power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters. Maximum allowed content length (500)</p> <div style="border: 1px solid #ccc; height: 20px; width: 100%;"></div>						

## Add Outcome Statistical Analysis (cont.)

**P-Value:** (e.g., <0.01) 0.002

**NOTE:** Both P-Value and estimated Confidence Interval have not been entered for a Statistical Analysis.  
**ERROR:** Either P-Value or estimated Confidence Interval or Estimated Value must be entered for a Statistical Analysis.  
If desired, provide additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.  
Maximum allowed content length (250)

**Statistical Test of Hypothesis:**

**Method:** t-test, 2 sided    If other, please specify: \_\_\_\_\_

Describe any other relevant information, such as adjustments or degrees of freedom.  
Maximum allowed content length (150)

**What parameter did you estimate**(e.g., Odds Ratio)?    -- Please Select --

If other, please specify: \_\_\_\_\_

**Estimated Value:** \_\_\_\_\_

When the confidence interval is entered, it must be fully specified. A fully specified confidence interval includes percentage and one of the following:

- 1-sided: enter either the lower or upper limit
- 2-sided (default): enter both lower and upper limits

Also, when a confidence interval is entered, an Estimated Value and parameter must be entered.

**Method of Estimation:** 95 % Confidence Interval:    Number of sides: -- Please Select --

Lower Limit: \_\_\_\_\_  
Upper Limit: \_\_\_\_\_

**Parameter Dispersion Type:** -- Please Select --

Describe any other relevant estimation information, including the direction of the comparison (e.g., describe which Arm/Group represents the numerator and denominator for relative risk).  
Maximum allowed content length (250)

**OK**    **Cancel**

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## Outcome Overview

1 **Posted**    **Type:** Primary    **Title:** Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24  
**Time Frame:** Baseline and Week 24  
**Description:** SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hr...  
**Safety Issue?** No

[View Post/ Delete](#)    [Copy](#)    [Collapse Section](#)

**Edit**

	Remuverol <i>Participants received Remuverol...</i>	Placebo <i>Participants received Remuverol...</i>
<b>Number of Participants Analyzed</b>	101	99
<b>Number of Units Analyzed</b>	Same as Number of Participants Analyzed	
<b>Analysis Population Description</b>	Intent to treat population (all participants who received at least one dose of intervention). Last observation carried forward (LOCF) imputation method.	
<b>units on a scale</b>	<b>Mean ± Standard Error</b>	<b>Mean ± Standard Error</b>
	-3.84 ± 0.61	-2.08 ± 0.51
<b>Statistical Analysis Overview</b>	<b>Comparison Groups</b> Remuverol, Placebo It was calculated for this study that, approximately 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α = 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.	
<b>Outcome 1: Analysis 1</b>	<b>Non-inferiority or Equivalence Analysis?</b> No <b>Statistical P-Value</b> 0.002 <b>Test of Hypothesis Method</b> t-test, 2 sided <b>Method of Estimation Confidence Interval Level:</b> 95 % <b>2-Sided</b> <= to <= < > to < > <b>Estimation Parameter = Estimated Value =</b> <= <=	

[Collapse Analysis](#)    [Add Statistical Analysis](#)

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## Enter Primary Outcome Measure

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

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## Additional Issues

- A pre-specified Outcome Measure is not analyzed (e.g., too few participants enrolled, equipment used for measurement not reliable)
- Certain data are not available (e.g., upper limit of 95% Confidence Interval, assays below detectable limit)
- Data collection is still ongoing and analysis not yet conducted for Secondary Outcome Measures

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