GIMBE EVIDENCE FOR HEALTH

Sperimentazioni Cliniche
Nuove Sfide per i Comitati Etici
Bologna, 7 novembre 2014

Registri di Trial

Cristiana Forni
Istituto Ortopedico Rizzoli

Outline

1. **Overview dei registri di trial**
2. **Come cercare i trial registrati: i meta registri**
3. **Cosa ci consentono di vedere**
4. **Focus su un registro di trial**

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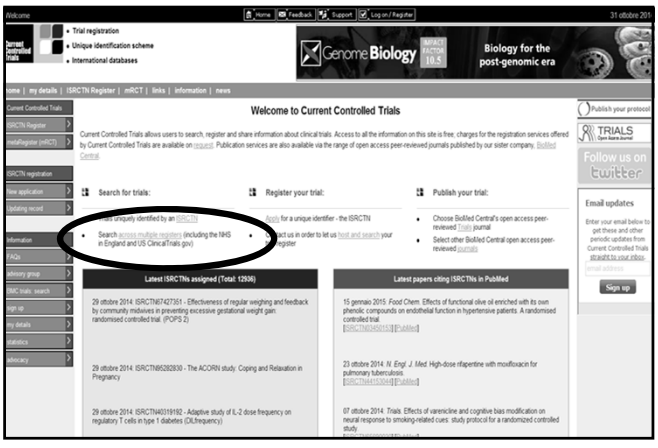
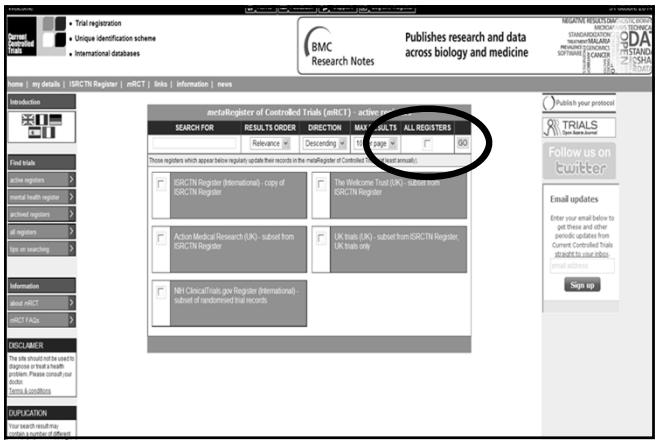
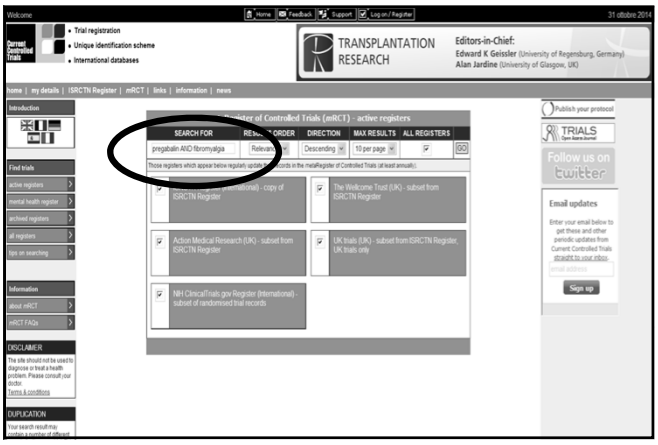
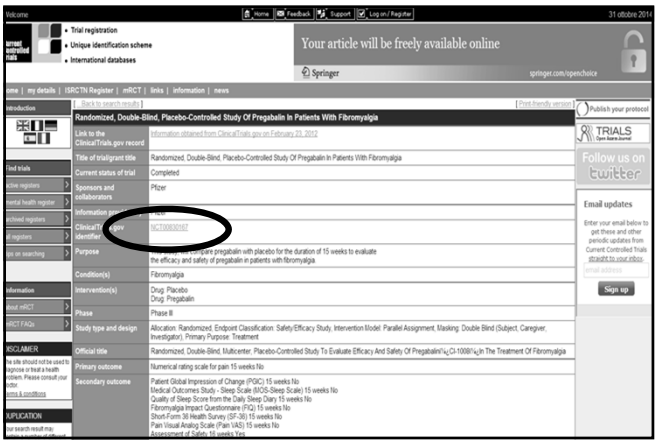


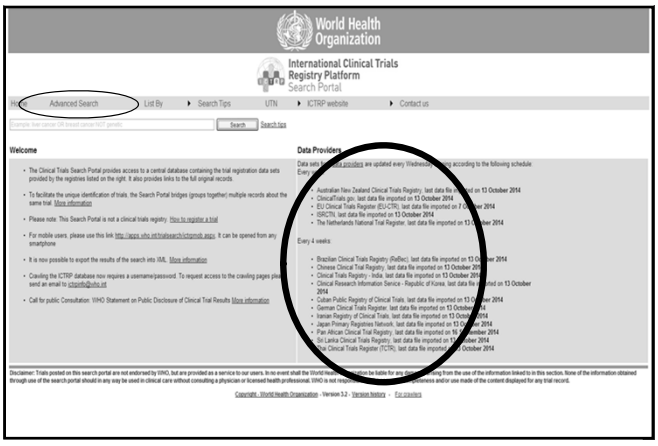


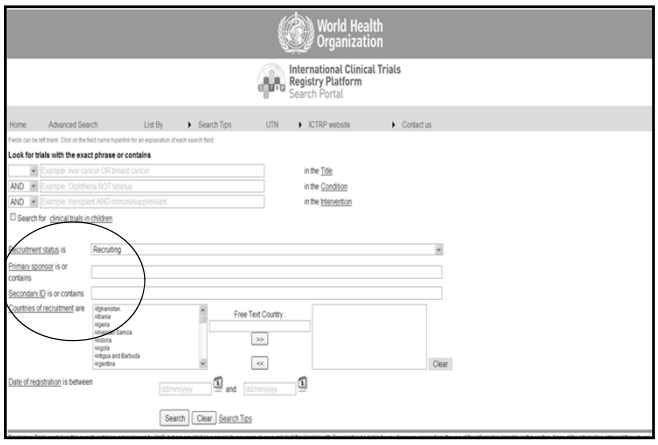


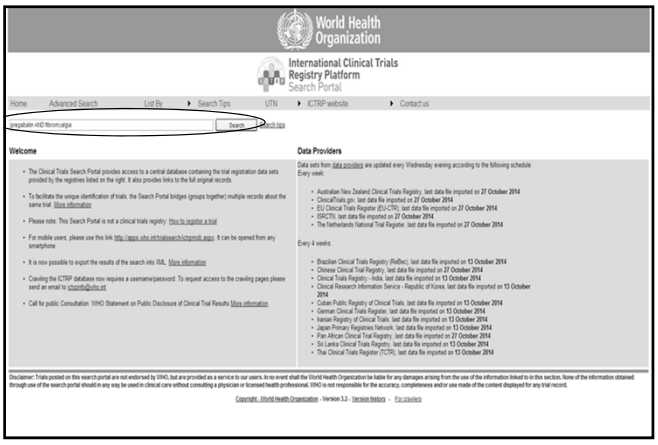


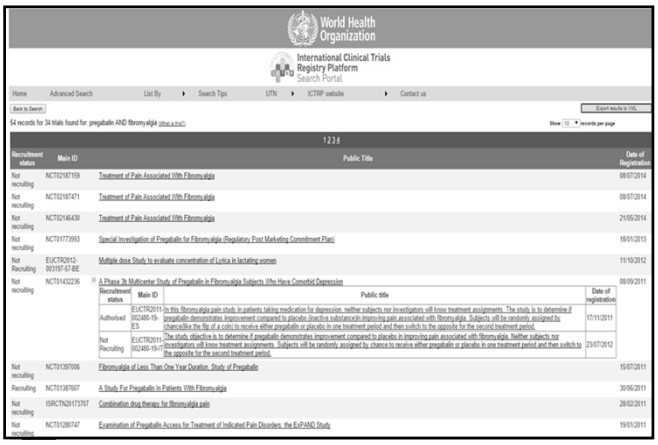
International Clinical Trials Registry Platform (ICTRP)

The mission of the WHO International Clinical Trials Registry Platform is **to ensure that a complete view of research is accessible to all those involved in health care decision making**. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.









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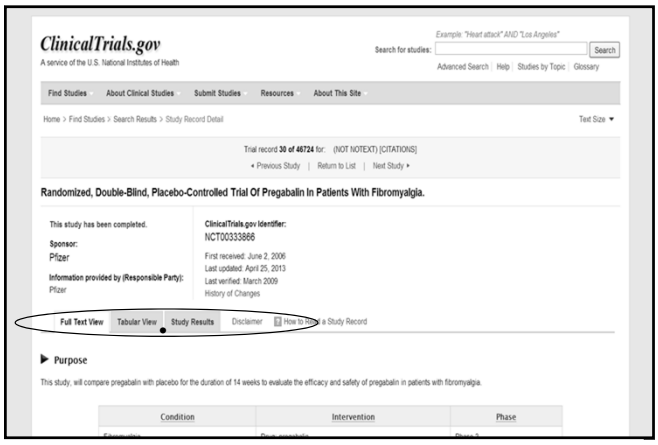
ClinicalTrials.gov
A service of the U.S. National Institutes of Health
Example: "Heart attack" AND "Los Angeles"
Search for studies:
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Advanced Search | Help | Studies by Topic | Glossary
Find Studies
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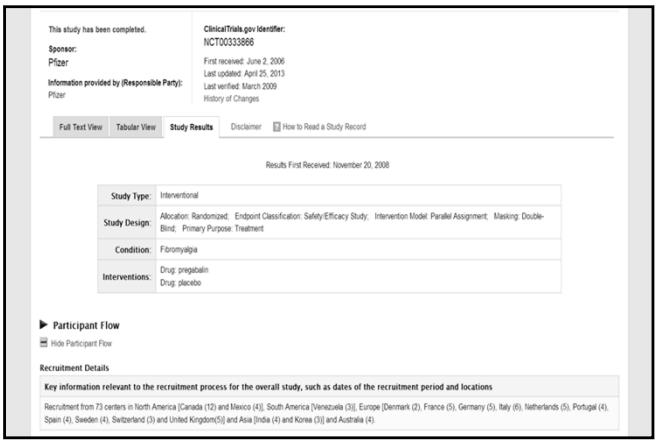
About This Site
Home > Find Studies > Search Results > Study Record Detail
Text Size
Trial record 30 of 46724 for: (NOT NOTEXT) [CITATIONS]
Previous Study | Return to List | Next Study
Randomized, Double-Blind, Placebo-Controlled Trial Of Pregabalin In Patients With Fibromyalgia.
This study has been completed.
Sponsor:
Pfizer
Information provided by (Responsible Party):
Pfizer
ClinicalTrials.gov Identifier:
NCT00333866
First received: June 2, 2006
Last updated: April 25, 2013
Last verified: March 2009
History of Changes
Full Text View
Tabular View
Study Results
Disclaimer
How to Read a Study Record
Purpose
This study, will compare pregabalin with placebo for the duration of 14 weeks to evaluate the efficacy and safety of pregabalin in patients with fibromyalgia.
Condition
Intervention
Phase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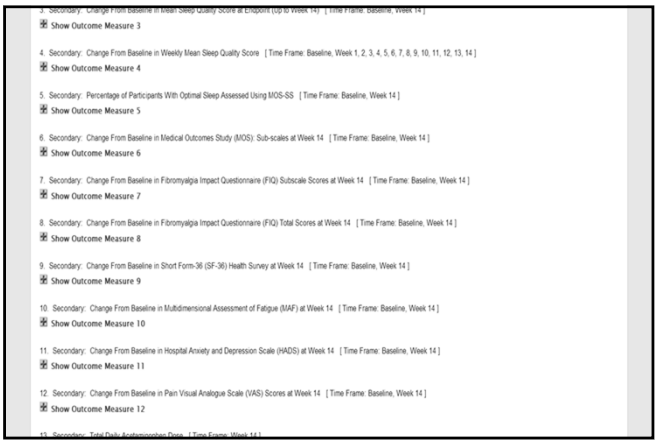
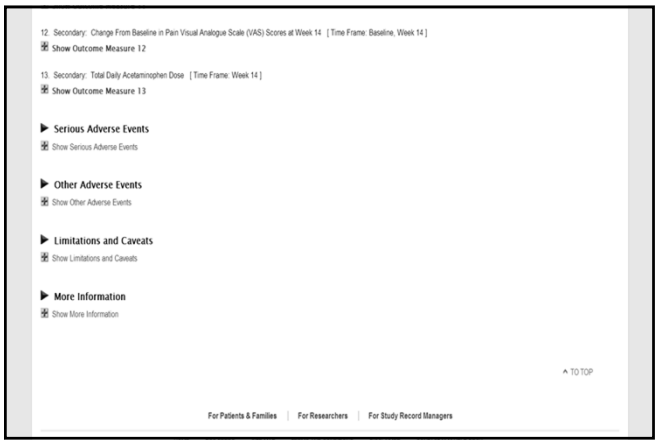
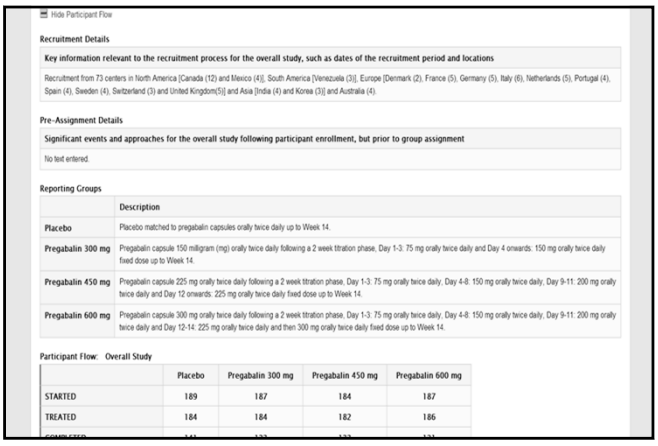
Results First Received: November 20, 2008
Study Type: Interventional
Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double-Blind; Primary Purpose: Treatment
Condition: Fibromyalgia
Interventions: Drug: pregabalin
Drug: placebo
Participant Flow
Hide Participant Flow
Recruitment Details
Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Recruitment from 73 centers in North America [Canada (12) and Mexico (4)], South America [Venezuela (3)], Europe [Denmark (2), France (5), Germany (5), Italy (6), Netherlands (5), Portugal (4), Spain (4), Sweden (4), Switzerland (3) and United Kingdom(5)] and Asia [India (4) and Korea (3)] and Australia (4).


Study Type: Interventional
Study Design: Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double-Blind; Primary Purpose: Treatment
Condition: Fibromyalgia
Interventions: Drug: pregabalin
Drug: placebo
Participant Flow
Show Participant Flow
Baseline Characteristics
Show Baseline Characteristics
Outcome Measures
Show All Outcome Measures
1. Primary: Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]
Show Outcome Measure 1
2. Primary: Patient Global Impression of Change (PGIC) [Time Frame: Week 14]
Show Outcome Measure 2
3. Secondary: Change From Baseline in Mean Sleep Quality Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]
Show Outcome Measure 3


Show Outcome Measure 3
4. Secondary: Change From Baseline in Weekly Mean Sleep Quality Score [Time Frame: Baseline, Week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14]
Show Outcome Measure 4
5. Secondary: Percentage of Participants With Optimal Sleep Assessed Using MOS-SS [Time Frame: Baseline, Week 14]
Show Outcome Measure 5
6. Secondary: Change From Baseline in Medical Outcomes Study (MOS): Sub-scales at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 6
7. Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Subscale Scores at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 7
8. Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Total Scores at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 8
9. Secondary: Change From Baseline in Short Form-36 (SF-36) Health Survey at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 9
10. Secondary: Change From Baseline in Multidimensional Assessment of Fatigue (MAF) at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 10
11. Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 11
12. Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 12


12. Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]
Show Outcome Measure 12
13. Secondary: Total Daily Acetaminophen Dose [Time Frame: Week 14]
Show Outcome Measure 13
Serious Adverse Events
Show Serious Adverse Events
Other Adverse Events
Show Other Adverse Events
Limitations and Caveats
Show Limitations and Caveats
More Information
Show More Information
^ TO TOP
For Patients & Families | For Researchers | For Study Record Managers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Recruitment Details
Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Recruitment from 73 centers in North America [Canada (12) and Mexico (4)], South America [Venezuela (3)], Europe [Denmark (2), France (5), Germany (5), Italy (6), Netherlands (5), Portugal (4), Spain (4), Sweden (4), Switzerland (3) and United Kingdom(5)] and Asia [India (4) and Korea (3)] and Australia (4).
Pre-Assignment Details
Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.
Reporting Groups
Description
Placebo: Placebo matched to pregabalin capsules orally twice daily up to Week 14.
Pregabalin 300 mg: Pregabalin capsule 150 milligram (mg) orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily and Day 4 onwards: 150 mg orally twice daily fixed dose up to Week 14.
Pregabalin 450 mg: Pregabalin capsule 225 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12 onwards: 225 mg orally twice daily fixed dose up to Week 14.
Pregabalin 600 mg: Pregabalin capsule 300 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12-14: 225 mg orally twice daily and then 300 mg orally twice daily fixed dose up to Week 14.
Participant Flow: Overall Study
Placebo | Pregabalin 300 mg | Pregabalin 450 mg | Pregabalin 600 mg
STARTED 189 187 184 187
TREATED 184 184 182 186

Participant Flow: Overall Study

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
STARTED	189	187	184	187
TREATED	184	184	182	186
COMPLETED	141	123	133	121
NOT COMPLETED	48	64	51	66
Adverse Event	23	37	38	47
Unspecified	3	2	2	2
Lack of Efficacy	8	6	3	5
Lost to Follow-up	1	2	2	2
Withdrawal by Subject	8	14	4	9
Randomized but not Treated	5	3	2	1

▶ Baseline Characteristics

Hide Baseline Characteristics

Population Description

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.

Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study medication, regardless of medication compliance.

Baseline Measures

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg	Total
Number of Participants [units: participants]	184	184	182	186	736
Age [units: years] Mean ± Standard Deviation	48.1 ± 11.3	48.4 ± 10.8	48.0 ± 11.3	49.6 ± 11.3	48.5 ± 11.2
Gender [units: participants]					
Female	168	167	169	169	673
Male	16	17	13	17	63
Mean Pain Score [1] [units: Units on a scale] Mean ± Standard Deviation	6.68 ± 1.48	6.76 ± 1.29	6.57 ± 1.31	6.59 ± 1.37	6.65 ± 1.36
Mean Sleep Quality Score [2] [units: Units on a scale] Mean ± Standard Deviation	6.01 ± 1.90	5.94 ± 1.70	5.94 ± 1.70	5.91 ± 1.80	5.95 ± 1.77
Percentage of Participants With Optimal Sleep Assessed Using MOS-SS [3] [units: Percentage of Participants]	20.33	25.27	24.57	17.03	87.2
Medical Outcome Study Sleep Scale (MOS-SS) [4] [units: Units on a scale] Mean ± Standard Deviation					

▶ Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

Measure Type	Primary
Measure Title	Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14)
Measure Description	Daily pain diary consists of 11-point NRS ranging from 0(no pain) to 10(worst possible pain). Participants rated their pain during past 24 hours, self-assessment done daily at awakening. Baseline=Last 7 available pain scores before taking study medication up to and including Day 1. Final weekly (endpoint) mean pain score is defined as the mean pain score from the last 7 pain diary entries in the study while the participant was on study medication.
Time Frame	Baseline, Week 14
Safety Issue	No

Population Description

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.

Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study medication, regardless of medication compliance. Missing data were imputed using last observation carried forward (LOCF) method. 'N' (number of participants analyzed) signifies participants evaluable for this measure.

Reporting Groups

	Description
Placebo	Placebo matched to pregabalin capsules orally twice daily up to Week 14.
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Measured Values

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Number of Participants Analyzed [units: participants]	184	184	181	186
Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [units: Units on a scale] Least Squares Mean ± Standard Error	-0.73 ± 0.14	-1.06 ± 0.14	-1.29 ± 0.14	-0.96 ± 0.14

Statistical Analysis 1 for Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14)

Groups [1]	Placebo vs. Pregabalin 600 mg
Method [2]	ANCOVA
P Value [3]	0.2361
Least Squares (LS) mean difference [4]	-0.23
95% Confidence Interval	(-0.61 to 0.15)

[1] Additional details about the analysis, such as null hypothesis and power calculation:

P value was calculated using Analysis of Covariance (ANCOVA) with treatment and center in the model, and the baseline mean pain score as covariate.

[2] Other relevant method information, such as adjustments or degrees of freedom:

Hochberg's approach was used to protect the Type I error rate at 0.05 level, Hochberg adjusted p-values were presented.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

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Measured Values

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Number of Participants Analyzed [units: participants]	183	179	174	178
Change From Baseline in Weekly Mean Sleep Quality Score [units: Units on a scale] Least Squares Mean ± Standard Error				
Week 1 (n=183,179,174,178)	-0.38 ± 0.14	-1.20 ± 0.15	-1.08 ± 0.15	-1.23 ± 0.15
Week 2 (n=180,172,168,174)	-0.62 ± 0.14	-1.48 ± 0.15	-1.43 ± 0.15	-1.59 ± 0.15
Week 3 (n=174, 164, 159,163)	-0.75 ± 0.15	-1.42 ± 0.15	-1.56 ± 0.15	-1.90 ± 0.15
Week 4 (n=165,157,155,156)	-0.73 ± 0.15	-1.52 ± 0.15	-1.67 ± 0.15	-2.01 ± 0.15
Week 5 (n=163, 150, 152,148)	-0.82 ± 0.15	-1.67 ± 0.15	-1.69 ± 0.15	-1.99 ± 0.15
Week 6 (n=159,145,148,144)	-0.84 ± 0.15	-1.56 ± 0.15	-1.76 ± 0.16	-2.15 ± 0.16
Week 7 (n=155,140,144,133)	-0.91 ± 0.15	-1.50 ± 0.16	-1.83 ± 0.16	-2.20 ± 0.16
Week 8 (n=149,133,142,127)	-0.99 ± 0.15	-1.60 ± 0.16	-1.95 ± 0.16	-2.25 ± 0.16
Week 9 (n=146,128,141,126)	-1.11 ± 0.15	-1.64 ± 0.16	-1.94 ± 0.16	-2.24 ± 0.16
Week 10 (n=144,125,139,126)	-1.14 ± 0.16	-1.75 ± 0.16	-2.03 ± 0.16	-2.34 ± 0.17
Week 11 (n=143,123,137,121)	-1.09 ± 0.16	-1.65 ± 0.17	-1.92 ± 0.16	-2.24 ± 0.17
Week 12 (n=141,121,135,119)	-1.22 ± 0.16	-1.62 ± 0.17	-1.95 ± 0.16	-2.29 ± 0.17
Week 13 (n=140,120,133,118)	-1.05 ± 0.16	-1.66 ± 0.17	-1.93 ± 0.17	-2.26 ± 0.17
Week 14 (n=134,115,128,111)	-1.08 ± 0.16	-1.73 ± 0.17	-1.95 ± 0.17	-2.29 ± 0.18

▶ Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Reporting Groups

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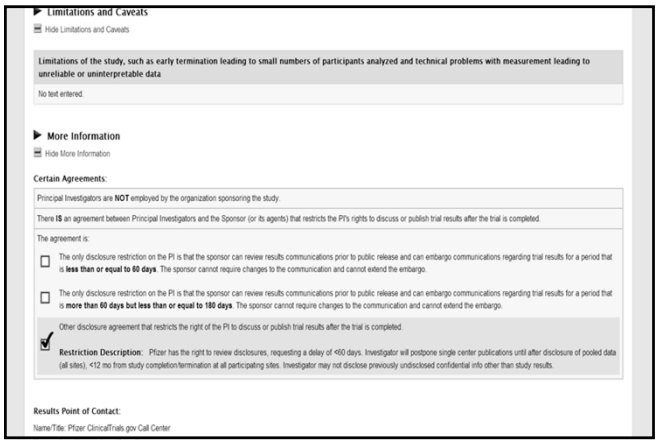
Serious Adverse Events

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Total, serious adverse events				
# participants affected / at risk	4/184 (2.17%)	2/184 (1.09%)	8/182 (4.40%)	4/186 (2.15%)
Blood and lymphatic system disorders				



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