



# CLINICAL TRIAL RESULTS

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

**Sponsor:** Pfizer, Inc.

**Medicine(s) Studied:** Pregabalin (Lyrica®)

**Protocol Number:** A0081106

**Dates of Trial:** 21 February 2012 to 22 August 2019

**Title of this Trial:** A 12-Month Study To Evaluate The Safety And Tolerability Of Pregabalin As Add-On Therapy In Pediatric Subjects 1 Month To 16 Years Of Age With Partial Onset Seizures And Pediatric And Adult Subjects 5 To 65 Years Of Age With Primary Generalized Tonic-Clonic Seizures

[A 12-Month Open-Label Study to Evaluate the Safety and Tolerability of Pregabalin as Adjunctive Therapy in Pediatric Subjects 1 Month to 16 Years of Age With Partial Onset Seizures and Pediatric and Adult Subjects 5 to 65 Years of Age With Primary Generalized Tonic-Clonic Seizures]

**Date of this Report:** 08 May 2020

– *Thank You* –

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

## WHY WAS THIS STUDY DONE?

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Epilepsy is a condition in which a person has recurring seizures. Epilepsy occurs in both adults and children and can affect multiple daily life activities. A seizure is a sudden increase in electrical activity in the brain. Seizures can cause many different symptoms, such as shaking, feeling confused, or losing control of your body.

When a seizure occurs in only one part of the brain, it is known as a partial onset seizure. When a seizure occurs throughout the whole brain, it is known as a generalized seizure. The most common type of generalized seizure is a primary generalized tonic-clonic (PGTC) seizure. Participants were asked to take part in this research study because they were diagnosed with epilepsy with either partial onset or PGTC seizures.

Pregabalin is the medicine that was used during this study. Pregabalin is prescribed by doctors for the treatment of partial onset seizures in young children and adults. Pregabalin is not approved for the treatment of PGTC seizures.

The purpose of this study was to learn more about the safety of pregabalin in children with partial onset seizures, and in children and adults with PGTC seizures.

## WHAT HAPPENED DURING THE STUDY?

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This study evaluated a group of participants to learn more about the safety of pregabalin. The study included participants between the ages of 1 month and 16 years who were diagnosed with epilepsy with partial onset seizures, and participants between the ages of 5 years and 65 years who were diagnosed with epilepsy with PGTC seizures. Some of these participants had participated in a previous study with pregabalin, and all participants were already taking 1 to 3 other treatments for epilepsy (antiepileptic drugs to help prevent seizures) in addition to pregabalin. Participants continued to take their other antiepileptic drugs during the study.

This was an “open-label” study, which means that the participants and the researchers knew which treatments and doses they received during the study. Pregabalin was divided into 2 or 3 daily doses and taken by mouth, either as tablets or a liquid, for approximately 1 year.

For participants between 1 month and 16 years old, the beginning pregabalin dose was based on weight:

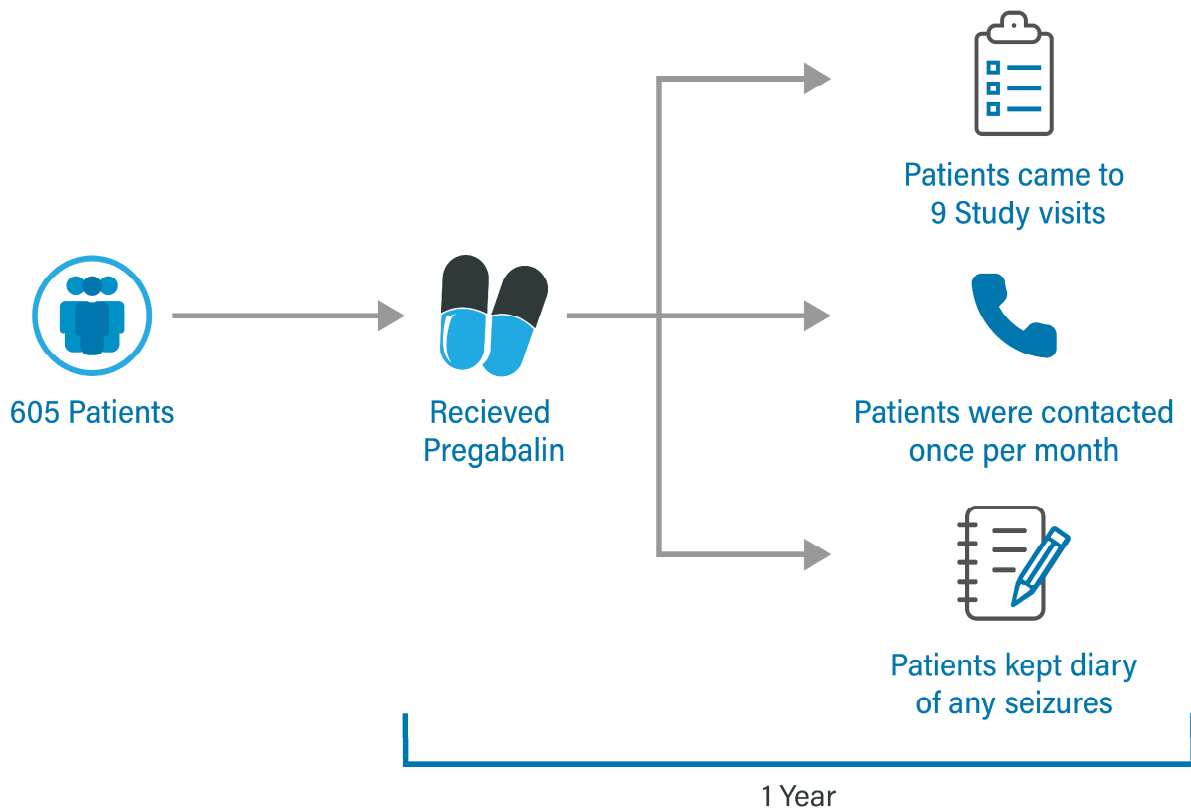
- 2.5 milligrams (mg) for each kilogram (kg) of body weight per day, for participants who weigh 30 kg (66 pounds) or more
- 3.5 milligrams for each kilogram of body weight per day, for participants who weigh less than 30 kg (66 pounds)

For participants 17 years and older, the beginning pregabalin dose was a total of 150 mg per day, divided into 2 daily doses of 75 mg.

The study doctor may have adjusted these doses, as needed, but study participants did not receive more than 600 mg of pregabalin per day.

Participants were asked to attend 9 visits at the study center, and were contacted by phone at least once per month. Participants (or their parents) were also asked to record any seizures in a diary.

The figure on the following page shows what happened during this study.



The sponsor ran this study at 142 locations in 31 countries in Asia, Europe, and North America. It began 21 February 2012 and ended 22 August 2019. A total of 319 (53%) males and 286 (47%) females participated. 491 (81%) participants were 16 years or younger, and 114 (19%) participants were 17 years or older.

A total of 76% (462 of 605) of the participants who started the study, finished. A total of 24% (142 of 605) of the participants left before the study was over by their choice, a doctor decided it was best that they stop the study, or they passed away for a reason not caused by taking pregabalin. Additionally, 1 (less than 1%) participant left the study safely, but further information could not be reported due to an issue with the approval required by local healthcare authorities.

When the study ended in August 2019, the Sponsor reviewed the information collected. The Sponsor then created a report of the results. This is a summary of that report.

## WHAT WERE THE RESULTS OF THE STUDY?

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To learn more about safety, the study doctors did a number of tests and exams, including lab tests, heart tracings, physical exams, exams of the nervous system and brain function, and vital signs (blood pressure and heart rate). There were no meaningful changes found on these tests.

Researchers also collected information on the frequency of seizures that happened during the study. On average, participants had less frequent seizures over the course of 28 days with pregabalin treatment.

This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

## WHAT MEDICAL PROBLEMS DID PARTICIPANTS HAVE DURING THE STUDY?

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The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment, or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across treatment groups in many studies, doctors try to understand what the side effects of an experimental drug might be.

A total of 66% (402 out of 605) of participants had at least 1 medical problem, including 68% (336 out of 491) of participants under 17 years old, and 58% (66 out of 114) of participants 17 years or older. A total of 18 (3%) participants left the study because of medical problems. The most common medical problems are listed on the following page.

## Most Common Medical Problems (Reported by More than 5% of Participants)

Medical Problem	Participants Younger than 17 Years (491 Participants Treated)	Participants 17 Years or Older (114 Participants Treated)	All Participants (605 Participants Treated)
Viral infection of nose, throat, and upper airways	87 (18%)	4 (4%)	91 (15%)
Fever	75 (15%)	2 (2%)	77 (13%)
Sleepiness	42 (9%)	12 (11%)	54 (9%)
Seizure	44 (9%)	3 (3%)	47 (8%)
Weight gain	39 (8%)	3 (3%)	42 (7%)
Lung infection	40 (8%)	0 (0%)	40 (7%)
Common cold	32 (7%)	6 (5%)	38 (6%)
Cough	35 (7%)	2 (2%)	37 (6%)
Headache	22 (5%)	14 (12%)	36 (6%)
Diarrhea	25 (5%)	5 (4%)	30 (5%)
Dizziness	18 (4%)	12 (11%)	30 (5%)
Vomiting	28 (6%)	0 (0%)	28 (5%)
Viral infection	27 (6%)	1 (1%)	28 (5%)

## WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

A total of 77 (13%) participants had serious medical problems: 15% (74 out of 491) of participants under 17 years old and 3% (3 out of 114) of participants 17 years or older. Six (6) participants died during the study and 1 participant died after they completed the study. The study doctor determined that none of these deaths were related to the study treatment.

The most common serious medical problems are listed below:

<b>Most Common Medical Problems (Reported by More than 2% of Participants)</b>	
<b>Serious Medical Problem</b>	<b>All Participants (605 Participants Treated)</b>
Lung infection	23 (4%)
Seizure	14 (2%)

## WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on this study protocol, please visit:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT01463306**

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

Use the study identifier **2011-001412-65**

[www.pfizer.com/research/research/clinical\\_trials/trial\\_results](http://www.pfizer.com/research/research/clinical_trials/trial_results)

Use the protocol number **A0081106**

Findings from this trial will be used to seek approval for using pregabalin for patients 1 month to 16 years of age with partial onset seizures. Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for participants.

**Again, thank you for volunteering.**

**We do research to try to find the best ways to help patients, and you helped us to do that!**