

## Who is taking part in the STARS Study?



Up to **250 people** in study sites across the **United States, Europe, Asia** and **Australia** are expected to take part. You may be able to take part if you:

- ★ Are 12 years of age or older
- ★ Have focal or generalized epilepsy, or a combination of the two
- ★ Have experienced at least 2 prolonged seizures within the past 3 months
- ★ Have an adult who can act as a study partner to assist you throughout the study

There are other criteria that you will need to meet to qualify, which the study staff will discuss with you and your study partner.

## What happens at the end of the study?



After your final follow-up visit, you and your study partner may have an opportunity to join the **STARS Extension Study**, during which all prolonged seizure participants will receive the investigational drug for up to approximately **4 years**. The purpose of the STARS Extension Study is to assess the safety and effectiveness of the investigational drug over a longer period.

## Want to know more?



To learn more about the STARS Study, visit [www.starsepilepsystudy.com](http://www.starsepilepsystudy.com) or contact:

Name:

Study site:

Address:

Telephone:

Email:

Contacting us does not mean that you must join the study or that you and your study partner will be able to participate.

STARS

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# Stand Together Against pRolonged Seizures

STARS  
Participant  
Brochure



 Inspired by patients.  
Driven by science.

STARS

## What are clinical research studies?



The aim of clinical research is to help people live longer, healthier lives. To achieve this, researchers develop drugs to improve the treatment and prevention of diseases. Testing of investigational drugs takes place in clinical studies.

## What is the STARS Study?



The STARS Study is testing an inhaler containing an investigational drug to see whether it could help people who experience **prolonged epileptic seizures** (i.e. lasting more than 3 minutes). Two versions of the inhaler will be tested in this study: one version will contain the **active investigational drug**; the other version will contain a **placebo**. Both versions of the inhaler look identical, but the placebo version contains no active medication.

## What happens during the study?



The STARS Study will last up to approximately **19 weeks** and is made up of **3 parts**:



### Part 1: Screening (6 weeks)

If you are interested in taking part, you will visit the nearest study site **twice** to have tests.



### Part 2: Study treatment (12 weeks)

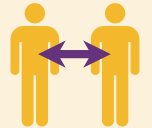
If eligible, you will be given an inhaler containing the study drug (investigational drug or placebo) to take during **1 qualifying prolonged seizure**, if experienced. During this period, you may have tests at the study site or your home. The study staff will also call you **every week** to check on your health.



### Part 3: Follow-up

If the inhaler was used, return to the study site for health checks **5–12 days later**. If the inhaler was not used, return to the study site **5–12 days after** the study treatment period ends.

## Which study drug will I receive?



A computer will randomly assign you to your study drug. You will have a **50% (1 out of 2) chance** of receiving the investigational drug and a **50% chance** of receiving placebo. You cannot choose which study drug to receive. Neither you nor the study staff will know which study drug you are receiving (although if it is medically necessary to find out, the study doctor can do so quickly). This ensures that results from the tests are handled in the same, unbiased way.

## What happens during study visits?



During study visits, you will be asked questions and have tests to check on your physical and mental health.

