

## What is a clinical research study?

Clinical research studies help scientists and doctors explore whether a medical strategy, drug, or device is safe and effective for people. Before a new drug or device can be used for therapy, it must go through several phases of clinical research:

- Phase 1: First study of the drug in people (often healthy volunteers)
- **Phase 2: Study of the drug in people with the condition the drug is designed to improve**
- Phase 3: Study confirming how effective the drug is for improving the condition
- Phase 4: Continued research after the drug is approved for public use

Harmonie is a **Phase 2** study. Clinical research studies rely on study volunteers. Remember that taking part in a study is optional, and participants can leave the study at any time, for any reason.



For more information about the Harmonie study, talk to your doctor, visit [harmonieresearch.com](https://www.harmonieresearch.com), or contact:

**Do you or a loved one have focal seizures that are not fully controlled by medication?**

Consider enrolling in the Harmonie study.

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## What is the Harmonie study?

The Harmonie study is researching EQU-001, a study medication that may be able to prevent or decrease focal onset seizures. The study medication will be researched in combination with approved medications. Researchers are looking for people who continue to have focal onset seizures, despite taking anti-seizure medication(s), to join the study.

## What is the study medication?

The study medication, called EQU-001, is an investigational medication being studied to see if it can prevent or decrease focal onset seizures. It is taken by mouth, in gel cap form, once per day. EQU-001 is called investigational because it is not approved for use outside of clinical trials like this one.

Participants will be randomly assigned to receive EQU-001 or placebo, which looks like EQU-001 but has no active ingredients. Every participant has a 2 out of 3 chance of receiving the study medication (high or low dose), and a 1 out of 3 chance of receiving placebo. The high dose, low dose, and placebo all look exactly alike. Neither participants nor study doctors will know who receives EQU-001 and who is assigned to receive placebo.

## What can study participants expect?

Participation in the Harmonie study is divided into the following periods:



### Screening (~8 weeks)

- Visit the study clinic for health assessments including blood tests, urine samples, and a brief neurological exam
- Complete a twice daily seizure diary for 8 weeks



### Dosing (16 weeks)

- Take 3 gelcaps of EQU-001 or placebo by mouth every morning
- Continue to complete the twice daily electronic seizure diary (or have a caretaker complete it)
- Visit the study clinic at weeks 1, 2, 4, 8, and 16 for study health assessments
- Have phone calls and video twice during the first week of the study, plus additional video visits throughout this period



### Optional study extension

- After the 16 week Dosing period, all participants will have the option to receive EQU-001 (even if they received placebo during the first 16 weeks) and continue to have study clinic visits, video visits, and phone calls
- Participants who choose not to enter the optional study extension will attend a follow-up visit 30 days after taking their last dose of EQU-001 or placebo



## Who can join the study?

People who meet the following criteria\* may be eligible to join:

- Age 18 to 65
- Willing to maintain a daily seizure diary (or has a caretaker willing to do the same)
- Diagnosed with focal epilepsy
- Has uncontrolled seizures despite being on at least 1, but no more than 3, anti-seizure medications (ASMs)
- Currently taking 1-3 ASMs

\*Other criteria apply.

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