What is a clinical study?

A clinical study is research where participants are assigned to one or more investigational drugs to find out if it works or works better than other treatments, and if it has side effects.

What is an investigational drug?

An investigational drug is a substance that is being studied to see if it works to improve a medical condition. It has been reviewed by an ethics committee for testing in people and may or may not be approved by the government health agency for treatment for this condition.

Why should my loved one take part in this study?

Clinical studies (also called clinical trials) help others by contributing to medical research and are important for medical advances. Current treatments for diseases are only available because of clinical study volunteers.

Thank you for your interest in this study.

For more information, please visit **pacificclinicalstudy.com** or contact:

As a caregiver, you're always at their side and never out of reach.

Research may offer a new level of hope.

Now enrolling: The PACIFIC study for the treatment of adults and adolescents with developmental and epileptic encephalopathies

Ask your doctor if your loved one is eligible for this study.

LONGBOARD PHARMACEUTICALS | PACIFIC Developmental and Epileptic Encephalopathies Study

LP352-201_caregiver_brochure_v2.0_15Jul2022_English

LONGBOARD PHARMACEUTICALS | PACIFIC Developmental and Epileptic Encephalopathies Study

Why is this study important?

Frequent seizures associated with developmental and epileptic encephalopathy (DEE) can have an overwhelming impact on brain function. This may cause many challenges for people who experience these episodes. DEE is an umbrella term for severe epilepsies that are characterized both by seizures and significant developmental delay. Examples of DEEs are Dravet syndrome, Lennox-Gastaut syndrome (LGS), tuberous sclerosis complex (TSC), CDKL5, Doose syndrome, and other genetic epilepsies. Family members, close friends, and caregivers may be affected by caring for a person who experiences these challenges. Because of the importance of effective seizure management, there is a need for additional research for this condition.

This study is testing an investigational drug for adults and adolescents with DEE. Clinical studies like this one help pharmaceutical companies learn more about investigational drugs.

Study volunteers can help us in this important research. Thank you for considering having your loved one take part in this study.

What is the purpose of this study?

In this study, researchers want to test the safety of the investigational drug, LP352 and find out how it works when given in addition to antiseizure medication in adults and adolescents with DEE. An investigational drug is one that is not approved for use by the general public.

Who can participate in this study?

To be eligible for this study, participants must have a reliable caregiver or study partner.
Participants must also be:

- 12 to 65 years of age
- Diagnosed with DEE
- Currently taking 1 to 4 antiseizure medications at a stable dose

This is not a complete list of study requirements. The study doctor will review the full requirements for this study with you.

How long will this study last?

This study will last up to 22 weeks. If you complete the study, you may be eligible to participate in a long-term study.

How is the investigational drug being tested?

Participants who qualify for the study will continue their antiseizure medication and will be assigned to receive either:

- LP352 immediate release liquid by mouth or through a feeding tube
- Placebo for LP352 by mouth or through a feeding tube (placebo is a substance that looks like the study drug but has no active drug in it)

Study group assignment is done randomly (by chance; like flipping a coin) by a computer. The study group assignment is blinded, meaning you and the study doctor will not know which study group your loved one is in. Participants will have an 80% chance of being assigned to active drug.

What can I expect if my loved one participates?

The study has 3 parts:

- Part 1 (Days 1 to 15): Dosing will be gradually increased over time
- Part 2 (Days 16 to 75): Dosing will remain at the level achieved in Part 1
- Part 3 (Days 76 to Day 90): Dosing will be gradually reduced over time

As the participant's caregiver, you will be asked to maintain a seizure diary throughout this study to record the number of seizures per day. When the participant takes the investigational drug at home, you will record the dose and dosing frequency in this diary. Diary entries must be completed by the beginning of each day to account for the previous day.

You will come to the study center with the participant up to 11 times over the study period.

Lab tests, physical exams, and other assessments and questionnaires will be conducted as part of this study.

What are the costs to take part in this study?

You do not have to pay for the study drug, study doctor visits, study supplies, or tests that are part of the study.

What risks are involved?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and participants will be closely monitored throughout the study.