

Are you looking for a new way to manage your depression?

If yes, this study may be for you.



The persons depicted in this advertisement are models and the images are being used for illustrative purposes only.

RENEW-MDD-1 study

A clinical research study for adults with major depressive disorder (MDD): the most common type of depression.



This brochure will

- explain clinical research studies
- give you an overview of the **RENEW-MDD-1** study
- help you decide if this study may be suitable for you

Understanding your options is important. We hope this brochure helps you make a decision and take action.

What is a clinical research study?

All drugs and treatments must be tested before doctors can prescribe them to patients. These tests are called clinical research studies.

An investigational drug is one that is being tested in a clinical research study. These studies help us answer important questions about the investigational drug :

- Is it safe to use?
- Does it work to treat the condition?
- Are there side-effects?

When people join clinical research studies, they help scientists find better drugs and treatments for future generations.



About this RENEW study

RENEW-MDD-1 is a clinical research study for people with major depressive disorder (MDD).

To join this study, you must:

- have MDD
- be taking a treatment for your depression
- currently your depressive symptoms are improved or well controlled

You will continue taking your current depression treatment.

This study will test if the investigational drug, together with the current depression treatment, is safe and can help people with MDD stay well for longer.

What does this RENEW study involve?

The **RENEW-MDD-1** study will have around 1,000 people from around the world.

Before you can join, the study doctor will check if the RENEW-MDD-1 study is suitable for you. They will ask you questions and check your health.

If you decide to join, a computer will randomly select your **study drug**. This study drug may be the **investigational drug** or a **placebo**.

You and your study team will not know which study drug you are getting. This helps to keep the study fair and balanced.

Once a week, you will give yourself an injection of the study drug. You will also continue taking your current treatment for depression as prescribed.

RENEW-MDD-1 is an **event-driven study**. This means the study will continue until the team has all the study information they need.

If you are feeling well, you will have at least 11 study visits over about 9 months. Most people will have more than 11 study visits and will be in the study for longer than 9 months.

If you have any questions, ask your doctor or a member of the study team. They can support and guide you.

Study drug may be the investigational drug or a placebo.

Investigational drug means that it is being tested in this clinical research study.

Placebo looks the same as the investigational drug, but it has no medicine in it.

What are the possible risks and benefits of taking part?

Safety is the most important part of any clinical research study. However, all clinical research studies have some possible risks.

If you are interested in taking part in this study, a team of doctors, nurses and other healthcare workers will explain any possible risks to you to help you decide.

This step is known as ‘informed consent’. Making an informed decision means that you have learnt as much as you can about the clinical research study to make a choice that is best for you.



Possible benefits:

- Getting actively involved in healthcare research for people with MDD
- Helping others by advancing medical research
- Playing an important role in researching a potential new medicine

If you choose to take part, you will get:

- All study-related medicines
- All study-related care and check-ins
- Access to specialist study doctors and researchers in major depressive disorder

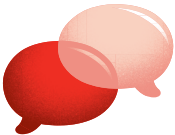
Can I take part in this study?

Yes, you may be able to take part in the **RENEW-MDD-1** study if you meet the criteria below:

- Aged 18 to 75 years
- Diagnosed and taking treatment for major depressive disorder (MDD)
- Currently your depressive symptoms are improved or well controlled
- Body mass index (BMI) of at least 22

Everyone who takes part will continue taking their current depression treatment.

If you are interested in taking part, the study team will explain the additional criteria you must meet.



Can I change my mind about taking part?

Taking part in the **RENEW-MDD-1** study is your choice. If you decide to take part, you may leave the study at any time without giving any reason.

What should I do next if I am interested in taking part?

- Talk to your doctor for advice or if you are unclear about the risks and benefits for your health.
- Talk to your family, friends or someone you trust. Their different views and information can help you decide if the study may be right for you.
- For more information, please contact the study team.

Thank you for taking the time to read about the
RENEW-MDD-1 study.

This study is from Eli Lilly and Company.

For more information:
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