The image depicted does not imply that is being used for illustrative purposes only.

Who participates in an observational research study?

Research participants are people who have a condition that is being studied and agree to be in the study. Study doctors/staff determine who is eligible to participate.

Study doctors, who are often experts in the condition or disease being studied, will closely track the health of study participants.

What is Informed Consent?

Informed Consent occurs before you agree to participate in a research study. It allows you to learn everything about a research study and why it is being done. A study team member will go over the informed consent form, which contains all the study details, with you and answer any questions you may have.

After your questions have been answered and if you wish to participate in the study, you will sign the informed consent form which says that you:

- Agree to participate in the study
- Understand what you will be asked to do in the study
- Understand that you can stop the study at any time and for any reason

If you do not understand something about the study, you may continue asking questions. However, you must read and sign the informed consent form before you can participate in the study.

To learn more, please contact:

PSYCH ATLANTA

Research

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[1] Rush AJ (2006), Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-1917.

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VenturaRWE

janssen

You can help bring more light to depression research.

Learn more about the **VENTURA-RWE** research study, which is an observational study for adults who have depression, are experiencing symptoms despite taking medication, and are about to begin a new prescribed antidepressant treatment.

While there are treatments available for depression, almost 40% of people with the condition continue to experience symptoms despite taking medication.[1] If you have depression, have not responded to your antidepressant medication, and are planning to take a new antidepressant, the VENTURA-RWE study may be an option for you.

The VENTURA-RWE study is an observational study, which means no investigational medication is given to study participants. Instead, study doctors only want to collect health-related information about you and your depression and antidepressant medication.

The results of this study may help doctors better understand depression and its symptoms, as well as the use of treatments for depression.

You may be able to participate in this study if you:

- Are 18 to 74 years old
- Have been diagnosed with depression
- Are experiencing depressive symptoms despite currently taking antidepressant medication
- Are planning to take a new antidepressant medication prescribed by your personal doctor

Additional criteria will apply, and there is no cost to participate in this study.

What will happen during the VENTURA-RWE study?

If you agree to participate in the study, study doctors will collect your health-related information for approximately 12 months. The information they collect may include:

- Your depression and treatment history
- Details about your depression symptoms during the study
  - Whether your symptoms improve, get worse, or return after improving
- Any visits with your personal doctor due to an improvement or worsening of your symptoms
- Changes to your antidepressant medication
- Your symptom severity, quality of life, and ability to do daily activities
- Any hospitalization for depression

Study doctors will collect this information from your personal doctor at various points throughout the study. These include:

- On Day 1 of starting your new antidepressant medication
- At Week 6 after starting your new antidepressant medication
- When you experience an improvement or worsening of your symptoms or a change in your antidepressant medication
- At Month 6
- At Month 12

What are the benefits and risks related to the VENTURA-RWE study?

You may or may not benefit from participating in the study. However, your study participation may help people with depression in the future.

If you decide to participate in optional blood sample collections, you may experience some discomfort or side effects. Before you begin the study, the study team will discuss this with you.

Do I have to participate in the VENTURA-RWE study?

No, it is your choice to participate in this study. Even if you agree to participate, you are free to stop being in the study at any time and for any reason.

Your decision about participating in this study will not affect your regular medical care. You may choose to talk with your doctor, family, and friends about whether this study could be right for you.

Frequently Asked Questions

How is an observational research study different from a standard research study?

In a standard research study, doctors want to learn more about an investigational medication, which is a medication that is not approved by any regulatory health authorities. Study doctors want to learn how safe the investigational medication is, how it makes people feel, and what the best dose may be.

What doctors learn in this type of study may help them decide if an investigational medication could one day be made available to the public.

In an observational study, no investigational medication is given to patients or evaluated by study doctors. Study doctors want to observe patients and collect health-related information from patients' personal doctors.

Patients in an observational study like the VENTURA-RWE study continue taking their approved prescribed medication and visiting their personal doctor on a regular basis.