

# What is Major Depressive Disorder?

Major depressive disorder (MDD) is a mental health condition characterized by persistent feelings of sadness, loss of interest in activities, changes in appetite and sleep, and low energy levels.

These symptoms can significantly impact a person's daily life and their ability to function. MDD is one of the most common mental disorders in the U.S., and according to the World Health Organization, over 280 million people suffer from MDD worldwide, nearly half of whom have treatment-resistant depression.

Far too many people with MDD experience suicidal thoughts. By comparison, conventional treatments for treatment-resistant depression take weeks to months to begin working and provide remission from depression for only a fraction of people. Currently, there are no approved rapidly acting treatment options available.



A Clinical Trial  
with the

## SAINT™ Neuromodulation System



## What is the SAINT™ Neuromodulation System?

The SAINT Neuromodulation System is a novel investigational treatment that may provide a faster, accurate application of personalized neurostimulation to stimulate specific areas of your brain that are involved in mood regulation and balance, to treat major depression.

### What is a clinical study?

Clinical studies are conducted to assess the effectiveness of medicines and devices as potential treatments for specific conditions. Research studies help determine if medication or therapies are safe and effective and work to improve people's health. When you volunteer to take part in a clinical study, you help doctors and researchers learn more about treatments to improve healthcare for people in the future. It also offers study participants the opportunity to have access to this novel investigational medical treatment.

### Information about this study.

The SAINT Neuromodulation System is a novel investigational treatment for major depressive disorder (MDD) that is being evaluated in this study to assess the effectiveness of *personalized* neurostimulation to rapidly treat adults with MDD in a real-world setting. The study will enroll up to 1,000 adults experiencing major depression who have failed to receive satisfactory improvement from a prior antidepressant medication. This is often referred to as "treatment-resistant major depression."

## How does SAINT Neuromodulation work?

The SAINT Neuromodulation System uses magnetic resonance imaging (MRI) scans of your brain to inform a proprietary algorithm that identifies the best target in your brain for focused neurostimulation. This novel investigational approach is delivered on an accelerated, five-day timeline, and it is precisely tailored to your own brain connectivity.

## What can I expect during the study treatment if I participate?

After meeting with the study physician and enroll in the study, you will undergo an MRI brain scan so doctors can locate the optimal location in your brain for neurostimulation. Once the MRI scan is completed, you will be scheduled for treatment with the SAINT Neuromodulation System. This involves a series of 10, 10-minute treatment sessions with 50-minute breaks each day for 5 days.

During each session, you will sit in a comfortable chair, and a specialized coil, the size of a large cell phone or small paperback book, will be placed next to your scalp. You will hear clicking sounds and you will feel a tapping sensation on your scalp, which is the magnetic field being generated by the coil.

## Who can participate in this study?

You may be eligible to participate in this study if you are:

- *18 years of age or older.*
- *Are in a major depressive episode, and you have tried a prior antidepressant medication in this current episode without benefit.*
- *Considered to be an appropriate candidate for neurostimulation.*

## Is the SAINT Neuromodulation study right for me?

The SAINT Neuromodulation System may be a good option if you have been diagnosed with major depressive disorder and have not found sufficient relief from medication. If you want to learn more about treatment with the SAINT Neuromodulation System, speak with your doctor to determine if you may be a candidate for the clinical trial.

## Is there a cost for participating in this study?

Yes, there is a participant cost for this breakthrough study. Please discuss with your study doctor