



If you have moderate to severe Crohn's disease, the VIVID-1 study may be of interest to you. This study is researching whether an investigational medication can reduce the symptoms of Crohn's disease. To learn more, talk to your doctor and visit VIVID-1.com today.

What you should know about clinical research studies.

Researchers use clinical research studies to:

- Answer specific health questions
- Learn about the effects and safety of investigational medications
- Help find new ways of using approved medications

Regulations and policies have been developed to help protect the rights, safety, and well-being of people who take part in clinical research studies and to help ensure that these studies are conducted according to strict scientific and ethical principles.

Participation in any clinical research study is completely voluntary, and you may withdraw from the study at any time for any reason.

If you or someone you know may be interested in this study, please contact the research site listed below.

Thank you for considering the VIVID-1 study!



GROWING

**There's life beyond
your Crohn's disease.**

Seeing Crohn's disease clearly.

As you know, Crohn's disease is a chronic inflammatory bowel disease that causes inflammation or ulceration in the digestive tract. While symptoms vary from person to person, they typically include diarrhea, abdominal pain and cramping, ulcers, fever, fatigue, and nutritional deficiencies. But perhaps the worst symptom is the unpredictability of this chronic disease.

While there are a lot of options out there for your flare-ups, maybe you haven't found the right one yet or your body has grown resistant. That's why right now, research is underway on an investigational medication option for adults with Crohn's disease. Clinical research studies are crucial to helping find new medication options for different conditions. The VIVID-1 study is playing an important part in clinical research work for Crohn's disease, and you may be able to take part.

About the VIVID-1 study.

The purpose of this clinical research study is to evaluate whether treatment with the investigational medication is effective by looking at the endoscopic response and patient outcomes compared to a placebo or an active comparator. "Investigational" means that the medication being tested has not been approved for use by doctors in their everyday practice and that its use is being allowed for research only. Individuals will be evaluated to determine their eligibility to participate in this study. We are looking for:

- Adults ages 18 to 80 who have been diagnosed with moderate to severe Crohn's disease for at least three months
- Those who have had an inadequate response to, loss of response to, or intolerance to at least one approved conventional or biologic treatment or therapy for Crohn's disease
- Those who are willing and able to complete the scheduled study assessments, including endoscopy and a daily diary entry

If you qualify, you will receive one of three available treatment options – the investigational medication, a currently approved medication for Crohn's disease, or placebo. The treatment received will be determined by chance, and neither you nor the study doctor will know which medication you are taking. However, in the event of a medical emergency, the study doctor can quickly find out.

The VIVID-1 study will enroll approximately 1,100 patients in approximately 36 countries.

Study participation.

Participation in the VIVID-1 study lasts up to 72 weeks and consists of the following four study periods:

- **Screening:** During this period, which could last up to four weeks, the study team will determine if you are eligible for study participation.
- **Treatment period 1:** If you qualify for the study, you will start to receive one of three available treatment options through either an infusion into a vein (IV), or an IV and a shot or shots under the skin. Treatment period 1 lasts 12 weeks and includes six study visits.
- **Treatment period 2:** This period lasts an additional 40 weeks and includes 10 visits.
- **Post-treatment follow-up:** Following your study participation, you will be asked to return to the study site for follow-up visits. These visits will occur four and 16 weeks after your final visit in treatment period 2. If you are eligible to participate in a maintenance study, I6T-MC-AMAX, you will not need to complete the post-treatment follow-up period.

Study-related medications and procedures will be provided to you at no cost.

