About Clinical Research Studies

Clinical research studies, also called clinical trials, are carefully designed scientific evaluations of an investigational medication. Research studies are conducted by a sponsor, which is usually a pharmaceutical company, academic institution, or non-profit group, and are run by a team of doctors and researchers.

Sponsors use research studies like this one to learn more about an investigational medication. Participating in a research study is not the same as standard medical care. However, participants in a research study do receive additional study-related care and ongoing evaluations from the study doctor/staff.

To conduct a research study, doctors need volunteer participants like you. However, before you can volunteer for a study, you must go through the informed consent process and sign an informed consent form. The informed consent form confirms that you understand the study details and agree to participate in the study.

If you would like to learn more about the DUET ENCORE-UC study, contact the study clinic listed in this brochure. The study staff will answer all your questions and give you additional information to help decide if this study is right for you.

Approved by Sterling IRB, IRB ID: 16254

For more information, please contact:

Johnson & Johnson

DUET ENCORE-UC

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Ulcerative colitis research invites you to add your voice.

Learn about the DUET ENCORE-UC research study of an investigational medication for moderately to severely active ulcerative colitis.

DUET ENCORE-UC

The image depicted contains models and is being used for illustrative purposes only.

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Since you were diagnosed with ulcerative colitis (UC), you have likely talked with your doctor, other medical professionals, and your family and friends about your next steps.

As you consider your path forward, one option that may be available to you is the DUET ENCORE-UC research study of an investigational medication for moderately to severely active UC.

What is the purpose of the DUET ENCORE-UC study?

The purpose of this study is to see how safe the investigational medication is and how well it works. In this study, doctors will compare the investigational medication to a comparator medication that is another medication already used to treat UC.

The investigational medication has not been approved by any regulatory authority for the treatment of UC. The results of this study may provide more information about the investigational medication.

Who can participate in this study?

To qualify for this study, you must:

- Be 18 years of age or older
- Have been diagnosed with moderately to severely active UC for at least 12 weeks (3 months)
- Have tried 2 or more biologic or oral medications for UC but stopped using them because they:
  - Weren't effective,
  - Stopped working, or
  - Caused side effects

Additional criteria will apply, which you can discuss with the study doctor/staff.

What happens if I join the DUET ENCORE-UC study?

If you are eligible for this study and agree to participate, you will be randomly assigned (like pulling a number out of a hat) to receive either the investigational medication or comparator medication. You have a 1 in 2 chance (50%) of receiving either study medication (investigational or comparator). You and the study doctor/staff will not know which study medication you are receiving.

You will receive 1 or 2 injections of your study medication every 4 weeks. You may be able to stay in the study for up to 3 years. During this time, you will have regular study visits for health exams and tests. All study-required visits, tests, and medication will be provided at no cost to you.

What are the potential benefits and potential risks related to this study?

You may not receive any benefit from this study, but your participation may help contribute to research for people with UC in the future.

It is also possible that you could experience side effects while in this study. Before you begin study participation, the study doctor/staff will review a full list of study risks and possible side effects with you. During the study, you will be closely monitored for any side effects related to your study participation.

The sponsor of this study was required to design a protocol, which explains all study procedures in detail. An independent review board (IRB), which is also known as an independent ethics committee (IEC), shares study participant safety responsibility with the study sponsor and has reviewed this protocol and requires that it be followed exactly.

Can I change my mind about study participation?

Yes, if you join the study, you may leave the study at any time and for any reason.