



The SEQUENCE Clinical Study

A new clinical study for Crohn's disease

SEQUENCE 
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What is a clinical research study?

A clinical research study is medical research with human volunteers to learn more about investigational new drugs or unapproved new drugs. Clinical research studies help us understand safety and effectiveness of the investigational medication being researched.

Volunteers for clinical research have different reasons for participating, including:

- Contributing to the advancement of science
- Gaining access to investigational medications or study procedures

The Sequence study is a Phase 3 study, which means the investigational medication has already been studied for safety and effectiveness in humans during previous studies. During this phase, researchers need to confirm the effectiveness of the investigational medication and monitor its side effects in a large group of study participants.

Whatever your reasons, if you decide to participate, we will closely monitor your health and protect your privacy.

What will my commitment look like?

Once you enter the study treatment phase, visits are every 4 weeks to 8 weeks and will involve procedures like endoscopy, blood tests, stool samples, and receiving the medication.

- **Visit frequency:** every 4 weeks to 8 weeks
- **Visit length:** less than 1 hour, plus intravenous (IV) infusion of ~2 hours (not including visits where an endoscopy occurs or medication is administered subcutaneously)
- **Study length:** 48 weeks of treatment, depending on your response to your study treatment, and an additional follow-up period

After the study period, you may qualify for participation in an extension study which may last several years and includes access to the investigational medication.

Participating in the study is voluntary – you can stop participating at any time for any reason.

Who can participate in these studies?

You may qualify to participate if you meet the following requirements:

- 18 to 80 years of age
- Diagnosed with Crohn's disease for at least 3 months
- Currently have Crohn's disease symptoms
- Have found that at least one Crohn's medication, referred to as a biologic agent, doesn't work well for you.

What happens if I want to participate?

Your ability to participate involves a few different steps to determine if you are a good candidate for the study:

- **Pre-screening:** answering questions about your medical history, including prior and current Crohn's medication
- **Informed Consent:** agreeing to participate in the research study after reviewing the Informed Consent Form with study staff
- **Screening:** undergoing screening procedures, including but not limited to a blood test and an endoscopy

If you still qualify after these steps, you will move into the study treatment period.

Compensation for your time and travel expenses may be available. Talk to study staff for more details.






Study procedures


At every study visit, the study staff will perform certain routine checks to monitor your health and safety, administer your study treatment, and check your Crohn's symptoms.


* Urine test and stool sample may not occur at every visit


Please note that an **endoscopy** will be performed to monitor your disease activity at the following points:

Procedure

	Vital sign check and physical exam
	Urine test*
	Stool sample*
	Blood test
	Study drug administration

 **Screening:** to determine whether you are eligible for the study

 **Week 24:** to assess your response to the study treatment

 **Week 48:** to assess your response to the study treatment

How will I receive the medication?

Study participants are assigned to receive the investigational medication or the approved comparator medication at random. You will know what treatment you are assigned to receive.

The medications will be given as IV infusions and subcutaneous injections. Your study doctor will inform you about the different administrations and their different frequencies.

You should talk to your personal doctor and the study doctor about which of your regular Crohn's treatments you can continue to take while you participate in the study.

Find out if you might qualify for the SEQUENCE study: www.ibdiscovercrohns.com

What are the study treatments?

The investigational medication is a drug that is being studied in people with inflammatory bowel disease and other inflammatory diseases. It works by blocking the actions of a protein that is involved in the immune response and also in the development of chronic inflammation.

In this study, the investigational medication will be compared to a medication already approved by the regulatory authorities. This medication works in a similar way as the investigational medication.

You should ask the study staff any questions you have about the investigational medication or the comparator medication, including potential side effects and standard treatments that are available for Crohn's disease.

What should I do if I still have questions?

Don't be shy about asking questions of the study doctor or staff to understand whether participating is right for you. You may also find useful resources online. Here are some examples that can help you:

- Understand more about clinical research: www.hhs.gov/About-Research-Participation
- Learn more about what participating may mean for you by visiting AbbVie's online resource www.ClinicalTrialsAndMe.com
- Connect with patient advocacy groups www.CrohnsColitisFoundation.org/research/clinical-trials-community

Learn More: