What are researchers looking for in clinical trials?

The FDA has guidelines for how researchers measure whether a treatment for IBD is effective. Since UC and Crohn’s are two unique conditions that have a wide range of symptoms, researchers measure the effectiveness of treatments for each condition in different ways.

When studying a treatment for UC, here are some things researchers will look at:

- Has the inflammation in your digestive tract decreased?
- How often are you having bowel movements?
- Is there any bleeding associated with your bowel movements?

When studying a treatment for Crohn’s, here are some things researchers will look at:

- Has the inflammation in your digestive tract decreased?
- How often are you having bowel movements?
- Are you experiencing any pain in your stomach?

What questions should I ask the trial staff?

- What are the possible risks and benefits of participating in IBD clinical trials?
- Are there any clinical trials that would be a good fit for my condition?
- Will my doctor be part of my care team if I choose to participate in a clinical trial?
- Would there be interactions with any medicines I am currently taking?

How can I find out more information?

Patient advocacy groups may be able to tell you about clinical trials for your condition. If you would like to learn more about current clinical trials, call 1-877-MED-HERO.

For more information about IBD clinical trials, please visit the AGA GI Patient Center: https://patient.gastro.org/

A panel of patients, professionals, and members of the public reviewed this educational brochure.

Produced by

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

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The American Gastroenterological Association (AGA) is the trusted voice of the GI community. Founded in 1897, AGA has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology.

This program was supported by an educational grant from AbbVie Inc.; Amgen; Bristol-Myers Squibb Company; Genentech, a member of the Roche Group; Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC; and Takeda Pharmaceuticals U.S.A., Inc., and a quality improvement grant from Pfizer Inc.
**Before I agree to participate, what should I expect?**

Clinical trials typically follow a schedule of events like the one listed below:

1. **Screening visit:** This is the first time you will visit the trial site. It includes a health check and basic testing to ensure that you are able to participate in the trial. This is the visit where you will go through the informed consent process. This is a process to fully inform you about the trial before you agree to be in it.

2. **Washout period:** This can occur before or during the clinical trial. During a washout period, you will not receive any active medication or treatment. A washout period helps ensure your safety and helps the researchers better study the trial treatment.

3. **Treatment period:** The clinical trial staff will provide you with a schedule of your visits and what to expect at each one. Not all visits will look the same, but here are some examples of what may happen:
   - **Health check:** Your overall health and vital signs will be checked by the trial staff.
   - **Receiving the trial treatment:** This could be in the form of a pill, an infusion or an injection. You might also receive a placebo. A placebo looks like the trial treatment but contains no active medicine.

4. **Follow-up:** The trial staff may want to observe or follow up with you after you stop receiving the treatment to see how you are doing.

**Blood tests:** The trial staff may draw your blood. This is done to better understand the trial treatment and to make sure you are healthy.

**Procedures:** Since IBD is a condition that affects the digestive system, throughout the course of a trial you may have to undergo one or more procedures to look at your digestive system. These can be uncomfortable or require sedation. Make sure to let your trial staff know if you are sensitive to any kind of procedures.

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**Keeping your data safe**

Keeping your protected health information safe is very important to the trial staff at your site. You have the right to ask about how your information is being handled to ensure your privacy at any time.

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**Can I decide to stop participating?**

During your clinical trial, you can withdraw from participating at any time and for any reason. Let the trial staff know if you would like to withdraw and they can help you do so safely.

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**What should I do when the trial is over?**

Follow up with your primary care physician and digestive disease doctor (gastroenterologist) throughout the course of the trial so that they can best help you once the trial is over. You should let your trial team know about any changes in your condition.