

IBD CLINICAL RESEARCH: PATIENT-DOCTOR DISCUSSION GUIDE AND GLOSSARY

Managing and treating **inflammatory bowel disease (IBD)** will be different for everyone. The key is to be aware of your options. Clinical research is exploring investigational medications for Crohn's disease and ulcerative colitis, and you may be considering participating in a clinical trial.

Use this guide to start a conversation with your doctor about whether participating in a clinical trial of an investigational medication for IBD is an appropriate option for you.

QUESTIONS TO DISCUSS WITH YOUR HEALTHCARE TEAM ABOUT IBD

Questions to Understand IBD	Notes
<ul style="list-style-type: none">• What is the severity of my IBD at this time? mild, moderate, or severe	<hr/> <hr/> <hr/> <hr/>
<ul style="list-style-type: none">• How will I know if I'm having a flare?	<hr/> <hr/> <hr/> <hr/>
<ul style="list-style-type: none">• What should I do if I have a flare?	<hr/> <hr/> <hr/> <hr/>
<ul style="list-style-type: none">• How will I know if my IBD is in remission?	<hr/> <hr/> <hr/> <hr/>
<ul style="list-style-type: none">• Will my IBD get worse over time?	<hr/> <hr/> <hr/> <hr/>

Questions to Understand IBD Medications	Notes
<ul style="list-style-type: none"> • What medications have you prescribed for me that treat my IBD? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • What kind or what category of medication is it? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • Will my symptoms return if I stop taking this medication? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • How long do we wait to see if the medication is working for me? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • How long will it take for me to feel better? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • If this medication doesn't work for me, are there other potential treatment options? 	<hr/> <hr/> <hr/>

Questions to Understand Clinical Research as an Option	Notes
<ul style="list-style-type: none"> • What kind of clinical trials are available for people with IBD? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • Would you still be my doctor if I join a trial? 	<hr/> <hr/> <hr/>
<ul style="list-style-type: none"> • Would participating in a clinical trial of an investigational medication for people with IBD be an option for me? 	<hr/> <hr/> <hr/>

If you think of other questions or don't have the opportunity to find out all the information you need at your appointment, ask your doctor or nurse for the best way to contact them in between appointments with follow-up questions.

Glossary

When discussing IBD with your healthcare team, it may help to know some key terms. This guide can help you become more comfortable with important words and terms, and help you prepare for your next conversation with your doctor.

Terms Related to Your Condition

Inflammatory bowel disease (IBD)	A chronic disease that causes inflammation in different parts of the gastrointestinal tract. There are generally two types: Crohn's disease and ulcerative colitis.
Crohn's disease	A type of IBD where any part of the gastrointestinal tract can be affected by chronic inflammation. ¹
Ulcerative colitis	A type of IBD where only the lining of the colon is affected, causing tiny open sores, or ulcers. ²
Flare	The reappearance or worsening of IBD symptoms, which may include frequent and/or urgent bowel movements, abdominal pain, lack of appetite, rectal bleeding, or diarrhea. ³
Gastrointestinal (GI) tract	The organs that food and liquids travel through when they are swallowed, digested, absorbed, and leave the body. These organs include the mouth, pharynx (throat), esophagus, stomach, small intestine, large intestine, rectum, and anus. The gastrointestinal tract is part of the digestive system. ⁴

¹ <https://www.crohnscolitisfoundation.org/what-is-crohns-disease>

² <https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis>

³ <https://www.crohnsandcolitis.com/living-with-crohns-uc/crohns/flare-ups>

⁴ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/gastrointestinal-tract>

Terms Related to Clinical Research

Clinical trial	Also called a clinical research study, it is the primary way that researchers test and find out if an investigational medication is safe and effective. ⁵
Investigational medication	A medication that has been tested in the laboratory and has obtained permission for further testing in trials with people. ⁶
Placebo	An inactive substance that looks like the investigational medication being tested. ⁷ They are used to help determine the safety and efficacy of the investigational medication being studied compared to the absence of the investigational medication.
Active comparator	An approved medication considered by healthcare providers to be effective in treating the condition being studied. ⁸ Active comparators are used in clinical trials to help determine if the investigational medication is safer and more effective than existing medications.
Standard of care	Treatment that most medical experts agree is an appropriate choice and that is widely used by healthcare professionals. ⁹

⁵ <https://www.clinicaltrials.gov/ct2/about-studies/learn#WhatIs>

⁶ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/investigational-drug>

⁷ <https://www.nia.nih.gov/health/placebos-clinical-trials>

⁸ <https://clinicaltrials.gov/ct2/about-studies/glossary>

⁹ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/standard-therapy>