

# Clinical Trials Community eNewsletter

Fall 2020

CLINICAL TRIALS  
Community   
CROHN'S & COLITIS  
FOUNDATION

## Learn about a Foundation-Sponsored Research Opportunity

### PROPS: A New Study for Ileoanal Pouch Patients

Up to one-third of ulcerative colitis patients may require surgery because of their disease.<sup>1</sup> The most commonly performed surgery is a proctocolectomy with ileal pouch-anal anastomosis, also known as the construction of a j-pouch. During this surgery, the entire colon and rectum are removed, and the small intestine is attached to the anal area, creating a j-pouch to collect waste. A j-pouch can significantly improve ulcerative colitis symptoms; however, many patients experience other symptoms or complications related to their internal pouch.

Last year, a group of researchers sponsored by the Crohn's & Colitis Foundation's Surgery Research Network conducted the Patient Reported Outcomes after Pouch Surgery (PROPS) Delphi Study looking to patients and clinicians to gain a better understanding of what constitutes the spectrum of normal life in the life of a patient with an internal pouch. The team received input from more than 200 patients and nearly 120 clinicians.

There's a new follow-up study ongoing for patients living with an internal (J, W, S) pouch! This time the PROPS team seeks to understand patient priorities and experiences after internal pouch surgery.

If you are an IBD patient with an internal pouch and want to help guide future research on ileoanal pouches, researchers want to hear from you and learn your perspective on living with a pouch! To read more about the PROPS study, check out a post on our #IBDVisible Blog!

[Learn more about the PROPS Study and how you can help.](#)



## Meet our Clinical Trials Ambassadors

**Amanda** was diagnosed with Crohn's disease at the age of 17 when she began experiencing symptoms during her junior year of high school. These symptoms led her to miss two-and-half weeks of school and undergo two surgeries to resolve fistulas before a confirmed diagnosis. Over seven years, Amanda has found a regimen that worked and kept her symptoms under control. She continues to engage with the Foundation through Team Challenge and meeting other patients with IBD. With a professional career in clinical research, Amanda views her participation as a Clinical Trials Ambassador as a way to give back to her community. [Get to know more about Amanda!](#)

## Power of Two Connections

You can speak to a Clinical Trials Ambassador through Power of Two! Interested in hearing more about what it's like to participate in a clinical trial? Our Clinical Trial Ambassadors are here for you. They can speak to you about their own clinical trial experiences and answer your questions. Get matched with another patient or caregiver and connect today!

Contact [powerof2@crohnscolitisfoundation.org](mailto:powerof2@crohnscolitisfoundation.org) for more information.

## Phrase of the Quarter: Open-Label Trial

An **open-label** trial is a type of clinical trial in which both researchers and participants know which drug (or other intervention) is being given to participants. Open-label is the opposite of a double-blind trial when neither the researcher nor the participant knows what treatment the participant is receiving.

## IBD & COVID-19 Resources

Are you returning to work and daily living during the COVID-19 pandemic? [Read tips on how to safely return to work, childcare, healthcare appointments and procedures, and more.](#) Guidance will vary based on where you live as states and local communities continue to track health data related to infection and hospitalization rates.

If you are a clinical trial participant or you are considering clinical research, check out our [COVID-19 & IBD: Clinical Trials](#) resource page. For other information on what IBD patients should know about COVID-19, visit our [IBD & Coronavirus](#) page.

## Featured Research Spotlight

### PFIZER TUSCANY 2 Study



A study to evaluate the efficacy and safety of PF-06480605 in adult participants with moderate to severe ulcerative colitis.

Do you feel different because of your ulcerative colitis? You're not alone. Ulcerative colitis can change your life in many ways, but it can be hard to talk about to people who don't have it. By taking part in a clinical research study, you may help doctors learn more about ulcerative colitis and find a support network too.

In this clinical research study, researchers want to test the effectiveness and safety of a study drug for treating ulcerative colitis. The first part of the study, which lasts 14 weeks, will compare the study drug to a placebo. In the second part of the study, which lasts 40 weeks, all participants will receive the study drug.

You may be eligible for the TUSCANY 2 study if you:

- Are between 18 and 75 years of age
- Have been diagnosed with moderate to severe ulcerative colitis for at least 3 months
- Your medication is not relieving your ulcerative colitis symptoms

[Learn more about the TUSCANY 2 study.](#)

i. The Facts About Inflammatory Bowel Disease. Published by the Crohn's & Colitis Foundation. November 2014.