Clinical Trials
Community eNewsletter
Fall 2018

CLINICAL TRIALS Community
CROHN'S & COLITIS FOUNDATION

Welcome to the Crohn's & Colitis Foundation's Clinical Trials Community eNewsletter. This newsletter will be sent on a quarterly basis to keep you up to date on research happenings in the inflammatory bowel diseases (IBD) research space.

Launch of the Clinical Trial Ambassador Training Program

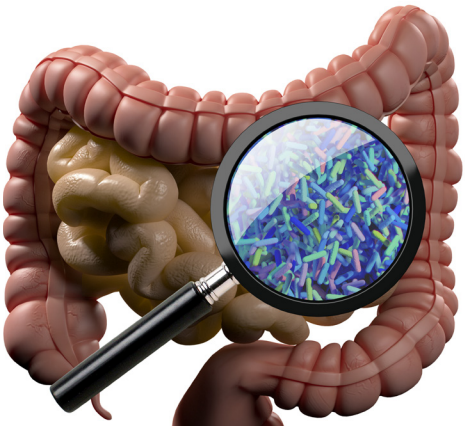
This fall, the Crohn's & Colitis Foundation hosted 35 participants in Chicago, Illinois, for our first Clinical Trial Ambassador Training Program. Participants in the program included those who have experience participating in an IBD clinical trial either as an adult patient or parent of a pediatric patient. Following our training, our Ambassadors are now trained to:

- Speak with other patients as mentors about their experience participating in an IBD clinical trial through our Power of Two platform
- Share their clinical trial story at local, regional, and national events
- Provide their input on clinical trial design

This winter, we will begin making matches with our Clinical Trial Ambassadors for those who are interested in speaking with them about clinical trial participation.

To learn more or to be matched with a Clinical Trial Ambassador, reach out to us at powerof2@crohnscolitisfoundation.org.

You can also be on the lookout for our Clinical Trial Ambassadors at your local events throughout 2019!



Munching With Your Microbiome

"What to eat?" is a common question among the IBD community. The Foundation's Research Manager, Nataly Shtraizent, PhD, summarizes a recent article addressing this topic on our "Research Updates" blog. The article, "Dietary Interventions to Modulate the Gut Microbiome—how far away are we from precision medicine," discusses the definition of the microbiome, how it relates to inflammatory bowel disease (IBD), its associations with nutrition, the need for clinical research in this area, and the DINE-CD research study (currently recruiting). Click here to read Nataly's summary.

Clinical Trials Community Featured Research Spotlight

DIVERGENCE 1 Study

A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Small Bowel Crohn's Disease (SBCD)

You may be eligible for the DIVERGENCE 1 study if you:

- Have a diagnosis of Crohn's disease
- Have moderate to severe disease with inflammation in at least one section of the small bowel

For more information on the DIVERGENCE 1 study, please visit here.

DIVERGENCE 2 Study

A Phase 2, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy and Safety of Filgotinib in the Treatment of Perianal Fistulizing Crohn's Disease

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

- Have a diagnosis of Crohn's disease
- Have no more than three draining perianal fistulae

For more information on the DIVERGENCE 2 study, please visit here.

MANTA Study

A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study to Evaluate the Testicular Safety of Filgotinib in Adult Males With Moderately to Severely Active Ulcerative Colitis

You may be eligible for the MANTA study if you:

- Are a male 25–55 years of age
- Have a diagnosis of moderate to severe ulcerative colitis for at least four months
- Previously demonstrated an inadequate clinical response, loss of response to, or intolerance to at least one of the following agents: corticosteroids, immunomodulators, tumor necrosis factor alpha (TNFα) antagonists, or vedolizumab

For more information on the MANTA study, please visit here.

DIVERSITY Study

Combined Phase 3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects With Moderately to Severely Active Crohn's Disease

You may be eligible for the DIVERSITY study if you:

- Have a diagnosis of Crohn's disease
- Have moderate to severe disease despite treatment with corticosteroids, or immunomodulators, or TNFα inhibitors, or vedolizumab, or ustekinumab

For more information on the DIVERSITY study, please visit here.

Improve Your Research Vocabulary With Our Word of the Quarter!

Informed Consent

Before enrolling in a clinical trial, a potential participant must always give informed consent. This document includes details on the study and outlines the potential risks and benefits of participation. During the informed consent process, the participant also has the chance to ask the research team questions. When the participant is satisfied, they then sign the document, giving their consent to participate in the trial. Additionally, it is important to remember that you may withdraw your consent at any time during the trial. Informed consent is an important piece of the clinical trial process, as it ensures that the participant understands the ins and outs of what the clinical trial entails.