

Clinical Trials Community eNewsletter

Winter 2018

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 inflammatory bowel diseases (IBD).

Announcements

Connect with a past clinical trial participant



If you are interested in connecting and speaking with another patient, or with a parent of a pediatric patient who has participated in an IBD Clinical Trial, our 2019 Clinical Trial Ambassadors will be available Winter 2019. If you would like to learn more about this opportunity and how to connect with a Clinical Trial Ambassador through our Power of Two Program, please contact Catherine Dermody at cdermody@crohnscolitisfoundation.org.

Pediatric clinical trial resources

Be on the lookout for two new pediatric clinical trial videos coming to the Clinical Trials Community Winter 2019.

In the meantime, click [here](#) to learn more about pediatric clinical trials through our infographics!

Looking Toward Future Treatments for IBD

Unique and individual: two words that describe every patient's journey with inflammatory bowel diseases (IBD). Gaining understanding through further research into the management and treatment of IBD gives hope for a better future ahead for all patients. Andres Hurtado-Lorenzo, Ph.D., Senior Director of Translation Research for the Foundation, recently presented "Towards Precision Medicine in Inflammatory Bowel Diseases" at the 5th Precision Medicine and Biomarkers Leaders Summit in Munich this fall, where his presentation focused on:

- The basics of IBD and what to expect as it progresses
- Customizing medicine using biomarkers to make helpful predictions and address challenges with implementation
- The role [IBD Plexus](#) plays in precision medicine

To listen to Andres's presentation and learn more about the Foundation's work in translational research, click [here](#).

The Quest to Increase Clinical Trial Enrollment



Curious as to why some patients choose to participate in clinical trials and others do not? The Foundation has partnered with RTI International to administer a survey for both adult patients and caregivers of pediatric patients with inflammatory bowel diseases, in the hope of discovering the reasoning behind clinical trial participation. This will help researchers find innovative ways to increase enrollment and participation in clinical trials as well as to integrate patient feedback in the clinical trial design process.

Click [here](#) to view more information about this survey. Although the survey is now closed, we will be sharing the results with you in the coming months.

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](#).

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, immunomodulators, TNF α inhibitors, vedolizumab, or ustekinumab

For more information on the DIVERSITY study, please visit [here](#).

BOEHRINGER INGELHEIM

655130 Induction Treatment in Patients with Moderate to Severe Ulcerative Colitis

In this clinical research study, doctors want to evaluate an investigational drug that is administered every four weeks through an infusion (a needle inserted into a vein). They want to compare the investigational drug to a placebo, which looks like the investigational drug, but contains no active medication. The investigational drug is unique in that it targets inflammation related to UC, which may help with UC-related complications. The investigational drug has not been approved for the treatment of UC or any other disease. It is considered experimental, and can only be given to patients in clinical research studies. The results of this clinical research study will provide more information about the investigational drug and its effect on moderate to severely active UC.

Who is eligible to participate in this clinical research study? To pre-qualify for this study, you must:

- Be 18 to 75 years of age, and have been diagnosed with UC for at least three months
- Have had an unsuccessful response to previous biologic treatments

To learn more about the clinical research study and to see if you may qualify, please visit [here](#).

Word of the Quarter:

Principal Investigator

The physician responsible for managing a clinical trial and assessing the gathered data from the trial. Principal Investigators also write and submit grant applications, supervise the research process throughout, and ensure that all key personnel are properly trained and qualified. They also provide the appropriate research facilities for the clinical trial and make sure that the study protocol is followed, including the informed consent process. Principal Investigators also communicate on a regular basis with the research staff (coordinators, nurses) throughout the study.