

Clinical Trials Community eNewsletter

Summer 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 the inflammatory bowel diseases (IBD) research space.

Approval of Tofacitinib

On May 30, the U.S. Food and Drug Administration (FDA) approved tofacitinib for the treatment of moderately



to severely active ulcerative colitis. Tofacitinib, which is made by Pfizer Labs, was previously approved in 2012 for rheumatoid arthritis and in 2017 for psoriatic arthritis.

FDA approval of a new treatment for any disease is a major achievement, requiring the efforts of thousands of people, including the clinical investigators and especially the thousands of patients who participate in clinical trials.

Tofacitinib is now available to ulcerative colitis patients whose doctors feel it is an appropriate course of treatment for their disease.

Learn more about IBD treatments in our [Medication Guide](#).

Hear From Investigators

Researchers are eager to find answers to the many questions surrounding the onset, treatment, and management of IBD. But to find the answers to these important questions, researchers first need patients to participate in research.

We understand that participating in research may seem a bit intimidating at first. In an effort to connect more patients with research investigators, we recently invited two IBD researchers to sit down with us and talk more about their research in our latest clinical trial vlogs and Q&A sessions.

New in Clinical Trials Vlogs



Ever wonder what fecal microbiota transplantation is? If you do, you are not alone. Dr. Neil Nandi, Director of the Inflammatory Bowel Disease Center at Drexel University, College of Medicine, sits down and explains this procedure and its relevance to the IBD community [here](#).



Dr. James Lewis, whose study we highlighted in the Spring 2018 issue, also sat down with us to discuss his study, the *Effectiveness of the Specific Carbohydrate Diet™ (SCD) Compared to the Mediterranean-Style Diet (MSD)*, for adult patients with active Crohn's disease in more depth [here](#).

Expansion of IBD Qorus Initiative



[IBD Qorus™](#) is the Crohn's & Colitis Foundation's quality improvement initiative designed to drive improved care and health outcomes for adult patients with IBD. Through IBD Qorus, health care teams from centers across the United States convene with patients to learn and share best practices for improved health care delivery. By applying best practices through IBD Qorus, we will ultimately improve the quality of care and health outcomes for IBD patients.

In an effort to increase awareness of this important initiative, the Foundation is currently preparing for a widespread expansion of the program. Alandra Weaver, director of IBD Qorus, shared her thoughts on why this expansion is critical to our mission:

“The Foundation’s steadfast commitment to improving patient outcomes and bettering quality of life necessitates widespread expansion and adoption of IBD Qorus in the United States, ensuring that all patients living with IBD receive the best care possible.”

Improve Your Research Vocabulary
With Our Word of the Quarter!

Randomization

Study participants are often assigned to one of two groups in such a way that each participant has an equal chance of being assigned to each treatment (or control) group. Randomization in clinical trials is important so that researchers can ensure that no specific criteria are used to assign certain patients to a particular group, thus making both groups equally comparable.

What Is It Like to Participate in a Clinical Trial?

Clinical trials play an important role in getting new treatment options approved for IBD patients. Yet making the personal decision to participate in a clinical trial can be a difficult choice for many.

If you're considering whether or not participating in a clinical trial is right for you, listen to our two newest additions to our [clinical trial video](#) series. Sara and Carly discuss:

- how they came to the decision to participate in a clinical trial
- what their experience was like working with the research team
- how they are doing today



Q&A With Dr. Randy Longman, Weill Cornell School of Medicine

Dr. Randy Longman sat down with Crohn's & Colitis Foundation Translational Research Manager Gerard Honig to discuss his research interests in the relationship between joint inflammation and gut inflammation as well as highlight how his research relates to precision medicine. See more [here](#).

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 3 draining perianal fistulae

For more information on the DIVERGENCE 2 study, please visit [here](#).

SELECTION Study

Combined Phase 2b/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 Ulcerative Colitis

You may be eligible for the SELECTION study if you:

- Have a diagnosis of ulcerative colitis
- Have moderate to severe disease despite treatment with corticosteroids, or immunomodulators, or TNFa inhibitors, or vedolizumab

For more information on the SELECTION 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 TNFa inhibitors, or vedolizumab, or ustekinumab

For more information on the DIVERSITY 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 4 months
- Previously demonstrated an inadequate clinical response, loss of response to, or intolerance to at least 1 of the following agents: corticosteroids, immunomodulators, tumor necrosis factor alpha (TNFa) antagonists, or vedolizumab

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

