

Clinical Trials Community eNewsletter

Spring 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. We also want to hear from you! Reach out to our team at clinicaltrials@crohnscolitisfoundation.org to share your clinical trial experiences, local research updates, or other opportunities on our blog.

Diet and IBD

There has been increasing interest throughout the IBD community about the role diet plays in disease management. Living with Crohn's disease or ulcerative colitis may have an impact on your dietary needs and nutritional status, and diet may play a role in the disease.

We are excited about a new diet study being led by Dr. James D. Lewis and his team at the University of Pennsylvania to examine the effectiveness of the Specific Carbohydrate Diet™ (SCD) compared to the Mediterranean-style diet (MSD) for adult patients with active Crohn's disease. The study hopes to determine whether the SCD diet is superior to the MSD diet in inducing clinical remission in patients.

[Click here](#) to learn more about this study.



Women in IBD: Q&A with Dr. Meena Bewtra, IBD Patient and Researcher

March was Women's History Month, and we were excited to highlight Dr. Meena Bewtra, a gastroenterologist and researcher at the University of Pennsylvania, on our blog.

Dr. Bewtra has been involved with the Foundation for several years, and is a co-investigator in our adult registry, SPARC IBD. We know that one-fits-all treatment is not ideal for most patients. With SPARC IBD, we are collecting clinical data and biosamples from patients across the country to help researchers determine if a treatment may be more or less likely to work for a specific patient. Already, close to 800 patients are participating in SPARC IBD and helping to accelerate the science.

We interviewed Dr. Bewtra to learn more about her journey as an IBD patient, researcher, and why public advocacy is so critical.

"There is one more aspect of research in IBD that I think is essential, and that is the aspect of public advocacy. I think all researchers, doctors and scientists need to be more vocal and active in our fields—and IBD is no exception. This is a disease of a lifetime, with ramifications beyond just the disease itself. Therefore, research cannot be limited to just finding new mechanisms of disease or new therapies—we need to advocate for the whole patient, including protections for their access to health care. I am so proud to see more and more physicians, especially in the field of IBD, doing this; the Crohn's & Colitis Foundation and patients themselves have been doing this advocacy work from the beginning—we as physicians need to catch up with all of you!"

Click [here](#) to read the full Q&A with Dr. Bewtra.



Clinical Trial Term of the Month: **Placebo**

A placebo is a pill or liquid that often looks like the real medical treatment except it does not contain active medication. Placebos play a very important role in clinical trials as they help researchers determine whether an effect is truly because of the new treatment or molecule being tested.

What is the Role of a Clinical Research Coordinator?



There are lots of people who work on clinical trials, including clinical research coordinators. This month, we are highlighting our Q&A with Miriam Perez, clinical research coordinator at the University of North Carolina Chapel Hill. Learn more from Miriam about how clinical trial participants work closely with the study's research coordinator throughout their participation by clicking [here](#).

Clinical Trials Community Featured Research Spotlight

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 a 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 a 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 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 (TNFa) antagonists, or vedolizumab

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

New Resources Launching Soon!

The Clinical Trials Community will be launching three new patient testimonial videos in our [series](#) this spring, featuring additional firsthand accounts of IBD patients who have participated in clinical trials across the country. Stay tuned to learn about the journeys of Sara, Brandon, and Carly.