For those who have never been involved in research studies, the words “clinical trial” may be a little bit scary. Often patients don’t realize exactly what a clinical trial entails and all the benefits they have to offer. The Inflammatory Bowel Disease research team here at UofM, along with many other divisions of medicine, dedicates a large part of their research to therapeutic drug trials for Crohn’s disease and ulcerative colitis. These trials are an opportunity for patients with IBD to try new therapies that they would not normally have access to otherwise.

A typical therapeutic clinical trial consists of an induction phase, aimed to induce remission and a maintenance phase aimed to maintain remission. In most trials, patients will have a chance of receiving placebo (inactive medication) during the induction phase in order to prevent any bias. Patients will often experience a placebo-effect, or the belief that a treatment is working when in reality there is no clinical sign of disease improvement. Once patients reach the maintenance phase of the study, there is typically no placebo involved anymore and everyone is given active medication for anywhere from 2-4 or more years depending on the trial. All patients on study receive the study medication at no cost to them and often receive a stipend at each visit to reimburse for travel and time lost from work.
Currently Enrolling IBD Clinical Studies

**ETROLUZUMAB**

**HICKORY**

**Drug:** etrolizumab, injection under the skin

This is a phase 3 study for patients with moderate to severely active Crohn’s disease. This medication is an anti-integrin β7 therapy that regulates white blood cell trafficking in the lining of the intestines.

**BERGAMOT**

**Drug:** etrolizumab, injection under the skin

This is a phase 3 study for patients with moderate to severely active Crohn’s disease to evaluate the safety and effectiveness of etrolizumab, a Beta 7 anti-integrin that acts on the lining of the gut to block white blood cell trafficking. If enrolled in the study, patients have the ability to receive free etrolizumab for up to 3 years.

**LUX-MEDI2070**

**Drug:** MEDI2070, injection under the skin

This is a phase 2 study for patients with moderate to severely active Crohn’s disease to evaluate the safety and effectiveness of a new biologic medication targeting interleukin-23.

**VERSIFY**

**Drug:** vedolizumab (Entyvio), infusion

This is a phase 4 study for patients with moderate to severely active Crohn’s disease. Patients receive medication for 26 weeks.

**UNIFI**

**Drug:** ustekinumab (Stelara), injection under the skin

This is a phase 3 study for patients with moderate to severely active Crohn’s disease. The total time in the study could be up to approximately 220 weeks (4.25 years). If you qualify, you will receive study-related medications and physical exams at no charge to you. Participation will require regular monthly visits for the duration of the study.

**MONGERSEN UC**

**Drug:** Mongersen (antisense to SMAD7)

A Phase 2, Open-label, Multicenter Study to Explore the Efficacy and Safety of Mongersen (GED-0301) in Subjects with Active Ulcerative Colitis.

**GILEAD**

**Drug:** GS-5745, injection under the skin

This is a phase 2 study for patients with moderate to severe active Crohn’s and ulcerative colitis to evaluate the safety and effectiveness of GS-5745, a new biologic medication targeting MMP9.

**OXAZOKAN**

**Drug:** OXAZOKAN

This is a phase 4 study for patients with moderate to severe active ulcerative colitis and another for those with Crohn’s disease.

**Observational Study Opportunities**

**GEM Project**

Our goal for this study is to follow healthy brothers, sisters and children of patients with Crohn’s disease to try to identify the different factors that may lead to the development of this disease.

**WHO CAN PARTICIPATE?** You can participate in this study if you are generally healthy, between the ages of 6 and 35, and have a sibling or parent that has been diagnosed with Crohn’s disease.

**WHAT IS INVOLVED?** Your participation would involve one visit where we would ask you to complete 3 questionnaire’s and give a blood, urine, and stool sample. You would then be contacted by telephone every 6 months for up to 6 years to ask if there are any changes to your health.

**Upcoming Clinical Studies**

**ELI LILLY**

**Drug:** LY3074828 (anti-IL23)

A Phase 2, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of LY3074828 in Subjects With Moderate to Severe Ulcerative Colitis.

**PIOONEER**

**Drug:** CROWN

A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effectiveness of a Nutritional Intervention in Improving the Intestinal Mucosal Health Status in Subjects with Crohn’s Disease (CD) Receiving Induction Anti-TNF Therapy PIONEER-CD.

Contact the UM IBD Clinical Trials Team!
email: higginsSCteam@umich.edu or call 734-647-4548

**facebook** www.facebook.com/UMIBD