WHY SHOULD I CONSIDER A CLINICAL TRIAL?
- Access to free physical examinations and diagnostic tests related to the clinical study
- Access to investigational treatments before they become widely available
- Opportunity to play a role in the discovery of treatments, cures, and preventions for certain diseases or medical conditions
- Ability to play a more active role in your own healthcare
- Potential compensation for time and travel related to the clinical study
- Opportunity to help people suffering from medical conditions

Take Steps Grand Rapids
June 4, 2016
John Ball Zoo
10:00 a.m. Registration Opens
11:30 a.m. Walk Begins

Take Steps Metro Detroit
June 18, 2016
Meininger Park, Royal Oak
9:00 a.m. Registration Opens
10:30 a.m. Walk Begins

Take Steps Northwest Ohio
September 24, 2016
Toledo Zoo
8:30 a.m. Registration Opens
9:30 a.m. Walk Begins

For more information or to register visit www.cctakesteps.org

Anti-adhesion Therapies:
There is a new medication that was approved for ulcerative colitis and Crohn’s Disease in May 2015 called Entyvio. This will be the first approved anti-adhesion therapy that is specific for Inflammatory Bowel Disease. But, what does anti-adhesion really mean?

Adhesion molecules in the gut direct white blood cells to the area of active inflammation. By blocking this molecule, fewer white blood cells are directed to the gut, and the inflammatory response decreases. What makes this different than some previous trials is that the immune suppression is limited to the gut only. Currently, we are studying a few other anti-adhesion medications in clinical trials here at the University to see if they are also effective in decreasing the inflammation for patients with Inflammatory Bowel Disease.

JAK Inhibitors:
JAK is a molecule known as a kinase. When active, it will turn on a mechanism in a cell that will cause the cell to make more inflammatory molecules. The increased number of inflammatory molecules can cause more inflammation in your gut and cause you to have a flare. By blocking the JAK molecule, we can block the production of these inflammatory molecules and reduce the inflammation in your gut. Currently, a medication known as Xeljanz is a JAK inhibitor that has only been approved in Rheumatoid Arthritis. However, we are studying this medication in clinical trials here at the University to see if they are effective in decreasing the inflammation for patients with Inflammatory Bowel Disease, such as Crohn’s disease and ulcerative colitis.
Currently Enrolling IBD Clinical Studies

**ETROLIZUMAB**

**HICKORY**
Drug: etrolizumab, injection under the skin
This is a phase 3 study for patients with moderate to severe active ulcerative colitis. 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 β7 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 biological medication targeting interleukin-23.

**GILEAD**
Drug: GS-5745, injection under the skin
This is a phase 2 study for patients with moderate to severely active Crohn’s and ulcerative colitis to evaluate the safety and effectiveness of GS-5745, a new biologic medication targeting MMP9.

**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 severe active ulcerative colitis. Participants receive medication during Part 1 of the study which lasts for 10 weeks. Those who respond to the treatment at the end of 10 weeks will enter Part 2 of the study, which may continue for an additional 42 weeks. There is also an extension to this study which will go 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.

**OZANIMOD**
Drug: RPC01, oral medication
There are two studies available. One for patients with moderate to severe active ulcerative colitis and another for those with Crohn’s disease.

**SASA SWITCH STUDY**
This is a study aimed to switch patients with ulcerative colitis from an expensive 5-ASA to the more cost efficient sulfasalazine. We will work closely with patients to ensure proper dosing of sulfasalazine and monitor disease symptoms.

**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.

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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.

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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.

**PIONEER**
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.

**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.

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**P2PEP**
Patient-2-Patient Education Project

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