

# IBD Patient News

Spring 2016

U-M Division of Gastroenterology

## P2PEP Patient-2-Patient Education Project



We hope you will join the Crohn's Colitis Student Initiative and the UMHS IBD program for the first Patient-2-Patient Education Project. The idea for this event came from a panel of patients along with each of the topics that will be discussed at the event. We hope this will be an informative and educational event for patients, their families, and healthcare providers.

Saturday, April 16, 2016  
10:00am to 3:00pm  
Palmer Commons  
100 Washtenaw Ave.  
Ann Arbor, MI 48109

### Topics

Traveling with IBD  
College and IBD  
IBD and Finances  
Supporting Loved Ones with IBD  
The Pediatric to Adult Transition  
IBD and the Work Place  
Life with an Ostomy  
And more!

### Here's How to Register

[https://  
www.surveymonkey.com/  
r/9Y3FYFT](https://www.surveymonkey.com/r/9Y3FYFT)

Please email or call Anna  
with further questions.

Anna Romans  
(734) 615-7977  
[aromans@med.umich.edu](mailto:aromans@med.umich.edu)

### Who can attend? Is there a fee?

Our audience includes patients as well as their family or friends. There is no cost to attend. There will be a registration to guarantee that we have enough seats available for participants.

### 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

## Terms to Know

### Anti-adhesion

#### Therapies:

There is a new medication that was approved for ulcerative colitis and

Crohn's Disease in May of 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.

## TAKE STEPS

FOR CROHN'S & COLITIS

### 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](http://www.cctakesteps.org)

# 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  $\beta 7$  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.

## 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.

## VERSIIFY

**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**. 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.

## 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

**The UC study** is a two part study where those who qualify to participate will receive investigational medication during Part 1 of the study which lasts for 10 weeks. Patients 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 until 2020.

**The Crohn's study** is a phase 2 that has no placebo arm. There is a 12 week induction period and for patients who are responding they can continue into the 100 week maintenance portion.

## 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.

## 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.

# 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.

## 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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[www.facebook.com/UMIBD](https://www.facebook.com/UMIBD)



Contact the UM IBD Clinical Trials Team!  
email: [higginsSCTeam@umich.edu](mailto:higginsSCTeam@umich.edu) or call 734-647-4548