

# Clinical Trials Community eNewsletter

Fall 2019

CLINICAL TRIALS  
Community  
CROHN'S & COLITIS  
FOUNDATION

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 inflammatory bowel disease (IBD).

## Therapy News: Investigating Acupuncture

Among the many IBD research studies, the use of acupuncture to help with gastrointestinal (GI) symptoms is also being investigated. Check out our latest research update blog post, [Acupuncture in Inflammatory Bowel Disease](#), and learn about IBD research looking at acupuncture's potential to help to control symptoms and ease pain, when used along with traditional medical treatment.

## PROPS: A New Study for Ileoanal Pouch Patients

There's a new study ongoing for patients living with an ileoanal (J, W, S) pouch! PROPS (Patient Reported Outcomes after Pouch Surgery) aims to give researchers a clearer picture about patient priorities and experiences after ileoanal pouch surgery.

If you are an IBD patient with an ileoanal pouch and want to help guide future research on ileoanal pouches, researchers want to hear



from you and learn your perspective on living with a pouch! You can learn more about this study [here](#).

## Get to Know Diane, a Clinical Trials Ambassador:



Diane K. is from Atlanta, GA and is one of our Clinical Trials Ambassadors. Her daughter Alysa, (pictured), was just seven years old when she was diagnosed with Crohn's disease. After trying different medications and switching doctors, Alysa's family was approached by her doctor about enrolling her in a clinical trial. Diane and her family learned about clinical trials and asked many questions before making their decision to enroll her in the trial. Read Diane and Alysa's story [here](#).

## The Clinical Trials Roadmap

Learn what to expect with clinical trials participation in our [roadmap](#) outlining the steps of the clinical trials process. This is just one of many resources within the Clinical Trials Community to help you gain a deeper understanding of the role of clinical trials in the treatment of IBD.

## IBD Treatment News

In July, the U.S. Food & Drug Administration (FDA) made two announcements regarding IBD treatments:

The FDA announced the approval of HADLIMA™ (adalimumab-bwvd), a biosimilar referencing HUMIRA (adalimumab) for the treatment of ulcerative colitis and adult Crohn's disease.

HADLIMA will not be available in the market until 2023.

The FDA approved new boxed warning about the increased risk of blood clots and death with the 10-milligram, twice-daily dose of Xeljanz (tofacitinib), which is used in patients with ulcerative colitis. Because of the risk of blood clots, use of Xeljanz will be limited to patients who are not treated effectively or who experience severe side effects with other medications.

Learn more from our [research updates post](#).



## Get Involved: Apply to Become a Clinical Trials Ambassador

Are you a Crohn's disease or ulcerative colitis patient or the parent of a pediatric patient who has participated in an IBD clinical trial before? Do you feel passionate about helping advance IBD research? If so, you may be interested in applying to become one of our Clinical Trials Ambassadors!

Visit the [Clinical Trials Community](#) to apply! The application deadline is August 30, 2019.

Improve Your Research Vocabulary  
With Our Phrase of the Quarter!

### Clinical Trials Sponsor

A clinical trials sponsor can be a person, group, company, institution, or an organization. The sponsor introduces and manages the study and is responsible for training and supervising medical personnel, such as principal investigators, who carry out the clinical trial procedures. Additionally, they are in charge of gathering and evaluating the data.

## Clinical Trials Quiz!

### During Which Clinical Trials Phase Does FDA Approval Occur?

Do you know the answer? Select your answer from the options below to see if you are in the know with clinical trials!

- A. Phase 1
- B. Phase 2
- C. Phase 3
- D. Phase 4



Correct Answer: C. Phase 3

Phase 3 trials occur if the study medication is showing positive results in Phase 2 trials. If the study medication continues to do well during this phase, the study sponsor can send an application to receive FDA approval. This process can take several months.

To learn more, visit [FDA's Drug Review Process](#).