

## DUET-CD Patient Fact Sheet

# EXPLORE RESEARCH OPTIONS FOR CROHN'S DISEASE

## Consider participating in a Crohn's disease clinical trial

Janssen is currently conducting clinical trials for people with Crohn's disease because there is still a need to find treatments that work for everyone. The good news is that we can continue to make progress and potentially find options through clinical research. Let's do it together.

### ABOUT THE DUET-CD STUDY

The purpose of the **DUET-CD Study** is to evaluate the safety and efficacy of a combination of two investigational medications compared with placebo in adults with moderately to severely active Crohn's disease.

You may be able to take part in the **DUET-CD Study** if you:

- Are at least 18 to 65 years old
- Have had a diagnosis of Crohn's disease or fistulizing Crohn's disease for at least 3 months
- Are currently experiencing a reappearance or worsening of your Crohn's disease symptoms, called a flare, which may include:
  - Frequent and/or urgent bowel movements
  - Abdominal pain
  - Lack of appetite
  - Diarrhea
- Have been unsuccessful with previous medications to treat your Crohn's disease

Additional eligibility criteria will be assessed by the trial doctor or staff.



## FAQS

### What's involved with participation in the DUET-CD Study?

Participants will receive their assigned trial medication(s) – one of two investigational medications, a combination of both investigational medications, or placebo – while completing various tests and procedures.

- The trial consists of four periods:
  - Screening Period (up to 8 weeks)
  - Induction Dosing Period (12 weeks)
  - Maintenance Dosing Period (36 weeks)
  - Follow-Up Period (12 weeks; starts after the last dose of trial medication)
- If the participant and treating physician agree that it is in the participant's best interest, participants may continue in the trial in what is called a Long-Term Extension (LTE) Period after the Maintenance Dosing Period ends. During the LTE, participants will continue receiving their trial medication for approximately 4 more years.
- Participation also includes regularly scheduled trial visits for tests and procedures every 4 weeks.

### Is there a placebo in this trial?

Yes, there is a placebo in this trial. A placebo is an inactive substance that looks like the investigational medications being tested, and it is used to help determine the safety and efficacy of the investigational medications being studied compared to the absence of the investigational medications. However, all participants will have an opportunity to receive the combination of investigational medications if they do not respond to initial trial medication.



**Participants have a 9% (or 1 in 11) chance of receiving placebo.**

### Does participating in this trial cost anything?

All trial-required visits, tests, and medications are provided at no cost. The trial will not pay for other medical care or current medication(s) needed to support your daily healthcare routine. In addition, reimbursement for trial-required travel, meals, and parking may be available.

### If prequalified, what can I expect on my first visit to the trial clinic?

This initial appointment is an opportunity for you to:

- **Ask any important questions you may have.** These can be any questions you may have about this trial or clinical trials in general.
- **Determine if the DUET-CD Study may be right for you.** You will speak with a trial coordinator and learn more about the trial. The trial coordinator will ask you about your health history to determine if you are eligible for the trial. If you are eligible, you will be given the opportunity to decide if participation is right for you. If you agree to take part, you will be asked to review and sign a consent form for trial participation. Once you have signed the trial consent form, the research staff will perform a series of tests to determine if you are right for the trial and if the trial is right for you. Even if you decide to participate, you can leave the trial at any time.

### What if my condition worsens or I have side effects?

You will be closely monitored while participating in the trial, and you should make sure to inform your doctor of any new symptoms you experience.

### Where are the trial clinics located?

There are trial clinics located around the world. Find a location near you by visiting [weknowibd.com/current-trials.html](http://weknowibd.com/current-trials.html).

**SEE IF THE DUET-CD STUDY IS RIGHT FOR YOU.**



844-329-1618



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