ForPatients
by Roche

Inflammatory Bowel Disease (IBD)

An Observational Study to Assess the Relationship Between Disease Flare States and Patient-Reported Health Data, Health Data from a Wearable Activity Tracker, and Biomarker Data Obtained Through a Decentralized Process in Patients with Inflammatory Bowel Disease

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	XA43467

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A Study to Assess the Relationship Between the Disease Flare States and Participant-Reported Health Data, Health Data from a Wearable Activity Tracker, and Biomarker Data in Participants with Inflammatory Bowel Disease (IBD)

F. Hoffmann-La Roche Ltd
Sponsor

XA43467
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	18 years and Above	No

Background and study aims:

Inflammatory bowel disease (IBD) is a group of disorders that cause chronic inflammation (pain and swelling) in the intestines. The cause of IBD remains unknown, although hereditary and environmental factors may trigger inflammation. IBD includes two related diseases, ulcerative colitis (UC) and Crohn's Disease (CD). Both cause chronic or long-term inflammation in the digestive tract (gastrointestinal tract; GI) which are characterized by diarrhoea, rectal bleeding, abdominal pain, fatigue (tired, feeling of weakness) and unintended weight loss.

The participants living with IBD experience flares (an increase or worsening of IBD symptoms), which are unpredictable reappearances of intestinal inflammation and associated symptoms. IBD flares may lead to invasive procedures such as a colonoscopy and often require an escalation in medical management. Implementing a proactive approach to monitoring IBD flares remains a challenge. This is an observational study wherein researchers observe participants, and no study medications or treatments are given. The main purpose of this study is: -

· To find out whether data collected from a Fitbit® activity tracker, surveys, and blood, stool, and saliva samples can be used to better understand and manage IBD.

· To improve early detection and monitoring of IBD flares which could allow for earlier treatment and decrease the need for more invasive procedures such as a colonoscopy.

· To find out whether data collected from a Fitbit® activity tracker, surveys, and blood, stool, and saliva samples can be used to predict IBD flares.

· To assess the feasibility of collecting blood, stool, and saliva samples, PRO data, and activity tracker data via a decentralized process and to assess the quality of the resulting data

Who can participate?

People aged 18 years and above with Crohn’s disease or Ulcerative Colitis.

What does the study involve?

Participants may be asked to be in the study for approximately 13 months. This includes: -

· Screening and Enrolment Period of up to 1 month where the participants will be checked for their eligibility by completing an online Screening Survey. Eligible participants will be provided with an activity tracker for data collection and asked to carry out a few tests at home. First, a mobile phlebotomist visit (home visit by personnel trained to collect blood and other biological samples) will be scheduled. Participants will also be asked to download the IBDoc CalApp to perform the first IBDoc at-home stool test.

· Observation Period of approximately 12 months where participants will have to complete daily, weekly, bi-weekly surveys from the mobile app. They will be required to wear the activity tracker 24 hours a day and will have to perform at-home tests, including stool and saliva (self-collected), and blood draws (collected by a trained mobile phlebotomist that will come to participant’s home, or place of choosing, to draw blood and gather the self-collected stool and saliva samples)

Participants will be placed in one of the following groups:

· Group 1: Participants with UC will be observed for approximately 12 months.

· Group 2: Participants with CD will be observed for approximately 12 months.

What are the possible benefits and risks of participating?

The participants will be paid based on the activities they perform in five payments, one payment upon enrolment and one payment every 3 months for the duration of the study. Apart from this, the information that is learned may help people with IBD in the future.

The study does not involve the testing of any new or experimental drugs or devices. Few potential risks are listed below:

· Drawing blood can cause pain, bruising, or infection where the needle is inserted

· Participants may experience dizziness, fainting, or upset stomach when the blood is drawn

· Participants may experience skin irritation or discomfort on the wrist from wearing the Fitbit. The lifestyle may be affected by having to wear a Fitbit all the time, including during sleep.

· The sample collection kits could get lost in the mail and there is some risk to privacy due to the participant’s name being present on the package

Genentech and Genentech's representatives (people and companies such as Evidation who work for Genentech) will not pay for any medical care for injury or illness related to the participation in this study.