ARE THERE ANY RISKS?

Blood sample collection may cause minor discomfort, bruising, or a temporary light-headed feeling.
There are always uncertainties regarding receiving a risk estimate for a disease. It could cause anxiety, especially if your score suggests a high risk for developing CD. It is also possible to feel a false sense of security if your score suggests a low risk. The estimated risk will be based on the data collected in this and earlier studies. It is not a definitive diagnosis or a guarantee that you will or will not develop the disease.

Furthermore, we assure you that:

- Your enrolment is entirely voluntary.
- You can withdraw your consent at any time with no consequences for your, or your rela- tive's, medical care.
- There are no costs associated with entering the study.

WHAT SAFETY MEASURMENTS WERE TAKEN?

- Your identity and personal information will be kept separate from your samples and data. Access to samples and data will only be possible with an assigned code to assure your privacy.
- None of your personal information will appear in any reports or publications resulting from this study.
- Your personal risk prediction will be kept confidential. You also have the option to not receive your risk estimate at the end of the study.

Study Coordinator: [.....]
Email: [.....]
Phone: [.....]

For more information on the project visit

www.intercept-ihi.eu

INTERCEPT

STUDY INFORMATION SHEET

THE PREDICT-CD STUDY

"Prospective Risk Evaluation and Detection of Crohn's Disease in First-degree Relatives"

WHAT IS INTERCEPT?

The INTERCEPT consortium is composed of clinicians, investigators, pharmaceutical companies, and patient associations, and is supported by a large European grant.
We are all working together to define biomarkers - specific molecules (such as DNA, RNA, proteins, metabolites or hormones) that indicate a normal or abnormal process taking place in your body - for predicting Crohn's Disease (CD) development with the overall goal of implementing early interventions
that may intercept disease and change the outcomes and course of the disease.
The PREDICT-CD is a prospective study promoted by the consortium, that aims to recruit first-degree relatives (parents, full siblings, or children of people with CD) and test them for biomarkers.

This project is supported by the Innovative Health Initiative Joint Undertaking and its members and Ludger Ltd, Celltrion Inc. and Prometheus Laboratories Inc., under grant agreement 101194780.

STUDY OBJECTIVES

Identify biomarkers that predict a high risk of developing CD.

Develop a risk score that incorporates biomarker (s) and potentially other risk factors (including lifestyle and others) that may identify individuals at high risk for disease development.

WHY ME?

You are invited to participate in the PREDICT-CD because you are between 16 and 35 and have a first-degree relative affected by CD. We know that first-degree relatives of someone with CD have an approximate 8-fold higher risk of developing the disease.
Your involvement will help us explore clinical, biological, analytical, and lifestyle factors that could predict the risk of CD.

WHAT AM I CONSENTING TO?

If you enroll in the study, you will be asked to donate serum (the fluid part of blood after clotting) and to fill out electronic questionnaires about your health and lifestyle at baseline and every 6 months, expectedly until the end of 2029. Additionally, you can also accept donating blood and stools.

BENEFITS

Knowing your estimated risk for CD may lead to earlier awareness and you may monitor symptoms and seek early prevention or treatment, which can improve your outcomes.

Also, your participation will contribute to:

- advancing our understanding of CD.
- identifying biomarkers that could lead to better diagnostic tools, treatments, and preventive strategies for at-risk individuals in the future.