

Innovative Health Initiative Launches INTERCEPT: A Pioneering Trial Aimed at Realizing a Future without Crohn's Disease

Multi-million Euro research initiative undertakes first-ever prevention and disease interception trial using biomarkers with the goal of transforming Crohn's Disease from an incurable condition to one that may be managed and potentially prevented.

Amsterdam, Lisbon, New York, Örebro, Groningen, St. Ingbert 22 January 2025 – In a groundbreaking effort to change the future of Crohn's Disease, the INTERCEPT project launches Europe's first-ever trial using biomarkers aimed at preventing the symptomatic onset of the disease before it even begins. This multi-million Euro initiative funded by the Innovative Health Initiative Joint Undertaking (IHI JU) with a total budget of more than EUR 38 million for the next five years aims to transform Crohn's Disease from an incurable condition to one that can be effectively managed and potentially halted before it even starts, improving the quality of life for millions globally.

Approximately three million people in Europe are affected by Inflammatory Bowel Disease (IBD) with an increasing incidence in children and young adults. In addition to the debilitating symptoms – such as diarrhoea, stomach pain and weight loss – patients also face increased risks of complications, including colon cancers, delayed growth in children and mental health challenges like depression. Crohn's Disease, one of the most common forms of IBD, is chronic and incurable, with patients enduring waves of remission and flare-ups. Despite major advances in medication and therapeutic treatments, remission is still far from a universal experience and there is a persistent treatment gap. Nearly 50% of patients require surgery within ten years of diagnosis and only a minority, around 10%, experience prolonged remission. This chronic condition presents a significant burden not only on individuals and their families but also on societal productivity and national health systems.

In other inflammatory conditions, such as Type 1 Diabetes and Rheumatoid Arthritis, biomarkers - measurable substances found in body fluids - can signal the presence of the earliest stages of the disease before it clinically manifests, enabling the potential for predicting who is at risk for developing these conditions. There is growing evidence that biomarkers could also be used to detect Crohn's Disease in the preclinical phase long before symptoms develop. Candidate biomarkers have been developed for Crohn's Disease but not yet validated across multiple populations.

INTERCEPT Project

This is where the newly launched INTERCEPT project comes in. In discussing the significance of the project, Prof Geert D'Haens, Project Coordinator from Stichting Amsterdam UMC (AUMC), stated: "We have been able to design this project due to our colleagues in North America laying the scientific



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foundation of predictive biomarkers for Crohn's Disease. Although our field is somewhat behind Type 1 Diabetes and Rheumatoid Arthritis, we are confident that we have strong and reliable biomarkers and very safe treatments to offer."

In continuing on the use of biomarkers, Awny Farajallah, MD, FACP, Chief Medical Officer at Takeda Pharmaceutical Company Limited, Industry Lead for INTERCEPT, continued: "Biomarkers are key to future research and have the potential to revolutionise the treatment landscape for IBD."

The INTERCEPT project aims to verify and clinically validate a panel of biomarkers and build a blood risk score that can identify individuals with a high risk of developing Crohn's Disease within five years after initial evaluation. The project will recruit 10,000 healthy first-degree relatives of individuals with Crohn's Disease from seven European countries to further validate the biomarkers and risk score. From this group, 80 with the highest risk of developing Crohn's Disease will take part in an innovative trial aimed at preventing full-blown disease development through an established and highly effective medical treatment. This early detection and prevention method has the potential to revolutionise the way we understand and treat Crohn's Disease. It would enable healthcare professionals to diagnose the disease early on, potentially keeping it from progressing to debilitating stages. INTERCEPT is setting its sights on a future where Crohn's Disease is highly manageable or even avoidable; committing itself to improving the lives of patients and their families.

To achieve this ambitious goal, 21 collaborative partners from Europe, North America and South Korea have joined forces. In discussing their role in the project and collaboration, Farajallah elaborated: "At Takeda, we are dedicated to improving IBD patient care and are excited to join forces with the Innovative Health Initiative with the aim of transforming the treatment of Crohn's Disease. In intercepting Crohn's Disease, we face complex scientific challenges that no one organisation can address alone. Our collaboration will unite public and private sector expertise and resources to more efficiently advance Crohn's research and potentially benefit IBD patients."

In highlighting the collaboration across continents, Prof Jean-Frédéric Colombel, Director of the Inflammatory Bowel Disease Center at Icahn School of Medicine at Mount Sinai in New York, USA and co-lead PI for INTERCEPT stated: "For the first time, researchers from multiple European countries, North America and South Korea are working together to predict and prevent Crohn's Disease, reaching a milestone in the long path we began to walk many years ago. Our combined success would reinforce the concept that immune-mediated diseases that not only affect the gut but also the joints, the skin and the brain can be prevented".

As INTERCEPT Project Coordinator D'Haens concluded with the immense potential of the project: "I am honoured to lead this unique collaboration of bright scientists from across the European continent, North America and South Korea. It really feels like this may lead to the most significant scientific progress in the field since the initial description of the disease by Burrill Crohn himself in 1932."



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The INTERCEPT project officially kicks off its activities with a consortium meeting in Berlin, Germany, on 19 February 2025.



Key Facts

Full Name: Verification and validation of a biomarker panel that identifies individuals at high risk to develop Crohn's Disease allowing INTERCEPTION of full-blown disease development.

Start Date: 01.01.2025

Duration: 60 months

Budget: EUR 38.05 million

Coordinator: Geert D'Haens, Stichting Amsterdam UMC (AUMC)

Website: www.intercept-ihl.eu

LinkedIn: [INTERCEPT IHI](https://www.linkedin.com/company/intercept-ihl)

Facebook: [Intercept IHI](https://www.facebook.com/Intercept-IHI)

Project Partners

Netherlands

- Stichting Amsterdam UMC
- Stichting VU
- University Medical Center Groningen (UMCG)
- Richard Vesely



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Portugal

- GLSMED Learning Health SA/Hospital da Luz

Sweden

- Örebro University

United States

- Icahn School of Medicine at Mount Sinai
- Prometheus Laboratories Inc

Denmark

- Aalborg Universitet

Italy

- Fondazione Policlinico Universitario Agostino Gemelli IRCCS

Austria

- United European Gastroenterology GmbH

Poland

- National Medical Institute of the Ministry of the Interior and Administration (PIM MSWiA)

Belgium

- European Federation of Crohn's and Ulcerative Colitis Associations

Spain

- Grupo Espanol de Trabajo en Enfermedad de Crohn y Colitis Ulcerosa Gettecu

France

- Centre Hospitalier Regional et Universitaire de Lille

Germany

- EURICE - European Research and Project Office GmbH

Norway

- Norges Teknisk-Naturvitenskapelige Universitet NTNU



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United Kingdom

- The Chancellor, Masters and Scholars of the University of Oxford
- Ludger Limited

Switzerland

- Takeda Pharmaceuticals International AG

South Korea

- Celltrion Inc

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About IHI

The Innovative Health Initiative is a public-private partnership between the European Union and the life sciences industry to advance health research and innovation. Established to address public health needs, IHI funds projects that leverage diverse scientific fields, including pharmaceuticals, biotechnology, and medical technology, to improve patient outcomes and enhance the competitiveness of Europe's health industries. The initiative integrates various sectors to develop innovative healthcare solutions that cover prevention, diagnosis, treatment, and disease management.

More here: <https://www.ihl.europa.eu/>



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