

Testimonial on the METHYLOMIC Project and BIRD's Role in Advancing Personalized Medicine for Crohn's Disease

METHYLOMIC: Targeting Hope for Personalized Medicine in Immune-Mediated Inflammatory Diseases

Project overview

The project METHYLOMIC, which kicked off in 2023 and will run for four years, is a pioneering effort funded by the European Union's Horizon Europe programme under grant agreement No 101095449. The project addresses the <u>call topic</u> 'Optimising effectiveness in patients of existing prescription drugs for major diseases with the use of biomarkers. It aims to personalize treatment allocation and consequently enhance the effectiveness of medications for chronic immune-mediated diseases (IMIDs) such as Crohn's Disease (CD), Rheumatoid Arthritis, and Psoriasis. Comprising 18 partners from 9 countries, METHYLOMIC focuses on advanced biological therapies that reduce inflammation, more specifically antibodies that target inflammatory proteins like Tumor Necrosis Factor (adalimumab), leukocyte trafficking (vedolizumab), and IL-12/IL-23 (ustekinumab).

The Challenge

Despite the crucial role of these biological therapies in IMID treatment, predicting their effectiveness in individual patients remains challenging. There is an imminent therapeutic ceiling, with only <40% of patients that have primary response to any given therapy. This leads to treatment failures, prolonged disease courses, complications, and subsequent increased healthcare costs. Moreover, this highlights the pressing need for predictive biomarkers to enable personalized treatment approaches.

Addressing the Need

METHYLOMIC addresses this need by building further on previous cohort studies that identified epigenetic biomarkers. More specifically, DNA methylation is recognized as a stringent predictor of response to biological therapy. Through validation of these biomarkers, METHYLOMIC aims to improve personalized treatment selection and enhance patient outcomes in CD and other IMIDs.

BIRD's Role in the OmiCrohn Trial

As one of the METHYLOMIC project partners, BIRD (Belgian IBD Research and Development group; <u>www.birdgroup.be</u>) is involved in the OmiCrohn trial, the prospective randomized clinical trial for individualized therapy in CD patients. BIRD supports patient recruitment, regulatory compliance, and data collection for Belgian sites, contributing to the clinical validation of the methylation biomarker assay. As a Belgian non-profit organization, BIRD is committed to advancing knowledge and care for inflammatory bowel diseases (IBD) through non-commercial studies and educational activities. Representing healthcare professionals across Belgium, including physicians, researchers, and paramedical staff, BIRD collaborates closely with patient organizations, industry partners, and regulatory bodies to ensure comprehensive and patient-focused IBD care.

Impact on IMID Management

METHYLOMIC is positioned to transform IMID management through personalized treatment selection. With BIRD's active role in the OmiCrohn trial, the project is set to deliver predictive, biomarker-based therapies that bring renewed hope and improved outcomes for Crohn's Disease patients across Europe.

Further information: For more details, please visit <u>METHYLOMIC's website</u>. Additional information about BIRD can be found at <u>www.birdgroup.be</u>.