Dear ECCO members,

Dear IBD National Study Group Representatives,

Dear colleagues,

**Invitation to collaborate on the multi-centre study**
***"Assessing the effect of newer treatment molecules for IBD on extra- intestinal manifestations and concurrent immune mediated inflammatory diseases"***

We are writing to invite your IBD centre to collaborate on a retrospective, multi-centre observational cohort study initiated by the IBD unit of the University Hospital of Ghent, Belgium.

**Background**

Immune mediated inflammatory diseases (IMIDs) represent a diverse group of conditions characterized by chronic inflammation affecting various organs, including the gut (inflammatory bowel disease (IBD)), joints (inflammatory arthritis such as spondyloarthritis (SpA)) or skin (psoriasis, hidradenitis suppurativa). Extra- intestinal manifestations (EIMs) of IBD can involve several organs such as the joints (axial and peripheral SpA (including psoriatic arthritis (PsA)), skin (erythema nodosum or pyoderma gangrenosum) and the eyes (uveitis). Effective disease control is essential due to the significant morbidity associated with EIMs and IMIDs.

With the advent of new therapeutic options for IBD, such as JAK- inhibitors and anti-IL23 molecules, questions regarding their efficacy and safety for treating IMIDs and EIMs in patients with IBD have arisen. Although some of these treatments have been approved for specific IMIDs and EIMs, their impact on patients with IBD and concurrent EIMs or IMIDs remains largely unexplored. This study aims to fill this critical knowledge gap.

**Study objectives**

The primary goal of this study is to evaluate the response and remission rates of EIMs and IMIDs following the initiation of JAK-inhibitors or anti-IL23 treatments for IBD. Additionally, we aim to assess the rate of new onset EIMs and IMIDs during treatment and correlate these manifestations with intestinal disease activity.

**Methodology**

Participating centres will retrospectively collect data on patients with IBD treated with JAK- or IL23-inhibitors who have at least one EIM or IMID at the start of treatment. The study will focus on the following conditions:

- Psoriasis
- Hidradenitis suppurativa
- Inflammatory arthritis such as axial and/or peripheral spondyloarthritis including psoriatic arthritis
- Uveitis
- Erythema nodosum
- Pyoderma gangrenosum

The finalized study protocol has been extensively reviewed by the Clinical Committee (ClinCom) of ECCO and is currently under review by the local Ethical Committee of the Coordinating Centre at the University Hospital of Ghent.

**Who can collaborate?**

We invite IBD centres that:

- Can retrieve data on the evolution of EIMs and IMIDs in IBD patients treated with JAK- or IL23-inhibitors.

- Are willing to fill out an electronic clinical research form (eCRF) via REDCap® software for all included patients.

- Can determine if local ethical committee approval and patient informed consent are required for a retrospective non-interventional study and, if so, handle the submission and consent collection.

**How to participate**

If your centre is interested in collaborating on this study, please contact Marie Truyens (marie.truyens@ugent.be) and Triana Lobaton (Triana.lobatonortega@uzgent.be) by September 20th, 2024. In your response, please indicate if ethical approval and informed consent are required in your jurisdiction and the expected timeline for obtaining them. We also encourage you to forward this invitation to other IBD centres in your country.

We aim to submit an abstract with initial data for ECCO 2025 and a full manuscript shortly thereafter. The authorship list will reflect the number of patients contributed by each centre.

We hope this collaborative study will be successful and foster further cooperation within the IBD research community. Thank you for considering this collaboration. We look forward to your positive response.

Sincerely,

Dr. Marie Truyens

Prof. Dr. Triana Lobatón