Dear ECCO members,
Dear IBD National Study Group Representatives,
Dear colleagues,

Anti-JAK inhibitor **tofacitinib** (TOFA) is the first small molecule that has been approved for the management of ulcerative colitis (UC). Real-life data on this medication are accumulating, particularly in complicated patients already experienced with multiple biologics. Since it is often considered the last medical option (particularly in the first period after approval), it is likely that patients with aggressive disease might need surgery while TOFA is still ongoing. Despite its short half-life, robust **evidence regarding the postoperative safety outcomes** of patients treated with this drug in the preoperative phase are lacking. In fact, surgery is often offered while the patient is still receiving the medication, and the decision on the exact timing of surgery and possible discontinuation of the immunosuppressant might be controversial.

In the near future, we as gastroenterologists will have an even wider range of treatment choices to induce disease remission and postpone the need for colectomy. Therefore, a **more confident** management of TOFA in the perioperative phase of an intestinal resection is necessary. The data that we will collect could also guide or at least serve as comparison with the new anti-JAKs that will be released soon in the market.

With this email, the IBD Referral Centre of the Careggi University Hospital of Florence (Italy) would like to ask different European IBD centres to collaborate on this topic in a **retrospective, multi-centre observational cohort study**. The aim of this study is to address the rate of postoperative complications of IBD patients treated with TOFA in the proximity of surgery, and **compare** them to that of the available biologics (including anti-TNFs, vedolizumab, and ustekinumab).

Each participating centre will be requested to retrospectively collect data on patients that underwent colectomy for medically refractory UC and received the last dose of biologic within 12 weeks or TOFA within 4 weeks from surgery. Patients operated in the setting of acute severe ulcerative colitis will be excluded from the analysis.

The final version of the study protocol (see attached) has been reviewed extensively by the Clinical Committee (ClinCom) of ECCO. The study is currently receiving approval by the local Ethical Committee of the Coordinating Centre (CEAVC – Comitato Etico Area Vasta Centro).

Who can collaborate?

- IBD centres with the possibility to retrieve data on UC patients undergoing colectomy and the necessary information in the perioperative period

- IBD centres who are willing to fill out an electronic clinical research form (eCRF) through **REDCap®** software for all included patients.

- IBD centres who are willing to verify themselves if approval by their local ethical committee and informed consent of the patient is mandatory in their jurisdiction for a retrospective non interventional study. If so, the IBD centre will be responsible for the submission to the local ethical committee as well as collection of the informed consent

If you are interested in collaboration to this study, please contact gabriele.dragoni@unifi.it and millam@aou-careggi.toscana.it by **September 15th 2022**, stating also if you need ethical approval and informed consent of each patient, and when you will expect this. Please also forward this email to other IBD centres in your country.

We will aim for the submission of an abstract (with initial data) for ECCO 2023 and a full manuscript shortly thereafter. The publication list will take into account the number of patients included in the study.

We truly hope that this retrospective study will become a success and might lead to an intense collaboration.

Sincerely,

Dr. Gabriele Dragoni