Dear ECCO National Representatives,

Dear IBD National Study Group Representatives,

Dear colleagues,

Few data are available regarding **checkpoint inhibitors-induced colitis** (ICIC) and ileo-colitis. Immune checkpoint inhibitors, including, among others, nivolumab, ipilimumab, atezolizumab, and pembrolizumab, are a relatively novel class of biologic therapies used for the treatment of several oncological diseases, including advanced melanoma skin cancer, non-small cell lung carcinoma, and kidney adenocarcinoma. Of note, one of the most common side effects of these drugs are immune mediated reactions, including the onset of ICIC that often require immunosuppressive therapy and ICI discontinuation.

No studies about ICIC with a long-term follow-up are available, and its pathological and clinical features, as well as its risk factors, are still under investigation.

The aim of this clinical research is to perform across different countries **a clinico-epidemiological study regarding patients diagnosed with ICIC** with at least 1 year of clinical follow-up after the first index colonoscopy (or until death if occurred within one year). The multicentric nature is necessary for enhancing the generalisability of the results.

With this email, the researcher groups from Pavia and of Turin (Italy) that promoted the study would like to ask to any research group, as well as individual centers, to take part to the study. Please note that the study will be composed of both a **retrospective and a prospective phase**. Each participating center will be requested to collect data -both in the retrospective and the prospective phases- on patients that have been diagnosed with ICIC.

The study protocol (here attached) has been reviewed by the Clinical Committee (ClinCom) of the ECCO. The study has also been approved by the local Ethics Committee of the IRCCS San Matteo Hospital, Pavia, Italy. We can provide all the documents for extending the approval to other IRBs.

Who can collaborate?

- any IBD, gastroenterological, oncological, or internal medicine center dealing with ICIC that are willing to provide data with an (expected) date of delivery of 31st December 2022 for the retrospective part and to enroll prospectively patients from January 2023 to December 2023 and follow them up for 12 months (prospective part)

- all centers that are willing to ask for approval to their local ethics committee, according to their local jurisdiction; each center will be responsible for the submission to the local ethics committee

Please note that even enrolling a few patients (3-5 per center) would be more than welcome. All **data will be collected through an electronic database -REDCap-** which has already been created and is ready to be shared. If you are interested in this collaboration study, please contact Marco Vincenzo Lenti (e-mail marco.lenti@unipv.it) by 31st October 2022. Inform us (marco.lenti@unipv.it) if you have any doubt or should you need an extension to the deadlines. Please also forward this email to other IBD/gastroenterological/oncological centers in your country that may be interested. We will aim for the submission of an abstract for the ECCO 2024 and a full manuscript shortly thereafter. We will fairly take into account the number of patients included in the study for the number authors to be included as full contributors; all collaborators will be included in any case in the "ICIC Collaborative Group" that will be reflected in PubMed.

This initiative was already discussed at the ECCO National Study groups meeting and received a lot of positive feedback and many centers have already shown their interest. Therefore, we truly hope that this study will become a success and will lead to new collaboration patterns.

Looking forward,

Dr. MV Lenti

Dr. DG Ribaldone

Dr. M Vernero

Dr. F Borrelli de Andreis