SOPs on Submission of Clinical Study Protocols

The European Crohn's and Colitis Organisation (ECCO) aims to promote the design and execution of innovative clinical studies in the area of Inflammatory Bowel Disease (IBD) in Europe. Thus, a Clinical research Committee (ClinCom) has been established to become the organ of advice on clinical studies in the field of IBD in Europe, based upon the comprehensive expertise existing within the structure of ECCO including the Governing Board, Committees and individual members.

ClinCom encourages the submission of clinical study protocols on patients with IBD to be drafted by individual members of ECCO and to be executed largely in Europe. The protocols are subjected to an objective and in-depth review process by ClinCom and assigned anonymous external reviewers, being individual members of ECCO with established expertise in the research question addressed in the study proposal. The aim of the review, which is without cost to investigator-initiated proposals, is to optimize study protocols and to help avoid redundant or scientifically questionable research efforts.

The assessment of a clinical research protocol encompasses a 2-stage process:

Stage 1:

During the first stage applicants are called upon to provide a synopsis at an early stage of the study, otherwise review and suggestions of ClinCom might be too late. The synopsis should include background, design, objectives, outcome parameters, major inclusion and exclusion criteria, statistics, and co-variates not exceeding 4 pages. A template will be provided by the ECCO Office. Within 6 weeks from receipt, ClinCom will respond to the applicant with a preliminary review, either encouraging or declining the submission of a full protocol. At this stage neither a budget nor the logistic framework for a clinical study will be provided by ECCO.

Stage 2:

Within 6 months the applicants are asked to submit the full protocol which will be subjected to a final review by ClinCom within 8 weeks of receipt. The full proposal should be written by using the template provided by the ECCO Office. The following information should be provided:

- ✓ Name, full address, and affiliations of the applicant
- ✓ Summary of the project (NOT exceeding one page)
- ✓ Introduction (including background information; there is no need to explain the basic nature of ulcerative colitis or Crohn's disease)

- ✓ Hypothesis
- ✓ Study Population
- ✓ Design and objective(s)
- ✓ Endpoints, co-variates and variables
- ✓ Inclusion and Exclusion criteria
- ✓ Prior, prohibited and concomitant medication
- ✓ Efficacy and safety measures, study procedures, study flow-chart
- ✓ Statistical considerations
- ✓ Considerations on safety reporting, ethics, feasibility and logistics
- ✓ Appendices

Applicants need to be individual ECCO members, but are not necessarily limited to the ECCO member countries. Submissions can be performed throughout the year. Applicants are asked to give a short annual update of one page until publication of the study results. A final report (a synopsis of 300 words) should be submitted to ClinCom to be announced in the ECCO Newsletter within 4 weeks of finalizing the protocol. Applicants will be expected to present the results of their work at the Annual ECCO IBD Congress in February and are required to inform ClinCom of all abstracts and publications of the project. When presenting or publishing results of the project ClinCom and ECCO should be mentioned in the acknowledgements. Authors are able to choose a journal of their choice, but ECCO would be pleased to find the paper offered to JCC for publication.

Projects, together with the up-to-date CV of the applicant, should be sent electronically only to the head of the Clinical research Committee of ECCO at the following address:

ECCO Office
Nicole Eichinger
Ungargasse 6/13
1030 Vienna, Austria
ecco@ecco-ibd.eu