Code of conduct

European Polyp Surveillance Trial

This document (hereafter referred to as "Document") describes the general terms and codes of conduct concerning research collaboration and cooperation in the European Polyp Surveillance Study (EPoS), a European multicentre study.

1. About the Study

EPoS (hereafter referred to as the "Study") refers to two randomized controlled trials and one single arm intervention trial. The aim is to compare different colonoscopy surveillance intervals in patients who have had low-risk adenomas, high-risk adenomas or serrated polyps removed. The primary end-point is incidence of colorectal cancer (CRC) after 10 years of follow-up. In the Study, surveillance colonoscopies at different pre-specified time-intervals will be offered to the participants. Individual patient data will be collected at the start of the study and at designated time-points during the course of the study.

2. Purpose of the Document

The Document describes the responsibilities and rights of all Study bodies, and all institutions participating in the Study. The Document is signed by the Study PI's and co-PI's, the chairpersons of the Study bodies, and the research-responsible person at all participating institutions, to ensure that the Study is conducted as regulated by the Document. Additional agreements may be required in addition to the Document with regard to specific bilateral or multilateral relationships of scientific, financial or database management and transfer purposes between institutions involved in the Study.

3. Study structure

Principal Investigators are Dr Rodrigo Jover at Alicante University Hospital and Professor Michael Bretthauer at the University of Oslo (Study principal investigators; "PI's").
Co-principal investigators ("Co-PI's") are Prof. Evelien Dekker at the Academic Medical Center, Amsterdam, Dr. Michal F. Kaminski at the Maria Sklodowska Curie Memorial Cancer Center, Warsaw, Dr. Joaquín Cubiella at the Complexo Hospitalario de Ourense, and Dr. Øyvind Holme at the University of Oslo.
The Study Secretariat is at the University of Oslo/Oslo University Hospital.
The **Data Management Centre** for the trial is located at Frontier Science (Scotland) (FSS).
Each participating site must identify a **Local Principal Investigator** (**local PI)** as research responsible individual at that site.

A **Data Safety and Monitoring Board** (DSMB) is in place to monitor the safety of participants in the study.
The Study has an executive committee and a scientific committee.

4. Roles and responsibilities

The **Study PI's and Co-PI's** are responsible for the overall integrity of the Study and the daily work during the course of the study. The Study PI's and Co-PI's report to the Board and the Committee.

The **Study Secretariat** provides administrative and scientific support for all trial-related activities.

The **Data Management Centre** is responsible for database design and maintenance, and for data management quality control, including ensuring adequate data security and data transfer procedures.

The **local PI** at all participating institutions is responsible for obtaining necessary approvals and re-approvals from the local Ethics Committee, local recruitment and management of patients into the Study, organising participation in surveillance colonoscopies of randomized patients according to allocation arm, training of local Study personnel, timely and accurate entry of data into the trial database, and response to queries from FSS. The local PI ensures compliance with Good Clinical Practice (as far as applicable to non-drug research) and rules of research ethics as defined by the Helsinki declaration, and the Study protocol and the Study Data Transfer Agreement.

The **Executive committee** constitutes the Principal and Co-Principal Investigators and one representative of Frontier Science (Scotland).
The Executive committee interacts regularly in person or via electronic media and whenever requested by any of the two Study PI's. The Executive committee has the responsibility and mandate to address:

- Issues of scientific matters (such as add-on studies, protocol amendments) for ultimate decision in the Scientific committee
- Urgent and unexpected issues that cannot await the next meeting of the Scientific committee
- Concerns related to misconduct of any kind, including but not limited to ethical, administrative, financial or scientific matters
- Any arising issues regarding authorship
- Reports on quality and adverse events from the Study secretariat and interaction with the Study DSMB.

Decisions of the Executive Committee should be taken by unanimity.

The **Scientific committee** constitutes:

- the members of the Executive committee

- the scientists who have designed and planned the study and are actively engaged in its conduct and analyses (including Antoni Castells, María Pellisé, Enrique Quintero, Pedro Zapater, Jaroslaw Regula, Paulina Wieszczy, Hans-Olov Adami, Miguel Hernán, Ann Zauber, Mette Kalager, Geir Hoff, Louise Emilsson, Magnus Løberg, Monique van Leerdam, Iris Lansdorp-Vogelaar, Manon Spaander, Iris Nagtegaal, Gerrit Meijer)
- At least one delegate per participant centre

The Scientific committee has oversight and decision authority for all scientific matters regarding the Study.

Under current circumstances, joint meetings of the Executive committee and the Scientific committee will be convened at least once a year during the course of the study.

5. Research data handling

Entry of patient data into the EPoS database management system by each participating institution is governed by the local Ethics Committees, the Study Protocol, and the Study Data Transfer Agreement. The Study Data Transfer Agreement (which complies with EU Data Protection requirements) must be in place between each participating institution and Frontier Science (Scotland) prior to enrollment of patients.

At completion of the Study, the participating institutions have a responsibility to ensure that local study research data stored at their own institution is treated in accordance with the requirements of their local Ethics Committee and the Protocol.

6. Ownership and publication

The owner of the study database is the Study, represented by the Scientific Committee. All data collected for the purpose of the Study are to be made available to the owner according to Study Data Transfer Agreement. Any and all information which arises from the Study may be used by the owner.
The Executive committee and Scientific committee and all participating institutions are to ensure openness around the research. Both positive and negative results from the Study are to be published. Co-authorship is offered to all local PI's at the participating institutions based on criteria as defined in the Vancouver-rules for authorship (see www.icmje.org).
Results from part of the Study, including local results generated from data collected for the purpose of the Study, may be published by the local participating institutions, but not prior to the main articles which include study data from all centers. The Executive committee decides on strategies for all joint publications from the Study.

7. Economy

The Study is financed by external funding. Joint funds are administered by the study secretariat. Local funds are administered locally.
All participating institutions are responsible for using the funding and administering the results of the Study according to the guidelines which form the basis for the funding.

8. Confidentiality

Any information that is exchanged between in connection with the Study, and which is not published previously, is to be treated confidentially between the partners.

9. Signatures

This Agreement is signed by the Study PI's, the members of the Executive committee and Scientific committee, and the research responsible person at all participating institutions

Study PI's

Rodrigo Jover

Michael Bretthauer

Study Co-PI's

Evelien Dekker

Michal F. Kaminski

Joaquín Cubiella,

Øyvind Holme

Executive committee member

Eleanor McFadden

Scientific committee members

Antoni Castells

María Pellisé

Enrique Quintero

Pedro Zapater

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Paulina Wieszczy

Hans-Olov Adami

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Ann Zauber

Mette Kalager

Geir Hoff	Louise Emilsson
Magnus Løberg	Monique van Leerdam
Iris Lansdorp-Vogelaar	Manon Spaander
Iris Nagtegaal	Gerrit Meijer

Centre PI's