

IBDnet: Study Application Procedure

Guidelines for clinical research project submission

I. Introduction

The IBDnet welcomes and encourages its members to submit clinical research projects linked to IBD and related diseases.

Clinical research projects can be submitted in a very early development stage (outline of two pages with primary objectives, secondary objectives, inclusion and exclusion criteria as well as a budget). If approval for the project is obtained, the IBDnet Scientific Committee will support finalization of the protocol and implementation of the study.

1. Who can submit a study?

All IBDnet members are encouraged to submit their outlines for clinical research.

2. Financial support

The principal investigator of the study is encouraged to support part of the study with own financial contribution. Further financial support can be requested from the IBDnet.

Therefore the budget of the study has to be appended to the study application and contain information about external funds, costs for personnel, consumables and running costs of the study.

Approved projects can obtain funding from the IBDnet up to a maximum of CHF 30'000. The IBDnet supports three clinical research projects per calendar year.

II. General Application Procedure

A study outline can be submitted to the IBDnet for support and funding. The Scientific Committee and Steering Committee formally evaluate the study outline. The principal investigator can obtain support and guidance from the Scientific Committee for the implementation of the study, if required. A quarterly status report is mandatory.

1. Submission

A study outline (named project) is submitted to the Chair of the Scientific Committee ((Gerhard)) of the IBDnet three weeks prior to the steering committee meeting. A study outline template is provided by the IBDnet and displayed on the website. The project outline should contain a summary, background information, study hypothesis, aims, objectives and materials and methods.

2. Evaluation

The Chair of the Scientific Committee shortly introduces the project to the Steering Committee. Following a short discussion, Steering Committee Members vote for approval or denial of the project by secret ballot. A simple majority vote of present Steering Committee members is required.

The applicant will be informed about approval or non-approval of the project with a written statement within one week after the steering committee meeting.

3. Assignment of tutors

For approved projects two tutors out of the Scientific Committee ((Gerhard, Pierre, Frank)) are assigned to coach implementation, roll-out and publication of the study. The principal investigator can obtain support from the tutors for the finalization of the protocol

(study design, methodics, statistics, study budget) submission to the ethical committee (study documents, CRF), and regulatory authorities, if required and necessary.

III. Study Implementation and Study Management

1. Study implementation and monitoring

The principal investigator can obtain support from the tutors for the start-up of the trial. Study monitoring, data – and quality management lays within the responsibility of the principal investigator. A concise progress report has to be submitted to the tutors quarterly.

2. Data analysis and publication

The tutors can consult the principal investigator for the data analysis and publication process.

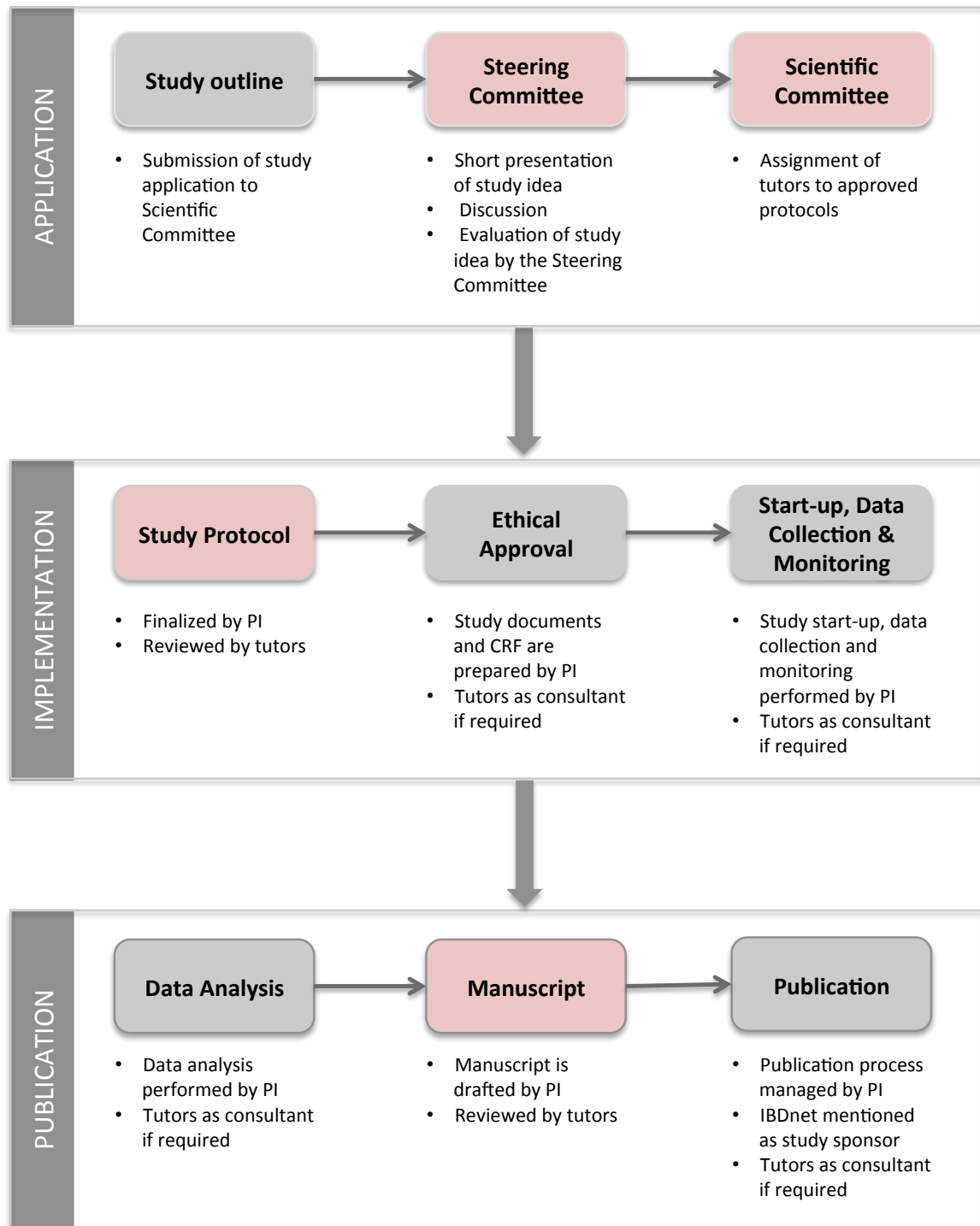
IV. Publication

All manuscripts conducted in the frame of the IBDnet should mention the IBDnet as study sponsor and study platform.

IV. Timelines

The study outline needs to be submitted three weeks prior to the steering committee meeting. Dates of the Steering Committee Meeting are published on the IBDnet website. The applicant will be informed about approval or non-approval of the project with a written statement within one week after the steering committee meeting.

V. IBDnet study application and study implementation process



Red boxes: Implication of IBDnet