

PRO-MC Collaboration

WELCOME LETTER PRO-MC COLLABORATION

Dear participant,

Thank you for your participation in the PRO-MC Collaboration!

To further inform you on the project we would like to request you to read this letter very carefully. It contains relevant information on *e.g.* the project, the registry and the requirements for participants.

Furthermore, it contains detailed instructions on the steps to take in order to initiate the study in your centre.

We really appreciate your contribution to the PRO-MC Collaboration, and you are welcome to contact use if you have any questions or if you need any help with the initiation or execution of this project in your centre.

Yours sincerely,

Andreas Münch,
Chairman of the PRO-MC Steering Group

Bas Verhaegh
Project manager of the PRO-MC Collaboration

info@pro-mc.eu

www.emcg-ibd.eu

THE PRO-MC PROJECT

1. Brief introduction and aim

In 2015, the European Microscopic Colitis Group (EMCG) has initiated the so-called PRO-MC Collaboration. This project aims to prospectively register MC patients across Europe, according to a standardized follow-up scheme. In this way we intend to create a unique MC dataset, which will answer questions on the disease course, treatment outcomes, and quality of life in MC patients.

Parallel to the web-based prospective registry, a pathology study is initiated applying the pathology data recorded in the PRO-MC registry. Moreover, pathologists from participating centres are offered the possibility to enhance their knowledge on MC via a digital slide kit. This will not only increase the number of identified cases, but will also decrease inter-observer variability across centres, enhancing data quality.

2. Obligations to the participant

The following obligations were formalized for participants in the PRO-MC Collaboration:

- a. Participants have to follow the predefined follow-up scheme for MC patients included in the PRO-MC Collaboration (see section 3 below).
- b. Participants have to inform the local pathologist(s) about this study and to provide them with study material for pathologists (slide kit, scientific paper). Furthermore, they have to stimulate them to diagnose MC cases according to the official diagnostic criteria for MC and to inform them on the possibility to join PRO-MC related pathology studies.

3. Methodology

Centres participating in the registry are requested to register all subsequent **incident cases** of MC in their centre. A population-based inclusion is stimulated, if feasible. It is explicitly not the intention to register established cases of MC.

The registry is web-based and therefore accessible for each participating centre. As soon as a patient is included in the study, an automatic follow-up process is initiated. This will notify the centre contact person by email when a new follow-up visit has to be scheduled. Next to the pre-fixed (follow-up) visits, so called 'inter visits' can be registered. These should be used when a patient contact took place in between the predefined follow-up visits.

Among others, disease activity and quality of life will be measured and registered. To obtain these data, the study defaecation diary and Short Health Scale (SHS) form are to be used, in order to accurately record these data. Be aware to provide the patient with the forms in time.

Below, a flow-chart of the study is shown. Further details on the various (follow-up) visits and the procedures to follow can be found in the study protocol which will be provided by the PRO-MC Steering Group. All documents can also be retrieved from the tab "European Registry PRO-MC" on the EMCG website (www.emcg-ibd.eu).

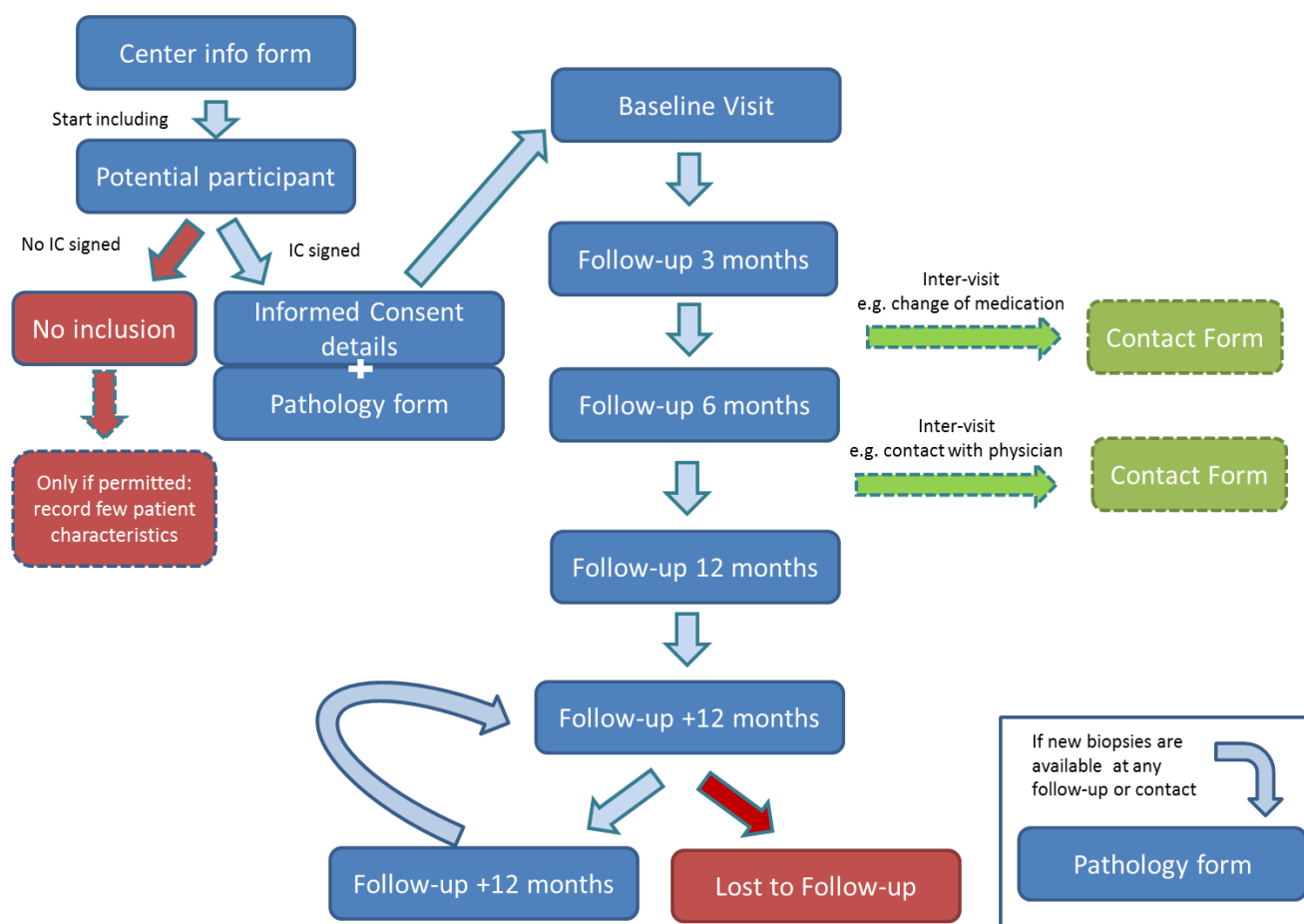


Figure 1. Flow chart of the PRO-MC Collaboration visits.

4. Ethical approval

It is the responsibility of the participating centre to obtain (local) ethical approval to initiate the PRO-MC Collaboration in their centre. The official letter of approval has to be sent to the PRO-MC steering group upon site initiation.

All documents required for ethical approval will be provided to the local participant by the PRO-MC Steering Group. Note: some documents might need translation from English to the local language before they can be submitted to the ethical committee!

5. The PRO-MC web-based registry

For the PRO-MC Collaboration a special web-based registry has been developed. Each participant will receive an access code for the registry. All data collected for the PRO-MC Collaboration have to be recorded in the designated eCRF forms in the registry. The registry will offer the possibility to see the completeness of the eCRFs of all included patients. Moreover, graphs on the overall progress of the study will be available.

More details on how to use the registry are described in the manual, which will be provided to the contact person of the participating centre at site initiation.

6. Pathology involvement

As described above, a pathology project will be executed parallel to the registry, as part of the PRO-MC Collaboration. Therefore, it is of relevance that pathology data are systematically recorded in the registry. In order to minimize the inter-observer variation in MC diagnosis, a slide kit with histology slides of MC will be available of pathologists from participating centres. The PRO-MC Steering Group encourages participants to inform their local pathologists in the study and to open the discussion on diagnosing MC in their centre. In this way we hope to create awareness for MC, to stimulate application of the official diagnostic criteria of MC, and to indirectly enhance the data quality in the PRO-MC registry.

7. Data handling and storage

All information and data concerning subjects or their participation in this study will be considered confidential and will be handled in compliance with all applicable regulations. All data will be stored in an encrypted (coded) fashion, so no the participant's identity cannot be derived from the registry. It is to the local investigator, to keep a file with the link between the code and the patient's credentials. A selected number of persons, appointed by the project's steering group, will have access to all (encoded) data in the registry. All other (local) investigators will only have access to their locally collected data. The general storage and the safety of the registry's data is the responsibility of the PRO-MC Steering Group in association with MEMIC, the company maintaining the registry. MEMIC applies to all relevant rules and regulations for save storage and management of the registry data.

8. Local research and general publication policy

All local data, generated and recorded in name of this project, will remain property of the participating centre. Local data can be retrieved from the registry and used in local projects. However, if a participant wants to answer a research question with data collected in name of the PRO-MC Collaboration, only center specific data are allowed to be used. Furthermore, the research question should not be in line with any question that will be addressed by the project itself. External research questions using PRO-MC data will have to be approved by the Steering Group up front. After approval, a data transfer form will be signed stating the agreed terms for data extraction. If the registry has to stop for whatever reason; participating centres will get access to their own data. All remaining data will be deleted.

The PRO-MC Steering Group does not automatically be a coauthor on all publications with PRO-MC data (*e.g.* when a project is a local initiative, using local data only).

All actively participating members will at least be included in a banner, that is listed in the list of co-authors of each PRO-MC publication with general project data.

9. Contact details

For any questions regarding the initiation or execution of the project, you can contact any of the contact persons listed below.

PRO-MC Steering Group

The PRO-MC Collaboration is an initiative of the European Microscopic Colitis Group. The project's steering group consists of the following EMCG members:

- Andreas Münch, chairman
- Bas Verhaegh, project manager
- Henrik Hjortswang
- Stephan Miehke
- Lars Munck
- Marieke Pierik

Contact: info@pro-mc.eu