

Rules of Procedure for Registry Queries

Regulations on the procedure of requests for Registry data from the German CF Registry

[Verfahrensordnung Registerstudien Dt. Mukoviszidose-Register]

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1. Introduction

The present Rules of Procedure regulates the procedures for processing in the context of all requests based on, or using data from the Registry.

2. Scope of Procedure for Registry queries

Requests based on Registry data are to be handled in line with the procedure set out. Any type of Registry analysis or Registry study, such as cohort, case, control, registry or post-authorisation safety studies (PASS) falls within this scope. Requests may only be processed through use of the "Registry Query Request Form".

Fees apply to the releasing of Registry data, whereby commercial requests and non-commercial requests are charged differently.

Internal Registry requests from Registry participants are free of charge under the cost and operational framework as defined yearly by the Mukoviszidose Institute gGmbH (MI), provided that no items widening the Registry data set have to be programmed or collected.

The fees for using the Registry data and the additional release of set items are regulated in the "Registry queries Schedule of Fees".

3. Committees and Responsibilities

Mukoviszidose Institut gGmbH (MI): Operator of the Registry

The German Cystic Fibrosis Association (Mukoviszidose e.V.) has instructed the MI, represented by the Managing Director, to manage the German CF-Registry. All responsibilities of the MI as the Operator of the Registry are described in the "General rules of procedure of the German CF-Registry".

Furthermore, the MI takes on responsibility for coordination of the processing of all requests for use of Registry data, including internal requests from Registry participants, from the benchmarking group, external requests from non-commercial research groups (academia), as well as commercial requests.

The MI is responsible for processing of all requests in compliance with procedure, and within the set time periods. In this process, MI is the contractual partner in respect of the clients (applicants for use of Registry data).

"Head Committee" of the CF-Registry:

The TFQ advisory board selects one medical director and one substitute by way of simple majority from the pool of AGAM members within the TFQ advisory board. The Managing Director of the MI, or a named substitute, is automatic member of the "Head committee". The "Head committee" is determined for a period of three years and, once this period is elapsed, it must be approved by the TFQ advisory board, or the members newly elected. The "Head committee" has the power to decide on internal Registry applications from Registry participants, which are within the fixed cost and operational framework ("Registry queries Schedule of Fees").

CF-Registry working group ("AG Register")

The members of the "CF-Registry working group" are nominated by the members of the "Head committee" and then approved by way of simple majority by the TFQ advisory board.

"CF-Registry working group" Composition

- 1 x clinician (medical director/member of the "Head committee")
- 1 x clinician(substitute of the medical director/member of the "Head committee")
- 6 x clinicians [ideal composition: 2 x pediatric, 2 x mixed, 2x specialized on adults. The FGM (Forschungsgemeinschaft Mukoviszidose) is also required to delegate at least 1 representative to the CF Registry working group]
- 3 patient representatives (parents or CF patients, members of the ARGE self-help group, or the AGECEF)
- 1 x Director of the MI (member of the "Head committee" or a named substitute)
- 2 x employees of the MI (Registry coordination and study requests)
- 1 x Statistician
- 1 x Documentalist
- Where needed: consulting IT specialist, legal support and ethical support.

The "CF-Registry working group" will assess whether the release of data for a Registry query application will be granted. For this, a simple majority is needed. The "CF-Registry working group" makes decisions on all external applications (commercial and non-commercial applicants) according to votes gained, as well as for all internal applications (from Registry participants), that are within the cost and operational framework based on the Schedule of Fees, and/or contain additional items. If no majority is achieved, the decision on the request is to be made by the executive board of the Mukoviszidose e. V. [Bundesvorstand]. It falls to the MI supervisory board to prepare a recommendation.

If required by the "CF-Registry working group", MI provides contact with service providers from the fields of IT/statistics/ethics and legal support for evaluation of requests.

All decisions on the realisation of Registry studies are to be communicated to the MI supervisory board.

4. Work processes and deadlines

All requests for the use of Registry data are to be directed to MI by using the "Registry Query Request Form". This form will request information on the issue to be studied, content of the data enquiry, the planned use of the analysis and whether a valid ethical approval is in place. The applicant is responsible for ensuring a valid ethical approval is in place.

The MI coordinates the processing of applications. The fees applicable for processing are regulated by the Schedule of Fees.

After formal verification by the MI, the applications for processing will be passed on to the "Head committee" of the CF-Registry. At regularly convened telephone conferences of the MI with the "Head committee" of the CF-Registry a decision will be made on which applications should be approved, rejected or passed onto the "CF-Registry working group" for further assessment.

Decisions which are to be made by the "CF-Registry working group" may be made in in-person meetings, during telephone conferences, and also through email exchanges. The MI is responsible for coordinating this.

Deadlines:

- Formal verification of requests (MI):
 - max. **2 weeks**
- Evaluation of requests by the "Head committee"/"CF-Registry working group":
 - max. **6 or 12 weeks** (12 weeks in cases requiring extended assessment by the "CF-Registry working group")

A template for creating reports will be made available by the MI to the "Head committee" of the CF-Registry and the "CF-Registry working group". The criteria for the evaluation of content for Registry analyses and studies are to be defined in consultation with the "CF Registry working group" and are to be regularly adapted.

The MI is to make all necessary documents electronically available (study reports and evaluation forms) to the "Head committee" and to the "CF-Registry working group".

Any decisions on requests are to be communicated to the client by the MI within a period of 2 weeks.

The planned evaluations and their applicants will be published in a yearly-updated overview on the homepage of the MI, and in the annual report.

5. Decision on the participation in Registry studies requiring additional data collection

The realisation of a study requiring additional Registry data collection is only possible if the "CF-Registry working group" approves the realisation of the study with a majority.

Whether a Registry participant (documenting CF sites) takes part in such a Registry study is decided independently by each centre (e.g. depending on interests in the issue studied, available patient population, staffing capacity). There is no requirement for participation in a Registry studies If a Registry participant takes part in a Registry study, then the participant is obliged to document data in an accordingly determined time frame.

An informed consent form of the patient for the purposes of collection and use of patient data, which goes beyond the agreed uses of the Registry data, is to be requested by the participating centre, and documented.

6. Financial Regulations

The processing of all external requests is charged (start-up fee for the processing of the request), at the rates set out in the "Registry Queries Schedule of Fees". For Registry participants, Registry queries, which find themselves within the cost and effort expenditure defined in the Schedule of Fees, are free of charge. The costs for Registry queries are dependent on expenditure in data recording and analysis, and will vary between commercial and non-commercial requests. The fees are regulated by the "Registry Queries Schedule of Fees".

7. Confidentiality

The rights to protection, use and exploitation of the German CF-Registry are held by the MI, and are described in the "General Rules and regulations" of the German CF-Registry. The MI is responsible for the exchange of confidentiality agreements between all contractual partners (clients, responsible committees and Registry participants), whose confidential documents are being transferred.

8. Publication Rules

All analyses and studies created using the German CF-Registry are to be made available to the public in a suitable format. The "Registry Publication Guidelines" which regulate this are to be followed.

9. Jointly Valid Documents

- General Rules and regulations of the German CF-Registry [Geschäftsordnung dt. Mukoviszidose-Register]
- Registry Publication Guidelines [Publikationsordnung des dt. Mukoviszidose-Registers]
- Register Queries Schedule of Fees (inpreparation) [Gebührenordnung Registerstudien (in Abstimmung)]