

## **General rules an regulations** of the German CF-Registry

Stand: 15.11.2016  
Version: 1.9

## **1. Preamble**

The German CF-Registry's objective is the comprehensive registration and structured analysis of data from CF patients in Germany in order to improve CF care.

To this end, the German CF-Registry collects both identification and medical data from CF patients. The patients' declaration of consent for participation in the operations of the Registry is essential for this, as is the involvement of the CF sites in the recording of patient data into the Registry. All data collected within the Registry may be viewed in a data dictionary on request.

During the yearly departmental reports data are made available to participating CF sites for quality management purposes. Furthermore, each participating CF site is permitted to export their own registry data for internal analysis using the registry tool MUKO.web.

Data above and beyond the CF sites own data, especially for scientific applications, are liable to special requirements. Special analyses and publications are handled according to the "Registry Publication Guidelines" [Publikationsrichtlinie Register].

Requests for Registry data are handled according to the "Rules of Procedure for Registry Queries"[Verfahrensordnung Registeranfragen].

An overview of fees incurred by the German CF-Registry through requests is presented in the "Register Study Schedule of Fees" [Gebührenordnung Registeranfragen].

An overview of fees that incur when requests are addressed to the German CF-Registry is presented in the document "Register Study Schedule of Fees".

## **2. Organisational Structure**

The German Cystic Fibrosis Association (Mukoviszidose e. V.) has tasked the Mukoviszidose Institute gGmbH (MI), represented by the Managing Director, with the management of the German CF-Registry. The MI acts as Registry Operator and is located at:

Mukoviszidose Institut gGmbH In den Dauen 6  
53117 Bonn

The rights concerning protection, use and exploitation of the German CF-Registry are conferred to the MI.

### **Responsibilities of the Operator of the German CF-Registry**

The Operator will make the Registry infrastructure and Registry software MUKO.web available to the CF sites. The Operator will coordinate and organise requests for Registry data analysis and/or inquiries regarding study-specific Registry data. The Operator will decide on participation in the German CF-Registry. The Operator will act as the contractual partner with actively operating service providers (data management, data hosting, software developers etc.). The Registry Operator will adhere to the data protection regulations that are legally required at the Registry location.

The Operator will be supported by the “CF-Registry working group” and its “Head committee” during the development, strategic planning and implementation of the Registry.

### **Legitimacy procedure of “Head Committee” and “CF-Registry working group (AG Register)”**

#### Appointment procedure of the “Head committee” of the CF-Registry:

The TFQ advisory board selects the medical director and one substitute by way of simple majority from the pool of AGAM members within the TFQ advisory board. The MI managing director, 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 re-approved by the TFQ advisory board, or the members newly elected.

#### Appointment procedure of the “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. Participation in the “CF-Registry working group” is not restricted to members of the TFQ advisory board. Interested parties may contact the “Head committee” directly. The “CF-Registry working group” members are appointed for a period of 3 years. Should additional expertise be required due to specific project requirements, further members may be nominated by the “Head committee” as temporary members of the “CF-Registry working group”. Additional members must also be approved by the TFQ advisory board by simple majority vote.

#### Structure:

The “CF-Registry working group” strives to achieve the most extensive representation of interests possible regarding the work of the Registry and orientates itself towards the structure of the TFQ advisory board:

- 1 x clinician (medical director/member of the “Head committee” and member of the AGAM)
- 1 x clinician (substitute of the medical director/member of the “Head committee” and member of the AGAM)
- 6 x clinicians [ideal composition: 2 x paediatric, 2 x mixed, 2 x 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 AGECECF)
- 1 x Managing Director of the MI or a named substitute (member of the “Head committee”)
- 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.

#### Rights to vote:

All members of the “CF-Registry working group” have a corresponding right to vote, with the exception of the consulting members (in statistics, IT, ethics and legal support):

- 1 x clinician (medical director/"Head committee") (1 vote)
- 1 x clinician (substitute of medical director/"Head committee") (1 vote)
- 6 x clinicians incl. (3 votes)
- 3 x patients representatives (3 votes)
- 1 x Managing Director of the MI or a named substitute (member of the "Head committee") (1 vote)
- 2 x employees, MI "Registry coordination and study requests" (1 vote)
- Statistician, documentalist, IT/legal support + ethical consultation (no right to vote)

Voting takes place during any meetings convoked (audio/web conference or in-person meetings) or prior to voting with notification in writing to the members of the "Head committee".

### **Responsibilities of the "Head Committee" of the CF-Registry and the "CF- Registry working group"**

The "Head committee" and the "CF-Registry working group" will support the Registry Operator during the development, strategic planning and management of the Registry. During the financial and strategic development of the German CF-Registry, including any external collaboration as well as reporting to the German Cystic Fibrosis Association, the "CF-Registry working group" and the MI are obliged to mutually exchange information and agreements.

The "CF-Registry working group" and the "Head committee" rule on all internal and external Registry requests. The regulations are described in the "Rules of Procedure for Registry Queries".

The "Head committee" complies and updates the "General rules and regulations", "Registry Publication Guidelines" and "Schedule of Fees".

The medical director of the Registry will function as the member of the "Head committee" and, in agreement with the federal executive board of the German Cystic Fibrosis Association [Mukoviszidose e.V.], as "national coordinator" for the ECFS in the Registry relevant committees.

### **3. Participating clinical sites**

Sites can participate in the German CF-Registry by request on a voluntary basis. The "Agreement on the quality management provision for patients with CF" [Ambulanzvergütungsvertrag], between the Registry Operator and the site, is a basic requirement for this. A complete and qualitative data recording is the explicit objective of these sites.

An informed consent form signed by the patients is required for recording of any patient data into the CF-registry. The site is responsible for obtaining the completed informed consent forms.

Recorded data from the previous year is to be completed by 31.03 of the following year, and any inquiries by data management must be responded to.

The Registry Operator provides the participants with a Registry infrastructure. Upon request, data collected by the sites can be exported back to the sites after

creation of a finalised master data set (cf. data dictionary). The MI creates an Annual data report based on all available data and makes this available to participating sites. Furthermore, each participating site is permitted to export their own registry data for internal analysis using the registry tool MUKO.web.

Sites may give notice at any time to the German CF-Registry should they wish to discontinue their participation in the Registry. This notice must be given in writing to the Registry Operator. All data recorded up until the point of time of the notice will remain in the German CF-Registry. On confirmation of discontinuation of participation in the Registry, the online access will be deleted by the responsible CF-Registry data management.

The sites are obliged to adhere to the defined regulations concerning data protection as part of the data protection concept of the CF-Registry.

A participating site may be expelled from the Registry should there be reasonable grounds for this. The exclusion procedure involves a majority decision of the "CF-Registry working group" and in coordination with the TFQ advisory board.

#### **4. Participating Patients**

Patients may withdraw their consent to the German CF-Registry by communicating this to their treating physician, at any time, and without giving reasons for doing so. The withdrawal is recorded by the hospital department treating the patient via the Registry software. The patient identification data will then be anonymised by identification management. All medical data will be deleted permanently from the Registry by data management from the date of withdrawal.

#### **5. Objectives**

The objective of the CF-Registry is to achieve a basis for the continuous improvement of treatment quality of CF patients by means of comprehensive registration and structured analysis of registry data. Furthermore, the Registry data serve as a basis for purposes of:

- Scientific research projects
- The benchmarking Project - "Learning from the best"
- Involvement in the European CF Registry (ECFS Registry) through yearly transfer of basic data sets.
- Public Reporting Project: Registry information for those affected by CF
- Registry-embedded clinical Studies (e.g. PASS: Post-authorisation safety studies)

The projects and scientific research projects are carried out with the objective of obtaining further knowledge about the disease, and information on the safety and uses of the medication administered compared with other treatments.

#### **6. Jointly Valid Documents:**

- Registry Publication Guidelines  
[Publikationsordnung des dt. Mukoviszidose-Registers]
- Rules of Procedure for Registry Queries  
[Verfahrensordnung Registerstudien]

- Register Queries Schedule of Fees (inpreparation)  
[Gebührenordnung Registerstudien (in Abstimmung)]
- Agreement on the provision of quality management for patient with CF  
(Clinical site agreement - in preparation)  
[Ambulanzvergütungsvertrag zur Qualitätssicherung Mukoviszidose]