ECFS Patient Registry - Terms of Reference

1. Aim:

The aim of the ECFS Patient Registry is to gather data that is accurate (measured against an internationally agreed standard) and which can be used for patient benefit as defined in the patient consent.
In reaching this aim, the ECFS Patient Registry is:

- To measure, and compare epidemiological and clinical aspects of cystic fibrosis in the participating countries, thereby encouraging the identification of new standards of CF management.
- To provide data for epidemiological research and identify groups of patients potentially eligible for multi-centre trials.

2. Deliverables:

1. Data that is of sufficient quality to permit epidemiological research.
2. An Annual epidemiological report to be submitted to the ECFS.

The annual epidemiological reports will be maintained at the ECFS office and will be published on both the ECFS and ECFS Patient Registry web pages.

The annual epidemiological report will include epidemiological presentation of core data.

Tables and graphs will show data aggregated on a European level and on individual country level. Data aggregated on individual Centre level will be accessible only to the center's director and to a national registry steering committee in the event that such a recognized organization exists for the country.

3. Governance:

ECFS Registry Contributors group:

The Registry Contributors Group is defined as anyone who contributes data to the ECFS Patient Registry.

The Registry Steering Group

The composition of the Registry Steering Group:

- ECFS Patient Registry Director, Chairperson
- One national representative per country contributing to the ECFS Patient Registry (Individual Country Manager or representative of the National Registry or an elected individual representing centres from a country)
- 2 members appointed by Cystic Fibrosis Europe, the Federation of Patients' organizations.

The above listed are the voting members.
The Registry Steering Group will be augmented by the following non-voting members:

- A statistical expert.
- A data protection legal and ethics expert on an ad hoc basis
- Representatives from Non European Cystic Fibrosis Patient Registries.
- The ECFS Patient Registry Executive Coordinator.
- A representative from the ECFS Clinical Trials Network.
- The "Trusted third party": responsible for center codes for anonymisation purposes)

The Registry Steering Group will set the strategic direction and areas of priority of the ECFS Patient Registry.

Responsibilities of the Registry Steering Group:

a. Ensures the project is aligned with general ECFS strategy.
b. Approves formal collaborations of ECFS Patient registry with external organizations.
c. Recommends individuals to serve on the Executive Committee to replace members rotating off. Such recommendations are subject to the approval of the ECFS Board
d. By a voting process, nominates the Registry Director. The nomination is subject to approval by the ECFS Board
e. Ensures the project makes good use of assets.
f. Assists with resolving strategic level issues and risks.
g. Provides advice and guidance on business issues facing the project.
h. Uses influence and authority to assist the project in achieving its outcomes.
i. Reviews and approves final project deliverables.

The Registry Steering Group will meet once a year, in conjunction with the European CF Conference.
The Registry Steering Group may create committees amongst its members to focus on specific aspects of the Registry.

The Registry Steering Group will be chaired by the Director.

The responsibilities of the Registry Director are as follows:

- Sets the agenda for each meeting.
- Ensures that agendas and supporting materials are delivered to members in advance of meetings.
- Makes the purpose of each meeting clear to members and explains the agenda at the beginning of each meeting.
- Clarifies and summarizes what is happening throughout each meeting.
- Encourages broad participation from members in discussion by calling on different people.
- Ends each meeting with a summary of decisions and assignments.
- Follows up with absent members.
- Reports to the ECFS Board and Annual General Meeting (AGM)

The ECFS Patient Registry Director is appointed by the ECFS Board, based on a nomination from the Registry Steering Group. The tenure will be of 4 years. In case of non compliance with the ECFS Strategy, the ECFS Board has the right to dismiss the Registry Director with a four weeks' notice. In the last year of tenure, the Director will train the new Director to the position. The ECFS Patient Registry Director is a co-opted member of the ECFS Board.

An Executive Committee of interested stakeholders will be assembled.

Responsibilities of the Executive Committee include the following:

- Implements the strategy and policies decided by the ECFS Board.
- Implements the ECFS Board's overall recommendations for change.
- Proposes new strategy and policies to the Registry Steering Group.
- Monitors the ECFS Patient Registry activities, the operation, and all activities where ECFS Patient Registry undertakes legal obligations.

- Reviews reports and budgets prepared by the ECFS Patient Registry Executive Coordinator and makes recommendations to the Registry Steering Group.
- Prepare an annual strategic and financial report to be submitted to the Registry Steering Group and subsequently to the ECFS Board for approval.

The Executive Committee is comprised of

- ECFS Patient Registry Director
- 3 Members of the Registry Steering Group
- One representative of the patient associations nominated by CF Europe

Ex Officio members (non-voting):

- The ECFS Executive Director.
- The ECFS Patient Registry Executive Coordinator.
- One Statistical Expert
- One CTN representative

An external Legal expert will be augmenting the Executive Committee as consultant on a ad hoc basis.

Members of the Executive Committee will be appointed for 3 years (except the Director who is appointed for 4 years) and on a rotational basis. In order to implement the rotation system, the members of the first Executive Committee will be appointed for either 2 years or 3 years.
The Executive committee is accountable to the ECFS board.
The Executive Committee will hold teleconferences twice a month and the minutes will be circulated to the entire Registry Steering Group.

The Patient Registry Executive Coordinator provides a central role for information exchange, project coordination, management of sensitive timelines and general administration.

Scientific Committee

All applications for data extracts from the ECFS Patient Registry will be reviewed and assessed by the Scientific Committee. Application Forms requesting data extracts are to be sent via email to the Registry Executive Coordinator who will liaise with the Scientific Committee and coordinate their findings.

Individual Centre data will be accessible only to the center's director and to a national registry steering committee in the event that such a recognized organization exists for the country (by a number – known to each centre only). Data extracts for individual centers are thus not subject to Scientific Committee approval.

Any applications from third country (non-EU) must ensure an adequate level of protection (Directive 95/46/EC (TBC) chapter IV, article 25.1), and must be approved by the Danish Data Protection agency before release of data.

The Scientific Committee will be composed of 5 members:

- 2 elected members from the Registry Steering Group
- One patient representative
- One statistical expert
- A member of the Executive committee

Successful applications are approved by simple majority vote of the Scientific Committee and should be answered within one month of reception.
The title of the project and contact person of all approved applications will be published in the annual activity report.
Applications should be scientific projects headed by individual independent scientists.
All associations with private companies, especially pharmaceutical companies, should be acknowledged in the application.
Applicants will be asked to sign an agreement that data will be used for the sole purpose indicated in the application and then destroyed
There will be an application fee for data requests. Data extracts will be subject to a fee calculated on hourly cost basis.

4. CTN and Registry cooperation:

The CTN Director is appointed as the CTN representative in the Registry Executive Committee. A member of the ECFS Patient Registry Executive Committee is appointed Registry representative in the CTN Executive Committee.

Data requests will be previewed by CTN as follows:

- The CTN Executive Committee assesses the requests for data analysis submitted by the Industry. Following approval by the CTN Executive Committee, the question is submitted to the ECFS Patient Registry Scientific Committee via a standard request form. The ECFS Patient Registry Scientific Committee has 1 week to agree/disagree with this request, explore feasibility and suggest a cost for the analysis.
- Data requests from individual researches/study groups, for epidemiological studies should be sent directly to the Registry Executive Coordinator by email for distribution to the Scientific Committee.
    - There will be an application fee for data requests from the pharmaceutical industry.
    - Cost of data extraction/analyses will be calculated for each request depending on workload.