



Terms of Reference for the Executive Committee

Version 1.0 (11-OCT-2023)

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Version History

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Abbreviations

CDA	Confidentiality disclosure agreements
CFF-TDN	Cystic Fibrosis Foundation Therapeutic Development Network
DOI	Declaration of interest
ECFS-CTN	European Cystic Fibrosis Society Clinical Trials Network
ECFSPR	European Cystic Fibrosis Society Patient Registry
PO	Patient organisation

1 Background

Under the EU Framework 6 initiative, the European Coordination Action for Research in Cystic Fibrosis (EuroCareCF) was funded. The project ran from 2006 to 2009 and was coordinated by Dr. David Sheppard from Bristol University, and Prof Margarida Amaral from the University of Lisbon. EuroCareCF paved the way for two important projects for the ECFS – a European Clinical Trials Network (CTN) and the further development of the European CF Patient Registry (ECFSPR).

One of the Work Packages (WP) was dedicated to clinical research (WP3), led by Prof Kris De Boeck. In November 2006, ECFS was approached by Prof. De Boeck to create an ECFS Clinical Trials Network.

A letter of interest was sent in April 2007 to 279 contacts. There were 139 answers, and 127 were willing to take part. A follow-up survey with more specific questions about the CF clinic and patient population was sent in September 2007.

In November 2007, a joint meeting ECFS – EuroCareCF WP3 was held. The aim of the meeting was to define the strategy for the implementation of a CTN. Bonnie Ramsey, representing CFF-TDN shared their experience in creating a clinical trial network.

A call for application was sent in February 2008 (deadline March 25, 2008). 28 applications were received and 18 centres were selected to form the first core for the ECFS CTN.

The assessment was carried out by the ECFS Executive Board with advice from an external assessor, member of the UK Cancer Clinical Trials Network.

On 18-19 September 2008, the first meeting of the ECFS CTN was held in Leuven. Representatives from the 18 European CF Centres selected to form the core of the ECFS-Clinical Trial Network attended the meeting.

At this first meeting, ECFS and the ECFS-CTN participants defined the functioning of the ECFS-CTN and its structure.

2 Purpose

The ECFS-CTN Executive Committee was established at the first ECFS-CTN meeting in 2008 to guide, oversee and manage the activities of ECFS-CTN.

3 Duties

The main duties of the ECFS-CTN Executive Committee include, but are not limited to, the following:

- Attend all Executive Committee bi-monthly teleconferences
- Attend all Steering Committee meetings (twice a year)
- Keep abreast of ECFS-CTN activities
- Develop network policies
- Steer actions to different committees within ECFS-CTN
- Approve clinical trials to add to the ECFS-CTN portfolio following protocol review

- Evaluate applications for new investigators at existing ECFS-CTN sites
- Evaluate applications for new members of EC
- Liaise with ECFS Patient Registry (ECFS-PR) and national clinical trial networks in Europe
- Develop strategy for ECFS-CTN
- Contribute towards the agenda for Steering Committee meetings

These terms of reference guide the composition and function of the EC. In case of an unanticipated situation, deviations from these terms of reference are possible, with the ratification of the ECFS Board and documentation of the deviation in the appendices of this document.

4 Committee roles

The Executive Committee is composed of 6 investigators and 1 patient organisation (PO) representative. For the purposes of this document, an investigator is defined as a CF clinician who participates in CF clinical trials at an ECFS-CTN centre in a role as CTN Principal Investigator or co-Investigator.

The different roles within the Executive Committee are described in the table below, as well as a summary of tasks specific to their role, and on top of the general tasks of the Executive Committee described in Section 3.

Other non-voting members supporting the EC include the ECFS Executive Director, quality manager, standardization coordinator and coordinating centre staff.

Role	Additional tasks and information
CTN director	<ul style="list-style-type: none"> - Oversees all activities of ECFS-CTN together with the Coordinating Centre - Represents ECFS-CTN in conversations and negotiations with sponsors, POs and other external partners. - Signs agreements with sponsors on behalf of ECFS-CTN for protocol review and feasibility services. - Attends weekly 1-hour meetings with ECFS-CTN staff (usually on Tuesday afternoon). - Acts as a co-opted voting Member of the ECFS Board for the duration of his/her mandate. - Is the ECFS-CTN spokesperson with the ECFS Board and seeks approval of the ECFS Board whenever needed for a new project or decision made by the ECFS-CTN Executive Committee - Presents CTN activities at the ECFS Annual General Meeting - Represents ECFS-CTN in monthly CFF-TDN call. - Drafts the agenda of ECFS-CTN Steerco Meetings together with the Coordinating Centre and has a lead role in these meetings - If there is equal voting in specific business matters, the director's vote is decisive, with exception of voting on protocol review outcomes, where the vote of the Chair of protocol review is decisive - The ECFS-CTN director is expected to spend approximately 4 hours per week on ECFS-CTN tasks, although increased effort may be required during busy periods (e.g. in the run-up to

Role	Additional tasks and information
	<p>Steerco).</p> <ul style="list-style-type: none"> - This is a non remunerated position. The ECFS provides a donation of €15,000 per annum to the director's employing institution, as a token of appreciation for the commitment to ECFS.
CTN deputy director	<ul style="list-style-type: none"> - Supports and deputises for the CTN director when required. - The deputy director will chair meetings which the director cannot attend. - If the director is unable to continue in office, the deputy director will take over the directorship until an application and selection process yields a new director.
Chair of protocol review	<ul style="list-style-type: none"> - Manages the protocol review committee - Presents the protocols for discussion at the Executive Committee calls - Signs outcome letters to sponsors - Presents a short update on protocol review activities at each Steerco meeting - Oversees the continual improvement of the protocol review processes and training - Works with the CTN quality manager to assess quality of the protocol review process.
Ordinary members	<ul style="list-style-type: none"> - No extra tasks
PO representative	<ul style="list-style-type: none"> - Provides the patient perspective on all tasks - Reports to ECFS-CTN Executive Committee on activities by POs and CF Europe - Reports to POs and CF Europe on ECFS-CTN activities
Immediate past ECFS-CTN director	<ul style="list-style-type: none"> - An ad hoc member (without a vote) for one year following the end of their directorship, to advise on issues where their expertise is useful.
Director-elect	<ul style="list-style-type: none"> - If the director-elect is not a current Executive Committee member, they sit on the Executive Committee as a non-voting member in the shadowing period prior to taking up the directorship - Shadows ECFS-CTN director during last 12 months of their tenure, in a handover period. - The director-elect can also have the role of CTN deputy director (see above)

5 Terms of service

A term of office is 3 years. Executive Committee members cannot have more than 2 consecutive terms of office (i.e. 6 consecutive years). This restriction does not apply when moving on to the position of director. The Director can only have 1 term of office.

A past Executive Committee member may re-apply for an open Executive Committee position.

Members who fail to attend 4 consecutive bimonthly Zoom calls, or 2 consecutive Steerco meetings may be replaced, at the discretion of the ECFS-CTN director.

If a member resigns, retires from clinical practice or moves institution to a non-CTN site prior to completion of their term, the process for recruiting a replacement committee member will be launched. If there is less than 12 months remaining of the replacement term, the new member will serve an additional full term. These months will be added to the term in office.

6 Process and criteria for choosing committee members

6.1 Ordinary Executive Committee members

Eligibility & selection criteria	Selection process
<ul style="list-style-type: none"> - Investigator at an ECFS-CTN member site for at least the previous 12 months, with ECFS membership up to date - Commits to the Executive Committee terms of reference and meeting schedule - Has actively participated in other ECFS European projects, international collaborations or in some ECFS-CTN activities - Demonstrates evidence of networking & communication capacities “across borders” - Reasonably fluent in English - Eager to share and collaborate with different representatives of the CF community, including POs - Significant previous contribution in an ECFS-CTN committee is a plus <p>Additional criteria will be considered to make sure the Executive Committee is balanced in terms of pediatric/adult physicians, country representation, new sites vs older sites, gender, etc.</p> <p>The Executive Committee should have no more than 2 members from one country.</p>	<p>The application process starts 4-6 months before the current member’s term ends.</p> <ul style="list-style-type: none"> - All site investigators and eligible outgoing EC members are emailed an invitation to apply - Based on the position to be filled (gender, geographic spread, adult vs pediatric doctor), applications may be solicited from certain investigators. - The Executive Committee considers all applications independently, then discusses and votes anonymously, taking into account the eligibility and selection criteria. - Chosen Executive Committee member ratified by ECFS board - Ratification of new ECFS-CTN Executive Committee member by all CTN sites (no reply means the site ratifies the decision). Objections are logged and discussed within the EC, and action will be taken if appropriate.

6.2 ECFS-CTN director

Eligibility & selection criteria	Selection process
<ul style="list-style-type: none"> • Eligible candidates will have served at least one term as an Executive Committee member in the 6 years prior to the new directorship term. • Eligible candidates must be resident in a different country to that of the outgoing ECFS-CTN director. • Previous experience as ECFS-CTN co-director or chair of an ECFS-CTN committee is a plus. • As per ECFS constitution, "The officers of the Board shall represent different European countries". This is mainly for elected ECFS Board members, but it is also true for Directors of the 5 main ECFS projects (CTN, Registry, Education, Standards of Care, Journal of Cystic Fibrosis). The selection process will strive to satisfy this criteria. 	<p>The application process for the next ECFS-CTN directorship will be opened 16 months before the current director's term ends. The timelines for selecting and onboarding the new ECFS-CTN director are as follows:</p> <ul style="list-style-type: none"> • September Year N-2: Application process opens • October Year N-2: Applications closed • November Year N-2, week 1-2: ECFS-CTN EC considers applications, proposes new director. In case of disagreement/no clear vote among the CTN EC, advice and/or decision is made by the ECFS Board • November Year N-2, week 3: ECFS board ratifies choice. • January Year N-1 : <ul style="list-style-type: none"> ○ Director-elect introduced at Steerco. ○ Director-elect starts attending Executive Committee meetings (as a non-voting member) if not a current Executive Committee member. ○ Director-elect starts shadowing current director. The current director may start delegating certain tasks to director-elect during the shadowing period. • January Year N: New director starts term

6.3 ECFS-CTN deputy director

At the start of a new directorship, the EC will elect a deputy director from among their number, with validation of the selection by the ECFS board. The deputy director may change during the term of the director, based on terms of EC members. The director-elect may take over as deputy director once elected.

6.4 Protocol review chair

This is outlined in the Terms of Reference for the Protocol Review Committee.

6.5 PO representative

The PO representative is nominated by the group of POs funding ECFS-CTN (PORG), with the choice ratified by Cystic Fibrosis Europe.

7 Confidentiality

Executive Committee discussions and reports should be considered confidential and should not be disclosed to external organisations, sponsors or other colleagues. Only the items approved for inclusion in the meeting minutes should be disclosed to ECFS-CTN investigators and PO partners.


To facilitate protocol review, Executive Committee members will be required to sign CDAs with sponsors for individual trials. These CDAs are directly between the sponsor and the Executive Committee member or the Executive Committee member's institution.

8 Declaration of interest

Executive Committee members will complete the ECFS-CTN declaration of interest (DOI) form when they join the committee. All committee members will update their DOI form every January of their term. The ECFS-CTN coordinating centre will provide DOI forms upon request by any interested person.

Executive Committee members will excuse themselves from voting on protocols where a direct conflict of interest arises. Examples of a direct conflict of interest include, but are not limited to:

- participation in an advisory board or the study steering committee for the protocol under review, or for the programme under review
- having the role of study principal investigator or country principal investigator for the protocol under review

ECFS-CTN Declaration of Interest form	 ECFS-CTN Declaration of Intere:
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9 Meetings

Twice monthly Zoom meetings are scheduled for Wednesday mornings, 0815-0900 CET. Minutes are recorded by a member of the ECFS-CTN coordinating centre.

The winter meeting is held every year in the last week of January. Executive Committee members need to be present all day on Thursday and Friday for the Steering Committee meeting and satellite meetings.

The summer Steering Committee meeting is held on the Wednesday afternoon directly preceding the ECFS annual conference. Executive Committee members are also strongly requested to attend the training morning in the morning of the same Wednesday.

Additional in-person meeting(s) may be added, to allow focused discussion of strategic direction of the network.

10 Additional reporting

The Executive Committee reports to:

- the ECFS annual general meeting in June
- the ECFS board, the ECFS CTN Director being co-opted to the ECFS Board
- the ECFS-CTN Steering committee at the winter January meeting and at the Summer Steerco meeting
- the ECFS-CTN PIs and co-investigators and PORG members (Steering committee) via a bimonthly newsletter with minutes of the last Executive Committee meeting
- ECFS-CTN research coordinators via a bimonthly newsletter

11 Resources

The Executive Committee does not have a specific budget within ECFS-CTN. Exceptional resource requirements are discussed with the ECFS secretariat and Board, as needed.

12 Publication authorship

ECFS-CTN sometimes publishes scientific articles describing the general activities or particular projects within the network. Executive Committee members are not automatically considered authors of all publications arising from ECFS-CTN. Rather authorship will be considered on a case by case basis, in accordance with the [ICMJE guidelines on authorship](#).

13 Authority

The Executive Committee has decision making authority for all matters concerning the activities of ECFS-CTN, except for the following which require ratification by the ECFS Board following a recommendation by the ECFS-CTN Executive Committee:

- confirmation of new Executive Committee members and Director-Elect selections
- decision on expansion of ECFS-CTN
- decision on revoking membership of ECFS-CTN centres due to low clinical trial activity

- new processes, projects or activities are to be presented to the ECFS Board and discussed before development and implementation

14 Required training for new committee members

New committee members must perform the following training and/or read and sign the following policies within 3 months of their appointment:

- ECFS-CTN training on protocol review
- IT security policy
- ECFS-CTN confidentiality disclosure agreement
- ECFS-CTN conflict of interest form

15 Documents and policies associated with committee

In addition to the policies mentioned in the section above, the documents outline processes relevant to the activities of the EC.

- Process for onboarding a new CTN director
- Process for advertising, recruiting and selecting new Executive Committee members
- Process for onboarding a new Executive Committee member
- Process for Executive Committee review and decision on protocols
- Travel expense policy (from ECFS)

16 Review of terms of reference

The terms of reference are:

- initially approved by the ECFS-CTN Executive Committee
- ratified by ECFS Board
- reviewed every 2 years by the ECFS-CTN coordinating centre team
- approved by the ECFS-CTN Executive Committee