European Cystic Fibrosis Society - Clinical Trials Network

Applications for membership in 2018

The European Cystic Fibrosis Society - Clinical Trials Network (ECFS-CTN) is a network of 43 Specialist Cystic Fibrosis Centres from 15 countries in Europe who are committed to a coordinated strategic approach to CF clinical trials in Europe and worldwide. The ECFS is inviting further applications from CF Centres to become Clinical Research Centres in this Network.

The aim of the European Cystic Fibrosis Society - Clinical Trials Network is to intensify clinical research in the area of cystic fibrosis and to bring new medicines to the patients as quickly as possible. This is achieved by:

- Sharing expertise among dedicated CF researchers
- Expert reviewing of clinical trial protocols
- Maintaining high quality within sites by monitoring site participation and performance in studies and issuing quality reports to the sites
- Standardising outcome measures by writing standardised operating procedures, implementing them and setting up certification procedures and central reading
- Validating new and alternative endpoints such as LCI, Chest-CT and MRI
- Providing training to the site's staff
- Involving and cooperating with the patient organizations and other stakeholders, such as the US CF Clinical Trials Network, the CFF-TDN (Cystic Fibrosis Foundation – Therapeutic Development Network).

Being an ECFS-CTN site implies that:

- The lead person of the site (called the Principal Investigator or PI) will ensure swift communication between the site and the ECFS-CTN coordinating centre. The PI will also ensure swift communication within this site about ECFS-CTN activities.

- The PI or a site representative will attend the 2 face-to-face meetings of the ECFS-CTN each year, a 2-day winter meeting at the Steering Committee Meeting and one half-day summer meeting at the annual ECFS Conference.
- Some site members will be involved in ECFS-CTN committees
- The site will only conduct pharma studies that have been reviewed and approved by the ECFS-CTN. Likewise, feasibility checks will only be filled out once an agreement has been reached between the sponsor and the ECFS-CTN. The site will inform the ECFS-CTN about planned interventional Investigator-initiated studies.
- A dedicated person will fill out enrolment information quarterly for the whole site on the online Trial Management System (adult and paediatric if relevant)

More information is available on the ECFS-CTN website: ecfs-ctn@uzleuven.be

The eligibility criteria to be an ECFS-CTN site are:

- To be a specialist CF Centre in a European country or in a country connected to Europe according to the European Neighbourhood Policy (http://ec.europa.eu/economy_finance/international/neighbourhood_policy/index_en.htm)
- Applications should be from "mixed" (adult and paediatric clinic in 1 hospital) or "joint" (adult and paediatric clinic in 2 different hospitals) paediatric/adult centres and satisfy the following: a) both sites together have at least 200 patients in total, b) they can show active collaboration, c) the site PI is willing to act as contact person for both areas and d) the PI and co-PI are representative of both paediatric and adult areas, e) the paediatric and adult clinics are in the same town or city. Please note that a centre composed of more than one paediatric and one adult centre i.e. "composite site" (grouping of several paediatric or adult centres in different locations) will not be eligible
- The site PI and co-PI must show, involvement in the care of CF patients, experience in CF clinical research, commitment to work within ECFS-CTN regulations and the ability to effectively communicate in a timely fashion
- The site works according to ECFS Standards of Care: https://www.sciencedirect.com/science/article/pii/S1569199318300298
- The site has experience in CF clinical research, particularly pharma initiated interventional drug trials

- ICH-GCP certification is held by at least the PI and co-PI, and preferably by the entire clinical research team
- The site has human, logistical, administrative and technical resources to run clinical trials
- The site has institutional support (as evidenced by personnel, space, contracting facility or other program support)
- The PI and co-PI are current ECFS members

Evaluation of applications:

An Evaluation Board will be appointed by the Board of the ECFS. The Evaluation Board will be responsible for the ranking of the received applications. The Evaluation Board will not include physicians from centres applying to participate in the network.

Applications will be reviewed for eligibility criteria and scored according to the following criteria:

- Quality of the centre (#50%)
- Experience in clinical research (#30%)
- Resources for clinical research (#20%)

Please fill out the application form below and send it back to ecfs-ctn@uzleuven.be

Deadline = October 15th, 2018

Privacy statement

The following application form asks or personal data regarding the investigators at your site. We only ask for personal data that is necessary to judge your site's application to join CTN.
Your data will be shared with the members of the evaluation board, which may include members from outside of the EU. We will not share the data in this application form with anyone for marketing or commercial purposes. We may share your data with trusted third party contractors for ECFS-CTN, such as the IT consultant who manages our servers.
We will retain your data as long as necessary to judge your application and to provide CTN related services to your site.
Please contact us at ecfs-ctn@uzleuven.be if you would like more information about how we protect your privacy, if you would like a copy of the data we hold about you, or if you would like us to delete all data we hold about you.

Centre information

Name and first name of PI:
Email address:
Telephone number:
Name and address of PI's CF Centre:
Centre: ☐ Adult
☐ Paediatric
☐ Adult and Paediatric
ECFS membership number for 2018:

Name and first name of co-PI:
Email address:
Telephone number:
Name and address of co-PI's CF Centre (if different):
Centre: ☐ Adult
☐ Paediatric
☐ Adult and Paediatric
ECFS membership number for 2018:

1 - PIs qualifications

Care of CF patients
What is your position in the CF centre? (e. g. (lead) physician, centre director…)

How many CF patients are currently under your direct care in your centre?
Adults
Children
If you don't personally follow CF patients, in what way are you involved in their care?

Experience in CF clinical trials
For how many CF industry-sponsored interventional drug trials have you been the principal investigator in the past 5 years (2014-2018)? (trials to be identified in section 4)
Phase 1 (including CF patients):
Phase 2:
Phase 3:

Commitment to work within ECFS-CTN
How many hours per month (on average), will you be able to dedicate to ECFS-CTN activities i.e. protocol review, ECFS-CTN meetings, telephone conferences and other network activities? (excluding the activities related to clinical trial preparation and conduct)

☐ less than 2 hours per month
☐ around 4 hours per month
☐ more than 4 hours per month

Publications
List your CF-related publications during the past 5 years (2014-2018): only original articles in peer-reviewed journals need to be listed.

Collaborative activities
List national or international CF-related working groups in which you have been involved during the past 5 years (2014-2018). If they had led to publications, please provide the reference.

Are you collaborating with a national patient organization? ☐ Yes ☐ No
If yes, please indicate which organization and explain how you collaborate:

List any other international collaborative activity:

2 – Co-PI qualifications

Care of CF patients
What is your position in the CF centre? (e. g. (lead) physician, centre director…)

How many CF patients did you personally take care of in 2018 in your CF centre?
Adults
Children
If you don't personally follow CF patients, in what way are you involved in their care?

Experience in CF clinical trials
For how many CF industry-sponsored trials have you been the principal investigator for in the past 5 years (2014-2018)? (trials to be identified in section 4)
Phase 1 (including CF patients):
Phase 2:
Phase 3:

Commitment to work within ECFS-CTN
How many hours per month (on average), will you be able to dedicate to ECFS-CTN activities i.e. protocol review, ECFS-CTN meetings, telephone conferences and other network activities? (excluding the activities related to clinical trial preparation and conduct)

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Are you collaborating with a national patient organization? ☐ Yes ☐ No
If yes, please indicate which organization and explain how you collaborate:

List any other international collaborative activity:

3 - Description of your centre

1 – **Number of patients** (not counting the transplanted patients)
Number of adults (≥ 18 years old) followed at your site in 2018:
Number of children (≤ 17 years old) followed at your site in 2018:

2 – **If it is a joint paediatric/adult application:**

- Please describe: in which ways do both sites collaborate?

3 – **Standards of care**

For the centre covered by this application:

Is your centre recognized by a National authority: ☐ Yes ☐ No

If yes, which one and date of acknowledgement:

Multidisciplinary Team

CF-dedicated resources	Full-time equivalent (dedicated to CF)
Consultants (MD)	
Specialist nurses	
Physiotherapists	
Dietitians	
Psychologists	
Social workers	
Pharmacists	
Secretarial support	

Patient follow-up:

Frequency of routine appointments	Every months
Full medical review is performed at least once a year	☐ Yes ☐ No
Full dietetic review is performed at least once a year	☐ Yes ☐ No
Full physiotherapy review is performed at least once a year	☐ Yes ☐ No
Full psychosocial review is performed at least once a year	☐ Yes ☐ No
Other: specify	

Are the below facilities available at your site?: :

Sweat test	☐ Yes ☐ No ☐ NA
CF-specialist in microbiology	☐ Yes ☐ No ☐ NA
CFTR geneticist	☐ Yes ☐ No ☐ NA
Program for transition from paediatric to adult care	☐ Yes ☐ No ☐ NA
Facilities for home IV treatment	☐ Yes ☐ No ☐ NA
Facilities allow for patient segregation (prevention of cross-infection)	☐ Yes ☐ No ☐ NA
Access to other specialists on the hospital site (gastroenterology and hepatology (with expertise to perform emergency endoscopic ligation of oesophageal varices); diabetes and endocrinology; ear, nose and throat surgery; cardiothoracic and general surgery; specialist anaesthesia and pain control; rheumatology; nephrology; obstetrics and gynaecology; psychiatry; intensive care; radiology incl. interventional radiology (with expertise in emergency bronchial arterial embolization, and elective percutaneous ultrasound-directed gastrostomy), palliative medicine.	☐ Yes ☐ No ☐ NA Comments:
Other: specify	

Do you have a national program for improving quality in CF care? ☐ Yes ☐ No
If yes, do you participate in this program? ☐ Yes ☐ No

Do you enter your patients into a Registry? ☐ Yes ☐ No
If yes, which one: ☐ National ☐ European ☐ Other: specify
If yes, what percentage of your patients were entered last year?

4 - Experience of the site in clinical research

Industry-sponsored trials

List the industry-sponsored trials in CF patients in which your site has participated during the past 5 years (2014-2018). (Trials not registered in clinical trials.gov or EUDRACT need not be listed)

Full name of the trial	Clinical trials.gov identifier or EUDRACT number	Name of the site's PI	Phase 1 (a or b), 2, 3 or 4	Number of patients enrolled by your site

Investigator-initiated-trials

List the CF-related investigator-initiated-trials in which your site has participated during the past 5 years (2014-2018) AND which was published or presented at an international conference (please list the references or provide the abstracts)

Full name of the trial and reference of the publication	National or Multinational	Was your site the site initiating the trial?	Name of the site's PI	Number of patients enrolled by your site

5 - Resources for clinical research

Personnel

		% time dedicated to CF clinical research	Years of experience in CF clinical research	Date of last GCP certificate
Investigators	Enter names: - - -	 - - -	 - - -	 - - -
Research nurses	-RN1: -RN2:	- -	- -	- -
Research coordinators	-RC1: -RC2: -RC3:	- -	- -	- -
Pharmacists specific for clinical trials	-	-	-	-
Additional personnel involved in clinical research e.g. research administrator	-	-	-	-

***Database*:**

Are the CF patients characteristics listed in a database at your site? ☐ Yes ☐ No

If yes:
How many patients are in the database?
Who is responsible for its maintenance?
How often is it filled out?

How does your site identify patients meeting certain inclusion/exclusion criteria for clinical trials? (multiple answers possible)

- ☐ Automatic query in the hospital or CF centre electronic database
- ☐ Manual search in the hospital or CF centre electronic database
- ☐ Via the national registry

CF-specific outcome parameters
Please indicate which of the following are available at your centre:

Multiple breath inert gas washout for lung clearance index ECFS-CTN certified?	☐ Yes ☐ No ☐ Yes ☐ No	
Nasal PD measurement ECFS-CTN certified?	☐ Yes ☐ No ☐ Yes ☐ No	
Intestinal current measurement	☐ Yes ☐ No	
High resolution CT scan	☐ Yes ☐ No	
Magnetic Resonance Imaging	☐ Yes ☐ No	
Fibreoptic bronchoscopy	☐ Yes ☐ No	
BAL inflammatory markers processing: cytology, IL and PG measurements	☐ Yes ☐ No	
Infant lung function test	☐ Yes ☐ No	
Sputum induction and processing	☐ Yes ☐ No	
Other (please specify):		

Clinical research facility:
Is there a dedicated area in your centre/hospital for clinical trials?

If yes, how many CF patients can you receive per day for a trial visit?

Phase 1 capacity:

a. Can your site perform phase 1 studies involving **CF patients**:

- involving overnight stays in hotels near your CF centre? ☐ Yes ☐ No
- involving overnight stays in your CF centre? ☐ Yes ☐ No
- involving overnight stays in a specialized phase 1 unit? ☐ Yes ☐ No
    - will this need contracting with a separate phase 1 unit? ☐ Yes ☐ No
    - Is this phase 1 unit
        - part of your hospital ☐
        - or a separate entity? ☐
- without overnight stays but with assessments outside business hours (e.g. PK 12 hours post dosing?) ☐ Yes ☐ No

b. <u>Can your site perform phase 1 studies involving **healthy volunteers**</u>:

- involving overnight stays in hotels near your CF centre? ☐ Yes ☐ No
- involving overnight stays in your CF centre? ☐ Yes ☐ No
- involving overnight stays in a specialized phase 1 unit? ☐ Yes ☐ No
    - will this need contracting with a separate phase 1 unit? ☐ Yes ☐ No
    - Is this phase 1 unit
        - part of your hospital ☐
        - or a separate entity? ☐
- without overnight stays but with assessments outside business hours (e.g. PK 12 hours post dosing?) ☐ Yes ☐ No

6 - Institutional support

Please provide a letter of support from the Head of Department or Clinical Director. You may also provide any other document you may find useful in showing your institutional support.

7 – Signatures PI and co-PI

PI name:

Date:

Signature:

Co-PI name:

Date:

Signature: