

# What we do...

## Brochure for sponsors



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# Our network

What we do

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**We train  
sites to  
improve  
quality**

**We  
support  
sponsors**

**We bring  
people  
together**

**We  
advise  
regulators**

**We build  
research  
capacity**

**We  
develop  
endpoints**



# Our sites

All around Europe

**Go to**

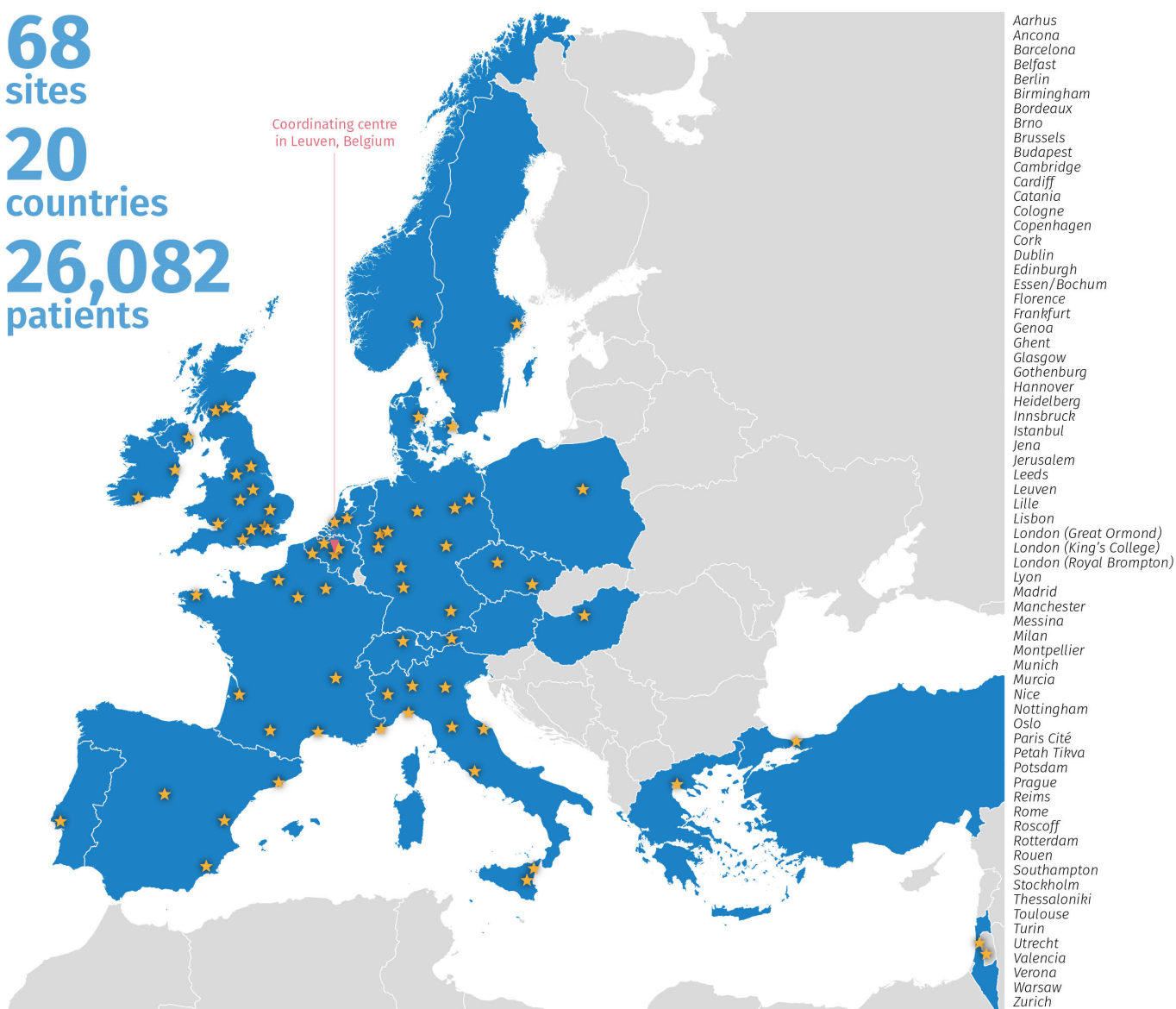
[www.ecfs.eu/ctn/  
list-ctn-centres](http://www.ecfs.eu/ctn/list-ctn-centres)  
for a list of  
investigators

**68**  
sites

**20**  
countries

**26,082**  
patients

Coordinating centre  
in Leuven, Belgium



# ECFS-CTN

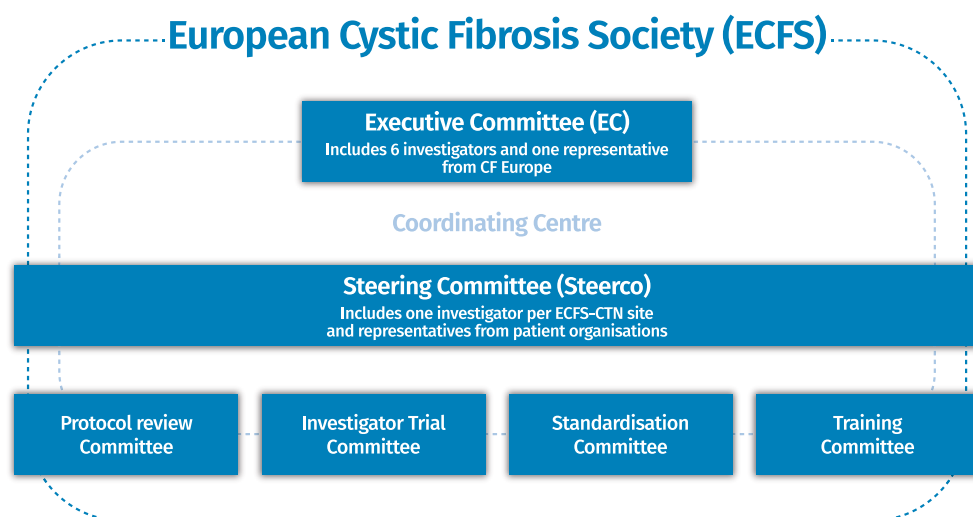
## Organisation

### Who we are

ECFS-CTN was founded in 2008 and is made up of 68 sites in 20 countries and a central coordinating centre in Leuven, Belgium.

### How we work

Visit [www.ecfs.eu/ctn](http://www.ecfs.eu/ctn) to learn more about how ECFS-CTN speeds up clinical trials of new therapies for CF.



### How does a European network streamline research?

The aim of ECFS-CTN is to intensify clinical research in the area of CF and to bring new medicines to people with CF as quickly as possible.



Increases cooperation between the whole CF community (people with CF, patient organisations, pharmaceutical industry and academic researchers)



Shares expertise across countries to standardise research procedures and measures



Accelerates study feasibility and setup



Encourages high quality research by training staff and monitoring site performance

# Ecosystem

Your central point of contact for CF trials in Europe

## Regulatory agencies

- European Medicines Agency
- EnprEMA voting member (European Network of Pediatric Research)

## CF patient organisations

- Cystic Fibrosis Europe
- National Patient Organisations in Europe
- The CFF and TDN in the USA

## Other clinical trial networks

- National CF clinical trial networks in the USA, Canada and some ECFS-CTN member countries (France, Germany, Netherlands and the UK)

## Other European partners

- ERN-LUNG
- HIT-CF
- Conect4children
- European Respiratory Society





# Planning your protocol

## Advice, SOPs and central reading hubs

### Contact us

as early as possible to integrate our expertise into your protocol and avoid delays.



### Protocol assistance / consultancy

ECFS-CTN experts can provide help in the early phase development of study design.

### Standardised outcome measures

Integrate the ECFS-CTN Standard Operating Procedures into your protocols and manuals for standardized measurement of clinical trial outcomes.

[Ask us](#) for the list of Standard Operating Procedures.

### Certification & central reading

Use our ECFS-CTN core facilities to certify clinical trial staff in trial sites and for central reading of trial outcomes. These services are also available to trial sites outside ECFS-CTN.

- [Lung Clearance Index Core Facility](#)
- [Lung Analysis CT Imaging Core Facility](#)

### A plain language glossary

We developed a [plain language glossary of CF terms](#) with CF Europe and people with CF. Use it to help develop your patient information leaflets and informed consent forms.

### Data Safety Monitoring Board

ECFS-CTN partners with an independent DSMB coordinator (based at the University of Lyon in France). [Ask us](#) for more details.

Sponsors planning global studies consider a global DSMB, organised by the CFF-TDN.

# ECFS-CTN protocol review

## Essential for running trials in Europe



### Improve your protocol and boost recruitment

Review by our expert multinational groups of CF doctors, research coordinators, academic researchers and people with CF and their families makes sure that protocols are:

- safe
- scientifically sound
- going to generate useful information
- logistically feasible to conduct at sites
- acceptable to trial participants and their families



#### BENEFITS OF BETTER PROTOCOLS

- Faster easier recruitment
- Robust results
- Faster access to new medicines for pwCF

### Which protocols do we review?

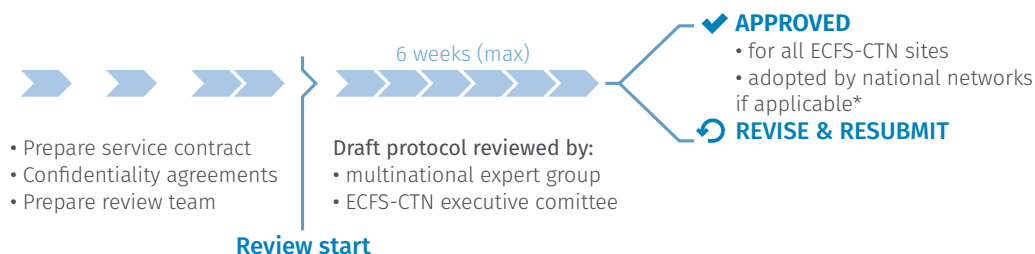
Essential for all commercial and academic interventional and real-world clinical trials planned to run **in at least one ECFS-CTN site**.

We review other non-interventional trials on a case-by-case basis.

Ask us about fees for commercial and academic trials.

We watch out for conflict of interest, and excuse reviewers from reviews, where appropriate.

### How the process works



A global review process is also available for trials planned to run in Europe and North America (USA & Canada).

Our review complements programme and trial-specific scientific advice from regulatory agencies.

\*We can refer companies to national networks in [France](#), [Germany](#), [the Netherlands](#) and the [UK](#).

# Feasibility

Find the right sites for your trial

Our sites only answer feasibility requests issued by the ECFS-CTN coordinating centre

If you contact them directly, they will refer you back to us.

 Protocol assistance

 Protocol review

 Feasibility service

## For approved protocols

We offer a site feasibility service for protocols approved by ECFS-CTN to run in the network.

Feasibility cannot start before protocol review is complete (except sometimes for later phase trials with compounds already known to ECFS-CTN)

## We know our sites

We can advise on country and site selection, based on our knowledge of:

- site expertise, experience, equipment & capacity
- standards of care in different countries

We work with the [ECFS Patient Registry](#) for feasibility requests concerning subpopulations, or specific *CFTR* variants.

## Feasibility optimisation

We review and advise on feasibility questionnaire design.

## Confidentiality

The sponsor signs confidentiality agreements directly with the site.

We will send you the right contact details for the lead investigator in each site.

## We get answers quickly

Our streamlined feasibility process gets answers within 3 weeks, once all confidentiality agreements have been signed.

We centrally handle feasibility requests for all ECFS-CTN sites.

**we**

send the request to the right people at each site.

follow-up responses.

keep you updated on progress.

check completed questionnaires.

regularly send you completed questionnaires, and a summary at the end of the process.

## Site selection

The sponsor selects which sites participate in the study.

- Please inform sites who are not selected, and give them feedback about the decision.
- We track whether sponsors notify unselected sites.





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