Cystic Fibrosis Trust

UK CF Clinical Trials Accelerator Platform

A guide for sponsors, CROs and researchers

Uniting for a life unlimited

Introduction

Launched in collaboration with the USA Cystic Fibrosis Foundation (CFF) in 2017, the Clinical Trials Accelerator Platform (CTAP) is a UK-wide initiative bringing together cystic fibrosis (CF) centres from around the UK to support delivery of CF clinical trials. CTAP provides the infrastructure to support sponsors with delivery of CF clinical trials (commercial and academic), and the platform to enable the CF community to gain access to these trials.

Each appointed CTAP centre is funded with a dedicated CF Trials Coordinator to support trial set-up and delivery. These posts have resulted in significantly **faster trial set-up times**, as well as increased participant screening and enrolment rates at respective CTAP centres.

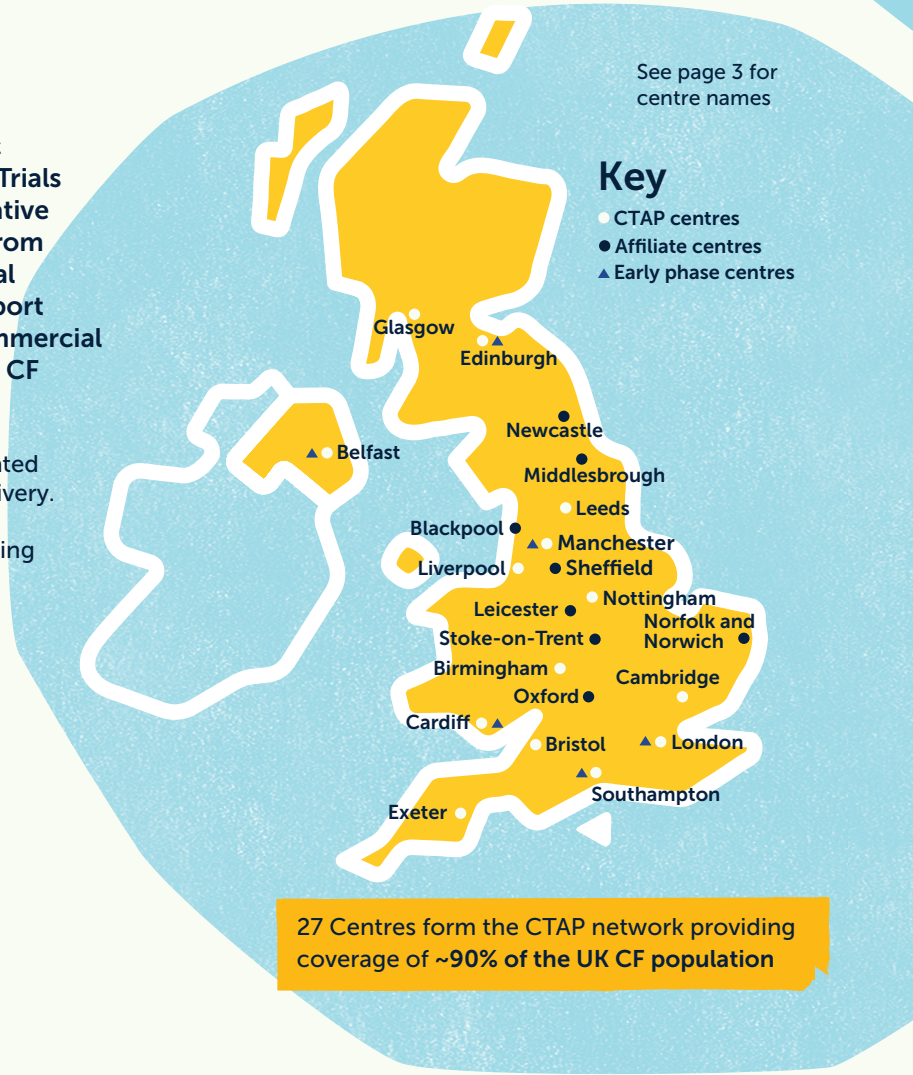
CTAP has four key workstreams, all of which will be explored throughout this booklet.

1 Network of CTAP centres

2 Supporting sponsors

3 Commercial Involvement (PPI)

4 Clinical Trials Digital Hub



1. Network of CTAP centres

England

	Paediatric	Adult
Addenbrooke's Hospital NHS Trust (Cambridge)[3]	+	
Alder Hey Children's NHS Foundation Trust (Liverpool)	+	
Barts Health NHS Trust (London)	+	+
Birmingham Women's and Children's NHS Foundation Trust	+	
Blackpool Teaching Hospital NHS Foundation Trust[3]		+
Manchester University NHS Foundation Trust[1, 2]	+	+
Great Ormond Street Hospital for Children NHS Foundation Trust	+	
King's College Hospital NHS Foundation Trust[1] (London)	+	+
Leeds Teaching Hospitals NHS Trust[1]	+	+
Newcastle upon Tyne Hospitals NHS Foundation Trust[3]		+
Norfolk and Norwich University Hospitals NHS Foundation Trust[3]	+	+
Nottingham University Hospitals NHS Trust[1]	+	+
Oxford University Hospitals NHS Foundation Trust[3]	+	+
Royal Papworth Hospital NHS Foundation Trust[1] (Cambridge)		+
Royal Brompton and Harefield NHS Foundation Trust[1, 2] (London)	+	+
Royal Devon University Healthcare NHS Foundation Trust	+	+
Sheffield Children's NHS Foundation Trust[3]	+	
South Tees Hospitals NHS Foundation Trust[3]	+	
University Hospitals Birmingham NHS Foundation Trust[1]		+
University Hospitals Bristol NHS Foundation Trust	+	+
University Hospitals of Leicester NHS Trust[3]	+	+
University Hospitals of North Midlands NHS Trust[3]	+	+
University Hospital Southampton NHS Foundation Trust[1, 2]	+	+

Northern Ireland

	Paediatric	Adult
Belfast Health and Social Care Trust[1, 2]	+	+

Scotland

	Paediatric	Adult
NHS Greater Glasgow and Clyde[1]	+	+
NHS Lothian[2]	+	+

Wales

	Paediatric	Adult
Cardiff and Vale University Health Board[1,2]	+	+

Paediatric **Adult**

[1]European Cystic Fibrosis Society Clinical Trial Network centre
[2]Early phase CTAP centre
[3]CTAP Affiliate Centre

Overview of CTAP centre trial capabilities (this list is not exhaustive)

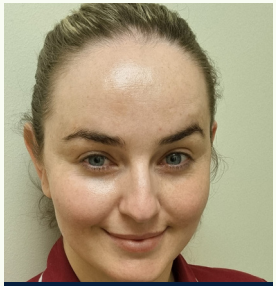
- Lung clearance index (LCI) trained staff
- LCI machine access for clinical trial use
- Early phase experience and capabilities
- Clinical trials pharmacy
- Sweat testing equipment
- Spirometry
- ECG
- Cardiopulmonary Exercise Testing (CPET)
- Bronchoscopy for research

National Team of CF Trial Coordinators

As part of the programme, CTAP funds 25 CF Trial Coordinators (including six specialist Early Phase Coordinators) who work across our network of CTAP centres. The team of Coordinators ensure efficient set-up of CF trials, supporting all of the requirements of trial set-up including regulatory approvals, contract and budget management.

They also support with identification and recruitment of trial participants in addition to overseeing trial follow-up and monitoring visits. Please visit our CF Trials Coordinator page on the Clinical Trials Hub to view the team's profiles.


Leonidas Pappas


Siobhan Moor


Shenna Cadiente


Jessica Longmate


Helen Chadwick


Sophie Whiteley


Juneka Begum

Sally Coplowe


Danielle Brown


Kate Alderton

Specialist early phase CTAP centres

To enable the UK to be at the forefront of early phase CF research, CTAP has created a specialist sub-network of CTAP centres with expert knowledge, facilities and resources to lead in the UK delivery of early phase CF clinical trials. Six CTAP centres are funded with an additional Early Phase Trial Coordinator to oversee the set-up and delivery of early phase CF trials (phase 1 & 2a):

- Belfast Health and Social Care Trust
- Cardiff and Vale Health Board
- Manchester University NHS Foundation Trust
- NHS Lothian (Edinburgh)
- Royal Brompton and Harefield NHS Trust (London)
- University Hospital Southampton NHS Foundation Trust

CTAP also has collaborative links with specialist early phase CRO companies along with the UK NIHRs Translational Research Collaboration (TRC).

2. Supporting Sponsors

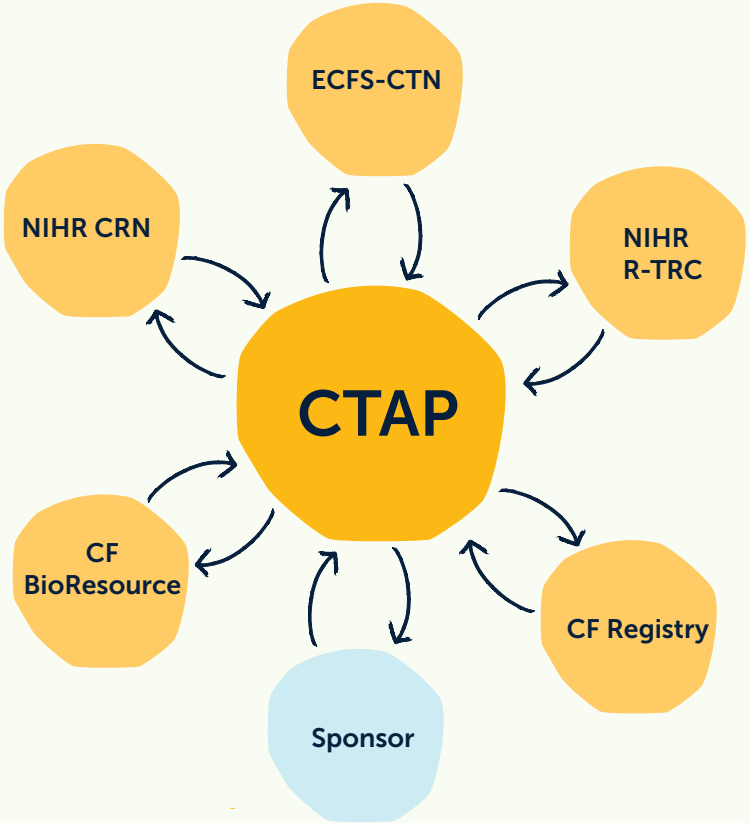
The infrastructure in the UK to support CF clinical research delivery is broad ranging.

CTAP not only sits within the centre of this rich clinical research ecosystem, but it plays a unique role in **unifying** the various services and streamlining access for sponsors, helping navigation of the various pathways to support.

Two CF clinical trial networks operate collaboratively within the UK:

- CTAP and the European CF Society's Clinical Trials Network (ECFS-CTN)
- All 11 UK based ECFS-CTN centres are also part of CTAP, they are referred to as 'dual centres'

Both networks are aligned and operate collaboratively



Alongside these networks:

- **NIHR BioResource** – supports targeted identification of eligible, research-interested participants through collecting clinical and genetic data

- **UK CF Registry** – supports sponsors with design of post-marketing and pharmacovigilance studies, supports country-and site-level feasibility, hosts and embeds studies into the Registry to support data collection

- **NIHR Respiratory Translational Research Collaboration (R-TRC)** – provides sponsors with expert CF-specific advice and support for trial design and protocol development for translational research

- **NIHR Clinical Research Network (CRN)** – supports delivery of clinical trials through funding research staff and some study delivery cost

Please email the CTAP coordinating team for more details, clinicaltrials@cysticfibrosis.org.uk

Or visit cysticfibrosis.org.uk/get-involved/clinical-trials/information-for-sponsors for more information.

The following chart illustrates how the various UK organisations support industry at each stage of the trials process

Trial design

- **NIHR R-TRC** – protocol development (early phase trials)
- **CTAP** – NIHR funding applications, protocol development & review* (early & late phase trials, RWE studies)
- **ECFS-CTN** – protocol development & review (early & late phase trials, RWE studies)
- **CF Registry** – funding applications & protocol development (RWE studies, pharmacovigilance & post-marketing studies)

*Only for studies not eligible for ECFS-CTN protocol review

Trial feasibility

- **CF Registry** – national feasibility service to support country selection / UK feasibility (early & late phase trials)
- **CTAP** – centralised feasibility service to support recruitment centre selection (early & late phase trials)
- **ECFS-CTN** – centralised feasibility service to support recruitment centre selection (early & late phase trials)
- **CF BioResource** - supports centre selection through participant identification according to specific genotypes (early & late phase trials)

Chart continued from previous page

Trial delivery

CTAP – recruitment (early & late phase)

CF BioResource – identification & recruitment of eligible, research interested patients (early & late phase trials)

CF Registry – randomisation & data collection for Registry based studies (late phase trials, RWE studies)

NIHR CRN – supports recruitment through funding research staff (early & late phase)

Post-marketing

CF Registry – long-term follow-up/data collection

CTAP's patient referral model

The use of patient identification centres (PICs) is widely used within CTAP. A PIC is an NHS Trust that acts as a referral centre, referring eligible patients to a recruitment centre for trial participation, without performing any further research activities for the trial.

The advantages of using PICs as a recruitment method are:

- The PIC model supports **efficient recruitment** and **widens access** to trials for the CF patient community.
- Including PICs reduces the number of recruitment centres a sponsor needs to open, **saving both time and money** from a sponsor's perspective.
- PICs will be a valuable recruitment method for trials involving **rare genotypes** and for **early phase trials**.

For more information on working with PICs in the UK, please contact the CTAP coordinating team.

CTAP Badging – endorsement and support from CTAP

For a clinical trial to receive support from CTAP, whether that's through the centralised centre-specific feasibility service or support from one of the CTAP funded Trial Coordinators, a trial will need to have CTAP Badging status. Only trials of high scientific quality and relevance to the CF community will be CTAP Badged. There are two routes through which a sponsor can gain CTAP Badging for a clinical trial.

Route 1: Via ECFS-CTN

1. Interventional or RWE trials which will open across Europe, including the UK, or
2. Interventional or RWE trials which will only open in the UK but will involve one or more of the 11 UK based ECFS-CTN centres

Sponsors will be required to submit the trial protocol to the ECFS-CTN for Protocol Review and Portfolio Adoption. All clinical trials adopted by the ECFS-CTN will **automatically receive CTAP Badging status** and will be **eligible for support by CTAP Trial Coordinators.**

Please follow the usual process for submitting clinical trials for adoption to the ECFS-CTN. Email **ECFS-CTN@uzleuven.be** for more information.

Route 2: Via CTAP

This route is suitable for:

1. UK-only commercial trials (interventional or RWE) which will **not** involve any UK ECFS-CTN centres
2. Commercial or academic trials (interventional or RWE) which were submitted and reviewed, but **not** adopted by the ECFS-CTN – these trials may or may not be accepted for review by CTAP and will be assessed on a case by case basis
3. UK-only academic trials (non-interventional) which are competitively funded and multi-centred

Sponsors will be required to submit the trial protocol and other supporting documentation to CTAP for Protocol Review and CTAP Badging. Trials will be scored on scientific design, impact and relevance to the CF community. Trials awarded **CTAP Badging status** will be **eligible for support by CTAP Coordinators.**

Please contact the CTAP Coordinating Office for more details and to request a CTAP Badging application form.

3. Commercial Involvement (PPI)

'Patient & Public Involvement' (PPI) is a UK term used to describe engagement of sponsors with patient advocacy groups.

At the Trust, we prefer to refer to PPI as Commercial Involvement, recognising that people living with CF only identify as 'patients' in a hospital setting. Involvement is regarded as a highly important component of the UK regulatory process, with the UK Health Research Authority (HRA) strongly encouraging all sponsors to engage with PPI during trial design. It is now widely acknowledged that the inclusion of community involvement at all stages of the trials process leads to better recruitment and retention rates.

CTAP has an established group of cystic fibrosis representatives (people with CF, and parents of children with CF) ready to share their lived experience to support sponsors with trial design and delivery.

This CTAP Community Involvement group can benefit sponsors by offering:

- Access to an engaged and diverse representation of the CF community
- Focus group discussions via remote technology
- One-to-one interviews to access a specific knowledge base
- Protocol reviews by trained CF representatives
- Review of design and content of patient information sheets and consent forms
- Lay trial summaries and lay result summaries

We encourage all sponsors to explore working with our Involvement group, please see supplementary Commercial Involvement summary for more information or contact the CTAP Involvement team, **involvement@cysticfibrosis.org.uk**

4. Clinical Trials Digital Hub

The Clinical Trials Digital Hub, hosted on Cystic Fibrosis Trust's website, provides a suite of information about taking part in clinical trials. The Hub includes the CF Trials Tracker, a publicly available clinical trials database listing all UK cystic fibrosis clinical trials in set-up and open to recruitment. The Trials Tracker is designed to support the CF community find suitable clinical trial opportunities, either locally or further afield.

Trials are searchable by therapeutic area, age and location. Each listed trial has its own profile page with a contact form to facilitate putting people in direct contact with clinical teams to request more information. Clinical trial results are also disseminated via the Trials Tracker including lay-friendly result summaries.

Please visit **cysticfibrosis.org.uk/trialstracker** to view the Trials Tracker. If you have a CF clinical trial or study in set-up or open to recruitment and it's not yet listed, please contact the CTAP Coordinating Office.

Find out more at
cysticfibrosis.org.uk/clinicaltrials

CTAP Coordinating Office

Email: **clinicaltrials@cysticfibrosis.org.uk**
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One Aldgate, London EC3N 1RE

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ADDING TOMORROWS

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