Cystic Fibrosis advancing care with clinical trials

UK Clinical Trials Accelerator Platform

A guide for Sponsors, CROs and researchers

Fighting for a Life Unlimited

Introduction

Launched in collaboration with the US Cystic Fibrosis Foundation (CFF) in 2017, the Clinical Trials Accelerator Platform (CTAP) is a UK-wide initiative bringing together cystic fibrosis centres from around the UK to support delivery of cystic fibrosis 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**

See page 3 for centre names

27 Centres form the CTAP network providing coverage of over **80%** of the UK CF population

1. Network of CTAP centres

England

- Addenbrooke's Hospital NHS Trust (Cambridge)[3]
- Alder Hey Children's Hospital NHS Trust (Liverpool)
- Barts Health NHS Trust (London)
- Birmingham Women's and Children's NHS Foundation Trust[1]
- Blackpool Teaching Hospital NHS Foundation Trust[3]
- Central Manchester University NHS Foundation Trust[1, 2]
- Great Ormond Street NHS Foundation Trust (London)
- King's College Hospital NHS Foundation Trust[1] (London)
- Leeds Teaching Hospital[1]
- Newcastle upon Tyne Hospitals NHS Foundation Trust[3]
- Norfolk and Norwich NHS Foundation Trust
- Nottingham University Hospitals NHS Trust[1]
- Oxford University Hospitals NHS Foundation Trust[3]
- Papworth Hospital NHS Trust[1] (Cambridge)
- Royal Brompton and Harefield NHS Foundation Trust[1, 2] (London)
- Royal Devon and Exeter Hospital NHS Foundation Trust
- Sheffield Children's Hospital NHS Foundation Trust[3]
- South Tees NHS Foundation Trust[3]
- University Hospital 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

- Belfast Health and Social Care Trust[1, 2]

Scotland

- NHS Greater Glasgow and Clyde[1]
- NHS Lothian and Royal Hospital for Sick Children[2], Western General Hospital (Edinburgh)

Wales

- Cardiff and Vale Health Board[1,2]

Paediatric **Adult**

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

National Team of CF Trial Coordinators

As part of the programme, CTAP funds 26 CF Trial 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 teams profiles.

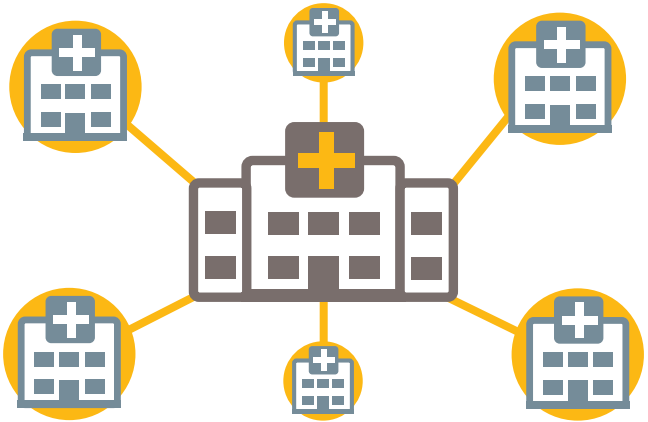
Top row L–R: Kevin Galono, Suzanne Sketchley, Diane Murray, Jessica Longmate, Helen Chadwick
Bottom row L–R; Sophie Whiteley, Juneka Begum, Sally Coplowe, Danielle Brown, Ryan Leslie

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
- Central Manchester University NHS Foundation Trust
- NHS Lothian (Edinburgh)
- Royal Brompton and Harefield NHS Trust (London)
- University Hospital Southampton NHS Trust

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



2. Supporting Sponsors

CTAP supports Sponsors to successfully deliver CF trials across the UK through :

- Facilitating engagement with CF representatives to collect feedback on trial design and trial documentation review (PPI).
- Supporting with identification of trial recruitment sites and patient identification centres (PICs) (see supplementary PIC summary for more information).
- Centralised **national** and **centre-specific** feasibility review.
- Network of 26 CF Trial Coordinators to oversee trial set-up and delivery, including a specialist team of six Early Phase Trial Coordinators.
- Collaborating with CROs and the European Cystic Fibrosis Society, Clinical Trials Network (ECFS-CTN) to ensure a harmonised and joined up cross-party approach.
- Facilitating collaborative opportunities with the UK CF Registry to support Registry-based Real World Evidence (RWE) trials and pharmacovigilance studies (long-term safety monitoring).

Find out more at:
cysticfibrosis.org.uk/get-involved/clinical-trials/information-for-sponsors

Feasibility Service

National Feasibility

The UK Cystic Fibrosis Registry is a secure centralised database, sponsored and managed by the Cystic Fibrosis Trust. It records health data on consenting people with cystic fibrosis (CF) in England, Wales, Scotland and Northern Ireland. To date it holds health record data on over 99% of the UK CF population.

Sponsors can submit a Data Request to apply for access to aggregated, anonymised data from the UK CF Registry to assess the number of eligible patients across the UK for a clinical trial. Any CF centres with eligible patients are then alerted about the trial and their respective eligible patients. National feasibility may be helpful when deciding the feasibility of the UK as a country to open a CF trial, or as a targeted method of recruitment for a difficult to recruit trial i.e. recruiting patients with rare mutations.

The average turnaround for a Registry Data Request is three to six weeks.

Centre Specific Feasibility

CTAP supports Sponsors and CROs with identification of suitable recruitment centres and patient identification centres (PICs) from the CTAP network of centres, tailored to the needs of the trial. Once a list of CTAP centres has been agreed with the Sponsor, subject to appropriate CDAs being in place, CTAP will centrally coordinate feasibility questionnaires with CTAP centres on behalf of Sponsors/ CROs to identify the best placed CTAP Centres to deliver a trial.

A timeframe for feasibility will be agreed in advance, however the average turnaround for a CTAP Feasibility Review is one week.

Please note, the Feasibility Service is a mandatory requirement of working with CTAP centres.

Fees

The National and Centre Specific feasibility services are chargeable – a single fee to cover both feasibility services can be agreed in advance upon discussion with the Head of CTAP.

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 **interventional** or **Real-World Evidence (RWE) 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 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

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

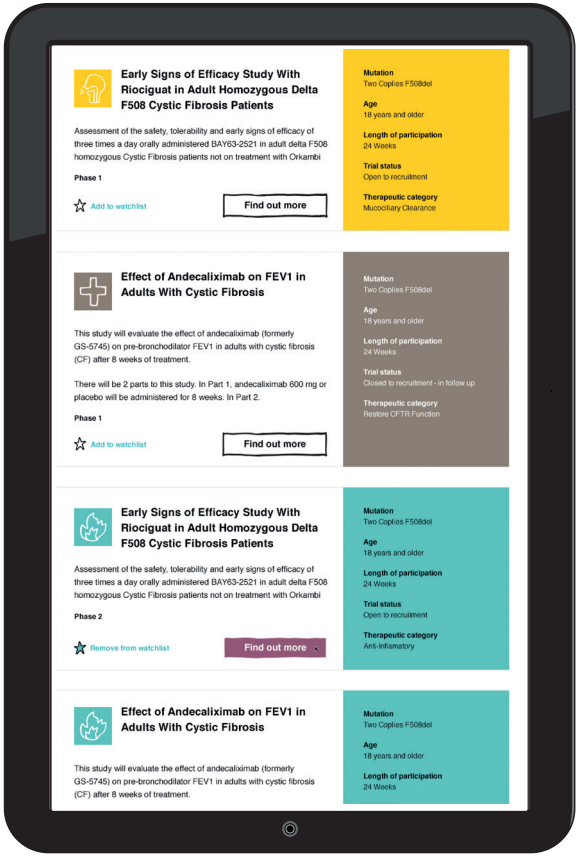
4. Clinical Trials Digital Hub

The Clinical Trials Digital Hub, hosted on the 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 and trial status. 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 can also be disseminated via the Trials Tracker.

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

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Cystic Fibrosis Trust

cysticfibrosis.org.uk

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