

Cystic Fibrosis advancing care with clinical trials



**Clinical Trials
Accelerator Platform**
A guide for Industry and Researchers

Introduction

The Clinical Trials Accelerator Platform (CTAP) is a UK-wide initiative bringing together cystic fibrosis (CF) centres to increase participation and improve delivery of CF clinical trials.

This new Cystic Fibrosis Trust flagship programme has created a network of CF centres who collectively with European Cystic Fibrosis Society's Clinical Trials Network (ECFS-CTN) UK sites, will lead in the delivery of commercial clinical trials.

Our objectives

Every person in the UK with CF who is eligible and who wants to participate in a clinical trial, can take part regardless of where they live or the geographical location of their CF care centre. This is supported by the range of resources available through our Clinical Trials Digital Hub, to engage, educate and empower the whole CF Community. To find out more visit cysticfibrosis.org.uk/get-involved/clinical-trials.

This initiative is building the infrastructure and funding the much-needed additional research capacity to support Industry with CF commercial clinical trial delivery, and enable UK CF centres to grow their CF clinical trial portfolios.

CTAP Centres

Collectively the 32 adult and paediatric CF centres which form the CTAP network of centres cover 80% of the UK CF population.

Each CTAP centre will be funded with a dedicated CF Trial Coordinator to oversee and support the efficient set-up and delivery of commercial CF clinical trials, ensuring trials are delivered to time and target.

Scotland

- Scottish Adult Cystic Fibrosis Service (Edinburgh) & West Scotland Cystic Fibrosis Service (Glasgow)

Northern Ireland

- Northern Ireland Regional Cystic Fibrosis Centre & Northern Ireland Regional Paediatric CF Centre*

North West

- Manchester University Hospital's Paediatric Cystic Fibrosis Centre & Adult Cystic Fibrosis Centre
- Leeds Adult Cystic Fibrosis Centre & Leeds Regional Paediatric Cystic Fibrosis Centre*
- Alder Hey Children's Hospital Paediatric Cystic Fibrosis Clinic

Midlands

- West Midlands Adult Cystic Fibrosis Centre* & Birmingham Children's Hospital Cystic Fibrosis Centre
- Nottingham Children's & Young Person's Cystic Fibrosis Clinic and Wolfson Adult Cystic Fibrosis Centre*

East

- Papworth Hospital Adult Cystic Fibrosis Centre*
- Addenbrooke's Hospital Paediatric Cystic Fibrosis Centre
- Norfolk and Norwich University Hospital Paediatric Cystic Fibrosis Centre & Adult Cystic Fibrosis Centre

London

- The Royal Brompton Paediatric Cystic Fibrosis Centre & The Royal Brompton Adult Cystic Fibrosis Centre*
- King's College Hospital Paediatric Cystic Fibrosis Centre & King's College Hospital Regional Cystic Fibrosis Unit
- Great Ormond Street Hospital Paediatric Cystic Fibrosis Clinic
- Barts Adult CF Centre, The Royal London, Paediatric CF Centre



Wales

- All Wales Adult Cystic Fibrosis Centre & Paediatric Cystic Fibrosis Centre, Noah's Ark Children's Hospital for Wales

South

- University Hospital Southampton Adult Cystic Fibrosis Unit & Wessex Regional Paediatric Cystic Fibrosis Service*
- Bristol Paediatric Regional Cystic Fibrosis Service & Bristol Adult Cystic Fibrosis Centre
- Royal Devon and Exeter Hospital Paediatric Cystic Fibrosis Centre & Adult Cystic Fibrosis Centre

*ECFS-CTN member centres

European Cystic Fibrosis Society, Clinical Trials Network (ECFS-CTN)



The UK CTAP works closely with the ECFS-CTN to support identification of UK centres to deliver ECFS-CTN trials.

In addition to the ECFS-CTN's European-wide protocol review and feasibility service, CTAP also offers the opportunity for 'CTAP badging' clinical trials not adopted by the ECFS-CTN, along with a centralised feasibility service for UK CTAP centres. Please read on to find out more.

Submitting clinical trials for support by CTAP centres

There are two routes through which clinical trials can be submitted for support by CTAP centres:

1. Via the ECFS-CTN

All clinical trials adopted by the ECFS-CTN will automatically be eligible for support by CTAP centres. Please contact the CTAP team to discuss setting up your trial at CTAP centres.

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

2. Via CTAP badging

Clinical trials and research studies not adopted by the ECFS-CTN may be submitted to the CTAP Research Scientific Oversight Board for 'CTAP badging'. Studies will be reviewed by a panel of CF clinical experts and CF representatives, and will be scored on scientific design, impact and relevance to the CF community. Those studies deemed to be of high priority and relevance to the CF community will be awarded 'CTAP badging' status and therefore eligible for support by CTAP centres.

For more information on the CTAP badging process, please email clinicaltrials@cysticfibrosis.org.uk.

Both ECFS-CTN adopted and CTAP badged studies are eligible for support from CTAP centres.

Feasibility Service

CTAP offers a centralised feasibility service for clinical trials eligible for CTAP centre support.

CTAP will facilitate completion of feasibility documents by liaising directly with each CTAP centre and returning feasibility information directly to the Sponsor within the timeframes agreed.

Please contact the CTAP team for further details on the feasibility process.

Patient & Public Involvement (PPI), Lay Review Service

Public involvement involves Sponsors and researchers engaging directly with patients and carers to gain their insight on the design, planning and conduct of research. PPI is regarded as a highly important component of the UK regulatory process; the Health Research Authority (HRA) strongly encourages patients to be involved in all parts of the research process, including the early design stage. It has been indicated that studies incorporating PPI at the earliest possible opportunity experienced better recruitment and retention rates than those which did not.

The CTAP Lay Review Group is formed of CF representatives (people with CF and CF parents) trained in conducting protocol, study design and patient information sheet reviews.

The Lay Review Group can review study documentation within an agreed timeline. Whilst CTAP will not charge for this service, lay reviewers are expected to be reimbursed for their time directly by the Sponsor/Researcher, as per INVOLVE's recommendations (www.invo.org.uk).

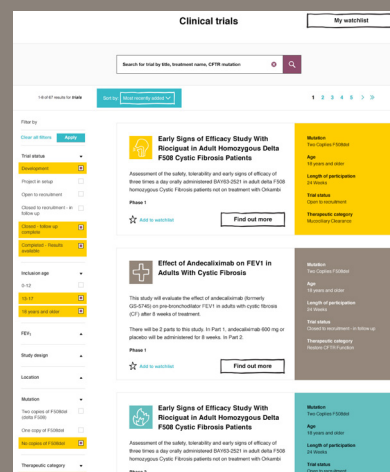
Please contact the CTAP PPI Coordinator, Lorna Allen for more information on the Lay Review Service: lorna.allen@cysticfibrosis.org.uk.

Cystic Fibrosis Trials Tracker

The Trust recently launched the CF Trials Tracker; a publicly available clinical trials database listing all UK CF clinical trials in set-up and open to recruitment. The CF Trials Tracker is designed to support the CF community and healthcare professionals find UK clinical trial opportunities.

Trials are searchable by genotype, therapeutic focus, location and age range. There is also a contact form associated with each clinical trial to facilitate putting people in direct contact with Sponsors/lead researchers. 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 email clinicaltrials@cysticfibrosis.org.uk.



Cystic Fibrosis Trust

Contact

Clinical Trials Accelerator Platform team
clinicaltrials@cysticfibrosis.org.uk
020 3795 1536

cysticfibrosis.org.uk

© Cystic Fibrosis Trust 2017. Registered as a charity in England and Wales (1079049) and in Scotland (SC040196). A company limited by guarantee, registered in England and Wales number 3880213. Registered office: 2nd Floor, One Aldgate, London EC3N 1RE.

Cystic
Fibrosis
supported by



Thank you to the Cystic Fibrosis Foundation,
USA for their generous support to this initiative.