

Clinical Trials Accelerator Platform (CTAP)

Application Form

Type of application:

- Funding application review
 - Draft funding application form
 - Draft protocol (if available)
 - Any other supporting information
- CTAP Study Badging
 - Protocol
 - Study synopsis
 - Evidence of independent protocol review (if appropriate)
- Protocol review
 - Trial protocol
 - Study synopsis
 - Evidence of independent protocol review (if appropriate)
- Out of remit study support
 - Study protocol
 - Study synopsis
 - Evidence of independent protocol review (if appropriate)

Introduction

The Clinical Trials Accelerator Platform (CTAP) is a UK-wide initiative bringing together 25 cystic fibrosis (CF) centres from around the UK to support CF clinical trials. CTAP provides the infrastructure to support sponsors with delivery of CF clinical trials, and the platform to enable the CF community to gain timely access to these trials. The network funds a national team of 25 trial coordinators to support CF trial set-up and delivery, alongside providing ~90% of the UK CF population access to clinical trials.

CTAP is governed by the Research Scientific Oversight Board (RSOB), made up of CF clinical experts, CF representatives (people with CF and CF parents), a senior statistician and CTAP trial coordinator representatives. Collectively the Board provides strategic leadership for CTAP in addition to offering a variety of review services, as summarised below.

CTAP works in collaboration with the [European Cystic Fibrosis Society's Clinical Trials Network \(ECFS-CTN\)](#), whose 13 UK based ECFS-CTN centres are also part of the CTAP network. The majority of CTAP supported studies undergo an ECFS-CTN protocol and sanctioning review. Studies which have undergone this review process and which receive ECFS-CTN sanctioning receive automatic CTAP badging status. However, there are some studies which are not appropriate for an ECFS-CTN protocol review, for example some smaller-scale, UK only, academic studies. For these studies, the RSOB is able to provide the following review services assuming the study fulfils the below CTAP study remit:

- a. Interventional clinical trials (medication and non-medication interventions) – commercial and academic
- b. Real-World Evidence (RWE) studies
- c. Non-interventional academic studies which are multi-centred and competitively funded

Types of RSOB review services

NIHR funding application review:

- Studies that fulfil CTAP remit
- Suitable for studies applying for NIHR funding or other competitively available funding
- RSOB will provide feedback on application and can provide a letter of support to support with the funding application if requested.

Protocol review:

- This is a paid service*
- Study fulfils CTAP remit and is not eligible for ECFS-CTN protocol review
- Suitable for studies which have not yet been submitted for regulatory approval
- Detailed feedback will be provided
- Note: a separate CTAP badging review may be required once protocol is finalised

*Commercial studies only

CTAP Badging Review:

- Studies that fulfil CTAP's remit and which are not eligible for ECFS-CTN protocol review and sanctioning
- Includes an abbreviated protocol review but detailed feedback is not routinely provided

- Suitable for studies which have already received an independent protocol review & regulatory approval (pending submissions will be considered)
- Studies awarded CTAP badging will proceed through the CTAP centralised feasibility process to support recruitment centre selection and will be eligible for direct support from the national team of CTAP funded trial coordinators.

Out of remit review:

- Studies which do not fulfil the CTAP remit but are classified as either of national priority or urgency
- Studies considered eligible to receive support will not receive official CTAP badging; studies that meet the criteria will be eligible for short-term support from CTAP trial coordinators (for study recruitment, data and sample collection)

Application form

I. Applicant Details

Sponsor name:	
Sponsor type:	Commercial <input type="checkbox"/> Academic <input type="checkbox"/>
Applicant name:	
Job title: Role within study:	
Contact details:	<i>Insert email</i> <i>Insert telephone number</i> <i>Insert address</i>
Applicant's signature:	
Date application submitted:	

II. Trial/Study Details

Trial funder:	
Trial name (full):	
Trial name (short):	
Trial phase (if applicable)	
Primary outcomes:	
Secondary outcomes: (please list first 3)	1. 2. 3.
Name of intervention (if applicable)	
UK recruitment target:	
No. of UK sites: How many of these UK sites will be CTAP centres? (see webpage here for a list of CTAP centres)	
Patient population	<i>Insert age range</i> <i>Insert mutation (if applicable)</i> <i>Insert other relevant characteristics</i>
Trial status: i.e. Planning / design	

In set-up	
Anticipated start date:	
Anticipated completion date (last patient):	

For 'Funding application review' applications ONLY:

Which NIHR programme do you plan to submit your proposal to?

NIHR programme		Please insert relevant deadline
Programme Grants for Applied Research (PGfAR)	<input type="checkbox"/>	
Efficacy and Mechanism Evaluation (EME)	<input type="checkbox"/>	
Health Technology Assessment (HTA)	<input type="checkbox"/>	
Programme Development Grants	<input type="checkbox"/>	
Health Services and Delivery Research (HS&DR)	<input type="checkbox"/>	
Research for Patient Benefit (RfPB)	<input type="checkbox"/>	
Other (non-NIHR) funding, please specify	<input type="checkbox"/>	

For 'Out of remit study support' applications ONLY:

Please outline why you consider this study to be of national priority or urgency?	
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III. Review and regulatory details

'Funding application review' applications can skip this section

<p>Has the trial undergone an independent protocol / peer review yet?</p> <p>If yes, please state by which committee and submit evidence of this review with your application</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
<p>If the protocol has undergone an independent review, were any major issues flagged?</p>	
<p>Is / will the trial be NIHR adopted?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please add date / anticipated date of adopted:</p> <p>If no, please explain why not:</p>
<p>Has the trial been submitted to the European Cystic Fibrosis</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

<p>Society's Clinical Trials Network (ECFS-CTN) for protocol review?</p> <p><i>If yes, there is no need for a separate CTAP protocol or badging review. All ECFS-CTN reviewed and approved studies receive automatic CTAP badging status</i></p> <p><i>If the ECFS-CTN rejected the trial, please summarise why</i></p> <p><i>If no, or n/a, please provide more details to support your answer</i></p>	<p>N/A <input type="checkbox"/></p>
<p>Has the trial received the following approvals yet?</p>	<p>MHRA Yes <input type="checkbox"/> No <input type="checkbox"/> <i>If yes please record date of approval:</i></p> <p>HRA Yes <input type="checkbox"/> No <input type="checkbox"/> <i>If yes please record date of approval:</i></p>
<p>Are you contracting with a CRO for this trial?</p> <p>If so, please provide name and contact details of the CRO</p>	

IV. CTAP Centre Details

'Funding application review' applications can skip this section

<p>Please list the names of the CTAP centres you anticipate the trial opening at, if known.</p> <p>See webpage here for a list of CTAP centres.</p> <p><i>If applying for CTAP badging status: As part of the conditions of CTAP badging, the study will proceed through the CTAP centralised feasibility process to support centre selection.</i></p>	
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<p>What ways do you envisage the local CTAP Coordinators (based at CTAP centres) supporting the trial?</p> <p><i>For 'out of remit study support' applications, please include estimations on staff time commitments if applicable</i></p>	<p><i>For example, screening, recruitment, data entry</i></p>
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V. Patient & Public Involvement & Engagement (PPI&E)

<p>Please summarise whether you have consulted with patient representatives with regards to the trial design, and in what capacity</p> <p>If you have not utilised any PPI&E groups yet, please explain why</p>	
<p>How do you plan to disseminate the trial results to trial participants and the wider CF community?</p>	
<p>Please highlight which James Lind Alliance priority the trial falls within (you can highlight more than one)</p>	<ol style="list-style-type: none"> 1. What options are available for those not able to take current CFTR modulators (including rarer mutations, not eligible and unable to tolerate)? 2. What is the best way to diagnose lung infection when there is no sputum e.g. children and those on modulators? 3. How can we relieve gastro-intestinal symptoms, such as stomach pain, bloating and nausea? 4. How do we manage an ageing population with CF? 5. Is there a way of reducing the negative effects of antibiotics e.g. resistance risk and adverse symptoms in people with CF? 6. What are the long-term effects of medications (including CFTR modulators) in CF? 7. What are the effects of modulators on systems outside the lungs such as pancreatic function, liver disease, gastrointestinal, bone density etc?

	<p>8. What are the effective ways of simplifying the treatment burden of people with CF?</p> <p>9. Can genetic therapies (such as gene editing, stem cell and mRNA technology) be used as a treatment for CF?</p> <p>10. Is there a way of preventing CF related diabetes (CFRD) in people with CF?</p>
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Please return completed application forms along with all supporting documentation (see above) to CTAP at clinicaltrials@cysticfibrosis.org.uk