

Cystic Fibrosis our focus

NIHR Cystic Fibrosis Themed Call: Application Development Support

At the beginning of October, the NIHR launched a [Themed Call for Cystic Fibrosis](#), inviting cystic fibrosis researchers and clinicians to submit funding applications to six of the NIHR's Programmes:

- Programme Grants for Applied Research (PGfAR)
- Efficacy and Mechanism Evaluation (EME)
- Health Technology Assessment (HTA)
- Programme Development Grants
- Health Services and Delivery Research (HS&DR)
- Research for Patient Benefit (RfPB)

The NIHR have advised the CF research community to come together to produce a small quantity of collaborative, high quality applications to the CF call. To facilitate this, the Cystic Fibrosis Trust has established an Application Development Group, offering to support their development.

Submission of informal applications to the Application Development Group is entirely optional and is not a pre-requisite for submission to the call.

How will the Application Development Group work?

Applicants to one of the NIHR calls may submit an informal application to the Application Development Group. Following an initial triage review, the applications will be forwarded to one of three groups of experts for more detailed consideration, depending on the nature of the application and the type of support requested by the applicants. The Application Development Group will provide feedback to the applicants on ways the application can be strengthened.

The groups that will give a more detailed consideration of the application are as follows:

- UK CF Clinical Trials Accelerator Platform Research Scientific Oversight Board (CTAP RSOB)
- UK CF Medical Association (CFMA) NIHR CF Themed Call Oversight Group
- the NIHR Respiratory Translational Research Collaboration CF National Research Strategy Group (NIHR R-TRC NRSRG)

Process and timelines

- Researchers and clinicians who wish to receive support from the Application Development Group are asked to email informal applications on the template to nihrccall@cysticfibrosis.org.uk.
- The applications will be considered by the next meeting of the triage group, and forwarded on for more detailed consideration.
- Applicants can expect to receive feedback approximately two weeks after the triage group meeting.

The triage group will meet on the following dates:

- 22 October 2020
- 19 November 2020
- 9 December 2020
- 7 January 2021
- 8 February 2021

The Application Development Group

The aims of the Group are to:

- Consider the scope of the proposed research and provide guidance if appropriate
- Provide guidance on the proposed research question, ensuring the anticipated outcomes of the research are of importance to and will benefit people with CF
- Provide guidance on study design
- Consider recruitment of study participants and make recommendations where appropriate
- Identify additional potential collaborators who could add value to an application
- Where possible, ensure a coordinated portfolio of applications which avoids unnecessary duplication and cross-over of applications

Remit

Representatives from the respective groups will initially triage outline applications in order to allocate the application to the most appropriate organisation to perform a more detailed review.

The organisations that may be allocated to perform the more detailed review are:

- UK CF CTAP Research Scientific Oversight Board (RSOB)
- [UK CFMA](#) NIHR CF Themed Call Oversight Group
- NIHR R-TRC CF NRSRG

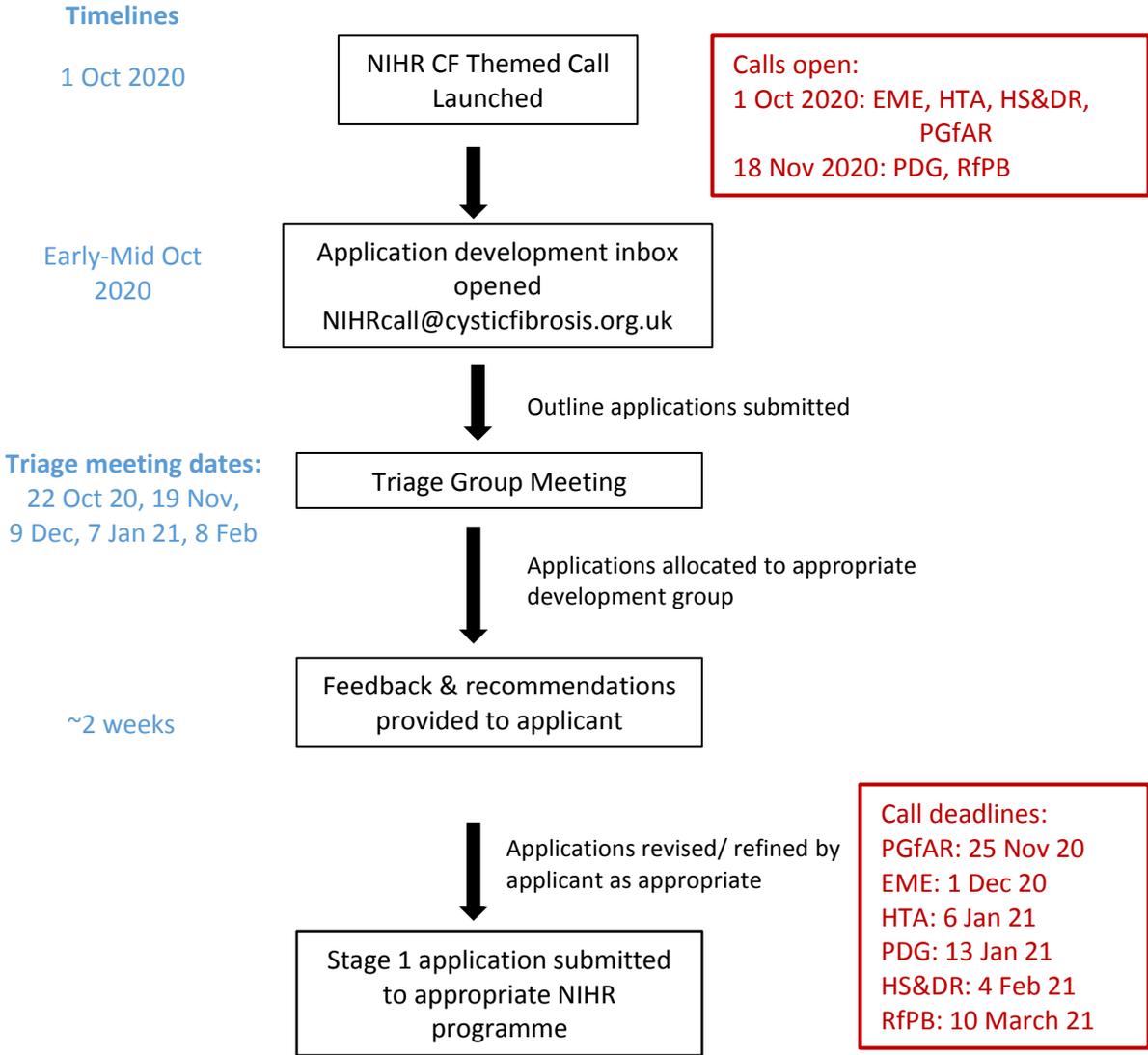
Further details of the remit of the RSOB and NIHR R-TRC CF NRSRG are provided below (Appendix 1).

The following individuals will meet to triage the applications. They will have responsibility for agreeing the allocation of the received applications to the appropriate member organisation for application development support.

Individual	Member Organisation
Alan Smyth	UK CFMA NIHR CF Themed Call Oversight Group
Caroline Elston	UK CFMA NIHR CF Themed Call Oversight Group
Jane Davies	NIHR R-TRC NRSRG & CTAP RSOB
Alex Horsley	NIHR R-TRC NRSRG & CTAP RSOB
Stuart Elborn	CTAP RSOB & UK CFMA NIHR CF Themed Call Oversight Group
Lorna Allen	PPI Lead, CF Trust
Lucy Allen	Director of Research, CF Trust
Keith Brownlee	Director of Medical Affairs, CF Trust

Nour Merzouki, NIHR R-TRC Operations Manager; Rebecca Brendell, Head of CTAP and Paula Sommer, Head of Research, at the Cystic Fibrosis Trust will also be invited to join these meetings.

Flow chart of the process



Appendix 1: NIHR CF Themed Call Application Development Group Member Organisations

UK CF CTAP Research Scientific Oversight Board (RSOB)

The RSOB is made up of CF clinical experts, CF representatives (people with CF and CF parents), a Senior Statistician and CTAP Trial Coordinator representatives. The Board is responsible for governing the CTAP programme, providing strategic leadership, completing protocol reviews and awarding clinical trials with CTAP badging status. Trials awarded CTAP badging status will be eligible for direct and regular support from the 20 CTAP funded Trial Coordinators based at CTAP Centres. The CTAP RSOB offers a Protocol Review and CTAP badging service to sponsors, complimenting the ECFS-CTNs globally renowned protocol review and adoption service and does not compete with this service.

The strategic objectives of the CTAP RSOB are:

- To prioritise interventional clinical trials (medication and non-medication interventions) and Real-World Evidence (RWE) studies which are scientifically sound and of relevance / importance to the UK CF community
- To prioritise trials which are likely to directly impact quality of life and ease the treatment burden
- To make evidence-based decisions when reviewing trials for CTAP badging, where possible based on the outcomes of the 2017 James Lind Alliance Priority Setting Partnership outlining the CF communities research priorities

Usually the RSOB only reviews protocols for trials which are already funded. However, in order to support the NIHR CF Themed Call the RSOB have agreed to extend the protocol review service to trials which are pre-funded.

As part of the application review, the RSOB will assess whether it is likely that CTAP badging status would be awarded, if the trial were successful in being funded. If the RSOB agree that CTAP Badging is likely, a letter of support for the trial will be provided from the RSOB which can be used to support your NIHR funding application.

NIHR R-TRC CF National Research Strategy Group

The NIHR Respiratory Translational Research Collaboration (R-TRC) brings together internationally recognised investigators in the UK's leading centres of excellence to carry out multi-centre experimental and early phase research with industry, charities and other funders. The R-TRC has a renewed and refreshed strategy since 2017 to move beyond industry-centric studies to large collaborative multi-centre research projects.

To help deliver this, the TRC has created a number of nation-wide research strategy groups across a number of priority respiratory disease areas, such as CF. The CF national research strategy groups aim to:

- To identify the key research priorities and/or barriers which would require a collaborative approach to overcome and accelerate research for the benefit of patients
- Develop and help deliver multi-site translational research projects/ activities which cannot be performed by one centre
- Work with external funders, including commercial organisations, specialist societies and charities, to identify appropriate funding opportunities that will enable the delivery of these priority research activities
- Support the alignment of research activities across the UK's research landscape order to maximise on existing or leveraged investments and add value to complementary initiatives