

Efficacy and Mechanism Evaluation Programme

Efficacy and Mechanism Evaluation Programme Commissioning Brief

Call for proposals in disorders of fibrosis

Applications are sought for clinical studies which aim to establish the clinical efficacy of novel interventions or tests and their potential to diagnose, investigate or slow the progression of organ specific fibrosis.

For the purpose of this call fibrosis includes all organ specific fibrotic disease where there is an excess in formation of fibrous connective tissue. However, the formation of superficial surgical scarring is excluded from this call.

Whilst the main part of an application should be focused on a clinical efficacy study applicants are also encouraged to consider opportunities for the evaluation of mechanisms. Mechanistic aspects of a proposal should focus on developing our understanding of the intervention or disease and be embedded within the main efficacy study.

Proposals must focus on a clinical study which is within the remit of the EME Programme (www.eme.ac.uk/about/commissioned_remit.asp). Applicants must make it explicit in their application how their proposed research meets the EME remit. Applications to this call may also include initial stages such as:

- the limited steps needed to progress the development of an intervention to a stage suitable for use in an accredited clinical service
- prospective clinical work or retrospective research utilising existing clinical samples or data to inform the main study
- pilot or feasibility studies

As a rough guide it is expected that these early stages will be complete within the first 18 months of the project and contribute no more than 25% to the total cost of the project. The remaining costs should be for the main efficacy study which must be clearly specified within the application.

Applicants will need to make a strong case for the future importance of the technology through providing a measurable positive impact on health, innovation or future wealth creation and for the ultimate benefit of individual patients' or the wider NHS.

Applicants may choose to complete a voluntary Expression of Interest, (close date 19th October). Feedback will be provided prior to completing an outline proposal (call opens in December 2012). Projects must have a strong collaborative approach; the EME Programme is particularly keen to encourage collaboration with small and medium enterprises. Funding must be activated within 9 months of a decision being made.

Guidance on applications

Proposed study design

Applications to the EME commissioned work stream must be within the remit of the EME Programme and meet the specification detailed in the commissioning brief. In particular proposals must evaluate the clinical efficacy of an intervention and may also add significantly to our understanding of biological or behavioural mechanisms and processes. The EME Programme will not support confirmatory studies or trials of incremental modifications, 'confidence in effect' studies or refinements to existing medical interventions.

Applications are expected to set out programmes of work which contain distinct stages. It is expected that the early stages of the study will, if successful, lead onto a full evaluative clinical study or trial, which must also be included and clearly specified within the application. Any clinical trials embedded within a programme of work should be large enough to detect a meaningful effect.

Study start-up

Applicants should ensure that they are in a position to start their proposed research rapidly and expenditure and funding must be activated within 9 months of a decision being made. Funding decisions will be communicated during October 2013.

Collaboration

Applications to the EME commissioned work stream should be in the form of a significant collaboration. All applications should include significant contributions from at least two of the following partners; industry, academia, and the NHS. Evidence of this collaboration must be provided and a draft collaboration agreement will be required at the full proposal stage. The involvement of charities is also welcome.

Applicant eligibility

The EME commissioned work stream welcomes applications from researchers in England, Scotland, Wales and Northern Ireland.

Team expertise

Proposals should demonstrate a multi-disciplinary team with appropriate skills and experience, including an appropriately experienced statistician on the trial team. The involvement of an accredited Clinical Trials Unit (CTU) is strongly encouraged in the design of clinical trials. Where appropriate, applicants are expected to work with suitably accredited clinical research facilities.

Monitoring of studies

Projects funded through the EME commissioned work stream should be organised into distinct stages (usually up to three). At the end of each stage there should be clearly delineated go/no-go decision points with measurable criteria which will allow an assessment of whether the stage has completed successfully. The purpose of this delineation is to clearly identify critical points that determine whether the research should proceed to the next stage. It is anticipated that there will be a significant number of projects that will fail to meet criteria in the early stages. The EME Programme retains the right to reassess project progress in light of other new developments in the research area before subsequent stages of funding are released.

Within each stage it is expected that there will be a number of milestones which will allow the project team and EME Programme to track progress through routine project reporting.

Project management

Applicants will need to demonstrate a clear management plan for all stages of the project as well as detailed plans for how they will actively manage individual stages.

Timescale

There are no fixed limits on the duration of projects and proposals should be tailored to fully address the questions posed. However, it is anticipated that the early stages of a project will be completed within the first 18 months.

Funding

Applicants should be aware that they are competing for limited funds and proposals should represent good value for money. All funding requested should be clearly justified. It is anticipated that the typical cost for an EME commissioned project will be in the range of £0.5-2million. However, there is no upper limit.

Public Involvement

Patient and public involvement (PPI) in study design, implementation and dissemination of results is important to the EME Programme. Evidence of PPI will be sought within applications, and patient representation is expected on management and steering committees. Comments from public and patient reviewers will be obtained during peer review and at the EME Board. For further guidance please see the EME website (www.eme.ac.uk/resources/involve.asp).

Research Networks

The EME Programme expects that applicants will work, where appropriate, with the relevant NIHR Clinical Research Network (www.crncc.nihr.ac.uk/).

Governance and Regulation

Applicants are asked to:

1. Follow the Medical Research Council's Good Clinical Practice guidelines (www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416) in planning how studies, particularly RCTs, will be supervised.
2. Note that trials involving medicinal products must comply with 'The Medicines for Human Use (Clinical Trials) Regulations 2004'. In the case of such trials, the NIHR expects the employing institution of the chief investigator to be nominated as the sponsor. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The NIHR is prepared to accept the nomination of multiple sponsors. Applicants who are asked to submit a full proposal will need to obtain confirmation of a sponsor(s) to complete their application. The NIHR reserves the right to withdraw from funding the project if they are not satisfied with the arrangements put in place to conduct the trial.

The MHRA (info@mhra.gsi.gov.uk, www.mhra.gov.uk) can provide guidance as to whether your trial would be covered by the regulations. The Department of Health/MRC website (www.ct-toolkit.ac.uk) also contains the latest information about Clinical Trials regulations and a helpful FAQ page.

Making an application

If you wish to submit a voluntary expression of interest in response to this commissioning brief please complete and submit the web based voluntary Expression of Interest form (www.eme.ac.uk/funding/Commissioning.asp) by 1pm on 19 October 2012 (further details are in the guidance for applicants). Applicants submitting an Expression of Interest will be provided with feedback prior to the formal opening of the call for outline proposals in December 2012.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: <http://transparency.number10.gov.uk/#>