Efficacy and Mechanism Evaluation Programme

Call for research proposals (15/180 Researcher- Led)

Detailed call specification

Applications are sought for research into interventions that are based or used by the NHS and its partners. This document provides the detailed call specification for applications to the EME researcher-led workstream. Applicants should note:

- applications should focus on establishing efficacy of an intervention;
- proof of concept in humans for the intervention already needs to be established and should be clearly demonstrated in the application;
- applications may include embedded mechanistic evaluations, however, stand-alone mechanistic studies are excluded from this call;
- applications may investigate novel or repurposed interventions and tests;
- the discovery of new biomarkers is excluded from this call;
- studies involving incremental or minor improvements to existing technologies are excluded from this call.

Applications are expected to set out programmes of work which may 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 is in the remit of the EME Programme. This study must also be included and clearly specified within the application. Clinical trials embedded within the programme of work must be large enough to detect a meaningful effect.

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 must not contribute more than 25% to the total cost or duration of the project.

Applicants will need to make a strong case for the future importance of the intervention 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.

Programme remit

The remit of the EME programme includes clinical trials and evaluative studies of novel and repurposed interventions. The term intervention is meant in the broadest sense and includes any method used to promote health, prevent and treat disease and improve rehabilitation or long-term care. "Technologies" in

The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D Division, Public Health Agency in Northern Ireland. It is managed by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) based at the University of Southampton.

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this context are not confined to new drugs but include procedures, devices, tests, settings of care, screening programmes and any intervention used in the treatment, prevention or diagnosis of disease. We support studies in patients which seek to:

- evaluate clinical efficacy of interventions where there is already evidence to support the use of the intervention in humans;
- add significantly to our understanding of biological or behavioural processes;
- explore new scientific principles;
- include the development or testing of new methodologies;

The EME Programme WILL support:

- research which seeks to determine definitive proof of clinical efficacy and size of effect, safety and possibly effectiveness;
- studies that use validated surrogate markers as indicators of health outcome;
- laboratory based, or similar, studies that are embedded within the main study, if relevant to the remit of the EME Programme;
- pilot and feasibility studies where the later main study would be within the remit of the EME programme

The EME Programme WILL NOT support:

- confirmatory studies or trials of incremental modifications and refinements to existing medical interventions;
- proof-of-concept, proof-of-mechanism in humans, nor 'confidence in effect' studies;
- research into 'global health', where 'global health' can be defined as 'areas where the health need is identified in developing countries (i.e. including diseases of developing countries), or where the health need does not yet exist in the UK but might in the future and the problem can be best addressed in developing countries;
- research involving animals.

Guidance on Applications

Applicant eligibility

Researchers in England, Northern Ireland, Scotland and Wales are eligible to apply for funding under this Programme. Anyone who considers that they can carry out high-quality research is likely to be eligible. If you have any concerns regarding your eligibility to apply we advise that you contact us before completing an application. We welcome applications from all sectors and recommend that lead applicants from Industry contact the EME office prior to submitting an application.

Studies funded by the EME Programme are generally UK based. We will consider funding an international study where the chief investigator and lead institution are based in the UK and the study is relevant to and a priority for the UK population, and where overseas recruitment is funded from other sources. It will be exceptional for NIHR programmes to fund recruitment overseas. The EME Programme is open to bids to support a UK recruitment arm of an international study where the study is relevant to and a priority for the UK population; a UK based principal investigator should be the lead applicant. Each project will be considered on a case by case basis and applicants interested in submitting a proposal for an international study should contact us for advice.

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Collaboration and team expertise

The EME researcher-led workstream welcomes applications proposing joint funding arrangements or collaboration with other organisations. The EME Board requires you to clearly explain how the

arrangement would work in practice and to be explicit about where responsibility lies contractually in terms of publication, and research governance issues. The EME researcher-led workstream will support studies involving partnerships with industry where these are for public benefit, and are not for the exclusive benefit of the industry partner. Where your research proposal involves industry collaboration, you should ensure the arrangements and details are determined early in the study development, and a draft collaboration agreement must be provided at the full proposal stage.

Proposals should demonstrate a multi-disciplinary team with appropriate skills and experience, including an appropriately experienced statistician on the study 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.

It is acceptable to have applicants from outside the UK and EME research may be conducted outside the UK where this is the best means of meeting a research requirement relevant to healthcare in the UK. The rationale for such an application should be clearly set out and each case will be judged on its merits.

Timescales and funding

There are no fixed limits on the duration of projects and proposals should be tailored to fully address the questions posed. 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, but there is no upper limit.

Project Management and monitoring of studies

Projects funded through the EME researcher-led workstream will be expected to provide detailed project timetable including milestones to represent specific steps towards achieving the stated research objectives. Milestones should include a defined start and end date, be measurable, concise and realistic as they will be used for project monitoring purposes. The precise type and number of milestones will depend on the size and nature of the project. If your application is successful, you will be required to submit progress reports against which relevant milestones will be checked. These progress reports will be based on the project timetable and milestones, and will occur at approximately six month intervals.

Public Involvement

The EME Programme expects Patient and public involvement (PPI) in study design, implementation and dissemination of results. Applications must demonstrate how patients or members of the public have been involved in the study design and how they will be involved in the conduct and management of a trial. Patient/public/carer representation is required 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.

Research Networks

The EME Programme expects that applicants will work, where appropriate, with the relevant NIHR Clinical Research Network.

Governance and Regulation

Applicants should follow the Medical Research Council's Good Clinical Practice guidelines in planning how studies, particularly RCTs, will be supervised.

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) can provide guidance as to whether your trial would be covered by the regulations. The Department of Health/MRC website also contains the latest information about Clinical Trials regulations and a helpful FAQ page.

Application Assessment Process and Criteria for Assessment

For information about the Application Assessment Process and Criteria for Assessment, please see http://www.nets.nihr.ac.uk/programmes/eme/application-process

Additional Resources for Applicants

For additional resources to support the development of your applications, please see http://www.nets.nihr.ac.uk/funding/eme-researcher-led

Making an application

If you wish to submit an outline proposal please complete the web based application form.

Further Information

Further information on applying to the EME programme is available from the Frequently Asked Questions (FAQs) section on the EME website http://www.nets.nihr.ac.uk/faqs

The EME team welcomes enquiries at info@eme.ac.uk or 02380 594303

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public.