

Efficacy and Mechanism Evaluation Programme

Call for research proposals (14/150 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.

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 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;

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- 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. For applicants to the MRC-funded EME researcher-led workstream, Research Councils UK eligibility rules apply. You should visit <http://www.nets.nihr.ac.uk/funding/eme-researcher-led> for further information on this requirement.

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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/carers 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 (link to web)

Additional Resources for Applicants

For additional resources to support the development of your applications, please see (link to web).

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.