Efficacy and Mechanism Evaluation Programme

RESEARCH BRIEF

Researcher Led Outline Applications (13/94)

Remit

The EME programme aims to support excellent clinical science with an ultimate view to improving health or patient care. Its remit includes clinical trials and evaluative studies - in patients - which:

- evaluate clinical efficacy of interventions (where proof of concept in humans has already been achieved);
- add significantly to our understanding of biological or behavioural mechanisms and processes;
- explore new scientific or clinical 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.

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.

The EME programme will support research proposals which are important to healthcare, from researchers based across the UK.

Applications to the EME Programme

Outline applications which are considered to be outside of the EME programme remit, non-competitive for funding or for which the application form has been incorrectly completed, will be rejected without further consideration. Applicants whose proposals are shortlisted by the EME Board will be invited to develop their outline applications into full proposals for a subsequent meeting.

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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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 (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.

Criteria for Assessment

In its assessment of applications, the EME Board is likely to use the following criteria:

1. *Scientific quality of the proposal including:*

a) What is the likelihood of a study making a substantial advance in scientific understanding and knowledge?
b) What is the likelihood of the study leading to a substantial health gain?
c) What is the likelihood of the study increasing our understanding of the broader topic area?

2. *Feasibility of the study*

a) Demonstration of the necessary skill mix, experience, project management and infrastructure for success
High quality clinical and evaluative studies need a multi-disciplinary team. Applicants need to show a commitment to team working and may wish to consider a collaborative approach between several institutions. The EME programme recommends applicants to engage an experienced trial manager for appropriate projects. It is important to involve service users.

b) *Explanation and justification for estimated recruitment rates.*
The EME programme wants studies to achieve their aims. Researchers should demonstrate that they can recruit the necessary number of participants.

c) *Ethical, legal and social implications of the research proposed have been considered.*

3. *Reasonable costs and value for money.*

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem.

Further Information

Further information on applying to the EME programme is available from the Frequently Asked Questions (FAQs) section on the EME website (www.eme.ac.uk). Please email any queries to info@eme.ac.uk