Efficacy and Mechanism Evaluation Programme

Call for proposals into passive and bioactive implantable medical devices

Proposals are sought for studies into the clinical efficacy of passive[1] and bioactive[2] implantable medical devices. Studies may investigate new, repurposed or existing devices and embedded mechanistic studies are encouraged. The emphasis of this call is on non-cardiac devices.

Proposals should have the potential to contribute work of significant benefit to the clinical management of patients.

Studies of incremental or minor improvements to existing technologies or discovery of new biomarkers are not within the remit of the EME Programme.

Proposals to this call may contain a series of linked stages (usually 2 to 3), with progression to the main clinical evaluation dependent on the outcome of the previous stage(s). Researchers who wish to submit such a programme of work must make the progression criteria clear. Early stages may include:

- 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.

The main stage must be a clinical evaluation that is within the remit of the EME Programme. It is expected that this stage will require more than 75% of the total project cost and commence within 18 months of the project start date. Any clinical trial included must be large enough to detect a meaningful effect.

Projects must have a strong collaborative approach; the EME Programme is particularly keen to encourage collaboration with small and medium enterprises.

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.

[1] A call for proposals into active implantable medical devices (as described in the Directive (AIMD 90/385/EEC as amended by 2007/47/EC)) has previously been advertised through the EME Programme. For further information please see the EME Programme.

[2] For the purpose of this brief, bioactive implantable medical devices refers to a category of implantable medical devices that unites the structural and mechanical functionality of device implants with the bioactivity and specificity of often novel therapeutic biologic agents across a wide range of clinical disciplines. They are excluded from the Medical Devices Directive and covered by the Medicines Directive 2001/83/EC.

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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Important Information for Applicants to this call

Programme remit

We support studies in patients which seek to:

- 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;
- pilot and feasibility studies where the later main study would be within the remit of the EME Programme (NETSCC Glossary).

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.

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.

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.

Collaboration and team expertise

Proposals should involve 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.

Applications to this call should be in the form of a collaboration. All applications should include significant contributions from at least two of the following partners; industry, academia, and the NHS. The EME Programme is particularly keen to encourage collaboration with small and medium enterprises. The involvement of charities is also welcome. Evidence of this collaboration must be provided and a draft collaboration agreement will be required at the full proposal stage.

The EME Programme welcomes applications proposing joint funding arrangements. You must clearly demonstrate how the arrangement would work in practice and be explicit about where responsibility lies contractually in terms of publication, and research governance issues for example. We expect that any other organisations contributing funding would provide an 'open grant' and not require any terms, conditions or limitations on the research. The Programme would require assurance that the funding contribution would be guaranteed for the duration of the research, and a letter of intent should be included with the application. If your application is successful, you should note that the EME Programme will require sight of the agreement between you and any other funding partners before any contract is issued.

Where your research proposal involves industry collaboration, you should ensure that the arrangements and details are determined early in the study development. The EME Programme will require assurance that any industry collaboration allows transparency in the project design and in the analysis and publication of results (including if these are negative). If the collaboration involves the supply of reagents, drugs or other technologies, we will require written assurances that the industry collaborator will provide these products for the duration of the study.

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.

Public Involvement

The EME Programme expects patient and public involvement 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 the trial. Patient, public or 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 Programme.

Project Management and monitoring of studies

Where appropriate, projects funded through this call 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. 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.

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 the application process.

Additional Resources for Applicants

For additional resources to support the development of your applications, please see resources.

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 Programme website. 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.