

Efficacy and Mechanism Evaluation Programme

**Call for proposals for research into diseases of
the skin**

Applications are sought for research into interventions used in the prevention, diagnosis or treatment of skin disease.

Applications should concentrate on determining the efficacy of interventions, and may also include the evaluation of mechanisms. The management and treatment of wound healing, infections, and metastatic skin cancers are excluded from this call.

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

Applications may investigate novel or repurposed interventions and technologies. Studies of incremental or minor improvements to existing technologies or discovery of new biomarkers are not within the remit of the EME programme. Applications must concentrate on determining the efficacy of interventions, and may also include the evaluation of mechanisms.

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 approximately 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.

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.

Programme remit

Proposals must focus on a clinical study which is within the remit of the [EME Programme](#). Applicants must make it explicit in their application how their proposed research meets the EME remit. The remit of the EME commissioned workstream includes clinical trials and evaluative studies in patients, which:

- evaluate clinical efficacy of interventions;
- add significantly to our understanding of biological or behavioural mechanisms and processes;
- explore new scientific or clinical principles;

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.

- include the development or testing of new methodologies.

The EME commissioned workstream supports:

- 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.

Guidance on applications

Proposed study design

Applications to the EME commissioned workstream 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 March or July 2014 depending on whether applications are received to the first or second close date (further details below).

Collaboration

Applications to the EME commissioned workstream 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

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. NETS programmes (with the exception of the EME programme researcher-led workstream*) welcome applications which are within the programmes' remits from all sectors. Applicants are strongly advised to consider establishing partnerships with other relevant sectors or organisations to demonstrate they have the full breadth of expertise to carry out their proposed research in their applications to NETS programmes. Applicants should always check individual call specification documents for any additional eligibility requirements.

*For anyone considering applying to the MRC-funded EME researcher-led workstream, Research Councils UK eligibility rules apply. You should visit www.rcuk.ac.uk/research/eligibility for further information on this requirement.

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Team expertise

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.

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/public/carer 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](#).

Monitoring of studies

Projects funded through the EME commissioned workstream 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.

Research Networks

The EME Programme expects that applicants will work, where appropriate, with the relevant [NIHR Clinical Research Network](#).

Governance and Regulation

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.

Making an application

If you wish to submit an outline proposal in response to this commissioning brief please complete the [web based application form](#). This call will have two close dates (further details in the guidance for applicants):

- 1pm on 3rd June 2013
- 1pm on 1st October 2013

The EME Programme will undertake initial checks on all outline proposals submitted to ensure that they are within the Programme remit and meet the specification of the commissioning brief and are therefore eligible for consideration. Applications which do not fulfil this criterion will be rejected at this stage.

Applications which are within remit will be reviewed and prioritised by the EME Prioritisation Group prior to assessment by the Board.

Outline proposals will be assessed by the EME Board in October 2013 or February 2014 depending on the close date. Shortlisted applicants will have approximately eight weeks to submit a full proposal.

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