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EME 21/545 - Efficacy and Mechanism Evaluation Programme - researcher-led

 Published: 11/08/2021  Read Time: 6 minutes  Version: 1.6 July 2021
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Call for research proposals (21/545 Researcher-led)

Closing date: 7 December 2021 (two stage – Stage 1 to Stage 2)

Stage 1 applications submitted to the Researcher Led call close on the 7 December 2021 assessed as in remit and competitive will be considered for shortlisting at the EME Funding Committee meeting in March 2022. If shortlisted, applicants will be invited to submit a Stage 2 application for consideration at the EME Funding Committee meeting in July 2022. We anticipate informing applicants of the outcome within a month of the meeting and that contracts will be signed within approximately 9 months after the date of the outcome letter, although this is project dependent.

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.

Applications are expected to set out programmes of work which may contain distinct stages. It is expected that the

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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 big data or clinical samples 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. Applicants should read the details of the [EME remit](#).

Important information for applicants

Programme remit

The EME Programme funds ambitious studies evaluating interventions that have the potential to make a step-change in the promotion of health, treatment of disease and improvement of rehabilitation or long-term care. Within these studies EME supports research to improve the understanding of the mechanisms of both diseases and treatments.

The programme supports translational research evaluating a wide range of novel or re-purposed interventions. The interventions may include diagnostic or prognostic tests and decision-making tools, drugs or biological compounds, psychological treatments, medical devices, and public health initiatives delivered within the NHS.

The EME Programme primarily supports clinical trials, and other robustly designed studies that test the efficacy of interventions. The interventions should have the potential

...ive patient care or benefit the public. The programme will only support studies where there is sufficient evidence that the intervention might work in man, i.e. that there is '[proof of concept](#)'.

Innovative study designs involving stratification, the use of routinely collected digital data or novel methodologies are strongly encouraged.

Where appropriate, the programme encourages [hypothesis-testing mechanistic studies](#) integrated within the main efficacy study. These studies could explore the mechanisms of action of the intervention, the causes of differing responses, or promote an understanding of any potential adverse effects and how these could be reduced; they could also contribute to understanding of the disease. The programme will also support stand alone mechanistic studies which can use data or samples from ongoing or completed clinical studies funded by the NIHR, or completed non-NIHR funded studies that have been subject to external peer review via the Mechanisms of Action of Health Interventions Call. Please see the [EME Funding Opportunities](#) page for more information about this call.

The programme will accept applications for studies that use clinical or well-validated surrogate outcomes. It will also consider studies that validate potential surrogate outcomes against a primary clinical outcome, within the main clinical trial.

The EME Programme will support

- Research to determine proof of clinical efficacy, size of effect, and long-term safety in a well-defined population.
- The evaluation of a broad range of interventions that have the potential to maintain health, treat disease or improve recovery.
- Hypothesis-testing research based on an efficacy study, to explore the mechanisms of action of interventions, causes of differing responses or disease mechanisms. These studies use data or samples obtained and stored from both treatment and control groups of a clinical study, to arrive at conclusions that would not arise from a simple cohort study.
- Proposals that include 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). The criteria for progression must be clearly defined. The main clinical evaluation should require more than 75% of the total project costs and commence within 18 months of the project start date.

- Pilot and feasibility studies where the main study would be within the remit of the EME programme. These studies may be either stand-alone or can be the initial part of a staged project that includes the main clinical evaluation as a subsequent stage.
- The limited steps needed to progress the development of an intervention to a stage suitable for use in an accredited clinical service when included as an initial stage prior to commencing the main clinical evaluation.
- Studies using novel or infrequently-used study designs that increase the value of a study, by maximising the chances of demonstrating the benefit of an intervention, increasing the knowledge that can be gained through the study, or by making the study more efficient.
- The EME Programme welcomes studies adopting novel and efficient study designs or that include the development or testing of new methodologies in an embedded methodological study (EMS). Where delivery of the EMS is integral to the main efficacy trial the additional costs should be modest and the purpose should be to explore issues that may potentially increase the efficiency of trials and value for money. The proposed work should be included in the EME application. Where the EMS requires more substantial funding and can be delivered independently from the running of the main trial, then applicants might wish to consider applying to the [MRC-NIHR Methodology Research Programme](#) (MRP). Any such application would be independent of the application to the EME Programme. For more information please contact the MRP programme: MRPGrants@headoffice.mrc.ac.uk

The NIHR programmes currently have a highlight notice for Brain Tumours. This highlight notice indicates the continuing interest of NIHR in receiving research proposals in this area, and it encourages collaborative applications that demonstrate how they build on recent initiatives and investment in the area made by the NIHR, the MRC and other research funders.

For details of this highlight notice, please see our [themed calls pages](#). Please note that the EME researcher led call is open to all relevant research areas, and does not just include these highlight notices. If you are responding to the highlight notices, please indicate this in the application form in Section 6, Question 1 'What is the problem being addressed?'

The EME Programme will not support

- Large effectiveness studies that test the impact of the introduction of an intervention in the wider NHS.
- Hypothesis-generating studies based on sample or data collections from patient cohorts.
- Confirmatory studies, equivalence studies, 'confidence in effect' studies or studies of incremental modifications to existing interventions.
- Research into areas where the health need is primarily outside the UK.
- Any research involving animals or animal tissues (see the NIHR research page for more information).

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