Efficacy and Mechanism Evaluation (EME) Programme Commissioning Brief

Call for proposals for research on Point of Care Tests

Applications are sought for studies of point of care tests* for early detection, diagnosis or monitoring (including response to treatment) of disease. The development stage should include sufficient analytical validation to ensure that any point of care test under development is an accurate and reproducible as existing tests, including internal and external quality assurance (a direct comparison). We would particularly welcome applications for research in areas of high disease burden.

Applications should have the potential to contribute work of significant clinical advantage to the diagnosis, treatment, monitoring or clinical management of patients. Incremental improvements to existing technologies are not within the remit of the EME programme.

The majority of the funding requested should be for the main evaluative clinical study. However, work funded as part of this call may include the limited steps needed to progress from early human studies to a stage suitable for use in an accredited clinical service, i.e. clinical validation. The initial stages of a project may include prospective clinical work or retrospective research utilising existing clinical data and these findings should be used to inform the main study.

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.

Applications should be made using the preliminary application form. 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.

Guidance on applications

Proposed study design

Applications to the EME commissioned work stream must be within the remit of the EME programme and meet the specification detailed in the commissioning brief. Applications are expected to set out programmes of work which contain distinct stages. Early stages may include late development of an intervention, proof of concept studies or feasibility and pilot studies. It is

*Definition of Point of care test:
An analytical test undertaken by a member of the healthcare team or non-medical individual in setting which is distinct from the normal hospital laboratory.
A point of care test may include:

- Non-instrumental systems, disposable systems or devices that vary from reagent test strips for a single analyte to sophisticated multi-analyte reagent strips incorporating procedure controls.
- Small analysers: usually hand-held devices but size dies vary considerably.
- Desktop analysers: these are larger devices and usually include systems designed for use in clinics

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NETSCC, Efficacy and Mechanism Evaluation

Alpha House, University of Southampton Science Park
Southampton SO16 7NS

tel: +44(0)23 8059 4303
fax: +44(0)23 8059 5639
email: info@eme.ac.uk

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 and must be specified within the application.

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 October 2012.

Collaboration
Applications to the EME commissioned work stream 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 and provide evidence of this collaboration. A draft collaboration agreement will be required at the full proposal stage. The involvement of charities is also welcome.

Applicant eligibility
The EME commissioned work stream welcomes applications from researchers in England, Scotland, Wales and Northern Ireland.

Team expertise
Proposals should demonstrate a multi-disciplinary team with appropriate skills and experience, including an appropriately experienced statistician on the trial 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.

Monitoring of studies
Projects funded through the EME commissioned work stream should be organised into distinct stages (usually between one and three). At the end of each stage there should be clearly delineated go/no-go decision point 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 NETSCC, EME 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.

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 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.

Research Networks

The EME programme expects that applicants will work, where appropriate, with the relevant NIHR Clinical Research Network (http://www.crncc.nihr.ac.uk/).

Governance and Regulation
Applicants are asked to:

1. Follow the Medical Research Council's Good Clinical Practice guidelines (http://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 (info@mhra.gsi.gov.uk, 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.

Making an application
If you wish to submit a preliminary application in response to this commissioning brief please complete the web based application form (www.eme.ac.uk/funding/Commissioning.asp) and submit it by **1pm on Monday 13 February 2012** (further details in the guidance for applicants).

The secretariat, in consultation with the Programme Director and Chair of the Board, will undertake initial checks on all preliminary applications 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 also be assessed on priority for the NHS, overall quality and the likelihood of meeting the fundable criteria when assessed by the EME Board. Applications which are not considered to be competitive for funding will be rejected at this stage.

Preliminary applications will be assessed by the EME Board in June 2012. 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. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#