EME Diagnostics for stratified medicine commissioning brief

Brief

Applications are sought for studies in the field of stratified medicine* that focus on the development, understanding or use of diagnostic or predictive tests or algorithms. Research may investigate any type of technology, used individually or as a potential companion diagnostic.

Any developmental work should be focussed around the final stages that are required to render the diagnostic suitable for use in an accredited clinical service. The outcome of developmental work should be used to inform the main evaluative study, which should form the majority of the funding requested.

Applications should have the potential to contribute work of significant clinical advantage to the diagnosis, treatment, monitoring or clinical management of patients.

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. Studies that focus on avoiding the use or the cessation of treatments of less benefit to certain groups of patients or individuals are within remit.

Research in any disease area is eligible for consideration although applications are particularly welcomed for those conditions that represent a considerable burden of disease in England.
Applications should be made using the expressions of interest (EoI) form. Projects must have a strong collaborative approach and funding must be activated within 12 months of a decision being made.

Guidance on applications

Proposed study design

Applications to the EME commissioned workstream are expected to set out programmes of work which contain distinct stages. Early stages may include feasibility and pilot studies and their inclusion should be fully justified. If successful there should be a clear plan detailing how they will lead to a full evaluative study which may or may not be included in 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 should commence in 2012/2013. Funding decisions will be communicated during February 2012.

***Stratified medicine definition**

For the purpose of this call stratified medicine describes an approach to patient management through the identification of key subgroups of patients with shared biological characteristics, distinct mechanisms of disease or particular responses to treatment. Stratification may be based on molecular, biochemical or diagnostic imaging and testing. It allows targeting of treatments to specific disease pathways and the identification of treatments that are effective for particular groups of patients to ensure that the right patient gets the right treatment at the right time.

The Efficacy and Mechanism Evaluation programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D, 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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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 and provide evidence of this collaboration. A collaborative agreement will be required at the full proposal stage. The involvement of charities is also welcome.

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.

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 each stage of the project.

Monitoring of studies
Research funded through the EME commissioned workstream will be milestone driven and monitored. There should be clear measurable criteria for success at each milestone. These criteria must be met if a study is to progress and funding for the next stage of work to be released. The EME programme retains the right to reassess project progress in terms of value for money or likely impact of research before subsequent stages of funding are released. Decisions on whether to allow projects to progress to subsequent milestones may be made on a competitive basis.

Applicant eligibility
The EME commissioned workstream welcomes applications from researchers in England, Scotland, Wales and Northern Ireland as it is funded by the NIHR with contributions from the CSO in Scotland, NISCHR in Wales and the HSC R&D, Public Health Agency in Northern Ireland.

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 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 an EoI in response to this commissioning brief please complete the online form at (www.eme.ac.uk/funding/Commissioning.asp) and submit it via email by 1p.m. on 27 July 2011 (further details in the guidance for applicants).

The secretariat, in consultation with the Programme Director and Chairman of the Board, will undertake initial checks on all EoIs submitted to ensure that they are within the programme remit and meet the specification of the commissioning brief and are therefore eligible for consideration. EoIs which do not fulfil this criterion will be rejected at this stage.

EoIs which are within remit will also be assessed on overall quality and the likelihood of meeting the fundable criteria when assessed by the EME Board. EoIs which are not considered to be competitive or meet the criteria for funding will be rejected at this stage.

We will expect to be able inform applicants of whether or not their EoI has been shortlisted by the end of August. Shortlisted applicants will have approximately eight weeks to submit a full proposal along with a collaborative agreement.

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/#