Joint Global Health Trials – Call 8

The UK Department for International Development (DFID), the National Institute for Health Research (NIHR) the UK Medical Research Council (MRC), and the Wellcome Trust are pleased to announce the launch of the eighth call for proposals under this initiative to fund global health trials.

Background

DFID, MRC and the Wellcome Trust each have a strong history of supporting research that aims to improve health in low and middle income countries. The NIHR is now also joining as a partner, under Overseas Development Assistance (ODA) funding. The four partner agencies share the view that in order to have maximum impact on health we need to work together to provide evidence of the best, and most appropriate interventions to improve health in LMIC settings. Pooling resources brings the necessary funds and experience together to achieve implementable results which address health problems affecting low and middle income countries. Together we will fund up to £20 million for the eighth call to be launched under the joint global health trials partnership.

Objectives and remit

The purpose of this scheme is to provide funding for the best proposals to generate new knowledge about interventions that will contribute to the improvement of health in low and middle income countries.

The scheme will give priority to proposals that are likely to produce implementable results and that are designed to address the major causes of mortality or morbidity in low and middle income countries. For call 8, the joint funders would like to stress that applications must engage with the potential users of research for future implementation and impact for policy. Stakeholders, such as policy makers, should be engaged throughout the research process in order to ensure trial results are implementable, scalable and in line with policy needs.

The scheme is open to the best proposals which address any major health related problem affecting low and middle income countries, particularly those that affect the most vulnerable populations. Although the breadth of the scheme is deliberately wide, we particularly welcome proposals for research into **chronic non-communicable diseases, including mental health, and reproductive, maternal and new born health.**

The joint global health trials scheme is aimed at funding randomised controlled trials (RCTs), although other types of methodologies can be used alongside RCTs to explore implementation and operational issues. Nested studies to explore these issues and support future implementation are encouraged.

The scheme focuses on late-stage (equivalent to phase III/IV) clinical and health intervention trials that evaluate efficacy and effectiveness. We may consider Phase IIb trials of major relevance to the objectives of the call, but please contact the office to discuss this beforehand.

The scope of the scheme includes, but is not limited to:

- Behavioural interventions
- Psychological therapies
- Disease management

- Drugs
- Vaccines
- Hygiene
- Diagnostic strategies.

For call 8, the joint funders would like to highlight an interest in funding complex interventions delivered in community settings including primary health care.

Geographical scope: Studies funded through this scheme should be based in countries with low or middle income economies. World Bank definitions of low and middle income economies can be found at DAC List of ODA Recipients. The scheme encourages Principal Investigators to apply from these countries.

You can choose between two proposal types:

- Global health trial research grants
- Trial development grants.

The scheme funds RCTs; innovative trial methodologies and adaptive designs are welcome. In all instances a clear justification for the chosen methodology must be provided and a clear reason for why the chosen trial design is likely to provide the most robust evidence to address the research question. Proposers are encouraged to submit applications that contain complex and sometimes high risk methodologies where appropriate.

Issues to consider which would strengthen your proposal:

- As the primary objective of this scheme is to develop and evaluate interventions with the potential for a significant impact on population health, applicants are encouraged to comment on the potential impact and broader applicability of the intervention beyond academic contributions.
- Proposers are encouraged to include social science and health economics expertise to ensure that the interventions are appropriate, acceptable and

feasible to their target populations and that any potential social, cultural and economic barriers to implementation are examined.

- It is important that the results of research funded under this scheme have the potential to be implemented at scale. We therefore encourage applicants to include, where relevant, health systems, economics and implementation research in their proposals to provide lessons relevant to scale-up.
- Strong partnership links policy makers and potential implementing partners in low and middle income countries will be important to the long-term impact of the research funded. This should be considered when applicants are preparing their consortia.
- Proposed trials should, as far as it is practicable, be fully developed and costed before they are allowed to start. Applications for full trials that require preliminary data should consider applying for the development grant strand of the scheme.

Support is conditional on the host institution being able to demonstrate that they are able to conduct the trial to the standards set out in the MRC guidelines for good clinical practice in clinical trials. Under this scheme it is expected that the host institute will be the sponsor of the trial. Support will be conditional on all required ethical, legal and regulatory approvals being obtained before the trial commences. The scheme is targeted at trials led by academic groups, and not at trials led by commercial companies or product development partnerships (PDPs). However, applications are welcome from investigators from academic institutions who wish to collaborate with commercial companies or PDPs. Academic-industry collaborations will be considered under the MRC Industry Collaboration Agreement (MICA) mechanism – please see the MRC website for more information.

Funding for development grant proposals

The scheme remains primarily a mechanism to support full trials. However, we recognise that preliminary work is often needed in order for applicants to develop innovative partnerships and trial proposals.

The aims of a trial development grant must be to address questions which need to be answered before a credible, competitive, full trial can be designed. Examples of work that a development grant can cover are:

- Studies to generate specific data that are needed to inform the trial design, such as to determine the sample size, outcome measures, recruitment strategy, follow-up strategy, appropriate monitoring activities and timings. Work to understand the likelihood of contamination within the trial e.g. in a cluster randomised trial, and how that contamination might be handled.
- Work to inform the design of the trial intervention, for instance feasibility and acceptability issues in a public health intervention.
- Trial development grant funding cannot be used in this scheme for drug, vaccine, device, diagnostic or other biomedical intervention development. This means that activities such as drug discovery research, preclinical and early phase 1 and 2 clinical studies are ineligible for funding through this scheme. However, it would be appropriate to use a trial development grant to address trial feasibility questions such as the best way to provide a particular drug within a specific context or population.

Trial development grant holders will not be automatically awarded funds for a full trial upon completion of their development grant. If the Joint Global Health Trials partnership is still live by that point, they could submit an outline proposal to the main trial application route in open competition with all other applicants. If the partnership is not live anymore, potential applicants will need to investigate other potential funding sources either with the individual funders who fund the Joint Global Health Trials scheme, or elsewhere.

How to apply?

Applications will be submitted to and processed by MRC on behalf of the four partner agencies.

There are two application types:

- Global health trial research grants (two stage application process, decisions for invitation for full stage in December 2017, funding decision in June 2018).

- Trial development grants (one stage application process, funding decision in December 2017)

Please see the Guidance documents for further information on applying through either route.

Development guidance
Outline guidance

The MRC must receive your outline proposal by 16:00 British Summer Time on Thursday 14th September 2017.

Funding Available

A total of up to £20 million is available. This is expected to fund several full trial awards. Up to £1 million of the total amount is expected to be spent on several trial development grants.

Successful trial proposals do not need to be large-multi-centre trials. Proposals will be evaluated on value for money and on whether the proposed scale of research is necessary and cost-effective for answering the research question.

You may request support for:

- All research costs that are attributable to the trial. For example, appropriate percentages of the investigators' time, scientific, technical and administrative staff including statisticians, research nurses, trial managers etc., consumables, items of equipment, data /sample handling and archiving and travel.
- The cost of holding trial steering and data monitoring committees.
- Training and support for a trial manager.

Regulation, ethical review and liability may vary across different countries. Principal Investigators and proposed sponsors should ensure that they have adequately understood the feasibility and costs of participation of proposed international centres.

For example, insurance arrangements will vary between countries and the sponsor (usually the host institution) is responsible for ensuring adequate arrangements are in place at each site.

Eligibility

Principal Investigators

This scheme is open to Principal Investigators who are employed by eligible institutions based in low or middle income countries (LMIC) where the research work will take place and to Principal Investigators who are employed by an eligible UK institution. Eligible UK institutions include UK Higher Education Institutions, Research Council institutes, and eligible Independent Research Organisations (IROs). All IROs listed on the Research Councils UK web page: www.rcuk.ac.uk

For researchers based in LMICs, eligible institutions include higher education institutions and non-profit research institutions. If the application is submitted by an LMIC organisation, the primary headquarters of that organisation must be in one of the LMIC countries where the trial will take place. This means that the institution sponsoring a PI must be legally registered in the UK or in a LMIC and the PI must be employed by the institution that is hosting the research

Research Institutions based outside the UK will be asked to complete additional eligibility and financial checks before an award is offered, and awards will be dependent on satisfactory completion of those checks and on-going monitoring.

MRC units and institutes can apply to this call; usual rules for funding grants to MRC units and institutes will apply. If you are based at an MRC unit or institute please contact your local MRC research support office for further information.

It is not permitted for the same person to be a Principal Investigator on more than two proposals submitted to this call.

Co-applicants and collaborators

The nature of this scheme means that we would expect applications to be predominantly based in LMIC. Funding for co-applicants and collaborators in other regions can be requested, but we would expect that the majority of funds would support the costs in the low or middle income country where the trial will be conducted. Investigators employed by an institution in a high income country outside the UK cannot be a Principal Investigator on a proposal, but can be a Co-investigator.

Resubmissions

We are not able to accept resubmissions of proposals that have already been considered under this scheme. If you have substantially changed a previous proposal and wish to discuss whether it might be eligible, please contact JGHT@headoffice.mrc.ac.uk.

Evaluation process

Applications will be considered by an expert panel convened specifically for this scheme jointly agreed by MRC, DFID, the Wellcome Trust and NIHR. Additional scientific experts will be invited to provide written comments if the funders and/or panel chair deem this necessary.

The panel's decision will be final and will not be open to appeal. Please ensure that all necessary information is incorporated in your outline proposal as there will not be an opportunity to add additional information after submission.

Terms and conditions

Funded grants will be managed according to MRC's standard terms and conditions DfID, MRC, the Wellcome Trust and NIHR require that all trials funded by this scheme are run according to the MRC guidelines for good clinical practice in clinical trials. Please also see the Wellcome Trust guidelines on research involving people living in low and middle income countries:

Dates

The joint funders of this scheme considers applications once a year:

Global health trial research grants

Outline proposal deadline - 14 September 2017 (16.00 BST)
Decision about outline proposals - Early December 2017
Invited full application deadline- February 2018
Final decision- June 2018

Trial development grants

Full application deadline - 14 September 2017 (16.00 BST)
Final decision- Early December 2017

Contacts and guidance

Guidelines for Good Clinical Practice in Clinical Trials

Clinical Trials Toolkit

Research involving human participants in developing societies

MRC ethics and research guidance policies

All enquiries should be directed in the first instance to the Medical Research Council: JGHT@headoffice.mrc.ac.uk