European Commission mentions new EDCTP-Plus funds for transition to EDCTP-2!!

Next EDCTP programme to continue delivering life-saving solutions for sub-Saharan Africa

[Date: 2013-07-25]

Preparations are underway for a second phase of the European & Developing Countries Clinical Trials Partnership programme (EDCTP2, 2014-2024), which is expected to start in the course of 2014 as part of the EU's Horizon 2020 research funding programme.

This phase will carry on the life-saving work of the first programme (EDCTP1, 2003-2012), which aimed to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against poverty-related diseases, more specifically on HIV/AIDS, tuberculosis and malaria. It funded clinical trials in sub-Saharan Africa with a focus on phase II and III of clinical development. EDCTP1 also supported capacity building and networking in order to create an enabling environment for conducting these trials in sub-Saharan Africa in line with international and European standards of scientific, ethical and clinical conduct.

The programme has been hugely successful. Under EDCTP1, a total of 241 projects were financially supported by EDCTP promoting African-European and notably trans-African research partnerships. The projects included 88 clinical trials: 31 on HIV/AIDS, 25 on tuberculosis and 32 on malaria.

While most clinical trials are still on-going, positive results have been achieved. A study of highly active antiretroviral therapy during pregnancy and breastfeeding, for example, demonstrated a 43 per cent reduction in HIV infections in infants and more than 50 per cent reduction of mother-to-child transmission during breastfeeding.

A malaria trial (4ABC) was conducted at 12 centres in seven sub-Saharan African countries (Burkina Faso, Gabon, Mozambique, Nigeria, Rwanda, Uganda and Zambia). More than 10,000 children between 6 and 59 months old were screened, and a total of 4116 children were included in the study and treated. Three novel artemisinin-based combination drugs were found to be safe and effective in treating children with a certain type of malaria.

A project examining severe malaria in children has also been successful, demonstrating that three doses of intravenous artesunate (a drug to treat malaria) over two days is as effective as five doses over three days. This finding has the potential to lower costs and reduce the risk of complications or incomplete treatment. A follow-up clinical study aims to further optimise the administration of the drug.

EDCTP1 has also provided 420 career and training awards to African scientists, including 50 senior fellowships. Almost all senior fellows continued working in their respective countries after the expiration of the grant. More than 1300 research collaborators in Africa and almost 800

in Europe have cooperated so far in EDCTP-funded activities.

Building on the success of the first phase the scope of the EDCTP2 programme may be expanded. This would allow EDCTP to also support clinical trials on other poverty-related diseases - such as neglected infectious diseases like sleeping sickness - at any stage of clinical development, including costly marketing authorisation trials for new vaccines or drugs, and to foster optimised delivery of better health solutions for the specific population groups in need.

In order to prepare for EDCTP2, the Commission has a dedicated FP7 Support action known as EDCTP-Plus. Its activities are laying the foundation for implementing and managing the EDCTP2 programme in view of the proposed expansion and increased budget.

The EDCTP was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases of HIV/AIDS, tuberculosis and malaria. Notwithstanding progress made, these three diseases accounted for over 3.5 million deaths in 2012, with the greatest burden of disease in sub-Saharan Africa, where besides ravaging lives, they impede development and cause poverty.

EDCTP currently unites 14 EU Member States plus Norway and Switzerland with sub-Saharan African countries. Its governance involves representatives of these European countries and sub-Saharan Africa. The programme is co-funded mainly by these European countries and the European Union while some co-funding is also provided by third parties, such as the Bill & Melinda Gates Foundation and pharmaceutical industries.

For more information, please visit:

EDCTP
http://www.edctp.org/

Related stories: 31409, 32998

Category: Projects
Data Source Provider: EDCTP
Subject Index: Medicine, Health

RCN: 35923

New joint UK grant call by MRC-UK, Wellcome Trust and DFID, deadline 1st October 2013!!

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 three 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. 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 invest up to a total of £15 million for the fourth call to be launched under the joint global health trials partnership. The costs will be shared equally between the three funders.

Back To Top

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 programme 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.

This scheme is primarily focused on late stage (equivalent to phase III/IV*) clinical and health intervention trials evaluating efficacy and effectiveness. The scheme is aimed at funding Randomised Controlled Trials (RCTs), although other types of methodologies may be used alongside the RCT to explore implementation and operational issues. In certain circumstances researchers may wish to propose methods other than an RCT; if this is the case the reasons for adopting a different method must be clarified in the proposal.

*Please note that this scheme will not include support for registration of pharmaceutical products.

Phase IIb trials of major relevance to the objectives of this scheme may be permitted. If you are considering submitting a phase IIb trial, please consult one of the partner agencies involved for further guidance.

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**, in recognition of the

increasing burden of these conditions in low and middle income countries. We also welcome innovative proposals which address **reproductive, maternal and newborn health**.

The scope of the scheme encompasses interventions of all kinds, including, but not limited to, behavioural interventions, complex interventions, disease management, drugs, vaccines, hygiene and diagnostic strategies.

Issues to consider which would strengthen your proposal:

- It is important that the results of research funded under this scheme are implementable; we therefore encourage applicants to include, where relevant, health systems, economics and operational research in their proposals to provide lessons relevant to scale-up.
- Proposers are encouraged to include social science and health economics expertise to ensure that the interventions are appropriate, acceptable and applicable to their target populations and that the social, cultural and economic barriers to uptake are examined.
- Strong partnership links with institutions and policy makers 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.
- An underlying principle of support is that the proposed trials should, as far as it is practicable, be fully developed and costed before they are allowed to start. Progress will be monitored throughout the lifetime of the trial.
- One objective of this scheme is to promote interventions with a significant potential impact. Therefore, we invite the applicants to comment on the broader applicability of the intervention, if appropriate.

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.

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 the following webpage: http://data.worldbank.org/about/country-classifications

Preference at the evaluation stage will be given to studies based in low and middle income countries in the following regions: Sub-Saharan Africa, South Asia and East Asia and the Pacific. The scheme also encourages Principal Investigators from these regions.

The geographical scope of the call is flexible but in all instances the choice of location and relevance to the problems considered should be addressed in the proposal.

Back To Top

Funding available

A total of £15 million is available. This amount is expected to fund several awards.

To be successful proposals do not need to be large-multi-centre trials. One of the evaluation questions will be whether the proposed scale of the 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.

Costs claimed by institutions based in low and middle income resource settings can be claimed at **100 per cent** of the directly incurred costs. Indirect costs at up to 20 per cent of the direct costs can be claimed by institutions based in low and middle income resource settings. These costs are defined as **"Exceptions"** in the guidance and in the proposal form.

Costs claimed by institutions based in the UK should be calculated according to the Transparent Approach to Costings (TRAC) methodology. These awards will be made on the basis of full economic costs (FEC) at 74 per cent to reflect collaborative funding from MRC, Wellcome Trust and DFID.

You should include in your proposal the total estimated cost of the project, and the total estimated cost requested from this funding scheme, bearing in mind that UK institution costs are calculated at 74 per cent.

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.

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.

Back To Top

How to apply?

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

Outline phase

Applicants are asked to submit an outline proposal in the first instance using the UK Research Councils' Joint electronic Submission (Je-S) System (https://je-s.rcuk.ac.uk/). Guidance on setting up a Je-S account and on filling out the Je-S forms can be found at: https://je-s.rcuk.ac.uk/jesHandbook/jhHome.aspx.

When you create your proposal in Je-S you will need to enter the following options to ensure that your proposal is considered under the correct funding scheme:

Select Council: MRC

Select Document Type: Outline Proposal

Select Scheme: MRC Jointly Funded Initiatives Outline

Select Call/Type/Mode: MRC/DfID/Wellcome Global Health Trials Out September 2013

When you have finished preparing your proposal, clicking 'submit document' on your proposal form in Je-S initially submits the proposal to your host organisation's administration, not to the MRC. Please ensure that you allow sufficient time before the call closing date for your organisation's checks and submission process.

The MRC must receive your outline proposal by 16:00 British Summer Time on 1 October 2013.

In addition to completing the information required by the Je-S form, you must submit the following items:

• Case for support (see separate guidance document)

• One document containing CVs and publications list for each named investigator

CVs and publications lists should be submitted for all applicants and co-applicants using a maximum of 3 sides of A4 per person. Please use Arial 11-point font, with 2 pages dedicated to the CV and the third page listing publications.

The CV should cover:

• Contact details: work address, e-mail address and telephone number (s)

• Employment History: a description of your current post and the source (s) of funding for this post (including dates); list and description of previous posts (including dates)

• Educational qualifications (including dates)

• Please state whether you are clinically qualified and/or clinically active

Your publications list should highlight relevant and recent publications, using a maximum of one side of A4.

Applicants should refer to the MRC applicant handbook for general information about the MRC application process.

Points to note about this scheme when referring to the MRC applicant handbook:

- The scheme differs from standard MRC grant provisions as it is open to Principal Investigators based in low and middle income countries.
- The MRC applicant handbook contains guidance for preparation of your case support. Whilst the core principles outlined in this section should be taken into consideration please refer to the 'Joint Global Health Trials Scheme Application and Case for Support guidance – Outline Stage Proposals' when preparing your submission as this document indicates the specific information required by this scheme.

- As these proposals will be primarily based in low and middle income countries, it is expected that most of the costs will be entered as “Exceptions”.

The DfID/MRC/Wellcome Trust global health trials panel will meet in November 2013 to decide which applicants should be invited to submit a full proposal, based on the panel’s assessment of the outline applications.

In exceptional circumstances the panel may decide at the outline panel meeting to offer a limited number of applicants small amounts of funding for them to conduct feasibility studies rather than immediately inviting a full trial application. This would happen in cases where the panel consider that a strong trial outline has been submitted, with an idea that has potential to make a major impact, but where further feasibility data is clearly needed before a full trial would be viable.

Full proposal phase

You will receive access to the full proposal application form and guidance if you are selected to proceed to the full proposal stage following review of your outline. You will be notified if you have been selected to proceed to the full proposal stage in late November 2013. We expect that the time between invitation to full application stage and deadline for submission of full applications will be approximately two and a half months.

Back To Top

Eligibility

Principal Investigators

This scheme is open to Principal Investigators based in low or middle income economies 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 low or middle income economies, eligible institutions include higher education institutions and non-profit research institutions. Non-UK research institutions that have not previously received substantial funding from one of the funding partners must be assessed for eligibility to apply for and to receive funds. In order to conduct the eligibility checks applicants will be required to provide financial information and documentation for their organisation. We will inform applicants of our requirements for this assessment if they are

successful at the full proposal stage. DfID, MRC and the Wellcome Trust reserve the right to decline funding to an organisation based on eligibility checks. For further advice on eligibility, please contact jointglobalhealthtrials@headoffice.mrc.ac.uk.

It is not permitted for the same person to be Prinicipal Investigator on any 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 low or middle income countries. 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.

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 jointglobalhealthtrials@headoffice.mrc.ac.uk.

Back To Top

Evaluation process

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

Applications will be assessed and scored using jointly agreed funding criteria. When assessing the outline proposals, panel members for this scheme will consider questions such as:

- Is there a real need for such a trial for this condition or group of patients in the proposed locations?
- What impact are the results likely to have on clinical practice or understanding of the proposed intervention?
- Is there evidence of an appropriate degree of liaison with community groups?
- Are the proposed methods appropriate and feasible for the delivery of the research question?
- Is there similar or complementary research underway elsewhere? Are the proposals competitive?
- Are the experimental plans realistic, given the aims of the research and the resources?
- Are the methods and study designs competitive with the best in the field?
- Have major scientific, technical or organisational challenges been identified, and will they be tackled well?

- Does the proposed team of investigators possess the necessary range of expertise and experience to successfully carry out the proposed trial?
- Does the proposed trial include consideration of health services, economics, social science and/or operational research which will increase the likely opportunities to scale-up the findings of the research?
- Is the proposed size and scale of the grant likely to be appropriate in relation to the potential impact of the trial

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.

Back To Top

Terms and conditions

Funded grants will be managed according to MRC's standard Terms and conditions.

DfID, MRC and the Wellcome Trust 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 developing countries www.wellcome.ac.uk and MRC Ethics Guide: Research involving human participants in developing societies.

Back To Top

Dates

The deadline for submission of outline applications is 4pm British Summer Time on **1 October 2013**.

We intend to inform applicants in late November 2013 whether they are invited to submit a full proposal.

The deadline for full proposals is likely to be in February 2014, with final decisions likely to be available in June 2014.

Back To Top

Contacts and guidance

- Joint Global Health Trials Scheme Application and Case for Support guidance – Outline Stage Proposals
- Guidelines for Good Clinical Practice in Clinical Trials
- Clinical trials toolkit
- Research involving human participants in developing societies
- Policy on antiretroviral therapy (ART)
- MRC ethics and research guidance policies

All enquiries should be directed in the first instance to the Medical Research Council:

Contact: Jill Jones
Telephone: +44 (0)20 7395 2207
Email: jointglobalhealthtrials@headoffice.mrc.ac.uk