EDCTP

European & Developing Countries Clinical Trials Partnership

Memorandum of Understanding
Research Partnership Agreement

This Memorandum of Understanding (hereinafter referred to as "MoU") dated 3 November 2017, and amended on 4 October 2018, on 15 November 2019, and subsequently on 28 August 2020, is made between the following parties:

On the one part,

The European & Developing Countries Clinical Trials Partnership (EDCTP), having its main office at Anna van Saksenlaan 51, The Hague, The Netherlands, legally represented by its Executive Director, Dr Michael Makanga; and its Director of Finance and Administration, Mr Abdoulie Barry;

and

On the other part, the United Kingdom Department of Health and Social Care (DHSC), having its main office at 39 Victoria Street, Westminster, London, SW1H 0EU, the United Kingdom, legally represented by its Director, Science Research and Evidence Directorate, Ms Louise Wood.

Hereinafter collectively referred to as the "parties"

This MoU is not legally binding except where it is specifically mentioned in any section of this MoU. Any funding commitments to downstream projects/partners (beneficiaries) made by either party or foreseen in this MoU will be effected through separate agreements between the parties.

Whereas, the EDCTP is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union. EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat poverty related as well as emerging and re-emerging infectious diseases affecting sub-Saharan Africa. The second EDCTP programme is implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020. The European Union will provide a contribution of up to €683 million for the 10-year programme (2014-2024), provided this is matched by contributions from the European Participating States. The countries currently participating in EDCTP as members of the EDCTP Association are: 14 European countries – Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom; and 16 African countries – Burkina Faso, Cameroon, Congo, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda and Zambia. The European Union (represented by the European Commission) and the EDCTP Association signed a Delegation Agreement in December 2014, under which the Commission entrusted budget implementation tasks to the EDCTP Association under Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014;

Whereas, the United Kingdom is one of the founding Participating States of EDCTP;

Whereas, the EDCTP and the UK government, represented by the Medical Research Council UK (MRC UK), see the need to work closely and to leverage their resources to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against poverty-related as well as emerging and re-emerging infectious diseases in sub-Saharan Africa;

Whereas, MRC UK has been mandated by the British Department for Business Energy Innovation and Strategy (BEIS) and the British Department for International Development (DFID) to be the lead for UK government's contributions to EDCTP;

Whereas, contributions from the DHSC, under this MoU, will count as part of the overall UK contribution to the EDCTP2 programme as a European Participating State;

Whereas, the EDCTP acknowledges that it is DHSC's intention that all monies paid to EDCTP will be properly categorised as ODA by the OECD. The parties shall undertake reasonable endeavours to ensure that all monies paid to beneficiaries can properly be categorised as ODA by the OECD;

Whereas, funds received from the UK must be used to fund high quality proposals selected following calls for proposals and a competitive, fair and transparent peer review processes centrally managed by the EDCTP. However, in the case of Scheme 6b the grants will be awarded to the EDCTP Regional Networks of Excellence, who will in turn be responsible for the awarding of fellowships following a fair and transparent mechanism to assess and select candidates. The parties have agreed that the respective EDCTP Regional Networks of Excellence will be responsible and accountable to the EDCTP for the contributions they receive under Scheme 6b. The EDCTP will in turn report to the DHSC;

Whereas, all beneficiaries receiving funding from EDCTP are expected to ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to its results in accordance with requirements stated in Article 29.2 of the EDCTP Model Grant Agreement;

Whereas, the EDCTP has a Fraud Response plan in place, available at http://www.edctp.org/web/app/uploads/2015/08/EDCTP_Association_-_Fraud_Response_Plan_-_5_Aug_2015.pdf

NOW THEREFORE, the parties agree as follows:

1. Purpose and areas of cooperation

The purpose of this MoU is to define how and in which areas EDCTP and DHSC will cooperate to reduce the individual, social and economic burden of poverty-related as well as emerging and re-emerging infectious diseases in sub-Saharan Africa, by supporting North–South clinical research collaborations to develop accessible, suitable and affordable medical interventions. The objectives of the parties include:

- To accelerate the development of new or improved medical interventions for poverty-related diseases – HIV, TB, malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infectious diseases;
- To strengthen cooperation to build research capacity in sub-Saharan Africa for conducting high-quality innovative clinical research consistent with fundamental ethical principles and international and national regulatory standards; and
- To better coordinate, align and, where appropriate, integrate their programmes to increase the impact and cost-effectiveness of their investments in health research on poverty-related and neglected infectious diseases.
- To work with a broad range of public and private partners to maximize the impact of research, to attract additional investment, and fully exploit the opportunities for high-quality clinical research offered by EDCTP's integrated approach.

2. Term of MoU

The MoU is effective from the date of signature of this MoU - the date the last representative signed the MoU - and will remain in force until 31 December 2026, the end date of the EDCTP2 programme.

3. Responsibilities of the parties

The EDCTP

The EDCTP will be responsible for the management of the calls for proposals, the grant applications and evaluation, in accordance with the applicable Horizon 2020 Rules for Participation (Regulation, the EDCTP 2 Basic Act (Decision No 556/2014/EU), and the EDCTP Annual Work Plan(s). However, in the case of Scheme 6b the EDCTP Regional Networks of Excellence will be responsible for the management of the fellowships. The parties have agreed that the respective EDCTP Regional Networks of Excellence will be responsible and accountable to the EDCTP for the contributions they receive under Scheme 6b. The EDCTP will in turn report to the DHSC.

Reporting

The EDCTP will submit a bi-annual financial report to DHSC (in April and October), outlining the payments made to awards under the DHSC supported Work-Plans (as per in Annex 1), including beneficiaries for a grant partly or fully funded by DHSC. This report must include the name of each beneficiary, the title of the project, and the amount disbursed. Any additional information pertaining to the financial management of these grants should be provided in this report.

EDCTP will submit an annual technical report (in April), to update DHSC on performance of all DHSC supported Work-Plans listed in Annex 1 , the performance of individual funded awards within each Work Plan and their progress against anticipated outputs and results, including the DHSC % funding contribution to each. The technical report (template provided by DHSC) should contain a summary of the performance of all DHSC-funded Work-Plans and awards, with individual project reports included as annexes. Beyond these standard reports, EDCTP will

endeavour to respond in a timely manner to any other reasonable requests from DHSC for information.

Performance review meetings will take place annually, or as required, and will be convened and chaired by EDCTP. EDCTP will provide information on outcomes of awards as part of those discussions. Where EDCTP is informed about imminent press releases or release of results EDCTP should share with DHSC outside of regular meetings.

ODA Transparency and Branding

The EDCTP will work towards applying transparency standards in line with the UK aid Transparency Guarantee and the International Aid Transparency Initiative (IATI), to the funds received from DHSC. In line with this Guarantee and DHSC's transparency commitment, EDCTP will publish information about the funded projects on its own website, in line with the EU requirements, and in so far as possible in line with relevant categories of the IATI standard. In line with DHSC's transparency commitments, the EDCTP gives consent for this arrangement (and any subsequent amendments) and associated funding to be published on DHSC's website.

The EDCTP shall provide all reasonable co-operation and assistance necessary to DHSC to meet its obligations under the International Development (Official Development Assistance Target) Act 2015 and the International Development (Reporting and Transparency) Act 2006. Such reasonable cooperation and assistance shall include but not be limited to the provision of all information and data necessary for the transparent, accurate, timely and comprehensive publishing of all data on all activities related to the awards.

EDCTP will explicitly mention in the Grant Agreement of the relevant projects that part or all of the funding for these projects comes from DHSC, and beneficiaries will be requested, where appropriate, to acknowledge DHSC's contributions. Such acknowledgements (where appropriate or as requested by DHSC) will include the name and logo of the UK's National Institute of Health Research (NIHR) (or any future name or logo required by DHSC) using the templates provided by DHSC from time to time.

Due diligence

In utilising DHSCs financial contribution, EDCTP will exercise the same care in the discharge of its functions under this MOU as it exercises with respect to the administration and management of its own resources and affairs. Additionally EDCTP shall take the necessary steps at the commencement of the programme activities and at regular intervals throughout implementation to assess the internal controls and systems of any Downstream Partners. These assessments will be shared with DHSC, upon request.

Audit

The EDCTP will provide copies of relevant records on request and, if required, make its records available for inspection by the National Audit Office or another party named by DHSC. DHSC reserves the ability to request additional audits during the course of the projects. The reason for

any requests will be justified by DHSC and the costs of such audit will be agreed, upfront between both parties.

Delivery Chain Mapping

EDCTP will maintain an up to date and accurate record of Downstream Partners (beneficiaries) in receipt of DHSC funds and/or DHSC funded inventory or assets. This delivery chain map should demonstrate how funds flow from the initial source to end beneficiaries, and the risks and potential risks along the chain.

The delivery chain map should be updated regularly by EDCTP and when there are material changes to the Downstream Partners (beneficiaries) in the chain. As a minimum, EDCTP will provide DHSC with an updated delivery chain map at the following intervals: within 6 months of the commencement of this MOU; annually part of the technical reporting; and at the end of the project.

DHSC

DHSC will make a financial contribution to the EDCTP for supporting highly rated projects resulting from thematic calls for proposals on health research and development (R&D) areas of mutual interest to DHSC and EDCTP (as outlined in Annex 2), following the EDCTP centrally managed independent scientific review process.

The DHSC's payment schedule to EDCTP for contributions to be made is detailed in Annex 1.

The Parties

Visibility and Acknowledgement

The Parties will not make any announcement or other disclosure concerning the contents of this MoU without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except as required by law, any governmental or regulatory authority, any court, or any other authority of competent jurisdiction. Where a formal public statement, press release or other publicity in relation to the initiative is required the parties shall work together to ensure that the publicity statements are coordinated.

Neither party shall use the name, logo, trademarks or other brand collateral of the other party without the owning party's prior written consent.

DHSC is subject to the requirements of Freedom of Information Act 2000 (FOIA). Where DHSC receives a request for Information under FOIA in connection with this MoU or its subject matter, it shall, as soon as reasonably possible, inform the other party. EDCTP agrees to assist and co-operate with DHSC to enable it to comply with its disclosure obligations under FOIA.

Data Protection

The Recipient shall (and shall procure that any of its agents and Employees involved in connection with the activities under the Agreement shall) comply with general data protection principles, namely it shall ensure that information is:

- used fairly, lawfully and transparently;
- used for specified, explicit purposes;
- used in a way that is adequate, relevant and limited to only what is necessary;
- accurate and, where necessary, kept up to date;
- kept for no longer than is necessary; and
- handled in a way that ensures appropriate security, including protection against unlawful or unauthorised processing, access, loss, destruction or damage.

Intellectual Property Rights

Intellectual Property Rights developed in all material (including, but not limited to, reports, data and designs, whether or not electronically stored) produced by EDCTP or its personnel, members or representatives in the course of this programme will be the property of EDCTP.

Subject to any third party arrangements for the purposes of implementation of the Programme, EDCTP will grant to DHSC a non-exclusive, worldwide, royalty-free license to use and reproduce the project and Programme outputs funded under this MOU for non-commercial purposes.

Safeguarding

1. EDCTP will take all reasonable steps to prevent the sexual exploitation, abuse and harassment of any person linked to the delivery of this Memorandum by both its employees and any downstream partners/beneficiaries.
2. Both parties have a zero tolerance approach towards sexual exploitation, abuse and harassment. The Partner will immediately contact DHSC to report any credible suspicions of, or actual incidents of sexual exploitation, abuse or harassment related to this Memorandum. The Partner should assess credibility based on the source of the allegation, the content, and the level of detail or evidence provided. All sexual activity with children (persons under the age of 18) is prohibited, regardless of the age of majority, or age of consent locally.
3. EDCTP should also report any credible suspicions of, or actual incidents that are not directly related to this Memorandum but would be of significant impact to their partnership with DHSC or the reputation of DHSC, the National Institute for Health Research (NIHR), or UK Aid. For example, events that affect the governance or culture of EDCTP, such as those related to senior management, must be reported.
4. Both parties will fully co-operate with investigations into such events, whether led by DHSC or any of its duly authorised representatives or agents, or the Partner.

Evaluation

DHSC may, and where possible through consultation and coordination with one or more donor partners, decide to commission an independent evaluation of the schemes in Annex 1 in receipt of a DHSC contribution, and EDCTP shall provide all reasonable co-operation and assistance necessary to allow the DHSC to do so.

Fraud and Corruption

DHSC and EDCTP will immediately and without undue delay inform the other participant of any event which interferes or threatens to materially interfere with the successful implementation of the Programme, including Financial Impropriety.

DHSC and EDCTP have a zero tolerance approach towards fraud and corruption that may lead to the misuse of funds and agree in principle to recover such funds. EDCTP will, at first, take timely and appropriate action to investigate credible allegations of fraud and corruption, and report any credible allegations of fraud to DHSC's Anti-Fraud Unit at fraud.enquiries@dhsc.gov.uk at the earliest opportunity. Both parties will fully co-operate with investigations into such events, whether led by the EDCTP or DHSC.

In the event of any credible indications that DHSC's contribution may have been subject to fraud or corruption, DHSC, may, at any time during the period of this arrangement and up to five years after the end of the programme, arrange for additional investigations, on-the spot checks and / or inspections to be carried out and will work with EDCTP to arrange these. These may be carried out by DHSC, or any of its duly authorised representatives in consultation with EDCTP.

DHSC reserves the ability to recover funds that have been subject to a proven fraud and will work with EDCTP to do so. Where Financial Impropriety is alleged, DHSC reserves the ability to suspend or terminate funding with immediate effect, in preference to the standard notice period and irrespective of any contractual requirements.

Consistent with numerous United Nations Security Council resolutions including S/RES/1269 (1999), S/RES/1368 (2001) and S/RES/1373 (2001), both DHSC and EDCTP are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of DHSC to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, EDCTP undertakes to use reasonable efforts to ensure that none of the DHSC funds provided under this arrangement are used to provide support to individuals or entities associated with terrorism.

Confidential Information

In respect of any confidential information it may receive directly or indirectly from the other Party, each Party agrees to keep secret and strictly confidential.

The Parties may disclose the confidential information to employees, officers, contractors, consultants and advisers who are directly involved in this MOU and who need to know the information, and the Party disclosing the confidential information shall ensure that such third parties are aware of these provisions.

The Parties shall not (and shall ensure that any employees, officers, contractors, consultants and advisers who have access to confidential information shall not) use any of the confidential information received, for any purpose other than for the purposes of this MOU.

4. Termination

Both Parties will at first negotiate in an attempt to resolve any issues that might arise throughout the Programme. However, this MOU can be terminated, at any time, by three months' written notice by either Party. All remaining funds other than those irrevocably committed in good faith to the project activities outlined in Annex 2 before the date of termination, and approved between the Parties as being required to finalise activities, will be returned to the DHSC.

If DHSC becomes concerned that the provisions of this MOU have not been fulfilled by EDCTP, or if any activities occur which in DHSC's opinion will significantly impair the development value of the project, DHSC will discuss with EDCTP and form an assessment. DHSC may then take any of the following actions:

(a) Signal a possible future response
(b) Delay or reduce the applicable funding
(c) Stop funding under the termination provisions set out within this arrangement

EDCTP will, in a timely manner, inform DHSC of any delays, obstructions or events which, in the opinion of EDCTP interfere or threaten to interfere with the successful implementation of any part of the programme. In the event that DHSC reasonably believes that timely and appropriate corrective action has not been taken to remove the delay or obstruction, it may request consultations at senior level between DHSC and EDCTP to determine the appropriate action to ensure that the Programme achieves the results as defined in Annex 2.

Notwithstanding any other provisions of this MOU, DHSC may immediately terminate this MOU by written notice to Dr. Michael Makanga in the event that there is proven fraud in relation to the Funded Activities and / or the Contribution.

DHSC contributions to scheme 2 of the 2016 Work Plan and all schemes under the 2017,2018 and 2020 Work Plans in Annex 1 will cover full project costs for the entire duration of the projects. Should the impact of BREXIT result in ineligibility of UK researchers involved in DHSC-funded projects to EU co-financing, EDCTP will prioritise continued participation and financing to UK researchers in the funded projects by making use of the DHSC contribution to the Programme. Should EDCTP not be in a position to disburse DHSC funding post-Brexit, DHSC has the right to terminate this agreement with immediate effect, recuperate unspent funds from EDCTP and make alternative arrangements to ensure continuation of the relevant projects.

EDCTP

European & Developing Countries Clinical Trials Partnership

Signed for and on behalf of

the EDCTP:

Place: The Hague

Date:

Dr Michael Makanga

Executive Director

Place: The Hague

Date:

Mr Abdoulie Barry
Director of Finance and Administration

For DHSC:

Place: 39 Victoria Street, Westminster, London, SW1H 0EU
Date:

Dr Louise Wood
Director, Science Research and Evidence Directorate

Annex 1: Payments schedule

Scheme 1 (2016 work plan): Research and clinical management of patients in PRD epidemics in sub-Saharan Africa

Date	Description	**Amount** €
1/12/2017	First payment	10,000,000
Total		10,000,000

Scheme 2 (2016 work plan): Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents

Date	Description	**Amount** €
1/12/2017	First payment	9,000,000
Total		9,000,000

Total **€19,000,000**

Scheme 3a (2017 work plan): Strategic Actions Supporting Large-Scale Clinical Trials

Date	Description	**Amount** £
30/11/2018	First payment	14,100,000
Total		14,100,000

Scheme 3b (2017 work plan): Clinical Trials to reduce health inequities in pregnant women, newborns and children

Date	Description	**Amount** £
30/11/2018	First payment	12,400,000
Total		12,400,000

Total 2017 work plan **£26,500,000**

Scheme 4a (2018 work plan) Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

Date	Description	**Amount** £
30/11/2018	First payment	5,000,000
13/12/2019	Second Payment	7,402,738
Total		12,402,738

Scheme 4b (2018 work plan): Diagnostic tools for poverty-related diseases challenge

Date	Description	**Amount** £
30/11/2018	First payment	5,000,000
13/12/2019	Second payment	5,507,069
Total		10,507,069

Scheme 4c (2018 work plan) Vaccines for diarrhoeal diseases or lower respiratory tract infections

Date	Description	**Amount** £
13/12/2019	First Payment	8,832,193
Total		8,832,193

Total 2018 work plan **£31,742,000**

Scheme 5: Contribution to EDCTP 2 programme management activities

Date	Description	**Amount** £
30/11/2018	First payment	500,000
13/12/2019	Second payment	258,000
25/09/2020	Third payment	167,500
Total		925,500

Scheme 6a (2020 work plan) Mobilisation of funding for COVID-19 research in sub-Saharan Africa

Date	Description	**Amount** £
25/09/2020	First Payment	1,800,000
Total		1,800,000

Scheme 6b (2020 work plan) Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence

Date	Description	**Amount** £
25/09/2020	First Payment	800,000
Total		800,000

Note: approved commitment is for £1,800,000, but reflected as £800,000 in this payment schedule because of a redirected £1,000,000 underspend from Scheme 4b

(2018 work plan – Diagnostics call) towards Scheme 6b (2020 work plan – Regional Networks)

Scheme 6c (2020 work plan) Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC

Date	Description	**Amount** £
25/09/2020	First Payment	750,000
Total		750,000

Total 2020 work plan **£3,350,000**

Note: approved total 2020 work plan commitment is for £4,350,000, but reflected as £3,350,000 in this payment schedule because of a redirected £1,000,000 underspend from Scheme 4b (2018 work plan – Diagnostics call) towards Scheme 6b (2020 work plan – Regional Networks)

N.B. The above schedule reflects the approved allocation of DHSC's Contribution against selected Work-plans. The final allocation of funds against each Work plan may be subject to change, but only if approved by DHSC in advance.

Annex 2 – Funded Activities

2016 Work Plan (£16.8m contribution to date, towards 2 calls): (Annex 2.1a)

- Research and clinical management of patients in PRD epidemics in sub-Saharan Africa (Scheme 2.1a)
- Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents (Scheme 2.1b)

2017 Work Plan (£26.5m contribution to date, towards 2 calls): (Annex 2.2)

- Strategic Actions Supporting Large-Scale Clinical Trials (Scheme 2.2a)
- Clinical Trials to reduce health inequities in pregnant women, newborns and children (Scheme 2.2b)

2018 Work Plan (£31.7m contribution to date, towards 3 calls): (Annex 2.3)

- Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities (Scheme 2.3a)
- Diagnostic tools for poverty-related diseases challenge (Scheme 2.3b)
- Vaccines for diarrhoeal diseases or lower respiratory tract infections (Scheme 2.3c)

2020 Work Plan (£4.35m contribution to date, towards 3 calls): (Annex 2.4)

- Mobilisation of funding for COVID-19 research in sub-Saharan Africa (Scheme 2.4a)
- Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence (Scheme 2.4b)
- Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC (Scheme 2.4c)

Annex 2.1
2016 Work Plan (£16.8m contribution to date, towards 2 calls)

Scheme 2.1a: Research and clinical management of patients in PRD epidemics in sub-Saharan Africa

Description

Background

Developing countries especially in sub-Saharan Africa have weak health systems, inadequate resources, and poor capacity to identify and respond quickly and effectively to disease outbreaks, making them very vulnerable to the devastating effects of most infectious diseases epidemics. The scale and overwhelming effects of the recent Ebola Virus Disease epidemic in West Africa clearly demonstrates the interconnectedness of poverty related and neglected diseases with the profound negative impact it had on other infectious diseases national programs. This situation is compounded by lack of preparedness capacity to conduct comprehensive and well-coordinated research in response to such disease threats. Moreover, with widespread population movement, immigration and global warming such epidemics have a global impact. There is a need to galvanise preparedness of health systems and services to conduct clinical management research of patients in severe epidemics in sub Saharan Africa.

Scope

This action aims to support the establishment of a multidisciplinary consortium able to provide accelerated evidence for the optimal clinical management of patients and for guiding the public health response to any severe infectious outbreak caused by pathogens within the scope of the EDCTP2 programme with pandemic potential or that may cause significant damage to health and socio-economics in Africa (including antimicrobial-resistant pathogens). Based on a comprehensive 'inter-epidemic' work programme, the consortium should for example: build a standardised methodological approach such as identification and strengthening of suitable clinical trial sites/centres; resolution of administrative, regulatory, ethical, and cultural barriers; harmonised clinical case definitions and management guidelines; pre-approval of adaptable protocols; mechanisms to rapidly exchange high quality data and samples. This work should aim at ensuring preparedness to perform coordinated large-scale multi-site clinical studies in response to an emerging threat. These clinical trials could include studies evaluating potential preventive or therapeutic interventions in a community or health-care setting; validation of diagnostic devices and observational clinical studies aimed at establishing the natural history and determinants of severity of the disease.

The consortium proposal should clearly outline the overall proposed operational plan with milestones and deliverables. Special attention should be given to plans for patient and public involvement and engagement; local personnel training as well as local partners' active involvement; and strengthening of information management including establishment or upgrading of existing communication and data management IT infrastructure. A clear description of proposed research support programme, roles and contributions of partners involved in the consortium; and a sustainability strategy, should be provided. The action should result in standardised protocols, definitions, and strategies for the optimal clinical management of patients in any severe infectious

outbreak with pandemic potential or significant risk of major damage to health and socio-economics in sub-Saharan Africa.

Expected impact

The consortium is expected to collaborate with similar initiatives at national, regional, European and international level, such as PREPARE and ISARIC ,and the EDCTP regional networks of excellence in order to contribute effectively to global preparedness and response activities, including the WHO blueprint, and ensure quick implementation of its findings into optimised clinical practices and to maximise synergy and complementarity.

The action should build the overall capacity for preparedness research to conduct comprehensive and well-coordinated research on the clinical management of patients in severe infectious outbreaks caused by emerging pathogens with pandemic potential or potential to cause significant damage to health and socio-economics in sub-Saharan Africa. This should facilitate the implementation of urgently needed research on emerging infectious epidemics which would provide evidence for a coherent, adequate and rapid public health response to emerging threats. The action should help public health authorities designing optimal prevention and clinical management strategies, particularly in pregnant women.

The action should also contribute to the coordination with relevant initiatives at a national, regional and international level, particularly within the context of the GLOPID-R (Global Research Collaboration for Infectious Diseases Preparedness and foster cross network collaboration to maximise synergy and complementarity and ensure quick implementation of its findings into optimised clinical practices.

Scheme 2.1b: Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents

Description

Background

Every year, more than 300 000 women die as a result of pregnancy, childbirth or postpartum complications and more than 6 million children die under the age of five, mostly from preventable diseases, according to WHO. The majority of these deaths occur in developing countries and represent the biggest global health inequity today. While substantial progress has been made in reducing maternal and child morbidity and mortality, many countries, particularly in sub-Saharan Africa, have failed to reach the

Millennium Development Goal 4 and 5 targets of reducing under-5 mortality by two-thirds and maternal mortality by 75% by 2015 from the 1990-baseline.

In countries in sub-Saharan Africa, poverty-related diseases (PRDs) remain the leading causes of morbidity and mortality, especially during pregnancy and childhood. The importance of PRDs for maternal and neonatal deaths is often poorly-recognised because of the limited evidence on the contribution of these diseases to maternal and neonatal mortality, over and above direct, obstetric causes of pregnancy-related mortality. Adolescents are subject to particular health risks that need to be targeted specifically, such as early pregnancies, and infections such as HIV, diarrhoeal diseases, lower respiratory infections and meningitis, which are important causes of death in this age group. Adolescents (10-19 years of age) are now included as a target for the updated UN Global Strategy for Women's, Children's and Adolescents' Health for 2016-2030, a platform to accelerate the new Sustainable Development Goals.

Roll-out of HIV treatment in large public health programmes has resulted in substantial reductions in HIV-related mortality across all ages, although ART coverage among children below 15 years of age, and especially below five years of age, is lagging behind coverage among adults. This is partly due to failure to timely diagnose vertically-acquired HIV infection in infants, but also due to children and adolescents not being seen in the healthcare system until late in the course of disease. Whereas prevention of mother-to-child transmission (PMTCT) programmes have largely been effective, a substantial number of HIV-infected pregnant women do not access PMTCT and are thus not benefitting from HIV treatment and care and continue to be at risk of morbidity and mortality for themselves and transmission and mortality for their offspring. Adolescents are often excluded from prevention of HIV infection public health efforts, because they are difficult to reach, are vulnerable at this time of their lives, and find it difficult to access healthcare systems to ask for the necessary prevention support.

Concerted efforts are needed to increase equitable access to potentially life-saving cost-effective interventions to treat PRDs in pregnant women, children, and adolescents. This is especially important in light of the frequent exclusion of both pregnant women and young infants and children from clinical trials and the paucity of available products that target these groups of the population. In this regard, little information is available on the pharmacokinetics and efficacy of drugs in late pregnancy and during breastfeeding. Adolescents are a difficult-to-reach group, not only for the prevention of PRDs such as HIV, but also for their treatment, and approaches dedicated to this age group need urgently to be developed. Few drugs for use in PRDs are optimised for use in children, as small children need age/weight-appropriate formulations, and expansion of drug choice for children in sub-Saharan Africa is urgently required.

There has been considerable success in HIV treatment and in PMTCT but little is known about the long-term adverse effects of lifelong treatment, both when treatment is started

in pregnancy, in women who are not HIV-symptomatic and in their uninfected children who may be exposed to antiretroviral drugs for possibly two years in foetal and early life. Post-registration research on the long-term effects of life-long drugs is required, especially when started in pregnancy, early childhood or adolescence, but is often outside the scope and capacity of existing public health systems.

Challenges associated with continued high risk of maternal, neonatal, child, and adolescent morbidity and mortality are related to failure in (timely) accessing the health care system for prevention and/or treatment, as well as health system failures in providing quality care and the existing tools. Understanding these barriers, which include health system and behavioural factors, is urgently needed to improve the effectiveness of new or improved products. Importantly, the high burden of disease and death among these groups of the population in low income countries also relates to the paucity of interventions such as effective vaccines and efficacious drugs for prevention and case management of infectious diseases.

Scope

The objective of this call is to optimise the use, delivery and access to PRD(1) medicinal products in sub-Saharan Africa for mothers, newborns, children and/or adolescents. Supported projects should contribute to a better understanding of the role of PRDs in maternal, neonatal, child, and adolescent mortality and morbidity, as well as the barriers for the optimal effectiveness of health products, such as existing drugs or vaccines against these diseases in sub-Saharan Africa. This call aims to support actions on preventive and therapeutic clinical interventions of post-registration products, as well as related behavioural studies, aimed at optimising use of new or improved products or combination of products for mothers, newborns, children and/or adolescents. The scope of this call is limited to clinical trials and operational studies with a product focus. Activities may include: studies on product (drugs, vaccines, microbicides and diagnostics) development, delivery, uptake and adherence; and strategies for equitable and full-scale access to diagnostics, prevention and treatment interventions. This includes community-based interventions/approaches and qualitative studies.

Assessment of behaviour of those who would benefit from such products (or interventions) in terms of access to the health care system and uptake of the product/intervention, with adherence to product use, is within scope of this call.

EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals of a different duration.

Expected impact

Actions funded under this Call for Proposals should contribute significantly to improving maternal, neonatal, child, and adolescent health in the world's region with the lowest health indicators in these populations. The EDCTP is currently among the most visible initiatives that could contribute to improve these outcomes through evaluation of new approaches in rigorously conducted clinical trials in sub-Saharan Africa.

Annex 2.2
2017 Work Plan (£26.5m contribution to date, towards 2 calls):

Scheme 2.2a: Strategic actions supporting large-scale clinical trials

Description

Background

There is an urgent need for new or improved products for tackling poverty-related diseases (PRDs). Late phase clinical trials find themselves at the critical juncture between clinical development and market authorisation by the regulators. These trials, which provide evidence to support the product approval process and/or influence policy and practice, are often large in scale, complex and expensive, beyond the resources of a single funder. Coordination and collaboration between partners and funders is essential to leverage the expertise, resources and investments needed that in turn accelerate the development of new or improved products for PRDs and maximise the impact of research funding investments.

Scope

The purpose of this Call for Proposals is to support strategic actions (clinical research activities) that are part of a large-scale clinical trial with the potential to achieve rapid advances in the clinical development of new or improved medical interventions (drugs, diagnostics, vaccines, microbicides) for PRDs. Proposals for a strategic action should focus on phase III study(ies) on PRDs within the remit of the EDCTP2 programme. The proposed EDCTP-funded study(ies) should be conducted in sub-Saharan Africa but may form part of a larger trial that is conducted globally. The clinical trial must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level.

Proposals for a strategic action must also present the broader large-scale clinical trial in its entirety, including details of the component(s) of the trial for which EDCTP funding is requested and the component(s) that are to be financed from other sources. Proposals

should make a clear distinction between the broader context (i.e. the large scale clinical trial) as opposed to the proposed action itself (i.e. the specific part of the clinical trial to be funded as a strategic action by the EDCTP Association). The clinical trial must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders, such as EDCTP2 Participating States and/or third parties.

The total cost of the large-scale clinical trial should not be less than € 10 million and ideally at least half the cost of the large-scale clinical trial should be supported by funders other than the EDCTP Association. EDCTP considers that proposals for a strategic action of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals with different total costs and/or a different duration. Proposals for strategic actions that address the priorities outlined in the EDCTP Strategic Research Agenda and that address topics not covered in the scope of the other EDCTP2 calls for proposals launched in 2017 are particularly encouraged.

Expected impact

Actions funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders; catalyse research synergies, and leverage resources and investments in order to achieve rapid advances in the development of new or improved products for PRDs. The large-scale clinical trial supported by the action should have the potential to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme. Proposals that leverage major support from other funders, in particular financial contributions, at the level of the large-scale clinical trial will be considered to have a higher impact.

Scheme 2.2b: Clinical trials to reduce health inequities in pregnant women, newborns and children

Description

Background

Poverty-related diseases (PRDs) remain the leading causes of morbidity and mortality in sub-Saharan Africa, especially during pregnancy and childhood. Despite progress in other age groups, effective treatment and prevention of PRDs in mothers, newborns and children is often lacking and/or lagging. The frequent exclusion of pregnant women and children from clinical trials and the paucity of available products that target these groups are factors that contribute to these populations having the lowest health indicators. Additional challenges relate to the limited financial incentives associated with the adaption of off-patent medicines to the specific needs of pregnant women and paediatric

populations. Therefore, concerted efforts are needed to increase access to potentially life-saving, cost-effective interventions to prevent and treat PRDs in pregnant women, newborns and children and to enhance use of existing interventions in these populations.

Scope

The objective of this call is to accelerate the adaption and/or optimisation of treatment and prevention products (excluding vaccines) for PRDs in sub-Saharan Africa for use in pregnant women, newborns and/or children. This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases and lower respiratory infections. Proposals that are in line with the priorities of EDCTP's strategic research agenda are encouraged.

Proposals should focus on adaption of existing medicines, including off-patent products, to the specific needs of pregnant women, newborns and/or children. Proposals should typically include one (or more) clinical trials conducted in sub-Saharan Africa to assess the pharmacokinetics, efficacy and safety, and/or the development of age-appropriate formulations. However, other trial methodologies and study designs may be considered where the methodology is justified in the proposal as being the most appropriate to provide robust evidence. Projects must assure that the clinical trials are appropriately conducted, respecting current legislation and considering the ethical aspects and particular needs of the study subjects and their families.

The proposal must include full details of the product development milestones including specific go/no-go criteria for the proposed clinical trial(s) as well as specific plans for the subsequent regulatory approval process; for trials involving children, this is ideally a paediatric investigation plan, which should aim at obtaining a relevant market authorisation, such as the Paediatric Use Marketing Authorisation (PUMA).

EDCTP considers that proposals for activities of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact

Projects are expected to contribute to expanding the availability of medicines for PRDs for pregnant women, newborns and children in sub-Saharan Africa. Projects should provide evidence for better use of medicinal products in pregnant women and/or paediatric populations, and the acquired knowledge should be used towards obtaining a relevant market authorisation such as the Paediatric Use Marketing Authorisation (PUMA) for products for newborns and children or an equivalent for products for pregnant women.

Annex 2.3
2018 Work Plan (£31.7m contribution to date, towards 3 calls):

Scheme 2.3a: Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

Description

Challenge
Co-infections with several pathogens are frequent in sub-Saharan Africa and represent an important public health problem in many areas due to accelerated and/or complicated disease progression, resulting in increased mortality and morbidity. These co-infections can result in unique challenges in treatment and prevention of disease, including increased drug toxicities and/or changes in efficacy of interventions. The rise in incidence of non-communicable diseases (NCDs) in sub-Saharan Africa and the necessity for long-term management of some poverty-related diseases and NCDs, often concurrently, adds to these complexities. There is therefore an urgent need for research that leads to advances in the development of new/improved products for the effective prevention, treatment and management of co-infections and co-morbidities.

Scope
The purpose of this Call for Proposals is to support actions that lead to improvements in the prevention, treatment and/or clinical management of co-infections and co-morbidities in sub-Saharan Africa. Proposals must include at least one infection within the EDCTP2 scope*. Proposals on co-infections and co-morbidities other than those involving HIV/AIDS are also encouraged.

Consortia should incorporate the latest innovations and advances in trial design and research methods in order to evaluate promising interventions. Proposals should include one or more clinical trial(s) to be conducted in sub-Saharan Africa. The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP) regulatory and ethical standards.

Stand-alone epidemiological studies are outside the scope of this call. Proposals on diagnostics are also outside the scope of this call, but may be relevant for the separate call under this annual work plan on “Diagnostic tools for poverty-related diseases”.

EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 2.0 and 4.0 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals for activities of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact
Projects funded under this Call for Proposals should:
•contribute towards the reduction of the number of cases of co-infections and co-morbidities in sub-Saharan Africa and thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages
•advance products through the product development pipeline, and/or provide evidence to support label extension and/or be in line with EDCTP2's strategic research agenda to be considered as having a higher impact.

Scheme 2.3b: Diagnostic tools for poverty-related diseases

Description

Background
Disease diagnosis in sub-Saharan Africa is highly challenging, as the population has limited access to health care systems. Early and rapid diagnosis of poverty-related diseases (PRDs) offers the best opportunity for patients to receive timely and appropriate treatment, but adequate diagnostic tools are not readily available because of a lack of drive to develop and deploy them in disease-endemic countries. In addition, co-infections with several pathogens are frequent in many populations and represent further challenges in the diagnosis of many PRDs. There is therefore a clear need for the development and uptake of rapid, accurate, cost-effective, scalable and field-friendly diagnostic tools.

Scope
Projects should focus on validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for the detection of any of the PRDs*, including co-infections. The proposed tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, with a significant impact on clinical decision and health outcomes. Proposals should focus on late stage development (e.g. evaluation and/or demonstration phase trials) or implementation studies in sub-Saharan Africa. Diagnostic algorithms to

detect multiple infections are also welcome. Additionally, proposals should provide detailed plans for the uptake of the diagnostic tools and technologies upon successful completion of the project, including engagement with WHO or other relevant policy makers as well as plans for product registration (i.e. CE mark).

Proposals focused entirely on early-stage, laboratory-based studies using biobanked samples are outside the scope of this call. Priority will be given to point-of-care diagnostics for use in resource-limited settings.

EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 1 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals of between 24 and 48 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact
Projects funded under this Call for Proposals should:
•contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
•lead to improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression and therapeutic response
•contribute towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings
•contribute to reduce infections by key antimicrobial resistant microorganisms in humans as recommended by the Global Action Plan Against Antimicrobial Resistance (PDF) and by the European Action Plan Against Antimicrobial Resistance (AMR) 2017
•be in line with EDCTP2's strategic research agenda (PDF) to be considered as having a higher impact.

Scheme 2.3c: Vaccines for diarrhoeal diseases or lower respiratory tract infections

Description

Background
Vaccines have contributed enormously towards the elimination of diseases, including the control of infectious diseases in low resource settings. Development of vaccines against

diarrhoeal diseases or lower respiratory tract infections is therefore one of the preferred strategies to reduce the high mortality and morbidity of these diseases. While investment in clinical development of vaccines for diarrhoeal diseases and lower respiratory tract infections has become more substantial, additional resources are needed to support clinical trials for these vaccine candidates in sub-Saharan Africa.

Scope
This Call for Proposals will support clinical trials that can accelerate the development of vaccines for diarrhoeal infections and lower respiratory tract infections in sub-Saharan Africa.

Proposals should include one or more clinical trials (phase I to III) in sub-Saharan Africa for vaccine candidates towards one or more of the following pathogens:
•Diarrhoeal diseases: Shigella and/or enterotoxigenic E. coli (ETEC)
•Lower respiratory tract infections: Respiratory Syncytial Virus (RSV) or Group B streptococcus (GBS).

Proposals should describe the target product profiles; particularly indication, target populations, safety and/or efficacy, and describe how the candidates contribute to the global product development pipeline for the disease.

Proposals may also include detailed analyses of host responses to advance the understanding of mechanisms of reactogenicity (safety), immunogenicity and/or efficacy. Proposals should aim to incorporate the latest innovations and advances in clinical trial design and research methods that allow for rapid results, cost-effective use of available resources and reduction in subject numbers.

Full details of the clinical product development plan, including specific go/no-go criteria must be included in the proposal, as well as specific plans for the regulatory approval process and access strategy for patients in low-resource settings. The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP) regulatory and ethical standards. Proposals should incorporate activities that enhance the capacity of existing trial sites and/or develop new trial sites in sub-Saharan Africa for the conduct of regulatory-standard vaccine trials.

EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 5 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact
Proposals that leverage major relevant financial contributions from funders other than the EDCTP Association will be considered to have a higher impact.

Projects funded under this Call for Proposals should:
•contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
•contribute towards the reduction of the burden of diarrhoeal diseases or lower respiratory tract infections in sub-Saharan Africa
•lead to the advancement of vaccine candidates along the product development pipeline.

Annex 2.4
2020 Work Plan (£4.35m contribution to date, towards 3 calls):

Scheme 2.4a: Mobilisation of funding for COVID-19 research in sub-Saharan Africa

Description

Background

The EDCTP "Emergency Funding Mechanism" allows rapid mobilisation of research funding based on a call for expressions of interest in exceptional and duly substantiated emergencies. EDCTP considers a situation as an emergency if it is unforeseen and presents a serious and immediate risk to human health. The "Emergency" status is adopted only after an official declaration of a situation as 1) a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, or 2) a public health emergency under Decision 1082/2013/EU or 3) an emergency under applicable national frameworks and regulations.
Following the novel Coronavirus disease (COVID-19) outbreak in December 2019, there has been an unprecedented rapid spread across more than 181 countries, with more than 1 million confirmed cases globally(1) as of 3 April 2020.
On 30 January 2020, following the recommendations of the Emergency Committee, the WHO Director-General declared that the COVID-19 outbreak constitutes a Public Health Emergency of International Concern (PHEIC) (2). On 11 March 2020, the WHO made the

assessment that COVID-19 can be characterised as a pandemic (3), following alarming levels of infection spread and disease severity.
In the light of rising numbers of cases being reported from affected countries, including several sub-Saharan African countries, the EDCTP Association has agreed to activate the emergency funding mechanism to support Research & Innovation Actions (RIAs) as part of the European response to the COVID-19 emergency.

Scope

EDCTP invites expressions of interest proposals for RIAs to support research activities in sub-Saharan Africa to manage and/or prevent the spread of the current COVID-19 outbreak. Proposals must demonstrate the following:

- Addressing urgent research questions in the context of the current COVID-19 outbreak, in line with the research priorities of the Global Research Roadmap (4) and the WHO R&D Blueprint for rapid activation of R&D activities during epidemics.
- Strengthening of national and local research capacity.
- Coordination and collaboration with other research and/or humanitarian activities operational in the countries affected, following principles of good participatory practice for emerging and re-emerging pathogens (5).
- Compliance with International Council on Harmonisation – Good Clinical Practice (ICH-GCP), regulatory and ethical standards.
- Commitment to open access and data sharing principles.

Proposals should provide novel, critical and timely insights into the COVID-19 outbreak in sub-Saharan Africa and/or potential avenues for its management or prevention.
Proposals must be timely, with rapid activation, to enable early and valuable outcomes to be established and/or to access time-dependent resources.
The call for expressions of interest priorities are based on the research gaps identified by the WHO Strategic and Technical Advisory Group for Infectious Hazards (STAG-IH) in its meeting of 12 March 2020.
The STAG-IH recommendations incorporate the research priorities agreed by the WHO Research and Development Blueprint Scientific Advisory Group that met on 2 March 2020, in Geneva, Switzerland, to prioritise the recommendations of an earlier WHO-GloPID-R meeting on COVID-19 research held on 11-12 February 2020.
Proposals submitted under this expression of interest must address one or more of the following research gaps:

1. Understanding of the natural history of infection to better define the period of infectiousness and transmissibility; improve surveillance capabilities to more accurately estimate the reproductive number in various outbreak settings and improve understanding of the role of asymptomatic infection in transmission.

2. Promote the development, adaptation, evaluation, and implementation of point-of-care diagnostic tests that can be used to screen all patients presenting with a history consistent with COVID-19 infection.
3. Support standardised, best evidence-based approaches for clinical management and better health outcomes for patients by contributing to the implementation of randomised, controlled trials for diagnostics and therapeutics as promising agents emerge, taking usability, including multi-centre/country trials and access in resource-constrained settings, into account.
4. Validation and adaptation of existing serological tests, including those that have been developed by commercial entities, and establishment of biobanks and serum panels of well characterised COVID-19 sera to support such efforts.

Applicants should be aware that proposals funded under this call for expressions of interest will be required to make available their research data of urgent policy relevance, at the latest within 30 days after it has been generated, through open access or, if agreed by the EDCTP Association or by the European Commission, by giving access rights to those third parties that need the research data to address the public health emergency, in accordance with the relevant option of Article 29.3 (1c) of the H2020 model grant agreement.

- It is expected that quality-controlled data are shared in accordance with the FAIR (findable, accessible, interoperable and re-usable) principles. The use of harmonised protocols in collaboration with ongoing EDCTP2 actions is recommended for this purpose.

A draft data management plan (DMP) must be submitted preferably with the proposal and at the latest before the signature of the grant agreement. The DMP should address the relevant aspects of making the data FAIR, including what data the project will generate, whether and how the data will be made accessible for verification and re-use, and how it will be circulated and preserved.
Eligibility of costs: costs related to data management and data sharing are eligible for reimbursement during the project duration.
The use of WHO harmonised protocols (such as the solidarity protocol and the generic protocol on the surveillance and clinical epidemiology) is highly recommended for this purpose. Proposals must also commit to open access to results and publications generated from the action, and to fair access to products developed or evaluated under this funding mechanism to address the declared Public Health Emergency.
Beneficiaries in grants awarded under actions relating to this Public Health Emergency will be allowed to charge the cost of clinical studies on the basis of unit costs established in line with a methodology set up in the Commission Decision C(2016) 7553, which is available on the H2020 Funding and tenders Portal.
EDCTP considers that proposals for activities of between 6 and 24 months duration would allow to contribute appropriately to this specific challenge.

Expected Impact

Proposals funded under this mechanism should answer the most pressing questions raised by responders in sub-Saharan Africa to the ongoing Public Health Emergency, as part of the efforts to manage and prevent the spread of the current pandemic. Proposals should result in new knowledge to manage and prevent the current COVID-19 outbreak, as well as strengthen the capacities of at-risk countries to manage outbreaks.

Scheme 2.4b: Addressing gender and diversity gaps in clinical research capacity at the EDCTP Regional Networks of Excellence

(draft call text as of 28 Aug 2020; not yet published on EDCTP website)

Description

As part of its contribution to the EDCTP2 Programme, the UK Department of Health and Social Care (DHSC) is supporting a Participating States Initiated Activity (PSIA) in 2020 titled 'Towards addressing gender and diversity capacity gaps in clinical research in sub-Saharan Africa'. The activity responds to the findings and recommendations of the EDCTP-Africa CDC workshop *Collaborating to improve gender-related and regional disparities in research funding* held on 19-20 November 2019, at Africa Union Headquarters, in Addis Ababa, Ethiopia, and aligns with EDCTP's COVID-19 related research capacity strengthening efforts as part of its 2020 Work Plan.

Challenge

Since 2003, EDCTP funding has had a major impact on the development of clinical research capacity in both human capital and infrastructure. This can be seen by the growing number of EDCTP Fellows and grant holders taking up scientific leadership positions in Africa, as well as the increased number of institutions across sub-Saharan Africa that have established or improved facilities with multidisciplinary research teams that are now capable of carrying out clinical studies of international standards. However, there remain significant geographical disparities in the EDCTP portfolio, with limited participation in EDCTP-funded projects and fellowships level from Central and West Africa, and at individual countries level as well as upcoming research institutions in East and Southern Africa. Furthermore, there is a gender imbalance with fewer women applying for and receiving EDCTP funding at the level of fellowships and as coordinators of research consortia. These regional disparities and gender imbalances may become increasingly pronounced in the context of infectious disease outbreaks. The ongoing COVID-19 pandemic and other recent outbreaks of emerging and re-emerging diseases

in sub-Saharan Africa have served to highlight the heterogeneity of health research infrastructures and the variation in preparedness capacity within and between countries and regions to handle emergencies and conduct comprehensive and well-coordinated research in response to such disease threats. Against this backdrop, this PSIA aims to address these disparities by supporting the training of 20 female PhD candidates at the EDCTP Regional Networks (five PhD candidates/network).

Scope

Proposals should describe how the Network will support the training of female PhD candidates, in line with the recent report and recommendations from the EDCTP-Africa CDC Workshop[1] and should include the following:

- Strategy to advertise, attract and support competitive applications from PhD candidates, particularly from under-represented countries within the Network
- Transparent and fair mechanism to assess and select candidates
- Framework to ensure adequate supervision and mentorship arrangements for each PhD candidate, including regular reporting to the independent advisory committee of the Network
- Compliance with highest international standards and ethical conduct of research
- Plans to support the career development of PhD candidates, including networking and training opportunities to extend their experience and expertise
- Development and/or refinement of a Network policy on diversity, equality and inclusion to be implemented at each institution in the network, including data collection and monitoring of the effectiveness of the policy.

Proposals must fit with the scope of EDCTP2 and should address key areas such as epidemic preparedness, health economics (e.g. on the impact of infectious diseases and epidemics like COVID-19), related non-communicable diseases (NCDs) and improvement of the investments of African countries in Research and Development (R&D) through capacity development related to health research and innovation that are contributors to the economic growth of African countries. Research on COVID-19 is strongly encouraged, as part of the efforts to strengthen the EDCTP Regional Networks so they are more resilient in responding to COVID-19 (or future emerging threats). The planned research studies should incorporate sex and gender considerations in the study designs[i].

Expected impact

Proposals are expected to contribute to the training and development of female scientists in sub-Saharan Africa to become future research leaders and to address geographical disparities in research capacity across sub-Saharan Africa.

Eligibility considerations

[1] https://edctpprint.maglr.com/edctp-africa-cdc-networking-workshop/cover1

Maximum budget per proposal is 500,000 Euros. Proposals must comply with the following requirements:

- Earmarked for EDCTP Regional Network-supported PhD applications by young female scientists with eligible qualifications for enrolment in a PhD programme and with a clear project proposal, academic registration status, and dedicated supervisors.
- Covering research across all disease areas under the remit of EDCTP2. Research on COVID-19 is strongly encouraged, as part of the efforts to strengthen the Regional Networks so they are more resilient in responding to COVID-19 (or future emerging threats)
- Awarded to training programmes based in Africa or where the majority (at least 70%) of training work will be done in Africa in case of enrolments being done as part of a sandwich programme
- Prioritising PhD studies, however, in under-represented regions such as some lusophone and some francophone countries, grant winners will be encouraged to enroll female MSc students under their mentorship, to start filling the capacity gaps
- Spread among applicants to also support PhDs that will cover under-served disciplines such as health economics
- In the funding range of 100,000 – 150,000 Euros per student over a period of 3 years; covering tuition and additional needs (such as maternity leave and childcare) including flexibility of an additional 6 to 12 months study period, where justifiable
- Applicable to students from EDCTP Regional Networks and hosting institutions that subscribe to the recommendations from the EDCTP gender/geographical gaps networking meeting
- Proposals are for a maximum duration of four years, with a start date of no later than 1 December 2020.

Application and evaluation procedure

Applications from EDCTP Regional Networks for this PSIA funding must be submitted by 17 October 2020.
Proposals will be subject to independent peer review evaluation, according to the procedure of EDCTP PSIAs
Decisions are expected by 16 November 2020.
Grant agreement must be signed by 30 November 2020 for activities to commence on 1 December 2020.

Scheme 2.4c: Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC

Description

Background

Reliable epidemiological data is often unavailable or severely limited in resource-limited settings in sub-Saharan Africa, and this knowledge gap is further aggravated by a shortage of skilled personnel in epidemiology and biostatistics to efficiently monitor, analyse and interpret these data to inform policy and decision making. Training programmes are needed to develop a cohort of epidemiologists across sub-Saharan Africa and beyond, which can work in collaboration with their national departments of health, national public health agencies, as well as with international organisations such as the World Health Organisation Regional Office for Africa (WHO AFRO) and Africa Centres for Disease Control and Prevention (Africa CDC), to collectively conduct routine surveillance, conduct public health research and respond timely to disease outbreaks.
As a specialised technical agency of the Africa Union, Africa CDC operates through a framework focused on harnessing regional resources (all five African regions); the Regional Integrated Surveillance and Laboratory Network (RISLNET) in order to carry out its mandate and achieve the strategic pillars (public health emergency preparedness and response, surveillance and disease intelligence, information systems, laboratory systems and networks, and public health research and institutes) through the National Public Health Institutes (NPHIs). Effective implementation of these strategic pillars depends on the efficiency of the NPHIs and/or affiliated agencies, such as academic institutions in Member States.
The Africa CDC has also developed a framework for public health workforce development. Building on numerous investments already made by EDCTP and its partners in sub-Saharan Africa for disease outbreak preparedness and response, this partnership between EDCTP and Africa CDC will further enhance the public health workforce capacity in NPHIs and National Ministries of Health to better enable them to respond timely to disease outbreaks.

Scope

The purpose of this Call for Proposals is to establish an African cohort of epidemiologists by supporting institutions in sub-Saharan Africa and Europe that provide master's training in epidemiology and biostatistics, as part of the Africa CDC's framework for public health workforce development. Master's courses with practical field research experience is the preferable level of training as it is relatively short and likely to deliver

the required numbers and high-quality fit-for-purpose calibre of personnel that are urgently needed in epidemic zones of sub-Saharan Africa.
Proposals can be submitted by a single institution or consortium of institutions which must provide master's training in epidemiology for 10 to 15 excellent, early- to mid-career researchers ("EPI Fellows") based in sub-Saharan Africa and working in a relevant field. The EPI fellows must commit to remain in Africa for a minimum of two years after completing their studies and provide evidence to demonstrate this through a letter of support from their host institution.
Proposals should include institutions with a proven track record in the provision of high-quality master's training with clear local and regional collaborations with NPHIs (or similar agencies), Ministries of Health and other academic institutions. Proposals must demonstrate the following:

- A high-quality master's programme in epidemiology and biostatistics relevant to infectious diseases of importance in sub-Saharan Africa.
- An open, fair and transparent procedure for selecting EPI Fellows based in different geographical regions of Africa, and with appropriate gender balance, for entry into the master's programme.
- Robust mentorship and supervision mechanisms to support EPI Fellows through to timely successful course completion.
- The master's programme must include a research component, which must be conducted in a country in sub-Saharan Africa, in collaboration with local or regional NPHIs (and/or affiliated agencies) or Ministries of Health.

Proposals should also include support for meetings and conferences for the trainees to participate in an annual networking meeting organised by Africa CDC, as well as the biennial EDCTP Forum. Tuition fees, enrolment fees or other types of university charges are not eligible for reimbursement by EDCTP.
Due to the extraordinary global crisis of COVID-19 that is also affecting African countries, this topic should also be considered by applicants.
The proposed action should start no later than 1 October 2021 and must be completed before the end of 2024.

Expected impact

Projects funded under this call for proposals should:

- Increase the number of skilled infectious disease epidemiologists working in Africa.
- Enhance research capacity in epidemiology across Africa.
- Encourage trans-national cooperation between epidemiologists in Africa and with Africa CDC.
- Strengthen the ability of African countries to prepare for and to manage epidemic disease outbreaks.
- Promote the career development and retention of postdoctoral and postgraduate researchers in Africa

- Contribute towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'.
- Enhance research capacity in poverty-related diseases and in clinical trials across Africa.

Ultimately these grants will contribute to the generation of a critical mass of epidemiologists and biostatisticians and institutional research capacity in sub-Saharan Africa.

[i] https://cihr-irsc.gc.ca/e/51939.html; https://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=gender