



EDCTP

The power of sharing science

EDCTP2 work plan 2019

Responsible person:

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Important notice:

This annual work plan covers 2019 and describes planned activities under the EDCTP2 programme in 2019.

The EDCTP2 Work Plan for 2019 was approved by the European Commission on 15 April 2019, following the positive outcome of its external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. The EDCTP Association Board subsequently approved the 2019 Work Plan on 22 April 2019. Final approval was given on 22 May 2019 by the EDCTP Association General Assembly.

Notice

Please note that until the UK leaves the EU, EU law continues to apply to and within the UK, when it comes to rights and obligations; this includes the eligibility of UK legal entities to fully participate and receive funding in Horizon 2020 actions such as those called for in this work plan. Please be aware however that the eligibility criteria must be complied with for the entire duration of the grant. If the UK withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, they will no longer be eligible to receive EU/JU funding and their participation may be terminated on the basis of Article 50 of the grant agreement.



About EDCTP

EDCTP's mission is to contribute to the reduction of the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa.

We support collaborative clinical research to accelerate the development of accessible, suitable and affordable medical interventions to identify, prevent or treat these diseases. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

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1. Introduction

The overall objective of the second programme of the European & Developing Countries Clinical Trials Partnership (“the EDCTP2 programme”) is to contribute to the reduction of the social and economic burden of poverty-related diseases (PRDs) in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable *medical interventions*¹ for PRDs in partnership with sub-Saharan Africa.

The EDCTP2 programme will run over a ten-year period from 2014 to 2024, and the European Union (EU) has decided to support the programme with a financial contribution of up to EUR 683 million from the Horizon 2020 programme’s societal challenge “*Health, Demographic Change and Well-being*” (“EDCTP2 Basic Act”²).

The EU’s financial contribution shall be conditional upon the following: (a) the implementation by the *EDCTP2 Implementation Structure* (“the EDCTP Association”) of the objectives and activities of the EDCTP2 programme as set out in annexes 1 and 2 of the EDCTP2 Basic Act; (b) the maintenance of an appropriate and efficient governance model for the EDCTP2 programme as set out in annex 3 of the EDCTP2 Basic Act; (c) the compliance by the EDCTP Association with the reporting requirements set out in Articles 154 and 155 of the EU’s Financial Regulation³; and (d) the fulfilment of the commitment by each Participating State⁴ to contribute to the financing of the EDCTP2 programme as referred to in Article 3.1 (point e) of the EDCTP2 Basic Act².

The EDCTP Association is legally established as an Association under Dutch law in the Netherlands⁵. The EDCTP Association currently counts 30 Partner States (PS) as full and equal members: 14 European and 16 African countries^{6,7}.

The EDCTP Association is composed of the *General Assembly* as the governing body, the Secretariat as the executive body led by the *EDCTP Executive Director*, and the *Board* supervising the *Secretariat*⁸.

1.1. Scope of the EDCTP2 programme

The activities of the EDCTP2 programme will contribute towards achieving the following five specific objectives⁹:

1. Increase the number of new or improved medical interventions for poverty-related diseases (PRDs), including neglected ones¹⁰;
2. Strengthen cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, EU and international legislation;
3. Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments;
4. Extend international cooperation with other public and private partners to ensure that the impact of all research is maximised and that synergies can be taken into consideration and to achieve leveraging of resources and investments;
5. Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance.

The drive to achieve the Millennium Development Goals (MDGs)¹¹ provided important impetus for the creation of EDCTP. Equally, the EDCTP2 programme shall contribute to the United Nations' Sustainable Development Goals (SDGs)¹² and is a major commitment of its 30 Partner States and the EU to that end. While the promotion of health is only one of the 17 goals (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'), the achievement of the other SDGs is affected by or depends significantly on good health of people, including vulnerable and neglected ones. Improved health and its attendant economic benefits will contribute to multiple social and economic goals.

1.2. Activities of the EDCTP2 programme

The activities of the EDCTP2 programme are either implemented by the EDCTP Association (EU-funded actions, supported with the EU contribution to the EDCTP2 programme) or by the EDCTP2 Participating and Partner States^{3,5,6} (non-EU funded activities, supported with national funds), as so-called "Participating and Partner States' Initiated Activities" (PSIAs).

EU-funded actions are evaluated, selected and funded in line with the Rules for Participation (RfP)¹³ of Horizon 2020 following open *Calls for Proposals* that are centrally managed by the EDCTP Association, whereas PSIAs are funded following national evaluation, selection and granting processes that are implemented by one or several PSs in line with common principles agreed between the EDCTP Association, on behalf of the PSs, and the European Commission (section 6.5). In order to support activities of strategic reach with a high expected impact but requiring a critical scale of resources, the EDCTP Association will partner with third countries, or their scientific and technological organisations and agencies; with international organisations; or, with other third parties to jointly fund activities.^{14,15}

The EDCTP2 programme supports clinical trials and related activities on PRDs and capacity development for clinical trials and related research in sub-Saharan Africa. All phases of clinical trials (phases I to IV) for new or improved medical interventions, as well as advanced testing and field validation of new diagnostic tools can be supported under the EDCTP2 programme. Similarly, the EDCTP2 programme supports capacity development activities to strengthen the enabling environment for conducting clinical trials in sub-Saharan Africa in compliance with fundamental ethical principles and relevant national, Union and international legislation. Moreover, the EDCTP2 programme promotes networking, coordination, alignment, collaboration and integration of national research programmes and activities on PRDs among the PSs at the scientific, management and financial level.^{13,16}

The activities of the EDCTP2 programme are supported along three distinct types of actions¹⁷: i) Research & Innovation Actions (RIA), ii) Coordination & Support Actions (CSA), and iii) Training & Mobility Actions (TMA). These types of actions are described in more detail in section 6.4.

1.3. Implementation of the EDCTP2 programme

The EDCTP2 programme is implemented by the EDCTP Association on the basis of annual work plans and a multi-annual strategic business plan¹⁸.

The present EDCTP2 annual work plan 2019 has been developed in compliance with the objectives and provisions set out in the EDCTP2 Basic Act, and following a comprehensive consultation process, involving multiple stakeholders. The consultation process has included meetings and workshops with academic researchers, pharmaceutical industry, product development partnerships (PDPs), charities and foundations, international organisations and

health research funders outside of Europe and Africa. In addition to these events, the EDCTP Association has conducted studies and assessments with regards to the outcome and impact of activities funded under the first EDCTP programme. Within the objective of cooperation with international development assistance initiatives, the EDCTP Association has also taken into account the recommendations issued by relevant initiatives of the World Health Organization (WHO).

The EDCTP2 annual work plan 2019 provides information about EU-funded Calls for Proposals in 2019 (Chapter 2), including the challenge, scope and expected impact, as well as the eligibility requirements and other specific conditions for applying. Detailed supporting information about the evaluation, selection and granting process, and applicable type of grant agreements and funding levels is summarised under each call topic, and described in more detail in the General Annexes (Chapter 6).

The EDCTP2 annual work plan 2019 also contains an overview of non-EU funded PSiAs in 2019 (Chapter 4). The PSiAs in the current EDCTP2 annual work plan are all funded and implemented directly by one or more PSs. They are major contributions (in-kind) of the PSs to the EDCTP2 programme and constitute an integral part of the EDCTP2 programme.

In accordance with the EDCTP2 Basic Act, the draft EDCTP2 annual work plan 2019 was subject to an external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. This evaluation was organised by the European Commission services and involved an international peer review panel composed of four independent senior research managers.

EDCTP acknowledges financial contributions for the implementation of the EDCTP2 programme and its 2019 calls from the EU and the governments of the following countries: Germany, Netherlands, Portugal, Spain, Sweden and United Kingdom. These are summarised in budget overview tables 2 and 14.

EDCTP also acknowledges contributions for the implementation of the EDCTP2 programme and its 2019 calls from the following organisations: the African Research Excellence Fund (AREF), *Novartis*, the Coalition for Epidemic Preparedness (CEPI), and *members of the European Federation of Pharmaceutical Industries and Associations (EFPIA)*. See Table 3 on the budgeted contributions to activities of the EDCTP2 programme in 2019 by Third Parties (TPs) and Third Countries (TCs).

1.4. Budget overview tables

Table 1. Overview of budgeted contributions to activities of the EDCTP2 programme in 2019 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)/ Third Countries (TCs)

Activities EU*		2019 Budgeted Contributions (in EUR)			Total 2019 Budgeted Contributions (in EUR)
		EU*	PSs*	TPs/TCs	Total
EU-funded activities	Calls for Proposals implemented by EDCTP	98,230,160	18,189,840	10,750,000	127,170,000
	Other Activities implemented by EDCTP	4,940,000	0	0	4,940,000
Administrative costs of EDCTP		4,829,840	408,631	0	5,238,471
Sub-Total EU funded activities		108,000,000	18,598,471	10,750,000	137,348,471
Non-EU funded activities	Non-EU funded PSAs implemented by PSs	0	173,357,432	0	173,357,432
	New activities including Calls for Proposals managed by EDCTP	0	304,000	920,000	1,224,000
Sub-Total non-EU funded activities		0	173,661,432	920,000	174,581,432
Total Budget		108,000,000	192,259,903	11,670,000	311,929,903

*Details in tables 2, 14 and 15.

**Details in table 3.

Table 2. Detailed overview of budgeted contributions to activities of the EDCTP2 programme in 2019 by the European Union (EU), and European and African Partner States (PSs)

	2019 Budgeted contributions (in EUR)				Total 2014-2019
	Financial contributions to be managed by EDCTP*	New activities, including Calls for Proposals managed by EDCTP**	PSAs*** / In-kind****	Total in 2019	
European Union (EU)					
European Commission (EU budget)	108,000,000	-	-	108,000,000	584,828,313
Sub-Total EU	108,000,000	-	-	108,000,000	584,828,313
Participating States**** (European Partner States)					
Austria (AT)	-	304,000	-	304,000	3,918,000
Denmark (DK)	-	-	-	-	7,705,992
Finland (FI)	-	-	475,980	475,980	2,263,480
France (FR)	-	-	5,326,035	5,326,035	81,473,782
Germany (DE)	3,000,000	-	670,000	3,670,000	132,706,056
Ireland (IE)	-	-	-	-	20,132,546
Italy (IT)	-	-	548,503	548,503	5,073,503
Luxembourg (LU)	-	-	-	-	2,300,000
Netherlands (NL)	100,000	-	5,585,000	5,685,000	23,033,918
Norway (NO)	-	-	10,000,000	10,000,000	38,314,847
Portugal (PT)	200,000	-	-	200,000	2,380,627
Spain (ES)	30,000	-	1,485,000	1,515,000	8,598,970
Sweden (SE)	2,500,000	-	128,303,184	130,803,184	206,540,751
United Kingdom (UK)	12,768,471	-	19,831,100	32,599,571	456,572,717

Sub-Total European PSs	18,598,471	304,000	172,224,802	191,127,273	991,015,189
African Partner States					
Burkina Faso (BF)	-	-	-	-	525,753
Cameroon (CM)	-	-	48,000	48,000	1,078,839
Congo (CG)	-	-	-	-	309,556
Ethiopia (ET)	-	-	-	-	-
Gabon (GB)	-	-	-	-	812,330
The Gambia (GM)	-	-	-	-	682,000
Ghana (GH)	-	-	115,705	115,705	3,099,932
Mali (ML)	-	-	760,735	760,735	3,367,422
Mozambique (MZ)	-	-	95,494	95,494	722,348
Niger (NE)	-	-	38,096	38,096	210,363
Nigeria (NG)	-	-	-	-	-
Senegal (SN)	-	-	-	-	796,379
South Africa (ZA)	-	-	-	-	26,720,846
Tanzania (TZ)	-	-	-	-	558,300
Uganda (UG)	-	-	74,600	74,600	867,651
Zambia (ZM)	-	-	-	-	8,973,000
Sub-Total African PSs	-	-	1,132,630	1,132,630	48,724,719
Sub-Total European+African PSs	18,598,471	304,000	173,357,432	192,259,903	1,039,739,908
Grand Total EU, European and African PS	126,598,471	304,000	173,357,432	300,259,903	1,624,568,221

*Financial contributions from PSs to EDCTP2 calls, other actions and administrative costs implemented by EDCTP that are co-funded by the EU.

** In-kind contributions to the EDCTP2 programme per Article 4.1, para. 2 of Decision No 556/2014/EU.

***Value of new contracts or legal obligations that PSs expect to sign in 2018, excluding direct financial contributions from PSs (i.e. managed by PSs) to EDCTP2 funded projects.

****Only the contributions of the European PSs count for calculating the matching contribution by the EU since these are the (European) PSs as defined in the EDCTP2 Basic Act.

Table 3. Overview of budgeted contributions to activities of the EDCTP2 programme in 2019 by Third Parties (TPs) and Third Countries (TCs)

Third Parties/ Third Countries	Budgeted Contributions by TPs/TCs (in EUR)		
	Financial	In-kind	Total
EFPIA members	0	500,000	500,000
AREF	0	420,000	420,000
CEPI	10,000,000	0	10,000,000
Novartis	750,000	0	750,000
Grand Total	10,750,000	920,000	11,670,000

2. EU-funded Calls for Proposals

2.1. Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2019:

2.1.1 Strategic actions supporting large-scale clinical trials

Challenge:

There is an urgent need for new or improved products for tackling poverty-related diseases (PRDs). Late phase clinical trials (Phase III/IV) are at a 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, vaccines, microbicides) or diagnostics, including multiplex diagnostic platforms, for PRDs. Proposals for a strategic action must focus on phase III/IV study(ies) or advanced field testing (in the case of diagnostics) on PRDs within the remit of the EDCTP2 programme. The proposed EDCTP2-funded study(ies) should be conducted in sub-Saharan Africa but may form part of 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. The proposal must include full details of the product development milestones, as well as details of any consultation with/advice received from regulatory agency(ies).

The Call for Proposals is open to all diseases within the scope of the EDCTP2 programme, with the exception of malaria that was covered by two targeted calls for Strategic Actions in the EDCTP2 work plan 2018. Proposals for strategic actions that address topics not covered in the scope of the other EDCTP2 calls for proposals launched in 2019 are particularly encouraged.

Proposals for a strategic action must 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. The EDCTP Association considers that proposals for a strategic action of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately.

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.

Table 4. Supporting information for the Call for Proposals 'Strategic actions supporting large-scale clinical trials'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-4
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Single-stage application procedure. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The standard award criteria, scoring, thresholds and weightings listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ¹⁹
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.2 Paediatric drug formulations for poverty-related diseases

Challenge:

Poverty-related diseases (PRDs) remain the leading causes of morbidity and mortality in sub-Saharan Africa, especially during childhood. Despite progress in other age groups, effective treatment and prevention of PRDs in paediatric populations is often lacking and/or lagging. The frequent exclusion of children and adolescents from clinical trials and the paucity of available products that target this group are factors that contribute to this population having one of 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 paediatric populations. Therefore, concerted efforts are needed to increase access to potentially life-saving, cost-effective interventions to prevent and treat PRDs in children and to enhance use of existing interventions in this population.

Scope:

Proposals should focus on adaptation of existing medicinal products (drugs), including off-patent products, to the specific needs of children (0-17 years of age). Proposals may address any of the PRDs within the remit of the EDCTP2 programme. Proposals should include one (or more) clinical trials conducted in sub-Saharan Africa to assess the safety, efficacy and pharmacokinetics of the drug(s), and/or the development of age-appropriate formulations. Projects must assure that the clinical trials are conducted appropriately, in line with guidelines on pharmaceutical development of medicines for paediatric use²⁰, respecting current legislation and considering the ethical aspects and particular needs of the study subjects and their families. Applicants should seek advice on clinical trial design from the appropriate regulatory agency(ies) before developing the application. The EDCTP Association considers that proposals for actions of between 36 and 60 months duration would allow this specific

challenge to be addressed appropriately.

The clinical need for paediatric dosing should be clearly explained in the proposal. The proposal must include full details of the strategy for the clinical paediatric development, including product development milestones and go/no-go criteria for the proposed clinical trial(s) as well as specific plans for the subsequent regulatory approval process, ideally a paediatric investigation plan, which should aim at obtaining a relevant market authorisation such as the Paediatric Use Marketing Authorisation (PUMA) or equivalent.

Expected impact:

The actions supported under this call should have the potential to achieve maximum impact in the field and to make a significant contribution to the objectives of the EDCTP2 programme, and in particular:

- contribute towards the development or adaptation of medicinal products for use in children.
- lead to the advancement of new drugs and/or drug combinations, with the aim of registration of new drug(s) and/or drug combinations for treatment and prevention of PRDs in children in sub-Saharan Africa and globally
- contribute to the reduction of mortality and morbidity in sub-Saharan Africa, particularly in children and thus contribute to achieving SDG 3 ‘Ensure healthy lives and promote well-being for all at all ages’.

Table 5. Supporting information for the Call for Proposals ‘Paediatric drug formulations for poverty-related diseases’

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	6-8
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ¹⁹
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.3 Strategic actions on product-related implementation research

Challenge:

Failure to translate research findings into policy and practice impedes research from achieving maximum public health benefit. New products and/or novel clinical interventions (i.e., new drug combinations/new formulations, clinical management algorithms), for poverty-related diseases (PRDs), may not reach the target populations, especially in resource-poor settings such as sub-Saharan Africa, because of challenges in ensuring the delivery and uptake of medical products into clinical practice. Further, barriers to adherence may compromise the effectiveness and public health benefit of new interventions. Therefore, concerted efforts by multiple stakeholders are needed to maximise the use of available, efficacious products and interventions in order to ensure that these innovations achieve their full potential in real-life

clinical and community settings.

Scope:

The purpose of this Call for Proposals is to support distinct strategic actions to translate medical interventions of proven efficacy (diagnostics, drugs, vaccines and microbicides) into routine care. Proposals may include testing of delivery methods to increase population coverage, retention in care and adherence to the intervention. Proposals must focus on PRDs in the scope of the EDCTP2 programme and should leverage major support from other funders. The study (ies), which may be interventional or non-interventional in design and which must take place in sub-Saharan Africa, should be presented in detail and with clear justification as to why this is the appropriate design to provide robust evidence that can lead to policy change at national, regional and/or international level. Proposals must include a landscape analysis of the most important product-related implementation research gaps to justify the importance of the proposed research. Proposals must include a clear, credible plan of the pathway to achieve policy change or uptake within a defined timeline. This could relate to products that are not licenced or not eligible for reimbursement but then the applicants must indicate a credible uptake plan. The EDCTP Association considers that proposals for actions of between 24 and 48 months duration would allow this specific challenge to be addressed appropriately.

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'
- contribute towards the reduction of the burden of PRDs in sub-Saharan Africa
- contribute to policy change at the national, regional and/or international level.

Table 6. Supporting information for the Call for Proposals 'Strategic actions on product-related implementation research'

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	4-7
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ¹⁹
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.4 Vaccines against Lassa virus – Joint call with the Coalition for Epidemic Preparedness Innovations (CEPI)

Challenge:

Vaccines have contributed enormously to the successful control and elimination of many

diseases, but few vaccines have so far been developed for the prevention and control of emerging infectious diseases. Lassa virus (LASV) has been added to the WHO [R&D Blueprint list](#) of diseases for which there is an urgent need for accelerated research and development, considering the disease's potential to cause a public health emergency, and given the absence of efficacious drugs and/or vaccines. In the coming years, several candidate vaccines against LASV will enter clinical development and there is an urgent need to fast track their development. The aim is to facilitate the development of promising vaccines and the preparation of investigational sites in affected countries to be ready to perform proof of concept and/or pivotal efficacy trials.

Scope:

The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are part of efforts to prepare and conduct a large-scale clinical trial that has the potential to achieve proof of concept and/or the demonstration of pivotal efficacy of novel candidate vaccines against LASV.

Applications are invited for large-scale collaborative projects which include one or more clinical trials (phase II to III) aiming to accelerate the clinical development of Lassa candidate vaccines. Applications must include a minimum of one clinical trial to be conducted in affected countries in sub-Saharan Africa to test the safety, immunogenicity and/or efficacy of a candidate vaccine. Proposals that include phase III trials are particularly encouraged.

Projects should incorporate activities to enhance the capacity of existing trial sites and/ or develop new trial sites in affected countries in sub-Saharan Africa for the conduct of vaccine trials. These activities could include observational (site set-up) studies, retrospective evaluation of available epidemiological data and prospective cohort studies to define incidence and case definitions for subsequent efficacy trials. Strengthening of laboratory testing capacity for case ascertainment and product evaluation is considered in scope when necessary for supporting the proposed clinical trial(s). This could include the evaluation of newly developed or newly standardized diagnostic assays for LASV and immunological read-outs for vaccine performance as well as the setup or strengthening of regional or in-country biobanks for sample storage and archiving.

These activities would ideally build on and leverage existing or developing networks of excellence or ongoing capacity development of researchers, institutions and sites, including existing national or regional biobanking facilities, in sub-Saharan Africa, to conduct clinical trials and related research, including observational studies. Inclusion of plans to involve public health authorities in disease-endemic countries are also encouraged.

Supporting information on the composition and scale, as well as on the management structures and procedures of the large-scale clinical trial must be presented to enable assessment of their appropriateness.

The EDCTP Association and CEPI consider that proposals for actions of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. When the EDCTP Association and CEPI deem participation of the entity essential for carrying out the action, legal entities from anywhere in the world will be eligible for funding through this call for proposals.

Expected impact:

Actions supported under this Call for Proposal should advance the development of promising LASV candidate vaccines moving towards regulatory licensure. The actions should also contribute towards a better understanding of the mechanisms of the reactogenicity (safety), immunogenicity and efficacy profile of the LASV candidate vaccine(s) and build capacity for the

evaluation of vaccines against LASV and other EIDs in sub-Saharan Africa.

Capacity enhancing activities should contribute to strengthening regional, national, institutional and individual capacities to conduct clinical trials for product evaluation according to ICH-GCP standards and generate data to inform trial design and appropriate endpoints.

Table 7. Supporting information for the Call for Proposals ‘Vaccines against Lassa virus - Joint Call with the Coalition for Epidemic Preparedness Innovations (CEPI)’

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	1-2
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply. ²¹
Submission and evaluation procedure	Single-stage application procedure. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ¹⁹
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.5 New drugs and vaccines for priority pathogens in antimicrobial resistance²²

Challenge

Antimicrobials are designed to kill or stop the growth of diseases-causing pathogens, but many of them have become increasingly ineffective due to emerging resistance by the targeted bacteria, viruses, protozoa or fungi. Selection pressure naturally leads to the emergence of resistance whenever microbes are exposed to agents who are meant to kill them or inhibit their growth, and the potentially spreading resistance can take days or years. Pathogens can also develop resistance to multiple agents, and as a result, very hard to control multi-drug resistant infections emerge and spread. To guide and promote research and development of new antibiotics and vaccines, the WHO has established a list of antibiotic-resistant priority pathogens. While new or improved antimicrobials is an essential tool to combat resistant pathogens at patient level, the first line of defense for containing the spread of antimicrobial resistance (AMR) at population level is an effective system to diagnose, detect, collect and integrate information about antimicrobial resistance on a large scale. In the context of large programmes to address AMR, isolated efforts will have very limited impact, and only coordinated actions will lead to a successful response against the emergence and spread of AMR.

Scope

The purpose of this Call for Proposals is to provide funding for clinical trials to be conducted in sub-Saharan Africa which aim to develop new or improved medicinal products (drugs and vaccines) or combinations thereof against pathogens from the WHO priority list that also falls within the scope of the EDCTP2 programme, specifically *Campylobacter*, *Salmonella*, *Streptococcus pneumoniae*, and *Mycobacterium tuberculosis*.

Proposals should include at least one clinical trial (phase I to IV) in sub-Saharan Africa. Proposals should clearly define the activities and mechanisms to be used within the project, including details of any collaboration with public authorities, international organisations or commercial partnerships that will be established in order to achieve the expected impact.

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.

Projects should include a detailed exploitation plan that describes how project results will be translated into products, policy or practice. The EDCTP Association considers that proposals for actions of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately.

Expected impact:

Projects funded under this Call for Proposals should contribute towards national and international plans for containment of antimicrobial resistance.

Table 8. Supporting information for the Call for Proposals ‘New drugs and vaccines for priority pathogens in antimicrobial resistance’

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-4
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Single-stage application procedure. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ¹⁹
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.2. Fostering capacity development for clinical trials and related research in sub-Saharan Africa

Proposals will be invited for the following topics in 2019:

2.2.1 Ethics and regulatory capacities

Challenge

Many partners contribute towards the establishment and capacity strengthening of ethical review frameworks and medicines regulatory bodies, as well as mapping, coordination, and where appropriate, practical, harmonisation of their processes in sub-Saharan Africa (SSA). Ensuring sustainable development, country ownership and collaboration among external partners are some of the key elements required to support ethics and regulatory functions in SSA.

The EDCTP Association has dedicated its efforts to ensure that all SSA countries hosting clinical trials have functional and effective ethics and regulatory review structures at institutional, national and regional levels. The current strategy promotes fortification and collaboration of national ethics committees (NECs) and National Regulatory Authorities (NRAs) to allow for long-term development plans building towards strong regional

collaboration and harmonisation goals.

Despite ongoing efforts by different partners and agencies, ethics and regulatory oversight in SSA countries requires targeted attention to address the following gaps:

- i. Growing amount and complexity of research activities in the African region requiring better systems and technologies (including digitisation) to improve harnessing of external expertise, processing of review of research applications, handling of documentation, as well as data handling and its analysis;
- ii. A better understanding for the needs and challenges facing countries with varied levels of clinical trial activity, and tailoring interventions;
- iii. Growing need for quality control, certification and accreditation of ethics and regulatory bodies, and adherence to common international standards; and
- iv. Growing need for efforts towards open data access and the need to promote linkages between ethics and regulatory functions with clinical trial registration and systematic research reviews.

Scope

The purpose of this Call for Proposals is to fund projects that are designed to support SSA countries to establish and/or develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies in humans, as well as national and international collaboration in compliance with established, internationally acceptable good practices. This scheme targets projects with active involvement of NECs and/or NRAs from countries with both weak and strong ethics and regulatory capacities in SSA.

The objectives of this call are to:

1. Improve the efficiency of the functioning of NECs and NRAs through the introduction of innovative systems, reliance practices and/or technologies that would facilitate the various functions of these bodies with better quality outputs and improved timelines;
2. To promote quality control systems and process for NECs and NRAs, as well certification and accreditation of the various bodies, as well as adherence to international standards;
3. To promote international cooperation in ethics and regulatory activities through transfer of promising and successful innovative systems and/or technologies from other regions outside Africa and within Africa, fostering national and regional collaboration among these bodies;
4. Strengthen linkages between ethics and regulatory functions with other important structures, such as clinical trial registries and systematic reviewers whilst simultaneously enforcing the sharing of data in compliance with global requirements;
5. Promote the adoption and update of AVAREF, WHO, and other international standards and best practices by countries, groups of countries, or regional harmonization initiatives;
6. Support already established training centers to provide both innovative training, and mentorship to NECs and NRAs.

This call will support proposed actions that address one or preferably more of the objectives outlined above. Proposals should include support for development or scale up of innovative systems and technologies that support ethics and regulatory functions, training, networking and promotion of good practices and evidence-based adoption of accreditation models from relevant internationally endorsed/peer-reviewed documented sources.

SSA countries fit within three categories:

1. Countries with intense clinical trial activity,
2. Emergency-prone countries (e.g. countries where epidemics are likely to emerge or have emerged in the recent past) with fragile health systems, and

3. Countries with low clinical trial activity and with low risk of emergency/epidemics.

Proposals should clearly indicate the category(ies) of countries involved and how the proposed project will address the objectives of the call in the selected countries.

Each project should have at least two new staff members added to the team and trained in the new functions proposed in the actions.

Linkage of the project to other on-going initiatives, such as the Regional Centres of Regulatory Excellence in Africa²³, WHO-TDR-SIDCER (Strategic Initiative for Developing Capacity in Ethical Review), Africa Vaccines Regulators Forum (AVAREF), Pan African Clinical Trials Registry (PACTR); African Medicines Regulatory Harmonisation (AMRH) and regional bodies, such as Africa Centre for Disease Control and Prevention (CDC), and WHO-AFRO is encouraged and should be demonstrated in the application. Plans to foster bi-lateral links between the European Medicines Agency (EMA) and the national regulatory authorities in SSA are also encouraged.

The EDCTP Association considers that proposals for actions of between 24 and 36 months duration would allow these specific challenges to be addressed appropriately. Nonetheless, this does not preclude submissions and selection of proposals for actions 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'
- Strengthen the functionality, recognition and performance of NECs and NRAs in SSA countries to ensure that the clinical trials meet the appropriate standards and generate principles that will contribute towards harmonised oversight for certification of ethics and regulatory bodies from both weak and strong countries.
- Contribute towards development of sustainable strategies for both NECs and NRAs, strengthen linkages between these bodies and other important structures, such as clinical trial registries and systematic reviewers, and sharing of data in compliance with global requirements.
- Provide lessons that will inform continental or regional certifiers of ethics committees and regulatory agencies on how to formalise their function in SSA.
- Involve NECs and/or NRAs from sub-Saharan African countries not previously funded under the EDCTP2 programme²⁴

Table 9. Supporting information for the Call for Proposals 'Ethics and regulatory capacities'

Type of action	Coordination and Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	5-7
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this call for proposals: <ol style="list-style-type: none">1. Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries²⁵2. The requested funder contribution per action shall not exceed EUR 500,000.
Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.

Evaluation rules	The award criteria, scoring, thresholds and weightings for CSA listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi or mono-beneficiary) ²⁶
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement (where applicable).

2.2.2 Senior Fellowships Plus

Challenge

EDCTP has supported the development of a pool of highly qualified senior researchers in the field of poverty related diseases (PRDs) in sub-Saharan Africa (SSA). In order to make an impact in the fight against the PRDs, it is important to ensure that there is continued support for the development and retention of early and mid-career scientists in the regions that are most affected. However, there is a huge regional disparity in the success rate of EDCTP fellowship applications that has resulted in limited capacity strengthening in resource-limited countries. Gender balance among fellows is also a challenge. This geographical and gender imbalance in capacity development has resulted in inequitable distribution of trained personnel in disease endemic areas and many high burden, low income countries have been left behind. New strategies are required to strengthen capacity for clinical research in more resource-limited countries in SSA.

Scope

The purpose of this Call for Proposals is to support capacity development of potential African research leaders and to mentor junior researchers with emphasis on hands-on research training linked to clinical trials activities conducted in SSA.

The objectives of the scheme are:

1. to support senior researchers to advance themselves as recognised research leaders in high quality clinical trial research and related activities
2. to equip senior researchers with the necessary skills and experience to train and mentor junior researchers, both at their home institution and at institutions in countries in SSA with limited human and infrastructural capacity.

Applications should focus on hands-on research activities equipping the Senior Fellow with competences to lead, train and mentor junior researchers in a scientific area within the scope of the EDCTP2 programme¹⁰. Applications should include a clear and concise individual capacity development plan for the Senior Fellow with measurable indicators of how the project will advance the Senior Fellow's personal development towards scientific leadership. As a key component, the proposed work must include training and supervision of a minimum of two postgraduate students (PhD and/or Masters) with a clear training and mentorship plan for each student. Additionally, the proposal must also include training and mentoring of one early career scientist (Trainee Fellow). The Trainee Fellow must come from a different institution, which must be located in a sub-Saharan African country that is different from the country of the home institution of the Senior Fellow. The Trainee Fellow should either be a PhD in a subject of relevance to the EDCTP2 programme and less than five years' of postdoctoral experience or a medical doctor with up to five years' research experience. The research project of the Trainee Fellow should be presented as a separate work package in the application. This work package should have a clear and concise capacity development plan for the Trainee Fellow with measurable indicators of how the project will advance the personal and institutional capacity development.

The Senior Fellow should indicate how their advancement in skills and competencies for training and mentorship, as well as the capacity development of the other researchers under their supervision, fit into the overall regional capacity development and sustainability strategies of the EDCTP Association in addressing geographical and gender imbalance. Senior Fellows who plan to use clinical trials for training and mentorship, must ensure that studies are appropriately designed and GCP-compliant; good manufacturing practice (GMP) compliant investigational product(s) are available and guaranteed; and all sponsor responsibilities can be fulfilled by the host institution (applicant legal entity where the Senior Fellow is employed) or product developer involved in the project. Senior Fellows should have a track record of publications in peer-reviewed journals in their chosen area of research and show potential to become future research leaders working in SSA.

Applications for a Senior Fellowship must be submitted by an established legal entity in SSA ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. The grants are awarded to the host organisation with the explicit commitment that this organisation offers appropriate conditions for the Senior Fellow to direct independently the proposed action and manage its funding for the duration of the fellowship. Trainee Fellows must be identified at the time the application is submitted, and can be affiliated to the host organisation of the Senior Fellow.

Senior Fellows funded under this Call for Proposals will undergo a mid-term review that may result in discontinuation of the grant after three years in case of unsatisfactory performance.

Expected impact

Projects funded under this Call for Proposals should contribute to the generation of a critical mass of researchers and institutional research capacity in sub-Saharan African countries where such capacities have been most lacking.

Furthermore, the projects should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- enable Senior Fellows to:
 - contribute to closing geographical and gender gaps among recognised research leaders and contribute to an increased pool of scientific knowledge and researchers in SSA
 - develop the ability to design, plan and execute complex research programmes in collaboration with interdisciplinary team members in geographical regions where the clinical research skills base is currently scanty
 - produce higher impact scientific and, where applicable, policy publications
 - produce more competitive Trainee Fellows capable of independently attracting funding from various sources.

Applications will be considered to have a higher impact if Trainee Fellows are based in organisations or countries with little or no participation in ongoing EDCTP2 projects.

Table 10 Supporting information for the Call for Proposals 'Senior Fellowships Plus'

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	3-4

Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be a legal entity established in sub-Saharan Africa (the applicant legal entity)²⁷. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation). 3. The applying fellow must: <ol style="list-style-type: none"> a. be resident of or be willing to relocate to a sub-Saharan African country; b. be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years' research experience after the post-graduate qualification; c. have a minimum of 5 first- and/or last-author publications in international peer-reviewed journals; d. not have a current senior fellowship from the EDCTP2 programme 4. The requested EDCTP2 contribution per action shall not exceed EUR 750,000 5. The maximum fellowship duration shall be 60 months.
Submission and evaluation procedure	<p>Single stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p> <p>The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative system to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship. The home organisation(s) of Fellowship trainee(s) included in the proposal must also provide a support letter confirming that the organisation is supportive of the proposed action and willing to support the Fellowship.</p>
Evaluation rules	<p>The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.</p>
Grant agreement	<p>General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships²⁸.</p>
Supplementary agreements	<p>Applicant legal entities (host organisations) selected for funding from this Call for Proposals will be required to conclude an employment agreement with the fellows prior to the conclusion of the EDCTP2 grant agreement.</p>

2.2.3 Career Development Fellowships

Challenge

For many young scientists in developing countries the bridge between doctoral qualification and an established research career is the most difficult to cross due to lack of continued research funding and lack of access to established research networks. As research in the field of poverty related diseases (PRDs) gains momentum, it is paramount to facilitate opportunities for early and mid-career scientists in sub-Saharan Africa to develop their clinical research skills. Providing possibilities for individual training would enable talented scientists to establish themselves as independent researchers and team leaders at host institutions in sub-Saharan Africa for long-term continuity, networking and research ownership in the region.

Scope

The purpose of this Call for Proposals is to support early to mid-career researchers (“fellows”) by providing them an opportunity to train and develop their clinical research skills.

The objectives are:

1. to promote retention of postdoctoral researchers and postgraduate medical researchers in the research field of sub-Saharan Africa
2. to equip the fellows to establish themselves as independent researchers with ability to initiate their own research teams at host institutions in sub-Saharan Africa.

The proposed training should specifically enhance the ability of the fellow to design, plan and execute clinical biomedical and/or social science/ethics research projects within the scope of the EDCTP2 programme¹⁰. Novartis aims to co-fund this call with at least five additional fellowships (to a maximum value of € 750,000) for proposals conducting research in the area of maternal and child health on the interaction between PRDs²⁹ and non-communicable diseases (NCDs). The contribution from Novartis aims to address a shortage of suitably trained mid-career researchers in sub-Saharan Africa working on maternal and child health in the context of a growing double burden of infectious diseases, malnutrition, and child and maternal mortality, in addition to emerging challenges of NCDs.

The proposed training should include an independent research activity and a clear description of the skills that will be acquired by carrying out the research. Fellows with training activities involving clinical trials and related studies must ensure that studies are appropriately designed and GCP-compliant. Individuals targeted by this Call for Proposals should have a track record of publications in peer-reviewed journals in their chosen area of research; a mentor who is an internationally recognised scientific leader working in sub-Saharan Africa; and a career development plan as part of the research proposal.

Proposals for an EDCTP Career Development Fellowship must be submitted by the prospective fellow in conjunction with and on behalf of their proposed host organisation (hereinafter 'the applicant legal entity'). The grants are awarded to the host organisation with the explicit commitment that this organisation offers appropriate conditions for the career development fellow to direct and manage its funding for the duration of the fellowship. Fellows can only be funded once under this grant scheme.

Expected Impact

Projects funded under this Call for Proposals should:

- contribute towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- promote career progression
- encourage entry and reintegration of African scientists trained abroad and
- enable the retention of postdoctoral and postgraduate researchers in their respective research fields and that the researchers develop into independent researchers and team leaders in sub-Saharan Africa.

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

Table 11. Supporting information for the Call for Proposals 'Career Development Fellowships'

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	16-20 grants

Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be a legal entity established in sub-Saharan Africa (the applicant legal entity)³⁰. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. Fellows must: <ol style="list-style-type: none"> a. be resident of or be willing to relocate to a sub-Saharan African country; b. be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and up to five years' relevant postdoctoral research experience, or a medical doctor with up to five years' research experience; c. have at least one publication in an international peer-reviewed journal; d. not have been funded under this fellowship scheme before³¹. 4. The requested EDCTP2 contribution per action shall not exceed EUR 150,000. 5. The maximum fellowship duration shall be 36 months.
Submission and evaluation procedure	<p>Single stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p> <p>The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.</p>
Evaluation rules	<p>The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.</p>
Grant agreement	<p>General EDCTP2 grant agreement (mono-beneficiary)²⁸ with options for fellowships.</p>
Supplementary agreements	<p>Applicant legal entities (host organisations) selected for funding from this Call for Proposals will be required to conclude an employment agreement with the fellow prior to the conclusion of the EDCTP2 grant agreement.</p>

2.2.4 Preparatory Fellowships – in collaboration with the Africa Research Excellence Fund (AREF)

Challenge

There is a need to provide aspiring African researchers the necessary tools for development in the form of structured mentorship support and stimulating research challenges. Such support can best be provided to early postdoctoral researchers by well-resourced and established institutions. Africa accounts for 15-20% of the world's population and a disproportionately large share of disease burden, yet scientific publications by African researchers account for less than 2% of the total academic journal output³². As a result, it is imperative to enable African researchers to enhance their competitiveness for international funding opportunities early in their careers while retaining them in Africa, working on Africa's health challenges and priorities.

Background

The capacity strengthening needs for health research in sub-Saharan Africa predominantly centre on lack of funding and limited systematic career development for researchers. In general, health research capacity building programmes in Africa and other low-income regions are more tailored to PhD candidates than to early-career postdoctoral scientists. Furthermore, international fellowship programmes typically focus on people who are already well-trained and who show exceptional talent and promise. The experience of global health research funders is that African scientists are under-represented and less competitive in local and international funding schemes: their science may be promising but the framing of research questions; the

research design; the proposed analyses and mentoring structure are often not well developed.

The Africa Research Excellence Fund (AREF) aims to bridge the critical gap early in the career path from research experience to research leadership. AREF is an independent charity established by the UK Medical Research Council and led from sub-Saharan Africa, with the support of the UK Medical Research Foundation.

Scope

The purpose of the AREF/EDCTP Preparatory Fellowship is to enhance the competitiveness of up and coming post-doctoral sub-Saharan African scientists and clinicians aspiring to receive international/regional/national fellowships or grant support, such as the EDCTP Career Development Fellowships. The AREF/EDCTP Preparatory Fellowship targets outstanding early-career researchers residing in or wishing to relocate to sub-Saharan Africa who demonstrate independent scientific thinking and have potential to deliver locally relevant research with measurable impact and within the scope of the EDCTP2 programme.

The objectives of this call are:

1. Enable outstanding sub-Saharan African researchers (0 to 3-year post-PhD) to (a) further advance their research skills, through short-course(s) and hands-on training, especially using biological samples and data they or their home organisations have generated; (b) strengthen their competencies in project and proposal design; and (c) enhance essential their generic/transferrable researcher skills that will allow them to secure research partnerships, and make effective use of fellowships; and (d) contribute to creating a pool of researchers optimally equipped with the expertise and skills to address local research needs
2. Enable individuals to deploy their own resourcefulness and research relationships to best effect in competing for early/mid-career fellowships, such as (but not limited to) the EDCTP Career Development Fellowships
3. Enhance career development and retention of postdoctoral researchers and postgraduate medical researchers in research in and for sub-Saharan Africa
4. To provide a firm foundation and increase the quality, efficiency and impact of fellowship projects funded by organisations such as the EDCTP Association.

The proposal for an AREF/EDCTP Fellowship Preparation Award must be submitted by the home organisation ('the applicant legal entity'). The grants will be awarded to the home organisation with the explicit commitment that this organisation offers appropriate conditions for the fellow to direct and manage their funding for the duration of the fellowship. AREF will fund fellows employed by a research institution based in sub-Saharan Africa (the fellow's home organisation and applicant legal entity), whereas the EDCTP2 programme will fund fellows employed by a sub-Saharan African legal entity (the fellow's home organisation and applicant legal entity).

Successful applicants will use the funding for a 3 to 9 months placement at a centre of research excellence in Europe and sub-Saharan Africa contracted to host the fellow before spending 3-months re-entry re-integration period to the fellow's home (employing) institution, making a total training period of up to 12 months. The re-integration project will be developed by the fellow with approval of the home institution so that it is aligned with its institutional research and human resources development plan.

Expected Impact

Projects funded under this Call for Proposals should:

- contribute towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages')
- enhance the ability of fellows to design, plan and execute clinical biomedical and/or social

science/ethics research proposals, and manage research relationships, within the scope of the EDCTP2 programme; and to generate competitive proposals into effective projects

- promote and enhance competitiveness for the next tier of fellowships and grants, such as (but not limited to) the EDCTP Career Development Fellowships
- lead to high impact research outputs by junior sub-Saharan African scientists who have not been supported by major funders previously
- foster new collaborations and mentorship opportunities for newly trained fellows
- equip the next generation of African researchers to sustain excellent and relevant research in sub-Saharan Africa, and engage as African citizens with African leaders, policy-makers and industries to drive forward evidence-based health improvement.

Table 12. Supporting information for the Call for Proposals ‘Preparatory Fellowships – in collaboration with the Africa Research Excellence Fund (AREF)’

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	6 grants funded by the EDCTP2 programme and 6 additional grants funded by AREF, subject to relevance to AREF’s remit and terms and conditions being met)
Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be a legal entity established in sub-Saharan Africa (the applicant legal entity)³³. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the home organisation) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. Fellows must: <ol style="list-style-type: none"> a. be a post-doctoral scientist; b. have been awarded their doctorate within 3 years before submission deadline of the AREF-EDCTP Preparatory Fellowship application; c. have been either a PhD student or MD, who have been active researchers for up to three years following award of their doctorate; d. be resident of or be willing to relocate to a sub-Saharan African country; e. not have been funded under this fellowship scheme before³⁴. 4. The requested EDCTP2 contribution per action shall not exceed EUR 70,000. 5. Placements sought shall be for a period of at least 3 and up to 9 months, following which there will be a re-integration period of up to 3 months. The maximum fellowship duration shall be 12 months.
Submission and evaluation procedure	<p>Single-stage application procedure.</p> <p>Applications will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP Association and AREF in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 Basic Act. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p>
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (Mono-beneficiary) with options for fellowships ²⁸ .

Supplementary agreement

The fellow's host organisation will have to sign a good practice charter prepared by the EDCTP Association for EDCTP2-funded fellows and by AREF for AREF-funded fellows. Host organisations need to meet a set of minimum requirements in order to qualify as prospective hosts: they should have some clinical research capacity, including staff who are GCP qualified or experienced, demonstrable ability to follow-up community involvement in clinical research, availability of institutional review board or national guidelines for conducting clinical research, GCLP compliant laboratories, adequate facilities with qualified staff, sufficient biostatistics capacity including its relevant computer technologies, experienced data management staff, ability to store some or all of samples locally and excellent IT platform. AREF requirements will be similar and appropriate to its remit, which includes non-clinical trial methods e.g. in laboratory and in social and behavioural sciences.

2.2.5 Clinical Research and Product Development Fellowships (CRDF) – Joint Call with WHO/TDR, the Special Programme for Research and Training in Tropical Diseases

Challenge

Researchers from low- and middle-income countries (LMICs)³⁵ who are involved in clinical research activities have limited opportunities to acquire experience and develop skills for conducting clinical trials outside an academic or public sector setting. As a result, there are few researchers and clinical staff from LMICs assuming leading roles in clinical research for poverty-related diseases (PRDs). The development of human capacities through fellowships will lead to enhanced and sustainable research capacity in LMICs on diagnostics, drugs and vaccines for PRDs by supporting career progression and retention of researchers in LMICs.

Background

As part of the EDCTP Association's capacity building efforts, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the EDCTP Association signed a Memorandum of Understanding (MoU) in January 2013 to implement a fellowship scheme that offers placements in European-based companies to individual researchers and clinical staff from sub-Saharan Africa working in the implementation of clinical trials. The TDR Career Development Fellowships (CDF) programme, which has been supported by the Bill & Melinda Gates Foundation and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), offers targeted training in research and development to skill local personnel in disease-endemic LMICs with competencies in clinical trials for drugs, vaccines and diagnostics on a broad range of infectious diseases of poverty. The CDF programme is implemented by the Special Programme for Research and Training in Tropical Diseases (TDR). TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO³⁶.

The EDCTP Association and TDR decided to implement this fellowship scheme through a Joint Call for Proposals. This Joint Call will have a leverage effect on the number of individuals trained, resulting in an increased impact on research and development capacity in LMICs. The partnership will ensure synergies between the different parties involved, and will facilitate communication with researchers and clinical staff, academic affiliated research institutions, clinical research organisations (CROs), pharmaceutical companies and product development partnerships (PDPs).

This call will have an incremental effect on the number of individuals trained, resulting in an increased impact on research and development capacity in LMICs. The partnership will ensure synergies and facilitate communication between the different parties involved.

Scope

The purpose of this Joint Call for Proposals is to provide funding to actions that aim to support researchers and key members of clinical trial research teams from LMICs to acquire specific skills in clinical research and development through placements in academic affiliated research organisations, CROs, pharmaceutical companies and PDPs. The home organisation may not be an affiliated entity to the host organisation³⁷.

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are employed by a legal entity in a LMIC where they are currently working on clinical research and clinical trials in the scope of the EDCTP2 programme¹⁰ and/or the TDR CDF programme³⁸. Placements supported by the EDCTP2 programme are for a period of 15 months (3 months will be used to prepare for the placement), following which there will be a re-integration period of 6 months. Placements supported by TDR are for a minimum period of 12 months following which there will be a re-integration period.

Proposals for an EDCTP-TDR Clinical Research and Product Development Fellowship (CRDF) must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. Fellows must commit to return to their home organisation for a minimum of two years after completion of the fellowship. Fellows should identify the skills and training required and should demonstrate how the acquired experience would be applied upon return to the home organisation.

The Joint Call will include a joint evaluation and selection process in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 Basic Act. However, grant awarding and budget management will remain separate under the management of each organisation. TDR will fund fellows employed by a research institution in any LMICs to be placed in academic affiliated research institutions, CROs, pharmaceutical companies and PDPs in or outside Europe, whereas the EDCTP2 programme will fund fellows employed by a sub-Saharan African legal entity (the fellow's home organisation and applicant legal entity) to be placed in European-based CROs, pharmaceutical companies or PDPs to train and develop specific clinical research skills of relevance to PRDs.

Placements may include but would not be restricted to the following areas: design and conduct of clinical trial studies, including operational planning, management and evaluation; clinical development of vaccines including associated epidemiological studies; assessment of drug development programmes; diagnostics; biostatistics/epidemiology; data management and pharmacovigilance. A list of participating host organisations and available placements will be published on the EDCTP Association and TDR websites.

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'
- support the development of human resources and should promote high quality research and development in LMICs
- add significantly to the development of promising researchers from sub-Saharan Africa, in order to enhance and maximise their contribution in research institutions in LMICs, including training of peers
- contribute to strengthening collaboration between research institutions, researchers and clinical staff in LMICs, pharmaceutical companies, CROs, PDPs and academic affiliated research organisations.

Table 13. Supporting information for the Call for Proposals ‘Clinical Research and Development Fellowships (CRDF) – Joint Call with TDR, the Special Programme for Research and Training in Tropical Diseases’ (applicable to the EDCTP2 programme only)

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	10-15 grants
Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be a legal entity established in sub-Saharan Africa and must be the home organisation employing the fellow³⁹. 2. The fellow must: <ol style="list-style-type: none"> a. be a post-graduate (MSc or PhD) or medical graduate with clinical and/ or research experience in infectious diseases; b. have obtained their post graduate or medical graduate degree within 15 years of submission of the application; c. be a researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa, and who has been conducting clinical research activities in the scope of the EDCTP2 programme; d. provide a letter of support from the home organisation for the fellowship which is justifying the training needs of the fellow and explaining how the home organisation will benefit from the fellowship and how the reintegration of the fellow will be ensured⁴⁰; e. not have been funded under this fellowship scheme before⁴¹. 3. Placements sought shall be for a period of 15 months, following which there will be a re-integration period of up to 6 months. 4. The requested EDCTP2 programme contribution per action shall not exceed EUR 100,000.
Submission and evaluation procedure	<p>Single stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p> <p>Eligible applications will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP Association and TDR. Applicants above the threshold in the first stage will be shortlisted and prospective host organisations will be invited to identify preferential candidate fellows. The identification of potential candidate fellows may include an interview of candidate fellows by the prospective host organisations.</p>
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships ²⁸ .
Supplementary agreements	Host organisations in actions resulting from this Call for Proposals will be required to sign up to the corresponding the EDCTP Association charter, while fellows will be required to sign a letter of engagement with the EDCTP Association prior to the conclusion of the EDCTP2 grant agreement.

2.3. Conditions for the Calls for Proposals

Grant agreements are expected to be signed within three months from the date of informing applicants about the evaluation result, unless the applicants request a longer period or in case of complex actions.

Table 14. Indicative timetable for 2019 Calls for Proposals

Type of Action	Call Topic (short titles)	Indicative dates by which calls will be open for applications		Indicative deadline for applications		Evaluation results are planned to be available on or before these dates	
RIA	Strategic actions supporting large-scale clinical trials	3 June 2019		7 November 2019 at 17:00:00 CET		30 March 2020	
	Paediatric drug formulations for poverty-related diseases	Stage 1 – 10 June 2019	Stage 2 – 21 December 2019	Stage 1 – 10 October 2019 at 17:00:00 CET	Stage 2 – 16 March 2020 at 17:00:00 CET	Stage 1 – 21 December 2019	Stage 2 – 24 July 2020
	Strategic actions on product-related implementation research	Stage 1 – 10 June 2019	Stage 2 – 21 December 2019	Stage 1 – 21 December 2019	Stage 2 – 16 March 2020	Stage 1 – 21 December 2019	Stage 2 – 10 June 2020
	Vaccines against Lassa virus – Joint Call with Coalition for Epidemic Preparedness Innovations (CEPI)	2 November 2019		7 April 2020		30 June 2020	
	New drugs and vaccines for priority pathogens in antimicrobial resistance	3 June 2019		7 November 2019		30 March 2020	
CSA	Ethics and regulatory capacities	2 August 2019		22 November 2019 at 17:00:00 CET		16 April 2020	
TMA	Senior Fellowships Plus	2 November 2019		1 February 2020 at 17:00:00 CET		1 June 2020	
	Career Development Fellowships	6 August 2019		27 November 2019 at 17:00:00 CET		19 April 2020	
	Preparatory Fellowships – in collaboration with the Africa Research Excellence Fund (AREF)	6 August 2019		27 November 2019 at 17:00:00 CET		19 April 2020	
	Clinical Research and Product Development Fellowships (CRDF) – Joint Call with the TDR, the Special Programme for Research and Training in Tropical Diseases	1 October 2019		28 February 2020 at 17:00:00 CET		28 July 2020 (Interviews are planned for May-June 2020)	

3. Other EU-funded activities

3.1. Independent experts assisting in proposal evaluations and project reviews in 2019

Objective: These activities will support the appointment of independent experts for the evaluation of proposals, the review of ongoing projects and activities, the meetings of the Scientific Advisory Committee, internal audits of EU-funded beneficiaries, and site visits to beneficiaries. Experts will be identified on the basis of a high level of expertise in the conduct of clinical trials, implementation research, research capacity building and/or regulatory strengthening as needed to effectively evaluate each Call for Proposals or other activities requiring independent expertise.

Type of action: Expert contracts.

Indicative budget: EUR 700,000.

Indicative timetable: Q2-Q4 2019

3.2. EDCTP2 Prizes

Objective: Awards have a strong potential to drive innovation through the recognition of achievements and the promotion of role models. In this regard, the EDCTP Association plans to award four prestigious international prizes dedicated to the promotion of scientific research, improved health and Africa-European collaboration. These prizes are presented to outstanding individuals and research teams, especially from sub-Saharan Africa and Europe and are announced at the biennial EDCTP Forum.

The four prestigious prizes are:

- **Scientific Leadership Prize:** Awarded to excellent world-class scientists in sub-Saharan Africa up to 50 years of age working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases (NIDS) in the scope of the EDCTP2 programme
- **Outstanding Female Scientist Prize:** Awarded to excellent world-class female scientists in sub-Saharan Africa and working in the remit of the EDCTP2 programme.
- **Outstanding Research Team Prize:** Awarded to outstanding research teams in sub-Saharan Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases (NIDS) in the scope of the EDCTP2 programme.
- **Dr Pascoal Mocumbi Prize:** This prize is in special recognition of the significant contribution made by Dr Pascoal Mocumbi, the first High Representative of the EDCTP Association. It is to be awarded to senior scientists, policy-makers or advocates for health and research, from anywhere in the world.

The specific rules of the contest will be published in 2019 on the EDCTP Association website and also actively publicised elsewhere to maximise participation.

Applications will have to clearly state the involvement of the contestants (nominees) in the research and innovation activities within the remit of the EDCTP2 programme. The natural person nominating will have to provide proof of eligibility and a written presentation of the achievements of the contestant, which will be presented to an independent panel of experts for evaluation.

Amount of prizes:

- **Scientific Leadership Prize:** This consists of a recognition trophy and a cash prize of € 10,000.
- **Outstanding Female Scientist Prize:** This consists of a recognition trophy and a cash prize of € 20,000.
- **Outstanding Research Team Prize:** This consists of a recognition trophy and a cash prize of € 50,000.
- **Dr Pascoal Mocumbi Prize:** This consists of a recognition trophy and a cash prize of € 50,000.

Eligibility criteria:

The contestants for the first three prizes (Scientific Leadership Prize, Outstanding Female Scientist Prize, and Outstanding Research Team Prize) must be residents of a sub-Saharan African country, an EU Member State, or a country associated with the Horizon 2020 programme.

The contest for the Dr Pascoal Mocumbi Prize is open to contestants from all parts of the world. Please note however that special rules may apply for entities from certain countries (see section 6.3).

The nomination of contestants who are currently employees of the EDCTP Association, or serving on one of the EDCTP Association advisory (Scientific Advisory Committee and Audit Committee) or governing (General Assembly and Board) bodies will not be permitted for any of the prizes.

Finally, contestants, who have already received an EDCTP2 programme prize before, cannot receive a second prize for the same activities.

Award criteria: All eligible applications will be evaluated by an independent panel of experts. The prizes will be awarded, after closure of the contest, to the contestant(s) who, in the opinion of the panel, best addresses the following criteria in their prize category:

- **Scientific Leadership Prize:** contestants have made significant achievements in their field and will continue to become leaders in their research field. In addition to their scientific excellence, the contestants should have made major contributions to the objectives of the EDCTP2 programme to strengthen research capacity in sub-Saharan Africa and to support South-South and North-South networking. Contestants nominated for this prize should not exceed 50 years of age, at the time of the launch of the contest.
- **Outstanding Female Scientist Prize:** the contestant must have been involved in research and innovation activities in sub-Saharan Africa within the scope of the EDCTP2 programme. Contestants should have made a significant scientific contribution and built measurable impactful research capacity through training and mentorship for the future generation of researchers/scientists in Africa. This prize is restricted to female scientists in sub-Saharan Africa and has no age restriction.
- **Outstanding Research Team Prize:** this prize recognises a consortium or group of partners who have achieved the goal of taking on the EDCTP2 programme priority issues in poverty related diseases (PRDs). In collaboration, the team has built effective and equitable South-North partnerships to answer the priority research questions and produced health-policy relevant deliverables, such as research data implemented into policy and practice, high impact publications and significant capacity building outputs at local research sites. Contestants should be actively involved in research, capacity development and networking in sub-Saharan Africa and Europe with outstanding achievements and scientific and policy impact in their respective fields.
- **Dr Pascoal Mocumbi Prize:** the contestant should have made significant achievements in

promoting Africa-Europe partnerships in global health research; unique contribution to promoting and facilitating the clinical development of products for poverty-related diseases; achievements in advancing capacity development for health research in sub-Saharan Africa; achievements in promoting international networking of researchers, policy makers, funders and donors on poverty-related diseases (PRDs).

Type of action: Recognition prizes.

Indicative timetable: Prize contests will be launched in the last quarter of 2019 and remain open until the first quarter 2020. Prize winners will be announced at the Tenth EDCTP Forum (see General Annexes 6.6 for Model Rules of Contest (RoC) for EDCTP2 Prizes).

Total indicative budget: EUR 130,000.

3.3. Training on project and programme management in research

Objective: The objective of this action is the organisation of workshops in sub-Saharan Africa to strengthen the research management capacity of project/programme managers and researchers. This will be achieved through the organisation of:

- Three workshops in sub-Saharan Africa, one for participants from Western and Central Africa, one for participants from Eastern and Southern Africa, and one for participants from Lusophone African countries to strengthen the capacity for financial and project management of EDCTP2-funded collaborative projects. The aim of the workshops is to provide information and training to new EDCTP2 grantees about the legal and financial rules and regulations associated with implementing EDCTP2 projects in accordance with Horizon 2020. This will equip the project and financial managers of EDCTP2 projects with a more detailed understanding of the rights and obligations of the EDCTP2 grant agreements, and thereby contribute to preventing delays and ineligible expenses during the implementation of the EDCTP2 projects. The workshops will consist of a mix of theory and active, participatory training. All new EDCTP2 beneficiaries from African organisations will be invited to attend the training, including coordinators and scientific and financial project managers of newly selected and on-going EDCTP2 projects. Each workshop is expected to attract 40-60 participants. The workshop for Lusophone African researchers is conditional on financial and technical support being provided from La Caixa and Gulbenkian Foundations (TBC).
- Two workshops on scientific proposal writing. Potential applicants will be invited to attend a hands-on and practical workshop on EDCTP2 Calls and grant proposal writing. Where possible, the EDCTP Association will engage its Partner States and collaborate with other organisations such as TDR, WHO, MRC-South Africa for the delivery of specific sessions. Between 30 and 40 participants will be selected and invited to attend the workshop through an open selection process. This group should be balanced with respect to geographical coverage, gender and institutional affiliation. The call for participants will be openly advertised through the EDCTP Association and Regional Networks of Excellence websites. Language translation services might be required.

Type of action: Public Procurement – up to 10 service contracts.

Indicative timetable: The procurement process will begin in the second quarter with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2019. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures⁴².

Indicative budget: EUR 400,000.

3.4. Communication and dissemination activities

Objective: External communication aims to create awareness and visibility of the EDCTP2 programme, its mission and goals, and to inform all stakeholders of the progress and results of the EDCTP Association-supported activities. The EDCTP Association plans to conduct the following activities in 2019 to support advocacy and outreach activities, and increase EDCTP's visibility:

- Production of materials for a strong presence at international conferences and meetings
- Production of two high quality videos on EDCTP2-funded projects in sub-Saharan Africa
- Photo media productions on EDCTP2-funded projects
- Hiring of external experts for technical maintenance of the EDCTP Association website
- Hiring of external medical writers to produce up to four articles about the EDCTP Association activities for publication in relevant journals
- Outsourcing of development, design and printing of advocacy materials
- Outsourcing translation in French and Portuguese of main publications of the EDCTP Association
- Quality improvement of communication services, including refresher training and internships.

Type of action: Public procurement – up to 12 service contracts.

Indicative timetable: The procurement process will begin in the second quarter of 2019. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures⁴².

Indicative budget: EUR 160,000.

3.5. Advocacy, networking and outreach activities

Objective: To develop and implement an advocacy and partnerships strategy aimed at contributing to the achievement of the EDCTP2 programme objectives, raising the visibility and impact of the programme, and mobilising support from governments and private actors for the current and potential successor programme. This strategy will focus for the most part on the mobilisation of financial resources from governments and private actors for future Calls for Proposals, as well as on the initiation of partnerships to ensure alignment of research agendas and development of joint funding strategies.

Outreach and cooperation with third parties to date has led to increased engagement of private partners, international organisations, and development cooperation in the EDCTP Association activities, as evidenced by joint Calls for Proposals in previous and current workplans. The EDCTP Association's participation in international conferences and high-level parliamentary meetings increased the visibility and mobilised support to the EDCTP2 programme. The regular exchange with various funders groups has proven to be essential for gathering intelligence, aligning strategies and initiating joint activities. As the momentum for a successor EDCTP programme grows, targeted outreach to the EDCTP2 programme PSs will be essential going forward. In order to give continuity to the previous outreach and advocacy efforts, the following specific activities will be conducted in 2019:

- Targeted country visits for increased visibility within the research community and with other public and private research partners;
- Organisation of bilateral meetings with key policy-makers, including members of Parliaments (MPs) in European and African countries, and Members of the European Parliament (MEPs)

- Participation in joint funders groups such as HIV, TB, malaria or NID funders platforms including ESSENCE on Health Research⁴³
- Participation in strategic initiatives, including contribution towards the development of a funders' strategy for supporting implementation science in sub-Saharan Africa;
- Participation in a selection of international conferences to mobilise support from the research community, policy-makers, funders and other key stakeholders;
- Data sharing workshops.

Type of action: Public procurement – up to 10 service contracts.

Indicative timetable: The procurement process will occur throughout the year. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures⁴².

Indicative budget: EUR 500,000.

3.6. Mobilisation of research funds in case of Public Health Emergencies

Objective: In case of a public health emergency (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082/2013/EU or under applicable national frameworks and regulations), research grants may be awarded in line with specific provisions of the Financial Regulation⁴⁴, that allow the awarding of grants without a call for proposals in exceptional and duly substantiated emergencies. At that time, the EDCTP grants portal will open a dedicated section where research applications can be received. This will be communicated to the EDCTP Association General Assembly members. In 2018 the Public Health Emergencies mechanism was used to fund research projects addressing an outbreak of Ebola in the Democratic Republic of Congo (DRC).

Beneficiaries in grants awarded under actions relating to Public Health Emergencies must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by the EDCTP Association or the European Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore the relevant option of Article 29.3 of the EDCTP2 Model Grant Agreement will be applied. It is expected that quality-controlled data are shared in accordance with the FAIR⁴⁵ principles. The use of harmonised protocols in collaboration with ongoing EDCTP2 actions is recommended for this purpose.

Type of Action: RIA - Grants awarded without a Call for Proposals (Article 195 of the Financial Regulation).

Indicative timetable: Will depend on the Public Health Emergency.

Indicative budget: EUR 2 million.

3.7. Preparations for the Tenth EDCTP Forum 2020

Objective: The biennial EDCTP Forum provides an international platform for the presentation and discussion of clinical studies for everyone involved in combating poverty-related diseases and the appropriate capacity development and networking activities. The Forum has established itself as a valuable opportunity to develop and reinforce cooperation and synergy among the EDCTP Association stakeholders at various levels including scientific and policy. Scientists involved in EDCTP2-funded projects are particularly encouraged to use this opportunity to share

new developments and results from their projects.

The Tenth EDCTP Forum will take place in 2020 in Africa (location TBC). It is expected that payments will be made in 2019 to cover expenses related to inspection and visit of potential venues; hire a local events management company; and secure a venue and block bookings in local hotels. This action will support all eligible costs necessary to organise the Forum.

Expected impact: The Forum is expected to draw 400-600 delegates, the majority of whom are working in sub-Saharan Africa, and provide a unique research communication platform for those stakeholders working in the field of PRDs.

Type of action: Public Procurement – up to 20 service contracts.

Indicative timetable: The procurement process for some of the services will begin in the third quarter of 2019 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which will be in the fourth quarter of 2020. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures. First payments are expected to be made in the last quarter of 2019.

Indicative budget: EUR 600,000.

3.8. Strengthening national health research systems (NHRS) in Africa for uptake of research results

Objective: The objective of this action is to organise training in sub-Saharan Africa to strengthen national health research systems for the effective uptake of clinical research results for translation into policy. The implementation of this action will facilitate Member State contributions to clinical research, improve linkages of NHRS with EDCTP regional networks and Regional Economic Communities (REC) in Africa, further increase NHRS barometer scores for resource-limited the EDCTP Association African Participating States, and enhance preparedness for clinical trials and public health emergencies.

This action builds on the recognition of the revised NHRS barometer as the tool for assessing national health research systems and informing progress towards the achievement of Universal Health Coverage (UHC). The new version of the NHRS barometer tool was supported jointly by the EDCTP Association and the Health Systems and Services cluster of WHO-AFRO. It was modified with contributions from the EDCTP2 programme African Participating States, RECs, NEPAD and Africa CDC at an EDCTP Association sponsored workshop in Accra, Ghana in 2018.

This action will be implemented in three phases:

1. Organisation of a workshop in a resource limited EDCTP2 programme African Participating State to review the low scoring elements of the barometer questionnaire with the objective of improving them, through linkages with high-scoring PSs (in the same region) and RECs, to ensure alignment with regional health research strategies. The workshop will consist of a mixture of theory and active participatory training. The EDCTP Association GA members and health professionals from national health research directorates will be invited to attend. EDCTP NoEs and focal points for health research in RECs will also be invited. The workshop will attract about 40-60 participants.
2. Implementation of the NHRS enhanced barometer tool in the nine EDCTP PSs with the lowest barometer scores. The implementation exercise in each of the nine PSs will be carried out jointly with a high scoring PS based on the 2018 surveys
3. Deployment of an independent consultant to conduct surveys in Participating Member States to demonstrate the actual value of cash and in-kind investments these states make in

the EDCTP Association relevant clinical research programmes.

This activity will be outsourced to a consultancy firm(s) selected following the procurement rules and will require close collaboration with WHO-AFRO and AU to implement this work.

Type of action: Public procurement – up to 7 service contracts.

Indicative timetable: The procurement process will begin in the second quarter of 2019. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures.

Indicative budget: EUR 300,000.

3.9. Enhancing networking among European and African scientists to close regional and gender disparities in EDCTP1 and EDCTP2 funded health research capacity activities in sub-Saharan Africa

Background: Evaluation of EDCTP1 and EDCTP2 programmes revealed geographical and gender disparities in success rates of applications for EDCTP1 and EDCTP2 programmes funding, with the least number of applications being both received and funded from Central and West Africa. Leaving this unaddressed will make it difficult to conduct clinical research in areas with the highest burden of PRDs therefore impact the EDCTP Association mission negatively.

Objective: The objective of this action is to organise a workshop that will facilitate collaborations between European and African scientists geared towards closing regional and gender imbalances seen in previously funded EDCTP1 and EDCTP2 projects. Any European and sub-Saharan African scientists intending to apply for future EDCTP2 grants will be eligible to attend the planned workshop. Participants in the workshop will be selected through an open, fair and transparent process. A call for applications to attend the workshop will be published on the EDCTP Association website. Selection of scientists to attend the workshop will be based on their ability to justify how their participation will meet the EDCTP2 programme objective. Applicants from underrepresented countries and females are encouraged to apply.

This action will implement a networking workshop which will come up with alliances and strategies that will improve coverage of both fellowships and clinical trial applications to EDCTP2 calls that improve gender and geographical representation. Up to 100 successful participants will be invited to attend the workshop.

Type of action: Public procurement – up to 7 service contracts.

Indicative timetable: The procurement process will begin in the second quarter of 2019 in readiness for calls launched in third quarter of the year. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures.

Indicative budget: EUR 150,000

Table 15. Financial contributions to be managed by the EDCTP Association towards Calls for Proposals, Other Activities and the Administrative Costs of the EDCTP Association in 2019

EU-funded EDCTP2 activities		TPs/TCs* (in EUR)	PSs** (in EUR)	EU (in EUR)	Budget cost (in EUR)
Research & Innovation Actions	Strategic actions supporting large-scale clinical trials	-	2,047,460	17,952,540	20,000,000
	Paediatric drug formulations for poverty-related diseases	-	2,047,460	15,952,540	18,000,000
	Strategic actions on product-related implementation research	-	2,047,460	17,952,540	20,000,000
	Vaccines against Lassa virus – Joint Call with Coalition for Epidemic Preparedness Innovations (CEPI)	10,000,000	10,000,000	20,000,000	40,000,000
	New drugs and vaccines for priority pathogens in antimicrobial resistance	-	2,047,460	15,952,540	18,000,000
Coordination & Support Actions	Ethics and regulatory capacities	-	-	3,000,000	3,000,000
Training & Mobility Actions	Senior Fellowships Plus	-	-	3,000,000	3,000,000
	Career Development Fellowships	750,000	-	2,500,000	3,250,000
	Preparatory Fellowships – in collaboration with the Africa Research Excellence Fund (AREF)	-	-	420,000	420,000
	Clinical Research and Product Development Fellowships (CRDF) – Joint Call with TDR, the Special Programme for Research and Training in Tropical Diseases	-	-	1,500,000	1,500,000
Sub-total		10,750,000	18,189,840	98,230,160	127,170,000
Other Activities	Independent experts assisting in proposal evaluations and project reviews in 2019	-	-	700,000	700,000
	EDCTP2 Prizes	-	-	130,000	130,000
	Training on project and programme management in research	-	-	400,000	400,000
	Communication and dissemination activities	-	-	160,000	160,000
	Advocacy, networking and outreach activities	-	-	500,000	500,000
	Mobilisation of research funds in case of Public Health Emergencies	-	-	2,000,000	2,000,000
	Preparations for the Tenth EDCTP Forum 2020	-	-	600,000	600,000
Strengthening national health research systems (NHRS) in Africa for uptake of research results	-	-	300,000	300,000	

Enhancing networking among European and African scientists to close regional and gender disparities in EDCTP2 funded health research capacity activities in sub-Saharan Africa	-	-	150,000	150,000
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Sub-total	-	-	4,940,000	4,940,000
Administrative costs	Personnel, missions, consumables and supplies, service contracts	-	408,631	4,829,840
Sub-total		-	408,631	4,829,840
Total planned contributions in 2019		10,750,000	18,598,471	108,000,000
				137,348,471

* Financial contributions only. In-kind contributions from TPs/TCs are not included in this table. The total financial contribution of EUR 10,750,000 is composed of contributions from the following TPs/TCs: CEPI (EUR 10,000,000) and Novartis International (EUR 750,000).

** Financial contributions only. In-kind contributions from PSs are not included in this table. The total financial contribution of EUR 18,189,840 is composed of contributions from the following PSs: Germany (EUR 3,000,000), Netherlands (EUR 100,000), Portugal (EUR 200,000), Spain (EUR 30,000), Sweden (EUR 2,500,000) and United Kingdom (EUR 12,768,471).

4. Non-EU funded National Programme Activities or Participating and Partner States Initiated Activities (PSIAs)

The European and African EDCTP Association Partner States (PS) implement and fund a broad array of national programme activities that contribute to the objectives of the EDCTP2 programme. These Participating and Partner States' Initiated Activities (PSIAs) are implemented and funded independently from the EDCTP Association by one PS alone or by several PS. PSIAs are an important contribution from PS to the EDCTP2 programme and form an integral part of it. PSIAs are therefore included in the EDCTP2 annual work plans and any communication related to PSIAs, whether undertaken by the EDCTP Association, a European Partner State (which are the Participating State as defined in the EDCTP2 Basic Act) or a African Partner State, or any of the participants in a PSIA, must clearly indicate that they are part of the EDCTP2 programme supported by the EU (see section 6.10). PSIAs are set up, funded and managed by PS according to national rules, but the implementation follows a set of common principles, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection (provided in section 6.5).

The total budgeted cost for new PSIAs in 2019 (Tables 2 and 15) comprises EUR 193,249,916 by the European PSs and EUR 1,132,630 by the African Partner States.

All PSIAs are listed in table 15 below, with a brief overview of the PS, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the total indicative commitment for the activity. Wherever relevant, local currencies have been converted into Euros using official exchange rates.

Disclaimer:

The European Commission's acceptance of the PSIAs as in-kind contribution of the (European) Participating States to the EDCTP2 programme will be based on an assessment of the information provided through the EDCTP Association's annual reporting to the European Commission. This reporting shall include reporting by the (European) Participating States according to the requirements agreed with the European Commission in line with Article 4 of the EDCTP2 Basic Act and included under Article 19 of the Delegation Agreement concluded between the EDCTP Association and the European Commission. This assessment will verify the costs incurred by the (European) Participating States for the implementation of those PSIAs, the relevance of those PSIAs in contributing to the specific objectives of the EDCTP2 programme, their correct labelling in any communication, and their compliance with the common principles agreed by the EDCTP Association, on behalf of the (European) Participating States, and the European Commission.^{3,7}

4.1. PSIAs to be initiated in 2019

The following **new PSIA**⁴⁶ will be initiated by PSs in 2019 as contributions to the EDCTP2 programme:

Table 16. PSIAs supported in 2019

Country	Code	Activity Title	Keyword	Type of action	African countries involved	Duration of PSIA (in months)	Total Budgeted Costs (EUR)
European Partner States (Participating States)							
Finland	PSIA-2019-2125	Preparedness for emerging zoonotic infections in Kenya	NIDs; Emerging diseases	RIA	Kenya	48	475,980
France	PSIA-2019-2134	IRD PhD Fellowships	Cross-cutting	TMA	TBC	40	44,635
France	PSIA-2019-2133	LMI RESPIRE	Emerging diseases	CSA	TBC	60	240,000
France	PSIA-2019-2132	Center for Translational Science - Institut Pasteur	Cross-cutting	CSA	TBC	36	79,600
France	PSIA-2019-2131	Center for Global Health - Institut Pasteur	Cross-cutting	CSA	TBC	36	650,000
France	PSIA-2019-2130	ESTHER (Low level of virological success in decentralized HIV care sites in Cameroon)	HIV/AIDS	RIA	Cameroon	36	261,800
France	PSIA-2019-2129	Stratifying tuberculosis disease using whole blood stimulation	Tuberculosis	RIA	South Africa	36	50,000
France	PSIA-2019-2128	Initiative 5% Operational Research Call for Proposal	Cross-cutting	RIA	TBC	12	4,000,000
Germany	PSIA-2019-2074	Low-Bandwidth Database Synchronization for Outbreak Response Management and Analysis in Low Resource Settings (SORMAS-LBS)	Cross-cutting	RIA	TBC	10	370,000
Germany	PSIA-2019-2075	Grand Challenges Africa	Cross-cutting	RIA	TBC	24	300,000
Italy	PSIA-2019-2072	Prevention of mother-to-child transmission of HIV: an analysis of maternal retention and of infants health in the first year after delivery	HIV/AIDS	RIA	Malawi	24	250,000
Italy	PSIA-2019-2097	Support for the Decentralization of the management of Tuberculosis Resistant in the Dodoma region, Tanzania (DETER-TB)	Tuberculosis	RIA	Tanzania	24	298,503
Netherlands	PSIA-2019-2126	Development of vaccines for poverty and neglected tropical diseases	Malaria; NIDs	RIA	Gabon, Uganda, Ghana	24	3,900,000
Netherlands	PSIA-2019-2127	Improved and innovative diagnostics for neglected and poverty related diseases	Malaria; NIDs	RIA	TBC	48	1,685,000
Norway	PSIA-2019-2106	Norwegian Contribution to the Coalition for Epidemic Preparedness Innovations	Epidemic preparedness	RIA	TBC	60	10,000,000
Spain	PSIA-2019-2143	Supporting the National Health Research System of Equatorial Guinea	Cross-cutting	CSA	Equatorial Guinea	12	360,000

Spain	PSIA-2019-2142	Support for health research capacities in Mozambique to provide the National Health System with scientific evidence to inform and guide public health decisions	Cross-cutting	CSA	Mozambique	12	1,125,000
Sweden	PSIA-2019-2109	Understanding the context of, and addressing sensitive sexual and reproductive health and rights issues in sub-Saharan Africa: A regional research and advocacy program	Cross-cutting	RIA	Burkina Faso, Kenya, Liberia, Malawi, Rwanda, Sierra Leone and Zambia	48	7,700,000
Sweden	PSIA-2019-2135	Estimated Grants in the scope of EDCTP funded by The Swedish Research Council	Cross-cutting	RIA	TBC	48	30,000,000
Sweden	PSIA-2019-2139	ReAct 2019-2023	AMR	RIA	TBC	48	75,160,000
Sweden	PSIA-2019-2137	Grand Challenges Africa	Cross-cutting	RIA	TBC	60	9,242,484
Sweden	PSIA-2019-2146	University of Rwanda research and HE 2019-2024- Health Research	Cross-cutting	RIA	Rwanda	60	6,200,700
United Kingdom	PSIA-2019-2076	MRC Research Grants	HIV; Malaria; TB; NIDs	RIA	TBC	60	6,684,640
United Kingdom	PSIA-2019-2077	MRC Fellowships	Capacity development	TMA	TBC	60	2,228,214
United Kingdom	PSIA-2019-2078	MRC/DFID African Research Leader (ARL) scheme	Capacity development	TMA	TBC	60	1,671,160
United Kingdom	PSIA-2019-2079	Joint Global Health Trials (JGHT) scheme	Cross-cutting	RIA	TBC	60	8,355,801
United Kingdom	PSIA-2019-2080	Late Phase Global Health Research	Cross-cutting	RIA	TBC	60	891,285

Sub-Total European PSs 172,224,802

African Partner States

Cameroon	PSIA-2019-2100	Sessions of National Ethics Committee for Human Health Research	Cross-cutting; Ethics; Health systems; Operational research; Implementation research	CSA	Cameroon	9	33,000
Cameroon	PSIA-2019-2101	Capacity building on good clinical practice and protection of research participants	Cross-cutting, Ethics; Capacity Development; Operational Research	TMA	Cameroon	1	15,000
Ghana	PSIA-2019-2150	Cluster randomized community-based trial of annual versus biannual single-dose Ivermectin plus Albendazole against Wuchereria bancrofti infection in human and mosquito populations	Malaria; Drugs; Capacity Building	RIA	Ghana	36	10,000

Ghana	PSIA-2019-2151	Pan-African Network For Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics	Diahorreal Diseases, Vibrio Cholera; AMR, Surveillance; Rapid response; Epidemics preparedness; Capacity Building; Networking	RIA	Ghana & countries in the EDCTP2 Regional Networks of Excellence	36	42,000
Ghana	PSIA-2019-2152	West African Network for TB AIDS and Malaria (WANETAM2)	TB; HIV; Malaria; Ebola; NTDs; Capacity Development; Data sharing; Diagnostics; Laboratory; Cross-cutting; Networking	CSA	Ghana and countries associated with WANETAM	36	42,000
Ghana	PSIA-2019-2153	Workshop on Data Management in Health Research	Data management; Capacity development	TMA	Ghana	1	10,503
Ghana	PSIA-2019-2154	Workshop on Ethical Issues in Health Research & Scientific Writing and Publications	Capacity development; Ethics; Health Research; Scientific writing	TMA	Ghana	1	5,601
Ghana	PSIA-2019-2155	Workshop on Operational Research for Health Professionals	Capacity Development	TMA	Ghana	1	5,601
Mali	PSIA-2019-2110	Host vulnerability and parasite genetics in the development of cerebral malaria	Malaria; Epidemiology; Genetics	RIA	Mali	12	15,743
Mali	PSIA-2019-2111	Developing Excellence in Leadership and Genetic Training for Malaria Elimination in Sub-Saharan Africa (DELGEME)	Malaria; Drugs; Capacity Development; Bioinformatics	TMA	Mali; Ghana; Gabon; Tanzania; The Gambia	24	300,000
Mali	PSIA-2019-2112	Malaria Research Capacity Development in West and Central Africa	Malaria; Vaccines; Drugs; Diagnostics; Capacity Development; Data Management; Epidemiology	TMA	Mali; Senegal	36	144,992
Mali	PSIA-2019-2113	Strengthening Malaria Research and Training Center (MRTC) clinical research capacity	Malaria; Vaccines; Drugs; Diagnostics; Capacity Development; Data Management; Epidemiology	CSA	Mali	24	300,000

Mozambique	PSIA-2019-2114	ROTA_FNI	Diarrhoeal diseases; Capacity Development; Laboratory; Cross-cutting; Data Management; National policy on Rotavirus vaccine.	RIA	Mozambique	24	80,073
Mozambique	PSIA-2019-2115	MEFI	Malaria; Drugs; Epidemiology; National policy on AMR	RIA	Mozambique; United States	24	15,421
Niger	PSIA-2019-2070	Study of the impact of Chemoprevention of seasonal malaria in Niger	Drugs	RIA	TBC	12	38,096
Uganda	PSIA-2019-2095	The 11th Annual National Research Ethics Conference	Cross-cutting	CSA	Uganda	12	50,000
Uganda	PSIA-2019-2096	The 7th East African Health and Scientific Conference & International Health Exhibition and Trade Fair	Cross-cutting; Networking	CSA	Uganda; Tanzania; Rwanda; Kenya	3	24,600
Sub-Total African PSs							1,132,630
Grand Total European + African PS							173,357,432

5. Administrative costs of the EDCTP Association in implementing the EDCTP2 programme

Administrative cost refers to costs directly linked to the implementation of the EDCTP2 programme that correspond to the costs incurred by the EDCTP Association for:

- Personnel directly assigned to the implementation of the EDCTP2 programme;
- Missions required for the implementation of the EDCTP2 programme;
- Depreciation of equipment directly used for the implementation of the EDCTP2 programme;
- Consumables and supplies directly used for the implementation of the EDCTP2 programme; and
- Service contracts (including non-recoverable taxes) required for the implementation of the EDCTP2 programme.

For 2019 the budget for administrative costs is set out in the table below:

Table 17. Administrative costs budget of the EDCTP Association for the implementation of the EDCTP2 programme in 2019

Description	Note	EU (in EUR)	PSs and TPs (in EUR)	Total (in EUR)
Personnel		3,949,667	408,631	4,358,298
Missions	1	200,000	-	200,000
Consumables and supplies	2	200,000	-	200,000
Service contracts (including non-recoverable taxes)	3	480,173	-	480,173
Total		4,829,840	408,631	5,238,471

Notes to the administrative budget summary

1. Missions: the costs budgeted under this category exclude the travel costs of expert groups (Scientific Advisory Committee and Scientific Review Committee) and for specific events, which are budgeted for under other EU-funded activities (chapter 3).
2. Consumables and supplies: the costs budgeted for under this category include bank charges incurred in making fund transfers to beneficiaries, postage and courier costs, office utilities, office consumables and stationery.
3. Service contracts (including non-recoverable taxes): the costs budgeted for under this category include annual audit fees in relation to secretariat's annual financial reports and statutory accounts, office cleaning, IT support services, office rent (for the EDCTP Association offices in The Hague and Cape Town), and other hosting costs.

Table 18. Projected staff headcount by functional area in 2019

Functional area	Headcount
General Administration and Finance	10
Operations (Calls and Grants)	12
Grants Financial Management	3
Strategic Partnerships	7
Communications	2
Total	34

Monitoring of administration costs

Article 2(3) of Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 set a ceiling for administrative costs of 6% of the Union's financial contribution of EUR 683,000,000 for the entire duration of the EDCTP2 programme. This means that the EDCTP Association can use up to EUR 40,980,000 of Union's contribution to cover administrations costs.

To ensure effective monitoring of the 6% administrative costs ceiling set out in article 2(3) of of Decision No 556/2014/EU, the EDCTP Association Secretariat has prepared an administrative expenditure plan for the duration of the EDCTP2 programme. The 6% administrative cost ceiling is identified as an EDCTP Association risk, and it has been listed in the EDCTP Association risk register. This risk is regularly reviewed to ensure the risk does not materialise. Periodic administrative costs are reviewed to ensure that they are within budget.

6. General Annexes⁴⁷

6.1. List of countries eligible for funding

Legal entities established in the following countries and territories will be eligible to receive funding through EDCTP2 grants⁴⁸:

- The Member States (MS) of the European Union (EU), including their outermost regions: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK;
- The Overseas Countries and Territories (OCT) linked to the Member States⁴⁹: Anguilla, Aruba, Bermuda, British Antarctic Territory, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Falkland Islands, French Polynesia, French Southern and Antarctic Territories, Greenland, Montserrat, Netherlands Antilles (Bonaire, Curaçao, Saba, Sint Eustatius, Sint Maarten) New Caledonia and Dependencies, Pitcairn Islands, Saint Barthélemy, Saint Helena, Saint Pierre and Miquelon, South Georgia and the South Sandwich Islands, Turks and Caicos Islands, Wallis and Futuna Islands.
- The associated countries (AC): the latest information on which countries are associated or in the process of association to Horizon 2020 can be found in the online manual⁵⁰; The following sub-Saharan African countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic People's Republic), Congo (Republic), Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Equatorial Guinea, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

International European interest organisations⁵¹ will also be eligible to receive funding from the EDCTP2 programme.

Legal entities established in countries not listed above will be eligible for funding when such funding is explicitly foreseen in the call.

In addition, legal entities established in countries not listed above and international organisations (IOs) will be eligible for funding:

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the EU and an international organisation or a third country⁵²;
- When the EDCTP Association deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme
- For Prizes, unless stated otherwise in the call conditions, any legal entity, regardless of its place of establishment, or international organisation may receive funding⁵³.

6.2. Standard admissibility conditions and related requirements

1. For all actions under this Work Plan, proposals/prize applications must comply with the admissibility conditions set out in this Annex, unless they are supplemented or modified in

the call conditions or rules of contest.

To be considered **admissible**, a proposal/application must be:

- a. submitted in the electronic submission system of the EDCTP Association before the deadline given in the call conditions or rules of contest;
 - b. readable, accessible and printable;
 - c. **complete** and include the requested administrative data, the proposal description, and any obligatory supporting documents specified in the call/contest;
 - d. include a **draft plan for the exploitation and dissemination** of the results, unless otherwise specified in the call conditions. The draft plan is not required for proposals at the first stage of two-stage procedures.
2. In addition to the above admissibility conditions, **word limits** will apply to proposals/ applications. The word limits will be clearly set out in the electronic submission system of the EDCTP Association. If a proposal exceeds the limits, the proposal cannot be submitted in the system and the applicant will receive an automatic warning that the proposal must be revised before submission.

The word limits for a full proposal per type of action and proposal section are set as follows:

Question	RIA	CSA	TMA
Abstract	400	400	400
Residency	Not asked	Not asked	250
Employment contract	Not asked	Not asked	250
Previous Projects	Not asked	Not asked	250
Publications	Not asked	Not asked	250
Presentations	Not asked	Not asked	250
Career Summary Motivation Statement	Not asked	Not asked	1200
Proposal	5000	5000	5000
References (for proposal section)*	3000	3000	3000
Impact	2500	2500	2500
Career Development	Not asked	Not asked	1000
References (for Impact section)*	3000	Not asked	Not asked
Data Management and Ownership	1500	1500	1500
Results and dissemination	1500	1500	1500
Generalisability of the trial/study results	800	Not asked	Not asked
Lead Applicant publications list	1000	1000	1000
Lead Applicant major achievements	500	500	500
Work Plan	1500	1500	1500
Work package (1500 words each - assume 3)**	4500	4500	4500
Milestones – means of verification (100 words each - assume 5)***	500	500	500
Management Structure and Procedures	1000	1000	Not asked
Consortium as a whole	1000	1000	Not asked
Critical Risks (100 words each – assume 5)****	500	500	500
Budget Justification	3000	3000	3000
Total	31,200	27,400	28,850

The word limit for a first-stage proposal is 3200 words (Abstract, Excellence and Impact sections) unless otherwise specified.

The structure of proposals must correspond to the requirements specified under each section of the proposal template.

3. The following supporting documents will be required to determine the **operational capacity**

of each applicant in grant proposals, unless otherwise specified in the call:

- A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed research and/or innovation activities;
- A list of up to five relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content;
- A list of up to five relevant previous projects or activities, connected to the subject of this proposal;
- A description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work;
- A description of any third parties that are not represented as project partners, but who will nonetheless be contributing towards the work (e.g. providing facilities, computing resources).

This scrutiny will be carried out by the evaluators during the evaluation process under the selection criteria, in particular the award criterion ‘Quality and efficiency of the implementation’. Please refer to General Annex 6.7 “Evaluation rules”.

6.3. Standard eligibility conditions

All proposals must comply with the eligibility conditions set out in the Rules for Participation Regulation No.1290/2013⁵⁴ and any derogations to these as specified in the EDCTP2 Basic Act⁵⁵.

Furthermore, for actions under this EDCTP2 Work Plan proposals/prize applications must comply with the **eligibility conditions** set out in this Annex, unless they are supplemented or modified in the call conditions.

A proposal/application will only be considered **eligible** if:

- a. its content corresponds, wholly or in part, to the topic/contest description for which it is submitted
- b. it complies with the eligibility conditions for participation set out in the table below, depending on the type of action:

Table 19. Standard eligibility criteria per type of action

Type of Action	Eligibility conditions for participation ^{56,57,58}
Research & Innovation Action (RIA)	At least three legal entities. Two of the legal entities shall be established in two different Participating States (European Partner States)* and one of the legal entities must be established in a sub-Saharan African country (listed in section 6.1). All three legal entities must be independent of each other.
Coordination & Support Action (CSA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Training & Mobility Action (TMA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Prizes	See conditions for participation in the Rules of Contest.

* *The Participating States (European Partner States) are: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom (see also footnote 3).*

Note: ‘Sole participants’ formed by several legal entities (e.g. European Research Infrastructure Consortia, European Groupings of Territorial Cooperation, central purchasing bodies) are eligible if the above-mentioned minimum conditions are satisfied by the legal entities forming together the sole participant.

6.4. Types of action: specific provisions and funding rates^{59,60}

6.4.1 Research & Innovation Actions (RIAs)

Description: Actions primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution⁶¹.

In the EDCTP2 programme these are actions primarily consisting of clinical research activities and clinical trials in partnership with sub-Saharan Africa aiming to increase the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones, in particular in sub-Saharan Africa. Actions should normally include one or more clinical trial (phase I to IV) conducted in sub-Saharan Africa, in particular phase II and/or III trials. Actions involving the conduct of phase II and III trials of drugs and vaccines shall normally include a regulatory strategy. Whilst clinical trial(s) represent the main activity, the action may involve additional relevant research studies such as nested sub-studies or epidemiological studies. These actions may also involve supporting activities fostering networking (within Africa and within Europe, as well as between Africa and Europe) or capacity development of researchers, institutions and sites in sub-Saharan Africa to conduct clinical trials and related research, including observational studies.

Funding rate: 100%

6.4.2 Coordination & Support Actions (CSAs)

Description: Actions consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of strategic planning, networking and coordination between programmes in different countries⁶².

In the EDCTP2 programme CSAs address activities such as: i) activities to develop, strengthen and extend clinical research capacities in sub-Saharan Africa, ii) activities to promote networking and collaboration both between European and African and among African researchers, clinical research institutions and sites, as well as iii) activities to foster coordination and cooperation between public and private funders. Actions may involve activities of standardisation, dissemination, awareness-raising and communication, conduct of preparatory and accompanying studies, networking, coordination or support services, policy dialogues and mutual learning exercises and studies. Actions may also include complementary activities of strategic planning, networking and coordination between regional and national programmes. Actions may also involve targeted measures to maximise the public health impact of research results stemming from EDCTP2-funded activities in sub-Saharan Africa by promoting their translation and supporting their uptake in policy-making, health systems and clinical practice at local, national and/or international level. In particular, CSAs will support sub-Saharan African countries in developing a robust ethical and regulatory framework for conducting clinical trials, targeting both national ethics committees (NECs) and national regulatory authorities (NRAs). Furthermore, CSAs will support regional clinical research networks in sub-Saharan Africa (“EDCTP regional networks”) in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials according to ICH-GCP standards.

Funding rate: 100%

6.4.3 Training and Mobility Actions (TMAs)

Description: In the EDCTP2 programme, these are actions consisting primarily of developing clinical research capacities and skills of researchers and clinical research staff from sub-Saharan Africa, and/or promoting mobility of researchers and research staff.

Funding rate: 100%

6.4.4 Prizes

Description: Prizes are financial contributions given as rewards following the publication of a contest. A 'recognition prize' is used to recognise past achievements and outstanding work after it has been performed, whereas an 'inducement prize' is used to spur investment in a given direction, by specifying a target prior to the performance of the work.

The Rules of Contest lay down the conditions for participation, the award criteria, the amount of the prize and the arrangements for the payment of the prize to the winners after their award. Model Rules of Contest are set out below in section 6.6.

Prize amounts: The amount of the prize is specified in the contest. It is not linked to the costs incurred by the winner.

6.5. Common principles applying to national programme activities (PSIAs)

The EDCTP2 Basic Act2 stipulates that the EDCTP2 programme activities may include national programme activities of PSs that are not funded by the EDCTP Association, including activities undertaken by public or private not-for-profit research organisations. Those activities included as so-called PSIAs in the EDCTP2 annual work plan shall be implemented in compliance with common principles to be agreed by the Participating States and the European Commission, taking into account the principles set out in EDCTP2 Basic Act2, in Title VIII of the Financial Regulation and in the Rules for Participation Regulation No 1290/2013, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection.

The European Commission and the EDCTP Association on behalf of the PSs have agreed to the common principles outlined below⁶³:

6.5.1 Equal treatment

- Participation in PSIAs, including the right to receive funding, should in general be open to any type of legal entity, private or public. It is understood and acceptable however, that national legislation or specific objectives of an action may dictate that only certain legal entities, e.g. public institutions, can participate and receive funding in certain actions.
- Funding to PSIA actions should to the largest possible extent be allocated through open calls for proposals, and the EDCTP2 programme should be mentioned in the call text. It is understood and acceptable however that existing national research infrastructures and organisations, e.g. publicly funded research institutes, can be used to implement parts or the entire PSIA. Funding may therefore not be allocated through open Calls for Proposals, but either through internal competition within the research infrastructure or according to an overall strategic research plan. It is further understood and acceptable that exceptional situations, for example in health emergencies such as the recent Ebola outbreak, allocation of funding through open calls may neither be practical or timely. In these situations, earmarked funding to a named beneficiary can be acceptable.

- The principle of equality and non-discrimination based on gender, racial or ethnic origin, religion or belief, disability, age and sexual orientation should be observed and promoted.

6.5.2 Transparency

- Evaluation and selection criteria and details of the review process should be published before applicants submit proposals.
- The awarding of funds through Calls for Proposals or through institutional funding is made public.
- Any communication or publication related to PSIA, whether undertaken by the EDCTP Association, a PS, or participants to an activity, shall be labelled or co-labelled as '[name of the PSIA] is part of the EDCTP2 programme supported by the European Union'.

6.5.3 Independent peer review evaluation

- Applications submitted through open Calls for Proposals should be evaluated by panels of leading independent domestic and/or non-domestic experts (peer review).
- In case of direct funding to a national research infrastructure or organisation, the quality of the research output by the national research infrastructures or organisation should be assessed on a regular basis and structured manner, preferably through independent peer review.

6.5.4 Ethics and scientific integrity

- The principles of scientific integrity as defined in the European Code of Conduct for Research Integrity should be observed and promoted⁶⁴.
- Fundamental ethical principles and in particular those related to the conduct of human clinical trials, including the Charter of Fundamental Rights of the EU, the European Convention on Human Rights and its Supplementary Protocols, the World Medical Association's Declaration of Helsinki of 2008 and the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), should be adhered to and enforced, both during the selection of actions for funding and during the subsequent implementation of the actions.

6.5.5 Appeal and complaints

- A peer review appeal system should be established to provide applicants the opportunity to seek reconsideration of the initial review results if they believe the review process was flawed.

6.5.6 Exploitation and dissemination of results

- The findings of research activities included as PSIA in the EDCTP2 annual work plan must be made available to the research community and the public in a timely manner.

6.6. Model Rules of Contest (RoC) for EDCTP2 Prizes

This section provides a model for the Rules of Contest that will be published for prizes under this EDCTP2 work plan.

6.6.1 EDCTP2 Prizes: Scientific Leadership Prize, Outstanding Female Scientist Prize, Outstanding Research Team Prize, and Dr Pascoal Mocumbi Prize

Objectives pursued

The objectives of the prize are as specified under the detailed description of the EDCTP2 Prizes (see chapter 3.2).

Expected results

All four prizes will recognize the particular achievements of the winners and promote the work of the winners. By awarding these prizes, it is expected that further attention will be drawn to the excellent scientific research being conducted within the remit of the EDCTP2 programme, the contributions to improved health, and scientific collaboration between Europe and sub-Saharan Africa.

6.6.2 Prize Amount

As specified in this work plan in chapter 3.2.

6.6.3 Deadlines and Admissibility

Deadlines

Opening of the submission:	Q4 2019
Closing date for submission:	Q2 2020 at hh:mm:ss CET ⁶⁵

Joint applications by a group of participants are admitted. In this case, the participants must appoint a 'lead participant' to represent them. The participants will be jointly responsible and must all fulfil and respect the conditions set out in these Rules of Contest.

Applications must be submitted by the (lead) participant via prizes@edctp.org, unless otherwise specified.

Applications must be readable, accessible and printable. Incomplete applications may be considered inadmissible if essential elements are missing (see section 6.2).

6.6.4 Eligibility criteria

The contest for the first three prizes (Scientific Leadership Prize, Outstanding Female Scientist Prize, and Outstanding Research Team Prize) is open to residents of a sub-Saharan African country, an EU Member State, or a country associated to the Horizon 2020 programme.

The contest for the Dr Pascoal Mocumbi Prize is open to contestants from all parts of the world. Please note however that special rules may apply for entities from certain countries (see section 6.3).

The nomination of contestants who are currently employees of the EDCTP Association, or serving on one of the EDCTP Association advisory (Scientific Advisory Committee and Audit Committee) or governing (General Assembly and Board) bodies will not be permitted for any of the prizes.

Finally, contestants that have already received an EDCTP2 prize cannot receive a second prize for the same activities.

6.6.5 Exclusion criteria

Participants will be excluded if they (or one of them):

- Are subject to an administrative sanction (i.e. exclusion)⁶⁶
- Are in one of the following situations⁶⁶:
 - bankrupt, being wound up, having their affairs administered by the courts, entered into an arrangement with creditors, suspended business activities or subject to any other similar proceedings or procedures under national law (including persons with unlimited liability for the participant's debts);
 - declared in breach of social security or tax obligations by a final judgment or decision (including persons with unlimited liability for the participant's debts);
 - found guilty of grave professional misconduct⁶⁷ by a final judgment or decision (including persons having powers of representation, decision-making or control);
 - convicted of fraud, corruption, involvement in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including persons having powers of representation, decision-making or control);
 - shown significant deficiencies in complying with main obligations under a procurement contract, grant agreement or grant decision financed by the EU or Euratom budget (including persons having powers of representation, decision-making or control);
 - found guilty of irregularities within the meaning of Article 1 (2) of Regulation No 2988/95 (including persons having powers of representation, decision-making or control);
- have misrepresented information required for participating in the contest or fail to submit such information;
- were involved in the preparation of the prize documents and this entails a distortion of competition.

6.6.6 Award Criteria

The prize will be awarded to the entry that in the opinion of the independent expert jury, the EDCTP2 Awards Panel, demonstrates to best address the cumulative criteria specified under the detailed description of the EDCTP2 Prizes in the annual work plan (please see section 3.2 above).

The Scientific Leadership Prize is awarded to the entry that best addresses the following cumulative criteria:

1. Contestants have made significant achievements in their field and will continue to become leaders in their research field.
2. Contestants should have made major contributions to the objectives of the EDCTP2 programme to strengthen research capacity in sub-Saharan Africa and to support South-South and North-South networking.
3. Contestants nominated for this prize should not exceed 50 years of age, at the time of the launch of the contest.

The Outstanding Female Scientist Prize:

1. Contestant must have been involved in research and innovation activities in sub-Saharan Africa within the scope of the EDCTP2 programme
2. Contestants should have made a significant scientific contribution and built measurable impactful research capacity through training and mentorship for the future generation of researchers/scientists in Africa.
3. This prize is restricted to female scientists in sub-Saharan Africa and has no age restriction.

The Outstanding Research Team Prize:

1. Contestants must be a consortium or group of partners who have achieved the goal of taking on EDCTP2 programme priority issues in poverty related diseases (PRDs).
2. In collaboration, the team has built effective and equitable South-North partnerships to answer the priority research questions and produced health-policy relevant deliverables, such as research data implemented into policy and practice, high impact publications and significant capacity building outputs at local research sites.
3. Contestants should be actively involved in research, capacity development and networking in sub-Saharan Africa and Europe with outstanding achievements and scientific and policy impact in their respective fields.

Dr Pascoal Mocumbi Prize:

1. The contestant should have made significant achievements in promoting Africa-Europe partnerships in global health research;
2. The contestant should have made unique contribution to promoting and facilitating the clinical development of products for poverty-related diseases
3. The contestant should have made achievements in advancing capacity development for health research in sub-Saharan Africa
4. The contestant should have made achievements in promoting international networking of researchers, policy makers, funders and donors on poverty-related diseases (PRDs).

6.6.7 Documents

The mandatory supporting documents are set out in the application form.

Participants may be asked at a later stage for further documents (for legal entity validation, bank account validation, ethics review, declaration of honour on exclusion grounds, etc.)

6.6.8 Procedure

Applications will be evaluated by an independent expert jury, the EDCTP2 Awards Panel, between May 2020 and June 2020 — first individually (by each panellist separately) and then as a group (by the whole Awards Panel together).

The independent expert jury, the EDCTP2 Awards Panel, will evaluate each application against the prize specific award criteria as specified above and score them out of a maximum of 5.

On the basis of the evaluation by the jury, the EDCTP Association will decide on the award of the prize.

The prize winner shall be notified through an official letter from the EDCTP Association Executive Director. This award letter shall clearly stipulate when the prize will be announced publicly, and the process and conditions for payment of the cash prize.

All participants will be informed on the outcome of their application.

6.6.9 Other Conditions

Payment arrangements

The prize money will be paid to the (lead) participant in one instalment after the award ceremony by bank transfer, provided all the requested documents have been submitted.

Publicity — Promoting the prize — Visibility of the EDCTP Association/EU funding

Publicity by the winner(s): The winner(s) must promote the prize and its results, by providing

targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

Unless the EDCTP Association requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) must:

- a. display the EDCTP Association logo and EU emblem;
- b. include the following text: “[*name of prize winner*] has been awarded the [*name of the prize*] which is part of the EDCTP2 programme supported by the European Union”; and
- c. when displayed together with another logo, the EDCTP Association logo and EU emblem must have appropriate prominence.

For the purposes of their obligations, the winner(s) of the prize may use the EDCTP Association logo and EU emblem without first obtaining approval from the EDCTP Association and the European Commission. This does not, however, give it the right to exclusive use. Moreover, the winner(s) of the prize may not appropriate the EDCTP Association logo, the EU emblem or any similar trademark or logo, either by registration or by any other means.

Publicity by the EDCTP Association and the European Commission: the EDCTP Association and the European Commission may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and deliverables as well as any other material, such as pictures or audio-visual material that it receives from the winner(s) of the prize (including in electronic form).

The EDCTP Association will publish the name of the winner(s), their origin, the amount of the prize and its nature and purpose, unless the winner(s) have requested the EDCTP Association to waive such publication (because disclosure risks threatening its security and safety or harms its commercial interest). Photos and videos taken by the EDCTP Association either in preparation of the award ceremony or during the award ceremony are the sole property of the EDCTP Association.

Dissemination and exploitation of results

The winner(s) must comply with the obligations set out in Title III of the Horizon 2020 Rules for Participation Regulation No 1290/2013⁵⁴.

Processing of personal data

Processing of personal data by the EDCTP Association:

The EDCTP Association complies with the provisions of the “General Data Protection Regulation (EU) 2016/679 (‘GDPR’) and collects data in accordance with the EDCTP Association privacy policy (<http://www.edctp.org/publication/edctp-privacy-policy/>) and the Privacy Statement on Grants Management (<http://www.edctp.org/web/app/uploads/2018/05/Privacy-Statement-Grants-Management.pdf>). Registration with EDCTP2 grants and submission will involve the recording and processing of personal data. These data will be held securely, processed lawfully and retained for no longer than necessary by the EDCTP Association. The EDCTP Association may publish the following information of the winner(s): name; state of origin (address or NUTS 2 region); their activities in relation to the award of the prize (via the provided summary for publication); and the prize amount. This information may be published in whatever form and medium. By accepting the prize, the winner(s) consent that this information may be used in this way.

Processing of personal data by the European Commission:

Any personal data will be processed by the European Commission under Regulation (EU) 2018/1725⁶⁸ and according to the ‘notifications of the processing operations’ to the Data

Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

Such data will be processed by the 'data controller' of the EDCTP Association and of the European Commission for the purposes of the award, implementation and follow-up of the prize or protecting the financial interests of the EU (including checks, audits and investigations; see below).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the privacy statement(s) that are published on the website(s) of the EDCTP Association and the European Commission.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS). The winner(s) consent that the EDCTP Association and the European Commission publish[es] (in whatever form and medium) the following information:

- Name;
- State of origin (address or NUTS 2 region);
- their activities in relation to the award of the prize (via the summary for publication they provided);
- prize amount in whatever form and medium.

Processing of personal data by the participants:

The participants must process personal data in compliance with applicable EU and national law on data protection (including authorisations or notification requirements, if any).

Ethics

The activities must be carried out in compliance with:

- a. ethical principles (including the highest standards of research integrity); and
- b. applicable international, EU and national law.

No prize will be awarded for activities carried out outside the EU, if they are prohibited in all Member States.

The participants must ensure that the activities have an exclusive focus on civil applications.

The participants must ensure that the activities do not:

- a. aim at human cloning for reproductive purposes;
- b. intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads); or
- c. intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Research activities involving human embryonic stem cells (hESC) are moreover subject to the conditions set out in the Statement of the Commission related to research activities involving human embryonic stem cells⁶⁹.

The participants must respect the highest standards of research integrity – as set out, for instance, in the European Code of Conduct for Research Integrity⁷⁰.

Security

The activities must be carried out in compliance with Commission Decision 2015/444, i.e. security-sensitive information must be EU-classified, if its unauthorised disclosure could adversely impact the interests of the EU or of one (or more) of its Member States. Applications

that are too security-sensitive cannot be awarded a prize.

For more information and best practice, see the Guidance — Guidelines for the classification of information in research projects, the Guidance — Guidelines for the handling of classified information in EU research projects, the Guidance note — Potential misuse of research results and the Guidance note — Research involving dual use items.

Conflict of interests

The participants must take all measures to prevent any situation where the impartial and objective award of the prize is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must inform the EDCTP Association without delay of any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The EDCTP Association may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

Liability for damages

The EDCTP Association cannot be held liable for any damage caused to the participants or to third parties as a consequence of the prize, including for gross negligence.

The EDCTP Association cannot be held liable for any damage caused by any of the participants in the context of the prize.

Checks, audits and investigations

The EDCTP Association, the European Commission, the European Anti-Fraud Office (OLAF) and the Court of Auditors may carry out checks, audits and investigations in relation to the prize.

Withdrawal of the prize — Recovery of undue amounts

The EDCTP Association may withdraw the prize after its award and recover all payments made, if it finds out that:

- a. false information or fraud or corruption was used to obtain the prize;
- b. a winner was not eligible or should have been excluded;
- c. a winner is in serious breach of its obligations under these Rules of Contest.

Exchange of information with the Commission

If a participant has misrepresented the information required as a condition for participating in the contest or has failed to supply that information or in any other case required by the Financial Regulation, the EDCTP Association will inform the Commission in accordance with the procedures set out in that regulation in view of the participant's potential inclusion in the database for the early detection and exclusion system (EDES). The EDCTP Association will also inform the Commission on the measures taken by the EDCTP Association.

Cancellation of the contest

The EDCTP Association may cancel the contest or decide not to award the prize – without any obligation to compensate participants -, if:

- a. no applications are received;
- b. the jury does not find a winner;
- c. a winner is not eligible or must be excluded

- d. or, the objective of the contest has already been achieved.

Complaints

Complaints concerning the procedural aspects of the contest can be brought by participants negatively affected by the alleged shortcoming in the procedure. Such a complaint must be brought in the form of a letter addressed to the EDCTP Association Executive Director, clearly indicating the contest, the name of the nominee and reference number, and the alleged shortcoming in the procedure. This letter must be submitted via prizes@edctp.org. The deadline for such complaints is 30 days from the date of dispatch of the outcome letters for the contest. The procedure used with regard to appeals against the evaluation of proposals (see section 10.3 of the EDCTP2 Grants Manual) will be followed to handle complaints brought against procedural aspects of the contest.

Contact

For more information, please see the EDCTP Association website at <http://www.edctp.org/prizes/>

In case of questions, please contact info@edctp.org.

6.7. Evaluation rules

6.7.1 Selection criteria

1. Financial capacity: In line with the Financial Regulation and the Horizon 2020 Rules for Participation Regulation No 1290/2013. For grants, coordinators will be invited – at the full proposal stage - to complete a self-assessment using an on-line tool.
2. Operational capacity: As a distinct operation, carried out during the evaluation of the award criterion ‘Quality and efficiency of the implementation’, experts will indicate whether each individual participant has, or will have in due time, a sufficient operational capacity to successfully carry out its tasks in the proposed work plan. This assessment will be based on the competence and experience of the applicant, including its operational resources (human, technical and other) and, if applicable, exceptionally the concrete measures proposed to obtain it by the time of the implementation of the tasks. For prizes and for first-stage proposals in a two-stage submission procedure, neither financial capacity nor operational capacity is subject to evaluation.

6.7.2 Award criteria, scores and weighting

1. Grant proposals will be evaluated by experts, on the basis of the award criteria ‘excellence’, ‘impact’ and ‘quality and efficiency of the implementation’ (see Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013). The aspects to be considered in each case depend on the types of action as set out in the table below, unless stated otherwise in the call conditions. For all proposals involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Table 20. Award criteria per type of EU-funded EDCTP2 action

Award criteria			
Type of Action	Excellence The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work plan.	Impact The following aspects will be taken into account:	Quality and efficiency of the implementation The following aspects will be taken into account:
All Types of Action	<p>Fit with the scope and objectives of the EDCTP2 programme, the EDCTP Association strategic research agenda and the call topic description.</p> <p>Importance, relevance/pertinence and clarity of the objectives.</p> <p>Soundness of the concept and credibility of the proposed approach/methodology.</p>	<p>Call specific aspects as listed under ‘expected impact’ in each individual call.</p> <p>The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.</p> <p>Likelihood to result in major advances in the field with potential benefit of the research to the affected populations.</p>	<p>Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;</p> <p>Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met.</p> <p>Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise.</p> <p>Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role.</p> <p>Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant.</p> <p>Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.</p> <p>Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).</p>
Research & Innovation Action (RIA)	<p>Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.</p> <p>Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.</p>	<p>Advancing the clinical development of new and improved products.</p> <p>Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results.</p>	<p>Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP).</p> <p>Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial.</p>

	<p>Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.</p> <p>Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge and gender dimension in research and innovation content.</p>	<p>Contribution to improved disease management and prevention through changes in policy and practice, with the ultimate goal of improving public health.</p> <p>Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials.</p> <p>Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data</p>	<p>Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).</p>
<p>Coordination & support action (CSA)</p>	<p>Clarity, pertinence and importance of the strategic vision.</p> <p>Soundness of the concept.</p> <p>Quality of the proposed coordination and/or support measures.</p>	<p>Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), and to manage research data where relevant.</p> <p>Sustainability of capacity beyond the end of the grant, where relevant.</p> <p>Contribution to networking, where relevant, including alignment with national, regional and/or pan-African development plans, and with other actors intervening in the same field.</p> <p>Communicate the project activities to different target audiences.</p>	<p>Quality of the leadership and a clear and effective governance structure.</p>
<p>Training & Mobility Action (TMA)</p>	<p>Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career.</p> <p>Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.</p> <p>Quality of the mentorship and/or training plan</p>	<p>Advancing the fellow's clinical research skills and career development.</p> <p>Contribution to development of research independence and/or scientific leadership</p> <p>Contribution to strengthening clinical research capacity at the home or host organisation.</p> <p>Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data.</p> <p>Sustainability and retention of capacity beyond the end of the grant.</p>	<p>Suitability of the fellow's home and/or host organisation to support the fellowship project.</p> <p>Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.</p>

2. Scoring and weighting:

Unless otherwise specified in the call conditions:

- Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For full proposals, each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.
- For the evaluation of first-stage proposals under a two-stage submission procedure, only the criteria 'excellence' and 'impact' will be evaluated. Within these criteria, only the aspects in bold will be considered. The threshold for both individual criteria will be 4. For each indicative budget-split in the call conditions, the overall threshold, applying to the sum of the two individual scores, will be set at the level such that the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and in any case, not less than two and a half times the available budget.
- The actual level will therefore depend on the volume of proposals and funding request per proposal received. The threshold is expected to normally be set at 8 or 8.5.
- For RIA second-stage proposals as well as for single-stage evaluation procedures (RIAs) only, unless otherwise indicated in the call text, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure). There is no rebuttal procedure for CSA and TMA calls
- If special procedures apply, they will be set out in the call conditions.

3. Priority order for proposals with the same score:

Unless the call conditions indicate otherwise, the following method will be applied (except for the first stage of two-stage calls, where proposals having the same score are kept together and no prioritisation is made).

If necessary, the EDCTP Association review committee will determine a priority order for proposals which have been awarded the same score within a ranked list. Whether or not such a prioritisation is carried out will depend on the available budget or other conditions set out in the topic description of the call. The following approach will be applied successively for every group of ex aequo proposals requiring prioritisation, starting with the highest scored group, and continuing in descending order:

- a. Proposals that address topics, or sub-topics, not otherwise covered by more highly-ranked proposals, will be considered to have the highest priority.
- b. These proposals identified under (a), if any, will themselves be prioritised according to the scores they have been awarded for the criterion excellence. When these scores are equal, priority will be based on scores for the criterion impact.
- c. If necessary, any further prioritisation will be based on the following factors, in order: gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the action (for TMAs, female fellowship candidates shall have priority); relative number of sub-Saharan African countries involved, in particular involvement/representation of countries with more limited research capacities; leverage of funding from third parties; quality of the networking activities.
- d. If a distinction still cannot be made, the EDCTP Association review committee may decide to further prioritise by considering the potential for synergies between proposals, or other factors related to the objectives of the call or the EDCTP2 programme in general. These factors will be documented in the report of the review committee.
- e. The method described in points (a), (b), (c) and (d) will then be applied to the remaining ex aequo proposals in the group.

4. For prizes, the award criteria, scoring and weighting will be set out in the Rules of Contest.

Evaluation procedure

- a. Calls may be subject to either a one-stage or two-stage submission and evaluation procedure.
- b. Proposals are evaluated by independent experts (see Article 15(7) Horizon 2020

Rules for Participation Regulation No 1290/2013 for exceptional cases). As part of the evaluation by independent experts, the EDCTP Association review committee will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above. A ranked list will be drawn up for every indicative budget shown in the call conditions.

- c. Proposal coordinators receive an Evaluation Summary Report (ESR), showing the results of the evaluation for a given proposal. For proposals that successfully pass the first stage of two-stage calls, common feedback is provided to all coordinators, but the first stage ESR is only sent after the second stage evaluation.
- d. If special procedures apply, they will be set out in the call conditions.

6.8. Budget flexibility

The budgets set out in this Work Plan are indicative.

Unless otherwise stated, final budgets may vary following evaluation.

Cumulated changes to the allocations to specific actions not exceeding 20% of the maximum contribution set in this Work Plan shall not be considered to be substantial within the meaning of Article 110 (5) of the Financial Regulation, where those changes do not significantly affect the nature of the actions and the objectives of the work plan.

The authorising officer responsible may apply the changes referred to in the first paragraph. Those changes shall be applied in accordance with the principles of sound financial management and proportionality.

6.9. Actions involving classified information

Not applicable

6.10. Actions involving financial support to third parties⁷¹

Not applicable

6.11. Co-labelling requirements

All participants to activities funded by the EDCTP2 programme or by Participating States of the EDCTP2 programme are required to label or co-label any communication or publication related to their activities with the following acknowledgement “[name of the activity/grant code] is part of the EDCTP2 programme supported by the European Union”. Whenever relevant and feasible, the EDCTP Association logo should also be included. For funding to PDPs the following wording should be used:

“[Name of PDP] is part of the EDCTP2 programme supported by the European Union”;

or

“[Name of PDP] is supported by [name of funding organisation/name of country, name of funding organisation/name of country] and part of the EDCTP2 programme supported by the European Union”.

6.12. Conditions related to open access to research data

Grant beneficiaries under this Work Plan will engage in research data sharing, according to Article 29.3 of the EDCTP2 Model Grant Agreement(s). This means that beneficiaries must deposit and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate, free of charge for any user: (1) data needed to validate the results presented in scientific publications ('underlying data'); and (2) other data as specified by the beneficiaries in their Data Management Plan (DMP, see below).

Projects can "opt-out" of these provisions before or after the signature of the grant agreement (thereby freeing themselves from the associated obligations) on the following grounds:

- a. Incompatibility with the Horizon 2020 obligation to protect results that are expected to be commercially or industrially exploited
- b. Incompatibility with the need for confidentiality in connection with security issues
- c. Incompatibility with rules on protecting personal data
- d. Incompatibility with the project's main aim
- e. If the project will not generate / collect any research data, or
- f. If there are other legitimate reasons not to provide open access to research data

Any costs related to the implementation of these provisions are eligible for reimbursement during the duration of the grant.

A proposal will not be evaluated more favourably if the consortium agrees to share its research data, nor will it be penalised if it opts-out.

Further information on open access to research data is available on the Horizon 2020 Participant Portal.

A Data Management Plan (DMP) details what data the project will generate, how it will be exploited and made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is obligatory for all projects that do not opt-out. Projects that opt-out are also strongly encouraged to submit a Data Management Plan if relevant for their planned research. Further information on Data Management Plans is available on the Horizon 2020 Participant Portal. ^{72,73}

7. Acronyms and abbreviations

AC	Associated country
ACT	artemisinin-based combination therapy
ANREC	Annual National Research Ethics Conference
ANRS	Agence nationale de recherches sur le sida et les hépatites virales
AREF	African Research Excellence Fund
ARL	African Research Leader
AVAREF	African Vaccine Regulators Forum
CAN	Cochrane Africa Network
CE	Conformité Européene
COHRED	Council for Health Research and Development
CRDF	Clinical Research and Development Fellowship
CRO	Clinical Research Organisation
CSA	Coordination & Support Action
CSA	Cochrane South Africa
DMP	Data Management Plan
DPO	Data Protection Officer
EC	European Commission
ECB	European Central Bank
EDCTP	European & Developing Countries Clinical Trials Partnership
EDPS	European Data Protection Supervisor
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIB	European Investment Bank
ESR	Evaluation Summary Report
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
ETEC	Enterotoxigenic Escherichia coli
EU	European Union
GA	EDCTP Association General Assembly
GBS	Group B streptococcus
GCP	Good Clinical Practice
GLOBVAC	Global Health and Vaccination Research Programme
GMP	Good manufacturing practice
GMS	Grant management support
GTN	Global Training Network
HEARD	Health Economics and HIV and AIDS Research Division
hESC	human embryonic stem cells
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
Horizon 2020	European Union's Framework Programme for Research and Innovation 2014-2020
H2020	Horizon 2020
HPV	<i>Human papillomavirus</i>
HSRI	Health systems research initiative
ICH-GCP	International Conference on Harmonisation's Guideline for <i>Good Clinical Practice</i>
ICH	International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
INN	infections néonatales nosocomiales
IPR	Intellectual property rights
IPT	Intermittent preventative treatment
IRB	Institutional review board

JGHT	Joint Global Health Trials
LMIC	Low- and middle-income country
MARC	Mapping of ethics review capacity in sub-Saharan Africa
MDG	Millennium Development Goal
MDR	multi-drug resistant
MEP	Member of the European Parliament
MoU	Memorandum of Understanding
MP	Member of Parliament
MRC	Medical Research Council
MRC/JUVRI	Medical Research Council/Uganda Research Unit on AIDS
M&E	Monitoring & Evaluation
NCD	Non-communicable diseases
NCP	National Contact Point
NEC	National ethics committee
NEPAD	New Partnership for Africa's Development
NoE	Network of Excellence
NHRS	National health research systems
NID	Neglected infectious disease
NIH	National Institutes of Health
NRA	National regulatory authority
OCT	Overseas countries and territories
OJ	Official journal
OLAF	European Anti-Fraud Office
PACTA	Pan-African Clinical Trials Alliance
PACTR	Pan African Clinical Trials Registry
PanACEA	Pan African Consortium for the Evaluation of Antituberculosis Antibiotics
PDP	Product development partnership
PRD	Poverty-related disease
PS	Partner State/Participating State
PSIA	Participating States' Initiated Activity/Participating and Partner States Initiated Activities
REC	Research Ethics Committee
RfP	Rules for Participation
RIA	Research and Innovation Action
RoC	Rules of Contest
RSV	<i>Respiratory syncytial virus</i>
R&D	Research & development
SAC	Scientific Advisory Committee
SDG	Sustainable Development Goal
SMC	Seasonal Malaria Chemoprevention
SORMAS	Surveillance, Outbreak Response Management and Analysis System
SSA	Sub-Saharan Africa
TB	Tuberculosis
TBD	To Be Determined
TBVI	TB Vaccine Initiative
TC	Third Countries
TDR	Special Programme for Research and Training in Tropical Diseases
TMA	Training & Mobility Action
TP	Third Parties
WHO	World Health Organization
XDR	Extreme Drug Resistant

8. Endnotes

- 1 In the EDCTP2 programme, “medical interventions” encompass measures whose purpose is to improve or sustain health or alter the course of a disease, in particular prevention and treatment based on medicinal products such as drugs, microbicides or vaccines, including their delivery modality, follow up of treatment and prevention in the affected population as well as medical diagnostics to detect and monitor disease/ health evolution.
- 2 EDCTP2 Basic Act: Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States, Official Journal of the European Union, OJ L 169, 7.6. 2014, p.38.
- 3 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, hereafter ‘the Financial Regulation’.
- 4 Only the following European countries are specified in the EDCTP2 Basic Act as the “Participating States” of the EDCTP2 programme and thus required to fulfil the conditions set for the EU’s financial contribution to the EDCTP2 programme: Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. Greece is specified as a Participating State even though it has neither provided any up-front commitment to the EDCTP2 programme nor requested membership in the EDCTP Association. Thus, it does not comply with the requirements set for “Participating States” in the EDCTP2 Basic Act. Switzerland is also specified as a Participating State but has not yet joined the EDCTP Association as full member.
- 5 Official registration No 60471700, Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands.
- 6 So far, the following 16 African countries have joined the EDCTP Association as members: Burkina Faso, Cameroon, Congo, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda, and Zambia. The EDCTP Association involves the following 14 European countries as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.
- 7 Since the EDCTP Association is a partnership between European and African countries that are jointly participating and implementing the EDCTP2 programme as full and equal members of the EDCTP Association, the notion “Partner States” will be used hereunder to refer similarly to European and African countries in the EDCTP Association. However, only the European Partner States are “Participating States” as defined by the EDCTP2 Basic Act that are required to meet the conditions and assume the responsibilities set in the EDCTP2 Basic Act for the EDCTP Association receiving the EU’s financial contribution to the EDCTP2 programme (see footnote 4):.
- 8 Deed of Incorporation of the EDCTP Association, 10.4.2014: http://www.edctp.org/web/app/uploads/2014/12/Deed_of_Incorporation_EDCTP_Association_10-04-2014_EN_FINAL.pdf
- 9 The objectives of the EDCTP2 programme are in full detail described in Annex 1 of Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 and are presented here in an abridged version.
- 10 In the EDCTP2 programme, “poverty-related diseases (PRDs)” include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola, yellow fever or Lassa fever.
- 11 <http://www.un.org/millenniumgoals/>
- 12 <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>
- 13 Rules for Participation (RfP) of Horizon 2020: Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in “Horizon

- 2020 - the Framework Programme for Research and Innovation (2014-2020)", OJ L 347, 11.12.2013, p. 81.
- 14 EDCTP2 Basic Act, Annexes I and II.
 - 15 EDCTP2 Basic Act, Article 6.4.
 - 16 Decision 556/2014/EU requires that clinical trials are conducted "in compliance with fundamental ethical principles and relevant national, Union and international legislation". In particular, this includes Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which calls for "data from a clinical trial to only be submitted in support of a clinical trial application if that clinical trial has been recorded in a publicly accessible and free of charge database which is a primary or partner registry of, or a data provider to, the international clinical trials registry platform of the World Health Organization (WHO ICTRP)". Furthermore, the Union's Horizon 2020 programme provides for mandatory open access to data under Article 29 of its model Grant Agreement unless in specific instances where an opt-out is considered necessary. Therefore, the EDCTP Association requires (i) the registration of clinical trials prior to the enrolment of the first subject in a registry complying with WHO's international agreed standards (www.who.int/ictcp) and (ii) in line with the WHO 'joint statement on public disclosure of results from clinical trials' the disclosure of the study results by posting to the results section of the registry within 12 months from primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure) and by journal publication within 24 months.
 - 17 An action (project) supported with an EDCTP2 grant can involve one or more activities that fit with the scope of the type of action.
 - 18 <http://www.edctp.org/see-work/strategy/>
 - 19 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
 - 20 Guideline on pharmaceutical development of medicines for paediatric use EMA, 1 august 2013: https://www.ema.europa.eu/documents/scientific-guideline/guideline-pharmaceutical-development-medicines-paediatric-use_en.pdf
 - 21 This call is implemented as a joint call between two funding organisations, the EDCTP Association and CEPI, but implemented according to the standard rules for participation for the EDCTP2 programme (as summarised in section 6).
 - 22 http://www.who.int/medicines/areas/rational_use/PPLreport_2017_09_19.pdf?ua=1
 - 23 African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 10 RCOREs throughout Africa: <http://www.nepad.org>
 - 24 Sub-Saharan African countries in which NECs and/or NRAs have not previously been funded under the EDCTP2 programme include: Botswana, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Congo (Republic), Djibouti, Eritrea, Equatorial Guinea, Gambia, Lesotho, Madagascar, Malawi, Mauritania, Mauritius, Namibia, Niger, Rwanda, São Tomé and Príncipe, Seychelles, Sierra Leone, Somalia, South Sudan, Swaziland.
 - 25 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objective of this Coordination & Support Action. It aims to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research on and use of medical interventions in humans. It is in line with the activities called for by the EU legislator (EDCTP2 Basic Act, Annex II, objective 1c) and contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards (EDCTP2 Basic Act, Annex I, objective 2b).
 - 26 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
 - 27 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support senior fellows in sub-Saharan Africa in line with the activities called for by the EU legislator (EDCTP2 Basic Act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 Basic Act, Annex I, objectives 2b).
 - 28 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf
 - 29 Subject to ongoing discussions and the conclusion of an agreement between the EDCTP Association and Novartis.
 - 30 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support junior fellows in sub-Saharan Africa in line with

- the activities called for by the EU legislator (EDCTP2 Basic Act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 Basic Act, Annex I, objectives 2b).
- 31 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.
- 32 <https://www.economist.com/news/middle-east-and-africa/21611112-scientific-research-africa-gathering-momentum-rise>
- 33 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support junior fellows in sub-Saharan Africa in line with the activities called for by the EU legislator (EDCTP2 Basic Act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 Basic Act, Annex I, objectives 2b).
- 34 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa
- 35 For the current 2019 fiscal year, low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of \$995 or less in 2017; lower middle-income economies are those with a GNI per capita between \$996 and \$3,895; upper middle-income economies are those with a GNI per capita between \$3,896 and \$12,055; high-income economies are those with a GNI per capita of \$12,056 or more.
- 36 http://www.who.int/tdr/capacity/strengthening/career_development/en/
- 37 An 'affiliated entity' is defined in this context as being either under the same direct or indirect control of a third legal entity; or directly or indirectly controlling the host organisation; or directly or indirectly controlled by the host organisation.
- 38 For WHO/TDR, "neglected infectious diseases (NIDs)" include: dengue/severe denque; rabies; chagas disease; Human African trypanosomiasis (sleeping sickness); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; buruli ulcer; leprosy (Hansen disease); trachoma; yaws.
- 39 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support researchers and key members of clinical trial research teams from sub-Saharan Africa to acquire specific skills in clinical research and development. It is in line with the activities called for by the EU legislator (EDCTP2 Basic Act, Annex II, activity 1c and 1d) and contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 Basic Act, Annex I, objectives 2b and 2d).
- 40 The points to be addressed in the support letter are elaborated in the application form and include: confirmation that the fellow is a current employee of the home organisation (details of contract duration should be included); confirmation that the home organisation supports this fellowship application; confirmation that the fellow is fully eligible in accordance with the criteria as set out in the call text; confirmation that the fellow will be supported with a leave of absence for the duration of the fellowship; confirmation that the fellow has the ability to successfully undertake the training he/she is applying for; details on how the fellowship will enhance the career development of the fellow; explanation of how the proposed training will strengthen the home organisation's capacity to conduct clinical research upon return of the fellow; confirmation that the fellow will have

a similar position at the home organisation once the fellowship has been completed.

- 41 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.
- 42 http://www.edctp.org/web/app/uploads/2017/11/EDCTP_procurement_policies_and_procedures_manual_November-2017.pdf
- 43 <http://www.who.int/tdr/partnerships/essence/en/>
- 44 See Articles 188, 189 (1), and 195 of the Financial Regulation
- 45 <https://www.force11.org/group/fairgroup/fairprinciples>
- 46 Value of new contracts or legal obligations that PSs expect to sign in 2018, excluding direct financial contributions from PSs (i.e. managed by PSs) to EDCTP2 funded projects.
- 47 The Supporting Information provided in this chapter is copied from the General Annexes of the Work Programme 2018-2020 of Horizon 2020 (Commission decision C(2017)7124 of 27 October 2017), unless the specificities of the EDCTP2 programme required an adaptation of the information to those specificities. Such EDCTP2-specific adaptations were required for section 6.1, 6.2 (5), 6.3, 6.4, 6.5, 6.6 (6.6.9.2, 6.6.9.6), 6.7 (Table 21) and 6.10.
- 48 Provided that natural or legal persons, groups or non-State entities are not covered by the Council sanctions in force. Please see: the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/archives/docs/cfsp/sanctions/docs/measures_en.pdf.
- 49 Entities from Overseas Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member States to which the OCT in question is linked.
- 50 http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf. As of 1 January 2017, the following 16 countries are Associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland, Faroe Islands, Ukraine, Tunisia, Georgia, Armenia.
- 51 These are international organisations, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.
- 52 No agreements or arrangements of this kind are currently existing
- 53 Provided that natural or legal persons, groups or non-State entities are not covered by the Council sanctions in force. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/archives/docs/cfsp/sanctions/docs/measures_en.pdf.
- 54 https://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf
- 55 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_169_R_0004
- 56 Natural or legal persons, groups or non-State entities covered by the Council sanctions in force are not eligible to participate in Union programmes. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at: http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm as in the H2020
- 57 The eligibility criteria formulated in Commission notice Nr. 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp.9-11: “Guidelines on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards”) apply for all actions under this Work Plan, including for third parties that receive financial support under the action (in accordance with Article 204 of the Financial Regulation).
- 58 Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol (in accordance with Article 204 of the Financial Regulation). Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this Work Plan will be revised.
- 59 Eligible costs for all types of action are in accordance with the Financial Regulation and the Horizon 2020 Rules for Participation Regulation No 1290/2013. In addition, as training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their

- proposal such activity and the following corresponding estimated costs that may be eligible for EU funding:
- i. Costs of delivering the training (personnel costs if the trainers are employees of the beneficiary or subcontracting if the training is outsourced);
 - ii. Accessory direct costs such as travel and subsistence costs, if the training is delivered outside the beneficiary's premises;
 - iii. Remuneration costs for the researchers attending the training, in proportion to the actual hours spent on the training (as personnel costs).
- 60 Participants may ask for a lower rate.
- 61 Excerpt from the General Annexes of the Horizon 2020 work programme 2018-2020.
- 62 Excerpt from the General Annexes of the Horizon 2020 work programme 2018-2020 (see also the Rules for Participation of Horizon 2020, Article 2, point 7).
- 63 Annex 5 to the Delegation Agreement concluded between the European Commission and the EDCTP Association ("the EDCTP"), which is the EDCTP2-Implementing Structure, on 23 December 2014.
- 64 https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf
- 65 Central European Time = Brussels local time.
- 66 See Article 207 (1) under c of the Financial Regulation.
- 67 Professional misconduct includes: violation of ethical standards of the profession, wrongful conduct with impact on professional credibility, false declarations/ misrepresentation of information, participation in a cartel or other agreement distorting competition, violation of IPR, attempting to influence decision-making processes or obtain confidential information from public authorities to gain an advantage.
- 68 Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39)
- 69 Declarations of the Commission (Framework Programme), OJ C373, 20.12.2013, p. 2
- 70 European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2017 http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf
- 71 This is not foreseen in the 2019 work plan.
- 72 http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
- 73 https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf

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