EDCTP

The power of sharing science

EDCTP2 work plan 2020

Responsible person: Dr Michael Makanga, EDCTP Executive Director

Important notice: This annual work plan covers 2020 and describes planned activities under the EDCTP2 programme in 2020-2024.

The EDCTP2 annual work plan 2020 was approved by the European Commission on 24 March 2020, 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 2020 work plan on 27 March 2020.

Notice

For UK applicants: please be aware that following the entry into force of the EU-UK Withdrawal Agreement* on 1 February 2020 and in particular Articles 127(6), 137 and 138, the references to natural or legal persons residing or established in a Member State of the European Union are to be understood as including natural or legal persons residing or established in the United Kingdom. UK residents and entities are therefore eligible to participate in calls in this work plan.

** Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.*

Supported by the European Union

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.

Contents

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]). This EDCTP2 annual work plan for 2020 is the last work plan under the EDCTP2 programme that includes EU-funded actions.

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 Regulation[3]); and (d) the fulfilment of the commitment by each Participating State[4] to contribute to the financing of the EDCTP2 programme as referred to in Article 3.1 (point e) of the EDCTP2 Basic Act.2

The EDCTP Association is legally established as an *Association* under Dutch law in the Netherlands[5]. 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 objectives[9]:

Increase the number of new or improved medical interventions for poverty-related diseases (PRDs), including neglected ones;[10]

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;

Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments;

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;

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 actions[17]: 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 plan.[18]

The present EDCTP2 annual work plan 2020 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 2020 provides information about EU-funded Calls for Proposals in 2020 (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 2020 is the last work plan with EU-funded actions for the EDCTP2 programme.

The EDCTP2 annual work plan 2020 also contains an overview of non-EU funded PSIAs in 2020 (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 2020 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 2020 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 12.

EDCTP also acknowledges contributions for the implementation of the EDCTP2 programme and its 2020 calls from the following organisations: Fondation Botnar and Novartis International. *See Table 3 on the* budgeted contributions to activities of the EDCTP2 programme in 2020 by Third Parties (TPs) and Third Countries (TCs).

In order to enhance joint learning, knowledge management and the role of the EU in global health, when the work plan will be published, EDCTP will inform the EU Delegations in sub-Saharan Africa about planned activities of particular relevance regarding 1) actions to strengthen pharma regulatory systems and 2) health security, more specifically the support to the Africa CDC. Moreover, in line with one of its specific programme objectives – increasing impact through collaborations with other EU initiatives, particularly those related to development assistance – EDCTP will seek to maximise synergies and complementarities with other EU-supported programmes (directly or indirectly), the initiatives of the national regulatory authorities, those of the Ministries of Health, and those of regional or Pan-African organisations under the parameters of its mandate.

1.4. Budget overview tables

Table 1. Overview of budgeted contributions to activities of the EDCTP2 programme in 2020 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)/ Third Countries (TCs)

Activities EU*		2020 Budgeted Contributions (in EUR)			Total 2020 Budgeted Contributions (in EUR)
		PSs*	TPs/TCs**	Total	
EU-funded activities	Calls for Proposals implemented by EDCTP	68,682,714	5,097,572	2,250,000	76,030,286
	Other Activities implemented by EDCTP	9,800,281	1,657,714	25,000	11,482,995
Administrative costs of EDCTP		**19,688,692**	**576,857**	**90,000**	**20,355,549**
Sub-Total EU funded activities		98,171,687	7,332,143	2,365,000	107,868,830
Non-EU funded activities	Non-EU funded PSIAs implemented by PSs	-	63,531,901	-	63,531,901
	New activities including Calls for Proposals managed by EDCTP	-	60,160	172,250	€ 232,410
Sub-Total non-EU funded activities		**-**	**63,592,061**	**172,250**	**63,764,311**
Total Budget		**98,171,687**	**70,924,204**	**2,537,250**	**171,633,141**

**Details in tables 2, 12 and 13.*
***Details in table 3.*

Table 2. Detailed overview of budgeted contributions to activities of the EDCTP2 programme in 2020 by the European Union (EU), and European and African Partner States (PSs)

	2020 Budgeted contributions (in EUR)				
	Financial contributions to be managed by EDCTP*	New activities, including Calls for Proposals managed by EDCTP**	PSIAs***/In-kind****	Total in 2020	Total 2014-2020
European Union (EU)					
European Commission (EU budget)	98,171,687	-	-	98,171,687	683,000,000
Sub-Total EU	98,171,687	-	-	98,171,687	683,000,000
Participating States*** (European Partner States)**					
Austria (AT)		20,000	-	20,000	3,938,000
Denmark (DK)		-	-	-	7,705,992
Finland (FI)		-	-	-	2,263,480
France (FR)		-	4,038,713	4,038,713	85,512,495
Germany (DE)	3,000,000	-	630,000	3,630,000	136,336,056
Ireland (IE)	-	-	-	-	20,132,546
Italy (IT)	-	-	200,000	200,000	5,273,503
Luxembourg (LU)	-	-	-	-	2,300,000
Netherlands (NL)	100,000	-	-	100,000	23,133,918
Norway (NO)	-	-	750,000	750,000	39,064,847
Portugal (PT)	200,000	-	-	200,000	2,580,627
Spain (ES)	50,000	-	1,420,000	1,470,000	10,068,970
Sweden (SE)	1,800,000	-	31,932,183	33,732,183	240,272,934
United Kingdom (UK)	2,182,143	-	21,385,004	23,567,147	480,139,864

Sub-Total European PSs	**7,332,143**	**20,000**	**60,355,900**	**67,708,043**	**1,058,723,232**
African Partner States					
Burkina Faso (BF)	-	-	-	-	525,753
Cameroon (CM)	-	-	-	-	1,078,839
Congo (CG)	-	-	-	-	309,556
Ethiopia (ET)	-	-	-	-	-
Gabon (GB)	-	-	-	-	812,330
The Gambia (GM)	-	-	-	-	682,000
Ghana (GH)	-	-	543,100	543,100	3,643,032
Mali (ML)	-	-	254,656	254,656	3,622,078
Mozambique (MZ)	-	-	-	-	722,348
Niger (NE)	-	-	-	-	210,363
Nigeria (NG)	-	-	-	-	-
Senegal (SN)	-	-	-	-	796,379
South Africa (ZA)	-	40,160	1,660,000	1,700,160	28,421,006
Tanzania (TZ)	-	-	-	-	558,300
Uganda (UG)	-	-	718,245	718,245	1,585,896
Zambia (ZM)	-	-	-	-	8,973,000
Sub-Total African PSs	**-**	**40,160**	**3,176,001**	**3,216,161**	**51,940,880**
Sub-Total European+African PSs	**7,332,143**	**60,160**	**63,531,901**	**70,924,204**	**1,110,664,112**
Grand Total EU, European and African PS	**105,503,830**	**60,160**	**63,531,901**	**169,095,891**	**1,793,664,112**

**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 2020 by Third Parties (TPs) and Third Countries (TCs)

	Budgeted contributions by TPs/TCs (in EUR)			
Third Parties / Third Countries	**Financial in 2020**	**In-kind in 2020**	**Total in 2020**	**Cumulative total for 2014-2020**
EFPIA members	-	-	-	2,550,000
AREF	-	-	-	1,220,000
WHO-TDR	-	-	-	5,000,000
GSK	-	-	-	1,500,000
Calouste Gulbenkian Foundation	-	-	-	465,000
Foundation Mundo Sano	-	-	-	2,000,000
LRI	-	-	-	400,000
CEPI	-	-	-	10,000,000
Switzerland	-	-	-	500,000
Fondation Botnar	1,615,000	-	1,615,000	1,615,000
Novartis International AG	750,000	172,250	922,250	1,672,250
Grand total	**2,365,000**	**172,250**	**2,537,250**	**26,922,250**

2. EU-funded Calls for Proposals

2.1. Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2020:

2.1.1 Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives

Challenge

Failure to translate research findings into policy and practice prevents research from achieving maximum public health benefit. Despite substantial investment by public and private partners in the development of new prophylactics, diagnostics and treatments of poverty-related diseases (PRDs), these interventions may not reach their target populations or be used to their full potential. This is particularly the case in resource-poor settings such as sub-Saharan Africa, where health systems are either weak or not adequately prepared for the delivery and uptake of new or improved products and interventions and the monitoring of their effectiveness, safety and adherence. Therefore, concerted efforts by multiple stakeholders are needed to maximise the uptake of new or improved 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 which are part of a large-scale programme of development cooperation actions. Projects should focus on research to maximise the uptake of products and health interventions in sub-Saharan Africa. This may include actions to: enhance the uptake of research findings or products and interventions; provide evidence to translate findings into policy guidelines and clinical practice; improve implementation, delivery and roll-out of interventions to increase population coverage, acceptability and adherence; improve the monitoring of product safety post-marketing and surveillance; pragmatic clinical trials evaluating interventions under real-world clinical care settings. The projects should be implemented in conjunction with development cooperation initiatives that are supported by national and/or international development cooperation initiatives and/or other funders, including relevant WHO initiatives where appropriate[19].

Applications from multidisciplinary consortia involving public and/or private legal entities are particularly encouraged. 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 for the proposed methodology and approach. Community engagement in design and implementation of the study(ies) is highly encouraged. Proposals must include a clear, credible plan of the pathway to achieve clinical practice and policy change or increase the uptake within a defined timeline. The proposals must relate to products, technologies or concepts that are already licensed, commercialised or otherwise approved.

Proposals should leverage major support from other funders and must present the large-scale programme of actions in its entirety and clearly describe: the actions in the large-scale programme for which EDCTP2 funding is requested; the actions to be supported by other funders; and how the financing from other funders is ensured. The large-scale programme of actions must be of a sufficient scale and ambition to justify EDCTP2 support in combination with financial (cash or in-kind) support from other funders. Ideally, at least half the cost of

the large-scale programme of actions should be supported by funders other than the EDCTP Association, such as national and/or international development cooperation initiatives and/or other funders (such as EDCTP2 Participating States, relevant WHO initiatives or other third parties), in order to ensure complementarity and increase the impact of the results of EDCTP2-funded activities. The action should start no later than 1 October 2021 and must be completed before the end of 2024.

Expected impact

Projects funded under this Call for Proposals should:

- Enhance the sustainable implementation, coverage, availability, accessibility, acceptability and effectiveness of products and interventions in endemic areas in sub-Saharan Africa
- Contribute to change in policy and clinical practice at the national, regional and/or international level
- Increase collaboration with development partners, including increasing leverage of funding from development cooperation initiatives
- 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.

Proposals that leverage major support from other funders, in particular financial contributions from national and/or international development cooperation initiatives will be considered to have a higher impact.

Table 4. Supporting information for the Call for Proposals 'Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	5-15
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)[20]
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 Innovative approaches to enhance poverty-related diseases research

Challenge

Despite large-scale investments in product development for poverty-related diseases (PRDs), progress in achieving public health gain is slow. Alongside sustained, long-term funding for product development, there is a need to encourage the use of new, innovative approaches and emerging technologies in sub-Saharan Africa, to achieve rapid progress and impact.

Scope

The purpose of this Call for Proposals is to fund a number of small- to medium-scale clinical trials and/or clinical research studies that can deliver proof-of-concept or validation of smart,

highly innovative technologies or concepts to prevent, treat or diagnose PRDs in sub-Saharan Africa. The call is strictly aimed at supporting novel innovations, and therefore excludes concepts and technologies that have previously been commercialised, rolled out, tested in large trials, or are already in routine use in healthcare settings. The proposed technologies must have the potential to:

- Provide pilot data to advance the testing of new technologies in future large-scale studies
- Generate results to inform the design of larger-scale studies
- Accelerate the development of new, low-cost, easy-to-implement solutions to address barriers to progress
- Strengthen research capacity of institutions to introduce and implement new technologies
- Increase collaboration with (development) partners, including increasing leverage of funding
- Contribute to creating solutions for improved development or delivery of medical interventions for vulnerable populations in low resource settings.

Proposals may address any disease or group of diseases within the scope of EDCTP2. Proposals should include one (or more) small- to medium-scale studies in sub-Saharan Africa. Proposals that combine medical and pharmaceutical technologies with other scientific areas such as mobile technologies and digital technologies (mHealth and eHealth), big data processing, and other emerging technologies are particularly encouraged, as are proposals involving small- or medium-sized enterprises. Applications must describe how the proposed research will inform future trials or implementation. The action should start no later than 1 October 2021 and must be completed before the end of 2024.

Expected impact

Projects funded under this Call for Proposals are expected to:

- accelerate the development of new or improved clinical interventions, or enhance the utility of existing interventions, in order to contribute towards the reduction of the burden of PRDs in sub-Saharan Africa
- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- contribute to increased uptake and implementation of innovative technologies in research and clinical practice in sub-Saharan Africa.

Table 5. Supporting information for the Call for Proposals 'Innovative approaches to enhance poverty-related diseases research'

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	5-15
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)[20]
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 2020:

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 ensuring 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 strengthening and collaboration of national ethics committees (NECs) and National Regulatory Authorities (NRAs) to allow for long-term development plans 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 harmonisation initiatives;
6. Support already established training centres 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.

Countries should clearly indicate their mismatch between disease burden, research activity and level of regulation that justify the need for support in the areas of ethical and regulatory oversight.

Each project should have at least two new technical staff members recruited to the NEC/NRA team and trained in the new functions proposed in the actions. The proposal should clearly describe the new functions for which the new staff members are to be trained and the expected outputs and outcomes for the individuals recruited.

Linkage of the project to other on-going initiatives, such as the Regional Centres of Regulatory Excellence in Africa[21], 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 maximum duration of the project is 24 months with a foreseen start date of 1 October 2021 or earlier.

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.

Table 6. 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	6-8
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: 1. Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries[22] 2. The requested funder contribution per action shall not exceed EUR 500,000. 3. The maximum duration of the project shall be 24 months.
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)[20]
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 EDCTP Regional Networks

Challenge:

There are significant clinical research disparities and a very heterogeneous clinical research landscape for conducting clinical trials in sub-Saharan Africa across African researchers, institutions, countries and sub-regions. Fostering research collaborations is a means of addressing this challenge through investing in a joint pathway towards a stronger and sustainable sub-Saharan African clinical research landscape.

Scope:

EDCTP has funded four regional networks[23], defined geographically as Southern[24], Eastern[25], Western[26], and Central Africa[27]. These were established following a call for proposals in the EDCTP work plan 2015. The specific objectives of these EDCTP Regional Networks included: strengthening clinical research capacity in order to be able to conduct multi-country clinical trials to ICH-GCP standards; enhancing collaboration and optimising the use of resources and infrastructures within the network; offering training and mentorship aimed at promoting professional development and scientific leadership in clinical trials; strengthening South-South and North-South collaborations between researchers and institutions; encouraging and promoting networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.

The purpose of this Call for Proposals is to provide continued funding to EDCTP Regional Networks that have demonstrated significant progress towards achieving the pre-defined deliverables set out in the 2015 call. The applicants must clearly demonstrate, point-by-point, in their proposal how they have progressed in the previous funding towards the following 2015 pre-defined deliverables:

Partnership:

- Publish at least three peer-reviewed scientific or policy publications as a demonstration of active collaboration and coordination.

- Organise at least one annual meeting, provide regular consortia communication (e.g. documented teleconferences), and develop annual work plans aimed at increased harmonisation of study methods, and sharing infrastructures.

Expertise:

- Initiate at least one ICH-GCP-compliant clinical trial in PRDs conducted and managed by appropriately qualified individuals within the network.
- Train or otherwise acquire at least five clinical research associates (CRAs) that are certified to monitor clinical trials and can be contracted by EDCTP, other funders or clinical trial sponsors to monitor the progress and quality of clinical trials.

Training:

- Develop a comprehensive training and mentorship plan to support the career development of talented individuals through dedicated courses, short term staff exchange programs, and active rotation process among sites for mentors/trainers and trainees.

Infrastructure:

- Incorporate at least one fully functional clinical laboratory, accredited to GCLP standards by recognised international or regional accreditation bodies such as, but not limited to, Kenya Accreditation Service (KENAS), South African National Accreditation System (SANAS), Institutio Portugues De Acreditacao (IPAC), Comite Francais d'Accrediation (COFRAC) to perform clinical trials research, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials
- Develop a functioning data management service, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials.

Organisation:

- Develop a robust strategic business plan with demonstrated commitment and support from its constituent organisations; a transparent, fully-functional management and governance structure; a long-term strategy to ensure the viability, sustainability and progression of the network after the end of the EDCTP funding
- Develop a communication strategy, including a regularly updated website and policies for dissemination data, results and other relevant information.

The four EDCTP Regional Networks are now invited to apply for an extension of up to 36 months. The maximum duration of the action is 36 months, with a foreseen start of the action no later than 1 October 2021. The scope of the proposal should cover at least three diseases in the scope of the EDCTP2 programme and include new value-adding deliverables. The networks should comprise sufficient participants to address all objectives but should not be too large to function and communicate effectively. Inclusion of new institutions is encouraged where appropriately justified, in particular when the institutions are based in countries, which currently have low uptake of EDCTP projects but high disease burden. Inclusion of younger scientists in the management and coordination of the proposals is also encouraged. While the participants, including the coordination, in the networks may change, including expansion or reduction in the number of partners, the core composition of partners should remain the same. The current call is restricted to applications from the four existing networks, and any institutions that would like to join an application should therefore contact the coordinator of the existing EDCTP Regional Network.

Applicants should have a clear governance structure, an independent advisory body and a

transparent process for acquiring new network participants and for excluding non-performing network participants. The overall responsibility for the scientific management and direction of the network should be firmly based in sub-Saharan Africa. The networks should support complementary networking and data or resource sharing activities driven by digital platforms that enhance ongoing projects embarked on under EDCTP1 and EDCTP2. As such, EDCTP will support new activities that galvanise and expand on previous investments. New activities should add value and build on work previously funded by EDCTP. The networks should have a comprehensive research and training strategy that includes plans to: build and strengthen research capacity in previously neglected areas such as, but not limited to, co-morbidities between communicable diseases and non-communicable diseases (NCDs); address inequity in human capital development; mobilise research resources using existing e-learning and networking plaforms; develop and retain indigenous research capacity with a definite career path for researchers; develop and support a network of skilled mentors who can lead the development of young clinical reseachers, as well as being able to engage with national and regional policy makers, African development bodies and initiatives and the private sector about research and development plans. New and innovative ways should be proposed to break language barriers, ensure inclusion of women and support identified weaker institutions to facilitate integration and harmonisation of technologies, protocols and expertise. In addition, the contribution of the networks to strengthening regional or national ethics and regulatory boards are acceptable activities that EDCTP can support within successful proposals.

Expected impact:

Networks 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 to a measurable and visible increase in collaborative research (south-south and north-south collaborations), competencies and capacity to conduct clinical trials
- Demonstrate the ability to conduct clinical trials to ICH-GCP standard and to successfully compete for funding from local and/or international global health R&D funders
- Demonstrate the ability to become sustainable after the end of the EDCTP funding
- Enhance research capacity in poverty-related diseases and in clinical trials across Africa.

Table 7. Supporting information for the Call for Proposals 'EDCTP Regional Networks'

Type of action	Coordination and Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	4
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: 1. A network shall comprise a minimum of six legal entities from at least three different sub-Saharan African countries and a minimum of two legal entities from two different European Participating States.[28] 2. The requested EDCTP contribution per action shall not exceed EUR 4.5 million. 3. The maximum project duration shall be 36 months. 4. The call is restricted to applications from the four existing networks.
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-beneficiary)[29].
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.

2.2.3 Research capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC

Challenge

Reliable epidemiological data is often unavailable or severely limited in resource-limited settings in sub-Saharan Africa, and this knowledge gap is further aggravated by a shortage of skilled personnel in epidemiology and biostatistics to efficiently monitor, analyse and interpret these data to inform policy and decision making. Training programmes are needed to develop a cohort of epidemiologists across sub-Saharan Africa and beyond, which can work in collaboration with their national departments of health, national agencies, as well as with international organisations such as the World Health Organisation Regional Office for Africa (WHO AFRO) and Africa Centres for Disease Control and Prevention (Africa CDC), to collectively conduct routine surveillance, conduct public health research and respond timely to disease outbreaks.

As a specialised technical agency of the Africa Union, Africa CDC operates through a framework focused on harnessing regional resources (all five African regions); the Regional Integrated Surveillance and Laboratory Network (RISLNET) in order to carry out its mandate and achieve the strategic pillars (public health emergency preparedness and response, surveillance and disease intelligence, information systems, laboratory systems and networks, and public health research and institutes) through the National Public Health Institutes (NPHIs). Effective implementation of these strategic pillars depends on the efficiency of the NPHIs and/or affiliated agencies, such as academic institutions in Member States. The Africa CDC has also developed a framework for public health workforce development. Building on numerous investments already made by EDCTP and its partners in sub-Saharan Africa for disease outbreak preparedness and response, this partnership between EDCTP and Africa CDC will further enhance the public health workforce capacity in NPHIs and National Ministries of Health to better enable them to respond timeously to disease outbreaks.

Scope

The purpose of this Call for Proposals is to establish an African cohort of epidemiologists by supporting institutions in Europe and sub-Saharan Africa that provide master's training in epidemiology and biostatistics, as part of the Africa CDC's framework for public health workforce development. Master's course with practical field research experience is the preferable level of training as it is relatively short and likely to deliver the required numbers and high quality fit-for-purpose calibre of personnel that are urgently needed in epidemic zones of sub-Saharan Africa. Proposals can be submitted by a single institution or consortium of institutions which must provide master's training in epidemiology for 10 to 15 excellent, early- to mid-career researchers ("EPI Fellows") based in sub-Saharan Africa, and working in a relevant field. The EPI fellows must commit to remain in Africa for a minimum of two years after after completing their studies and provide evidence to demonstrate this through a letter of support from their host institution. Proposals should include institutions with a proven track record in the provision of high-quality master's training with clear local and regional collaborations with NPHIs (or similar agencies), Ministries of Health and other academic institutions. Proposals must demonstrate the following:

- A high-quality master's programme in epidemiology and biostatistics relevant to infectious diseases of importance in sub-Saharan Africa
- An open, fair and transparent procedure for selecting EPI Fellows based in different geographical regions of Africa, and with appropriate gender balance, for entry into the master's programme
- Robust mentorship and supervision mechanisms to support EPI Fellows through to timely successful course completion

- The master's programme must include a research component, which must be conducted in a country in sub-Saharan Africa, in collaboration with local or regional NPHIs (and/or affiliated agencies) or Ministries of Health.

Proposals should also include support for meetings and conferences for the trainees to participate in an annual networking meeting organised by Africa CDC, as well as the biennial EDCTP Forum. Tuition fees, enrolment fees or other types of university charges are not eligible for reimbursement by EDCTP.

The proposed action should start no later than 1 October 2021 and must be completed before the end of 2024.

Expected Impact

Projects funded under this Call for Proposals should:

- Increase the number of skilled infectious disease epidemiologists working in Africa
- Enhance research capacity in epidemiology across Africa
- Encourage trans-national cooperation between epidemiologists in Africa and with Africa CDC
- Strengthen the ability of African countries to prepare for and to manage epidemic disease outbreaks
- Promote the career development and retention of postdoctoral and postgraduate researchers in Africa
- Contribute towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- Enhance research capacity in poverty-related diseases and in clinical trials across Africa.

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

Table 8. Supporting information for the Call for Proposals 'Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC'

Type of action	Coordination and Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	7-10
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: 1. At least one legal entity established in a Participating State or a sub-Saharan African country. 2. The maximum duration of the grant is 36 months 3. The maximum duration of the master's programme is 30 months (including research component).
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)[30]
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).

2.2.4 Career Development Fellowships in poverty-related diseases and maternal, child and adolescent health

Challenge

For many young scientists in developing countries the transition from doctoral qualification to becoming an established, independent researcher is very difficult due to a lack of sustainable research funding and limited 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 for fighting PRDs, including areas that lack enough trained researchers, such as maternal, child and adolescent health (MCAH). In the next 10 years it is essential for researchers in sub-Saharan Africa to establish centres of excellence in research for MCAH. These require trained personnel in this health area and well equipped centres.

Scope

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

The objectives are:

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

Proposals should 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 programme[31].

Fondation Botnar[32] will co-fund this call with a contribution of € 1,500,000 for proposals conducting research in the area of child and adolescent health and wellbeing. Fondation Botnar's contribution to this call aims to address the shortage of suitably trained early- to mid-career paediatric researchers in sub-Saharan Africa. In the frame of this call, Fondation Botnar encourages research proposals aimed at improving the wellbeing of adolescents suffering from PRDs (e.g. mental health, malnutrition) through the development, validation and/or implementation of new solutions. In keeping with its strategy and approach, Fondation Botnar wishes to support applications aiming to exploit scalable and sustainable Artificial Intelligence and digital technologies in urban environments.

Novartis International AG[33] 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 PRDs[32] and non-communicable diseases (NCDs, including e.g. sickle cell disease). 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.

Proposals should include an independent research activity to be conducted by the fellow 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 ICH-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 at their host organisation who is an internationally recognised scientific leader working in sub-Saharan Africa; and a career development plan as part of the research proposal. Applicants must also show how their proposals will address geographical and gender imbalances in areas of sub-Saharan Africa that are highly burdened with MCAH problems but are still weak in attracting research grants.

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. The maximum duration of the proposed action is 36 months, with a foreseen start of the action no later than 1 October 2021. Proposals from women are encouraged.

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 of researchers in Africa
- 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 at host institutions in sub-Saharan Africa.

Ultimately these grants will contribute to the generation of a critical mass of clinical or field/social science/ethics researchers and institutional research capacity in sub-Saharan Africa.

Table 9. Supporting information for the Call for Proposals 'Career Development Fellowships in poverty-related diseases and maternal, child and adolescent health International AG'

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	16-25 grants
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: 1. The applicant must be a legal entity established in sub-Saharan Africa (the applicant legal entity)[34]. 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: a. be resident of or be willing to relocate to a sub-Saharan African country; b. be either a graduate (non medical doctor), 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 before[35]. 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	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. 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. 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.
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)[36] with options for fellowships.

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 10. Indicative timetable for 2020 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 to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives	**2 June 2020**	**29 October 2020** at 17:00:00 CET	**25 March 2021**
	Innovative approaches to enhance poverty-related diseases research	**2 June 2020**	Stage 1 – **22 October 2020** at 17:00:00 CET	**25 March 2021**
CSA	Ethics and regulatory capacities	**2 June 2020**	**15 October 2020** at 17:00:00 CET	**18 March 2021**
	EDCTP Regional Networks	**2 June 2020**	**29 October 2020** at 17:00:00 CET	**25 March 2021**
	Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC	**2 June 2020**	**29 October 2020** at 17:00:00 CET	**25 March 2021**
TMA	Career Development Fellowships in poverty-related diseases and maternal, child and adolescent health, in collaboration with Fondation Botnar and Novartis International AG	**2 June 2020**	**22 October 2020** at 17:00:00 CET	**25 March 2021**

3. Other EU-funded activities

3.1. Independent experts assisting in proposal evaluations and project reviews in 2020-2024

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 3,000,000

Indicative timetable: 2020-2024.

3.2. 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:

- Up to six workshops in sub-Saharan Africa in the period from 2020 to 2022 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.

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

Indicative timetable: The procurement process will occur in 2020-2022. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures[37].

Indicative budget: EUR 1,000,000.

3.3. 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 2020-2024 to support advocacy and outreach activities, and increase the visibility of EDCTP and its strategic partners:

- Production of (advocacy) materials for a strong presence at international conferences and meetings, which may include outsourcing of their development, design and printing
- 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 update project case summaries and draft up to six articles about the EDCTP Association activities for publication in relevant journals
- Outsourcing translation in French and Portuguese of main publications of the EDCTP Association.

Type of action: Public procurement – up to 30 service contracts.

Indicative timetable: The procurement process will occur in 2020-2023. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures[38].

Indicative budget: EUR 2,000,000.

3.4. 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 EDCTP2 programme, and mobilising support from governments and private actors. This strategy will focus for the most part on the mobilisation of financial resources from governments and private actors for future EDCTP2 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. In order to give continuity to previous outreach and advocacy efforts, the following specific activities will be conducted in 2020-2024:

- 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 Research[39]
- 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;
- Continued collaboration with WHO-AFRO on regional activities towards strengthening of

health research systems (NHRS) for uptake of research results

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

Indicative timetable: The procurement process will occur in 2020-2023. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures[40].

Indicative budget: EUR 2,017,995.

3.5. 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 Regulation[41], that allow the awarding of grants without a call for proposals in exceptional and duly substantiated emergencies. At that time, the EDCTPgrants 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 FAIR[42] principles. The use of harmonised protocols in collaboration with ongoing EDCTP2 actions is recommended for this purpose.

In case of no public health emergency warranting the mobilisation of the EDCTP Public Health Emergencies mechanism in 2020, the indicative budget for this activity may be used towards funding emergency preparedness response activities.

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 2,250,000.

3.6. Preparations for the EDCTP Forum in 2022

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 Eleventh EDCTP

Forum will take place in 2022 in Europe (location TBC). It is expected that payments will be made in 2021 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 2021 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which will be in the fourth quarter of 2022. All procurements will be made in accordance with the EDCTP Association procurement policies and procedures[43]. First payments are expected to be made in the last quarter of 2021.

Indicative budget: EUR 1,025,000.

3.7. EDCTP Prizes in 2022

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.

Type of action: Recognition prizes.

Indicative timetable: Prize contests will be launched in the last quarter of 2021 and Prize winners will be announced at the EDCTP Forum in 2022 (see General Annexes 6.6 for Model Rules of Contest (RoC) for EDCTP2 Prizes).

Total indicative budget: EUR 130,000.

3.8. EDCTP scholarships for the Advanced Course of Vaccinology (ADVAC)

Objective: ADVAC is a prestigious, two-week training programme aimed at high-level experts in the field of vaccinology. It targets scientists and decision-makers involved in vaccine development, in the elaboration of new vaccination strategies or in policy decisions related to the introduction of new vaccines in public health programmes, at national or international levels.

ADVAC has 20 years' track record with a comprehensive curriculum delivered by world-leading experts in vaccinology from academia, industry, governmental and non-governmental agencies covers all aspects related to vaccines and vaccination, including inter alia vaccine trials, development of new vaccines, vaccination strategies and policies, vaccine-specific issues, ethical issues related to vaccine trials, regulatory issues, financing of immunisation, implementation of immunisation programs, and communication. This programme has also established an online interactive alumni platform that offers free annual updates on developments in vaccinology to all alumni members. ADVAC is therefore a unique opportunity

for mid-career and senior sub-Saharan scientists and policy makers dealing with vaccines, to meet, learn from, interact and network with the world's leading experts in vaccinology. Participation in the ADVAC course will train their ability in critical decision-making in vaccinology by providing a comprehensive overview of the field, from immunology to vaccine development and clinical trials and the social, economic, political and ethical issues of vaccination.

EDCTP is member of ADVAC's Scientific Committee, and has been requested to provide financial support to increase the participation of vaccinologists from sub-Saharan Africa at a subsidised rate that only covers the participants' travel, accommodation and upkeep costs. EDCTP will support up to 10 scholarships for participants from sub-Saharan Africa in order to develop individuals to become leaders in vaccinology research and immunisation programmes. Candidates will be selected by the ADVAC international scientific committee on the basis of an application procedure and criteria in terms of the following:

Candidate's educational background

- Involvement in vaccinology
- Decision-making responsibilities in vaccinology
- Expected impact of the course at personal, institutional and national levels.

Type of action: Grant to Identified beneficiary – Coordination and Support Action.

Legal entity: Merieux Foundation, 17 rue Bourgelat 69002 Lyon, France.

Indicative timetable: The grant will be awarded in 2020.

Indicative budget: EUR 60,000.

3.9. Budgetary information for other EU-funded activities

Table 11. Other activities budget of the EDCTP Association for implementation of the EDCTP2 programme (2020 – 2026)

Description	2020 EUR	2021 EUR	2022 EUR	2023 EUR	2024 EUR	2025 EUR	2026 EUR	Total EUR
Other activities budget	3,660,000	1,500,000	2,000,000	1,500,000	1,622,995	900,000	300,000	11,482,995

Table 12. Financial contributions to be managed by the EDCTP Association towards Calls for Proposals, Other Activities and the Administrative Costs of the EDCTP Association in 2020

EU-funded EDCTP2 activities		TPs/TCs (in EUR)	PSs (in EUR)	EU (in EUR)	Budget cost (in EUR)
Research & Innovation Actions	Strategic actions to maximise the impact of poverty-related diseases research in collaboration with development cooperation initiatives		2,548,786	20,841,357	23,390,143
	Innovative approaches to enhance poverty-related diseases research		2,548,786	20,841,357	23,390,143
Coordination & Support Actions	Ethics and regulatory capacities			2,500,000	2,500,000
	EDCTP Regional Networks			18,000,000	18,000,000
	Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC			5,000,000	5,000,000
Training & Mobility Actions	Career Development Fellowships in poverty-related diseases and child and adolescent health	2,250,000		1,500,000	3,750,000
Sub-total		**2,250,000**	**5,097,572**	**68,682,714**	**76,030,286**
Other Activities	Independent experts assisting in proposal evaluations and project reviews in 2020	25,000	-	2,975,000	3,000,000
	Training on project and programme management in research	-	25,000	975,000	1,000,000
	Communication and dissemination activities	-	-	2,000,000	2,000,000
	Advocacy, networking and outreach activities	-	1,607,714	410,281	2,017,995
	Mobilisation of research funds in case of Public Health Emergencies	-	-	2,250,000	2,250,000
	Preparations for the EDCTP Forum in 2022	-	25,000	1,000,000	1,025,000
	EDCTP Prizes in 2022	-	-	130,000	130,000
	EDCTP scholarships for the Advanced Course of Vaccinology (ADVAC)	-	-	60,000	60,000
Sub-total		**25,000**	**1,657,714**	**9,800,281**	**11,482,995**
Administrative costs	**Personnel, missions, consumables and supplies, service contracts**	**90,000**	**576,857**	**19,688,692**	**20,355,549**
Sub-total		**90,000**	**576,857**	**19,688,692**	**20,355,549**
Total planned contributions in 2020		**2,365,000**	**7,332,143**	**98,171,687**	**107,868,830**

** Financial contributions only. In-kind contributions from TPs/TCs are not included in this table. The total financial contribution of EUR 2,365,000 comprises contributions from the following TPs/TCs: Fondation Botnar (EUR 1,615,000) and Novartis International AG (EUR 750,000).*
*** Financial contributions only. In-kind contributions from PSs are not included in this table. The total financial contribution of EUR 7,332,143 comprises contributions from the following PSs: Germany, Netherlands, Portugal, Spain, Sweden and United Kingdom.*

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 2020 (Tables 2 and 13) comprises EUR 60,355,900 by the European PSs and EUR 3,176,001 by the African Partner States.

All PSIAs are listed in table 13 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 2020

The following **new PSIAs**[44] will be initiated by PSs in 2020 as contributions to the EDCTP2 programme:

Table 13. PSIAs supported in 2020

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)							
France	PSIA2020-2574	ANRS 12401 UMBRELLA	HIV	RIA	South Africa	24	649,515
France	PSIA2020-2575	ANRS 12404 TIMPANI	HIV/TB coinfection	RIA	Mozambique	48	1,291,370
France	PSIA2020-2576	ANRS 12412 IPOP	HIV	RIA	Guinea Conakry	36	205,235
France	PSIA2020-2577	ANRS 12418 TB SPEED	TB/HIV coinfection	RIA	Uganda, Zambia	24	160,404
France	PSIA2020-2578	ANRS 12392 Sanu Gundo	HIV	RIA	Mali	36	343,690
France	PSIA2020-2579	ANRS 12390 OPTIMISE	HIV	RIA	Burkina Faso, Côte d'Ivoire, Mali, Togo	36	508,504
France	PSIA2020-2580	ANRS 12381 PRINCESSE	HIV	RIA	Côte d'Ivoire	48	879,995
Germany	PSIA2020-2551	"A Multicenter Study of the Immunogenicity of Recombinant Vesicular Stomatitis Vaccine for Ebola-Zaire (rVSVΔG-ZEBOV-GP) for Pre-Exposure Prophylaxis In Individuals at Potential Occupational Risk for Ebola Virus Exposure (PREPARE)"	Emerging and re-emerging infectious diseases	RIA	Gabon	36	630,000
Italy	PSIA2020-2557	Initiative "RicercaItaliaAfrica" of Istituto Superiore di Sanita	Cross-cutting	CSA	Multiple TBD	36	200,000
Norway	PSIA2020-2553	Support to TDR	Cross-cutting	RIA	Multiple TBD	60	300,000
Norway	PSIA2020-2554	Support to UNITAID	HIV; TB; malaria	RIA	Multiple TBD	60	450,000
Spain	PSIA2020-2562	Science by Women Programme: Visiting Senior Research Fellowships	Capacity building	TMA	TBC	6	15,000
Spain	PSIA2020-2563	Support for health research capacities in Mozambique to provide the National Health System with scientific evidence to inform and guide public health decisions 2020	Capacity building	CSA	Mozambique	12	1,125,000
Spain	PSIA2020-2565	Continuous Improvement of Assistance Quality and Clinical Management of Endemic Diseases (HIV/AIDS, Malaria, Tuberculosis and NTDs) in the provinces of Litoral, Wele Nzas, Kie Ntem and South Center (Equatorial Guinea)	Cross-cutting	CSA	Equatorial Guinea	12	280,000

Sweden	PSIA2020-2583	University of Rwanda Sweden Programme for Research, Higher Education and Institutional Advancement: Infectious Diseases Programme	Cross-cutting	RIA	Rwanda	60	1,932,183
Sweden	PSIA2020-2585	Estimated Grants in the scope of EDCTP funded by The Swedish Research Council - 2020 onwards	Cross-cutting	RIA	TBC	36	30,000,000
United Kingdom	PSIA2020-2542	MRC Research Grants	Cross-cutting	RIA	Multiple TBD	60	6,546,430
United Kingdom	PSIA2020-2543	MRC Fellowships	Cross-cutting	TMA	Multiple TBD	60	2,182,143
United Kingdom	PSIA2020-2544	MRC/DFID African Research Leader (ARL) scheme	Cross-cutting	TMA	Multiple TBD	60	1,636,607
United Kingdom	PSIA2020-2545	Joint Global Health Trials (JGHT) scheme	Cross-cutting	RIA	Multiple TBD	60	8,183,038
United Kingdom	PSIA2020-2546	Late Phase Global Health Research	Cross-cutting	RIA	Multiple TBD	60	1,745,714
United Kingdom	PSIA2020-2547	Global Maternal and Neonatal Health	Cross-cutting	RIA	Multiple TBD	36	1,091,072
Sub-Total European PSs							**60,355,900**
		African Partner States					
Ghana	PSIA2020-2586	Workshop on communicating research findings to policymakers	Cross-cutting	TMA	Ghana	1	13,000
Ghana	PSIA2020-2587	Workshop on Data Management in Health Research	Cross-cutting	TMA	Ghana	1	18,500
Ghana	PSIA2020-2588	Identification of Novel HIV Reactivation Agents: Towards Building Translational HIV Cure Research Infrastructure in Ghana (H-CRIS)	HIV	RIA	Ghana	60	500,000
Ghana	PSIA2020-2589	Workshop on Ethical Issues in Health Research, Scientific Writing and Publications	Cross-cutting	TMA	Ghana	1	11,600
Mali	PSIA2020-2582	"PYRAPREG - Efficacy and safety of Pyronaridine-artesunate (Pyramax) for the treatment of malaria in pregnant women"	Malaria	RIA	Burkina Faso, Democratic Republic of Congo, Mali, Mozambique, The Gambia "	48	254,656
South Africa	PSIA2020-2572	CAPRISA 012: Phase I/II trial of Subcutaneous Administration of Monoclonal Broadly-neutralizing Antibodies (SAMBA Trial)	HIV	RIA	Zambia	48	1,660,000
Uganda	PSIA2020-2558	Prevalence of Placental Malaria in the different Malaria Endemic Zones in Uganda	Malaria	RIA	Uganda	12	54,550
Uganda	PSIA2020-2559	Assessment of Healthcare Worker Adherence to the Malaria Test, Treat and Track Policy in Uganda	Malaria	RIA	Uganda	36	145,107
Uganda	PSIA2020-2560	Implementation process and success indicators for the Integrated community case management (ICCM) strategy of malaria during the scale up in global fund supported districts	Malaria	RIA	Uganda	24	182,462

Uganda	PSIA2020-2561	Efficacy and safety of artemether-lumefantrine, and artesunate – amodiaquine for the treatment of uncomplicated Plasmodium falciparum malaria in Uganda	Malaria	RIA	Uganda	24	182,462
Uganda	PSIA2020-2564	Cross-sectional Survey on HIV Drug Resistance (HIVDR) among Children and Adolescents Receiving Antiretroviral Therapy (ART) in Uganda	HIV	RIA	Uganda	24	76,832
Uganda	PSIA2020-2567	Cross-sectional Survey of HIV Drug Resistance in Adults and Children Failing Second Line Antiretroviral Therapy in Uganda	HIV	RIA	Uganda	24	76,832
Sub-Total African PSs							**3,176,001**
Grand Total European + African PS							**63,531,901**

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 2020 the budget for administrative costs is set out in the table below:

Table 14. Administrative costs budget of the EDCTP Association for the implementation of the EDCTP2 programme in 2020

Description	Note	EU (in EUR)	PSs and TPs (in EUR)	Total (in EUR)
Personnel		3,847,648	516,857	4,364,505
Missions	1	200,000	40,000	240,000
Consumables and supplies	2	200,000	50,000	250,000
Service contracts (including non-recoverable taxes)	3	400,000	60,000	460,000
Total administrative Budget 2020		**4,647,648**	**666,857**	**5,314,505**
Total administrative Budget 2021- 2026 (Table 15)		**15,041,044**		**15,041,044**
Total		**19,688,692**	**666,857**	**20,355,549**

Table 15. Administrative costs budget of the EDCTP Association for implementation of the EDCTP2 programme (2021 – 2026)

Description	2021 EUR	2022 EUR	2023 EUR	2024 EUR	2025 EUR	2026 EUR	Total EUR
Administrative Budget	4,705,362	3,712,808	2,412,097	1,940,777	1,360,000	910,000	**15,041,044**

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 16. Projected staff headcount by functional area in 2020

Functional area	Headcount
General Administration and Finance	10
Operations (Calls and Grants)	14
Grants Financial Management	3
Strategic Partnerships	6
Communications	2
Total	**35**

5.1. 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 Annexes[45]

6.1. List of countries eligible for funding

1. Legal entities established in the following countries and territories will be eligible to receive funding through EDCTP2 grants:[46]
   - 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 and Sweden;
   - the United Kingdom;
   - The Overseas Countries and Territories (OCT) linked to the Member States[47]: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 Barthélémy, 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 to Horizon 2020 can be found in the online manual;[48]
   - 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.

2. International European interest organisations[49] will also be eligible to receive funding from the EDCTP2 programme.

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

4. 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 country;[50]
- 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 funding[51].

6.2. Standard admissibility conditions, word limits and supporting documents

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:

- submitted in the electronic submission system of the EDCTP Association before the deadline given in the call conditions or rules of contest;
- readable, accessible and printable;
- **complete** and include the requested administrative data, the proposal description, and any obligatory supporting documents specified in the call/contest;
- 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 (if available) should be provided 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.1290/2013[52] and any derogations to these as specified in the EDCTP2 Basic Act[53].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 17. Standard eligibility criteria per type of action

Type of Action	Eligibility conditions for participation[54], [55], [56]
Research & Innovation Actions (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 Actions (CSA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Training & Mobility Actions (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 4).*

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[57,58]

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 solution.[59]

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 countries.[60]

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 below:[61]

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 though institutional funding is made public.
- Any communication or publication related to PSIAs, 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 promoted.[62]
- 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[63] 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 PSIAs 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 Theme [insert name of the prize]

Objectives pursued

The objectives of the prize are to:

- [insert objective from work plan];
- [same for all objectives].

Expected results

- [insert text from work plan].

Prize Amount

- As specified in this work plan in chapter 3:
- Prize amount [insert amount] EUR.

Deadlines and Admissibility

Deadlines	
Opening of the submission:	dd Month yyyy
Closing date for submission:	dd Month yyyy at hh:mm:ss CET[64]

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 EDCTPgrants, accessible on the call page, 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).

The page-limit for the prize is : [insert number] pages.

Eligibility criteria

[OPTION 1 by default: The contest is open to all legal entities (i.e. natural or legal persons, including International organisations) or groups of legal entities]. [OPTION 2 if provided in the work plan/call: The contest is open to [insert eligibility criteria from work plan/call].]

Please note however that special rules may apply for entities from certain countries (see section 6.3).

Moreover, applicants that have already received an EDCTP prize cannot receive a second prize for the same activities.

Exclusion criteria

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

- Are subject to an administrative sanction (i.e. exclusion)[65]
- Are in one of the following situations[66]:
  - 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 misconduct[67] 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.

Award Criteria

The prize will be awarded to the entry that in the opinion of the independent expert jury, the EDCTP Awards Panel, demonstrates to best address the following cumulative criteria:

1. [list the essential / specific award criteria from the work plan/call]

2. [...]

3. [...]

4. [same for all other essential/specific award criteria from the work plan/call].

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.)

Procedure

Applications will be evaluated by an independent expert jury, the EDCTP Awards Panel, between [month yyyy] and [month yyyy] — first individually (by each panellist separately) and then as a group (by the whole Awards Panel together).

The independent expert jury, the EDCTP Awards Panel, will evaluate each application against the [insert number] award criteria and score them as follows (only full points; no half marks or decimals):

Criterion	Threshold	Maximum points
1. [insert award criterion]	[insert threshold, e.g. 3]	[insert max points, e.g. 5]
2. [same for other award criteria]	[insert threshold, e.g. 3]	[insert max points, e.g. 5]
Total	[insert total, e.g. 18]	[insert total, e.g. 30]

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 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.

6.6.2 Other Conditions

Payment arrangements

[OPTION 1 by default: The prize money (EUR [insert amount]) 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.]

[OPTION 2 for special payment schemes: [insert other payment arrangements]]

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:

c. display the EDCTP Association logo and EU emblem;
d. 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
e. 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 1290/2013[68] [and the following additional [dissemination][and] [exploitation] obligations:

- [insert additional obligation from work plan/call]
- [same for further additional obligations]].

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) 2018/1725[69] 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 cells.[70]

The participants must respect the highest standards of research integrity – as set out, for instance, in the European Code of Conduct for Research Integrity.[71]

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, 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

a. 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.
3. 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 18. 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	**Fit with the scope and objectives of the EDCTP2 programme, the EDCTP Association strategic research agenda and the call topic description.** **Importance, relevance/pertinence and clarity of the objectives.** **Soundness of the concept and credibility of the proposed approach/ methodology.**	**Call specific aspects as listed under 'expected impact' in each individual call.** **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.** **Likelihood to result in major advances in the field with potential benefit of the research to the affected populations.**	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; 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. Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise.

			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. Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).
Research & Innovation Actions (RIA)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.** Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. **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.** Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge and gender dimension in research and innovation content.	**Advancing the clinical development of new and improved products.** Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results. **Contribution to improved disease management and prevention through changes in policy and practice, with the ultimate goal of improving public health.** Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. 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.	Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).
Coordination & support actions (CSA)	Clarity, pertinence and importance of the strategic vision. Soundness of the concept. Quality of the proposed coordination and/or support measures.	Effectiveness 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, where relevant. Sustainability of capacity beyond the end of the grant, where relevant. 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.	Quality of the leadership and a clear and effective governance structure.

		Communicate the project activities to different target audiences.	
Training & Mobility Actions (TMA)	**Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career.** **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.** **Quality of the mentorship and/or training plan**	**Advancing the fellow's clinical research skills and career development.** **Contribution to development of research independence and/or scientific leadership** **Contribution to strengthening clinical research capacity at the home or host organisation.** Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities to different target audiences, and to manage research data, where relevant. Sustainability and retention of capacity beyond the end of the grant.	Suitability of the fellow's home and/or host organisation to support the fellowship project. Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.

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

1. Calls may be subject to either a one-stage or two-stage submission and evaluation procedure.
2. Proposals are evaluated by independent experts (see Article 15(7) Horizon 2020 Rules for Participation Regulation No 1290/2013 for exceptional cases).
3. 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.
4. 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.
5. 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 parties[72]

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

Participants 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. [73, 74]

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	*Human papillomavirus*
HSRI	Health systems research initiative
ICH-GCP	International Conference on Harmonisation's Guideline for *Good Clinical Practice*
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/UVRI	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	*Respiratory syncytial virus*
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); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; 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/ictrp) 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 Explanatory note: The EDCTP2 basic act (Annex II, 2d, 2e and 3f) requires EDCTP to "establish cooperation and launch joint actions with Union, national and international development assistance initiatives, including where appropriate, relevant WHO initiatives, in order to ensure complementarity and increase the impact of the results of EDCTP-funded activities."

20 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf

21 African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 11 RCOREs throughout Africa: https://www.nepad.org/publication/regional-centres-regulatory-excellence-rcores

22 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).

23 Information about the four regional networks can be accessed on http://www.edctp.org/edctp-regional-networks-2015/

24 Southern Africa is the geographical region that includes the following countries: Botswana, Lesotho, Madagascar, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, and Zimbabwe.

25 Eastern Africa is the geographical region that includes the following countries: Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Mauritius, Rwanda, Seychelles, Somalia, South Sudan, Sudan, Tanzania, and Uganda.

26 Western Africa is the geographical region that includes the following countries: Benin, Burkina Faso, Cape Verde, Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

27 Central Africa is the geographical region that includes the following countries: Angola, Cameroon, the Central African Republic, Chad, the Republic of the Congo, the Democratic Republic of the Congo, Equatorial Guinea, Gabon, and São Tomé and Príncipe.

28 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the nature and objectives of this Coordination & Support Action. It aims to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with international standards of good clinical practice by supporting networking at a regional level in sub-Saharan Africa. In light of this, it is necessary to have several African institutions within each network. It is in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 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).

29 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

30 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf

31 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); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; 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 or yellow fever.

32 Fondation Botnar is a Swiss-based foundation which champions the use of Artificial Intelligence and digital technology to improve the health and wellbeing of children and young people in growing urban environments. To achieve this, the foundation supports research, catalyses diverse partners, and invests in scalable solutions around the world. Find out more at: www.fondationbotnar.org

33 Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, it uses innovative science and digital technologies to create transformative treatments in areas of great medical need. In its quest to find new medicines, Novartis consistently ranks among the world's top companies investing in research and development. Find out more at: www.novartis.com

34 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).

35 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.

36 http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

37 http://www.edctp.org/web/app/uploads/2017/11/EDCTP_procurement_policies_and_procedures_manual-November-2017.pdf

38 http://www.edctp.org/web/app/uploads/2017/11/EDCTP_procurement_policies_and_procedures_manual-November-2017.pdf

39 http://www.who.int/tdr/partnerships/essence/en/

40 http://www.edctp.org/web/app/uploads/2017/11/EDCTP_procurement_policies_and_procedures_manual-November-2017.pdf

41 See Articles 188, 189 (1), and 195 of the Financial Regulation

42 https://www.force11.org/group/fairgroup/fairprinciples

43 http://www.edctp.org/web/app/uploads/2017/11/EDCTP_procurement_policies_and_procedures_manual-November-2017.pdf

44 Value of new contracts or legal obligations that PSs expect to sign in 2020, excluding direct financial contributions from PSs (i.e. managed by PSs) to EDCTP2 funded projects.

45 The Supporting Information provided in this chapter is copied from the General Annexes of the Work Programme 2018-2020 of Horizon 2020 (European Commission Decision C(2019)4575 of 2 July 2019), unless the specificities of the EDCTP2 programme required an adaptation of the information to those specificities. Such EDCTP2-specific adaptions 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.

46 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.

47 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.

48 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.

49 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.

50 No agreements or arrangements of this kind are currently existing.

51 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.

52 https://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

53 https://eur-lex.europa.eu/legal-content/EN/T/?qid=1402932108252&uri=OJ:JOL_2014_169_R_0004

54 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

55 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).

56 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.

57 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).

58 Participants may ask for a lower rate.

59 Excerpt from the General Annexes of the Horizon 2020 work programme 2018-2020.

60 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).

61 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.

62 https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

63 Updated in October 2013: https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf

64 Central European Time = Brussels local time.

65 See Articles 131(4) and 106(1) Financial Regulation.

66 See Articles 138(2) and 106(1), 107 of the Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1).

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 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, 20.12.2013 p.81).

69 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)

70 Declarations of the Commission (Framework Programme), OJ C373, 20.12.2013, p. 2

71 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

72 This is not foreseen in the 2020 work plan.

73 http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

74 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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The Hague, The Netherlands, March 2020
European & Developing Countries Clinical Trials Partnership

The EDCTP2 programme is supported by the European Union's Framework Programme for Research and Innovation under Horizon 2020.

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