EDCTP

European & Developing Countries
Clinical Trials Partnership

EDCTP2 WORK PLAN 2016

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Important notice: This annual work plan covers 2016 and describes planned activities under the EDCTP2 programme in 2016.
It has been approved by the EDCTP Association General Assembly on 2 June 2016. The European Commission approved it on 9 June 2016 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 approved it on behalf of the EDCTP Association General Assembly on 15 June 2016.

Contents

Acronyms

AHRI	Armauer Hansen Research Institute
AMRH	Africa Medicines Regulatory Harmonisation
ANRS	Agence nationale de recherches sur le sida et les hépatites virales
CSA	Coordination & Support Action
DFID	Department for International Development
DNDi	Drugs for Neglected Diseases Initiative
DVI	Dengue Vaccine Initiative
EDCTP	European & Developing Countries Clinical Trials Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
EU	European Union
EVD	Ebola virus disease
EVI	European Vaccine Initiative
FIND	Foundation for Innovative New Diagnostics
GCP	Good Clinical Practice
GMP	Good manufacturing practice
HIV/AIDS	Human immunodeficiency virus/ acquired immunodeficiency syndrome
Horizon 2020	European Union's Framework Programme for Research and Innovation 2014-2020
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IPM	International Partnership for Microbicides
IPR	Intellectual property rights
IRB	Institutional review board
IRD	L'Institut de recherche pour le développement
LMIC	Low- and middle-income country
MDR-TB	Multi-drug resistant tuberculosis
MMV	Medicines for Malaria Venture
MRC UK	Medical Research Council United Kingdom
NEC	National ethics committee
NID	Neglected infectious disease
NRA	National regulatory authority
OCT	Overseas countries and territories
PDP	Product development partnership
PMTCT	Prevention of mother-to-child transmission
PRD	Poverty-related disease
PSIA	Participating States' Initiated Activity
RIA	Research & Innovation Action
TB	Tuberculosis
TB Alliance	Global Alliance for TB Drug Development
TBVI	TB Vaccine Initiative
TMA	Training & Mobility Action
WHO-TDR	World Health Organization Special Programme for Research and Training in Tropical Diseases

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 €683 million from the Horizon 2020 programme's societal challenge *"Health, Demographic Change and Well-being"* ("EDCTP2 basic act"[2]).

The EU's financial contribution shall be conditional upon the following: (a) the implementation by the *EDCTP2 Implementation Structure* ("the EDCTP Association") of the objectives and activities of the EDCTP2 programme as set out in annexes 1 and 2 of the EDCTP2 basic act; (b) the maintenance of an appropriate and efficient governance model for the EDCTP2 Programme as set out in annex 3 of the EDCTP2 basic act; (c) the compliance by the EDCTP2 Association with the reporting requirements set out in Article 60(5) of the EU's Financial Regulation (Regulation (EU, Euratom) No 966/2012); and (d) the fulfilment of the commitment by each Participating State[3] to contribute to the financing of the EDCTP2 Programme commitments as referred to in Article 3.1 (point e)[2].

The EDCTP Association (hereafter *"EDCTP"*) is legally established as an *Association* under Dutch law in the Netherlands[4]. The Association currently counts 28 Partner States (PS) as full and equal members: 14 European and 14 African countries.[5,6]

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*[7].

1.1 Scope of the EDCTP2 programme

The activities of the EDCTP2 programme will contribute towards achieving the following five specific objectives[8]:

1. Increase the number of new or improved medical interventions for poverty-related diseases (PRDs), including neglected ones[9];
2. Strengthen cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, EU and international legislation;
3. Better coordinate, align and, where appropriate, integrate relevant national programmes to increase the cost-effectiveness of European public investments;
4. Extend international cooperation with other public and private partners to ensure that the impact of all research is maximised and that synergies can be taken into consideration and to achieve leveraging of resources and investments;
5. Increase impact due to effective cooperation with relevant EU initiatives, including its development assistance.

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 States3,5,6 (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)[10] 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 PS in line with common principles agreed between the EDCTP Association, on behalf of the Participating States, and the European Commission (section 6.5). In order to support activities of strategic scope with 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[11,12].

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. Capacity development activities aim 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, both at scientific, management and financial level[10].

The activities of the EDCTP2 programme are supported along three distinct types of actions[13]: 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[14].

The present EDCTP2 annual work plan 2016 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. It has also included a series of thematic stakeholder meetings (on Neglected Infectious Diseases (NIDs), HIV/AIDS, malaria, tuberculosis and other mycobacterial infections, ethics and regulatory affairs, and capacity development) resulting in specific recommendations for the EDCTP2 programme[15]. In addition to these events, the EDCTP Association has commissioned studies and assessments with regards to the outcome and impact of activities funded under the first EDCTP programme, in particular with respect to capacity building in sub-Saharan African countries. 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 Organisation (WHO).

The EDCTP2 annual work plan 2016 provides information about EU-funded Calls for Proposals in 2016 (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 2016 also contains an overview of non-EU funded PSIAs in 2016 (Chapter 3). The PSIAs in the current EDCTP2 annual work plan are all funded and implemented directly by one or more PS, and are an integral part of the EDCTP2 programme.

In accordance with the EDCTP2 basic act, the draft EDCTP2 annual work plan 2016 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 cash contributions for the implementation of the EDCTP2 programme and its 2016 calls from the European Union and the governments of the following countries: Austria, Finland, Germany, Luxembourg, Portugal, South Africa, Spain, Sweden, the Netherlands and UK. These are summarised in budget overview table 2, section 1.4.

1.4 Budget overview tables

Table 1: Overview of planned commitments to activities of the EDCTP2 programme in 2016 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)

Activities	Contributions (in €)			
	EU	PSs	TPs	TOTAL
EU-funded Calls for Proposals implemented by the EDCTP Association	121,336,000	15,264,000	2,000,000	138,650,000
Other EU-funded Activities implemented by the EDCTP Association	2,240,000	170,000		2,360,000
Sub-Total	123,576,000	15,434,000	2,000,000	141,010,000
Non-EU funded PSIAs implemented by the PSs		185,131,787		185,131,787
Sub-Total Implementation	0	185,131,787	0	185,131,787
EU-funded administrative costs of the EDCTP Association	5,057,568	429,000	50,000	5,536,568
Non-EU funded administrative costs of the PSs*		988,902		988,902
Sub-Total Administration	5,057,568	1,417,902	50,000	6,525,470
Total Budget	128,633,568	201,983,689	2,050,000	332,667,257

** The non-EU funded administrative costs of the PSs refer to all non-grant related in-kind contributions provided by the PS to the EDCTP2 programme. This can include administrative costs of PSs' work contributing to the implementation of the EDCTP2 programme, such as the participation in meetings of the EDCTP Association.*

Table 2: Detailed overview of planned commitments to activities of the EDCTP2 programme in 2016 by the European Union (EU), and European and African Partner States (PSs)

	Cash contributions*	PSIAs**	In-kind Admin.***	Total in 2016	Total cumulative commitment in 2014-2016
European Union (EU)					
European Commission (EC)	128,633,568	0	0	128,633,568	214,798,993
Sub-Total EU	128,633,568	0	0	128,633,568	214,798,993
Participating States** (European Partner States)					
Austria (AT)	560,000	0	570,000	1,130,000	3,900,000
Denmark (DK)	0	200,000	20,000	220,000	7,187,000
Finland (FI)	500,000	200,000	1,500	701,500	1,591,700
France (FR)	0	15,000,000	10,000	15,010,000	34,925,000
Germany (DE)	3,050,000	51,381,056	112,000	54,543,056	90,598,056
Ireland (IE)	0	9,050,000	5,000	9,055,000	20,137,546
Italy (IT)	0	500,000	0	500,000	2,225,000
Luxembourg (LU)	100,000	0	0	100,000	2,300,000
Netherlands (NL)	100,000	0	5,000	105,000	17,158,918
Norway (NO)	0	4,967,271	26,019	4,993,290	17,560,221
Portugal (PT)	500,000	0	0	500,000	1,790,627
Spain (ES)	0	3,295,317	8,000	3,303,317	6,413,317
Sweden (SE)	2,500,000	18,928,084	4,000	21,432,084	45,159,084
United Kingdom (UK)	7,800,000	58,272,500	97,500	66,170,000	316,390,000
Sub-Total European PSs	**15,110,000**	**161,794,228**	**859,019**	**177,763,247**	**567,336,469**
African Partner States					
Burkina Faso (BF)	0	0	0	0	355,753
Cameroon (CM)	0	53,415	4,000	57,415	1,040,449
Congo (CG)	0	206,992	22,000	228,992	345,556
Gabon (GB)	0	0	0	0	250,778
The Gambia (GM)	0	210,000	12,000	222,000	699,000
Ghana (GH)	0	950,000	12,000	962,000	2,996,227
Mali (ML)	0	361,200	4,400	365,600	1,140,600
Mozambique (MZ)	0	0	47,183	47,183	595,541
Niger (NE)	0	0	0	0	204,069
Senegal (SN)	0	0	0	0	303,800
South Africa (ZA)	633,000	17,121,000	13,300	17,767,300	26,081,146
Tanzania (TZ)	0	0	0	0	576,740

Uganda (UG)	0	102,952	5,000	107,952	662,860
Zambia (ZM)	0	4,332,000	10,000	4,342,000	8,988,000
Sub-Total African PSs	**633,000**	**23,337,559**	**129,883**	**24,100,442**	**44,240,519**
Sub-Total European + African PSs	**15,743,000**	**185,131,787**	**988,902**	**201,863,689**	**611,576,988**
Grand Total	**144,376,568**	**185,131,787**	**988,902**	**330,497,257**	**826,375,981**

** Cash contributions from PSs to EDCTP2 calls and other actions implemented by the EDCTP Association that are co-funded by the EU*

*** Value of new contracts or legal obligations that PSs expect to sign in 2016.*

**** The administrative costs of the PSs refer to all non-grant related in-kind contributions provided by the PS to the EDCTP2 programme. This can include administrative costs of PSs' work contributing to the implementation of the EDCTP2 programme, such as the participation in meetings of the EDCTP General Assembly.*

***** Only the commitments of the European PSs count for calculating the matching contribution by the EU since these are the (European) Participating States as defined in the EDCTP2 Basic Act*[3,6].

Table 3: Overview of planned disbursements to activities of the EDCTP2 programme in 2016 by European and African Partner States (PSs)

	Planned disbursements (in €)				
	2016				Total cumulative disbursements in 2014-2016
	EU-funded EDCTP2 calls and other activities	PSIAs	In-kind Admin.**	Total	
Participating States** (European Partner States)**					
Austria (AT)	280,000	275,000	10,000	565,000	1,135,000
Denmark (DK)	0	2,481,667	20,000	2,501,667	6,520,334
Finland (FI)	500,000	362,500	1,500	864,000	1,429,200
France (FR)	0	5,333,333	10,000	5,343,333	25,258,333
Germany (DE)	3,050,000	23,646,056	112,000	26,808,056	62,863,056
Ireland (IE)	0	1,810,000	5,000	1,815,000	12,897,546
Italy (IT)	0	138,667	0	138,667	1,863,667
Luxembourg (LU)	100,000	0	0	100,000	2,300,000
Netherlands (NL)	100,000	2,567,000	5,000	2,672,000	11,183,918
Norway (NO)	0	3,465,487	26,019	3,491,506	14,718,663
Portugal (PT)	100,000	190,560	0	290,560	1,300,927
Spain (ES)	0	1,197,113	8,000	1,205,113	4,115,113
Sweden (SE)	2,500,000	7,485,617	4,000	9,989,617	30,016,617
United Kingdom (UK)	7,800,000	68,774,500	97,500	76,672,000	219,962,000
Sub-Total European PSs	14,430,000	117,727,500	299,019	132,456,519	395,564,374
African Partner States					
Burkina Faso (BF)	0	40,000	0	40,000	280,753
Cameroon (CM)	0	53,415	4,000	57,415	1,040,449
Congo (CG)	0	222,367	22,000	244,367	321,049
Gabon (GB)	0	94,948	0	94,948	250,778
The Gambia (GM)	0	187,667	12,000	199,667	411,333
Ghana (GH)	0	551,818	12,000	563,818	1,322,058
Mali (ML)	0	494,567	4,400	498,967	803,134
Mozambique (MZ)	0	57,030	47,183	104,213	595,541
Niger (NE)	0	78,765	0	78,765	200,003
Senegal (SN)	0	20,000	13,300	33,300	317,100
South Africa (ZA)	633,000	7,204,334	0	7,837,334	13,184,512
Tanzania (TZ)	0	92,909	0	92,909	537,165

Uganda (UG)	0	81,245	5,000	86,245	641,153
Zambia (ZM)	0	1,914,833	10,000	1,924,833	5,191,666
Sub-Total African PSs	633,000	11,093,898	129,883	11,856,781	25,096,694
Grand Total	15,063,000	128,821,398	428,902	144,313,300	420,661,068

** The predicted disbursement from PSs of funding to new activities (i.e. based on planned commitments in 2016) and ongoing activities (i.e. based on commitments made before 2016). Where unknown, it has been assumed for multi-annual commitments that disbursements will occur evenly over the lifetime of the PSIA.*

*** The administrative costs of the PSs refer to all non-grant related in-kind contributions provided by the PS to the EDCTP2 programme. This can include administrative costs of PSs' work contributing to the implementation of the EDCTP2 programme, such as the participation in meetings of the EDCTP General Assembly.*

Table 4: Overview of planned contributions to activities of the EDCTP2 programme in 2016 by Third Parties (TPs)

Third Parties	TPs contributions (in €)			
	In-kind	EDCTP-funded	Admin.	Total
EFPIA members	500,000	-	50,000	550,000
WHO-TDR	-	1,500,000	-	1,500,000
Grand total	500,000	1,500,000	50,000	2,050,000

2. EU-funded Calls for Proposals

2.1 Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2016:

2.1.1 Vaccines for poverty-related diseases (PRDs)[16]

Challenge

Vaccines have contributed enormously to the successful control and elimination of many diseases. To date, few vaccines have been developed for controlling poverty-related diseases (PRDs). In recent years, several candidate vaccines against PRDs have entered clinical development and there is an urgent need to fast track their development. The aim is to increase the number of promising vaccines targeted for use especially in Africa.

Scope

Applications are invited for large-scale collaborative projects which include one or more clinical trials (phase I to IV) aiming to accelerate the clinical development of new vaccines (preventive or therapeutic) against one of the PRDs. Applications must include at least one clinical trial which will be carried out in sub-Saharan Africa to test the safety, immunogenicity and/or efficacy of the vaccine(s).

Target product profiles, particularly indication, target populations, safety and/or efficacy should be included. Additionally, a clear list of product development milestones including specific go/no-go criteria for the implementation of the proposed clinical trial must be included.

Projects may include detailed analyses of host responses to advance the understanding of mechanisms of reactogenicity (safety), immunogenicity and/or efficacy. Projects should incorporate activities to enhance the capacity of existing trial sites and/or develop new trial sites in sub-Saharan Africa for conduct of vaccine trials.

Applications that leverage support from other funders, particularly the pharmaceutical industry and Product Development Partnerships, are encouraged.

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

Expected impact

Actions supported under this Call for Proposal should advance the development of promising candidate vaccines for PRDs moving towards regulatory licensure. The actions should also contribute towards a better understanding of the mechanisms of reactogenicity (safety), immunogenicity and/or efficacy profile of the vaccine candidate(s). The projects will build capacity for the evaluation of different vaccines against PRDs in sub-Saharan Africa.

Table 5: Supporting information for the Call for Proposals "Vaccines for poverty-related diseases (PRDs)"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	3-5
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility condition applies to this Call for Proposals: • The requested EDCTP contribution per action shall not exceed €15.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used. For the first stage, only the Excellence and Impact criteria will be evaluated.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
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 Research and clinical management of patients in PRD epidemics in sub-Saharan Africa

Challenge

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

Scope

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

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

Expected impact

The consortium is expected to collaborate with similar initiatives at national, regional, European and international level, such as PREPARE (http://www.prepare-europe.eu/) and ISARIC (https://isaric.tghn.org/), and the EDCTP regional networks of excellence in order to contribute effectively to global preparedness and response activities, including the WHO blueprint, and ensure quick implementation of its findings into optimised clinical practices and to maximise synergy and complementarity.

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

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

Table 6: Supporting information for the Call for Proposals "Research and clinical management of patients in PRD epidemics in sub-Saharan Africa"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	Up to 1
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility condition applies to this Call for Proposals: • The requested EDCTP contribution per action shall not exceed €10 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)

Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.3 Strategic actions supporting large-scale clinical trials

Challenge

There are multiple research opportunities arising continuously, some of which are of utmost strategic importance to advance clinical research in poverty-related diseases (PRDs). These research opportunities are often complex and resource-intensive, requiring financial investments that a single funder cannot bear. Extended international cooperation with other funders is vital to harness synergies and to ensure that the impact of research is maximised and resources and investments are leveraged.

Scope

The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are part of a large-scale clinical trial that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs. Such large-scale clinical trials are often expensive and may require clinical research in different countries or on different continents, including outside of Europe and Africa. Applications for a strategic action should focus on clinical trials on PRDs in sub-Saharan Africa, and may address any disease within the scope of the EDCTP2 programme[17]. Proposals that include phase III trials are encouraged.

Proposals must present the large-scale clinical trial in its entirety, clearly indicate for which part of the trial EDCTP2-funding is requested and how the financing of the other parts of the trial is ensured if applicable, and present its relevance to reaching the objectives of the EDCTP2 programme. The ambition and design of the proposed large-scale clinical trial as well as the relevance of the proposed strategic action for the large-scale clinical trial must be presented clearly. Supporting information on the composition and scale, as well as on the management structures and procedures of the large-scale clinical trial must be presented to enable assessment of their appropriateness.

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

The large-scale clinical trial must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders (i.e. from EDCTP2 Participating States and/or third parties). EDCTP considers that at least half of the costs of the large-scale clinical trial should be supported by other funders (i.e. from EDCTP2 Participating States and/or third parties) and that the foreseen total costs of the large-scale clinical trial should not be less than €3.0 million to provide this specific challenge with a strategic dimension.

Expected impact

Actions funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders; catalyse research synergies; leverage resources and investments; and maximise the impact of global research in PRDs. The large-scale clinical trial supported by the action should have the potential to achieve maximum impact in the field of PRDs and to make a significant contribution to the objectives of the EDCTP2 programme.

Proposals that clearly document major financial support from other funders at the level of the large-scale clinical trial will be considered to have a higher impact.

Table 7: Supporting information for the Call for Proposals "Strategic actions supporting large-scale clinical trials"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-5
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility condition applies to this call for proposals: • The requested EDCTP contribution per action shall not exceed €15.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The standard award criteria, scoring, thresholds and weightings listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

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

Challenge

Every year, more than 300 000 women die as a result of pregnancy, childbirth or postpartum complications and more than 6 million children die under the age of five, mostly from preventable diseases, according to WHO. The majority of these deaths occur in developing countries and represent the biggest global health inequity today. While substantial progress has been made in reducing maternal and child morbidity and mortality, many countries, particularly in sub-Saharan Africa, have failed to reach the Millennium Development Goal 4 and 5 targets of reducing under-5 mortality by two-thirds and maternal mortality by 75% by 2015 from the 1990-baseline.

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

Roll-out of HIV treatment in large public health programmes has resulted in substantial reductions in HIV-related mortality across all ages, although ART coverage among children below 15 years of age, and especially below five years of age, is lagging behind coverage among adults. This is partly due to failure to timely diagnose vertically-acquired HIV infection in infants, but also due to children and adolescents not being seen in the healthcare system

until late in the course of disease. Whereas prevention of mother-to-child transmission (PMTCT) programmes have largely been effective, a substantial number of HIV-infected pregnant women do not access PMTCT and are thus not benefitting from HIV treatment and care and continue to be at risk of morbidity and mortality for themselves and transmission and mortality for their offspring. Adolescents are often excluded from prevention of HIV infection public health efforts, because they are difficult to reach, are vulnerable at this time of their lives, and find it difficult to access healthcare systems to ask for the necessary prevention support.

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

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

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

Scope

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

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

Expected impact

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

Table 8: Supporting information for the Call for Proposals "Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children, and/or adolescents"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	5-10
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility condition applies to this Call for Proposals: • The requested EDCTP contribution per action shall not exceed €3.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used. For the first stage, only the Excellence and Impact criteria will be evaluated.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
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 2016:

2.2.1 Strategic actions supporting health systems/services optimisation research capacities in cooperation with development assistance initiatives

Challenge

Poverty-related diseases (PRDs) represent a huge burden in many communities in sub-Saharan Africa. Investments for developing new drugs, vaccines, microbicides and diagnostics for PRDs are being made by various entities including pharmaceutical companies and public-private partnerships. Following registration of new and improved clinical interventions, there is a significant challenge of ensuring that these products reach the target populations and that their safety and effectiveness is assessed in real world settings. Currently health systems in PRD endemic areas in sub-Saharan Africa are either weak or not adequately prepared for delivery and uptake of new or improved clinical interventions and to monitor their effectiveness and safety. Concerted collaborative efforts are needed to

strengthen the governance, personnel and infrastructures for uptake as well as effectively deliver and monitor the implementation of new cost-effective interventions for PRDs in endemic areas.

Scope

The purpose of this Call for Proposals is to support distinct strategic actions (Coordination & Support Actions) which are part of a large-scale programme of actions that is supported by EU, national and/or international development assistance initiatives and/or other funders, including relevant WHO initiatives where appropriate, for strengthening the capacity of health systems to effectively deliver new products and to monitor their post-market safety[18]. This should lead to better planning for the introduction of new medical interventions for PRDs; improved delivery; and, better understanding of the safety profile of and reporting mechanisms for products introduced in sub-Saharan Africa.

Proposals addressing one or both of the following topics are particularly encouraged:

Development of pharmacovigilance (PV) capacities in sub-Saharan Africa

- Activities may include: analysis of the current PV policies, regulations and infrastructure in sub-Saharan African countries (e.g. with the use of the Indicator-based Pharmacovigilance Assessment Tool (IPAT)); implementation of tools, technologies or mechanisms to establish and/or improve the efficiency of systems for adverse event detection, reporting, analysis and dissemination to relevant stakeholders; support of staff from sub-Saharan African countries to attend training courses in established PV training centres. Initiatives aligned with the African Medicines Regulatory Harmonization Programme (AMRH) are particularly encouraged.

Translation of research into policy and practice

- Activities may include: the development of methodological tools for the successful translation of research into public health programmes or practices; optimising strategies for widespread adoption and institutionalisation of research results within public health systems; or, the evaluation of research uptake activities. This may entail the analysis of established methods and frameworks from the field of policy analysis to improve the understanding of the process of health policy development in a given sub-Saharan African country and international context. Proposals should clearly define the activities and mechanisms to be used within the project, including details of any collaboration with public authorities, international organisations or commercial partnerships that will be established in order to achieve the expected impact.

Proposals must present the large-scale programme of actions in its entirety, clearly indicate for which part EDCTP2-funding is requested and how the financing of the other parts is ensured if applicable, and present its relevance to reaching the objectives of the EDCTP2 programme, in particular to increase the impact of EDCTP-funded activities and their results. The ambition and design of the proposed large-scale programme of actions as well as the relevance of the proposed strategic action for the large-scale programme of actions must be presented clearly. Supporting information on the composition and scale, as well as on the management structures and procedures of the large-scale programme of actions must be presented to enable assessment of their appropriateness.

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

The large-scale programme of actions must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from EU, national, international development assistance initiatives and/or other funders. EDCTP considers that at least half of the costs of the large-scale programme of actions should be supported by EU, national and/or international development assistance 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 EDCTP-funded activities.

Expected impact

Actions funded under this Call for proposals should increase the readiness of health systems to introduce and absorb new interventions for PRDs and increase the coverage, accessibility and effectiveness of existing evidence-based interventions in endemic areas in sub-Saharan Africa. Furthermore, PV-related actions should contribute to the establishment and/or strengthening of sentinel surveillance systems in sub-Saharan African countries where new drugs or vaccines are implemented, in addition to developing a cohort of PV-trained staff to lead and manage the PV process in these countries.

Proposals that clearly document major financial support from EU, national and/or international development assistance initiatives will be considered to have a higher impact.

Table 9: Supporting information for the Call for Proposals "Strategic actions supporting health systems/services optimisation research and capacities in cooperation with development assistance initiatives"

Type of action	Coordination & Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	1-6
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility condition applies to this Call for Proposals: • The requested EDCTP contribution per action shall not exceed €3 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used. For the first stage, only the Excellence and Impact criteria will be evaluated.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.2.2 Ethics and regulatory capacities

Challenge

Many African countries lack sound ethical review mechanisms and some even lack medicines regulatory bodies. There is a pressing need to develop and strengthen the national ethics and medicines regulatory frameworks in

sub-Saharan Africa in order to strike a balance between the public health interest, the interests of the pharmaceutical industry, and ethical values.

Scope

The purpose of this Call for Proposals is to provide funding to actions that aim to support sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies for use in humans. This scheme targets both National Ethics Committees (NECs) and National Regulatory Authorities (NRAs).

The objectives of this call are:

1. To support NECs' development of institutional and personnel capacities to enable them to perform their national ethical oversight function over the institutional review boards; efficiently review clinical trial applications; and to provide ethical oversight for clinical trials and health research in general;

2. To support NRAs' development of institutional and personnel capacities to enable improved regulatory pathway activities directly related to clinical trials and registration of new medicinal products. This may also include strengthening pharmacovigilance systems.

Proposals may include support for training, networking and promotion of good practices through improved recognition and accreditation of the relevant bodies. This may include relevant long-term training of regulatory staff, in particular through regulatory curricula provided by Regional Centres of Regulatory Excellence in Africa. National collaborative activities involving NECs and Institutional Review Boards, and/or transnational collaborations involving regional networking activities between NECs or NRAs and other partners from any EU country or country associated with Horizon 2020 are encouraged. Joint NEC and NRA applications are also encouraged. Undergraduate training and Masters and PhD studies that are not directly relevant and applicable to the daily activities of NECs and IRBs will not be supported under this scheme.

EDCTP considers that proposals for actions of between 24 and 36 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for actions of a different duration.

Expected impact

Actions funded under this Call for Proposals should strengthen the functionality, recognition and performance of NECs and NRAs in sub-Saharan African countries. They will also contribute towards development of sustainable strategies for both NECs and NRAs.

Table 10: Supporting information for the Call for Proposals "Ethics and Regulatory capacities"

Type of action	Coordination & Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	6-12

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[19]. 2. The requested EDCTP contribution per action shall not exceed €300,000.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono- or multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.2.3 EDCTP-WHO/TDR Clinical Research and Development Fellowships

Challenge

Researchers from low- and middle-income countries (LMICs)[20] who are involved in clinical research activities have limited opportunities to acquire experience and develop skills for conducting clinical trials outside an academic or public sector setting. As a result, there are few researchers and clinical staff from LMICs assuming leading roles in clinical research for poverty-related diseases (PRDs). The development of human capacities through fellowships will lead to enhanced and sustainable research capacity in LMICs on diagnostics, drugs and vaccines for PRDs by supporting career progression and retention of researchers in LMICs.

Background

As part of EDCTP's capacity building efforts, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the EDCTP have signed a Memorandum of Understanding in January 2013 to implement a fellowship scheme that offers placements in European-based companies to individual researchers and clinical staff from sub-Saharan Africa working in the implementation of clinical trials. Furthermore, the European Commission and the Bill & Melinda Gates Foundation signed a Memorandum of Understanding in June 2013 to cooperate in the fight against PRDs.

The WHO/TDR Career Development Fellowships (CDF) programme , which has been supported by the Bill & Melinda Gates Foundation and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), offers targeted training in research and development within pharmaceutical companies and product development partnerships (PDPs) to develop highly skilled local personnel for disease-endemic LMICs to enhance competencies in clinical trials for drugs, vaccines and diagnostics on a broad range of infectious diseases of poverty. The CDF programme is implemented by the Special Programme for Research and Training in Tropical Diseases (WHO/TDR). WHO/TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO[21].

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

Scope

The purpose of this Joint Call for Proposals is to provide funding to actions that aim to support researchers and key members of clinical trial research teams from LMICs to acquire specific skills in clinical research and development through placements in pharmaceutical companies and PDPs.

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are employed by a legal entity in LMICs where they are currently working on activities in the scope of the EDCTP2 programme[22] and the WHO/TDR CDF programme[23]. Placements are for a minimum period of 12 months up to a maximum period of 18 months, following which there will be a re-integration period of 6 months (subject to the approval of a final re-integration plan).

The home organisation (applicant legal entity employing the prospective fellow) submits the application. Fellows must commit to return to their home organisation for a minimum of two years after completion of the fellowship. Fellows should identify the skills and training sought and should demonstrate how the experience would be applied upon return to the home organisation.

The Joint Call will include a joint evaluation and selection process in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. However, grant awarding and budget management will remain separate under the management of each organisation. WHO/TDR will fund fellows employed by a research institution in any LMICs to be placed in pharmaceutical companies and PDPs in or outside Europe, whereas EDCTP will fund fellows employed by a sub-Saharan African legal entity (the fellow's home organisation and applicant legal entity) to be placed in European-based pharmaceutical companies (the host organisation) to train and develop specific clinical research skills of relevance to PRDs. The EDCTP2 grant includes funds for re-integration, conditional upon the approval of a final re-integration plan.

The EDCTP and WHO/TDR will collaborate with EFPIA and IFPMA. A list of participating companies (i.e. host organisation) and placements available will be published on the EDCTP and WHO/TDR websites.

Expected impact

Actions funded under this Joint Call for Proposals will support the development of human resources and should promote high quality research and development in LMICs. Fellowships are expected to add significantly to the development of the best and most promising researchers from LMICs, in order to enhance and maximise their contribution in research institutions in LMICs, including training of peers. The actions should also contribute to strengthening collaboration between research institutions, researchers and clinical staff in LMICs, pharmaceutical companies, and PDPs.

Table 11: Supporting information for the Joint Call for Proposals "EDCTP-WHO/TDR Clinical Research and Development Fellowships"

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs

Expected number of grants	Up to 10 grants funded by the EDCTP2-IS (up to 15 additional grants funded by WHO-TDR).
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) and must be the home organisation employing the fellow[24]. 2. The fellow must[24]: • be a post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases; • have obtained their post graduate or medical graduate degree within 15 years of submission of the application; • have been a researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa, conducting clinical research activities in the scope of the EDCTP2 programme; • not have been funded under this fellowship scheme before[25]. 3. Placements sought shall be for a minimum period of 12 months up to a maximum period of 18 months, following which there will be a re-integration period of up to 6 months.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the applicant legal entity by the indicated deadline. The letters of intent will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP and WHO/TDR in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. Successful candidate fellows in the first stage will be shortlisted and prospective host organisations will be invited to identify preferential candidate fellows. The identification of preferential candidate fellows may include an interview of candidate fellows by the prospective host organisations. For the second stage, the prospective host organisation, the preferred fellow and his/her home organisation must submit a comprehensive training plan (including a draft re-integration plan) that will be evaluated by a panel of independent experts. 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 TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships.
Supplementary agreements	Host organisations in actions resulting from this Call for Proposals will be required to sign up to the corresponding EDCTP charter, while fellows will be required to sign a letter of engagement with EDCTP prior to the conclusion of the EDCTP2 grant agreement.

2.2.4 Senior Fellowships

Challenge

There is a shortage of senior researchers and research mentors in sub-Saharan Africa in the field of poverty-related diseases (PRDs). Support to develop senior researchers within an appropriate and supportive mentorship structure is required to build sustainable research capacity and provide a career pathway for researchers in sub-Saharan Africa.

Scope

The purpose of this Call for Proposals is to provide funding to actions that aim to support capacity development of potential African research leaders using the train-the-trainer model and to mentor junior researchers with emphasis on hands-on research training linked to clinical trials activities conducted in sub-Saharan Africa.

The objectives of the scheme are:

1. To support senior researchers to advance themselves as recognised research leaders in product development through clinical trials and related activities

2. To equip senior researchers with the necessary skills and experience to train and mentor junior researchers at host institutions in sub-Saharan Africa.

Applications should focus on hands-on research activities equipping the fellow with competences to train and mentor junior researchers in a scientific area within the scope of the EDCTP2 programme[26]. Applications should include a clear and concise individual capacity development plan for the fellow with measurable indicators of how the project will advance the fellow's personal development towards scientific leadership. As a key component, the proposed work must include training and supervision of a minimum of two postgraduate students (PhD and/or Masters) with a clear training and mentorship plan. Additionally, the fellow should indicate how their advancement in skills and competences for training and mentorship, as well as the capacity development of the junior researchers under their supervision fit into the overall institutional capacity development and sustainability strategies. Fellows who plan to conduct the training and mentorship on clinical trials must ensure that studies are appropriately designed and good clinical practice (GCP)- compliant and that good manufacturing practice (GMP)-compliant investigational product(s) are available and guaranteed, and all sponsor responsibilities can be fulfilled by the host organisation (applicant legal entity where the fellow is employed) or product developer involved in the project. Fellows should have a track record of publications in peer-reviewed journals in their chosen area of research and show potential to become future research leaders working in sub-Saharan Africa.

Application for a Senior Fellowship must be submitted by the prospective fellow in conjunction with and on behalf of their proposed host organisation in sub-Saharan Africa ('the applicant legal entity'). The grants are awarded to the host organisation with the explicit commitment that this organisation offers appropriate conditions for the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.

Grants will be awarded for up to five years with a total funding of up to a maximum of €500,000. Fellows funded under this Call for Proposals will undergo a mid-term review that may result in discontinuation of the grant after three years in case of unsatisfactory performance.

Expected impact

Fellows funded under this Call for Proposals will develop into recognised research leaders and contribute to an increased pool of scientific knowledge and mentors in sub-Saharan Africa. Fellows will have developed the ability to initiate, design, plan, execute and lead complex clinical research programmes and trials through interdisciplinary collaboration and, where relevant, across sectors. The fellows will produce high impact scientific and where applicable policy publications, and will be more competitive, assuming scientific leadership and capable of attracting funding from various sources. Ultimately this grant will contribute to the generation of a critical mass of researchers and the progression of institutional research capacity in sub-Saharan Africa. The senior fellowship grants will also contribute to reduce and reverse the brain drain of African scientists that moved out of or trained outside Africa by offering an opportunity to return to Africa and progress their career as independent research leaders.

Table 12: Supporting information for the Call for Proposals "Senior Fellowships"

Type of Action	Training & Mobility Action (TMA)
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. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).[4] 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[27]. 3. The fellow must[27]: • be resident of or be willing to relocate to a sub-Saharan African country; • be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a minimum of five years' research experience; • not have been funded under this fellowship scheme before[28]; 4. The requested EDCTP contribution per action shall not exceed €500,000. 5. The maximum fellowship duration shall be 60 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.
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships.
Supplementary agreement	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.

2.2.5 Career Development Fellowships

Challenge

There is a severe shortage of opportunities for junior and mid-career researchers to acquire and develop clinical research skills in sub-Saharan Africa. Increased possibilities for individual training would enable talented scientists to establish themselves as independent researchers and team leaders at host institutions in sub-Saharan Africa.

Scope

The purpose of this Call for Proposals is to provide funding to actions that aim to support junior to mid-career researchers ("fellows") to train and develop their clinical research skills.

The objectives are:

1. To promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa;

2. To equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research and team at host organisations in sub-Saharan Africa.

The proposed action should specifically enhance the ability of the fellow to design, plan and execute clinical biomedical and/or social science/ethics research projects within the scope of the EDCTP2 programme[29]. The proposed training should include an independent research activity and a clear description of the skills that will be acquired by carrying out the research. Fellows with training activities involving clinical trials and related studies must ensure that studies are appropriately designed and good clinical practice (GCP)-compliant and that good manufacturing practice (GMP)-compliant investigational product(s) are available and guaranteed, and all sponsor responsibilities can be fulfilled by the host organisation (applicant legal entity where the fellow is employed) or product developer involved in the project. Individuals targeted by this Call for Proposals should have a track record of publications in peer-reviewed journals in their chosen area of research, a mentor who is an internationally recognised scientific leader working in sub-Saharan Africa, and a career development plan as part of the research proposal.

Application for an EDCTP Career Development Fellowship must be submitted by the prospective fellow in conjunction with and on behalf of their proposed host organisation ('the applicant legal entity'). The grants are awarded to the host organisation with the explicit commitment that this organisation offers appropriate conditions for the fellow to direct and manage its funding for the duration of the fellowship.

Expected impact

Activities funded under this Call for Proposals will promote career progression, encourage entry and re-integration of African scientists trained abroad, and ensure the retention of postdoctoral and postgraduate researchers in their respective research fields and that the researchers develop into independent researchers and team leaders in sub-Saharan Africa. The progressive generation of independent researchers, re-entry of ones trained abroad and retention of those working in sub-Saharan Africa will ultimately contribute to creation of a critical mass of internationally recognised scientific leaders, institutions and networks that will sustain high quality research in sub-Saharan Africa. The career development fellowship grants will also contribute to reduce and reverse the brain drain of African scientist that moved out of or trained outside Africa by offering an opportunity to return to Africa and progress their career to establish themselves as independent researchers, thereby empowering them to assume a leadership role in clinical research and contributing to sustainable development.

Table 13: Supporting information for the Call for Proposals "Career Development Fellowships"

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	14-17
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: 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 an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity)[30]. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant[30]. 3. Fellows must:[30] • be resident of or be willing to relocate to a sub-Saharan African country • be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and up to five years' relevant postdoctoral research experience, or a medical doctor with up to five years' research experience; • must not have received funding for this fellowship scheme before[31].

	4. The requested EDCTP contribution per action shall not exceed €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.
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships.
Supplementary agreement	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.

2.3 Conditions for the Calls for Proposals

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

Table 14: Indicative timetable for Calls for Proposals in 2016

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	**Vaccines for PRDs**	Stage 1 – **14 July 2016**	Stage 2 – **12 January 2017**	Stage 1 –**13 October 2016** at 17:00:00 CET	Stage 2 –**14 March 2017** at 17:00:00 CET	Stage 1 – **12 January 2017**	Stage 2 – **4 August 2017**
	Research and clinical management of patients in PRD epidemics in sub Saharan Africa	Stage 1 – **14 July 2016**	Stage 2 – **12 January 2017**	Stage 1 –**13 October 2016** at 17:00:00 CET	Stage 2 –**14 March 2016** at 17:00:00 CET	Stage 1 – **12 January 2017**	Stage 2 – **4 August 2017**
	Strategic actions supporting large-scale clinical trials	Stage 1 – **14 July 2016**	Stage 2 – **12 January 2017**	Stage 1 –**13 October 2016** at 17:00:00 CET	Stage 2 –**14 March 2016** at 17:00:00 CET	Stage 1 – **12 January 2017**	Stage 2 – **4 August 2017**
	Clinical trials and operational research studies to optimise the use of products for PRDs in mothers, newborns, children and/or adolescents	Stage 1 – **14 July 2016**	Stage 2 – **12 January 2017**	Stage 1 –**13 October 2016** at 17:00:00 CET	Stage 2 –**14 March 2016** at 17:00:00 CET	Stage 1 – **12 January 2017**	Stage 2 – **4 August 2017**

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	
CSA	**Strategic actions supporting health systems/ services optimisation research capacities**	**3 November 2016**		Single stage –**16 February 2017** at 17:00:00 CET		Single stage – **6 July 2017**	
	Ethics & Regulatory Capacities	Single stage – **13 October 2016**		Single stage – **19 January 2017** at 17:00:00 CET		Single stage – **23 May 2017**	
TMA	**EDCTP-WHO/TDR Clinical Research and Capacity Development Fellowships**	Stage 1 – **22 October 2016**	Stage 2 – **14 June 2017** at 17:00:00 CET	Stage 1 – **28 January 2017** at 17:00:00 CET	Stage 2 – **21 July 2017** at 17:00:00 CET	Stage 1 – **14 June 2017** Interviews are planned for April/ May 2017	Stage 2 – **7 October 2017**
	Senior Fellowships	**10 November 2016**		Single stage – **9 February 2017** at 17:00:00 CET		Single stage – **29 June 2017**	
	Career Development Fellowships	**10 November 2016**		Single stage – **9 February 2017** at 17:00:00 CET		Single stage – **29 June 2017**	

Table 15: Overview of planned contributions towards EDCTP2 Calls for Proposals and other activities for the implementation of the EDCTP2 programme in 2016, including administrative expenses of the EDCTP Association in 2016

EU-funded EDCTP2 activities		Allocation TPs (in €)	Indicative allocation PS (in €)	Indicative EU contribution (in €)	Indicative budget (in €)*
Research & Innovation Actions	Vaccines for PRDs		8,000,000	62,000,000	70,000,000
	Research and clinical management of patients in PRD epidemics in sub-Saharan Africa		3,000,000	7,000,000	10,000,000
	Strategic actions supporting large-scale clinical trials		0	28,000,000	28,000,000
	Clinical trials and operational research studies to optimise the use of products for PRDs in mothers, newborns, children, and adolescents		3,000,000	7,000,000	10,000,000
Coordination & Support Actions	Strategic actions supporting health systems/services optimisation research capacities		250,000	9,750,000	10,000,000
	Ethics and regulatory capacities		14,000	1,986,000	2,000,000
Training & Mobility Actions	EDCTP-WHO/TDR Clinical Research and Development fellowships*	2,000,000	0	1,500,000	3,500,000
	Senior fellowships		500,000	2,500,000	3,000,000
	Career development fellowships		500,000	1,600,000	2,100,000

Other Activities	Independent experts			700,000	700,000
	Prizes			80,000	80,000
	Alumni platform			100,000	100,000
	Forum 2016		170,000	430,000	600,000
	Stakeholder meetings			150,000	150,000
	Financial and project management training			150,000	150,000
	Open Source pilot for clinical trials			250,000	250,000
	Web-based Financial Management Assessment Tool			200,000	200,000
	Mapping the biomedical research projects funded by major funding organisations around the world			30,000	30,000
	Advocacy and outreach activities			150,000	150,000
Administrative costs of the EDCTP Association	Personnel, Missions, Consumables and supplies Service contracts	50,000	429,000	5,057,568	5,536,568
Total planned contributions in 2016		**2,050,000**	**15,863,000**	**128,633,568**	**146,946,568**

3. Other EU-funded activities

3.1 Activities supporting programme operations

3.1.1 Independent experts assisting in proposal evaluations and project reviews in 2016

Objective: These activities will support the appointment of independent experts for the evaluation of proposals, the meetings of the Scientific Advisory Committee; external audits of and site visits to beneficiaries of EU-funded activities.

Type of action: Expert contracts.

Indicative budget: €700,000.

3.1.2 EDCTP Prizes

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

The four awards are:

- **Scientific Leadership Award:** Awarded to excellent world-class scientists in Africa up to up to 50 years of age
- **Outstanding Female Scientist:** Awarded to excellent world-class female scientists working and residing in sub-Saharan Africa in the remit of EDCTP2.
- **Outstanding Research Teams:** Awarded to outstanding research teams in Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases (NIDS) in the scope of the EDCTP2 programme.
- **Dr Pascoal Mocumbi Award:** This is an award set up in recognition of the work of Dr Pascoal Mocumbi towards the mission of EDCTP. It is to be awarded scientists, policy makers or advocates for health and research from anywhere in the world and has no age restriction. This award was published in the EDCTP2 2015 work plan and will not be repeated in 2016.

The specific rules of the contest will be published in 2016 on the EDCTP website and also actively publicised elsewhere to maximise participation. EDCTP will directly launch and manage the contest and award the prize based on the judgement of independent experts as well as board members of the EDCTP Association.

Applications have to be submitted by the contestant (natural person) via the web-based submission forms on EDCTPgrants (https://www.edctpgrants.org). Applications will have to clearly state the involvement of the contestants in the research and innovation activities within the remit of the EDCTP2 programme. The candidates will have to provide proof of eligibility and a written presentation of their achievements, which will be presented to an Awards Panel for evaluation.

Expected result:

- Scientific Leadership Award: The cash prize should be used to further the research programmes of the winners and may support activities such as supporting study visits and training attachments to collaborating institutions, data collection for baseline studies, conference and meeting attendance, and other relevant research-related activities.

- Outstanding Female Scientist Award: The cash prize should be used to further the research programmes of the winners and may support activities towards training and mentorship of the future generation of researchers in Africa.

- Outstanding Research Team Award: The cash prize should be used to further the research programmes of the winners and may support activities such as supporting study visits and training attachments to collaborating institutions, data collection for baseline studies, conference and meeting attendance, and other relevant research-related activities. The objective of this award is to encourage scientific/research excellence, translation of research into policy and practice, sustainable capacity development coupled with skills and technology transfer.

Amount of prize:

- Scientific Leadership Award: This award consists of a recognition trophy and a cash prize of 10,000 Euros

- Outstanding Female Scientist Award: This award consists of a recognition trophy and a cash prize of 20,000 Euros.

- Outstanding Research Team Award: This award consists of a recognition trophy and a cash prize of 50,000 Euros.

Eligibility criteria: The contestant must be a resident of a sub-Saharan African country, an EU Member State, or a country associated to the Horizon 2020 programme.

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

- Scientific Leadership Award: contestants have made significant achievements in their field and will continue to become leaders in their research field. In addition to their scientific excellence, the contestants should have made major contributions to the objectives of the EDCTP2 programme to strengthen research capacity in sub-Saharan Africa and to support South-South and North-South networking. This award has an age restriction of 50 years.

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

- Outstanding Research Team: this award recognises a consortium or group of partners who have achieved the goal of taking on EDCTP priority issues in poverty related diseases (PRDs). In collaboration, they have built effective and equitable South-North partnerships to answer the priority research questions, achieving high

impact health-policy relevant deliverables, such as research data implemented into policy and practice, high impact publications and significant capacity and training outputs achieved in parallel with the local researchers in the settings where the research is actually done. Contestants should be actively involved in research, capacity development and networking in sub-Saharan Africa and Europe with outstanding achievements and scientific and policy impact in their respective fields.

Type of action: Recognition prizes.

Indicative timetable: Prize contests will be launched in the second quarter of 2016 and remain open until the third quarter 2016. Prize winners will be announced at the Eighth EDCTP Forum (see General Annexes 6.6 for Model Rules of Contest (RoC) for EDCTP2 Prizes).

Indicative budget: €80,000.

3.1.3 Tender for hosting an EDCTP Alumni Platform

Objective: To further increase the impact of the EDCTP fellows, networking between recipients of EDCTP grants (current and past) will be enhanced through the implementation of an alumni interaction platform. This could be extended to include fellowship supervisors. Activities will include support for virtual communities, networking listservs and promotion of other services related to alumni activities. For this purpose, one service contract will be concluded.

Type of action: Public Procurement, 1 service contract. Direct contract

Indicative timetable: Call for tender will be open in third quarter of 2016. All procurements will be made in accordance with EDCTP procurement policies and procedures[32].

Indicative budget: €100,000.

3.1.4 Eighth EDCTP Forum 2016

Objective: The biennial EDCTP Forum provides an international platform for the presentation and discussion of frontier research for everyone involved in combating poverty-related diseases and the appropriate capacity development and networking activities. The Forum has established itself as valuable opportunity to develop and reinforce cooperation and synergy among EDCTP stakeholders at various levels including scientific, policy, funding and political interactions. Scientists involved in EDCTP-funded projects are particularly encouraged to use this opportunity to share new developments and results from their projects.

This action will support all eligible costs necessary to satisfactorily organise the forum, including meeting the travel costs of selected EDCTP staff and beneficiaries to attend the forum.

The Eighth EDCTP Forum is expected to be held in Lusaka, Zambia.

EDCTP will invite keynote speakers for the plenary sessions. Oral and poster presentations will be selected on merit from abstracts submitted to a call for abstracts launched in the first quarter of 2016. A selection of applicants with well-rated abstracts especially from sub-Saharan Africa working in the remit of EDCTP2 will be awarded

scholarships. Details of submission of abstracts and applications for scholarships will be published in the call for abstracts.

Expected impact: The Forum is expected to draw 500-700 delegates, the majority of whom are working in sub-Saharan Africa and to 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. Direct contracts

Indicative timetable: The procurement process for some of the services will begin in the second quarter of 2016 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which is in the fourth quarter of 2016. All procurements will be made in accordance with EDCTP procurement policies and procedures[32].

Indicative budget: €600,000.

In addition, the following Participating States have already provided a contribution of €170,000 towards the organisation of the Forum: Germany €50,000; UK €70,000; Sweden €50,000.

3.1.5 Stakeholder Meetings

Objective: Up to two thematic stakeholder meetings will be organised to contribute to the definition and fine-tuning of future strategic priorities under EDCTP2. This action will support all costs necessary to satisfactorily organise the stakeholder meetings, including the travel costs of selected EDCTP staff and selected external stakeholders.

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

Indicative timetable: The procurement process will begin in the second quarter with the objective of holding the two joint stakeholder meetings in the third quarter of 2016. All procurements will be made in accordance with EDCTP procurement policies and procedures[32].

Indicative budget: €150,000.

3.1.6 Financial and Project Management Training

Objective: Organisation of workshops in sub-Saharan Africa to strengthen the capacity for financial and project management of EDCTP2-funded collaborative projects. The coordinators and the scientific and financial project managers of newly selected and on-going EDCTP2 projects will be invited to attend a two-day workshop. The aim of the workshops is to inform participants about the rules and regulations associated with implementing EDCTP2 projects in accordance with Horizon 2020. The workshops will consist of a mix of passive (presentations) and active, participatory training. This action will support all costs necessary to satisfactorily organise the workshops, including the costs for venue and travel costs of selected EDCTP staff and selected external presenters and participants. It is planned to organise up to two workshops in sub-Saharan Africa.

Type of action: Public Procurement – up to 6 service contracts. Direct contracts

Indicative timetable: The procurement process will begin in the second quarter with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2016. All procurements will be made in accordance with EDCTP procurement policies and procedures[32].

Indicative budget: €150,000.

3.1.7 Open Source pilot for Clinical Trials

Objective: It is increasingly required that results and data that are generated by publicly funded research should also be made publicly available. The EDCTP requires that all publications are made available through open access publications, but there is currently no mechanism to make the underlying data, in particular clinical trials protocols, clinical trials reports, and clinical trials data publicly available. The aim of this action is to establish a suitable and adequate electronic platform for securely storing data from EDCTP2-funded clinical trials and making them publicly available. The platform will consist of 1) a repository, where clinical trials protocols, clinical trials reports and clinical trials data can be deposited and accessed by third parties in order to mine, exploit, reproduce or disseminate free of charge, and 2) an active interface where protocols for clinical trials can be discussed, and new or improved protocols for PRDs may be conceived, developed and refined. The open source platform will be aligned with participation in the Horizon 2020 open data initiative.

Type of action: Public Procurement – up to 2 service contracts. Direct contracts

Indicative timetable: Call for tender will be opened in the fourth quarter of 2016. Procurements will be made in accordance with EDCTP procurement policies and procedures.32

Indicative budget: €250,000.

3.1.8 Contribution to the development of a web-based Financial Management Assessment Tool (FMAT)

Objective: EDCTP will make a contribution towards the development of a web-based Financial Management Assessment Tool (FMAT), which can be used by both funders and beneficiaries. This is a joint initiative between the UK Medical Research Council (MRC-UK), the Wellcome Trust, EDCTP and other funders of clinical trials in sub-Saharan Africa. Funders can use this tool to assess the financial management capacity of beneficiaries and beneficiaries can use it to perform a self-assessment of their financial systems with the objective of identifying improvement areas, if any, to address. The long-term objective is to develop FMAT as a standard of Good Financial Grant Practices (GFGP)[33].

Legal entities: Funding will be provided through a CSA grant to the secretariat of the International Financial Governance Consortium (IFGC), hosted by the African Academy of Sciences, 8 Miotoni Lane, P.O. Box 24916-00502, Nairobi, Kenya.

Type of action: Grant to identified beneficiary - Coordination and Support Actions.

The basis for awarding the grant to an identified beneficiary are Article 1 and Article 11.2 of the Rules for Participation in H2020 (Regulation (EU) No 1290/2013), applicable to the indirect actions funded by funding bodies (article 4.4 of EDCTP2 basic act).

Only IFGC has the unique expertise and capacity to implement this action.

The standard evaluation rules for this type of action are provided in section 6.7 of the General Annexes.

Indicative timetable: second quarter of 2016

Indicative budget: €200,000.

In addition, the MRC-UK and the Wellcome Trust have already committed €700,000 to this initiative.

3.1.9 Grant for mapping the biomedical research projects funded by major funding organisations around the World

Objective: A contribution will be made to ensure the upgrade and maintenance of the World RePORT. This unique, web-based information sharing platform mapping biomedical research funded projects was created by major funding organisations around the World to facilitate communication and coordination between funders, to provide more transparency and openness on funding flows and to allow increased cost-effectiveness of funding. Created as a pilot project in 2011 by the Heads of International Research Organizations (HIRO), including the EC, it is hosted by the National Institutes of Health (NIH) of the United States, and maintained and upgraded by the NETE Solutions Corporation, the IT service provider of NIH. The platform brings together leading health research funding agencies of key countries and organisations (currently USA, Canada, France, the United Kingdom, Germany, Sweden, the EC and the European and Developing Countries Clinical Trials Partnership). The World RePORT facilitates also the development of common standards for data on publicly released funding and enables data aggregation. It will also contribute to the implementation of the G7 strategy for research funding in the area of poverty-related and neglected diseases and to the international cooperation in research and innovation.

Legal entities: Funding will be provided through an action grant to NETE ("NET ESOLUTIONS CORPORATION"). NETE Corporate Headquarters, 8280 Greensboro Drive, Suite 200, Mclean, VA 22102, United States.

Type of action: Grant to identified beneficiary - Coordination and support actions.

The basis for awarding the grant to an identified beneficiary are Article 1 and Article 11.2 of the Rules for Participation in H2020 (Regulation (EU) No 1290/2013), applicable to the indirect actions funded by funding bodies (article 4.4 of EDCTP2 basic act).

Only NETE has the unique expertise and capacity to implement this action, i.e. to upgrade and maintain the World RePORT.

The standard evaluation rules for this type of action are provided in section 6.7 of the General Annexes.

Indicative timetable: second quarter of 2016.

Indicative budget: €30,000.

3.1.10 Support advocacy and outreach activities, including engagement with key stakeholders

Objective: In order to engage in strategic initiatives that foster collaboration with like-minded funders, raise awareness regarding the EDCTP2 programme and increase its visibility, EDCTP will participate in joint funders groups such as HIV, TB and malaria vaccine funders platforms including ESSENCE on Health Research[34]; in strategic initiatives and a selection of international conferences to ensure a wider pool of potential applicants for EDCTP2 Calls for Proposals. EDCTP will use such opportunities to showcase its activities and organise two to four small scale meetings or symposia with the objective of collecting information necessary for future updating of its strategic business plan especially in priority areas where larger stakeholders meetings are not feasible in 2016. In addition to the Forum (3.1.4), EDCTP aims to have a strong presence in at a least four large international conferences in 2016.

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

Indicative timetable: The procurement process will begin in the second quarter of 2016. All procurements will be made in accordance with EDCTP procurement policies and procedures[32].

Indicative budget: €150,000.

4. Non-EU funded National Programme Activities (PSIAs)

The European and African EDCTP 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 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 EDCTP, 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 European Union (see section 6.10). PSIAs are 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 planned contributions from PS to PSIAs for 2016 (Table 2 and 3) comprises planned commitments of €161,794,228 from the European Participating States and €23,337,559 from African Partner States; and, planned disbursements of €117,727,500 from the European Participating States and €11,093,898 from the African Partner States.

All PSIAs are listed below, with a brief overview of the PS and funding institutions involved, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the indicative commitments for 2016. 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, including reporting by the (European) Participating States based on the requirements agreed with the European Commission in accordance with article 4 of the EDCTP2 basic act and included in 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.

4.1 PSIAs to be initiated in 2016

The following new PSIAs will be initiated by PSs in 2016 as contributions to the EDCTP2 programme:

Table 16: PSIAs supported in 2016.

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
European Partner States *(Participating States)*							
DE.PS.2016.1	Cumulative Support to PDPs including DNDI, FIND, EVI, DVI	PDP	RIA	TBD	60	50,000,000	10,000,000
DE.PS.2016.2	Call for Proposals on Zoonoses	NIDs	RIA	TBD	60	100,000	20,000
DE.PS.2016.3	Defeating Ebola Virus Disease (EVD) in West Africa: Clinical evaluation (phase I) of an Ebola vaccine (VSV-deltaG-ZEBOV-GP) and tools for follow ups	NIDs	RIA	TBD	24	500,000	500,000
DE.PS.2016.4	Biotechnological production of new natural ingredients for use against malaria and other poverty-related diseases (formerly Platform for new Drugs on poverty-related diseases)	Cross Cutting	RIA	TBD	14	781,056	781,056
DK.PS.2016.1	H56 POI Phase II Trial to Evaluate Prevention of Infection with Mycobacterium tuberculosis of H56:IC31, a novel TB vaccine, in Tanzanian Adolescents	Tuberculosis	RIA	Tanzania	12	200,000	200,000
ES.PS.2016.1	Study and evaluation of Host-Directed Therapies against Tuberculosis	Tuberculosis	RIA	Multiple across Africa	24	106,045	53,023
ES.PS.2016.2	Institutional support to the National Centre for Epidemic Control in Guinea Equatorial	Institutional capacity building	CSA	Equatorial Guinea	18	243,000	162,000
ES.PS.2016.3	Biomedical Research at the Health Research Centre in Maniça	Cross-cutting	RIA	Mozambique	36	2,946,272	982,091

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
FI.PS.2016.1	Development research - Joint programme by the Academy of Finland and the Finnish Ministry for Foreign Affairs	Cross-cutting	RIA	TBD	TBD	200,000	200,000
FR.PS.2016.1	Expertise France - 5% Program - clinical research and / or capacity strengthening	Cross Cutting	RIA	TBD	36	8,000,000	2,666,667
FR.PS.2016.2	ANRS research grants: multidisciplinary and/ or multi-country research programme	HIV/AIDS	RIA	TBD	36	5,000,000	1,666,667
FR.PS.2016.3	Pasteur Institute - clinical research and / or capacity strengthening	Cross Cutting	RIA	TBD	24	1,500,000	750,000
FR.PS.2016.4	IRD - capacity strengthening	Institutional capacity building	CSA	TBD	24	500,000	250,000
IE.PS.2016.1	Support to International AIDS Vaccine Initiative (IAVI)	PDP	RIA	TBD	60	1,200,000	240,000
IE.PS.2016.2	Support to International Partnership on Microbicides (IPM)	PDP	RIA	TBD	60	2,000,000	400,000
IE.PS.2016.3	Support to European Vaccine Initiative (EVI)	PDP	RIA	TBD	60	1,950,000	390,000
IE.PS.2016.4	Support to TB Alliance	PDP	RIA	TBD	60	1,900,000	380,000
IE.PS.2016.5	Support to Medicines for Malaria Venture (MMV)	PDP	RIA	TBD	60	2,000,000	400,000
IT.PS.2016.1	Retention in care of adult HIV patients initiating antiretroviral therapy in Tigray, Ethiopia: a three years cohort study implemented within the CASA Project.	HIV/AIDS	RIA	Ethiopia	36	290,000	96,667
IT.PS.2016.2	Comorbidities in adult HIV-infected patients on antiretroviral therapy in Tigray, Ethiopia, within CO-CASA study: a prospective observational cohort study	HIV/AIDS	RIA	Ethiopia	60	210,000	42,000

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
NO.PS.2016.1	Phase II Trial to Evaluate Prevention of Infection with Mycobacterium tuberculosis of H56:IC31, a novel TB vaccine, in Tanzanian Adolescents	Tuberculosis	RIA	Tanzania	60	2,647,999	529,600
NO.PS.2016.2	The practice and ethics of collaboration in transnational medical research in East Africa. An ethnographic approach	Cross-cutting	CSA	East African countries	36	575,078	191,693
NO.PS.2016.3	ESSENCE TDR - the Special Programme for Research and Training in Tropical Diseases	Cross-cutting	RIA	TBD	12	73,659	73,659
NO.PS.2016.4	Support to International AIDS Vaccine Initiative (IAVI)	PDP	RIA	TBD	12	182,468	182,468
NO.PS.2016.5	Support to International Partnership on Microbicides (IPM)	PDP	RIA	TBD	12	304,114	304,114
NO.PS.2016.6	Support to Tuberculosis Vaccine Initiative (TBVI)	PDP	RIA	TBD	12	190,500	190,500
NO.PS.2016.7	Support to Drugs for Neglected Diseases initiative (DNDi)	PDP	RIA	TBD	12	165,100	165,100
NO.PS.2016.8	Support to Medicines for Malaria Venture (MMV)	PDP	RIA	TBD	12	254,000	254,000
NO.PS.2016.9	Support to Armauer Hansen Research Institute (AHRI)	Cross-cutting	RIA	Ethiopia	12	522,637	522,637
NO.PS.2016.10	Network for molecular epidemiology of Mycobacterium tuberculosis in Ethiopia, Sudan and South Sudan: the cradle of the new lineage 7	Cross-cutting	CSA	Ethiopia; Sudan; South Sudan	4	51,716	51,716
SE.PS.2016.1	Research Capacity Strengthening for the Control of HIV in Tanzania	HIV/AIDS	CSA	Tanzania	60	1,921,400	384,280

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
SE.PS.2016.2	Strengthening Capacity for Development of Interventions for Control and Elimination of Malaria and Neglected Tropical Diseases as an Integral Part of Global Efforts for Sustainable Development in Tanzania	Malaria	CSA	Tanzania	60	375,000	75,000
SE.PS.2016.3	Strengthening health system research capacity for enhancing innovations and sustainable socio-economic development	Cross-cutting	CSA	Tanzania	60	698,750	139,750
SE.PS.2016.4	Innovations for accelerating reduction in maternal, newborn and child mortality in post conflict Uganda	Cross-cutting	CSA	Uganda	60	970,000	194,000
SE.PS.2016.5	Towards better treatment of infectious diseases in children in rural Uganda. Better diagnostics and algorithms for increased quality of care, rational use of medicines and minimized antimicrobial resistance.	Cross-cutting	CSA	Uganda	60	1,191,884	238,377
SE.PS.2016.6	Quality improvement of Makerere University's population-based health and demographic surveillance site: maximising the potential of the research platform for capacity development and generation of valid population data to inform policy formulation	Cross-cutting	CSA	Uganda	60	1,371,050	274,210
SE.PS.2016.7	WHO-TDR including ESSENCE Secretariat	Cross-cutting	RIA	Various	24	7,400,000	1,480,000
SE.PS.2016.8	Armauer Hansen Research Institute (AHRI) Core support 2016-2020	Cross-cutting	RIA	Ethiopia	60	5,000,000	1,000,000
UK.PS.2016.1	MRC Research Grants	Cross-cutting	RIA	TBD	60	3,900,000	780,000
UK.PS.2016.2	MRC Fellowships	Cross-cutting	TMA	TBD	60	1,300,000	260,000

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
UK.PS.2016.3	MRC/DFID African Research Leader (ARL) scheme	Cross-cutting	TMA	TBD	60	1,950,000	390,000
UK.PS.2016.4	Health Systems Research Initiative	Cross-cutting	RIA	TBD	60	650,000	130,000
UK.PS.2016.5	Joint Global Health Trials scheme	Cross-cutting	RIA	TBD	60	7,800,000	1,560,000
UK.PS.2016.6	MRC Unit The Gambia	Cross-cutting	RIA	The Gambia	60	40,560,000	8,112,000
UK.PS.2016.7	Late Phase Global Health Research	Cross-cutting	RIA	TBD	60	812,500	162,500
UK.PS.2016.8	UK Research and Development Vaccines Network	Cross-cutting	CSA	TBD	60	1,300,000	260,000
Sub-Total European PSs						**161,794,228**	**38,085,775**
African Partner States							
CG.PS.2016.01	Strengthening networking of malaria scientists for malaria vaccine trials through the development of an IT communication platform	Malaria	CSA	Republic of Congo; Germany	12	152,200	152,200
CG.PS.2016.02	Improvement of the case management of Tuberculosis in the main prison of Brazzaville and preparation to Host directed therapies for tuberculosis clinical trials	Tuberculosis	RIA	Republic of Congo; Cameroon; Zambia; Gabon	12	45,660	45,660
CG.PS.2016.03	Establishment of regional training platform for Health Research	Networking	CSA	Republic of Congo; Germany; WHO Afro	24	9,132	4,566
CM.PS.2016.1	Capacity building of members of ethics committee & research officers at central level on good clinical practice and protection of research participants	Cross-cutting	CSA	Cameroon	2 days	15,250	15,250
CM.PS.2016.2	Study under the topic: Elaboration of a draft law on the regulation of ethics and bioethics	Institutional capacity development	CSA	Cameroon	4	38,165	38,165

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
GH.PS.2016.01	Clinical trials site preparation and conduct of adjunct Host-directed therapies trials for improving TB treatment outcomes and reducing duration of chemotherapy	Tuberculosis	RIA	Ghana; South Africa; Tanzania; Zambia	60	600,000	120,000
GH.PS.2016.02	Diabetes and TB and HIV co-morbidity studies and interventions	Tuberculosis	RIA	Ghana; South Africa; Tanzania; Zambia	60	150,000	30,000
GH.PS.2016.03	Improved diagnosis and treatment of TB and TB/HIV co-infection in pregnant mothers and neonates	Tuberculosis	RIA	Ghana; South Africa; Tanzania; Zambia; Uganda	60	200,000	40,000
GM.PS.2016.1	Regulatory capacity building for Medicines Control Agency, The Gambia	Institutional capacity building	CSA	The Gambia	60	210,000	42,000
ML.PS.2016.1	Comparative study of TB diagnostic tools (culture, Genexpert, biomarkers) in children in Mali	Tuberculosis	RIA	Mali	36	75,000	25,000
ML.PS.2016.2	Phase 2 PfSPZ study with the targeted high dose in phase 1	Malaria	RIA	Mali	12	105,000	105,000
ML.PS.2016.3	Safety and efficacy of AS-PYR, DHA-PQP compared to AL in real-life conditions in West Africa	Malaria	RIA	West Africa	36	181,200	60,400
UG.PS.2016.1	The 8th Annual National Research Ethics Conference (ANREC) and a planned forum for the chairpersons of Research Ethics Committees	Networking	CSA	Uganda	3 days	46,771	46,771
UG.PS.2016.2	East Africa community Health and Science meeting 2016	Networking	CSA	Uganda, Rwanda, Burundi, Tanzania and Kenya	3 days	23,620	23,620

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
UG.PS.2016.3	Clinical trials sites preparation for Africa-Europe HDT-NET for Host-directed therapies trials for reduction of duration of TB therapy and improving treatment outcomes of MDR-TB	Tuberculosis	CSA	Uganda, Tanzania, Ethiopia and South Africa	36	32,561	10,854
ZA.PS.2016.01	TB and MDR-TB and TB/ HIV co-infection	Tuberculosis	RIA	South Africa; Zambia; Zimbabwe; Mozambique; Madagascar; Uganda; Kenya	36	10,000,000	3,333,333
ZA.PS.2016.02	Field validation of a multi-lateral point-of-care assay for differential diagnosis of 5 febrile illnesses including Malaria and Ebola	Malaria	RIA	Western Cape	24-36	21,000	21,000
ZA.PS.2016.03	TB Vaccines Development for prevention/ recurrence, TB biomarker discovery& Therapeutic vaccines	Tuberculosis	RIA	South Africa; Zambia; Zimbabwe; Mozambique; Madagascar; Uganda; Kenya	36	7,100,000	2,366,667
ZM.PS.2016.1	Leprosy case finding through existing and new diagnostics	NIDs	RIA	Zambia	36	1,500,000	500,000
ZM.PS.2016.2	Phase III clinical trial to assess the safety and efficacy of dolutegravir in treatment of HIV infection in Zambia	HIV/AIDS	RIA	Zambia	30	720,000	144,000
ZM.PS.2016.3	Safety and efficacy of DSM265 in naïve travellers from South to North of Zambia	Malaria	RIA	Zambia	36	432,000	144,000

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2016 (€)
ZM.PS.2016.4	Optimizing malaria prevention among African HIV infected pregnant women: safety and efficacy of DHA-PPQ as Intermittent Preventive Treatment of malaria in HIV-infected pregnant women on daily cotrimoxazole prophylaxis	HIV/AIDS	RIA	Zambia	60	720,000	144,000
ZM.PS.2016.5	Evaluation of 5 Host-Directed Therapies as adjunct treatment for tuberculosis	TB	RIA	Zambia	60	960,000	192,000
Sub-Total African PSs						**23,337,559**	**7,604,486**
Grand Total European + African PS						**185,131,787**	**45,690,261**

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 2016 the indicative budget for administrative costs is as follows:

Table 17: Indicative budget for the administrative costs of the EDCTP Association for the implementation of the EDCTP2 programme in 2016

Description	Note	EU	PSs and TPs	Total
Personnel		4,094,570		4,094,570
Missions	1	217,000	479,000	696,000
Consumables and supplies	2	219,000		219,000
Service contracts (including non-recoverable taxes)	3	526,998		526,998
Total		**5,057,568**	**479,000**	**5,536,568**

Notes to the administrative budget summary

1. Missions: the costs budgeted under this category excludes 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 EDCTP offices in The Hague and Cape Town), and other hosting costs.

Table 18: Projected staff headcount by functional area in 2016

Functional area	Headcount
Senior Management (Directors)	4
Finance	2
Grants Financial Management	5
General Administration (IT, Legal, HR, Travel and Admin)	6
Operations	10
North-North Networking	4
South-South Networking	1
Communications and programme support	4
Total	**36**

6. General Annexes[35]

6.1 List of countries eligible for funding

Legal entities established in the following countries and territories will be eligible to receive funding through EDCTP2 grants[36]:

- The Member States of the European Union, including their overseas departments: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK;

- The Overseas Countries and Territories (OCT) linked to the EU Member States[37]: Anguilla, Aruba, Bermuda, Bonaire, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, French Southern and Antarctic Territories, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, South Georgia and the South Sandwich Islands, Turks and Caicos Islands, Wallis and Futuna;

- The associated countries (AC): the latest information on which countries are associated or in the process of association to Horizon 2020 can be found in the online manual[38];
  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, Gabon, Gambia, Ghana, Guinea, Guinea-Buissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

International European interest organisations[39] will also be eligible to receive funding from the EDCTP2 programme.

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

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

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and an international organisation or a third country[40]

- When the EDCTP Association deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme

- For Prizes, any legal entity, regardless of its place of establishment, or international organisation may receive funding[41].

6.2 Standard admissibility conditions and related requirements

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

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

a. Submitted in the electronic submission system of EDCTP before the deadline given in the call conditions or rules of contest;

b. Readable, accessible and printable.

2. **Incomplete** proposals/applications may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting documents specified in the call/contest.

3. The following supporting information will be required to determine the **operational capacity** for 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).

4. Grant proposals must 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.

5. **Word limits** will apply to proposals/applications. The limits will be clearly set out in the electronic submission system of EDCTP. 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
Workplan	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**

6.3 Standard eligibility conditions

All proposals must comply with the eligibility conditions set out in Rules for Participation of Horizon 2020 Regulation No.1290/2013 and any derogations to these as specified in the EDCTP2 Basic Act.

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 set out in the table below, depending on the type of action:

Table 19: Standard eligibility criteria per type of action

Type of Action	Eligibility conditions for participation[42,43,44]
Research & Innovation Action (RIA)	At least three legal entities. Two of the legal entities shall be established in two different Participating States (European partner states)* and one of the legal entities must be established in a sub-Saharan African country (listed in section 6.1).All three legal entities shall be independent of each other.
Coordination & Support Action (CSA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Training & Mobility Action (TMA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Prizes	See conditions for participation in the Rules of Contest.

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

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

6.4 Types of Action: specific provisions and funding rates[45,46]

6.4.1 Research & Innovation Actions (RIAs)

Description: Action 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[47].

In the EDCTP2 programme these are actions primarily consisting of clinical research activities and clinical trials in partnership with sub-Saharan Africa aiming at increasing 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[48].

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 EDCTP-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 primarily consisting 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 sections 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 EDCTP2 activities may include national programme activities of Participating States that are not funded by the EDCTP2-IS (i.e. the EDCTP Association), including activities undertaken by public or private not-for-profit research organisations. Those activities included as so-called Participating and Partner States Initiated Activities (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 VI of the Financial Regulation No 966/2012 and in the Rules for Participation of Horizon 2020 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 Participating States have agreed to the common principles outlined below[49]:

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 EDCTP2-IS, a Participating State, 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[50].

- Fundamental ethical principles and in particularly those related to the conduct of human clinical trials, including the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, the World Medical Association's Declaration of Helsinki of 2008 and the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), should be adhered to and enforced, both during 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]

6.6.1.1 Objectives pursued

The objectives of the prize are to:

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

6.6.1.2 Expected results

- [insert text from work plan].

6.6.2 Prize Amount

As specified in this work plan in chapter 3:

- Prize amount [insert amount] EUR.

6.6.3 Deadlines and Admissibility

Deadlines	
Opening of the submission:	dd Month yyyy
Closing date for submission:	dd Month yyyy at hh:mm:ss CET[51]

Applications must be normally submitted by the (lead) contestant 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

6.6.4 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, regardless of place of establishment]. [OPTION 2 if further specific eligibility criteria are provided in the work plan/call: The contest is open to [insert eligibility criteria from WP/call].]

Please note however that special rules apply for Israeli entities[52] and for Crimean legal persons and that entities from non-EU Member States that are covered by Council sanctions are not eligible to participate[53] (see section 6.3).

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

6.6.5 Exclusion criteria

Contestants will be excluded if they (or for points (a)(b) a natural or legal person that assumes unlimited liability for the debts of the contestant; or for points (c)(d)(e)(f) a natural person who is a member of the administrative, management or supervisory body of the contestant, or who has powers of representation, decision or control with regard to that contestant)[54] are in one of the following situations:

a. it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations;

b. it has been established by a final judgement or a final administrative decision that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the authorising officer is located or those of the country of the performance of the contract;

c. it has been established by a final judgement or a final administrative decision that the applicant is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the applicant belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:
(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract, a grant agreement or a grant decision;
(ii) entering into agreement with other persons with the aim of distorting competition;
(iii) violating intellectual property rights;
(iv) attempting to influence the decision-making process of the [Commission] [Agency] during the award procedure;
(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

d. it has been established by a final judgement that the applicant is guilty of any of the following
(i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;
(ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the authorising officer is located, the country in which the applicant is established or the country of the performance of the contract;
(iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
(iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
(v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
(vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

e. it has shown significant deficiencies in complying with the main obligations in the performance of a contract, a grant agreement or a grant decision financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;

f. it has been established by a final judgment or final administrative decision that the applicant has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;

g. for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to:
(i) facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;
(ii) non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;
(iii) decisions of the ECB, the EIB, the European Investment Fund or international organisations;
(iv) decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law.
(v) decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

Contestants will also be excluded if they misrepresent the information required as a condition for participating in the procedure or fail to supply that information.

However contestants will not be excluded where:

a. they have taken remedial measures[55], thus demonstrating their reliability. This point shall not apply in the case referred to in point (d) above;

b. such an exclusion would be disproportionate[56].

Evidence upon request: Whenever requested by EDCTP and where this is necessary to ensure the proper conduct of the procedure, the contestant, as well as the entity on whose capacity the contestant intends to rely, shall provide appropriate evidence that the contestant or a natural or legal person that assumes unlimited liability for the debts of the contestant; a natural person who is a member of the administrative, management or supervisory body of the contestant, or who has powers of representation, decision or control with regard to that contestant is not in one of the exclusion situations referred to above.

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

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

6.6.7 Documents

The mandatory supporting documents are set out in the application form. Contestants may be asked at a later stage for further documents (for legal entity validation, bank account validation, ethics review, declaration of honour on exclusion grounds, etc.

6.6.8 Procedure

Applications will be evaluated by an independent expert jury, the 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, the EDCTP2 Association will decide on the award of the prize.

All contestants will be informed. 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 contestants will be informed [insert indicative date, e.g. at the end of 2016].

6.6.9 Other Conditions

6.6.9.1 Liability

The EDCTP Association shall not be held liable for any damage caused or sustained by any of the participants, including any damage caused to third parties as a consequence of or during the implementation of the activities related to the contest.

6.6.9.2 Applicable law and competent jurisdiction

The contest is governed by the applicable Union law complemented, where necessary, by Belgium law. The competent national court of the Netherlands shall have sole jurisdiction to hear any dispute between the EDCTP Association and any participant concerning the interpretation, application or validity of the rules of this contest, if such dispute cannot be settled amicably.

For participants that are International organisations such disputes with the EDCTP Association relating to the contest must - if they cannot be settled amicably - be referred to arbitration.

The Permanent Court of Arbitration optional Rules for Arbitration involving International Organisations and States, in force at the date of entry into force of the Contest, will apply.

6.6.9.3 Payment arrangements

[OPTION 1 by default: The prize money (EUR [insert amount]) will be paid 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]]

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

Publicity by the winner(s): The winner(s) must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

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

a. display the EDCTP logo and EU emblem;

b. include the following text: "[name of prize winner] has been awarded the [name of the prize] which is part of the EDCTP2 programme supported by the European Union"; and

c. when displayed together with another logo, the EDCTP logo and EU emblem must have appropriate prominence.

For the purposes of its obligations, the winner(s) of the prize may use the EDCTP 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 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 publishing 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. The winner(s) may request the EDCTP Association to waive such publication if disclosure risks threatening its security and safety or harm 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.

6.6.9.5 Dissemination and exploitation of results

The winner(s) must comply with the obligations set out in Title III of the Rules for Participation Regulation of Horizon 2020 No 1290/2013[57] *[*and the following additional *[*dissemination*]* *[*and*]* *[*exploitation] obligations:

- [insert additional obligation from work programme/call];
- [same for further additional obligations]*]*.

6.6.9.6 Processing of personal data

Processing of personal data by the EDCTP Association:

Registration and submission of application shall be made in writing, which implies by letter or by electronic means (as specified in the rules of the contest), provided that they are non-discriminatory in nature and ensure integrity, confidentiality and protection of personal data.

The EDCTP Association complies with the provisions of the "Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)", dated 6 July 2000, which Act is based on Directive nr. 95/46/EG (PbEG L 281) and adapted to the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD). Registration with EDCTPgrants and grant proposal 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. Data may be used to compile lists, including project details, of EDCTP grants, which will be made publicly available. By submitting the application, the participants in the project give the EDCTP Association their consent to do so.

Processing of personal data by the European Commission: Any personal data used by the European Commission will be processed in compliance with EU Regulation No 45/2001 and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Commission.

Contestants may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the data controller of the EDCTP Association, via the contact person announced in the rules of the contest or to the data controller of the European Commission, via the contact point indicated in the 'service specific privacy statement(s) (SSPS)' that are published on the Commission websites. Please send in addition a scanned copy of your letter to the email address announced in the rules of the contest.

Contestants may, at any time, enquire or make a complaint about the processing of their personal data to the EDCTP Data Protection Supervisor or the European Data Protection Supervisor.

The winner(s) consent that the EDCTP Association and the European Commission are authorised to publish, in whatever form and on or by whatever medium, the following information:

- The name of winner(s)
- Member State of origin (address or NUTS 2 region)
- The general purpose of the activities of the winner(s) in relation to the award of the prize, in the form of the summary provided by the winner(s)
- The amount of the prize awarded.

Processing of personal data by the contestants: The contestants must process personal data in compliance with applicable EU and national law on data protection (including authorisations or notification requirements). The contestants may grant their personnel access only to data that is strictly necessary for the award, implementation or follow-up of the prize.

The contestants must inform the personnel whose personal data are collected and processed by the EDCTP Association and the European Commission. For this purpose, they must provide them with the contact details of the contact person announced in the rules of the contest, before transmitting their data to the EDCTP Association or the European Commission.

6.6.9.7 Ethics

The activities must be carried out in compliance with:

a. ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[58] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct)

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

The contestants 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)

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[59].

6.6.9.8 Conflict of interests

The contestants 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.

6.6.9.9 Liability for damages

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

The EDCTP Association cannot be held liable for any damage caused by any of the contestants, as a consequence of activities linked to the prize.

6.6.9.10 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.

6.6.9.11 Withdrawal of the prize — Recovery of undue amounts

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

a. false information or fraud or corruption was used to obtain the prize

b. the winner was not eligible or should have been excluded.

6.6.9.12 Contact

For more information, please see the EDCTP website at [insert link to prize contest call/notification/website].

In case of questions, please contact [insert functional mailbox].

6.7 Evaluation rules

Selection criteria

1. Financial capacity: In line with the EU's Financial Regulation No 966/2012 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 the participants have operational capacity to carry out the proposed work, based on the competence and experience of the individual participant(s).

3. For prizes, neither financial capacity nor operational capacity is subject to evaluation.

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 type 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 1: Award criteria per type of EU-funded actions

	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 and the call topic description.** **Importance, relevance/pertinence and clarity of the objectives.** **Soundness of the concept and credibility of the proposed approach/methodology.**	**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 for the field.**	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 Action (RIA)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) 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**	**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, 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 where relevant.	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 action (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), and to manage research data where relevant. Sustainability of capacity beyond the end of the grant, where relevant. Contribution to networking, where relevant.	Quality of the leadership and a clear and effective governance structure.
Training & Mobility Action (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.	Contribution of the fellowship to the fellow's clinical research skills and career development. 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, and, where relevant, to manage clinical data. Sustainability and retention of capacity post-award.	Suitability of the fellow's home 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. 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. 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 the EDCTP-TDR Clinical research and development fellowships all three evaluation criteria will be applied in both stages and 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, an arithmetic average (mean value) or median of the individual scores may be taken as the consensus score. The consensus report may consist of a collation of the individual evaluation reports or extracts from them. As part of the evaluation, a review committee may be convened to reach consensus on the applications proceeding to the second stage. For second-stage proposals as well as for single-stage evaluation procedures, unless otherwise indicated in the call text, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure).

- 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 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.
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; leverage of funding from third parties; relative number of sub-Saharan African countries involved; quality of the networking activities.

If a distinction still cannot be made, the EDCTP 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.

c. The method described in point (b) 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). As part of the evaluation by independent experts, the EDCTP 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.

3. 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, standardised feedback is provided to all coordinators, but the first stage ESR is only sent after the second stage evaluation.

4. 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.

The final figures may vary by up to 20% compared to those indicated in this Work Plan, for the following budgeted activities:

- Total expenditure for calls (up to 20% of the total expenditure for each call);
- Repartition of call budgets within a call (up to 20% of the total expenditure of the call);
- Evaluation and monitoring (up to 20% of the total expenditure for all these activities);
- Other individual actions not implemented through calls for proposals (up to 20% for each one).

Changes within these limits shall not be considered to be substantial within the meaning of Article 94(4) of Delegated Regulation (EU, Euratom) No 1268/2012.

6.9 Actions involving financial support to third parties[60]

Where a topic allows for grant proposals which foresee a financial support to third parties (in accordance with Article 137 of the Financial Regulation No 966/2012), the proposal must clearly detail the objectives and the results to be obtained and include at least the following elements:

- A fixed and exhaustive list of the different types of activities for which a third party may receive financial support,
- The definition of the persons or categories of persons which may receive financial support,
- The criteria for awarding financial support,
- The criteria for calculating the exact amount of the financial support,
- The maximum amount to be granted to each third party (may not exceed EUR 60 000 for each third party unless it is necessary to achieve the objectives of the action) and the criteria for determining it.

Projects must publish widely their open calls and adhere to Horizon 2020 standards with respect to transparency, equal treatment, conflict of interest and confidentiality. All calls for third parties must be published on the EDCTP2 website and linked with the Horizon 2020 Participants Portal, and on the projects' own web site. The calls must remain open for at least three months. If call deadlines are changed this must immediately be published on the call page on the participant's portal and all registered applicants must be informed of the change.

The calls must have a clear European dimension – either by carrying out cross border experimentation or in other ways expanding the impact of local experiments to European scale.

The financial support may also take the form of a prize awarded following a contest organised by the beneficiary.

In this case, proposals must clearly detail at least the following elements:

- The conditions for participation;
- The award criteria;
- The amount of the prize;
- The payment arrangements.

Further boundary conditions regarding the above listed elements or other elements may be laid down in the relevant call allowing a financial support to third parties.

The grant beneficiary must ensure that recipients of the financial support allow the EDCTP Association, the European Commission, the European Anti-fraud Office and the Court of Auditors to exercise their powers of control, on documents, information, even stored on electronic media, or on the final recipient's premises.

6.10 Co-labelling requirements

All participants to activities funded by the EDCTP Association 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 logo should also be included. For funding to PDPs the following wording should be used:

"[Name of PDP] is part of the EDCPT2 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 EDCPT2 programme supported by the European Union".

6.11 Conditions relating to open data

Grant beneficiaries under this work plan will engage in research data sharing, according to Article 29.3 of the Horizon 2020 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.

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. 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. It needs however to be noted that there is currently no bilateral agreement between the EU and Switzerland that supports the status of "Participating State" for Switzerland, and thus Switzerland has to be regarded as Third Country. Also 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.
4. Official registration No 60471700, Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands, VAT number 853925653.
5. So far, the following 14 African countries have joined the EDCTP Association as members: Burkina Faso, Cameroon, Congo, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, 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.
6. Since the EDCTP 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 3).
7. 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
8. 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.
9. 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); echinococcosise; foodborne trematodiases; lymphatic filariasis; 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.
10. 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.
11. EDCTP2 basic act, Annexes I and II.
12. EDCTP2 basic act, Article 6.4.
13. An action (project) supported with an EDCTP2 grant can involve one or more activities that fit with the scope of the type of action.
14. http://www.edctp.org/web/app/uploads/2015/03/EDCTP_Strategic_Business_Plan_EDCTP2.pdf
15. EDCTP2 stakeholder meeting reports: http://www.edctp.org/stay-up-to-date/meeting-reports/.
16. For the purpose of this call, PRDs include: HIV/AIDS, malaria, tuberculosis, and also 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; 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 yellow fever. Ebola Virus Disease vaccine development is specifically excluded from this call since it has already been extensively funded by other parts of the Horizon 2020 programme.
17. All stages of clinical trials can be supported, from phase I to IV, including implementation research on the optimisation of health services. For the purpose of this Call for Proposals, 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; 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 yellow fever. Ebola Virus Disease is specifically excluded from this call since it has already been extensively funded by other parts of the Horizon 2020 programme.
18. 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."
19. 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).
20. Countries as defined by the World Bank: low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of $1,045 or less in 2013; middle-income economies are those with a GNI per capita of more than $1,045 but less than $12,746 in 2013; high-income economies are those with a GNI per capita of $12,746 or more in 2013.

21. http://www.who.int/tdr/capacity/strengthening/career_development/en/.
22. 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); echinococcosise; foodborne trematodiases; lymphatic filariasis; 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.
23. For WHO/TDR, "neglected infectious diseases (NIDs)" include: dengue/severe denque; rabies; chagas disease; Human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; buruli ulcer; leprosy (Hansen disease); trachoma; yaws.
24. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support researchers and key members of clinical trial research teams from sub-Saharan Africa to acquire specific skills in clinical research and development. It is in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c and 1d) and contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 basic act, Annex I, objectives 2b and 2d).
25. 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
26. For the purpose of this Call for Proposals, 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; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.
27. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support senior fellows in sub-Saharan Africa in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 basic act, Annex I, objectives 2b).
28. 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
29. For the purpose of this Call for Proposals, 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; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.
30. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support junior fellows in sub-Saharan Africa in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c). It contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards, and for extended cooperation with private partners (EDCTP2 basic act, Annex I, objectives 2b).
31. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 basic act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa
32. For details on EDCTP's procurement policies and procedures please consult its manual available at: http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf
33. In line with Article 11.2 of Regulation (EU) No 1290/2013 on the Rules for Participation of Horizon 2020, this action does not fall under the scope of an EDCTP2 call for proposal and will not be subject of a call for proposals. The action will be implemented by the African Academy of Sciences (AAS) who hosts the secretariat of the International Financial Governance Consortium (IFGC). The IFGC was initiated and launched in 2012 by EDCTP, UK's Medical Research Council (MRC) and the Wellcome Trust with the aim to establish Good Financial Grant Practice (GFGP) in developing countries, in particular in sub-Saharan Africa. EDCTP will award a grant to the African Academy of Sciences (AAS) for the development of a standardised assessment tool (SMAT) for Good Financial Grant Practice (GFGP). The EDCTP grant will complement the contributions provided by the UK MRC, Wellcome Trust and other funders for the development of the SMAT.
34. ESSENCE on Health Research is an international collaboration between research funders, development agencies, philanthropists and multilateral initiatives. It aims to harmonize the way that research is funded in order to improve the impact of investments and enhance both research capacity and the conditions for doing research worldwide.

35. The Supporting Information provided in this chapter is copied from the General Annexes of the Work Programme 2016-2017 of Horizon 2020, 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.
36. 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/cfsp/sanctions/consol-list_en.htm.
37. 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.
38. http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/international-cooperation_en.htm. As of 1 January 2016, the following countries are Associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland (partial association, see online manual34), Faroe Islands, Ukraine, Tunisia, Georgia.
39. These are international organisations, the majority of whose members are EU Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.
40. No agreements or arrangements of this kind are currently existing.
41. 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/cfsp/sanctions/consol-list_en.htm.
42. Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in EU-funded activities. 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.
43. 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 137 of the EU's Financial Regulation No 966/2012).
44. 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 ction 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 137 of the EU's Financial Regulation. Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this work plan will be revised.
45. Eligible costs for all types of action are in accordance with the EU's Financial Regulation No 966/2012 and the Rules for Participation of Horizon 2020 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 research and innovation 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).
46. Participants may ask for a lower rate.
47. Excerpt from the General Annexes of the Horizon 2020 work programme 2015-2016.
48. Excerpt from the General Annexes of the Horizon 2020 work programme 2015-2016 (see also Rules for Participation of Horizon 2020, Article 2, point 7).
49. Annex 5 to the delegation agreement concluded between the European Commission and the EDCTP Association ("the EDCTP"), which is the EDCTP2-IS, on 23 December 2014.
50. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
51. Central European Time = Brussels local time.
52. See Commission 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 (OJ C 205 of 19.7.2013, pp. 9-11).
53. For the list of persons, groups and entities subject to EU financial sanctions, see http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.
54. See Article 106 of Regulation (EU, EURATOM) 2015/1929 of the European Parliament and of the Council of 28 October 2015 amending Regulation (EU, EURATOM) No 966/2012 on the financial rules applicable to the general budget of the Union. (OJ L 286, 30.10.2015, p.1).
55. The measures which remedy the exclusion situation may include, in particular: measures to identify the origin of the situations giving rise to exclusion and concrete technical, organisational and personnel measures within the relevant business area of the economic operator, appropriate to correct the conduct and prevent its further occurrence; proof that the economic operator has undertaken measures to compensate or redress the damage or harm caused to the Union's financial interests by the underlying facts giving rise to the exclusion situation; proof that the economic operator has paid or secured the payment of any fine imposed by the competent authority or of any taxes or social security contributions.
56. In particular taking into account the seriousness of the situation, including the impact on the Union's financial interests and image, the time which has elapsed since the relevant conduct, its duration and its recurrence, the intention or degree of negligence, the limited amount at stake for point (b) above or any other mitigating circumstances, such as the degree of collaboration of the economic operator with the relevant competent authority and its contribution to the investigation as recognised by the contracting authority, or the disclosure of the exclusion situation by means of the declaration.
57. 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).
58. The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf
59. Declarations of the Commission (Framework Programme), OJ C373, 20.12.2013, p. 2
60. This is not foreseen in the 2016 work plan.

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Colophon

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