



EDCTP

European & Developing Countries
Clinical Trials Partnership

EDCTP2 WORK PLAN 2017

Responsible person: Dr Michael Makanga, EDCTP Executive Director
Important notice: This annual work plan covers 2017 and describes planned activities under the EDCTP2 programme in 2017.

This document has been approved by the EDCTP Association General Assembly on 23 May 2017. The European Commission approved it on 3 July 2017 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 5 July 2017.

Please refer to the [2016 Strategic Research Agenda](#)



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1 Introduction

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

The EDCTP2 programme will run over a ten-year period from 2014 to 2024, and the European Union (EU) has decided to support the programme with a financial contribution of up to € 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 State³ to contribute to the financing of the EDCTP2 programme as referred to in Article 3.1 (point e) of the EDCTP2 Basic Act.²

The EDCTP Association (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}

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).

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 objectives⁸:

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.

The drive to achieve the Millennium Development Goals provided important impetus for the creation of EDCTP. Equally, the EDCTP2 programme shall contribute to the United Nations' Sustainable Development Goals (SDGs)^{10, 11} and is a major commitment of its 28 Partner States and the European Union to that end. While the promotion of health is only one of the 17 goals (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'), the achievement of the other SDGs is affected by or depends significantly from good health of people, including vulnerable and neglected ones. Improved health and its attendant economic benefits will contribute to multiple social and economic goals.

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); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.

¹⁰ <http://www.un.org/millenniumgoals/>

¹¹ <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>

1.2 Activities of the EDCTP2 programme

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

EU-funded actions are evaluated, selected and funded in line with the Rules for Participation (RfP)¹² 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.^{13,14}

The EDCTP2 programme supports clinical trials and related activities on PRDs and capacity development for clinical trials and related research in sub-Saharan Africa. All phases of clinical trials (phases I to IV) for new or improved medical interventions, as well as advanced testing and field validation of new diagnostic tools can be supported under the EDCTP2 programme. Similarly, EDCTP2 supports capacity development activities to strengthen the enabling environment for conducting clinical trials in sub-Saharan Africa in compliance with fundamental ethical principles and relevant national, Union and international legislation. Moreover, the EDCTP2 programme promotes networking, coordination, alignment, collaboration and integration of national research programmes and activities on PRDs among the PSs, both at scientific, management and financial level.^{13,15}

The activities of the EDCTP2 programme are supported along three distinct types of actions¹⁶: 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.

¹² 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.

¹³ EDCTP2 basic act, Annexes I and II.

¹⁴ EDCTP2 basic act, Article 6.4.

¹⁵ Decision 556/2014/EU requires that clinical trials are conducted "in compliance with fundamental ethical principles and relevant national, Union and international legislation". In particular, this includes Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which calls for "data from a clinical trial to only be submitted in support of a clinical trial application if that clinical trial has been recorded in a publicly accessible and free of charge database which is a primary or partner registry of, or a data provider to, the international clinical trials registry platform of the World Health Organization (WHO ICTRP)". Furthermore, the Union's Horizon 2020 programme provides for mandatory open access to data under Article 29 of its model Grant Agreement unless in specific instances where an opt-out is considered necessary. Therefore, EDCTP requires (i) the registration of clinical trials prior to the enrolment of the first subject in a registry complying with WHO's international agreed standards (www.who.int/ictprp) and (ii) in line with the WHO 'Joint statement on public disclosure of results from clinical trials' the disclosure of the study results by posting to the results section of the registry within 12 months from primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure) and by journal publication within 24 months.

¹⁶ An action (project) supported with an EDCTP2 grant can involve one or more activities that fit with the scope of the type of action.

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.¹⁷

The present EDCTP2 annual work plan 2017 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 also included two thematic stakeholder meetings (on diarrhoeal diseases and lower respiratory infections, respectively) resulting in specific recommendations for the EDCTP2 programme.¹⁸ 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 2017 provides information about EU-funded Calls for Proposals in 2017 (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 2017 also contains an overview of non-EU funded PSiAs in 2017 (Chapter 3). The PSiAs in the current EDCTP2 annual work plan are all funded and implemented directly by one or more PSs. They are major contributions (in-kind) of the PS to the EDCTP2 programme and constitute an integral part of the EDCTP2 programme.

In accordance with the EDCTP2 basic act, the draft EDCTP2 annual work plan 2017 was subject to an external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. This evaluation was organised by the European Commission services and involved an international peer review panel composed of four independent senior research managers.

EDCTP acknowledges financial contributions for the implementation of the EDCTP2 programme and its 2017 calls from the European Union and the governments of the following countries: Germany, the Netherlands, Portugal, Sweden and the United Kingdom. These are summarised in budget overview table 2, section 1.4.

EDCTP also acknowledges contributions for the implementation of the EDCTP2 programme and its 2017 calls from the following organisations: the African Research Excellence Fund (AREF); Calouste Gulbenkian Foundation; GlaxoSmithKline (GSK); Leprosy Research Initiative (LRI); Mundo Sano

¹⁷ <http://www.edctp.org/see-work/strategy/>

¹⁸ EDCTP2 stakeholder meeting reports: <http://www.edctp.org/stay-up-to-date/meeting-reports/>.

Foundation; the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR); as well as from members of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

1.4 Budget overview tables

Table 1. Overview of budgeted costs and contributions to activities of the EDCTP2 programme in 2017 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)/Third Countries (TCs)

Activities		Budgeted Contributions (in €)			Budgeted Costs (in €)
		EU*	PSs**	TPs/TCs***	TOTAL
EU-funded activities	Calls for Proposals implemented by the EDCTP Association	138,700,260	11,270,103	6,565,000	156,535,363
	Other Activities implemented by the EDCTP Association	3,130,000	0	0	3,130,000
	Administrative costs of the EDCTP Association	5,200,840	329,897	0	5,530,737
Sub-Total Implementation		147,031,100	11,600,000	6,565,000	165,196,100
Non-EU funded activities	PSIAs implemented by the PSs	0	97,243,489	0	97,243,489
Total Budget		147,031,100	108,843,489	6,565,000	262,439,589

*Details in table 16

**Details in table 2

***Details in table 3

Table 2. Detailed overview of budgeted contributions to activities of the EDCTP2 programme in 2017 by the European Union (EU), and European and African Partner States (PSs)

	Budgeted contributions (in €)			
	Cash*	In-kind/PSIAs**	Total in 2017	Total 2014-2017
European Union (EU)				
European Commission (EC)	147,031,100	0	147,031,100	361,830,093
Sub-Total EU	147,031,100	0	147,031,100	361,830,093
Participating States*** (European Partner States)				
Austria (AT)	0	0	0	3,310,000
Denmark (DK)	0	360,992	360,992	7,505,992
Finland (FI)	0	0	0	1,587,500
France (FR)	0	25,070,087	25,070,087	59,985,087
Germany (DE)	1,000,000	2,250,000	3,250,000	93,736,056
Ireland (IE)	0	0	0	20,132,546
Italy (IT)	0	700,000	700,000	2,925,000
Luxembourg (LU)	0	0	0	2,300,000

Netherlands (NL)	100,000	0	100,000	17,248,918
Norway (NO)	0	3,073,908	3,073,908	20,582,610
Portugal (PT)	200,000	0	200,000	1,980,627
Spain (ES)	0	0	0	6,395,317
Sweden (SE)	2,500,000	13,403,159	15,903,159	61,058,243
United Kingdom UK)	7,800,000	51,022,900	58,822,900	374,955,400
Sub-Total European PSs	11,600,000	95,881,046	107,481,046	673,703,296
African Partner States				
Burkina Faso (BF)	0	200,000	200,000	525,753
Cameroon (CM)	0	0	0	1,030,839
Congo (CG)	0	0	0	309,556
Gabon (GB)	0	561,552	561,552	812,330
The Gambia (GM)	0	0	0	682,000
Ghana (GH)	0	0	0	2,984,227
Mali (ML)	0	0	0	1,136,200
Mozambique (MZ)	0	0	0	531,358
Niger (NE)	0	0	0	172,267
Senegal (SN)	0	0	0	290,000
South Africa (ZA)	0	530,000	530,000	26,587,846
Tanzania (TZ)	0	0	0	558,300
Uganda (UG)	0	70,891	70,891	713,751
Zambia (ZM)	0	0	0	8,973,000
Sub-Total African PSs	0	1,362,443	1,362,443	45,307,427
Sub-Total European + African PSs	11,600,000	97,243,489	108,843,489	719,010,723
Grand Total	158,631,100	97,243,489	255,874,589	1,080,840,816

* Financial contributions from PSs to EDCTP2 calls, other actions and administrative costs 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 2017, excluding direct financial contributions from PSs (i.e. managed by PSs) to EDCTP2 funded projects

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

Table 3. Overview of budgeted contributions to activities of the EDCTP2 programme in 2017 by Third Parties (TPs) and Third Countries (TCs)

Third Parties / Third Countries	Budgeted contributions by TPs/TCs (in €)			
	Cash	In-kind	Total	Cumulative total for 2014-2017*
AREF	0	400,000	400,000	400,000
Calouste Gulbenkian Foundation	265,000	0	265,000	465,000
EFPIA members	0	500,000	500,000	1,550,000
Foundation Mundo Sano	2,000,000	0	2,000,000	2,000,000
GSK	0	1,500,000	1,500,000	1,500,000
LRI	400,000	0	400,000	400,000

Switzerland	0	0	0	500,000
TDR	0	1,500,000	1,500,000	5,000,000
Grand total	2,665,000	3,900,000	6,565,000	11,815,000

**Including budgeted contributions of TCs and TPs included in the 2015 and 2016 work plans*

2 EU-funded Calls for Proposals

2.1 Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2017:

2.1.1 Treatment innovations for poverty-related diseases

Challenge:

Poverty-related diseases (PRDs) represent a major obstacle to the sustainable development of sub-Saharan Africa. There is limited availability of effective, safe, suitable and affordable products to diagnose and treat PRDs in sub-Saharan Africa, and the number of new chemical entities that are registered remains very low. There is therefore an urgent need to accelerate the development of new and improved products through the clinical development pipeline.

Scope:

The purpose of this Call for Proposals is to provide funding for the clinical evaluation and development of new and innovative drug candidates for HIV/AIDS, malaria, tuberculosis, diarrhoeal infections or lower respiratory infections, including co-infections.

Proposals should include at least one clinical trial (phase I-III) in sub-Saharan Africa to evaluate the safety, dosage, pharmacokinetics, pharmacodynamics, and/or efficacy of a new candidate drug product. The candidate drug should consist of active substance(s) or biologicals that have not previously been authorised anywhere in a medicinal product. However, combination therapies are within the scope of this call insofar they contain at least one new active substance. Furthermore, re-purposed drugs and novel combinations thereof are also within the scope of this call, provided these have not previously been authorised for use against an infectious disease anywhere in the world.

The proposed clinical trial(s) must be conducted to ICH-GCP regulatory and ethical standards. The proposal should include a product development plan including clear go/no-go criteria as well as specific plans for the regulatory approval process, which should aim at obtaining a relevant market authorisation. Proposals must further outline the target product profile of the investigational product and describe how it fits within the global product development pipeline for the disease. Proposals that are in line with EDCTP's strategic research agenda¹⁹ are particularly encouraged.

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

Expected impact:

¹⁹ <http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf>

Projects funded under this Call for Proposals shall contribute towards the achievement of the United Nations' Sustainable Development Goal 3 (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'). Projects should lead to the advancement of drugs candidates through the development pipeline towards registration or WHO endorsement, leading to more effective clinical management of PRDs in sub-Saharan Africa.

Table 4. Supporting information for the Call for Proposals 'Treatment innovations for poverty-related diseases'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	3-5
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ²⁰
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.2 Targeting control and elimination of NIDs through clinical trials

Challenge:

Neglected Infectious Diseases (NIDs, also known as Neglected Tropical Diseases) are a diverse group of diseases that affect an estimated 1.2 billion people worldwide. These diseases disproportionately affect the world's poor, causing significant mortality and morbidity. Global investment into research and development of new products for NIDs is limited and there is an urgent need to develop new or improved products and to optimise the use of existing products in order to achieve disease elimination.

Scope:

The objective of this Call for Proposals is to provide funding for clinical trials to accelerate the development of new or improved therapeutics for NIDs²¹ in sub-Saharan Africa. Proposals that are in line with EDCTP's strategic research agenda²² are encouraged.

Proposals must include one or more clinical trial(s) (phases I to III) conducted in sub-Saharan Africa

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

²¹ For the purpose of this call, NIDs include: *Buruli ulcer*, cysticercosis/taeniasis, dengue, dracunculiasis, echinococcosis, foodborne trematodiasis, leprosy (Hansen disease), human African trypanosomiasis, leishmaniasis, lymphatic filariasis, mycetoma, onchocerciasis, rabies, schistosomiasis, soil-transmitted helminthiasis, trachoma, yaws.

²² <http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf>

to evaluate the safety and efficacy of new or improved drugs, drug regimens and formulations, including for prevention and post-exposure prophylaxis. Proposals should clearly describe the desired target product profile for the drug candidate(s) and describe how it contributes to the global product development pipeline for the disease. Full details of the product development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorization, and an access strategy that will allow patients in low-resource settings to access the final product.

Proposals focused exclusively on implementation of mass drug administration programmes or health systems strengthening are outside the scope of this Call.

EDCTP considers that proposals for activities of between 36 and 60 months duration and requesting funding of up to € 5 million would allow the specific challenges to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting another duration and/or funding.

Expected impact:

Projects funded under this Call for Proposals shall contribute towards the achievement of the United Nations' Sustainable Development Goal 3 (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'). Projects should lead to the advancement of candidate products along the product development pipeline.

Table 5. Supporting information for the Call for Proposals 'Targeting control and elimination of NIDs through clinical trials'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	4-6
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
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 RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ²³
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.

²³ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf

2.1.3 Targeting control and elimination of NIDs through product-focused implementation research

Challenge:

Neglected Infectious Diseases (NIDs, also known as Neglected Tropical Diseases) are a diverse group of diseases that affect an estimated 1.2 billion people worldwide. These diseases disproportionately affect the world's poor, causing significant mortality and morbidity. Global investment into research and development of new products for NIDs is limited and there is an urgent need to develop new or improved products and to optimise the use of existing products in order to achieve disease elimination.

Scope:

The objective of this Call for Proposals is to provide funding for product-focused post-registration implementation studies for NIDs²⁴ in sub-Saharan Africa. Proposals that are in line with EDCTP's strategic research agenda²⁵ are encouraged.

Proposals should focus on implementation research studies to translate medical interventions (diagnostics, drugs for treatment and prevention) of proven efficacy into routine care, or on improving population coverage and access to the intervention, retention in care and/or adherence to the intervention. Proposals including randomised controlled trials (RCTs) are encouraged, although other study designs and methodologies can be used, where the design is justified and appropriate to provide robust evidence to support policy changes.

Proposals should include detailed plans for uptake of research results in international, regional or national guidelines and/or obtaining World Health Organisation (WHO) endorsement for improved disease management upon successful completion of the project.

Proposals focused exclusively on implementation of mass drug administration programmes or health systems strengthening are outside the scope of this Call.

EDCTP considers that proposals for activities of between 24 and 48 months and requesting funding of up to € 3 million would allow the specific challenges to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting another duration and/or funding.

Expected impact:

Projects funded under this Call for Proposals shall contribute towards the achievement of the United Nations' Sustainable Development Goal 3 (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'). Projects should generate robust scientific evidence for the effectiveness and optimisation of existing drugs or diagnostics that can be translated into health policy and clinical practice in sub-Saharan Africa.

²⁴ For the purpose of this call, NIDs include: *Buruli ulcer*, *cysticercosis/taeniasis*, *dengue*, *dracunculiasis*, *echinococcosis*, *foodborne trematodiasis*, *leprosy (Hansen disease)*, *human African trypanosomiasis*, *leishmaniasis*, *lymphatic filariasis*, *mycetoma*, *onchocerciasis*, *rabies*, *schistosomiasis*, *soil-transmitted helminthiasis*, *trachoma*, *yaws*.

²⁵ <http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf>

Table 6. Supporting information for the Call for Proposals 'Targeting control and elimination of NIDs through product-focused implementation research'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	3-5
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
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 RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ²⁶
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.4 Strategic actions supporting large-scale clinical trials

Challenge:

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

Scope:

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

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

²⁶ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf.

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

The total cost of the large-scale clinical trial should not be less than € 10 million and ideally at least half the cost of the large-scale clinical trial should be supported by funders other than the EDCTP Association. EDCTP considers that proposals for a strategic action of between 36 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals with different total costs and /or a different duration. Proposals for strategic actions that address the priorities outlined in the EDCTP Strategic Research Agenda²⁷ and that address topics not covered in the scope of the other EDCTP2 calls for proposals launched in 2017 are particularly encouraged.

Expected impact:

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

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	2-4
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The standard award criteria, scoring, thresholds and weightings listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ²⁸
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.

²⁷ <http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf>

²⁸ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf

2.1.5 Clinical trials to reduce health inequities in pregnant women, newborns and children

Challenge:

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

Scope:

The objective of this call is to accelerate the adaption and/or optimisation of treatment and prevention products (excluding vaccines) for PRDs in sub-Saharan Africa for use in pregnant women, newborns and/or children. This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases and lower respiratory infections. Proposals that are in line with the priorities of EDCTP's strategic research agenda²⁹ are encouraged.

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

The proposal must include full details of the product development milestones including specific go/no-go criteria for the proposed clinical trial(s) as well as specific plans for the subsequent regulatory approval process; for trials involving children, this is ideally a paediatric investigation plan³⁰, which should aim at obtaining a relevant market authorisation, such as the Paediatric Use Marketing Authorisation (PUMA).

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

Expected impact:

Projects are expected to contribute to expanding the availability of medicines for PRDs for

²⁹ <http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf>

³⁰ http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000608.jsp&mid=WC0b01ac0580925b1b

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

Table 8. Supporting information for the Call for Proposals 'Clinical trials to reduce health inequities in pregnant women, newborns and children'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	5-10
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary) ³¹
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 2017:

2.2.1 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:

³¹ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf

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 Africa³². National collaborative activities involving NECs and Institutional Review Boards, and/or transnational collaborations involving regional networking activities between NECs or NRAs and other partners such as the African Medicines Regulatory Harmonisation Programme (AMRH)³³ 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 9. 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	8-10
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional

³² African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 10 RCOREs throughout Africa: <http://www.nepad.org/resource/understanding-role-regional-centres-regulatory-excellence-strengthening-medicines>

³³ <http://www.nepad.org/content/african-medicines-regulatory-harmonisation-armh-programs>

	<p>eligibility conditions apply to this call for proposals:</p> <ol style="list-style-type: none"> 1. Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries.³⁴ 2. The requested EDCTP contribution per action shall not exceed € 300,000.
Submission and evaluation procedure	<p>Single-stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p>
Evaluation rules	<p>The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used.</p>
Grant agreement	<p>General EDCTP2 grant agreement (mono-beneficiary³⁵ or multi-beneficiary³⁶)</p>
Consortium agreement	<p>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.</p>

2.2.2 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 clinical trial research 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.

³⁴ 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).

³⁵ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono_en.pdf

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

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 programme³⁷. 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 for each student³⁸. 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.

Applications for a Senior Fellowship must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. 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

³⁷ For the purpose of this call, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal diseases, lower respiratory tract infections, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.

³⁸ The Calouste Gulbenkian Foundation may support the EDCTP2 programme with a total contribution of up to € 265,000. This cash contribution is restricted in use by the EDCTP Association for funding students that participate in actions resulting from this Call for Proposals, which are legally established in Portuguese-speaking sub-Saharan African countries. The call evaluation and grant management is centrally managed by the EDCTP Association in line with the Rules for Participation of Horizon 2020.

out of or trained outside Africa by offering an opportunity to return to Africa and progress their career as independent research leaders.

Table 10. 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	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).³⁹ 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.³⁸ 3. The fellow must:³⁸ <ul style="list-style-type: none"> • 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 post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years’ research experience after the post-graduate qualification; • have a minimum of 5 first-author publications in international peer-reviewed journals; • not have been funded under this fellowship scheme before.⁴⁰ 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	<p>Single-stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of</p>

³⁹ Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of this Training & Mobility Action. It aims to support 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).

⁴⁰ 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

	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. ⁴¹
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.

2.2.3 EDCTP-GSK Senior Fellowships for co-morbidities between poverty-related diseases (PRDs)⁴² and non-communicable diseases (NCDs)⁴³ - Joint Call with GlaxoSmithKline (GSK)

Challenge:

There is a shortage of senior researchers and research mentors in sub-Saharan Africa with skills in the prevention, diagnosis and management of co-morbidities between poverty-related diseases (PRDs) and non-communicable diseases (NCD). 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.

Background:

Healthcare in Africa is facing a significant challenge from the double burden of non-communicable diseases (NCDs) on top of high rates of poverty-related diseases (PRDs). Often studied as two separate categories of disease, there is growing evidence for bi-directional relationships between PRD and NCD manifestation and progression, with a number of co-morbidities relevant to African healthcare identified to date. Examples include the inter-relationship between diabetes and tuberculosis; the link between Burkitt's lymphoma and malaria; the role of certain viral infections in tumorigenesis; and the potential increased risk of cardio-metabolic dysregulation reported for people living with HIV.

GSK and EDCTP are interested in implementing a Joint Call for Proposals to support clinical research and capacity development into the relationship between PRDs and NCDs in sub-Saharan

⁴¹ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

⁴² 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); Leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as yellow fever.

⁴³ For the purposes of this call, NCDs include: cancers, cardio-metabolic diseases, respiratory disorders and chronic kidney disease.

Africa. Both partners have indicated willingness to contribute an equal amount of cash funding to the initiative. The budget will be used to support a number of Training and Mobility Actions (TMAs) that will be selected through an open call for proposals. The maximum budget allocated to each action will be up to € 500,000.

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, at the discretion and under the management of each respective organisation. EDCTP will fund fellows employed by a research institution in any sub-Saharan African country, whereas GSK is focusing initially on a subset of sub-Saharan African countries and will fund fellows employed by a legal entity in Cameroon, Cote d'Ivoire, Ethiopia, Ghana, The Gambia, Kenya, Malawi, Nigeria, Uganda, Senegal, South Africa and Tanzania.

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 in sub-Saharan Africa in the area of prevention, therapeutic management and prognosis of PRD and NCD co-morbidities.

The objectives of the scheme are two-fold:

1. To support senior researchers to advance themselves as recognised research leaders in clinical trial research 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 the area of prevention, therapeutic management and prognosis of PRD and NCD co-morbidities. 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 for each student. 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 training and mentorship on clinical trials must ensure that: 1) studies are appropriately designed and good clinical practice (GCP) compliant, 2) interventional studies only use regionally appropriate medicines; 3) All sponsor responsibilities can be fulfilled by the host institution (applicant legal entity where the fellow is employed).

In particular, fellows who plan to conduct training and mentorship on clinical trials should focus on clinical research that incorporates a significant PRD and NCD component in line with disease burden in resource-constrained regions of Africa and represents regionally appropriate standard of

care. The studies should include one or more aspects of investigator-driven clinical research, clinical management and/or prevention and diagnosis of patients with PRD-NCD co-morbidities.

The following aspects in particular are out of scope for proposed work within this Call for Proposals: 1) Clinical studies involving GSK proprietary medicines and investigational products. 2) Clinical studies designed to test novel interventions using investigational, branded or proprietary drug products that do not represent regionally appropriate standard of care. Fellows should have a track record of publications in peer-reviewed journals in the area of prevention, therapeutic management, diagnostics and prognosis of PRD and NCD co-morbidities and show potential to become future research leaders working in sub-Saharan Africa.

Application for an EDCTP-GSK Senior Fellowship must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. 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:

Senior 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 11. Supporting information for the Joint Call for Proposals 'EDCTP-GSK Senior Fellowships for co-morbidities between PRDs and NCDs'

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	3-4 grants funded by EDCTP and 3-4 additional grants funded by GSK

Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).⁴⁴ 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.⁴³ 3. The fellow must:⁴³ <ul style="list-style-type: none"> • 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 post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years' research experience after the post-graduate qualification; • have a minimum of 5 first-author publications in international peer-reviewed journals; • not have been funded under this fellowship scheme before.⁴⁵ 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	<p>Single-stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p> <p>The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.</p>
Evaluation rules	<p>The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.</p>

⁴⁴ 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).

⁴⁵ 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.

Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships for EDCTP-funded fellows. ⁴⁶ GSK-funded fellows will be required to enter into agreements with GSK.
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.

2.2.4 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.⁴⁷

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 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 programme⁴⁸. 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

⁴⁶ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

⁴⁷ The Calouste Gulbenkian Foundation will support the EDCTP2 programme with a total contribution of up to € 265,000 to this Call for Proposals. This cash contribution is restricted in use by the EDCTP Association for funding participants in actions resulting from this Call for Proposals, which are legally established in Portuguese-speaking sub-Saharan African countries. The call evaluation and grant management is centrally managed by the EDCTP Association in line with the Rules for Participation of Horizon 2020.

⁴⁸ For the purpose of this call, 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 trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal diseases, lower respiratory tract infections, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.

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 a Career Development Fellowship must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. 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 12. Supporting information for the Call for Proposals 'Career Development Fellowships'

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	16-18
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals: <ol style="list-style-type: none"> 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).⁴⁹ 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.⁴⁸ 3. Fellows must:⁴⁸ <ul style="list-style-type: none"> • be resident of or be willing to relocate to a sub-Saharan African country; • be either a graduate in a subject relevant to the

⁴⁹ 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).

	<p>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;</p> <ul style="list-style-type: none"> • have at least one publication in an international peer-reviewed journal; • not have been funded under this fellowship scheme before.⁵⁰ <p>4. The requested EDCTP contribution per action shall not exceed € 150,000.</p> <p>5. The maximum fellowship duration shall be 36 months.</p>
Submission and evaluation procedure	<p>Single-stage application procedure.</p> <p>A full proposal must be submitted by the indicated deadline.</p> <p>An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p> <p>The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.</p>
Evaluation rules	<p>The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.</p>
Grant agreement	<p>General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships.⁵¹</p>
Supplementary agreement	<p>Applicant legal entities (host organisations) selected for funding from this Call for Proposals will be required to conclude an employment agreement with the fellow prior to the conclusion of the EDCTP2 grant agreement.</p>

2.2.5 EDCTP-AREF Preparatory Fellowships – Joint call with the Africa Research Excellence Fund (AREF)

Challenge:

Many aspiring African researchers lack the mentorship, intellectual challenge and rigour that well-funded established institutions in the North can offer to their early postdoctoral researchers. Africa accounts for 15-20% of the world's population and a disproportionately large share of disease burden, yet scientific publications by African researchers account for less than 2% of the total academic journal output. The challenge is therefore to enable African researchers to enhance their

⁵⁰ 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

⁵¹ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

competitiveness for international funding opportunities early in their careers while retaining them in Africa, working on Africa's health challenges and priorities.

Background:

Capacity strengthening needs for health research in Africa have been documented by EDCTP, the World Bank and others. Lack of funding and systematic career development for researchers are two significant gaps. In general, health research capacity building programmes in Africa and other low-income regions are more tailored to PhD candidates than to early-career postdoctoral scientists. Furthermore, international fellowship programmes typically focus on people showing exceptional talent and promise. The experience of global health research funders is that Africans are under-represented and less competitive in their funding schemes: their science may be promising but the framing of research questions; the research design; the proposed analyses and mentoring are often not well developed.

The Africa Research Excellence Fund (AREF) aims to bridge the critical gap early in the career path from research experience to research leadership. AREF is an independent charity, legally registered in the UK under the umbrella of the Medical Research Foundation. The Medical Research Foundation is a company limited by guarantee and a charity registered in UK whose registered office is at MRC Head office (Swindon), Polaris House, North Star Avenue, Swindon SN2 1FL.

Scope:

The purpose of the EDCTP-AREF Preparatory Fellowships is to enhance the competitiveness of up and coming post-doctoral African scientists and clinicians aspiring to win international /regional /national fellowships or grant support, such as the EDCTP Career Development Fellowships, through short-term placements at a host organisation in EU Members States, in countries associated to Horizon 2020 or in Sub-Saharan Africa which will be contracted by the home organisation to host the fellow.

The objectives of this call are to:

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

Application for an EDCTP-AREF Preparatory Fellowship must be submitted by an organisation with an established legal entity in sub-Saharan Africa ('the applicant legal entity') on behalf of the prospective fellow employed by that organisation. The Joint Call will include a joint evaluation by

independent experts selected by both EDCTP and AREF, and a 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.

The grants will be awarded to the applicant legal entity employing the fellow (the home organisation in sub-Saharan Africa) 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.

Successful applicants must use the funding for a 3 to 9 months placement at a host organisation legally established in an EU Member State, a country associated to Horizon 2020 or in a Sub-Saharan African country which will be contracted by the home organisation to host the fellow. The fellow will spend a re-entry period of up to 3-months at their home organisation, making a total training period of up to 12 months.⁵²

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

Expected Impact:

The Action will specifically:

1. Enhance the ability of fellows to design, plan and execute clinical biomedical and/or social science/ethics research proposals, and manage research relationships, within the scope of the EDCTP2 programme; and to generate competitive proposals into effective projects;
2. Promote and enhance competitiveness for the next tier of fellowships and grants, such as (but not limited to) the EDCTP Career Development Fellowships;
3. Lead to high impact research outputs by junior African scientists who have not been supported by major funders previously;
4. Foster new collaborations and mentorship;
5. Equip the next generation of African researchers to sustain excellent and relevant research in sub-Saharan Africa, and engage as African citizens with African leaders, policy-makers and industries to drive forward evidence-based health improvement.

⁵² The Calouste Gulbenkian Foundation will support the EDCTP2 programme with a total contribution of up to € 265,000 to this Call for Proposals. This cash contribution is restricted in use by the EDCTP Association for funding participants in actions resulting from this Call for Proposals, which are legally established in Portuguese-speaking sub-Saharan African countries. The call evaluation and grant management is centrally managed by the EDCTP Association in line with the Rules for Participation of Horizon 2020.

Table 13. Supporting information for the Joint Call for Proposals “EDCTP-AREF Preparatory Fellowships”

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	6 grants funded by EDCTP and 6 additional grants funded by AREF
Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).⁵³ 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the home organisation) where they intend to remain working for a minimum of two years after the expiration of the grant.⁵² 3. Fellows must:⁵² <ul style="list-style-type: none"> • be a post-doctoral scientist; • have been awarded their doctorate within 3 years before submission deadline of the AREF-EDCTP Preparatory Fellowship application; • have been either a PhD student or MD, and have been active researchers for up to three years following award of their doctorate; • be resident of or be willing to relocate to a sub-Saharan African country; • not have been funded under this fellowship scheme before.⁵⁴ 4. The requested EDCTP contribution per action shall not exceed €70, 000 5. Placements sought shall be for a period of at least 3 and up to 9 months, following which there will be a re-integration period of up to 3 months. The maximum fellowship duration shall be 12 months.

⁵³ 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).

⁵⁴ 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

Submission and evaluation procedure	<p>Two-stage application procedure.</p> <p>For the first stage, a letter of intent must be submitted by the fellow with a letter of support from the applicant legal entity (home organisation employing the fellow) by the indicated deadline. The letters of intent will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP and AREF in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. Up to thirty six successful candidate fellows will be shortlisted in the first stage and invited to a preparatory workshop led, organised and financed by AREF.</p> <p>For the second stage, the fellow and his/her home organisation (applicant legal entity) must submit a comprehensive training and development plan (including a draft re-integration plan) taking into account guidance provided in the workshop that will be evaluated by a panel of independent experts to select the 12 best proposals.</p> <p>An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p>
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (Mono-beneficiary) with options for fellowships for EDCTP-funded fellows. ⁵⁵ AREF-funded fellows will be required to enter into agreements with AREF.
Supplementary agreement	Host organisations participating in 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.

2.2.6 EDCTP-TDR Clinical Research and Development Fellowships – Joint call with the Special Programme for Research and Training in Tropical Diseases (TDR)

Challenge:

Researchers from low- and middle-income countries (LMICs)⁵⁶ 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

⁵⁵ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

⁵⁶ Countries as defined by the World Bank: For the current 2017 fiscal year, low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of \$1,025 or less in 2015; middle-income economies are those with a GNI per capita of more than \$1,026 but less than \$12,475 in 2015; high-income economies are those with a GNI per capita of \$12,476 or more in 2015.

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 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 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, product development partnerships (PDPs), clinical research organisations (CROs) and academic affiliated research organisations 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 (TDR). TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO.⁵⁷

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

Scope:

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

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are currently working on activities in the scope of the EDCTP2 programme⁵⁸ and the TDR CDF programme⁵⁹. EDCTP supports researchers who are employed by a legal entity in a sub-Saharan African country while TDR supports

⁵⁷ http://www.who.int/tdr/capacity/strengthening/career_development/en/

⁵⁸ In the EDCTP2 programme, "poverty-related diseases (PRDs)" include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.

⁵⁹ For TDR, "neglected infectious diseases (NIDs)" include: dengue/severe dengue; rabies; chagas disease; Human African trypanosomiasis (sleeping sickness); leishmaniasis; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiasis; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiasis; buruli ulcer; leprosy (Hansen disease); trachoma; yaws.

researchers from any LMICs, including sub-Saharan African countries. Placements supported by EDCTP are for a minimum period of 15 months (3 months will be used to prepare for the placement), following which there will be a re-integration period of 6 months. Placements supported by TDR are for a period of 12 months.

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

This Joint Call will include a joint evaluation and selection process in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. However, grant awarding and budget management will remain separate under the management of each organisation. TDR will support fellows employed by a research institution in any LMICs to be placed in pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs located worldwide, 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 host organisations (pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs) to train and develop specific clinical research skills of relevance to PRDs. The EDCTP and TDR grant includes funds for re-integration.

Host organisations may offer placements in the following areas: design and conduct of clinical trial studies, including operational planning, management and evaluation; clinical development of vaccines including associated epidemiological studies; assessment of drug development programmes; diagnostics; biostatistics/epidemiology; data management and pharmacovigilance. A list of participating pharmaceutical companies, CROs, clinical or academic affiliated research organisations and PDPs (i.e. host organisations) and available placements will be published on the EDCTP and TDR websites. The EDCTP and TDR will collaborate with EFPIA and IFPMA.

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, CROs, academic affiliated research organisations and PDPs.

Table 14. Supporting information for the Joint Call for Proposals 'EDCTP-TDR Clinical Research and Development Fellowships'

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	10-15 grants funded by EDCTP and up to 15 additional grants funded by TDR.

Additional eligibility conditions	<p>In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals:</p> <ol style="list-style-type: none"> 1. The applicant must be a legal entity established in sub-Saharan Africa and must be the home organisation employing the fellow.⁶⁰ 2. The fellow must:⁵⁹ <ul style="list-style-type: none"> - 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; - be a researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa, and who has been conducting clinical research activities in the scope of the EDCTP2 programme; - provide a letter of support from the home organisation for the fellowship which is justifying the training needs of the fellow and explaining how the home organisation will benefit from the fellowship and how the re-integration of the fellow will be ensured;⁶¹ - not have been funded under this fellowship scheme before.⁶² 3. Placements sought shall be for a period of 15 months, following which there will be a re-integration period of up to 6 months. 4. The requested EDCTP contribution per action shall not exceed € 100,000.
Submission and evaluation procedure	<p>Single stage application procedure. A full proposal must be submitted by the indicated deadline. The full proposal should comprise of a proposed training plan</p>

⁶⁰ 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).

⁶¹ The points to be addressed in the support letter are elaborated in the application form: Confirm that the Fellow is a current employee of the home organisation (details of contract duration should be included); State that the home organisation supports this fellowship application; Confirm that the Fellow is fully eligible in accordance with the criteria as set out in the Call Text; Confirm that the Fellow will be supported with a leave of absence for the duration of the fellowship; Confirm that the Fellow has the ability to successfully undertake the training he/she is applying for; Explain how the fellowship will enhance the career development of the Fellow; Explain how the proposed training will strengthen the home organisation's capacity to conduct clinical research upon return of the Fellow; Confirm that the Fellow will have a similar position at the home organisation once the fellowship has been completed.

⁶² 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.

	<p>reflecting the training needs of the applicant, a re-integration plan and the requested EDCTP contribution for the action. The full proposal will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP and TDR in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act.</p> <p>Proposals above the threshold will be forwarded to prospective host organisations, who will identify suitable fellows that match placements on offer. The identification and selection of fellows may include an interview with prospective host organisations. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.</p>
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships for EDCTP-funded fellows. ⁶³ TDR-funded fellows will be required to enter into agreements with TDR.
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.

⁶³ http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-mono-fellows_en.pdf

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 15. Indicative timetable for Calls for Proposals in 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	
RIA	Treatment for poverty-related diseases	Stage 1 – 1 June 2017	Stage 2 – 15 December 2017	Stage 1 – 5 September 2017 at 17:00:00 CET	Stage 2 – 14 March 2018 at 17:00:00 CET	Stage 1 – 22 December 2017	Stage 2 – 28 July 2018
	Targeting control and elimination of NIDs through clinical trials	4 July 2017		31 October 2017 at 17:00:00 CET		28 February 2018	
	Targeting control and elimination of NIDs through product-focused implementation research	4 July 2017		31 October 2017 at 17:00:00 CET		28 February 2018	
	Strategic actions supporting large-scale clinical trials	Stage 1 – 1 June 2017	Stage 2 – 15 December 2017	Stage 1 – 13 October 2017 at 17:00:00 CET	Stage 2 – 28 March 2018 at 17:00:00 CET	Stage 1 – 15 December 2017	Stage 2 – 28 July 2018
	Clinical trials to reduce health inequities in pregnant women, newborns and children	Stage 1 – 4 July 2017	Stage 2 – 22 December 2017	Stage 1 – 13 October 2017 at 17:00:00 CET	Stage 2 – 14 March 2018 at 17:00:00 CET	Stage 1 – 22 December 2017	Stage 2 – 4 August 2018
CSA	Ethics & Regulatory Capacities	3 August 2017		21 November 2017 at 17:00:00 CET		16 April 2018	
TMA	Senior Fellowships	03 November 2017		Single stage – 02 March 2018 at 17:00:00 CET		Single stage – 11 July 2018	
	EDCTP-GSK Senior Fellowships	03 November 2017		Single stage – 02 March 2018 at 17:00:00 CET		Single stage – 11 July 2018	
	Career Development Fellowships	03 November 2017		Single stage – 02 February 2018 at 17:00:00 CET		Single stage – 11 June 2018	
	EDCTP-TDR Clinical Research and Capacity Development Fellowships	26 October 2017		1 February 2018 at 17:00:00 CET		7 August 2018 (Interviews are planned for May-July 2018)	
	EDCTP-AREF Preparatory Fellowships	Stage 1 – 14 July 2017 at 17:00:00 CET	Stage 2 – 12 January 2018 at 17:00:00 CET	Stage 1 – 13 October 2017 at 17:00:00 CET	Stage 2 – 14 March 2018 at 17:00:00 CET	Stage 1 – 12 January 2018 at 17:00:00 CET	Stage 2 – 4 August 2018 at 17:00:00 CET

Table 16. Overview of budgeted cost and contributions towards EDCTP2 Calls for Proposals and other activities for the implementation of the EDCTP2 programme in 2017, including administrative expenses of the EDCTP Association in 2017

EU-funded EDCTP2 activities		Budgeted Contributions			Budgeted Cost (in €)
		TPs/TCs (in €)	PS (in €)	EU (in €)	
Research & Innovation Actions	Treatment innovations for poverty-related diseases	-	3,000,000	27,000,000	30,000,000
	Targeting control and elimination of NIDs through clinical trials	1,200,000 ⁶⁴	2,000,000	15,600,000	18,800,000
	Targeting control and elimination of NIDs through product-focused implementation research	1,200,000 ⁶⁵	1,000,000	9,000,000	11,200,000
	Strategic actions supporting large-scale clinical trials	-	-	43,000,000	43,000,000
	Clinical trials to reduce health inequities in pregnant women, newborns and children	-	5,270,103	32,965,260	38,235,363
Coordination & Support Actions	Ethics and regulatory capacities	-	-	2,500,000	2,500,000
Training & Mobility Actions	Senior Fellowships	66,250 ⁶⁶	-	2,933,750	3,000,000
	EDCTP-GSK Senior Fellowships	1,500,000 ⁶⁷	-	1,500,000	3,000,000
	Career Development Fellowships	66,250 ⁶⁴	-	2,433,750	2,500,000
	EDCTP-AREF Preparatory Fellowships	466,250 ⁶⁸	-	333,750	800,000

⁶⁴ €1,000,000 from Mundo Sano Foundation and €200,000 from LRI

⁶⁵ €1,000,000 from Mundo Sano Foundation and €200,000 from LRI

⁶⁶ €66,250 from the Gulbenkian Foundation

⁶⁷ €1,500,000 from GSK

⁶⁸ €400,000 from AREF and €66,250 from the Gulbenkian Foundation

	EDCTP-TDR Clinical Research and Development Fellowships	2,066,250 ⁶⁹	-	1,433,750	3,500,000
Other Activities	Independent experts assisting in proposal evaluations and project reviews in 2017	-	-	700,000	700,000
	Prizes	-	-	130,000	130,000
	Alumni launch meeting	-	-	150,000	150,000
	Preparations for the Ninth EDCTP Forum 2018	-	-	600,000	600,000
	Stakeholder meetings	-	-	100,000	100,000
	Regional workshops on EDCTP Calls and scientific proposal writing	-	-	200,000	200,000
	Workshops on GCP, GCLP and Ethics	-	-	200,000	200,000
	Financial and project management training	-	-	200,000	200,000
	Contribution to global initiative for clinical data sharing in global health	-	-	400,000	400,000
	Programme monitoring and evaluation	-	-	150,000	150,000
	Support advocacy, fundraising and outreach activities, including engagement with key stakeholders	-	-	300,000	300,000
Administrative costs of the EDCTP Association	Personnel, Missions, Consumables and supplies, Service contracts	-	329,897 ⁷⁰	5,200,840	5,530,737
Total planned contributions in 2017		6,565,000	11,600,000	147,031,100	165,196,100

⁶⁹ €1,500,000 from TDR, €500,000 from EFPIA and €66,250 from the Gulbenkian Foundation

⁷⁰ €329,897 from the UK

3 Other EU-funded activities

3.1 Activities supporting programme operations

3.1.1 Independent experts assisting in proposal evaluations and project reviews in 2017

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

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 prizes are presented to outstanding individuals and research teams, especially from Africa and Europe and are announced at the biennial EDCTP Forum.

The four prestigious prizes are:

- **Scientific Leadership Prize:** Awarded to excellent world-class scientists in Africa up to 50 years of age working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases (NIDS) in the scope of the EDCTP2 programme
- **Outstanding Female Scientist Prize:** Awarded to excellent world-class female scientists in sub-Saharan Africa and working in the remit of the EDCTP2 programme.
- **Outstanding Research Team Prize:** Awarded to outstanding research teams in Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases (NIDS) in the scope of the EDCTP2 programme.
- **Dr Pascoal Mocumbi Prize:** This prize is in special recognition of the significant contribution made by Dr Pascoal Mocumbi, the first High Representative of the EDCTP. It is to be awarded to senior scientists, policy-makers or advocates for health and research (aged 51 years and above), from anywhere in the world.

The specific rules of the contest will be published in 2017 on the EDCTP website and also actively publicised elsewhere to maximise participation. After the work plan is approved the EDCTP will directly launch and manage the contest and award the prize, based on the judgement of the independent experts as well as board members of the EDCTP Association.

Applications have to be submitted by the contestant (natural person who is nominee/nominator) via the web-based submission online EDCTPgrants portal (<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 contestant [nominee/nominator] will have to provide proof of eligibility and a written presentation of their achievements, which will be presented to an independent panel of experts for evaluation.

Expected result:

- **Scientific Leadership Prize:** 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 Prize:** 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 Prize:** 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.
- **Dr Pascoal Mocumbi Prize:** The prize will not only allow rewarding of specific achievements but will also raise awareness with the general public on the prize winner, their specific achievements, and the EDCTP2 programme.

Amount of prizes:

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

Eligibility criteria: The contestant must be a resident of a sub-Saharan African country, an EU Member State, or a country associated to the Horizon 2020 programme. The nomination of contestants who are currently employees of EDCTP, or serving on one of the EDCTP advisory (Scientific Advisory Committee) or governing (General Assembly and Board) bodies will not be permitted.

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

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

Type of action: Recognition prizes.

Indicative timetable: Prize contests will be launched in the last quarter of 2017 and remain open until the first quarter 2018. Prize winners will be announced at the Ninth EDCTP Forum (see General Annexes 6.6 for Model Rules of Contest (RoC) for EDCTP2 Prizes).

Total indicative budget: € 130,000.

3.1.3 Alumni launch meeting

Objective: An EDCTP Fellows' Alumni programme is aimed at tracking, networking, monitoring impact and encouraging trained Fellows to continue working together in sub-Saharan Africa. An online Alumni platform for EDCTP Fellows will be launched in the second quarter of 2017. As part of the launch of this interactive online platform, EDCTP will organise a 2-day-workshop, tentatively planned for Cape Town, South Africa, for all Fellows (current and past) to meet, learn more about the alumni platform and other EDCTP activities, and network with each other. For initiating the platform, EDCTP will invite current or past Senior Fellows, Career Development Fellows, and EDCTP-TDR Fellows, as well as awardees of EDCTP prizes. This could be extended to include fellowship supervisors. This action will support all costs necessary to satisfactorily organise the workshop.

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

Indicative timetable: The procurement process will begin in the second quarter of 2017 with the objective of holding the workshop in the third quarter of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷¹

Indicative budget: € 150,000.

3.1.4 Preparations for the Ninth EDCTP Forum 2018

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

Although the Ninth EDCTP Forum will take place in 2018 and the location is yet to be determined, it is expected that payments will be made in 2017 to cover expenses related to inspection and visit of potential venues; hire a local events management company; and secure a venue and block bookings in local hotels. This action will support all eligible costs necessary to organise the Forum.

Expected impact: The Forum is expected to draw 500-700 delegates, the majority of whom are working in sub-Saharan Africa, and provide a unique research communication platform for those stakeholders working in the field of PRDs.

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

Indicative timetable: The procurement process for some of the services will begin in the second quarter of 2017 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which will be in the fourth quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷² First payments are expected to be made in the last quarter of 2017.

Indicative budget: € 600,000.

3.1.5 Stakeholder Meetings

Objective: One thematic stakeholder meeting will be organised to contribute to the definition and fine-tuning of future strategic priorities of the EDCTP2 programme. This action will support all costs necessary to satisfactorily organise the stakeholder meetings. It is estimated that there will be 30-40 external participants.

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

⁷¹ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

⁷² http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

Indicative timetable: The procurement process will begin in the second quarter of 2017 with the objective of holding one stakeholder meeting in the third quarter of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷³

Indicative budget: € 100,000.

3.1.6 Regional workshops on EDCTP Calls and scientific proposal writing

Objective: The objective of this action is the organisation of up to three workshops in each of the three language communities in sub-Saharan Africa (i.e. anglophone, francophone and lusophone), to strengthen the capacity of researchers to apply to EDCTP Calls for Proposals. Researchers interested in EDCTP Calls will be invited to attend a two-day workshop. Each workshop will take place in a different region (locations to be defined) and interpretation/translation of materials into the local language is foreseen. The objective of the workshops is twofold: 1) to inform participants about the main EDCTP funding mechanisms, review process and eligibility criteria; 2) to deliver hands-on and practical sessions on scientific proposal writing. Where possible, EDCTP will partner with other organisations, such as TDR or Institut Pasteur, for the delivery of specific sessions. This action will support all costs necessary to satisfactorily organise the workshops. Around 20-25 participants will be invited to participate in each workshop. The workshops will be openly advertised on the EDCTP webpage, and participants will be selected to obtain a balanced composition with respect to geographical coverage, gender and affiliation.

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

Indicative timetable: The procurement process will begin in the first quarter of 2017 with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷⁴

Indicative budget: € 200,000.

3.1.7 Workshops on international ethical, scientific and practical research standards

Objective: The objective of this action is the organisation of up to three workshops in sub-Saharan Africa, focused on good clinical practice (GCP), good clinical laboratory practice (GCLP) and ethics to strengthen the capacity of sub-Saharan African researchers to conduct high quality research. Where possible, EDCTP will partner with other organisations, such as TDR, which has developed training materials that can be used in the workshops. This action will support all costs necessary to satisfactorily organise the workshops. All EDCTP beneficiaries from African organisations will be invited to participate. Between 20-25 participants are expected to attend each workshop.

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

⁷³ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

⁷⁴ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

Indicative timetable: The procurement process will begin in the first quarter of 2017 with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷⁵

Indicative budget: € 200,000.

3.1.8 Financial and Project Management Training

Objective: The objective of this action is the organisation of up to two 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. EDCTP expects to organise up to two workshops in sub-Saharan Africa, of which one will cover Western and Central Africa and one will cover Eastern and Southern Africa. All new EDCTP beneficiaries from African organisations will be invited to attend the training. Each workshop is expected to attract 40-60 participants.

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

Indicative timetable: The procurement process will begin in the second quarter with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷⁶

Indicative budget: € 200,000.

3.1.9 Contribution to global initiative for clinical data sharing in global health

Objective: EDCTP requires that beneficiaries must register their clinical trial in a WHO-recognised clinical trials registry, such as the Pan African Clinical Trials Registry (PACTR), and make their clinical trials protocols and clinical trials reports on results and outcomes available there. EDCTP also urges beneficiaries on making the underlying clinical study metadata available in an 'open access' data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data.

Other major funders of global health research have similar requirements for data sharing and open access to clinical trials data, clinical trials protocols and clinical trials reports. However, the usefulness of open access to clinical research data is severely hampered by insufficient capacity for good data management in many low-resource settings, the lack of a common global standard for data sharing, and the limited inter-operability between different repositories for clinical research data. EDCTP will contribute to the on-going joint effort between some of the major funders of global health research by setting up a portal for data management for EDCTP-funded clinical trials which will require the procurement of specialist services from IT providers, data base specialists and clinical data management companies, in particular to:

⁷⁵ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

⁷⁶ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

- 1) Providing access to free and suitable data management systems for clinical researchers in low-resource settings. This will be combined with the development of associated training material and guidance documents on good data management and data sharing.
- 2) Providing IT support for transferring clinical study metadata to a suitable repository.
- 3) Providing IT, logistic and administrative support for submitting patient level data sets to a suitable repository for such data, such as clinicalstudydatarequest.com (CSDR) or similar.
- 4) Providing management, logistic and administrative support for contributions defining '*standards to support the acquisition, exchange, submission and archive of clinical research data and metadata*' in collaboration with the Clinical Data Interchange Standards Consortium (CDISC) for poverty-related diseases, where no such standards exist.

Type of action: Public Procurement – up to 4 service contracts.

Indicative timetable: Call for tender will be opened in the third quarter of 2017. Procurements will be made in accordance with EDCTP procurement policies and procedures.⁷⁷

Indicative budget: € 400,000.

3.1.10 Programme monitoring & evaluation

The implementation of the EDCTP2 programme will be monitored on a regular basis using key performance indicators (KPIs). Each three-year term, an internal evaluation will be conducted to assess the progress made towards the objectives of the EDCTP2 programme and determine the impact of the programme including its influence on health policies, healthcare, capacity building, strengthening of partnerships and synergy with other programmes.

Objective: The collection and quality assurance of programme data gathered for the evaluation of KPIs, as established in the delegation agreement, needs to be better facilitated in order to support the reporting on the development and progress of the programme. To accomplish this, upgrade and further customisation of the existing grant management system, CC-tracker, will be done (software, training) will be necessary to ensure planning, process and management as well as data analysis.

Type of action: Public procurement – up to 4 service contracts.

Indicative timetable: The procurement process will begin in the second quarter of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁷⁸

Indicative budget: € 150,000.

3.1.11 Support advocacy, fundraising and outreach activities, including engagement with key stakeholders

In order to engage in strategic initiatives that foster collaboration with like-minded funders, raise awareness regarding the EDCTP2 programme and increase its visibility and impact, EDCTP will conduct advocacy, communication and outreach activities.

⁷⁷ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

⁷⁸ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

Advocacy, networking and fundraising

Objective: EDCTP will participate in joint funders groups such as HIV, TB, malaria or NID funders platforms including ESSENCE on Health Research⁷⁹; in strategic initiatives (in particular those identified by the two High Representatives), and a selection of international conferences to ensure a wider pool of potential applicants for EDCTP2 Calls for Proposals. This will create opportunities for EDCTP to showcase its activities and organise small scale meetings with partners or potential partners with the objective of discussing potential areas for collaboration, and collecting information necessary for future updating EDCTP's Strategic Research Agenda and Strategic Business Plan, especially in priority areas not covered by the stakeholder meeting (1.1.5). EDCTP also aims to have a strong presence in at a least four large international conferences in 2017.

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

Indicative timetable: The procurement process will begin in the second quarter of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.⁸⁰

Indicative budget: € 200,000.

Advocacy and Communication

Objective: Advocacy and communication aim to secure moral, political and financial support to sustain the activities of EDCTP. External communication is an essential support for North-North, North-South and South-South coordination and networking activities. External communication aims to create awareness and visibility of EDCTP, its mission and goals, and to inform all stakeholders of the progress and results of EDCTP-supported activities.

In alignment with EDCTP Specific objective number 5 and based on the EDCTP Communication strategy 2014-2014, the following support for advocacy and communication activities is needed in 2017:

- Production of materials for a strong presence at international conferences (4) and meetings
- Production of short video with a clear advocacy message on the reasons, goals and character of the EDCTP2 programme
- Production of photography on EDCTP-funded projects in sub-Saharan Africa
- Services of external expert for technical upgrade of the EDCTP website
- Outsourcing of development, design and printing of advocacy materials
- Outsourcing to medical writer/editor of reports of meetings organised by EDCTP – as editorial assistance for scientific publications on results of the EDCTP2 programme
- Other advocacy materials to be tailored to the requirements of the two EDCTP High Representatives.

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

Indicative timetable: The procurement process will begin in the second quarter of 2017. All procurements will be made in accordance with EDCTP procurement policies and procedures.

Indicative budget: € 100,000.

Total indicative budget: € 300,000.

⁷⁹ [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.

⁸⁰ http://www.edctp.org/web/app/uploads/2016/02/EDCTP_procurement_policies_and_procedures_manual1.pdf

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 set up, funded and managed by PS according to national rules, but the implementation follows a set of common principles, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection (provided in section 6.5).

The total budgeted cost for new PSIAs in 2017 (Tables 2 and 4.1) comprises €95,881,046 by the European Participating States and €1,362,443 by the African Partner States.

All PSIAs are listed in table 4.1 below, with a brief overview of the PS, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the budgeted cost for 2017. Wherever relevant, local currencies have been converted into Euros using official exchange rates.

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

4.1 PSIA's to be initiated in 2017

The following **new PSIA's**⁸¹ will be initiated by PSs in 2017 as contributions to the EDCTP2 programme:

Table 17. PSIA's supported in 2017

Country	Code	Activity Title	Keyword	Type of action	African countries involved	Duration of PSIA (in months)	Total Budgeted Costs (€)
European Partner States (Participating States)							
Germany	PSIA-2017-1233	Optional Interim support to the Central African Network on TB HIV Aids and Malaria (CANTAM)	Networking	CSA	Congo, Gabon	12	250,000
Germany	PSIA-2017-1232	Phase IA/B study of BTZ043 / add on to PANACEA	Tuberculosis	RIA	Tanzania, South Africa, Mozambique, Uganda, Gabon, Malawi	12	2,000,000
Denmark	PSIA-2017-1197	C-Tb	Tuberculosis	RIA	South Africa	12	200,000
Denmark	PSIA-2017-1179	Core-funding to IAVI	HIV/AIDS	RIA	Kenya, South Africa, Uganda, Rwanda, Zambia	12	160,992
France	PSIA-2017-1213	Merit	Cross-cutting	RIA	Benin	12	1,606,116
France	PSIA-2017-1214	Clinical research and capacity strengthening on the big three pandemics	Cross-cutting	RIA	TBC	12	8,000,000
France	PSIA-2017-1215	Partnership for Research on Ebola VACCinations - PREVAC	Ebola	RIA	Liberia, Guinea and Sierra Leone	12	5,700,000
France	PSIA-2017-1216	International Network Clinical ResEArch Sustainable InitiatiVEs (Increase Initiative)	Capacity building	TMA	Cameroon, Ivory Coast, Madagascar, Senegal	12	350,000

⁸¹ Value of new contracts or legal obligations that PSs expect to sign in 2017, 2017, excluding direct financial contributions from PSs (i.e. managed by PSs) to EDCTP2 funded projects

France	PSIA-2017-1217	AFRIBIOTA	Diarrhoeal diseases	RIA	Madagascar, Central African Republic	24	3,220,000
France	PSIA-2017-1218	LMI PreVIHMI	HIV/AIDS	CSA	Cameroon, Democratic Republic of Congo	12	40,000
France	PSIA-2017-1219	TRANSVIHMI	Cross-cutting	RIA	Senegal, Cameroon and others (TBC)	36	1,542,330
France	PSIA-2017-1220	JEAI RI3M	Malaria	RIA	Mauritania	24	15,000
France	PSIA-2017-1221	Support to research sites in West Africa	Cross-cutting	CSA	Burkina Faso, Cameroon, Ivory Coast, Senegal	12	1,134,218
France	PSIA-2017-1222	Support to doctoral and post-doctoral scholarships	Capacity building	TMA	Burkina Faso, Cameroon, Ivory Coast, Senegal, Mali, Zambia, Uganda	36	259,801
France	PSIA-2017-1223	Research grants on HIV/AIDS and associated diseases for multidisciplinary and/or international programs	Cross-cutting	RIA	South Africa, Ivory Coast, Uganda, Zambia, Senegal, Cameroon, Burundi, Guinea, Mali, Mozambique	48	2,586,502
France	PSIA-2017-1224	Intertryp	NIDs	RIA	TBC	12	561,120
France	PSIA-2017-1225	LMI CONS-HELM	NIDs	RIA	Ghana, Benin	12	40,000
France	PSIA-2017-1226	JEAI MAHEVA	Malaria/NIDs	RIA	Ghana	12	15,000
Italy	PSIA-2017-1208	Operational research project to increase retention in ART through decentralization of care and community involvement	HIV/AIDS	RIA	Ethiopia	36	700,000
Norway	PSIA-2017-1234	GLOBVAC call for proposals	Cross-cutting	RIA	TBC	60	2,694,663
Norway	PSIA-2017-1236	Support to IPM	HIV/AIDS	RIA	TBC	12	43,096
Norway	PSIA-2017-1237	Support to TBVI	Tuberculosis	RIA	TBC	12	96,966
Norway	PSIA-2017-1238	Support to MMV	Malaria	RIA	TBC	12	129,288
Norway	PSIA-2017-1239	Support to DNDi	NIDs	RIA	TBC	12	84,037
Norway	PSIA-2017-1240	Support to IAVI	HIV/AIDS	RIA	TBC	12	25,858

Sweden	PSIA-2017-1196	Consortium for Advanced Research Training in Africa (CARTA)	Cross-cutting	CSA	Kenya	60	4,026,000
Sweden	PSIA-2017-1195	African Population and Health Research Council	Cross-cutting	RIA	Kenya	60	774,000
Sweden	PSIA-2017-1194	Building a stronger MUHAS in supporting research and innovation	Cross-cutting	CSA	Tanzania	60	1,758,270
Sweden	PSIA-2017-1193	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	Cross-cutting	CSA	Tanzania	60	1,361,800
Sweden	PSIA-2017-1191	Strengthening health system research capacity for enhancing innovations and sustainable socio-economic development	Cross-cutting	RIA	Tanzania	60	698,770
Sweden	PSIA-2017-1189	Research Capacity Strengthening for the Control of HIV in Tanzania (The HIV Sub-programme)	HIV/AIDS	CSA	Tanzania	60	1,921,390
Sweden	PSIA-2017-1188	Quality improvement of Makerere University's population-based health and demographic surveillance site: maximizing the potential of the research platform for capacity development and generation of valid population data to inform policy formulation	Cross-cutting	CSA	Uganda	60	1,371,049
Sweden	PSIA-2017-1181	Innovations in the Health System: 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	RIA	Uganda	60	1,191,880

Sweden	PSIA-2017-1244	Glucose needs in children with acute febrile illness in Uganda- challenging the existing guidelines for improved survival	Cross-cutting	RIA	Uganda	36	300,000
United Kingdom	PSIA-2017-1182	GCRF Antibacterial Resistance (ABR) call	Cross-cutting	RIA	TBC	18	390,000
United Kingdom	PSIA-2017-1170	DELTA Africa Initiative	Cross-cutting	RIA	Ivory Coast, Ghana, Kenya, Mali, Senegal, South Africa, Uganda, Zimbabwe	44	6,000,000
United Kingdom	PSIA-2017-1171	GCRF Foundation Awards	Cross-cutting	RIA	TBC	24	15,600,000
United Kingdom	PSIA-2017-1169	GCRF Call in Networks for Vaccine R&D	Cross-cutting	CSA	TBC	36	650,000
United Kingdom	PSIA-2017-1164	MRC/UVRI Uganda Research Unit on AIDS	HIV/AIDS	RIA	Uganda	60	17,550,000
United Kingdom	PSIA-2017-1163	MRC Fellowships	Cross-cutting	TMA	Burkina Faso	60	1,300,000
United Kingdom	PSIA-2017-1162	MRC Research Grants	Cross-cutting	RIA	Cameroon, Cape Verde, Kenya, Uganda, South Africa, Tanzania	60	3,900,000
United Kingdom	PSIA-2017-1161	Health Systems Research Initiative (HSRI)	Cross-cutting	RIA	South Africa	60	432,900
United Kingdom	PSIA-2017-1160	Joint Global Health Trials scheme	Cross-cutting	RIA	TBC	60	5,200,000
Sub-Total European PSs							95,881,046
African Partner States							
Burkina Faso	PSIA-2017-1184	Training of 4 PhD in Basic and clinical research	Capacity development	TMA	Burkina Faso	12	60,000
Burkina Faso	PSIA-2017-1185	Malaria Clinical Trial Platform management including staff salary equipment and reagent cost for malaria, meningitis, dengue tuberculosis and other NTD	Cross-cutting	CSA	Burkina Faso	12	120,000

Burkina Faso	PSIA-2017-1187	Maintaining an institutional position for three EDCTP grantee	Capacity development	TMA	Burkina Faso	12	20,000
Gabon	PSIA-2017-1173	Anti-malarial drugs resistances markers surveillance in rural areas of Gabon	Malaria	RIA	Republic of Gabon	12	234,032
Gabon	PSIA-2017-1174	Epidemiology of Tuberculosis and a short course regimen (9months) protocol for the treatment of multidrug resistance-tuberculosis (TB-MDR) patients in Lambaréné, Gabon	Cross-cutting/TB/Interventions	RIA	Republic of Gabon	12	327,520
South Africa	PSIA-2017-1206	TB child and adolescent multi-drug resistant preventive therapy trial (TB CHAMP) - phase III trial	Cross-cutting/TB/Interventions	RIA	Republic of South Africa	40	330,000
South Africa	PSIA-2017-1211	Development of a better & more robust second-line antiretroviral regimen for HIV infection	HIV/Interventions	RIA	Republic of South Africa	24	200,000
Uganda	PSIA-2017-1228	The 9th Annual National Research Ethics Conference (ANREC) and a planned forum for the chairpersons of Research Ethics Committees	Cross-cutting (Ethics)	CSA	Republic of Uganda	1	47,271
Uganda	PSIA-2017-1229	The 6th Health and Scientific Conference and International Health Exhibition and Trade Fair	Cross-cutting	CSA	Republic of Uganda	1	23,620
						Sub-Total African PSs	1,362,443
						Grand Total European + African PS	97,243,489

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 2017 the indicative budget for administrative costs is as follows:

Table 18. Budgeted administrative costs of the EDCTP Association for the implementation of the EDCTP2 programme in 2017

Description	Note	Budgeted Contributions (in €)			Budgeted Costs (in €)
		EU	PSs	TPs/TCs	
Personnel		4,267,131	329,897	-	4,597,028
Missions	1	200,000	-	-	200,000
Consumables and supplies	2	228,000	-	-	228,000
Service contracts (including non-recoverable taxes)	3	505,709	-	-	505,709
Total		5,200,840	329,897	-	5,530,737

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 the EDCTP Association'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 19. Projected staff headcount by functional area in 2017

Functional area	Headcount
Senior Management Team (Directors)	4
Financial and Management Accounts	3
Grants Financial Management	4
General Administration (IT, Legal, HR, Travel and Admin)	7
North-North Operations	7
South-South Operations	4
North-North Networking	4
South-South Networking	1
Communications and programme support	4
Total	38

6 General Annexes⁸²

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:⁸³

- 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:⁸⁴
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 Barthélemy, 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;⁸⁵

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-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

International European interest organisations⁸⁶ 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.

⁸² The Supporting Information provided in this chapter is copied from the General Annexes (version 2.0) of the Work Programme 2016-2017 of Horizon 2020 (Commission decision C(2016)4614 of 25 July 2016), unless the specificities of the EDCTP2 programme required an adaptation of the information to those specificities. Such EDCTP2-specific adaptations were required for section 6.1, 6.2 (5), 6.3, 6.4, 6.5, 6.6 (6.6.9.2, 6.6.9.6), 6.7 (Table 21) and 6.10.

⁸³ 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.

⁸⁴ 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.

⁸⁵ http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/international-cooperation_en.htm. As of 1 January 2017, the following 16 countries are Associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland, Faroe Islands, Ukraine, Tunisia, Georgia, Armenia.

⁸⁶ 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.

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

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the EU and an international organisation or a third country,⁸⁷
- 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 funding⁸⁸.

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

⁸⁷ No agreements or arrangements of this kind are currently existing.

⁸⁸ 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.

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
Work Plan	1500	1500	1500
Work package (1500 words each - assume 3)**	4500	4500	4500
Milestones – means of verification (100 words each - assume 5)***	500	500	500
Management Structure and Procedures	1000	1000	Not asked
Consortium as a whole	1000	1000	Not asked
Critical Risks (100 words each – assume 5)****	500	500	500
Budget Justification	3000	3000	3000
Total	31,200	27,400	28,850

6.3 Standard eligibility conditions

All proposals must comply with the eligibility conditions set out in the Rules for Participation of Horizon 2020 (EU 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 20. Standard eligibility criteria per type of action

Type of Action	Eligibility conditions for participation ^{89, 90, 91}
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.

⁸⁹ 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.

⁹⁰ 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).

⁹¹ Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol in accordance with Article 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.

6.4 Types of action: specific provisions and funding rates^{92,93}

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.⁹⁴

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.⁹⁵

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

⁹² Eligible costs for all types of action are in accordance with the EU's Financial Regulation No 966/2012 and the Horizon 2020 Rules for Participation (EU Regulation No 1290/2013). In addition, as training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposal such activity and the following corresponding estimated costs that may be eligible for EU funding:

- i. Costs of delivering the training (personnel costs if the trainers are employees of the beneficiary or subcontracting if the training is outsourced);
- ii. Accessory direct costs such as travel and subsistence costs, if the training is delivered outside the beneficiary's premises;
- iii. Remuneration costs for the researchers attending the training, in proportion to the actual hours spent on the training (as personnel costs).

⁹³ Participants may ask for a lower rate.

⁹⁴ Excerpt from the General Annexes of the Horizon 2020 work programme 2016-2017.

⁹⁵ Excerpt from the General Annexes of the Horizon 2020 work programme 2016-2017 (see also the Rules for Participation of Horizon 2020, Article 2, point 7).

("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 section 6.6.

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

6.5 Common principles applying to national programme activities (PSIAs)

The EDCTP2 basic act² stipulates that EDCTP2 activities may include national programme activities of PSs 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 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 PSs have agreed to the common principles outlined below.⁹⁶

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

⁹⁶ 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.

that exceptional situations, for example in health emergencies such as the recent Ebola outbreak, allocation of funding through open calls may neither be practical or timely. In these situations, earmarked funding to a named beneficiary can be acceptable.

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

6.5.2 Transparency

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

6.5.3 Independent peer review evaluation

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

6.5.4 Ethics and scientific integrity

- The principles of scientific integrity as defined in the European Code of Conduct for Research Integrity should be observed and promoted.⁹⁷
- Fundamental ethical principles and in particular 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 the selection of actions for funding and during the subsequent implementation of the actions.

6.5.5 Appeal and complaints

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

6.5.6 Exploitation and dissemination of results

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

6.6 Model Rules of Contest (RoC) for EDCTP2 Prizes

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

⁹⁷ http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

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 ⁹⁸

Applications must be submitted by the (lead) contestant via EDCTP grants, 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]. [OPTION 2 if 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 entities⁹⁹ and for Crimean legal persons and that entities from non-EU Member States that are covered by Council sanctions are not eligible to participate¹⁰⁰ (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,

⁹⁸ Central European Time = Brussels local time.

⁹⁹ 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).

¹⁰⁰ For the list of persons, groups and entities subject to EU financial sanctions, see http://eeas.europa.eu/cfsp/sanctions/consolidated_en.htm.

decision or control with regard to that contestant)¹⁰¹ 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

¹⁰¹ 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).

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.

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. [list the essential / specific award criteria from the work plan/call]
2. [...]
3. [...]
4. [same for all other essential/specific award criteria from the work plan/call].

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.

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 2017'].

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 the law of Belgium. 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 1290/2013¹⁰² [and the following additional [dissemination]/[and] [exploitation] obligations:

- [insert additional obligation from work plan/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 EDCTP grants 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 will be processed by the European Commission under EU Regulation No 45/2001 and according to the ‘notifications of the processing operations’ to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

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

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

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

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

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).

¹⁰² 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).

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 privacy statement(s) (see above), before transmitting their data to the EDCTP Association.

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 Integrity¹⁰³ — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct); and
- b) applicable international, EU and national law.

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

The 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); or
- c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

Research activities involving human embryonic stem cells (hESC) are moreover subject to the conditions set out in the Statement of the Commission related to research activities involving human embryonic stem cells.¹⁰⁴

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.

¹⁰³ 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

¹⁰⁴ Declarations of the Commission (Framework Programme), OJ C373, 20.12.2013, p. 2

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; or
- 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

6.7.1 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 sufficient 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.

6.7.2 Award criteria, scores and weighting

1. Grant proposals will be evaluated by experts, on the basis of the **award criteria** 'excellence', 'impact' and 'quality and efficiency of the implementation' (see Article 15 of the Horizon 2020 Rules for Participation Regulation No 1290/2013). The aspects to be considered in each case depend on the 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 21. Award criteria per type of EU-funded EDCTP2 action

Type of Action	Award criteria		
	Excellence	Impact	Quality and efficiency of the implementation
	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work plan.	The following aspects will be taken into account:	The following aspects will be taken into account:

<p>All Types of Action</p>	<p>Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.</p> <p>Importance, relevance/pertinence and clarity of the objectives.</p> <p>Soundness of the concept and credibility of the proposed approach/methodology.</p>	<p>The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.</p> <p>Likelihood to result in major advances in the field.</p>	<p>Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables;</p> <p>Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met.</p> <p>Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise.</p> <p>Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role.</p> <p>Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant.</p> <p>Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues.</p> <p>Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).</p>
<p>Research & Innovation Action (RIA)</p>	<p>Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.</p> <p>Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial.</p> <p>Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.</p> <p>Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge</p>	<p>Advancing the clinical development of new and improved products.</p> <p>Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results.</p> <p>Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.</p> <p>Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials.</p> <p>Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data</p>	<p>Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP).</p> <p>Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial.</p> <p>Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).</p>

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, and in any case, not less than two and a half times the available budget. The actual level will therefore depend on the volume of proposals and funding request per proposal received. The threshold is expected to normally be set at 8 or 8.5.
- For 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: relative number of sub-Saharan African countries involved; 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; 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, common 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 parties¹⁰⁵

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 call 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

¹⁰⁵ This is not foreseen in the 2017 work plan.

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 related to open access to research data

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

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

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

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

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

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

A Data Management Plan (DMP) details what data the project will generate, how it will be exploited and made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is obligatory for all projects that do not opt-out. Projects that opt-out are also strongly encouraged to submit a Data Management Plan if relevant for their planned research. Further information on Data Management Plans is available on the Horizon 2020 Participant Portal.^{106, 107}

¹⁰⁶ http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf

¹⁰⁷ https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf

7 Acronyms

ALM	American Leprosy Missions
ANRS	Agence nationale de recherches sur le sida et les hépatites virales
AREF	African Research Excellence Fund
CC	Cross-cutting
CREC	Centre de Recherche Entomologique de Cotonou
CRO	Clinical Research Organisation
CSA	Coordination & Support Action
EDCTP	European & Developing Countries Clinical Trials Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
EU	European Union
EVI	European Vaccine Initiative
GA	EDCTP General Assembly
GCP	Good Clinical Practice
GLOBVAC	Global Health and Vaccination Research Programme
GLP	Good Laboratory Practices
GLRA	German Leprosy and Tuberculosis Relief Association
GMP	Good manufacturing practice
GSK	GlaxoSmithKline
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
Horizon 2020	European Union's Framework Programme for Research and Innovation 2014-2020
HSRI	Health systems research initiative
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
IPT	Intermittent preventative treatment
IRB	Institutional review board
LMIC	Low- and middle-income country
LRI	Leprosy Research Initiative
MMV	Medicines for Malaria Venture
MoU	Memorandum of Understanding
MRC/UVRI	Medical Research Council/Uganda Research Unit on AIDS
MUHAS	The Muhimbili University of Health and Allied Sciences
NCD	Non-communicable diseases
NEC	National ethics committee
NGO	Non-governmental organisation
NID	Neglected infectious disease
NLR	Netherlands Reprosy Relief
NRA	National regulatory authority
OCT	Overseas countries and territories
OJ	Official journal
PanACEA	Pan African Consortium for the Evaluation of Antituberculosis Antibiotics
PATH	Program for Appropriate Technology in Health
PDP	Product development partnership
PRD	Poverty-related disease
PS	EDCTP Partner State
PSIA	Participating States' Initiated Activity
RIA	Research and Innovation Action
RfP	Request for Proposals
RoC	Rules of Contest
SAC	EDCTP Scientific Advisory Committee
SHIP	Strategic Health Innovation Partnerships
Sida	Swedish International Development Cooperation Agency
STH	Soil-transmitted helminths
TB	Tuberculosis
TBVI	TB Vaccine Initiative

TC	Third Countries
TP	Third Parties
TMA	Training & Mobility Action
TDR	Special Programme for Research and Training in Tropical Diseases
TLMI	The Leprosy Mission International
WHO	World Health Organization