EDCTP

European & Developing Countries Clinical Trials Partnership

EDCTP2 WORK PLAN 2015

Status of this version:	**Final version approved by the EDCTP General Assembly on 5 October 2015**
Responsible person:	**Professor Charles Mgone, EDCTP Executive Director**
Important notice:	**This annual work plan covers 2015 and describes planned activities under the EDCTP2 programme in 2015. It has been approved by the European Commission on 3 September 2015 following the positive outcome of its external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. The Board of the EDCTP Association has approved it on 16 September 2015 and the General Assembly of the EDCTP Association has approved it on 5 October 2015.**

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Contents

Acronyms

Aeras	Aeras Global TB Vaccine Foundation
AFD	French Agency for Development (Agence Française de Développement)
AHPSR	Alliance for Health Policy and Systems Research
AHRI	Armauer Hansen Research Institute
AMRH	Africa Medicines Regulatory Harmonisation
ANRS	Agence nationale de recherches sur le sida et les hépatites virales
ARL scheme	African Research Leader scheme
BMBF	German federal ministry of education and research
BMZ	German federal ministry for economic cooperation and development
CC	Cross-cutting
Centre CRCF de l'hôpital Fann	Le Centre Régional de Recherche et de Formation à la Prise en Charge Clinique de Fann
CIRDES	Centre International de Recherche-Développement sur l'Elevage en zone Subhumide
CPLP	Community of Portuguese Language Countries
RIA	Research & Innovation Action
CREC	Centre de Recherche Entomologique de Cotonou
CRFiMT	Centre de Recherche sur les Filarioses et autres Maladies Tropicales
CSA	Coordination & Support Action
DAAD	German academic exchange services
Danida	Danish International Development Agency
DFG	German Research Foundation
DFID	Department for International Development
DGCS	Directorate General for Development Cooperation
DNDi	Drugs for Neglected Diseases Initiative
DST	Department for Science and Technology
DVI	Dengue Vaccine Initiative
ECHO	Evidence for contraceptive options and HIV
EDCTP	European & Developing Countries Clinical Trials Partnership
EEA-EFTA	European Economic Area-European Free Trade Association
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ESRC	Economic and Social Research Council
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau
EU	European Union
EVD	Ebola virus disease
EVI	European Vaccine Initiative
FCT	Foundation for Science and Technology
FIND	Foundation for Innovative New Diagnostics
FORSK	Swedish Unit for Research Cooperation
FP6	European Union's Sixth Framework Programme for Research and Innovation (2003-2006)
FP7	European Union's Seventh Framework Programme (2007-2013)
FSS	Faculté des Sciences de la Santé
GA	EDCTP General Assembly
GCP	Good Clinical Practice
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GLOBVAC	Global Health and Vaccination Research Programme
GMP	Good manufacturing practice
HEARD	Health economics and HIV/AIDS research division
HHVI	(Sabin Vaccine Institute for the) Human Hookworm Vaccine Initiative
HIV/AIDS	Human immunodeficiency virus/ acquired immunodeficiency syndrome

Horizon 2020	European Union's Framework Programme for Research and Innovation 2014-2020
HSR	Health systems research
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
IHI	Ifakara Health Institute
INDEPTH Network	International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries
INMI	Istituto Nazionale per le Malattie Infettive
IPM	International Partnership for Microbicides
IPR	Intellectual property rights
IPT	Intermittent preventative treatment
IRB	Institutional review board
IRD	L'Institut de recherche pour le développement
IRSS	Institut de Recherche en Sciences de la Santé
ISS	Instituto Superiore di Sanità
IVCC	Innovative Vector Control Consortium
KNCV TB Foundation	Netherlands TB Foundation (Koninklijke Nederlandse Centrale Vereniging voor tuberculosebestrijding)
LMIC	Low- and middle-income country
LMU	Ludwig-Maximilians University Munich
LRP	Laboratoire de Recherche sur le paludisme
LSHTM	London School of Hygiene and Tropical Medicine
MCDC	Malaria Capacity Development Consortium
MDR-TB	Multi-drug resistant tuberculosis
MMV	Medicines for Malaria Venture
MoU	Memorandum of Understanding
MPIIB	Max Planck Institute for Infection Biology
MRC UK	Medical Research Council United Kingdom
MRC/UVRI	Medical Research Council/Uganda Research Unit on AIDS
MTRC	Strengthening Malaria Training Research Training Centre
MUHAS	The Muhimbili University of Health and Allied Sciences
MVI	Malaria Vaccine Initiative
NACCAP-2	Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty-related Diseases
NEC	National ethics committee
NGO	Non-governmental organisation
NID	Neglected infectious disease
NNRTI	Non-nucleoside reverse-transcriptase inhibitors
Norad	Norwegian Agency for Development Cooperation
NOURISH	Nourishing Our Understanding of Role Modeling to Improve Support and Health
NRA	National regulatory authority
NWO-WOTRO	Netherlands Organisation for Scientific Research - Science for Global Development (Nederlandse organisatie voor Wetenschappelijk Onderzoek-Stichting voor Wetenschappelijk Onderzoek van de Tropen en Ontwikkelingslanden)
OCEAC	Organisation de Coordination et de Coopération pour la lutte contre les grandes Endémies en Afrique Centrale
OCT	Overseas countries and territories
PanACEA	Pan African Consortium for the Evaluation of Antituberculosis Antibiotics
PATH	Program for Appropriate Technology in Health
PDP	Product development partnership
PMTCT	Prevention of mother-to-child transmission

PNLTHA	Programme national de Lutte contre la Trypanosomose Humaine Africaine
PRD	Poverty-related disease
PACCI	Programme de recherché sur le vih/sida et les maladies associées
PS	EDCTP Partner State
PSIA	Participating States' Initiated Activity
SAC	EDCTP Scientific Advisory Committee
SADC	Swiss Agency for Development and Cooperation
SERI	Swiss Secretariat for Education, Research and Innovation
SBFI	Staatssekretariat für Bildung, Forschung und Innovation
SHIP	Strategic Health Innovation Partnerships
Sida	Swedish International Development Cooperation Agency
SMN	Swedish Malaria Network
TB	Tuberculosis
TB Alliance	Global Alliance for TB Drug Development
TBVI	TB Vaccine Initiative
TMA	Training & Mobility Action
UEM	University Eduardo Mondlane
VINNOVA	Swedish Governmental Agency for Innovation Systems
VR	Swedish Research Council (Vetenskapsrådet)
WHO-TDR	World Health Organization Special Programme for Research and Training in Tropical Diseases

1. Introduction

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

The EDCTP2 programme will run over a ten-year period from 2014 to 2024, and the European Union (EU) has decided to support the programme with a financial contribution of up to € 683 million from the Horizon 2020 programme's societal challenge "*Health, Demographic Change and Well-being*" ("EDCTP2 basic act"[2]).

The EU's financial contribution shall be conditional upon the following: (a) the implementation by the EDCTP2 Implementation Structure ("the EDCTP2-IS") 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 annexe 3 of the EDCTP2 basic act; (c) the compliance by the EDCTP2-IS with the reporting requirements set out in Article 60(5) of the EU's Financial Regulation (Regulation (EU, Euratom) No 966/2012); and (d) the fulfilment of the commitment by each Participating State[3] to contribute to the financing of the EDCTP2 Programme commitments as referred to in Article 3.1 (point e).[2]

The EDCTP2-IS is the EDCTP which is legally established as Association under Dutch law in the Netherlands[4]. The EDCTP currently counts 27 Partner States (PS) as full and equal members of the Association: 14 European and 14 African countries[5,6].

The EDCTP Association is composed of the General Assembly as the governing body, the *Secretariat* as the executive body led by the *EDCTP Executive Director*, and the Board supervising the *Secretariat*[7].

1 In the EDCTP2 programme, "medical interventions" encompass measures whose purpose is to improve or sustain health or alter the course of a disease, in particular prevention and treatment based on medicinal products such as drugs, microbicides or vaccines, including their delivery modality, follow up of treatment and prevention in the affected population as well as medical diagnostics to detect and monitor disease/health evolution.

2 EDCTP2 Basic Act: Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States, Official Journal of the European Union, OJ L 169, 7.6. 2014, p.38

3 Only the following European countries are specified in the EDCTP2 Basic Act as the "Participating States" of the EDCTP2 programme and thus required to fulfil the conditions set for the EU's financial contribution to the EDCTP2 programme: Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. It needs however to be noted that there is currently no bilateral agreement between the EU and Switzerland that supports the status of "Participating State" for Switzerland, and thus Switzerland has to be regarded as Third Country. Also Greece is specified as a Participating State even though it has neither provided any up-front commitment to the EDCTP2 programme nor requested membership in the EDCTP Association. Thus, it does not comply with the requirements set for "Participating States" in the EDCTP2 basic act.

4 Official registration No 60471700, Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands, VAT number 853925653.

5 So far, the following 14 African countries have joined the EDCTP Association as members: Burkina Faso, Cameroon, Congo, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda, and Zambia. The EDCTP Association involves the following 14 European countries as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.

6 Since the EDCTP is a partnership between European and African countries that are jointly participating and implementing the EDCTP2 programme as full and equal members of the EDCTP Association, the notion "Partner States" will be used hereunder to refer similarly to European and African countries in the EDCTP Association. However, only the European Partner States are "Participating States" as defined by the EDCTP2 basic act that are required to meet the conditions and assume the responsibilities set in the EDCTP2 basic act for the EDCTP Association receiving the EU's financial contribution to the EDCTP2 programme (see footnote 3).

7 Deed of Incorporation of the EDCTP Association, 10.4.2014, http://www.edctp.org/app/uploads/2014/12/Deed_of_Incorporation_EDCTP_Association_10-04-2014_EN_FINAL.pdf

Scope of the EDCTP2 programme

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

1. Increase the number of new or improved medical interventions for poverty-related diseases (PRDs), including neglected ones[8];
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.

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)[9] 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 by 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[10,11].

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

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

9 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.

10 EDCTP2 basic act, Annexes I and II.

11 EDCTP2 basic act, Article 6.4.

and activities on PRDs among the PSs, both at scientific, management and financial level.[10]

The activities of the EDCTP2 programme are supported along three distinct types of actions[12]: 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.

Implementation of the EDCTP2 programme

The EDCTP2 programme is implemented by the EDCTP Association on the basis of an annual work plan and a multi-annual strategic business plan[13].

The present EDCTP2 annual work plan for 2015 has been developed in compliance with the objectives and provisions set out in the EDCTP2 basic act, and following a comprehensive consultation process, involving multiple stakeholders. The consultation process has included meetings and workshops with academic researchers, pharmaceutical industry, product development partnerships (PDPs), charities and foundations, international organisations and health research funders outside of Europe and Africa. It has also included a series of thematic stakeholder meetings (on Neglected Infectious Diseases (NIDs), HIV/AIDS, malaria, tuberculosis and other mycobacterial infections, ethics and regulatory affairs, and capacity development) resulting in specific recommendations for the EDCTP2 programme[14]. 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 2015 provides information about EU-funded Calls for Proposals in 2015 (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 2015 also contains an overview of non-EU funded PSIAs in 2015 (Chapter 3). The PSIAs in the current EDCTP2 annual work plan are all funded and implemented directly by one or more PS, and are an integral part of the EDCTP2 programme.

In accordance with the EDCTP2 basic act, the draft EDCTP2 annual work plan 2015 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. It resulted in a positive outcome with some recommendations from the review panel that were taken into account by the EDCTP Association in the present EDCTP2 annual work plan 2015.

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

13 http://www.edctp.org/app/uploads/2015/03/EDCTP_Strategic_Business_Plan_EDCTP2.pdf

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

Budget overview tables

Table 1: Overview of planned commitments to activities of the EDCTP2 programme in 2015 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)

Activities	Contributions (in €)			
	EU	PSs	TPs	TOTAL
EU-funded Calls for Proposals implemented by the EDCTP Association	68,800,000	10,540,000	3,200,000	**82,540,000**
Other EU-funded Activities implemented by the EDCTP Association	470,000	-	-	**470,000**
Non-EU funded PSIAs implemented by the PSs	-	46,542,553	-	**46,542,553**
Sub-Total Implementation	**69,270,000**	**57,082,553**	**3,200,000**	**129,552,553**
EU-funded administrative costs of the EDCTP Association	2,495,425	-	-	**2,495,425**
Non-EU funded administrative costs of the PSs*	-	264,959	-	**264,959**
Sub-Total Administration	**2,495,425**	**264,959**	**-**	**2,760,384**
Total Budget	**71,765,425**	**57,347,512**	**3,200,000**	**132,312,937**

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

Table 2: Detailed overview of planned commitments to activities of the EDCTP2 programme in 2015 by the European Union (EU), and European and African Partner States (PSs)

	Planned commitments (in €)				
	Cash contributions*	PSIAs**	In-kind Admin.***	Total in 2015	Total cumulative commitment in 2014-2015
European Union (EU)					
European Commission (EC)	71,765,425	-	-	71,765,425	86,165,425
Sub-Total EU	**71,765,425**	**-**	**-**	**71,765,425**	**86,165,425**
Participating States** (European Partner States)**					
Austria (AT)	-	-	10,000	10,000	2,770,000
Denmark (DK)	-	2,000,000	22,000	2,022,000	6,967,000
Finland (FI)	-	687,500	2,700	690,200	890,200
France (FR)	-	-	-	-	19,915,000
Germany (DE)	3,000,000	4,000,000	-	7,000,000	36,055,000
Ireland (IE)	-	-	-	-	11,082,546
Italy (IT)	-	-	-	-	1,725,000
Luxembourg (LU)	200,000	-	-	200,000	2,200,000
Netherlands (NL)	100,000	11,250,000	5,000	11,355,000	17,053,918
Norway (NO)	-	2,339,774	25,500	2,365,274	12,566,931
Portugal (PT)	200,000	-	5,000	205,000	1,290,627
Spain (ES)	200,000	-	5,000	205,000	3,110,000
Sweden (SE)	2,500,000	-	-	2,500,000	23,727,000
United Kingdom (UK)	4,340,000	16,800,000	80,000	21,220,000	250,220,000
Sub-Total European PSs	**10,540,000**	**37,077,274**	**155,200**	**47,772,474**	**389,573,222**
African Partner States					
Burkina Faso (BF)	-	325,753	25,000	350,753	355,753
Cameroon (CM)	-	45,000	3,740	48,740	983,034
Congo (CG)	-	-	7,000	7,000	116,564
Gabon (GB)	-	250,778	-	250,778	250,778
The Gambia (GM)	-	348,000	5,000	353,000	477,000
Ghana (GH)	-	-	-	-	2,034,227
Mali (ML)	-	775,000	-	775,000	775,000
Mozambique (MZ)	-	514,858	10,000	524,858	548,358
Niger (NE)	-	172,267	13,599	185,866	204,069
Senegal (SN)	-	40,000	9,200	49,200	303,800
South Africa (ZA)	-	4,450,000	10,000	4,460,000	8,313,846
Tanzania (TZ)	-	160,000	9,220	169,220	576,740

Uganda (UG)	-	213,623	12,000	225,623	554,908
Zambia (ZM)	-	2,170,000	5,000	2,175,000	4,646,000
Sub-Total African PSs	-	9,465,279	109,759	9,575,038	20,140,077
Sub-Total European + African PSs	82,305,425	46,542,553	264,959	57,347,512	409,713,299
Grand Total	82,305,425	46,542,553	264,959	129,112,937	495,878,724

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

*** Value of new contracts or legal obligations that PSs expect to sign in 2015.*

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

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

Table 3: Overview of European and African Partner States (PSs) planned disbursements in 2015

PSs	PS planned disbursements (in €)*				
	EU-funded EDCTP2 calls and other activities	PSIAs	In-kind Admin.**	Total	Total cumulative disbursements in 2014-2015
		Participating States**** (European Partner States)			
Austria (AT)	-	275,000	10,000	285,000	570,000
Denmark (DK)	-	2,281,667	22,000	2,303,667	4,018,667
Finland (FI)	-	362,500	2,700	365,200	565,200
France (FR)	-	-	-	-	19,915,000
Germany (DE)	3,000,000	18,845,000	-	21,845,000	36,055,000
Ireland (IE)	-	5,541,273	-	5,541,273	11,082,546
Italy (IT)	-	700,000	-	700,000	1,725,000
Luxembourg (LU)	200,000	1,000,000	-	1,200,000	2,200,000
Netherlands (NL)	100,000	4,043,351	5,000	4,148,351	8,511,918
Norway (NO)	-	6,265,063	25,500	6,290,563	11,227,157
Portugal (PT)	200,000	298,252	5,000	503,252	1,010,367
Spain (ES)	200,000	800,000	5,000	1,005,000	2,910,000
Sweden (SE)	2,500,000	-	-	2,500,000	23,727,000
United Kingdom (UK)	4,340,000	69,620,000	80,000	74,040,000	143,290,000
Sub-Total	**10,540,000**	**110,032,106**	**155,200**	**120,727,306**	**266,807,855**
		African Partner States			
Burkina Faso (BF)	-	210,753	25,000	235,753	240,753
Cameroon (CM)	-	45,000	3,740	48,740	983,034
Congo (CG)	-	31,341	7,000	38,341	76,682
Gabon (GB)	-	155,830	-	155,830	155,830
The Gambia (GM)	-	145,666	5,000	150,666	211,666
Ghana (GH)	-	361,818	-	361,818	758,240
Mali (ML)	-	304,167	-	304,167	304,167
Mozambique (MZ)	-	457,828	10,000	467,828	491,328
Niger (NE)	-	89,436	13,599	103,035	121,238
Senegal (SN)	-	35,000	9,200	44,200	283,800
South Africa (ZA)	-	3,310,255	10,000	3,320,255	5,347,178
Tanzania (TZ)	-	292,908	9,220	302,128	444,256

Uganda (UG)	-	213,623	12,000	225,623	554,908
Zambia (ZM)	-	790,833	5,000	795,833	3,266,833
Sub-Total	**-**	6,444,458	109,759	6,554,217	13,239,913
Grand Total	10,540,000	116,476,564	264,959	127,281,523	280,047,768

** The predicted disbursement from PSs of funding to new activities (i.e. based on planned commitments in 2015) and ongoing activities (i.e. based on commitments made before 2015). Where unknown, it has been assumed for multi-annual commitments that disbursements will occur evenly over the lifetime of the PSIA.*

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

Table 4: Overview of planned Third Parties (TPs) contributions to the EDCTP2 programme in 2015

Third Parties	TPs contributions (in €)			
	In-kind	EDCTP-funded	Admin.	TOTAL
EFPIA members	500,000	-	-	500,000
Calouste Gulbenkian Foundation	-	200,000	-	200,000
WHO-TDR	-	2,000,000	-	2,000,000
Switzerland	-	500,000	-	500,000
Grand total	500,000	2,700,000	-	3,200,000

6. EU-funded Calls for Proposals

Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2015:

Improved treatment and clinical management of poverty-related diseases

Challenge:
Poverty-related diseases (PRDs) represent a major obstacle to the sustainable development of sub-Saharan Africa. Effective, safe, suitable and affordable medical treatments tailored to developing countries' specific circumstances do not exist for most PRDs.

Scope:
The purpose of this Call for Proposals is to provide funding to research actions that aim to evaluate new or significantly improved drugs or drug regimens in humans or to optimise the efficacy and use of existing therapeutics for any of the PRDs[15], including co-infections of PRDs. Proposals should include one or more clinical trial(s) (phase I to IV) of therapeutics for PRDs to be conducted in sub-Saharan Africa. Applications addressing the following topics are particularly encouraged:

HIV

- Evaluation of new drugs and optimisation of existing drug treatments, particularly for paediatric use.
- Evaluation of new treatment strategies for the prevention of anti-retroviral drug resistance.
- Models of delivery to increase population coverage, retention in care and adherence to treatment.

Tuberculosis

- Evaluation of new drugs, drug regimens and combinations to shorten and simplify treatment.
- Optimisation of treatment of paediatric tuberculosis.
- Evaluation of new drugs and drug regimens to prevent and treat multi-drug resistant tuberculosis (MDR-TB) and extensively multi-drug resistant tuberculosis (XDR-TB).
- Models of delivery to increase population coverage, retention in care and adherence to treatment.

Malaria

- Evaluation of new drugs, drug regimens and combinations, particularly where there are product development gaps in the global portfolio for treatment of uncomplicated (symptomatic and asymptomatic) and severe Plasmodium falciparum malaria.
- Optimisation of treatment and chemo-protection in pregnant women and children.

NIDs

- Evaluation of new drugs, drug regimens and combinations, particularly where there are product development gaps in the global portfolio.
- Large-scale trials to evaluate optimal delivery of existing interventions.

Co-infections

- Improved clinical management of HIV and tuberculosis, with a focus on managing co-infections.
- Phase II-IV trials of clinical management of PRD co-infections.

15 The PRDs targeted through this Call for Proposals are: HIV/AIDS, malaria, tuberculosis, dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

Proposals for conducting phase II and/or III clinical trials are encouraged.

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

Expected impact:
Actions funded under this Call for Proposals should lead to improvements in public health as a result of policy change at national, regional or global level, through evidence-based formulation and implementation of treatment guidelines and/or lead to the advancement of product candidates through the clinical pipeline or registration or pre-qualification of new products.

Table 5: Supporting information for the Call for Proposals "Improved treatment and clinical management of PRDs"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	3-5
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criterion applies to this Call for Proposals: 1. The requested EDCTP contribution per action shall not exceed €15.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used. For the first stage, only the Excellence and Impact criteria will be evaluated.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

Strategic actions supporting large-scale clinical trials

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

Scope:
The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are part of a large-scale clinical trial that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs. Such large-scale clinical trials are often expensive and may require clinical research in different countries or on different continents, including outside of Europe and Africa.

Applications for a strategic action should focus on clinical trials on PRDs in sub-Saharan Africa, and may address any disease within the scope of the EDCTP2 programme[16]. Proposals that include phase III trials are encouraged.

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

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

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

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

16 All stages of clinical trials can be supported, from phase I to IV, including implementation research on the optimisation of health services. For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa such as Ebola.

contribution to the objectives of the EDCTP2 programme.

The requested EDCTP2 contribution should be leveraged by at least the same amount of funding from other funders (i.e. from EDCTP2 Participating States and/or third parties). Proposals that clearly demonstrate major support from other funders at the level of the large-scale clinical trial will be considered to have a higher impact.

Table 6: Supporting information for the Call for Proposals "Strategic actions supporting large-scale clinical trials"

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-5
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this call for proposals: 1. The requested EDCTP contribution per action shall not exceed €10.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The standard award criteria, scoring, thresholds and weightings listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

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

Proposals will be invited for the following topics in 2015:

Ethics and regulatory capacities

Challenge:
Many African countries lack sound ethical review mechanisms and some even lack medicines regulatory bodies. There is a pressing need to develop and strengthen the national ethics and medicines regulatory frameworks in sub-Saharan Africa in order to strike a balance between the public health interest, the interests of the pharmaceutical industry, and ethical values.

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

The objectives of this call are:

1. To support NECs' development of institutional and personnel capacities to enable them to perform their national ethical oversight function over the institutional review boards; efficiently review clinical trial applications; and to provide ethical oversight for clinical trials and health research in general.
2. To support NRAs' development of institutional and personnel capacities to enable improved regulatory pathway activities directly related to clinical trials and registration of new medicinal products. This may also include strengthening pharmacovigilance systems.

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

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

The Calouste Gulbenkian Foundation will support the EDCTP2 programme with a total cash contribution of up to €200,000 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.

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 7: 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	5-10
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this call for proposals: 1. Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries[17]. 2. The requested EDCTP contribution per action shall not exceed €300,000.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono- or multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

17 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).

EDCTP regional networks

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

Scope:
The purpose of this Call for Proposals is to provide funding to actions that aim to support regional networking in sub-Saharan Africa and with Europe in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with the International Conference on Harmonization guidelines for Good Clinical Practice (ICH-GCP). The networks should contribute to overcoming the lack of capacity, critical mass and adequate infrastructures that prevent many African institutions from engaging in high quality clinical research activities. The networks should build on results from former EDCTP-funded regional networking actions with the aim of strengthening the scientific and clinical research environment for conducting clinical trials to prevent and treat poverty-related diseases in sub-Saharan Africa.

EDCTP may fund up to four regional networks, defined geographically as Southern[18], Eastern[19], Western[20], and Central Africa[21].

The specific objectives of the networks should include:

1. To strengthen collaboration and optimise the use of resources and infrastructures within the network. This could include the establishment of shared facilities such as clinical laboratories or data management centres, and setting rules and guidelines for sharing and accessing these.
2. To offer training and mentorship aimed at promoting professional development and scientific leadership in clinical trials. This would require the establishment of a formal training programme and platform for exchange of expertise in key skills such as design of clinical trials, monitoring, data management, pharmacokinetics, laboratory techniques, biostatistics, clinical epidemiology, pharmacovigilance, as well as financial management, administration, and quality assurance.
3. To strengthen South-South and North-South collaborations between researchers and institutions with a specific focus on supporting less established institutions in building capacity for conducting high quality clinical research.
4. To encourage and promote networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.

The proposed networks should have a clear governance structure, an independent advisory structure and a transparent process for acquiring new network participants and for excluding non-performing network participants. The networks should also have a clear strategy for succession in leadership, and a detailed business plan for becoming self-sustainable by the end of the award period. The overall responsibility for the scientific management and direction of the network should be firmly based in sub-Saharan Africa. The proposed networks should propose activities that address all four objectives listed above and cover all the major

18 Southern Africa: Botswana, Lesotho, Madagascar, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, and Zimbabwe.

19 Eastern Africa: Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Mauritius, Rwanda, Seychelles, Somalia, South Sudan, Sudan, Tanzania, and Uganda.

20 Western Africa: Benin, Burkina Faso, Cape Verde, Gambia, Ghana, Guinea, Guinea-Bissau, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

21 Central Africa: Angola, Cameroon, the Central African Republic, Chad, the Republic of the Congo, the Democratic Republic of the Congo, Equatorial Guinea, Gabon, and São Tomé and Príncipe.

disease categories (HIV/AIDS, tuberculosis, malaria and neglected infectious diseases and emerging infectious diseases of particular relevance to Africa such as Ebola) within the scope of the EDCTP2 programme. The proposed networks should present the proposed management of IPR and measures to communicate the project, to increase competitiveness, to reduce research capacity inequalities, and, where relevant, to manage research data. The proposed networks should also present their arrangements to encourage career development within the network. The proposed networks should comprise sufficient participants to address all objectives, but should not be too large to function and communicate effectively. The grant is strictly limited to 36 months, whereupon successful networks that demonstrate satisfactory progress may be given an opportunity to apply for an additional 5 year grant.

Successful networks should achieve the following deliverables during the 36-month project period:

Partnership:

- Publish at least three peer reviewed scientific or policy publications as a demonstration of active collaboration and coordination.
- Organise at least one annual meeting, provide regular consortia communication (e.g. documented teleconferences), and develop annual work plans aimed at increased harmonisation of study methods, and sharing infrastructures.

Expertise:

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

Training:

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

Infrastructure:

- Incorporate at least one fully functional clinical laboratory, accredited to GLP to perform clinical trials research, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials
- Develop a functioning data management service, which can be used by the network or contracted by an external clinical trial sponsor to support clinical trials.

Organisation:

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

Expected impact:
Networks funded under this Call for Proposals should contribute to measurable increase in collaborative research (south-south and north-south collaborations), competences and capacity to conduct clinical trials. By the

end of the award period, the networks should collectively be able to conduct clinical trials to ICH-GCP standard. Additionally, they should have published at least three peer reviewed scientific or policy publications and been able to competitively attract alternative funding from local and/or international global health R&D funders.

Table 8: Supporting information for the Call for Proposals "EDCTP regional networks"

Type of action	Coordination & Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	4
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this call for proposals: 1. A network shall comprise a minimum of six legal entities from at least three different sub-Saharan African countries and a minimum of two legal entities from two different European PSs.[22] 2. The requested EDCTP contribution per action shall not exceed €3.0 million. 3. The maximum project duration shall be 36 months.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

22 Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the nature and objectives of this Coordination & Support Action. It aims to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials in line with international standards of good clinical practice by supporting networking at a regional level in sub-Saharan Africa. In light of this, it is necessary to have several African institutions within each network. It is in line with the activities called for by the EU legislator (EDCTP2 basic act, Annex II, activity 1c) and contributes to the specific objectives of the EDCTP2 programme which calls, e.g., for cooperation with sub-Saharan Africa on building their capacity for conducting clinical trials in compliance with fundamental ethical principles, relevant legislations and international standards (EDCTP2 basic act, Annex I, objective 2b).

Research capacity development in support of the EVD response*

** Please note that the wording of this call text may slightly differ from the version published on the calls section of the EDCTP website.*

Challenge:
The outbreak of Ebola virus disease (EVD) in West Africa has catalysed a number of research and development activities that are focused on delivering effective therapeutic, diagnostic and preventive interventions. However, the successful testing and implementation of these interventions requires the availability of functioning health research infrastructures and increased research capacity in the affected countries, as well as willingness of affected populations to engage in research and development activities.

Scope:
The purpose of this Call for Proposals is to build and strengthen regional, national, institutional and individual capacities to conduct high quality health research (e.g. clinical trials, operational and/or implementation research) during infectious disease outbreaks resulting in health emergencies. Proposals should complement current and future research initiatives for treatment, prevention and containment of EVD or other emerging infectious diseases of particular relevance to Africa. Applications should address one or more of the following areas:

- Establish training or other capacity building activities for health care and laboratory personnel to detect and respond to infectious disease epidemics, conduct clinical trials and analyse samples in an emergency context to ensure clinical trial site preparedness
- Generate evidence for and implement ethically sound approaches to the introduction and clinical testing of new prevention tools or treatments during outbreaks of EVD or other emerging infectious diseases of particular relevance to Africa
- Identify and implement best practices for building both community and national health authority support and engagement in clinical trials being conducted in emergency situations. This may include activities related to the development of appropriate mechanisms for surveillance, identification, tracking and referral of cases, as well as reintegration of survivors into the community.

The proposals may include support for networking, development and promotion of policies and guidelines, innovative approaches for best use of existing protocols and good clinical and laboratory practices, as well as concrete plans for sharing of research infrastructures, personnel and know-how. Actions involving transnational collaboration and regional networking are encouraged. Applicants are encouraged to establish links with relevant WHO and EDCTP-funded activities, including the EDCTP Regional Networks as well as Regional Training Centres and networks supported by the Special Programme for Research and Training in Tropical Diseases (WHO/TDR) which is hosted at the World Health Organization (WHO). It is considered that proposals for activities of between 12 and 24 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.

WHO/TDR and the UK Medical Research Council (MRC) provide a cash contribution to this EDCTP2 Call for Proposals of €500,000 and around €340,000 (£ 250,000) to support the EVD response in West Africa, plus €500,000 from the EU contribution to the EDCTP2 programme (i.e. a call budget of approximately €1.340 million). The call, evaluation and grant management is centrally

managed by EDCTP in line with the Rules for Participation of Horizon 2020.

A separate Call for Proposals will be launched in early April 2015 by the Canadian Institutes of Health Research (CIHR), which aims to support EVD research in the areas of: EVD biology; EVD treatment; transmission, spread and containment of EVD; and studies of the impacts of EVD on health system utilisation patterns by different populations groups in affected regions, the cost-effectiveness of health system resource development strategies in response to the EVD crisis, and the sustainability of health workforce and other health system resource allocation strategies once the EVD crisis subsides. Researchers who are funded through the respective calls will be required to attend a joint workshop hosted by the funders, to identify opportunities for international synergy and collaboration. Applicants must allocate sufficient funds to attend this workshop in their submitted budgets.

Expected impact
Actions funded under this Call for Proposals should contribute towards increasing health system preparedness and community engagement in research and development activities. By improving community trust and health research capacity, they will facilitate rapid testing and introduction of high quality research interventions in emergency situations caused by infectious disease outbreaks

Table 9: Supporting information for the Call for Proposals "Research capacity development in support of the EVD response"

Type of action	Coordination & Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	5-7
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this Call for Proposals: • The requested EDCTP contribution per action shall not exceed €250,000.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono- or multi-beneficiary).
Consortium agreement	Participants in actions resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

EDCTP-WHO/TDR Clinical Research and Development Fellowships

Challenge:
Researchers from low- and middle-income countries (LMICs)[23] who are involved in clinical research activities have limited opportunities to acquire experience and develop skills for conducting clinical trials outside an academic or public sector setting. As a result, there are few researchers and clinical staff from LMICs assuming leading roles in clinical research for poverty-related diseases (PRDs). The development of human capacities through fellowships will lead to enhanced and sustainable research capacity in LMICs on diagnostics, drugs and vaccines for PRDs, and supporting career progression and retention of researchers in LMICs.

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

The WHO/TDR Career Development Fellowships (CDF) programme , which has been supported by the Bill & Melinda Gates Foundation and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), offers targeted training in research and development within pharmaceutical companies and product development partnerships (PDPs) to develop highly skilled local personnel for disease-endemic LMICs to enhance competencies in clinical trials for drugs, vaccines and diagnostics on a broad range of infectious diseases of poverty. The CDF programme is implemented by the Special Programme for Research and Training in Tropical Diseases (WHO/TDR). WHO/TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO[24].

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

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

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are employed by a legal entity in LMICs where they are

23 Countries as defined by the World Bank: low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of $1,045 or less in 2013; middle-income economies are those with a GNI per capita of more than $1,045 but less than $12,746 in 2013; high-income economies are those with a GNI per capita of $12,746 or more in 2013.

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

currently working on activities in the scope of the EDCTP2 programme[25] and the WHO/TDR CDF programme[26]. Placements are for a minimum period of 12 months up to a maximum period of 24 months, following which there will be a re-integration period of 6 months (subject to the approval of a final re-integration plan).

The applicant legal entity (hereinafter 'the applicant') employing the prospective fellow submits the application. Fellows commit to return to their home institution 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 institution.

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

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

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

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

26 For WHO/TDR, Neglected Infectious Diseases (NIDs) include: dengue/severe denque; rabies; chagas disease; Human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; buruli ulcer; leprosy (Hansen disease); trachoma; yaws.

Table 10: Supporting information for the Joint Call for Proposals "EDCTP-WHO/TDR Clinical Research and Development Fellowships"

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	Up to 10 grants funded by the EDCTP (up to 15 additional grants funded by WHO/TDR).
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this Call for Proposals: 1. The applicant legal entity must be a legal entity established in sub-Saharan Africa and must be the home institution employing the fellow.[27] 2. The fellow must:[27] – be a post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases; – have obtained their first degree within 15 years of submission of the application; – have been a researcher or clinical staff member employed for the last 12 months in an institution with a registered legal entity in sub-Saharan Africa , conducting clinical research activities in the scope of the EDCTP2 programme. 3. Placements sought shall be for a minimum period of 12 months up to a maximum period of 24 months, following which there will be a re-integration period of six months (subject to the approval of a re-integration plan).
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the applicant legal entity by the indicated deadline. The letters of intent will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP and WHO/TDR in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. Successful candidate fellows in the first stage will be shortlisted and prospective host organisation will be invited to identify preferential candidate fellows. The identification of preferential candidate fellows may include an interview of candidate fellows by the prospective host organisations. For the second stage, the prospective host organisation, the preferred fellow and his/her home institution (applicant) must submit a comprehensive training plan (including a draft re-integration plan) that will be evaluated by a panel of independent experts. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.

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

Evaluation criteria	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) adapted as appropriate.
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.

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 to serve as long-term trainer-of-trainers and mentors for junior researchers with emphasis on hands-on research training linked to clinical trials activities.

The objectives of the scheme are:

1. To support senior researchers to advance themselves as recognised research leaders in product development through clinical trials and related activities.
2. To equip senior researchers with the necessary skills and experience to train and mentor junior researchers at host institutions in sub-Saharan Africa.

Applications should focus on hands-on activities equipping the fellow with competences to serve as a long-term trainer of trainers in research and mentorship in a scientific area within the scope of the EDCTP2 programme[28]. 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 one or more PhD or at least two Masters students with a clear training and mentorship plan. Additionally, the fellow should indicate how their advancement in skills and competences for training and mentorship, as well as the capacity development of the junior researchers under their supervision fit into the overall institutional capacity development and sustainability strategies. Fellows who plans to conduct the training and mentorship on clinical trials, must ensure that studies are appropriately designed and GCP-compliant; good manufacturing practice (GMP) compliant investigational product(s) are available and guaranteed; and all sponsor responsibilities can be fulfilled by the host institution 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.

28 For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

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

Table 11: 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	4-6
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this Call for Proposals: 1. The applicant must be an institution with an established legal entity in sub-Saharan Africa.[29] 2. The fellow must be employed or have guaranteed employment by the applicant (the host institution) where they intend to remain working for a minimum of two years after the expiration of the grant.[29] 3. The fellow must:[29] – be resident of or be willing to relocate to a sub-Saharan African country – be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a minimum of five years' research experience.

29 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).

	4. The requested EDCTP contribution per year shall not exceed €100,000. 5. The maximum fellowship duration shall be 60 months.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3. The host institution (applicant) must provide a support letter confirming that the institution 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 criteria	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) adapted as appropriate.
Supplementary agreement	Applicant legal entities (host institutions) 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.

Career Development Fellowships

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

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

The objectives are:

- To promote career development and retention of postdoctoral researchers and postgraduate medical researchers in the research field and in sub-Saharan Africa.
- To equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research and team at host institutions in sub-Saharan Africa.

The proposed action should specifically enhance the ability of the fellow to design, plan and execute clinical biomedical and/or social science/ethics research projects within the scope of the EDCTP2 programme[30]. The proposed training should include an independent research activity and a clear description of the skills that will be acquired by carrying out the research. Fellows with training activities involving clinical trials and related studies must ensure that studies are appropriately designed and GCP-compliant. Individuals targeted by this Call for Proposals should have a track record of publications in peer-reviewed journals in their chosen area of research; a mentor who is an internationally recognised scientific leader working in sub-Saharan Africa;

30 For the purpose of this Call for Proposals, PRDs include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); Leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; and yaws, as well as emerging infectious diseases of particular relevance for Africa, such as Ebola.

and a career development plan as part of the research proposal.

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

Expected impact:
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.

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	8-10
Additional eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following additional eligibility criteria apply to this Call for Proposals: 1. The applicant must be an institution with an established legal entity in sub-Saharan Africa.[31] 2. The fellow must be employed or have guaranteed employment by the applicant (the host institution) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. Fellows must: – be resident of or be willing to relocate to a sub-Saharan African country

31 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).

	– be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and up to five years' relevant post-doctoral research experience, or a medical doctor with up to five years' research experience. 4. The requested EDCTP contribution per year shall not exceed €50,000. 5. The maximum fellowship duration shall be 36 months.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3. The host institution (applicant) must provide a support letter confirming that the institution 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 criteria	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) adapted as appropriate.
Supplementary agreement	Applicant legal entities (host institutions) 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.

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 13: Indicative timetable for Calls for Proposals in 2015*

Call Topic (code)	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	
Treatment for PRDs	Stage 1 - 3 September 2015	Stage 2 – 8 January 2016	Stage 1 – 15 October 2015 at 17:00:00 CET	Stage 2 –10 March 2016 at 17:00:00 CET	Stage 1 – 8 January 2016	Stage 2 – 30 June 2016
Senior Fellowships	12 November 2015		Single stage –4 February 2016 at 17:00:00 CET		Single stage – 10 June 2016	
Career Development Fellowships	12 November 2015		Single stage – 4 February 2016 at 17:00:00 CET		Single stage – 10 June 2016	

EDCTP-TDR Clinical Research and Capacity Development Fellowships	Stage 1 - 22 October 2015	Stage 2 – 14 June 2016 at 17:00:00 CET	Stage 1 – 28 January 2016 at 17:00:00 CET	Stage 2 – 21 July 2016 at 17:00:00 CET	Stage 1 – 14 June 2016 Interviews are planned to be held in April/ May 2016	Stage 2 – 7 October 2016
Ethics & Regulatory Capacities	Single stage - 15 October 2015		Single stage –21 January 2016 at 17:00:00 CET		Single stage – 26 May 2016	
EDCTP Regional Networks	5 November 2015		Single stage –18 February 2016 at 17:00:00 CET		Single stage – 7 July 2016	
Research capacity development in support of the EVD response	Single stage - 3 August 2015		Single stage – 11 August 2015 at 17:00:00 CET**		Single stage - 1 October 2015	
Strategic projects supporting large-scale clinical trials	Stage 1 - 3 September 2015	Stage 2 – 12 January 2016	Stage 1 – 15 October 2015 at 17:00:00 CET	Stage 2 –15 March 2016 at 17:00:00 CET	Stage 1 – 12 January 2016	Stage 2 – 7 July 2016

** Please note that these indicative dates and deadlines may differ from the final dates indicated in the call texts published on the EDCTP website*
***This is a CSA call to award low-value grants. The call has been pre-announced and the template form made available. The budgetary planning of the other funders (WHO/TDR and UK-MRC) has necessitated a short deadline.*

Table 14: Overview of planned contributions towards EDCTP2 Calls for Proposals in 2015 and other activities for the implementation of the EDCTP2 programme, including administrative expenses of the EDCTP Association

EU-funded EDCTP2 activities		Indicative budget (in €)	Indicative EU contribution (in €)
Research & Innovation Actions	Treatment for PRDs	35,000,000	28,500,000
	Strategic actions supporting large-scale clinical trials	25,700,000	21,000,000
Coordination & Support Actions	Ethics and regulatory capacities	1,500,000	1,300,000
	EDCTP Regional Networks	12,000,000	12,000,000
	Research capacity development in support of the EVD response	1,340,000	500,000

Training & Mobility Actions	EDCTP-WHO/TDR Clinical Research and Development fellowships	3,000,000	1,500,000
	Senior fellowships	2,500,000	2,500,000
	Career development fellowships	1,500,000	1,500,000
Other Activities	Independent experts	420,000	420,000
	Dr Pascoal Mocumbi Prize	50,000	50,000
Administrative costs of the EDCTP Association	Personnel, Missions, Consumables and supplies Service contracts	2,495,425	2,495,425
Total planned contributions in 2015		**85,505,425**	**71,765,425**

3. Other EU-funded activities

Activities supporting programme operations

Independent experts assisting in proposal evaluations and project reviews in 2015

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

Type of action: Expert contracts.

Indicative budget: €420,000.

Dr Pascoal Mocumbi Prize

This prize is in recognition of Dr Pascoal Mocumbi, EDCTP's first High Representative and former Prime Minister of Mozambique, for his outstanding contribution to fostering global partnerships in health research and his support for capacity strengthening in Africa. During his 10-year-tenure as High Representative of EDCTP (2004-2013), he has worked to promote capacity development initiatives and networking, as well as championing African ownership in various partnerships. He has urged policy makers to support funding of health research in their own countries and to commit themselves to solving national health problems.

Objective: The prize rewards an individual in recognition of his/her outstanding achievements in advancing health research and capacity development in Africa with significant impact on the wellbeing of the African population.

Expected result: The prize not only allows rewarding specific achievements, but also raise awareness with a more general public on both the prize winner and his/her specific achievements, and on EDCTP and the EDCTP2 programme.

Amount of prize: The Dr Pascoal Mocumbi Prize consists of a recognition trophy and a cash prize of €50,000. The cash prize shall be used by the prize winner to further the capacity development and networking activities contributing to the objectives of the EDCTP2 programme and promote international cooperation between Africa and Europe.

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

Award criteria: The winner of the "Dr Pascoal Mocumbi Prize" will be selected according to the following award criteria, which will be assessed by an independent external jury:

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

The prize will be awarded, after closure of the contest, to the contestant that in the opinion of an independent external jury has allowed for outstanding, original and excellent achievements in the above-stated and thereby contributed to an improvement of the health of the African population.

Indicative timetable: The contest will be opened in the third quarter of 2015 and closed in the fourth quarter of 2015. Decisions on awards will be made by an independent external jury. The general Rules of Contest for EDCTP2 Prizes are provided in section 6.5. The specific rules will be published in 2015.

Type of action: Recognition prize.

Indicative budget: €50,000 from the 2015 budget.

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 plan and any communication related to PSIAs, whether undertaken by EDCTP, a European Partner State (which are the Participating State as defined in the EDCTP2 basic act) or a African Partner State, or any of the participants in a PSIA, must clearly indicate that they are part of the EDCTP2 programme supported by the European Union (see section 6.10). PSIAs are funded and managed by PS according to national rules, but the implementation follows a set of common principles, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection (provided in section 6.5).

The total planned contributions from PS to PSIAs for 2015 (Table 2 and 3) comprises €46,542,553 on planned commitments (of which €37,077,274 from the European PS/ Participating States) and €116,476,564 on planned disbursements (of which €110,032,106 from the European PS/Participating States).

All PSIAs are listed below, with a brief overview of the PS and funding institutions involved, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the indicative commitments for 2015. Wherever relevant, local currencies have been converted into Euros using official exchange rates.

Disclaimer: The European Commission's acceptance of the PSIAs as in-kind contribution of the (European) Participating States to the EDCTP2 programme will be based on an assessment of the information provided through the EDCTP Association's annual reporting to the European Commission, including reporting by the (European) Participating States based on the requirements agreed with the European Commission in accordance with article 4 of the EDCTP2 basic act and included in the delegation agreement concluded between the EDCTP Association and the European Commission. This assessment will verify the actual commitments by the (European) Participating States to 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]

PSIAs supported by PSs in 2015The following new PSIAs will be initiated by PSs in 2015 as contributions to the EDCTP2 programme:

Table 15: PSIAs supported by PSs in 2015

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
			European Partner States (Participating States)				
DE.PS.2015.1	Call for Proposals on Research Networks for Health Innovations in Sub-Saharan Africa, Networks on NIDs, TB, HIV and/or Malaria	CC	CSA	Various - TBD	TBD	4,000,000	4,000,000
DK.PS.2015.1	International AIDS Vaccine Initiative (IAVI)	HIV	RIA	Kenya (Kenya Medical Research Institute-Centre; Kenya Aids Vaccine Initiative), South Africa (Aurum Institute), Rwanda (Project San Francisco), Uganda (Uganda Virus Research Institute), Zambia (Zambia Emory Research Center)	36	2,000,000	666,667
FI.PS.2014.1	Development research - Joint programme by the Academy of Finland and the Finnish Ministry for Foreign Affairs	CC	RIA	TBD	TBD	200,000	200,000
FI.PS.2015.2	Detection and burden of dengue (DENGUE-DETECT)	NID	RIA	Ethiopia, Kenya (University of Nairobi; University of Helsinki Taita Research Station in Kenya), Tanzania (Muhimbili University of Health and Allied Sciences)	36	487,500	162,500

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
NL.PS.2015.1	PDP Fund: Call for Proposals	CC	RIA	TBD	60	11,250,000	2,250,000
NO.PS.2015.1	Evaluation of Ebola vaccine safety and efficacy in a prefecture of Guinea	NID	RIA	Guinea (Ministry of Health), Mali (Center for Vaccine Development)	30	2,339,774	1,000,000
UK.PS.2015.1	MRC Research Grants	CC	RIA	TBD	TBD	3,600,000	3,600,000
UK.PS.2015.2	MRC Global Health Trials Programme	CC	RIA	TBD	TBD	1,800,000	1,800,000
UK.PS.2015.3	Joint Global Health Trials scheme	CC	RIA	TBD	TBD	7,200,000	7,200,000
UK.PS.2014.4	MRC Fellowships	CC	TMA	TBD	TBD	1,200,000	1,200,000
UK.PS.2014.5	MRC/DFID African Research Leader (ARL) scheme	CC	TMA	TBD	TBD	1,800,000	1,800,000
UK.PS.2015.6	Health systems research (HSR) initiative	CC	RIA	Various	TBD	1,200,000	1,200,000
					Sub-Total European PSs	**37,077,274**	**25,079,167**
				African Partner States			
BF.PS.2015.1	Malaria Clinical Trial Platform management including staff salary equipment and reagent cost for malaria, meningitis and tuberculosis	MAL	CSA	Burkina Faso	12	169,152	169,152
BF.PS.2015.2	Training of 4 PhD in Basic and clinical research	CC	TMA	Burkina Faso	48	155,000	40,000
BF.PS.2015.3	Early detection of HIV in children	HIV	RIA	Burkina Faso	TBD	1,601	1,601

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
CM.PS.2015.1	Study under the topic: effectiveness of strategies and controls against malaria in pregnant women and children under five years in the region of the Far North	MAL	RIA	Cameroon – Public hospitals	6	45,000	45,000
GA.PS.2015.1	Evaluation of a short duration treatment regimen for MDR- TB patients in Gabon	TB	RIA	Gabon	24	189,895	94,947
GA.PS.2015.1	Antimalarial drug resistance in South East of Gabon	MAL	RIA	Gabon	12	60,883	60,883
GM.PS.2015.1	Population based approach to malaria research and control (ICEMR)	MAL	CSA	The Gambia	84	17,000	5,666
GM.PS.2015.2	Reactive household-based self-administered treatment against residual malaria transmission (RHOST)	MAL	CSA	The Gambia	40	293,000	100,000
GM.PS.2015.3	Monitoring the safety, coverage, efficacy and impact of Seasonal Malaria Chemoprevention programmes	MAL	CSA	The Gambia	27	38,000	19,000
ML.PS.2015.1	Comparative study of TB diagnostic tools (culture, genexpert, biomarkers) in children in Mali	TB	RIA	Mali (Centre d'Infectiologie Charles Mérieux de Bamako; Centre de Recherche et de Formation sur la TB et le VIH/ SIDA (SEREFO); National TB Control Program)	36	500,000	166,667

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
ML.PS.2015.2	Tolerance and Efficacy of short treatment regimen in MDR-TB patients in Mali	TB	RIA	Mali (Centre hospitalo-universiaire du Point G de Bamako (CHU Pt G); Institute National de la Recherche en Santé Publique (INRSP); Centre de Recherche et de Formation sur la TB et le VIH/SIDA (SEREFO); National TB Control Program)	24	275,000	137,500
MZ.PS.2015.1	Impact of HTLV infection on clinical presentation of tuberculosis patients with and without HIV infection	TB	RIA	Mozambique	24	56,260	28,130
MZ.PS.2015.2	Prevalence of pulmonary Tuberculosis in pregnant women in the District of Manhiça	TB	RIA	Mozambique	24	57,800	28,900
MZ.PS.2015.3	Maintenance of personnel and infrastructure allocated to clinical research	CC	CSA	Mozambique	12	400,798	400,798
NE.PS.2015.1	Scientific Writing Workshop And Support Of Research	CC	CSA	Republic of Niger	24	149,400	74,700
NE.PS.2015.2	Effectiveness And Tolerance Of Protocol Therapy Short 9 Months Of Treatment Of Multi Resistant Tuberculosis In Benin, Niger, Togo And Cameroon 2015-2017	TB	RIA	Republic of Niger	36	12,196	4,065
NE.PS.2015.4	Operational Study On The Use Of Diagnostic Rapid Test	MAL	RIA	Republic of Niger	3	10,671	10,671

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
SN.PS.2015.1	Pilot Study: evaluation of allergy-associated inflammatory responses as components of clinical manifestations of malaria.	MAL	RIA	Senegal (Department of Immunology, Faculty of Medicine, Pharmacy and Odontology, UCAD; Intensive Health care Unit, Hospital Principal Dakar; Immunogenetics Unit, Institut Pasteur de Dakar, Senegal)	24	40,000	20,000
TZ.2015.PS.1	Phase II trial of PfSPZ Vaccine Age de-escalation in Tanzanian adults and children	MAL	RIA	Tanzania (Ifakara Health Institute)	11	160,000	160,000
UG.PS.2015.1	The 7th Annual National Research Ethics Conference (ANREC) and a planned forum for the chairpersons of Institutional Ethics Committees	CC	CSA	Uganda	-	36,765	36,765
UG.PS.2015.2	The East African community health and science meeting	CC	CSA	Uganda	-	176,858	176,858
ZA.PS.2015.1	Clinical trials sites preparation for Africa-Europe HDTNET for Host-directed therapies trials for reduction of duration of TB	CC	RIA	South Africa; Zambia; Zimbabwe; Mozambique; Madagascar; Uganda; Kenya	36	3,800,000	1,266,666
ZA.PS.2015.2	Development of a better tolerated and more robust second-line antiretroviral regimen for HIV infection	HIV	RIA	South Africa	31	650,000	216,666
ZM.PS.2015.1	Developing Good Clinical Practice and Good Laboratory practice	CC	CSA	Zambia	60	200,000	40,000

Code	Activity Title	Keyword	Type of action	African countries (& legal entities) involved)	Duration of PSIA (in months)	Total Indicative PS commitment (€)	Planned disbursement in 2015 (€)
ZM.PS.2015.2	Improving diagnosis of TB in pregnant women	CC	RIA	Zambia; South Africa	48	70,000	17,500
ZM.PS.2015.3	Safety, Efficacy , tolerability and acceptability of IPTp-Euratesim compared to IPTp SP	MAL	RIA	Zambia; The Gambia	36	1,300,000	433,333
ZM.PS.2015.4	Artemisinin efficacy and resistance monitoring in border towns in Zambia	MAL	RIA	Zambia	24	600,000	300,000
					Sub-Total African PSs	**9,465,279**	**4,055.468**
					Grand Total European + African PS	**46,542,553**	**29,134,635**

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 2015, the indicative budget for administrative costs is as follows:

Table 16: Indicative budget for the administrative costs of the EDCTP Association for the implementation of the EDCTP2 programme in 2015.

Cost Category	Total
Personnel	1,340,000
Missions	310,000
Consumables and supplies	60,000
Service contracts (including non-recoverable taxes)	785,425
Total	**2,495,425**

In preparing the budget set out in the table below, it has been assumed that staff will spent 20% of their total time in the first eight months of 2015 (January–August 2015) and 35% of their time for the remaining four months (September–December 2015) on EDCTP2 activities equivalent to 9 fulltime FTE (25% of total staff projected headcount of 36). Obviously in reality the personnel cost of each funding programme (EDCTP2 and EDCTP1) will depend on the staff time spent on each programme as recorded on the timesheets.

Table 16b: Projected staff headcount by functional area

Functional area	2015
Senior Management (Directors)	4
Finance and General Administration	17
Operations (calls/grants)	9
North-North Networking	3
South-South Networking	1
Communications	2
Total	**36**

Apportionment of general administrative costs: general administrative costs, which includes office rental and utilities, for each of the EDCTP offices (the head office in the Hague and the liaison office in Cape Town) will be apportioned between funding programmes (EDCTP2 and EDCTP1) on the basis of suitable cost drivers (allocation key) as set out in the table below. The apportionment will also take into account whether the administrative costs are specific for the The Hague or the Cape Town Office, i.e. whether either the personnel costs for the The Hague office or the Cape Town office will be used as cost driver only:

General administrative cost item	Apportionment basis (cost driver)
Audit fees in relation annual statutory accounts	Amount of expenditure audited
Non-grant related postage charges	Actual Personnel costs of the relevant period (personnel time)
Office cleaning	Actual Personnel costs of the relevant period (personnel time)
Office utilities – electricity, water and gas	Actual Personnel costs of the relevant period (personnel time)
Equipment repairs and maintenance	Actual Personnel costs of the relevant period (personnel time)
Office rent (EDCTP offices in The Hague and Cape Town) and other hosting costs	Actual Personnel costs of the relevant period (personnel time)
Computers and other IT equipment	Actual Personnel costs of the relevant period (personnel time)
Office consumables & stationery	Actual Personnel costs of the relevant period (personnel time)
IT Support services	Actual Personnel costs of the relevant period (personnel time)

6. General Annexes[32]

List of countries and applicable rules for funding

Legal entities established in the following countries and territories will be eligible to receive funding through the EDCTP2 programme:[33]

- 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:[34] Anguilla, Aruba, Bermuda, Bonaire, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna.
- The countries associated to Horizon 2020. The latest information on which countries are associated, or in the process of association to Horizon 2020 can be found in the online manual.[35] As of 17 April 2015, the following countries are Associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland (partial association, see online manual[35]), Faroe Islands.
- The following sub-Saharan African countries:
  Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic People's Republic), Congo (Republic), Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Buissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

International European interest organisations[36] 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 relevant call text in this work plan.

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

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and an international organisation or a third country;
- When the EDCTP Association deems participation of the entity essential for carrying

32 The Supporting Information provided in this chapter is copying information provided in the General Annexes of the Work Programme 2014-2015 of Horizon 2020, unless the specificities of the EDCTP2 programme required an adaptation of the information to those specificities. Such EDCTP2-specific adaptions were required for section 6.1, 6.4, 6.5, 6.6, 6.7 and 6.10.

33 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.

34 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.

35 http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/international-cooperation_en.htm

36 These are international organisations, the majority of whose members are Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.

out the action funded through the EDCTP2 programme.

Standard admissibility conditions for grant proposals, and related requirements

1. To be considered admissible, a proposal must be:

- Submitted in the electronic submission system of EDCTP before the deadline given in the call for proposals;
- Readable, accessible and printable.

2. Incomplete proposals may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting information specified in the Call for Proposals or requested in the application form. The following supporting information will be required to determine the operational capacity, unless otherwise specified:

- A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed 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 for Proposals content;
- A list of up to five relevant previous projects or activities connected to the subject of the proposal with a summary of their major outputs;
- 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).

3. Proposals shall include a draft plan for the exploitation and dissemination of the results, unless otherwise specified in the Call for Proposals. The draft plan is not required for proposals at the first stage of two-stage procedures.

4. Character limits will apply to proposals. The limits will be clearly set out in the electronic submission system of EDCTP. If a submitted 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.

Standard eligibility criteria

All proposals must conform to the conditions set out in the EDCTP2 Basic Act and the Rules for Participation of Horizon 2020.

Furthermore, in this EDCTP2 annual work plan, the following conditions apply unless they are supplemented or modified in the topic description of the call for proposals (chapter 2).

A proposal will only be considered eligible if:

- its content corresponds, wholly or in part, to the topic description against which it is submitted;
- it complies with the eligibility conditions set out in the table below, depending on the type of action.

Table 17: Standard eligibility criteria per type of action

Type of Action	Eligibility criteria[37, 38, 39]
Research & Innovation Action (RIA)	At least three different 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 Participating State* or sub-Saharan African country.
Training & Mobility Action (TMA)	At least one legal entity established in Participating State* or sub-Saharan African country.

** The Participating States (European partner states) as defined in the EDCTP2 basic act2 are: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom.*

37 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.

38 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") shall apply for all actions under this Work Programme, including with respect to third parties receiving financial support in the cases where the respective action involves financial support to third parties by grant beneficiaries in accordance with Article 137 of the EU's Financial Regulation.

39 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 respective 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 shall be revised in the work plan.

Type of Actions: specific provisions and funding rates[40,41]

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.[42]

More specifically, 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,

40 Eligible costs for all types of action are in accordance with the EU's Financial Regulation and the Horizon 2020 Rules for Participation. In addition, as training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of research and innovation actions, applicants may include in their proposal such activity and the following corresponding estimated costs that may be eligible for EU funding:
i. Costs of delivering the training (personnel costs if the trainers are employees of the beneficiary or subcontracting if the training is outsourced);
ii. Accessory direct costs such as travel and subsistence costs, if the training is delivered outside the beneficiary's premises;
iii. Remuneration costs for the researchers attending the training, in proportion to the actual hours spent on the training (as personnel costs).

41 Participants may ask for a lower rate.

42 Excerpt from the General Annexes of the Horizon 2020 work programme 2014-2015.

institutions and sites in sub-Saharan Africa to conduct clinical trials and related research, including observational studies.

Funding rate: 100% of eligible costs

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.[43]

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

Funding rate: 100% of eligible costs

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% of eligible costs

Common principles applying to national programme activities (PSIAs)

The EDCTP2 basic act[2] stipulates that EDCTP2 activities may include national programme activities of Participating States that are not funded by the EDCTP2-IS (i.e. the EDCTP Association), including activities undertaken by public or private not-for-profit research organisations. Those activities included as so-called Participating States Initiated Activities (PSIAs) in the EDCTP2 Annual Work Plan shall be implemented in compliance with common principles to be agreed by the Participating States and the European Commission, taking into account the principles set out in EDCTP2 basic act[2], in Title VI of the Financial

43 Excerpt from the General Annexes of the Horizon 2020 work programme 2014-2015 (see also Rules for Participation of Horizon 2020, Article 2, point 7).

Regulation[44] and in the Rules for Participation of Horizon 2020[9], in particular the principles of equal treatment, transparency, independent peer review evaluation and selection.

The European Commission and the EDCTP Association on behalf of the Participating States have agreed to the common principles outlined below:[45]

Equal treatment

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

Transparency

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

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.

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.[46]

44 Financial Regulation: Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, OJ L 298, 26.10.2012, p. 1.

45 Annex 5 to the delegation agreement concluded between the European Commission and the EDCTP Association, which is the EDCTP2-IS, on 23 December 2014.

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

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

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.

Exploitation and dissemination of results

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

General Rules of Contest for EDCTP2 Prizes

Prizes awarded under the EDCTP2 programme (EDCTP2 prizes) will be implemented in compliance with Title VII of the Financial Regulation[45] and the Rules for Participation of Horizon 2020[9].

This section provides a general model for the rules of contest for EDCTP2 prizes.

Objectives pursued, Expected results and specific award criteria

Specified under the detailed description of the EDCTP2 Prize.

Arrangements and final dates for the registration of contestants, if required, and arrangements and final dates for the submission of entries

Required entry forms and deadlines for submission.

Amount of prize(s) including specific amount for each prize, if applicable

Specified under the detailed description of the EDCTP2 Prize.

Arrangement for the payment of the prize to the winner after its award

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.

Conditions for cancellation of the contest, if any

The EDCTP Association has the right to terminate the contest before its closing date without any obligation to indemnify contestants in case the objective of the contest has been achieved by a non-registered or non-eligible contestant.

The EDCTP Association has the right to decide not to award any prize if no entries are received or if no entries are to be awarded by the prize selection committee.

Conditions for participation

The contestant must not have received any other EDCTP2 prize before that is the subject of the current competition

Eligibility criteria

As already specified in the work plan, or, if the work plan only provides essential eligibility criteria, then specific eligibility criteria detailing the essential eligibility criteria shall be provided.

Exclusion criteria

Contestant will be excluded from participating in the competition if they fall under any of the following situations:[47]

The contestant:

a. is bankrupt or being wound up, is having his/her affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
b. has been convicted of an offence concerning professional conduct by a judgment of a competent authority, which has the force of res judicata;
c. has been guilty of grave professional misconduct proven by any means which the EDCTP Association can justify including by decisions of the European Commission and other EU bodies, the European Investment Bank and international organisations;
d. is not in compliance with all his/her obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which he/she is established, with those of the country of the authorizing officer responsible and those of the country where the action is to be implemented;
e. has been the subject of a judgement which has the force of res judicata for fraud, corruption, involvement in a criminal organization, money laundering or any other illegal activity, where such activity is detrimental to financial interests of the EDCTP Association or the EU;
f. is subject to an administrative penalty for being guilty of misrepresenting the information required as a condition of participation in a procurement procedure or another grant award procedure or failing to supply this information, or having been declared to be in serious breach of his/her obligations under contracts or agreements covered by the EU's budget.

Furthermore, contestants must:

g. have no conflict of interests in connection with the prize; a conflict of interests could arise in particular as a result of economic interests, political or national affinity, family, emotional life or any other shared interest;
h. inform the EDCTP Association, without delay, of any situation considered a conflict of interests or which could give rise to a conflict of interests;
i. have not been granted, and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to the award of the prize.

In case of award of a prize, the following evidence shall be provided upon request

47 Contestants which are in one of the situations referred to in Article 106(1) and Articles 107, 108 and 109 of the Financial Regulation are excluded from participating in the contest.

and within the time limit set by the EDCTP Association:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the contestant is a legal person and the national legislation of the country in which the contestant is established does not allow the provision of such documents for legal persons, the documents should be provided by natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the contestant.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the country concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the contestant is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in the two paragraphs above is not issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his/her country of origin or provenance.

If the contestant is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the EDCTP Association.

Sole liability of contestants

The EDCTP Association may not be held responsible for any claim relating to the activities carried out in the framework of the contest by the contestant. The EDCTP Association shall not be held liable for any damage caused or sustained by any of the contestant, including any damage caused to third parties as a consequence of or during the implementation of the activities related to the contest.

Checks and audits

The contestants accept that, if they are awarded a prize, the EDCTP Association, the European Commission, OLAF and/or the Court of Auditors may carry out checks and audits in relation to the contest and the received prize.

Publicity

Publicity by the winner of the prize

The contestants accept, if they are awarded a prize, to 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 and

(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".

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

For the purposes of its obligations, the winner 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 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 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 public deliverables as well as any other material, such as pictures or audio-visual material that it receives from the winner of the prize (including in electronic form).

The EDCTP Association will publish the name of the winner, its locality, the amount of the prize and its nature and purpose. The contestant may request the EDCTP Association to waive such publication if disclosure risks threatening its security and safety or harm to his/her 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.

Processing of personal data

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 is registered under the "Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)" and complies with the provisions of this Act (dated 6 July 2000), which is based on Directive nr. 95/46/EG (PbEG L 281) and the General Data Protection Regulation, dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD). Application submissions 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. These data may be used to compile lists of award holders, which will be made publicly available.

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

Contestants may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the Controller, via the contact person announced in the rules of the contest. Please send in addition a scanned copy of your letter to the email address announced in the rules of the contest.

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

The EDCTP Association shall be authorized to publish, in whatever form and on or by whatever medium, the following information:

- The name of winner(s);
- The locality of winner(s)
- The general purpose of the activities of the winner(s) in relation to the award of the prize, in the form of the summary provided by the winner(s);
- The amount of the prize awarded.

Applicable law and competent jurisdiction

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

If international organizations are eligible, this general rule may be complemented by the special conditions proposed in the model grant agreement on dispute settlement - arbitration and applicable law.

Dissemination and exploitation obligations

Obligations regarding dissemination of results laid down in Title III of the Rules for Participation of Horizon 2020[9] apply, as well as any additional rules provided in the EDCTP2 annual work plan.

Evaluation of proposals submitted to EU-funded calls

Selection criteria

1. Financial capacity: In line with the EU's Financial Regulation and the Rules for Participation of Horizon 2020. At the proposal stage, coordinators will be invited 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 meet the selection criterion related to operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).

Award criteria

Experts will evaluate proposals on the basis of the criteria 'excellence', 'impact' and 'quality and efficiency of the implementation'. 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 for proposals. For all applications involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Table 18: Award criteria per type of EU-funded actions

Type of Action	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 extent to which the outputs of the proposed work should contribute at the European, African and/ or International level to:	The following aspects will be taken into account:
All Types of Actions	**Fit with the scope and objectives of the EDCTP2 programme and the call topic description.** **Importance, relevance and clarity of the objectives.** **Credibility of the proposed approach.**	**The expected impacts listed in the work plan under the relevant topic.** **Likelihood to result in major advances for the field.**	Coherence and effectiveness of the proposed work, including appropriateness of the allocation of tasks and resources. Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. 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. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. Complementarity of the participants within the consortium and gender balance among consortium members (when relevant). Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).

Research & Innovation Actions (RIAs)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now.** Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.**	**Advancing the clinical development of new and improved products**. Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results. **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.** Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).
Coordination & Support Actions (CSAs)	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. 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. Support from and relationships with the host institutions.
Training & Mobility Actions (TMAs)	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 institution. 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 institution to support the fellowship project. Intention of the fellow's home institution to develop and commit to a career post-fellowship or re-integration plan.

Note:

Unless otherwise specified in the topic description of the call for proposals (chapter 2):

a. 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.
b. 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 highlighted above in bold will be considered.
   The threshold for each individual criterion will be 4. However, for the EDCTP-TDR Clinical research and development fellowships all three evaluation criteria will be applied in both stages, and each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.
c. For the evaluation of first-stage proposals under a two-stage submission procedure, an arithmetic average (i.e. median or mean value) of the individual scores may be taken as the consensus score. The consensus report will consist of a collation of the individual evaluation reports or extracts from them.

Priority order for proposals with the same score

Unless otherwise specified in the Call for Proposals (chapter 2), the following method will be applied.

As part of the evaluation by independent experts, a 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 topic description of the call for proposals.

If necessary, the 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 for proposals. The following approach will be applied successively for every group of proposals that have achieved equal scores and therefore require prioritisation, starting with the highest scored group, and continuing in descending order:

1. Proposals that address topics not otherwise covered by more highly-ranked proposals will be considered to have the highest priority.
2. These proposals will themselves be prioritised according to the scores they have been awarded for the criterion excellence. When these scores are equal, priority will be based on scores for the criterion *impact*.
   If necessary, any further prioritisation will be based on the following factors, in order: gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the proposed work; leverage of funding from third parties; relative number of sub-Saharan African countries involved; quality of the networking activities.
   If a distinction still cannot be made, the panel 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.
3. The method described in point 2 will then be applied to the remaining proposals that have achieved equal scores in the group.

Budget flexibility

Budgetary figures given in this work plan are indicative. Unless otherwise stated, final budgets may vary following the evaluation of proposals.

The final figures may vary by up to 20% with respect to those indicated in this work plan for the following budgeted activities:

- Total expenditure for each call for proposals;
- Any repartition of the call budget 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;
- Each other individual action not implemented through calls for proposals;
- Other activities and administrative expenses of the EDCTP Association for implementing the EDCTP2 programme.

Financial support to third parties

Where this possibility is indicated under the relevant topic, proposals which foresee a financial support[48] to third parties, shall clearly detail the objectives and the results to be obtained and include at least the following elements:

- A closed list of the different types of activities that qualify for financial support;
- 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).

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

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

Co-labelling requirements

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

48 Article 137 of the Financial Regulation

Colophon

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