EDCTP

The power of sharing science

EDCTP2 work plan 2018

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Important notice: This annual work plan covers 2018 and describes planned activities under the EDCTP2 programme in 2018.

It has been approved by the EDCTP Association General Assembly on 9 May 2018. The European Commission approved it on 30 May 2018 following the positive outcome of its external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. The EDCTP Association Board approved it on behalf of the EDCTP Association General Assembly on 1 June 2018.

Supported by the European Union

About EDCTP

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

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

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

Contents

1. Introduction

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

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

The EU's financial contribution shall be conditional upon the following: (a) the implementation by the EDCTP2 Implementation Structure ("the EDCTP Association") of the objectives and activities of the EDCTP2 programme as set out in annexes 1 and 2 of the EDCTP2 Basic Act; (b) the maintenance of an appropriate and efficient governance model for the EDCTP2 Programme as set out in annex 3 of the EDCTP2 Basic Act; (c) the compliance by the EDCTP Association with the reporting requirements set out in 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 as referred to in Article 3.1 (point e) of the EDCTP2 Basic Act.[2]

The EDCTP Association (hereafter "EDCTP") is legally established as an Association under Dutch law in the Netherlands[4] . The Association currently counts 30 Partner States (PS) as full and equal members: 14 European and 16 African countries[5,6].

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

1.1. Scope of the EDCTP2 programme

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

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

The drive to achieve the Millennium Development Goals (MDGs)[10] provided important impetus for the creation of EDCTP. Equally, the EDCTP2 programme shall contribute to the United Nations' Sustainable Development Goals (SDGs)[11] and is a major commitment of its 30 Partner States and the EU to that end. While the promotion of health is only one of the 17 goals (SDG3: 'Ensure healthy lives and promote well-being for all at all ages'), the achievement of the other SDGs is affected by or depends significantly on good health of people, including vulnerable and neglected ones. Improved health and its attendant economic benefits will contribute to multiple social and economic goals.

1.2. Activities of the EDCTP2 programme

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

EU-funded actions are evaluated, selected and funded in line with the Rules for Participation (RfP)[12] of Horizon 2020 following open Calls for Proposals that are centrally managed by the EDCTP Association, whereas PSIAs are funded following national evaluation, selection and granting processes that are implemented by one or several PSs in line with common principles agreed between the EDCTP Association, on behalf of the PSs, and the European Commission (section 6.5). In order to support activities of strategic reach with a high expected impact but requiring a critical scale of resources, the EDCTP Association will partner with third countries, or their scientific and technological organisations and agencies; with international organisations; or, with other third parties to jointly fund activities.[13,14]

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

The activities of the EDCTP2 programme are supported along three distinct types of actions[16]: i) Research & Innovation Actions (RIA), ii) Coordination & Support Actions (CSA), and iii) Training & Mobility Actions (TMA). These types of actions are described in more detail in section 6.4.

1.3. Implementation of the EDCTP2 programme

The EDCTP2 programme is implemented by the EDCTP Association on the basis of annual work plans and a multi-annual strategic business plan.[17]

The present EDCTP2 annual work plan 2018 has been developed in compliance with the objectives and provisions set out in the EDCTP2 Basic Act, and following a comprehensive consultation process, involving multiple stakeholders. The consultation process has included meetings and workshops with academic researchers, pharmaceutical industry, product development partnerships (PDPs), charities and foundations, international organisations and

health research funders outside of Europe and Africa. It also included thematic stakeholder meetings on the different areas within the scope of the EDCTP2, including lower respiratory diseases and diarrhoeal diseases (2016) and co-infections and co-morbidities (2017), resulting in specific recommendations for the EDCTP2 programme[18]. In addition to these events, the EDCTP Association has conducted studies and assessments with regards to the outcome and impact of activities funded under the first EDCTP programme. Within the objective of cooperation with international development assistance initiatives, the EDCTP Association has also taken into account the recommendations issued by relevant initiatives of the World Health Organization (WHO).

The EDCTP2 annual work plan 2018 provides information about EU-funded Calls for Proposals in 2018 (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 2018 also contains an overview of non-EU funded PSIAs in 2018 (Chapter 4). The PSIAs in the current EDCTP2 annual work plan are all funded and implemented directly by one or more PSs. They are major contributions (in-kind) of the PSs to the EDCTP2 programme and constitute an integral part of the EDCTP2 programme.

In accordance with the EDCTP2 Basic Act, the draft EDCTP2 annual work plan 2018 was subject to an external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. This evaluation was organised by the European Commission services and involved an international peer review panel composed of four independent senior research managers.

EDCTP acknowledges financial contributions for the implementation of the EDCTP2 programme and its 2018 calls from the EU and the governments of the following countries: Germany, the Netherlands, Portugal, Spain, Sweden and the United Kingdom. These are summarised in budget overview tables 2 and 16.

EDCTP also acknowledges contributions for the implementation of the EDCTP2 programme and its 2018 calls from the following organisations: the African Research Excellence Fund (AREF) and members of the European Federation of Pharmaceutical Industries and Associations (EFPIA). See Table 3 on the budgeted contributions to activities of the EDCTP2 programme in 2018 by Third Parties (TPs) and Third Countries (TCs).

1.4. Budget overview tables

Table 1. Overview of budgeted contributions to activities of the EDCTP2 programme in 2018 by the European Union (EU), European and African Partner States (PSs) and Third Parties (TPs)/Third Countries (TCs)

		2018 Budgeted Contributions (in EUR)			Budgeted Costs (in €)
Activities		**EU***	**PSs***	**TPs/TCs****	**Total**
EU-funded activities	Calls for Proposals implemented by the EDCTP Association	€ 104.454.200	€ 13.445.800	€ 0	€ 117.900.000
	Other Activities implemented by the EDCTP Association	€ 5.210.000	€ 0	€ 0	€ 5.210.000
	Administrative costs of the EDCTP Association	€ 5.334.020	€ 384.200	€ 0	€ 5.718.220
Sub-Total Implementation		**€ 114.998.220**	**€ 13.830.000**	**€ 0**	**€ 128.828.220**
Non-EU funded activities	Non-EU funded PSIAs implemented by PSs	€ 0	€ 113.583.434	€ 0	€ 113.583.434
	New activities including Calls for Proposals managed by EDCTP	€ 0	€ 1.055.848	€ 900.000	€ 1.955.848
Sub-Total non-EU funded activities		**€ 0**	**€ 114.639.282**	**€ 900.000**	**€ 115.539.282**
Total Budget		**€ 114.998.220**	**€ 128.469.282**	**€ 900.000**	**€ 244.367.502**

**Details in tables 2 and 16.*
***Details in table 3.*

Table 2. Detailed overview of budgeted contributions to activities of the EDCTP2 programme in 2018 by the European Union (EU), and European and African Partner States (PSs)

	2018 Budgeted contributions (in EUR)				
	Cash contributions to be managed by EDCTP*	**New activities, including Calls for Proposals managed by EDCTP****	**PSIAs***/ In-kind****	**Total in 2018**	**Total 2014-2018**
European Union (EU)					
European Commission (EC)	114.998.220	-	-	114.998.220	476.828.313
Sub-Total EU	114.998.220		-	114.998.220	476.828.313
Participating States** (European Partner States)**					
Austria (AT)	0	304.000	0	304.000	3.614.000
Denmark (DK)	0	0	200.000	200.000	7.705.992
Finland (FI)	0	0	200.000	200.000	1.787.500
France (FR)	0	0	16.162.660	16.162.660	76.147.747
Germany (DE)	4.000.000	0	31.300.000	35.300.000	129.036.056
Ireland (IE)	0	0	0	0	20.132.546
Italy (IT)	0	0	1.600.000	1.600.000	4.525.000
Luxembourg (LU)	0	0	0	0	2.300.000

Netherlands (NL)	100.000	0	0	100.000	17.348.918
Norway (NO)	0	0	7.732.237	7.732.237	28.314.847
Portugal (PT)	200.000	0	0	200.000	2.180.627
Spain (ES)	250.000	6.000	432.653	688.653	7.083.970
Sweden (SE)	2.500.000	0	12.179.324	14.679.324	75.737.567
United Kingdom (UK)	6.780.000	0	42.237.746	49.017.746	423.973.146
Sub-Total EU	**13.830.000**	**310.000**	**112.044.620**	**126.184.620**	**799.887.916**
African Partner States					
Burkina Faso (BF)	0	0	0	0	525.753
Cameroon (CM)	0	0	0	0	1.030.839
Congo (CG)	0	0	0	0	309.556
Gabon (GB)	0	0	0	0	812.330
The Gambia (GM)	0	0	0	0	682.000
Ghana (GH)	0	0	0	0	2.984.227
Mali (ML)	0	606.148	864.339	1.470.487	2.606.687
Mozambique (MZ)	0	0	95.496	95.496	626.854
Niger (NE)	0	0	0	0	172.267
Nigeria (NG)	0	0	0	0	0
Senegal (SN)	0	0	506.379	506.379	796.379
South Africa (ZA)	0	133.000	0	133.000	26.720.846
Tanzania (TZ)	0	0	0	0	558.300
Uganda (UG)	0	6.700	72.600	79.300	793.051
Zambia (ZM)	0	0	0	0	8.973.000
Sub-Total Africa	**0**	**745.848**	**1.538.814**	**2.284.662**	**47.592.089**
Sub-Total EU+Africa	**13.830.000**	**1.055.848**	**113.583.434**	**128.469.282**	**847.480.005**
Grand Total	**128.828.220**	**1.055.848**	**113.583.434**	**243.467.502**	**1.324.308.318**

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

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

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

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

******Nigeria and Ethiopia became a member of the EDCTP Association in September and November 2017 respectively, after the deadline for submission of PSIAs and therefore were not requested to submit contributions for the 2018 work plan.*

Table 3. Overview of budgeted contributions to activities of the EDCTP2 programme in 2018 by Third Parties (TPs) and Third Countries (TCs)

Third Parties / Third Countries	Budgeted contributions by TPs/TCs (in €)		
	Cash	In-kind	Total
EFPIA members	-	500.000	500.000
AREF	-	400.000	400.000
Grand total	**-**	**900.000**	**900.000**

2. EU-funded Calls for Proposals

2.1. Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2018:

2.1.1 Strategic action for overcoming drug resistance in malaria

Challenge

There is a need to develop safe and effective drugs that can be used to progress the malaria elimination agenda, and with a particular emphasis on pregnant women, infants and children. Current treatment of malaria is highly dependent on artemisinin-based combination therapies (ACT), but emerging resistance has highlighted the need to develop a broader portfolio of antimalarial drugs, including new or repurposed non-ACT drugs for chemoprevention and treatment as well as long-acting products with transmission blocking potential. Clinical trials to support the product approval process for new drugs are often large in scale, complex and prohibitively expensive for a single funder. Coordination and collaboration between partners and funders is therefore essential to leverage sufficient expertise, resources and investments for accelerating the development of new or improved products and maximise the impact of research investments.

Scope

The purpose of this Call for Proposals is to support one large-scale strategic action (clinical research activities) that is part of a bigger portfolio of clinical trials with the capacity to develop new and diverse antimalarial drugs against *Plasmodium falciparum* and/or *Plasmodium vivax*, including combination therapies that may be used for treatment or chemoprevention of malaria in sub-Saharan Africa. The proposed action shall evaluate and compare novel drug candidates or drug combinations, develop criteria for early selection/deselection of candidates and speed up drug development through innovative trial designs that allow for a reduction in subject numbers and rapid generation of conclusive results. Proposals should present an attractive R&D portfolio and include one or more clinical trials (phase I to III) with appropriate consideration of relevant target populations, including pregnant women, infants and children. The proposed study(ies) should be conducted in sub-Saharan Africa but may form part of a larger trial that is conducted globally.The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP)[19] regulatory and ethical standards. Furthermore, the proposal must clearly document the consortium's proven capacity to bring a medicinal product to market.

Proposals for a strategic action must also present the broader description of the portfolio of clinical trials/studies in their entirety, including details of the trial(s) for which EDCTP funding is requested and the component(s) that are to be financed from other sources. Proposals should make a clear distinction between the broader context of the portfolio of studies as opposed to the proposed action itself (i.e. the specific clinical trials or part of trial to be funded as a strategic action by the EDCTP Association). The portfolio must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders, such as EDCTP2 Participating States and/or third parties.

The maximum amount requested from EDCTP Association shall not exceed EUR 22 million

to be matched by an eaqual or greater financial contribution from other funders. EDCTP considers that proposals with a total cost of between EUR 25 and 50 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals for a large-scale strategic action of between 48 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact

The action funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to achieve rapid advances in the development of new or improved anti-malarial drugs or drug combinations. Proposals that leverage major relevant financial contributions from funders other than the EDCTP Association will be considered to have a higher impact.

The action should have the potential to achieve maximum impact in the field and to make a significant contribution to the objectives of the EDCTP2 programme, and in particular:

- contribute towards combatting drug resistance through development of new or improved antimalarial products
- lead to the advancement of new drugs and/or drug combinations, with the aim of registration of new drug(s) and/or drug combinations for treatment and prevention of malaria in sub-Saharan Africa and globally
- contribute to the reduction of malaria mortality and morbidity in sub-Saharan Africa, particularly in pregnant women, infants and childrenand thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages'

Table 4. Supporting information for the Call for Proposals 'Strategic action for overcoming drug resistance in malaria'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs of the EDCTP2-funded part of the action;
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Expected number of grants	1
Submission and evaluation procedure	Single stage application procedure. Full proposals must be submitted by the deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[20]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.2 Strategic action for the comparison, selection and development of malaria vaccine candidates

Challenge

An effective and affordable malaria vaccine would present a major tool towards the eradication of malaria. The recently licensed malaria vaccine for human use (RTS,S) is an important step in this direction, but it is crucial to develop new and more effective second generation vaccines superior to RTS,S. A number of promising second generation vaccine candidates are currently under clinical or advanced preclinical development. Clinical trials to support the product approval process are often large in scale, complex and prohibitively expensive for a single funder. Coordination and collaboration between partners and funders is therefore essential to leverage sufficient expertise, resources and investments for accelerating the development of new or improved products and maximise the impact of research investments

Scope

The purpose of this Call for Proposals is to support support one large-scale strategic action (clinical research activities) that is part of a bigger portfolio of clinical trials with the capacity to compare and select the most promising malaria vaccine candidates, and manage their progress through clinical development. This should be achieved by establishing an objective set of stage-gate criteria that can be used for comparing and evaluating a diverse set of vaccine candidates developed by different research groups, with the aim of bringing them together in a joint portfolio.

Proposals should include one or more clinical trials (phase I to III), and may also include detailed analyses of host responses to advance the understanding of mechanisms of reactogenicity (safety), immunogenicity and/or efficacy. The consortium should incorporate the latest innovations and advances in clinical trial design and research methods in order to accelerate vaccine development, achieve rapid results, reduce subject number and ensure cost-effective use of available resources.

Proposals should include details of the target product profile for the vaccine candidate making reference to the Malaria Vaccine Technology Roadmap[21] and to the WHO Preferred Product Characteristics for Malaria Vaccines[22], including details of the indication, target populations, desired safety and efficacy. The product profile should have the ambition of selecting vaccine candidates with a superior safety and efficacy profile, as demonstrated through published clinical study reports or publications, in comparison with the existing RTS,S vaccine.

Full details of the clinical product development plan, including specific go/no-go criteria must be included in the proposal, as well as specific plans for the regulatory approval process and access strategy for patients in low-resource settings. The proposed study(ies) should be conducted in sub-Saharan Africa but may form part of larger trial that is conducted globally. The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP)[23] regulatory and ethical standards. Furthermore, the proposal must clearly document the consortium's proven capacity to bring a medicinal product to market.

Proposals are expected to incorporate activities to enhance the capacity of existing clinical trial sites and/or develop new trial sites in sub-Saharan Africa for the conduct of vaccine trials. Successful applicants will be requested to coordinate their activities with other ongoing EDCTP and H2020 funded actions of relevance to malaria vaccine development.

Proposals for a strategic action must also present the broader description of the portfolio of

clinical trials/studies in their entirety, including details of the trial(s) for which EDCTP funding is requested and the component(s) that are to be financed from other sources. Proposals should make a clear distinction between the broader context of the portfolio of studies as opposed to the proposed action itself (i.e. the specific clinical trials or part of trial to be funded as a strategic action by the EDCTP Association). The portfolio must be of a sufficient scale and ambition to justify EDCTP support in combination with financial support from other funders, such as EDCTP2 Participating States and/or third parties.

The maximum amount requested from EDCTP Association shall not exceed EUR 18 million to be matched by an eaqual or greater financial contribution from other funders. EDCTP considers that proposals with a total cost of between EUR 20 and 40 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals for activities of between 48 and 60 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact

The action funded under this Call for Proposals should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to compare multiple vaccine candidates and achieve rapid advances in the development of new malaria vaccines. Proposals that leverage major relevant financial contributions from funders other than the EDCTP Association will be considered to have a higher impact.

The large-scale strategic action should have the potential to achieve maximum impact in the field and to make a significant contribution to the objectives of the EDCTP2 programme. In particular, the large-scale, strategic action should:

- lead to the advancement of vaccine candidates through the development pipeline towards registration, leading to more effective prevention and clinical management of malaria in sub-Saharan Africa
- contribute to the reduction of malaria mortality and morbidity in sub-Saharan Africa and thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages'.

Table 5. Supporting information for the Call for Proposals 'Strategic action for the comparison, selection and development of malaria vaccine candidates'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs of the EDCTP2-funded part of the action
Expected number of grants	1
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs s listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[24]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.3 Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

Challenge

Co-infections with several pathogens are frequent in sub-Saharan Africa and represent an important public health problem in many areas due to accelerated and/or complicated disease progression, resulting in increased mortality and morbidity. These co-infections can result in unique challenges in treatment and prevention of disease, including increased drug toxicities and/or changes in efficacy of interventions. The rise in incidence of non-communicable diseases (NCDs) in sub-Saharan Africa and the necessity for long-term management of some poverty-related diseases and NCDs, often concurrently, adds to these complexities. There is therefore an urgent need for research that leads to advances in the development of new/improved products for the effective prevention, treatment and management and prevention of co-infections and co-morbidities.

Scope

The purpose of this Call for Proposals is to support actions that lead to improvements in the prevention, treatment and/or clinical management of co-infections and co-morbidities in sub-Saharan Africa. Proposals must include at least one infection within the EDCTP2 remit[25]. Proposals on co-infections and co-morbidities other than those involving HIV/AIDS are also encouraged.

Consortia should incorporate the latest innovations and advances in trial design and research methods in order to evaluate promising interventions. Proposals should include one or more clinical trial(s) to be conducted in sub-Saharan Africa. The clinical trial(s) must be supported by an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP)[26] regulatory and ethical standards.

Stand-alone epidemiological studies are outside the scope of this call. Proposals on diagnostics are also outside the scope of this call, but may be relevant for the separate call under this annual work plan on "Diagnostic tools for poverty-related diseases".

The EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 2.0 and 4.0 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

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

Expected impact

Projects funded under this Call for Proposals should:

- contribute towards the reduction of the number of cases of co-infections and co-morbidities in sub-Saharan Africa and thus contribute to achieving SDG 3 'Ensure healthy lives and promote well-being for all at all ages'
- advance products through the product development pipeline, and/or provide evidence to support label extension and/or be in line with EDCTP2's strategic research agenda to be considered as having a higher impact.[27]

Table 6. Supporting information for the Call for Proposals 'Advances in product development for the effective prevention, treatment and management of co-infections and co-morbidities'

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	4-7
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[28]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.4 Vaccines for diarrhoeal diseases or lower respiratory tract infections

Challenge

Vaccines have contributed enormously towards the elimination of diseases, including the control of infectious diseases in low resource settings. Development of vaccines against diarrhoeal diseases or lower respiratory tract infections is therefore one of the preferred strategies to reduce the high mortality and morbidity of these diseases. While investment in clinical development of vaccines for diarrhoeal diseases and lower respiratory tract infections has become more substantial, additional resources are needed to support clinical trials for these vaccine candidates in sub-Saharan Africa.

Scope

This Call for Proposals will support clinical trials that can accelerate the development of vaccines for diarrhoeal infections and lower respiratory tract infections in sub-Saharan Africa.

Proposals should include one or more clinical trials (phase I to III) in sub-Saharan Africa for vaccine candidates towards one or more of the following pathogens:

- Diarrhoeal diseases: Shigella and/or enterotoxigenic E. coli (ETEC)
- Lower respiratory tract infections: Respiratory Syncytial Virus (RSV) or Group B streptococcus (GBS).

Proposals should describe the target product profiles; particularly indication, target populations, safety and/or efficacy, and describe how the candidates contribute to the global product development pipeline for the disease.

Proposals may also include detailed analyses of host responses to advance the understanding of mechanisms of reactogenicity (safety), immunogenicity and/or efficacy. Proposals should aim to incorporate the latest innovations and advances in clinical trial design and research methods that allow for rapid results, cost-effective use of available resources and reduction in subject numbers.

Full details of the clinical product development plan, including specific go/no-go criteria must be included in the proposal, as well as specific plans for the regulatory approval process and access strategy for patients in low-resource settings. The clinical trial(s) must be supported by

an appropriate regulatory approval and access strategy and/or include plans for uptake into policy and practice at national or international level. The proposed clinical trial(s) must be conducted to International Council on Harmonisation – Good Clinical Practice (ICH-GCP)[29] regulatory and ethical standards. Proposals should incorporate activities that enhance the capacity of existing trial sites and/or develop new trial sites in sub-Saharan Africa for the conduct of regulatory-standard vaccine trials.

EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 5 and 10 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

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

Expected impact

Proposals that leverage major relevant financial contributions from funders other than the EDCTP Association will be considered to have a higher impact.

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- contribute towards the reduction of the burden of diarrhoeal diseases or lower respiratory tract infections in sub-Saharan Africa
- lead to the advancement of vaccine candidates along the product development pipeline.

Table 7. Supporting information for the Call for Proposals 'Vaccines for diarrhoeal diseases or lower respiratory tract infections'

Type of action	Research and Innovation Actions (RIA)
Funding level	100% of eligible costs
Expected number of grants	2-4
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply.
Submission and evaluation procedure	Single stage application procedure. Full proposals must be submitted by the deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[30]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.1.5 Diagnostic tools for poverty-related diseases

Challenge

Disease diagnosis in sub-Saharan Africa is highly challenging, as the population has limited access to health care systems. Early and rapid diagnosis of poverty-related diseases (PRDs)[31] offers the best opportunity for patients to receive timely and appropriate treatment, but adequate diagnostic tools are not readily available because of a lack of drive to develop and deploy them in disease-endemic countries. In addition, co-infections with several pathogens are frequent in many populations and represent further challenges in the diagnosis of many

PRDs. There is therefore a clear need for the development and uptake of rapid, accurate, cost-effective, scalable and field-friendly diagnostic tools.

Scope

Projects should focus on validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for the detection of any of the PRDs, including co-infections. The proposed tools and technologies should improve the performance of diagnosis, prediction, monitoring, intervention or assessment of therapeutic response, with a significant impact on clinical decision and health outcomes. Proposals should focus on late stage development (e.g. evaluation and/or demonstration phase trials) or implementation studies in sub-Saharan Africa. Diagnostic algorithms to detect multiple infections are also welcome. Additionally, proposals should provide detailed plans for the uptake of the diagnostic tools and technologies upon successful completion of the project, including engagement with WHO or other relevant policy makers as well as plans for product registration (i.e. CE mark).

Proposals focused entirely on early-stage, laboratory-based studies using biobanked samples are outside the scope of this call. Priority will be given to point-of-care diagnostics for use in resource-limited settings.

The EDCTP considers that proposals requesting a contribution from the EDCTP2 of between EUR 1 and 3 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

EDCTP considers that proposals of between 24 and 48 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for activities of a different duration.

Expected impact

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- lead to improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression and therapeutic response
- contribute towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.
- contribute to reduce infections by key antimicrobial resistant microorganisms in humans as recommended by the Global Action Plan Against Antimicrobial Resistance[32] and by the European Action Plan Against Antimicrobial Resistance (AMR)2017[33]
- be in line with EDCTP2's strategic research agenda to be considered as having a higher impact.[34]

Table 8. Supporting information for the Call for Proposals 'Diagnostic tools for poverty-related diseases'

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	6-12
Additional eligibility conditions	The standard admissibility (section 6.2) and eligibility (section 6.3) conditions apply

Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[35]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

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

Proposals will be invited for the following topics in 2018:

2.2.1 Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems

Challenge

Universal health coverage is paramount to all the health-related SDGs. The most significant impediments to ensuring this achievement are the incremental challenges in providing access to good quality, effective, preventive and curative products to all populations within a wide range of existing health systems. Currently, health systems in poverty-related diseases (PRDs) endemic areas in sub-Saharan Africa are either weak or not adequately prepared for delivery and uptake of new or improved medical interventions. Concerted collaborative efforts are needed to strengthen the governance, personnel and infrastructures for uptake as well as effective delivery and monitoring of the implementation of existing and new cost-effective interventions. In collaboration with WHO AFRO and TDR, EDCTP has supported small grants to individual scientists for implementation research conducted between researchers and national disease programmes. EDCTP also supports product-focused implementation research on delivery and uptake of clinical research, which also provides new opportunities for partnerships in the field of health systems and optimisation of health services.

Scope

Despite the abundant evidence on the safety and efficacy of available life-saving medical interventions, there is little understanding of how to deliver these interventions effectively to populations that urgently need them. The purpose of this Call for Proposals is to support actions that will facilitate the translation of research results of medical interventions in policies and practices for national health programmes to strengthen health systems.

Proposals addressing the following activities are particularly encouraged:

- development of methodological tools for the successful translation of research againt PRDs into policies and practices for public health programmes. This includes health information system tools and analytics
- optimising strategies for widespread adoption and institutionalisation of research results within public health systems. This may entail the analysis of established methods and frameworks from the field of policy analysis to improve the understanding of the process of health policy development in a given sub-Saharan African country and international context
- successful adoption of one or more products coming out of previously-funded EDCTP grant(s) into national health policies.

Proposals should clearly define the activities and mechanisms to be used within the project, including details of any collaboration with national and/or public authorities, international organisations or commercial partnerships that will be established in order to achieve the expected impact.

The EDCTP considers that proposals requesting a contribution from the EDCTP2 of up to EUR 2.25 million would allow this specific challenge to be addressed appropriately.

EDCTP considers that proposals for activities of up to 60 months duration would allow this specific challenge to be addressed appropriately.

Expected impact

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- contribute to reduction of the burden of PRDs in sub-Saharan Africa
- lead to improved methodological tools that will strengthen the functionality, recognition and performance of national disease control programmes in sub-Saharan African countries.

Table 9. Supporting information for the Call for Proposals 'Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems'

Type of action	Coordination and Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	3-4
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this call for proposals: 1. Applications must include at least one legal entity hosting in sub-Saharan African countries[36] 2. The requested EDCTP contribution per action shall not exceed EUR 2.25 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for CSA listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[35]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.2.2 Ethics and regulatory capacities

Challenge

Whereas strides have been made towards establishment and strengthening of ethical review frameworks and medicines regulatory bodies in sub-Saharan Africa, targeted support is paramount to ensuring their continued development and consolidation within the ever-expanding R&D landscape in the region. Dedicated efforts are particularly required in countries where there are no or limited capacity for ethics review and national medicines regulatory bodies. The fortification of National Ethics Committees (NECs) and National Regulatory Authorities (NRAs) will allow for long-term development plans for regional regulatory harmonisation goals.

Scope

The purpose of this Call for Proposals is 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, as well as national and international collaboration. This scheme targets both NECs and 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.[37]

EU countries or countries associated with Horizon 2020 are encouraged to participate. Proposals involving regulatory agencies should clearly indicate how they align their functions and activities with the African Vaccine Regulators Forum (AVAREF) guidelines and standards. 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 NRAs and NECs will not be supported under this scheme. EDCTP considers that proposals for actions of between 24 and 36 months duration would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals for actions of a different duration.

Expected impact

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- strengthen the functionality, recognition and performance of NECs and NRAs in sub-Saharan African countries to ensure that the clinical trials meet the appropriate standards.
- contribute towards development of sustainable strategies for both NECs and NRAs.

Table 10. Supporting information for the Call for Proposals 'Ethics and regulatory capacities'

Type of action	Coordination and Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	10-15
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this call for proposals: 1. Applications must include at least one legal entity hosting NECs or NRAs in sub-Saharan African countries[36] 2. The requested EDCTP contribution per action shall not exceed EUR 300,000.

Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for CSA listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)[38]
Consortium agreement	Participants in actions resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2.2.3 Senior Fellowships

Challenge

The EDCTP programme has achieved gradual successes in developing a pool of highly qualified senior researchers in the field of poverty related diseases (PRDs) in sub-Saharan Africa. In order to continue growing the number of senior researchers, now more than ever, it is important to ensure there is continued support for the development and retention of senior fellows in the region. This in turn will ensure supportive mentorship structure, sustainable research capacity and provide a career pathway for researchers in sub-Saharan Africa.

Scope

The purpose of this Call for Proposals is to support capacity development of potential sub-Saharan African research leaders to become 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 world class research leaders in product development through clinical trials and closely related fields.
2. to equip senior researchers in training and mentoring junior researchers at host institutions in sub-Saharan Africa.

Proposals 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[39] . 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 and/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 plan 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.

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 senior fellow to direct and manage its funding for the duration of the fellowship. Fellows can only be funded once under this grant scheme. Fellows funded under this Call for Proposals will undergo a mid-term review that may result in discontinuation of the grant after three years in case of unsatisfactory performance.

Expected impact

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- enable fellows to:
  - develop into recognised research leaders and contribute to an increased pool of scientific knowledge and mentors in sub-Saharan Africa
  - develop the ability to design, plan and execute complex research programmes in collaboration with interdisciplinary team members and, where relevant, across sectors
  - 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, these grants will contribute to the generation of a critical mass of researchers and institutional research capacity in sub-Saharan Africa.

Table 11. Supporting information for the Call for Proposals 'Senior Fellowships'

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	10-12 grants
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals: 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity)[40]. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. The fellow must: a. be resident of or be willing to relocate to a sub-Saharan African country; b. be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and a minimum of five years' relevant research experience after the doctorate, or a medical doctor with a post-graduate qualification in a subject relevant to the EDCTP2 programme, and a minimum of five years' research experience after the post-graduate qualification; c. have a minimum of 5 first-author publications in international peer-reviewed journals; d. not have been funded under this fellowship scheme before.[41] 4. The requested EDCTP contribution per action shall not exceed EUR 500,000. 5. The maximum fellowship duration shall be 60 months.
Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3. The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.

Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary) with options for fellowships.[42]
Supplementary agreements	Applicant legal entities (host organisations) selected for funding from this Call for Proposals will be required to conclude an employment agreement with the fellow prior to the conclusion of the EDCTP2 grant agreement.

2.2.4 Career Development Fellowships

Challenge

As research in the field of poverty related diseases (PRDs) gains momentum, it is paramount to facilitate opportunities for early and mid-career scientists in sub-Saharan Africa to develop their clinical research skills. Providing possibilities for individual training would enable talented scientists to establish themselves as independent researchers and team leaders at host institutions in sub-Saharan Africa for long-term continuity and research ownership in the region.

Scope

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

The objectives are:

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

The proposed training should specifically enhance the ability of the fellow to design, plan and execute clinical biomedical and/or social science/ethics research projects within the scope of the EDCTP2 programme[31]. The proposed training should include an independent research activity and a clear description of the skills that will be acquired by carrying out the research. Fellows with training activities involving clinical trials and related studies must ensure that studies are appropriately designed and GCP-compliant. Individuals targeted by this Call for Proposals should have a track record of publications in peer-reviewed journals in their chosen area of research; a mentor who is an internationally recognised scientific leader working in sub-Saharan Africa; and a career development plan as part of the research proposal.

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

Projects funded under this Call for Proposals should:

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

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

Table 12. Supporting information for the Call for Proposals 'Career Development Fellowships'

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	16-18 grants
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals: 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity)[43]. 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity). 4. Fellows must: a. be resident of or be willing to relocate to a sub-Saharan African country; b. be either a graduate in a subject relevant to the EDCTP2 programme, with a PhD and up to five years' relevant postdoctoral research experience, or a medical doctor with up to five years' research experience; c. have at least one publication in an international peer-reviewed journal; d. not have been funded under this fellowship scheme before[44]. 5. The requested EDCTP contribution per action shall not exceed EUR 150,000. 6. The maximum fellowship duration shall be 36 months.
Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3. The host organisation (applicant) must provide a support letter confirming that the organisation is supportive of the proposed action and willing through its financial and administrative systems to enable the fellow to direct independently the proposed action and manage its funding for the duration of the fellowship.
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary)[42] with options for fellowships.
Supplementary agreements	Applicant legal entities (host organisations) selected for funding from this Call for Proposals will be required to conclude an employment agreement with the fellow prior to the conclusion of the EDCTP2 grant agreement.

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

Challenge

There is a need to provide aspiring African researchers the necessary tools for development in the form of structured mentorship support and stimulating research challenges. Such support can best be provided to early postdoctoral researchers by well-resourced and established institutions.. Africa accounts for 15-20% of the world's population and a disproportionately large share of disease burden, yet scientific publications by African researchers account for less than 2% of the total academic journal output.[45] As a result, it is imperative to enable African researchers to enhance their competitiveness for international funding opportunities early in

their careers while retaining them in Africa, working on Africa's health challenges and priorities.

Background

The capacity strengthening needs for health research in sub-Saharan Africa predominantly centre on lack of funding and limited systematic career development for researchers. In general, health research capacity building programmes in Africa and other low-income regions are more tailored to PhD candidates than to early-career postdoctoral scientists. Furthermore, international fellowship programmes typically focus on people who are already well-trained and who show exceptional talent and promise. The experience of global health research funders is that African scientists are under-represented and less competitive in local and international funding schemes: their science may be promising but the framing of research questions; the research design; the proposed analyses and mentoring structure are often not well developed.

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

Scope

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

The objectives of this call are:

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

The proposal for an AREF/EDCTP Fellowship Preparation Award must be submitted by the home organisation ('the applicant legal entity'). The grants will be awarded to the home organisation with the explicit commitment that this organisation offers appropriate conditions for the fellow to direct and manage their funding for the duration of the fellowship.

Successful applicants will use the funding for a 3 to 9 months placement at a centre of research excellence in Europe and sub-Saharan Africa contracted to host the fellow before spending 3-months re-entry re-integration period to the fellow's home (employing) institution, making a total training period of up to 12 months.

Expected Impact

Projects funded under this Call for Proposals should:

- contribute towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages')
- enhance the ability of fellows to design, plan and execute clinical biomedical and/or social science/ethics research proposals, and manage research relationships, within the scope of the EDCTP2 programme; and to generate competitive proposals into effective projects
- promote and enhance competitiveness for the next tier of fellowships and grants, such as (but not limited to) the EDCTP Career Development Fellowships
- lead to high impact research outputs by junior sub-Saharan African scientists who have not been supported by major funders previously
- foster new collaborations and mentorship opportunities for newly trained fellows
- equip the next generation of African researchers to sustain excellent and relevant research in sub-Saharan Africa, and engage as African citizens with African leaders, policy-makers and industries to drive forward evidence-based health improvement.

Table 13. Supporting information for the Call for Proposals 'Preparatory Fellowships – Joint Call with the Africa Research Excellence Fund (AREF)'

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	6 grants funded by EDCTP and 6 additional grants funded by AREF, subject to relevance to AREF's remit and terms and conditions being met)
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals: 1. The applicant must be an organisation with an established legal entity in sub-Saharan Africa (the applicant legal entity).[46] 2. The fellow must be employed or have guaranteed employment by the applicant legal entity (the home organisation) where they intend to remain working for a minimum of two years after the expiration of the grant. 3. Fellows must: a. be a post-doctoral scientist; b. have been awarded their doctorate within 3 years before submission deadline of the AREF-EDCTP Preparatory Fellowship application; c. have been either a PhD student or MD, who have been active researchers for up to three years following award of their doctorate; d. be resident of or be willing to relocate to a sub-Saharan African country; e. not have been funded under this fellowship scheme before.[47] 4. The requested EDCTP contribution per action shall not exceed EUR 70, 000. 5. Placements sought shall be for a period of at least 3 and up to 9 months, following which there will be a re-integration period of up to 3 months. The maximum fellowship duration shall be 12 months.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the fellow with a letter of support from the applicant legal entity (home organisation employing the fellow) by the indicated deadline. The letters of intent will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP and AREF in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 Basic Act. Up to thirty six successful candidate fellows will be shortlisted in the first stage and

	invited to a preparatory workshop led, organised and financed by AREF. For the second stage, the fellow and his/her home organisation (applicant legal entity) must submit a comprehensive training and development plan (including a draft re-integration plan) taking into account guidance provided in the workshop that will be evaluated by a panel of independent experts to select the 12 best proposals. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (Mono-beneficiary) with options for fellowships[42].
Supplementary agreement	The fellow's host organisation will have to sign a good practice charter prepared by EDCTP for EDCTP-funded fellows and by AREF for AREF-funded fellows. Host organisations need to meet a set of minimum requirements in order to qualify as prospective hosts: they should have some clinical research capacity, including staff who are GCP qualified or experienced, demonstrable ability to follow-up community involvement in clinical research, availability of institutional review board or national guidelines for conducting clinical research, GCLP compliant laboratories, adequate facilities with qualified staff, sufficient biostatistics capacity including its relevant computer technologies, experienced data management staff, ability to store some or all of samples locally and excellent IT platform. AREF requirements will be similar and appropriate to its remit, which includes non-clinical trial methods e.g. in laboratory and in social and behavioural sciences.

2.2.6 EDCTP Clinical Research and Product Development Fellowships

Challenge

Researchers from sub-Saharan Africa who are involved in clinical research activities have limited opportunities to acquire experience and develop skills outside an academic or public sector setting for conducting clinical trials that adhere to stringent regulatory standards. As a result, there are few researchers and clinical staff from sub-Saharan Africa assuming leading roles in clinical research for poverty-related diseases (PRDs) . The development of human research capacities through these fellowships will lead to enhanced and sustainable research competency in Africa on diagnostics, drugs and vaccines for PRDs, and support career progression and retention of researchers in sub-Saharan Africa.

Background

As part of EDCTP's capacity building efforts, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and EDCTP signed a Memorandum of Understanding (MoU) in January 2013 to implement a fellowship scheme that offers placements in European-based companies to individual researchers and clinical staff from sub-Saharan Africa working in the implementation of clinical trials.

This call will have an incremental effect on the number of individuals trained, resulting in an increased impact on research and development capacity in sub-Saharan Africa. The partnership will ensure synergies between the different parties involved, and will facilitate communication with researchers and clinical staff, pharmaceutical companies, clinical research organisations (CROs) and product development partnerships (PDPs).

Scope

The purpose of this Call for Proposals is to provide funding towards actions that aim to support researchers and key members of clinical trial research teams from sub-Saharan Africa to acquire specific skills in clinical research and development through placements in pharmaceutical companies, PDPs and CROs.

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 sub-Saharan Africa where they are currently working on clinical research and clinical trials in the scope of the EDCTP2 programme[31]. EDCTP supports research team members who are employed by a legal entity in a sub-Saharan African country. Placements are for a period of 15 months (3 months will be used to prepare for the placement), following which there will be a re-integration period of 6 months.

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

EDCTP will fund fellows employed by a sub-Saharan African legal entity (the fellow's home organisation and applicant legal entity) to be placed in European-based host organisations (pharmaceutical companies, CROs and PDPs) to train and develop specific clinical research skills of relevance to PRDs. The EDCTP2 grant includes funds for re-integration.

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

Expected impact

Projects funded under this Call for Proposals should:

- contribute to the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages'
- support the development of human resources and should promote high quality research and development in sub-Saharan Africa
- add significantly to the development of promising researchers from sub-Saharan Africa, in order to enhance and maximise their contribution in research institutions in sub-Saharan Africa, including training of peers
- contribute to strengthening collaboration between research institutions, researchers and clinical staff in sub-Saharan Africa, pharmaceutical companies, CROs and PDPs.

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

Type of action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs
Expected number of grants	10-15 grants
Additional eligibility conditions	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) conditions, the following additional eligibility conditions apply to this Call for Proposals: 1. The applicant must be a legal entity established in sub-Saharan Africa and must be the home organisation employing the fellow[48]. 2. The fellow must: a. be a post-graduate (MSc or PhD) or medical graduate with clinical and/or research experience in infectious diseases;

	b. have obtained their post graduate or medical graduate degree within 15 years of submission of the application; c. be a researcher or clinical staff member employed for the last 12 months in an organisation with a registered legal entity in sub-Saharan Africa, and who has been conducting clinical research activities in the scope of the EDCTP2 programme; d. provide a letter of support from the home organisation for the fellowship which is justifying the training needs of the fellow and explaining how the home organisation will benefit from the fellowship and how the reintegration of the fellow will be ensured[49]; e. not have been funded under this fellowship scheme before[50]. 3. Placements sought shall be for a period of 15 months, following which there will be a re-integration period of up to 6 months. 4. The requested EDCTP contribution per action shall not exceed EUR 100,000.
Submission and evaluation procedure	Single stage application procedure. A full proposal must be submitted by the indicated deadline. The full proposal should comprise of a proposed training plan reflecting the training needs of the applicant, a re-integration plan and the requested EDCTP contribution for the action. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation rules	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.7.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary)[42] with options for fellowships.
Supplementary agreements	Host organisations in actions resulting from this Call for Proposals will be required to sign up to the corresponding EDCTP charter, while fellows will be required to sign a letter of engagement with EDCTP prior to the conclusion of the EDCTP2 grant agreement.

2.3. Conditions for the Calls for Proposals

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

Table 15. Indicative timetable for Calls for Proposals in 2018

Type of Action	Call Topic (short titles)	Indicative dates by which calls will be open for applications		Indicative deadline for applications		Evaluation results are planned to be available on or before these dates	
RIA	Strategic action for overcoming drug resistance in malaria	Stage 1 – **4 July 2018**		Stage 1 – **30 October 2018** at 17:00:00 CET		Stage 1 – **14 March 2019**	
	Strategic action for the comparison, selection and development malaria vaccine candidates	Stage 1 – **4 July 2018**		Stage 1 –**1 November 2018** at 17:00:00 CET		Stage 1 – **14 March 2019**	
	Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities	Stage 1 – **4 July 2018**	Stage 2 – **21 December 2018**	Stage 1 –**18 October 2018** at 17:00:00 CET	Stage 2 – **28 March 2019** at 17:00 CET	Stage 1 – **21 December 2018**	Stage 2 – **25 July 2019**
	Vaccines for diarrhoeal diseases or lower respiratory tract infections	Stage 1 – **4 July 2018**		Stage 1 – **30 October 2018** at 17:00 CET		Stage 1 – **14 March 2019**	
	Diagnostic tools for poverty-related diseases	Stage 1 – **4 July 2018**	Stage 2 – **21 December 2018**	Stage 1 – **11 October 2018** at 17:00 CET	Stage 2 – **21 March 2019** at 17:00 CET	Stage 1 – **21 December 2018**	Stage 2 – **25 July 2019**
CSA	Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems	Stage 1 – **12 June 2018**	Stage 2 – **21 December 2018**	Stage 1 – **11 October 2018** at 17:00 CET	Stage 2 –**28 March 2019** at 17:00:00 CET	Stage 1 – **21 December 2018**	Stage 2 – **25 July 2019**
	Ethics and regulatory capacities	**2 August 2018**		**22 November 2018** at 17:00 CET		**16 April 2019**	
TMA	Senior Fellowships	**2 November 2018**		**28 February 2019** at 17:00 CET		**11 July 2019**	
	Career Development Fellowships	**6 August 2018**		**27 November 2018** at 17:00 CET		**19 April 2019**	
	Preparatory Fellowships - Joint call with the Africa Research Excellence Fund (AREF)	Stage 1 – **2 November 2018**	Stage 2 – **30 April 2019**	Stage 1 – **1 February 2019** at 17:00 CET	Stage 2 – **4 July 2019** at 17:00 CET	Stage 1 – **30 April 2019**	Stage 2 – **7 October 2019**
	EDCTP Clinical Research and Product Development Fellowships	**25 October 2018**		**1 February 2019** at 17:00 CET		**7 August 2019** (Interviews are planned for May-July 2019)	

3. Other EU-funded activities

3.1. Independent experts assisting in proposal evaluations and project reviews in 2018

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

Type of action: Expert contracts.

Indicative budget: EUR 700,000.

Indicative timetable: Q2-Q4 2018

3.2. Training on project and programme management in research

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

- Two workshops in sub-Saharan Africa, one for participants from Western and Central Africa and one for participants from Eastern and Southern Africa, to strengthen the capacity for financial and project management of EDCTP2-funded collaborative projects. The aim of the workshops is to inform EDCTP2 grantees about the rules and regulations associated with implementing EDCTP2 projects in accordance with Horizon 2020. The workshops will consist of a mix of theory and active, participatory training. All new EDCTP2 beneficiaries from African organisations will be invited to attend the training, including coordinators and scientific and financial project managers of newly selected and on-going EDCTP2 projects. Each workshop is expected to attract 40-60 participants
- Two workshops on scientific proposal writing. Potential applicants will be invited to attend a hands-on and practical workshop on EDCTP2 Calls and grant proposal writing. Where possible, EDCTP will engage its Partner States and collaborate with other organisations such as TDR, WHO, MRC-South Africa for the delivery of specific sessions. Between 30 and 40 participants will be selected and invited to attend the workshop through an open selection process. This group should be balanced with respect to geographical coverage, gender and institutional affiliation. The call for participants will be openly advertised through the EDCTP and Regional Networks of Excellence websites. Language translation services might be required.

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

Indicative timetable: The procurement process will begin in the second quarter with the objective of ensuring the required services are procured before the trainings are held in the second and third quarters of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.[51]

Indicative budget: EUR 400,000.

3.3. Consolidating EDCTP supported platforms for linking African regulators, ethics committee members and clinical trials registration

Objective: The goal of this activity is the implementation of the Pan-African Clinical Trials Alliance (PACTA) approach which WHO and partners recommended in 2007, through (1) identifying key stakeholders in the region involved with regulatory, ethical, clinical trial oversight and registration including the NEPAD Agency's AMRHI and (2) hosting up to two data sharing and networking workshops in Africa in 2018. This is part of the activities covered in the memorandum of understanding between EDCTP and NEPAD Agency. EDCTP1 funded the establishment of the Pan African Clinical Trials Registry – PACTR (www.pactr.org) to support regional clinical trial registration in TB, HIV malaria (this has since expanded) and increased awareness for the need for prospective registration of clinical trials in Africa. PACTR is a WHO-endorsed primary register and is the only primary register for the African region. PACTR is hosted at Cochrane South Africa (CSA). Through CSA the Cochrane collaboration has trained African systematic reviewers and developed their Cochrane Africa Network (CAN).

Joint funding from EDCTP1, Pfizer and the NIH Fogarty international centre supported the Council for Health Research and Development (COHRED) in their mapping of research ethics committees (RECs) and drug regulatory bodies across Africa onto a web platform – MARC project (www.researchethicsweb.org). To date this online platform has successfully mapped 167 (Level 1) RECs which are fully operational and continues to collect vital data regarding bioethics capacity strengthening (training, infrastructure, membership, etc.) on the African continent.

Moreover, EDCTP1 supported the WHO's Global Training Network (GTN) and the establishment of the African Vaccine Regulators Forum (AVAREF). From initial meetings of AVAREF, PACTR and other partners (including EDCTP), a vision was borne to develop a functional, collaborative and integrative network of organisations, institutions and other agencies involved in the review, approval and oversight of medicine, vaccine and device interventional clinical trials in Africa.

This concept was called PACTA. The objective of this activity is to organise two information and networking workshops in Africa to link African regulators, ethics committee members, PACTR and CAN to align review of clinical research applications and their results for changing policy and practice.

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

Indicative timetable: The procurement process will begin in the third quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.[52]

Indicative budget: EUR 200,000.

3.4. Support to the follow-up of programme implementation

Objective: To upgrade and further customise the existing grant management system, CC Tracker (software maintenance and updates, training, etc.) to ensure smooth planning, processes and management to provide reliable data for analysis.

The grant management system (GMS) supports the entire grant cycle from launching of the call to project approval, the management of granted projects from implementing to reporting and the submission and reporting of PSIAs. Since 2017, it also accommodates monitoring & evaluation (M&E) system content. The collection and quality assurance of programme data needs to be better facilitated in order to support reporting on the further development and progress of the programme.

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

Indicative timetable: The procurement process will begin in the second quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.[52]

Indicative budget: EUR 150,000.

3.5. Communication support to advocacy and outreach activities

Objective: External communication aims to create awareness and visibility of the EDCTP programme, its mission and goals, and to inform all stakeholders of the progress and results of EDCTP-supported activities. EDCTP plans to conduct the following activities in 2018 to support advocacy and outreach activities, and increase EDCTP's visibility:

- Production of materials for a strong presence at international conferences and meetings
- Production of two high quality videos on EDCTP-funded projects in sub-Saharan Africa
- Photo media productions on EDCTP-funded projects in sub-Saharan Africa
- Hiring of external experts for technical maintenance of the EDCTP website
- Outsourcing of development, design and printing of advocacy materials
- Outsourcing translation in French and Portuguese of main publications of EDCTP
- Quality improvement of communication services, including refresher training and internships.

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

Indicative timetable: The procurement process will begin in the second quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.[52]

Indicative budget: EUR 160,000.

3.6. Advocacy, networking and fundraising

Objective: To initiate and sustain strategic partnerships with organisations in EDCTP member countries as well in countries that are not members of the EDCTP-Association, which will contribute towards the achievement of the EDCTP2 objectives, and will raise the visibility and impact of the programme. These partnerships will be achieved through networking and advocacy activities including:

- Targeted country visits for increased visibility within the research community and with other public and private research partners;
- Participation in joint funders groups such as HIV, TB, malaria or NID funders platforms including ESSENCE on Health Research;[53]
- Participation in strategic initiatives (in particular those identified by the two EDCTP High Representatives);
- Participation in a selection of international conferences to mobilise support from the research community, policy-makers, funders and other key stakeholders;
- Organisation of a high-level meeting in Africa. A side meeting event is planned during the 68th session of the WHO regional committee for Africa, to be held in Dakar, Senegal in third quarter of 2018;
- Organisation of a high-level meeting in Europe. This meeting is planned to be linked to the 9th EDCTP Forum to be held in Lisbon, Portugal in the third quarter of 2018.

EDCTP will also hold bilateral discussions with current and potential partners from the public and private sector aiming at aligning research agendas and developing joint funding strategies.

Furthermore, in addition to these bilateral meetings, outreach is planned to policy-makers, including Members of Parliament (MPs) of relevant governments and Members of the European Parliament (MEPs). Research community outreach and information about EDCTP2 funding opportunities will be shared through the network of National Contact Points (NCPs), referred to as Health NCP Net (HNN 2.0)[54], and the General Assembly (GA) representatives in the EDCTP PSs.

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

Indicative timetable: The procurement process will occur throughout the year. All procurements will be made in accordance with EDCTP procurement policies and procedures.[52]

Indicative budget: EUR 350,000.

3.7. Coordination of EDCTP TB vaccine-funded research

Objective: Following the implementation of actions of previous work plans, EDCTP has made significant investments in TB vaccine research. The purpose of this action is to contribute to enhanced coordination and collaboration between research actions by EDCTP in the area of TB vaccine research. The action shall further facilitate the coordination of EDCTP funded actions with national research programmes in EDCTP partner states, as well as the Global TB Vaccine Partnership and other global research initiatives of relevance to TB vaccine development. It shall enable these different initiatives and actions to pursue common visions and develop a common strategic research agenda. This will include an improved communication and coordination and development of commonly agreed milestones for developing TB vaccines among the EDCTP funded actions, as well as engaging in global initiatives for establishing stage-gate criteria and preferred product profile(s) for TB vaccine development. This will specifically involve:

- External expertise for technical oversight of EDCTP funded actions in TB vaccine research
- External expertise to establish common support structures for EDCTP funded actions on TB vaccine research, including a directory of clinical trials sites in sub-Saharan Africa, standardised template(s) for clinical trials protocols, establishment of common website and other electronic tools for rapid data sharing
- Organisation of a joint meeting between EDCTP funded actions on TB vaccine research
- Supporting the establishment of stage-gate criteria and a preferred product profile for TB vaccine development in collaboration with WHO and the Global TB Vaccine Partnership
- Contribute to the production of technical and financial reports and materials to present the importance of TB vaccine development as a global health priority by engaging specialist service providers in the field of medical writing

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

Indicative timetable: The procurement process will begin in the second quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures.

Indicative budget: EUR 500,000.

3.8. Development and strengthening of the national health research systems of African Partner States of EDCTP

Objective: To develop a strategic policy plan document that will outline the linkage between EDCTP programme activities, and the development and strengthening of the national health research systems (NHRS) of the African Partner States of EDCTP. The implementation of this plan will provide guidance and support to African Partner States of EDCTP for strengthening

their NHRS in order to optimise research production and utilisation (translation to knowledge and practice).

There are recurrent demands to increase the visibility of the EDCTP programme, demonstrate clear linkage between research supported and its utilisation by host countries, attract more African countries to participate and to demonstrate the programme's impact both in R&D and capacity development for health research. This is partly attributed to the fact that most of the activities of EDCTP have concentrated on institutions and universities with limited linkage to the African governments. Targeted strengthening of the NHRS will help to bridge this gap. It will also help the African Partner States of EDCTP to strengthen their research system which is critical for the attainment of Universal Health Coverage and the SDGs.

This work will be implemented in two phases, namely:

1. Development of a strategic policy plan document to guide the process.
2. A pilot project to implement the policy plan with close alignment to the NHRS Barometer developed and published by WHO AFRO to conduct a survey in all the Partner States of EDCTP to do a situation analysis of developments and gaps in the functions. This will provide baseline data to guide future developments in the African Partner States of EDCTP.

This activity will be outsourced to a consultancy firm (to be identified through open competition) and will require close collaboration with WHO-AFRO to implement this work.

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

Indicative timetable: The procurement process will begin in the second quarter of 2018. All procurements will be made in accordance with EDCTP procurement policies and procedures[52].

Indicative budget: EUR 500,000.

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

Objective: In case of a public health emergency (such as a Public Health Emergency of International Concern (PHEIC) according to the World Health Organization, a public health emergency under Decision 1082/2013/EU or under applicable national frameworks and regulations), research grants may be awarded in line with specific provisions of the Financial Regulation[55,56], that allow the awarding of grants without call for proposals in exceptional and duly substantiated emergencies. At that time, EDCTPgrants will open a dedicated section where research applications can be received. This will be communicated to the EDCTP General Assembly members.

Beneficiaries in grants awarded under actions relating to Public Health Emergencies must make available their research data, at the latest within 30 days after it has been generated, through open access or, if agreed by EDCTP or the European Commission, by giving access rights to those third parties that need the research data to address the public health emergency. Therefore the relevant option of Article 29.3 of the EDCTP Model Grant Agreement will be applied. It is expected that quality-controlled data are shared in accordance with the FAIR[57] principles. The use of harmonised protocols in collaboration with ongoing EDCTP actions is recommended for this purpose.

Type of Action: RIA - Grants awarded without a Call for Proposals (Article 128 Financial Regulation and Article 190 of the Rules of Application).

Indicative timetable: Will depend on the Public Health Emergency.

Indicative budget: EUR 2.25 million.

Table 16. Overview of budgeted costs towards EDCTP2 Calls for Proposals and other activities for the implementation of the EDCTP2 programme in 2018, including administrative expenses of the EDCTP Association in 2018

EU-funded EDCTP2 activities		TPs/TCs* (in EUR)	PSs** (in EUR)	EU (in EUR)	Budget cost (in EUR)
Research & Innovation Actions	Strategic action for overcoming drug resistance in malaria	-	2.689.160	19.310.840	22.000.000
	Strategic action for the comparison, selection and development of malaria vaccine candidates	-	2.689.160	15.310.840	18.000.000
	Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities	-	2.689.160	11.310.840	14.000.000
	Vaccines for diarrhoeal diseases or lower respiratory tract infections	-	2.689.160	20.310.840	23.000.000
	Diagnostic tools for poverty-related diseases	-	2.689.160	15.310.840	18.000.000
Coordination & Support Actions	Capacity development to facilitate the delivery and uptake of new or improved medical interventions in African health systems	-	-	9.000.000	9.000.000
	Ethics and regulatory capacities	-	-	4.500.000	4.500.000
Training & Mobility Actions	Senior Fellowships	-	-	5.000.000	5.000.000
	Career Development Fellowships	-	-	2.500.000	2.500.000
	Preparatory Fellowships - Joint call with the Africa Research Excellence Fund (AREF)	-	-	400.000	400.000
	EDCTP Clinical Research and Prioduct Development Fellowships	-	-	1.500.000	1.500.000
Sub-total		**-**	**13.445.800**	104.454.200	117.900.000
Other Activities	Independent experts assisting in proposal evaluations and project reviews in 2018	-	-	700.000	700.000
	Training on project and programme management in research	-	-	400.000	400.000
	Consolidating EDCTP supported platforms for linking African regulators, ethics committee members and clinical trials registration	-	-	200.000	200.000
	Support to the follow-up of programme implementation	-	-	150.000	150.000
	Communication support to advocacy and outreach activities	-	-	160.000	160.000
	Advocacy, networking and fundraising	-	-	350.000	350.000
	Coordination of EDCTP TB vaccine-funded research	-	-	500.000	500.000
	Development and strengthening of the national health research systems of African Partner States of EDCTP	-	-	500.000	500.000
	Mobilisation of research funds in case of Public Health Emergencies	-	-	2.250.000	2.250.000
Sub-total		**-**	**-**	**5.210.000**	**5.210.000**
Administrative costs	Personnel, missions, consumables and supplies, service contracts	-	384.200	5.334.020	5.718.220
Sub-total		**-**	**384.200**	**5.334.020**	**5.718.220**
Total planned contributions in 2018		**-**	**13.830.000**	**114.998.220**	**128.828.220**

** In-kind contributions from TPs/TCs are not included in this table*

***Includes cash committed by PSs to be allocated through EDCTP: Germany (EUR 4,000,000), Netherlands (EUR 100,000), Portugal (EUR 200,000), Spain (EUR 250,000 (plus EUR, 6,000 for bursaries for the Ninth EDCTP Forum not included in this table), Sweden (EUR 2,500,000), United Kingdom (EUR 6,780,000).*

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

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

The total budgeted cost for new PSIAs in 2018 (Tables 2 and 17) comprises EUR 112,044,620 by the European PSs and EUR 1,538,814 by the African Partner States.

All PSIAs are listed in table 17 below, with a brief overview of the PS, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the total indicative commitment for the activity. Wherever relevant, local currencies have been converted into Euros using official exchange rates.

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

4.1. PSIAs to be initiated in 2018

The following **new PSIAs**[58] will be initiated by PSs in 2018 as contributions to the EDCTP2 programme:

Table 17. PSIAs supported in 2018

Country	Code	Activity Title	Keyword	Type of action	African countries involved	Duration of PSIA (in months)	Total Budgeted Costs (EUR)
European Partner States (Participating States)							
Denmark	PSIA2018-1697	SSI co-funding	Tuberculosis	RIA	TBD	12	200,000
Finland	PSIA2018-1741	Academy Programme for Development Research	Cross-cutting	RIA	TBD	48	200,000
France	PSIA2018-1712	UVE	Emerging infections, including Ebola	RIA	TBD	60	6,412
France	PSIA2018-1714	Center for Global Health - Institut Pasteur	Cross-cutting	CSA	TBD	12	650,000
France	PSIA2018-1715	Center for translational science - Institut Pasteur	Cross-cutting	CSA	TBD	12	79,600
France	PSIA2018-1717	Radcyst	Cysticercosis/ Taeniasis	RIA	TBD	12	233,000
France	PSIA2018-1718	5% Initiative grants 2018	Cross-cutting	RIA	TBD	12	5,000,000
France	PSIA2018-1719	ANRS research grants 2018	HIV; Co-infections; Tuberculosis	RIA	Sub-Saharan African Countries	12	5,000,000
France	PSIA2018-1720	ANRS scholarships 2018	HIV; Tuberculosis	TMA	Sub-Saharan African Countries	36	400,000
France	PSIA2018-1721	ANRS sub-Saharan African sites support	HIV; Tuberculosis	CSA	Sub-Saharan African Countries	12	1,000,000
France	PSIA2018-1723	12378 Modelling HIV incidence and HIV cascade of care at district level to HIV to optimize HIV control policies in Cote d'Ivoire	HIV	RIA	Ivory Coast	12	19,850
France	PSIA2018-1725	12375 Evaluation of HPV Xpert assay-based screening algorithms for the prevention of cervical cancer among HIV-infected women in low-income countries	HIV	RIA	LMICs	24	598,443
France	PSIA2018-1726	12369 Access to pre-exposure prophylaxis for men who have sex with men : acceptability and feasibility in community-based clinics in West Africa	HIV	RIA	West African Countries	36	879,579
France	PSIA2018-1727	12365 MOTUHS-BOT	HIV	RIA	Ivory Coast	12	20,072
France	PSIA2018-1728	12372 MODERATO	HIV	RIA	West African Countries	48	1,966,036
France	PSIA2018-1729	12362 DREAMM	HIV	RIA	LMICs	36	164,500
France	PSIA2018-1730	12363 TIVINA	HIV	RIA	TBD	24	145,168
Germany	PSIA2018-1676	German Contribution to the Coalition for Epidemic Preparedness Innovations	Emerging infections, including Ebola	RIA	TBD	60	30,000,000

Germany	PSIA2018-1677	Surveillance, Outbreak Response Management and Analysis System (SORMAS)	Emerging infections, including Ebola	RIA	West African Countries	18	1,200,000
Germany	PSIA2018-1686	German Contribution to Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme	Cross-cutting	RIA	LMICs	18	100,000
Italy	PSIA2018-1662	Malaria control in Burkina Faso: Training and research in malariology	Malaria	TMA	Burkina Faso	36	1,300,000
Italy	PSIA2018-1685	Italy-South Africa joint Research Programme ISARP	Cross-cutting	RIA	African Countries	36	300,000
Norway	PSIA2018-1680	GLOBVAC Call for Proposals	Cross-cutting	RIA	LMICs	60	7,324,034
Norway	PSIA2018-1678 PSIA2018-1679 PSIA2018-1681 PSIA2018-1682 PSIA2018-1683	Funding for Product Development Partnerships (PDPs)	Cross-cutting	RIA	LMICs	12	408,203
Spain	PSIA2018-1736	Biomedical Research at the Health Research Center in Manhiça (Mozambique)	Cross-cutting	RIA	Sub-Saharan African Countries	12	250,000
Spain	PSIA2018-1737	Institutional support to National Programs for Neglected Diseases Control in Guinea Equatorial	HIV; Malaria; TB	CSA	Guinea Equatorial	18	182,653
Sweden	PSIA2018-1687	Health Economics and HIV and AIDS Research Division (HEARD)	HIV	CSA	South Africa	48	8,202,324
Sweden	PSIA2018-1701	Estimated Grants in the scope of EDCTP funded by The Swedish Research Council	Cross-cutting	RIA	TBD	36	2,300,000
Sweden	PSIA2018-1702	Sexual and reproductive health and cancer	Co-infections; HIV	RIA	Mozambique	60	1,577,000
Sweden	PSIA2018-1705	Joint WHO-AFRO/TDR/EDCTP Scheme for implementation research on infectious diseases of poverty	Cross-cutting	RIA	WHO African Region Countries	12	100,000
United Kingdom	PSIA2018-1665	MRC Fellowships	Capacity development	TMA	Uganda	60	1,116,470
United Kingdom	PSIA2018-1666	MRC Research Grants	HIV; Malaria; TB; NIDs	RIA	Malawi; Gambia; Uganda; Botswana; South Africa; Tanzania; Central African Republic; Zimbabwe; Kenya	60	3,349,410
United Kingdom	PSIA2018-1667	Health Systems Research Initiative (HSRI)	Health systems	RIA	LMICs	60	334,941
United Kingdom	PSIA2018-1668	Joint Global Health Trials (JGHT) scheme	Diagnostics; Drugs; Microbicides; Vaccines	RIA	Burkina Faso; Gambia; Mali; Uganda; South Africa; Kenya; Malawi; South Africa; Botswana; Zimbabwe; Tanzania	60	8,373,526
United Kingdom	PSIA2018-1669	MRC/DFID African Research Leader (ARL) scheme	Capacity development	RIA	Burkina Faso; Tanzania; Malawi; Kenya	60	1,674,705
United Kingdom	PSIA2018-1670	Late Phase Global Health Research	Health systems; Research	RIA	Zimbabwe	60	1,786,352
United Kingdom	PSIA2018-1671	Antimicrobial Resistance in the Global Setting - phase II	Capacity development	RIA	LMICs	36	1,004,823

United Kingdom	PSIA2018-1673	Joint WHO-AFRO/TDR/EDCTP Scheme for implementation research on infectious diseases of poverty	Implementation Research	RIA	Sub-Saharan African Countries	12	100,000.00
United Kingdom	PSIA2018-1674	GCRF Interdisciplinary Research Hubs	Capacity development	RIA	TBD	60	2,168,116
United Kingdom	PSIA2018-1672	Research funding for Product Development	Diagnostics; Drugs; Microbicides; Vaccines	RIA	LMICs	60	22,329,403
Sub-Total European PSs							112,044,620
			African Partner States				
Mali	PSIA2018-1747	Optimization of SMC delivery and its effects on the acquisition of malaria immunity	Malaria	RIA	West African Countries	36	56,683
Mali	PSIA2018-1749	A comparative trial of seasonal administration of the malaria vaccine RTS,S/AS01 or seasonal malaria chemoprevention and a combination of both interventions	Malaria	RIA	West African Countries	24	176,351
Mali	PSIA2018-1750	Monitoring and Evaluation of Seasonal Malaria Chemoprevention (SMC) Programmes	Malaria	RIA	West African Countries	36	74,209
Mali	PSIA2018-1751	Survey of prevalence and investigation of emerging and re-emergent viral diseases and infectious causes of fever in Mali	Emerging infections, including Ebola; Yellow Fever	RIA	Mali	12	11,378
Mali	PSIA2018-1768	Phase 1 trial of PfSPZ-Cvac in Malian adults	Malaria	RIA	Mali	12	142,143
Mali	PSIA2018-1776	Host vulnerability and parasite genetics in the development of cerebral malaria	Malaria	RIA	Mali	12	78,713
Mali	PSIA2018-1777	Evaluation of strategies based on Intermittent Preventive Treatment during pregnancy to improve maternal and children health	Malaria	RIA	Mali	36	324,862
Mozambique	PSIA2018-1699	ROTA_FNI	Diarrhoeal diseases	RIA	Mozambique	24	80,074
Mozambique	PSIA2018-1700	MEFI	Malaria	RIA	Mozambique	24	15,422
Senegal	PSIA2018-1689	Etude des infections néonatales nosocomiales (INN) dans trois hôpitaux de Dakar	Co-infections	RIA	Senegal	24	150,490
Senegal	PSIA2018-1690	Recherche du portage génital du streptocoque du groupe B chez les femmes enceintes et étude de sensibilité des souches aux antibiotique	Co-infections	RIA	Senegal	12	81,245
Senegal	PSIA2018-1691	Evaluation virologique chez les enfants et adolescents infectés par le VIH-1 sous deuxième ligne de traitement antirétroviral au Sénégal	HIV	RIA	Senegal	12	53,245
Senegal	PSIA2018-1692	Traitement préventif intermittent et réponse immune spécifique antiplasmodiale chez les femmes enceintes vivant dans deux régions d'endémicité différentes : le Sénégal et le Gabon	Malaria	RIA	Senegal; Gabon	36	75,490

Senegal	PSIA2018-1693	Etude du portage rhinopharyngé des souches de S. pneumoniae et de Haemophilus influenzae chez les enfants de moins de 5 ans	Lower respiratory infections; Co-infections	RIA	Senegal	24	43,245
Senegal	PSIA2018-1694	Etude des déterminants immunogénétiques du paludisme du nourrisson de moins de six mois en zone endémique : Tambacounda (Sénégal)	Malaria	RIA	Senegal	24	51,630
Senegal	PSIA2018-1695	Etiologies virale et bactérienne des infections respiratoires aigues chez les enfants de moins de 5 ans	Lower respiratory infections; Co-infections	RIA	Senegal	24	51,034
Uganda	PSIA2018-1760	The 10th Annual National Research Ethics Conference (ANREC) and a planned forum for the chairpersons of Research Ethics Committees	Ethics	CSA	Uganda	1	47,900
Uganda	PSIA2018-1761	The 7th Health and Scientific Conference and International Health Exhibition and Trade Fair	Cross-cutting	CSA	East African Countries	1	24,700
Sub-Total African PSs							**1,538,814**
Grand Total European + African PS							**113,583,434**

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 2018 the indicative budget for administrative costs is as follows:

Table 18. Administrative costs budget of the EDCTP Association Secretariat for the implementation of the EDCTP2 programme in 2018

Description	Note	EU (in EUR)	PSs and TPs (in EUR)	Total (in EUR)
Personnel		4,372,917	384,200	4,757,117
Missions	1	200,000		200,000
Consumables and supplies	2	275,598		275,598
Service contracts (including non-recoverable taxes)	3	485,505		485,505
Total		**5,334,020**	**384,200**	**5,718,220**

Notes to the administrative budget summary

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

Table 19. Projected staff headcount by functional area in 2018

Functional area	Headcount
Senior Management Team (Directors)	4
Financial and Management Accounts	2
Grants Financial Management	4
General Administration (IT, Legal, HR, Travel and Admin)	6
North-North Operations	6
South-South Operations	4
North-North Networking	4
South-South Networking	1
Communications and programme support	4
Total	**35**

6. General Annexes[59]

6.1. List of countries eligible for funding

Legal entities established in the following countries and territories will be eligible to receive funding through EDCTP2 grants:[60]

- The Member States (MS) of the European Union (EU), including their outermost regions: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK;
- The Overseas Countries and Territories (OCT) linked to the Member States[61] : Anguilla, Aruba, Bermuda, British Antarctic Territory, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Falkland Islands, French Polynesia, French Southern and Antarctic Territories, Greenland, Montserrat, Netherlands Antilles (Bonaire, Curaçao, Saba, Sint Eustatius, Sint Maarten) New Caledonia and Dependencies, Pitcairn Islands, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, South Georgia and the South Sandwich Islands, Turks and Caicos Islands, Wallis and Futuna Islands.
- The associated countries (AC): the latest information on which countries are associated or in the process of association to Horizon 2020 can be found in the online manual[62] ; The following sub-Saharan African countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic People's Republic), Congo (Republic), Côte d'Ivoire, Djibouti, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Somalia, South Africa, South Sudan, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

International European interest organisations[63] will also be eligible to receive funding from the EDCTP2 programme.

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

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

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the EU and an international organisation or a third country;[64]
- When the EDCTP Association deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme
- For Prizes, unless stated otherwise in the call conditions, any legal entity, regardless of its place of establishment, or international organisation may receive funding.[65]

6.2. Standard admissibility conditions and related requirements

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

1. To be considered **admissible**, a proposal/application must be:
   a. submitted in the electronic submission system of EDCTP before the deadline given in the call conditions or rules of contest;
   b. readable, accessible and printable;
   c. **complete** and include the requested administrative data, the proposal description, and any obligatory supporting documents specified in the call/contest;
   d. include a **draft plan for the exploitation and dissemination** of the results, unless otherwise specified in the call conditions. The draft plan is not required for proposals at the first stage of two-stage procedures.

2. In addition to the above admissibility conditions, **word limits** will apply to proposals/applications. The limits will be clearly set out in the electronic submission system of EDCTP. If a proposal exceeds the limits, the proposal cannot be submitted in the system and the applicant will receive an automatic warning that the proposal must be revised before submission.

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

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

3. The following supporting documents will be required to determine the **operational capacity** of each applicant for grant proposals, unless otherwise specified in the call:
   - A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed research and/or innovation activities;
   - A list of up to five relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the call content;
   - A list of up to five relevant previous projects or activities, connected to the subject of this proposal;

- A description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work;
- A description of any third parties that are not represented as project partners, but who will nonetheless be contributing towards the work (e.g. providing facilities, computing resources).

This scrutiny will be carried out by the evaluators during the evaluation process under the selection criteria, in particular the award criterion 'Quality and efficiency of the implementation'.

6.3. Standard eligibility conditions

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

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

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

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

Table 20. Standard eligibility criteria per type of action

Type of Action	Eligibility conditions for participation[66, 67, 68]
Research & Innovation Action (RIA)	At least three legal entities. Two of the legal entities shall be established in two different Participating States (European Partner States)* and one of the legal entities must be established in a sub-Saharan African country (listed in section 6.1). All three legal entities shall be independent of each other.
Coordination & Support Action (CSA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Training & Mobility Action (TMA)	At least one legal entity established in a Participating State* or a sub-Saharan African country.
Prizes	See conditions for participation in the Rules of Contest.

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

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

6.4. Types of action: specific provisions and funding rates[69, 70]

6.4.1 Research & Innovation Actions (RIAs)

Description: Action primarily consisting of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution[71].

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

Funding rate: 100%

6.4.2 Coordination & Support Actions (CSAs)

Description: Actions consisting primarily of accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies, including design studies for new infrastructure and may also include complementary activities of strategic planning, networking and coordination between programmes in different countries.[72]

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

Funding rate: 100%

6.4.3 Training and Mobility Actions (TMAs)

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

Funding rate: 100%

6.4.4 Prizes

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

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

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

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

The EDCTP2 Basic Act[2] stipulates that EDCTP2 activities may include national programme activities of PSs that are not funded by the EDCTP2-IS (i.e. the EDCTP Association), including activities undertaken by public or private not-for-profit research organisations. Those activities included as so-called PSIAs in the EDCTP2 Annual Work Plan shall be implemented in compliance with common principles to be agreed by the Participating States and the European Commission, taking into account the principles set out in EDCTP2 Basic Act[2], in Title VI of the Financial Regulation No 966/2012 and in the Rules for Participation Regulation No 1290/2013, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection.

The European Commission and the EDCTP Association on behalf of the PSs have agreed to the common principles outlined below:[73]

6.5.1 Equal treatment

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

earmarked funding to a named beneficiary can be acceptable.
- The principle of equality and non-discrimination based on gender, racial or ethnic origin, religion or belief, disability, age and sexual orientation should be observed and promoted.

6.5.2 Transparency

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

6.5.3 Independent peer review evaluation

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

6.5.4 Ethics and scientific integrity

- The principles of scientific integrity as defined in the European Code of Conduct for Research Integrity should be observed and promoted.[74]
- Fundamental ethical principles and in particular those related to the conduct of human clinical trials, including the Charter of Fundamental Rights of the EU, the European Convention on Human Rights and its Supplementary Protocols, the World Medical Association's Declaration of Helsinki of 2008 and the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), should be adhered to and enforced, both during the selection of actions for funding and during the subsequent implementation of the actions.

6.5.5 Appeal and complaints

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

6.5.6 Exploitation and dissemination of results

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

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

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

6.6.1 Theme [insert name of the prize]

Objectives pursued

The objectives of the prize are to:

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

Expected results

- [insert text from work plan].

6.6.2 Prize Amount

As specified in this work plan in chapter 3:

- Prize amount [insert amount] EUR.

6.6.3 Deadlines and Admissibility

Deadlines	
Opening of the submission:	dd Month yyyy
Closing date for submission:	**dd Month yyyy** at hh:mm:ss CET[75]

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

Applications must be submitted by the (lead) participant via EDCTPgrants, accessible on the call page, unless otherwise specified.

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

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

6.6.4 Eligibility criteria

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

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

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

6.6.5 Exclusion criteria

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

- Are subject to an administrative sanction (i.e. exclusion)[76]
- Are in one of the following situations:[77]
  - bankrupt, being wound up, having their affairs administered by the courts, entered into an

arrangement with creditors, suspended business activities or subject to any other similar proceedings or procedures under national law (including persons with unlimited liability for the participant's debts);
  - declared in breach of social security or tax obligations by a final judgment or decision (including persons with unlimited liability for the participant's debts);
  - found guilty of grave professional misconduct[78] by a final judgment or decision (including persons having powers of representation, decision-making or control);
  - convicted of fraud, corruption, involvement in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including persons having powers of representation, decision-making or control);
  - shown significant deficiencies in complying with main obligations under a procurement contract, grant agreement or grant decision financed by the EU or Euratom budget (including persons having powers of representation, decision-making or control);
  - found guilty of irregularities within the meaning of Article 1(2) of Regulation No 2988/95 (including persons having powers of representation, decision-making or control);
- have misrepresented information required for participating in the contest or fail to submit such information;
- were involved in the preparation of the prize documents and this entails a distortion of competition.

6.6.6 Award Criteria

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

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

6.6.7 Documents

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

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

6.6.8 Procedure

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

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

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

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

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

All participants will be informed [insert indicative date, e.g. 'at the end of 2018'] on the outcome of their application.

6.6.9 Other Conditions

Liability

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

Applicable law and competent jurisdiction

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

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

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

Payment arrangements

[OPTION 1 by default: The prize money (EUR [insert amount]) will be paid to the (lead) participant in one instalment after the award ceremony by bank transfer, provided all the requested documents have been submitted.]

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

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

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

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

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

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

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

The EDCTP Association will publish the name of the winner(s), their origin, the amount of the prize and its nature and purpose, unless the winner(s) have requested the EDCTP Association to waive such publication (because disclosure risks threatening its security and safety or harms its commercial interest).

Photos and videos taken by the EDCTP Association either in preparation of the award ceremony or during the award ceremony are the sole property of the EDCTP Association.

Dissemination and exploitation of results

The winner(s) must comply with the obligations set out in Title III of the Horizon 2020 Rules for Participation Regulation No 1290/2013[79] [and the following additional [dissemination][and] [exploitation] obligations:

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

Processing of personal data

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

The EDCTP Association complies with the provisions of the "Wet bescherming persoonsgegevens (Dutch Law on protection of personal data)", dated 6 July 2000, which Act is based on Directive nr. 95/46/EG (PbEG L 281) and adapted to the General Data Protection Regulation dated 25 January 2012 (Com 2012 11 final; 2012/0011 COD). Registration with EDCTPgrants and grant proposal submission will involve the recording and processing of personal data. These data will be held securely, processed lawfully and retained for no longer than necessary by the EDCTP Association. Data may be used to compile lists, including project details, of EDCTP grants, which will be made publicly available. By submitting the application, the participants in the project give the EDCTP Association their consent to do so.

Processing of personal data by the European Commission:
Any personal data will be processed by the European Commission under EU Regulation No 45/2001[80] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the Commission (publicly accessible in the DPO register).

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

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

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS). The winner(s) consent that the EDCTP Association and the European

Commission publish[es] (in whatever form and medium) the following information:

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

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

Security:
The activities must be carried out in compliance with Commission Decision 2015/444, i.e. security-sensitive information must be EU-classified, if its unauthorised disclosure could adversely impact the interests of the EU or of one (or more) of its Member States. Applications that are too security-sensitive cannot be awarded a prize.

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

Ethics

The activities must be carried out in compliance with:

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

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

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

The participants must ensure that the activities do not:

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

Research activities involving human embryonic stem cells (hESC) are moreover subject to the conditions set out in the Statement of the Commission related to research activities involving human embryonic stem cells[81].

The participants must respect the highest standards of research integrity – as set out, for instance, in the European Code of Conduct for Research Integrity.[82]

Conflict of interests

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

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

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

Liability for damages

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

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

Checks, audits and investigations

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

Withdrawal of the prize — Recovery of undue amounts

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

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

Exchange of information with the Commission

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

Cancellation of the contest

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

a. no applications are received;
b. the jury does not find a winner;
c. a winner is not eligible or must be excluded
d. or, the objective of the contest has already been achieved.

Complaints

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

Contact

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

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

6.7. Evaluation rules

6.7.1 Selection criteria

1. *Financial capacity:* In line with the EU's Financial Regulation No 966/2012 and the Horizon 2020 Rules for Participation Regulation No 1290/2013. For grants, coordinators will be invited – at the full proposal stage- to complete a self-assessment using an on-line tool.
2. *Operational capacity:* As a distinct operation, carried out during the evaluation of the award criterion 'Quality and efficiency of the implementation', experts will indicate whether the participants have sufficient operational capacity to carry out the proposed work, based on the competence and experience of the individual participant(s).
3. For prizes, neither financial capacity nor operational capacity is subject to evaluation.

6.7.2 Award criteria, scores and weighting

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

Table 21. Award criteria per type of EU-funded EDCTP2 action

Award criteria			
Type of Action	**Excellence** *The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the work plan.*	**Impact** *The following aspects will be taken into account:*	**Quality and efficiency of the implementation** *The following aspects will be taken into account:*
All Types of Action	**Fit with the scope and objectives of the EDCTP2 Programme, the EDCTP strategic research agenda and the call topic description.** **Importance, relevance/ pertinence and clarity of the objectives.** **Soundness of the concept and credibility of the proposed approach/ methodology.**	**Call specific aspects as listed under 'expected impact' in each individual call.** **The extent to which the outputs of the proposed work would contribute, at the European, African and/or International level, to each of the expected impacts listed in the work plan under the relevant topic.** **Likelihood to result in major advances in the field.**	Quality and effectiveness of the work plan, including extent to which the resources assigned to work packages are in line with their objectives and deliverables; Appropriateness of the management structures and procedures, including risk and innovation management, and how responsibilities for research data quality and sharing, and security will be met.

			Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise. Appropriateness of the allocation of tasks and resources, ensuring that all participants have a valid role and adequate resources in the project to fulfil that role. Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant. Compliance with national and international standards of research, Good Clinical Practice, ethics and safety related issues. Participants have the operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).
Research & Innovation Action (RIA)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) or research study now.** Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.** Appropriate consideration of interdisciplinary approaches, and where relevant, use of stakeholder knowledge	**Advancing the clinical development of new and improved products.** Generalisability of the trial/ study results beyond the immediate research setting in a way that will maximise the impact of the results. **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.** Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. Effectiveness and quality of the proposed measures to exploit and disseminate the project results (including management of IPR) to communicate the project activities to different target audiences, and to manage research data	Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).

Coordination & support action (CSA)	Clarity, pertinence and importance of the strategic vision. Soundness of the concept. Quality of the proposed coordination and/or support measures.	Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), and to manage research data where relevant. Sustainability of capacity beyond the end of the grant, where relevant. Contribution to networking, where relevant.	Quality of the leadership and a clear and effective governance structure.
Training & Mobility Action (TMA)	**Suitability of the candidate, considering their track record, degree of independence and/ or potential, and how the fellowship will further the individual's career.** **Quality of the project and its fit with the fellow's expertise and career development plan, including acquired competencies and skills to be developed further.**	**Contribution of the fellowship to the fellow's clinical research skills and career development.** **Contribution to strengthening clinical research capacity at the home or host organisation.** Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data. Sustainability and retention of capacity post-award.	Suitability of the fellow's home organisation to support the fellowship project. Intention of the fellow's home organisation to develop and commit to a career post-fellowship or re-integration plan.

2. Scoring and weighting:

Unless otherwise specified in the call conditions:

- Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For full proposals, each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.
- For the evaluation of first-stage proposals under a two-stage submission procedure, only the criteria 'excellence' and 'impact' will be evaluated. Within these criteria, only the aspects in bold will be considered. The threshold for both individual criteria will be 4. The overall threshold, applying to the sum of the two individual scores, will be set at the level such that the total requested budget of proposals admitted to stage 2 is as close as possible to three times the available budget, and in any case, not less than two and a half times the available budget. The actual level will therefore depend on the volume of proposals and funding request per proposal received. The threshold is expected to normally be set at 8 or 8.5.
- For the evaluation of first-stage proposals under a two-stage submission procedure, an arithmetic average (mean value) or median of the individual scores may be taken as the consensus score. The consensus report may consist of a collation of the individual evaluation reports or extracts from them. As part of the evaluation, a review committee may be convened to reach consensus on the applications proceeding to the second stage.

For second-stage proposals as well as for single-stage evaluation procedures, unless otherwise indicated in the call text, the Coordinator has a 'right to reply' to the expert assessments (rebuttal procedure).

- If special procedures apply, they will be set out in the call conditions.

3. Priority order for proposals with the same score:

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

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

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

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

Evaluation procedure

1. Calls may be subject to either a one-stage or two-stage submission and evaluation procedure.
2. Proposals are evaluated by independent experts (see Article 15(7) Horizon 2020 Rules for Participation Regulation No 1290/2013 for exceptional cases). As part of the evaluation by independent experts, the EDCTP review committee will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above. A ranked list will be drawn up for every indicative budget shown in the call conditions.
3. Proposal coordinators receive an Evaluation Summary Report (ESR), showing the results of the evaluation for a given proposal. For proposals that successfully pass the first stage of two-stage calls, common feedback is provided to all coordinators, but the first stage ESR is only sent after the second stage evaluation.
4. If special procedures apply, they will be set out in the call conditions.

6.8. Budget flexibility

The budgets set out in this Work Plan are indicative.

Unless otherwise stated, final budgets may vary following evaluation.

Cumulated changes to the allocations to specific actions not exceeding 20% of the maximum

contribution set in this Work Plan shall not be considered to be substantial within the meaning of Article 94(4) of Delegated Regulation (EU) No 1268/2012, where those changes do not significantly affect the nature of the actions and the objectives of the work plan.

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

6.9. Actions involving financial support to third parties[83]

Not applicable

6.10. Co-labelling requirements

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

"[Name of PDP] is part of the EDCTP2 Programme supported by the European Union";

or

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

6.11. Conditions related to open access to research data

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

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

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

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

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

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

A Data Management Plan (DMP) details what data the project will generate, how it will be exploited and made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is obligatory for all projects that do not opt-out. Projects that opt-out are also strongly encouraged to submit a Data Management Plan if relevant for their planned research. Further information on Data Management Plans is available on the Horizon 2020 Participant Portal.[84,85]

7. Acronyms and abbreviations

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

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

8. Endnotes

1. In the EDCTP2 programme, "medical interventions" encompass measures whose purpose is to improve or sustain health or alter the course of a disease, in particular prevention and treatment based on medicinal products such as drugs, microbicides or vaccines, including their delivery modality, follow up of treatment and prevention in the affected population as well as medical diagnostics to detect and monitor disease/health evolution.
2. EDCTP2 Basic Act: Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States, Official Journal of the European Union, OJ L 169, 7.6. 2014, p.38
3. Only the following European countries are specified in the EDCTP2 Basic Act as the "Participating States" of the EDCTP2 programme and thus required to fulfil the conditions set for the EU's financial contribution to the EDCTP2 programme: Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. Greece is specified as a Participating State even though it has neither provided any up-front commitment to the EDCTP2 programme nor requested membership in the EDCTP Association. Thus, it does not comply with the requirements set for "Participating States" in the EDCTP2 Basic Act. Switzerland is also specified as a Participating State but has not yet joined the EDCTP Association as full member.
4. Official registration No 60471700, Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands, VAT number 853925653.
5. So far, the following 16 African countries have joined the EDCTP Association as members: Burkina Faso, Cameroon, Congo, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda, and Zambia. The EDCTP Association involves the following 14 European countries as members: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom.
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 endnote 3)
7. Deed of Incorporation of the EDCTP Association, 10.4.2014: http://www.edctp.org/web/app/uploads/2014/12/Deed_of_Incorporation_EDCTP_Association_10-04-2014_EN_FINAL.pdf
8. The objectives of the EDCTP2 programme are in full detail described in Annex 1 of Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 and are presented here in an abridged version.
9. In the EDCTP2 programme, "poverty-related diseases (PRDs)" include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.
10. http://www.un.org/millenniumgoals/
11. http://www.un.org/sustainabledevelopment/sustainable-development-goals
12. Rules for Participation (RfP) of Horizon 2020: Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)", OJ L 347, 11.12.2013, p. 81.
13. EDCTP2 Basic Act, Annexes I and II.
14. EDCTP2 Basic Act, Article 6.4.
15. Decision 556/2014/EU requires that clinical trials are conducted "in compliance with fundamental ethical principles and relevant national, Union and international legislation". In particular, this includes Regulation (EU) No 536/2014 on clinical trials on medicinal

products for human use, which calls for "data from a clinical trial to only be submitted in support of a clinical trial application if that clinical trial has been recorded in a publicly accessible and free of charge database which is a primary or partner registry of, or a data provider to, the international clinical trials registry platform of the World Health Organization (WHO ICTRP)". Furthermore, the Union's Horizon 2020 programme provides for mandatory open access to data under Article 29 of its model Grant Agreement unless in specific instances where an opt-out is considered necessary. Therefore, EDCTP requires (i) the registration of clinical trials prior to the enrolment of the first subject in a registry complying with WHO's international agreed standards (www.who.int/ictrp) and (ii) in line with the WHO 'Joint statement on public disclosure of results from clinical trials' the disclosure of the study results by posting to the results section of the registry within 12 months from primary study completion (defined as the last data collection time point for the last subject for the primary outcome measure) and by journal publication within 24 months.

16. An action (project) supported with an EDCTP2 grant can involve one or more activities that fit with the scope of the type of action.
17. http://www.edctp.org/see-work/strategy/
18. EDCTP2 stakeholder meeting reports: http://www.edctp.org/stay-up-to-date/meeting-reports
19. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001251.jsp&mid=WC0b01ac0580032ec4
20. http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
21. http://www.who.int/immunization/topics/malaria/vaccine_roadmap/en/
22. http://apps.who.int/iris/bitstream/10665/149822/1/WHO_IVB_14.09_eng.pdf?ua=1
23. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001251.jsp&mid=WC0b01ac0580032ec4
24. http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
25. 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); echinococosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.
26. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001251.jsp&mid=WC0b01ac0580032ec4
27. http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf
28. http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
29. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001251.jsp&mid=WC0b01ac0580032ec4
30. http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
31. In the EDCTP2 programme, "poverty-related diseases (PRDs)" include HIV/AIDS, malaria, tuberculosis and the following neglected infectious diseases (NIDs): dengue/severe dengue; rabies; human African trypanosomiasis (sleeping sickness); leishmaniases; cysticercosis/taeniasis; dracunculiasis (guinea-worm disease); echinococcosis; foodborne trematodiases; lymphatic filariasis; mycetoma; onchocerciasis (river blindness); schistosomiasis; soil-transmitted helminthiases; Buruli ulcer; leprosy (Hansen disease); trachoma; yaws; diarrhoeal infections; lower respiratory infections; as well as emerging infectious diseases of particular relevance for Africa, such as Ebola or yellow fever.
32. http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf
33. https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf
34. http://www.edctp.org/web/app/uploads/2016/12/Strategic-Research-Agenda-version-1-December-2016.pdf
35. http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf
36. 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).

37. African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 10 RCOREs throughout Africa: http://www.nepad.org

38. 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).

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

40. 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).

41. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.

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

43. 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).

44. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.

45. https://www.economist.com/news/middle-east-and-africa/21611112-scientific-research-africa-gathering-momentum-rise

46. 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).

47. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa

48. 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).

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

50. Explanatory note: This additional condition for participation according to RfP Art. 9.5 is required due to the objectives of the EDCTP2 programme which requires that the capacity for conducting clinical trials in sub-Saharan Africa are built and strengthened (EDCTP2 Basic Act, Annex II). Allowing fellows in sub-Saharan Africa to only receive once a specific EDCTP2 fellowship will increase the number of different fellows supported and promoted under the EDCTP2 programme, and in turn strengthen more broadly the corresponding clinical research capacity in sub-Saharan Africa.

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

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

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

54. http://www.healthncp.net/

55. Article 128.1 of Regulation (EU, Euratom) 966/2012"Grants shall be subject to a work programme, to be published prior to its implementation. That work programme shall be implemented through the publication of calls for proposals, except in duly justified exceptional cases of urgency or where the characteristics of the beneficiary or of the action leave no other choice for a given action, or where the beneficiary is identified in a basic act."

56. Article 190.1 (b) of the Commission Delegated Regulation (EU) No 1268/2012 "Exceptions to calls for proposals: 1. Grants may be awarded without a call for proposals only in the following cases: [...](b) in other exceptional and duly substantiated emergencies[...]"

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

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

59. The Supporting Information provided in this chapter is copied from the General Annexes of the Work Programme 2018-2020 of Horizon 2020 (Commission decision C(2017)7124 of 27 October 2017), unless the specificities of the EDCTP2 programme required an adaptation of the information to those specificities. Such EDCTP2-specific adaptions were required for section 6.1, 6.2 (5), 6.3, 6.4, 6.5, 6.6 (6.6.9.2, 6.6.9.6), 6.7 (Table 21) and 6.10.

60. Provided that natural or legal persons, groups or non-State entities are not covered by the Council sanctions in force. Please see: the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/archives/docs/cfsp/sanctions/docs/measures_en.pdf.

61. 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.

62. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf. As of 1 January 2017, the following 16 countries are Associated to Horizon 2020: Iceland, Norway, Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Israel, Moldova, Switzerland, Faroe Islands, Ukraine, Tunisia, Georgia, Armenia.

63. 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.

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

65. Provided that natural or legal persons, groups or non-State entities are not covered by the Council sanctions in force. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/archives/docs/cfsp/sanctions/docs/measures_en.pdf.

66. Natural or legal persons, groups or non-State entities covered by the Council sanctions in force are not eligible to participate in Union programmes. Please see the consolidated list of persons, groups and entities subject to EU financial sanctions, available at: http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm as in the H2020

67. The eligibility criteria formulated in Commission notice Nr. 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp.9-11: "Guidelines on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards") apply for all actions under this Work Plan, including for third parties that receive financial support under the action (in accordance with Article 137 of the EU's Financial Regulation No 966/2012).

68. Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol (in accordance with Article 137 of the Financial Regulation No 966/2012). Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this Work Plan will be revised.

69. Eligible costs for all types of action are in accordance with the EU's Financial Regulation No 966/2012 and the Horizon 2020 Rules for Participation Regulation No 1290/2013. In addition, as training researchers on gender issues serves the policy objectives of Horizon 2020 and is necessary for the implementation of R&I actions, applicants may include in their proposal such activity and the following corresponding estimated costs that may be eligible for EU funding:
i. Costs of delivering the training (personnel costs if the trainers are employees of the beneficiary or subcontracting if the training is outsourced);
ii. Accessory direct costs such as travel and subsistence costs, if the training is delivered outside the beneficiary's premises;
iii. Remuneration costs for the researchers attending the training, in proportion to the actual hours spent on the training (as personnel costs).

70. Participants may ask for a lower rate.

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

72. Excerpt from the General Annexes of the Horizon 2020 work programme 2018-2020 (see also the Rules for Participation of Horizon 2020, Article 2, point 7).

73. Annex 5 to the Delegation Agreement concluded between the European Commission and the EDCTP Association ("the EDCTP"), which is the EDCTP2-IS, on 23 December 2014.

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

75. Central European Time = Brussels local time.

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

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

78. Professional misconduct includes: violation of ethical standards of the profession, wrongful conduct with impact on professional credibility, false declarations/misrepresentation of information, participation in a cartel or other agreement distorting competition, violation of IPR, attempting to influence decision-making processes or obtain confidential information from public authorities to gain an advantage.

79. Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for

participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

80. Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1)
81. Declarations of the Commission (Framework Programme), OJ C373, 20.12.2013, p. 2
82. European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2017 http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf
83. This is not foreseen in the 2018 work plan.
84. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-data-mgt_en.pdf
85. https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf

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