EDCTP

European & Developing Countries Clinical Trials Partnership

EDCTP2 WORK PLAN 2014

Date and version number:	19 December 2014; version 18
Status of this version:	Final version approved by the EDCTP General Assembly on 16 January 2015
Responsible person:	Professor Charles Mgone, EDCTP Executive Director
Important notice:	This work plan covers 2014 and describes planned activities under the EDCTP2 programme in 2014. European Commission approval was granted on 5 December 2014 following the positive outcome of its external evaluation by international peer review with regard to the objectives of the EDCTP2 programme. The General Assembly of the EDCTP Association has approved it on 16 January 2015.

Contents

1. Introduction

The overall objective of the second programme of the European & Developing Countries Clinical Trials Partnership ("EDCTP2") 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.

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

The EU's financial contribution to EDCTP2 is conditional on contributions of an equal amount or more provided, either in cash or in-kind, by the European Participating States (PSs) of EDCTP2, and the designation by the PSs of a legal entity as EDCTP2 dedicated implementation structure ("EDCTP2-IS") in charge of implementing the EU contribution to the EDCTP2 programme, which is the *EDCTP Association* established in the Netherlands ("EDCTP").[3]

EDCTP2-IS is composed of the *General Assembly* as the governing body, the *Secretariat* as the executive body, and the *Board* supervising the Secretariat on behalf of the General Assembly.[4]

Scope of the EDCTP2 programme

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

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

1 In EDCTP2, "*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 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, 7.6.2014, OJ L 169/38.

3 So far, the following 13 European Participating States have joined the EDCTP Association as *members*: Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain and the United Kingdom, while Switzerland has been admitted as *aspirant member*. Moreover, the EDCTP Association involves 11 African Participating States as *members* which are: Cameroon, Congo, The Gambia, Ghana, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda, and Zambia.

4 Deed of Incorporation of the EDCTP Association, 10.04.2014, http://www.edctp.org/towards-edctp2. http://www.edctp.org/fileadmin/documents/Towards_EDCTP_II/Deed_of_Incorporation_EDCTP_Association_10-04-2014_EN_FINAL.pdf.

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

Activities of EDCTP2

EDCTP2 activities are either implemented by the EDCTP2-IS (EU-funded activities based on the EU contribution to the EDCTP2 programme) or by the EDCTP2 Participating States (non-EU funded activities but based on national funds), as so-called Participating States' Initiated Activities (PSIAs). EU-funded activities are evaluated, selected and funded in line with the Rules for Participation (RfP)[6] of Horizon 2020 following open Calls for Proposals that are centrally managed by the EDCTP2-IS, whereas PSIAs are funded following national evaluation, selection and granting processes that are implemented by one or several Participating States. In order to support activities of strategic scope, with high expected impact but requiring a critical scale of resources, EDCTP may partner with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties to jointly fund activities.[7]

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 EDCTP2. Capacity development activities aim to strengthen the enabling environment for conducting clinical trials in sub-Saharan Africa in compliance with fundamental ethical principles and relevant national, Union and international legislation. Moreover, EDCTP2 promotes networking, coordination, alignment, collaboration and integration of national research programmes and activities on PRDs among the PSs, both at scientific, management and financial level.[8]

Three distinct types of actions are supported under the EDCTP2 programme: i) Research & Innovation Actions (RIA), ii) Coordination & Support Actions (CSA), and iii) Training & Mobility Actions (TMA).

Implementation of the EDCTP2 programme

The EDCTP2 programme is implemented by the EDCTP2-IS on the basis of an annual work plan and the EDCTP2 Strategic Business Plan[9]. The present work plan for 2014 has been developed in compliance with the objectives and provisions set out in the EDCTP2 basic act, and following a comprehensive consultation process, involving multiple stakeholders. The consultation process has included meetings and workshops with academic researchers, pharmaceutical industry, product development partnerships (PDPs), charities and foundations, international organisations and health research funders outside of Europe and Africa. It has also included a series of thematic stakeholder meetings (on Neglected Infectious Diseases (NIDs), HIV/AIDS, malaria, tuberculosis and other mycobacterial infections, ethics and regulatory affairs, and capacity development) resulting in specific recommendations for EDCTP2.[10] In addition to these events, EDCTP has commissioned studies and assessments with regards to the outcome and impact of activities funded under the first EDCTP programme, in particular with respect to capacity building in sub-Saharan African countries.

6 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)" and repealing Regulation (EC) No 1906/2006, OJ L 347/81.

7 EDCTP2 basic act, Article 6.4.

8 EDCTP2 basic act, Annexes I and II.

9 http://www.edctp.org/fileadmin/documents/Towards_EDCTP_II/Strategic_Business_Plan_for_EDCTP2_-_October_2013.pdf.

10 EDCTP2 stakeholder meetings: http://www.edctp.org/towards-edctp2/stakeholder-meetings/.

Within the objective of cooperation with international development assistance initiatives, EDCTP2 has also taken into account the recommendations issued by relevant World Health Organisation initiatives.

The present EDCTP2 work plan provides information about EU-funded Calls for Proposals in 2014 (Chapter 2), including the challenge, scope and expected impact, as well as supporting information about eligibility requirements and other specific conditions for applying. Detailed 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 chapter 6.

The work plan also contains an overview of non-EU funded Participating States Initiated Activities (PSIAs) in 2014 (Chapter 3). The PSIAs in the current work plan are all funded and implemented directly by one or more Participating States, and are an integral part of the EDCTP2 programme.

Budget overview tables

Table 1: Overview of planned contributions to EDCTP2 activities in 2014

Activities	Contributions (in million €)			
	EU	PS	TP	Total
EU-funded Calls for Proposals implemented by the EDCTP2-IS	12.69	6.4	0.4	**19.49**
Other EU-funded Activities implemented by the EDCTP2-IS	0.11	-	-	**0.11**
Non-EU funded Participating States Initiated Activities (PSIAs) implemented by the PSs	-	324.3	-	**324.3**
Sub-Total Implementation	**12.8**	**330.7**	**0.4**	**343.9**
EU-funded Administrative provisions of the EDCTP2-IS	1.6	-	-	**1.6**
Non-EU funded Administrative provisions of the PSs	-	0.144	-	**0.144**
Sub-Total Administration	**1.6**	**0.144**	**-**	**1.744**
Total budget	**14.4**	**330.8**	**0.4**	**345.6**

Abbreviations: EU = European Union; PS = EDCTP2 Participating States; TP = Third Parties.

Table 2: Overview of planned PSs' contributions to EDCTP2 in 2014

Participating State (PS)	PS contributions (in €)			
	PSIAs**	EDCTP-funded	Admin.	Total
Austria (AT)	2,750,000	-	10,000	2,760,000
Denmark (DK)	4,945,000	-	-	4,945,000
Finland (FI)	200,000	-	-	200,000
France (FR)	19,915,000	-	-	19,915,000
Germany (DE)	27,555,000	1,500,000	-	29,055,000
Ireland (IE)	11,082,546	-	-	11,082,546
Italy (IT)	1,725,000	-	-	1,725,000
Luxembourg (LU)	2,000,000	-	-	2,000,000
Netherlands (NL)	5,698,918	-	-	5,698,918
Norway (NO)	10,201,657	-	-	10,201,657
Portugal (PT)	1,080,627	-	5,000	1,085,627
Spain (ES)	2,000,000	900,000	5,000	2,905,000
United Kingdom (UK)	224,920,000	4,000,000	80,000	229,000,000
Sub total	**314,073,748**	**6,400,000**	**100,000**	**320,573,748**
Cameroon (CM)	932,424	-	1,870	934,294
Congo (CG)	102,564	-	-	102,564
The Gambia (GM)	-	-	-	-
Ghana (GH)	2,034,227	-	-	2,034,227
Mozambique (MZ)	16,500	-	7,000	23,500
Niger (NE)	-	-	18,203	18,203
Senegal (SN)	250,000	-	4,600	254,600
South Africa (ZA)	3,853,846	-	-	3,853,846
Tanzania (TZ)	240,000	-	9,220	249,220
Uganda (UG)	326,285	-	2,763	329,048
Zambia (ZM)	2,471,000	-	-	2,471,000
Sub total	**10,226,846**	**-**	**43,656**	**10,270,502**
Grand total	**324,300,594**	**6,400,000**	**143,656**	**330,844,250**

* Costs that Participating States expect to incur in implementing PSIAs in 2014.

2. EU-funded Calls for Proposals

Supporting clinical trial research and related activities

Proposals will be invited for the following topics in 2014:

1. Diagnostic tools for poverty-related diseases

Challenge:
Disease diagnosis in sub-Saharan Africa is highly challenging, as the population is predominantly rural and the health care systems often have limited resources. Early and rapid diagnosis of poverty-related diseases[11] (PRDs) 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. Therefore, there is a clear need for the development and uptake of rapid, accurate, cost-effective, scalable and field-friendly diagnostic tools.

Scope:
The purpose of this Call for Proposals is to provide funding to activities focusing on validation of the clinical performance and/or implementation of new or improved diagnostic tools and technologies for detection of any of the PRDs, including as co-infections. These 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. Applications should focus on late stage development (e.g. evaluation and/or demonstration phase trials) or implementation studies in sub-Saharan Africa. Applications should further provide detailed plans for World Health Organisation (WHO) endorsement and/or implementation of the diagnostic tools and technologies upon successful completion of the activity. 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.

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:
Activities funded under this Call for Proposals should lead to improvements in patient care through early detection and treatment of disease and/or enhanced monitoring and tracking of disease progression. Activities should thus contribute towards the implementation of innovative, rapid and simple diagnostics that can be deployed at low cost in health systems in resource-poor settings.

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

Table 3: Supporting information for Diagnostic tools for PRDs Call for Proposals

Type of action	Research & Innovation Action (RIA)
Funding level	100% of eligible costs
Expected number of grants	4-8
Eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criterion applies to this Call for Proposals: • The requested EDCTP contribution per activity shall not exceed €3.0 million.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the first deadline. Successful applicants in the first stage will be invited to submit a full proposal for the second stage. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for RIAs listed in section 6.5.2 will be used. For the first stage, only the Excellence and Impact criteria will be evaluated.
Grant agreement	General EDCTP2 grant agreement (multi-beneficiary)
Consortium agreement	Participants in activities resulting from this Call for Proposals will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

2. Maximising the impact of EDCTP research: translation of research results into policy and practice

Challenge:
Failure to translate research findings into policy and practice prevents research from achieving maximum public health benefit. Despite substantial investment in clinical research in HIV/AIDS, tuberculosis and malaria, the exploitation and use of research results beyond academia is often limited. Limited opportunities for engagement between researchers and policy-makers, lack of experience in exploiting research results beyond academia, and structural and cultural differences between research and policy-making are some of the barriers to an efficient uptake of research results. Health managers and policy makers can also face challenges in dealing with a large volume of research evidence and difficulties in adapting evidence from systematic reviews to make it locally relevant.

Scope:
The purpose of this Call for Proposals is to accelerate translation of research findings from EDCTP-funded activities into policy and practice in order to maximise their public health impact in sub-Saharan Africa. Applications must be based on research findings from previously EDCTP-funded activities. Applications from multidisciplinary consortia are particularly encouraged. Proposals should focus on the translation and uptake of research findings from the former EDCTP-funded research activity into policy guidelines and defined changes in health systems or clinical practice, including advancing public health interventions; developing methodological tools for the successful translation into public health programmes or practices; or optimising strategies for widespread adoption and institutionalisation of research results within the public health systems. Examples of relevant activities include but are not limited to guidelines, development initiatives, roll-out of new interventions, and

contributions to changes in policy and practice. Proposals could also include the evaluation of translational research activities. Applications should clearly define the activities and mechanisms to be used within the project, including details of any collaboration with public authorities, international organisations or commercial partnerships that will be established in order to achieve the expected impact. Dissemination activities, which constitute an integral component of the original research proposal, such as scientific publications, and feedback to trial participants and community advisory boards, are outside the scope of this call.

EDCTP considers that proposals for activities 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 activities of a different duration.

Expected impact:
Activities funded under this Call for Proposals should contribute towards the formulation and adoption of national and international guidelines and policies as well as contribute to evidence-based policies within the public health systems in sub-Saharan Africa.

Table 4: Supporting information for Maximising the impact of EDCTP research Call for Proposals

Type of action	Coordination & Support Action (CSA)
Funding level	100% of eligible costs
Expected number of grants	6-8
Eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this call for proposals: • The requested EDCTP contribution per activity shall not exceed €0.5 million.
Submission and evaluation procedure	Single-stage application procedure. A full proposal must be submitted by the indicated deadline. An indicative timeline for the submission and evaluation of applications can be found in section 2.3.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for CSAs listed in section 6.5.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono- or multi-beneficiary)
Consortium agreement	Participants in activities resulting from this Call for Proposals that involve multiple beneficiaries will be required to conclude a consortium agreement prior to the conclusion of the EDCTP2 grant agreement.

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

Proposals will be invited for the following topics in 2014:

1. EDCTP-TDR Clinical Research and Development Fellowships

Challenge:
Researchers from low- and middle-income countries (LMICs)[12] who are involved in clinical research activities have limited opportunities to acquire experience and develop skills for conducting clinical trials outside an academic or public sector setting. As a result, there are few researchers and clinical staff from LMICs assuming leading roles in clinical research for poverty-related diseases (PRDs). The development of human capacities through fellowships will lead to enhanced and sustainable research capacity in LMICs on diagnostics, drugs and vaccines for PRDs, and supporting career progression and retention of researchers in LMICs.

Background:
As part of EDCTP's capacity building efforts, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the EDCTP2-IS have 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. Furthermore, the European Commission (EC) and the Bill & Melinda Gates Foundation signed a Memorandum of Understanding in June 2013 to cooperate in the fight against PRDs.

The WHO-TDR Career Development Fellowships (CDF) programme , which has been supported by the Bill & Melinda Gates Foundation and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), offers targeted training in research and development (R&D) within pharmaceutical companies and product development partnerships (PDPs) to develop highly skilled local personnel for disease-endemic LMICs to enhance competencies in clinical trials for drugs, vaccines and diagnostics on a broad range of infectious diseases of poverty. The CDF programme is implemented by the Special Programme for Research and Training in Tropical Diseases (WHO-TDR). WHO-TDR is hosted at the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Bank and WHO.[13]

The EDCTP2-IS and TDR have decided to implement this fellowship scheme through a Joint Call for Proposals. This joint initiative will have a leverage effect on the number of individuals trained, resulting in an increased impact on research and development capacity in LMICs. The partnership will ensure synergies between the different parties involved, and will facilitate communication with researchers and clinical staff, pharmaceutical companies, PDPs and research institutions.

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

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

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

The scheme targets junior to mid-career researchers or clinical staff (clinicians, pharmacists, medical statisticians, data managers, other health researchers) who are employed by a legal entity in LMICs where they are currently working on activities in the scope of the EDCTP2 programme[14] and TDR CDF programme[15]. Placements are for a minimum period of 6 months up to a maximum period of 24 months.

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

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

EDCTP and TDR will collaborate with EFPIA and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). A list of participating companies (i.e. host organisation) and placements available will be published on the EDCTP and TDR websites.

Expected impact:
This Joint Call for Proposals will develop human resources to promote high quality research and development in LMICs. Fellowships are expected to add significantly to the development of the best and most promising researchers from LMICs, in order to enhance and maximise their contribution in research institutions in LMICs, including training of peers. The scheme will strengthen collaboration between research institutions, researchers and clinical staff in LMICs, pharmaceutical companies and PDPs.

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

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

Table 5: Supporting information for EDCTP-TDR Clinical Research and Development Joint Call for Proposals

Type of Action	Training & Mobility Action (TMA)
Funding level	100% of eligible costs. Direct costs are limited to the following cost categories: stipend, educational materials, travel and visa, attendance to meetings, health insurance, re-integration costs.
Expected number of grants	Up to 10 grants funded by the EDCTP2-IS (up to 15 additional grants funded by WHO-TDR).
Eligibility criteria	In addition to the standard admissibility (section 6.2) and eligibility (section 6.3) criteria, the following eligibility criteria apply to this Call for Proposals: • The applicant legal entity must be a legal entity registered in sub-Saharan Africa and must be the home institution employing the fellow[16]. • The fellow must: – be a post-graduate with clinical and/or research experience in infectious diseases; – have graduated up to 15 years prior to submitting their application; – have been a researcher or clinical staff member working for the last 12 months in an institution with a registered legal entity in sub-Saharan Africa , conducting activities in the scope of the EDCTP2 programme. • Placements sought shall be for a minimum period of 6 months up to a maximum period of 24 months, excluding the re-integration period.
Submission and evaluation procedure	Two-stage application procedure. For the first stage, a letter of intent must be submitted by the applicant legal entity by the indicated deadline. The letters of intent will be reviewed by an independent evaluation committee comprising experts jointly identified by the EDCTP2-IS and TDR in compliance with the provisions set in the Rules for Participation of Horizon 2020 and the EDCTP2 basic act. Successful candidate fellows in the first stage will be shortlisted and prospective host organisation will be invited to identify preferential candidate fellows. The identification of preferential candidate fellows may include an interview of candidate fellows by the prospective host organisations. For the second stage, the prospective host organisation, the preferred fellow and his/her home institution (applicant) must submit a comprehensive training plan that will be evaluated by a panel of independent experts. An indicative timeline for the submission and evaluation of applications can be found in section 2.4.
Evaluation criteria	The award criteria, scoring, thresholds and weightings for TMAs listed in section 6.5.2 will be used.
Grant agreement	General EDCTP2 grant agreement (mono-beneficiary)

16 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).

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 6: Indicative deadlines for Calls for Proposals in 2014

Indicative deadlines for Calls for Proposals

Call Topic	Indicative deadline for applications		Evaluation results are planned to be available on or before these dates	
Diagnostics for PRDs	Stage 1–2 March 2015 at 17:00:00 CET	Stage 2–7 July 2015 at 17:00:00 CET	Stage 1–30 April 2015	Stage 2–30 September 2015
Maximising the impact of EDCTP results	Single stage–16 March 2015 at 17:00:00 CET		Single stage–30 June 2015	
EDCTP-TDR Clinical Research and Development Fellowships	Stage 1–30 January 2015 at 17:00:00 CET		Stage 1–30 June 2015 Interviews are planned to be held in May 2015	

Table 7: Overview of indicative EDCTP2 commitments towards Calls for Proposals in 2014

EU-funded EDCTP2 activities		EDCTP2 Indicative Commitments (in million €)
EU-funded Calls for Research & Innovation Actions	Diagnostics for PRDs	14.99
EU-funded Calls for Coordination & Support Actions	Maximising the impact of EDCTP results	3.0
EU-funded Calls for Training & Mobility Actions	EDCTP-TDR Clinical Research and Development fellowships	1.5
Other EU-funded Activities	Independent experts	0.11
Administrative expenses of the EDCTP2-IS	Administrative provisions	1.6
Total EDCTP2 commitments		**21.2**

3. Other EU-funded activities

Activities supporting programme operations

Independent experts assisting in proposal evaluations and project reviews in 2014 (OA.2014)

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

Type of action: Expert contracts.

Indicative budget: € 110,000.

4. Non-EU funded National Programme Activities (Participating States' Initiated Activities, PSIAs)

The Participating States implement and fund a broad array of national programme activities that contribute to the objectives of the EDCTP2 programme. These Participating States' Initiated Activities (PSIAs) are implemented and funded independently from the EDCTP2-IS by one Participating State alone or by several Participating States. PSIAs are an important contribution from Participating States to the EDCTP2 programme and form an integral part of it. PSIAs are therefore included in the EDCTP2 annual work plan and any communication related to PSIAs, whether undertaken by EDCTP2-IS, a Participating State, or any of the participants in a PSIA, must clearly indicate that they are part of the EDCTP2 programme supported by the European Union (see section 6). PSIAs are funded and managed by Participating States 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.

The total indicative contribution by Participating States to PSIAs for 2014 comprises € 324.3 million (Table 2). It comprises the costs that Participating States expect to incur in implementing PSIAs in 2014.

All PSIAs are listed below, with a brief overview of the Participating States and funding institutions involved, the subject matter of the activity, the countries in sub-Saharan Africa where the activity is conducted, and the indicative commitments for 2014. Wherever relevant, local currencies have been converted into Euros using official exchange rates.

Disclaimer: The European Commission's ultimate acceptance of the Participating States Initiated Activities (PSIAs) as in-kind contribution to EDCTP2 will be based on the assessment of the information provided through the EDCTP2-IS's annual reporting to the European Commission, including reporting by the Participating States to the EDCTP2-IS based on the requirements agreed with the Commission in accordance with article 4 of the EDCTP2 basic act and included in the delegation agreement. This assessment will verify the actual commitments by PSs to those PSIAs, the relevance of those PSIAs in contributing to the specific objectives of the EDCTP2 programme, their correct labelling in any communication, and their compliance with the common principles agreed by the participating states and the Commission, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection, as referred to in article 4 and Annex 1 of the EDCTP2 basic act.

PSIAs supporting clinical trial research and related activities

HIV/AIDS

The following PSIAs on HIV/AIDS will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 8: PSIAs on HIV/AIDS supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved	Indicative PS contributions (€)
UK.PS.2014.7	UK	MRC, DFID	MRC/UVRI Uganda Research Unit on AIDS	Uganda	12,960,000
FR.PS.2014.3	FR	ANRS, IRD	ANRS clinical trials in HIV/AIDS and co-infections	Cameroon, Ivory Coast, Senegal, Burkina Faso	6,684,000
UK.PS.2014.12	UK	DFID	Evidence for Contraceptive Options and HIV (ECHO) - multicentre clinical trial of the effects of injectable depot contraception on the risk of HIV acquisition	Various (TBC)	4,800,000
ZA.PS.2014.2	ZA	DST / Technology Innovation Agency	CAPRISA 008: Open-Label Randomized Controlled Trial to Assess the Implementation Effectiveness and Safety of 1% Tenofovir Gel Provision through Family Planning Services in KwaZulu-Natal, South Africa	South Africa	2,153,846
IE.PS.2014.1	IE	Irish Aid and Trinity College, Dublin	NOURISH: Nutrition and Treatment Outcome: Development of a Ugandan – Irish HIV/Nutrition Research Cluster	Uganda	1,082,546
IT.PS.2014.5	IT	Italian Ministry of Health ISS Comunità San Egidio	Global Health Project - Fighting HIV/AIDS in Africa (Progetto Salute Globale-1) Prevention of Mother to Child Transmission	Malawi	1,000,000
DE.PS.2014.1	DE	BMBF	German Centre for Infection Research - Thematical translational unit HIV	Gabon, Ghana, Tanzania, South Africa, Burkina Faso	645,000

IT.PS.2014.6	IT	Italian Ministry of Health and ISS	Global Health Project - Fighting HIV/AIDS in Africa (Progetto Salute Globale-3): ARV and first/ second line regimen long-term outcome assessment in various African countries	Ethiopia, Tanzania, Cameroon, Burkina Faso	300,000
IT.PS.2014.4	IT	Italian Ministry of Health and Instituto Superiore di Sanità (ISS)	Prevention and fighting HIV/AIDS in resources limited countries - women and children health project (Progetto Salute della Donna e del Bambino-Progetto B) pilot evaluation of WHO new PMTCT strategies in resource limited setting	Ethiopia, Burkina Faso	115,000
UG.PS.2014.7	UG	Government of Uganda with a Global Fund grant	PMTCT cohort Retention and adherence study	Uganda	93,829
UG.PS.2014.6	UG	Government of Uganda with a Global Fund grant	Preparatory operational research on barriers and opportunities for increasing access to HIV prevention and care services among MARPs as an entry point for potential HIV prevention and care clinical trials	Uganda	33,090
SN.PS.2014.5	SN	Ministry of Health and Social Welfare / Ministry of High Education and Research, Senegal	Strengthening compliance and treatment with the duranavir and raltegravir in adults infected with HIV-1 in virological failure of second ARVs line in sub-Saharan Africa: therapeutic cohort THILAO	Senegal, Côte d'Ivoire, Burkina Faso, Mali, Cameroon	30,000
CG.PS.2014.2	CG	Centre National de Lutte contre le SIDA (CNLS)	Early diagnosis of HIV-1 in children born to HIV positive mothers: Assessment of Prevention of Mother-to-Child-Transmission of HIV	Republic of Congo	22,800
Total					**29,920,111**

Tuberculosis

The following PSIAs on tuberculosis will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 9: PSIAs on tuberculosis supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved	Indicative PS contributions (€)
DE.PS.2014.4	DE	BMBF / Federal State of Berlin	The Max Planck Society, Max Planck Institute for Infection Biology (MPIIB) TB Drug and Vaccine development	Ethiopia, The Gambia, Ghana, Namibia, Uganda, South Africa	3,900,000
NO.PS.2014.3	NO	GLOBVAC, The Research Council of Norway	Improving diagnosis of extrapulmonary tuberculosis by implementation of a sensitive and specific assay in routine tuberculosis diagnostics	Tanzania, Zanzibar	1,208,199
DE.PS.2014.2	DE	BMBF	German Centre for Infection Research, Thematical translational unit TB	Gabon, Ghana, Tanzania, South Africa	550,000
DE.PS.2014.5	DE	German Federal Ministry of Health, Land of Lower Saxony	Research Center Borstel	Various	400,000
ZA.PS.2014.4	ZA	Strategic Health Innovation Partnerships (SHIP), MRC South Africa	Clinical validation of novel point of care diagnostics for TB	South Africa	200,000
UG.PS.2014.1	UG	The East African Community (EAC) to the Government of Uganda with funds from the World Bank	Evaluation of the impact of new tuberculosis diagnostics on patient health outcomes; an East Africa multi-country proposal	Uganda, Kenya, Tanzania, Rwanda, Burundi	61,596
Total					**6,319,795**

Malaria

The following PSIAs on malaria will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 10: PSIAs on malaria supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved	Indicative PS contributions (€)
ZM.PS.2014.6	ZM	Ministry of Health, PATH MACEPA	Mass drug administration of dihydroartemisinin piperaquine in Southern province	Zambia	2,080,000
NO.PS.2014.1	NO	GLOBVAC, The Research Council of Norway	Malaria Chemoprevention for the post-discharge management of severe anaemia in children in Malawi, Uganda and Kenya: Moving towards policy. Centre for International Health, University of Bergen	Malawi, Uganda, Kenya	1,995,000
GH.PS.2014.1	GH	University of Ghana	Malaria Research Centre of Excellence	Ghana	1,269,200
DE.PS.2014.3	DE	BMBF	German Centre for Infection Research, Thematical translational unit Malaria	Gabon, Ghana, Tanzania, South Africa, Burkina Faso	900,000
GH.PS.2014.3	GH	Government of Ghana	Malaria Clinical Trial Project: Development of a Herbal-Based Anti-Malaria Drug	Ghana	730,423
TZ.2014.PS.1	TZ	COSTECH	Phase I trial of PfSPZ Vaccine in Tanzanian adults	Tanzania	80,000
CG.PS.2014.1	CG	Ministry of scientific Research and Technology, Institut National de la Recherche en Santé and Fondation Congolaise pour la Recherche Médicale, Laboratoire National de Santé Publique	Surveillance of malaria in sentinels sites in the country	Republic of Congo	79,764

UG.PS.2014.2	UG	The East African Community (EAC) to the Government of Uganda with funds from the World Bank	A multi-country, multi-site evaluation of the effectiveness of artemisinin combination therapy in East Africa	Uganda, Kenya, Tanzania, Rwanda, Burundi	61,596
ZM.PS.2014.5	ZM	TDRC, Ministry of Health (MOH) and National Research Authority	Daily cotrimoxazole prophylaxis for prevention of malaria in pregnancy	Zambia	50,000
SN.PS.2014.1	SN	Ministry of Health / Ministry of High Education and Research, Senegal	Evaluation of the efficacy of a vaccine diet "ChAd63-ChAd63-MVA ME-TRAP 'against Plasmodium falciparum by a strategy of prime-boost vaccination	Senegal	20,000
MZ.PS.2014.2	MZ	Ministry of Health and National Research Fund	Evaluation of intermittent preventive treatment during pregnancy (IPTp): coverage and effect on clinical and parasitological outcomes	Mozambique	16,500
Total					**7,282,483**

Neglected infectious diseases (NIDs)

The following PSIAs on NIDs will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 11: PSIAs on NIDs supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved	Indicative PS contributions (€)
ZM.PS.2014.3	ZM	Ministry of Health	Loop Mediated Isothermal Amplification (LAMP) for HAT Good Clinical Laboratory Practice	Zambia	176,000
SN.2014.PS.7	SN	Ministry of Health and Social Welfare	Evaluation of Lymphatic Filariasis in Zones where by Distributions Ivermectin is administrated to fight against onchocerciasis	Senegal	120,000
IT.PS.2014.9	IT	Dir General of the Dev and Coop – Italian Ministry of Foreign Affairs – Project AID9562 INMI-Spallanzani Hospital	Prevalence and incidence of dengue infection in Tanzania Coastal and Lake Regions	Tanzania	120,000
SN.2014.PS.6	SN	Ministry of Health and Social Welfare	Entomological assessment of Onchocerciasis in the former endemic regions of Tambacounda, Kolda and Kédougou (Senegal)	Senegal	80,000
Total					**496,000**

Cross-cutting issues

The following PSIAs addressing multiple diseases or cross-cutting issues will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 12: PSIAs on multiple diseases or cross-cutting issues supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved	Indicative PS contributions (€)
UK.PS.2014.3	UK	MRC, DFID, Wellcome Trust	Joint Global Health Trials scheme	South Africa, Uganda, Malawi, Kenya, The Gambia, Guinea Bissau, Senegal, Ethiopia, Burkina Faso, Mali	43,200,000
UK.PS.2014.1	UK	MRC, DFID	MRC Research Grants	The Gambia, Kenya, Tanzania, Uganda, South Africa, Ghana, Mozambique, Benin, Cameroon, Malawi, Mali, Nigeria, Senegal, Zambia, Zimbabwe	20,040,000
UK.PS.2014.8	UK	MRC, DFID	MRC Unit The Gambia – programmes in the scope of EDCTP2	The Gambia	12,000,000
NO.PS.2014.4 / DE.PS.2014.8 / LU.PC.2014.1	NO / DE / LU	Norad, BMZ, Ministry for Cooperation in Luxembourg	WHO-TDR including ESSENCE Secretariat; Special Programme for Research and Training in Tropical Diseases; Core funding	Various sub-Saharan African countries	3,547,318
UK.PS.2014.2	UK	MRC, DFID	MRC Global Health Trials Programme	Uganda, Kenya, Tanzania, Malawi, Zambia, Cameroon, Vietnam, South Africa, India, Ethiopia	7,800,000

DE.PS.2014.11	DE	DFG	Africa Programme "infectious diseases" of the German Research Foundation	Benin, Cameroon, Ivory Coast, Ethiopia, Gabon, Ghana, Guinea, Kenya, Mozambique, Namibia, Nigeria, Sierra Leone, South Africa, Sudan, Tanzania, Uganda, Zambia	6,000,000
UK.PS.2014.9	UK	MRC, DFID	MRC UK Units - programmes in the scope of EDCTP2	Uganda, South Africa, Zimbabwe, Zambia, Malawi & Tanzania	13,200,000
FR.PS.2014.1	FR	ANRS, IRD	ANRS research grants: multidisciplinary and/or multicountry research programme	Cameroon, Senegal, Burkina Faso, Ivory Coast, Zambia, Uganda	1,604,000
UK.PS.2014.10	UK	MRC, ESRC, DFID, Wellcome Trust	Health systems research (HSR) initiative	Various	1,200,000
FI.PS.2014.1	FI	Academy of Finland	Development research - Joint programme by the Academy of Finland and the Finnish Ministry for Foreign Affairs	TBD	200,000
PT.PS.2014.1	PT	Foundation for Science and Technology (FCT)	Research and development projects	Angola	183,747
Total					**108,975,065**

Support to PDPs

Support will be provided by PSs to PDPs and their activities in 2014 in the scope of EDCTP2 will be considered as part of the EDCTP2 programme:

Table 13: PDPs supported in 2014

Code	PDP	PS	Funding institution(s)	Indicative PS contributions (€)
NL.PS.2014.9	Aeras	NL	Dutch Ministry of Foreign Affairs	836,000
NO.PS.2014.9 / FR.PS.2014.4 / NL.PS.2014.10	Drugs for Neglected Diseases initiative (DNDi)	NO	Norad	1,270,000
		FR	AFD	1,000,000
		NL	Dutch Ministry of Foreign Affairs	400,000
IE.PS.2014.4	European Vaccine Initiative (EVI)	IE	Irish Aid	2,000,000
NL.PS.2014.12	Foundation for Innovative New Diagnostics (FIND)	NL	Dutch Ministry of Foreign Affairs	323,000
IE.PS.2014.2 / NO.PS.2014.5 / NL.PS.2014.6	International AIDS Vaccine Initiative (IAVI)	IE	Irish Aid	2,000,000
		NO	Norad	1,520,570
		NL	Dutch Ministry of Foreign Affairs	949,000
IE.PS.2014.3 / NO.PS.2014.6 / NL.PS.2014.7	International Partnership for Microbicides (IPM)	IE	Irish Aid	2,000,000
		NO	Norad	1,520,570
		NL	Dutch Ministry of Foreign Affairs	672,000
IE.PS.2014.6 / NO.PS.2014.8	Medicines for Malaria Venture (MMV)	IE	Irish Aid	2,000,000
		NO	Norad	1,270,000
IE.PS.2014.5	Global Alliance for TB Drug Development (TB Alliance)	IE	Irish Aid	2,000,000
NL.PS.2014.8	PATH: Women-initiated protection	NL	Dutch Ministry of Foreign Affairs	145,214
NL.PS.2014.11	Sabin Vaccine Institute (for the Human Hookworm Vaccine Initiative (HHVI))	NL	Dutch Ministry of Foreign Affairs	238,000
NO.PS.2014.7	TB Vaccine Initiative (TBVI)	NO	Norad	1,270,000
DE.PS.2014.10	Multiple PDPs combined, including: DNDI, FIND, EVI & DVI	DE	BMBF	12,200,000
UK.PS.2014.11	Multiple PDPs combined, including: DNDi, IAVI, IPM, MMV, TB Alliance, FIND, PATH Malaria Vaccine Initiative (MVI), Innovative Vector Control Consortium (IVCC)	UK	DFID	100,000,000
Total				**133,614,354**

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

Institutional capacity development

The following PSIAs on institutional capacity development will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 14: PSIAs on institutional capacity development supported in 2014

Code	PS	Funding institution(s)	Activity Title and Recipient Institution(s)	African countries involved	Indicative PS contributions (€)
FR.PS.2014.7	FR	IRD	IRD support to malaria research in Benin Recipient institution(s): Faculté des Sciences de la Santé (FSS) and Centre de Recherche Entomologique de Cotonou (CREC)	Benin	2,927,000
AT.PS.2014.1	AT	Austrian Ministry of Science and Research/ Medical University Vienna	Human and Trial Site Capacity Building for Establishing a Platform for Clinical Development of Antimalarial Drugs Recipient institution(s): Centre de Recherches Médicales de Lambaréné, Gabon, and the University of Gondar, Ethiopia	Gabon, Ethiopia	2,750,000
FR.PS.2014.2	FR	ANRS, IRD	ANRS Support of Research Sites in West Africa Recipient institution(s): Pasteur Institute and Hôpital central de Yaoundé, Cameroon; Centre Muraz (Bobo Dioulasso) and Université de médecine de Ouagadougou, Burkina Faso; Programme PACCI, Hôpitazl de Treichville, Abidjan, Ivory Coast; Centre CRCF de l'hôpital Fann, Dakar, Senegal	Burkina Faso, Cameroon, Ivory Coast, Senegal	2,491,000

FR.PS.2014.9	FR	IRD	IRD support to NID's research in Africa Recipient institution(s): Centre International de Recherche-Développement sur l'Elevage en zone Subhumide (CIRDES), Programme National de Lutte contre la Trypanosomose Humaine Africaine (PNLTHA), Institut Pierre Richet Bouaké, Institut de Recherche en Elevage pour le Développement, Centre de Recherche sur les Filarioses et autres Maladies Tropicales (CRFiMT)	Burkina Faso, Guinea Bissau, Ivory Coast, Chad, Cameroon	2,206,000
FR.PS.2014.8	FR	IRD	IRD support to malaria research in Africa Recipient institution(s): Institut de Recherche en Sciences de la Santé (IRSS), Laboratoire de Recherche sur le paludisme (LRP), Institut de Recherche de Yaoundé, Organisation de Coordination et de Coopération pour la lutte contre les grandes Endémies en Afrique Centrale (OCEAC)	Burkina Faso, Cameroon	1,699,000
ES.PS.2014.2	ES	AECID-ISCIII	Impact of Clinical Research on Health System and Care Services Recipient institution(s): Manhiça Health Research Centre, Mozambique	Mozambique	1,500,000
NL.PS.2014.3	NL	NWO-WOTRO (Dept of Foreign Affairs)	NACCAP-2: High quality research and sustainable research capacity building through a Research Support & Training Center network for sub-Saharan Africa Recipient institution(s): College of Health Science, Makerere University; College of Medicine, University of Malawi; Faculty of Medicine, National University of Rwanda; College of Health Sciences, University of Zimbabwe	Malawi, Rwanda, Uganda, Zimbabwe	1,148,561
CM.PS.2014.4	CM	Ministry of Public Health, Ministry of Finances, Ministry of Scientific Research and Innovation	Equipment for Research Institutes	Cameroon	916,394
NL.PS.2014.4	NL	NWO-WOTRO (Dept of Foreign Affairs)	NACCAP-2: Productizing Affordable Tests to Quality Monitor HIV Treatment in Africa. ARTA phase II Recipient institution(s): Joint Clinical Research Center, Kampala, Uganda	Uganda	811,143
FR.PS.2014.5	FR	AFD	Strengthening Malaria Training Research Centre (MTRC) Recipient institution(s): MTRC	Mali	800,000

ES.PS.2014.1	ES	ISCIII/ Spanish Agency of Cooperation	Institutional support to the National Centre for Epidemic Control in Guinea Equatorial for increasing observational epidemiological studies on NIDs Recipient institution(s): National Centre for Epidemic Control, Equatorial Guinea	Equatorial Guinea	500,000
TZ.2014.PS.2	TZ	COSTECH	Strengthening institutional infrastructure	Tanzania	160,000
NL.PS.2014.5	NL	Leiden University Medical Center	Capacity building: Studies of parasitic infections in Gabon and Ghana Recipient institution(s): Albert Schweitzer Hospital Research, Gabon; University Hospital Aristide Le Dantec, Senegal; Noguchi Memorial Institute for Medical Research, Ghana	Gabon, Ghana	86,000
GH.PS.2014.2	GH	University of Ghana	University of Ghana Research Fund for faculty Recipient institution(s): University of Ghana	Ghana	34,604
UG.PS.2014.4	UG	Government of Uganda through the line Ministry of Finance, Planning and Economic Development	Revising national health research guidelines; accrediting Institutional Review Committees & monitoring research sites Recipient institution(s): Uganda National Council for Science and Technology (UNCST)	Uganda	24,705
Total					**18,054,407**

Workshops and training

The following PSIAs on workshops and training will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 15: PSIAs on workshops and training supported in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved in the PSIA	Indicative new PS contributions (€)
DK.PS.2014.2	DK	Danida, Universities Denmark	Building Stronger Universities Initiative: Platform for Human Health	Ghana, Tanzania	4,845,000
FR.PS.2014.10	FR	Ministry of French Foreign Affairs, Pasteur Institute	Support of Research and Clinical Trials in Madagascar	Madagascar	504,000
ZM.PS.2014.4	ZM	Ministry of Health	Good Clinical Laboratory Practice	Zambia	165,000
IT.PS.2014.2	IT	Italian Ministry of Health and ISS	Capacity building and training of health care workers in Liberia (ESTHER Italia-Liberia Project)	Liberia	40,000
CM.PS.2014.1	CM	Ministry of Public Health	Capacity building of members of ethics committee, research officers at central, intermediate and peripheral level on good clinical practice and protection of research participants	Cameroon	16,030
UG.PS.2014.5	UG	Government of Uganda through the line Ministry of Finance, Planning and Economic Development	On-site basic research ethics training	Uganda	14,705
Total					**5,584,735**

Fellowships

The following PSIAs on fellowships will be implemented and supported by PSs in 2014 as part of the EDCTP2 programme:

Table 16: PSIAs on fellowships supported by PSs in 2014

Code	PS	Funding institution(s)	Activity Title	African countries involved in the PSIA	Indicative new PS contributions (€)
UK.PS.2014.5	UK	MRC, DFID	MRC/DFID African Research Leader (ARL) scheme	Ghana, Kenya, Nigeria, Uganda	4,320,000
UK.PS.2014.4	UK	MRC, DFID	MRC Fellowships	South Africa, Zimbabwe, Uganda, Tanzania, Niger, The Gambia, Kenya, Ghana, Guinea Bissau, Burkina Faso, Mali, Senegal	4,200,000
ZA.PS.2014.6	ZA	South Africa DST	Regulatory capacity building exchange programme	Southern African countries	1,500,000
UK.PS.2014.6	UK	MRC, LSHTM, Wellcome Trust	MRC-LSHTM West African Global Health Research Fellowship Programme	West Africa	1,200,000
DE.PS.2014.7	DE	BMZ	German Academic Exchange Service (DAAD), Center International Health / PhD Programme for poverty related diseases PhD students research projects	Various (TBC)	1,000,000
PT.PS.2014.2	PT	Foundation for Science and Technology (FCT)	Doctoral and postdoc fellowships	Mozambique, Angola, Gabon, DRC, Benin	896,880
DK.PS.2014.1	DK	University of Copenhagen	Malaria Capacity Development Consortium (MCDC)	Malawi, Tanzania, Ghana, Uganda, Senegal	100,000
Total					**13,216,880**

PSIAs promoting networking, coordination and collaboration of national research programmes and activities

The following PSIAs on networking will be supported by PSs in 2014 as part of the EDCTP2 programme:

Table 17: PSIAs on networking supported in 2014

Code	PS	Funding institution(s)	Activity Title & Overview	African countries involved in the PSIA	Indicative new PS contributions (€)
DE.PS.2014.6	DE	BMBF	Call for Proposals on Research Networks for Health Innovations in Sub-Saharan Africa, Networks on NIDs, TB, HIV and/or Malaria	Various (TBC)	360,000
DE.PS.2014.9	DE	BMZ via Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)	Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau (ESTHER)	Ivory Coast, Ghana, Cameroon, Uganda, Rwanda, Tanzania, Malawi, Nepal	200,000
IT.PS.2014.7	IT	ISS Pontificio Consiglio Operatori Sanitari del Vaticano	Training, research and improving quality of care for populations living in the Great Lake zone of East Africa – Africae Munus – Pilot Phase	Uganda, Tanzania, Democratic Republic of Congo	150,000
NL.PS.2014.1	NL	KNCV TB Foundation	TB surveillance research unit International networking	Tanzania	90,000
UG.PS.2014.3	UG	Government of Uganda through the line Ministry of Finance, Planning and Economic Development	Annual National Research Ethics Conference (ANREC) and a planned forum for the chairpersons of Institutional Ethics Committees	Uganda	36,764
Total					**836,764**

5. Administrative expenses of the EDCTP2-IS

In compliance with the EU's Financial Regulation and the Rules for Participation of Horizon 2020, the eligible management costs for the implementation of the EDCTP2 programme which cannot be identified as directly attributable to EU-funded activities in the EDCTP2 work plan are classified as either administrative expenses or indirect costs (overheads):

- The administrative expenses are defined, in the context used in this work plan, as those eligible costs which are not directly attributable to a specific EU-funded activity but are expenditures that arise from the EDCTP2 programme.
- Indirect costs (overheads) are defined, in the context used in this work plan, as those eligible costs of the general management, facilities and other running costs incurred by the Association's offices in The Hague and Cape Town that are not categorised as administrative expenses.

The detailed expenditure classification used in preparing and monitoring the annual EDCTP2 budget is set out below:

Administrative expenses

- Personnel costs of staff not working exclusively on activities
- Travel costs not identifiable to specific calls or specific activities
- Postage and courier others (excludes grant agreements)
- Audit fees Secretariat (EC audit certificate required for reporting to the EC)
- Meetings of the EDCTP General Assembly and EDCTP Scientific Advisory Committee
- Corporate communication
- Office consumables & stationery
- Printing and photocopying

Costs for the management of specific EU-funded actions (calls, other activities)

- Personnel cost of staff working exclusively on activities
- Grant management system (software and support costs)
- EDCTP initiated audit of beneficiaries (audit fees grantees)
- Site visits to beneficiaries
- Bank charges
- Postage and courier grant agreements

Indirect costs (overheads)

- Audit fees Secretariat (annual statutory accounts)
- Non-grant related postage charges
- Office furniture and equipment
- Office cleaning
- Office utilities – electricity, water and gas
- Repairs and maintenance
- Office rent (EDCTP2-IS offices in The Hague and Cape Town) and other hosting costs
- Computers and other IT equipment
- IT Support services (Excluding Grant Management System)

Table 18: Budget summary on the administrative, actions management and indirect costs for the implementation of the EDCTP2 programme in 2014

Cost category and type	Notes*	Admin	Indirect	Grants and other activities	Total (€)
Personnel		350,000		250,000	600,000
Travel and subsistence	1	70,000		110,000	180,000
Hosting Agreement	2		60,000		60,000
Audit fees		15,000	15,000		30,000
Audit of beneficiaries					-
Other expenses	3	450,000	235,500		685,500
Total		**885,000**	**310,500**	**360,000**	**1,555,500**

***Notes to the budget summary:**

1. Travel and subsistence: Travel and subsistence budgeted here excludes the travel costs of expert groups (Scientific Advisory Committee and Scientific Review Committee), which are budgeted for under other EU-funded activities.
2. Hosting agreement: The hosting agreement costs include rent for Cape Town and The Hague offices and service.
3. Other expenses: These include communication expenses, recruitment costs, office consumable, office equipment, software licences, professional services, external printing and telephone costs.

6. Supporting information

List of countries and applicable rules for funding

Legal entities established in the following countries and territories will be eligible to receive funding through the EDCTP2 programme:[17]

- Member countries of the EDCTP Association (which is the EDCTP2-IS), including their overseas departments:
  - Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, and the United Kingdom ("European Participating States" in the EDCTP2 programme).
  - Cameroon, Congo (Republic of), The Gambia, Ghana, Mozambique, Niger, Senegal, South Africa, Tanzania, Uganda, Zambia ("African Participating States" in the EDCTP2 programme).
- Other countries of sub-Saharan Africa: Angola, Benin, Botswana, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Comoros, Congo (Democratic Republic of), Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Guinea, Guinea-Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Namibia, Nigeria, Rwanda, São Tomé and Príncipe, Seychelles, Sierra Leone, Somalia, South Sudan, Sudan, Swaziland, Togo, Zimbabwe.
- Other Member States of the European Union, which are not member countries of the EDCTP Association (which is the EDCTP2-IS), including their overseas departments:

Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, Sweden.

- The Overseas Countries and Territories (OCT) linked to the EU Member States:[18] Anguilla, Aruba, Bermuda, Bonaire, British Virgin Islands, Cayman Islands, Curaçao, Falkland Islands, French Polynesia, Greenland, Montserrat, New Caledonia, Pitcairn Islands, Saba, Saint Barthélémy, Saint Helena, Saint Pierre and Miquelon, Sint Eustatius, Sint Maarten, Turks and Caicos Islands, Wallis and Futuna.
- The Countries Associated to Horizon 20202: the latest information on which countries are associated, or in the process of association to Horizon 2020 can be found in the online manual.[19]

International European interest organisations[20] will also be eligible to receive funding from the EDCTP2 programme.

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

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

- When funding for such participants is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and

17 Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in EU-funded activities. Please see: the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

18 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.

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

20 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.

an international organisation or a third country;
- When the EDCTP2-IS deems participation of the entity essential for carrying out the action funded through the EDCTP2 programme.

Standard admissibility conditions for grant proposals, and related requirements

1. To be considered admissible, a proposal must be:
   - Submitted in the electronic submission system of EDCTP before the deadline given in the call for proposals
   - Readable, accessible and printable.
2. Incomplete proposals may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting information specified in the Call for Proposals or requested in the application form. The following supporting information will be required to determine the operational capacity, unless otherwise specified:
   - A curriculum vitae or description of the profile of the persons who will be primarily responsible for carrying out the proposed activities
   - A list of up to five relevant publications, and/or products, services (including widely-used datasets or software), or other achievements relevant to the Call for Proposals content
   - A list of up to five relevant previous projects or activities connected to the subject of the proposal with a summary of their major outputs
   - A description of any significant infrastructure and/or any major items of technical equipment, relevant to the proposed work
   - A description of any third parties that are not represented as project partners, but who will nonetheless be contributing towards the work (e.g. providing facilities, computing resources).
3. Proposals shall include a draft plan for the exploitation and dissemination of the results, unless otherwise specified in the Call for Proposals. The draft plan is not required for proposals at the first stage of two-stage procedures
4. Character limits will apply to proposals. The limits will be clearly set out in the electronic submission system of EDCTP. If a submitted proposal exceeds the limits, the proposal cannot be submitted in the system and the applicant will receive an automatic warning that the proposal must be revised before submission.

Standard eligibility criteria

All proposals must conform to the conditions set out in the EU decision on EDCTP2 and the Horizon 2020 Rules for Participation.

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

1. A proposal will only be considered eligible if:
   - its content corresponds, wholly or in part, to the topic description against which it is submitted
   - it complies with the eligibility conditions set out in the table below, depending on the type of action.

Table 28: Standard eligibility criteria per type of action

Type of Action	Eligibility criteria[21, 22, 23]
Research & Innovation Action (RIA)	At least three different legal entities. Two of the legal entities shall be established in two different European PSs and one of the legal entities must be established in a sub-Saharan African country. All three legal entities shall be independent of each other.
Coordination & Support Action (CSA)	At least one legal entity.
Training & Mobility Action (TMA)	At least one legal entity.

Type of Actions: specific provisions and funding rates[24,25]

Research & Innovation Actions (RIAs)

Description: Action 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% of eligible costs.

21 Some entities from third countries are covered by the Council sanctions in place and are not eligible to participate in EU-funded activities. Please see: the consolidated list of persons, groups and entities subject to EU financial sanctions, available at http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm.

22 The eligibility criteria formulated in Commission notice Nr. 2013/C 205/05 (OJEU C 205 of 19.07.2013, pp.9-11: "Guidelines on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards") shall apply for all actions under this Work Programme, including with respect to third parties receiving financial support in the cases where the respective action involves financial support to third parties by grant beneficiaries in accordance with Article 137 of the EU's Financial Regulation.

23 Given that the EU does not recognise the illegal annexation of Crimea and Sevastopol, legal persons established in the Autonomous Republic of Crimea or the city of Sevastopol are not eligible to participate in any capacity. This criterion also applies in cases where the respective action involves financial support given by grant beneficiaries to third parties established in the Autonomous Republic of Crimea or the city of Sevastopol in accordance with Article 137 of the EU's Financial Regulation. Should the illegal annexation of the Autonomous Republic of Crimea and the City of Sevastopol end, this shall be revised in the work plan.

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

25 Participants may ask for a lower rate.

Coordination & Support Actions (CSAs)

Description: Actions primarily consisting of accompanying measures, such as: i) activities to develop, strengthen and extend clinical research capacities in sub-Saharan Africa, ii) activities to promote networking and collaboration both between European and African and among African researchers, clinical research institutions and sites, as well as iii) activities to foster coordination and cooperation between public and private funders. Actions may involve activities of standardisation, dissemination, awareness-raising and communication, conduct of preparatory and accompanying studies, networking, coordination or support services, policy dialogues and mutual learning exercises and studies. Actions may also include complementary activities of strategic planning, networking and coordination between regional and national programmes. Actions may also involve targeted measures to maximise the public health impact of research results stemming from EDCTP-funded activities in sub-Saharan Africa by promoting their translation and supporting their uptake in policy-making, health systems and clinical practice at local, national and/or international level. In particular, CSAs will support sub-Saharan African countries in developing a robust ethical and regulatory framework for conducting clinical trials, targeting both national ethics committees (NECs) and national regulatory authorities (NRAs). Furthermore, CSAs will support regional clinical research networks in sub-Saharan Africa ("EDCTP Regional Networks") in order to build and strengthen regional, national, institutional and individual capacities to conduct clinical trials according to ICH-GCP standards.
Funding rate: 100% of eligible costs.

Training and Mobility Actions (TMAs)

Description: Actions primarily consisting of developing clinical research capacities and skills of individual researchers and clinical research staff from sub-Saharan Africa, and/or promoting mobility of individual researchers and research staff.
Funding rate: 100% of eligible costs.

Evaluation of proposals submitted to EU-funded calls

Selection criteria

6.5.1.1 Financial capacity: In line with the EU's Financial Regulation and the Rules for Participation of Horizon 2020. At the proposal stage, coordinators will be invited to complete a self-assessment using an on-line tool (accessible via EDCTP website at http://www.edctp.org).

6.5.1.2 Operational capacity: As a distinct operation, carried out during the evaluation of the award criterion 'Quality and efficiency of the implementation', experts will indicate whether the participants meet the selection criterion related to operational capacity, to carry out the proposed work, based on the competence and experience of the individual participant(s).

Award criteria

Experts will evaluate proposals on the basis of the criteria 'excellence', 'impact' and 'quality and efficiency of the implementation'. The aspects to be considered in each case depend on the type of action as set out in the table below, unless stated otherwise in the call for proposals. For all applications involving human participants, and/or human tissues, cells or personal data, the evaluation process will include an assessment of ethical issues.

Table 29: Award criteria per type of EU-funded actions

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

Research & Innovation Actions (RIAs)	**Importance of the question being addressed and the rationale/need for the proposed clinical trial(s) now.** Excellence and appropriateness of the clinical trial design, including the proposed location(s) of the trial. **Extent that the proposed trial will advance the field. In particular, how it differs from or complements any relevant planned, ongoing or recently completed trials internationally.**	**Advancing the clinical development of new and improved products.** Generalisability of the trial/study results beyond the immediate research setting in a way that will maximise the impact of the results. **Contribution to improved disease management and prevention through changes in policy, with the ultimate goal of improving public health.** Contribution to strengthening the capacity in sub-Saharan Africa to conduct clinical trials. Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	Competence of the participants and their investigators in conducting trials according to international standards of Good Clinical Practice (ICH-GCP). Involvement of sub-Saharan African researchers in the scientific leadership of the clinical trial. Arrangements and plans to take forward clinical development of the products under evaluation (where applicable).
Coordination & Support Actions (CSAs)	Clarity, pertinence and importance of the strategic vision. Soundness of the concept. Quality of the proposed coordination and/or support measures.	Effectiveness of the proposed measures to exploit and disseminate the project results. Sustainability of capacity beyond the end of the grant, where relevant. Contribution to networking, where relevant.	
Training & Mobility Actions (TMAs)	Suitability of the candidate, considering their track record, degree of independence and/or potential, and how the fellowship will further the individual's career. Quality of the project plan and, where applicable, its fit with the fellow's expertise and plans of career development, including acquired competencies and skills to be developed further.	Contribution of the fellowship to the fellow's clinical research skills and career development. Contribution to strengthening clinical research capacity at the home or host institution. Effectiveness of the proposed measures to exploit and disseminate results generated during the fellowship (including management of IPR), to communicate the fellowship activities, and, where relevant, to manage clinical data. Sustainability and retention of capacity post-award.	Suitability of the fellow's home institution to support the fellowship project. Intention of the fellow's home institution to develop and commit to a career post-fellowship or re-integration plan.

Note:

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

1. 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.
2. For the evaluation of first-stage proposals under a two-stage submission procedure only the criteria 'excellence' and 'impact' will be evaluated. Within these criteria, only the aspects highlighted above in bold will be considered.
   The threshold for each individual criterion will be 4. However, for the EDCTP-TDR Clinical research and development fellowships all three evaluation criteria will be applied in both stages, and each criterion will be scored out of 5. The threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10.

Priority order for proposals with the same score

Unless the topic description of the call for proposals indicates otherwise (chapter 2), the following method will be applied.

As part of the evaluation by independent experts, a review committee will recommend one or more ranked lists for the proposals under evaluation, following the scoring systems indicated above. A ranked list will be drawn up for every topic description of the call for proposals.

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

1. Proposals that address topics not otherwise covered by more highly-ranked proposals will be considered to have the highest priority.
2. These proposals will themselves be prioritised according to the scores they have been awarded for the criterion *excellence*. When these scores are equal, priority will be based on scores for the criterion *impact*.
   If necessary, any further prioritisation will be based on the following factors, in order: gender balance among the personnel named in the proposal who will be primarily responsible for carrying out the proposed work; leverage of funding from third parties; relative number of sub-Saharan African countries involved; quality of the networking activities.
   If a distinction still cannot be made, the panel may decide to further prioritise by considering the potential for synergies between proposals, or other factors related to the objectives of the call or EDCTP2 in general. These factors will be documented in the report of the review committee.
3. The method described in point 2 will then be applied to the remaining proposals that have achieved equal scores in the group.

Budget flexibility

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

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

- Total expenditure for each call for proposals;
- Any repartition of the call budget within a call, up to 20% of the total expenditure of the call;
- Evaluation and monitoring, up to 20% of the total expenditure for all these activities;
- Each other individual action not implemented through calls for proposals;
- Administration and other activities of the EDCTP2-IS.

Financial support to third parties

Where this possibility is indicated under the relevant topic, proposals which foresee a financial support[26] to third parties, shall clearly detail the objectives and the results to be obtained and include at least the following elements:

- A closed list of the different types of activities that qualify for financial support;
- The persons or categories of persons which may receive financial support;
- The criteria for awarding financial support;
- The criteria for calculating the exact amount of the financial support;
- The maximum amount to be granted to each third party (may not exceed EUR 60,000 for each third party unless it is necessary to achieve the objectives of the activity).

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

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

Co-labelling requirements

All participants to activities funded by the EDCTP2-IS or by Participating States under 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.

26 Article 137 of the Financial Regulation

Acronyms

Aeras	Aeras Global TB Vaccine Foundation
AFD	French Agency for Development *(Agence Française de Développement)*
AHPSR	Alliance for Health Policy and Systems Research
AHRI	Armauer Hansen Research Institute
AMRH	Africa Medicines Regulatory Harmonisation
ANRS	Agence nationale de recherches sur le sida et les hépatites virales
ARL scheme	African Research Leader scheme
BMBF	German federal ministry of education and research
BMZ	German federal ministry for economic cooperation and development
Centre CRCF de l'hôpital Fann	Le Centre Régional de Recherche et de Formation à la Prise en Charge Clinique de Fann
CIRDES	Centre International de Recherche-Développement sur l'Elevage en zone Subhumide
CPLP	Community of Portuguese Language Countries
RIA	Research & Innovation Action
CREC	Centre de Recherche Entomologique de Cotonou
CRFiMT	Centre de Recherche sur les Filarioses et autres Maladies Tropicales
CSA	Coordination & Support Action
DAAD	German academic exchange services
Danida	Danish International Development Agency
DFG	German Research Foundation
DFID	Department for International Development
DGCS	Directorate General for Development Cooperation
DNDi	Drugs for Neglected Diseases Initiative
DST	Department for Science and Technology
DVI	Dengue Vaccine Initiative
ECHO	Evidence for contraceptive options and HIV
EDCTP	European & Developing Countries Clinical Trials Partnership
EDCTP2-IS	EDCTP2 Implementation Structure
EEA-EFTA	European Economic Area-European Free Trade Association
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ESRC	Economic and Social Research Council
ESSENCE	Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts
ESTHER	Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau
EU	European Union
EVI	European Vaccine Initiative
FCT	Foundation for Science and Technology
FIND	Foundation for Innovative New Diagnostics
FORSK	Swedish Unit for Research Cooperation
FP6	European Union's Sixth Framework Programme for Research and Innovation (2003-2006)
FP7	European Union's Seventh Framework Programme (2007-2013)
FSS	Faculté des Sciences de la Santé
GA	EDCTP General Assembly
GCP	Good Clinical Practice

GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GLOBVAC	Global Health and Vaccination Research Programme
GMP	Good manufacturing practice
HEARD	Health economics and HIV/AIDS research division
HHVI	(Sabin Vaccine Institute for the) Human Hookworm Vaccine Initiative
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
Horizon 2020	European Union's Framework Programme for Research and Innovation 2014-2020
HSR	Health systems research
IAVI	International AIDS Vaccine Initiative
ICH	International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IHI	Ifakara Health Institute
INDEPTH Network	International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries
INMI	Istituto Nazionale per le Malattie Infettive
IPM	International Partnership for Microbicides
IPR	Intellectual property rights
IPT	Intermittent preventative treatment
IRB	Institutional review board
IRD	L'Institut de recherche pour le développement
IRSS	Institut de Recherche en Sciences de la Santé
ISS	Instituto Superiore di Sanità
IVCC	Innovative Vector Control Consortium
KNCV TB Foundation	Netherlands TB Foundation (*Koninklijke Nederlandse Centrale Vereniging voor tuberculosebestrijding*)
LMIC	Low- and middle-income country
LMU	Ludwig-Maximilians University Munich
LRP	Laboratoire de Recherche sur le paludisme
LSHTM	London School of Hygiene and Tropical Medicine
MCDC	Malaria Capacity Development Consortium
MDR-TB	Multi-drug resistant tuberculosis
MMV	Medicines for Malaria Venture
MoU	Memorandum of Understanding
MPIIB	Max Planck Institute for Infection Biology
MRC UK	Medical Research Council United Kingdom
MRC/UVRI	Medical Research Council/Uganda Research Unit on AIDS
MTRC	Strengthening Malaria Training Research Training Centre
MUHAS	The Muhimbili University of Health and Allied Sciences
MVI	Malaria Vaccine Initiative
NACCAP-2	Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty-related Diseases
NEC	National ethics committee
NGO	Non-governmental organisation
NID	Neglected infectious disease
NNRTI	Non-nucleoside reverse-transcriptase inhibitors

Norad	Norwegian Agency for Development Cooperation
NOURISH	Nourishing Our Understanding of Role Modeling to Improve Support and Health
NRA	National regulatory authority
NWO-WOTRO	Netherlands Organisation for Scientific Research - Science for Global Development (*Nederlandse organisatie voor Wetenschappelijk Onderzoek-Stichting voor Wetenschappelijk Onderzoek van de Tropen en Ontwikkelingslanden*)
OCEAC	Organisation de Coordination et de Coopération pour la lutte contre les grandes Endémies en Afrique Centrale
OCT	Overseas countries and territories
PanACEA	Pan African Consortium for the Evaluation of Antituberculosis Antibiotics
PATH	Program for Appropriate Technology in Health
PDP	Product development partnership
PMTCT	Prevention of mother-to-child transmission
PNLTHA	Programme national de Lutte contre la Trypanosomose Humaine Africaine
PRD	Poverty-related disease
PACCI	Programme de recherché sur le vih/sida et les maladies associées
PS	EDCTP Participating State
RfP	Requests for proposals
PSIA	Participating States' Initiated Activity
SAC	EDCTP Scientific Advisory Committee
SADC	Swiss Agency for Development and Cooperation
SERI	Swiss Secretariat for Education, Research and Innovation
SBFI	Staatssekretariat für Bildung, Forschung und Innovation
SHIP	Strategic Health Innovation Partnerships
Sida	Swedish International Development Cooperation Agency
SMN	Swedish Malaria Network
TB	Tuberculosis
TB Alliance	Global Alliance for TB Drug Development
TBVI	TB Vaccine Initiative
TMA	Training & Mobility Action
UEM	University Eduardo Mondlane
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
VINNOVA	Swedish Governmental Agency for Innovation Systems
VR	Swedish Research Council (*Vetenskapsrådet*)
WHO-TDR	World Health Organization Special Programme for Research and Training in Tropical Diseases

Colophon

The Hague, February 2015
European & Developing Countries
Clinical Trials Partnership

Europe Office

Postal address
P.O. Box 93015
2509 AA The Hague
The Netherlands

Visiting address
Anna van Saksenlaan 51
The Hague, The Netherlands

Phone +31 70 344 0880
Fax +31 70 344 0899
E-mail info@edctp.org
Internet www.edctp.org

Africa Office

Postal address
P.O. Box 19070
Tygerberg 7505, Cape Town
South Africa

Visiting address
Francie van Zijl Drive, Parowvallei
Cape Town, South Africa
Phone +27 21 938 0690
Fax +27 21 938 0569