



European & Developing Countries Clinical Trials Partnership (EDCTP)



Overview of EDCTP2

H2020 - Open Info Day

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EDCTP, The Hague, Netherlands





EDCTP: Mission and objectives



EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in sub-Saharan Africa

Objectives:

1. Increase the number of medical interventions for poverty-related diseases
2. Strengthen capacity for clinical trials in sub-Saharan Africa
3. Coordinate and align European national programmes
4. Cooperate with other public and private partners
5. Cooperation with EU initiatives, incl. development assistance



Background & Mission



Background

- Established in 2003 by a co-decision of the European Parliament and Council: Article 185 Initiative (Ex 169)
 - Pool clinical research activities to achieve greater impact against PRDs
 - Promote integrated approach to health research in Europe
- In response to MDGs and global health crises caused by PRDs
 - No economic incentive for private investments in PRDs
 - Public investments sparse and know-how fragmented
- EDCTP-1: 2003-2015
- EDCTP-2: 2014-2024



The EDCTP2 Programme



Third parties
(Private sector, PDPs,
International
Development Partners)

\geq € 683 M

\leq € 683 M

\geq € 500 M

IN-KIND/CASH

CASH

IN-KIND/CASH

**PARTICIPATING STATES'
INITIATED ACTIVITIES**

**EDCTP2 CALLS
FOR PROPOSALS**

- Administered by Participating States
- Selected and funded by Participating States
- Application of Participating States' funding rules

- Administered by EDCTP
- Funded by the EU, Participating States and third parties
- Horizon 2020 rules for participation

**Capacity for
Clinical Trials in
Africa**

Synergy



**Clinical Trials in
Africa on PRDs**



Who we are: EDCTP Association



EDCTP2 Participating States (PSs)

14 European Countries

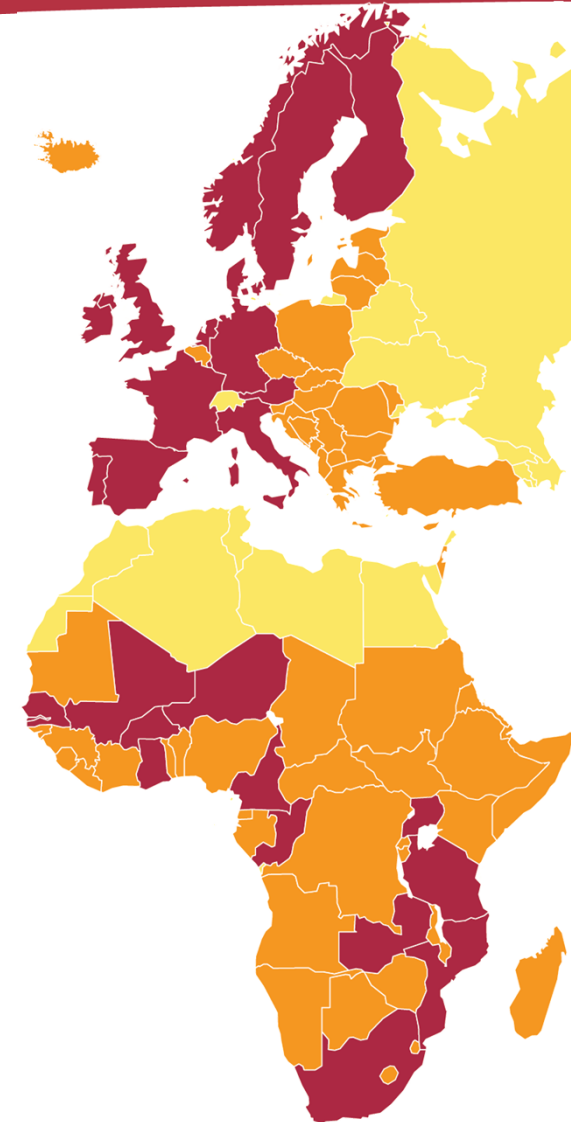
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and UK

14 African Countries

Cameroon, Burkina Faso, Rep of Congo, Gabon, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, Gambia, Uganda, Zambia

Countries that can receive funding

- All sub-Saharan African countries
- All EU MSs and Associated Countries





GMZ2: EDCTP-funded malaria vaccine candidate in Phase 2



Vaccine candidate (GMZ2):

- Hybrid of glutamate-rich protein and MSP3+Alum
- Targeting blood stage of the parasite

4 clinical trial sites in Africa:

- CNRFP (Burkina Faso), Makerere University (Uganda), Albert Schweitzer Hospital (Gabon) and NHRC-Navrongo (Ghana)

2 European Partners:

- SSI (Denmark – Project Coordinator), Tübingen University (Germany)

1747 children:

- 3 vaccinations at day 0, 28 and 56
- Followed up for 24 months after 1st vaccination
- Close-out: Feb 2014

Total Budget: EUR 6.6 M (from EDCTP)



Comparison of H2020 and EDCTP2



	SC1, H2020	EDCTP2
Programme planning and publication of calls	Work programme + participant portal	Work plan + EDCTP website
Rules for participation	H2020	H2020 with derogation
Funding instruments (project types)	RIA, CSA, TMA	RIA, CSA, TMA
Minimum participants (RIA)	3 MS/AC	2 PS + 1 SSA
Indirect costs (overhead rate)	25%	25%
Who can participate?	Almost all	Almost all
Who can receive funding?	Most, except OECD and BRIC	Only EU/AC + SSA
Electronic proposal submission	Participant portal	EDCTPgrants
Model grant agreement	H2020	Modified H2020



Funding instruments in EDCTP2



1. Research and Innovation Actions (RIA)

Clinical Trials

Consortia of ≥ 2 European PS and ≥ 1 sub-Saharan African country

100% funding or co-funding

2. Training and Mobility Actions (TMA)

Fellowships to individuals

Career development (0-5 years); Senior (5+ years); specialised

100% funding

3. Coordination and Support Actions (CSA)

Capacity development of institutions, networking and supporting activities

100% funding



Calls for Proposals in EDCTP2: outcome



Call	Scheme	Proposals	Grants	Success rate	Funding per grant (max)	Total Budget
Diagnostic tools •Validation of new or improved diagnostic tools	RIA	96	6	6%	€ 3,000,000	€ 15M
Maximizing impact •Translation of research findings from EDCTP-funded projects into policy and practice	CSA	14	5	36%	€ 500.000	€ 3M
EDCTP-TDR Clinical Research & Development Fellowship •Support individual researchers from Africa to train for 6-24 months in pharma companies	TMA	149	21	14%	€ 200,000	€ 3M
Research capacity development in support of the EVD response •Capacity strengthening for confronting emerging epidemics	CSA	38	(5-7)	TBC	€ 250,000	€ 3M



Calls for Proposals 2015: Improved treatment and clinical management of PRDs



- Clinical evaluation of new or significantly improved drugs or drug regimens in humans or to optimise the efficacy and use of existing therapeutics for PRDs, including co-infections of PRDs
- Should include one or more clinical trial(s) (phase I to IV) of therapeutics for PRDs to be conducted in sub-Saharan Africa.

Call open; deadline on 15 October

Grant scheme	RIA (100% funding + 25% overhead)
Call budget:	€ 35.0 M
Maximum funding per project:	€ 15.0 M
Expected nr/duration of grants:	3-5 / 36-60 months
Minimum consortium criteria:	≥ 2 European PSs & ≥1 SSA country
Submission/evaluation process:	Two-stage (LoI; full proposal)



Calls for Proposals 2015: Strategic actions supporting large-scale clinical trials



- Strategically important, ambitious, large-scale clinical trials with potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs
- Total activity cost \geq € 3.0 M
- Financial commitment from other funders (PSs and/or third parties) of \geq 50% of activity costs

Call open; deadline on 15 October

Grant scheme	RIA
Call budget:	€ 28 M
Maximum funding per project:	€ 10.0 M
Expected duration of grants:	36-60 months
Minimum consortium criteria:	\geq 2 European PSs & \geq 1 SSA country
Submission/evaluation process:	Two-stage (LoI; full proposal)



Other Planned Calls in 2015: Capacity Development



- EDCTP Regional Networks (CSA)
(open: 1 Oct; deadline: 26 November; € 12M - **TBC**)
- Ethics and regulatory capacities (in collaboration with the Calouste Gulbenkian Foundation) (CSA)
(open: 1 Oct; deadline: 26 November; € 1.5M - **TBC**)
- Fellowships (TMA)
 - Senior fellowships
 - Career development fellowships(open: 1 Oct; deadline: 26 November; € 4.0M - **TBC**)
- EDCTP-TDR Clinical Research and Development Fellowships (TMA)
(open: 15 Oct; deadline: 27 January 2016; € 3.0M - **TBC**)



Future Calls: Workplan 2016 (and beyond)



Thematic topics: ~60-70% of WP?

- Research and Innovation actions addressing specific gaps (RIA)
- Capacity and networking activities addressing specific gaps (CSA)
- Joint calls with other organisation

Annually recurring topics: ~30-40% of WP?

- Strategic actions supporting large-scale clinical trials (RIA)
- Ethics and regulatory capacities (in collaboration with the Calouste Gulbenkian Foundation) (CSA)
- Fellowships (TMA)
 - Senior fellowships
 - Career development fellowships
- EDCTP-TDR Clinical Research and Development Fellowships (TMA)



Joint activities with other organisations

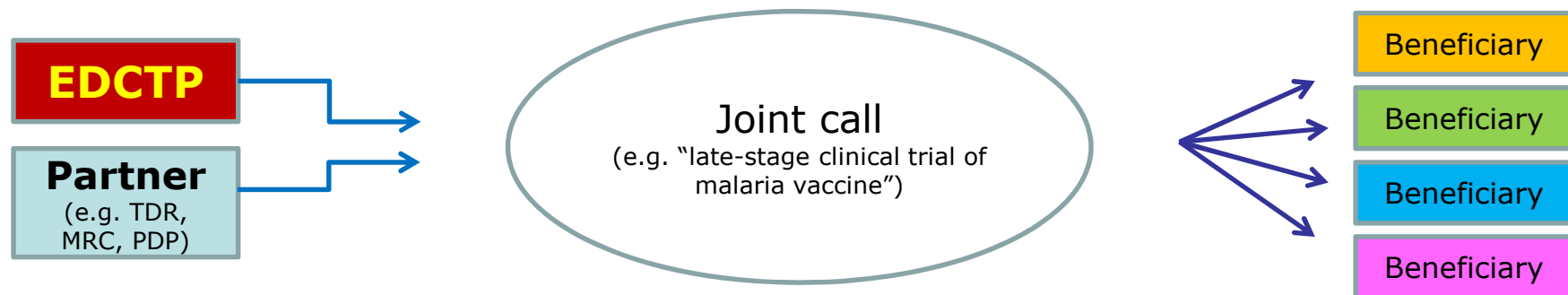


What we cannot do:

- Provide direct funding to an organisation (core funding)
- Provide direct funding to a specific activity (contract research)

What we can do:

- Leverage funding with other organisations (Strategic actions supporting large-scale..)
- Joint calls with other organisations



Principles:

- Equal treatment, transparency, fairness, independent peer review on the basis of pre-defined evaluation criteria
- Joint call included in EDCTP2 workplan (endorsed by SAC, approval by EC and GA) 14



Other ways to engage with EDCTP



- **Participating States' Initiated Activities (PSIA)**
Managed independently by the EDCTP Participating States. Implemented by national funding agencies (e.g. MRC or DFID in the UK, BMBF in Germany etc)
- Engage with national EDCTP representative, ministries, research councils and development cooperation agencies
- Register as EDCTP expert reviewer:
<http://www.edctp.org/calls-and-grants/information-for-reviewers/call-for-expert-reviewers/>
- EDCTP bi-annual Forum (next time in October 2016) gathers about 500 scientists, stakeholders, policy makers
- EDCTP thematic stakeholder meetings



Thank you!



EDCTP Operations and networking teams



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