

# The European & Developing Countries Clinical Trials Partnership (EDCTP2)

[www.fitforhealth.eu](http://www.fitforhealth.eu)

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# EDCTP2 Background and Mission

## Background

- Established in 2003 by a co-decision of the European Parliament and Council under Article 185 Initiative (Ex 169)
  - Coordinate European national research programmes
  - Establish a genuine partnership with sub-Saharan counterparts
  - Collaborate with other partners including private sector
- Contribute to the achievement of MDGs and global health crises caused by Poverty-Related Diseases (PRDs)
  - No economic incentive for private investment in PRDs
  - Public investment is sparse and fragmented

## Mission

- Reduce the burden of PRDs and generally improve the health of people living in sub-Saharan Africa through accelerating R&D of new or improved interventions against HIV/AIDS, tuberculosis, malaria and other neglected diseases

## EDCTP2 Objectives

1. Increase the number of **new or improved medical interventions** for PRDs, including neglected ones
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 internal 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

# EDCTP Association

## EDCTP2 Participating States (PSs)

### 14 European Countries

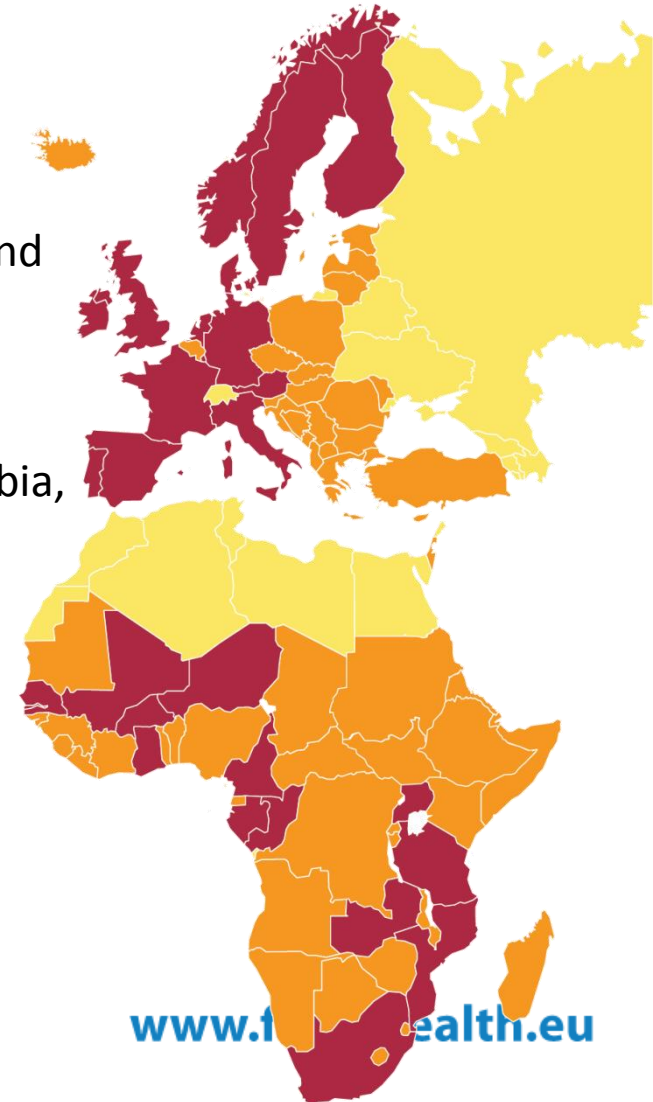
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

### 14 African Countries

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

## Countries that can receive funding

- All sub-Saharan African countries
- All EU MSs and Associated Countries to H2020



# The EDCTP2 Programme



≥ € 683 M

IN-KIND/CASH



≤ € 683 M

CASH

Third parties

(Private sector, PDPs,  
International  
Development Partners)

≥ € 500 M

IN-KIND/CASH

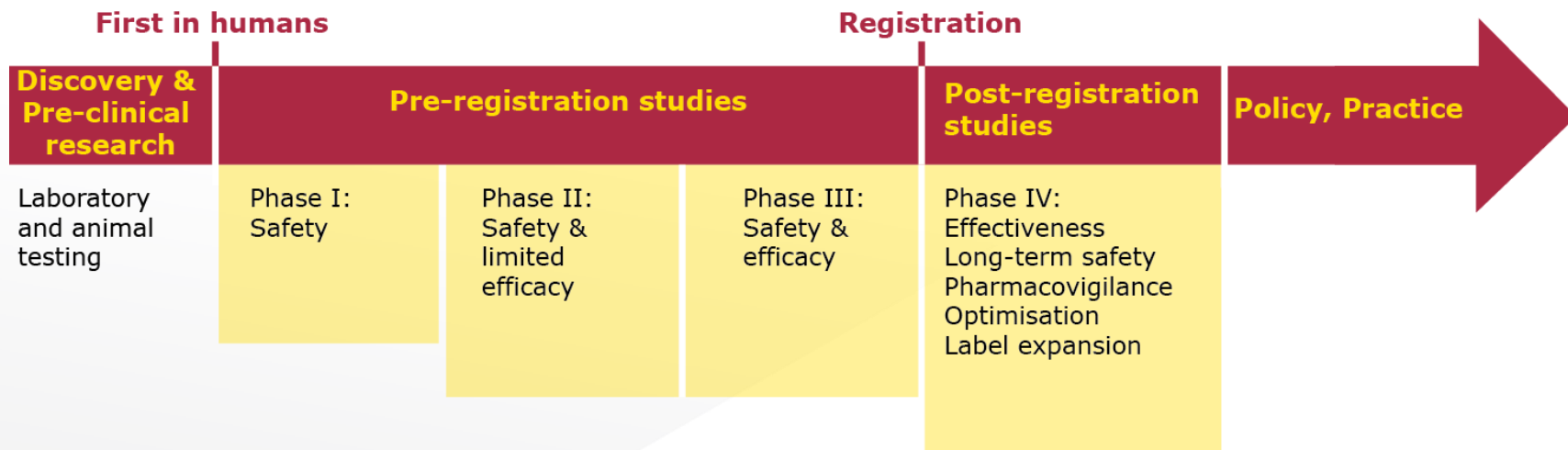
*Synergy*

Capacity for Clinical  
Trials in Africa

Clinical Trials in Africa on  
PRDs

# What EDCTP funds

EDCTP2 supports 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.



- **Diseases:** HIV/AIDS, TB, Malaria, NIDs, emerging infectious diseases of particular relevance for Africa, including Ebola
- **New tools and interventions:** Diagnostics, drugs, vaccines and microbicides
- **Capacity Development:** Fellowships, Networks, Ethics, Regulatory

## EDCTP2 - Future plans

- Support more than 150 clinical trials
- Sustain or increase the proportion of clinical trials with African leadership
- Produce over 1400 peer-reviewed articles
- Sustain or increase participation of sub-Saharan African countries in the partnership
- Support over 400 fellows, MSc and PhD students (encourage retention in sub-Saharan Africa)
- Increase number of capacity building activities supporting the conduct of clinical trials to > 74
- Establish cooperation and launch joint actions with private and public funders, EU, WHO initiatives, development agencies, etc.



# Project Types

## **Research and Innovation Actions (RIA) incl. Strategic actions supporting large-scale clinical trials**

- Primarily clinical research and clinical trials
- Phase I to IV trials
- Additional activities such as sub-studies, networking, capacity development, etc.
- Recent change: cofunding from 'eligibility' to 'evaluation' criterion

## **Coordination & Support Actions (CSA)**

- Accompanying measures such as
  - a. Strengthening research capacities in sub-Saharan Africa
  - b. Promoting networking and collaboration
  - c. Fostering cooperation between public and private funders

Activities may comprise: dissemination, awareness-raising, communication, networking, support services, policy dialogues, mutual learning exercises, strategic planning, etc.

# Project Types

## Training and Mobility Actions (TMA)

- Fostering career development of sub-Saharan African fellows
- Training and mentorship of researchers
- Promoting mobility of individual researchers and research staff

# Eligibility

**Legal entities from the following countries may receive EDCTP funding:**

- Member countries of EDCTP Association
  - Countries of sub-Saharan Africa
  - Member States of the European Union
  - Overseas countries and territories linked to EU Member States
  - Countries associated to Horizon 2020
- Note: any legal entity, public or private, anywhere in the world may participate, but only those from countries listed above are eligible to receive funding

**check Participant Portal H2020 and EDCTP Grants Manual for up-to-date lists**

# Eligibility

## Research and Innovation Actions (RIA)

- At least three different legal entities
- Two of the legal entities shall be established in two different European Participating States (see EDCTP website) and one in a sub-Saharan African country

## Coordination & Support Actions (CSA) & Training and Mobility Actions (TMA)

- One legal entity, unless otherwise specified in the call

# Funding Rates and Funding Levels

## Funding Rate

100% of direct costs + 25% indirect costs

For some calls, cofunding from other sources is strongly recommended

→ Check call text!

Don't forget:

Note the **maximum EDCTP contribution** that can be requested in the action you are applying for.

# Submission Procedures

## Single Stage Procedure

Full proposal is evaluated against criteria of excellence, impact and implementation

## Two-Stage Procedure

1st stage: Letter of Intent (short outline proposal) evaluated against criteria of excellence and impact

2nd stage: full proposal evaluated against criteria of excellence, impact and implementation

Submission procedure is specified in the call document!

Proposal at second stage **must not substantially differ** from the first stage submission.

# Current open calls

<http://www.edctp.org/funding-opportunities/calls/>

## Calls

EDCTP Calls for Proposals

[Open](#) [Planned](#) [Closed](#) [All calls](#)

### OPEN

#### CHANGE IN CALL TEXT: Strategic actions supporting large-scale clinical trials

Changes to call text: The EDCTP call for 'Strategic projects with major cofunding' has been updated in order to conform...

[Read more](#) →

Type: RESEARCH AND INNOVATION ACTION (RIA)

Open date: 28 January 2015, 01:00

Close date: 3 September 2015, 17:00

### OPEN

#### Improved treatment and clinical management of poverty-related diseases

Deadline is extended to 3 September 2015 pending the final approval by the European Commission of the 2015 EDCTP2 Workplan and...

[Read more](#) →

Type: RESEARCH AND INNOVATION ACTION (RIA)

Open date: 28 January 2015, 17:00

Close date: 3 September 2015, 17:00

### OPEN

#### Research and capacity development in support of the EVD response

Deadline is extended to 6 August 2015 pending the final approval by the European Commission of the 2015 EDCTP2 Workplan...

Type: COORDINATION & SUPPORT ACTIONS (CSAS)

Open date: 10 March 2015, 17:00

# Current open calls

## 1) Strategic actions supporting large-scale clinical trials

- Type of action: Research and Innovation Action (RIA)
- Open date: 28 January 2015, 01:00
- Two-stage application procedure
- Close date for stage 1, Letter of Intent: extended to 3 September 2015, 17:00 (pending the final approval by the European Commission of the 2015 EDCTP2 Workplan and its associated budget)
- Stage 2 deadline (Full proposal): TBC
- Funding level: 100% of eligible costs
- Expected number of grants: 2-5



# Current open calls

## 1) Strategic actions supporting large-scale clinical trials

### Scope

The purpose of this Call for Proposals is to support distinct strategic actions (clinical research activities) which are **part of a large-scale clinical trial** that has the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs. Such large-scale clinical trials are **often expensive** and may require clinical research in different countries or on different continents, including outside of Europe and Africa. Applications for a strategic action should focus on clinical trials on PRDs in sub-Saharan Africa, and may address **any disease within the scope of the EDCTP2 programme**. Proposals that include **phase III trials are encouraged**.

Proposals must present the large-scale clinical trial in its entirety, **clearly indicate for which part of the trial EDCTP2 funding is requested and how the financing of the other parts of the trial is ensured**, and present its relevance to reaching the objectives of the EDCTP2 programme. [...]

## Current open calls

### **2) Improved treatment and clinical management of poverty-related diseases**

- Type of action: Research and Innovation Action (RIA)
- Open date: 28 January 2015, 17:00
- Two-stage application procedure
- Close date for stage 1, Letter of Intent: extended to 3 September 2015, 17:00 (pending the final approval by the European Commission of the 2015 EDCTP2 Workplan and its associated budget)
- Stage 2 deadline (Full proposal): TBC
- Funding level: 100% of eligible costs
- Expected number of grants: 3-5

# Currently open calls

## 2) Improved treatment and clinical management of poverty-related diseases

### Scope

The purpose of this Call for Proposals is to provide funding to projects that aim to [evaluate new or significantly improved drugs or drug regimens](#) in humans or to optimise the efficacy and use of existing therapeutics for any of the PRDs, including co-infections of PRDs. Proposals should include one or more clinical trial(s) of therapeutics for PRDs to be conducted in sub-Saharan Africa. [A list of topics that are particularly encouraged is given in the call text](#) (specific topics indicated for HIV, Tuberculosis, Malaria, NIDs, and Co-infections). Proposals for conducting [phase II and/or III clinical trials](#) are encouraged. Recommended project duration: between 36 and 60 months

### Expected impact

[improvements in public health as a result of policy change](#) at national, regional or global level, through [evidence-based formulation and implementation of treatment guidelines and/or the advancement of product candidates](#) through the clinical pipeline or registration or pre-qualification of new products

## Currently open calls

### **3) Research and capacity development in support of the Ebola Virus Disease (EVD) response**

- Coordination & Support Actions (CSAs)
- Open date: 19 March 2015, 17:00
- Single-stage application procedure
- Close date for full proposal: extended to 6 August 2015, 17:00 (pending the final approval by the European Commission of the 2015 EDCTP2 Workplan and its associated budget)
- Funding level: 100% of eligible costs
- Maximum funding: 250,000 Euros per application
- Expected number of grants: 5-7

## Currently open calls

### 3) Research and capacity development in support of the EVD response

#### Scope

The purpose of this Call is to **build and strengthen [...] capacities** to conduct high quality health research [...] during **infectious disease outbreaks** resulting in health emergencies. Proposals should complement current and future research initiatives for treatment, prevention and containment of EVD or other emerging infectious diseases of particular relevance to Africa. Applications should address one or more of the following areas:

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

**[www.fitforhealth.eu](http://www.fitforhealth.eu)**

## Currently open calls

For more information please go to and regularly check the EDCTP calls website

<http://www.edctp.org/funding-opportunities/calls/>

# Proposal Submission Process

## EDCTPgrants home page

- Starting point to create applications and updating professional details (CV)
- Log in or create account
- To apply for open calls, follow instructions under 'New Grant Application'
- Start online application and fill out online form
- Attach annexes as requested/necessary (e.g. Gantt chart, organogram, draft protocol)
- Add other participants to the proposal (they will receive a message and need to confirm their participation)
- Provide info on budget details
- Before submitting the proposal, perform the validation check to confirm completeness
- Submit application
  - Confirmation e-mail is sent to each participant and the legal representatives of their institutions

# Proposal Submission Tool



The goal of the European and Developing Countries Clinical Trials Partnership (EDCTP) is to reduce the diseases in developing countries, in particular sub-Saharan Africa, by accelerating the clinical development of affordable medical interventions for HIV/AIDS, tuberculosis, malaria and neglected infectious diseases.

Find out more about our grant opportunities by registering or signing in below.

If you are experiencing difficulties please contact EDCTP by emailing [EDCTPgrants@edctp.org](mailto:EDCTPgrants@edctp.org) or calling

## Existing users

Please log in to access your account.

Email

Password

[Forgotten Password?](#)

☐ Remember me.

## New users

Please register with us

[System](#)

## EDCTPgrants (online submission system)

EDCTP

Diagnostic R&F Application 2014

EDCTP

Diagnostic R&F Application 2014

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Proposal Title

Acronym

EDCTP

Lead Applicant:

Proposed Start Date:


Proposed Duration:


Budget:

proposal structure



## EDCTPgrants : create new application or edit existing one



**EDCTPgrants**CC Grant Tracker

**Mrs Julia Buech**  
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### My Applications

You have 2 applications awaiting submission.



To view more details or to update an application please select it from the grid below.

Reference	Title	Last Updated	Status	
2675	Test CSA	21/07/2015 13:43:16	Pre-Submission	
2674	Test RIA	21/07/2015 13:33:29	Pre-Submission	

**New Application**  
To start a new application click here:  
[New Application](#)

## EDCTPgrants : application start page

<a href="#">Home</a> <a href="#">My Applications</a> <b>Strategic RIA</b> <b>Ref: 2674</b> <a href="#">Details</a> <a href="#">View History</a> <a href="#">Journal (0)</a> <a href="#">Sign-off Status</a> <a href="#">My Co-applications</a> <a href="#">My Grants</a> <a href="#">My Review Responses</a> <a href="#">Manage My Details</a> <a href="#">Contact Us</a> <a href="#">Logout</a> <a href="#">System Help</a>	<b>Title</b>	Test RIA	<b>Role: Lead Applicant</b> Actions shown below are for your involvement as a Lead Applicant
	<b>Reference</b>	2674	
	<b>Status</b>	Pre-Submission	
	<b>Lead Applicant</b>	Mrs Julia Buech	
	<b>Organisation</b>	European Research and Project Office GmbH	<b>Edit the application</b> Please click on the 'Edit' button if you wish to make any changes to your application.  <input type="button" value="Edit"/>
	<b>Grant Type</b>	Strategic RIA	
	<b>Funding Round</b>	Strategic RIA - LOI 2015	
	<b>Closing Date</b>	03 September 2015 16:00 CET (GMT+1)	
	<b>Created On</b>	21 July 2015	<b>PDF the application (Print)</b> Please click on the 'View/Print' button to generate this application form as a PDF file.  Please note: if your browser blocks the file download, please follow the instructions to allow the file to be downloaded.  <a href="#">PDF Formatting Problems?</a>  <input type="button" value="View/Print"/>
	<b>Last Updated</b>	21 July 2015	
<b>Validated</b>	Not Complete		
<b>Applicant Submitted</b>			
<b>Submitted On</b>		<b>Validate the application</b> To validate the application click 'Validate' and then 'Validate Form' within the application form.  <input type="button" value="Validate"/>	
		<b>Submit the application</b> The application form cannot be submitted until it has been validated to ensure that all required fields have been entered, and the data meets our submission requirements.  <input type="button" value="Submit"/>	

Strategic RIA - LOI 2015  
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## Summary Information

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### 1.1 Title

Please insert the title (maximum 150 words / 1000 characters) of your proposal.

### 1.2 Acronym

Please add an acronym or abbreviation to identify your proposal.

### 1.3 Abstract

Please provide an abstract (maximum 400 words) of the proposal.

 **B** *I* U   $x_2$   $x^2$        

Test RIA

2 words (400 words max)

### 1.4 Keywords

Please select a maximum of five keywords relevant to the scope of your proposal.

+ Keyword List

### Other Keywords

[Add Other Keyword...](#)

### 1.5 Proposed Start Date

(Cannot be before 01/12/2015)



EDCTP-TDR - CSA - Ebola  
2015

2675











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## Excellence

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### Research Proposal











*Provide a summary of the purpose, aims, objectives and methods*

 **B** *I* U   $x_2$   $x^3$  |   |   |   |  

(2500 words max)

### References

*Please provide a list of any references cited in the research proposal.*

 **B** *I* U   $x_2$   $x^3$  |   |   |   |  

(3000 words max)

### Upload of graphic file in support of application

*You may use this section to upload a single document of supporting graphics, tables, scatter plot, chart etc.*

*The upload must be limited to no more than three pages in a single document*

 [Attach](#)

**Perform a validation check before submitting!****Validate the application**

To validate the application click 'Validate' and then 'Validate Form' within the application form.

**Validation Summary****Validation Summary**

Please complete the validation checks below before submitting this application.

**Summary Information**

- [At least one applicable keyword must be selected](#)

**Excellence**

- [The abstract is required.](#)
- [References is required.](#)

**Impact**

- [Details on expected Impact are required](#)
- [Details on Impact are required.](#)
- [Details on Results and dissemination are required.](#)

**Participants**

- [Please confirm if your CV details are updated.](#)
- [Confirm the organisation which is the legal entity that will be managing the grant does not have a valid institution selected.](#)
- [Confirm the country in which the legal entity is based does not have a valid country selected.](#)
- [Career Summary is required.](#)
- [Current Grants held is required.](#)
- [Previous Activities is required.](#)
- [Publications is required.](#)
- [Please confirm if all participants have been added.](#)

## Some helpful advice

- Create a budget table and collect all relevant information
  - justification of costs
  - personnel and staff efforts
  - subcontracts & Third Parties
  - calculate direct, indirect and total costs
- List all „key players“ as participants in the submission system
  - start early as all co-applicants need to **be registered** in the system and have to **confirm their participation** electronically
  - Coordinators: Have participants declare that their institutions
    - are aware and have agreed to participate
    - are fully eligible
    - have capacity to carry out the work

## Some helpful advice

- Annexes may be uploaded as .pdf attachments in the system
- Pay attention to word limits in the online submission
- Read carefully the „system help“ document. If in doubt: Ask EDCTPgrants for help.  
[edctpgrants@edctp.org](mailto:edctpgrants@edctp.org)

# Evaluation of proposals

## Main evaluation criteria

- EXCELLENCE
- IMPACT
- QUALITY AND EFFICIENCY OF IMPLEMENTATION



# Evaluation of proposals

## EXCELLENCE

- Fit with scope and objectives of EDCTP2 and call topic
- Importance, relevance and clarity of objectives
- Credibility of proposed approach

# Evaluation of proposals

## IMPACT

- Expected impacts listed in the work plan under relevant topic
- Likelihood to result in major advances for the field

# Evaluation of proposals

## QUALITY AND EFFICIENCY OF THE IMPLEMENTATION

- Coherence and effectiveness of proposed work
- Feasibility and appropriateness of methods and project management
- Appropriateness of management structures and procedures
- Compliance with national and international standards (GCP, ethics, safety, ...)
- Complementarity of participants and gender balance
- Operational capacity based on competence and experience of participants

# Evaluation of proposals

- Experts score each criterion on a scale from 0 to 5
- Maximum overall score is 15 (3x5), unless weighing is applicable
- To be considered for funding, a proposal must achieve a threshold on each criterion and an overall qualifying score
- Qualifying scores vary between types of action and between 1st and 2nd stage submission

# Evaluation of proposals

Priority order for proposals with the same score:

- Topics not otherwise covered by other proposals
- Score awarded for the 'Excellence' section
- Score awarded for the 'Impact' section
- Gender balance
- Leverage of funding from Third Parties
- Number of sub-Saharan African countries
- Quality of networking activities
- Synergies between proposals or other factors related to the call or EDCTP2 in general

## Evaluation Results

- Proposal Outcome Letter sent to coordinator
- Grant Agreement preparation. Timeframe: 3 months
- Integration of evaluators' feedback/recommendations and ethical requirements, if needed
- Strict deadlines!

## Grant Agreement & Consortium Agreement

- Grant Agreement enters into force on day of last signature (usually by EDCTP)
- Beneficiaries other than CoO must accede to the GA within 30 days after its entry into force
- **Consortium Agreement is mandatory** in EDCTP projects for multi-beneficiary actions!
- Should be negotiated and concluded **before signing the GA**

## Further information

Current calls:

<http://www.edctp.org/funding-opportunities/calls/>

Proposal submission tool:

<https://www.edctpgrants.org/>

IPR helpdesk:

<https://www.iprhelpdesk.eu/>

Fit for Health 2.0:

<http://www.fitforhealth.eu/>

(incl answers to questions asked today, and future webinar on EDCTP2 project implementation and management)





Thank you!

Dr. Claudia Schacht | Eurice GmbH

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