

EDCTP2 - Opportunities for clinical research on poverty-related diseases in sub-Saharan Africa.

Info Day, Horizon 2020

Societal Challenge 1: 'Health, demographic change and wellbeing'

8 July 2016, Brussels



E D C T P

European & Developing Countries
Clinical Trials Partnership

Our mission

To reduce poverty and improve health in sub-Saharan Africa by funding **collaborative research** to accelerate the development of new or improved medical interventions against **poverty-related and neglected infectious diseases**.

Who we are

- The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union.

Background

- Established in 2003 by a co-decision of the European Parliament and Council: Article 185 Initiative (Ex 169)
 - Pool research activities to achieve greater impact PRDs
 - Promote integrated approach to clinical 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
- First EDCTP programme: completed in December 2015
- Second EDCTP programme: will run from 2014-2024

What we do

- Fund research in SSA to accelerate the clinical development of effective, safe, accessible, suitable, and affordable medical interventions for PRDs
- Support international alignment, coordination and integration of national research agendas and programmes for PRDs.
- Seek the advice, support and collaboration of many stakeholders including research institutions, development organisations, private charities and funders, pharmaceutical companies, and PDPs.
- Offer a single European-African platform for research cooperation and funding.
- Promote African co-ownership of the EDCTP programme and the development of clinical research capacity and scientific leadership in sub-Saharan Africa.
- Support SSA countries to develop their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant (inter)national standards and regulations.

EDCTP partnership

14 European Countries

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

1 Aspirant Member

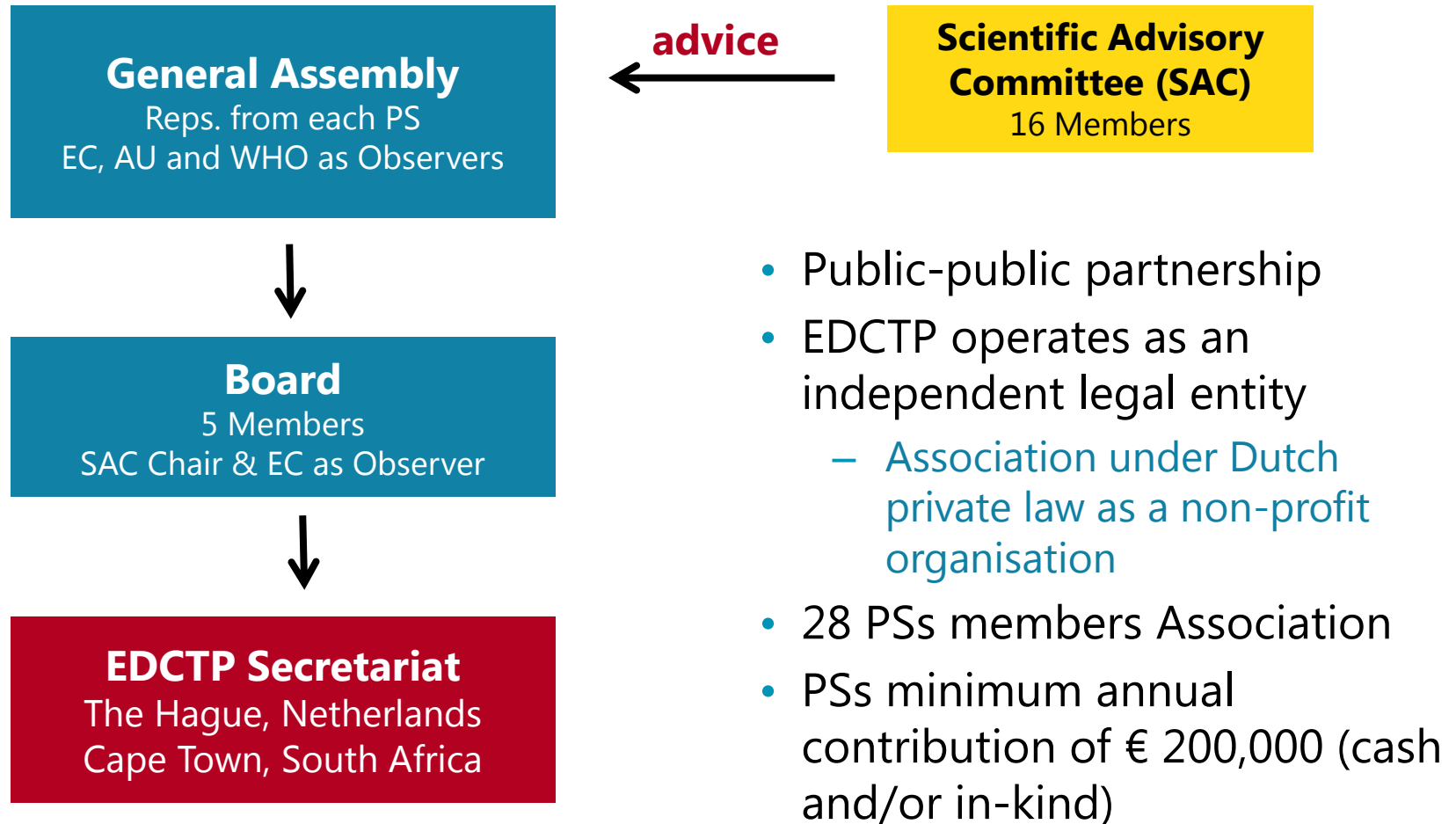
Switzerland

14 African Countries

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



Governance



The EDCTP programme

EDCTP PARTICIPATING STATES



≥ € 683 M



≥ € 30 M

EUROPEAN UNION



≤ € 683 M

THIRD PARTIES

Private sector
PDPs
Development organisations
Research institutions

≥ € 500 M

CASH/IN-KIND

CASH/IN-KIND

CASH

CASH/IN-KIND

**PARTICIPATING STATES'
INITIATED ACTIVITIES**

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

**EDCTP CALLS
FOR PROPOSALS**

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

DEROGATIONS FROM H2020 RULES FOR PARTICIPATION (ART.6 DECISION No 556/2014/EU)

- Participation and funding of African entities:
 - *2 legal entities established in 2 different European PSs and a third legal entity in a sub-Saharan African country*
 - *Any legal entity established in a sub-Saharan country shall be eligible for funding*
- Cooperation with other legal entities:
 - *EDCTP may launch joint calls with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties, in particular NGOs*

Diseases covered by EDCTP

- **HIV, tuberculosis, malaria**
- **Neglected infectious diseases (NIDs)**
Buruli ulcer; cysticercosis/taeniasis; dengue; dracunculiasis; echinococcosis; foodborne trematodiasis; Hansen disease; human African trypanosomiasis; leishmaniasis; lymphatic filariasis; mycetoma; onchocerciasis; rabies; schistosomiasis; soil-transmitted helminthiasis; trachoma; yaws
- **Diarrhoeal diseases**
- **Lower respiratory tract infections**
- **Emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.

EDCTP scope



The diagram features two blue rectangular boxes, one at the top and one at the bottom. A large orange arrow starts from the bottom box, points upwards, and then turns 90 degrees to the right, pointing towards the top box. The word 'Synergy' is written in orange text next to the vertical part of this arrow.

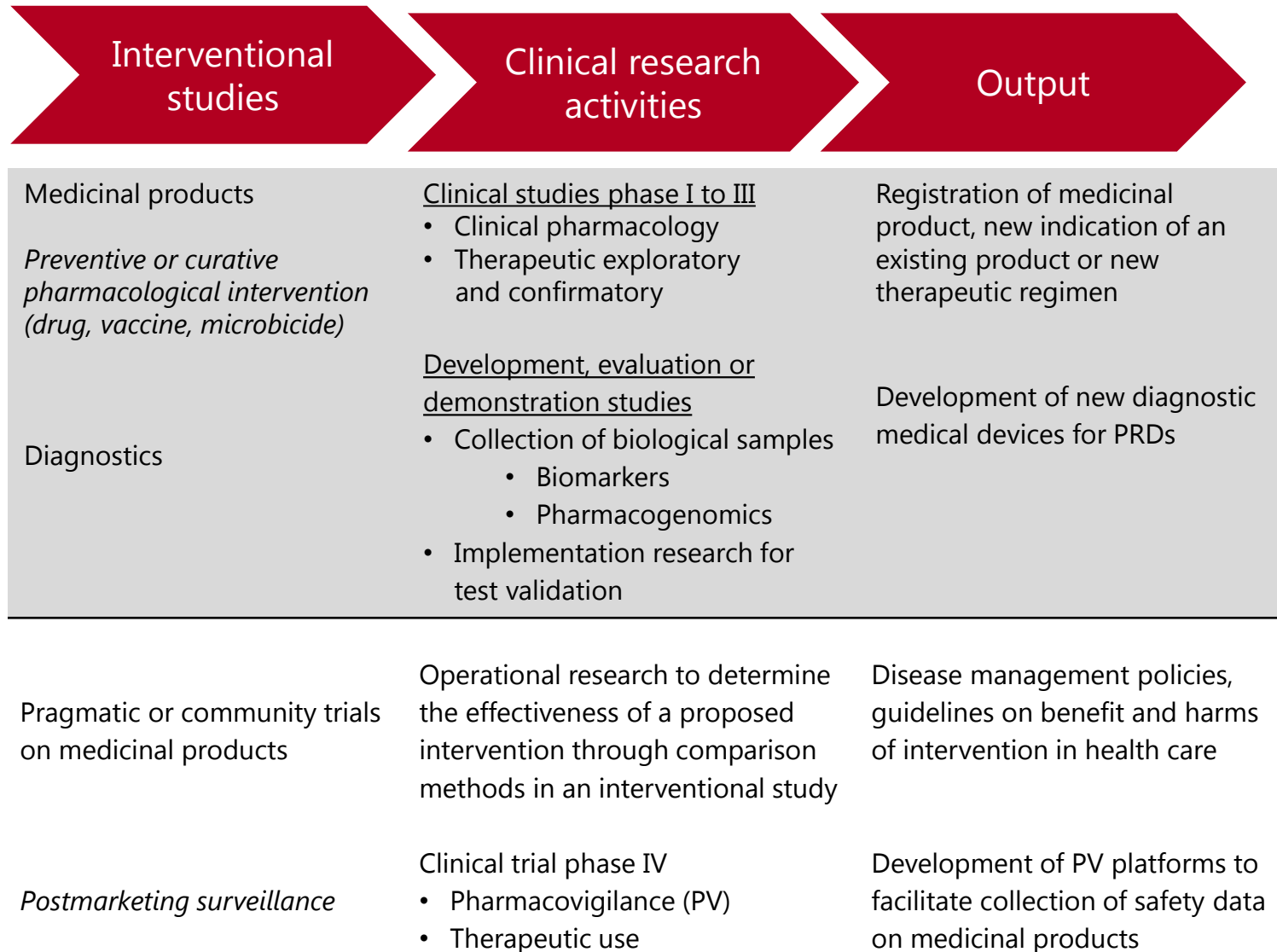
**Conduct collaborative
research on PRDs**

- Conducting interventional clinical studies on medicinal products (*) in compliance with fundamental ethical principles and relevant regulation

**Capacity
development for
clinical research**

(*) Community code relating to medicinal products for human use

Clinical research in scope EDCTP



Type of grants

Research & Innovation Actions (RIA)

Multicentre clinical trials conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.

Coordination & Support Actions (CSA)

Support of activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.

Training & Mobility Actions (TMA)

Fellowships that focus on the career development of individual researchers or research team members.

2016 CALLS FOR PROPOSALS

Research & Innovation Actions (RIAs)

1. Clinical trials aiming to accelerate the clinical development of new vaccines (preventive or therapeutic) against PRDs
 - Call budget: €70M – max funding / project €15M
 - 2-stage call
 - 1st Open date: 7 July 2016 / Close date: 13 October 2016
 - 2nd: Open date: 22 December 2016 / Close date: 16 March 2017

2. Clinical trials and **operational research studies** to optimise the use, delivery and access to products for PRDs in SSA for mothers, newborns, children and/or adolescents
 - Call budget: €10M – max funding / project €3M
 - 2-stage call
 - 1st Open date: 7 July 2016 / Close date: 29 September 2016
 - 2nd: Open date: 12 December 2016 / Close date: 2 March 2017

2016 CALLS FOR PROPOSALS

Research & Innovation Actions (RIAs)

3. The establishment of a consortium for research and clinical management of patients in PRD epidemics in sub-Saharan Africa
 - Call budget: €10M – max funding / project €10M
 - 2-stage call
 - 1st Open date: 7 July 2016 / Close date: 29 September 2016
 - 2nd: Open date: 22 December 2016 / Close date: 2 March 2017

3. Strategic actions supporting large-scale clinical trials that have the potential to achieve rapid advances in the clinical development of new or improved medical interventions against PRDs
 - Focus on phase 3 clinical trials and $\geq 50\%$ costs of trial should be supported by other funders
 - Foreseen total costs of the entire trial \geq €3.0 million
 - Call budget: €28M – max funding / project €15M
 - 2-stage call
 - 1st Open date: 14 July 2016 / Close date: 13 October 2016
 - 2nd: Open date: 22 December 2016 / Close date: 16 March 2017

2016 CALLS FOR PROPOSALS

Coordination & Support Actions (CSAs)

- Strategic actions supporting **health systems/services optimisation research capacities** in cooperation with development assistance initiatives, including development of PV capacities in SSA and the translation of research into policy and practice

- Call budget: €10M – max funding / project €3M
- 2-stage call
- 1st Open date: 14 July 2016 / Close date: 29 September 2016
- 2nd: Open date: 8 December 2016 / Close date: 2 March 2017

- **Ethics and regulatory capacities** to strengthen the functionality, recognition and performance of NECs and NRAs in SSA

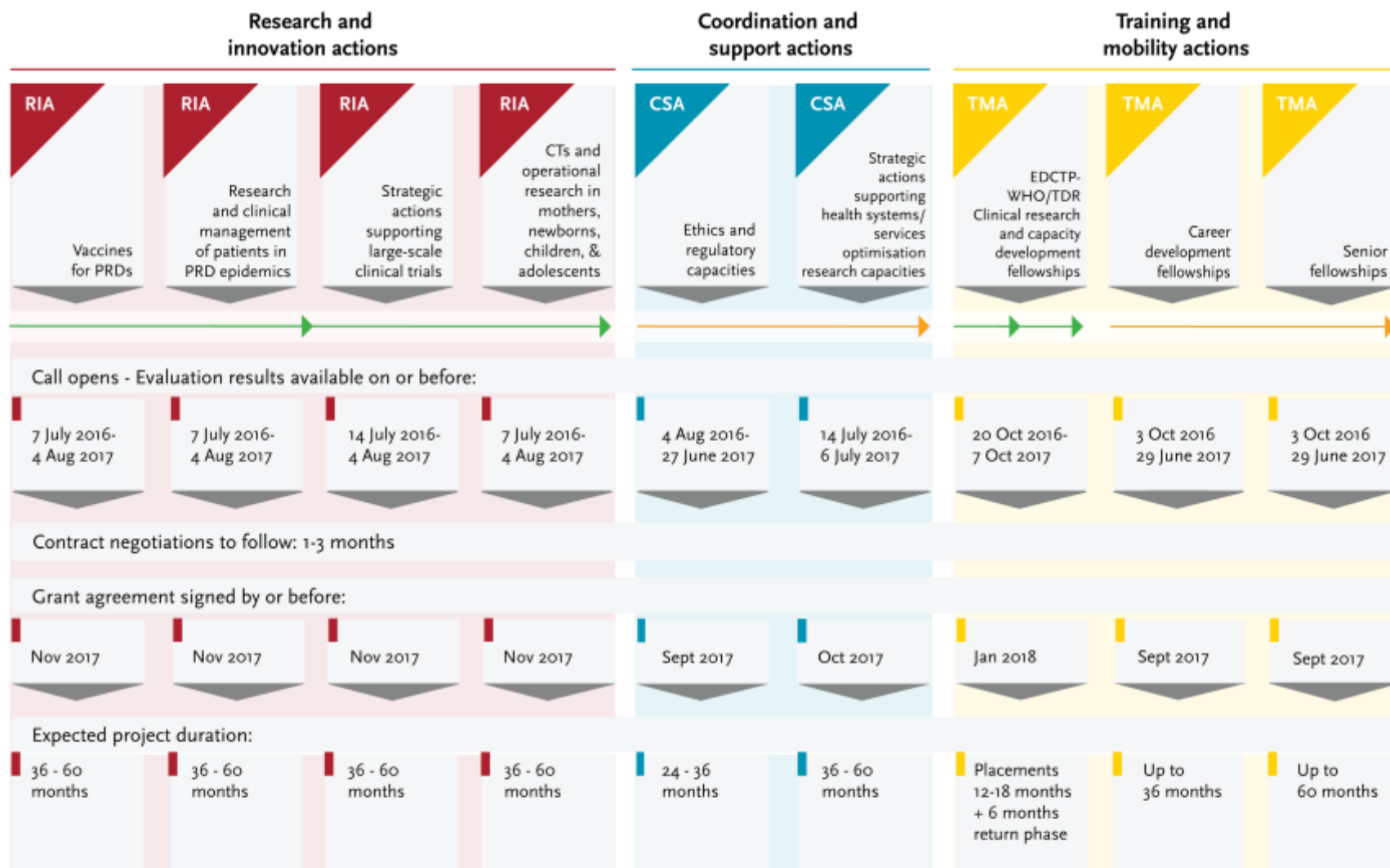
- Call budget: €2M – max funding / project €300k
- 1-stage call
- Open date: 4 August 2016 / Close date: 22 November 2016

2016 CALLS FOR PROPOSALS

Training & Mobility Actions (TMAs)

- **EDCTP-TDR Clinical Research and Development Fellowships** for junior to mid-career researchers or clinical staff from low- and middle-income countries to provide targeted training in clinical research and development within pharmaceutical companies and PDPs
- **Career Development Fellowships** to support junior to mid-career researchers to train and develop their clinical research skills
- **Senior Fellowships** to support the capacity development of potential African research leaders

Calls for proposals 2016 - Timelines



One-stage application procedure →

Two-stage application procedure →

HOW TO ACCESS INFORMATION

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

The screenshot shows the EDCTP website with the following elements:

- Browser Address Bar:** www.edctp.org/funding-opportunities/calls/
- EDCTP Logo:** Located at the top center of the page.
- Language Selector:** A dropdown menu set to "English" with a search icon to its right.
- Primary Navigation Bar:** Contains links for Home, Our Calls, Our Projects, Get to know us, How we work, and Stay up to date.
- Secondary Navigation Bar:** Contains links for Calls, FAQs on Calls, Scope, Types of Grants, and Expert reviewers.
- Section Header:** "Calls" in a large blue font.
- Sub-section:** "EDCTP Calls for Proposals" in a smaller grey font.
- Filter Tabs:** "Open", "Planned", "Closed", and "All calls". The "Open" tab is selected and highlighted with a yellow arrow.
- Call Listing:**
 - Status:** OPEN (in green text)
 - Title:** Clinical trials and operational research studies to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents
 - Description:** This call aims to support actions on preventive and therapeutic clinical interventions of post-registration products, as well as related behavioural...
 - Type:** RESEARCH AND INNOVATION ACTION (RIA)
 - Open date:** 7 July 2016, 17:00
 - Close date:** 6 September 2016, 17:00
 - Action:** Read more →

The Windows taskbar at the bottom shows various application icons and the system clock indicating 21:58 on 07/07/2016.

BENEFITS AND OPPORTUNITIES FROM PARTICIPATION IN EDCTP

EDCTP offers researchers:

- Opportunities to participate in large international clinical research consortia across Europe and Africa
- Increased networking opportunities, including with major pharmaceutical companies, public and private funders
- Collaborative research = higher citation impact

Other opportunities to engage include:

- EDCTP organises a biennial Forum (next on 6-9 November 2016 in Lusaka, Zambia) – gathers ~600 scientists, stakeholders, policy-makers
- Thematic stakeholder meetings (on average 1-2 per year)
 - In 2016: Diarrhoeal disease and lower respiratory tract infections, 5-6 July 2016
- Register as an EDCTP expert reviewer
 - <http://www.edctp.org/calls-and-grants/information-for-reviewers/call-for-expert-reviewers/>



THANK YOU

WWW.EDCTP.ORG

For more information, please contact:

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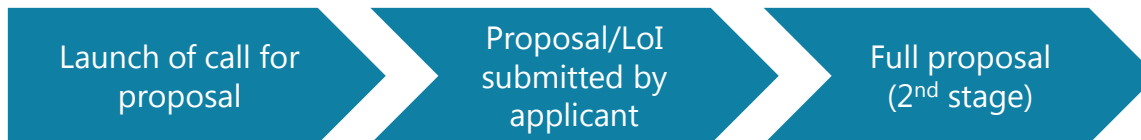


Calls and grants procedure

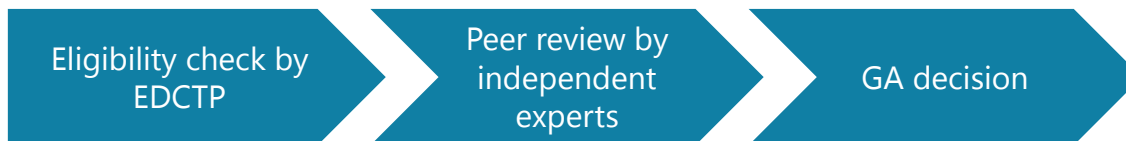
Annual work plan with call topics



Proposal preparation and submission



Proposal review and approval



Project award



Monitoring and grant closure

