EDCTP perspective on biopreparedness and related capacity development in Africa

Consultation workshop on Preparedness for emerging diseases

Dr. Michael Makanga
EDCTP Executive Director.

29 September 2016
EDCTP public-public 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
EDCTP Business model

To reduce poverty in SSA through improved health by funding collaborative research to enhance research capacity and accelerate the development of new or improved medical interventions against PRNDs.

Mission

To reduce the social and economic burden of PRNDs in SSA

Specific objectives (Pillars)

- Increase new or improved medical interventions against PRNDs
- Increase Cooperation with SSA through capacity building (CTs, Ethics & Regulatory)
- Improve coordination alignment and integration of European National Programmes
- Increase International Cooperation with third parties
- Increase interaction with Development partners (incl.EU and WHO initiatives)

Implementation: RBM Approach

Expected results in measurable terms (outputs/outcomes)

Performance indicators

Targets and benchmarks for each indicator

Vision (overall goal)

Mission

Specific objectives (Pillars)

Implementation: RBM Approach

Values (Anchors)

Mission Focus
Cooperation
Excellence
Integrity
Transparency
Respect
Key features of EDCTP

- We have been established as a **flagship European–Africa partnership** and recognised international funder on clinical research for PRNIDs.
- EDCTP operates as a true ‘**partnership of equals**’ between North and South, with input from African countries at all levels.
- We are **enhancing the capacity of sub-Saharan Africa countries** to conduct clinical studies.
- The EDCTP2 programme encompasses **target populations** often excluded from clinical studies but with major unmet medical needs.
- Expansion of EDCTP2 to cover **implementation research** on delivery and uptake of medical research makes its work even more relevant to health services in sub-Saharan Africa countries.
- We focus on **clinical challenges and policy-relevant questions**, ensuring the results of research feed directly into national and international policy-making.
- We are committed to **working with like-minded partners**, to take advantage of the platform established for high-quality research.
EDCTP target diseases

• **HIV, tuberculosis, malaria**

• **Neglected infectious diseases**
  Buruli ulcer; cysticercosis/taeniasis; dengue; dracunculiasis; echinococcosis; foodborne trematodiases; Hansen disease; human African trypanosomiasis; leishmaniasis; lymphatic filariasis; mycetoma; onchocerciasis; rabies; schistosomiasis; soil-transmitted helminthiases; trachoma; yaws

• **Diarrhoeal diseases**

• **Lower respiratory tract infections**

• **Emerging and re-emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.
EDCTP strategy for capacity development

Site preparation for conducting clinical research

Strengthening product-focused health systems research
Phase IV studies
- Pragmatic studies
- Implementation research with a product focus
- Pharmacovigilance

Comprehensive fellowship programme
- Preparatory fellowships
- Industry Fellowship (EDCTP-WHO/TDR Fellowship)
- Career Development Fellowship
- Senior Fellowship

Regional Networks of Excellence

Strengthening ethics capacity and regulatory framework
EDCTP Call: “Research and clinical management of patients in PRD epidemics in sub-Saharan Africa”

Background and Scope

**Background**

Countries in sub-Saharan Africa have weak health systems, inadequate resources, and poor capacity to identify and respond quickly and effectively to disease outbreaks.

**Scope**

The “EDCTP PRD Epidemics Call” aims to support the establishment of a multidisciplinary consortium able to provide accelerated evidence for the optimal clinical management of patients and for guiding the public health response to any severe infectious outbreak caused by pathogens within the scope of the EDCTP programme with pandemic potential or that may cause significant damage to health and socio-economics in Africa (including antimicrobial-resistant pathogens).
The EDCTP PRD Epidemics Call

Budget and timelines

**Budget**

Total Call Budget: 10 Million €
Maximum budget per grant: 10 Million €
  - 1 Consortium will be funded

**Timelines**

Stage 1 Launch: 7 July 2016
Stage 1 Closing: 29 September 2016

Stage 2 Opening: 22 December 2016
Stage 2 Closing: 2 March 2016.
The EDCTP PRD Epidemics Call

Expected impact

The consortium is expected:

- To collaborate with similar initiatives at national, regional, European and international level (e.g. PREPARE, ISARIC, EDCTP regional networks of excellence)

- To carry out a project aiming at ensuring preparedness to perform large-scale multi-site clinical studies (in response to an emerging threat) which include:
  - Evaluation of potential preventive or therapeutic interventions
  - Validation of diagnostic devices
  - Establishment of disease natural history and determinants of disease severity

- To establish standardised protocols, definitions, and strategies for the optimal clinical management of patients in any severe infectious outbreak.
EDCTP2 Ebola projects

CSA-Ebola-360
Building research capacity for infectious diseases in Sierra Leone

CSA-Ebola-334
Strengthening Laboratory Capacities for Clinical Trials on infectious diseases in Liberia

CSA-Ebola-355
Institutional capacity for health research in Sierra Leone

CSA-Ebola-353
Capacity for phase 1 trials in Uganda

CSA-Ebola-363
Vaccine trials and Ebola virus control

CSA-Ebola-337
Enhancing outbreak response capacity in Northern Uganda

CSA-Ebola-339
Affects, perceptions and understandings of the response to Guinea’s Ebola Virus epidemic

€1.7m
Calls for proposals 2016

### Research and innovation actions
- **RIA**
  - Vaccines for PRDs
  - Research and clinical management of patients in PRD epidemics
  - Strategic actions supporting large-scale clinical trials

### Coordination and support actions
- **CSA**
  - CIs and operational research in mothers, newborns, children, & adolescents
  - Ethics and regulatory capacities
  - Strategic actions supporting health systems/services optimisation research capacities

### Training and mobility actions
- **TMA**
  - EDCTP-WHO/UNDP Clinical research and capacity development fellowships
  - Career development fellowships
  - Senior fellowships

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**Call opens - Evaluation results available on or before:**
- 7 July 2016 - 4 Aug 2017
- 7 July 2016 - 4 Aug 2017
- 14 July 2016 - 4 Aug 2017
- 7 July 2016 - 4 Aug 2017
- 4 Aug 2016 - 27 June 2017
- 14 July 2016 - 6 July 2017
- 20 Oct 2016 - 7 Oct 2017
- 3 Oct 2016 - 29 June 2017
- 3 Oct 2016 - 29 June 2017

**Contract negotiations to follow: 1-3 months**

**Grant agreement signed by or before:**
- Nov 2017
- Nov 2017
- Nov 2017
- Nov 2017
- Sept 2017
- Oct 2017
- Jan 2018
- Sept 2017
- Sept 2017

**Expected project duration:**
- 36 - 60 months
- 36 - 60 months
- 36 - 60 months
- 36 - 60 months
- 24 - 36 months
- 36 - 60 months
- Placements 12-18 months + 6 months return phase
- Up to 36 months
- Up to 60 months

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**One-stage application procedure**

**Two-stage application procedure**
THANK YOU

WWW.EDCTP.ORG