

EDCTP perspective on biopreparedness and related capacity development in Africa

Consultation workshop on Preparedness for emerging diseases



E D C T P

European & Developing Countries
Clinical Trials Partnership

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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

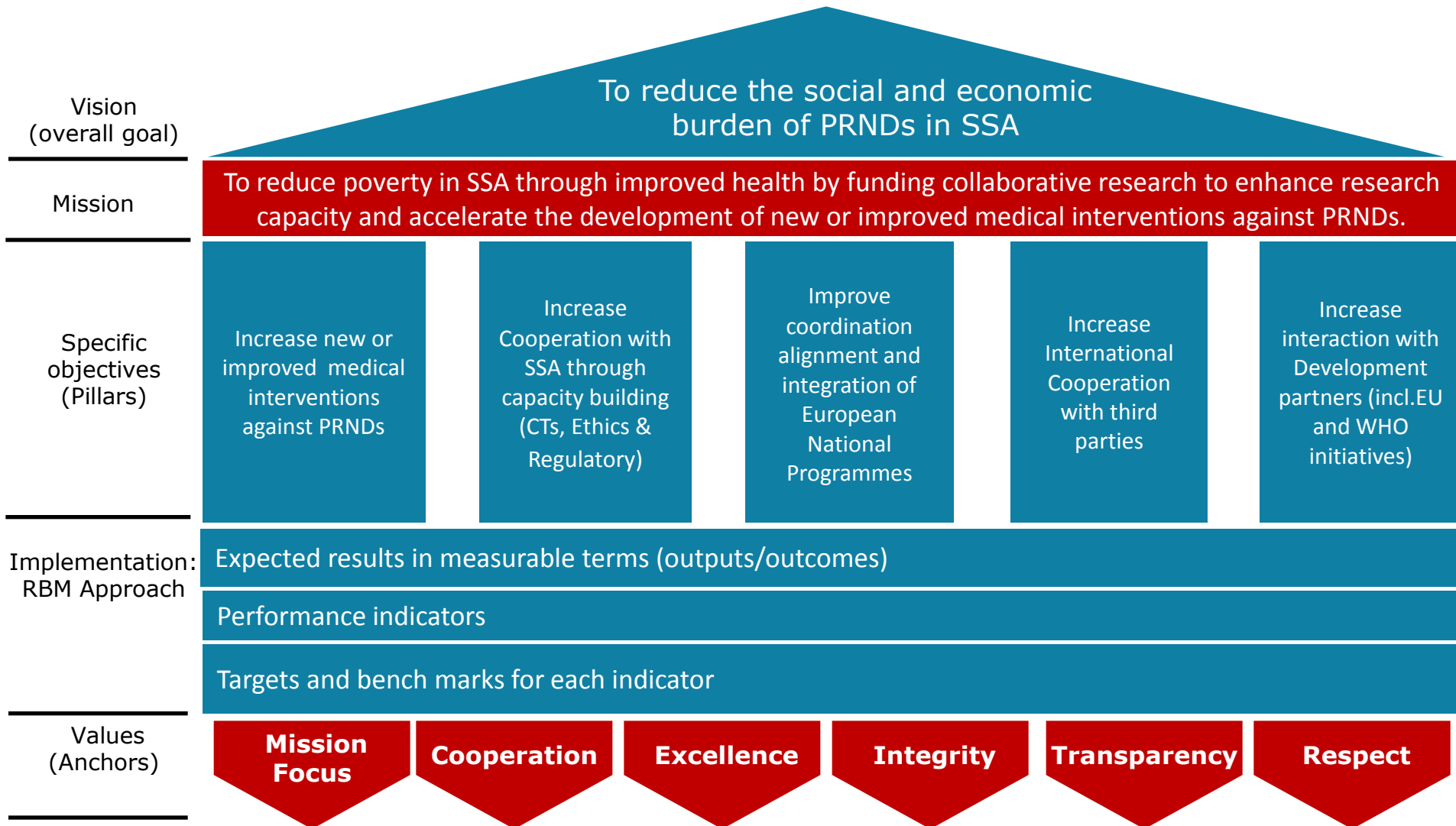
Switzerland

14 African Countries

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



EDCTP Business model



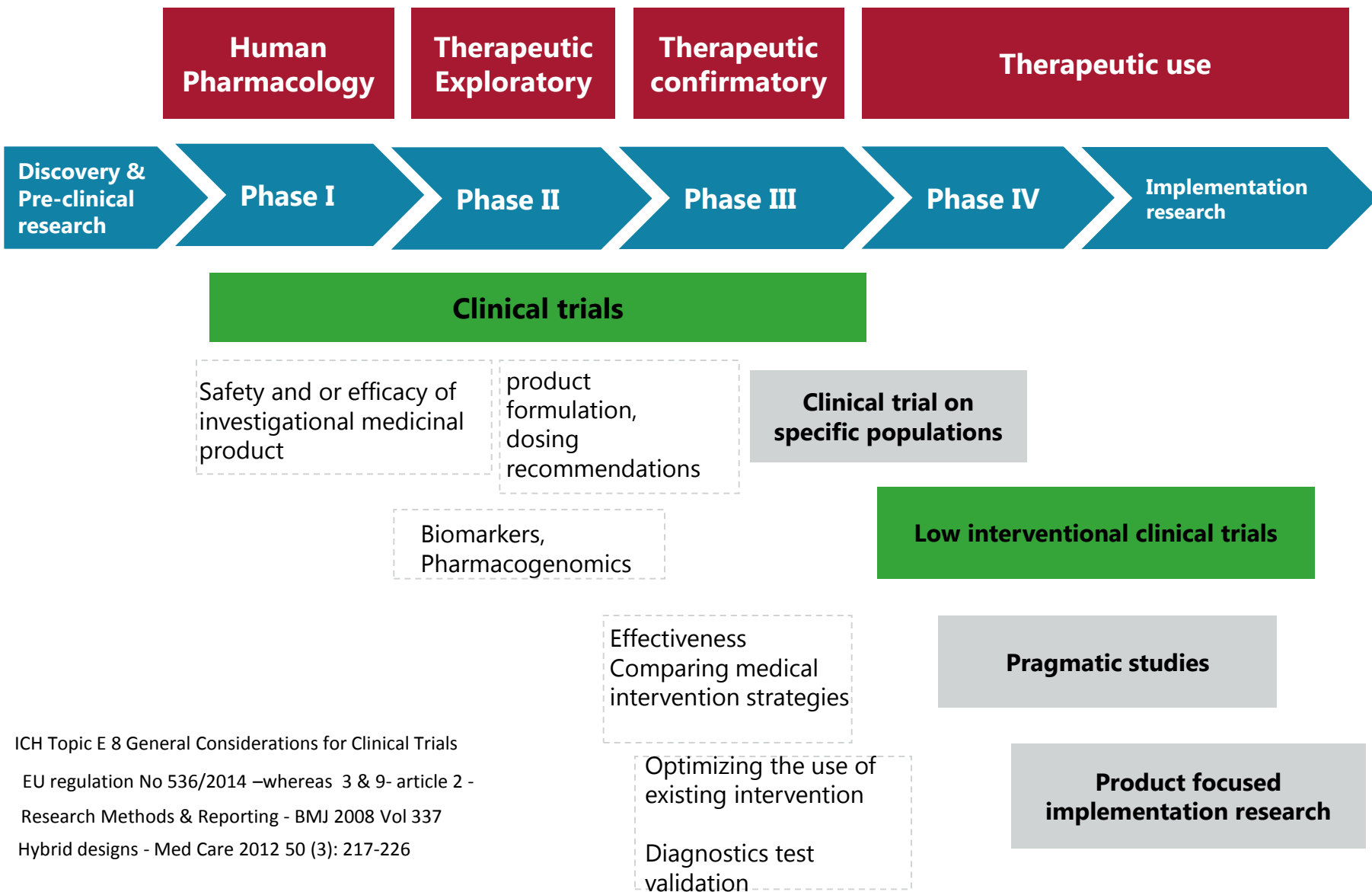
Key features of EDCTP

- 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.
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EDCTP target diseases

- **HIV, tuberculosis, malaria**
- **Neglected infectious diseases**
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 and re-emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.

Clinical studies supported by EDCTP



ICH Topic E 8 General Considerations for Clinical Trials

EU regulation No 536/2014 –whereas 3 & 9- article 2 -

Research Methods & Reporting - BMJ 2008 Vol 337

Hybrid designs - Med Care 2012 50 (3): 217-226

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



Overall EDCTP funding approach for sustainable research



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

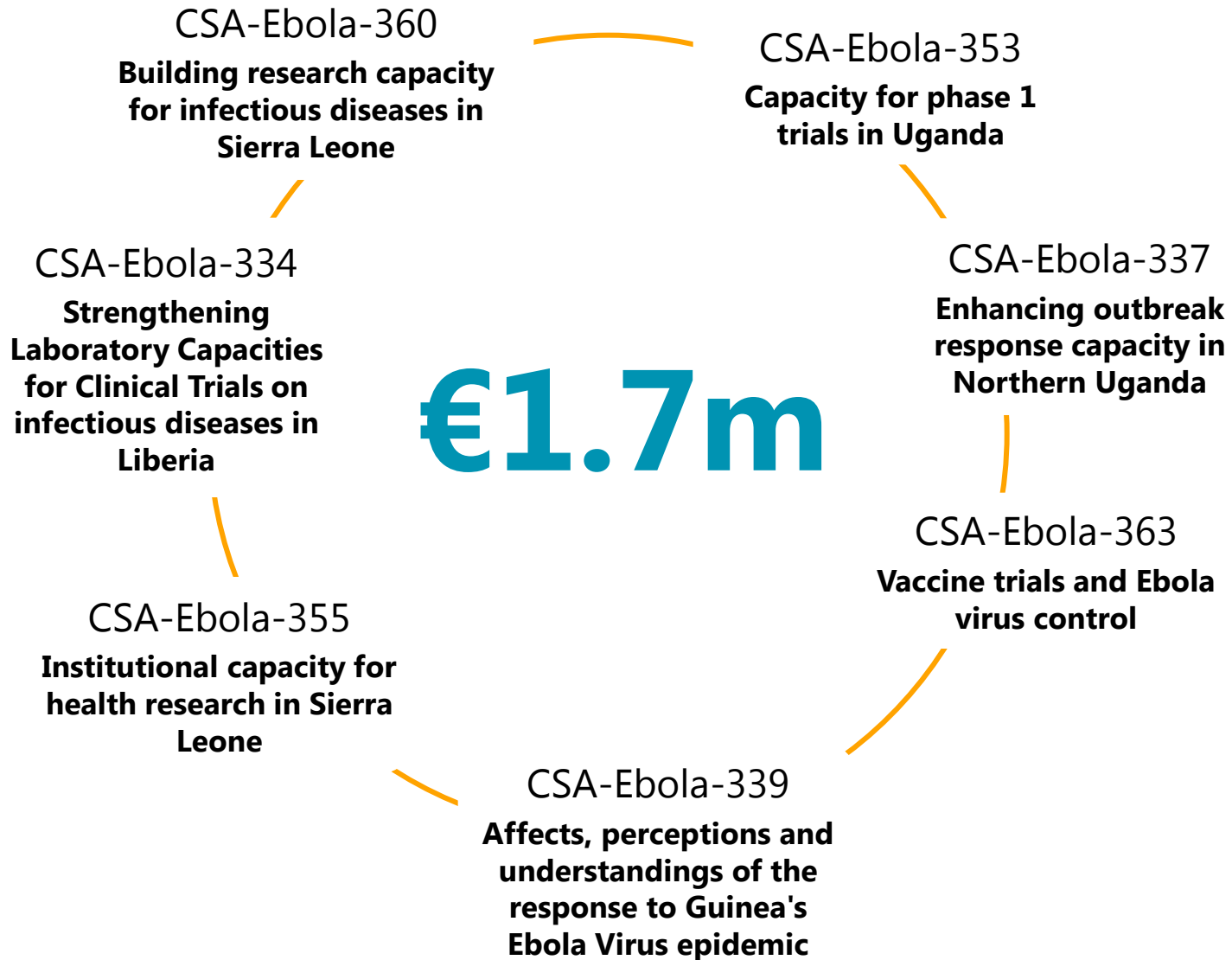
The consortium is expected:

- 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

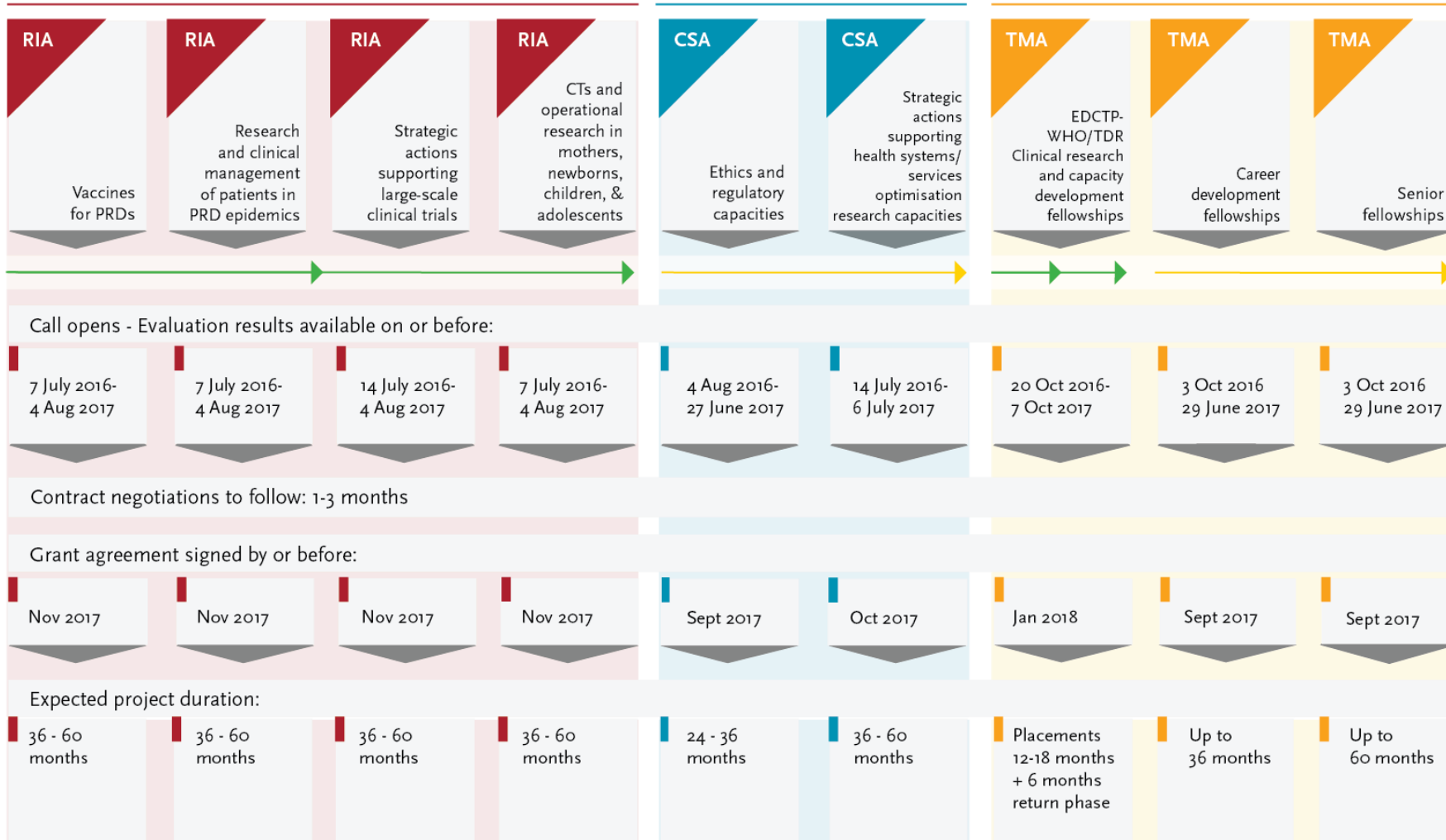


Calls for proposals 2016

Research and innovation actions

Coordination and support actions

Training and mobility actions



One-stage application procedure →

Two-stage application procedure →



THANK YOU

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