

EDCTP 2

European and Developing Countries
Partnerships for Clinical Trial on Poverty
Related and Neglected Infectious
Diseases

II Conferencia H2020 y Salud
Instituto de Salud Carlos III,
Laura Mohedano
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EDCTP

European and Developing Countries Partnerships for Clinical Trial on Poverty Related and Neglected Infectious Diseases

- Programa para el desarrollo de **Ensayos Clínicos** en **África subsahariana** de **enfermedades infecciosas**, relacionadas con la **pobreza**.
- Creación en el año **2003** (base legal en el **Art. 185 TFUE**).

EDCTP. Misión



To reduce poverty in sub-Saharan Africa through improved health by funding collaborative research to enhance research capacity and accelerate the development of new or improved medical interventions against **P**overty-**R**elated and **N**eglected **I**nfectious **D**iseases (PRNIDs)

EDCTP. Objetivos



Medical interventions

New or improved medical interventions against poverty-related infectious diseases



Collaboration and capacity development

Increase cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards



European coordination

Improve coordination alignment and integration of European National Programmes



External partnerships

Increase international cooperation with public and private partners



EU cooperation

Increase interaction with other EU initiatives, including those linked to development assistance

Países que participan en EDCTP

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. Estructura de gobierno

General Assembly

Representatives:

- Partner State (14 UE & 14 África)
- Observers: WHO, EC and African Union (55 Estados africanos)



Scientific Advisory Committee (SAC)

15-17 members

Board

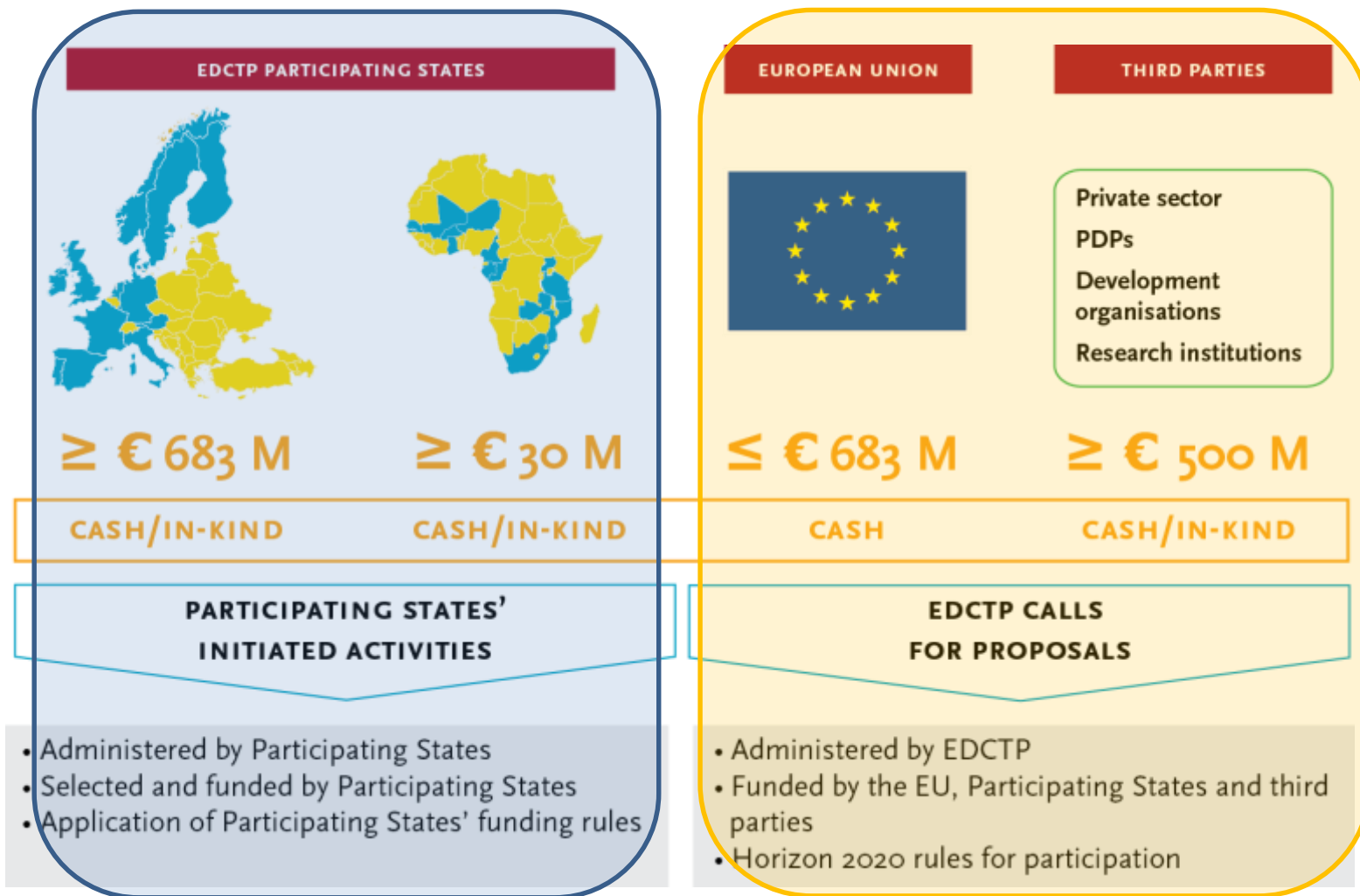
5 members +
SAC Chair + EC (observer)



EDCTP Secretariat

The Hague, Netherlands
Cape Town, South Africa

EDCTP. Modelo de financiación



EDCTP. Enfermedades

- **HIV, tuberculosis, malaria**
- **Neglected infectious diseases***
Buruli ulcer; Chikungunya; Dengue; Dracunculiasis (guinea-worm disease); Echinococcosis; Foodborne trematodiasis; Human African trypanosomiasis (sleeping sickness); Leishmaniasis; Leprosy (Hansen's disease); Lymphatic filariasis; Mycetoma; Onchocerciasis (river blindness); Rabies; Schistosomiasis; Soil-transmitted helminthiasis; Taeniasis/Cysticercosis; Trachoma; Yaws (Endemic treponematoses)
- **Diarrhoeal diseases**
Rotavirus, *Shigella*, ETEC (ST and/or LT), *Cryptosporidium*, Norovirus
- **Lower respiratory tract infections**
Group B streptococci, RSV & pneumococcus in neonats; RSV, pneumococcus & CMV in children; pneumococcus in adults
- **Emerging and re-emerging infectious diseases** of particular relevance for Africa, such as Ebola virus disease and yellow fever.

* Based on the WHO list of neglected tropical diseases (excluding Chagas disease)

EDCTP. Evolución



EDCTP en el ciclo de la innovación

PRODUCT DEVELOPMENT PIPELINE

Discovery
Proof of
Concept

Preclinical
research

Clinical research

Implementation
research

H2020 collaborative translational research projects

EDCTP2 programme

SME-Instrument

IMI2 programme

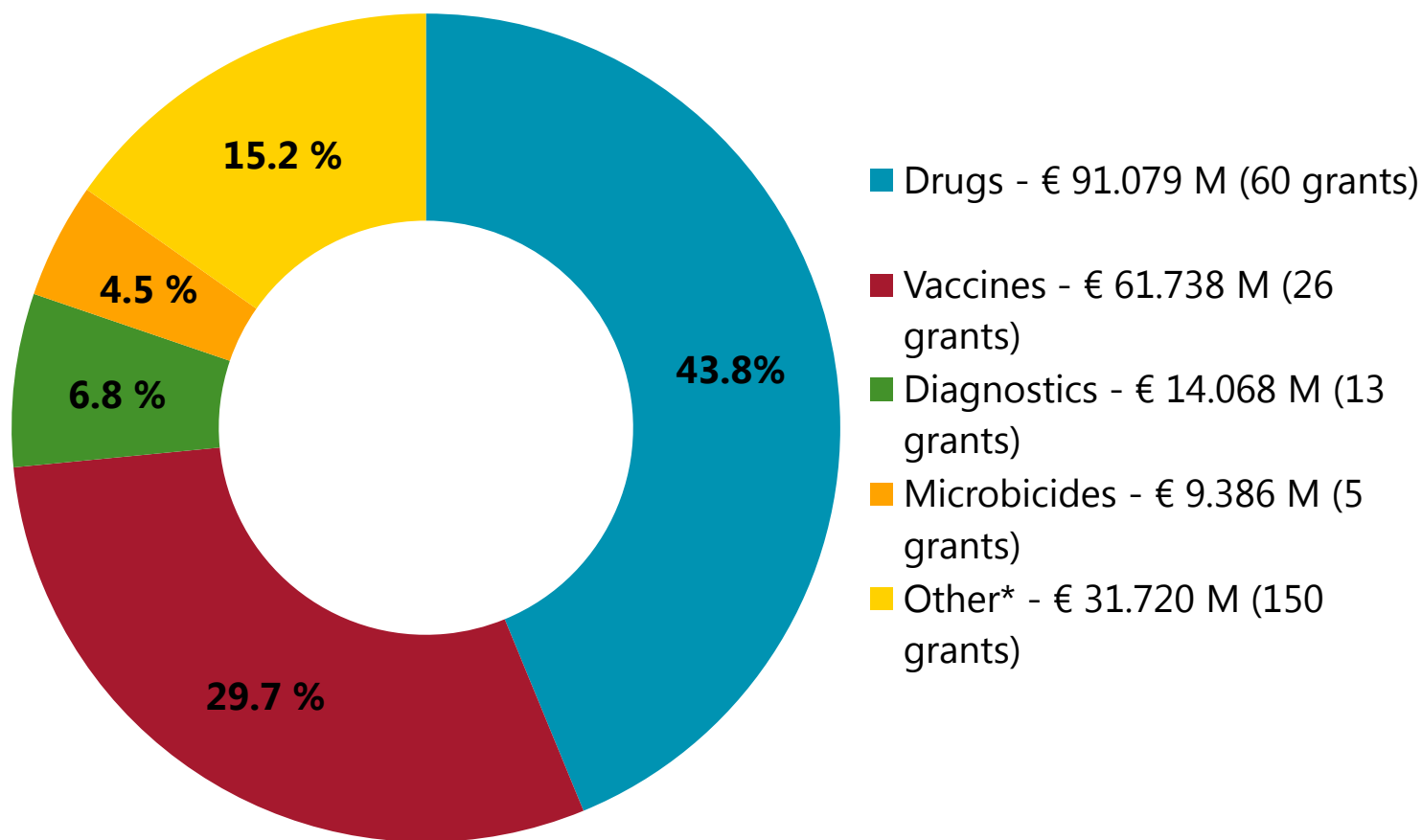
InnoFin ID – Infectious Diseases Financing Facility (IDFF)

EDCTP. Tipos de convocatorias

- RIA for treatment
- RIA for diagnostic
- RIA for vaccines
- RIA for strategic actions
- CSA for Ethical and Regulatory issues
- CSA for African networks support
- Training and mobility action (TMA)

Research and Innovation Action: RIA
Coordination and Support Actions: CSA

Fondos EDCTP, según objetivos de proyecto (2014-2016)



EDCTP: Main results so far (2003-2016)

| | |
|-----------------------------|--|
| AIDS/HIV | Second-line antiretroviral treatment for children |
| | Developing a new HIV prevention device for young women in Africa |
| | Evaluating a promising vaccine to end HIV |
| | HIV-associated infection with cryptococcal meningitis |
| Tuberculosis | Shortening TB treatment |
| | Biomarkers to predict TB treatment duration |
| | Diagnostic approaches of active TB |
| | Effective implementation of TB diagnostics |
| Malaria | Malaria prevention in pregnancy |
| | Optimizing a dosing regimen |
| Neglected Tropical Diseases | Diagnostic tools to eliminate sleeping sickness |
| | Point-of-care diagnosis for taeniasis and (neuro)cysticercosis |

EDCTP. Previsión de convocatorias

| Expected Next Years Work Plan | 2018 | | | | | | | 2019 | | | |
|---|------|---------------------------|-------------------|-----|-----|-----|-----|----------------------|-----|-----|-----|
| | JUN | JUL | AGO | SEP | OCT | NOV | DIC | ENE | FEB | MAR | ABR |
| Treatment innovations for poverty-related diseases | | RIA 1 st Stage | | | | | | 2 ^o Stage | | | |
| Strategic actions supporting large-scale clinical trials | | RIA 1 st Stage | | | | | | 2 ^o Stage | | | |
| Clinical trials to reduce health inequities in pregnant women, newborns and children | | RIA 1 st Stage | | | | | | 2 ^o Stage | | | |
| Targeting control and elimination of NIDs through clinical trials | | RIA Full Proposal | | | | | | | | | |
| Targeting control and elimination of NIDs through product-focused implementation research | | RIA Full Proposal | | | | | | | | | |
| Ethics and regulatory capacities | | | Capacity Research | | | | | | | | |
| Career Development Fellowships | | | TMA | | | | | | | | |
| EDCTP-TDR Clinical Research and Development Fellowships | | | | | TMA | | | | | | |
| Senior Fellowships | | | | | | TMA | | | | | |
| Senior Fellowships for co-morbidities between PRD and non-communicable diseases | | | | | | TMA | | | | | |

EDCTP. Conclusiones

- Dirigido a grupos de investigación que quieren **desarrollo clínico** de productos innovadores en las enfermedades de EDCTP
- Programa centrado en **enfermedades Tropicales**
- Se recomienda la formación de **consorcios fuertes** (participación de PYMES e industria)
- Se recomienda alineamiento con los principios de la **Cooperación para el Desarrollo** (apropiación, predictividad alineamiento con los países africanos y armonización)

Delegado de España para EDCTP

Tomás Lopez-Peña Ordoñez
tlpena@isciii.es

Laura Mohedano

EDCTP 2017 Call Topics (1º)

| Call topics | Type | Budget (€) |
|---|--------------------------------------|------------|
| Treatment innovations for PRDs | Research and Innovation Action (RIA) | 30,000,000 |
| Targeting control and elimination of NIDs through clinical trials | RIA | 19,800,000 |
| Targeting control and elimination of NIDs through product-focused implementation research | RIA | 10,200,000 |
| Strategic actions supporting large-scale clinical trials | RIA | 43,000,000 |
| Clinical trials to reduce health inequities in mothers, newborns and children | RIA | 38,235,363 |

EDCTP 2017 Call Topics (II)

| Call topics | Type | Budget (€) |
|---|-------------------------------------|------------|
| Ethics and Regulatory Capacities | Coordination and Support Action | 2,500,000 |
| Senior Fellowships | Training and Mobility Actions (TMA) | 3,000,000 |
| EDCTP-GSK Senior Fellowships | TMA | 3,000,000 |
| Career Development Fellowships | TMA | 2,500,000 |
| EDCTP-AREF Preparatory Fellowships | TMA | 800,000 |
| EDCTP-TDR Clinical Research and Development Fellowships | TMA | 3,500,000 |