

EDCTP Stakeholder Meeting on Capacity Development

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Mission

- To reduce the burden of poverty related diseases (HIV/AIDS, malaria and tuberculosis) and generally **improve the health** of people living in developing countries

Objectives

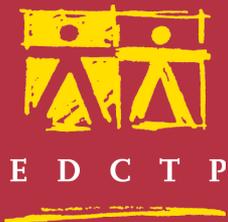
- To accelerate research and development of new or improved interventions against these diseases through the coordination of the European member state national programmes working in **partnership** with sub-Saharan African countries

EDCTP1 Partnership

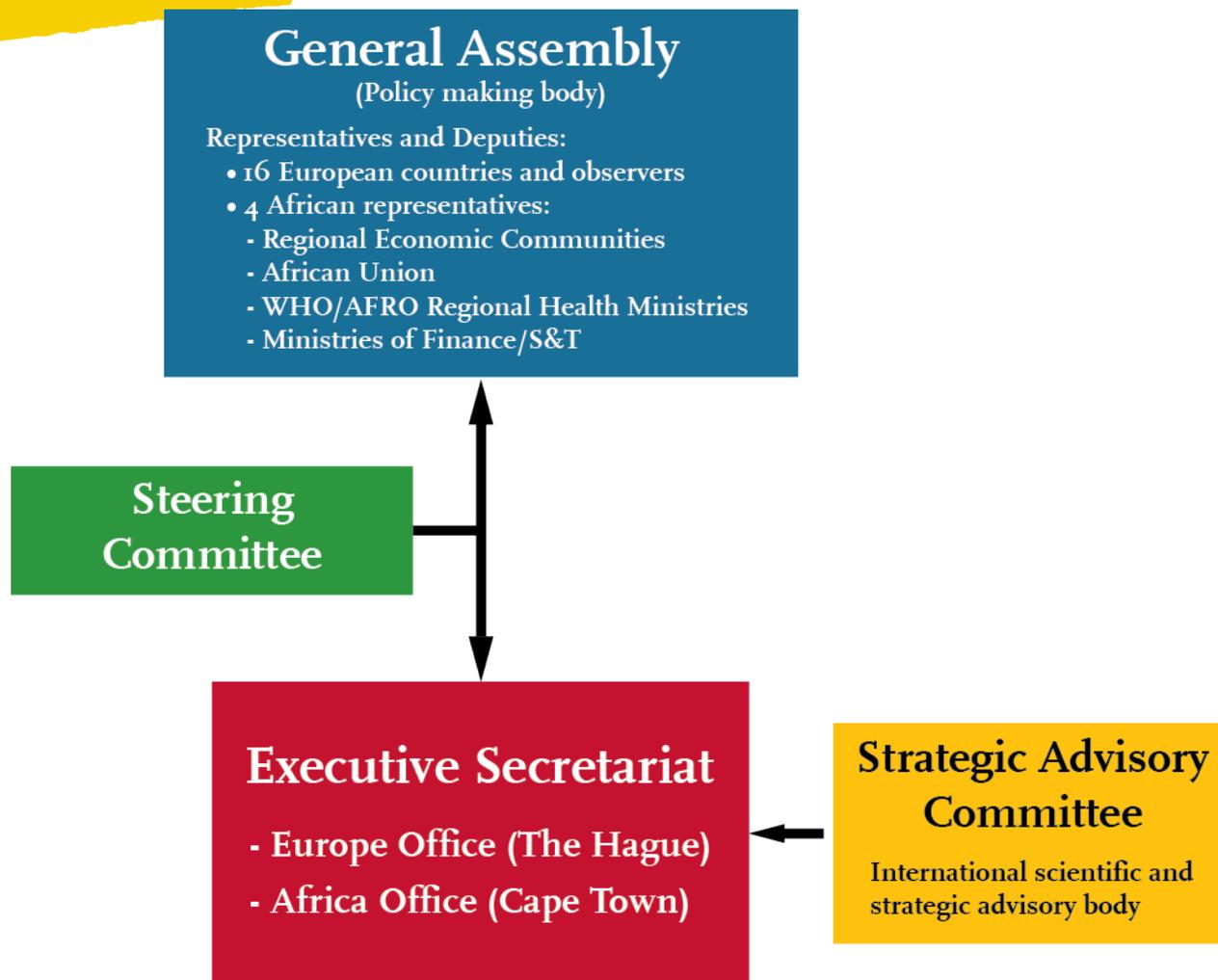
16 European Countries

- **14 EU countries:** Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and United Kingdom
- **2 Associated Countries:** Norway and Switzerland
- **Aspiring Members:** Finland, Latvia, Poland, Slovakia

48 sub-Saharan African Countries



EDCTP1 Governance: European Economic Interest Group (EEIG)



Participating States

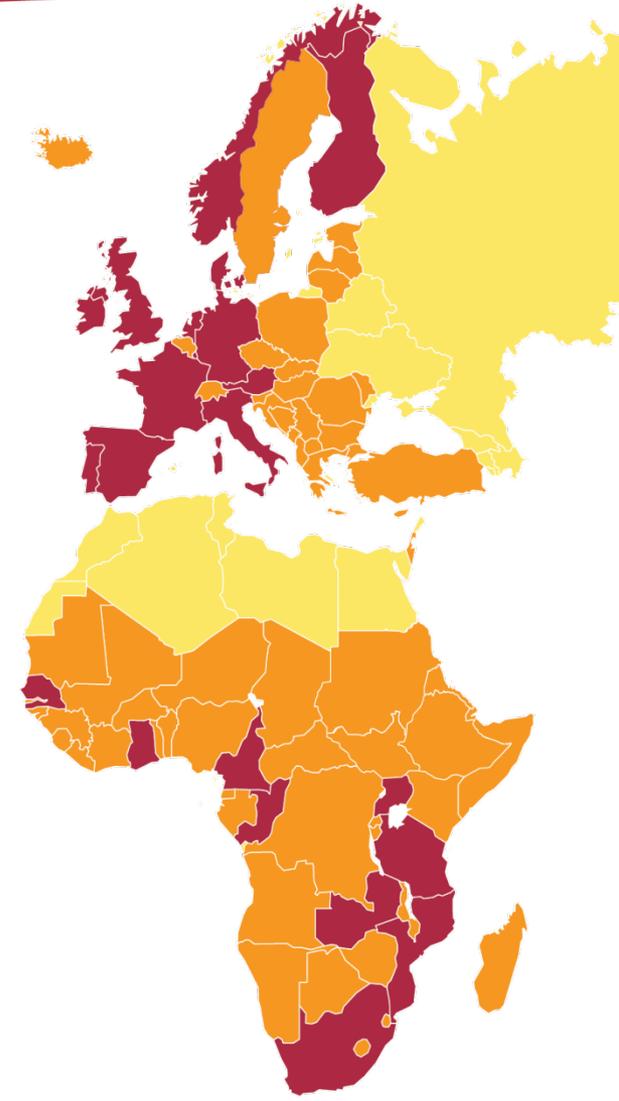
Participating States

- 13 European countries
- **9 African countries**
- 2 candidate countries

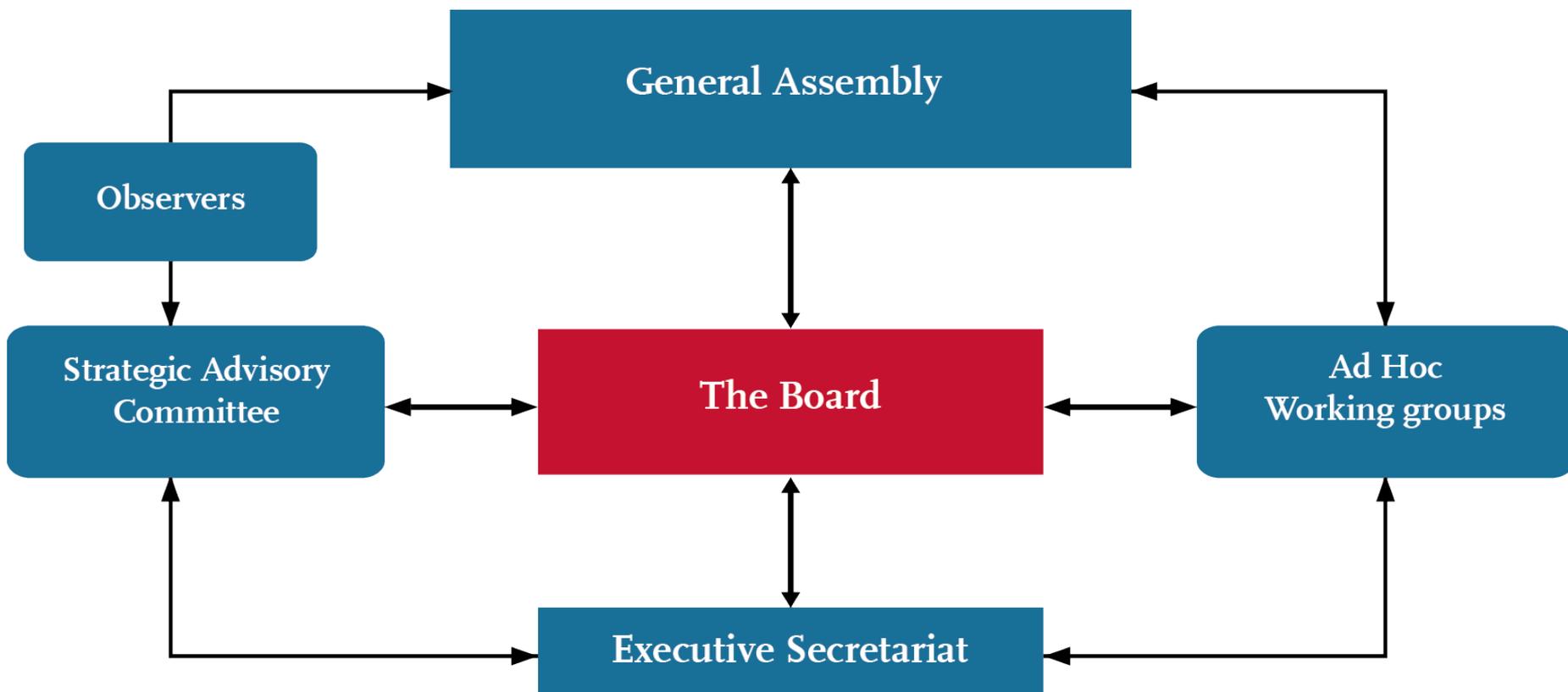
Affiliated

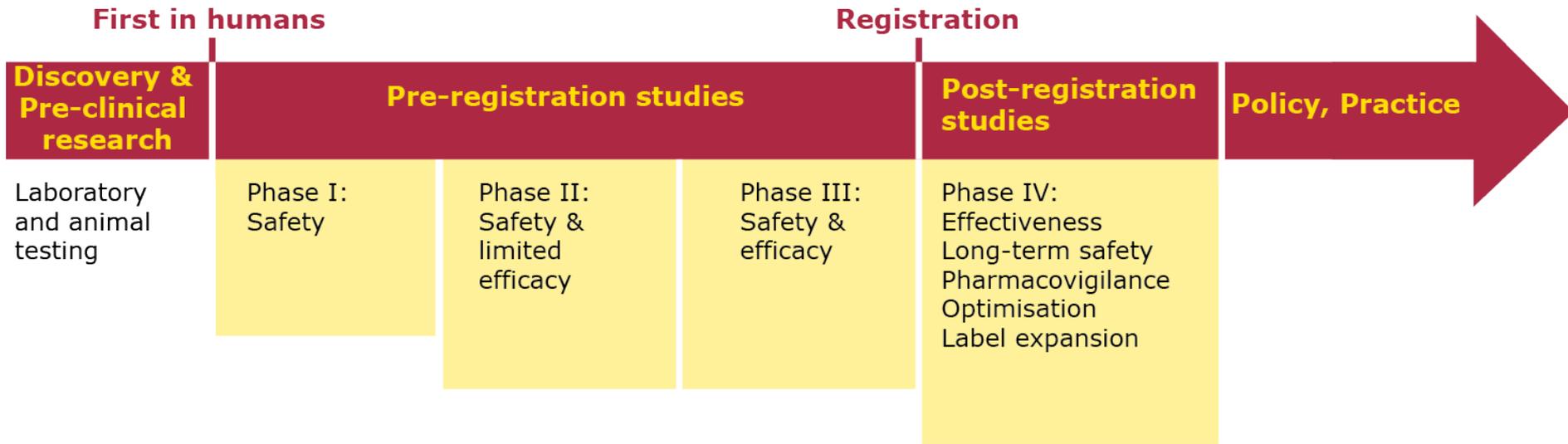
(countries that can receive funding)

- All sub-Saharan African countries
- All EU Member States and Associated Countries



EDCTP-Association





Disease profile:
HIV/AIDS, TB, Malaria, **NIDs**

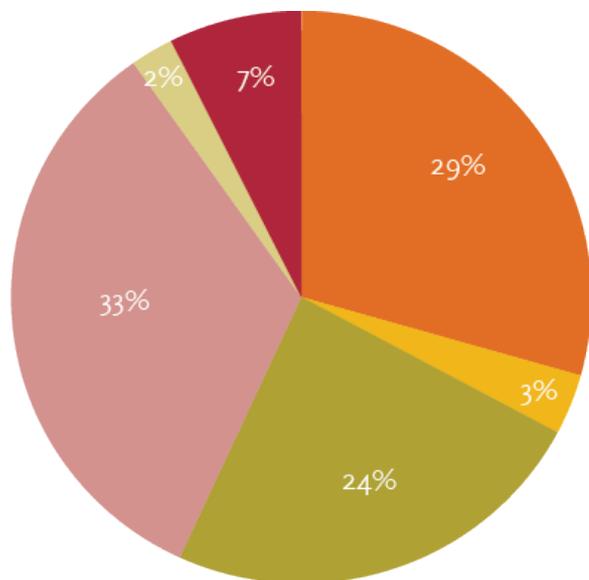
Interventions:
Drugs, Vaccines, Microbicides, Diagnostics

EDCTP grants scheme

- Integrated Projects (Clinical trials; project management; capacity strengthening; and networking)
- Senior Fellowships
- Strategic Primer Grants (SPG)
- Ethics and Regulatory Projects
- Networks of Excellence
- Member State Initiated projects (MSI)
- Joint Call by Member States (JCMS).

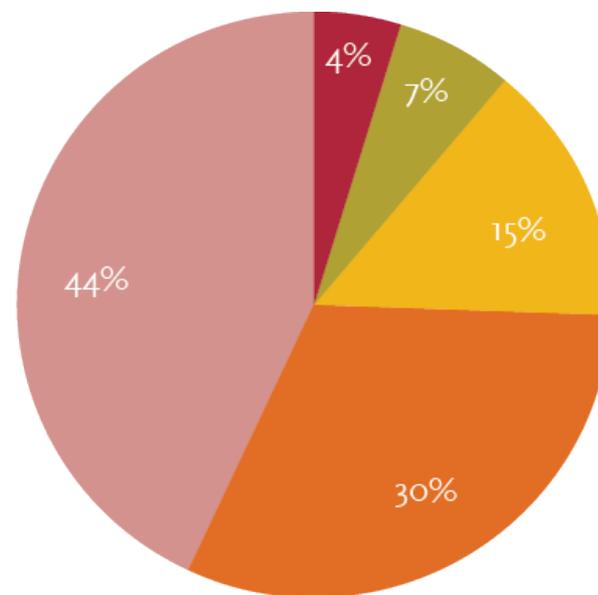
Thematic project funding

Area



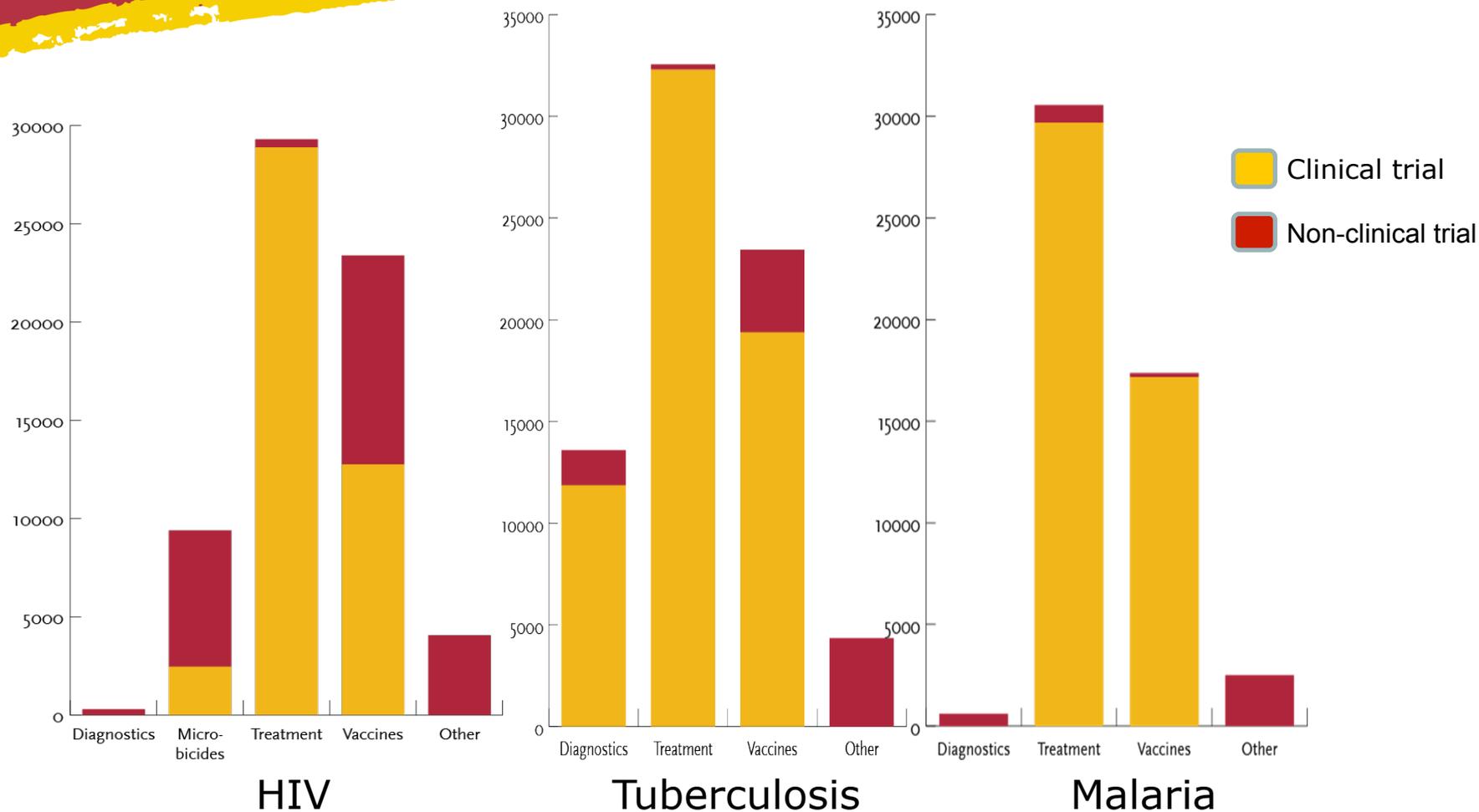
■ HIV/AIDS	€ 62,398,977
■ HIV/TB coinfection	€ 7,232,680
■ Malaria	€ 50,991,323
■ Tuberculosis	€ 70,726,968
■ Ethics and regulatory	€ 5,097,114
■ Other	€ 15,671,599
Total	€ 212,118,662

Intervention



■ Treatment	€ 92,394,925
■ Vaccines	€ 64,196,280
■ Diagnostics	€ 14,477,836
■ Microbicides	€ 9,386,976
■ Non intervention specific	€ 31,662,644
Total	€ 212,118,662

Funding according to disease and activity



Strengthening of clinical trials capacity



1

Regulatory framework
 - AVAREF
 - Harmonisation and joint review
 - Training



2

Ethics review
 - Operational support
 - Training (e-based/workshops)
 - Mapping

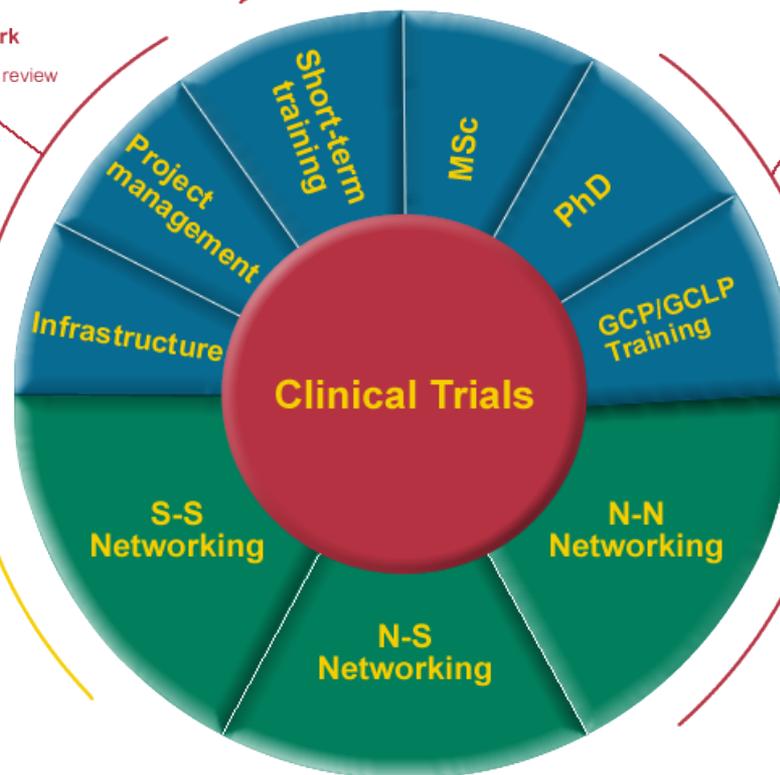


Clinical trials registry
 - Collaboration with NRA and ERC

3

6

Site preparation & networking



Networks of Excellence
 - Capacity Building
 - S-S / N-N networking
 - Synergy with other networks

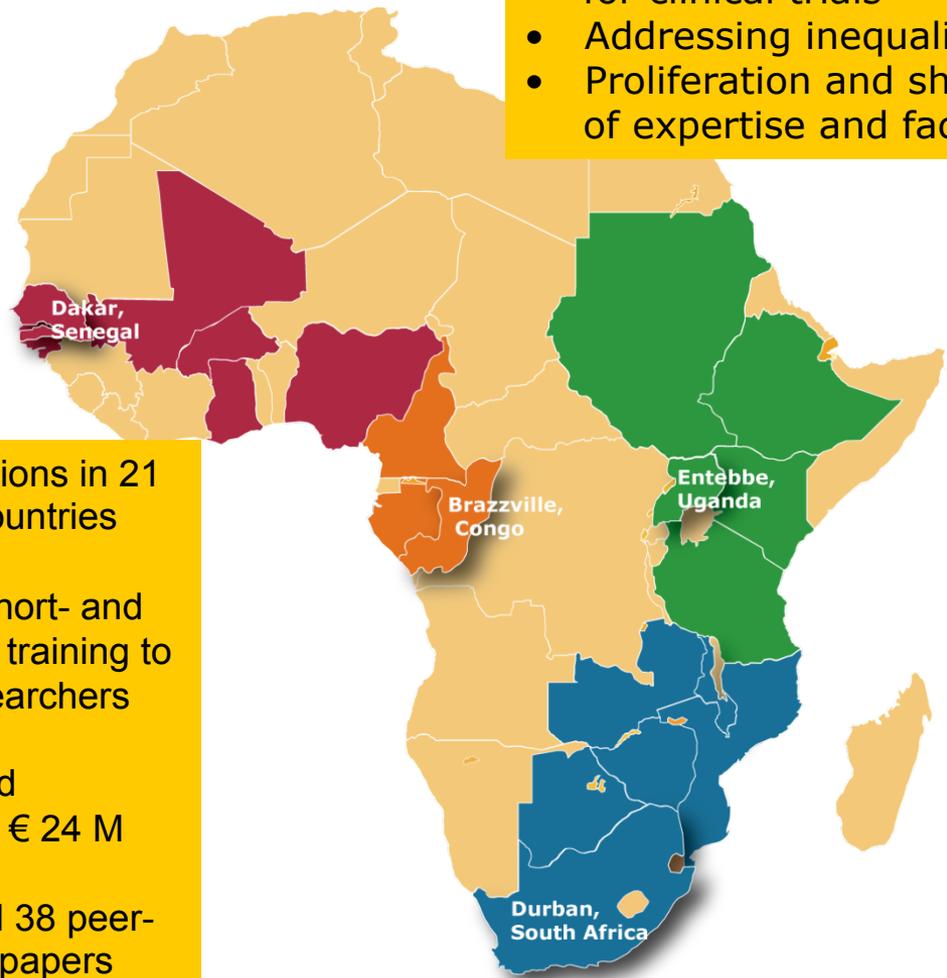
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5

Senior Fellowships

EDCTP Regional Networks of Excellence for clinical trials

- Strengthening of capacity for clinical trials
- Addressing inequality
- Proliferation and sharing of expertise and facilities



Western Africa: WANETAM
 Website: www.wanetam.org

- Burkina Faso
- The Gambia
- Ghana
- Guinea-Bissau
- Mali
- Nigeria
- Senegal
- United States

Central Africa: CANTAM
 Website: www.cantam.org

- Cameroon
- Congo, Republic of the
- Gabon
- France
- Germany

Eastern Africa: EACCR
 Website: www.eaccr.org

- Kenya
- Sudan
- Ethiopia
- Tanzania
- Uganda
- Germany
- Sweden
- United Kingdom
- United States

Southern Africa: TESA
 Website: www.tesafrica.org

- Botswana
- Malawi
- Mozambique
- South Africa
- Zambia
- Zimbabwe
- France
- Germany
- Netherlands
- United Kingdom

- 64 institutions in 21 African countries
- Offered short- and long-term training to 1000 researchers
- Leveraged additional € 24 M
- Published 38 peer-reviewed papers

Facts and figures

Number of projects - 246

- 259 institutions participate and receiving funds from EDCTP
- 3442 posts are supported on EDCTP grants

Clinical trials - 100

Training of scientists and development of scientific leadership - 514

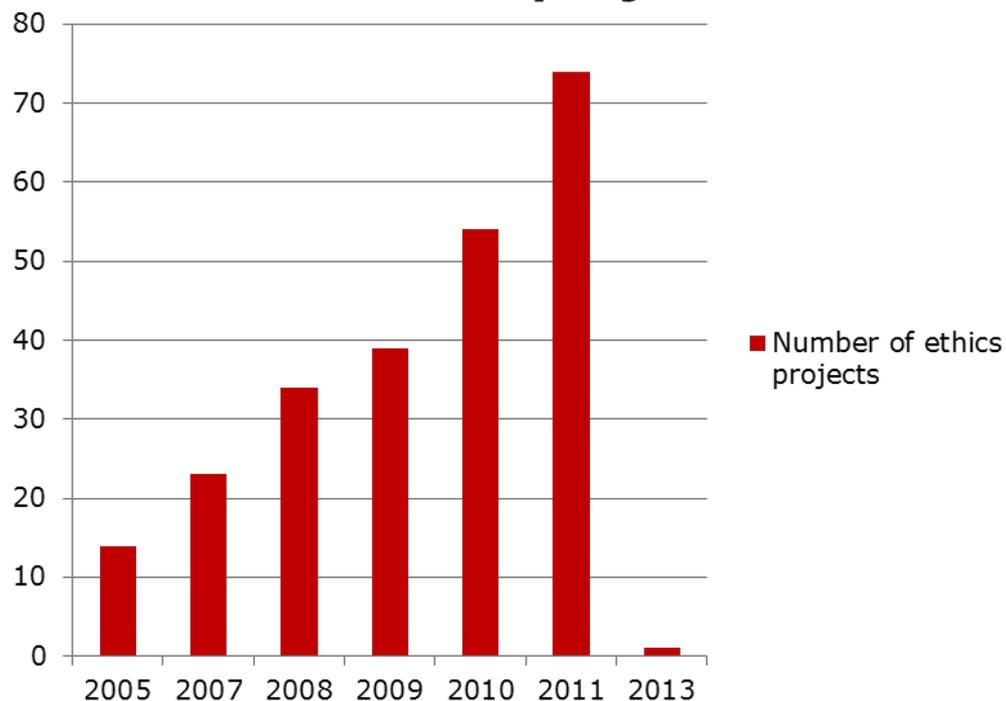
Publications - 485

Ethics Projects

- EDCTP1 funded 75 ethics projects
- Project status: 70 completed and 5 in progress
- No calls launched in ethics in 2012 and 2013
- Ethics capacity for health research remains a priority in the EDCTP2 strategic plan.

Ethics summary

Number of ethics projects

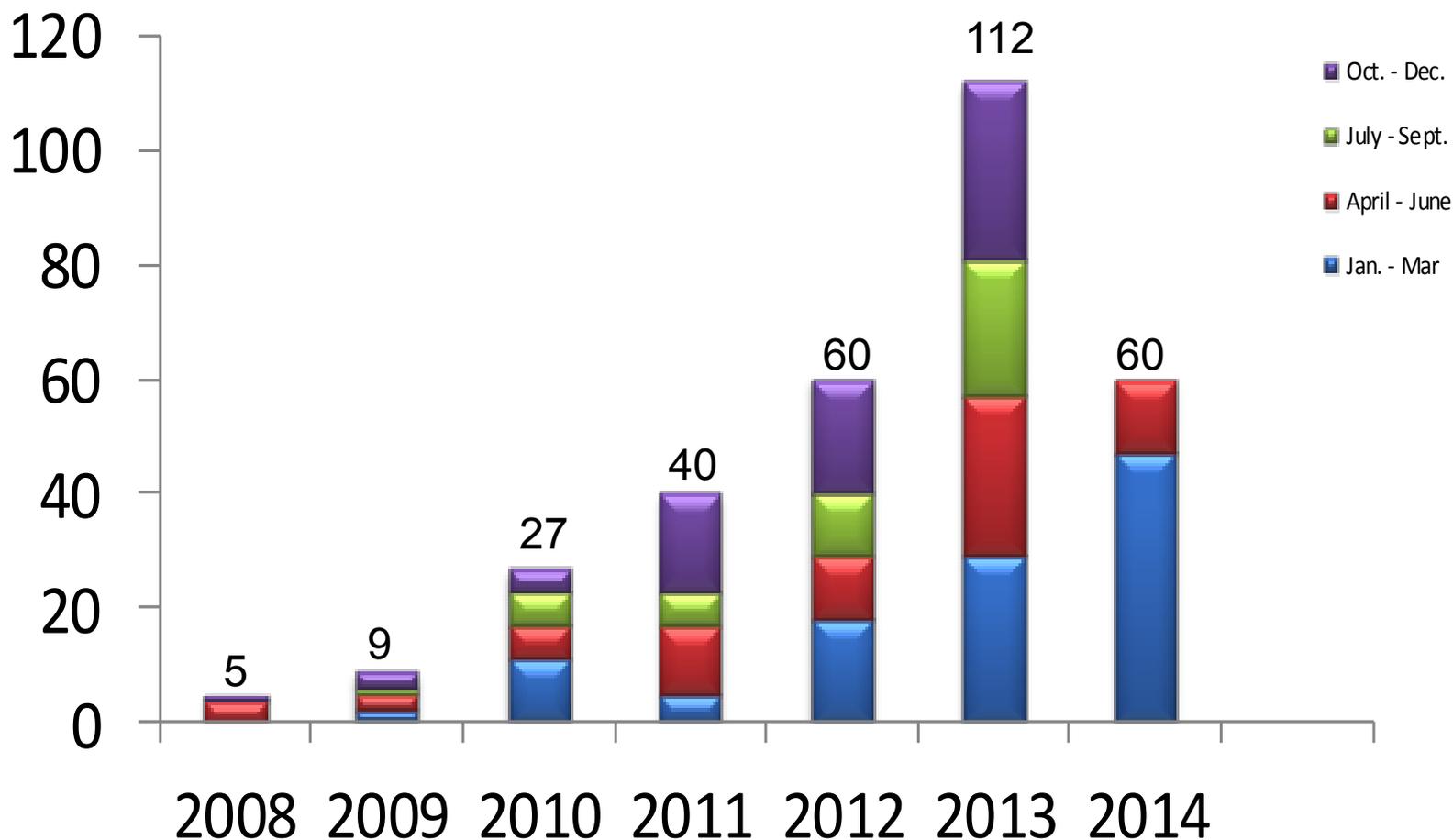


Call	Number of projects	Cumulative total
2005	14	14
2007	9	23
2008	11	34
2009	5	39
2010	15	54
2011	20	74
2013	1	75



Clinical trials register

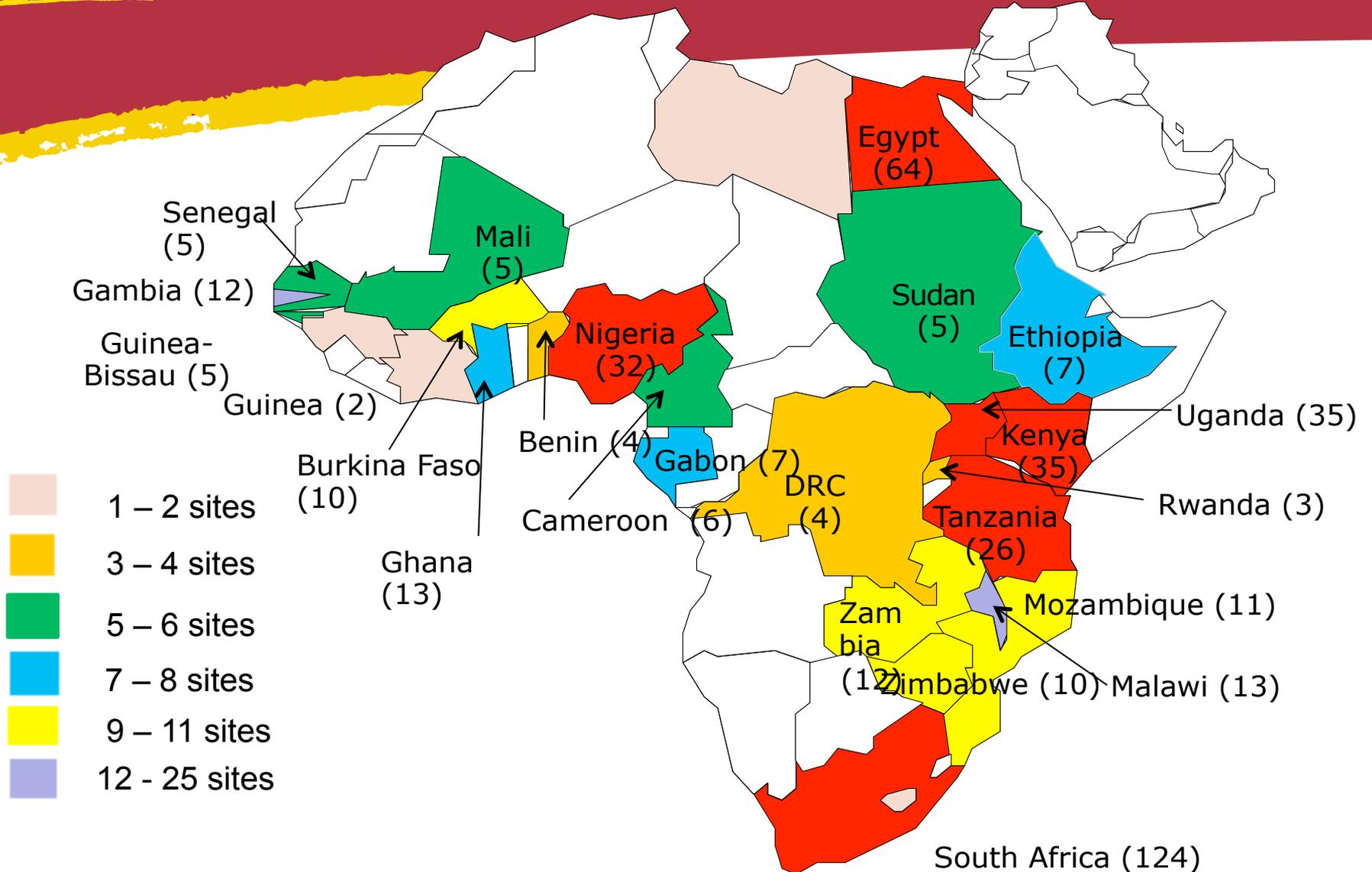
www.pactr.org





EDCTP

PACTR: CT Centres



Towards EDCTP2

Transition to EDCTP2

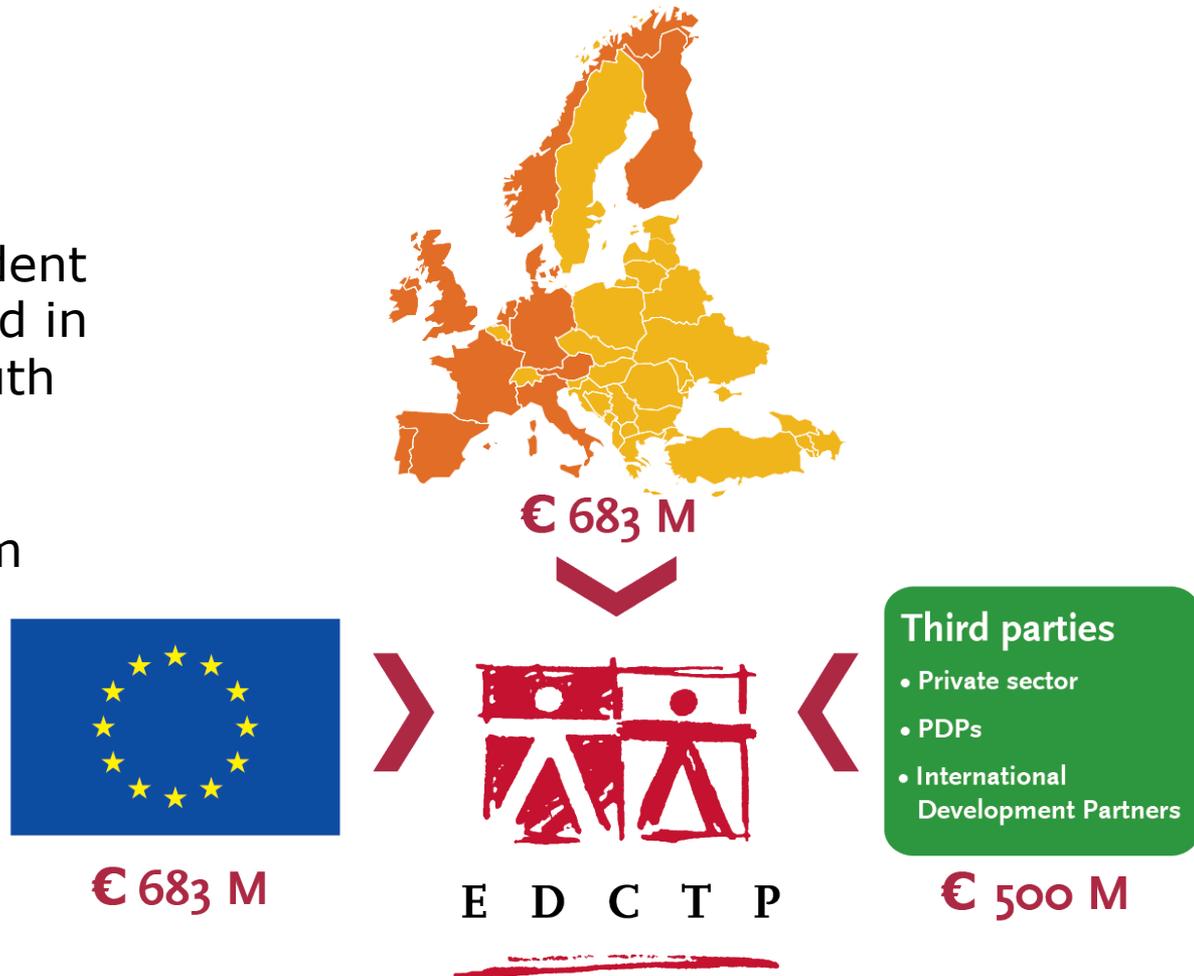
- End of no-cost extension for EDCTP – 2015
- EDCTP-Plus 2012-2014
 - Landscape mapping
 - Stakeholders' meetings
 - Upgrading and accreditation of clinical laboratories
 - Continued capacity strengthening of NoE
 - Strategic and operational business plans, workplans
 - Establishment of the Scientific Advisory Committee
 - Expansion of the Secretariat
 - Master's Fellowships in Epidemiology and Medical Statistics Call
 - Inviting new EU Member States and Associated Countries.

Building on the current programme



- Expanded scope of EDCTP2 under Horizon 2020
 - Involve all phases of clinical trials
 - Health services optimisation research
 - Partnering in phase III clinical trials
- Closer collaboration with partners
 - Acknowledgment of sub-Saharan contribution
 - Closer working relationship with the private sector
 - Closer ties with other international development partners
 - Potential collaborative research with other developing countries outside sub-Saharan Africa
- Improved governance
 - Implementation structure
 - Scientific Advisory Committee

- Public-Public Partnership
- Operates as an independent legal entity (offices based in the Netherlands and South Africa)
- EDCTP2 will operate from 2014-2024.





Overall objective of EDCTP2

Contribute to the reduction of the social and economic burden of PRNDs and in SSA, by accelerating the clinical development of effective, safe and affordable medical interventions, in partnership with SSA.

Specific Objectives of EDCTP2

- Increase number of new or improved medical interventions for HIV/AIDS, TB, malaria and NIDs;
- Strengthen cooperation with SSA countries, in particular on building their capacity for conducting clinical trials;
- Improve coordination, alignment and integration of relevant national programmes to increase the cost-effectiveness of European public investments;
- Achieve extended international cooperation with other public and private funders;
- Increase impact due to effective cooperation with relevant European Union initiatives, including its development assistance.

EDCTP2 Programme Activities

- Promoting networking, coordination, alignment, collaboration and integration of national research programmes and activities on PRNDs, at scientific, management and financial level;
- Supporting clinical trial research and related activities on PRDs, in particular HIV/AIDS, malaria, TB and NIDs;
- Fostering capacity development for clinical trials and related research in SSA, through grants for:
 - Career development of junior and senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentorship and partnerships at individual, institutional and regional level;

EDCTP2 Programme Activities

- Establishing cooperation and launching joint actions with other public and private funders;
- Ensuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication in Africa, EU and globally.

Types of projects under EDCTP2



- Integrated Activities
 - Clinical trials; networking; project management; capacity strengthening
 - Fellowship schemes
 - Ethics/Regulatory
 - Networks of Excellency
- Participating States Initiated Activities
- Joint Activities

Recommendations from earlier SHMs

- Continue supporting integrated projects (research infrastructure development; short-term and long-term training (Masters, PhDs and post-doctoral training); and baseline /epidemiological studies to support development of future clinical trial centres)
- Promote post-doctoral programmes within African settings
- Support training for mid-level staff: nurses, laboratory managers, project and finance managers
- Encourage institutions to have clear career path for staff as part of institution development plans and to promote leadership training
- Extend scope of fellowships schemes to cover NIDs, ethics, social sciences and regulatory fields
- Establish fellowship schemes for more senior scientists to provide mentorship for upcoming scientists

Recommendations from earlier SHMs

- NoEs to create collaborations that cover extended scope of EDCTP2
- Develop capacity in epidemiology, statistics and modelling to support clinical trials in Africa
- Laboratory capacity to be improved in a systematic way and to couple these developments with research activities
- Develop local pharmacokinetics and pharmacodynamics (PK/PD) facilities and skilled personnel
- Establishment of local laboratory reference ranges based on larger baseline studies
- Need more standardised testing (e.g. laboratory assays and trial designs for vaccines)
- Support for supranational laboratories that can perform external quality assurance and reference testing

Recommendations from earlier SHMs

- Establishing accessible biobanks in SSA
- Support harmonisation and standardisation of data collection, recording and secure long term storage in centralised data management systems
- NoEs to serve as potential platforms for the development and dissemination of quality assured, standardised assays and protocols, e.g. for real time PCR, microscopy and other diagnostics
- Support development of capacity for health services optimisation research including treatment delivery capacity involving task shifting
- Promote capacity building in Africa to support translational studies (phases I and IIa)
- Support training of technical staff at clinical sites in maintenance and repair of equipment
- Devise mechanisms for developing clinical trials sponsorship capacity in Africa.

EDCTP2 CD Activities

- Continuation of Integrated approach for implementation of clinical trials (CT, PM, capacity development and networking)
- Fellowship schemes:
 - Career Development Fellowships
 - Senior Fellowships
 - EDCTP-TDR Industry fellowships (in collaboration with EFPIA)
 - Regulatory Fellowships (in collaboration with AMRHI and EMA).
- Ethics and Regulatory grants
- Regional NoEs

Meeting objectives

1. Review and identify current and emerging capacity development gaps
2. Ensure that EDCTP remains focused on high priority capacity development needs and opportunities, and to align these to its strategic planning and funding
3. Identify priority areas and implementation approaches to be addressed in future calls for proposals and other funding modalities
4. Identify interested and potential partners to collaborate with in the execution of future EDCTP capacity development activities especially in large and long-term undertakings
5. Harness the views of stakeholders to promote integration of national programmes of EDCTP Participating States and strengthen the partnership with African researchers.

Thank you



www.edctp.org



Thank you!