



International Cooperation in Health Research The European and Developing Countries Clinical Trials Partnership EDCTP

- An Art 185 based Public-Public Partnership -

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The European and Developing Countries Clinical Trials Partnership (EDCTP)

- Established in 2003 as Part of the Union's response to the global health crisis caused by HIV/AIDS, malaria and tuberculosis
- Mission of the first EDCTP programme (EDCTP1):

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

- Collaboration between 16 European countries, the EU and 30 sub-Saharan African countries
- Operates as an independent legal entity (based in The Hague, Netherlands).
- **Pioneered joint programming**, i.e. the coordination, alignment and integration of European national research programmes. First application of Art 185 TFEU (ex-Art 169)







Article 185 of the Treaty on the Functioning of the European Union (TFEU)

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EN

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Article 185 (ex Article 169 TEC)

In implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes.



EDCTP2 - Renewal of the "European and Developing Countries Clinical Trials Partnership"

Countries Clinical Trials Partnership"

Second phase of EDCTP with:

a) extended scope: neglected diseases of poverty, all clinical phases, diagnostics and delivery optimization

b) increased budget:

ca. €1.7 bn from participating European states

+ up to €683 million from EU

c) Extended duration - 10 Years

 Political and financial up-front commitment from 16 European countries (Finland joint but Belgium left)

 EU will provide <u>matching</u> co-funding through Horizon 2020 (2014-2020)





EDCTP2 – Other Changes

- EDCTP2 is part of Horizon 2020 and needs to comply with H2020 Rules for Participation (a few derogations apply)
- The EDCTP2 governance involves:
 - > A General Assembly in which all PS (Participating States) are represented
 - > A Management Boards as the executive body of EDCTP2 (at least 5 board members)
 - A Scientific Advisory Committee (SAC)
 - > A Secretariat tasked with, e.g., executing the annual work plan
- Clear objectives and specific targets have been set.
- EC to approve Annual Work Plan

And

EDCTP decided to change its legal status:

• EDCTP2 will be implemented by the EDCTP Association (under Dutch law, based in The Hague, with Liaison Office in Cape Town), i.e. the current EDCTP European Economic Interest Group (EDCTP-EEIG) will be dissolved as soon as EDCTP1 funding operations are concluded (2015).



EDCTP2: State-of-Play

- EU decision on EDCTP2: adopted by the European Parliament (16 April) and Council (6 May)
- EDCTP Association (under Dutch law) was founded on 10 April 2014 and involves currently 13 European (AT, DK, FI, FR, DE, IE, IT, LU, NL, NO, PT, ES and UK, while SE is expected to sign soon) + 8 African member countries (Cameroon, Congo-Brazzaville, Ghana, Mozambique, Senegal, South Africa, Tanzania and Uganda, while Zambia is expected to sign soon)
- EC financing decision for 2014
- EC-EDCTP Delegation Agreement on EU budget implementation tasks
 - Ex-ante assessment of EDCTP's administrative capacities
 - Model Grant Agreements
 - Annual Work Plan 2014-2015 (incl. international peer review + EC approval)
- Pre-Announcement of calls (under discussion)
- EDCTP Forum, 30 June 2 July 2014, Berlin
- EDCTP2 launch event, 2 Dec 2014, Cape Town