



**EGHRIN**

European Global Health Research Institutes Network

## European Global Health Research Institutes Network (EGHRIN) Initiative

### Position Paper on EDCTP

This Position Paper on the future of the European & Developing Countries Clinical Trials Partnership (EDCTP), **aims to further politicians', policy makers' and opinion leaders' understanding of the fundamental role** of the continuing support to Clinical research of excellence in collaboration with Sub Saharan African countries.

This short document shows the importance of EDCTP, the value of Global Health research to EU member states and provides recommendations for the future design of the EDCTP programme.

The position paper is based on the longstanding experience **and activities of the leading institutions participating in the European Global Health Research Institutes Network (EGHRIN)** –many of them linked with the League of European Research Universities (LERU).

## Recommendations

### Main Recommendation

**Government representatives** voting in the Council of the European Union and **MEPs** should:

- aim to ensure the future of the EDCTP programme **under the Horizon Europe budget**:
- **Recommend that the EU ring-fence €1 billion** for the next EDCTP programme in order to maintain the quality of EDCTP funded research as well as ensure a renewed future outlook of the programme, including greater emphasis on phase III and IV trials, and addressing the interaction between infectious and non-infectious diseases, among others.
- **Promote the continuation of the EDCTP programme**, while ensuring that the funding mechanism adequately complies with the following key attributes:
  1. **Accountability**: ensuring mid-term independent external assessment of the programme and public consultations on the ex-ante impact assessment and preparation of Work Plans.
  2. **African countries participation**: as African states contribute to EDCTP both in cash and in kind, it is important to ensure that they can participate in the governance on an equal footing with Europeans: e.g. in the identification of thematic priorities and preparation of Work Plans.
  3. **EU financial contribution**: ensuring a guaranteed EU financial contribution of €1 billion. The use of loan-based mechanisms for funding is *not recommended*.

4. **Participating States (PS) contribution:** the PS may contribute in cash or in kind, where in-kind contributions should be reported in a transparent and simplified manner to avoid delays to Work Plan preparations.
5. **Private partners participation:** private partners may co-fund but not co-programme. It is *not recommended* that private partners sit in the governance structure. Incentive mechanisms to leverage private and third-party investments should be explored.
6. **Minimum number of participants:** Ensuring 40% EU member state participation.
7. **Implementation:** Management of calls and projects is centralised by Dedicated Implementing Structure (EDCTP Secretariat).
8. **Duration:** the future EDCTP should continue as a 10-year programme, thus ensuring financial stability to achieve objectives.

#### Other Recommendations for improvements to EDCTP

- Focus on unmet medical needs of vulnerable populations and infectious diseases. There is a clear niche to fill relating to conducting, and strengthening clinical, epidemiological and implementation research.
- Maintain scope on end-to-end clinical development of medical interventions but with a greater emphasis on phase III and IV trials and product-focused implementation studies as this is where there is need and greater potential for impact There is a need for better alignment of up- and downstream research in the development of new products for Poverty Related Neglected Diseases (PRND). A portfolio approach where several products within the pipeline are being tested based on longer-term strategic decisions and closer and more flexible links with other research funders should be considered. This was also proposed by EDCTP2's midterm evaluation panel.
- A drive towards more patient-centered approaches that promote cross disease, interdisciplinary research, and explore opportunities offered by new technologies in context of integrated patient care
- Cognizance to changes in clinical trials regulation (CTR) revolutionizing the way clinical trials processes run in PSs and companies
- Address the vital gap on the interaction on the between infectious and non-infectious diseases
- Consolidate role in preparation for, prevention and effective management of infectious disease outbreaks and the growing threat of antimicrobial resistance, ensuring greater flexibility to address new research needs and questions as they come along.
- EDCTP should encourage participation from less represented African countries. It may only be expanded beyond Sub Saharan Africa if the budget is also increased.
- Calls could be made more flexible with regard to the designs of intervention studies.
- The call and review system should be revised, as it enhances conservatism in the selection of project applications.
- The expertise of the Scientific Advisory Board could be further leveraged; they could contribute to strategic formulation and making timely strategic adjustments if needed. Greater transparency on decision making processes are also recommended.

- It is recommended that EDCTP introduce a high-level Strategic Advisory Board, as recommended by EDCTP2's midterm evaluation panel.

## About EGHRIN

European Global Health Research Institutes Network (EGHRIN) is an emerging network of leading European Global Health research institutions, assembled to promote excellence in Global Health (GH) research and to make an impact on the EU's GH research agenda. The core of its founding institutions includes a significant number (currently 11) LERU-related institutes, while others have expressed interest in joining the network.

Some of the EGHRIN activities include:

- Agenda setting for Global Health research and innovation in Europe
- Harmonization of Global Health research activities at national, EU and global levels
- Advocacy and Dialogue for Global Health research activities at national, EU and global levels
- Promote/Nurture collaboration on high quality research, within the network and with global partners and relevant stakeholders
- Promote/Foster/share capacity strengthening activities for GH Research
- Joint coordination and implementation of capacities in GH education

## What is the Global Health research agenda?

- Global Health is the field of Research and Innovation that deals with **health problems and solutions that transcend geographic and political boundaries** in an inter-, transdisciplinary and integrated way.
- It covers poverty-related and neglected **infectious diseases** such as HIV/AIDS, tuberculosis, malaria and helminth infections, but also **non-communicable diseases** such as heart disease, cancer, chronic respiratory diseases and diabetes that are becoming the leading cause of mortality in the world.
- It deals with **emerging infections** and the growing epidemic of **antimicrobial resistance**, and is concerned with **environmental health hazards** including climate change and uncontrolled urbanization.

## Why support Global Health?

- Global health Research and Innovation (R&I) contributes to European leadership in science, knowledge and innovation.
- Global health R&I has **positive effects on the economy**, because it offers health products, services and jobs.
- Global Health R&I provides knowledge insights that can help to improve the **sustainability of health care in Europe**.
- Global health R&I contributes to global health **security** (i.e., emerging epidemics such as Ebola, AMR, vector/air-borne and other environmental and climate threats).

- Global health R&I provides insights on **migration/population mobility and addresses some of the root causes for migration.**
- Global health R&I contributes to the guarantee of the **right to health** and works towards achieving the **Sustainable Development Goals**, including equity and sustainability.
- We have a **shared responsibility** because of global interdependence, consistently with our European values.

## EDCTP and Global Health

- The European & Developing Countries Clinical Trials Partnership (EDCTP) aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV/AIDS, tuberculosis, malaria and neglected infectious diseases in Sub-Saharan Africa (SSA). It supports the creation and strengthening of research capacities in SSA, and it is the only EU mechanism for research for improving health in Low and Medium Income Countries (LMICs).
- EDCTP has had proven socio economic impact for Global Health<sup>1</sup>. Examples of impact include provision of scientific evidence:
  - On the safety and efficacy of drugs to **assist national malaria control programmes** in sub-Saharan Africa in choosing the most appropriate ACTs for their specific setting<sup>2</sup>.
  - To confirm that priority must be given to early diagnosis and treatment in order to expand treatment to all HIV infected children, supporting WHO 2013 guidelines<sup>3</sup>.
  - To confirm that drug combinations to treat TB can be administered by a nurse in primary-care clinics, **resulting in more patients starting same-day treatment, more culture-positive patients starting therapy, and a shorter time to treatment**<sup>4</sup>.
  - To advance significantly the development of **malaria vaccine candidates**<sup>5</sup>.
- The second EDCTP programme is **implemented as part of the European Framework Programme for Research and Innovation, Horizon 2020.**
- **EDCTP is a public-public partnership** between countries in Europe and sub-Saharan Africa, and the European Union.
- The European Union has currently committed to provide a contribution of up to €683 million for the 10-year programme (2014-2024), provided this is matched by contributions from the European Participating States. **For every Euro contributed by the EU, the EDCTP member states should contribute a Euro. Contributions can be measured in cash or in kind.**

<sup>1</sup> Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU. [https://ec.europa.eu/research/evaluations/pdf/20171009\\_a185\\_swd.pdf](https://ec.europa.eu/research/evaluations/pdf/20171009_a185_swd.pdf)

<sup>2</sup> For more info: visit The 4ABC study summary: <http://www.edctp.org/projects-2/success-stories/malaria-treatment/>

<sup>3</sup> For more info: visit The CHAPAS Trials study summary: <http://www.edctp.org/projects-2/success-stories/hiv-treatment-chapas/>

<sup>4</sup> For more info: visit GeneXpert development study summary: <http://www.edctp.org/projects-2/success-stories/tb-diagnostics/>

<sup>5</sup> For more info: visit MVVC consortium study summary: <http://www.edctp.org/projects-2/success-stories/malaria-vaccines/>

## Opportunities and Return on Investment for EU Member States

- The European Participating states of EDCTP<sup>6</sup> have **contributed in a significant way to Global Health Research and Innovation**, running trials fighting HIV and AIDS, tuberculosis (TB), malaria, diarrheal diseases and lower respiratory infections – as well as emerging and re-emerging infections of epidemic potential.
- EDCTP2 has awarded €447 million value of signed grants to date to EU and African research consortia and career development fellowships<sup>7</sup>, with 189 projects funded between 2014-2018. The European Commission has contributed €476 million and Participating States have contributed €128.8 million.
- **European Universities alone have been awarded €84.3 million of that competitive grant funding** from EDCTP2 between 2014-2018<sup>8</sup>. This represents a **significant return on investment** when compared to the in-cash funding contributed by the university member state governments.
- The mechanism by which Member States contribute in cash or in kind to EDCTP allows countries to drive the global health agenda under Horizon Europe.
- This funding is used not only for direct implementation of the research in LMICs, but each grant also ensures 25% contribution to the overheads of European Union universities and research institutions as well as the direct costs of salaries for EU researchers and associated salary taxes. **This kind of funding model helps to retain researchers and other staff of excellence and knowledge in member state.**
- Such investments contribute to **placing member states in an international leadership position to build strategic partnerships** in specific research areas in Poverty Related Neglected Diseases like malaria, tuberculosis and HIV and AIDs, and to expand influence in highly competitive research networks, both in Europe and in Africa, as well as in other continents.

## EGHRIN recommendations on the future of EDCTP

**EDCTP should continue as a dedicated mechanism** for funding global health research within Horizon Europe, and ideally under the current mechanism of Article 185, because:

- It is the only dedicated mechanism for GH research within H2020.
- It is the only mechanism where the focus is on improving health in LMIC - funding and accelerating R&D for poverty-related and neglected diseases (PRND)
- It received a positive interim evaluation (2017). It was noted in the evaluation that EDCTP contributes to wider EU policy objectives, for example the EU's commitment to the United Nations' Sustainable Development Goals (SDGs) and is clearly linked to international Global Health policy agendas.
- The financial input of EDCTP participating states required under Article 185 has been essential to reach the funding volume that is required

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<sup>6</sup> Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, UK

<sup>7</sup> Michael Makanga, Chief Executive Officer of the EDCTP Association Secretariat, presentation at EDCTP Forum, 17 September, Lisbon 2018

<sup>8</sup> Information provided by EDCTP project officer, 7<sup>th</sup> November 2018

## ANNEX 1. LIST OF EGHRIN INSTITUTIONS (IN PROGRESS)

### In alphabetical order

- Amsterdam Institute for Global Health and Development, University of Amsterdam  
Amsterdam, Netherlands
- Barcelona Institute for Global Health (ISGlobal), University of Barcelona  
Barcelona, Spain
- Centre for Global Health, University of Milan, Milan, Italy
- Center for International Health, Ludwig-Maximilians-Universität, Munich, Germany  
Centre for Social Medicine and Global Health, Lund University, Lund, Sweden
- George Institute for Global Health, University of Oxford, Oxford, UK
- Global Health at Julius Center, University of Utrecht, Utrecht, Netherlands
- Imperial College London, London, UK
- Institute for Global Health, Heidelberg University, Heidelberg, Germany
- Institute for Global Health, University College London, London, UK
- Institute for Tropical Medicine, Antwerp, Belgium (\*)
- Leiden University Medical Center, Leiden University, Leiden, Netherlands
- London School of Hygiene and Tropical Medicine, London, UK (\*)

(\*) no LERU affiliation