

PDP position paper on a successor to EDCTP

Enhanced opportunities, partnerships, and flexibility for greater impact



As Product Development Partnerships (PDPs), our non-profit organizations are working to develop and provide access to new drugs, vaccines, diagnostics, and devices to address poverty-related and neglected diseases (PRNDs) globally. We have decades of expertise creating collaborations between the public, private, and non-profit sectors to advance products through the development pipeline, and together we have advanced products that have impacted hundreds of millions of lives in low- and middle-income countries. We want to highlight the critical role that the European Union (EU) and its Member States, particularly through the European & Developing Countries Clinical Trials Partnership (EDCTP), play in advancing lifesaving tools and strengthening research capacity across sub-Saharan Africa.

As decisions are being made about the future of partnerships under Horizon Europe, we call on the EU institutions and their Member States to once again include an ambitious partnership exclusively dedicated to funding research for the prevention and treatment of PRNDs. Specifically, we encourage enhanced partnership opportunities to bolster collaboration and leverage funding from partners, including PDPs and the private and philanthropic sectors, a more flexible portfolio approach to funding, and an ambitious doubling of the programme to 1.36 billion Euros from the European Commission.

Critical Role of EDCTP

Diseases such as tuberculosis (TB), HIV/AIDS, malaria, and neglected tropical diseases still impact over one billion people worldwide, including those in EU Member States. Although important progress has been achieved, continued investments in the development of new tools to address these health challenges remain critical. For example, very few products are appropriate for especially vulnerable populations such as young children and pregnant women. Half of the global population remains at risk of malaria, and drug resistant strains are growing. TB is still the leading infectious disease killer in the world, with multi-drug resistant TB representing one third of the world's social and economic burden of antimicrobial resistance (AMR). HIV/AIDS continues to be a major threat; in 2017 HIV-related causes resulted in the loss of nearly one million lives around the world.¹ More than one billion people worldwide remain affected by the 20 neglected tropical diseases.²

The EU is a global leader in funding research and development for new tools to address PRNDs, with a large part of that funding coming through EDCTP, the only dedicated partnership within the EU for global health

research and innovation. EDCTP has shown significant value to the EU, contributing toward the success of the European Research Area, producing important economic returns to Europe, and playing a key role in advancing lifesaving medicines and in building critical capacity of African scientists and infrastructure.

Since its inception in 2003, EDCTP has advanced tools through the research pipeline by funding over 150 clinical trials³ resulting in life-changing impacts. For instance, half of all new malaria drugs approved since 2000 have relied on EDCTP-funded trials to support their registration,⁴ and advancements in the development of paediatric formulations of HIV treatment and TB diagnostics, vaccines, and treatment have also been made possible through support from EDCTP.^{5,6} Current EDCTP projects include funding for trials to shorten TB treatments for drug sensitive and resistant patients, a new vaccine to prevent post kala-azar dermal leishmaniasis, a new formulation of PrEP to prevent HIV in young women, three new TB vaccines to prevent TB in adults and adolescents, and a new drug to treat Soil-Transmitted Helminths.

Bringing value at home and abroad

In addition to advancing tools through the pipeline, EDCTP has demonstrated its economic and capacity strengthening value in both Europe and Africa, thereby responding to the requirements of institutionalised partnerships under the framework programmes.

In Europe, EDCTP has boosted scientific excellence and Europe's global competitiveness in research and innovation, developed European capacities in clinical research for PRNDs, and provided mechanisms to prepare for and respond to public health emergencies.⁷ Support for EDCTP also has the dual benefit of growing the European economy and investing in European researchers. A recent analysis found that, on average, 80 cents of every Euro spent by the EU on research and development (R&D) for PRNDs was invested back into European laboratories, universities, and companies.⁴

EDCTP has bolstered clinical research capacity across sub-Saharan Africa and enhanced the safety and quality of clinical research and development through strengthened ethics reviews and national regulatory capacities. Through EDCTP, the EU is making a critical contribution toward its commitment to fulfil the United Nations' Sustainable Development Goals (SDGs), and in particular SDG 3.

Evolution not revolution: How to make EDCTP3 more effective

As EDCTP enters its next phase, we urge the Commission and Participating States to equip EDCTP with an adequate budget for its mission and the right tools for greater impact. EDCTP has demonstrated its potential; however we see opportunities for even greater value add within Horizon Europe. The following recommendations are based on our experience working with EDCTP and decades of expertise working across sectors to advance and scale lifesaving products in low- and middle-income countries. We believe uptake of these recommendations will strengthen the impact of EDCTP3, ensuring support for pivotal trials and the development of lifesaving products.

- **Greater inclusivity and flexibility to get the job done**

Create a more inclusive partnership model: The current restrictions around EDCTP funding have been a significant barrier to greater impact. As PDPs, our organizations create global partnerships and we have specialized expertise in advancing products through the pipeline and into the market. However, current restrictions around EDCTP, and particularly the strict geographic restrictions, limit the scientific expertise that EDCTP could benefit from. These restrictions also often limit the involvement of relevant product development organizations which may not be based in Europe or sub-Saharan Africa. This limitation creates

undue organizational and financial hurdles that delay and increase the costs of product development. By their very nature, diseases of poverty are already neglected and suffer from a lack of resources. Limiting access to scientific excellence and expertise in product development should not be an additional barrier to advancing lifesaving tools.

Support for flexible funding models: We applaud the steps that EDCTP has recently taken to allow partners to seek funding for multiple projects within a single call for proposal. This is a step in the right direction, but EDCTP3 should have greater flexibility to invest in a portfolio of products. Investing in a portfolio of products, especially in Phase 1 and Phase 2 trials, allows for shifts in funding priorities between products from those showing diminishing promise to those with increasing promise. This approach allows technical experts to make the most strategic decisions about which products show the most promise and helps reduce stranded assets and risks to funders. Additional flexibility to invest strategically in partnership with other funders or investors would allow EDCTP the flexibility to quickly react to new data and developments and make more strategic, well-leveraged, and timely investments.

- **Ensure sustainability and growth**

EDCTP3 should have an institutional partnership modality that supports a long-term, sustained approach. Regardless of which partnership modality is advanced, it is critical that it allows EDCTP greater flexibility to bring together a wider group of stakeholders. Continued Member State participation is critical, but to ensure EDCTP fulfils its ambition funding from the EU must be flexible enough to be leveraged with resources from other funders and investors, product developers, and scientific experts globally, creating opportunities to leverage investments to co-fund and co-design activities. Recent political shifts, including Brexit, make increased flexibility more critical than ever. The United Kingdom (UK) has been a key contributor to EDCTP and it will be imperative that whatever modality is chosen enables continued funding and partnership from the UK. Creating opportunities for other funding partners, including the EU's development programme DG DEVCO, the private and social sectors, and other countries such as the United States, Switzerland, and Japan, will require adaptations to the current model.

- **Ambitious Funding**

We call for an ambitious doubling of funding to 1.36 billion Euros from the European Commission that, coupled with enhanced and more flexible opportunities to leverage funding from new sources, will significantly support EDCTP3's goal of funding more Phase III and IV trials. Late stage clinical trials

required to bring products to development are costly, with Phase III trials often costing hundreds of millions of Euros. A recent analysis estimated that the cost to move current neglected disease product candidates through the pipeline and launch critical to-be-developed products (such as a highly efficacious vaccine for TB, HIV or malaria) would cost between US\$4.5–5.8 billion per year over five years.⁸ Global funding for neglected diseases R&D is still only a fraction of what is needed.⁹ To increase impact, awards must be adequate to support more of the pivotal but costly later stage clinical trials and post-registration studies which support adoption and scale-up of new products. Funding from prior EU investments including Horizon 2020 and the Innovative Medicines Initiative have increased the global product pipeline. However, without funding for late stage development and introduction, the funds expended in early development will be for naught. Ambitious new funding will help move these products through the pipeline and result in new treatment options, vaccines, diagnostics, and devices, creating life-saving interventions for patients globally as well as spurring economic development.

Product Development Partnerships



- **Focused Scope**

EDCTP should retain its current focus on the development of new products against TB, HIV/AIDS, malaria, and neglected tropical diseases in sub-Saharan Africa. Retaining this scope should allow EDCTP to grow its investment in late stage clinical development, a requirement to successfully bring products to market and into the hands of those in need. While we acknowledge the critical need for new tools to address both poverty-related and neglected diseases prevalent on other continents, as well as non-communicable diseases in low-income settings, EDCTP's resources do not allow for an expanded scope unless accompanied by a significantly expanded budget.

Endnotes

1. World Health Organization website. HIV/AIDS page. <https://www.who.int/en/news-room/fact-sheets/detail/hiv-aids>.
2. World Health Organization website. Neglected tropical diseases page. https://www.who.int/neglected_diseases/diseases/en/.
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