

# CALL FOR A DEDICATED R&I INSTRUMENT FOR DISEASES OF POVERTY UNDER FP9: BUILDING ON THE SUCCESS OF EDCTP



**One billion people worldwide are affected by poverty-related and neglected diseases (PRNDs), including major diseases like HIV&AIDS, tuberculosis, and malaria, and a range of neglected infectious diseases<sup>1</sup>. PRNDs impose an unacceptable moral and health burden on individuals and societies, costing lives, and hampering human and economic development<sup>2</sup>.**



Major product- and research-gaps persist, as there are limited market incentives for the private sector to invest in new or improved tools to fight PRNDs. Where treatments exist, many are losing their effectiveness as the pathogens causing **PRNDs are developing drug resistance**, making infections harder and more costly to treat. Already today, globally, around one third of deaths caused by antimicrobial infections are due to drug-resistant tuberculosis<sup>3</sup>.



**Investing in PRND R&I saves lives, combats ongoing epidemics, can prevent future outbreaks, delivers on the SDGs, and has a great return on investment for Europe, creating high-quality jobs, boosting our economies and driving scientific excellence.**



**The European Union and the African Union** have committed to strengthening preparedness to detect, prevent and respond to disease outbreaks, and to increase efforts in research and innovation (R&I) for sustainable development<sup>4</sup>.

**Ensuring an impact of FP9 in addressing PRNDs will require a dedicated R&I partnership instrument** building on the success of the European and Developing Countries Clinical Trials Partnership (EDCTP).

## EDCTP HAS DEMONSTRATED IMPACT

From its inception in 2003, EDCTP has significantly contributed to

- **Advancing tools against PRNDs through the research pipeline** by funding more than 150 clinical trials of new or improved drugs, vaccines, and diagnostics;
- **Building health resilience in Africa by strengthening clinical research capacity** across sub-Saharan Africa;
- **Enhancing the quality and safety of health products in Africa by improving regulatory environments**, strengthening ethics review and national regulatory capacities in many sub-Saharan African countries.

The EDCTP2 interim evaluation conducted by independent experts found that

- **EDCTP is a highly relevant programme:** it aligns with the EU's aim of strengthening ties with Africa, and it delivers on its development cooperation objectives by addressing poverty, improving health and education, and fostering partnerships.
- **EDCTP's mission is directly linked with the Sustainable Development Goals**, which are high priorities for the EU.



<sup>1</sup> Cf WHO definition and list of NTDs, available at: [http://www.who.int/neglected\\_diseases/diseases/en/](http://www.who.int/neglected_diseases/diseases/en/)

<sup>2</sup> For more information, please see: <http://www.dsw.org/en/wp-content/uploads/2017/06/DSW-PRND-Infographic-WEB.pdf>

<sup>3</sup> Cf. The review of AMR, chaired by Jim O'Neil, available at: [https://amr-review.org/sites/default/files/160525\\_Final%20paper\\_with%20cover.pdf](https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf)

<sup>4</sup> Cf. AU-EU Summit 2017 declaration, available at: [http://www.consilium.europa.eu/media/31991/33454-pr-final\\_declaration\\_au\\_eu\\_summit.pdf](http://www.consilium.europa.eu/media/31991/33454-pr-final_declaration_au_eu_summit.pdf)

# THE FUTURE PRND R&I PARTNERSHIP INSTRUMENT SHOULD CONTINUE EDCTP'S PROGRAMME AND MISSION THROUGH:

## An ambitious budget to capitalise on past EU investments

- 700 million EUR contribution from the EC, not dependent on matched funding
- European participating states should increase their contributions in cash.
- Greater investment from sub-Saharan African participating states should be encouraged through stronger governance and funding incentives



## A flexible funding approach to better deal with contingency and opportunity

- Including a portfolio approach to development to help mitigate risks of failure and to focus on the most promising products within the portfolio as needed
- Providing the possibility to invest strategically (without Call for Proposals), once approved by an independent external review committee, e.g. if there is only one viable candidate that can be progressed through the next phase of development
- Offering a flexible and simple mechanism to partner with third parties (public and private) to facilitate co-funding and co-designing PRND R&I activities
- With fewer restrictions on geographic locations of applicants to attract global expertise



## An inclusive governance to enhance efficiency and accountability

- Safeguarding the equal partnership nature with sub-Saharan African countries as it contributes to closer collaboration, network strengthening and capacity building
- Including a high-level, strategic advisory board, separate from the scientific advisory committee and the board, to ensure more long term strategic planning
- Promoting high standards of transparency at all levels, including by providing more detailed feedback within proposal evaluations



## Strong mechanisms for improved alignment and coherence

- of EU funded PRND R&I and Participating States activities, including a strategy that identifies synergies, gaps and overlaps
- with other EU programmes, e.g. activities under the development and international cooperation instruments, for instance by including support to harmonisation efforts in the field of health regulation which fosters long-term sustainability of PRND R&I activities



## Clear conditions on access, suitability and affordability

- Guarantee open access to research results, and promote open access to research data, with strict criteria for derogations of open data requirements
- Require proposals to include measures for ensuring accessibility and affordability of potential end products

