



EDCTP

The power of sharing science

EDCTP's investment in global health and clinical trials: current progress and future perspective

EDCTP session at SSUNGA76

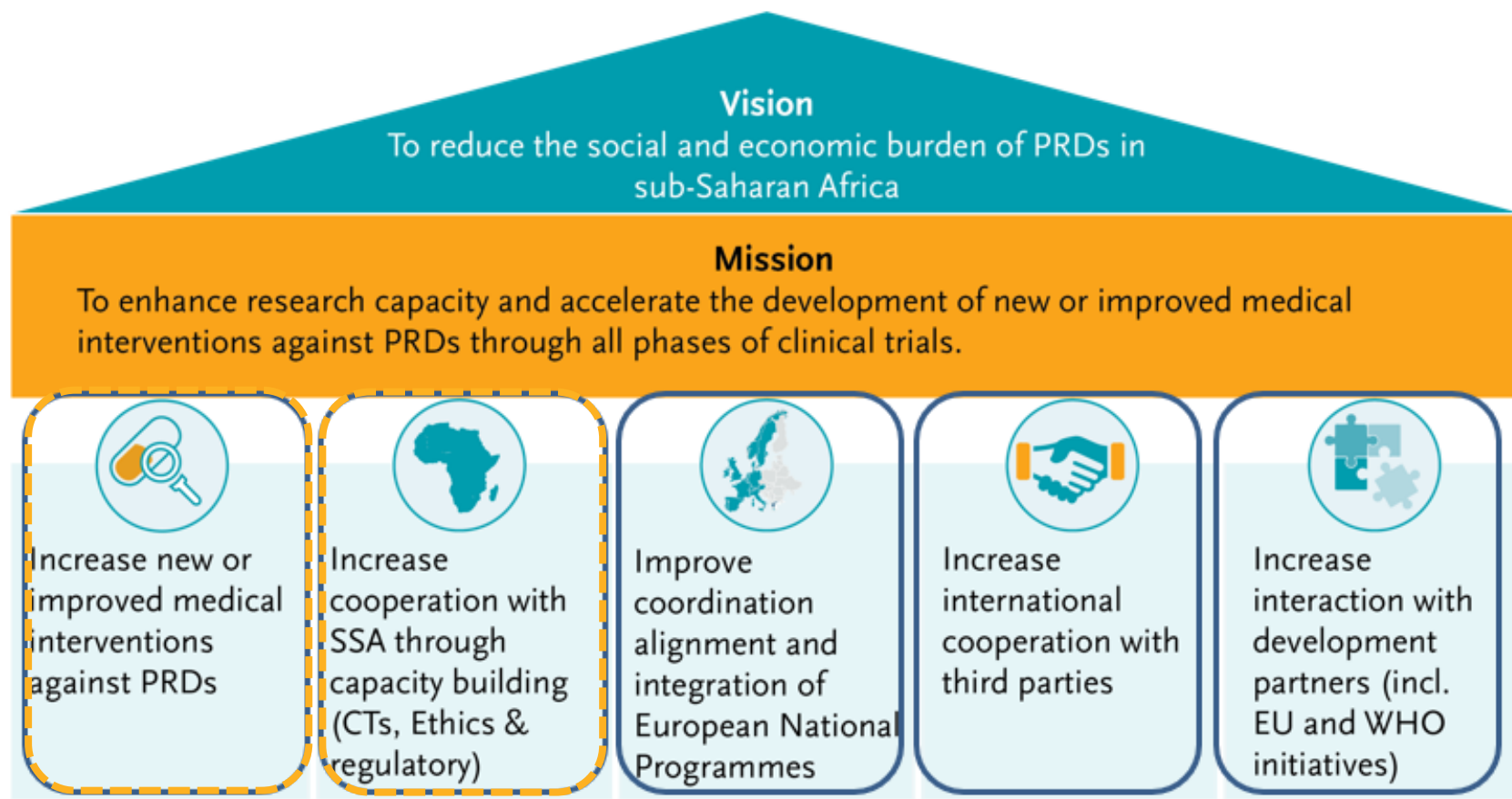
22 September 2021

Michael Makanga, MD PhD FRCP,
EDCTP Executive Director

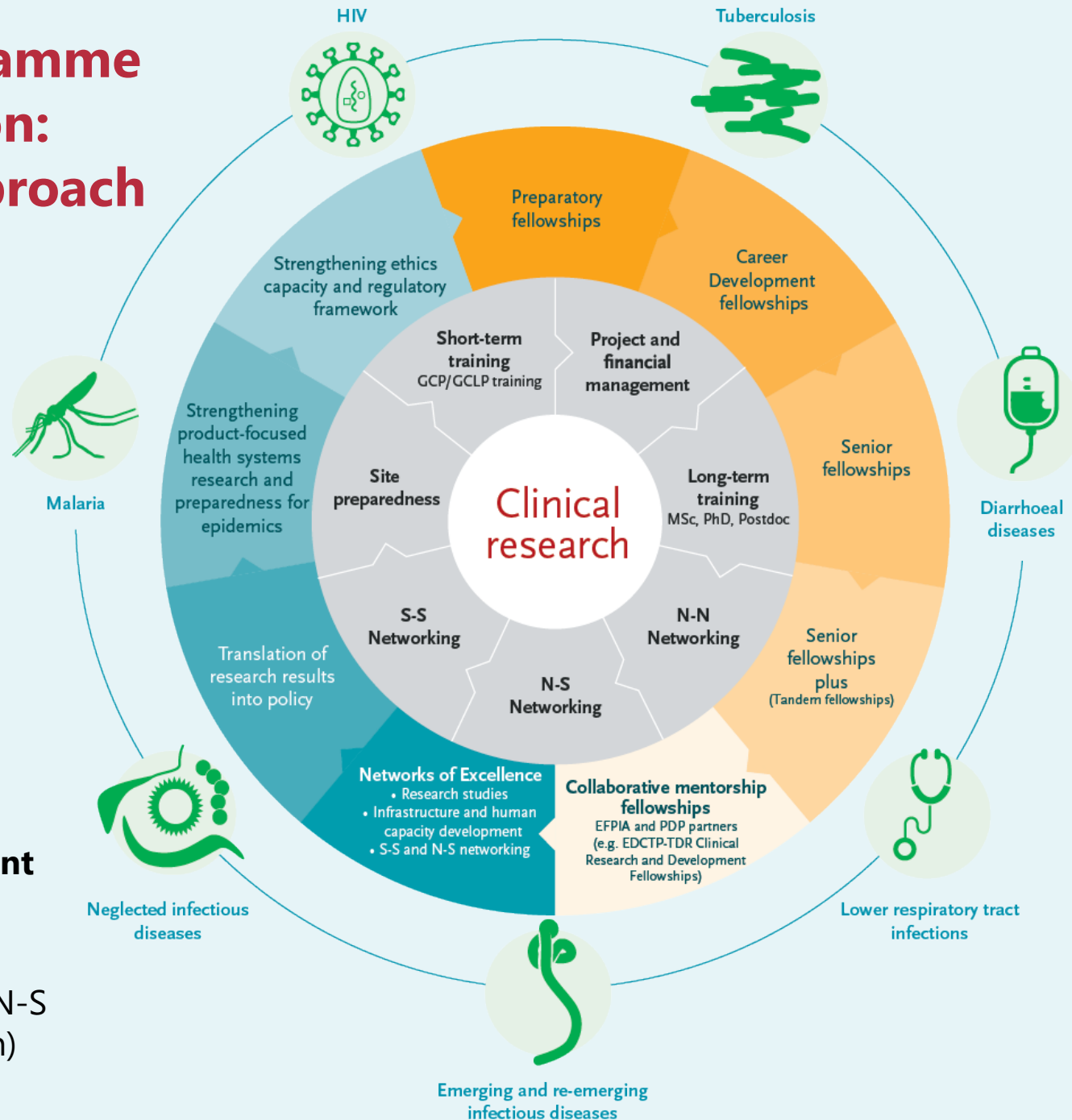


EDCTP strategic approach

- Public-public partnership between 16 African and 14 European countries, with co-funding from the EU
- Launched in 2003 and renewed in 2014
- Focal point of EU support for global health research in Africa, and a palpable sign of commitment to the Sustainable Development Goals (SDGs).



EDCTP2 programme implementation: integrated approach



SDG 17: Global partnership for sustainable development

Target 17.9: Targeted capacity building (N-N, N-S & triangular cooperation)

SDG 17: Global partnership for sustainable development

Target 17.3: Mobilising resources from multiple sources

The EDCTP financing model combines funding from Participating States and the European Union, as well as public and private partners (third parties).

Participating States



€1.33 Bn

- €1.16 Bn (in-kind, 301 PSiAs)
- €171.09 M (cash)

Third parties



€397 M

- €295.29 M (cash)
- €102.01 M (in-kind)

European Union

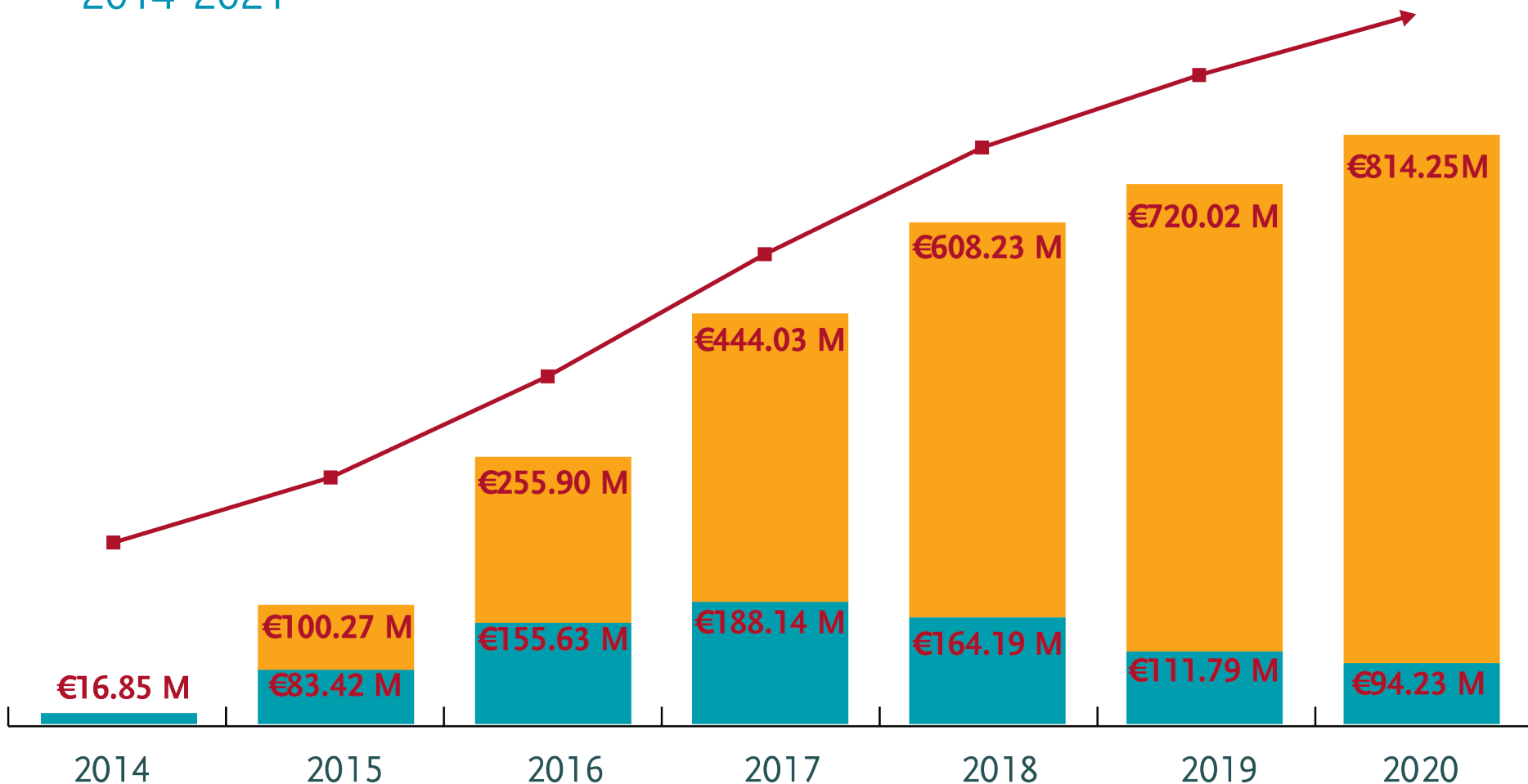


€683 M

- €683 M (cash)
Fully committed in work plans 2014-2020

EDCTP2 Annual investments

2014-2021

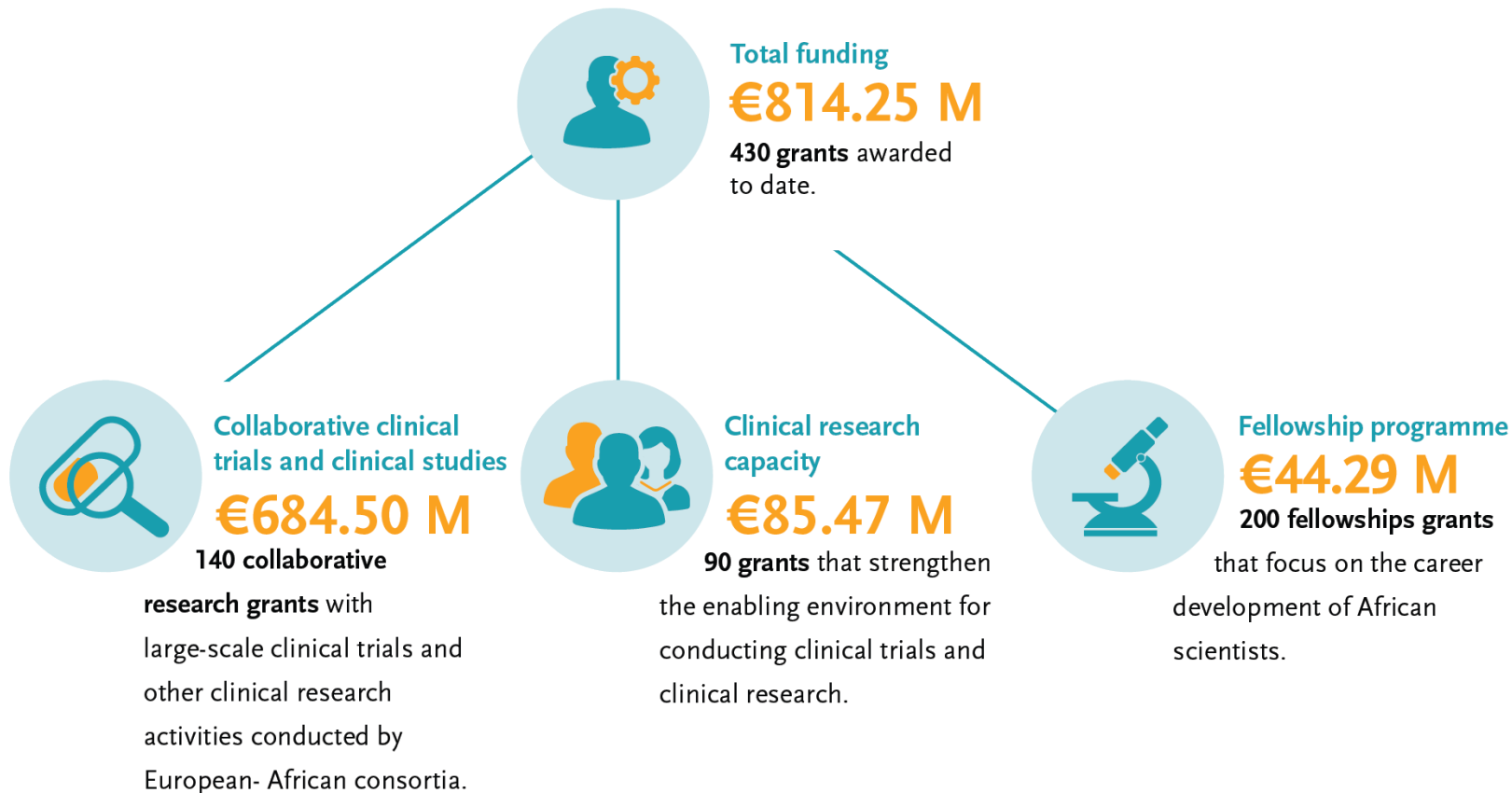


■ Investments to call for proposals by year

■ Cumulative Investments to call for proposals by year

EDCTP2 grants

2014-2021



EDCTP-supported activities (#60)

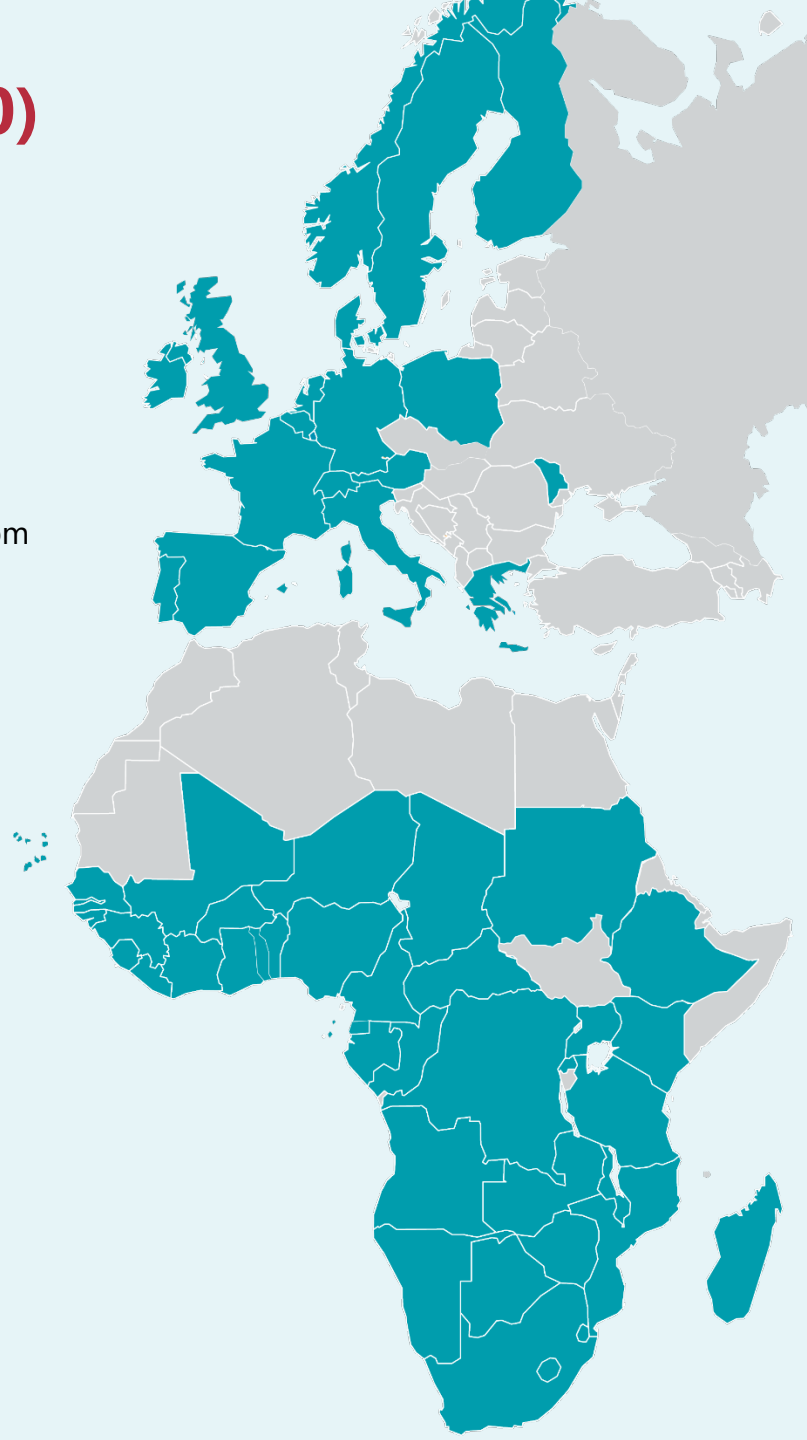
2014-2021

European countries

- | | | |
|------------|-----------------|--------------------|
| 1. Austria | 8. Ireland | 15. Portugal |
| 2. Belgium | 9. Italy | 16. Spain |
| 3. Denmark | 10. Luxemburg | 17. Sweden |
| 4. Finland | 11. Moldova | 18. Switzerland |
| 5. France | 12. Netherlands | 19. United Kingdom |
| 6. Germany | 13. Norway | |
| 7. Greece | 14. Poland | |

African countries

- | | | |
|----------------------------------|-------------------|---------------------------|
| 1. Angola | 16. The Gambia | 31. Rwanda |
| 2. Benin | 17. Ghana | 32. São Tomé and Príncipe |
| 3. Botswana | 18. Guinea | 33. Senegal |
| 4. Burkina Faso | 19. Guinea-Bissau | 34. Sierra Leone |
| 5. Cabo Verde | 20. Ivory Coast | 35. South Africa |
| 6. Cameroon | 21. Kenya | 36. Sudan |
| 7. Central African Republic | 22. Liberia | 37. Tanzania |
| 8. Chad | 23. Lesotho | 38. Togo |
| 9. Comoros | 24. Madagascar | 39. Uganda |
| 10. Congo | 25. Malawi | 40. Zambia |
| 11. Democratic Republic of Congo | 26. Mali | 41. Zimbabwe |
| 12. Equatorial Guinea | 27. Mozambique | |
| 13. Ethiopia | 28. Namibia | |
| 14. Eswatini | 29. Niger | |
| 15. Gabon | 30. Nigeria | |



Geographical coverage of EDCTP2 COVID-19 grants

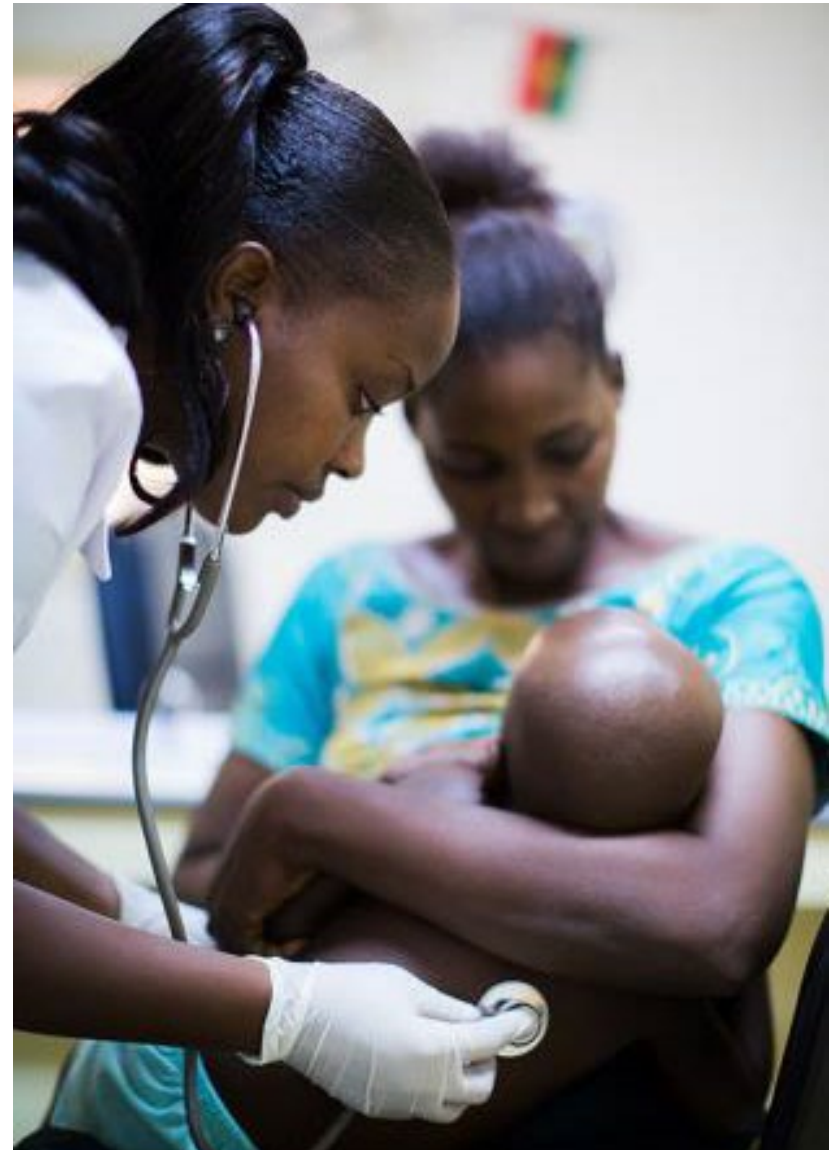
27 Consortia



Key populations

- Pregnant women
- Newborns
- Children and adolescents
- People living with co-infections and co-morbidities
- Genetic diversity.

The programme supports gender equity and promotes the interest of populations with major unmet medical needs – steps that are instrumental to realising the SDGs.



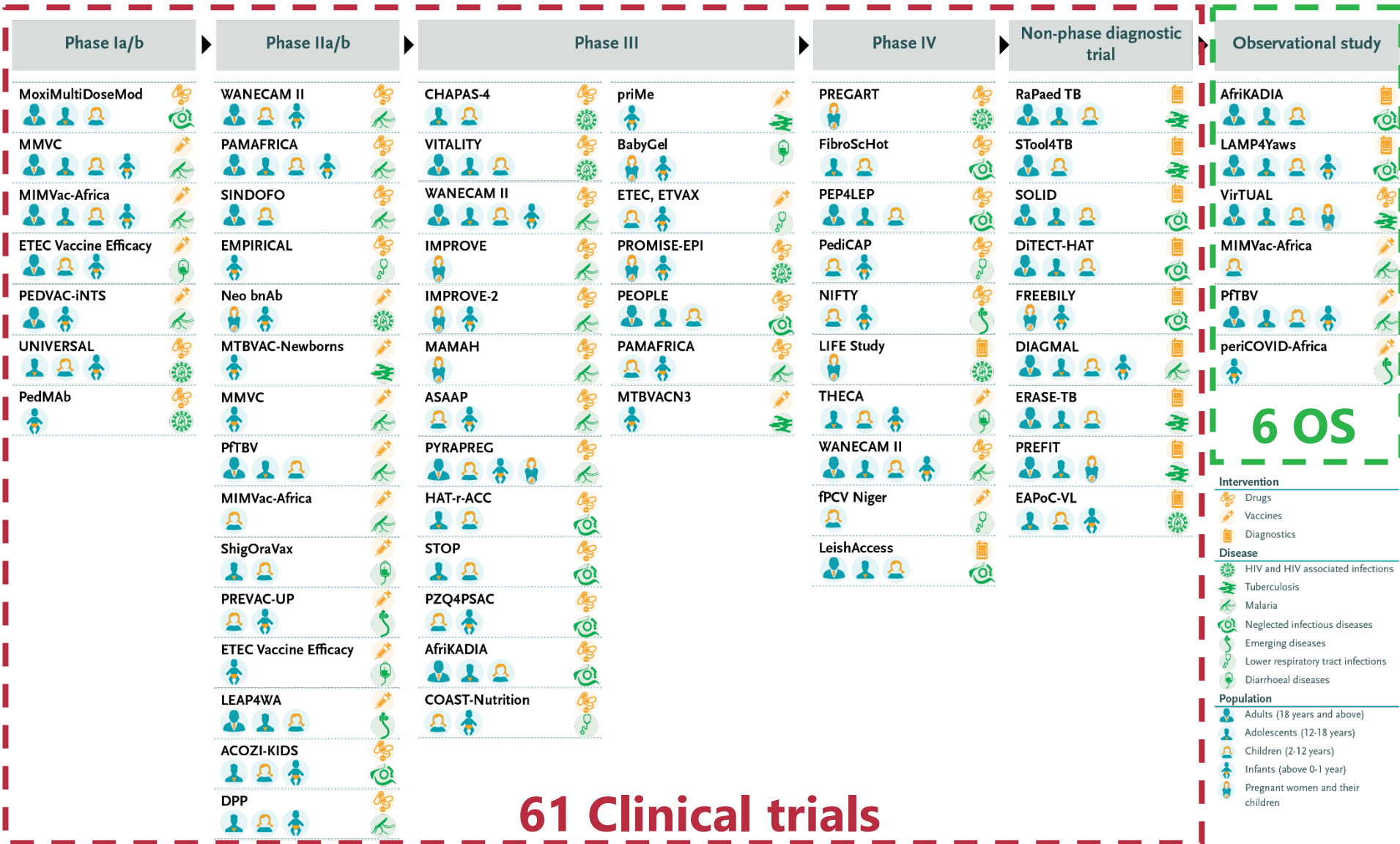
What is the investment delivering towards SDGs?

Evidence base developed for national and international policy-making

- Data from the **CHAPAS trials** contributed to the approval of fixed-dose antiretroviral drug formulations for children by the US Food and Drug Administration, paving the way for their distribution through global philanthropic programmes and greatly enhancing African children's access to life-saving antiretroviral drugs.
- The **Kesho Bora study** provided some of the earliest and strongest evidence that triple antiretroviral therapy could dramatically reduce mother-to-child transmission of HIV during breastfeeding. It informed the development of revised WHO guidelines, which recommended more extensive use of antiretrovirals in pregnant and breastfeeding women.
- The **WANECAM study** demonstrated the safety and efficacy of Pyramax® (pyronaridine-artesunate) and evaluation of a formulation specifically developed for children, paving the way for its approval by the European Medicines Agency and recommendation by WHO.
- The **MiPPAD study** provided high-quality evidence on mefloquine for prevention of malaria in pregnancy. Although safe and effective, mefloquine was not well tolerated. The results provided valuable input to WHO policymakers and are ensuring that resources are now devoted to investigating more promising alternatives.

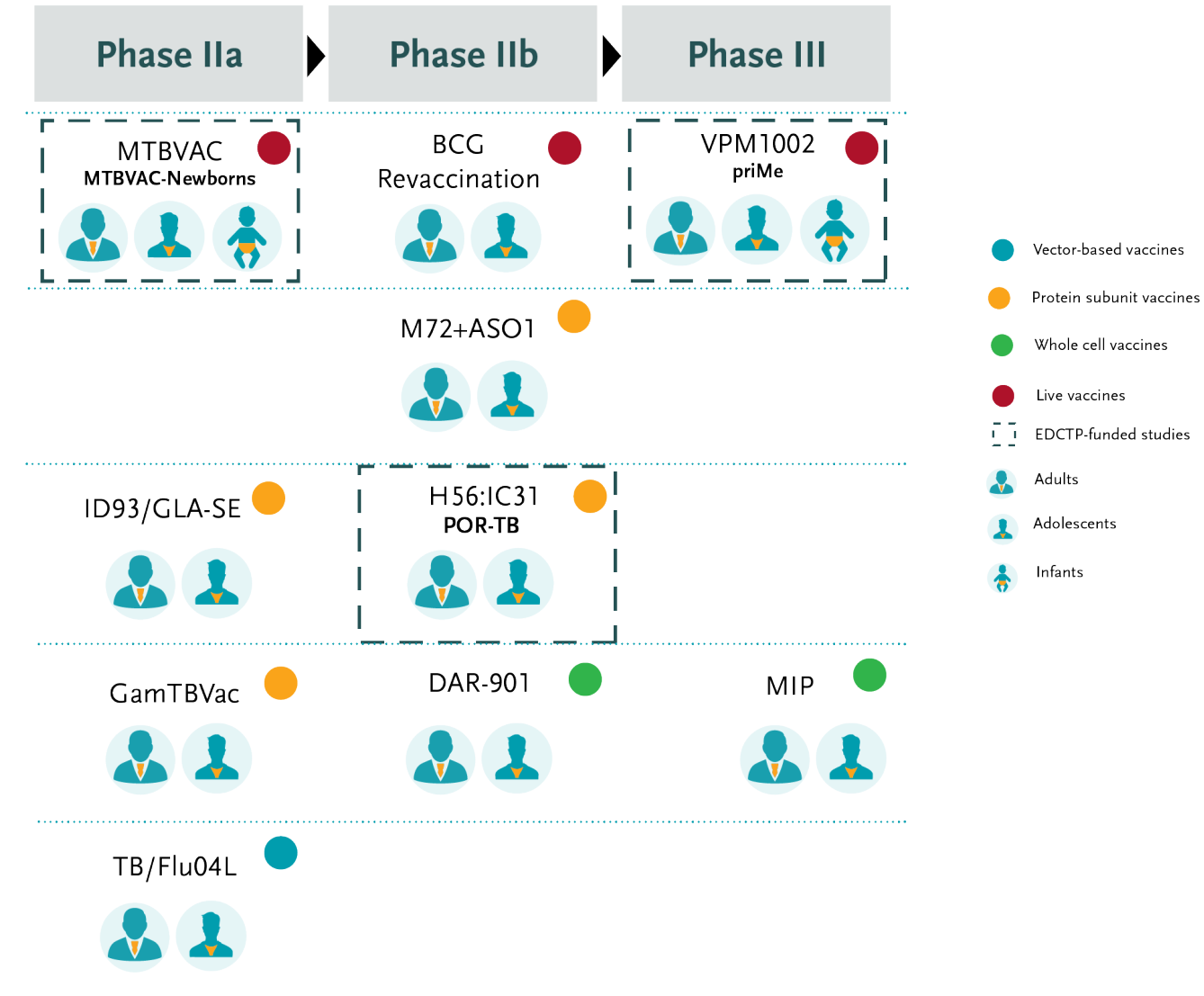
SDG 3: Healthy lives and well-being for all at all ages

EDCTP-supported collaborative clinical trials and clinical studies on maternal and child health



SDG 3: Healthy lives and well-being for all at all ages

Global TB vaccines pipeline: frontrunner candidates in clinical development



SDG 3: Healthy lives and well-being for all at all ages

Targets 3.1/3.2/3.3: Reduce global maternal mortality, end preventable deaths of newborns and children under 5 years of age & end the epidemics of HIV/AIDS, TB, malaria, NTDs

Prevention of TB in newborns

- MTBVAC vaccine – a novel TB candidate – two projects: **MTBVAC-Newborns** and **MTBVACN3**, evaluating MTBVAC in phase IIa and phase III sequential trials in newborns.
- Phase III clinical development of **VPM1002**: a promising BCG-derived vaccine candidate. The trial sample size is approx. 7,000 newborn infants from South Africa, Tanzania, Kenya, Uganda and Gabon. It will provide definitive evidence of the safety and efficacy of VPM1002 in both HIV-free and HIV-infected newborn infants.

Prevention of mother-to-child transmission of HIV

- **PREGART**: a multi-national clinical trial to identify the optimal treatment regimen to prevent mother-to-child transmission of HIV
 - Enrolling nearly 1,830 HIV-infected pregnant and breastfeeding mothers in Ethiopia and Uganda.



SDG 3: Healthy lives and well-being for all at all ages

ARTICLES | [VOLUME 397, ISSUE 10287, P1809-1818, MAY 15, 2021](#)



PDF [606 KB]

Figures

Efficacy of a low-dose candidate malaria vaccine, R21 in adjuvant Matrix-M, with seasonal administration to children in Burkina Faso: a randomised controlled trial

[Mehreen S Dattoo, MRCP](#) * • [Magloire H Natama, PhD](#) * • [Athanase Somé, MD](#) • [Ousmane Traoré, PhD](#) •

[Toussaint Rouamba, PhD](#) • [Duncan Bellamy, MSc](#) • et al. [Show all authors](#) • [Show footnotes](#)

[Open Access](#) • Published: May 05, 2021 • DOI: [https://doi.org/10.1016/S0140-6736\(21\)00943-0](https://doi.org/10.1016/S0140-6736(21)00943-0)

The **Multi-Stage Malaria Vaccine Consortium (MMVC)** carried out a trial of R21/Matrix-M malaria vaccine and demonstrated efficacy of 77%, exceeding the WHO goal of 75% efficacy for malaria vaccines. These promising results are from phase Ib/IIb trial in Burkina Faso, children aged 5-17 months that were randomised to receive either the R21/Matrix-M candidate (low- or high-dose) or a control vaccine (rabies). Preparations for a large-scale phase III trial are underway.

SDG 3: Healthy lives and well-being for all at all ages

Examples of projects receiving scientific advice from EMA



Better tools for control of parasitic worm infections

The **STOP study** is developing a convenient pill to improve control of parasitic worm infections in Africa. It will generate key evidence to support a licensing decision on the albendazole–ivermectin co-formulation.

The combination could improve the effectiveness of mass drug administration campaigns against common but neglected parasitic worm infections and protect a vital drug against the development of resistance.



Partnering up in the battle against schistosomiasis

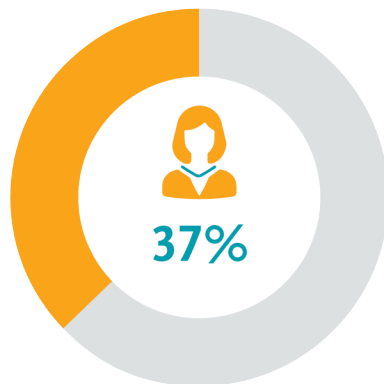
The Pediatric Praziquantel Consortium has developed an orodispersible new praziquantel pill for young children suffering from schistosomiasis.

The **PZQ4PSAC study** is conducting a phase III trial to test the safety and efficacy of this new formulation in young children in Cote d'Ivoire and Kenya. The trial results will feed directly into submissions to regulatory agencies to facilitate the new pills to rapidly be made available to pre-school children through the **ADOPT** programme, which is also co-funded by EDCTP and the GHIT Fund.

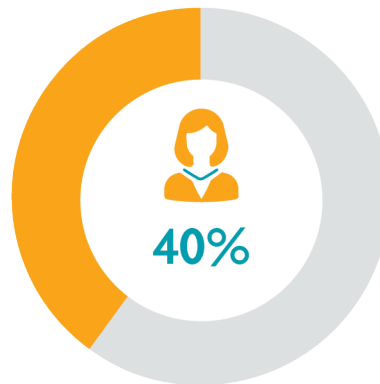
SDG 5: Gender equality and empowerment of women and girls

Targets 5.1/5.5/5.C: End all forms of discrimination against all women and girls everywhere and ensure full and effective participation and equal opportunities for leadership

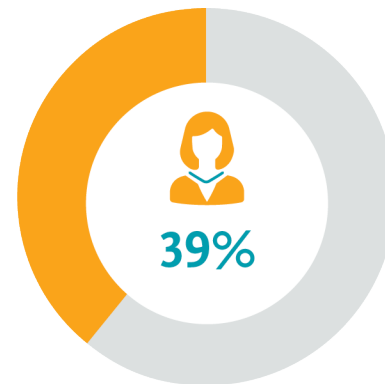
Gender ratios in EDCTP grant activities



of EDCTP-funded projects are coordinated by female researchers



of EDCTP-funded fellows are female researchers



of experts contracted for EDCTP call for proposals evaluation procedures are females

SDG 5: Gender equality and empowerment of women and girls

Funding calls and projects with a gender focus

€ 2 million

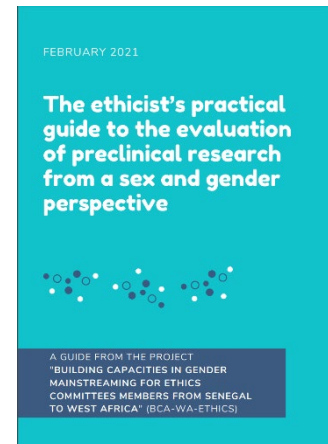
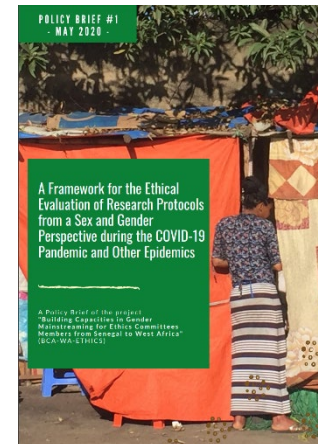
(Ring-fenced female PhD training funding):

Addressing gender and diversity gaps in clinical research capacity through the EDCTP Regional Networks of Excellence

BCA-WA-ETHICS

An EDCTP-funded international consortium mainstreaming a gender perspective into the activities of ethics committees in Senegal, and encouraging the adoption of good gender-related practice in clinical research in West Africa.

www.bcawaethics.com



African Women Scientists & SDGs

Examples of EDCTP2 strategic (portfolio) funding



Advancing a portfolio of malaria drugs

The **PAMAFRICA** grant is advancing the development of a suite of drugs to address unmet needs in malaria treatment.

Grant at a glance

Project: PAMAFRICA

Project lead: Dr Timothy Wells, Medicines for Malaria Venture, Switzerland

Countries involved: Burkina Faso, Gabon, Germany, Mozambique, Spain, Switzerland and Uganda

Target population(s): Adults and children

Year funded: 2019

EDCTP funding: €22 M

Total project funding: €41.9 M



Shorter treatment for drug-resistant TB

The **Simplici-TB** study is evaluating a new combination of drugs that could significantly shorten treatment times for both drug-sensitive and drug-resistant TB.

Grant at a glance

Project: Simplici-TB study

Project lead: Professor Stephen Gillespie, University of St Andrews, UK

Countries involved: Gabon, Germany, Malawi, Mozambique, the Netherlands, South Africa, Switzerland, Tanzania, Uganda, United Kingdom, and the United States

Target population(s): All age groups

Year funded: 2018

EDCTP funding: €12 M

Total project funding: €32.4 M



Advancing a portfolio of malaria vaccines

The **MIMVaC-Africa** consortium has a highly ambitious programme to rapidly test and compare a portfolio of five malaria vaccine candidates in Europe and Africa.

Grant at a glance

Project: MIMVaC-Africa

Project lead: Dr Sodiomon Sirima, Groupe de Recherche Action en Santé (GRAS), Burkina Faso

Countries involved: Burkina Faso, Gabon, Germany, Japan, Luxembourg, Mozambique, the Netherlands, Tanzania, and the United Kingdom

Target population(s): Adults

Year funded: 2020

EDCTP funding: €12 M

Total project funding: €21.6 M



Global Health EDCTP3 Joint Undertaking (JU)

Future outlook of the Global Health EDCTP3 programme

The Global Health EDCTP3 programme will be formed under Horizon Europe in Q1 2022

Key features of the Global Health EDCTP3 programme:

- Focus on unmet medical needs of vulnerable populations, infectious diseases and Africa – with more inclusive global collaboration
- Maintain scope on clinical development of medical interventions but with a greater emphasis on late stage R&D – phase III and IV trials and product-focused implementation studies
- A drive towards more patient-centred approaches that promote cross disease, interdisciplinary research, and explore opportunities offered by new technologies in context of integrated patient care
- Cognisance to the critical issue of enabling the regulatory environment for conducting clinical trials, and lessons learnt from the global COVID-19 impact on R&D in general
- Address the vital gap on the interaction 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.

Global policy relevance of Global Health EDCTP3

The [Global Action Plan for Healthy Lives and Well-being for All](#), launched at the UNGA in September 2019, noted that extra efforts would be required if health-related SDGs were to be met by 2030.

- It identified R&D as a key accelerator of progress and emphasised the importance of global collaboration and alignment.

Global Health EDCTP3 will:

- Provide a powerful voice for Europe in global health research, and an important mechanism to promote European objectives and values, in partnership with Africa
- Be a demonstration of the EU's commitment to the health and wellbeing of disadvantaged populations in sub-Saharan Africa, and its pursuit of the SDGs
- Be fully in line with the ['EU-Africa Alliance for Sustainable Investments and Jobs'](#) of September 2018
- Contribute to the EC's ['Towards a comprehensive Strategy with Africa'](#) adopted in March 2020, and to the ['Global EU response to COVID-19'](#)
- Make a major contribution to the fifth EU policy priority identified by the EC President - ['A stronger Europe in the world'](#) - which emphasises the need for international partnerships and multilateral initiatives to tackle global challenges, including threats to global health.

Thank you



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