Milestones, new platforms and strategies for HIV and TB vaccine research: an EDCTP overview

EDCTP satellite symposium

4 December 2019 | 10:45-12:15 | Joel Nana (AD10)
About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP’s vision is to reduce the individual, social and economic burden of poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP’s mission is to accelerate the development of new or improved medical interventions for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The second EDCTP programme is implemented by the EDCTP Association supported under Horizon 2020, the European Union’s Framework Programme for Research and Innovation.
EDCTP session on
Milestones, new platforms and strategies for HIV and TB vaccine research: an EDCTP overview

This symposium will highlight the specific challenges, opportunities and strategies for developing HIV and TB vaccines and demonstrate how EDCTP-funded research is trying to address these together with international partners, including through locally developed solutions.

The session will also discuss common areas with other infectious diseases of relevance to sub-Saharan Africa and explore possibilities for cross-cutting coordination, knowledge sharing and learning through established networks and platforms.

This session aims to generate discussion on how future collaborative HIV and TB vaccine research can address the challenges and needs identified. It will also discuss how best to engage the relevant actors in order to build on progress to date and ensure the development of practical, accessible and affordable vaccines for sub-Saharan African populations.
## Agenda

### Chairpersons

Tandakha Ndiaye Dieye, Centre National de Transfusion Sanguine (CNTS), Senegal  
Roger Tatoud, International AIDS Society (IAS), Switzerland

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<td>10:45-10:50</td>
<td><strong>Welcome and introduction</strong></td>
<td>Tandakha Ndiaye Dieye and Roger Tatoud</td>
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<td>10:50-11:00</td>
<td><strong>Investing in HIV and TB vaccines – EDCTP’s portfolio</strong></td>
<td>Shingai Machingaidze (EDCTP, South Africa)</td>
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<td>11:00-11:50</td>
<td><strong>EDCTP project and partners presentations:</strong></td>
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<td>PrEPVacc: A Phase IIb three-arm, two-stage HIV prophylactic vaccine trial with a second randomization to compare TAF/FTC to TDF/FTC as pre-exposure prophylaxis</td>
<td>Eugene Ruzagira (Uganda Virus Research Institute, Uganda)</td>
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<td>Prevention of recurrence of TB: a phase II double-blind, randomised placebo-controlled trial</td>
<td>Álvaro Borges (Statens Serum Institute, Denmark)</td>
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<td>Challenges in conducting HIV-TB clinical research in Central Africa: Experience from the Republic of Congo</td>
<td>Laure Ghoma Linguissi (Fondation Congolaise pour la Recherche Médicale, Congo)</td>
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<td>Strengthening Ethics and regulatory systems in Africa: In the context of HIV and TB clinical trials</td>
<td>Yolanda Moyo (International AIDS Vaccine Initiative (IAVI), South Africa)</td>
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<td>11:50-12:15</td>
<td><strong>Discussion, including questions from the audience</strong></td>
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Álvaro Borges MD, MSc, PhD

Álvaro Borges is an infectious diseases physician with a MSc in Tropical and Infectious Diseases by the Liverpool School of Tropical Medicine (2011) and a PhD in Immunology and Infectious Diseases by the University of Copenhagen (2015). He has joined the Center for Vaccine Research at the Statens Serum Institut in Denmark as a chief medical officer to work on clinical trials testing new vaccine candidates in humans.

Tandakha Ndiaye Dieye PhD, Prof.

Tandakha Ndiaye Dieye is full Professor at Cheikh Anta Diop University, Head of the immunology Unit of IRESSEF (Research Institute of Health for Epidemiology & training) & head of the immunology unit at Le Dantec University hospital, Dakar. He is also head of the National blood transfusion laboratories in Senegal.

Prof. Dieye is the acting Secretary general of the society of AIDS in Africa (SAA) and also the past president of African Society for Immunodeficiencies (ASID). Dr Dieye participates in several projects on primary immunodeficiency in Africa. He managed several Tuberculosis and EBOLA vaccine trials Phase I and Phase II in HIV volunteers.

Prof. Dieye is currently vice-president of the scientific committee of the Africa Centre of Excellence (ACE) for mother to child transmission and member of the WHO regional Verification Commission of Measles and Rubella Elimination.

Laure Ghoma Linguissi Msc, MPH, PhD

Laure Stella Ghoma Linguissi, is a Molecular Biologist. She has a thesis in Applied Biotechnology, Molecular Biology Option, University of Ouaga I Joseph Ki-Zerbo, Burkina-Faso. Her areas of expertise are HIV, tuberculosis and hepatitis.

In April 2017, she was appointed Research Associate at the Congolese Foundation for Medical Research (FCRM) and supervisor of TB research activities at the Research Center on Infectious Diseases Christophe Mérieux (CeRMI-CM).
**Shingai Machingaidze MPH**

Shingai Machingaidze joined EDCTP in September 2015 as a Project Officer. She received undergraduate and postgraduate training in molecular and cell biology at the University of Cape Town (UCT), South Africa where she worked on probiotic strains for Kidney Stone Disease. In 2011 she obtained a Master of Public Health in Epidemiology and Biostatistics also from UCT. Shingai is currently studying towards a PhD in Public Health.

Before joining EDCTP, Shingai worked as a researcher at UCT for five years with the South African TB Vaccine Initiative (SATVI), as well as with the Vaccines for Africa Initiative (VACFA) coordinating research on vaccination programmes (EPI). She subsequently worked with the Centre for Tuberculosis at the National Institute of Communicable Diseases, and at the South African Medical Research Council where she was a Project Manager for the South African Guidelines Excellence (SAGE) Project.

Shingai has published in the fields of vaccines, TB epidemiology, clinical guidelines and translation of research into policy and practice. She is a peer-reviewer for several international medical journals and is a member of faculty of the Annual African Vaccinology Course.

**Yolanda Moyo RN, MSc**

Yolanda Moyo is the Senior Director for Policy Advocacy and Research Preparedness at IAVI where she leads the strategic design and implementation of advocacy activities across IAVI’s overall portfolio in Africa, as well as key aspects of policy advocacy, ranging from policy analysis to advocating for evidence informed policy change. Additionally, she guides the research preparedness activities in Africa to ensure gender balance, recruitment and retention in clinical research; and meaningful engagement with communities most affected by the HIV epidemic.

Yolanda has worked in private sector product development clinical trials and in academia managing the regulation compliance of clinical trials, medical devices and non-commercial translational research to research regulations. She has a master’s degree in Clinical Drug Development from Queen Mary University of London, UK and is a second-year Doctor of Public Health (DrPH) candidate at the London School of Hygiene and Tropical Medicine.

Yolanda is passionate about access to life saving health technologies by those who need them the most, she has spent most of her career advocating for equitable access to health and health technologies in Africa.
Eugene Ruzagira MBChB, MPH, PhD

Dr Eugene Ruzagira trained as a medical doctor from Mbarara University of Science and Technology, Uganda. He later obtained a MSc in Community Health from The University of Innsbruck, Austria, and a PhD in Epidemiology from the London School of Hygiene & Tropical Medicine, United Kingdom. His interests are in the epidemiology and control of infectious diseases, including HIV infection and other sexually transmitted infections. He has particular interest in the development and evaluation of interventions against HIV and strategies to strengthen the HIV care continuum in Africa. He is a co-investigator for PrEPVacc, a multicentre phase IIb HIV vaccine trial, involving sites in Uganda, Tanzania, Mozambique and South Africa.

Roger Tatoud PhD

Roger Tatoud is the Director of the Global HIV Vaccine Enterprise based at the International AIDS Society in Geneva. He is an executive who has worked with global health research organisations to translate strategic plans into tactical realities and improve organisational operations towards excellence. Roger has a comprehensive background in science, research, operations, finance, legal and management of not-for-profit organisations and believe that a people-centered and systems approach are key to deliver on organisational goals and business development.

Roger has supported academic and not-for-profit organisations and worked with the pharmaceutical industry in diverse diseases areas, with a focus on infectious diseases and especially HIV since 2008. Previously, Roger was responsible for the operations and management of a clinical immunology reference laboratory in London with connections to East African partners. He also led a key research service office dedicated to the development and management of clinical and translational research, overseeing and contributing to the management of national and international multicentre clinical research programmes.

Roger holds a Ph.D. from university Pierre and Marie Curie (Paris 6) and a degree in Systems Thinking (Open University). Roger enjoys working in a multicultural environment and has lived in various places on three continents. He is also an HIV prevention advocate supporting research engagement with the public and end users and evidence-based roll out of new HIV prevention and treatment tools.
MICROBIOLOGY
EDCTP’s investment in research & development

2014-2019

Total funding €608.60 M
In 267 projects awarded to date

Clinical studies €526.04 M
to support 84 projects
with large-scale clinical trials and other clinical research activities conducted by European-African consortia.

Clinical research capacity €51.28 M
to support 57 projects
that strengthen the enabling environment for conducting clinical trials and clinical research.

Fellowship programme €31.28 M
to support 126 fellowships
that focus on the career development of individual researchers.

Collaborative clinical trials and clinical studies

By disease

- Tuberculosis, 25 grants
  €146.74 M
- Malaria, 12 grants
  €118.51 M
- HIV & HIV-associated infections, 16 grants
  €96.74 M
- Neglected infectious diseases, 13 grants
  €48.86 M
- Diarrhoeal diseases, 5 grants
  €45.50 M
- Emerging diseases, 9 grants
  €41.60 M
- Lower respiratory tract infections, 4 grants
  €28.09 M
EDCTP’s investment in HIV-TB vaccine research

€67.40M
7 grants

- HIV & HIV-associated infections, 4 grants
  €35.58 M
- Tuberculosis, 3 grants
  €31.82 M

EDCTP portfolio: vaccine research

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<th>Phase Ia/b</th>
<th>Phase IIa/b</th>
<th>Phase III</th>
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<td><strong>CAP012 SAMBA Trial</strong>&lt;br&gt;South Africa, Zambia</td>
<td><strong>GREAT</strong>&lt;br&gt;Kenya, Uganda, Zambia</td>
<td><strong>priMe</strong>&lt;br&gt;Gabon, Kenya, South Africa, Tanzania, Uganda</td>
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<td><strong>PrEPVacc</strong>&lt;br&gt;Mozambique, Tanzania, Uganda, South Africa</td>
<td><strong>POR TB</strong>&lt;br&gt;South Africa, Tanzania</td>
<td><strong>MTBVAC-Newborns</strong>&lt;br&gt;South Africa</td>
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<td><strong>Neo bnAb</strong>&lt;br&gt;Mozambique, Tanzania</td>
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**Caption**<br>**Disease**<br>**Population**

- **Project name**<br>Site(s) in sub-Saharan Africa
- **HIV & HIV-associated infections**
- **Tuberculosis**
- Adults (≥18 yr and above)
- Pregnant women and/or newborns (birth to 1mo)
Country involvement in HIV-TB vaccine research

- Netherlands: 4 grants
  - France: 1 grant
  - United Kingdom: 3 grants
  - United States: 2 grants
  - Spain: 1 grant
  - Senegal: 1 grant
  - Gabon: 1 grant
- South Africa: 5 grants
- Zambia: 2 grants
- Mozambique: 2 grants
- Madagascar: 1 grant
- Tanzania: 4 grants
- Uganda: 3 grants
- Kenya: 2 grants
- Italy: 1 grant
- Germany: 3 grants
- India: 1 grant
- Switzerland: 1 grant
- Netherlands: 4 grants
- Sweden: 1 grant
- Denmark: 1 grant

United States, Netherlands, and South Africa have the highest numbers of grants, with South Africa leading with 5 grants.
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The EDCTP2 programme is supported under Horizon 2020, the European Union’s Framework Programme for Research and Innovation.
The power of sharing science