Global Health EDCTP3 Joint Undertaking 4th Stakeholders' Group meeting 21 March 2024 – Online

Participants:

Members: Marieme Ba (Pharmalys), Christian Burri (Swiss TPH), Franck Cobelens (Univ of Amsterdam and European Global Health Research Institute Network), Aubrey Justin Cunnington (Imperial College, London), Helen Demarest (MMV), Charles Gore (Medecine Patent Pool), Hans Hagen (GloPidR, Charite); Stacey Hannah (AVAC), Regina Mariam Kamoga (Community Health and Information Network), Chinyenze Kudai V. (IAVI), Lorna Leal Alexander (EMA), Lut Lynen (Institute for Tropical Medicine), Shingai Machingidze (African CDC), Neeraj Mistry (Chair, Future Africa Institute), Claude Muvunyi (Rwanda Biomedical Centre), Christine Nabiryo (Vice-Chair, PATH), Joseph Okeibunor (WHO AFRO), Folu Olugbosi (TB Alliance), Peggy Oti-Boateng (African Academy of Science), Ole Petter Ottersen (The Guild), Patel Deepali (AMR Action Fund), Greg Perry (IFPMA), Ralf Sudbrak (Global AMR R&D Hubà), Francisco Saute (Trials of Excellence in Southern Africa), Subasree Srinivasan (GARDP), Marieke van der Werf (ECDC), Saul Walker (CEPI), Constance Walyaro (International Society for Infectious Diseases (ISID).

Observers: Tom Nyirenda (EDCTP Association), Jan Paehler (European Commission), Lara Pandya (EDCTP Association),Programme office: Lydia Boudarène, Aleksandra Conversano, Veronique Canters, Antonia Forte, Silvia Garcia Perez, Claudia Gutierrez Arbizu, Jean-Marie Habarugira, Michael Makanga, Julia Molto Lopez, Sandra Ramos, Laurent Schell.

1. Opening remarks

1.1 Objectives of the year, introduction of new members and latest updates

Dr. Michael Makanga, Executive Director of Global Health EDCTP3, opened the 4th meeting of the Stakeholders' Group and welcomed the members. He introduced three new members: Dr. Helen Demarest (MMV), Dr. Charles Gore (MPP) and Dr. Ole Petter Ottersen (The Guild), and four permanent observers: Dr. Thomas Nyirenda (EDCTP Association, Africa office), Dr. Lara Pandya (EDCTP Association), Dr. Jan Paehler (European Commission), the future participation of Dr. Jimmy Volmink (Wellcome Trust) and highlighted the participation of the Chair of the Scientific Committee, Dr. John Gyapong.

Mandates between the Scientific Committee and the SG groups were clarified, with the SG aiming to embed the Global Health EDCTP3 programme and funding in the global health context. To ensure alignment and communication between the two groups, Dr. Makanga and the Chairs of the respective advisory committees will be attending each of the meetings along the year and a timeline is designed by the programme office to ensure streamlined inputs from the two groups.

The Stakeholders' Group timeline for 2024 was reviewed, with meetings to be held on 13th June (online) and 12th October, as a side meeting of the World Health Summit in Berlin (hybrid). The work programme of the year includes:

- **Update of the Strategic Research and Innovation Agenda (SRIA) by November** (survey will remain open until 1st June)
- **Inputs to the Annual Research and Innovation Agenda** (ARIA), serving as intermediate prioritisation framework between SRIA and Annual Work Programmes.
- **2025 EDCTP forum – June 2025**: prioritisation of themes and coordination
- **Adjacent sectors integration** into SRIA November 2024 (survey will remain open until 1st June)

An update of last EDCTP3 latest activities since the 3rd SG meeting included the nomination of Dr. Makanga as Executive Director on November 16, the establishment of financial autonomy of the programme, expansion of the programme officers team, publication of the Work Programme 2024 in Dec 2023, of which evaluations are planned in May and September 2024.

2. Adoption of the agenda, previous meeting minutes and Rules of Procedure

Following the adoption of the agenda and previous meeting minutes, the Chair Dr. Neeraj Mistry launched the discussion on the updated Rules of Procedures, which led to their formal adoption.
Laurent Schell, EDCTP3 legal officer, described the implementation of the modifications to the Rules of Procedure document discussed in the meeting in November such as clarifications, editing and partial restructuring of some articles, but the main core of the document was not changed. In particular: Article 1 about elaboration on the tasks of the SG, Article 2 about membership, meetings, and Article 11 about confidentiality of documents and internal consultation within their organisation. The Rules of Procedures were formally adopted.

3. Deliverable 2: 2025 EDCTP Forum

In addition to the SG contact points for the Forum elected in 2023 (Dr. Marieke Van der Werf and Dr. Hans Eckhardt Hagen), two focal points have been nominated by the ED in 2024: Dr. Claude Muvunyi and Dr. Kundai Chinyenze.
Julia Molto Lopez, Communicatons officer at EDCTP3 provided an update on the 12th EDCTP forum, taking place in June 2025 at the Kigali Convention Centre (Rwanda) in collaboration with the Rwanda Biomedical Centre (RBC). It was shared that three committees will be established in the coming two weeks as following:
- Forum Programme Committee (main role is to contribute to the programme development)
- Organising committee (focal point for the Forum, oversees the organization (budget, timelines, venues, etc)
- Local Committee (support EDCTP3 in logistics and organisational matters)

Marieke Van der Werf invited participants to propose potential themes for the EDCTP forum and invited the group to vote for the proposed themes. After the response analysis, the discussion resulted in 5 upvoted potential themes:

Overarching themes & ranking	Forum potential themes	Votes
1. Sustainaible partnerships	Building sustainaible Partnership for health research and innovation in Africa Partnerships to Strengthen Evidence use for better health in Africa Working together to effect meaningful and positive change in people we serve African Research Partnerships for Global health Risk and Response	18
2. Enhancing R&D ecosystem for equitable access	Moving research to reality: ensuring equitable global access through engaged research Building a sustainaible R&D workforce Enhancing R&D ecosytem in Africa Global Health Research for Development	18
3. AMR	Antimicrobial resistance (AMR)- The Not So Silent Pandemic	13
4. Building sustainaible CT networks	Building sustainaible networks for clinical research and innovation in health Bridging routine and epidemic health research capacity through adaptable clinical trial networks Networking networks- aligning with regional leadership for sustainable clinical research capacity	12
5. Clinical trials capacity	Bridging the Global Health Equity gap by building clinical trials capacity Research Capacity in Africa and Pandemic preparedness Capacity building	12

The full list of proposals can be found in annex I. Some of the preferred themes are complementary and could be merged into more comprehensive or broad overall theme for the Forum. These themes will be presented to the Global Health EDCTP3 Scientific Committee in April 2024 for discussions.

Recommendations regarding the length and structure of the forum were discussed: 3 full days (as per the current tentative dates, 2-4 June) were agreed to be a good length. However, certain SG members suggested that a longer Forum of 4 days would allow the programme to be less dense and allow further networking opportunities. An option to plan for a pre-Forum sessions (the day before) was suggested, with themes including: early career researchers (e.g., mentorship programmes, master classes) and community engagement to translate the scientific concepts. Recommendation was made to include a high-level summary of the science content and the implications for community/ policy makers during the Forum (either at the end of every day or at the end of the Forum). The SG members agreed that the Eleventh EDCTP Forum held in Paris in November 2023 worked well in terms of dynamism, diversity and combining scientific sessions with keynotes and poster presentations sessions during breaks. In view of the increasing number of participants, a request was made to ensure capability of rooms to host all participants and having additional rooms for side meetings to allow networking, and the sessions should reflect the diversity and participants' interests. In view of the influence of adjacent sectors on the clinical trials landscape, it was suggested to host a session or organise a workshop that connects cross-cutting themes with clinical research such as: Digital/AI, Climate-change related crisis, AMR/One health, patient-centric approaches, epidemic preparedness.

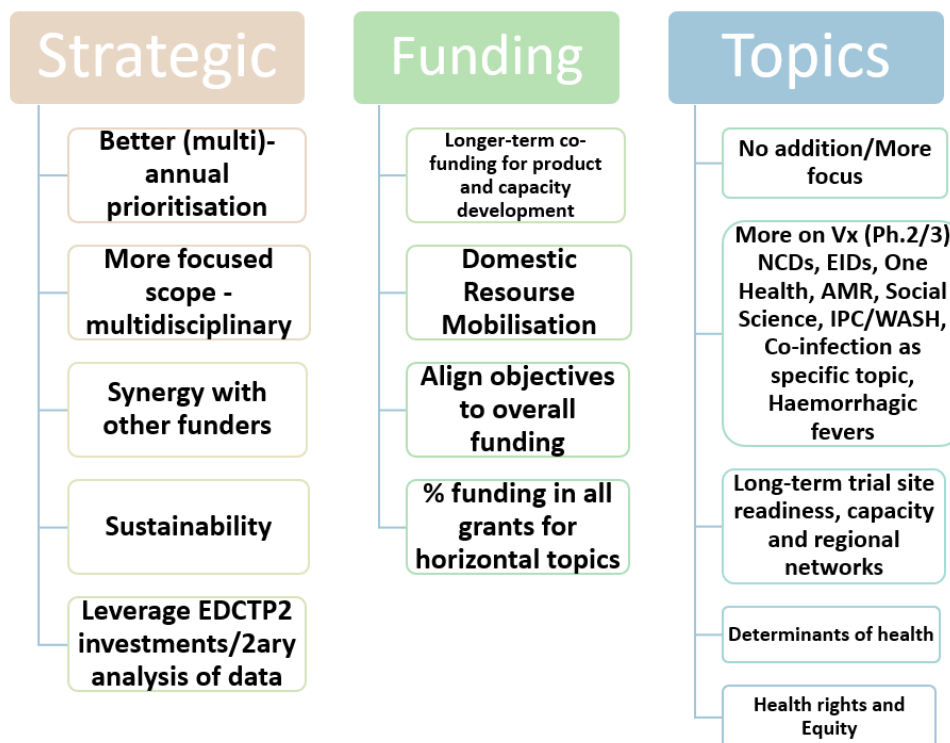Further recommendations regarding the organisation included:
- Proposing roundtables/discussion between funders, regulators, policymakers and researchers.
- Highlighting the meaning and impact of global health research, e.g. by inviting a science journalist interviewing speakers throughout the conference
- Hosting side visits for networking purposes (e.g., AMA or industry sites)

As next steps, SG focal points and EDCTP3 Secretariat will bring the SG input to the Forum Program Committee (once established) for further development of the programme.

4. Deliverable 1: SRIA update & ARIA

Lydia Boudarène, Senior Scientific Officer, presented the SRIA update survey results: 76% of respondents were in favour of a sight update of the SRIA. The survey results included strategic, financial and topic-specific recommendations, as per the below figure. Recommendations will be integrated to the current version of the SRIA by mid-May and a review from the SG will be established with sub-groups reviewing specific sub-sections. Final recommendations will be discussed at the SG meeting on June 13, for a final version to be agreed in October and submitted to the GB in November.

The

establishment of an intermediary framework between the SRIA and the annual work programme through an Annual Research and Innovation Agenda (ARIA) was supported by 81% of the survey respondents, of which 35% suggesting re-discussions on the periodicity of the ARIA, the need to keep flexibility or to align the clinical trials timeframe with the yearly agenda. The first draft of the ARIA was developed by the Secretariat and the methodology was presented, including a literature review of each SRIA topic, the identification of key ongoing programmes and funders linked to topic. It aims to be structured with an evidence-based prioritisation of topics to align with SRIA objectives and that enables continuity of the funding based on previous EDCTP funding (EDCTP2 and EDCTP3).

SG members were invited to provide input to identify the gaps for each of the target diseases, following four questions:

1- What are the key research gaps to tackle in 2025 for the EDCTP target diseases?
2- What are the key capacity gaps to be tackle in the scope of EDCTP?
3- What are the important like-minded initiatives investing in the same scope as EDCTP3?
4- Which founders shall we collaborate with?

The detailed identified gaps and relevant programmes/partners can be found in Annex II.
It was confirmed that a mapping of current in-kind contributions by EDCTP association members will be integrated, along with current strategies and research priorities of broad organisations such as WHO and African countries that are implementing projects.

The SG members were invited to forward any existing resource allocation, investment or funding databases links and possible contributing partners not considered yet, to EDCTP3 Secretariat
The next step of the development of the ARIA and prioritisation of topics for 2025 consist in:
- End April: Integration of the SG and SC input into the ARIA and identification of topics for WP 2025
- May 2024: consultation with EC and EDCTP Association to be submitted to Governing Board (GB) 27 June
- October 2024: Final input to the WP 2025 by SG and SC for submission to GB in November
- 3 Dec 2024: adoption by GB It was confirmed that the 1st draft of WP2025 will be shared with EDCTP Association for consultation at the same time as EC in May

5. Deliverable 3: Adjacent sectors

In the context of the adjacent sectors, Silvia Garcia Perez, Scientific Project Officer, presented the survey summary results for adjacent sectors and cross-cutting themes and actors. She invited SG members to provide input on additional cross-cutting themes and actors per topic disease to be integrated in the SRIA. Please see annex III for the full results of cross-cutting topics.

Next steps: to integrate the list of adjacent sectors to the SRIA update by November 2024 and to the future topic calls text of annual work programmes.

6. AOB and next steps

1. LUSAKA Agenda: Conclusions of the future of Global Health Initiatives Process

Considering the mandate and scope of the Global Health EDCTP3 and the five key shifts for the long-term evolution of the Global Health Initiatives (GHI) ecosystem, SG members were asked to provide their view on the relevant sections and needs for adjustment to ensure successful implementation and increased impact of the Global Health EDCTP3 programme, after the meeting. Members have highlighted the R&D section of the Lusaka declaration which would be relevant to the programme.

The meeting was closed by Dr. Michael Makanga and Chair Dr. Neeraj Ministry. The next meeting will be held on June 13 2024, online. Actions expected from the SG members ahead of the 5th SG meeting are: i) Completion and signature of the Conflict of interest forms; ii) Inputs on the Lusaka Agenda; iii) Inputs to Annual Report 23-24; iv) Inputs to ARIA; v) Forum Representatives to attend Committees and report to SG

Annex I: EDCTP Forum : themes suggestion
Which theme would you suggest for the next EDCTP Forum 2025 in Kigali?

Q&A word cloud

slido

Overarching themes & ranking	Forum potential themes	Votes
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Ranking	Forum potential themes	Votes
6	Turning the tide: renewing battle against resurgence of infectious diseases through the EDCTP collaborations	6
7	How can EDCTP3 be linked to the manufacturing agenda in Africa Linking the clinical trials outputs to the manufacturing agenda in Africa	4
8	Connecting innovation and impact to improve health	1
9	Challenging times	1
10	NTD, Preparedness, Lessons learned	1
11	Digitalisation	1
12	Regulatory capacity	1
13	Role of research in health security	1
14	Managing climate and change impact	1
15	Promoting translation of research results into policy and practice	1
16	Ensuring equity in gender and geographic representation	1

Annex II: Inputs to the Annual Research and Innovation Agenda: identification of research and capacity gaps, and ongoing initiatives and like-minded partners of interest to Global Health EDCTP3.

1- What are the key research gaps to tackle in 2025 for the EDCTP target diseases?

HIV

Implementation of PrEP for HIV prevention
HIV vaccines both therapeutics and preventive - combined strategies
Long-acting PrEP implementation
advanced HIV disease implementation barriers

TB

cost-effective and affordable screening tools for subclinical TB
pan-tb regimens
drivers of vaccine uptake beyond infancy
innovative vaccine trial designs
better tools for targeting TB preventive therapy
understanding the causal association between malnutrition and TB
Implementation aspects of TB preventive therapy beyond PLWH and young children
personalised medicine
TB diagnostics
Vaccines for TB
new vaccines for prevention of TB in adults/adolescents

Malaria

focus on complimentary tools for maximum impact (Vaccines, treatments, prophylaxis, vector control)
R&D for malaria therapeutics in the light of emerging resistance
resistance to current treatments
Acceptance of Malaria vaccine

Diarrheal Diseases

rural access to interventions.

Climate & Health

tease out the different effects of CC on specific disease types (i.e. in addition to vector-borne: water-borne, food shocks etc)
Health systems preparedness for climate resilience
Prospective modelling of climate change on vector patterns and zoonosis.
Impact of climate change on AMR
Impact of climate change on health outcomes
Impact of Climate change on Chronic disease and NCDs including economic analyses

climate change impact in Africa- shifting of risk areas

Design and evaluation of models for climate resilience and environmentally sustainable health systems strengthening.

Digital Health

Can AI take the place of doctors via mobile phone interactions?

technologies for surveillance

using AI for smarter immunogen design and prioritisation of candidates for late stage trials.

AMR

Impact of Climate Change on AMR

burden & surveillance

DoxyPEP or other STI interventions for women

diagnostic tools

AMR Vaccines

Gender and Equity in AMR

understanding the burden of AMR through the lens of other major African health issues- HIV, TB, inadequate access to antibiotics/ vaccines

NCD-Co-infections

overlap with AMR

(re)-emerging diseases

Coordination of efforts across regional priorities for different viral/bacterial families.

Ethics/Regulatory/PV

Rapid approval modalities for emergency products - e.g immuno-bridging and immune markers

NTDs

See WHO Paediatric drug optimization (PADO) prioritisation

Non-Disease specific

Health Security

Health rights and equity

Determinants of health

Non-prescriptive call to identify more relevant issues within a given setting

Innovative clinical trial design

Drug discovery and innovation

Monitoring/ evaluation of community and stakeholder engagement in trials/research agendas

Increase uptake of medical countermeasures with community-based implementation strategies

Impact modelling

Big data management, open/broad access data management systems to support surveillance and other

EID sequencing

Community engagement

Capacity

personalised medicine in relation to genetic variation and the efficacy of products

2– What are the key capacity gaps to be tackle in the scope of EDCTP?

HIV

Clinical trials units

TB

TB vaccine trial sites

TB research should expand to Mycobacterial including Leprosy

Malaria

Elimination strategy

malaria drug resistance

Climate & Health

Leadership capacity for research programming across diseases and cross cutting areas PLUS Climate Change

Digital Health

Develop collaborative forums

strengthen and empower AVAREF for better follow up and responses, digitise the systems

Equity in CTs capacity; data and digital ownership (most clinical trial data still sits or is owned by organisations in the global north); funders need to align their funding with what Africa or global south needs rather than with their interests

AMR

Behavioural research

strengthen and empower AVAREF for better follow up and responses, digitise the systems

malaria drug resistance

lab capacity to assess isoates and support research

workforce capacity (eg microbiology for R&D)

Surveillance and databasing of AMR

Ethics/Regulatory/PV

Twinning in MA dossier review between Northern / southern Reg Agencies

Technical and financial support towards electronic submission platform (harmonization by AMA?)

Encourage adding Regulatory aspects within proposals

Infrastructure :competence of regulators and ethics

strengthen and empower AVAREF for better follow up and responses, digitise the systems

Non-Disease specific

R&D workforce

coordination and integration of different streams of work in Africa

Capacity for sound financial management of research grants

Leadership capacity for research programming across diseases and cross cutting areas PLUS Climate Change

Formalization/ professionalization of community and stakeholder engagement in trials

Postdoc fellowships, a cadre of early/mid-career researchers and follow-on career grants

Synergies among initiatives for capacity strengthening

Clinical trial capacity for Phase I/II for Africa
Site readiness for vaccine testing in Africa
Regional networks strengthening
strengthen health systems, collaboration with governments and ministries for health to ensure research agenda and infrastructure
Community (marginalized/disadvantaged) engagement and empowerment
Research governance and management
ensure a focus and apportunity for gender equity in reaserch
capacity for (high-level) stattistical analysis including bioinformatics
Regulatory systems strengthening
Establishment of clinical trial units in low income countries
capacity for social science research
capacity in health economics
IPC
Health threats preparedness
Access to clinical trial material production in Africa.
Supporting clinical sites to be more networkable in different configurations (to be less tied to specific trial/diseases) - information sharing networks, core capabilities, etc
Behaviour and sexual behaviour studies
Capacity for research project management
Access to validated platforms to accelerate research
Personalised medicine in clinical trials can be linked to capacity building (genomics)

3– What are the important like-minded initiatives investing in the same scope as EDCTP3?

Evolving Africa CDC and clinical trials workstreams and priority disease list (published in 2022)
African clinical trials ecosystem initiative
CARB-X
CEPI
CIFF
country MOH
EU MAV+ programme link to manufacturing and regulatory.","Non-Disease specific"
Evolving ACDC R&D and clinical trials Bold programmes
Fleming Fund
Fleming Fund
GHIT Fund
ICARS
Leprosy Research Initiative
Like minded Donors: BMGF for Malaria, AMR, Epidemic preparedness   HIV/TB : PEPFAR   Climate change: Wellcome Trust and IDRC
Mundo Sano Foundation

NIH/DAIDS (RePORT)
PEPFAR
Private sector funding groups around tech and digital platforms
The Trinity Challenge
USAID (eg SMART4TB)

4– Which founders shall we collaborate with?

IDRC
BMGF/Gates MRI
CEPI
CIFF
Country MOH
Development banks
Development organisation
European Commission
GHIT Fund
HERA (and HERA CEPI joint calls)
Like minded Donors: BMGF for Malaria, AMR, Epidemic preparedness   HIV/TB : PEPFAR   Climate change: Wellcome Trust and IDRC
Private sector funding groups around tec and digital platforms
UK Government
US NIH
USAID
Wellcome Trust

Annex III: Complete list of adjacent sectors and actors to be involved

Suggested Adjacent sectors:

1- Education/Education IECs/ education vaccines uptake ;
2- Migration;
3- Digital technology and AI/ Digital initiatives/ Digital health
4- Climate change/ environment/ environmental agencies
5- Health financing
6- Community trust/ Misinformation and trust in R&D /transparency
7- Non-communicable Diseases (NCDs) / cancer
8- Nutrition – Tuberculosis
9- Indigenous knowledge practitioners/higher education
10- Mental Health
11- Disaster Response
12- Urbanisation

Suggested Actors:

1- Civil Society
2- Public health programs/ National government programmes per disease
3- Private sector/ Pharma/ SMEs /Foundations linked to private sector
4- Community health workers, representatives and leaders
5- Stakeholders from affected communities
6- Patient advocacy groups/ patient groups
7- Communities marginalised/Disadvantaged;
8- Regulatory agencies /regulators/ Ethics committees/ regulatory authorities
9- WHO
10- Military
11- National Public health institutes; Professional societies
12- Governments/ Ministry of research and education/ Ministry of health
13- Clinicians /medical/ Healthcare workers
14- Pharmacists and their associations / Pharmacies
15- Country disease programs/ Public health programs /Health systems
16- Patients and family
17- Non-Governmental Organisations (INGOs)
18- Disease networks
19- GLOPID-R Africa Office
20- EDCTP Africa Office
21- Beneficiaries
22- Insurance companies/organizations
23- Academia
24- EID & UNEP
25- Health care workers
26- Africa Regional Center (IEC)