Global Health
EDCTP3

Global Health EDCTP3 Joint Undertaking

Summary Report of the 8th meeting of the Scientific Committee

13 June 2025

Kigali, Rwanda

WEBSITE
https://globalhealth-edctp3.eu

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Introduction

The purpose of the eight meeting of the Scientific Committee of the Global Health EDCTP3 Joint Undertaking was:

1. To appreciate the contributions of the outgoing Members of the Scientific Committee, bid them farewell and welcome the new Members.
2. To update the Scientific Committee on the progress of the Programme's Portfolio analysis.
3. Obtain strategic and scientific advice on the first version of the draft Work Programme 2026 (WP26) and the future.
4. To seek advice on the Global Health EDCTP3 JU's contribution to the implementation of the WHO global action plan for Clinical Trials Ecosystem strengthening.
5. To seek advice on any other themes the Scientific Committee would like to address, considering its mandate and tasks as defined in the Council Regulation establishing the Joint Undertakings under Horizon Europe.
6. To elect a new Scientific Committee Chair.

The meeting was held on the 13 June 2025 in Kigali, Rwanda.

Agenda Flow

The agenda included the following sessions:

- Session 1: Welcome, Agenda Adoption, Seventh meeting report
- Session 2: New Scientific Committee membership
- Session 3: Drafting the Work Programme 2026
- Session 4: Discussion of the JU's contribution to WHO global action plan for Clinical Trials Ecosystem strengthening
- Session 5: SC next steps and Other Updates

More detailed information can be found in Annex 1.

Summary - updates, discussion, outcomes, follow-up and agreed actions

SESSION 1 - Welcome, Agenda Adoption, Seventh meeting report

The Chairperson of the Scientific Committee (SC) welcomed all SC Members, the Executive Director and the Programme Office (PRO) staff members. A tour de table took place where attendees introduced themselves.

The Executive Director gave his opening remarks, outlining the key outcomes for this meeting, as well as summarizing the investment of EDCTP programmes to date.

With no further comments from the members, the Chairperson confirmed adoption of the agenda.

The seventh meeting report was adopted by the Scientific Committee members.

SESSION 2 – New Scientific Committee membership

The SC was updated on the closure of the SC membership and selection procedure. Five new members of the SC have joined the group with immediate appointment, and the next six will join from the 1st of July. Six Members of the current SC are remaining for another six months. The new Members were welcomed.

The Legal Officer provided a reminder of the Rules of Procedure (RoPs) of the SC. An amendment to the RoPs was proposed to Article 10(5) about the incompatibility between SC membership and participation in any ongoing or future EDCTP3 project/ proposal. The amendment suggests rephrasing the article to the following: "*Members of the Scientific Committee must refrain from participating in the preparation of any proposals for calls launched by the Global Health EDCTP3 JU, or from taking part in the activities to be co-funded by the Joint Undertaking if they were involved in discussions about the relevant topic or had access to confidential information about it*.". The amendment was adopted by the SC. The final text will be signed by the Chair and shared with all members.

SESSION 3 – Drafting the Work Programme 2026

The Chairperson gave the floor to the Head of Unit of the Scientific Operations team (HoU) who gave an update on the Portfolio of EDCTP3 including a summary of proposed topics for WP2026.

The Chair gave the floor to the Senior Scientific Officer (SSO) and the Programme Officer (PO) to open the discussion of the six proposed topics of Work Programme 2026. The SSO and PO introduced the expected outcomes and scope of each topic, and the Chair moderated the discussion of each topic between the SC Members. The summary of the discussions of each topic is as per below.

The following comments applicable to most of the calls were raised

- Advice to focus topics' scope (as opposed to broad topic) to enable higher impact
- Consider specifying gender and age-related differences around disease burden and treatment response
- Host -strengthening interventions across topics where relevant

Topic 1: Development of TB drugs for therapy, chemoprevention or chemoprophylaxis in adults and children in sub-Saharan Africa

Discussion points:

- Consider inclusion of long-acting injectable therapeutics in the call description.
- Focusing the call further.

Comorbidities:

- Wording could allow for the inclusion of additional important comorbidities, for example diabetes as a recognised comorbidity of high importance to TB. Currently it reads as though no other comorbidities/vulnerabilities will be considered beyond those specifically mentioned.

Population subgroups:

- Explicitly reference children in the scope.

- Emphasise reaching underserved populations in the implementation of existing and relatively new interventions.

Trial phase and distribution of funding:

- Late-phase (Phase 2b/3) clinical trials are expensive and should go with co-funding (Global Collaborative actions).
- Limit funding of early-phase clinical trials and focus on funded programmes for late stage requiring less time to implementation and impact. Applicants should be informed that there will be less focus on early-stage clinical trial proposals and that the majority of funding will focus on later stage proposals: this is to be clarified accordingly in the topic text.
- Highlight the need for partnerships, including with pharma, to support implementation and scale-up.

Operational Considerations:

- It is possible for applicants to have good achievements with available funding with careful planning, for example reduced sample size and number of trial sites to improve feasibility and cost-effectiveness.

Cross-Cutting Themes

- Avoid diluting focus with broad cross-cutting topics; retain a sharp focus on how to best use available tools.
- Digital and Diagnostic Integration: Support integration of improved diagnostics (e.g. X-ray, sputum testing) and digital solutions into TB management. Furthermore, consider whether AI in TB trials should be part of this call or reserved for the dedicated digital health call.
- For proposals on developing treatment of latent TB, focus should be on individuals with increased risk of progressing the disease - in particular the risks most sensitive to climate change.
- Consider prioritising interventions already reflected in updated TB guidelines, especially for latent TB and prophylaxis: Focus on available new guidelines for latent TB and prophylaxis and how best to use these, rather than incorporating too many cross-cutting topics

Topic 2: Prevention and management of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa

Scope of Pathogens and Interventions

- The Committee welcomed the call topic and agreed on the need for flexibility in the pathogen list. To avoid narrowing innovation potential, the recommendation is to rephrase to "pathogens such as..." rather than using a fixed list of pathogens.
- Explicit exclusion of M. *tuberculosis*, CMV, fungi, and human coronaviruses is appropriate, and development of new diagnostics should remain (as stated in: out of scope – "Mycobacterium tuberculosis/Tuberculosis, Cytomegalovirus (CMV), Human coronaviruses and fungi, as well as development of diagnostics").

- There was a clear preference to emphasise on viral respiratory infections, especially RSV, given the current medical need and interventions available in EU and US.

- RSV including monoclonal antibodies (mAbs) was identified as high priority. Products with demonstrated efficacy and safety in other regions (e.g. Europe/US) should become available to SSA requiring bridging studies generating relevant clinical data for SSA as well as cost-effectiveness and accessibility studies in SSA, ideally involving children under 5 years.

- There should be more focus on implementation research.

Diagnostics and Treatment Strategies

- The Committee expressed some reservations about the current phrasing on point-of-care (POC) diagnostics and recommended a more nuanced inclusion. Available POC diagnostics/tools should be integrated into a comprehensive diagnostic and management algorithm for LRTIs.

- Key considerations include interpretation and clinical management pathways, the diagnostic utility and challenges of POC tools (e.g. co-infections with bacterial and viral agents), and the role of host-response-based diagnostics as adjuncts to diagnostic POC tools in guiding clinical management and antibiotic stewardship.

- The point on oxygen therapy and ventilation support was suggested for removal but could remain in the text if the topic is not addressed by recent EDCTP-funded projects.

Access, Equity, and Settings

- The importance of including informal urban settlements and remote or rural areas was strongly emphasised to reflect real-world equity challenges.

- Access and delivery of interventions should address structural and systemic barriers, particularly for marginalised populations.

- A preference was expressed for evaluating existing products rather than focusing on early-phase development, unless justified by significant innovation or contextual need.

Cross-cutting Themes

- Themes such as antimicrobial resistance, climate and health, digital solutions, and comorbidities are essential, but should be framed as optional cross-cutting elements rather than mandatory requirements.

- The value of WASH promotion, stewardship training, and engagement with local SSA leadership was recognised, but should remain flexible and context specific. Link to AMR reduction.

Call Structure and Strategic Considerations

- As the scope is broad, there was interest in splitting the topic into two complementary calls: for example, a call addressing barriers to access, implementation research, and health system integration and a call focused on treatment and prevention, including late-stage clinical trials and evaluation. Overall, suggestion to significantly narrow down the scope.

- Proposals should be encouraged to include real-world effectiveness and cost-effectiveness studies, especially for existing interventions such as RSV prevention products.

Call text

- The SC commented on the need to have background and scope section more aligned.

- Expected outcomes were considered appropriate. Any mandatory outcomes should remain general (e.g. evidence of clinical utility or public health impact).

- The proposed lists of pathogens and interventions are appropriate, provided they are framed as indicative rather than exhaustive.

Topic 3: Training networks for sustained capacity building related to ethics, regulatory and pharmacovigilance

Discussion points:

- Connection with the Ethics Networks was seen as important and should go beyond the Regional blocks.
- A reflection was made on EDCTP already having funded the four EDCTP Regional Networks of Excellence, therefore it should be clear that this call is referring to Networks and not just to the specific EDCTP Regional Networks of Excellence.
- The SC Members reflected that in SSA there are only seven regulatory bodies approved by WHO, and therefore there is a need to further strengthen capacity in this area. It was suggested to focus on the remaining regulatory authorities to make it to the WHO list, and to encourage applications from countries to accelerate their NRA to maturity level 3 or encouraging those that have already reached this level to be part of the consortium, to act in a mentoring role.
- The call might help to create Pharmacovigilance Networks that could bring experienced partners with less-experienced partners.
- Leveraging cross-country alignment and collaborating with other countries especially in the area of Pharmacovigilance (PhV) will be important.
- Cross cutting topic considered relevant is digital solution: It is becoming increasingly necessary for RECs to be able to review protocols on big data and AI. It will be important to develop Data Access Committees and other specialised committees. National Regulatory Agencies in SSA also will be involved in assessments and approvals of AI devices and algorithms as do major agencies such as the FDA and EMA.

- Uppsala Monitoring Centre could provide the data to see where there are the most opportunities for EDCTP3 to allocate funding – action to get in touch with this centre.
- To remove the phrasing of "leveraging NoE".

Topic 4: Towards a better prevention, treatment and clinical management of HIV and its co-infections and co-morbidities in sub-Saharan Africa

Discussion points:

- The call should consider including the following scope:
    - Co-morbidities, especially in the elderly HIV population. The number of HOIV patients surviving to older ages is increasing, therefore NCDs such as Obesity, Hypertension and Diabetes are important to consider.
    - Advanced HIV is to be included. Opportunistic infections remain problematic in both elderly and young patients with advanced HIV resulting in hospitalizations. These pathogens include cryptococcus and TB. Applications serving this population should be welcomed.
    - New long-acting injectable drugs – these have had a major impact on HIV management and should be introduced in LMICs acknowledging the high costs.
- Healthcare systems should be included in the scope. There is a large impact of healthcare systems structures on outcomes of co-morbidities. Examining issues such as the impact of polypharmacy, health systems access and quality of co-morbidity management could potentially be an "easy win ".
- Pediatric age groups have high mortality; therefore the prevention of HIV transmission is an import area to include in the scope. Early diagnostics is critically important. Funds cuts from the USA have had significant negative impact on this area and ECDTP3 could help fill some of the gap.
- The rationale for broadening the call beyond HIV was questioned as interventions should be targeted to those in need and those who lost US funds. The Executive Director clarified that this was potentially a call which could receive co-funding. The call text is to be co-shaped with the co-funder reflecting their interest in specific NCDs to increase the budget availability for calls without negatively impacting the initial scope.
- It would be important to harmonize cross-cutting issues such as research networking age and gender for HIV related topics.
- Furthermore, the call scope could include proposals that explore host strengthening interactions as with other areas such as TB.

Topic 5: Climate and Health in SSA

An expert group is being called by the EDCTP3 Programme Office, likely in July, to further discuss this topic, and to collaborate with contributing partners.

Discussion points:

- Most importantly, the SC suggested to focus the call on vector-borne, water-borne and food-borne diseases, and to remove the suggested focus on AMR.
- It was also advised to ensure focus on vulnerable populations such as children, pregnant women, elderly people, people with co-morbidities, and displaced populations including those living in informal settlements in urban or peri-urban areas.
- The topic call should focus on diseases which would be fueled by climate change and pandemic potential diseases. Interventions which decrease the impact of these diseases or reduce the impact of human activities (like manufacturing of drugs etc), should be prioritized.
- The WHO has published their priorities in climate and health, as well as the Canadian Institute has conducted a survey on climate health and have recommendations. This data can be leveraged for the drafting of this call.
- Partners to engage with were mentioned, including (but not limited to) the Adaptation Fund, the Green Climate Fund and UNITAID.
- At country level, it was discussed that MoH and researchers should be encouraged to work more closely together.
- Best practices to reduce carbon admissions can be added by applicants, but this should not be a focus of the call.
- Including the One Health aspect, such as animal health, will be important, for example, for emergencies: finding collaborations in package interventions.
- For call on interventions to address climate provoked changes, focus is to be kept on main objective. The call can encourage the applicants to include best practices on the negative impact of healthcare: such as waste disposal, clinical trials, big data (in terms of water and electricity consumption) on the environment.

Topic 6: Enhancing Integrated Research and Healthcare in Sub-Saharan Africa Through Digital Innovation and Artificial Intelligence in SSA

Discussion points:

- Need for better alignment between the background and scope: the background refers to both developing new tools and better use of available tools: "The goal is not to create new technologies, but to make better use of what already exists ….." and the scope text states "enhance the development and use of existing and new digital health tools", and cleared

from potential left-overs of earlier draft versions. In addition, it was mentioned that the scope refers to more physical products as opposed to digital tools.

- It was suggested that the call is to be disease agnostic (plug-and-play platform) as far as possible and should not focus on any particular disease.

- Each tool is as good as the data that is available. The call should emphasise the importance of generating good quality data.

- The topic should also emphasise the scaling up of innovations including the expansion of Electronic medical records. It is important to ensure that interventions do not remain as pilots to build a thriving innovation landscape and foster sustainability. Small and medium-sized enterprises (SME) could support scaling up. Collaboration between the research industry and society is crucial to ensure sustainability.

- The call should explicitly refer to work with SME and industry to ensure scape up bringing a sustainable solution and encourage further networking with consortia, ministries of health and ministries of ICT essential for scaling up as relevant.

- Society engagement with a look on sustainability is recommended.

- It was recommended to engage with AIFOD to forge a collaboration given their level of advancement in AI. Working with Africa CDC, countries need to be supported to put in place a supportive legal framework to anchor digital innovations and AI.

- DHIS2 is a widely adopted digital platform in the majority of health systems especially in LMIC. The DHIS2 team in Oslo are a potential resource in supporting integration of digital innovations in health systems.

- It is encouraged to explore how digital tools can facilitate clinical trials and establishing an efficient research system, as well as enable countries to pass relevant legislations.
- Direct application of digital tools on how clinical trials are approved should be encouraged (UK gold standard digital tool).

Other actions not subject to call for proposals

SC Members were informed about the two following proposed actions which are not subject to call for proposals:

- Mobilisation of research funds in case of Public Health Emergencies
- HORIZON-JU-GH-EDCTP3-2026: Expansion and consolidation of the EDCTP Knowledge Hub

Following a discussion on the need to expand and consolidate the EDCTP Knowledge Hub, SC members endorsed the proposal to include this in the 2026 work programme.

SESSION 4 - Discussion of the JU's contribution to WHO global action plan for Clinical Trials Ecosystem strengthening

The chair opened session 4 and gave the floor to the SSO and Dr Vaseeharan Sathiyamoorthy,

the WHO Observer. The WHO Observer introduced the WHO global action plan for Clinical Trials. The aim is to enable efficient clinical trial systems.

The EDCTP Knowledge Hub is aiming at tackling 5/9 of the WHO global action plan for Clinical Trials' actions.

The SC Members endorsed (see above) the WHO global action plan for Clinical Trials Ecosystem strengthening and EDCTP3's contribution to its work, mainly via the Knowledge Hub grant.

SESSION 5 – SC next steps and Other Updates

The new Chair was elected via a secret ballot as per the Rules of Procedure with a two-third majority. The election involved participation of 16 (out 18) members and Prof Harleen Grewal is the Chair Elect. The current Chair was thanked for his Chairmanship, and all present SC members supported the proposal to have the current chair as a co-chair for the coming 6 months, to support the Chair Elect.

The SSO outlined the preliminary planning for the next SC meeting in-person in October (online). At this meeting, the remainder of the new SC Members will be welcomed.

A reminder was given for the role of the SC Members in the EDCTP Forum in Kigali.

For each of the leaving SC Members, a gift ceremony was held, where the Executive Director extended his thanks for their services as part of the SC.

The Chair closed the meeting.

Global Health EDCTP3

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Annex 1: Adopted agenda

Global Health EDCTP3 Joint Undertaking: Agenda of the 8th Meeting of the Scientific Committee

13 JUNE 2025

10:00 – 17:05 (CAT)

Hybrid – Kigali Convention Centre, Rwanda

Purpose of the meeting
1) To appreciate **the contributions of the outgoing Members of the Scientific Committee, bid them farewell and welcome the new Members.** 2) To update the Scientific Committee on the **progress of the Programme's Portfolio analysis.** 3) Obtain **strategic and scientific advice on the first version of the draft Work Programme 2026 (WP26) and the future.** 4) To seek advice on **the Global Health EDCTP3 JU's contribution to the implementation of the WHO global action plan for Clinical Trials Ecosystem strengthening.** 5) **To seek advice** on **any other themes the Scientific Committee would like to address**, considering its mandate and tasks as defined in the Council Regulation establishing the Joint Undertakings under Horizon Europe[1] . 6) To elect a **new Scientific Committee Chair and Vice-Chair.**
Expected Outcomes
- Consolidation of the 2026 Work Programme and priorities for 2027. - Alignment of our Work Programme's implementation with the WHO global action plan for Clinical Trials Ecosystem strengthening. - Having the new composition of the Scientific Committee including new Chair and Vice-Chair.
Timing & location of the meeting
The meeting is scheduled to be held in person at the **Kigali Convention Centre – Room AD4** from 10.00 to 17:05 (CAT) on Friday 13 June 2025 (yet accessible via the Teams link below). **Link to meeting** Meeting ID: 346 201 529 041 Passcode: ij25Ep3r

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2085&qid=1647607319587&from=en

Agenda

Time	Item	Doc	Chair or Speakers
10.00-10.20	SESSION 1 - Welcome, Agenda Adoption, Seventh meeting report		
	1.1 Opening remarks		M. Makanga
	1.2 Draft agenda & expected outcomes – *for adoption*		J. Gyapong, All
	1.3. Seventh Meeting report – *for adoption*	1	J. Gyapong, All
10.20-10.50	SESSION 2 – New Scientific Committee membership		
	2.1. Update and closure of the Selection Procedure		M. Makanga JMV. Habarugira
	2.2. Welcoming new members		J. Gyapong, All
	2.3 Reminder on rules and procedures (RoP) of the SC, and proposed amendment to the RoP	2	L. Schell
	2.4. Questions and discussion		All
10.50-11.05	Coffee Break		
10.50-16.20	SESSION 3 – Drafting the Work Programme 2026		
11.05-11.25	3.1. Portfolio update, including Evaluations Stage 1 topics of WP2025 and summary of proposed topics for WP26	3	L. De Cock JMV. Habarugira
11.25-12.55	3.2. Discussion and feedback per potential topic **(part 1)** *Each topic to be briefly introduced by the Programme Office, before a consensus discussion which is **moderated by the SC Chair***		
	3.2.1 Development of TB drugs for therapy, chemoprevention or chemoprophylaxis in adults and children in sub-Saharan Africa		
	3.2.2 Prevention and management of Lower Respiratory Tract Infections (LRTIs) in sub-Saharan Africa		

	3.2.3 Training networks for sustained capacity building related to ethics, regulatory and pharmacovigilance		
12.55-14.00	Lunch Break		
14.00-15.30	2. Discussion and feedback per potential topic **(part 2)** *Each topic to be briefly introduced by the Programme Office, before a consensus discussion which is **moderated by the SC Chair***		
	3.2.4 Towards a better prevention, treatment and clinical management of HIV and its co-infections and co-morbidities in sub-Saharan Africa		
	3.2.5 Climate and Health in SSA		
	3.2.6 Enhancing Integrated Research and Healthcare in Sub-Saharan Africa Through Digital Innovation and Artificial Intelligence in SSA		
15:30 – 16:00	SESSION 4 - Discussion of the JU's contribution to WHO global action plan for Clinical Trials Ecosystem strengthening		
	4.1. Feedback on the JU's contribution to WHO global action plan for Clinical Trials Ecosystem strengthening	5, 6, 7, 8	JMV Habarugira V. Sathiyamoorthy All
16.00-16.15	Coffee Break		
16:15 – 17.05	SESSION 5 – SC next steps and Other Updates		
	5.1. Election of a new Chair and vice-chair		M. Makanga JMV. Habarugira
	5.2. Planning the next SC meeting		JMV. Habarugira
	5.3. Any outstanding business regarding the upcoming Forum and other AOB		SC Chair JMV. Habarugira
	5.4. Goodbye ceremony for SC Members that are departing		All
Meeting Closure			
19:00	Joint Dinner Scientific Committee and Stakeholders Group Members Location: Filini Italian Restaurant		

ANNEXES

Documents (for reference or review) shared via TEAMS or linked to this Agenda:
Scientific Committee - Global Health EDCTP3 - 8th meeting of the SC – 13 June 2025 All Documents

1 7th SC meeting report
2 Draft RoP amendment (to follow)
3 The draft 2026 Work Programme
4 Slide deck for the 8th SC Meeting
5 WHO Guidance on Clinical Trials: Guidance for best practices for clinical trials
6 WHO action plan for Clinical Trials Ecosystem strengthening: Global action plan for clinical trial ecosystem strengthening
7 Set of Papers published in a Clinical Trials in Global Health series in The Lancet in April 2025:
   - 7.1 Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice
   - 7.2 Strengthening the paediatric clinical trial ecosystem to better inform policy and programmes
   - 7.3 Advancing maternal and perinatal health through clinical trials: key insights from a WHO global consultation
   - 7.4 Democratising clinical trials research to strengthen primary health care
   - 7.5 Reporting summary results in clinical trial registries: updated guidance from WHO
   - 7.6 A roadmap for fostering timely regulatory and ethics approvals of international clinical trials in support of global health research systems

8 Examples on advocacy papers:
   - EGHRIN position paper
   - PDP position paper
   - DSW brochure
   - Scientific Advisory Committee members comment in The Lancet Infectious Diseases.

1. List of Participants

1.1. Scientific Committee (SC)

1) Prof. John Gyapong, **Chair**
2) Prof. Electra Gizeli (joining at noon)
3) Prof. Halidou Tinto
4) Prof. Nicki Tiffin
5) Prof. Christine Stabell Benn
6) Prof. Martin Meremikwu
7) Dr Claudia Filippone
8) Dr Juliet Nabyonga-Orem
9) Prof. Pablo Rojo
10) Dr Jutta Reinhard-Rupp
11) Dr Anthony Man
12) Dr Thomas Egwang
13) Prof. Harleen Grewal
14) Prof. Keymanthri Moodley (online)
15) Prof. Paulo Ferrinho (online)
16) Dr Enrica Alteri (online)
17) Dr Xavier Anglaret (apology)
18) Prof. Meta Roestenberg (apology)

1.2. Global Health EDCTP3 Programme Office

19) Dr Michael Makanga, Executive Director

20) Ms Liesbet De Cock, Head of Unit Scientific Operations
21) Dr Jean Marie Vianney Habarugira, Senior Scientific Officer
22) Ms Aleksandra Conversano, Programme Officer
23) Mr Laurent Schell, Legal Officer
24) Ms Claudia Gutierrez-Arbizu, Events and Administrative Assistant
25) Ms Antonia Forte, Governance Officer (online)

1.3. Observers

26) Dr Vaseeharan SATHIYAMOORTHY, Word Health Organisation (online)
27) Dr Jan Paehler, European Commission, DG RTD