

Meeting report of the Third Meeting of the Global Health EDCTP3 Joint Undertaking Scientific Committee

May 30th & 31st 2023 White Atrium – Avenue de la Toison 56–60 – 1060 Brussels

Global Health EDCTP3 Joint Undertaking WEBSITE

ı https://globalhealth-edctp3.eu VISITING ADDRESS

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1. Introduction

The purpose of the Third Scientific Committee meeting was **1**) to advise on the scientific priorities to be addressed for the work programme 2024 (WP2024) of the Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU) and the scope of calls for proposals, and 2) to discuss and advise 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.

This was the third meeting of the GH EDCTP3 Scientific Committee (SC) with a majority (Thirteen) of the members attending in person and other members joining online.

A *tour-de-table* was held. Two SC members having resigned in 2022, the GH EDCTP3 informed the SC that 2 members have been appointed. One of the 2 new members joined the meeting. The SC meeting was chaired by Professor Gyapong.

All SC members including the new appointed members have signed a conflict-of-interest declaration when joining the Global Health EDCTP3 Scientific Committee.

2. Agenda Items

The 2-day hybrid meeting agenda included the following sessions:

- 1) Welcome, Agenda Adoption
- 2) Follow up Actions from the August 2022 Meeting
- 3) Updates 2022 and 2023 Work Programmes (WPs)
- 4) Update and Discussion on Strategic Content Developments
- 5) Research areas still to be addressed
- 6) Recap Day
- 7) 2022 SC Annual Report
- 8) The EDCTP bi-annual Forum
- 9) Working Groups
- 10) Planning for the next meeting

3. Summary - updates, discussions and agreed actions

Welcome and Agenda Adoption

After a brief welcome address by a representative of the GH EDCTP3 Secretariat (SEC), the Scientific Committee Chair (SC Chair) opened the meeting and gave the opportunity for a tour de table to get to know each other, as some SC members are meeting for the first time and the new SEC team is also growing with new members joining. The SC Chair proceeded with the agenda adoption. All members present in person and online adopted the proposed agenda without further changes.

Follow up Actions from the August 2022 Meeting

After a unanimous adoption of the agenda, the meeting proceeded with a follow up on Actions that emanated from the second SC meeting held in August 2022.



First, the SEC gave a presentation on the "Role and tasks as defined by Council Regulation 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe. After the presentation, the SC Chair opened the floor and gave time for questions and discussion. Most questions were on issues that are not yet fully clear, especially on the relation between different governing bodies. The SEC legal officer addressed the SC members questions and confirmed his availability for any further clarification during and after the meeting.

Second, the SEC presented the GH EDCTP3 SC Decision N° SC 01/2023, adopted in March 2023, amending Decision SC 01/2022 on the Rules of Procedure (RoP). It was clarified that following a written procedure launched by the SEC in December 2022, a majority of SC members approved the proposed amendment allowing additions of specific paragraphs to Article 3 of the SC's rules of procedure. The added paragraphs provide the SC with the possibility to appoint a permanent observer from the World Health Organisation for a maximum duration of three years. The SEC further presented the GH EDCTP3 SC Decision N° SC 02/2023, adopted in March 2023, establishing SC Working Groups.

Third, through the same above-mentioned written procedure, a majority of SC members approved the proposed decision to establish the following Working Groups (WGs): a WG on **Ethics and Data Sciences** and a WG on **Gender Equality and Community Engagement.** An extensive discussion was held on the scope of the two groups. The SC members proposed revising the names of the second group. Later in the groups discussion (see session on WG discussion) it was proposed to change the name from "Gender Equality and Community Engagement" to "**Equity and Diversity**".

Actions:

- SEC to prepare amendment of GH EDCTP3 SC Decision N° SC 02/2023 to capture the change of the WG name
- SC to adopt the amended version of GH EDCTP3 SC Decision N° SC 02/2023

Fourth, the SEC reminded the SC of the obligation to submit an annual report on its activities in 2022. An outline of the draft report was presented, and SC members were invited to comment and advise on activities to be added if any missed.

Actions:

- SEC to share the draft report for final edits
- SC members to make final edits
- SC chair to submit the report to the Governing Board

Fifth, the relations and interactions with the Stakeholders Group (SG) were discussed. SC members welcomed the SG Chair (Dr Neeraj Mistry) who was invited as an observer as a start of what will become regular communication and exchanges between the two groups. After a presentation of the role and composition of the SG, SC members agreed that such regular exchanges will be instrumental to a fruitful functioning of the two bodies. SC members were given the opportunity to ask questions on how SG members were recruited, how SEC insures transparency and management of conflicts of interests. SC members were provided with more information on the SC members recruitment procedure and understood the SG role in the Governance structure of the Joint Undertaking. It was agreed that meeting will be aligned to allow exchange of documents and two-way input.

Actions:



- SC and SG Chair to invite each other to meetings of their respective group/committee
- SEC to coordinate with SC and SG Chair to organise (if possible) a joint meeting to be at the 11th EDCTP Forum in Paris.

Updates 2022 and 2023 Work Programmes (WPs)

The SEC gave an update on 2022 WP, with informative data on Calls process and output. Starting with an outline of the GH EDCTP3 diseases scope, the SEC presented an overview of the 5 call topics launched as part of the 2022 WP:

- 1) Promoting implementation of research results into policy and practice (RIA, EUR 38 million)
- 2) Implementing adaptive platform trials (RIA, EUR 30 million)
- 3) Genomic epidemiology (RIA, EUR 22 million)
- 4) Creating a sustainable clinical trial network (CSA, EUR1 million)
- 5) Strengthening regulatory capacity for supporting conduct of clinical trials (CSA, EUR 5 million)

The two first RIA call topics have generated projects in the area of malaria, HIV, TB, Soil-transmitted helminths, Human African trypanosomiasis, Neurocysticercosis, onchocerciasis, loiasis, mansonellosis and trichuriasis, sepsis in infants and neonates, antimicrobial resistance and Lassa Fever. The projects from the first topic are largely implementation research on existing intervention, while the second topic on adaptive platforms includes research on novel and repurposed products. The third topic generated innovative projects that will enable expansion of genomic epidemiology across several sub-Saharan African Countries using existing surveillance of emerging infectious diseases, antimicrobial resistance, HIV and TB, co-funded with the Bill and Melinda Gates Foundation. The fourth topic has generated a project that will seek to map and re-coordinate existing clinical research networks across Africa.

The fifth topic has led to projects on ethics and regulatory affairs looking at sub-regional capacity strengthening rather than keeping a focus just within national boundaries.

Updating the SC on the call topics under the 2023 WP, the SEC highlighted the diseases areas to be potentially (eligible) covered by future projects:

- 1) Under the "*Global Health EDCTP3 Training Networks*" call topic, proposals can focus on any disease in the GH EDCTP3 scope
- 2) The call topic on "*Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic (RIA)*" will focus on 23 pre-identified clinical studies funded by EDCTP2 covering malaria, Onchocerciasis, leprosy, typhoid infection, TB/HIV and other areas in EDCTP2 scope.
- 3) The call on "*Implementation research/real life assessment of existing interventions in women and children's health (RIA)*" is restricted to HIV, malaria, tuberculosis, diarrhoeal diseases, bacterial infections (especially those where AMR is an issue), sepsis and lower respiratory tract infections.
- 4) The call on "*Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa (RIA*)" will logically focus on Ebola
- 5) The fifth topic is a repeat of the "Ethics and Regulatory *capacity*" call



- 6) The sixth call topic on "Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research (RIA)" will accept proposal on any disease in GH EDCTP3 scope
- 7) The seventh call topic on "Advancing point-of-care diagnostics to the market (RIA)" will accept all diseases in GH EDCTP3 scope, except Ebola.

Update and Discussion on Strategic Content Developments

SEC presented several ongoing discussions with potential contributing partners interested in Joining investment. As these are still in early phase of discussion, it was agreed that SC will be kept informed so that it can strategically and timely advise on the research priorities. SEC indicated that in some of the ongoing discussions, the SC chair was invited and if needed, this conversation will involve the Chair who will join and contribute on behalf of the SC. An important highlight was on the joint GH EDCTP3-BMGF genomic epidemiology consortia which are in the process of grant agreement finalisation. SC members reiterated the need to ensure that GH EDCTP3 continues to take the lead in defining areas of interest in which potential contributing partners can invest, rather than letting future partners drive the agenda.

Further, SEC briefly mentioned several relevant projects and initiatives supported by other EU agencies and directorates (e.g. DG Research and Innovation), and indicated that where possible GH EDCTP3 will be exploring joint strategic investment with similar organisations such as INTPA. Further information was shared in writing through a PowerPoint presentation.

Research areas still to be addressed and key priority areas for 2024 WP

Kicking off the discussion on areas still to be addressed in 2024 WP onwards, the SEC highlighted the following facts and guiding references:

- Total EU funding available for the calls for proposals in 2024 is approx. EUR 140 M. Final allocation will be decided by the Governing Board which will consider the recommendations of the Scientific Committee.
- The scientific priorities listed in the GH EDCTP3 SRIA are to be addressed over the lifetime of GH EDCTP3 JU and should be spread across years and topics in different annual WPs.
- The WP2024 should not address areas that were already addressed in WP2022 and 2023 unless the SC strongly recommends specific areas for reconsideration
- As WP2023 did not have topics addressing specifically Climate crisis-related infections and antimicrobial resistance, the SC should advise on the best ways address these areas in WP2024 or later once further experts' input has been received.
- In addition to the different priority disease areas, the Scientific Committee could consider transversal areas, in line with the specific objectives of the GH EDCTP3 SRIA such as research capacity development, including new types of Fellowships or other schemes like the Training Networks in 2023 WP.
- In the 2022 Work Programme, there was no dedicated call topics on HIV, TB, or Malaria. However, several proposals selected from the 2022 Calls include HIV, TB or Malaria in their scope, but it should be noted that most of them are in Implementation Research. In addition, projects covering these areas are expected from the from 2023 WP Call Topics (e.g. calls on vaccines, COVID-19-affected EDCTP2-funded projects, diagnostics, maternal and child health)



To focus the discussion on potential priority areas for WP 2024, research areas or topics were grouped as follows:

- 1) HIV, TB, Malaria
- 2) Climate crisis-related infections
- 3) Neglected Infectious Diseases (NIDs)
- 4) Antimicrobial Resistance One Health
- 5) Lower Respiratory Tract Infections (LRTIs)
- 6) Diarrheal diseases (DD)
- 7) Emerging Infectious Diseases (EIDs)
- 8) Fellowships (new types or Training networks)
- 9) Framing the 'Global Health' in the GH EDCTP3 Scope
- 10) Other areas

After extensive exchange on the above-listed categories, having in mind the activities supported by WP2022 and to be potentially supported under WP2023:

- SC members agreed that the SRIA should be updated to clarify the inclusion of co-infections that are inevitably part of diseases prevention and management in **HIV** patients. Sexually Transmitted Infections (STIs) were highlighted as an example of an area that should be clearly expressed in the scope of HIV call topics. As this may not be a key reason to amend the SRIA, it was advised that if the SRIA undergoes a revision, the wording in the HIV section of the SRIA should be carefully revisited to ensure a clear mention of the co-infections affecting HIV patients.
- On **Tuberculosis**, it was highlighted that GH EDCTP3 should not lose the momentum in the vaccine R&D, including the promising candidates supported by EDCTP2. Ongoing discussions with potential contributing partners should seek to advance the field further based on the EDCTP2 <u>Global TB Vaccines R&D Roadmap</u> which was commissioned by EDCTP2 (see <u>full Version of the Roadmap</u>).
- On **Malaria**, SC members made a recommendation to align GH EDCTP3 priorities with the Malaria elimination plan 2030, taking opportunities and investing in ongoing efforts to register new vaccines, and addressing challenges that limit impact of malaria vaccines, such as the lack of head-to-head comparison of registered malaria vaccines and/or combinations of novel vaccine candidates, or hyporesponsiveness of vaccines in highly endemic areas and young infants. In addition, an increased focus on measures to counter the growing resistance is needed.
- Under the "Climate crisis-related infections" category, SC members took note of the article shared ahead of the meeting and highlighted a few areas that may be of relevance to GH EDCTP3. SC members indicated that this a new area where in-house (with SC) expertise may be limited, and if necessary, a specialists meeting or consultation may be required at some stage to advise on research priority matters in this area. SC members commented that extreme weather conditions have an impact on vector-borne diseases and advised on exploring the possibility of a topic that focuses on vector control and future innovative mechanisms for surveillance of Rodent-borne diseases and tick-transmitted diseases. SC members advised on the need to investigate cross cutting issues between climate crisis and emerging infectious diseases.
- **Neglected Infectious Diseases (NIDs) –** SC members agreed that **NIDs** are a large group of diseases that require a focussed analysis of currently unmet needs. It was highlighted that the already signed or under preparation grant agreements have addressed few NIDs in Implementation Research, but more investment is required in areas where products under



development can be pushed towards registration. Given the large scope of diseases under the NID category, initiatives with the potential to accelerated product development and licensure should be encouraged.

- In the area of **Lower Respiratory Tract Infections (LRTIs)**, SC members noted the impact of LRTIs across all age groups and increasingly in the elderly but agreed that mortality is still a major issue among infants. Therefore, the focus of future calls should be children and infants but research ideas focussing on health in the elderly will not be excluded from the scope.
- While this category was not discussed at length, it was noted that **Diarrheal diseases (DDs**) are still a heavy burden, especially on the children and infants.
- In relation to **Emerging Infectious Diseases (EIDs**), a link was made with the Climate crisis-related infectious diseases, indicating a need to tailor call topics to cross cutting strategic investment in surveillance and preparedness in the context of One Health.
- On **Fellowships**, the SC emphasised that new types of Fellowships or repeated schemes like the 2023 Training networks, especially in discussion with potential contributing partners, should consider lessons learnt from EDCTP2-funded Fellowships and their impact over time in developing the clinical research capacity across sub-Saharan Africa. Seen as backbone of clinical research capacity building, Fellowships should stay as priority in GH EDCTP3, and SEC should continue exploring ways to tailor fellowships to the career need of potential fellows and retention options in home countries of skilled researchers. SC members advised SEC to explore the possibility of a continued investment in individual fellowships, and/or use the training networks to ensure availability of equal opportunity across all stages of career development in all parts of sub-Saharan Africa.

In the context of **framing the 'Global Health' in the GH EDCTP3 Scope,** SC members agreed that when the SRIA enters a revision round, those involved will have the opportunity to ensure there is clarification of what global health means in the context of social aspects that affect the control of infectious diseases.

- Other areas discussed included the Networks of Excellence in the context of a continuous support for clinical research capacity strengthening. SC members expressed their support for the concept of a long-term vision for the networks of Excellence but also highlighted concerns of the potential risks of funding again the same groups including those that perform less. The idea of opening space for new consortia, especially a new type of superregional network that can unite the regional silos. An important highlight was the recently signed CTCAN which is aiming to address the same issue of silos by pulling together all existing and relevant networks.
- Further, it was noted that **Implementation research** has been a major focus area for the 2022 and 2023 WP, enabling GH EDCTP3 to address a range of diseases areas including several NTDs. It has been agreed that implementation research should not be prioritized in 2024 as it has been relatively well covered by the 2022 and 2023 WPs. An important advice from the SC is to develop a set of **impact indicators** that the GH EDCTP3 will use to assess the impact of these important IR projects in the coming years. Although this will be an impact assessment targeting individual projects, it is important that such impact indicators include, where possible, overall health indicators such as all-cause mortality/hospitalisations.

Revision of the Strategic Research and Innovation Agenda - timing and rationale for revisions: Regarding the revision of the SRIA, SC members agreed to prepare a draft note on the rationale for proposing a revision. The note which will lead to a white paper will be drafted via a shared Teams



document which will be discussed and finalised in a brief online meeting that will take place outside the framework of meetings described in the SC members contracts.

2022 SC Annual Report

A draft of the annual report for the SC activities in 2022 was shared with the SC members prior to the meeting. The main components were the minutes of the 1st and 2nd SC meeting held in March and August 2022, respectively. The draft report was discussed, and SC members were asked to comment and suggest edits. One SC member indicated that the summary does not accurately capture comments sent in November 2022, in response to the request to review the draft minutes of the August 2023 SC meeting. The GH EDCTP3 SEC confirmed that all comments were considered and promised to have another look at the comment and assess the need to re-edit.

The SEC reminded the SC members of the obligation of publish SC meeting reports and annual reports on the GH EDCTP3 Website, and emphasised on the need to review the report, keeping in mind that it is a document which will go in the public domain.

The SEC and SC agreed to work on an expedited process to finalise the report with the aim of submitting it to the Board by end of June 2023.

As this is the first report, the draft was produced by the SEC, but it was agreed that going forward, the drafting of the SC annual report will be a task of the SC. The SC Chair will agree with SC members on the process of drafting and finalising the report. The SEC will ensure all necessary and available data are timely provided to the SC.

The EDCTP bi-annual Forum

This session was proposed to discuss and gather input for the 2023 EDCTP Forum, and to discuss ways forward in the implementation of the next fora as of 2025 onwards.

The SEC presented the latest draft agenda of the 11th EDCTP Forum, taking place in Paris in Nov 2023, and recalled the historical background of this bi-annual conference as major global health event that started in the early days of EDCTP1 in 2005.

The 11th Forum coincides with the 20th anniversary EDCTP and comes at a point in time when GH EDCTP3 is implementing its second annual work programme.

SC Members noted the importance of ensuring good continuity of this important conference and agreed with the need to add it as a key activity to be budgeted for in the 2024 WP.

SC members were reminded that the 2025 Forum hosting should be by a French speaking country in sub-Saharan Africa, in line with the alternance tradition vis-à-vis Africa and Europe, and in the context of Anglophone-Francophone-Lusophone Africa. The frequency of the Forum was discussed, and it was agreed that a Forum in Q1 of 2025 would be more suitable.

Actions:

- a) The SEC will coordinate with the SC Chair to determine the time for the SC meeting in Paris, and this will be communicated as soon as possible, to have time for travel arrangements.
- b) Members of the SC who would like to see their countries hosting the 2025 Forum can approach the representatives in the EDCTP Association and sensitise them on the procedure of candidature to host the conference.

Working groups



As part of the agreed actions from the August 2022 meeting, SC members had proposed establishing working groups (see above) to advise the GH EDCTP3 on matters related to ethics, data governance, gender and equity etc. The SEC had subsequently advised on establishing just 2 working groups to tackle the following themes: a group focussing on Ethics and Data Sciences and another focussing on Gender Equality and Community Engagement.

Memberships per working group are as follows:

Working Group on Ethics and Data Sciences: Nicki Tiffin, Keymanthri Moodley, Electra Gizeli, Selidji T. Agnandji, Xavier Anglaret, Joachim Doua, Juliet Nabyonga-Orem, Martin Meremiku, Claudia Filippone, John Gyapong

Working group on Gender Equality and Community Engagement (name change – see below): **Nicola Viebig, Marleen Temmerman, Ali Zumla, Christine Stabell Benn, Paulo Ferrinho and Halidou Tinto.**

In their first meeting, on 31 May 2023, members of the GDWG agreed on the following:

- The name of the WG must be formally changed through amendment of DECISION N° SC 02/2023 establishing working groups of the Scientific Committee. Specifically, Article 2 should be revised to rename the second WG as Working Group on "Equity and Diversity" in replacement of the initially adopted name "Gender Equality and Community Engagement"

N.B. SC Members who were not present on Day 2 will be informed of the WG memberships and redefined objectives so they can confirm which group they would like to join.

The Draft minutes of each WG meeting are attached to this report as Annexes.

Planning for the next SC meeting

The meeting was concluded by a planning for the next SC meeting with a focus on 1) items and timing for the Fourth SC meeting, 2) content and timelines for the annual report on the SC activities in 2023, and 3) any other issues that that the SC members would like to raise and bring to the attention of the SEC.

Following a discussion that led to a consensus on the need to revise the SRIA, SC members agreed that before the 4th meeting, an informal brief online meeting should take place to agree on the way to timely bring forward ideas that relevant to both the call topics and SRIA revisions. The SEC will keep the SC informed on ongoing discussion with partners and other stakeholders contributing to call topics and the finalisation of topics should be concluded after the SC has submitted its advice on the necessity to amend or keep the current SRIA version.

It was agreed that for the 4th meeting, all members will be given more time to shape the agenda. In coordination with the SEC, the Chair will issue a call for agenda items early enough to collect ideas from all members.

SC members requested the SEC to send meeting documentation well in advance to give enough time for a proper preparation for the meeting.

Other raised issues relate to comments sent in November, responding to the call for edits of the August 2023 SC meeting minutes. Some comments may have been missed.



Actions:

- SC Chair to convene a brief online meeting before the 4th SC meeting to review the progress of ongoing activities and better prepare for the Paris meeting. The online meeting will focus among on concrete ideas to justify the revisions of the SRIA. It should be noted that this in between meeting will not qualify as an Expert working day (as described in the contract)
- SEC to set up a Microsoft Teams (MT) channel to facilitate sharing, reviewing and editing of documents related to the SC work in the short and medium term.
- The GH EDCTP3 SEC to start drafting themes for the 2024 Work Programme and drafting outlines for call topics to share with the SC for input where necessary.
- SEC to re-verify if all comments have been captured in the final version of the second SC meeting minutes and in the draft 2022 SC activities report.



4. Annexes

Annex 1: List of Participants

- 1. Prof. John Gyapong, Chair
- 2. Prof. Marleen Temmerman, Vice-Chair
- 3. Prof. Electra Gizeli, SC Member
- 4. Dr Nicola Viebig, SC Member
- 5. Prof. Halidou Tinto, SC Member (online)
- 6. Prof. Nicki Tiffin, SC Member
- 7. Prof. Christine Stabell Benn, SC Member
- 8. Dr Selidji T. Agnandji, SC Member
- 9. Prof. Paulo Ferrinho, SC Member (online)
- 10. Prof. Keymanthri Moodley, SC Member
- 11. Dr Xavier Anglaret, SC Member
- 12. Dr Joachim Doua, SC Member (in person Day 1, online on Day 2)
- 13. Prof. Sir Ali Zumla, SC Member
- 14. Dr Juliet Nabyonga-Orem, SC Member (online)
- 15. Prof. Martin Meremiku, SC Member (online)
- 16. Prof. Meta Roestenberg, SC Member (in person Day 1)
- 17. Dr Claudia Filippone, SC Member
- 18. Dr Elmar Nimmesgern, GH EDCTP3 Interim Executive Director
- 19. Dr Jean Marie Vianney Habarugira, GH EDCTP3 Senior Scientific Officer
- 20. Dr Lydia Boudarene, GH EDCTP3 Senior Scientific Officer
- 21. Dr Laurent Schell, GH EDCTP3 Legal Officer
- 22. Mr Milan Popovic, GH EDCTP3 Scientific Project Officer
- 23. Ms Aleksandra Conversano, GH EDCTP3 Scientific Project Officer
- 24. Ms Julia Molto Lopez, GH EDCTP3 Communications Officer
- 25. Dr Steffi Sowinski, Policy Officer, DG RTD, European Commission
- 26. Dr Jan Paehler, Policy Officer, DG RTD, European Commission
- 27. Dr Neeraj Mistry, SG Chair (online Day 1)



Annex 2: Guidance notes and Reference Documents

1.1. Discussion on potential areas to be addressed by the 2024 Work Programme

- Total EU funding available for the calls for proposals in 2024 is approx. EUR 140 M. Final allocation will be decided by the Governing Board considering the recommendations of the Scientific Committee.
- Reference to the scientific priorities listed in the <u>GH EDCTP3 SRIA</u> to be addressed over the lifetime of GH EDCTP3 JU

Specific considerations:

- WP2024 should not address areas that were already addressed in WP2023¹ unless the SC strongly recommends specific areas for reconsideration.
- WP2023 did not have topics addressing specifically Climate crisis-related infections and antimicrobial resistance how can we best address this gap in WP2024 or later?
- In addition to the different priority disease areas, the Scientific Committee could **consider transversal areas**, in line with the specific objectives of the GH EDCTP3 SRIA such as research capacity development – New type of Fellowship or similar to the Training Networks in 2023 WP?
- In the 2022 and 2023 Work Programmes, no dedicated call topics on HIV, TB, or Malaria, but several proposals selected from the 2022 Calls include HIV, TB or Malaria in their scope, in addition, projects covering these areas are expected from the 2023 Calls (e.g. calls on vaccines, COVID-19-affected EDCTP2-funded projects, diagnostics, maternal and child health)
- **1.2.** List of background/reference documents:
- GH EDCTP3 WP 2023: <u>https://research-and-innovation.ec.europa.eu/research-area/health/edctp_en#work-programme-2023</u>
- <u>GH EDCTP3 WP 2022</u>, calls for proposals including in-kind contributions to additional activities (IKAA) plan from EDCTP Association Member States
- GH EDCTP3 Strategic Research and Innovation Agenda (SRIA)
- Council Regulation establishing the Joint Undertakings under Horizon Europe
- General guidance on documents on Horizon Europe funding: <u>Horizon Europe Guide_en.pdf</u> (europa.eu)
- <u>EU Funding & Tenders Online Manual_en.pdf (europa.eu)</u>
- <u>General-annexes_horizon-2021-2022_en.pdf (europa.eu)</u>

1.3. Meeting Slide deck
1.4. Booklet GH EDCTP3 projects portfolio from 2022 Call Topics and 2021 Bridging call topic
1.5. Scientific Committee Decision adopting the revised Rules of Procedure, Version Mar 2023
1.6. Scientific Committee Decision adopting the setting up of 2 working groups, Version Mar
2023
1.7. Draft report SC activities in 2022
1.8. COUNCIL RECOMMENDATION on stepping up EU actions to combat antimicrobial
resistance in a One Health approach
1.9. Nature 2022. Mora C. et al. Over half of known human pathogenic diseases can be
aggravated by climate change

¹Search Funding & Tenders (europa.eu)



Annex 3: Minutes of the Ethics and Data Sciences Working Group (WG) meeting

Composition of the Working Group:

Members:

- Nicki Tiffin (acting Chair for the purposes of this meeting)
- Keymanthri Moodley
- Electra Gizeli
- Selidji T. Agnandji
- Xavier Anglaret
- Claudia Filippone
- John Gyapong
- Joachim Doua
- Juliet Nabyonga-Orem
- Martin Meremiku

GH EDCTP3 JU Representative/Observer : Jean Marie Vianney Habarugira

The WG discussed several issues relating to the mandate of the WG:

- Data science was described as encompassing data governance and data use
- Ethics was described as meaning that EDCTP3 should practice research ethically, uphold equitable partnership practices and ensure good international practice for research.

The WG particularly noted that many guidelines already exist, and some guidelines and frameworks were specifically mentioned e.g. African Academy of Sciences Data and Biospecimen governance policy [1], GDPR and other data governance frameworks e.g. [2]

The WG also noted that different hierarchies exist to describe how data governance and ethics topics relate to each other, and that it would be prudent for the WG to decide on a descriptive hierarchy and work with that consistently.

The WG noted that a Chair should be elected for the WG.

Particular areas were identified as important, including:

• Data management

Noted that funded projects already do need to demonstrate that they can properly manage data, that they have data and research infrastructure that can support responsible data use. Data structures: ensuring the use of appropriate data standards and ontologies (e.g. OMOP), data harmonisation, interoperability standards where appropriate (e.g. FHIR in mobile health) Ensuring human resources are sufficient for data management: data managers, data engineering and management should be budgeted for, technicians, systems administration, etc

• Data governance

Existing requirement for details about how data are collected, stored and used, and for sufficient data infrastructure.

Adherence to relevant legislation - both of African countries and GDPR.

• Data sharing and access, ethics and informed consent



Requirement that data should be FAIR, and where possible they should be Open – also noting that not all data can be made Open Access without appropriate oversight.

• Research equity

Ensuring appropriate power balance between African and EU research groups Managing retention of data, biospecimens and researchers within Africa

Some of the areas recognised as being current are:

- Good scientific and research practice
- The transition from paper-based to digital health data across Africa
- Al and research integrity e.g. [3]
- GDPR compliance, and what does it mean for researchers recognising that African countries also have their own legislation to uphold.
- Governance and ethics for commercial collaboration

WG can potentially advise on:

- How GH EDCTP3 drafts certain topics, and the language used, e.g. for ensuring equity in research; for ensuring use of appropriate data standards and ontologies
- Ensuring there are sufficient project resources available for ethical research and appropriate data governance, including budget
- Providing policy guidance in areas of ethics and data governance
- Reviewing climate impact of data storage and analysis
- Reviewing and augmenting existing ethics and data management checklist that includes standard elements, those highlighted above, as well as sometimes overlooked elements such as long-term follow up of data use, non-exclusive licenses, data use information in the future, how to follow up data use (use of licences?)

References:

Policy Paper: Recommendations for Data and Biospecimen Governance in Africa | The AAS. https://www.aasciences.africa/publications/policy-paper-recommendations-data-andbiospecimen-governance-africa (accessed 15 Mar 2021).

2 Tiffin N, George A, LeFevre AE. How to use relevant data for maximal benefit with minimal risk: digital health data governance to protect vulnerable populations in low-income and middle-income countries. *BMJ Global Health* 2019;**4**:e001395. doi:10.1136/bmjgh-2019-001395

3 South African Journal of Science. Special issue on 'Big data and Al in health sciences research in sub-Saharan Africa'. May/June 2023 <u>https://www.sajs.co.za/v119n5-6</u>

Annex 4: Minutes of the Equity and Diversity Working Group (WG) meeting

1. Name: Equity and Diversity

- Rationale:
 - Diversity not necessarily included in equity as it covers only part of equity.
 - Community engagement to be covered under a different Working group, to be reflected "Global Health EDCTP3 Joint Undertaking DECISION N° SC 02/2023 establishing working groups of the Scientific Committee
- 2. Composition



Members:

- Marleen Temmerman,
- Ali Zumla,
- Halidou Tinto,
- Christine Stabell Benn,
- Nicola Viebig,
- Paulo Ferrinho

GH EDCTP3 JU Representative/Observer: Jean Marie Vianney Habarugira

- **Chair:** Marleen Temmerman to chair this meeting, election of WG chair to be postponed to next meeting allowing attendance of all members
- Rapporteur: Nicola Viebig

3. Objectives

- To ensure equity and diversity in all GH EDCTP3 JU activities by focusing on: gender, language (anglophone/lusophone/francophone), geography (North/South, as well within SSA) and others (e.g. social inequities)

4. Deliverables (short- and long-term)

- Define short- and long-term deliverables specific for the EDCTP3 program
- Define the WG Terms of Reference (ToR) next meeting

5. Activities & Information

Statistics:

Specific statistics on grants awarded in each EDCTP3 call for proposals, proposal round and/or annual work program:

- Statistics on gender and geography, and grouped by lusophone, francophone, anglophone participants for the JHU EDCTP3 calls:
 - Data to be presented stratified on the above variables for coordinator, scientific leader, and each participant for Projects and Training calls (submitted and awarded)
 - \circ $\,$ Data to be presented stratified on the above variables for publication outputs:
 - Lead authors (first and last/corresponding author)
 - o Statistics to be published on EDCTP3 website
 - Presentation should focus on both absolute numbers and percentages:
 - o Any other relevant statistics?

Steps and Activities to be considered:

- Increase participation and/or success rate of non-English speaking participants? How can lusophone/francophone participants be supported?
 - Existing possibility of lusophone/francophone participants to submit proposals in their language under the European Commission schemes (with some challenges on proposal evaluations)
 - o Balance project membership across different regions/countries?
 - Proposal drafting in e.g. French/Spanish/Portuguese with translation by other consortium partners and/or revision/correction of proposals by anglophone consortium members prior to submission
 - Training in English writing skills? Training in grant submission procedures in respective languages.
 - o Support for translations of proposals prior to submission?



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- Options in the EC systems & application forms to be checked: "Male, female and others/prefer not to do disclose" to be included/implemented (if not yet covered)
- WG to review call documents to ensure equity and diversity is built into future call texts:
 - \circ To be implemented for the next calls for 2024
 - Strict wording to be included into the call text, across all call texts
 - Adapted to each topic
 - Requirement to have a resource-poor countries in a project with an essential role and a fair share of funding.
 - Ensure fair split of funding across countries
 - Contribution to be further considered for publication?
- EU Membership, Associated Countries and Science & Technology Agreement:
 - Currently the only African entities that can formally coordinate projects, are South African organizations
 - Risk of biasing towards South Africa partners/coordinators while, creating imbalance of participation of other African countries/organizations, causing further inequity
 - Change of underlying regulation to be explored.
 - What is the legal basis? How can this be changed?
 - How can we get more countries to pay membership fees/become a member?
 - Membership fee is still blocking, even if it is a small amount, further increasing inequity. GA to change rules allowing more members to join?

6. WG Meetings

- Next meeting in first two weeks of July 2023, Nicola to circulate a Doodle for date finding.
- Meeting frequency to be decided, with e.g. higher frequency in the beginning and e.g. further meetings every 2 months, and ad hoc, if required