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

August 30th & 31st 2022
White Atrium - Avenue de la Toison 56-60 – 1060 Brussels

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Introduction

The purpose of the meeting was to advise on the scientific priorities to be addressed for the Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU) work programme 2023 in line with the Global Health EDCTP3 Strategic Research and Innovation Agenda (SRIA). The purpose was also to advise on the scope of calls for proposals and to raise any other themes for discussion the Scientific Committee considered relevant.

This was the first face-to-face meeting of the GH EDCTP3 Scientific Committee (SC). A *tour-de-table* was held. The chair of the SC having resigned with effect before the meeting, the vice-chair Professor Gyapong chaired the proceedings. The item election of chair was added to the agenda. It was decided to take this item on the second day of the meeting.

All SC members had signed a conflict-of-interest declaration when joining the Global Health EDCTP3 Scientific Committee. The members participating at the meeting were reminded that any new Conflicts of Interest having occurred since that time need to be declared.

Global Health EDCTP3: Main features and comparison with EDCTP2

Elmar Nimmesgern, interim Executive Director, presented the GH EDCTP3 JU and main differences between EDCTP2 and GH EDCTP3. Slides shown are attached to the minutes.

- There is an important change on legal basis: from an initiative based on Article 185 of the EU Treaty for EDCTP2 (where the EU participates in a research and development programme undertaken by several EU Member States), to an initiative based on Article 187 of the EU Treaty (where EU sets up a Joint Undertaking (JU) for the efficient execution of EU research, technological development and demonstration programmes). This JU is between the European Union, represented by the European Commission and the EDCTP Association representing European and African countries.
- Legal basis:
    - Global Health EDCTP3 Joint Undertaking regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2085&qid=1662132842362&from=en (in particular articles 99-114).

The list of countries members of the EDCTP Association was provided.

The governance of GH EDCTP3 with the Governing Board as the central decision-making body was presented. Both the EDCTP Association (representing European and African countries) and the European Commission (representing the European Union) have equal votes. The Executive Director is appointed by and reports to the Governing Board. The Scientific Committee and the Stakeholders Group (still to be constituted) are advisory bodies of the GH EDCTP3 JU.

For the set-up of the GH EDCTP3 JU, the Governing Board was constituted in January and held a second meeting in May. At that meeting the 2022 work programme including the call for proposals for this year were approved. Thereafter the official launch event was held in Paris. Furthermore, offices have been rented, an interim website was created and the first staff members have been recruited.

Annual work programmes consist of a description of the activities of GH EDCTP3 and importantly contain the call topics to be launched during the year. Also, the call conditions and the activities to be

provided in in-kind by the EDCTP Association member countries are part of the annual work programme. The work programme for 2023 should be adopted by the Governing Board before the end of 2022. The input from the Scientific Committee coming out of this meeting is the starting point for developing the content of the calls for proposals.

The overall framework for the funding activities of GH EDCTP3 is fully aligned with the set-up of Horizon Europe. The main funding instruments are Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA). Calls can be organised as single-stage or two-stage calls. Two-stage calls are used when call topics are broad and at stage one short expression of interest proposals are submitted. The top-ranked applications from stage one is then invited to submit full proposals at stage two.

The work programme topics within the 2022 work programme as well as major investments in infectious disease research through the European health research funding were presented. Information about relevant policy initiatives at EU level was provided.

He also replied to questions summarised here below:

- Sub-Sarahan African (SSA) countries that have not signed an S&T agreement with the European Union cannot have legal entities managing EU funds and be (financial) coordinators.
- The EDCTP2 programme continues to implement the ongoing EDCTP2 projects until they will be finished, but EDCTP2 cannot launch any more calls for proposals (EDCTP2 budget for calls has been committed). It is up to the GH EDCTP3 JU to launch new calls for proposals.
- The lessons learned from the EDCTP2 are being transferred to EDCTP3. For instance, the initial draft of the GH EDCTP3 SRIA was defined with the help of EDCTP2; the topic on implementation research of the Annual Work Programme 2022 is intended to target projects of EDCTP2 to move to the next step.
- African countries' contributions could not be taken into account under EDCTP2 for calculating the matching with EU funds because it was '*a programme of EU member states*', however under GH EDCTP3 JU these contributions can be taken into account. EDCTP Association and European Commission are making efforts to involve all sub-Saharan Africa countries. The list of current member countries from Africa can be found here.
- The EDCTP Association members are national authorities representing the country (not regional or private organisations).
- In-kind contributions from the countries are the research activities that are carried out with the funding from the countries.
- The EDCTP High Representatives have an important role under EDCTP2. Their role under GH EDCTP3 is to be defined.
- The EDCTP Networks of Excellence are implemented by the EDCTP2. Through involvement in projects to be funded, as appropriate, their achievements can be included in the activities under GH EDCTP3.
- Funding for countries that are normally not eligible to receive funding under GH EDCTP3 can be provided under certain exceptions, such as a duly justified provision in the work programme, or in the event of a call addressing a public health emergency.
- EDCTP Office in The Hague is the Secretariat of the EDCTP Association. The Africa Office is run by the EDCTP Secretariat and is expected to receive a grant from GH EDCTP3 to support implementing the GH EDCTP3 activities in Africa.

- EDCTP Association needs funding from the EDCTP member states to carry out the coordination of the countries that are members of the EDCTP Association and that are participating in GH EDCTP3.
- A joint meeting between the EDCTP Association GA and the GH EDCTP3 Scientific Committee is requested for the members to present their concerns about the fact that sub-Saharan African countries need to pay membership fees to the EDCTP Association.
- More countries should join the EDCTP Association. Scientific Committee members mentioned countries with significant research activities such as Malawi, Botswana, or Zimbawe.
- Scientific Committee members were encouraged to suggest names of experts for contributing to the peer review evaluations. Membership in the Scientific Committee is incompatible with reviewing proposals under the GH EDCTP3 programme.

After a short introduction on contacts from the Secretariat with relevant organisations, a discussion on contributing partners was held. Overall, the SC members expressed concern that the scientific priorities for EDCTP3 will be decided by contributing partners. It was emphasised that as for all the priorities to be addressed in the work programmes, the SC gets to provide its advice on all areas proposed for collaboration by contributing partners. Furthermore, also the call topics in collaboration with contributing partners are drafted by the GH EDCTP3 JU secretariat. The collaboration with a contributing partners must be approved by the Governing Board and the Board also has to approve any call topics.

Some areas for collaboration proposed by the Bill & Melinda Gates foundation were presented to the SC. It was decided that more information on the proposed areas would be needed.
- The Scientific Committee emphasised that the benefit for Global Health EDCTP3 needs to be clear in the collaboration with contributing partners.
- Cash or in-kind contributions are both possible also under GH EDCTP3. The Scientific Committee considered that cash contribution from contributing partners should be preferred.
- It was suggested that Global Health EDCTP3 should reach out to other funders to explore collaboration under the Contributing partner's scheme: CEPI, GAVI and FIND.
- Initial discussions with the European Federation of Pharmaceutical Industries and Associations (EFPIA) have taken place to involve industry in EDCTP3 projects.

<u>Discussion on priorities and preliminary recommendations</u>

To prepare this discussion, the members of the Scientific had been invited to each list three priorities they would like to see addressed. Out of the input received, in agreement with chair and vice-chair, the Secretariat grouped the proposed priorities into four blocks of areas for discussion in one group session, each. Two rounds of group discussions were held, with the SC members split into the groups according to preference.

The following questions were used to kick off the discussions:
- What are the specific needs that triggered your proposal of the scientific priority area?
- What could be the niche and specific impact of EDCTP3 in this scientific area? And what outcomes would you like to see?
- Would there be specific actions EDCTP can undertake (resources permitted) that could help to reach the expected outcomes?

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DAY 1 Working Group 1

Participants: Christine S. Benn, Nicola Viebig, Selidji Agnadji, Marleen Temmerman, Halidou Tinto, Joachim Doua, Ali Zumla (online), Juliette Nabyonga (on line), Martin Meremikwu (on line).

- ➔ Immunisation & Vaccine
- ➔ Women and child health
- ➔ Host immunity

1. Immunization & Vaccines

Deployment and uptake of vaccines trough phase IV/implementation research (operational aspects, access, coverage, acceptability/vaccine hesitancy, community engagement, real life impact on overall health, etc.);
Due to limited funding, it will be challenging to fund early stage products development, EDCTP2 has funded several vaccine trials in middle/late stage of development while Horizon 2020 has focused on funding early stage development.

Questions addressed during the discussion

- Should we focus on completed/newly registered vaccines or include existing vaccines?
- Should we target specific groups: Women & Children?
- Should we target specific diseases: malaria, HIV, TB, etc?

2. Women & Child Health

- Innovative & simple interventions beyond vaccines to improve women & children's' health;
- Infectious morbidity/mortality affecting women & children;
- Infections affecting the child through the mother (mother-child dyad);
- This should be based on evidence-based interventions or combination of interventions.

The focus should be beyond pregnant women to consider women in general.

Questions addressed during the discussion

- Should we consider interventions that were successfully tested under EDCTP2/Horizon 2020 funding as a requirement (for synergy)? It was clarified that in a strict sense this is not possible. Calls for proposals under Horizon Europe and thus under GH EDCTP3 have to be open. Nevertheless, it is possible to encourage building on previous results in the description of call topics.
- In duly justified specific cases, funding can be limited to previously supported research.

3. Host immunity

- Understanding and strengthening host Innate Immunity through clinical trials;
- All interventions that increase the general host resilience towards infections in children and elderly including:
  - Bacterial phage that is under development by few companies;
  - Some live vaccines that induce innate immune training like BCG vaccines;
  - Probiotics, etc.

It was considered important for GH EDCTP3 to continue to support the capacity strengthening of clinical trial facilities to meet ethics, ICH/GCP requirements.

DAY 1 Working Group 2:

Participants: John Gyapong, Paulo Ferrinho, Xavier Anglaret, Electra Gizeli, Nicki Tiffin, Keymanthri Moodley, Joachim Doua.

- ➔ AMR research (incl. Sepsis);
- ➔ Emerging epidemics/pandemics and climate crisis-related infectious disease.

Noting that climate change is a driver for many issues across various priorities that include AMR, maternal health, malnutrition, etc.

1. AMR research areas

Research areas addressed the following key themes for AMR:

- Developing capacity for AMR diagnostics;
- Best use of new and existing medications;
- Better laboratory capacity for AMR diagnosis (engage with other funders?);
- Stakeholder engagement for AMR and behavioural interventions;
- Rapid identification of AMR evolution and outbreaks;
- Effective, evidence-based AMR-sensitive syndromic treatment.

1.1. Sociological research, science of medicines:

How are pharmaceuticals managed in society – across different sectors – e.g. vets, doctors, medicine retailers, informal sectors, and what are successful interventions to promote behaviour change. E.g. interventions and changes in marketing, regulations, education.

1.2. Leveraging existing data and sample resources to track and respond to evolution of AMR

Using existing resources such as routine health data, dispensing data, existing cohort studies, sewage water sampling, national/existing laboratory services for surveillance approaches and/or identifying hotspots for emerging AMR and designing rapid response approaches.

NOTE: there is limited laboratory capacity for testing for AMR, and a need to build capacity for testing. Suggestion that this might be a good area to engage with other funders, who could accompany this kind of call with their own for developing laboratory capacity.

1.3. Better PoC diagnostics for AMR

Developing and testing PoC diagnostics/devices for AMR that will allow rapid identification of AMR for patients, to ensure best use of pharmaceuticals. Important to stress that solutions must be locally manufactured and that local affordable access is to be assured.

1.4. Training interventions for best practice in the use of new medications

Training interventions towards better use of new medications such as cefiderocol

1.5. Evidence based syndromic treatment to mitigate AMR development

Where diagnostic testing is not used/available, syndromic treatment approaches with broad spectrum treatments are widely used. Research would support development of novel/evidence-

based approaches to syndromic treatment that is context-appropriate i.e. uses existing contextual evidence; or research would generate data for developing evidence-based syndromic treatment approaches e.g. taking into account local AMR profiles, prevalence of AMR and IDs etc.
Note that the work from these studies should have generalizable outputs that can be used in diverse contexts across the continent.

2. Emerging Epidemics and Pandemics

Note that with the unforeseen nature of an emerging epidemic, financial rearrangements will have to be undertaken to free up some of the budget to address this.

2.1. Known pathogens/ re-emerging infectious diseases

This theme refers to previous pandemic-related pathogens, or pathogens which have pandemic potential; e.g. cholera, bubonic plague, influenza, measles and polio, Lassa fever (often vector-borne).
Suggestion to identify groups of pathogens rather than single pathogens, multiplexing approaches for surveillance, diagnostics, etc.;
Ensuring effective tools for a response are in place; e.g.

- Trials for effective diagnostics, preventative approaches, treatments, vaccines;
- Ensuring tools are easily deployable and accessible (e.g. supply chains, matching instruments with reagent availability; surveillance systems);
- Modelling and algorithms to predict requirements, risk factors (including climate change events, droughts, floods, temperature change etc).

3. Comment on COVID-19 studies

It was noted that there are still new variants and new vaccines for COVID-19, and it remains a priority. The group considered that this research can fit within a multi-morbidity context i.e. impact of COVID-19 in context of other IDs. Also consider reducing waste for testing methodologies (climate change transversal theme).

3.1. Innovation in vaccines, e.g. modes of delivery such as intranasal delivery

Should have generalizable learnings

3.2. Behavioural interventions – vaccine uptake

Behaviour change interventions, effectiveness interventions; require generalizable lessons

4. Comments on some cross-cutting (transversal) themes

- Data management and governance – ensuring that programmes support health services and have components of benefit-sharing, public-, stakeholder- and community engagement;
- Aim to initiate conversation with researchers on how they support health services and ensure best use of data etc. to also support health care delivery in the process of doing research, whilst recognising that this may not always be actionable but at least should be considered and discussed;
- Explore links to climate change in research findings and outcomes;
- Understand impact by and on climate change of ongoing research – ensuring good research practice with respect to climate change – ensure exemplary approach of all projects towards mitigating climate change impacts e.g. reduce clinical trial waste,

digitise records and processes, reduce travel where possible, reduce footprint of clinical trials;
- Potential for capacity development of Ethics Review Boards. Specific logistical support to digitalise submission processes to reduce carbon footprints and streamline processes; develop capacity at the level where clinical trial protocols are reviewed (depending on context/country might be institutional, provincial, national). Empower ethics review boards to be able to implement regulations ;
- Stakeholder engagement in all projects – including meaningful community engagement, end-user engagement.

Day 2 (31 August 2022): Continuation of discussion on priorities and preliminary recommendations

Day 2 Working Group 1:

Participants: Marleen Temmerman, Joachim Doua, Selidji Agnandji, Halidou Tinto, Nicki Tiffin, Christine S. Benn, Paulo Ferrinho, Keymanthri Moodley, John Gyapong, Joachim Doua, Ali Zumla, (on line), Juliette Nabyonga (on line), Martin Meremikwu (on line).

- ➔ Implementation research, also considering hard-to-reach populations and vulnerable groups (newborns etc.);
- ➔ Real-life evaluation of health interventions for their effect on overall health & Evidence-based public health decisions.

There is a lack of evidence on real life effects of existing interventions in various populations in SSA. This implies drugs, vaccines, diagnostic tools and infection control programmes. Implementation research is suggested to address the lack of evidence.

1- Elderly populations in sub-Saharan Africa are often not addressed. Targeting elderly with interventions on innate immunity such as with the BCG vaccine could be explored. Aging and co-morbidities could also be addressed. It was clarified that according to WHO elderly represents > 60 of age;
2- Maternal and child morbidity and mortality: real life assessment of existing interventions like prevention of HIV/syphilis mother to child transmission, essential programmes on immunization. Social sciences in pregnant women, how do we monitor for impact in the future;
3- Co-morbidities: link existing infection control programmes to comorbidities (chronic diseases); e.g. association between respiratory infections control and chronic respiratory diseases;
4- HPV-related diseases including cervical cancer. Implementation of prevention with vaccine, early detection, including self and point of care diagnostic tests, as well as and therapeutic care. Perceptions of communities on vaccine uptake in young females?
5- Vaccine hesitancy to be considered in the context of the specificities of each vaccine and diseases, perceived risks, benefits, incentives;
6- Urban poor and intersectional vulnerability.

Day 2 Working Group 2:

Participants: Electra Gizeli, Nicola Viebig and Xavier Anglaret.

- ➔ Sustainable & efficient funding for promising products under development & previously funded EDCTP sites;
- ➔ Support for African Innovations, including engagement with investors and local/global procurement agencies and regulators;
- ➔ Promotion of partnerships between industry & academia/research.

Diagnostics: Point-of-Care tests in the field for infectious diseases and/or antimicrobial resistance that have either been previously funded by EDCTP or with a certain readiness level to get products across the finish line:

- Evidence-based use, useful in terms of deciding on treatment option and improving disease outcome (i.e. good data showing not only good sensitivity and specificity but also their ability to improve clinical outcomes when used in the field);
- Tests with high technology readiness level, plans to translate from prototype to industrial design, implementation and sustainability plans of the innovation:
  - Presentation of a plan for sample to result to the use of result & treatment option (e.g., use of which drug & treatment option);
  - How to report data & results (mobile health/portable technology);
- Specific criteria: robust, simple to use, as little equipment as possible (according to ASSURED criteria (Affordable, Sensitive, Specific, User friendly, Rapid and Robust, Equipment free and Deliverable to end users), and if available for an indication, according to WHO Target Product Profiles for diagnostics);
- Validation & certification;
- Plans to encourage engagement of local and global procurement organizations;
- Encourage African SME involvement, leveraging on capacity developed for COVID for diagnostics to other diseases;
- Partnering events with industry (organized by EDCTP for pitching of ideas);
- Comparative testing of e.g., diagnostics tests is desired, if feasible, and sufficient (validated) diagnostic tools are available for comparative testing;
- To be evaluated if link can be established with FIND;
- Information requested by the Scientific Committee: Overview of what has been funded in EDCTP1/2 regarding projects on diagnostic platforms and tests and stage of development.

Adaptive trial platforms (for e.g., drugs, vaccines) for comparative side-by-side testing or if not possible to test in similar conditions/environment, and to ensure site sustainability.

DAY 2: Fellowships discussion and preliminary recommendations (all experts)

Amongst the priorities proposed by the SC members for discussion, also the issue of fellowships was raised. It was decided to discuss this in plenary, this topic being of interest to all the members. Furthermore, based on timing it would have been challenging to fit a third round of group discussion into the schedule without compromising on time available for discussion. And grouping all the other proposed themes into only three groups, to have a fourth group for discussion about fellowships, was not considered a good option.

Under GH EDCTP3, the support for training fellowships is to be granted to one or more organisations, and it will be up to these organisations to select the fellows and manage the funds.

- The GH EDCTP3 fellowship programme should be based on the EDCTP2 experience: with similar budget proportion (~5% overall) and similar type of fellowships supporting researchers' career: from early stages to senior fellowships.
- Since no funds were made available for fellowships in 2022, for the work programme 2023, around 10 % should be invested in the fellowship programme.
- It is important that the selected fellow who receives the funding from the African institution, will still be recognized as a EDCTP fellow for enhancing career opportunities through prestigious fellowship;
- Clear criteria for the selection of fellows by the institutes have to be applied. The quality of the selected fellows has to be ensured;
- This includes opportunities for small countries, contributing to the research capacity building of the weakest SSA countries, a twinning between advanced and less advanced institutions in SSA could be foreseen;
- The fellowships should also contribute to strengthen the South-South collaboration between African countries (e.g. French-English speaking countries exchange);
- Caution should be taken that some funds to the fellows are not held back. It was clarified that the model grant agreement has provisions in this regard;
- Focus should be on training fellows in their countries and if training takes place in Europe, the fellowship could foresee a grant for returning to the African institution allowing the fellow to conduct research in the home country to develop their career;
- Institutes could run the fellowships in any language;
- A plan for transfer of knowledge (twining activities between 2-3 institutes) and a plan for sustainability should be required in the call for proposals for each fellowship programme and for each fellow;
- Institutes can be academic or industrial;
- It was clarified that the limitation of funding to legal entities in certain sub-Saharan African countries does not extend to fellows being selected by the networks to be funded;
- Expectations or outputs at the end of the fellowship (e.g. scientific publications) should be clearly listed in the call;
- The senior fellowship programme should have criteria where senior fellows can clearly own his/her career development;
- The Scientific Committee members requested a derogation should be foreseen to allow a SSA Institute to manage the funds, learning grant management and interaction with the funder. Commission staff clarified that it was unlikely that such a derogation would be granted;
- Collaborations with the partners such as EDCTP Association member countries should be sought;
- Synergies with other research training programmes under GloPID-R, GAVI, Team Europe Initiatives, Fogarty, NIH, etc. should be explored.

Election of chair and (vice-)chair

The vice-chair Professor Gyapong was proposed as chair unopposed. The SC elected him as chair and he accepted the nomination. With the vice-chair having been elected chair, a new vice-chair needed to be elected. Professor Temmerman was proposed as vice-chair unopposed. The SC elected her as vice-chair and she accepted the nomination.

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Summary of meeting progress and next steps

- There should be a transfer of knowledge from the EDCTP2 SAC and the GH EDCTP3 SC. For instance, the documents prepared by the EDCTP2 SAC working groups on gender, ethics, community engagement, etc. should be shared with GH EDCTP3 SC;
- The GH EDCTP3 Secretariat should recruit a communication person to implement a GH EDCTP3 visibility strategy - this position has been advertised for EDCTP3 and recruitment process is ongoing;
- Recognising that the membership of the SC is clearly defined, the committee requested to open the possibility for having an observer to the SC from the WHO. The SC would like to invite the WHO division of Science – Chief scientist. The Secretariat clarified that this issue should be addressed in the SC Rules of Procedure and will make a proposal for this;
- The SC should continue/create several working groups:
    - "Diversity" to promote gender balance among EDCTP3 grantees and in research and ensure equity for grantees in SSA:
        - Nicki Tiffin offered to share "Global Equity Questionnaire" that she helped to develop as a template to be considered for EDCTP grantees;
    - "Data Governance" to discuss common informed consent, standardisation, harmonisation, data sharing sustainability in clinical trial conducted by EDCTP3 grantee;
    - "Innovation & Technology" to discuss recommendations to EDCTP3 on how to best bring products developed in grants to the market;
    - Also the issue of working groups of the SC should be addressed in a revision of the SC Rules of Procedure;
- There is a need to replace the SC members that have resigned. This will be done from the reserve list looking for balance on expertise, North-South and gender;
- EDCTP3 should reach out to industry to advertise clinical sites capacity in Africa that was built through EDCTP projects and could be used for industry-sponsored studies;
- Next meeting: 30-31 May 2023.

Requested actions by the EDCTP3 SC

- Organise joint sessions between the GH EDCTP3 SC and EDCTP General Assembly;
- Organise joint session between GH EDCTP3 SC and the Stakeholder Group;
- Set-up a meeting with SC members to go through the legal documents relevant to the SC and GH EDCTP3, e.g. Council Regulation setting up GH EDCTP3, SC rules of Procedure, eligibility criteria for African countries.

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Annex 1: Participant list

Participants:
Electra Gizeli
Nicola Viebig
Halidou Tinto
Nicki Tiffin
Marleen Temmerman
Christine Stabell Benn
Selidji T. Agnandji
Paulo Ferrinho
Keymanthri Moodley
Xavier Anglaret
John Gyapong
Joachim Doua
Ali Zumla (online)
Juliette Nabyonga (online)
Martin Meremiku (online)
Elmar Nimmesgern, Interim Executive Director of GH EDCTP3 JU, DG RTD, European Commission
Steffi Sowinski, Policy Officer, DG RTD, European Commission
Inma Peñas, Policy Officer, DG RTD, European Commission