Work programme 2023 Global Health EDCTP3
Call topics

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2023-01-01: Global Health EDCTP3 Training Networks - Clinical Research Fellowships

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 15.30 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 300 000. This is justified since the main objective of these projects is to provide fellowship support. The relevant options of the Model Grant Agreement will apply.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

The Global Health EDCTP3 Training Networks aim to train and develop skilled, innovative, and resilient African researchers, scientists, clinicians, and other public health professionals working in the area of infectious disease research. The main objective is that these professionals can face current and future clinical research challenges, efficiently carry out clinical trials, mentor young scientists, implement research results, apply knowledge into development of products and services and/or analyse data to

inform policy and practice for better health for all in sub-Saharan Africa (SSA). Through the training being offered to the fellows, important research questions within the framework of the Strategic Research and Innovation Agenda of Global Health EDCTP3[1] will be addressed.

The Global Health EDCTP3 Training Networks will strengthen the clinical research capacity and attractiveness of clinical research in SSA countries. They will equip health research professionals with the right combination of research-related competences and capabilities to enhance their career perspectives.

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Provide answers to research questions in the area of infectious disease clinical research of relevance for SSA and especially in the countries most severely affected by infectious diseases;
- Contribute to generate plausible solutions to improve uptake of innovations and new medical products;
- Increase the number of skilled infectious disease personnel working in SSA;
- Promote the career development and retention of skilled personnel in SSA;
- Strengthen the SSA countries' clinical human capital base in Research and Innovation (R&I);
- Enhance talent retention and knowledge circulation and uptake across the SSA R&I landscape;
- Improve the attractiveness of infectious disease clinical research careers in SSA;
- Contribute to the generation of a critical mass of clinicians and institutional clinical research capacity in SSA;
- Enhance clinical research capacity in poverty-related diseases, especially in the countries with the highest infectious disease burden;
- Enhance the application of One Health approaches across SSA;
- Strengthen the ability of SSA countries to prepare for and to manage epidemic disease outbreaks;
- Encourage cooperation between researchers and clinicians in SSA with Africa CDC[2], African Union Development Agency New Partnership for Africa's Development AUDA-NEPAD[3], World Health Organization African Region (WHO-Afro)[4], African Vaccine Regulatory Forum AVAREF[5] and other organisations relevant for R&I;
- Establish sustainable and mutually beneficial collaboration between clinical research organisations within SSA and Europe;
- Foster a culture of collaboration with Global Health EDCTP3 like-minded funders working in SSA;
- Foster a culture of open science, innovation, and entrepreneurship in SSA;
- Improve equity in research between the genders and across anglophone, francophone and lusophone sub-Saharan Africa.

1 https://commission.europa.eu/system/files/2022-01/ec_rtd_edctp3-sria-2022.pdf
2 African Union Africa CDC Centres for Disease Control and Prevention https://africacdc.org/
3 https://www.nepad.org/
4 https://www.afro.who.int/
5 https://www.afro.who.int/health-topics/immunization/avaref

Scope:

The Global Health EDCTP3 Training Networks will implement training programmes through consortia of clinical research institutions, academia, industry, businesses (including SMEs) and other socio-economic actors from different countries across SSA and Europe, with the objective to strengthen the health research systems of the SSA countries with the highest disease burden. Proposals should include training programmes for researchers, scientists, clinicians and/or other public health professionals in the area of infectious disease research, with practical field research experience. The individuals being trained will carry out ambitious and relevant clinical research projects on infectious diseases affecting SSA.

Global Health EDCTP3 Training Networks proposals should be submitted by a consortium of institutions which must provide training through research programmes to early- to mid-career researchers based in SSA. The fellows must commit to be in Africa for a minimum of two years after completing their training and provide evidence to demonstrate this through a letter of support from their host institution(s).

Proposals should include institutions with a proven track record in the provision of high-quality research training and established regional and global collaborations. These may include research organisations, institutions of higher learning such as universities, national public health institutes or similar agencies, research councils, or other relevant institutions or government ministries. Proposals may also include industry, businesses (including SMEs) and other socio-economic actors.

These consortia should respond to well-identified needs on infectious disease research and innovation in SSA and describe the transfer of knowledge towards the countries with higher disease burden[6], ensuring that the benefit of the training goes to less-experienced institutions/countries. South-South collaboration is strongly encouraged, although North-South collaboration is not excluded. Where appropriate, the training programmes should expose the fellows to collaboration with national departments of health as well as with international and regional organisations[7].

The consortia should also offer transferable skills and competences relevant for innovation and fellows' long-term employability, including financial administration, communication, commercialisation of results, entrepreneurship, intellectual property rights, etc.

The maximum duration of a training programme of a Global Health EDCTP3 Training Network should be 54 months.

The training programme should include two levels of fellows to be trained by experienced researchers, where the higher level provides training and mentorship for the lower one:

- **Early-Stage Career Fellowships** to support researchers and other members of clinical research teams from SSA to acquire specific skills in clinical research through placements in pharmaceutical companies, contract research organisations (CROs), clinical or academic affiliated research organisations and/or product development partnerships (PDPs). This category covers both hands-on-training apprenticeship and Master and PhD training arrangements where the candidates can spend part of their training and supervision at a more established or complementary institution with skill sets, expertise and or competences not available at the fellows' host African institution(s).
  Target individuals should meet all the following criteria:

6 https://www.who.int/data/gho/data/countries

7 International and regional organisations mentioned above

1. Citizens or residents from a SSA country with a higher infectious disease burden than the country of the host organisation;
2. Exceptionally, be citizens from non-SSA country willing to relocate to a SSA country with higher infectious disease burden;
3. Preference to citizens or residents from a SSA low-income countries with lower clinical research capacity[8];
4. Be either postgraduate MD, MSc, or PhD candidate, in an area relevant to infectious diseases or clinical staff with experience in infectious diseases employed for the last 12 months in an organisation with a registered legal entity in SSA;

Duration of a single fellowship: between a minimum of 6 and a maximum of 36 months with the possibility of secondments up to a third of the single fellowship duration.
Expected minimum number of Early-Stage Career fellowships per proposal: 4, expected maximum number of Early-Stage Career fellowships per proposal: 10.

- **Mid-Career Fellowships** to support researchers and key members of clinical research teams from SSA in their mid-career to develop their clinical research skills. The objective is to promote career development and retention of post-doctoral clinical researchers in SSA, to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research at host organisations in the SSA countries with the highest disease burden.
  Target individuals should meet all the following criteria:
  1. Be citizens or residents from a SSA country with higher infectious disease burden;
  2. Exceptionally, be citizens from non-SSA country willing to relocate to a SSA country with higher infectious disease burden;
  3. Preference to citizens or residents from a SSA low-income country with lower clinical research capacity[20];
  4. MD/PhD related to infectious diseases or clinical research or a medical graduate with at least five years' relevant research experience;
  5. At least one publication in an international peer-reviewed journal.

  Duration of a single fellowship: between a minimum of 6 and a maximum of 24 months and can have secondments up to a third of the fellowship duration.
  Expected minimum number of Mid-Career fellowships per proposal: 2, expected maximum number of Mid-Career fellowships per proposal: 5.

The two training levels must be well integrated and designed to provide the required training support for the fellows. Training programmes should develop different training modules, including digital ones, addressing key transferable skills and competences common to all fields of clinical research, including research management and financial aspects, research collaboration and information-sharing, made possible by (digital) technologies (e.g. collaborative tools, opening access to publications and to other research outputs including data, FAIR data management, societal engagement and citizen science, etc.), and fostering the culture of Open Science, innovation and entrepreneurship as well as good scientific conduct such as research integrity.

[8] See Figure 4 – Scatter plot - severity/urgency of need vs relative research capacity – low-income countries at https://tdr.who.int/docs/librariesprovider10/essence/essence-mechanism-consultant-report-2020.pdf

Training programmes should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between candidates. The selection procedure for candidates must be open, transparent, and merit-based, in line with the Code of Conduct for the Recruitment of Researchers[9]. The vacancy notices should be widely advertised in SSA countries and include the gross salary to be offered to the fellows (not including employer's social contributions). The selection of the fellows should address gender and language/regional equity barriers.

Proposals must demonstrate the following:

- A high-quality training programme related to clinical research or implementation research on infectious diseases of importance in SSA, including One Health;
- An open, fair, and transparent procedure for selecting the fellows coming from different geographical regions of SSA, based on quality and with appropriate gender balance, with an active open promotion of the vacancies specifically addressed to female candidates, as well as to candidates from French speaking and Portuguese speaking countries to ensure that candidates from these groups can be well represented;
- Robust mentorship mechanisms to support the fellows through their training period up to completion;
- A robust monitoring and evaluation mechanism used to assess the career progression of the fellows, the impact of the training programme in the region and compile lessons learnt that can be used to inform future training programmes;
- The training programme must be conducted in SSA, in collaboration with relevant local or regional organisations such as National Public Health Institutes (and/or similar agencies), Ministries of Health, Research Councils and other relevant institutions;
- Whenever relevant, training programmes should expose fellows to collaboration with regional and international organisations, e.g., Africa CDC, AUDA-NEPAD, WHO-Afro, AVAREF and/or other organisations relevant for R&I;
- Training programmes should be designed with different training modules addressing also key transferable skills and competences concerning clinical research management including communication, ethical, regulatory, administrative, and financial aspects;
- Training programmes should include individual fellows training packages so that the fellows can deliver on their individual expected results;
- Proposals should also include support for meetings and conferences for the trainees to participate in the annual networking meetings, conferences and forums organised by relevant African organisations such as Africa CDC, EDCTP, WHO-Afro, AUDA-NEPAD, and other relevant events;
- Linkages with other EDCTP actions should be foreseen (e.g., EDCTP Networks of Excellence[10] or Alumni Network[11]).
- Capacity to provide adequate training on skills and competences relevant for innovation, e.g., entrepreneurship, commercialisation of results, intellectual property rights, etc.

9 https://euraxess.ec.europa.eu/jobs/charter

10 http://www.edctp.org/networks-excellence/

11 http://www.edctp.org/our-work/fellowship-programme/edctp-alumni-network/

To strengthen the clinical research capacity in the SSA regions with the highest disease burden, expert evaluators will be asked to take the possibility/likelihood of the transfer of knowledge particularly into account when evaluating the 'impact' criterion of the proposal.

Financial contributions from EDCTP-Association and third parties (e.g., foundations) interested in this scheme are encouraged to contribute to increase the budget, diversity, and impact.

Contributions for recruited researchers and institutions per person-month

Monthly contributions are based on the Marie Skłodowska Curie schemes (MSCA) contributions. To the living allowance a country correction coefficient[12] for the recruited researcher will be applied to ensure equal treatment and purchasing power parity for all fellows. The mobility allowance will cover additional, private mobility-related costs (e.g., travel and accommodation costs), but not travel for professional or research purposes. A family allowance will contribute to mobility-related costs of researchers with family obligations which can be granted during the project.

Early-Stage Career (taken from the MCSA Work Programme 2023-2024 Doctoral Fellowships)

MSCA Doctoral Networks	**Contributions for recruited researchers per person-month**					**Institutional unit contributions per person-month**	
	Living allowance	**Mobility allowance**	**Family allowance** (if applicable)	**Long-term leave allowance** (if applicable)	**Special needs allowance** (if applicable)	**Research, training, and networking contribution**	**Management and indirect contribution**
	EUR 3 400	EUR 600	EUR 660	EUR 4 000 x % covered by the beneficiary	Requested unit x (1/number of months)	EUR 1 600	EUR 1 200

Mid-Term Development Career (taken from the MSCA Work Programme 2023-2024 Postdoctoral Fellowships)

MSCA Postdoctoral Fellowships	**Contributions for the recruited researcher per person-month**					**Institutional unit contributions per person-month**	
	Living allowance	**Mobility allowance**	**Family allowance** (if applicable)	**Long-term leave allowance** (if applicable)	**Special needs allowance** (if applicable)	**Research, training, and networking contribution**	**Management and indirect contribution**
	EUR 5 080	EUR 600	EUR 660	EUR 5680 x % covered by the beneficiary	Requested unit x (1/number of months)	EUR 1 000	EUR 650

[12] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-2-msca-actions_horizon-2023-2024_en.pdf

HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of between EUR 0.25 and 2.5 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 14 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[13], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

[13] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

	2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other conditions	Only proposals addressing the clinical trials, listed by their registration number in a clinical trial registry in the topic description below, can be selected for funding.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Clinical trials of medical technologies that were funded by EDCTP2 and whose activities were disrupted during the COVID-19 pandemic, can be concluded;
- Information about medical technologies can be used by health care professionals and health care systems.

Scope:

The following clinical trials – identified by their clinical trial registration numbers - are addressed by this topic:

ISRCTN[14] 61526229 PACTR[15]202010540737215	Assessing the safety and tolerability of artemether-lumefantrine+atovaquone-proguanil tri-therapy for malaria treatment in adults and adolescents in Gabon
ISRCTN 14750348	A multicentre phase III trial to evaluate the

[14] https://www.isrctn.com/

[15] Pan-African clinical trials registry https://pactr.samrc.ac.za/

PACTR 202201797112873	safety, tolerability, and efficacy of a combination of three antimalaria drugs (artemether-lumefantrine+atovaquone-proguanil) versus two malaria drugs (artemether-lumefantrine) +placebo in African children aged 6-59months with an uncomplicated malaria infection
PACTR 202011812241529	Efficacy and safety of pyronaridine-artesunate (Pyramax) for the treatment of falciparum malaria in African pregnant women
NCT[16] 03876262 PACTR 202004639229710	Safety and Efficacy of Annual or Biannual Doses of Moxidectin or Ivermectin for Onchocerciasis
NCT 04311671 PACTR 202003567524647	Safety of a Single Dose of Moxidectin Compared With Ivermectin in Individuals Living in Onchocerciasis Endemic Areas
NL7294 (NTR7503) https://trialsearch.who.int/Trial2.aspx?TrialID=NTR7503	Integrated skin screening and SDR-PEP administration for leprosy prevention: comparing the effectiveness and feasibility of a community-based intervention to a health centre-based intervention in Ethiopia, Mozambique, and Tanzania (PEP4LEP)
PACTR 202011804563392	A cluster-randomised controlled Phase IV trial (cRCT) assessing the impact of a Vi-Polysaccharide conjugate vaccine in preventing typhoid infection in Asante Akim, Ghana (TyVEGHA)
NCT 05119426	Effectiveness of a Typhoid Conjugate Vaccine in DRC (TyVECO)
NCT 05047315	Evaluating a New Stool Based qPCR for Diagnosis of Tuberculosis in Children and People Living With HIV (Stool4TB)
NCT 05048472	East Africa Point of Care Viral Load Study (EAPoC-VL)
NCT 05175794	Triage Test for All Oral DR-TB Regimen (TRiAD Study)
NCT 05317247	Cough Audio Classification as a TB Triage Test (CAGE-TB)
NCT 04145258	Intensified Tuberculosis Treatment to Reduce the Mortality of Patients With Tuberculous Meningitis (INTENSE-TBM)
NCT 04600167	Preventive Treatment Of Latent Tuberculosis Infection In People With Diabetes Mellitus (PROTID)

[16] US National Library of Medicine clinical trial registry https://clinicaltrials.gov/

ISRCTN 77382043	Metformin treatment for diabetes prevention in Africa
NCT 04653948	Maternal, Neonatal and Infant Outcomes at Kawempe National Referral Hospital (PREPARE)
NCT 04732026	Serocorrelate of protection against GBS
NCT 04596878	Study of a Group B Streptococcus Vaccine in Pregnant Women Living With HIV and in Pregnant Women Who do Not Have HIV
PACTR202208844472053	Increasing the uptake of intermittent preventive treatment using sulfadoxine-pyrimethamine through seasonal malaria chemoprevention channel delivery
NCT05441410	Comparing Safety and Protective Efficacy of Vaccine Candidate PfSPZ-CVac and MVA ME-TRAP/ ChAd63 ME-TRAP in Adults (SPICY)
NCT04601714	Baseline Cohort Malaria Morbidity Study (BLOOMy)
PACTR201909810587438	Safety and efficacy of Dolutegravir and EFV400 for pregnant and breastfeeding women: a randomized non-inferiority clinical trial

This funding will ensure that essential clinical trials working to deliver answers of immediate public health relevance in SSA can be concluded. Focussing funding to projects previously supported under the EDCTP2 programme is justified by the advanced stage ongoing studies have reached. It is also justified by ethical issues, such as fully validating the willingness of trial participants to take part in the clinical investigations.

The proposals need to address all of the following:

- Demonstrate the work performed so far, such as number of recruited trial participants, follow-up status as well as analyses to be performed;
- Explain the impact of COVID-19-related delays and disruption in relation to the trial timing (start, recruitment, follow-up period);
- Clearly explain the additional work to be carried out, with a comprehensive plan and budget to conclude the planned studies in a tight timeframe;
- Proposals should present a sound assessment of the feasibility of the planned clinical investigations. Realistic plans for recruiting and following up trial subjects must be presented and corroborated by demonstrated success from previous studies and/or the current study;
- Whilst it is acknowledged that the projects build on previous studies, the proposals should briefly recall the justification of the choice of populations to be enrolled into the trials and explain how they relate to the larger population;
- It should also be explained how the full range of relevant determining characteristics (sex, gender, age, socio-economic status, etc.) is considered.

HORIZON-JU-GH-EDCTP3-2023- 01-03: Implementation research/real life assessment of existing interventions in women and children's health

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 26 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[17], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

[17] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

	2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. Proposals under this topic should aim for delivering results that are contributing to the following expected outcomes:

- Better understanding of the role of poverty-related diseases (PRDs), diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in maternal, neonatal and child mortality and morbidity, as well as the barriers for the uptake of health interventions against these diseases in sub-Saharan Africa (SSA).
- Evaluation of the real-life impact of existing interventions in women and children's health.
- Uptake of research findings on medical interventions (such as diagnostics, drugs, vaccines, and microbicides) of proven efficacy into clinical practice and routine care so that women and children in SSA can have access to safe health technologies for the management of PRDs.
- Widespread adoption of research findings into national, regional and/or international policy guidelines.
- Improved maternal, neonatal and child health in SSA.

Background & Scope:

According to the 2022 report of the World Health Organization, more than half of the world's maternal deaths occur in SSA, where the rate stands at 525 deaths per 100 000 live births and 27 neonatal deaths per 1000 live births[18]. Current trends show that by 2030 the region will still record 390 maternal deaths per 100 000 live births and 54 neonatal deaths per 1000 live births, very far from the targets set by the Sustainable Development Goals (SDGs). The factors contributing to maternal and child deaths are numerous.

In countries in SSA, infectious diseases remain the leading causes of morbidity and mortality, especially during pregnancy and childhood. Because of limited evidence on the contribution of these diseases to maternal and neonatal mortality, the importance of PRDs for maternal, foetal, and neonatal deaths is often poorly recognised. Despite the progress made in other age groups, effective treatment and prevention of PRDs and other diseases such as diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in mothers, newborns and children is often lacking and/or lagging. The frequent exclusion of pregnant women and children from clinical trials and the limited number of available products targeting these groups, are factors that contribute to the lowest health indicators in these vulnerable populations. In addition, there is a need for critical appraisal of existing health interventions, which may have been introduced and used by healthcare systems without rigorous evaluation in clinical trials. It is thus important to understand whether such interventions lead to better overall health in these populations.

Moreover, failure to translate research findings into policy and practice prevents research from achieving maximum public health benefits. Despite substantial investment in clinical research in infectious diseases, including PRDs, exploitation, and use of results beyond research groups to date remains limited. Barriers to an efficient uptake of research findings include limited interaction between researchers, policymakers, patients' community and other stakeholders, lack of experience in exploiting research results beyond academia, limited health systems capacity, affordability issues, and differences between the research, programme planning and policymaking structures and actors.

Concerted efforts are needed to increase access to potentially lifesaving, cost-effective interventions to prevent and treat PRDs and other diseases such as diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in pregnant women, newborns, and children to ensure solid evidence is produced for the recommended interventions and to enhance the use of existing interventions in these populations.

Proposals should address the following activities:

- Carry out registration (phase III) and/or post-registration studies of health technologies that tackle infectious diseases affecting women and children to demonstrate clinical effectiveness;
- Demonstrate the cost-effectiveness of the health technologies being investigated in the relevant populations and communities;
- Identify the barriers to the uptake of the health technologies under investigation and address them in the proposed studies;

[18] Africa's advances in maternal, infant mortality face setbacks: WHO report | WHO | Regional Office for Africa

- Develop methods that can ensure translating clinical research results into healthcare policy and practice in a SSA setting. These methods should be broadly applicable to improve patients' quality of life beyond the specific health technology being investigated;
- Early involvement and regular interaction with policy- and decision-makers, including end-users, to ensure adoption of the health technology by health systems in SSA.

This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections.

The research carried out and the health technologies developed in the study should tackle infections affecting the health of pregnant women and children up to five years of age.

Neither pre-clinical research nor early-stage clinical trials in the context of product development are within the scope of this call.

Applicants need to concisely describe any proven research evidence of previous findings and explain how the proposal builds on these results. Building on results from projects supported under previous EDCTP programmes is encouraged.

Proposals should present a sound assessment of the feasibility of the proposed work, in particular as regards the proposed clinical interventions. Realistic plans for recruitment of subjects (as part of the clinical trial plan with projected dates) should be presented and documented by demonstrated success from previous studies. The proposals should justify the choice of populations to be enrolled into the interventions. Relevant determining characteristics (such as socio-economic status) also need to be considered.

Proposals must assure that the clinical trials are conducted in line with national and international standards of research, to comply with current legislation, Good Clinical Practice, ethics, and safety-related issues, as well as Good Manufacturing Practice, as relevant.

Proposals should describe how stakeholder views of the proposal's relevance and the study design have been incorporated into the work plan of the research proposal. Proposals should indicate explicitly the plans for good participatory practices for engaging stakeholders at every step of the research life cycle.

Proposals should provide details on the methodology for linking clinical research aspects with the translation into healthcare practice and policy.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and relevant.

HORIZON-JU-GH-EDCTP3-2023- 01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around 3.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for this topic is EUR 11.00 million
Type of Action	Research and Innovation Action
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe19, grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to

[19] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

	their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals submitted under this topic should aim at delivering results that are contributing to some of the following expected outcomes:

- An increased portfolio of therapeutics and diagnostic tools are available to researchers to move along the clinical development phases to combat Ebola disease;
- An improved surveillance system to rapidly detect novel Ebola virus outbreaks in Africa;
- A better understanding of the social dynamics within communities affected by Ebola virus outbreaks and a better awareness from these communities when it comes to the implementation of public health measures such as social restrictions and/or medical interventions;

Scope**:**

Proposals submitted under this call topic are expected to advance knowledge on Ebola virus disease with the aim of contributing to an efficient patient management and public health response, as well as better epidemic preparedness in Africa. Special focus should be on improving our understanding of the Sudan virus disease, in view of the recent outbreak in East Africa and the lack of available interventions for this viral strain. There are currently no licensed vaccines or therapeutics for the prevention and treatment of Sudan virus disease[20].

Ebola is a severe disease, with high mortality risk, first identified in 1976 when two simultaneous outbreaks occurred in South Sudan and the Democratic Republic of the Congo. Ebola viruses are primarily transmitted to humans through close contact with blood, secretions, organs, or other bodily

[20] https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON410

fluids of infected humans or animals, and contaminated surfaces and materials. Infected people generally present with fever, fatigue, muscle pain, headache, and sore throat, followed by vomiting, diarrhoea, rash, and/or symptoms of impaired kidney and liver function. The average Ebola case fatality rate is estimated around 50% with rates varying from 25% to 90% in past outbreaks. Ebola outbreaks have most commonly been caused by the Zaire and Sudan Ebola virus.

The scope of the proposals submitted under this call topic should include one or more of the following areas:

- Clinical development of therapeutics. This can include early phase testing of candidates for safety, validation of standardised animal models that adequately recapitulate the clinical hallmarks of human infection and illness to enable acceleration of regulatory pathways for vaccines and therapeutics, or platform trial designs or networks that can be pivoted to outbreaks where they occur. Best practices for the use and deployment of intervention tools, including storage and transport should be considered.
- Clinical development of point-of-care (POC) diagnostics, ensuring rapid evaluation of POC tools based on existing technologies to allow for fast case detection and better surveillance. It should be possible that the developed diagnostic tools can easily be taken up by health care systems and health care centres, also in rural settings.
- Social sciences research to improve risk communication activities, provide responses to social dynamics of Ebola virus outbreaks and increase acceptance of the public health response and medical countermeasures.

Promotion of close communication between clinical experts, patient communities, regulators, health care workers and policy makers is expected to increase the uptake of a developed intervention and improve outbreak response.

Interaction with relevant national public health institutes and regulatory authorities, African Medicines Agency, Africa Centres for Disease Control and Prevention, World Health Organization - Regional Office for Africa and/or other regional and international relevant organisations are expected to adequately address research needs.

Vulnerable populations need to be included in the clinical study population, including children, pregnant women, people with co-infections and comorbidities, older people and people living in hard-to-reach communities (unless excluded for physiologic or metabolic reasons). Collaboration and coordination with existing outbreak response initiatives and ongoing Ebola research actions are highly encouraged to facilitate knowledge exchange, collaboration, synergies, and coordination of response activities. Community engagement should be supported.

Sex and gender aspects should be taken into account. All data should be disaggregated by sex, age, and other relevant variables, such as by measures of socioeconomic status (i.e., considering the socioeconomic gradient).

HORIZON-JU-GH-EDCTP3-2023-01-05: Strengthening ethics and regulatory capacity

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 1.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 8.00 million.
Type of Action	Coordination and Support Actions
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

Projects funded under this Call for Proposals should contribute to the following outcomes:

- Stronger functionality, recognition, and performance of National Ethics Committees (NECs) and National Regulatory Agencies (NRAs) working in sub-Saharan Africa (SSA);
- Clinical trials authorised in these areas meet the appropriate standards;
- Improved efficiency regarding the process of clinical trial protocol authorisation for the development of new or improved health technologies;
- Improved efficiency of the NRAs concerning clinical trials oversight with alignment to continental initiatives of African Medicine Agency (AMA) and African Medicines Regulatory Harmonisation (AMRH);
- Better equipped health research systems to integrate new or improved health technologies;
- Sustainable health research strategies for both NECs and NRAs;
- Adoption of standardised training of both ethics committees and regulatory boards available in SSA through EDCTP partners;
- Generation of principles towards harmonised oversight for certification of clinical trial ethics and regulatory bodies in SSA countries;
- Creation of sustainable links and collaboration between NECs and NRAs and other important structures, such as clinical trial registries, research integrity offices and data access committees;
- Establishment of systematic reviews and data sharing in compliance with global requirements;
- Implementation of digital technologies to facilitate ethical and/or regulatory review processes.

Scope:

The aim of this call is to improve the functionality, recognition and performance of NECs and NRAs for carrying out clinical trials in SSA countries**.**

Despite ongoing efforts by different partners and agencies, ethics, and regulatory oversight in SSA countries requires prioritisation and ownership by these countries to ensure sustained strengthening with a long-term perspective. There is a need to better understand the challenges that these countries are facing. They include the varied levels of clinical trial activity, with no health research legislation in some of them; as well as the need of better quality control, certification and accreditation of ethics and regulatory bodies, adherence to common international standards and open data access. Coherent linkages between ethics and regulatory functions are needed, as well as linkages with clinical trial registration and more systematic research reviews. Furthermore, better systems and technologies, including more external expertise and digitalisation for processing research application review and handling of documentation and data, are required.

Several initiatives have already established capacity development tools and structures that add value to the capacity development efforts of ethics and regulatory agencies in SSA[21] and should be taken into consideration.

The projects funded under this call will support the SSA countries to establish and/or develop own robust capacities for ethics review and national medicines regulatory systems. This also includes support towards national and international collaboration in compliance with established international standards. This scheme targets proposals with active involvement of NECs and/or NRAs from SSA countries, and in particular with those countries with the highest infectious disease burden.

Proposals should address several of the following activities:

- Improvement of the efficiency of the functioning of NECs and NRAs through the introduction of innovative systems, reliance practices and/or technologies that would facilitate the various functions of these bodies with better quality outputs and improved timelines;
- Development of national health research legislation;
- Promotion of quality control systems and processes for NECs and NRAs, as well as certification and accreditation of the various bodies, as well as adherence to international standards;
- Promotion of international cooperation in ethics and regulatory activities through transfer of promising and successful innovative systems and/or technologies from other regions in Africa or other continents, fostering national and regional collaboration among these bodies;
- Creation of linkages between ethics and regulatory functions with other important structures, such as clinical trial registries, whilst simultaneously enforcing the sharing of data in compliance with global requirements;
- Promotion of the adoption and update of AVAREF, WHO and other international standards and best practices, by countries, groups of countries, or regional harmonisation initiatives;
- Support already established training centres to provide both innovative training, and mentorship to NECs and NRAs.
- Development or scale-up of innovative systems and technologies that support ethics and regulatory functions, training, networking and promotion of good practices and evidence-based adop-

[21] WHO AFRO, through AVAREF, has established a training course for ethics committees in both English and French. AUDA-NEPAD has established Regional Centres of Regulatory Excellence (RCOREs) designated with regulatory science expertise and training capabilities. Moreover, WHO has also developed standards for ranking maturity of regulatory boards as a measure to indicate advancement in capacity of these agencies.

tion of accreditation models from relevant internationally endorsed/peer-reviewed documented sources.

Proposals should clearly indicate the mismatch between the country disease burden, research activity and level of ethical review and regulatory oversight that justify the need for support in these areas.

Linkages of the proposal to relevant on-going initiatives and regional bodies is encouraged and should be demonstrated.[22] Plans to foster bi-lateral links between the European Medicines Agency (EMA) and the national ethics and regulatory authorities in the SSA countries of the participants are encouraged.

Each proposal should have at least two new technical staff members recruited to the NEC/NRA team to be trained and integrated in the new functions proposed in the action. The new staff members should have a well-defined function and objectives in the participating NEC and NRA with a systems approach. The new staff members should stay in the team for at least two years and participate in relevant networking and international events.

Particular attention should also be paid in the proposal for ensuring complementarity and coherence with other activities supported by the European Union and EU Member States in the countries involved. This concerns for example the EDCTP Regional Networks of Excellence[23] and the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) in Africa[24] or other health Team Europe initiatives[25] of the Global Gateway investment package.

To strengthen the clinical research capacity in the SSA regions with the highest disease burden, the quality of the transfer of knowledge should be taken particularly into account when evaluating the criterion 'impact'.

Proposals should provide details on the steps to be taken to ensure gender balance and contribute to have representation from French speaking and Portuguese speaking SSA countries in the project team.

22 These initiatives include: the African Medicines Agency (AMA), the Africa Vaccines Regulators Forum (AVAREF), the Regional Centres of Regulatory Excellence (RCORE) in Africa, the WHO-TDR-SIDCER initiative (Strategic Initiative for Developing Capacity in Ethical Review), the Pan African Clinical Trials Registry (PACTR), the African Medicines Regulatory Harmonisation (AMRH) and the Africa Centre for Disease Control and Prevention (ACDC) and WHO-AFRO.

23 EDCTP regional networks of excellence strengthen regional networking and provide platforms for research training and multicentre studies http://www.edctp.org/our-work/edctp-regional-networks-of-excellence/

24 The Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594 directly funds the European Medicines Agency (EMA), African Medicine Agency AUDA-NEPAD (AMA) and the World Health Organization (WHO).

25 Team Europe Initiative with Africa on sustainable health security using a One Health approach https://europa.eu/capacity4dev/tei-jp-tracker/tei/sustainable%C2%A0health-security-africa

HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 5 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 30 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[26], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

[26] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

	2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. To that end, proposals submitted under this topic should aim for delivering results that are directed, tailored towards, and contributing to all the following expected outcomes:

- Public health authorities and health care professionals in sub-Saharan Africa (SSA) have access to novel logistical and clinical solutions for vaccine delivery and have a better understanding of the behavioural barriers driving vaccine hesitancy, resulting in improved rates of vaccine deployment and uptake, particularly in poor and vulnerable communities.
- People in SSA have improved access, coverage, and trust in vaccines against all preventable infectious diseases within the scope of the Global Health EDCTP3[27]. Better tools as well as data on immunisation levels and the individual and public health benefit of immunization will drive vaccination even in hard-to-reach regions, thus helping to contribute towards the WHO Immunization Agenda 2030[28].
- Health professionals and especially clinicians as well as policy makers have access to comprehensive phase IV/implementation research results, making use of them to ensure widespread translation and adoption of research findings into national and international policy guidelines for better delivery, deployment, and uptake of vaccines in clinical practice in SSA.

[27] Strategic Research and Innovation Agenda of the Global Health EDCTP3 Joint Undertaking: ec_rtd_edctp3-sria-2022.pdf (europa.eu)

[28] Immunization Agenda 2030: A Global Strategy To Leave No One Behind (who.int)

Scope:

Despite offering strong protection against infectious diseases, global vaccination rates have been declining for a few years resulting in the re-emergence of preventable infectious diseases that were thought to be on the verge of elimination. This trend further worsened during the COVID-19 pandemic because of severe interruptions in public health services, restrictions of non-urgent medical care and diversion of limited health care resources, resulting in cancellation or delays of routine vaccinations. Underserved communities in SSA have been most affected, leaving them less protected against vaccine-preventable diseases. Under immunised individuals and zero-dose-children (not having received any vaccine) are also found in other communities. Furthermore, there has been a significant erosion of trust in governments and public health institutions that coordinate and conduct such immunisation efforts. Novel logistical and clinical solutions for vaccine delivery and a better understanding of the behavioural barriers driving vaccine hesitancy in SSA as well as better data to document beneficial vaccine effects on individual and public health are therefore of critical importance. Furthermore, there remain open questions on the use of vaccines, also in view of changing environments.

Accordingly, the proposed research is expected to deliver on the following:

- Carry out phase IV/implementation research studies on the deployment and uptake of registered vaccines[29] in SSA, examining operational aspects, access, coverage, vaccine acceptability/hesitancy, community engagement, real-life impact on overall health and cost-effectiveness;
- Develop and test novel logistical solutions for vaccination;
- As relevant, develop and test novel clinical solutions for vaccine delivery, including new delivery modes;
- Gain a better understanding of different health care systems in sub-Saharan Africa as regards the factors driving structural inequalities in vaccine deliveries;
- Identify the social, economic, political, religious, cultural, and personal factors driving vaccine hesitancy in SSA and develop targeted solutions, as appropriate. Vaccine hesitancy should be considered in the context of the specificities of different types of vaccines and their perceived risks and benefits. It is further essential to investigate the factors that are undermining coverage in different countries, regions, or communities both in terms of vaccine types and doses received. In many cases, this means targeted collaborations with local leaders who can effectively address their communities' concerns and with caregivers who bring children to vaccination services. Applicants are also encouraged to develop evidence-based tools that can guide people towards informed vaccination decisions, delivering tailored information based on each user's concerns;

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results. Building on relevant results from projects supported under previous EDCTP programmes is encouraged.

[29] It is recognized that the vaccines may not have a marketing authorization in the country or all the countries where the study is being carried out. Registered vaccines need to meet WHO-recommended standards of quality, safety and immunogenicity: Health products policy and standards (who.int)

The implementation research to be conducted must involve vulnerable groups, including participants from poorer, underserved, or hard-to-reach communities in SSA. The full range of relevant determining characteristics (sex, gender, age, socio-economic status, etc.) needs to be considered. Applicants are also encouraged to provide methodologies for translating research findings into public health practice and policy guidelines. They are welcome to draw on any relevant lessons from the COVID-19 vaccination strategies.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and relevant.

The proposals should involve all stakeholders, most notably policy makers, public health authorities, health care professionals and end-users. The applicants must ensure strong community engagement. International cooperation is encouraged, and the proposed research is expected to be multidisciplinary through the involvement of medical sciences, psychological sciences, social sciences, and the humanities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Global Health EDCTP3 Joint Undertaking may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-JU-GH-EDCTP3-2023-02-02-two-stage: Advancing point-of-care diagnostics to the market

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 26 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[30], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse, or abuse of health technologies (e.g., antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the

[30] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

	participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

Expected Outcome:

Proposal under this topic should aim to deliver results that are directed, tailored towards, and contributing to all of the following expected outcomes:

- Health care providers and professionals have access to novel or improved point-of-care diagnostic (POC) devices that are suited to rapidly detect infectious diseases of relevance in sub-Saharan Africa (SSA) and within the scope of the Global Health EDCTP3 Scientific Research and Innovation Agenda.
- A diverse and robust pipeline of in vitro diagnostics is available, increasing options for clinical deployment, also in case of an infectious diseases outbreak with epidemic or pandemic potential, that can reach the most vulnerable populations.
- Health authorities and health care systems have access to health data and evidence to better develop and implement informed health policies and improved clinical surveillance of infectious diseases in SSA.

Scope:

POC diagnostic tests that are easy to use, affordable and can rapidly diagnose diseases will lead to more timely treatment and thereby reduce mortality, morbidity, and transmission of diseases. POC diagnostic tests should improve the quality of healthcare for resource-poor communities in developing countries, where the burden of disease is the highest. A diagnostics gap for many diseases affecting SSA still exists and needs to be closed urgently to contribute the global and national disease elimination targets.

Hence, proposals submitted under this topic should implement clinical studies that lead to market authorisation of the relevant POC diagnostic test. The POC diagnostic test device should be aimed at detection of diseases that currently lack POC diagnosis tests or where POC diagnostics are inadequate. Tests that can in the same specimen simultaneously and rapidly detect and thereby distinguish a wide range of diseases for improved clinical decision-making are encouraged (e.g., distinction between bacterial versus viral pathogens). The POC diagnostic tools are expected to be affordable and suitable for use in SSA countries. POC diagnostics for all diseases in scope of the current Global Health EDCTP3 programme[31], for example antimicrobial resistance and emerging diseases, are included in this call (exception is Ebola Virus disease, covered under topic HORIZON-JU-GH-EDCTP3-2023-01-04).

Proposals should address **all** of the following areas:

- Clinical performance studies in several sites across SSA of POC diagnostics that are of high technology readiness level to achieve regulatory approval and market launch (i.e., CE mark); post-market surveillance studies are excluded from this call and are covered by other initiatives such as the African Health Diagnostics Platform[32];
- Studies need to provide evidence-based practice for the POC diagnostic test especially in terms of the ability to decide on treatment options after diagnosis and improving disease outcome; the possibility of the POC diagnostic to be deployed in the field, its usability by primary care and community health care workers in resource-limited patient communities should be especially considered;
- Inclusion of a clear regulatory path to market to ensure future compliance with the legal requirements; early engagement with regulatory authorities is expected;
- Product development plans for translation from prototype to industrial design, to implementation and sustainability of the innovation should be provided, also including a plan for the process of "sample to result to the use of result & treatment option" and how to report data & results (e.g., via mobile health/portable technology);
- Where available and relevant, World Health Organization target product profiles for diagnostics need to be addressed;[33]
- Involvement of industry, notably of small and medium-sized enterprises (SMEs), especially African SMEs, is expected. Involvement of African SMEs is highly encouraged to contribute to developing the African industry and access to health products.[34]

Proposals submitted under this topic are encouraged to consider innovative diagnostics sampling methods or samples bringing a significant improvement, such as less invasive sampling methods and self-testing at home. The POC diagnostic should allow for easy storage, such as at room temperature. Consideration of environmental friendliness of diagnostic tests would be advantageous. Transmission and

[31] https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

[32] AHDP - AFRICAN HEALTH DIAGNOSTICS PLATFORM (eib.org)

[33] The list of target product profiles that have been developed by the World Health Organization can be accessed at: https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs; please note that this list includes target product profiles for different types of healthcare interventions.

[34] The Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) https://europa.eu/capacity4dev/tei-jp-tracker/tei/manufacturing-and-access-vaccines-medicines-and-health-technology-products-africa

economic modelling to examine the impact of the POC diagnostic assay on performance of long-term health outcomes and cost-effectiveness could be envisioned. Relevant partnerships with local and international organisation to create solutions for improved deployment of diagnostics for vulnerable populations in low-resource settings could be sought.

In addition, where relevant, the link between the diagnostic devices to relevant infectious disease surveillance strategies to inform public health authorities and advise public health policies should be made. This can include monitoring the impact of relevant POCs on the use of antibiotics.

For all proposed research activities, attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability. Populations for POC diagnostic test development and evaluation of the POC diagnostic test performance and appropriateness should also include vulnerable populations, including children, pregnant women, people with co-infections and co-morbidities, older people, and people living in hard-to-reach communities. Rapid feedback from end-users through community engagement on the performance and acceptance of the technologies and their most effective use in endemic settings is expected.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results. Building on relevant results from projects supported under previous EDCTP programmes is encouraged.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and relevant.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Global Health EDCTP3 Joint Undertaking may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.