4. ANNEX 1A to Work Programme 2024

4.1 Calls for proposals 2024

This is the third work programme under the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU). The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board.[1] The Global Health EDCTP3 programme is implemented under the framework of the EU global health strategy[2] adopted in November 2022, the EU-AU summit deliverables[3] and the AU-EU innovation agenda launched in July 2023[4] and will play a key role in achieving the objectives of these strategies and initiatives.

Under this year's work programme, two calls for proposals are launched:

- HORIZON-JU-GH-EDCTP3-2024-01-two-stage covering six topics for Research and Innovation Actions (RIA);
- HORIZON-JU-GH-EDCTP3-2024-02-two-stage covering one topic for Coordination and Support Actions (CSA).

The work programme also foresees other actions, including: (a) expenditure related to experts carrying out monitoring of running actions for the Global Health EDCTP3 JU, and (b) funding to be mobilised in case of a public health emergency.

With the 2024 work programme we extend the range of topics addressed under the Global Health EDCTP3 JU, building on the activities launched previously in 2022 and 2023. The work programme this year puts particular emphasis on supporting the development of interventions, ranging from pharmaceutical interventions (medicines and vaccines) and a possibly broad range of interventions for vector control to digital health tools. Training activities are addressed through a programme where academic training is to be followed by a return phase (HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage). For all topics in the work programme, where relevant, the support to African scientists through degree training in clinical research and/or hands on training during implementation of research projects should be provided to assist them in advancing their scientific careers. These scientists should be selected keeping gender and regional balance in mind.

[1] https://www.globalhealth-edctp3.eu/sites/default/files/2023-05/EDCTP3%20SRIA.pdf
[2] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
[3] Sixth European Union - African Union Summit: A Joint Vision for 2030 - Consilium (europa.eu)
[4] https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf

The work programme addresses a range of conditions within the scope of the objectives of Global Health EDCTP3 JU, including HIV/AIDS, Malaria, neglected tropical diseases and antimicrobial resistance (AMR). This support through topics targeted to a particular disease area complements support provided through broader topics under the previous work programmes of Global Health EDCTP3 JU[5].

Clinical studies

In the context of this work programme, a clinical study covers clinical studies/trials/investigations/ cohorts and is defined as any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies, as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices).

Studies must be registered in a registry meeting WHO Registry criteria[6] before recruitment of the first subject. From 31 January 2023, all initial clinical trial applications in the European Union (EU) must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022[7].

For stage-2 proposals, the use of the "Essential information on clinical studies" template is recommended:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

[5] Tuberculosis, emerging infectious diseases as well as HIV/AIDS, Malaria and neglected infectious diseases have all been addressed through projects funded from previous calls.
[6] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
[7] https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-newclinical-trial-applications-eu

Also, the three mandatory deliverables below should be included in the stage-2 proposals with clinical studies, to the extent relevant depending on the stage of the study:

1. Study initiation package (before enrolment of the first study participant) including:

- Registration number of the clinical study in a registry meeting WHO Registry criteria[8]
- Final version of study protocol as approved by the regulator(s) / ethics committee(s)
- Regulatory and ethics (if applicable, institutional) approvals required for the enrolment of the first study participant (In case of multicentre clinical studies, submission of approvals for the first clinical site is sufficient).

2. Midterm recruitment report

This report is due when 50% of the study population is recruited. The report shall include an overview of the number of recruited participants by clinical sites, any problems in recruitment and, if applicable, a detailed description of implemented and planned measures to compensate for any incurred delays.

3. Report on the status of posting results

Irrespective of the successful completion of the clinical study, summary results must be posted in the applicable registry/ies (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

FAIR data principles and open access of publications are required in line with the Model Grant Agreement[9]. In the context of this work programme, FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency, and the GEO initiative. For further details, see the FAIR principles website[10], the FAIR cookbook[11] and the guides for researchers on how to make your data FAIR[12]. Data

[8] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
[9] unit-mga_he_en.pdf (europa.eu)
[10] https://www.go-fair.org/fair-principles/
[11] https://faircookbook.elixir-europe.org/content/home.html
[12] https://www.openaire.eu/how-to-make-your-data-fair

quality and integration as well as issues of cybersecurity and data protection must be addressed. Use of explainable and transparent artificial Intelligence tools[13] in all research is encouraged where appropriate.

The proposals should put emphasis on involving vulnerable groups, including participants from poorer, underserved, or hard-to-reach communities in SSA. 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. As 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.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries where possible and relevant. Whilst Horizon Europe primarily supports excellence in research, proposals are encouraged to involve organisations from countries with relatively lower research capacities.

Where relevant It will be important for proposals to consider and support the existing and emerging partnerships between the European Union (EU)/Team Europe (EU institutions, Member States and EU Financing Institutions) and the African Union (AU) and their key agencies, notably the Team Europe Initiatives on MAV+[14], Sustainable Health Security[15], Public Health Capacity[16], Digital Health[17] and align with the Africa CDC Strategic Plan 2023-2027[18] and the African Medicines Agency. Moreover, collaborations with the African Regional Intellectual Property Organisation[19] (ARIPO) and the African Intellectual Property Organisation (OAPI)[20] should also be fostered as well as strengthened promoting the development and assessment of innovative tools.

[13] See: European strategic research agenda in artificial intelligence: https://www.elise-ai.eu/work/agendaand-programs
[14] Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (europa.eu)
[15] Sustainable Health Security - Africa | Capacity4dev (europa.eu)
[16] Public Health Capacity - Africa | Capacity4dev (europa.eu)
[17] Digital Health - Africa | Capacity4dev (europa.eu)
[18] Africa CDC Strategic Plan 2023 – 2027 – Africa CDC
[19] African Regional Intellectual Property Organization (ARIPO)
[20] African Intellectual Property Organization (OAPI)

It will also be important that the projects arising from this call will contribute to the implementation of the short-term and medium-term actions of the AU-EU Innovation Agenda[21] in the area of Public Health and the EU global health strategy[22].

Proposals must clearly demonstrate their added value, beyond the state of the art within their respective areas complementing existing research and funding and building on success of past programmes and projects financed by the EDCTP Association and/or other funders, in line with Article 100 of the Council Regulation 2021/2085[23].

Proposals must comply with all ethics requirements arising out of the research, in line with Article 112 of the Council Regulation 2021/2085. In addition to the scientific evaluation, proposals above threshold and considered for funding will undergo an ethics screening carried out by independent ethics experts. The ethics appraisal process focuses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of the research methods, and the applicants' awareness of the ethical aspects and social impact of their planned research.

Finally, the proposals should consider the impact of climate change in the research as appropriate, for example as regards the ability to carry out the proposed activities. Also, proposals should address how the climate impact of the planned research can be minimised.

Of note, despite blind evaluation being mentioned in the standard application form for stage 1 proposals, available in the Funding and Tenders Portal (at the stage of adoption of this Work Programme), please note that this call is not part of the 'blind evaluation pilot', therefore no anonymisation is required for stage 1 proposals of the two-stage calls.

[21] AU-EU Innovation Agenda: https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf
[22] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
[23] 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. 17–119;*
https://eur-lex.europa.eu/eli/reg/2021/2085

BUDGET

Call	Budget (EUR million)	Deadline
Horizon-JU-GH-EDCTP3-2024-01-two-stage	136.432	4 April (first stage)*
Horizon-JU-GH-EDCTP3-2024-02-two-stage	3.500	4 April (first stage)*
Other actions	1.728	
Total	141.661	

*to be confirmed when call planning is finalised

General conditions related to this work programme

Unless specified otherwise, the sections of the General Annexes to the Horizon Europe work programme[24] apply *mutatis mutandis* to the Global Health EDCTP3 JU work programme.

Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B except for the specific conditions for the Global Health EDCTP3 JU funding as regards entities eligible for funding and consortium composition, the specific issue of countries where the coordinator may be established and the obligation to designate a scientific project leader. Participation conditions related to Russia's illegal invasion of Ukraine are also set out below.
Financial and operational capacity and exclusion criteria	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D. The scores and weighting section as regard Research and Innovation Actions (RIA) second stage of two-stage evaluations is set out below.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G and the application of the right to object is described below. For the topics under the call Horizon-JU-GH-EDCTP3-2024-01-two-stage, specific conditions regarding affordable access apply. For the topic under the call Horizon-JU-GH-EDCTP3-2924-02, specific conditions regarding financial support to third parties apply. The conditions are spelled out under the respective topics.

[24] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-13-general-annexes_horizon-2023-2024_en.pdf

Replacing relevant sections in General Annex B to the Horizon Europe work programmes on eligibility (*" Entities eligible for funding")*

To become a beneficiary, legal entities must be eligible for funding.

To be eligible for funding, applicants must be established in one of the following countries:

- The Member States of the European Union, including their outermost regions: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden;
- The Overseas Countries and Territories (OCTs) linked to the Member States: Aruba (NL), Bonaire (NL), Curação (NL), French Polynesia (FR), French Southern and Antarctic Territories (FR), Greenland (DK), New Caledonia (FR), Saba (NL), Saint Barthélemy (FR), Sint Eustatius (NL), Sint Maarten (NL), St. Pierre and Miquelon (FR), Wallis and Futuna Islands (FR);
- Countries associated to Horizon Europe[25]: Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo[26], Moldova, Montenegro, New Zealand (associated to Pillar II 'Global Challenges and European Industrial Competitiveness' as from the Work Programmes 2023 onwards, including for the institutionalised European partnerships), North Macedonia, Norway, Serbia, Tunisia, Turkey, Ukraine, United Kingdom.

Until association agreements start producing legal effects either through provisional application or their entry into force, transitional arrangements apply. The transitional arrangements apply, at the time of the adoption of this Work Programme, with regard to the following countries and legal entities established in these countries, with which association negotiations are being processed or where association is imminent):

1. Canada

2. Morocco

[25] The list is correct at the time of adoption of this work programme. Please see the Horizon Europe List of Participating Countries on the Funding & Tenders Portal for up-to-date information on the current list and on the position for Associated Countries.
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

[26] This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

– The following countries which are constituent states of the EDCTP Association[27]: Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Gabon, The Gambia, Ghana, Guinea-Bissau, Guinea-Conakry, Kenya, Liberia, Malawi, Mali, Mozambique, Niger, Nigeria, Republic of the Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Tanzania, Uganda, Zambia, Zimbabwe.

Consortium composition

Unless otherwise provided for in the specific call conditions, for all actions, due to the policy objectives of the Global Health EDCTP3 JU, legal entities forming a consortium are eligible to participate in actions under the programme provided that the consortium includes:

- At least three legal entities independent from each other and established in different countries, where legal entities are eligible to receive funding;
- At least one independent legal entity established in a Member State or an associated country; and
- At least one independent legal entity established in a sub-Saharan African (SSA) country that is a member of the EDCTP Association.

This condition applies to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA).

Specific cases:

Affiliated entities — Affiliated entities (i.e. entities with a legal or capital link to a beneficiary[28] which participate in the action with similar rights and obligations to the beneficiaries, but which do not sign the grant agreement and therefore do not become beneficiaries themselves) are allowed, if they are eligible for participation and funding.

Associated partners — Entities not eligible for funding (and therefore not able to participate as beneficiaries) may participate as associated partners, unless specified otherwise in the specific call conditions.

International organisations – International European research organisations are eligible to receive funding. Other international organisations are not eligible to

[27] The list is correct at the time of adoption of this work programme. For an update, please check the EDCTP Association website www.edctp.org
[28] See Article 187 EU Financial Regulation 2018/1046.

receive funding unless their participation is considered essential for implementing the action by the granting authority. International organisations with headquarters in a Member State or associated country are eligible to receive funding when provided for in the specific call conditions.

Specific rules regarding legal entities that may be the coordinator of an indirect action

In accordance with Article 110(2) of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[29], where entities established in a third country without an agreement to protect the financial interests of the Union participate with funding in an indirect action, the financial coordinator of the indirect action must be established in a Member State or associated country. Of the SSA countries members of the EDCTP Association, only South Africa concluded such an agreement at the moment[30].

Scientific project leader

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 below 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 scientific project leader oversees the project scientific governance and leadership. For this purpose, proposals must include a work package where the details of scientific project leadership are laid down. The scientific project leader should indicatively perform the following tasks:

- During the call for proposals and selection process, coordinate meetings on and drafting of the full project proposal;
- Work with the coordinator and other beneficiaries on the drafting and negotiation of the consortium agreement and other legal agreements among the beneficiaries;
- Act as the key contact point for the Global Health EDCTP3 JU regarding all scientific action governance issues, steer and provide oversight in the

[29] 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. 17–119;* https://eur-lex.europa.eu/eli/reg/2021/2085

[30] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/europe-world/international-cooperation/south-africa_en

development of the scientific actions, without prejudice to the tasks entrusted directly to the coordinator as per the Model Grant Agreement;
- Support and collaborate with the coordinator on its monitoring activities and the adoption of appropriate internal measures, to ensure that beneficiaries are fulfilling their obligations regarding budget, timeline, deliverables, and scientific quality;
- Review the action's deliverables and reports before their submission by the coordinator;
- Lead the work packages(s) related to the tasks of scientific project leadership.

Annex 1 to the grant agreement and the consortium agreement should address the relationship of the scientific project leader with the coordinator regarding their respective tasks, for example sharing of the information received from or sent to the Global Health EDCTP3 JU on all issues of interest for the proper scientific management of the action.

Replacing the *scores and weighting* section in General Annex D to the Horizon Europe work programmes as regards Research and Innovation Actions (RIA) second stage of two-stage evaluations.

Scores and weighting

Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the table. For full applications, each criterion will be scored out of 5. The threshold for individual criteria 1 (Excellence) and 2 (Impact) will be 4 and for criteria 3 (Quality and efficiency of the implementation) will be 3. The overall threshold, applying to the sum of the three individual scores, will be 12.

Proposals that pass the individual threshold and the overall threshold will be considered for funding, within the limits of the available call budget. Other proposals will be rejected.

Nota bene, for the first stage of the two-stage evaluation, the scores and weighting as indicated in Annex D of the General Annexes of the Horizon Europe work programme 2023/2024 apply. Furthermore, the scores and weighting for Coordination and Support Actions apply.

General Annex G to the Horizon Europe work programmes

The Global Health EDCTP3 JU may, up to 4 years after the end of the action, object to a transfer of ownership or to the exclusive licensing of results, as set out in the specific provision of Annex 5 of the Model Grant Agreement. In addition, in accordance with Article 24(3) of Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[31] and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU.

[31] 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

HORIZON-JU-GH-EDCTP3-2024-01-two-stage

CONDITIONS FOR THIS CALL

INDICATIVE BUDGET(S)

Topics under Call HORIZON-JU-GH-EDCTP3-2024-01-two-stage	Type of Action	Indicative GH EDCTP3 JU Budget (EUR million)	Expected GH EDCTP3 JU contribution per project (EUR million)	Number of projects expected to be funded
Opening: 18 January 2024 Deadline stage 1: 4 April 2024				
HORIZON-JU-GH-EDCTP3-2024-01-01-two-stage	RIA	22.000	5.50	4
HORIZON-JU-GH-EDCTP3-2024-01-02-two-stage	RIA	30.000	15.00	2
HORIZON-JU-GH-EDCTP3-2024-01-03-two-stage	RIA	22.000	5.00	4
HORIZON-JU-GH-EDCTP3-2024-01-04-two-stage	RIA	24.000	6.00	4
HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage	RIA	18.432	6.14	3
HORIZON-JU-GH-EDCTP3-2024-01-06-two-stage	RIA	20.000	5.00	4
Overall indicative budget		136.432		

Expected Impacts:

Activities funded under the 2024 work programme of the Global Health EDCTP3 JU calls for proposals should contribute to:

- Reduce the individual, social, and economic burdens of infectious diseases in sub-Saharan Africa through the development and uptake of new or improved interventions, and
- Increase health security in sub-Saharan Africa and globally by reducing the risk of outbreaks and pandemics and enhancing national and regional capacity to address antimicrobial resistance.
- Progressing towards the achievement of SDG3 'Ensure healthy lives and promote well-being for all at all ages' in sub-Saharan African (SSA) countries;

- Enable the implementation of the short- and medium-term actions foreseen by the AU EU Innovation Agenda (adopted in July 2023) in the area of public health and the EU Global Health Strategy (November 2022);
  - Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable diseases;
  - Expand partnerships based on equal footing, co-ownership, mutual interest and strategic priorities;
- Provide evidence for informed health policies and guidelines within public health systems in SSA and at international level;
- Enhance sustainable global scientific collaboration in health research and international cooperation across SSA;
- Develop novel, innovative HIV therapeutics for reducing the disease burden of HIV in SSA
- Research on existing Malaria vaccines and development of new promising candidates
- Accelerating development and integration of therapeutics against neglected tropical diseases (NTDs) in SSA;
- Tackle Antimicrobial Resistance (AMR) through R&D in novel and existing antimicrobials
- Develop new tools, technologies and approaches for vector control in SSA;
- Develop innovative digital health solutions for SSA.
- Build appropriate local capacity.

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2024-01-01-two-stage: Developing novel, innovative HIV therapeutics for reducing the disease burden of HIV in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5.5 million would allow the outcomes of this topic 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 22 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[32], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[32] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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 at least two of the following expected outcomes:

- Evidence of efficacy, safety and clinical utility for health care professionals and clinicians in sub-Saharan Africa about novel, targeted HIV therapeutics that improve treatment outcomes and quality of life;
- Innovative HIV therapeutics that have demonstrated meaningful advances over existing therapeutic interventions for patients living with HIV in terms of their ability to improve efficacy, safety, adherence, quality of life and reduce HIV-associated mortality and morbidity.
- Public health authorities and policy makers have information from comprehensive clinical trial data on the overall health effects of novel therapeutic HIV interventions, helping them to draft updated or new evidence-based clinical guidelines and best practices as well as design tailor-made HIV policies.

Background:

Over the last few decades, antiretroviral therapy has dramatically increased the life expectancy of HIV patients, turning HIV from a death sentence into a chronic illness. Nevertheless, there are currently around 39 million infected people around the globe and HIV remains a major cause of death, disability and ill-health. The HIV disease burden continues to be high in sub-Saharan Africa, in particular for children and adolescents, and those with co-morbidities. There is therefore a strong need to achieve the 2030 UNAIDS 95-95-95 target[33] (95% of people with HIV know their HIV status; 95% of people with diagnosed HIV infection receive antiretroviral therapy; 95% of people receiving antiretroviral therapy have effective viral suppression) and develop novel HIV therapeutics, novel clinical delivery modes for their administration and novel biomarkers for optimising treatment decisions.

[33] Joint United Nations Programme on HIV/AIDS (UNAIDS). (2014). Fast-Track: ending the AIDS epidemic by 2030. https://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

Scope:

Accordingly, the proposed research must deliver on the following:

- Carry out advanced stage clinical trials of promising HIV therapeutic interventions, for example but not limited to broadly neutralising antibodies, long-acting antiretrovirals or gene therapy approaches.

It may additionally also include:

- Creation and testing of novel clinical delivery routes for the administration of HIV therapeutic interventions that bring meaningful benefit for HIV patients in terms of safety, efficacy, adherence and quality of life;
- In the context of the planned clinical investigations, identification and validation of biomarkers for better optimisation and personalisation of HIV treatment decisions as well as more accurate predictors of progression towards AIDS.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results.

Proposals must carry out late-stage clinical research. Implementation research is not in scope for this topic. The research to be conducted must be inclusive and involve vulnerable groups, in particular infants, children and adolescents. Applicants are further encouraged to involve populations with limited clinical trial data, as well as HIV patients with co-infections and co-morbidities, both of which are associated with polypharmacy and present a serious risk for drug-drug interactions. Sex and gender differences and the effects of age should be duly taken into account.

Proposals should engage all relevant stakeholders, most notably researchers, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Collaboration with other international research groups developing HIV therapeutics is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-02-two-stage: Research on existing Malaria vaccines and development of new promising candidates

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 15 million would allow the outcomes of this topic 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[34], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[34] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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. Proposals submitted under this topic should aim at delivering results that contribute to at least two of the following expected outcomes:

- Generating evidence required for accelerating registration of new vaccine candidates;
- Generating long-term safety and efficacy data on currently registered vaccines;
- Safety and efficacy results from other vaccines, especially those targeting all stages of plasmodium falciparum lifecycle, including promising candidates in phase 2a/b;
- Generating evidence-based recommendations on how to boost manufacturing capacity and build an efficient supply chain for vaccines in general, and malaria vaccines in particular sub-Saharan Africa.

Background:

Currently, two vaccines are recommended for malaria prevention, RTS'S and R21/Matrix-M. At the same time, more candidates are in the pipeline undergoing safety and/or efficacy trials. To maximise the impact of currently recommended malaria vaccines in the context of the global technical strategy for malaria 2016-2030, it is important for the Global Health EDCTP3 JU to capitalise on the 1) recommendation of RTS'S as the first malaria vaccine recommended for large scale, 2) latest WHO recommendation of R21/Matrix-M for malaria prevention in updated advice on immunization.

As a longstanding public health crisis, malaria requires a multidimensional approach, including more and better vaccine strategies. Therefore, further R&D on other promising candidates in the pipeline is required, and further research on cross-cutting issues is necessary, to ensure both pharmaceutical and non-pharmaceutical prevention strategies are part of future evidence-based malaria prevention and control measures. Cross-cutting issues may include social sciences and community engagement activities as part of vaccines studies in malaria endemic regions. Synergy between researchers and other relevant stakeholders is required to develop

and strengthen vaccines manufacturing capacity and to build an efficient supply chain in sub-Saharan Africa.

Scope:

Proposals submitted under this topic are expected to advance knowledge on the safety, efficacy and effectiveness of currently recommended malaria vaccines or new malaria vaccines. To this end, proposals submitted under this call topic should address at least two of the following:

- Trials from Phase 2a should be considered, to ensure continuation of R&D on new generations of vaccines targeting all stages of plasmodium falciparum lifecycle;
- Long term effectiveness studies through aligned primary endpoints should be considered where possible;
- Collection, analysis and sharing of pharmacovigilance data on vaccines that are currently registered or candidates in late-stage efficacy trials.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) is encouraged. The proposers could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-03-two-stage: Accelerating development and integration of therapeutics against Neglected Tropical Diseases (NTDs) in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5 million would allow the outcomes of this topic 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 22 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[35], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[35] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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 at least two of the expected impacts for this call. Proposals under this topic should aim at delivering results that are contributing to the following expected outcomes:

- Accelerate development of therapeutics towards registration to make progress in the control and elimination of NTDs in sub-Saharan Africa;
- Improve the understanding of barriers for progression of existing and new therapeutics against NTDs through the R&D pipeline;
- Generate evidence-based recommendations on how to better integrate research and innovation in efficient supply chains for NTDs;
- Gain a better understanding of different country or region-specific health and research needs, to ensure a better case management of patients with NTDs;

Background:

There is some progress in eliminating and eradicating NTDs as per WHO publication[36] in October 2023: "*nineteen countries in Africa have eliminated at least one NTD and there are currently 18 million fewer people requiring interventions against NTDs. Togo achieved a world first by eliminating four NTDs. Guinea worm disease (dracunculiasis) is on the verge of eradication; sleeping sickness (T. b. gambiense human African trypanosomiasis) has been eliminated as a public health problem in seven countries; and the number of reported Buruli ulcer cases decreased by 71% between 2010 and 2021*". However, diseases such as schistosomiasis, onchocerciasis, and other NTDs continue to affect hundreds of millions of people who are most often society's poorest, in sub-Saharan Africa. The WHO Global report provides information for 2021-2022 on regional progress in Africa NTDs[37].

Many of NTDs are vector-borne diseases (NTD vector control is in scope of topic HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage of this call: new tools, technologies and approaches for vector control in sub-Saharan Africa), have animal reservoirs and are associated with complex life cycles. The epidemiology of NTDs is

[36] Ending the neglect: lessons from a decade of success in responding to Neglected tropical diseases in Africa
[37] Global report on neglected tropical diseases 2023 (who.int)

complex and multifactorial, often related to environmental conditions, that makes their public-health control challenging. Moreover, COVID-19 pandemic severely disrupted health systems, including conduct of clinical trials, supply chains for NTD therapeutics and health products and the implementation of prevention strategies. Thus, pharmaceutical interventions combined with interventions such as house improvements, improved access to safe water, sanitation and hygiene (WASH) are also critical in the prevention for the majority of the NTDs, especially[38] *for Trachoma, Soil-transmitted helminthiases (STHs), Schistosomiasis and Dracunculiasis.*

Scope:

The proposals submitted to this call topic are expected to address at least one of the following activities in scope:

- Conduct clinical trials on therapeutics for NTDs in the scope of the Global Health EDCTP3JU:

Buruli ulcer, dengue and chikungunya, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, and yaws. Global Health EDCTP's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

    - For existing therapeutics for specific indications, there is need to conduct clinical trials of combination therapies against multiple diseases and applicability to vulnerable populations
    - For infections where therapeutics are lacking entirely, clinical trials will be required for the development of new interventions (early stage) or extension of indications (re-purposing)

- Implementation research of pharmaceutical interventions for several NTDs and, when possible, their mainstreaming into national health systems in combination with other control measures

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and health products (TEI-MAV+) is encouraged. The proposals could show, for example, willingness to enter into technology transfer agreements with

[38] Information on cross-cutting issues in NTDs | InfoNTD

African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Activities related to community engagement are encouraged in the context of developing new pharmaceutical interventions targeting NTDs.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results.

The research to be conducted must involve vulnerable groups, including participants from poorer, underserved or hard-to-reach communities in sub-Saharan Africa. 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.

The proposals should involve all stakeholders, most notably policy makers, public health authorities, health care professionals and end-users. Activities related to community engagement are encouraged in the context of developing new pharmaceutical interventions targeting NTDs. International cooperation is encouraged, and the proposed implementation research for pharmaceutical interventions 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. The details of these joint activities will be defined during the grant agreement preparation phase.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-04-two-stage: Tackling Antimicrobial Resistance (AMR) through R&D in novel and existing antimicrobials

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 6 million would allow the outcomes of this topic 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 24 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[39], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[39] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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:

Proposals under this topic should aim to deliver results that are directed, tailored towards, and contributing to the following expected outcomes. Proposals need to address at least two of these, with the first bullet point being compulsory:

- Improvement of the use of existing antimicrobials to reduce AMR and providing data contributing to their equitable access in sub-Saharan Africa, and/or the advancement of late-stage clinical R&D of novel antimicrobials with improved properties (efficacy, safety, resistance pattern, useability) in the clinical trials pipeline;
- Data about development and implementation of antimicrobial stewardship (AMS) processes to optimise the use of antimicrobial medicines in human health and reduce antimicrobial resistance (AMR), employing the One Health approach;
- Effective infection prevention control measures, sanitation and hygiene to reduce the need for and the use of antimicrobial medicines.

Background:

The WHO has declared that AMR is one of the top 10 global public health threats facing humanity. Each year, at least 1.27 million people die as a consequence of AMR, with Africa having the world's highest mortality rate from AMR infections, resulting in over 27 deaths per 100,000[40]. Without action, the death toll could rise even higher, to as many as 10 million deaths annually by 2050[41].

Tackling AMR requires multi-modal interventions, the collaboration of many disciplines and countries. According to the Organisation for Economic Co-operation and Development (OECD), measures to prevent infections such as vaccinations, promoting hand hygiene and better hygiene in health-care facilities more than halves the risk of death and decreases the health burden of AMR. Antimicrobial stewardship

[40] The Lancet AMR analysis: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
[41] World Bank, Antimicrobial Resistance: https://www.worldbank.org/en/topic/health/brief/antimicrobial-resistance-amr and Global AMR R&D Hub and WHO, Incentivising the development of new antibacterial treatments 2023: https://globalamr.e-laborat.eu/incentivising-the-development-of-new-antibacterial-treatments-progress-report-by-the-global-amr-rd-hub-and-who/

(AMS) could further reduce the burden of drug-resistant infection[42]. The WHO defines AMS as a coherent set of integrated actions which promote the responsible and appropriate use of antimicrobials to help improve patient outcomes across the continuum of care. Responsible and appropriate use of antimicrobials includes prescribing only when needed, selection of the optimal drug regime, drug dosing, route of administration and duration of treatment following proper and optimized diagnosis. These actions are complemented by the implementation of infection prevention and control (IPC), enhancing water, sanitation and hygiene (WASH), and optimizing vaccination coverage[43].

AMR is one of the Global Health issues which can hugely benefit from the employment of the One Health approach. The One Health approach is defined as a joint effort of various disciplines that come together to provide solutions for human, animal, and environmental health, including food safety[44]; more information can also be found in the Global research priorities agenda for One Health AMR[45]. AMR transmission is a critical global problem affecting humans, the environment, and animals. Hence, proposals need to have the One Health approach at their centre[46].

Furthermore, the availability and access to existing antibiotics is also a challenge[47]. The Global Leaders Group on AMR recently established that the world faces a serious antibiotic pipeline and access crisis that requires innovative financing measures. In

[42] OECD, Stemming the Superbug Tide: https://www.oecd.org/els/stemming-the-superbug-tide-9789264307599-en.htm; Antimicrobial stewardship programmes in health-care facilities in low-and middle-income countries: a WHO practical toolkit: https://www.who.int/publications/i/item/9789241515481; A European One Health Action Plan against Antimicrobial Resistance (AMR): https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en#ref-2017-eu-one-health-action-plan-against-amr; Antimicrobial stewardship: can we add pharmacovigilance networks to the toolbox? https://link.springer.com/article/10.1007/s00228-020-03035-3

[43] WHO policy guidance on integrated antimicrobial stewardship activities: https://www.who.int/publications/i/item/9789240025530;
WHO Global research agenda for antimicrobial resistance in human health: https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health;
Global Action Plan on Antimicrobial resistance: https://www.who.int/publications/i/item/9789241509763

[44] Antimicrobial resistance: global report on surveillance: https://iris.who.int/handle/10665/112642;
Council recommendation published in June 2023: https://www.consilium.europa.eu/en/press/press-releases/2023/06/13/tackling-antimicrobial-resistance-council-adopts-recommendation/#:~:text=Overall%2C%20the%20Council's%20recommendation%20seeks,become%20resistant%20to%20medical%20intervention

[45] WHO Global One Health priority research agenda for antimicrobial resistance: https://iris.who.int/bitstream/handle/10665/370279/9789240075924-eng.pdf?sequence=1

[46] ILRI One Health Strategy: Stopping the global rise of high-impact zoonotic disease, foodborne disease and antimicrobial resistance: https://cgspace.cgiar.org/bitstream/handle/10568/125264/OneHealthStrategy.pdf?sequence=1&isAllowed=y

[47] Progress report by the Global AMR R&D Hub and WHO 2023: https://globalamr.e-laborat.eu/incentivising-the-development-of-new-antibacterial-treatments-progress-report-by-the-global-amr-rd-hub-and-who/;
The Global Response to AMR, Wellcome Trust: https://wellcome.org/sites/default/files/wellcome-global-response-amr-report.pdf

particular, efforts to ensure equitable access to antibiotics in LMICs that experience the highest burden of AMR, are needed.

Scope:

Proposals must address at least two of the following areas, with the delivery of the first bullet point being compulsory:

- Conduct R&D on the better use of existing antimicrobials to reduce AMR and provide data to contribute to their equitable access in SSA, and/or conduct late-stage clinical R&D on novel antimicrobials with improved properties (efficacy, safety, resistance pattern, useability) for infections within the scope of EDCTP3 to reduce AMR;
- Develop innovative antimicrobial stewardship strategies in human health on how to tackle AMR based on the One Health approach within the scope of EDCTP3 in SSA;
- Develop and implement cost effective, acceptable and feasible infection prevention and control (IPC) strategies, in reducing AMR in healthcare facilities and communities.

Only proposals focusing their research on existing and/or novel antimicrobials from phase 3 onwards will be eligible. Neither pre-clinical research nor early-stage clinical trials in the context of product development are within the scope of this call.

The inclusion of industry partners involved in the development and/or manufacturing of the antimicrobials in the consortium is strongly encouraged.

Where possible, collaboration and coordination with the Team Europe Initiative on Sustainable Health Security in Africa or Manufacturing and health products (TEI-MAV+) is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Environmental aspects relating to antimicrobial resistance in the production of antimicrobials and the waste of antimicrobials should be considered.

For the purposes of this call, existing antimicrobials are classified as those already on the market, but impacted by AMR, and in need of improvement of their use to

minimise AMR, whilst by novel antimicrobials we refer to those in the clinical trial development pipeline, but not yet on the market.

Proposals should assess the impact, contribution, utility, accessibility, equity and cost-effectiveness of proposed interventions on AMR across socioeconomic settings in SSA.

Sepsis is included in the scope of this call. According to the Berlin Declaration on Sepsis, calling upon the enforcement of the WHA70.7 resolution, sepsis should be tackled as part of actions against AMR to maximise efficiencies and reduce the burden of disease.[48]

Applicants are encouraged to work among international sectors and actors, including human and veterinary medicine, agriculture, finance and environment experts.

Applicants need to concisely describe any proven research evidence of previous findings and explain how the proposal builds on these results.

Proposals should present a sound assessment of the feasibility of the proposed work, in particular as regard to 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.

[48] 2023 Berlin Declaration on Sepsis: https://www.esaic.org/esa-news/the-2030-world-sepsis-declaration/#:~:text=The%20Berlin%20Declaration%20on%20Sepsis%20is%20an%20urgent%20call%20for,reinvigorated%20global%20action%20on%20sepsis

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

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 both in terms of the consortium composition and the selection of study participants. 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).

FAIR data principles and open access of publications are required.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage: New tools, technologies and approaches for vector control in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 6.14 million would allow the outcomes of this topic 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 18.432 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[49], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[49] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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:

Proposals under this topic should aim to deliver results that are directed, tailored towards, and contributing to the development and evaluation of tools, technologies and approaches for vector-borne diseases, including vector control and disease management technologies.

Background:

Vector-borne diseases[50] account for more than 17% of all infectious diseases, causing more than 700000 deaths annually. They are human illnesses caused by parasites, virus and bacteria that are transmitted by vectors, living organisms that can transmit infectious pathogens between humans or from animals to humans. Most vectors are bloodsucking insects, such as mosquitos and ticks.

The burden of vector-borne diseases is highest in tropical and subtropical areas, and they disproportionately affect the poorest populations. Continuing urbanization and climate change are driving the expansion of the geographic range in which many of these vectors can thrive. Increasing numbers of autochthonous cases have also been reported from European countries[2].

The "Global Vector Control Response (GVCR) 2017–2030", approved by the World Health Assembly in 2017, supports the implementation of approaches to vector control that will enable the achievement of disease-specific national and global goals and contribute to achievement of the Sustainable Development Goals and Universal Health Coverage.

Many of vector-borne diseases are preventable, through protective measure and community mobilisation. Vaccines can help prevent some vector-borne diseases, such as yellow fever, Japanese encephalitis, tick-borne encephalitis. Another crucial element in reducing the burden of vector-borne diseases is behavioural change. Access to water and sanitation is another very important factor in disease control and elimination. However, not all vector-borne diseases have effective vaccines available and/or can be effectively prevented.

[50] Vector-borne diseases (who.int) and Disease vectors (europa.eu)

Scope:

Within the scope of this topical area should be innovative interventions that target any vector-borne disease including transmission through mosquitos, ticks, flies, fleas, lice, aquatic snails, and bugs.

Proposals submitted to this call topic must focus on vectors responsible for the transmission of one or more diseases with the scope of the Global Health EDCTP3 JU scope (see Table 1). To that end, the following diseases are considered as relevant to this call topic:

Chikungunya, Dengue, Lymphatic filariasis, Rift Valley fever, Yellow Fever, Schistosomiasis, Onchocerciasis, Plague, Leishmaniasis, Crimean-Congo haemorrhagic fever, Sleeping sickness and malaria.

Table 1: Vector-Borne infectious diseases in the scope of the Global Health EDCTP3 JU

Vector		Disease caused	Type of pathogen	GH EDCTP3 JU scope category
Mosquito	*Aedes*	Chikungunya	Virus	NTDs
		Dengue	Virus	NTDs
		Lymphatic filariasis	Parasite	NTDs
		Rift Valley fever	Virus	EIDs
		Yellow Fever	Virus	EIDs
	Anopheles	Lymphatic filariasis	Parasite	NTDs
		Malaria	Parasite	PRDs
	Culex	Lymphatic filariasis	Parasite	NTDs
Aquatic snails		Schistosomiasis (bilharziasis)	Parasite	NTDs
Blackflies		Onchocerciasis (river blindness)	Parasite	NTDs
Fleas		Plague (transmitted from rats to humans)	Bacteria	EIDs
Sandflies		Leishmaniasis	Parasite	NTDs
Ticks		Crimean-Congo haemorrhagic fever	Virus	EIDs
Tsetse flies		Sleeping sickness (African trypanosomiasis)	Parasite	NTDs

Intervention could include novel or improved approaches of:

- Vector traps;
- Genetic manipulation;

- Sterilization agents;
- Reduced pathogen transmission by microorganisms;
- Insecticide-treated nets (ITN);
- Chemosensory interference, specifically spatial repellents, bait station and repel and lure strategies;
- Systemic insecticides and endectocides;
- Improvements in housing/urbanisation;
- Monitoring and surveillance tools.

Emphasis should be given to interventions at the community level and to the barriers of vector-control in the health system. Initiatives with linkage to climate change impact are welcome.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-06-two-stage: Innovative digital health solutions for sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5 million would allow the outcomes of this topic 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 20 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[51], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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. 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, participants 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.

[51] 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

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 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 from a country in sub-Saharan Africa, the designation of a scientific project leader 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 outcomes for this call. Proposals under this topic should aim to deliver results that are contributing to the following expected outcomes:

- Development, improvement and/or scaling-up of digital innovative solutions supporting clinical research through smart, highly innovative digital health technologies or concepts to accelerate the development of preventive, therapeutic or diagnostic interventions addressing poverty-related diseases in sub-Saharan Africa;
- Development, improvement and or Scale-up of digital technologies in public health interventions that can serve as drivers for the strengthening of health systems in sub-Saharan Africa. The proposed digital solutions should allow notably but not exclusively the improvement of development, production and access to health countermeasures, data and research evidence for better health outcomes and for the development and implementation of informed health policies and/or improved clinical guidelines in sub-Saharan Africa;
- Contribution to the implementation of national and/or overarching regional digital health strategies.

Background:

The recent rapid advancements in digitalisation and the unprecedented opportunities created by digital health, data or AI promise to accelerate the achievement of the health-related SDGs. The EU-AU summit declaration[52] identified digitalisation, health, scientific cooperation and technology sharing (through the AU-EU innovation Agenda) as key pillars of the joint EU-U commitments. Digital health and health research have a central role, both in the EU Global Health Strategy[53] and the Africa CDC's Digital Transformation Strategy. Whilst aligning with the WHO Global Strategy on Digital Health 2020-2025[54], this call will contribute to the implementation of the EU-AU summit commitments, including the EU-AU innovation agenda[55]; to the

[52] https://www.consilium.europa.eu/media/54412/final_declaration-en.pdf
[53] EU Global Health Strategy - Guiding Principles 4 and 5: https://health.ec.europa.eu/system/files/2023-03/international_ghs-report-2022_en.pdf
[54] https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf
[55] AU-EU Innovation Agenda: https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf

implementation of the EU Global Health Strategy and contribute to enabling the implementation of the Africa CDC's Strategic Plan 2023-2027, by enhancing and integrating digital and analytics approaches to public health in Africa.

Integration of digital health innovations in national and/or regional strategies and context will be instrumental to ensure long-term impact and sustainability.

Scope:

Proposals are expected to:

- Be anchored in the scope of Global Health EDCTP3 and national/regional igital health strategies;
- Target demonstrated highest medical needs in Sub-Saharan Africa;
- Tackle justified context-specific needs;
- Develop, improve or upscale solutions, with early-stage involvement of end users and health services implicated;
- Propose solutions which demonstrate seamless integration interoperability with key existing national, regional or global systems;
- Propose tools which are sustainable, accessible, open-source, evidence-based and which follow the standards of data protection and digital health global public goods[56] [57].

Propose a sound sustainability/integration strategy and prevent further fragmentation of the digital health ecosystem through a multiplication of pilots. Proposals of new tools must justify the need for additional developments and the shortcomings of available solutions. Strong evidence is expected for the justification of proposed actions. Access to evidence for existing solutions must be demonstrated. Scoping studies/Evidence generation on the need for proposed solutions are encouraged in the initiation phase of projects.

Proposals could be related to one or more of the following areas:

- Scaling-up of digital innovations that have already yielded proven results, and their transferring to other countries where they have not yet been adopted;
- Digital systems used in the implementation of clinical research and patients management;

[56] Indicative standards (to be agreed which reference should be): https://digitalpublicgoods.net/standard/
[57] https://digitalpublicgoods.net/standard/

- Integration of digital health resources and data systems in sub-Saharan African countries with limited capacity, defining best practices, open standards, and quality-assured building blocks such as data harmonisation;
- Remote access to diagnostics capabilities and health professionals;
- Optimisation and adaptation of bioinformatics pipeline for next-generation-sequencing data and omics analyses in relation to the infectious diseases in scope;
- Systems biology applications to sustain health technology manufacturing, development, and optimisation;
- Systematic architectures and warehouses, at both national and provincial level, for clinical and epidemiological data collection, respecting the FAIR guidelines (Findable, Accessible, Interoperable, Reusable);
- Adaptation of image-based analysis tools and software for diagnostics systems of diseases in scope.

Where possible, collaboration and coordination with the Team Europe Initiative on Digital Health[58] is encouraged. Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

[58] Digital Health - Africa | Capacity4dev (europa.eu)

HORIZON-JU-GH-EDCTP3-2024-02-two-stage

CONDITIONS FOR THIS CALL

Topics under Call HORIZON-JU-GH-EDCTP3-2024-02-two-stage	Type of Action	Indicative GH EDCTP3 JU Budget (EUR million)	Expected GH EDCTP3 JU contribution per project (EUR million)	Number of projects expected to be funded
Opening: 18 January 2024 Deadline stage 1: 4 April 2024				
HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage	RIA	3.50	3.50	1
Overall indicative budget		3.50		

Expected Impacts

Activities funded under the 2024 work programme of the Global Health EDCTP3 JU calls for proposals should contribute to:

- Achieve SDG3 'Ensure healthy lives and promote well-being for all at all ages' in sub-Saharan African (SSA) countries;
- Enable the implementation of the short- and medium-term actions foreseen by the AU EU Innovation Agenda (adopted in July 2023) in the area of public health and the EU Global Health Strategy (November 2022);
  - Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable diseases;
  - Expand partnerships based on equal footing, co-ownership, mutual interest and strategic priorities;
- Enhance sustainable global scientific collaboration in health research and international cooperation across sub-Saharan Africa.
- Improve opportunities for training of researchers and healthcare professionals in sub-Saharan Africa.

Proposals are invited against the following topic:

HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage: Global Health EDCTP3 JU training fellowship with return phase

Topic expected to be implemented with contributions from contributing partners from the pharmaceutical industry (to be confirmed at a later stage):

Expected JU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 3.5 million would allow the outcomes of this topic 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 3.5 million.
Type of Action	Coordination and Support Action, one project will be funded following the second stage evaluation
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 maximum amount to be granted to each third party is EUR 300,000. The support to third parties can only be provided in the form of grants. These grants are the fellowships to be awarded. For multi-annual fellowships, the amount of up to EUR 300,000 is needed.
	.

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Foster the culture of pharmaceutical innovation and entrepreneurship in sub-Saharan Africa;
- Increase the number of skilled clinical researchers and innovators in sub-Saharan Africa;
- Promote the career development and retention of skilled personnel in sub-Saharan Africa;
- Strengthen sub-Saharan African countries clinical human capital base in Research and Innovation (R&I);
- Enhance talent retention, knowledge circulation and uptake across the research and innovation landscape in sub-Saharan Africa;
- Establish sustainable and mutually beneficial collaboration between clinical research organisations, academia, and Industry Partners across sub-Saharan Africa and Europe.

Background:

Sub-Saharan Africa (SSA) has a disproportionally low number of skilled researchers and innovators working on interventions against infectious diseases that are highly prevalent in SSA. To establish a sustainable and robust ecosystem of clinical research and innovators in sub-Saharan Africa synergy between funders, academia, and industry is planned to advance relevant skills. This Global Health EDCTP3 training fellowship programme will target early and mid-career African global health scientists seeking international academic credentials and other professional enrichment.

By providing this funding for return-home R&D studies, after a period training enriched with industry mentorship, the fellowship programme will enable the alumnae fellows to position themselves as pivotal leaders in improving global health and R&D equity.

Where relevant, it will be important for proposals to consider and support the existing and emerging partnerships between the EU/Team Europe and the AU and their key agencies, notably the Team Europe Initiatives on MAV+, One Health, Public Health Institutes, and the collaboration with the Africa CDC and the AMA. Moreover, collaborations with the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organisation (AIPO) should also be fostered as well as strengthened promoting the development and assessment of innovative tools.

It will also be important that the projects arising from this call will contribute to the implementation of the short-term and medium-term actions of the AU-EU Innovation Agenda around Public Health.

Scope:

Proposals submitted to this topic should implement a master's level training programme in a discipline relevant for the Global Health EDCTP3 JU, providing transferable R&D skills, fostering innovation and entrepreneurship, incl. commercialisation of results, Intellectual Property Rights, communication, public engagement, and citizen science. The training provided by the academic institutions is expected to be complemented by training modules provided by pharmaceutical companies. It is expected that pharmaceutical companies will join the consortium as beneficiaries and/or associated partners at a later stage. The companies are expected to bring cash or in-kind contributions to the training programme for the fellows.

The training will address the research and development value chain from pre-clinical to clinical research including pharmaceuticals and vaccines.

Proposals must demonstrate all of the following:

- A high-quality training programme related to R&D on diseases in the scope of the Global Health EDCTP3 JU at master level in global health/clinical research;
- 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;
- Design of a programme where training for each fellow includes a first phase (or outgoing phase) of minimum 12 and maximum 24 months enrolment into an academic organization, and a second phase (or return phase) of at least 12 months in the country of origin of the fellow;
- A robust training and mentorship mechanisms to support the fellows through their first training phase and second home return phase;
- Linkages with other Global Health EDCTP3 JU actions should be foreseen as relevant (e.g. Global Health EDCTP3 Training Networks or Global Health EDCTP3 Genomic Epidemiology Networks).

Proposals should be made by 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.

The proposals must explain how many fellows they plan to recruit, what the cost of the training in the first phase will be and how much funding will be provided to the fellows for the return phase.

Based on the described skills and curricula offered by the successful consortium, future fellows will apply to the available training opportunities in line with their own professional development plans.

Proposals should also clearly outline how future fellows will be mentored in the development and implementation of the second phase (return phase) at the home institution in SSA.

In-kind and financial contributions from private (profit and non-profit) entities, clinical research organisations and others interested in this scheme are encouraged. Financial contributions can be made with or without direct participation in the project implementation.

Especially, consortium members established in countries that are not eligible for the Global Health EDCTP3 JU funding, will have to cover the costs related to their tasks within the project without JU funding.

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

OTHER ACTIONS NOT SUBJECT TO CALLS FOR PROPOSALS

1. External expertise

This action will support the use of appointed independent experts for the monitoring of running actions (grant agreement, grant decision, public procurement actions, financial instruments) funded under Horizon Europe and include ethics checks, where appropriate, as well as compliance checks regarding the Gender Equality Plan eligibility criterion.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2024

Indicative budget: EUR 1000 from the 2024 budget.

2. Mobilisation of research funds in case of Public Health Emergencies

Expected Outcome:

Proposals should set out a credible pathway to contributing to one or several expected impacts of this work programme.

Project results are expected to contribute to the following expected outcome:

Allow the Union and sub-Saharan African countries to respond to Public Health Emergencies.

Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases. This will allow the EU and sub-Saharan African member countries of the EDCTP Association to respond to public health emergencies. Funds will be raised if a public health emergency is to occur[59]. For example: a public health emergency that is considered to be of international concern (PHEIC) by the World

[59] Should there be no Public Health Emergency in 2024, the indicative budget may be reallocated.

Health Organization; a public health emergency under Regulation (EU) 2022/2371[60]; or a public health emergency under applicable national frameworks and regulations. I

In line with Article 195 (b) of the EU Financial Regulation[61], funding will be raised to award grants without a call for proposals in exceptional and duly justified emergencies.

At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be widely communicated, including on the Global Health EDCTP3 JU website and to the National Contact Points.

The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances;

and/or ·

The award of additional funding for ongoing grant agreements funded through EU Framework Programmes for Research and Innovation to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing EU Framework Programmes for Research and Innovation grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing EU Framework Programmes for Research and Innovation actions.

It is expected that quality-controlled data are shared in accordance with the FAIR[62] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in the

[60] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance) OJ L 314 6.12.2022, p. 26 (see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371&qid=1673372768554)

[61] Article 195 (b) of the Financial Regulation 2018/1046 'Grants may be awarded without a call for proposals only in the following cases: […] (b) in other exceptional and duly substantiated emergencies'.

[62] See the Horizon Europe programme guide available on the Funding & Tenders portal at https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

introduction to this work programme and in parts A to G of the General Annexes to the Horizon Europe work programmes 2023-2024.

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

Specific conditions	
Indicative timetable	Will depend on the Public Health Emergency
Indicative budget	EUR 1.00 million from the 2024 budget
Type of Action	Will depend on the Public Health Emergency
Procedure	The following derogation to the evaluation procedure described in General Annexes F applies to open invitations to submit applications: In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	The action may also include justified derogations from the standard limits to financial support to third parties (maximum EUR 60,000 unless justified). Where applicable, the relevant grant agreement options will be applied.
Legal and financial set-up of the Grant Agreements -	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085

Standard deliverables	establishing[63], grants that implement clinical studies awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants 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, participants 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.

[63] 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.