

Global Health EDCTP3

Info Day 2025

11 February 2025 09:00 - 12:30 CET

Co-funded by the European Union





Welcome

Lara Pandya

Team Leader Strategic Partnerships and Communications, Global Health EDCTP3



Time	Торіс	Speaker
09:00-09:05	Welcome	Lara Pandya, Team Leader Strategic Partnerships and Communications
09:05-09:10	Opening remarks	Michael Makanga, Executive Director
09:10-09:20	Global Health EDCTP3 overview	Liesbet De Cock, Head Scientific Operations
09:20-09:30	EU Policy context	Jan Paehler, Policy Officer, DG RTD, European Commission
09:30-09:40	Joining the EDCTP Association	Tom Nyirenda, Strategic Partnerships and Capacity Development Manager, Head of Africa Office EDCTP Association



Time	Торіс	Speaker
09:40-10:25	Work Programme 2025: Calls for proposals and topics	Liesbet De Cock, Head Scientific Operations
		Aleksandra Conversano, Scientific Programme Officer
		Jean-Marie Vianney Habarugira, Senior Scientific Officer
10:25-10:55	Financial and legal matters	Vincent Declerfayt, Head of Finance and Administration
		Laurent Schell, Legal Officer
10:55-11:35	Q&A session	
11:35-12:05	Lump-sum (CSA topics only)	Vincent Declerfayt, Head of Finance and Administration
		Silvia Garcia, Scientific Project Officer
12:05-12:25	Q&A session	
12:25 -12:30	Closing	Lara Pandya, Team Leader Strategic Partnerships and Communications

Housekeeping

- The meeting is being recorded and will be made available after the Info Day
- All participants are muted
- Questions are to be sent via the Q&A
- Participants can upvote questions



- Two Q&A sessions: one on the Work Programme call topics and one on lumpsums
- FAQ document will be published ten working days after the Info Day







Opening remarks

Michael Makanga

Executive Director, Global Health EDCTP3



Global Health EDCTP3 overview

Liesbet De Cock

Head Scientific Operations, Global Health EDCTP3

Global Health EDCTP3

Established in 2021, Global Health EDCTP3 is a **partnership** between the **European Union**, represented by the **European Commission**, and the **EDCTP Association**, representing the governments of 15 European and 30 sub-Saharan African countries.

Global Health EDCTP3 contributes to:

The Sustainable Development Goals



- The EU Global Health Strategy
- The AU-EU Innovation Agenda



EU Glob

Health Strated







Strategic approach



Vision

- Reduce the socioeconomic **burden of infectious diseases** in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies.
- Increase **health security** in sub-Saharan Africa and globally, by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases.



Mission

To support global collaborative research, capacity strengthening, and international initiatives **to accelerate the development, evaluation, and implementation** of interventions to prevent, identify, and treat infectious diseases including emerging/re-emerging infections in SSA to reduce overall mortality and morbidity.



Strategic approach





Advance biomedical interventions towards improved overall health

Research capacity development



Enhance

coordination and alignment of countries around a common SRIA



Strengthen

capacity for outbreaks/ epidemic/ pandemic preparedness



Networking,

building partnerships and strategic alliances



Scope

We focus on the **major infectious disease threats** facing sub-Saharan Africa.

We tackle all stages of clinical evaluation but particularly **later-stage studies** with a special focus on vulnerable population groups.

We strengthen and build **research capacities** in sub-Saharan Africa.



Governance structure







EU policy context

Jan Paehler

Policy Officer, European Commission, DG RTD

Governance structure



Ekaterina Zaharieva Commissioner for Startups, Research and Innovation

COMPETITIVENESS COMPASS



The future — — of European competitiveness



Mario Draghi



Global Health Strategy – Better health for all in a changing world

 The Commission adopted the <u>strategy</u> in Nov. 2022, Council Conclusions 2024.

Europear Commiss				
Home > Press corner > EU	Global Health Strategy			
Available languages: Eng	aa ∽			
Press rokase 30 November 2022 Brussels				
EU Global Health Strategy to improve global health security and deliver better health for all				
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on the Global Gateway. As the external dimension of the an Health Union, the strategy is designed to guide EU acti



- Part of the <u>EU Global Gateway</u> and represents the external dimension of the European Health Union.
 - Deliver better health and well-being across the life course
 - Strengthen health systems and advance universal health coverage, including research
 - Prevent and combat health threats, pandemics, through One Health
- Expand bilateral, regional, and global partnerships through Team Europe approach
- 20 guiding principles
- Global Health EDCTP3 JU mentioned as key initiative



EU contribution to Global Health EDCTP3

- As a strategic partner, the EU seeks to enhance cooperation with Africa to promote actions targeted to finding solutions to challenges that are global in nature and mutually important for Africa and Europe.
- The Commission has supported the establishment of EDCTP since the first programme was launched in 2004.
- The Global Health EDCTP3 is a key instrument for implementing the AU-EU Innovation Agenda and the EU Global Health Strategy.
- The governance of the Global Health EDCTP3 is led by a Governing Board, in which both the EDCTP Association and the European Commission, representing the Union, have equal votes.



Funding 2021-2031 €1.86Bn EDCTP

> European Union €910 M

Member States (EDCTP Association) €550 M

Third parties €400 M

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Regional EU-AU partnership in health

EU-Africa: Global Gateway Prosperity Package - Health

MAV+

Manufacturing & access to vaccines, medicines & health techs.

Digital Health

for UHC and Pandemic Preparedness

Public Health Institutes

Support core functions

Regional collaboration Collaboration Africa/Europe <u>Health Security /</u> <u>One Health</u> Coordination Surveillance Labs Workforce Research



Team Europe Initiatives

	MAV+	Digital Health	Public Health	Health Security /
	(<u>link</u>)	(<mark>link</mark>)	Institutes	One Health
Indicative financial contributions (EUR)	TE: 1.9B	TE: >100M	TE: 71.8	TE: >350M
	EC: 580 M	EC: 27M	EC: 50M	EC: 123M
Members	EC, BE, FR, DE,	EC, DE, FR, BE,	EC, FI, DE, FR,	EC, BE, FR, DE,
	NL, ES, PT, EIB	PT	BE, PT	ES, PT, SE EIB
Key partners	Africa CDC, PAVM, AUC, AUDA-NEPAD- AMRHs-AMA, international partners	Africa CDC, AUC	Africa CDC, AUC, RECs, WHO, IANPHI	Africa CDC, AUC, RECs, WOAH and the Quadripartite (WOAH-FAO- UNEP-WHO)

Further information: <u>INTPA-G4@ec.europa.eu</u>



Association to Horizon Europe















Joining the EDCTP Association

Thomas Nyirenda

EDCTP Association

Role of the EDCTP Association

One of the two founding members of the GH-EDCTP3-JU, representing its European and SSA member countries in the Governing Board

Europe office, The Hague, The Netherlands

- Oversees governance matters in relation to the GH-EDCTP3-JU through the EDCTP Association Board & GH-EDCTP3 JU Committee
- Oversees relationship management with European member states & stakeholders
- Contributes to GH-EDCTP3-JU communication & outreach activities

Africa Office, Cape Town, South Africa

- Provides technical support for the design & implementation of the GH-EDCTP3-JU capacity development activities
- Oversees relationship management with African member states & regional stakeholders
- Contributes to GH-EDCTP3-JU communication & outreach activities



EDCTP Association Members

European Countries

- 1. Austria
- 2. Belgium
- 3. Denmark
- 4. Finland
- 5. France
- 7. Ireland
 8. Italy
 9. Luxembourg

6.

10. Netherlands

Germany

African countries

- 1. Benin
- 2. Burkina Faso
- 3. Cameroon
- 4. Cote d'Ivoire
- 5. Democratic Republic 15. Liberia
- of the Congo
- 6. Congo
- 7. Eswatini
- 8. Ethiopia
- 9. Gabon
- 10. The Gambia

- 11. Ghana
 12. Guinea-Bissau
 13. Guinea-Conakry
 14. Kenya
 c 15. Liberia
 16. Mali
 17. Malawi
 - 18. Mozambique
 - 19. Namibia
 - 20. Niger
 - 21. Nigeria

12. Portugal

11. Norway

- 13. Spain
- 14. Sweden
- 15. United Kingdom
 - 22. Rwanda
 - 23. Senegal
 - 24. Sierra Leone
 - 25. Somalia
 - 26. South Africa
 - 27. Tanzania
 - 28. Uganda
 - 29. Zambia
 - 30. Zimbabwe

Aspirant members

- 1. Angola
- 2. Switzerland



Procedure





When seeking membership countries commit to:

- Minimum contribution of €200,000 annually within the scope of the EDCTP programme (in cash, in-kind, or both).
- Cash contributions for administration expenditure: costs for the EDCTP Association's internal business related to participation in the GH EDCTP3 JU.

Calculated as fixed contributions (40%) to be paid equally by all members and (60%) which will be calculated according to the member state's GDP. African members cover 10% and European members cover 90% In-Kind Contribution to Additional Activities:

- Main mechanism by which EDCTP Association members can make inkind contributions to the GH-EDCTP3-JU
- Activities funded & managed by one or more participating countries – independently or jointly - that fall within the scope of the GH EDCTP3 JU
- **Examples**: Laboratory/Clinical site infrastructure, Personnel, Expertise etc.

Active participation in the EDCTP General Assembly

 Observe all the rights and obligations as outlined in the internal regulations of the EDCTP Association



Key message:

Countries may join the EDCTP Association at any time. However, for legal entities to

be eligible for funding under the open calls for proposals their respective country

must be a member of the EDCTP Association by the time of grant agreement

signature (typically 6-8 months post-call closure).





Work Programme 2025 – Calls for proposals and topics

Liesbet De Cock Head of Scientific Operations, Global Health EDCTP3

Aleksandra Conversano Scientific Programme Officer, Global Health EDCTP3

Jean-Marie Vianney Habarugira Senior Scientific Officer, Global Health EDCTP3

2025 Work Programme

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Adopted by the Governing Board of Global Health EDCTP3 Joint Undertaking on 13 December 2024



Includes 4 two-stage open and competitive calls covering 7 topics



Includes a "mobilisation of research funds in case of public health emergencies"



Total indicative budget for Calls for proposals and other actions not subject to Calls for proposals: € 214M*



2025 Work Programme – 4 open competitive Calls

Calls	Topic Code	Call Topic Title	Budget (€)	Total budget(€)	
01	HORIZON-JU-GH-EDCTP3-2025- 01 -TB-01-two-stage	Global collaboration action for the development of vaccines for reducing the disease burden of Tuberculosis in sub-Saharan Africa	45,9M	122,7M	
	HORIZON-JU-GH-EDCTP3-2025- 01-MALARIA-02-two-stage	Global collaboration action for research on existing Malaria therapeutics and clinical development of new antimalarial candidates	30,9M		
	HORIZON-JU-GH-EDCTP3-2025- 01 -NTD-03-two-stage	Accelerating the development of prophylactic vaccines against Neglected Tropical Diseases (NTDs) in sub-Saharan Africa	45,9M		
02	HORIZON-JU-GH-EDCTP3-2025- 02-FELLOWSHIP-01-two-stage	Global Health EDCTP3 JU and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling	6,7M*	6,7M*	
03	HORIZON-JU-GH-EDCTP3-2025- 03-NETWORKS-01-two-stage	Global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia	40M*	40M*	
04	HORIZON-JU-GH-EDCTP3-2025- 04 -CH-01-two-stage	Global collaborative action tackling Diarrheal Diseases in the context of Climate and Health	30,6M	44,6M	
	HORIZON-JU-GH-EDCTP3-2025- 04-ACCESS-02-two-stage	Transformative Innovations in global health	14M		

+ Mobilisation of research funds in case of Public Health Emergencies

€ 1M



HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage

Global collaboration action for the development of vaccines for reducing the disease burden of tuberculosis in sub-Saharan Africa



HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage

Global collaboration action for the development of vaccines for reducing the disease burden of tuberculosis in sub-Saharan Africa

Research and Innovation Action (RIA) Indicative call topic budget: EUR 45,9 M Expected project size: maximum of EUR 15.3M

Expected outcomes (at least two, with the first being mandatory)

- Obtain evidence of immunogenicity, efficacy, safety or clinical utility on vaccine candidates under development and licensed vaccine(s)
- Generate clinical data on TB prophylactic vaccines serving adolescents and adults, and including where
 appropriate pregnant and lactating women, new-borns, children, other vulnerable and neglected populations,
 and people with co-infections and co-morbidities at risk in SSA
- Contribute to the data package related to immunisation/vaccination enabling public health authorities and policy makers to recommend on vaccination strategies, publish updated or new evidence-based clinical guidelines and best practices or design tailor-made TB policies targeting SSA



HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage

Global collaboration action for the development of vaccines for reducing the disease burden of tuberculosis in sub-Saharan Africa

Scope

- Development of vaccine candidates under research on licensed TB vaccines, especially targeting the population in low-middle countries, particularly in SSA
- Early and/or late-stage clinical studies to evaluate the safety, immunogenicity, efficacy and/or clinical utility on vaccine candidates under development and licensed vaccines in sub-Saharan Africa
- Proposals are to generate clinical data on TB prophylactic vaccines in adults and adolescents, and including where appropriate, pregnant and lactating women, new-borns, children, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA when relevant. A comparative arm with BCG and an assessment of overall health outcomes may be included when appropriate.
- Out of scope: Implementation research



HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage

Global collaboration action for research on existing malaria therapeutics and clinical development of new antimalarial candidates



HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02two-stage

Global collaboration action for research on existing malaria therapeutics and clinical development of new antimalarial candidates

Research and Innovation Action (RIA) Indicative call topic budget: EUR 30,9 M Expected project size: maximum of EUR 10,3 M

Expected outcome (at least two)

- Generate clinical data progressing development of new or improved antimalarial treatment regimen combatting drug resistance.
- Progress new drug(s) and/or drug combinations towards registration for treatment of malaria in sub-Saharan Africa
- Generate clinical data on special populations, including pregnant women, newborns, children, adolescents and immune-compromised individuals in living in high transmission regions.
- Generation of evidence on resistance to current treatments including combined therapies, as secondary outcome



HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02two-stage

Global collaboration for research on existing malaria therapeutics and clinical development of new antimalarial candidates

Scope

- Clinical trials (from Phase 2a onwards) evaluating safety, efficacy and effectiveness for novel therapeutic candidates or combinations of existing and new antimalarials
- Generate clinical data targeting children, pregnant women, and immune-compromised individuals or adolescents living in high transmission regions as relevant
- Interventions may target both P. Falciparum and/ or P. Vivax.
- Promising transmission blocking agents may be included as part of combination therapies
- Evidence on resistance to current treatments including combined therapies as secondary outcome
- Proposals are encouraged to embed if possible:
 - · Long term effectiveness studies through aligned primary endpoints where possible;
 - Generation of pharmacovigilance data on currently registered therapeutics or candidates in late-stage efficacy trials.



Out of scope: The development of prophylactic vaccines and monoclonal antibodies

HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-two-stage

Accelerating the development of prophylactic vaccines against neglected tropical diseases (NTDs) in sub-Saharan Africa


HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-twostage

Accelerating the development of prophylactic vaccines against neglected tropical diseases (NTDs) in sub-Saharan Africa

Research and Innovation Action (RIA) Indicative call topic budget: EUR 45,9 M Expected project size: maximum of EUR 15,3 M

Expected outcome (least one)

- Generate data on novel or existing vaccines to make progress towards prevention, control and elimination of NTDs in sub-Saharan Africa
- Improve the understanding of barriers for progression of new or improved vaccines against NTDs through the R&D pipeline
- Generate clinical data including pregnant and lactating women, newborns, children, adolescents, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA as relevant.



HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-twostage

Accelerating the development of prophylactic vaccines against neglected tropical diseases (NTDs) in sub-Saharan Africa

Scope

- Clinical studies to evaluate the safety, immunogenicity, efficacy in Africa in NTDs
- General population and/or, when relevant, vulnerable and neglected populations morbidities at risk in SSA including pregnant/lactating women, new-borns, children, adolescents, co-infections/morbidities.
- Development of integrated preventive measures across NTDs and combined approaches targeting the host/reservoir (One Health Research) is strongly encouraged
- **Out of scope:** Implementation research and any research on Chagas, chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

NTDs in scope:

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.

To ensure diversification of the portfolio across different diseases, the funding decision will consider ranking of the proposals taking into account diversity of the respective diseases for proposals above the funding threshold.



Global Health EDCTP3 JU and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling



Global Health EDCTP3 JU, and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

Coordination and Support Action (CSA) Indicative call topic budget: EUR 6,7 M Expected project size: maximum of EUR 1,34 M

- Contributing Partner involvement under discussion (to be published before call closure)
- Pilot Lump sum
- EDCTP Association as Project coordinator from the second stage application
- Expected outcomes (at least three)
 - Increase the number of public health experts: skilled epidemiologists, biostatisticians, and infectious diseases modellers in SSA
 - Promote the career development and retention of skilled personnel in SSA
 - Strengthen sub-Saharan African countries clinical human capital base in Research and Innovation
 - Enhance talent retention, knowledge circulation and uptake across the research and innovation landscape in SSA
 - Establish sustainable and mutually beneficial collaboration between national public health institutes, clinical research organisations and academia across SSA and Europe



Global Health EDCTP3 JU, and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

Scope

- A high-quality training programme: 1) Master's training in Epidemiology and/or Biostatistics, or broader Master's in public health majoring in epidemiology or biostatistics, or 2) Specific training courses/seminars/workshops infectious disease mathematical modelling
- 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
- Robust mentorship and supervision mechanisms to support fellows through to timely successful course completion
- The applicant must be an organisation with an established legal entity in SSA
- Proposals must be submitted by a consortium of institutions which must provide above mentioned trainings for up to 50 early- to mid-career researchers per consortium;
- Proposals should provide details on the methodology for linking clinical research aspects with the translation into healthcare practice and policy
- The fellow must:
 - Be resident of or be willing to relocate to a sub-Saharan African country, member of the EDCTP Association;
 - Not have been funded under a similar previous EDCTP or Global Health EDCTP3 fellowship scheme before.



Global Health EDCTP3 JU, and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

In addition, for the Master's degree training

- Master's programme must include a R&D component aligned with the scope of the Global Health EDCTP3 JU and must be conducted in a country in SSA in line with Africa CDC Workforce development strategy
- Proposals should include institutions with a proven track record in the provision of high-quality training with clear local and regional collaborations with National Public Health Institutes-NPHIs (or similar agencies), Ministries of Health and other academic institutions;
- The maximum fellowship duration shall be 24 months;
- Fellows for the Master training must be employed or have guaranteed employment for a minimum of two years after the expiration of the grant

In addition, for the modelling training:

- A contributing partner, via Global Health EDCTP3, will provide funding on modelling training, meeting the need for modellers to strengthen NPHIs core functions.
- The funding will support institutions to deliver comprehensive short term Modelling training programmes, workshops and/or seminars, and provide mentorship and support to facilitate the application of acquired skills in real world settings for key LMIC implementors.



Global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia



Global collaborative action for strengthening Regional Networks of Excellence and Epidemic Preparedness Consortia Contributing Partner involvement under discussion (to be published before call closure)

- **Pilot Lump sum** •

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- EDCTP Association as Project coordinator from the first stage proposal ۰
- **Expected outcomes (all)** •

Coordination and Support Action (CSA) Indicative call topic budget: EUR 40 M Expected project size: maximum of EUR 10 M

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- Strengthening clinical research capacity to conduct multi-country clinical trials to ICH-GCP standards and compliance with WHO Guidance for Best Practices for Clinical Trials
- Enhancing collaboration and optimising the use of resources and infrastructures within the network ٠
- Offering training and mentorship to senior scientists to promote professional development and scientific leadership in clinical trials ٠
- Strengthening South-South, North-North and North-South collaborations between researchers and institutions ٠
- Encouraging and promoting networking and dialogue between researchers, communities and policy makers to maximise the ٠ impact of clinical research in Africa.
- Promote resource sharing and harmonisation ٠
- Establishing or strengthen partnerships with National Public Health Institutes ٠
- Strengthening/expanding multidisciplinary epidemiology networks, generating accelerated evidence for optimal management of ٠ patients and for guiding public health response to any severe infectious outbreak caused by pathogens within the scope of Global Health EDCTP3 Health EDCTP3

Global collaborative action for strengthening Regional Networks of Excellence and Epidemic Preparedness Consortia

Scope (three of the following)

1) Expertise

- Strengthening expertise on clinical research in all disease areas in the scope of the Global Health EDCTP3. Proposals on HIV/AIDS clinical research are encouraged to align with activities supported by PEPFAR across SSA;
- Strengthening expertise and preparedness for research response to emerging and re-emerging diseases with epidemic potential. Proposals are encouraged to align with activities supported by other funders;
- Supporting National Public Health Institutes in collaboration with Team Europe Initiative. Strengthening/establishment, in conjunction
 with African CDC, of at least one ICH-GCP-compliant clinical trial site (compliant with WHO Guidance for Best Practices for Clinical
 Trials).
- Pool of interdisciplinary experts organised in networks Including at least one NPHI, able to provide accelerated evidence on Infectious diseases.
- Training of a specified number of clinical research associates, certified to monitor clinical trials for progress and quality.
- Strengthening the ethics, regulatory, and pharmacovigilance capacities.



Global collaborative action for strengthening Regional Networks of Excellence and Epidemic Preparedness Consortia

2) Training, mentorship and support to senior researchers

- Develop a comprehensive training/mentorship plan to support career development through dedicated courses, short term staff exchange programs, and active rotation process among sites for mentors/trainers and trainees
- Support a specified number of senior researchers to conduct a research project leveraging the Infrastructure, network and expertise supported through this call and EDCTP2 funding

3) Partnerships

- Enhance South-South and North-South collaboration, and strengthen partnership with National Public Health Institutes and regional public health bodies
- Propose a sustainability plan and networks that can be pivoted to respond to outbreaks within the respective sub-regions
- Provide a coordination function to align with Africa CDC and other funders' strategies and activities to strengthen the African clinical trial ecosystem

4) Infrastructure

- Upgrade at least one additional clinical laboratory, accredited to the GCLP standards.
- Develop/upgrade or expand a functioning data management service, which can be used by the network or contracted by external clinical trial sponsors.



HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage

Tackling diarrhoeal diseases in the context of climate and health



HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage

Tackling diarrhoeal diseases in the context of climate and health

Research and Innovation Action (RIA) Indicative call topic budget: EUR 30,6 M Expected project size: maximum of <u>EUR 5,1 M</u>

Expected outcomes (at least two, with the first being mandatory)

- Develop interventions to identify and control diarrhoeal diseases through generating late-stage clinical data in sub-Saharan Africa;
- Implementation research combining interventions with current standard of care (including vaccines);
- Generate evidence to evaluate the populations and geographies of most vulnerable to diarrheal diseases, understand the key underlying factors including those related to climate change, and understand the barriers to protect the people affected.



HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage

Tackling diarrhoeal diseases in the context of climate and health

Scope

Late-stage clinical studies evaluating safety, efficacy, accelerating the development of novel or existing treatment against DD, or late-stage development of novel or existing diagnostics against DD

Where appropriate, implementation research combining interventions with current standard of care (including vaccines) as well as complementary research components that help to improve the understanding on how diarrhoeal diseases are currently influenced by climate and weather and may be further exacerbated by climate change.

Multidisciplinary approaches integrating adjacent sectors are strongly encouraged (i.e. nutrition, IPC/WASH). Proposals are to generate clinical data serving newborns, children, people with co-infections and comorbidities and other vulnerable and neglected populations at risk in SSA when relevant.

Applicants are expected to provide methodologies for translating research findings into public health/climate practice and policy guidelines.

Pathogens in scope:

Rotavirus, shigella, cholera, enterotoxigenic E. coli, cryptosporidium, and norovirus

Including solutions having the potential to reduce AMR in context of above pathogens.

N.B. Other pathogens are out of scope



HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage

Transformative innovations in global health



HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage

Transformative innovations in global health

Research and Innovation Action (RIA) Indicative call topic budget: EUR 14 M Expected project size: maximum of EUR 1.4-2.33 M

Expected outcomes (at least one)

- Generate beyond proof-of-concept data with innovative ideas or inventions that will improve the uptake, adherence or implementation of preventative/treatment/diagnostic solutions
- Progress an innovative approach that makes products and services (more) accessible and affordable to commercially unattractive markets or serves vulnerable populations in SSA
- Progress an innovative approach that addresses community-driven and trusted demand for new or repurposed tools, including those needed by hard-to-reach communities
- Deliver innovative technologies which can generate accelerated cross-disease tools, including communicable disease specific solutions
- Repurpose or extend the use of an existing preventative/treatment/diagnostic intervention.



HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage

Transformative innovations in global health

Scope

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- Innovations in R&D or products implementation, focusing on new or improvement of existing medicinal products and delivery systems; including but not limited to use of new technologies
- New interventions or improvements of an existing intervention for age-specific formulations or underserved populations; including but not limited to paediatric or geriatric formulations generating data for patients with co-morbidities;
- Development of tools to improve affordability or accessibility of preventative/treatment/diagnostic solutions; including but not limited to thermostable or humid resistant formulations, lower cost of goods, dose sparing approaches
- Development of delivery systems to improve efficacy or uptake of the preventative/treatment/diagnostic solution; including but not limited to assessing different route of administration ensuring easier access, new or improved devices or equipment ensuring higher efficacy or uptake, etc.
- Leverage existing data to repurpose and expand the use of the preventative/treatment/diagnostic intervention. including but
 not limited to using well-established safety and pharmacological data from its use in one disease area into the infectious
 disease field in the scope of the Global Health EDCTP3
- Scope includes infectious diseases in scope of the Global Health EDCTP3 including HIV/AIDS. The proposals are to be beyond Proof of Concept.

Out of scope: infectious diseases not in scope of the Global Health EDCTP3, as well as potential solutions treating chronic diseases (potentially caused by infections) and non-communicable diseases



The two-stage application process

Stage 1 Application Successful projects to be invited to 2nd stage, (Approx. 3 x available budget)

Stage 2 Application

- Shorter (outline) proposal
- Two criteria to be evaluate: Excellence and Impact

Note: For HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01two-stage: EDCTP Association is the coordinator at first stage

- Only by Invitation to successful stage 1 applicants
- Full proposal
- Changes in consortium allowed, including Coordinator*
- Independent evaluation from stage 1
- All three criteria -Excellence, Impact and quality /Efficiency of Implementation- to be evaluated

*Note: For HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01two-stage and For HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage: EDCTP Association is the coordinator







Other actions non-subject to calls for proposals

Mobilisation of research funds in case of public health emergencies

Grants not subject to calls for proposals Research and Innovation Action (RIA) or Coordination and Support Action (CSA) Indicative budget : EUR 1 M

Expected Outcomes:

- Contribute to one or several expected impacts of this work programme
- Allow the European Union and sub-Saharan African member countries of the EDCTP Association to respond to Public Health Emergencies
- Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases.



Other actions non-subject to calls for proposals

Mobilisation of research funds in case of public health emergencies

Scope and process:

- In case of duly justified health emergencies(*)
- F&T Portal and broad communication
- 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.

(*) In case of 1) a public health emergency (such as a public health emergency of international concern (PHEIC) according to the World Health Organization; 2) a public health emergency under Regulation (EU) 2022/2371 70; or 3) a public health emergency under applicable national frameworks and regulations).





Legal and financial aspects

Vincent Declerfayt

Head of Finance and Administration, Global Health EDCTP3

Laurent Schell Legal Officer, Global Health EDCTP3



Legal aspects



Eligibility to receive funding



(FRII)

EU COUNTRIES

- Member States (MS)
- Overseas Countries and Territories (OCT) linked to MS

NON-EU COUNTRIES

- Countries associated to Horizon Europe (AC)
- Countries which are members of the EDCTP Association
- Other countries when announced in the call or exceptionally if their participation is essential



SPECIFIC CASES

For example:

- EU bodies
- International organisations (IO)

- International European research organisations are eligible for funding

- Other IO can be eligible for funding only exceptionally



Consortium

To be eligible, consortia must include:

- 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 in an associated country that is a member of the EDCTP Association; and
- At least one independent legal entity established in a sub-Saharan African (SSA) country that is a member of the EDCTP Association.



Gender Equality Plan

Having a gender equality plan is an <u>eligibility criterion</u> for Public bodies, Higher Education establishments and Research organisations from Member States and Associated Countries.

- It must cover:
- ✓ publication: formal document published on the institution's website and signed by the top management
- ✓ dedicated resources: commitment of resources and expertise in gender equality to implement the plan
- \checkmark data collection and monitoring
- ✓ sex/gender disaggregated data on personnel and annual reporting based on indicators
- ✓ training: awareness raising/training on gender equality and unconscious gender biases for staff
- A self-declaration will be requested at proposal stage.

Global Health EDCTP3

• If the proposal is selected, having a GEP will be necessary <u>before</u> GA signature.

Types of participants

Grant Agreement articles 7 to 9 GA

Beneficiary

- Must be eligible for funding
- Signs the grant agreement

Associated partner

- Is not eligible for funding
- Performs tasks but may not claim costs



- Does work and invoices the beneficiary
- The beneficiary may declare the invoice

Affiliated entity

- With a legal or capital link with the beneficiary
- Does work and may declare costs

Third party providing contributions

- Does not perform tasks, only provides a contribution to a
- beneficiary
 - The beneficiary may declare the costs under its own budget



Components of the Grant Agreement

The Grant Agreement is composed of:

- Preamble
- Terms and Conditions (including Data Sheet)
- Annex 1 Description of the action
- Annex 2 Estimated budget for the action
- Annex 2a Additional information on unit costs and contributions (if applicable)
- Annex 3 Accession forms (if applicable)
- Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)
- Annex 4 Model for the financial statements
- Annex 5 Specific rules (if applicable)



Project implementation



Deliverables and milestones

Deliverables continuous reporting Milestones Continuous reporting Periodic reporting

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Project Reporting



Ethical Aspects

Documentation

and record-keeping



Dissemination activities



Exploitation of project results and IPR



Deliverables and milestones

Annex 1 – Description of the Action

LIST OF DELIVERABLES



Grant Preparation (Deliverables screen) — Enter the info. The labels used mean:

Public — fully open (automatically posted online) Sensitive — limited under the conditions of the Grant Agreement EU classified — RESTREINT-UE/EU-RESTRICTED, CONFIDENTIE

Deliverable No	Deliverable Name	Work Package No
D1.1	Project annual reports	WP1
D2.1	Project initiation meeting Notes	WP2
D2.2	Staff recruitment report	WP2

LIST OF MILESTONES

Milestones Grant Preparation (Milestones screen) — Enter the info.				
Milestone No	Milestone Name	Work Package No		
1	Project initiation meeting held	WP2		
2	Project staff recruited	WP2		
;	Stakeholder's engagements held	WP2		

Article 21 - Reporting 21.1 Continuous reporting

j<u>St</u> Vork WP1 WP2 The beneficiaries must continuously report on the progress of the action (e.g., **deliverables, milestones**, ...) in the Portal Continuous Reporting tool

	I: HORIZ Ic: HORI	ZON-JU-I	IT) HORIZON HI-EDCTP3-2022-01 GH-EDCTP3-2022-CALL1-01	Project Researche involved I the project	n	Milestones	Critical Risks	Publications	Results	Disse activ	
	actual de labels u Public — fu	sed mea			ith an explanation	n for the delay)	In the Comm	nents, please i	ndicate if	the deliveral	ole
S E k to	ensitive –	d — REST arism to			DNFIDENTIAL, SEC	RET-UE/EU-SEC	RET under De	ecision 2015/4	144. For ite	ems classifie	d uni
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Project reporting

Article 21 – Reporting

21.1 Continuous reporting

21.2 Periodic reporting: Technical reports and financial statement





Periodic reporting

Activated at the end of a reporting period

Technical part

Part A (structured information through continuous reporting)

- Project summary
- Deliverables, milestones, risks, etc.
- Impact questionnaire

Part B (narrative part submitted in a PDF through **periodic reporting**)

- Explanation of the work carried out by the beneficiaries and overview of progress
- Explanations on deviations from DoA

Financial part

Financial statements (individual and consolidated).

Explanation on the **use of resources** and information on subcontracting and in-kind contributions by third parties (Not applicable for lump sum grants).

Certificates on the financial statements (CFS), only at final payment if threshold is reached (uploaded as PDF) (Not applicable for lump sum grants).



Ethical aspects and approvals

See Annex 1 – Description of the Action

Associated with document Ref. Ares(2022)8855197 - 20/12/2022 Ethics Summary Report

•

***	Call Reference Proposal Number	HORIZON-JU-GH-EDCTP3-2022-01
****	Acronym	

Ethics Issues

Humans	Yes
Does this activity involve human participants?	Yes
Are they volunteers for non medical studies (e.g. social or human sciences research)?	Yes
Are they healthy volunteers for medical studies?	Yes
Are they patients for medical studies?	Yes
Are they potentially vulnerable individuals or groups?	Yes

Ethics requirements Work Package:

- Requirements that must be fulfilled before grant agreement signature
- Requirements that must be fulfilled afterduring project implementation (deliverables)
- Mandatory approvals **before starting specific activities**



Contributing Partners

Who can be a contributing partner?

- Any country, international organisation or legal entity other than the Global Health EDCTP3 JU members
- ✓ that supports the objectives of the Global Health EDCTP3 JU in its specific area of research;
- ✓ that accepts the legal framework of the Global Health EDCTP3 JU by submitting an application (letter of endorsement), that details the scope of their engagement in terms of contribution (in-kind and/or financial), activities and duration;
- ✓ that is assessed and approved by the JU's Governing Board to be a Contributing Partner.



Contributing partners

How to apply to become contributing partner?

- Submit an endorsement letter to the Global Health EDCTP3 JU formally addressed to its Governing Board
- The Global Health EDCTP3 Governing Board shall assess the letter and shall approve or reject the application by way of a decision.
- Informal discussion with the PRO beforehand.



Contributing partners

Forms of contributions

• Financial Contributions (FC)

Cash

- In-kind Contributions to Operational Activities (IKOP)
 - eligible costs incurred by the Contributing Partner in implementing the project activities without JU funding.



Global Collaborative Action

Specific condition for 4 topics

- For 4 topics : TB, malaria, networks, fellowships
- Contributing Partner at level of the proposal
- Consortia to reach out for their Contributing Partners
- JU contribution to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners would allow the outcomes of the topic to be addressed appropriately

 Additional aspects of award criteria: "impact" and 'quality and efficiency of the implementation" – yet it is not an eligibility criterion




Financial aspects





Financial administration





Costs

Types of costs Forms of costs General eligibility conditions Main categories

Financial reporting

Timing Submission Financial statement Currency used in reporting Certificate on Financial Statements (CFS)

Ex-post audit



Project budget

ANNEX 2

		-			Esti	mated eligible ¹ cos	ts (per budget cate	gory)			77	0	Estimated EU contribution ²			
		Direct costs Indirect costs							EU contribution to eligible costs							
	A. Personnel costs		B. Subcontracting costs		C. Purchase costs		D. Other cost categories		E. Indirect Total costs costs ³	Funding rate % ⁴	Maximum EU contribution ⁵	Requested EU contribution	Maximum grant amount ⁶			
	A.1 Employees (o A.2 Natural person contract A.3 Seconded per	ns under direct	A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	invoiced goods and services	D.3 Transnational access to research infrastructure unit costs	D.4 Virtual access to research infrastructure unit costs	E. Indirect costs					
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs ⁷	Actual costs	Actual costs	Actual costs	Actual costs	Unit costs (usual accounting practices)	Unit costs ⁷	Unit costs ⁷	Flat-rate costs ⁸					
	al	a2	a3	b	cl	c2	ය	d2	d3	d4	e = 0.25 * (a1 + a2 + a3 + c1 + c2 + c3)	f=a+b+ c+d+e	U	g = f * U%	h	m

ESTIMATED BUDGET FOR THE ACTION



Types of costs

Direct Costs

- Specific costs which are directly linked to the performance of the action/project and which can therefore be directly booked to it
- Beneficiaries must be able to show records and supporting evidence

Indirect Costs

- Costs which cannot be identified as specific costs directly linked to the action
- No need of supporting evidence

A flat-rate of 25% of the declared direct costs (personnel and purchase costs) is automatically provided unless the entity is recipient of an operating grant from any EU funding programme, in which case the flat-rate may be reduced or removed entirely.



Forms of costs

- <u>Actual costs</u>
- Unit costs
- Flat-rate costs

General eligibility conditions for **actual costs**:

- 1. Actually incurred by the beneficiary
- 2. Incurred during the action duration
- 3. Declared under one of the budget categories set out in Article 6.2 and Annex 2
- 4. Connected to the action as described in Annex1 and necessary for its implementation

- 5. Identifiable and verifiable
- 6. In compliance with applicable national laws on taxes, labour and social security; and
- 7. Reasonable, justified and must comply with the principles of sound financial management, in particular regarding economy and efficiency



Cost categories

- 1. A. Personnel costs
 - A.1 Employees (or equivalent)
 - A.2 Natural persons under direct contract
 - A.3 Seconded persons
 - A.4 SME owners and natural person beneficiaries
 - A.5 Volunteers (not applicable)
 - A.6 Others (includes Personnel unit costs)
- 2. B. Subcontracting costs
- 3. C. Purchase costs
 - C.1 Travel and subsistence
 - C.2 Equipment
 - C.3 Other goods, works and services
- 4. D. Other cost categories
 - D.1 Financial support to third partiesD.2 Internally invoiced goods and servicesOthers
- 5. E. Indirect costs



Financial reporting

Timing

- Deadline for submission of reports 60 days after the end of the reporting period.
- Deadline for payments: 90 days after first submission (subject to approval of reports). If reports incomplete – session back to Coordinator (suspension of the payment deadline)

Submission

- All Beneficiaries receive a notification
- Each beneficiary to complete own Financial Statement in the portal
- Each beneficiary e-signs and submits (PFSIGN) Financial Statements to the Coordinator
- The Coordinator checks & submits the elements (Technical part and Financial Statements) of the Periodic Report
- EDCTP3 reviews the submitted Periodic Report and accepts or rejects it.
- Interim Payment/Payment Of the Balance is processed



Certificate on financial statements (CFS)

- CFS to be submitted with the final report
- Threshold: EUR 430,000
 - Increased from EUR 325,000 in H2020
 - Calculated on all costs
 - Tip: familiarise yourself with the CFS template early



Ex-post audits

- Article 25.2 Grant Agreement (Art. 25 Checks, Reviews, Audits and Investigations-Extension of findings)
- Cost eligibility on the costs declared
- Audited by European Commission or external audit firm

Timeframe:

- Anytime after you receive first interim payment
- up to the number of years indicated in the data sheet after payment of the balance (incl. extension of findings from other grants)

Tips:

- Be diligent and keep evidence from the FIRST DAY OF THE PROJECT
- Costs declared MUST be actual and real
- Keep time records
- Best value for money and no conflict of interest





Q&A Session

Other Info Days

- **25 February, 14:00-15:30 CET:** Online French-language Info Day hosted by the French Ministry of Higher Education and Research.
 - Registration open: <u>https://www.horizon-europe.gouv.fr/participez-la-journee-d-information-global-health-edctp3-en-francais-38687</u>
- 27 February, 12:00 CET: Online Portuguese-language Info Day hosted by the Portuguese Agency for Clinical Research and Biomedical Innovation
- **27 February (TBC):** Hybrid Spanish-language Info Day hosted by the Spanish Foundation for Science and Technology
- → Presentations and recordings will be made available on our website.



Twelfth EDCTP Forum



BETTER HEALTH THROUGH GLOBAL RESEARCH PARTNERSHIPS

15-20 June 2025 Kigali, Rwanda



www.edctpforum.eu





Lump-sums (CSA topics only)

Vincent Declerfayt

Head of Finance and Administration, Global Health EDCTP3

Silvia Garcia Scientific Project Officer, Global Health EDCTP3

Why do we use lump-sum funding?

Significant simplification potential

- Despite all simplification, funding based on reimbursement of actual costs remains complex and error-prone. Little scope for further simplification
- Lump-sums remove the obligation to report actual costs and resources
- Easier to use for beneficiaries with limited experience

Focus on content

 Less focus on financial management and more focus on the scientific-technical content of projects

Opportunity for the Global Health EDCTP3 to integrate the overall European Commission Research Family strategy, and pilot model for simplification in a pilot to learn from its programme specificities



Pilot WP 2025

Piloted for two Coordination and Supported Action (CSA) topics only:

- HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-twostage: Global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia
- HORIZON-JU-GH-EDCTP3-2025-02-FELLOW-01-twostage: Global Health EDCTP3 JU and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling





Basic principles

Lump-sum evaluation and grant agreement follow the standard approach (similar as for actual costs grants) with the same:

- Evaluation criteria
- Pre-financing and payment scheme
- Reporting periods and technical reporting, though focusing on completion of work packages

One lump sum share is fixed in the grant agreement for each work package:

PAYMENT

- Work package completed
- Payments do not depend on a successful outcome, but on the completion of activities
- Work packages can be modified through amendments (e.g. to take into account new scientific developments)
- No intention and nor basis for judging the performance of lump-sum grants more strictly than the performance of other grants

Two lump-sums options



Lump-sum fixed in the call for proposal

Type 2

You define the lump-sum in your proposal

Used for CSA topics in EDCTP 3 WP 2025



Writing a lump-sum proposal

No impact on the writing of the stage 1 (short proposal) but in stage 2 – full proposal

To write a lump-sum proposal

- Use the standard Horizon Europe application form
- Present the objectives and methodology of your project and address the expected outcomes and impacts as in any Horizon Europe proposal

To define and justify the lump-sum

- Need to provide a detailed budget table with cost estimations that are an approximation of your actual costs
- Costs estimations needed for each cost category per beneficiary (and affiliated entity if any) and WPs

Describe in detail the activities covered by

each work package.

Detailed budget table (Excel file) Fill in and submit as annex of part B How to fill in the lump sum budget table provided in Funding & Tenders portal. Best practices for lump-sum grants Future events: 27 March 2025, from 10:00h to 12:00h (CET) Lump Sum Funding in Horizon Europe: How does it work? How to write a proposal?



Project design – work packages

Work package distribution

As many as needed but not more than what is manageable

A work package (WP) is a major sub-division of the work plan of your project

- A single activity is not a WP
- A single task is not a WP
- A % of progress is not a WP (e.g. 50 % of the tests)
- A lapse of time is generally not a WP (e.g. activities of year 1)

Work packages with a long duration may be split along the reporting periods (e.g., Coordination and Management, Dissemination and Exploitation, etc.). In this way, the relevant activities can be paid at the end of the reporting period



Evaluation of a lump-sum proposal

Evaluation of lump-sum occurs at stage 2 only (full proposal)

- Your proposal will be evaluated by independent experts against the standard evaluation criteria: excellence, impact, and implementation. The cost estimations will be assessed against the proposed activities under the implementation criterion.
- Experts will:
 - ensure that the cost estimations are reasonable and non-excessive (including with checking the budget estimate on the basis of relevant statistical data)
 - evaluate whether the proposed resources and the split of the lump sum allow completing the activities described in the proposal.
 - Verify that proposals include the declaration by beneficiaries of having used their own accounting practices

The JU will provide statistical data to experts that shall be used as an orientation to ensure that budgets are reasonable and non-excessive

Applicants justify high personnel costs in the 'Any comments' tab of the Excel detailed budget table.

- If the experts find overestimated costs, they make concrete recommendations on the budget that are recorded in the Evaluation Summary Report. This will be reflected in a modified lump sum amount in the grant agreement or requested to be followed-up by the JU during GAP phase.
- Cost estimations that are clearly overestimated or underestimated lead to a decreased score under the implementation Criterion.
 Giobal Health EDCTP3

Grant agreement preparation

- The grant agreement for your project will be based on the <u>Model Grant Agreement for lump sum</u> grants.
- The 'no negotiation' principle applies. The grant agreements is prepared on the basis of the proposal you submitted. However, some changes might be necessary:
 - correcting obvious errors and inconsistencies
 - other changes necessary to comply with applicable rules
 - adjustment of the lump sum to the amount specified in the Evaluation Summary Report (ESR)
- The breakdown of lump sum shares per beneficiary and per work package is included in the grant agreement as Annex 2. The submitted detailed lump sum budget table is not part of the lump sum grant agreement.
- Once the lump sum is fixed in the grant agreement, it will not be questioned if the prices for goods or services change later on.



Budget allocation

Budget allocation (annex 2 to the grant agreement)

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	Total
Beneficiary A	250.000			50.000	300.000	250.000		300.000	1.150.000
Beneficiary B		250.000	350.000	50.000			100.000	150.000	900.000
Beneficiary C	100.000	100.000		50.000		280.000			530.000
Beneficiary D		120.000		50.000			100.000	150.000	420.000
Total	350.000	470.000	350.000	200.000	300.000	530.000	200.000	600.000	3.000.000
_								Γ	Lump si
	Shares o	of the lum	p sum pe	er WP					Maximum amour

You can **use the budget as you see fit** as long as the project is implemented as agreed. The actual distribution of the lump sum is invisible to us.

Budget transfers between work packages and/or partners require an amendment if the consortium wants to reflect them in the grant agreement.



Shares of the lump sum per beneficiary

Payment schedule

€

Types of payments

payment **Pre-financing** Same function and same rules as for other grants

 Coordinator distributes the amount according to consortium agreement

payment(s) nterim

One or more • We pay the shares of the lump sum set out in Annex 2 for the work packages completed & approved in the reporting period

balance Closes the the of ayment Ω

ılı €

- financial aspects of the grant • Partial payment for partially completed WPs possible
- Releases the amount retained for the Mutual Insurance Mechanism



Reporting and payment

- The financial report is much **simplified** and to a large extent automated.
- The financial statement for all beneficiaries is **automatically generated** (based on the accepted work packages and the corresponding lump sum shares).



Interim payments pay the lump sum shares for completed work packages.

Final payments can also pay partially completed work packages.

Payment = 350 000 + 0 + 350 000 + 0 = 700 000 €



Acceptance of work packages

- Work packages are accepted if the activities have been carried out. We can also accept them when all essential tasks have been completed, when equivalent tasks have been carried out, or when deviations have been justified.
- Lump-sum projects can be amended according to scientific-technical needs (or deviations can be justified in the reports). Use these mechanisms to make completion of work packages feasible.
- Before a lump-sum work package (that you declared completed) is rejected as incomplete, you are invited to respond to the observations of the project officer.
- If the rejection is upheld the lump sum share concerned is not paid at that point in time. You should complete the work package later and declare it at the end of any subsequent reporting period.
- If it is not possible to complete a work package by the end of the project (e.g., for technical reasons or due to force majeure), the lump-sum is paid partially in line with the degree of completion. The decision on the partial amount is taken on a case-by-case basis. You will be able to provide observations.



Ex-post controls

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Checks, reviews and audits for:

Proper implementation of the action (e.g. technical review) Compliance with the other non-financial obligations of the grant, e.g.

IPR obligations

Ethics and integrity

Open science

Dissemination

Etc.



No financial checks, reviews and audits by EU services



Ex-post controls

Consortium **needs to** Consortium doesn't need **keep** (e.g.) to keep* **Technical documents** Time-sheets Pay-slips or contracts Publications, prototypes, deliverables Depreciation policy Documentation required by good research practices such as lab books Invoices ...any document proving that ...any documents proving the the work was done as detailed actual costs incurred in Annex 1 *Participants still need to comply with financial record keeping obligations outside the grant agreement, if any (e.g., under national law or internal procedures) Same as for all Horizon Europe grants





How to fill in the detailed budget table in lump-sum proposals?



Detailed budget table for lump-sum proposals

	zon Europe Programme ed lump sum budget	Generate the Excel file in macro-free format Ready for the online submission system
	Instructions	
Go to Beneficiaries and Affiliated Entities	ist ! Double click buttons !	Go to Work packages list
Vou must not change the structure of this wo	book (e.g., do not add, remove or modify rows, columns or tabs). <u>Ap sum funding under Horizon Europe</u> is available on the Funding & s includes details on how to complete this Excel workbook. The we kcel 2016 (Mac OS) or more recent.	
You must complete the following sheets: 'BE I sheets ('BEx') will be generated automatically The information in this workbook must corresp Likewise, the tables in section 3.1 of Part B of t	ith data from the 'BE list' and 'WP list' sheets. nd to the main proposal. For example, the list of beneficiaries and	on costs' (if any). The appropriate number of individual beneficiary d affiliated entities and the list of work packages must be the same. able 3.1h 'purchase costs', and table 3.1i 'internally invoiced goods
and services'). Instructions BE list WP list Lump su	breakdown Person-months overview Summary per WP BE1	Depreciation costs Any comments Change Log 🕘

- Use Excel 2013 or a more recent version
- The currency used in the Excel template is EURO
- Read the detailed instructions on the first tab of the Excel file
- For your proposal, you must always use the file provided in the online submission system.



Fill in the beneficiaries list 'BE list' sheet

	U	ist of beneficiaries (BE) and	affiliated ent	ities (AE)		Add BE	Delete OLD_BEx backup sheets	Apply changes
BE/AE nr	Role	BE/AE name	Acronym	Country	Funding rate			
BE1	Coordinator	University 1	Uni1	Belgium (BE)	100%		Add AE to BE1	0000001-0001-0001-
BE1-AE2	Affiliated entity	Laboratory 1	Lab1	Netherlands (NL)	100%	Clear BE1-AE2		
BE3	Beneficiary	SME 1	SME1	Croatia (HR)	100%	Clear BE3	Add AE to BE3	20c30d25-feb7-4f6a-b
BE4	Beneficiary	Research organisation 1	RES1	Ireland (IE)	70%	Clear BE4	Add AE to BE4	cd288bed-6b17-4cb8-8
BE5	Beneficiary	University 2	Uni2	Estonia (EE)	100%	Clear BE5	Add AE to BE5	ca611702-69f4-4fb4-a
BE6	Beneficiary	SME 2	SME2	Luxembourg (LU)	100%	Clear BE6	Add AE to BE6	2159e514-b933-4d45-

Funding rate for EDCTP3 grants: 100%



Fill in the work packages list ('WP list' sheet)

	List of Work Packages	Add WP	! Double click buttons !	Apply changes
WP number	WP name			
WP1	Analysis			
WP2	Technical part		Clear WP2	
WP3	Experiment 1		Clear WP3	
WP4	Experiment 2		Clear WP4	
WP5	Communication & dissemination		Clear WP5	
WP6	Project management 1		Clear WP6	
WP7	Project managmeent 2		Clear WP7	



Fill in the individual beneficiary sheets ('BEx' tab)

Affiliated entities

oordinator: BE1 - BUDGET SHEET		View Summary			BE1-AE2	\sum	
000001-0001-0001-00000000000000001		University	/1		Laboratory	1	
COST CATEGORY	ITEMS		BE TOTAL COSTS	ITEMS	COST PER ITEM	AE TOTAL COSTS	BE+AE TOTAL COSTS
COSTS WORK PACKAGE 1: WP1 name							
DIRECT PERSONNEL COSTS							
1 Employees (or equivalent)							
SENIOR SCIENTISTS (or equivalent in the private sector)			0.00			0.00	0.0
JUNIOR SCIENTISTS (or equivalent in the private sector)			0.00			0.00	0.
TECHNICAL PERSONNEL (or equivalent in the private sector)			0.00			0.00	0.
ADMINISTRATIVE PERSONNEL (or equivalent in the private sector)			0.00			0.00	0.
OTHERS			0.00			0.00	0.
2 Natural Persons under direct contract			0.00			0.00	0.
3 Seconded Persons			0.00			0.00	0.
4 SME owners and natural person beneficiaries		5990	0.00		6685	0.00	0.
DIRECT SUBCONTRACTING COSTS		0000			0000	0.00	
			0.00			0.00	0.0
DIRECT PURCHASE COSTS							
1 Travel and subsistence			0.00			0.00	0.0
2 Equipment (complete 'Depreciation costs' sheet)							
Equipment			0.00			0.00	0.0
Infrastructure			0.00			0.00	0.0
Other assets			0.00			0.00	0.0
3 Other goods, works and services							
Consumables			0.00			0.00	0.0
Services for meetings, seminars			0.00			0.00	0.0
Services for dissemination activities (including website)			0.00			0.00	0.0
Publication fees			0.00			0.00	0.0
Other (shipment, insurance, translation, etc.)			0.00			0.00	0.0
OTHER COST CATEGORIES							



Fill in the individual beneficiary sheets

Personnel costs

	A	В	С	D
1	Beneficiary: BE3 - BUDGET SHEET		View Summary	
2	cb8eb8c0-aa62-4a25-a495-6eaa8dc4a243		SME 1	
3	COST CATEGORY	ITEMS	COST PER ITEM	BE TOTAL COSTS
4				
5	COSTS WORK PACKAGE 1: WP1 name			
6				
7	A. DIRECT PERSONNEL COSTS			
8	A.1 Employees (or equivalent)			
9	SENIOR SCIENTISTS (or equivalent in the private sector)	5.0	7000	35000.00
10	JUNIOR SCIENTISTS (or equivalent in the private sector)	10.0	4900	49000.00
11	TECHNICAL PERSONNEL (or equivalent in the private sector)	5.0	5300	26500.00
12	ADMINISTRATIVE PERSONNEL (or equivalent in the private sector)			0.00
13	OTHERS			0.00
14	A.2 Natural Persons under direct contract			0.00
15	A.3 Seconded Persons			0.00
16	A.4 SME owners and natural person beneficiaries		4798	0.00



Lump-sum breakdown

Part A (online forms)

				No	Name of Beneficiary	Country	Requested grant amount
				1			0
					Total		0
Even al file							
Excel file							
			· · · ·				
	ESTIMATED BREA	KDOWN OF THE LUN	NP SUM				
	WP1	WP2	WP3				
BENEFICIARIES \ WORK PACKAGES	Work package 1	Work package 2	Work package 3	Total	Pct %		
BE1: University 1	65,625.00	72,881.25		208,506.25			
BE2: University 2	29,750.00	56,000.00	62,842.50	148,592.50			
> BE2-AE3: Laboratory 1	59,250.00	48,750.00	53,400.00	161,400.00			
BE4: Research Org 1	30,000.00	61,425.00	85,275.00	176,700.00	20.76%		
BE5: Research Org 2	40,000.00	67,287.50	48,750.00	156,037.50	18.33%		
Total:	224,625.00	306,343.75	320,267.50	851,236.25	i 100.00%		
Percentage:	26.39%	35.99%	37.62%	100.00%			

- The lump-sum breakdown table is generated automatically. It displays the lump sum shares per ٠ beneficiary/affiliated entity and per work package
- It applies the funding rate you have chosen in the BE list. ۰
- In the part A of the application (online forms), you have to fill in the 'Budget for the proposal' table, entering ٠ the requested grant amount for each participant. To do so, please use the total amounts per beneficiary in the table 'Estimated breakdown of the lump sum' in the Excel file.



0.00

0.00

Summary tables

SUM OF ALL BENEFICIARIES (including AFFILIATED ENTITIES) F	OR ALL THE	WORK PACK	AGES		
		ALL BENEFICIARIES (with affiliated entities)			
COST CATEGORY	ITEMS (TOTAL)	AVERAGE COST PER ITEM	TOTAL COSTS		
COSTS WORK PACKAGE 1. Work marked	. 1				
COSTS WORK PACKAGE 1: Work packag	e 1				
A. DIRECT PERSONNEL COSTS					
A.1 Employees (or equivalent)					
SENIOR SCIENTISTS (or equivalent in the private sector)	5.0	8000.00	40000.00		
JUNIOR SCIENTISTS (or equivalent in the private sector)	2.5	5000.00	12500.00		
TECHNICAL PERSONNEL (or equivalent in the private sector)	5.0	6400.00	32000.00		
ADMINISTRATIVE PERSONNEL (or equivalent in the private sector)	13.0	7384.62	96000.00		
OTHERS	0.0		0.00		
1.2 Natural Persons under direct contract	0.0		0.00		
1.3 Seconded Persons	0.0		0.00		
1.4 SME owners and natural person beneficiaries	0.0		0.00		
3. DIRECT SUBCONTRACTING COSTS					
	0.0		0.00		
DIRECT PURCHASE COSTS					
.1 Travel and subsistence	20.0	470.00	9400.00		

- The 'Summary per WP' and 'Personmonths overview' tables are produced automatically.
- They will be used by evaluators during the evaluation of your proposal.

TOTAL PERSON-MONTHS												
SENEFICIARIES \ WORK PACKAGES	WP1 Work package 1	WP2 Work package 2	WP3 Work package 3	Total	Pct %							
SE1: University 1	7.50	0.00	8.00	15.50	17.32%							
SE2: University 2	4.00	8.00	9.00	21.00	23.46%							
> BE2-AE3: Laboratory 1	6.00	5.00	6.00	17.00	18.99%							
3E4: Research Org 1	3.00	6.00	9.00	18.00	20.11%							
E5: Research Org 2	5.00	7.00	6.00	18.00	20.11%							
Total:	25.50	26.00	38.00	89.50	100.00%							
Percentage:	28.49%	29.05%	42.46%	100.00%								





Q&A Session





Lara Pandya

Team Leader Strategic Partnerships and Communications, Global Health EDCTP3



Thank you for your attention!







