Global Health EDCTP3

Co-funded by the European Union

Annex to Decision GB/12/2025
Phasing-out plan of the Global Health EDCTP3 Joint Undertaking
April 2025

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1. Executive Summary and Introduction

Pursuant to Article 17(a1) of the Council Regulation 2021/2085, the Governing Board shall adopt by the end of 2023 a plan for the phasing-out of the joint undertaking from Horizon Europe funding upon recommendation of the executive director.

Based on this obligation, the phasing-out plan of the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU) will be finalised in 2024, with this first version on the preparedness stage to be adopted by 31/12/23 focusing mainly on Chapter 5. It may be complemented by 2025. This is the latest version that reflects the additions made in 2025.

Please find below the executive summary that provides the context of the scope and the objectives of the Global Health EDCTP3 JU.

1.1. A brief history of the JU including its predecessors

The Global Health EDCTP3 JU is a partnership between the European Union (EU), represented by the European Commission and the EDCTP Association, which brings together several European and African countries. The Global Health EDCTP3 JU was established by Council Regulation 2021/2085 of 19 November 2021 establishing the joint undertakings under Horizon Europe and operates in the frame of the Horizon Europe programme.

EDCTP was initially established as the first initiative based on Article 185 of the Treaty on the Functioning of the EU (ex-Art. 169), which allows the EU's participation in research programmes jointly undertaken by several EU countries. During its first programme (EDCTP1, 2003-2015), EDCTP operated as a European Economic Interest Grouping (EEIG) incorporated in the Netherlands, with its membership restricted to 16 countries in the European Economic Area. Based on the success of EDCTP1, the second EDCTP programme (EDCTP2) was launched in 2014 as another Article 185 Initiative as part of the next European Framework Programme for Research and Innovation – Horizon 2020.

1.2. A brief outline of the policy context of the focus area of the JU

In the context of the European Commission's priorities of the United Nations Sustainable Development Goals, in particular Sustainable Development Goal 3, and the joint communication from the Commission of 9 March 2020 entitled 'Towards a Comprehensive Strategy with Africa', the EU is committed to contribute to ensuring healthy lives and promoting well-being for all, to building an even stronger partnership between the two continents and to supporting the development of research and innovation capacities within Africa. The Global Health EDCTP3 JU addresses the lack of appropriate diagnostics, treatments and vaccines, among other so-called health technologies, as counter measures to infectious diseases, such as HIV, malaria and tuberculosis but also other poverty-related and neglected infectious diseases, that are prevalent in Africa, especially in sub-Saharan Africa. The COVID-19 pandemic revealed that, with the increased connectivity of different regions in the world, through world trade and tourism, infectious diseases can rapidly spread all over the world. Developing health technologies is therefore crucial to limit the spread of infectious diseases, as well as to fight them once they have spread, to protect the health of citizens in the countries concerned and in the EU. In order to achieve a stronger global health leadership than the preceding EDCTP2 initiative, the scope of the partnership was extended to cover preparedness and response to (re)-emerging infectious diseases threats, the increasing problems of antimicrobial resistance and non-communicable diseases co-morbidities.

1.3. An outline of the JU's objectives and contribution to broader strategic EU priorities

Based on Article 99(1) of the Council Regulation 2021/2085, the objectives of the Global Health EDCTP3 JU are to contribute to the reduction of the socioeconomic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies and to contribute to the increase of health security in sub-Saharan Africa and globally by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases.

Furthermore, based on Article 99(2) of the Council Regulation 2021/2085, the Global Health EDCTP3 JU has specific objectives, such as:

(a) to advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials, in sub-Saharan Africa;

(b) to strengthen research and innovation capacity and the national health research systems in sub-Saharan Africa for tackling infectious diseases;

(c) to facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment;

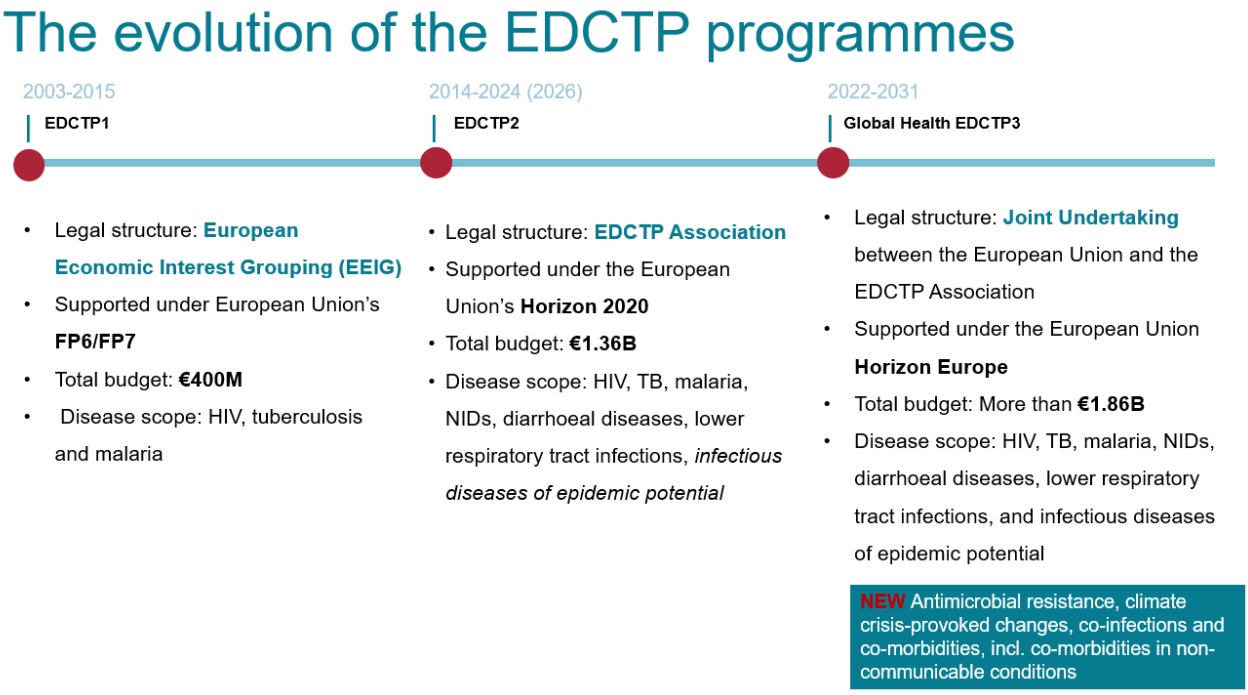
(d) to strengthen capacity in sub-Saharan Africa for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential;

(e) to promote productive and sustainable networking and partnerships in the area of global health research building North–South and South–South relationships with multiple private and public-sector organisations.

2. Short and long-term targets

Global Health EDCTP3 continues to work on the identification of new opportunities for future development and progress for the purpose of maintaining the drive necessary to achieve the objectives of the JU beyond the end of the Union's participation, if possible.

Since 2003, the EDCTP1, EDCTP2 and Global Health EDCTP3 programmes have sequentially remained consistent in their vision to reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa, by supporting collaborative research to develop accessible, suitable and affordable medical interventions. Notwithstanding this, the budget, legal structure and disease scope of the programmes has evolved with each iteration to reflect the changing research and funding landscape and needs, as summarised below.



EDCTP1 and EDCTP2 highlights of achievements (2003-2024):

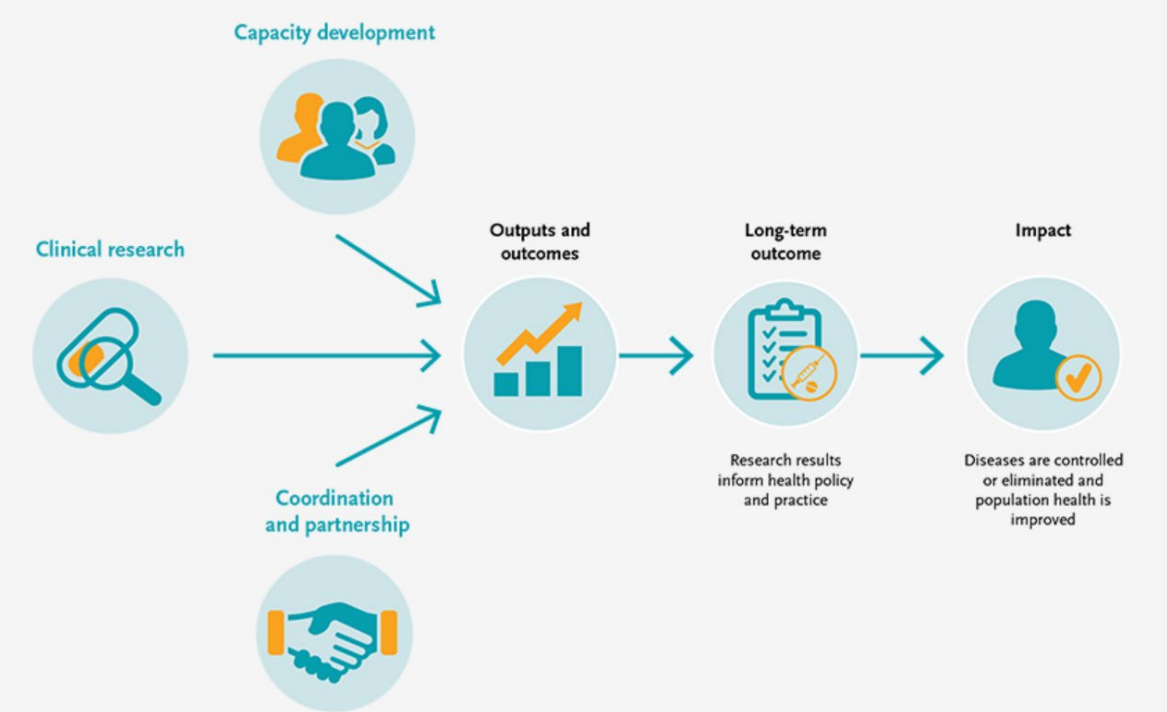
- Supported 692 research and capacity development grants since 2003 with a total combined investment of €1.03 billion (€208 million EDCTP1; €824.30 million EDCTP2).
- Supported 477 clinical studies (102 EDCTP1; 375 EDCTP2), of which 150 are phase II and III clinical studies of drugs and vaccines (52 EDCTP1; 98 EDCTP2).
- Generated more than 2,000 peer-reviewed publications (more than 700 EDCTP1; more than 1,300 EDCTP2).
- Supported 121 grants to enhance ethics and regulatory capacity in sub-Saharan Africa (75 EDCTP1; 46 EDCTP2).
- Provided 271 fellowship grants to researchers from sub-Saharan Africa (56 EDCTP1; 215 EDCTP2).
- Supported more than 2,000 trainees from sub-Saharan African countries through EDCTP projects (460 EDCTP1; 1,202 EDCTP2).
- Launched three emergency calls to respond to the Ebola (EDCTP2, 2018) and COVID-19 (EDCTP2, 2020) outbreaks/pandemics
- Established four African Regional Networks of Excellence for clinical research.
- Established the Pan African Clinical Trials Registry (PACTR), which became a WHO Primary Clinical Trials Registry.
- Leveraged €258 million financial contributions from European member countries (€51 million EDCTP1; €207 million EDCTP2).
- Leveraged €667 million in-kind contributions from European member countries through the EDCTP2 Participating States' Initiated Activities (PSIA) from 2014-2023.
- Leveraged €528 million financial and in-kind contributions from partners (€73 M EDCTP1; €455 M EDCTP2).

Global Health EDCTP3 highlights (2022-2025):

- Launched 11 calls for proposals to date (2022-2025) with a combined total JU indicative contribution of €677 million.
- Supported 74 research and capacity development grants since 2022 with a total investment of €254 million. €223 million is supporting 55 research and innovation projects conducting clinical research and €21 million is supporting 19 coordination and support action projects related to capacity development, networking and training activities.
- Planned investment of €210 million from the 2024 calls for proposals to support projects under grant preparation.
- Launched one emergency call to respond to the mpox outbreak in 2024, through which €12.1 million has been invested in nine research and innovation projects.
- Leveraged €34.5 million indicative financial contributions from EDCTP Association member countries across work programmes 2024-2025.
- Leveraged €665.5 million indicative in-kind contributions from EDCTP Association member countries through the Global Health EDCTP3 In-Kind contributions to Additional Activities (IKAA) across work programmes 2022-2025.
- Leveraged €49.7 million indicative financial and in-kind contributions from contributing partners (€33 million from Gates Foundation; €2.2 million from BioNTech; and €14.5 million from the Coalition for Epidemic Preparedness Innovations (CEPI)) across work programmes 2022-2025.

- The European Medicine Agency has recently provided positive scientific opinions on three medical products funded through the EDCTP2 and EDCTP3 programmes with EU funding (an albendazole–ivermectin combination for parasitic worm infections, arprazequantel for treatment of schistosomiasis in young children and fexinidazole winthrop for treatment of an acute form of sleeping sickness).

In line with internationally recognised principles of results-based management, we monitor and evaluate the Global Health EDCTP3 programme to report on its operational performance and results. We monitor the performance of individual projects to ensure that they achieve their specific objectives and deliverables as well as contribute to our programme objectives. Our monitoring and evaluation approach draws on a 'theory of change' model (see figure below) that maps out the route through which our funding generates immediate outputs (such as the published results from clinical trials), outcomes (such as changes in health policy and practice) and impact (improvements in health and wellbeing and economic gain).



The EDCTP theory of change for tracking progress towards impact on health

Our theory of change model (also known as programme logic) distinguishes different aspects of our work – clinical research, capacity development, and coordination and partnerships – and recognises that activities in these areas enable us to achieve our strategic objectives in different ways. To ensure a smooth phase-out process, progress will be tracked by assessing attainment of short-, medium-, and long-term results derived from Global Health EDCTP3's programme logic that will be achieved through a combination of Global Health EDCTP3-funded grants, IKAA supported by the EDCTP Association, and Programme Office advocacy, networking and outreach activities. These will be measured at regular intervals using programme-wide key performance indicators at various levels (activities, outputs, outcomes and impact), baseline values, and target benchmarks.

By 2030, Global Health EDCTP3 aims to progress to licensure **at least two new health technologies** tackling infectious diseases, and to have **progressed at least 20 products through key clinical development milestones**. Moreover, the programme aspires to support **at least 100 research institutes** in **30 countries** to enable effective and rapid research response to develop health technologies against re-emerging epidemics.

In addition to the above, during 2025 baseline values and targets for all relevant indicators are being established and systematically communicated for effective monitoring and assessment of programme implementation. Below is a list of key results along with a selection of their corresponding indicators.

Short-term results

Results	***Indicators***
1. Launch grant calls, evaluate proposals, and select grantees for clinical research, capacity building, networking, and epidemic response	• # calls for grant proposals launched • # grant proposals submitted • # and % proposals accepted to receive a Global Health EDCTP3 grant • amounts allocated to project grants (EUR), committed and actual
2. Foster North-North, North-South, & South-South networking and collaborations in global health and efforts tackling infectious diseases	• # stakeholders with which Global Health EDCTP3 held discussions about potential collaboration/to maintain existing collaboration • # active users of the EDCTP networks
3. Raise awareness among relevant stakeholders about research objectives, key results, strategic priorities, and funding opportunities related to infectious diseases in sub-Saharan Africa	• # public grant portals with which Global Health EDCTP3 shares data on funding of clinical research • # events where presentation about Global Health EDCTP3 was included in the agenda • # subscribers/followers to Global Health EDCTP3 online media outlets

Mid-term results

Results	***Indicators***
1. New knowledge on new/improved health technologies on infectious diseases in sub-Saharan Africa is produced and communicated to the public and relevant stakeholders	• # peer-reviewed scientific publications resulting from the Programme • # new/ improved medical interventions developed and/ or progressed in clinical development, with description of each intervention
2. Stakeholders and communities in participating countries are appropriately engaged in all stages of Global Health EDCTP3-supported projects	• # and % projects where [EU] citizens and end users contribute to the co-creation of R&I content • # and % participating legal entities which have citizens and end user engagement mechanisms in place after the end of projects funded by the programme
3. Enhanced institutional and technical capacity of organisations involved in EDCTP3-supported projects, incl. upgraded laboratories and clinical facilities	• # full time equivalent (FTE) jobs created, and jobs maintained in participating legal entities for the projects funded by the Programme

Results	***Indicators***
	• # laboratories and clinical facilities upgraded with the direct contribution of an EDCTP-funded project
4. Established/strengthened functional ethics and regulatory frameworks in project countries, based on international standards for GCP	• # countries with newly established or revised ethics and regulatory frameworks with the direct contribution by an EDCTP-funded project • # ethics and regulatory frameworks at regional levels developed or revised with EDCTP contribution
5. Individuals in sub-Saharan Africa complete training, mentoring and coaching in clinical research implementation, oversight, and governance	• # researchers who were involved in EDCTP grant projects implementation and/or who receive(d) EDCTP-funded fellowship/research/training grants • # and % researchers involved in upskilling (training, mentoring, fellowships, mobility and access to R&I infrastructures) activities in projects funded by the programme
6. Increased co-funding and joint actions with other stakeholders for research and capacity development to tackle infectious diseases	• Amount of public and private investment mobilised with the initial investment from Global Health EDCTP3 • # entities with which Global Health EDCTP3 has formal collaboration agreements
7. Widened scope of countries and stakeholders aware of and/or engaging in the EDCTP governance, actions, and funded projects	• # and types of organisations and countries represented in the partnership (members) • # and % EDCTP-funded projects coordinated by an institution in SSA • # mentions of EDCTP in media sources, research publications, and policy documents at the global, regional, and national level
8. Increased exchanges and collaborations among institutions and individuals on tackling infectious diseases across sub-Saharan Africa and Europe	• # active members in the Africa network of clinical research stakeholders • # and % peer-reviewed publications co-authored by African and European researchers who were involved in EDCTP-funded actions

Long-term results

Results	***Indicators***
1. The new knowledge created through Global Health EDCTP3 grants advances the medical field and clinical practice for tackling infectious diseases	• Mean Normalised Citation Score (MNCS) of peer-reviewed publications resulting from Global Health EDCTP3-funded projects or actions
2. New/improved technologies are approved for use and included in relevant protocols, policies and guidelines	• # medical products resulting from Global Health EDCTP3-funded projects pre-qualified by WHO recommendations and/or that received regulatory approval to be marketed • # new or changed guidelines and/or policies for improved or extended use of existing medical interventions resulting from Global Health EDCTP3-funded projects
3. New/improved technologies are available, affordable, known and accepted for use by intended end beneficiaries	• # new/improved technology known to be available for use by end beneficiaries
4. Strengthened clinical research institutions, with improved equipment, job opportunities, internal processes, and market share	• # and % of Global Health EDCTP3-supported laboratories and clinical sites demonstrating sustained improvements in diagnostic capacity after project completion, including those maintaining or newly achieving accreditation
5. Increased maturity of national regulatory and ethics systems for health product development, enabling sustainable oversight beyond EDCTP projects	• # and % countries that received Global Health EDCTP3 support for strengthening their regulatory frameworks that attained regulatory systems maturity level 3 or higher on the WHO benchmarking scale • # and % countries that received Global Health EDCTP3 support for strengthening their ethics systems with national ethics committees having achieved international accreditation
6. Upskilled individuals become more effective in producing and disseminating knowledge and practice on tackling infectious diseases in sub-Saharan Africa	• # and % researchers involved in Global Health EDCTP3 grants who joined implementation teams or assumed key roles in other research initiatives addressing infectious diseases in sub-Saharan Africa after receiving Global Health EDCTP3 support # and % researchers who contributed to/authored research publications, reports, guidelines or policies in an area linked to tackling infectious diseases in sub-Saharan Africa

Results	*Indicators*
7. Better alignment across Europe and Africa of global, regional, national research programs on poverty related and infectious diseases	• # sub-Saharan African and European countries that developed strategies/programs, implementation plans, and assigned budgets dedicated to tackling infectious diseases • Most significant examples of synergies between Global Health EDCTP3 actions and global, regional, national relevant initiatives and policies
8. Better aligned regulatory mechanisms among sub-Saharan African countries and increased common regulatory reviews in the sub-Saharan African region for new health products	• # of sub-Saharan African regulatory authorities known to have adopted common review processes or shared regulatory frameworks for new health products • # of sub-Saharan African countries known to have mutual recognition agreements or regulatory alignment partnerships for clinical trials or health product approvals
9. Increased co-funding and joint actions across sectors to develop, exploit or scale up Global Health EDCTP3-supported new/ improved health technologies	• Additional investments triggered by the EU contribution, notably for exploiting or scaling up results (linked to but outside the partnerships, including qualitative impacts and success stories)
10. New/improved technologies are used for diagnosing, treating and preventing infectious diseases in sub-Saharan Africa	• # and % of new/improved technologies that became integrated into healthcare services, national healthcare programmes, or disease-specific initiatives

3. Strategic alignment

The phasing-out plan is part of Global Health EDCTP3's overall strategy and central to its future operations. As such, it will feed into the annual updates to the JU's strategies.

The strategic implementation of the activities of the JU is guided by the multi-annual **Strategic Research & Innovation Agenda (SRIA)**. The SRIA is calibrated annually considering the current global and regional developments within the scope of this strategy and the investments already made towards the implementation of this strategy. In order to strategically develop its annual research, the Global Health EDCTP3 Programme Office, along with scientific and strategic advice from the Scientific Committee and the Stakeholders Group, develops an Annual Strategic Research and Innovation Agenda (ARIA). This document is updated annually and provides a prioritisation framework to rationally design the annual work programmes to be proposed to the Governing Board for approval.

The ARIA's objectives are to provide:

1. An overview of the global state of play of priority diseases within the scope of Global Health EDCTP3
2. A retrospective mapping of Global Health EDCTP3's funding against the priority areas of the SRIA
3. A mapping of current and prospective funding and partners working on priority areas within the scope of Global Health EDCTP3, with the aim of strategically identifying potential contributing partners

4. A systematic prioritisation framework for the identification of topics to be integrated to the next work programme.
5. Highlights of promising prior EDCTP programme investments that could be leveraged in the future Global Health EDCTP3 work programmes.

In addition, the ARIA helps researchers and other partners better understand current Global Health EDCTP3 research priorities, considering Global Health EDCTP3's overall mission to accelerate the development, evaluation, and implementation of medical interventions to prevent, identify, and treat infectious diseases and emerging/re-emerging infections in sub-Saharan Africa to reduce overall mortality and morbidity.

The ARIA is structured around the five specific objectives of the SRIA and populated with the outputs of i) comprehensive literature reviews of the SRIA identified targeted diseases, allowing to outline the key research and capacity gaps; ii) current policy developments; iii) ongoing and upcoming funding from countries, donors, and other public and private entities; and iv) previous Global Health EDCTP3 work programmes and funding, including In-Kind contributions to Additional Activities (IKAA), with both IKAA and Global Health EDCTP3 grants mapped out across identified priorities areas to demonstrate how they are filling gaps and contributing to the JU's overall strategic objectives and research priorities.

In terms of strategic alignment, Global Health EDCTP3's objectives aim for enhanced coordination, including alignment of strategies between EU Initiatives and AU-based funders, research institutions and policy makers, and the attraction of additional investments through north-north collaboration and global private-public and public-public partnerships. Consequently, the JU's strategy should be aligned with other relevant EU programmes, such as initiatives of DG INTPA, HERA and the Innovative Health Initiative (IHI) JU, as well as regional partners in Africa, such as the World Health Organization Regional Office for Africa (WHO-AFRO), Africa Centres for Disease Control and Prevention (Africa CDC), and the African Union Development Agency-NEPAD (AUDA-NEPAD), along with other like-minded organisations. To this end, a Memorandum of Understanding (MoU) has been signed between Global Health EDCTP3 and Africa CDC in February 2025 and there is the intention to sign a MoU with WHO and a renewed MoU with WHO-AFRO. Global Health EDCTP3 will continue looking for synergies with other funders in the global health sector, for example governments outside Europe and Africa, philanthropies, public/private entities and internationals organisations. Boosting the synergies' potential can be achieved through communication and awareness raising activities, as part of the JU's communication strategy. However, with the changing global geopolitical environment many of the partnerships and alliances may significantly change within the next five years and consequently – with the governing boards approval – increased flexibility has been weaved into the JU's strategic partnership strategy for engaging with with Third Parties.

Furthermore, Global Health EDCTP3 will explore potential approaches for adapting or evolving a potential follow-up partnership beyond the current Multi-Annual Financial Framework (MFF), to ensure long-term continuity of its strategic objectives. The main driver for the options will be the future decision by the EU on the next MFF. Such a decision can be expected in 2027 after a general agreement on the next MFF. To influence the discussions and decision, the Global Health EDCTP3 Programme Office will: a) evaluate the progress and success of the JU based on the set of programme KPIs and the Monitoring and Evaluation Framework currently under development; and b) analyse the global health research and funding landscape to identify the need for future related activities.

4. Financial sustainability

Funding sources

A potential future funding source for Global Health EDCTP3 could be provided by the current or future members of Global Health EDCTP3 or its successor. Currently, the only member other than the Union is the EDCTP Association, which currently represents the governments of 30 African and 15 European countries. Association membership could include EU Member States, sub-Saharan African States,

and countries associated to Horizon Europe or the next MFF programme. Under the EDCTP2 programme, the European Member States have so far made a financial contribution of €206 million but their main form of contribution has been in-kind, with a value of €666 million to date. Efforts will be made to maintain financial contributions from the EDCTP Association members, although in the current period of challenging geopolitics financial resources are becoming increasingly constrained and some countries are consequently reducing their levels of overseas development assistance. It is currently not a legal requirement under the founding regulation for EDCTP association members to provide financial contributions. In addition, the founding regulation provides that the entirety of the administrative costs of the JU is to be funded by the EU. Additionally, the EDCTP Association members already fund research at the national level or for many indirectly at the EU level, through their contributions to the EU budget or specifically to the Horizon Europe programme in the case of associated countries, meaning that IKAA is likely to remain the main form of contributions to Global Health EDCTP and any successor programme.

Global Health EDCTP3 already seeks to attract funding sources other than the EU and EDCTP Association by involving so-called contributing partners. These can be any country, international organisation or legal entity, other than a member of the JU, that supports the objectives of the programme. Contributing partners contribute through: 1) In-kind contributions to operational activities (IKOP), which are eligible costs incurred under an EDCTP3 project minus reimbursement by EDCTP3 ; or 2) Financial contributions. So far, Global Health EDCTP contributing partners include the Gates Foundation, BioNTech and the Coalition for Epidemic Preparedness Innovations (CEPI), with active outreach and liaison with other potential contributing partners ongoing. Furthermore, in the work programme 2025, new approaches and ways of collaboration have been introduced to allow more flexible ways of working with contributing partners in an effort to facilitate increased engagement and forge new and stronger partnerships.

Based on the above, it is clear that currently as well as in the future, without EU funding, this JU will not be in capacity to operate at a similar scale. Morever, without EU co-funding the EDCTP member countries may not have the incentive to continue with this longstanding partnership. It is also unlikely that contributing partners, most of which are international funders, will continue to contribute as co-funders in case EU funding is not present. This is because the added-value of the co-funding is the cooperation and the synergies. In its absence, they could simply use their own (or cooperate with other) funding schemes.

Revenue streams

Global Health EDCTP3 has not been designed to have revenue streams, nor the provision of consultancy services which may be perceived as a conflict of interest with the independent and transparent role of the JU over the allocation of EU funds to R&I activities.

Long-term commitment of the members other than the Union

Global Health EDCTP3 is the third iteration of the EDCTP programmes, which have been running for over two decades since the partnership was established in 2003. The majority of the European Member States that were the founding members of EDCTP are still members of the EDCTP Association, demonstrating their long-term commitment, both politically and financially, as long-standing members who are highly committed to the partnership and its success.

In 2014, the legal structure of the partnership evolved from a European Economic Interest Grouping (EEIG) to the EDCTP Association in order to allow for sub-Saharan African countries to formally join, establishing a true European-African partnership. Since then, the membership has only grown in number and strength, with currently 30 African and 15 European countries. Outreach to other prospective member countries is ongoing, with more countries expected to join under Global Health EDCTP3.

Surplus assets following procedure for winding-up

In accordance with the accounting construction mechanism, a JU is created similarly as a joint venture, but without real capital assets or investments transferred to the JU net assets. The in-kind contribution validated and transferred to the net assets does correspond to real financial investments from the JU Members, but reported as such, and not brought to the JU. It is presented financially in this way in order to establish factually the leverage effect, expected as per the Council regulation. Consequently, no surplus of assets is expected to be made available from the JU in the context of the phase out.

However, the investments of each of the members other than the Union, that have been reported as in-kind contribution by the end of the programming period may be considered, in agreement with the EDCTP Association, and depending on their possible mobilised resources post 2031, in the context of possible activities associated after the phasing-out plan. This should be established from 2028.

5. Administrative and operational adaptations

5.1. Legal status [legal form, private entity, public/private association…]

The Global Health EDCTP3 JU is an EU body and its private member is the EDCTP Association. The EDCTP Association is established as a private organisation under Dutch law, with offices in The Hague. The members of the EDCTP Association are several countries from Europe and sub-Saharan Africa.

The EDCTP Association could task itself with the continuation of the implementation of the strategic and policy objectives of the JU, as it did implement a programme under Article 185 of the TFEU in the past. However, by definition without EU funding, the EU would not be part of this partnership and the EDCTP Association may lack resources to fund research projects on its own, unless its members decide to contribute financially for this purpose. The governance structure already exists within the EDCTP Association.

5.2. Staffing

The legislative financial statement attached to the Commission proposal for the Council Regulation establishing the Joint Undertakings under Horizon Europe already foresees a gradual reduction of staff from its peak of 36 staff members for the period from 2024-2027 towards the planned end of the Joint Undertaking on 31 December 2031, with 18 staff foreseen for the year 2031.

Due to its limited size, many key roles in the JU (for example HR or IT officers) are only undertaken by one or two officers. These positions would have to be maintained in any event. Depending on the volume of ongoing grant agreements and their duration (which cannot be anticipated yet), it might be realistic to reduce the number of posts of scientific project officers and financial officers in the last two years of the lifetime of the JU.

After 2031, without programme funding from the EU, there would be no budget for administrative costs. There can therefore not be any staff after phasing out of programme funding. The small staff supported by the member states at the EDCTP Association that are managing and organising the contribution from the private member cannot take on roles beyond the limited remit, and may not be familiar with integration together with EC Research Family, tools, procedure, legal review, as well as with the integrated programme with Contributing Partners, etc.

5.3. Accounting and Cashflow

The needs are considered stable. The accounting functions would have to be assured as long as the JU exists as a legal entity either under the current scheme of back-office arrangements (BOA) or via the European Commission.

The needs of cashflow should follow the operational needs and are expected to follow the payment scheme as per the Legislative Financial Statement of the legislative proposal.

5.4. Procurement, Logistics and IT

The list below includes commitments (service level agreements and framework contracts) that may need to be concluded before the date of the JUs' winding up.

Agreements in place	Description
Service Level Agreement – DG BUDG	ABAC and Treasury services
Service Level Agreement – DG HR	HR services: Use of HR tools and related services, learning and development, medical services, and health & wellbeing and security services
Service Level Agreement – PMO	Services related calculation of salaries, health and accident insurance (JSIS), pensions, leaving and unemployment allowances, determination of rights upon employment, expert and mission reimbursements (MIPS)
Service Level Agreement – DIGIT	Access to DIGIT ICT framework contracts
Service Level Agreement – EPSO / EUSA	Services on personnel selection and development
Service Level Agreement – SG	Repository, Recording and Document Management System for official documents, including HERMES, ARES and NONCOM (HAN)
Service Level Agreement – EU-RAIL JU	Back Office Arrangement with the other JUs Accounting services
Service Level Agreement – CBE JU	Back Office Arrangement with the other JUs on HR
Service Level Agreement – CAJU	Back Office Arrangement with the other JUs on Procurement
Service Level Agreement – CHJU	Back Office Arrangement with the other JUs on ICT
Service Level Agreement – EU-RAIL JU	Back Office Arrangement with the other JUs on Data Protection Officer externalisation

Service Level Agreement – CERT-EU	Organisation and operation of a computer emergency response team for the Union's institutions, bodies and agencies (CERT-EU)
New Usufruct Contract with White Atrium SA	Offices
FWC Baker Tilly	Accounts auditing services
FWC Aqua Vital	Water supplies
FWC Real Dolmen	IT services
FWC Netcompany-Intrasoft	Events organisation
FWC MGH SRL	Coffee machines rental and coffee supplies
FWC GUSTO COMMUNICATIONS ('CIBACCO') and HUIS VAN DIJCK	Catering services

Where these agreements do not come to an end before late 2031, Global Health EDCTP3 JU will have to ensure that it terminates its participation at an adequate effective date. The building rental contract ends on the end date of the existence of the organisation.

5.5. Follow up of grant agreement obligations after the end of projects.

It is challenging to estimate the number of grant agreements still running on 31 December 2031. Based on the current average situation of about 37 grant agreements being signed per year and considering that the year following the launch of the call and project duration of the clinical trial projects often extending to 60 months, one would assume that a significant number of grant agreements from the 2026 and 2027 calls would still be active by the time the Global Health EDCTP3 JU is supposed to be wound up. Clinical trial projects may also run into delays during project implementation, further extending the termination of the grants. After the end of the grant agreement, 6 months need to be assumed as the time required for receiving the reporting and finalising the assessment (approving deliverables and reports and financial operations) and paying the outstanding balance at the end of the project.

If the legal entity of the Global Health EDCTP3 JU no longer exists, the European Commission or HADEA could be considered a natural legal successor to ensure a proper follow-up of the grant agreement obligations of all parties.

Need for a follow-up is considered highly likely since:

(a) at least some projects may last beyond 2031; and,

(b) for several projects that would have finished by 2031, obligations of the beneficiaries and other participants that go beyond the end of the project still need a follow-up (e.g. additional exploitation obligations that last up to 4 years after the end of the project).

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Addendum 1

Legal basis, procedural aspects, including reporting and timeline

Legal basis

Horizon Europe Regulation[1]

- Article 10(2)(c): *"European Partnerships shall (…) have a clear life-cycle approach, be limited in time and include conditions for phasing-out the Programme funding".*
- Annex III: *"in the absence of renewal, appropriate measures ensuring phasing-out of the Programme funding according to the conditions and timeline agreed with the legally committed partners ex ante, without prejudice to possible continued transnational funding by national or other Union programmes, and without prejudice to private investment and on-going projects".*

Single Basic Act (SBA)[2]

- Article 17(2)(1a): The Governing Board (GB) shall "*adopt by the end of 2023 a plan for the phasing-out of the joint undertaking from Horizon Europe funding upon recommendation of the executive director".*
- Article 19(4)(v): The Executive Directors shall *"prepare and submit for adoption to the governing board a plan for the phasing out of the joint undertaking from Horizon Europe funding"*.
- Article 45: The JUs shall be wound up on the 31 December 2031. This will require the Governing Board of each of the JUs to "appoint one or more liquidators, who shall comply with the decisions of the Governing Board".
- Article 171(4): *"The evaluations shall also take due account of the phasing-out plan adopted by the Governing Board in accordance with Article 17(2), point (1a)*".
- Article 171(8): "*Periodic reviews and evaluations shall be taken into consideration in the winding up or phasing out of the joint undertaking referred to in Article 45 of this Regulation, in line with Annex III to the Horizon Europe Regulation".*

Nota bene: Although the Regulation setting up the **EuroHPC JU** does not expressly refer to an obligation to adopt a phasing-out plan, this JU is bound by the provisions of the Horizon Europe Regulation requiring the Governing Board to set out "conditions" and "timeline" for such phasing out.

Procedure for the adoption of the plan

- Article 19(4)(v) SBA: *"Each JU Executive Director prepares a draft that s/he submits to the GB; The GB adopts the plan before the 31 December 2023. Following which it will oversee and monitor the appropriate implementation and ensure that all relevant targets are met."*

In adopting the plans, JUs should seek the advice and **consult their advisory bodies** (although this is not mandatory). This could provide insight to identify possibilities of future collaboration or new synergies while identifying new avenues for the continuation of research in the relevant field.

The JU may **amend** the plan as necessary, following this same adoption procedure. This may be necessary also by (lack of) progress and new realities in implementing the Framework Programmes.

[1] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).
[2] 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).

Renewal of the JUs

The adoption of phasing-out plans does not predetermine the (dis)continuation of a JU. This decision will rest on:

- **JU evaluations** based on Article 171(4) SBA, and particularly: *a)* the assessment of the most effective policy intervention mode for future action; *b)* the relevance and coherence of renewal with overall policy priorities and the R&I support landscape, notably compared to other initiatives supported by the Framework Programme;
- JU **contribution to broader strategic EU priorities**;
- JU assessment in the **overall European Partnerships landscape** and policy priorities.

Some **indicators may justify non-renewal** and should be duly considered when developing the plan (*see "Monitoring and evaluation criteria", below*). In particular:

- The JU has fully **delivered** on its expected impact and met its objectives and targets;
- The JU has been renewed over more than one Framework Programme and is still **far from delivering** its objectives and expected impact;
- The activities still to be implemented are **not eligible for funding** under the Framework Programme (e.g., deployment under Horizon Europe);
- Union **participation is no longer necessary** as the members other than the Union can deliver without the need for Horizon Europe funding.

Winding up

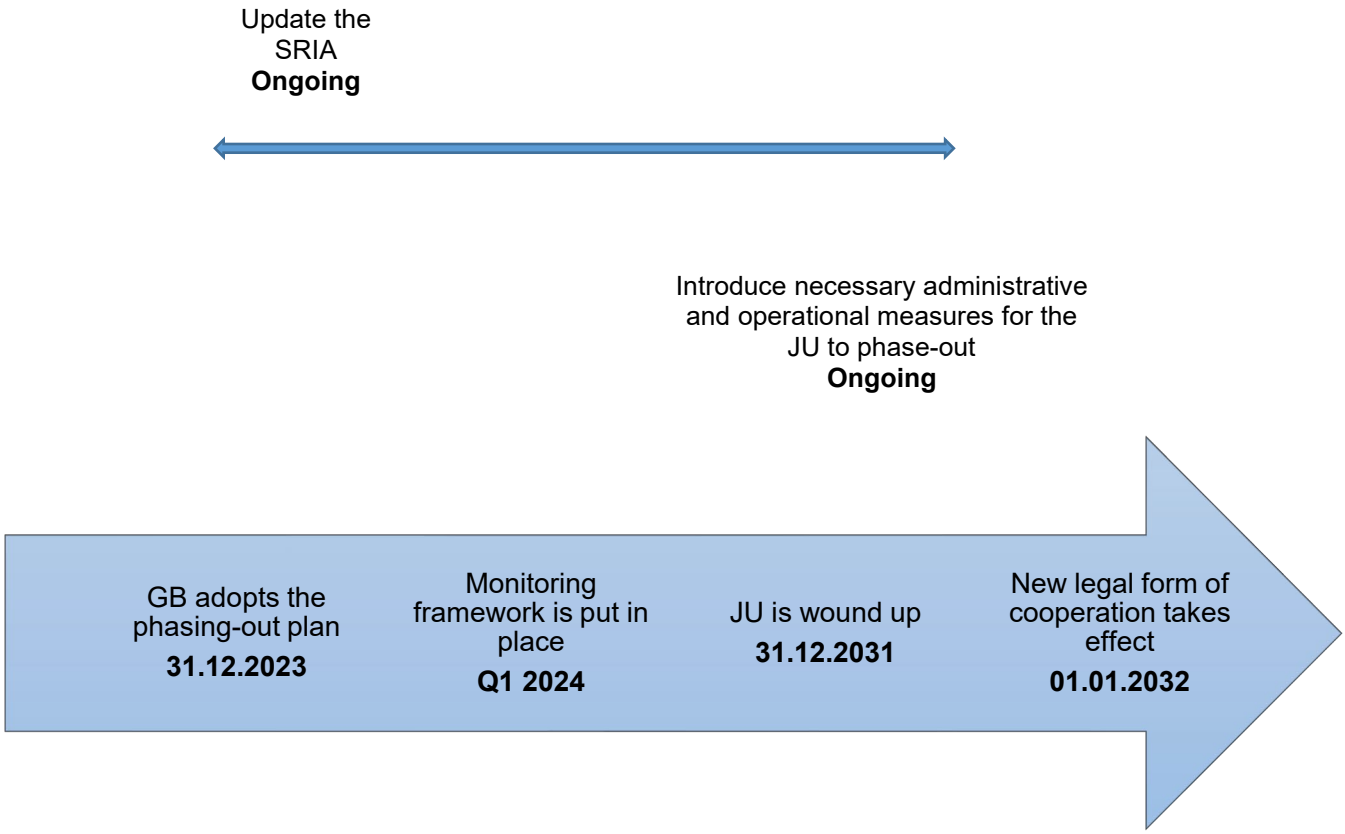
- In terms of the SBA, the JUs will be wound up on the 31 December 2031. For this purpose, the Governing Board of each of the JUs will appoint one or more liquidators. The procedure for winding up is **without prejudice to the possibility of a renewal** of any (or all) of the JUs and the possibility that specific provisions in the applicable legislative act(s) may impact the relevant provisions in the SBA,
- The **liabilities of the JUs and any costs relating to the winding up procedure** itself will be covered by **its own assets**. In case of any **surplus**, this will be distributed among all the members of the JU in proportion to their share of the financial contribution.
- The Governing Board will adopt **ad hoc procedures** addressing the impact of the winding up on ongoing contractual obligations including procurement contracts as well as on decisions adopted by the JU. Such procedures will take due account of the relevant elements in the phasing out plan.

Reporting and timeline:

- **Report in the Annual Activity Reports (AARs)**: The **JUs' respective AARs** should outline both the progress made towards achieving the targets and milestones for the administrative and operational adaptations as well as indicating how the plan coincides with the JUs' strategy as included in the SRIA.
- **Report to the Governing Board:** The Executive Director will **regularly report to the Governing Board** on progress, thereby allowing it to maintain a continuous supervision and enabling it to provide strategic guidance as necessary. The Governing Board may also decide on remedial or corrective action if progress is inadequate or does not sufficiently reflect existing realities.
- **Commission support:** The Commission will support JUs in developing and monitoring plans, both as a representative of the Union in the Governing Boards of each JU, as well as within the wider scope of operational cooperation between Commission services and the JUs. In its role as member of the Governing Board, the Commission will ensure that the targets set in the phasing-out plans will be sufficiently ambitious to achieve financial independence while, at the same time,

that the necessary level of commitment is in place to drive forward the JU's objectives. The Commission will also set out the groundwork for assessing possibilities for future cooperation with the Union.

- **Generic Timeline:**



Addendum 2

Additional substantive information and contextual elements

Non-exhaustive list of elements to be addressed

Cross-cutting aspects:

- **Short and long-term targets, including monitoring and evaluation criteria:** The phasing-out plans will be set on clear and well-defined short- and long-term targets that will capture the necessary ambition from a financial, operational and administrative perspective, towards the financial independence of the programme/initiative from Union funding. These targets should determine the form of future cooperation and activities to be carried out for the purpose of maintaining the drive necessary to achieve the objectives of the JUs beyond the end of the Union's participation. In turn, these targets should be set on **clear, measurable, and transparent criteria and include relevant benchmarks** for the purpose of monitoring and evaluating the JUs' activities and progress in terms of the plans towards the achievement of these same targets. The plans will also look into the systematic, organisational, and behavioural adaptations necessary to achieve the targets.
- **Administrative and operational adaptations**: Phasing-out plans will set out concrete milestones and timeframes for administrative and operational adaptations necessary for the JUs' winding up in relation to staffing, accounting, procurement, logistics, follow up of grant agreement obligations that must be respected after the end of the project (e.g. IPR related including right to object, record keeping) etc.
- **Alignment with the Strategic Research and Innovation Agendas** (**SRIA)**: Phasing-out plans are **not intended to be standalone documents.** The phasing-out strategy developed in the plans will be part of the JUs' overall strategy and central to the JUs' operations and as such this should be aligned with (and feed into) the JUs' SRIA. As the JUs progress, the plans will be reviewed in line with the JUs' own evolution.

Sustainability and alternative funding sources

- **Self-sustainability:** The plans should foresee adequate measures to ensure that the JU continues contributing to the policy objectives supported by Horizon Europe funding once it is wound up. To this end, the objective is for the JU to **achieve self-sustainability** while continuing to pursue its objectives in a smooth and orderly manner.
- **Funding sources:** A smooth phasing-out will require commitment by the members other than the Union towards achieving and building on the objectives of the JUs. Accordingly, plans will include **measures to mobilise alternative private and/or public funding** sources with due regard to avoiding conflicts of interest and safeguarding the Union's financial interests. To ease this shift, the strategy should **promote a lesser dependence** on EU funding towards the end of the life of the JU.
- **Revenue streams:** The JUs should look into mechanisms that will enable a **diversification of the revenue streams** generated by the JUs themselves while ensuring due regard of the JUs' financial rules and the principle of sound financial management. The contribution by these revenue sources towards the JUs' financial independence will be monitored and regularly reported to the Governing Board.
- **Establishment of a legal entity:** The plan will require a clear definition of the legal form of the collaboration following the winding up of the JU and therefore, following the end of its status as an institutionalised European partnership. To this end, the strategy may foresee the establishment of a **separate legal entity** operating under national law, developing alternative sources of revenue for the purpose of its economic subsistence while focusing on following up on the R&I activities of the JU. Alternatively, a memorandum on future cooperation among members other than the Union

could be concluded that could be extended to other stakeholders and set the framework for pursuing the work of the JUs.

Continued stakeholder engagement

- **Long-term commitment of the members other than the Union: Beyond** the mobilisation of alternative funding and revenue sources, the plans should ensure the **long-term engagement of the members other than the Union** beyond the lifetime of the JU, presupposing a gradual incrementation of their financial contribution to the JUs. For this purpose, the plan should foresee the reduction of funding rates as a means to leverage an increased level of private and public funding thereby driving forward the JUs' financial independence. In determining the applicable funding rates, the Governing Board should assess progress made towards the targets.
- **Benefit of collaboration:** Plans should focus on **accentuating the benefits of collaboration** among members, and how this collaboration can be sustainably increased over time to new actors and therefore on making the JU more attractive to diverse stakeholders. This should seek to promote benefits such as increased visibility, co-creation, knowledge-sharing, as well as new and innovative forms for future stakeholder engagement.

Simplification

- **Reduction of administrative burden:** Phasing-out plans should be implemented and monitored efficiently, effectively and in a timely manner, while being mindful not to be unduly onerous on the JUs' resources. In addition, the administrative costs of implementing the provisions of the present Guidance should be kept to a minimum.

Synergies:

- **Collaboration between JUs:** Plans should explore how the JUs can **maintain existing synergies while establishing new ones** between the JUs themselves as well as with national and regional initiatives and with other Union programmes and policies. This should build on identified R&I priorities and make full use of potential interconnections and collaborations for the purpose *inter alia* of establishing new revenue and funding sources but also garnering efficiencies and know-how.
- JUs are encouraged to **cooperate and exchange among themselves** also as they develop and implement their plans. In addition to these guidelines and to the support that will be provided by the Commission, these exchanges will promote a common coherent approach. These exchanges should also help identify potential synergies and collaboration opportunities following the phasing-out.