



**GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING  
DECISION N° GB/31/2023**

**Approving the date on which the Global Health EDCTP3 Joint Undertaking will have the  
capacity to implement its own budget**

THE GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING, (hereafter referred as "GH EDCTP3 JU")

Having regard to the Treaty on the Functioning of the European Union;

Having regard to Council Regulation (EU) No 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 (hereafter the "Founding Regulation"), the GH EDCTP3 JU and in particular Article 173(4) thereof;

WHEREAS:

- (1) The Executive Director was appointed by Governing Board Decision GB/23/2023 of 18 September 2023.
- (2) The Interim Executive Director, with the agreement of the incoming Executive Director, has determined the date on which GH EDCTP3 JU will have the capacity to implement its own budget (hereafter "the date of financial autonomy"), based on the content of the Readiness Assessment Report set out in annex of this present decision.
- (3) As agreed with the responsible European Commission services, GH EDCTP3 JU will be able to access the relevant IT tools and in particular the accounting system to implement its own budget on the 23 November 2023.

HAS DECIDED AS FOLLOWS:

*Article 1*

In line with the date proposed in the Readiness Assessment Report in annex of the present decision, the date of 23 November 2023 is hereby approved as the date of financial autonomy of the GH EDCTP3 JU.

*Article 2*

This Decision shall take effect on the day following that of its adoption.

Done at Brussels, 07.11.2023

*For the Global Health EDCTP3 Joint Undertaking Governing Board*

A handwritten signature in blue ink, consisting of a large 'H' followed by a stylized, cursive name.

Dr. Henning Gädeke

*Chairperson of the Governing Board*

Annex:

1. Readiness Assessment Report



## **READINESS ASSESSMENT REPORT**

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## 1. Introduction

### (a) The purpose of the report

This report provides the state of development with the requirements which are necessary for the Global Health EDCTP3 Joint Undertaking to demonstrate its financial autonomy, i.e., capacity to implement its own budget.

This financial autonomy is considered as acquired on the basis on a checklist of criteria developed by the Commission services to be fulfilled. The checklist takes into consideration the criteria used by DG BUDG for judging the readiness for financial autonomy of previous European Bodies.

This Readiness Assessment Report represents an overview of the step-by-step procedure followed by the Global Health EDCTP3 JU programme office to reach the adequate level of effectiveness for this financial autonomy. It leads to the conclusion that the Global Health EDCTP3 JU is ready to implement its own budget by 23 November 2023.

### (b) The legal framework and state of play

The Global Health EDCTP3 JU is a Public-Private Partnership established by the Council Regulation (EU) 2021/2085, published in the Official Journal on 30 November 2021 and entered into force the same day (Annex 1).

According to Article 101 of the Council Regulation (EU) 2021/2085, the members of the Global Health EDCTP3 JU are the European Union, represented by the European Commission (EC), and the EDCTP Association, a non-profit organisation registered under Dutch law.

Based on Article 173 of the Council Regulation (EU) 2021/2085, and although the Global Health EDCTP3 JU already has its legal personality independent from the Commission since 30 November 2021, the Commission is responsible for the establishment and initial operation of the Global Health EDCTP3 JU until the JU has the operational capacity to implement its own budget. DG RTD as parent DG of the Commission, carries out all necessary actions in collaboration with the EDCTP Association and with the involvement of the JU competent bodies.

The governance of the Global Health EDCTP3 JU is led by a Governing Board, in which both the EDCTP Association and the European Commission, representing the European Union, have equal votes. Global Health EDCTP3 is advised by a Scientific Committee and a Stakeholders Group. The implementation of the programme is ensured by a Programme Office based in Brussels, under the lead of the Global Health EDCTP3 Executive Director.

On the operational part, the Global Health EDCTP3 JU adopted on 3 May 2022 and 2 April 2023 respectively its Annual Work Programmes (AWPs) 2022 and 2023, to launch the calls for R&I grants foreseen for the implementation of its Strategic and Research Agenda (SRIA; adopted on 12 January 2022). In performing this task, the Global Health EDCTP3 JU followed the Horizon Europe Rules for Submission and Evaluation and used the Horizon Europe IT tool chain.

There are currently 27 grants running, stemming from Call 1 (2022) and one action not subject to call of proposals (2022), with a total funding of EUR 103.04 mil. The relevant scientific fields covered are implementation of research results, implementation of adaptive platform trials into policy and practice, genomic epidemiology for surveillance and control of poverty-related and emerging/re-emerging infections in sub-Saharan Africa, creation of a sustainable clinical trial network for infectious diseases in sub-Saharan Africa, strengthening regulatory capacity for supporting conduct of clinical trials, as well as support the EDCTP Africa Office with the objective to enhance the Global Health EDCTP3 activities and involvement in the African region.

There also are 27 proposals that will be asked to enter into grant preparation, pending GB approval, stemming from Call 1 (2023), with a total funding of EUR 78.2 mil. The relevant scientific fields covered are clinical research fellowships, finalisation of clinical trials from EDCTP2, negatively impacted by the COVID-19 pandemic, implementation of research/real life assessments of existing interventions in women and children's health, research to rapidly evaluate interventions on Ebola outbreaks in Africa, and strengthening of ethics and regulatory capacity.

Furthermore, a two-stage call (2023) is ongoing with the evaluation of the first stage foreseen to be completed by mid-November this year. The relevant scientific fields covered are improvement of modes of delivery, deployment and uptake of vaccines through phase IV/implementation research and advancement of point-of-care diagnostics to the market through comparative testing.

The AWP 2024 and its corresponding Calls are currently in preparation. Priorities for 2024 are: developing novel tests and interventions for HIV, Malaria vaccines, accelerating development of therapeutics and non-pharmaceutical interventions against Neglected Tropical Diseases (NTDs), tackling antimicrobial resistance: R&D on existing antimicrobials and antimicrobial stewardship, vector control, innovative digital health solutions for Africa, academia/industry fellowships with return phase and mobilisation of research funds in case of public health emergencies.

Regarding communication activities, a launch event for the Global Health EDCTP3 Joint Undertaking was held in May 2022, following the adoption of the first work programme. A web-presence for the new Joint Undertaking was established within the frame of the European Commission websites with information on Research & Innovation from Q1/2022 and in May 2023 the Global Health EDCTP3 JU dedicated website was launched. The website includes all key information on the Joint Undertaking and it is where funding opportunities, news, activities and resources are published. Funding opportunities are also made public through the Funding & Tenders Portal of the European Commission. The Global Health EDCTP3 dedicated website is regularly updated to be kept up to date. Social media accounts have been created in the social media networks X and LinkedIn, where information on Global Health EDCTP3 activities as well as relevant activities by other stakeholders are shared, ensuring continuous engagement with relevant partners. Following has grown since their launch with currently over 700 followers in X and over 2300 followers on LinkedIn. When announcements have been made, such as the publication of the 2023 Work Programme or the announcement of the new Executive Director, these have been published on the website, promoted on social media as well as sent to relevant partners directly.

In May 2022 a virtual info day was held to inform about the calls for that year and in March and April 2023, two virtual Info days were held to provide potential applicants with specific

information on the Global Health EDCTP3 calls for proposals under Work Programme 2023, as well as information on eligibility criteria and other relevant administrative matters. Projects funded under Global Health EDCTP3 JU have only recently started (in 2023) and as such, little results have been produced that could merit a communication action from the side of Global Health EDCTP3 JU. For the time being, communication activities regarding projects have been focused on communicating when the grant was signed, when their kick-off meetings were held and promoting other activities that the projects have carried out.

Global Health EDCTP3 staff also represent a key tool to increase visibility of the programme and have represented the organisation in a number of events, conferences and workshops, including the Grand Challenges Annual Meeting and the World Health Summit. Within the Grand Challenges Annual Meeting a session highlighting the projects funded under the genomic epidemiology topic from the 2022 work programme was held and attracted a large audience and relevant social media engagement.

## 2. Requirements for the Global Health EDCTP3 JU financial autonomy

The requirements for the autonomy of Joint Undertakings mentioned above and in annex were specified by the Commission services when the first generation of JUs were preparing for autonomy in 2009 and were adapted to the specificities of the Council Regulation setting up the Global Health EDCTP3 JU.

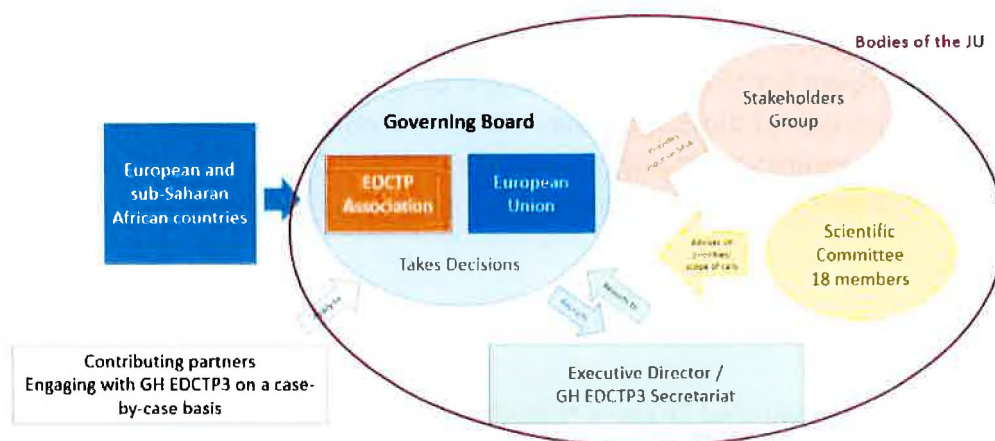
On that basis, the Global Health EDCTP3 JU has followed the actions stated in a table summarising the state of readiness of the requirements for autonomy of the Global Health EDCTP3 JU (Annex 2).

### (a) The Global Health EDCTP3 JU bodies

The bodies of the Global Health EDCTP3 JU have been established in accordance with Article 14 of the Council Regulation (EU) 2021/2085.

Required bodies	Description	Status
Governing Board	Establishment of the GB	COMPLETED 12/01/2022
Executive Director	Appointment of the interim ED  Appointment of the ED	COMPLETED 22/12/2021  COMPLETED 18/09/2023
Scientific Committee	Establishment of the SC	COMPLETED 18/03/2022
Stakeholders Group	Establishment of the SG	COMPLETED 28/02/2023





## i. Governing Board

The Governing Board is composed of the following:

- six representatives of the European Commission on behalf of the European Union (50% of the voting rights)
- six representatives of the EDCTP Association (50% of the voting rights)

Currently, 15 European and 27 African countries are members of the EDCTP Association. The list of member countries can be found [here](#).

The Governing Board adopted its Rules of Procedure (Annex 3) at its first meeting, which took place on 12 January 2022 and the Financial Rules of the Global Health EDCTP3 Joint Undertaking (Annex 4) at its meeting of 3 May 2022.

Over the period 2022-2023, the Governing Board held six meetings.

Besides, its Rules of Procedure and its Financial Rules, the Governing Board adopted the Global Health EDCTP3 JU Strategic Research and Innovation Agenda (SRIA) and two Work Programmes (2022 and 2023). It approved the launch of one call and two actions not subject to calls for proposals in 2022 and two calls in 2023.

Following these calls the GB approved the corresponding portfolios of 29 projects as well as another 27 projects pending GB approval with a total budget of EUR 176.368.579,25 (up to end of October 2023).

The Work Programme for 2024 is currently in preparation and will be finalised for adoption before end of December 2023.

The Governing Board also adopted a series of staff implementing rules (SIR) and other policies. It endorsed the Back Office Arrangement (BOA) on accounting services (excluding treasury services) and appointed its Accounting Officer (Annex 5) and adopted the BOA on human resources and procurement.

A list of all Governing Board decisions is annexed to this document (Annexes 6A and 6B). The names of the representatives of the GB members and their declaration of interests as well as the agendas of the GB meetings and the non-confidential GB decisions are also publicly available on the Global Health EDCTP3 JU website: [Governance | Global Health - EDCTP3](#)

## ii. Executive Director

In 2021, the Commission designated Dr Elmar NIMMESGERN, official of the European Commission, to be the Interim Executive Director of the Global health EDCTP3 JU, pending the recruitment and nomination of the first Executive Director of the JU.

The Global health EDCTP3 Governing Board appointed Dr Michael MAKANGA as the first Global health EDCTP3 Executive Director on 18 September 2023. He takes up his duties on 16 November 2023. Dr MAKANGA was selected from a list of candidates proposed by Commission Decision on 6 September 2023 after consultation with the other member of Global health EDCTP3 JU, the EDCTP Association, according to Article 18 of the Council Regulation (EU) 2021/2085.

A list of the ED decisions is provided in Annex 7 (up to end of October 2023).

## iii. Scientific Committee

The Global Health EDCTP3 Scientific Committee (SC) has been established in 2022 and adopted its Rules of Procedure (RoP) at its first meeting on 18 March 2022. It is composed of up to 18 members, with expertise in different areas related to the GH EDCTP3 remit. Their names are published on the Global Health EDCTP3 JU website. In the same first meeting, the SC proceeded with the election of the Chair and Vice-Chairpersons. In August 2022, at its second meeting, following resignation of the Chair, the SC nominated the vice-Chair to become the new Chair and proceeded to elect a new vice-Chair. In March 2023, via written procedure, the SC amended its Rules of Procedure (RoP). The amended RoP provides the SC with the possibility to appoint a permanent observer from the World Health Organisation. In March 2023, the SC also decided to establish SC Working Groups.

The names of the SC members are published on the Global Health EDCTP3 JU website.

## iv. Stakeholders Group

The Global Health EDCTP3 Stakeholders' Group (SG) has been established in Q1 2023 and extended in Q3 2023. Adoption of its Rules of Procedure is foreseen in its first extended membership configuration meeting that will take place on 7 November 2023. It is composed of representatives of key stakeholders in global health such as academia, industry, CSO, patients'

representatives, as well as key actors in specific topic areas of the SRIA. It proceeded with the election of the Chair and Vice-Chairpersons as well as its representatives to the EDCTP Forum committees. It provides guidance on strategic issues (particularly on the SRIA, on engagement of other sectors relevant to the EDCTP3 vision and on the EDCTP Forum) as well as all relevant activities of the partnership.

The names of the SG members are published on the Global Health EDCTP3 JU website.

## (b)The Global Health EDCTP3 JU financial management

All key aspects of the Global Health EDCTP3 JU financial management have been established or are in progress. Some steps can only be finalised when the Global Health EDCTP3 JU ABAC accounting system will be in place latest on 23 November 2023.

Below you will find a table summarising the main documents to adopt, the main actions to perform (JU or Commission) in view of the establishment of this autonomous financial management by Global Health EDCTP3 JU:

Requirements	Description	Action	Status
<b>Financial Rules</b>	Adoption of the Global Health EDCTP3 Financial Rules by the Governing Board	Global Health EDCTP3 GB	COMPLETED
<b>Manual of Financial Circuits/Workflows and key roles of the ex-ante control (table)</b>	Adoption by the Executive Director	Global Health EDCTP3 ED	COMPLETED
<b>Accounting Officer</b>	Appointment of the Accounting Officer by the Governing Board	Global Health EDCTP3 GB	COMPLETED
<b>Accounting and Budget Implementation System (ABAC Workflow)</b>	Signature SLA of Global Health EDCTP3 JU with DG BUDG on ABAC SAP systems and treasury services (to be done by DG BUDG)	DG BUDG	ONGOING (expected by end of October)
<b>Transfer of open commitments</b>	Identification of Open Commitments from EC ABAC and transfer to Global health EDCTP3 ABAC	DG RTD/DG BUDG	SCHEDULED WITH DG BUDG
<b>Appointment of specific roles to Global Health EDCTP3 staff</b>	Appointment by the Executive Director of Global Health EDCTP3 JU Staff on specific roles	Global Health EDCTP3 ED	COMPLETED

<b>Legal Entity File (LEF)</b>	Registration in ABAC	DG BUDG	COMPLETED
<b>Bank Account &amp; Bank Account File (BAF)</b>	Virtual Bank Account and BAF created by DG BUDG	DG BUDG	COMPLETED
<b>Access to Early Detection and Exclusion System</b>	Access to the Early Detection and Exclusion System (EDES) database	Global Health EDCTP3 JU/DG DIGIT	TO BE ACQUIRED VIA EGRANTS AND PPMT ONCE AUTONOMOUS
<b>Global Health EDCTP3 Budget and Annual Work Plan 2023</b>	Adoption by the Governing Board	Global Health EDCTP3 JU	COMPLETED
<b>The official notes requested by DG BUDG for the Autonomy (Annex 8)</b>	Submission of necessary support documents for the assessment of the readiness of Global Health EDCTP3 JU for its financial autonomy following the autonomy decision by the GB.	RTD/ Global Health EDCTP3 JU/BUDG	ONGOING Deadline: 13/11/2023

### The Global Health EDCTP3 JU Financial rules

The Global Health EDCTP3 Governing Board adopted the specific Global Health EDCTP3 JU Financial Rules on 3 May 2022 (Annex 4). The Global Health EDCTP3 Financial Rules do not depart from the Commission Delegated Regulation (EU) 2019/887 of 13 March 2019 on the model financial rules for public private partnership bodies referred to in Article 71 of Regulation (EU, Euratom) 2018/1046.

### The Global Health EDCTP3 JU Financial circuits

Financial circuits to be applied by the Global Health EDCTP3 JU are described in its Manual of Financial Circuits. The key actors executing the ex-ante control of the financial transactions are also detailed in this document. Both manual and key actors are approved by the Executive Director (Annexes 7 and 9).

The general rule is that the main transactions, commitments and payments, are subject to “Standard workflow” composed of operational and financial initiation and operational and financial verification, before the validation by the Authorising Officer.

For transactions related to administrative budget, the operational and financial initiation can be performed by the same agent, as well as the operational and financial verification. This is justified in case of transactions which have very low risk associated and is especially suitable in a context with limited number of staff. For transactions related to operational budget, the four roles are executed by four different agents.

Transactions with higher level of risk may be subject to a more reinforced ex-ante control by involving additional actors that will contribute to the quality of the transaction.

The transactions related to administrative budget are processed through ABAC and ARES, bearing in mind that the operational agents will give visa only in ARES. Those transactions related to operational budget are processed through Sygma/Compass and e-Experts tools. All transactions can be validated by the responsible Authorising Officer in ABAC only.

The key actors that will execute the ex-ante control of the financial transactions are appointed by the Executive Director. Each key-actor has at least one back-up to avoid any delay or interruption of payments or other financial matters.

The financial circuits comply with the requirements of segregation of duties and, given its limited staff, it also provides the flexibility necessary to ensure the continuity of operations.

The relevant staff members will follow all necessary trainings related to expenditure lifecycle/ABAC Workflow and will have access to the related guidelines and manuals needed to perform the ex-ante control and validation of expenditure.

The Financial circuits will be regularly updated to cover for organisational or other operational changes within the JU.

### **The Global Health EDCTP3 JU Authorising Officer**

The Authorising Officer of Global Health EDCTP3 JU is the new Executive Director, Dr Michael MAKANGA.

### **The Global Health EDCTP3 JU Accounting Officer**

According to the segregation of duties, the Accounting Officer of Global Health EDCTP3 JU is a staff member of another JU, Mr Andrei Hretu (EU-Rail JU). He was appointed by the Governing Board decision (Annex 5). Ms Andrea Toth (CAJU) and Ms Katty Hancq (SESAR 3 JU) were appointed as the deputy accounting officers of the GH EDCTP3 JU by the same GB decision.

Furthermore, the Global Health EDCTP3 JU signed the Service Level Agreement (SLA) on Back Officer Arrangement (BOA) on Accounting Services for the provision of accounting services together with the other joint undertakings (please see below list of SLAs, point 2(f) of this Report).

### **The Global Health EDCTP3 JU Financial and grant management systems**

DG BUDG and Global Health EDCTP3 JU is in the process of signing a Service Legal Agreement on the use of ABAC/SAP and on the treasury services.

The list of users of ABAC/SAP is ready to be communicated to DG BUDG (one of the autonomy notes). By the key date, all users will have done the necessary trainings, including the relevant newcomers from the Global Health EDCTP3 JU staff.

DG BUDG is in charge of the creation of the environment of Global Health EDCTP3 JU in ABAC and will be ready for the date of autonomy. In the meantime, Global Health EDCTP3 JU has nominated the actors (roles) that will be authorised to give visa in ABAC (Ares(2023)7267283).

### **The Global Health EDCTP3 JU Transfer of data**

The Transfer of Files (TOF) in ABAC is part of the data migration from DG RTD to Global Health EDCTP3 JU. This progresses in accordance with the instructions provided by DG BUDG. The transfer of data will be formalized via one of the autonomy notes that Global Health EDCTP3 JU will prepare and will submit to DG BUDG as part of the transition to autonomy.

### **Appointment of the Global Health EDCTP3 JU specific roles**

According to the criteria for the financial autonomy, the Interim Executive Director already appointed:

- an External Administration Manager (ExAM),
- a Single Point of Contact (SPOC) for ABAC and SYGMA/COMPASS,
- a Document Manager Officer (DMO),
- a Data Protection Officer (DPO),
- an Accounting Correspondent,
- an ABAC Coordinator (Ex-AC),
- an External Security Officer (ExISO),
- an External Financial Liaison Officer,
- an External ABAC IT Helpdesk,
- an External Technical IT Manager,
- an OLAF correspondent,
- an Audit Liaison Officer,
- an Organisation User Admin (for EDES),
- an e-procurement change lead.

Please find the list of ED decisions and the ED notes appointing the specific roles in Annex 10.

### **The Global Health EDCTP3 JU Legal Entity File (LEF)**

DG BUDG has created the Legal Entity File (LEF) in ABAC with code 6000781684. Global Health EDCTP3 JU LEF will be unblocked by DG BUDG once ABAC will go into production. (Annex 11)

### **The Global Health EDCTP3 JU Bank Account & Bank Account File (BAF)**

DG BUDG has created the Bank Account File in ABAC with code 0002960473. It will be linked to the LEF of Global Health EDCTP3 JU after autonomy. (Annex 12)

### **The Access to Early Detection and Exclusion System (EDES) for Global Health EDCTP3 JU**

The users in Global Health EDCTP3 JU will request access to EDES right after the autonomy following the instructions of the DG BUDG (EDES panel). The necessary appointment will be done in due time. One relevant user has already followed the training. The rest of the relevant users will follow the appropriate training courses and access will be granted before the signature of any contract or grant agreement to ensure compliance in due time.

### **The Budget of the Global Health EDCTP3 JU**

As already explained above, the Global Health EDCTP3 JU 2023 Budget was adopted by the Governing Board on 3 April 2023 (Annex 6B), together with the 2023 Annual Work Programme. In view of the financial autonomy by November 2023, DG RTD will transfer to the JU the unused budget. This transfer will be formalised with a Framework Partnership Agreement between the European Commission and the Global Health EDCTP3 Joint Undertaking and a Contribution Agreement (see below). The Global Health EDCTP3 JU staff is working on the Annual Work Programme 2024 including the budget for the coming year.

### **The Global Health EDCTP3 JU Financial Framework Partnership Agreement and Contribution agreement**

The Financial Framework Partnership Agreement (former “delegation agreement”) is an agreement between the European Commission and Global Health EDCTP3 JU to:

- define the budget implementation tasks that are entrusted to the JU under the Founding Regulation 2021/2085
- to establish the rules for the implementation and for the payment of the Union Contribution, and
- to define the relations between the JU and the Commission.

The Contribution Agreement (former “transfer of Funds agreement”) is an agreement between the European Commission and Global Health EDCTP3 JU to set out the tasks to be carried out by Global Health EDCTP3 JU each year, and the corresponding EU financial contribution to be paid.

The FFFPA and the Contribution Agreement for year 2023 (covering the period from 24 November 2023 until the end of the year) are already prepared in draft and will be signed by the Global Health EDCTP3 JU and the European Commission after Global Health EDCTP3 JU acquires its financial autonomy. Both documents are based on a template developed by EC services (Annex 13).

The Contribution Agreement for year 2024 will be also prepared as soon as the Work Programme of 2024 will be approved by the Global Health EDCTP3 Governing Board.



## (c) The Global Health EDCTP3 JU internal control

DG RTD ensures that the rules applicable to the Global Health EDCTP3 JU fully comply with the requirements of the Financial Regulation. In compliance with Article 71 of Regulation (EU, Euratom) 2018/1046 the Joint Undertaking will respect the principle of sound financial management.

Monitoring arrangements, including through the Union representation in the Governing Board of the Global Health EDCTP3 JU, as well as reporting arrangements will ensure that the Commission services can meet the accountability requirements both to the College and to the Budgetary Authority.

The internal control framework for the Global Health EDCTP3 JU is built on:

- the implementation of the Internal Control Framework (ICF) offering at least equivalent guarantees to those of the Commission;
- procedures for selecting the best projects through independent peer review evaluation, and for translating them into legal instruments;
- project and contract management throughout the lifetime of every project;
- ex-ante checks on 100% of claims, including receipt of audit certificates and ex-ante certification of cost methodologies;
- ex post audits on a sample of claims as part of the Horizon Europe ex-post audits;
- scientific evaluation of project results.

Various measures have been established to mitigate the inherent risk of conflict of interest within the Global Health EDCTP3 JU, especially:

- one vote for the Commission; the EDCTP Association as the member other than the Union through internal arrangements also votes with one voice in the Governing Board,
- selection of the Executive Director by the Governing Board based on a proposal by the Commission,
- independence of staff,
- evaluations by independent experts based on published selection criteria together with appeal mechanisms and full declarations of any interests,
- a requirement for the Governing Board to adopt rules for the prevention, avoidance and management of conflicts of interest in the Joint Undertaking in accordance with the financial rules of the Joint Undertaking and with the Staff Regulations in respect of staff.

The establishment of ethical and organisational values will be one of the key roles of the Global Health EDCTP3 JU and will be monitored by the Commission.

The Global Health EDCTP3 JU system and process for internal control is in progress and the core documents have already been adopted:

Requirements	Description	Status
<b>Internal Control Framework (ICF) (Annex 14)</b>	Adoption by the GB	ADOPTED Decision GB 11/2023
<b>ICF Action Plan (Annex 15)</b>	Adoption by the ED	ADOPTED Decision ED 22/2023
<b>List of Internal Procedures/rules/framework</b>	Adoption by the ED	ADOPTED Decision ED 23/2023
<b>Manual of Financial Circuits</b>	Adoption by the ED	ADOPTED Decision ED 21/2023
<b>Rules on conflicts of interests</b>	<p>GB decision setting out rules on Confidentiality and on Conflicts of Interest of the Global Health EDCTP3 Joint Undertaking -covering members of bodies and staff of Global Health EDCTP3 JU</p> <p>GB decision on the code of Conduct applicable to the participants of the meetings of the Governing Board of the Global Health EDCTP3 JU</p> <p>Declaration of confidentiality and interest from Board members, renewed every year.</p> <p>Conflict of interest forms and other relevant declarations requested to participants at every meeting of the Global Health EDCTP3 bodies.</p> <p>GB Decision setting out rules on the prevention and management of conflicts of interest in respect of the staff members of the Global Health EDCTP3 Joint Undertaking</p>	<p>ADOPTED</p> <p>ADOPTED</p> <p>COMPLETED</p> <p>COMPLETED</p> <p>ONGOING - Procedure of Article 110 SR, expected to be finalised before autonomy</p>

<b>Anti-Fraud Strategy</b>	Adoption by the GB (not a criterion for the financial autonomy)	PLANNED - Proposed in the ICF Action Plan.
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**Internal Control Framework (ICF) and ICF Action Plan**

The Global Health EDCTP3 JU Governing Board has adopted the Global Health EDCTP3 JU Internal Control Framework (ICF) on 3 August 2023. The JU Internal Control Framework consists of 5 components and 17 Internal Control Principles (ICPs) for an efficient management of the Global Health EDCTP3 JU (Annex 14). These ICPs are based on the same principles as applied by the Commission. It provides generic management principles and sets out the minimum requirements for Global Health EDCTP3 JU control activities.

The ICF action plan has been adopted by the Executive Director before the autonomy (Annex 15). This action plan will help the Global Health EDCTP3 JU by facilitating the response to different types of risks and by providing reasonable assurance regarding the proper execution of the whole operational system.

**List of Global Health EDCTP3 JU Procedures/rules/frameworks**

A list of procedures, rules and frameworks has been adopted by the Executive Director (Annex 16). This list is a living document and will be regularly updated when necessary.

**Manual of Financial Circuits**

This manual has been adopted by the Executive Director (Annex 9) to be used by the Global Health EDCTP3 JU staff. This manual describes the financial circuits for the implementation of the Global Health EDCTP3 JU budget. The financial circuits concern all financial operations taking into account the lean structure of the Global Health EDCTP3 JU and any risks associated with the management environment and the nature of the financing operations. The financial circuits are established in order to standardise the mandatory steps of the processing of financial transactions and to clarify who the different actors are and their responsibilities (grants and procurements).

**Anti-Fraud Strategy (not a criterion for the autonomy but recommended)**

Global Health EDCTP3 JU acknowledges that an anti-fraud strategy is based on the identification of the potential risks for the entity and the measures to manage those risks. However, due to the new entity status of Global Health EDCTP3 JU, more experience is needed to generate the sufficient knowledge on the activity and risks associated. Therefore, Global Health EDCTP3 JU will plan the adoption by analogy of the anti-Fraud strategy of the Research Family, pending for the adoption of the specific Global Health EDCTP3 JU anti-fraud strategy that is planned for 2024.

In the meantime, a number of actions have been planned, such as, awareness raising amongst staff on anti-fraud measures (planned for November 2023); joining the Committee for Fraud and Irregularity in Research (FAIR) (confirmed membership in October 2023).

## (d)The Global Health EDCTP3 JU human resources and relevant regulatory framework

In order to provide the Global Health EDCTP3 JU staff with the adequate regulatory framework (rights and obligations), the Global Health EDCTP3 JU Governing Board already adopted the main staff implementing rules (SIRs).

A first package of Global Health EDCTP3 JU SIRs was adopted already on 1 February 2022 to allow necessary rules to be in place before the entry into service of the first staff members. Those SIRs were complemented by the adoption by the Governing Board of series of SIRs in 2023. Some SIRs were adopted by analogy with the ones in place at the level of the European Commission, while some others were adopted on models developed specifically by the Commission (following a Commission’s ex ante agreement) for Joint Undertakings and/or Executive agencies in order to adapt the rules to the size and specificities of those bodies. The last package of seven decisions has been sent to GB for adoption.

The decisions adopted by the Global Health EDCTP3 Governing Board include implementing rules adopted by analogy as well as implementing rules adopted on model decisions following an ex-ante agreement of the Commission (list of SIRs in Annex 17).

Three decisions had to go through the procedure of Article 110(2) of Staff Regulation, which is still ongoing at the level of the European Commission services and expected to finish by the date of the new Executive Director takes up duties (16 November 2023). These decisions are:

- Decision setting out rules on the prevention and management of conflicts of interest in respect of the staff members of the Global Health EDCTP3 Joint Undertaking.
- Decision on the delegation of the Executive Director of Global Health EDCTP3 Joint Undertaking of the powers conferred by the Staff Regulations on the Appointing Authority and by the Conditions of Employment of Other Servants of the European Union on the Authority Authorised to Conclude Contracts of Employment.
- Decision concerning the probationary period, management trial period and the annual appraisal of the Executive Director the Global Health EDCTP3 Joint Undertaking.

Requirements	Description	Status
<b>Staff Implementing Rules (by analogy or based on model decisions)</b>	Decisions on Staff Implementing Rules by the Governing Board	COMPLETED (last package of seven decisions sent to the GB for adoption)
<b>Staff implementing rules (procedure of Article 110(2) of Staff Regulations)</b>	Decisions on Staff Implementing Rules by the Governing Board	ONGOING (expected by mid-November)

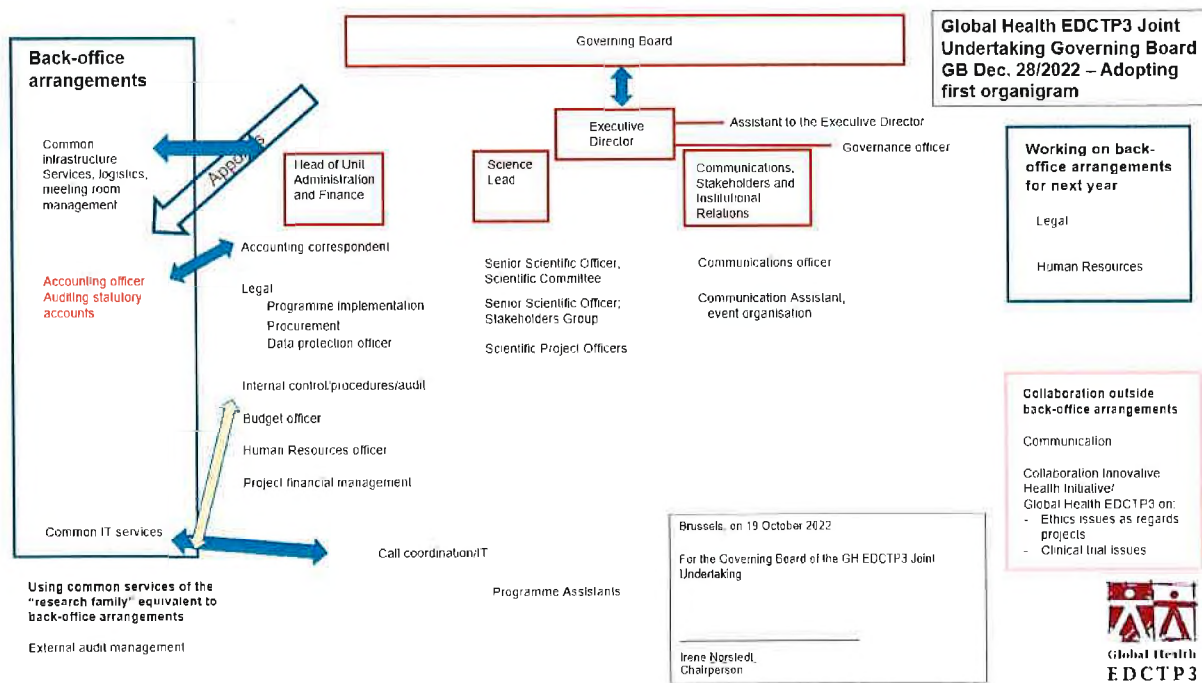
### (e)The Global Health EDCTP3 JU organigram

The Staff Establishment plan (SEP) of the Global Health EDCTP3 JU is based on the Legislative Financial Statement (LFS) accompanying the Commission proposal for a Council Regulation. It is adopted and updated every year together with the Annual Work Plan and Budget. It foresees up to 34 staff members over the lifetime of the Global Health EDCT3 JU.

Key staff has already taken up their positions -please see below the detailed list. The Executive Director will take up duties on 16 November 2023. On that same day, a total of 17 persons, including the ED, will be working for Global Health EDCTP3 JU. Five recruitment processes are ongoing (Head of Administration and Finance, one Personal Assistant two Administrative Assistants and one Financial and Operations Assistant).

According to the table of roles agreed by the Executive Director, the Global Health EDCTP3 JU has sufficient staff to ensure its financial management, respecting the segregation of duties of initiation and ex-ante verification and securing the performance of support functions in relation to the workload.

The organigramme below has been approved by the Governing Board of the Global Health EDCTP3 JU.



The list of staff functions already filled on 16 November 2023 is the following:

Unit / Entity	Title	Date of entering into service
<b>Executive Director</b>	Executive Director	16/11/23
<b>Admin &amp; Finance</b>	HR Officer	1/6/2023
<b>Admin &amp; Finance</b>	Budget Officer	1/7/2023
<b>Admin &amp; Finance</b>	Legal Officer & Data Protection Officer	1/3/2023
<b>Admin &amp; Finance</b>	Legal Officer	1/3/2023
<b>Admin &amp; Finance</b>	Financial and Operations Assistant	1/11/23
<b>Admin &amp; Finance</b>	Financial and Operations Assistant	16/3/2023
<b>ED Office</b>	IT Officer / Call coordinator	1/2/2023
<b>ED Office</b>	Communications Officer	16/4/2023
<b>ED Office</b>	Governance Officer	1/7/2023
<b>ED Office</b>	Internal Control Officer / Audit Manager	1/6/2023
<b>Science &amp; Operations</b>	Senior Scientific Officer	16/2/2023
<b>Science &amp; Operations</b>	Senior Scientific Officer	1/3/2023
<b>Science &amp; Operations</b>	Scientific Project Officer	1/3/2023
<b>Science &amp; Operations</b>	Scientific Project Officer	16/6/2023
<b>Science &amp; Operations</b>	Scientific Project Officer	1/6/2023
<b>Science &amp; Operations</b>	Scientific Project Officer	16/10/2022

This situation will have to be re-assessed at a later stage when the Global Health EDCTP3 JU has reached its full speed, taking into account the workload of the Global Health EDCTP3 JU Staff at that time.



## (f) The Global Health EDCTP3 JU service level agreements

In preparation for autonomy, different Service Level Agreements (SLAs) were already concluded by Global Health EDCTP3 JU with the relevant EC Directorates-General to ensure that the necessary support is given to the Global Health EDCTP3 JU as a body of the European Union.

Different SLAs were also signed with the other JUs in the frame of the Back-Office Arrangements (BOAs), according to Article 13 of the Council Regulation, for synergies, cooperation and support on:

- Accounting services
- HR matters
- Joint procurements and
- ICT services

The BOA on accounting services was signed and implemented, following the decision from the Commission -DG BUDG, not to provide such services for Joint Undertaking under Horizon Europe.

The BOA on Joint Procurements was signed by the JUs based in the White Atrium building (Brussels), mainly to launch contracts for building, catering and other supplies.

The SLAs on BOAs (HR and ICT) SLA are to be expected before the end of the year 2023.

Some other BOAs (like Building facilities) are still under discussion.

Global Health EDCTP3 JU is one of the signatories of the BOAs Accounting and Procurement and is involved in the two other BOAs currently on the table. It is also part of the discussion on the other potential joint initiatives.

Requirements	Description	Status	ARES ref.
Service Level Agreement – DG BUDG	ABAC and Treasury services	ONGOING (expected before autonomy)	N/A
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	SIGNED	Ares(2022)1621091
Service Level Agreement – PMO	Services related calculation of salaries, health and accident insurance (JSIS), pensions, leaving and unemployment allowances, determination of rights	SIGNED	Ares(2023)2251151  Updated version: Ares(2023)3525849

	upon employment, expert and mission reimbursements (MIPS)		
Service Level Agreement – DIGIT	Access to DIGIT ICT framework contracts	SIGNED	Ares(2023)3873710
Service Level Agreement – EPSO / EUSA	Services on personnel selection and development	SIGNED	Ares(2023)4819713
Service Level Agreement – SG	Repository, Recording and Document Management System for official documents, including HERMES, ARES and NONCOM (HAN)	TO BE SIGNED BY FEBRUARY 2024 As advised by SG to be launched together with the testing of the environment	N/A
Service Level Agreement – EU-RAIL JU	Back Office Arrangement with the other JUs Accounting services	SIGNED	Ares(2022)8761674
Service Level Agreement – CBE JU	Back Office Arrangement with the other JUs on HR	TO BE SIGNED BY THE END OF 2023	N/A
Service Level Agreement – CAJU	Back Office Arrangement with the other JUs on Procurement	SIGNED	Ares(2023)2099888
Service Level Agreement – CHJU	Back Office Arrangement with the other JUs on ICT	TO BE SIGNED BY THE END OF 2023	N/A
Service Level Agreement – EU-RAIL JU	Back Office Arrangement with the other JUs on Data Protection Officer externalisation	SIGNED	Ares(2023)3942433
Service Level Agreement – CERT-EU	Organisation and operation of a computer emergency response team for the Union's institutions, bodies and agencies (CERT-EU)	ONGOING	N/A



## (g) The Global Health EDCTP3 JU infrastructure and IT tools

In order to be financially autonomous, the Global Health EDCTP3 JU also had to develop its own infrastructure and IT tool environment to fit the standards of the European Commission.

### Physical infrastructure

Requirements	Description	Status
<b>Office – White Atrium</b>	SLA with IHI JU (subleasing, services and transfer of equipment) - From 1 July 2022 until 31 December 2024	SIGNED Ares(2022)4648333
<b>Office – White Atrium</b>	Amendment to the SLA	SIGNED Ares(2023)3949219
<b>New Usufruct Contract with the White Atrium</b>	Public Procurement procedure with the other JUs – January 2025 to December 2029	PROCEDURE FINALISED AWARD TO WHITE ATRIUM Contract to be signed in 2023-2024

### IT Tools

The Global Health EDCTP3 JU will use the EC corporate tools such as ABAC, SYSPER, ARES, Horizon Europe IT toolchain (e-Grants and e-Experts tools), MIPS, ECS, EU-LEARN, JSIS. For eGrants, no SLA is required because Global Health EDCTP3 is running Horizon Europe calls.

The Global Health EDCTP3 JU entered into Service Level Agreements to have access to the EC corporate tools. Some of the tools have already been configured to the Global Health EDCTP3 JU specific needs and other are on-going.

In terms of risks, it has to be pointed out that the Commission informed the JUs that the current ABAC system (accounting system of the EU) will be soon replaced by a new system (successor) called SUMMA. This new system is currently under testing in some JUs already (like Clean Aviation Joint undertaking) and the migration for the other JUs is planned for 2025-2027 (with some modules already to be put in place in 2024). Therefore, the Global Health EDCTP3 JU will have to prepare for this migration.

## (h) Other obligations

### Obligations towards the host country

As the Global Health EDCTP3 JU is a newly established EU body that will be based in Brussels, Belgium, several legal and diplomatic obligations had to be fulfilled in order to comply with the regulatory framework of the host country.

Those obligations described in the table below:

Requirements	Description	Status
<b>Host Agreement</b>	To define the legal status of the JU in Belgium. Its aim is to guarantee the independence of Global Health EDCTP3 JU and its agents, which leads the host State to grant privileges, such as immunities for the organization's agents, or an extraterritorial status for its premises.	ONGOING – The JU took the necessary steps in March 2023 to be recognised by the Belgian government. The ministry of foreign affairs communicated to the JU that it registered it on 13 April 2023. Subsequently, discussions started with the ministry regarding the host agreement. The JU requested in May 2023 a modification of a provision of the draft proposed so that Protocol No 7 on the privileges and immunities of the European Union applies to representatives of the EDCTP Association in the Governing Board in the same way as it applies to representatives of EU Member States in other JUs. Despite reminders, the ministry has not provided feedback on this request yet. However, the conclusion of a host agreement is not a prerequisite for financial autonomy.
<b>Belgian Business Register</b>	Registration in the Belgian Companies Register (Banque Carrefour des Entreprises – BCE)	REGISTRATION Number: 0801.547.721 (Annex 18)

<b>VAT exemption</b>	Administrative formality requested by the Belgian Authorities	As advised by DG HR, the tax exemption for the ED should be sent to Belgian authorities, as soon as the new ED takes up his duties
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### Obligations relevant to data protection

The Executive Director has already appointed of a Data Protection Officer and a Deputy Data Protection Officer.

Furthermore, the Global Health EDCTP3 JU has adopted the important documents below, following official consultation of European Data Protection Supervisor:

<b>GB Decision on the Restrictions of the rights of the data subjects</b>	ADOPTED and <a href="#">PUBLISHED on the Official Journal of the European Union – 16 October 2023</a>
<b>ED Decision on DPO Implementing Rules</b>	ADOPTED

The Public Registry of the Global Health EDCTP3 JU is under finalisation and also expected to be published on the JU's website by the date of the autonomy.

### 3. Conclusion

This Readiness Assessment Report and its annexes clearly demonstrate that the Global Health EDCTP3 JU programme office and its governance structure have the capacity to implement the Global Health EDCTP3 JU budget by 23 November 2023, and therefore the Global Health EDCTP3 JU is ready to become autonomous on that date. The test of onboarding of Global Health EDCTP3 JU in the ABAC accounting system has been completed successfully.

All key requirements are met, as described in the report. Key staff members have the appropriate competences and training, and the ABAC system was tested to be ready to go in production.

Consequently, the Global Health EDCTP3 JU has the operational capacity to implement its budget legally, regularly, and effectively in the sense of Article 173 (4) of the Council Regulation (EU) 2021/2085 by **23 November 2023**. This is the date proposed by the Interim Executive Director with the agreement of the Executive Director of the Global Health EDCTP3 JU.

The decision on Financial Autonomy is submitted to the Global Health EDCTP3 Governing Board for approval.

## 4. List of Annexes

1. Council Regulation (EU) 2021/2085 establishing the Global Health EDCTP3 JU
2. Table of Readiness Requirements
3. Global Health EDCTP3 JU Governing Board Rules of Procedure (GB decision)
4. Global Health EDCTP3 JU Financial Rules (GB Decision)
5. Global Health EDCTP3 JU GB Decision appointing the Accounting Officer
6. A. List of decisions adopted by the Governing Board in 2022  
B. List of decisions adopted by the Governing Board in 2023
7. List of decisions adopted by the JU Executive Director
8. List of Autonomy notes to be prepared and sent to DG BUDG
9. Global Health EDCTP3 JU Manual of Financial circuits/workflows
10. List of ED decisions and the ED notes appointing specific roles in Global Health EDCTP3 JU
11. Legal Entity Fiche (LEF) of Global Health EDCTP3 JU
12. Bank Account & Bank Account File (BAF) of Global Health EDCTP3 JU
13. Model of Financial Framework Partnership Agreement and Contribution Agreement
14. Global Health EDCTP3 JU Internal Control Framework (ICF) (GB Decision)
15. Global Health EDCTP3 JU Internal Control Framework (ICF) Action Plan (ED Decision)
16. List of Procedures/rules/frameworks (ED decision)
17. List of all Staff implementing rules of Global Health EDCTP3 JU
18. Registration to the BCE (Banque Carrefour enterprises)