



Finance & Project Management Training

Johannesburg, 25-26 April 2025

Abdoulie Barry, Pauline Beattie, Liesbet De Cock, Vincent Declerfayt, Silvia Garcia





This project (Grant Agreement No 101103640) is supported by the Global Health EDCTP3 Joint Undertaking and its members.



Housekeeping

Hybrid training session

41 in-person trainees 150+ registrations online

Please use the Chat function to introduce yourself or to report any technical issues

Please use the Q&A function to post your questions

Video and microphone have been disabled for online participants

To automatically translate the speech to subtitles in your chosen language, navigate to the **Show Captions** function and select your language























1 Introductions

Financial Management Trainer – Abdoulie Barry

Executive Director, EDCTP Association



Mr. Abdoulie Barry joined EDCTP on 7 September 2011 as the Director of Finance & Administration. Before joining EDCTP, he was Head of Finance and Procurement at the Medical Research Council (MRC) Unit in The Gambia. Abdoulie has extensive experience in auditing, risk management and implementing computerised accounting, HR and payroll systems. Abdoulie's experience includes working in the audit and consulting departments of Deloitte, KPMG Peat Marwick and Pannel Kerr Forster.

He holds an MBA in Management from the University of Manchester Business School and is a Fellow of the Chartered Association of Certified Accountants (FCCA) and the Chartered Association of Management Accountants (ACMA)

Project Management Trainer – Pauline Beattie

Operations Manager & Scientific Adviser, EDCTP Association



Dr Pauline Beattie joined EDCTP in August 2011 as the Operations Manager. She is responsible for the management and oversight of the EDCTP2 project portfolio from development of calls for proposals, management of peer review, through to monitoring and evaluation of projects. Before joining EDCTP in 2011, she was a Science Portfolio Manager in Infection and Immunity at Wellcome Trust, UK.

Dr Beattie has a Bachelors, Masters and DPhil in Parasitology, with particular interests in malaria and neglected infectious diseases.

From the EDCTP Association Office in the Hague

Senior Administrative Support Officer – Andreia Coelho



Andreia joined EDCTP in August 2017. As Senior Administrative Officer Operations, she supports the Operations Manager, the Calls and Grants, and Monitoring and Evaluation team. Andreia is also the focal person on the EDCTPgrants online system matters.

Andreia has a degree in Sociology as well as a Master's degree in Human Resources Development Policies. Before joining EDCTP, she worked in Human Resources and at international organisations and companies in various assignments, including project data processing, managing project and dossier documentation, and quality checking.

From the EDCTP Association Office in the Hague

Senior Administrative Support Officer - Jennifer Stamatelos



Jennifer Stamatelos joined EDCTP in November 2014. As a Senior Administrative Officer, she is responsible for the day-to-day general administration of the organisation and also provides assistance to the Executive Director and staff. Jennifer has a degree in Economics from Columbia University and a Master's degree in Sustainable Development from Utrecht University. Prior to joining EDCTP, Jennifer worked as an assistant portfolio manager focused on sustainable investing. Besides her work experience in finance, Jennifer's international work background includes campaign and legal support management.

Global Health EDCTP3 trainer –Vincent Declerfayt



Head of Administration & Finance Global Health EDCTP3 Joint Undertaking

GH EDCTP3 Joint Undertaking – Liesbet De Cock



Head of Scientific Operations
Global Health EDCTP3 Joint Undertaking

GH EDCTP3 Joint Undertaking – Silvia Garcia



Scientific Project Officer Global Health EDCTP3 Joint Undertaking

Meet the course participants

Introductions

Name

Affiliation

What is your role? Job title, responsibilities

Global Health EDCTP3 and EDCTP2 project(s) that you work on

Objectives and learning goals

General

- To present the mission, objectives, achievements of EDCTP and how it has evolved from EDCTP1 to EDCTP2 to GH EDCTP3
- To introduce the trainers from the EDCTP Association and the GH EDCTP3 Joint Undertaking
- To promote networking between course participants

By the end of workshop, participants should understand the mission of EDCTP, the EDCTP Association, and the GH EDCTP3 Joint Undertaking.

Objectives and learning goals

Financial

- To strengthen financial management capacity of course participants
- To provide financial management knowledge and skills required for managing financial aspects of a Global Health EDCTP 3 JU-funded project
- To help organisations to comply with financial reporting requirements for GH EDCTP3 and in general

Participants should be able to: avoid ineligible expenses, interpret auditor reports, implement an internal control system to ensure quality of financial reports

Objectives and learning goals

Project management

- To strengthen project management capacity
- To provide knowledge and skills to manage technical aspects of a GH EDCTP3 (Horizon Europe) project
- To assist institutions to comply with technical reporting requirements

Participants should understand the grant agreement and reporting obligations, be able to submit deliverables and reports of satisfactory quality, ensure compliance with ethics, open access and data sharing conditions, understand and be able to submit amendment requests

Disclaimer

About this training and slides

The presentation on **Project Management** has been prepared by **Dr Pauline Beattie, Operations Manager at the EDCTP Association**

The presentation on **Financial Management** has been prepared by **Mr Abdoulie Barry, acting Executive Director and Director of Finance & Administration at the EDCTP Association**

The presentation is non-binding and is designed for information purposes to support you as a participant in GH EDCTP3 JU actions in the management of your EDCTP3 project(s).

The presentation is based on the legal framework applicable to GH EDCTP3 JU activities, namely Council Regulation 2021/2085 (basic act), European Parliament and Council Regulation 2021/695 (Horizon Europe Regulation), the GH EDCTP3 JU work programmes and the Horizon Europe Model Grant Agreement.

The presentation comprises an **overview** of key information and concepts needed to prepare your grant and manage it. Links are provided to additional information.

You will receive a copy of the slides after this workshop, including additional slides and resources to help you navigate the grants system and to communicate with and report to GH EDCTP3.

Hybrid (Zoom Webinar) – please use the microphones at all times

Translated captions available via Zoom

Questions – will cover questions at end of each session





This project (Grant Agreement No 101103640) is supported by the Global Health EDCTP3 Joint Undertaking and its members.

EDCTP – mission, origin and future

Mission

 EDCTP aims to support collaborative research that accelerates the clinical development of new or improved interventions to prevent or treat HIV, tuberculosis, malaria, neglected infectious diseases and emerging diseases in sub-Saharan Africa

Background

- Established in 2003 in response to MDGs and global health crises caused by PRDs
 - Pool research, activities to achieve greater impact against PRDs
 - Promote integrated approach to health research in Europe
- EDCTP1: 2003-2015
- EDCTP2: 2014-2025
- GH EDCTP3 JU: 2022-2031

The evolution of EDCTP programmes

EDCTP1: 2004-2015 EDCTP2: 2014-2024 (2026) Global Health EDCTP3: 2022-2031

- Legal structure: European Economic Interest Grouping (EEIG)
- Supported under European Commission's FP6/FP7
- Total budget: €400 M (European Union: €200M; Participating States: €200M) and Third parties: €200M
- Disease scope: HIV, tuberculosis and malaria

- Legal structure: EDCTP Association
- Supported under European Union's Horizon 2020
- Total budget: €1.36Bn (European Union: €683M; Participating States: €683M) and third parties: €500M
- Disease scope: HIV, TB, malaria, NIDs, diarrhoeal diseases, lower respiratory tract infections, infectious diseases of epidemic potential

- Legal structure: Joint Undertaking between the European Commission and the EDCTP Association
- Total budget: €1.86Bn (EU Horizon Europe: €900M; Participating States: €550M; Third parties: €400M)
- Disease scope: HIV, TB, malaria, NIDs, diarrhoeal diseases, lower respiratory tract infections, and infectious diseases of epidemic potential

Tuberculosis HIV **EDCTP2** integrated approach and scope Preparatory fellowships Career Strengthening ethics Development capacity and regulatory fellowships framework Short-term Project and training financial GCP/GCLP training management Strengthening product-focused Senior health systems fellowships Site Long-term research and Clinical preparedness training preparedness for Malaria Diarrhoeal MSc. PhD. Postdoc epidemics diseases research S-S N-N Networking Senior Networking Translation of fellowships research results N-S plus into policy (Tandem fellowships) Networking Networks of Excellence Collaborative mentorship · Research studies fellowships · Infrastructure and human EFPIA and PDP partners capacity development (e.g. EDCTP-TDR Clinical . S-S and N-S networking Research and Development Fellowships) **Neglected infectious** Lower respiratory tract diseases infections Emerging and re-emerging infectious diseases

EDCTP1: Results of supported clinical studies

CHAPAS-3 projects supported licensing applications for formulations for children with HIV and provided evidence in support of WHO recommendations on updated treatment options

The **4ABC trial** demonstrated that **DHAPQ as a new option** for the treatment of uncomplicated malaria with the added value of its longlasting prophylaxis in comparison to two other ACTs. The trial results contributed to **the registration of DHAPQ by the EMA**.

The landmark **Kesho Bora trial** generated compelling evidence of the power of antiretrovirals to **prevent mother-to-child transmission of HIV during breastfeeding**. It informed the development of revised WHO guidelines.

The **WANECAM study** provided high-quality evidence that **PA** and **DHAPQ** are safe and effective in West Africa. It supported applications to the EMA for two paediatric formulation. The formulations are now on the list of WHO-pregualified medicines.

Facilitating research

Clinical trial registry for Africa



The Pan-African Clinical Trials
 Registry (PACTR), the only WHO endorsed clinical trial database
 in Africa, is the premier source of
 information on African trials.

Innovation in ethics and regulatory review



- Developed an interactive platform to increase communication between African health research ethics committees (HRECs).
- Mapped Medicines Regulatory
 Authorities (MRAs) and facilitated
 better links between MRAs and
 HRECs.
- In partnership with WHO the establishment of AVAREF.

EDCTP2 grants

2014-2023



Clinical studies

€691.55 M

to support **140 collaborative research grants** with large-scale clinical trials and other clinical research activities conducted by European-African consortia.

Clinical research capacity

€87.56 M

to support **92 grants** that strengthen the enabling environment for conducting clinical trials and clinical research.

Fellowships

€45.19 M

to support **206 fellowships** that focus on the career development of individual researchers.

Simpler and safer treatment of cryptococcal meningitis

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

MARCH 24, 2022

VOL. 386 NO. 12

Single-Dose Liposomal Amphotericin B Treatment for Cryptococcal Meningitis

J.N. Jarvis, D.S. Lawrence, D.B. Meya, E. Kagimu, J. Kasibante, E. Mpoza, M.K. Rutakingirwa, K. Ssebambulidde, L. Tugume, J. Rhein, D.R. Boulware, H.C. Mwandumba, M. Moyo, H. Mzinganjira, C. Kanyama, M.C. Hosseinipour, C. Chawinga, G. Meintjes, C. Schutz, K. Comins, A. Singh, C. Muzoora, S. Jjunju, E. Nuwagira, M. Mosepele, T. Leeme, K. Siamisang, C.E. Ndhlovu, A. Hlupeni, C. Mutata, E. van Widenfelt, T. Chen, D. Wang, W. Hope, T. Bover-Chammand, A. Loyse, S.F. Molloy, N. Youssouf, O. Lortholary, D.G. Lalloo, S. Jaffan, and T.S. Harrison.

DOI: 10.1056/NEJMoa2111904

- Phase III trial of the EDCTP-funded AMBITION-cm project is the largest HIV-associated cryptococcal meningitis treatment trial undertaken so far.
- Results showed that a simplified treatment for cryptococcal meningitis was as good as the WHO-recommended treatment at that time, less harmful to patients and would be more suitable for resource-poor settings.

Rapid WHO advice:

New WHO guidelines strongly recommend a single high dose of liposomal amphotericin B as part of the preferred induction regimen for the treatment of cryptococcal meningitis in people living with HIV.

A new malaria vaccine for children





WHO recommends R21/Matrix-M vaccine for malaria prevention in updated advice on immunization

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 Русский

 Español

THE LANCET

Efficacy of a low-dose candidate malaria vaccine, R21 in adjuvant Matrix-M, with seasonal administration to children in Burkina Faso: a randomised controlled trial

Mehreen S Datoo*, Magloire H Natama*, Athanase Somé, Ousmane Traoré, Toussaint Rouamba, Duncan Bellamy, Prisca Yameogo, Daniel Valia, Moubarak Tegneri, Florence Ouedraogo, Rachidatou Soma, Seydou Sawadogo, Faizatou Sorgho, Karim Derra, Eli Rouamba, Benedict Orindi, Fernando Ramos Lopez, Amy Flaxman, Federica Cappuccini, Reshma Kailath, Sean Elias, Ekta Mukhopadhyay, Andres Noe, Matthew Cairns,

DOI: 10.1016/S0140-6736(21)00943-0

- In October 2023, WHO recommended a second malaria vaccine, R21/Matrix-M, for prevention of malaria in children.
- R21/Matrix-M was developed by the Multi-Stage Malaria Vaccine Consortium (MMVC).
- A critical phase II trial, funded through the EDCTP2 programme, identified a vaccine efficacy of 77% in children aged 5–17 months, with no significant safety issues.
- R21/Matrix-M is the first vaccine to achieve the WHO's target of 75% efficacy and can be used at significantly lower doses than RTS,S/AS01, which should boost vaccine supply.

Schistosomiasis treatment to under-fives



- Led by the Pediatric Praziquantel
 Consortium, the PZQ4PSAC project is cofunded by EDCTP and the Global Health Innovative Technology (GHIT) Fund
- Development of a potential new pediatric treatment option tailored to preschoolaged children with schistosomiasis.
- Results from the phase III trial showed excellent efficacy, achieving cure rates of 90% or above, and was safe and welltolerated by young children.
- In December 2022, EMA validated the regulatory application for this potential new treatment option. EMA is currently assessing the application under the EU-M4all procedure for high-priority medicines intended for countries outside the European Union. Expected response by end of 2023.
- If positive, it will facilitate the inclusion into the WHO's list of prequalified and essential medicinal products and support regulatory pathway in African endemic countries.

Eliminating sleeping sickness in Côte D'Ivoire

The DiTECT-HAT project has made key contributions to the WHO-certified elimination of human African trypanosomiasis (HAT) in Côte D'Ivoire.

PLOS NEGLECTED TROPICAL DISEASES

RESEARCH ARTICLE

Passive surveillance of human African trypanosomiasis in Côte d'Ivoire: Understanding prevalence, clinical symptoms and signs, and diagnostic test characteristics

Minayégninrin Koné^{1,2}, Dramane Kaba¹, Jacques Kaboré ^{3,4}, Lian Francesca Thomas ^{5,6}, Laura Cristina Falzon ^{5,6}, Mathurin Koffi², Cyrille Mambo Kouamé¹, Bernardin Ahouty ², Charlie Franck Alfred Compaoré³, Emmanuel Kouassi N'Gouan⁷, Philippe Solano⁸, Eric Fövre ^{5,6}, Philippe Büscher ⁹, Veerle Lejon⁶,

DOI: 10.1371/journal.pntd.0009656

- In 2021, WHO verified elimination in Côte d'Ivoire, an achievement that drew heavily on the work of the EDCTP-funded DITECT-HAT project.
- The project has been evaluating three point-of-care rapid diagnostic tests and comparing results with laboratory-based methods, at sites in the DRC, Côte d'Ivoire and Guinea. The Côte d'Ivoire studies identified tests suitable for use in the country, as well as symptoms associated with positive test results, which could act as a trigger for testing for HAT.
- The project has also been assessing a potential approach for post-elimination monitoring, which will require testing on a population scale.
- Côte d'Ivoire's submission to WHO included DiTECT-HAT's passive case-detection activities.
- As well its contribution to Côte d'Ivoire's success in 2021, the DiTECT-HAT project's work will also be highly relevant to other countries targeting HAT elimination.

The EDCTP Association

European countries

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

- 9. Luxembourg
- 10. Netherlands
- 11. Norway
- 12. Portugal
- 13. Spain
- 14. Sweden
- 15. United Kingdom

African countries

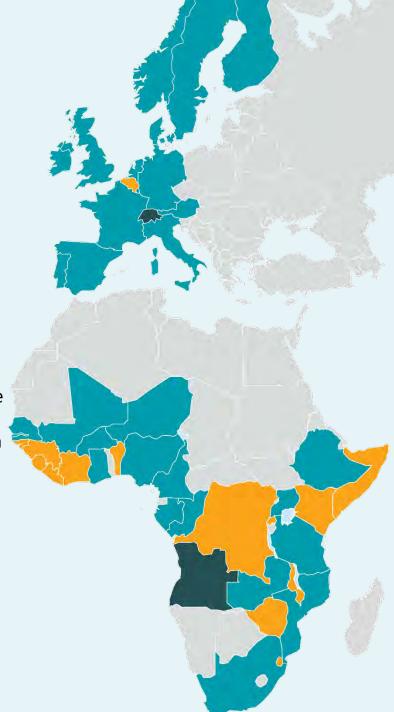
- 1. Benin
- 2. Burkina Faso
- 3. Cameroon
- 4. Cote d'Ivoire
- 5. Democratic

Republic of the

- Congo
- 6. Congo
- 7. Eswatini
- 8. Ethiopia
- 9. Gabon
- 10. The Gambia

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

- 23. Senegal
- 24. Sierra Leone
- 25. Somalia
- 26. South Africa
- 27. Tanzania
- 28. Uganda
- 29. Zambia
- 30. Zimbabwe



Aspirant members

- 1. Angola
- 2. Switzerland

Current roles of EDCTP Association and GH EDCTP3 JU

2

Grant Agreement and beneficiaries

GH EDCTP3 Grant Agreement

Focus on Annex 1 in the project management training

Terms and Conditions (including Data Sheet)

Annex 1 Description of the action (DoA)

Annex 2 Estimated budget for the action

Annex 2a Additional information on unit costs

and contributions (if applicable)

Annex 3 Accession forms

Annex 3a Declaration on joint and several liability

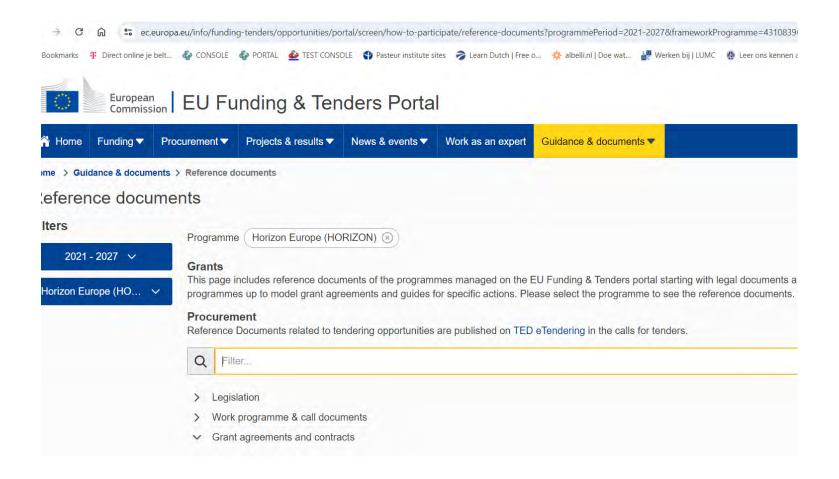
of affiliated entities (if applicable)

Annex 4 Model for the financial statements

Annex 5 Specific rules (if applicable)

GH EDCTP3 Model grant agreement (Horizon Europe)

Horizon Europe reference documents online



Horizon Europe Model Grant Agreement

Summary of chapters and articles

Chapter 1 – General.

Introductory chapter about the subject of the agreement and the major definitions.

Chapter 2 – Action

Duration and starting date

Chapter 3 – Grant

Details about the grant, maximum amount, eligibility of costs and other articles

Chapter 4 – Implementation

- 4.1 Beneficiaries, affiliated entities and other participants
- 4.2 Rules for implementing the action (inc. data, ethics, IPR, dissemination)
- 4.3 Administration, including reporting, non-compliance, impact evaluation, checks, audits

Chapter 5 – Consequences of non-compliance

Rejection, reduction, suspension, termination, sanctions

Chapter 6 – Final provisions

Communication, deadlines, amendments, applicable law, disputes

Horizon Europe (GH EDCTP3)

Annotated Grant Agreement

- Latest version available (May 2024)
- The AGA Annotated Grant Agreement is a user guide that aims to explain to applicants and beneficiaries the EU Model Grant Agreements for the EU funding programmes 2021-2027
- The purpose of this document is to help users understand and interpret their Grant Agreements (GAs)
- Avoids technical vocabulary, legal references and jargon
- Helps applicants and grant holders to find answers to the practical questions they may come across when setting-up or implementing their projects.

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf

GH EDCTP3 Grant Agreement

Data sheet of the grant agreement

- Start and end date
- Maximum grant amount
- Reporting periods
- Pre-financing amount
- Mutual Insurance Mechanism (MIM)
- Bank account
- Cost categories
- Other important information

Data sheet

Taken from Model Grant Agreement (MGA)

Project: [insert number] — [insert acronym] — [insert call identifier]

EU Grants: HE MGA — Multi & Mono: V1.2 – 01.04.2024

DATA SHEET

1. General data

Project summary:

Project summary

Text from DoA Annex 1 Part A (same text as proposal abstract)

Keywords: [keywords from proposal]

Project number: [project number, e.g. 690853330]

Project name: [full title]
Project acronym: [acronym]

Call: [call ID, e.g. PROG-(SUBPROG-)YEAR-CALLABREV]

Topic: [topic ID, e.g. PROG-(SUBPROG-)YEAR-CALLABREV-NN/TOPICABBREV]

Type of action: [ToA, e.g. HORIZON Research and Innovation Actions]

Granting authority: /European Commission – EU/ /European Commission – Euratom/ /[name of Executive Agency]/ /[name of EU funding body]/

Grant managed through EU Funding & Tenders Portal: Yes (eGrants)

[OPTION for SGAs: Framework Partnership Agreement No [insert number] — [insert acronym]

Project starting date⁷: [OPTION 1 by default: first day of the month following the entry into force date] [OPTION 2 if selected for the grant: fixed date: [dd/mm/yyyy]/

Project end date: [dd/mm/yyyy]

Project duration: [number of months, e.g. 48 months]

Grant Agreements

Chapters and Articles

Important reference document

Familiarise yourself with the Grant Agreement

You do not need to be a lawyer to understand the agreement – check the AGA

Understand the rights and obligations of your institution

Ensure that you manage the grant correctly

The beneficiaries and the consortium

GH EDCTP3 (Horizon Europe) project types

Main types of action

Action type determines scope of the proposal, reimbursement rate, specific evaluation criteria, forms of costs

Research and Innovation Action (RIA)

Activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution. Includes basic and applied (clinical) research, technology development and integration, testing and validation etc.

Coordination and Support (CSA)

Accompanying measures such as standardisation, dissemination, awareness-raising and communication, networking, coordination or support services, policy dialogues and mutual learning exercises and studies.

Other: Identified Beneficiary Action

Eligibility requirements GH EDCTP3

Composition of a consortium

The consortium must include*

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

Eligibility conditions are the same for RIA and CSA

Associated Country to Horizon Europe

Closest form of cooperation with non-EU countries

Allows institutions in Associated Countries to participate on equal terms, as far as possible, with institutions of EU countries

It makes it easier to work on and fund joint projects

The Associated Country provides a financial contribution based on an international agreement with the EU

Eligible to receive funding under EDCTP3 but does not count towards eligibility criteria (number of institutions) unless is a member of the EDCTP Association

Associated Countries to Horizon Europe

Current list as of April 2025

Albania	Armenia	Bosnia and Herzegovina		
Canada	Faroe Islands	Georgia		
Iceland	Israel	Kosovo		
Moldova	Montenegro	New Zealand		
North Macedonia	Norway	Serbia		
Türkiye	Tunisia	Ukraine		
United Kingdom				

EDCTP Association

African Association members are eligible for GH EDCTP3 funding

15 European and 30 African countries are members of the EDCTP Association*

The EDCTP Association is the legal structure for the implementation of the second EDCTP programme (2014-2024)

EDCTP Association is a partner in the Global Health EDCTP3 Joint Undertaking

The JU is led by a Governing Board, in which both the EDCTP Association and the European Commission, representing the European Union, have equal votes

^{*}As of April 2025

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

Eligible: Senegal, Malawi, Spain and South Africa, Norway, France Ineligible: Belgium, Senegal, Chad as Chad is not a member of the EDCTP Assocation

Ineligible: Canada, Senegal, Portugal as Canada, although an Associated Country to Horizon Europe, is

not a member of EDCTP Association

Multi-beneficiary grants

- Grant Agreement is between GH EDCTP3 JU and Institutions (not individuals/people)
- All beneficiaries in a consortium must sign (adhere to) the Grant Agreement
- Grant Agreement is signed by the authorised legal representative (not the principal investigator)
- Grant "belongs" to the institution (not to individuals) with rights and obligations (cf investigator moves to another institution)
- Coordinator is the main focal point between the Consortium and GH EDCTP3 JU
- Relationship between project partners (including coordinator) is regulated through a "Consortium Agreement"

Role and responsibilities of Coordinator

Beneficiary with specific 'administrative' responsibilities

Coordinator is the consortium beneficiary who serves as the central contact point and represents the consortium towards the funder

Coordinator acts on behalf of the project consortium

Coordinator must coordinate and manage the grant, including distribution of payments received from the funder

Coordinator submits all reports, payment requests, deliverables and amendment requests to the funder

May have specific scientific responsibilities set out in Annex 1

The Coordinator is the project's 'administrator'

The beneficiaries are jointly responsible for the technical implementation of the project

Global Health EDCTP3

Coordinators

- GH EDCTP3 Legal entities established in an EU Member State or an <u>Associated Country</u> to Horizon Europe can be the Coordinator
- 'Third countries' can only be Coordinator if they have concluded a bilateral Science & Technology agreement with the EU
- 'Third countries' are states that are neither members nor contractual partners of the EU
- South Africa is currently the only African country that has a Science & Technology agreement with the EU

Coordinator and Scientific Project Leader

Coordinator ≠ Scientific lead

- Project should assign an African 'Scientific Project Leader'
- Acts as the key contact point for the GH EDCTP3 JU alongside the coordinator on scientific governance & leadership actions including external communication
- Monitors that the scientific tasks are implemented properly
- Collaborates with the coordinator on the project monitoring and adoption of measure to ensure beneficiaries are fulfilling their obligations
- Inclusion of a work package on Scientific Leadership is mandatory

Coordinator responsibilities

Article 7 of the grant agreement

The coordinator must:

- Monitor that the action is implemented properly (see Article 11) Act as the intermediary for all communications between the consortium and the funder
- Submit the pre-financing guarantees to the funder (if any)
- Request and review any documents or information required and verify their quality and completeness before passing them on to the funder
- Submit the deliverables and reports to the funder
- Inform the funder about the payments made to the other beneficiaries (report on the distribution of payments; if required, see Articles 22 and 32)
- Distribute the payments received from the funder to the other beneficiaries without unjustified delay (see Article 22).

Beneficiaries

Obligations and responsibilities

Each beneficiary

- Must ensure that it complies with its obligations under the Grant Agreement
- Must ensure swift and proper implementation of the action (i.e. that there are no delays and that the work is done properly)
- Is responsible for the tasks performed by its subcontractors, affiliated entities and associated partners

The beneficiaries are jointly responsible for the technical implementation of the action

If one of the beneficiaries leaves the action (irrespective of the reason), the remaining beneficiaries must carry out the action as set out in the description of the action

Consortium agreement

Internal agreement between beneficiaries

Art. 7 GA: The beneficiaries must have internal arrangements regarding their operation and coordination, to ensure that the action is implemented properly.

The funder is not a party to the consortium agreement

The funder does not approve the consortium agreement

Model consortium agreement **DESCA** (compliant with Horizon Europe)

- Governance structure
- Decision-making, meetings and quorum
- Ownership of results
- Dissemination of results, publications

Important that there is an agreement in place especially in the event of disagreements

The grant agreement takes precedence

Guidance: How to draw up your consortium agreement (H2020)

See also Slides from National Contact Point https://horizoneuropencpportal.eu/sites/default/files/2022-04/Consortium%20Agreement%20in%20HE.pdf

Types of partners

Beneficiaries (including beneficiaries not receiving funding)
Responsible for implementation of the action/project

Affiliated entities

Have a legal link or are affiliated to one of the beneficiaries

- Evidence of the legal link may be requested
- Do not sign the grant agreement
- Have the same obligations and rights
- Reporting is done via the beneficiary to which the entity is linked
- Charge actual costs (no profit)

Example – hospital or a centre linked to a university

Types of partners

Associated partners (GH EDCTP3)

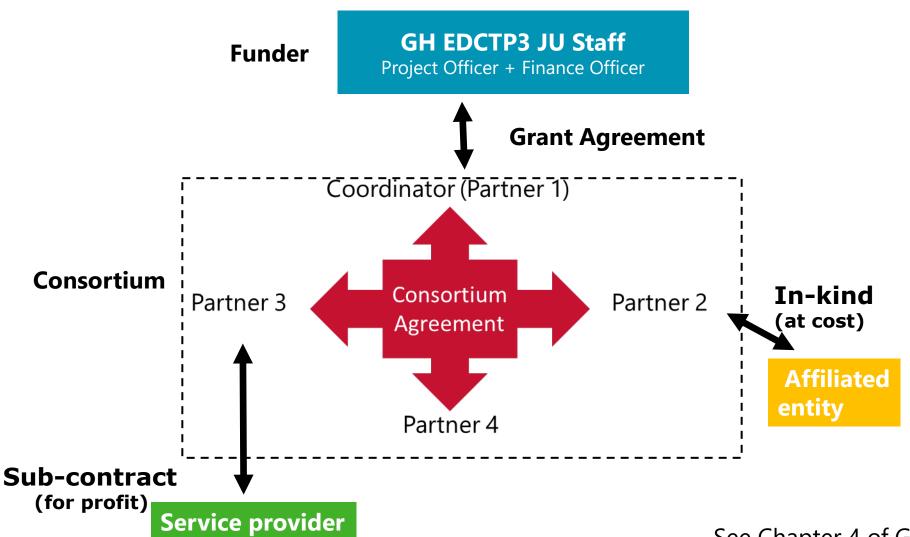
- Do not sign the grant agreement
- Cooperate with the beneficiaries to implement the action
- Their tasks are outlined in the Annex 1
- May not charge costs or contributions to the action
- Beneficiaries are responsible for the proper implementation of the tasks implemented by Associated Partners (quality, timely delivery, etc)
- Associated partners also have obligations (ethics, record keeping, confidentiality and security, visibility/acknowledging EU, proper implementation, avoidance of conflict of interest etc)

Types of partners

Subcontracts (sub-contractors)

- Do not sign the grant agreement
- Beneficiaries sign a contract with subcontractors
- Beneficiaries pay subcontractors to provide works or services or for implementation of specific action tasks
- Cost is the price charged to the beneficiary by the contractor or subcontractor (usually containing a profit margin for the contractors or subcontractors but not for the beneficiary)
- Beneficiary must award contracts and subcontracts on the basis of best value for money (or lowest price) and absence of conflict of interests
- Not a way to get around eligibility criteria
- Subcontractor is not a 'true partner' in the project

Structure of a project



Coordinator & partners

Coordinator

- Monitor the project implementation
- Act as focal point for EDCTP communication
- Collect and submit reporting to EDCTP
- Receive and distribute EDCTP funding

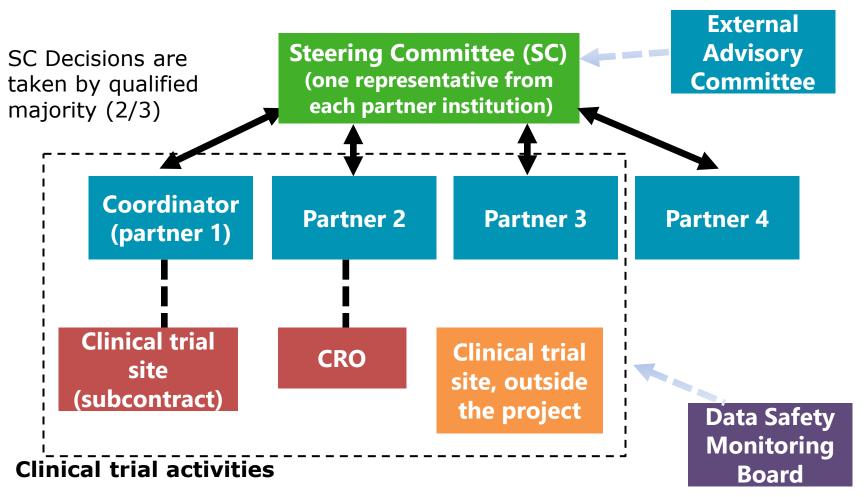


- Notify of any changes in name, address, legal representative, ownership etc.
- Events that affect/delay project
- Timely submit financial and technical reports, ethics and
- Clinical trials approvals and any other relevant documentation

The Coordinator is the project's "administrator"; the scientific leader may be another partner

Project Management structure

Example of equal partnership



Questions and comments?

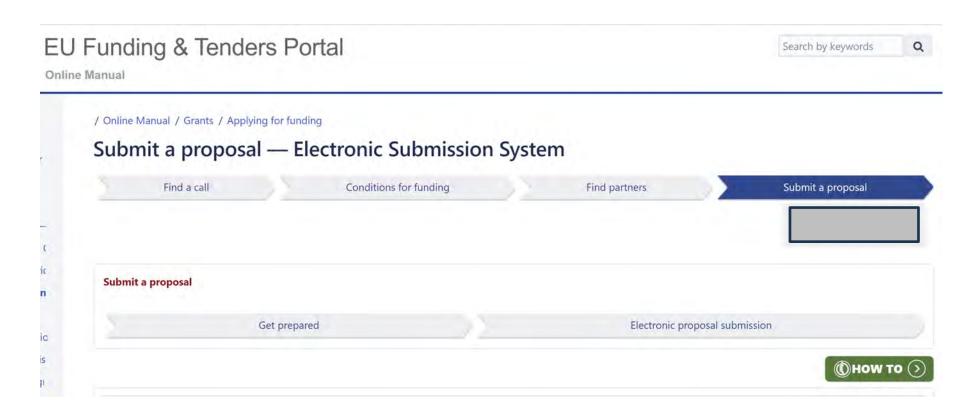
Consortium partners

- Experience of Coordinators
- Experience of Beneficiaries
- Consortium agreement

4 Annex 1 of the grant agreement

From Proposal to Annex 1

Submitting a proposal



Structure of a proposal

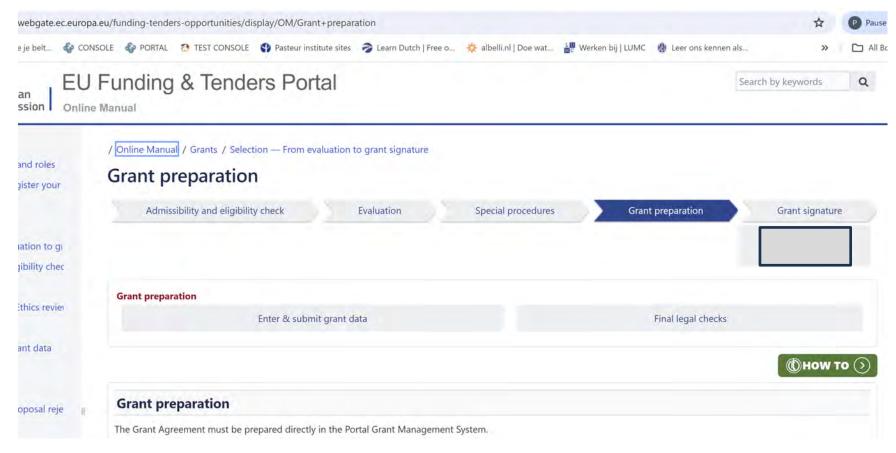
Part A and Part B

- The **application form** is structured in two parts, Parts A and B:
- Part A: contains the structured Administrative Forms with data on the participants, legal declarations and contact persons (retrieved from the Submission System screens). It may also include some programme-specific questions.
- Part B (the narrative part): Technical Description of the project with the planned activities, work packages, costs, etc. (is uploaded as PDF).
- Part A is generated while entering the data into the Submission System; Part B needs to be prepared in advance (using the template downloaded from the system)
- Part B will also include annexes and supporting documents if required by the call conditions (detailed budget table, declarations from national authorities, CVs, annual activity reports, etc.)

Standard template (for reference only) can be found in the call text

Preparing Annex 1

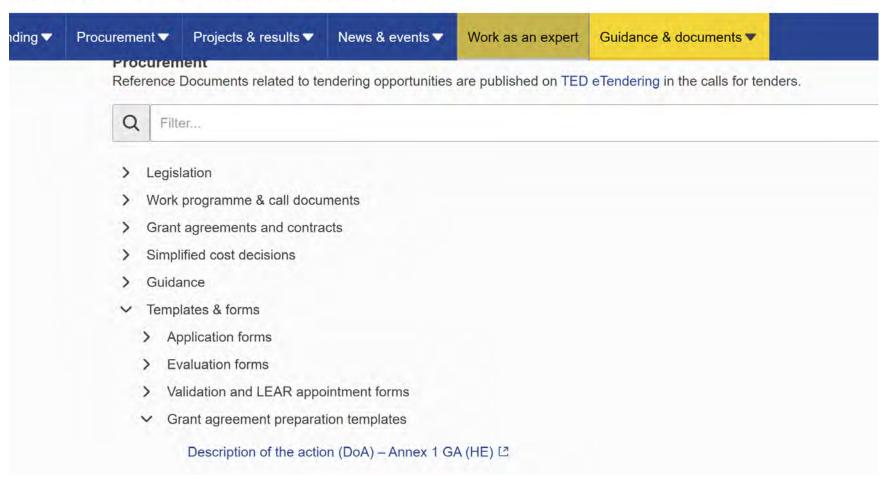
Step by step guide



Creating Annex 1

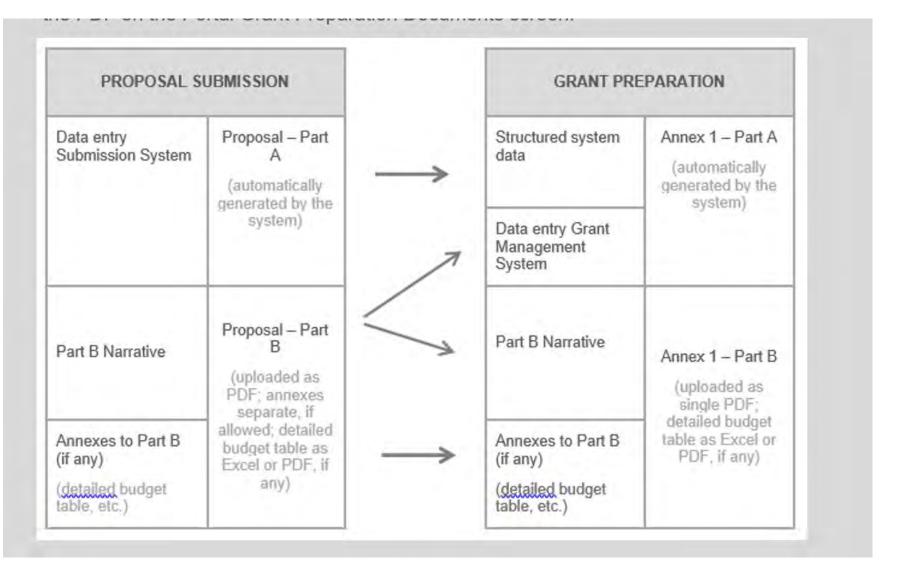
Instructions and guidance in the EU portal

European EU Funding & Tenders Portal



Proposal to Annex 1

Steps in the portal



Annex 1

Part A

- Tables with project information; explanation of each component
- Project summary
- List of participants
- Work packages
- Deliverables
- Milestones
- Critical implementation risks
- Research infrastructure
- JU contributions

Annex 1

Part B

Part B (merging B1 and B2)

- History of changes (proposal to annex 1)
- Table of Contents: Excellence, Impact, Implementation
- Excellence
 - a. Objectives and ambition
 - b. Methodology
- Impact
 - a. Pathway to impact
 - b. Measures to maximise impact dissemination, exploitation and communication
 - c. Summary: Needs → Results → DEC measures → Target groups, outcomes, impact
 - d. Additional exploitation obligations
- Implementation
 - a. Work Plan and resources
 - b. The consortium capacity of participants and consortium as a whole; responsibilities for deliverables; transfer of tasks and responsibilities; budget allocation
- General overview Record-keeping; progress reporting and submission of deliverables

Annex 1 in summary

- Annex 1 is the proposal you submitted but modified (slightly) during grant preparation
- Technical description:
 - What will be done, when, where and by whom
 - Organised in a logical manner (WPs)
 - Meaningful outputs (Deliverables)
 - Milestones track the pathway to the results
 - Dissemination, exploitation and communication explains how you will inform others about the project, make the results available and to whom to achieve impact
- (Major) changes to Annex 1 require an amendment

Annex 1 components

Work package (WP) – major subdivision of project

Organises the proposal in a logical, consistent and structured way into group of activities in a work package

Presents a clear, logical link to the project objectives and to the other work packages

Is a sub-part of the project, a step leading to the achievement of the project's overall goals

How many work packages?

As many as you need; as few as possible

WP1 — management and coordination activities

WP2 — outputs related to the project goals

Other WPs depending on project objectives, complexity and scope

Describe objectives, activities to be implemented, outputs

Annex 1 components

Work package (WP) – major subdivision of project

Examples of work packages

- Management and Coordination
- Clinical trial or clinical study
- Capacity building
- Data management
- Ethics
- Scientific leadership

Expectation that there is balance in the consortium

Each beneficiary has clear roles and responsibilities

Deliverables and milestones

Outputs and progress points

Milestones

Control points in the project that help to chart progress

Examples: kick-off meetings, steering committees, first draft of a survey, production of a prototype, key decision-points in project progress

Deliverables

- Meaningful outputs from the project
- To be submitted to the funder
- Be specific in your description of the deliverable
- Be realistic about what you can achieve within the project duration
- Be ambitious but not unrealistic
- The scope of your project should be large enough to make a difference, but it doesn't need to produce an excessively high number of outputs.
- Refer only to major outputs and do not include minor (internal) items
- Adapt the number of deliverables to the size of your project and work packages (use as many as necessary, as few as possible).
- You may be asked to reduce or increase the number during grant preparation.

Deliverables

Number, type, dissemination level

Number	Deliverable name	Short description	WP number	Name of lead participant	Туре	Dissemination level	Delivery date (months)
1.1	DMP	data management plan	1	UCAD	DMP	PU	6
2.2	Project website	Website of project	1	ALIMA	DEC	PU	7

R: Document, report (excluding the periodic and final reports)

DEM: Demonstrator, pilot, prototype, plan designs

DEC: Websites, patents filing, press & media actions, videos, etc.

DATA: Data sets etc.

DMP: Data management plan

ETHICS: Deliverables related to ethics issues

SECURITY: Deliverables related to security issues

OTHER: other types, e.g. models, alogarithms, software

Deliverables

Dissemination levels

PU (public)

Fully open

SEN (sensitive/confidential) — limited under the conditions of the Grant Agreement (Article 13)

EU classified (EUCI) under Decision 2015/444:

EU-RESTRICTED, EU-CONFIDENTIAL, EU-SECRET

Information or results could have security implications

GH EDCTP3 funding comes mainly from public sources (taxpayers)

- Requirement for open access
- Expectation that (many) deliverables can be made public
- Personal data protection must be taken into consideration

Deliverables

Examples of outputs of the project

Protocol

Publication or report

Conference abstract (presentation/poster)

Website

Database

Specific deliverables to be added, for example:

Data management plan, ethics-related deliverables, clinical studies, stewardship plan, global access plan

Article 21 Reporting

Article 21.1 Continuous reporting

The beneficiaries must continuously report on the progress of the action (e.g. deliverables, milestones, outputs/outcomes, critical risks, indicators, etc; if any), in the Portal Continuous Reporting tool and in accordance with the timing and conditions it sets out (as agreed with the granting authority).

Standardised deliverables (e.g. progress reports not linked to payments, reports on cumulative expenditure, special reports, etc; if any) must be submitted using the templates published on the Portal.

Article 21.1 Continuous reporting

Expectations

Continuous reporting includes:

- progress in achieving milestones
- deliverables
- updates to the public summary
- response to critical risks
- publications, communications activities, IPRs
- programme-specific monitoring information (if required).

Where? The **Continuous Reporting Module** is accessible through the link you receive at the beginning of the project.

Who? Milestones and deliverables should be uploaded by each beneficiary for their work.

What? You should report on milestones and deliverables in accordance with the schedule set out for them.

GH EDCTP3 Article 21 Reporting

Submission of deliverables

GH EDCTP3

Continuous reporting on the implementation of the action

Continuous submission of deliverables via the online system

Required to report delays in progress

Submission of deliverables is not linked to the periodic report

Don't wait until the report to submit your deliverables

Deliverables

<u>https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Completing+the+Deliverables</u>



EU Funding & Tenders Portal

IT How To

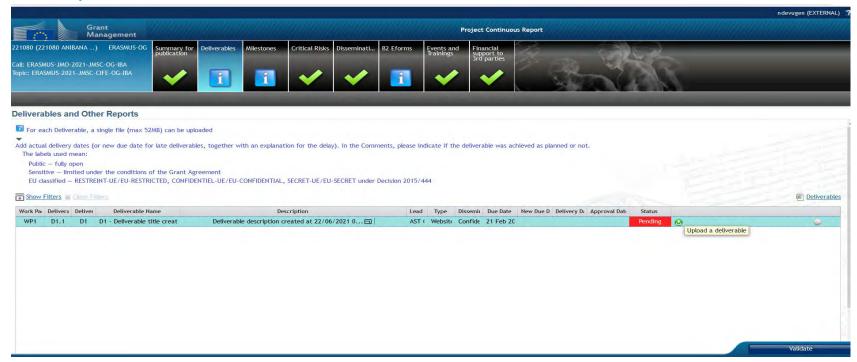


Completing the Deliverables



Continuous reporting

Upload of deliverables



- . Pending, when a deliverable hasn't been uploaded yet.
- · Draft, when a deliverable has been uploaded

. Once uploaded, a deliverable can be downloaded

, deleted

×

or submitted

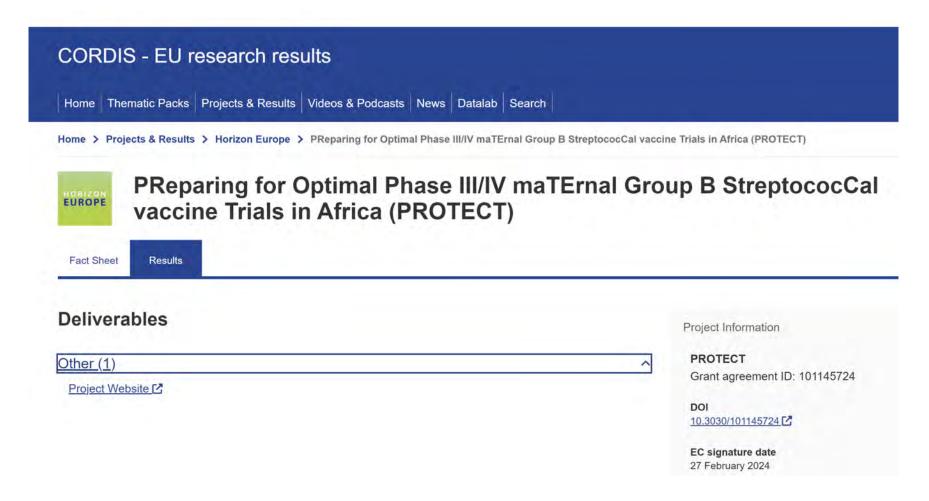
- Submitted, when a deliverable has been submitted. You can add a comment (optional) and you are asked to confirm that you wish to submit the deliverable. The date the deliverable has been submitted, will appear in the column "Delivery date". Once the EU Officer has accepted the deliverable, the date he/she accepted will appear in the column "Approval date".
- Note that only the Primary Coordinator Contact (PCOCO) can Submit deliverables.

When the status is displayed with a red background (

) this means that the due date (or the new due date, if revised) has passed.

Publication of project info and deliverables

https://cordis.europa.eu/projects



SNIP-AFRICA

Deliverables



SNIP-AFRICA

Deliverable 1.1



D1.1 Project Handbook

Project title	SNIP-AFRICA – Severe Neonatal Infection Adaptive Platform Trials in Africa
Deliverable number	D1.1
Deliverable name	Project Handbook
Deliverable type	R
Work Package	WP1
Organisation and person responsible	Penta
Dissemination level	PU
Contractual delivery date (month)	M3
Actual delivery date (month)	M3
Version	1.0
Total number of pages	40

What might go wrong during the project?

How will the project prevent this happening?

How will the project deal with the issue if it happens?

Critical implementation risks and mitigation actions

Continuous monitoring and updating of risks by the Coordinator

Implementation risks must be set out in the project proposal and become part of the Description of Action

Types of risks – general, technical, management, personnel, external factors

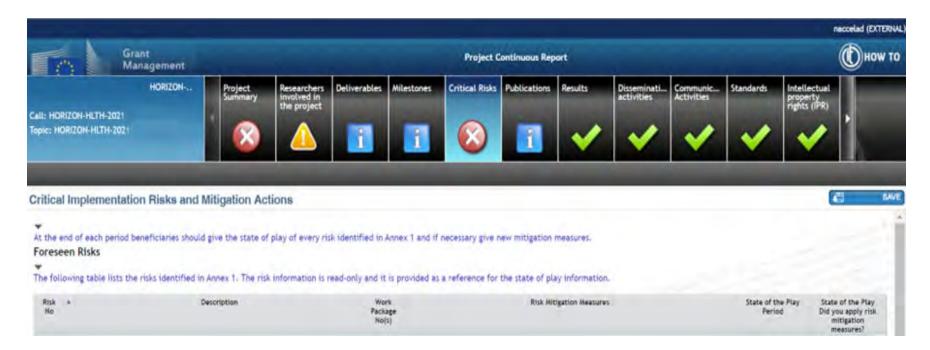
- Identify the risks
- Assess the likelihood and impact
- Define a response plan (frequency, who is responsible, measuring)
- Monitoring and implementation of the plan

Examples

Recruitment delays, Loss to follow-up, political unrest, test results disappointing, ethics and regulatory issues, WHO policy changes, epidemics/pandemic

Continuous reporting - example

Description of risk	Probability/Impact	Proposed-risk
	severity	mitigation measures
Failure to reach	Low/high	Widen the inclusion
recruitment target		criteria; open new
		centres



Periodic reporting – List of critical risks

Foreseen risks

oreseen risks he table shows to	ne risks already listed in Annex 1 of the Grant Agreeme	ent (read-only).	
Risk No	Description	Work Package No(s)	Proposed Mitigation Measures
[risk number as in Annex 1 GA]	[description as in Annex 1 GA]	[WP numbers]	[mitigation measure as in Annex 1 GA]

Unforeseen risks

Unforeseen risks			
Risk No	Description	Work Package No(s)	Proposed Mitigation Measures
[unforeseen risk number]	[insert description]	[insert WP numbers]	[insert mitigation measure]

State of play

State of play Continuous Reporting (Critical Risks screen) — Give the state of play of the risks that were identified in Annex 1 of the Grant Agreement (and new risks that materialised during project implementation) and add new mitigation measures, if needed. Reporting Period Did you apply risk Did your risk Risk No Comments mitigation measures? materialise? [risk number] [RP number] [YES] [NO] [YES] [NO] [insert comment (mandatory if no risk mitigation measures where applied or planned risk mitigation measures were not applied)]

Communication, dissemination & exploitation

Grant agreement sections

ARTICLE 16 — Intellectual property rights (IPR) — background and results — access rights and rights of use

 Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5.

ARTICLE 17 — Communication, dissemination and visibility

Impact

Achieving impact from your project

Pathways to achieve the expected outcomes and impacts specified in the work programme

Likely scale and significance of the contributions due to the project

Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

Impact section

Proposal to Annex 1

Specific needs	What are the specific needs that triggered this project?
Expected results	What do you expect to generate by the end of the project?
D&E&C measures	What dissemination, exploitation and communication measures will you apply
Target groups	Who will use or take up the results of the project? Who will benefit from the results of the project?
Outcomes	What change do you expect to see after successful dissemination and exploitation of project results to the target group(s)?
Impact	What are the expected wider scientific, economic and societal effects of the project contributing to the expected impacts

Article 17

Communication, dissemination, open science and visibility

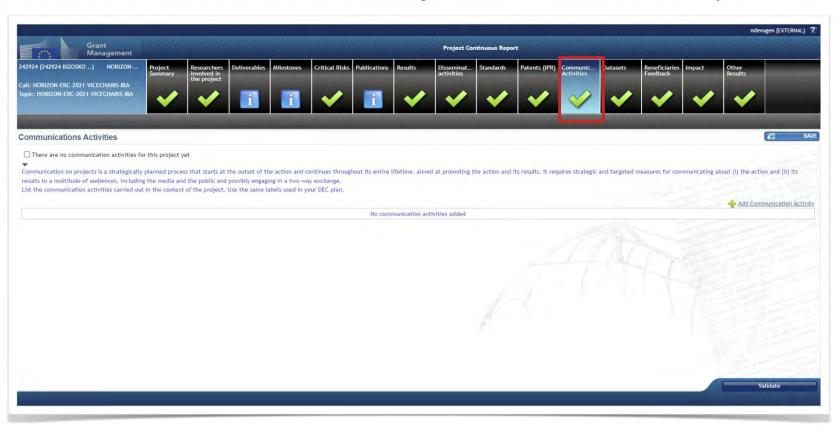
Unless otherwise agreed with the granting authority, the beneficiaries must promote the action and its results

- By providing targeted information to multiple audiences (including the media and the public)
- In accordance with Annex 1 and in a strategic, coherent and effective manner
- Before engaging in a communication or dissemination activity expected to have a major media impact, the beneficiaries must inform the granting authority (GH EDCTP3).

Communication activities

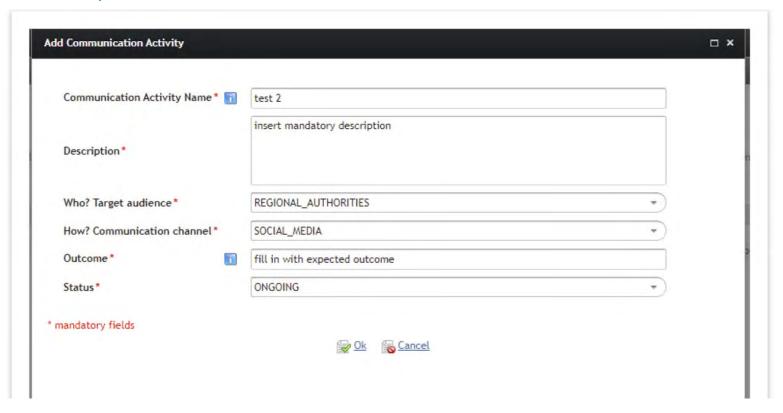
Continuous and periodic reporting

The **Communication activities** tab contains a table listing all communication activities for the Project.



Communication activities

Description

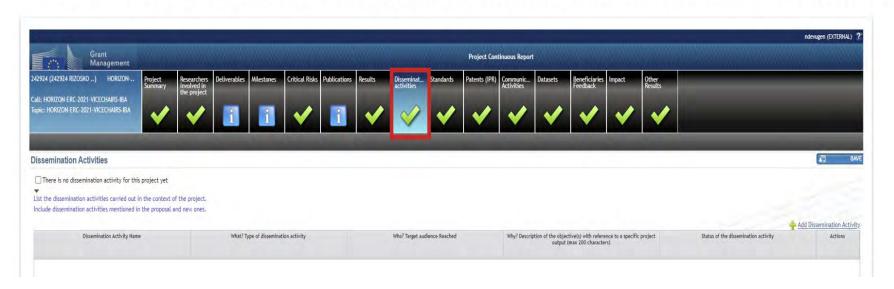


Dissemination activities

Continuous and periodic reporting

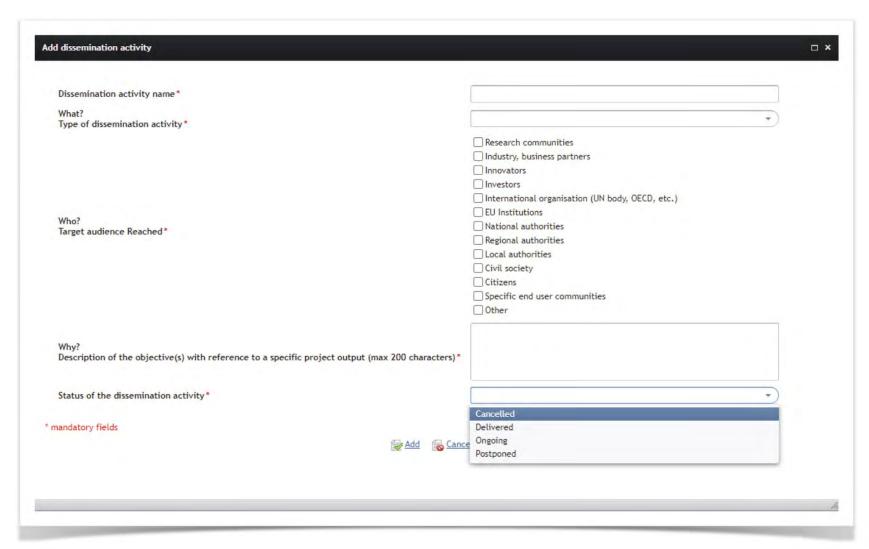
- Public disclosure of the project results
- Dissemination activities by any appropriate means (other than resulting from protecting or exploiting the results), including the scientific publications in any medium

The **Dissemination activities** tab contains a table listing all dissemination activities envisioned for the Project results



Dissemination activities

Description



Funding acknowledgements

From Article 17.4 and Annex 5 of the Grant Agreement

Projects must display the following:

- EU emblem (Co-funded by the European Union)
- Global Health EDCTP3 logo
- The statement: "This project (Grant Agreement No XXXXX) is supported by the Global Health EDCTP3 Joint Undertaking and its members (as well as [if any → insert names of contributing partners])"

Example from this training workshop which is supported by GH EDCTP3





Co-funded by the European Union

This project (Grant Agreement No 101103640) is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Quality of information - Disclaimer

Article 17.3

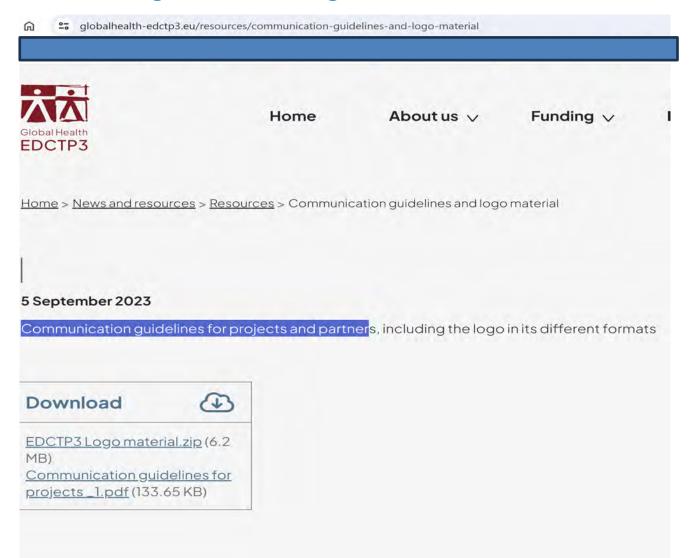
Any communication or dissemination activity must be factually accurate

Disclaimer

"Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Global Health EDCTP3 Joint Undertaking. Neither the European Union nor the granting authority can be held responsible for them."

Communication guidelines for projects and partners

GH EDCTP3 guidance on logo and text



Additional exploitation obligations

Specified in the work programme

Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions.

In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions

In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results

For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

Additional obligations

Affordable access

Provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085

Projects must include the following deliverables:

Stewardship plan

Outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials).

Draft plan – to be submitted halfway through the project

Final plan – to be submitted with the final report

Global access plan

An appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to intellectual property and other strategies that reflect ability to pay and ensure that economic barriers to access are low

To be submitted with the final report

Useful guidance on developing access plans

Uniting Efforts for Innovation, Access and Delivery



Information available on the website

https://www.unitingeffortsforhealth.org/

https://www.unitingeffortsforhealth.org/planning-for-access







Example from DNDi

Taken from Planning for Access report

Table 3. Essential elements of a public-interest target product profile by DNDi*

Indications	Which disease(s)?
Population	Which type(s) of patients, and where and in what conditions do they live?
Clinical efficacy	What is the level of efficacy required and how will it be measured?
Safety and tolerability	What level of acceptability is there for adverse events (i.e. side effects)?
Stability	How long is the shelf-life of the drug(s) and what are the storage conditions (i.e. does it require refrigeration)?
Route of administration	What is an acceptable way to administer the treatment to the patient population (e.g. oral, injectable)?
Dosing frequency and treatment duration	How often and how long must it be given?
Price	Will it be affordable to the target population or health system?

^{*} Reproduced from DNDi. 15 years of needs-driven innovation for access (2019). More information here.

5 Ethics issues

Ethics requirements

Ethics and values (Article 14)

14.1 Ethics

The action must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles. Specific ethics rules (if any) are set out in Annex 5.

14.2 Values

The beneficiaries must commit to and ensure the respect of basic EU values (such as respect for human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

Ethics self assessment at proposal stage

Ethics requirements follow from ethics self assessment and review

'<u>How to</u>' ethics self assessment guide (Horizon Europe)

- 1. Human embryonic stem cells
- 2. Humans
- 3. Human cells and tissues
- 4. Personal data
- 5. Animals
- 6. Non EU countries
- 7. Environment, health and safety
- 8. Artificial intelligence
- 9. Other ethics issues
- 10. Potential misuse of results

Ethics issues

2. Humans

Projects with activities involving work with humans (not staff, beneficiaries) Research or study participants, persons concerned by the project activities, etc., regardless of its nature or topic

This applies to collection of biological samples, personal data, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other projects, officially collected information, social media sites, etc

Considerations

- Respect for persons and for human dignity
- Fair distribution of benefits and burden
- The rights and interests of the participants
- Ensuring participants' free informed consent with particular attention to vulnerable categories of individuals such as children, patients, discriminated people, minorities, persons unable to give consent

Ethics issues

Informed consent and information sheets

Witten in a language and terms that can be fully understood

Describe the aims, methods and implications of the project activity

Describe the nature of the participation and any benefits, risks or discomfort that might occur

Explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences

State how biological samples and data will be collected, protected during the project and whether they will be destroyed or reused afterwards

State what procedures will be implemented in the event of unexpected or incidental findings

How and when participants will be informed about such finding, whether they have the right "not to know" about any such findings, and whether relevant findings (e.g. genetic information) might affect relatives as well).

Individuals unable to give consent

Activities involving children (or other persons unable to give consent) — should be carried out only if

- Studies with consenting adults would not be effective
- Participants are subject to only a minimal risk and burden
- Results of the research will benefit the individual or group represented by the participant

Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents/legal representatives. Dissent should be respected.

Human cells/tissues

From within the project, from another project, from a biobank

Details on cell types including the source of the material, the amount to be collected and the procedure for collection

Details on the duration of storage and what will be done with the material at the end of the activity

Confirmation that informed consent has been obtained

Biobanks: strict compliance with appropriate European and national ethical standards (in particular, regarding privacy and data protection) and import/export regulations

Ethics issues

Personal data

Principle of 'data minimisation'

Data may be processed **only** if it is really adequate, relevant and limited to what is necessary for the project

Personal data must be processed in accordance with certain principles and conditions that aim to limit the negative impact on the persons concerned and ensure fairness, transparency and accountability of the data processing, data quality and confidentiality.

Personal data – information relating to an identified or identifiable person (can identify directly or indirectly the individual)

Special categories of personal data (formerly known as 'sensitive data')

Full consent must be given by subjects for personal data processing, including where data sets are being 're-used'

Anonymisation or pseudonymisation techniques may be required

Ethics issues

Non – EU countries

Activities are conducted, partially or wholly, in a non-EU country

- Participants or resources come from a non-EU country
- Material is imported from or exported to a non-EU country.

Awareness of potential issues

- Exploitation of participants
- Exploitation of local resources
- Risks to project teams and staff
- Activities (research) that are prohibited in the EU cannot be done
- Beneficiaries must confirm in the ethics self-assessment that the activities are allowed in at least one EU member state.

Identifying serious and complex ethics issues in EU-funded research

2021 Guidance Note for beneficiaries

Generally, ethics issues raised by research activities may be considered as "**serious**" when the proposed research, method(s), or outcome(s):

have the **potential to violate fundamental rights or freedoms** set out in the EU Charter of Fundamental Rights and European Convention on Human Rights, or undermine fundamental EU values such as human dignity, freedom, democracy, equality and the rule of law; or

have the **potential to result in significant harm** to researchers, research participants, the public, animals or the environment; or

in light of the <u>European Code of Conduct for Research Integrity</u>, fundamentally call into question the integrity of the data and information included in the proposal or the integrity of the practices of the researchers

<u>Guidance note:</u> https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf

Identifying serious and complex ethics issues in EU-funded research

2021 Guidance Note for beneficiaries

Ethics issues raised by research activities may be considered as **complex** when the proposed research, method(s) or outcome(s):

involve the development or application of particularly complicated methods or technologies that have not been sufficiently tested and give rise to uncertainty as regards to the safety of participants and/or the impact of the expected results or outcomes on fundamental rights or research integrity; or

raise **significant ethics issues 'at scale'** – for example, due to the number of research participants, controversial methods, high-risk technologies or jurisdictions involved; or

raise multiple or 'intersectional' ethics issues – meaning that the ethics issues may compound one another to exacerbate the potential impact on a particular group (e.g. research into marginalised or vulnerable groups that exposes them to the risk of stigmatisation, exclusion, reprisals or increased marginalisation).

Identifying serious and complex ethics issues in EU-funded research

2021 Guidance Note for beneficiaries

The ethics issues pertaining to a particular research proposal may also be considered as 'serious and/or complex' if:

the area of research is the subject of **widespread debate among scientists and ethicists** and the specific methods or techniques involved get to the heart of those debates; or

there are grave doubts about the **capacity of the researchers or participating institutions to effectively mitigate the risks** arising from the project's execution; or

there is a high risk that the **research results/findings could be misused**, and adequate measures to mitigate or contain this risk cannot be identified or implemented; or

there is an **objective and serious lack of awareness** of key ethical issues in the proposal

Ethical issues

Deliverables

Ethics evaluation identified issues to be addressed – take these into consideration as you conduct your research

Ethics-related deliverables may be included, such as

- Ethics/regulatory approvals
- Ethics mentor or advisor, ToR and reports
- Data protection plan/statement
- Incidental findings policy

Ethical compliance may be checked during audits, site visits, ethics checks

Ensure record-keeping is consistent and accurate

Ethics issues

Resources, legislation and guidance

<u>Declaration of Helsinki</u> Ethical principles for medical research involving human subjects

Oviedo Bioethics Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine

The <u>TRUST Code</u> A Global Code of Conduct for Equitable Research Partnerships

<u>PREPARED project</u> developing a framework to accelerate research during a crisis without sacrificing ethics and integrity.

Horizon Europe

Ethics rules and guidance

How to complete your ethics self-assessment

Online Manual on Funding & Tender Opportunities Portal

Ethics and Data Protection

Ethics in Social Science and Humanities

See also links to other information under the Ethics section of the <u>Horizon Europe Program Guide</u>

<u>Guidelines on serious and complex ethical issues</u>

6

Clinical studies and clinical trials

Clinical studies

Proposal and mandatory deliverables

Clinical study template to be submitted with proposal – applies to any 'clinical study' (not only clinical trials)

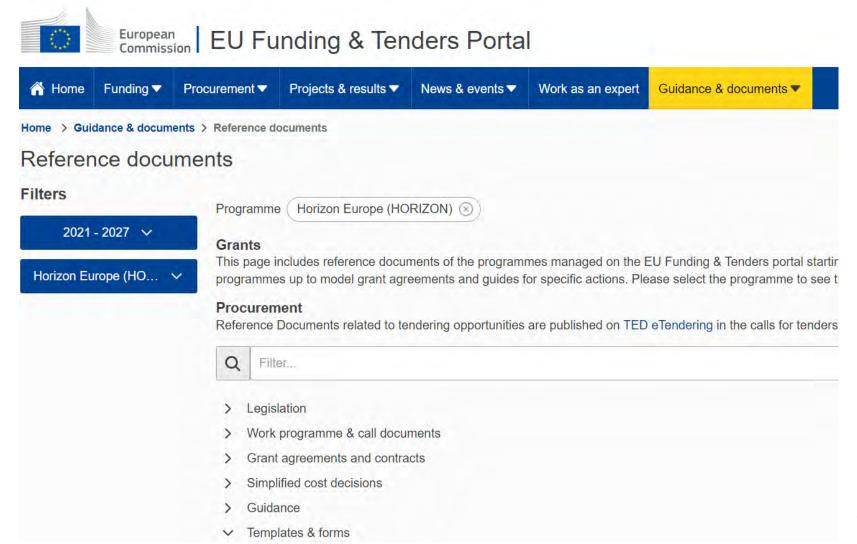
Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition

It includes but it is not limited to clinical studies as defined by EU Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices).

Information on clinical studies template

Additional template to be submitted with proposal

Upload it as separate annex to the proposal part B in the Submission System.



Clinical studies

Mandatory deliverables

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

- Registration number of the clinical study in a registry that meets WHO criteria
- Final version of study protocol as approved by the regulator(s) / ethics committee(s)
- Regulatory and ethics approvals required for the enrolment of the first study participant

Midterm recruitment report

Due when 50% of the study population is recruited.

- Overview of the number of recruited participants by sites
- Any issues/delays
- Description of measures taken to compensate for delays

Report on the status of posting results

- Summary results must be posted in the applicable registry
- Report to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

Clinical studies

Points to consider in your proposal and at reporting

(Almost) all proposals underestimate time needed to recruit subjects

(Almost) all proposals underestimate the time needed to get ethical and regulatory approvals

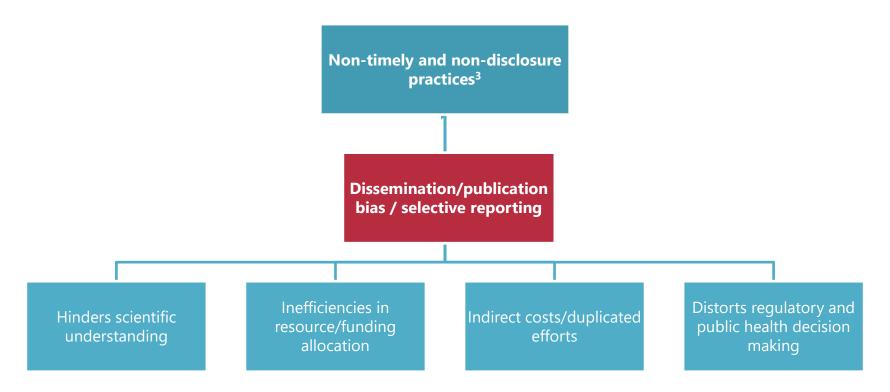
Most reports state that 'recruitment is much lower than expected', 'ethical approval was really slow'

Mitigation measures not well expressed (we will ask for a no-cost extension)

Clinical studies template is an excellent document to frame your study in a realistic, operationally feasible timeline

WHO mandates prompt reporting and public disclosure of interventional clinical trial results¹

 "the registration of all interventional trials is a scientific, ethical, and moral responsibility"²



World Health Organization. WHO Statement on Public Disclosure of Clinical Trial Results. https://www.who.int/news/item/09-04-2015-japan-primary-registries-network#~ https://www.who.int/news/item/09-04-2015-jap

World Health Organization. International Clinical Trials Registry Platform (ICTRP). https://www.who.int/clinical-trials-registry-platform

^{3.} Moorthy VS, et al. 2015. Rationale for WHO's new position calling for prompt reporting and public disclosure of interventional clinical trial results. PLoS Med. https://pubmed.ncbi.nlm.nih.gov/25874642/

Clinical trials: transparency and prompt reporting

- EDCTP and the European Commission are signatories to WHO Joint statement on public disclosure of results from clinical trials¹
- EDCTP is committed to ensuring that grant holders²:
 - Register trials prospectively in a registry that meets <u>WHO Registry criteria</u>
 - Update records regularly
 - Timely disclose the summary of results
 - Publish results in open-access journals
- Reporting/posting of results timeframes
 - Summary of results: within 12 months from primary study completion (the last visit of the last subject for collection of data on the primary outcome)
 - Journal publication: within 24 months from study completion to allow for peer review, etc.
 - The trial ID or registry identifier code/number should be included in all scientific publications

WHO Joint statement on public disclosure of results from clinical trials. 2017: https://www.who.int/news/item/18-05-2017-joint-statement-on-registration
 EDCTP2 policy on clinical trials registration, publication and data sharing, 2021: https://www.edctp.org/about-us/policies/

EDCTP expectations for a final report

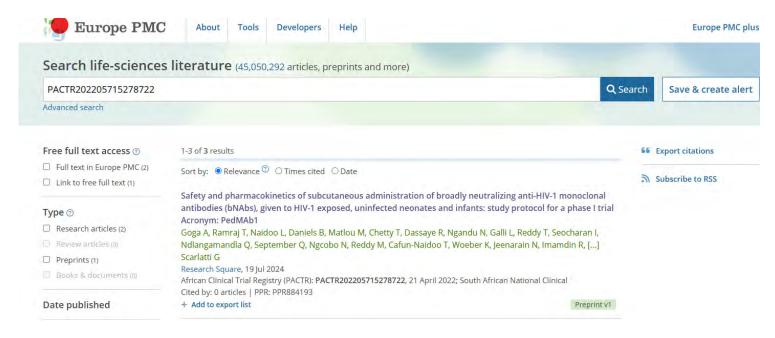
Report on status of posting results is a key deliverable

- Mandatory deliverable irrespective of the successful completion of the clinical study
- The deliverable (status of posting results) is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier
- The report format should follow <u>CONSORT</u> guidelines
- Key timelines and structure to be covered in the 'report on status of posting results':
 - Recruitment was completed by XX
 - Follow-up was completed by XX
 - Data collection was completed by XX
 - Database lock was completed by XX
 - Data analysis will be completed by XX
 - The results will be available by XX
 - Report of the results will be sent to EDCTP by XX
 - The summary results will be posted/uploaded to the registry by XX (which is within 12 months of collection of the last data point)
 - Confirmation that subsequent publications will be provided to EDCTP

EDCTP expectations for a final report

Updating and posting study results on the registry

- Clinical study registry records must be up to date
 - If the study is registered on multiple registries, all registries must be up-to-date
- Summary of results must be posted within 12 months from primary study completion (the last visit of the last subject for collection of data on the primary outcome)
 - Beneficiaries failing to report trials on time without due justification may be subject to audit
- Registry ID must be linked to all publications



Clinical trials – must-know

Registration and reporting of findings of clinical trials

- WHA75.8 Strengthening clinical trials to provide high-quality evidence and to improve research quality and coordination https://www.who.int/news/item/12-09-2022-new-wha-resolution-on-clinical-trials leading to Guidance for best practices for clinical trials
- Joint statement on public disclosure of results from clinical trials, 2017 https://www.who.int/news/item/18-052017-joint-statement-on-registration
- Joint statement on transparency and data integrity (International Coalition of Medicines Regulatory Agencies and WHO) <a href="https://www.who.int/news/item/07-05-2021-joint-statement-on-transparency-and-data-integrityinternational-coalition-of-medicines-regulatory-authorities-(icmra)-and-who
- ICMJE Registration of trial is essential for journal publication <u>https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html</u>

Dissemination

Dissemination of results (Article 17)

Beneficiaries must disseminate their results as soon as feasible, in a publicly available format, subject to any restrictions due to the protection of intellectual property, security rules or legitimate interests

Beneficiary that intends to disseminate its results must give at least 15 days advance notice to the other beneficiaries (unless agreed otherwise)

Any other beneficiary may object (within 15 days) if it can show that its legitimate interests in relation to the results or background would be significantly harmed.

Open access to publications, data and results

EU Open Science Policy

Early and open sharing of research:

- pre-registration, registered reports, data deposition in shared repositories, pre-prints
- open collaboration within science and with other knowledge producers/users

Providing immediate and unrestricted open access to scientific publications, research data, models, algorithms, software, protocols, notebooks, workflows, and all other research outputs

Ensuring verifiability and reproducibility of research outputs

Practising responsible research output management (publications, data, and other outputs) in line with the **FAIR** (Findable, Accessible, Interoperable, and Reusable) principles

Promoting public engagement in research and innovation, bolstering citizen science and enhancing public trust in science

Open access to publications

Beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results.

A machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is

- deposited in a trusted repository for scientific publications
- immediate open access is provided to the deposited publication via the repository under the latest available version of the Creative Commons Attribution International Public Licence (CC BY)
- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication

Only publication costs in full open access venues for scientific publications are eligible for reimbursement

Research data management

Beneficiaries must manage the digital research data generated in the action ('data') responsibly, in line with the FAIR principles and by taking all of the following actions:

- Produce a data management plan ('DMP') (and regularly update it)
- As soon as possible and within the deadlines set out in the DMP, deposit the data in a
- trusted repository
- As soon as possible and within the deadlines set out in the DMP, ensure open access —
- via the repository to the deposited data, under the latest available version of the
- Creative Commons Attribution International Public License (CC BY) following the principle
 'as open as possible as closed as necessary',
- Provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data

Unless providing open access would in particular:

- Be against the beneficiary's legitimate interests, including regarding commercial exploitation, or
- Be contrary to any other constraints, in particular the EU competitive interests
- or the beneficiary's obligations under this Agreement

If open access is not provided (to some or all data), this must be justified in the DMP

Data sets

Continuous and periodic reporting

See Article 17 of the Grant Agreement and Annex 5 dedicated section on 'Open Science'

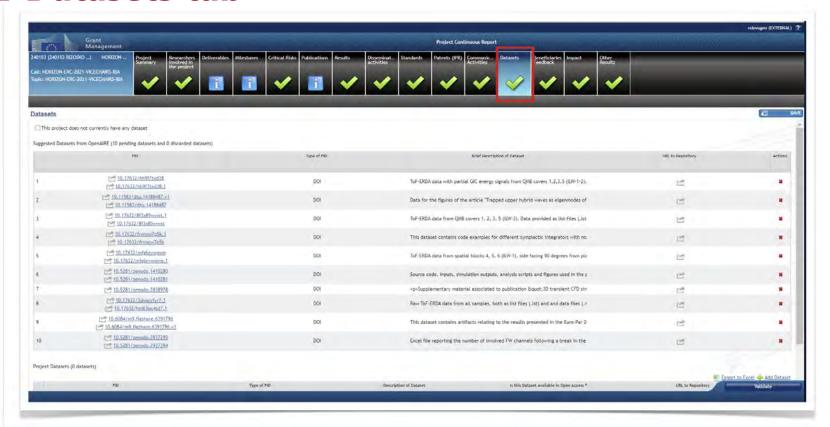
Guidance on completing the Data sets tab

Datasets lists the:

Project Datasets: shows the datasets linked to the project and that have been imported by the Consortium.

Datasets suggested by OpenAIRE: a list of available datasets retrieved directly from OpenAire and linked to the Project. Each record can then be imported to the Project Datasets or discarded (removed)

Datasets tab



PID Persistent Identifier of the publication linked to the dataset. Type of PID Description of the Persistent Identifier eg : DOI, ARK, etc.. Description of Dataset URL to Repository Is a dataset available in Open Access

OpenAIRE

https://www.openaire.eu/

Non-profit organisation that promotes open scholarship and improve discoverability, accessibility, shareability, reusability, reproducibility, and monitoring of data-driven research results, globally

Operates a European e-infrastructure offering a diverse set of public <u>services</u> to accelerate the adoption of Open Science and is supported by a network of experts placed in key national organisations across European countries, the National Open Access Desks.

Open Research Europe

Open access platform without author fees





https://open-research-europe.ec.europa.eu/

Mobilisation of research funds in case of Public Health Emergencies Data sharing requirements

Proposals funded under this mechanism must share the relevant generated data within 30 days after generation with all parties that need and can use the findings to address the public health emergency

Access rights for the granting authority to results in case of a public emergency

If requested by the granting authority in case of a public emergency, the beneficiaries must grant nonexclusive, world-wide licences to third parties — under fair and reasonable conditions — to use the results to address the public emergency.

Continuous reporting (Art. 21.1) and Periodic reports (Art. 21.2)

In addition to the continuous reporting and in order to receive payments beneficiaries must submit reports for payment to document the technical (and financial) implementation of the action.

Periodic reports must be submitted (normally) within 60 days following the end of the reporting period

 Example: A grant that started on 1 April 2023 with a first reporting period of 18 months needs to report on the first 18 months (1 April 2023–30 Sept 2024) on 29 November 2024

This is the periodic reporting (Technical – Part A and Part B; Financial) which is done via the Grant Management System

Periodic report is prepared by all beneficiaries and is submitted by the Coordinator

Review of reports is done by EDCTP3 project (technical review) and finance (financial review) officers

Reporting is done via the grants system

Reporting periods divide the project into regular periods for technical reporting and monitoring

Reporting periods are expressed in months from the project start date

Reporting periods are consecutive and do not overlap

Reporting periods are linked to payments

Depending on the type of payment they may involve only technical reporting or also financial reporting

For interim/final payments: technical and financial reporting is required

The periodic reporting process consists of several phases:

- Logging in to the Funding & Tenders Portal when you have received a notification.
- Completing the report.
- Submitting the report to GH EDCTP3 JU.
- The EDCTP3 JU assesses the report.
- The EDCTP3 JU makes the interim payment.

Understanding the reporting cycle

Extensions are not given to submission of reports, late=late

Repeated failure to submit a report (or revision) in time is a breach of the grant agreement

If this is not addressed, then the grant may be suspended or terminated by the funder

This could result in you and your institution having to return funds

Don't forget to submit your deliverables when they are due

General tips

Getting started

- Familiarise yourself with the template so you know what information to collect/ report on
- Follow the guidance given in the report
- Make sure that you report the activities due in the reporting period in question (including items that were delayed from a previous year).
- Check your previous reports for items not achieved
- Stick to word limits for each section
- Run a spell check, be consistent in font size and style- deliver a nice to read report

Report may seem repetitive at times, but you still need to complete all sections and be consistent

Horizon Europe report template is available for information but download the template in the Grants System for your project

Technical report

Components

Technical Report consists of 2 parts:

- Part A contains structured tables with project information
- Part B is the narrative description of the work carried out during the reporting period.

Part A is generated by the IT system. It is based on the information which you enter into the Portal Continuous and Periodic Reporting modules

Part B needs to be uploaded as PDF on the Technical Report (Part B) screen. The template to use is available there.

Maximum PDF size for upload is 20MB

Preparing and submitting the periodic report

Technical aspects

Periodic Report is prepared by the **Consortium** in the Continuous and Periodic Reporting modules

Periodic Report is submitted by the **Coordinator**

Remember that the **Continuous Reporting** module is **always open** and can be updated at any moment during the project (ie. Submission of deliverables, milestones)

The **Periodic Reporting** module is opened **after** the end of the reporting period

The information that you submitted in the Continuous Reporting module automatically feeds into Part A of the report

Make sure that all the information (e.g. deliverables) in the Continuous Reporting module has already been updated before 'locking the periodic report for review' or these deliverables will end up in the next reporting period

Coordinator is responsible for consolidating the report (including financial statements) and for uploading the report

Project summary for publication (Part A)

- Don't include confidential data
- The summary must be written as a stand-alone text, be of suitable quality and easy to read for the general public
- Make sure your summary covers the below elements:
 - A summary description of the context and overall objectives of the project.
 - A description of the work performed from the beginning of the action to the end of the period covered by the report, and the main results achieved so far.
 - Where applicable: Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the action so far) = highlight extremely positive/ground-breaking results
 - Policy relevance of the project

Don't: keep writing we will do this when you are already in year 3.

Part B narrative report

Explanation of the work carried out by the beneficiaries and overview of progress

1.1 Objectives

Describe the objectives and progress made towards the objectives in high level terms- provide more details under section 2.

- Highlight significant activities in support of these achievements
- Provide clear and measureable details
- Give an update on objectives not fully achieved or not on schedule.

1.2 Explanation of the work carried out by work package

Describe for each work package what work was done during the reporting period. If you have written tasks in Annex 1, present updates for each task

If something is not yet due, you can simply state that: work package 4- data

analyses: not due this reporting period.

Part B narrative report (continued)

1.3 Impact

Include in this section whether the information provided in the Annex 1 on Impact is still relevant or needs to be updated. Where an update has been made, please include more details to explain the changes.

For example, there may be changes due to new research results reported elsewhere or changes in policy affecting how your results would be viewed, and you can include this information here

Or if there were no updates: The information provided in the Annex 1 on Impact is still relevant

1.4 Update of the plan for exploitation and dissemination of results

Include in this section any updates to the plan for exploitation and dissemination of results and give details.

Part B Narrative report

Sections 2 to 4

2. Follow-up of recommendations and comments from previous review(s)

Check the previous report comments and include a table explaining if and how each recommendation from previous reviews and/or Project Officer assessment has been addressed.

3. Exploitation primarily in non-associated third countries

Provide a justification how this exploitation is still in the interest of the EU.

4. Open Science

Describe the Open Science practices related to **early and open sharing** of research (e.g. through pre-registration, registered reports, pre-prints or crowd-sourcing of solutions to a specific problem).

Describe the concrete **measures that ensure the reproducibility** of the results obtained during the project i.e., measures to ensure that the same results can be obtained by using the same data and/or methods, etc.

Deviations from Annex 1 and/or Annex 2 (if applicable)

Section 5.1 Tasks/Objectives

Provide in this section explanations for tasks not fully implemented, critical objectives not fully achieved and/or not on schedule.

Explain the **consequences** - the impact on other tasks and on the available resources and the overall planning

Describe any corrective actions taken

.

For example, due to Covid-19 the clinical study could not start during month 16 as originally planned and is foreseen to start during month 26. As a result of this delay, etc.

Your explanation and projections on the impact of delays/issues should be clear and realistic so that EDCTP can assess whether the project is on track and can deliver

Deviations from Annex 1 and/or Annex 2 (if applicable)

5.2 Use of resources

Explanations on deviations of the use of resources between **actual** and **planned** use of resources in Annex 1 (Description of the Action)

In other words:

What did you say you would spend and what did you actually spend? Why does the expenditure differ from what you expected (more or less)? Explain

- For example, person-months/WP
- Transfer of funds between cost categories, beneficiaries

<u>Do not go into minute detail</u> (e.g. each pencil cost 5 euros instead of 3 euros)

Provide an explanation, where it is needed

The funder is looking at what you did and what you spent compared to what you said you would do

If there a big differences, you need to explain them with reference to the activities undertaken

5.2.1 and 5.2.2 Unforeseen subcontracting/ use of in-kind contributions

Subcontracting should be specified in Annex 1 of the grant agreement

Sometimes during the project there is a need to subcontract although this was not included at the start (Unforeseen subcontracting)

5.2.1 Unforeseen subcontracting can be reported in the periodic report

- Subcontracting should only cover a limited part of the project
- Explain why there was a need/what circumstances led to this
- Confirm that the subcontractor has been selected ensuring the best value for money
- or, if appropriate, the lowest price and avoiding any conflict of interests
- Indicate name of subcontractor and amount

The funder may approve the subcontracting at the reporting stages

This means that it approves that you subcontracted the task

The subcontracting procedure will be checked at audit, if applicable, to make sure the costs are eligible

5.2.2 Unforeseen use of in kind contributions

Similar to above, please explain

- Identity of the third party
- Resources made available by the third party respectively against payment or free of charge
- Explanation of the circumstances which led to the need for using these resources for the project

Gender

Continuous reporting and periodic reporting

2 components to be addressed

Gender of researchers and other workforce involved in the Project

- Fill in the number of female and male researchers
- Fill in the number of females and males in the workforce other than researchers
- Workforce is counted using Head Count not Full Time Equivalents.
- Workforce participating in the project must be counted (either when paid by EU funding or as in-kind contribution from Affiliated Entities)

Gender dimension in the project (refers to the research) Indicate whether the project includes a gender dimension e.g. Analysis stratified by gender; project on pregnant women

9 Amendments

Amendments

- Grant agreement is flexible
- Formal amendment may not be needed
- Essential for all substantive or important changes to the Grant Agreement, e.g. changes impacting the project outcome, changes that affect the description of the action in Annex 1
- Consult reference documents (and PO) before submitting the request
- Check the Horizon Europe guidance on the supporting information needed for types of amendment
- Make modifications as requested
- Submission procedure via the portal

Flexibility in budget and task distribution

Flexibility to move budgets around....

- Budget amounts can be freely transferred between beneficiaries (from one partner to another) - provided that no change in activities in Annex 1
- Amounts can be freely transferred between existing budget categories - provided that no change in activities in Annex 1

Flexibility to move tasks around....

Assays, analyses – but pay attention to North-South balance

....if the project partners can agree!

Is an amendment needed? Check the grant agreement and check with your Project Officer

Amendments of the Grant Agreement

Article 39 of the Grant Agreement

Any significant deviation from the DoA (Annex 1) requires an amendment

- Changes in the partners
 - Partner leaving consortium
 - Partner entering consortium
 - Change of coordinator
- Changes in duration of action (no-cost extension)
- Changes of legal status of a beneficiary
- Change of banking details

Horizon Europe <u>Amendments</u> guidance

Amendments of the Grant Agreement "significant" changes to Annex 1

Art. 39 Conditions

Unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants'

- Interpreted in real life context, scientific necessity, or scientific developments, due to force majeure - difficult balance!
- Prevention, Mitigation, Alternatives:
 - risk and mitigation measures included in DoA
 - usually less problematic: do more or less of something already foreseen in GA
 - reduction of scope → reduction of grant

Amendments of the Grant Agreement:

Awareness on both sides

- Raise awareness in consortium (at any time, at kick-off meetings, linked to reporting):
 - without amendment no legal security: 'agreement by PO' in an e-mail or call has no legal value
- 'Grant agreement maintenance': keep list of necessary changes and integrate them when amendment needed for major/significant reason
- Amendments are normally done at the initiative of the consortium, but they may also be initiated by the granting authority (e.g. where errors need to be corrected; to change Annex 1 after a review of the action)

Amendments of the Grant Agreement

- Prior informal discussion between Coordinator and PO recommended
- Submitted by Coordinator (only exception is request for change of coordinator) on behalf of consortium
- Select the Amendment Type (AT) in the portal
- Provide the necessary supporting documents
- Decision normally within 45 days
- Horizon Europe <u>Amendments</u> guidance
- Additional slides in this presentation on how to launch an amendment in the system

Amendments quiz

Is an amendment needed?

Deliverable 1.2 was due in M3 but will not be ready until M14

Clinical trial recruitment target was 1000 but has been reduced to 800

Inclusion criteria (e.g. age group) for clinical trial have changed

Clinical trial in 3 countries was planned, now only 1 country

Beneficiary A is not carrying out some tasks, but instead Beneficiary B will do them

Beneficiary C has changed its name

Change in the Acronym

Amendments quiz

Is an amendment needed?

Deliverable 1.2 was due in M3 but will not be ready until M14 NO

Clinical trial recruitment target was 1000 but has been reduced to 800 Likely NO, provide advice from TSC or DSMB

Inclusion criteria (e.g. age group) for clinical trial have changed Likely NO unless major change (children to adults)

Clinical trial in 3 countries was planned, now only 1 country

Likely YES, change of scientific scope and impact

Beneficiary A is not carrying out some tasks, but instead

Beneficiary B will do them NO

Beneficiary C has changed its name NO

Change in the Acronym YES

10

Useful information and guidance ('How to' in the system)

Resources and information

Useful guidance

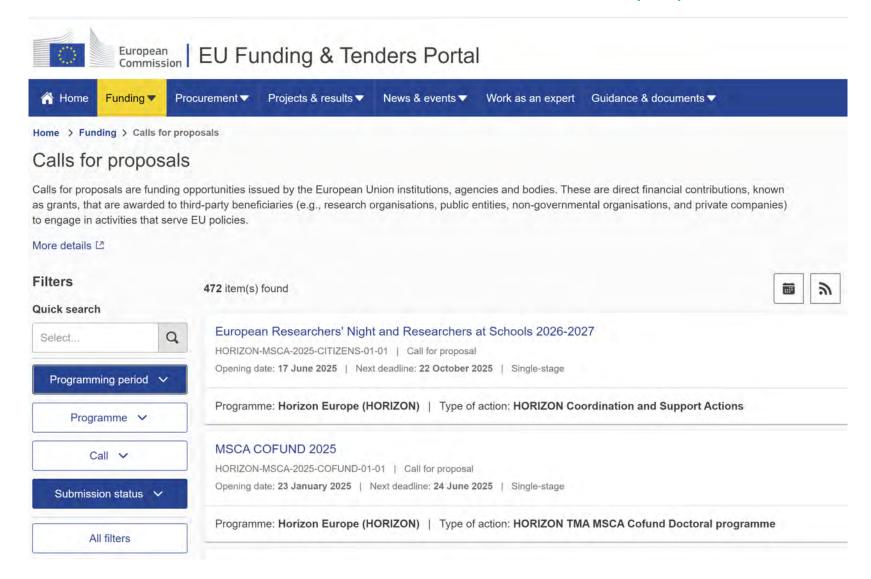
EU Funding and Tenders Portal – find everything about funding opportunities, application process, evaluation procedure, managing your GH EDCTP3 project, information on other projects that have been funded

https://ec.europa.eu/info/fundingtenders/opportunities/portal/screen/home



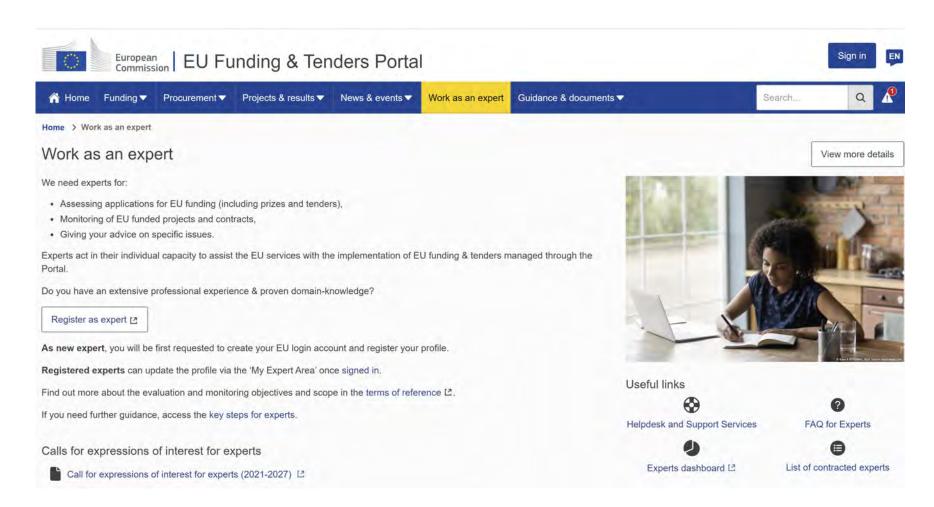
EU funding opportunities (web link)

Use the filters on the left to find relevant calls for proposals



Apply to be an expert reviewer

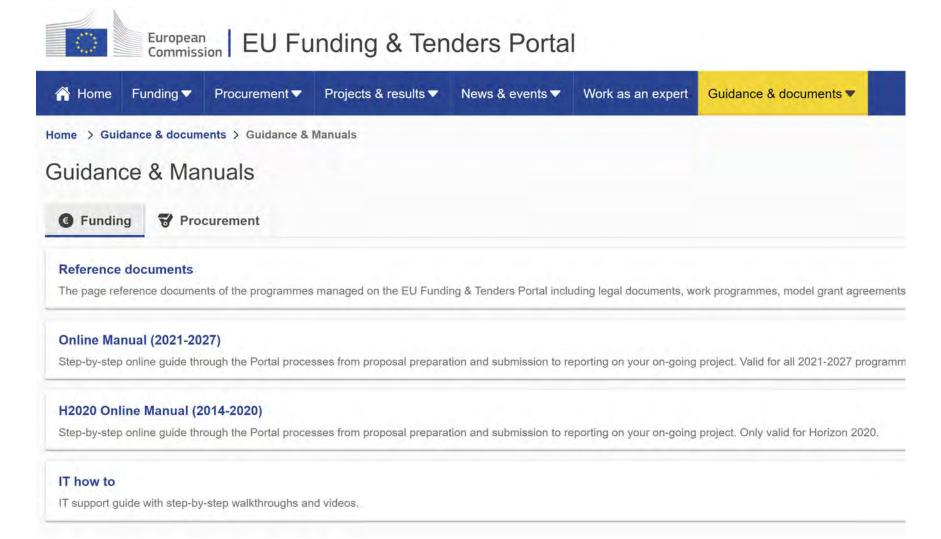
https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert



Becoming an expert reviewer can help you understand the evaluation process better and you may gain useful experience that helps you become a better applicant

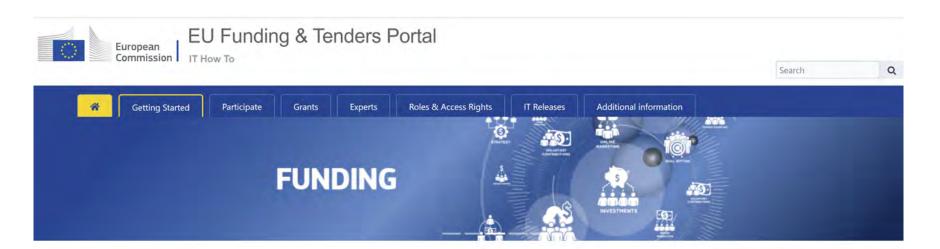
'How to' guides

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/manuals



'How to' use the IT tools – guides and videos

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/IT+How+to





How to Participate

Learn all that you need to apply for EU funding, from how to register your organisation to how to submit your proposal, including how to manage the roles and access rights to your organisations, proposals and future projects.



Manage your Grant

All IT support information to help you with the signature of your Grant Agreement, as well as the management of your project in the IT tools: amendments, continuous and periodic reporting, communication with the granting authorities, audits, etc.

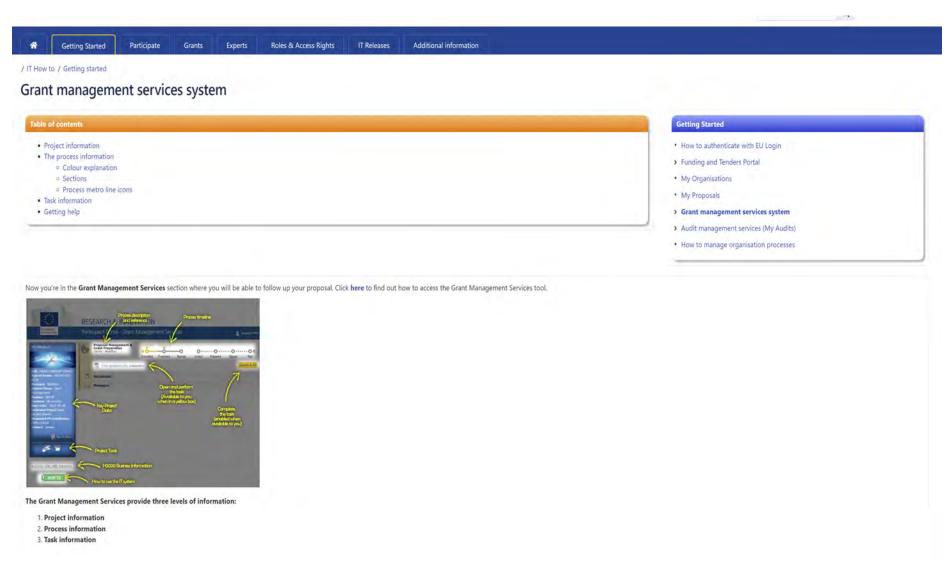


Work as an Expert

Learn all you need as an expert, from the registration process, including how to read and sign your expert contracts and how to draft and submit payment requests, to how to evaluate the proposals assigned to you using the IT tools.

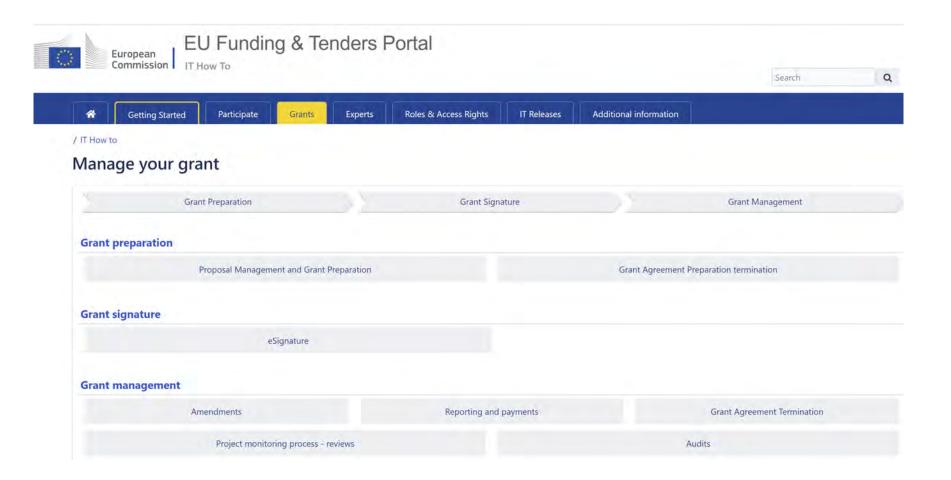
Guide to the Grants Management system

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Grant+management+services+system



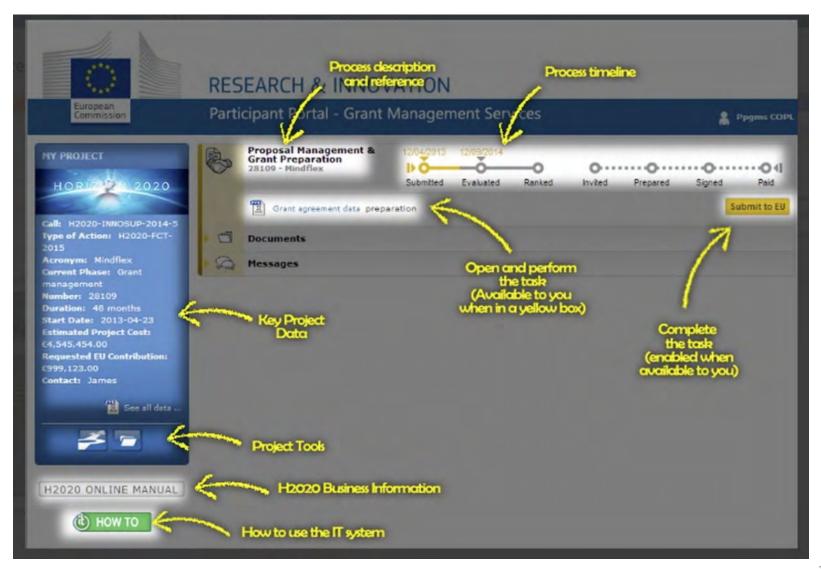
How to manage your grant in the IT system

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Manage+your+grant



Grants system

Navigating the system



Grants system

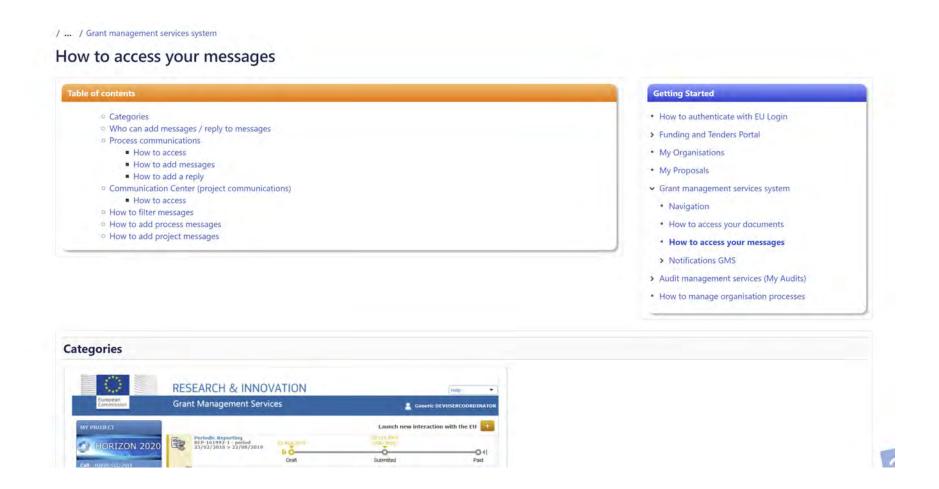
Information on display when you are logged in

The Grant Management Services provide three levels of information:

- 1. Project information
- 2. Process information
- 3. Task information

How to – Communicate and access messages in the grants system

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/How+to+access+your+messages



Types of messages: Process and Project

Process communications and Communications Centre at Project level



Messages are stored at two levels:

- 1. Process communications: at process level
- 2. Communication Centre: at project level (all process messages are also stored here together with all other project messages)

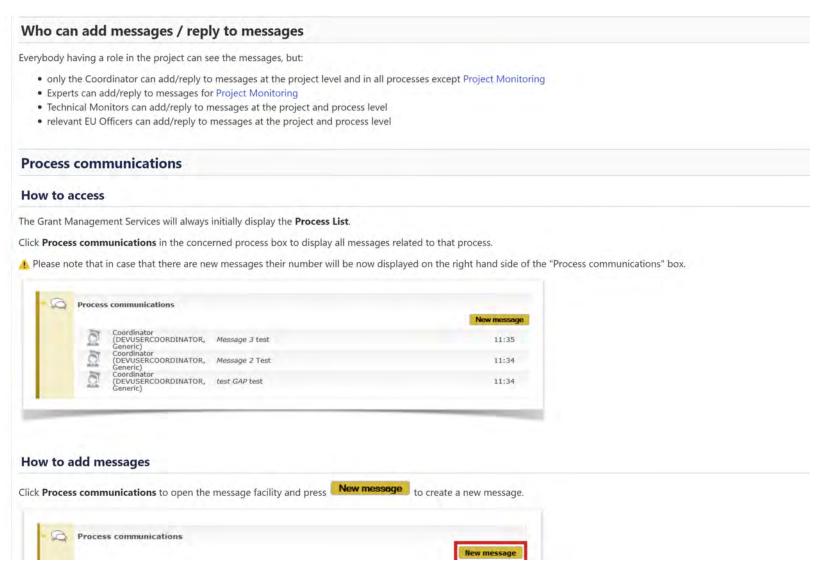
The messaging feature allows fast and easy communication between the consortium and the European Union (EU). Particularly during an ongoing **process**, messaging can be useful. These messages will be stored within the process. All messages are also stored at **project** level though, where they can be filtered and sorted according to your needs.

Use "Process communications" to exchange messages concerning a specific process. Use the Communication Centre to exchange messages concerning the project and not necessarily to a specific process. The Communication Centre can be also used after the project ended and/or there are no more active process.

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/How+to+access+your+messages#Howtoaccessyourmessages-Howtoaccess

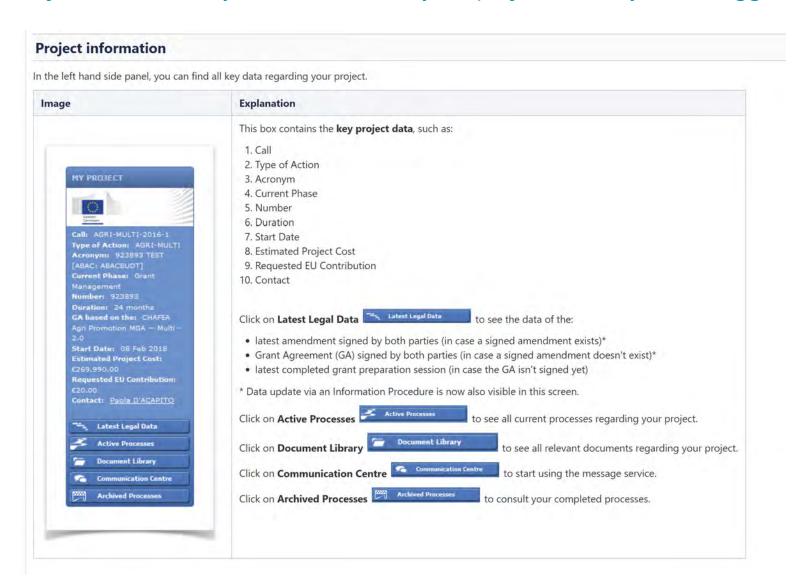
Messages in the system: who can see and who can reply

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/How+to+access+your+messages#Howtoaccessyourmessages-Howtoaccess



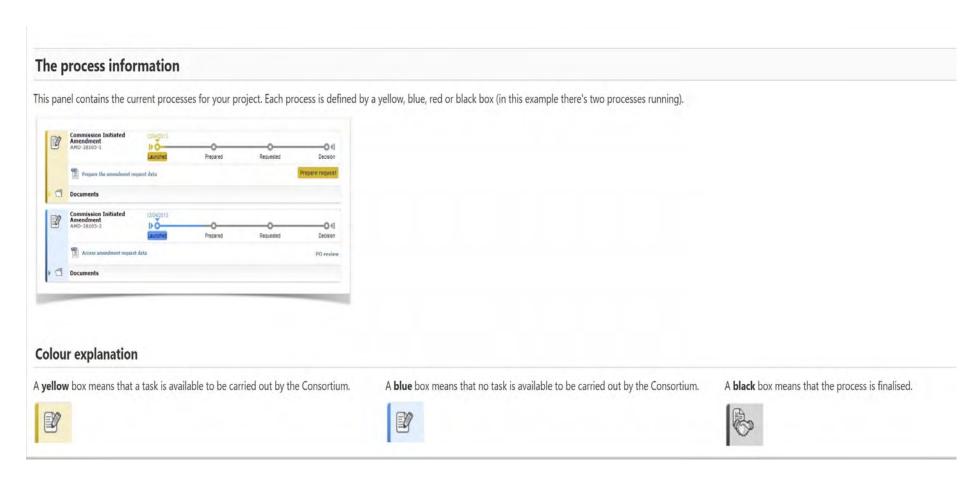
Grants system

Project information you can see about your projects when you are logged in



Grants system

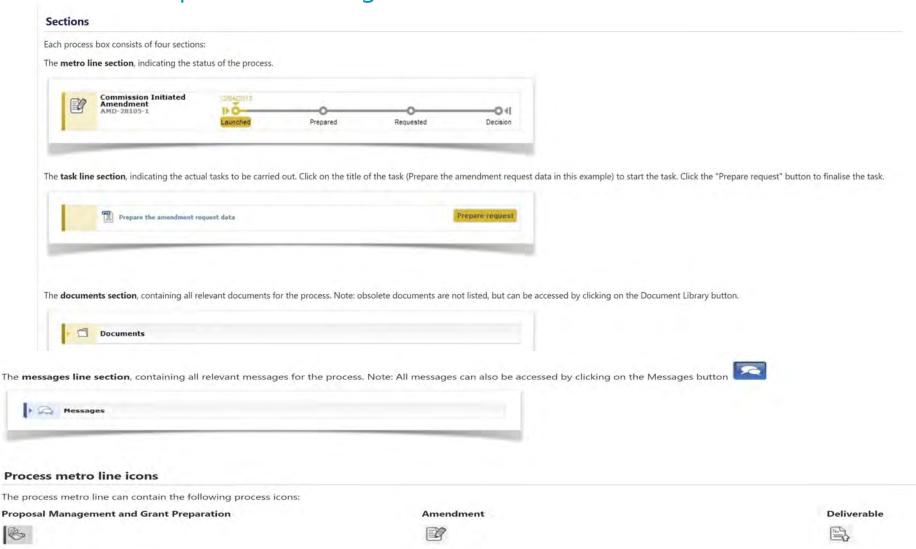
Process information - tells you what 'processes' are going on



An amendment is an example of a process

Understanding a 'process' in the system

Status of a process: the stage it has reached



Task information

Examples of tasks

Task information

This is what a task looks like. Each button belonging to the task, will also display a tooltip/ help message when hovering over it.



The task line can contain the following document icons:

Type of document	Description	Document icons
Document	Incoming or outgoing document without electronic signature	
Draft document	Document under preparation	
Obsolete document	Document that has been replaced by another or that is no longer relevant	
Pack document	Several documents belonging to the same group	(11)
Sealed document	Document that is ready for signature	3
Sealed and signed document	Document that is signed and in force	
Form to complete	Redirects to a form to complete	

Task information

Finding out more and status of tasks

• To open/expand the task, click the 🚨 button:



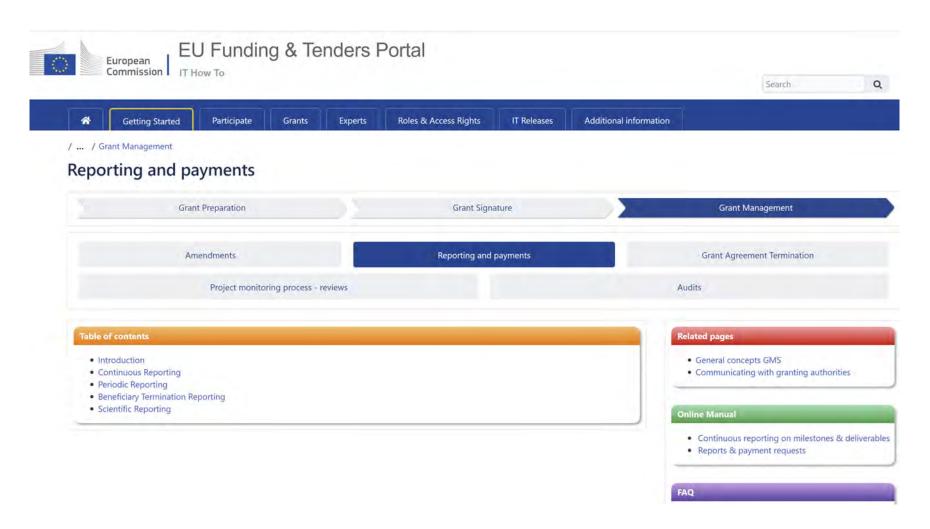
• For open tasks, a progress status is being displayed when clicking on the task:

When clicking on a task document, the progress status of signing the document is displayed with the help of the following signature icons:

Description	icons
The coordinator has signed	
The coordinator hasn't signed yet	101
The beneficiary has signed	2
The beneficiary hasn't signed yet	5
The EU has signed	2
The EU hasn't signed yet	0

How to report

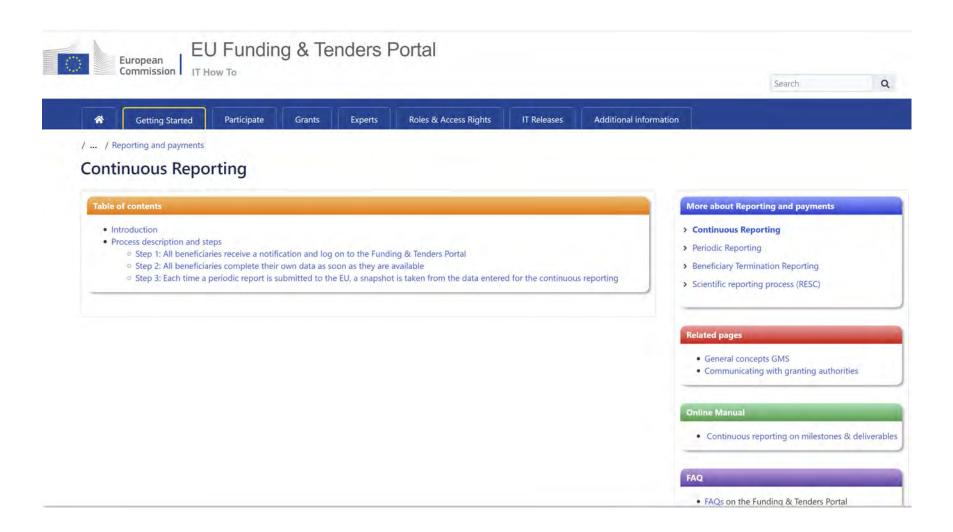
https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Reporting+and+payments



You have to report continuously (uploading deliverables, risks etc) as well as submit periodic reports as specified in the Grant Agreement

Continuous reporting

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Continuous+Reporting



Continuous reporting by beneficiaries

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Continuous+Reporting#ContinuousReporting-Step1:AllbeneficiariesreceiveanotificationandlogontotheFunding&TendersPortal

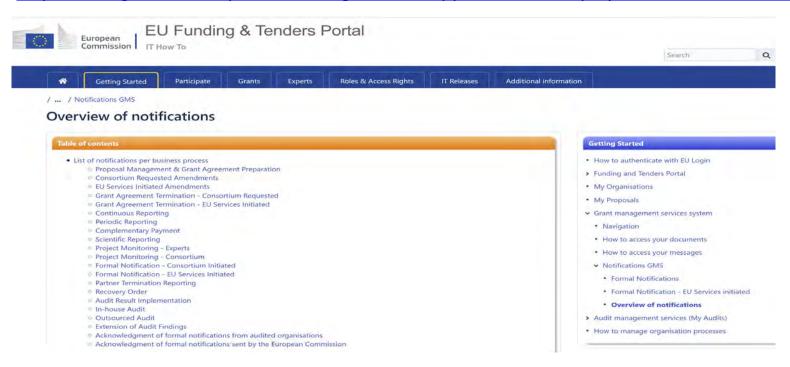
Step 1: All beneficiaries receive a notification and log on to the Funding & Tenders Portal

At the beginning of each project, all beneficiaries will receive a notification to contribute to the continuous reporting tabs. The continuous reporting is collaborative.

To fill in the information the beneficiary must log on to the Funding & Tenders Portal and access the relevant project.

Types of notifications

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Overview+of+notifications



Types of notification

For Action (FA) or For Information (FI)

https://webgate.ec.europa.eu/funding-tendersopportunities/display/IT/Overview+of+notifications#Overviewofnotifications-ContinuousReporting

List of notifications per business process

The table below offers you an overview of the Portal Notification Service (PNS) messages, grouped by business process, and of their recipients' roles.

In order to comply with personal data protection requirements, the messages are sent by the system individually, to each recipient, and not as group e-mails to all concerned users. This way, no personal data of other recipients are disclosed.

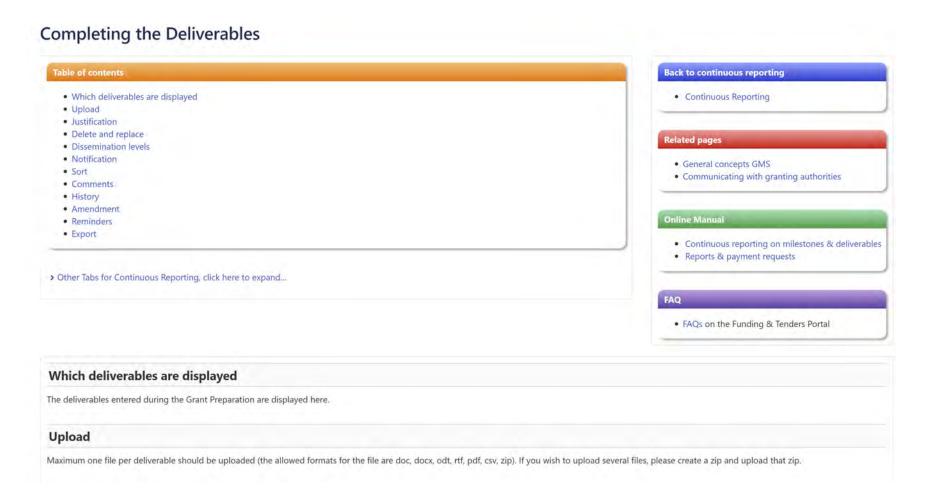
Some of the users will be notified for information purposes only, while others will be asked to take action. In the table, the roles who receive the e-mails only for information are marked with **FI (For Information)** and those who need to take on an action task with **FA (For Action)**.

Legend:

- FA = For Action
- FI = For Information
- FA/FI = addressed to all users having this role
- FA/FI (task) = addressed to all users having this role of the organisation(s) that have this task
- · FA/FI (co) = only addressed to users having this role in the coordinating organisation
- FA/FI (t) = addressed to all users having this role of the terminated organisation
- FA/FI (a) = addressed to all users having this role of the audited organisation
- FA/FI (a, ap) = addressed to all users having this role of the audited organisation in the audited projects;
- . FA/FI (a, MB) = addressed to all users having this role of the Main Beneficiaries (if the Audited PIC is a Third Party in the project)
- FA/FI (a, universal takeover) = addressed to all users having this role of the universal takeover beneficiary (if the audited PIC had an universal takeover* to it in the project)
- FA/FI (a, partial takeover) = addressed to all users having this role of the partial takeover beneficiary (if the audited PIC had a partial takeover** to it in the project)
- * Universal takeover: In all the projects where the PIC is Beneficiary, it is replaced by another PIC. This PIC is the one that receives the universal takeover.
- ** Partial takeover: this is the same as an universal takeover, but in this case the replacement of the PIC is not in all projects where it is beneficiary. In some projects it will remain beneficiary, in some others it will be replaced by the PIC that receives the partial takeover.

How to - Submitting deliverables

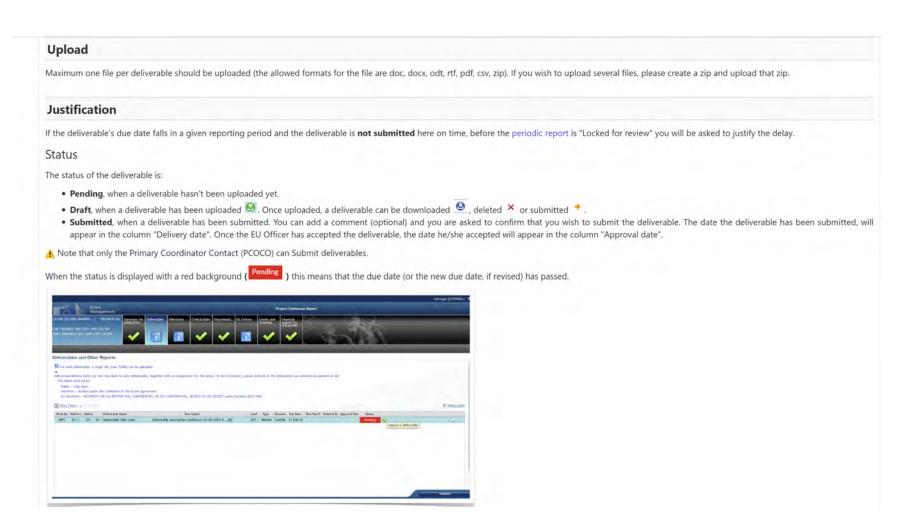
https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Completing+the+Deliverables



Remember to submit all deliverables when they are due Do not wait for the Periodic Report

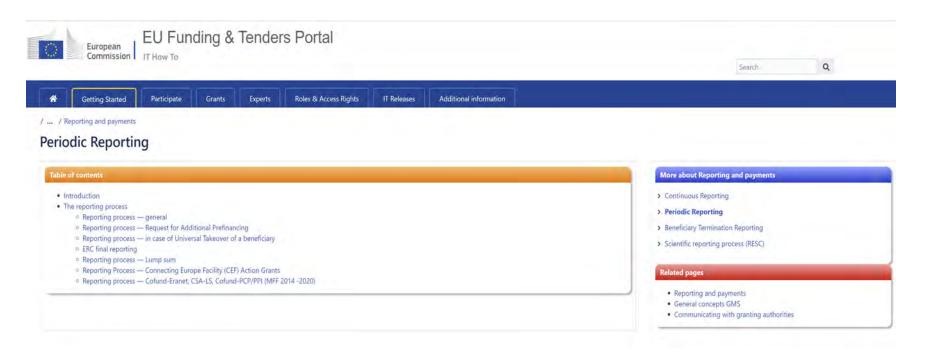
How to – Uploading deliverables

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Completing+the+Deliverables#CompletingtheDeliverables-Upload



How to - Periodic reporting

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Periodic+Reporting



Reports comprise Technical and Financial sections

System guidance

The periodic reporting process consists of phases:

- Logging in to the Funding & Tenders Portal when you have received a notification
- Completing the report
- Submitting the report to the EDCTP3
- EDCTP3 assesses the report
- EDCTP3 makes the Interim Payment, where applicable

The reporting process

Reporting process — general

<u>Reporting process — Request for Additional</u>
<u>Prefinancing</u>

<u>Reporting process — in case of Universal Takeover of a beneficiary</u>

Steps in the system - Step 1

Step 1: All beneficiaries receive a notification and log on to the Funding & Tenders Portal

At the end of each reporting period, a beneficiary will receive a notification to complete:

- . Their own Financial Statement (and the financial report of their Affiliated Entity (Third Party), if any).
- . Their contribution to the Technical Part of the Periodic Report (this is common for all beneficiaries in the project)

To fill in the information the beneficiary must log on to the Funding & Tenders Portal and access the relevant project.

In the right-hand side of your screen, in the process list, you will find the Periodic Reporting process.



🚣 In the right-upper corner of the process box, a link to the Periodic Reporting will lead you to an overview of the periodic report consisting of both the Financial Statement and the Technical Part of the Periodic Report.

Step 1 continued



Step 1 (continued)

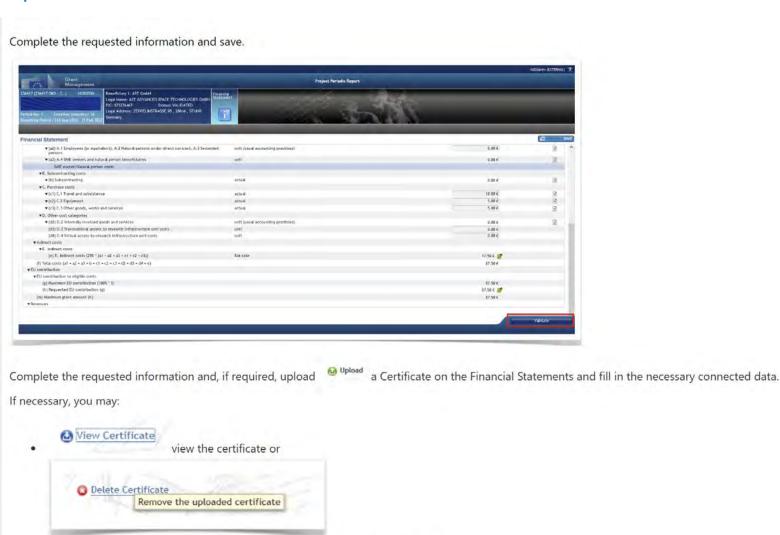


Step 2 Beneficiaries complete Financial Part and contribute to Technical Part

Beneficiaries e-sign and submit their Financial Statement to the Coordinator Read the <u>guidance</u> first on producing the financial statement



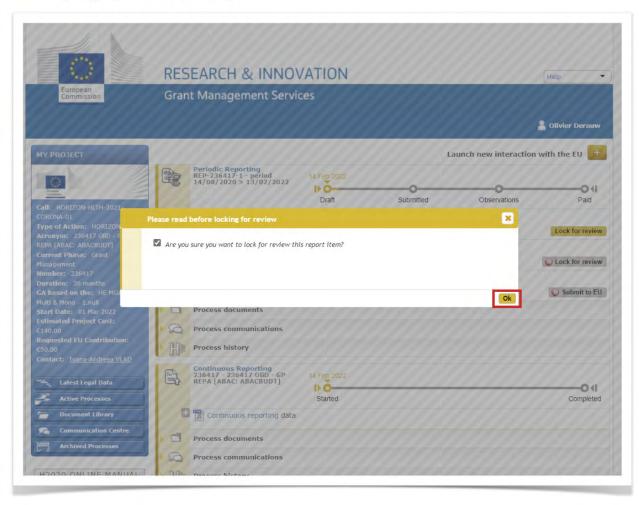
Step 2 (continued)



delete the certificate

Step 2 Locking the report for review

Confirm by flagging the box and clicking OK.

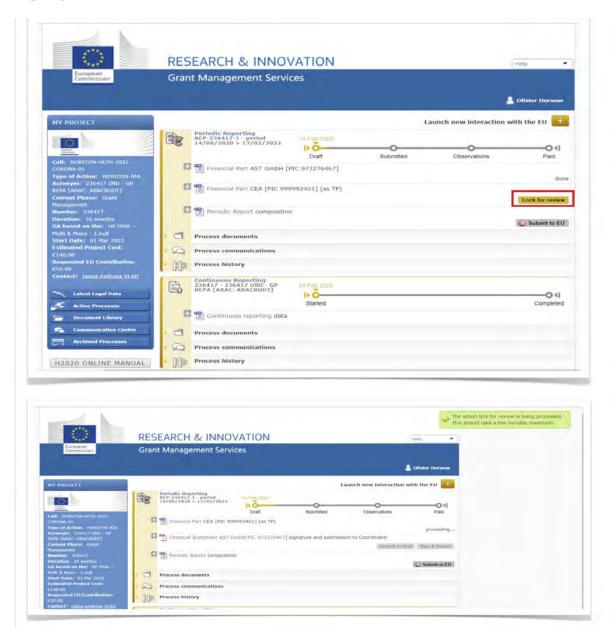


Step 2 (continued) – Validation and locking for review

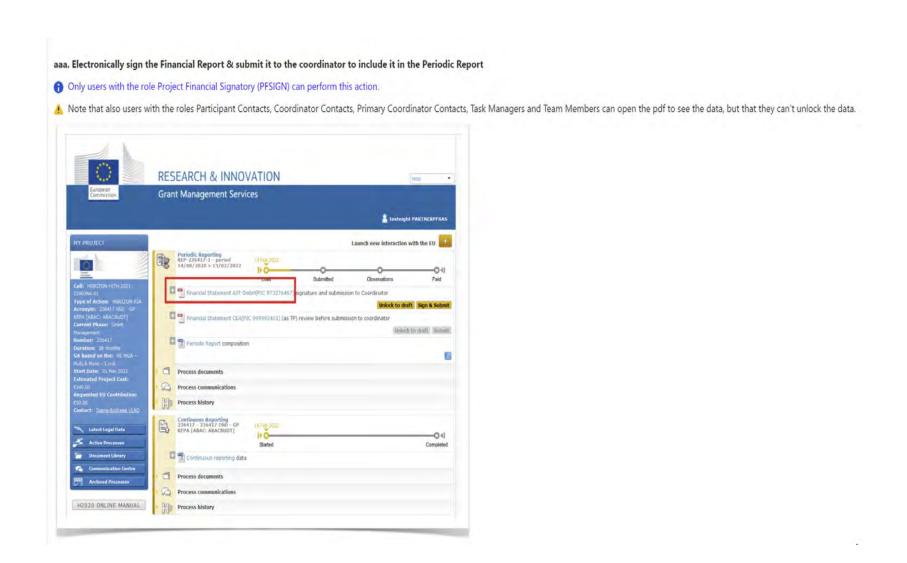
Click the Validation button to see whether you have filled in all information correctly, then close the current screen and return to the the Funding & Tenders Portal. aa. Lock the financial statement for review A Participant Contacts (or Coordinator Contacts if it concerns the coordinating organisation) can finish the drafting and lock the data in order to review the generated report. Click the "Lock for Review" button, which will prevent further editing and generate a pdf document (A This might take a few minutes.) **RESEARCH & INNOVATION Grant Management Services** Launch new interaction with the EU Financial Part AST GmbH [PIC 973276467] The Francial Part CEA [PJC 4999324] Participant Contacts, Project Financial Signatories and Task Managers can draft the financial report. Once complete, the Participant Contacts can Periodic Report composition -O4I

Confirm by flagging the box and clicking OK.

Locking your financial statement in the system

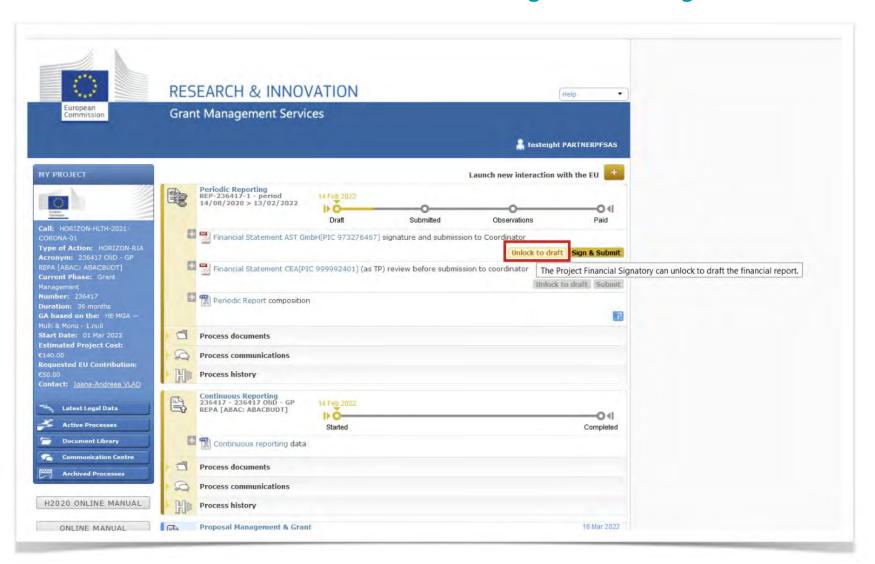


Signing the financial statement in the system



Unlocking the Financial Statement for revision

Use command 'Unlock to draft" for re-editing and then sign and submit



Ready to sign and send to the Coordinator

Electronic signature by the Financial Signatory



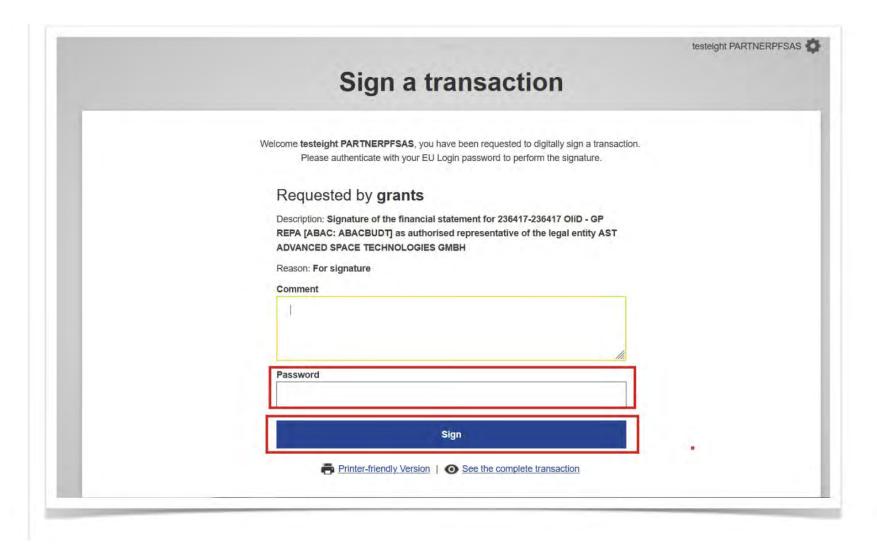
Confirmation step before signature

Declaration by beneficiary



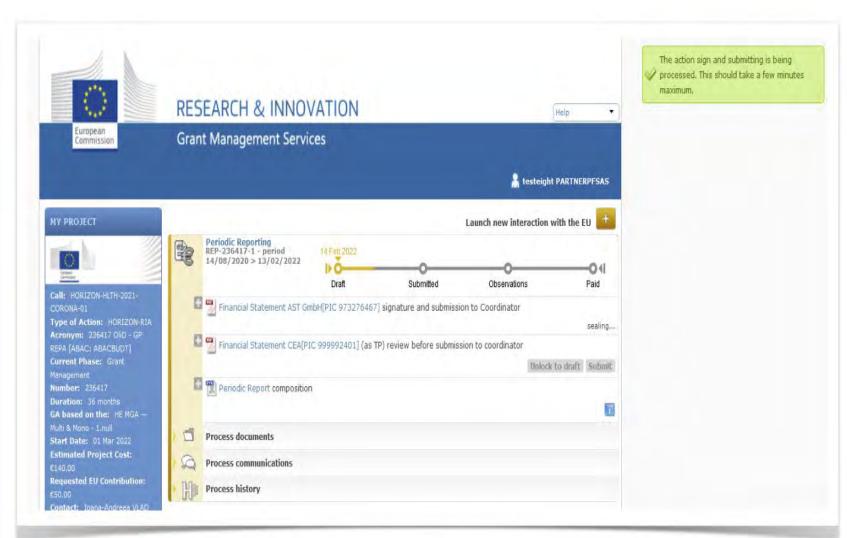
Signature of the financial statement

Authentication of signature is required



Processing of the signed statement

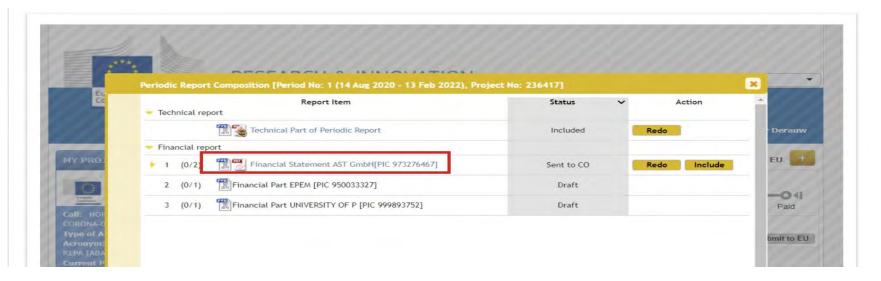
What you will see in the system



Completion of Financial Statement

Check via task 'Periodic Report composition' to see the Financial Statement





Technical reporting in the system

All beneficiaries contribute to the technical reporting



Technical reporting

Tabs relating to the Continuous Reporting (applicable tabs depend on the funding instrument)

Completing the Communication Activities	Completing the Critical Risks	Completing the Datasets (Horizon Europe)	Completing the Deliverables	Completing the Dissemination Activities
Completing the Events and Trainings	Completing the Financial support for 3rd parties questionnaire	Completing the Gender	Completing the Impact continuation (Horizon Europe)	Completing the Impact questionnaire (Horizon Europe)
Completing the Infrastructures (Horizon Europe)	Completing the Key Performance Indicators (KPI) tab	Completing the Milestones	Completing the Other Results questionnaire (Horizon Europe)	Completing the Intellectual Property Rights (IPR)
Completing the Project Summary	Completing the Publications (Horizon Europe)	Completing the Researchers involved in the project (Horizon Europe)	Completing the Results questionnaire (Horizon Europe)	Completing the Standards Questionnaire (Horizon Europe)

Periodic reporting will be much easier if you have already fulfilled the continuous reporting requirements

Technical reporting

Important points

All beneficiaries contribute to the technical part

Be careful that two beneficiaries are not working on the same section at the same time inadvertently

If two beneficiaries happen to work on the same data at the same time, then only the one that was first working will have their data saved

The second beneficiary will receive a notification that 'data have been changed' and that their data are lost

When you have completed your contribution or wish to stop, Click the SAVE button

Use the VALIDATION button to check in case errors are preventing saving

Close current screen and return to the main Funding & Tenders Portal

See also <u>Guidance</u> on completing the Technical Report

Locking the technical section

Click the **Lock for review** button

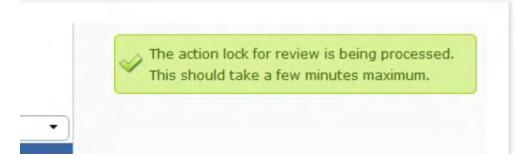


Confirm the report lock

Confirm the action by flagging the checkbox and clicking "OK".



The process of locking the report for review may take a few minutes



Preparing to submit to EDCTP3

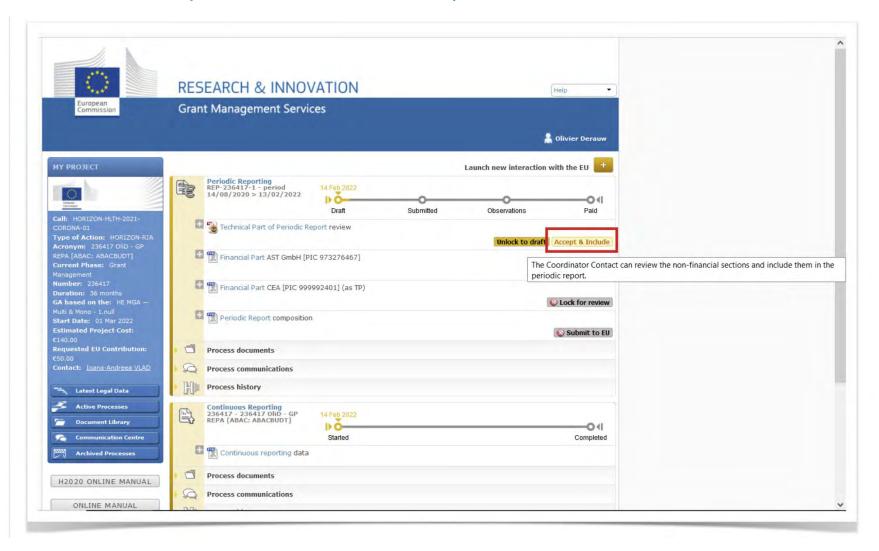
Sections completed



All beneficiaries can open the pdf data, but they can't unlock the data or accept & include in the report.

Step 3 Coordinator checks report

Reviews, accepts and submits the report to EDCTP3



The report can also be 'unlocked to draft' and re-edit

Step 3: Coordinator role

Checks and submission by the Coordinator

The Coordinator must review and explicitly approve those elements of the Periodic Report to be submitted to EDCTP3

The Coordinator can reject a Financial Statement back to a beneficiary for further editing

(by clicking the Redo button)

The Coordinator can approve the Financial Statement and include it in the Periodic Report

the Include button)

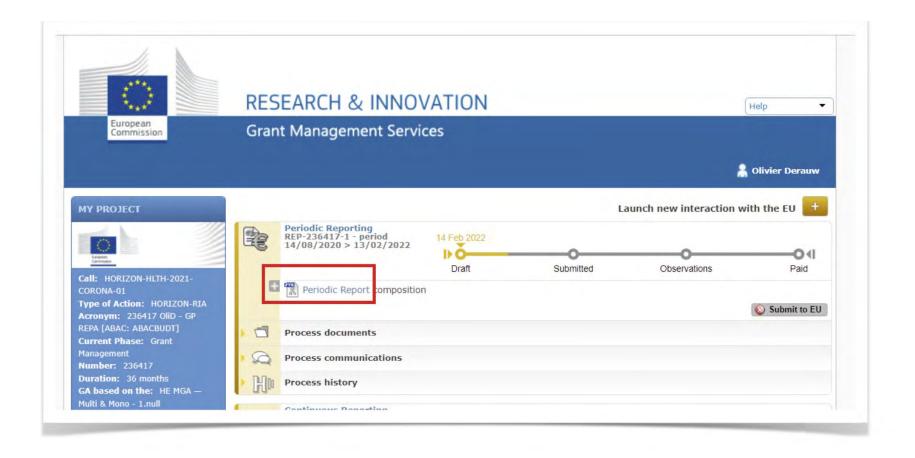
The Coordinator can unlock the Technical Part of the Periodic Report for further editing

(by clicking the

C

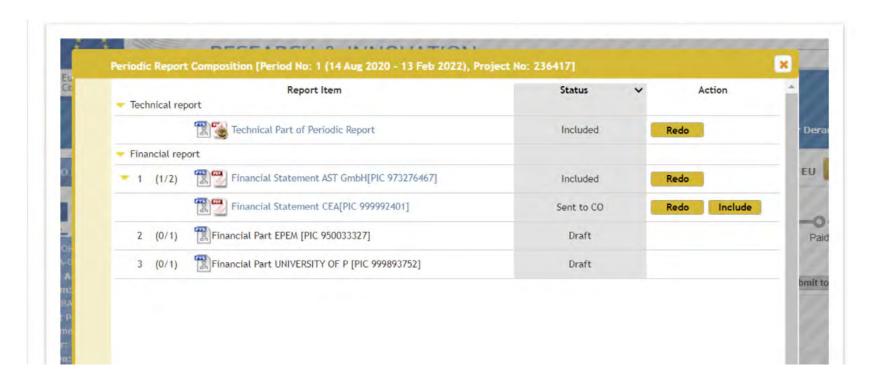
Step 3 Coordinator rejects or approves elements

Click on the task Periodic Report composition as shown below



Coordinator approves the report in the system

The elements of the report are displayed on screen



Once the elements of the Periodic Report are approved by the Coordinator, the Periodic Report can be submitted **by the Coordinator** to EDCTP3

The Financial Statements and the Technical Part of the Periodic Report are submitted in a single submission.

Step 4 Review by EDCTP3

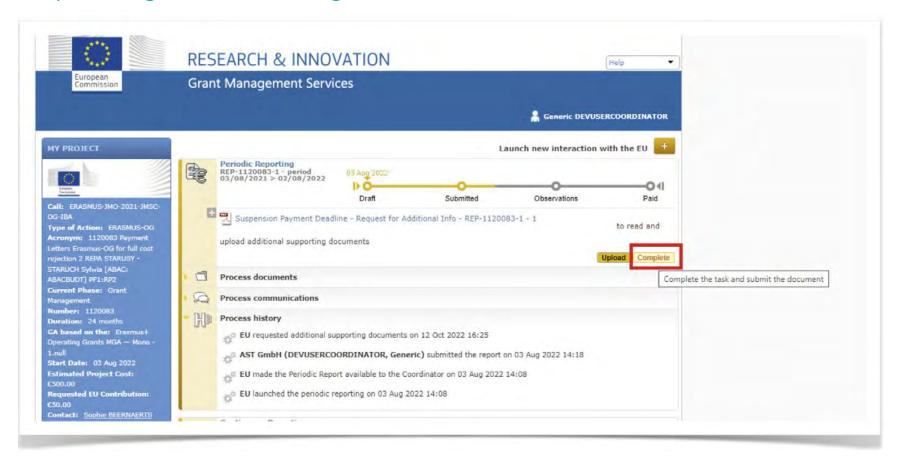
EDCTP3 can accept, request additional information or reject the report



A notification is sent to the Coordinator via the Participant Notification System and a response (in this case additional info) should be uploaded

Coordinator completes the task via system

Uploading and submitting additional information



In the event of rejection or request for revision by EDCTP3 the process starts again

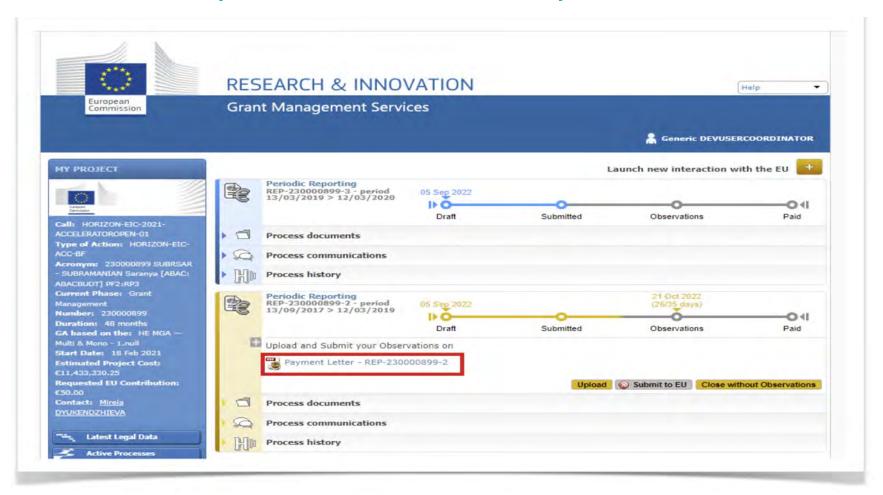
Step 4 Review process

Coordinator uploads new information and press OK



Approval process by EDCTP3

Notification by EDCTP3 is sent with the Payment Letter

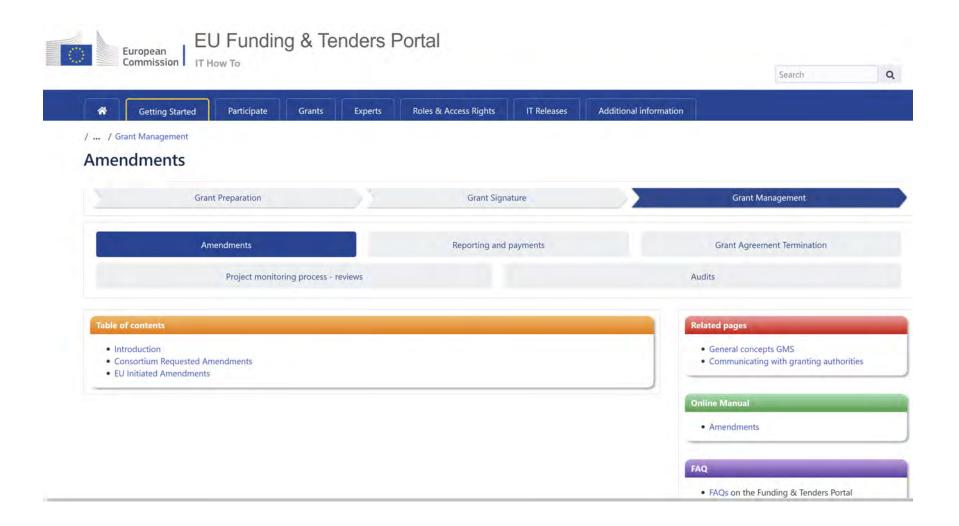


Payment letter can also be found under **Process documents**

Coordinator can submit '**Observations**' about the payment or can accept the payment and **Close without Observations**. A final payment letter and notification is sent by EDCTP3.

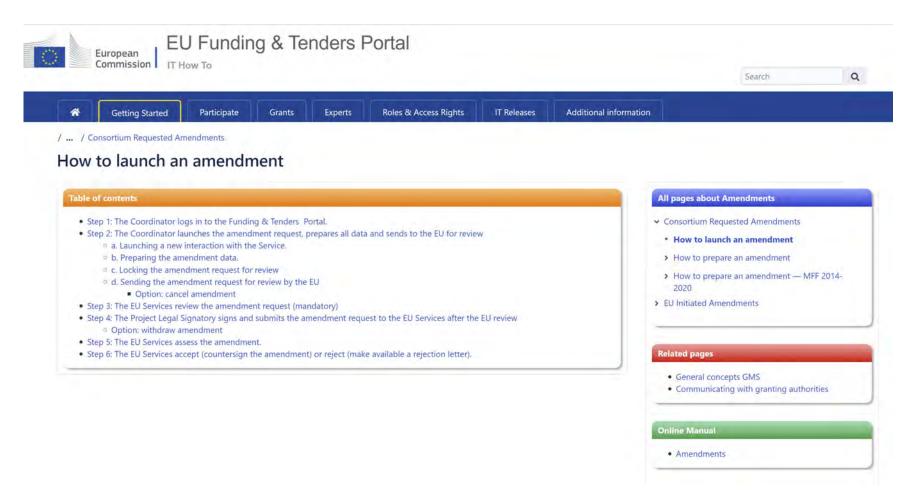
Amendments and how to submit them

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Amendments



How to - Launch an amendment

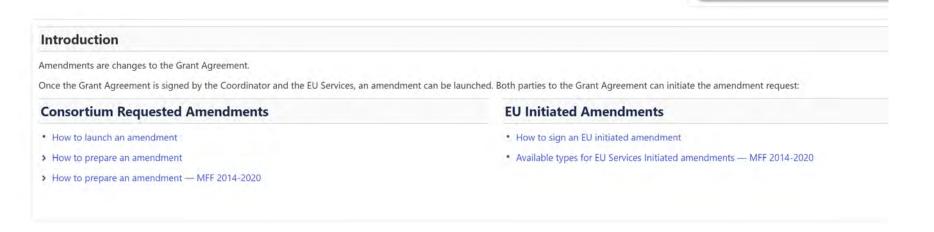
https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/How+to+launch+an+amendment



Coordinator submits an amendment request on behalf of the consortium

Requesting amendments (by the consortium)

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/Amendments#Amendments-ConsortiumRequestedAmendments



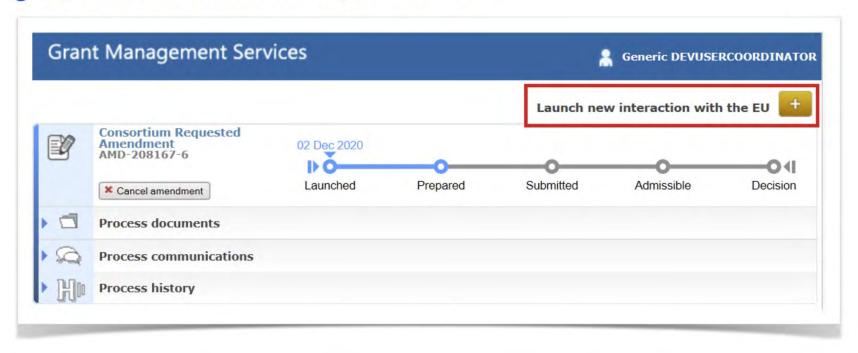
Amendments are usually requested by projects

The funder (EDCTP3) may initiate an amendment

Coordinator launches amendment

Steps in the system

- a. Launching a new interaction with the Service.
- nly the Coordinator Contact Person can perform this action.



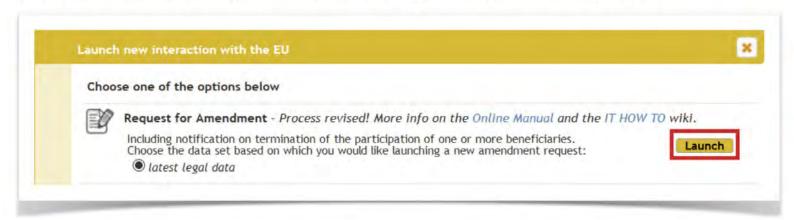
Validity of the request is assessed before it can be signed and submitted Once it is considered valid, Coordinator locks the data for review which generates a PDF

Amendment request is 'prepared' and status moves accordingly

Coordinator selects an option in the system

Creating the amendment request

a) launch a new amendment request based on the latest legal data (option selected by default):

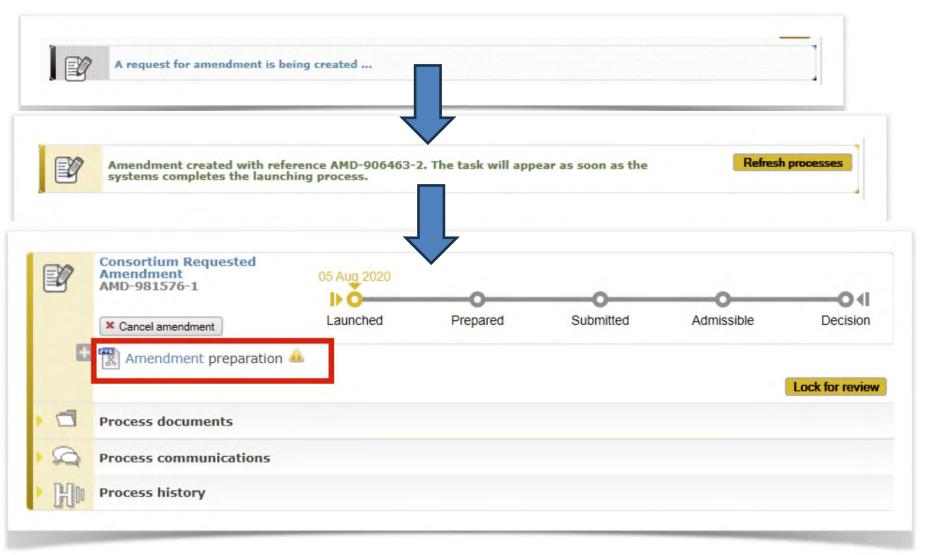


b) or launch a new amendment request based on a previous amendment (for the same project):



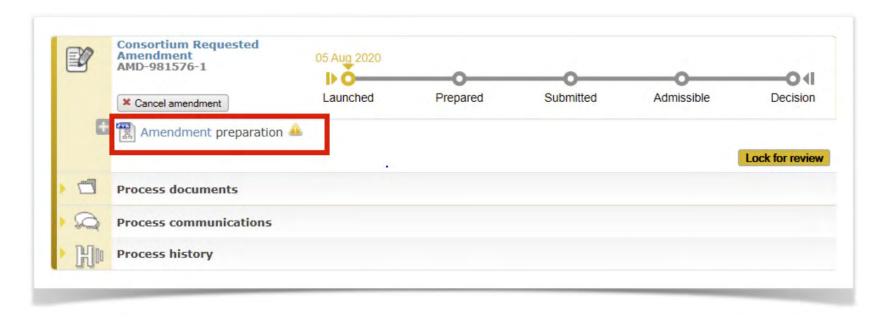
Creating the request for amendment

Generating reference number ready to prepare the amendment



Preparing the amendment

All beneficiaries are involved in process

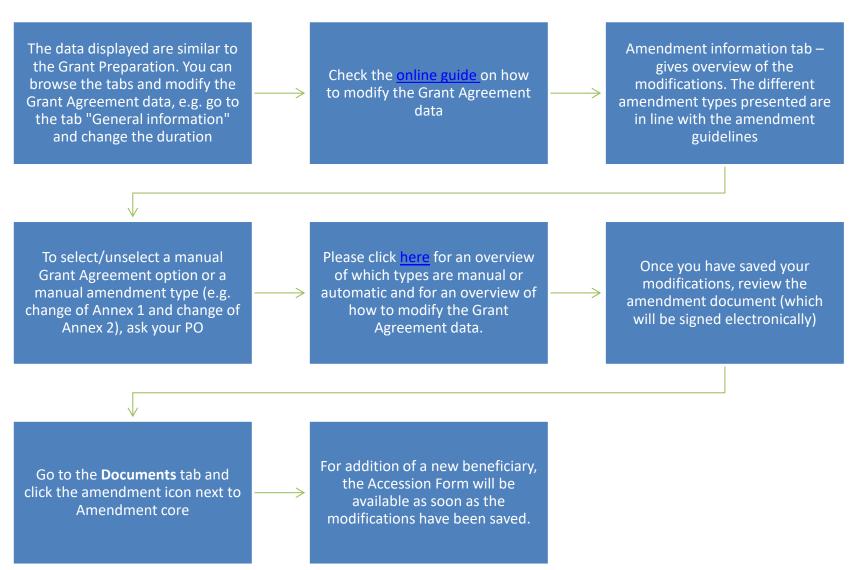


Click on Amendment Preparation This opens a new window Click on Amendment Information Prepare the amendment data



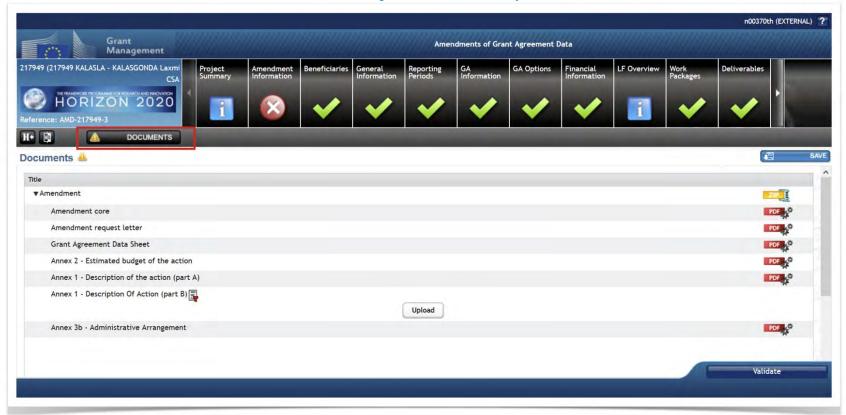
Preparing the Amendment

https://webgate.ec.europa.eu/funding-tenders-opportunities/display/IT/How+to+prepare+an+amendment



Amendments in the grants system

Overview of documents and system set up



The grants system guides you through the amendment process

- Automatic selection of the relevant amendment types, based on which Grant Agreement information is modified
- List of relevant supporting documents
- Overview and tracking of all changes

Amendment types (AT) are predefined – check the guidance

View from the grants system

Amendment information tab

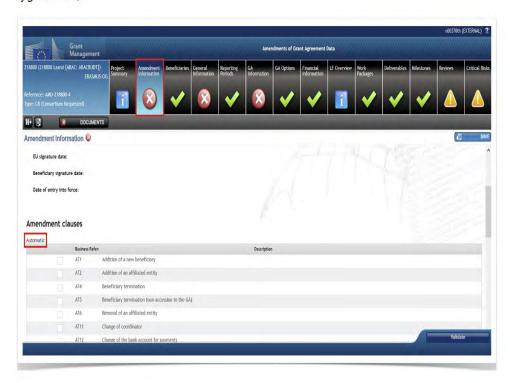


Number	The amendment number, automatically assigned as soon as the amendment is signed by both parties
Reference	Amendment request reference number is created automatically when launching the amendment request
Туре	
Amendment	Amendment is Commission Initiated (CI) or Consortium Requested (CR)
Notification-based (NB)	Changes of the Grant Agreement that follow a formal notification
Information Procedure (IP)	Changes of the Grant Agreement that do not depend on the agreement of the parties and are applied using an information procedure
Justification	Reason why an amendment is requested
Additional Information	Text to further explain the background of the amendment. This field is optional.
EU signature date	Date the EU/EDCTP3 signed the amendment
Beneficiary signature date	Date the consortium signed the amendment
Date of entry into force	The date the amendment goes into force

Amendment types

Automatic types

First the <u>"Automatic" types</u> are listed - (the system automatically selects the appropriate types according to the updates which have been done in the different Sygma tabs)



Amendment types

Manual types

Then the "Selected by EU" types are listed - (the Project Officer manually selects the appropriate type)



Contact the PO to enable you to launch any of the Manual amendment types (e.g. change of Annex 1)

Changes to Annex 1

Changing Annex 1 Part B (DoA)

The Upload button is available once the PO selects this manual type of amendment



Comparing versions of Annex 1

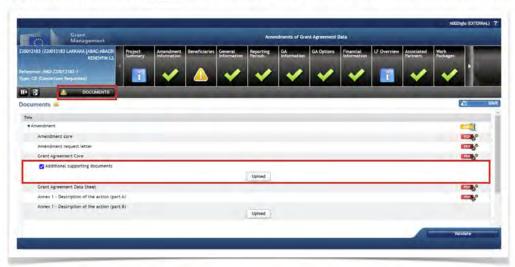
1 Optionally, you may also compare the Annex 1 (part B) document with its previous version.



Annex 1 amendment

Uploading additional documents

Optionally, you may upload extra files (.pdf, .doc, .docx or .zip) under the Documents tab, by ticking the box 'Additional supporting documents'



Pressing the reset button allows you to delete/replace the added files

The Reset button is available once you have completed your upload

Click on SAVE once you have completed the upload

Selecting the amendment type

By beneficiary or EDCTP3



'On demand' amendment type also available – not shown here

View/preview or edit the amendment text

How to view the text that will appear in the grant agreement



Click



the download icon next to the relevant amendment type

Clicking the document icon, displays a pop-up window with the text to be printed in the Grant Agreement

Adding variable data to the amendment

How to in the system

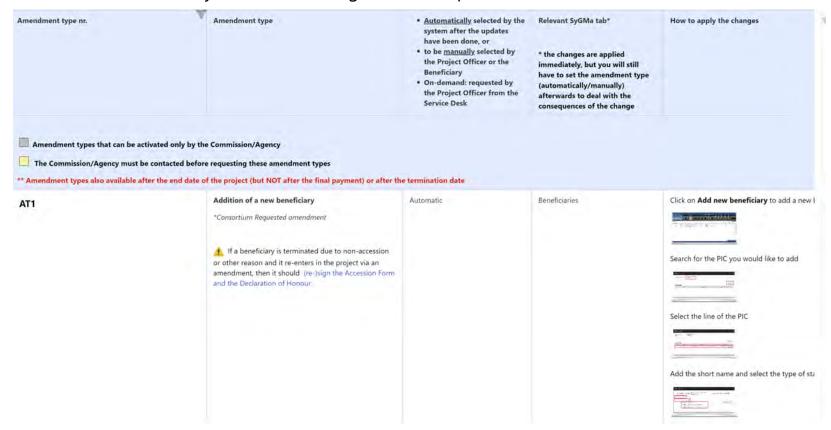
Click the pencil icon to view/edit variable data to the amendment. Click the download icon to preview the amendment. Amendments of Grant Agreement Data 18800 (218800 Laxmi [ABAC: ABACBUDT]) DOCUMENTS Amendment Information @ Change of the project starting date Change of the project duration Change of the reporting periods Change of the MIM contribution Change of the prefinancing guarantee Change of Beneficiary Details (legal name, legal address, VAT, ...) Change of legal status Universal Transfer of Rights and Obligations Selected by EU **Business Refer** Change of Annex 1 Change concerning linked actions Change of additional information GA termination (early termination) Selected by beneficiary

Some of the data (e.g. dates) can be added via pop-up screens

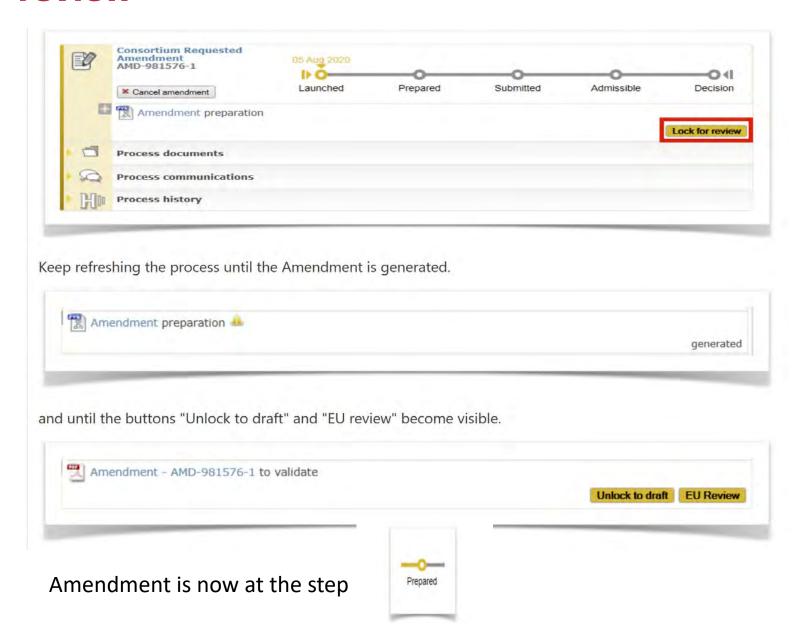
How to apply the changes for the amendment

https://webgate.ec.europa.eu/funding-tendersopportunities/display/IT/How+to+prepare+an+amendment

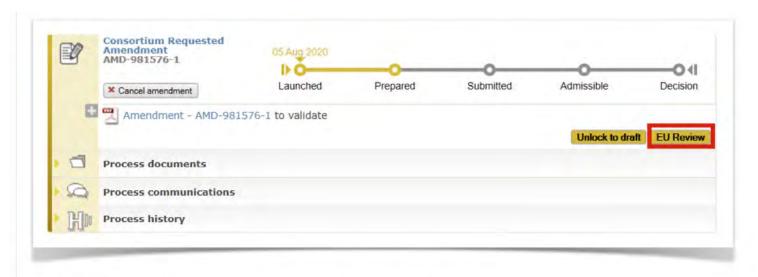
See guidance at end of link above where you can find a table with a detailed guide to each type of amendment (AT) and what you need to change. See example below.



Coordinator locks the amendment request for review

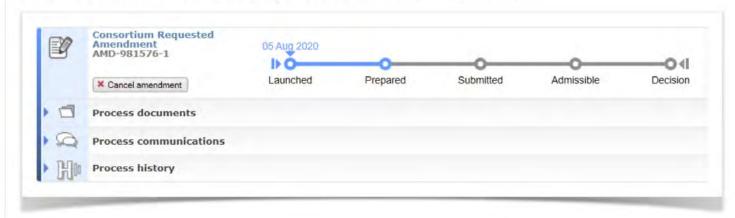


Coordinator can submit for review or can cancel the 'prepared' amendment



Note: "Unlock to draft" will make the amendment request editable again.

After clicking the "EU Review" button, the process will be in the hands of the EU.



The Coordinator can **Cancel amendment** by clicking the button

Coordinator signs and submits request

Similar procedure to GA signature

Request is complete and the system generates the 2 documents (amendment request letter and amendment core) for signature (PDF document, digitally signed to guarantee its security, reliability and authenticity).

The Coordinator's PLSIGN logs into My Projects > Actions > Manage Project > Amendment > Sign & Submit (same procedure as for Grant Agreement; see Signing the Grant Agreement guidance).

The amendment can be previewed, downloaded or printed (before or after signature) from the Documents screen if desired.

The request <u>cannot be altered</u> after it has been signed and submitted.

At this stage the only options are:

- Coordinator withdraws the request
- EDCTP3 rejects the request

Review of the amendment request by EDCTP3

Timeline of 45 days to accept or reject the request

EDCTP3 may extend this deadline in circumstances such as

- Complex amendment
- Checks needed about a new participant
- Scientific changes that may require review by independent experts

EDCTP3 will keep the Coordinator informed

Formal assessment of request by EDCTP3

Rejection

Consortium informed of rejection via Amendment Rejection Letter

Rejected amendment request is assigned a number e.g. R1, R2

The rejected request is saved and so the information can be recycled/re-used to prepare a new request

Coordinator can withdraw a request up until it is countersigned

Withdrawn requests are saved in the system and can be reused

Formal assessment of request by EDCTP3

Acceptance

Acceptance leads to signature (same procedure as <u>Grant</u> <u>Agreement signature</u> process)

Coordinator and Beneficiaries are informed

View the Countersigned Amendment in Portal Library (*My Projects > Actions > Manage Project > Project Library*)

The countersigned amendment is coded with a sequential amendment number e.g. Grant reference plus assigned number 2 means Amendment 2

Coordinator can withdraw a request up until it is countersigned

Entry into force and taking effect

Date from which amendment applies

An amendment proposed by the consortium **enters into force** on the day EDCTP3 signs it

It **takes effect** (meaning when the changes to the grant agreement start to apply) can be either:

On a specific date specified in the amendment OR

On the date of entry into force (signature date by EDCTP3)

Check carefully to ensure eligibility of costs (e.g. Addition of beneficiary is the date specified in the accession form)

Unusual amendments

Change of Coordinator without their agreement

This can happen in rare cases

A beneficiary must submit the amendment request <u>acting on</u> <u>behalf of the other beneficiaries</u>

Contact the PO to discuss this amendment - special access rights must be given to the beneficiary in the system

Evidence needed

- Proof of consortium decision to change the Coordinator
- Proof that consortium has selected the beneficiary to act on their behalf
- Opinion of the 'to be removed' Coordinator'(or proof that their opinion was sought)

Final remarks

Guidance on the **IT tools** that you need to use to apply for funding and to manage your grant is available at

https://webgate.ec.europa.eu/funding-tendersopportunities/display/IT/IT+How+to



Guidance on all aspects of applying for and managing funding is available at https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

