



**EDCTP**

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# **EDCTP Webinar: Requesting amendments to the grant agreement**

13 October 2022



# Welcome & introduction

## Housekeeping

- Please note that this session is being recorded. A recording will be made available on our website. (Please contact [info@edctp.org](mailto:info@edctp.org) if you have any questions about this.)
- During the presentation, you can write your questions in the Q&A box. There is also time for questions at the end of the presentations.

# Introductions



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# Agenda

1. Welcome & Introductions

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2. Changes that require an amendment

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3. Changes that don't require an amendment

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4. Who can request amendments?

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5. Most commonly received types of amendment requests

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6. The procedure for requesting an amendment

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7. Do's and don'ts

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8. Questions & Answers

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# Introduction to the EDCTP amendments webinar

# The evolution of EDCTP programmes

## EDCTP1: 2004-2015

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

## EDCTP2: 2014-2024 (2026)

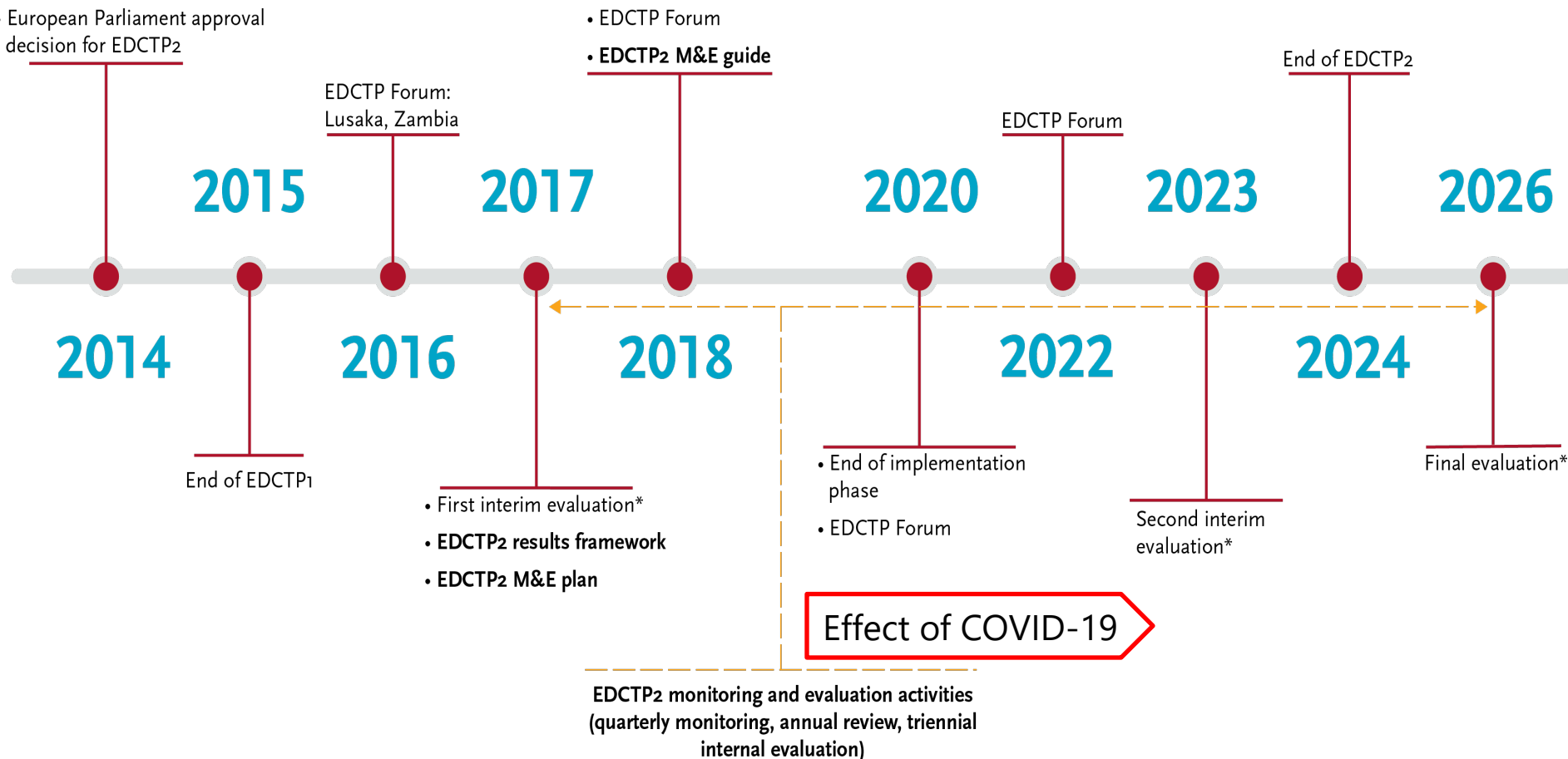
- Legal structure: EDCTP Association
- Supported under European Union's Horizon 2020
- Total budget: €1.36 Bn (European Union: €683 M; Participating States: €683 M) and Third parties: €500 M
- Disease scope: HIV, tuberculosis, malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory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

## Global Health EDCTP3: 2022-2031

- Legal structure: Joint Undertaking between the European Commission and the EDCTP Association
- Total budget: €1.6 Bn (EU Horizon Europe: €800 M; Participating States: €400 M; Third parties: €400 M)
- Disease scope: HIV, tuberculosis, malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and infectious diseases of epidemic potential

# Implementation of EDCTP2: timelines.

- Launch of EDCTP2
- Council of the European Union approval decision
- European Parliament approval decision for EDCTP2





# Amendments to the grant agreement

- Amendments may be requested for various reasons (including disruptions due to COVID-19).
- This webinar is intended to help EDCTP grant holders who need to request an amendment to the grant agreement.
  - Changes that require an amendment
  - Changes that don't require an amendment
  - Who can request amendments?
  - Most commonly received types of amendment requests
  - The procedure for requesting an amendment
  - Do's and don'ts

## 2

Changes that require an amendment

# When is an amendment necessary

When is it necessary and what can be changed?

- An amendment is necessary when there is a need to change the GA (i.e. the agreement itself and/or its Annexes)
- The general terms and conditions of the GA can not be changed via an amendment; only GA-specific data and the options in the GA can be changed
- Amendments may not result in changes that would call into question the decision to award the grant (e.g. a change in the composition of the consortium resulting in the consortium no longer meeting the eligibility criteria; changes to Annex 1 so substantial that the action no longer corresponds to the scope of the call.)

# When is an amendment necessary?

Changes involving beneficiaries and linked third parties

- Adding a new beneficiary
- Removal of a beneficiary whose participation has been terminated
  - Specific case: if a beneficiary's participation is terminated at the initiative of other beneficiaries ([Article 50.2](#))
- Change of beneficiary due to '[partial takeover](#)'
- Removal or addition of linked third party ([Article 14](#))

# When is an amendment necessary?

Changes involving the coordinator and payment arrangements

- Change of coordinator (the beneficiary and/or the principal investigator)
- Change in the bank account the coordinator (or in specific cases: beneficiary) uses for payments
- Change to the payment arrangements
- Change in the 'authorisation to administer' option

# When is an amendment necessary?

Changes involving the project or its implementation

- Change in the:
  - Title
  - Acronym
  - Starting date
  - Duration
  - Reporting periods
- Resumption of project activities after a temporary suspension ([Article 49](#))
- Changes to Annex 1

# When is an amendment necessary?

Changes involving the financial aspects of the grant

- Changes to Annex 2
  - Removal of a beneficiary (and/or linked 3<sup>rd</sup> party)
  - Addition of a beneficiary (and/or linked 3<sup>rd</sup> party)
  - Change in status of a beneficiary (eg from beneficiary not receiving funding to beneficiary receiving funding)
  - Other changes to the budget: e.g. addition of a subcontract ([Article 13](#))

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Changes that don't require an amendment



## When is an amendment not necessary?

- If the name or address of a beneficiary, linked third party or coordinator changes.
  - If a [universal takeover](#) results in a change of beneficiary
- NB:** this does trigger the obligation in Article 17.2 of the GA to notify EDCTP of these changes.
- For certain budget transfers:
    - Transfer of budget between **existing** budget categories and/or between partners (unless there is a major change in a project activity)

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Who can request amendments?

# Who can request amendments?

For RIAs and CSAs:

The **consortium** is free to propose amendments.

Role of the **coordinator**:

- Check that the consortium has reached agreement through an internal decision-making process, as set out in the consortium agreement (*e.g. unanimously or by simple or qualified majority*).
- Submit the amendment request on behalf of the consortium (signed by the legal representative).

# Who can request amendments?

For TMAs (fellowships):

Role of the **fellow**:

- Submit the amendment request (signed by legal representative).

In exceptional cases, EDCTP can also propose amendments (e.g. where an error would need to be corrected).

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Most commonly received types of amendment requests

## Most commonly received types of amendment requests

- Extension of project duration (with corresponding change to the reporting periods)
- Addition/removal of a beneficiary
- Change of coordinator's bank account information
- Change of Annex 1
- (Accession form delay)

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## Procedure for requesting an amendment

## ■ Procedure for requesting an amendment

1. Before submitting your request, please contact your Project Officer/Grants Finance Officer
2. Preparing the **request letter and supporting documents (including Annexes)**
  - Annex 1
  - Annex 2
3. Submitting the request
4. Assessment and decision by EDCTP
5. Formal outcome notification



# Procedure for requesting an amendment

## 1. Contact your Project Officer/Grants Finance Officer

Each project is different and may have different needs. Always contact the Project Officer and Grants Finance Officer before requesting the amendment. They can advise on the procedure and guide you on the documents to provide.

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes

An amendment request consists of a letter explaining the reasons why and supporting documents

Letter requirements	Comments
Timely submission	Before the end date of the grant
Indicates that the request is submitted on behalf of the consortium	For RIAs and CSAs only
Request is clear and logical	Corresponds to project circumstances that EDCTP is aware of via reports and correspondence
Provides justification for the amendment	Credible case that makes sense in terms of activities and timing. It matches the amended supporting documents and what has been reported
Makes reference to attached supporting documents	Amended Annex 1 (tracked changes and clean) Amended Annex 2 if applicable Other documents such as accession forms in specific cases
Signed by legal representative of the coordinator	Same person as grant agreement signatory or another verified legal representative for the organisation

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes

### **Example: requesting an extension to the duration of the action**

*Request: "On behalf of the consortium, I am requesting an amendment of the grant agreement for {grant code, title and coordinator} to extend the duration of the action by 6 months (Article 3) and to adjust the reporting periods by addition of a reporting period (Article 20.2).*

*These changes require amendment of Annex 1 of the grant agreement. Please find enclosed an updated Annex 1 (tracked changes version and clean version) to support this request."*

*Justification: "The extension is required because of .....unforeseen circumstances"*

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes

Type of amendment request	Annexes to submit
Extension of project duration	Annex 1
Addition of a beneficiary	Annex 1; Annex 2 Annex 3 (accession form) + if new beneficiary: Legal Entity information
Removal of a beneficiary	Annex 1 Annex 2 Opinion of the beneficiary whose participation is terminated or proof that this has been requested
Change in Annex 1	Annex 1
Change in Annex 2	Annex 2 (not commonly an amendment by itself but sometimes in combination with for example change to Annex 1)
Change in bank details	New bank account information Financial Identification Form (FIF) Bank statement

More information may be required depending on the project and the request

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1



### EDCTP Application Form – Full Proposal

#### TITLE OF PROPOSAL

[Redacted title of proposal]

#### ACRONYM

[Redacted acronym]

Change in duration

DURATION (MONTHS)

60

EDCTP CONTRIBUTION (€)

[Redacted contribution amount]

Change in coordinator or participants

#### COORDINATOR

1.

[Redacted coordinator name]

#### PARTICIPANTS

1. Stichting Katholieke Universiteit-Radboudumc (RUMC), Netherlands
2. University of Zimbabwe, Zimbabwe
3. University College London (UCL), United Kingdom
4. Moi University, Kenya
5. Joint Clinical Research Centre Limited (JCRC), Uganda
6. London School of Hygiene and Tropical Medicine (LSHTM), United Kingdom
7. University of York (UoY), United Kingdom
8. Enhancing Care Foundation NPC (ECF), South Africa
9. Fondazione Penta Onlus (Penta), Italy
10. KwaZulu-Natal Research Institute for TB-HIV (K-RITH, AHRI), South Africa
11. Makerere University, Uganda

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

### 1. 1. PARTICIPANTS (ORGANISATIONS)

Table to be updated in case of change in coordinator or participants

Participants [Organisations, including coordinating organisation]

Organisation	Country	Role	H2020 type of organisation	Public or private	Profit or non-Profit
Baylor College of Medicine Children's Foundation Uganda Limited (Baylor)	Uganda	Coordinator	Private not-for profit	Private	Non-profit
Stichting Katholieke Universiteit-Radboudumc (RUMC)	Netherlands	Participant	Secondary or higher education establishment	Public	Non-profit
University of Zimbabwe	Zimbabwe	Participant	Secondary or higher education establishment	Public	Non-profit
University College London (UCL)	United Kingdom	Participant	Secondary or higher education establishment	Public	Non-profit
Moi University	Kenya	Participant	Secondary or higher education establishment	Public	Non-profit
Joint Clinical Research Centre Limited (JCRC)	Uganda	Participant	Research organisation	Public	Non-profit
London School of Hygiene and Tropical Medicine (LSHTM), incorporating the Uganda Virus Research Institute (UVRI)	United Kingdom	Participant	Secondary or higher education establishment	Public	Non-profit
University of York (UoY)	United Kingdom	Participant	Secondary or higher education establishment	Public	Non-profit
Enhancing Care Foundation NPC (ECF)	South Africa	Participant	Research Organisation	Private	Non-profit
Fondazione Penta Onlus (Penta)	Italy	Participant	Research Organisation	Private	Non-profit
KwaZulu-Natal Research Institute for TB-HIV (K-RITH, AHRI)	South Africa	Participant	Research Organisation	Private	Non-profit
Makerere University	Uganda	Participant	Secondary or higher education establishment	Public	Non-profit

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

### 7. 7. PARTICIPANTS (INDIVIDUALS)

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#### 7.1 Coordinator: Baylor College of Medicine Children's Foundation Uganda Limited (Baylor)

Organisation	Baylor College of Medicine Children's Foundation Uganda Limited (Baylor)
Country	Uganda
H2020 type of organisation	Private not-for profit
Public or private	Private
Profit or non-profit	Non-profit

Tables to be updated in case of change in coordinator or participants

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

### 9. 9. WORK PACKAGES

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#### WORK PACKAGE(S) 1

Work package identifier	1.00
Work package title	Management and Coordination
Organisation that leads the work package	Baylor College of Medicine Children's Foundation Uganda
Start month of work package	1.00
End month of work package	60.00
Objectives	

Workpackage section to be updated with changes in timelines, or changes in objectives or work to be conducted under the workpackage



# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

List of Deliverables from Work packages

Deliverable Number	Deliverable Name	Lead Participant Organisation	Type of deliverable	Dissemination Level	Month of project when deliverable will be achieved
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List of Milestones from Work packages

Milestone number	Milestone name	Means of verification	Month of project when milestone will be attained
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Deliverables and milestones tables to be updated with changes in **timelines**, or changes in the **actual deliverables/milestones**

Please note that compulsory deliverables cannot be removed/changed (including ethics or other trial-related deliverables)

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

Third parties involved in the project (including use of third party resources)

Do the participants plan to subcontract certain tasks? (Please note that core tasks of the project should not be sub-contracted).
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No
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Do the participants envisage that part of its work is performed by linked third parties?	No
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Do the participants envisage the use of contributions in kind provided by third parties? (Articles 11 and 12 of the General Model Grant Agreement)
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No
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Section to be updated in case of the addition of a **subcontract**, **linked third party** (in principle an update of Annex 2 is also required) or use of **in-kind contributions by third parties**.

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

Gantt chart or similar document upload [REDACTED] df is included as an Appendix within this file.

Gantt chart to be updated in case of changes in timelines

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

### Critical risks for implementation

Description of risk	Work package involved	Proposed risk-mitigation measures
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Risk management table to be updated where applicable (for example in case of disruptions due to COVID-19).

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 1

### APPENDICES

List of appendices to be updated where applicable (for example with an updated Gantt chart).

# Procedure for requesting an amendment

## 2. Preparing the request letter and Annexes – Annex 2

Addition of a beneficiary:

- The beneficiary must submit a budget unless it is a beneficiary not receiving funding

Removal of a beneficiary:

- The beneficiary needs to submit the expense report up to the date that they stay in the grant.
- The beneficiary also needs to submit the funds received up to the date.

# Procedure for requesting an amendment

## 3. Submitting the request

Once the letter and supporting documents are ready, please submit them over e-mail to:

- The Project Officer (PO) assigned to your grant
- CC the Grants Finance Officer (GFO)
- CC [edctpgrants@edctp.org](mailto:edctpgrants@edctp.org)

# Procedure for requesting an amendment

## 4. Assessment and decision by EDCTP

Once received, EDCTP has 45 days to assess the request.

The deadline may - exceptionally - be extended on a discretionary basis, e.g. if the amendments are complex, specific compliance checks are needed (e.g. on ethical issues), or if the project has to be reviewed to assess the changes.



# Procedure for requesting an amendment

## 5. Formal outcome notification

A formal notification of the outcome will be sent to the coordinator.

- **Acceptance:** If EDCTP accepts the request, the coordinator will receive a formal letter to notify the consortium of the decision. Attached to the acceptance letter are the finally approved (clean) annexes submitted as part of the request.
- **Rejection:** if the request is invalid (if it breaches the grant agreement's terms or conditions, for instance), incomplete or wrong, or if EDCTP disagrees with it, the request is formally rejected. The coordinator will be notified of the rejection via a rejection letter.
- If you do not receive a notification within the 45-day deadline, the request is considered to have been rejected.
- The legal representative of the coordinating organisation can withdraw a submitted request provided that EDCTP has not approved it.

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Do's and don'ts

## Do's and don'ts

Do:

- Discuss the amendment request before submission with the PO/GFO
- In case of an extension – make sure the extra time requested matches with updates in Annex 1 and gantt chart
- Use the right version of Annex 1 to make edits
- Make sure the request letter is signed by the legal representative
- If there have been small changes occurring before this amendment, include these 'tidying up' changes in Annex 1
- Take into consideration that if deliverables, activities and work packages are removed or reduced substantially, this should lead to a reduction in the grant amount

## Do's and don'ts

Don't:

- Submit the request close to or after the end date of the grant
- Submit requests that are not credible – eg don't ask for an extension of x months if there is no chance of completing the project even within the extended timeframe
- For extensions, don't simply push deliverables to the last month of the project
- For extensions, don't submit the request before there is a clear estimate of the additional time needed

## Impact of COVID-19 on EDCTP2 projects

- EDCTP is committed to working with EDCTP-funded beneficiaries and other stakeholders to help to minimise the impact of the COVID-19 pandemic on EDCTP projects.
- **EDCTP beneficiaries can request an amendment of article 3 of the Grant Agreement to extend the duration of the action.** The maximum budget amount set out in article 5 can never be increased.
- The latest end date for all EDCTP2 projects is 31 December 2025.

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Q&A

# Thank you



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