EDCTP

The power of sharing science

EDCTP Information Session on Final Reporting for EDCTP2 grant holders - Technical reporting session

05 June 2025

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Housekeeping

- Please note that this session is being recorded. The recording will be made available on our website. (Please contact info@edctp.org if you have any questions about this.)

How to ask questions:

- Use the Q&A functionality
- Write them in the chat
- Questions from registration form will be addressed in the Q&A after the presentation

Disclaimer

About this workshop

- This presentation has been prepared under the EDCTP2 programme and provides information to EDCTP2 grantees on the Periodic and Final reports.
- The presentations shared during this workshop are non-binding and designated for information purposes only. All matters related to your project should be formally discussed with your Project Officer or Grants Finance Officer.
- The content of the presentations is based on the legal framework applicable to EDCTP2 activities, namely decision no. 556/2014/EU of the European Parliament and of the Council, Horizon 2020, the EDCTP2 annual workplans and the EDCTP2 Model Grant Agreement

This workshop does not cover Global Health EDCTP3 funding
For GH EDCTP3 information on funding, please check this website:
https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

Any questions related to GH EDCTP3 funding should be addressed to: EC-GLOBAL-HEALTH-EDCTP3@ec.europa.eu

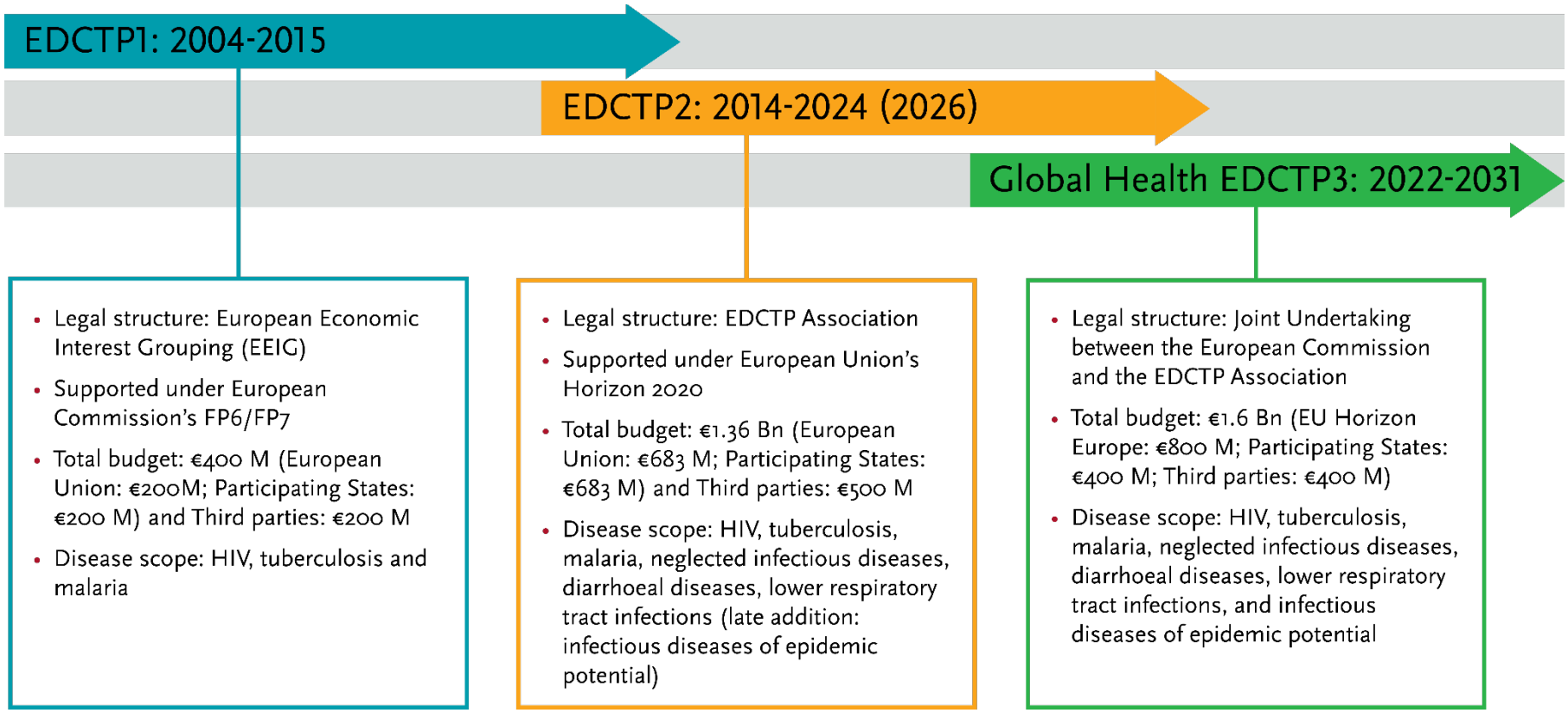
https://globalhealth-edctp3.eu/

Agenda

Technical Session, 05 June 2025, 11:00 – 12:30 (CEST)

Time	Agenda item
11.00-11.10	Welcome and Introductions
11.10-11.30	Technical Reporting • Final report and last periodic report submission • What if not everything is achieved by the grant end date • Update on the project's impact • Acknowledgements and communications • Open access, data sharing and updating of trial registries • Obligations and requirements after the grant end date • Reporting cofunding
11:30-12:30	Questions & answers • Addressing questions and topics sent in advance by participants • Q&A open session
12:30	End of the Technical session

The evolution of EDCTP programmes



- Currently the two programmes: EDCTP2 and the GH EDCTP3 are overlapping.

Reporting – Final technical report

Important reminders

- The final periodic report must be submitted **within 60 days** following the end of the grant
- We do not offer extensions for submission of reports, late = late
- Repeated failure to submit a report (or revision) in time is a breach of the grant agreement and warning letter will be sent

Final technical report consists of two parts:

Last periodic report

- Explanation of the work carried out
- Overview of progress (must justify any differences between work expected and work carried out)
- Submit all deliverables and milestones that are outstanding

Final report

- Overview of the results and their exploitation and dissemination
- Conclusions on the action
- Socio-economic impact of the action

Reporting – Final technical report

Always keep in mind project outputs:

- Exploitation and dissemination of results (*EDCTP is a signatory to the WHO joint statement on public disclosure of results from clinical trials*)
- Update ***trial registry(-ies)*** with primary endpoint results
- Update ***project webpage*** *with results*
- Financial contributions from other sources (**cofunding**)
- Summary for publication, with findings
- Engagement with policymakers, WHO, etc.

Deliverables and Milestones

Deliverables and milestones must be achieved during the lifetime of the project (**article 19**).

If there are deliverables that can't be submitted, projects have to:

- Provide an explanation and drafts or progress report
- Provide forecast dates
- If deliverables are not provided, the grant value might be decreased (contact your project officer to discuss individual cases)

Consortium's commitment letter for unachieved deliverables/ milestones may be requested

- List the unachieved deliverables/milestones and state they will be provided once available
- Provide forecast date when each deliverable/milestone will be submitted
- Proactively send pending deliverables to EDCTP when achieved
- *Of particular interest are deliverables/milestones related to* ***trial results***, ***publications***, ***IP registration***, ***policy briefs***, *and* ***graduation of students***

Update on project impact

Please provide an update on the **impact of the project**

- You have completed the activities and should have the results
- How have the results of your project impacted the field
- There may be changes due to new research results reported elsewhere
- Changes in policy may affect how your results would be viewed

Provide an update on the impact of the project in the context of your results and the most recent scientific developments in the field ***in the final report and in the public summary***

Provide updated:

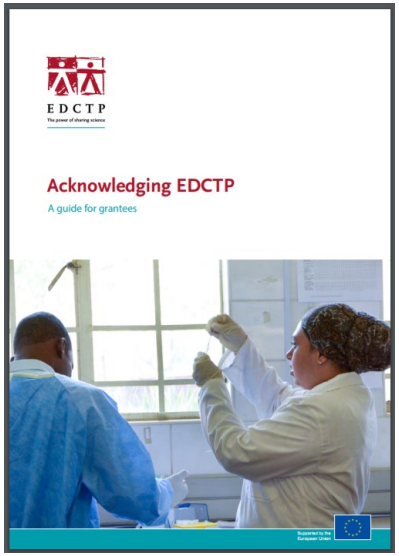
- Data management plan
- Dissemination and exploitation plan

Acknowledgement of EDCTP funding

- Ensure **EDCTP/EU are acknowledged**. We recommend:

This project is part of the EDCTP2 programme (grant number XXX – acronym) supported by the European Union

- **EDCTP financial contribution** such as salary support, data, subcontracted activities, etc. must be acknowledged in scientific publications, including MSc/PhD thesis.
- **If** the funder **acknowledgement is missing** – you must contact the journal editor to include the acknowledgement. If not corrected, publications' costs will not be eligible.
- Inform your PO in advance about publications and seek advice concerning the funder's acknowledgement statement.
- **Cofunders** (via EDCTP) may need to be acknowledged too, check with your PO.



Acknowledging EDCTP: A guide for grantees

Scientific publications and open-access

- Research publications must be **Open Access**

*(**Article 29.2** of the EDCTP2 Grant Agreement outlines the legal requirements for open access to scientific publications.* For more information, see the H2020 guidelines on Open Access. *Each beneficiary must ensure open access to all peer-reviewed scientific publications relating to its results).*

- Open access to other types of publications is also recommended

Publication costs after the end date of the grant are <u>not</u> eligible for reimbursement

They might be eligible in specific cases and where the following conditions are met:

- Evidence that the manuscript was submitted before the project end date – date, time and details (email from Journal acknowledging receipt)
- Evidence of the amount, invoice received but not paid (due to final payment not received from EDCTP)
- A debt, pertaining to the said invoice, should exist in the beneficiary's accounting system.
- Details of the deliverable that this relates to and draft manuscript

Scientific publications and open-access

Europe PMC

- EDCTP is a member of **Europe PMC** (PubMed Central), an **open science platform** that maintains a worldwide **collection of scientific articles and research outputs**.
- EDCTP expects that electronic copies of any research papers accepted for publication in a **peer-reviewed journal** (financially supported in whole or in part by EDCTP funding) **to be made available through Europe PMC** as soon as possible, and in any event, within 6 months of the journal publisher's publication date.
- Publications are deposited automatically in Europe PMC from many journals.
- Compliance with EDCTP **open-access** policy.
- **EDCTP-funded researchers** to share their publications via one **central location**.
- Intuitive and powerful **search tools available to anyone**, anywhere for free.

More information: ***https://www.edctp.org/event/webinar-making-edctp-funded-research-open-with-europe-pmc-plus/***

Scientific publications and open-access

Open Research Europe

- **Scientific manuscripts written after the grant end date** can be submitted to the **Open Research Europe (ORE)** Publishing Platform as this is an **open-access resource** that does **not** charge authors any **fees for article/publication processing**.

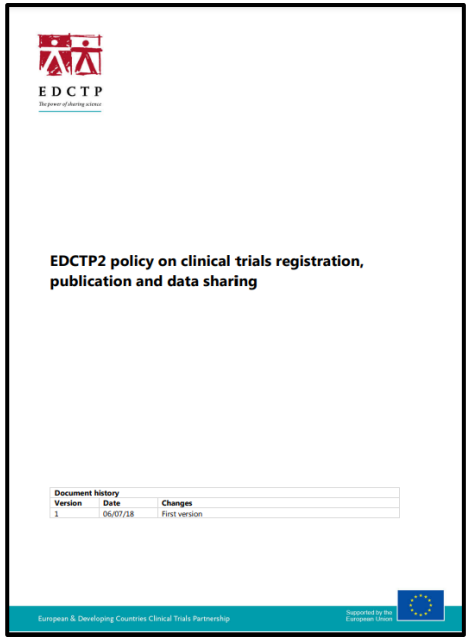
- Open Research Europe (ORE) is the **open-access publishing platform of the European Commission** for all disciplines for research stemming from Horizon Europe. **Currently** only articles can be published on this platform if **at least one author is/was involved** in a running or finished **Horizon 2020, Horizon Europe or Euratom project** from the European Commission and if the article is a result of that project.

More information:* *EDCTP on Open Research Europe – EDCTP: https://www.edctp.org/event/workshop-edctp-on-open-research-europe/

Clinical trials: transparency and prompt reporting

EDCTP/Horizon 2020 requirements:

- Prospective **registration**
- Update of **trial registry**
- Posting **summary results within 12 months from primary study completion** (usually the last visit of the last subject for collection of data on the primary outcome)
  - Uploading the results for the primary outcome in the trial registry
  - Uploading the publication(s) on primary outcome



EDCTP2 policy on clinical trials registration, publication and data sharing

Open research data

- The grant agreement requests that **research data be made available for use by others** (Article 29.3)
  - Beneficiaries must deposit in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate – free of charge for any user – the following:

    (i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible

    (ii) other data (and its metadata), as specified and within the deadlines laid down in the 'data management plan' (part of the proposal, i.e. Annex 1 of grant agreement) - updated data management plan must be provided (if applicable)
- If you opted into this, provide information on where datasets have been deposited (making sure no personal data are being shared)

Report on status of posting results

- 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 CONSORT 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 and data 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

END OF PROJECT

Rights & Obligations related to Grant Administration (Articles 18, 22, 26 and 28)

- Which obligations do we still have as a consortium after project's end?
- For how long should I maintain the project website after project's end?
- How long should I keep the supporting documents?

END OF PROJECT

- **Article 18** – obliges the consortium to **keep the records for a period of up to 5 years** after the last payment. The records should be verifiable and stored in the **original versions**, in the format in which they were created and must be available upon request. The reason for this is to be able to prove the correct project implementation and compliance with the obligations under the GA.

- **Article 22** – **checks, reviews, and audits** can be done at any moment in order to verify any aspect related to the grant. EC check or audit can occur until **5 years** post-grant end date.

END OF PROJECT: obligations & opportunities

- **Article 26** – **ownership of results**, results are owned by the beneficiary that generates them. The EDCTP Association may, with the consent of the beneficiary concerned, assume ownership of results to protect them (up to four years after the grant end date). Check Article 30 (right to object).
- **Article 28** – the consortium must take measures to **ensure exploitation of the project results**, meaning turning them into concrete value for society. This obligation is to be undertaken within **4 years** after the end of the project. If the obligation is not fulfilled, the EC has the right to take ownership of the consortium results. Grantees should **take measures aiming to ensure 'exploitation' of the results** by using them in further research activities; developing, creating or marketing a product or process; creating and providing a service, or using them in standardization activities

For recording and presentation please visit:
EDCTP Webinar: Final Reporting for EDCTP2 grant holders, November 2024

Declare co-funding

Some grant are awarded in response to a call requiring co-funding (please see Annex 1 as reference).

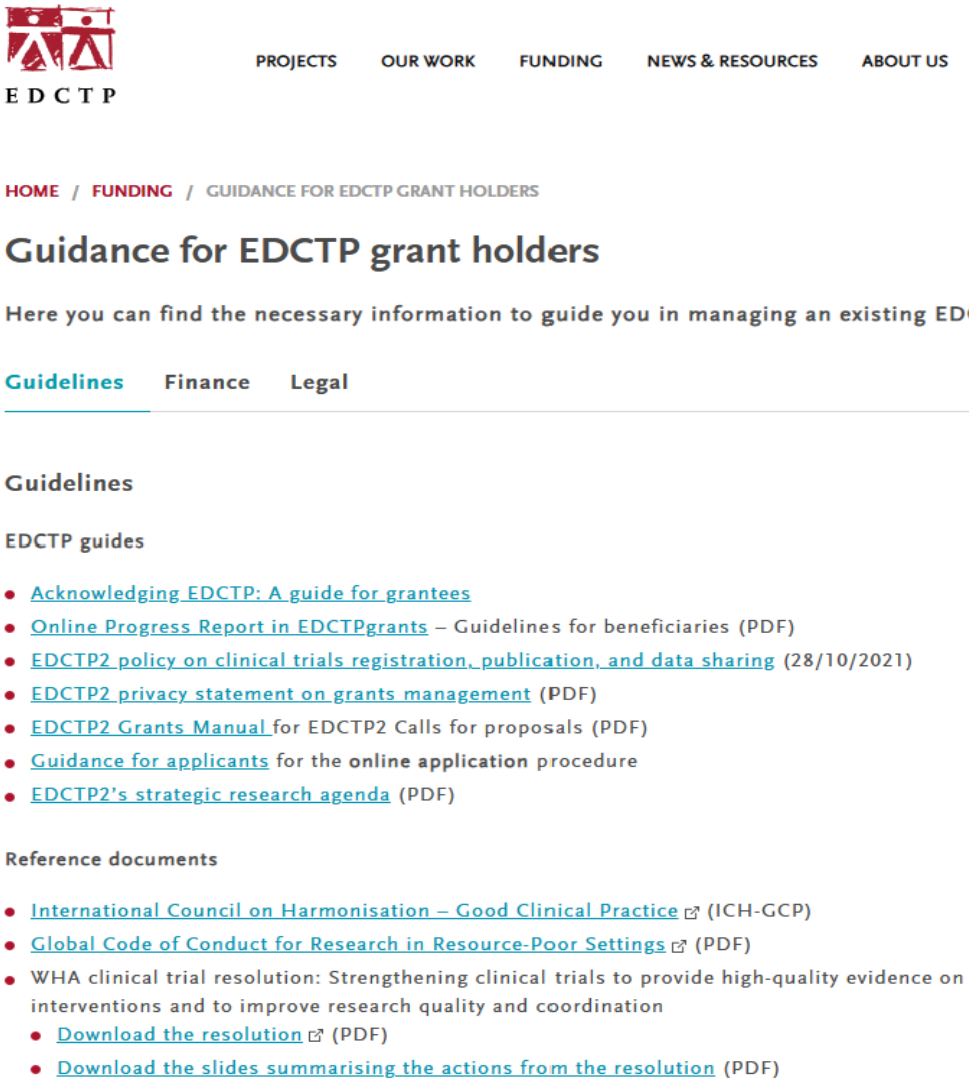
Obligation for Strategic RIA (matching EDCTP funding)

Overview other financial contributions to the project								
EDCTP2 project reference code	**Coordinator organisation**	**Name of cofunder organisation e.g. funding agency, organisation,**	**Country where cofunder is based**	**Type of organisation (private for profit, private not for profit, public)**	**Type of financial contribution (in kind / in cash*)** ** If a combination of both 'in cash' and 'in kind' cofunding, please use separate rows for the given funding agency.*	**Brief description of project activity(-ies) costs covered by cofunding, including start and end dates of the financial contribution**	**Amount (in €)**	**Institutional documentation of financial contribution** (if applicable, provide a copy of *cofunding letter*): ***Yes / No***

Final tips and keep in touch

- Inform your PO and GFO about any delays or issues with the final report
- Keep us informed about key events and outputs from the project (presentations, publications)
- Let us know about newsworthy items in advance (press releases, publications, awards/prizes to people)

Resources



https://www.edctp.org/funding/templates-and-guidelines/

Q&A

Questions

- What funding alternatives does EDCTP have with regards to **payment of publication fees for open access** for papers published after the project has ended?// Payment of publication fees for papers that will be published after the project has ended?
- When is the **report due** after getting an extension of the grant?
- Can you please explain the **important focus points** to highlight in the final reporting?
- What measures should be taken if some of the **deliverables are not accomplished** by the end of the project? // At the end of the project should the remaining funds be sent to EDCTP before all the deliverables have been achieved? // How do we deal with deliverables that are still in process? // What measures should be taken if some of the deliverables are not accomplished by the end of the project?
- How to **report deliverables** which were not mentioned in the Annex list?

Questions

- What are the **differences between the last periodic report and the final report**? // Is the final technical report the same as the previous reports in terms of the format, contents of the report and depth?
- Clarification on **Open research Data** section of the technical report
- Due to university processes some of our **students are severely delayed**. Can we have a no cost extension for them?
- What are the specifications for **photos** added to the technical report?
- How can we **communicate** on the end of the project?

THANK YOU

The EDCTP programme is supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

Clinical trial registries used by EDCTP grant holders

ClinicalTrials.gov / PACTR / ISRCTN

Feature	International Standard Randomised Controlled Trial Number (ISRCTN)	Pan African Clinical Trials Registry (PACTR)	ClinicalTrials.gov
Scope/study sites	International, but mostly UK	Primarily African countries	Primarily US, but international
Trial types	Interventional and observational	Interventional*	Interventional and observational
Registration fee, data access	**Registration fee**, publicly accessible	Free registration, publicly accessible	Free registration, publicly accessible
Minimum required information for registration[1]	24-item data set - WHO Trial Registration Data Set (TRDS)	24-item data set - WHO Trial Registration Data Set (TRDS)	24-item data set - WHO Trial Registration Data Set (TRDS)
Recognition by WHO's ICTRP	Yes	Yes	Yes
Ethics Approval requirement during registration and before recruitment	Ethics approval must be confirmed/pending. **Recruitment cannot begin until ethical approval is confirmed**	Ethics approval must be confirmed/pending. **Recruitment cannot begin until ethical approval is confirmed**	Ethics approval must be confirmed/pending. **Recruitment cannot begin until ethical approval is confirmed**
Required by FDA	No	No	Yes (for FDA-regulated trials)
Data update frequency	Regular updates required (recruitment status, sample size, etc.)	Regular updates required (recruitment status, sample size, etc.)	Regular updates required (recruitment status, sample size, etc.)
Timeframes for posting of study result summary	**Primary outcomes within 12 months of trial completion** or termination/withdrawal*	**Primary outcomes within 12 months of trial completion** or termination/withdrawal*	**Primary outcomes within 12 months of trial completion** or termination/withdrawal*
Key result summary (per CONSORT or STROBE guidelines)	Participant flow (enrolment, allocation, follow-up, data analysis), Baseline and demographic characteristics, Outcome measures (primary, and secondary if applicable), Adverse events		

1. WHO Trial Registration Data Set. https://www.who.int/clinical-trials-registry-platform/network/who-data-set