EDCTP

The power of sharing science

EDCTP2 Workshop: Reporting for multi-beneficiary grant holders – Technical reporting

14 November 2024

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EDCTP

Housekeeping

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

- If you have any questions, please pose them in the Q&A functionality; there is also room for questions at the end of the presentations.

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 Europe, the EDCTP2 annual workplans and the EDCTP2 Model Grant Agreement

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/

Set up of workshop

Morning session: 10:00-12:00

- Technical reporting:
  - Andreia Coelho
  - Johanna Schaefer
  - Montserrat Blazquez
  - Phindile Ximba
  - Debora Bade
  - Daniela Pereira

BREAK

Afternoon session: 13:00-15:00

- Financial reporting
  - Abdoulie Barry

Set up of workshop

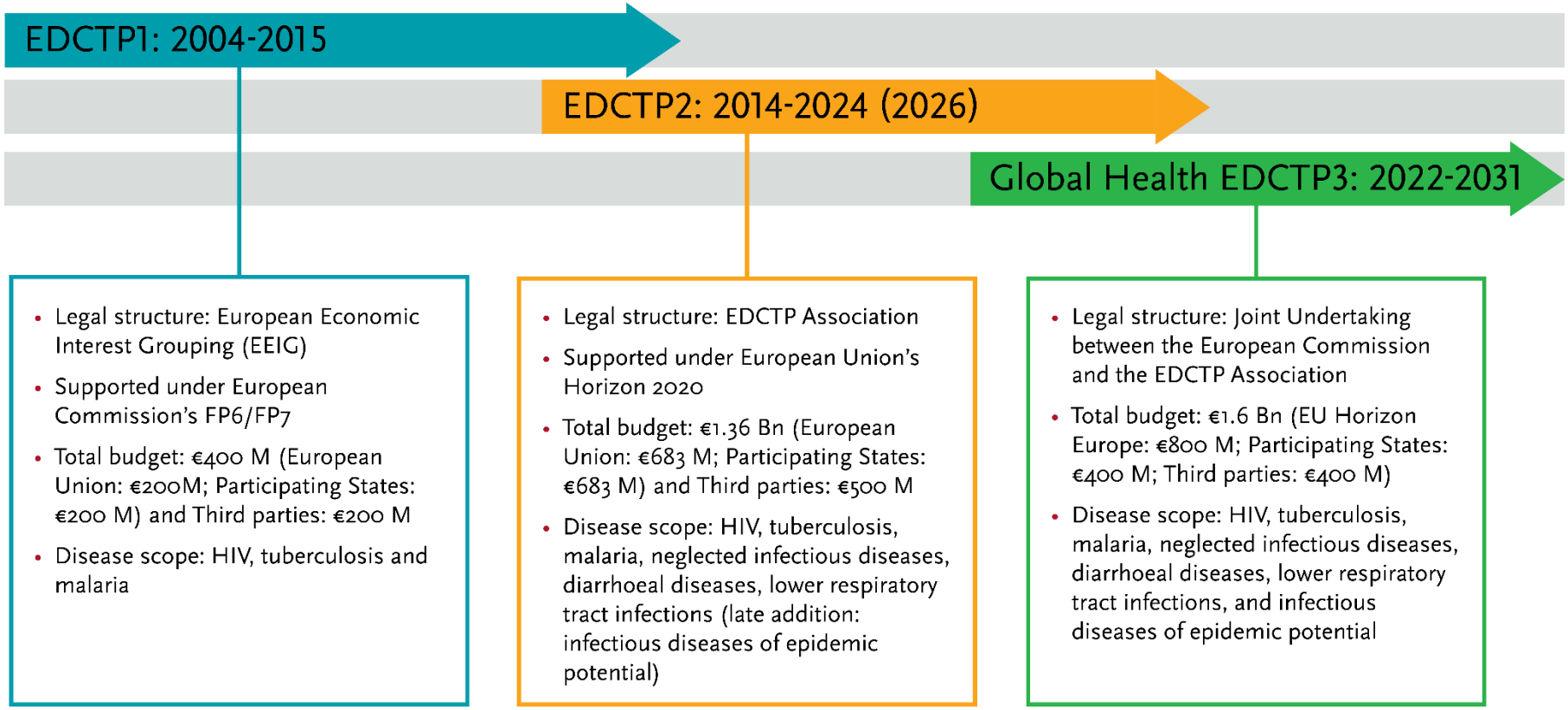
Agenda for today: Technical reporting: 10:00-12:00 CET

1. Welcome
2. Must-knows of the EDCTP2 Grant Agreement
3. Anatomy of the periodic and final (technical) report
4. Scientific publications and open access
5. Dissemination and communication
6. Clinical trials/studies
7. Questions & answers

1

Welcome

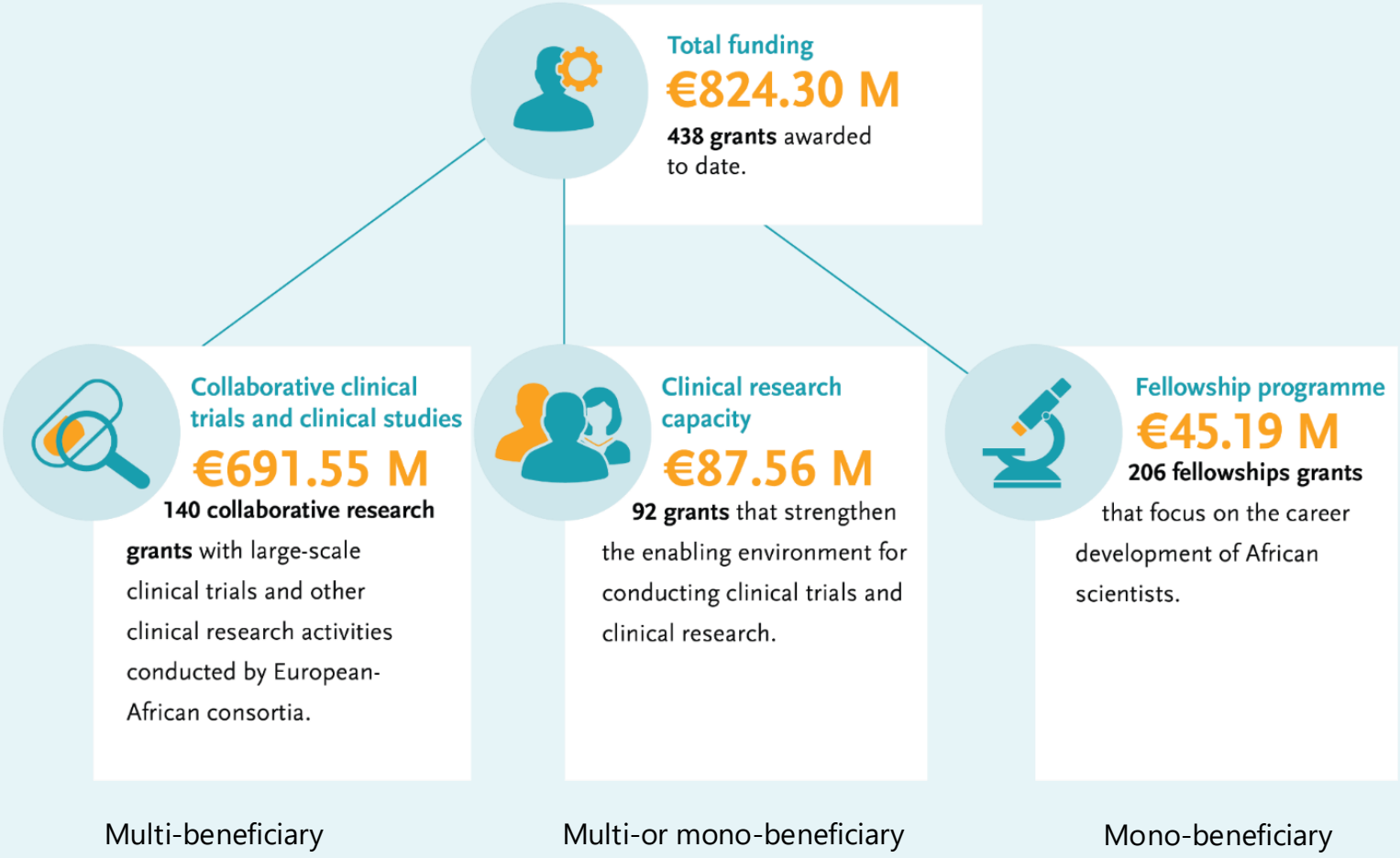
The evolution of EDCTP programmes



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

EDCTP2 grants

2014-2024



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Must-knows of the EDCTP2 Grant Agreement

Grant Agreement

Reporting requirements (Article 20)

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 Obligation to submit reports

The beneficiary must submit to the EDCTP Association (see Article 52) the technical and financial reports set out in this Article. The financial reports must be drawn up using the forms and templates provided in Annexes 4 and 5. These reports include the requests for payment. The technical reports must be drawn up using the forms and templates provided in Annex 7.

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- RP2: from month 13 to month 24
- RP3: from month 25 to month 36

Grant Agreement

Reporting requirements (Article 20)

20.3 Periodic reports — Requests for interim payments

The beneficiary must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiary;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**';

The report must indicate the communication activities.

(i) a **summary** for publication by the EDCTP Association;

(ii) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the key performance indicators and monitoring requirements of the Horizon 2020 and EDCTP2 Programmes;

(b) a financial report

Grant Agreement

Understanding the reporting cycle

- Periodic reports must be submitted **within 60 days** following the end of the reporting period
  - Example: A grant that started on 1 April 2020 with a first reporting period of 12 months needs to report over the first 12 month (1 April 2020 – 31 March 2021) on 30 May 2021.
- Review of reports is done by EDCTP project (technical review) and finance (financial review) officers; reports are approved by EDCTP management.
- EDCTP has 90 days to approve report from the date the complete version is received (no further questions)
- At the end of the project, besides the periodic report a final report is also required to be submitted (see article 20.4)

Grant Agreement

Understanding the reporting cycle

- 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
- An official warning letter will be sent to you and the legal representative of your institution
- If this is not addressed, then the grant may be suspended or stopped by EDCTP
- This could result in you and your institution having to return funds

Grant Agreement

Dissemination of results – open access – visibility of EDCTP2 funding (Article 29)

29.2 Open access to scientific publications

Each beneficiary must ensure **open access** (free of charge, online access for any user) to **all peer-reviewed scientific publications** relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(i) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

Grant Agreement

Dissemination of results – open access – visibility of EDCTP2 funding (Article 29)

29.3 Open access to research data

Regarding the digital **research data** generated in the action ('data'), the beneficiaries must:

(a) 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;

(iii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (see Annex 1);

(b) provide information — via the repository — about tools and instruments at the disposal of the beneficiaries and necessary for validating the results (and — where possible — provide the tools and instruments themselves).

3

Anatomy of the periodic and final report

Project code

EDCTP – PERIODIC REPORT of the ACTION

Grant Title

Grant Acronym

DURATION (MONTHS)		EDCTP BUDGET TOTAL (€)

COORDINATOR

1. Insert legal entity name, country and (name of the Coordinator)

Some general tips to start

- Familiarise yourself with the template so you know what information to collect/ report on
- Follow the guidance given in the report
- Make sure what you report are 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

And yes, the report is a bit repetitive at times but you still need to complete all sections, and be consistent

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

Follow the suggested structure

1. Objectives

Describe the objectives and progress made towards these in high level terms- we can read more details under section 2.

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.*

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

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

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

- Provide in this section explanations for tasks not fully implemented, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks and on the available resources and the overall planning.

  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.

- Explanations on deviations of the use of resources between actual and planned use of resources in Annex 1 (Description of the Action), especially related to person-months per work package.

Summary for publication

- Summaries are published on the EDCTP website (Public Portal: https://www.edctpgrants.org/publicportal#/search), **so 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
  - The address (URL) of the action's public website if applicable.

*Don't: keep writing **we will** do this in the last report.*

Deliverables and milestones (D&M)

- Copy the deliverables and milestones exactly like described in Annex 1 – do not update text/dates
- Report on all D&M due in the reporting period or those delayed from previous years
- Use actual delivery dates for items due (not when you submit the report to EDCTP)
- Project for items not achieved (or partially achieved) when you will deliver these
- Provide for all items not achieved an explanation in the tables below on why this happened.

Deliverables and milestones (D&M)

Deliverables

Please add the deliverables due in this reporting period **exactly as mentioned in Annex 1** of the Grant Agreement in terms of the numbering (e.g. 1.2) and name of the deliverable
Reporting is only required for those deliverables that fall within the reporting period (or were delayed from previous years).

Deliverable no.	**Deliverable name** *Exactly as given in Annex 1*	**Responsible organisation** *From Annex 1- if different from responsible organisation in Annex 1, elaborate below*	**Type of deliverable**	**Dissemination level**	**Delivery date from Annex I (project month)**	**Actual delivery date**	**Forecast delivery date if appropriate** *If deliverable has not been submitted on time*
Numeric	Text	Organisation	R, DEC, DEM, Other	PU, CO, CL	e.g. M30	Date	Insert month & date e.g. M40, June 2024
1.1							
1.2							

Provide details for deliverables not reached or where changes were made compared to Annex 1 including justification in the comments' box

Deliverable number	**Comments**
Number e.g. 3.1	Give details to explain

Deliverables & Milestones continued

- Be diligent and check your Annex 1 and previous reports so that no items are missed
- Make sure all items achieved are provided as evidence with the report (uploaded as annex), clearly labelled
- Prepare the deliverable cover page (using the template) for each deliverable and name the files with the deliverable or milestone number associated; e.g., D2.1_study_protocol
- In cases where an item features for multiple deliverables/milestones this should be indicated on the cover sheet and in the naming of the file; e.g., D2.1_M1.1_study_protocol

Deliverables not (yet) achieved at the end of project

- provide an explanation why the deliverable/milestone is delayed
- project date of completion
- where possible submit draft document. You are expected to submit final versions once completed.
- submit commitment letter signed by legal representative and project lead detailing missing deliverables/milestones and their projected date of completion and confirming that these deliverables will be provided to EDCTP after the end date.

Capacity building

- Short term trainings and workshops table
  - Give details of any short course and workshops conducted under the project

- Long term training table
  - Include details of trainees supported by the project, these are most commonly MSc/PhD students
  - Be mindful of timelines for completion of training (if this is after grant end date we expect institution to guarantee completion)
  - Also include details of trainees using data from the project (but supported elsewhere) – these can be captured as working 0% on the action
- Briefly summarise training activities in the 'Capacity building summary of progress' box, focusing both on short- and long-term trainings

Open research data

- The grant agreement requests that research data is 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:

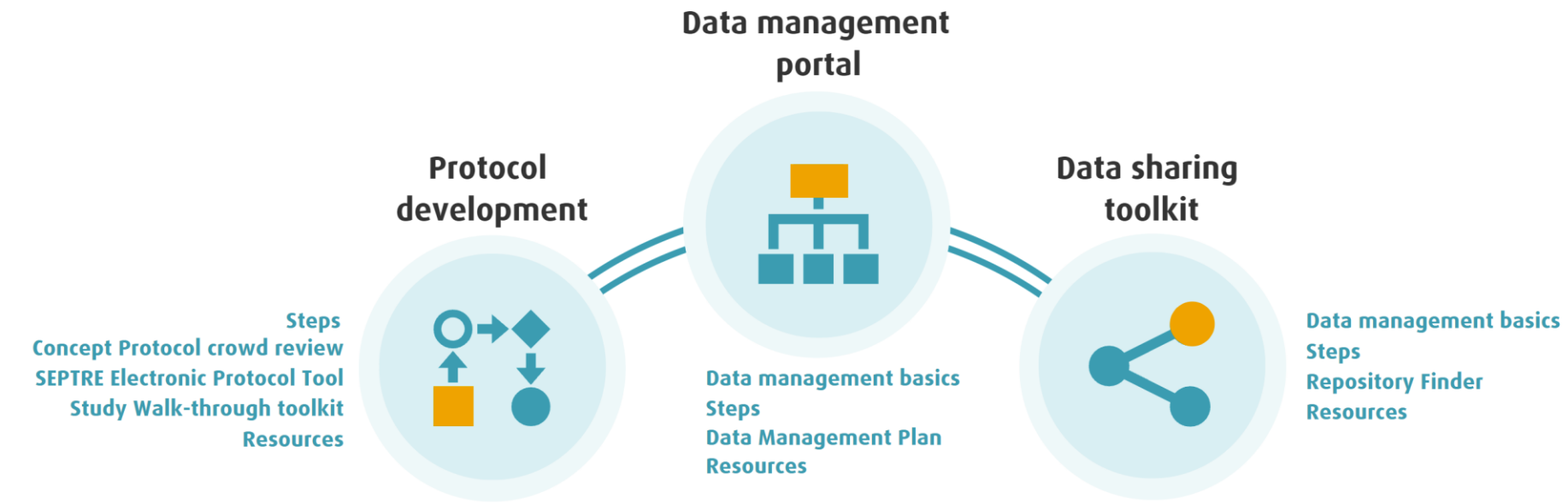
    (i) the data, including associated metadata, needed to validate the results presented in scientific publications as soon as possible

    (ii) other data, including associated metadata, as specified and within the deadlines laid down in the 'data management plan' (part of Annex 1)
- If you opted into this, provide information on where datasets have been deposited (making sure no personal data are being shared)

The EDCTP Knowledge Hub

Launched in November 2020

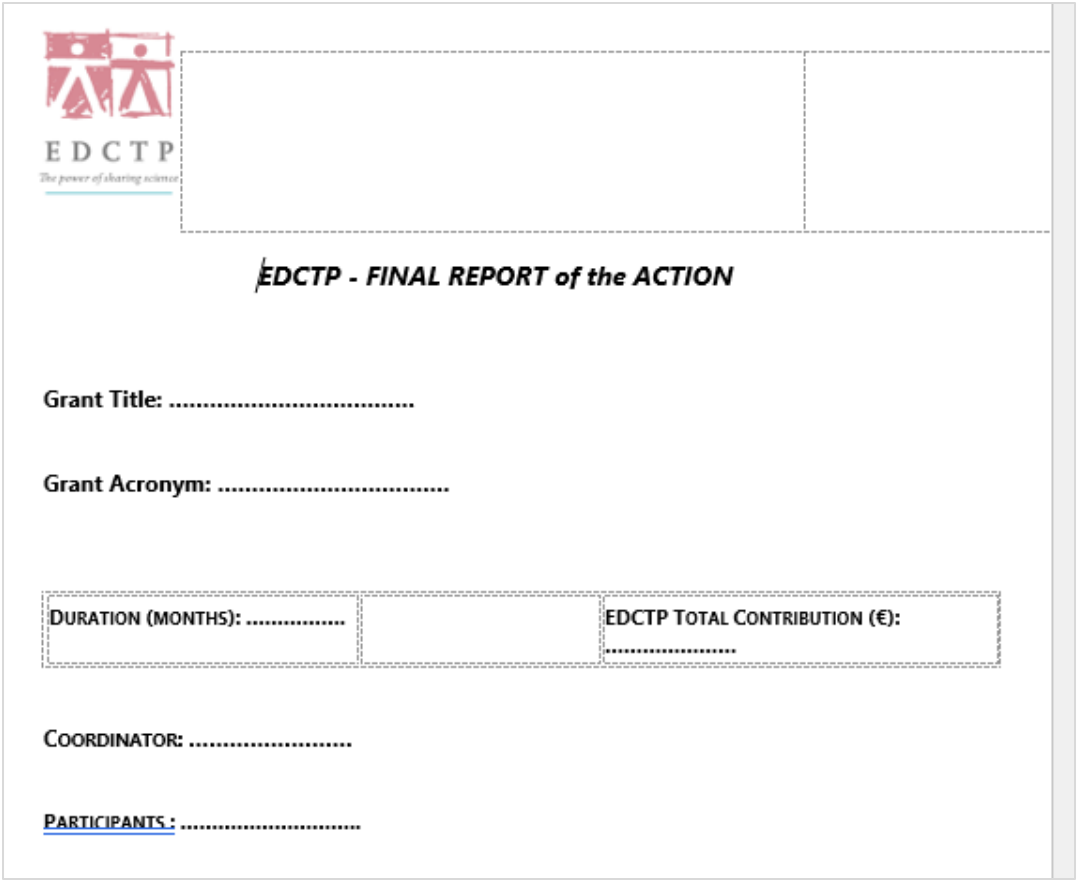
Together with **The Global Health Network (TGHN)**, and with financial support from the EU and the Swedish government, we have created the EDCTP Knowledge Hub and developed three online tools to facilitate high-quality health research:



https://edctpknowledgehub.tghn.org

Final report

- At the end of the project, besides a periodic report you must also submit the final report
  - This is a separate template to be completed



EDCTP

EDCTP - FINAL REPORT of the ACTION

Grant Title: .....

Grant Acronym: .....

DURATION (MONTHS):		**EDCTP TOTAL CONTRIBUTION (€):** .....

COORDINATOR: .....

PARTICIPANTS : .....

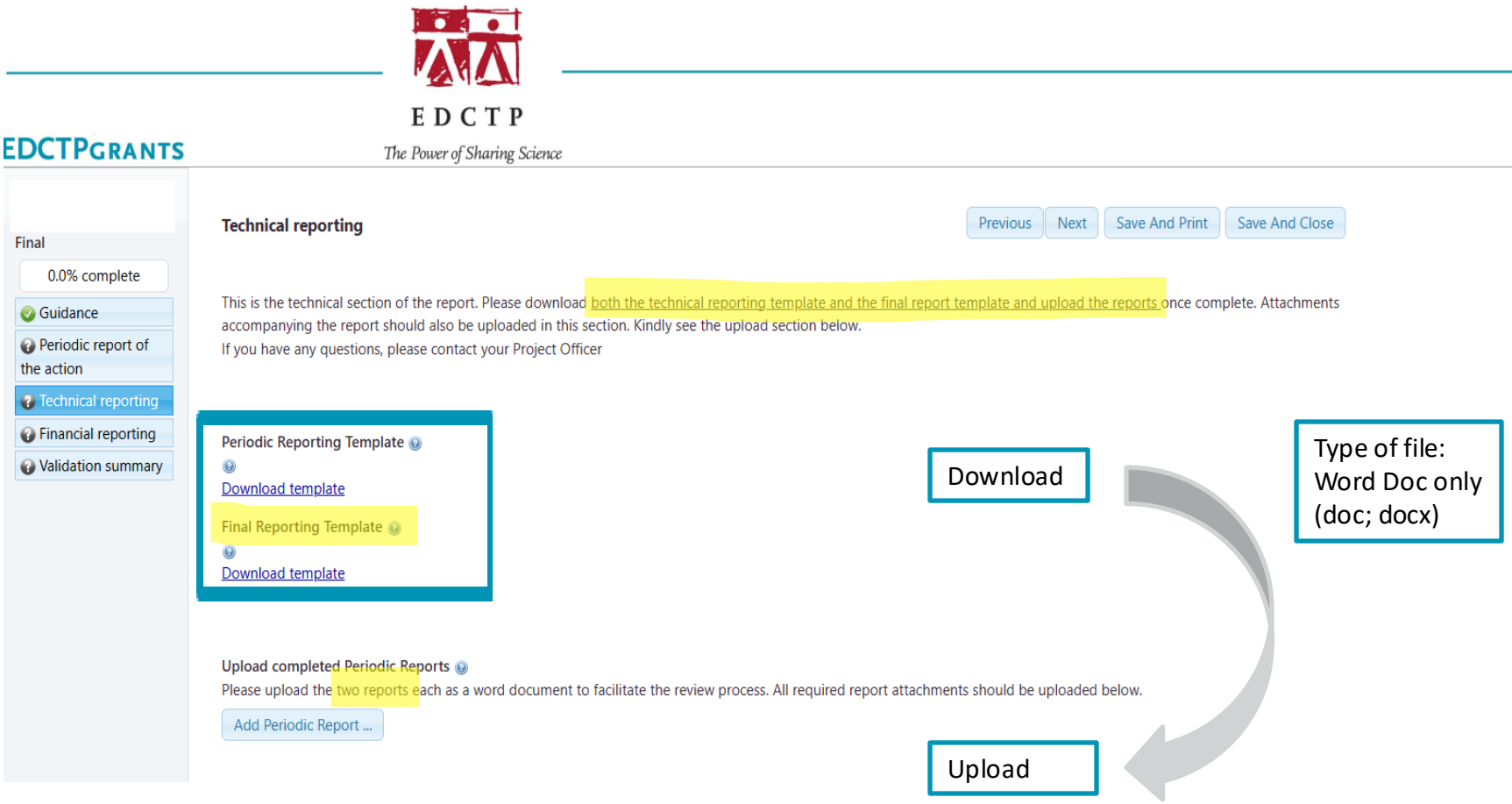
Final report

This template consists of one textbox that must cover the following elements:

- A lay summary of the action and the overall objectives
- A description of the work performed during the action
- An overview of the results (outputs, achievements) and their exploitation and dissemination
- The conclusion of the action
- 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), including the address (URL) of the action's public website.

Reporting in the EDCTPgrants system

Periodic and Final Report – Technical reporting



Declare co-funding

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

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***

EDCTP review to finalisation

- Once submitted – PO/GFO review documents submitted:
  - If incomplete/major issues seen, report is rejected and grantee is requested to submit a new version
  - Otherwise – review starts with questions to follow
- Review of documents/ next versions to be submitted happens over email (unless edits require many uploads and then EDCTPgrants may be used)
- Grantees must use track changes when making edits so PO can quickly review updates
- Check that you have addressed all comments made/ provided all items requested so that we do not need to go through many rounds of revisions

EDCTP review to finalisation (continued)

- Turn around report reviews in reasonable time/ by deadline set by PO/GFO
- Once final versions are agreed upon, grantee is requested to upload final files in EDCTPgrants and press submit
- Make sure any additional appendices shared over email are uploaded online so the online record reflects the final complete set of documents shared
- Once the report is approved by EDCTP, the grantee receives a notification of approval via email, and payment (if applicable) occurs.

Common issues seen (1)

- Report submitted with incomplete sections- you must **complete all sections in the report**
- Deliverables/milestones forgotten - check against Annex 1 and your previous report
- Incorrect use of delivery dates for D&M- this is not the date the report was submitted to EDCTP
- Incorrect labelling of deliverables/milestones – impossible to find items
- Incorrect use of coversheets (not combining coversheet with item)
- Not providing a list of appendices

Common issues seen (2)

- Sloppy reports- formatting all over the place
- Taking a long time to respond to queries/ submission of next draft
- Not uploading final files in EDCTPgrants – results in delay of approval/payment

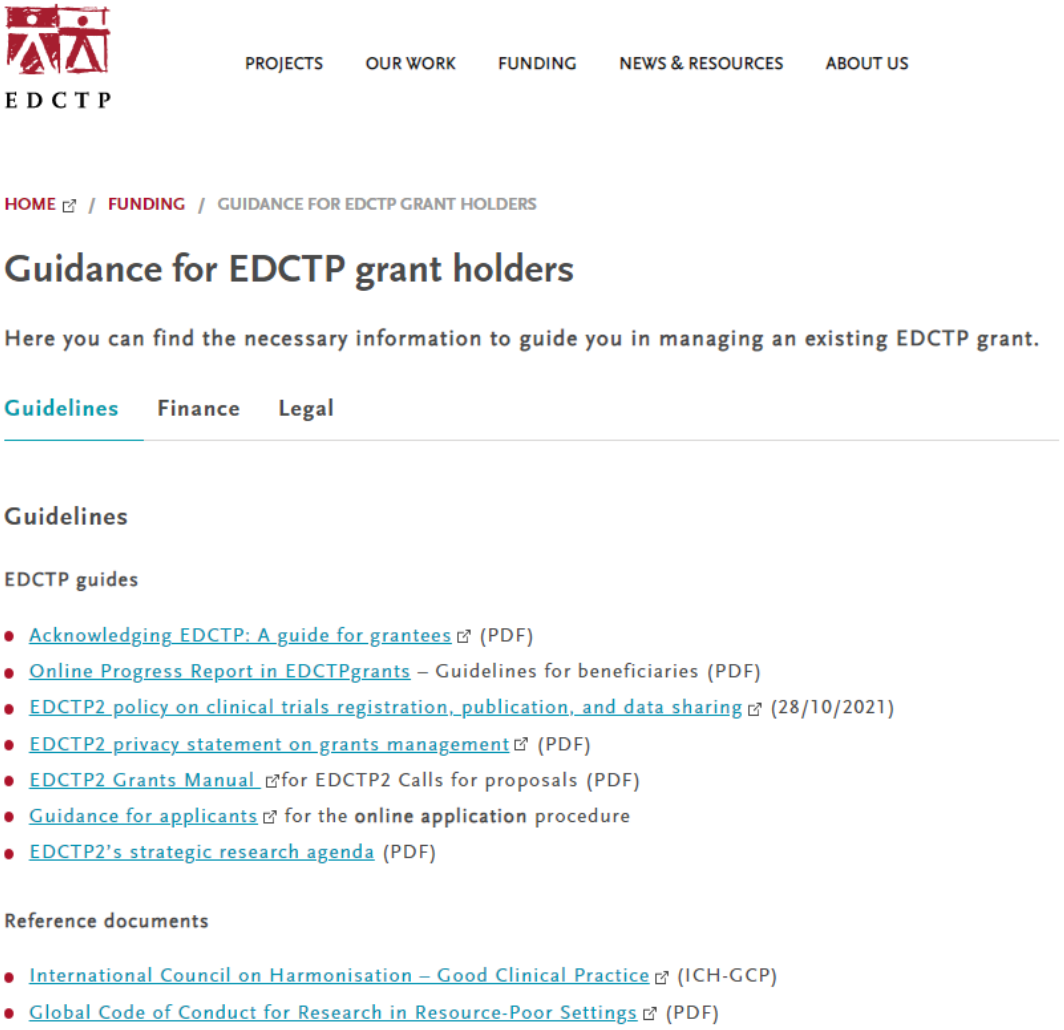
Some final tips

- Read the guidance and follow this
- If you are unsure about something – ask your PO/GFO
- Submit the report on time, and if delays occur that you cannot control- inform your PO of this
- Turn around revisions in time and inform your PO/GFO if delays occur
- Make sure you keep PO/GFP informed throughout the year, do not wait for the report to inform us about major deviations/delays (which may need an amendment) or excellent achievements/success.

Keep in touch!

- Keep in contact with PO and GFO
- Keep us informed about key events in the project
- Let us know about newsworthy items in advance (press releases, publications, awards/prizes to people)
- Let us know about important delays
- Let us know immediately if something goes seriously wrong

Resources



EDCTP

PROJECTS OUR WORK FUNDING NEWS & RESOURCES ABOUT US

HOME / FUNDING / GUIDANCE FOR EDCTP GRANT HOLDERS

Guidance for EDCTP grant holders

Here you can find the necessary information to guide you in managing an existing EDCTP grant.

Guidelines Finance Legal

Guidelines

EDCTP guides

- Acknowledging EDCTP: A guide for grantees (PDF)
- Online Progress Report in EDCTPgrants – Guidelines for beneficiaries (PDF)
- EDCTP2 policy on clinical trials registration, publication, and data sharing (28/10/2021)
- EDCTP2 privacy statement on grants management (PDF)
- EDCTP2 Grants Manual for EDCTP2 Calls for proposals (PDF)
- Guidance for applicants for the **online application** procedure
- EDCTP2's strategic research agenda (PDF)

Reference documents

- International Council on Harmonisation – Good Clinical Practice (ICH-GCP)
- Global Code of Conduct for Research in Resource-Poor Settings (PDF)

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

4

Scientific publications and open access

Scientific publications

Funding Statement

The **Acknowledgment statement** should be mentioned in any online or printed scientific articles (**Article 29.4** of the grant agreement):

- Funding agency (EDCTP)
- Grant number and project acronym in brackets
- Multiple grant numbers separated by comma and space
- Other funding agencies separated by semicolon
- Recommended wording:

> *This [project/study/workshop] is part of the EDCTP2 programme (grant number XXXXXXXXX-ACRONYM) supported by the European Union.*

Ex: *This project is part of the EDCTP2 programme (grant number RIA2018DS-2306 - PAMAfrica) supported by the European Union*

Ex: *This project is part of the EDCTP2 programme (grant number TRIA-2015-1076 - IMPROVE) supported by the European Union, and the UK Joint Global Health Trials (JGHT) scheme to the Liverpool School of Tropical Medicine.*

Scientific publications

Funding Statement

- EDCTP's contribution in the form of salary support, data, subcontracted activities, etc. must be acknowledged in scientific publications.

- If the funder acknowledgement is missing – you must contact the journal editor to include the acknowledgement. If not corrected, publication(s) costs will not be eligible.

- Inform your PO in advance about publications and seek advice concerning the funder's acknowledgement statement (*including press releases*).

- Other Member States funds (via EDCTP) may need to be acknowledged too (e.g. the Swedish International Development Cooperation Agency (Sida), the UK Department of Health and Social Care (UK-DHSC), etc.).

Scientific publications

Open Access requirements

- Research publications must be made **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.

- For periodic/final reports: complete the table for each scientific publication, providing details as requested (and where applicable).
  - Indicate whether access is **gold** or **green**

- Only report on publications directly related to the action.

Europe PMC

- EDCTP is a member of Europe PMC (PubMed Central).

"EDCTP is a member of Europe PubMed Central and expects that electronic copies of any research papers that have been accepted for publication in a peer-reviewed journal, and are supported in whole or in part by funding from EDCTP, to be made available through PubMed Central (PMC) and Europe PMC, as soon as possible and in any event within six months of the journal publisher's official date of final publication."

The article should be available via Europe PMC within 6 months of publication in a journal.

How can Europe PMC help you to comply with the EDCTP open access policy?

- you can submit your article to a journal that will send it to PubMed Central

or

- you can use Europe PMC submission system to self-archive – Europe PMC Plus

Useful resource:

Webinar: Making EDCTP-funded research open with Europe PMC plus

Europe PMC

Sign in | Create an account

Europe PMC plus

Europe PMC | About | Tools | Developers | Help

Search life-sciences literature (45,050,292 articles, preprints and more)

Search

Advanced search

Innovative features

Intuitive and powerful search tools, linked resources and author services help you stay on top of the cutting edge of science. To learn more, see Why use Europe PMC.

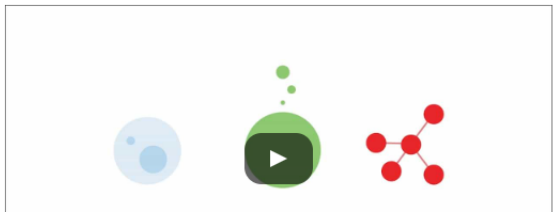
Comprehensive search

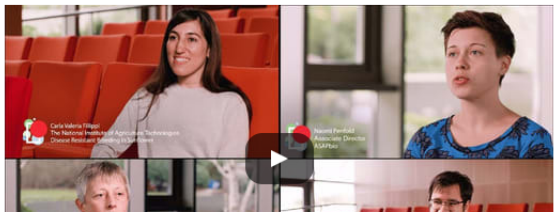
Search life sciences literature from trusted sources around the globe, all in one search, accessible by anyone anywhere, for free. Learn more About Europe PMC.

Trusted partnerships

Europe PMC is the partner of PubMed Central (PMC), an ELIXIR core data resource, and the repository of choice for many international science Funders.

Learn more about Europe PMC





Feedback

Open Research Europe

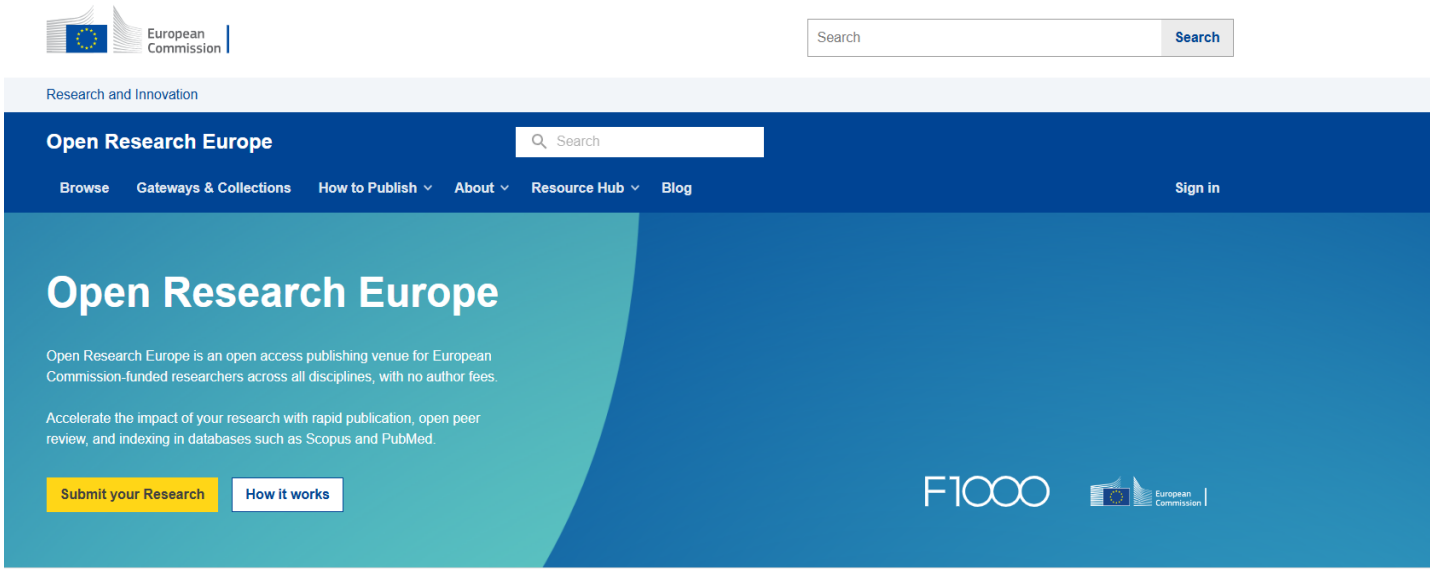
The European Commission's Open Access publishing platform

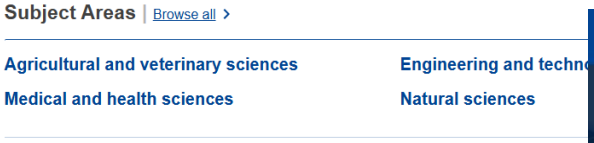
- Open Research Europe is an open access publishing platform that facilitates beneficiaries and researchers from Horizon 2020, Horizon Europe and Euratom funding to comply with open access policies by providing an easy, high-quality peer-reviewed venue to publish, at no cost.

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

- Workshop: EDCTP on Open Research Europe

Open Research Europe





5

Dissemination and Communication

Acknowledging EDCTP

Why acknowledging EDCTP and EU funding is important

- Contractual obligation (EDCTP2 grant agreement) to recognise funding by EDCTP and the EU in all dissemination activities and publications from the grant.
- Enables EDCTP to monitor and evaluate the research it funds.
- Helps promoting the EDCTP programme.

Where should you acknowledge EDCTP2 and EU funding?

All communications activities related to EDCTP2-funded projects, such as:

- Website
- Scientific publications
- Slide/poster presentations
- Press releases
- Newsletter
- Promotional materials
- Videos

Where should you acknowledge EDCTP2 and EU funding?

Purchase of assets/infrastructure upgrade

- All assets purchased under EDCTP grant
  - To place stickers provided by the EDCTP Secretariat
- Infrastructure developments funded through EDCTP grants must acknowled EDCTP
  - Install permanent plaque in a prominent and public visible location.

How to acknowledge EDCTP and EU funding?

Logos and acknowledgement text

- Display the EDCTP logo, AND
- Display the EU emblem, AND
- Include the following text: "This project is part of the EDCTP2 Programme supported by the European Union"

How to acknowledge EDCTP and EU funding?

Usage of the logos

- When displayed together with another logo, the EDCTP logo and the EU emblem must have appropriate prominence.
- The EDCTP logo, the EU emblem and acknowledgement text must not be used for advertising or endorsement purposes.
- Materials should not feature the EDCTP logo and EU emblem in such a way that suggests EDCTP authorship or endorsement.

The EDCTP logo and EU emblem should only be used to acknowledge their role as funder.

How to acknowledge EDCTP and EU funding?

Scientific publications or promotional materials

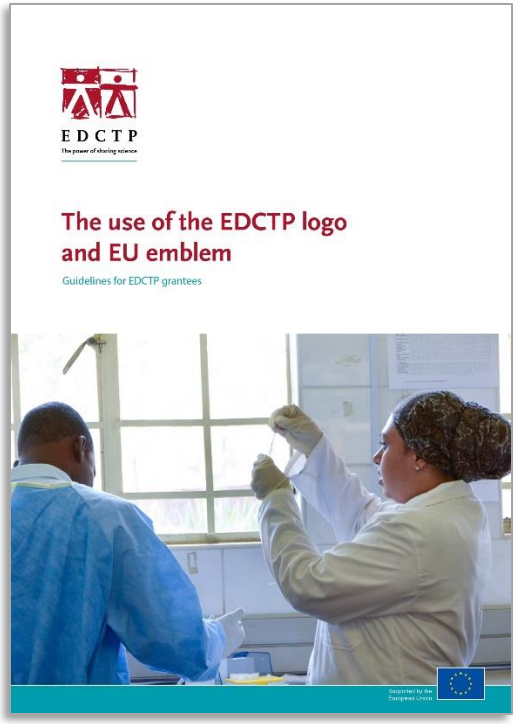
Statement to acknowledge EDCTP funding in online or printed articles:

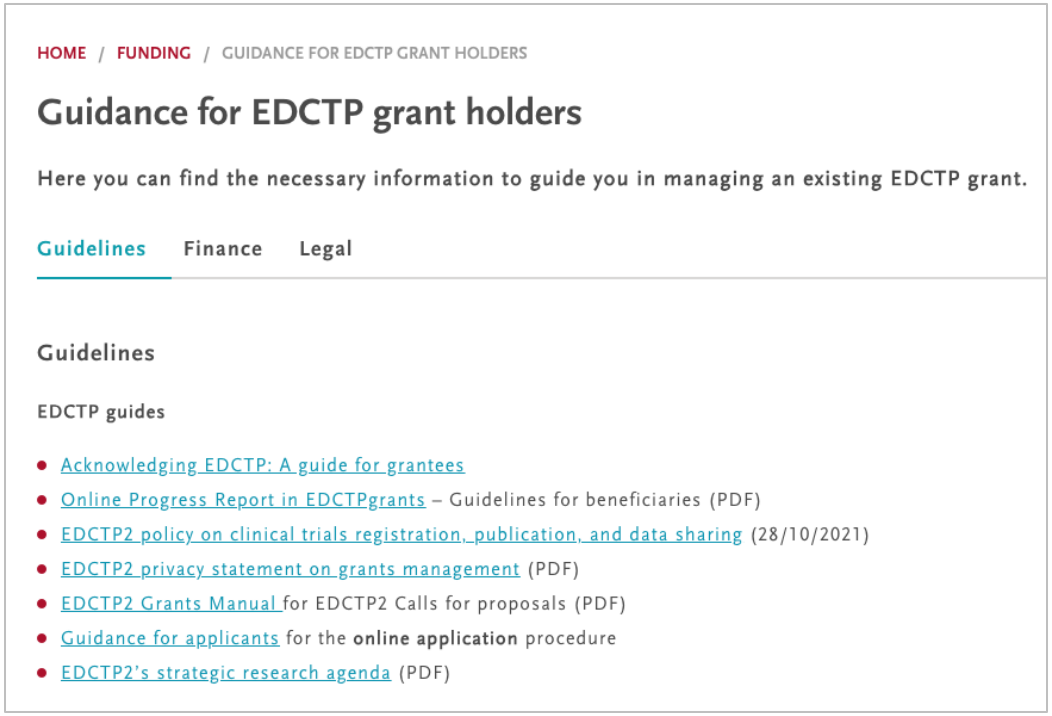
- This [project/study/workshop] is part of the EDCTP2 programme (grant number XXXXXXXXX-ACRONYM) supported by the European Union.

Disclaimer to acknowledge EDCTP funding in other promotional materials:

- This [publication/article/newsletter] was produced by [Project ACRONYM] which is part of the EDCTP2 programme (grant number XXXXXXXXX-ACRONYM) supported by the European Union. The views and opinions of authors expressed herein do not necessarily state or reflect those of EDCTP.

Guidance for EDCTP grant holders





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

Logos available in Media Kit:
https://www.edctp.org/stay-up-to-date/media-kit/

EDCTP communications

Communications tools

- Newsletter
  - Monthly: EDCTP Update (email)
  - Biannual: eMagazine (digital)
- Website
- Reports
- Brochures and fact sheets
- Videos and photo library
  - YouTube channel (/edctpmedia) and Vimeo (vimeo.com/edctp)
- Posters/banners
- Social media
  - X (@edctp)
  - LinkedIn

Sharing news about your grant

Press releases

- Acknowledgement text must be included
- Additional cofunding may need to be mentioned

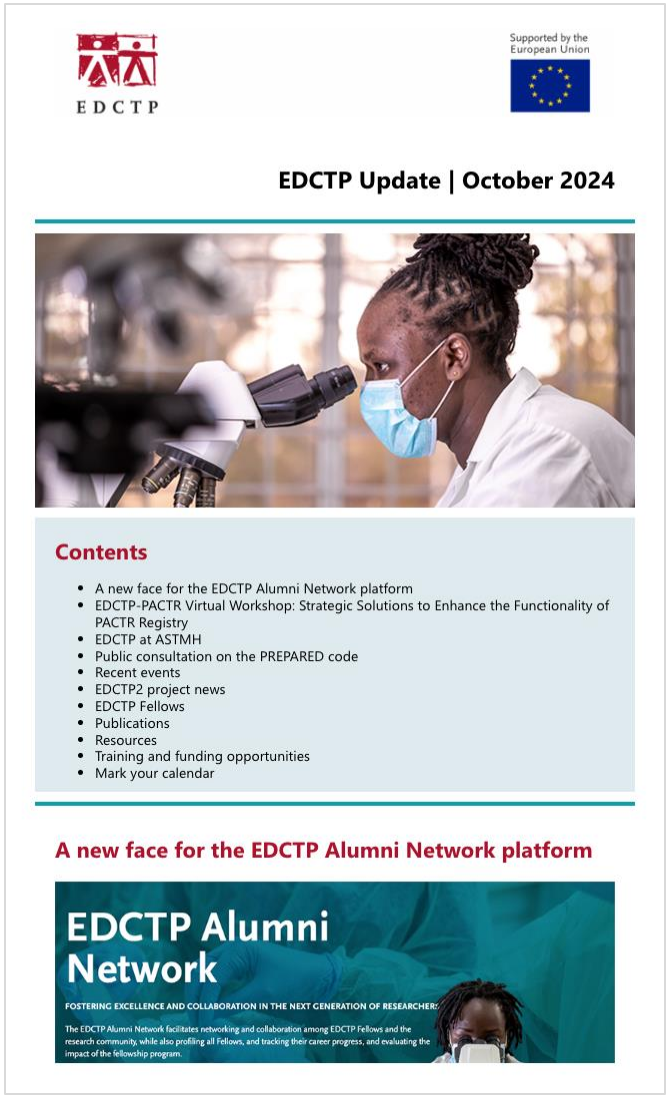
Please always check with PO/EDCTP Comms Officer before publication.

Social media posts

- X (former Twitter): @edctp
- LinkedIn: @European & Developing Countries Clinical Trials Partnership

Grants funded by EDCTP2 and Global Health EDCTP3 must acknowledge/tag both programmes.

EDCTP Update



EDCTP

Supported by the European Union

EDCTP Update | October 2024

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- A new face for the EDCTP Alumni Network platform
- EDCTP-PACTR Virtual Workshop: Strategic Solutions to Enhance the Functionality of PACTR Registry
- EDCTP at ASTMH
- Public consultation on the PREPARED code
- Recent events
- EDCTP2 project news
- EDCTP Fellows
- Publications
- Resources
- Training and funding opportunities
- Mark your calendar

A new face for the EDCTP Alumni Network platform

EDCTP Alumni Network

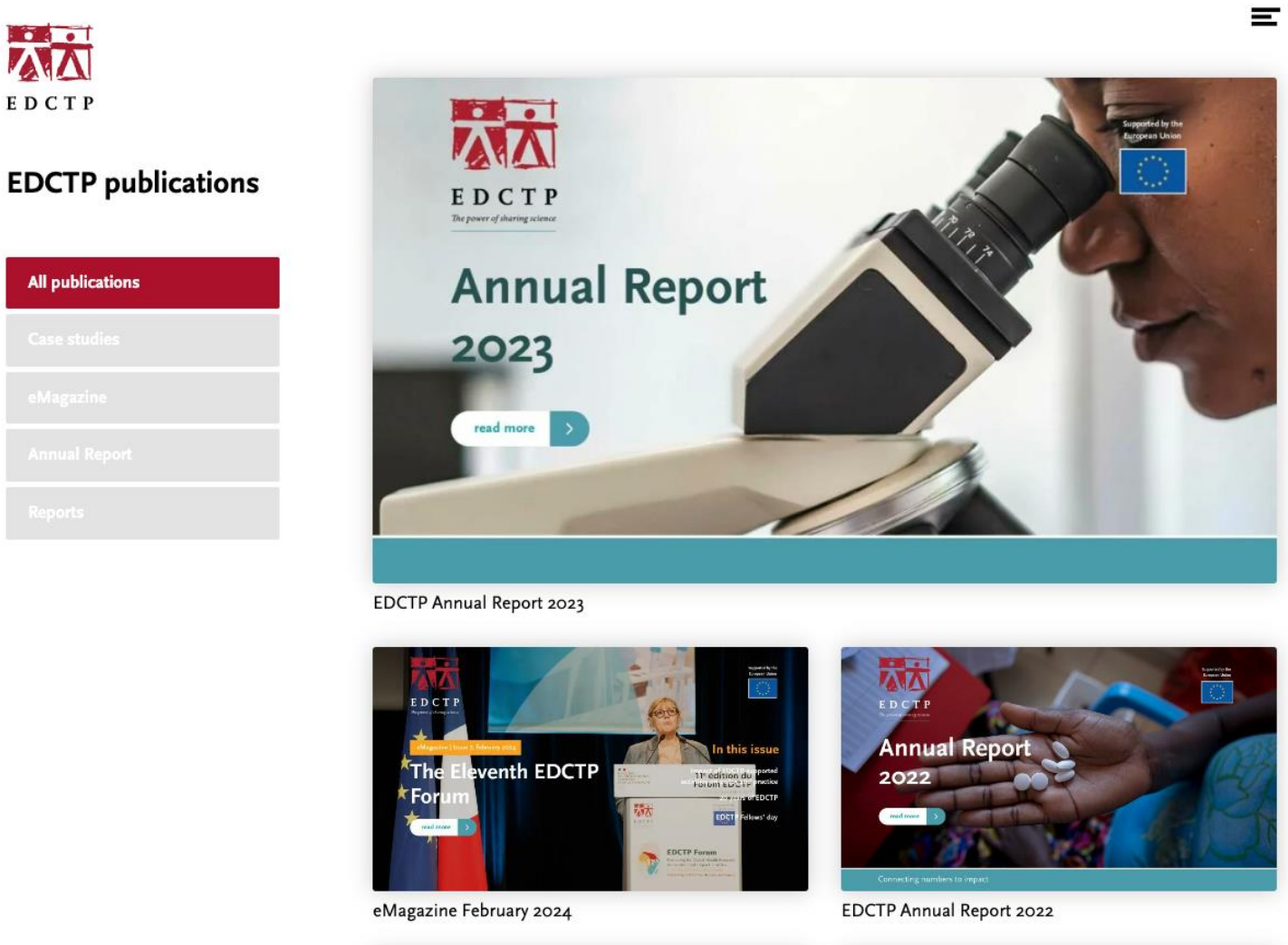
FOSTERING EXCELLENCE AND COLLABORATION IN THE NEXT GENERATION OF RESEARCHERS

The EDCTP Alumni Network facilitates networking and collaboration among EDCTP Fellows and the research community, while also profiling all Fellows, and tracking their career progress, and evaluating the impact of the fellowship program.

- Monthly newsletter – circulated by the end of the month
- Section dedicated to promote news from EDCTP2 projects
  - Milestones and results from projects
  - Meetings and workshops
- Recent publications from EDCTP2-funded activities
- News from (current and former) EDCTP Fellows

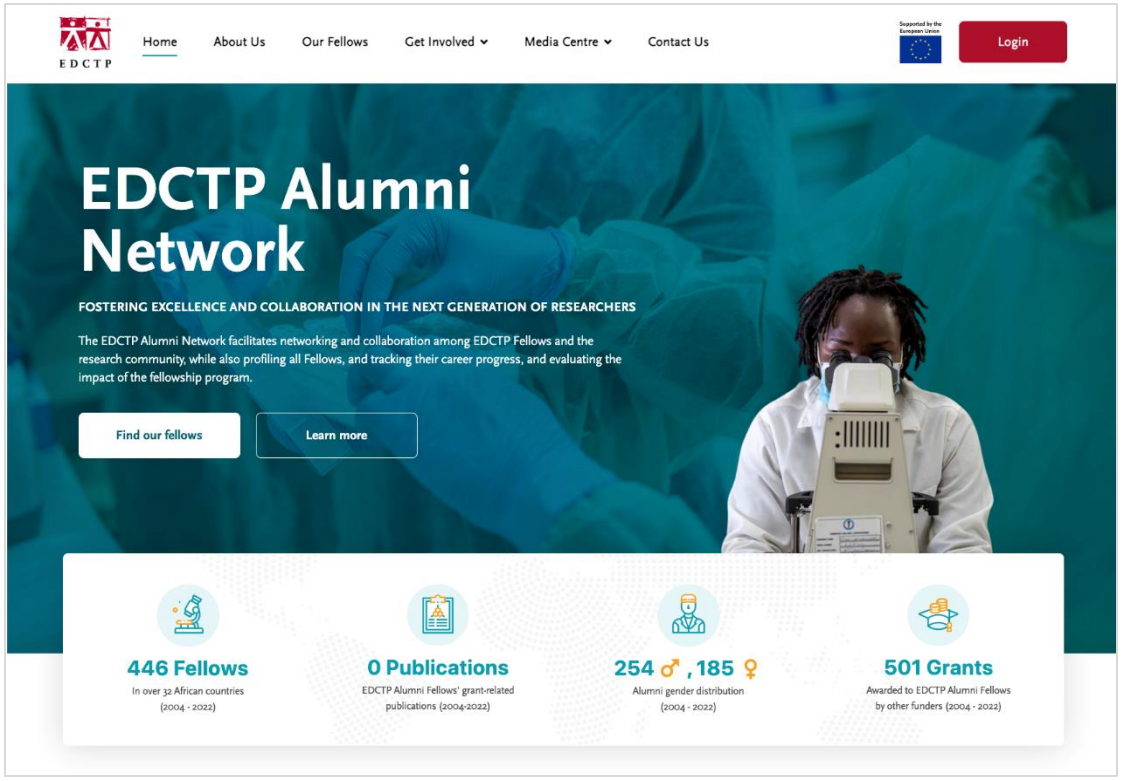
Send your news to your PO and/or pereira@edctp.org

EDCTP2 publications portal



https://publications.edctp.org/

EDCTP Alumni Network



- Revamped platform
- Interactive map to search for Fellows by location, type of fellowship or research area/topic
- An important tool to promote the work of current and former EDCTP fellows
- It helps EDCTP to track the progress and achievements of its Fellows.

https://edctpalumninetwork.org

6

Clinical trials/studies

Clinical studies

- **A clinical study** is a broader concept, which encompasses several categories: **interventional studies** (clinical trials/interventions, public health interventions), and **observational studies** (e.g., case control studies, cohort studies, diagnostic studies) involving human subjects.

- Data is collected from individual patients or healthy individuals, either prospectively or retrospectively.

- These studies aim to address scientific questions related to the understanding, prevention, diagnosis, monitoring, or treatment of diseases, mental illnesses, or physical conditions.

Periodic reporting of clinical studies to EDCTP

- **Q: Does the action involve any clinical studies?**
  - Complete the template in the periodic report if you are conducting a clinical study
  - Do not answer 'NO' when you are doing a clinical study (if in doubt ask your Project Officer)

- Complete all sections in the clinical study section, stating not applicable in case something does not apply to your clinical study
  - Clinical sponsor (institution/department/company responsible for overseeing and managing a clinical study)
  - Protocol
  - Monitoring reports
  - Status
  - Insurance policy
  - Trial Steering Committee (TSC)
  - Data Safety and Monitoring Board (DSMB)

Periodic reporting of clinical studies to EDCTP

- The recruitment table should be completed for the figures available around time of submission of the report
- Provide information on any deviations from timelines or **changes to sample size**
  - **Unjustified reduction to the sample size may later raise concerns about the appropriate use of financial resources**

Clinical study (recruitment) sites

1	2	3	4	5	6	7	8	9	10	11	12
Site Principal Investigator(s)	**Clinical study (recruitment site)**	**Country**	**Estimated site start date of recruitment**	**Actual site start date of recruitment**	**Estimated/target recruitment at time of submission of report**	**Number screened**	**Actual recruitment**	**Number of withdrawals**	**Number lost to follow up**	**Out of study for other reasons**	**Number enrolled excluding drop-outs (column 9-11)**
Name	Name of recruitment site		Month, year	Month, year	Number	Number	Number	Number	Number	Number	Total enrolled
Add each site											

Clinical study: details and progress

Clinical Study section in periodic reports

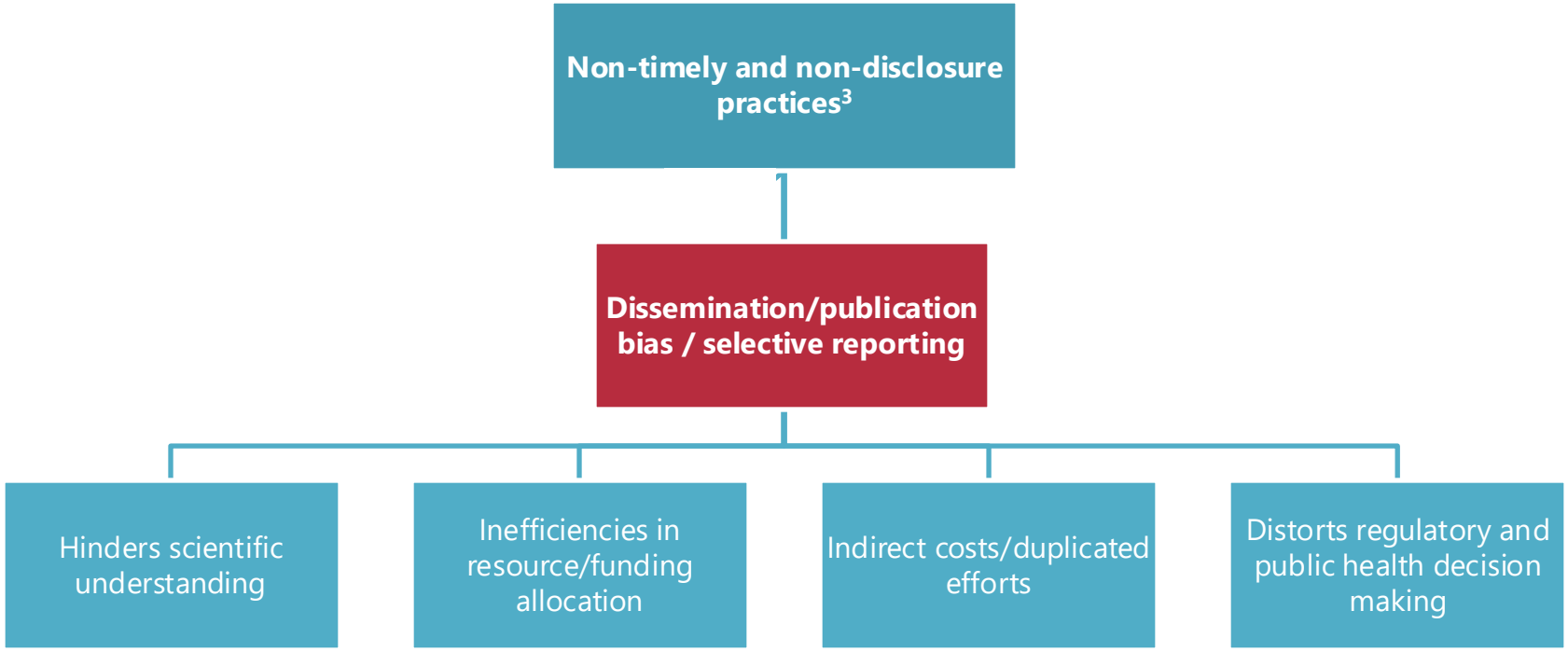
CLINICAL STUDY SECTION

Title and acronym of the clinical study	Insert text
Type of clinical study	**Interventional or Observational** Interventional: studies in human beings in which individuals are prospectively assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed. Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.
Clinical study registration EDCTP requires that all clinical trials are registered in a public trials registry at or before the time of first patient enrolment. The registry must be a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or data provider to the WHO ICTRP (e.g. ClinicalTrials.gov). Please give details of where the trial is registered and provide the URL. The trial entry must be up to date at the time of submission of this report. Other (observational) clinical studies should also be registered, where this can be done. Note that all diagnostics studies must be registered.	URL [text field 100 characters]

- **It is mandatory registration of clinical interventional studies**
- EDCTP recommends registration of observational studies too!

WHO mandates prompt reporting and public disclosure of interventional clinical trial results[1]

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



1. 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#:~:text=The%20main%20findings%20of%20clinical,publicly%20at%20most%20within%2024
2. 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 is a signatory to WHO Joint statement on public disclosure of results from clinical trials[1]

- EDCTP is committed to ensuring that grant holders[2]:
  - Register trials prospectively in a registry that meets WHO Registry criteria
  - 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**

1. 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
2. EDCTP2 policy on clinical trials registration, publication and data sharing. 2021: https://www.edctp.org/about-us/policies/

EDCTP expectations for a final report

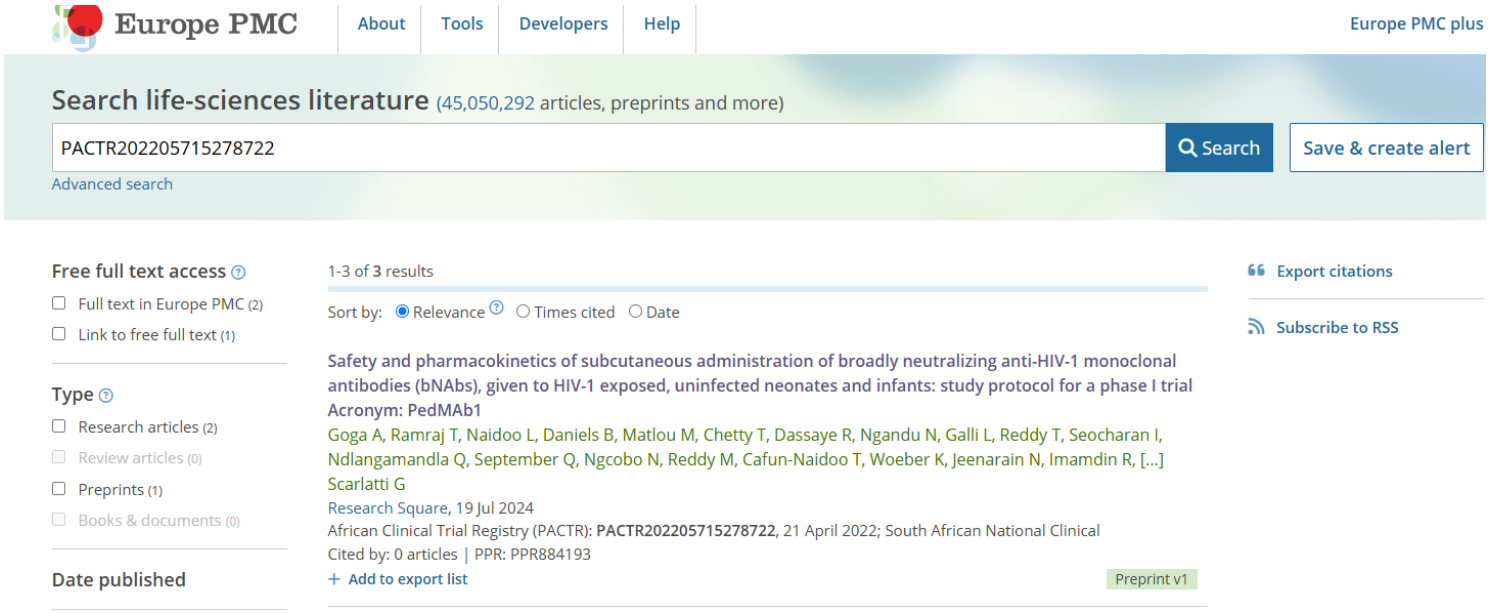
Report on status of posting results is a key deliverable

- 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 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 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 and be searchable on Europe PMC



PACTR – upcoming workshop

Cochrane South Africa

EDCTP-PACTR: Strategic Solutions to Enhance the Functionality of PACTR Registry

VIRTUAL WORKSHOP

20 November 2024 | 10h00-12:00 SAST | Microsoft Teams

We are excited to invite you to a virtual workshop hosted by the Pan African Clinical Trials Registry (PACTR) in collaboration with the European & Developing Countries Clinical Trials Partnership (EDCTP) Africa office. This event will focus on developing actionable strategies to optimise the usability and impact of the PACTR registry (https://pactr.samrc.ac.za/).

Insights gathered from the pre-webinar survey will inform our discussions and help shape the key topics of the session. We will also address frequently asked questions about updating and posting clinical trial results on the registry. Don't miss this opportunity to contribute to enhancing PACTR's functionality and improving the transparency of clinical trial research!

Objectives of the workshop are to:

√ Provide an overview of the registry functionalities and benefits of registration.
√ Provide a platform to discuss the primary obstacles faced in using the PACTR.
√ Enable participants to share their experiences, insights, and best practices in managing and utilising PACTR.
√ Foster more robust collaboration between EDCTP, PACTR, and researchers.

PLEASE REGISTER FOR THE EVENT (LINK)

saMRC advancinglife | Cochrane South Africa | EDCTP

PACTR Pan African Clinical Trials Registry

ICTRP

Clinical trial registries used by EDCTP grant holders

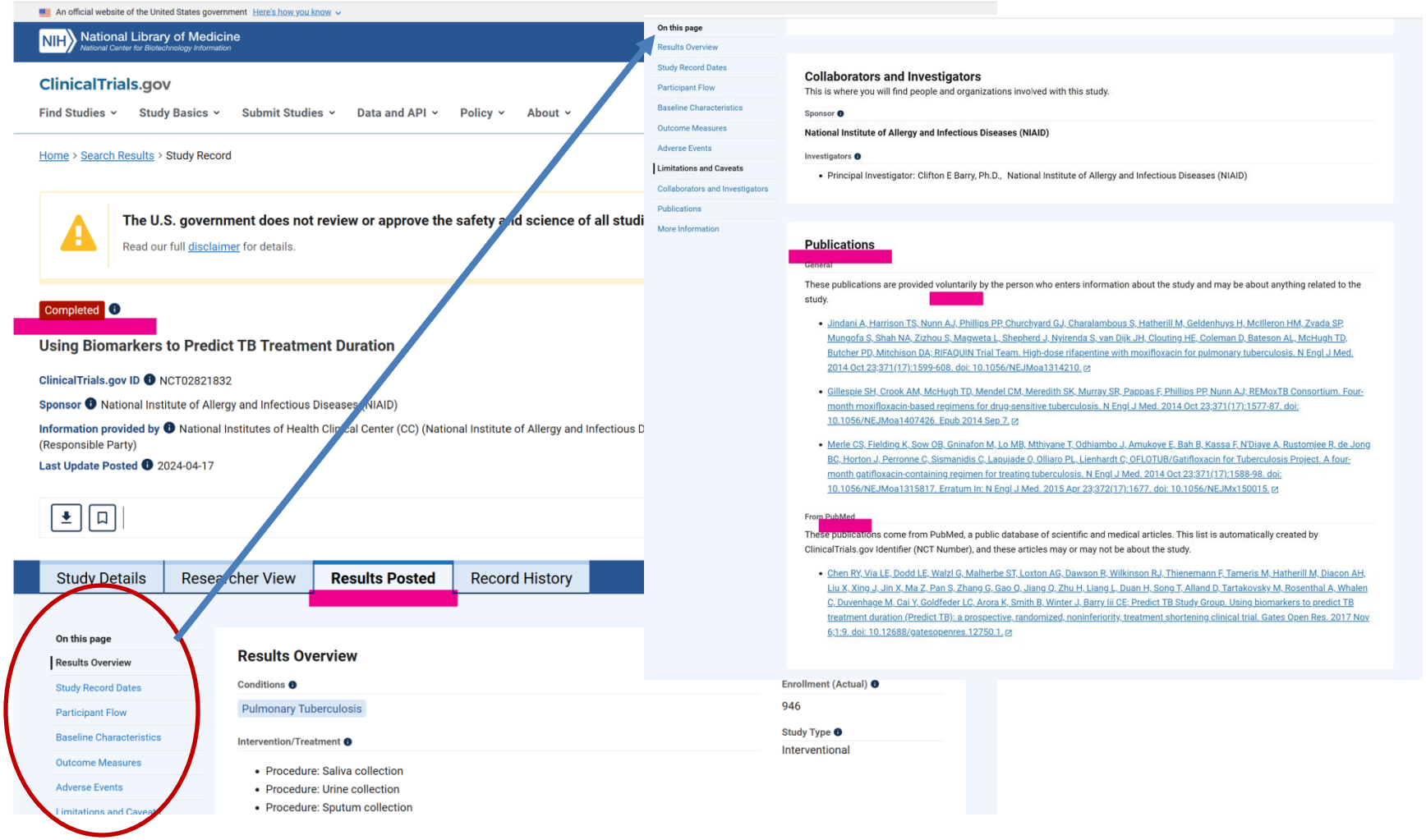
ClinicalTrials.gov / PACTR / ISRCTN

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

Clinical trials: examples of clinical study records in registries

Example 1: *Predict-TB – results are posted* https://clinicaltrials.gov/study/NCT02821832



Clinical trials: examples of clinical study records in registries

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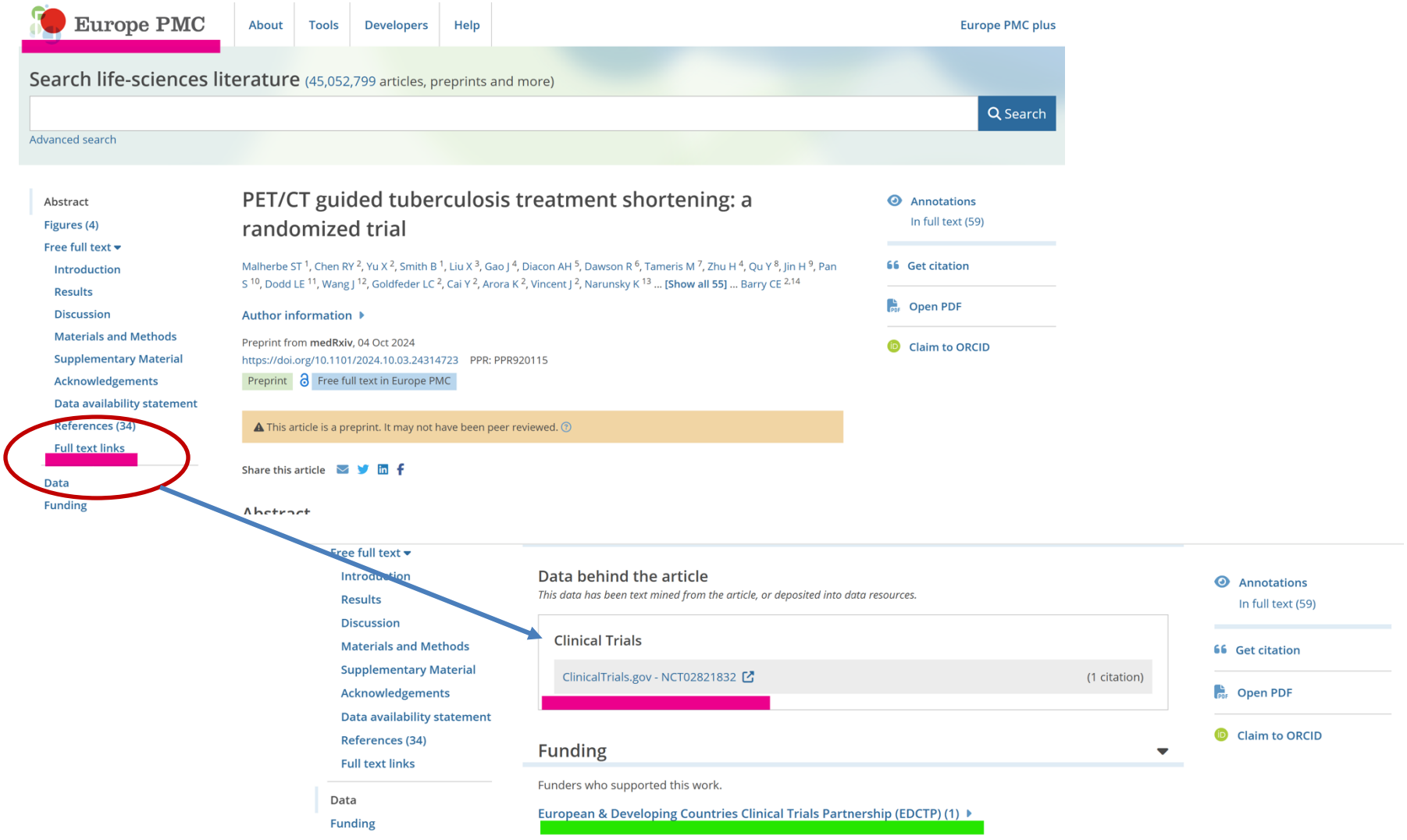


Clinical trials: examples of clinical study records in registries

Example 2: *AMBITION – results are posted https://doi.org/10.1186/ISRCTN72509687*

BMC
Part of Springer Nature

ISRCTN registry
The UK's Clinical Study Registry

View all studies | Why register? | Register your study | Update your record | Report your results | Get help

High dose AMBISOME on a fluconazole backbone for cryptococcal meningitis induction therapy in sub-Saharan Africa

Result 1 of 2 for ISRCTN72509687 — Previous study | Back to results | Next study

ISRCTN	ISRCTN72509687
DOI	https://doi.org/10.1186/ISRCTN72509687
Secondary identifying numbers	Ambition P3

Submission date
23/06/2017

Registration date
13/07/2017

Last edited
02/09/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

- (●) Prospectively registered
- (●) Protocol
- ( ) Statistical analysis plan
- (●) Results
- ( ) Individual participant data

Results and Publications

Intention to publish date	30/12/2021
Individual participant data (IPD) Intention to share	No
IPD sharing plan summary	Data sharing statement to be made available at a later date
Publication and dissemination plan	Planned publication in a high-impact peer reviewed journal within 6-12 months of overall trial end date.
IPD sharing plan	The current data sharing plans for the current study are unknown and will be made available at a later date.

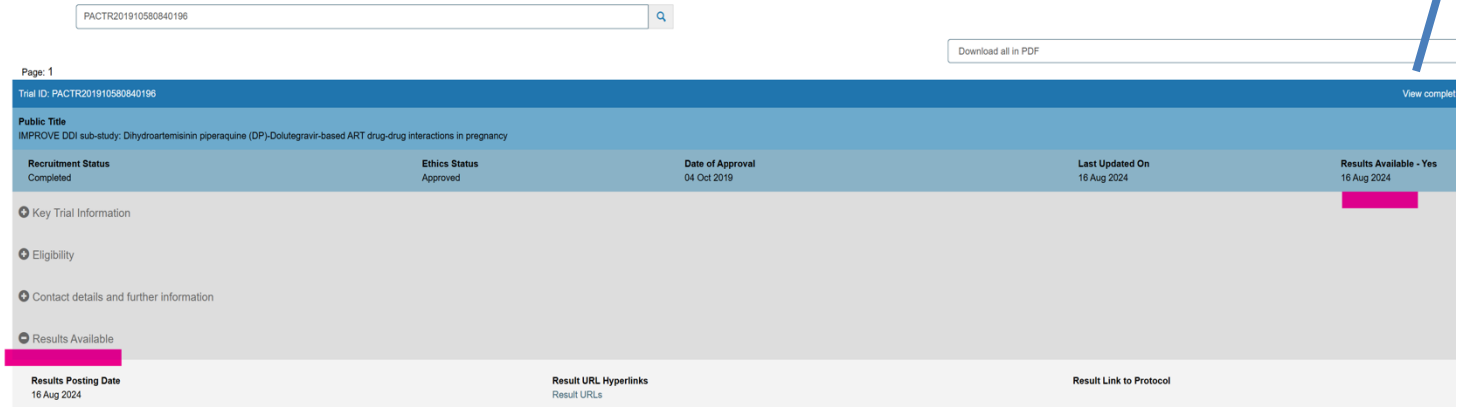
Study outputs

Search:

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Analysis of HIV drug resistance mutations	02/11/2022	03/11/2022	Yes	No
Other publications	sub-study	27/08/2024	02/09/2024	Yes	No
Protocol article	protocol	23/11/2018		Yes	No
Protocol article	economic evaluation protocol	01/04/2019	04/04/2019	Yes	No
Results article		24/03/2022	24/03/2022	Yes	No
Results article	Cost-effectiveness	01/12/2022	21/11/2022	Yes	No

Clinical trials: examples of clinical study records in registries

Example 3: *IMPROVE DDI sub-study – results are posted*
https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=9433



Pan African Clinical Trials Registry

South African Medical Research Council, South African Cochrane Centre
PO Box 19070, Tygerberg, 7505, South Africa
Telephone: +27 21 938 0506 / +27 21 938 0834 Fax: +27 21 938 0836
Email: pactradmin@mrc.ac.za Website: pactr.samrc.ac.za

Trial no.:	PACTR201910580840196	Date of Approval:	04/10/2019
Trial Status:	Registered in accordance with WHO and ICMJE standards		

TRIAL DESCRIPTION

Public title	IMPROVE DDI sub-study: Dihydroartemisinin piperaquine (DP)-Dolutegravir-based ART drug-drug interactions in pregnancy
Official scientific title	Impact of dolutegravir-based antiretroviral therapy on the pharmacokinetic profile of piperaquine administered as dihydroartemisinin-piperaquine for intermittent preventive treatment of malaria in pregnant women living with human immunodeficiency virus in Malawi: a fixed sequence cohort study
Brief summary describing the background and objectives of the trial	Dihydroartemisinin-piperaquine (DP) is being studied as an alternative to sulfadoxine-pyrimethamine (SP) in Malawi in pregnant women not living with HIV (the IMPROVE I trial) and in pregnant living with HIV (the IMPROVE II trial). Although unexpected, any possible effect of dolutegravir on piperaquine concentrations, or of piperaquine on dolutegravir concentrations in the blood, is not yet known. This needs to be investigated to make sure that these drugs do not impact on each other's blood levels,and potentially change their effectiveness or tolerability. The aim of this pharmacokinetic IMPROVE DDI sub-study is to understand whether the malaria preventive treatment, DP, and the HIV treatment, dolutegravir-based ART, impact on each other's blood levels when administered together in pregnant women living with HIV . The primary objective is to compare the mean trough plasma concentrations and pharmacokinetic parameters of piperaquine, administered as standard 3-day treatment course of dihydroarteminin-piperaquine, when coadministered with dolutegravir-based ART regimen, and when co-administered with efavirenz-based ART regimen in pregnant women living with HIV in Malawi. The secondary objectives is to compare steady-state trough and pharmacokinetic parameters of dolutegravir when administered alone as dolutegravir based-ART, and when co-administered with dihydroartemisinin-piperaquine for IPTp in pregnant women living with HIV in Malawi
Type of trial	CCT
Acronym (If the trial has an acronym then please provide)	IMPROVE DDI
Disease(s) or condition(s) being studied	Infections and Infestations,Pregnancy and Childbirth

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) 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 https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

7

Q&A

Q&A session – Further funding and co-funding

Q: What are funding opportunities after EDCTP2

A: Please see the website (https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home) for funding opportunities under GH JU EDCTP3

Q: If a project is co-funded by EDCTP2 and another funder, how should we differentiate the report sent to each funder?

A: While you can report on co-funded activities, you need to specify which activities are paid for by which funder.

Q&A session – changes to the action

Q: What should we do if the scope/objectives of the project change?

A: You need to discuss with your assigned project officer if the grant agreement/description of the action needs to be amended

Q: Can we change deliverables and/or milestones in the course of the project

A: Changing deliverables and milestones is only possible via an amendment to the grant agreement. However, if a deliverable is not yet achieved at the end of the grant period, you can submit a draft document and submit the final version (proactively) at a **reasonable** later timepoint. See section with letter of commitment.

Q: How to report minor changes to the project objectives?

A: Minor changes can be reported in the 'deviations from Annex 1 section' of the technical report.

Q&A session – gender dimension

Q: The technical report includes the section ‘Gender dimension in the action’. What does this mean?

A: Considering gender is important on many levels and exceeds considerations on the composition of your team. (Pregnant) women are still underrepresented in clinical trials and certain social/cultural factors differ between sex. In this section, you should specify whether gender/sex was considered during trial/study design and whether it is considered in the analysis state (e.g. do you stratify your data based on sex?)

Thank you

www.edctp.org | media@edctp.org

Break