EDCTP

The power of sharing science

EDCTP Workshop: Reporting for Fellows – Technical reporting

7 June 2022

Michelle Helinski, 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.

Set up of workshop

7 June

- Technical reporting; introducing the team today:
  - Tom Nyirenda
  - Michelle Nderu
  - Johanna Roth
  - Andreia Coelho
  - Michelle Helinski

8 June

- Financial reporting, led by Neodia Flores with colleagues

Set up of workshop

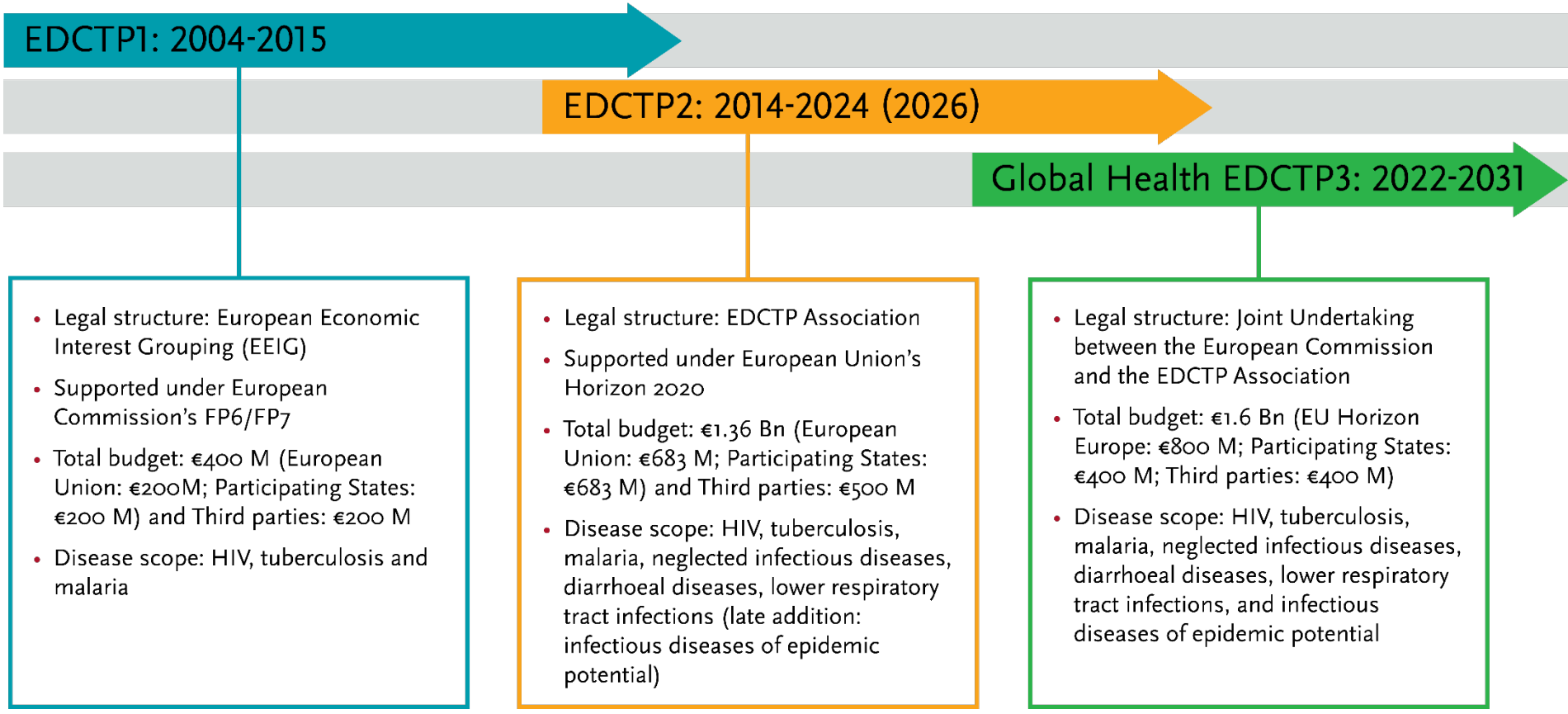
Agenda for today: 13:00-16:00 CEST

1. Welcome/ Overview of EDCTP Fellowships
2. Understanding the EDCTP2 Grant Agreement
3. Anatomy of the periodic report (technical)
4. Reporting in the EDCTPgrants system
5. EDCTP review to finalisation
6. EDCTPs Knowledge Hub
7. Questions & answers

1

Welcome/ overview of EDCTP Fellowships

The evolution of EDCTP programmes



EDCTP2 strategic approach

Vision
To reduce the social and economic burden of PRDs in sub-Saharan Africa

Mission
To enhance research capacity and accelerate the development of new or improved medical interventions against PRDs through all phases of clinical trials.

Increase new or improved medical interventions against PRDs

Increase cooperation with SSA through capacity building (CTs, Ethics & regulatory)

Improve coordination alignment and integration of European National Programmes

Increase international cooperation with third parties

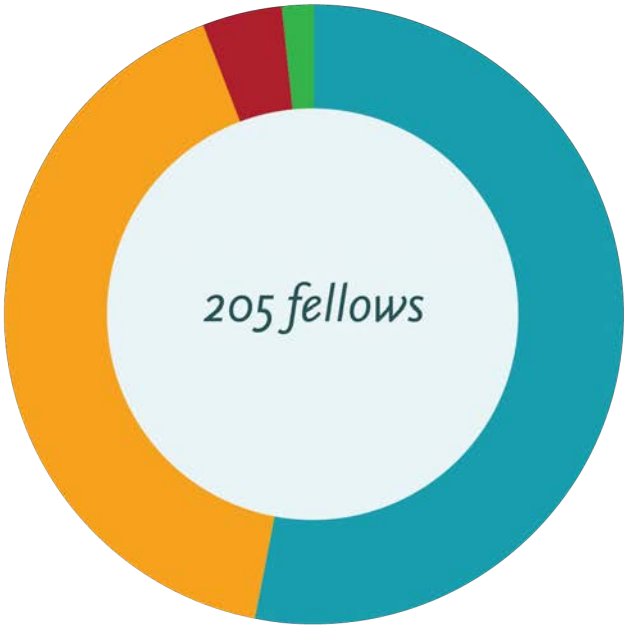
Increase interaction with development partners (incl. EU and WHO initiatives)

EDCTP fellowship programme

Fellowship programme

2014-May 2022

By type



- Senior Fellowships, *45 fellows*
- Career Development Fellowship, *125 fellows*
- Industry Fellowships, *24 fellows*
- EDCTP-AREF Preparatory Fellowships, *11 fellows*

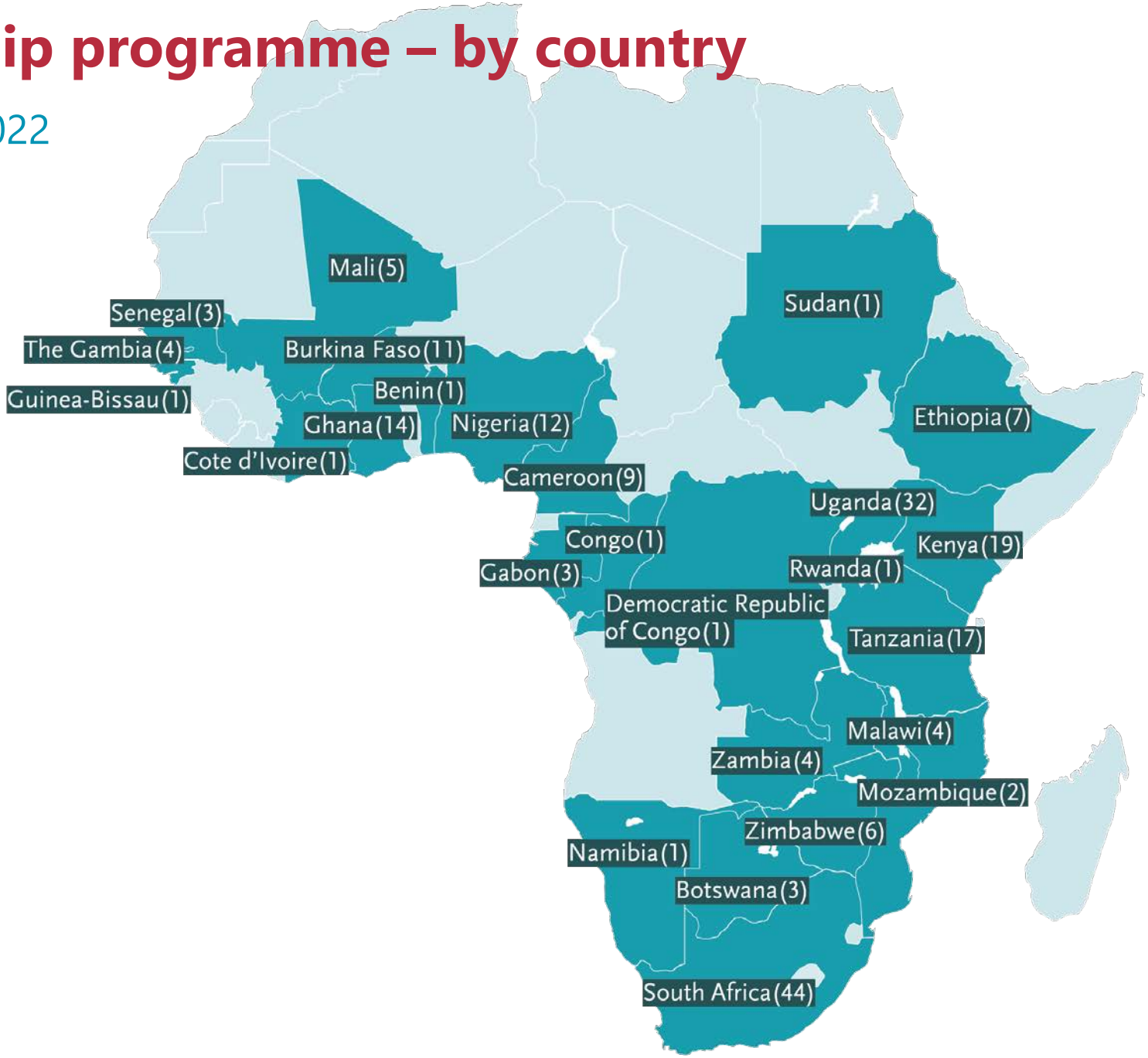
By gender

39%
Female fellows

61%
Male fellows

Fellowship programme – by country

2014-May 2022



2

Understanding the EDCTP2 Grant Agreement

Grant Agreement

Overall structure

Core grant agreement

Annex 1: **Description of the Action (DoA)** Technical description of activities

Annex 2: Budget table

Annex 3: *Accession form (not applicable for fellowships)*

Annex 4: Model for the financial statements

Annex 5: Model for the certificate on the financial statements

Annex 6: Model for the certificate on the methodology

Annex 7: Model for technical reports

Grant Agreement

Section 2: Rights & Obligations related to Grant Administration (Articles 17-20)

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

- Beneficiary must provide – during or after the action – any information requested to verify eligibility of the costs, proper implementation of the action and compliance with any other obligation under the Agreement.

- Beneficiary has an obligation to keep information up to date and to inform EDCTP about events and circumstances likely to affect the Agreement such as
  - changes to organisation (name, address, legal representative etc)
  - events which are likely to affect significantly or delay the implementation of the action or the EDCTP Association's financial interests;
  - circumstances affecting the decision to award the grant or compliance with requirements under the Agreement.

In other words: 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

Grant Agreement

Section 2: Rights & Obligations related to Grant Administration (Articles 17-20)

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

- Records, documents and other supporting documentation on scientific and technical implementation of the action must be kept and preserved in line with the accepted standards
- Records must be kept for 5 years following the end of the project
- Documentation (originals) must be made available upon request

Grant Agreement

Section 2: Rights & Obligations related to Grant Administration (Articles 17-20)

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The beneficiary must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

- Online reporting is open 4 months before report is due
- Key deliverables can be shared by email with POs (and also have to be shared again with the periodic report)

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;

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

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

3

Anatomy of the periodic report (technical)

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

Webpage, include correct acknowledgement

PERIODIC REPORT of the ACTION

Please complete the table below

Grant code	Insert details
Acronym	Project acronym
Title	Title of project
Periodic report	Insert year covered by report (1, 2, 3, 4, 5 etc)
Period covered by report	From to
Start date of the action	Project start date
End date of the action	Project end date
Version and date of report	Version number, date submitted
The report is elaborated on the basis of the: Original or amended grant agreement	Amended Grant Agreement through amendment number (insert number – amendment 1, 2, 3 etc)

Action website address Please provide the URL of the action (project) website. The action website must display the EDCTP logo (available in electronic format from the EDCTP website – see the EDCTP Media Kit link) and the European emblem (available in electronic format at http://europa.eu/abc/symbols/emblem/index_en.htm). The action website must include the following text: "This project (grant code) is part of the EDCTP2 programme supported by the European Union". The website should acknowledge any other cofunders of the action, including the display of the cofunders' logos. **If there is no action (project) website, the participants should include details of the project on their organisation/personal web page and provide more details about this (including the URLs) in the report.**
Insert URL

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

Update plan for exploitation and dissemination/ data management plan

I.1.1 Update of the plan for exploitation and dissemination of results (if applicable) *Include in this section whether the plan for exploitation and dissemination of results has been updated and give details.*

I.1.2 Update of the data management plan (if applicable) The Data Management Plan (DMP) should give details of what data the action will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. The purpose of the DMP is to support the data management life cycle for all data that will be collected, processed or generated by the action (project). Include in this section whether the data management plan has been updated. If an update has been made, please give details to explain the changes.

You have already described elements of this in the Impact section of Annex 1.

Provide information on any updates to the plans- they may also be a deliverable in your Annex 1.

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.

Unforeseen subcontracting/ use of in-kind contribution from third party

- Almost never applicable in a fellowship; however, if this took place you must report this here

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 when you are already in year 3.*

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

D&M 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

More on formatting of appendices including coversheets later

Ethical issues (1)

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

- Ethics-related deliverables may be included, such as
  - Ethical/regulatory approvals
  - Ethics mentor, Terms of Reference and reports
  - Data protection plan/statement
  - Incidental findings policy

- Ethical compliance may be checked during audits, site visits

- Ensure record-keeping is consistent and accurate

Ethical issues (2)

- Provide a list of all ethical/regulatory reviews required (and obtained) for the project. Insert details on which body provided the review, what date the approval was granted and for how long approval was given (to see when a renewal is needed)
- Ensure that the ethical approval makes reference to the EDCTP project (title, code, etc)
- For fellowships embedded in a larger study where the approval refers to the parent study, you must demonstrate that the approval also covers the fellowship activities
- Include reports from ethics mentor/ethics board (if not already a deliverable) as well
- Provide approval letters as attachments (if not already provided as a deliverable/milestone)

Critical implementation risks and mitigation actions

- Copy the risks from Annex 1 exactly and provide updates:
  - Where the mitigation strategies applied (Yes/No)
  - Did the risk materialize (Yes/No)
  - If a yes is answered, please provide further explanations.

- New risks identified during the course of the project should be added, for instance COVID-19

Scientific publications (1)

- Article 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.
- 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

https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-dissemination_en.htm

Scientific publications (2)

- Make sure EDCTP/EU are correctly acknowledged. We recommend:

  This project is part of the EDCTP2 programme supported by the European Union (grant number TMA2020CDF-3000 - STEADY).

- If acknowledgement is missing- you must correct this with journal (and if not corrected, cost may not be eligible)

- Inform your PO in advance about publications. We can also review the acknowledgement

Europe PMC

- EDCTP signed up as a member to Europe PMC https://europepmc.org/- online repository publications
- EDCTP 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 Europe PMC, as soon as possible and in any event within six months of the journal publisher's official date of final publication.
- Publication deposited automatically in Europe PMC for many journals if you acknowledge EDCTP correctly
- More information: https://www.edctp.org/event/webinar-making-edctp-funded-research-open-with-europe-pmc-plus/

Dissemination and communication activities

- Include all dissemination/communication events that took place during the reporting period
- Only provide information for events directly related to the action
- Estimate attendance if no exact number is known (if this is truly impossible you can write ‘unknown’)
- Make sure EDCTP is correctly acknowledged when disseminating information, such as on your poster/slides for a conference (if this is not done - it may affect eligibility of the cost)
- Upload evidence of these activities (such as slides presented) as appendix with the report.

Dissemination and communication activities

- Please confirm whether you acknowledged EDCTP/EU as per article 29

Only list activities directly linked to the project.
Please confirm that the EDCTP Association and the EU has been acknowledged as per Article 29 of the Grant Agreement. - Yes/No

Type of activity	**Date**	**Type of audience reached**	**Number of persons reached/attending event**	**Details**
Choose one of the following: Organisation of or participation in conference, workshop,stakeholder or policymakers meeting,community engagement event, other event, including events organised by EDCTP or H2020 Exhibition Radio, TV event Video/film Social media Website, databases Press release Policy document Flyer Training manual Other	Month, year	E.g. scientists, clinicians, government officials, patient group, public	Enter number	Open text – maximum 250 words per event

Clinical studies

- Complete the template if you are conducting a clinical trial/ public health intervention study, but also for any other type of clinical study and investigation, including cohort studies, case control studies, other observational studies.
  - Do not answer No when you are doing a clinical study- when in doubt ask your PO.
- Try and complete all the sections, stating not applicable in case something is not applicable to your study (for instance no TSC, no DSMB and etc).

Clinical studies

- 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
- Provide copies of protocol, clinical trial insurance (where applicable), TSC/DSMB meetings if not already shared as deliverables

Clinical trials: transparency and prompt reporting

EDCTP is a signatory to WHO Joint statement on public disclosure of results from clinical trials
https://www.who.int/ictrp/results/jointstatement/en/index1.html

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)

Capacity building

- Short term trainings and workshops table
  - Give details of any short course and workshops conducted under the project
  - Also include trainings undertaken by the fellow
- 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

Capacity building continued

- Infrastructure improvements
  - Give details of any site upgrade or improvement
  - Provide pictures where relevant as attachment

- Other comments
  - Here you can share other noteworthy information such as winning a prize or attraction of additional funding as a result of the award, or a promotion.
  - These are best shared with your PO in advance/when they occur so we can publicize your achievements

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)

Gender

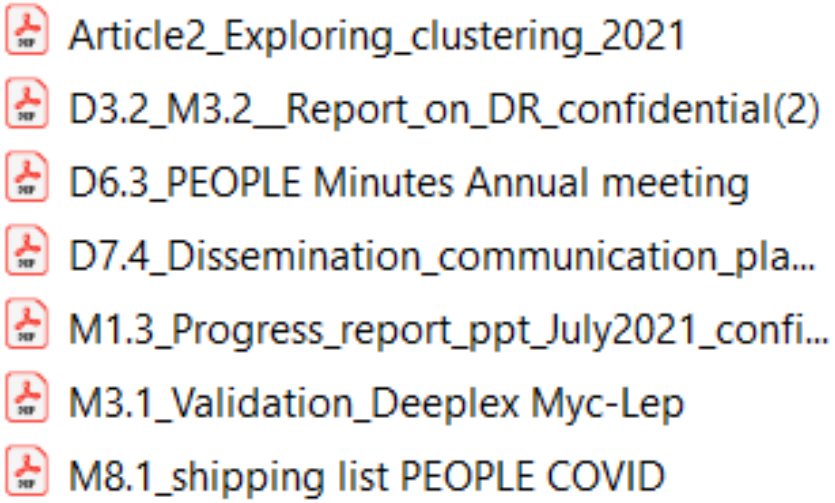
- Provide information on gender of numbers of people working as (non-)researchers **on the action** according to the categories indicated in the table
- Answer the question on Gender dimension **in the action (i.e. the research question)** and provide details on your answer given
  - Yes – give details of the gender dimension
  - No – explain why gender is not considered a relevant variable in your research

Other items

- IP, SMEs – if applicable complete these tables. If not answer No
- Infrastructures- this is not applicable to EDCTP grants (so just say No)

Appendices

- Provide a list of appendices provided with the report
- Label appendices correctly and informatively
  - D1.1_study design
  - Insurance policy



Appendices – use of coversheets

- Each deliverable and milestone provided should start on page 1 with the coversheet where details as requested are noted. These details should match the information provided in the tables

- Do not
  - Send us a separate coversheet with each attachment, these should be combined into one file
  - Prepare coversheets for items not achieved, these can be provided when the item is delivered (next year).

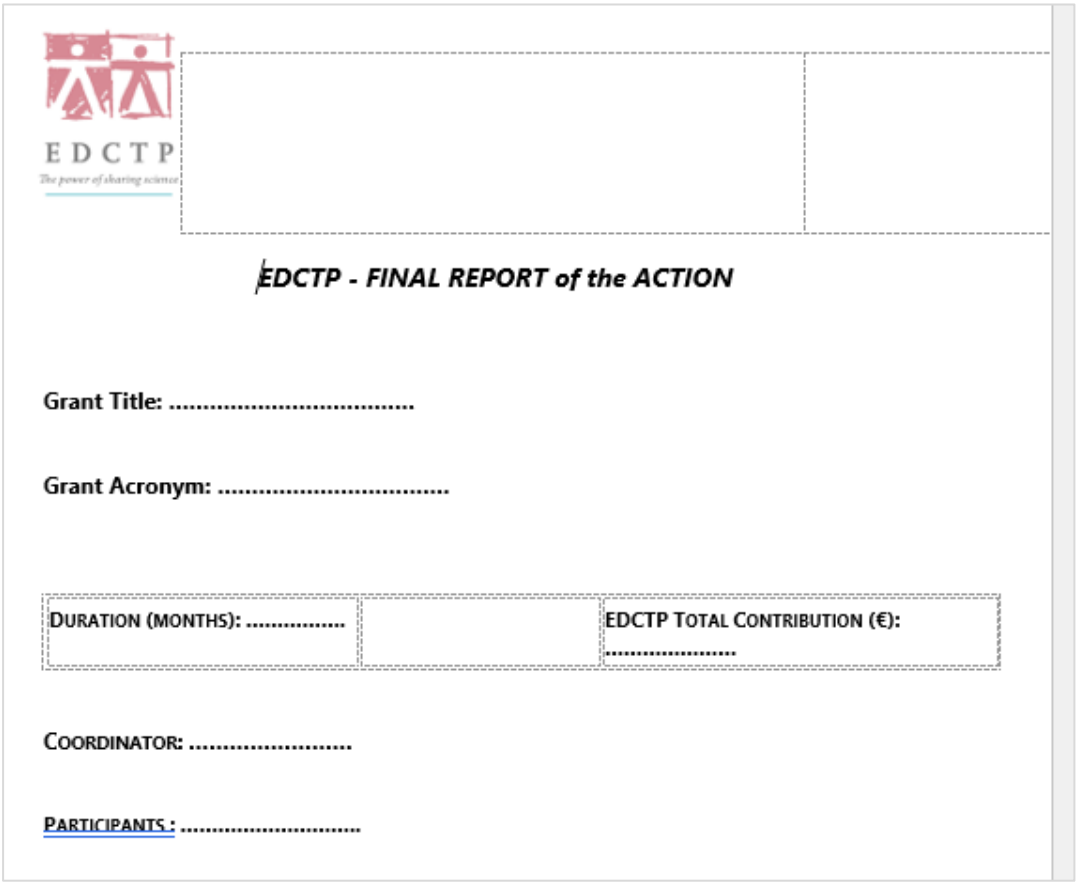
Example of coversheet used

DRIA2014-306-DiTECT-HAT

Grant code	DRIA2014-306-DiTECT-HAT
Project title	Diagnostic Tools for Human African Trypanosomiasis Elimination and Clinical Trials
Deliverable number	1.4
Deliverable name	Final consortium meeting
Deliverable type	R
Milestone number	
Milestone name	
Work Package	WP1
Organisation and person responsible	PNLTHA-RDC
Dissemination level	Public
Contractual delivery date (month)	58
Actual delivery date (month)	50
Version	v1.0
Total number of pages	12

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.

Break

4

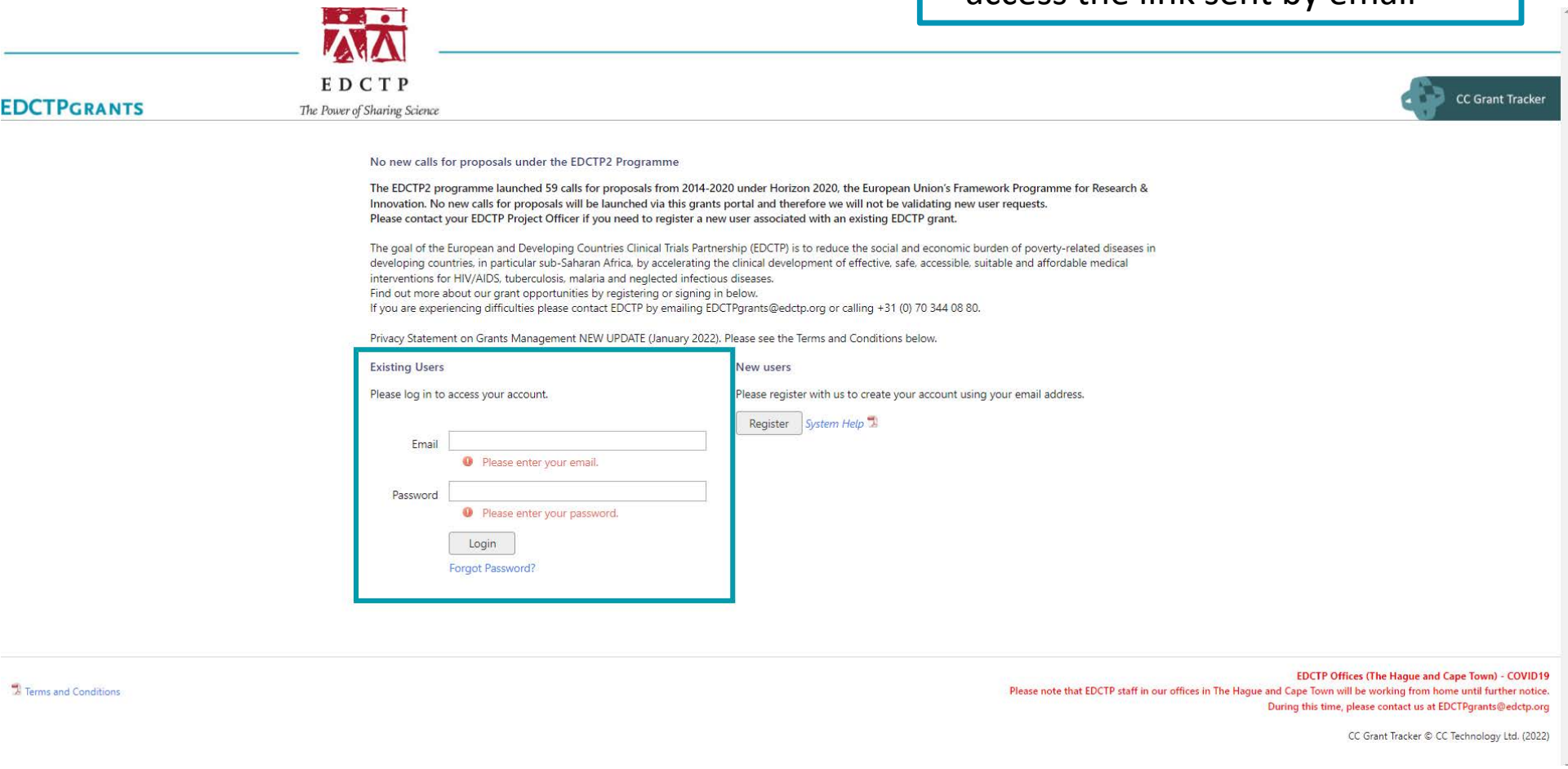
Reporting in the EDCTPgrants system

Reporting in the EDCTPgrants system

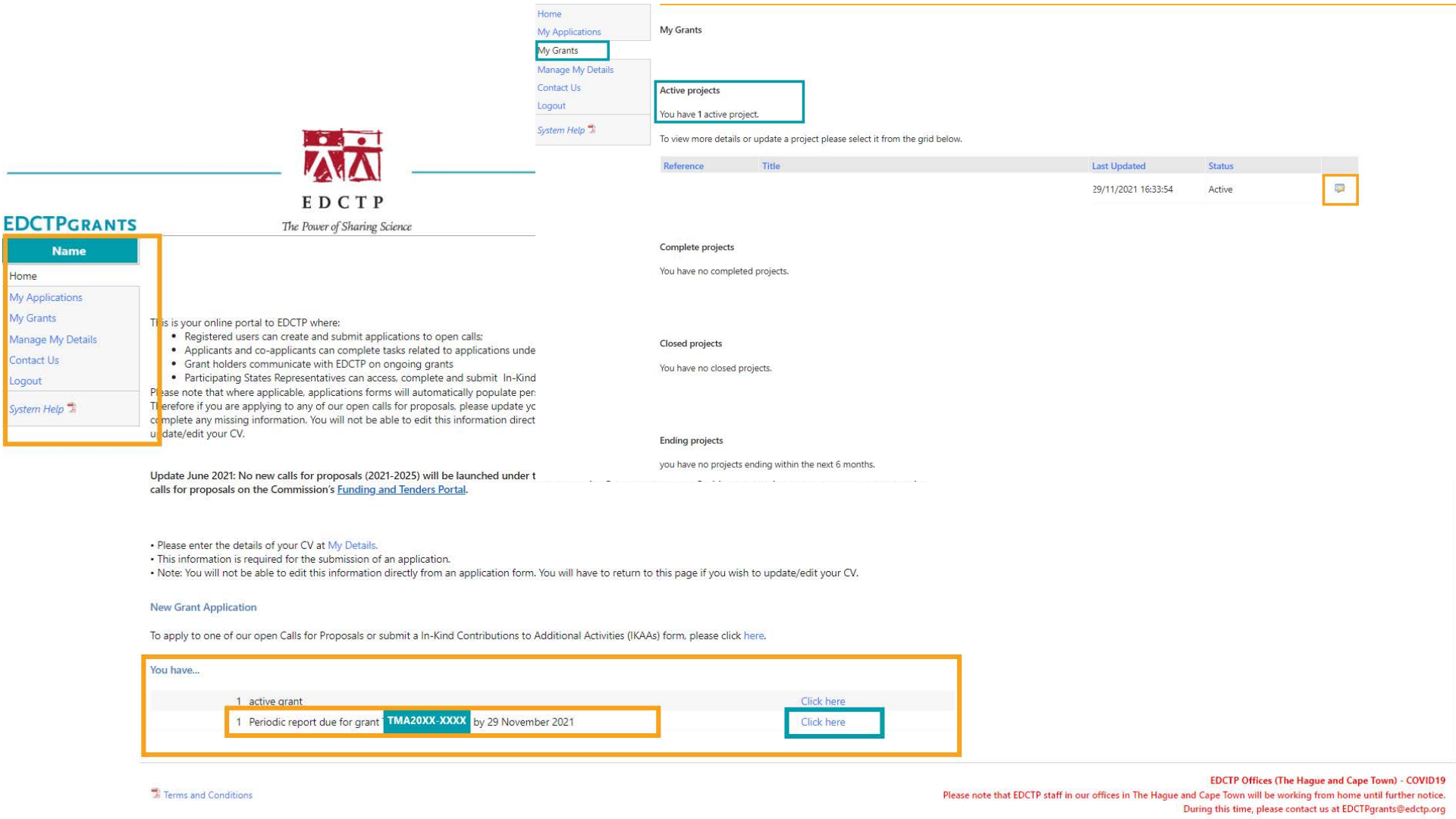
Navigating the system:

- login to www.edctpgrants.org

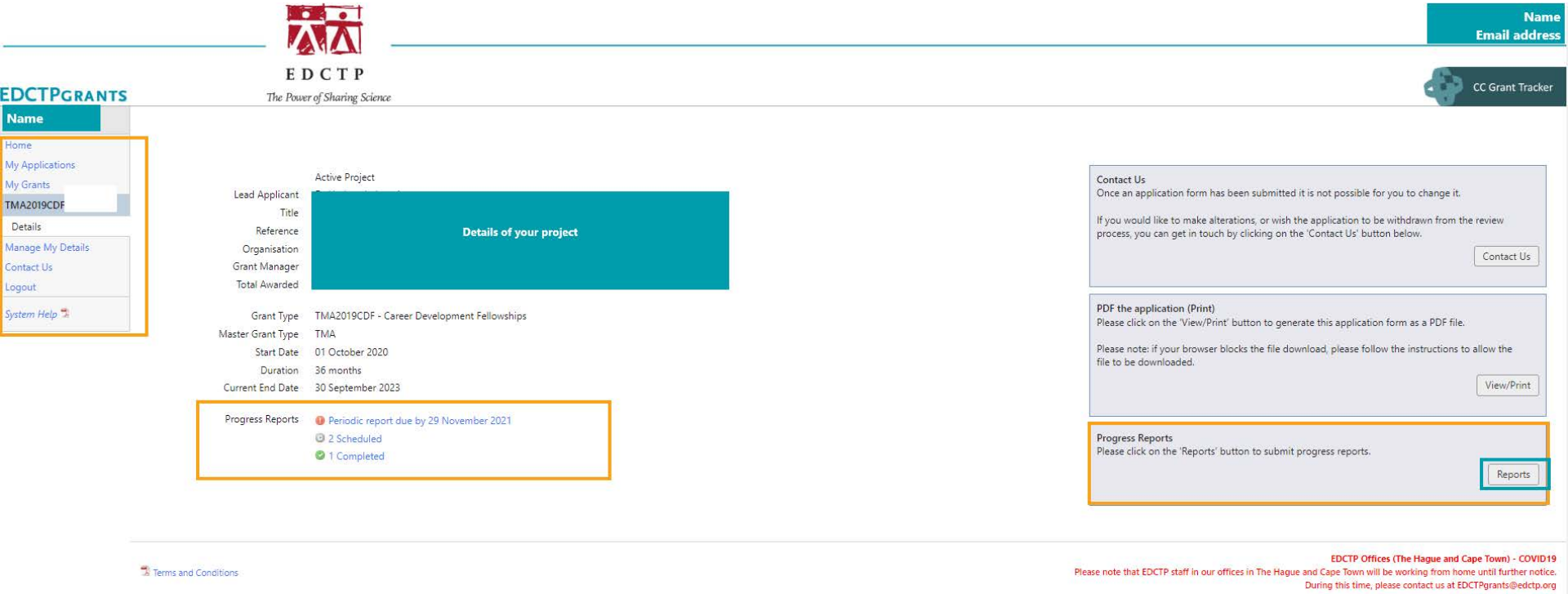
2 ways to access the periodic reports:
- login and check under my grants
- access the link sent by email



User's page – My Grants



My Grant details
Periodic Reports overview



System automated requests and reminders

To: your email address View Recipients
CC: EDCTP PO and GFO email address
Sent By: Scheduled Task User
Subject: Final report request for grant (Title ref TMA20xx-xxxx ;

Dear

In accordance with article 20.2 of the EDCTP grant agreement, I am requesting submission of the periodic report (technical and financial) for (TMA201) for period 3. Since s reporting period for period will end on 30 June 2021 this periodic report is due 60 days after the end of the reporting period, which is **29 August 2021.**

The periodic report must include the following:

a) a 'periodic technical report' containing:

a. an explanation of the work carried out by the beneficiaries;
b. 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 also 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';
c. a summary for publication by the EDCTP Association;

b) a 'periodic financial report' containing:

a. an 'individual financial statement' (see Annex 4) from each beneficiary, for the reporting period concerned. The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the EDCTP Association. If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period. The individual financial statements of the last reporting period must also detail the receipts of the action (see Article 5.3.3). Each beneficiary [and each linked third party] must certify that:

i. the information provided is full, reliable and true;

ii. the costs declared are eligible (see Article 6);

iii. the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and

iv. for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

b. an explanation of the use of resources and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary [and from each linked third party], for the reporting period concerned;
c. a 'periodic summary financial statement' (see Annex 4), consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the request for interim payment.

Should you have any questions, please contact me or the Grants Finance Officer for this project,

Please log in here **https://www.edctpgrants.org/forms//en/ProgressReports/Form/Edit/7c** **https://www.edctpgrants.org/** order to download the progress report template and submit your report by the indicated deadline. Here https://www.edctp.org/web/app/uploads/2020/11/Online_Progress_Report_in-EDCTPgrants-_-Guidelines-for-Beneficiaries-2020.pdf you can find the guidelines for submitting the online periodic report.

Yours sincerely,

Project Officer
EDCTP

Please leave this footer on any reply as it contains important tracking information.

CCGT_ID=02b59ec5-d8ca-4800-b549-add60021cc15

Click the link to access the report
You will be asked to login to the system

System automated requests and reminders

Sent By: Scheduled Task User
Subject: Report Request Follow-up for grant

Dear

This is a kind reminder to submit the progress report for for year 1 by 01 March 2022

Please log in here **https://www.edctpgrants.org/forms//en/ProgressReports/Form/Edit/7** **https://www.edctpgrants.org/** to download the progress report template and submit your report by the indicated deadline.

Kind regards,

EDCTP Project Officer

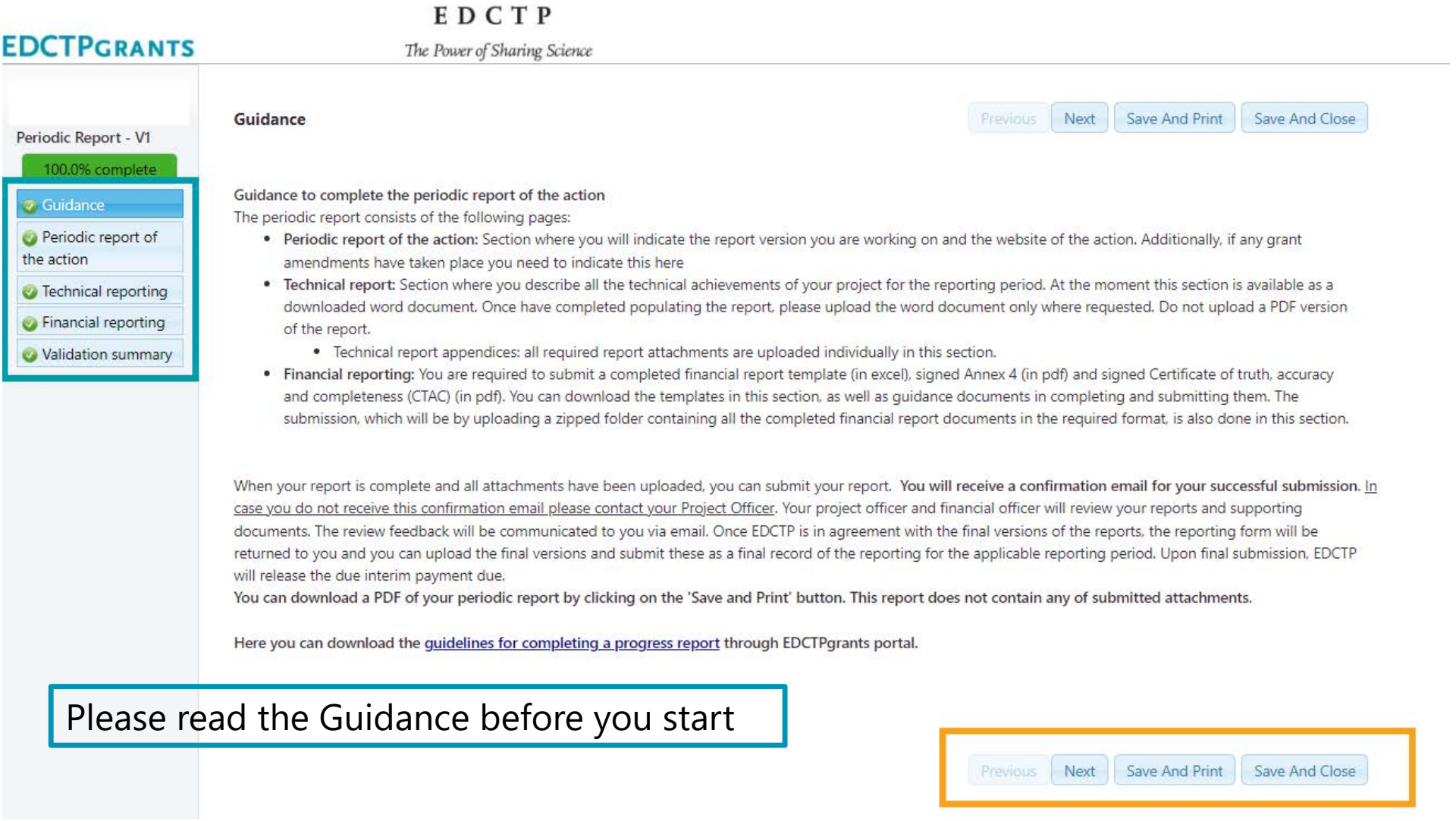
Please leave this footer on any reply as it contains important tracking information.

CCGT_ID=fffd9c2d-f5d0-4d04-bc4f-ae2d0021ef2a

Requests:
The system will send a request to submit a periodic report 120 days before the due date;
- e.g. Periodic report 1 due on 29/Aug – will be available and request will be sent on 1/May

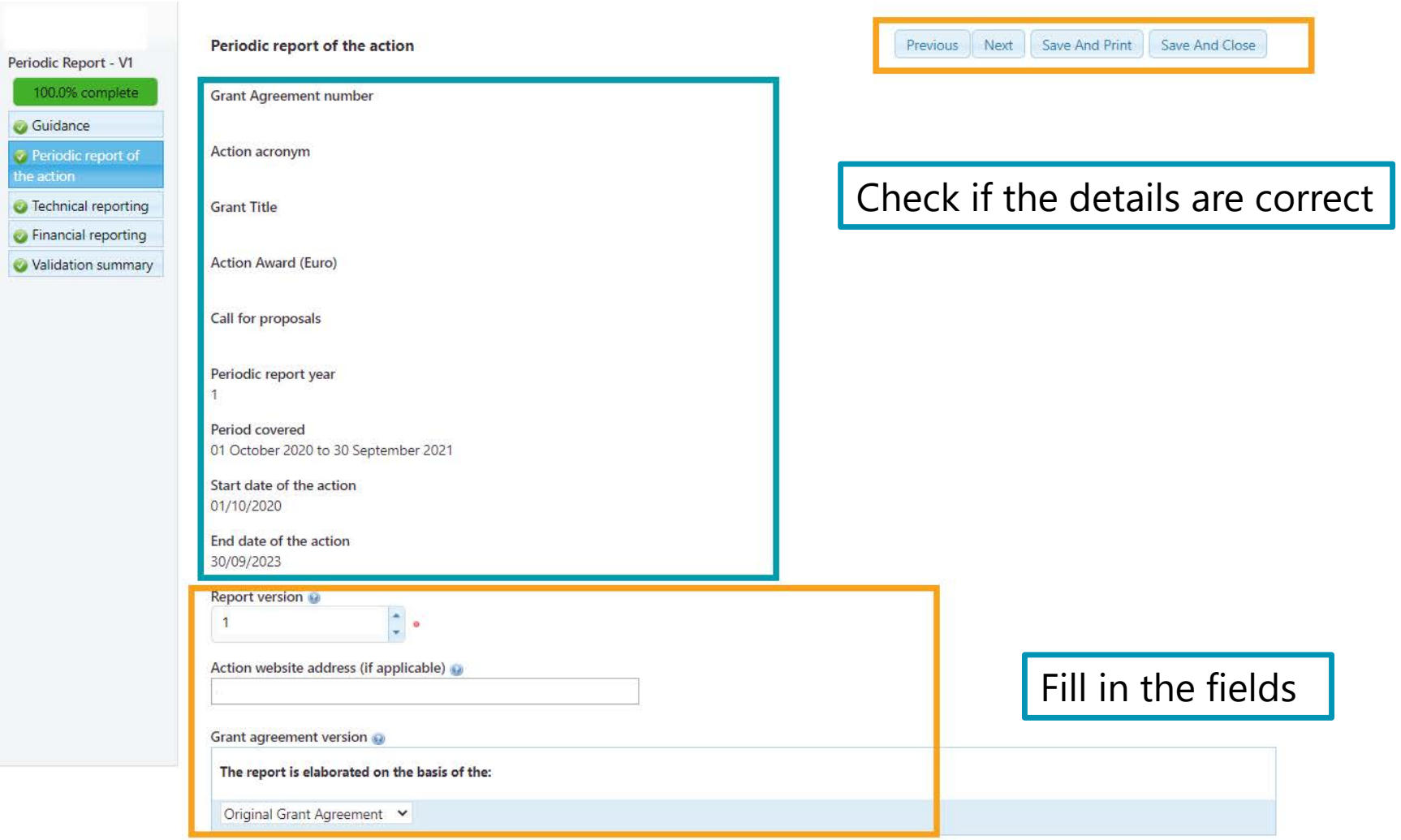
Reminders:
30 days before due date
10 days before due date
1 day before due date
14 days after due date
21 days after due date
30 days after due date

Periodic Report – Guidance

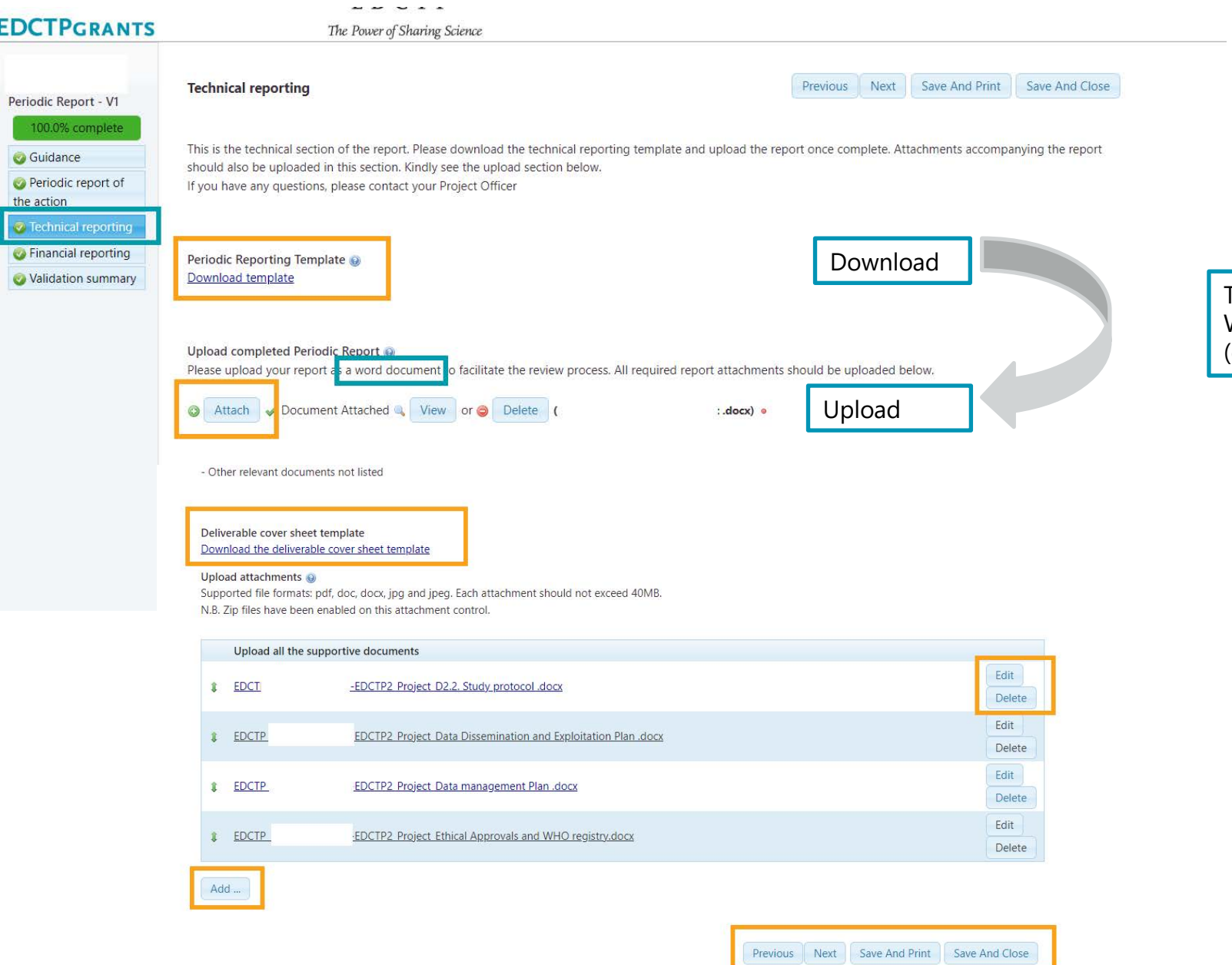


Please read the Guidance before you start

Periodic Report – online form edits

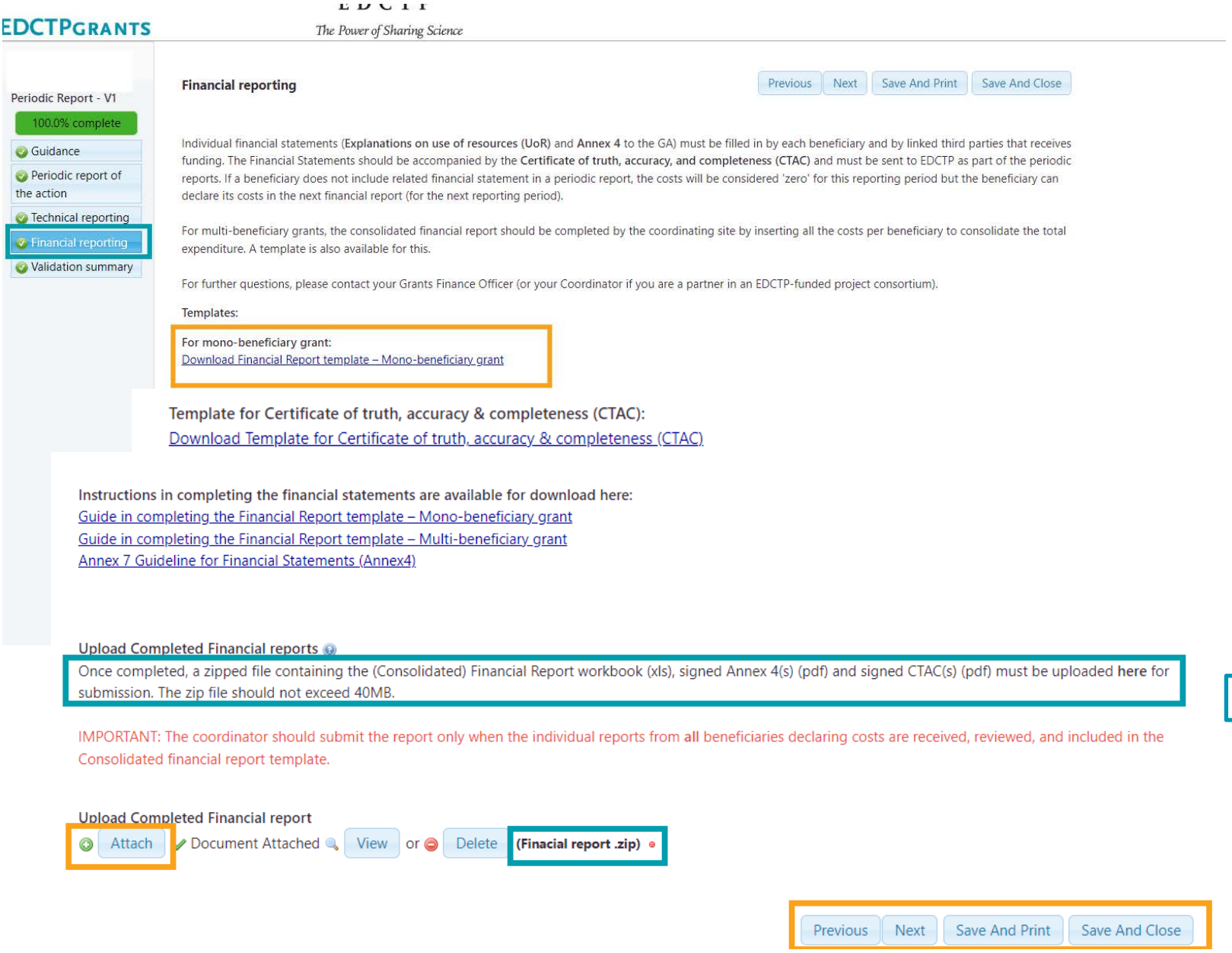


Periodic Report – Technical reporting



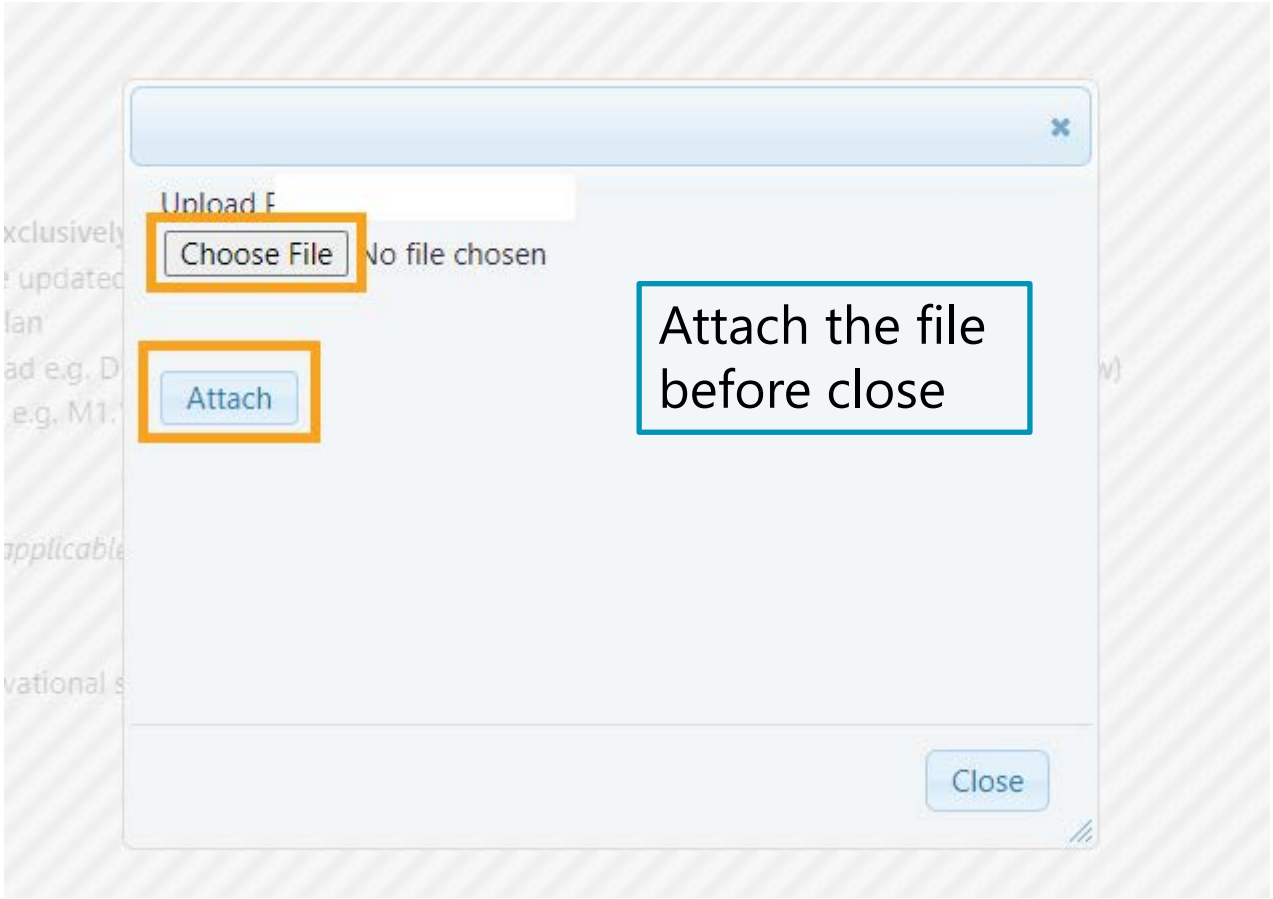
Type of file:
Word Doc only
(doc; docx)

Periodic Report – Financial reporting

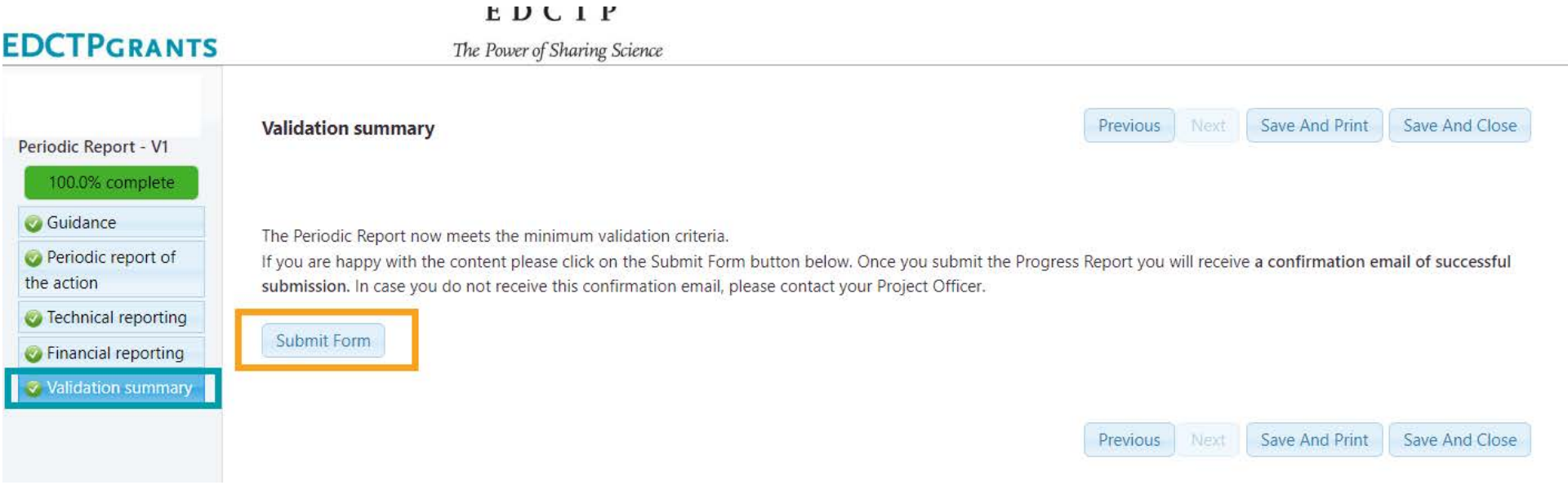


Zip file only

Periodic Report – Uploading files



Periodic Report – Submit the report

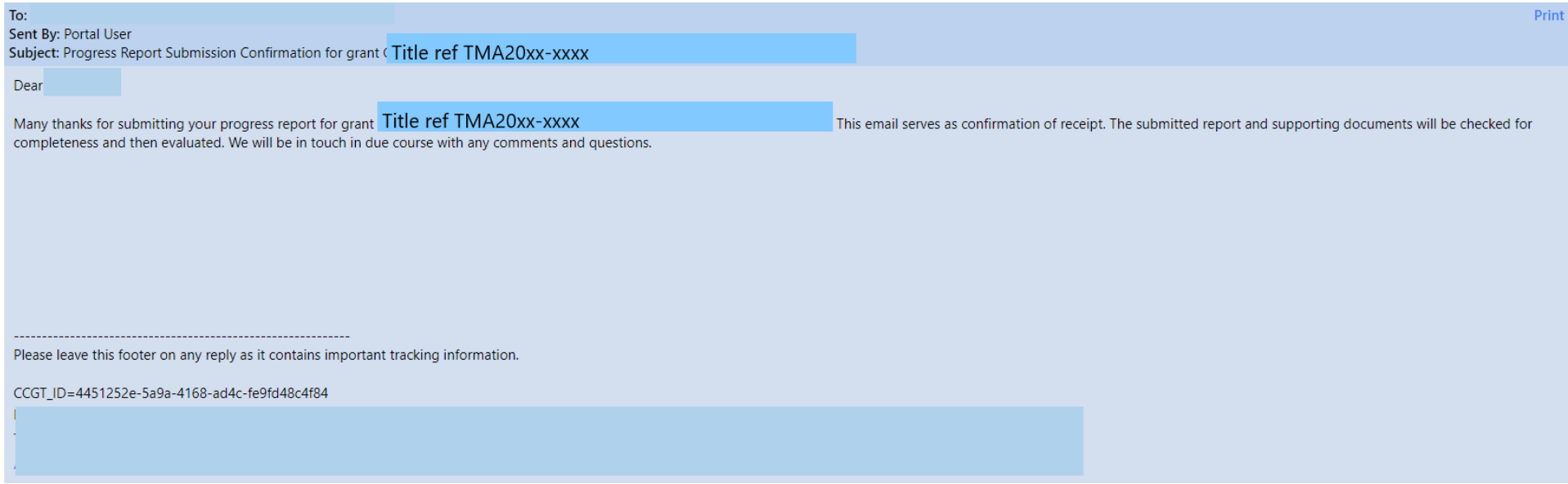


After submit
Check if report status have changed to Received and check received on date

	Type	Status	Available On	Required By	Received On	Contact Type	
✓	Progress Report Final	Received	15/11/2021	15/03/2022	24/05/2022	Project Manager, Lead Applicant	
✓	Progress Report 2020	Received	30/12/2018	29/04/2019	15/03/2022	Project Manager, Lead Applicant	View

Periodic Report – Confirmation received

After submission the system will send an automated email as confirmation of receipt.



To:

Print

Sent By: Portal User

Subject: Progress Report Submission Confirmation for grant (Title ref TMA20xx-xxxx

Dear

Many thanks for submitting your progress report for grant Title ref TMA20xx-xxxx This email serves as confirmation of receipt. The submitted report and supporting documents will be checked for completeness and then evaluated. We will be in touch in due course with any comments and questions.

Please leave this footer on any reply as it contains important tracking information.

CCGT_ID=4451252e-5a9a-4168-ad4c-fe9fd48c4f84

The Project Officer and Grants Finance Officer will start reviewing your report

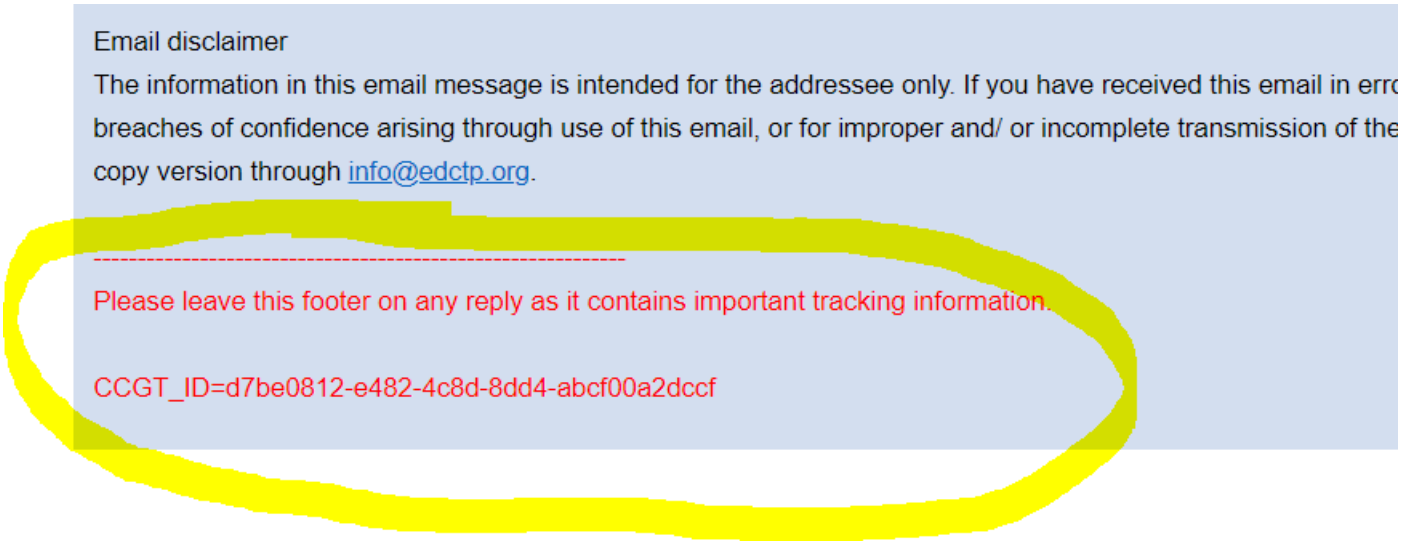
Periodic Report – Review

Once the Project Officer and Grants Finance Officer have agreed on the final version, the report will be rejected in the system and you will be requested to upload the final versions including all final annexes.

✓	Periodic report	Complete (Rejected)	01/09/2021	30/12/2021	20/12/2021	Project Manager, Lead Applicant	View
✓	Periodic report	Complete (Approved)	01/09/2021	30/12/2021	01/04/2022	Project Manager, Lead Applicant	View
◷	Final	Scheduled	02/03/2023	30/06/2023		Project Manager, Lead Applicant	

Once approved the status will change to Complete (Approved) and the Project Officer will send an email approving the periodic report.

Last but not least….



Besides your Project Officer and Grants Finance Officer, don't forget to copy edctpgrants@edctp.org when sending messages about your grant and make sure the tracker code is always at the bottom of the message.

5

EDCTP review to finalisation

Review of reports (1)

- 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

Review of reports (2)

- 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 them all
- 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.

6

EDCTP Knowledge Hub

The importance of protocol development and the growing prominence of clinical research data sharing

- **Protocol development** is an essential first step in turning a research question into a study
- Good **data management** is an essential precursor to data sharing and critical for ensuring the validity and quality of data in all types of clinical research (clinical trials and non-interventional studies)
- **Data sharing** is recognised as a crucial step in maximising the knowledge and benefits of clinical research
- Research funders, research publishers, regulatory agencies, ethics committees, policy makers and patient groups increasingly implement strong endorsement policies to promote adherence to protocol development and study reporting guidelines and require open access data sharing
- Most recently, the COVID-19 pandemic has demonstrated the importance of timely and open publication of trial protocols and data sharing, for transparency, clear reporting and to avoid duplication of efforts

EDCTP's requirements on study protocols

- Study protocols for clinical trials should comply with the SPIRIT Statement (Standard Protocol Items: Recommendations for Interventional Trials)

- EDCTP expects the study protocol and analysis plan to be made publicly available. It is recommended that details of where and how this information may be accessed be provided in the registry entry (WHO-primary registry or ICMJE-approved registry).

- In 2018, EDCTP's policy on clinical trials registration, publication and data sharing was published
  - Covering expectations around study protocols, clinical study registration, reporting timeframes for clinical trials and clinical studies, and open access to scientific publications and research data

EDCTP's approach to open access data sharing

- Open access to research data is firmly anchored in the EU Horizon 2020 (H2020) Regulations

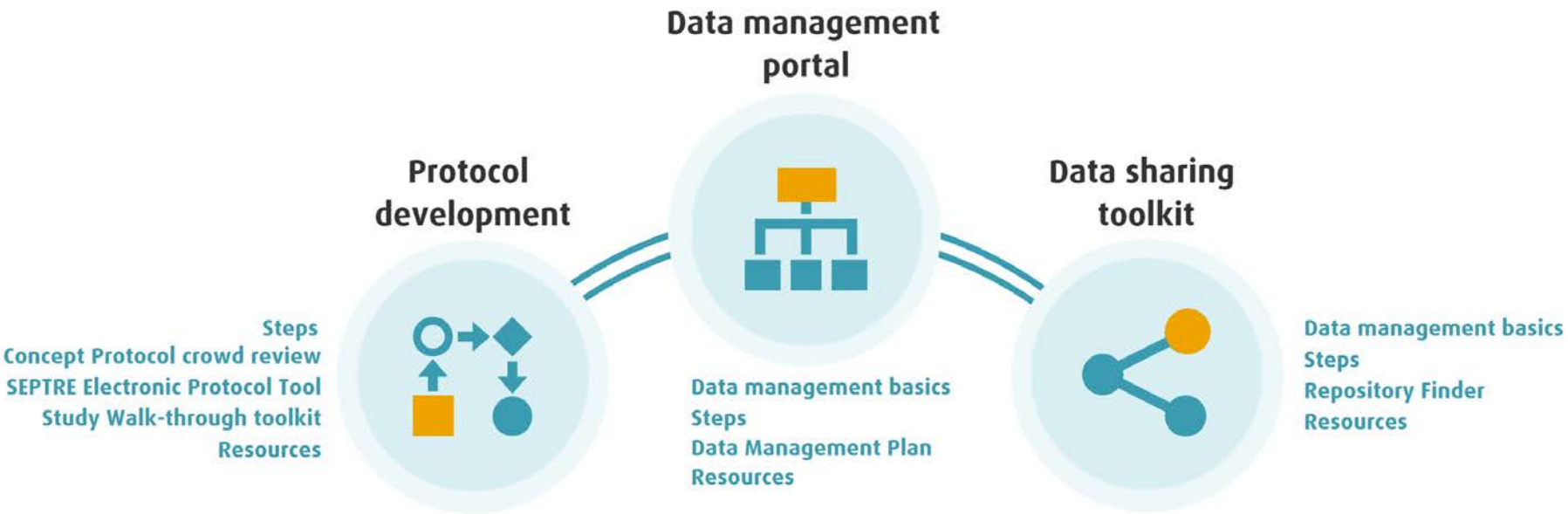
- EDCTP's Grant Agreements (GAs) require all grantees to make it possible for third parties to access, mine, exploit, reproduce and disseminate – free of charge for any user – the data that they generate (in keeping with H2020), unless it goes against their legitimate interests as laid out in the GAs

- EDCTP became a signatory to the Joint statement on public disclosure of results from clinical trials on 5 July 2017

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

Protocol development toolkit

Protocol Development Steps

The Protocol Development Steps provide guidance on all elements of Protocol development in addition to practical advice on how to navigate regulations and guidelines...

Concept Protocol Crowd Review

Use the Concept Protocol Crowd Review Tool to invite feedback and advice on your concept protocol from the EDCTP Knowledge Hub and The Global Health Network community.

SEPTRE Electronic Protocol Tool

SEPTRE (SPIRIT Electronic Protocol Tool & Resource) is an innovative, web-based software solution that makes it easier to create, manage, and register high-quality...

Study Walk-through Toolkit

The 'Study Walk-through' is a method to help translate your protocol into an accurate and successful study. This toolkit describes the study walkthrough approach, why it might...

Resources

We have also collated an extensive collection of resources linked to Protocol Development which can be searched and filtered depending on their type.

PROTOCOL DEVELOPMENT STEPS »

Data management portal

Data Management Steps

1 Getting started

Data Management

Getting started

Planning is a critical step in Data Management and this should commence before the Protocol has been finalised. See the steps below for getting started with Data Management, the link in the sidebar will take you to more detailed sections on the topics covered.

Requirements and Guidelines

Make sure you are familiar with the regulations associated with your data and any funder and/or institutional requirements with regard to data management, they may have policies or guidance stipulating how data should be monitored, shared, archived and timeframes for these activities.

Protocol Development

'The Clinical Data Management (CDM) process, like a clinical trial, begins with the end in mind. This means that the whole process is designed keeping the deliverable in view. As a clinical trial is designed to answer the research question, the CDM process is designed to deliver an error-free, valid, and statistically sound database. To meet this objective, the CDM process starts early, even before the finalisation of the study protocol.' **Data management in clinical research: An overview**

Good data management requires proper planning and should begin in parallel with protocol development to ensure that all of the protocol-specified data is accurately captured. Plans for how assessments will be performed, what and how data will be collected, entered, coded, stored, protected, analysed and quality controlled all need to captured in the protocol or separately with a reference to where this information can be located. The **SPIRIT Checklist** provides a list of recommended Items to address in a clinical trial protocol several of which are focused on data management.

For further information on developing your protocol see node 4 on the **Process Map** and the **Protocol Development Toolkit**.

Data Management Plan

The **Data Management Plan (DMP)** is a very important piece of study documentation and should be included as annex to the protocol. Depending on the

1 **Getting started**
- Protocol Development Toolkit
- TGHN Process Map: Protocol
- The SPIRIT Checklist
- Data Management Plan

System Design 2
- CRF Design & examples
- Choosing a CDMS

3 **Data Organisation**

Data Entry 4

5 **Data Processing**
- Example from an SOP

Data Monitoring 6

7 **Interim Data Lock**

Data Management Plan Template Questions

Data Management Plan: Background and methodology

What type of study are you conducting?
E.g. experimental (including clinical trials), a laboratory or epidemiological study, qualitative research observational or an economic evaluation?

What type of data is being collected?
Consider what data and software outputs your research will generate. What file formats will you use for your data? Tip: Have you considered whether these formats allow for data re-use, sharing and long-term access to the data?

What is the origin of the data?
s existing data being reused? If so, what is the relationship between the data you are collecting and the existing data?

hat is the purpose of the data collection/generation?
lain the relation to the objectives of the project. Outline the data utility: to whom might it be useful?

methodologies will be used for data collection and management?
will you capture or create the data? Describe what codes of practice, if any, will you follow for creating and handling data. What rmats or standards will be utilised for data collection and management? Include the procedures for quality assurance that will ed out on the data collected at the time of data collection, data entry, digitisation and data checking. What software tools will to create, analyse or use data?

e expected size/volume of the data?

Data Management Plan: Documen

How will you organise your data
What method will yo
use and

Data sharing toolkit

How do I share my data?

Toolkit

OVERVIEW OF THE MAIN STEPS

1. CHOOSE A SUITABLE REPOSITORY & SET UP AN ACCOUNT

- Your funder may require you to submit the data to a specific repository. Some funders have strict requirements, while others provide a list of recommended repositories.
- Journals may also require deposits to a specific repository and/or may recommend repositories.
- There may be discipline-specific and disease-specific repositories that are preferable. You can also look up repositories in your discipline using re3data and FAIRsharing.
- If your funder/journal do not provide any guidance, or if you are not familiar with repositories used in your field, we provide guidance on how to choose a suitable repository in the Repository Checklist.
- Make sure to familiarise yourself with the repository guidelines.

2. ORGANISE YOUR DATA

- Decide on the best way to organise your data - sometimes it is best to merge several files into one dataset, but in other cases depositing separate files makes more sense.
- Structure and name your files well - for your own use and to assist others.

3. PREPARE YOUR DATA

- Are your data clean and labelled consistently? Be explicit in your naming to ensure that others can understand your data.
- Are you using non-proprietary formats to ensure accessibility now and in the future? If you need to use discipline-specific format you may consider submitting two versions of the file – one in the discipline-specific format and one in non-proprietary format.
- If data are in a discipline-specific format you should double check that the repository will accept that format.

4. PREPARE DOCUMENTATION FILES

- All variable labels, codes and acronyms should be either self-

1

Repository Finder
Different models of access
Options offered by repositories
List of funder & journal recommended repositories
Funder requirements

2

Data organisation
File organisation
File naming

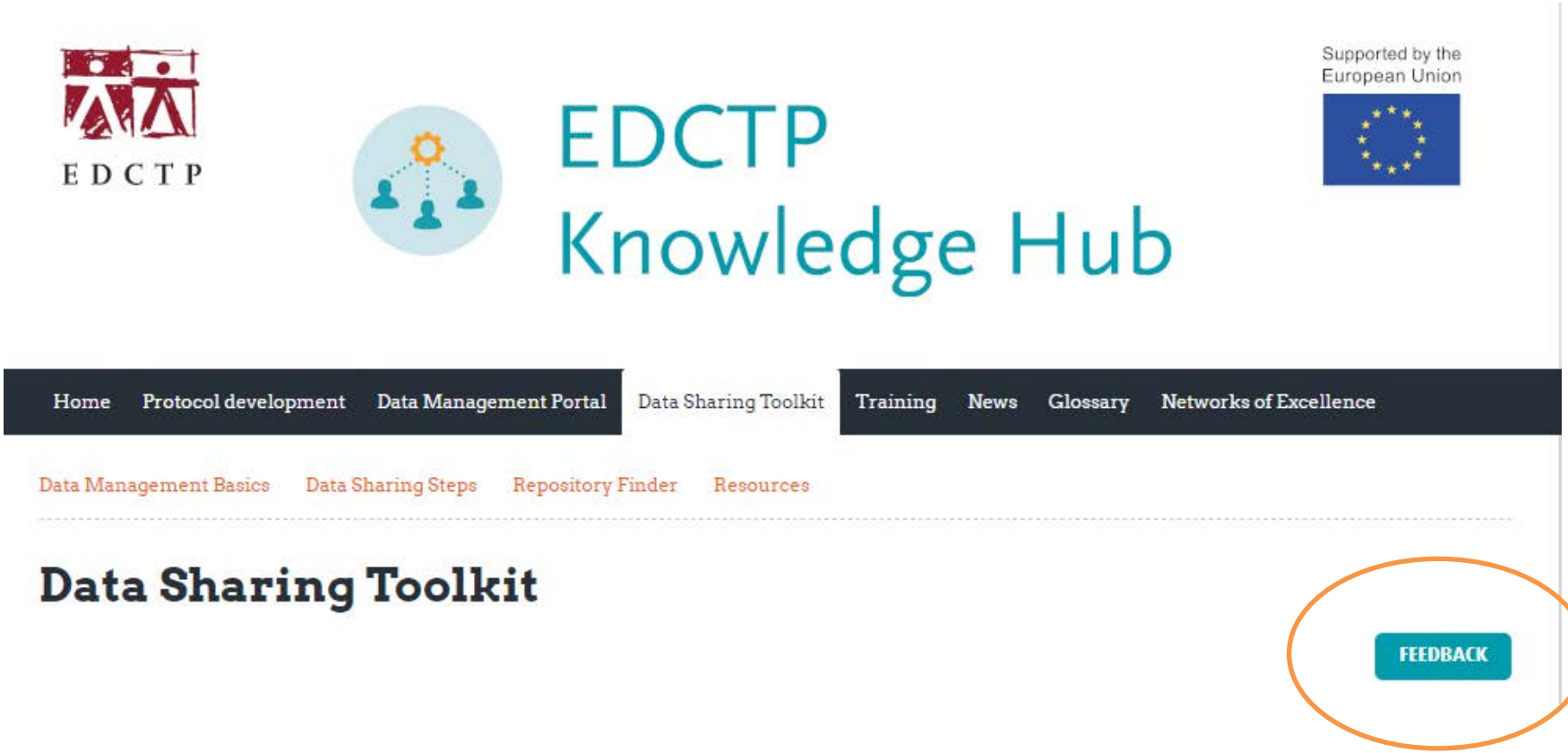
3

Example: data structure
Example: data labelling
Non-proprietary formats list
Anonymisation and de-identification

4

Example: README file
Checklist of potential files to include

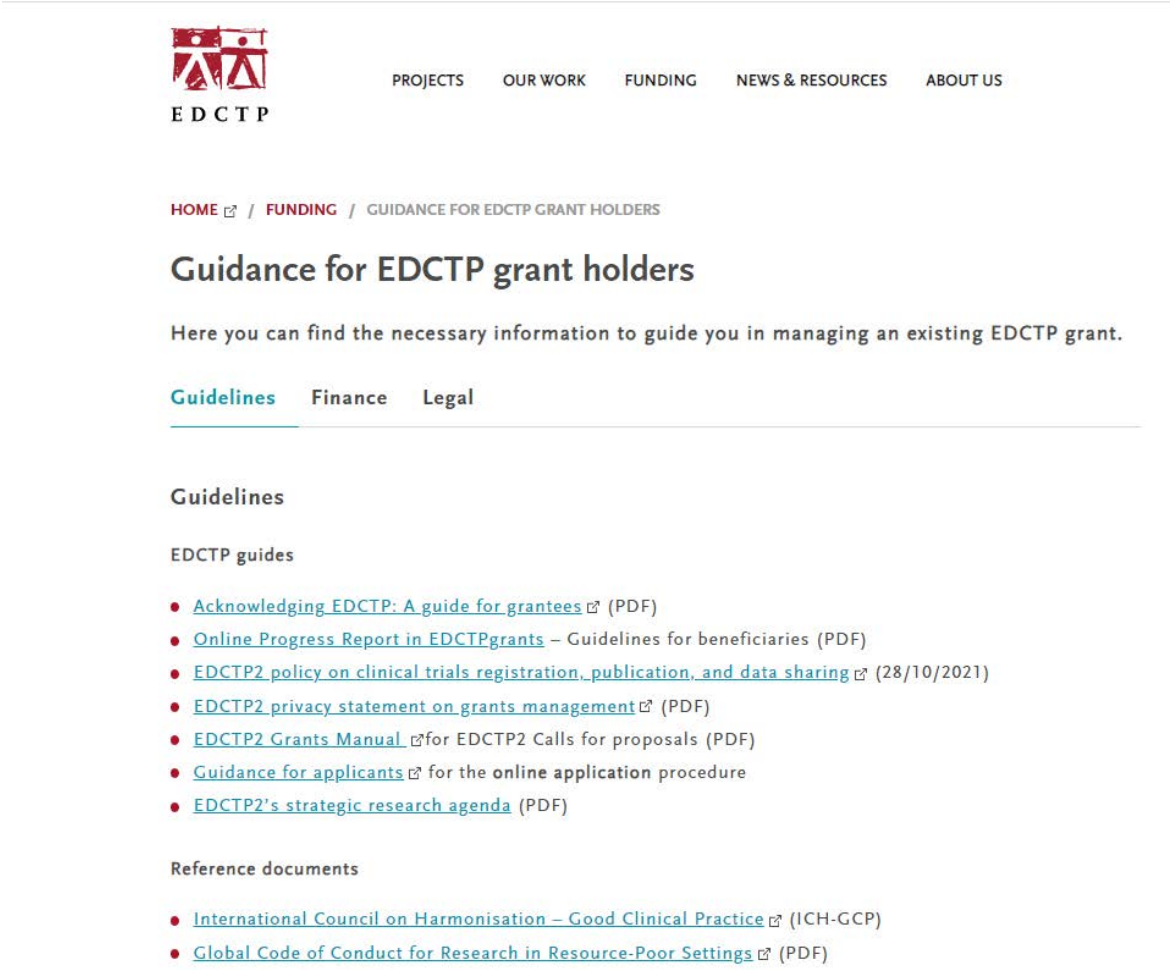
Feedback options



7

Q&A

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/

Thank you

www.edctp.org | media@edctp.org