

EDCTP2 policy on clinical trials registration, publication and data sharing

Document history		
Version	Date	Changes
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Background

EDCTP became a signatory to [the Joint statement on public disclosure of results from clinical trials¹](#) on 5 July 2017. This policy document sets out the expectations of EDCTP and the requirements that EDCTP grant holders conducting clinical trials and clinical studies must comply with.

1 Introduction

EDCTP is a major funder of clinical trials and clinical studies in sub-Saharan Africa. As a signatory to the WHO joint statement, EDCTP affirms that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore, timely results disclosure reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health.

EDCTP expects that all grant holders will comply with the joint statement and will ensure that trial results are published in a timely manner through prompt disclosure of summary results and Open Access publications.

2 Features of this policy

The following studies are included in this policy:

2.1 Clinical trials and clinical intervention studies

Studies which meet the broad definition used by the World Health Organization (WHO) for a clinical trial, which includes all studies evaluating the impact of interventions on human participants: *"any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."*

Interventions may include drugs, vaccines, cells and other biological products, surgical procedures, radiological procedures, devices including diagnostic devices, behavioural treatments, process-of-care changes, preventive care, or other treatments. Clinical trials at all stages, from Phase 1 to Phase 4 and global health trials, are included in this policy.

2.2 Public health intervention studies

Studies in which there is a public health intervention to promote or protect health, or prevent ill-health, in communities or populations rather than individuals.

2.3 Observational studies

Studies in which the researcher assesses outcomes in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle or behaviours, or interventions that are part of routine care and not influenced by the researcher.

Studies on human tissues and cells that have already been collected are not part of this policy.

3 Clinical Study Registration

It is mandatory that all clinical trials and interventional studies (categorised as 1 and 2 above) are registered. EDCTP recommends the registration of observational studies (category 3).

3.1 Choice of registry

Studies must be registered in a primary registry in the [WHO International Registry Network²](#) or [ICMJE approved registry³](#) before recruitment of the first subject. Registration of EDCTP-funded clinical trials is mandatory and is a deliverable in EDCTP2 projects. EDCTP supports the Pan-African Clinical Trials Registry for clinical trials registration.

3.2 Completeness and accuracy of the clinical study registry record

EDCTP expects the registry record to be as complete and accurate as possible. All relevant fields of the registry entry must be completed. The entry must be updated regularly (at least annually) in order to chart accurately the progress of the study.

In particular, the following information must be recorded and updated to ensure accuracy:

- Final enrolment numbers achieved
- Date of primary study completion (defined as the last data collection timepoint for the last subject for the primary outcome measure).

If clinical trials/studies are terminated, their status should be updated to note the date of termination, and to report the numbers enrolled up to the date of termination.

3.3 Study protocol

To ensure transparency, EDCTP expects the study protocol and analysis plan to be made publicly available. EDCTP recommends that details of where and how this information may be accessed be provided in the registry entry. The study protocol for clinical trials should comply with the [SPIRIT Statement⁴](#) (Standard Protocol Items: Recommendations for Interventional Trials). It should be noted that the ICJME requires all submitted manuscripts that report clinical trials results to include a [data sharing plan⁵](#) in the trial's registration.

4 Reporting timeframes for clinical trials and clinical studies

EDCTP expects that the results of EDCTP-funded trials and studies will be made available without undue delay. The summary results of clinical trials should be made publicly available in a timely manner following primary study completion. This may be done by posting to the results section of the clinical trial registry and by journal publication.

4.1 Publication of summary results (primary outcome)

EDCTP expects that grant holders will disclose the summary results of the study within **12 months** from primary study completion (the last visit of the last subject for collection of data on the primary outcome).

4.2 Publication in a peer-reviewed journal

Publication in a journal is expected within **24 months** from study completion. The Trial ID or registry identifier code/number should be included in all publications of clinical trials, and should be provided as part of the abstract to PubMed and other bibliographic search databases for easy linking of trial related publications with clinical trial registry site records. This is essential for linking journal publications with registry records.

Beneficiaries must acknowledge [EDCTP funding⁶](#)

At the end of each grant, the final report to EDCTP must include a report on the status of posting results in the study registry (including timelines when final posting of results is scheduled after end of the funding period). To be scheduled for the time of expected results posting or for the last months of the project, whichever comes earlier).

Research results should be reported in accordance with the recommendations of the [CONSORT Statement⁷](#) or an alternative reporting guideline appropriate to the study design (see the [EQUATOR Network⁸](#)).

4.3 Monitoring the registration and reporting of EDCTP-funded trials

EDCTP tracks the registration and reporting of EDCTP-funded trials during the lifetime of the EDCTP grant and post grant closure. Beneficiaries that fail to report trials in a timely manner without due justification may be subject to audit. Furthermore, as part of the application process, EDCTP may request applicants to provide details of previous studies and when these were reported. This may be taken into consideration during the evaluation of the operational capacity of the applicants.

5 Open access to scientific publications and research data

The EDCTP2 programme is funded under the Horizon 2020 programme (H2020) and is committed to open access. Open access refers to the practice of providing online access to scientific information that is free of charge to the end-user and reusable. This encompasses:

- Peer-reviewed scientific research articles (published in scholarly journals)
- Research data (data underlying publications, curated data and/or raw data).

5.1 Peer-reviewed scientific publications

Article 29.2 of the EDCTP2 grant agreement sets out the legal requirements on open access to scientific publications. Each beneficiary must ensure open access to all peer-reviewed scientific publications relating to its results. EDCTP is a member of Europe PubMed Central (Europe PMC <https://europepmc.org/>) 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.

Open access to other types of publications is also recommended.

5.2 Open Research Data

Open access is the default setting for research data generated in EDCTP2 and H2020. For more information see the [H2020 guidelines on Open Access⁹](#). The legal requirements for projects participating in the Open Research Data pilot are set out in Article 29.3 of the EDCTP2 grant agreement. However, not all data can be open. Beneficiaries must ensure data privacy and that personal data are not shared.

Projects may opt out of the open research data pilot at any stage (either before or after signing the grant) and so free themselves retroactively from the obligations associated with the conditions if:

- Participation is incompatible with rules on protecting personal data
- Participation is incompatible with the obligation to protect results that can reasonably be expected to be commercially or industrially exploited
- Participation is incompatible with the need for confidentiality in connection with security issues
- Participation would mean that the project's main aim might not be achieved
- The project will not generate / collect any research data or
- There are other legitimate reasons

EDCTP expects all projects conducting clinical studies to have a data management plan that is updated during the course of the project. A data management plan is a mandatory deliverable for EDCTP2 projects (RIAs). Data sharing should follow FAIR principles¹⁰ and projects should have robust mechanisms, such as a Data Access Committee¹¹ in place for responding to requests for data. EDCTP has partnered with the Global Health Network to create the EDCTP Knowledge Hub (<https://edctpknowledgehub.tghn.org/>) to assist researchers conducting clinical trials through provision of tools for protocol development, data management and data sharing.

5.3 Research actions targeting public health emergencies

For actions targeting public health emergencies, the beneficiaries must deposit the digital research data generated in the action in a research data repository and take measures to make it possible for third parties to access, mine, exploit, reproduce and disseminate the data free of charge for any user, at the latest within 30 days after it has been generated.

References

1. Joint statement on public disclosure of results from clinical trials:
<http://www.who.int/ictrp/results/jointstatement/en/>
2. WHO International Registry Network <http://www.who.int/ictrp/network/primary/en/>
3. ICMJE-approved registry: <http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>
4. SPIRIT Statement (Standard Protocol Items: Recommendations for Interventional Trials)
<http://www.spirit-statement.org/>
5. ICMJE Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf
6. Acknowledging EDCTP: A guide for grantees
<http://www.edctp.org/web/app/uploads/2018/05/Acknowledging-EDCTP-a-guide-for-grantees.pdf>
7. CONSORT Statement <http://www.consort-statement.org/>
8. EQUATOR Network Reporting Guidelines for Main Study Types <https://www.equator-network.org/>
9. Guidelines to the Rules on Open Access to Scientific Publications and Open Access to Research Data in Horizon 2020
http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf
10. FAIR Guiding Principles for scientific data management and stewardship <https://www.go-fair.org/fair-principles/>
11. Cheah, PY and Piasecki, J 'Data Access Committees' BMC Medical Ethics (2020) 21:12
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