



EDCTP

European & Developing Countries
Clinical Trials Partnership

Terms of Reference for the “Development of a Data Management Portal” in support of open access of clinical data from EDCTP2-funded clinical trials

Background

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between 16 African and 14 European countries. These 30 countries, also called the Participating States, are members of the EDCTP Association. The Association is the legal structure for the implementation of the second EDCTP programme (EDCTP2; 2014-2024) which is cofunded by the European Union (EU) under its Framework programme for research and innovation; Horizon 2020.

EDCTP aims to support collaborative research that accelerates the clinical development of new or improved medical interventions (drugs, vaccines, microbicides and diagnostics) to prevent or treat HIV, tuberculosis (TB), malaria and neglected infectious diseases in sub-Saharan Africa. EDCTP funds mainly clinical trials in sub-Saharan Africa, but also supports relevant individual, institutional, national and regional capacities for clinical research as well as research ethics review in sub-Saharan countries.

EDCTP, like many funders and academic journals, promotes the sharing of primary clinical data is increasingly required by academic journals and funders, including EDCTP. The usefulness of open access to clinical research data is, however, severely hampered by insufficient capacity for good data management in many low-resource settings, the lack of a common global standard for data sharing, and the limited inter-operability between different repositories for clinical research data. EDCTP requires the services of a consultant to develop an online resource centre on data management for researcher in low to middle-income countries.

The deliverables of this assignment are expected to support EDCTP beneficiaries in fulfilling their contractual obligations to develop a final dataset that is valid, curated and harmonised for sharing through an openly accessible data repository so that third parties can access, mine, exploit, reproduce and disseminate openly accessible research data free of charge.

Purpose of the assignment

The main purpose of this assignment is to establish an online resource centre for researchers involved in clinical trials in low-resource settings by providing them:

1. access to free, suitable high standard data management tools/systems
2. access to guidance documents on good data management and data sharing
3. training resources and online expert support to enable better data management practices with the ultimate goal for researchers in LMICs to share primary clinical and associated metadata in a suitable data repository.

Scope of work

The assignment will be in two phases

The contractor/consultant would be required to conduct first an in-depth analysis of available repositories, electronic tools and current practices in data management that are applicable to clinical trials on PRDs (poverty-related diseases). The activities will include:

- Conducting a comprehensive review of existing data management systems that are available free-of-charge for clinical researchers in low- and middle-income countries.



EDCTP

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Clinical Trials Partnership

- Developing an online interactive decision tool that allow researchers from low- and middle-income countries to access suitable data management tools for clinical research
- Developing new or enhanced data management tools for clinical research to close any identified gaps
- Maintaining and updating the digital resource centre for at least 36 months.

Outputs

The overall output is an online digital resource centre for data management for clinical researchers from low- and middle-income countries, including EDCTP-funded grants. The digital resource centre should include guidance and practical information on good clinical data management, and provide easy access to the most suitable, free-of-charge, online data management tools. The data management tools may include existing data management tools, or may include new tools or extensions to existing tools that are developed as part of the current assignment.

Procedures and deadline for submission of proposals

The proposal must include at least a technical section and a financial section. The technical section should include:

- The proposed approach to the engagement, including timelines and deliverables at different time points
- Summary of previous experience including reference to any similar assignments previously carried out
- Technical expertise/specialist skills in this field
- Project management skills: ability to complete the task according to time, budget and scope, and management of relationships with relevant information providers (ability to obtain quality data from likely sources)
- Proposed staffing for this assignment, including names and qualifications of the personnel
- The financial section must clearly show the total fee charge for the assignment and how it has been calculated, including a breakdown of the expected man hours and the charge out rate for each proposed team member

The proposal should be submitted via email (attachment) to Ms Andreia Coelho at coelho@edctp.org, with "Data management resource centre" in the subject line of the email no later than **01 May 2018 at 18:00 CET**.

Alternatively, you may send it in a sealed envelope clearly marked "Data management resource centre" to Ms Andreia Coelho, EDCTP Secretariat, Anna van Saksenlaan 51, 2593 HW The Hague, The Netherlands before the deadline of 27 April 2018.

Further information may be obtained from Ms Andreia Coelho, EDCTP Administrative Officer (coelho@edctp.org) during working hours (Tuesday – Friday, 9.30 -17.30, CET). Late submissions will not be considered.

Please note that any inquiries and requests for information will be made available to the public on the EDCTP website. Inquiries sent after 27 April 2018 will not be responded to.

Currency of the proposal

The proposed fee shall be in euros.

Evaluation criteria for the proposal

The proposals will be evaluated using one of two methods:



EDCTP

European & Developing Countries
Clinical Trials Partnership

- **Quality-price selection method**
A minimum score for the technical proposal is specified. A quality-price ratio is calculated for all proposals that exceed the minimum score for the technical proposal, and the proposal with the highest quality-price ratio will be selected.
- **Least selection method**
A minimum score for the technical proposal is specified, and the proposal with the lowest price is selected.

Legal framework

Any subsequent contract shall be governed by Dutch law.

Timing

| Activity | Timeline |
|--|-------------------------------------|
| Receipt of proposals from eligible firms/consultants | 27 April 2018 |
| Evaluation and selection of firm/consultant | 28 May 2018 |
| Deadline for completion of digital data management resource centre | 1 year after the contract signature |