

REQUEST FOR PROPOSAL (RFP)
**CONTRACT RESEARCH ORGANIZATION TO SUPPORT SITE MONITORING OF FIND-
SPONSORED CLINICAL TRIALS**

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1. LIST OF ACRONYMS AND DEFINITIONS

AE	ADVERSE EVENT
CDA	CONFIDENTIALITY DISCLOSURE AGREEMENT
CRA	CLINICAL RESEARCH ASSOCIATE
CRF	CASE REPORT FORM
CRO	CLINICAL RESEARCH ORGANIZATION
CTU	CLINICAL TRIALS UNIT
CV	CURRICULUM VITAE
EDC	ELECTRONIC DATA CAPTURE
GCP	GOOD CLINICAL PRACTICE
HSR	HUMAN SUBJECT RESEARCH
IEC	INSTITUTIONAL ETHICS COMMITTEE
IRB	INSTITUTIONAL REVIEW BOARD
IVD	IN VITRO DIAGNOSTIC DEVICE
LMIC	LOW- AND MIDDLE-INCOME COUNTRY
PD	PROTOCOL DEVIATION
PV	PROTOCOL VIOLATION
R&D	RESEARCH AND DEVELOPMENT
RFP	REQUEST FOR PROPOSALS
SAE	SERIOUS ADVERSE EVENT
SOP	STANDARD OPERATING PROCEDURE
USD	UNITED STATES DOLLAR
WHO	WORLD HEALTH ORGANIZATION

2. BACKGROUND INFORMATION

FIND seeks to ensure equitable access to reliable diagnosis for all. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems. We are working to save 1 million lives through accessible, quality diagnosis and save USD 1 billion in healthcare costs to patients and health systems. We are a co-convenor of the Access to COVID-19 Tools (ACT) Accelerator diagnostics pillar and a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. FIND, under various disease programmes, conducts studies through its Clinical Trials Unit (CTU). CTU's mission is to deliver high-quality human subject research (HSR) and strengthen clinical research capacity in low- and middle-income countries (LMICs). FIND's CTU ensures fairness, respect, care and honesty towards all study participants and collaborators by conducting adequate oversight, management and monitoring of study sites and data, as per Good Clinical Practice (GCP) and local regulations. To support our clinical studies in LMICs, FIND is currently seeking to engage external partners who can provide onsite management and site monitoring.

More information about FIND and our programmes can be found at www.finddx.org.

3. STATEMENT OF PURPOSE

The purpose of this Request for Proposals (RFP) is to enter into a master contractual agreement with a successful applicants and engage them as a partner to carry out onsite management and monitoring of clinical studies, as and when the requirement arises.

FIND as an organization is dependent on the budgetary and extra-budgetary contributions it receives for the implementation of its activities. Bidders are therefore requested to propose competitive and highly cost-effective solutions to meet FIND's requirements, while ensuring a high level of service.

4. SCOPE OF WORK AND DELIVERABLES

The purpose of trial monitoring activities is to verify that:

- The rights and well-being of human participants are protected.
- The trial data captured are accurate, complete and verifiable from source documents.
- The conduct of the trial complies with the approved protocol/amendment(s), with GCP, and with any other relevant local and international standards.

Activities will include conducting in-person visits to study sites. These visits will include assessing study documentation, assessing the use of the investigational product, source data verification, and query generation and resolution (as required). The successful Bidder will receive the respective trials' monitoring manuals and standard reporting templates, to guide monitoring and reporting activities.

Monitoring visits will include:

- Verifying the correct preparation, storage and use of the investigational product.
- Verifying that the investigator(s) are following the approved protocol.
- Verifying that written informed consent was obtained before each subject's participation in a trial.
- Ensuring that the investigator has all study documents and trial supplies needed to correctly conduct the trial.
- Verifying that the investigator is enrolling only eligible participants and is accurately reporting the subject recruitment rate.
- Verifying that source documents, case report forms (CRFs) and other trial records are accurate, complete and up to date.
- Informing the investigator and sponsor of any errors or omissions.
- Determining whether all adverse events (AEs), serious adverse events (SAEs), protocol deviations (PDs) and protocol violations (PVs) are appropriately managed and reported, including reporting within the time periods required by GCP, the protocol, the Institutional Review Board/Institutional Ethics Committee (IRB/IEC), the sponsor and any other relevant standards.
- Determining whether the investigator is maintaining the essential study documents in the investigator's site file.
- Communicating any deviations or issues to the investigator and the trial sponsor.
- Following up on any queries/problems already identified by a study's data management team.
- Preparation of brief, written monitoring reports, to be submitted to FIND in a timely manner.

FIND staff will conduct orientation training for the clinical research organization (CRO) or team of clinical research associates (CRAs) in the study protocol and the EDC(Electronic Data Capture) system before commencing any activity. In addition, the selected Applicant will undergo training in FIND's internal policies and standard operating procedures (SOPs).

5. PERFORMANCE STANDARDS

- FIND pays close attention to the qualifications and experience of all individuals involved and to continuity of the services provided. The qualifications and experience of the personnel proposed for these services should be included in the technical proposal. Please note the following:
- All staff associated with the project must be GCP-accredited.
- All staff must have full professional working proficiency/native or bilingual proficiency in English.
- The Bidder is expected to present a clear organogram and outline the roles and responsibilities of all staff to be involved, as part of the technical proposal.

6. APPLICATION GUIDELINES

The selection of successful applicants will be based upon an assessment of the applications. FIND reserves the right to request further information throughout the RFP process.

Candidates interested in responding to this RFP should submit a proposal, in Microsoft Word or PDF format, that includes the following information:

- Organizational profile: a short overview of your organization and a brief outline of services/products provided.
- Experience: relevant experience, including a list of relevant projects you have worked on in the past (with a description and the duration of each assignment, along with the size of the team involved). Ideally, short case studies should also be included.

Additionally, please utilize the information in the text box as assumptions to offer further details.

Case Study (to be used as assumptions for the additional information requested underneath)

This is a multicentric study to evaluate new molecular point-of-care diagnostics for the detection of tuberculosis among adults with signs and symptoms of tuberculosis presenting to peripheral health centres and hospitals in five countries.

- Scope of work: support end-to-end monitoring, data monitoring and cleaning
- Study duration: 12 months (enrolment 10 months, follow-up 1 month, data cleaning 1 month)
- Study sites: five sites around the world (two in India, one in Kenya, one in South Africa and one in Indonesia)
- Type of monitoring visits: SIV(Site Initiation Visit), IMV(Interim Monitoring Visit) and COV(Close Out Visit)
- Site visits per site: one SIV, two onsite monitoring visits, and one COV; additionally, regular data monitoring and cleaning will be required
- Number of participants: 250 per site
- Number of CRFs: 10 CRFs and 300 data points per patient

Based on the Case Study:

- Proposed work plan: the work plan should explain the plan for implementing the main activities/tasks related to the Case Study, their content and duration, phasing and interrelationships, milestones (including interim deliverables), and tentative delivery dates for the reports.
- The proposed work plan should be consistent with the technical approach and methodology you would propose for the outlined study.
- Deliverables: a list of the final documents (including reports) to be delivered as the final output(s) should be included.
- Budget: a financial proposal for this Case Study, with a full breakdown (in USD) of staff cost components/level of effort (for staff) and/or of 8-hour days, with daily rates required per deliverable (for consultants) and any other direct costs (please refer to the budget template provided in Appendix A). In the budget estimate, please include any additional expenses expected to be incurred during the execution of the scope of work.
- Proposed team: short biographies of key staff to be involved in the work, along with their roles and responsibilities; include complete CVs of key personnel proposed as team members.

- Networks and partnerships in the countries in scope: provide details of local teams, partners and/or other stakeholders that are to be involved in the completion of this work.
- In cases where subcontractors are to be involved, describe the role(s) and expertise of each organization/individual chosen to participate in this project as a subcontractor.
- Complete and submit the Vendor Assessment Form ([Link](#))

7. AWARD CONDITIONS

Applicants/Bidders that are selected for final award are required to:

- Be legally permitted to perform work in the country where the contract will be executed.
- Commit to and follow the [FIND Global Access Policy](#) (mandatory for the research and development (R&D), manufacture and supply of in vitro diagnostic devices (IVDs)) and the [FIND Code of Conduct and Ethics](#).
- Meet any other conditions that are relevant to this call.

8. HOW TO APPLY

If you wish to express your interest in this RFP, please prepare an application (comprising a cover letter and technical proposal including a budget), explaining how your skills would support our needs. All documents must be written in English and formatted in Microsoft Word or as a PDF.

9. EVALUATION AND AWARD PROCESS

The evaluation process is designed to be objective, independent and transparent, to ensure that the most suitable proposals are identified. Proposals from Applicants will be evaluated by an internal review panel comprising members of the FIND Medical Affairs department. Proposals will be evaluated against the following criteria:

- The proposed work plan, indicating Applicants' understanding of the scope of work based on the assumptions of the Case Study and the extent to which the proposed activities match the activities listed in this RFP.
- Experience in conducting monitoring for diagnostic studies in LMICs.
- The quality of the financial proposal as well as the transparency and breakdown of all financial elements. Applicants should provide as much information as possible to explain their proposed budget and include further assumptions if needed.
- Proposed team: the "quality" (i.e. composition, experience) of the team that would work on the outlined study. Applicants must describe all team members, detailing their background and experience; complete CVs for all proposed team members must also be submitted.
- Physical locations of Applicants in the countries in scope, e.g. access to networks of relevant stakeholders in the specific countries.

The selection of successful applicants will be based upon an assessment of the applications. FIND reserves the right to request further information throughout the RFP process.

10. TERM OF CONTRACT

The contract will be awarded for 1 year initially and subsequently renewed based on quality and performance.

11. CONFIDENTIALITY

FIND considers any proposal received under the RFP to be confidential. If required, FIND can sign a confidentiality disclosure agreement (CDA) with interested Applicants prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the proposal submitter. Review of proposals will be carried out by an internal review panel comprising members of the FIND Medical Affairs department all of whom are bound by confidentiality agreements and will be recused if

found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team (see Section 13).

12. TIMELINES

	Activity	Expected date
1	Publication of RFP	15 May 2023
2	Closing date for submission of written queries	31 May 2023
3	Closing date for RFP proposals	31 May 2023
4	Communication of award(s) of contract	30 June 2023
5	Contract(s) signed with successful Applicants	7 July 2023

13. QUESTIONS AND COMMUNICATIONS PROTOCOL

Please email any questions to: ctu@finddx.org. Questions will be accepted and promptly responded to until 31 May 2023 at 6pm CET.

14. APPENDIX A

Download the Appendix A: [Budget Template for Applicants](#)

NAME OF THE APPLICANT :						
TITLE OF THE PROJECT :						
PROJECT FUNDER:		FIND				
PROJECT TERM:		dd/mm/yyyy				
BUDGET ASSUMPTION, CALCULATION AND VALUES						
STAFF						
Position	Location	Mesurement Unit	Unit Cost	Number of Units	Total requested (USD)	Comments and Justifications
			\$ -	0.00	\$ -	
			\$ -	0.00	\$ -	
Fringe benefits, if any				0%	\$ -	
Total staff costs (USD)					\$ -	
CONSULTANTS						
Budget line	Location	Mesurement Unit	Unit Cost	Number of Units	Total requested (USD)	Comments and Justifications
			\$ -	0.00	\$ -	
			\$ -	0.00	\$ -	
Total consultant costs (USD)					\$ -	
TRAVEL RELATED						
Budget line		Mesurement Unit	Unit Cost	Number of Units	Total requested (USD)	Comments and Justifications
					\$ -	
					\$ -	
Total consultant costs (USD)					\$ -	
SUPPLIES AND EQUIPMENT						
Budget line		Mesurement Unit	Unit Cost	Number of Units	Total requested (USD)	Comments and Justifications
					\$ -	
					\$ -	
Total consultant costs (USD)					\$ -	
OTHER PROJECT EXPENSES						
Budget line		Unit Cost	Unit Type	# of Units	Total requested (USD)	Comments and Justifications
					\$ -	
					\$ -	
TOTAL PROJECT COSTS					\$ -	