

FM 03-05-05

REQUEST FOR PROPOSAL (RFP)

COMMUNITY-BASED APPLICATIONS OF SARS-CoV-2 ANTIGEN RAPID DIAGNOSTIC TESTS (AG-RDTS) FOR TIMELY AND EFFECTIVE PUBLIC HEALTH RESPONSE

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Ag-RDTs	Antigen rapid diagnostic tests
COVID-19	Coronavirus disease 2019
LMICs	Low- and middle-income countries
LOI	Letter of intent
NAAT	Nucleic acid amplification tests
OR	Operational research
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
WHO	World Health Organization

1. ACRONYMS AND DEFINITIONS:

2. BACKGROUND INFORMATION:

The Access to COVID-19 Tools Accelerator is a global collaboration focused on accelerating the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. The ACT-Accelerator aims to deliver 2 billion vaccine doses by the end of 2021, 245 million courses of treatment, and 800 million diagnostic tests to low- and middle-income countries (LMICs). The diagnostics pillar of the ACT-Accelerator is co-convened by FIND and the Global Fund. It aims to rapidly identify game-changing new diagnostics and bring 900 million affordable, high-quality tests to LMICs by 2022. In September 2020, the ACT-Accelerator announced that 120 million antigen rapid diagnostic tests (Ag-RDTs) had been reserved for LMICs at a maximum price of US\$ 5 per unit, with subsequent investments in manufacturing further reducing Ag-RDT prices to under US\$2.50 in Q1 2021.

FIND, the global alliance for diagnostics, was established in 2003 as a global non-profit organization dedicated to accelerating the development, evaluation, and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, Ebola virus disease, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, and acute febrile illnesses. FIND functions as a global health product development partnership, engaging in active collaboration with over 150 partners. FIND's headquarters are in Geneva, Switzerland, with country offices in India, South Africa, Kenya, and Vietnam. More about FIND and our programmes can be found on www.finddx.org.

Testing for SARS-CoV-2 infection is essential for the control of COVID-19, enabling epidemiological surveillance and implementation of public health measures. At the community level, swift identification and isolation of new cases, combined with contact tracing, are important tools for controlling virus transmission.

While nucleic acid amplification tests (NAAT) have high sensitivity and specificity and are considered the gold standard for detection of SARS-CoV-2, they are expensive, their availability is limited, and they require uninterrupted power supply, as well as laboratory-qualified personnel. Thus, NAAT testing is frequently performed in centralized laboratories only, which can limit use and delay results, especially in LMICs. In contrast, Ag-RDTs are relatively cheap, simple to perform, and provide results in less than 30 minutes. A number of Ag-RDTs have received WHO Emergency Use Listing. The sensitivity of Ag-RDTs is less than NAAT, thereby resulting in some false negatives, especially in asymptomatic individuals. However, the relative ease of use and low cost of Ag-RDTs make them a potentially valuable tool for community-based applications to rapidly detect SARS-CoV-2 transmission and guide response. Furthermore, modeling studies have indicated that the benefit of frequent testing and immediate result with Ag-RDTs may outweigh the limitations from their lower sensitivity.



In light of this, on behalf of the ACT Accelerator Operational Research Working Group, FIND is requesting operational research proposals for *projects optimizing the use of Ag-RDTs for community-based detection and response in LMICs*.

We are seeking qualified research teams whose community-based projects are tailored to country priorities and whose proposed actions are acceptable to local stakeholders. *All projects must be linked to specific actions to control SARS-CoV-2 within and beyond community settings.*

3. STATEMENT OF PURPOSE AND OBJECTIVES:

We are seeking operational research (OR) proposals that aim to provide actionable evidence to local health authorities and policy makers on the most effective use of Ag-RDTs to ensure rapid detection of and swift response to SARS-CoV-2 in community settings, thereby saving lives and protecting economies.

3.1. OBJECTIVES

- Work with local stakeholders (including Ministries of Health, where possible) to identify key factors driving SARS-CoV-2 transmission in communities or sections within a community.
- Conduct research to provide evidence on the effectiveness and feasibility of Ag-RDTs to reduce the spread of SARS-CoV-2 within and beyond these communities.
- Provide evidence and approaches that have the potential to be replicated across several geographies and sociocultural contexts.

4. SCOPE OF WORK AND DELIVERABLES:

4.1. SCOPE OF WORK

Projects should be rapidly implementable to generate actionable evidence. We will consider projects focusing on one or more of the following:

- Highly trafficked areas, such as markets, arcades, border areas, and transit hubs
- Mobile populations, such as lorry, taxi, and bus drivers; long distance and intercity travellers; or nomadic populations
- Places where people from multiple households regularly convene, such as schools and places of work and worship, as well as mass events and congregate settings
- Projects that focus on making Ag-RDTs more widely available within a community, such as testing within pharmacies and outreach in congregate settings
- Projects using Ag-RDTs to inform COVID-19 vaccination
- Multi-disciplinary projects, including technological aspects, behavioural/social sciences and/or health economics

Projects that focus on testing within healthcare facilities or exclusively testing symptomatic persons to facilitate individual patient management will not be considered.

4.2. DELIVERABLES

The project deliverables will include:

• Ethics and regulatory approval, as applicable. Since these projects are intended to provide rapid evidence, applicants should have confidence that ethics and regulatory approval can be expedited.



- Monthly updates to FIND throughout the duration of the project.
- A preliminary summary of findings to be provided to FIND within two weeks of study conclusion. A full report is to be provided within one month of study conclusion.
- Reports must be approved by FIND before being shared with local stakeholders and before publication.
- The findings must be shared with local stakeholders, after which publication in peer-reviewed journals is encouraged. However, FIND cannot support payment of the publication beyond the budget period of the project.

Participant rights, including confidentiality, and well-being must be protected at all times.

5. **PERFORMANCE STANDARDS:**

- Each study is expected to enrol the number of participants required to evaluate the intervention (in line with the sample size agreed in the proposal). FIND will require monthly project updates.
- All relevant data must be collected and reported in line with study procedures. The data collected should consider cost-effectiveness of an intervention, although formal cost-effectiveness analysis is not required.
- Participants' confidentiality must be maintained at all times.
- Each study must highlight if and how the results of the study could be used in the local, sub-national and/or national response. This should be included in the proposal and the final report.
- Results that have clear public health implications should be swiftly communicated to public health authorities for consideration of appropriate response.

6. APPLICATION GUIDELINES:

Applicants are required to submit the following documents:

- 1. A **Letter of Intent (LOI)** with a short summary of local priorities prior to submitting a full proposal (see below). The letter should outline how local priorities were determined and confirm support from local stakeholders. Only applicants who are selected in the LOI round will be invited to submit full proposals.
- 2. A **full study proposal** in MS Word, standard spacing with font size not less than ten points. The applicant's proposal must include the following information:
 - i. Applicant's qualifications and competence to perform the intended contract
 - About the applicant(s) and organization(s):
 - Organization's name, address/location, mission and vision, legal status (registration, for private/public/non-profit)
 - Applicant's names, titles, organizations and contact details
 - Relevant experience: Short CVs (maximum 2 pages) of the named researchers should be provided as part of the appendices, along with a proposed team structure. These should demonstrate experience in two or more of the following:
 - Experience in conducting healthcare operational research in LMICs
 - Experience in COVID-19-related research
 - Experience in policy development
 - o Expertise in statistical analysis, modelling or health economics
 - Experience in working with local communities



- Conflict of interest disclosure statement. These should be provided as part of the appendices.
- ii. Technical proposal (maximum 15 pages): The section should contain:
 - Study summary, including flow diagram
 - Background, including in-country context and project rationale
 - Study objectives
 - Study design and methodology, including:
 - Details of study population
 - Sample size calculations
 - o Data collection
 - Statistical analyses
 - Results visualization and reporting
 - Quality assurance and control, including risk assessment and mitigation strategies
 - Statement on local requirements for ethical review and approval
 - A timetable of activities
- iii. Financial proposal: Financial proposal in Excel file format

7. Award Conditions (Exclusion Criteria):

Applicants selected for final awards are required to:

- Be legally permitted to perform work in the country where the contract will be performed.
- Commit to and follow FIND Global Access Policy and FIND Code of Conduct and Ethics.
- The maximum amount available per project is USD 250,000. Ag-RDTs must be costed as part of the proposal (i.e. FIND will not provide these free of charge).
- FIND anticipates funding up to 12 proposals but reserves the right to not fund if a sufficient number of high-quality proposals is not received. A given Institution should submit **no more than three proposals** for consideration.

8. How to APPLY

Please submit queries, LOI and Proposal via email to OR@finddx.org

The timelines for submission are provided in Section 13 "Timelines".

9. EVALUATION AND AWARD PROCESS:

It must be evident from the LOI that the proposed research meets the scope of the RFP, and that local stakeholders have been engaged when identifying key factors driving SARS-CoV2 transmission in local settings. Reference to relevant local stakeholder meetings or reports will suffice; these should be no older than six months. Please contact FIND's operational research team at <u>OR@finddx.org</u> if you have any questions with regards to evidence for stakeholder engagement.

Full-length proposals will be evaluated on the following criteria:

• Proposal relevance and clarity (60% score weighting):



- The proposal meets the criteria described in the RFP, including all essential requirements.
- The proposed strategy indicates a clear and pragmatic understanding of the project objective, innovative approach, and desired outcomes.
- The implementation approach suggested is practical and focuses on the local country context.
- Organization capacity & experience (20% score weighting):
 - The applications will be assessed on in-country presence and capability in the context of the project objectives, particularly experience in implementing similar projects, and suitability of key team members.
- Budget and rationale (10% score weighting):
 - The proposed budget is reasonable and realistic, aligned with the proposed implementation strategy, and gives clear justification for key budget line items and details of any in-kind support (where applicable).
 - The proposed budget must not exceed USD 250,000.
- Timelines (10% score weighing)
 - It must be possible to complete the proposed research and all project-related activities by 30 November 2022.

10. CONTRACTUAL TERMS AND CONDITIONS:

FIND will use a commercial-level contractual mechanism where the standard Terms and Conditions address the requirements of supplying a product for public health, particularly in LMICs. A contractual template will be provided to all those who are invited to submit full proposals.

11. TERM OF CONTRACT:

All **projects must be completed within six months** following ethical and regulatory approval, as applicable.

All project-related activities are to be completed within **nine months of contract commencement**, at **the latest by 30 November 2022**. This includes obtaining all relevant approvals, set-up, management and close-out of the projects, data analyses and the final stakeholder report.

12. CONFIDENTIALITY:

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested Applicants/Bidders 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 FIND team as well as a team of external experts (which may or may not include members of FIND's independent Scientific Advisory Committee), all of whom are under confidentiality and are 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.



13. TIMELINES:

	Activity	Expected date
1	Publication of RFP	22 Oct 2021
2	Submission of letter of intent (LOI)	05 Nov 2021
3	Feedback on LOI	12 Nov 2021
4	Closing of RFP	10 Dec 2021
5	Communication on Award/s of Contract	22 Dec 2021
6	Contract/s signed with selected Contractors	28 Feb 2022
	Go/No-go milestone	
7	Public announcement of Award/s of Contract	28 Feb 2022
8	Ethics and regulatory approvals obtained	31 Mar 2022
	Go/No-go milestone	
9	Project kick-off meeting/s completed	31 Mar 2022
10	Mid-way project review	30 Jun 2022
11	Projects completed	30 Sep 2022
12	Preliminary summary of findings shared with FIND	14 Oct 2022
13	Final reports and performance data shared with FIND	31 Oct 2022
14	Final report published more widely	30 Nov 2022

14. QUESTIONS AND COMMUNICATIONS PROTOCOL:

FIND is available to further discuss this opportunity via email or in a telephone conference. Please contact FIND's operational research team at <u>OR@finddx.org</u>.