REQUEST FOR PROPOSALS (RFP)

AN RDT-READING MOBILE APP FOR AMR SURVEILLANCE

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Contents

1. LIST OF ACRONYMS AND DEFINITIONS

AMR	Antimicrobial Resistance
CDA	Confidential Disclosure Agreement
HIS	Health Information Systems
LMICs	Low- and Middle-Income Countries
RDT	Rapid Diagnostic Test
RFP	Request for Proposal
TPP	Target Product Profile
WHO	World Health Organization

2. STATEMENT OF PURPOSE

FIND is seeking to collaborate with an organization to develop, launch, and support a mobile app that photographically reads rapid diagnostic tests (RDTs) and makes their data available for surveillance.

This Request for Proposals (RFP) details the Background, Scope, Objectives, and Deliverables related to the project. This document also provides Instructions to Applicants, Proposal Requirements, a summary of Selection Criteria, and the RFP Schedule.

3. BACKGROUND INFORMATION

FIND is a global non-profit organization that drives innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our work bridges R&D to access, overcoming scientific barriers to technology development; generating evidence for regulators and policy-makers; addressing market failures; and enabling accelerated uptake and access to diagnostics in low- and middle-income countries (LMICs). Since 2003, we have been instrumental in the delivery of 21 new diagnostic tools used in 150 LMICs. Over 50 million FIND-supported products have been provided to our target markets since the start of 2015. A WHO Collaborating Centre, we work with more than 200 academic, industry, governmental, and civil society partners worldwide, on over 70 active projects that cross six priority disease areas. FIND is committed to a future in which diagnostics underpin treatment decisions and provide the foundation for disease surveillance, control and prevention.

3.1. UNMET NEEDS

The proliferation of antimicrobial resistance (AMR) – which knows no borders – poses a serious threat to global disease control efforts. "The Review on Antimicrobial Resistance"[1] estimates that, if left unchecked, AMR will cause ~10 million deaths per year and a loss of over 100 trillion USD in economic output by 2050; most of the direct and indirect impact of AMR will fall on low- and middle-income countries (LMICs).

To effectively combat AMR, it is critical for countries to have visibility into their field-level diagnostic practices so that they can track and ensure accurate diagnosis to reduce unnecessary antibiotic prescriptions.

To address this need, FIND aims to create a mobile phone application that collects data from rapid in vitro diagnostic tests (RDTs) and that can aid an RDT user in interpreting the test results. We are looking to partner with health programmes such as malaria control programmes where a correct diagnosis with an RDT can prevent incorrect prescription of antimicrobials. After photographing an RDT, the app will suggest an interpretation of the test to the user, who can either accept the analysis or choose an alternate interpretation. The app will transmit the test data as well as patient data entered by the user and contextual data, such as the phone's location, to the health programme.

3.2. BENEFITS OF WORKING WITH FIND

FIND is aiming to catalyse the development of this app by establishing the right partnerships and providing assistance and resources in areas such as R&D, pilot studies, and access. Our activities are mainly donor-funded, and we are able to partially fund product development projects. That said, we expect a major commitment of the collaborating organization to bring a product solution to the market. In addition, to make the product accessible to the highest-burden settings, FIND will provide implementation support by working closely with national ministries of health in LMICs, and FIND will also promote the product with other stakeholders.

4. PROPOSAL GUIDELINES

4.1. PROJECT OBJECTIVES AND SCOPE

The objective of this project is to produce an app that meets the needs described in the **Target Product Profile (TPP) for an RDT-reading app for AMR surveillance**, provided in Appendix I. FIND is requesting proposals to establish a partnership with an organization capable of delivering this app. Please note that the final TPP may differ slightly, since FIND is currently assessing the regulatory pathways for this app and reviewing the TPP with experts and stakeholders.

The scope of the project includes development of the app and supporting uptake of the app in several pilots in 2–3 countries.

The objective of this project is that this app will be suitable for use with many types of RDTs in several LMIC health programmes.

4.2. PREREQUISITES

FIND expects the selected applicant to bring demonstrated expertise in one or more of the following:

- Lateral flow tests
- Computer vision
- Mobile apps for community health workers and health workers in clinics
- Health Information Systems (HIS) data integration

The applicant must have the ability to develop, market, maintain, and provide technical support for the app during and after this project.

In the event that several entities form a consortium to apply to this RFP (for example, a computer vision company and an HIS organization), a primary applicant must be identified for the purpose of this application. This primary applicant must have the ability to market and provide technical support for the app during and after this project.

Organizations that would like help to form a consortium should contact FIND immediately with an explanation of the type or types of partners required. FIND, at its sole discretion, may facilitate introductions with other potential RFP respondents. Once established, any consortium applying to this RFP should submit a single, unified proposal.

5. OUTCOME AND PERFORMANCE STANDARDS

FIND will be responsible for:

- defining high-level needs in the TPP (some revisions may be made early in the project)
- establishing relationships with and funding for the pilot sites
- study design and oversight
- project and partner coordination
- funding to support the personnel and material expenses incurred by the app provider in this project

The app provider will be responsible for:

- app development, verification, and all other activities necessary to meet the project goals and schedule
- supporting the 2–3 pilot projects through regular visits and calls, from understanding their needs to training users to resolving issues during the studies
- procuring all materials, such as various smartphones and RDTs, used internally for development (materials for the pilots will be provided separately)

6. DELIVERABLES

The minimum deliverables of the project are as follows:

- a product development plan
- technical requirements (Software Requirements Document or similar)
- early versions of the app for preliminary evaluation and feedback before the pilots
- a test plan or plans
- a test report or reports

- an app or apps for use in the pilots capable of interpreting at least three RDTs. These RDTs will be selected by FIND and the pilot partners
- a final report summarizing the work performed, the product, the outcomes, and lessons learned

The proposal should describe the applicant's full set of deliverables, including the above.

7. TIMELINE OF THE PROJECT

The app should be ready for use at pilot sites by the end of September 2019. The pilot period will be for six months but can be extended.

8. BUDGET

A budget should be submitted as part of the proposal. Please list self-funded activities and in-kind contributions in the budget. Self-funding of parts of the project is a strong advantage as it demonstrates the commitment of the organization. The final contract will provide additional details on the financial terms.

9. COMMUNICATION PLAN

FIND proposes calls every two weeks to track project progress, define action items, review risks, and identify and address challenges. Additional meetings will be held to review milestones and as needed.

10. TERM OF CONTRACT

The scope of this project is 12 months from the date of signature of the contract, with a possibility of extension based on project requirements and progress.

11. REQUIREMENTS FOR PROPOSAL PREPARATION

This RFP is an invitation for any suitable establishment to submit a proposal for the project described above. Accordingly, this RFP must not be construed, interpreted, or relied upon, whether expressly or implicitly, as an offer capable of acceptance by any person, or as creating any form of contractual, promissory or other rights.

Recommended length: 15–25 pages. Supplementary information can be included as appendices.

Applicants should use the following outline:

1. **Executive Summary**
2. **Organization**
   - 2.1. Brief history of the organization and key achievements in the context of the project
   - 2.2. Leadership team
   - 2.3. Total number of employees
   - 2.4. Annual financial turnover

3. Business & Operations

3.1. Geographic presence
3.2. Locations of facilities and subsidiaries relevant to the project
3.3. Resources in R&D, technical support, regulatory affairs, and other fields relevant to the project
3.4. Outsourced activities relevant to the project
3.5. Any supporting information that would facilitate scoring of the Organization Assessment Criteria listed in Appendix II.

4. Technology & Product

4.1. User-oriented description and demo of the existing app
4.2. Principles of operation
4.3. Stage of development of the existing product / technology to be used in the project
4.4. If not yet commercialized: timeline to commercialization of the organization's existing product / technology to be used in the project
4.5. Results from performance evaluations and usability studies. Please include the handset specifications on which the app has been tested/used
4.6. IP: Freedom-to-operate, patents and licenses related to the project

5. Project

5.1. Proposed approaches for the project's key issues, including all of the following:
  5.1.1. Ensuring good performance in varying conditions, such as having a smudged camera lens
  5.1.2. Helping the user to correctly interpret RDTs without the app becoming a regulated IVD. Becoming a regulated IVD would mean that the app is restricted for use only on a few mobile devices and for only a few RDTs
  5.1.3. Training the app to work with additional RDTs during and after the project: who should do so; what capabilities, tools, and time will they need; how RDT-specific instructions, which may also be health-program-specific, can be included and updated
  5.1.4. Providing a good user experience and delivering timely, useful data, which may be constrained by mobile connectivity that may be intermittent and costly per megabyte
  5.1.5. Level of involvement with the RDT manufacturers, keeping in mind the large number involved in these markets
  5.1.6. Accommodating the health programme's needs for configurability: connecting to their HIS, collecting their particular data fields, interoperating with other mobile medical apps used by their workers, providing the option to disable the app's result-suggestion feature
  5.1.7. Offering the core RDT-reading functionality as a module (in addition to offering a complete app that provides all the functionalities described in the TPP). This module will enable the technology to be integrated into other mobile apps that are responsible for the configurable elements.
  5.1.8. Approach to verification and validation before the pilots, including any bench testing, automated testing (physical or using prior data sets), and usability studies
  5.1.9. Any other items considered significant or challenging
5.2. Workplan and timeline
5.3. Deliverables
5.4. Budget
5.5. Risks
5.6. (As an appendix) Self-assessment against the TPP and other criteria: For each TPP item, state whether it is "not met", "minimal met" or "optimal met" with explanation and supporting data. State this two ways: for the current state of the product / technology and for the end-of-project state. For other items, use the assessment scales provided in the spreadsheet. Use the spreadsheet template provided with this RFP, and submit the native spreadsheet file (not only a PDF).

5.7. List of key personnel planned to be involved in the project and their expertise
5.8. Business model for long-term sustainability of this product complying with FIND's Global Access policy (https://www.finddx.org/find-policies/), including how that fits with the organization's typical business model.

12. Evaluation and Award Process

Proposals will be assessed, and partners selected, through a systematic process. The process is designed to be an objective, independent and transparent way to ensure that the most suitable technologies are supported, potential conflicts of interest are avoided, and the global community understands and has access to the selection process and its outputs. The selection process is described in detail in our Technology and Partner Selection Guidelines and the way FIND works with private sector partners in our Policy & Guidelines for Working with Private Sector Partners. A particular focus will be put on:

- Technology and product:
  - Current capability with respect to the TPP's optimal criteria. (The minimal criteria must be met.)
  - Future likelihood of meeting TPP's optimal criteria. (The minimal criteria must be met.)
  - Approach to addressing key project issues listed in Section 13
- Partnership opportunity:
  - Organizational assessment criteria
  - Cost of the project

13. Confidentiality

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested organizations prior to proposal submission. FIND will not disclose the proposal to third parties without the prior written agreement of the applicant. Review of proposals will be carried out by FIND, subject matter expert(s) hired by FIND and FIND's independent Scientific Advisory Committee. The members of the SAC and the expert(s) are also 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 raised with FIND.

14. Process Schedule

Activity	Date (2019)	RFP week number
RFP issued	Tues 12 March	0
Deadline for receipt of notice regarding intention to respond to RFP and for any requests for FIND to facilitate introductions to form a consortium	Wed 20 March	1
Deadline for questions to be submitted to FIND (responses will be sent to all registered applicants)	Wed 27 March	2
Deadline for submission of proposals [18h00 Geneva time]	**Wed 10 April**	**4**
Proposal reviews and discussions with applicants	Wed 10 April – Tues 30 April	4–7
Notification of decision	Wed 1 May	7

15. POINTS OF CONTACT FOR FUTURE CORRESPONDENCE

Proposals and any other correspondence are to be sent in English by e-mail to **rdt-app-rfp@finddx.org**.

FIND team member	Role
Rigveda Kadam, Senior Access Officer	Project Lead
Nick Banks, Technical Officer - Connectivity	Project Support

16. APPENDIX I: TPP

Target Product Profile (TPP) for an RDT-reading mobile app for AMR surveillance

11 February 2019: Version for Feedback Round 2

Introduction

To effectively combat antimicrobial resistance (AMR), it is critical for countries to have visibility into their field-level diagnostic practices so that they can track and ensure accurate diagnosis to reduce unnecessary antibiotic prescriptions.

To address this need, FIND is working with developers to create a mobile phone application that collects data from rapid in vitro diagnostic tests (RDTs) and aids an RDT user in interpreting the results. The app will be compatible with many brands and types of both RDTs and mobile devices, enabling broad use. The app, after photographing each RDT, will suggest an interpretation of the test to the user, who can either accept that or choose an alternate interpretation. The app will transmit these test data as well as patient data entered by the user and contextual data such as the phone's location to the health program.

FIND's long-term vision goes farther, to an app that definitively interprets RDTs and provides a diagnosis without needing the user to confirm the result. Such an app will have to go through a regulatory approval process and is not the subject of this TPP but will instead be addressed separately in the future. However, this TPP document and the apps that are built on the basis of this TPP will be the starting point for achieving this vision.

Potential uses for healthcare programs

This capability will support countries' efforts to decentralize surveillance and evaluate on-the-ground diagnostic practices by providing greater information on the use of these trusted, widely used diagnostics. The app will also aid field-level health care workers in interpreting RDTs accurately, reduce their manual data entry efforts and minimize transcription errors.

Countries can use this app to capture diagnostic results for several of their disease programs such as malaria, STIs, NTDs and other programs where RDTs are currently being used. The app will remain flexible to support the incorporation of additional RDTs as they become available for more purposes, including antibiotic resistance profiling. This is an important feature in the context of universal health coverage and integrated service delivery.

Countries can also use this app to capture clinical diagnostic data and provide input into surveillance programs for outbreaks and other diseases. The app can also be used for RDTs in animal health and agriculture, to enable a One Health approach.

Potential uses for various stakeholders

The value of the data available from the app is summarized below by the type of data recipient:

Data recipient	Value of the data from app
Surveillance systems within local, national and international public health programs	Improved timeliness, frequency, consistency, and breadth of data collection. Tracing of resistant cases back to their initial encounter and tests. Outbreak detection.
Healthcare providers (HCPs) and administrators within public health programs	Improved interpretation of RDT results. Capture of clinical cases and RDT results into electronic systems. Monitoring of field-level diagnostic practices. External quality assessment (EQA). Stock control.
Manufacturers of the RDTs and the app	Quality assurance, post-market surveillance, and enhancement of the products

A typical use of the app

The following example describes how a user may interact with the app. This narrative presumes an app version that meets all of the optimal characteristics in the TPP below. Some steps would differ for an app that only meets minimal characteristics.

1. After deciding to perform an RDT, the user starts the app on an ordinary smartphone.
2. The user enters the patient's identifier and other required data (as configured by the health program).
3. The user points the phone's camera at the RDT's package, allowing the app to determine the test's type and check its expiration.
4. The user follows the RDT's instructions, which the app shows in condensed form as a job aid.
5. After the user has added the sample and all required reagents to the RDT, the user starts a countdown timer on the app according to this RDT's waiting period. When the timer expires, the app prompts the user.
6. The user photographs the completed RDT, with guidance from the app to ensure a valid photo. The app analyses the photo according to the rules for that RDT.
7. If the app detects a problem with the RDT, such as a missing Control line, the app warns the user. The app asks the user whether to mark the result as invalid, in which case the next step is skipped.
8. After explaining the RDT's instructions for determining a result, the app presents its calculation of the result and asks the user to confirm it or override it.
9. The user has finished using the app. The app transmits all of the test's data to the health program's server whenever online.

In the event of any conflicts between the above description and the characteristics described in the rest of this document, the characteristics take precedence.

Target Product Profile for the RDT-reading mobile app

Characteristic	Minimal	Optimal	Notes
Scope of the app			
1. Intended use	The app, after photographing each RDT, will suggest an interpretation of the test to the user, who can either accept that or choose an alternate interpretation. The app will transmit these test data as well as patient data entered by the user and contextual data such as the phone's location to the health program.		
2. Target use setting	Community outreach (Level 0) and primary care (Level 1)[2]		
3. Target users of the app	Community health workers with minimal training and any health worker with a similar or superior training level		
4. Target population	Total population presenting for care at relevant settings		This characteristic is not applicable for the RFP response evaluation
5. Training requirements	Less than 2 hours of in-person training	Same plus an option for users to train themselves (without a teacher). This could be done via the app itself or by providing web-based training resources	Assuming the users already use RDTs and mobile devices
6. Ease of use	Not substantially more burdensome than using paper forms for equivalent record-keeping	Less burdensome than using paper forms for equivalent record-keeping	Once a health system has completed its roll-out of this app, it is expected to replace paper forms

[2] Ghani AC, Burgess DH, Reynolds A, Rousseau C. Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. Nature 2015;528:S50-52

Characteristic	Minimal	Optimal	Notes
System components			
7. Compatible mobile devices (smartphones and tablets)	The app maker shall publish and maintain a list of ≥ 10 models of Android mobile devices that are readily available in LMICs	Same plus Most Android mobile devices with a rear-facing camera and flash that are readily available in LMICs The app maker shall publish a way (such as an optical calibration functionality) for users to confirm the compatibility of any device. Devices using the app shall remain functional for other apps and uses.	The minimal is intended to support scenarios in which LMIC health systems provide mobile devices to their health care workers. The optimal is intended to support less-controlled scenarios, including "bring your own device" (BYOD). The optimal app shall not require a "dedicated device" or "lock task mode" as defined in Android.[3]
8. Compatible RDT types	Qualitative lateral flow tests The app shall be compatible with conventional RDTs of many brands and types, not requiring special versions or packages.	Same plus Semi-quantitative (threshold) lateral flow tests	These semi-quantitative tests involve comparison of the intensity of a test line to a reference
9. Additional physical components required for use of the app	Acceptable if they are highly portable and nearly universal (not specific to a small number of mobile devices or RDTs)	None	Examples: a stand or an optical calibration target. Dependence on these is not optimal since they would have to be supplied and maintained for extended periods.

[3] Dedicated Devices Overview, Android Developers Documentation. https://developer.android.com/work/dpc/dedicated-devices/ retrieved 29 January 2019.

Characteristic	Minimal	Optimal	Notes
Functional requirements			
10. Language support	English, French and Spanish	Same plus The app can be configured by the health program to include a local language or languages	
11. Help provided by the app to the user on how to use the RDT	The app shall include a countdown timer to prompt the user to read the RDT after development. The user shall be responsible for setting the duration of this timer appropriately.	The app will provide the user with access to RDT instructions equivalent to Quick Reference Instructions (QRI) or a job aid. The app shall include a countdown timer to prompt the user to read the RDT after development. The app shall set the duration according to each RDT's QRI or job aid.	Minimal: Users should follow regular instructions for operation of the RDT, just like they should without this app. Regardless of this characteristic, the app will provide instructions for use of the app, such as how to photograph the RDT and how to use gloves to avoid contamination of the mobile device.
12. Quality control	• Check of elapsed time to reading of result • Check of the RDT's internal control(s) • Check of sufficient capability of the mobile device's camera	Same plus • Analysis of background to check sufficient washing of the sample by the buffer • Check of expiration by date	Failures of these checks will result in warnings to the user and in the record

Characteristic	Minimal	Optimal	Notes
13. Result determination	The app suggests the result and requires the user to confirm or override. If the user overrides, the app asks the user to provide a reason.		The app should make it easy to provide a reason that will be useful for subsequent review. For example, the app could allow selection from a short list or entry in an "other reason" text field.
14. Diagnostic data reported	• Brand and type of test (possibly by photographing the test and its packaging) • Underlying values and outcome of quality controls (e.g. elapsed time value and whether the time was in the expected range or not) • Result as selected by user • Result as calculated by the app • Photograph used to calculate result, without patient-identifiable information, to be transmitted for select cases as determined by the health program (e.g. discordance between results determined by the app and the user)	Same plus • Lot number and expiration date of the test (possibly by photographing the test and its packaging) • RDT instruction version • Intermediate data and parameters used to calculate the result (e.g. intensities of test line and control line) • Other relevant diagnostic data as inputted by the user	By removing patient-identifiable information, which might be written on the RDT, from the photograph of the RDT, the photograph can more easily be managed and used for non-clinical purposes like quality control. For example, the app might crop the photo to show only the test strip.
15. Patient/case data reported	• As determined by the health program (e.g. patient identification, patient location, patient consent)		

Characteristic	Minimal	Optimal	Notes
16. Contextual data reported	• User identification • Location of test (if enabled by the health program) • Time and date of test • Model of mobile device • OS version • App version		
17. Methods for user data entry	• Typing • Scanning 1D and 2D barcodes		The user can choose from these methods when entering the data types listed above
18. User access rights	Provides access to specific data and app features for users with different roles		Roles may include data manager (facility supervisor) or RDT user (health care worker)
Operational requirements			
19. Lighting of the operating environment	Any setting in which the user can see well enough to run the test. Infrequently, the app may tell the user that it cannot operate in the current lighting. If the user continues using the app without moving to a better-lit location, the app will not suggest a result; it will capture and transmit only the user's interpretation of the result and a photograph of the RDT.		Example settings: • dim indoors without artificial lighting • window-less indoors with fluorescent lighting • mixed lighting • outdoors in direct sun • outdoors in dappled, moving shadows from a tree • outdoors in shade with indirect sunlight off a red wall
Data characteristics			
20. Data ownership	Data ownership shall be in compliance with the in-country regulations		
21. Data flow	De-identified output data can be exchanged with different authorities with authorization by local authorities		
22. Data exchange standards	The app supports at least one of the following formats: HL7, FHIR, ASTM or JSON	The app supports all of the following formats: HL7, FHIR, ASTM and JSON	For connections to systems such as LISs, DHIS2, EHRs, national registries and surveillance systems

Characteristic	Minimal	Optimal	Notes
23. Handling of intermittent connections	The user shall be able to perform tests offline, in which case the app shall transmit that data when back online	Same plus The app shall synchronize automatically (without user action) in the background when back online	
24. Security and privacy	The app complies with the EU General Data Protection Regulation (GDPR) and operates under secure connectivity to avoid loss and corruption of sensitive data and to mitigate cyber-attacks, whether data are at rest or in transmission.		Ensures a system that: • preserves data integrity • identifies and mitigates risks • provides relevant parties clear security processes Implementation is expected to include processes such as: • Two-factor authentication • De-identified data • Data encryption
25. Data storage	The health program shall be able to choose the destination of the app's data		
Performance requirements			
26. Accuracy of results as calculated by the app (for non-clinical purposes)	>= 95% concordance with an expert user	>= 98% concordance with an expert user	
Pricing and accessibility			
27. Pricing within the public sector in LMICs	The pricing structure should be adapted to LMICs (including open-source and open-access solutions), and strategies for further cost reductions should be in place		Details to be established in a Global Access agreement. For applicable markets, see https://www.finddx.org/find-negotiated-product-pricing/

17. APPENDIX II: ORGANIZATIONAL ASSESSMENT CRITERIA

Criterion	Description	Scoring
Strength of the team	Based upon experience of the management team as well as key positions within R&D, manufacturing, product realization, quality	0: team has no experience and no track record 1: adequately experienced, complementary team but limited track record for this specific organization 2: highly experienced, complementary team with track record in development of products similar to this one
Technology maturity and time to market	Technology maturity and length of time it takes until the app is available	0: low: product is in concept phase 1: middle: proof-of-concept done and validated, initial field evaluations of closely related product were successful 2: high: closely related product has been commercialized and performed well in independent studies
Organization business model	Is the organization's business model compatible with global health	0: low: mostly not 1: middle: neutral 2: high: mostly positive aspects