

REQUEST FOR PROPOSALS (RFP)
**PRICING-ACCESS FRAMEWORK FOR DIGITAL TOOLS AND APPLICATIONS IN LOW- AND
MIDDLE-INCOME COUNTRIES**

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1. LIST OF ACRONYMS AND DEFINITIONS:

Acronym	Definition
COVID-19	novel coronavirus 2019
EUA	Emergency Use Authorization
HIC	high-income country
IVD	in vitro diagnostic device
LMIC	low- and middle-income country
R&D	research and development
RDT	rapid diagnostic test
WHO	World Health Organization

2. BACKGROUND INFORMATION:

About FIND

FIND, the global alliance for diagnostics, is headquartered in Geneva, Switzerland. We are a global non-profit organization driving innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest populations. Our vision is a world where diagnosis guides the way to health for all people. Our priorities are aligned with those of the global public health community, and we turn complex diagnostic challenges into simple solutions through unique partnerships with the public, private and non-profit sectors. Our work bridges research and development (R&D) to access, working on technical and practical aspects of diagnostic needs assessments, development of fit-for-purpose products, evidence generation for regulators and policymakers through clinical trials and other studies, analysis of market dynamics, the introduction of new products, capacity development to strengthen laboratory systems and manufacturing, and advocacy to expand access.

Digital health tools

Digital health tools¹ provide opportunities to bridge gaps and expand access to diagnostics. In particular, the increasing availability of mobile devices in emerging markets has been a key driver for digital health and has opened a new channel for reaching underserved communities. While there has been considerable investment in developing or adapting technologies to meet evolving human and ecosystem needs, the market framework to deploy, optimize and ensure effective access to these digital tools is nascent. Specific to the in vitro diagnostics (IVD) market, pricing strategies and business model norms based on assumptions from the economy of physical products should not be assumed to apply to software/digital solutions.

In addition to the barriers to the sustained uptake of digital tools in high-income countries (HICs), financing the linkage between diagnostics and digital tools in low- and middle-income country (LMIC) contexts faces additional challenges. For example, digital solutions for emerging markets need to consider implementation challenges associated with the reliability of electricity and connectivity, variable technology literacy among health workers, and the need for support post-deployment. As the convergence of diagnostics and digital tools continues to evolve, further understanding is needed of the pricing and access strategies that reflect the nuances of these use cases.

First use-case in focus: RDT reader applications (apps)

Lateral-flow rapid diagnostic tests (RDTs) continue to play a vital role in global health for infectious diseases. Visually interpreted RDTs, more than any other class of diagnostics, fulfil the World Health Organization (WHO) [ASSURED criteria](#)ⁱ, enabling their use at the lowest levels of healthcare systems. Their utility, however, is compromised each time a test is not performed correctly, or its result is not reported accurately and promptly. For instance, in an external quality assessment of 1849 health laboratory staff reading malaria RDTs, interpretation error rates were 31.2% for weak-positive results and 32.5% for certain invalid testsⁱⁱ.

¹ Digital health tools use computing platforms, connectivity, software, and sensors, for healthcare and related uses. These technologies span a range of uses: as medical products, in medical products, as companion diagnostics, or as adjuncts to other medical products (devices, drugs and biologics).

RDT readers and mobile apps could promote more consistent, accurate test performance and reporting, recognized in a follow-up article about the ASSURED criteriaⁱⁱⁱ and in a study that compared the rate of positive results reported manually to that reported automatically by an instrument^{iv}. While the cost and logistics of hardware readers have limited their adoption, in the past decade mobile apps for RDTs have moved from research to practical use, first in HICs for low-risk tests^v and more recently around the world for malaria tests through FIND's work with Scanwell Health and Dimagi^{vi}. To tackle the novel coronavirus 2019 (COVID-19) pandemic, Emergency Use Authorizations (EUAs) or similar for home tests, also referred to as lay tests or self-tests, were issued beginning in 2021 in India^{vii} and the United States^{viii}.

It is now clear that RDT apps can deliver good diagnostic performance, but it is unclear how to sustainably scale-up and finance the adoption of these tools in target LMIC markets. In delivering equitable access to this technology, it must be considered how the services are priced, deployed and managed to meet both welfare optimization and financially sustainable outcomes.

Most apps that reach market have been delivered as a free download as part of the RDT manufacturer's offering (a "first-party app"). The app developer fits into the RDT company's business as a component supplier, alongside vendors of, for example, nitrocellulose and reagents. This appears to have emerged as the default business model, but it poses challenges in terms of data fragmentation and use in key public health decision-making processes, at a minimum, and the overall decision-making ecosystem more broadly. Furthermore, while the IVD industry has continued to focus on proprietary software, the growing LMIC preference in relation to digital health is for open-source solutions, particularly when co-financed or managed by public sector counterparts. These factors may have contributed to the limited uptake of these tools.

One alternative to this model is the use of a third-party app that can read several brands of RDTs, as much of the development effort is common across RDT brands. This also recognizes that proprietary software from IVD companies can complicate a customer's choice of the IVD itself and leave health programmes with too many tools to manage. However, a sustainable market for a third-party, multi-brand RDT app has not been established, and any such app is likely to face competition from apps produced by the RDT companies.

Second use-case in focus: data analytics applications for diagnostic systems planning

Diagnosis is the weakest link in the cascade of care, especially at the primary healthcare level, which is where most people first seek care. Large gaps exist for key diseases, including tuberculosis, HIV/AIDS, hepatitis, and non-communicable diseases, leaving many people undiagnosed. This hinders evidence-based policy decision-making, and it has a negative impact on individuals' health outcomes. Diagnostic systems remain largely siloed and inefficient. The optimal network design to deliver the right tests at the right time in the right place at an affordable cost is highly context-specific and includes disease epidemiology, health systems infrastructure, and geography. Optimizing diagnostic services requires multiple data inputs and assumptions, as well as the balancing of competing priorities, necessitating advanced data analytics applications for systems analysis and optimization.

Such network analytics tools are commonplace in the corporate sector and have seen increased application in the public health sector, specifically in diagnostic network analysis, in LMICs over the past several years. These tools have been used to inform countries' operational planning and shape donor funding requests.

A range of business models exists for currently available tools, from licensed proprietary software to open-access or open-source solutions. To enable scale-up of advanced network analytics as a routine element of health systems planning in LMICs, a sustainable business model is needed.

FIND market-shaping and access

[FIND's efforts in market shaping](#) have grown over the past five years. Furthermore, in the past two years, and driven by the COVID-19 pandemic, FIND has expanded its market-shaping work by building out its market intelligence function and coordinating with key procurers and stakeholders.

FIND now encompasses a wider range of market interventions, including creating a marketplace for buyers in LMICs not served by traditional routes, through exploring private sector and innovative channels as routes to expand access to diagnostics in LMICs across five dimensions, as shown in Figure 1.

Figure 1: The five dimensions through which FIND aims to expand access to diagnostics in LMICs

Impact measurement	
Affordability	Extent to which price maximizes efficiency between payers and suppliers to support health outcomes.
Availability	Capacity and stability of the global supply to meet demand. Consistency of local access at service delivery points.
Assured quality	Evidence that a product is continuously safe and efficacious.
Appropriate design	Degree to which a technology maximizes cultural acceptability, ease of use, and choice.
Awareness	Extent to which end-users, health providers, and influencers can make informed choices.

3. STATEMENT OF PURPOSE:

The purpose of this RFP is to invite applicants with experience in digital health products for LMICs to propose a project to inform FIND's market-shaping activities for digital tools. The specific purposes of the project are to develop the following:

- a. A strategic advisory report on FIND's pricing and access policy for digital tools.
 - The driving principle behind FIND's investments is equitable public health impact and sustainable financing models to maintain and grow this impact. Furthermore, FIND's vision for access is based on the principles of availability, affordability, assured quality, appropriate design, and awareness (Figure 1). Based on this vision statement, the applicant will define specific principles and a strategic decision framework to determine which pricing and software licensing models FIND should consider.
 - This work should be based on a comprehensive analysis of sustainable, social-impact-focused business models for digital tools in HICs and LMICs, with a forward view on which models to prioritize in LMICs.
 - Findings and analyses will inform senior management decision-making, so a clear assessment of trade-offs, recommended models and next steps grounded in an understanding of FIND's business model will be key.
- b. Recommendations relating to RDT reader apps and data analytics to inform diagnostic system planning.
 - The proposed framework for establishing the recommendations will explore a specific use case, i.e., the outcomes it results in for immediate business questions in the space of developing RDT-reading apps.
 - The framework should assess which software licensing models are appropriate in different contexts. For example, some apps are free to use under licence. A few projects are open source, but most of the apps on or near the market are proprietary, in contrast to the preference for open-source tools for digital health in LMICs.
 - Recommendations should also cover sustainable adoption and financing for digital tools in LMICs, which should address the following considerations, without being limited to them:
 - What is the value of these applications to different users in the ecosystem, and how should access and pricing agreements be structured, based on the principles of risk-sharing and cost-effectiveness and building on the shared value generated for the individual (user), system and private actors?²
 - How can we structure sustainable financing for these apps?
 - Linked to the above, what can app developers expect to earn or what models of payment can app developers expect?³
 - What are the licence restrictions and implications considering LMIC government preferences?

We propose that this work involves the various key stakeholders: ministries of health, other health programmes, policymakers, funders, implementing partners, patient and community healthcare worker representatives, digital tool providers (of RDT apps and diagnostic systems planning), and related companies (such as RDT manufacturers).

² For RDT reader apps, sources of value could include prevention of user interpretation errors and ensuing changes in clinical decisions, improved data collection for epidemiological surveillance, improved post-market surveillance for RDT manufacturers, decreased inappropriate prescribing unsupported by test results, and objective data for measurement and evaluation programmes. Both professional use and lay use (self-testing) should be evaluated.

³ For RDT reader apps, possibilities could include fee per RDT scanned, fee per user per year, or flat fee per health program or RDT model per year, plus fees for setup of health-program-specific items like data connections.

4. SCOPE OF WORK AND DELIVERABLES:

a. Develop a strategic advisory report on FIND's pricing and access policy for digital tools that includes the following:

- A recommended framework for FIND to consider for a digital health access and pricing framework.
- The key social-impact-focused business models for digital tools that are to be prioritized in LMIC contexts.

This deliverable should be in the form of:

- An MS Word report that includes a literature review, analysis, methodology and findings.
- MS PowerPoint slides summarizing the main findings.

b. Develop recommendations for RDT-reader app projects:

- Apply the recommended digital health access framework to this use case. Specific negotiation examples will be provided by FIND.
- The final output will be recommendations, with supporting analyses, on the access and pricing terms to be considered, balancing risk-sharing, scale of adoption, and cost-effectiveness of the solution.

c. Develop recommendations on data analytics for the diagnostic system planning project:

- (See the bullet points for item b, above).

Note: A timeline, schedule of tasks, and final planned approach (this may include stakeholder interviews) is to be agreed upon with the Project Manager at the start of the consultancy. All data and analyses conducted must be [sharable, transparent, reproducible and replicable](#), as per standard FIND terms.

5. PERFORMANCE STANDARDS:

Applicants will be expected to provide feasible solutions to the questions asked. The output will be judged on the feasibility, applicability and economic impact of the solutions provided.

6. APPLICATION GUIDELINES:

Interested applicants should submit three documents:

a. Relevant competencies, including but not limited to:

- A company overview and profile.
- Examples of previous work similar to this scope of work.
- Organization and staffing of the applicant's team, including a curriculum vitae and references for each member of the team.

b. A technical response outlining the plan of action, including but not limited to:

- The applicant's understanding of the project.
- An approach and detailed methodology, including a list of key opinion leaders to approach during the project.
- A detailed workplan.

c. A summary of their budget, including but not limited to:

- A deliverables-based payment schedule corresponding to the required level of effort.

Any additional information the applicant considers relevant may be included as an appendix.

Kindly note that the lead applicant is expected to participate in all key meetings during the proposal selection process and the project itself.

7. AWARD CONDITIONS (EXCLUSION CRITERIA):

Applicants that are 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's Global Access Policy](#) (mandatory for research, R&D, manufacture or supply of IVDs, etc.) and [FIND's Code of Conduct and Ethics](#).
- Accept the Terms and Conditions of KfW Declaration of Undertaking (please see Appendix 1).

8. HOW TO APPLY:

Interested applicants are invited to submit a proposal, in English, to RDT-MIU-DH@finddx.org, no later than 27 September 2022 at 23:59 CET.

9. EVALUATION AND AWARD PROCESS:

Proposals will be assessed, and partners selected, through a systematic process. A first-pass evaluation of all applications will be performed for an assessment of the scope of work and clarification of essential technical and applicant-specific details. Those applications deemed suitable for a potential collaboration will then undergo an in-depth second-pass evaluation, which may include interviews. Applicants will be notified of FIND’s decision after the final partner selection. The evaluation matrix is outlined in Appendix 2.

10. CONTRACTUAL TERMS AND CONDITIONS:

FIND will use a consultancy contracting mechanism where the standard Terms and Conditions (T&Cs) apply. The total budget available is **up to US\$120 000**.

11. TERM OF CONTRACT:

The contract is expected to start in early October 2022 and run until March 2023. The general T&Cs will reflect standard consultancies, where the successful applicant is expected to work independently to complete the tasks as set out.

12. CONFIDENTIALITY:

FIND considers any proposal received under this RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested applicants prior to proposal submission. FIND will not disclose any 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, all of whom are bound under confidentiality agreements 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 the RFP	5 September 2022
2	Closing date for submission of written queries	21 September 2022
3	Closing date of the RFP	27 September 2022
6	Communication about award(s) of contract(s), kick-off, and work-planning with the project team	Early October 2022
7	Draft recommendations on the strategic pricing framework, RDT use case	15 November 2022
8	Final reports and performance data (RDT-related)	15 December 2022
9	Final reports and performance data (diagnostic systems planning-related)	15 February 2023
10	Wrap up and final project review	By 1 March 2023

14. QUESTIONS AND COMMUNICATIONS PROTOCOL:

Please email any questions to: RDT-MIU-DH@finddx.org. Questions will be accepted and responded to promptly until 21 September 2022.

15. APPENDICES:

Appendix 1: Declaration of Undertaking

.....Name of the tender (the “Contract”)

1. KfW finances projects of the Foundation for Innovative New Diagnostics (“FIND”) that are subject to the terms and conditions of a binding Funding Agreement. FIND is responsible for the preparation and implementation of the RFP/RFQ and the performance of the Contract. No legal relationship exists between KfW and our organization, our Consortium⁴ or our Subcontractors under the Contract with FIND.
2. In keeping with FIND’s responsibilities, we acknowledge that we are required to be able to provide certain certifications. To that end, we hereby certify that neither we nor any of our board members or legal representatives nor any other member of our Consortium, including Subcontractors under the Contract, are in any of the following situations:
 - 2.1) being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganization or being in any analogous situation;
 - 2.2) convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union or Germany for involvement in a criminal organization, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons who themselves are subject to such convictions or sanctions;
 - 2.3) having been convicted by a final court decision or a final administrative decision by a court, the European Union, national authorities in Switzerland or in Germany for Sanctionable Practice in connection with a Tender Process or the performance of a Contract or for an irregularity affecting the EU’s financial interests (*in the event of such a conviction, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this conviction is not relevant in the context of this Contract and that adequate compliance measures have been taken in response*);
 - 2.4) having been subject, within the past five years to a contract termination fully settled against us for significant or persistent failure to comply with our contractual obligations during such Contract performance, unless this termination was challenged, and dispute resolution is still pending or has not confirmed a full settlement against us;
 - 2.5) not having fulfilled applicable fiscal obligations regarding payments of taxes either in the country where we are constituted or in Switzerland;
 - 2.6) being subject to an exclusion decision of the World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank (*in the event of such exclusion, the Applicant or Bidder shall attach to this Declaration of Undertaking supporting information showing that this exclusion is not relevant in the context of this Contract and that adequate compliance measures have been taken in reaction*); or
 - 2.7) being guilty of misrepresentation in supplying the information required as a condition to participation in this Request for Proposals (RFP/Request for Quotes (RFQ)).
3. We hereby certify that neither we, nor any of the members of our Consortium or any of our Subcontractors under the Contract are in any of the following situations of conflict of interest:
 - 3.1) being an affiliate controlled by FIND or a shareholder controlling FIND, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;
 - 3.2) having a business or family relationship with FIND’s staff involved in the RFP or the supervision of the resulting Contract, unless the stemming conflict of interest has been brought to the attention of KfW and resolved to its satisfaction;

⁴Or Joint Venture, or Collaboration, whichever applies.

- 3.3) being controlled by or controlling another Applicant or Bidder, or being under common control with another Applicant or Bidder, or receiving from or granting subsidies directly or indirectly to another Applicant or Bidder, having the same legal representative as another Applicant or Bidder, maintaining direct or indirect contact with another Applicant or Bidder which allows us to have or give access to information contained in the respective Applications or Offers, influencing them or influencing the decisions of FIND;
- 3.4) being engaged in a Consulting Services activity, which, by its nature, may be in conflict with the assignments that we would carry out for FIND;
- 3.5) in the case of procurement of Works, Plant or Goods:
- i. having prepared or having been associated with a Person who prepared specifications, drawings, calculations and other documentation to be used in the Tender Process of this Contract;
 - ii. having been recruited (or being proposed to be recruited) ourselves or any of our affiliates, to carry out works supervision or inspection for this Contract.
4. If we are a state-owned entity, and compete in a Tender Process, we certify that we have legal and financial autonomy and that we operate under commercial laws and regulations.
5. We undertake to bring to the attention of FIND, which will inform KfW, of any change in the situation with regard to points 2 to 4 above.
6. In the context of the RFP and performance of the corresponding Contract:
- 6.1) neither we nor any of the members of our Joint Venture, nor any of our Subcontractors under the Contract, have engaged or will engage in any sanctionable practice during the RFP process and, in the case of being awarded a Contract, will not engage in any sanctionable practice during the performance of the Contract;
- 6.2) neither we nor any of the members of our Joint Venture or any of our Subcontractors under the Contract shall acquire or supply any equipment nor operate in any sectors under an embargo of the United Nations, the European Union or Germany; and
- 6.3) we commit ourselves to complying with and ensuring that our Subcontractors and major suppliers under the Contract comply with international environmental and labour standards, consistent with laws and regulations applicable in the country of implementation of the Contract and the fundamental conventions of the International Labour Organization⁵ (ILO) and international environmental treaties. Moreover, we shall implement environmental and social risks mitigation measures when specified in the relevant environmental and social management plans or other similar documents provided by FIND and, in any case, implement measures to prevent sexual exploitation and abuse and gender-based violence.
- In the case of being awarded a Contract, we, as well as all members of our Joint Venture partners and Subcontractors under the Contract, will (i) upon request, provide information relating to the RFP application and the performance of the Contract, and (ii) permit FIND and KfW or an auditor appointed by either or both of them, and in the case of financing by the European Union also to European institutions having competence under European Union laws, to inspect the respective accounts, records and documents, to permit on the spot checks and to ensure access to sites and the respective project.
7. In the case of being awarded a Contract, we, as well as all our Joint Venture partners and Subcontractors under the Contract, undertake to preserve the above-mentioned records and documents in accordance with applicable laws, but in any case, for at least six years from the date of fulfilment or termination of the Contract. Our financial transactions and financial statements shall be subject to auditing procedures in accordance with applicable laws. Furthermore, we accept that all data (including personal data) generated in connection with the preparation and implementation of the RFP and the performance of the Contract are stored and processed according to the applicable law by FIND and KfW.

Name: _____ In the capacity of: _____

⁵ In case ILO conventions have not been fully ratified or implemented in the Employer's country, the Applicant/Bidder/Contractor shall, to the satisfaction of the Employer and KfW, propose and implement appropriate measures in the spirit of the said ILO conventions with respect to a) worker grievances on working conditions and terms of employment, b) child labour, c) forced labour, d) worker's organizations and e) non-discrimination.

Duly empowered to sign in the name and on behalf of ⁶: _____

Signature: _____ Date: _____

Appendix 2: Scoring system

During the second-pass evaluation, each proposal will receive a weighted total score based on the following:

<u>Area of review</u>	<u>Score</u>
Relevant competencies (see section 6.a)	0–4
Technical approach and plan (see section 6.b)	
Cost of delivering the project (see section 6.c)	

Kindly note that 70% weighting is given to technical competencies, previous work, proposed approach and ability to deliver within the indicated timelines, while 30% weighting is given to cost-effectiveness.

Scoring scale for each area:

- 0: No response
- 1: Limited, poor
- 2: Fair, possibly acceptable
- 3: Good, soundly acceptable
- 4: Excellent, surpasses expectations

References:

ⁱ Mabey, D., Peeling, R., Ustianowski, A. *et al.* Diagnostics for the developing world. *Nat Rev Microbiol* 2, 231–240 (2004). <https://doi.org/10.1038/nrmicro841>

ⁱⁱ Mukadi P, Gillet P, Lukuka A, Mbatshi J, Otshudiema J, Muyembe J-J, et al. (2013) External Quality Assessment of Reading and Interpretation of Malaria Rapid Diagnostic Tests among 1849 End-Users in the Democratic Republic of the Congo through Short Message Service (SMS). *PLoS ONE* 8(8): e71442. <https://doi.org/10.1371/journal.pone.0071442>

ⁱⁱⁱ Land, K.J., Boeras, D.I., Chen, X.S. *et al.* REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. *Nat Microbiol* 4, 46–54 (2019). <https://doi.org/10.1038/s41564-018-0295-3>

^{iv} Adah, P., Maduka, O., Obasi, O. *et al.* The role of the Deki Reader™ in malaria diagnosis, treatment and reporting: findings from an Africare pilot project in Nigeria. *Malar J* 17, 221 (2018). <https://doi.org/10.1186/s12936-018-2356-8>

^v Kadam R, White W, Banks N, Katz Z, Dittrich S, Kelly-Cirino C (2020) Target Product Profile for a mobile app to read rapid diagnostic tests to strengthen infectious disease surveillance. *PLoS ONE* 15(1): e0228311. <https://doi.org/10.1371/journal.pone.0228311>

^{vi} <https://www.finddx.org/newsroom/09sep21-dsme/>

^{vii} <https://www.icmr.gov.in/chometest.html>

^{viii} <https://news.bd.com/2021-08-25-BD-Receives-Emergency-Use-Authorization-for-First-At-Home-COVID-19-Test-to-Use-Smartphone-to-Interpret,-Deliver-Results>

⁶ In the case of a «Joint Venture», insert the name of the JV (Consortium). The person who will sign the application, bid or proposal on behalf of the Applicant/Bidder shall attach a power of attorney from the Applicant/Bidder.