REQUEST FOR INFORMATION (RFI)

FROM DIGITAL HEALTH PARTNERS DEVELOPING AND MANAGING CONNECTIVITY TOOLS FOR POINT OF CARE DIAGNOSTIC TECHNOLOGIES

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CONTENTS

1. List of acronyms and definitions:

DH	Digital Health
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level Seven
IVD	In-vitro diagnostic
LFD	lateral flow device
LMICs	low and middle-income countries
MDx	molecular diagnostic platforms
POC	point-of-care
RFI	request for information
RFP	request for proposal
UX	User experience
WHO	World Health Organisation

2. EXECUTIVE SUMMARY

Background	In healthcare systems, insufficient interoperability[1] continues to hamper access to timely diagnostic data from medical devices and point-of-care technologies. Additionally, there has been an evolution in in-vitro diagnostic (IVD) tests, characterized by a significant transition from traditional laboratory settings to a range of non-laboratory-based technologies such as point-of-care (POC) molecular diagnostic platforms (MDxs) and lateral flow device (LFDs). In these non-laboratory settings, conventional data collection and reporting systems are not seamlessly integrated when compared to systems linked with lab-based tests. This unavailability of seamless diagnostic data sharing from diagnostic tools into health information system directly, compromises the speed and precision of diagnosis. To fill this gap, FIND is looking to work with partners to bridge the gap between diagnostic devices and digital systems.
Purpose of partner engagement	FIND is opening a Request for information (RFI) in an effort to identify digital health partners with extensive experience in developing or managing off-the-shelf and/or opensource "middleware" versatile enough to allow the seamless plug-in of emerging POC MDx, Near/POC, and LFDs into the digital ecosystem of low- and middle-income countries (LMICs).
Type of partners & Technologies	FIND is looking to work with digital health partners to adapt existing, standards-compliant middleware tools that enable the digitized collection of diagnostic data from decentralized MDx technologies and develop a standardized middleware that bridges the gap between diverse HIS and POC systems. Applicants must be willing to commit to affordable pricing and service models for LMICs, together with other access conditions, to be negotiated as part of the partner agreement.
Benefits for the applicants	Through this RFI: • Applicants with relevant solutions will be added to a pool of eligible partners to work with for projects related to the scope of work described in this RFI. • Such partners may be contacted for further discussion on their middleware solution and invited to respond to a Request for Proposal (RFP). Winning the RFP could lead to subsequent funding support.
Application deadline	The deadline for receipt of submissions is **28 August 2024**, 23h59 (CEST)
Contact	Please email questions to rfp.bi@finddx.org with the subject line: "*Inquiries: RFI for Middleware Development*"

[1] https://www.measureevaluation.org/resources/publications/tl-17-03d.html

3. About FIND

FIND is accelerating equitable access to reliable diagnosis around the world. We are working to close critical testing gaps that leave people at risk from preventable and treatable illnesses, enable effective disease surveillance, and build sustainable, resilient health systems. In partnership with the World Health Organization (WHO), other global health agencies and the G20/G7, we are driving progress towards global health security and universal health coverage. We are a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. For more information, please visit https://www.finddx.org/

4. Background:

In healthcare systems, insufficient interoperability[2] continues to hamper access to timely diagnostic data from medical devices and point-of-care technologies. Additionally, there has been an evolution in in-vitro diagnostic (IVD) tests, characterized by a significant transition from traditional laboratory settings to a range of non-laboratory-based technologies such as point-of-care (POC) molecular diagnostic platforms (MDxs) and lateral flow device (LFDs). In these non-laboratory settings, conventional data collection and reporting systems are not seamlessly integrated when compared to systems linked with lab-based tests. This unavailability of seamless diagnostic data sharing from diagnostic tools into health information system directly, compromises the speed and precision of diagnosis.

There are a variety of POC MDxs used for diagnosis, each with its own data format, standards, and specifications, which encounter difficulties in direct connectivity with health information systems (HIS) due to a combination of software and hardware issues. Interoperability issues arise when POCs and HISs utilize different data formats, and communication protocols, or lack standardized interfaces, making seamless integration challenging. Additionally, hardware limitations such as outdated infrastructure or incompatible devices further impede direct connectivity. These issues lead to fragmented data management, hindering real-time data sharing and decision-making processes.

5. Partner Engagement Opportunity:

FIND is looking to work with digital health partners to adapt existing, open standards-compliant middleware that enables the digitized collection of diagnostic data from conventional and decentralized MDx technologies and provides a standardized communication platform that bridges the gap between diverse HIS and POC systems as shown in Figure 1. We define a “middleware”, in this context, as a digital tool that acts as a bridge between HIS and different diagnostic software applications and devices. A middleware will have the capability to integrate with HIS, and record data from different sources and formats, including clinical data and other records shared by diagnostic test devices. This integration capability streamlines data management as recommended in the “WHO Global Digital Health Strategy[3]”. Such a middleware solution should facilitate the exchange and utilization of diagnostic information by clinical decision support algorithms, such as those contained with the WHO SMART Guidelines, and by clinicians.

[2] https://www.measureevaluation.org/resources/publications/tl-17-03d.html

[3] https://iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf?sequence=1, Pg 12

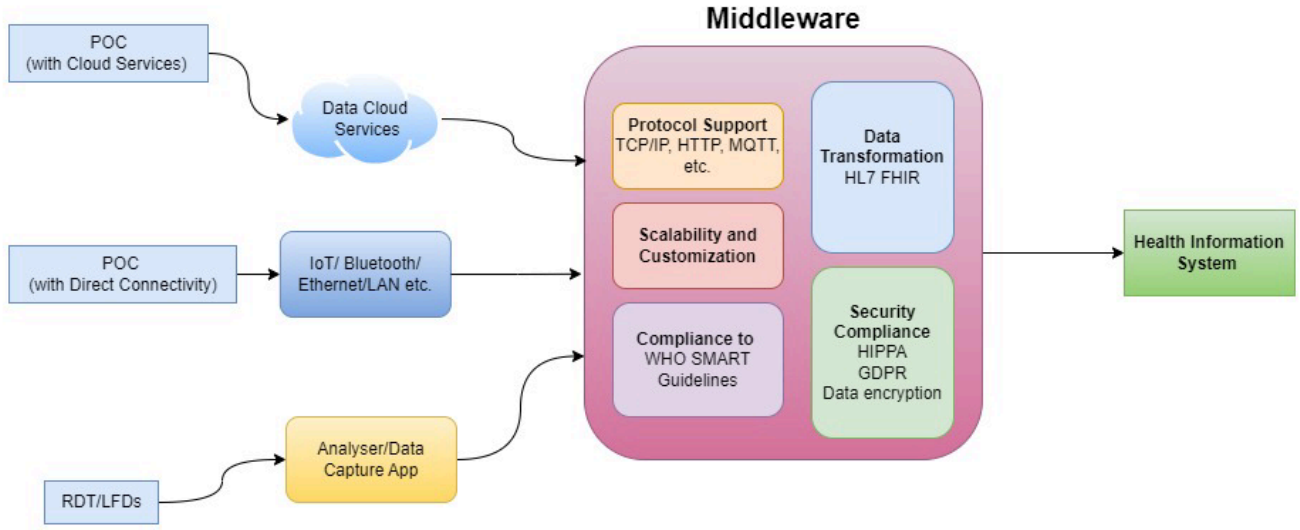

Figure 1Integration flow of Middleware with POCs/LFDs and HIS

6. Call For Information:

FIND issues this Request for Information (RFI) in an effort to identify digital health partners with extensive experience in developing or managing off-the-shelf and/or opensource "middleware" versatile enough to allow the seamless plug-in of emerging POC MDx, Near/POC, and LFDs into the digital ecosystem of low- and middle-income countries (LMICs).

7. Eligibility Criteria:

The following categories of partners are invited to respond to this RFI who:

- Have extensive experience in developing and integrating software solutions for POC MDx, LFDs, etc.
- Are experienced with open-source middleware characterized by compatibility with diverse information exchange protocols and instruments, high performance, and low latency for optimal response time.
- Have extensive experience working with open digital health standards, in particular HL7 FHIR, ICD, and LOINC.
- Have developed products taking into consideration health data privacy regulations like HIPAA or GDPR, the capability to implement strong connectivity security measures, and a nuanced understanding of diverse data sovereignty approaches compliant with LMIC requirements.
- Have a track record in developing robust application business requirement/adaptation kits, optimizing application performance, scaling connectivity applications with low latency, and tailoring offerings to user/stakeholder needs.
- Have a dedicated approach to UX design, committed to providing comprehensive and robust documentation, coupled with reliable technical support while maintaining cost-effectiveness.

The following categories of partners are not in the scope of this RFI:

- Partners who have no prior experience or a track record in developing and integrating software solutions for POC MDx, LFDs, or similar diagnostic technologies.
- Entities that operate outside the public health sector technologies and do not have experience with health information systems or interoperability.
- Partners involved solely in advisory services or consulting, rather than direct development of technologies.
- Partners without awareness of LMICs health architectures, as this could hinder effective communication, local infrastructure understanding, and project execution.
- Entities that may have conflicts of interest with FIND that could compromise the integrity and objectivity of the project.

8. BENEFITS TO APPLICANTS:

Based on the outcome of the review of the submissions, interested Digital Health partners with a relevant middleware solution or with the potential to contribute and align with our objectives may be contacted for further discussion on their middleware solution.
Moreover, applicants with relevant solutions will be recognized as eligible partners for projects related to the scope of work described in this RFI and will be invited to respond to a Request for Proposal (RFP). This RFP will focus on procuring and funding an application that includes adapting the open-source middleware to meet FIND's business requirements and ensuring seamless integration with POC MDx technologies at FIND-selected trial sites.

9. HOW TO APPLY

Submit applications via the FIND Technology Scouting Submission Webform. Templates for the documents requested for the application can be downloaded from the submission portal. An incomplete dossier will not be considered for review.

10. DEADLINE

The deadline for receipt of submissions is **28 August 2024**, 23h59 (CEST).

11. Questions and Further Information

Please email questions to rfp.bi@finddx.org with the subject line: "*Inquiries: RFI for Middleware Development*"

CONFIDENTIALITY:

FIND acknowledges that the information received from Applicants under the RFI may be of a confidential nature. FIND shall use the same degree of care with Applicant's confidential information as it uses to protect its own confidential information. If required, FIND can sign a CDA with interested Applicants prior to Information submission. FIND will communicate the confidential information only to its employees, independent contractors, institutional donors and other financial sponsors, legal, financial, scientific or technical advisors (together "Representatives") who: (a) need to know such confidential information for FIND's internal purposes, and (b) such Representative has previously agreed in writing to be bound by terms and conditions substantially similar to those contained in this RFI, including but not limited to confidentiality and non-use restrictions. Review of submissions 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.