Request for Proposal # 2022-050
RDT Capture and Reporting in Uganda

I. Summary of Deadlines

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<th>Deadline</th>
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<tr>
<td>Release of Request for Proposal</td>
<td>October 7</td>
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<tr>
<td>Confirmation of interest due</td>
<td>October 14</td>
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<tr>
<td>Fact-finding questions received by</td>
<td>October 14</td>
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<td>Response to fact-finding questions</td>
<td>October 21</td>
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<tr>
<td>Proposals due</td>
<td>November 11</td>
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<tr>
<td>Bidders notified of decision</td>
<td>November 18</td>
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Note that PATH reserves the right to modify this schedule as needed. All parties will be notified simultaneously by email of any changes.

II. PATH Statement of Business

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.
III. Project Background

RDT Capture and Reporting

The U.S. President’s Malaria Initiative (PMI) Insights project is a multidisciplinary partnership that collaborates with PMI, other donors, research institutions, and national malaria programs (NMPs) to create and implement high quality, ethically sound program evaluation and operational research activities to inform PMI programs, NMPs and the global malaria community. As one of its research priorities for FY2022, PMI Insights seeks support in conducting an assessment of malaria rapid diagnostic test (RDT) result capture and reporting into the national health management information system (HMIS). This assessment will be conducted in four countries in sub-Saharan Africa.

RDTs are widely used in the management of febrile illness to diagnose cases of malaria to inform appropriate case management. The test positivity rate (TPR) is an important malaria surveillance indicator collected in the HMIS as the proportion of all RDTs that return a positive result. However, despite known seasonality in malaria transmission, TPRs obtained from HMIS data do not always demonstrate a seasonal pattern. Moreover, studies have shown that at the peripheral level, TPRs from HMIS data may be inflated compared to actual readings of RDTs. This study will answer the question: Is there a significant discrepancy between actual TPR from RDTs and TPR reported to the national HMIS? To determine whether a discrepancy exists, TPR and related measures of malaria burden will be captured through digital RDT readers and collection of used RDTs and the study will be implemented in four countries to understand the extent of and potential causes of any discrepancy.

Two methods to evaluate whether a discrepancy exists between actual and reported TPR will be investigated: one will use an automated RDT reader with data uploaded into a central database, while the second will use a data quality audit approach.

Automated RDT readers have been shown to be as good as trained healthcare workers at interpreting RDT results\(^1\). Discrepancies in RDT TPR between automated readers and HMIS have been seen in several settings\(^2\). From early 2016 to mid-2019 automated malaria RDT readers, Deki Readers, were deployed in health facilities across two provinces in southern Democratic Republic of Congo (DRC). A retrospective review of malaria data was conducted comparing TPRs reported from the Deki Readers against TPRs reported from the same facilities in the DRC HMIS. Data from 102 health facilities that regularly used the Deki Readers in 2017 and 2018 were extracted. Paired t-testing showed a statistically significant (p<0.001) difference in TPRs of 30.2 percentage points by source, with an average annual Deki Reader TPR of 23.6% (CI: 22.7 – 24.6), compared to 53.8% (CI: 52.6 – 55.0) from HMIS (see Annex 1 for more details).

The data quality audit approach to evaluating whether a discrepancy exists will make use of the WHO surveillance assessment toolkit service delivery data quality audit module with the addition of inspection of all RDTs used in the facility. The number of tests conducted and the number of positives, negatives and inconclusive results will be recorded.

The objectives of this study are as follows:

1) To compare malaria testing indicator data, including number of suspected malaria cases tested by

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RDT, number of positive RDT cases, and TPR, obtained from automated RDT readers and data quality audits compared to HMIS and assess patterns of concordance and discordance.

2) To assess provider perceptions and behaviors related to RDT result capture and reporting using qualitative methods to better understand social and systemic root causes leading to any discrepancies between actual and reported TPR.

IV. Scope of Work and Deliverables

A. Scope of Work:

PATH seeks multiple research partner(s) to co-lead activities under this research study in the following countries: Uganda. Additional study countries include Benin, Cote D’Ivoire, and Nigeria. In addition, subsequent phases of this study in one or more these countries may also be considered.

PATH expects that interested offerors will be able to cover the expected scope of work in one of the above listed countries, and will collaborate with other selected offerors completing this scope of work in the other envisioned countries. Therefore, we expect that as a result of this solicitation, PATH will identify one or, likely, multiple research partners who will each perform the below scope of work in one or more of the countries identified above.

Overall, the envisioned scope of work includes finalizing of the overall study design, obtaining national research ethical approval, developing data collection tools, collecting data, accessing and managing malaria HMIS data, data analysis, report writing, publication of findings and dissemination. This work will be completed within the following phases:

1) Protocol development and harmonization with protocols in the other countries
2) Obtaining ethical approval
3) Facility-based data collection using either automated RDT readers or data quality audits
4) Access facility-level HMIS data and complete data analysis for Objective 1
5) Review data and finalize qualitative data collection tools for Objective 2 accordingly
6) Implement qualitative data collection
7) Complete data analysis for Objective 2
8) Writing, publication in peer-reviewed journal and dissemination

In particular, PATH expects that selected institutions will contribute to the finalization of the study protocol and methodology, which may necessitate changes in the below scope of work; as noted in Section F below, PATH reserves the right to negotiate the final scope of work and budget based on the final study protocol developed in collaboration with the selected partner institution(s). The partner institution will also be expected to provide leadership in engaging and updating the National Malaria Program during each phase of the study.

Activities for a partner institution may include, but are not limited to:

**Phase 1: protocol development and ethical approval**

- Be available to attend an initial in-person meeting the week of December 5th; the final location for this meeting will be determined based on the final selected offerors
- Collaborate with PMI, the National Malaria Program, and investigators from other study sites to finalize a country-specific protocol based on a master protocol developed to guide work across
multiple study countries. Additionally collaborate to develop standard operating procedures and data collection tools. Ensure translation of the study protocol and tools from English to local language as needed.

- Obtain access to HMIS/DHIS2 data and use relevant malaria data elements to examine historical TPRs for health facilities. Use these data to develop a sampling frame for sampling facilities for the study.
- Submit the study protocol for national research ethics review. Obtain approval prior to data collection.
- Obtain approval for conducting data collection in government health facilities at all relevant levels
- Obtain approval and access to facility level national HMIS data that will be required for the study

**Phase 2: facility-based data collection using either automated RDT readers or data quality audits**

The study is based at peripheral health facilities and will include three arms: health facilities in all arms will be provided with sufficient RDTs to ensure there are no stock-outs during the study period. One arm will receive automated readers; a second arm will have weekly collection and inspection of RDTs and monthly data quality audits; the third arm will serve as a comparison.

The arm with automated readers will entail using trained data collectors positioned at health facilities. The data collectors will use an automated RDT reader application deployed using a smartphone to capture RDT results.

The arm with weekly collection of RDTs and monthly data quality audits will have no staff positioned in the health facilities but will require a study staff to collect the used RDTs.

Approximately 20-30 peripheral government health facilities will be included in the activity. The facilities will be sampled from four districts (administrative level 2) across two regions (administrative level 1). The RDT readers will be deployed continuously (seven days per week) during all hours of operation for the health facility for approximately six months and also involve collecting basic, anonymized data from each patient tested including patient age and gender. The weekly collection of RDTs will also continue for six months. Facility-based data collection will also include extracting malaria RDT information from patient and lab registers.

- Sensitize selected health facilities to the study and obtain facility approval for the activity.
- Design and implement training for data collectors.
- Deploy and supervise data collectors.
- Regularly review RDT reader data being collected from health facilities to identify issues with poor quality or incomplete data collection.
- Troubleshoot challenges with the RDT reader application, hardware, and/or data transmission as needed.

**Phase 3: access HMIS data and complete data analysis for Objective 1**

- Obtain relevant malaria data elements for the study period as outlined in the study protocol from the national HMIS (DHIS2 or other system).
- Collaborate with PMI, the National Malaria Program, and investigators from other study sites to analyze data according to multi-site standard operating procedures.
- Note: interim analysis of RDT reader data and HMIS data (from national DHIS2 systems or from data captured from facility registers) may be undertaken before Phase 2 is completed. This
interim analysis would be used to guide data review and finalization of qualitative data collection plans and tools in parallel to completing Phase 2.

**Phase 4: review data and finalize qualitative data collection tools for Objective 2 accordingly**

- Facilitate data review with PMI and the National Malaria Program to jointly review results from the work conducted under Objective 1.
- Collaborate with PMI, the National Malaria Program, and investigators from other study sites to develop qualitative data collection tools for Objective 2.

**Phase 5: implement qualitative data collection**

The qualitative data collection will entail using appropriate methods to understand differences between RDT auto-reader data and HMIS data. These could include methods such as in-depth interviews and focus group discussions with key informants (e.g., providers, patients, district staff). Interviews should be recorded to facilitate full transcription and translation to English as needed. For initial illustrative budget purposes, investigators should plan to conduct approximately 20-30 in-depth interviews and 12 focus-group discussions.

- Sensitize sampled health facilities to the study and obtain facility approval for the activity.
- Design and implement training for data collectors.
- Deploy and supervise data collectors.
- Transcribe all interviews.
- Translate transcriptions to English.

**Phase 6: complete data analysis for Objective 2**

- Collaborate with PMI, the NMP, and investigators from other study sites to analyze data according to multi-site standard operating procedures.

**Phase 7: writing and dissemination**

- Collaborate with PMI, the NMP, and investigators from other study sites to develop dissemination products, including reports, study briefs, PowerPoint presentations, and peer-reviewed publications.
- Facilitate meetings with stakeholders in country (e.g. national and sub-national malaria program team members, study participants, PMI country team) to review study results and discuss implications for HMIS data interpretation, case management and potential intervention strategies.

**Deliverables**

- Final study protocol and data collection tools.
- Approval from national research ethical institutions.
- All necessary approvals to conduct research activities in government health facilities.
- Approval and access to the national health-facility level HMIS (DHIS2 or other system) data required for the study.
- Final quantitative dataset containing auto-reader data.
- Final quantitative dataset containing results from RDTs collected weekly.
- Final quantitative dataset containing extracted malaria testing data from facility registers.
- All qualitative transcripts translated into English.
- Final report summarizing results from Objective 1 activities.
• Final report summarizing results from Objective 2 activities.
• Contributions to dissemination products.
• Complete dissemination activities including meetings with national stakeholders.

V. Proposal Requirements - Financial

Provide itemized costs for the total scope of this project, based on the scope of work and deliverables outlined in Section IV. The final scope of work may be subject to negotiation however, bidder selection will be made against the original scope of work. Bids should include itemized costs for key elements of the scope of work, as follows:

• Percent participation in total level of effort according to key staff.
• Rates of key staff.
• Estimated total level of effort and associated costs.
• Itemization of all other costs, e.g., agency costs, agency fees, sub-contracted resources, administrative costs, supplies, tax, etc.

VI. Proposal Requirements – Technical

Provide a narrative on your technical approach to accomplish the Scope of Work and Deliverables per section IV, including:

• Description of technical approach.
• Description of the process to obtain ethical approval including description of any exemption for non-human subjects research or expedited review for low-risk research.
• Discussion of project management and roles of project team.
• Identification of the specific geographical zones that Offeror is proposing to implement the proposed scope of work in.
• Approach to conducting study activities in one or more of the specified geographical zones, as appropriate.
• Description of ethics approvals experience, inclusive of what local/national approvals are necessary and what the expected timeline for these approvals will be
• Timeline to meet the deliverables.
• Potential obstacles and plan to overcome them.

Provide information on your overall qualifications, including:

• Profile of relevant corporate qualifications.
• Profile of relevant experience and examples of related work.
• Qualifications of key members of the proposed project team (attach CVs and provide details of back-up/standby teams).
VII. Proposal Evaluation Criteria

The following is a list of significant criteria against which proposals will be assessed. The criteria are listed in order of priority, however they are not weighted.

1. Technical understanding of the scope of work, including how the proposed technical approach will meet the requirements of the SOW and achieve the outlined deliverables.
2. Relevant institutional capabilities and past experience, including specific experience with data collection and implementing operational research; stakeholder consultations and in-depth interviews; qualitative work; experience across malaria technical areas; partnerships and collaborations with national malaria programs, especially those identified in the Scope of Work; and relevant language capability.
3. Relevant institutional capabilities and past experience operating in one or more of the specified geographical zones, as appropriate.
4. Demonstrated ability to collaborate with PMI, host country national malaria control programs, and other research institutions in the completion of research studies.
5. Appropriateness of proposed personnel who will perform this scope of work.
6. Costs (as detailed in Section V), evaluated based on a best value determination.

Note: PATH reserves the right to include additional criteria.

VIII. Instructions and Deadlines for Responding

A. PATH contacts

Technical/Program Contact: Megan Littrell, mlittrell@path.org
Procurement Contact: Hoang-Kim Vu, kvu@path.org

B. Confirmation of interest

Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than October 14. Please send the confirmation to the contacts listed above.

C. Fact-finding questions

Questions on this solicitation will be accepted via email to the contacts listed above through October 14. Questions and answers to all questions will be provided on October 21 to all participants who confirmed interest. Please note that responses will not be confidential except in cases where proprietary information is involved. Inquiries after this date cannot be accommodated.

D. Proposals due: November 11

Completed proposals should be submitted by email to the contacts listed above. The subject line of the email should read: RFP # 2022-050 Your Company Name.
E. Conclusion of process
Applicants will be notified of PATH’s decision by November 18. Final award is subject to the terms and conditions included in this solicitation, as well as successful final negotiations of all applicable terms and conditions affecting this work.

B. Terms and Conditions of the Solicitation

A. Notice of non-binding solicitation
PATH reserves the right to reject any and all bids received in response to this solicitation and is in no way bound to accept any proposal.

B. Confidentiality
All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed. Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

C. Conflict of interest disclosure
Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could be present if there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the supplier’s obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

D. Communication
All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section VIII. A. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the proposal.

E. Acceptance
Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists’ proposals, as well as the option of accepting partial components of a proposal if appropriate.

F. Right to final negotiations
PATH reserves the option to negotiate on the final costs and final scope of work and reserves the option to limit or include third parties at PATH’s sole and full discretion in such negotiations.
G. Third-party limitations
PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

H. Proposal Validity
Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.