

Request for Quote (RFQ)

Thailand: a country market assessment for the launch of a *Neisseria gonorrhoea* point-of-care test

14 April 2020

1. ABOUT FIND

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 development of 24 new diagnostic tools. Over 50 million FIND-supported products have been provided to 150 LMICs 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.

2. BACKGROUND

In 2017, the World Health Organization (WHO) published target product profiles for diagnostics for sexually transmitted infections (STIs), including gonorrhea. Additionally, efforts are underway to develop new antibiotics for gonorrhea, and, in connection with this, FIND is working with WHO and GARDP on a stewardship plan for new as well as existing antibiotics. FIND has developed two target product profiles (TPPs) for a point-of-care (POC) test to identify *Neisseria gonorrhoea* (NG) resistance to antibiotics and a POC test that can distinguish gonorrhoea from *Chlamydia trachomatis* (CT) infection at primary care.

A high-level market assessment conducted by FIND in 2019 showed that while the potential LMIC target population for an NG/CT diagnostic test is estimated to represent more than 70 million people in LMICs, there is high uncertainty around the size of the likely demand and the major access barriers regarding the launch and roll-out of the two POC tests in high-priority LMICs.

As a result, FIND has decided to undertake more in-depth market assessments in selected high-burden or potential early-adopter countries. The goal of these country assessments is to better understand the national context around NG/STI treatment and testing, to help inform FIND and partner strategies for case management policy adoption, and, ultimately, assess uptake of NG POC testing in the context of antimicrobial stewardship.

As of April 2020, one country market assessment was finalized for South Africa, one is nearly complete for Kenya, and a workshop is being planned tentatively for October or November 2020 to discuss access challenges and implementation of gonorrhea testing in a selection of countries (i.e. South Africa, Zambia, Kenya, Papua New Guinea, Philippines, Vietnam and Thailand).

3. OBJECTIVE

As new diagnostic products often experience challenges associated with the shift from product commercialization to in-country roll-out, FIND aims to support the shift of diagnostic solutions from development and evidence generation to adoption through key activities that support governments, suppliers, and partners to plan for product roll-out. The goal is to reduce barriers to market entry and encourage demand for new, promising diagnostic

solutions through informed market strategies for high-priority countries.

In this context, FIND is seeking a partner — an individual or organization — to work with our market analysis team to conduct a national market assessment for the launch of a <u>POC test</u> to distinguish gonorrhoea from Chlamydia infection at primary care in Thailand.

The market assessment should cover the following topics:

- Understanding the current national STI context
 - o STI/NG public health burden, epidemiology, surveillance
- Structure of the health care system
 - o Public health sector: structure, coverage, access etc.
 - National STI response
 - National AMR response
 - Public laboratory services
 - o Private health sector
- Current STI management
 - STI care seeking, access to care
 - STI guidelines, diagnostics and treatment
 - Clinic operations / clinic flow for STI patient
 - STI Surveillance,
 - o Process for treatment and guideline updates
- Understanding priority use case scenarios for a new NG/CT POC test in the country:
 - Determine the use case and patient populations targeted by the test
 - Identify key market access challenges faced by the tests
 - Highlight potential market interventions to be done by FIND and partners
 - o Identify drivers of demand and build a demand forecast
- Understanding the perspective of key stakeholders
 - Stakeholder mapping: who are the main stakeholders that have or should have an impact on NG testing and treatment?
 - o Provider acceptance, and patient acceptance
- Financing and adoption consideration
 - o NG funding situation and mechanisms
- Regulatory environment
- Test selection, procurement and distribution
 - o Public sector: mechanisms and distribution
 - o Private sector: mechanisms and distribution

4. ACTIVITIES AND DELIVERABLES

The following project activities are planned:

Review of literature and data to assess current NG epidemiology and control programs in Thailand

A comprehensive review of the available data will be conducted to develop a holistic and thorough assessment of the current NG situation in Thailand. Key elements that will be researched include:

- a. Epidemiology of NG
 - o STI/NG public health burden, epidemiology and surveillance
 - o Estimates of current NG incidence and prevalence
 - Specific populations most affected by STIs (demographic and geographic)
- b. Current STI service delivery systems in the public and private sectors
 - Implementation of STI services (e.g., types and number of facilities in which STI diagnosis and treatment are offered, diagnostic tests currently in use for NG/CT, etc.)
 - o If available this will be disaggregated by public and private sector
 - National laboratory system background for STIs
 - o STI Healthcare provider profiles
 - o Monitoring indicators in use relevant to STI burden
 - Supply chain systems in place for STI diagnostics and medications
 - Access to care for NG
 - Patient flow for NG including integrated care within other departments, such as dermatology, HIV units, or sexual and reproductive health
 - Stakeholder mapping
- c. Key policy and clinical guidelines
 - o Clinical algorithms in use for STI diagnosis and treatment
 - National strategic action plans for STI control and antimicrobial resistance (AMR) response
 - Regulatory mechanisms that relate to POCT adoption and uptake
 - National program targets for STIs
- d. Funding sources of STI program (specifically NG/CT) and budget
- e. List of all key national stakeholders:
 - Names of departments and persons in charge of STI prevention and treatment within the Ministry of Health
 - Main NGOs implementing STI programs or advocating for better access to STI services at the national level
 - o Private sector practitioners and decision-makers
 - Other key STI stakeholders such as international organizations (e.g., UNFPA, WHO), health care provider associations, and academic researchers

Deliverable #1: Desk review source data file in readable format with list of source documents (preferably MS word or Excel).

Deliverable #2: Develop list and contact info for key stakeholders (Excel/Google sheets) for sharing/review with FIND. This list should note background and any outreach, engagement, contact. The key stakeholders will be interviewed or surveyed through an online survey (Activity 2).

2) Key Stakeholders Semi-Structured Interviews and Survey

After compiling and reviewing all relevant data, semi-structured interviews with selected key stakeholders (10 min. interviews, longer if time and budget allow) will be conducted using an interview guide provided by FIND. The guides will serve as a basis for the interviews but

probing questions outside of the interview structure will be asked as appropriate to gain more insight. Free discussion of the topics at hand will also be encouraged.

These discussions will serve to:

- o provide contextual information for the collected data,
- assess political will and commitment to STI diagnosis and control, including willingness and ability to provide financial and human resources for NG POCT implementation at national and global levels,
- elucidate perceived barriers to NG POCT roll-out at national, regional, and facility levels,
- o determine awareness of the need to improve diagnosis of STIs to reduce AMR and
- elicit insight on test characteristics and other factors that may influence test uptake.

To supplement the interviews, a 15 minute on-line survey tool has been developed by FIND. This tool aims to broaden the reach of the activities by providing additional stakeholder input, and complements the interviews. The consultant can work with FIND to identify 20 additional survey respondents, representing a range of different perspectives.

Potential stakeholders to be interviewed or surveyed will include:

- Program managers from relevant areas at the national and sub-national levels (e.g., STI control, sexual and reproductive health, primary health care/outpatient departments, HIV care and treatment)
- Healthcare providers and laboratory staff at facilities with a high volume of STI patients
- o National Ministry of Health public health policy-makers
- STI surveillance and monitoring staff
- In-country implementing partners
- Regionally relevant donors
- Diagnostic distributors /suppliers (if relevant in Thailand)

Deliverable #3: Detailed notes for all Key Stakeholder Interviews (KSIs).

3) Potential use scenarios and market segments for an NG/CT POCT:

Understanding the use scenarios for the TPP is a key part of the market assessment. Using information collected through the desk research and Key Stakeholder Interviews (KSIs), the team will:

- Refine the "general" use scenarios (provided by FIND) in the context of Thailand
- Determine the patient populations targeted by the tests use scenario
- Identify key market access challenges faced by the tests, including acceptance by patients and health care providers
- Highlight potential market interventions
- Identify drivers of demand and develop market sizing.

This deep-dive national market assessment will build upon the global assessment previously completed by FIND, and specifically consider the unique diagnostic landscape of Thailand. The

market sizing will be based upon established methodology agreed upon with FIND following the review of available in-country statistics and estimates.

Deliverable #4: A report of consolidated and synthesized research and interview results and high level write up of market sizing. A template / example report will be provided by FIND.

Deliverable #5: An Excel file, detailing market sizing methodology

5. TIMELINE

Completion is expected by 31 July 2020, with flexibility to extend timelines if coordination with other partners warrants extensions.

The schedule for individual country work and deliverables will be determined based on coordination with other partners.

6. BUDGET

A maximum of USD 15,000 (including professional expenses and traveling) may be provided for submitting a proposal to the full RFQ. The maximum amount is to be adjusted downwards for a partial proposal to the RFQ (see section 7).

7. QUOTE GUIDELINES

If you are interested, please send your Quote (in English, and formatted in Microsoft Word or PDF) to mael.redard@finddx.org by **5pm CET on May 8, 2020**.

Applicants may choose to *partially apply* to the RFQ, i.e. applying to one or several activities and deliverables of the RFQ (see section 4. ACTIVITIES AND DELIVERABLES).

Selection of the applications will be based upon separate assessments of the offers. FIND reserves the right to request further information throughout the RFQ process.

Any questions or clarifications regarding this Request for Quote (RFQ) should be submitted in writing via e-mail to mael.redard@finddx.org prior to the closing date.

8. EVALUATION CRITERIA

To ensure consideration for this RFQ, your offer should be complete and include all of the following criteria:

- Individual CV or organizational profile: Bidders will be evaluated on their organizational strategy (where appropriate), experience and capability as it pertains to access to diagnostics, therapeutics and treatment in the global health domain.
- Experience, capability & capacity: Bidders will be evaluated on their capability and capacity, including history of their work pertaining to the development of access programs for infectious diseases, including roll-out plans, within the global health domain as well as client testimonials and references.
- Understanding of key access challenges for medical products (diagnostics
 especially) in Thailand: Bidders will be evaluated on their understanding of key
 diagnostic challenges when commercializing and distributing diagnostic products for
 infectious diseases Thailand. Bidders should briefly discuss what they consider key
 access challenges in the diagnostics/pharmaceutical space in Thailand and provide

possible solutions to those issues by linking with the bidder's own experience on the matter (case studies if possible).

- **Financial proposal:** Bidders will be evaluated on the quality of the financial proposal for this RFQ as well as the transparency and breakdown of all financial elements comprising the final bid. Bidders should provide as much information as possible to explain the proposed budget.
- Proposed team: Bidders will be evaluated on the quality of the team that will work on the RFQ. Bidders are asked to submit complete CVs of the proposed team and present the working team, detailing how their background and experience will be of benefit for this work.

Where FIND judges more than one application to be complementary, FIND reserves the right to suggest partnership within the RFQ process.