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## Accelerating access to diagnosis

*Supporting uptake & effective use of diagnostic solutions to achieve health impact*

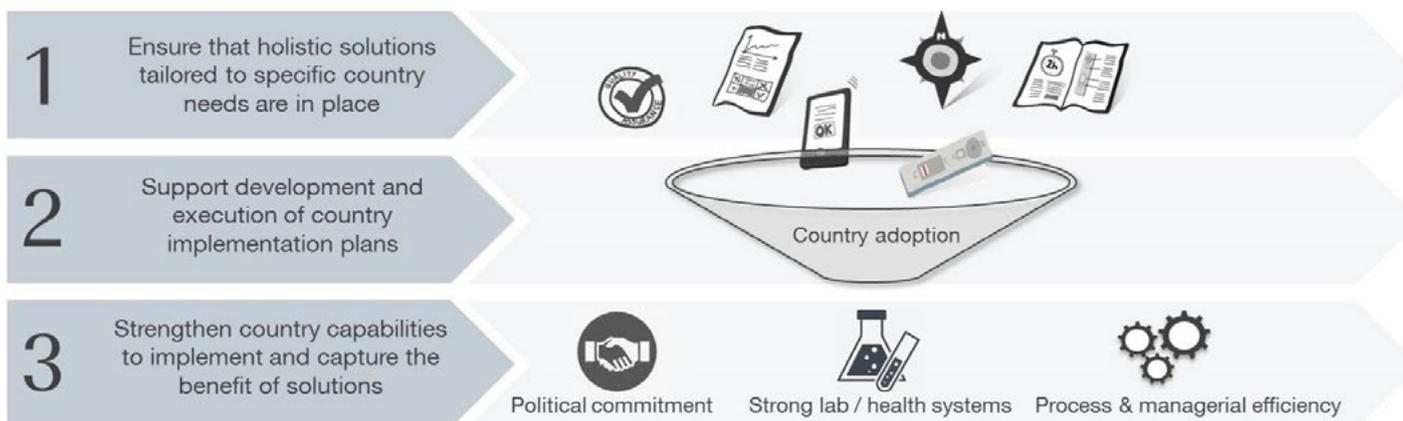


*Reaching targets for disease control and elimination requires new, easy-to-use diagnostic tools that provide rapid results and – just as importantly – comprehensive approaches to maximizing health impact.*

FIND has made a strategic commitment to support countries in:

- **Building strong networks** of high-quality laboratories and testing sites, equipped with the right tools and trained staff;
- **Engaging all care providers** in diagnostic service delivery;
- **Ensuring systems are in place** to effectively link diagnosed patients to care and treatment;
- **Using local diagnostics data** to inform decision-making and measure impact.

### Approach: Ensuring impact of diagnostic tools



## Implementation support

### **FIND provides tools & data to enable countries to more easily prioritize choice & placement of diagnostic tools**

The rich diagnostic development pipeline will lead to a more complex product and site selection process. Countries will need to select products that are appropriate for their own contexts and disease burdens, and assess design of diagnostic algorithms to enable access to diagnosis to those in need. FIND supports this by:

- Developing product selection tools that match products and diagnostic algorithms with national requirements, based on performance, throughput, pricing, cold-chain requirements, multi-disease platform functionality, integrated sample referral networks and connectivity, such as:
  - The Interactive Guide for high-quality malaria RDT selection (*available at <http://www.finddx.org/malaria/interactive-guide/>*)
  - The TB diagnostic product selection and placement tool (*available in 2017*)
- Mapping health facilities and testing sites, specimen referral, workload and epidemiological data;
- Building local government capacity to select products, design responsive diagnostic networks, prioritize sites for roll-out and document procurement decisions.

### **FIND generates evidence for diagnostics implementation strategies & demonstrates impact**

The development, evaluation and approval of new diagnostic tests are only the beginning. Achieving health impact depends on the success of national implementation efforts. FIND helps to generate needed evidence and demonstrate impact by:

- Supporting demonstration projects to gather evidence and evaluate the impact of new diagnostic solutions to inform global and national policy-making;
- Supporting countries to translate global guidance into detailed implementation plans, and early implementation;
- Promoting integration of testing for multiple diseases on the same diagnostic platforms.

### **FIND expands demand & uptake of quality diagnosis in the private sector**

Private health-care providers serve a large proportion of the population in many countries. To support health ministries in improving the standard of care in the private sector, FIND is:

- Working with the private sector and national programmes to improve access to quality testing;
- Establishing locally-appropriate incentive schemes for private sector providers;
- Improving access to products at negotiated prices, and negotiating minimized operating margins for high-quality diagnostics to reduce cost to patients; and
- Measuring uptake and impact.

## Case studies

### **Bringing malaria rapid diagnostic tests into the private sector in sub-Saharan Africa**

In collaboration with health ministries and funded by UNITAID, FIND and partners are working in five countries to stimulate private sector demand for RDTs and ensure appropriate use. FIND has:

- Supported compliance with best practices in lot testing and procurement;
- Contributed to development of tools for training and supervision of provider proficiency;
- Guided correct transport and storage of RDTs; and
- Improved quality assurance through implementation of a troubleshooting guide and new availability of positive control wells.

### **Integrating HCV diagnosis & treatment in public sector HIV programmes**

FIND is the lead partner on a pioneering hepatitis C project funded by UNITAID. The project will create the case for policy change at global and national levels, and help pave the way for a public health approach to HCV, integrated into HIV programmes to maximize impact and cost efficiency. In India, Georgia, Myanmar, Vietnam, Cameroon, Malaysia and Thailand, demonstration projects will build an efficient, sustainable public health response by:

- Trialling new, simpler HCV tests;
- Establishing innovative models for screening and treatment in HIV/HCV co-infected patients;
- Increasing the affordability of HCV testing; and
- Providing the evidence for policy change to drive scale-up in sustainable public health programmes.

Demonstration projects also include a laboratory quality assurance scheme and diagnostic connectivity.

### **Expanding access to rapid, molecular TB diagnosis**

FIND, India's Revised National Tuberculosis Control Programme, WHO and USAID have conducted a pilot project to inform national scale-up of paediatric TB testing. The project has:

- Established high-throughput GeneXpert labs in nine cities, covering a population of 47 million;
- Tested (free of charge) more than 53,000 children with TB symptoms, in public and private facilities;
- Increased TB detection four-fold; and
- Supported same-day results via SMS or email to paediatricians in 90% of cases, and linked 85% of diagnosed TB cases to treatment.



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*Malaria lot testing workshop, Addis Ababa, Ethiopia, 2016*

### Malaria RDT quality assurance programme

FIND collaborates with the World Health Organization (WHO) to promote the quality-assured use of malaria rapid diagnostic tests (RDTs) by guiding procurement and assuring RDT performance before and during use in the field. This programme is based on three tiers: product testing (part of WHO product pre-qualification), lot testing (before or after shipping orders) and positive control wells (at the field-level).

Major new initiatives planned for 2017:

- Transition to a new, decentralized system for malaria RDT lot testing using new methods: endemic countries will now conduct lot testing using recombinant antigen panels and standardized protocols. The transition has already begun with a UNITAID-funded pilot project involving nine countries in Africa and three in Asia, with training also extended to Nigeria and Brazil.
- Commercial availability of positive control wells and the release of a new malaria RDT troubleshooting guide (available in English, French and Swahili) and an RDT problem-response protocol.

### Improving quality of HIV rapid testing

FIND works with the U.S. Centers for Disease Control & Prevention (CDC) in sub-Saharan Africa and Caribbean, and Central and South-East Asia as part of the HIV Rapid Test Quality Improvement Initiative to:

- Support changes in national policies related to rapid HIV testing and quality assurance;
- Introduce the use of dried tube specimens to test the proficiency of those who conduct rapid tests;
- Use standardized logbooks for recording results and following up on associated corrective actions;
- Provide a comprehensive training programme on rapid HIV tests, with certification of both testing sites and testers.

## Assuring quality diagnostic testing

High-quality diagnostic test results are accurate, reproducible and timely. Quality assurance (QA) focuses on ensuring consistently correct use and interpretation of diagnostic tests. Tailored to the local context, QA is an essential part of the appropriate use of diagnostic tools, but its effectiveness is often undermined by poor implementation and a lack of real-time data for decision-making. FIND's work includes:

- Leveraging connectivity solutions for real-time access to diagnostics data;
- Routine collection and review of quality indicators to monitor performance;
- Building country capacity for lot testing of diagnostic products;
- Quality controls for test procedures;
- External quality assurance, such as proficiency testing, on-site supervision or blind re-checking of test results.

**Laboratory quality management systems (QMS)** are the coordinated activities that direct and control the quality of diagnostic test results. Accreditation is the formal recognition of implementation of an effective QMS and assurance of quality results. Accreditation, particularly of reference and referral laboratories, is a critical step in building strong national diagnostic networks.

To support QMS and lab accreditation, FIND:

- Develops and implements QMS training, including the Strengthening TB Laboratory Quality Management Towards Accreditation (TB SLMTA) Programme;
- Mentors country personnel to plan and implement quality improvements;
- Supports laboratories to progress towards national and international laboratory accreditation;
- Measures the impact of quality improvements on quality of services and patient care.

## Diagnostics connectivity

### *Leveraging information and communications technology to drive the collection and use of local data, and measure impact*

Merging diagnostics with communications technology offers huge opportunities to maximize the health impact of diagnostic tests by enabling efficient collection, storage and transmission of test and patient data. Connected diagnostic tests can provide real-time results to clinicians and mobile alerts to patients, facilitating prompt treatment and reducing loss to follow-up. Likewise, connected diagnostics can improve supply chain management and forecasting, contribute to disease surveillance, and track the functioning of lab equipment.

Currently, FIND is:

- Assisting manufacturers and solutions providers with the design, development and implementation of connectivity solutions;
- Demonstrating the impact of connectivity solutions for health systems through data utilization frameworks and best practices;
- Guiding the development of connectivity solutions that meet priority needs with target product profiles developed in collaboration with global partners;
- Establishing a framework for data use and sharing agreements;
- Establishing pre-negotiated, discounted contracts for global SIM cards and data bundles;
- Working with countries to build the capacity to use diagnostic data for decision-making; and
- Generating impact data to inform scale-up decisions by health ministries and investment decisions by donors.



### About FIND

FIND, established in 2003 as a global non-profit, is dedicated to accelerating the development, evaluation and use of high-quality, affordable diagnostic tests for poverty-related diseases, including tuberculosis, malaria, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, febrile illnesses and infectious diseases with outbreak potential, such as Ebola. Over the last decade, FIND has partnered in the delivery of 14 new diagnostic tools, including eight for tuberculosis, and created an enabling environment for countless more through the provision of specimen banks, reagent development and better market visibility.

**FIND**   
Because diagnosis matters

Campus Biotech  
Chemin des Mines 9 - 1202 Geneva - Switzerland  
T: +41 (0)22 710 05 90 - F: +41 (0)22 710 05 99  
[www.finddx.org](http://www.finddx.org)