FIND

Because diagnosis matters

MAXIMIZING THE HEALTH IMPACT OF DIAGNOSTIC SOLUTIONS

ACCESS STRATEGY 2018

ABOUT FIND

FIND was founded in 2003 to bridge existing development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector and the in vitro diagnostics industry. Today, FIND is a leading partner across the value chain of diagnostics development and delivery. We have programmes in tuberculosis and acute febrile respiratory infections, malaria and acute febrile syndrome, hepatitis C and neglected tropical diseases. We also have mini-portfolios in areas affecting reproductive and child health: HIV; sexually transmitted infections; and infections and nutritional deficiencies in children less than five years of age. At FIND, we envision a world where diagnostics guide the way to health for all people. We aim to turn complex diagnostic challenges into simple solutions to transform lives and overcome diseases of poverty. To do this we focus on four strategic goals throughout all the disease areas in which we work:

Catalyse development

Identify needed diagnostic solutions and remove barriers to their development

Guide use & policy

Lead products through the clinical trials pathway to global policy on use and market entry

Accelerate access

Support uptake and appropriate use of diagnostics to achieve health impact

Shape the agenda

Improve understanding of the value of diagnostics and strengthen commitment to their funding and use

FIND's Vision

A world where diagnosis guides the way to health for all people

FIND's Mission

Turning complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives

ABBREVIATIONS

AMR	Anti-microbial resistance
CD4	cluster of differentiation 4, a glycoprotein found on the surface of immune cells
CDC	Centers for Disease Control and Prevention
CEA	cost-effectiveness analysis
CHAI	Clinton Health Access Initiative
DBS	dried blood spot
EXPAND-TB	Expanding Access to New Diagnostics for TB
FIND	Foundation for Innovative New Diagnostics
HAT	human African trypanosomiasis
HCV	hepatitis C virus
HIC	high-income countries
HIV	human immunodeficiency virus
LAM	lipoarabinomannan, a glycolipid and a virulence factor associated with *Mtb*
LMIC	low- and middle-income countries
MDR-TB	multidrug-resistant tuberculosis
NGS	next-generation sequencing
NTD	neglected tropical disease
POC	point-of-care
PSK	paediatric stool sampling kit
R&D	research and development
RDT	rapid diagnostic test
RNA	ribonucleic acid
TB	tuberculosis
TPP	target product profile
USAID	United States Agency for International Development
WHO	World Health Organization
XDR	extensively drug-resistant

EXECUTIVE SUMMARY

FIND's access goal is to maximize the health impact of diagnostic solutions by accelerating their uptake and appropriate use. To achieve this, we work to ensure that the diagnostics we support meet the four A's of global access, i.e., that they are **A**vailable, **A**ffordable, **A**ppropriate for use in low- and middle-income countries (LMICs), and **A**dopted in these settings.

In its 5-year (2015–2020) strategic plan, FIND identified a three-pronged approach to accelerate access: 1) support rapid translation of global policy into relevant and actionable country plans; 2) enable quality-assured scale-up and use of proven diagnostic solutions; and 3) support creation of long-lasting, broad diagnostic capacity as a center-piece of disease control. Activities for the first half of the strategic period have been mostly focused on the third, i.e., building diagnostic capacity in more than 30 LMICs, as this was a priority need expressed by countries. For the remaining period, and to lead us into the next 5-year strategic period, we will shift the weight of the team's activities further up the value chain, to work increasingly on the scale-up of proven diagnostics solutions, and we will seek to carve out at least one of three potentially high-impact interventions as a "signature" FIND initiative. This way we will bridge product development to country scale-up and help ensure that the full value of diagnostics is realized in LMICs.

Five strategic objectives will guide the programme through this next period:

1. **Shape product development in line with the four A's**
   a. Collect market intelligence to inform product design
   b. Negotiate Global Access Terms with industry partners
2. **Optimize evidence generation**
   a. Engage stakeholders in evidence generation, building product confidence
   b. Align trial and evidence plan with WHO, country and implementation needs
3. **Create the market**
   a. Develop roll-out plan (country prioritization, regulatory, implementing partner mapping etc.)
   b. Set up terms and conditions for product supply and support with procurers and manufacturers
   c. Support in-country policy change in representative countries
4. **Establish best implementation practices and showcase impact**
   a. Design and demonstrate new service delivery models for diagnostics
   b. Package "how-to" guidance and case-studies
5. **Enable programmatic scale-up**
   a. Work to scale models directly and through implementation partners
   b. Provide targeted technical assistance to build capacity and improve diagnostic quality

Within these objectives we have defined priority interventions for each of FIND's current disease programmes. For malaria, the focus is on establishing cost-effective test-and-treat models for elimination; for HAT, it is on enabling a post-elimination surveillance strategy integrated into malaria programmes; for TB and multidrug-resistant (MDR)-TB, the focus is on establishing case detection and care strategies where patients first present; for HCV, it is getting simplified algorithms for cure into policy and use; for AMR, it is demonstrating the role of rapid tests and decision aids in reducing antibiotic use and enabling surveillance; and for Outbreaks, the focus is on market sustainability and response speed.

Based on lessons learnt during the first half of FIND's 2015–2020 strategy period, we will narrow in on two cross-cutting areas that currently hamper impact: 1) stakeholder coordination and advocacy; and 2) the establishment of quality management systems in the delivery of diagnostic solutions. We intend to further develop a third cross-cutting area into a high-impact initiative on the use of connected data to aid surveillance and inform service delivery.

FIND's access programme relies heavily on partnering, particularly when it comes to in-country implementation. Our lean operating model is built around strong global capabilities, with five resource hubs in select high burden countries. We work with these early-adopter countries to generate evidence for policy change, to develop and test implementation models and to influence regional diagnostic practice. This allows FIND to maximize global and national impact with a relatively small footprint. However, as resourcing trends for access work are clearly heading toward increased funding directly to countries rather than to international organizations, FIND will consider strengthening its presence in up to two additional countries to secure funds for critical access work.

WHAT ACCESS MEANS FOR FIND

Access to diagnosis is critical to improve individual health outcomes, reduce the global burden of disease, save healthcare costs to LMICs, and meet Sustainable Development Goal health objectives. To achieve health impact, it is not enough to develop innovative diagnostics; it is important to also ensure their uptake. For FIND, access means that diagnostic solutions are not only available, affordable, and appropriate for use in LMICs, but also that they have been adopted in these settings.

- **Available:** Products that address consensus-defined needs are developed, brought to market (i.e. registered for use) in LMICs, and sustainably supplied.
- **Affordable:** Cost-structure is adapted to LMICs and strategies for further cost reductions are in place.
- **Appropriate:** Diagnostic test meets the needs of the target population and is complemented by interventions that facilitate use in a weak health system infrastructure, to become a smart diagnostic solution.
- **Adopted:** Introduction of diagnostic solutions following national policy decision and tailored roll-out strategies.

Access encompasses key activities along the entire diagnostic value chain, including research and development, global policy and regulatory, establishing market demand, transition to scale and scale-up, with a feedback loop from local implementation back into R&D. We will increasingly invest in and rely on market analysis to understand changing needs and tailor roll-out strategies.

As a Product Development and Delivery Partnership, FIND has learned from experience that to successfully introduce and scale a diagnostic, it needs to have a complex implementation package built around it. Our country footprint, described on page 13, provides entry to key markets where we are "hands-on" in the development of best implementation practices and scale-up, allowing us to develop and test these packages in relevant settings.

The capacity to create demand for a new product, starting from the early stages of development through delivery, is crucial and FIND achieves this through strong global capabilities and five resource hubs in select high burden countries. These hubs are spread across the globe in South and Southeast Asia, and Southern and Eastern Africa, meaning they are relevant across FIND's disease focuses. In these early-adopter countries, we work to generate evidence for policy change, develop and test implementation models, and influence regional diagnostic practice, creating demand for new products and solutions.

In addition, cross-cutting enabling interventions are required at global, national and local levels to turn diagnostic tools and services into diagnostic solutions, including:

- **Stakeholder coordination and advocacy:** alignment of stakeholders around the key role of diagnostics solutions within health systems as well as disease specific interventions.
- **Quality:** ensuring compliance with global (e.g., ISO 13485 and CE Mark registrations) and national guidelines and establishing a well-trained set of staff.
- **eHealth and connectivity:** using technology and computing power to improve services to patients and programme management.
- **Market intelligence:** compiling market information at various stages of product development and roll-out that supports governments, industry and partners to more quickly and efficiently reach scale up.

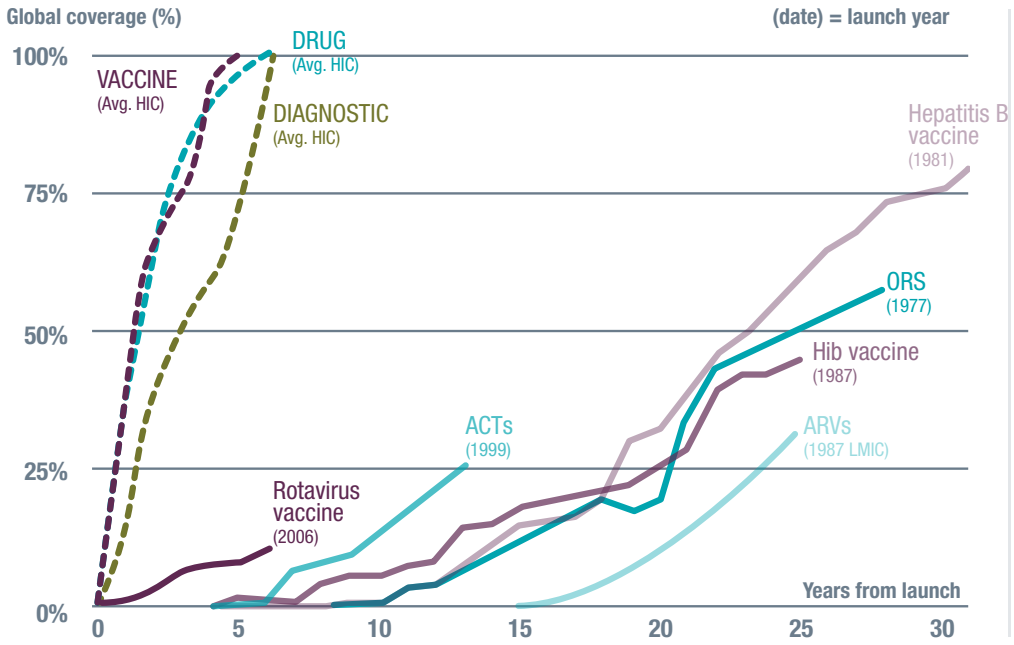
BARRIERS TO ACCESS

Several major barriers to uptake exist along the value chain of diagnostics solutions that impede access. These include:

- **Lack of market intelligence on LMICs:** Current diagnostics R&D is typically targeted at high-income countries (HICs) which are traditionally more profitable markets for industry and where more reliable market information is available. As a result, cost structures of solutions are not adapted to LMICs and products are often not adapted to LMIC needs (e.g., climatic conditions).
- **Lag in global and national policy development:** Both global and national policy developments involve lengthy processes to demonstrate impact of proposed solutions (e.g., evaluation studies) and stakeholder alignment. The route to roll-out is further complicated by the difficulty to translate global recommendations and guidelines into clear national regulations defining the use of diagnostics.
- **Limited uptake systems in place for new products and solutions:** Except for TB, malaria and HIV, global procurement and supply chain mechanisms are limited. This inhibits investment outside of these areas and stymies the momentum of potentially impactful products being used within national programmes.
- **Underlying health systems weaknesses:** Underlying systems of quality and capacity remain an issue in many countries. New products and diagnostic solutions require quality systems to perform and monitor testing which, without careful planning and training, can put services at risk and slow down uptake.

Weak health-systems also hinder diagnostics solutions and service delivery including limited funding for diagnostic services, poorly resourced laboratories, and under-trained, or shortages of, physicians and lab specialists. While the full scale of health systems strengthening falls outside of FIND's remit, we have seen increased programmatic focus on strengthening systems to be able to take advantage of new and impactful technologies.

As a consequence of these and other barriers, the uptake of diagnostic solutions can be slow, taking years until the solutions reach those who are most in need.



ACT: artemisinin-based combination therapy

Hib: Haemophilus influenza type B

LMIC: lower- and middle-income countries

ARV: antiretroviral

HIC: high-income countries

ORS: oral rehydration solution

Figure 1: Uptake curves of different medical interventions in HICs and LMICs

FIND'S ACCESS STRATEGY

FIND's mission is to turn complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives. Our commitment to access entails working towards making appropriate products available and affordable, and seeing their implementation where people seek care. To achieve this, FIND works to bring appropriate products to market, and to guide their adoption and uptake through a set of key activities (Figure 1) designed to break down barriers to access.

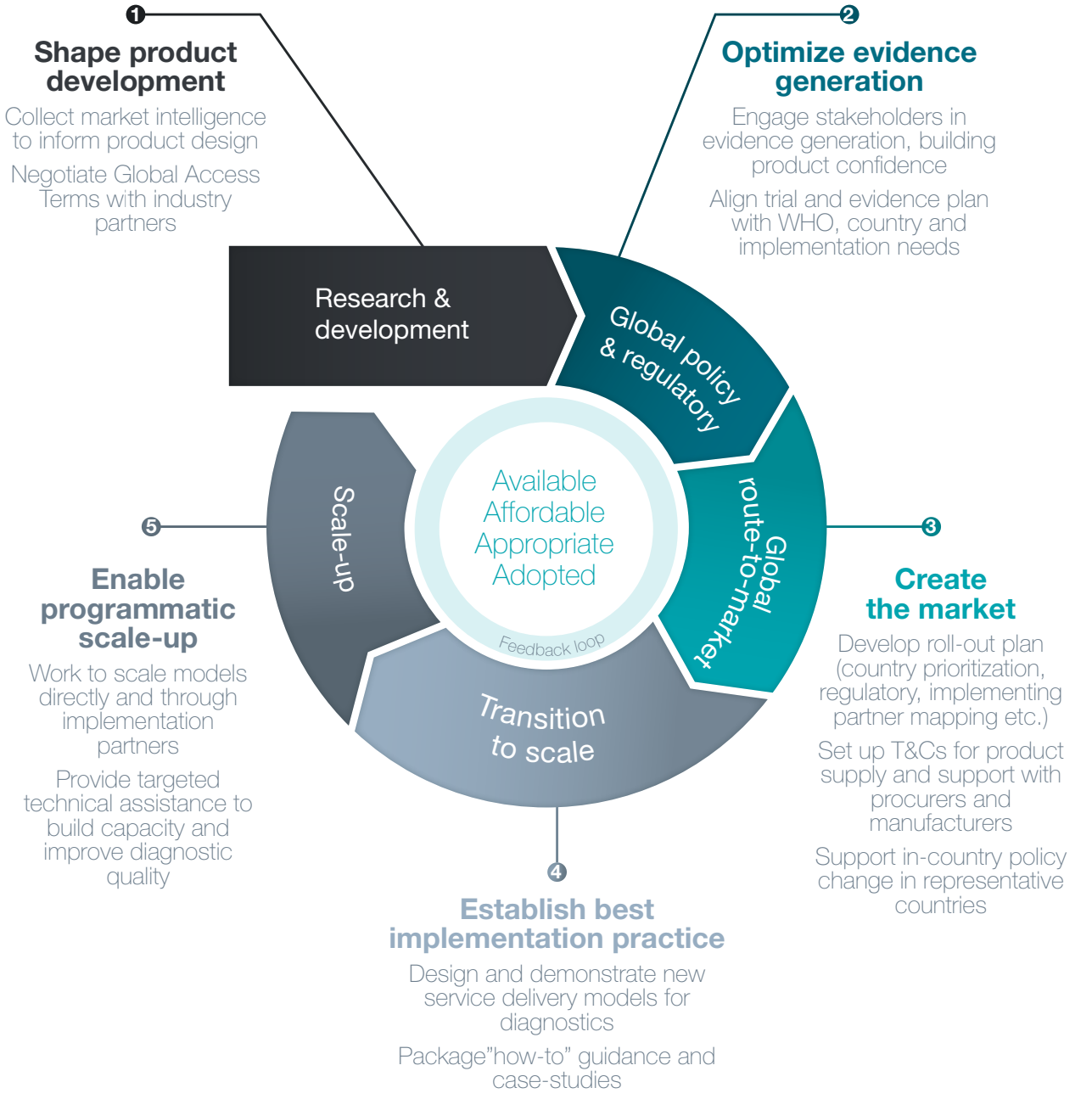


Figure 2: FIND strategic goals along the value chain for diagnostic solutions: access needs and principles must be considered at every step of the development and implementation pathways

FIND will work on five strategic objectives corresponding to targeted activities along the value chain.

1. Shape product development

a. Collect market intelligence to inform product design

b. Negotiate Global Access Terms with industry partners

FIND's objective in driving R&D is to develop diagnostic tools that are made for LMICs, determined through a consensus-based process supported by WHO target product profiles. In tandem, FIND establishes market intelligence for key products that informs product design, supports the business case for companies to invest in these products, and provides insight into their uptake.

All FIND's product development uses a standardized and transparent process to identify and select partners that can meet a number of set criteria, including Global Access requirements. Early on in the R&D process, we ensure that appropriate pricing and intellectual property (IP) for new products is agreed upon by development partners.

Specifically:

- We seek to obtain the lowest sustainable prices for a product, i.e., prices as low as possible, while also maintaining quality, providing security of supply and a fair return on investment for suppliers. We take into account the feasibility of attaining an affordable price for the end product when considering whether to enter into any product development project. In the course of product development, we will set a target price in agreement with the commercial partner.
- We consider IP as essential to ensure that the cost structure of new products befits LMICs and is in line with the objective to support affordable products, as well as to maximize freedom for others to use the outputs of our development projects. IP discussions may cover patent-protected intangibles, copyrights, trademark, trade secrets and data rights, for instance.

2. Optimize evidence generation pathway

a. Engage stakeholders in evidence generation, building product confidence

b. Align trial and evidence plan with WHO, country and implementation needs

Evidence generation for new products, whether clinical trials, evaluations, or demonstrations are often the first time that global and national stakeholders can see new products in action and is thus a key point of advocacy. The resulting data informs review by regulatory authorities, national programmes and WHO; these activities thus provide an opportunity to involve key decision makers in study design so that evidence generation is relevant to how products will be used in public systems. FIND will engage a range of stakeholders in our evidence generation activities as a way to build product confidence and interest. In addition, FIND will work to streamline evidence generation so that single trials or evidence generation activities can inform multiple needs – i.e., WHO and national policy, global regulatory and national regulatory.

3. Create the market

a. Develop roll-out plan (country prioritization, regulatory, implementing partner mapping, etc.)
b. Set up terms and conditions for product supply and support with procurers and manufacturers
c. Support in-country policy change in representative countries

FIND will support the shift of diagnostic solutions from development and evidence generation into adoption through key activities that support governments, suppliers, and partners to plan for roll-out. We will work to reduce barriers to market entry and generate demand for new solutions through the creation of a global roll-out plan that includes actionable information such as suggestions for country prioritization, regulatory requirements, and partner mapping (Figure 3).

SOLUTION	DEFINITION
1. Update market assessment	Brings up-to-date market understanding of the new diagnostic device (needs, users, competitor landscape, market size, structure & access, funding, regulatory & policy issues, etc.).
2. Develop a set of strategic launch activities within a selection of early adopter countries with uptake targets	Describes the rationale, activities, and timeline for launch in a set of appropriate early adopter countries for scale-up, while specifying uptake targets.
3. Identify partnership opportunities in early adopter countries	Identifies partnerships with local manufacturers, distributors, and NGOs
4. Develop pricing strategy	Gathers input from likely purchasers and key stakeholders to establish prices recommendations for user segments and by channel.
5. Update end-user needs assessment	Updates definition of target population segment, and quantifies and prioritizes segments for roll-out; integrates updates on the understanding of the context, needs, and constraints of users of the diagnostic device.
6. Support demand generation strategies and creation of marketing material	Describes the different audiences or key influencers that are involved in the decision to purchase, recommend, or use the product. Includes messages that have been tested with each target audience as well as appropriate channels for delivering those messages

Figure 3: Components of a global roll-out plan

FIND will also work with a handful of representative countries on the requirements for policy change, stemming from the evidence generation activities outlined above. This includes coordination with in-country stakeholders to adapt national policies and include solutions into updated national diagnostics algorithms.

We will work with industry and procurement partners where relevant to establish clear terms and conditions for service and maintenance, training, support and supply terms for new products and solutions.

4. Establish best implementation practice and showcase impact

a. Design and demonstrate new service delivery models for diagnostics and demonstrate impact
b. Package "how-to" guidance and case studies

A product alone is not a solution. To realize the potential impact of a product requires a holistic set of activities which are often implemented in a piecemeal fashion. FIND will use its footprint and strategic partnerships to evaluate scale-up progress, demonstrate promising implementation models for new products and use the experience to package best practices, how-to guidance, and case studies.

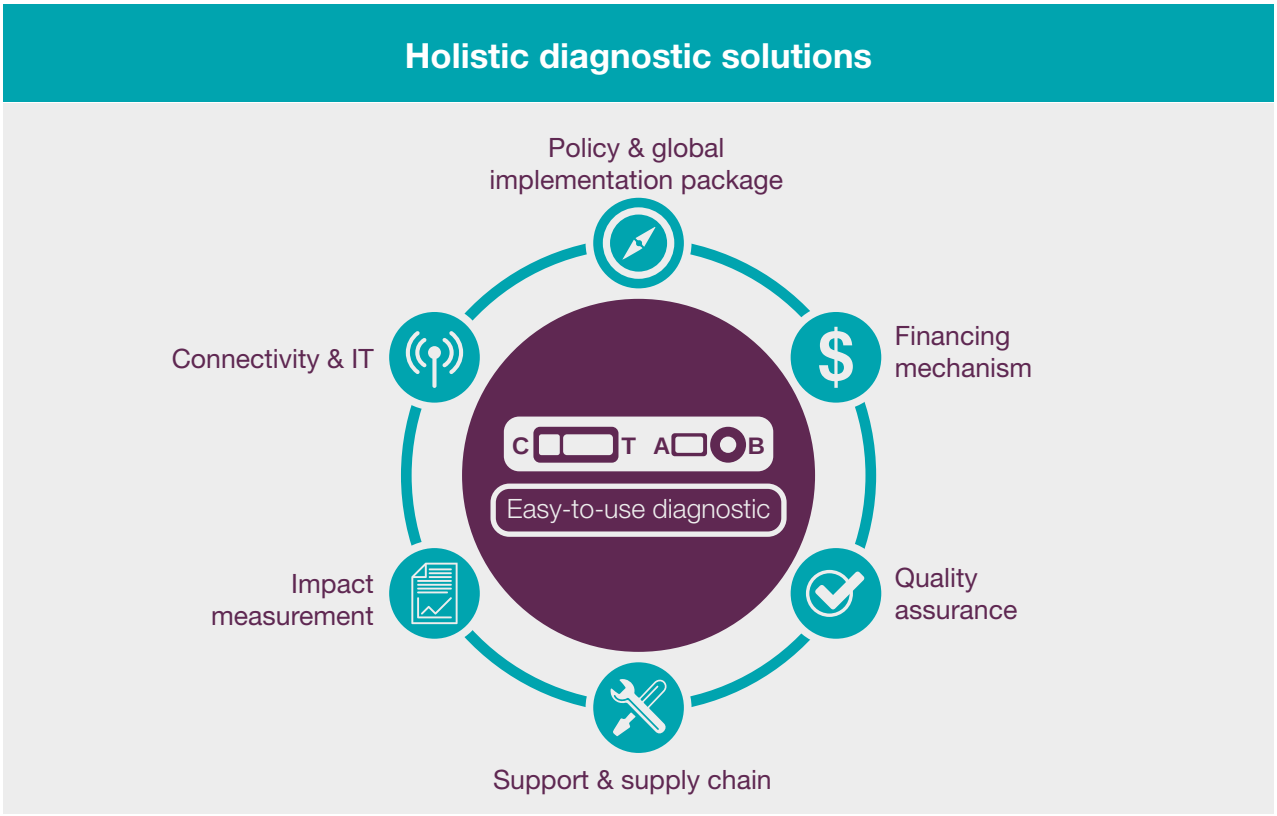


Figure 4: Characteristics of uptake models

5. Enable programmatic scale-up

a. Work to scale models directly and through implementation partners
b. Provide targeted technical assistance to build capacity and improve diagnostic quality

FIND will seek to amplify impact by establishing a set of strategic partnerships with country ministries of health, in-country partners and implementers to support the creation and expansion of guidance and best implementation practices.

Except in specific contexts (e.g., in India), FIND will achieve health impact locally by leveraging partner networks and strong expertise of local contexts. Partnerships will both ensure impact at point-of-care and allow FIND to incorporate feedback from field implementation into the design of national and global interventions.

FIND will also provide technical assistance and build capacity of national programmes to manage and maintain diagnostic services at scale and with a high level of quality.

PROGRAMME GOALS AND PRIORITY INTERVENTIONS

Since 2015, FIND has implemented a wide breadth of access activities across disease programmes. Over ~50% of FIND's budget has supported access projects in over 40 countries, across disease areas. We manage both disease-specific projects across programme areas along with crosscutting projects based on specific capabilities (e.g., connectivity).

Going forward through our current strategy period to mid-2020, the access programme aims to support scale-up of at least eight diagnostic solutions through a set of work packages that can be applied across diseases. The choice of solutions is based on FIND's R&D pipeline of products and our current experience in demonstrating the potential for their wider impact.

See Annex for detailed plans across programmes.

As a priority, FIND has identified a set of three targeted interventions that will be of particular focus for resource mobilization. These interventions are highlighted as those that the access team finds particularly promising based on the needs seen across multiple countries, and based on the current and near-term technology pipeline.

1. Paediatric TB Initiative

FIND's India team has worked to establish a public/private initiative in ten cities that expands first-line molecular TB testing to children, for they are notoriously challenging to test since they cannot produce sputum samples. India, along with a number of countries in south and Southeast Asia, has active private sectors which are the first points of contact for the majority of people with TB. The programme in India has focused on training of public and private providers and linking clinics to the national TB diagnostics infrastructure. The work has resulted in close to 100,000 tests performed on children and a change in national policy to upfront GeneXpert testing for all paediatric patients.

In the TB development pipeline is a sampling kit that uses stool rather than sputum and is optimized for use with GeneXpert, and theoretically can be used with all molecular tests. The stool kit will be an alternative method to sputum sampling and is thus well suited for paediatric TB cases. Through the proven public/private model in India, and an improved sample collection methodology, FIND can dramatically improve the ease and expansion of paediatric diagnosis of TB, which claims the lives of up to 500 children every day.

In the Paediatric TB Initiative, FIND will:

- Document best implementation practice of the India programme for scale-up in additional countries where the private sector is an active part of the TB case-finding infrastructure.
- Complete the development of and demonstrate the paediatric stool sampling kit, seeking WHO endorsement.
- Combine the model and stool sampling kit into a full solution for demonstration and uptake in 3–5 countries.

In countries where the HIV burden is high, and where there is a typically less active private sector (namely, sub-Saharan Africa), FIND will also explore the use of integrated platforms across early infant diagnosis of HIV and TB diagnosis to improve coverage.

We estimate roughly a need of an additional USD$5–7 million to establish a multi-country initiative that will significantly increase coverage, case detection, and notification of paediatric TB patients.

2. Get Data/Use Data Initiative

In the last 10 years, the availability of data from health systems has exploded. Connectivity has become a standard requirement of diagnostic platforms. Even tests that previously have been unconnected – such as rapid diagnostic tests – today have readers and apps that are either available or in development. Thus, results and other pertinent information can be collected, stored and transferred, allowing for real-time analysis of aggregated data. Diagnostics systems have historically relied on paper-based reporting, so the availability of real-time data is a technological revolution.

In the same timeframe, there has been a great decentralization of diagnostics use and treatment, driven in large part by malaria, HIV and TB. Where only a handful of sites may have been testing for HIV CD4 or MDR-TB in a country in the past, hundreds or thousands of sites globally now have the capacity, making the establishment and management of a diagnostics network increasingly complex.

The Get Data/Use Data Initiative will focus on ways in which data can support the management and delivery of diagnostics, building off of existing FIND programmes. Specifically, the programme will include three core components:

- **Diagnostic network mapping:** By the end of 2018, FIND will have completed mapping projects in four geographies that aim to optimize the purchase and placement of diagnostic devices across diseases, and the flow of patients between services. As diagnostic devices increasingly have multiplex capacity and the private sector continues to play a strong role in public health, mapping forms the rationale for the placement and linkages of new services.
- **Get data:** FIND will continue to support diagnostics developers in the hardware and software requirements that facilitate connectivity. In 2017, FIND supported the testing of Cepheid's Omni, which has resulted in improved performance pre-launch and decreased data transfers, lowering the cost of connectivity. Similarly, FIND will work with the data aggregators who develop the tools that collect and analyze data. In a current project in Myanmar, FIND is working with the data aggregation software provider to improve the interface between the software and those who enter data.
- **Use data:** In Myanmar, FIND is working at the national and regional level to use real-time data every day in the review and management of the national TB programme. In 2018, sites will begin to see updated targets for testing of sub-populations (HIV patients, children, etc.), driving regional and national management to better track targets and, importantly, improve interventions when needed. The work in Myanmar will be written up as a case study, which will be used elsewhere and in other disease areas (e.g., HIV, AMR), resulting in best implementation practice.

In addition, FIND will explore ways in which quality assurance can be increasingly managed remotely. This is a relatively new area of thinking, but the traditional system of external quality assurance which relies on panel-based testing at sites will be increasingly challenging considering the explosion in the number of sites where disease is diagnosed.

The initiative will seek USD$3–5 million from a variety of sources to establish mapping as a pre-requisite for large investments in diagnostics, and to become the recognized leader in the use of diagnostics data in national programmes.

3. Diagnostics Quality and Capacity Initiative

Through a number of previous initiatives (CDC, EXPAND-TB), FIND has worked to improve the capacity and quality of diagnostics systems in LMICs. This work continues to be of utmost importance to the scale-up of diagnostic solutions and to the sustainability of national programmes. FIND will continue to seek opportunities that take advantage of our extensive training experience and capacity. With the trend in funding opportunities moving into countries, FIND will seek new opportunities to liaise more directly with national programmes and partners to establish diagnostics quality and training initiatives through donors like The Global Fund and USAID.

This initiative will seek to partner with at least five countries on multi-year training and quality programmes, with a fundraising target of USD$2 million.

OPERATING MODEL

At the nexus between development and policy design, FIND is strategically positioned to act as a bridge builder between global diagnostics solutions and national implementation.

FIND's operating model for access relies on internal capacity as well as partnerships for implementation. In order to support global access efforts, FIND has developed capabilities within disease programmes and additional skills in the cross-cutting areas of market intelligence, analytics, eHealth/connectivity and partnership management.

In addition to its global headquarters in Geneva, Switzerland, FIND operates four country offices in India, Vietnam, East Africa and South Africa. Of these, India and Vietnam are currently well placed to seek in-country funding, and East Africa[1] will be by the end of the current strategy period. FIND's country offices have developed expertise in relevant topics for their regions. The South African office is leading the development of access toolkits (such as training materials) and has developed specific expertise in lab strengthening and capacity building for TB. The Indian office is supporting FIND scientific work on TB and is spearheading the development of private sector-driven diagnostics delivery models. All regional offices have the ability to manage local / regional partnerships, such as with CHAI in Vietnam. Before 2020, FIND will consider the addition of a sixth country office.

1. Uganda and Kenya opening

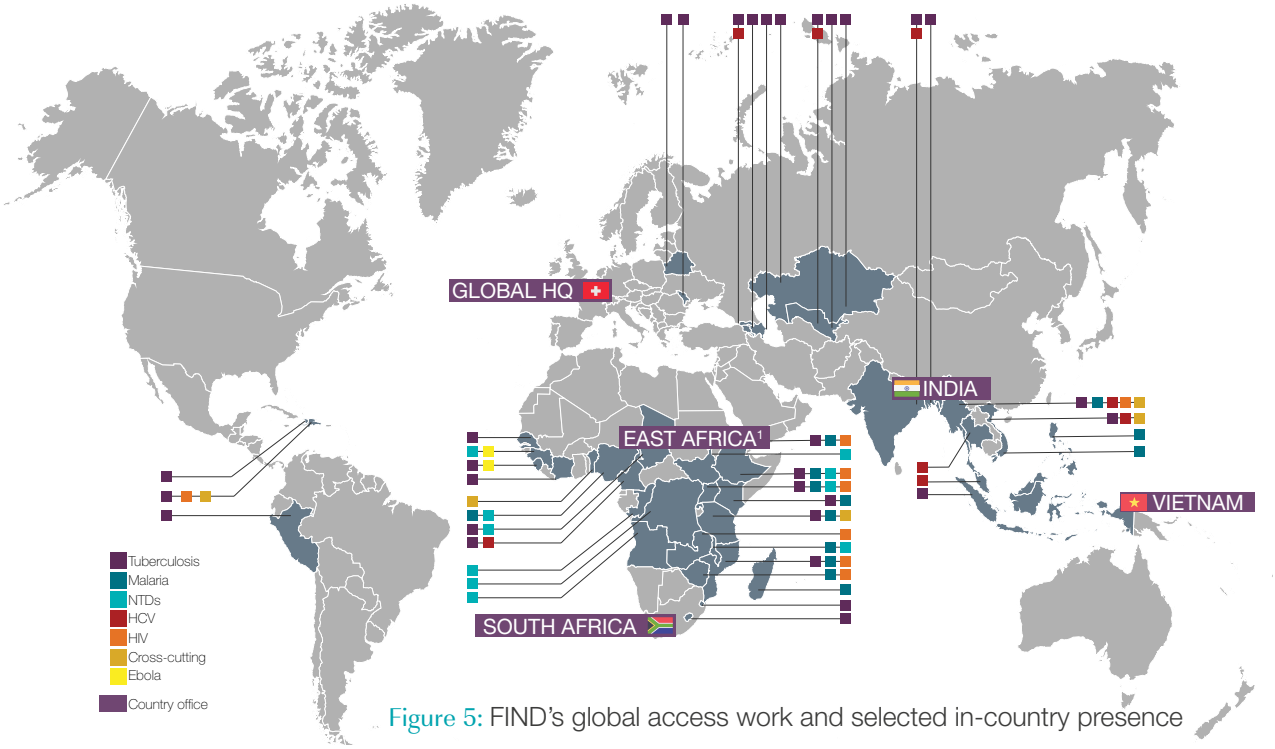


Figure 5: FIND's global access work and selected in-country presence

FIND's access programme has established and will continue to establish several strategic partnerships. As a technical organization, FIND does not have the implementation network of dedicated access organizations that have developed, or are managing, a wider breadth of local operation. Local, regional or global access partners – including country stakeholders – are essential to ensure long-term sustainable health. All FIND partners will benefit from our recognized expertise in diagnostics. They will also have co-ownership of the models they help develop. Access partnerships serve two main purposes: 1) establishing best implementation practices and empowering local scale-up; and 2) informing and partnering for market intelligence to support product development and creation of the market.

Figure 6: FIND partnership approach to local implementation

FIND's strategic partners include several implementers with a global presence and a strong record of delivering health impact. This decentralized, highly resilient operating model enables FIND to maximize its global and national impact with a relatively small footprint.

Please reach out to **Catharina Boehme, CEO, catharina.boehme@finddx.org** or **Zachary Katz, Chief Access Officer, zachary.katz@finddx.org** if you are interested in collaborating with us on this important programme.

ANNEX

TUBERCULOSIS: FIND's tuberculosis programme aims to enable access to fit-for-purpose diagnostics and linkages to treatment for all people afflicted with tuberculosis and to support the WHO in their goal of a world free of this disease. The Access goal in tuberculosis is to establish case detection and care strategies where patients first present.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
Paediatric stool sampling kit (PSK): Sales in at least 3 countries to more easily test TB and MDR-TB in children	Inform product design	Support trial design & establish evidence generation activities in key market countries informed by market intelligence	Create rollout plan that defines early market efforts for supplier and establish supply terms; establish kit in at least 2 countries	Demonstrate PSK in 2 countries and draft and publish best implementation practices	Uptake of PSK in at least 2 countries in addition to the demonstration countries
Paediatric testing: Establish best implementation practices from India programme experience				Draft and publish best implementation practices; engage stakeholders & strategic partners	Support partners to expand paediatric programme in 2 additional locations
Triage test: Roll-out plan with early market targets for RDT to determine active TB	Inform product design	Support trial design & establish evidence generation activities in key market countries informed by market intelligence & stakeholder engagement	Create rollout plan for supplier & establish supply terms; work with stakeholders for policy change in at least 2 countries		
XDR testing: Establish best implementation practices for scale up with new centralized & POC diagnostics	Inform product design	Support trial design & establish evidence generation activities in key market countries with strategic partners	Create rollout plan that defines early market efforts for supplier & establish supply terms; achieve policy approval in at least 2 countries	Demonstrate decentralized MDR/XDR diagnosis in 2 countries & draft publish best implementation practices	
LAM: Create rollout plan for early market countries		Support trial design & establish evidence generation activities including in HIV+/- in key market countries	Create rollout plan that defines early market efforts for supplier & establish supply terms		
NGS: Establish best implementation practices & guidance for the use of next-generation sequencing		Support trial design & establish evidence generation activities in key market countries with strategic partners	Create rollout plan that defines early market efforts for supplier & establish supply terms; achieve policy approval in at least 2 countries	Demonstrate NGS in 2 countries and draft & publich best implementation and use practices	
POC TB/MDR-TB: Establish best implementation practices for TB & MDR TB diagnosis at the point-of-care	Support usability testing for device and connectivity solution	Support evidence generation activities in key market countries with strategic partners	Policy approval in at least 5 countries	Demonstrate decentralized TB and MDR-TB diagnosis in 2 countries and draft & publish best implementation practices	Uptake in at least 2 countries in addition to the demonstration countries

MALARIA & FEVER: The vision of FIND's malaria programme is a world where everyone with suspected malaria has aacess to adequate diagnosis to enable appropriate care. Improving case management & accelerating malaria elimination will only be achieved through the scale-up of innovative, high-quality diagnostic solutions worldwide. Access work will support establishing cost-effective test and treat models for elimination & improved management of patients who test negetive for malaria

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
High-sensitivity RDT: Create roll-out plan to inform best practice & scale-up, + scale-up in at least 2 countries		Support trial design & establish evidence generation activities in key market countries	Create roll-out plan that defines early market efforts for supplier and establish supply terms	Demonstrate in 2 countries and draft and publish best implementation practices that improve case detection	
hs Combo Pf/Pv: Inform product design and evidence generation for roll-out	Support usbility testing for device and connectivity solution	Support trial design & establish evidence generation activities in 2 key market countries with strategic partners			
G6PD: generate evidence on cost-effectiveness of the options for diagnostics to accompany the roll-out of tafenoquine		Support cost-effectiveness evidence generation activities in 2 key market countries with strategic partners			
Non-invasive POC: Inform product design & evidence generation for roll-out	Support usbility testing for device and connectivity solution	Support trial design and establish evidence generation activities in key market countries			
Fever triage test (with AMR): support evidence generation for rollout & demonstrate in 1 country	Inform product design	Support trial design and support evidence generation activities in 2-3 key market countries	Create roll-out plan that defines early market efforts for partners and establish supply terms for leading products	Demonstrate triage testing in at least 1 country and draft and publish best implementation practices	
POC multiplex fever identification: Create roll-out plan	Inform product design	Support trial design and establish evidence generation activities in key market countries	Create roll-out plan that recommends early market efforts for supplier and establish supply terms		
eHealth Fever management: Support demonstrations in 2 countries and create best implementation practices		Support trial design and establish evidence generation activities for the use of diagnostics data in fever management tools	Create roll-out plan for eHealth tools and bundled diagnostics that defines early market efforts for supplier and partners	Demonstrate in 2 countries and draft and publish best implementation practices	

HEPATITIS C: FIND's HCV programme supports the WHO Global Hepatitis Programme to decrease morbidity and mortality due to viral hepatitis through improving the care of patients with the disease and diminish the socio-economic impact of viral hepatitis at individual, community and population levels. The Access goal is to see simplified algorithms for diagnosis, treatment and cure in policy and use.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
DBS for RNA: Facilitate scale up of DBS as a tool for HCV confirmation in 4 countries	Complete market analysis; negotiate pricing	Inform and support evidence generation for regulatory filings	Create roll-out plan that defines early market efforts for supplier and establish supply terms	Establish DBS demonstrations in least 2 countries and draft and publish best implementation practices	Uptake of DBS in at least 2 national programmes in addition to the demonstration countries
Self-testing: Approval in at least 2 countries; create roll-out plan for key market countries	Complete market analysis; Inform product design; negotiate pricing	Support trial design and establish evidence generation activities in key market countries	Create roll-out plan that defines early market efforts for supplier and establish supply terms; Product approval in least 2 countries		
cAg Test of Cure: Inform evidence generation and establish case study for the use of cAg in the testing algorithm		Support trial design and trial implementation in early market country	Create roll-out plan that defines focus countries for supplier and establish supply terms; achieve policy approval in at least 1 country	Demonstrate cAg in the testing algorithm (confirmation and cure) in at least 1 country and draft and publish case study	
Platform Integration: Establish best practices through demonstration in 2 countries and facilitate scale up through partners		Support evidence generation activities in key market countries with strategic partners	Achieve policy approval in at least 2 countries	Demonstrate centralized and decentralized platform integration in 2 countries and draft and publish best implementation practices	
POC Confirmation: : Establish best practices through demonstration in 2 countries and facilitate scale up through partners		Support trial design and establish evidence generation activities for key populations in key market countries/ geographies	Create roll-out plan for 2-3 key market countries	Demonstrate decentralization of HCV diagnosis in 2 countries and draft and publish best implementation practices	
CEA : costing analysis of simplified testing algorithms		Calculate the diagnostic costs per patient initiating treatment for different testing algorithms		Evidence generated used to draft and publish best implementation practices with WHO GHP	

Neglected Tropical Diseases: FIND's NTD programme is supporting the World Health Organization's 2020 Roadmap and the London Declaration of 2012 to eliminate or bring under control 10 NTDs by developing diagnostic solutions for HAT, leishmaniasis, Chagas disease and Buruli ulcer. The Access goal is to support the elimination of HAT by 2020 and enable a post-elimination surveillance strategy embedded in malaria programmes, while building programmes in additional NTDs.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
HAT/Malaria Combo: Support evidence generation and create roll-out plan for 5 key countries		Support trial design and establish any further evidence generation activities in key market countries required for regulatory approval	Create roll-out plan for 5 countries and achieve policy approvals; establish supply terms; establish kit in least 2 countries		
Integrated Approach HAT: Draft and package best implementation practices				Draft and publish best implementation practice; engage stakeholders and strategic partners	Expand approach in 3 additional countries
Integrated Approach to visceral leishmaniasis: Draft and package best implementation practices				Demonstrate approach in 1 country; draft and publish best implementation practice; engage stakeholders and strategic partners	Expand approach in 1 additional geography

Outbreaks: The vision for FIND's Outbreak programme is to move from a reactive to a proactive global outbreak response through diagnostic preparedness. The goal for access is to establish market sustainability and improve outbreak response speed.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
Outbreak panel: Establish evidence and use cases for outbreak panel		Support evidence generation in a set of key market countries	Establish roll-out plan through market intelligence		

Antimicrobial Resistance: FIND's AMR strategy is focused on halting and preventing AMR by 1) optimizing use of antimicrobials, 2) preserving new drugs and 3) empowering surveillance efforts. The focus for Access is on reducing the use of unnecessary antibiotics through the use of triage tests.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
Blood culture ID: Inform product design and evidence generation for roll-out	Support usability testing for device	Support evidence generation activities in key market countries with strategic partners			
Fever triage test (with fever): support evidence generation for roll-out and demonstrate in 1 country	Inform product design	Support trial design and support evidence generation activities in 2-3 key market countries	Create roll-out plan that defines early market efforts for partners and establish supply terms for leading products	Demonstrate triage testing in at least 1 country and draft and publish best implementation practices	
Gonorrhea: develop diagnostic for expected new treatment	Inform product design	Support trial design and establish evidence generation activities in key market countries	Support aligned roll-out plan with new treatment		
UTI: expansion of diagnostics for the reduction in prescription of antibiotics		Support evidence generation for existing products to safely decrease prescription of antibiotics			

Cross-Cutting: Across diseases, the goal is to support donors, countries and implementers in prioritizing interventions and improve data availability, quality and use. FIND's primary goals are to promote the use and integration of data through connectivity tools and other means by national programmes to improve health services.

Priority intervention	SHAPE R&D	Optimize Evidence Generation	Create the Market	Best Implementation Practices	Enable Programmatic Scale-up
Data utilization for improved service deliver: Publish best practices and scale up in 2 additional countries		Establish evidence on the impact of real-time data use in the improvement of national TB and HIV programme diagnostics management	Baseline assessment in 2 countries to map need	Demonstrate real-time data use within 2 MOHs; draft and disseminate best practices	Uptake of data utilisation efforts in at least 2 additional countries
Global SIM: Establish pricing for all partners, create guidance for use and facilitate sales			Establish Global SIM solution across LMIC, available to all public sector partners; negotiate price, terms and conditions	Draft guidance for to purchase, initiation, and management of Global SIM solutions	Sales of of Global SIMs into at least 10 countries
Diagnostics network mapping: Establish implementation guidance and map at least 5 countries				Mapping in at least 5 countries to that informs WHO supported implementation guidance	

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