



PARTNERING FOR  
DIAGNOSTIC EXCELLENCE

ANNUAL REPORT **2017**





# CONTENTS

Leadership Message	4
2017 in Numbers	5
Key Achievements in Country Offices	6
Taking Stock: Mid-Term Strategy Review	9
Taking Action	
Catalyse Development	10
Guide Use & Inform Policy	12
Accelerate Access	13
Shape the Agenda	15
Spotlight on Diseases	
Fever, AMR & Outbreaks	16
Hepatitis C	18
Malaria	19
Neglected Tropical Diseases	21
Tuberculosis	22
Governance	23
2017 Financial Statements	26

# LEADERSHIP MESSAGE



**Dr Catharina Boehme**  
Chief Executive Officer



**Mark Kessel**  
Chair of the Board

The year 2017 marks the halfway point in the delivery of our 2015–2020 strategy. We are on track, as confirmed by an external mid-term review, and we enter the second half of this strategic period with renewed energy and concrete plans for further portfolio strengthening.

In the past year, more than 15 million FIND-supported products were provided to simplify diagnosis in low- and middle-income countries. We added 9 *in vitro* diagnostic projects to our portfolio, bringing the total in development to 48. Ensuring access to diagnostic tools is as important as developing the tools themselves, and this year, we formalized our diagnostic access strategy. In ten cities in India, we tripled the diagnosis rate of children presumed to have TB (compared with conventional microscopy) by implementing a new molecular test – 90% of the children found to have TB are now on appropriate treatment. As a result, national TB policy has been changed, and the technology is being rolled out across the whole country by the Indian government.

We continue to intensify our laboratory strengthening activities, clinical trials and infrastructure support, particularly via our offices in Viet Nam and South Africa. We also joined a new task force on diagnostic connectivity - launched by the Global Laboratory Initiative - which aims to build on the positive momentum experienced in this rapidly growing field since 2016. Together with our partners, we developed the first ever international standard for malaria diagnostics – endorsed by the World Health Organization (WHO) – which will be used to ensure that malaria rapid

diagnostic tests are quality assured. We continue to contribute to global research: this year we published 65 peer-reviewed manuscripts, and collaborated with WHO to develop target product profiles for new tests, as well as in-depth landscape reports and market analyses of diagnostic products. For TB, we provided data to support the WHO recommendation of the Xpert MTB/RIF Ultra assay, which will advance TB diagnostic capabilities in difficult-to-diagnose populations, such as children and those with HIV co-infection or extra-pulmonary TB.

As an organization we continue to grow. This year the FIND leadership team welcomed Rangarajan (Ranga) Sampath, Chief Scientific Officer, and Cassandra Kelly-Cirino, Head of AMR & Outbreaks. Our Board of Directors was joined by David L Heymann, Professor of Infectious Disease Epidemiology at the London School of Hygiene & Tropical Medicine and Head of the Centre on Global Health Security at Chatham House, London, UK.

On behalf of FIND we would like to convey our appreciation of the efforts of the team, our partners, our funders and all those with whom we collaborate around the world, especially the patients participating in our clinical trials. Without you, our work would not be possible.

**Mark Kessel, Chairman of the Board of Directors**  
**Catharina Boehme, Chief Executive Officer**

## 2017 IN NUMBERS

---

>15 million FIND-supported products estimated to have been provided to LMICs (27% increase from 2016)

---

>10 reports/landscapes and technical guidance documents co-developed with partners

---

13 clinical trials carried out in 19 countries

---

>11,300 participants enrolled in FIND-sponsored clinical studies

---

10 specimen collection trials carried out

---

104,153 specimens collected for TB and malaria

---

1,450 health workers trained

---

321 laboratories and testing sites strengthened in Africa, Asia and Eastern Europe

---

9 new in vitro diagnostic projects added to FIND portfolio, bringing current total to 48

---

5 new projects ongoing for non-IVD products

---

65 peer-reviewed manuscripts published by FIND authors – over 430 citations

---



# KEY ACHIEVEMENTS IN COUNTRY OFFICES

“This year we contributed to TB diagnostic network strengthening across the value chain, from building partnerships for new tools development and evaluation in South Africa, to establishing innovative, data-driven approaches to diagnostic network optimization using country data to inform strategic planning to improve access of patients to diagnosis and treatment.”

– Heidi Albert, Head of FIND South Africa

## Cape Town – South Africa

- + Together with local partners, conducted multi-site evaluations of a new point-of-care TB diagnostic device, including data connectivity assessment and usability study in settings of intended use; findings informed subsequent product development to meet target product profile specifications
- + Contributed to the development of a new stool processing kit for improving diagnosis of TB in children, and built partnerships with local industry, academia and donors needed to take the product to market
- + Expanded TB diagnostic network optimization work: completed project with the Ministry of Health in Lesotho that informed donor investment, making a case for procurement and placement of TB diagnostics, and initiated new projects in Kenya and the Philippines
- + Co-led consultancy on national TB diagnostic network assessment in India, and contributed to the development of a national TB diagnostic network scorecard for assessment and network quality improvement
- + Continued contribution to global guidelines and tool development together with Global Laboratory Initiative (GLI) and GLI Africa, and provided country support for early adoption of new tools in the region through country workshop (e.g. transition to Xpert MTB/RIF Ultra in Kenya and Swaziland)

Geneva - Switzerland  
HEADQUARTERS

“In 2017, we initiated a new project targeting hepatitis C virus (HCV) diagnosis and treatment in India, a country with close to 12 million HCV-infected individuals. We completed preparatory work and site assessments for the project, which aims to advance policy change at global and national levels, and help pave the way for a public health approach to HCV testing and treatment.”

– Sanjay Sarin, Head of FIND India

### New Dehli - India

- + 277,687 patients tested for TB and drug-resistant TB using newer diagnostic technologies across FIND-supported laboratories, with 13,909 cases of multidrug-resistant TB detected
- + Scale-up and transfer of paediatric TB project, including the testing of 25,401 presumptive paediatric TB cases with 1,348 cases diagnosed, of which 108 were RIF resistant
- + 65 continuing medical education sessions on managing paediatric TB delivered to 2,630 healthcare providers; 54 on-site training sessions for 394 laboratory personnel
- + Technical support provided for the implementation of a laboratory information management system software solution in 61 Revised National Tuberculosis Control Programme (RNTCP) labs, procurement assistance provided for 20,000 tablets for the RNTCP; 45 mobile vans equipped with GeneXpert (CBNAAT) machines to carry out active case-finding drives
- + Support and capacity-building activities for 74 TB laboratories, which included providing laboratory supplies plus annual maintenance, whole genome sequencing capacity for 5 of the labs, and pyrosequencing technology for 1 lab. Fifteen labs were upgraded to culture and DST (C&DST) facilities, including providing 34 categories of equipment to establish MDR-TB testing capacity. This grew the total number of labs able to do to C&DST testing to 61.
- + Memorandum of Understanding signed with the Government of Punjab, establishing a partnership to increase access to HCV diagnostics in the HIV/HCV co-infected population.

“In March 2017, FIND was honored to be recognized by the Viet Nam Ministry of Health for contributions to TB control in Viet Nam for the period 2014–2016. Awards were given to in-country and international organizations on the occasion of the 60th anniversary of the establishment of the National Lung Hospital.”

– Yen Nguyen, Representative of FIND in Viet Nam

### Hanoi – Viet Nam

- + Started implementation of the second round of the Strengthening Laboratory Management Toward Accreditation programme – adapted for TB laboratories (TB SLMTA) – for 6 clinical TB laboratories; completed baseline audits as well as the first training workshop for 18 laboratory technicians and managers. Supervision visits conducted for all 6 TB SLMTA first-round labs
- + National annual technical workshop conducted for external quality assessment (EQA) for line probe assay (LPA), liquid culture (LC) and LC drug susceptibility testing (LC DST); workshops delivered for 6 laboratories with 23 participants for LPA and LC DST and 32 labs with 43 participants for LC
- + Organized a national technical workshop with 95 participants for EQA for 74 Xpert MTB/RIF testing sites
- + Supported National TB Control Programme for in-country manufacture of proficiency testing (PT) panels and technical support for roll-out of PT rounds. The second pilot of in-country Xpert MTB/RIF PT panels for 11 labs was completed before the first PT roll-out for 35 laboratories and second PT roll-out for 75 labs were successfully implemented. Follow-up onsite visits were conducted to support sites having non-conformities in EQA results
- + Finalized development of guidelines for quality assurance of molecular diagnostic TB testing (LPA and Xpert MTB/RIF) and a standard operating procedure for panel development of Xpert MTB/RIF (EQA) and LPA (1st line & 2nd line) and presented to the National TB Programme with a fully established EQA programme for the two testing procedures.

*PERSPECTIVE:*

## **RANGA SAMPATH** *CHIEF SCIENTIFIC OFFICER*



Global health has always been close to my heart. After two decades working in the molecular diagnostics industry, I was eager to join FIND and lead a team of dedicated researchers working on novel products and making an impact where it really matters. The opportunity to work across sectors and bring together different players – product developers, donors, policy makers, implementers and end-users – is something you don't get so much in private industry.

FIND is engaged in numerous exciting projects across our portfolio of diseases, including point-of-care tests to help identify the “missing millions” of TB cases; a triage test for fever patients; novel and rapid diagnostic tests that are helping control morbidity and support elimination of numerous neglected tropical diseases, and near-patient, highly sensitive diagnostic tests for hepatitis C and malaria. This year we have started to formalize our programme in antimicrobial resistance and outbreaks, strengthening our commitment to preparedness and management of emerging infectious disease threats. We are also making

headway in eHealth, connectivity and data utilization, as well as clinical decision support tools.

We are dedicated to identifying game-changing technologies that can transform how infectious diseases are managed. Wearable sensors that can monitor heart rate, blood glucose or other metabolites offer the ability to have non-invasive, continuous monitoring over a period of time: could these types of technologies help measure exposure to pathogens in an outbreak setting, so that patient triaging could be done even before the first specimen is taken?

Besides technology, pioneering ideas are also needed to create sustainable business models, with greater investment in and from local communities to find health solutions that are affordable and cost-effective. FIND has led the awareness and introduction of many of the current technologies for low- and middle-income countries, and our focus remains relevant as we continue to work on the next generation of diagnostic tools for infectious diseases.



# TAKING STOCK: MID-TERM STRATEGY REVIEW

Our 2015–2020 strategy focuses on FIND’s role as bridge builder and mobilizer, translating the technical world of product development into access to diagnostic solutions that will meet patient needs in low-resource settings.

An external mid-term strategy review was completed in June 2017 by the FIND Scientific Advisory Committee and Board of Directors. The report showed

that FIND has successfully implemented the strategy, reacted to changes in the external environment and met many of its goals. Overall and with moderate course corrections, we are on track to deliver against our 5-year plan.

Figure 1 depicts the four strategic pillars that guide our activities, together with key achievements to date.

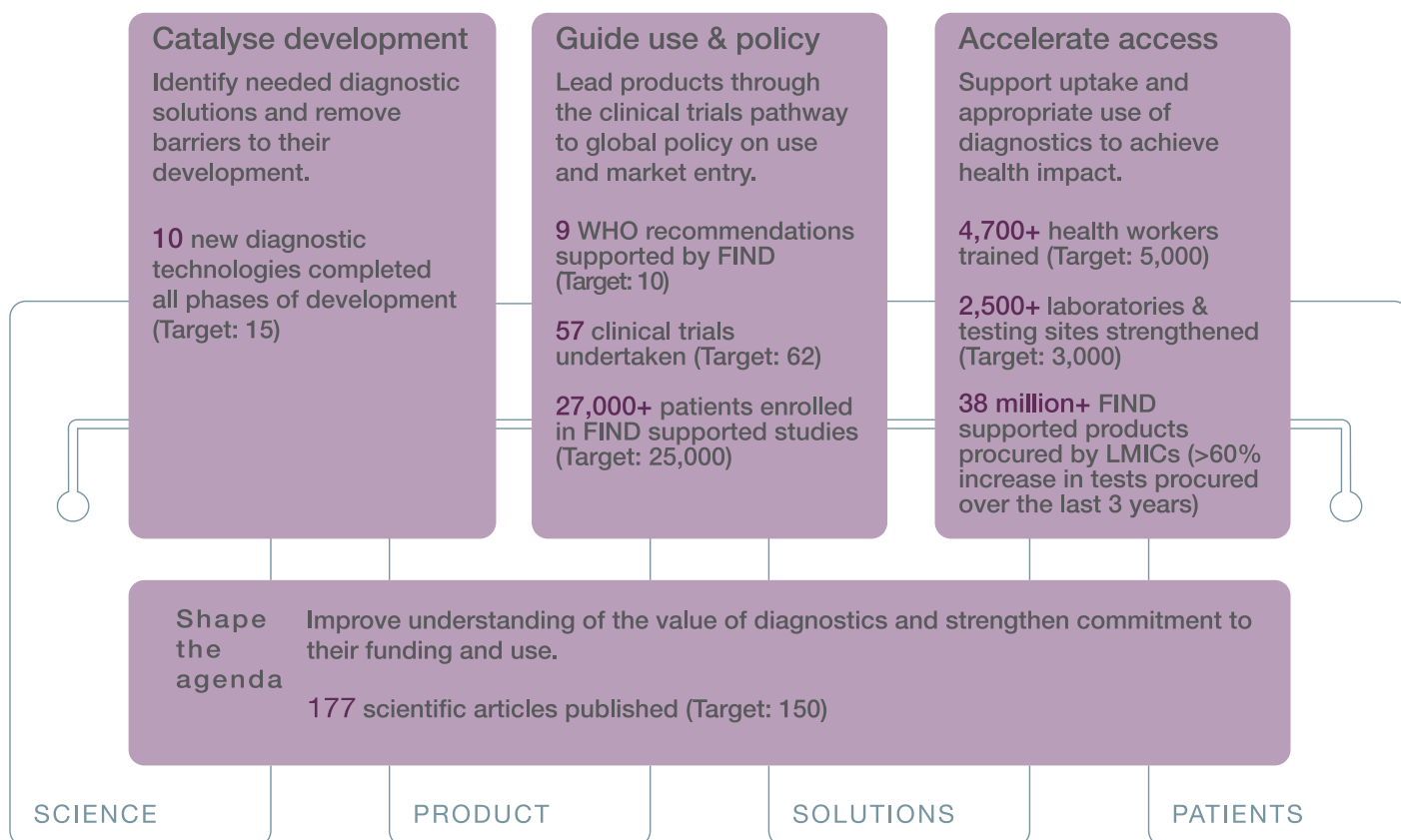


Figure 1. Bridging science and patients: progress towards our 2015–2020 strategic targets.

*Taking action:*

# CATALYSE DEVELOPMENT

In line with our 5-year strategy goals, our focus is centred on “packaged solutions” for diagnostics, leveraging our strength as an interpreter between the technical world of product development and the realities of end users.

## R&D technology scouting

In the quest for innovative diagnostic solutions for poverty-related diseases that meet specific, priority needs, FIND has ensured that R&D is linked to target product profiles, and that our technology solutions, whenever possible, can be used across several diseases. We implement an objective, independent and transparent approach to technology scouting and partner selection to ensure that i) the most suitable technologies are supported, ii) potential conflicts of interest are avoided, iii) the partner can meet the requirements laid out in the FIND Global Access Policy, and iv) the health community has access to the selection process and its outputs.

### In 2017, we reviewed 82 product and technology proposals:

60 were unsolicited external proposals received via our web-portal

7 resulted from requests for proposals

15 originated from internal scouting activities

## Specimen bank

The ability to have access to specimens is a cornerstone for development of diagnostic tests, biomarker discovery and quality control. FIND manages biorepositories for TB, malaria, fever, hepatitis C virus and neglected tropical diseases that store well-characterized specimens collected *ad hoc* during trials or sourced from third parties. This year,

we worked with specimen collection sites in Africa, South America, Asia and Eastern Europe to bank over 70,000 samples. All specimens are collected at qualified clinics, under a protocol approved by an institutional review board and with informed consent from patients meeting the inclusion criteria for sample collection.

### FIND also launched:

**A virtual strain bank** – an online database containing meta-data for 409 strains in the FIND specimen bank, giving researchers and test developers an overview of globally accessible TB strains.

**A *Mycobacterium* detection panel** to support the evaluation of new TB tests – the panel contains five intact TB strains intended solely for research purposes.

**FINDings** – a support service providing an independent report based on data generated from the use of specimens distributed by FIND.

## Diagnostic pipeline tracker

With funding support from the Australian government and UK aid from the UK government, FIND developed an interactive, dynamic online tool to map the status and estimated release dates of TB and malaria diagnostics. The diagnostic pipeline tracker exhibits the progress of novel tests and information including company name and size, type of technology and product, lowest health level in which the product can be used, target product profile or target condition for classification. FIND is now collaborating with the WHO Global Observatory on Health R&D, using the tracker as a critical knowledge source.

“In 2017 we increased the number of samples that we both collected and distributed to partners and requestors worldwide. We also focused on improving the efficiency and quality of our specimen bank, which resulted in the adoption of a new database, the redefinition of several processes from collection to distribution, and the initiation of a thorough quality control routine.”

– Stefano Ongarello, Head of Data Services & Biobanking



## TB diagnostics critical pathway

The TB diagnostics critical pathway is a virtual management tool that documents the progress of TB diagnostics from development and commercialization to roll-out and implementation. Developed in collaboration with Stop TB Partnership, McGill International TB Centre, Unitaid, WHO and other partners, the Pathway supports diagnostic innovators, country representatives, policy makers and community advocates. The online interface links to key documents – target product profiles for test development, guidance and protocol documents for clinical trials, and resources for WHO review and national approval processes.

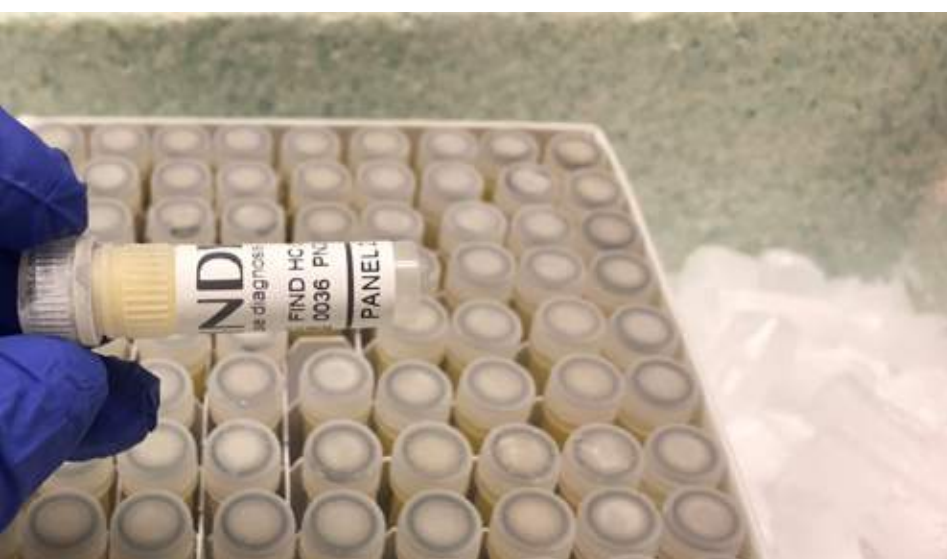
## Product development

Recommendations based on FIND's mid-term review suggested the need to augment the product pipeline and define optimal implementation strategies. As a result, we introduced 9 IVD projects to our portfolio, bringing the total to 48 projects, and started investing in game-changing technology innovations (e.g. BLINK DX's "Lab-in-a-Box") and novel partnering approaches (e.g. semi-open platforms) to help drive value for money, sustainability and utility of proposed solutions in LMICs.



“We know that promising innovations need to navigate a long, complex pathway to reach patients who really need them. The TB Diagnostics Pathway aims to demystify this path and support innovators in navigating it. The McGill International TB Centre is pleased to have contributed to this excellent resource that will help innovators.”

– Prof Madhukar Pai, Director,  
McGill International TB Centre



*Taking action:*

# GUIDE USE & INFORM POLICY

FIND supports global processes for developing policy guidance and assuring quality across multiple diseases. This year we worked closely with WHO to produce several guidance documents.

## Clinical trials and implementation research

FIND continues to increase local research capacity at clinical trial and study sites by providing training, strengthening laboratory infrastructure and facilitating collaborations with other partner institutions.

### Highlights of our clinical trial activities include:

**In Malawi**, we conducted 8 days of on-site training focusing on technical skills at the bench, use of study SOPs, logs and data collection.

**In Georgia**, we gave a Good Clinical Practice (GCP) refresher training for 5 HCV principal investigators (PIs), 1 governmental organization (National Centre for Disease Control), and 2 NGOs (Georgia Harm Reduction Network and Health Research Union).

**In Peru**, we conducted a GCP audit of a longstanding partner for TB and malaria research, resulting in improvements to participant recruitment, data integrity and laboratory oversight.



## Case study: transforming the public sector malaria diagnostics market

Following a decade of collaboration between FIND and WHO to improve the quality of rapid diagnostic tests (RDTs) for malaria through monitoring and evaluating test performance, the final WHO Malaria Rapid Diagnostic Test Performance report was published in July 2017. Today, 96% of tests meet WHO desired quality standards – compared with 23% when the programme began in 2006 – giving patients and healthcare providers confidence in test results, and ensuring treatment can be initiated in those who need it.

We also updated the online interactive guide that allows procurers to search all malaria RDTs evaluated against relevant criteria, including performance, product characteristics and target antigens – providing an easy way for procurers to make purchasing decisions that are in line with the WHO policy on RDT procurement.



Taking action:

# ACCELERATE ACCESS

FIND works with governments, national disease programmes and implementing partners to ensure that diagnostic solutions are holistic and tailored to country needs; to help countries prepare for their adoption; and to strengthen the underlying infrastructure and capacity to enable effective uptake and impact measurement.

## Access strategy

For the first half of the strategic period, FIND's access activities were largely focused on building country capacity for roll-out of new diagnostics.

### Our formalized access strategy now focuses on:

- + Ensuring FIND co-develops tests that are available, affordable, appropriate for use in LMICs, and adopted in these settings
- + Optimizing evidence generation
- + Creating the market
- + Establishing best implementation practices and showcase impact
- + Facilitating programmatic scale-up

## Laboratory QMS/scale-up for access to diagnostics

Our laboratory strengthening initiatives include infrastructure investments, providing equipment and supplies (e.g. reagents), developing quality management systems and enabling EQA/ISO certification. Eleven labs in India applied for ISO certification at the end of the year.

### This year's highlights include:

Capacity-building activities were performed in **74 TB labs** in India, of which **5 were equipped** with whole genome sequencing capacity, **1 with pyro sequencing technology**, and **61 were equipped to do MDR-TB testing**.

FIND's NTD programme delivered equipment and provided QMS training to **98 labs in Guinea, 86 in Angola, 18 in Kenya and 12 in Uganda**.

FIND's Malaria team conducted RDT lot testing workshops involving staff from national reference labs in **15 malaria endemic countries**.





## Connectivity

In recent years, we have seen a tremendous increase in available data and the importance of data-based decision-making.

### FIND's data-centered initiatives in 2017:

#### **Data aggregation platform:**

FIND's connected diagnostics platform (CDP) was handed to a commercial entity to continue its development and guide its implementation in LMICs.

**Data utilization:** Two projects in Myanmar and Mozambique studied the utilization and impact of data gathered through the use of real-time connected diagnostics. A number of interventions are planned for Myanmar to improve data usability in collaboration with MoH, CHAI and commercial entities.

#### **Diagnostics network mapping:**

FIND worked with the central TB division in India and the national TB programme in Lesotho to optimize their diagnostics infrastructures and services based on where patients seek care.



*Taking action:*

# SHAPE THE AGENDA

FIND continues in its efforts to increase prioritization of diagnostics through dedicated, evidence-based advocacy. We actively engage country governments and global procurers to support improved market dynamics, increase funding for diagnostics, and promote regulatory systems strengthening.

## Publications and scientific reports

This year, we added to the scientific evidence base with 65 peer-reviewed scientific publications, of which 59 were open access.

### Key reports & landscapes to which FIND contributed in 2017:

HCV diagnostics market intelligence report, published with the Clinton Health Access Initiative (CHAI).

A target product profile (TPP) for a test to predict progression from TB infection to active disease.

TB Diagnostics Technology Landscape report, published by Unitaid.

With GII, guides on i) planning for country transition to Xpert MTB/RIF Ultra cartridges, ii) model TB diagnostic algorithms, iii) TB laboratory strengthening, and iv) TB diagnostics connectivity solutions.

A technical expert group report on commercial products for preserving clinical specimens for the diagnosis of TB.

Report on a multicentre non-inferiority diagnostic accuracy study of the Ultra assay compared with the Xpert MTB/RIF assay, published by WHO

## Case study: uncovering the HCV diagnostics market

In collaboration with the Clinton Health Access Initiative (CHAI), we produced the first HCV diagnostics market intelligence report covering 29 LMICs. The report provides 5-year forecasts on need and demand for screening, confirmatory and monitoring testing, and outlines the elements driving market projections and what factors will allow countries to diagnose more patients.





Spotlight on:

# FEVER, AMR & OUTBREAKS

“FIND is focussed on diagnostic gaps that must be urgently filled so that we can correctly diagnose diseases, and support linkage to care. We are very pleased to be working with WHO to define diagnostic needs for pandemic preparedness, as well as global health partners on research and development for triage and fever management.”

– Cassandra Kelly-Cirino,  
Head of AMR and Outbreaks



- + Fever is one of the most common symptoms of illness around the world, but we lack essential diagnostics to identify whether the cause is bacterial, viral or something else
- + In the absence of adequate diagnostic tests to differentiate common causes of fever, people are often treated with unnecessary antimalarials or broad spectrum antibiotics – fuelling AMR
- + Lack of these diagnostics also challenges national and regional health systems, which rely on diagnostics to monitor disease patterns and identify potential outbreaks
- + There is an urgent need for affordable and appropriate new tests that can support healthcare providers to make informed treatment decisions for optimal patient outcomes, and enable public health systems to prevent spread of disease, conduct disease surveillance, and limit the spread of AMR

## Key projects

### Rapid test for malaria infection and fever management

SD Biosensor Inc. and FIND inked a partnership to develop an RDT that can simultaneously detect malaria and C-reactive protein in the blood. This test could facilitate fever management in low-resource settings by offering healthcare workers a single, low-cost test to decide whether a fever is caused by malaria parasites, bacterial infection or both.

### Multiplexed fever test

Together with Chembio Diagnostics Inc., FIND started work on a simple, rapid and inexpensive point-of-care test that would be able to detect parasitic (*P. falciparum*, pan-*Plasmodium*), viral (dengue, Zika, chikungunya) and bacterial (*Leptospria* spp, *Rickettsia typhi*, *Burkholderia pseudomallei*, and *Orienta tsutsugamushi*) pathogens.

### Point-of-care triage test

FIND and Becton, Dickinson and Company joined forces to address the urgent need for a point-of-care triage test to guide the appropriate use of antibiotics.

### **Bacterial versus viral infection biomarker validation**

Following publication of a target product profile and biomarker landscape, FIND, the London School of Hygiene and Tropical Medicine in Malawi, and FioCruz in Brazil completed the development of clinical trial protocols and biobanking procedures, and kicked off enrollment of 1500 patients for an evaluation study.

### **Collaboration with WHO on diagnostic landscapes for priority outbreak diseases**

FIND and WHO have developed diagnostic landscapes for WHO priority diseases, including Middle East respiratory syndrome coronavirus, Crimean-Congo haemorrhagic fever, Lassa fever, Nipah virus, and filoviruses. These landscapes will be published in the coming months.



Spotlight on:

# HEPATITIS C

“An important milestone this year was the launch of the Unitaid project to unlock the HCV diagnostics market in six countries and create the case for policy change at global and national levels to help pave the way for a scalable public health approach to HCV. A stepping stone in this direction would be the integration of HCV diagnosis into HIV programmes, where possible, to maximize patient outcomes and cost efficiency.”

– Francesco Marinucci, Head of HCV & HIV



- + Approximately 71 million people worldwide are chronically infected with HCV
- + More than 80% of people with HCV live in LMICs
- + Over the last fifteen years, mortality has steadily increased to over 400,000 deaths annually
- + Despite its high prevalence, morbidity and mortality, only 1 in 5 HCV-infected individuals have been diagnosed – of whom only 7% have received treatment worldwide

## HEAD-Start

FIND is the lead partner in a multi-year, multi-country hepatitis C virus (HCV) project, funded by Unitaid, called Hepatitis C Elimination through Access to Diagnostics – or HEAD-Start. The project aims to increase the availability of affordable, high-quality HCV diagnostic tests in Cameroon, Georgia, India, Malaysia, Myanmar and Viet Nam. Important advances on this project in 2017 included:

- + Tested feasibility of models for HCV viremia screening among people who inject drugs
  - First project successfully implemented in Georgia
- + Established HCV specimen bank
  - The HCV specimen bank – consisting of 70 fully characterized bulk plasma specimens (about 5,000 aliquots) and 5 reference panels of 320 samples each – became fully operational
- + Completed feasibility study with Molbio Diagnostics



Spotlight on:

# MALARIA



“This year our activities in malaria have been strongly focused on quality, as a decade-long product and lot testing programme for malaria RDTs with WHO was completed, and we worked to establish international standards for reference materials. We continue to work to fill critical R&D gaps in diagnostics that must be addressed in order to revitalize efforts to meet the global target of ending the malaria epidemic by 2030.”

– Ranga Sampath, Chief Scientific Officer

- + In 2016, there were an estimated 216 million malaria cases worldwide, an increase of 5 million cases over the previous year; 445,000 people died from the disease.
- + Although the number of malaria cases has dropped overall since 2010, the rate of decline has stalled and even reversed in some places since 2014, prompting a renewed sense of focus from the global health community.
- + Prompt diagnosis enables early treatment, which remains the most effective means of preventing a mild case of malaria from developing into severe disease that can result in death. Yet significant diagnostic gaps remain.

## Key projects

### WHO-FIND malaria RDT product and lot testing programme transitioned to WHO

The 10-year WHO-FIND product and lot testing programme is now completed and its coordination has been handed over to WHO. The product testing continues as part of the WHO Prequalification of Diagnostics Programme, while the lot testing is now conducted at the Research Institute of Tropical Medicine (RITM) in the Philippines, coordinated by the WHO Global Malaria Programme. Today, 96% of malaria RDTs now meet WHO quality standards, compared with just 23% back in 2006 when the programme began.

### First rapid test to screen asymptomatic malaria infections

Alere Inc. launched a new highly sensitive rapid test for detecting *Plasmodium falciparum* HRP-2 antigen in individuals with very low parasitemia, with or without evident symptoms of malaria infection. FIND worked closely with PATH and the Bill & Melinda Gates Foundation to complete development, and continues to support clinical evaluation and demonstration studies.

### First international standard for *Plasmodium falciparum* antigens and other reference material

The UK National Institute for Biological Standards and Controls, together with FIND, created the first reference material to serve as a WHO International Standard (IS) for two common antigens used in malaria rapid diagnostic tests (RDTs). The new IS will be used globally to assure the quality and harmonization of existing malaria rapid tests and support the development of better, more sensitive RDTs in the future. Further, together with Microcoat Biotechnologie GmbH, FIND announced the commercial launch of the HRP2 recombinant panel for malaria diagnostic tests. The panel assesses the limit of detection of different HRP2 malaria RDTs on the market and will be used to monitor lot-to-lot quality variation or lot degradation of malaria RDTs over time.

### WHO external quality assessment for malaria nucleic acid amplification testing

With FIND support, WHO and the UK National External Quality Assessment Service launched the WHO malaria nucleic acid amplification EQA scheme for public health and research laboratories in malaria endemic and non-endemic settings. Two rounds of panel distributions to a total of 55 and 53 laboratories, respectively, have been completed, and FIND has led the development of online available documentation, which includes an operational manual, FAQs, and 'Dos and Dots' for molecular testing.

### LAMP kit for *Plasmodium vivax*

Together with Eiken Chemical Co., FIND began development of a *P. vivax*-specific loop-mediated isothermal amplification kit that could be integrated into existing LAMP kits. *P. vivax* malaria is responsible for close to half of all malaria cases outside of Africa.



Spotlight on:

# NEGLECTED TROPICAL DISEASES

“Uganda is on the verge of eliminating *Trypanosoma brucei gambiense* human African trypanosomiasis (gHAT) - more commonly known as sleeping sickness - as a public health problem. This elimination would be historic. In 2016, four cases were reported, and none in 2017. Uganda is now in a position to eliminate the disease as a public health problem by 2020.”

– Joseph Ndung’u, Head of Neglected Tropical Diseases



- + Neglected tropical diseases (NTDs) are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in 149 countries; together they affect more than 1 billion people.
- + WHO has published a roadmap to overcome the challenges of NTDs, including strategies for their prevention, control, elimination and eradication.
- + FIND is focused on leveraging diagnostics to contribute to the implementation of these strategies, particularly in the areas of human African trypanosomiasis (sleeping sickness), Buruli ulcer, visceral leishmaniasis and Chagas disease.

## Key projects

### LAMP test for leishmaniasis completed

In a collaboration with Eiken Chemical Co. Ltd., Japan and other partners, we completed development of a robust nucleic acid amplification test, Loopamp Leishmania Detection Kit. Its simplicity and excellent diagnostic performance make this kit ideal for parasitological confirmation of visceral leishmaniasis in less equipped laboratories.

### 2nd generation rapid test for sleeping sickness launched

Together with Standard Diagnostics, Inc. (SD/Alere, now Abbott), we launched a 2nd generation RDT for screening *gambiense* human African trypanosomiasis.

Unlike the first HAT RDT, SD BIOLINE HAT 2.0 is made using recombinant parasite antigens, making its production not only cheaper but also easier to standardize, control and scale up.

### Buruli ulcer fluorescent thin-layer chromatography

Evaluation with Harvard University and WHO of fluorescent thin-layer chromatography test to detect mycolactone (the toxin that causes tissue damage in Buruli ulcer patients) was completed. WHO will conduct further evaluation in multiple countries.

### Improving access to diagnosis of Buruli ulcer

A new collaboration between FIND and Anesvad seeks to develop, evaluate and introduce diagnostic tools for early detection of Buruli ulcer, and to establish advocacy and communication initiatives at international, regional, national and community levels.

### Launch of Swiss Alliance against Neglected Tropical Diseases

Twelve Swiss NGOs, including FIND, founded the Swiss Alliance against Neglected Tropical Diseases in Geneva. Our Head of NTDs, Professor Joseph Ndung’u, was elected to its Board.

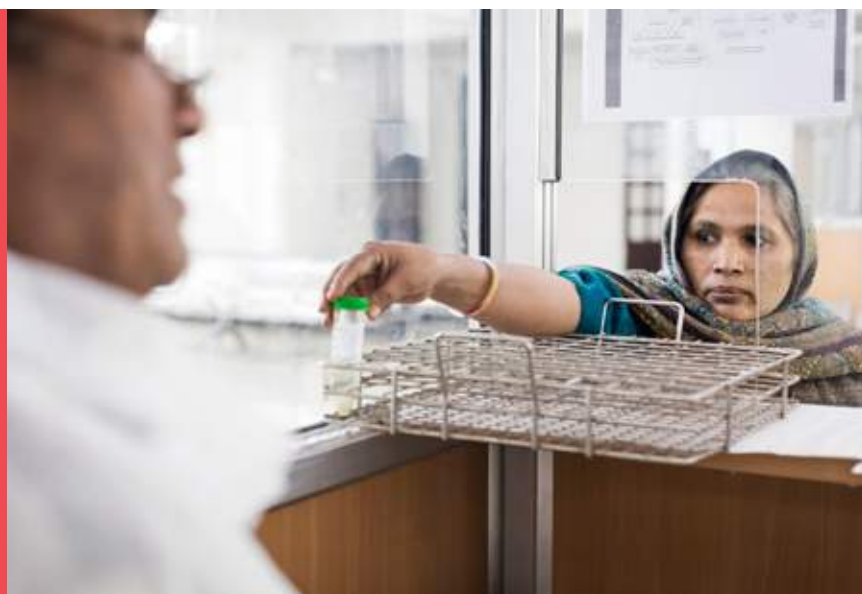


Spotlight on:

# TUBERCULOSIS

“Momentum is growing around TB, as the community lays the ground for significant political commitments that are anticipated next year – a key moment in 2017 being the Moscow Declaration to End TB. The opportunity has never been greater as we unite to achieve global targets; for our part we are working to realize the potential of our TB diagnostics programme.”

– Claudia Denking, Head of Tuberculosis



**+ Tuberculosis (TB) continues to be a major public health threat despite being a curable disease.**

**According to WHO, in 2016:**

- Approximately 10.4 million people contracted TB
- 1.7 million people died from TB
- 600,000 new cases of drug-resistant TB occurred, of which 490,000 were multidrug-resistant cases
- 4.1 million of the 10.4 million cases were not diagnosed or reported

**+ Under-diagnosis is due to limited and delayed access to appropriate diagnosis and care**

## Key projects

### Launch of TB test Ultra

A new version of the Xpert MTB/RIF test, Xpert® MTB/RIF Ultra (Cepheid) for the diagnosis of TB and rifampicin resistance, was announced in March. WHO recommends that Ultra can be used as an alternative to the existing Xpert MTB/RIF test in all settings.

### Rapid multi-analyte technology

FIND initiated a partnership with BLINK DX for a “lab-in-a-box” diagnostic solution, a potentially disruptive technology in low-resource settings near the point of care.

## Expanded DST for decentralized settings

The Xpert XDR continues in development, achieving planned milestones through the partnership of FIND and Cepheid.

## Centralized MDR-TB testing

FIND conducted an evaluation of 4 existing centralized molecular systems for multidrug resistant (MDR)-TB (Abbott; Hain; BD; Roche) to provide WHO with data needed to make a recommendation on use.

## Promising biomarker signature for triage test

After many years of biomarker research, for the first time a signature has been identified that can enable a triage point-of-care lateral flow test that is set to meet the WHO target product profile.

## Negotiated pricing for TB test extended to an additional 40 countries

FIND, Becton Dickinson and Company (BD), Stop TB Partnership and the United Nations Development Programme (UNDP) agreed to improve access to BD technology to diagnose TB and conduct drug susceptibility testing using liquid culture for an additional 40 LMICs – bringing the total to 85 countries that are now eligible for negotiated product pricing of the BD BACTEC MGIT technology.





# GOVERNANCE

## Board of Directors

Mark Kessel (Chairman)  
Daniel Camus  
David L. Heymann  
Andrew Jack  
Ilona Kickbusch  
Bob More  
Carlos Morel  
Marcel Tanner  
Noel N. Tata  
Sheila D. Tlou  
Michael Watson  
Catharina Boehme (ex officio)

## Scientific Advisory Committee – Core Members

Marcel Tanner (Chairman)  
Manica Balasegaram  
Madhukar Pai  
Ana Rabello  
Thomas White

---

Co-opted members are eligible for a one year membership and are invited to join the SAC based on their expertise across new technologies and disease areas.

## FIND Team – Senior leadership

Chief Executive Officer: Catharina Boehme  
Chief Access Officer: Zachary Katz  
Chief Scientific Officer: Ranga Sampath  
Director of Finance: Louisa Chaubert  
Director of Operations: Sharon Saacks  
Head of TB: Claudia Denkinge  
Head of AMR & Outbreaks: Cassandra Kelly  
Head of Clinical & Reg. Affairs: Jennifer Kealy  
Head of Communications: Sarah-Jane Loveday  
Head of Data Services & Biobanking: Stefano Ongarello  
Head of Fever: Sabine Dittrich  
Head of FIND India: Sanjay Sarin  
Head of FIND South Africa: Heidi Albert  
Head of HCV & HIV: Francesco Marinucci  
Head of Malaria: Iveth González  
Head of NTD: Joseph Ndung'u  
Head of TB: Claudia Denkinge  
Representative in Viet Nam: Yen Nguyen

**We are very grateful to all our donors for their  
commitment and support in 2017**

Anesvad Foundation  
Australian Government  
Botnar Foundation  
Bill & Melinda Gates Foundation  
Centers for Disease Control and Prevention / African Society for Laboratory Medicine  
Elma Foundation, South Africa  
European & Developing Countries Clinical Trials Partnership  
The Global Fund to Fight AIDS, Tuberculosis and Malaria  
Global Health Innovation Technology Fund  
Government of Germany  
Government of Netherlands  
Government of Switzerland  
Paul G. Allen Philanthropies  
Save the Children International  
Service de la solidarité internationale, République et Canton de Genève  
TB Reach through Stop TB Partnership  
UK aid from the UK government  
Unitaid  
United States Agency for International  
Development / KNCV Tuberculosis Foundation  
World Health Organization

On 16 February, our Catharina Boehme (FIND CEO), joined Bill Gates, Carlos Moedas (European Commissioner for Research, Science and Innovation), Nick Chapman (Policy Cures) and others for the launch of the 2016 G-FINDER report on funding for research into neglected diseases.



## PHOTO CREDITS

©Ben Phillips: cover page, 15, 16, 17, 22, 23

©Jennifer Ogden: 10 & 11

©John Rae: 11, 12

©Will Bembridge: 18

©Ana Campillo: 13, 14, 19

©Joseph Ndung'u: 21

©F. de Ribaucourt: 25

© FIND 2018  
Design and layout by Gregory VAN DER DONK



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)