FIND

ACCELERATING ACCESS TO DIAGNOSIS AND CARE

ANNUAL REPORT 2016

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Our vision

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

Our mission

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

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LEADERSHIP MESSAGE

Catharina Boehme
Chief Executive Officer

Mark Kessel
Chairman of the Board

Marking the second year of our 5-year strategy, 2016 was a year of expansion and growth. More than 12 million FIND-supported diagnostic products were procured by low- and middle-income countries (LMICs) over the course of the year, supporting the drive for faster treatment and lower transmission rates in priority disease areas.

Two new programmes were inaugurated: Fever, AMR & Outbreaks; and Hepatitis C. The fever programme, which in 2016 encompassed non-malarial febrile illnesses, outbreaks and antimicrobial resistance (AMR), has set the stage for further development in these areas. As treatment for hepatitis C becomes more feasible and affordable in LMICs, our hepatitis C programme is poised to develop, accelerate access to and demonstrate the impact of improved and innovative diagnostic solutions.

Accurate diagnostics lead to appropriate use of therapeutics, and we are pleased to have completed the development of six new diagnostic products for malaria, tuberculosis (TB), leishmaniasis and sleeping sickness. Over the course of the year, we offered support to 39 institutions and added eight new technologies to FIND's diagnostic development pipeline through our comprehensive scouting process.

Programmes spanning multiple stakeholders, countries and disease areas yielded particularly encouraging steps forward. The proof-of-principle shown for multiplex rapid diagnostic test (RDT) technology able to detect up to eight pathogens is game-changing for the application of fever management. The integration of molecular testing for Ebola with HIV and TB control programmes in Guinea, Liberia and Sierra Leone achieved this year will ensure local capacity to respond quickly in the event of another Ebola outbreak.

For the first time ever, the number of malaria RDTs procured exceeded the number of malaria treatments (artemisinin-based combination therapies or ACTs) distributed in the WHO African region. Based on emerging successes in coordinating tsetse fly control with human African trypanosomiasis (HAT) screening and treatment, FIND, together with several partners, established Trypa-NO!, a multi-country consortium to support the WHO goal of eliminating HAT as a public health problem by 2020.

Our offices in South Africa, Viet Nam and India have implemented new projects and initiatives, including the expansion and strengthening of laboratory capacity and quality assurance. Our first stakeholders' forum – *Swasth Bharat*: Better outcomes through better diagnosis – was held in Delhi, bringing together key partners from the public, private and non-profit sectors to focus on the advancement of medical diagnostic tests in India.

Alongside this geographic growth, our capabilities also continued to expand. In 2016, we welcomed Chief Access Officer, Zachary Katz, whose background in building sustainable markets for affordable, high-quality therapies and diagnostics is critical to our work in accelerating access to integrated diagnostic solutions. We also welcomed Francesco Marinucci to Head our HCV and HIV programmes. He brings a unique mix of corporate, non-profit, academic research and laboratory management expertise to FIND.

We are always mindful that FIND works within a broad and diverse landscape of key global health players, and we are honoured by the recognition of our work from external bodies and peers. This year, FIND was recognized by three countries for work that built diagnostic capacity. Claudia Denkinger, Head of FIND's TB programme, was awarded the Gertrud Meissner Award for contributions to research in the mycobacteriology field.

Our work would not be possible without the sustained support and confidence of our funders and partners. We thank you for your ongoing support in accelerating access to affordable, high-quality diagnostics for the most vulnerable populations throughout the world.

Mark Kessel, *Chairman of the Board of Directors*

Catharina Boehme, *Chief Executive Officer*

2016 IN NUMBERS

An estimated ***12 million*** FIND-supported tests were procured by LMICs

6 new tests completed development with FIND support – for malaria, TB, sleeping sickness (2), leishmaniasis and Chagas disease

FIND set up ***2 new programmes***, encompassing 4 new disease areas (hepatitis C, fever, AMR, outbreaks)

FIND trained ***1,562 healthcare workers*** and strengthened ***1,126 testing sites***, with a ***34% quality improvement*** in participating labs

Safe collection of blood from a finger-prick was enabled in more than ***170 million patients*** through a safe blood transfer device for malaria developed by FIND and partners

4 WHO recommendations were issued for tests submitted for review with evidence from FIND-led trials

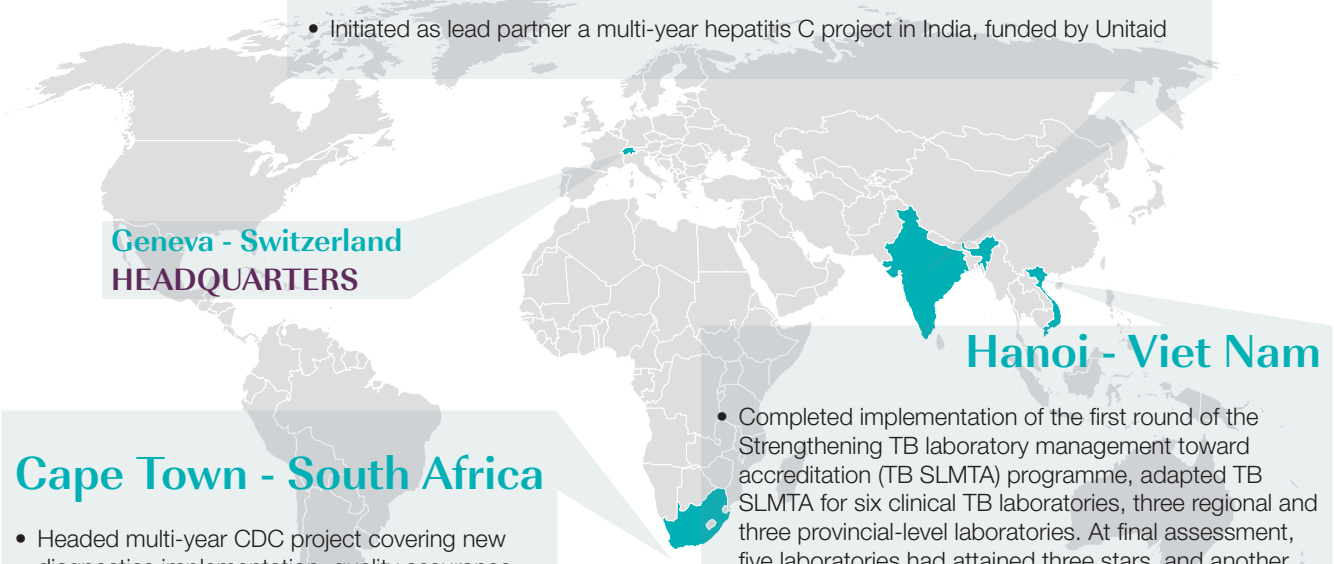
FIND authors published ***67 scientific papers*** and editorials in peer-reviewed publications

FIND received awards from ***3 governments*** – Dominican Republic, Uganda and Viet Nam – for building diagnostic capacity

KEY ACHIEVEMENTS IN COUNTRY OFFICES

New Delhi - India

- Accelerated access to TB diagnosis and care for more than 2,500 paediatric TB patients, including 225 multidrug-resistant cases, through the testing of approximately 35,000 children
- Helped provide universal access to drug-resistant TB services, with 14,692 cases of drug resistant TB detected in FIND-supported laboratories
- Supported the development of 15 liquid culture and DST laboratories, introduced second-line LPA testing and developed genome sequencing capabilities with the Revised National TB Control Programme (RNTCP)
- Carried out 16 technical capacity building trainings for 105 personnel from state and national laboratories to perform high quality TB and MDR-TB testing
- Held first stakeholder meeting,"*Swasth Bharat* (Healthy India): better outcomes through better diagnosis," bringing together key actors from the public, private and non-profit healthcare sectors for the advancement of medical diagnostic tests in India
- Initiated as lead partner a multi-year hepatitis C project in India, funded by Unitaid



Geneva - Switzerland
HEADQUARTERS

Hanoi - Viet Nam

- Completed implementation of the first round of the Strengthening TB laboratory management toward accreditation (TB SLMTA) programme, adapted TB SLMTA for six clinical TB laboratories, three regional and three provincial-level laboratories. At final assessment, five laboratories had attained three stars, and another lab went from 0 stars at baseline audit to one star over the course of the programme. After completing the first TB SLMTA round in Viet Nam, an experience-sharing workshop was conducted for national stakeholders in September
- Supported the Viet Nam National TB Control Programme in in-country manufacture of proficiency testing (PT) panels and established external quality assurance (EQA) programme for Xpert® MTB/RIF and line probe assay (LPA). In-country production of Xpert® MTB/RIF PT panels was successfully piloted through the enrolment of 11 Xpert® MTB/RIF testing sites. 1st and 2nd line LPA PT panels were produced and maintained at National TB Reference Laboratory
- Organized a national technical EQA workshop for 59 Xpert® MTB/RIF testing sites
- Conducted TB lab strengthening activities at 61 sites
- Initiated a hepatitis C project funded by Unitaid

Cape Town - South Africa

- Headed multi-year CDC project covering new diagnostics implementation, quality assurance and quality management systems strengthening in 14 countries in Africa, Asia and the Caribbean
- Core group member of the Global Laboratory Initiative (GLI) and GLI Africa, contributing to global guidelines and tool development
- Led a survey of National TB Reference Laboratories in Africa region with GLI partners, and was lead consultant on USAID-funded national TB diagnostic network assessment in Nigeria
- Developed and hosted in-person and online training courses for laboratory and healthcare workers
- Initiated work on diagnostic network mapping in Lesotho and Delhi with partner Llamasoft

"In 2016, we renewed our commitment to support national and local efforts to build ever greater capacity for TB diagnosis, and to fight antimicrobial resistance by ensuring better, more rapid diagnosis of drug-resistant TB."

– Sanjay Sarin, Head of FIND India

"We are proud of our contributions to building country capacity for quality-assured diagnostic services in the African region as well as developing and disseminating global and national guidelines and tools in collaboration with our partners throughout the world."

– Heidi Albert, Head of FIND South Africa

"In 2016, we contributed to national and local TB lab strengthening efforts through lab quality management system building and external quality assessment for new TB diagnostics, enhancing quality TB testing results and underscoring the fact that 'TB labs save lives'."

–Yen Nguyen, Representative of FIND in Viet Nam

Contributing to the Global Agenda

We have redoubled our commitment to global objectives and strategies to combat infectious diseases in low- and middle-income countries (LMICs). Our work informs comprehensive health initiatives through the submission of diagnostics trial evidence and systematic reviews that advise global policy on diagnosis. In 2016 alone, FIND supported five WHO policy recommendations for TB diagnostics and diagnostic connectivity, providing valuable evidence to guide funding and programmes for TB diagnostics and connectivity globally.

The multi-year HCV project funded by Unitaid and the Trypa-NO! Partnership, both initiated this year, serve to support WHO goals of eliminating HAT and viral hepatitis as public health problems by 2020 and 2030, respectively.

FIND is actively involved in diagnostics research and development (R&D), as well as in key diagnostic working and advisory groups whose decisions and outputs shape regional, national and international policies and programmes. These include the Stop TB New Diagnostics Working Group, the Global Laboratory Initiative for Africa, the WHO Scientific Technical & Advisory Group for Tuberculosis, the Asia Pacific Malaria Elimination Network, the Asia Pacific Leaders Malaria Alliance and the HAT Platform for Clinical Research. FIND is also an NGO in special relations with the World Health Organization and is a WHO Collaborating Centre for Tuberculosis.

FROM STRATEGY TO ACTION: 2 YEARS IN

FIND's 2015–2020 strategy focuses on our role as bridge builder and mobilizer, translating the technical world of product development into access to diagnostic solutions for patient needs. To ensure our work has impact, the link between accurate and affordable diagnosis, and treatment and care is paramount in everything that we do. Figure 1 depicts the four strategic pillars that guide our activities in the field of global health.

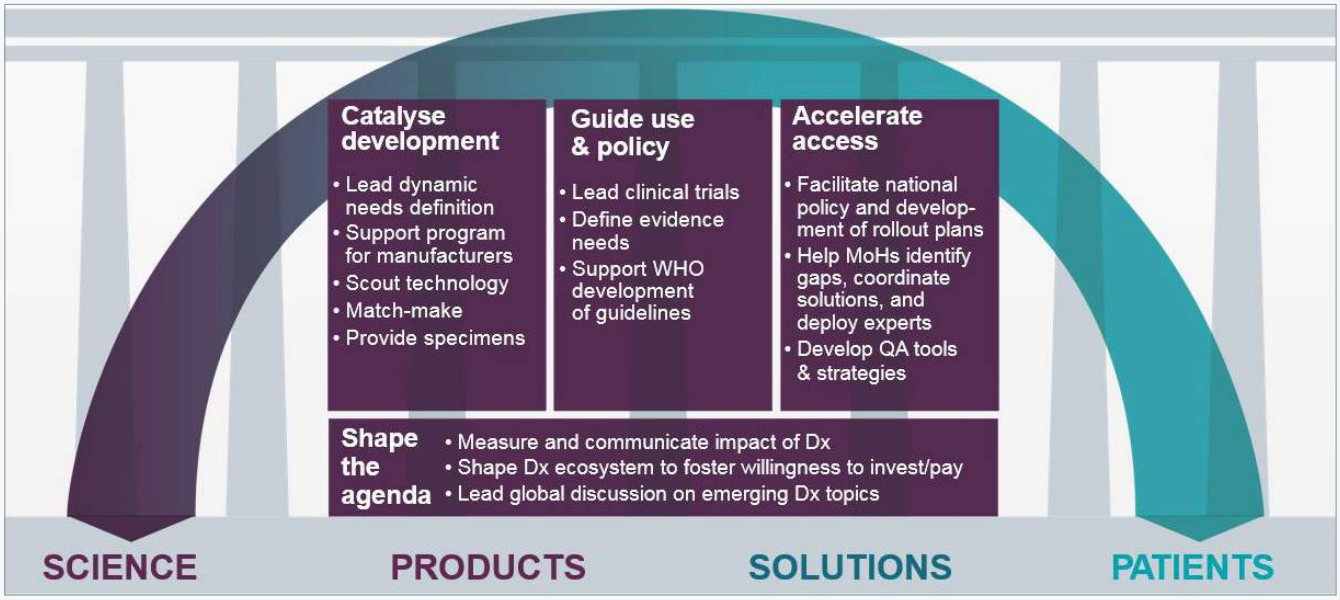


Figure 1: From R&D, WHO endorsement and access to improving understanding of diagnostics

Our work is concentrated on poverty-related diseases, including TB, malaria and neglected tropical diseases. In 2016, we broadened our portfolio to include hepatitis C, fever, AMR and outbreak diseases, such as Ebola, which was a major concern in sub-Saharan Africa from 2013-2016. These disease areas are complemented by cross-cutting programmes concentrated on access and connectivity. An independent mid-term review of the FIND strategy is planned for 2017.

Taking action:

CATALYSE DEVELOPMENT

In accordance with FIND's 5-year strategy, 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. In catalysing the roll out of new diagnostic solutions, FIND leads dynamic needs definitions through contributions to target product profiles, supports manufacturers for success, scouts for promising technologies, match-makes to broker or form the best partnerships, and provides specimen banks and platforms for feasibility studies.

Enabling the scientific community

More than 10 million people in LMICs are hospitalized with severe fever every year. Many of these patients are not properly diagnosed and treated due to a lack of accurate diagnosis.

In collaboration with MSF, FIND started early work on a programme to develop a novel multiplex fever diagnostic (MFD) system with a platform that can perform several tests for people presenting with severe fever. The goal for the fever cartridge is to aid individual patient management by determining whether an infection is bacterial or not – and if the infection is bacterial, to identify resistance markers.

TPPs

Consensus-based target product profiles (TPPs) guide the development of new diagnostic tests that will meet agreed priority needs, and are appropriate and affordable for LMIC settings. TPPs provide details on the minimum and optimal performance and operational characteristics of priority diagnostic tests. Researchers, developers and manufacturers use TPPs to ensure that R&D activities are focused on relevant products and designed for the contexts and needs of end users. FIND drove the development of two TPPs published in 2016 and submitted three draft TPPs for WHO review. A total of nine TPPs published were represented in FIND's portfolio, through 25 projects.

Open access for community development

FIND began work on a "Developers' Toolset" for its TB and malaria programmes. These comprise of open-access support materials, tools and information that are critical to bring about the development of new tools by any group with the capacity to do so.

This toolset will allow manufacturers and researchers to work with standardized panels of drug-resistant and drug-sensitive disease strains. The panels will enable testing for dynamic range and limit of detection, comparison of performance between different assays, and performing external quality assurance.

The initial panel will contain five strains across a number of different lineages, including one resistant to rifampicin and another multidrug-resistant. Following availability of the five-strain panel, FIND has plans to further expand the Toolset.

R&D technology scouting

FIND looks for innovative solutions, such as diagnostic platforms, that can be used to diagnose several diseases endemic LMICs. We provide varying levels of support for the development of promising diagnostic technologies, ranging from basic support to formal partnering. Basic support may include access to patient samples or critical reagents, feasibility studies, support for success services and connectivity guidance.

In 2016, we reviewed 94 product and technology proposals:

- 59 were unsolicited external proposals via the FIND website
- 24 were found by the technology scouting team
- 32 were identified through landscape assessments performed by disease programme teams

Following in-depth analysis and review by our independent Scientific Advisory Committee, we provided support to **39 institutions**, and added **eight technologies** to our diagnostic development pipeline.

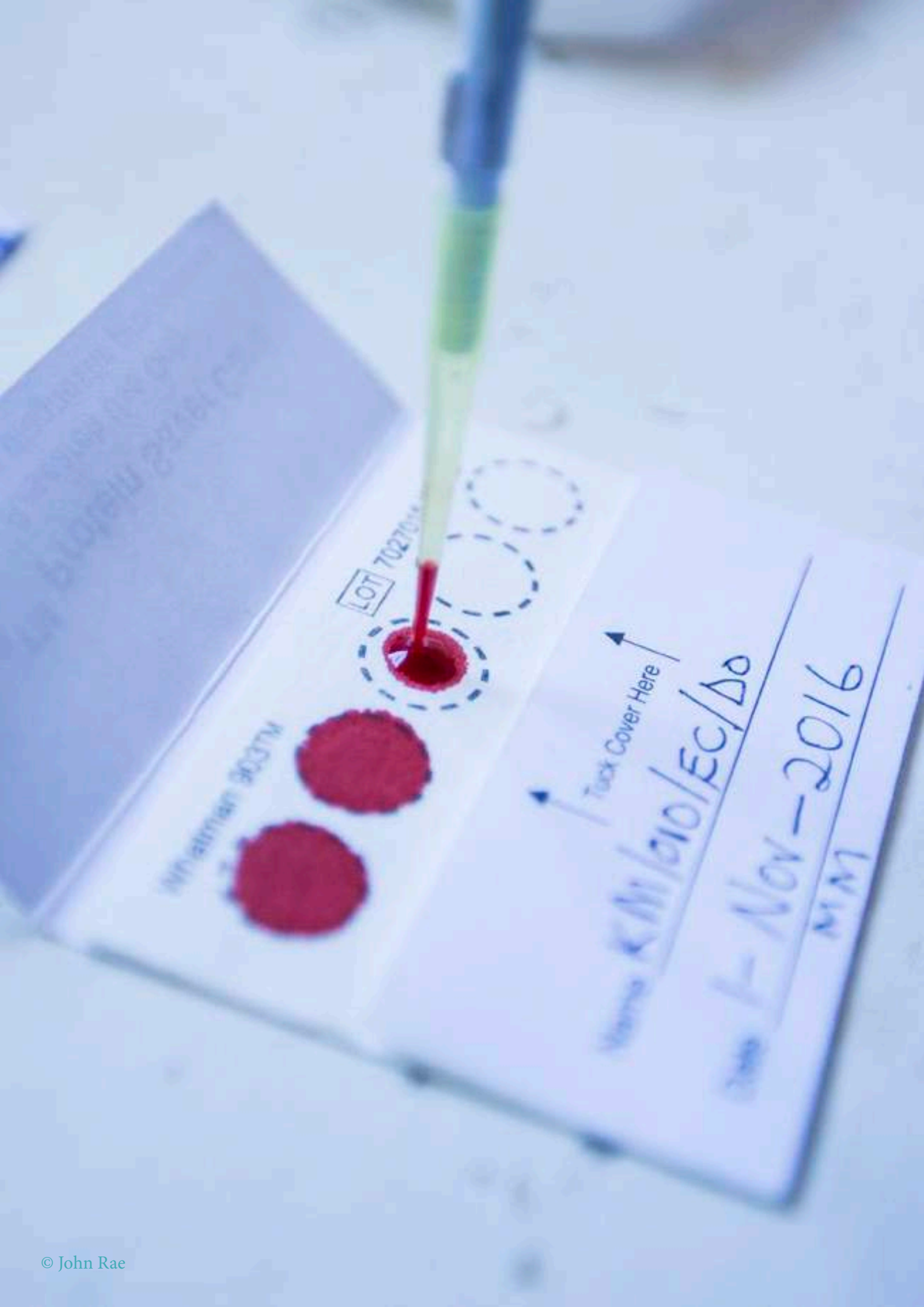
Support for Success (S4S)

FIND supported three partners through its Support for Success (S4S) programme, all focused on the design, development and commercialization of new TB diagnostic products. S4S is designed to accelerate development and market entry for urgently needed new tests. Through this programme, small and medium enterprises gain access to our extensive network of technical professionals in the diagnostics industry and other fields.

Ustar Biotechnologies (China) – Ustar's molecular diagnostic assays are designed for POC use in resource-limited settings. To ensure quality compliance, FIND supported the implementation of a phased development process under a comprehensive quality management system. We identified two engineering companies to support Ustar in the design and development of their system and helped develop a regulatory and product registration strategy.

QuantuMDx (UK) – FIND provided feedback on the design and initial development of a prototype sample enrichment and extraction process, which has been shown to work on sputum samples spiked with *M. smegmatis* and *M. tuberculosis*. The QuantuMDX assay and platform have the potential to transform molecular diagnosis at lower levels of care, with the greatest benefit and impact in LMICs.

Molbio Diagnostics (India) – FIND has worked with Molbio on a point-of-care molecular diagnostics platform since 2014. In 2016, the Molbio platform and TB assay received CE IVD regulatory clearance and underwent initial testing in India. Support services from FIND included final validation of Molbio's universal sample preparation platform, design improvements and validation of the TB and rifampicin resistance assays. This will be the first TB assay developed by a high-burden country.



Six diagnostic tests completed development

Six diagnostic tests completed development with FIND support, introducing innovative diagnostic solutions for malaria, TB, human African trypanosomiasis (sleeping sickness) and leishmaniasis.

1 Alere Malaria Ag P.f (Alere/SD, Korea)

FIND provided clinical evaluation and technical support in the development of a highly sensitive malaria RDT that offers a greater than tenfold improvement in the detection of a protein secreted by *Plasmodium falciparum* parasites. This first-ever rapid test can screen for malaria infection in people who are carrying the malaria parasite but show no signs of illness.

2 GeneXpert® Ultra (Cepheid, USA)

Ultra is a second-generation automated molecular TB test with greater sensitivity in diagnosing paediatric patients and people living with HIV – two populations that are especially difficult to diagnose. We coordinated and conducted a multi-centre non-inferiority study at ten sites in eight LMICs to assess Ultra's performance. The study found that Ultra sensitivity was up to 17% higher than earlier versions, with the greatest sensitivity gains seen among patients who would have been missed in microscopy centres and in HIV-positive patients living with TB.

3 Truelab (Molbio, India)

The Truelab Real Time micro PCR system is a chip-based nucleic acid amplification test designed to detect *M. tuberculosis*. The system works in combination with an automated sample preparation instrument (Trueprep). This system and its assays are comparable to other molecular TB diagnostic tools and are the first to be developed in a BRICS country. A first version of the Truelab system has completed development and been approved for use in India. Further work with Molbio to improve this test is ongoing.

4 HAT RDT 2nd generation (SD/Alere, Korea)

A second-generation version of the HAT RDT that uses recombinant antigens is less expensive to produce than the native antigens used for the first-generation test, driving the price of testing down while improving test quality. A clinical trial to evaluate the new test took place in the Democratic Republic of the Congo in January and the final results became available by the second quarter of 2016. The second-generation RDT is planned for commercialization in 2017.

By 2020, we envision having a total of 15 essential diagnostic solutions in use and contributing to improved health for all.

LAMP (Eiken, Japan)

FIND completed its long-term development programme for the loop-mediated amplification molecular platform (LAMP) with LAMP assays for multiple diseases. LAMP kits for HAT and leishmaniasis were CE marked in 2016. FIND coordinated a partnership between HUMAN Diagnostics (Germany) and Eiken (Japan) to maintain the commercial availability of these products for the global health community at affordable prices:

5 HAT LAMP

The HAT LAMP test is being used as an additional screening test in elimination programmes. Since it detects parasitic DNA sequences in patient blood, it is more specific then current serological tests. In several countries, it has been shown to improve the accuracy of diagnosis, which significantly improves patient outcomes and contributes to elimination efforts.

6 Leishmaniasis LAMP

The high sensitivity, simplicity and robustness of the Leish LAMP kit allows confirmatory diagnosis of visceral leishmaniasis using peripheral blood and enables accurate diagnosis of cutaneous leishmaniasis in settings with limited infrastructure. FIND and partners conducted clinical trials of this kit in Kenya, Sudan, Afghanistan and Surinam.

Spotlight on:

FIND INDIA

In 2016, FIND India improved capacity for TB diagnosis in collaboration with local and national partners. Alongside this, FIND India contributed to the fight to control the spread of anti-microbial resistance through the promotion of better, more rapid diagnosis of drug-resistant TB. Through FIND's collaboration with the Global Fund in their new funding model, activities in building TB laboratory capacity and implementing high-quality diagnostics were scaled up through the development of 15 liquid culture and DST labs (ongoing), the introduction of second-line LPA testing, and the incorporation of genome sequencing capabilities within the Revised National TB Control Programme (RNTCP).

FIND India continues to ensure uninterrupted service delivery through the existing network of 46 RNTCP laboratories, on-site training and maintenance of laboratory equipment. We successfully scaled up our paediatric TB initiative by expanding access to more than 35,000 presumptive paediatric TB patients and have developed an operational service delivery model for replication within programme settings.

FIND signed a new agreement with Unitaid to unlock the hepatitis C diagnosis and treatment market in India, a country with more than 7.5 million HCV-infected individuals. As part of this project, we aim to bring new and simpler HCV tests to market, establish innovative models for screening and treatment in HIV/HCV co-infected patients and improve the affordability of HCV testing. The project will contribute to 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 cost-efficiency.

255,530 patients tested for TB and drug-resistant TB using newer diagnostic technologies across FIND- supported laboratories

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35,627 presumptive paediatric TB cases tested

14,692 cases of multidrug-resistant TB detected at FIND supported sites, more than 1/3 of all cases detected in India

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2,512 paediatric TB cases diagnosed, of which 225 were rifampicin resistant

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53 continuing medical education sessions, and 2,185 individual meetings, about managing paediatric TB reached 4,924 healthcare providers

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16 on-site training sessions conducted for laboratory personnel

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Taking action:

GUIDE USE & INFORM POLICY

FIND supports global processes for developing policy guidance and assuring quality across multiple diseases. We operate an open clinical platform, working closely with WHO, industry, ministries of health, and implementers to collect and synthesize the evidence that is needed to guide roll out of new diagnostic solutions. Relevant groups, such as WHO and endemic country governments, use this evidence to inform decision-making.

Evaluating and validating new tools to support policy recommendations

FIND leads numerous trials and studies every year to validate and evaluate new diagnostic tools, and to assess effectiveness in the context of low-income settings. The resulting data contribute an important part of the evidence submitted to WHO for review. In 2016, we led 15 studies at 56 sites, of which 10 were concluded during the year, and supported six additional studies led by other partners across TB, HIV, malaria, sleeping sickness, visceral and cutaneous leishmaniasis, and connected diagnostics.

FIND-led or -supported trials and studies provided valuable evidence for five WHO policy recommendations for TB diagnostics and diagnostic connectivity. These recommendations will guide funding, procurement and programme decisions globally, which in turn will increase access to essential diagnostics.

GLI Quick Guide to TB Diagnostics Connectivity Solutions

FIND is a core member of the Global Laboratory Initiative (GLI), a network of international partners working to enhance and expand access to quality assured laboratory services for TB and HIV diagnosis. GLI's integrated and multi-faceted approach to laboratory capacity strengthening is in close alignment with FIND's strategy and collaborators at FIND have contributed to many GLI activities and publications.

FIND supported the development of the GLI Quick Guide to TB Diagnostics Connectivity Solutions, which provides guidance on the adoption and use of diagnostic connectivity solutions – key components of the nine priority digital health concepts identified by the WHO Agenda for Action on Digital Health for the End TB Strategy. The document provides instructions for remote monitoring and quality assurance, sending automatic results, managing inventory and surveillance, as well as information on connectivity training, budgeting and priority hardware and software.

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Informing WHO TB policy guidance

The results from 200 patients in a FIND study were included in a review to inform WHO policy on the use of molecular line probe assays (LPA) for the detection of resistance to second-line (SL) anti-tuberculosis drugs.

The lessons learned from FIND's studies of Genotype MTBDR*sl* V2 contributed to WHO's policy guidance document that compares the diagnostic accuracy of SL-LPA for second-line drug resistance with direct testing in sputum specimens and culture isolates, and guides the clinical use of the assay in the initiation of appropriate MDR-TB treatment regimens and therapies.

Evaluating new tools to support policy development

The European Society of Mycobacteriology (ESM) presented Claudia Denkinger, Head of TB at FIND, with the Gertrud Meissner Award at their 37th annual congress. The award is given annually to an early-career scientist conducting leading research in the mycobacteriology field.

Dr Denkinger received the honour in recognition of her extensive work defining priority diagnostic needs and promoting TB diagnostic solutions, helping to make TB testing more accurate and widely accessible.

The ESM is an international scientific society focused on mycobacteriology and related diseases. The society promotes research, knowledge-sharing and improved diagnostic procedures, and provides policy advice, training and advocacy.

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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. Key activities for FIND include facilitating national policy decisions, supporting the development and execution of roll out plans, and assisting Ministries of Health to identify gaps and deploy solutions.

Sharpening our focus on access

In 2016, FIND welcomed Chief Access Officer, Zachary Katz, to oversee and strengthen all implementation activities across disease areas, particularly for TB diagnostics in India.

Reaching targets for disease control and elimination doesn't only require new, easy-to-use diagnostic tools that provide rapid results, but also comprehensive approaches to maximize their health impact. In addition to strong political commitment and coordination to translate plans into action, robust laboratory and health systems are essential to fully capture the benefits of new diagnostic tests. This year, two large initiatives were launched to introduce and implement products for use in new national treatment programmes in HCV and in efforts to eliminate HAT.

Partnering to say Trypa-NO! to sleeping sickness

An important new project to eliminate sleeping sickness was launched by the newly formed Trypa-NO! Partnership in the second half of this year. The project is mainly funded by the Bill & Melinda Gates Foundation and led by FIND, and aims to eliminate human African trypanosomiasis (HAT), also known as sleeping sickness, in Côte d'Ivoire and Uganda in the next three years, and to reduce cases by 90% in Chad and Guinea.

Trypanosoma brucei gambiense (gHAT) is a form of HAT endemic in 24 sub-Saharan countries, including Côte d'Ivoire, Uganda, Chad and Guinea, where 7.6 million people are living at risk of catching the disease. gHAT is almost always fatal if left untreated and there is no vaccine to prevent the disease.

Sleeping sickness has been targeted by WHO for elimination as a public health problem by 2020. The Trypa-NO! Partnership expands efforts to prevent transmission by integrating new tsetse fly control methods with intensive screening, diagnosis and treatment.

Over the last couple of years, HAT control had been constrained in Chad by security issues and in Guinea by the Ebola epidemic. Trypa-NO! Partnership activities in project countries will contribute to national efforts to strengthen and rebuild public health systems.

"As a specialized global health organization, FIND is uniquely poised to support implementation of diagnostic solutions in ways that improve patient outcomes and achieve the greatest impact. I am especially excited by the work we are doing to enhance diagnostic algorithms and create delivery models that can be replicated by partners and national health systems in both new and existing disease areas."

– Zachary Katz

Building in-country diagnostic capacity

In 2016, FIND built in-country diagnostic capacity by training 1,562 healthcare workers and strengthening 1,126 testing sites, with 34% quality improvement in participating labs. FIND is honoured to have been recognized by three national governments for its work in building diagnostic capacity in the Dominican Republic, Uganda and Viet Nam.

Dominican Republic

FIND's laboratory strengthening work in the Dominican Republic was lauded in an external evaluation, released in July 2016. The evaluation, conducted by Primex Consulting Group, assessed a project supported by the Centers for Disease Control and Prevention and led by FIND in HIV clinical laboratories, TB laboratories and blood bank centres from 2011 to 2015. According to the external evaluation, this work created measureable improvements in key laboratory performance indicators and a positive growth in customer and physician satisfaction with the laboratory services. FIND conducted baseline and follow-up assessments and found average laboratory performance increased by 27% following Strengthening Laboratory Management Toward Accreditation (SLMTA), by 42% following blood bank trainings, and by 12% following TB SLMTA.

Uganda

FIND received an award from the Uganda Trypanosomiasis Control Council (UTCC) for its role in helping increase the number of patients screened for sleeping sickness (HAT) in endemic districts, resulting in early treatment and interruption of ongoing transmission. FIND has been working with the Ugandan Ministry of Health since 2013 to screen for HAT using a rapid and inexpensive diagnostic test, co-developed with Alere/Standard Diagnostics. With the introduction of HAT screening in primary healthcare facilities, where patients first seek care, the programme is finding residual cases, thus contributing to elimination.

"Since FIND started providing support, our manner of working has changed a lot and we have made incredible achievements. Thanks to FIND and the knowledge gained from SLMTA workshops, we have been able to improve performance in the laboratory."

– Melania Arias, participant from Hospital Nuestra Señora de la Altagracia in Higuey, DR

Viet Nam

FIND and in-country partners did a wide array of work this year: supported implementation of EXPAND-TB; provided external quality assurance by establishing in-country proficiency testing panels for Xpert® MTB/RIF, line probe assay for first- and second-line drugs, laboratory strengthening and capacity building using TB SLMTA; conducted operational research projects and funded the pilot study on the evaluation and implementation of the Connected Diagnostics Platform, as well as routine tests using fluorescent smear microscopy, MTB culture, Xpert® MTB/RIF and drug susceptibility testing.

Tackling the Ebola outbreak

Even after countries have been declared Ebola-free, new cases can emerge due to the presence of persistent, sub-clinical infections and viruses transmitted in bodily fluids. Preventing these flare-ups from reigniting large-scale outbreaks requires constant vigilance and robust capacity to diagnose and rapidly initiate contact tracing.

In Guinea, the National Ebola Response Committee mobilized a rapid diagnostic response when new cases emerged in the eastern region of the country. To complement testing being done in the regional hospital laboratory, FIND was contacted for urgent assistance in establishing rapid diagnostic capacity. This included moving a GeneXpert® machine from the capital, Conakry, to a facility near the site of the outbreak to provide rapid, high-throughput, near-patient diagnosis, as well as providing technical support and advising on testing procedures and protocols. Along with a parallel ramping-up of testing in Liberia, several hundred tests were being run per day.

Through examination of buccal swabs (from the cheek) and whole blood samples from suspected and confirmed Ebola patients, the testing facilitated disease surveillance, contact tracing and treatment monitoring. The connectivity of the GeneXpert® machines also played a central role in the secure, accurate and rapid transmission of test results electronically.

FIND remained active in Guinea, Liberia and Sierra Leone, providing training, technical assistance and advice on the development of a long-term testing algorithm for case-finding and enhanced surveillance. With the introduction of GeneXpert® machines in all three countries as part of the Ebola response, the capacity is now in place to use these platforms to diagnose other diseases. Cartridges for the diagnosis of HIV and TB were delivered in Guinea, and training was conducted.

Connectivity in action - India

The global roll out of the GeneXpert® MTB/RIF TB test – known in India as cartridge-based nucleic acid amplification test (CBNAAT) – has changed the TB diagnostic landscape. More than 13 million tests have been performed worldwide in at least 116 countries since 2011, and the detection of multidrug-resistant TB (MDR-TB) has increased eight-fold compared to conventional testing.

Under its Revised National TB Control Programme's (RNTCP) National Laboratory Scale-up Plan (2015–2019), India aims to attain the capacity needed to provide universal access to quality-assured diagnosis and follow-up for all forms of drug-resistant TB and all notified TB cases by the year 2019. Under this plan, 629 CBNAAT sites in the public health sector in India are now providing diagnosis for drug-susceptible TB and rifampicin-resistant TB. FIND and the RNTCP have initiated a project to connect all CBNAAT machines in India for the purpose of remote data collection.

Connectivity enhances patient data management, the quality assessment of testing, laboratory activity monitoring and disease surveillance. It also reduces the time it takes for patients to receive test results, leading to more rapid treatment and better care.

"FIND leveraged investments in Ebola control to support other diagnostic needs by integrating molecular testing for Ebola with HIV and TB control programmes in Guinea, Liberia and Sierra Leone. This ensures rapid local response to any new Ebola outbreaks in these countries while increasing HIV and TB diagnosis capacity."

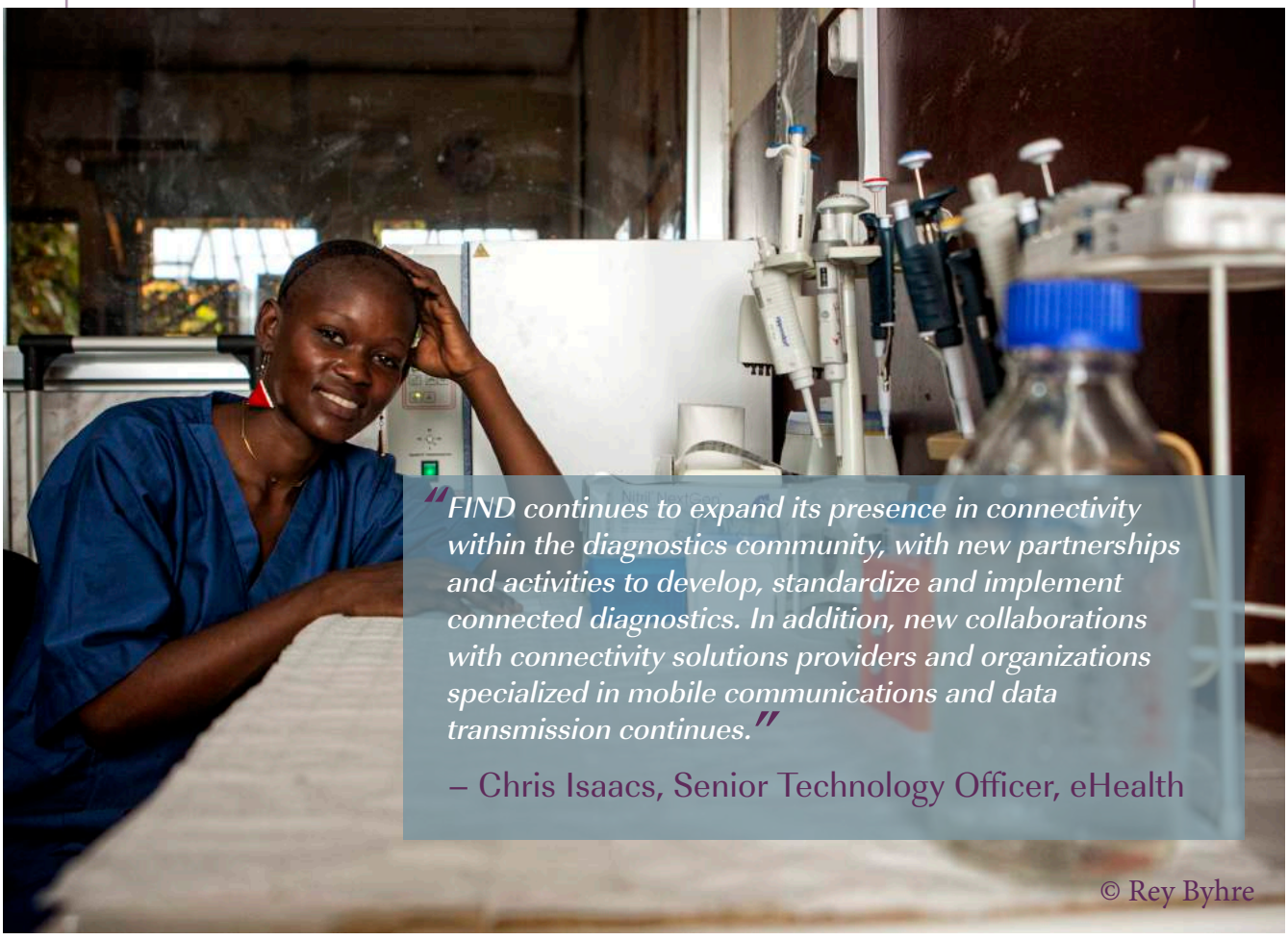
– Sharon Saacks, Director of Operations

Harnessing the power of connectivity

Connecting diagnostics in resource-limited settings has progressed significantly over the past few years. From initial ideas, through proof of concepts all the way to implementation, we have seen connectivity become one of the most important and desirable interventions in the diagnostic community. The goal is to implement solutions that are fit for purpose, allowing use to drive positive change in outcomes for patients as well as productivity and efficiency in health systems. Solutions should be considered using an end-to-end approach and integrated seamlessly, providing benefit rather than burden to end-users.

This year, completion of the FIND case-based Connected Diagnostics Platform (CDP) was followed by a successful study in Viet Nam. In addition, FIND's project to implement Ebola surveillance and case detection in West Africa included an important connectivity component, enabling rapid notification to Ebola teams when testing was performed and positive cases were identified.

Interest in connectivity continues to gain momentum. A WHO mandate that all WHO-approved rapid tests for TB should be connected for remote data transmission by 2020 is also driving FIND connectivity projects. As interest and realization of benefits and possibilities grow, attention is now turning to the use of accessible data, and the measurement of impacts and efficiencies. Replicable models for diagnostics that are interoperable with databases, implementation and utilization knowledge complemented by operational change and support along with international data ownership policies are all needed in order to ultimately succeed.



"FIND continues to expand its presence in connectivity within the diagnostics community, with new partnerships and activities to develop, standardize and implement connected diagnostics. In addition, new collaborations with connectivity solutions providers and organizations specialized in mobile communications and data transmission continues."

– Chris Isaacs, Senior Technology Officer, eHealth

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Taking action:

SHAPE THE AGENDA

FIND has significantly expanded 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 and increase funding for diagnostics.

Swasth Bharat: better outcomes through better diagnosis

In April 2016, FIND held its first regional stakeholders meeting in India. The forum, entitled *Swasth Bharat* (Healthy India): better outcomes through better diagnosis, convened stakeholders from the public, private and non-profit health-care sectors in Delhi, India.

The forum provided a platform for leaders with diverse health backgrounds to share insights on tackling some of the most pressing healthcare challenges, such as TB, hepatitis C, and AMR. Participants discussed the urgent need to accelerate the availability of new, high-quality and affordable diagnostic tests, particularly in light of India's infectious disease burden.

Highpoints included a panel chaired by Dr Jagdish Prasad, Director General of Health Services, Ministry of Health and Family Welfare, India, on the role of public-private partnerships in developing better TB and hepatitis C tests, and fighting the growing threat of AMR.

The event received wide media coverage in India and marked the formal announcement of a partnership between FIND and the Indian pharmaceutical company Cipla to make hepatitis C treatment and care more available and affordable. FIND also announced a collaboration with the US Centers for Disease Control and Prevention to strengthen TB laboratories in India.

> *"Today's forum is the first step towards establishing fruitful partnerships with the pharma and research industries in India and to engage with all stakeholders in the public, private and non-profit sectors who can partner with us in a shared mission to ensure that diagnostics are in place to enable efficient health delivery and improved patient health outcomes."*
>
> – Dr Sanjay Sarin, Head of FIND India

> *"Global health goals will not be met without accessible tests for priority diseases. What we need now is a collaborative effort to address the need for investment in diagnostics research and development. It is my hope that today's forum is a conversation starter in India, where the national commitment to public health is strong, as is private sector engagement, and where the R&D capacity is high."*
>
> – Mark Kessel, Chairman of the Board

Growing the evidence base

FIND continued to contribute to the scientific evidence base with 67 scientific publications in peer-reviewed publications, of which 90% were published in open access journals for the widest possible use.

© Sandrine Regeon

"In order to reach the greatest number of people, we need innovative and cost-effective diagnostic delivarables. Ease-of-use, minimal operating requirements, and affordability are key for point-of-care tests, as is the need to ensure there are no breaks in the diagnostics-to-treatment continuum."

–Catharina Boehme, CEO

Spotlight on:

FEVER, AMR & OUTBREAKS

The fever programme was added to FIND's portfolio this year and included the cross-cutting initiatives of non-malarial febrile illness, AMR and outbreaks. Global attention to these disease areas has created numerous partnership opportunities to address diagnostic gaps.

Priorities

Our priority activities range from research and development to the implementation of new and existing tools for primary health care based disease management.

FEVER

FIND is working with partners to support the development of affordable and appropriate new tests that meet the needs of lower-income countries. These include a rapid triage test to distinguish between bacterial and non-bacterial infections, and rapid point-of-care tests to identify the most common infectious diseases that cause fever in different regions.

AMR

Our antimicrobial resistance strategy is focused on halting and preventing AMR by reducing the inappropriate use and prescription of antibiotics and empowering surveillance efforts through the development of "fit-for-purpose" diagnostics, providing evidence on tests for WHO-prioritized needs and guiding country introduction and scaled access.

OUTBREAKS

We support diagnostic preparedness through capacity building and lab strengthening, and by supporting the development and evaluation of new tests for the rapid detection of pathogens with outbreak potential. We also support the development and evaluation of new tests for priority pathogens to support the validation and use of new vaccines to prevent future epidemics.

Key projects

Combination test for malaria & bacterial infection:
FIND is working with SD Biosensor (South Korea) to develop a simple test to simultaneously detect malaria and indicate the presence of a bacterial infection. This test would help health providers to make appropriate decisions about using antibiotics to treat illness.

Alternative to blood culture for diagnosing bloodstream infections:

In collaboration with Specific Technologies (USA), FIND is working on a feasibility project to develop an automated instrument for identifying pathogens in blood without skilled laboratory technicians for the diagnosis of bloodstream infections in children and adults in low-resource settings.

Evaluation of promising biomarkers to identify nonbacterial fever:

FIND is partnering with Philips and RPS Diagnostics to evaluate biomarkers with the potential to differentiate bacterial from nonbacterial infections. Biomarkers will be assessed at sites in different regions, as the most prevalent infectious diseases that cause fever can vary widely by region.

Multiplexed panel assays:

FIND launched two separate projects toward the end of 2016 with BD (USA) and Chembio (USA) to develop new multiplexed immunoassays for identifying fever-causes, including pathogens with outbreak potential, at the point-of-care. If successful, these projects will yield simple tests appropriate for low-resource settings that can test for several pathogens at once.

About Fever, AMR & Outbreaks

FEVER

Fever is one of the most common symptoms of illness around the world. With more than 182 million cases per year in sub-Saharan Africa alone, febrile illnesses are the most common causes of health facility visits in low- and middle-income countries Thanks to the increased use of malaria RDTs, we know that less than half of presenting fevers in malaria-endemic countries are caused by malaria parasites. In the absence of adequate diagnostic tests for common causes of fever other than malaria, people are often treated unnecessarily with broad spectrum antibiotics, leading to the extensive overuse of antibiotics with significant consequences for patient and global health.

AMR

The inappropriate use of antibiotics and other medicines is fueling the emergence of antimicrobial resistance globally, and is reducing the effectiveness of the few treatment options we have left to treat severe bacterial illnesses. Currently, 700,000 deaths per year are attributed to drug-resistant strains of common bacterial infections, HIV and malaria and it is estimated that by 2050, 10 million deaths will be caused by AMR each year. The urgent need for new diagnostic tests to guide appropriate treatment has been identified as an R&D priority by global stakeholders, including the WHO, the UK Review on Antimicrobial Resistance, and many others, and wider availability of such tests outside specialized labs would enable more rapid treatment for affected populations.

OUTBREAKS

Epidemics of emerging and re-emerging infectious diseases are a significant and growing global threat. Since 2002, the world has experienced over a dozen major infectious disease outbreaks.
Diagnosing patients quickly is essential to break the transmission chain and contain epidemics.
For instance, in the West Africa Ebola outbreak, diagnostics and diagnostic response were critical factors in the absence of interventions. Earlier diagnosis could have controlled 30–70% of cases.

Spotlight on:

HEPATITIS C

After years of universal inaction on HCV, a global health strategy on viral hepatitis for 2016–2021 was endorsed at the 69th World Health Assembly in May 2016.

Novel, simplified and affordable tests are crucial to unlocking markets for effective HCV treatment globally. FIND's programme includes a product development arm with a heavy focus on demonstrating intervention impact and driving access.

Priorities

FIND's activities to support the development and validation of new tests included:

- Accelerating the development of new assays and validating them in LMIC settings
- Establishing an HCV specimen bank to support R&D
- Conducting pilot projects to determine optimal diagnostic algorithms and use of tests
- Supporting the implementation of new diagnostic tools for HCV in the public and private sectors
- Advocating for increased prioritization of HCV diagnosis based on data and modelling around impact and cost-effectiveness.

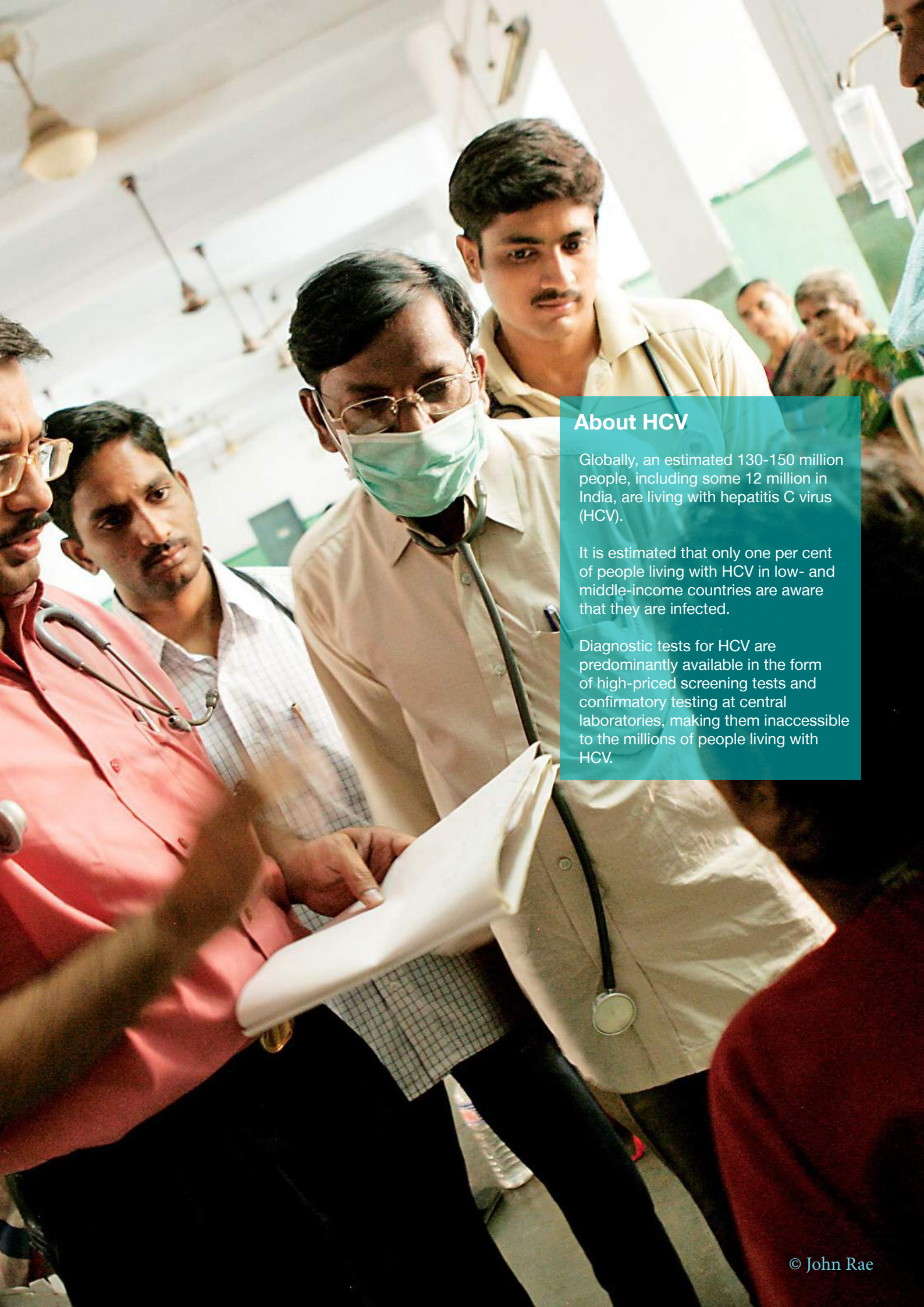
Key projects

A six-country hepatitis C project

Our newly established HCV programme was formally launched with the signing of a grant with Unitaid for a catalytic intervention to increase the availability of affordable and high-quality HCV diagnostic tests and to help create a viable market for HCV drugs at reduced prices. FIND is the lead partner in this multi-year, six-country hepatitis C project.

Under this grant, FIND is partnering with CHAI, Centre Pasteur, DNDi, and national and state governments in Cameroon, Georgia, India, Malaysia, Myanmar and Viet Nam, together with key civil society actors in each country. FIND is also working closely with other international agencies, including WHO and the Global Fund.

Through this project, and in close collaboration with the WHO Global Hepatitis Program, FIND will generate best practices for implementing testing pathways and service delivery approaches in multiple settings. The project will unlock the HCV diagnostics and treatment market in these countries, create the case for policy change at global and national levels, and help pave the way for a scalable public health approach to HCV, including integration into HIV programmes where possible to maximize cost efficiency.



About HCV

Globally, an estimated 130-150 million people, including some 12 million in India, are living with hepatitis C virus (HCV).

It is estimated that only one per cent of people living with HCV in low- and middle-income countries are aware that they are infected.

Diagnostic tests for HCV are predominantly available in the form of high-priced screening tests and confirmatory testing at central laboratories, making them inaccessible to the millions of people living with HCV.

Spotlight on:

NTD

Our Neglected Tropical Disease (NTD) programme supports the development of new diagnostic tools in four disease areas. There is a serious need for readily available, easy to use, reliable and low-cost diagnostics for NTDs. These tools are critical for identifying infected patients, and for detecting disease re-emergence, guiding delivery of appropriate control measures, and monitoring the impact of interventions.

Priorities

HAT

- Improving screening and case confirmation through the development and introduction of highly accurate RDTs for screening HAT, an RDT that detects both HAT and malaria, improved microscopy tools, and highly sensitive molecular methods
- Supporting related cost-effectiveness, policy, access and advocacy activities

Leishmaniasis

- Improving access to visceral leishmaniasis diagnosis in Kenya
- Developing RDTs to address the following gaps: accurate diagnosis of VL across different geographies and in immunosuppressed patients, test of cure or treatment monitoring and point-of-care diagnosis of the different forms of dermal leishmaniasis

Chagas disease

- Supporting development of a molecular test and a point-of-care test for congenital Chagas disease
- Working with partners to catalyse the development of a test to monitor treatment success
- Improving access to diagnostic solutions for Chagas disease, which includes supporting advocacy, driving public policy, and training health care workers

Buruli ulcer

- Supporting the use of improved case finding strategies
- Establishing diagnostic solutions for early detection of BU close to where people live
- Enabling the development of faster, less burdensome confirmation of BU through improved tools

Key projects

LAMP tests for sleeping sickness & leishmaniasis

Loop-mediated isothermal amplification (LAMP) diagnostic kits (Eiken, Japan) for sleeping sickness and leishmaniasis were CE marked. Feasibility studies for LAMP for Chagas disease was also completed.

Access to new reagents for diagnosis of leishmaniasis

Access was gained for a comprehensive assembly of monoclonal antibodies, paving the way for the development of urgently needed, high performance, point of care tests for leishmaniasis.

Second-generation sleeping sickness RDT

The year saw the completion of development of a second-generation sleeping sickness RDT that is planned for launching in 2017. The test is easier and less expensive to manufacture than the first generation rapid test, also co-developed with FIND.

Combination sleeping sickness-malaria rapid diagnostic test

We are evaluating a prototype combination sleeping sickness-malaria rapid diagnostic test, using stored clinical samples. A test that could simultaneously diagnose both diseases could ensure continued surveillance and detection of sleeping sickness cases and prevent re-emergence in the post-elimination era, as all settings where sleeping sickness is found are also endemic for malaria.

Target product profiles for NTDs

There are currently few TPPs for NTD diagnostics. In order to address this gap, our NTD team published the results of a survey of experts to identify current diagnostic needs for Chagas disease. A similar survey and prioritization of unmet diagnostics needs for leishmaniasis was completed and five surveys were conducted to inform consensus-based TPPs for new sleeping sickness tests.

About NTDs

NTDs are endemic in low- and middle-income countries, disproportionately affecting the poorest people. NTDs have been largely overlooked by the global health community, including drug and diagnostics developers.

HAT

More than 65 million people live in areas at risk of exposure to sleeping sickness, which is transmitted by the bite of the tsetse fly. The disease is fatal if not diagnosed and treated. Elimination programmes in 36 endemic countries have successfully reduced the number of cases over the last 20 years. Now 98% of cases occur in just seven countries. Early diagnosis is critical because it enables more effective treatment. Late diagnosis when the disease is advanced makes treatment much more difficult.

Leishmaniasis

Some 350 million people are at risk of leishmaniasis, which is transmitted through the bite of the sandfly. Cutaneous leishmaniasis causes lesions that can leave stigmatizing scars and disability. Visceral leishmaniasis is fatal if not treated. Together, both forms cause over 1.3 million new infections and 20,000–30,000 deaths annually. Sensitive, point-of-care tests are needed to increase access, early diagnosis and effective treatment.

Chagas disease

Chagas disease, or American trypanosomiasis, is caused by the protozoan parasite *Trypanosoma cruzi*. It is mainly endemic in 21 Latin American countries and mostly transmitted by the infected faeces of blood-sucking triatomine bugs. Some 6–8 million people are infected worldwide. Diagnostic gaps include the lack of a point-of-care test for newborns who may have contracted the disease from their mothers, and a test to monitor treatment success.

Buruli ulcer

Every year, more than 2,000 cases of BU are reported, and some 25% are detected too late to prevent disability. BU is caused by a toxin-producing bacterium, *Mycobacterium ulcerans*, which is endemic in 30 countries. The disease occurs largely in rural areas among children 5–15 years of age. Central and West Africa have the largest number of cases, followed by Australia and Southeast Asia. Diagnosis is a major challenge in BU control. A confirmatory test with high sensitivity and wider availability outside specialized labs would enable more rapid treatment for affected patients.

"FIND's role in supporting the development of the new HAT screening test has included the selection of candidate antigens, collection of clinical samples and conducting clinical trials. The test is facilitating diagnosis of sleeping sickness, even in remote regions, and enhancing the prospects of achieving and sustaining elimination of the disease."

– Joseph Ndung'u, Head of NTDs

Spotlight on:

MALARIA

WHO recommends that all patients with suspected malaria have a quality-assured test to confirm diagnosis. However, access to testing is far from universal. Despite the number of RDTs on the market, test quality, and proper storage and use in remote tropical settings remain challenging. Inadequate surveillance and the lack of tests to support elimination are also major gaps. As rates of drug-resistant malaria increase, so does the need for better systems for detecting and containing transmission.

Priorities

Our malaria strategy focuses on quality assurance for existing tests and on malaria elimination through support for the development of new, highly sensitive diagnostic tests for all malaria strains.

Priority areas, based on identification of acute needs, aim to:

- Improve detection and management of non-*falciparum* malaria
- Maximize impact of high-quality malaria tests
- Enable elimination through new tools for surveillance and response
- Guide global prioritization of diagnostic solutions for malaria across all of FIND's activities

Key projects

High-sensitivity infection detection test

FIND provided clinical evaluation and technical support in the development of the Malaria Ag P.f (Alere/SD, Korea), the first-ever rapid test that can screen for malaria infection in people who are carrying the malaria parasite but show no signs of illness.

Instant quality assurance of rapid diagnostic tests

In 2016, FIND and Microcoat Biotechnologie GmbH concluded the project to develop a field-stable, instant quality assurance tool for malaria RDTs. Positive control wells are easy-to-use and designed to test the performance of malaria rapid diagnostic tests in even the most remote rural settings. They also provide an on-the-spot quality check that can be used by health providers or clinical supervisors with limited training to ensure that malaria rapid tests are functioning properly.

International quality assurance standards for molecular tests

FIND began working on the development of a global external quality assurance (EQA) scheme for nucleic-acid amplification assays (NAATs) tests for malaria with WHO's Global Malaria Programme and the UK National External Quality Assessment Service for Microbiology. NAATs, such as the loop-mediated isothermal DNA amplification test, are currently being used to screen for and treat malaria in elimination programmes. A global EQA system will ensure that data obtained from the use of NAATs for malaria surveillance are reliable and comparable. This EQA system will support the development and standardization of more sensitive diagnostic tests needed for malaria elimination programmes.

About Malaria

In 2015, there were an estimated 212 million malaria cases globally and 429,000 malaria associated deaths.

The risk of death due to malaria is greatest in children under the age of 5 years, and most malaria deaths occur in young children in sub-Saharan Africa. The World Malaria Report 2016 noted an increase in public sector diagnostic testing for malaria in this region, from 40% to 74% over five years, largely due to the widespread distribution of rapid diagnostic tests. However, there are ongoing problems with rapid test quality.

Few rapid tests can detect *P. vivax* infections, and far more sensitive rapid tests are needed in order to eliminate the malaria parasite reservoir. Consistent and accurate diagnosis of malaria during pregnancy requires more sensitive rapid tests.

Spotlight on:

TUBERCULOSIS

Rapid and accurate detection of TB and drug resistance is the essential first step in guiding treatment that can cure patients and prevent the ongoing spread of drug resistance. Diagnosis also enables disease monitoring and better targeting of interventions, which are essential in controlling TB transmission in populations. Since 2010, FIND has worked in high burden countries to support the scale up of WHO endorsed diagnostics to ensure rapid diagnosis for TB and drug resistance.

Priorities

FIND's strategic approach to TB is guided by a vision of the future in which all people affected by TB have access to accurate and affordable diagnostics that can guide treatment. Our activities are focused around four key objectives:

- Cutting transmission through early detection
- Providing correct treatment through early drug susceptibility testing (DST), preventing antimicrobial resistance and decreased morbidity and mortality
- Maximizing the impact of available TB diagnostics through comprehensive, country-specific solutions
- Demonstrating the vital role of diagnostics in controlling TB

These activities are conducted with a wide range of partners from companies, academic and research institutions, international organizations, health ministries and civil society organizations.

Key projects

Xpert® MTB/RIF Ultra evaluation

We completed an evaluation of Xpert® MTB/RIF Ultra (Ultra) (Cepheid, USA), a second-generation automated molecular TB test with greater diagnostic sensitivity in children and people living with HIV. The evaluation was conducted in eight countries at 10 sites, and data were analysed and prepared for presentation to WHO, leading to their endorsement of the test.

Stool test for TB

We are working with Rutgers University (USA) and 42T (UK) to improve detection of TB in children by testing stool, an easily accessible sample, using a simple processing kit. With the ability to test stool in children, diagnosis avoids invasive procedures and can be done in more decentralized settings.

Connectivity for GeneXpert® Omni

We are supporting the connectivity aspects of Omni (Cepheid, USA), a new and highly mobile diagnostic device that will be used with existing diagnostic test cartridges for TB and numerous other diseases, including Ebola. Full connectivity will mean that test results can be shared with clinicians immediately, reducing time to treatment, even for TB patients in remote areas.

About Tuberculosis

TB is an infectious disease and one of the top 10 causes of death worldwide.

In 2015, some 10.4 million people developed active TB and 1.8 million died as a result. However, an estimated 4.3 million were "missed" – most because they were never diagnosed at all and some because they were not linked to treatment and care.

Simpler and more sensitive TB tests are needed to avoid missing TB cases and to more easily diagnose TB in health facilities with limited laboratory infrastructure. Better tests to catch TB in children and in people living with HIV are also needed, as they are more difficult to diagnose.

There are currently several test technologies in the TB diagnostics development pipeline; however, numerous manufacturers have discontinued their engagement due to insufficient funding for development and trialling.

GOVERNANCE

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Head of Fever: Sabine Dittrich
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Head of NTD: Joseph Ndung'u
Director of Operations: Sharon Saacks
Head of FIND India: Sanjay Sarin
Head of FIND South Africa: Heidi Albert
Representative in Viet Nam: Yen Nguyen

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We are immensely grateful to our loyal donors for their unfailing support in 2016 (by alphabetical order):

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Global Health Innovative Technology Fund, Japan
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FIND would also like to thank all collaborators that have helped to support our vision and mission.


QUA HAIN TEST
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Foundation for Innovative New Diagnostics (FIND), Geneva

Report of the Statutory Auditor on the Consolidated Financial Statements to the Board of the Foundation

Consolidated Financial Statements 2016

KPMG SA
Geneva, 28 April 2017
Ref. PHP/PHD/st

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Report of the Statutory Auditor to the Board of the Foundation of

Foundation for Innovative New Diagnostics (FIND), Geneva

Report of the Statutory Auditor on the Consolidated Financial Statements

As statutory auditor, we have audited the accompanying consolidated financial statements of Foundation for Innovative New Diagnostics (FIND), which comprise the balance sheet, statement of revenue and expenditure, cash flow statement and notes for the year ended 31 December 2016.

Board of the Foundation's Responsibility
The Board of the Foundation is responsible for the preparation of the consolidated financial statements in accordance with the requirements of Swiss law and the foundation's charter and regulations. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error. The Board of the Foundation is further responsible for selecting and applying appropriate accounting policies and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility
Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Those standards require that we plan and perform the audit to obtain reasonable assurance whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers the internal control system relevant to the entity's preparation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system. An audit also includes evaluating the appropriateness of the accounting policies used and the reasonableness of accounting estimates made, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the consolidated financial statements for the year ended 31 December 2016 comply with Swiss law and the foundation's charter and regulations.

Report on Other Legal Requirements

We confirm that we meet the legal requirements on licensing according to the Auditor Oversight Act (AOA) and independence (article 728 CO and article 11 AOA) and that there are no circumstances incompatible with our independence.

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists, which has been designed for the preparation of consolidated financial statements according to the instructions of the Board of the Foundation.

We recommend that the consolidated financial statements submitted to you be approved.

KPMG SA

Pierre-Henri Pingeon
Licensed Audit Expert
Auditor in Charge

Philippe Delparte

Geneva, 28 April 2017

Enclosure:
- Consolidated financial statements (balance sheet, statement of revenue and expenditure, cash flow statement and notes)

STATEMENT OF REVENUE AND EXPENDITURE FOR THE YEAR ENDED 31 DECEMBER 2016

(all amounts in US dollars)

	Note	2016	2015
REVENUE			
Grant revenue	3	33,789,961	33,926,140
Exchange gains		-	
Other operating income		330,960	357,759
Total revenue		**34,120,921**	**34,283,899**
EXPENDITURE			
Programme services			
Tuberculosis		7,157,378	6,924,030
Fever & Outbreaks		3,322,641	4,088,190
Neglected tropical diseases		4,133,869	3,866,242
Malaria		3,888,671	3,718,324
HIV and HCV		3,671,934	3,875,736
Access and other		8,353,661	8,514,466
Total programme services		**30,528,154**	**30,986,988**
Supporting Services			
Information & communication		101,542	134,510
Governing & advisory bodies		63,147	56,287
General administration		2,597,460	2,563,846
Total supporting services		**2,762,149**	**2,754,643**
Total operating expenditure	5	**33,290,303**	**33,741,631**
Excess of operating revenue over expenditure for year		**830,618**	**542,268**
Revenue relating to prior year	6	592,938	-
Financial income		307,354	278,617
Financial expenses		35,183	32,151
Accumulated surplus brought forward		1,773,229	984,495
Accumulated surplus carried forward		**3,468,956**	**1,773,229**

The accompanying notes form an integral part of these financial statements.

BALANCE SHEET AS AT 31 DECEMBER 2016

(all amounts in US dollars)

	Note	2016	2015
ASSETS			
Current assets			
Cash and cash equivalents	7	31,064,595	21,052,872
Accounts receivable		967,174	2,260,708
Prepayments		933,468	131,621
Total current assets		32,965,237	23,445,201
Non-current assets			
Rental guarantee deposit		215,408	218,095
Total non-current assets		215,408	218,095
Total assets		**33,180,645**	**23,663,296**
LIABILITIES AND CAPITAL			
Current liabilities			
Accounts payable and accrued expenses		5,397,764	4,242,162
Deferred revenue	8	24,078,345	17,287,486
Unrealized exchange gains		195,150	319,989
Total current liabilities		**29,671,259**	**21,849,637**
Capital and reserves			
Foundation capital	13	40,430	40,430
Accumulated surplus		3,468,956	1,773,229
Total liabilities, capital and revenue		**33,180,645**	**23,663,296**

The accompanying notes form an integral part of these financial statements.

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2016

(all amounts in US dollars)

	2016	2015
Excess (deficit) of revenue over expenditure for year	1,695,727	788,734
	1,695,727	**788,734**
Cash flows - operating activities		
Increase (decrease) in deferred revenue	6,790,860	(4,913,977)
Increase (decrease) in accounts payable and accruals	1,155,602	1,060,377
(Increase) decrease in accounts receivable	1,293,534	(808,049)
(Increase) decrease in prepayments	(801,847)	76,901
Increase (decrease) in unrealized exchange gains on foreign currencies	(124,839)	(92,053)
Net cash provided by operating activities	**8,313,310**	**(4,676,801)**
Cash flows - investing activities		
(Increase) decrease in rental guarantee deposit	2,687	174,070
Net cash used in investing activities	**2,687**	**174,070**
Net increase (decrease) in cash and cash equivalents for year	10,011,724	(3,713,997)
Cash and cash equivalents at start of year	21,052,872	24,766,869
Cash and cash equivalents at end of year	31,064,595	21,052,872
Net increase (decrease) in cash and cash equivalents for year	10,011,723	(3,713,997)

The accompanying notes form an integral part of these financial statements.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

1. General information

1.1 Legal aspects

The Foundation for Innovative New Diagnostics (FIND) is an independent Swiss Foundation established as a not-for-profit legal entity created under Article 80 of the Swiss Civil Code and registered in the Geneva Register of Commerce on 29 July 2003.

FIND's mission is to drive the development and early implementation of innovative diagnostic tests that have a high impact on patient care and disease control in low-resource settings.

FIND is monitored by the Swiss Federal Supervisory Board for Foundations.

1.2 Tax exemption

On 9 December 2010, FIND and the Swiss Federal Council signed an agreement granting FIND certain privileges and immunities under the revised Host State Act, which came into force on 1 January 2008. In accordance with this agreement, FIND has been granted exemption from all federal, cantonal and communal taxes, from Value-Added Tax, and from regulations governing the employment of foreign nationals in Switzerland. This agreement came into effect on 1 January 2011.

1.3 Regional offices

FIND is headquartered in Geneva, Switzerland and has regional offices in New Delhi, India; Cape Town, South Africa; Kampala, Uganda; Hanoi, Vietnam

Since 2007, FIND has played a key role in demonstrating the effectiveness of new diagnostics in country settings, and scaling up the delivery of strong programmatic management of drug-resistant Tuberculosis in India and South-East Asia. FIND India was established as a liaison office through a Collaborative Agreement with Ministry of Health & Family Welfare of the Indian Government. In addition, the Foundation for Innovative New Diagnostics India was incorporated under section 8 of the Companies Act as a non-profit company, limited by guarantee, in July 2015; this entity will become operational in 2017.

FIND Uganda was established in 2008 and provides support for FIND's research and field activities for Tuberculosis, Malaria and Human African Trypanosomiasis in Uganda. It is established as a non-governmental organization on the basis of a Memorandum of Understanding with the republic of Uganda.

FIND Dx in South Africa was registered as a non-profit company in December 2014 and is FIND's principal representative office in Africa with a main focus on access-related work. This company has no share capital and is not limited by guarantee.

FIND's operations as a non-governmental organization in Vietnam were registered with the People's Aid Coordinating Committee in August 2015. FIND's work in Vietnam aims to support research and treatment of infectious diseases, primarily tuberculosis, supporting the National TB Program, Pham Ngoc Thach Hospital and the National Institute of Malariology, Parasitology and Entomology.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

2. Significant accounting policies

2.1 Basis of presentation
These financial statements have been prepared in accordance with the principles of the Swiss law on accounting and financial reporting (title 32 of the Swiss Code of Obligations). The presentation of the Income and Expenditure Statement and Deferred Revenue in note 8 have been revised to reflect the current organizational structure. Comparative information has been re-presented accordingly. Significant items are accounted for as follows:

2.2 Cash and cash equivalents
Cash and cash equivalents comprise cash balances and short-term money market deposits with original maturities of 3 months or less.

2.3 Rental guarantee deposit
The deposits relate to the rental of FIND office premises in Geneva, India and Vietnam and are recoverable in accordance with the rental contract upon vacation of the premises.

2.4 Foreign currency
Accounting records are maintained in US dollars (USD). Revenue and expenditures in other currencies are recorded in USD approximating actual rates in effect at the time of the transaction. Year-end balances for assets and liabilities in other currencies are translated into US dollars at rates of exchange prevailing at balance sheet date. At 31 December 2016, the rate of exchange used for the Swiss franc, the main foreign currency for 2016, was USD/CHF = 1.016 *(2015 –1.00)*. Realized exchange gains as well as realized and unrealized exchange losses are included in the determination of surplus (deficit) for the year. Unrealized exchange gains are deferred.

2.5 Recognition of revenue
Revenue on grants is recognized in the period to the extent that the related project expenses and recoverable overheads are incurred. Interest income is recognized on an accrual basis and other operating income is recognized when received. Grants received relating to activities in future years are recorded in the balance sheet as deferred revenue.

2.6 Donations in-kind
Donations in-kind are not recorded but disclosed in the notes to the financial statements based on information provided by partners. They are valued at the price FIND would have had to pay if the goods or services were to be provided in exchange for payment under usual contractual terms. Services rendered or goods transferred to FIND must exclude any monetary transfer and must be clearly identifiable to a FIND project.

2.7 Consolidation

The following entities' results have been included in the consolidated financial statements:

FIND India and FIND Dx in South Africa.

The foundation's financial statements are consolidated according to the full consolidation method. All inter-company investments, balances and transactions have been eliminated.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

3. Donations received

During 2016, the following donations were received from donors (*other currency amounts are converted to USD at exchange rates on date of receipt*):

	2016	2015
The Bill & Melinda Gates Foundation	11,663,764	3,443,725
UNITAID	7,876,470	4,788,175
Government of the United States	5,191,897	3,788,677
Dutch Ministry of Foreign Affairs (DGIS), Netherlands	4,251,440	-
Department for International Development (DFID), United Kingdom	2,928,213	3,055,770
Department of Foreign Affairs and Trade, Australia	2,399,806	2,499,508
Paul G. Allen Family Foundation	1,705,500	2,349,750
Federal Ministry of Education And Research (BMBF) through KfW, Germany	1,522,995	3,523,586
Swiss Agency for Development and Cooperation (SDC), Switzerland	1,210,074	809,846
Global Health Innovative Technology Fund (GHIT), Japan	1,087,393	88,501
The Global Fund to Fight AIDS, Tuberculosis and Malaria	787,056	1,765,681
Swiss State Secretariat for Education, Research and Innovation (SERI)	472,107	837,446
Médecins Sans Frontières International	279,845	-
World Health Organization	255,362	859,701
JSI Research & Training	250,000	187,500
United Nations Office for Project Services	219,262	-
UBS Optimus Foundation, Switzerland	201,819	126,263
The ELMA Foundation	175,000	-
Republic and Canton of Geneva, Switzerland	153,218	157,233
Becton Dickinson and Co	5,000	100,000
Other	11,114	81,774
European Union	-	55,719
Total contributions received	**42,647,335**	**28,518,855**

Donor agreements in effect as at 31 December 2016 provide for a total of USD 77 million to be paid to FIND between January 2017 and December 2021.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

4. Donations in-kind

FIND operations are funded through financial contributions and donations. In addition to financial contributions, generous partners, private companies and academic groups provide FIND with goods and services at no cost as donations in-kind. The analysis of goods and services received is as follows:

	2016	2015
Tuberculosis	1,894,996	1,251,892
Neglected Tropical Diseases	800,096	415,211
Malaria	990,123	381,821
Sexually transmitted infections	269,891	-
Total donations in-kind	**3,955,106**	**2,048,924**

The above amounts include 70% for infrastructure and supplies, 29% for personnel and consultants plus 1% for travel, *(2015 – 64% for infrastructure and supplies 35% for personnel and consultants, and 1% for travel).*

5. Expenditure by cost type

The breakdown of programme and supporting services by expense type is shown below:

	2016	2015
Project partners	12,107,215	11,919,455
Personnel	8,082,309	7,829,089
Consultants	5,920,890	6,017,550
Travel	2,466,814	2,500,969
Equipment	974,007	2,199,390
Supplies and other expenses	3,739,068	3,275,178
Total expenditure	**33,290,303**	**33,741,631**

Commitments at 31 December 2016 for future payments to partners under contracts signed up until 31 December 2016 total USD 8,378,815 *(2015 – USD 4,875,183).*

At 31 December 2016 and 2015, there are no amortization and depreciation expenses as all fixed assets are totally depreciated.

The annual average number of full-time personnel equivalents for the reporting year, as well as the previous year, did not exceed 250.

6. Revenue relating to prior year

This represents revenue recognised for expenditure incurred in 2015.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

7. Cash and cash equivalents
Cash and cash equivalents as at 31 December 2016 were as follows:

	2016	2015
Petty cash	900	1,277
Bank current accounts	18,087,087	13,051,147
Short-term deposits	12,976,608	8,000,448
Total cash and cash equivalents	**31,064,595**	**21,052,872**

8. Deferred revenue
Deferred revenue represents donor contributions received in advance. These funds are expected to be utilized in the following financial year. The following table shows the breakdown of these funds by disease area.

	2016	2015
Tuberculosis	4,923,650	5,633,834
Fever & outbreaks	3,789,828	1,884,402
Neglected tropical diseases	3,515,637	2,104,062
Malaria	2,381,390	2,901,618
HIV and HCV	6,321,281	318,193
Access and other	3,146,559	4,445,377
Total deferred revenue	**24,078,345**	**17,287,486**

9. Pension fund liabilities
USD 59,473 was due to the pension fund as at 31 December 2016 *(2015 – USD 34,068)*.

10. Rent commitments
At 31 December 2016, FIND had future rent commitments totalling USD 1,273,660 up to 31 May 2019 *(2015 – USD 1,782,577 up to 31 May 2019)*. Of this amount, USD 541,839 is due within 12 months *(2015 – USD 525,515)*.

11. Operating lease commitments
At 31 December 2016, FIND had future rent commitments on operating leases totalling USD 42,515 up to 30 September 2018 *(2015 – USD 67,829 up to 30 September 2018)*, USD 24,294 of which is due within 12 months *(2015 – USD 24,665)*.

12. Audit fees
Fees for auditing services totalled USD 73,700 for 2016 *(2015 – USD 40,959)* and fees paid to the auditors for other services totalled USD 10,272 in 2016 *(2015 – USD 4,848)*.

13. Foundation capital
The Endowment Capital of CHF 50,000 is fully subscribed and equates to USD 40,430 at the rate of exchange on the date of payment.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2016
(all amounts in US dollars)

14. Events subsequent to 31 December 2016
No events occurred subsequent to 31 December 2016 which could have a material impact on the understanding of these financial statements.

PHOTO CREDITS

John RAE (cover, p. 9, 11, 13, 15,18, 29, 31, 35); Pamela NABETA (p. 19); Rey BYHRE (p. 23, 27); Sandrine REGEON (p. 25); Xavier DING (p. 33, 51); Tobias BROGER (p. 38).

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