



ANNUAL REPORT 2018

Marking 15 years of diagnostic innovation

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LEADERSHIP MESSAGE



Dr Catharina Boehme
Chief Executive Officer



Mark Kessel
Chair of the Board

2018 marked our organization's 15th anniversary and a major diagnostic milestone: the release of the World Health Organization (WHO) Essential Diagnostics List (EDL) – more than 40 years after the Essential Medicines List. The formation of the EDL finally sends a strong signal that diagnostic tests are as necessary as medicines. FIND worked with WHO to support the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD) as well as the EDL mechanisms. Following its release, many countries are now seeking to set up national EDLs and we are partnering with WHO and early-adopter countries to support these efforts – an important step towards improving diagnostic availability and affordability in countries, and a prerequisite for universal health coverage (UHC).

These efforts have manifested in an expansion of our relationship with WHO, and our Collaborating Centre status has now been broadened to “Laboratory Strengthening and Diagnostic Technology Evaluation”.

We have now officially launched our Antimicrobial Resistance (AMR) and Pandemic Preparedness programmes, housed within a new Emerging Threats unit. Together with the WHO R&D Blueprint team, we have published analyses that highlighted to developers and funders the huge diagnostic gaps for outbreak pathogens that threaten global health security. We also took a fresh look at our malaria strategy and merged our Malaria and Fever programmes, a move that allows us to focus on patient needs whether or not their fever is due to malaria. Within our well-established Neglected Tropical Diseases (NTD) portfolio, we laid the groundwork for a forthcoming new initiative to tackle schistosomiasis, a disease with urgent unmet diagnostic needs despite affecting over 200 million people.

It was a particularly big year for tuberculosis (TB), with the UN high-level meeting on TB taking place in September. Among other things, the public statement we made on behalf of all PDPs working on TB, together with our participation in *The Lancet* Commission on TB, led to recognition of the importance of diagnostics to find the “missing millions” and identify drug resistance

in the final TB political declaration – as well as in the action plans of international stakeholders, including The Global Fund and Stop TB Partnership. Building on a decade of research we conducted with partners, 2018 also saw the CE marking of a potentially breakthrough urine test for TB in people with HIV. We contributed data to a WHO report on next-generation sequencing (NGS) technologies for detection of TB mutations, directly impacting TB policy. Our access work in paediatric TB diagnosis, which takes a public-private partnership approach, was awarded the prestigious Public Health Initiative prize at the India Health & Wellness Summit.

This year our India office leadership was bolstered as Dr Sarabjit Chadha joined our team as Regional Technical Director. We also welcomed two new members to the FIND Board of Directors, strengthening representation from Asia: Professor George F. Gao, Director General of the Chinese Center for Disease Control and Prevention, and Ms Shobana Kamineni, Executive Vice Chairperson of Apollo Hospitals Enterprises in India. Mr Bob More stepped down from our Board at the end of his term and we thank him again sincerely for his valuable contributions.

These are exciting times for diagnostics. On behalf of FIND, we would like to thank everyone who has worked with us over the last 15 years – our team, our partners, funders and collaborators. Over 30,000 patients have participated in our clinical trials, just since we started keeping count in 2015. Our mission depends on every one of you. As we enter the final furlong of our current strategic period, we look forward to continuing to work with you to catalyse game-changing diagnostic innovation and ensuring it reaches those who need it most.

Mark Kessel, Chairman of the Board of Directors

Catharina Boehme, Chief Executive Officer

2018 IN NUMBERS

~17 million FIND-supported products estimated to have been provided to LMICs (13% increase from 2017)

3 new tests developed, bringing current total to 24

2 FIND-supported products achieved WHO recommendations

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

16 clinical studies active in 20 low-and middle-income countries (LMICs)

>40,000 patient samples collected for the FIND specimen bank

>8,000 patient samples collected and used in FIND-sponsored clinical studies

>1,700 health workers trained across 20 LMICs

>900 laboratories and testing sites strengthened in Africa, Asia, and Eastern Europe

6 new *in vitro* diagnostic projects added to our R&D portfolio, bringing the total to 56 products in our portfolio

1 new non-IVD project added

69 peer-reviewed manuscripts published by FIND authors – over 750 citations

COUNTRY OFFICE KEY ACHIEVEMENTS



CAPE TOWN – SOUTH AFRICA

- Contributed to Kenya's National Strategic Plan for Tuberculosis, Leprosy and Lung Health 2019–2023 through our TB diagnostic network optimization work, informing better design of the laboratory network and sample referral system to help close the diagnostic gap
- Expanded diagnostic network optimization work in Kenya and the Philippines (with preparations made to add future countries), and secured additional funding to initiate development of an openly available network optimization tool
- Together with the Africa Centres for Disease Control and Prevention and partners from industry (Becton, Dickinson and Company), developed and piloted an Antimicrobial Resistance (AMR) Laboratory Quality Scorecard aimed at building quality-assured AMR testing to improve appropriate antimicrobial use and strengthen surveillance efforts
- Contributed to evaluations of various diagnostic technologies in the region, including a TB LAM urine test, stool processing for TB diagnosis in children and centralized TB assays
- Continued contribution to global policy, guidelines and tool development in collaboration with regional and global partners, including WHO and the Global Laboratory Initiative (GLI)

“Diagnostic network optimization conducted with FIND and partners at national and county level will help us improve patient access to services and cost efficiency by optimizing the placement and utilization of existing diagnostics, designing integrated sample referral systems and informing new investments. Patient pathway analysis showed that only 43% of TB patients currently get diagnosed, and gaps exist in access to drug susceptibility testing. Kenya’s National Strategic Plan 2019–2023 prioritizes finding the ‘missing’ TB patients wherever they seek care in the health system. This work will help to ensure we can meet our goal of closing the diagnostic gap.”

Sheilla Chebore, Laboratory Technical Advisor, Centre for Health Solutions, Kenya



NEW DELHI – INDIA

- 510,977 patients tested for TB and drug-resistant TB in FIND-supported laboratories, with 13,694 cases of MDR and XDR TB detected
- Over 5,000 healthcare providers engaged as part of the Joint Effort for Elimination of Tuberculosis (JEET) project initiated this year. A total of 28,161 case notifications were made in 2018, exceeding the target of 22,599, and 164 of 285 hubs were functional by end of December. Between July and December, 3,431 samples were transported for CBNAAT testing, with an average positivity rate of 18%
- As part of the Unitaaid-funded HEAD-Start project, commencement of hepatitis C diagnostic services were introduced in Punjab in 13 antiretroviral therapy (ART) centres with HCV screening facilities and 4 centres with confirmatory testing facilities. Up to the end of December, over 3,992 HIV+ people were screened for HCV, and 599 HCV infections were confirmed
- Dr Sarabjit Chadha, Regional Technical Director for FIND India, was elected as Chair of the Global Drug-resistant TB Initiative (GDI) Core Group, and Dr Sanjay Sarin, Head of FIND India, was elected as a member of the WHO SEAR rGLC Advisory Committee on MDR-TB
- In September, WHO published their guidance document entitled “Best practices in child and adolescent tuberculosis”, which featured our Challenge TB project as a recommended model for replication, under access strategies for improved diagnostic coverage
- Our work in paediatric TB diagnosis in India, supported by USAID and KNCV under the Challenge TB project, was awarded the prestigious “Public Health Initiative” prize at the India Health & Wellness Summit and Awards, hosted in New Delhi in December

“The implementation of the HEAD-Start project in Delhi has been possible thanks to the support of FIND, Government of NCT Delhi and the dedicated team of ILBS. We are working together to develop a well-functioning network that provides decentralized diagnosis for HCV, with effective linkage to treatment centres. Decentralized screening and treatment management for hepatitis C at the primary healthcare level is essential to tackle this disease.”

Dr S K Sarin, Director, Institute of Liver and Biliary Sciences (ILBS)



HANOI – VIET NAM

Jointly organized a workshop on improving access to HCV diagnosis, together with the Viet Nam Administration of Medical Services, WHO and Unitaaid, which facilitated larger discussion among representatives from several in-country agencies on how HIV, HBV and HCV testing and treatment can be scaled up as part of the national response. Opportunities and key barriers to integration were defined, alongside next steps for integrated mapping of laboratory infrastructure, instrumentation and service delivery for HIV, TB, and HCV, to inform national testing policy.

“We are impressed with FIND’s world-leading sample bank, which includes well-characterized TB clinical reference materials that facilitate the development of new TB diagnostics suitable for use in high-burden countries. We are looking forward to close collaboration on our TB Reference Materials Project in Viet Nam, which will catalyse development of TB diagnostics in our region.”

Associate Professor Nguyen Van Hung MD, PhD, Head of Department of Microbiology and National TB Reference Laboratory, National Lung Hospital, Viet Nam

Perspective

SARABJIT CHADHA

Regional Technical Director, FIND India



Having worked in various health programmes for over two decades as a clinician and public health expert in India and South-East Asia, I have seen first-hand that the cornerstone for the success of any disease control programme is the availability and use of simple and rapid diagnostics. Hence, it was a terrific opportunity to join the FIND team, dedicated to making these urgently needed tools a reality. In my role with The Union, I got to know FIND for the commendable work in the area of TB, particularly their contribution to the development, validation and enhanced access to rapid diagnostics like Xpert MTB/RIF and Line Probe Assay (LPA), as well as strengthening laboratory networks in high TB burden countries, including India.

What impresses me most is the spectrum of health challenges that FIND is trying to address. I am particularly excited about the pioneering work FIND is doing to address the rapidly emerging threat of antimicrobial resistance (AMR). This is a global challenge but the bulk of the impact is being felt by countries with lower resources. The rising incidence of AMR poses a direct risk to the achievement

of 'good health and well-being for all' (Sustainable Development Goal 3) – already, over 700,000 people die every year due to AMR, and this figure is estimated to reach 10 million by 2050.

At FIND, we are working with partners and donors to address this challenge holistically, focussing on developing new point-of-care diagnostic tests, ensuring that the tests are accessible and used, and strengthening AMR surveillance through diagnostic connectivity solutions. A unique and innovative initiative led by FIND is the AMR Diagnostic Use Accelerator, which is evaluating a package of interventions in several low- and middle-income countries in Africa and Asia. I am coordinating the study in India where we have four sites across the country. The study aims to promote the use of rapid diagnostic tests and clinical algorithms for patients presenting with fever. It will demonstrate a model that ensures access and use of rapid diagnostics in primary healthcare settings, and rationalize the use of antibiotics. Scaling up these interventions can be game-changer in a country like India where antibiotics are routinely misused.

STRATEGY & PROGRESS

Our current work is guided by our 2015–2020 strategy, which focuses on our role as bridge builder and mobilizer, translating the technical world of product development into access to diagnostic solutions that meet patient needs in low-resource settings.

The strategy comprises four pillars, shown in Figure 1, together with key indicators of our achievements so far during this strategic period.

A major milestone this year was the release of the WHO Model List of Essential *In Vitro* Diagnostics

(known as the Essential Diagnostics List, or EDL), which will facilitate procurement and uptake of key diagnostics in LMICs. We worked closely with WHO to support the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE-IVD), as well as the EDL mechanisms. Many countries are now in the process of setting up national EDLs, and we are working with WHO and early-adopter countries to support these efforts. We are also participating in the development of the second edition of the WHO EDL.



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



PRE-NEGOTIATED RATES

Fixed price
Low-cost roaming



SINGLE SIM

One contract and vendor
Over 900 roaming partners
in >190 countries



SUPPORT

24/7 customer support
Personalized service



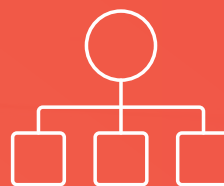
UNIFIED BILLING

Multiple SIMs allowed under
one account
Multiple currencies



CENTRALIZED MANAGEMENT

Accessible user portal



BEST PRACTICE

High-quality service,
support and security



Innovative mobile data transmission for clinical trials in remote areas

The Drugs for Neglected Diseases *initiative* (DNDi), a not-for-profit research and development organization, is piloting SIMplicity, a global SIM service designed by FIND and launched in 2018, to support clinical trial operations in the Democratic Republic of Congo (DRC). SIMs are small cards containing chips that are used in mobile phones and other connected devices to transmit data over the internet in a secure manner.

DNDi is using the global SIM cards to create portable Wi-Fi zones to enable the secure sharing of clinical data in remote locations where connectivity is unreliable. Powered by cross-border mobile network operator Telecom26 AG, SIMplicity provides cost-effective and dependable mobile data capabilities for diagnostics and other connected healthcare devices, via global SIM cards. Where a global system for mobile communications (GSM) is available, the SIM cards are a less expensive alternative to putting satellite dishes at clinical trial sites to transmit data.

“This is a great example of product development partnerships (PDPs) working together to record and track disease diagnoses in remote and low-resource areas,” said Pascal Carpentier, Head of Information Systems and Technology at DNDi. “FIND faces similar challenges to DNDi in transmitting data to and from places with limited connectivity, and we are benefitting (we should use British spelling) from this new product that is in a nascent phase, while providing them with valuable information to help refine the service.”

The digital connectivity service, which was launched last year and specifically designed to support global health partners, is part of FIND's commitment to developing and expanding access to connected diagnostic tools for poverty-related diseases. Healthcare programmes using locally purchased, pay-as-you-go SIM cards for connectivity in LMICs may face issues such as deactivation, managing multiple subscriptions, and a lack of quality assurance and reporting mechanisms.

“This product gives us an immediate global answer to connectivity and we are looking at using it at additional clinical sites in Uganda and Guinea,” Mr Carpentier said.



2003

FIND is launched at the World Health Assembly in Geneva, to support the health of people in LMICs through the introduction of new, affordable and rapid diagnostics for infectious diseases



2007

FIND India is established, following an MoU with the government of India, to introduce new, rapid and quality-assured diagnostic tests for TB at affordable prices for the public health sector in India

FIND AT FIFTEEN

Reflections from our Director of Operations, Sharon Saacks

I have been at FIND for over a decade – through the up and down cycles of life in the non-profit global health sector – and the work that we do still fascinates me greatly. Our organization has grown and evolved; we've overcome difficult times, seen some ground-breaking successes, and today we are stronger than ever.

Technically, diagnostics can be pretty complex, and that has always appealed to the scientist in me. Is it really possible to make an accurate TB test that doesn't depend on laboratory infrastructure? We've always believed so, and that's just one of the innovations we've been tenaciously pursuing for many years. This year we are finally seeing those efforts start to bear fruit as we gear up for clinical trials of a new TB LAM rapid test.

What FIND has always done well is to balance our portfolio so that we can bring later stage developments through the pipeline rapidly, while we whittle away at the more complex but high-potential innovations. This way, we can ensure that patients in countries where there is very limited access to innovative solutions, benefit from technologies as they become available. This side of our work – knowing that

what you are doing is going to have some impact – is hugely rewarding and very interesting, even if achieving it can be challenging!

FIND started back in 2003 with a focus on TB R&D, with our founding being announced at the World Health Assembly that year. TB is the world's biggest killer – surpassing HIV – and yet remains woefully underfunded and politically overlooked. In 2018, the TB community finally got some long-overdue airtime with the UN General Assembly High-Level Meeting on TB, and I am optimistic that the global targets might really be achieved. But there is still a lot of work to be done to get there.

R&D continues to be a critical gap for many diseases, and there are multiple cases in which the right diagnostics just don't exist (yet). FIND recognized early that there are fundamental barriers that prevent diagnostics from reaching the patients who would benefit from them, and that these must be addressed. So, today we try to take a more holistic view and will support evidence collection (that can be used toward regulatory or policy dossiers), adoption and scale-up of diagnostic tools beyond those that we have supported for development, provided that they meet a global



2014

FIND is appointed as a WHO Collaborating Centre for Tuberculosis Laboratory Strengthening and TB Diagnostic Technology Evaluation, acknowledging the role of the organization in evaluating and introducing new TB diagnostic solutions and building laboratory capacity needed to effectively control TB.



2015

FIND receives certificate of operation in Viet Nam to develop support activities and humanitarian assistance, and to support research and treatment of infectious diseases.

FIND office opens in Cape Town, South Africa, supporting public health initiatives and systems strengthening across the region



2014

FIND WHO Collaborating Centre status is broadened to Laboratory Strengthening and Diagnostic Technology Evaluation



2018

health need and will benefit our target populations. This approach was crystallized in our 2015 strategic plan.

Some diagnostic challenges are common or similar across disease areas. Over the years, our disease portfolio has expanded, and today we have active projects not just in TB, but also malaria (another global emergency), and viral hepatitis, alongside more amorphous areas such as antimicrobial resistance and pandemic preparedness, which we have just formalized under the umbrella of a new Emerging Threats programme. Since the major Ebola outbreak in 2014, we have turned some of our attention to pathogens that could lead to epidemics and pandemics – not just Ebola, but also Zika, yellow fever, and most recently, Lassa fever.

We are also working to address quite a few neglected tropical diseases. They are a category all by themselves, and especially interesting as there is so little market incentive for commercial enterprise in this area, which makes developing diagnostics for these highly debilitating diseases somewhat unattractive. Numbers are small but fatalities are very high, and the consequences of these diseases are awful. We have

a long-running programme in sleeping sickness, for which we co-developed new diagnostics including a rapid test that is vital for active screening initiatives, and is now underpinning elimination programmes in multiple countries. We have also been working in leishmaniasis, and Buruli ulcer for many years. Building on all our experience in this area, we are now setting up a new programme to develop tests that are urgently needed to help control schistosomiasis.

Diagnostic tools are critical to fighting – and ultimately, we hope, eradicating – these horrible diseases. A correct diagnosis means a person can get the care they actually need, and not something that might make them sicker, as well as potentially putting them at risk of infecting their children and everyone around them. There are still detractors who say that good physicians should be able to diagnose empirically, and that may be true in instances where there is access to an excellent physician and a first-rate microscopist, but that is just not the case in most places in the world. Being able to confirm one course of action or another, whether you should treat a patient with first- or second-line drugs, whether they should be referred to another hospital, or whether you can send them home with an antimalarial drug, remains vitally important.

Highlights

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) is a global health emergency: decades of medical progress are under threat as our ability to treat infectious diseases reliably with antibiotics is compromised. Bacteria will eventually develop resistance to all antibiotics. Some infections are already showing high levels of resistance, such as super-gonorrhea, and are particularly dangerous because they are easily transmitted and difficult to accurately diagnose. Resistance to antibiotics can develop rapidly when antibiotics are used to treat the wrong infection or non-bacterial infections, which makes diagnosing the specific cause of the infection so critical.

Diagnostics enable the optimal use of existing drugs and the protection of new treatments. A simple diagnostic test flagging the presence or absence of a bacterial infection can dramatically cut antibiotic overuse. Rapid tests can reduce the time to pathogen identification and facilitate faster, optimized antimicrobial treatment. Diagnostics also allow for active surveillance of drug resistance, data that can be used to effectively target health interventions and ultimately save costs.

Our AMR programme officially launched this year, housed within a new Emerging Threats unit. We are working with our partners and donors to tackle AMR holistically by focusing on urgent unmet needs across the spectrum of R&D and access:

- *Developing new tests specifically designed to address AMR, such as stewardship diagnostics that will help to safeguard new medicines*
- *Addressing barriers to diagnostic access that must be overcome to enable the use and impact of both existing and new tests*
- *Building diagnostic connectivity solutions that can facilitate and strengthen AMR surveillance*



AMR DX USE ACCELERATOR LAUNCHED

This flagship initiative was launched during the Call to Action on AMR meeting that took place in November 2019 in Ghana, of which FIND was an official partner. The AMR Diagnostic (Dx) Use Accelerator is a demonstration study platform designed to stimulate research and speed up data generation from in-country projects. A package of interventions will be evaluated and provide evidence to inform policy change that can positively impact AMR and contribute to UHC. It will ultimately help to prepare for the introduction of new diagnostics and provide a safe environment for new antibiotics to enjoy a longer useful therapeutic lifespan. It complements R&D initiatives for both diagnostics and drugs from FIND, GARDP and CARB-X, by ensuring there is a robust downstream mechanism for driving uptake and implementation.





FIND AMR STRATEGY UNVEILED ALONGSIDE FOUR NEW AMR COLLABORATIONS

AMR + Africa + Diagnostics, held in January 2018 in Cape Town, South Africa, and hosted by the South African Medical Research Council (SAMRC) and FIND, was the first international conference to be held in Khayelitsha, a community profoundly affected by HIV and TB, both of which have particular significance to AMR. Speakers from across Africa, including senior representatives from the South African Department of Health, Africa Centers for Disease Control, Right to Care, Médecins Sans Frontières (MSF), top clinicians and academics, patients and community representatives, and industry, discussed critical diagnostic needs and solutions that will help prevent and better treat drug-resistant infection to a wide range of diseases. Over 100 people attended the conference, which marked the launch of our AMR strategy.

The conference also showcased four new AMR collaboration agreements between FIND and BD (Becton, Dickinson and Company), Fondation Botnar, GARDP, and SAMRC, to address AMR and other diagnostic challenges in resource-poor settings.



PARTNERSHIP ANNOUNCED TO HELP SAFEGUARD NEW DRUGS AND COMBAT SUPER-GONORRHOEA

Gonorrhoea is one of the most common sexually transmitted infections in the world. *N. gonorrhoeae*, the bacterium that causes the disease, is evolving into a superbug that has already defeated penicillin, spectinomycin, tetracycline, ceftriaxone and azithromycin. It may soon become untreatable. As is the case for AMR in general, the burden of this public health threat is currently falling most heavily on LMICs. New drugs to fight so-called “super-gonorrhoea” are needed urgently – but we already know that sooner or later the bacteria will develop resistance to them. Companion diagnostics, designed to protect new antibiotics for as long as possible, are therefore as essential as the drugs themselves.

To develop diagnostics to guide correct use of zoliflodacin, we announced a new collaboration with the WHO Department of Reproductive Health and Research (RHR) and GARDP, in November 2018.





Highlights

HEPATITIS C & HIV

With over 70 million people infected, hepatitis C is one of the world's most common infectious diseases, but 4 out of 5 people infected don't know it – only 7% have received treatment worldwide. Hundreds of thousands of people die as a result from the disease every year, and numbers are on the rise. It is usually contracted through unsafe healthcare or injection drug use, and the vast majority of people with hepatitis C virus (HCV) live in LMICs.

We are working with our partners and donors on diagnostic solutions that can slow disease transmission, and reduce the morbidity, mortality and socio-economic impact of viral hepatitis at individual, community and population levels. Our activities are focused on three key areas, under the umbrella of the Unitaied-funded HEAD-Start (Hepatitis C Elimination through Access to Diagnostics) programme:

- *Supporting the development of affordable, fit-for-purpose diagnostics that can be used at the point of care and the community level*
- *Facilitating access to diagnosis and enabling the prevention of infection by interventions including cost-saving, effective integration of HCV care into HIV diagnostics and public health programmes*
- *Demonstrating the need and benefit of interventions for HCV by championing HCV prioritization in national agendas, and driving icy change and simplification of the HCV testing algorithm.*

MAJOR STEP FORWARD TO DECENTRALIZE HCV CARE IN GEORGIA

As part of our efforts to prepare the market for the introduction, use and placement of new technologies for HCV screening, confirmation and test-of-cure, we are implementing studies to generate data that can inform national HCV policy. In Georgia, over 60% of study enrolment was completed in 2018, and across 8 harm reduction sites over 1,200 people received confirmatory RNA tests. As a result, linkage to care (from screening to confirmatory test) increased from <50% to >99%, which has already spurred the government to decentralize HCV treatment to harm reduction sites.

NATIONAL HEPATITIS EFFORTS AMPLIFIED IN INDIA

Our HCV work in India coincides with a time of increased attention and action on hepatitis by the Indian government. On World Hepatitis Day 2018, The Ministry of Health and Family Welfare (MoHFW) and the Government of India launched the National Viral Hepatitis Control Program (NVCHP). On the same day, they also released the Operational Guidelines for the National Viral Hepatitis Control Program, National Laboratory Guidelines for Viral Hepatitis Testing, and National Guidelines for Diagnosis and Management of Viral Hepatitis. Our work has supported the national effort on HCV diagnostics by organizing a national “train the trainers” workshop with the MoHFW, which educated more than 70 trainers on HCV laboratory processes. In the Punjab region, the introduction of HCV care – via decentralized screening and confirmatory testing – into 13 existing antiretroviral treatment (ART) centres enabled screening of nearly 4,000 people living with HIV.



“TEST AND TREAT” ADVANCES IN MALAYSIA

In July, we announced that FIND and DNDi are teaming up to support the Malaysian government in their efforts to enhance the country’s public health approach to hepatitis C. Decentralized HCV screening using pre-qualified rapid diagnostic tests have been initiated to expand the reach of screening initiatives. A part of this initiative commenced in December: those who screen positive and are subsequently confirmed to have HCV are linked to direct-acting antiviral (DAA) treatment as part of a DNDi clinical trial, or in government hospitals. This work is being conducted in collaboration with the Malaysian Ministry of Health and Clinical Research Malaysia, and evidence from these coordinated interventions will be used to support policy change and scale-up of HCV diagnosis and treatment in the country and beyond.



ADVOCACY AT AIDS2018 FOR INTEGRATION OF HCV/HIV DIAGNOSTIC SERVICES

As part of our HCV advocacy efforts, we hosted a symposium at the 22nd International AIDS Conference in the Netherlands in July 2018, a conference that brought together more than 15,000 researchers, activists and policy makers from over 160 countries. Our symposium was entitled *Tackling Co-Infection with Collaboration: Can Integration of Diagnostic Services and Technologies Help Maintain Critical Momentum in Infectious Disease Control?* and was chaired by Dr Eric Goosby, the UN Special Envoy on Tuberculosis. The symposium aimed to raise the profile of integrated diagnostic services and the associated benefits to both patients and healthcare systems, in particular calling for integration of screening for HCV into HIV testing pathways.



CE MARKING FOR XPERT HCV VL FINGERSTICK TEST

Following a FIND-led validation study that was implemented in Georgia, Cameroon, Malaysia, Greece, Denmark and the USA, including over 1,400 patients, the Xpert HCV Viral Load Fingerstick test was CE marked by Cepheid in September 2018. The test can be performed on a drop of blood from a finger prick (capillary blood), and is sensitive enough for both active case-finding and use as a potential test-of-cure at the point of care. Results are available within 1 hour, enabling HCV diagnosis and treatment initiation to take place during the same clinic visit.





Highlights

MALARIA & FEVER

Management of fever (febrile illness) is a huge medical challenge. In Africa alone, over 600 million childhood fevers occur every year. Many febrile illnesses, especially in children, present with highly non-specific and overlapping signs and symptoms that are difficult to distinguish clinically. This is largely because the tools available to health professionals for diagnosing and managing childhood illnesses are limited in resource-poor settings.

In some countries – particularly in Africa – the cause of the fever is very often malaria. Malaria is ambitiously targeted for global elimination by 2030, but WHO has flagged that we are currently “off course” to meet this goal. The latest World Malaria Report estimated that there were 219 million cases of malaria in 2017, and the 10 highest burden African countries actually saw an estimated 3.5 million more malaria cases in 2017 compared with the previous year.

By combining our malaria and fever programmes, we are able to take an approach that starts with the patient, irrespective whether they may or may not have malaria. As well as supporting malaria elimination efforts, we are working with our partners and donors on diagnostic solutions that can inform optimal treatment solutions for all patients presenting with fever. Our work is therefore focused in three areas:

- *R&D for improved malaria diagnostics that can detect the disease in hard-to-diagnose populations, differentiate between parasite strains to inform treatment decisions and facilitate the introduction of targeted treatments, and support elimination strategies*
- *R&D for fever diagnostics that can identify the cause of fever when it is not malaria, based on likely pathogens in specific geographic areas, and help to guide appropriate treatment, promoting patient care and antimicrobial stewardship*
- *Addressing barriers to access and appropriate use of quality diagnostics that must be overcome to enable the use and impact of both existing and new tests, including the deployment of technological solutions to support implementation.*



COMMERCIAL LAUNCH OF RECOMBINANT PANELS FOR MALARIA DIAGNOSTIC TESTS

Recombinant panels for malaria tests, specifically *P. falciparum* and *P. vivax* lactate dehydrogenase (pLDH), were launched commercially in 2018. We developed the panels in partnership with Microcoat Biotechnologie GmbH. They complement existing quality control measures that are based on whole parasite samples and are intended to improve the detection of *P. falciparum* and *P. vivax* infections by current tools. They have been shown to react with most of the malaria rapid diagnostic tests on the market.



TRACKING DOWN MALARIA INFECTIONS IN PREGNANT WOMEN

We supported the development of a rapid test to detect *P. falciparum* parasites that is 10 times more sensitive than current rapid tests when tested in the laboratory. This is one of a range of improved rapid tests that could be particularly useful for pregnant women and other difficult-to-diagnose populations. Low parasite densities coupled with their tendency to hide out in the placenta means that infections during pregnancy are typically missed by light microscopy or conventional rapid tests.

In 2018, the first patient was enrolled in a prospective clinical study we are conducting in Papua New Guinea – the first time the performance of this next-generation rapid test will be evaluated in pregnancy.

ELECTRONIC CLINICAL DECISION-SUPPORT TOOLS FOR IMPROVED PATIENT OUTCOMES

Electronic clinical decision-support algorithms (eCDAs) are important tools with the potential to improve patient outcomes in the context of UHC. In November 2018, FIND and WHO convened a workshop to define the role of eCDAs in translating diagnostic results into therapeutic decisions.

Discussions from the meeting provided important guidance for an eHealth toolbox, which brings together eCDAs, point-of-care diagnostics, and implementation guidelines.

TWO NEW TESTS COMPLETED DEVELOPMENT

The STANDARD™ Q Malaria/CRP Duo Test (SD Biosensor), designed to simultaneously detect malaria infection and C-reactive protein (CRP) from a fingerprick blood sample, received its CE marking in 2018. CRP is a biomarker routinely used to identify bacterial versus non-bacterial infections; integration of these tests at the point of care enables clinicians to identify malaria while simultaneously indicating whether or not an antibiotic may be needed to treat a bacterial infection.

A multiplex lateral flow immunoassay (DPP® Fever Panel II Assay, Chembio) also completed late stages of development. This test detects serum IgM and specific antigens of common treatable causes of fever in Asia – a big move towards a “one stop shop” diagnostic that can identify multiple diseases such as malaria, dengue, chikungunya and typhus. Retrospective studies have started in Thailand and Australia to assess its performance, and finalize cutoffs are underway.

LARGEST-EVER STUDY TO EVALUATE FEVER BIOMARKERS UNDERWAY

Biomarkers that can reliably predict the cause of fever remain elusive. To address this vital gap, we have initiated the largest-ever, multicentre study to evaluate priority biomarkers. The study will be conducted in Brazil, Malawi and Gabon, with partners including FIOCRUZ, the London School of Hygiene and Tropical Medicine (LSHTM) and CERMEL. Enrolment of 1,000 patients is already complete in Malawi. More than 23,000 clinical samples from those patients have been stored in our biorepository (hosted by ZeptoMetrix), including whole blood, plasma, serum, PAXgene and urine.



Highlights

NEGLECTED TROPICAL DISEASES

As a group, neglected tropical diseases (NTDs) affect more than 1 billion people – and cost economies billions of dollars – every year. These diseases have suffered a historical lack of attention, largely because they thrive in conditions of poverty. Beyond their neglect, NTDs have little in common, being caused by a variety of pathogens, ranging from viruses to bacteria, fungi, protozoa, and helminths.

Diagnostics are critical for control and elimination of NTDs. They are also important for surveillance, with large-scale screening initiatives needed to track down the last cases so that they can be treated and do not become a source of infection for others. Diagnostics can confirm or rule out disease following a positive screening test. They are also a crucial complement to treatment strategies, monitoring treatment response in individuals as well as the success of public health initiatives such as mass drug administration.

Our FIND NTD portfolio focuses on those with significant unmet diagnostic needs, particularly human African trypanosomiasis (HAT; also known as sleeping sickness), leishmaniasis and Buruli ulcer. In 2018, we started working in schistosomiasis, ahead of a formal programme launch planned for 2019.

Together with our partners and donors, we are working on diagnostic solutions that can address the lack of readily available, easy-to-use, reliable and low-cost diagnostic tools to identify infections, detect disease re-emergence, monitor the impact of mass drug administration and guide delivery of appropriate control measures.

Our work supports the targets defined in the WHO Roadmap on NTDs and the London Declaration on NTDs – as well as SDG3 – in two specific areas.

- *Interrupt transmission of HAT, Buruli ulcer and visceral leishmaniasis (Indian subcontinent) through early diagnosis*
- *Drive elimination of schistosomiasis through improved diagnostics.*



TACKLING VISCERAL LEISHMANIASIS IN KENYA

We are working with the Kenyan government, DNDi and WHO to generate the evidence to inform an access strategy for the control and elimination of visceral leishmaniasis, in line with WHO priorities for eastern Africa. In 2018, over 2,500 people suspected to have the disease were screened, enabling the identification of over 300 cases in two counties. In 2018, the programme was expanded to two additional counties.



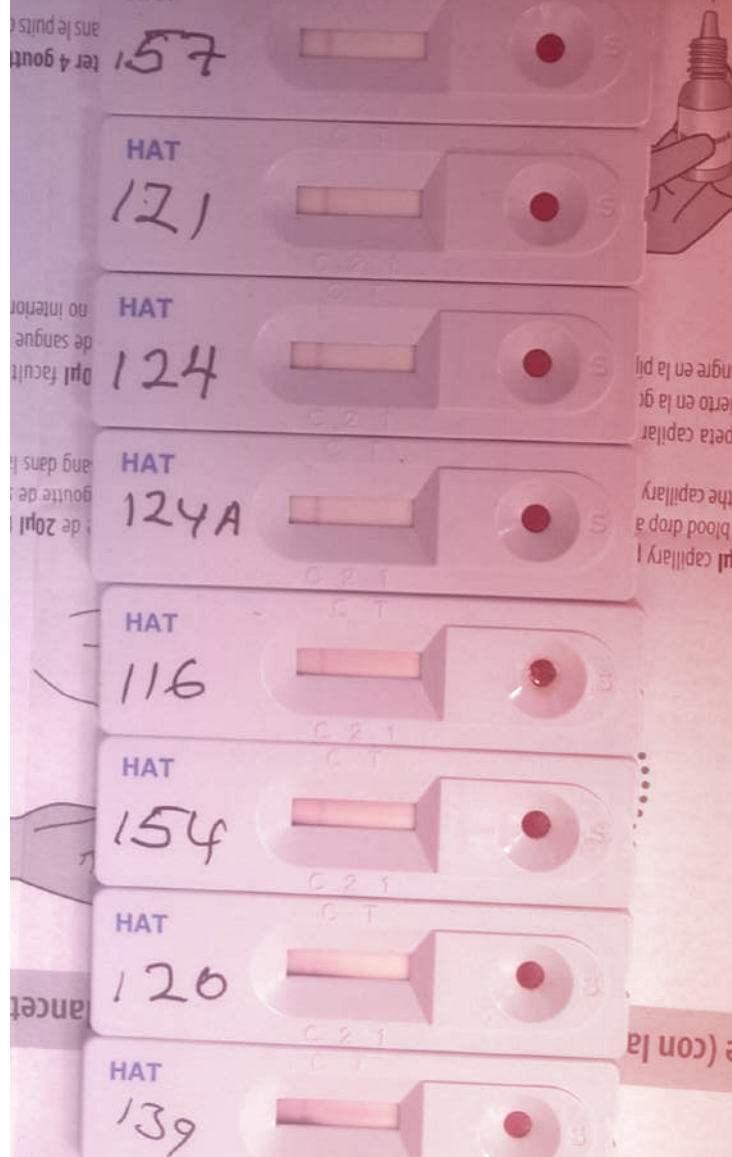
OVERCOMING TRANSBOUNDARY CHALLENGES TO DEFEAT HAT IN BAS CONGO

In remote and hard-to-reach places, people are often unable to get a reliable HAT diagnosis; one such area is the transboundary region of Bas Congo in the

Democratic Republic of the Congo, Republic of Congo and Angola, where we have been supporting HAT elimination efforts. Activities have included capacity building through health facility upgrades and training, and the introduction of novel screening and diagnostic tools such as a rapid diagnostic test that we co-developed. All facilities that perform rapid diagnostic testing also receive ongoing on-the-job training on the diagnostic process, targeting laboratory technicians and clinicians,

and a diagnostic algorithm is being implemented to ensure that no infected patient goes undetected.

As a result of these efforts, between June 2016 and December 2018, over 10,000 people in the Bas Congo region were screened for HAT using the rapid test. In Angola, over 250 public and primary health facilities have been supported and at least 600 health workers trained. Since the project started in 2014, detection of HAT cases in Angola has substantially improved, with 19 cases reported in 2016, rising to 18 in 2017, and 79 in 2018. The number of cases is expected to be fewer this year, as elimination draws closer. The project was designed to be both sustainable and replicable, as demonstrated by the fact that HAT rapid tests are now being used for case finding and surveillance in at least 16 sub-Saharan African countries. Several African countries have already adopted an approach to HAT similar to that used in Bas Congo, and Uganda is now on the brink of achieving elimination.



PREPARING THE GROUND FOR A NEW SCHISTOSOMIASIS PROGRAMME

Work started this year to prepare for a new programme that will support schistosomiasis control and elimination. Activities will focus on the development of sensitive rapid diagnostic tests for schistosomiasis that can support national control and elimination programmes in countries where the disease is regularly found. As well as helping to find and link individual patients to care, rapid tests for schistosomiasis are needed for essential surveillance and disease tracking, so that mass drug administration programmes can be appropriately targeted and their impact measured.

The FIND schistosomiasis programme formally launches in 2019.



Highlights

PANDEMIC PREPAREDNESS

Global health security is an ever-present concern. Pandemics caused by emerging and re-emerging infectious diseases put lives, health and prosperity at risk. While outbreaks are often unpredictable, this is not always the case; Lassa fever, for example, appears every year in Nigeria, but few regulatory-approved diagnostics – and no vaccines or medicines – are available.

Diagnostics are fundamental to the identification, containment and eventual resolution of disease outbreaks. Poor diagnostic capacity compromises surveillance activities, outbreak detection and response, both at a national level and in community healthcare settings. In the case of the 2013–16 Ebola epidemic in West Africa, it took 3 months to figure out that the infection was indeed Ebola. That delay resulted in the loss of thousands of lives and billions of dollars in the cost of response.

Our Pandemic Preparedness programme officially launched this year, housed within a new Emerging Threats unit. Together with our partners and donors, we are working to strengthen diagnostic preparedness for the WHO R&D Blueprint pathogens, as well as yellow fever, dengue and bacterial meningitis. Activities are organized across three areas:

- *Identifying technical solutions that will close R&D gaps, including diagnostic platforms that can support tests for multiple pathogens, with enhanced connectivity to enable swift identification of an outbreak*
- *Improving outbreak response speed by ensuring readiness to conduct robust clinical trials at short notice, supported by regulatory pathways that can expedite approval of successful diagnostic candidates*
- *Supporting market sustainability by exploring innovative new financing solutions, procurement and supply mechanisms, for ongoing affordability and availability of critical diagnostics.*



DIAGNOSTIC INPUT FOR WHO DISEASE COMMODITIES PACKAGES

The WHO disease commodities packages are a series of disease-specific datasheets that list the critical commodities for each disease of interest along with their technical specifications, for use as tools for countries to guide procurement decisions and to serve as full coverage packages for outbreak responses. As part of this initiative, FIND was asked to contribute summaries of the diagnostic situations for the 36 pathogens of interest, including those with high outbreak potential such as Ebola, Lassa fever, Nipah, Zika, yellow fever and pandemic influenza.

These comprehensive, centralized lists of diagnostics for pathogens of outbreak potential inform countries of available resources and materials to facilitate rapid procurement in the event of an outbreak or emergency. FIND was invited by WHO to provide the diagnostic information for this project, as leading knowledge experts in diagnostics for infectious diseases. The complete disease commodity packages are now available on the WHO website.



WHO R&D BLUEPRINT DIAGNOSTIC LANDSCAPES PUBLISHED

To support the WHO R&D Blueprint list of priority diseases at risk for outbreak, FIND developed a number of landscape analyses and participated in the WHO roadmap meetings. The landscape analyses for Nipah, Lassa fever, Crimean–Congo haemorrhagic fever, filoviruses and MERS-coronavirus, as well as a use-case summary of diagnostic applications for Lassa fever in low-resource settings, were later published in *BMJ Global Health* (January 2019), prefaced by an introductory article on the importance of diagnostics in epidemic and pandemic preparedness. Since publication, these articles have been the subject of over 200 tweets and have been downloaded more than 6,500 times.

The landscaping work led to the rapid development of two target product profiles for Lassa diagnostics, which are approaching finalization and will be published in the near future.

As a result of this work, FIND was asked to assist with prioritisation of Lassa diagnostic needs during the 2017/2018 outbreak in Nigeria, which led to our selection as the preferred partner to deliver a Lassa fever response programme in Nigeria, funded by the German government and CEPI, designed to address diagnostic gaps and build diagnostic capacity to strengthen Nigeria's ability to respond to future Lassa fever outbreaks.

"Reliable, sustainable and affordable diagnostics for Lassa fever are essential for patient management and future clinical trials. Our collaboration with FIND supports the rapid development and evaluation of current and new diagnostics, and will enable a model that can address diagnostic gaps across the WHO Blueprint pathogens."

Professor Dr Stephan Günther, Bernhard-Nocht-Institute for Tropical Medicine, Germany

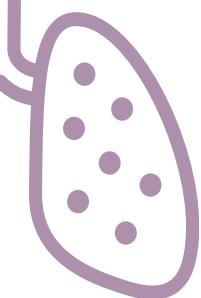
A NEW BUSINESS MODEL FOR DIAGNOSTIC FLEXIBILITY

For a great number of emerging diseases, tests do not exist. Strengthening surveillance, and speeding up development and roll out of new tests in response to potential outbreaks is essential. However, diseases with small markets – including pathogens with outbreak potential – are challenging for commercial

test developers. It can also be difficult for countries to implement many different platforms to address individual diseases.

To tackle some of these challenges, we are evaluating an innovative new partnership mechanism that could improve testing capacity and improve market sustainability, both of which are urgently needed to support outbreak preparedness in LMICs. Through a semi-open business model, we have brought together two commercial entities (Altona Diagnostics and Cepheid) to rapidly bring new assays for Lassa fever, Zika, dengue fever and chikungunya to an existing platform. The aim is to enable development costs to be shared between different companies, and for new assays to be developed quickly in response to new or emerging pathogens – significantly shortening the gap between outbreak identification and testing.





Highlights

TUBERCULOSIS

Tuberculosis (TB) kills more people than any other single infectious disease, including HIV. Latest WHO data estimate that 10 million people developed the disease in 2017. LMICs overwhelmingly bear the highest burden, and the impact of the disease on individuals and communities is devastating. Every year, millions of TB infections go unidentified, preventing patients from accessing treatment, and allowing the disease to spread. Drug resistance is a growing threat.

Diagnostics are needed to detect exposure, diagnose disease and drug resistance, and monitor improvement under treatment in both primary healthcare and laboratory settings. Ensuring that the right tools are accessible where they are needed is not straightforward, and development of any new diagnostic test has to take into account the context in which it would be used.

We are working with our partners and donors to make easy-to-use, robust, reliable and highly accurate tests a reality in routine clinical settings, particularly at the lower levels of care. Our R&D efforts are focused on areas of critical unmet need:

- *A user-friendly, low-cost, non-sputum-based rapid test for diagnosing active TB that can be used for active case-finding and in primary healthcare facilities*
- *Rapid drug-resistance tests that enable treatment regimens to be tailored to individuals and help to safeguard medicines against AMR.*

In parallel, we are developing strategies to increase and speed up access to both new and existing tools. We are also exploring digital technologies to enhance diagnostic connectivity and data utilization for optimal health impact.

MILESTONE FOR NEXT-GENERATION URINE TEST TO IDENTIFY TB IN HIV+ PATIENTS

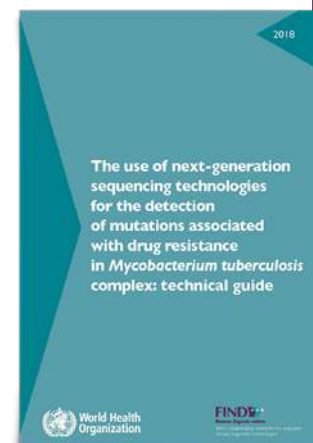
Most commonly, TB diagnosis is made based on sputum analysis. However, HIV infection can affect TB symptoms, sometimes resulting in the absence of a productive cough: 20–60% of HIV-positive patients presenting for TB diagnosis are unable to produce a sputum sample. A urine sample, on the other hand, is usually easily accessible. The SILVAMP TB LAM test is a novel, urine-based, point-of-care test for TB diagnosis in people living with HIV in low-resource settings. Its development builds on a decade of research conducted by FIND with partners, and opens a pathway to point-of-care assays that enable highly sensitive antigen detection.

Fujifilm obtained CE marking for the test in 2018. Prospective clinical trials are now ongoing in order to generate the evidence package for WHO policy development.



PUBLICATION OF WHO/FIND TECHNICAL GUIDE ON NGS FOR TB DIAGNOSIS

In partnership with WHO, FIND has been active in establishing global standards for using next-generation sequencing (NGS) for TB diagnosis. NGS has great potential as a method for rapidly diagnosing drug-resistant TB in diverse clinical reference laboratory settings worldwide, however, there are considerable technical training and skill requirements for utilization of the technology, and for the management and clinical interpretation of the data output. To address these needs, FIND and WHO authored the Technical Guide on next-generation sequencing technologies for the detection of mutations associated with drug resistance in *Mycobacterium tuberculosis* complex, available on the WHO website.



DIAGNOSING TB IN ADOLESCENTS AND CHILDREN

FIND contributed to a WHO-led compilation of examples of best practices in scaling up response to childhood TB. The FIND work featured in the report details our project to accelerate access to quality TB care for children with suspected TB in India, through improved diagnostic strategies. Through a focus on public-private activities targeting paediatric populations in key cities (which helped build paediatric diagnostic capacity in both public and

private sectors), it was the first time that a large proportion of extra-pulmonary specimens were routinely tested using Xpert MTB/RIF.

The project was carried out in close coordination with the India National TB Program and their state and district teams. Over 100,000 specimens – around half of which were non-sputum – from over 90,000 patients were tested. Of the total diagnosed TB cases, around 89% have been confirmed to be accessing treatment. Our work in paediatric TB diagnosis in India was also awarded the prestigious Public Health Initiative prize at the India Health & Wellness Summit and Awards in December 2018.

HIGH-LEVEL ADVOCACY DURING THE UN GENERAL ASSEMBLY

We participated in two side-events at the United Nations General Assembly High-Level Meeting on TB in September 2018. The first was co-hosted by FIND: *Leave No-one Behind: Scaling up Integrated People-Centred TB/HIV Care Towards Universal Health Coverage*. It brought together ministers of health, representatives of the United Nations, TB/HIV programme implementers and technical experts to discuss current challenges, gaps and opportunities in serving people and communities affected by TB/HIV. Catharina Boehme, FIND CEO, was on the expert panel, alongside a number of highly respected leaders in the field, including Dr Tedros Adhanom Ghebreyesus, Director-General of WHO.

The second event, *Accelerating Global TB Response Through Technical Innovation*, explored effective ways to apply ground-breaking innovations to the frontlines of the battle against TB. FIND Head of TB, Claudia Denking, spoke at the event on behalf of all the TB PDPs during the subsequent multi-stakeholder panel, broadcast on UN Web TV.

IMPROVING TB DATA UTILIZATION IN MYANMAR

Myanmar is designated by WHO as a high-burden TB country, with three TB-related deaths every hour. The existing network of GeneXpert machines throughout the country has the potential to provide high-quality data for disease monitoring to inform national-level decisions, but incomplete datasets and difficulties interpreting the platform's dashboard meant that the data collected were not optimally used. In 2018, we implemented a project to enhance data utilization in the country, providing training and bench aids for sites with issues such as high offline time, failure to complete data forms, and machine and reagent health issues. Overall, the project increased the use of platform and data by 88% countrywide and by over 180% in some regions.

Data collected also made it possible to determine individual patient pathways through the care system. Of approximately 1,400 patients tested, 45% were shown to have a unique pathway, highlighting an urgent need for streamlining of the treatment pathway. Additionally, the data allowed re-initiation of contact with 28 of 43 patients who had been previously lost to follow up, as the point in the pathway at which they had been lost could be seen.



FIND GOVERNANCE

Board of Directors

Mark Kessel (Chairman)
Daniel Camus
George F. Gao
David L. Heymann
Andrew Jack
Shobana Kamineni
Ilona Kickbusch
Carlos Morel
Marcel Tanner
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 1-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
Director of Business Development & Resource Mobilization: Jon Bastow
Director of Emerging Threats: Cassandra Kelly-Cirino
Head of Hepatitis C & HIV: Francesco Marinucci
Head of Malaria & Fever: Sabine Dittrich
Head of Neglected Tropical Diseases: Joseph Ndung'u
Head of Tuberculosis: Claudia Denking
Head of Clinical & Regulatory Affairs: Jennifer Kealy
Head of Communications: Sarah-Jane Loveday
Head of Data Services & Biobanking: Stefano Ongarello
Head of FIND South Africa: Heidi Albert
Head of FIND India: Sanjay Sarin
Regional Technical Director, FIND India: Sarabjit Chadha
FIND Representative in Viet Nam: Yen Nguyen

We thank all our donors for their commitment and support in 2018

Anesvad

Australian Government

Bill & Melinda Gates Foundation

Canton of Geneva, Switzerland

US Centers for Disease Control and Prevention (CDC) /African Society for
Laboratory Medicine (ASLM)

Coalition for Epidemic Preparedness Innovations (CEPI)

European and Developing Countries Clinical Trials Partnership (EDCTP)

Fondation Botnar

Fundacion PROBITAS

Global Health Innovative Technology (GHIT) Fund

Government of the Netherlands

Government of Germany (Federal Ministry for Education and Research, BMBF)

Horizon 2020

KfW

South African Medical Research Council (SAMRC)

Swiss Agency for Development and Cooperation (SDC)

TB REACH (Stop TB Partnership)

The ELMA Foundation

The Fleming Fund

The Global Fund to Fight AIDS, Tuberculosis and Malaria

Unitaid

United States Agency for International Development (USAID) / KNCV
Tuberculosis Foundation

UK aid from the British people

World Health Organization



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 2018**

KPMG SA
Geneva, 8 May 2019
Ref. PHP/CRI/lte



KPMG SA
Audit Western Switzerland
111 Rue de Lyon
CH-1203 Geneva

PO Box 347
CH-1211 Geneva 13

Telephone +41 58 249 25 15
Fax +41 58 249 25 13
www.kpmg.ch

Report of the Statutory Auditor to the Board of the Foundation of the
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 the Foundation for Innovative New Diagnostics (FIND), which comprise the statement of revenue and expenditure, statement of changes in capital, balance sheet, cash flow statement, and notes for the year ended 31 December 2018.

Board of the Foundation's Responsibility

The Board of the Foundation is responsible for the preparation of the consolidated financial statements in accordance with Swiss GAAP RPC and the requirements of Swiss law. 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 consolidated 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 2018 give a true and fair view of the financial position, the results of operations and the cash flows in accordance with Swiss GAAP RPC and comply with Swiss law.



*Foundation for Innovative New Diagnostics (FIND), Geneva
Report of the Statutory Auditor
on the Consolidated Financial Statements
to the Board of the Foundation*

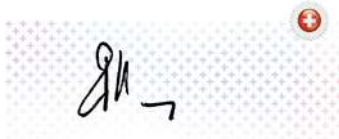
Report on Other Legal Requirements

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*



Cédric Rigoli
Licensed Audit Expert

Geneva, 8 May 2019

Enclosure:

Statement of revenue and expenditure, statement of changes in capital, balance sheet, cash flow statement and notes

STATEMENT OF REVENUE AND EXPENDITURE FOR THE YEAR ENDED 31 DECEMBER 2018
(all amounts in US dollars)

	2018	2017
REVENUE		
Grant revenue	59,513,727	48,242,841
Other operating income	447,040	315,314
Total revenue	59,960,767	48,558,155
of which is restricted	58,321,515	47,049,808
EXPENDITURE		
Programme services		
Tuberculosis	9,276,383	9,987,814
AMR and Outbreaks	3,748,848	826,379
Fever and Malaria	5,506,213	9,719,358
Neglected tropical diseases	5,703,620	3,753,038
HCV and HIV	8,250,318	3,772,251
Access TB India	20,428,646	12,165,896
Access in other countries and cross cutting	2,345,430	3,949,311
Total programme services	55,259,458	44,174,047
Supporting Services		
Information & communication	186,535	174,063
Governing & advisory bodies	89,622	83,359
General administration	3,908,694	3,527,621
Depreciation & amortization	4,129	2,953
Total supporting services	4,188,980	3,787,996
Total operating expenditure	59,448,438	47,962,043
Operating result	512,329	596,112
Financial income	340,946	96,253
Financial expenses	116,039	101,004
Financial result	224,907	(4,751)
Result before changes in restricted funds	737,236	591,361
Change in restricted funds	(157,736)	276,226
Annual result before allocation to organization capital	579,500	867,587
Allocations/appropriation		
Free capital	(579,500)	(867,587)

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

STATEMENT OF CHANGES IN CAPITAL AS AT 31 DECEMBER 2018 AND 31 DECEMBER 2017

(all amounts in US dollars)

	Balance 1.1.2018	Allocation	Use	Total change	Balance 31.12.2018
Restricted funds	309,363	(58,321,515)	58,163,779	(157,736)	467,099
Organization capital					
Foundation capital	40,430	-	-	-	40,430
Unrestricted surplus	4,336,543	579,500	-	579,500	4,916,043
Total organization capital	4,376,973	579,500	-	579,500	4,956,473

	Balance 1.1.2017	Allocation	Use	Total change	Balance 31.12.2017
Restricted funds	585,590	(47,049,808)	47,326,034	276,226	309,364
Organization capital					
Foundation capital	40,430	-	-	-	40,430
Unrestricted surplus	3,468,956	867,587	-	867,587	4,336,543
Total organization capital	3,509,386	867,587	-	867,587	4,376,973

BALANCE SHEET AS AT 31 DECEMBER 2018

(all amounts in US dollars)

	Note	2018	2017
ASSETS			
Current assets			
Cash and cash equivalents	8	37,815,208	42,798,161
Accounts receivable		300,560	517,587
Prepayments and accrued income		2,767,698	2,467,716
Total current assets		40,883,466	45,783,464
Non-current assets			
Fixed assets		5,317	9,447
Rental guarantee deposit		235,563	227,074
Total non-current assets		240,880	236,521
Total assets		41,124,346	46,019,985
LIABILITIES AND CAPITAL			
Current liabilities			
Accounts payable and accrued expenses		7,419,530	9,991,292
Deferred revenue	9	28,281,244	31,342,356
Total current liabilities		35,700,774	41,333,648
Restricted funds		467,099	309,364
Organization capital			
Initial foundation capital	13	40,430	40,430
Free capital		4,916,043	4,336,543
Total Capital		4,956,473	4,376,973
Total liabilities, capital and reserves		41,124,346	46,019,985

CASH FLOW STATEMENT FOR THE YEAR ENDED 31 DECEMBER 2018

(all amounts in US dollars)

	2018	2017
Annual result before allocation to organization capital	579,500	867,587
Change in restricted funds	157,736	(276,226)
Add back non-cash charge - depreciation & amortization	4,129	2,953
	741,365	594,314
Cash flows - operating activities		
Increase (decrease) in deferred revenue	(3,061,111)	7,849,601
Increase (decrease) in accounts payable and accruals	(2,571,762)	4,593,528
(Increase) decrease in accounts receivable	217,026	449,587
(Increase) decrease in prepayments	(299,982)	(1,534,248)
Increase (decrease) in unrealized exchange gains on foreign currencies	-	(195,150)
Net cash provided by operating activities	(5,715,829)	11,163,318
Cash flows - investing activities		
(Increase) decrease in rental guarantee deposit	(8,489)	(11,666)
Acquisition of computers & printers	-	(12,400)
Net cash used in investing activities	(8,489)	(24,066)
Net increase (decrease) in cash and cash equivalents for year	(4,982,953)	11,733,566
Cash and cash equivalents at start of year	42,798,161	31,064,595
Cash and cash equivalents at end of year	37,815,208	42,798,161
Net increase (decrease) in cash and cash equivalents for year	(4,982,953)	11,733,566

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

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

(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 became 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.

2. Significant accounting policies

2.1 Basis of presentation

These consolidated financial statements have been prepared in accordance with the Accounting and Reporting Recommendations Swiss GAAP RPC and more specifically with Swiss GAAP RPC 21 for charitable non-profit organisations. These consolidated financial statements gives a true and fair view which reflect the economic facts and are thus free of deception and manipulation.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018 (all amounts in US dollars)

Consolidated financial statements are based on the individual financial statements established as at 31 December in accordance with single accounting principles for all entities within the group.

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 maturities of 3 months or less from the balance sheet date at the most.

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 2017, the rate of exchange used for the Swiss franc, the main foreign currency for 2018, was USD/CHF = 0.986 (2017 – 0.974).

2.5 Recognition of revenue

Grants requiring the return of unspent funds are recorded in accordance with the principle of matching related revenues and expenses in the same period. Unused funds from such grants at the end of the period are recorded in the balance sheet under deferred revenue and recognised as revenue in future periods.

Grants which do not require unspent funds to be returned are recognised in the statement of revenue and expenditure at the time when FIND takes control of the funds.

Service revenue is recognised when the service is rendered.

2.6 Classification of restricted funds

Restricted funds are comprised of funds that are subject to restrictions in purpose as determined by third parties. The portion of restricted funds that are not used during the year or deferred, is recognised in the balance sheet through allocation to restricted funds and as a reduction of the result for the year. Conversely, when such funds are used in subsequent years, they will be recognised in the statement of revenue and expenditure through the use of funds.

2.7 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.

2.8 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 2018

(all amounts in US dollars)

3. Grant revenue

The breakdown of grant revenue by area of activity is shown below:

	2018	2017
HQ activities	38,657,536	35,618,160
India access activities	20,518,762	12,261,444
South Africa activities	337,429	363,237
Total grant revenue	59,513,727	48,242,841

4. Donations received

During 2018, the following donations were received from donors (other currency amounts are converted to USD at exchange rates on date of receipt):

	2018	2017
Unitaid	9,651,846	1,252,279
Department for International Development (DFID), UK	9,335,553	11,349,401
The Global Fund to Fight AIDS, Tuberculosis and Malaria	7,341,443	22,409,348
The Bill and Melinda Gates Foundation	6,838,924	8,563,542
Federal Ministry of Education And Research (BMBF) through KfW, Germany	5,731,724	1,760,597
Department for Health and Social Care, UK	4,134,325	-
Australian Department of Foreign Affairs and Trade	2,825,925	2,480,160
Dutch Ministry of Foreign Affairs (DGIS), Netherlands	2,592,280	2,413,664
Global Health Innovative Technology Fund (GHIT), Japan	1,810,272	858,486
Swiss Agency for Development and Cooperation	1,773,372	1,557,236
Government of India, Ministry of Health & Family welfare, The Central TB Division	1,498,432	-
Médecins Sans Frontières	701,925	400,000
Fondation Botnar	502,008	406,504
Government of the United States	427,511	1,618,591
European and Developing Countries Clinical Trials Partnership (EDCTP) Association	346,146	-
African Society of Laboratory Medicine	281,255	-
South African Medical Research Council	273,783	-
Roche Molecular Systems, Inc	270,144	-
Hain Lifescience GmbH	194,331	-
The ELMA Foundation	175,000	-
Other	845,728	735,636
Total contributions received	57,551,927	55,805,444

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

(all amounts in US dollars)

Donor agreements in effect as at 31 December 2018 provide for a total of USD 110 million to be paid to FIND between January 2019 and June 2023.

In accordance with Swiss GAAP RPC 21, donations are recognised as revenue, when FIND has a control over the funds. As such, contributions received may differ from grant revenue.

5. 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:

	2018	2017
Tuberculosis	690,597	683,660
Fever and Malaria	3,846,367	1,885,236
Neglected tropical diseases	971,325	912,791
HCV and HIV	1,067,184	379,710
Total donations in-kind	6,575,473	3,861,397

The above amounts include 50% for infrastructure and supplies, 47% for personnel and consultants, 1% for partners and 2% for travel, (2017 – 34% for infrastructure and supplies 59% for personnel and consultants, 6% for partners and 1% for travel).

In-kind contributions are reported above based upon information provided by our partners and are valued at the price FIND would have to pay in an arm's length transaction.

NOTES TO THE FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

(all amounts in US dollars)

6. Expenditure by cost type

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

2018	HQ activities	India access activities	South Africa activities	Total
Project partners	16,002,845	282,021	-	16,284,866
Personnel	11,114,108	76,230	279,753	11,470,091
Consultants	5,596,170	2,224,190	652	7,821,012
Travel	1,609,022	323,998	40,198	1,973,218
Equipment	671,462	14,771,793	33	15,443,288
Supplies and other expenses	3,693,985	2,750,414	11,564	6,455,963
Total expenditure	38,687,592	20,428,646	332,200	59,448,438

2017	HQ activities	India access activities	South Africa activities	Total
Project partners	14,940,970	-	-	14,940,970
Personnel	9,287,134	23,510	298,646	9,609,290
Consultants	6,158,720	2,129,323	30,622	8,318,665
Travel	1,882,746	316,809	25,567	2,225,122
Equipment	397,064	5,445,713	1,174	5,843,951
Supplies and other expenses	2,751,488	4,250,541	22,016	7,024,045
Total expenditure	35,418,122	12,165,896	378,025	47,962,043

Note India activities includes supporting services incurred in India

Commitments at 31 December 2018 for future payments to partners under contracts signed up until 31 December 2018 total USD 13,621,458 (2017 – USD 9,496,841).

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

(all amounts in US dollars)

7. Remuneration

The total amount of remuneration paid to the members of the leadership team amounts to CHF 1,033,681. Remuneration is consistent with requirements, qualifications, responsibility and work performance

Members of the Foundation board do not have a paid relationship with the organisation as defined by labour law. Travel expenses incurred are reimbursed based upon receipts.

8. Cash and cash equivalents

Cash and cash equivalents as at 31 December were as follows:

	2018	2017
Petty cash	952	1,156
Bank current accounts	29,776,833	27,808,408
Short-term deposits	8,037,423	14,988,597
Total cash and cash equivalents	37,815,208	42,798,161

9. Deferred revenue

Deferred revenue represents assets to which the donor has attached a condition specifying the right to return of the transferred funds. As such, revenue on these grants is deferred until the condition is met and the right to the return of the funds is extinguished and will then be recognised in the income statement as grant revenue.

The following table shows the breakdown of these funds by program.

	2018	2017
Tuberculosis	8,086,958	5,616,819
AMR & Outbreaks	5,463,412	1,188,301
Fever and Malaria	3,343,455	3,799,822
Neglected tropical diseases	3,669,950	3,485,184
HIV and HCV	4,865,153	3,209,382
Access and other	2,852,316	14,042,848
Total deferred revenue	28,281,244	31,342,356

10. Pension fund liabilities

USD 249,830 was due to the pension fund as at 31 December 2018 (2017 – USD 131,814).

11. Rent commitments

At 31 December 2018, FIND had future rent commitments totalling USD 833,219 up to 31 May 2020 (2017 – USD 807,177 up to 31 May 2019). Of this amount, USD 611,314 is due within 12 months (2017 – USD 582,698).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

(all amounts in US dollars)

12. Operating lease commitments

At 31 December 2018, FIND had future rent commitments on operating leases totalling USD 35,616 up to 31 October 2020 (*2017 – USD 19,003 up to 30 September 2018*), USD 19,427 of which is due within 12 months (*2017 – USD 19,003*).

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.

14. Events subsequent to 31 December 2018

No events occurred subsequent to 31 December 2018 which could have a material impact on the understanding of these financial statements.



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