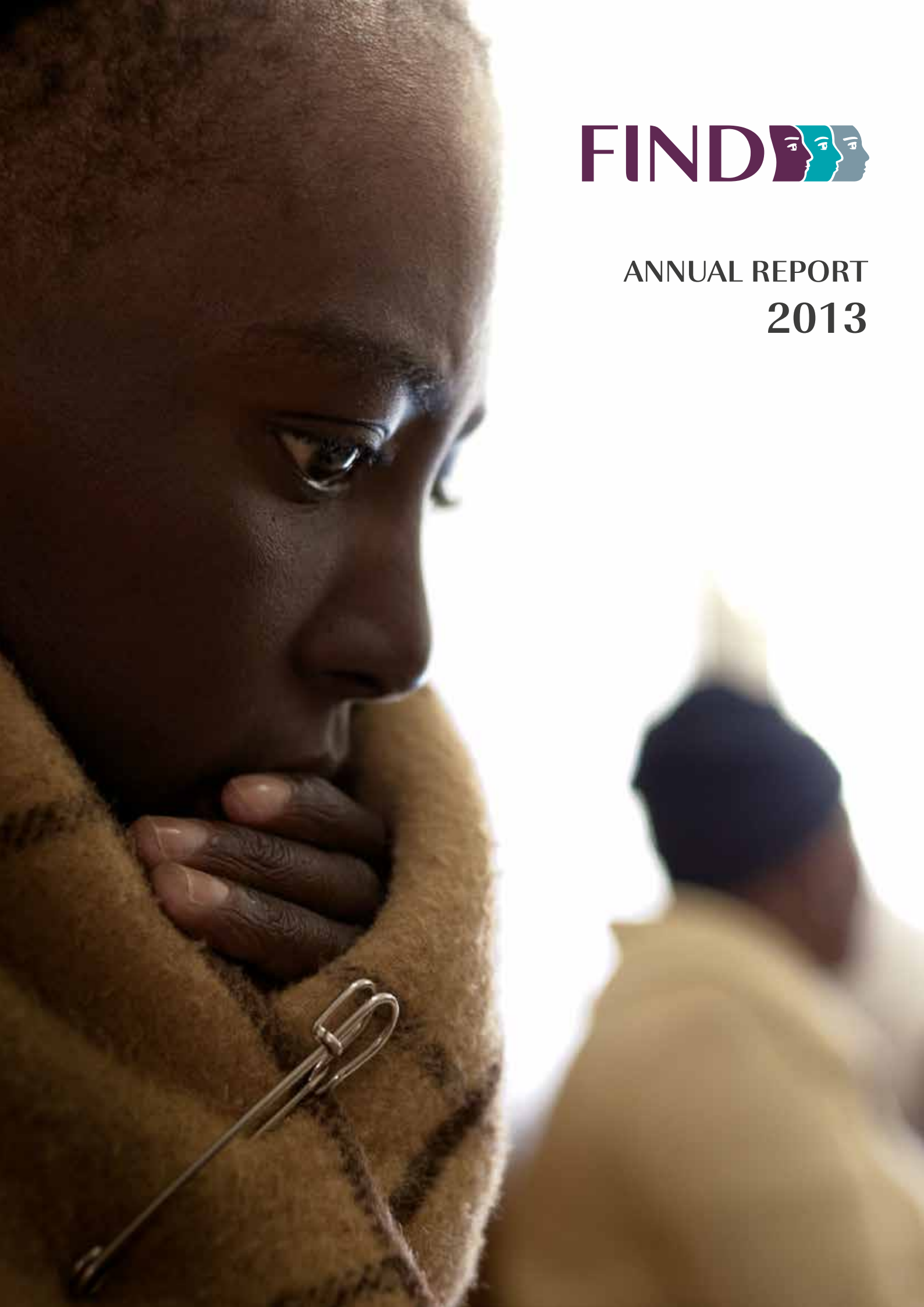




ANNUAL REPORT
2013

ABOUT FIND

FIND was founded in 2003 to bridge existing development gaps for essential diagnostics by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector, and the *in vitro* diagnostics industry. Today, FIND is a leading partner across the value chain of diagnostics development and delivery. We have programmes in Tuberculosis and Acute Febrile Respiratory Infections, Malaria and Acute Febrile Syndrome, Hepatitis C, and Neglected

Tropical Diseases. We also have mini-portfolios in areas affecting reproductive and child health: HIV; sexually transmitted infections; and infections and nutritional deficiencies in children under five years old. At FIND, we envision a world where diagnostics guide the path to health for all people. We aim to turn complex diagnostic challenges into simple solutions to transform lives and overcome diseases of poverty. To do this we focus on four strategic goals throughout all the disease areas in which we work:

■ Catalyse development:

Identify needed diagnostic solutions and remove barriers to their development.

■ Guide use & policy:

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

■ Accelerate access:

Support uptake and appropriate use of diagnostics to achieve health impact.

■ Shape the agenda:

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

FIND is a non-profit organization, recognized by the Swiss government as an “other International Organization”. Our headquarters are located in

Geneva, Switzerland, and we have offices in New Delhi (India), Cape Town (South Africa), and Kampala (Uganda).

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LEADERSHIP MESSAGE



Catharina Boehme,
Chief Executive Officer

Mark Kessel,
Chair of the Board

The year 2013 marked a decade since FIND first opened its doors as the nexus of public-private collaboration to bridge development gaps for essential diagnostics. There is much to celebrate.

In ten short years, FIND has become a pioneer in the development and delivery of 11 life-saving tests for tuberculosis, sleeping sickness and malaria that have made diagnosis more rapid, effective and affordable. FIND is recognized as a partner of choice within the field of global health care, collaborating with the international research community, the public and private sectors, national health ministries and health care providers to bring about more effective testing and build local diagnostics capacity.

Over the last year, we made tremendous progress in the development of new and innovative diagnostic

solutions and reaffirmed our role as a leader in overcoming poverty-related diseases.

Through our tuberculosis programme, we have come one step closer to providing a test for difficult to diagnose patients, including children, people living with HIV and those with extrapulmonary forms of tuberculosis. In July 2013, WHO endorsed the use of the Xpert MTB/RIF assay for diagnosis among these patients. Major progress has also been made for children suspected of having TB with the development of a stool test, which is being validated by FIND, as well as rapid drug susceptibility testing for second-line drugs.

Our partnerships are stronger than ever in the fight against tuberculosis. Through joint FIND/WHO/CDC laboratory-strengthening efforts in 2013, multi-drug

resistant tuberculosis testing capacity was scaled up significantly in many high-burden countries, with a specific emphasis on Myanmar, Viet Nam, India and Indonesia. Our UNITAID-funded Expand-TB programme has also been successful in diagnosing multi-drug resistant tuberculosis; for example in India alone, 92% of the multi-drug resistant cases that were detected and reported to the national tuberculosis programme for treatment were diagnosed through this collaborative global effort. Our team will continue to bring new tools through the pipeline to interrupt transmission and prevent the further spread of drug resistant tuberculosis.

In the fight against malaria, FIND has launched innovative solutions to respond to new challenges in screening for malaria elimination. Last year, we developed a new molecular test based on the Loop-mediated isothermal amplification technique with partners in the United Kingdom and Japan, which has been implemented for population screening in support of disease elimination efforts in five low-transmission countries. We also developed a blood transfer device that has been widely adopted by malaria rapid test manufacturers to overcome volume accuracy and blood safety issues when doing a test. In 2013, this innovative tool reached more than 100 million patients with fever and is also being implemented for other diseases, including HIV.

In 2013, FIND scaled up the fight against sleeping sickness, leishmaniasis and Chagas disease by improving existing diagnostic tools and conducting research to identify related biomarkers. With a partner in Republic of Korea, we launched a rapid test for human African trypanosomiasis that costs less than US \$0.60 per test and is now being used as a core tool in disease elimination efforts in early-adopter countries, including Uganda, Democratic Republic of Congo, and Republic of Guinea. Our work in this field shows the promising potential of our cross-platform disease diagnostic strategy.

FIND underwent several important organizational changes in 2013. Mark Kessel was appointed Chair of the Board in March, and the Board of Directors has continued to grow in expertise and size with the appointment of three new members who joined

in January 2014: Mr. Deepak Gupta from India, Dr. Carlos Morel from Brazil, and Dr. Michael Watson from France. In December 2013, our Scientific Advisory Committee (formerly known as the Scientific Advisory Board) held its first meeting as a team of 15 prominent experts from various scientific disciplines chaired by Marcel Tanner, Director of the Swiss Tropical and Public Health Institute.

Over the past year, we have examined the structure and work of FIND to better position ourselves within the diagnostics landscape and respond to future challenges. We are convinced that now more than ever, the world needs new diagnostic solutions, and FIND is committed to leading the development and delivery of them. Out of the 28 diseases that we have researched, 21 still have major unmet diagnostic needs. Moreover, proper diagnosis will reduce the growing threat of anti-microbial resistance and increase the impact of effective health care.

We began work on our new 2015-2020 strategy last year with the objectives of increasing our sustainability and providing a new direction for the future of FIND. We are pleased to have launched our strategy to guide us as we move forward to meet the world health challenges. We will develop innovative partnerships, coalitions, consortia and goal-driven collaborations to achieve our mission. FIND will take the next step in comprehensive diagnosis support for the needs of end-users by linking diagnostics to treatment and care and delivering “packaged solutions” rather than tests alone.

We are looking towards the future of diagnostics and believe that through FIND’s global partnerships, we will be able to dramatically improve the diagnosis of diseases of poverty and move closer to the elimination of these diseases that unequally burden developing countries. By the end of 2020, FIND aims to have another 15 essential and innovative diagnostic solutions in use to support improved health for all.

FIND’s work would not be possible without the generosity and confidence of our donors and collaborators. Thank you for partnering with us to save lives through the development of more effective and affordable diagnostic solutions!

CURRENT GOVERNANCE

Board of Directors



Mark Kessel (Chair)
Partner, Symphony Capital LLC



Gerald Möller (Vice Chair)
MD, PhD, Vice Chair,
Chair on several boards, among them Brahms
AG, Bionostics Inc, Febit AG, and 4sigma



Daniel Camus
PhD, Chief Financial Officer,
The Global Fund to Fight AIDS,
Tuberculosis and Malaria



Deepak Gupta
Independent Commission for Health and
the Voluntary Health Association of India



Ilona Kickbusch
PhD, Director, Global Health Programme,
Graduate Institute of International and
Development Studies, Geneva



Bernard Mach
MD, PhD, Founder and Chair of
NovImmune



Carlos Medicis Morel
PhD, Director, Center for Technological
Development in Health, Oswaldo Cruz
Foundation



Michael Watson
PhD, VP Vaccination Policy and Advocacy,
Sanofi Pasteur



Catharina Boehme,
MD (ex officio)

Scientific Advisory Committee

Marcel Tanner, Professor,
PhD, MPH

Clifton E. Barry III, PhD

Manica Balasegaram, MD

Prof. Dr. Frank Bier

Prof. Peter Chiodini, PhD

Renuka Gadde

Emma Hannay, MD

Prof. Sanjeev Krishna

Crispin Lumbala, MD

Ken H. Mayer, MD

Madhukar Pai, MD, PhD

Prof. Ana Rabello MD, PhD

Alejandro Schijman, MD

Karin Weyer, MD

Thomas J. White, PhD

FIND Team

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Scientific Officer, Malaria

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Project Coordinator, CDC CoAg

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Tobias Broger,
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Christophe Broggi,
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Biostatistics and Data Manager

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Scientific Team Administrator, EXPAND-TB

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Heidi Hopkins,
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Head of Downstream Operations

Mark Perkins,
Chief Scientific Officer

Sandrine Regeon,
Executive Assistant to CEO & Board

Sharon Saacks,
Head of Operations

Jérôme St-Denis,
Senior Advocacy & Resource Mobilization
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Scientific Team Administrator, HAT & OND

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Social Media

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Technology and Business Development

Tatiana Titova,
Website

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Head, FIND India & SE Asia

Pravakar Adhikaree,
Project Manager & Technology Officer

Umesh Alavadi,
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Satyender Kumar Johri,
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Coordinator-Malaria Diagnostics
Implementation Project

Daniel Kyabayinze,
Medical Officer

Jeff Lemaire,
Programme Officer

George Lukyamuzi,
Scientific Officer

Jean Nsekera,
Office Manager

OVERVIEWS OF OUR PROGRAMMES

TUBERCULOSIS

FIND is at the forefront of the battle against TB: we are leading the development of novel diagnostic tools for TB detection, which are essential to improving health outcomes and stemming the spread of the disease. We played a pioneering role in the development of the Xpert MTB/RIF test: since being endorsed by the WHO it has achieved worldwide uptake and recognition by international organizations, government health ministries, and the TB scientific community. Despite the widespread success of this innovative tool, TB is still the second leading cause of mortality from an infectious disease in the world, second only to HIV/AIDS. More must be done to fight the steady rise of drug-resistant TB for which most available drugs prove ineffective. Today, multidrug-resistant TB (MDR-TB) is the biggest hurdle in making decisive advances to decrease the incidence of TB.

Although it is often perceived as a disease with a cure, TB still kills almost three people every minute somewhere in the world. TB elimination has become a global priority with much progress made worldwide. According to data from the WHO 2013 Global Tuberculosis Report, however, we will not achieve the 2015 United Nations Millennium Development Goal of reversing TB incidence unless the estimated three million patients without access to health care are diagnosed and treated. The rise of MDR-TB has also created a public health crisis that is beginning to outweigh the progress made in case detection and treatment. Although the number of people detected for MDR-TB with rapid diagnostic tests has almost doubled between 2011 and 2012, three out of four MDR-TB cases still remain undiagnosed.

Between 2007 and 2012, FIND and our partners completed the development of six new diagnostic products for TB. Five have been endorsed by WHO for use in national disease control programmes and are being implemented at central and decentralized settings in high-burden countries.

One of FIND's primary goals is to bring accurate testing to primary care and first referral settings and to expand the menu of drug resistance testing to

support on-going development of novel regimens. Through our TB programme, we are working to reduce delays in the diagnosis and appropriate treatment of TB through the development of new diagnostic approaches in three priority areas.

These include:

- developing molecular methods to detect resistance to the key drugs in use today and those in development for future treatment regimens;
- improving access to screening for TB while decreasing the cost of case detection by developing a triage test that can be used at the community level to identify people who are symptomatic but do not have TB thus selecting high-risk individuals for further testing;
- maximizing the impact of molecular testing through tools that reduce reporting delays and allow molecular treatment monitoring.

Our goal is to fight diseases that impact the poorest populations through a focus on diagnostic solutions.

In 2013, FIND continued to research technologies applicable to molecular drug susceptibility testing (DST), with two platforms already selected for development in 2014. This will be complemented by our collection of reference materials, in particular well-characterized specimens and strains that can be used for product development and validation.

We are broadening the scope of our TB work to address the urgent needs of vulnerable populations like children, HIV-positive patients and others with extra-pulmonary forms of TB. The Xpert MTB/RIF was endorsed in July 2013 by WHO for use among these patients. Diagnosing TB in children remains a crucial



NEW PT. PUT ON DOTS

MON	CATI	CATI	TOTAL
FEB 2017	7	3	10
NSP-2			

TOTAL NO OF PT. ON DOTS

MON	CATI	CATI	TOTAL
	41	14	55

WE AIM TO TURN COMPLEX
DIAGNOSTIC CHALLENGES INTO
SIMPLE SOLUTIONS TO OVERCOME
DISEASES OF POVERTY AND
TRANSFORM LIVES.

focus for FIND, and we are encouraged by the results of studies on using Xpert MTB/RIF as a stool test for children with suspected TB.

A novel approach to stimulating product development is the FIND Support for Success (S4S) programme for small and medium size companies (SMEs) to help them develop new diagnostics and release them on the market. In 2013, our S4S began in India, where we enabled a partner to improve its performance in the development of an assay. A team of selected mentors worked with the company on-site and remotely to produce a product development plan and a milestone-based timeline.

Under the auspices of the UNITAID-funded EXPAND-TB project, FIND is concentrating efforts to scale up diagnostic capacity for MDR-TB in 27 high-burden countries. By the end of 2013, 92 laboratories in all participating countries had been established and were using new diagnostic tools – this resulted in 32,000 cases of MDR-TB being identified.

Our work thrives because of our valuable collaborations and partnerships that enable us to scale-up our efforts to empower our partners in low-resource countries. The FIND-CDC Cooperative Agreement Programme is an example of this. Under this programme we are strengthening laboratory

capacity and providing long-term support towards laboratory accreditation so our local partners can offer quality services and increase access to new diagnostic tests. In 2013, we conducted training workshops, improvement projects and follow-up visits in Latin America and the Caribbean, maximizing our impact by focusing on laboratories in large hospitals with maternal and child health programmes.

In response to the presence of Xpert MTB/RIF on the market across a wide range of countries, we are working to deliver consistent, user-friendly quality assurance tools. In order to ensure that this test is implemented with the same level of excellence, FIND has developed an Xpert training package in English and French, and provided technical assistance, training courses and support to partners in Africa and the Caribbean.

Last year, FIND reaffirmed its commitment to eliminating TB through fit-for-purpose diagnostics and linkage to treatment for all people with the disease. We will continue our work in cutting transmission through early detection and preventing antimicrobial resistance. We will also develop comprehensive solutions for vulnerable patients, support guidance for use and advocate for the prioritization of TB diagnostics within the global health care community.

MALARIA AND ACUTE FEBRILE SYNDROME (AFS)

Malaria can be both detected accurately and treated effectively – yet more than 200 million people are affected by malaria each year, 600,000 of whom will die from the disease. Many people at risk in countries where malaria is endemic have little access to adequate diagnosis and health care. A major

challenge with malaria lies in its ability to present with symptoms similar to other febrile diseases. Rapid, accurate, and cost-effective detection of malaria has the potential to significantly diminish its prevalence in high-endemic areas and to support elimination efforts in low-endemic countries. The

differential diagnosis of acute febrile syndrome (AFS) is a major challenge for field health workers in malaria endemic countries. While many sources of fever – particularly viruses – cause temporary and self-limiting illness, some are severe and can cause greater mortality than malaria. Most of these diseases are readily curable if appropriately diagnosed and treated.

FIND's malaria and AFS strategy is based on widespread access to high-quality diagnostic tools and on ensuring that the tests are conducted and managed correctly. If the ultimate goal of malaria elimination is to be achieved, quality assurance of existing and new tests remains a central aspect of FIND's work. Efforts to develop new tools while maximizing the impact of existing RDTs will lead the way to helping communities affected by malaria to control and eventually eliminate the disease. With the decline of malaria burden, appropriate tools that detect people with low parasitemia, as well as guidance for diagnosis and management of other causes of fever are required.

Among our accomplishments in 2013, FIND:

- Completed testing of a 5 µl blood transfer device (BTD) that is easy to use and that has the capacity to precisely and safely transfer a small blood sample from finger pricks to RDT; the product is now commercially available, with one RDT manufacturer having distributed more than 100 million units to the market
- Published results of the clinical evaluation of the LAMP kit for malaria, a simple and field stable molecular test able to detect sub-microscopic infections. Several groups in endemic countries started using this kit for population screening and treatment in elimination activities.
- Published the first ever complete guide for implementation of malaria RDTs in endemic countries; a document with a step-by-step

methodological approach that covers aspects from training in the use of RDTs to tools for implementation planning at different levels of the health system.

- Contributed to the better understanding of causes of fever in the Mekong region; results from prospective studies in Cambodia and Lao PDR have been published and interactive maps with data from published literature are available at FIND's web site.
- Introduced three new projects:
 - the first responds to the need for simple serological tests for surveillance and response in malaria elimination programmes and aims to validate the utility of different antigens as serological markers of recent exposure to *P. vivax* parasites
 - the second addresses quality control of antimalarial drugs – since poor-quality drugs represent around 30% of total sales in developing countries around the world, we are evaluating the feasibility of a simple, rapid, and affordable quantitative assay to measure active pharmaceutical ingredients in artemisinin-based combination therapies (ACT) in endemic countries
 - the third aims to stimulate the creation of a private sector market for malaria RDTs in five endemic African countries – over 40% of people who seek care and treatment for febrile illness are part of the private sector, where RDTs are either non-existent or more expensive than ACT; the project will address delays in the correct management of febrile illness and will promote treatment adherence, leading to a reduction of overtreatment with ACT and promoting the rational use of antimalarials.

HUMAN AFRICAN TRYPANOSOMIASIS (HAT) AND OTHER NEGLECTED DISEASES (OND)

Human African trypanosomiasis (HAT), or sleeping sickness, was the first neglected tropical disease to be included in FIND's portfolio in 2006. In 2010 and 2012, we added leishmaniasis and Chagas disease, respectively. Now called HAT and Other Neglected Diseases (OND), the programme has achieved numerous successes. The first-ever rapid diagnostic test (RDT) for screening sleeping sickness was launched at the end of 2012 in Kinshasa, Democratic Republic of the Congo (DRC). The elimination of this disease is now within sight and the HAT RDT is playing a major role towards realizing this goal.

According to the WHO roadmap and the London Declaration on neglected tropical diseases, elimination by 2020 has become a primary target for several diseases. Consequently, we are focusing more on diagnostic tools that can be used toward the achievement and sustainability of elimination programmes. The feasibility of adding other diseases, such as Buruli ulcer, to the FIND OND portfolio was explored in 2013 at a WHO/FIND meeting of experts and will be addressed in 2014..

In the case of HAT, diagnosis and subsequent treatment remain difficult: until recently, existing diagnostic tools – which rely, in part, on the use of microscopy to confirm the presence of parasites in the blood – could not be used effectively in remote, impoverished settings where the disease is almost always found. In its early stages, infection presents few explicit symptoms, and cases are rarely detected until they are in the advanced stage, when treatment is difficult and expensive, and the appropriate drugs are associated with toxic side effects. The HAT RDT is a major step forward in overcoming this diagnostic hurdle.

HAT presents in a chronic form (*gambiense*), which accounts for over 90% of all cases, and an acute form (*rhodesiense*). Treating HAT in its early stages is relatively safe and inexpensive. Determining the disease's stage with a given patient is a major

contributor to treatment efficacy. Once the brain becomes infected with the parasites, treatment is difficult, and the chances of irreversible sequelae increase. In 2013, we worked on identifying a number of biomarkers for a new diagnostic that will indicate whether or not the central nervous system of a patient has already been affected, which could also be used to detect treatment failure.

From dialogue to diagnosis, we advocate from the perspective of users in resource-poor countries.

The first generation RDT for *T.b. gambiense* HAT was evaluated in DRC and was shown to be significantly more sensitive than existing tests. A three-year project to introduce the test in Uganda was launched at 197 health facilities and is expected to dramatically accelerate elimination of HAT through early detection and the interruption of disease transmission. We made significant progress in developing a second generation HAT RDT using recombinant antigens, which would be cheaper and easier to manufacture than the current version. *T.b. gambiense*: HAT has continued to pose challenges in view of the low number of parasites present in the blood. Overcoming this difficulty is now possible, thanks to the iLED fluorescence microscope developed jointly by FIND and Carl Zeiss. Concentrating the parasites and staining them with acridine orange improves sensitivity, speed and ease of reading compared to bright field microscopy. The microscope, which has formally been adopted for clinical use in Uganda and DRC, can operate on solar power, making it suitable for remote areas.

Studies on the LAMP kit for HAT in 2012 confirmed the test to be highly sensitive for *T.b. rhodesiense* HAT, and clinical evaluation of patients in Uganda in 2013 further validated the test's high sensitivity and specificity.

FIND has maintained its strategy of expanding technological platforms – diagnostic tools with the potential to be applied to more than one disease. This is proving particularly successful in the case of leishmaniasis, a disease that can take on four forms, each with specific symptoms. In the case of visceral leishmaniasis (VL), also known as Kala Azar, failure to apply treatment can result in a 100% fatality within two years of infection. Results on a new molecular assay for VL based on the LAMP platform have been promising. Building on the prototype ELISA kit that was tested in 2012, we held a training course for laboratory technicians in east Africa in collaboration with Drugs for Neglected Diseases initiative (DNDi).

FIND initiated a market survey for leishmaniasis diagnostics in general, and to establish current demand for an antigen detection test for diagnosis and follow-up of VL patients. The survey will also be used to better understand how to prepare the market for the LAMP assay.

Chagas disease is widely spread in Latin America, currently infecting between eight and 15 million people, with more than 30 million at risk of infection. Every year, there are more than 40,000 new cases and more than 12,000 deaths due to complications from the disease. If left untreated, patients remain infected for life, with pregnant women being a particularly high-risk group. Screening is not mandatory in the affected regions and is usually done with serological assays. Testing of pregnant women is only mandatory in Argentina. We believe that a field-applicable LAMP test for the disease could save a significant number of lives; however, its impact will be determined by the degree to which it is integrated into comprehensive health policies and advocacy campaigns in the affected countries.

Although most projects in this programme are related to HAT, our cross-disease diagnostic platform strategy has allowed for rapid migration of scientific and technological know-how to other neglected diseases.

ACHIEVEMENTS IN 2013



FIND IS AN ENABLER AND A
MOBILIZER. WE PROVIDE A
RESOURCE PLATFORM FOR
OUR PARTNERS AND BRING
STAKEHOLDERS TOGETHER
TO CATALYSE SCIENTIFIC AND
TECHNICAL DEVELOPMENT.

CATALYSE DEVELOPMENT

Tuberculosis

Drug resistance testing comes closer to the patient

Identifying molecular approaches for near-patient testing of resistance to first- and second-line drugs

This project identifies technical approaches that could be used for near-patient testing of resistance to the key drugs in current and future treatment regimens. It includes the development of consensus Target Product Profiles (TPPs) and the collection of reference materials. A first TPP version has been revised after review by the assay development working group of the NIH-funded Critical Path Institute, co-chaired by FIND. It then went through a consensus-building process, which was followed by a meeting of key stakeholders convened by the New Diagnostics Working Group and the Global Laboratory initiative, resulting in the TPPs being endorsed.

The project's primary focus is on the design and development of a genotypic DST approach that is adaptable to any appropriate instrument platform for both centralized and near-patient testing. Options for phenotypic drug susceptibility testing (DST) are also being evaluated. The objective: select two assays and prove their feasibility for molecular DST. One assay

using 'sloppy' molecular beacons (SMB's) has been selected and significant progress has been made in the development of a set of reagents. Molecular platforms have been identified that can host the assay, and development and feasibility studies are planned for 2014. A line probe assay (LPA) for pyrazinamide is being evaluated as part of on-going LPA feasibility studies at the FIND trial sites. The final component is the establishment of a collection of well-characterized MDR-XDR TB specimens and strains that can be used as reference materials for product development and validation. The groundwork was completed in 2013 and collection is scheduled to begin in early 2014.

FIND partners: McGill University, Canada; Nipro Corporation, Japan; Rutgers University, USA

Key funder(s): Australian Agency for International Development (AusAID), Australia; Bill & Melinda Gates Foundation, USA; Department for International Development (DFID), UK

Accelerating the time taken from lab to market

Mentoring SMEs – a complementary success factor in product development

Endorsed by WHO in 2010, Xpert® MTB/RIF is still the only nucleic acid amplification test (NAAT) available for TB. There are, however, promising fast-follower technologies that have shown similar operational characteristics in early studies. Notably, the Epistem Genedrive® and the Molbio Diagnostics Truenat™ tests show potential in terms of ease-of-use, diagnostic accuracy, and robustness, and could provide an opportunity to foster much-needed competition in this arena. To generate more clinical data on performance, FIND worked in collaboration with the Tuberculosis Clinical Diagnostics Research

Consortium (TBCDRC) on setting up an evaluation trial of these two PCR technologies. The study, which will be carried out in 2014 at three sites in South Africa, Uganda, and Brazil, will collect data to support the WHO endorsement process.

FIND also started providing support to Molbio Diagnostics for the development of a next generation molecular platform based on Truenat. The Indian company is the first small-medium enterprise (SME) to benefit from FIND's formalized mentoring programme as part of a pilot project designed to

help SMEs overcome some of the challenges they face in moving their scientific expertise from lab to market. FIND established a mentorship team, which performed an assessment of the situation and needs. After producing a development plan and arranging weekly discussion sessions, the company was soon eight weeks ahead of the timeline target and was on track to complete development of the pre-analytical frontend of the assay and to produce the volumes

necessary to perform clinical evaluations and studies.

FIND partners: Epistem, UK; Molbio Diagnostics Pvt. Ltd, India; Tuberculosis Clinical Diagnostics Research Consortium, USA

Key funder(s): Bill & Melinda Gates Foundation, USA; Department for International Development (DFID), UK

New collaborations open encouraging pathways in TB detection

A potential lateral flow LAM assay for sputum

One of our high priority goals is to develop a rapid point-of-care test that can be used at community levels within health systems. Lipoarabinomannan (LAM) was identified as a promising target for antigen detection, and FIND has access to some unique monoclonal antibodies that recognise LAM on the bacterial cell wall as well as related LAM fragments found in sputum. Initial work with these showed promising results and studies are being pursued. Given an appropriate sample preparation method, it may be feasible to have a lateral flow LAM assay for sputum. To analyse this possibility, we have partnered with Standard Diagnostics-Alere to develop a rapid test for detection of active pulmonary TB and for disseminated

infection with *M. tuberculosis* based on LAM detection in sputum, which are targeted to microscopy centres. In parallel, and primarily with Standard Diagnostics as well as other potential engineering partners, work will continue on sample processing methods and the addition of complementary antibodies to enhance test performance.

FIND partners: Standard Diagnostics-Alere, Republic of Korea

Key funder(s): Australian Agency for International Development (AusAID), Australia; Dutch Ministry of Foreign Affairs (DGIS), Netherlands

A low-cost image-based screening platform with the potential to detect more TB cases

In partnership with BD (Becton, Dickinson and Company), FIND announced at the end of 2013 that it would embark upon a feasibility project to evaluate the potential use of a low-cost, image-based TB screening platform currently in development. The platform provides ease-of-use and semi-quantitative automated results that may improve reproducibility and possibly accuracy by standardizing LED microscopy and eliminating associated user subjectivity. This diagnostic advancement streamlines the staining and detection process compared to

conventional microscopy. With the potential to more accurately identify smear negative and otherwise culture positive patients, this test could enhance TB detection and have possible applications for treatment monitoring.

FIND partner: BD (Becton, Dickinson and Company), USA

Key funder(s): Australian Agency for International Development (AusAID), Australia

Malaria

Responding to new challenges in screening for malaria elimination

High-throughput LAMP malaria kit for rapid screening and treatment in low-resource settings

FIND is dedicated to delivering the diagnostic tools needed to support global goals for malaria control and elimination. With the relative decline of the disease in some countries, elimination becomes achievable in a higher number of settings – but this demands targeted efforts and diagnostic tools that can detect continuing reservoirs of infection and cases of low parasite density. The only simple field test currently available at the commercial level is the recently launched LAMP kit for malaria.

The LAMP kit offers new possibilities in the implementation of surveillance and response activities in malaria elimination campaigns. In alignment with global goals, FIND and its partners are now working on the development of a lower-cost, high-throughput version of the LAMP kit that could test a high number of samples in a single day and allow prompt treatment.

The current focus is to identify options for this format of LAMP, which simplifies sample collection and processing methods, and uses flexible approaches for assay incubation and reading of results. Studies have been launched in endemic areas of Africa, Asia, and South America to demonstrate the feasibility of the use of LAMP as a potential tool for population screening to detect and treat asymptomatic sub-microscopic infections.

FIND partners: Hospital for Tropical Diseases, UK; 42 Technology Ltd, UK; Lumora, UK; Porvair, UK; Eiken Chemical Co., Ltd., Japan; Institut Pasteur du Cambodge, Cambodia; Karolinska Institutet, Sweden; University of California, San Francisco, USA; Caucaseco Scientific Research Center, Colombia

Key funder(s): Australian Agency for International Development (AusAID), Australia; KfW Development Bank, Germany; Department for International Development (DFID), UK

Interactive maps track pathogens causing fever

Addressing knowledge gaps on the prevalence of various causes of febrile syndrome

The introduction of confirmatory tests and the increasing use of rapid diagnostic tests for malaria are highlighting the fact that most fevers in malaria-endemic areas are due to other causes. Coupled with a declining malaria burden in many countries, other causes of febrile disease require appropriate tools for early detection and appropriate treatment. Although some small-scale studies have been conducted, there is no global database to guide future studies and health programmes for managing fever. A map of febrile disease aetiology would prove to be an

invaluable resource – it will address knowledge gaps and help guide further targeted surveys, and facilitate the development and implementation of management strategies and appropriate diagnostic tools. Better understanding of causes of acute fever will also help raise awareness and advocate for more attention and funding in support of this global health concern.

FIND and its partners have concluded a pilot project to gather background information on the causes of fever in malaria endemic areas. A literature search

revealed the frequency and distribution of pathogens involved in Non-Malaria Fever Illness (NMFI) in the Mekong region. Over 1,000 published studies of infectious diseases in Thailand, Lao PDR, Cambodia, Viet Nam, Myanmar, and the Yunnan province of China were reviewed. The data were transferred to a set of interactive maps showing the location of pathogens known to cause NMFI. These are accessible both on the websites of both FIND and the Worldwide Antimalarial Resistance Network (WWARN), and are published in PLoS ONE. The methodology is readily scalable and our partners are now extending the project to sub-Saharan Africa and other Asian countries. Global maps of pathogen distribution would form a strong foundation for developing a rational

approach to the management of the high burden of acute febrile disease, particularly in malaria-negative cases. FIND is participating in meetings of the group of experts to define the research agenda that will lead to improved management of acute febrile illness.

FIND partners: Worldwide Antimalarial Resistance Network (WWARN), UK; University of Oxford, UK; Mahosot Hospital, Lao PDR; ACT Consortium, UK; London School of Hygiene and Tropical Medicine (LSHTM), UK

Key funder(s): Australian Agency for International Development (AusAID), Australia; Department for International Development (DFID), UK

HAT & OND

Second generation screening test for HAT

Use of recombinant antigens shows promise as a method to lower production costs

Efforts are being made by FIND and Standard Diagnostics to develop a second generation RDT using recombinant antigens, which would be easier and cheaper to manufacture and would significantly reduce the cost of the final product. Such a test can be manufactured in large volumes, as manufacture of the first generation RDT is limited due to antigen availability.

FIND partner: Standard Diagnostics, Republic of Korea

Key funder(s): Bill & Melinda Gates Foundation, USA; Department for International Development (DFID), UK; Republic and Canton of Geneva, Switzerland

Investigation to determine the stage of disease

Accurate staging of HAT is essential for appropriate treatment

Treating a patient with HAT depends on accurate knowledge of the stage of the disease. In the early phase, when the parasites are still present in the blood and lymphatic system, treatment of HAT is relatively safe and cheap. The difficulty with the early stages of the disease is that clinical signs are not easily apparent and existing tests are problematic in terms of sensitivity and specificity. As a consequence, many cases remain undetected and, over time, the parasites invade the brain (Stage 2 of the disease) for which treatment is

lengthy, expensive, and difficult to administer, and has potentially fatal side effects. Diagnosis of HAT in the early stage, when the brain is not affected, ensures safer and more efficient treatment.

In the face of currently available non-specific and relatively insensitive tests, FIND and its partners are working on a rapid test that will accurately determine the stage of the disease and confirm cure after treatment.

A number of biomarkers that discriminate with a high degree of precision between HAT patients with and without central nervous system involvement have been identified. Two of these markers – neopterin and CXL13 – can also detect cases of relapses and confirm cure within six months after treatment. Development of tests based on these biomarkers continued in 2013.

FIND partners: concile GmbH, Germany; Shenzhen Kang Sheng Bao, China; Standard Diagnostics, Republic of Korea

Key funder(s): Department for International Development (DFID), UK; Swiss Agency for Development and Cooperation, Switzerland; UBS Optimus Foundation, Switzerland

Technology platforms for detecting leishmaniasis

ELISA and LAMP-based assays complete Phase 1 development

In 2012, FIND and its partners developed a prototype ELISA kit for *Leishmania* antigens in urine. Following optimization of test conditions in 2013, promising results were obtained when the prototype was evaluated using urine samples from Kenya. However, the ideal time to test patients after treatment to confirm that a cure has been obtained still needs to be established. A training course to strengthen the capacity in ELISA diagnostics in east Africa was held in Nairobi in September in collaboration with Drugs for Neglected Diseases initiative (DNDi); participants included laboratory technicians from various sites where DNDi is conducting trials. The feasibility of transforming the test into a lateral flow assay format is being explored.

A molecular test for leishmaniasis based on the LAMP technology is also being developed. Reagents have been optimized and a new prototype LAMP assay has been developed by combining two primer sets. Evaluation of the assay has been done using purified parasite DNA at various dilutions. Prototype assays have also been tested on a range of *Leishmania* species to confirm that amplification was stable and consistent within species and geographic regions; this included checking for cross-reactivity with a number of other pathogens. After the promising preliminary results, the prototype was tested on a number of clinical samples. Optimization of sample preparation in order to improve sensitivity of the LAMP assay is currently underway.

A market survey on diagnostics for leishmaniasis has been initiated with a threefold purpose:

- to establish the current need for an antigen detection test for diagnosis and follow-up of visceral leishmaniasis (VL) patients
- to understand how best to prepare the market for uptake of a LAMP assay
- to determine whether there is need for a species-specific assay

The market survey will also help to identify other unmet needs in diagnostics for leishmaniasis.

FIND partners: Drugs for Neglected Diseases initiative (DNDi), Switzerland; Eiken Chemical Co., Ltd., Japan; Kalon Biological Limited, UK; KEMRI, Kenya; Institute of Primate Research, Kenya; Instituto de Salud Carlos III; Spain; Royal Tropical Institute (KIT), Netherlands; University of Strathclyde, UK

Key funder(s): Department for International Development (DFID), UK; Drugs for Neglected Diseases Initiative (DNDi), Switzerland; Dutch Ministry of Foreign Affairs (DGIS), Netherlands; Federal Ministry of Education And Research (BMBF) through KfW, Germany; Swiss Agency for Development and Cooperation, Switzerland; UBS Optimus Foundation, Switzerland; TI Pharma, Netherlands

A simple molecular test for congenital Chagas disease

LAMP technology as an alternative to PCR for the diagnosis of congenital Chagas disease

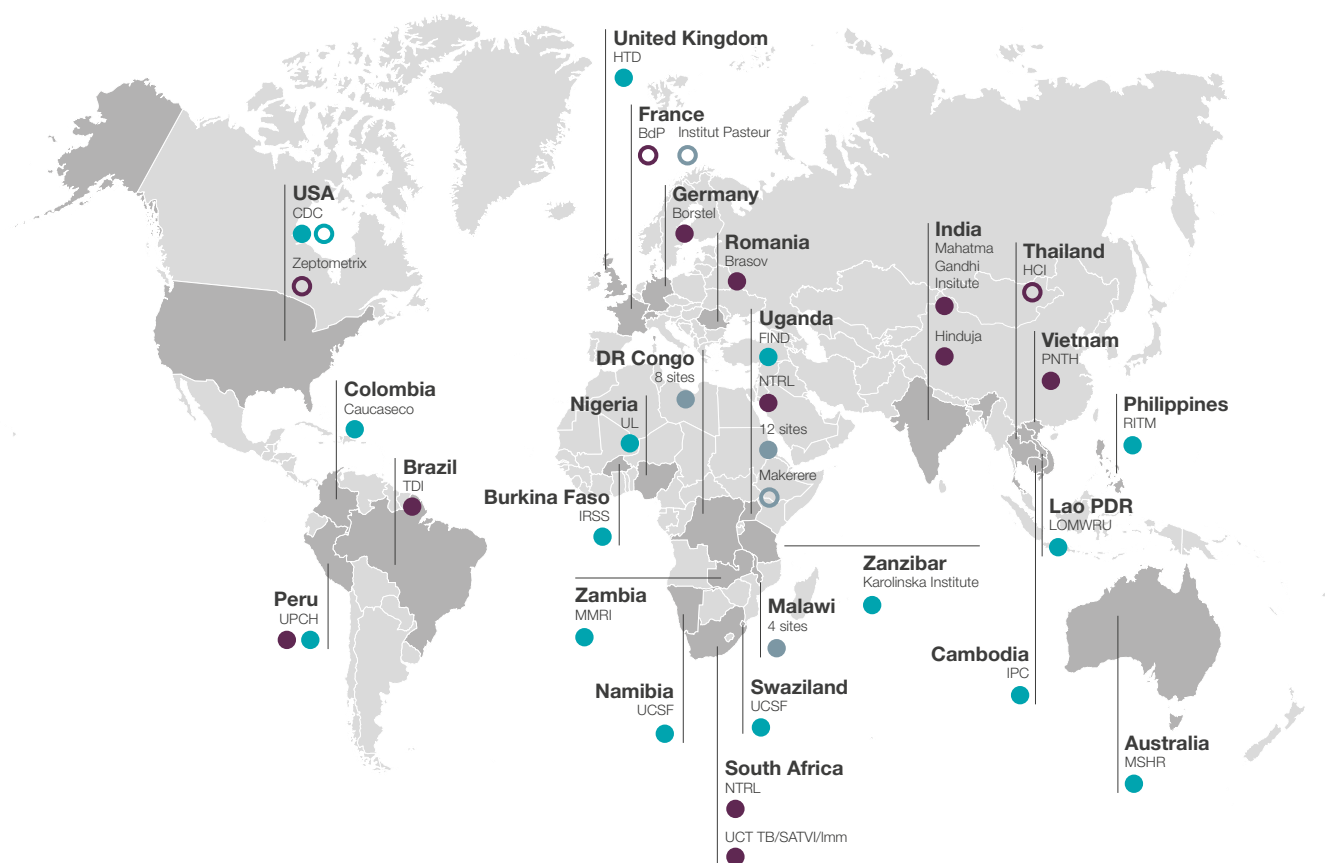
Chagas disease – infection with *Trypanosoma cruzi* – is common in pregnant women in South America. Transmission of the disease from mother to child has been reported in the range of 4% to 12% for women of childbearing age who have the illness in chronic form. The disease is not confined to South America: it spreads through migration to numerous countries including North America and Europe, and is becoming a worldwide health problem. Left untreated, patients remain infected for life, increasing the chances for further transmission and potentially life-threatening side effects. In 2012, FIND commissioned a market survey to understand the current testing landscape for Chagas disease in endemic countries. Interviews were conducted with professionals working directly on the disease in countries in Latin America, North America, and Europe. The survey revealed that ELISA is the most widely used serological test for pregnant women. While testing is mandatory for all pregnant women in Argentina, in other countries, it is based on family history or possible exposure to the insect vector. Approximately half of the participants interviewed

were aware of LAMP and perceived it as a feasible option for diagnosis. A field-applicable LAMP test for congenital Chagas could halt spread of the disease and save a significant number of lives. A feasibility study on LAMP was completed in 2013 and development and optimization of sample preparation were initiated. While LAMP is likely to play an important role in diagnosis of congenital Chagas disease, it will need to be accompanied by health policies, including advocacy initiatives in endemic countries.

FIND partners: Eiken Chemical Co., Ltd., (Japan), Instituto de Investigaciones en Ingeniería Genética y Biología Molecular (INGEBI/CONICET), Argentina; London School of Hygiene & Tropical Medicine, UK; Pontificia Universidad Javeriana, Colombia

Key funder(s): Department for International Development (DFID), UK; Federal Ministry of Education And Research (BMBF) through KfW, Germany; Swiss Agency for Development and Cooperation, Switzerland

Clinical trial sites involved in FIND studies - 2013



TB

- Trial/specimen collection
- Specimen bank repository

Malaria

- Trial/Specimen collection
- Specimen bank repository

HAT & OND

- Trial/Specimen collection
- Specimen bank repository



WE OPERATE AN OPEN
CLINICAL PLATFORM
TO SUPPORT GLOBAL
PROCESSES FOR DEVELOPING
POLICY GUIDANCE AND
ASSURING QUALITY.

GUIDE USE AND POLICY

Tuberculosis

Policy update extends use of Xpert MTB/RIF to paediatric and extra-pulmonary TB

WHO recommends wider application of the assay based on evidence collected by FIND and its partners

A WHO recommendation in July 2013 to use the Xpert MTB/RIF assay for the diagnosis of paediatric TB and extra-pulmonary TB (EPTB) has resulted in a substantial reduction in the long-standing diagnostic challenges associated with these forms of the disease. The initial WHO endorsement of the technology in 2010, based on evidence presented by FIND and its partners, recommended that Xpert MTB/RIF for rapid and simultaneous detection of tuberculosis and rifampicin resistance be used as an initial diagnostic test in individuals suspected of MDR- or HIV-associated TB. Given the large amount of additional

data on Xpert MTB/RIF published since 2010, and acknowledging the difficulties in the microbiological diagnosis of childhood TB and EPTB, the WHO commissioned three systematic reviews on the utility of Xpert MTB/RIF for the diagnosis of TB and rifampicin resistance in a) pulmonary, b) extra-pulmonary, and c) paediatric TB. A review of published studies on the affordability and cost-effectiveness of the assay was also undertaken. The evidence from these reviews was submitted to a WHO expert group in May 2013 and the updated policy guidance and recommendations were published in October.

Xpert MTB/RIF shows promise for diagnosis of childhood TB

New child-friendly sampling method under evaluation

Diagnosing TB in children can be particularly challenging – collecting a sputum sample for examination from young children is not always feasible because they are unable to expectorate. TB diagnostic tests adapted to children are urgently needed and there is general consensus that a non-sputum based test would be the most suitable for this population. Work on the development of a stool sample processing method that can be used with the Xpert MTB/RIF assay is in progress, and initial data on stool samples from apes look promising. Further proof of principle data is required and FIND is setting up a trial in South Africa for this purpose. The study, with a planned start date of early 2014,

aims to optimize current processing methods and to collect proof of principle data on stool samples and compare them to sputum culture and Xpert. Should the results prove to be promising, FIND would aim to develop a low-cost kit that can be easily implemented in laboratories currently performing Xpert MTB/RIF.

FIND partners: National Health Laboratory, South Africa; University of the Witwatersrand, South Africa; Rutgers University, USA

Key funder(s): Bill & Melinda Gates Foundation, USA; Dutch Ministry of Foreign Affairs (DGIS), Netherlands

Reference materials for TB – a vital asset for accelerating development of new diagnostics

The development of diagnostics, unlike drugs or vaccines, is critically dependent on the availability of clinical materials and study populations in disease-endemic countries in all phases of development.

FIND's reference materials project was initiated in 2007 to collect and store well-characterized specimens from suspected TB cases. In 2013, FIND carried out clinical studies for TB at 27 trial sites in nine countries, including two new trial sites in Uganda and South Africa. A total of 69,000 participants were enrolled in these studies; a significant number came from an implementation study in India. The main trial sites remain located in India, Peru, South Africa, and Vietnam. and an expansion of activities to new sites is planned for 2014. The FIND repository currently holds over 65,000 aliquots (serum, plasma, plasma P800, urine, and sputum) from approximately 4,100 patients from Africa, Asia, and South America.

Following an agreement signed in 2012 with WHO/TDR (Special Programme for Research and Training in Tropical Diseases) to hand over management of

the TDR TB bank, samples are now available through FIND. A contractual agreement between FIND and TDR has resulted in open access to these repositories for test developers. The new initiative has generated a substantial increase in specimen turnover, with a growing number of requests coming from non-FIND partners. In 2013, more than 6,000 aliquots were distributed to 19 different partners.

In 2014, FIND will continue to collect well-characterized samples focusing on suspected MDR-TB cases and will seek new sites to increase the geographical distribution of the collection. A more stringent quality control system for stored specimens will be established while we explore options to relocate the current FIND collection to a more cost-effective storage facility.

FIND Partners: Health Concept International, Thailand (FIND main repository); World Courier (shipper); Zeptomatrix, USA (TDR repository); Biobanque de Picardie, France (TDR repository)

Key funder(s): Bill & Melinda Gates Foundation, USA

Malaria

First commercially available field-stable LAMP test for diagnosis of malaria

A PCR-equivalent test in the hands of technicians in a remote setting

FIND has completed the development of the first commercially available field-stable molecular test for the diagnosis of malaria based on LAMP. Results from clinical studies with travellers in the UK and with febrile patients in a malaria endemic area in Uganda were published in 2013. The studies generated an increased interest in the technology and demonstrated that the LAMP kit for malaria has equivalent sensitivity and specificity to PCR and that it is able to detect sub-microscopy infections. The availability of the kit opens

new perspectives for surveillance and screening in cases when a highly sensitive assay is needed, such as for detection of malaria during pregnancy and for detection and treatment of asymptomatic infections.

The clinical evaluation of this kit began in 2010 and the results were published in the *Journal of Infectious Diseases* in April, 2013 under the title 'Highly sensitive detection of malaria parasitemia in an endemic setting: Performance of a new LAMP kit in a remote

clinic in Uganda'. This kit has been distributed to over 10 countries worldwide. Collaborations have been established with research groups to evaluate the use of the kit with DNA extracted from different types of samples processed by different methods, as well as the potential use of the kit to predict infectivity of mosquitoes.

The high level of interest in this kit within national malaria control programmes and research institutions has exceeded expectations and a suitable commercialization and distribution partner will be identified in 2014.

FIND partners: Eiken Chemical Co., Ltd., Japan; Swiss Tropical and Public Health Institute, Switzerland; London School of Hygiene and Tropical Medicine, UK; Macha Research Trust, Zambia; Menzies School of Health Research, Australia

Key funder(s): KfW Development Bank, Germany; Australian Agency for International Development (AusAID), Australia; Department for International Development (DFID), UK

The TB specimen bank is comprised of a tight network between collection sites, repository, end users and FIND



A big leap in the apparently simplest of technologies

The improved blood transfer device for malaria RDTs is widely adopted

To overcome blood safety issues, FIND developed a simple 5 ul blood transfer device that has been widely adopted by malaria rapid test manufacturers after several years of successful field trials. Its unique feature is totally invisible – it is free from all patent and IP restrictions. In 2013, some 100 million of the devices reached patients with fever.

As rapid diagnostic tests (RDTs) for malaria are scaled up in endemic countries, they will be used increasingly by personnel with little or no training in laboratory techniques. The correct transfer of blood from a patient to a point-of-care test – a seemingly simple procedure – is vital to both diagnostic accuracy and the safety of the community health care worker. Most commercially available RDT kits are packaged with individual-use disposable blood transfer devices to collect, transfer, and deposit a specified amount of blood from a finger-prick site to a well on the RDT cassette. Existing transfer devices usually take the form of a loop, straw, squeezable pipette, or capillary tube.

Reports have repeatedly indicated that blood transfer is an aspect of RDT use that poses a significant challenge to many health care workers, notably in the first stage – obtaining a precise amount of blood for the test. To overcome this, FIND developed the 5 ul

blood transfer device with an inverted cup design. After extensive field evaluation studies in Uganda, Nigeria, and the Philippines, the design was found to perform more effectively than alternative designs: it was accurate, consistent, and easy to use. An additional asset is its compatibility with most of the RDTs on the market.

Following the field study, FIND coordinated the design and manufacture of the device based on a previous non-commercialized design. Prototype development was completed in Geneva, where innovative skills were on hand to guide the FIND malaria team through the early stages of this ground-breaking project.

During 2013, FIND worked on the development of a 20 ul blood transfer device with inverted cup design that can be used with other lateral flow assays for HIV and HAT. Field testing on ease-of-use and acceptability of this 20 ul device with the HAT rapid test was launched in Uganda in 2013.

FIND partners: ORMANCE Sàrl, Switzerland; Althéo Sàrl, Switzerland; Injection74, France

Key funder: Department for International Development (DFID), UK

HAT & OND

High sensitivity and specificity of HAT LAMP on *T.b. rhodesiense* confirmed

First phase clinical evaluation completed and kit now part of elimination strategies

Following the launch of the LAMP kit for HAT in 2011, studies in 2012 confirmed the test to be highly sensitive and specific in the detection of *T.b. rhodesiense*, confirmed in 2013 by a clinical evaluation of patients in Uganda. As a result, evaluation of the kit for *T.b. gambiense* HAT will be completed in the DRC, and demonstration and early implementation studies initiated in multiple sites. Cost effectiveness studies to guide novel strategies for the introduction of LAMP in the diagnosis of HAT are also planned.

FIND partners: Eiken Chemical Co., Ltd., Japan; governments of the Democratic Republic of Congo (DRC), Uganda, and Malawi; Institute of Primate Research; Kenya; Liverpool School of Tropical Medicine, UK; Makerere University, Uganda

Key funder(s): Department for International Development (DFID), UK; Federal Ministry of Education And Research (BMBF) through KfW, Germany; Republic and Canton of Geneva, Switzerland; UBS Optimus Foundation, Switzerland

Low number of parasites in *T.b. gambiense* HAT poses diagnostic challenges

LED FM (light-emitting diode fluorescent microscopy) technology introduced in solar-powered health centres

A LED fluorescence microscope, Primo Star iLED, developed jointly by FIND and Carl Zeiss AG, has been formally adopted for clinical use in the DRC, Uganda, and Malawi. The microscope has high-grade optics, uses reflected rather than transmitted blue light for fluorescence applications, and permits easy switching between fluorescent and bright light viewing. It can be operated on battery power, does not need a dark room, and uses an inexpensive bulb with a life of over 10,000 hours.

Its widespread introduction in remote areas is being undertaken as part of studies on strategies to accelerate elimination of HAT. Evaluation of the microscope in confirmatory diagnosis of *T.b. gambiense* HAT in rural settings was completed at multiple sites in the DRC, which were renovated

and had solar power installed. Other equipment required in the diagnosis of HAT was provided, and technicians were trained in fluorescence microscopy with acridine orange. In Uganda, 12 health facilities were similarly equipped with facilities for parasitological diagnosis of HAT using LED fluorescence microscopy as part of a new strategy integrating this technology with the HAT RDT for screening and LAMP.

FIND partners: Governments of the Democratic Republic of Congo (DRC), Uganda, and Malawi

Key funder(s): Department for International Development (DFID), UK; Republic and Canton of Geneva, Switzerland; Swiss Agency for Development and Cooperation, Switzerland

FIND WORKS WITH
ENDEMIC COUNTRY
GOVERNMENTS TO SECURE
POLITICAL COMMITMENTS
FOR IMPLEMENTATION,
SUPPORTING THE
STRENGTHENING OF
HEALTH AND LABORATORY
SYSTEMS.



ACCELERATE ACCESS

Tuberculosis

Capacity building through strong technical assistance network

EXPAND-TB project aims to narrow diagnostic gap in MDR-TB control

FIND is the main implementing partner in the UNITAID-funded EXPAND-TB project, which is addressing bottlenecks in the scale-up of rapid and accurate diagnostic capacity for MDR-TB by creating adequate capacity in 27 high-burden countries. By the end of the year under review, all countries had reached the full operational phase and 92 laboratories had been established and were routinely using new diagnostic tools, such as liquid culture, line probe assay, and Xpert MTB/RIF. As a result, in 2013 alone, laboratories detected 32,000 cases of MDR-TB and identified many more patients with susceptible TB, enabling the timely administration of effective anti-TB treatment.

The increasing trend in cases reported has continued as a result of strengthened project management, engaging laboratory staff, the efforts of EXPAND-TB consultants, and the support given to supranational TB reference laboratories and national counterparts. Additional funding has enabled further technical assistance through the existing expertise network to accelerate the roll-out of Xpert MTB/RIF in 10 project countries. During the course of the year, 37 out of 47 Xpert testing sites have been established. Combined with referrals to central reference laboratories, the introduction of this technology has further strengthened networks and increased demand for confirmatory testing.

After five years of operation, the EXPAND-TB project is on track to meet its ambitious targets, with 72,000 MDR-TB patients already diagnosed. It has been – and continues to be – a major driver in the unprecedented expansion of diagnosis and treatment of MDR-TB. In 2012, nearly one third of globally-notified MDR-TB cases were being detected using rapid TB diagnostics with support provided through EXPAND-TB. By 2012, the number of MDR-TB cases being notified in the 27 project countries had tripled to over 35,000 cases, compared to a total of 10,008 cases in 2008, prior to the start of the project. Political commitment was secured and the new TB diagnostic tools have been incorporated into national policy in all 27 countries. The project has also made a significant contribution to building human resource capacity and mentoring with over 2,000 laboratory personnel trained, including technicians, laboratory managers, health workers, and clinicians. This results in strengthened laboratory capacity and facilitated introduction and widespread use of WHO-recommended TB diagnostics.

FIND partners: Ministries of Health in project countries, World Health Organization (WHO), Switzerland; Stop TB Partnership's Global Laboratory Initiative and Global Drug Facility, Switzerland

Key funder(s): UNITAID, Switzerland

Sustaining gains from EXPAND-TB project

Transitioning strategies underway in pilot countries

EXPAND-TB has entered its last phase and transitioning activities are underway. The gains from the project need to be sustained and diagnostic capacity should be further expanded. We engaged with the other partners in the project to develop a model for a

transitioning strategy to ensure project sustainability. After being piloted in Djibouti, the model was implemented in Tanzania, Uganda, Ethiopia, Lesotho, Moldova, and Kyrgyzstan in 2013. The experience will be used as a model for implementation across all 27

countries over the remainder of the project's duration in order to ensure a smooth transition of the project back to local ministries of health and partners. Four countries have already committed to covering the cost of commodities through other resources.

Identifying alternative sources of funding is key to ensuring sustainability. Thirteen of the project countries (Azerbaijan, Bangladesh, Belarus, Cameroun, Djibouti, Georgia, Haiti, Indonesia, Kazakhstan, Lesotho, Rwanda, Uganda, and Tanzania) have been selected for the initial phase of implementation of the transitioning strategy based on overall progress, outcomes, and feasibility of sustaining its activities beyond EXPAND-TB support. Transitioning of these countries' laboratories to be independent is expected to be completed by the end of 2014. Reference laboratories in these countries are now well-established, equipped, and upgraded to ensure appropriate levels of biosafety, and personnel are proficient in the use of the diagnostics. To maintain diagnostic capacity, project partners are holding consultations with national programmes and their

partners. The established diagnostic capacity will be sustained, notably, through the new funding model of the Global Fund.

Fourteen of the EXPAND-TB project countries (Cote d'Ivoire, Ethiopia, India, Kenya, Kyrgyzstan, Mozambique, Myanmar, Peru, Moldova, Senegal, Swaziland, Tajikistan, Uzbekistan, and Viet Nam) will not be ready for reliable transition – the risks of backtracking and losing gains are high. At the time of writing, a no-cost extension of the EXPAND-TB project until the end of 2015 was granted by UNITAID, which will enable laboratory operations to continue without interruption. These countries will then be eligible for support from the new funding model of the Global Fund.

FIND partners: Ministries of Health in project countries, World Health Organization (WHO), Switzerland; Stop TB Partnership's Global Laboratory Initiative and Global Drug Facility, Switzerland

Key funder(s): UNITAID, Switzerland

Strengthening Laboratory Management Towards Accreditation – SLMTA

Providing long-term support towards laboratory accreditation

New diagnostic technologies can only be implemented successfully within a well-functioning laboratory system. The FIND-CDC Cooperative Agreement Programme, 'Building Global Capacity for Diagnostic Testing of Tuberculosis, Malaria, and HIV through Laboratory Strengthening and Integration of Services under the President's Emergency Plan for AIDS Relief (PEPFAR)', is addressing this need and builds on FIND's considerable experience in implementing new TB diagnostics and building laboratory capacity in many diverse, resource-limited settings. FIND is successfully implementing the SLMTA (Strengthening Laboratory Management Towards Accreditation) programme developed by CDC and its partners. This is a structured and highly task-based approach incorporating training workshops, improvement projects, and follow-up visits. FIND introduced SLMTA (FOGELA in Spanish) in the Dominican Republic, where work has

primarily focused on implementing laboratory quality management systems and prioritizing laboratories in large hospitals with large maternal and child health programmes. The first Latin American regional Training of Trainers for SLMTA/FOGELA was held in Spanish in July and August of 2013. A FIND consultant was selected as a SMLTA Master Trainer for the region.

FIND has also developed a TB-specific programme based on SLMTA, which incorporates guidance and best practices with a specific focus on the needs of TB laboratories working towards international accreditation. The TB-specific programme based on SLMTA was piloted in April 2013 in Cape Town, and the first African regional Training of Trainers took place in Lesotho in November with participants from Ethiopia, Tanzania, Lesotho, Rwanda, Cameroon, and Kenya.

FIND partners: Centers for Disease Control and Prevention (CDC) country offices; Ministries of Health

Key funder(s): Centers for Disease Control and Prevention (CDC) under the President's Emergency Plan for AIDS Relief (PEPFAR), USA

Ensuring quality-assured TB diagnostic testing

A comprehensive approach to Xpert MTB/RIF quality assurance

One of the predominant activities of the FIND-CDC Cooperative Agreement Programme involves accompanying countries through the early implementation of new diagnostic tools. A particular focus has been placed on the roll-out of Xpert MTB/RIF, ensuring quality of testing through external quality assurance (EQA), routine monitoring of laboratory indicators, and supervisory visits to testing sites. Even with well-established guidelines, quality assurance continues to be poorly and inconsistently implemented. Leveraging our unique expertise in co-developing Xpert MTB/RIF, FIND is providing technical assistance to the ministries of health in a number of countries implementing this new tool, namely Haiti, Lesotho, Tanzania, and Viet Nam. To this aim, FIND has developed a comprehensive five-day Xpert MTB/RIF training programme. In 2013, the Xpert training package was made available in French, with translation by FIND, and in June, a training session was held in French in Haiti.

FIND accompanies countries through the early implementation of Xpert MTB/RIF by means of long-term country engagement with ministries of health.

We work together on phased implementation; we help develop comprehensive approaches to strengthen laboratory quality assurance and quality management systems; and we support country level adoption in a holistic fashion. FIND is contributing to a growing body of evidence around best practices for Xpert MTB/RIF implementation, including placement of instruments, patient populations, training, and practical and operational factors.

FIND, with partners, has evaluated EQA panels for Xpert in South Africa, and is supporting country implementation of CDC pilot EQA programme. We are also providing critical country coordination, feedback to laboratories, and links to corrective actions for quality improvements.

FIND partners: Centers for Disease Control and Prevention (CDC) country offices; Ministries of Health

Key funder(s): Centers for Disease Control and Prevention (CDC) under the President's Emergency Plan for AIDS Relief (PEPFAR), USA

Malaria

Final report of Round 4 RDT product testing published

Malaria RDT testing results show significant improvement in quality performance

The global programme for quality control (QC) of malaria RDTs has been coordinated by FIND and WHO since 2008. RDT manufacturers annually submit their products for testing with blood samples in the

specimen bank at the US Centers for Disease Control and Prevention. The published results form the basis for RDT selection by major procurement agencies and national malaria control programmes.

The final report of Round 4 RDT product testing was published in 2013. A comparison of results between RDTs submitted in previous rounds, which were re-evaluated in Round 4, has shown a significant improvement in RDT performance. This suggests that the results of the global RDT QC programme is stimulating manufacturers to improve their RDTs. Round 5 was initiated this year, with 42 out of 99 submitted RDT products accepted for testing. This was completed at the end of the year and the data analysis is scheduled for publication in early 2014.

To ensure long-term sustainability for this programme, current plans include the use of recombinant proteins as reference materials. A survey in seven countries was finalized with the purpose of gathering information about current policies and practices for RDT registration, as

well as to obtain feedback on the transition to a recombinant-based quality control programme. Preliminary data on equivalence testing on RDTs were presented to the WHO Expert Committee on Biological Standardization as part of the submission process for WHO endorsement.

FIND partners: Global Malaria Programme – World Health Organization (WHO), Switzerland; WHO Regional Office for the Western Pacific (WPRO); Research Institute for Tropical Medicine, the Philippines; Institut Pasteur du Cambodge, Cambodia, in collaboration with the National Center for Parasitology, Entomology and Malaria Control, Cambodia

Key funder(s): UNITAID, Switzerland; JSI Research & Training Institute, Inc., USA

Two-fold increase in RDTs submitted for lot testing

More RDT products are submitted to quality testing before being distributed in endemic countries

As part of FIND's quality control activities, the Lot Testing Programme aims to detect RDTs that perform poorly before they are sent to the field. To this end, the programme supports two regional lot testing sites in Cambodia and the Philippines. These have the capacity to carry out rapid and reliable quality control of RDT lots sent from anywhere in the world. The number of RDT lots submitted for testing to these sites in 2013 was twice as high as for the previous year. More than half the requests came from procurement agencies and about one third from manufacturers. All of them passed evaluation when screened.

The increase in the number of RDT lots submitted for testing and their generally high scores are offset

by a decrease in malaria prevalence in Cambodia and The Philippines. It is becoming difficult to obtain the required number of samples, and their replacement with recombinant proteins is becoming necessary.

FIND partners: Institut Pasteur du Cambodge, Cambodia, in collaboration with the National Center for Parasitology, Entomology and Malaria Control, Cambodia; Research Institute for Tropical Medicine, the Philippines; World Health Organization (WHO) Global Malaria Programme (GMP) and Regional Office for the Western Pacific (WPRO)

Key funder(s): UNITAID, Switzerland

Guide for implementation of malaria RDTs is now available

The product of a collaboration between multiple partners, this step-by-step approach to implementing RDTs breaks new ground

As national programmes undertake large-scale implementation of RDT-based diagnosis, the need for

guidance and research to implement best practices has increased. There is an abundance of information

available on the need for diagnosis with malaria RDTs, but guidance as to how this should be achieved is lacking. The Implementation Guide for malaria RDTs, coordinated by FIND and published in June, provides specific instructions on RDT incorporation into national malaria programmes. The Guide:

- provides direction for well-planned and effective parasite-based diagnosis using quality RDTs;
- ensures that cross-cutting aspects of other programmes are appropriately addressed in the planning and implementation of RDTs;
- supports the implementation of the WHO policy for the treatment of malaria, based on parasitological diagnosis.

A comprehensive 'toolbox' provides examples of budgets, work plans, supervisory checklists, diagnosis-specific malaria case management indicators, a fever

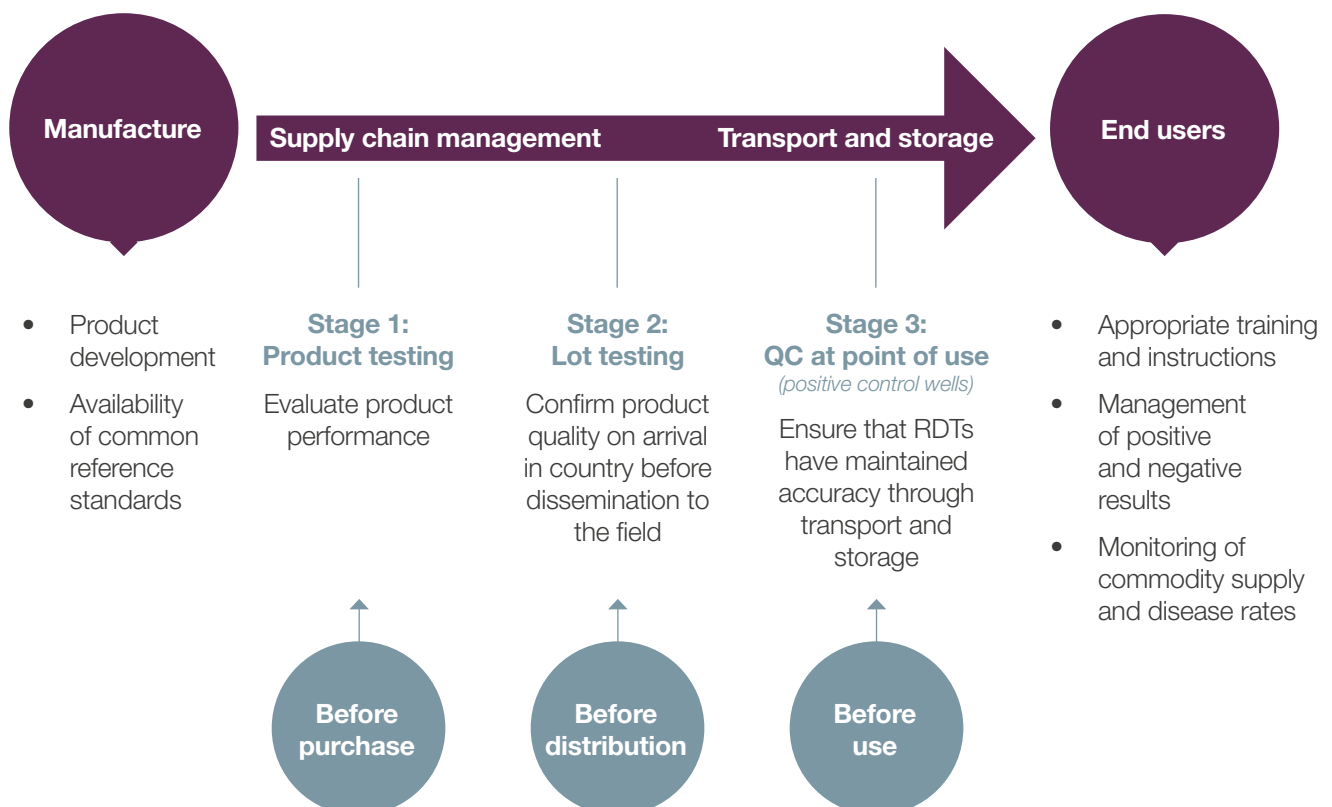
management algorithm, and guidance on transport and storage – these can be adapted to the needs of each national malaria control programme.

The toolbox is designed for personnel engaged in malaria programmes, donors, and public and private sector organizations with an interest in implementing a malaria parasite-based diagnosis agenda.

FIND partners: National Malaria Programmes of Uganda, Tanzania, Senegal and Zambia; Roll Back Malaria Partnership (RBM), Switzerland; Malaria Consortium, UK; Medical Care Development International (MCDI), USA; US President's Malaria Initiative (PMI), USA; KEMRI-Wellcome Trust Research Programme, Kenya; Pilipinas Shell Foundation, the Philippines; African Medical and Research Foundation (AMREF), Kenya

Key funder(s): Department for International Development (DFID), UK

Quality assurance of RDT-based diagnosis: Delivering a quality product and effectively using results



HAT & OND

Improved screening for HAT at lower cost

*1st generation RDT for *T.b. gambiense* HAT rolled out*

The ease of use of this test – which is low cost and requires no electric power – makes it a serious contender for improved screening for *T.b. gambiense* HAT.

FIND has negotiated an ex-works price of US\$ 0.50, which is lower than any other currently available test for screening HAT. The tests are packed individually, are stable at 40°C for at least 24 months, and are performed on fresh blood from a finger prick. In 2013, the test, SD BIOLINE HAT, was further evaluated at multiple sites in the Democratic Republic of Congo (DRC). Results showed that the new test was significantly more sensitive than the Card Agglutination Test for Trypanosomiasis (CATT), a screening test that has played a major role in controlling *T.b. gambiense* HAT over the last decades, and which is still widely used today.

Results of a cost-effectiveness study also conducted in the DRC has shown the new test to be more

cost-effective in detecting HAT cases than the CATT test for both active and passive screening. An innovative three-year project to introduce the test was launched in Uganda in July 2013. Comprising 197 health facilities that are implementing the new RDT, the project will involve all areas where *T.b. gambiense* sleeping sickness is reported. This project is expected to dramatically accelerate elimination of HAT through early detection of patients and interruption of disease transmission.

FIND partners: Governments of the Democratic Republic of the Congo (DRC) and Uganda; Institute of Tropical Medicine, Belgium; Standard Diagnostics, Republic of Korea

Key funder(s): Bill & Melinda Gates Foundation, USA; Department for International Development (DFID), UK; Republic and Canton of Geneva, Switzerland

Accelerated elimination of *T.b. rhodesiense* HAT

Clinical use of LED FM and LAMP technologies now formally adopted

The government of Uganda, with Makerere University, has been implementing a project to eliminate *T.b. rhodesiense* HAT using a strategy that combines:

- passive screening of patients
- active screening and treatment of infected livestock to eliminate their status as reservoirs of the disease
- control of the tsetse fly vector, using insecticides applied on livestock

Parasitological diagnosis of the disease in both livestock and humans is being done using the LED FM microscope, supplemented by the LAMP technology.

Towards the end of 2013, FIND signed an agreement with the Ministry of Health of Malawi to intensify the control of *T.b. rhodesiense* HAT by focusing on

early diagnosis of the disease and strengthening the diagnostic capacity of health centres adjacent to the Vwaza Marsh Game Reserve. Four health centres in the area of the park are to be refurbished and equipped to diagnose HAT and other prevalent diseases. Laboratory personnel will be trained on routine and LED fluorescence microscopy, as well as on LAMP. If the project is successful, this strategy of intensified surveillance around conservation areas will be recommended for replication in other HAT-endemic countries where conservation areas act as a source of infection.

FIND partner: Government of Malawi

Key funder(s): Department for International Development (DFID), UK; Federal Ministry of Education And Research (BMBF) through KfW, Germany; Swiss Agency for Development and Cooperation, Switzerland

Implementation of novel tools spurs early detection in patients

Intensified surveillance and control of HAT in Uganda

The signing of a three-year agreement with the Government of Uganda launched an initiative which, if successful, could lead to the elimination of *T.b. gambiense* HAT in the country, and serve as a model for other endemic countries such as Guinea, Chad, and South Sudan. The project includes the use of new tests developed with the support of FIND along with efforts to shorten the distance a sick person travels to obtain diagnosis.

The project is being implemented in 197 health facilities across the *T.b. gambiense* belt, in an approach that combines screening of suspected patients using a recently developed RDT, followed by confirmation of these cases by LED fluorescence microscopy. This is complemented with detection of parasite DNA

by means of LAMP. The project is an extension of the long-term relationship between FIND, Makerere University, and the Government of Uganda, and their other collaborations on diseases such as TB and malaria.

FIND partners: Government of Uganda; Makerere University, Uganda

Key funder(s): Bill & Melinda Gates Foundation, USA; Department for International Development (DFID), UK; Federal Ministry of Education And Research (BMBF) through KfW, Germany; Government of Uganda; Republic and Canton of Geneva, Switzerland; Swiss Agency for Development and Cooperation, Switzerland

Country presence

Building capacity for drug susceptibility testing in India

EXPAND-TB provides strong support to Revised National Tuberculosis Control Programme for expanding access to diagnosis of drug-resistant TB

India has one quarter of the global burden of tuberculosis. The country is on track to reach the 2015 targets for reductions in TB prevalence and mortality, and for several years treatment success rates have been above 85%. However, case notification still needs to be improved and the challenge of responding to the number of MDR-TB cases with new and rapid diagnostics is compounded by the need to ensure their proper implementation in upgraded laboratories. FIND has been operating in India since 2007 and continues to make a significant contribution to scaling up the delivery of strong programmatic management of drug-resistant TB (PMDT) under the Revised National TB Control Programme (RNTCP).

In this context, the UNITAID-funded EXPAND-TB project aims to expand and accelerate access to new and rapid diagnostic technologies in line with the National Laboratory Scale-up Plan. Line probe assay

(LPA), liquid culture and drug susceptibility testing (DST), and GeneXpert facilities are being established. As the lead technical and implementing partner for EXPAND-TB, FIND has been coordinating activities and managing operational implementation and monitoring of the project in 27 countries worldwide. In India, the project has continued to support the Government's goal to expand quality-assured, rapid diagnosis of TB and MDR-TB.

Among key accomplishments up to 2013, FIND India provided equipment, consumables, training, and technical assistance to establish 35 LPA facilities out of the targeted 43, and 23 liquid culture facilities out of 37. The remaining eight and 14 laboratories performing LPA and liquid culture respectively are expected to be established by the end of 2014. To provide decentralized DST, the EXPAND-TB Xpert project also supplemented laboratory capacity by establishing testing using Xpert MTB/RIF at 14 sites.

In addition, 18 Xpert MTB/RIF sites were developed by FIND India under a feasibility and assessment study supported by WHO.

Human resources training was supported by the International Centre of Excellence for Laboratory Training (ICELT), which was set up in 2011 at the National TB Institute in Bangalore. Seven national level training courses were conducted at ICELT ensuring training of 47 senior level laboratory staff in the

appropriate use of newer TB diagnostic technologies. Trainers at ICELT also facilitated onsite training courses as part of the activities supported by the Global Fund.

FIND partners: Government of India; World Health Organization (WHO), Switzerland; Stop TB Partnership's Global Laboratory Initiative and Global Drug Facility, Switzerland

Key funder(s): UNITAID, Switzerland

Providing universal access to drug resistant TB control services

The Global Fund project complements efforts towards achieving a national laboratory scale-up plan in India

Since 2010, FIND's interventions through the EXPAND-TB project have contributed to the development of a well-functioning laboratory network across India. As of 2011, The Global Fund to fight AIDS, Tuberculosis and Malaria (The Global Fund) has provided support to established laboratories to ensure sustainability and quality assurance of the facilities through improved infrastructure, technical support, and human resources.

The project has contributed to the functioning of LPA and liquid culture facilities established under EXPAND-TB by supplying additional specimen processing equipment for 38 labs and upgrading biosafety level 3 infrastructure for 17 sites. The project has provided

an additional 275 laboratory staff to the 38 sites to ensure continuous operation, and supported 32 onsite training sessions for 196 personnel. Training of technical laboratory staff in the working environment of their own labs remains a foundation towards achieving proficiency benchmarks and quality service delivery. Training on additional activities such as disease monitoring, infection control, biosafety, and laboratory management are contributing to quality assurance expertise.

FIND partners: Government of India

Key funder(s): The Global Fund to fight AIDS, Tuberculosis and Malaria (The Global Fund), Switzerland

Progress in diagnosis of MDR-TB in India

Exponential increase in MDR-TB case detection

As a result of combined efforts and initiatives, the detection rate of MDR-TB in India has been progressing significantly since 2010 and the country has been able to diagnose a greater number of patients than ever before. FIND India's laboratory strengthening activities have made a major contribution to achieve this result. In 2013, nearly 175,000 people at risk of MDR-TB were tested in the facilities established under various projects implemented by FIND India, while 23,700 patients were diagnosed with MDR-TB. 20,763 patients received appropriate treatment with second-line drugs under the national

programme. Based on data from the latest WHO Global Tuberculosis report, 90% of all MDR-TB cases reported in 2012 in the country were diagnosed in laboratories supported by EXPAND-TB.

With help from various funding and collaborative partners, FIND India has contributed to building the necessary laboratory capacity for rapid and quality-assured diagnosis of TB and MDR-TB. This has fulfilled a long-felt need, expressed by clinicians and public health experts, that appropriate MDR-TB treatment be initiated as early as possible.

Testing for TB among HIV-positive patients in Uganda

Introducing Xpert MTB/RIF as an initial test

FIND established its office and a TB research laboratory in Kampala, Uganda, in 2008. Since then, it has been the focal point for the organization's research and field activities in Africa. Efforts in 2013 have focused on early implementation studies for TB and malaria to facilitate and guide the scale-up of new technologies in the country.

Uganda is one of the 22 countries most affected by TB worldwide and has an equally high HIV burden. Over half of all TB patients are also infected with HIV; TB is the primary cause of death among people living with HIV/AIDS. FIND, in partnership with the National TB and Leprosy Programme (NTLP), is working to improve detection and treatment in Uganda. We have successfully completed a TB-REACH wave 2 project, aimed at introducing Xpert MTB/RIF as an add-on test to microscopy to improve the detection of smear negative TB in people living with HIV. The project enabled testing for TB for approximately 7,500 HIV-positive individuals who had previously undergone TB sputum microscopy examination. Of these, over 1,000 patients were diagnosed with TB using Xpert MTB/RIF. The goals of the technical assistance programme under TB-REACH are to provide strategic guidance with respect to policy review, algorithm implementation, and the preparation of guidelines.

A TB-REACH wave 3 project launched in 2013 builds on the previous project to improve access to testing with Xpert in isolated communities. In collaboration with NTLP and The Union, the project is introducing Xpert MTB/RIF as an initial test for the diagnosis of TB among HIV-positive patients as per WHO recommendations. The study involves seven HIV-TB care facilities; six are in Kampala district, and one is at

Kasese regional hospital. The goal is to detect 3,966 additional cases of TB co-infection over a period of two years. Every patient visiting health facilities will be asked, irrespective of the reason of their visit, if they are suffering from one of the key symptoms presumptive of TB. This helps identify cases that would otherwise be missed.

A large component of this project includes innovative approaches to sputum transportation and to ensuring uninterrupted power supply. All sites involved will soon be using a shared electronic TB-unit registry, which can be accessed using smart phones. This improves data quality and ensures prompt access and easy aggregation for timely case notification and management. The registry is being designed so that it will be possible to scale up its use in the future. To further increase access to the services delivered, the project uses local 'boda-boda' motorcycles to transport patient samples to referral sites at no cost to the patient.

In the first six months of operation, 2,684 individuals were tested; 542 were found to be TB-positive and an additional 46 were diagnosed to be resistant to Rifampicin. Preliminary data show that the number of MDR-TB cases detected is higher than estimated. The project will continue to gather further information, which could guide future evidence-based policy decisions by the Ministry of Health.

FIND partners: National TB and Leprosy Programme, Uganda; The Union, France

Key funder(s): Stop TB Partnership TB-REACH, Switzerland

FINANCIAL INFORMATION

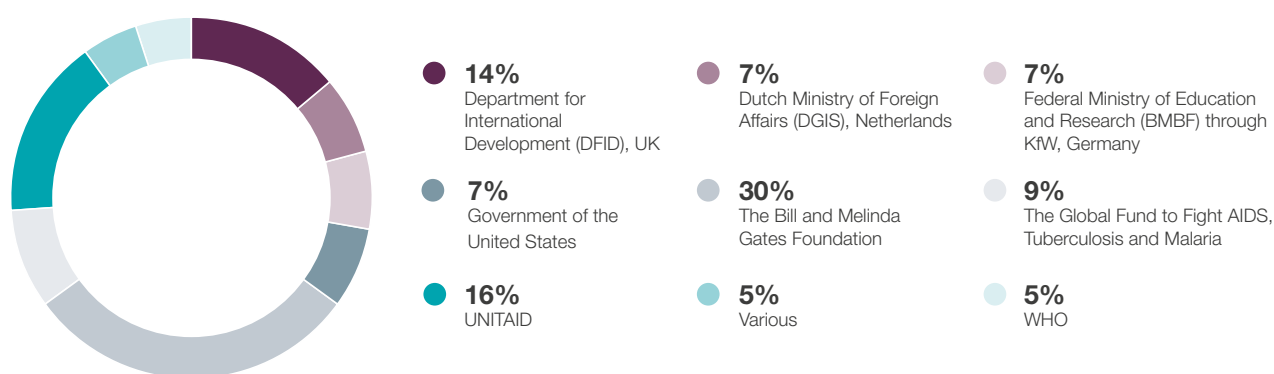
Financial Statement
for the Year ended 31 December 2013
and Report of the Statutory Auditor

SUMMARY

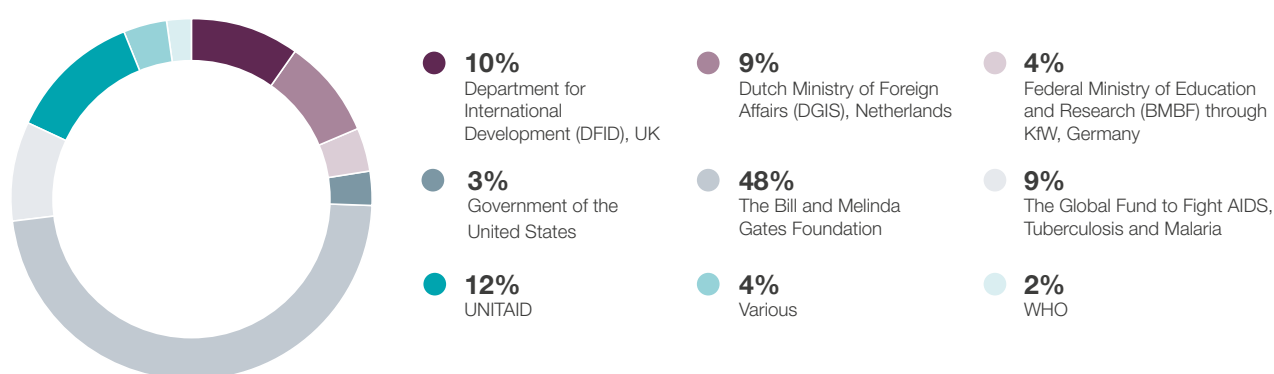
In 2013, FIND reached \$27 million in programmatic expenditure, an increase of 11 % compared with 2012, mainly driven by greater Malaria and Human African Trypanosomiasis activities. In 2013, contributions from donors and other income brought the level of revenue

to \$32 million generating an excess of revenue over expenditures of \$2.3 million. This excess included an exceptional unrestricted contribution of \$1.7 million from a major donor. At the end of 2013, FIND closed with an accumulated surplus of \$0.7 million.

2013 Revenue by Donor



Cumulative donations committed to FIND and/or received in 2013



Statement of revenue and expenditure for the year ended 31 December 2013

(all amounts in US dollars)

	Note	2013	2012
REVENUE			
Grant revenue	5, 6	32,252,996	33,097,887
Sundry income		225,233	106,009
Total revenue		32,478,229	33,203,896

	Note	2013	2012
EXPENDITURE			
Programme services			
Tuberculosis		15,530,926	14,811,112
Human African Trypanosomiasis		2,405,929	1,729,591
Malaria		4,400,746	2,950,748
Human Immunodeficiency Virus		1,383,295	1,344,782
Other/cross disease		3,330,873	3,559,199
Total programme services		27,051,769	24,395,432
Supporting Services			
Information & communication		42,060	58,988
Governing & advisory bodies		50,680	80,078
General administration		1,814,214	3,096,224
Finance & service expenses		1,150,134	1,062,217
Depreciation & amortization		53,674	104,944
Total supporting services		3,110,762	4,402,451
Total expenditure		30,162,531	28,797,883

Excess (deficit) of revenue over expenditure for year		2,315,698	4,406,013
Accumulated surplus brought forward		(1,621,481)	(6,027,494)
Accumulated surplus (deficit) carried forward		694,217	(1,621,481)

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

Balance sheet as at 31 December 2013

(all amounts in US dollars)

	Note	2013	2012
ASSETS			
Current assets			
Cash and cash equivalents		22,848,325	8,458,675
Accounts receivable		880,750	2,721,281
Prepayments		560,594	316,506
Total current assets		24,289,669	11,496,462
Non-current assets			
Fixed assets	4.1	36,684	90,358
Rental guarantee deposit		211,230	210,171
Total non-current assets		247,914	300,529
Total assets		24,537,583	11,796,991

	Note	2013	2012
LIABILITIES AND CAPITAL			
Current liabilities			
Accounts payable		3,537,818	1,042,369
Accrued expenses		649,269	1,265,401
Deferred revenue		19,615,849	11,070,272
Total current liabilities		23,802,936	13,378,042
Capital and reserves			
Capital	10	40,430	40,430
Accumulated surplus (deficit)		694,217	(1,621,481)
Total liabilities and capital		24,537,583	11,796,991

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

Cash flow statement for the year ended 31 December 2013

(all amounts in US dollars)

	Note	2013	2012
Excess (deficit) of revenue over expenditure for year		2,315,698	4,406,013
Add back non-cash charge - depreciation & amortization		53,674	104,944
		2,369,372	4,510,957
Cash flows - operating activities			
Increase (decrease) in deferred revenue		8,545,577	(7,093,334)
Increase (decrease) in accounts payable		2,495,449	(2,129,806)
Increase (decrease) in accrued expenses		(616,132)	(215,127)
(Increase) decrease in accounts receivable		1,840,531	(1,883,715)
(Increase) decrease in prepayments		(244,088)	115,655
(Increase) decrease in rental guarantee deposit		(1,059)	(10,403)
Increase (decrease) in unrealized exchange gains on foreign currencies		-	(120,958)
Net cash provided by operating activities		12,020,278	(11,337,688)
Cash flows - investing activities			
Acquisition of office furniture & fittings		-	-
Acquisition of computers & printers		-	(15,299)
Acquisition of faxes and telephones		-	-
Net cash used in investing activities		-	(15,299)
Net increase (decrease) in cash and cash equivalents for year		14,389,650	(6,842,030)
Cash and cash equivalents at start of year		8,458,675	15,300,705
Cash and cash equivalents at end of year		22,848,325	8,458,675
Net increase (decrease) in cash and cash equivalents for year		14,389,650	(6,842,030)

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

Notes to the financial statements for the year ended 31 December 2013

(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 and in Kampala, Uganda.

Since 2007, FIND India has played a key role in scaling up the delivery of strong programmatic management of drug-resistant Tuberculosis in India and in 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.

FIND Uganda was established in 2008 and is the focal point for FIND's research and field activities

in Africa. It is established as a non-governmental organization on the basis of a Memorandum of Understanding with the Republic of Uganda.

2. Significant accounting policies

2.1 Basis of presentation

The financial statements are prepared under the historical cost convention and in accordance with Swiss law.

2.2 Fixed assets

Fixed assets are recorded at cost and are depreciated under the straight-line method at 20% annually for office furniture and fittings, electrical installations, fax machine and telephones and 33.3% annually for computers and printers.

2.3 Patents

Certain patents were purchased as part of an agreement completed with a project partner early in 2004, and are subject to amortization under the straight-line method. At 31 December 2013, the patents were fully amortized.

2.4 Foreign currency

Accounting records are maintained in US dollars (USD). Revenue and expenditures in other currencies are recorded at accounting rates 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 2013, the rate of exchange used for the Swiss franc, the main foreign currency for 2013, was USD/CHF = 0.889 (2012 – 0.915). 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 restricted grants is recognized in the period to the extent that the related project expenses and recoverable overheads are incurred. Revenue on unrestricted grants is recognized on a cash basis. Interest income is recognized on an accruals basis and sundry donations are recognized on a cash basis. 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. Services rendered or goods transferred to FIND must exclude any monetary transfer and must be clearly identifiable to a FIND project.

2.7 Accounts payable

Accounts payable represents expenditure chargeable, for which invoices were not received for payment before the year-end.

2.8 Rental guarantee deposit

The deposits relate to the rental of FIND office premises in Geneva and India and are recoverable in accordance with the rental contract upon vacation of the premises.

3. Going concern

In 2011, FIND changed its revenue recognition policy to better reflect the funds available to the organization at the end of the financial year. This change in accounting policy resulted in a prior year adjustment of (USD 5,828,298) and an accumulated deficit of (USD 6,027,494).

In 2012 and 2013, FIND raised respectively USD 5 million and USD 1.7 million (USD 6.7 million in aggregate) from major donors. For the period ended 31 December 2013 there was a surplus of USD 2,315,698 thereby resulting in the accumulated deficit being eliminated.

Management forecasts another surplus for 2014 and sufficient cash to cover FIND's operations throughout the period. Accordingly, the issue of going concern previously discussed is no longer applicable.

4. Fixed assets

4.1 Fixed assets as at 31 December 2013 were as follows:

	2013	2012
AT COST		
Office furniture & fittings	118,790	118,790
Computers & printers	353,723	353,723
Electrical installations	12,392	12,392
Fax machine & telephones	41,965	41,965
Total cost	526,870	526,870
	2013	2012
LESS		
Accumulated depreciation	490,186	436,512
Net book value	36,684	90,358

Fire insurance coverage as at 31 December 2013 was USD 112,486 (2012 – USD 109,250).

5. Donations received

During 2013, the following grants were received from donors (other currency amounts are converted to USD at exchange rates on date of receipt):

	2013	2012
The Global Fund to Fight AIDS, Tuberculosis and Malaria	11,143,449	135,279
The Bill and Melinda Gates Foundation	9,867,823	10,884,824
Department for International Development (DFID), UK	4,467,576	2,544,937
Dutch Ministry of Foreign Affairs (DGIS), Netherlands	3,419,188	1,785,711
UNITAID	3,345,831	-
Australian Department of Foreign Affairs and Trade	2,408,444	-
WHO	2,390,186	1,545,433
Government of the United States	1,880,575	2,210,961
Federal Ministry of Education And Research (BMBF) through KfW, Germany	1,767,558	3,133,886
Swiss Agency for Development and Cooperation	892,857	-
UBS Optimus Foundation, Switzerland	322,581	491,188
JSI Research & Training	254,167	275,000
TI Pharma	150,313	91,918
Republic and Canton of Geneva	64,516	-
Intellectual Ventures Management LLC	46,535	-
DNDI	39,113	-
European Union	19,434	1,000
Global BioDiagnostics	-	50,000
Becton Dickinson and Co	-	15,584
Total contributions received	42,480,146	23,165,721

Donor agreements in effect as at 31 December 2013 provide for a total of USD 55.8 million to be paid to FIND between January 2014 and December 2018.

6. 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:

	2013	2012
Human African Trypanosomiasis	184,300	248,605
Malaria	392,948	14,250
Human Immunodeficiency Virus	2,844,273	-
Other/cross disease	492,129	535,278
Total donations in-kind	3,913,650	798,133

In the 2012 comparative figures, donations in-kind were included under Grant Revenue and as expenditure under Programme Services.

7. Project partners

Payments to project partners during 2013, under contracts signed up to 31 December 2013, totalled USD 9,792,064 (2012 – USD 6,029,279). Commitments at 31 December 2013 for future payments under those contracts total USD 5,409,253 (2012 – USD 2,841,352).

8. Pension fund liabilities

USD 28,329 was due to the pension fund as at 31 December 2013 (2012 – USD 82,262).

9. Rent commitments

At 31 December 2013, FIND had future rent commitments totalling USD 385,000 up to 30 June 2014 (2012 – USD 1,089,000 up to 30 June 2014).

10. Funds

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.

11. Events subsequent to 31 December 2013

No events occurred subsequent to 31 December 2013 which could have a material impact on the understanding of these financial statements.

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 Financial Statements

As statutory auditor, we have audited the accompanying financial statements of the Foundation for Innovative New Diagnostics (FIND) presented on pages 45 to 51, which comprise the statement of revenue and expenditure, balance sheet, cash flow statement and notes for the year ended 31 December 2013.

Board of the Foundation's Responsibility

The Board of the Foundation is responsible for the preparation of these financial statements in accordance with the requirements of Swiss law and the charter of the Foundation. This responsibility includes designing, implementing and maintaining an internal control system relevant to the preparation of 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 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 financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, 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 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 financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

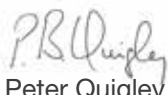
In our opinion, the financial statements for the year ended 31 December 2013 comply with Swiss law and the Charter of the Foundation.

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 83b Civil Code (CC) in connection with article 728 Code of Obligations (CO)) and that there are no circumstances incompatible with our independence.

In accordance with article 728a para. 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 financial statements according to the instructions of the Board of the Foundation.

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

Deloitte SA

Peter Quigley
Licensed Audit Expert
Auditor in Charge



Joelle Herbette
Licensed Audit Expert

Geneva, 2 April 2014
PBQ/JOH/jh

Enclosures:

Financial statements (statement of revenue and expenditure,
balance sheet, cash flow statement and notes)

PUBLICATIONS

Tuberculosis

1. Tuberculosis screening by tuberculosis skin test or QuantiFERON Gold In-Tube assay among an immigrant population with a high prevalence of tuberculosis and BCG vaccination by Painter JA, Graviss EA, Hai HH, Nhung DTC, Nga TTT, Ha NP, Wall K, Loan LTH, Parker M, Manangan L, O'Brien R, Maloney SA, Hoekstra RM, Reves R. PLoS ONE 8(12): e82727. doi:10.1371/journal.pone.0082727
2. Comparative Evaluation of GenoType MTBDRplus Line Probe Assay with Solid Culture Method in Early Diagnosis of Multidrug Resistant Tuberculosis (MDR-TB) at a Tertiary Care Centre in India by Yadav RN, Singh BK, Sharma SK, Sharma R, Soneja M, Sreenivas V, Myneedu VP, Hanif M, Kumar A, Sachdeva KS, Paramasivan CN, Vollepore B, Thakur R, Raizada N, Arora SK, Sinha S. PLoS ONE 8(10): 10.1371/annotation/e90efdb7-91c1-45f0-ae98-a88fcb407acc. doi:10.1371/annotation/e90efdb7-91c1-45f0-ae98-a88fcb407acc
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A photograph of a woman with dark skin and a black headband, wearing a purple sweater, smiling and holding a young child. The child has dark skin and small braids, wearing a white t-shirt and grey patterned leggings. The woman is holding a black plastic bag in her left hand. In the background, other people are visible, including a man in a white shirt and a woman in a pink shirt. The setting appears to be outdoors, possibly in a community center or a public space.

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