

2011

Activity Report

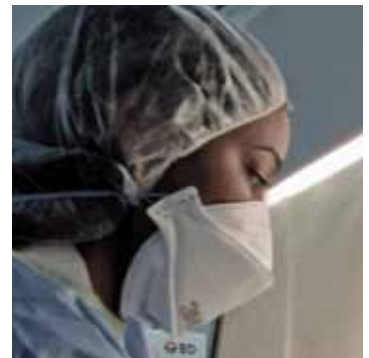


Our vision is of a world where everyone has equitable and timely access to high quality and affordable diagnosis.

Our 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.

2011

Activity Report





FIND's rationale

FIND was set up to address some of the market failures that have resulted in the paucity of appropriate diagnostics in disease-endemic countries. FIND's area of expertise is in the development of innovative tools that are readily field-applicable, with significant impact in low-resource settings. FIND's aim is to demonstrate the early impact of improved diagnostics, and provide technical support for the introduction and implementation of these into national health systems. The process requires bringing together knowledge of the needs on the ground with technological know-how, and a sound understanding of the intricacies of diagnostics development.

Table of contents

On course towards new discoveries	4
<i>Dr Gerald H. Möller, Chairman of the Board</i>	
Releasing the potential of a winning formula	6
<i>Philippe Jacon, Chief Executive Officer</i>	
FIND in 2011	8
Key achievements and projects	12
Tuberculosis	12
Malaria	18
HAT & Other Neglected Diseases	22
Early implementation projects	26
Board of Directors	29
FIND in figures	30

On course towards new discoveries

Dr Gerald H. Möller, Chairman of the Board



This has been a year of significant achievement as well as a year of transition into, what I would call, the maturity stage in the life of FIND. We will soon reach our tenth anniversary and when I look back at those “start-up” days in 2003, I cannot but be proud of what the team and

its partners have achieved in such a relatively short space of time. However, we can't become complacent and as we embark on a new phase of growth, we need to focus our efforts and become more selective in deciding where and why we invest our energies.

Faithful to our core values

Our consistency and growth owe much to our core values, to which we have remained faithful from the start. From the beginning, excellence in quality has been our badge of distinction. Equity is another value; we have to ensure the product of our research and development is accessible to all levels of the health system and must be affordable in resource poor settings. We place value in our contribution to global health which, without effective and appropriate diagnostics and their technological evolution, could not progress. And, lastly we need to keep our feet firmly on the ground and close to those communities where diagnostics can have the greatest impact – diagnosis as close to the point of care as possible. These core values can be summed up in four words: excellence, equity, technology and impact.

Significant achievements – pushing into new territory

Our main achievements in the course of 2011 are central to this publication; I will just mention what I consider to be the highlight in each of the disease areas in which we operate.

For Tuberculosis, the Xpert MTB/RIF automated molecular test for TB and drug resistance stands out in my opinion as a perfect example of what a PDP is designed to do – develop products in partnership. It puts TB detection onto a new and higher technological level and represents a true innovation.

In the case of malaria, a number of diagnostic products do not reach acceptable quality levels. We have worked with WHO to address this issue and are building a sustainable quality assurance system to ensure that febrile patients receive accurate diagnosis and appropriate treatment. Our message to industry as well as to donors is that we shall not compromise on quality.

With Human African Trypanosomiasis (HAT) we have moved onto a new technology platform and are getting close to the introduction of a patient-friendly rapid diagnostic test. We are also starting to work in two other neglected disease areas: Leishmaniasis and Chagas disease.

Managing our path to growth

At the end of the year, we started work on a new five-year strategic plan for implementation from 2012 with the objectives of strengthening our leadership position and earning our place as a PDP of choice and a trusted partner. We also recognize that this is the time for a cultural shift in our organization, whether this is in accountability, customer service or transparency. As we grow, we need to ensure we are an employer of choice providing a motivating working environment and lastly, we must continue to build up our long-term financial sustainability. These are the broad objectives that will underpin FIND at least over the next five years.

A transition in leadership

FIND has been led and inspired since 2003 by Giorgio Roscigno. Under his leadership FIND has spearheaded some of the most significant advances in diagnostics for the developing world. We can be thankful to him for where we are today. Giorgio left us at the end of 2011 to take up a new challenge close to his heart; the strengthening of laboratory capacity as an essential factor in the implementation of diagnostic tools. He is now part of the team leading the African Society of Laboratory Medicine to which I am sure his contribution will be invaluable. Our new CEO, Philippe Jacon, who joined us at the end of 2011, has my full confidence to implement the transition in our organization that is now timely. Philippe comes to us with a strong background in the diagnostics industry and lately led the European Diagnostics Manufacturers Association.

Our Board has not remained static either. We have increased its breadth of experience with the appointments of Mark Kessel, co-founder of Symphony Capital LLC, a private equity firm investing in the clinical development of biopharmaceutical companies and Gene Walther, Deputy Director – Diagnostics of the Bill & Melinda Gates Foundation. I expect the Board to become more active in fund raising and in nurturing our relationships with our donor partners. The work of the Board will also be complemented by the contribution of a new scientific advisory board to be established in 2012. The full Board composition as of the date of this publication can be found at the end of this report.

Confidence in the promise

I do believe FIND is in a position to build on its strengths and reach new heights. We have established solid foundations for the organization, we have a constellation of trusted partners in R&D and our donors have reaffirmed their belief in the direction we are taking. This 2011 Review demonstrates that we are achieving results that make a difference and gives me the confidence to say that we remain true to our promise to deliver quality diagnostic solutions where and to whom they are most needed.

Releasing the potential of a winning formula

Philippe Jacon, Chief Executive Officer



Diagnosis – the first step of an intervention

An accurate diagnosis for whatever disease or medical condition is key to the administration of appropriate treatment or medicine and in the case of infectious diseases it reduces the emergence of new resistant strains. This statement of

the obvious has not always been understood, especially in resource-poor settings where health systems lack the administrative or political instruments to control or supervise the market for diagnostics and drugs. The use of inefficient diagnostic tools is an unacceptable situation that continues to deny treatment to millions and even proves fatal to countless thousands.

Of equal importance, diagnostics allow the measurement of the impact of the programmes put in place to fight the various diseases. It gives us a baseline and tracks progress. Indeed, you cannot manage what you cannot measure.

The global healthcare community, represented by the WHO and composed of national health ministries, NGOs, donor institutions, R&D establishments and, in the last decade, a growing number of public-private partnerships, is seriously addressing the global health challenge according to their various areas of competence. At FIND, we believe we occupy a particularly important position in the healthcare continuum – there is no proper health intervention without the proper diagnosis.

The winning formula

I believe that the product development partnership (PDP) model has proven to be a winning formula whether this is in the area of vaccine research, drug development or diagnostic tool innovation as we practice it at FIND. We have had our successes and there will be more to come. However, it is how we manage our PDP that will be the final determinant of our achievement or winning formula. For that to happen we must constantly fine-tune our mode of operation and ensure we derive the full potential that I know we are capable of delivering.

Our Chairman has mentioned the objectives of our five-year strategic plan; the four areas where we will concentrate our energies:

- Our position in the value chain will focus on the five midstream phases, from concept development and feasibility all the way to capacity building. We must also expand our partnership base.
- In the last couple of years our technology platforms have demonstrated they have applicability across more than one disease area. We will adopt a platform strategy that focuses on emerging technologies and leverage existing ones such as GeneXpert and LAMP. Our platform potential also allows us to consider neglected diseases such as Leishmaniasis and Chagas into which we are now moving.
- Our donors have been both “faithful and generous”, and I want to take this opportunity to thank them all for their invaluable support, yet we are living in a tough economic environment that will require us to expand and diversify our donor base.
- Finally, in a fast-moving world in which communication plays such an important role, we must increase our “share of voice” in the environment in which we operate.

One technology for several diseases

On the following pages we provide an overview of the many projects that have been the focus of our attention in 2011. I consider the potential of multi-disease platforms to be one of our most promising developments. For example; the GeneXpert technology can also be used to diagnose sexually transmitted diseases such as HIV and CT/NG (*Chlamydia trachomatis/Neisseria gonorrhoea*). Likewise, the LAMP platform is now used in all three of our disease areas and is being adapted to leishmaniasis and Chagas. However, the medical technology is only one dimension of our work. We must remember the patient and the context – the healthcare system and the setting (e.g. rural, urban). Therefore, we must turn our attention to the rural realities of poor economies, as well as to the urban poor in more affluent societies.

Moving ahead with confidence

A major challenge is the management of our growth both in terms of people and activities, and adapting our business model to new realities. Although FIND has now reached maturity, we have not yet integrated this maturity into all of our standard operating procedures. In the immediate future, this is one of my key priorities.

Since taking up my position, I have undertaken a number of “quick fixes” in our management procedures and longer-term change-management measures will come online in 2012. We have strong and motivated teams in Geneva, Kampala and New Delhi and a wide network of consultants and partners sharing our vision. I am counting on them to ensure that FIND maintains its leadership in the development and early implementation of affordable diagnostics in low-resource settings.

With FIND’s five-year plan as our guide, I share in the confidence of our Chairman. Only by unleashing the full potential of our PDP as a “winning formula” will we be able to confirm confidence in our promise and expand the frontiers of diagnostics.



FIND in 2011

Over the past decade, PPPs (Public Private Partnerships) and PDPs (Product Development Partnerships) have had an impact on the healthcare arena that can best be described as revolutionary. This is particularly the case with respect to HIV/AIDS, tuberculosis and malaria and a number of so-called neglected diseases of poverty mostly prevalent in tropical regions. Whether they are searching for new drugs, vaccines or developing new diagnostic tools, all these partnerships share an additional “P” in common. The “P” for Promise.

FIND was established to develop and deliver innovative diagnostic tools for poverty-associated diseases, starting first with TB, then adding malaria and human African trypanosomiasis (HAT), also known as sleeping sickness. More recently, we have added leishmaniasis and Chagas disease. This document, which focuses mainly on achievements during 2011, testifies to the progress which has been made since FIND was established in 2003 and gives us confidence that the original commitment continues to drive our search for innovative and improved diagnostics.

TB tests – worldwide progress

Until a few years ago, no new TB tests had been developed in the public sector for a long while. The WHO did not have a mechanism for approving tests and little was being done to strengthen the capacity of laboratories, or to establish new lab capacity closer to the point of care, where patients are treated. Fair pricing mechanisms for tools in endemic coun-

tries were non-existent and there was no recognized public sector platform for the discovery and development of new TB tests.

By the end of 2011 all this has changed. There are a number of new TB tests in public sector use around the world and a WHO approval mechanism is in place. Already at a January 2008 meeting in Maputo, Mozambique, the representatives of governments, multilateral agencies, development partners, professional associations, and academic institutions, resolved to establish a global initiative to address laboratory challenges in services for tuberculosis, malaria and HIV.

Funding for TB diagnostics was significantly increased by agencies such as UNITAID, PEPFAR (US President’s Emergency Plan for AIDS Relief) and the Global Fund to Fight AIDS, TB and Malaria. A negotiated pricing mechanism is in place and interest in discovery and development continues to be strong.

Malaria – quality leads

Until recently, there was a large variation in the performance of rapid diagnostic tests for malaria being used in developing countries. No standard of quality control existed to ensure their safe and accurate use. The lowest price tests gained market share, however there was no reliable method to establish the quality and effectiveness of these tests, leading to low levels of confidence globally in RDTs.



FIND has been working with a number of partners to improve RDT quality control and overcome obstacles to their implementation, whilst also advancing the next generation of malaria diagnostic devices tailored to support elimination, and developing a strategy to address non-malarial fever. Our work on malaria diagnostics quality control directly influences most of the 99 countries that still have malaria transmission. Today, quality control programmes have fundamentally changed the market for RDTs and now forms the basis of the procurement policies of many funders. We have increased trust in RDTs and created a greater incentive for manufacturers to invest in quality. Further targeted products such as

a new blood transfer device and improved job aids provide substantial benefits in resource poor settings. These outputs have enabled national malaria control programmes and implementing agencies to work more effectively and efficiently towards malaria control.

HAT – new platforms open the way

Since the 1970's there had been no new test for HAT and little interest on the part of manufacturers to develop new technologies. HAT was not only neglected by the market, but also by endemic country governments who lacked awareness of the severity of the diseases.

Status of technologies and projects in FIND's portfolio as at year end 2011



TB&HIV

- Enzymatic detection of β lactamase
- HIV VL
- Volatile Organic Compounds
- Trans renal DNA (on hold)
- Antigen discovery
- Antibody detection
- Colorimetric culture

- TB LAMP (re-run)
- LPA second line

- TB LAMP Phase 1
- LPA second line (2012)

Scaling up - TB

- Rapid detection and speciation
- Liquid culture MTB
- Liquid culture DST
- Line probe assay
- Automated NAAT GeneXpert

HAT & OND

- HAT Antigen detection
- HAT staging markers and test of cure (blood)
- Chagas LAMP
- Leishmaniasis LAMP
- Leishmaniasis ELISA

- HAT Antibody detection
- HAT staging markers and test of cure (CSF)

- HAT LAMP

- HAT LED fluorescence microscopy

- HAT Advocacy

Malaria

- Roadmap for technical improvement of RDTs
- Malaria high throughput (HTP) LAMP
- (G6PD to be introduced; NMFI HTP screening in concept)

- Positive control wells
- Recombinant panels
- 20 μ l blood transfer device

- Field evaluation of existing RDTs (RDTs in pregnancy study)
- Malaria LAMP

- Obstacles to implementation of RDTs (evaporative cooler box)
- Product testing with reference materials
- 5 μ l blood transfer device



FIND is entirely focused on diagnostics, bringing together a critical mass of expertise in technology design with specialists in roll-out and implementation in the field. FIND's experience with diagnostic platforms designed to address solutions for several diseases, together with its public health expertise, enables it to bring an in-depth understanding of the quality assurance of diagnostics and their performance to ministries of health and other implementing agencies.

Horse and bike power boost TB detection in rural Lesotho

FIND has been working with partners to develop diagnostic tests for HAT that are inexpensive, easy to use, sensitive and specific enough to accurately detect cases of sleeping sickness, determine the stage of disease, confirm cure after treatment and detect relapses after a failed treatment. We now have the prototype of a first generation RDT for screening in communities and the first ever field-applicable molecular test for HAT. Currently, there is a pipeline of second-generation tests to support the elimination of this disease, which is a strong probability in the coming years. FIND's advocacy activities have resulted in 11 endemic countries now having dedicated HAT control programmes in place with committed budgets in support of this.

Other neglected diseases – expanding the portfolio

In addition to HAT, leishmaniasis and Chagas disease have now been added to our neglected diseases portfolio. Leishmaniasis is caused by the bite of a sand fly carrying a protozoan parasite of the genus *Leishmania*. Chagas disease, also known as American trypanosomiasis, is potentially life-threatening and mostly transmitted to humans by triatomine bugs (“kissing bugs”). FIND is expanding the LAMP diagnostic platform to include these neglected diseases.

Implementation – proof of concept

Detecting more disease cases, identifying them early, and rapidly spotting drug resistance are essential for improving individual patient health and reaching epidemiological impact targets. This requires universal access and timely as well as accurate detection of disease using contemporary diagnostic tests and innovative strategies that can reach the poorest and most vulnerable groups of patients. FIND concentrates on “early” implementation projects to verify its products under field conditions.



Lesotho, with both the second highest incidence of TB and the second highest HIV co-infection rate of adult TB cases in the world, presents the added challenge of its rural and mountainous terrain. Diagnosis is simply unavailable at most of the local health facilities, resulting in specimens needing to be transported to distant analysis centres. This leads to delays in diagnosis because of the difficulties associated not only with specimen transport but also with the reporting of results via paper-based forms in areas where there is no regular postal service. FIND has come up with a novel solution to overcome these logistic challenges in rural Lesotho. The sputum samples are first collected on horseback and then transferred to motorbikes who speed-up delivery to the final point of analysis at the TB culture and molecular facility at the Central TB Reference Laboratory in the capital city of Maseru. The expansion of the project in this new and unexpected manner has been made possible by a grant from TB REACH in 2010. So far, over 4000 TB suspects have been registered using the text messaging system. Of these, about 10% tested positive for TB.



The horse riders use Basotho ponies that are well known for their hardiness and sure footedness, as well as their docile temperament. They carry out two to three weekly visits reaching a total of 120 villages in the two districts where the project operates. The riders are supported by a team of village health workers, who screen patients for TB and use a novel text message system to track patients' test results. The health workers receive an alert as soon as the results are ready so that patients can be put onto TB treatment immediately. The system, which is based on open source software, has the advantage of very low operating costs.



Tuberculosis

Overview

Under FIND's leadership, TB LAMP (Loop-mediated Isothermal Amplification), a manual molecular test for tuberculosis, was registered in Japan and the first phase of Evaluation and Demonstration projects for the test in developing countries was completed.

Working with its partners, FIND continued to lead advancements in the area of TB drug resistance, as well as improvements in the ability to react quickly to findings during early implementation, a hallmark of an effective diagnostic development group. In providing technical support for a World Health Organization policy statement on Xpert[®] MTB/RIF, an automated molecular test for TB and drug resistance that is accurate and easy to use, FIND applied the results of a root-cause analysis based on field reports of slightly variable performance for rifampin resistance screening. This led to minor redesign (and retesting) of reagents and software to improve accuracy. In collaboration with the U.S. Centers for Disease Control, FIND played a major role in advising and guiding countries during the implementation of Xpert MTB/RIF, facilitating its rapid uptake. In December 2011, WHO endorsed the modified Xpert MTB/RIF cartridge that will provide countries with improved testing results. By the end of the year, over 600,000 Xpert MTB/RIF cartridges had been procured in the public sector in over half of the 145 countries eligible for concessional pricing. There are now hundreds of "early implementers of Xpert MTB/RIF",

having varied experiences and generating additional evidence on the effective use of this breakthrough diagnostic tool. Collectively, this information will be invaluable to guide the thousands of laboratories, hospitals and clinics around the world interested in using this technology. We also initiated methods to increase the robustness in packaging and calibration of both the TB LAMP and Xpert MTB/RIF tests.

This year, FIND made progress in increasing the capacity to diagnose multidrug-resistant (MDR) TB in high-burden countries through projects with three close partners. Resources from the Global Fund enabled us to strengthen the TB laboratory network in India, while our partnership with CDC enabled us to build up the Dominican Republic as a regional centre of excellence for laboratory systems strengthening, quality assurance and accreditation. In all, 58 of the 104 laboratories targeted under the EXPAND-TB project have been set up and training provided.

A simple assay (usable outside a reference laboratory) for direct colorimetric culture for TB and drug susceptibility testing completed prototype development and analytic assessment. There is hope that an upcoming feasibility study of this method could lead to its commercialization.

The line probe assay for extensively drug-resistant (XDR) TB underwent additional studies under FIND supervision in order to support a conclusive WHO position on its usage in the public sector.



Meanwhile, two new projects produced exciting new data. One using anti-LAM monoclonal antibodies to accurately detect TB in sputum, and a second generating species-specific substrates cleaved by the *M. tuberculosis* β -lactamase. This latter test offers hope for improving the sensitivity and simplicity of sputum examination for TB in microscopy laboratories.

TB Projects

Manual isothermal NAAT for TB (LAMP)

Together with our partner Eiken Chemical, a Japanese diagnostics company, we continued to work on loop-mediated isothermal amplification technology for TB detection in sputum in the form of a convenient kit format (Loopamp®) with a simple visual readout. Evaluation trials in several countries are being re-run with changes in field staff training and will be completed in 2012. The trials verify the efficacy of a specially designed sputum transfer device to ensure appropriate volumes of sputum transfer. A root-cause analysis of deviations from target performance, which resulted in improvements of the assay, was also undertaken.

Automated NAAT for TB (Xpert MTB/RIF)

In 2011, FIND and its partner, the U.S. based molecular diagnostics company Cepheid, made significant progress on the Xpert MTB/RIF system, a sophisticated product that maximizes ease of use for TB case detection and delivers additional data on drug sensitivity. The WHO followed up on its 2010 “road map” for scaling up use of the system with specific recommendations in a May 2011 policy statement. Meanwhile, the FIND and Cepheid teams agreed on changes to the microfluidics software and to the reagent, and a new set of Beta trials on the improved cartridge with assay files was launched in December. FIND has already negotiated with Cepheid a cost-plus pricing strategy for Xpert for 145 eligible countries, as well as an agreement to develop and implement a remote

calibration kit that will eliminate the need to send the modules back to a central geographical point.

Solid culture colour test for MDR-XDR TB

FIND has funded development work in Peruvian laboratories for a low cost colorimetric method to rapidly detect TB and screen for isoniazid, rifampin, and ciprofloxacin resistance on thin-layer agar plates. This *colour test* has now been put in an inexpensive kit format that can be safely used in basic regional laboratories currently using only microscopy. With the proof of concept established, FIND is working with the EU-funded project TB PANNET to carry out a prospective feasibility study in a regional laboratory in Brasov, Romania, and in a referral laboratory in Lima, Peru. This study will begin in 2012.

Study shows new TB test can reduce delays in diagnosis and treatment

(LONDON – 19 April) The results of a study by FIND and its partners, published today in the medical journal *The Lancet*, show that the new Xpert MTB/RIF test for TB and rifampicin resistance can effectively be used in low-resource settings to simplify access by patients to early and accurate diagnosis. While controlled studies have previously shown that the test can detect TB and drug resistance with high sensitivity and specificity, this is the first performance data from the intended point of use in district and sub-district health facilities in tuberculosis-endemic countries.

The study followed more than 6,500 patients at urban health centres in South Africa, Peru and India, drug-resistance screening facilities in Azerbaijan and the Philippines, and an emergency room in Uganda. The potential impact of the Xpert MTB/RIF test – which is co-developed by FIND, Cepheid and the University of Medicine and Dentistry of New Jersey – is a reduction in the morbidity associated with diagnostic delay, dropout and mistreatment.

Cepheid and FIND join to develop HIV viral load test

(SUNNYVALE, CA and GENEVA – 3 February) Cepheid and FIND have announced a new collaboration to accelerate the development of a rapid molecular test for the measurement of human immunodeficiency virus (HIV) viral load. The new test, which will run on Cepheid's GeneXpert® platform, is expected to complement the ground-breaking Xpert MTB/RIF test for tuberculosis (TB) and drug-resistance, which itself was the result of a collaboration between Cepheid, FIND and other partners.

Under the agreement, FIND will also obtain concessionary pricing in developing countries for Chlamydia and gonorrhoea tests that Cepheid is currently developing. The resulting programme is expected to deliver the benefits of rapid and accurate molecular testing for TB, HIV and STDs using a single diagnostic instrument in some of the most challenging geographies across the globe.

Antibody detection (serology POC test for detection of active TB)

Working with our partners, mBio Diagnostics Inc. in the United States and the German Natural and Medical Sciences Institute, we are seeking to determine a set of serodiagnostic TB antigens for diagnosis of active disease in final point of care assay format. All of the 61 target proteins discovered in a TB whole proteome screen that we previously completed have now been expressed and purified on a large scale, and a sizeable panel of sera from patients with confirmed active TB has been screened to generate a pool of sera strongly reactive with all proteins in a Luminex assay. The studies show significant improvements in dynamic range due to protein purification and further improvements resulting from use of Luminex bead technology, thereby opening the door for remaining issues to be investigated in further detail. Meanwhile, all tools and materials from the studies are being developed into a point of care test that will enter field evaluation in 2012.

Line probe assay (LPA), second line

With the goal of rapidly diagnosing extensively drug-resistant TB in laboratories that are using the line probe assays for MDR TB screening, FIND has been collaborating with partners on a LPA that detects the genetic mutations associated with resistance to fluoroquinolone antibiotics and to the second-line injectable drugs amikacin, kanamycin and capreomycin. In response to WHO requests for additional data in support of direct testing of sputum, we implemented further studies to demonstrate test performance in AFB smear-positive sputum specimens: data will be presented to WHO in 2012.

Enzymatic detection, *MTb* β -lactamase reporter assay

Studies undertaken with U.S. partners are showing promise for the development of a point of care TB detection product using reporter enzyme fluorescence. The work points to a significant opportunity to further enhance sensitivity and specificity of fluorometric substrates for the *MTb* complex, with the results to date indicating that there are excellent candidates for development into a low-cost, near-patient TB diagnostic.


Antigen detection (lipoarabinomannan, LAM, mycolic acids)

We have undertaken a number of studies to identify and validate pathogen-derived molecules for diagnosis of active disease to be translated into point of care assay format. This work has focused on various immunoassay techniques comprised of monoclonal antibodies generated against lipoarabinomannan (LAM) to confirm LAM as a biomarker in urine and sputum for TB case detection. While these efforts have yet to be conclusive, specific mycolic acids have been identified by FIND, in collaboration with the National University of Singapore, as additional biomarkers for TB case detection.

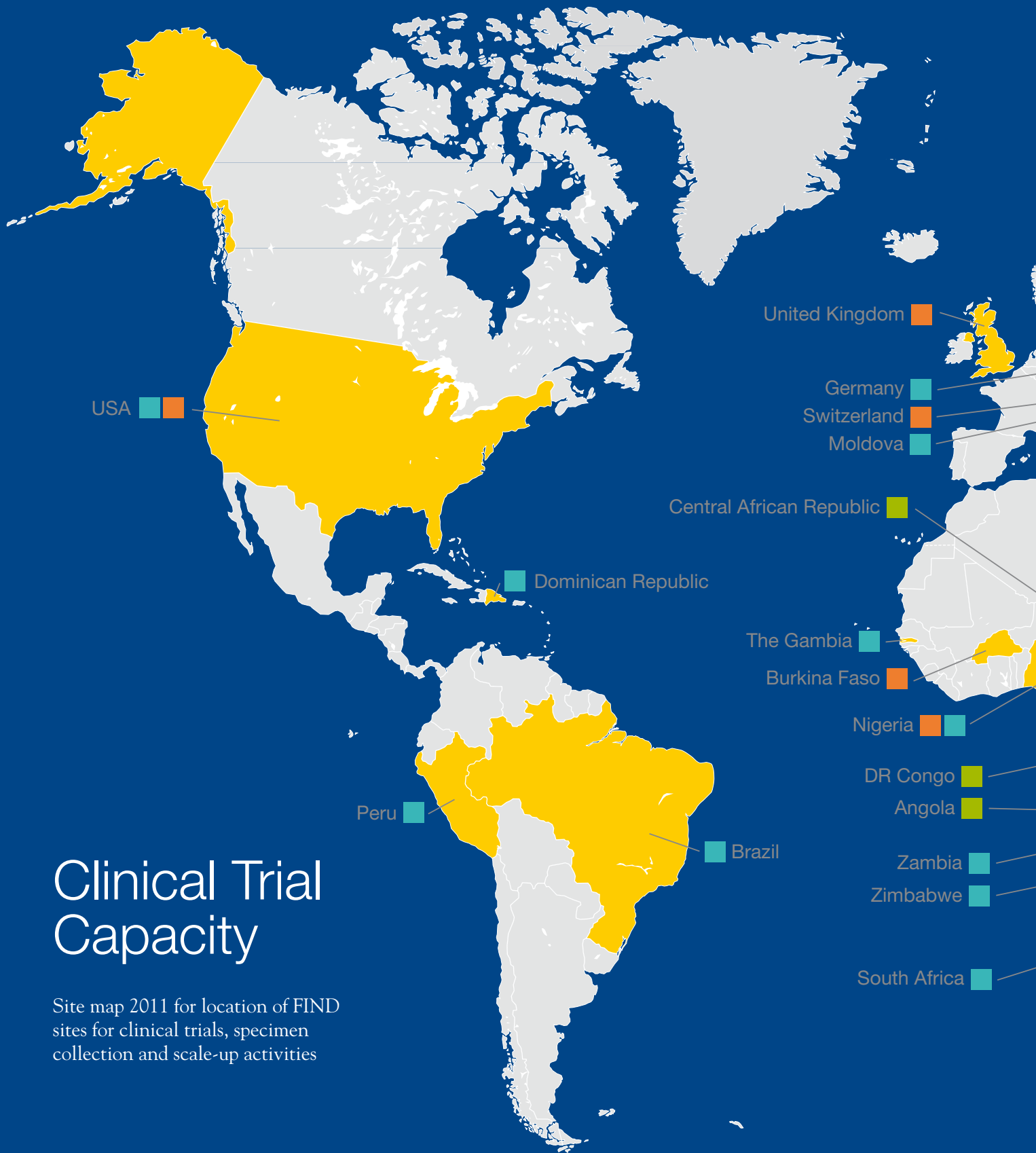


Automated NAAT for HIV viral load (Xpert VL)

FIND and Cepheid have also initiated the development of an HIV viral load assay to complement Xpert MTB/RIF mentioned above. During 2011, the partners completed the definition of product requirements, the clinical regulatory plan, the market requirements and intended use, the programme timeline and roles and responsibilities. The project's technical feasibility phase will conclude after successful testing of the prototype assay in internal Alpha trials in 2012, with a market launch envisioned for 2014. As part of the agreement, we have already negotiated a cost-plus pricing strategy with Cepheid for the same 145 countries that are eligible for the Xpert MTB/RIF product.



**By the end of the year, over
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Clinical Trial Capacity

Site map 2011 for location of FIND sites for clinical trials, specimen collection and scale-up activities

Programs:

■ TB
 ■ Malaria
 ■ HAT



Tajikistan

Kazakhstan

Kyrgyzstan

Ukraine

Nepal

South Korea

Azerbaijan

Turkmenistan

China

Sudan

Pakistan

India

Laos

Vietnam

Philippines

Djibouti

Kenya

Uganda

Rwanda

Tanzania

Myanmar

Thailand

Cambodia

Madagascar

Malawi

Mozambique

Swaziland

Lesotho



Malaria

Overview

Considerable progress was made in 2011 on malaria LAMP, a molecular diagnostic assay suitable for field use, with the completion of field trials in the Hospital for Tropical Diseases in London and at the clinic level in Uganda, while the LAMP assay completed manufacturing lock for CE-marking at Eiken Chemical Co. in preparation for general release in 2012.

Meanwhile, results of a new, safer blood transfer device for point of care tests were published and the device has been introduced at the country level for use with malaria RDTs. These new tools, which can vastly simplify and improve safety of RDT preparation by health workers, are now being taken up by commercial RDT manufacturers.

FIND continues to make progress in addressing reporting, stock management and resource planning challenges related to malaria RDT roll-out, using an SMS-based reporting system. Results of a pilot project initiated by FIND and the Uganda Ministry of Health were published, and nationwide scale-up by the Ministry is now underway.

We also continued to work in close partnership with WHO on improving quality control for RDTs, with the release of the Round 3 product testing report, bringing to over 100 the number of tests assessed by the programme. This report forms the basis for

procurement policy for all major international procurement agencies and programmes supported by the Global Fund. Development is well advanced towards transitioning the entire quality control programme to recombinant antigen tests, which will enable the global RDT evaluation programme to move to a long-term sustainable model.

Also in 2011, FIND agreed to a new joint initiative with University College London to assess feasibility of new approaches to field tests to detect glucose-6-phosphate dehydrogenase deficiency, a common enzyme deficiency that prevents safe use of drugs necessary to achieve elimination of *P. vivax* malaria and is identifying other key interventions towards improved quality of care in this area.

Malaria Projects

Manual NAAT for malaria (LAMP)

With LAMP technology showing promise as a tool for screening and treatment of malaria, FIND and its partners have developed a LAMP assay that requires only basic laboratory equipment and has 1 parasite/Micro-l sensitivity. This makes it a practical technology for use in both developed and developing world laboratories, all the way down to the clinic level. Field evaluations in London and Uganda were completed in 2011 and showed good equivalence to polymerase chain reaction, while assessment collaborations were established with research groups in



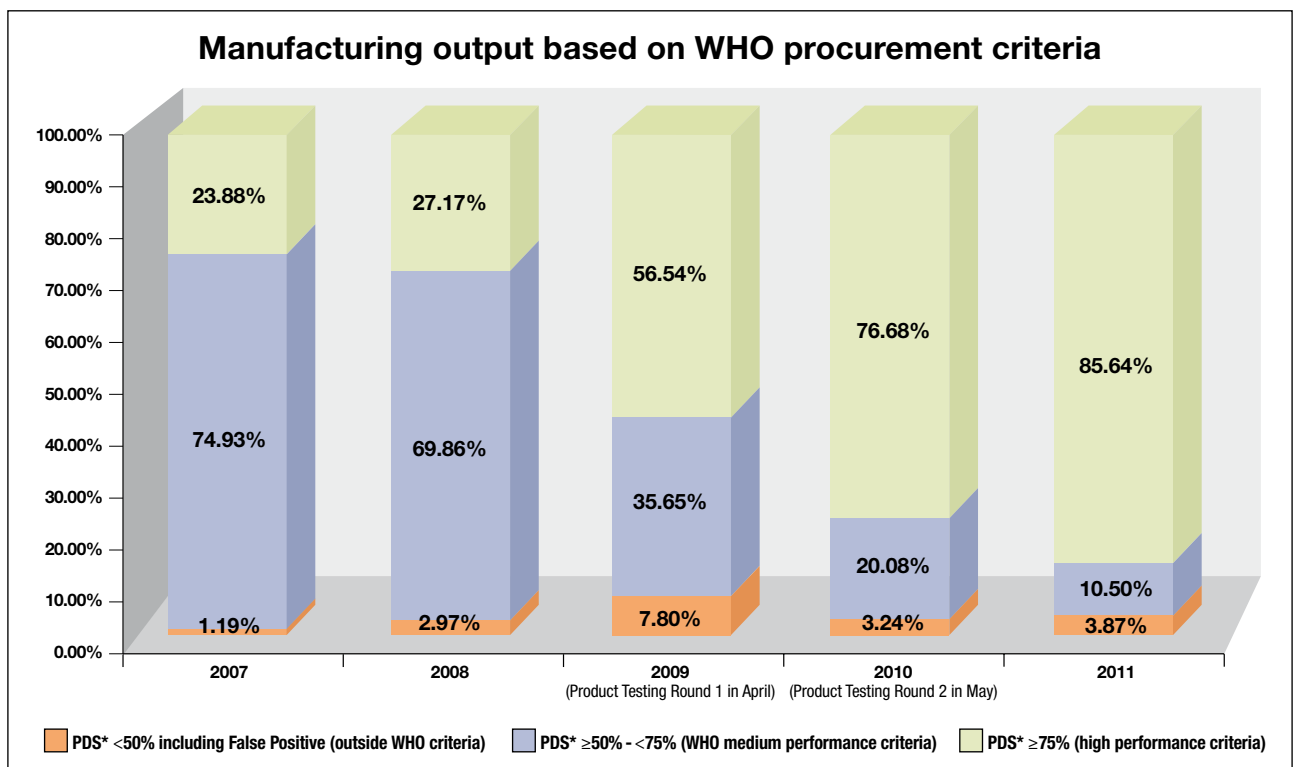
FIND/Sandra Incañona

Asia, Africa and South America. Work continues on simplifying the format and sample preparation, and we have initiated a project to adapt to a lower-cost, high-throughput format suited to screening populations in endemic settings as part of surveillance and elimination strategies, and to develop primers specific for non-falciparum malaria species. A final product is expected to be launched in 2012.

Technical improvements to RDTs

While rapid diagnostic tests (RDTs) for malaria have been in use for 15 years, the tests still show some deficiencies, particularly with regard to their reliability for detection of non-falciparum malaria.

Accordingly, FIND is working with several partners on technical improvements, particularly in terms of new targets and more stable antibodies. Progress in 2011 includes the completion of two projects, one to develop specific monoclonal antibodies against novel proteins – with promising reagents being made available for use in 2012 – and the other on assessing sequence polymorphisms and blood concentrations of the HRP2 protein and their impact on RDT sensitivity. Since there is some uncertainty about whether major gains can be made using lateral flow technology for RDTs, FIND is scouting new reagents and adaptations to the current format that may enable significant steps forward.



In the past few years there has been a radical transformation in the RDT market. The quality of the products now procured meets the highest standards in large part thanks to investments made by funding agencies in PDPs such as FIND. In a short time span, preliminary analysis of RDTs manufactured shows an overall increase in the proportion of high performing RDTs produced and a decrease in proportion of low performance RDTs (2007-2011).

Positive control wells

With increasing calls for the use of rapid diagnostic tests in areas where good-quality microscopy is unavailable, maintaining health worker and patient confidence in RDTs is critical to their adoption and use. To ensure that they meet requirements for quality and durability, particularly in the often harsh conditions of malaria-endemic regions, FIND and WHO have coordinated a global evaluation programme for malaria RDTs. In parallel, FIND and partners have been developing materials to enable a sustainable RDT evaluation into the future, based on evaluation panels and positive control wells (PCWs) containing recombinant antigens. PCWs will allow health workers to determine whether or not their RDTs are of sufficient quality to be used inpatient care while recombinant panels will enable countries, and manufacturers, to perform independent testing to global standards.

It is expected that a PCW suitable for more than 90% of the RDT market will enter field demonstration in 2013.

Evaluation of RDT-based screening in pregnancy

With pregnant women at particular risk of malaria infection and its consequences for maternal and foetal health, the use of RDTs for malaria in pregnancy remains one of the major gaps in diagnostic knowledge.

FIND is following up on evidence suggesting that detection of circulating parasite antigens by RDTs may give a reliable indicator of placental infections and thereby offer an accurate and practical way to identify pregnant women who will benefit from targeted therapy. Samples collected in 2011 during a clinical study in Burkina Faso and Uganda are undergoing analysis, which is expected to provide solid and timely data on the suitability of RDT-based screening as a replacement for the widespread but failed policy of intermittent presumptive anti-malarial treatment in pregnancy.

Acute febrile syndrome (AFS) / Non-malaria febrile illness (NMFI)

One of the consequences of the increased use of malaria RDTs and improved parasitological diagnosis is the realization that a large proportion of acute fever cases are turning out not to be due to malaria. In fact, little is known about the actual causes of these non-malaria fevers in malaria-endemic regions because research on the subject is scarce and laboratory tools are limited. Accordingly, FIND and a range of partners have completed a Non-Malaria Febrile Illness (NMFI) study, conducted in the Lao PDR and Cambodia, that has produced evidence to guide management of malaria parasite-negative acute fever and to assess the need for diagnostic tools applicable in field conditions.

Results of the study, along with a review of published literature and an interactive map to improve data availability, will be released in 2012. We are looking at specific interventions to improve population screening and detect markers of severity and responsiveness to treatment to advance the quality of early case management in this area.

Inverted cup blood transfer device (BTD)

The precise and safe transfer of blood from a patient to a point of care test is vital both to the accuracy of the diagnosis and safety of the community health care worker. For this reason, FIND, the University of Lagos (Nigeria) and the Research Institute for Tropical Medicine (Philippines) evaluated a range of blood transfer devices used with malaria rapid diagnostic tests. We then developed, together with Swiss partners, the inverted cup BTD which was based on a previous, out-of-use design. The new device was found to perform with greater safety, and equal or greater accuracy, than other devices. It was also reported to be very easy to use.



To eliminate malaria, we need to be able to identify the people who carry the parasite without showing symptoms and treat them rapidly to avoid further transmission. FIND and partners have developed and successfully field-tested the first practical field molecular diagnostic test for malaria, achieving 98% sensitivity at only 2 parasites per microlitre in a remote rural clinic. This has potential to be a game changer.

98%



HAT & OND

Human African trypanosomiasis (HAT) and other neglected diseases (OND)

Overview

FIND and Standard Diagnostics (SD) in Korea have developed a prototype RDT for *Trypanosoma brucei* (*T. b.*) *gambiense* the parasite that causes African sleeping sickness. Preliminary data from trials in Angola and the Democratic Republic of Congo show that the new tool is performing as well as the existing screening methods. Since the RDT is simple and easy to use, and does not require any special instruments, it will be easy to deploy into primary health care systems in remote areas where HAT occurs.

Meanwhile, FIND and Eiken Chemical Co. have completed development of the first field-applicable molecular diagnostic test for HAT based on LAMP. The test was launched in Mali in September 2011, and is undergoing evaluation in the DRC and Uganda.

FIND and a consortium of academic partners led by the University of Geneva have also identified biomarkers in the cerebrospinal fluid of HAT patients that distinguish patients with brain disease (known as Stage 2 disease) with a high degree of accuracy. This will be important in ensuring that only true Stage 2 patients are treated for HAT, and that people who don't have this stage of the disease will not be exposed to toxic drugs. FIND and SD signed an agreement to develop an RDT based on these biomarkers for staging patients and for confirming cure after treatment.

HAT & OND Projects

Antibody and antigen detection

We are working with partners to develop a simple and low-cost rapid diagnostic test that would ideally be effective for both forms of HAT, *T. b. gambiense* and *T. b. rhodesiense*. A first generation

Simple test for sleeping sickness draws near as Gates Foundation renews FIND grant

(GENEVA – 5 December) Progress in the development of a simple, inexpensive screening test for human African trypanosomiasis (HAT) was in the spotlight as the Bill & Melinda Gates Foundation announced the renewal of a four-year grant to FIND and its partners to complete development of the technology, which will enable health workers to conduct the tests in the most remote settings and without much training.

Since 2010, FIND has been working with Standard Diagnostics on the low-cost lateral flow test for HAT that uses blood from a finger prick and can deliver results in 15 minutes, thus making it possible to dramatically increase the population screened by mobile teams and at remote health posts in endemic areas. HAT affects mainly poor rural communities in sub-Saharan Africa where 60 million people are thought to be at risk of contracting the disease, which can cause severe neurological damage when not diagnosed and treated early.



First field-based molecular diagnostic test for African sleeping sickness in sight

(GENEVA – 16 September) FIND and the Japanese diagnostics company Eiken announced today that a next-generation molecular test designed specifically for sleeping sickness – a deadly parasitic disease also known as human African trypanosomiasis (HAT) – is ready to enter accelerated field trials in sites across the Democratic Republic of Congo and Uganda. If all goes well, the LAMP loop-mediated isothermal amplification test – which has completed design and development phases – will be available for clinical use in 2012.

Designed to be suitable for use in rural African settings where the disease is most common, the LAMP test promises to dramatically improve the ability to confirm a diagnosis of sleeping sickness – even when parasites are present in low numbers – through detection of the parasite's DNA in patient samples. FIND is also exploring LAMP's utility as a tool to confirm cure after treatment of HAT, which would significantly reduce the follow-up period, and could eliminate the need for repeated lumbar punctures.



prototype RDT combining two native antigens that is effective for only *T. b. gambiense* has been developed in collaboration with Standard Diagnostics. Since there is currently no RDT for *T. b. gambiense*, the most widespread form of the disease, development of this first generation RDT is being advanced, while encouraging work continues on a second generation test that promises to be effective for both forms. Meanwhile, our work with the Flanders Interuniversity Institute for Biotechnology has raised the hope that antigen-detection tests can circumvent limitations that often occur when classical antibodies are unable to reach some of the invariant epitopes present on the trypanosome antigenic coat.

Paratryp (LED fluorescence microscopy)

In order to advance the effectiveness of the microscopic diagnosis of HAT, FIND has optimized and evaluated a parasite detection method based on red blood cell lysis, concentration, staining the sediment with acridine orange and examination using an LED fluorescence microscope. During 2011, demonstration studies on the use of this method were completed at three sites in Africa, and the method operates very well using a solar energy platform.

Manual NAAT for HAT (LAMP)

Detection of trypanosome DNA in suspected HAT patients could be a significant improvement over current parasitologic examination. With this in mind, FIND and Eiken have developed the same LAMP technology that is used for TB and malaria detection into a highly sensitive assay for HAT that uses blood and other body fluids. Activities thus far have focused on optimization of sample collection and preparation methods that would be applicable to settings where the disease occurs. The most appropriate method appears to be treatment of blood samples with SDS and their application on Whatman filter paper or microscopy slides before they are shipped to a central laboratory for analysis.

Clinical evaluation of LAMP in detecting HAT has now been initiated at sites in the Democratic Republic of Congo and Uganda.

Staging markers

FIND is leading pioneering biomarker discovery work in collaboration with a consortium of partners led by the University of Geneva. Thus far, the partners have identified eight markers of disease progression that have a high degree of precision in discriminating between HAT with and without central nervous system involvement (i.e. between Stage 1 and Stage 2 disease). When the markers were further evaluated, neopterin was found to be the best at detecting relapses and confirming cure, with a high degree of accuracy by the sixth month after treatment. Based on these results, a development agreement has been signed with Standard Diagnostics to develop a qualitative test for neopterin in the cerebrospinal fluid, which will have the dual function of staging HAT patients and confirming cure after treatment.

ELISA assay for leishmaniasis

In the search for a simple antigen detection assay for leishmaniasis that can be easily used at the lowest levels of the health system, FIND and partners are working to develop an ELISA format from a latex agglutination test that has been commercialized in Europe by Kalon Biological. If successful, a lateral flow version of the assay will be developed



for peripheral use to confirm leishmaniasis by testing urine specimens, thereby avoiding the need for splenic puncture or bone marrow aspiration.

LAMP assay for leishmaniasis

In an effort to develop a molecular assay for leishmaniasis that can be used in resource-poor settings, FIND's partners at the Royal Tropical Institute in the Netherlands and Wellcome Trust Sanger Institute in the U.K. have identified a number of promising *Leishmania* DNA sequence targets. FIND and Eiken Chemical Co. have signed an agreement to develop a LAMP assay based on one of the identified targets. FIND is also working with the Institute of Primate Research in Nairobi, Kenya, to study the feasibility of using the LAMP assay to monitor the clearance of parasite DNA from the body after cure.

LAMP assay for congenital Chagas disease

About 10 percent of children born to women infected with Chagas disease, caused by the parasite *Trypanosoma cruzi* and present in 21 countries in the Americas, will themselves have a congenital form of the disease that is likely to cause death if not treated early. While infected newborns can now be cured with an almost 100% success rate, the current microscopy method of diagnosis is not sensitive enough and many cases of congenital Chagas disease are still missed. FIND and partners are working on a LAMP assay for Chagas disease, aimed at vastly improving diagnosis and treatment of infants in rural areas.

In both
Angola and DRC

over

10,000

people

were tested using

the HAT RDT

**prototype that is
under evaluation.**

Early implementation projects

EXPAND-TB collaboration

FIND is involved in the EXPAND-TB project, which focuses on increasing the capacity to diagnose drug-resistant and HIV-associated TB in 27 developing countries. By the end of 2011, 58 of 101 targeted laboratories had been successfully established, while 21 of the targeted countries received new laboratory infrastructure and transfer of liquid culture and line probe assay technologies.

Results have been immediate and impressive, with more than 10,000 MDR-TB patients diagnosed in 13 countries since 2009 and a doubling of the number of reported cases for 2011 over 2010. The WHO has recognized the contribution of the EXPAND-TB project to increased drug susceptibility testing and for the uptake of newer, rapid diagnostic technologies across 27 high-burden countries. EXPAND-TB recipient countries also stand to benefit from WHO's endorsement of the Xpert MTB/RIF assay, which has the potential to dramatically change the dynamics of TB diagnostic testing.

Laboratory preparedness to improve access, China

As part of a Bill & Melinda Gates Foundation initiative to improve TB control in China, FIND is partnering with PATH/China and the Hong Kong TB Reference Laboratory on demonstration projects to guide the Ministry of Health's efforts to scale-up use of the LED fluorescent microscope, line probe assay, TB LAMP, and Xpert MTB/RIF. LED FM studies to date have shown improvements in case detection and lowering costs, while evaluations of the molecular assays are also demonstrating good test performance.

Improving TB case detection, Lesotho

Lesotho, a largely rural and mountainous country with the world's second highest incidence of TB and HIV co-infection rate, presents special challenges for controlling TB. Working with the Ministry of Health, FIND has implemented strategies aimed at improving timely TB case detection and patient management in remote districts.

These include TB screening by village health workers based at peripheral health centres and in the community, establishment of a horse rider sputum

Excellence in laboratory training

Inaugurated on 20 January 2011 by FIND Chairman Dr Gerald Möller, the International Centre for Excellence in Laboratory Training – ICELT, will ensure that the newer diagnostics now available in India will be implemented in the best possible conditions. Three national line probe assay courses have already been conducted as well as a biosafety and a culture training session.

Our ability to strengthen the TB laboratory network in India was significantly facilitated by the release of funds from the Global Fund.

Report points to progress in fight to eliminate malaria; FIND role highlighted

(GENEVA – 20 October) In a new report, the *Roll Back Malaria* partnership outlines the advances being made around the world towards reducing the burden of malaria, and singles out the role of the Rapid Diagnostic Test evaluation programme developed by FIND and the World Health Organization.

The report – *Eliminating Malaria, Learning from the Past, Looking Ahead* – commends the programme for enabling WHO's recommendation in 2010 for universal diagnostic testing of all individuals with malaria-like symptoms.

The FIND/WHO programme, which is the largest-ever independent and laboratory-based evaluation of RDTs for malaria, works to ensure that well-performing malaria RDTs are used in national disease control programmes. Commenting on the *Roll Back Malaria* report, Dr. Robert Newman, Director of the Global Malaria Programme of WHO, said "better diagnostic testing and surveillance has provided a clearer picture of where we are on the ground – and has shown that there are countries eliminating malaria in all endemic regions of the world."

transport service and, with partner Vodacom, implementation of an SMS text message-based system for registering suspected TB cases, reporting results and providing patient support. With a focus on the most remote areas of the country, the programme has had success in significantly improving TB case detection, while the SMS system showed marked improvements in reporting and was well accepted by health workers.

Building global capacity for TB diagnostic testing

Under a five year grant agreement with the U.S. Centers for Disease Control and Prevention to enhance in-country capacity for diagnostic testing of tuberculosis, malaria and HIV through laboratory strengthening, FIND and its partners are working in a number of high-burden countries to improve the quality of laboratory services, introduce new and more rapid diagnostic tools and increase human resource capacity.

In the first year of the programme, which ended in September 2011, FIND worked in Vietnam to implement molecular testing by line probe assay and the new Xpert MTB/RIF technology for MDR-TB. Activities were also underway in Botswana to help the Ministry of Health develop a national monitoring and evaluation plan for the public health laboratory network, and in the Dominican Republic to support the implementation of point of care CD4 testing using PIMA (Alere, Inc.) technology and the establishment of a national HIV RDT external quality assurance programme. In the second year of the programme, FIND expanded its activities in Vietnam and the Dominican Republic and began adding new initiatives in Lesotho, South Africa, Tanzania and India.

Improving TB case detection, Uganda

With funding from TB REACH, FIND is working with the Ugandan National TB Laboratory Programme to strengthen case detection through introduction of the Xpert MTB/RIF for detecting smear negative TB cases in TB/HIV co-infected patients and to use motor cycle based sputum transport so that people in remote areas can benefit from the technology. The one-year project, launched in October 2011, is expected to reach 7,900 additional patients and significantly increase overall “bacteriologically positive” TB case notification rates. The initiative is presently working to overcome challenges related to disruptions in the electric power supply needed to run the tests, and will be providing invertors with external batteries where needed.

Reference materials and evaluation of existing RDTs

As the number of rapid diagnostic tests for malaria heads toward an expected 100 million in 2012, FIND has been coordinating a global programme of comparative RDT product evaluations, as well as lot-testing of procured production lots. That programme



Text messaging put to good use in Uganda's far-flung regions

(GENEVA – 12 July) A new paper from FIND says that with quality health management requiring the transmission of timely and accurate data, efforts to diagnose and combat tropical diseases need to move beyond paper-based reporting systems and into the realm of mobile technology. In a project aimed at remote areas of Uganda, the organization is looking to leverage mobile networks, and particularly text messaging capabilities, to add direct data transmission and feedback capabilities to the recent advancements in malaria diagnostics presented by the new rapid diagnostic tests that are finding their way into the field.

SMS-based reporting systems provide potential to improve timeliness in reporting of specific, time-sensitive metrics at modest cost, while bypassing current bottlenecks in the flow of data. With the development of specific capacity to manage stock data at district level, the availability of real-time data offers a way to address commodity distribution problems and reduce stock-outs.

completed the third year of such testing in 2011 and the data now forms the basis of RDT procurement decisions of UN agencies, USAID, Global Fund recipient programmes and other major international procurers and country malaria programmes. In 2011, the pass rate of RDT lots submitted for routine quality control testing was 99.44%.

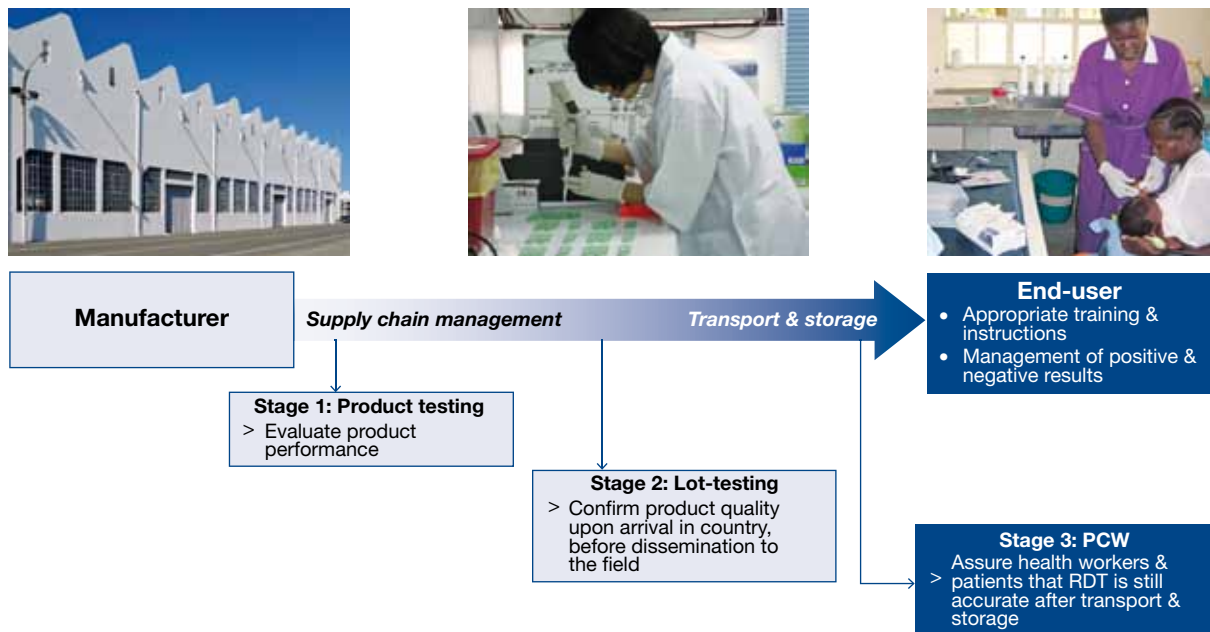
Addressing challenges to implementation

The enormous potential of Malaria RDT products to advance point of care diagnosis of the disease has been blunted in some cases by bottlenecks, product deficiencies and other implementation challenges in high-burden countries. That is why FIND continues to identify and address the impact these issues are having on the success of malaria diagnostics in-country and to devise solutions.

We have also worked directly with the Ministry of Health in Uganda to use the Rapid SMS cell-phone platform to bridge gaps in information transfer that were impeding RDT roll-out in that country, as well as with the national malaria control programmes in

Senegal and Zambia to assess impact of wide-scale RDT use on disease reporting and drug consumption and to build evidence to guide expansion of their use.

FIND model for point of care diagnostics quality control



Product and lot testing evaluations (stages 1 and 2 above) conducted by FIND, WHO and partners have provided a standard against which malaria rapid tests can be compared. Over 120 products have now been evaluated through the global product testing activity, with reports published in 2010 and 2011, and further results to be published in 2012. The results of the evaluations are now directly informing procurement by UN and other agencies, shifting the emphasis from price to quality and it has established a basis for the quality policy on malaria diagnostics of the Global Fund to Fight AIDS, TB and Malaria. A preliminary analysis has shown that the relative market share of high quality RDTs has increased substantially over the past few years.

Board of Directors



Gerald Moeller
(Chairman)

Dr. Moeller spent much of his career with Boehringer Mannheim, a leader in the diagnostic and biopharmaceutical industry. He headed various business units in the company such as Decentralized Diagnostics and Advanced Diagnostics & Biochemicals before being appointed CEO. He is currently Chairman on several boards, among them Brahms AG, Bionostics Inc, Febit AG and 4sigma.



Mark Kessel

Mr. Kessel is widely recognized as the leader in structuring product development investments for the biopharmaceutical industry. He is a director of Dynavax Technologies Corporation and Fondation Santé: He has also served as a director of the Global Alliance for TB Drug Development, the Biotechnology Industry Organization, OXiGENE and Antigenics, among others.



Bernard Mach

Dr. Mach is founder and chairman of NovImmune, a Geneva-based biotech company specializing in the discovery and development of monoclonal antibodies to treat people suffering from inflammatory diseases and immune-related disorders. He is also Chairman of the NovImmune Scientific Advisory Board.



Mphu Ramatlapeng

The Honourable Dr. Mphu Keneiloe Ramatlapeng is the Minister of Health and Social Welfare of the Kingdom of Lesotho. In this role, she has been a champion in Lesotho's significant achievements in reducing the transmission of HIV to children from their parents. Under her leadership, the Ministry introduced a 2010 innovative package to support mothers who cannot return to clinics to receive the basic package of care services they need to stay healthy and give birth to HIV-negative children.



Gene Walther

Mr. Walther is Deputy Director, Diagnostics, at the Bill and Melinda Gates Foundation where he is responsible for the Foundation's diagnostics strategy to organize and harmonize cross-Global Health Diagnostics efforts to achieve maximum impact.



Philippe Jacon
(ex officio)

Mr. Jacon joined FIND from EDMA (European Diagnostic Manufacturers Association), where he acted as the Director General *ad interim* since March of 2011. Prior to EDMA, he spent most of his career with BD (Becton Dickinson and Co) in various positions and locations.

FIND in figures

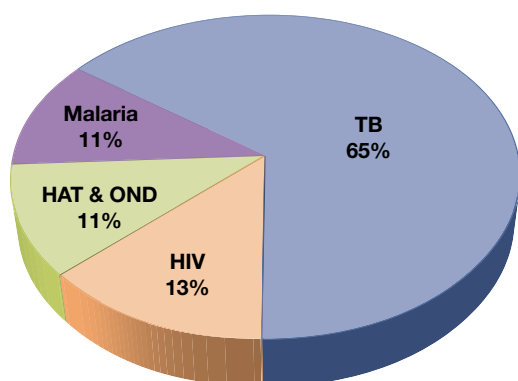
2011 saw a significant increase in programme activity, with total spending reaching \$32.1M, up from \$25.7M in 2010. Approximately two-thirds of this was on our TB programme. The other one-third comprises, in roughly equivalent levels, Malaria, HIV, and HAT/Other Neglected Diseases).

The Bill and Melinda Gates Foundation funded approximately 44% of the 2011 activity. The support of BMGF, along with the Netherlands Ministry of Foreign Affairs, UNITAID, and the Department for International Development of the United Kingdom (DFID), accounted for over 90% of FIND's 2011 activity funding. Other donors included WHO India, TDR and TB REACH (with funding from the Canadian International Development Agency), the KfW Bankengruppe of Germany, The Global Fund, PEPFAR/CDC, UBS Optimus Foundation, The European Union, USAID, Becton Dickinson, The National Institutes of Health, and Drugs for Neglected Diseases initiative.

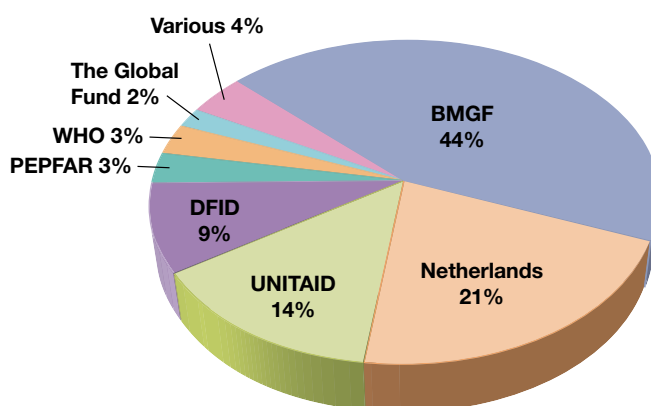
In 2011, FIND received a total of \$45 M in commitments for new project work. These grants have lives ranging from 1 to 4 years, with a weighted average life of 3 years. The most significant of these was a \$24.7 M grant from the Global Fund for the implementation of tuberculosis diagnostics in India.

This year also saw a significant investment in upgrading our financial accounting platform and processes. FIND adopted a new ERP system to accommodate increasing complexity in its donor base and reporting needs, developed new reporting tools, and revised key accounting policies to improve transparency and accountability.

2011 Spending by Disease

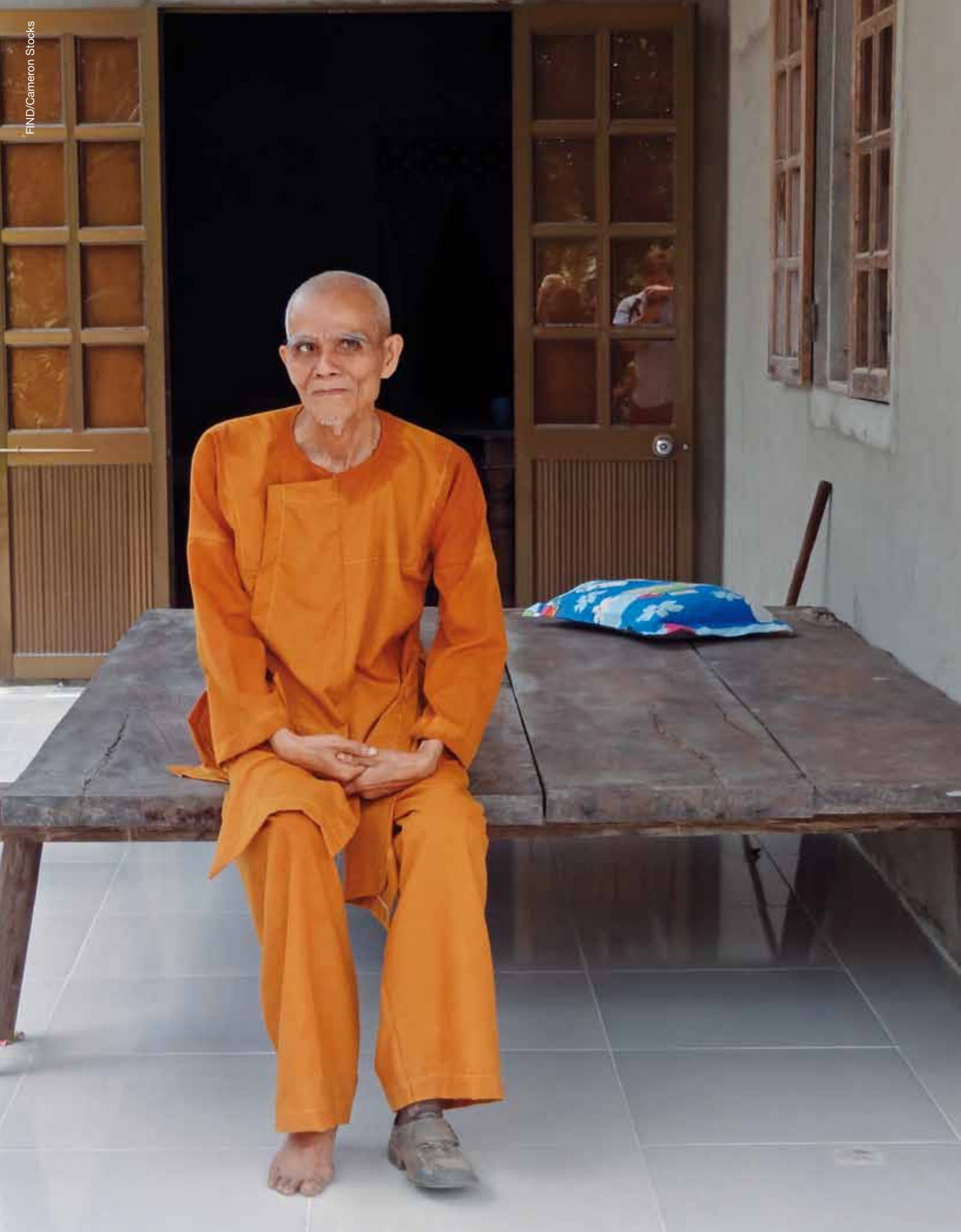


2011 Spending by Donor



New Donor Commitments Made in 2011

Donor	USD Amount (\$000s)	Grant Life (Years)
Global Fund – Round 9 India	24,709	4
Government of Germany (KfW) – LAMP for neglected diseases	9,267	4
Bill & Melinda Gates Foundation – improved HAT diagnostics	2,389	4
WHO – demonstration of TB rapid tests in India	1,954	1
CDC – building capacity for diagnostic testing of TB, malaria, HAT	1,474	4
Bill & Melinda Gates Foundation – biomarker discovery	1,436	3
WHO OGAC – lab strengthening	315	1
UBS Optimus Foundation – biomarkers for HAT	932	3
Global Fund – malaria RDT testing	676	2
UNITAID – WHO’s AMDS clearing house	487	1
WHO – TB detection	362	1
Stop TB Partnership/TB REACH – TB detection in Lesotho	291	1
TI Pharma – tools for leishmaniasis, TB & trachoma	267	3
USAID/JSI – malaria RDT QA	250	2
Anonymous donor	136	-
Becton Dickinson – lab strengthening	70	1
Total New Grants	45,015	



The greatest obstacle to the care and control of many diseases in the developing world is a lack of effective and appropriate diagnostic tests – reliable and inexpensive tools that can rapidly and accurately identify who is sick with which disease, so that appropriate treatment begins promptly.

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Production and editing: FIND Communications

Writer: Tony Murdoch

Design: www.latitudesign.com

Printer: NBmedia

Photo cover page: FIND/Mark Perkins

