



# **Delivering on the promise**

Summary on five years of progress  
2003 - 2008

*Partnering for better diagnosis for all*

Our vision *is of a world where everyone will have equitable access to high quality diagnosis*

Our mission *is to drive the development and implementation of accurate and affordable diagnostic tests that are appropriate to patient care in low-resource settings*

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## Introduction

### Background

FIND (Foundation for Innovative New Diagnostics) was established in 2003 as a not-for-profit Swiss organization to address a 21st century global health paradox: In an era of unprecedented ability to deliver drug treatment for a wide variety of diseases, millions of people in the developing world are unable to access appropriate treatment for lack of a clear diagnosis.

Launched at a meeting of the World Health Assembly with an initial grant from the Bill and Melinda Gates Foundation, FIND set out to develop tools for diagnosis of tuberculosis (TB) and for identification of patients with multidrug-resistant (MDR) and extensively drug-resistant (XDR) forms of the disease. Two other diseases have since been added to its portfolio: malaria, and one of the world's most neglected diseases, human African trypanosomiasis, also known as sleeping sickness. FIND's donor base is also expanding, with funding received so far from the Government of the Netherlands and from the European Union. Financial support from other sources, especially public sector funding, is actively being solicited with the aim to bring better health – and with that, social progress and economic development – to the world's poorest countries.

Five years on, FIND is now an influential part of the process for developing and delivering new diagnostic tests. One of the principal reasons for FIND's success has been its ability to bring together private companies, academic institutions, national and international health agencies, and a broad range of organizations and individuals who share a commitment to human health and a determination to advance diagnostic solutions for poverty-related diseases.

### Why diagnostics?

Over the last 100 years, and particularly during the past two decades, there have been enormous improvements in health sciences with new technologies for disease control – new and more accurate ways to diagnose them, new drugs to treat them, and new health care systems to cure those afflicted with them. Yet the benefits of this progress have not flowed to most of the developing world, where tuberculosis, malaria and other preventable and treatable diseases continue to spread, destroy lives and perpetuate the cycle of poverty.

For most of these diseases, effective treatment exists that allows detected cases to be cured and, in turn, disease to be controlled. The greatest obstacle to care and control of many diseases in the developing world is 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.

Without these, most people who contract a disease are not diagnosed until later stages of infection, when drug therapies are more expensive and less effective, and after the patient has already spread the infection to many others. Worse yet, an incorrect diagnosis is often a root cause of ineffectual and inappropriate therapies, which can have disastrous results.

### The FIND solution: A partnership approach to diagnostics

FIND was established as a bridge between the health industry, the research community, and global and national health programs to address the immense challenges of bringing new diagnostics to developing countries. Over the past five years, it has served as an expert project manager that brings together all the entities that are involved in developing effective diagnostic solutions and transferring them to the developing world. FIND works aggressively to identify potential breakthroughs and build effective partnerships designed to overcome the complex challenges and ensure success. This includes everything from developing the concept, obtaining the financing and working out the right manufacturing approach, to conducting clinical trials, managing the intellectual property rights, collaborating with national health agencies on implementation policies, and financing strategies.

All of this is targeted at one thing - a patient-centered approach that focuses on diagnostics as a platform to shorten the cycle between disease and treatment, stop transmission, and minimize the consequences of disease on families.

By fostering a continuous process of improvement, FIND does not stop at product development, but accompanies technologies through evaluation and into clinical use to ensure impact measurement and a constant flow of feedback information from the field.

For this reason, FIND has spent enormous energies working to understand the needs of target countries. In 2007, FIND established an office in India, where tuberculosis rates are the highest in the world, and has been working with national health authorities in Lesotho, Côte d'Ivoire, Ethiopia and Uganda on pilot programmes to strengthen local laboratories so that they can facilitate the success of new diagnostic tools and in-country techniques for their use.

FIND is committed to quality. On 29 June 2007, the procedures or quality management systems (QMS) followed by FIND were audited by the SWISS TS / TÜV-Süd authority who confirmed that all processes at FIND were structured, organized and documented at a very high level and that ISO standards were being implemented throughout the organizational procedures. On this basis, FIND received ISO 13485:2003 and ISO 9001:2000 certification. The International Standards certification covers FIND's operations in the areas of Project Management, Finance, Quality Assurance, Logistics, Human Resources and Communications - in other words, all functional departments.

Guided by the approaches outlined above, FIND is currently carrying out more than 35 projects in three major disease areas, and is now at the crest of a wave of exciting advancements in diagnostic tools that can be applied in the developing world.

## Tuberculosis

### Faster and more accurate testing is at hand

The focus of our efforts has been to make TB diagnostic tests that are more accurate and faster than methods currently in use. Tuberculosis is one of the greatest threats to global health, with nearly nine million new cases and 1.6 million deaths each year. Left untreated, each person with the active form of the disease infects an average of 10 to 15 people each year. Yet currently, fewer than a quarter of new TB cases worldwide are detected and reported annually due to inefficiency of the standard diagnostic test deployed in developing countries, sputum microscopy.

More accurate and faster methods would have enormous impact on the control of the disease. This is particularly important in the face of the emergence of MDR and XDR TB. Current methods for the diagnosis of these forms of the disease take months.

The work on TB diagnostics has concentrated both on improving existing technologies, including microscopy, as well as promoting the development of new tools that greatly improve the safety, speed and accuracy of detection.

Among the accomplishments over the first five years, FIND has been instrumental in advancing promising diagnostic tools for use in TB-endemic countries. For example, FIND has:

- Made liquid culture much cheaper and established paradigms for its effective use;
- Negotiated access to an extremely simple slide test for confirmation of *Mycobacterium tuberculosis* in sputum cultures – something which otherwise requires very expensive molecular methods or very slow biochemical testing;
- Developed, with Eiken Chemical Co. Ltd. of Japan, a simple molecular test for case detection based on loop-mediated isothermal amplification (LAMP) technology. This test is read visually and detects positive or negative TB samples within two hours and with minimal instrumentation;



Liquid culture halves the time for performing TB culture and drug susceptibility testing compared to classic solid culture



A TB hospital in the Philippines

- Developed, with Carl Zeiss MicroImaging GmbH, a high quality but low cost microscope with dual fluorescence and brightfield capability, that can be used outside of the darkroom and in settings with frequent power interruptions. Fluorescent microscopy has several advantages, including greater sensitivity and speed than conventional microscopy now widely employed in the developing world;
- Developed, with Cepheid, Inc. and the University of Medicine and Dentistry of New Jersey, an automated rapid test for TB and MDR detection based on the GeneXpert® platform. This is a self-contained system which uses a disposable cartridge in which sample preparation, amplification, and detection can be carried out in one process in a wide range of environments. Test results are delivered in less than 90 minutes;
- Responded, with Hain Lifescience GmbH, to the rise of resistant forms of TB by fast-tracking GenoType® MTBDRplus, a rapid molecular test for MDR-TB, in large scale demonstration studies in South Africa in collaboration with the South African Medical Research Council and the National Health Laboratory Service. In June 2008, the WHO Scientific and

Technical Advisory Group for TB (STAGTB) endorsed recommendations, prepared by a WHO committee, on the use of this test in low-income countries.

Dr. Mario Raviglione, Director of the World Health Organization (WHO) Stop TB Department, had this to say about these exciting times in the world of TB diagnostics:

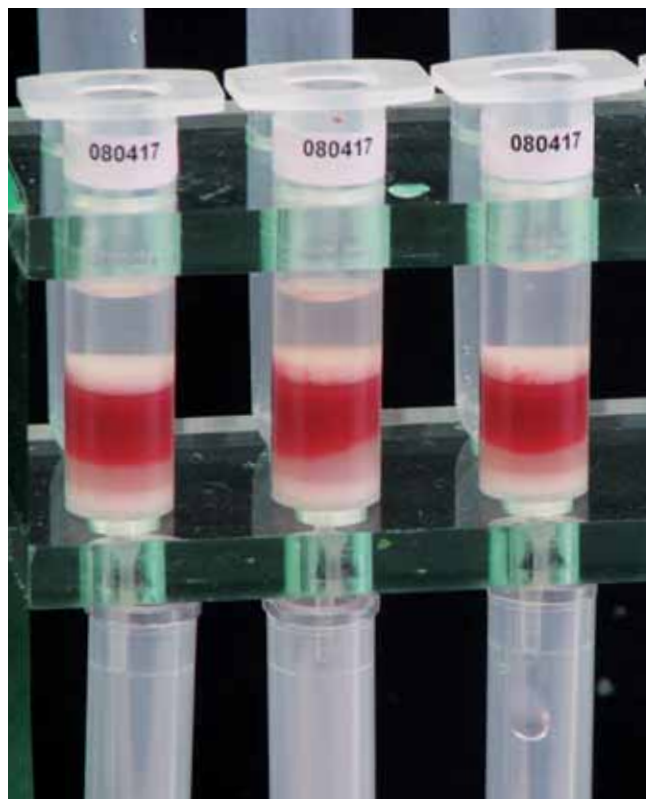
*“The possibility today to apply new molecular methods to rapidly detect MDR TB is a major boost to the morale of those who have worked on TB for years without any innovation. The fruits of research must move very quickly from the labs in the North into policy and practice in the South, showing that, by working closely together, we can come up with solutions for TB control. FIND is a model that must inspire all those involved in R&D.”*

In addition, FIND has entered into agreements with the governments of South Africa, Lesotho, Ethiopia, and Uganda to transfer these technologies for use in national TB reference laboratories.

## Human African Trypanosomiasis (HAT)

### Zeroing in on new tests to accelerate elimination of this rural scourge

FIND's programme on diagnostics for human African trypanosomiasis was launched in 2006 in collaboration with the WHO and a variety of partners in research, industry and government. It focuses on the development of user-friendly tests that can be easily applied in remote settings, and capable of detecting the disease in its early stages.



Parasite separation from blood using 2nd generation minicolumns

Sleeping sickness, which is spread by the bite of the tsetse fly, poses a risk to more than 60 million people, most of whom live in rural sub-Saharan Africa. The disease is fatal if left untreated.

Currently, diagnosis and subsequent treatment is difficult because existing analytic tools – which rely in part on the use of microscopy to confirm the presence of parasites in the blood – cannot be used effectively in remote, impoverished settings where the disease is almost always found. Moreover, infection results in few specific symptoms in the early stages and cases are rarely detected until they are in advanced stages when treatment is difficult and expensive, and the drugs used are highly toxic.

The areas of focus in this programme include technologies for parasite separation from blood and cerebrospinal fluid, serological tests, molecular assays and the search for biomarkers for determining whether the infection has reached the central nervous system. The most exciting advancements so far include:

- Development of a molecular test for diagnosis of HAT – one that could quickly detect, with minimal equipment, the presence of the parasite in blood, urine or saliva. For this purpose, the use of Eiken's LAMP technology, which the company and FIND have been directing towards a simple and effective test for tuberculosis (see the section on TB), has now been proven as a potential molecular platform for a similar test for this neglected disease.
- FIND has engaged in work on other improvements in parasite detection, including collaboration with the Institute of Tropical Medicine in Antwerp, Belgium, to improve the mini anion exchange

centrifugation technique (mAECT), which is currently the most sensitive method for detecting trypanosomes in blood, but is still too expensive and time consuming. This technology has been transferred to a local facility in the Democratic Republic of Congo where it is being produced.

- There has also been progress in efforts to develop an alternative serological assay that is simpler, more sensitive and specific than current tests through use of purified, recombinant or synthetic antigens.
- In collaboration with scientists at the University of Geneva, FIND has identified unique proteins in the cerebrospinal fluid of sleeping sickness patients which can discriminate between early and late (central nervous system) stages of the disease. Distinguishing between late and early disease stages is critical because the drugs used for the treatment of late stages are different from those for the early stage.
- FIND has partnered with the WHO in the establishment of a HAT specimen bank that will guarantee

more efficient use of limited resources, reduce the need for repeated collections, promote product comparisons and facilitate quality control.

The addition of human African trypanosomiasis to the FIND disease portfolio attracted the attention of those interested in neglected diseases, as is expressed here by Dr. Bernard Pécoul, Executive Director, Drugs for Neglected Diseases *initiative*, who had this to say about it:

*“As head of an organization dedicated to making new medicines available for the world's most neglected, we recognize the invaluable contribution of FIND in developing critically needed diagnostics that are a key element in providing adequate treatment for the poorest. In particular, I am pleased to acknowledge that by choosing sleeping sickness as one of its priorities, FIND is showing a strong commitment towards controlling this debilitating disease in rural Africa.”*



Screening a community in a sleeping sickness endemic area

## Malaria

### Guaranteeing quality diagnostic testing in the field



Bringing accurate malaria RDT to the household level in remote villages

Malaria was added to FIND's disease portfolio in 2007. This parasitic disease is one of the greatest global threats to public health, causing more than 300 million cases of acute illness worldwide and killing more than one million people each year, the vast majority of them children in sub-Saharan Africa. In some developing countries, malaria accounts for as much as 40 percent of the public health expenditure. Early and accurate diagnosis is critical to malaria control. What's more, inaccurate diagnosis fuels drug resistance, wastes scarce resources and often results in death from mistreatment.

A major advance in malaria diagnosis has been the development of rapid diagnostic tests (RDTs) which can detect malaria antigens in a finger prick blood sample. However, the proliferation of test manufacturers has

presented difficulties for national malaria control programs in determining which tests are reliable. In addition, many of the RDTs are susceptible to degradation at temperatures commonly found in countries where malaria is a problem.

FIND's malaria programme, undertaken in partnership with the WHO, has been directed at creating a global solution to ensure the quality of malaria rapid diagnostic tests (RDTs) used in national disease control programs. The programme aims to evaluate the performance of existing RDTs and to identify improvements that can be incorporated into new tests. Large scale product testing has begun in collaboration with the U.S. Centers for Disease Control and Prevention and the Hospital of Tropical Diseases in London. The program has already yielded the following results...

- Establishment of a globally-representative reference collection of blood from infected individuals, as well as extensive characterization and gene sequencing to form a stable reference panel that can be used to reproducibly evaluate RDTs.
- To ensure the quality of test kits already purchased and held by national disease control programmes, three regional lot-testing sites – in the Philippines, Cambodia, and Ethiopia – are supported to carry out rapid quality checks of RDTs after purchase for national programs.
- A development and supply agreement has been signed to provide positive control wells; a simple tool that will empower community health workers to assess the quality of RDTs at the point of use of the test kits. Large scale field trials of a prototype are anticipated to begin in 2009.
- Early development of a simple and sensitive molecular test for malaria based on the LAMP technology platform (already discussed under the TB section) that can be used to diagnose complex cases, support clinical trials and detect infections with low parasite numbers.



LED fluorescence microscopy – a multiple disease platform

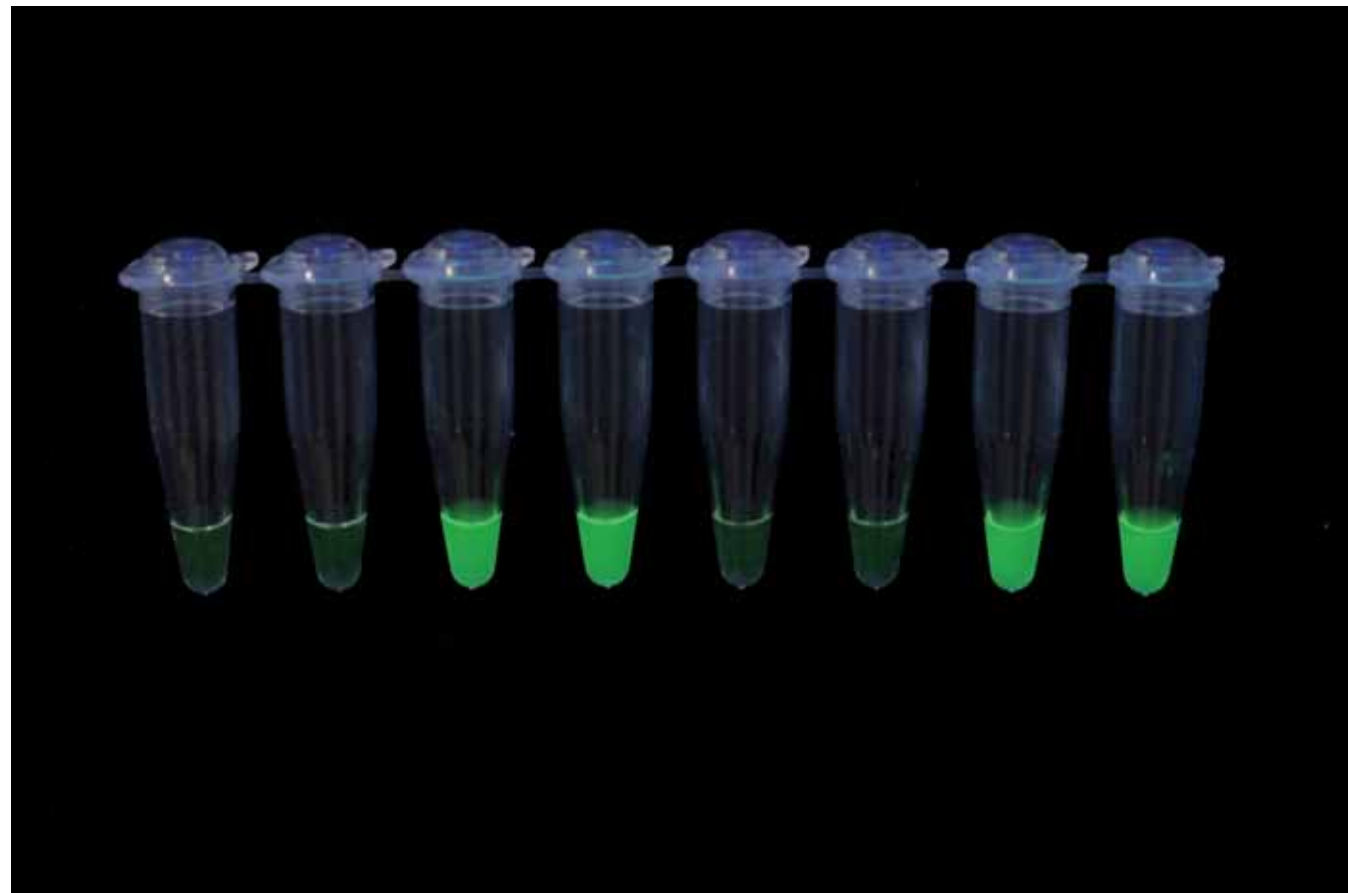
## Five years on – the investment is paying off

Taken together, the various advances that FIND has nurtured are bringing global health care to the brink of an exciting new era – one in which diagnostic technologies are expected to begin delivering on their enormous potential to advance the struggle against poverty-related diseases. The prospect that many of the methods now used to diagnose these diseases will give way to simpler, more reliable and more cost-effective technologies – as well as those better suited to be used in remote conditions – provides encouraging prospects for saving millions of lives and breaking the stranglehold that ill-health has on the developing world.

Founded with the goal of improving the detection of tuberculosis and having since grown into other disease areas, FIND's team of professionals and diverse partners has efficiently leveraged its

business model to develop synergies that can be applied across a wide range of poverty-related illnesses. Today, as the first wave of better diagnostic tools enters late-stage development and as tools are being rolled out into national disease control programs, FIND and its partners are focusing on the next wave of better tests for the future.

Moving forward, FIND's top priority for all three diseases is to focus most of its current resources on the development of tests for use at point of care, where the patient first seeks help. To be able to proceed expeditiously in the search for these much needed technologies, FIND applauds the continued participation of current partners, and welcomes involvement from other partners, including funding support from public sector donors.



Visual reading of amplified microorganisms using LAMP

## FIND Team



From left to right (standing) C. Boehme, R. O'Brien, R. Sutherland, L. Chaubert, H. Clemens, C.N. Paramasivan, M. Perkins, J. Ndung'u, V. Nantulya, S. Biéler, G. Michel, B. Gordis, E. Adam, P. Nabeta, E. Lee, A. Varga (seated) J. Vercauysse, B. Porstmann, H. Yirga, G. Roscigno, D. Choa, J. Thomas, N. Champouillon

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### FIND Team

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**Richard O'Brien:** Head of Product Evaluation and Demonstration, TB Programme  
**Madhukar Pai\*:** Consultant for Latent TB Infection  
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