



Application from the Foundation for Innovative New Diagnostics for admission into official relations with WHO

1. **Year of establishment of the organization:** 2003

2. (a) **Address of the headquarters of the organization.**

Chemin des Mines 9
1202 Geneva
Switzerland

Tel: +41 22 710 0590

Website: <http://www.finddx.org>

(b) **Contact information, name(s) and titles of officer(s) who may speak and correspond authoritatively on behalf of the organization.**

Ms Sharon Saacks
Head of Operations

Dr Catharina Boehme
Chief Executive Officer

Mr Jérôme St Denis
Senior Advocacy and Resource
Mobilization Officer

Chemin des Mines 9
1202 Geneva
Switzerland

3. **Aims (or purposes, objectives) of the organization as they appear in its constitution, by-laws or equivalent document.** To promote health and to relieve the poor and distressed in the developing world by developing and introducing novel products for diagnosis of infectious diseases, such as tuberculosis and other communicable diseases. In pursuing this objective, the Foundation intends to save lives and improve health of individuals living in developing countries.

4. **Main fields of work of the organization.** Health care professionals (doctors, medical technologists, medical engineers); health promotion/disease prevention; communicable diseases (HIV/AIDS, malaria, tuberculosis, hepatitis C, Chagas disease); blood safety, medical technology, quality control; and community/district health services.

5. Main types of activities of the organization.¹ Advisory, advocacy, data collection/surveillance, education/training, and research.

The organization has activities in the following countries: Australia, Azerbaijan, Bangladesh, Belarus, Botswana, Brazil, Burkina Faso, Cambodia, Cameroon, Colombia, Democratic Republic of the Congo, Djibouti, Dominican Republic, Ethiopia, France, Georgia, Germany, Haiti, India, Indonesia, Iran (Islamic Republic of), Kazakhstan, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Lesotho, Malawi, Mozambique, Myanmar, Namibia, Nigeria, Peru, Philippines, Republic of Moldova, Romania, Rwanda, Senegal, South Africa, Swaziland, Tajikistan, Thailand, Uganda, United Republic of Tanzania, Uzbekistan, Viet Nam, Zambia.

6. Membership information.

The Foundation is a non-membership organization; see section 7 below.

Regional offices/representatives in the following countries: India, South Africa, Uganda, Viet Nam.

7. Name, composition, function and frequency of meetings of the main, or if applicable, the two main decision-making bodies.

Name: Board of Directors

Composition: The Board has a minimum of three and maximum of 15 members. The members are selected based on their experience especially in research and development in pharmaceutical and biotechnical fields, in business or clinical development, public health, fund-raising, finance, law, communication and advocacy. They are selected also for their commitment to the public interest, their experience, and support for the goals of the Foundation. The nomination process, coordinated by its Secretariat, is held in order to generate a pool of candidates. From among the candidates, the founding Board elects the additional members for three years by a simple majority vote. The Board members act in their personal capacity.

Function: The Board of Directors is the ultimate authority for approval of all the Foundation's policies, strategy decisions and objectives. The Board approves all operations related to the management team, including work plans and budgets, oversees the progress of all the activities of the Foundation, hires and evaluates the senior executives, ensures the integrity of the Foundation (corporate accounting, financial reporting systems and audits), participates in fund-raising activities, supports public relations, initiates new partnerships, and selects new Board members.

Frequency of meetings: Quarterly.

Name: Scientific Advisory Committee

Composition: The Committee is composed of at least five and at the most 18 scientists

¹ For an explanation of the types of activities, please see the Annex to the application.

who have experience in different disciplines. The Committee itself, the Board and the Scientific Director can propose members for the Committee. The Scientific Director selects the members for the Committee subject to ratification by the Board.

Function: The Committee advises the Board directly or through the latter's Science Committee on best technology and disease portfolio options for the Foundation in line with its strategic objectives; assists the Foundation in developing its strategy and by providing advice on scientific matters; supports and reviews the scientific management process of projects; and provides, as requested by the Board or the Science Committee, expertise on diagnostics development, licensing, and any other public health or scientific issue.

Frequency of meetings: At least once a year.

8. Human resources of the organization.

Number of paid staff at headquarters/secretariat:	33
Number of volunteer staff at headquarters/secretariat:	3
Number of paid staff worldwide (including staff at headquarters/secretariat):	48
Number of volunteers worldwide (including staff at headquarters/secretariat):	3

9. Financial information on the organization.¹

Annual income and expenditure in the range US\$ 10 million to US\$ 50 million

10. Formal relations with organizations and bodies in the United Nations system and nongovernmental organizations.

Not applicable.

11. Collaboration with WHO.

(a) Activities carried out jointly with WHO during the working relations period.

The EXPAND-TB Project was initiated in 2009 to accelerate access to diagnostics for patients at risk of multidrug-resistant tuberculosis in 27 countries. The project is funded by UNITAID and is a collaboration between WHO, the Global Laboratory Initiative, the Global Drug Facility and the Foundation. The project's aim of establishing and implementing diagnostic capacity to detect multidrug-resistant tuberculosis in 27 high-endemic countries has been achieved in all 27 countries, where a total of nearly 72 000 cases of new multidrug-resistant tuberculosis had been detected by the end of 2013. The project is continuing with the aim of detecting some 40 000 new such cases annually. The current plan is to shift from funding of the EXPAND-TB project by UNITAID to direct funding

¹ In order to facilitate comparison, nongovernmental organizations are requested to express their annual income and expenditure in United States dollar equivalents, and to provide estimates of these annual figures in cases where their accounts cover different periods.

of the countries by the Global Drug Facility. The transition will be made country by country and is expected to be completed by the end of 2015.

In October 2013, the Foundation received a grant from the Global Laboratory Initiative to provide technical assistance for the roll-out of the Xpert® MTB/RIF diagnostic test, which is a self-contained and cartridge-based technological platform that integrates sputum processing, DNA extraction and amplification, and tuberculosis and multidrug-resistant tuberculosis diagnosis. The roll-out was planned for selected countries in Asia/central Asia (Kyrgyzstan, Myanmar, Tajikistan and Uzbekistan) and Kazakhstan, Central/western Africa (Cameroon, Côte d'Ivoire and Senegal), and East and southern Africa (Mozambique and Rwanda) through the Foundation's existing network of expertise. The goals of the technical assistance are to provide strategic support and guidance in relation to policy review, algorithm implementation and preparation of guidelines; and assessment, installation, training and monitoring of instrument use in the selected countries. The training has been completed in every country with the exception of Myanmar. Additionally, a joint project with WHO to introduce Xpert® MTB/RIF in India, under the auspices of the Indian national tuberculosis programme, was agreed in 2012. This project is a multisite programme-based demonstration of the Xpert® MTB/RIF assay for the diagnosis of tuberculosis and multidrug-resistant tuberculosis in India.

The Foundation, in collaboration with WHO and the Centers for Disease Control and Prevention (United States of America), is implementing a global evaluation programme for malaria quality assurance based on three tiers of quality control to guide procurement of rapid diagnostic tests and assure rapid diagnostic tests performance before and during use in the field.

From 2009 to date, five rounds of product testing have been carried out, resulting in evaluations of a total of 170 individual products. The results of the latest round are now available on both WHO's and the Foundation's websites. The number of products submitted for testing is indicative of the growing interest of manufacturers and demonstrates the importance now attributed to the programme.

The malaria rapid diagnostic test lot testing programme is an independent evaluation programme that is coordinated by WHO and the Foundation, and funded by UNITAID and other donors. It supports two regional lot-testing sites that carry out rapid and reliable quality control of rapid diagnostic test lots sent from anywhere in the world. In 2013, 1083 lots were tested, double the figure from the previous year. 99 Per cent of the rapid diagnostic tests submitted for lot testing had adequate quality before introduction into the field.

A project to develop a quality assurance product, a positive control well that can be used at the community level to ensure that rapid diagnostic tests are still functioning properly after exposure to variable transport and storage conditions, started in 2008 in partnership with WHO, the Centers for Disease Control and Prevention, the Hospital for Tropical Diseases (London) and other partners. The current status of the project is that the positive control well has been developed, evaluated in the field for ease of use, and is being manufactured for limited deployment by the end of 2014.

(b) Planned collaborative activities with WHO for the coming three-year period.

The main objective of collaboration between the Foundation and WHO is to transfer appropriate diagnostics that meet identified needs and performance criteria into settings where they are most required and will have the most significant public health impact. Without them, appropriate treatment is not possible and disease transmission cannot be controlled.

The Foundation works closely with WHO to guide and facilitate test development for new diagnostic tools through jointly defining diagnostic needs, coordinating evidence collection in the form of data packages suitable for WHO's expert review, and leading policy guidance on use of the new diagnostics.

In defining and developing diagnostics needs, the Foundation engages in:

- (i) the development of simple, accurate diagnostic tests to improve the care of people with Buruli ulcer and ensure that these tests are made widely available in countries where the disease is endemic, at affordable or preferential prices;
- (ii) multiple, broad-based collaboration on diagnostics for use in the elimination of human African trypanosomiasis;
- (iii) the development and consensus-based approval of target product profiles and other diagnostic related parameters for tuberculosis, including drug resistance.

The programme for the quality assurance of rapid diagnostic tests for malaria undertakes product and lot testing in centralized and decentralized settings in order to guide test procurement and assures rapid diagnostics test performance before and during use in the field. The aim is to develop a self-sustaining and decentralized (such as through positive control wells) malaria rapid diagnostics test quality assurance system. These activities started in 2009 and will run until the end of 2017, and their goal is to attain a self-sustaining programme that will be transferred to, and housed and managed by, WHO.

Training materials on the correct use of malaria quality assurance for rapid diagnostics tests are being developed for the private sector and the training will be implemented in five countries in which malaria is endemic: Kenya, Madagascar, Nigeria, Uganda and United Republic of Tanzania. WHO will work with the Foundation to increase the availability of affordable quality assurance rapid diagnostics tests and to improve the quality of case management; the Foundation will focus on testing and quality assurance, and WHO on guidance and quality control systems.

The Foundation helps to ensure efficacy of diagnostics through quality assurance strategies, both centralized and for local implementation. Equivalency studies are performed in the Foundation's laboratories in India and Uganda and/or partners' laboratories.

Through collaboration with WHO, the Foundation will aim to maximize the impact of new diagnostic tools by facilitating their expanded use through: (i) turning tests into practical tools (for example, developing quality assurance and remote monitoring for Xpert® MTB/RIF and other molecular assays); (ii) helping to strengthen laboratories and laboratory systems in countries through the Expand-TB Project as well as general training, laboratory accreditation and other activities; and (iii) reaching joint agreement on data interface standards for electronic and mobile communication device tools.

The Foundation works to strengthen WHO leadership in the development of, and setting norms and standards for, diagnostics through representation on expert panels, and help with drafting diagnostics-related guidelines.

ANNEX

EXPLANATION OF TYPES OF ACTIVITIES

Advisory – the organization regularly advises governments, nongovernmental organizations and institutions, intergovernmental bodies, or the media on matters within its competence.

Advocacy – the organization regularly undertakes campaigns, or its main purpose is, to influence decision- or policy-makers, or individual or societal behaviours or attitudes.

Conferences – the organization regularly holds scientific conferences, or other forums, excluding governing body meetings.

Data collection/surveillance – the organization, for example, maintains a register of specific diseases, up-to-date data about the number of people in a particular profession, etc.

Education/training – the organization, or its members, regularly provides educational or training courses for individuals or organizations (governmental and nongovernmental), is an examining or licensing body, or develops curricula.

Funding/donations – the organization funds the work of others and/or donates goods to others, for example, hospital equipment and pharmaceuticals.

Journals/publications/media – the organization regularly publishes a peer-reviewed professional or scientific journal and/or regularly produces and revises books and other media, e.g. CDs and videos, and maintains a publications/resources catalogue.

Research – the organization undertakes commissions or funds research as a regular activity.

Service delivery – the organization provides, commissions or is contracted on a long-term basis to provide services to non-members, for example, child counselling/protection, hospital care, suicide prevention services and delivery of food aid.

Sponsoring – the organization maintains a sponsorship programme, for example, for children, the elderly or young scientists.

Standard-setting – the organization formulates standards, ranging from professional conduct to goods and services.

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