

## GLOBAL ACCESS POLICY

### STATEMENT

FIND's mission is to turn complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives. Achieving our mission requires that we ensure access to *diagnosis* for those who are most in need. To achieve Global Access for the diagnostic products it supports, FIND works toward making diagnostic solutions available, affordable, and appropriate for use in low- and middle-income countries (LMICs), as well as ensuring they are adopted for use in these settings.

FIND's Global Access objectives are shaped to meet these "four A's", which, in the context of diagnostics and the scope of what FIND seeks to accomplish either directly or through its public-private development partnership collaborations, mean the following:

**Available:** Diagnostic products are developed, brought to market (i.e., registered for use) in LMICs, and their supply to LMICs is secured.<sup>1</sup>

**Appropriate:** Diagnostic products meet the needs of the target population and complement interventions that facilitate use in a weak health system infrastructure to become smart diagnostic *solutions*.

**Affordable:** The pricing structure is adapted to LMICs and strategies for further cost reductions are in place.

**Adopted:** The introduction of diagnostic solutions follows national policy decision and tailored rollout strategies in LMICs.

FIND works with ~160 partners each year, and its partnerships and projects span a diverse range of health care solutions. Developing a Global Access strategy for any specific intervention with our partners is one of the earliest project planning considerations. While there is no one-size-fits-all path to achieving our global access objectives, this policy outlines our principles and overall approach and builds on over a decade of practical experience delivering diagnostic solutions for diseases of poverty.

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<sup>1</sup> In alignment with the Global Access Principles of the Bill & Melinda Gates Foundation.

## **Objective 1: To make high quality diagnostic products available in LMICs**

The three main aims under this objective are:

### **1. Drive the development of diagnostic products that best fit the needs of high-burden LMICs**

FIND strives to ensure that its partnerships with academia, clinical trial sites, commercial companies, funders, and others result in novel tools that address priority needs for diagnosing diseases of poverty in low- and middle-income countries.

#### **1.1 Selecting best-fit products and partners**

To ensure that the right tools become available, FIND seeks to develop diagnostic tools that meet the priority needs and capacity of its target populations and markets. To achieve this, FIND:

- aims to develop diagnostic tools with desired features that are determined through a consensus-based process and supported by the World Health Organization (WHO), e.g., target product profiles (TPP), which are then published on the FIND website;
- in the absence of a relevant WHO-supported TPP, FIND works with national programmes (or ministries of health), implementers, researchers and other experts to define a list of desired product characteristics, also seeking WHO review of these characteristics;
- uses a standardized and transparent [process](#) to identify and select partners that can meet a number of set criteria, including Global Access requirements, for their products;
- conducts early-stage analyses around the likelihood that products resulting from R&D processes will later be procured and taken up in LMICs;
- submits partnership proposals for product investments that exceed \$200,000 to its independent Scientific Advisory Committee (SAC) for recommendation;
- provides high-quality data for regulatory and policy decisions;
- through FIND-sponsored trials, aims to inform review by stringent regulatory authorities, national regulatory authorities and WHO, for policy recommendations and guidelines on use;
- as a signatory to the ICTRP Joint Statement on Public Disclosure of Results from Clinical Trials, adheres to the registration of all clinical trials, submitting all results (whether negative, inconclusive, or positive) for publication in peer reviewed journals within 12 months of study completion, or otherwise makes the data available publicly at most within 24 months of study completion; upon request, FIND will share raw data (with appropriate protections) from clinical trials with third parties.

#### **1.2 Quality commitment**

FIND is committed to maintaining optimal quality standards, believing that product and service quality should not be compromised despite aiming for lowest cost delivery of diagnosis to patients in need.

- FIND requires that co-developed products conform to the ISO 13485 quality management systems standard, and to at least obtain CE Mark registration in Europe or its equivalent in the country of origin. In addition, partners agree to meet requirements to export the product to FIND's target markets.
- FIND will support WHO and LMICs in the creation of detailed materials, such as implementation frameworks, quality assurance processes, standard operating procedures to accompany new tools, etc.

- FIND will also support improvements in the capacity and quality of diagnostics systems in LMICs through technical and training initiatives, as well as through more advanced technology-based interventions as they become available.

## 2. Catalyse innovation and R&D through knowledge sharing

To cast the problem-solving net as widely as possible and to support innovation that could potentially lead to the next pioneering technology, FIND seeks to contribute to scientific advancement and the development of new diagnostic solutions through sharing data and publications.

### 2.1 Publications

- FIND supports the timely communication of all research in which it plays a part and will facilitate the rapid and accurate communication of such research and clinical trial results to the wider scientific and medical communities in a timely fashion.
- FIND prefers immediate, unrestricted, online access to peer-reviewed and published research papers, free of any access charge and with maximum opportunities for reuse.<sup>2</sup>
- All publications will provide appropriate attributions, citations and references, including acknowledgement of the generation of data.
- Notwithstanding the above principles, FIND will neither publish, nor request publication of, any information that would otherwise be inconsistent with confidentiality obligations of FIND or its partners.

### 2.2 Data

- FIND is committed to managing adequately and responsibly all data arising from its partnerships and has appropriate data governance plans in place to fulfil these obligations.
- All data, results, know-how and other deliverables generated through FIND project partnerships must be made available, at a minimum, to FIND.
- To the maximum extent agreed by the relevant partner, FIND seeks to ensure data is made publicly available, free of charge, in a timely and usable manner. FIND supports the FAIR (Findability, Accessibility, Interoperability, and Reusability) Guiding Principles that have been developed for scientific data management and stewardship.<sup>3</sup>

## 3. Secure sustainable product supply

FIND seeks to establish *security of supply*, defined as the timely delivery of functional products in sufficient quantities to meet demand, to its defined target markets. FIND requires its commercial partners to formulate a manufacturing and distribution strategy, including forecasts of anticipated annual sales volumes. FIND also seeks early involvement of key stakeholders such as WHO, governments and other procurers in generating independent demand forecasts to mitigate risk.

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<sup>2</sup> Any project that receives direct funding from the Bill & Melinda Gates Foundation must conform with this requirement.

<sup>3</sup> Mark D. Wilkinson, The FAIR Guiding Principles for scientific data management and stewardship (2016). *Nature Research Journal*, <http://www.nature.com/articles/sdata201618>

## Objective 2: To ensure appropriateness of diagnostic solutions

A diagnostic test or tool is not sufficient to ensure acceptability in FIND's target markets. It will need interventions that facilitate its uptake in a weak health system infrastructure. FIND thus needs to ensure that diagnostic tools and services are turned into *diagnostic solutions*. Interventions that FIND will support to achieve this are:

- Stakeholder coordination and advocacy: Alignment of stakeholders around the key role of diagnostics solutions within health systems, as well as disease specific interventions.
- Quality: Providing a) data for establishing global and national recommendations and guidelines and b) health worker training to build capacity for compliance and quality service delivery.
- eHealth and connectivity: Using technology and computing power to improve services to patients and programme management.
- Market intelligence: Compiling market information at several points during product development and roll-out that supports governments, industry, and partners to reach scale-up more quickly and efficiently.

## Objective 3: To seek diagnostic solutions that are affordable to LMICs

- 3.1 Lowest sustainable prices: FIND seeks to obtain the *lowest sustainable prices* for a product, defined as prices that are as low as possible while maintaining quality, providing security of supply and a fair return on investment for suppliers. From the earliest stages of research, FIND considers the feasibility of attaining an affordable price for the final product when considering whether to enter any product development project. This does not preclude FIND from supporting a leading-edge technology that does not meet price points yet has significant life-saving potential; in this instance, FIND will engage large global health players, including procurers, donors, and stakeholders, in pursuit of a solution.
- 3.2 Target price: During product development, FIND sets a target price together with the commercial partner and stipulates the price in the development agreement. The goal is to arrive at the lowest sustainable product price based on the manufactured cost of goods plus an agreed reasonable profit margin (COGs-plus). If a manufacturing partner is unable to provide the product i) at the agreed target price, ii) in sufficient volumes, or iii) at an acceptable level of quality once the product is brought to market, FIND retains the right to require the partner to transfer the technology, associated IP license and know-how to another manufacturer to be identified by FIND. Cost-effectiveness analysis, relative to currently existing technologies, is always required for the WHO endorsement process; product cost is but one of the factors analysed in such a process.
- 3.3 Target populations & markets: FIND's goal is to obtain the lowest sustainable prices for the public sector and, ultimately, those private sectors that serve the general public of all low- and middle-income countries<sup>4</sup> and Least Developed Countries (LDCs).<sup>5</sup>
- 3.4 Managing intellectual property (IP), which includes, but is not limited to, intangibles that are protected by the principles of patents, copyrights, trademark, trade secrets and data rights, is a critical component of Global Access.
  - a. FIND's **objectives** in managing IP are to:

<sup>4</sup> As classified annually by the World Bank: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>

<sup>5</sup> UN classification: <https://www.un.org/development/desa/dpad/least-developed-country-category/lDCs-at-a-glance.html>

- Provide required freedom to operate for the development, manufacture and commercialization of diagnostic products and services for its target diseases, pathogens and populations.
  - Minimize costs (e.g. from royalty burdens) to maximize affordability.
  - Maximize freedom for others to use the outputs of FIND projects (including but not limited to: data, algorithms, reagents including cell lines, software, know-how) for follow-on research.
- b. **Managing Background, Third party and Foreground IP:** FIND works through partnerships with for-profit IVD developers who are contractually bound, through the partnership with FIND, to ensure Global Access to FIND-supported products. These partners are asked to balance profitability and making the products available at a low price to in-need populations. All pre-existing intellectual property (IP) rights should be clearly identified, to the degree possible, at the start of the project. The management of all project IP rights are to be clearly agreed and contractually defined.
- Definitions: Background IP refers to the IP rights of project partners and of FIND that existed prior to a relationship between FIND and said project partners. Third party IP are IP rights belonging to third parties from whom a license or covenant not to sue may be required to ensure freedom to operate (FTO). Foreground IP is defined as IP rights that are generated or developed because of any project in which FIND has been involved with its project partners.
  - FIND requires potential commercial partners to conduct an FTO analysis to identify relevant IP rights and minimize potential encumbrances. Partners are expected to negotiate and facilitate access to any necessary Background IP and to manage risks that may arise through the life of the product.
  - Any inventions or other IP rights generated by or pursuant to any projects in which FIND is involved should be managed to achieve the IP objectives articulated above.
  - *FIND will not enter into projects where it is clear that IP may pose an insurmountable barrier to research, affordability or availability in LMICs.*
- c. Where necessary to achieve its broader mission, FIND might take an ownership position or accept rights that are limited to use only for target diseases, pathogens, or non-profit purposes. *Generally, FIND will not take an exclusive position on IP rights.*
- d. In the future, FIND will reassess its IP position in the light of changing business models, for example, the open diagnostic platform concept, to ensure the executability of potentially cutting-edge models.
- 3.5 Sustainability of pricing: FIND will work to secure the support of large-scale procurement agencies (such as The Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Drug Facility) in interventions to develop strategies that can increase affordability, predictability of demand and security of supply.
- 3.6 Transparency on pricing: FIND will publish data on agreed prices on the FIND website. FIND retains the right to audit, or have independently audited, the cost of goods and/or royalty burden of any FIND-supported product.

**Objective 4: Shaping pathways to accelerated adoption**

In-country delivery and uptake: Working directly with Ministries of Health, both in-country and implementing, FIND aims to facilitate product uptake at the country level by:

- a. Supporting developers and countries to develop and execute product roll-out plans and commitments;
- b. Providing assistance to governments to establish data-driven policies, algorithms and quality assurance programmes, creating replicable models that can be extended to multiple settings;
- c. Establishing strategic partnerships with large-scale implementers that are able to execute to implementation models in multiple countries;
- d. Working with local laboratory systems to develop sustainable and locally appropriate quality assurance plans, and support implementation;
- e. Collaborating with governments, distributors, vendors, laboratories, and other implementers to strengthen supply chains and distribution networks, and to define the terms and conditions of warranty, service and maintenance with partners.