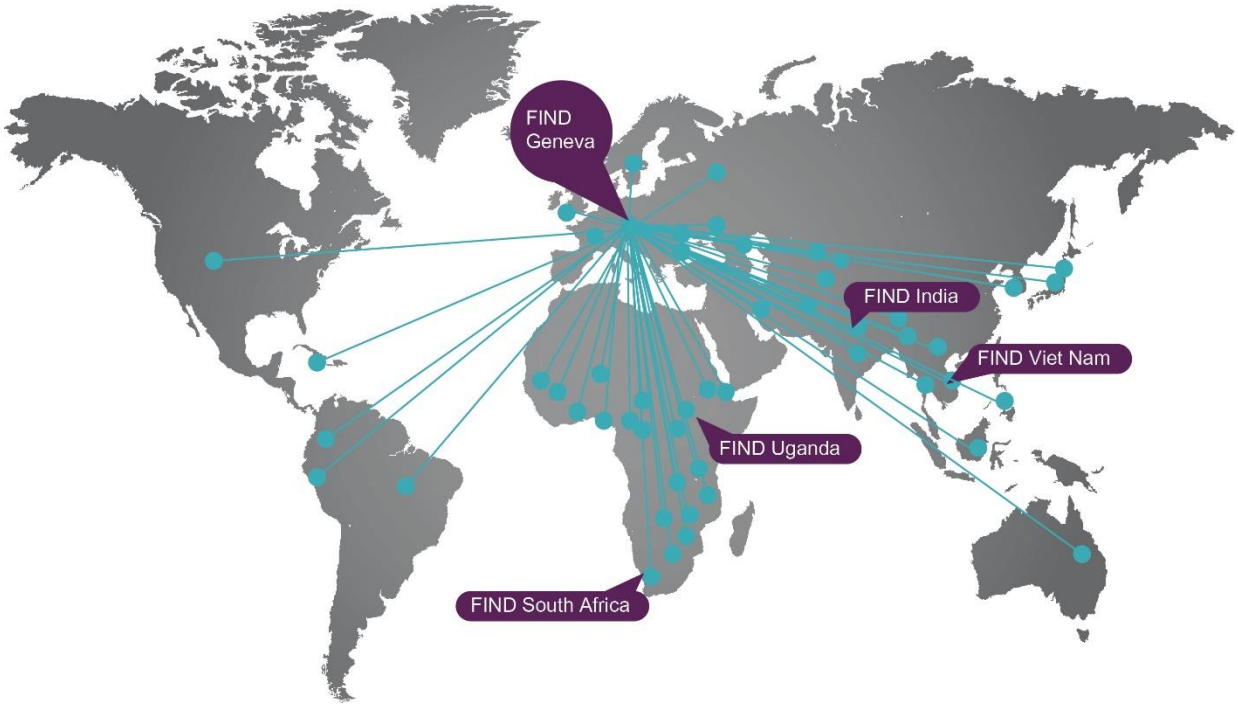
PRIVATE SECTOR PARTNERS POLICY

STATEMENT

FIND is a global non-profit organization, recognized by the Swiss government as an international organization under Swiss UID No. CHE-110.162.567. With headquarters located in Geneva, Switzerland, FIND has offices in India, Uganda, Vietnam and South Africa. Its mission is to turn complex diagnostic challenges into simple solutions to overcome diseases of poverty and transform lives.



To accomplish its mission, FIND has four strategic goals, described in FIND's 2015-2020 strategy: 1. Catalyse development; 2. Guide use & inform policy; 3. Accelerate access; 4. Shape the agenda.

The purpose of this document is to outline how FIND works with private sector partners, which includes all entities that are privately owned, or are developing or commercializing products or services for commercial purposes. It addresses the need for transparency, independence, absence of conflicts of interest, and objective standards to which FIND is held accountable when working with private sector partners.

To achieve its strategic goals, FIND works closely with private and public sector entities. FIND is in official relations with the World Health Organization (WHO) and provides data on diagnostics that can help to inform public health policies. FIND depends on sustainable financing for its projects. This requires the ability to enter into partnerships that are compatible with FIND's core mission and operating policies. These partnerships, especially those with private sector *in vitro* diagnostic developers and manufacturers, must be transparent and available for review and monitoring by FIND's independent Scientific Advisory Committee (SAC)[1] or another appropriate external review body. These review bodies must also be familiar with FIND policies, its governance controls and practices.

FIND catalyses product development, accelerating access to fit-for-purpose tools and technologies that serve its mission. These activities are based on scientifically validated or independently reviewed data and objective[2] standards. They are conducted in compliance with FIND's Code of Conduct and Ethics (the "Code") and its Statement of Recognition of Independence for Private Sector Partners, which describe the principles to which FIND adheres at all times in its governance, workforce environment, collaborations, research and financial stewardship.

FIND promises to act transparently and without favouritism, free of any conflicts of interest to the best of its ability and scope of control, with all its stakeholders. FIND offers indirect support by providing access to specimen banks and clinical trial platforms, as well as its disease, regulatory, technical and laboratory expertise, to facilitate the development and implementation of diagnostic products for use in LMICs. It also provides independent product evaluation data to WHO and national disease control programmes. FIND sometimes provides direct support to overcome bottlenecks or critical obstacles in the development of essential diagnostics projects in LMICs, e.g, through limited co-funding with other partners.

This document describes the principles to which FIND adheres to ensure that its partnerships, projects and programmes are free of any conflicts of interest or inappropriate private sector, political, organizational, social, and economic or other influences. FIND's decisions and actions should be congruent at all times with its strategic goals and ethical standards. FIND (which includes its personnel and consultants), are expected to comply with a number of overarching ethical principles in everything the organization does, including:

- Adhere to FIND's Code and comply with all local applicable laws, administrative requirements and regulations in countries where the organization works.
- Require all experts and private and public sector partners to accept FIND's Code (whenever possible), or a similar set of rules for avoiding any unethical behaviour or undeclared conflicts of interests; and
- Generate (whenever possible) effective, objective and meaningful ways of tracking, implementing and communicating progress, feedback and lessons learnt from each programme.

Further standards in relation to each of FIND's four strategic goals are presented below.

[1] Throughout this document, "SAC" refers to either the full SAC or a relevant sub-group.

[2] Definition of "objective" for this document is: as defined by a stakeholder/expert group that includes parties other than FIND

1. Catalyse development

FIND's primary objectives in catalysing development are to identify unmet diagnostic needs, find solutions for those needs and remove barriers to development of such solutions. This requires defining needs, scouting for and assessing new and complementary technologies, and providing access to FIND's support platform for manufacturers, comprising its Support for Success (S4S) programme (e.g., know-how and expertise); match-making to broker or generate new development partnerships; specimen collections; and a clinical platform for feasibility studies. This work may include giving access to research sites, reference materials, samples, biomarkers, new prototypes or experimental equipment. In all of these activities, FIND is expected to:

i. Identify and use target product profiles (TPPs) that have been externally validated by WHO, public health bodies or an equivalent global consensus process, as a basis for decision-making.

ii. Where TPPs do not exist, work closely with appropriate policy groups, researchers, country partners and implementers, in order to define a list of desired features and characteristics for any new diagnostic tools.

iii. Set clear product requirement documents (PRDs) that are based on TPPs (whenever available) and are available for review by FIND's SAC or other external review body.

iv. Adhere to FIND's technology scouting and selection process in order to facilitate access to FIND's support platforms in a fair, reasonable and non-discriminatory manner, based on objective parameters and selection criteria that can be reviewed by the SAC or another external review body whenever needed.

v. Generate clear, standardized assessments to ensure equal opportunity access based on relevant TPPs and PRDs.

vi. Ensure that the criteria used during the prioritization and selection of private sector partners, as well as the comparative advantages of each candidate (whenever several possible partners are identified), can be reviewed by the SAC or other external review body. This also applies to work done by any private sector partnership selected to assist in developing new TPP- or PRD-based products.

vii. Build and support open platforms, and meet global access requirements such as open access technologies, intellectual property freedom-to-operate, publication of data, access to appropriate biological materials, which are all subject to FIND's global access and intellectual property policies and any pre-existing contractual constraints. The goal is to ensure clear access rights whenever possible in order to facilitate broad adoption by manufacturers, research partners, suppliers and users for the development of affordable diagnostic products and services.

viii. Support a broad range of products, developers and manufacturers to meet identified needs in LMICs, especially those having high disease burden rates.

2. Guide use and inform policy

FIND's primary objective in providing guidance and informing policy is to reduce the time from development-to-market of diagnostic products for particular diseases with unmet needs. FIND also seeks to facilitate a greater understanding of how, when and where to provide diagnostic solutions, and to vouch for access to objective and actionable data to inform and improve public policy guidelines and decision-making. This work includes: (a) supporting national and global processes for policy guidance and defining optimal quality assurance processes; (bi) providing openly-available clinical platforms to collect and synthesize evidence and raw data to guide new diagnostic strategies; and (c) promoting and facilitating data exchange between WHO, industry, governments, laboratories and healthcare practitioners to inform and improve decision-making. FIND works with partners to establish what data is needed, how to collect and store it, and how to make it accessible and retrievable in useful ways. This involves leading or taking part in clinical trials and ensuring that such trials are aligned with product, policy and regulatory needs.

FIND's work in this field does not involve acting as an industry lobbyist or seeking to advance the interests of any private sector entities or group of companies; it seeks only to support public health policies to the extent that they assist patients in LMICs. FIND's primary goal here is to assist WHO and other public sector healthcare bodies in the design, collection, packaging, facilitation, and implementation of data-driven public policy guidelines, quality assurance processes and standard operating procedures. In all of these activities relating to this goal, FIND and partners are expected to:

i. Adhere to relevant standard operating procedures (SOPs);

ii. Prioritize products for trials using similar processes to those set out in section 1. above;

iii. Set appropriate pre-trial, primary and/or secondary clinical trial endpoints, consistent with validated TPPs;

iv. Prioritize trial needs and design studies in agreement with normative bodies, a global consensus process, FIND's SAC or another external body;

v. Use only clinical trial protocols that have been reviewed and accepted by the appropriate entity in any one country (WHO, appropriate national public health bodies, or their relevant ethics review boards);

vi. Seek to establish and use standardized protocol templates that have been externally endorsed, ideally by WHO or relevant national public health bodies, if available, in order to ensure comparability and consistency of data for similar product categories by applying standardized templates and protocols;

vii. Ensure independent statistical analysis of data;

viii. Organize an independent data oversight committee or equivalent body;

ix. Assist in the registration of trials with a national trial authorization body;

x. Only accept project-specific private sector funds for projects that are described in written agreements that can be independently reviewed by the SAC or another independent review body;

xi. Declare on FIND's website all substantial contributions (greater than US$ 5,000) from any private sector partners, whether received in cash or in kind (e.g., equipment, tests, or funded personnel);

xii. Submit all trial data, whether or not relating to commercial products, for publication;

xiii. Make data used to reach the conclusions of a manuscript (e.g., related meta data and methods) available for review; and

xiv. Facilitate the ability of WHO and other public sector bodies to cross-check data and monitor trials.

3. Accelerate access

FIND's primary objectives in accelerating access to appropriate diagnostic products in LMICs are to: (a) support rapid translation of global policies into actionable country plans; (b) enable quality assurance, approval, roll-out, adoption and use of proven diagnostic solutions; and (c) support long-term and integrated diagnostic capabilities as a centrepiece of disease control. FIND achieves this by working closely with WHO, public sector entities, local governments and health ministries, medical, disease or patient-oriented associations, and externally validated private sector partners, who can assist in reaching these goals. This includes expanding and strengthening networks of high-quality diagnostic facilities, engaging with relevant healthcare providers, and providing timely and effective information to support public health programmes and enable patients to obtain diagnoses and appropriate care. In all of these activities, FIND is expected to:

i. Prioritize products for implementation based on similar processes to those set forth in Section I above, as may be feasible and appropriate in each set of circumstances;

ii. Restrict implementation support to products or classes of products that have been approved or supported by WHO (e.g., based on WHO policy guidelines or pre-qualification approvals) or, for HIV and hepatitis, have strict regulatory approval from one of the founding members/countries of the Global Harmonization Task Force;

iii. Work in an impartial and objective manner with all private and public sector partners, based on evidence-based decision-making measures and any country-specific needs;

iv. Work collaboratively with all stakeholders to facilitate meaningful uptake;

v. Coordinate activities with WHO and any local public health bodies;

vi. Facilitate data tracking or post-market surveillance, and ensure transparent reporting and data sharing to the extent possible;

vii. Provide assistance to countries to establish product registration policies, where requested, as well as data-driven testing policies and algorithms; and

viii. Assist countries with their diagnostic capacity-building needs, including for the detection of new diseases or epidemics, and new technologies, and assist them in working suitably and transparently with private sector partners.

4. Shape the agenda

FIND's primary objectives in implementing this strategic goal are: (a) to champion and communicate the role of diagnostics as an essential part of good healthcare; and (b) to shape the diagnostics landscape to foster investment and public sector willingness to support it. FIND seeks to do so by engaging in thought leadership, advocacy, and tracking of effective expenditure and allocation of resources to support viable and sustainable diagnostic solutions. In all of these activities relating to shaping the agenda, FIND is expected to:

i. Generate objective, statistically relevant and validated data whenever possible about the benefits of integrating diagnostics as part of a public healthcare strategy, such as cost effectiveness, accuracy, sensitivity, and patient-centred benefits of integrating diagnostic solutions in the prevention, reduction or elimination of diseases;

ii. Promote evidence-based advocacy programmes, free of undue private sector influences or political interests;

iii. Act as an independent and objective facilitator or advocate of evidence-based public healthcare programmes and policies, which align public and private sector interests with affordable, effective, sustainable, and patient-centred healthcare;

iv. Measure and communicate empirical metrics for assessing the benefits and areas for improvement regarding the integration of diagnostics into national and global health agendas as identified by WHO and other public healthcare bodies; and

v. Create new opportunities for global healthcare funders, providers and public sector bodies to work together in designing optimal strategies for addressing unmet diagnostics needs in LMICs, especially those having high burden disease rates.

5. Role of FIND's Scientific Advisory Committee

FIND's SAC plays an important role as an independent body capable of reviewing all of FIND's programmes and its activities with private sector partners. It ensures transparency and acts as an external committee of experts that can independently assess, monitor and provide feedback on FIND's efforts and decisions in implementing the policies and guidelines set forth in this document. The SAC reports directly to FIND's Board of Directors, which has the ultimate authority and responsibility for approving all of FIND's policies, strategic decisions and objectives. The Board consults regularly with the SAC and considers all SAC recommendations. The SAC is capable of:

i. Providing independent, external and objective scientific input into all relevant activities related to FIND's strategic goals;

ii. Providing recommendations to the FIND Board directly, or through the Board's Scientific Committee, on optimal technologies, partnering opportunities and disease portfolio strategies that are in line with FIND's strategic objectives;

iii. Assisting FIND in building and developing its strategy, and providing technical advice and support to FIND staff;

iv. Advising FIND as a whole on all scientific matters, and supporting and reviewing the

scientific management and progress of projects and partnerships; and

v. Providing expertise on diagnostics, relationship development and any other public health or scientific issue as may be requested by the Board, the Board's Scientific Committee or FIND senior management.

All members of the SAC are required to comply with the FIND Code, and all relevant documents relating to or defining SAC activities and responsibilities. SAC members are prominent experts in the field of healthcare, who contribute independent and complementary feedback based on their individual fields of expertise. With the exception of a maximum of three (3) SAC members who may be appointed by not-for-profit diagnostic industry associations, SAC members may not be private sector employees. SAC operations are regulated by FIND's Board of Directors. All SAC members must inform the SAC Chairman in writing of any consulting activities they may have with any private sector entities that may be relevant to FIND's activities, and of any possible conflicts of interest relating to or arising out of their activities for FIND. In the event of any possible conflicts of interest, SAC members must recuse themselves from any votes on topics relating to such a project and from any involvement in such a project. The SAC is expected to review all private sector partnerships having a commercial value (whether in kind or in cash) in excess of US$ 200,000. This review function may also be done by other independent and external review bodies.

6. Review of ethical issues

In keeping with FIND's desire to ensure that all of its decisions and actions are in keeping with this document, all partners and stakeholders working with FIND are expected to report any behaviour not deemed to be in accordance with the provisions set forth in this document. Reports can be filed using the NAVEX EthicsPoint web-based reporting system that FIND has set up. This reporting system can be accessed via the "Ethics hotline" link on FIND's website. Also, in order to address any ethical issues that may result from the nature of its work with private sector partners, FIND has access to external and independent medical and legal bioethicists who can assist as circumstances warrant; an ethics review process may be advisable.

7. Board governance and oversight

FIND's implementation and compliance with this policy and the guidelines contained in it shall be overseen and regulated by the FIND Board of Directors. The Board shall periodically review how this policy is being applied, what private sector partnerships have been reviewed by the SAC or other external review body, and when such independent reviews are needed. The Board has the right to review and approve all private sector partnerships.