TECHNOLOGY REVIEW & PARTNER SELECTION

FIND
Because diagnosis matters

Q4 2017 – Q4 2018 Activity report & updates

About technology scouting

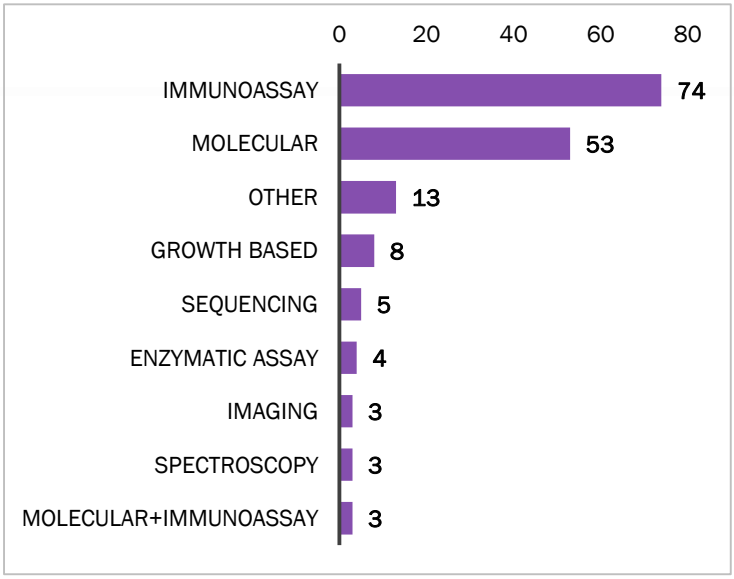
FIND seeks out innovative, new diagnostic solutions for poverty-related diseases that meet specific, priority needs linked to target product profiles (TPPs), as well as platform solutions that can be used across several diseases. FIND uses a transparent and accountable process for technology scouting and partner selection to ensure that the most suitable tools are supported, that potential conflicts of interest are avoided, and that the global community understands and has access to the selection process and its outputs.

Overview of the past year

FIND reviewed 166 product and technology proposals from various sources, of which 77 came via the FIND web-portal, 48 from active scouting, and 41 were responses to requests for proposals (RFPs) by the FIND HCV and Emerging Threats programmes. 41% of the submissions targeted TB, 22% HCV, 9% Emerging Threats, 11% Fever & Malaria, 12% cross-disease, and 5% NTDs.

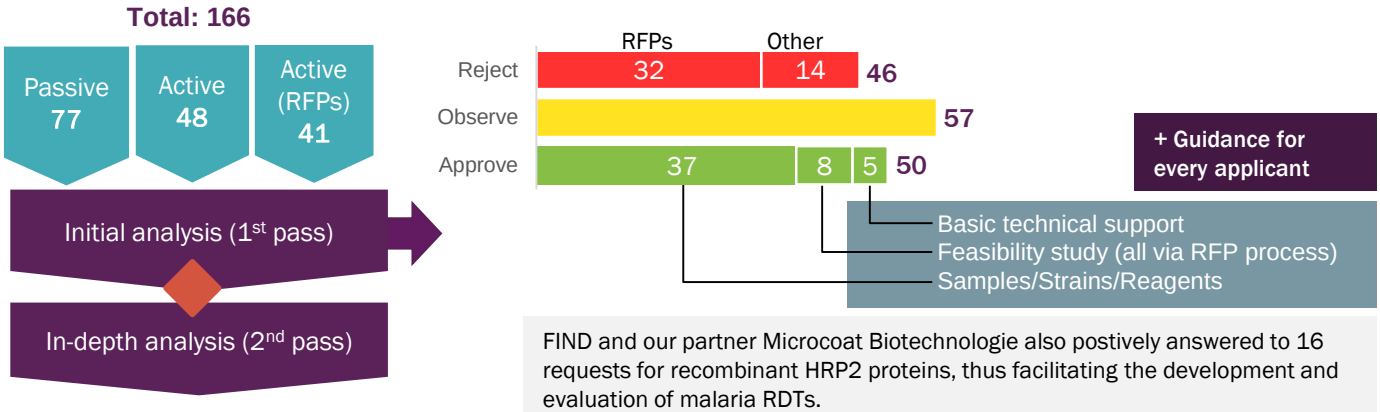
We went through the two stage assessment process. The **initial analysis (1st pass)** determines whether a proposal has the potential to address the specific diagnostic and market needs within FIND's priority disease areas. The 1st pass may lead to basic FIND support and investment and/or an opportunity for **in-depth analysis (2nd pass).** The 2nd pass may lead to further FIND investment and inclusion in our portfolio.

166 Technology submissions covering multiple technologies



1st pass analysis (153)

FIND catalyzed the development of diagnostic solutions by delivering basic support to 50 submissions (access to patient samples, strains or reagents N=37, did a feasibility study N=8, gave basic support for success N=5) while providing detailed feedback to every applicant:



FIND and our partner Microcoat Biotechnologie also postively answered to 16 requests for recombinant HRP2 proteins, thus facilitating the development and evaluation of malaria RDTs.

2nd pass analysis

Following the 2nd pass analysis and review by FIND's Scientific Advisory Committee (SAC), 6 product development partnerships were identified. The new projects aim to:

1. impact the diagnosis of tuberculosis with a community-based triage test (Precision Biosensor)
2. bring a point-of-care test for HCV to improve access to care (Molbio)
3. deliver innovative rapid diagnostic tests (RDTs) for multiple diseases (Mologic)
4. Improve patient management and AMR control by expanding assays for carbapenem resistance (Cepheid)
5. support outbreak preparedness through menu expansion (collaboration of Cepheid, altona Diagnostics, and BNI)
6. bring a transformative and versatile technology to primary care health level settings (BLINK).

Partner	Programme	Platform	Application
Precision Biosensor	TB	Instrumented RDT	Triaging of TB patients
Molbio	HCV	POC NAAT	Access to more HCV patients
Mologic	Multiple	Visual RDTs	High sensitive RDTs
Cepheid	AMR	Decentralized NAAT	AMR control
- altona - Cepheid - BNI	Pandemic Preparedness	Decentralized NAAT	Menu-expansion for emerging diseases
BLINK	Multiple	Immuno/NAAT	Multi-analyte detection system
Total approved: 6			

RFP for identifying technology partners

FIND published 4 request for proposals (RFPs) in this period: The Emerging Threats/Pandemic Preparedness team solicited partners for "Menu-expansion of existing Platforms for Emerging Diseases" while the HCV team had 3 independent RFPs targeting point of care technologies for molecular diagnostics and core antigen (cAg) RDT as well as platform-based products. Of the 41 proposals received, FIND made 9 awards involving a total of 11 organizations to

a. support outbreak preparedness through menu expansion
b. show feasibility of HCV tests

	Outbreaks	HCV		
Title	Menu expansion of existing platforms for emerging diseases	POC RNA assay on a polyvalent, fully integrated platform	POC high-sensitivity immunoassay on an integrated platform	RDT for core antigen
Awardees	Cepheid, altona Diagnostics, & BNI partnership [out of 4 proposals]	Abbott, Blink, & Diagnostics for the Real World [out of 16 proposals]	Chembio, DCN, & Mologic [out of 12 proposals]	Qorvo Biotechnologies, Novel Biomarkers Catalyst Lab B.V. [out of 9 proposals]

Landscapes for identifying technology partners

In addition to the aforementioned technology scouting activities, FIND completed several comprehensive industry/technology landscapes of **over 500 products** to identify platforms offering:

a. tuberculosis detection and drug-susceptibility testing solutions available in China (2017Q4): **27 suitable platforms out of 86 identified** technologies
b. sample-to-answer solutions to triage fever patients using a lead biomarker (2018Q1): **7 lead candidates out of a screen of nearly 150** POC platforms
c. portable and small-benchtop haematology solutions (2018Q3): **12 suitable platforms out of 31 identified technologies**
d. point-of-care rapid tests to support management of childhood febrile illness (2018Q4): commercially available tests were screened and data from independent evaluation were synthesized
e. simplified and accessible workflows for blood culture and antimicrobial susceptibility testing (2018Q1): **12 suitable platforms out of 26 identified technologies**
f. molecular and/or immunoassay detection capabilities for use in a semi-open business model:
    - Molecular landscape (2018Q2): **Assessment of 107 technologies with 22 lead candidates**
    - Immunoassay landscape (2018Q2): **Assessment of 54 technologies with 13 lead candidates**
e. information on currently available diagnostics for a list of various pathogens (2018Q2, Disease Commodity Packages)

These landscapes will inform the selection of partners and the initiation of new development projects.

Fever	TB	AMR & Outbreaks
Triage, POC CBC, rapid tests for childhood febrile ilnesses	MTB and DST molecular assays in China	Blood culture & AST, MAPDx-related molecular & immuno, Disease Commodity Packages

Review process

FIND has consolidated its Technology and Partner selection review process with a financial due diligence check list and review points on compliance with global access terms. This integration streamlines the overall process, ensures fairness in selection and favours rapid turnaround time.

Diagnostic Pipeline Tracker

We further developed and expanded our Dx Pipeline Tracker, which maps the status and estimated release dates of different diagnostic tools for tuberculosis, malaria, fever, HAT, Chagas, Buruli ulcer and leishmaniasis, allows stakeholders to visualize the diagnostic landscape and estimate when products may become available for implementation. Malaria diagnostics were added in December 2017, Fever in March 2018, and NTDs in April 2018. The status view of the tracker maps each technology along the stages of product development, as described in the TB Diagnostics Critical Pathway, a virtual knowledge management tool developed by FIND and partners to support an innovator's path from concept to access. The timeline view of the tracker illustrates the approximate date of commercial availability in low- and middle-income countries (LMICs) for each product, based on data that is publicly available or disseminated by developers.

Bm2Dx

In collaboration with McGill and the New Diagnostics Working Group, FIND launched Bm2Dx, a one-stop-shop for diagnostic biomarker evidence, quality and R&D progress. This web platform maps the status of biomarker research and allows stakeholders to visualize the R&D landscape and access comprehensive information on biomarker candidates. Thanks to advanced search and analysis tools, IVD developers and donors can focus resources on candidate tests with potential to meet the target product profiles.

Looking ahead

Building on the past achievements and lessons learned, FIND will continue to develop and further refine the support offered to diagnostic test developers. FIND hopes to identify and support the development of cross-disease, versatile technologies and solutions, as they are a critical for the future of diagnostic solutions in LMIC.