



TESTING

for healthy and safe lives

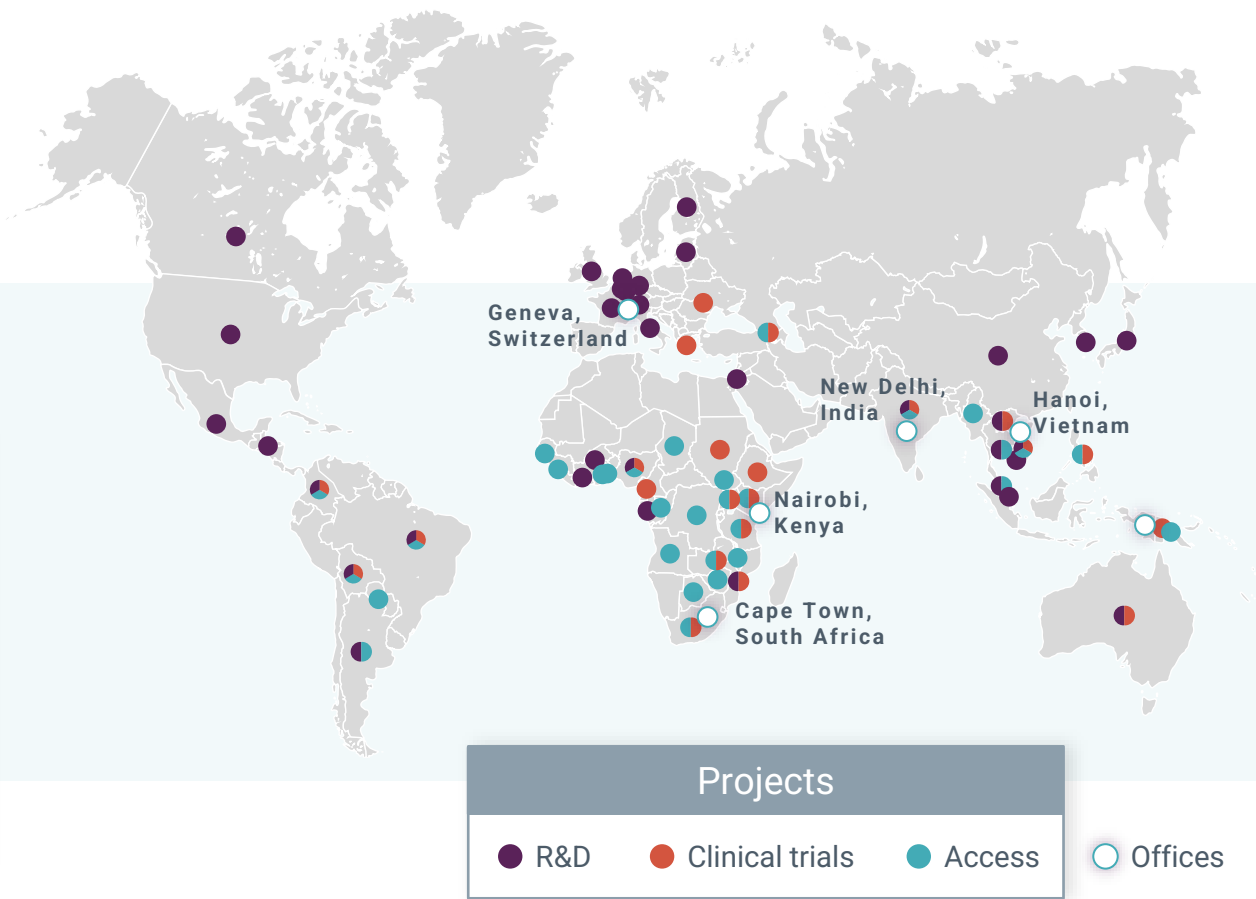
◆ November 2024



FIND ACCELERATES EQUITABLE ACCESS TO QUALITY DIAGNOSIS AROUND THE WORLD

In partnership with WHO, other global health agencies and the G20/G7, we are driving progress towards **universal health coverage** and **global health security**

- Established in 2003 as a product development & delivery partnership
- Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member



OUR GOAL: TRANSFORM TESTING TO ACCELERATE GLOBAL EFFORTS TOWARDS UNIVERSAL HEALTH COVERAGE & HEALTH EMERGENCY RESPONSE

Universal health coverage

Expand primary care testing to combat diseases that disproportionately affect vulnerable populations

- ◆ Tuberculosis
- ◆ Neglected Tropical Diseases
- ◆ Hepatitis
- ◆ Fever & Malaria
- ◆ Cervical Cancer
- ◆ Diabetes & Cardiometabolic Diseases

Health emergencies

Strengthen diagnostic surveillance and response systems to contain outbreaks and improve pandemic preparedness, aligned with a One Health approach

- ◆ Antimicrobial Resistance
- ◆ Pandemic Threats



FOUNDED AS A PDP, FIND HAS EVOLVED TO PROVIDE END-TO-END SUPPORT
TURNING DIAGNOSTIC INNOVATION INTO HEALTH IMPACT



RESEARCH & DEVELOPMENT
40 IVD products and **4 multi-disease** platforms in development

REGULATION & EVIDENCE GENERATION
124 active studies generating data for regulatory and LMIC decision making



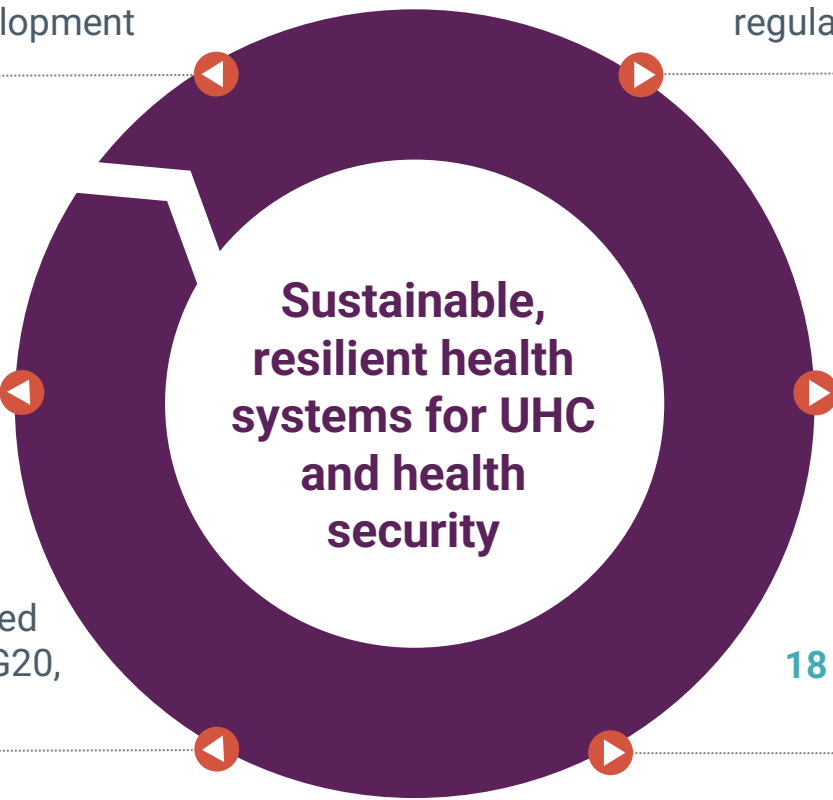
SCALE-UP & SUSTAINABILITY
58 countries supported to implement tests for patient care and/or disease surveillance

MANUFACTURING
3 regional RDT manufacturers supported in Brazil, India and Senegal



AWARENESS & ADVOCACY
60+ peer-reviewed publications released and engaged globally with the G7, the G20, WHO and almost 300 global partners

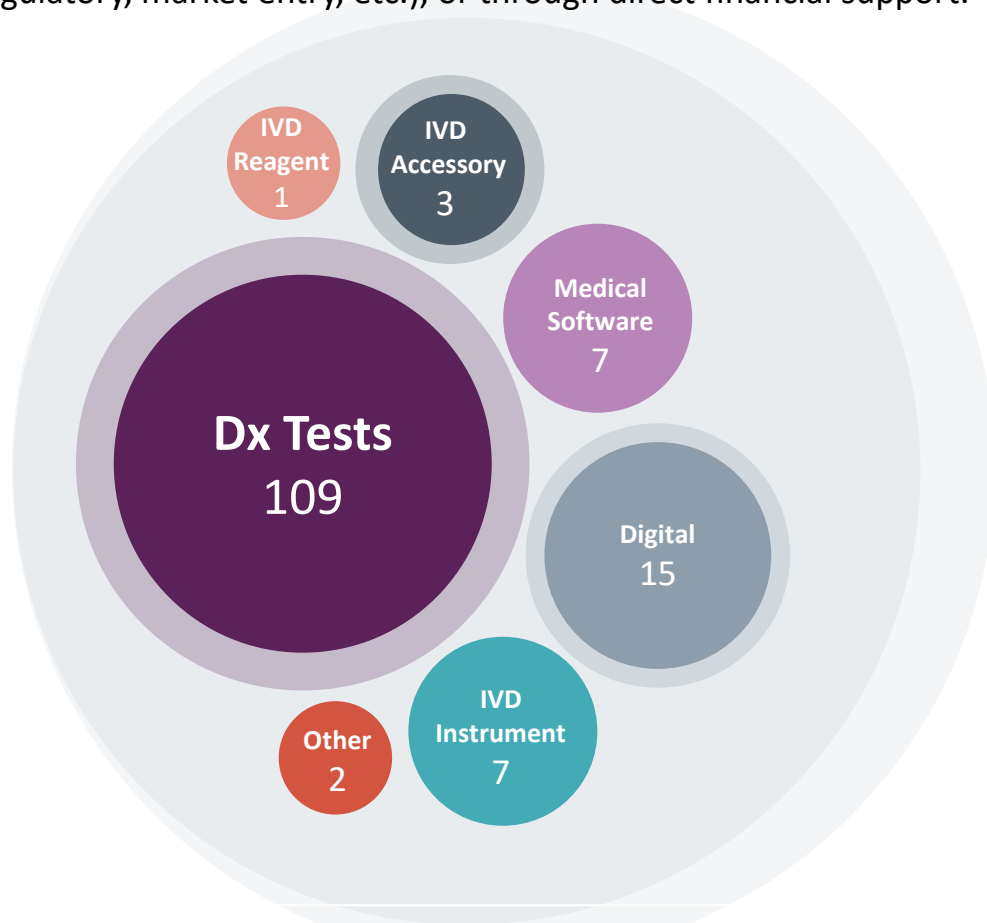
PROCUREMENT & SUPPLY
18 market access agreements with manufacturers



2023 IN NUMBERS

FIND Portfolio in 2023

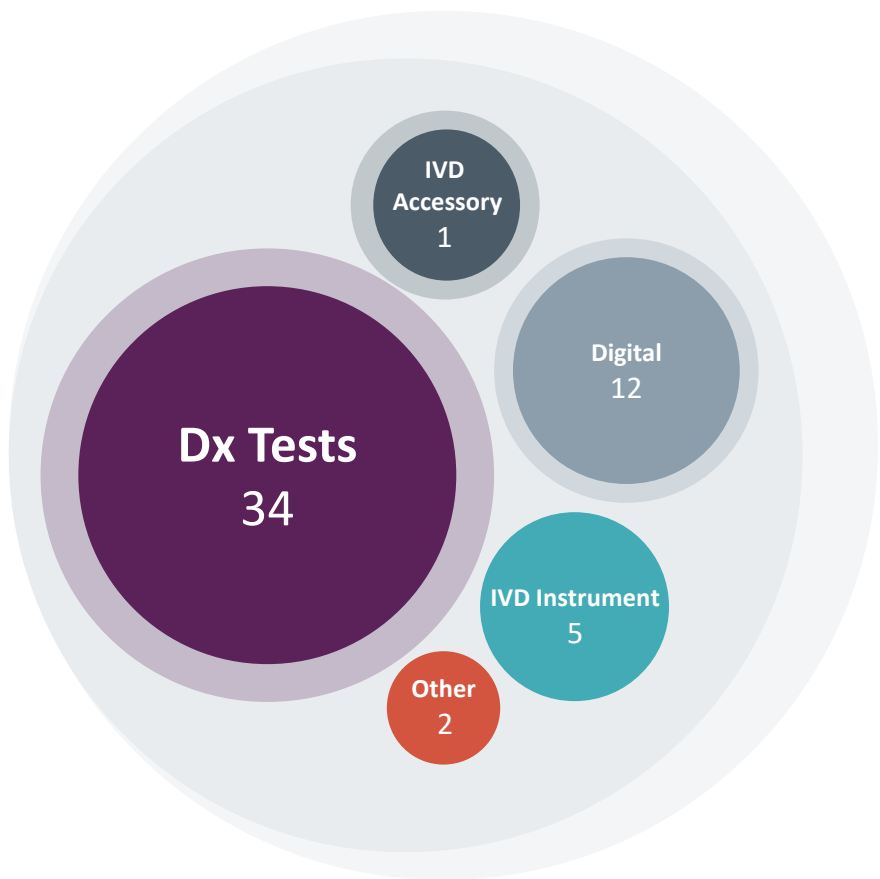
All products that FIND supports through conductance of feasibility studies, clinical trials, and independent evaluation studies, or through provision of technical assistance (manufacturing, regulatory, market entry, etc.), or through direct financial support.



Total FIND Portfolio: 144 products

FIND R&D Pipeline in 2023

The subset of the FIND Portfolio for which FIND, as a PDP, provides direct financial support for product development. (Note: direct FIND financial support is generally accompanied by technical assistance).



Total FIND Product Pipeline: 54

FIND STRATEGIC PRIORITIES TO TO STRENGTHEN HEALTH SYSTEMS AND MAXIMIZE IMPACT



Responding to countries' priorities

- Support packages tailored to country / regional needs for sustainable uptake and impact
- Strong partnership with MoH to influence policy on critical regional global health priorities

Collaboration with:
Brazil, Indonesia,
India, Kenya and
South Africa

Multiplex point-of-care molecular test launch



Identifying multiple pathogens from a single test enables health systems to be structured around patients, not diseases

Primary care and patient-centered diagnostics



Accessible diagnosis and health management where patients seek care is critical to Universal Health Coverage

Regional diagnostic manufacturing



Manufacturing RDTs closer to those who need them ensures sustained, secure and affordable supply

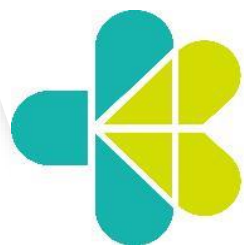
Disease surveillance



Reliable, connected and optimized networks provide essential early warning systems and track disease elimination

Equitable access to reliable diagnosis around the world

FIND



KEMENTERIAN
KESEHATAN
REPUBLIK
INDONESIA

FIND AND INDONESIA'S
STRATEGIC
COLLABORATION TO DRIVE
ACCESS TO ESSENTIAL
DIAGNOSTICS



THE GOAL AND OBJECTIVES OF OUR COLLABORATION

A strategic collaboration to expand access to essential diagnostics in Indonesia

◆ **Strategic collaboration focuses on strengthening primary care in Indonesia** through improved access and use of quality diagnostic tools, enhanced local manufacturing, and sustainable domestic investments in testing, to close diagnostic gaps and build resilience into the country's health system.

Particular emphasis will be placed on **synergies between diagnostics, digital health solutions, and laboratory strengthening initiatives.**

FIND'S SUPPORT IS ORGANIZED INTO SEVEN INTERLINKED AREAS OF WORK

Seven areas of work within MoU

1

Diagnostic Access

Expand, integrate and standardize lab and public health services to deliver universal access to diagnostics for 14 priority diseases

2

Local manufacturing of IVDs

Strengthen capacity of local IVD manufacturers to allow Indonesia to respond to current and future health threats within the country and regionally

3

Digital health

Support interoperability of diagnostic data systems and implementation of new digital tools to accelerate digital health transformation into Health Services platform - SATUSEHAT

4

Next generation sequencing

Strengthen the capacity of labs to use NGS to improve Indonesia's surveillance and treatment of AMR, TB and emerging threats

5

Antimicrobial resistance

Implement diagnostic and digital solutions and expand genomic surveillance to minimize the inappropriate use of antibiotics and address AMR

6

Tuberculosis

Trial point-of-care and near-point-of-care TB Molecular Diagnostics (incl. locally produced) to strengthen the quality and accessibility of Indonesia's TB lab network

7

Health talent transformation

Provide international learning opportunities for Ministry leaders to support goal of health workforce transformation and sustainability of implementation



IVD MANUFACTURER BOOTCAMP

Keys to successfully bring
new quality-assured IVD
products to the market

◆ Nov 20th- 22nd, 2024



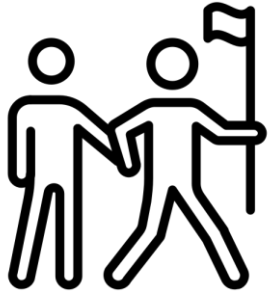
**PROVIDE KEY TOOLS TO SUCCESSFULLY DEVELOP,
MANUFACTURE AND BRING TO MARKET QUALITY-
ASSURED IVD PRODUCTS**

- ◆ ➤ **Product development**
- **Quality management**
- **Regulatory and procurement pathways**

BOOTCAMP ROADMAP

1. IVD Product Lifecycle: why phase gating is important?
2. Introduction to Regulatory
3. Defining Product Needs:
 - Product Requirement Document (PRD)
 - Regulatory Requirements
 - Market Assessment
 - Target Product Profile (TPP)
4. Quality Management System principles
5. Design Control
6. Risk management approach
7. Tech Transfer to manufacturing
8. Verification & Validation
9. Creating a Regulatory strategy
10. Introduction to WHO PQ

IVD MANUFACTURER BOOTCAMP BOOTCAMP RULES



Training on good practices – not the full and only truth

The training provided by FIND is based on our experience, however, there are no single way of developing quality diagnostics



Interact, challenge, share, question

Therefore, please share your practices, challenge and question us as to make this as interactive as possible

We are not here to judge but to learn and improve together



Disconnect

Please do not use mobile phones and computers during sessions – frequent breaks are also meant for this



Photographs will be used for external communication and reports. Please let us know if you do not want to your pictures to be used.

OBJECTIVES DAY 1

1. IVD Product Lifecycle: why phase gating is important?
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AGENDA – DAY 1

	Topic	Speaker
08:30 - 09:00	Registration	
09:00 - 09:15	Opening remarks	MoH
09:15 - 09:30	FIND introduction and support to Indonesia	Sara Fröjdö
09:30 - 09:45	Bootcamp objectives and agenda	Sara Fröjdö
09:45 - 10:30	Introduction of participants	All
10:30 - 11:00	<i>Break</i>	
11:00 -12:00	IVD product lifecycle. Why phase gating is important	Olga Ordeig
12:00 - 13:00	<i>Lunch</i>	
13:00 - 13:30	Introduction to Regulatory	Michelle Zaharik
13:30 – 14:00	Defining Product Needs – Product requirements	Olga Ordeig
14:00 – 14:30	Defining Product Needs – Regulatory requirements	Michelle Zaharik
14:30 – 15:30	Task 01: Define Intended Use/Indications for Use	All / breakout session
15:30 – 16:00	<i>Break</i>	
16:00 – 16:15	Defining Product Needs – Market requirements	Sara Fröjdö
16:15 – 16:45	Defining Product Needs – Target Product Profile	Olga Ordeig
16:45 - 17:00	Key take aways from Day 1 and Q&A	Sara Fröjdö

INTRODUCTION OF PARTICIPANTS



Please introduce yourselves per company:

- Company name
- Company activity in 1-2 sentences
- Name and position of each participants