

**FIND** 

SUPPORTING  
INNOVATIONS IN AI  
ENABLED DIAGNOSIS FOR  
LOW- AND MIDDLE-INCOME  
COUNTRIES

◆ September 2022



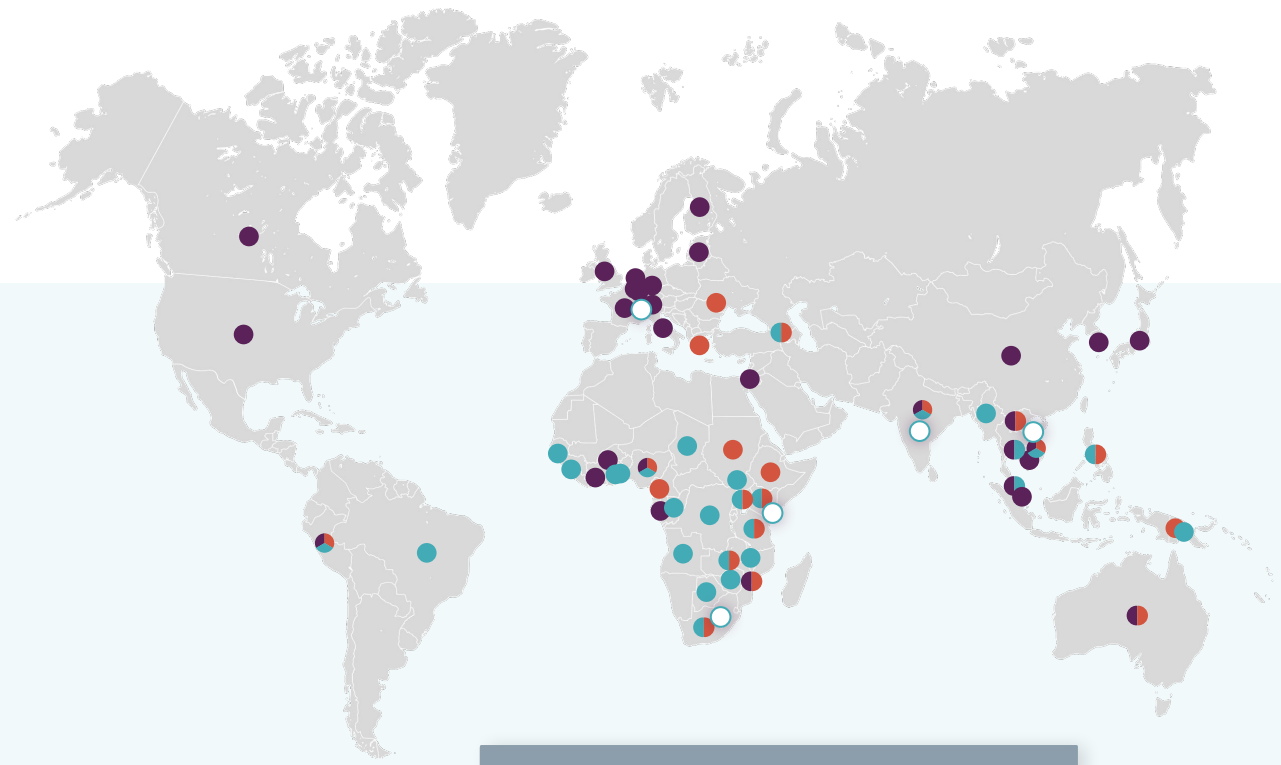
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INTRODUCTION

# FIND, THE GLOBAL ALLIANCE FOR DIAGNOSTICS

We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of **sustainable, resilient health systems**



- ◆ Established in 2003 as a not-for-profit 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

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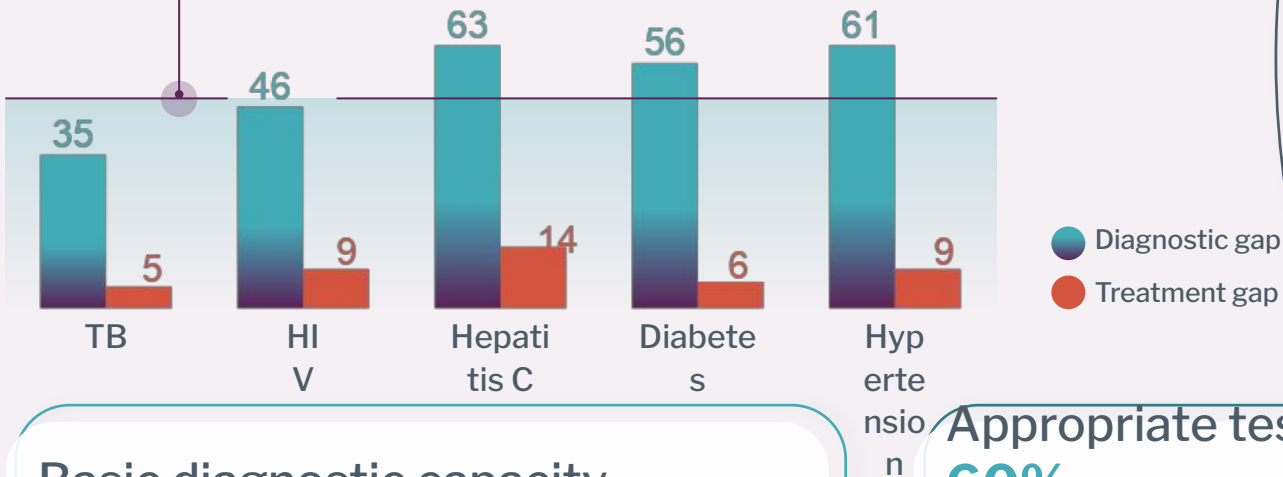
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FOCUS ON DIAGNOSIS  
IN LMICS



# UNADDRESSED DIAGNOSTIC GAPS ARE MASSIVE

~50% of patients do not get diagnosed



Basic diagnostic capacity is available in only **1%** of primary care clinics and **14%** of hospitals in some LMICs<sup>1</sup>

Appropriate tests do not exist for **60%** of infectious agents with outbreak potential<sup>2</sup> and **50%** of the top 20 diseases responsible for most lives lost<sup>3</sup>

<sup>1</sup> Leslie et al. *Bull World Health Organ* 2017;95:738–748, <http://dx.doi.org/10.2471/BLT.17.191916>.

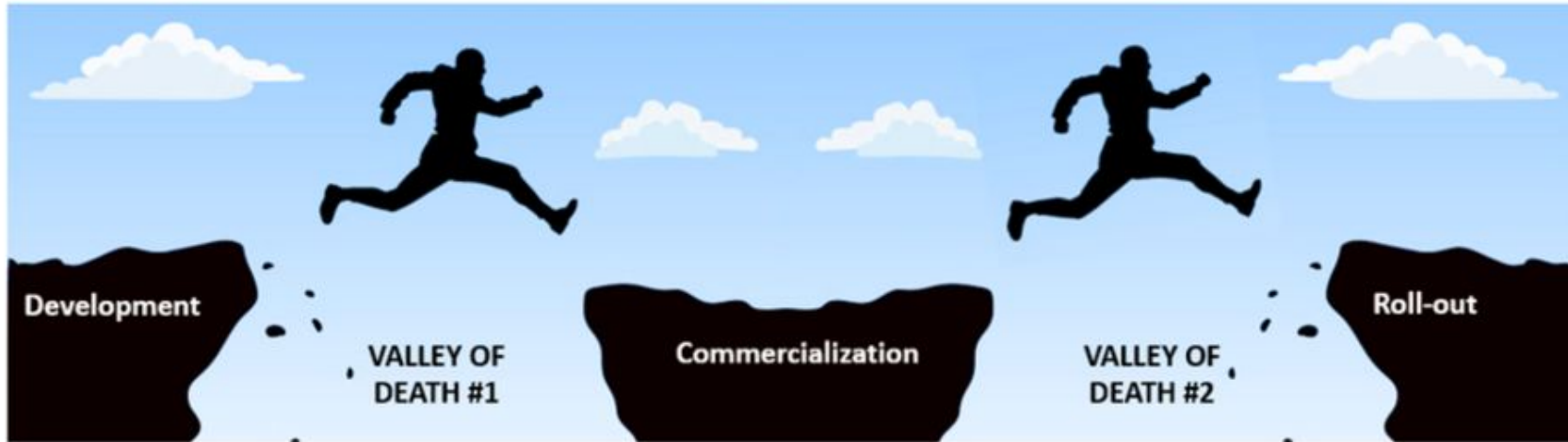
<sup>2</sup> Kelly-Cirino et al. *BMJ Glob Health* 2019;4:e001179. doi:10.1136/bmjgh-2018-001179

<sup>3</sup> Pai et al. Analysis from Global Burden of Disease Report 2020



# DIAGNOSTIC PRODUCT DEVELOPMENT AND INTRODUCTION

## VALLEYS OF DEATH IN DIAGNOSTIC PRODUCT INTRODUCTION



- Need Identification
- Concept and Feasibility
  - Development
- Lab & Clinical Validation

- WHO Evaluation
- Country Adoption
- Country Transition to Scale
- Scale-up and Monitoring

# OPERATING MODEL: PARTNERING FROM INNOVATION TO IMPLEMENTATION

## CREATING A VIRTUOUS CYCLE FOR (AI-BASED) DIAGNOSTIC SUSTAINABILITY

### Technology innovation

Partner with users and buyers to co-create fit-for-purpose tools with policy in place and a path to procurement

### Access innovation

Partner with countries to embed testing as an integral part of sustainable, resilient health systems



### OBJECTIVES

	Develop transformational diagnostic tools	Generate evidence	Build out local production	Develop marketplace & market interventions	Design new delivery models	Support countries to embed testing & surveillance into health	Strengthen diagnostic capacity	Support advocacy & mutually agreed accountability frameworks
Direct funding	✓ Co-creation of new tools	✓ Trial sites	✓ Tech transfer Manufacturing capacity		✓ Catalytic introduction		✓ Diagnostic capacity Training	
Lead	✓ Shaping R&D agenda Open-access resources	✓ Trial design & coordination	✓ Matchmaking	✓ Market intelligence	✓ Evidence generation for policy		✓ Training material Technical assistance	✓ Advocacy agenda
Coordination /support	✓ R&D portfolio mgt & RFPs (inc multi-source funding)			✓ Market-shaping		✓ Global guidance tailored to local context		✓ M&E

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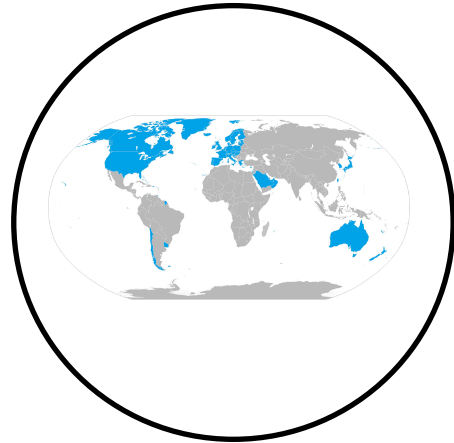
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SUPPORTING AI  
DIAGNOSTIC  
INNOVATION-  
EXAMPLE

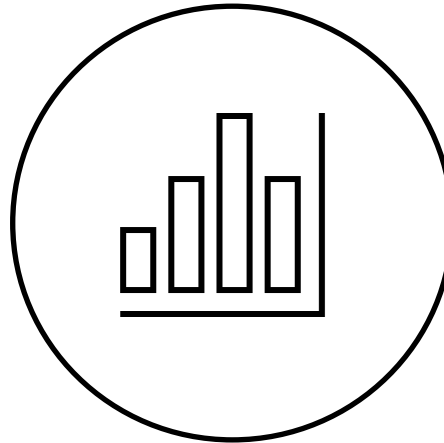


AI BASED DIAGNOSTICS AND EVALUATION

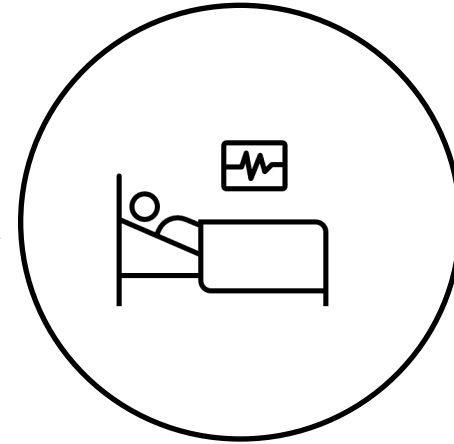
BARRIERS TO UPTAKE FOR AI-BASED DIAGNOSTICS IN LMICS



Most digital health solutions are currently built and scaled for use in high income countries



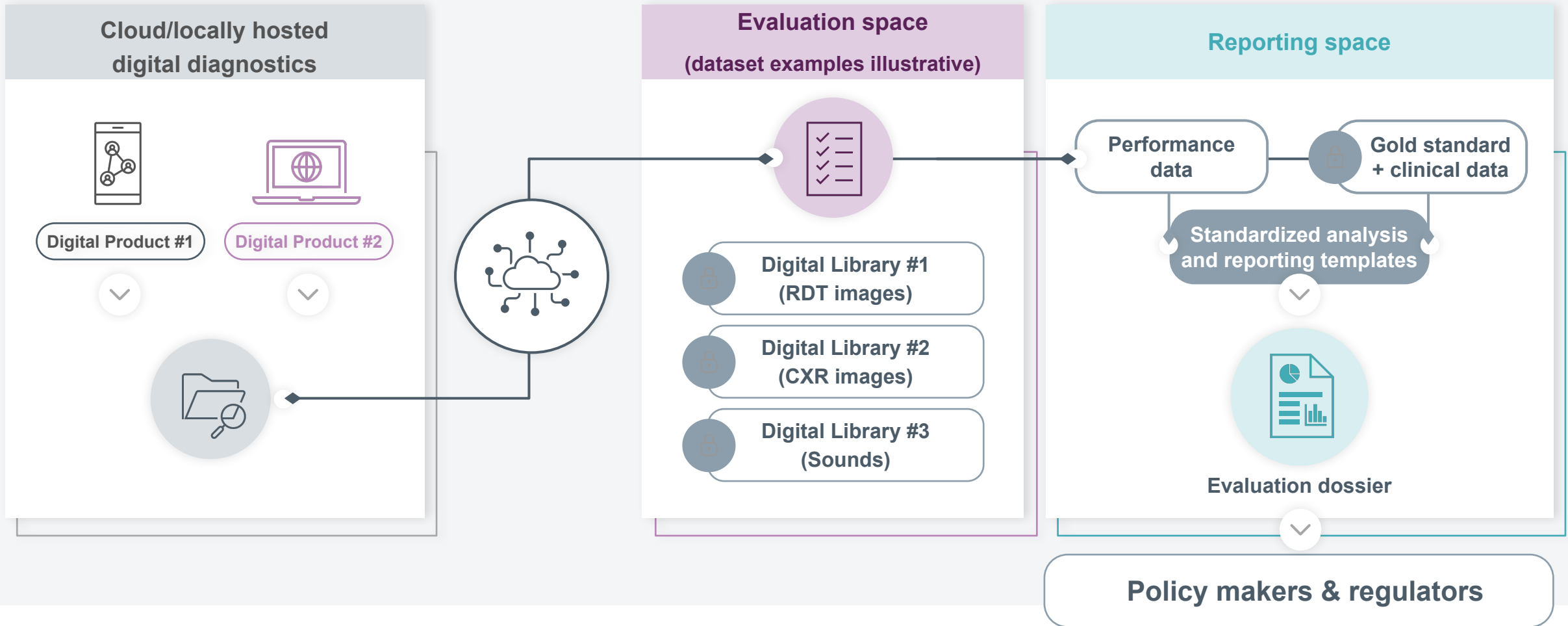
It unclear how and when these solutions will work in LMICs, which in turn impedes global and in-country policy approval and uptake



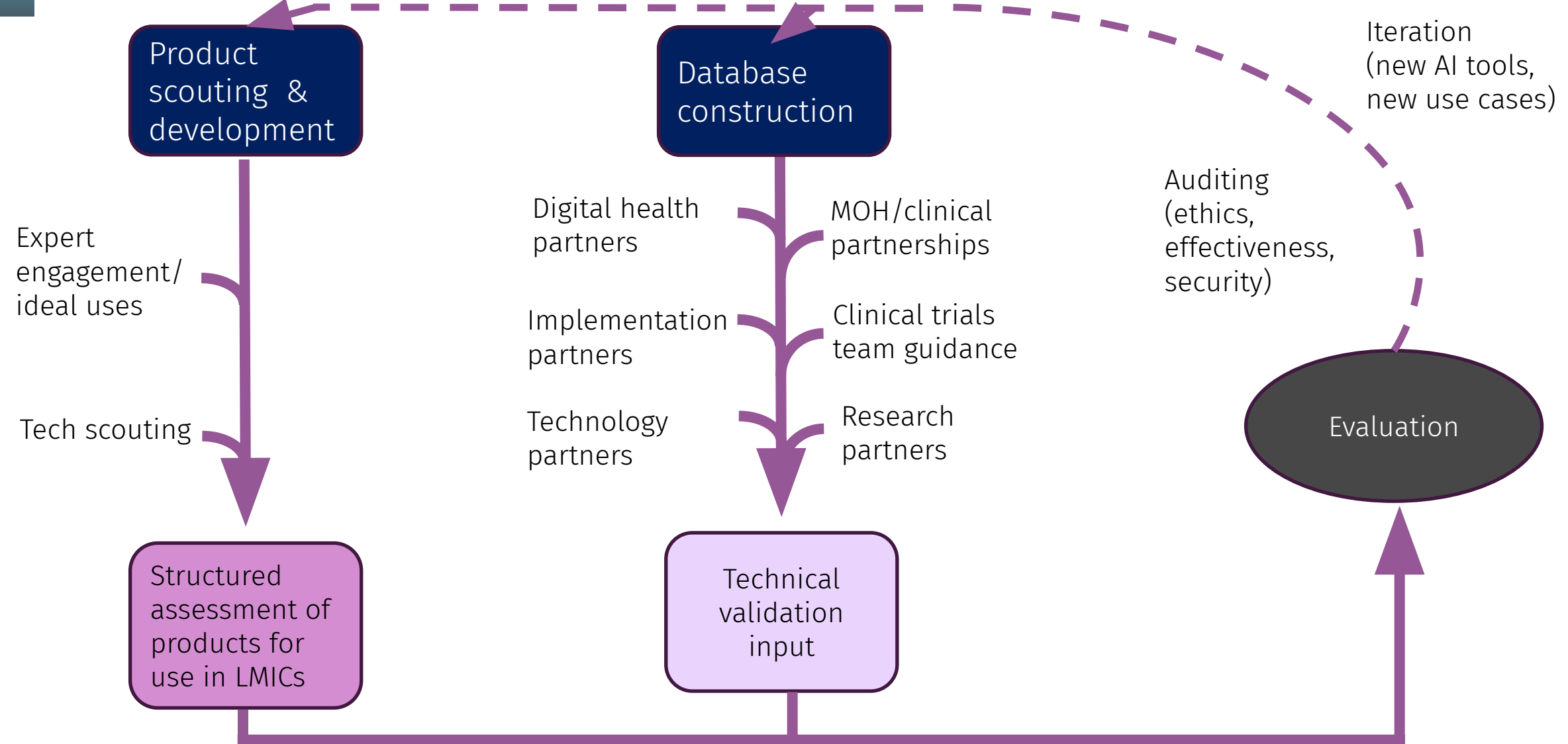
It is important to create and implement evidence generation frameworks for AI-based diagnostics that tailor to address policy and regulatory barriers at a global and national level to enable uptake

# EVALUATION PLATFORM FOR DIGITAL DIAGNOSTIC TOOLS

Designed to generate evidence on, and inform adoption of, digital diagnostics in LMICs



# EVALUATION APPROACH



# CAD AIs FOR TB A FAST-MOVING FIELD

 <b>TiNir</b> Certification: Pending Development Stage: Validation Intended Age Group: 18+ years	 <b>Genki</b> Certification: CE (pending) FDA (pending) Development Stage: On the market Intended Age Group: 16+ years	 <b>CAD4TB</b> Certification: CE-marked Class IIa Development Stage: On the market Intended Age Group: 6+ years	 <b>Dr-CADx</b> Certification: Pending Development Stage: Validation Intended Age Group: 16+ years
 <b>XrayME</b> Certification: Pending Development Stage: On the market Intended Age Group: 18+ years	 <b>RADIFY</b> Certification: FDA (pending) CE (pending) SAHRA Class A (certified) Development Stage: On the market Intended Age Group: 2+ years	 <b>InferRad DR Chest</b> Certification: CE-marked Class IIa Development Stage: On the market Intended Age Group: 12+ years	 <b>JFCB-2</b> Certification: China NMPA ncd3 (pending) Development Stage: On the market Intended Age Group: 15+ years
 <b>JD-02K (JMEWER)</b> Certification: CE-marked Class I Australia TGA Others Development Stage: On the market Intended Age Group: 10+ years	 <b>INSIGHT CIR</b> Certification: CE-marked Class I Korea MFDS Development Stage: On the market Intended Age Group: 6+ years	 <b>TISepTB</b> Certification: Korea MFDS (pending) Development Stage: On the market Intended Age Group: 20+ years	 <b>ChestLink, ChestEye</b> Certification: ChestEye: CE Class IIa ChestLink: CE Class II (pending) Development Stage: On the market Intended Age Group: 18+ years
 <b>qXR</b> Certification: CE-marked Development Stage: On the market Intended Age Group: 6+ years	 <b>ASX</b> Certification: CE-marked Development Stage: On the market Intended Age Group: 16+ years	 <b>OpenTB (provisional)</b> Certification: Not available Development Stage: Under development Intended Age Group: 18+ years	 <b>VUNO MedChest Xray, Pro</b> Certification: VUNO MedChest Xray: MFDS (KFDA), CE Pro: MFDS Development Stage: VUNO MedChest Xray: On the market Pro: under development Intended Age Group: 10+ years
 <b>Imagifor</b> Certification: Pending Development Stage: Validation Intended Age Group: 8+ years			

- 2017 - 1 PRODUCT**
- 2020 - WHO EVIDENCE REVIEW OF 3 CE MARKED PRODUCTS**
- 2021 - WHO POLICY ISSUED**
- 2022 - >17 PRODUCTS**

- **FREQUENT VERSION UPGRADES AND NEW FEATURES ADDED**
- **NEW AREA FOR POLICY MAKERS AND REGULATORS**

WHO consolidated guidelines on tuberculosis

Module 2: Screening  
Systematic screening for tuberculosis disease



# CADS SYSTEMS EVALUATION IMPACT OF THE PROJECT

Global CXR archive supports policy development

**2500** TB cases  
**6000** non-TB cases

**8 countries** (in Africa, Australia, Europe and South-East Asia)

**~ 10,000** Images from >15 academic partners

Enables rapid comparative assessment of CAD technologies in line with product development



Assessment across different use cases with bias reduced through independent evaluation from test developers

Improve patient care

“CAD may be used as an alternative to human reader interpretation of chest X-ray for pulmonary TB in individuals ≥ 15 y.o”

Updated WHO screening guidelines

Technology landscape supports country implementation

Provides an overview of digital X-ray and CAD technologies for TB diagnosis in the market



Implementation experience of early adopters in high-TB-burden countries

Ai4hlth resource centre (developed with the [Stop TB Partnership](#)) already provides implementation-relevant information for:

**17 CAD** products

**FIND is now expanding the evaluation platform to COVID-19 and other areas**

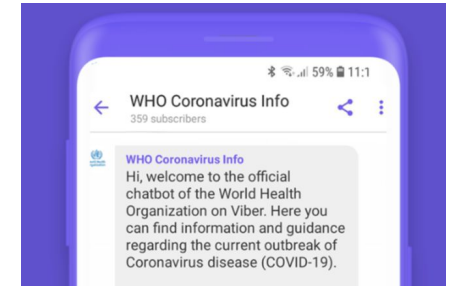
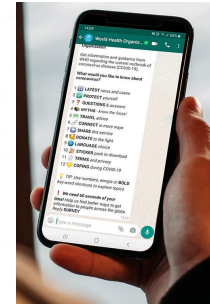


# FOCUS AREAS IN AI AND DIGITAL HEALTH

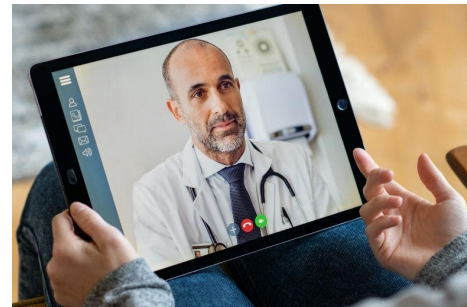
## EMERGING TECHNOLOGIES – FOCUS AREAS



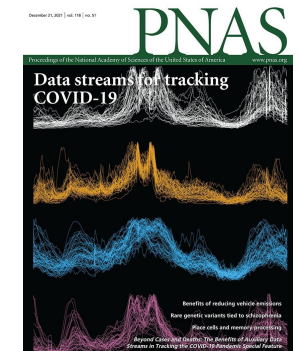
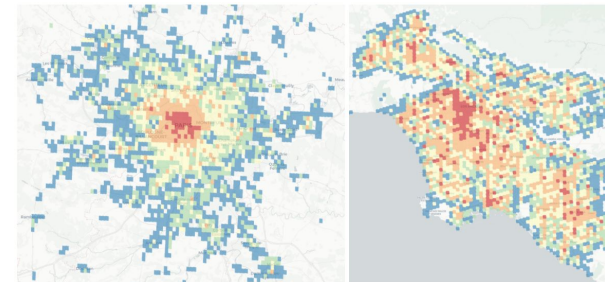
**Empower patients**  
Tools that empower patients with health and care knowledge



**Enable HCWs**  
Tools that enable HCWs to provide reliable and timely screening and diagnosis



**Inform public health response**  
Tools that enable surveillance and inform public health action



**Thank you**