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# Closing the Diagnostic Gap: RIGHT Foundation's Approach

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**RIGHT**  
국제보건기술연구기금

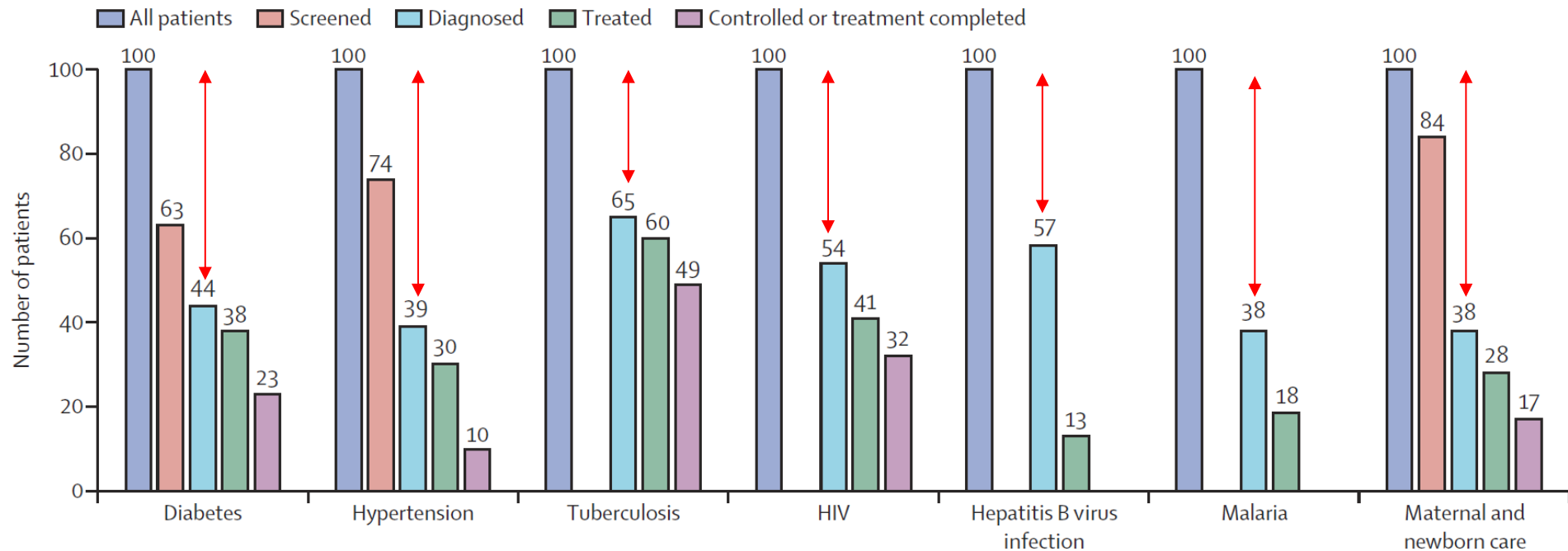
- What are the current gaps and needs in access to diagnostics?
- What does RIGHT Foundation aspire to do to contribute to closing the diagnostic gap?

# Current Gaps and Needs in Diagnostics



# Diagnostics gap is the major bottleneck in the cascade of care for five of the six health conditions

- Diagnostic gap ranges between 35-62% across the six conditions  
(Dx gap defined as the proportion of the population with a particular health condition who are undiagnosed)

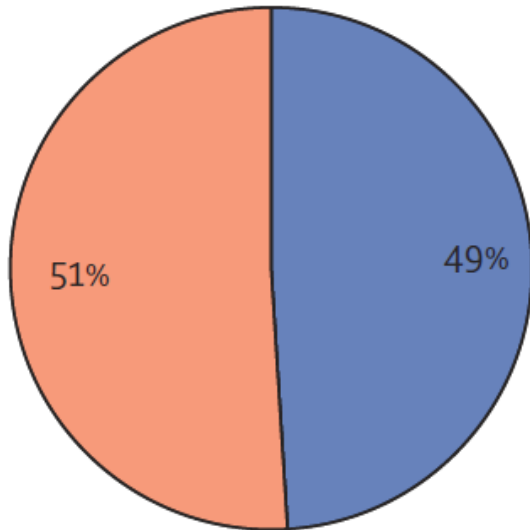


Results of a scoping review for six tracer conditions based on global data including LMICs EXCEPT HepB. HepB data include Australia only.

# Manufacturers in HICs dominate the global supply of IVD and Medical Imaging

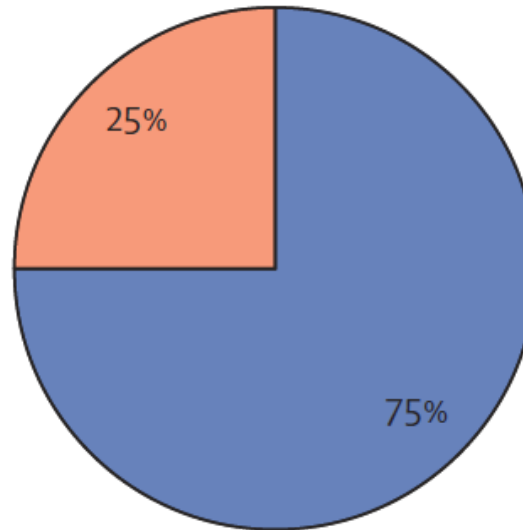
## In Vitro Diagnostics

- Top 4 (2 North America [USA], 2 Europe)
- Others



## Medical Imaging

- Top 4 (1 North America [USA], 2 Europe, 1 Asia-Pacific [Japan])
- Others



- Gap in Dx manufacturing capacity in LMICs
- China accounts for 14% of IVDs and 20% diagnostic imaging of the global total

# Priorities to improve diagnostic technologies for pandemic preparedness

Technology	Advantages	Drawbacks	Priorities for Improvement
Central laboratory NATs	High sensitivity and specificity, high throughput, multiplex across diseases	Limited access, slow test turnaround time	<ul style="list-style-type: none"> <li>• Lower-cost, high-volume PCR systems</li> <li>• Rapid sample transport and electronic results delivery system</li> </ul>
Point-of-care NATs	High sensitivity and specificity, detection near patient, fast turnaround time	Lower throughput, potentially high cost, few technologies available to date	<ul style="list-style-type: none"> <li>• Routine multi-disease tests across &gt;80% of primary healthcare facilities</li> <li>• Low-cost and easy-to-use platforms</li> <li>• Simple device-based and instrument-free technologies</li> </ul>
Rapid immunologic tests	Low cost, easier to deploy in most settings	Lower sensitivity, higher risk of test errors due to manual operation	<ul style="list-style-type: none"> <li>• Systems for rapid development, validation, and deployment of novel rapid tests</li> <li>• Standardized test formats to reduce training requirements</li> <li>• Data systems to transmit test results for disease tracking</li> </ul>

NAT, nucleic acid test

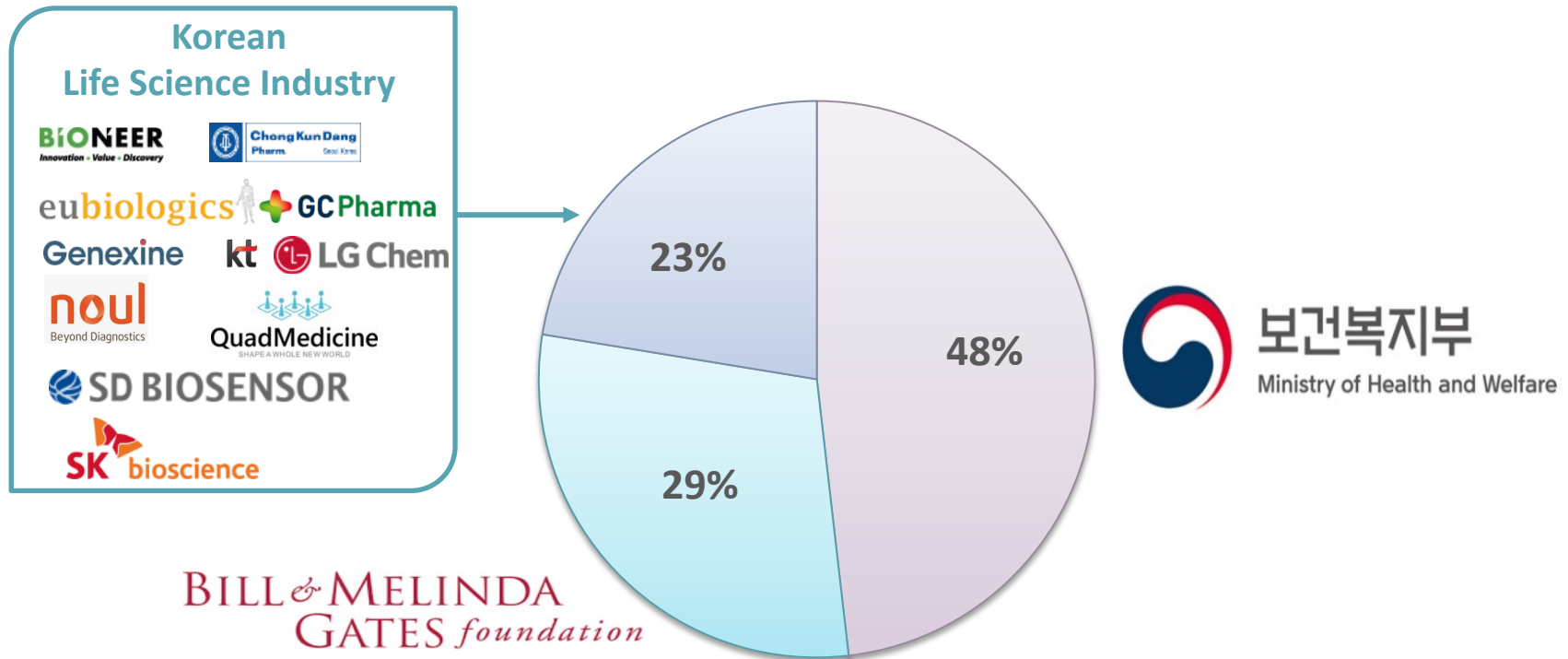
**RIGHT foundation's approach to contributing to  
closing the global diagnostic gap**



# RIGHT Foundation: Korea's first non-profit organization dedicated to funding global health R&D

- Established in 2018 to engage Korean life science partners to develop and make available critical health technologies as *global public good*
- Leverages the Korean Ministry of Health and Welfare's Official Development Assistance

## Committed funding (2018 – 2027)



# Our Mission and Goals

## Mission

Alleviate the burden of infectious diseases that disproportionately affect the people in low and middle-income countries (LMICs)



## Strategic Goals

### Product Development

Develop essential health technologies as global public good

### Collaboration

Catalyze international partnerships for co-creation/co-development

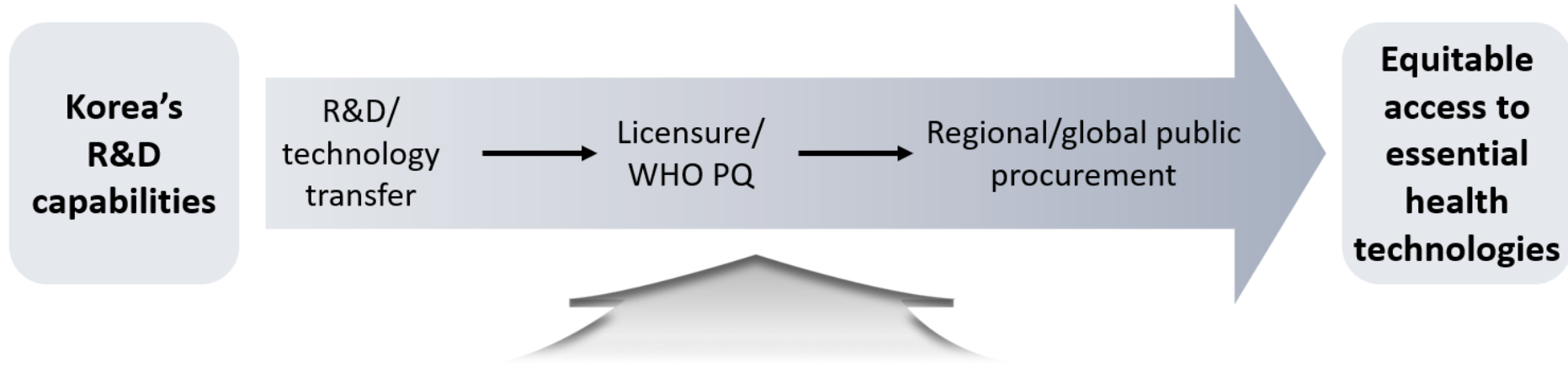
### Evidence Generation

Strengthen evidence base to guide product development

### Training

Train LMIC workforce in manufacturing essential health technologies

# We strive to contribute Korea's strengths to global public health and health equity



## Provide

- Funds for product development, evidence generation and training
- Insights on gaps and needs in global health R&D and competitive landscape

## Engage

- Key national, regional and global stakeholders to create or enable paths to public procurement



## Catalyze

- Partnerships between Korean and international R&D institutions

## Advocate to

- Regional and global funders to leverage Korea's strengths in the regional and global R&D ecosystem



# Korea has strengths in R&D and regulatory capabilities for Dx

## Exports of Korean-made COVID19 testing kits

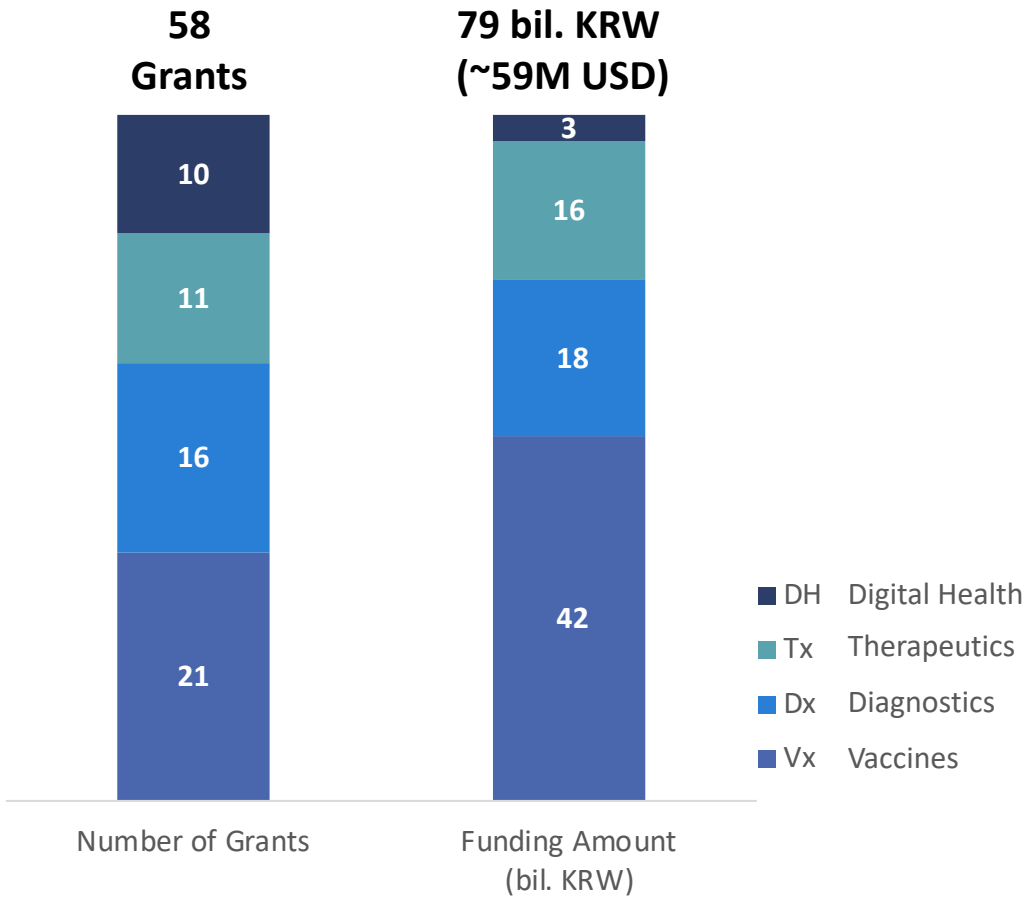
<b>Seegene</b>	90% of total production go to 45 countries
<b>SolGent</b>	Exports to 35 countries including Poland and Ukraine
<b>Kogene Biotech</b>	Exports to 37 countries including 7 Latin American countries
<b>Gene Matrix</b>	Exports to 4 countries including Italy, UAE and Chile
<b>GenBody</b>	Signs 4.8 bn won export contracts with 15 countries including Brazil & Ireland
<b>LabGenomics</b>	Exclusive supply to India through Germany's Siemens Healthineers
<b>Bioneer</b>	5 bn won export contract with Qatar's state oil company
<b>Clinomics</b>	Waits for MFDS export permission after 4.8 bn won contract with Hungary

<https://pulsenews.co.kr/view.php?year=2020&no=374050>

- **484** COVID-19 IVDs approved by KMFDS for export between 2020-2023 (Source: KMFDS (Korean Ministry of Food and Drug Safety))
- Korean-made COVID-19 test kits demanded by over 100 countries
- Korea's testing method of infectious diseases, including Covid-19 designated as an international standard by the International Organization for Standardization (ISO) on December 2020

# Diagnostics represent the second largest area of funding for RIGHT Foundation

**Cumulative Funding Commitment  
by RIGHT Foundation Since 2018**



As of 31 Dec 2023

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# RIGHT's Product Development Award funds clinical validation to licensure and technology transfer

## Product Development Award for Diagnostics

### Award Amount & Duration

- Up to 4 billion Korean won per project for up to 36 months
- Co-funding required for at least 50% of the project cost from for-profit entities

### Target Diseases, Infections or Pathogens

- Neglected tropical diseases (NTDs) especially Visceral Leishmaniasis (see the [WHO list of NTDs](#))
- Sexually transmitted infections (e.g., chlamydia and gonorrhoea, HepB, syphilis, HIV)
- Antibiotic resistant bacteria listed under the [WHO Priority 1 and 2](#)
- Malaria, tuberculosis, dengue, cholera

### Funding Scope

- True or near point-of-care (POC) molecular diagnostic platforms that can offer:
  - High sensitivity and specificity
  - Detection near patient
  - Fast turnaround time
  - Routine multi-disease tests across >80% of primary healthcare facilities
  - Low-cost and easy-to-use platforms
  - Simple device-based and instrument-free technologies
- New platforms to simultaneously detect multiple pathogens using minimal specimen volume
- Improvements in existing diagnostics to reduce complexity for end users across diverse resource settings (e.g., rural, community settings), to reduce cost and assay time
- Technology transfer to or from a Korean partner

### Development Stage

From or near the initiation of the clinical development or validation phase to regulatory approval with a clear path to public procurement (i.e. delivery within the local public health system)

## RIGHT Foundation Global Access Policy

### Supply

- Commitment to ensure sufficient supply of the funded products to LMICs

### Pricing
















- Commitment to set affordable prices for *public procurement* in the World Bank-defined low-income countries (LICs), and tiered pricing for middle income countries (MICs).

### License

- If the grantee decides not to supply to the LMICs, commitment to grant royalty-free, non-exclusive licenses to users operating for the benefit of the public market in LMICs.

# Our grantees aim for public procurement for equitable access

## Five most advanced Dx grantees aiming for WHO PQ or local regulatory approval in LMIC by 2028

Focus Disease	Grantee & Collaborator(s)	Project Description
MALARIA	     	AI-driven all-in-one diagnostic platform for malaria species differentiation
	 	The second-generation G6PD test
TUBERCULOSIS	  	POCT for Multidrug-Resistant TB
	 	The second-generation TB LAM assay
PNEUMONIA	 	POCT for COVID19, Influenza and RSV



# We strive to achieve impact on global public health: G6PD Test



Product Description	WHO PQ submission (Submitted in Oct, 2020)	Australian TGA (Approved in April, 2021)	WHO PQ Site Audit (Completed in May, 2023)	ERP (Renewed in Oct, 2023)	WHO PQ Approval
STANDARD G6PD					

- Glucose-6-phosphate dehydrogenase (G6PD) deficiency is the most common human enzyme defect that affects red blood cells and is highly prevalent in malaria endemic areas
- G6PD-deficient individuals risk having severe adverse reactions if exposed to a widely used class of malaria drugs
- POC G6PD tests can significantly aid in governments' efforts to treat and eliminate malaria
- Tafenoquine Roll-out Study (TRuST) with the Brazilian Ministry of Health and Medicines for Malaria Venture conducted a study to understand the feasibility of providing appropriate radical cure treatment (primaquine – PQ – or tafenoquine – TQ) based on the results of G6PD testing
- Brazil became the first malaria-endemic country to adopt single-dose tafenoquine and STANDARD G6PD Test for the treatment of relapsing P.v malaria.**



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# Acknowledgements



BILL & MELINDA  
GATES *foundation*

Full  
Partner

e**u**biologics 

 SD BIOSENSOR

 SK bioscience

 LG Chem

Associate  
Partner

**BIONEER**  
*Innovation • Value • Discovery*

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SHAPE A WHOLE NEW WORLD

감사합니다  
Thank you

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