



# Hepatitis C Diagnostics – the Bottleneck to Unlocking a Global Market

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Meeting at the Occasion of AASLD 2014 and 13<sup>th</sup> HCV DrAG Meeting  
Boston, November 11, 2014



Forum for  
Collaborative HIV Research



## Summary

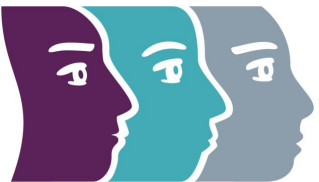


Forum for  
Collaborative HIV Research

### Agenda:

- 1. FIND – an innovative partner in diagnostics for limited-resource settings**  
*-- Peter Dailey*
- 2. Hepatitis C diagnostic tests - strategy and vision to address global market**  
*-- Peter Dailey, Cami Graham*
- 3. New opportunities for cross-sector partnerships**  
*-- Barbara Bulc*
- 4. Q&A and Discussion**

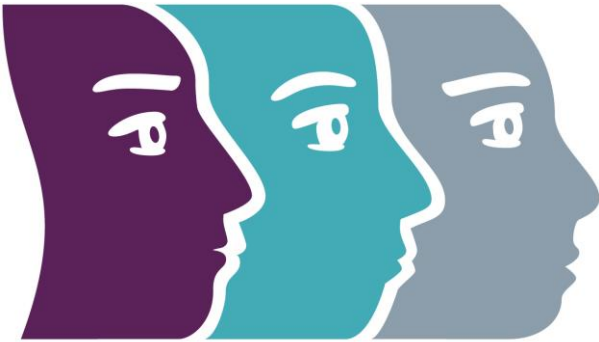
*Moderated by Veronica Miller, Forum for Collaborative HIV Research*



## Objectives

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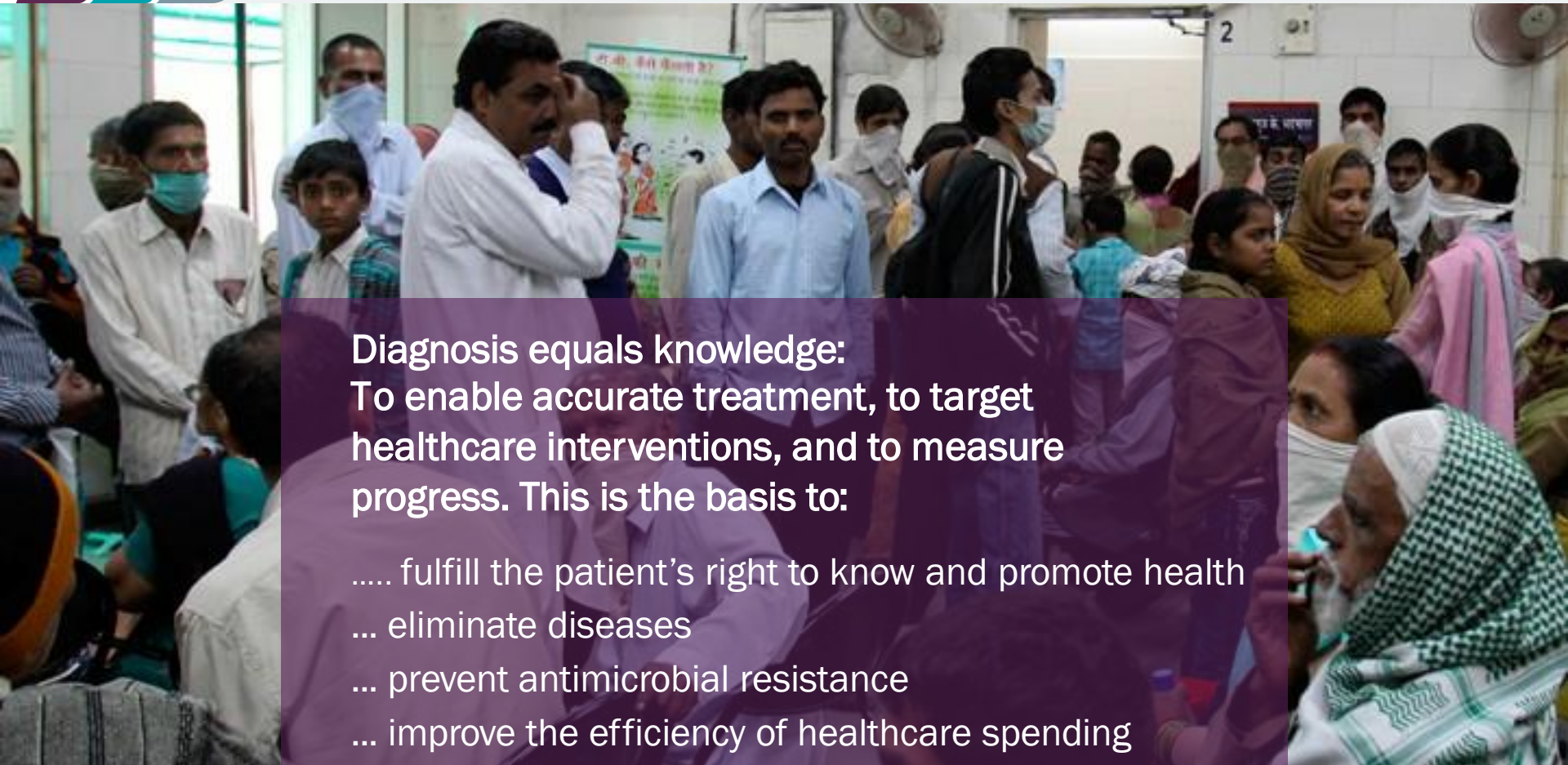
- **DRIVE ACCESS** What is potential of new diagnostic tests to drive access to care and treatment of HCV in limited-resource settings, and beyond
- **CONVERGE PERSPECTIVES** Converge diverse perspectives to enable new partnerships and innovation in support of HCV diagnostics and treatment
- **CATALYZE COLLABORATIONS** Share opportunities for collaboration with FIND as a catalyst to unlock a global market for HCV diagnosis and treatment



**FIND – an innovative partner in diagnostics for limited-resource settings**



# Why diagnostics matter



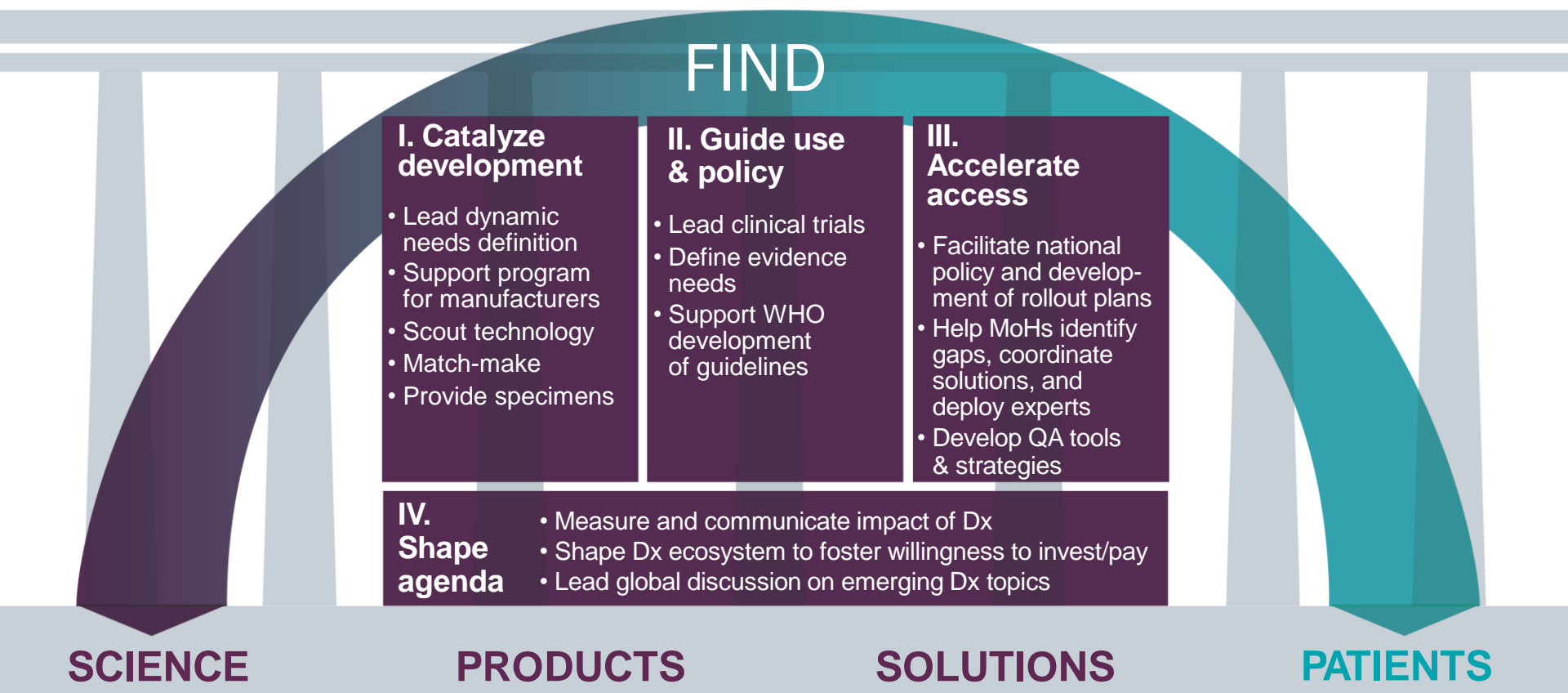
Diagnosis equals knowledge:  
To enable accurate treatment, to target  
healthcare interventions, and to measure  
progress. This is the basis to:

- .... fulfill the patient's right to know and promote health
- ... eliminate diseases
- ... prevent antimicrobial resistance
- ... improve the efficiency of healthcare spending



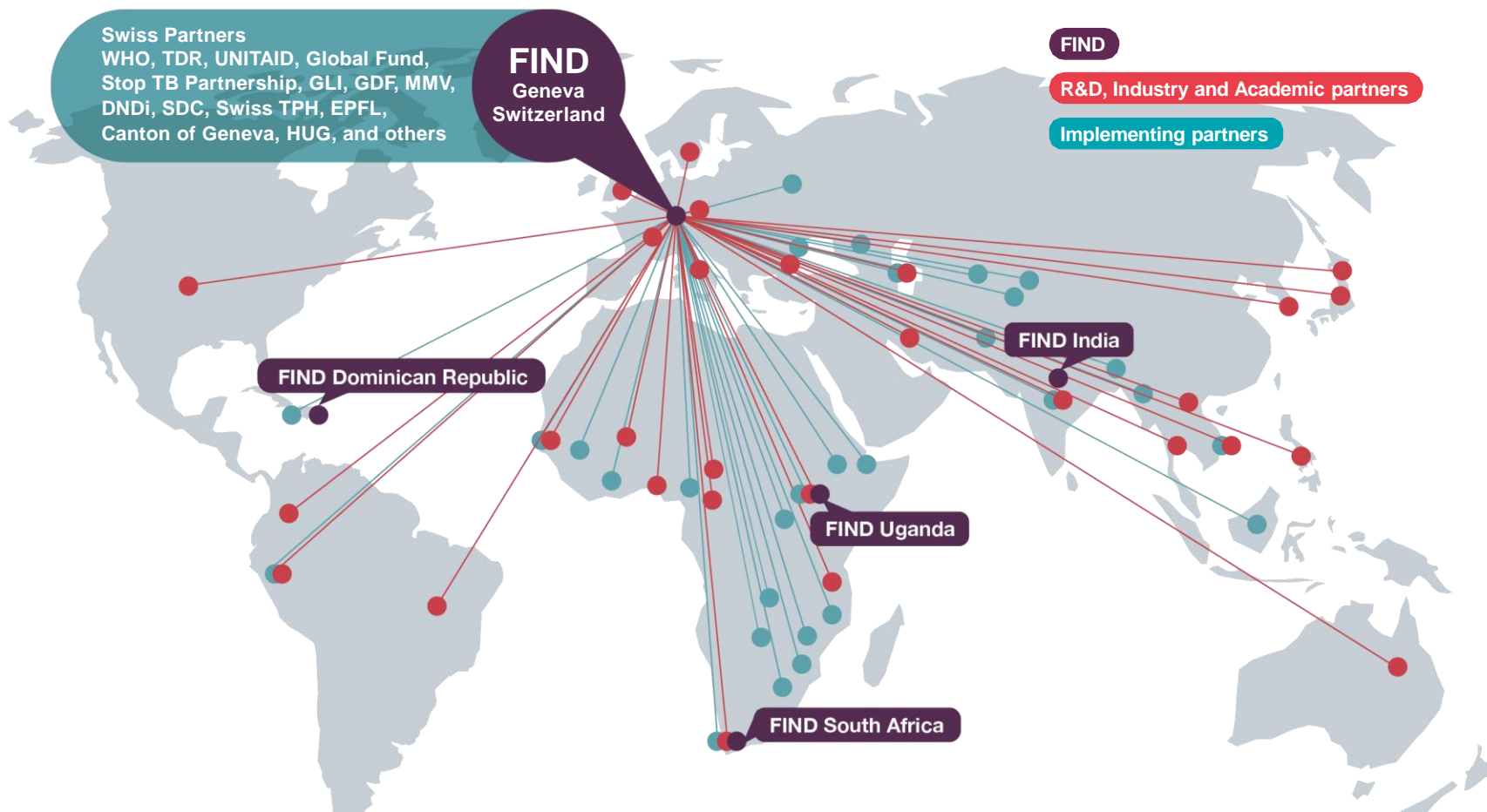
# Toward a world where diagnosis guides the way to health for all people

**Mission:** Turning complex diagnostic challenges into simple solutions to transform lives and overcome diseases of poverty





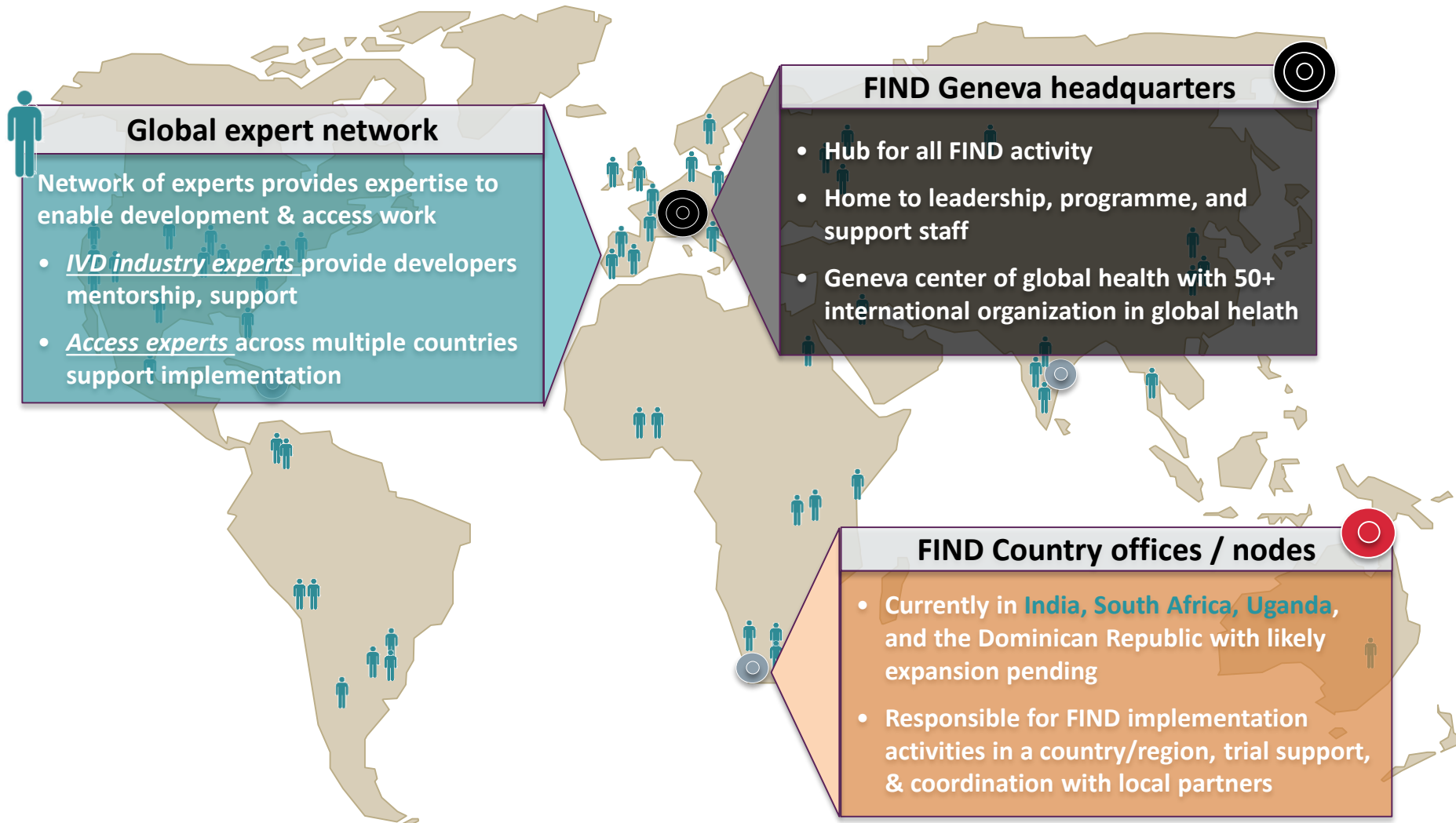
# Partnering for the right solutions



With **partnerships and opportunities** growing, we are determined to keep our role simple: ask the right questions, team up for the right answers. That is, after all, the root of diagnostic success.



# How we are structured

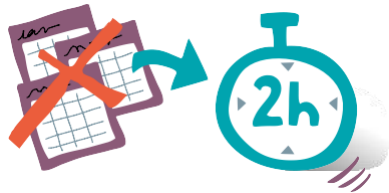






# Significant progress achieved in the last 10 years

## TB



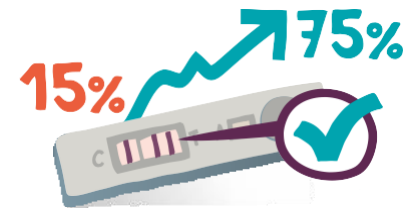
**Patients can now get drug susceptibility testing in 2 hours at a district hospital.** This used to take up to 120 days and was only available at national reference labs.

## Sleeping sickness



**The development of a rapid diagnostic test has helped make disease elimination a reality.**

## Malaria

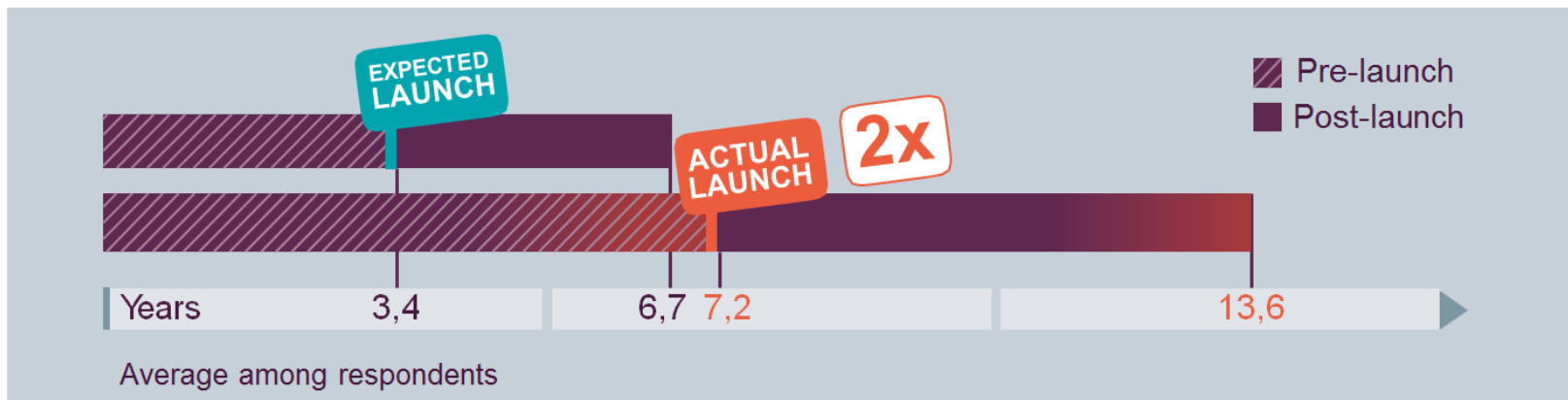


**Joint FIND-WHO efforts to assure the quality of rapid tests have increased the % of quality products in use from 15% to 75%.**

















# FIND's new Support for Success programme eases the way to uptake for promising products

■ **The problem** Market penetration for diagnostics relevant to Global Health markets takes 2x as long as product developers think:



► **The solution** Through IVD expert support, accelerate development and market entry:

Technical expertise	Disease expertise	Market & regulatory expertise
Manufacturing 	Malaria/AFS 	Logistics & Distrib. 
R&D 	TB/AFRI 	Quality 
IT solutions 	HIV 	Market understanding 
	Hep C 	Regulatory 
	NTDs 	Commercialization 
	Other 	

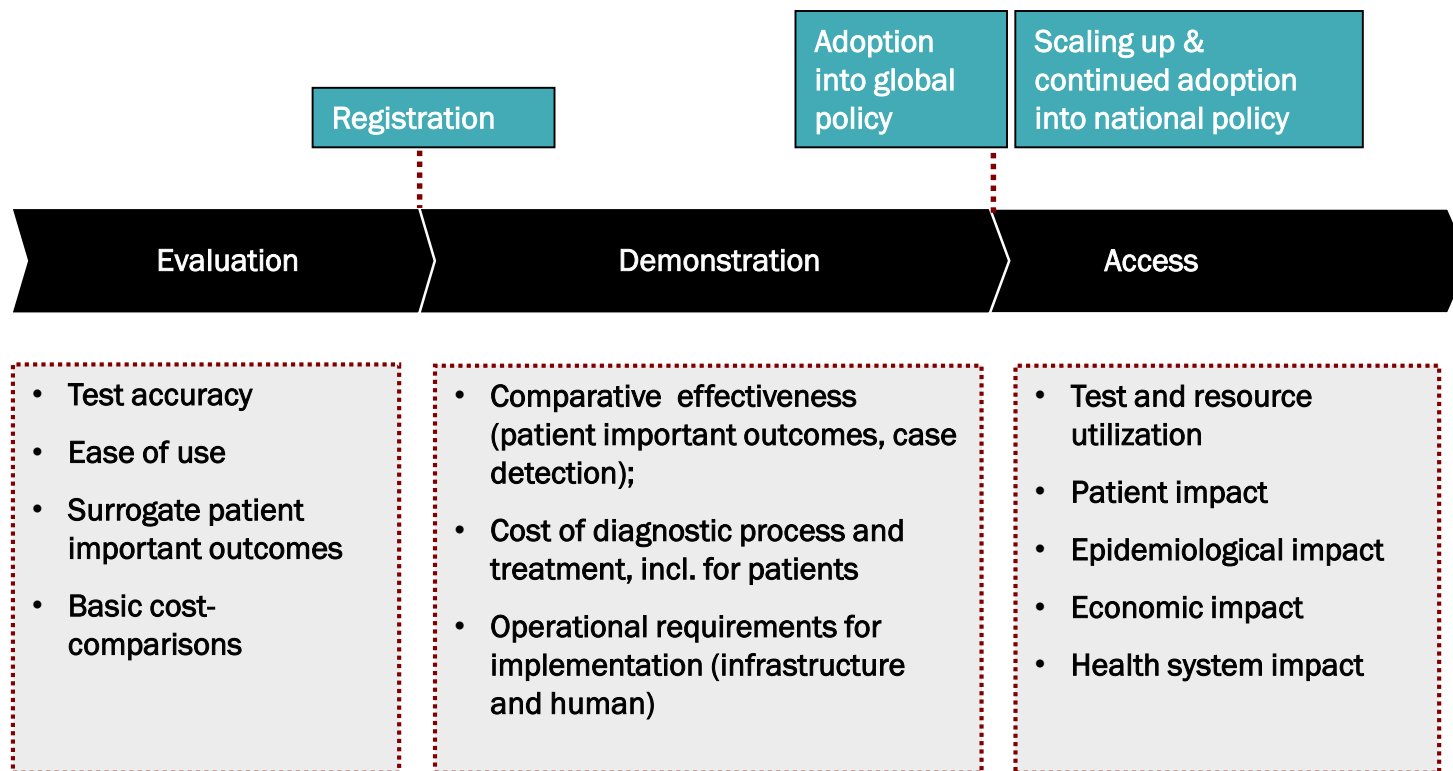


## FIND's unique global **biorepository** and **feasibility studies**

- The FIND biorepository currently counts over 60,000 aliquots among sputum, serum, EDTA plasma, P800 plasma and urine.
- Samples have been provided to more than 40 developers all over the world
- Also serving as the main provider of specimens for the BMGF TB Biomarkers Discovery project
- Technical feasibility and proof-of concept studies for the assessment of new TB diagnostic technologies are integrated into collections



# Diagnostic trials are a centerpiece of every step in the value chain



- Provide an open platform and ensure adequate firewalls to avoid conflicts of interest
- **Combining specimen banks and strong trial infrastructure to streamline the pathway**
- **Trial design, planning and coordination optimized to inform policy review**

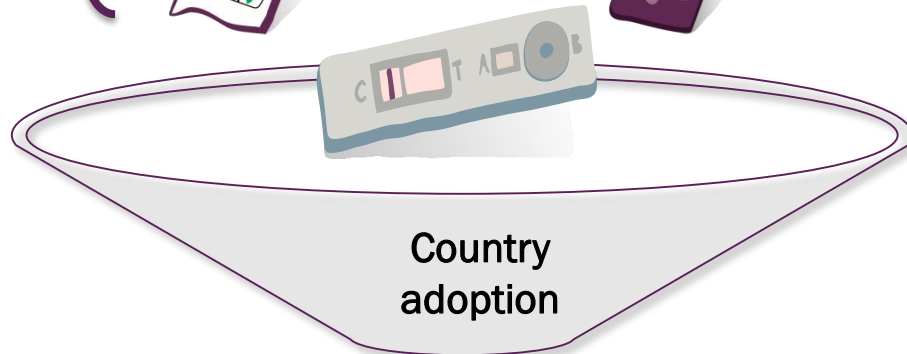


# FIND's Access team accelerates uptake through a multi-pronged approach

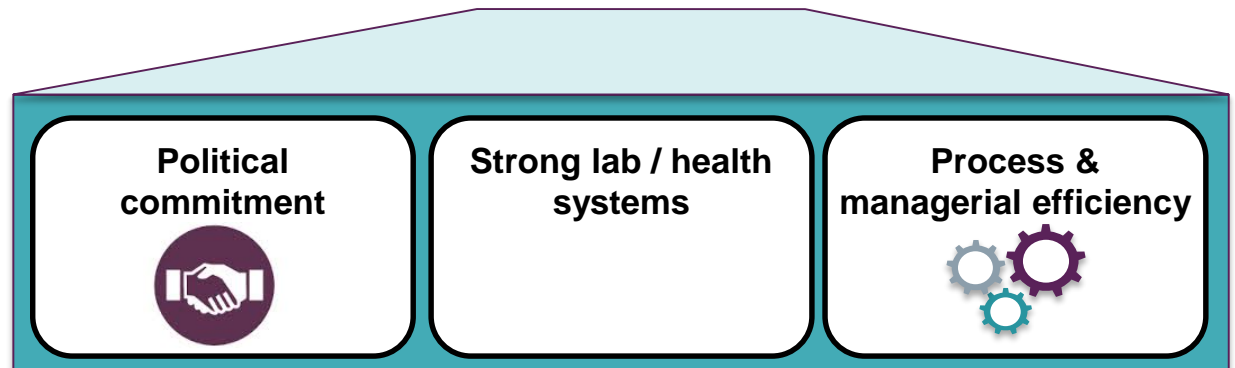
**1** Ensure that holistic solutions tailored to specific country needs are in place



**2** Support development of country implementation plans for solutions

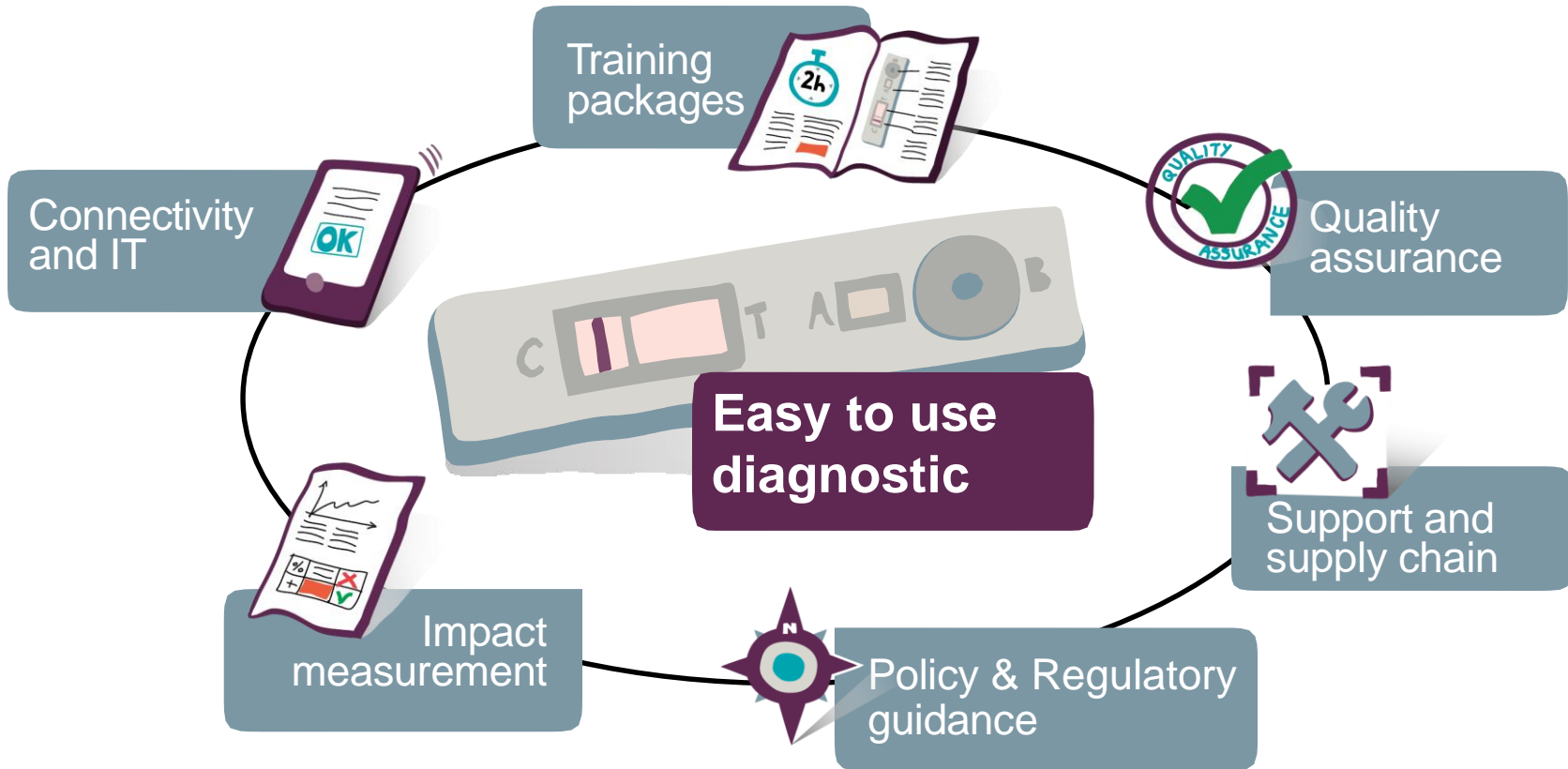


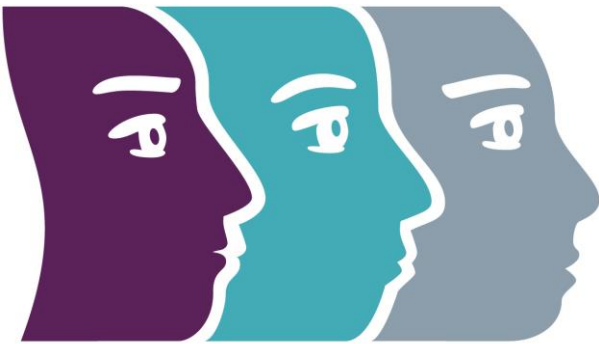
**3** Strengthen country capabilities to implement and capture benefit of solutions





# From tests to comprehensive diagnostic solutions

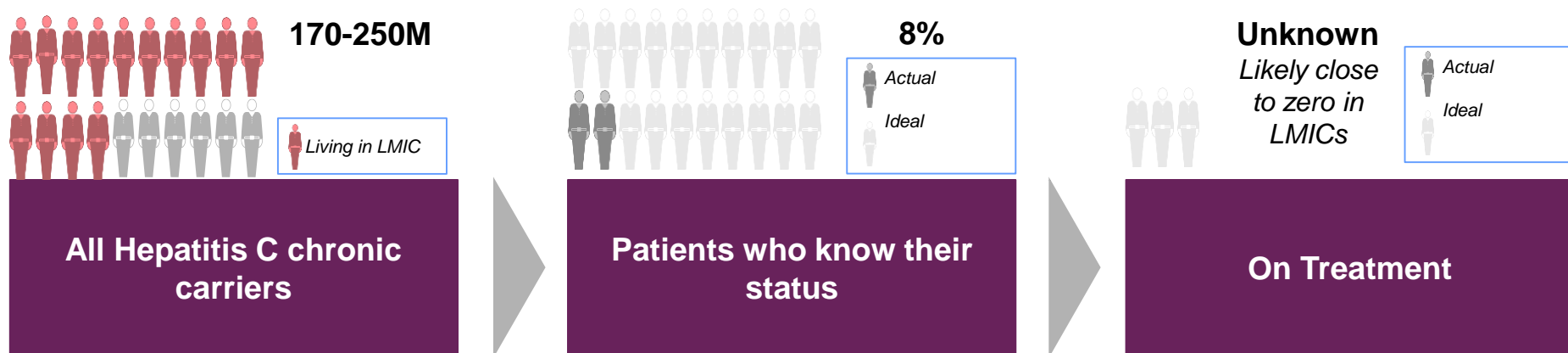




## Hepatitis C diagnostic tests - Strategy and vision to address global market



## State of the HCV disease



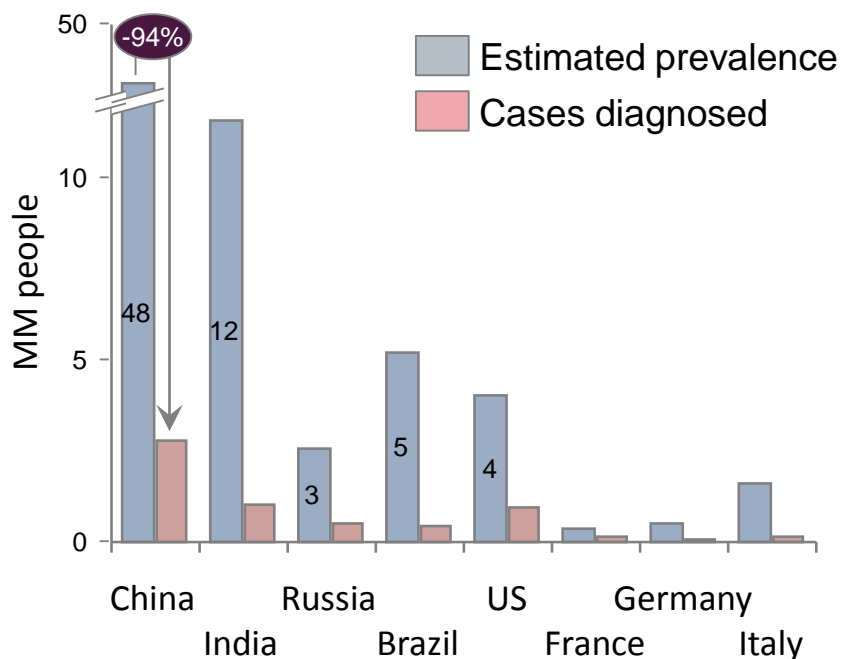
- Hepatitis C virus causes an estimated 350,000 deaths/year
- The majority of infections and deaths occurs in low/middle-income countries
- A large proportion of the burden of infections and also co-infections (with HIV and TB) occurs in vulnerable populations





## Today, HCV infection is severely under-diagnosed

<8% of cases diagnosed in MICs,  
even less in LICs



**Lack of reliable data for LMICs. Available data suggests a major problem of under-diagnosis**

**Roots of under-diagnosis include lack of appropriate tools & delivery issues**

### Current diagnostic algorithm is complex

- 6 different diagnostic tests needed for a total cost of \$250-2500 per patient
- RDT screening tests are expensive (~\$10) and of highly variable quality, esp in sub-Saharan Africa

**NAAT-based Dx tools that are currently needed to confirm infection and & for treatment monitoring can only be performed at centralized labs**

- Most low-income countries lack capacity to conduct viral load testing
- Complicates medical management of hepatitis C and blood-banking

**Current treatment regimens are complex and expensive – LMICs<sup>1</sup> unable to implement at scale**

- Injectable IFN-based treatment can cost up to \$20k per patient plus costs of monitoring and AEs

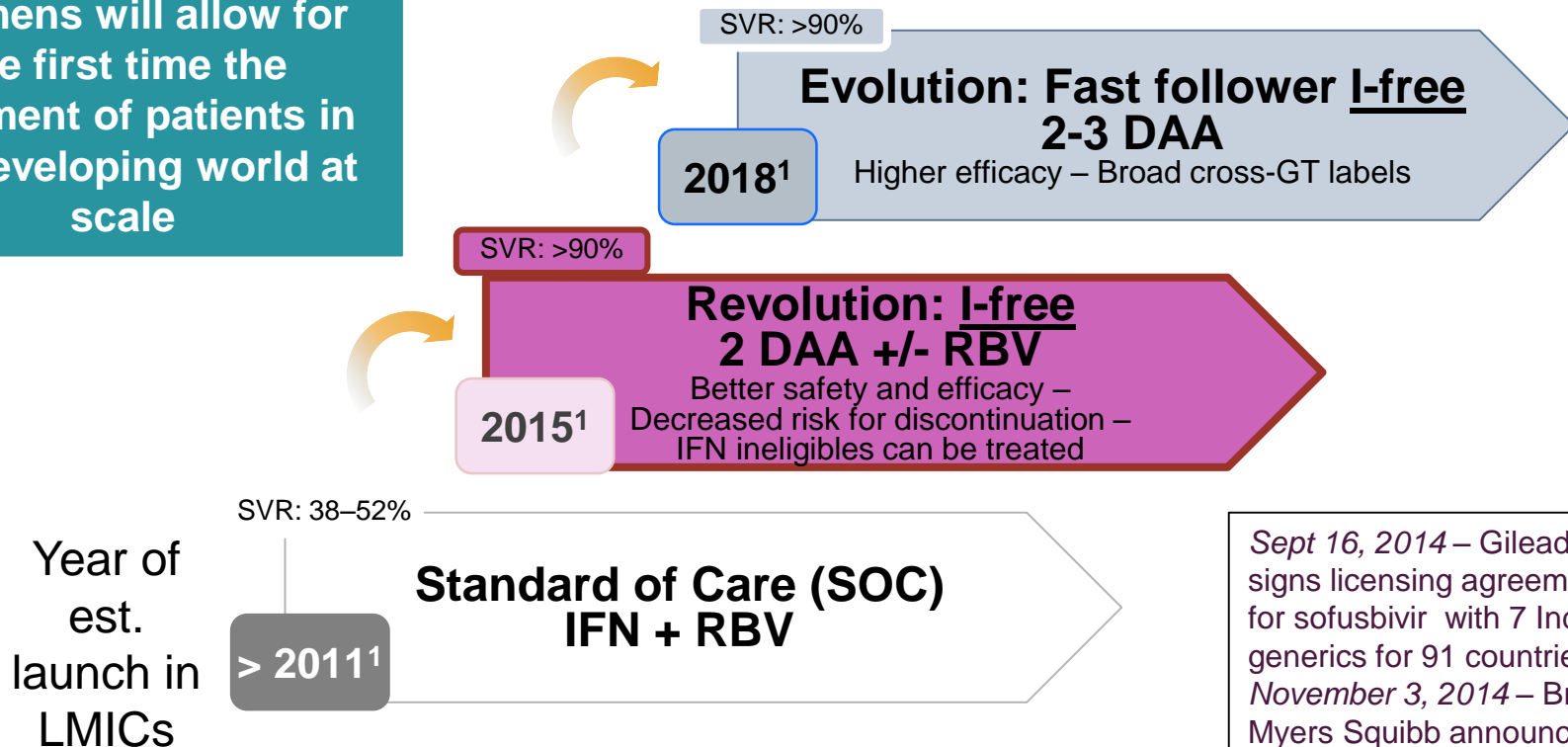
**Impossible for low-income countries to diagnose and treat patients at scale**

1. Low & Middle Income Countries



# IFN-free treatment regimens are revolutionizing HCV care

Oral, affordable, IFN-free regimens will allow for the first time the treatment of patients in the developing world at scale



Sept 16, 2014 – Gilead signs licensing agreements for sofosbuvir with 7 Indian generics for 91 countries  
November 3, 2014 – Bristol-Myers Squibb announces intention to work with licensed generic manufacturers for 90 countries

1. First approval and market entry

Note: DAA: Direct Acting Antiviral; FDV: Faldaprevir; HCP: Health care professional; I-based: Interferon based; I-free: Interferon free; IFN: Interferon; NSOC: New Standard Of Care; RBV: Ribavirin; SOC: Standard Of Care; SVR: Sustained Virological Response (measure for cure effectiveness)

Source: BCG



# **FIND's strategy is focused on addressing challenges around diagnosis to meet global goals**

## *Long-term vision*

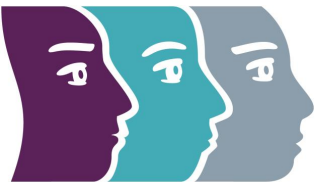
**Enable a world free of Hepatitis C**

## *5-year goal*

**To support the Global Hepatitis Programme in its goals: to reduce transmission, reduce the morbidity and mortality, and reduce the socio-economic impact of viral hepatitis at individual, community and population levels**

## *Strategy objectives*

- 1 Enable affordable and fit-for-purpose diagnosis**
- 2 Enable access to diagnosis**
- 3 Support the prevention of infection**
- 4 Demonstrate the need and benefit of interventions for HCV**



## Detail: potential for dramatic simplification of HCV diagnosis in the mid- to long-term

### Current

### Mid-term

### Long term

#### Cost

\$17-55

\$17-80

\$20-478

\$100-1,625

TBD

\$17-320

\$17-80

Screening – RDT/ELISA

Quantitative molecular – for confirmation of active infection

Genotype

Biomarker/Imaging/Biopsy – for staging

+/- IL28B - for prognosis

Quantitative molecular - Test of treatment response

Quantitative molecular - Test of cure

Screening – RDT/ELISA

Quantitative molecular – for confirmation of active infection

Biomarker/Imaging/Biopsy – for staging

Quantitative molecular - Test of treatment response

Quantitative molecular - Test of cure

~~Screening – RDT/ELISA~~

Qualitative – for confirmation of active infection

Biomarker – Cirrhosis versus no cirrhosis

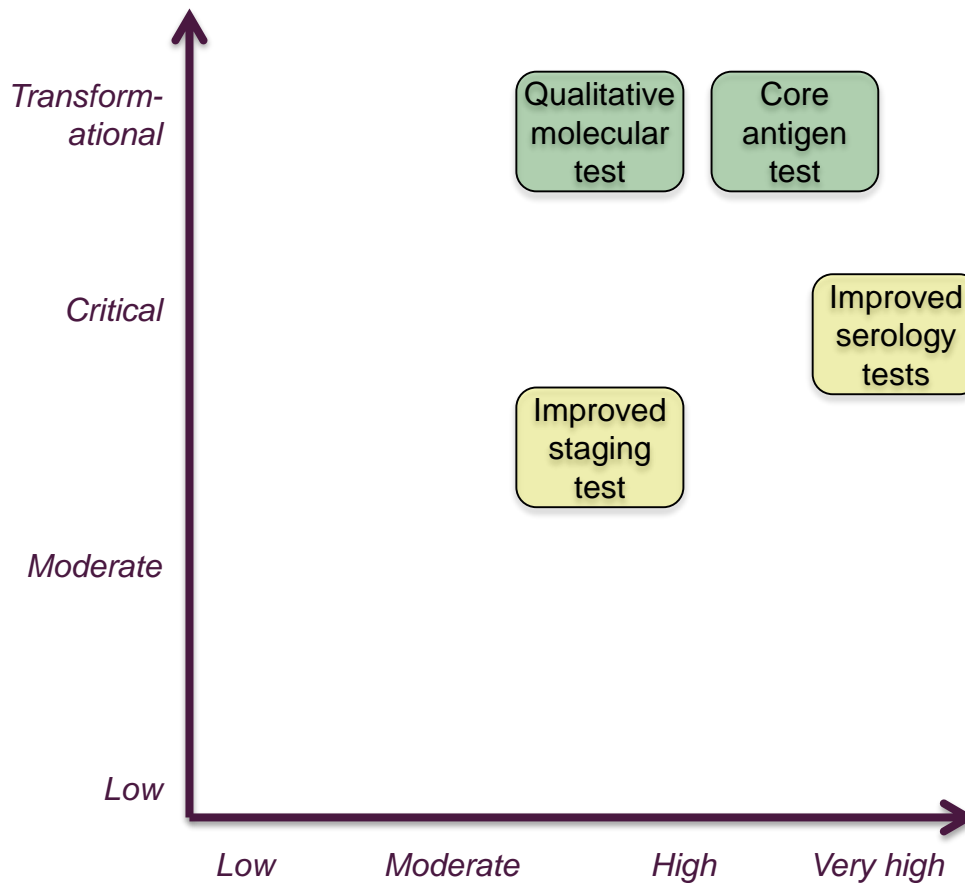
Qualitative molecular - Test of cure



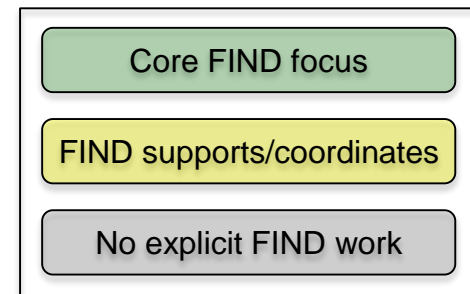
# FIND will prioritize needs in development based on potential impact and likelihood of FIND success

## Impact

- Public health impact
- Individual impact

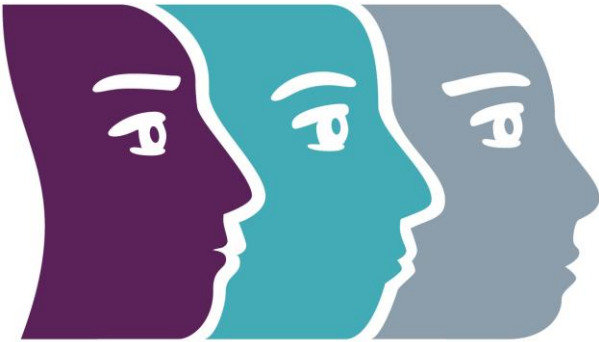


## Key

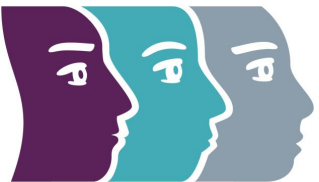


## Likelihood of FIND success

- Technical feasibility
- Availability of funding
- Fit with FIND capabilities/strategy



**New opportunities for cross-sector  
collaborations**



## Global health stakeholders are beginning to address needs

### Examples of stakeholders supporting increased global work on HCV



World Health Organization



#### WHO Global Hepatitis Program, CDC

- Coordination and leadership of global efforts
- Agenda shaping and policy definition
- Monitoring and surveillance



#### Medecins Sans Frontieres

- Provision of care & evaluation of new approaches / tools
- Advocacy for increased prioritization of HCV



#### Coalition Internationale SIDA and CHAI

- Advocacy for increased prioritization of HCV
- Price negotiations to lower cost of HCV care (early stages)



#### Treatment action group

- Advocacy for increased prioritization of HCV



#### IVD & pharma industries

- Development of diagnostic platforms and drugs that could have impact in low resource settings



#### UNITAID, The Global Fund

- Exploring increased funding through relationship of HCV with comorbid diseases (HIV and TB)
- Potential support for HCV via polyvalent viral load testing



The Global Fund  
To Fight AIDS, Tuberculosis and Malaria

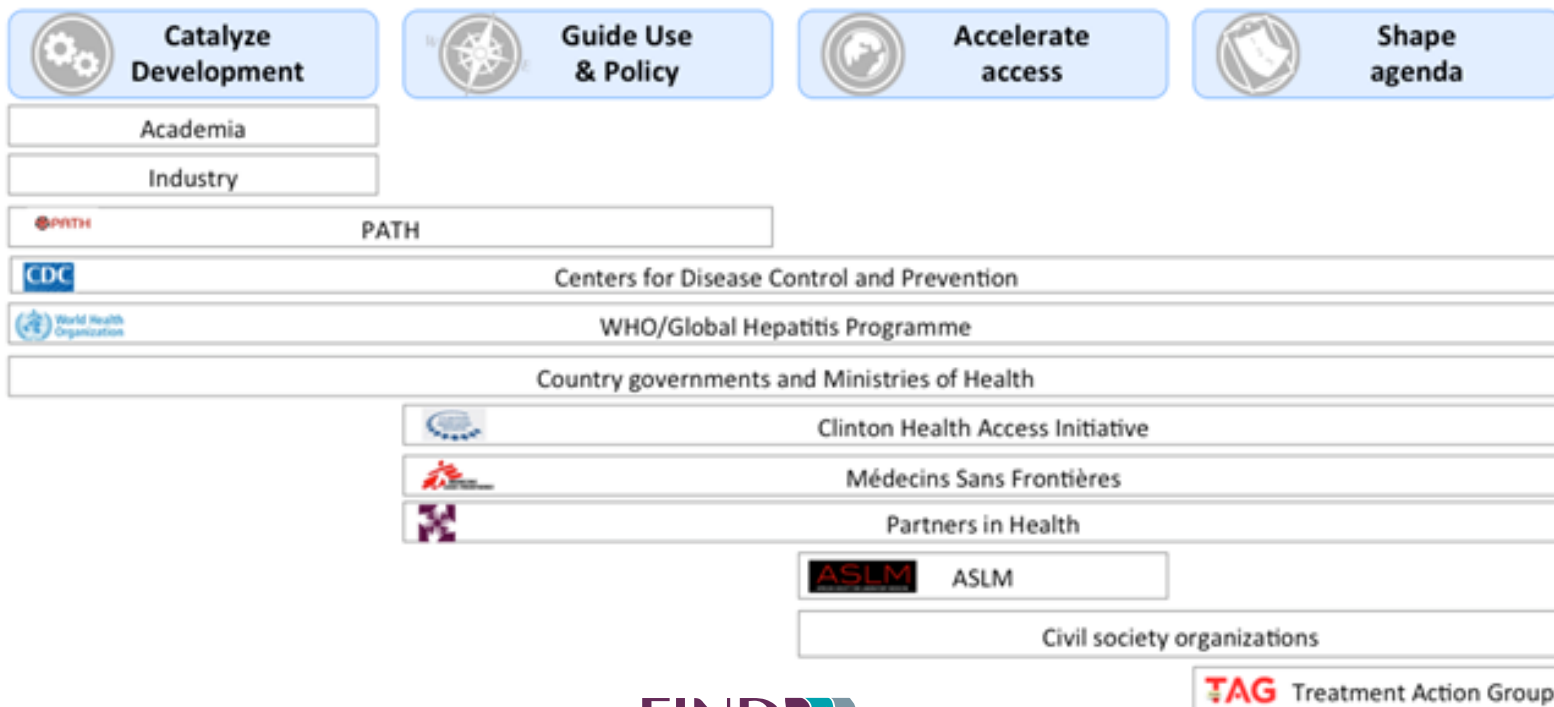


# FIND's objective : Unlocking a global market for HCV

WHAT?

**Catalyze cross-sector partnerships**  
**Transform HCV diagnostics in developing markets**  
**Turn HCV into treatable disease globally**

HOW?







## Opportunities for collaborations 2014/15



### Catalyze product development:

#### **Develop new partnerships with developers of diagnostics**

- Build on two TPPs (Technical Product Profiles)
- Products developed and launched in 3-5 years

#### **Develop partnerships with pharmaceutical manufacturers**

- Build on business case and win-win for collaboration
- Expand access to treatment through diagnostics

#### **Conceptualize and develop a “Public-Private Funding Consortium”**

- Develop an investment case
- Increase investments in development of cost-effective HCV diagnostics



## Opportunities for collaborations 2014/15 (Cont.)



### Guide use and policy



### Accelerate access

#### Ensure early inclusion of key partners (e.g. WHO, CDC, MoH)

- Catalyze development of target product profiles (TPPs)
- Ensure engagement in WHO processes



### Shape the agenda

#### Advocacy to raise awareness for HCV solutions & investments

- Convene 1-2 meetings in 2014/15 with experts, industry and influencers
- Strengthen HCV initiative (movement) with partners and patients
- Develop strong advocacy story based on existing technical knowledge



# Opportunities to continue dialogue in 2014/15



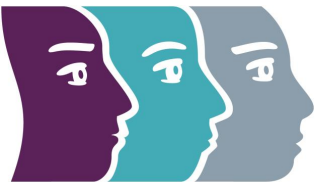
## Shape the agenda

### 2014

- AASLD, Boston, 7-11 Nov'14
- Pre-meeting at the 13<sup>th</sup> DrAG meeting, Boston, 11 Nov'14
- The Global Fund Board Meeting, 20-21 Nov' 14
- UNAIDS Program Coordinating Board (PCB), 9-11 Dec'14

### 2015

- WHO Executive Board, Geneva, Jan'15
- World Economic Forum (WEF), Davos 21-24 Jan '15
- World Innovation Summit for Health (WISH), Doha, 17-18 Feb '15
- FIND Board meeting, Geneva, Mar'15
- The Global Fund Board Meeting, 31 Mar'15 - 1 Apr'15
- EASL Meeting (EU Assoc. for the Study of Liver Disease), Vienna, 22-26 April
- WHO World Health Assembly (WHA), Geneva, May'15
- The Forum's 2015 National Summit on HCV and HIV Diagnosis, Prevention and Access to Care, Washington, 4-6 June '15
- UN General Assembly (UNGA), New York, Sep t'15
- World Hepatitis Summit, Glasgow, 2-4 September '15



## Summary – and going forward

- Dramatic improvements in Hepatitis C treatment hold the potential for curing this deadly disease impacting est. 170-250M people globally
- New diagnostics are needed to fully benefit from these treatments especially in developing countries
- FIND is dedicated to working with partners to *Catalyze diagnostic development, Guide use and policy, Improve access and Shape the agenda*
- Today is an important step towards building the cross-sector partnerships needed for innovative diagnostics solutions
- Our goal is to continue to collaborate with urgency to benefit Hepatitis C patients in need around the world

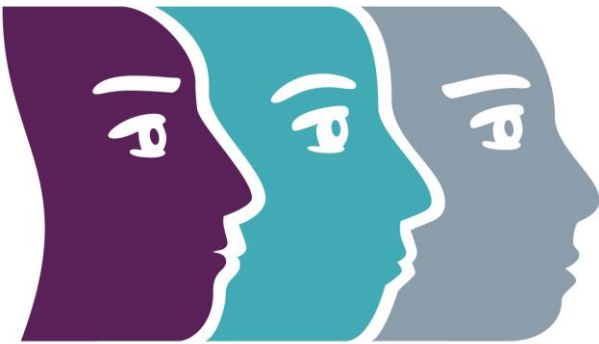


**Thank you!**



**Forum for  
Collaborative HIV Research**





**Q & A :**  
**Unlocking a global market for Hepatitis C**



# Similar Peak in HCV Prevalence at Age 55 (Globally)

## 2005

