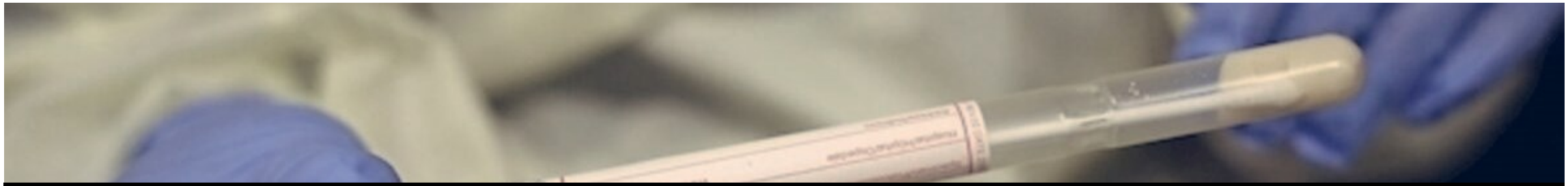
FIND

Because diagnosis matters



SDC antigen rapid diagnostic tests session

ACT-A Diagnostics Pillar

May 2021

In 2021, testing will play an even more critical role in COVID response

To enable surveillance and targeted interventions:

- Accelerating detection of new variants, with potential to also impact efficacy and coverage of Vx & Tx
- Enhancing accuracy and knowledge of real-time epidemiology across regions

To inform vaccination and containment strategies:

- Rapidly identifying and containing hotspots/ flare-ups
- Understanding optimal use and cost-effectiveness of Dx tools to guide and inform Vx roll-out and other containment strategies

To optimize treatment delivery (i.e., test & treat):

- Targeting individuals at greatest risk who can benefit from innovative treatments coming to market

FIND & ACT-A Global response to COVID-19

Access to COVID-19 Tools (ACT)- Accelerator

Facilitation group to oversee and report progress, mobilize resources and engage with stakeholders
Public sector and private not-for-profit partners, such as:

Coordination hub at WHO

Vaccine pillar

Co-convener

CEPI

WHO (lead on product allocation)

- Research
- Foundations
- International organizations
- Industry
- Funders
- Regulators

Co-convener

Gavi The Vaccine Alliance

Therapeutics pillar

Co-convener

Therapeutics Accelerator

WHO (lead on product allocation)

- Research
- Foundations
- International organizations
- Industry
- Funders
- Regulators

Co-convener

Unitaid

Diagnostics pillar

Co-convener

FIND
Because diagnosis matters

WHO (lead on product allocation)

- Research
- Foundations
- International organizations
- Industry
- Funders
- Regulators

Co-convener

The Global Fund

Health Systems Connector

Co-conveners

THE WORLD BANK

The Global Fund

FIND focuses on driving **innovation in the development & delivery of diagnostics**

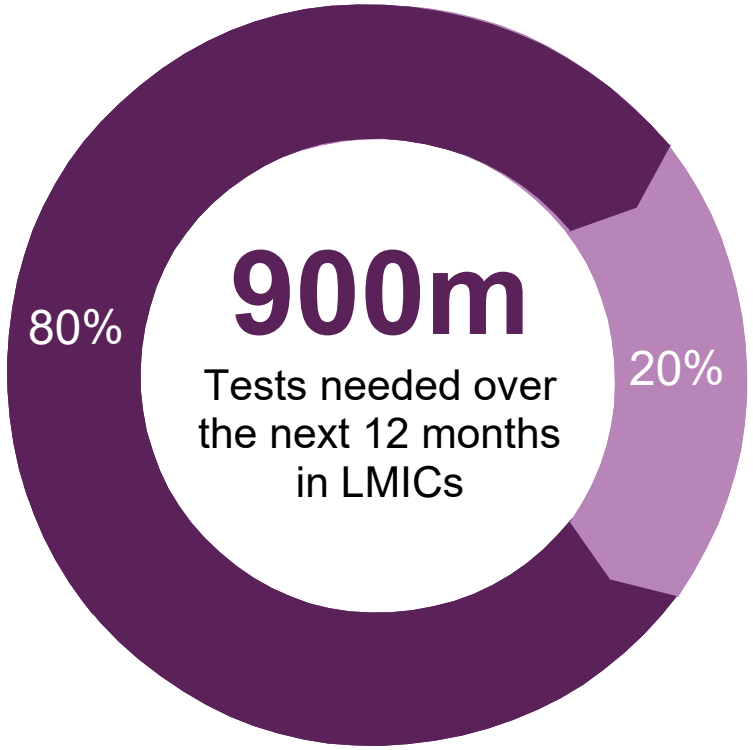
Co-convener of ACT-A Dx with the Global Fund, aimed at **harnessing innovation, securing access & deploying affordable, quality point-of-care tests in countries**

Antigen rapid tests are an easy-to-use, affordable complement to molecular testing

Antigen rapid tests

- ⊕ Rapid turnaround: under 30 min
- ⊖ Lower accuracy
- ⊕ Administered at point-of-care or home settings
- ⊕ Can be scaled with appropriate funding
- ⊕ More affordable

Used for early detection, patient management and surveillance



Molecular tests (or PCR)

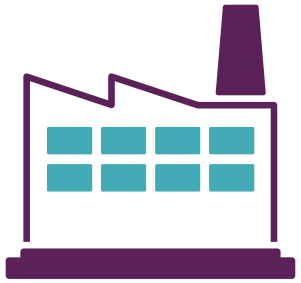
- ⊖ Slow turnaround: often 48h+
- ⊕ High accuracy
- ⊖ Require labs & trained health workers
- ⊖ Challenging to rapidly scale in LMICs
- ⊖ More expensive

Used for patient management

Note: The estimated test split was informed by the necessary trade-off between testing accuracy, speed to result, ease of use and affordability and was calculated based on four use cases (triage and confirmation of symptomatic severe cases, triage and confirmation of symptomatic mild cases, triage of asymptomatic at-risk cases and surveillance of asymptomatic cases). For patient triage, it is assumed that a split of 85% RDT (preferably Ag) and 15% molecular will be used; for surveillance, it is assumed that only antibody RDTs are used; antibody RDTs can be substituted with ELISA.

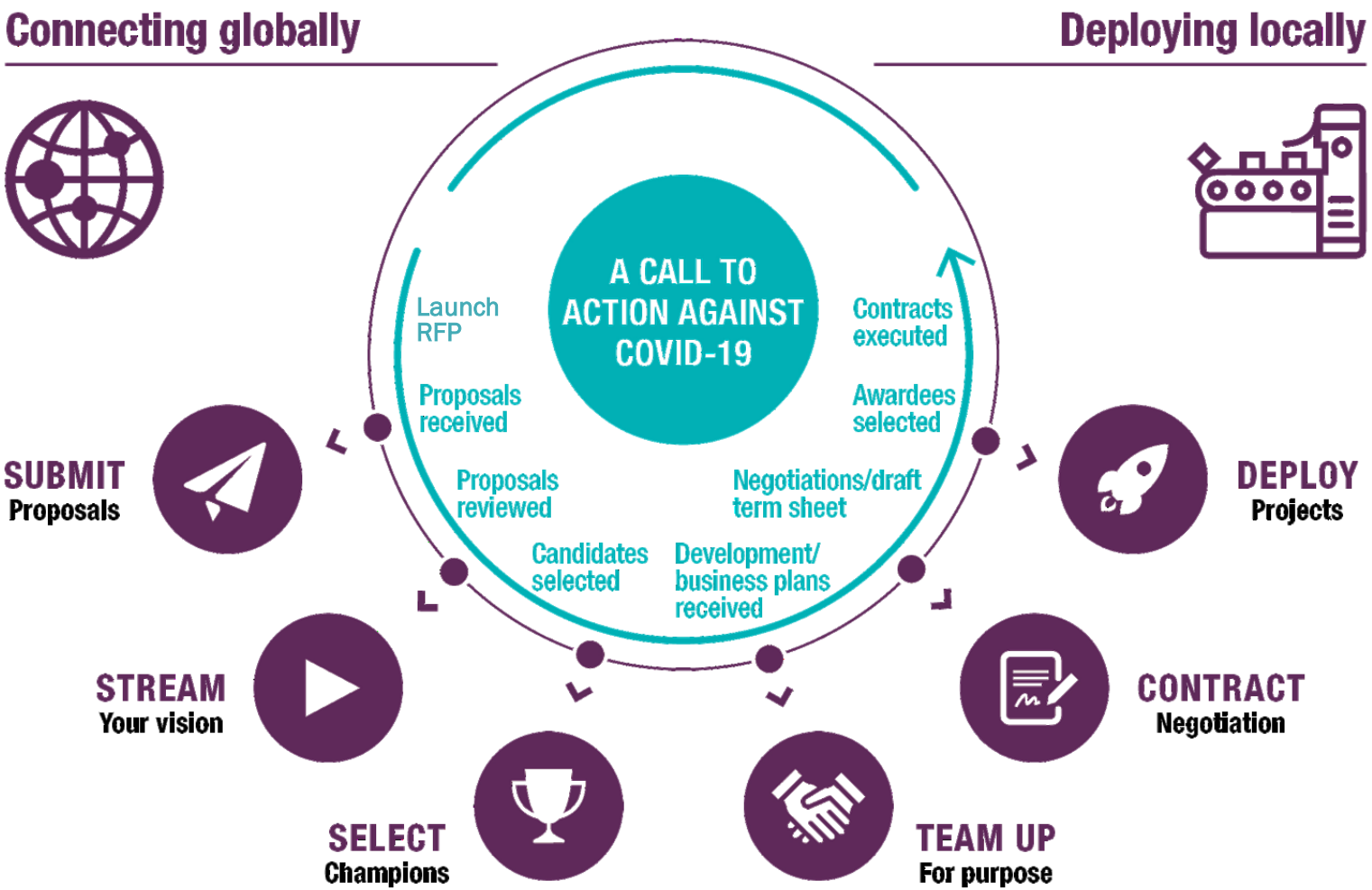
EOI focused on two aspects of ensuring access to Ag RDTs for LMICs

Accelerating development and market entry of improved, quality-assured SARS-CoV-2 Ag RDTs for expanded use in LMICs



Rapidly creating the supply conditions (manufacturing capacity, diversity of supplier base, affordability) to meet the needs of LMICs

EOI followed a compressed timeline with first set of contracts finalized in December 2020



100+ applications received

1. 30+ reviewed by independent panel of external experts
2. 5-7 discussed in detail by Investment Committee
3. 4 finalists with signed contracts

Investments being made focused on two EOI goals

Initial investments finalized: US$2.50/ RDT incl. price matching agreement and larger supplier base in Q1 '21

Short-term: investments in R&D and tech transfer agreements for lower-cost tests; continued utility improvements with shift to nasal & clearer temperature stability

- Global supply of $2.50 test starting Q1 ’21, with volumes available of 20M tests/ month by Q3 '21

Premier Medical Corporation (PMC): investment in manufacturing capacity expansion & automation to scale-up low-cost production in exchange for ensured access pricing and test volume for LMICs

Long-term: strengthening local manufacturing capacity & support for product transfer

- Capacity expansion to 80M tests/ year (LMICs)

Partnership between established US RDT developer & local Brazilian manufacturer for tech transfer, focusing on LatAm region

Partnership between West African manufacturer & British manufacturer for tech transfer

The price of quality assured rapid tests for LMICs has decreased

R&D Investments

- Investments in local manufacturing and automation and increased efficiency to scale capacity

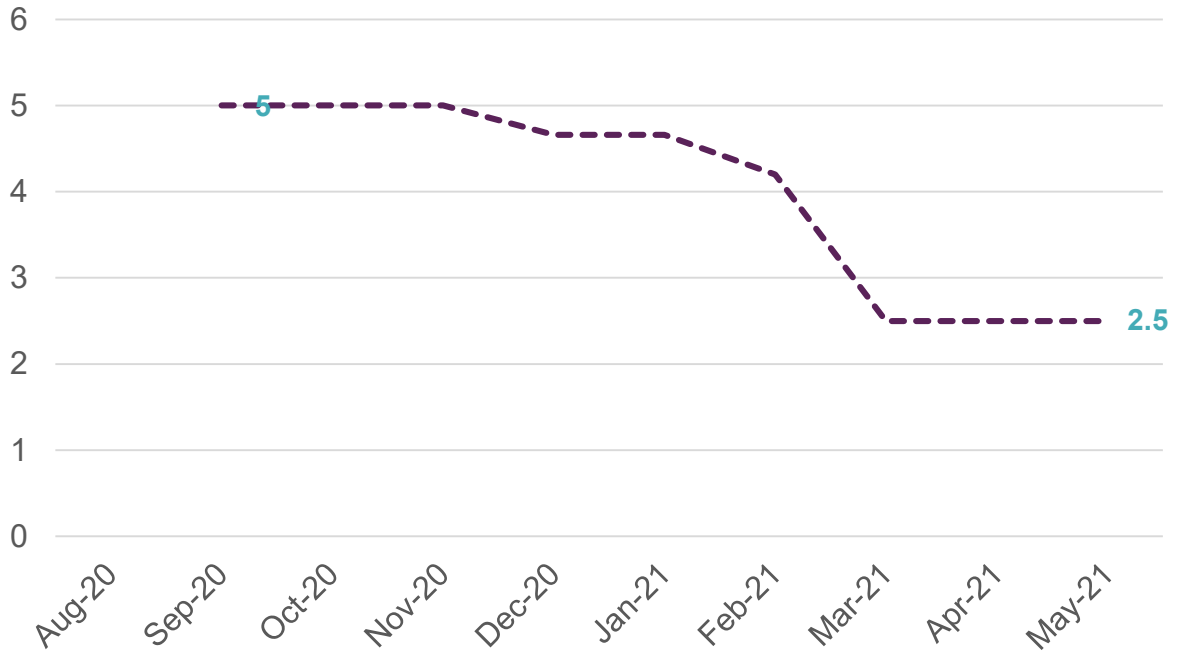
Market Shaping Interventions

- Coordination negotiations across procurement organizations
- Investments in key suppliers and support for regulatory processes increased number of high-quality suppliers in the market

Policy guidance and development

- Support to generate new policy guidance and rapid uptake of products to ensure adequate pull in the market

Price of quality assured* COVID rapid tests over time (USD)



*WHO Emergency Use Listed
Source: Diagnostics Consortium for COVID data as 27 April 2021

FIND is now using the same approach in other areas for COVID diagnostics

UNDERWAY

- Accelerate availability of **high-performing self-tests for COVID** at 1-3USD, suitable for LMICs
- Develop **interoperable digital tools** to support diagnostic test deployment

PLANNED

- Accelerate development of **molecular POC multi-pathogen diagnostic tests** suitable for LMICs

1. Former Mylan, now Viatris after merger with Upjohn.

Appendix

Five strategic objectives

1

R&D of tests & digital tools.

Accelerate development of high performing, affordable rapid diagnostic tools, and create robust digital, data and analytics solutions

2

Market readiness.

Implement market shaping interventions to accelerate implementation including assessment of product performance, validation of use-cases, support for manufacturing and commercialization, price negotiation, and regulatory support

3

Supply, pooled procurement & equitable distribution of tests.

Support cost of test procurement and deployment in low- and middle-income countries unable to shoulder such costs on their own

4

Country access.

Strengthen health systems and build country capacity and preparedness for rapid and effective test implementation

5

Genomic surveillance.

Harmonize, coordinate & accelerate priority activities across partners to improve geographic representation of sequencing at national, regional and global levels

EOI for antigen RDTs launched in July '20 to address market challenges to equitable access of fit-for-purpose SARS-CoV-2 Ag RDTs in LMICs

	Fit-for-purpose product	Manufacturing	LMIC availability
Challenges	▪ **Few products meeting requirements:** performance, usability and affordability ▪ Scope to **move from "minimal" TPP requirements** to "optimal"	▪ **Few companies with fit-for-purpose Ag RDTs** and sufficient manufacturing capacity to meet demand	▪ **Competition** from high income countries (HIC) buyers ▪ Global **supply chain vulnerability**
EOI approach to address challenges	▪ Funding for innovations / activities **rapidly translated into RDT production at scale** ▪ **Matching** products / innovations with manufacturing and commercialization capacity	▪ Supporting companies with fit-for-purpose products to **expand manufacturing** ▪ **Matching** companies with underutilized manufacturing capacity with fit-for-purpose products	▪ **Commitment to access policy** (affordability & supply) ▪ **Geographical diversification** of manufacturing capacity; capacity building in LMICs

EOI received over 100 applications, screened and independently reviewed to select finalists

100+
applications

Submissions received over two rounds

34
applications

Selected for review and assessed by independent panel of external experts

5-7
applications

Prioritized for investment and under discussion

4
finalists

With agreements signed after several weeks of negotiations