Le diagnostic de la Covid-19 et ses challenges : de la R&D à l'implémentation dans les pays en voie de développement

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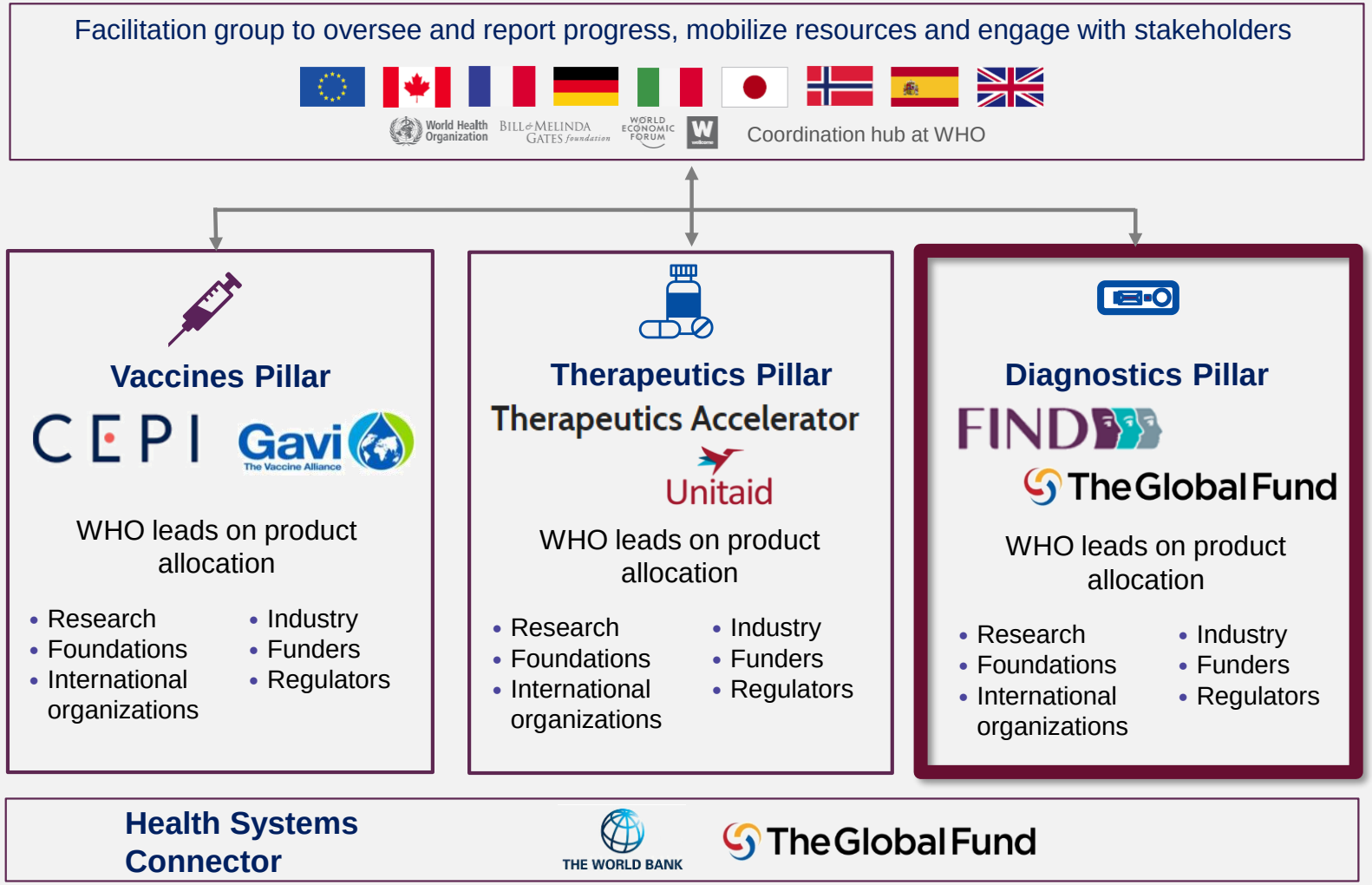
FIND co-convenes the ACT-Accelerator Diagnostics Pillar, harnessing innovation, securing access & deploying affordable, quality point-of-care tests in countries

ACTaccelerator
ACCESS TO COVID-19 TOOLS



Short history of COVID-19 diagnostic tests and highlights

Molecular tests

- Very good performance
- WHO EUL (20 tests)
- Used for patient management
- Does completely cover the needs for LMICs (25%*)
- Shortage of extraction kits

Serology tests

- ELISA and RDTs
- High-Capacity expansion
- No recommendation from WHO
- Used for prevalence studies
- Poor uptake in LMICs

Antigen rapid tests 2nd Gen

- Performance highly improved
- Recommendation from WHO
- WHO-EUL (2 tests)
- Adapted to LMICs
- Used for early detection, patient management and surveillance

Dx Consortium for COVID-19

Immediate-term capacity reservation, procurement, delivery

To date: **37.4 million tests procured** across partners (Global Fund, GDF/StopTB, PAHO, UNDP, Unicef, WHO) with **over 27.1 million in transit or delivered**

Clinical performance evaluation

Several partner sites (n=17) across the world

- **25 molecular tests**
- **35 antibody-detection RDTs**
- **17 antibody-detection ELISAs**
- **11 antigen-detection RDTs**

(ACT)- Accelerator EOI

>100 proposals received for Ag RDTS

- **Increase in manufacturing & reduction of per-test price**
- **Near-term improvements or alternate sample types**
- **Expansion of manufacturing to LMICs**

*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.

Challenges - The antigen RDT model

Access to samples

- **Prospective clinical studies** are highly dependent on the dynamic of the pandemic
- **Availability of samples for development** *(frozen samples)*
- **Access to samples restricted** in some countries *(ex : Korea)*

Regulatory and guidelines

- **CE-IVD – self certification** *(~ 45 Ag RDTs regulatory approved and <10 approved by SRAs)*
- **Difference between SRAs** (number of positive samples required *n=100 WHO EUL and n=30 FDA EUA)*
- Some countries have **switched back to more stringent requirements** (e.g. Brazil, China)

Assessment of performance

- **Analytical performance** *(pg/ml, $TCID_{50}$/ml, pfu/ml, copies/ml, buffer vs. matrix)*
- **Clinical performance** *(CT<33, days after onset of symptoms, the cohort)*
- Only **few independent studies**
- **Population variability**
- **Lack of training** in some countries

ACTIONS

- FIND Integrated Biobanks (FIB) concept
- Support to companies for matrix equivalency studies for new claims
- Evaluation sites set up in different countries to perform independent evaluation
- Providing data per CT values range and number of days
- SARS-CoV-2 Ag RDT training packageV1.0 designed and developed by FIND and WHO https://www.finddx.org/covid-19/rdt-imp/rdt-training-pack/

Merci

Useful links:

- **Technology and submission → technology@finddx.org**
- **Evaluation of Antigen test → RFP_ET@finddx.org**
- **General info → Info@finddx.org**

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Because diagnosis matters