

WHO Health Technology Access Program (HTAP) – A targeted approach to bridging the access gap

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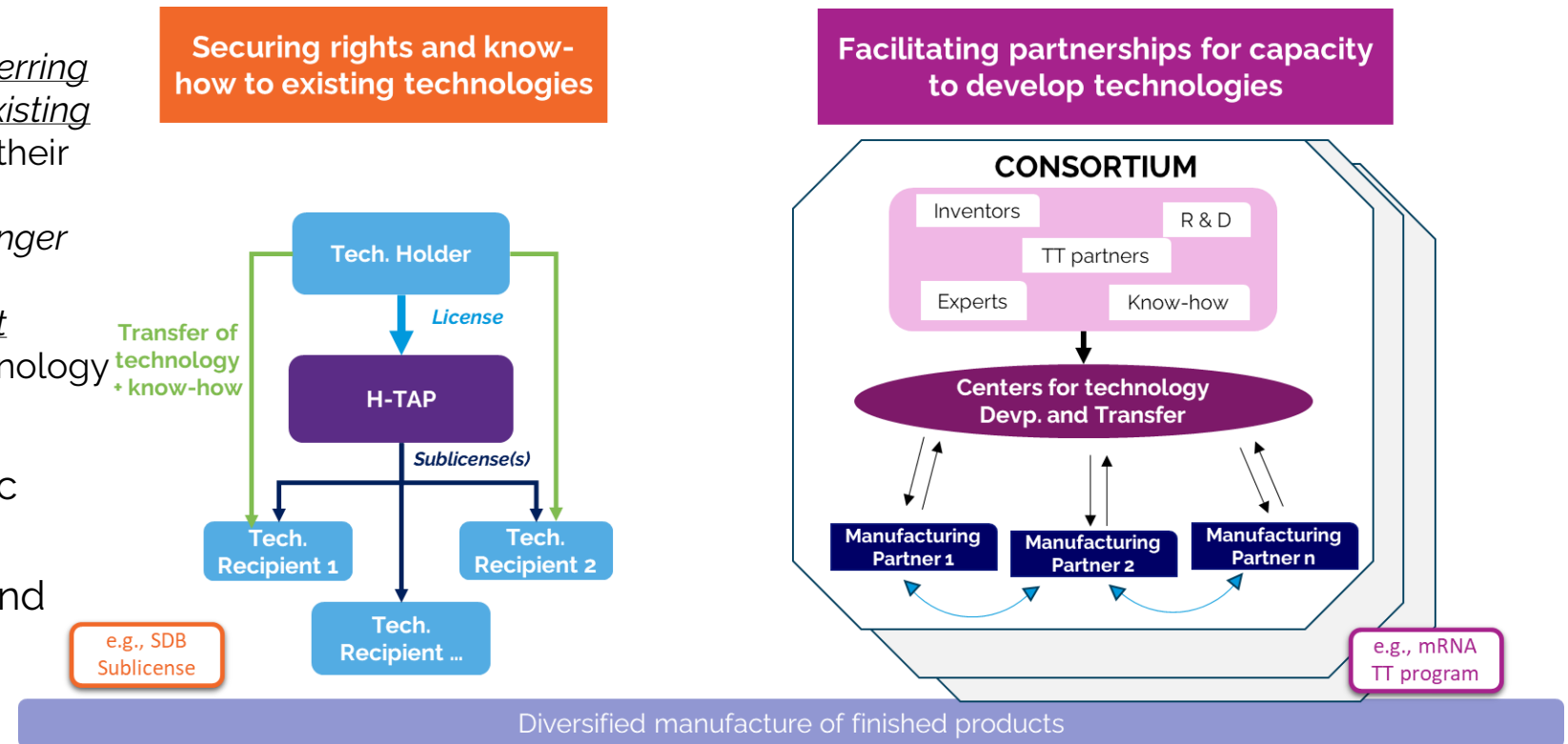
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HTAP: an evolution and integration of two programs

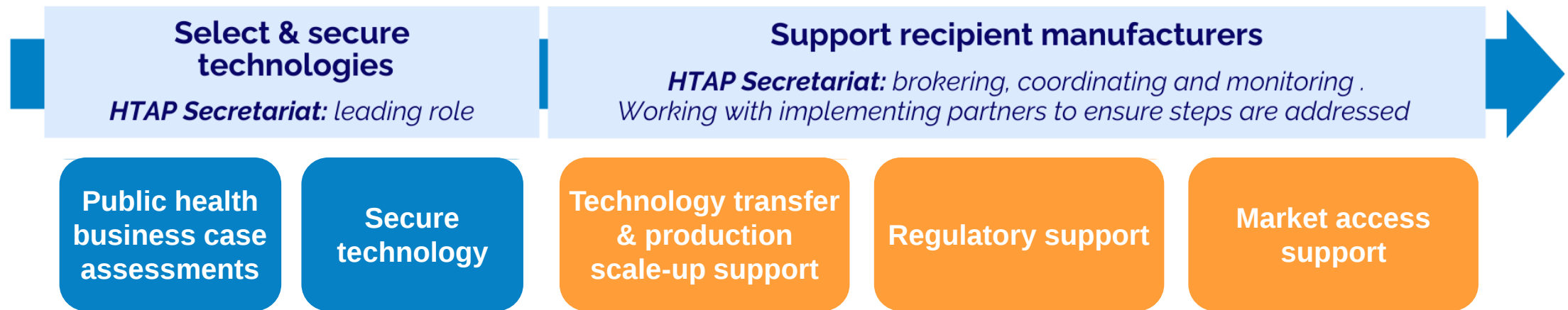
- WHO launched C-TAP ([COVID-19 Technology Access Pool](#)) and the [mRNA technology transfer programme](#) to address access inequities seen during the pandemic.
- Both programs have since evolved and now represent complementary operating models of the **WHO Health Technology Access Program** :

- *Selecting, securing and transferring the rights and know-how to existing technologies* and supporting their geo-diversified transfer to manufacturers - *and in the longer term...*
- *Building product development capacity* through health technology consortia.

- Focus on PPPR and other public health priorities
- Target platform technologies and products

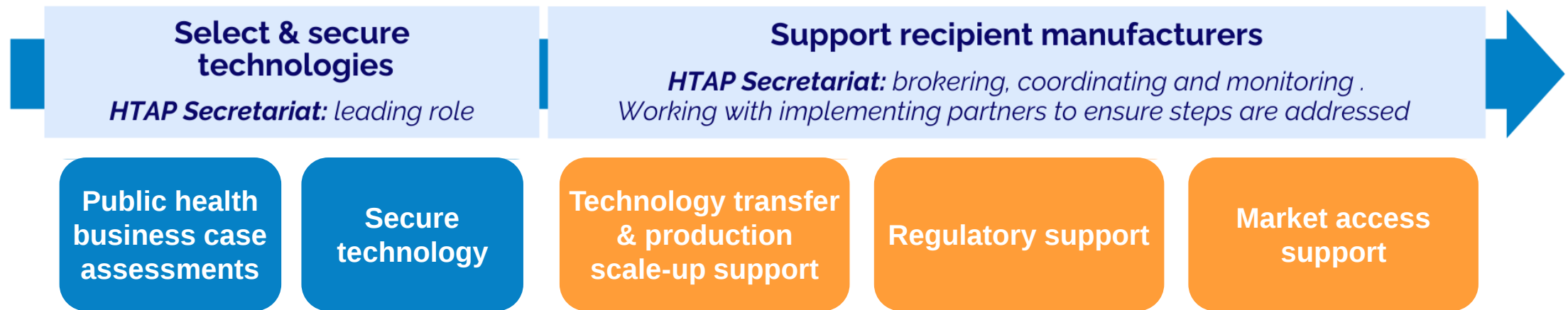


HTAP – mechanism for aligning resources required to address a health technology access gap



- Using technology platforms to build capabilities in LMICs.
- Technologies selected based on the prioritization process and business case assessment.
- Considers critical factors and support required to translate licenses into sustainable, diversified production -> *working in partnership with WHO programs and external partners.*
- Approach amplifies the attractiveness of licensed technologies to recipient manufacturers in realizing greater market opportunities and financial sustainability.

HTAP – mechanism for aligning resources required to address a health technology access gap



Harnessing WHO's strengths – convening and facilitatory role

- Prioritising research agendas and emerging technology for global health.
- Scientific advice to support scientific and technical improvement of health products.
- Facilitate dialogue to identify enablers (policy ; procurement; markets etc.).
- Biomanufacturing training.
- Specialised assistance to manufacturers.
- Regulatory system strengthening to build trust in products.
- Collaborative Procedure for Accelerated Registration.

SD Biosensor license: RDT technology transfer

- **License**

- SD Biosensor (SDB) - Medicines Patent Pool (MPP) license signed December 2023.
- Provides rights, know-how and material required to produce rapid diagnostic tests (RDT) based on the licensed technology.
- Territory: Worldwide, except the countries where SDB production plants are located.

- **Why this is important:**

- Multi-pathogen platform; targets include COVID-19, HIV, Malaria, Syphilis and Hepatitis.
- Sublicensed manufacturers benefit from comprehensive, phased tech transfer plan.
- Support that can be provided to address gaps in ability to absorb and sustainably produce transferred technology.

- **Status: 5 applications received; 3 applicants under final review**



Reflections to date – relevant to RDT technology transfer

- Goal of sublicensing: contribute to sustainable manufacture of quality-assured RDTs at competitive prices.
- SMEs in most LMICs have limited experience with the manufacture of RDTs (incl. receiving technology transfer)
 - => Most are transitioning from health product distribution to manufacturing
- SMEs exist in nascent manufacturing ecosystems that need to be capacitated.
- Conditions for success are very complex:
 - Tech transfer experience/support, realistic business strategies, access to funding, manufacturing/control/regulatory experience, supply infrastructure, procurement/demand considerations, market access etc.
- HTAP selection process is designed to identify manufacturers that could successfully absorb and produce SDB technology, if adequately supported.

Reflections to date – relevant to RDT technology transfer

As expected with an “emerging” industry, manufacturers would benefit from support with

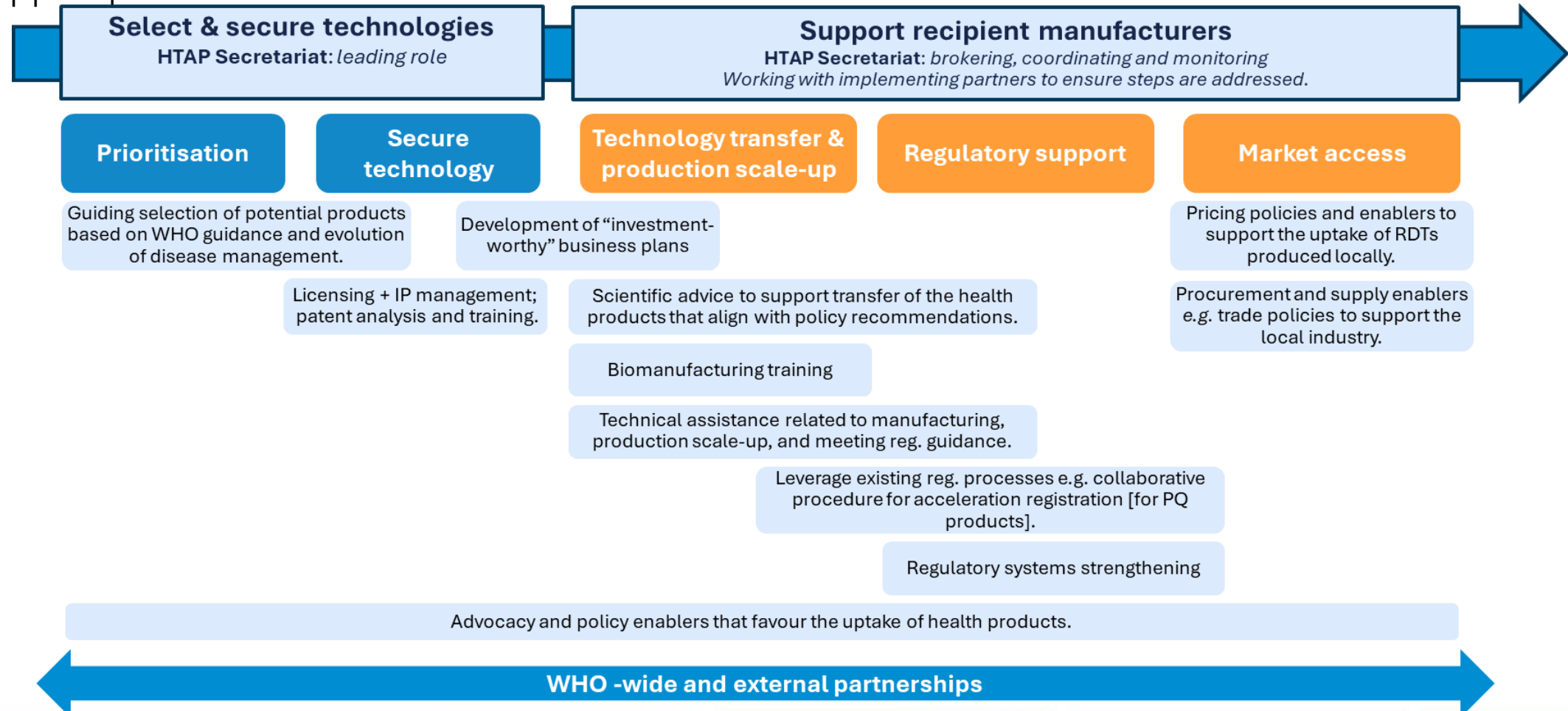
- Technology transfer and business agreement negotiations
- Establishing QMS aligned with RDT manufacturing that meets the necessary technical requirements
- Regulatory compliance - specialized technical assistance to reach prequalification status

⇒ Efforts to support manufacturers can be isolated, potentially contributing to duplication of efforts

⇒ There is a need for a coordinated approach to providing support which draws on the strengths and mandates of relevant programs, if success is to be realized.

HTAP – mechanism for aligning resources required to address a health technology access gap

WHO programs and partners could provide coordinated support under a unified implementation support plan



mRNA TT programme - model of multilateral technology transfer

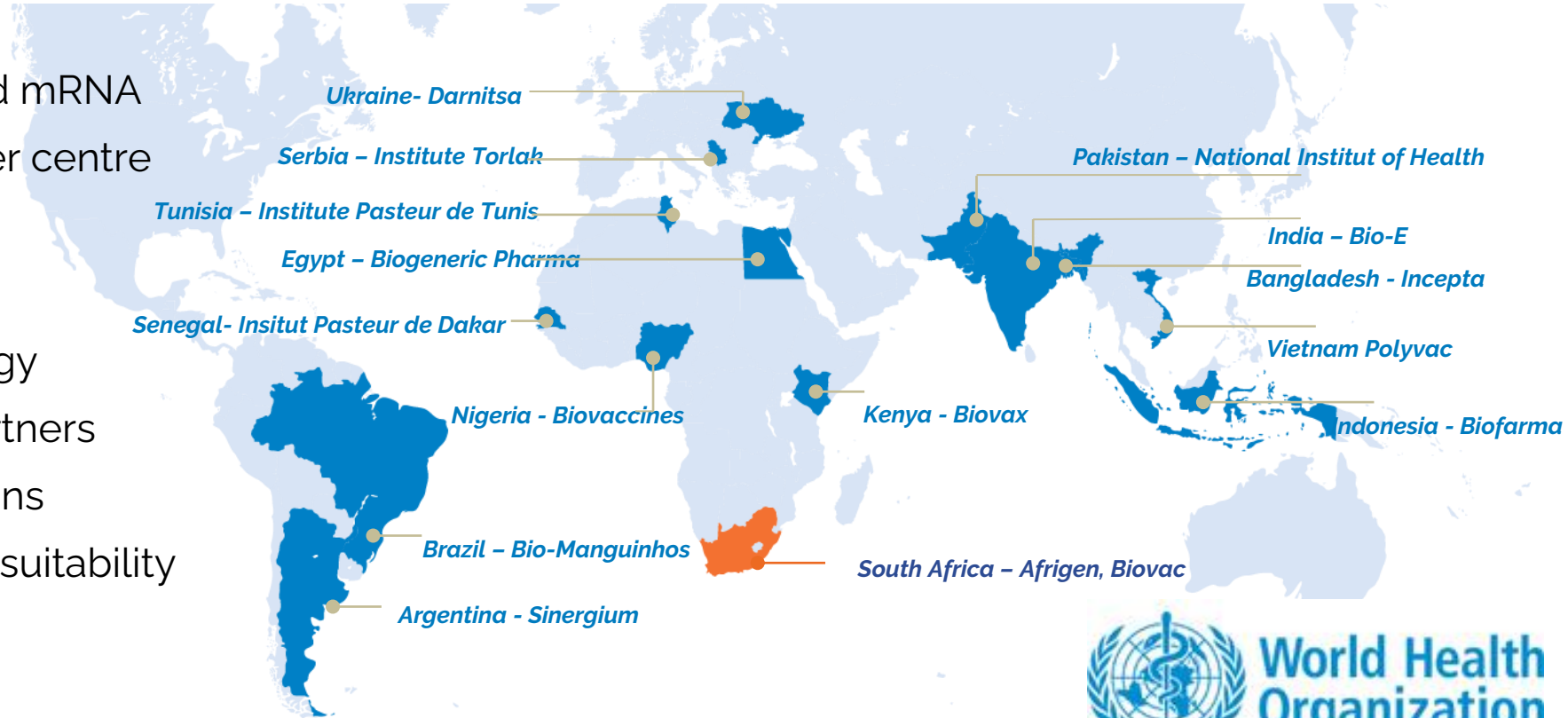
Established in 2021

15 manufacturing partners and mRNA tech development and transfer centre

OBJECTIVES

1. Establish mRNA Technology
2. Technology transfer to partners
3. Innovation – R&D as a means towards sustainability and suitability for LMICs settings

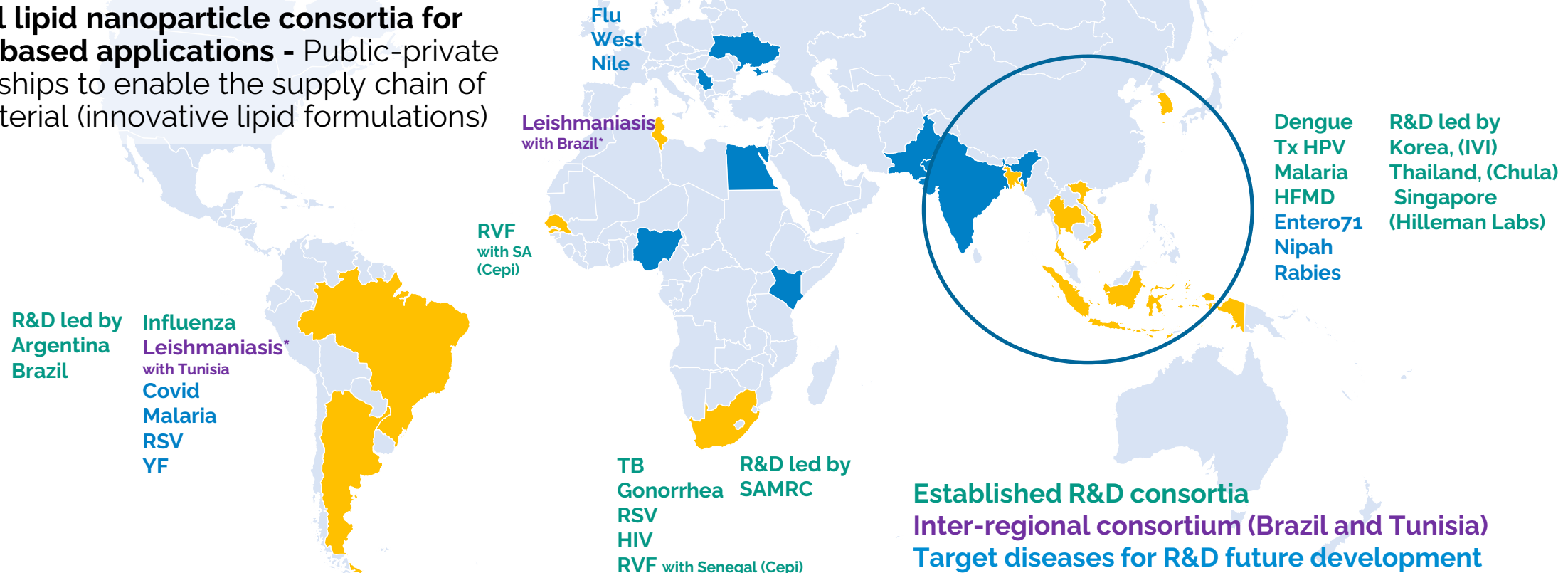
- mRNA Technology Development and Transfer Centre – established in South Africa
- Partners – 14 countries to develop mRNA R&D and production capacities
- Platform technology: COVID-19 as a “proof of concept” – *deprioritized*



Sustainability plan: R&D vaccine consortia

- ✓ Regional collaborative **network of R&D institutions and manufacturers** to develop commercially viable mRNA products for **unmet needs**
- ✓ **Global lipid nanoparticle consortia for mRNA-based applications** - Public-private partnerships to enable the supply chain of raw material (innovative lipid formulations)

- ✓ Identification of initial **23 disease targets** for R&D based on regional/country needs & priorities



Summary

Platform to promote geo-diversified production through

⇒ traditional TT

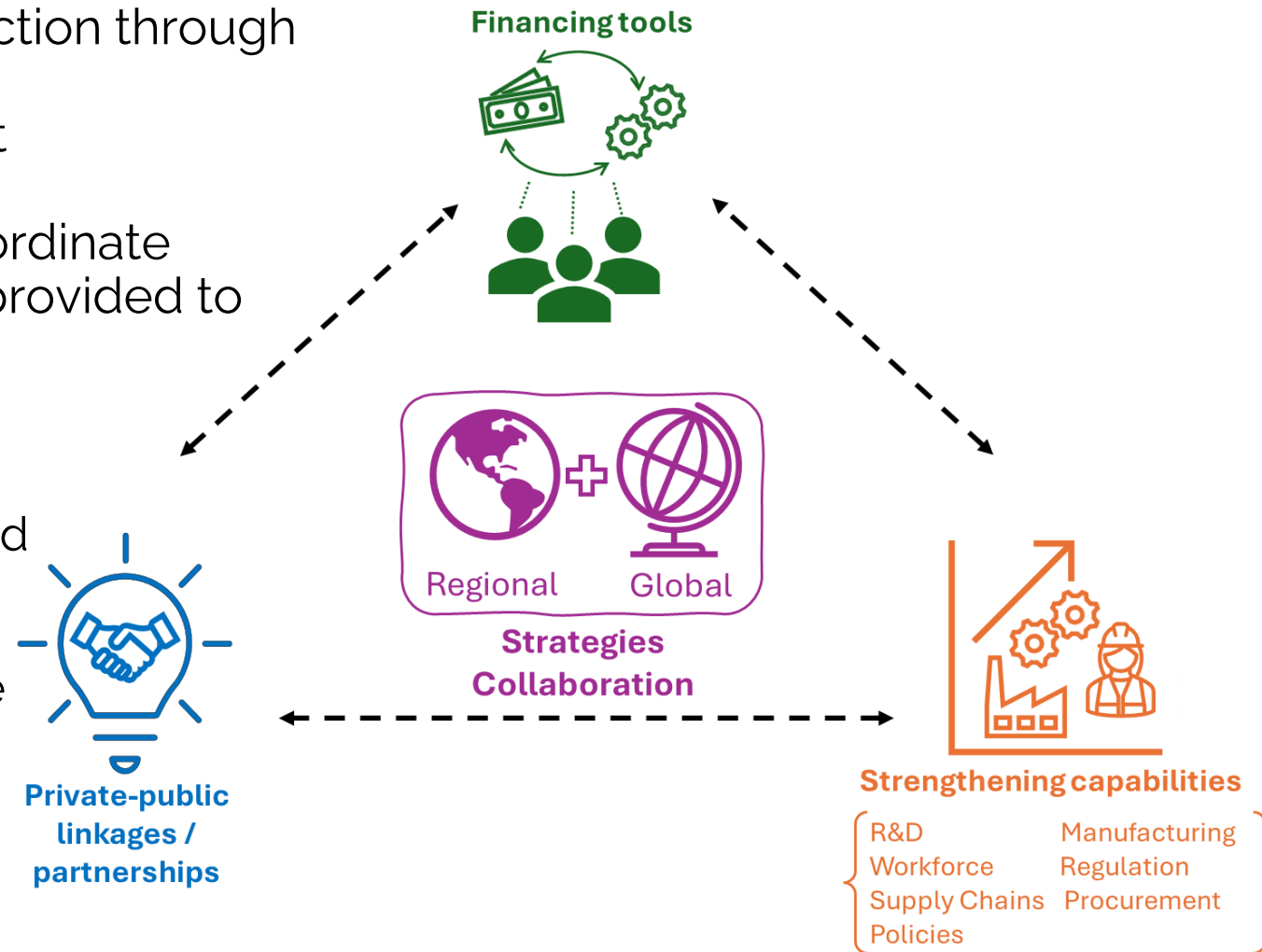
⇒ multilateral TT product development

Consortia approach to collaborate and coordinate support for health product manufacturing provided to manufacturers and countries

⇒ Harnessing WHO's strengths

⇒ Facilitatory and coordinating role in aligning efforts to support geo-diversified production of prioritized platform technology [mRNA, RDTs]

⇒ Reduces risks and generates extra value for emerging technologies.



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mRNA TT Programme Partners

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Biovaccines Nigeria
Darnista
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Polyvac
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TT partners

SD Biosensor

mRNA TT PDP

International Vaccine Institute
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THANK YOU

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