

Member States briefing mRNA Technology Transfer Programme

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**World Health
Organization**

Session outline

History and chronology of the mRNA tech transfer programme

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Progress to date

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Regulatory system strengthening

Mariângela Simao

Challenges and ways forward

Soumya Swaminathan

Q&A

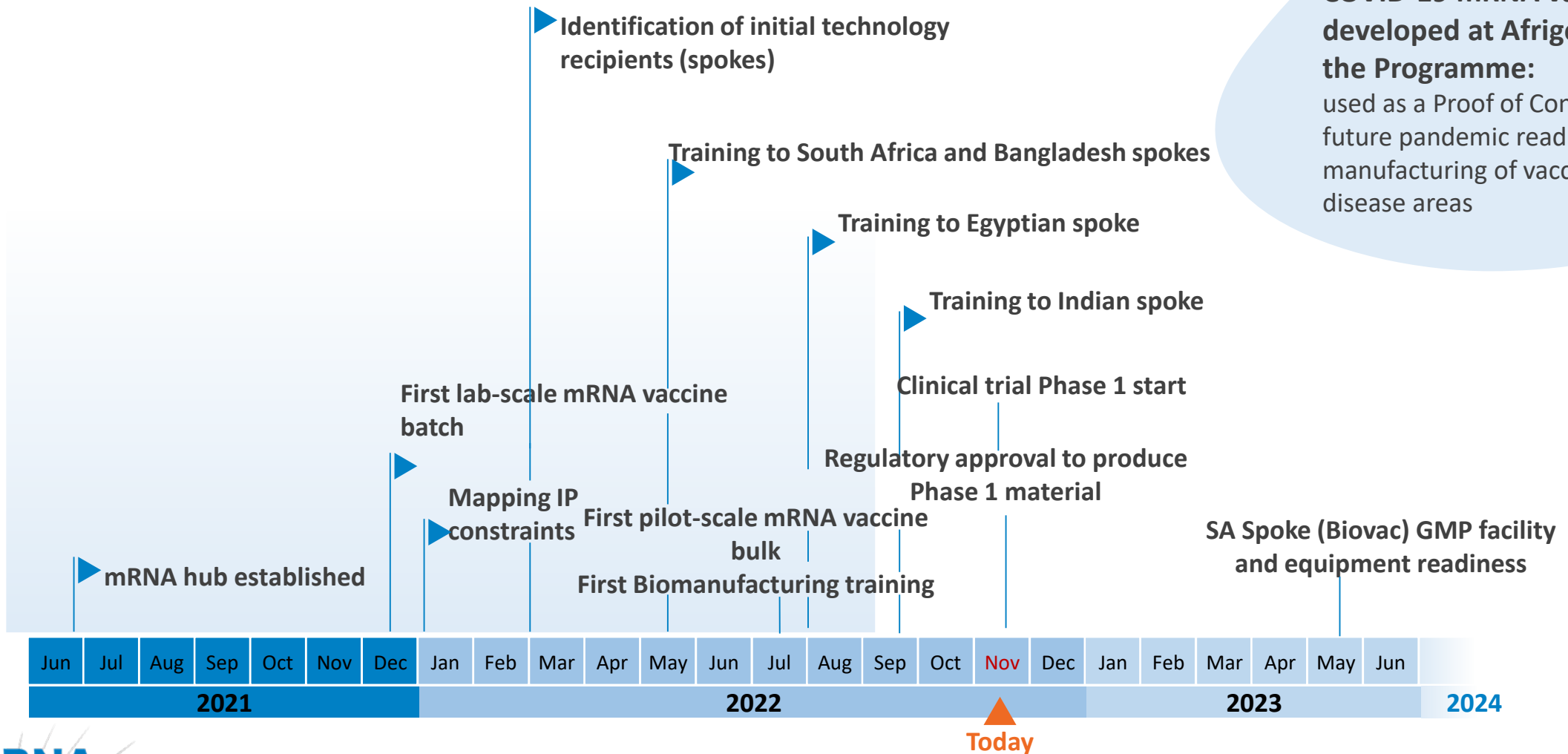
Soumya Swaminathan, Mariângela Simao

Martin Friede, Charles Gore

Chronology of the mRNA Tech Transfer Programme



Progress to date



COVID-19 mRNA vaccine developed at Afrigen as part of the Programme:
 used as a Proof of Concept to enable future pandemic readiness and manufacturing of vaccines in other disease areas

Establishing R&D Network and Collaborations

mRNA vaccine developer	Country	Animal studies partners	Labs partners	Clinical sites	Disease Areas interests (Hypothetical)	R&D gaps (Hypothetical)	Resources to help address R&D gaps (Exploratory)
Spoke 1	Country 1	Univ 1, 2, ,,,	PH lab 1, 2, ,,,	Health Center 1, ,,,	Dengue	Access to NHP	Finding partners through the Network
Spoke 2	Country 2	Univ 1, 2, ,,,	PH lab 1, 2, ,,,	Health Center 1, ,,,	Dengue, Zika	FTO on Zika	MPP IP Landscape
Spoke 3	Country 3	Univ 1, 2, ,,,	PH lab 1, 2, ,,,	Health Center 1, ,,,	HIV, Malaria, TB	Clinical Development Plan	WHO R&D Roadmap and PPC
Spoke 4	Country 4	Univ 1, 2, ,,,	PH lab 1, 2, ,,,	Health Center 1, ,,,	Rabies, Leishmaniasis	Run Immuno Study	Small research grant

mRNA R&D network meeting to be held in Cape Town on 17-21 April 2023



Biomanufacturing Workforce Training Initiative

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- **To address the shortage of skilled workforce** through training in Biomanufacturing
- **Generic training** (not product-specific, hands-on)
- **The Republic of Korea** to host the Global Training hub
 - Introductory training in July 2022-117 trainees (16 from spokes)
 - GxP training in Nov 2022 – 200 trainees (25 from spokes)
 - Korean Global Bio campus fully operational in 2026
- Link to **WHO Academy** to ensure appropriate curriculum/training





Biomanufacturing Workforce Training Initiative

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- Complemented by other **training partners**
 - Advanced certificate in biopharmaceutical manufacturing at NCTM (Texas, USA): 31 trainees from hub and spokes (July-Sep and Dec 2022)
 - Practical training on bioprocessing by ICGEB (Trieste, Italy): 13 trainees (Dec 2022)
 - Aseptic Behavior Course by NIBRT (Dublin, Ireland): 7 trainees (Nov 2022), 20 trainees (virtual Dec 2022)
 - Practical training on vaccine manufacturing by BIT (Leiden, The Netherlands): 19 trainees (Nov-Dec 2022)
- Ongoing discussion on **placement opportunities** in private companies and development of **regional training centers**

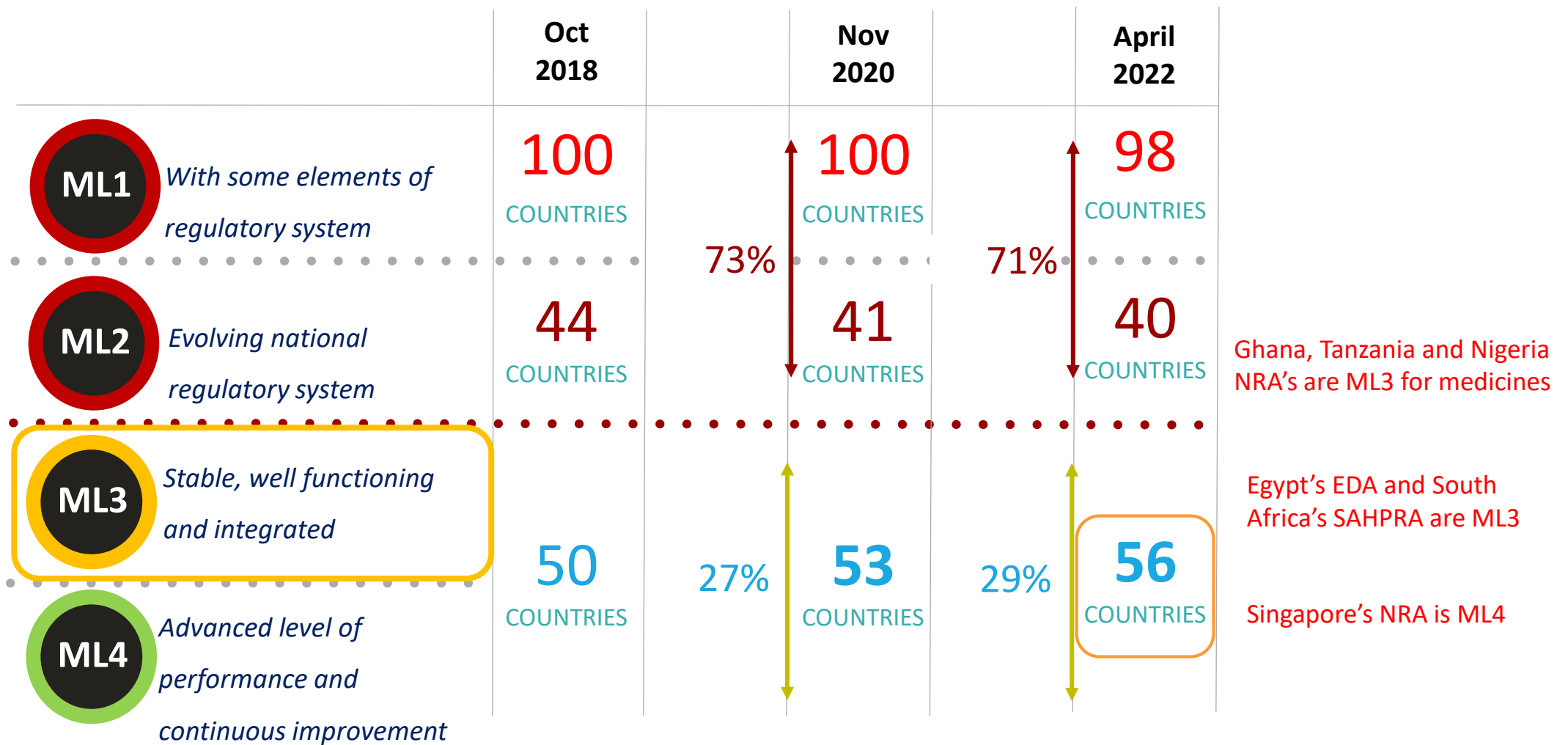
Regulatory System Strengthening

Regulatory system strengthening

- Countries with mRNA hubs will produce and export vaccines to other countries
- Need stable, well-functioning and integrated regulatory system (**GBT maturity level 3**) to:
 - Provide an **oversight of quality, safety and efficacy** of vaccines and other medical products
 - Meet WHO requirements for **Emergency Use Listing and Prequalification**
 - Be relied upon by other regulators as well as regional and global procurement agencies



Global status of national regulatory systems, April 2022



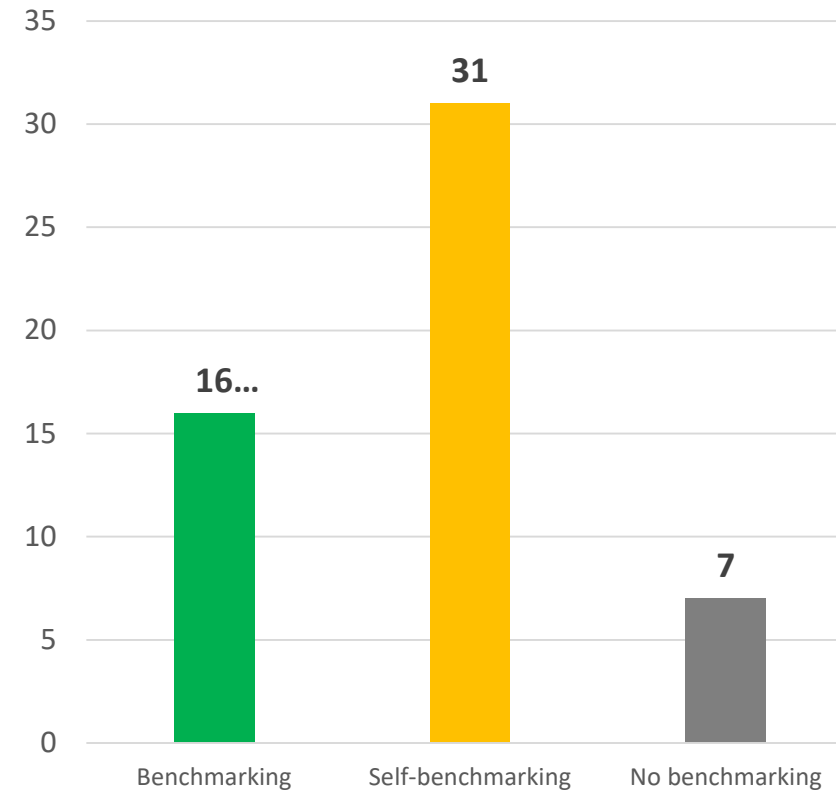
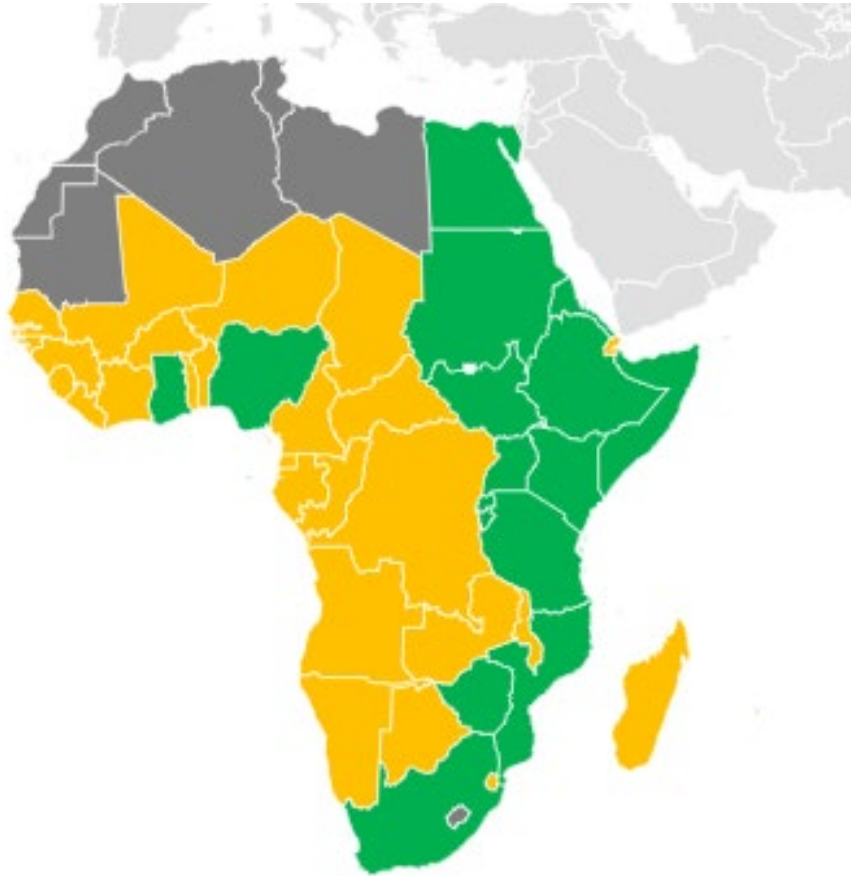
ML3 GOAL of WHO Resolution 67.20

ML= (regulatory system) maturity level

Vaccines developed in countries with weak regulatory systems, i.e., ML1/ML2, are not eligible for WHO EUL or Prequalification

Countries using WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory

System of Medical Products 47 WHO-AFR and 7 WHO-EMR* Regions (March 2022)



- **Djibouti, Egypt, Libya, Morocco, Somalia, Sudan and Tunisia*
- ***8 countries fully benchmarked: Egypt**, Ghana**, Nigeria**, Rwanda, South Africa**, Tanzania**, Uganda and Zimbabwe*
- ***countries with regulatory capacity at ML 3 (vaccines only Egypt and South Africa; others ML3 for medicines)*

Challenges and ways forward

Challenges to conducting COVID-19 clinical trials

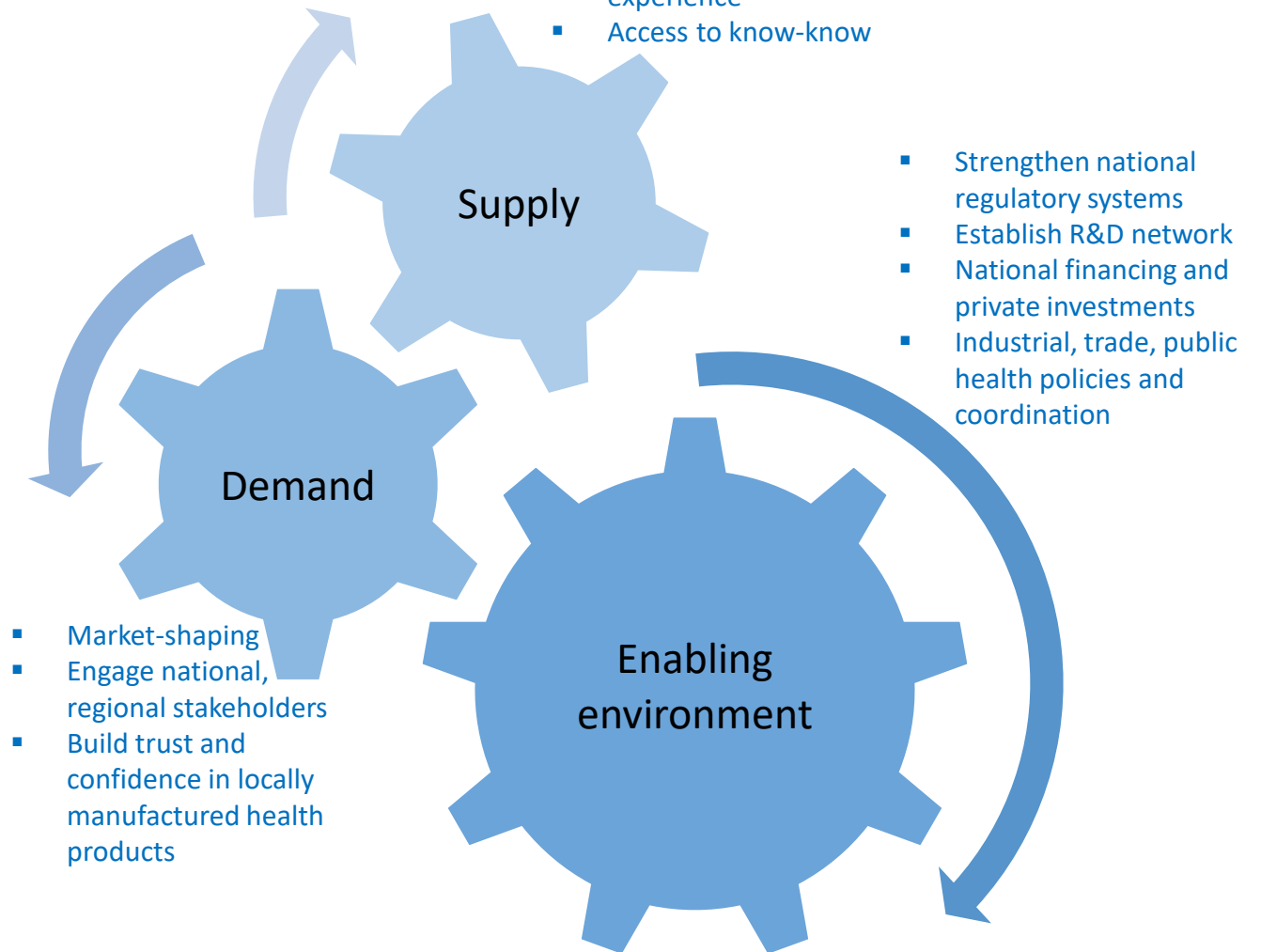
- COVID-19 becoming endemic
- Mutated strains of SARS-COV-2 continue to emerge
- Increased population exposed to the virus
- Increased vaccination coverage

➔ Pathway to approval of locally-produced COVID-19 vaccine based on immunogenicity and safety






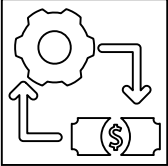


Towards sustainability

- Distributing **supply chain** elements across the region to achieve **regional coherence** and build the foundation for **global equity in access**
- **Building mRNA R&D pipeline** (beyond COVID-19)
- Evidence-based information package for the spokes considering three basic business models being developed to inform decisions on initial investment
- Paper in preparation for **cost analysis** (CAPEX/OPEX) relating to setting up and maintaining mRNA production capability
- Dialogue with Member States to coordinate relevant policies and strategies for a coherent approach to capacity building
- Strong engagement of regional offices for coordination of regional approaches



Expectations and value for hubs, recipients, local governments

	 Hub	 Local government supporting hub	 Recipient	 Local government supporting recipient
Main expectation 	Participate in tech transfer, develop tech, provide training	Support hub in the long run (e.g., min. quantity ordered)	Technical capacity to receive, implement and scale up tech	Support recipient in the long run (e.g., min. quantity ordered)
Value proposition 	WHO/MPP support on critical enablers Specific funding for training and procurement of equipment	(Inter-)regional collaboration and recognition Access to essential health products; local know-how	WHO/MPP support on critical enablers Specific funding for training	Improved regional health/health security Sustainable local biomanufacturing capacity/ know-how

First mRNA hub with full support as a pilot over a 5-year timeline

Q & A