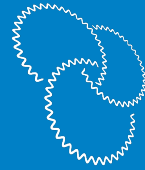


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Technology sharing and managing collective knowledge within the WHO mRNA technology transfer Hub

16th January 2023

A faint, light blue outline of the African continent is visible in the bottom right corner of the slide, set against a background of white lines radiating from the bottom right corner.

The mRNA Technology Transfer Hub Programme was established to improve health security in LMICs through sustainable, regional production of mRNA vaccines



Objective 1

Establish or enhance **sustainable mRNA vaccine manufacturing capacity** in regions with no or limited capacity



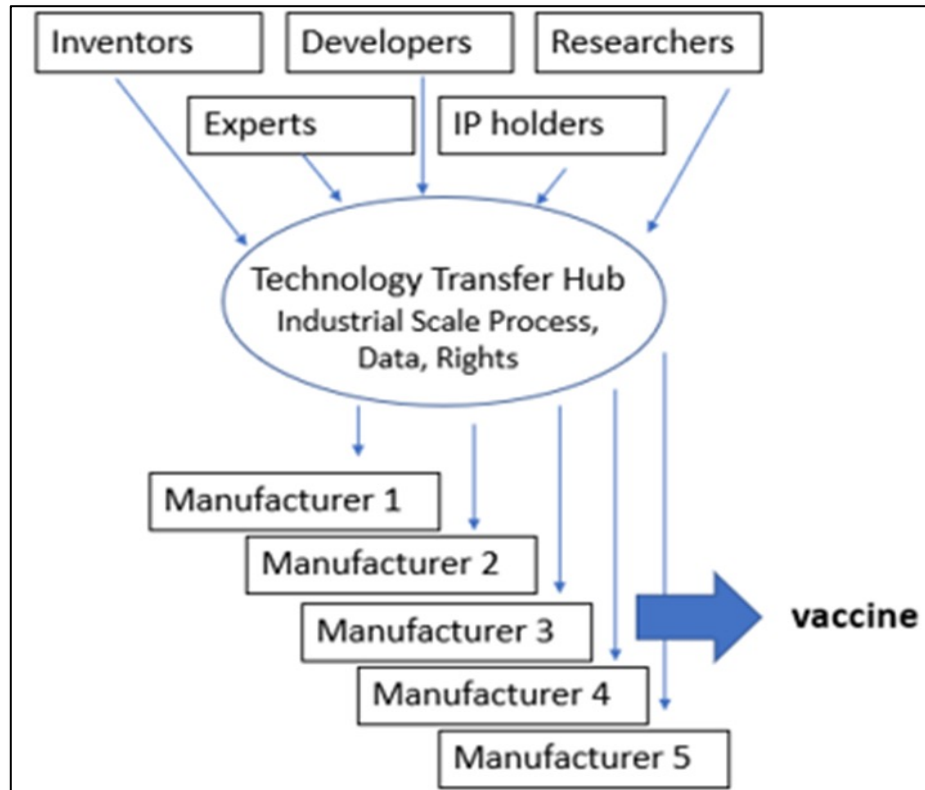
Objective 2

Build human capital for regulation and biomanufacturing in LMICs

The Programme is guided by three key principles:

- Principle 1: ***Equitable access to technologies suitable to respond to pandemics - mRNA technology***
- Principle 2: ***Value and share intellectual property - multilateral technology transfer***
- Principle 3: ***Promote establishment of sustainable capacity to produce mRNA vaccines - coherent policies and adequate investments***

Technology Transfer: “Hub & Spokes” model



Hub

- Develop mRNA technology
- Implement mRNA technology for vaccine(s) production at scale and testing according to GMP
- Serve as training center on mRNA technology for spokes
- Develop technology transfer content
- Assist spokes during technology transfer



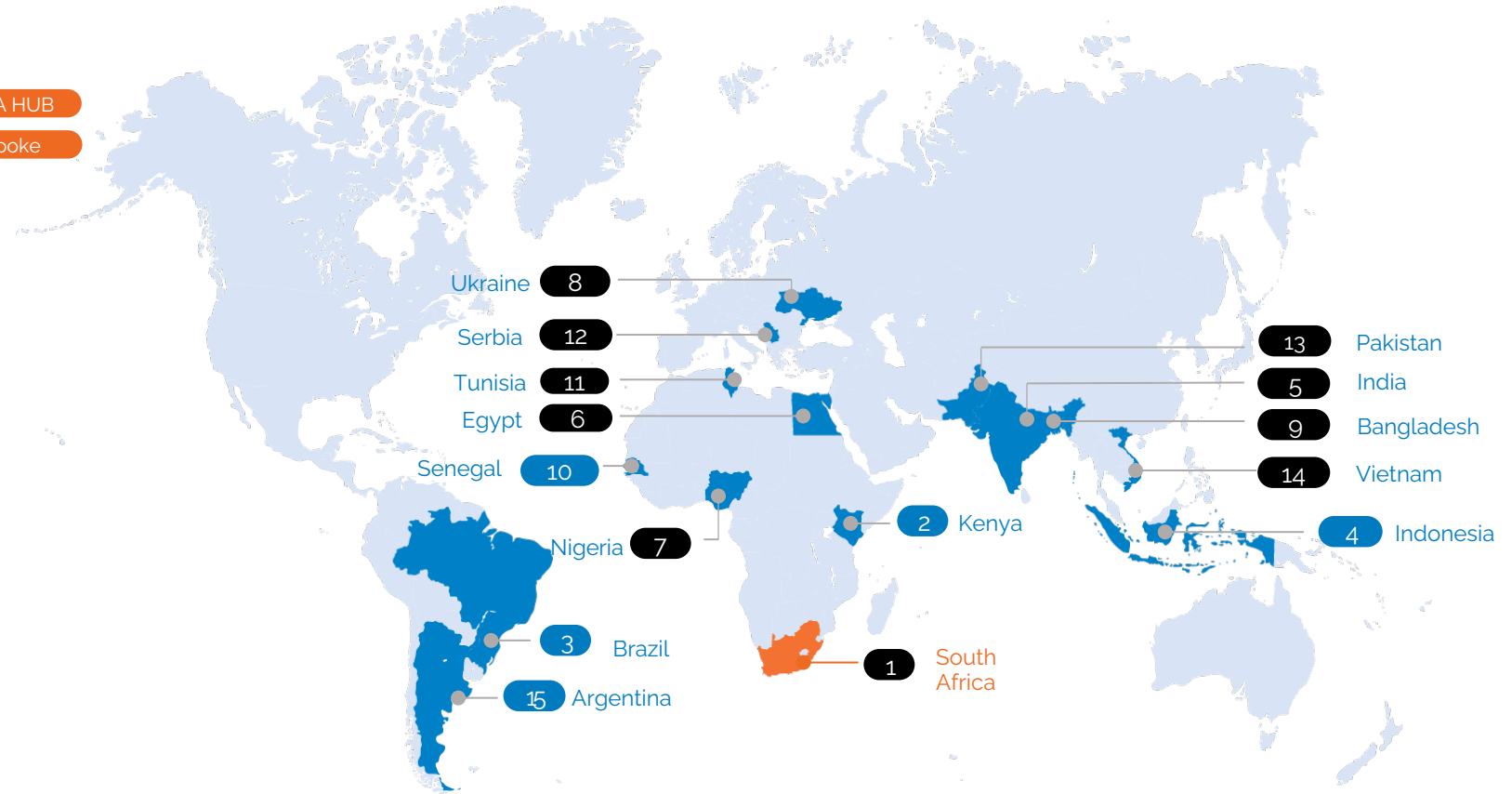
Technology recipient “spoke”

- Develop viable business model incl. required upfront financing
- Establish required infrastructures and workforce to receive mRNA technology
- Receive and execute technology transfer from the Hub according to an agreement signed with MPP
- Implement and scale up/out (if needed) the technology according to own business model and needs

10/15 Spokes have already signed a Technology Transfer Agreement to receive the technology from the Hub

- 1 Afrigen
- 2 TBD
- 3 Bio-Manguinhos
- 4 Biofarma
- 5 BiologicalE
- 6 BioGeneric Pharma
- 7 Biovaccines Nigeria
- 8 Darnitsa
- 9 Incepta Vaccine
- 10 Institut Pasteur de Dakar
- 11 Institut Pasteur de Tunis
- 12 Institut Torlak
- 13 National Institute of Health
- 14 Polyvac
- 15 Sinergium Biotech

mRNA HUB
1st spoke



- **Status:** 10 contracts signed
- **Contract content:** parties obligations, technology transfer packages description, IP and data sharing clauses

Intellectual property obligations ensure know-how/data sharing

1. Freedom to Operate (FTO):

MPP and WHO will not guarantee FTO at country level but will provide an IP landscape analysis detailed at country level. The confirmation of actual status and scope of patents/claims filed and/or granted in the country is each Spoke's responsibility.

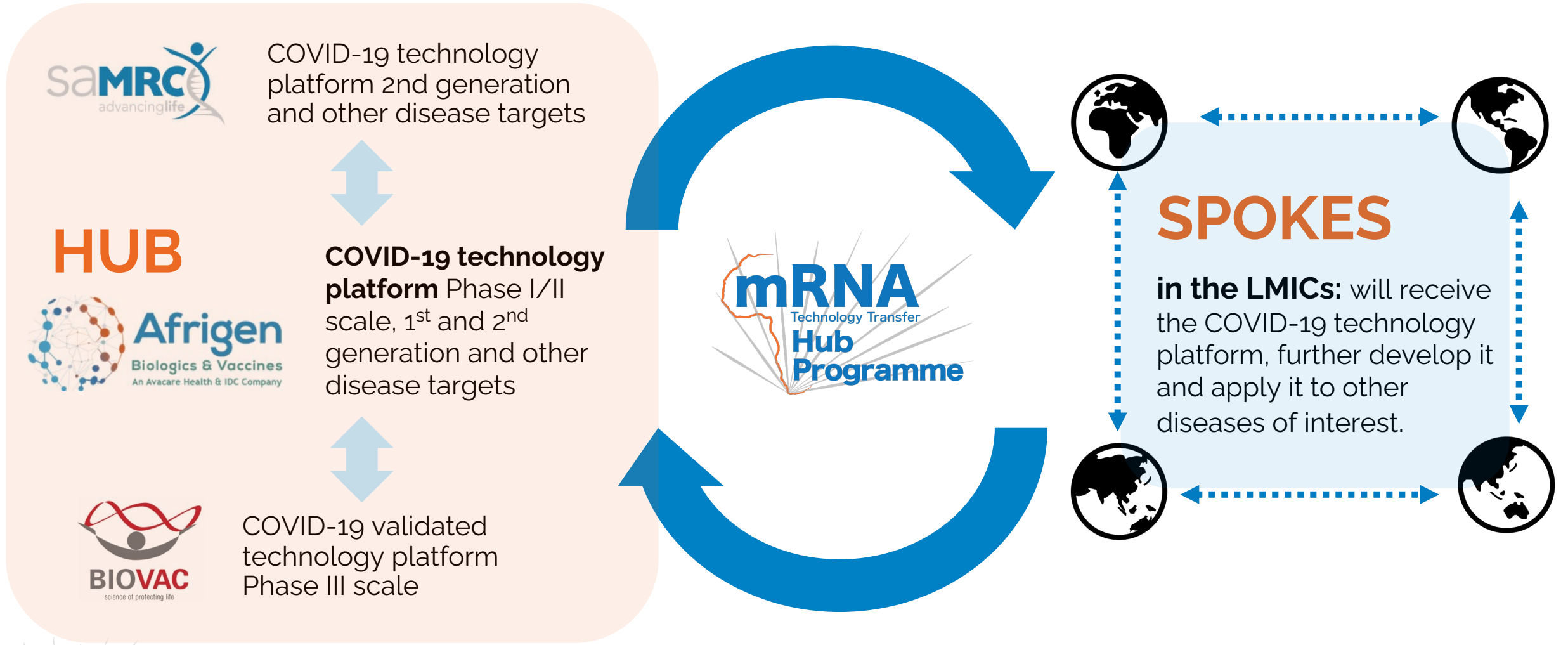
2. MPP grant of licence to Spoke:

- MPP grants to each Spoke a non-exclusive licence to technology transfer packages to develop and commercialise “Products” based on the technology
- MPP agrees to grant to each Spoke non-exclusive rights to data/inventions developed by other Spokes (see below) and any other sublicensable rights it obtains through other Hub agreements (e.g., through SAMRC grantees)

3. Spoke grant-back to MPP

- Each Spoke agrees to grant to MPP a non-exclusive licence to any data or inventions it develops based on the technology transfer to make available to other Spokes
- To the extent that Third Party IP is used by Spoke, Spoke undertakes to make efforts to make such Third Party IP available to MPP on same or similar terms

Technology and know-how sharing process



Design features/tradeoffs inherent in Hub

Operating in a Competitive IP/R&D environment

- Many third-party players active in mRNA R&D actively staking out IP claims on the mRNA “commons” who are not bound by same terms as Hub agreements
- Is pure “open access” feasible/desirable in such an environment?

Speed and convenience vs Freedom to operate

- Quickest way to develop an mRNA platform may not result in greatest freedom to operate for Spokes later on. Strategic decisions to identify potential barriers and evaluate options – e.g., to design around, need to be made early on (e.g., mRNA modification, choice of lipids)

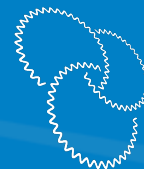
Sustainability vs Access

- Potential tension in ensuring the long-term sustainability of each Spoke vs defining equitable access as lowest possible price
- Obligations Spokes take on for receiving technology must be commensurate to potential benefits they expect to derive from it

THANK YOU



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