



# **Manufacturing Task Force - Workstream 3: Increasing Manufacturing capacity in LMICs**

Consultative Forum

December 9, 2021

# **COVAX and Manufacturing Task Force Workstream 3**



# COVAX Manufacturing Taskforce was structured around three workstreams, addressing different needs

## Workstream 0



### Shared Fact Base / Task Force Coordination Office

- Create aligned supply baseline
- Conduct supply and manufacturer ecosystem mapping
- Document and share lessons learned across focus areas

Conveners **CEPI**   
 

## Workstream 1



### Immediate COVAX Response

- Create voluntary input supply visibility partnership
- Accelerate export permits/custom clearance for critical SKUs

Convener **CEPI**

## Workstream 2



### Short- and Mid-Term COVAX Response

- Expand fill & finish match making mechanisms
- Create overview of global manufacturing capacities
- Better utilize existing capacities, e.g., voluntary bilateral tech transfer
- Develop regulatory & manufacturing workforce

Conveners **CEPI** 

## Workstream 3



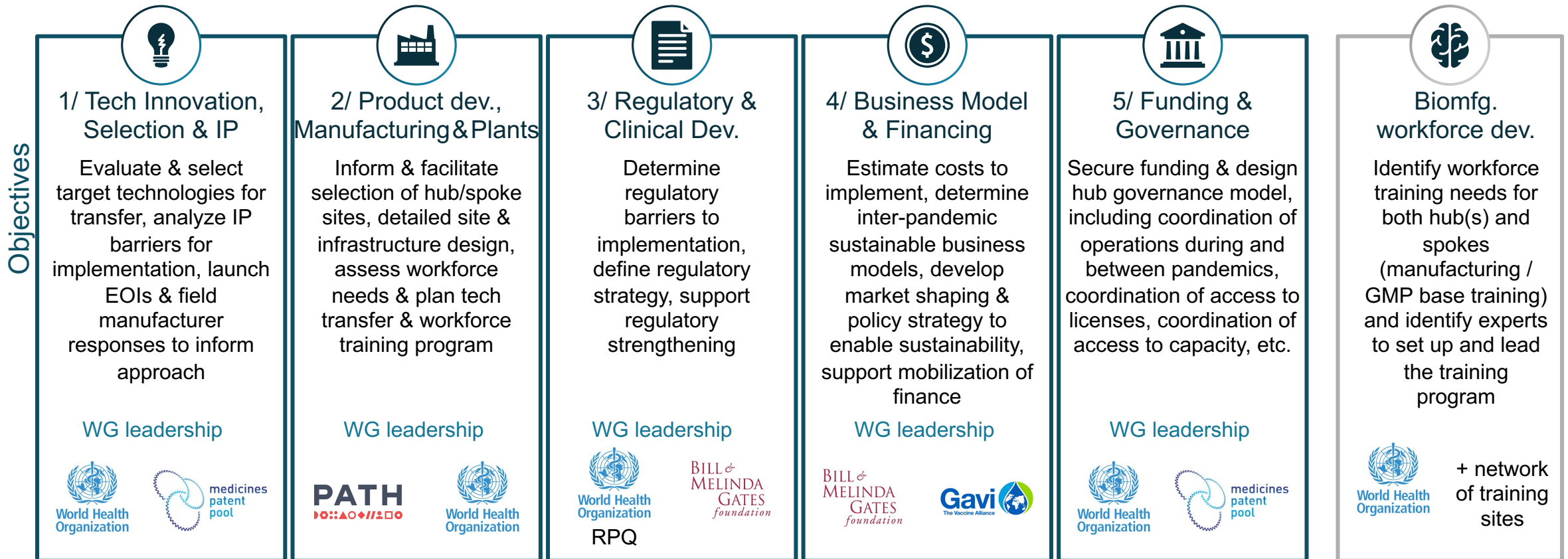
### New & Expanded Sustainable Capacity in LMICs

- Establish or enhance sustainable biomanufacturing capacity in regions with no significant capacity
- Build human capital for regulation and biomanufacturing in LMICs

Conveners  

# WS3 is structured around five Working Groups

## Workstream 3 working groups

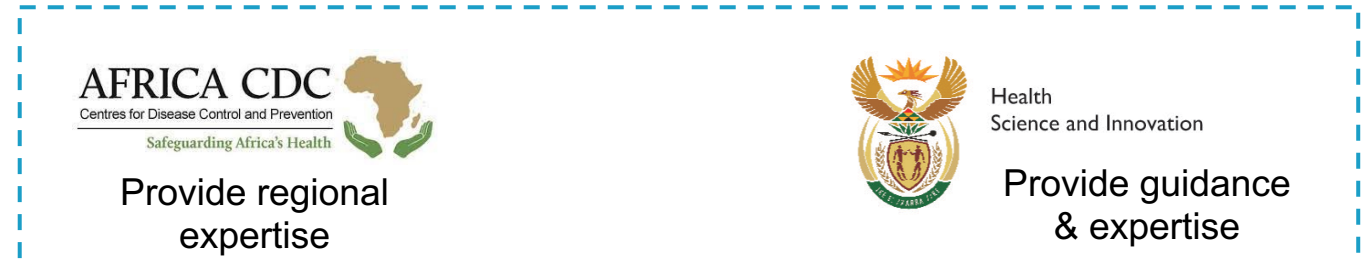


Note: In addition, Technical Advisory Panel (PDVAC) with expertise across topics areas (from industry, academia, etc.) reviews workstream proposals and provide input and recommendations to shape final solution on hubs / spokes network

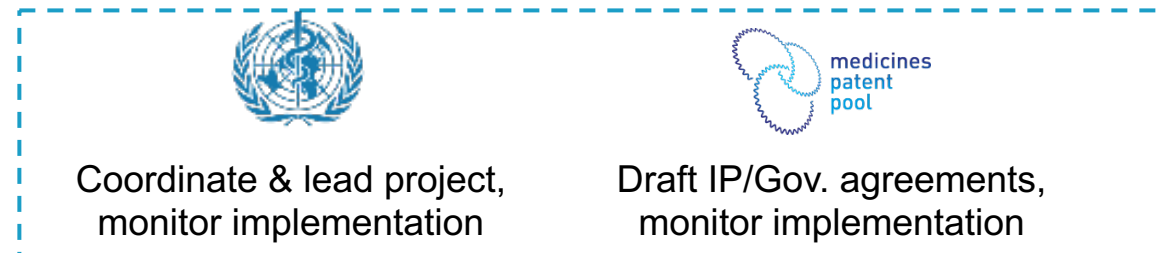
# South African consortium set up to build tech transfer hub & spokes network with local/regional partners



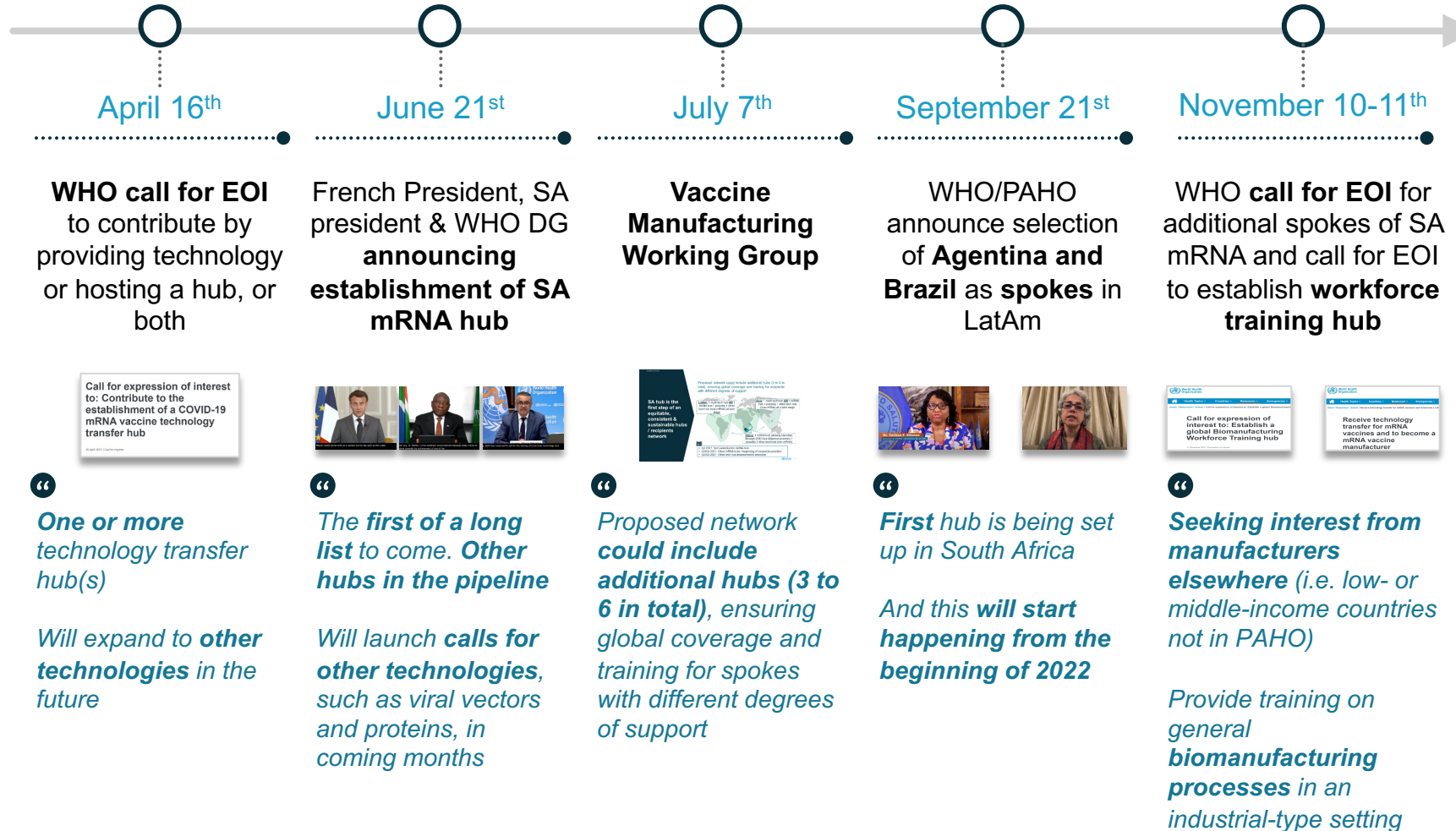
## Local/regional partner



## Global partners



# Overview of project status and summary of communications to date



## Status to date

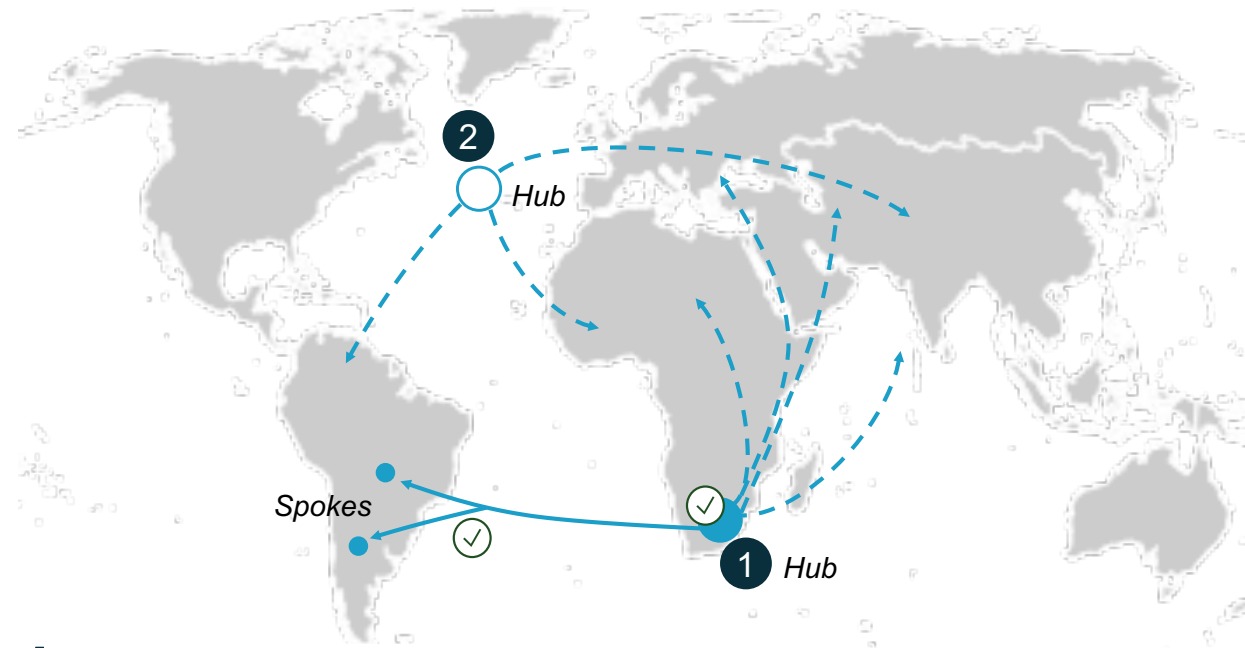
SA hub announced with LOI signed and first spokes identified in SA and LatAm

EOI process ongoing:

- additional spokes of SA mRNA hub
- establishment of a global biomanufacturing workforce training hub

# Target network will include spokes for SA mRNA hub, additional hubs/spokes for non-mRNA tech and 1+ biomanufacturing training hubs

- 1 To date, **SA mRNA hub** announced with first spokes in LatAm – objective: **~12 add'l spokes** for mRNA hub
- 2 Number, location and technology of **other, non-mRNA hubs not yet decided on** – depends on interest of spokes
- > Hubs to leverage COVID for initial training purposes; **long-term focus beyond COVID**, with wider **biologicals** scope

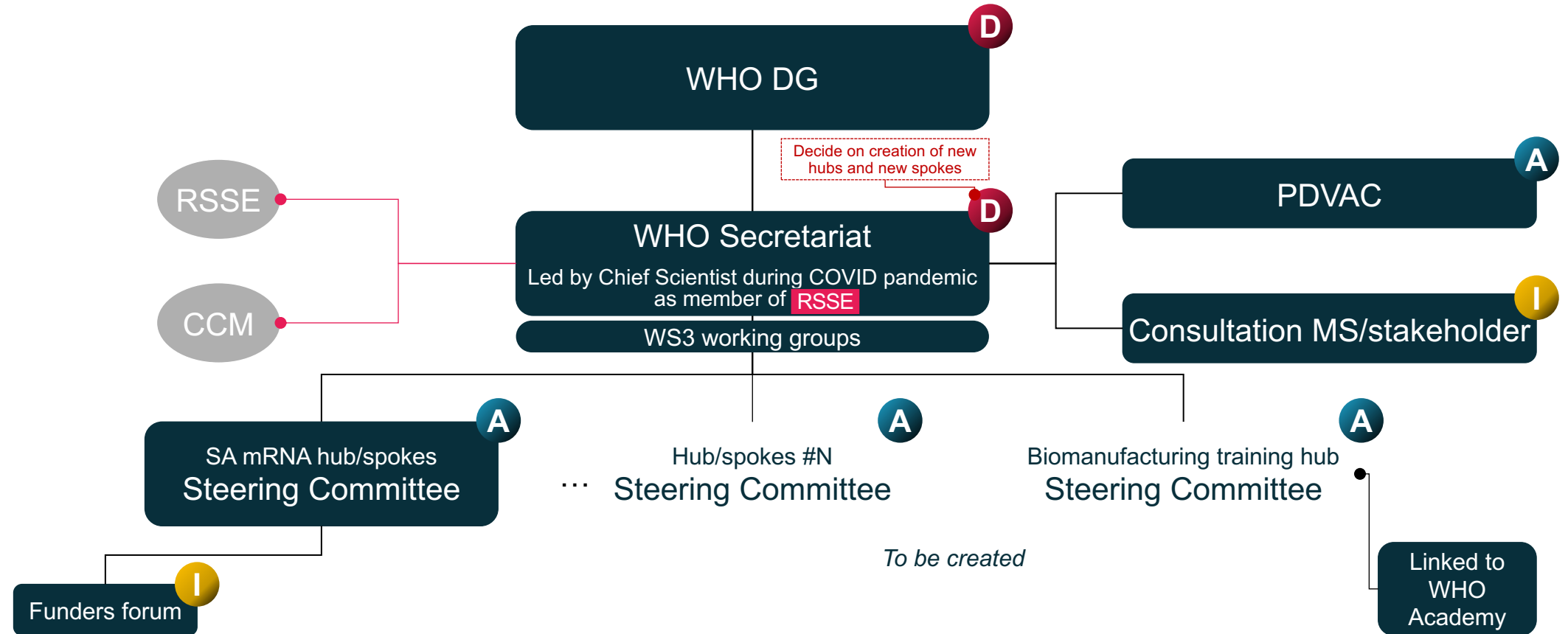


## Upcoming milestones

- ✓ 10 Nov: Call for EOI for additional mRNA hub spokes
- ✓ 11 Nov: Call for EOI to become a Biomanufacturing training hub
- 1 Jan 2022: Additional spokes for mRNA hub announced
- 2 Q1/2022: Call for EOI for non-mRNA hubs/spokes
- Q1/2022: Selection of non-mRNA hubs/spokes

# Overall governance anchored around WHO Secretariat

## Multilateral Technology Transfer Initiative for Biologicals



Note: Governance might be revised in the future in light of evolution of portfolio (biologicals, beyond Vx); PDVAC = Product Dev. For Vaccines Advisory Committee; MS = Member State



Decide



Advise



Inform/is informed



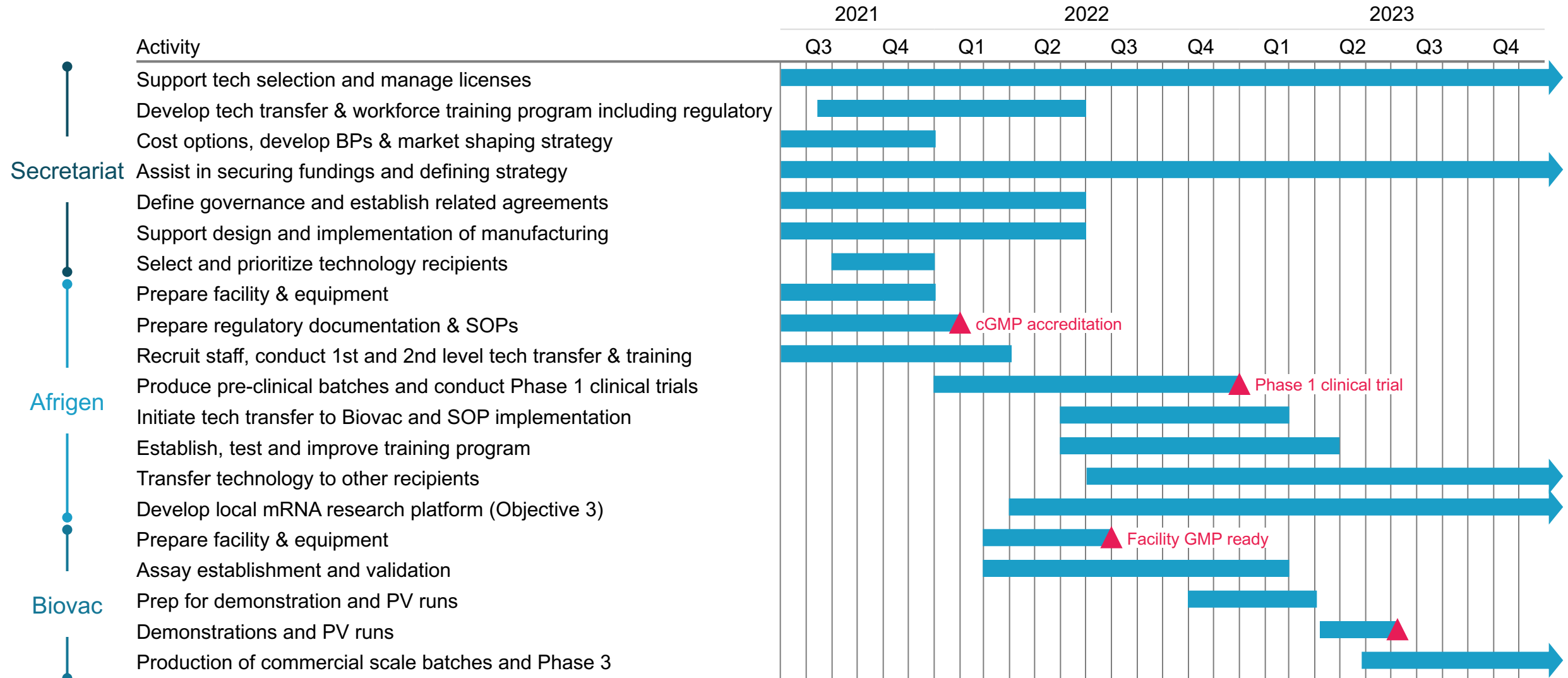
Existing COVAX body

# **South Africa hub:** **Timeline,** **Milestones &** **Governance** **Structure**



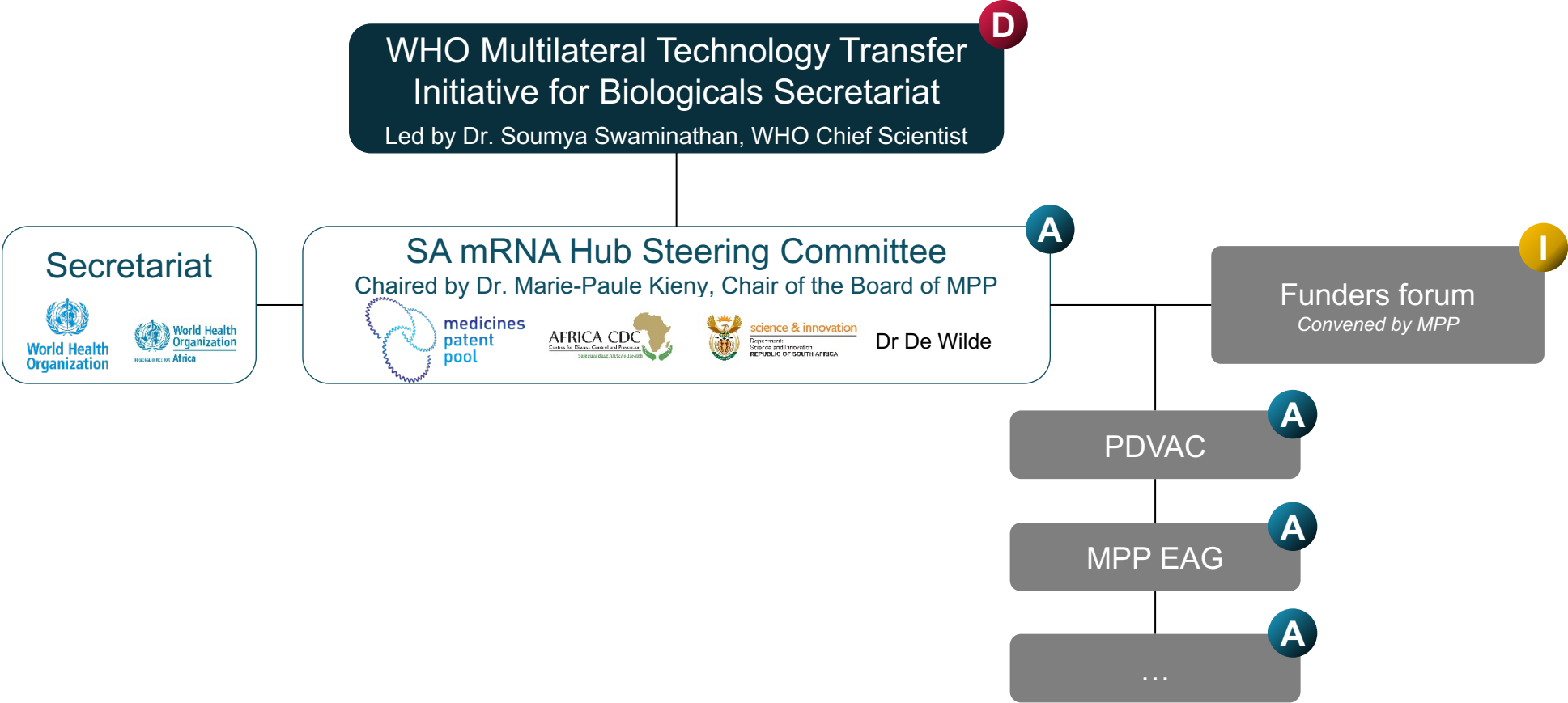
# Timeline of SA mRNA hub has been laid out

Timeline subject to change and continuous refinement



# Governance for South African mRNA Hub

## WHO South African mRNA Technology Transfer Hub



Decide



Advise



Inform/is informed

# Budget and funding



# SA mRNA hub budget estimated at ~€92M for 2021-26

Excl. Objective 0

## Objective 1 Hub



### Establishment of the hub

- Prepare facilities and receive technology
- Review IP, agreements & regulatory process for facility
- Conduct pre-clinical & clinical trials & prepare clinical protocols
- Design TT program
- Open & maintain training center

## Objective 2 Spoke



### Establishment of the first spoke

- Establish plan for equipment & processes, for DS & DP
- Prepare facilities
- Train staff and receive technology from Afrigen
- Perform demonstration and process validation runs
- Produce vaccines

## Objective 3 Academic partners



### Development of local innovation & products

- Build a pipeline of vaccine candidates (TB, HIV, etc.) with pre-clinical testing
- Optimize technology for LMIC application
- Collaborate with genomic sequencing centers
- Conduct surveillance activities

2021-22

~€16M

~€12M

~€4M

2021-26

~€39M

~€30M

~€23M

~€92M total hub budget for 2021-26 – thereof ~€32M for 2021-22

# Initial grants mobilized, with 50%+ of hub budget secured

Funding pledges towards Objectives 1-3 only  
(excl. Secretariat costs)

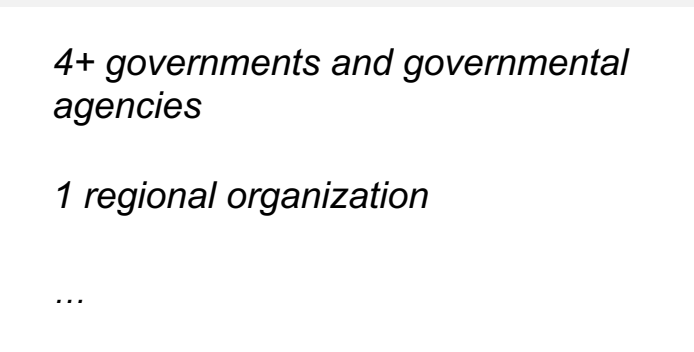
~€28M confirmed and formally announced



~€24M yet to be formally confirmed and announced<sup>1</sup>



... and further alignments ongoing with different parties



**Indicative view:** ~€52M likely covered out of €92M budget for Objectives 1-3  
– further discussions ongoing

Note: Indicative, preliminary view only  
1. Amount in alignment

# ~€28-40M funding gap vs €92M budget (excluding Obj. 0)

Excl. Objective 0



Base case



€52M covered out of €92M total budget (2021-26)

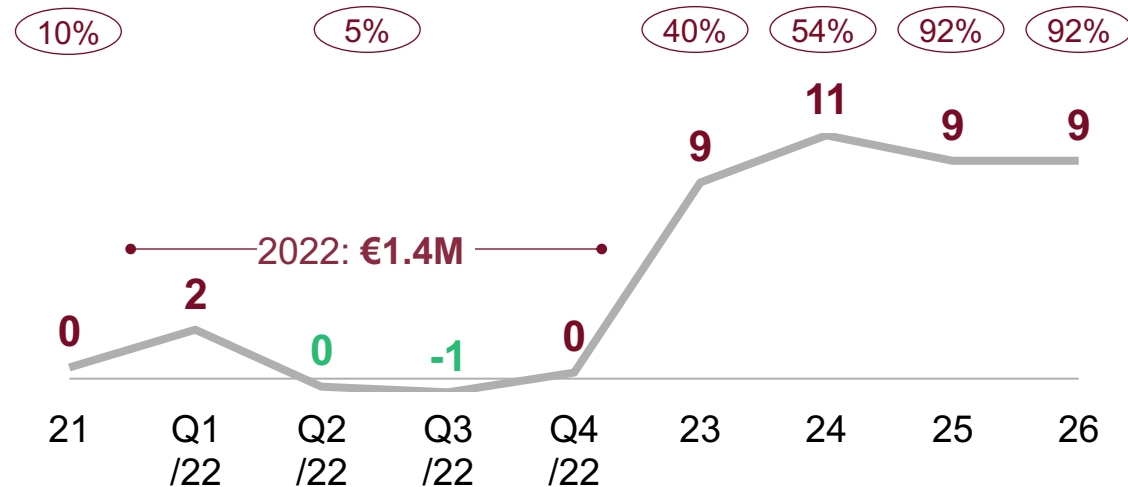


High case

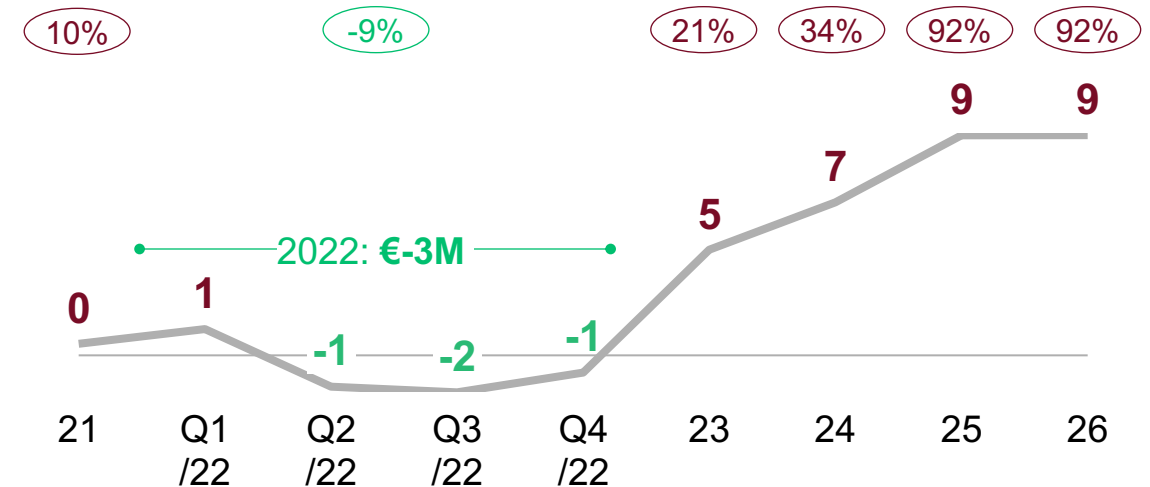


€64M covered out of €92M total budget (2021-26)

Funding gap (€M), absolute and relative



Funding gap (€M), absolute and relative



# What's next?



## WHO has recently announced the following Calls for Expression of Interest (EOIs):

- EOI to receive technology transfer for mRNA vaccines and become an mRNA vaccine manufacturer
- EOI to host the Global Biomanufacturing Workforce Training Hub



## CSO engagement & comms update

- Workstream 3 is currently looking into new ways to effectively engage with the civil society
- MPP Comms Team has made a short film production about the mRNA vaccine technology transfer Hub in South Africa
- Communications plan in development

# COVAX

Thank you