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

**Convener**
- CEPI
- World Health Organization
- Gavi
- UNICEF

**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

**Convener**
- CEPI
- Gavi

**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

**Convener**
- World Health Organization
- Medicines Patent Pool
WS3 is structured around five Working Groups

### Workstream 3 working groups

<table>
<thead>
<tr>
<th>Objective</th>
<th>Working Group</th>
<th>Description</th>
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<tbody>
<tr>
<td>1/ Tech Innovation, Selection &amp; IP</td>
<td>Evaluate &amp; select target technologies for transfer, analyze IP barriers for implementation, launch EOI &amp; field manufacturer responses to inform approach</td>
<td>WG leadership</td>
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<tr>
<td>2/ Product dev., Manufacturing &amp; Plants</td>
<td>Inform &amp; facilitate selection of hub/spoke sites, detailed site &amp; infrastructure design, assess workforce needs &amp; plan tech transfer &amp; workforce training program</td>
<td>WG leadership</td>
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<td>3/ Regulatory &amp; Clinical Dev.</td>
<td>Determine regulatory barriers to implementation, define regulatory strategy, support regulatory strengthening</td>
<td>WG leadership</td>
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<td>4/ Business Model &amp; Financing</td>
<td>Estimate costs to implement, determine inter-pandemic sustainable business models, develop market shaping &amp; policy strategy to enable sustainability, support mobilization of finance</td>
<td>WG leadership</td>
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<tr>
<td>5/ Funding &amp; Governance</td>
<td>Secure funding &amp; design hub governance model, including coordination of operations during and between pandemics, coordination of access to licenses, coordination of access to capacity, etc.</td>
<td>WG leadership</td>
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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

- **Hub**
  - Afrigen
  - Receive tech and transfer to spokes

- **Spoke**
  - BIOVAC
  - Receive tech and produce vaccines

- **Support**
  - saMRC
  - Provide academic/clinical dev. support

**Local/regional partner**
- AFRICA CDC
  - Provide regional expertise

**Global partners**
- Coordinate & lead project, monitor implementation
- Draft IP/Gov. agreements, monitor implementation
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

April 16th
WHO call for EOI to contribute by providing technology or hosting a hub, or both

French President, SA president & WHO DG announcing establishment of SA mRNA hub

One or more technology transfer hub(s)
Will expand to other technologies in the future

June 21st

The first of a long list to come. Other hubs in the pipeline
Will launch calls for other technologies, such as viral vectors and proteins, in coming months

July 7th

Vaccine Manufacturing Working Group

Proposed network could include additional hubs (3 to 6 in total), ensuring global coverage and training for spokes with different degrees of support

September 21st

WHO/PAHO announce selection of Argentina and Brazil as spokes in LatAm

First hub is being set up in South Africa
And this will start happening from the beginning of 2022

November 10-11th
WHO call for EOI for additional spokes of SA mRNA and call for EOI to establish workforce training hub

Seeking interest from manufacturers elsewhere (i.e. low- or middle-income countries not in PAHO)
Provide training on general biomanufacturing processes in an industrial-type setting
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
3. 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
- Jan 2022: Additional spokes for mRNA hub announced
- 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

WHO DG

WHO Secretariat
Led by Chief Scientist during COVID pandemic as member of WS3 working groups

RSSE

CCM

SA mRNA hub/spokes Steering Committee

Funders forum

PDVAC

Consultation MS/stakeholder

To be created

Hub/spokes #N Steering Committee

Biomanufacturing training hub Steering Committee

Linked to WHO Academy

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

Decide on creation of new hubs and new spokes

Decide

Advise

Inform/is informed

Existing COVAX body
South Africa hub: Timeline, Milestones & Governance Structure
Timeline of SA mRNA hub has been laid out

Activity

Support tech selection and manage licenses
Develop tech transfer & workforce training program including regulatory
Cost options, develop BPs & market shaping strategy
Assist in securing fundings and defining strategy
Define governance and establish related agreements
Support design and implementation of manufacturing
Select and prioritize technology recipients
Prepare facility & equipment
Prepare regulatory documentation & SOPs
Recruit staff, conduct 1st and 2nd level tech transfer & training
Produce pre-clinical batches and conduct Phase 1 clinical trials
Initiate tech transfer to Biovac and SOP implementation
Establish, test and improve training program
Transfer technology to other recipients
Develop local mRNA research platform (Objective 3)
Prepare facility & equipment
Assay establishment and validation
Prep for demonstration and PV runs
Demonstrations and PV runs
Production of commercial scale batches and Phase 3

Timeline subject to change and continuous refinement
Governance for South African mRNA Hub

WHO South African mRNA Technology Transfer Hub

WHO Multilateral Technology Transfer Initiative for Biologics Secretariat
Led by Dr. Soumya Swaminathan, WHO Chief Scientist

SA mRNA Hub Steering Committee
Chaired by Dr. Marie-Paule Kieny, Chair of the Board of MPP

Funders forum
Convened by MPP

- PDVAC
- MPP EAG
- ...

Decide A Advise I Inform/is informed
Budget and funding
SA mRNA hub budget estimated at ~€92M for 2021-26

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

2021-22 ~€16M
2021-26 ~€39M

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

2021-22 ~€12M
2021-26 ~€30M

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 ~€4M
2021-26 ~€23M

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

Note: budgets are continuously refined, and therefore subject to change and not binding
Initial grants mobilized, with 50%+ of hub budget secured

~€28M confirmed and formally announced

~€24M yet to be formally confirmed and announced¹

... and further alignments ongoing with different parties

4+ governments and governmental agencies

1 regional organization

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)

Base case

56% funded

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

High case

69% funded

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

Funding gap (€M), absolute and relative

2022: €1.4M

Excl. Objective 0
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
Thank you