First vaccine technology transfer hub identified in South Africa – Key takeaways from WHO announcement on June 21st, 2021

WHO Media briefing on June 21st, 2021

Through COVAX, WHO announced it is supporting South African consortium to establish first COVID mRNA hub

Key takeaways

South African consortium comprises:
- Afrigen
- Biovac
- A network of universities

Follows WHO's call for EOI on April 16th, 2021
- 28 offers received to either provide technology or to host a hub or both

Tech being identified with 2-pronged approach
- "Late-stage" tech: fast & secured option (9-12 months) but with potential constraints
- "Early-stage" tech: lengthier & more uncertain, but offering broad scope / high program suitability

Next steps
- Confirm technology donor
- Implement (governance, funding, etc.)
- Identify subsequent hubs, launch of EOI calls for other techs and recipients
Critical next steps following SA mRNA hub announcement

**Implement South African proposal**
- Set up dedicated cross-working group team within WS3 / South African consortium
- Continue discussions on hub design (governance, regulatory, funding, etc.)
- Prepare (virtual) site visit Mid-July

**Select technology for mRNA hub**
- Questionnaires shared & received - under review with independent committee
- Select technology donor with 2-pronged strategy: pro-active reach out to late stage tech holders while progressing with earlier stage tech holders

**Identify other potential hub(s)**
- Finalize detailed due diligence to assess opportunity of additional mRNA hub(s)
- Assess opportunity & initiate EOI for other technologies
For South Africa hub, WS3 is leading a 2-pronged strategy to select tech partner

Discussions being led with potential tech partners with a 2-pronged strategy:
- Option 1 - "Late-stage" tech: fast & secured option but with potential geographical constraints / lower programmatic suitability
- Option 2 - "Early-stage" tech: lengthier & more uncertain option, but offering broad scope / high programmatic suitability

Both options present pros & cons and could be concomitantly implemented within South Africa

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<th>&quot;Late-stage&quot; tech</th>
<th>&quot;Early stage&quot; tech</th>
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<tr>
<td>Timeline before 1st vaccine prod.</td>
<td>++ 9-12 months (F&amp;F)</td>
<td>-= 24-48 months</td>
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<td>Efficiency</td>
<td>++ Proven</td>
<td>-= Uncertain (e.g., Curevac)</td>
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<td>Programmatic suitability</td>
<td>-= Ultra-cold chain required to date</td>
<td>++ Thermostability at higher temperature and lower COGS (TBC)</td>
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<td>Access &amp; application</td>
<td>-= Expected limited access, limited application beyond COVID &amp; constraints for recipients</td>
<td>++ Open access &amp; freedom to operate</td>
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**Zoom | Short- and medium-term SA hub activities**

(Under discussion with hub consortium and Advisory Group)

Hub is comprised of two main entities supported by academic partners

- Product developer and subsequently, training center for manufacturers from other countries
- Manufacturer and 'pilot' recipient to test and improve training & TT

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**Initial tech(s) reception**

- Product development and process selection
  - Possible acceleration path explored with late-stage tech

**mRNA facility preparedness**

- Clinical studies
  - SOP design and validation

- Establish training program
  - Select and prioritize tech recipients

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**WIP**

- Open training center to trainees for mRNA Tech Transfer (also as needed light GMP and QMS trainings)

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**Possible acceleration path explored with late-stage tech**

- Initiate tech transfer from Afrigen + SOP implementation

- Test and improve training program

- Finalize product development, seek approval
  (Clinical data package shared with all tech recipients to accelerate product approval in geographies)

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

SA hub is the first step of an equitable, consistent & sustainable hubs / recipients network.

**LaTam:** 1 multi-tech hub OR 1 mRNA hub + possibly 1 other tech hub (non-mRNA) at later stage

**Asia:** 1 multi-tech hub OR 1 mRNA hub + possibly 1 other tech hub (non-mRNA) at a later stage

**Africa:** 1 mRNA hub (already identified through WHO due diligence process) + possibly 1 other tech hub (non-mRNA)

- Q3 2021: Tech selection for mRNA hub
- Q3/Q4 2021: Other mRNA hubs / beginning of recipients selection
- Q3/Q4 2021: Other tech hub assessment & selection
Deep-dive: WS3 has been structured around five Working Groups

**Workstream 3**

- **WG1: Tech Innovation, Selection & IP**
  - Evaluate & select target technologies for transfer, analyze IP barriers for implementation, launch EOs & field manufacturer responses to inform approach

- **WG2: Prod. Dev, Manufacturing & Plants**
  - Inform & facilitate selection of hub/recipient sites, detailed site & infrastructure design, assess workforce needs & plan tech transfer & workforce training program

- **WG3: Regulatory & Clinical Dev.**
  - Inform & facilitate selection of hub/recipient sites, detailed site & infrastructure design, assess workforce needs & plan tech transfer & workforce training program

- **WG4: Business Model & Financing**
  - Estimate costs to implement, determine inter-pandemic sustainable business models, develop market shaping & policy strategy to enable sustainability, support mobilization of finance

- **WG5: Hub & Recipient Governance**
  - Design hub governance model, including coordination of operations during and between pandemics, coordination of access to licenses, coordination of access to capacity, etc.

**Technical Advisory Panel**

Group of working group participants with expertise across topics areas (from industry, academia, etc.) who will review workstream proposals and provide input and recommendations to shape final solution