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
- Soumya Swaminathan

Progress to date
- Soumya Swaminathan

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

**April 2021**
- **Call for EOI** to contribute by providing technology or hosting a hub, or both

**June 2021**
- President of France, President of South Africa, WHO DG announce the establishment of the mRNA Technology Transfer Hub in South Africa

**September 2021**
- **WHO/PAHO announce selection** of Argentina & Brazil as spokes in Latin America

**November 2021**
- **Call for EOI** for additional spokes
- **Call for EOI** to establish a biomanufacturing workforce training hub

**February 2022**
- **WHO announces 15 spokes**
- WHO announces the establishment of a global biomanufacturing training hub in the Republic of Korea

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**Dear [Recipient],**

I am pleased to inform you that the mRNA Tech Transfer Programme has been launched. This initiative focuses on transferring mRNA technology and related competencies to various regions around the world, with the ultimate goal of strengthening global health security and preparedness.

The programme consists of several key components:

- **Call for EOI** to contribute by providing technology or hosting a hub, or both.
- Selection of spokes, including Argentina and Brazil, to represent different regions.
- Establishment of hubs and training initiatives to support biomanufacturing workforce development.

**Key Dates**

- **April 2021**: Launch of the programme.
- **June 2021**: Selection of spokes.
- **November 2021**: Call for additional spokes and training hub establishment.
- **February 2022**: Further selection and establishment of biomanufacturing training hubs.

**Getting Involved**

If you are interested in participating in the programme, please contact us at mRNATechTransfer@WHO.org to discuss how you can contribute.

We look forward to working with you to advance the cause of global health security and preparedness through the mRNA Tech Transfer Programme.

Yours sincerely,

[Assistance Name]
[Organization]
[Contact Information]
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.

- mRNA hub established
- First lab-scale mRNA vaccine batch
- Mapping IP constraints
- First pilot-scale mRNA vaccine bulk
- First Biomanufacturing training
- Identification of initial technology recipients (spokes)
- Training to South Africa and Bangladesh spokes
- Training to Egyptian spoke
- Training to Indian spoke
- Clinical trial Phase 1 start
- Regulatory approval to produce Phase 1 material
- SA Spoke (Biovac) GMP facility and equipment readiness
- Regulatory approval to produce Phase 1 material
- First Biomanufacturing training
- First pilot-scale mRNA vaccine bulk
- First lab-scale mRNA vaccine batch
- mRNA hub established

Timeline:
- Jun 2021
- Jul 2021
- Aug 2021
- Sep 2021
- Oct 2021
- Nov 2021
- Dec 2021
- Jan 2022
- Feb 2022
- Mar 2022
- Apr 2022
- May 2022
- Jun 2022
- Jul 2022
- Aug 2022
- Sep 2022
- Oct 2022
- Nov 2022
- Dec 2022
- Jan 2023
- Feb 2023
- Mar 2023
- Apr 2023
- May 2023
- Jun 2023
- Jul 2023
- Aug 2023
- Sep 2023
- Oct 2023
- Nov 2023
- Dec 2023
- Jan 2024
- Feb 2024
- Mar 2024
- Apr 2024
- May 2024
- Jun 2024
- Today
## Establishing R&D Network and Collaborations

<table>
<thead>
<tr>
<th>mRNA vaccine developer</th>
<th>Country</th>
<th>Animal studies partners</th>
<th>Labs partners</th>
<th>Clinical sites</th>
<th>Disease Areas interests (Hypothetical)</th>
<th>R&amp;D gaps (Hypothetical)</th>
<th>Resources to help address R&amp;D gaps (Exploratory)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Spoke 1</strong></td>
<td>Country 1</td>
<td>Univ 1, 2, „„</td>
<td>PH lab 1, 2, „„</td>
<td>Health Center 1, „„</td>
<td>Dengue</td>
<td>Access to NHP</td>
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<td><strong>Spoke 2</strong></td>
<td>Country 2</td>
<td>Univ 1, 2, „„</td>
<td>PH lab 1, 2, „„</td>
<td>Health Center 1, „„</td>
<td>Dengue, Zika</td>
<td>FTO on Zika</td>
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<tr>
<td></td>
<td><strong>Spoke 3</strong></td>
<td>Country 3</td>
<td>Univ 1, 2, „„</td>
<td>PH lab 1, 2, „„</td>
<td>Health Center 1, „„</td>
<td>HIV, Malaria, TB</td>
<td>Clinical Development Plan</td>
</tr>
<tr>
<td></td>
<td><strong>Spoke 4</strong></td>
<td>Country 4</td>
<td>Univ 1, 2, „„</td>
<td>PH lab 1, 2, „„</td>
<td>Health Center 1, „„</td>
<td>Rabies, Leishmaniasis</td>
<td>Run Immuno Study</td>
</tr>
</tbody>
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mRNA R&D network meeting to be held in Cape Town on 17-21 April 2023
Biomanufacturing Workforce Training Initiative

- 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

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

<table>
<thead>
<tr>
<th>Regulatory System Level</th>
<th>Oct 2018</th>
<th>Nov 2020</th>
<th>April 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>ML1 With some elements of regulatory system</td>
<td>100 COUNTRIES</td>
<td>100 COUNTRIES</td>
<td>98 COUNTRIES</td>
</tr>
<tr>
<td>ML2 Evolving national regulatory system</td>
<td>44 COUNTRIES</td>
<td>41 COUNTRIES</td>
<td>40 COUNTRIES</td>
</tr>
<tr>
<td>ML3 Stable, well functioning and integrated</td>
<td>50 COUNTRIES</td>
<td>53 COUNTRIES</td>
<td>56 COUNTRIES</td>
</tr>
<tr>
<td>ML4 Advanced level of performance and continuous improvement</td>
<td>27%</td>
<td>29%</td>
<td>27%</td>
</tr>
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Egypt’s EDA and South Africa’s SAHPRA are ML3 for medicines
Singapore’s NRA is ML4
Ghana, Tanzania and Nigeria NRA’s are ML3 for medicines

GOAL of WHA Resolution 67.20

ML= (regulatory system) maturity level
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

- **Manufacturing capacity development**
- **Workforce with skills and experience**
- **Access to know-know**

- **Strengthen national regulatory systems**
- **Establish R&D network**
- **National financing and private investments**
- **Industrial, trade, public health policies and coordination**

- **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)

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- Strong engagement of regional offices for coordination of regional approaches
Expectations and value for hubs, recipients, local governments

**Hub**
- Participate in tech transfer, develop tech, provide training
- WHO/MPP support on critical enablers
- Specific funding for training and procurement of equipment

**Local government supporting hub**
- Support hub in the long run (e.g., min. quantity ordered)
- (Inter-)regional collaboration and recognition
- Access to essential health products; local know-how

**Recipient**
- Technical capacity to receive, implement and scale up tech
- WHO/MPP support on critical enablers
- Specific funding for training

**Local government supporting recipient**
- Support recipient in the long run (e.g., min. quant. ordered)
- Improved regional health/security
- Sustainable local biomanufacturing capacity/ know-how

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