



mRNA Technology Transfer Programme

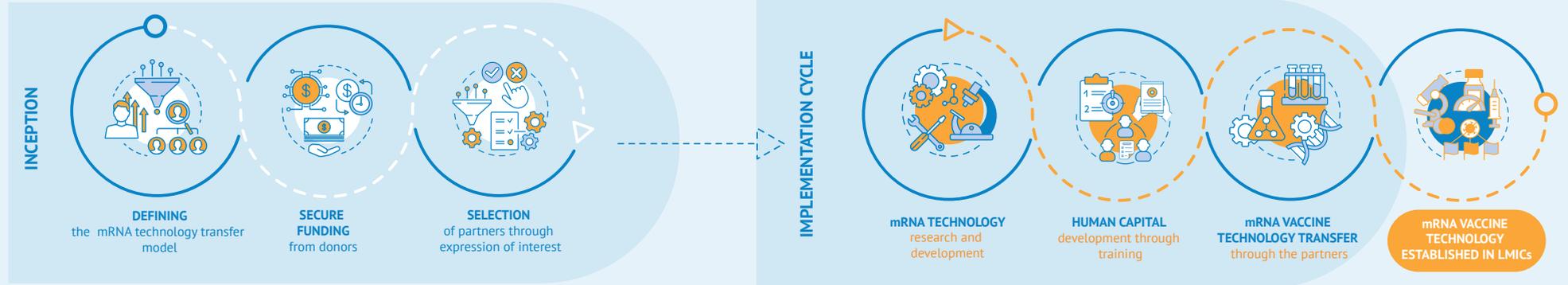
mRNA
Technology Transfer
Programme

A global initiative to scale up global mRNA vaccine manufacturing through the establishment and the expansion of capacity in **low- and middle-income countries**.

Increasing health security through empowerment.

mRNA TECHNOLOGY TRANSFER CHRONOGRAM

LMICs = Low-and-Middle Income Countries



The mRNA Technology Transfer Programme was set up to address the inequalities in access to vaccines in low- and middle-income countries (LMICs) that emerged during the COVID-19 pandemic.

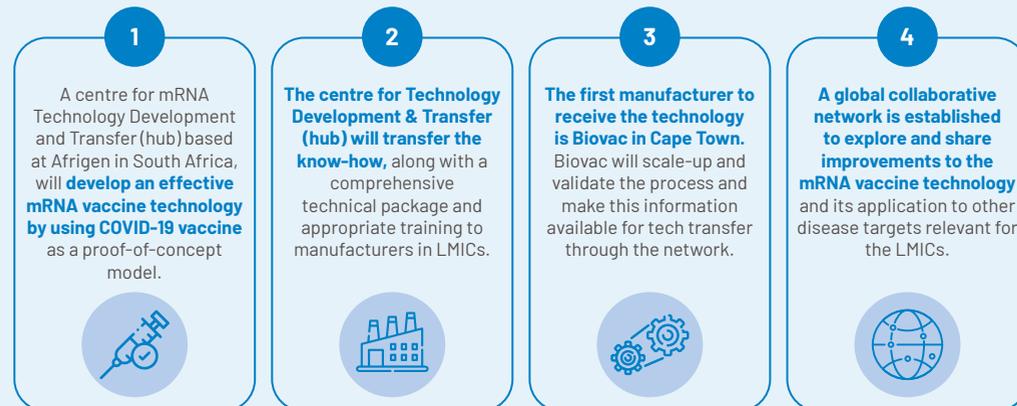
The objectives of the Programme are to establish and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in the regions where mRNA vaccine manufacturing capacity is established or can be enhanced.

THE KEY PRINCIPLES

leading the Programme activities are:

- 1) Equitable access to mRNA technologies suitable for pandemic response.
- 2) Create value and share intellectual property through open access to innovation.
- 3) Promote sustainable capacity to produce mRNA vaccines with coherent policies and adequate investments.

THE PROGRAMME OPERATING MODEL is a global collaborative network driven by multilateral technology transfers

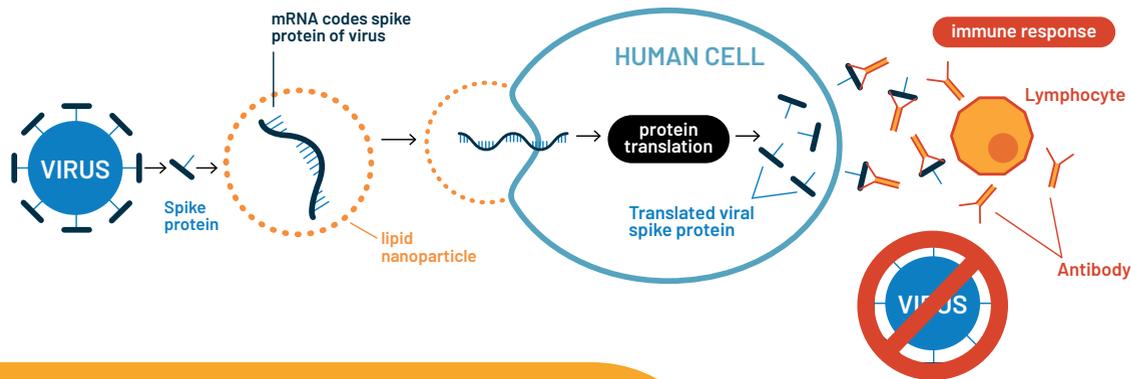


KEY ACHIEVEMENTS BY APRIL 2023

- July 2021**
 - Launch of the mRNA Technology Transfer Programme. Afrigen is selected as the Centre for mRNA Technology Development and Transfer (hub) and Biovac as the first partner to receive the technology. A Consortium is formally established between African Union/Africa CDC, Afrigen, Biovac, Medicines Patent Pool, SAMRC, and the World Health Organization.
- September 2021**
 - WHO selects Bio-Manguinhos from Brazil and Sinergium Biotech from Argentina as the partners in the PAHO region.
- February 2022**
 - The Republic of Korea is selected as a global biomanufacturing training centre that will serve all LMICs wishing to produce biologicals, such as vaccines, insulin, and monoclonal antibodies.
- April 2022**
 - Following an expression of interest, WHO publishes the full list of biomanufacturing companies selected to become Programme Partners and receive the mRNA vaccine technology platform from Afrigen.
- July 2022**
 - The COVID-19 mRNA vaccine produced in South Africa is demonstrated to be immunogenic and not reactogenic in mice.
- October 2022**
 - The COVID-19 mRNA vaccine manufacturing process is successfully scaled up to 10 ml – in vitro transcription (target 1 litre for Phase I/II clinical trial).
- December 2022**
 - The COVID-19 mRNA vaccine manufacturing process is successfully scaled up to 100 ml.
- January 2023**
 - Immunisation of hamsters with a representative vaccine batch to demonstrate pre-clinical immunogenicity and efficacy initiated.
- February 2023**
 - Phase I/II clinical trial design is internally approved.
- Between March 2022 – April 2023**
 - Representatives from 11 countries have received the hands-on Introduction to the mRNA technology training at Afrigen: Argentina, Bangladesh, Brazil, Egypt, India, Indonesia, Senegal, Serbia, South Africa (Biovac), Tunisia and Vietnam.

How do mRNA vaccines work?

For an mRNA vaccine to be effective, the mRNA that encodes a component of the virus (spike protein for COVID-19), has to be able to enter into human cells; this is achieved by including the mRNA in lipid nanoparticles (LNP). Once the mRNA has entered into the cells, the cellular machinery uses the mRNA sequence to synthesise the viral protein, which is then recognised as a “foreign substance” by the human immune system. This triggers the production of antibodies that are protecting the vaccinated person against the disease when infected with the SARS-CoV-2 virus.



Why use mRNA technology?

- It is faster to develop and to scale-up production
- It enables a rapid response to outbreaks
- It is highly adaptable as variants evolve
- It can be used to develop vaccines for other infectious diseases such as influenza, dengue, malaria, tuberculosis and HIV

AfriVac January 2023

AfriVac 2121 is the COVID-19 vaccine (based on the ancestral Wuhan strain sequence) under development at Afrigen, the centre for mRNA technology development and transfer (hub). Afrivac 2121 will be the first mRNA vaccine candidate developed in Africa from concept to proof of concept in pre-clinical and clinical studies.

Why AfriVac 2121?

The name AfriVac 2121 captures the significant date of 21 June 2021 when the World Health Organization and partners announced the creation of the mRNA Technology Transfer Programme to empower LMICs to develop their own vaccines.



Sharing expertise across the global collaborative network

Sharing is an essential component of sustainability. The Programme will create an environment supporting joint research and development projects. The sharing of expertise and technology, and the co-development of new technologies and disease targets, including COVID-19 and beyond, will be shared through royalty-free license agreements across the network.

As new technologies emerge from the collaboration it will lead to decreased cost of goods and improved vaccine characteristics (e.g. thermostability) and products that are readily available and better suited to LMICs.

So far WHO has selected 15 partners for the mRNA technology



- | | | | |
|---|-----------------------------|----|------------------------------|
| 1 | First Partner - Biovac | 9 | Incepta Vaccine Ltd |
| 2 | BioVax | 10 | Institut Pasteur de Dakar |
| 3 | Bio-Manguinhos/Fiocruz | 11 | Institut Pasteur de Tunis |
| 4 | Biofarma | 12 | Institut Torlak |
| 5 | BiologicalE | 13 | National Institute of Health |
| 6 | BioGeneric Pharma S.A.E | 14 | Polyvac |
| 7 | Biovaccines Nigeria Limited | 15 | Sinergium Biotech |
| 8 | Darnitsa | | |

Success is not singular

The project is long-term and constructed with sustainability in mind. It is co-led by WHO and MPP. The organisations participating in the South African consortium are: Afrigen – the centre for mRNA technology development and transfer (hub), Biovac – the first partner, SAMRC – working on the research and training aspects, South African Department of Science and Innovation and Africa CDC. The 15 partners are also part of the collaboration along with leading research institutions.

The Consortium engages regularly with stakeholders, as this Programme is inclusive and relies on partnerships. The Programme keeps stakeholders updated on developments and provides an opportunity to input and build its success. These include consultations with funders, biomanufacturing companies and civil society organisations.



The Programme funders

The Programme continues to receive exceptional support both from high-income countries and LMICs. **The overall budget for the activities conducted by the South African Consortium and the WHO Secretariat is estimated to be ~\$117m for 2021-2026 period with ~\$81m for 2021-2024 period.**

This is catalytic money and the aim is for the project to be self-sustaining after 2026. Funding covers the coordination of the project, the establishment of the centre for mRNA technology development and transfer activities in South Africa and the development of local innovation and products. A significant portion of funds to cover for the South African consortium needs has been secured.

The Programme is collecting funds to support the partners in the following areas: staff training in GxP biomanufacturing, national regulatory agencies strengthening, site assessments and critical equipment procurement.

The project is funded by:

African Union/ Africa CDC, Belgium, Canada, ELMA Foundation, European Commission, France, Germany, Norway, SAMRC and South Africa.





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