



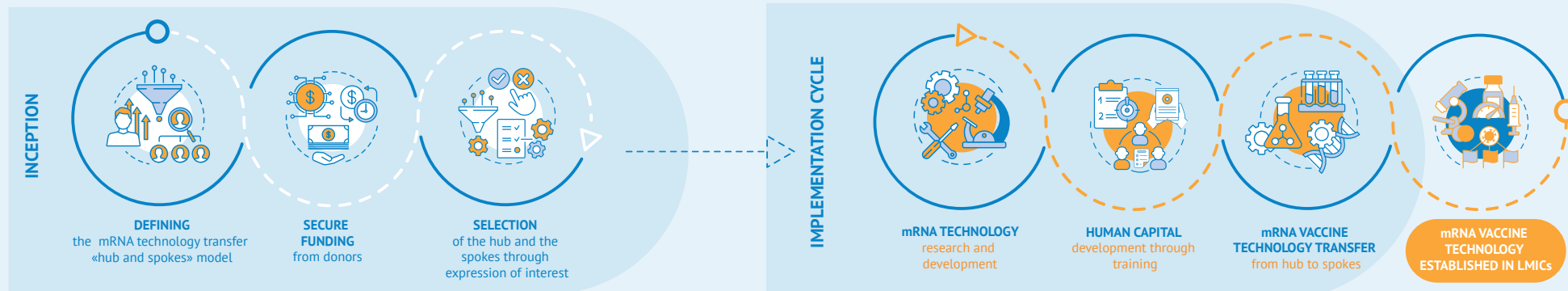
mRNA Technology Transfer Hub Programme

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

Hub = technology sending unit
Spoke = technology receiving unit
LMICs = Low-and-Middle Income Countries



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

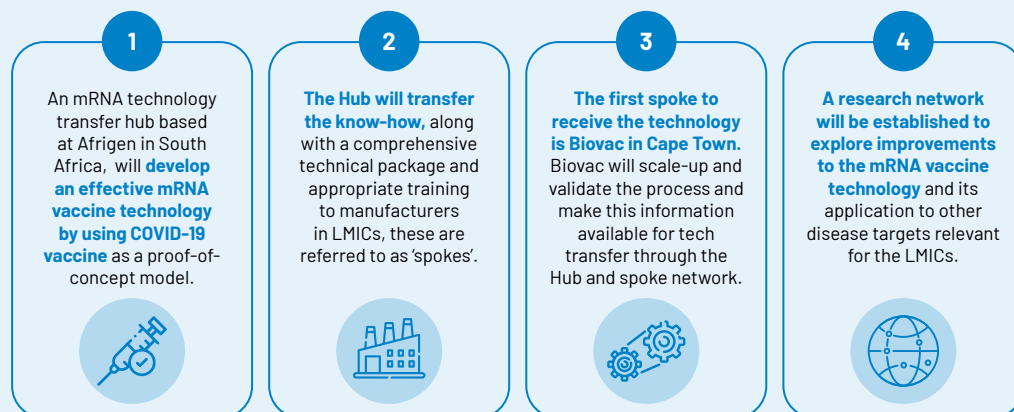
The objectives of the Programme are to establish and enhance sustainable mRNA vaccine manufacturing capacity and to develop skilled human capital in the regions where mRNA vaccine manufacturing capacity is established or can be enhanced.

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 the multilateral technology transfer via a global “hub and spoke” network

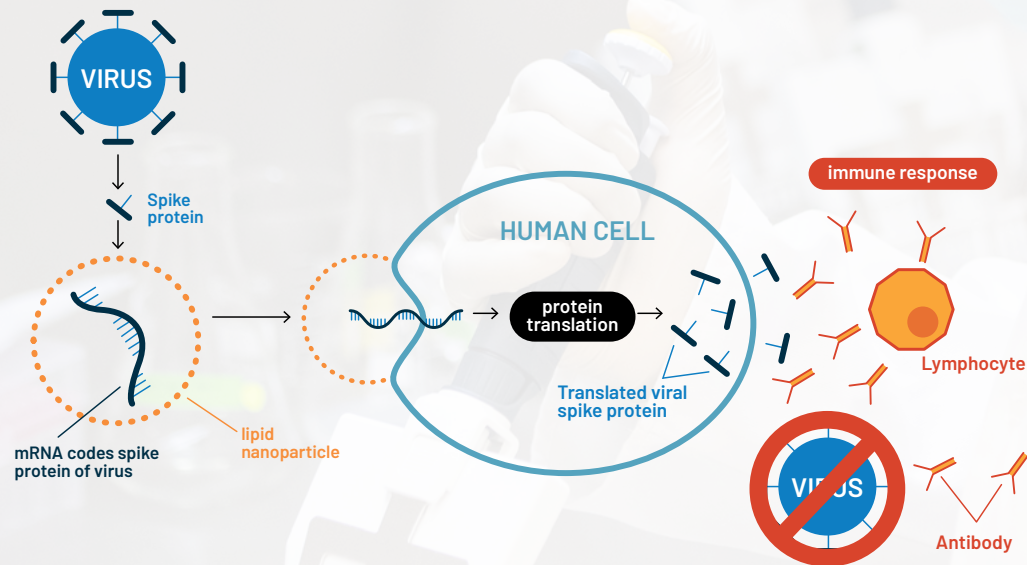


KEY ACHIEVEMENTS BY DECEMBER 2022

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| July 2021 | <ul style="list-style-type: none"> • Launch of the mRNA technology transfer hub. Afrigen is selected as the “hub” and Biovac as the first “spoke”. A Consortium is formally established between African Union/Africa CDC, Afrigen, Biovac, Medicines Patent Pool, SAMRC, and the World Health Organization. |
| September 2021 | <ul style="list-style-type: none"> • WHO selects Bio-Manguinhos from Brazil and Sinergium Biotech from Argentina as the “spokes” in the PAHO region. |
| January 2022 | <ul style="list-style-type: none"> • The first batch of COVID-19 mRNA vaccine is manufactured at the Hub-Afrigen (laboratory scale). |
| February 2022 | <ul style="list-style-type: none"> • The Republic of Korea is selected as a global biomanufacturing training hub that will serve all LMICs wishing to produce biologicals, such as vaccines, insulin, and monoclonal antibodies. |
| April 2022 | <ul style="list-style-type: none"> • Following an expression of interest, WHO publishes the list of 15 biomanufacturing companies “spokes” selected to receive technology transfer for mRNA vaccines from the Hub. |
| July 2022 | <ul style="list-style-type: none"> • The COVID-19 mRNA vaccine produced in South Africa is demonstrated to be immunogenic and not reactogenic in mice. |
| October 2022 | <ul style="list-style-type: none"> • The mRNA vaccine manufacturing process has been scaled up to 10ml (target 1L for Phase 1/2 clinical trial). |
| Between March-December 2022 | <ul style="list-style-type: none"> • Representatives from 10 spokes-countries have received the hands-on Introduction to the mRNA technology training at Afrigen: Argentina, Bangladesh, Brazil, Egypt, India, Indonesia, Senegal, 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 provides a rapid response during 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

Sharing Expertise across the Hub and Spokes network

Sharing is an essential component of sustainability. Technologies that come from the research will be shared through licensing agreements that will allow for freedom to operate across the whole network of hub and spokes. 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 technology recipients “spokes” of the mRNA technology



- | | |
|-------------------------------|---------------------------------|
| 1 Biovac | 9 Incepta Vaccine Ltd |
| 2 Aga Khan Kenya | 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 into the consortium are: Afrigen – the Hub, Biovac – the first spoke, SAMRC – working on the research and training aspects, South African Department of Science and Innovation and Africa CDC. The 15 “spokes” 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 is estimated to be ~\$117m for 2021-2026 period with ~\$80m for 2021-2024 period.** This is seed 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 mRNA hub activities in South Africa and the development of local innovation and products. A significant portion of the funds have been secured.

The project is funded by: African Union, Belgium, Canada, ELMA Foundation, European Commission, France, Germany, Norway, SAMRC and South Africa.





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