mRNA Technology Transfer Programme

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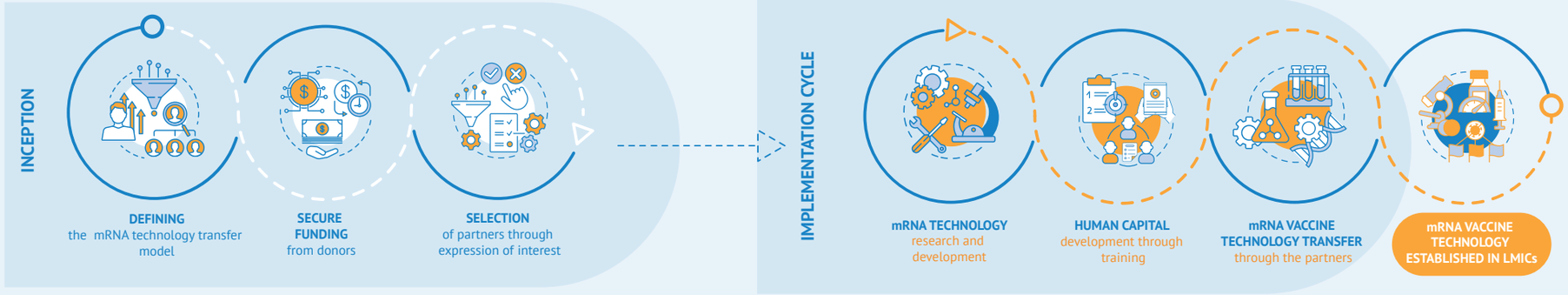
A global initiative to scale up global mRNA vaccine manufacturing through the establishment and the expansion of capacity in **low- and middle-income countries.**

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

1

A centre for mRNA Technology Development and Transfer (hub) based at Afrigen in South Africa, will **develop an effective mRNA vaccine technology by using COVID-19 vaccine** as a proof-of-concept model.

2

The centre for Technology Development & Transfer (hub) will transfer the know-how, along with a comprehensive technical package and appropriate training to manufacturers in LMICs.

3

The first manufacturer to receive the technology is Biovac in Cape Town. Biovac will scale-up and validate the process and make this information available for tech transfer through the network.

4

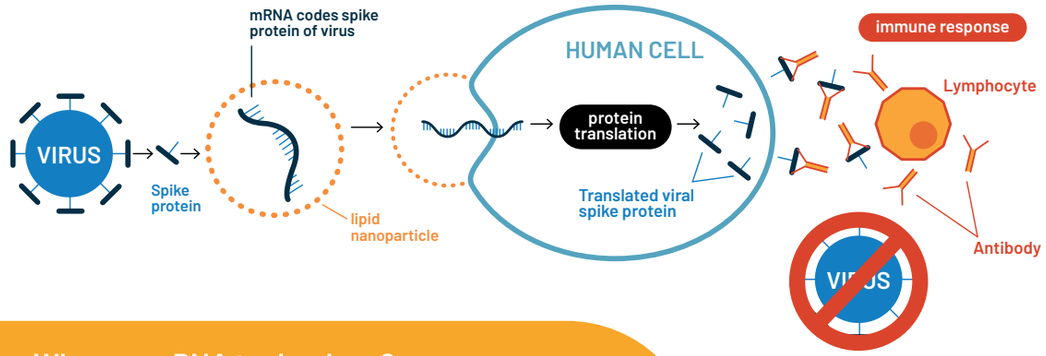
A global collaborative network is established to explore and share improvements to the mRNA vaccine technology and its application to other disease targets relevant for the LMICs.

KEY ACHIEVEMENTS BY AUGUST 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.
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	• WHO publishes the list of 15 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.
April 2023	• The COVID-19 mRNA vaccine manufacturing process is successfully scaled up to 1L.
April 2023	• Technology Transfer Package 1a, including equipment and raw materials to manufacture vaccine up to 1L IVT and facility layouts, is shared with the Partners. Afrigen launches the mRNA technology hub facility in the presence of Dr. Tedros Adhanom Ghebreyesus, Director General of WHO.
May 2023	• Immunogenicity, safety, and efficacy of a representative vaccine batch is demonstrated in a pre-clinical hamster challenge animal model.
July 2023	• Process description at 100ml IVT scale is shared with the Partners.
August 2023	• Technology Transfer activities kick off at Biovac with a workshop attended by Afrigen (sending unit) and Biovac (receiving unit).
August 2023	• On-site gaps and needs assessment conducted by MPP at Biovac (South Africa) and Institut Pasteur de Tunis (Tunisia).
March 2022 – August 2023	• Representatives from 13 countries have received the hands-on Introduction to the mRNA technology training at Afrigen: Argentina, Bangladesh, Brazil, Egypt, India, Indonesia, Nigeria, Pakistan, 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 synthetise 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.

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.

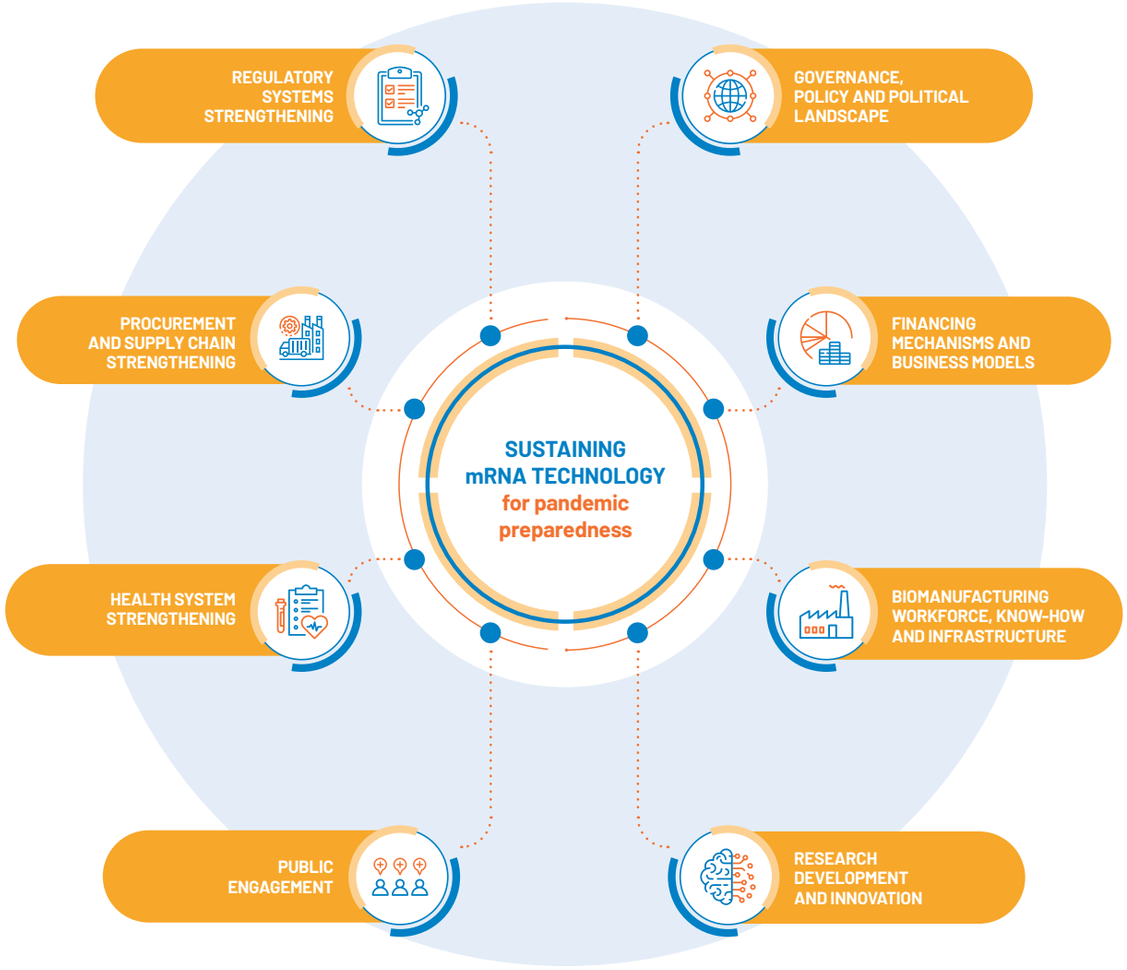
As new technologies emerge from the collaboration it will lead to decreased cost of goods and improved vaccine characteristics (e.g. thermostability) and products that are readily available and better suited to LMICs.

So far WHO has selected 15 partners for the mRNA technology

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

Fostering a Sustainable mRNA Vaccine Production Ecosystem

8 points of consideration



Governance, Policy, and Political Landscape

Realising the full potential of this endeavor and achieving sustainability requires a comprehensive, multisectoral approach. Policies spanning health, finance, education, trade, transport, industry, science and technology, public procurement, public engagement, and labour need to be harmonised. Leadership commitment, spanning international, regional, country, and community levels, is paramount. A whole-of-society approach is essential for innovating and regulating vaccines and, critically, nurturing trust for these life-saving products.

Financing Mechanisms and Business Models

Innovative financing mechanisms are needed to enable the transition from donor-based to government-based local manufacturing investment. Public-private collaborations are key, fostering systems that generate profits for reinvestment in further discoveries.

Empowering the Biomanufacturing Workforce

Governments will need take the lead in prioritising and promoting the development of a skilled vaccine-biomanufacturing workforce. This includes investing in training, capacity building, and strategies for retaining valuable professionals. The establishment of regional training hubs is a key step in enhancing the knowledge and expertise of this critical workforce.

Driving Research, Development, and Innovation

The advancement of vaccine development and production requires a concerted effort to strengthen research and innovation capabilities. This involves supporting public and private research institutions and fostering collaboration within regional research centres. These institutions should work collaboratively across the entire vaccine development pipeline, from initial research and development to the practical implementation of vaccines. Additionally, there is a need to fortify pre-clinical and clinical trial processes and enhance disease surveillance to ensure the safety and effectiveness of vaccines.

Public Engagement

Engaging the public is paramount for vaccine acceptance. Health promotion, community engagement, and effective communication campaigns are vital components. Collaboration with civil society organisations and healthcare workers fosters trust, acceptance, and meaningful behaviour change.

Health System Strengthening

Resilient health systems form the foundation for effective vaccines, pandemic preparedness, and addressing broader health challenges. This involves investments in training and retaining healthcare workers, as well as infrastructure improvements.

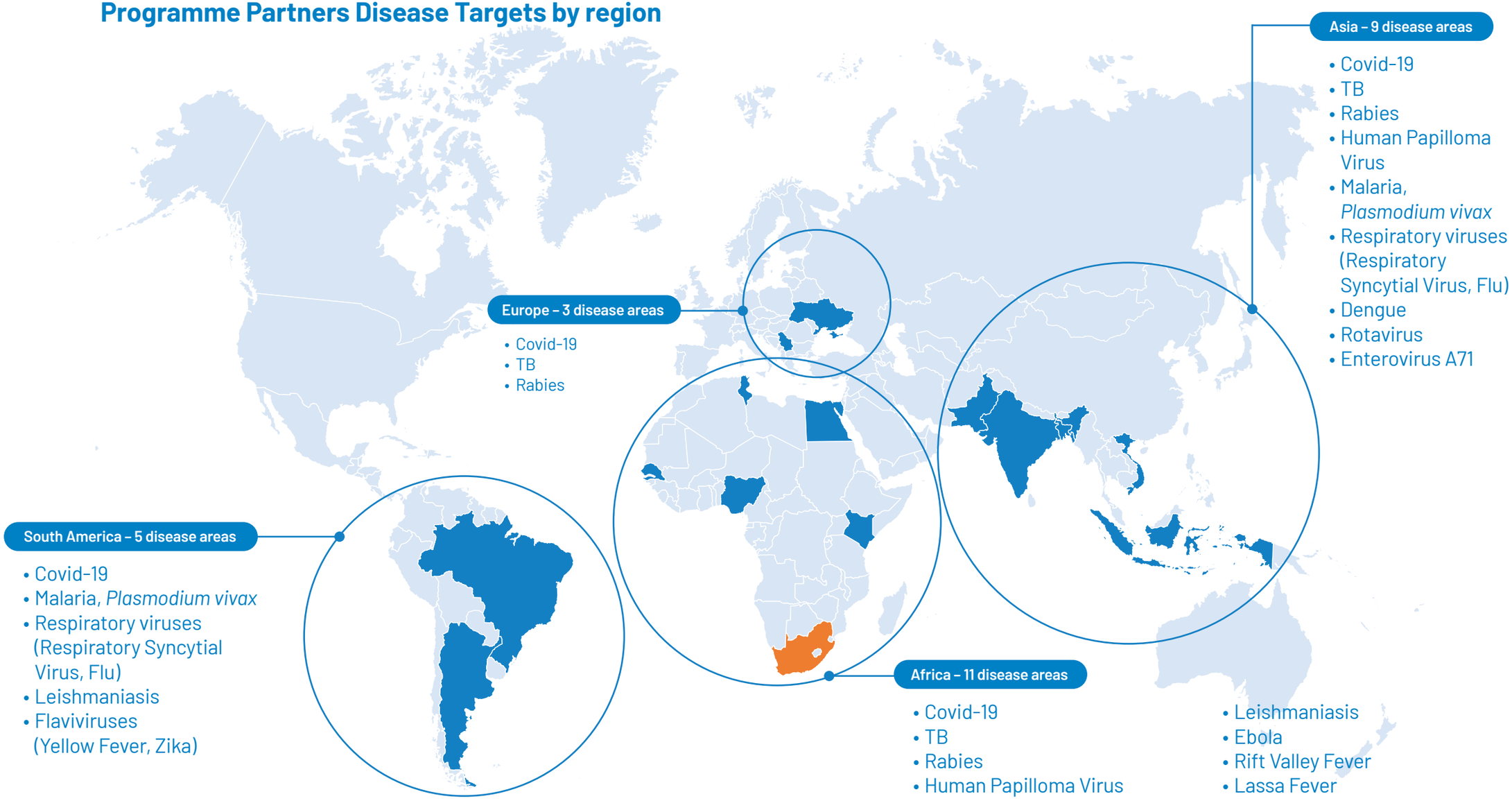
Procurement and Supply Chain Strengthening

Local procurement of vaccines is vital for supporting domestic manufacturers and fostering industrial growth. Collaborative strategies are essential for demand forecasting, advanced market commitment, pooled regional procurement, and efficient vaccine delivery. Regional hubs for manufacturing key raw materials are part of this strengthening effort.

Reinforcing Regulatory Systems

To facilitate efficient vaccine approval processes and build public confidence in vaccine products, it is imperative to focus on regulatory system strengthening. This can be achieved by promoting regional and international harmonisation efforts. The key is to enhance the capacity and performance of national regulatory authorities, enabling them to attain maturity level 3/4 certification. These measures will significantly improve the regulation of vaccines on both regional and global scales.

Programme Partners Disease Targets by region



Asia – 9 disease areas

- Covid-19
- TB
- Rabies
- Human Papilloma Virus
- Malaria, *Plasmodium vivax*
- Respiratory viruses (Respiratory Syncytial Virus, Flu)
- Dengue
- Rotavirus
- Enterovirus A71

Europe – 3 disease areas

- Covid-19
- TB
- Rabies

South America – 5 disease areas

- Covid-19
- Malaria, *Plasmodium vivax*
- Respiratory viruses (Respiratory Syncytial Virus, Flu)
- Leishmaniasis
- Flaviviruses (Yellow Fever, Zika)

Africa – 11 disease areas

- Covid-19
- TB
- Rabies
- Human Papilloma Virus
- Respiratory viruses (Respiratory Syncytial Virus, Flu)
- Leishmaniasis
- Ebola
- Rift Valley Fever
- Lassa Fever
- HIV
- Malaria, *Plasmodium falciparum*

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.

20th April 2023
in Cape Town, South Africa

mRNA Technology Transfer Programme

Afrigen Biologics & Vaccines · BIOVAC · saMRC · African Union · Africa CDC · Science & Innovation · medicine patent pool · World Health Organization

BGP · Instituto de Tecnologia em Imunobiológicos Bio-Manguinhos · biofarma · Biological E. Limited · BioVaccines Nigeria Limited · BIOVAX · DARNITSA

incepta · Institut Pasteur de Dakar · معهد باستور تونس Institut Pasteur de Tunis · POLYVAC · Sinergium Biotech · TORLAK

Belgium partner in development · In partnership with Canada · ELMA vaccines & immunization foundation · german cooperation · Ministère de l'Europe et des Affaires étrangères · Norwegian Ministry of Foreign Affairs

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