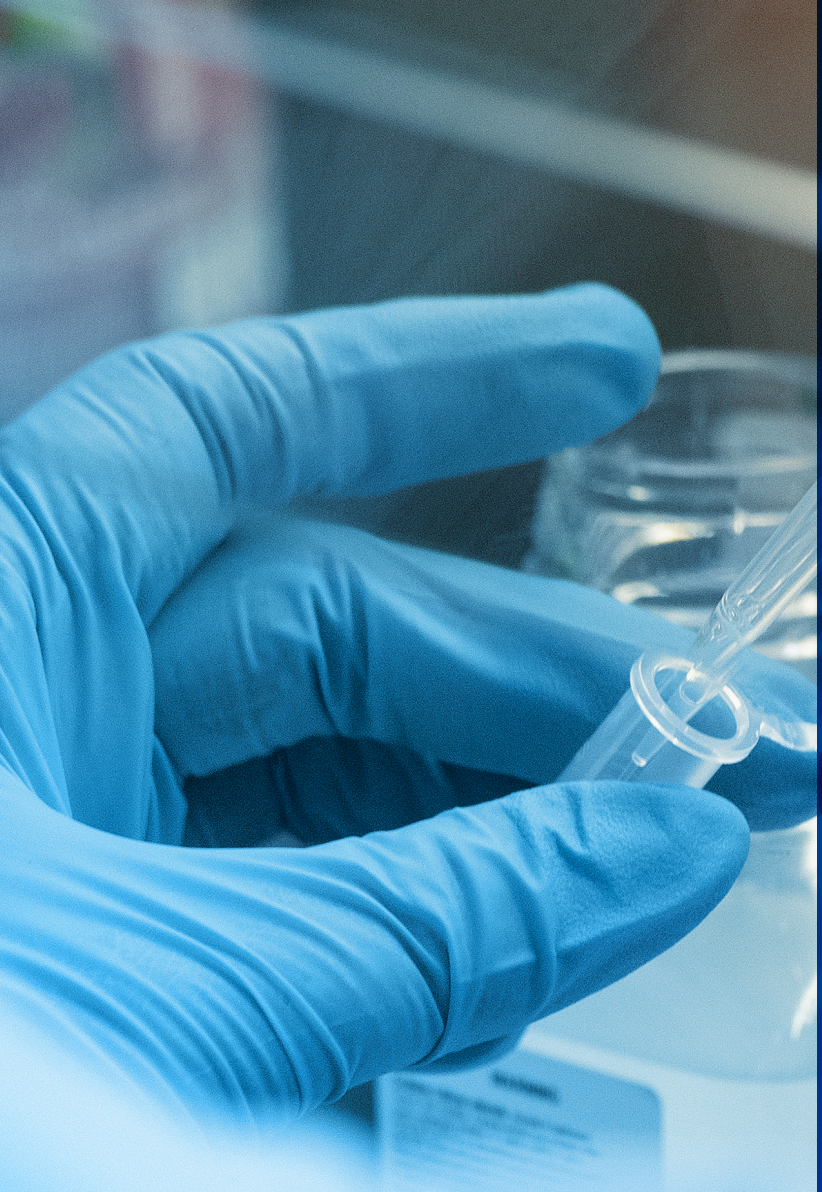


mRNA Technology Transfer Programme

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 Programme

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.

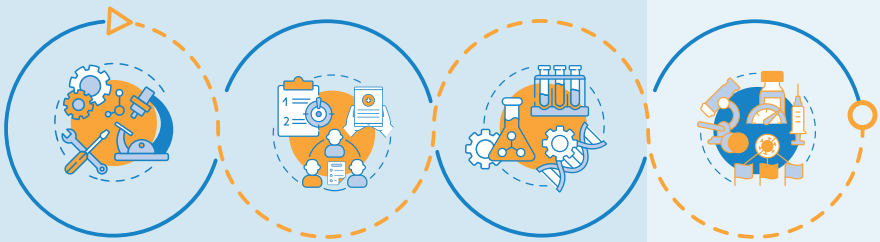
3

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.

IMPLEMENTATION CYCLE



mRNA TECHNOLOGY
research and development

HUMAN CAPITAL
development through training

mRNA VACCINE TECHNOLOGY TRANSFER
through the partners

mRNA VACCINE TECHNOLOGY ESTABLISHED IN LMICs

ACHIEVEMENTS BY APRIL 2024

1. Establishment of facilities in Cape Town, South Africa (at Afrigen and Biovac) to manufacture and test mRNA-based vaccines to support preclinical and clinical activities.
2. Development of an mRNA technology platform (manufacturing processes and analytical methods) suitable to develop new mRNA vaccines targeting new COVID-19 variants of concern, as well as infectious diseases relevant to LMICs.
3. Demonstration of immunogenicity and efficacy of the Afrigen COVID-19 vaccine candidate in preclinical animal models.
4. In-person introductory training to the mRNA technology at Afrigen to 14 Programme partners.
5. Establishment of a network of programme partners who have initiated preparatory activities for technology transfer and implementation of the mRNA technology for other disease targets of interest.
6. 12 Site gaps and needs' assessments at Programme Partners manufacturing sites informing the preparation of detailed work plans for technology transfer.

mRNA Technology Transfer Programme

2021 2022 2023

July

Launch of the mRNA Technology Transfer Programme and establishment of South African Consortium (technology donor)

February

Selection of the Republic of Korea as a global biomanufacturing training centre

March 2022 – October 2023

Introduction to the mRNA technology training conducted at Afrigen

April

Publication of the list including the 15 Programme Partners Manufacturers (technology recipients)

July

First demonstration of immunogenicity and not reactogenicity of the COVID-19 vaccine in mice

October

Process scaled up to 10ml *in-vitro* transcription

December

Process scaled up to 100ml *in-vitro* transcription

April

Process scaled up to 1L *in-vitro* transcription

2024

Aug 2023-April 2024

12 on-site gaps' and needs' assessment conducted by MPP

May

Demonstration of Immunogenicity, safety, and efficacy in a preclinical hamster challenge animal model

Technology Transfer Package 1a shared with the Partners (facility layouts, equipment and raw materials lists)

July

Process description at 100ml *in-vitro* transcription scale is shared with the Partners

August

Technology Transfer activities kick off at Biovac

September

Process description at 1L *in-vitro* transcription scale is shared with the Partners

December

Technical batch 1 manufacturing

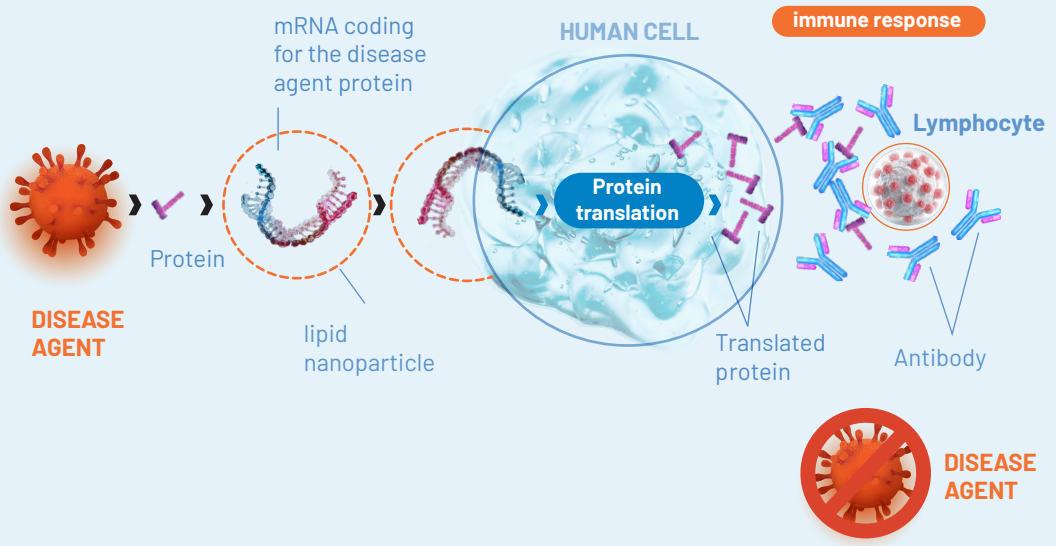
January

Technical batch 2 manufacturing

Biovac training on final process and analytical methods

How do mRNA vaccines work?

For an mRNA vaccine to be effective, the mRNA that encodes a protein 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 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.



Why use mRNA technology?

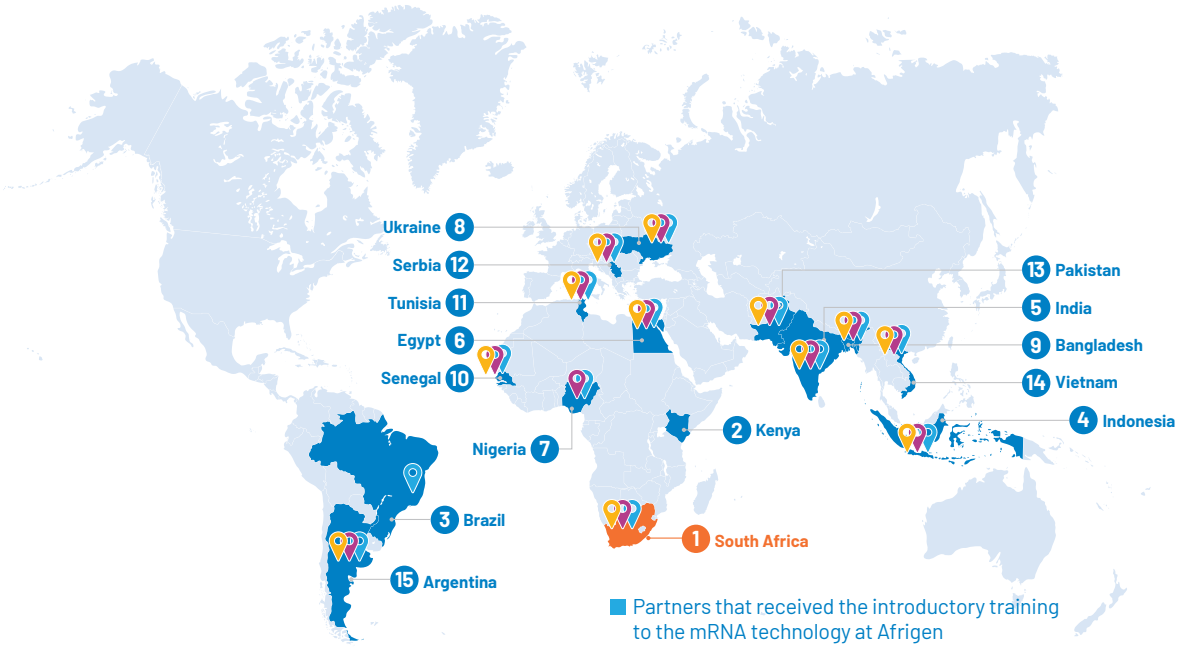
- It is faster to develop and to scale-up production
- It enables a rapid response to outbreaks
- It can be used to develop vaccines for other infectious diseases such as influenza, dengue, malaria, tuberculosis and HIV
- Small facility footprint

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 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.

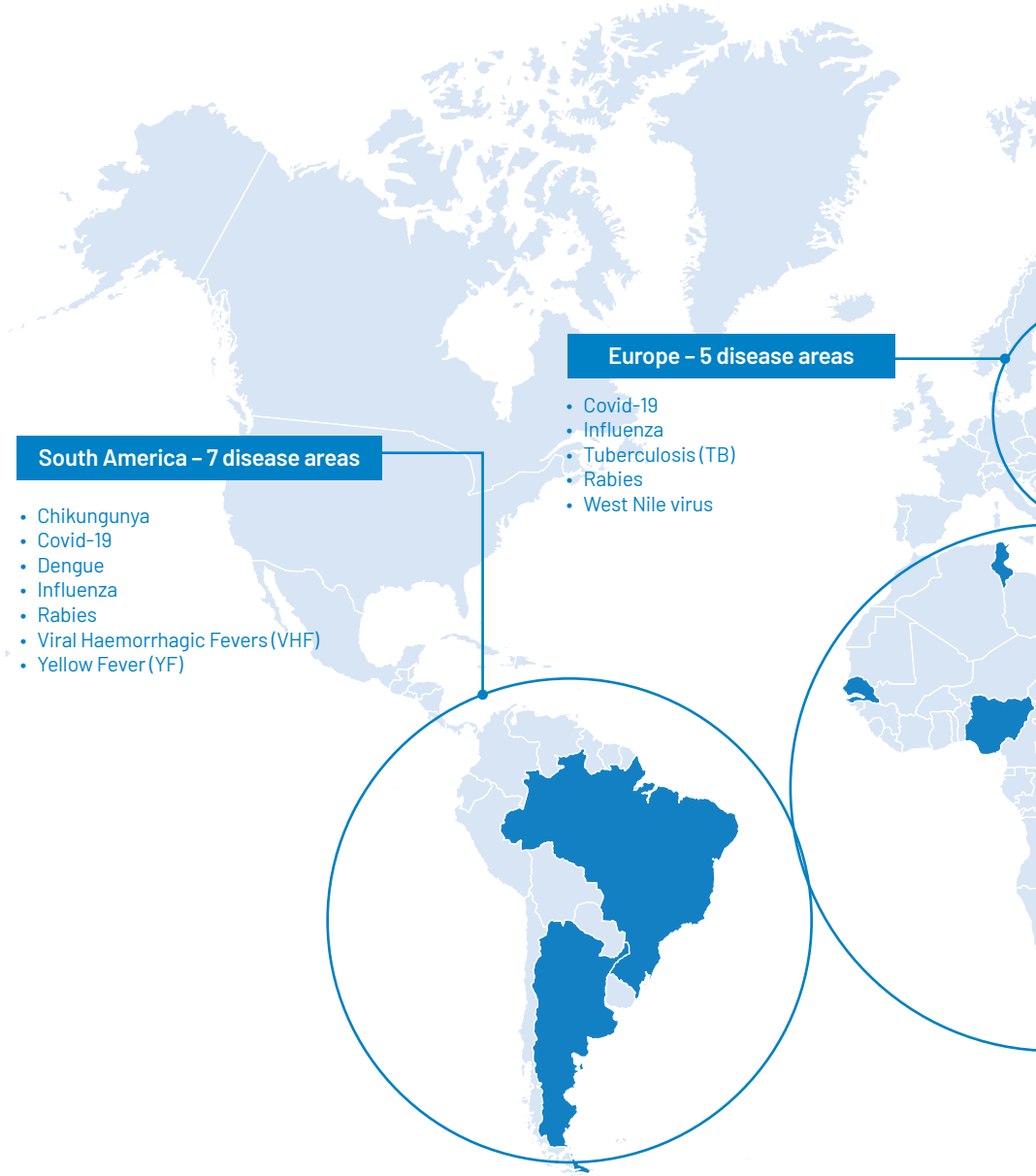
WHO has selected 15 manufacturers to join the mRNA Technology Transfer Programme to receive the mRNA technology platform



1. Afrigen (Hub); Biovac (first partner)
2. BioVax
3. Bio-Manguinhos/Fiocruz
4. Biofarma
5. BiologicalE
6. BioGeneric Pharma S.A.E
7. Biovaccines Nigeria Limited
8. Darnytsia
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

mRNA Technology Transfer Programme

Programme Partners



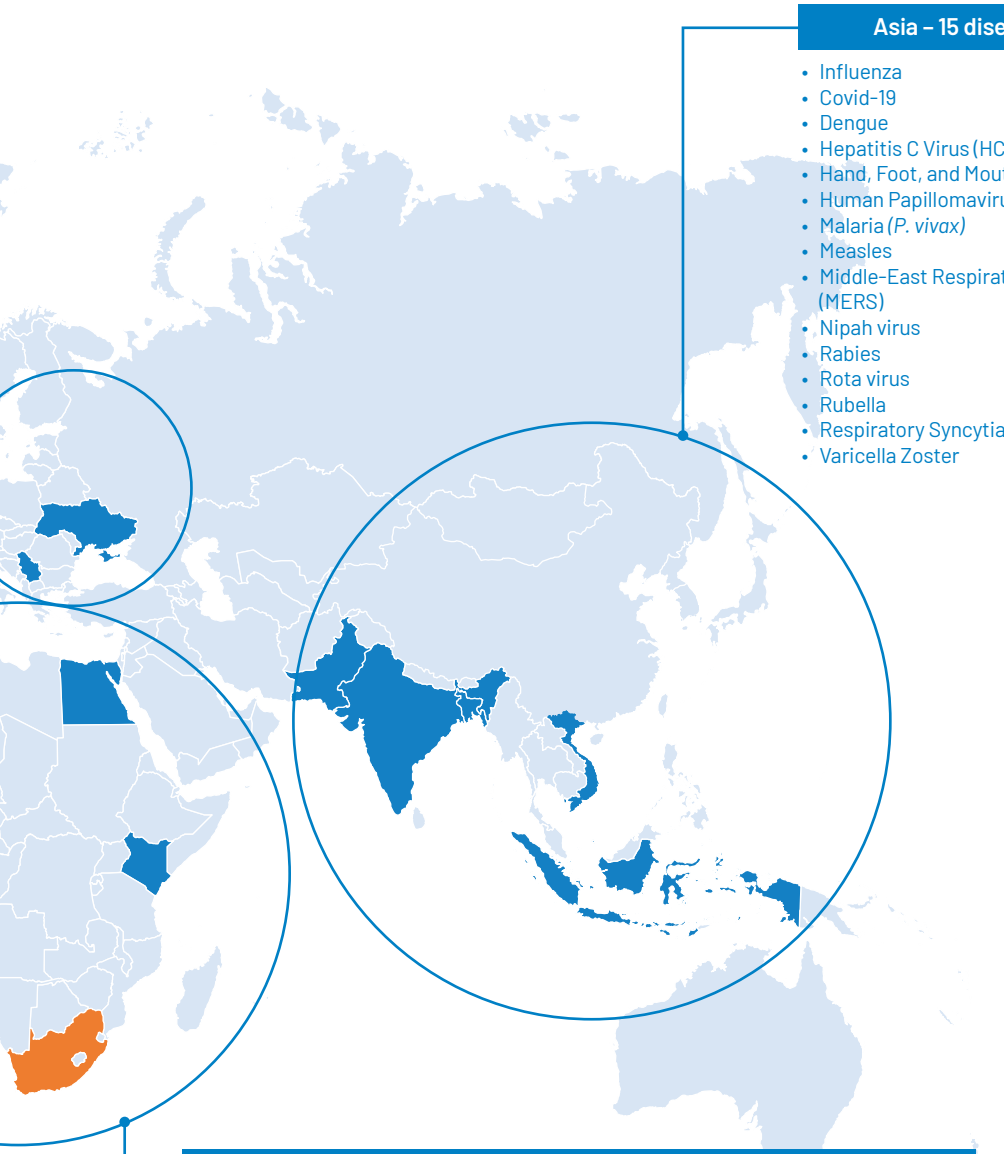
South America – 7 disease areas

- Chikungunya
- Covid-19
- Dengue
- Influenza
- Rabies
- Viral Haemorrhagic Fevers (VHF)
- Yellow Fever (YF)

Europe – 5 disease areas

- Covid-19
- Influenza
- Tuberculosis (TB)
- Rabies
- West Nile virus

Disease Targets by region



Asia – 15 disease areas

- Influenza
- Covid-19
- Dengue
- Hepatitis C Virus (HCV)
- Hand, Foot, and Mouth Disease (HFMD)
- Human Papillomavirus (HPV)
- Malaria *(P. vivax)*
- Measles
- Middle-East Respiratory Syndrome (MERS)
- Nipah virus
- Rabies
- Rota virus
- Rubella
- Respiratory Syncytial Virus (RSV)
- Varicella Zoster

Africa – 9 disease areas

- Crimean-Congo Haemorrhagic Fever (CCHF)
- Covid-19
- Human Immunodeficiency Virus (HIV)
- Leishmaniasis
- Malaria (P. falciparum)
- Rabies
- Respiratory Syncytial Virus (RSV)
- Rift Valley Fever (RVF)
- Tuberculosis (TB)

Fostering Regional Health Innovation: South-East Asia's mRNA Consortia

In March 2024, a significant milestone was reached as four South-East Asia research consortia signed a declaration of commitment during a WHO/MPP meeting of Programme Partners held in Singapore. Establishing these four consortia signifies a crucial step forward in combating prevalent diseases in the region.

The consortia are:

- **DENGUE MRNA VACCINE CONSORTIUM**

  Spearheaded by the International Vaccine Institute (IVI), this initiative focuses on dengue mRNA vaccine product development. The other members of the consortium are Duke-NUS, Chula VRC, Hilleman, Bio Farma and Incepta.

- **HAND, FOOT, AND MOUTH DISEASE (HFMD) CONSORTIUM**

  Led by Hilleman Labs, this consortium is dedicated to HFMD mRNA product development. The other members of the consortium are Hilleman Labs, NUS, A*STAR, Chula VRC, Polyvac.

- **THERAPEUTIC HUMAN PAPILLOMAVIRUS (Tx HPV) CONSORTIUM**

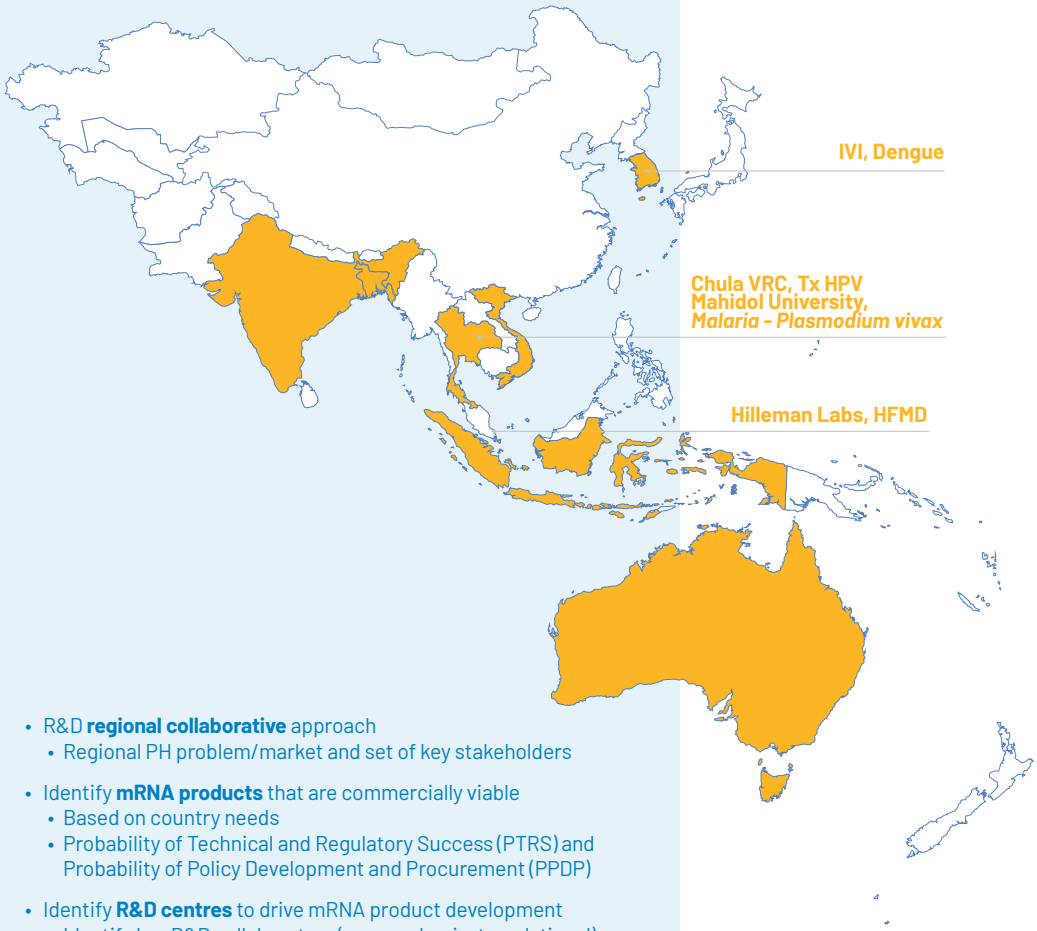
  Initially headed by Chula VRC, Chulalongkorn University, this collaborative effort centres on therapeutic HPV mRNA product development. The other members of the consortium are Chula VRC, A*STAR, Incepta, Afrigen, NVI.

- ***PLASMODIUM VIVAX* MALARIA CONSORTIUM**

  Led by Mahidol University, this consortium focuses on *Plasmodium vivax* malaria mRNA product development. The other members of the consortium are Mahidol University, Chula VRC, Burnet Institute, Eijkman Institute, Bio Farma.

The signing of the declaration underscores the collective dedication of the South-East Asia health community toward harnessing the transformative potential of the mRNA Technology Transfer Programme in and for LMICs. Through this commitment, they agree to share material, data, and intellectual property equitably and non-exclusively with the Programme Partners. Through these collaborative research efforts, we hope to accelerate R&D and ultimately contribute to improved health outcomes and bolster disease prevention efforts across South-East Asia and beyond.

R&D consortia in SEARO/WPRO



- R&D **regional collaborative** approach
  - Regional PH problem/market and set of key stakeholders
- Identify **mRNA products** that are commercially viable
  - Based on country needs
  - Probability of Technical and Regulatory Success (PTRS) and Probability of Policy Development and Procurement (PPDP)
- Identify **R&D centres** to drive mRNA product development
  - Identify key R&D collaborators (e.g. academic, translational)
  - Recognizing that manufacturers have limited R&D capacity
- **Bangkok scientific consultation, October 2023**
  - Discuss mRNA vaccine development
  - Dengue, HFMD, Tx HPV, *P. vivax*
- **Singapore meeting, March 2024**
  - Establish consortia to drive mRNA product development
  - IVI (dengue), Hilleman (HFMD), Chula University (Tx HPV), Mahidol University (Malaria, *P.vivax*)

mRNA Technology Transfer Programme

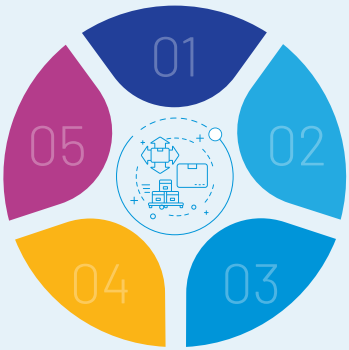
What is Technology Transfer?

Technology Transfer is the process of sharing knowledge, skills, scientific and technological developments between governments, organisations, or manufacturers to ensure products and technologies are available to those who need them.

Despite sounding simple, it is not – the requirements are far ranging and must align to be successful.

Technology Transfer is **not instantaneous** and **cannot occur in a vacuum**

Pandemic readiness needs pre-existing infrastructure and know-how



01. Ecosystem

A robust and reliable infrastructure is essential for local manufacturing to thrive. This includes governments, transportation networks, energy systems, communication networks, health care system, the people, etc.

02. Research and Development

can help to create an ecosystem that promotes innovation, entrepreneurship, and the development of new technologies

03. Education and skill development

A skilled workforce is critical to the success of local manufacturing and technology development. Developing countries need to invest in education and training programmes to ensure that their citizens have the skills and knowledge required to participate in the modern economy

04. Access to technology and innovation

Developing countries need to have access to the latest technologies and innovations in order to remain sustainable

05. Foster regional and international collaboration

Regional and international collaboration is needed to ensure that everyone has access to the vaccines and other medical products they needed. This includes sharing information, technology, and resources to achieve common goals as well as encourage investment and build resilience through demand signals and procurement models that prioritise locally produced vaccines

A success based on partnerships and sustainability

The project is long-term and constructed with sustainability in mind. It is co-led by WHO and MPP. The organisations participating in the consortium are: Afrigen – the 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 mobilised budget is $123M (to cover the South African consortium and Partners activities) for the period 2021-2025.** This is seed money and the aim is for the project to be self-sustaining after 2026. Funding covers the coordination of the project, activities at Afrigen and the development of local innovation and products by programme partners. A significant portion of the funds have been secured.

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

mRNA Technology Transfer Programme

Bio E training

visit at the Afrigen site in Cape Town


Visitors Only
Afrigen
Afrigen

20th April 2023
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 Imunobiologicos Bio-Manguinhos · biofarma · Biological E. Limited · BioVaccines Nigeria Limited · BIOVAX · DARNYTSIA

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

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

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