

Topic brief

SAVax Support to Innovative Projects in the Biotechnology Sector in South Africa

Africa currently produces just 1% of the vaccines it needs, making local production crucial to reduce reliance on imports. South Africa, with its advanced industry, skilled workforce, and research expertise, is well-positioned to help meet this need. The GIZ South Africa, eSwatini and Lesotho SAVax program (Vaccines for Africa: Rollout and production in South Africa) **supports the South African government** in their efforts to prevent pandemics and ensure widespread access to vaccines and essential pharmaceutical products.

VALUE CHAIN: Surveillance Innovation (R&D) Manufacture Regulation Procurement Demand

SAVax structures its intervention along a value chain that covers surveillance, innovation, manufacture, regulation, procurement and demand.

Supporting Innovation - Research and Development (R&D)

In the field of research and development of vaccines, pharmaceuticals and diagnostics, South Africa is placed as a front-runner on the continental level. There is a need, however, for greater investment in research and development from the private sector, and for strengthening cooperation through public-private partnerships.

In August 2024, SAVax together with the Department of Science, Technology and Innovation (DSTI) launched a competitive call for proposals targeting consortia of private sector companies and academia. The selected projects support the development of innovative vaccines, pharmaceuticals, diagnostics and technologies that address healthcare challenges in South Africa and the African continent.

They translate research findings into tangible products and solutions that benefit public health. All projects focus on creating value in South Africa sustainably. SAVax is a Joint Action funded by the Federal Ministry for Economic Cooperation and Development (BMZ) and the European Union (EU) under the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies for Sub-Saharan Africa (TEI MAV+). The project is implemented in partnership with the National Ministry of Health of South Africa and the Department of Science, Technology and Innovation.



Rapid Diagnostics Made in Africa

Local Production of Oligonucleotides – Crucial Elements for Rapid Testing Kits

Project name	The development of oligonucleotides synthesis platform for in vitro diagnostics (IVDs) kits of human reportable infectious diseases
Consortium	CapeBio Diagnostics and Wits Health Consortium
Duration	01.05.2025 – 01.05.2027

Challenge: Lack of rapid diagnostic tools for infectious diseases in Africa

The capacity to deliver rapid and high-quality diagnostic kits is important to effective healthcare. This applies particularly to Africa, where infectious diseases impose a heavy burden, and systemic barriers often delay medical intervention. Diseases such as HIV, tuberculosis, hepatitis, and meningitis need prompt diagnosis to prevent severe complications, irreversible health deterioration, and preventable mortality. In low-resource settings, where laboratory infrastructure may be inadequate and skilled personnel scarce, advanced diagnostic tools are indispensable for bridging gaps in healthcare accessibility and ensuring timely treatment initiation.

Oligonucleotides are the basis for such rapid testing kits. They are utilized to detect genetic material from a virus or bacteria by attaching to the material, if it's present, and generating a signal – e.g. colour change – that indicates a positive or negative test result. Oligonucleotides are fundamental components in molecular diagnostic tests and are currently entirely imported into the region. This reliance on international suppliers creates multiple systemic challenges, including prohibitive costs, unpredictable delays in procurement, and vulnerabilities in supply chain logistics, all of which hinder timely responses to disease outbreaks across Africa.



Innovative Approach and Partnership: Producing Oligonucleotides Locally

CapeBio Diagnostics is a frontrunner in localizing the production of in vitro diagnostics, such as COVID-19 PCR test kits. In strategic partnership with the Wits Health Consortium, CapeBio is pioneering the localized production of oligonucleotides in South Africa. This helps to reduce costs, enhances accessibility, and strengthens Africa's diagnostic supply chain. This strategy improves healthcare affordability, fosters biotech self-sufficiency, and enables faster distribution of diagnostic kits, particularly in underserved regions, aiding early detection and treatment of diseases.

Impact: Strengthen South Africa's Biotech Infrastructure

This initiative represents a critical step toward diagnostic self-sufficiency for the African continent. By reducing dependence on foreign suppliers and establishing an in-country oligonucleotide manufacturing ecosystem, CapeBio is not only strengthening South Africa's biotechnology infrastructure but also fostering a more sustainable and independent healthcare future for the entire region. The long-term impact includes faster outbreak response, improved disease surveillance, and greater accessibility to precision diagnostics – all essential components of a resilient public health system.

CapeBio's local production of diagnostic kits helps to advance healthcare and stimulate economic growth. The initiative supports SDG 3 (Good Health and Well-Being) through affordable, rapid testing for HIV, TB, and meningitis; SDG 9 (Industry, Innovation, and Infrastructure) by developing Africa's biotech sector and reducing dependence on imports; and SDG 8 (Decent Work and Economic Growth) by creating skilled jobs in biotech manufacturing. Through sustainable production and partnerships, it also fosters innovation and builds a more resilient African healthcare system.



Combating the Respiratory Syncytial Virus (RSV) in South Africa

Development of a local mRNA Vaccine

Project name	Development of a highly potent low-cost RSV mRNA-LNP vaccine for clinical testing in Africa
Consortium	Afrigen & University of Cape Town
Duration	01.05.2025 – 01.05.2027

Challenge - RSV in Southern Africa – A Silent Threat

Respiratory Syncytial Virus (RSV) is a leading cause of severe lung infections, especially in infants and young children. Each year, RSV leads to around 3.6 million hospitalisations and 100,000 deaths among children under five, with the highest impact felt in low- and middle- income countries like those in Africa and South Asia. In South Africa, RSV infection rates are alarmingly high, affecting over 70 out of 100 children under five annually. Beyond the health risks, RSV places a huge financial strain on families and healthcare systems. Treating a child hospitalised with RSV in South Africa can cost between ZAR 10,000 and ZAR 50,000, a burden many families struggle to afford. The World Health Organization (WHO) estimates that RSV's global economic toll runs into hundreds of millions of dollars annually, deepening the healthcare challenges in low and middle-income countries.

Innovative Approach and Partnership: A locally produced vaccine against RSV

SAVax supports the development of an affordable RSV and mRNA vaccine through its implementing partner, Afrigen Biologics - a leading South African biotech company. The vaccine is designed for local production and aims at making RSV prevention more accessible and reducing hospitalisations and deaths. Afrigen's approach focuses on both maternal and infant immunisation, providing protection even before birth and throughout early childhood. Afrigen has partnered with the University of Cape Town (UCT) to drive this groundbreaking vaccine initiative.

UCT's researchers and facilities play a crucial role in developing and testing the mRNA vaccine: their expertise in molecular biology, genomic analysis, and preclinical studies ensures the vaccine meets global safety and effectiveness standards.

Afrigen and UCT are conducting critical research to optimise the RSV mRNA vaccine for large-scale production and effectiveness. The work includes developing and testing the vaccine in preclinical models, ensuring it provides strong immunity while remaining affordable and scalable for low- and middle-income countries.

Impact: Better access, fewer hospitalisations, financial relief, and strong protection

- ✓ Better Access – Affordable pricing, wider availability in low- and middle-income countries
- ✓ Fewer Hospitalisations & Deaths – Preventing severe infections that ease the burden on families and hospitals.
- ✓ Financial Relief – Lower medical costs that reduce economic pressure on families and healthcare providers.
- ✓ Stronger Protection for Mothers & Babies – Immunisation during pregnancy will protect newborns, and direct vaccination will ensure continued safety

Afrigen and UCT's work aligns with the World Health Organization's mRNA technology transfer initiative, supporting low- and middle-income countries to independently produce vaccines. This project strengthens Africa's ability to develop, manufacture, and distribute lifesaving vaccines without reliance on high-income countries developed nations. Through this partnership, Afrigen and UCT are shaping a healthier future through local innovation that drive global health solutions.



Tiny Lipids - Big Impact for mRNA Vaccine Development

Local large-scale production of ionizable lipids

Project name	Local large-scale production of ionizable lipids
Consortium	Wits Health Consortium & CPT Pharma
Duration	01.05.2025 – 01.05.2027

Challenge: Limited access to key components for mRNA vaccines

mRNA vaccine technologies became especially prominent during the COVID-19 pandemic and are now seen as crucial for the future global health. Ionizable lipids are key components used in these vaccines. They play a pivotal role in safely delivering mRNA into cells. Once inside a cell, they assist in releasing the mRNA so proteins can be produced. Currently there is a shortage of ionizable lipids on the South African market, and available ones are either expensive, controlled by patents, or made from petroleum products. Subsequently, alternative, environmentally friendly, and sustainable compounds are needed.

Innovative Approach and Partnerships: Ionizable lipids from cashew nutshell liquid

The SAVax project supports a consortium of academia and private sector with the main goal fostering a large-scale production of ionisable lipids. At the University of the Witwatersrand scientists from the Synthetic Organic Chemistry team and Antiviral Gene Therapy Research Unit have created a collection of special ionizable lipids from cashew nutshell liquid, which is a renewable resource found in Africa. Cashew nutshell liquid is turned into a substance called hydrogenated cardol, which is used to make special lipids. By changing the structure, scientists made different types of lipids that can carry and deliver mRNA effectively.

In partnership with Chemical Process Technologies (CPT) Pharma, a local industry partner, the special lipids shall be produced on a large scale in South Africa at a lower cost. This is an important step before they can be used in medical products. The CPT group has a team of researchers who use new and creative ways to make important ingredients for medicines.

These methods have a lot of potential to be successful in the market. Together, the Wits and CPT Pharma scientists will create ingredients needed to make vaccines both locally and internationally.

Impact: Speed up Vaccine Development in Africa

Africa produces about 54% of the world's cashew nutshell liquid (CNSL), which is usually discharged. The supported project supports the production of special lipids from cashew nutshell liquid on a large scale and at a low cost. This technology will help improve health and expand the use of mRNA vaccines, especially in low and middle-income countries. The project aims at lowering costs, use eco-friendly materials, and speed up vaccine development in Africa.



Vaccines Made in Africa: Scaling-up Local Vaccine Ingredients

Manufacturing affordable, high-quality in-vitro transcription enzymes locally

Project name	Bringing South African manufactured mRNA vaccine raw materials to market: scaling and setting up quality standards
Consortium	Stellenbosch University & Fluorobitech
Duration	01.05.2025 – 01.05.2027

The Stellenbosch Biofoundry introduces simplified quality control methods, further reducing costs and producing enzyme formulations that eliminate the need for costly and energy-intensive cold-chain logistics.

Impact: Enhance pandemic preparedness

The initiative significantly reduced dependence on international suppliers and enhances global pandemic preparedness by developing efficient, robust technologies suited for resource-limited settings. The project boosts South Africa's vaccine production capabilities and stimulates local economic growth. Scaling up production will provide vital data to support future national-scale manufacturing. The initiative will also train skilled professionals, benefiting not only vaccine manufacturing but also wider biotechnology sectors like diagnostics. Strengthening international partnerships is crucial for effective pandemic response. By fostering global collaboration and developing technologies designed for low-resource environments, this initiative promotes equitable access to vaccines and contributes to global health security. Additionally, these efficient and sustainable technologies have broader applications worldwide, benefiting global health infrastructure and energy efficiency.

Challenge: Expensive raw materials

Africa relies heavily on imported vaccines, producing only about 1% locally. During the COVID-19 pandemic, low- and middle-income countries faced vaccine shortages, highlighting global health inequalities. Improving health in low- and middle-income countries not only benefits these regions but enhances global health security overall. While mRNA vaccines offer fast development and adaptability, they remain costly due to expensive imported raw materials, supply disruptions, and limited local expertise. Most costs for mRNA vaccine production come from raw materials, especially in-vitro transcription enzymes, which account over 50% of total costs. Nearly 90% of vaccine producers report struggles with high enzyme costs, often requiring subsidies to remain competitive. Producing these enzymes locally therefore reduces costs, secures supply chains, and builds resilience.

Innovative Approach and Partnerships: Manufacture enzymes locally

The SAVax project supports a collaboration between Stellenbosch Biofoundry and Fluorobitech, which leverages innovative biotechnology developments in South Africa. The collaboration has the goal to manufacture affordable, high-quality in-vitro transcription enzymes locally. Fluorobitech's technology allows quicker, cheaper enzyme production without costly equipment, which helps to significantly lowering overall vaccine production expenses. This makes vaccines made in South Africa more affordable and competitive.



Preventing Cervical Cancer

Stronger Community Health through Low-Cost Diagnostics for Human Papilloma Virus (HPV)

Project name	Built by Africans for Africans: Low-Cost HPV Diagnostics for Community Health
Consortium	Council for Scientific and Industrial Research (CSIR), Medical Diagnostech and University of Cape Town (UCT)
Duration	01.05.2025 – 01.05.2027

Challenge: Gaps in Cervical Cancer Care

Cervical cancer is one of the leading causes of cancer deaths among women in Africa. Early detection of the human papillomavirus (HPV), the main cause of cervical cancer, can save thousands of lives. However, current HPV tests are often too expensive and hard to access for women in remote or low-income communities. In many African communities, women therefore struggle to get screened for cervical cancer. As a result, cervical cancer often isn't caught early enough, leaving many women untested until it's too late. In South Africa alone, over 10,000 women are diagnosed with cervical cancer each year and nearly 6,000 die from it. Most of these deaths could be prevented with timely screening and treatment. The lack of affordable, accessible testing means women from low- and middle-income countries are at high risk.

Innovative Approach and Partnerships: Saving Lives through Affordable Cervical Cancer Screening

The SAVax project supports a joint initiative between the Council for Scientific and Industrial Research (CSIR), Medical Diagnostech and the University of Cape Town that aims at developing low-cost, easy-to-use HPV tests which bring screening closer to the people who need it most. This will make testing for HPV affordable for vulnerable population groups. Two portable HPV tests will be developed that local clinics and mobile health units can use at point of care:



- 1 HPV DNA Test:** A simple genetic test that detects high-risk HPV strains from a woman's swab sample. It uses a tiny handheld device (no big lab needed) to amplify the viral DNA if present. In about an hour or less, health workers will know if a patient has the virus.
- 2 HPV Sensor Strip:** A small sensor device that works like a "check engine light" for HPV. A cervical swab sample is applied to a strip that contains special enzymes. If HPV is present, the strip triggers an electrical signal on a portable reader – like a quick yes/no result. This test gives results in seconds.

Both test methods are low-cost and battery-powered, designed for use even in remote areas without full laboratories. The tests are significantly cheaper than current options, meaning clinics can afford to screen more women. The tools are being developed with local conditions in mind – they are easy to use and require minimal training so that community health workers and nurses can operate them.

Impact: Healthier Women, Stronger Communities

Both test methods are low-cost and battery-powered. With these new tools, more women will get tested early, before cancer develops or progresses. Early detection means treatment can start sooner, greatly improving the chances of preventing cervical cancer. Over time, regular community screening will reduce cervical cancer deaths and relieve the burden on hospitals by detecting infections earlier. Families stay healthier when mothers and daughters stay cancer-free. This project puts women's health first and builds trust in local healthcare services – women will know that life-saving screening is available right in their community at little or no cost.



Making Life-Saving Treatments Affordable

Producing biosimilars for cancer treatments

Project name	Establishment of an optimised, commercially viable manufacturing process of a pembrolizumab biosimilar for local production and registration
Consortium	National Bioproducts Institute (NBI) & Council for Scientific and Industrial Research (CSIR)
Duration	01.05.2025 – 01.05.2027

Challenge: Limited access to life-saving medicines for cancer

Cancer is one of the world's leading causes of death, with over 10 million lives lost in 2020 alone. Sadly, 70% of these deaths occur in low- and middle-income countries, where access to effective cancer treatments is limited. Innovative medicines like pembrolizumab - a monoclonal antibody used in the treatment of various cancers - have transformed cancer care globally. Monoclonal antibodies are proteins made in a laboratory meant to stimulate the immune system. The high cost and limited availability of such therapies, however, place them out of reach for many in South Africa and across the African continent.

Innovative Approach and Partnerships: Biosimilars produced locally

Biosimilars have the potential to bridge this gap: They are near-identical versions of approved biological medicines that offer the same effectiveness and safety—at a lower

cost—making them more accessible to patients who need them most. To improve access to life-saving biologics, the National Bioproducts Institute (NBI) is partnering with the Council for Scientific and Industrial Research (CSIR) and the International Centre for Genetic Engineering and Biotechnology (ICGEB) to develop a biosimilar version of pembrolizumab, for local manufacturing in South Africa. The work will be completed in five structured phases, including process optimisation, analytical validation and technology transfer, ensuring a disciplined path to regulatory approval and commercial readiness.

Impact: Affordable life - saving treatments

Local development and production means more affordable treatment options can be provided to meet regional healthcare needs, improving patient outcomes while reducing dependency on international supply chains. The initiative is a transformative step toward equitable healthcare in Africa. By localising the development and manufacturing of high-quality biosimilars, NBI and CSIR are assisting to reduce costs, increase availability, and build a sustainable path towards greater health access for all.

Key benefits include:

- ✓ Increased access to high-quality cancer treatment
- ✓ Reduced costs compared to imported therapies
- ✓ Faster availability of urgently needed medicines
- ✓ Strengthening of local scientific and technical capabilities
- ✓ A platform to develop additional biosimilars for other diseases.



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