



Afrigen's Mission to Empower Developing Countries with mRNA Vaccine Production

Addressing Global and Regional Health Inequalities through Local Manufacturing Initiatives
Joanne Gibson, Ph.D., New England Biolabs

The global disparity in vaccine distribution was brought into sharp focus by the COVID-19 pandemic. While affluent nations quickly secured and distributed life-saving vaccines, lower-income countries faced severe shortages, exacerbating health inequities and prolonging the crisis. To address this issue, Afrigen Biologics & Vaccines (www.afrigen.co.za), supported by the World Health Organization (WHO; www.who.int), was given a bold mission to bridge the vaccine gap and empower regions traditionally left behind by global healthcare advancements.

Afrigen, founded in 2014 and operational since mid-2016, is at the forefront of advancing vaccine innovation and manufacturing in Africa — a continent that uses 25-30% of global vaccine supplies but is only able to produce 1% of its needs. Initially focused on in-licensing a TB vaccine from the Infectious Disease Research Institute (IDRI) in Seattle (now known as AAHI), Afrigen now sits at the center of a program born from the COVAX initiative (www.who.int/initiatives/act-accelerator/covax) and jointly run by the WHO and the Medicines Patent Pool (MPP) (medicinespatentpool.org). The program aims to address vaccine inequity by creating a hub for technology transfer and training that could be passed to lower-middle-income countries, which in turn would become regional manufacturers of mRNA vaccines.

Overcoming Initial Obstacles and Long-Term Vision

The WHO/MPP program envisioned Afrigen as a central hub for mRNA vaccine production technology, aiming to transfer this technology to 15 global partners in low-middle-income countries across four continents. However, initial expectations of a technology transfer during the recent COVID-19 pandemic from major manufacturers fell through. By September 2021, Afrigen realized they would need to develop the mRNA technology from scratch. With a team of only 20 people, none of whom had prior mRNA experience, Afrigen embarked on a journey to learn, innovate, and collaborate. They partnered with universities in South Africa, expert advisors, and suppliers, including New England Biolabs®, to gain the necessary knowledge and resources. Over nearly three years, Afrigen has grown its staff by 150 people, built an end-to-end research, development and GMP manufacturing facility, and developed the technology to a point where it is ready for phase 1-2 clinical trials.

“The realization that we had to start from scratch was daunting, but it also gave us the unique opportunity to truly embed the know-how and create a robust foundation for future developments.”, says Dr. Caryn Fenner, Executive Director: mRNA Hub, Afrigen Biologics.

While these collaborations allowed Afrigen to fast-track the development of mRNA vaccines, it was also realized that in terms of the timeline, they would not be able to participate in the manufacture of the COVID-19 vaccine. However, the program included medium- to long-term sustainability goals, with each partner using the technology to address specific regional health needs while also contributing to global health security. For example, in South Africa, Afrigen is prioritizing vaccines relevant to the burden of disease in Africa in a quest to address unmet needs. The current product development pipeline includes HIV, TB, Rift Valley Fever virus, gonorrhea, and RSV.

“We are not just looking at immediate pandemic response but also at long-term health security for the regions we serve,” explains Dr. Fenner. *“Our goal is to create a sustainable mRNA vaccine platform that can be adapted to various disease targets based on regional health needs.”*





The 15 partners include six countries in Africa (South Africa, Senegal, Tunisia, Nigeria, Kenya, Egypt), two in Eastern Europe (Serbia, Ukraine), five in Southeast Asia (Pakistan, Vietnam, India, Indonesia, Bangladesh), and two in South America (Brazil, Argentina). These partners have varying levels of bio-manufacturing maturity. Some lack an R&D component and collaborate with research institutes, while others, without manufacturing capabilities, partner with commercial companies. Afrigen partners with Biovac, a South African vaccine producer and the first manufacturing partner in this network. Given these differences in bio-manufacturing maturity, a phased approach to technology transfer has been implemented between Afrigen and its partner countries, tailored to each country's specific needs and existing capabilities. Many partners who were previously unfamiliar with mRNA technology have received training at Afrigen's facility at the laboratory scale. This diverse consortium ensures that countries with different bio-manufacturing capabilities can effectively contribute to and benefit from the global vaccine initiative.

In addition to these international partnerships, Afrigen is part of a local R&D consortium managed and funded by the South African Medical Research Council. Supported by the South African Department of Science and Innovation, the consortium focuses on specific disease priorities for South Africa, such as TB and HIV. Afrigen also fosters partnerships around the globe to address specific priorities for the long-term sustainable introduction of mRNA vaccines into public health systems. The focus of these innovation partnerships is to improve manufacturing processes to reduce costs as well as improve thermostability to address supply and logistic challenges of the current mRNA vaccines.

Current Progress and Global Impact

Afrigen has now completed the scale-up process and is preparing for GMP certification, with plans to enter the engineering and GMP phases soon. They will host another round of on-site training for their 15 global partners. The company's comprehensive and inclusive approach involves extensive training and capacity-building efforts, ensuring that each partner is well-equipped to handle mRNA technology. Afrigen's staggered approach to training and technology transfer also allows them to continuously adapt and refine their processes.

Afrigen's story is one of determination and ingenuity. From its inception as a small adjuvant formulation vaccine development company, it is now poised to significantly impact global health using mRNA technology addressing immediate health needs as well as building a foundation for sustainable vaccine manufacturing in Africa and beyond.

Looking ahead, Afrigen is committed to continuing its work in vaccine development and expanding its impact. The company plans to advance its mRNA technology further, ensuring it is accessible and adaptable to meet various regional health challenges. Afrigen's ongoing projects and future goals reflect a deep commitment to improving health outcomes and achieving vaccine equity. Their journey demonstrates the power of collaboration, innovation, and resilience in the face of adversity. With continued support from global partners and a commitment to equity, Afrigen is well-positioned to achieve its mission and contribute to a healthier future for all.

"The essential ingredients of Afrigen's progress and success are diverse partnerships, suppliers such as NEB who walked the extra mile for us, innovative collaborations, a dedicated 'can do' attitude team, and society believing in us – all inspired by the vision of equitable health for all universe. Afrigen says: Thank you", says Professor Petro Terblanche, CEO Afrigen Biologics



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New England Biolabs GmbH, Brünigstr. 50, Geb. B852, 65926 Frankfurt/Main, Germany

Tel: +49/(0)69/305-23140 Toll Free: (Germany) 0800/246-5227 Toll Free: (Austria) 00800/246-52277 Fax: +49/(0)69/305-23149 e-mail: info.de@neb.com