



BioNTainer-based manufacturing in Kigali, Rwanda



Building a resilient vaccine ecosystem



There is still a lack of global access to vaccines: Africa produces less than 1% of the human vaccines it uses.¹ The African Union has set a target for the African vaccine manufacturing industry to develop, produce and supply over 60 percent of the total vaccine doses required on the continent by 2040.²

¹ <https://www.nature.com/articles/d41586-021-01048-1>

² <https://www.telegraph.co.uk/global-health/science-and-disease/vaccine-manufacturing-africa-pandemic-preparedness/>



Achieving this target requires a globally coordinated effort. BioNTech is working closely with partner countries from the African Union and local authorities, such as the Africa CDC and Rwanda FDA, European partners, including the European Commission and the European Medicines Agency, as well as global institutions and scientific partners such as WHO, CEPI and the Gates Foundation.



BioNTech believes that mRNA is a powerful new drug class that can help address the global challenge of vaccine access. We aim to contribute by building mRNA-manufacturing capacities where they are needed.

The Challenge

Establishing GMP production for mRNA-based vaccines is complex and time-consuming

Technical solutions for manufacturing sites must **comply with internationally harmonized GMP standards**

Complex mRNA manufacturing encompassing approximately 50,000 steps that have **highest quality standards**, including about 40 quality control tests for each manufactured batch to ensure safety and efficacy

Transferring complex processes keeping the systems up-to-date and employing **highly qualified personnel**

The Solution

Modular production units, GMP-compliant set-up and personnel training

Container-based **approach with modular design, standardized equipment and software components** that can be regularly updated with the aim to remain one of the most sophisticated mRNA manufacturing facilities

Facilitating **GMP process implementation and maintenance** through validation packages, automation, digital solutions, as well as **local and global quality control**

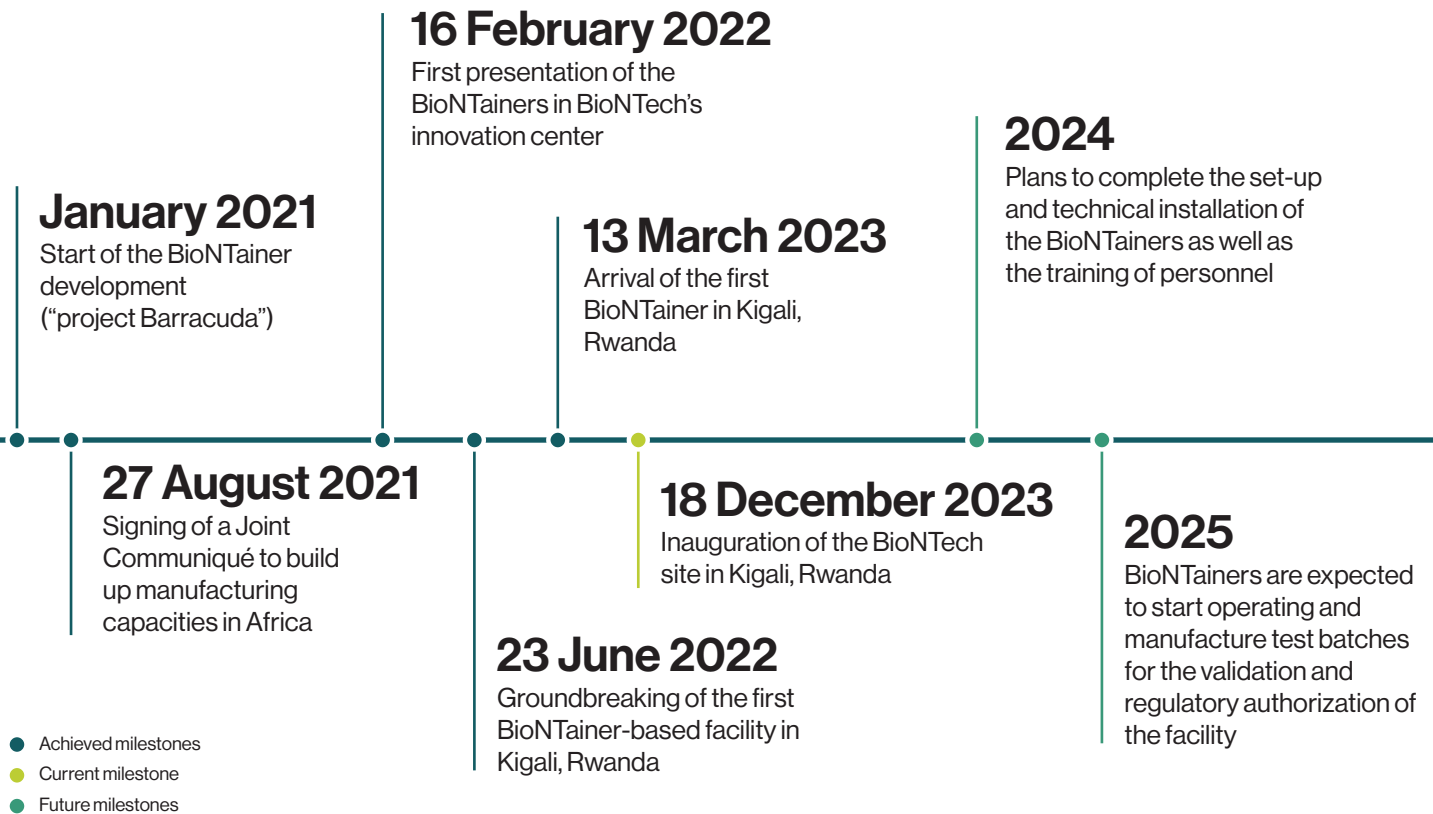
Staffing of the BioNTainers and training of local employees

BioNTainers as a solution to help promote vaccine equity for Africa

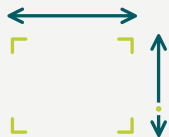


Funding	Fully funded by BioNTech to date (committed investment of approximately \$150 million)
Structure	6-8 containers = 1 module 6 containers = 1 drug substance module 8 containers = 1 drug product module
Container size	ISO sized (2.6m x 2.4m x 12m)
Shipment	Plane, freighter, truck or train
Production volume	Commercial-scale facility, could manufacture up to 50 million doses annually of a product with an RNA process similar to that of the Pfizer-BioNTech COVID-19 Vaccine
Associated capabilities	E.g. logistics, quality, control labs, quality assurance set-up, warehousing, cold and frozen storage

Developing the BioNTainers



Constructing a commercial-scale mRNA facility in Africa



The Rwandan facility has a total size of about

35,000 sqm

of which 800 square meters will be occupied by the initial two BioNTainers.

Approximately

190,000 cubic meters

of soil were moved during the construction process to level the ground.



A total of

6 buildings

are being constructed at the BioNTech site in Kigali.

2 stationary cranes & 2 mobile cranes

were needed to build the manufacturing hall, the taller one having a height of 35 m.



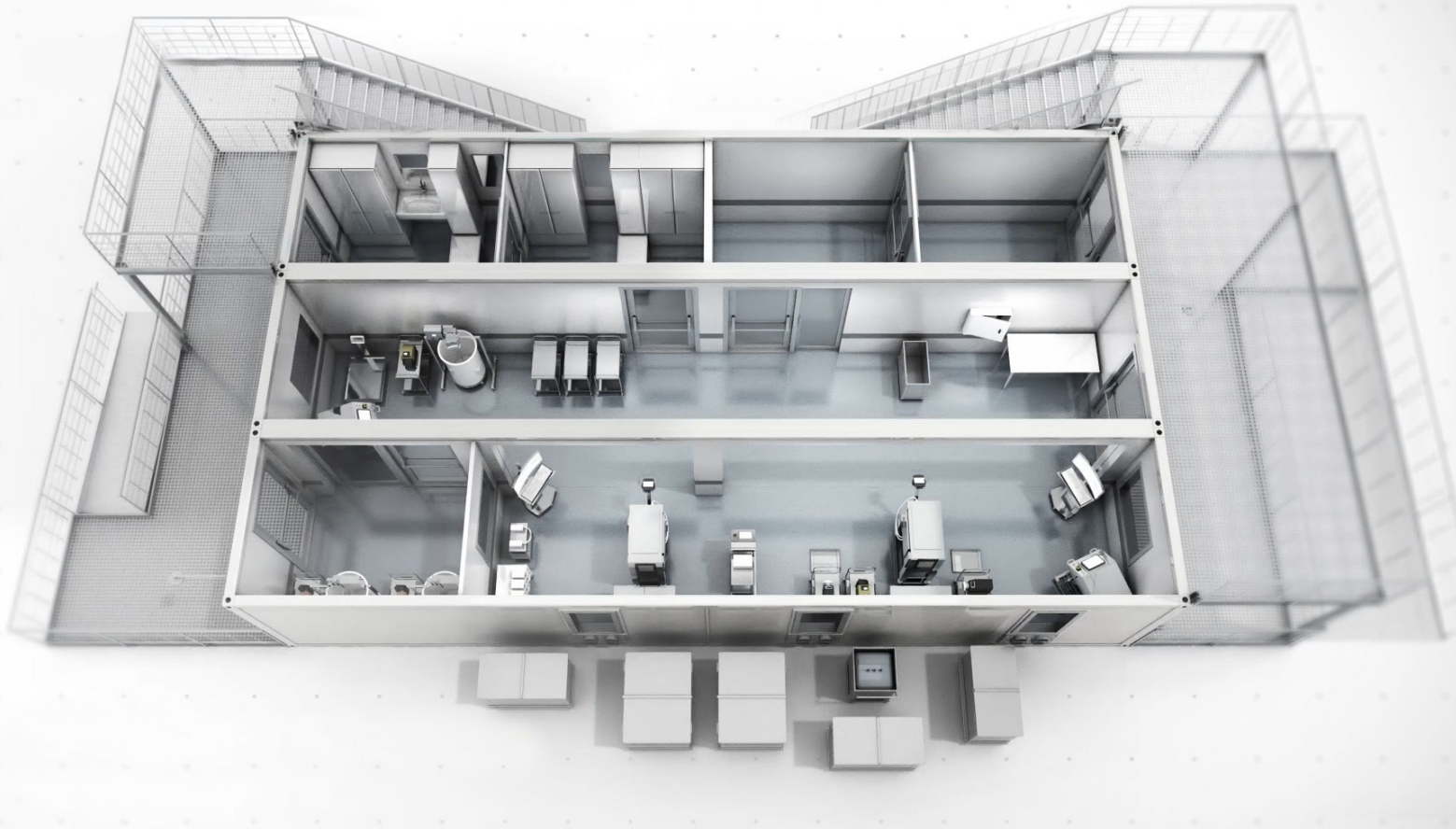
The team in Kigali currently consists of

20 members and is planned to grow to **60 members** by the end of 2024.

The BioNTainers could in principle produce a range of mRNA-based products, including

investigational malaria and tuberculosis vaccines

if successfully developed and approved.



Manufacturing mRNA-based vaccines in a BioNTainer

