A sustainable solution to vaccine access in Africa

The learnings of the global COVID-19 pandemic: public health requires a globally coordinated effort and a better preparedness to address new challenges.

However, there is still a lack of global access to vaccines: Africa produces less than 1% of the human vaccines it uses.
(Source: https://www.nature.com/articles/d41586-021-01048-1).

BioNTech believes that mRNA is a powerful new drug class that is a scalable, innovative technology to help address the global challenge of vaccine access. We aim to make this technology globally accessible.
BioNTainers as a solution to promote sustainable local vaccine production in the African Union

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

Transferring process and keeping the systems up-to-date and employing highly qualified personnel

**The solution**
Turnkey package that includes modular production units, GMP-compliant set-up and personnel training

Container-based "Plug & Play" approach with modular design, standardized equipment and software components to support rapid set-up of fully functional mRNA manufacturing facility

The GMP process implementation and maintenance will be facilitated by validation packages, automation, digital solutions, as well as local and global quality control

BioNTech will initially staff the BioNTainers and train local employees to hand-over the site in the mid- or long-term

As a decentralized solution, BioNTainers aim to offer greater independence and faster vaccine supply within the African Union and support the development of talent as well as an emerging biotechnology industry

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**BioNTainers as a solution to promote sustainable local vaccine production in the African Union**

<table>
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<tr>
<th>Scope</th>
<th>12 containers</th>
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| Structure | 6 containers = 1 module  
| | > 1 drug substance (DS) module  
| | > 1 drug product (DP) module |
| Container size | ISO sized (2.6m x 2.4m x 12m) |
| Shipment | Shipped via freighter, truck and train |
| Production volume | E.g. approx. 50 million doses of the Pfizer-BioNTech COVID-19 vaccine |
| Production | BioNTech jointly with local support |
| Quality control | BioNTech jointly with local support |
| Local infrastructure | E.g. logistics, quality control labs, quality assurance set-up, warehousing, cold and frozen storage |
| Technical autonomy | Fully self-sufficient |
| Value offering | Single to multi-drug production & clinical trials |
Overview of mRNA vaccine manufacturing process

1. mRNA production
2. mRNA purification & concentration
3. Drug product formulation
4. Filling & packaging

DS module
- 6 containers = 1 BioNTainer for Drug Substance

DP module
- 6 containers = 1 BioNTainer for Drug Product

Local Partners
How BioNTech’s solution is being set up

1. Manufacturing of modules and procurement of process equipment coordinated at BioNTech’s innovation center in Marburg. In parallel, construction of production hall in target location

2. Shipment and delivery of containers and equipment to target location after testing to verify functionality

3. Set-up at target location where infrastructure is provided on-site (e.g. power and water supply, labs for quality control and assurance, warehousing, cold and frozen storage)

4. Local qualification runs to ensure GMP-compliant vaccine production; training of local employees

5. Start of production