



OCV Project overview

Oct 2024

Biovac is an established vaccine manufacturer with unique capabilities



Established African vaccine manufacturer

- Founded in **2003** and has been operational for **>20 years**
- Skilled, diversified and experienced workforce of **~350 employees**
- Unmatched **product development capability** on the continent, giving edge to secure tech transfers



Demonstrated know-how

- **2 operational filling lines** (vials & pre-filled syringes)
- Successfully completed **3 F&F technology transfers** with top pharma companies
- Moved up the value chain through reverse integration, now covering the **full value chain** from R&D to packaging



Seasoned Leadership & Support team



Morena Makhoana
Chief Executive Officer



Farrah Losper
Chief Commercial Officer



Lauren Bhayat
Chief People & Brand Officer



Craig Mitchell
Chief Financial Officer



Mark MacNoughton
Chief Operations Officer

+ Experienced and skilled operational teams: ~100 Production staff, ~90 Quality staff, ~40 Science staff, ~10 Regulatory staff



Industry Leadership

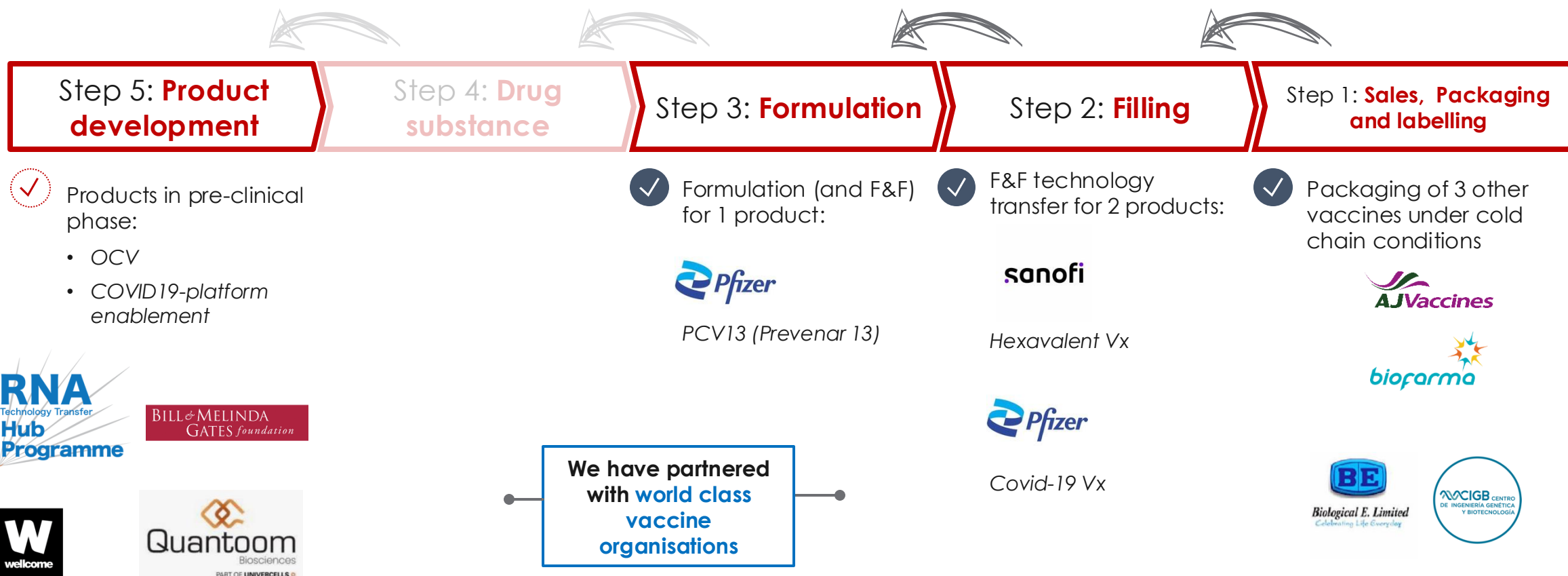
- Biovac is a founding member of the **African Vaccine Manufacturing Initiative (AVMI)**
- It was the first African company to be a member of the **Developing Country vaccine Manufacturers Network (DCVMN)**

Biovac built capabilities

Formulation, fill and finish as well as product development



Biovac reverse integration approach



AVMA incentive for African manufacturers



Financial mechanism

AMVA¹, designed by GAVI to be officially launched in June 2024, will **counterbalance the lack of price competitiveness** observed on the continent in the mid-term by **allocating \$ 1Bn** to support African vaccine manufacturers



Launched in June 2024

Gavi regards Biovac as the primary recipient of AMVA

Eligible vaccines	
AMVA Priority Vaccines	Other Gavi Vaccines
<ul style="list-style-type: none">• Oral Cholera (OCV)• Malaria• Measles- Rubella (MR)• Hexavalent• Yellow Fever• Rotavirus – 1 dose in blow fill seal• Ebola – effective against 2 species, thermostability from 20C• Pneumococcal Conjugate (PCV) - minimum 13 valent	<ul style="list-style-type: none">• COVID-19• Inactivated Polio (IPV)• Measles• HPV• Meningococcal• Pentavalent• Japanese Encephalitis• Typhoid Conjugate

On WHO PQ
Only market authorisation holders eligible
(Contract Manufacturing Organisations (CMOs) excluded)

OCV Project represents the best example of how end to end capabilities can be achieved if the right ingredients are in place



Growing Disease burden afflicting developing countries mostly in Africa

Cholera

Regulatory strengthening of local authority as well as WHO PQ licensing of end to end African developed and African produced vaccine

SAHPRA & WHO PQ

Willing **technology transfer partner** aligned to assisting with end to end capability in Africa

IVI

OCV

Market enabling environment e.g. AVMA and its priority

GAVI-AVMA

Willing **African Company** seizing the opportunity to fulfil its long-standing objective of being an end-to-end manufacturer and having developed skills and capability matching the type of technology

Willing **Funders** able to take upstream risk (product development risk)

GF, WT, Open Philanthropies

Biovac

OCV Project overview



OCV Process & Analytical Development Manufacture of 3 x Clinical Trial Lots

Clinical Development

SA Licensure & WHO PQ



- Tech transfer partner
- Technical support

Biovac



- Developer & manufacturer of clinical trial material

Biovac



- Management of tox studies
- Clinical Trial Sponsor

IVI



- Collaborative partner/Co-Sponsor
- Clinical Trial Oversight
- Clinical immunogenicity testing

SAMRC



- Clinical trial sites

Biovac



- Dossier submission
- Commercial manufacturer

Mar 2023 – May 2025

(27 months)

Q4 2025 – Q1 2027

(~ 19 months)

2027 – 2028

PQ timelines can be expedited with parallel review of dossiers



BIOVAC

science of protecting life



THANK YOU