

AFRICA IN THE GLOBAL VACCINE MANUFACTURING LANDSCAPE: ADVANCEMENTS



THE BIOVAC INSTITUTE

BIOVAC's Contribution to AVMI's Mission of Advancing Vaccine Development and Manufacturing



1. **Developed a Hib conjugate vaccine technology**, outlicensed to Indonesia, Japan and USA
 - Royalty income stream
2. **Fully funded novel GBS conjugate vaccine project**
 - Hexavalent vaccine funded up to FIH trial
 - Supported by PATH, USA
3. **Two significant commercial technology transfer deals** with Sanofi and Pfizer
4. Significant investment in **facility and skills development**
5. Hosting of **the AVMI secretariat** since 2012

Biovac Overview



- A Centre of Excellence routed in Africa for the development and manufacture of affordable vaccines

- Establish **end-to-end vaccine development and manufacturing capability** for local and export markets

Product Development

Manufacturing

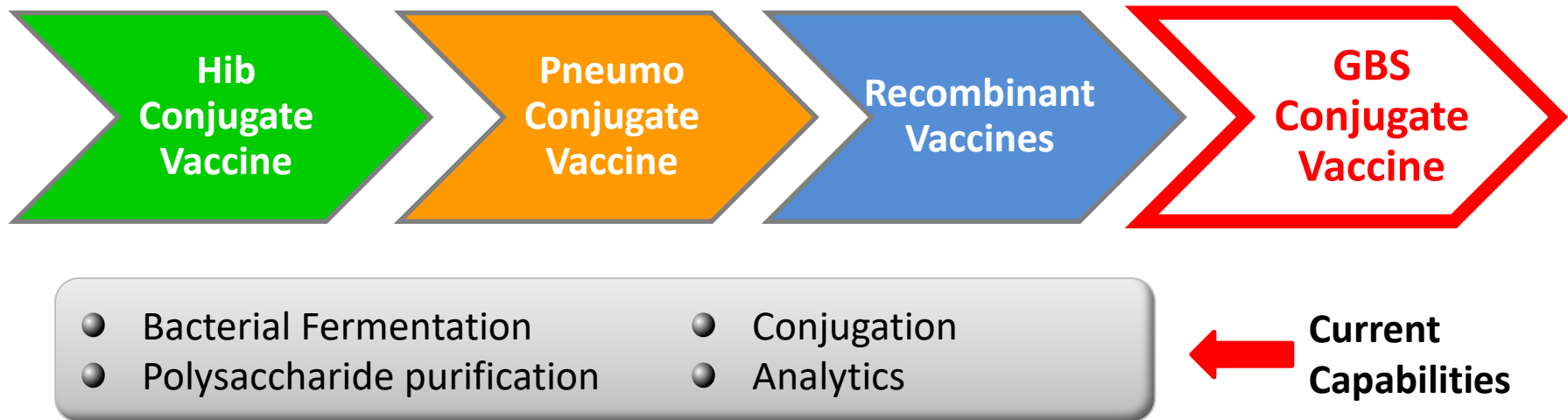
Distribution

- ...through **product development partnerships and tech transfer partnerships**

Conjugate vaccine technology platform

Achievement 1

Step-wise capacity building...



GBS Global Disease Burden

Achievement 2: Novel vaccine development

21.7 million
pregnant women
colonized with GBS



Increased risk of
maternal death
but unable to
quantify

At least 33,000
Maternal invasive
GBS disease



Increased risk of
neurodevelopmental
disability
but unable to quantify

57,000
stillbirths

At least 57,000
Fetal invasive
GBS disease



Increased risk of
neurodevelopmental
disability
but unable to quantify

90,000 infant deaths
(mostly neonatal)

At least 320,000
Infants with GBS
Sepsis and Meningitis



Including at
least 7,000 also
with neonatal
encephalopathy

10,000 with
neurodevelopmental
disability after
meningitis, unable to
quantify after sepsis

Increased risk of
neonatal death
but unable to
quantify

Up to 3.5 million
Preterm births
attributable to GBS



Increased risk of
neurodevelopmental
disability
but unable to quantify

PLUS UNQUANTIFIED CASES, DEATH AND DISABILITY FOR UNMEASURED GBS DISEASE
AND UNMEASURED BURDEN IN NON-INVASIVE GBS DISEASE

Phase 1: Roadmap & Timelines

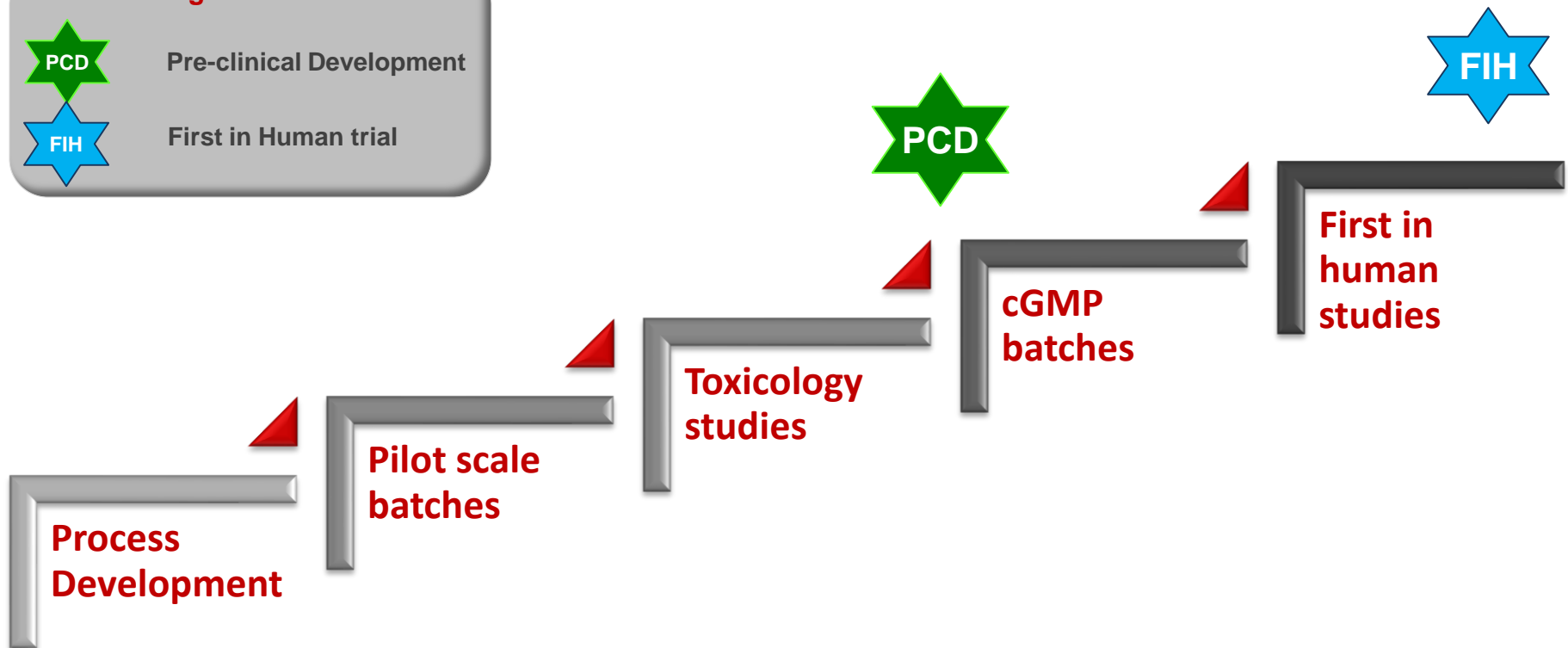
Stage Gates

PCD

Pre-clinical Development

FIH

First in Human trial



- Partnerships formally established in **Q1 2017** and work at Biovac began in **Q2 2017**.

- First-in-human trial to start **2020**

2017



2021

GBS Project: African context and significance



Achievement 2: Novel vaccine development

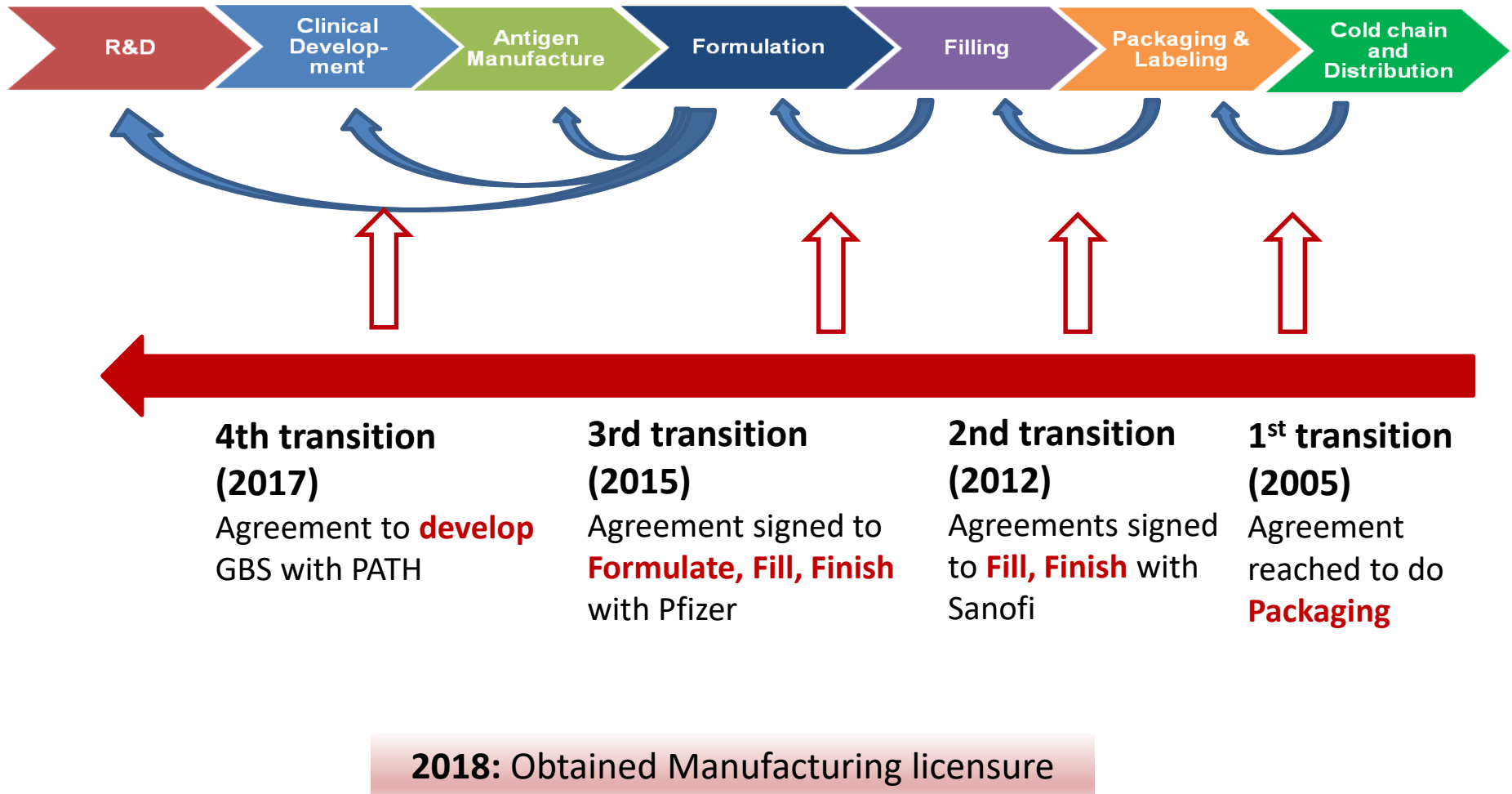
- ❑ Last successful novel vaccine development project in South Africa was OPV in 1950s.
- ❑ Addresses specific African disease burden
- ❑ Contributes to socioeconomic development and the bioeconomy in Africa

Biovac GBS Vaccine....

Developed in Africa
Tested in Africa
Made in Africa
...for Africa

Commercial deals with Multinationals

Achievement 3: Backward Integration Strategy

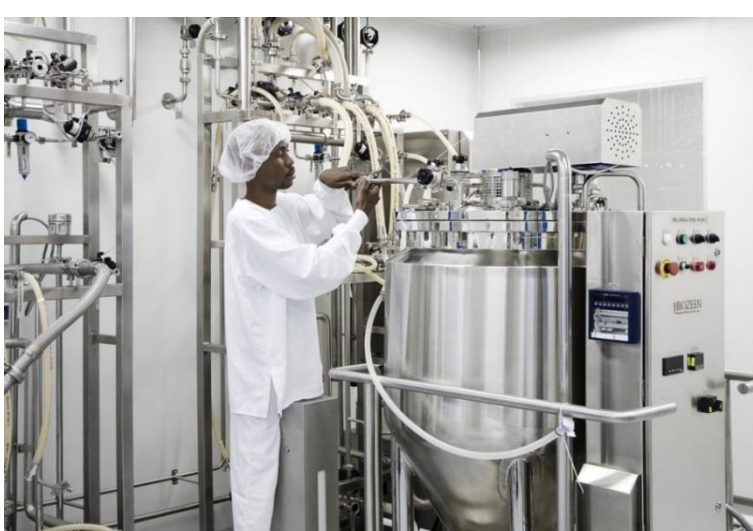


Vaccine Manufacturing Infrastructure

Existing



Virtual site tour: Manufacturing



Virtual site tour: Process development



Vaccine Manufacturing Infrastructure

Achievement 4: Expansion concept

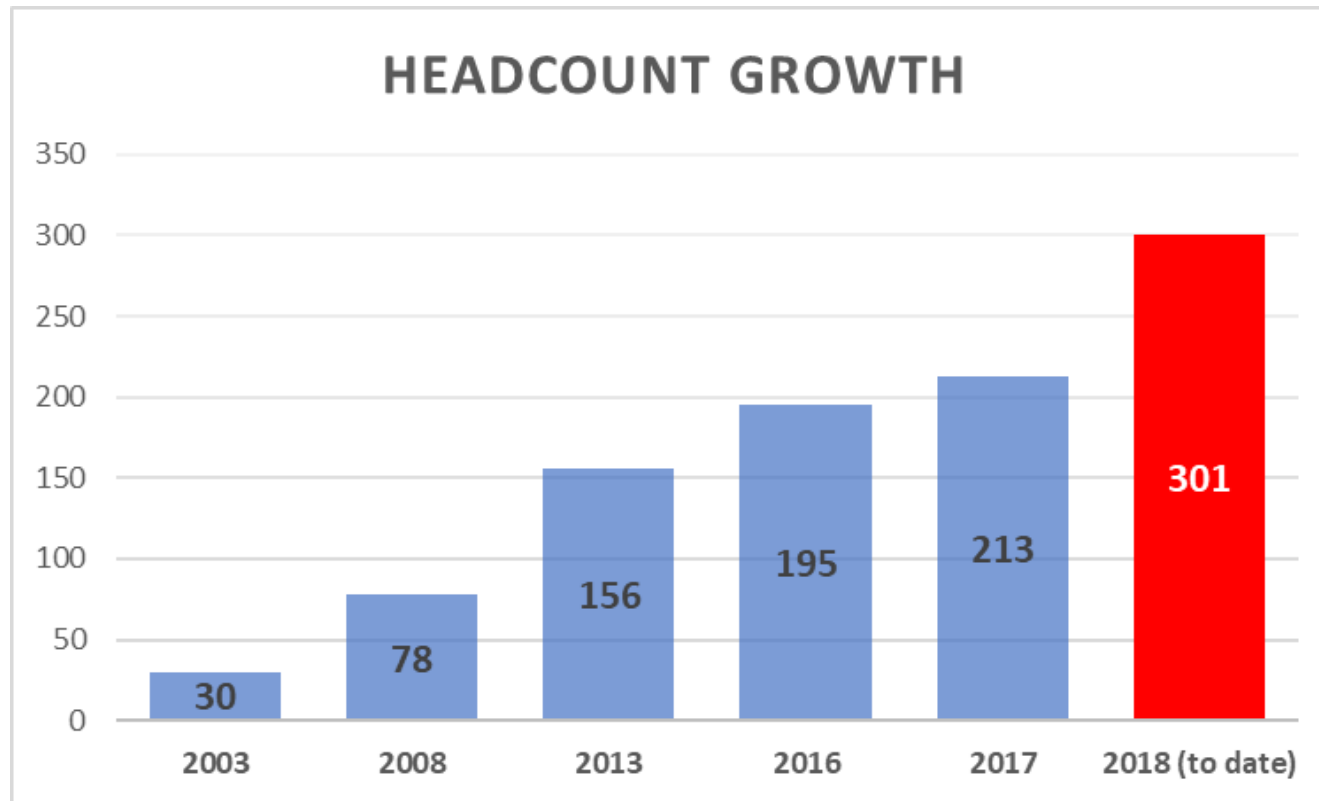


Staff

Achievement 4: Skills and recruitment



Focused in investment in developing local skills



Massive headcount increase over last two years:

1. **Ops departments:** Production, QC, S&I
2. **Supporting departments:** Eng, Procurement, RA, Supply Chain, QA, Finance, HR

Biovac Capacity & Capability

VMPPA Study 2015: Value chain assessment

African Companies CAPABILITIES	GROUP 2: Companies at late stage of vaccine development & manufacturing
	Biovac (South Africa)
Level 1: Import for Distribution	
Level 2: Packaging and Labeling	
Level 3: Product Manufacturing (fill & finish)	
Level 4: API Manufacturing	
Level 5: Research and Development	

Biovac Capacity & Capability

Advances 3: Update to VMPA Study

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THANK YOU

