



BIOVAC

science of protecting life

WCBP 2026

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**Overcoming Barriers to local GMP
Manufacturing and testing in LMICs:
Doing Things we never had**

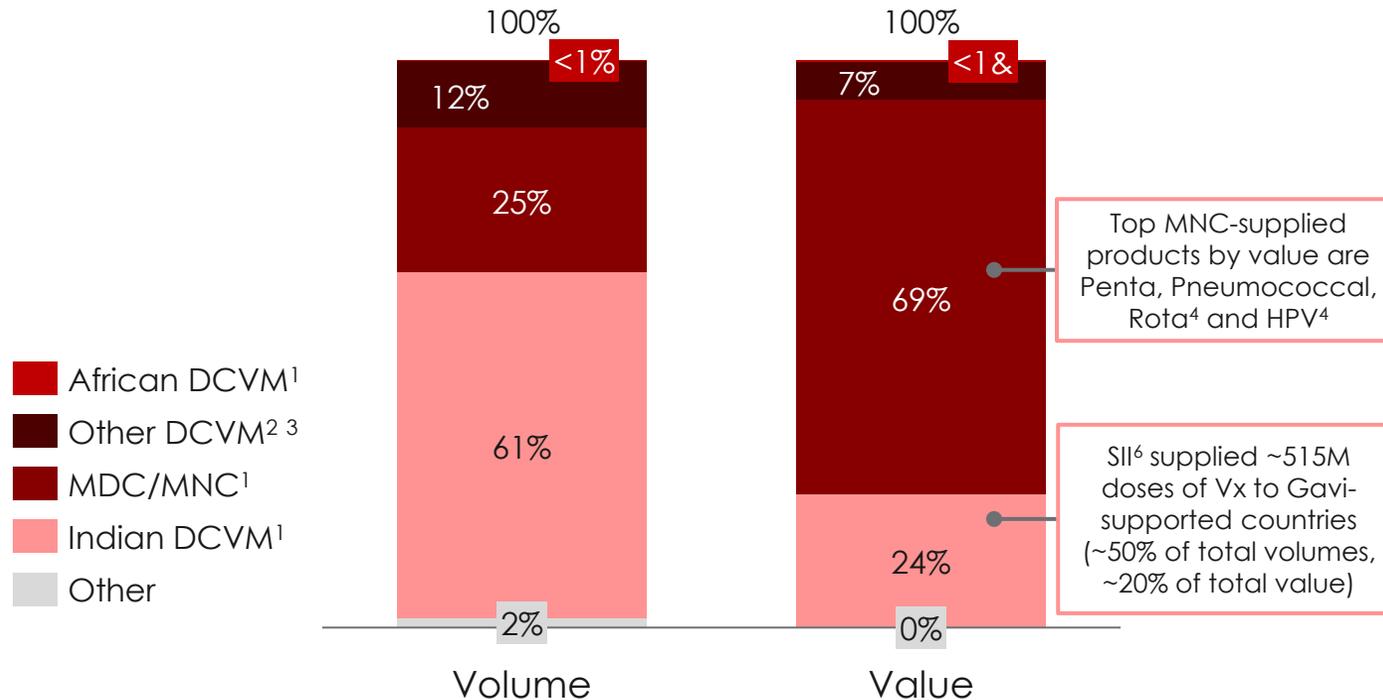
Outline of Presentation

1. The African Continent Vaccine Manufacturing Landscape
– a snapshot
2. South African Vaccine ecosystem
- a snapshot
3. Biovac - a South African Vaccine manufacturing initiative
 - a. Case study of end to end vaccine development and manufacture

Prior* to COVID-19, <1% of vaccines in supplied to Africa were locally Manufactured



Split of African vaccine market (volume and value) by manufacturer origin (2019)



- Indian DCVMs account for **~61% of total volumes** supplied to African countries but **less than 30% of total value**
- Less than 1% of the market** is supplied by local manufacturers

1. DCVM: Developing Countries Vaccine Manufacturers ; 2. MDC: More Developed Country ; 3. MNC: Multinational Company ; 4. Rotavirus ; 5. HPV: Human Papillomavirus ; 6. Serum Institute of India
Source: M14A

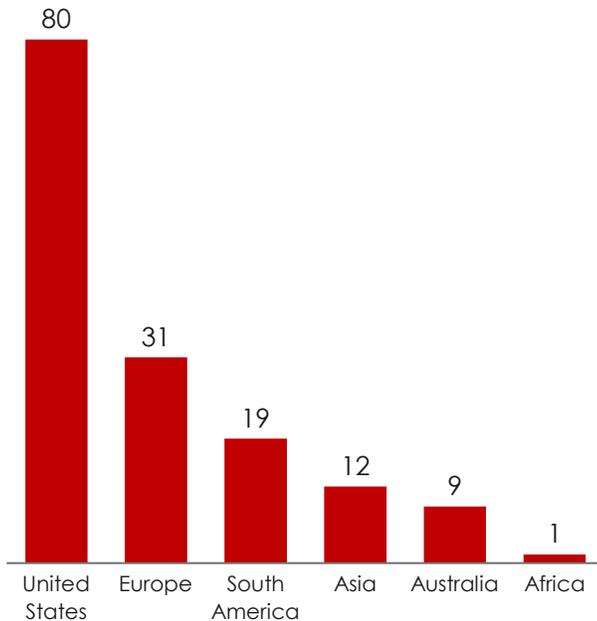
* The % of vaccine produced hasn't changed in 2026 as technology transfers and building of capability is still ongoing

The Covid-19 pandemic highlighted the continent's gaps and vulnerability

Africa faced limited vaccine supply due to reliance on other countries...

COVID-19 vaccines/100p

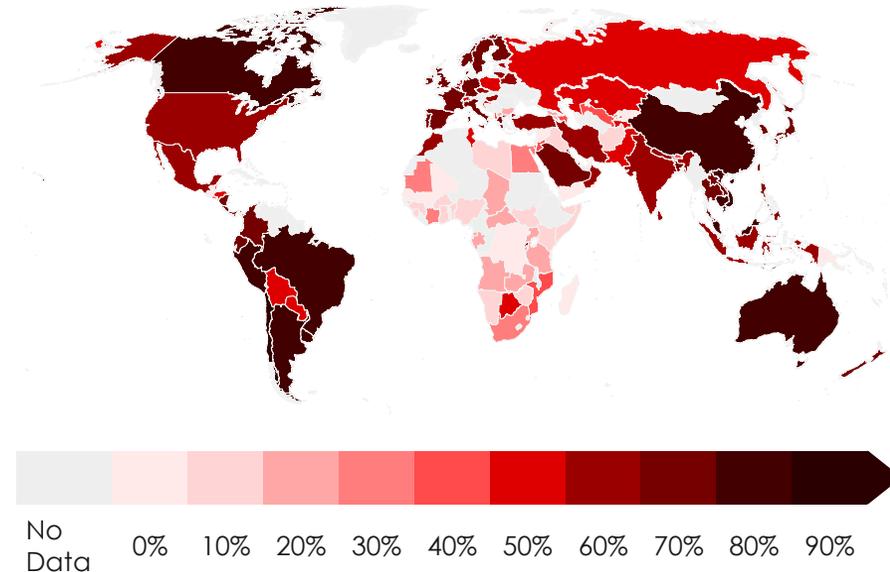
May 2021



...by the end of 2021, African countries had barely been able to vaccinate 10% of their populations

COVID-19 vaccines coverage

End of Year, 2021



With little local capacity and capabilities, African countries had to **rely on donations from other countries**



Covax supply faced additional delays when **India decided to ban vaccine export**, preventing African countries from receiving hundreds of millions of doses of AstraZeneca vaccines produced by the Serum Institute of India



As a result, African countries were **last in line for vital supply**. In May 21, there were ~60 doses of Covid-19 vaccines/100p in HIC¹ vs 0.8 doses/100p in LMICs²

COVID-19 PANDEMIC SAW A MULTIPLICATION OF AFRICAN MANUFACTURING ANNOUNCEMENTS & PROJECTS

Countries which announced intentions of starting up or of additional manufacturing capacity by 2021

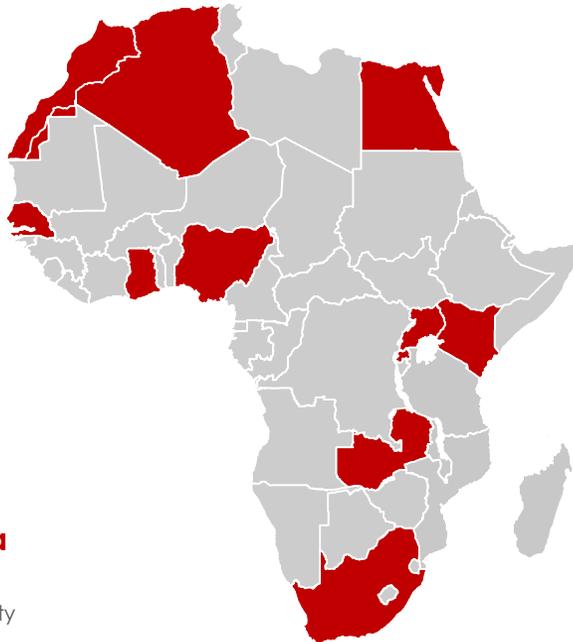
 **Morocco**
360Mn F&F capacity

 **Senegal**
25Mn F&F capacity
50Mn DS capacity

 **Ghana**
50Mn F&F capacity

 **Nigeria**
10Mn F&F capacity

 **South Africa**
500Mn F&F capacity
1Bn end-to-end capacity



 **Algeria**
60Mn F&F capacity

 **Egypt**
>1Bn F&F capacity
20-60Mn end-to-end capacity

 **Kenya**
500Mn end-to-end capacity

 **Rwanda**
50Mn DS capacity

 **Zambia**

In 2024, there are 25 active AVM projects which can be divided into three segments based on overall supplier maturities and capabilities

Seg. 1:
Facilities w/ TTs underway

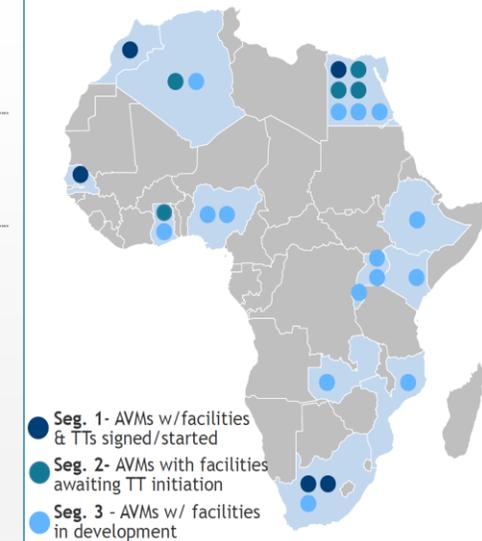
-  Marbio
-  Vacsera
-  IP de Dakar
-  Aspen Pharmacare
-  Biovac

Seg. 2:
Facilities awaiting TT

-  Eva Pharma
-  Minapharm
-  Biogeneric
-  Saïdal¹
-  Atlantic Biotech

Seg. 3:
Facilities in dev.

-  VBC
-  Polygon
-  Gennecs
-  IP de Algerie
-  DEK
-  Innovative Biotech
-  BVNL²
-  DEI Biopharma³
-  VAI Uganda
-  Biovax
-  Shieldvax
-  BioNtech
-  Yash Life Pharma
-  Mozambique Holdings⁴
-  Afrigen⁵



-  **Seg. 1** - AVMs w/ facilities & TTs signed/started
-  **Seg. 2** - AVMs with facilities awaiting TT initiation
-  **Seg. 3** - AVMs w/ facilities in development

Key Findings

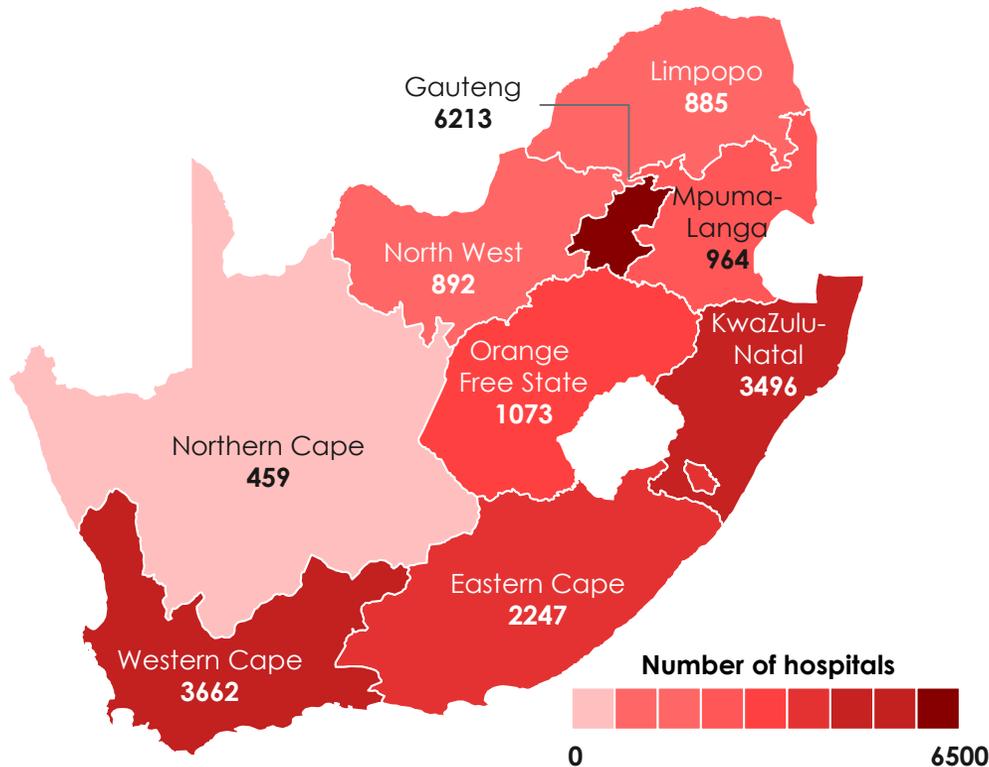
- 5 Suppliers in Segment 1 already have commercial scale facilities and tech transfers (TTs) underway or complete and are relatively close to commercialization
- 5 Additional suppliers in Segment 2 have commercial scale facilities qualified and are ready to receive TTs
- The remaining 15 suppliers in Segment 3 are still in development stages
- Rationalizing AVM projects remains an ongoing need as the long tail of pipeline projects may face challenges to gain a viable market share

South Africa

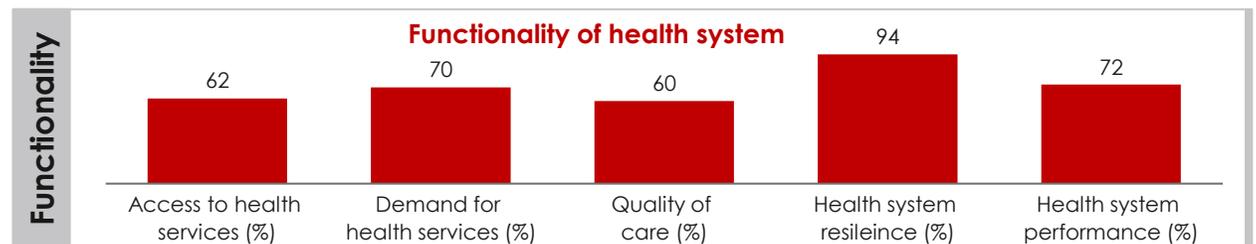
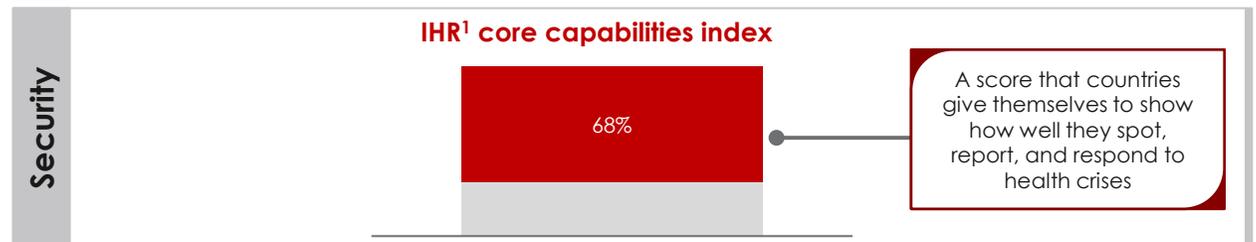
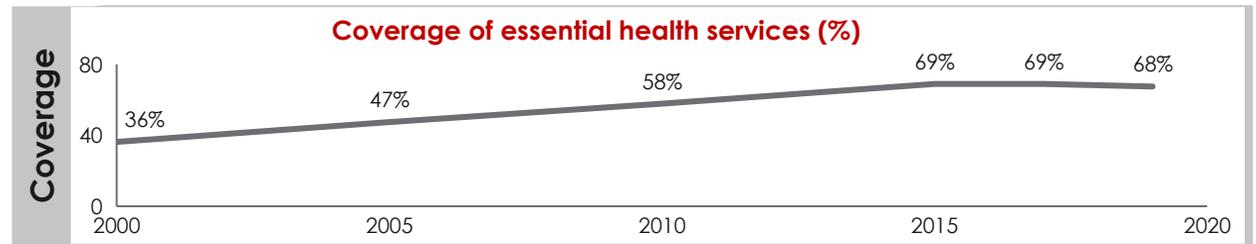
Advanced healthcare system, with modern facilities across the country



South Africa boasts ~20,000 registered hospitals and clinics across 9 provinces ...



... and offers a high-quality, functional and efficient health care system



1. International Health Regulations;
Source: [MEDPAGES: Hospitals and Clinics in South Africa](#); [WHO: Atlas of African Health Statistics 2022](#)



Strong network of R&D institutions, with top-class clinical trial infrastructure



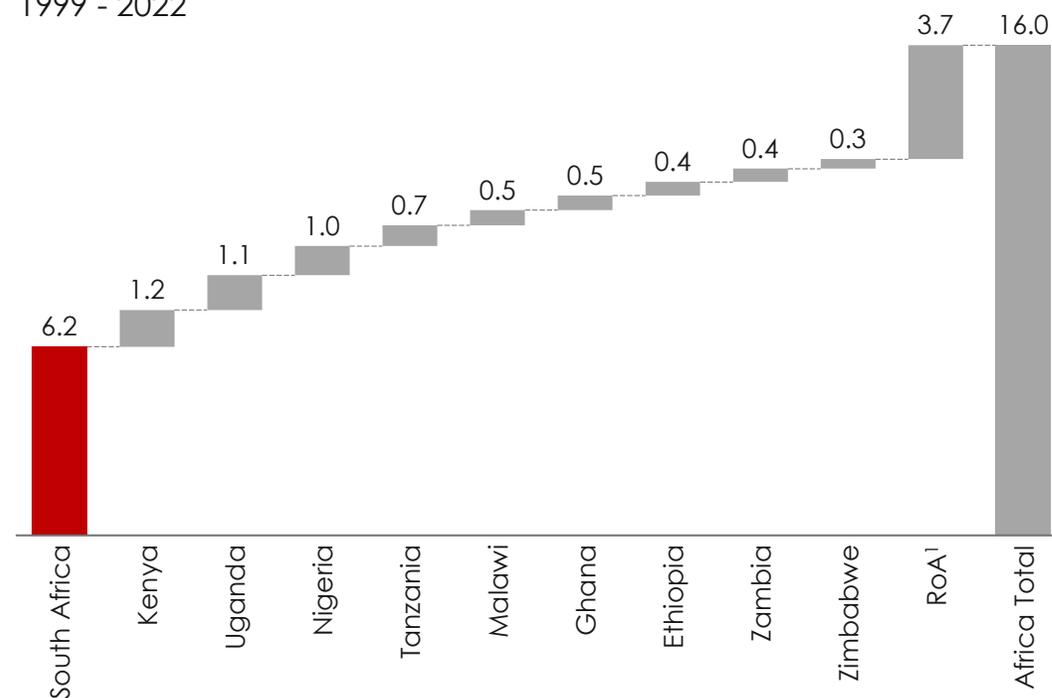
South Africa is home to major continental R&D institutions



South Africa accounts for approximately 40% of clinical trials conducted on the African continent



Number of clinical trial registrations ('000) 1999 - 2022



1. Rest of Africa
Source: [WHO: Clinical Trial Data](#); press search



Established ecosystem with a significant presence of biopharma companies

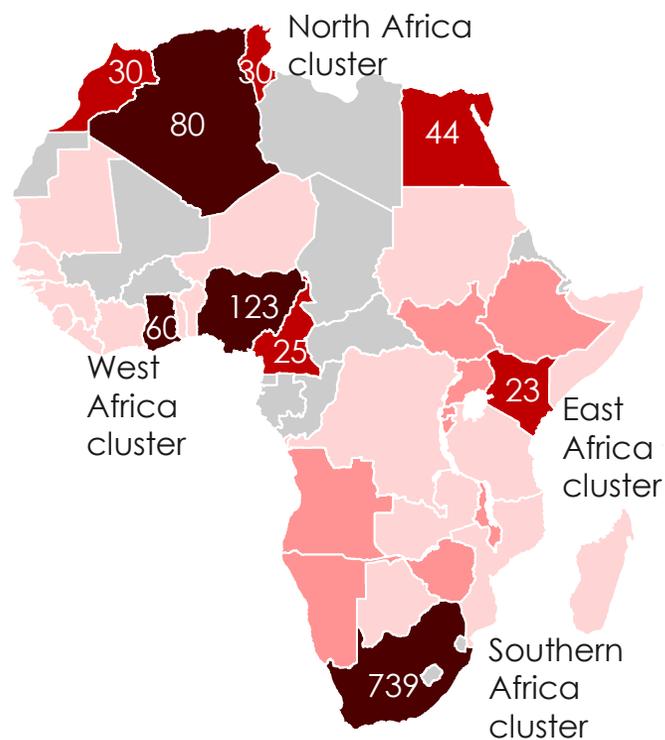
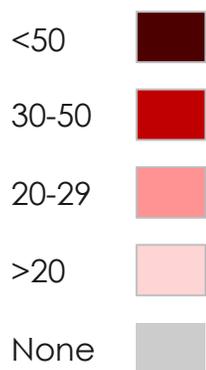


South Africa has the largest concentration of pharmaceutical companies in Africa



Examples of key biopharma companies in South Africa include...

Number of pharmaceutical manufacturers per country (in 2022)

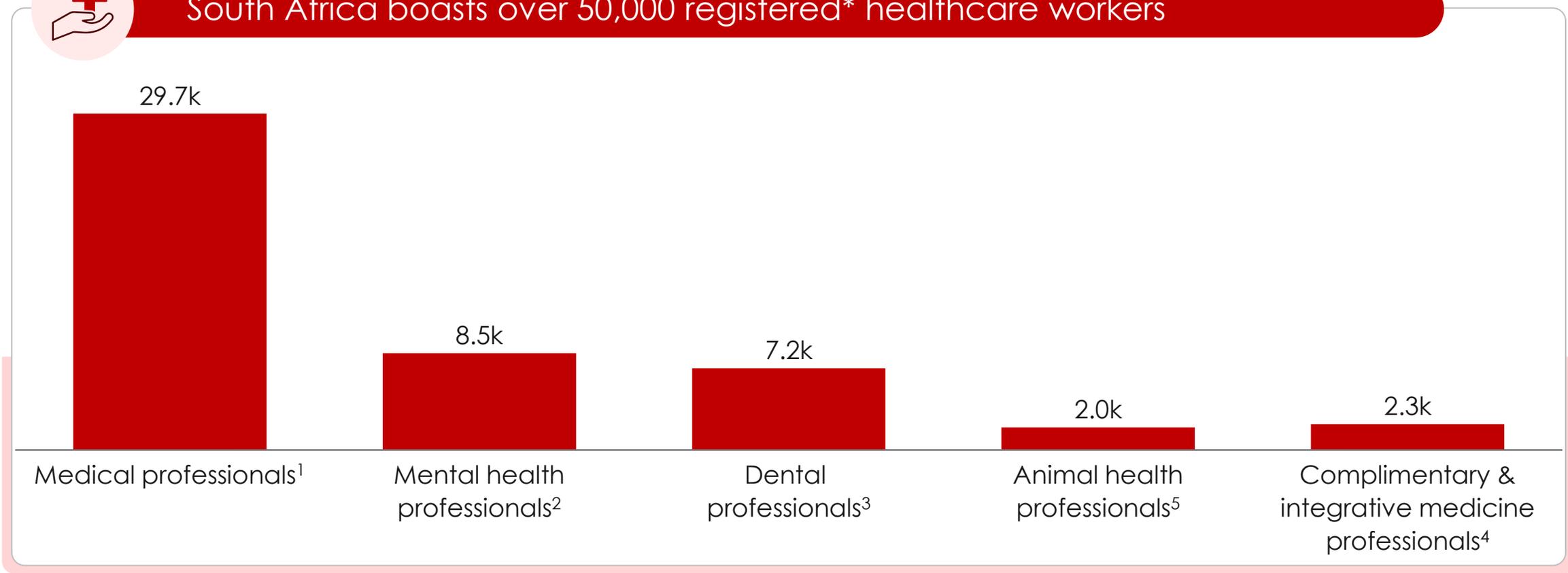




Relatively large talent pool of skilled healthcare professionals



South Africa boasts over 50,000 registered* healthcare workers

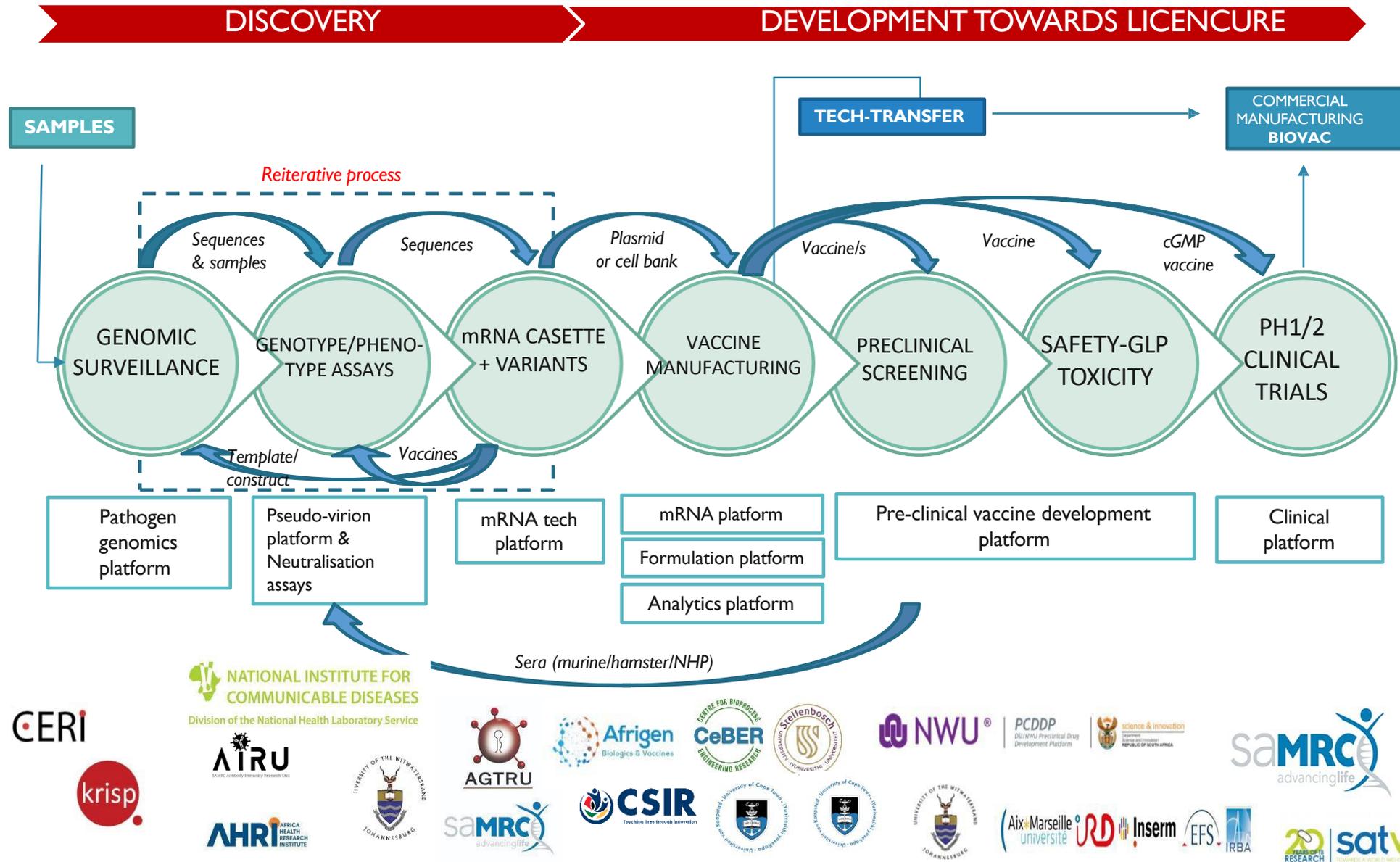


1. Medical professionals include medical doctors across different specialisations; 2. Mental health professionals include psychologists and counsellors; 3. Dental professionals include dentists, oral hygienist, orthodontists, etc.; 4. Complimentary and integrative medicine professionals include acupuncturist, chiropractor, etc. ; 5. Animal health professionals include veterinary practitioners; 6. Health and fitness professionals include personal trainers and nutritionists

Note: * Data represents medical professionals registered on Medpages

Source: [MEDPAGES](#)

Vaccine development value chain in South Africa: Public Private Partnerships

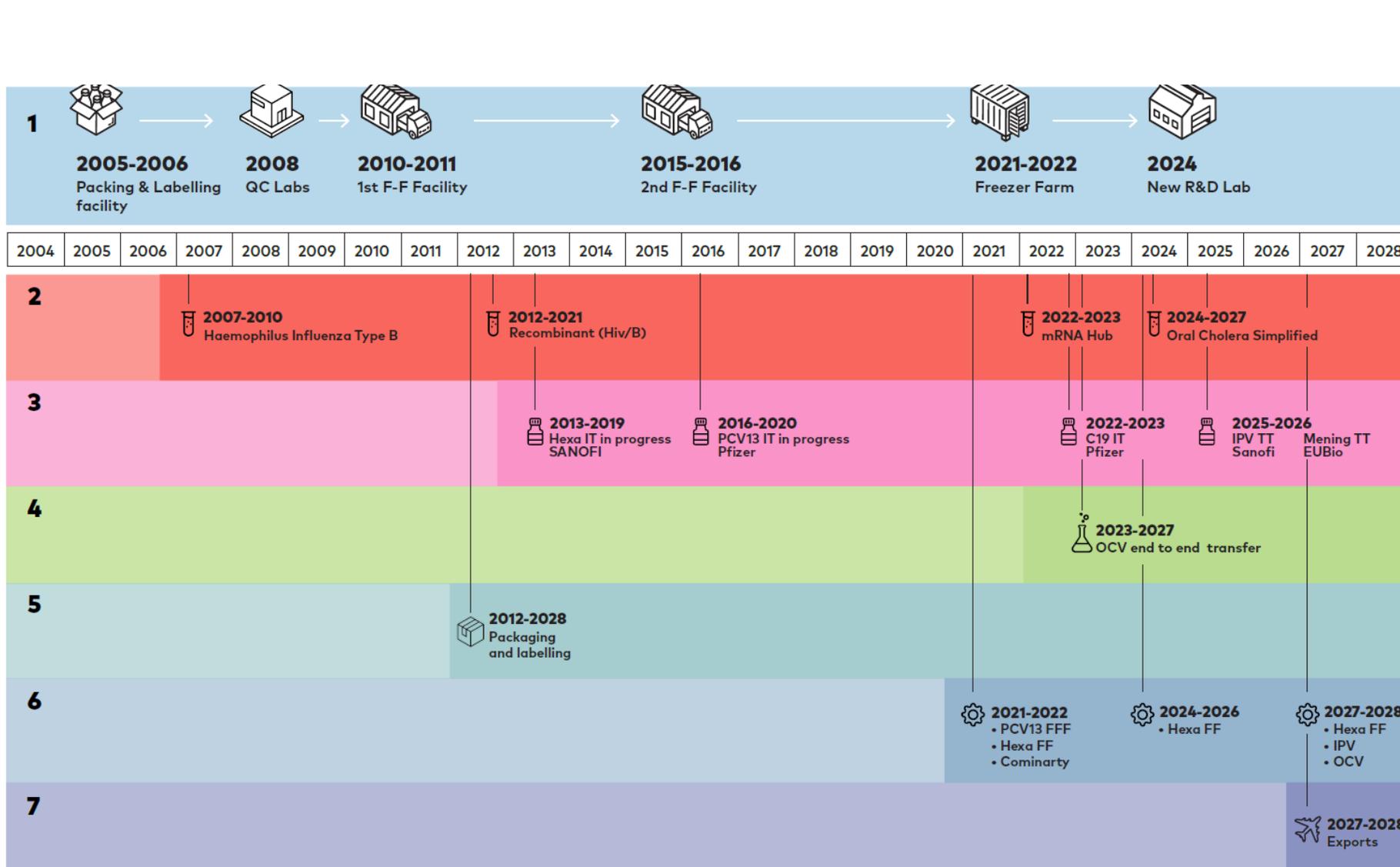


BUILDING VACCINE MANUFACTURING CAPABILITY AT THE SOUTHERN TIP OF AFRICA

Biovac: Building Africa's Vaccine Independence



Less than 1% of vaccines used in Africa are made locally. Through funding we aim to become Africa's first end-to-end vaccine manufacturer, reducing reliance on imports and ensuring supply security.



Growth Through Funding
Funding enabled Biovac to expand step by step—from vaccine filling to packaging, full-scale production, and exports.

Facilities Built
Built new vaccine production sites, including fill-finish facilities, packaging, R&D labs, and cold storage.

Product development
Developed vaccines like Haemophilus Influenza Type B, IPV, and Oral Cholera to reduce reliance on imports.

Technology transfer
Partnered with Pfizer and Sanofi to bring advanced vaccine technology to Africa for local production.

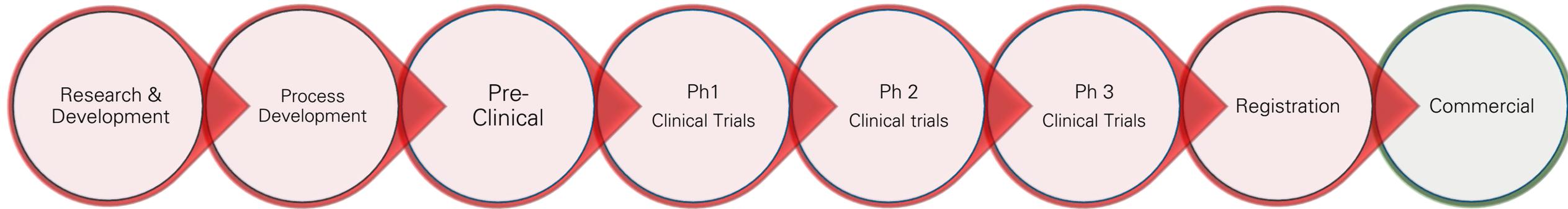
Drug Substance
Launched in-house drug substance manufacturing to control key production steps and reduce reliance on global supply chains.

Packaging and labelling
Developed packaging and labelling capabilities to meet regulatory standards for local and export markets.

Fill Finish (routine)
Expanded local vaccine production with fill-finish operations for faster delivery across Africa.

Exports
Scaling up to supply Africa and global markets, with WHO prequalification in progress.

TYPICAL VACCINE DEVELOPMENT PROCESS



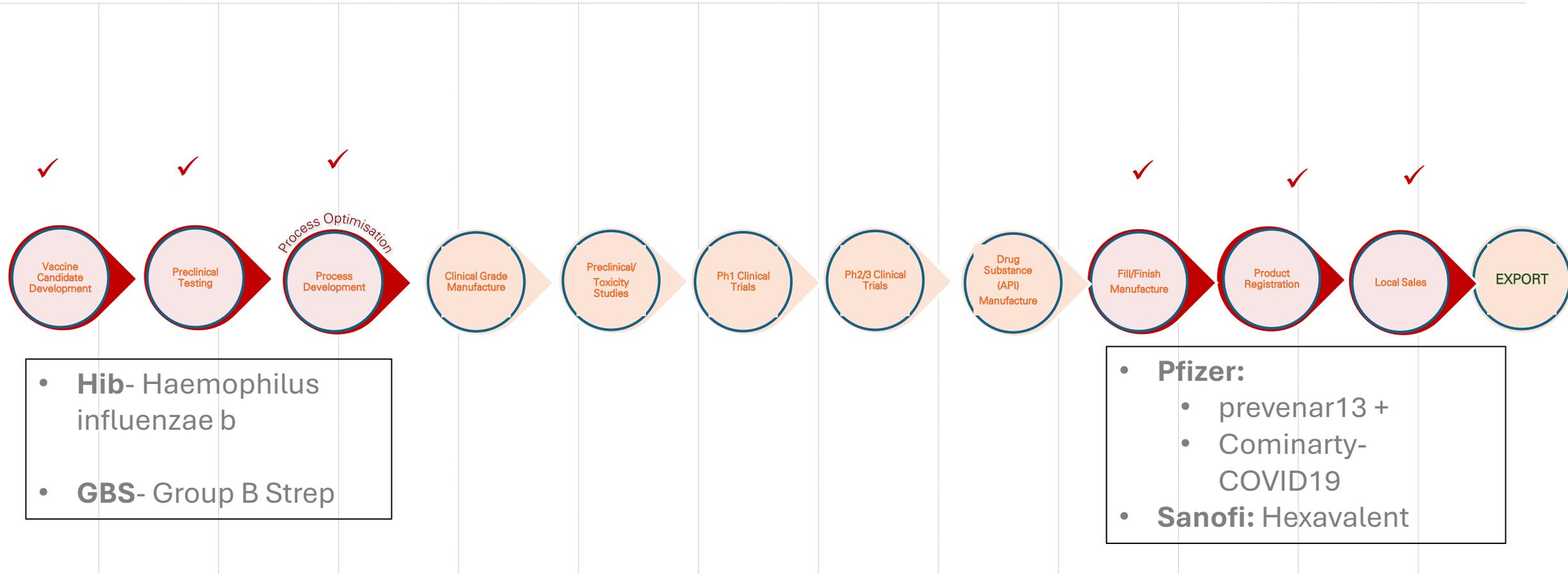
World Health Organisation

Technical Report Series, No. 927, 2005

Annex 1: WHO guidelines on nonclinical evaluation of vaccine

1. In vitro potency
2. Immunology in relevant animal model
3. Challenge test in relevant animal model
4. Product characterization (CMC)
5. Toxicology evaluation
6. Production of cGMP lots for Clinical Trials

BIOVAC VACCINE DEVELOPMENT VALUE CHAIN: PRE-COVID 2006-2020



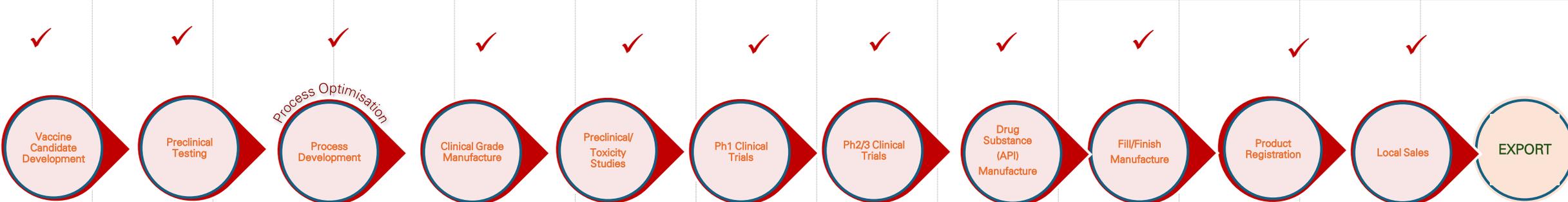
BIOVAC VACCINE DEVELOPMENT VALUE CHAIN: Post COVID - 2026 STATUS



Post-COVID

- Oral Cholera Vaccine (OCV)

- **OCV**- end to end Biovac project
- **Injectable Polio Vaccine** (FF Sanofi tech transfer)
- **Pneumo Conjugate Vaccine14** (FF BioE tech transfer)
- **Meningitis- 5 valent**(FF Eubiotics tech transfer)



Pre-COVID

- Hib- Haemophilus influenzae b
- GBS- Group B Strep

- Pfizer
 - Prevenar13
 - Cominarty
- Sanofi
 - Hexavalent

CASE STUDY OF DEVELOPING END TO END VACCINE MANUFACTURING AND DEVELOPMENT

Overall: Status and Progress



Sending unit	Receiving unit
IVI	Biovac



Tech transfer Scope

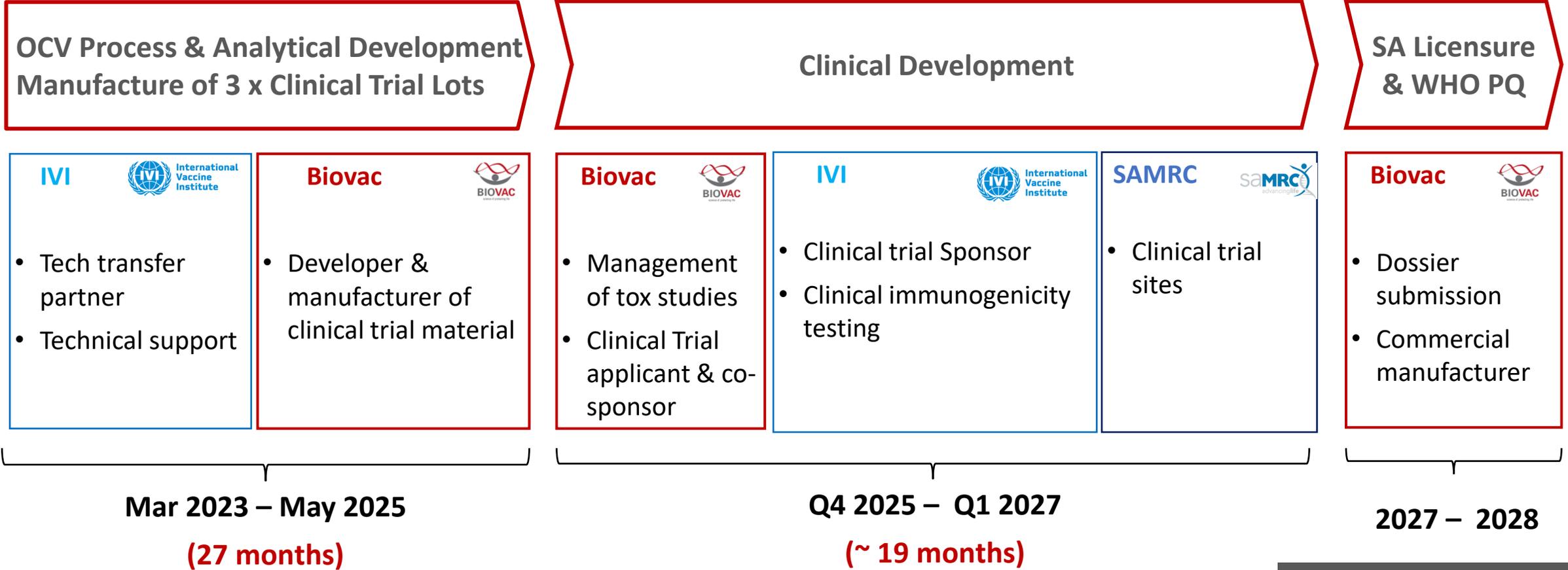
1. Process and Analytical method transfer from cell bank to DP formulation
2. CMC support through scale up from IVI
3. Oversight of clinical study based on Euvichol-S

Pre-tech transfer site assessment, Training at IVI for 3 weeks, Witnessing & closure by IVI team of 2L scale process at Biovac, Tech transfer report and GARAMP, Consultancy on manufacturing facility design

Target Product – Biovac OCV
Bivalent Cholera Vaccine: strains O1 Inaba & Ogawa. Oral, whole cell, 2-dose vaccine

Project Milestone	Deliverable
Tech transfer	Receive training at sending unit Implement technology at 2L scale
Scale up: 20L + Facility readiness	Scale up to 20L, Development of CPPs + Qualification of assays
Scale up: 200L	Prep of GMP cell banks , Scale up to 200L, Assay validation
Eng + CTM batches	Engineering runs, Clinical trial batches
Clin study	Protocols and Ph I / Ph III clinical trial, Licensure in SA. WHO PQ
Optimization: Ahead of PPQ Q2 2025	Improving tires and design for further scale to 1000L +, and robustness for PPQ readiness

GLOBAL & LOCAL PARTNERSHIPS AND SUPPORT



PQ timelines can be expedited with parallel review of dossiers or should SAHPRA be WLA-listed authority

Oral Cholera Vaccine Development Progress



1
Pre-Clinical
Development

2
Facility

3
Clinical Trial Material
Manufacture

4
Clinical
Development

5
Licensure

2022-2024

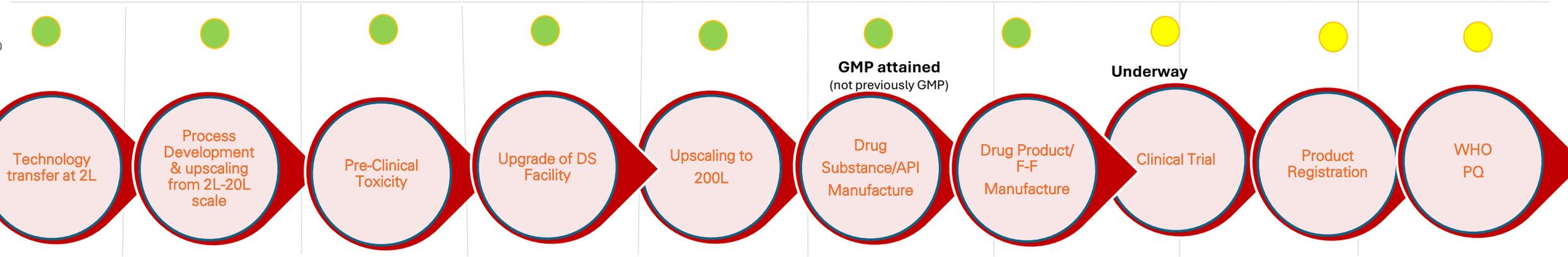
2023/4

2024/5

2025/6/7

2028/9

Progress



Partners

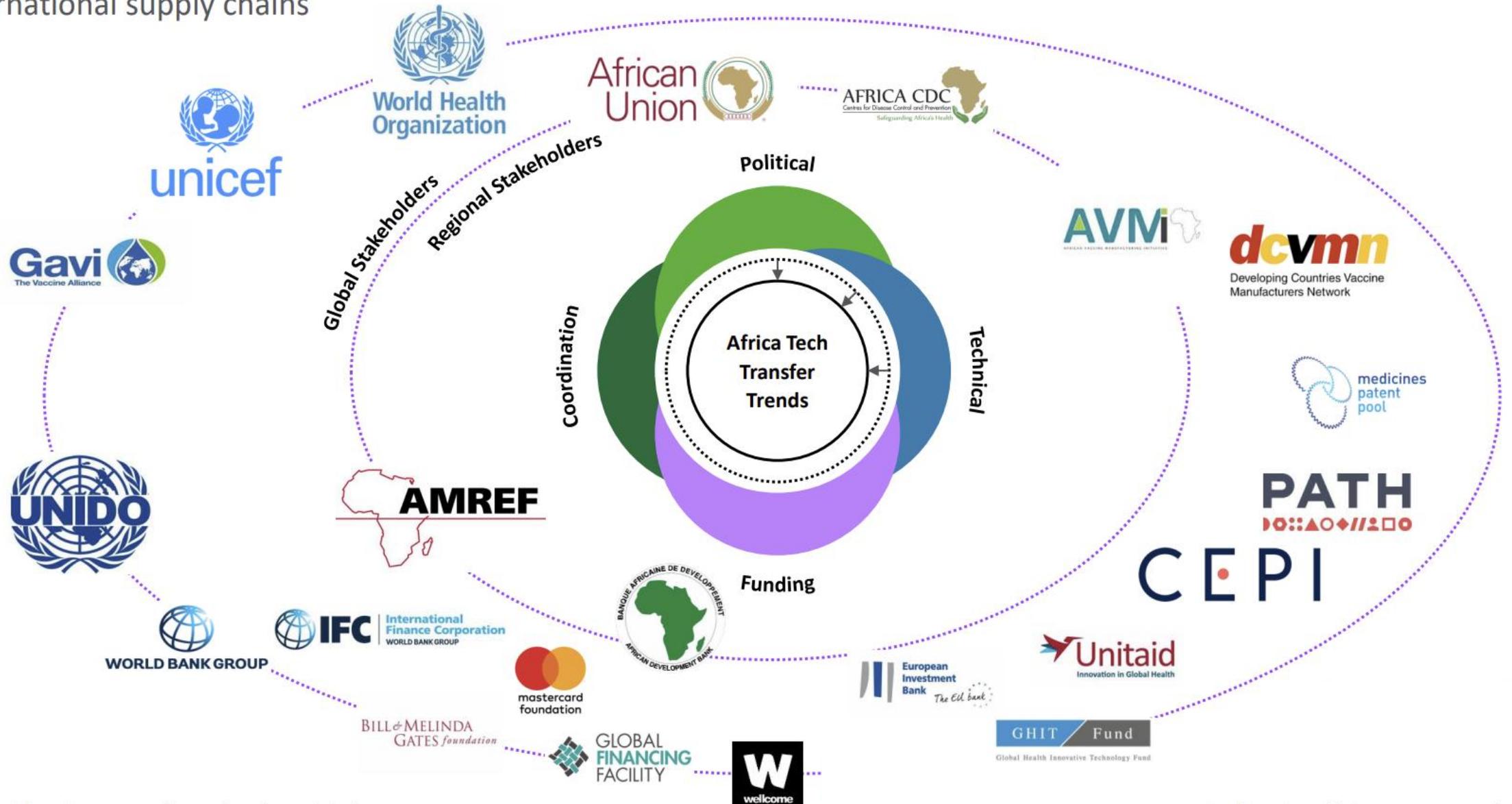


Support



The ecosystem relevant to technical transfers in Africa involves a broad range of stakeholders

Regional stakeholders are the main drivers of planning and the calls for building Africa's capacity to reduce reliance on international supply chains



AFRICA'S VALUE PROPOSITION IN VACCINES & IMMUNISATION



- 1) Biggest population by 2050
- 2) Epidemiological Diversity & Disease Burden (Real-World Evidence Engine)
- 3) Genetic & Immunological Diversity (Gold Standard for Vaccine Robustness)
- 4) World-Class Clinical Trial Infrastructure (Especially South Africa)
- 5) Manufacturing & Innovation Potential (Strategic Geopolitical Value)
- 6) Cost-Efficient, High-Impact Research Environment
- 7) Implementation Science & Health Systems Innovation

Thank You