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Biovac in the context of COVID-19

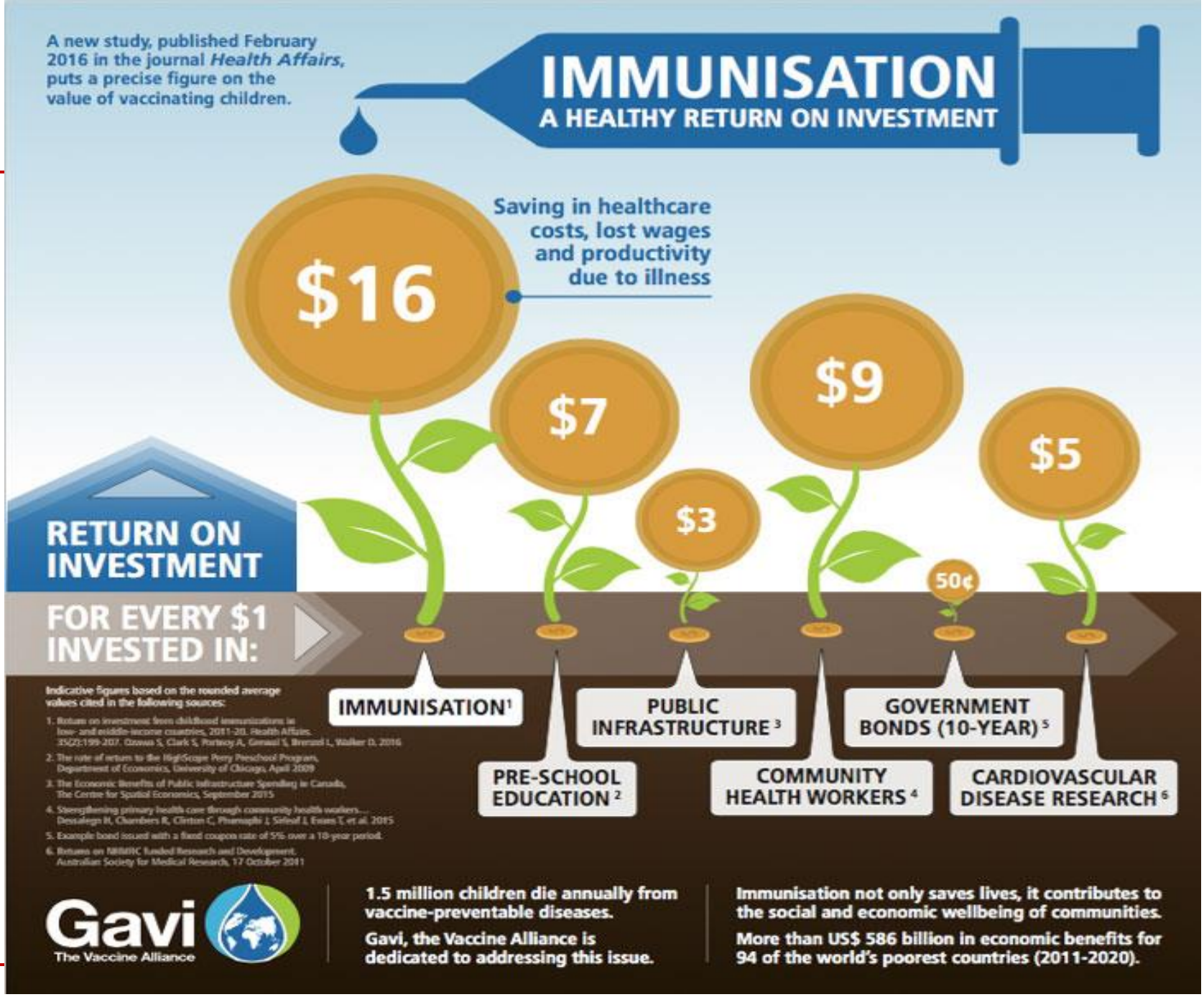
Outline of Presentation

1. Vaccine Market

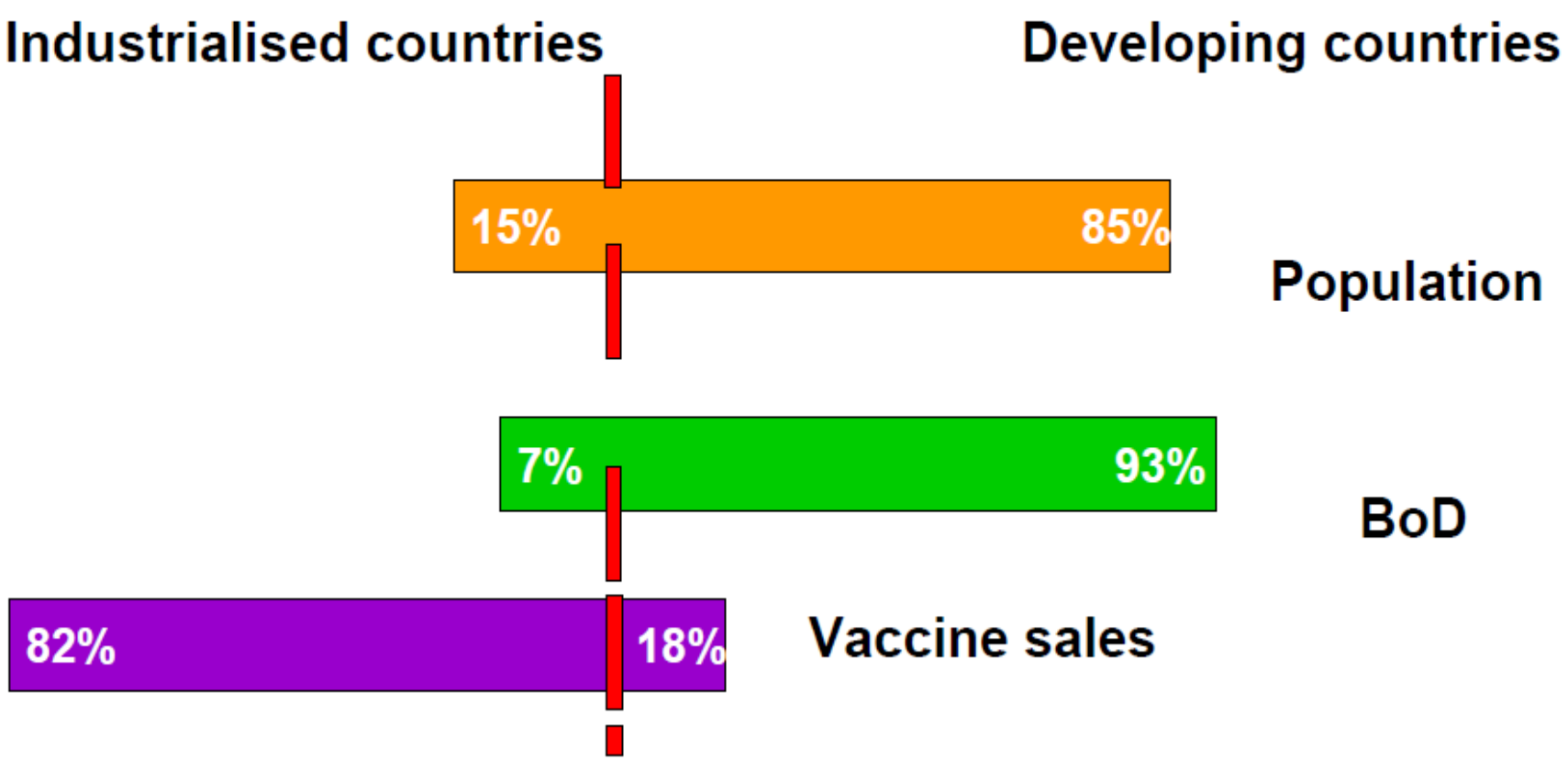
2.About Biovac

3.COVID-19 Vaccines manufacturing possibility

1. Vaccine Market


A new study, published February 2016 in the journal *Health Affairs*, puts a precise figure on the value of vaccinating children.
IMMUNISATION
A HEALTHY RETURN ON INVESTMENT
$16
Saving in healthcare costs, lost wages and productivity due to illness
$7
$3
$9
50¢
$5
RETURN ON INVESTMENT
FOR EVERY $1 INVESTED IN:
IMMUNISATION[1]
PRE-SCHOOL EDUCATION[2]
PUBLIC INFRASTRUCTURE[3]
COMMUNITY HEALTH WORKERS[4]
GOVERNMENT BONDS (10-YEAR)[5]
CARDIOVASCULAR DISEASE RESEARCH[6]
Indicative figures based on the rounded average values cited in the following sources:
1. Return on investment from childhood immunizations in low- and middle-income countries, 2011-20. Health Affairs. 35(2):199-207. Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker D. 2016
2. The rate of return to the HighScope Perry Preschool Program, Department of Economics, University of Chicago, April 2009
3. The Economic Benefits of Public Infrastructure Spending in Canada, The Centre for Spatial Economics, September 2015
4. Strengthening primary health care through community health workers... Dessalegn M, Chambers R, Clinton C, Pharmphil J, Sirinof J, Evans T, et al. 2015
5. Example bond issued with a fixed coupon rate of 5% over a 10-year period.
6. Returns on NHMRC funded Research and Development. Australian Society for Medical Research, 17 October 2011
Gavi
The Vaccine Alliance
1.5 million children die annually from vaccine-preventable diseases.
Gavi, the Vaccine Alliance is dedicated to addressing this issue.
Immunisation not only saves lives, it contributes to the social and economic wellbeing of communities.
More than US$ 586 billion in economic benefits for 94 of the world's poorest countries (2011-2020).

Vaccine Industry - Globally



BoD= burden of Disease

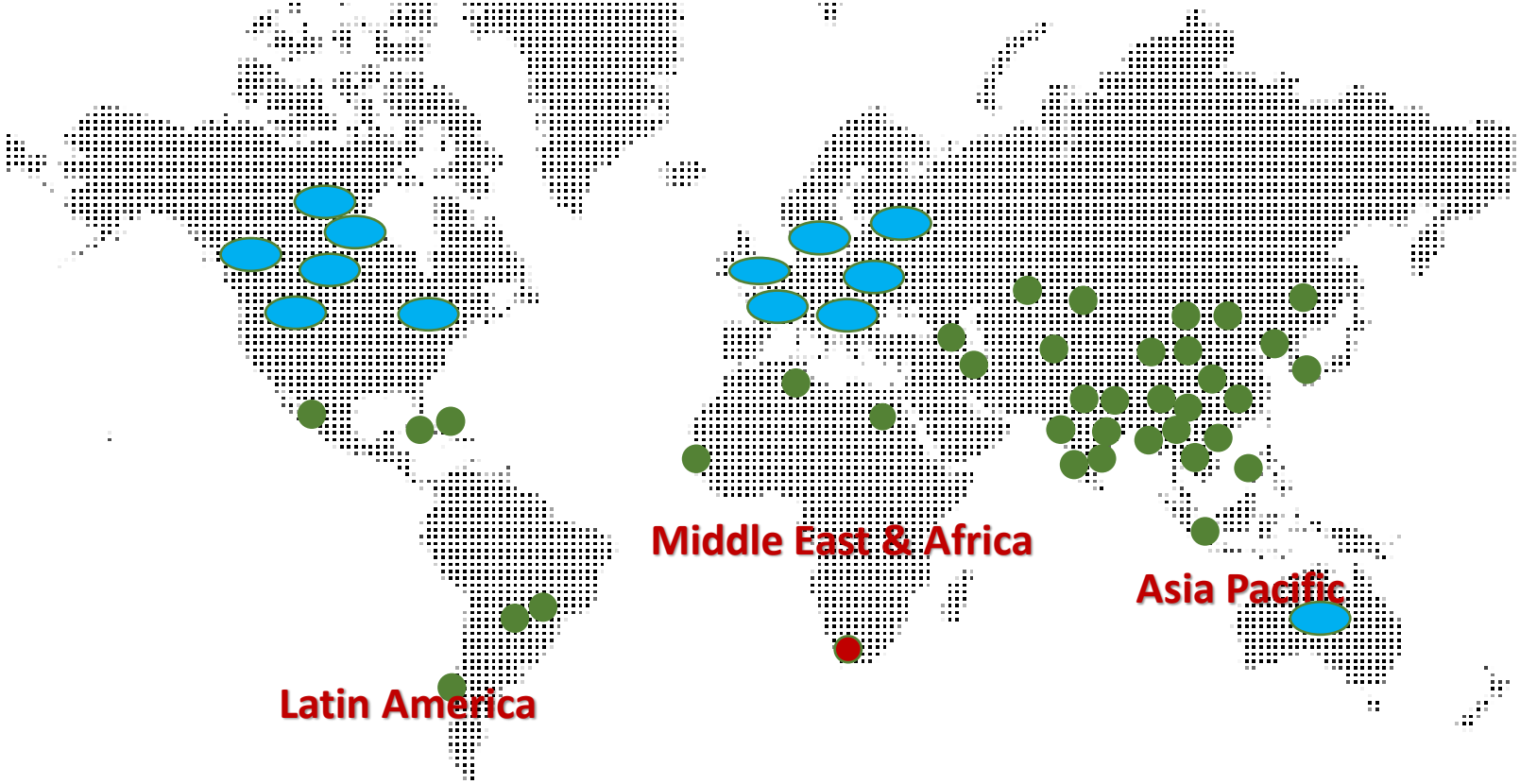
Human Vaccine Manufacturers

Multinational

About **80%** of global vaccine sales come from five large multi-national corporations (MNC) that were the product of various mergers and acquisitions of pharmaceutical companies over the past decades-WHO

Developing world manufacturers

They now supply about half of UNICEF's vaccine procurement in volume of doses, representing about **30%** of the value of UNICEF's total vaccine procurement- WHO



Africa has limited vaccine purchasing capacity: Donor dependent

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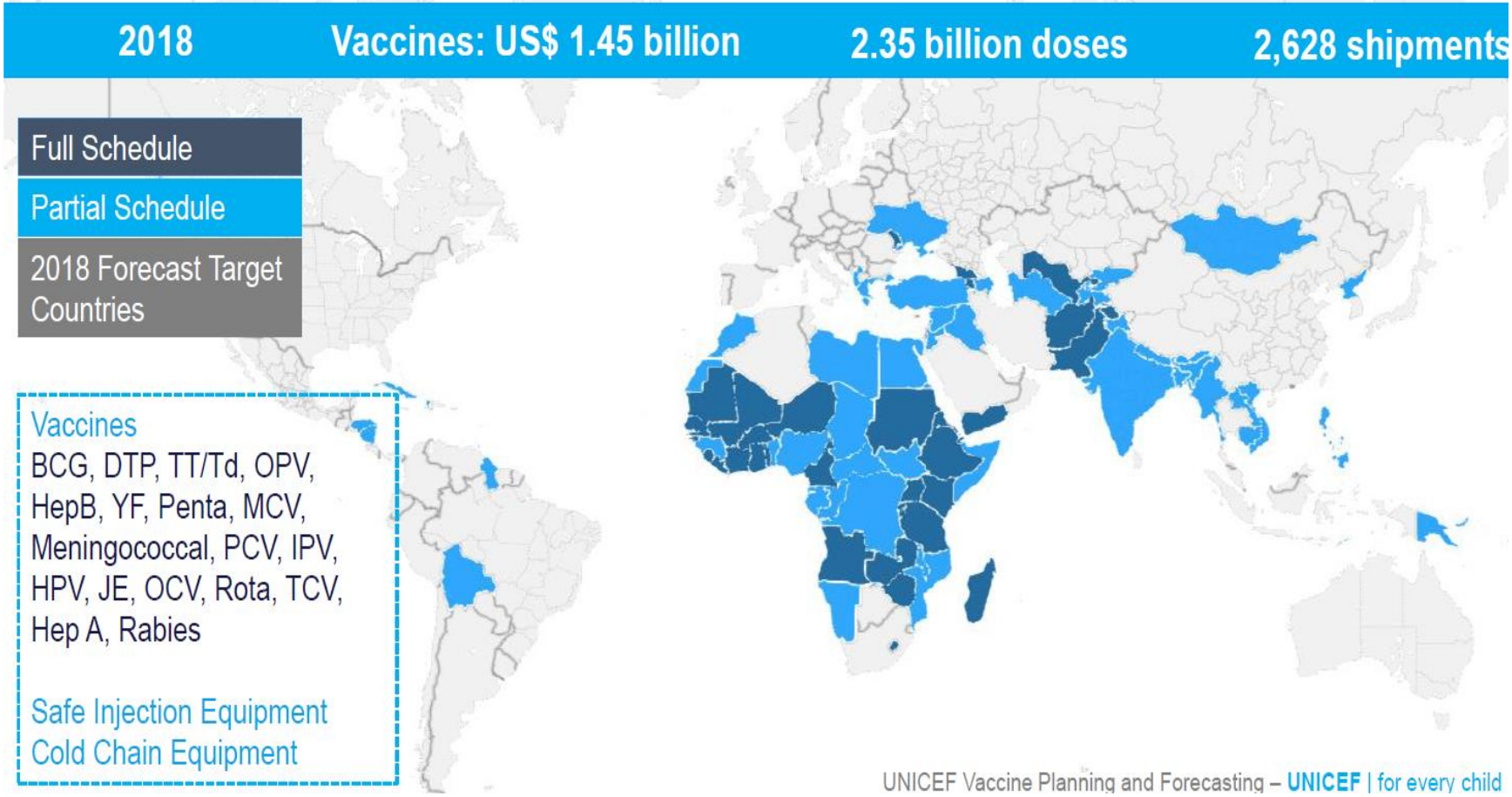

Technology Transfers take 5- 7 years

(under normal circumstances)

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"before conducting transfer of technology it is important to look beyond 5–10 years to see what the long-term value of the product is. This is especially true for vaccines, where even with transfer of a mature technology it may take up to 5–7 years for the locally produced product to be tested and licensed, by which time the market may have changed."

Source: WHO – Increasing access to vaccine through technology transfer, 2011

2. About Biovac

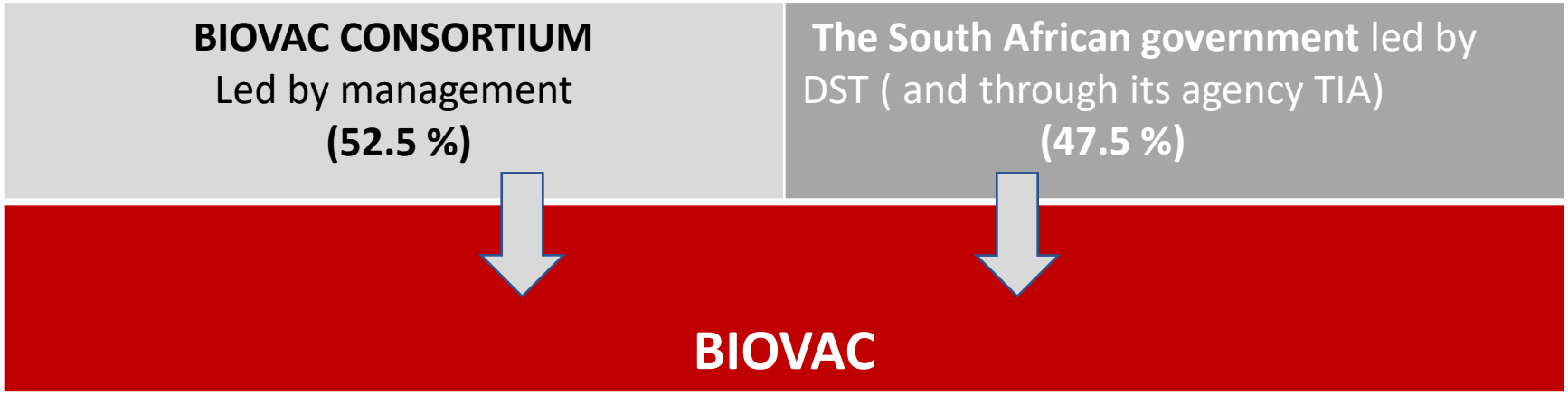
History: ….prior 2000

- **South Africa once used to have vaccine manufacturing capability as below**
- **All entities were state owned**

Name	Established	Production	Ceased
National Institute of Virology (NIV)	1950's	Oral polio Yellow fever	1995
SAIMR	1935	antivenoms typhoid	2000
State Vaccine Institute (SVI)	1965	Rabies, human growth hormone, small pox	2001

- All the capability was lost and the last vaccine that was produced was percutaneous BCG in 2001
- During the late 90's a decision was made to revive vaccine manufacture but that the state should not have a majority stake. That it should be built with Public Private Partnership (PPP) principles

Public Private Partnership*
(2003- June 2020)



Mandates given to Biovac by government:

1. Establish vaccine manufacturing capacity

2. Supply uninterrupted EPI Vaccines*

*Formal PPP ends in June 2020. Biovac now needs to participate in tender procurement

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Establish domestic vaccine production capacity

Ensure economic viability

Develop and retain local vaccine production skills

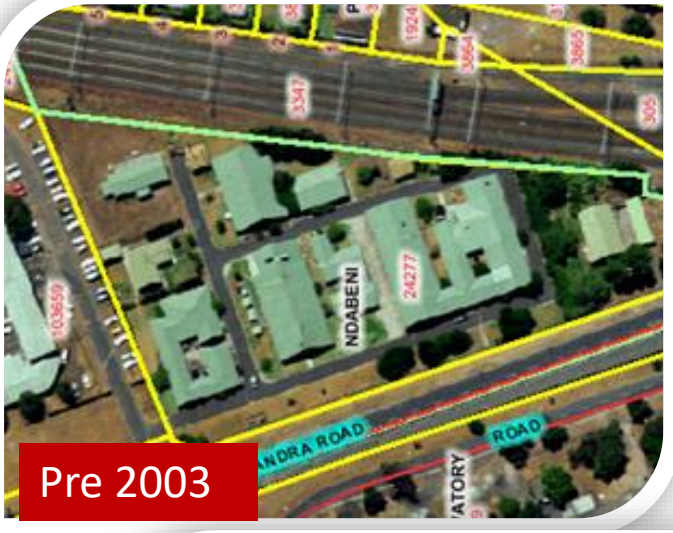
To be a Centre of Excellence rooted in Africa for the development and manufacture of affordable quality vaccines for Africa and the developing world's needs

Establish strong R&D capability

Create a competitive platform for export

Enable BBBEE

Infrastructure



Pre 2003

2005-2008

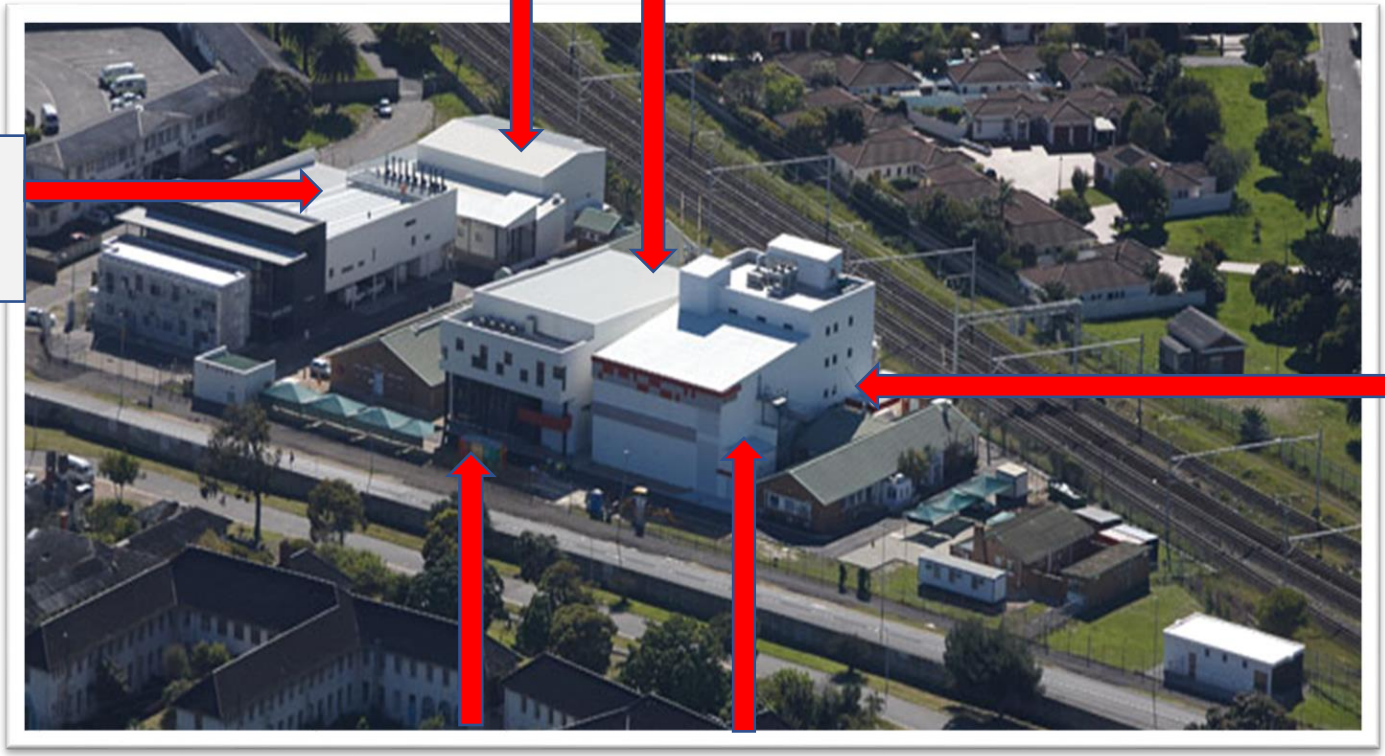
2009-2020

Infrastructure

Building I
Cold room storage
Manual and Automated Inspection

Building C
Aseptic vial manufacturing facility

Building A
QC Labs



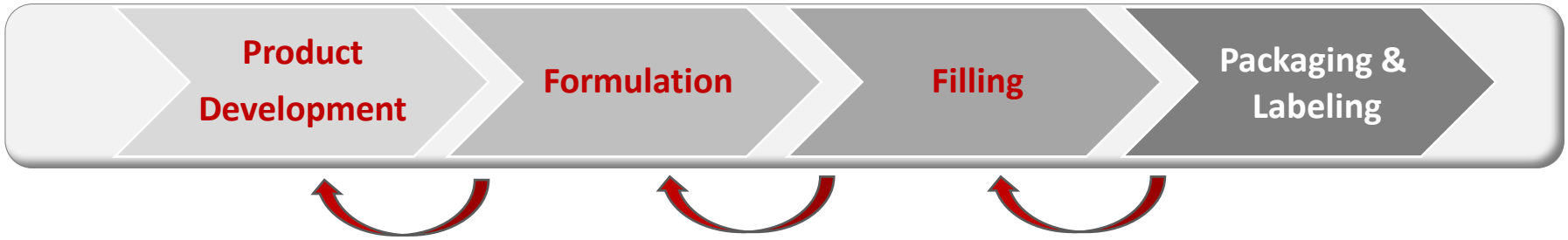
Building C1
, Labelling & Packaging

Building C
API (fermentation & purification) manufacturing facility

Building C1
Aseptic pre-filled syringe manufacturing facility

Vaccine Manufacturing Infrastructure

Reverse Integration Strategy



4th transition
bacterial vaccines

3rd transition

2nd transition

1st transition

Internal vaccine development: GBS	Technology transfer with Pfizer	Technology transfer with Sanofi	Packaging of 5 vaccines under cold chain conditions

Human Capital Overview:

Building a transformed biotech company

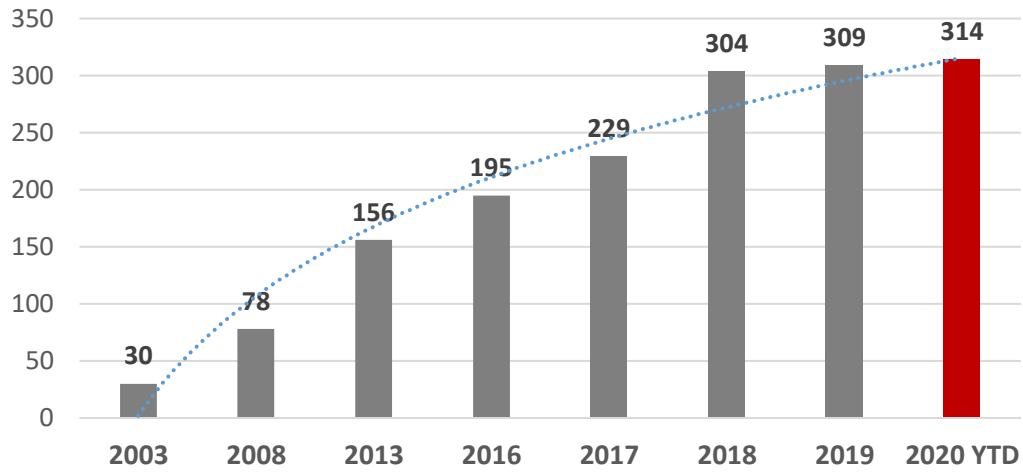
Headcount
314

Turnover
'19: 4.04%
'20: 2.5%

BEE LEVEL 1

- Shareholders
- Management Control
- Employment Equity
- Enterprise/ Supplier Development
- Community Development

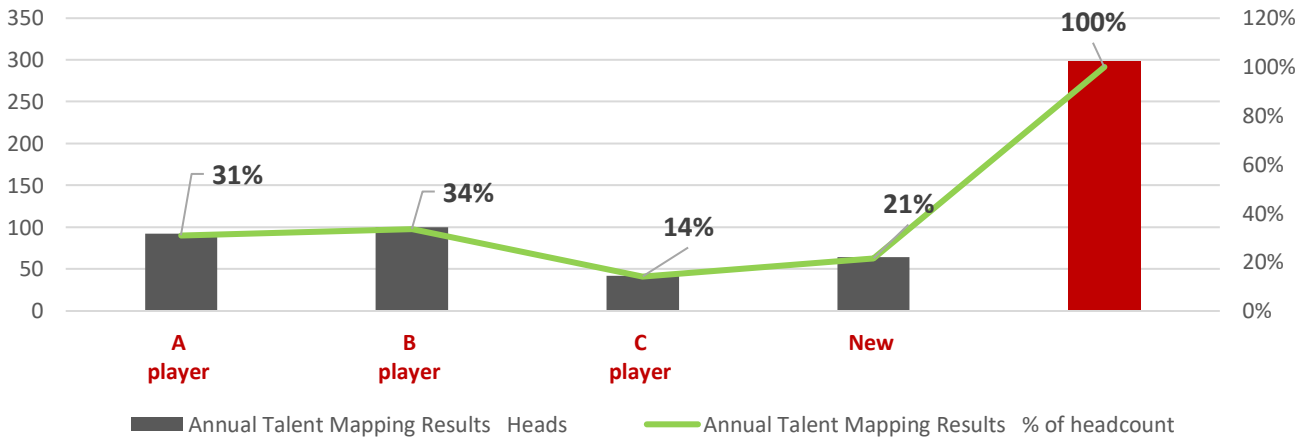
Headcount Growth 2003 - 2020



Our Team Diversity Portfolio

Females	58%
Black Employees	90%
Emp with Disabilities	2%

Our Internal Talent Map

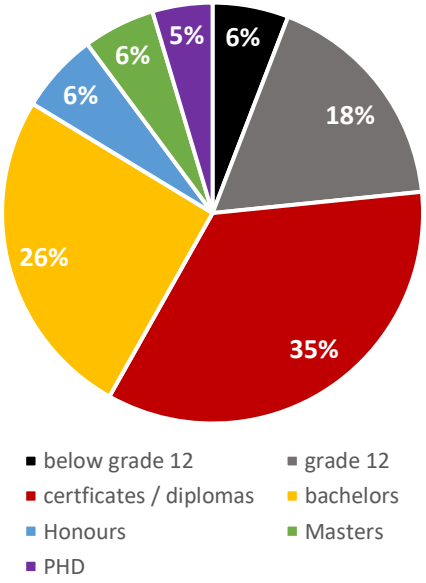


Attracting & Developing Skills within our Industry

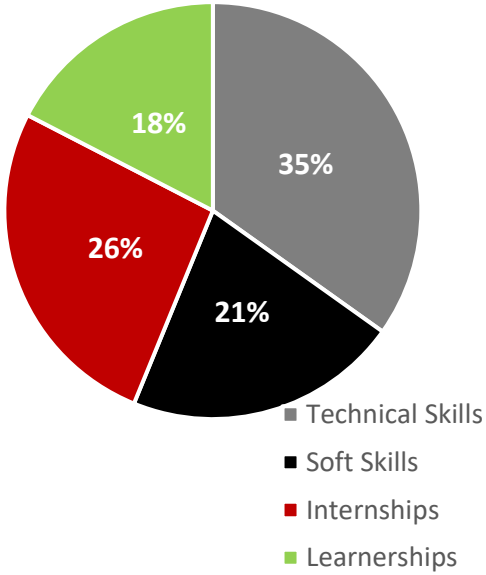
Sourcing Core Scientific Skills:

- Internal staff referrals
- Agency – Sci staff
- UCT Job boards
- UCT student referrals
- LinkedIn
- Interns mainly from CPUT/ Stellenbosch

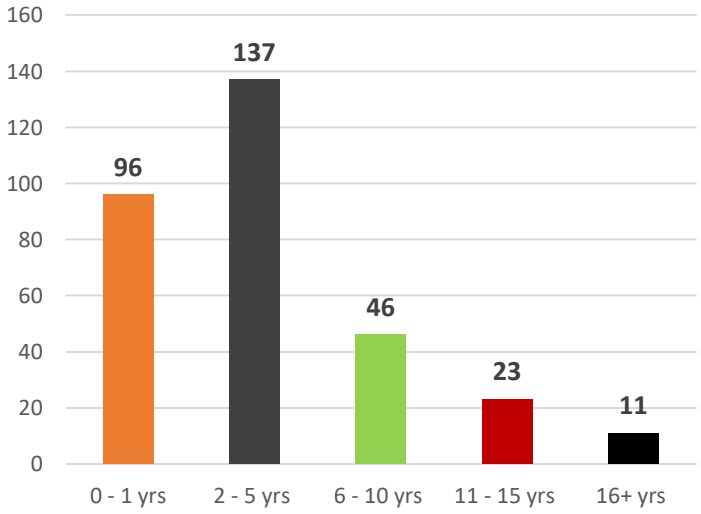
Current Education Credentials:



Skills Development Spend (4% of payroll):



Employee Tenure



Year	Interns recruited	Total Interns absorbed post Internship
2019	11	27%
2018	13	77%
2017	17	71%
2016	15	87%
2015	12	67%

Trade Balance Impact Assessment

Biovac contributing R650m economic benefit to the economy

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Biovac Packaging & Distribution

Biovac Formulation & Filling

Trade Balance = Exports - Imports

Trade Balance = Exports R48 million – R1.47 billion

Trade Balance = -R1.42 billion

Assumption: Biovac cost and import reduction due to local packaging

Trade Balance = Exports R48 million – R1.16 billion

Trade Balance = -R1.12 billion

Assumption: Biovac cost and import reduction due to local filling & formulation

-R1.42 billion < -R1.12 billion

-R1.77 billion

R650 million benefit to the South African Economy,annually

-R1.12 billion

Note: *Biovac estimates

Source: Frost & Sullivan

3. COVID-19 VACCINE IN SOUTH AFRICA- FOR AFRICA

Africa was not prepared for a flu pandemic -Not Prepared for COVID-19 vaccines

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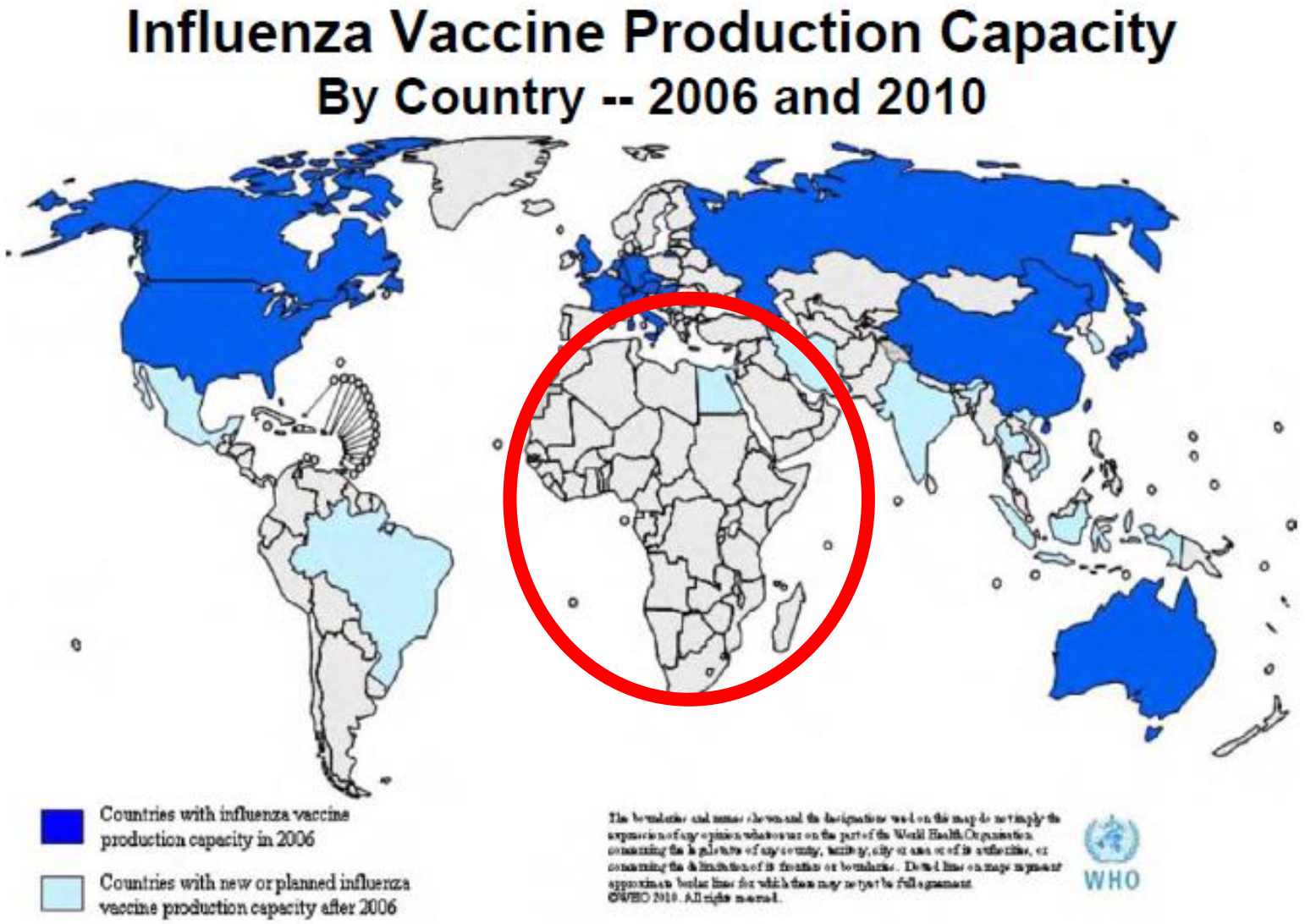

Of the global COVID vaccine candidates, what can Biovac possibly manufacture?

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Platform/type of vaccine	Developer	API	Formulation /Fill	Finish
		Ability of Biovac to manufacture in current facilities		
RNA-based vaccines virus gene(s) mainly S gene derived	Moderna/NIAID Pfizer/ BioNtech Sanofi/Translate Bio			
DNA vaccines S gene derived	Innovio			
Inactivated whole virion vaccines	Sinovac			
Replicating Viral Vector Recomb live VSV or measles viruses	IAVI/Batavia Institute Pasteur)		**Requires biosafety**	
Non-Replicating Viral Vector Adenovirus-with S gene	Oxford University Janssen			
MVA expressing VLPs	Geovax			
Protein subunit S protein derivatives made in tissue/cell culture	Sanofi/GSK; Univ. Queensland/ Dynavax/ GSK/CEPI; Clover Biopharmaceuticals (China)/GSK/Dynavax			
S protein derivatives made in plants/ S protein-based VLPs	Medicago; BAT/KBP;			
S protein derivatives made in yeast cell culture	TechInvention			

Short Term vs Long term ability to manufacture

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Biovac capacity	Current / Short Term view (0 – 18 months)	Future / Long Term view (4 – 7 years)
Drug Product (Formulation, Fill, Finish)	**Number of doses that can be filled:** Capacity per annum: 10 million vials and 12 million prefilled syringes **Readiness:** Facility available immediately Technology transfer activities can start in 3 months Product readiness: 12 – 18 months dependent on technology	**Investment in larger, flexible, containment facility required for pandemic readiness & possibly future HIV vaccines** **Number of doses that can be filled:** 50 - 100 million doses **Facility readiness timelines:** 3 – 5 years An expanded facility could create an addition 500 (science-related) jobs
Regulatory approval	Commercial manufacturing can be expedited through ongoing collaboration with SAHPRA throughout the roll out.	

Summary

- **Packaging, Labelling and Distribution:**

Biovac is well positioned to handle any of the vaccine products in development assuming vial or pre-filled syringe (pfs) presentations and normal cold chain requirements.

- **Formulation and Filling:**

Biovac's current formulation and filling facilities are limited to liquid presentations in vials or pfs. Live virus vaccines cannot be processed in the current form/fill facilities as they do not meet the required biosafety standards for live virus vaccines

- **API Manufacture:**

Existing API facilities at Biovac could be modified to manufacture most of the vaccine candidates in the current pipeline at small scale and with varying degrees of effort and expense (and time), except those produced through plant-based technologies.

- **Large scale production:**

requires investment in a new facility

What is needed?

No one partner or entity can do it on their own

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BIOVAC + **Technology Transfer Partner** + **Enabling Environment** = **SA MADE VACCINE FOR SA AND AFRICA**

PEOPLE

PROCESS

SUSTAINABLE PROCUREMENT FRAMEWORK

FACILITIES

PRODUCT

Development Finance

EQUIPMENT

REGULATORY

THANK YOU

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