African Vaccine Manufacturing Initiative

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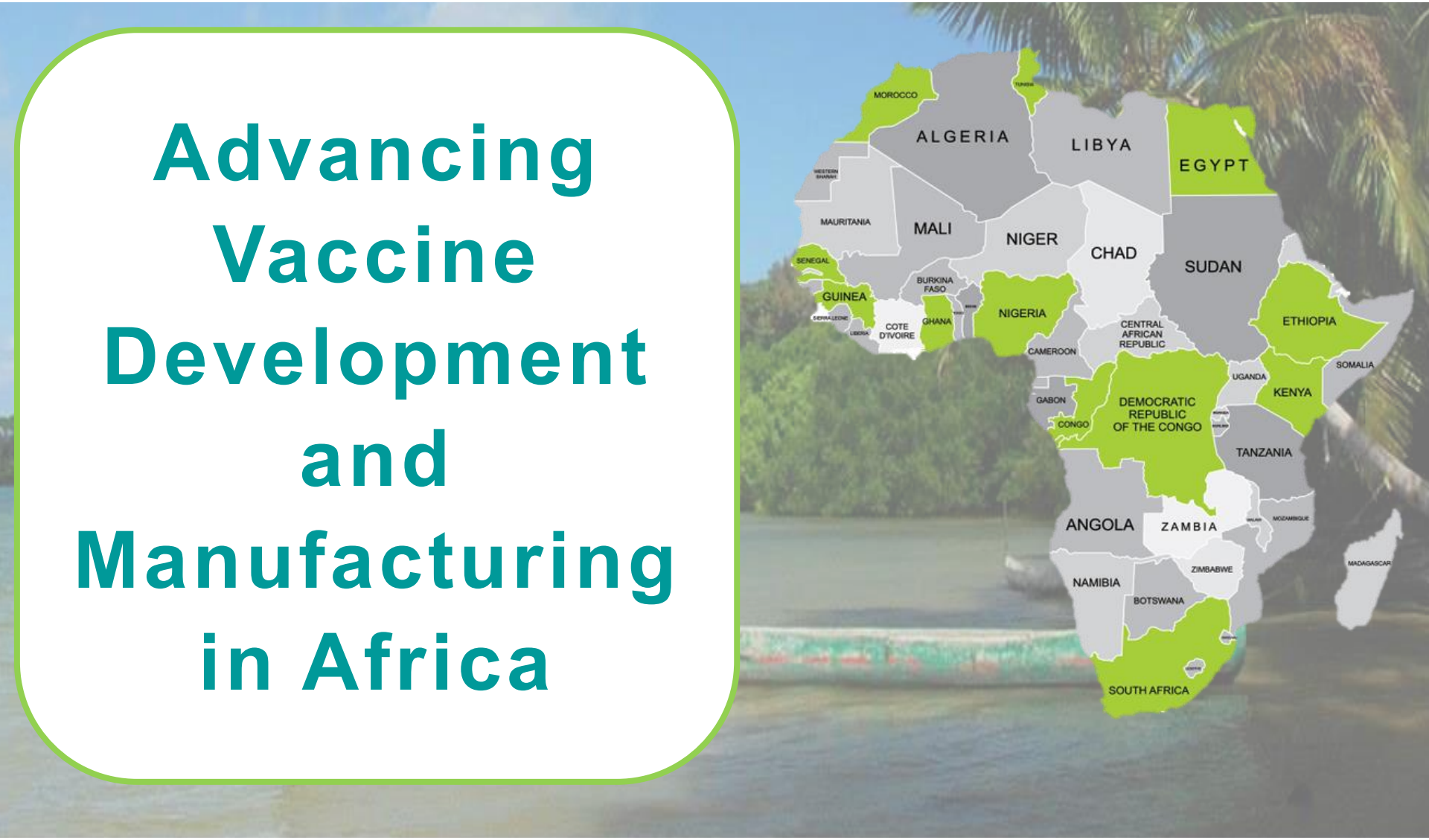
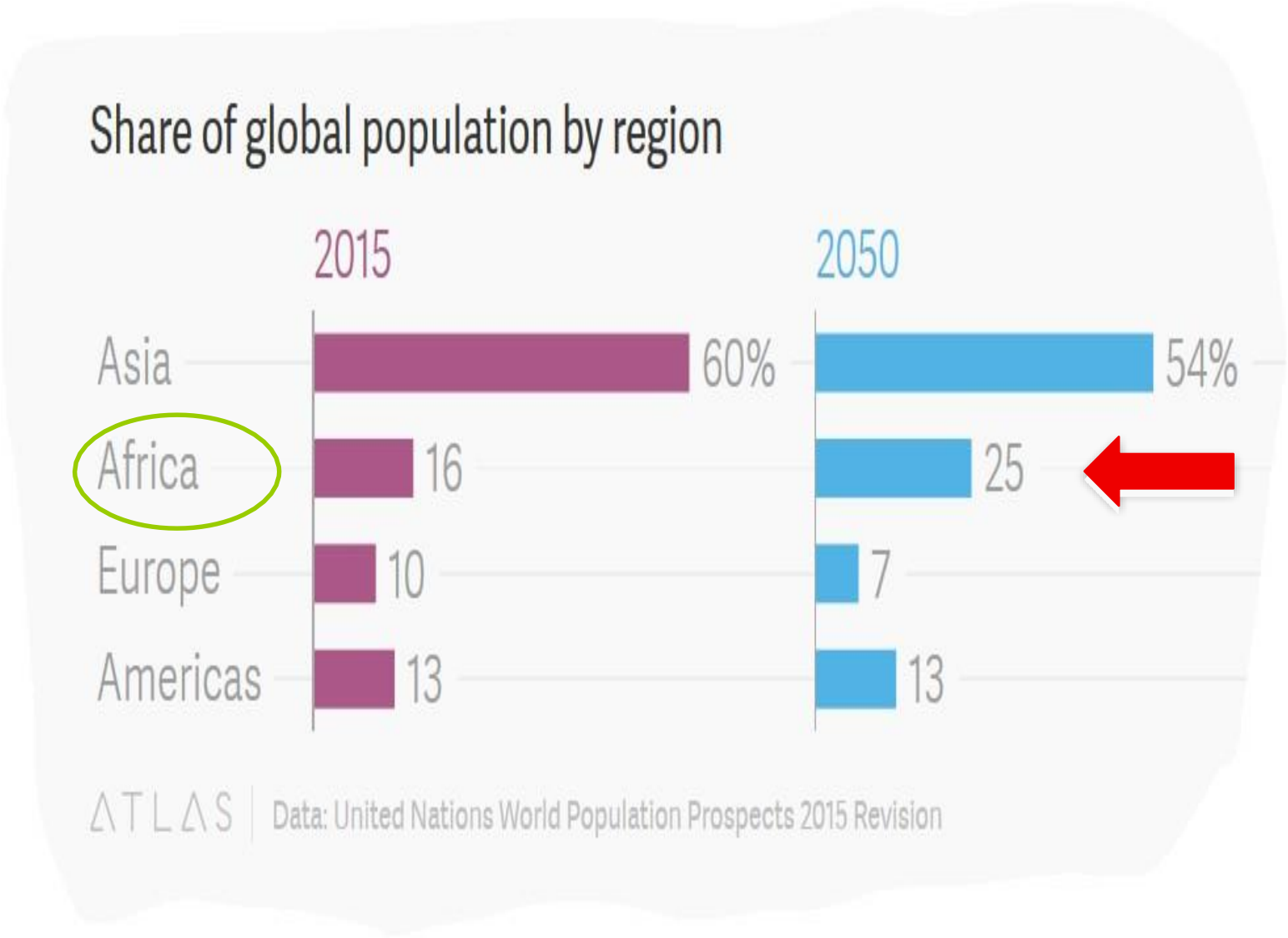
Advancing Vaccine Development and Manufacturing in Africa



Freetown, Sierra Leone

24 – 25 September 2018

A quarter of the world's population will live in Africa by 2050…



Source: WHO

Over 60% of unicef volumes come to Africa

2013 Vaccines Supplies: US$ 1, 285 million | 2.79 billion doses | 2,185 shipments

Source UNICEF Supply Division

Immunization Supplies

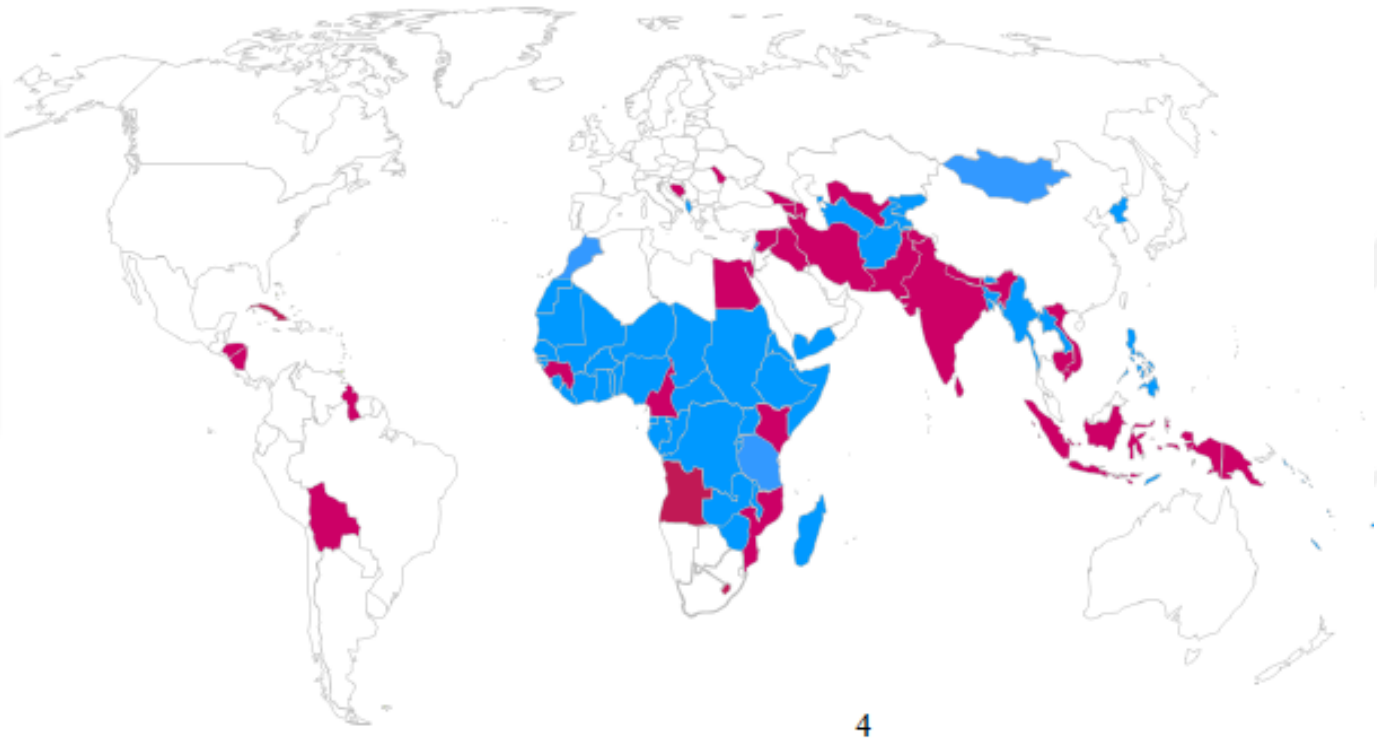
Vaccines
BCG , DTP, TT/Td/DT, Measles containing, OPV, HepB, YF, DTP-HepB, DTP-HepB/Hib, DTP/Hib, Hib, MR, Meningitis, MMR, PCV, RV IPV, HPV etc.

Safe Injection equipment

Cold Chain Equipment

Countries UNICEF procures on behalf of

- Full schedule
- Partial schedule



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Source: UNIICEF Supply Division

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One in five children in Africa lack access to all available vaccines.

It's time to accelerate action toward universal access to immunization across the continent.

#VaccinesWork

One in five children in Africa does not receive the vaccines they need.

It's time to accelerate action toward universal access to immunization in Africa.

#VaccinesWork

ADDIS DECLARATION ON IMMUNIZATION

The Current Reality

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Africa produces

less than 1%

of its own vaccine needs!

2018: No African flu manufacturing capacity

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Countries with influenza vaccine production capacity in 2006 and following implementation of the WHO Technology transfer project

World Health Organization

Source: WHO

The Current Reality

Lack of vaccine manufacturing capacity could potentially lead to:

- **Poor sustainability** due to supply insurance
- **Vulnerability** to epidemics and pandemics
- **Poor** emergency preparedness, **e.g. Ebola**
- **Weakened** Health/National Security
- **Poor** socio-economic development

Vaccine Manufacture is a complex multi-step process

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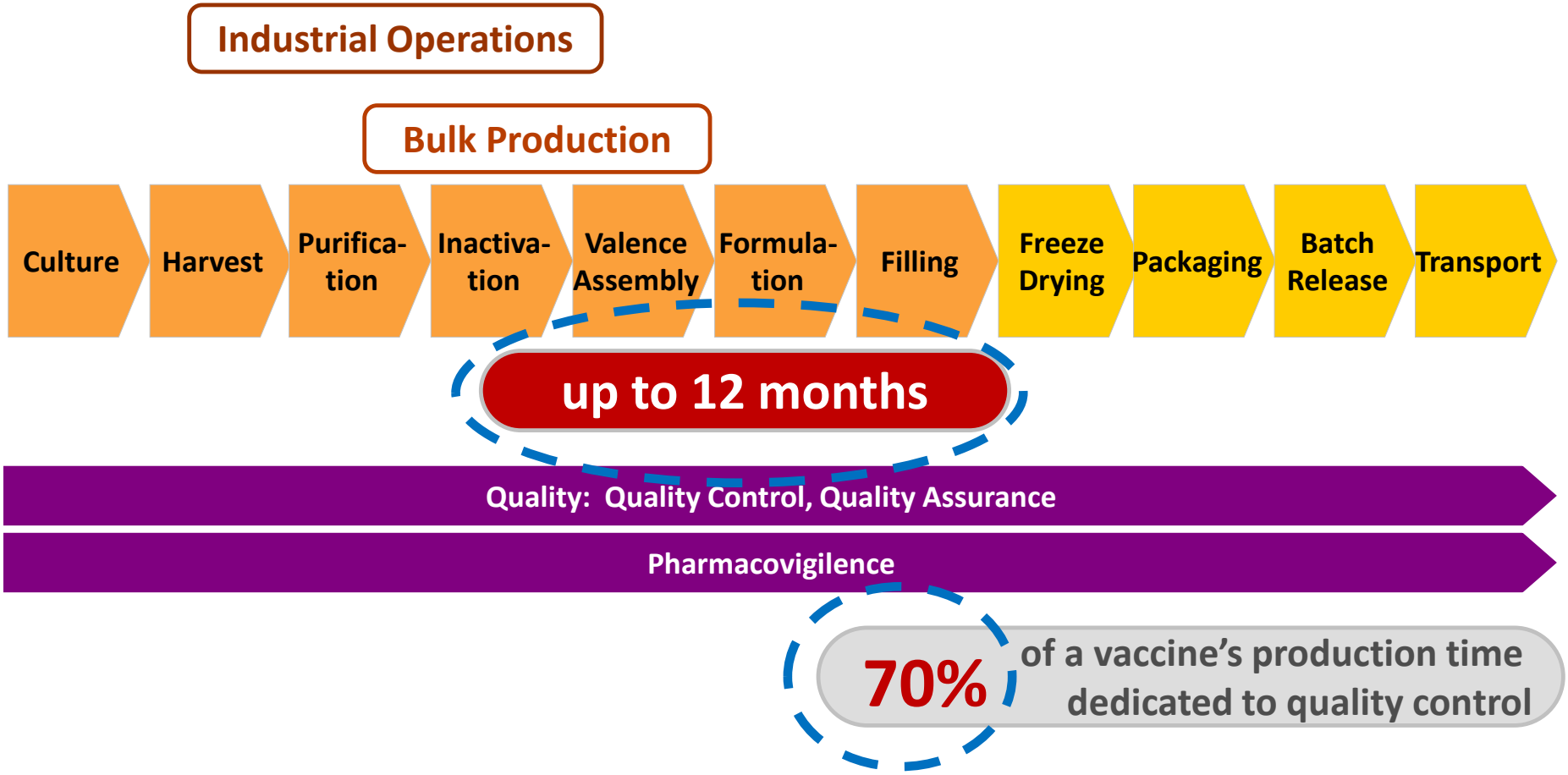
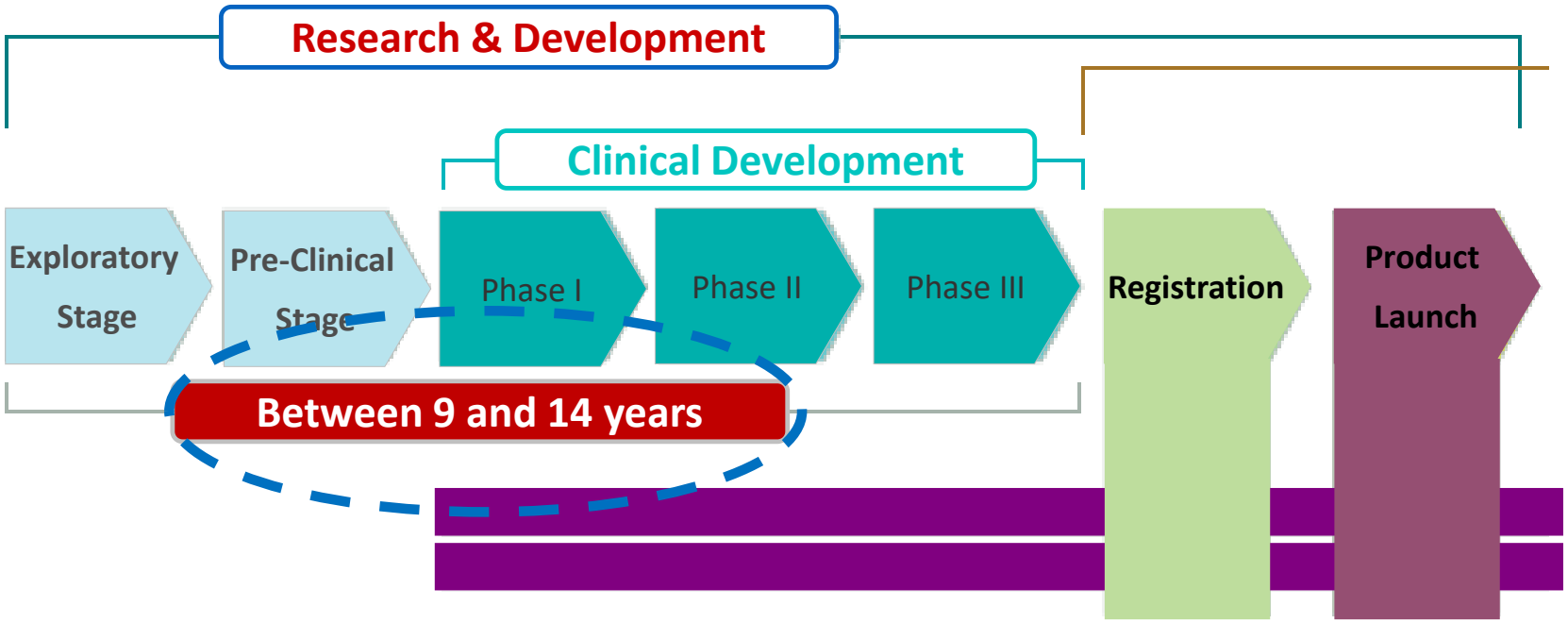


Vaccine development is a complex process



60-100 million USD investment

Setting up vaccine capacity

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- It takes longer than planned!
- It costs more than estimated!
- It’s not as simple as you think!

Vaccine Economics

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“Vaccines are Good for Children and Economies”

THE BLOG, Feb 08, 2017

By Dr Orin Levine

“Expanding use of vaccines could save up to $44 for every dollar spent”

Science Daily: February 8, 2016

Source: Johns Hopkins Bloomberg School of Public Health

Vaccine Industry Swot Analysis

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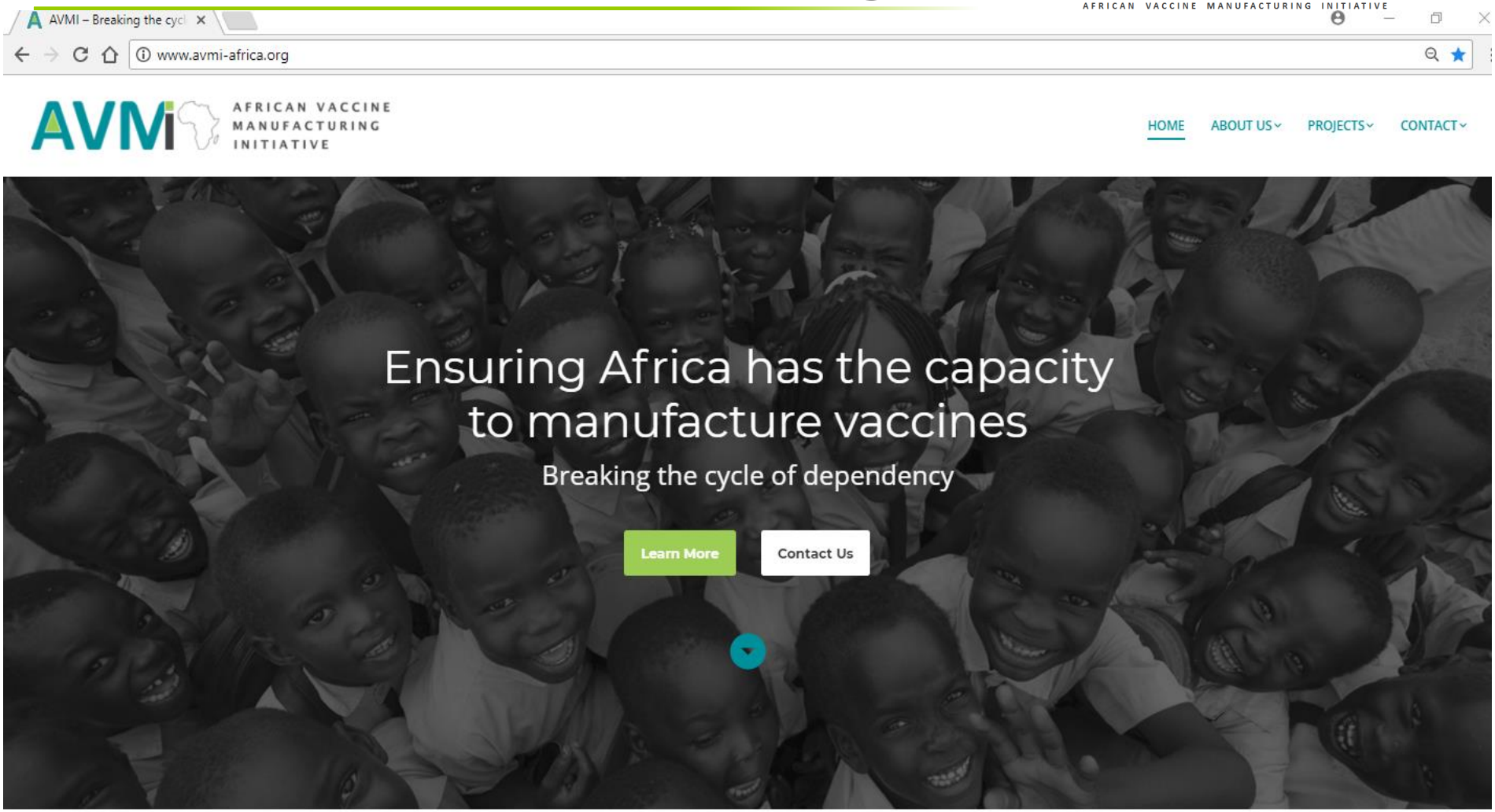
Strengths	Weaknesses
• Prevent Diseases • Vaccines are widely available • National Program have reduced the cost as a barrier to vaccination • There are no 'generics' in vaccines • Few decision makers (governments/ unicef/WHO/GAVI)	• Vaccine R&D is lengthy and expensive • Less awareness to the benefit of vaccines • Vaccine manufacturing: one of the highest cost in the pharmaceutical industry • Regulatory approvals are lengthy even when there are similar products
Opportunities	**Threats**
• Global recognition of the benefits of immunisation • Vaccines for Diseases currently without a vaccine • Vaccines are looked at for treatment of non- communicable diseases	• Only the strongest survive • India and China depend on large populations an cohorts and protectionism • "western companies" protect their IP • Anti- vaccination movements

Enter…

Website: www.avmi-africa.org



Our Mission

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To promote the establishment of sustainable human vaccine manufacturing capacity in Africa

Role of Catalyst and Coordinator

- **Promote, support and coordinate efforts of the African vaccine manufacturers and other interested parties.**
- **Work with partners (public and private).**

Vaccine Manufacturing in the PMPA context

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- **Vaccine manufacturing is considered highly important in today's Africa**
  - Establish with **long term** goals/vision
  - the production capacity to **rapidly respond to Africa's needs**
  - provide a **sustainable** source of **high quality** products to address vaccine preventable diseases.

VMPA STUDY

VACCINE MANUFACTURING AND PROCUREMENT IN AFRICA

An analytical assessment of vaccine manufacturing capacity and procurement mechanisms for establishing sustainable vaccine manufacturing capacity in Africa

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World Health Organization

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An **analytical assessment** of vaccine **manufacturing** capacity and **procurement** mechanisms for establishing sustainable vaccine manufacturing capacity in Africa.

A comprehensive overview of the current situation, main directions, issues, challenges and opportunities relating to vaccine manufacture on the continent.

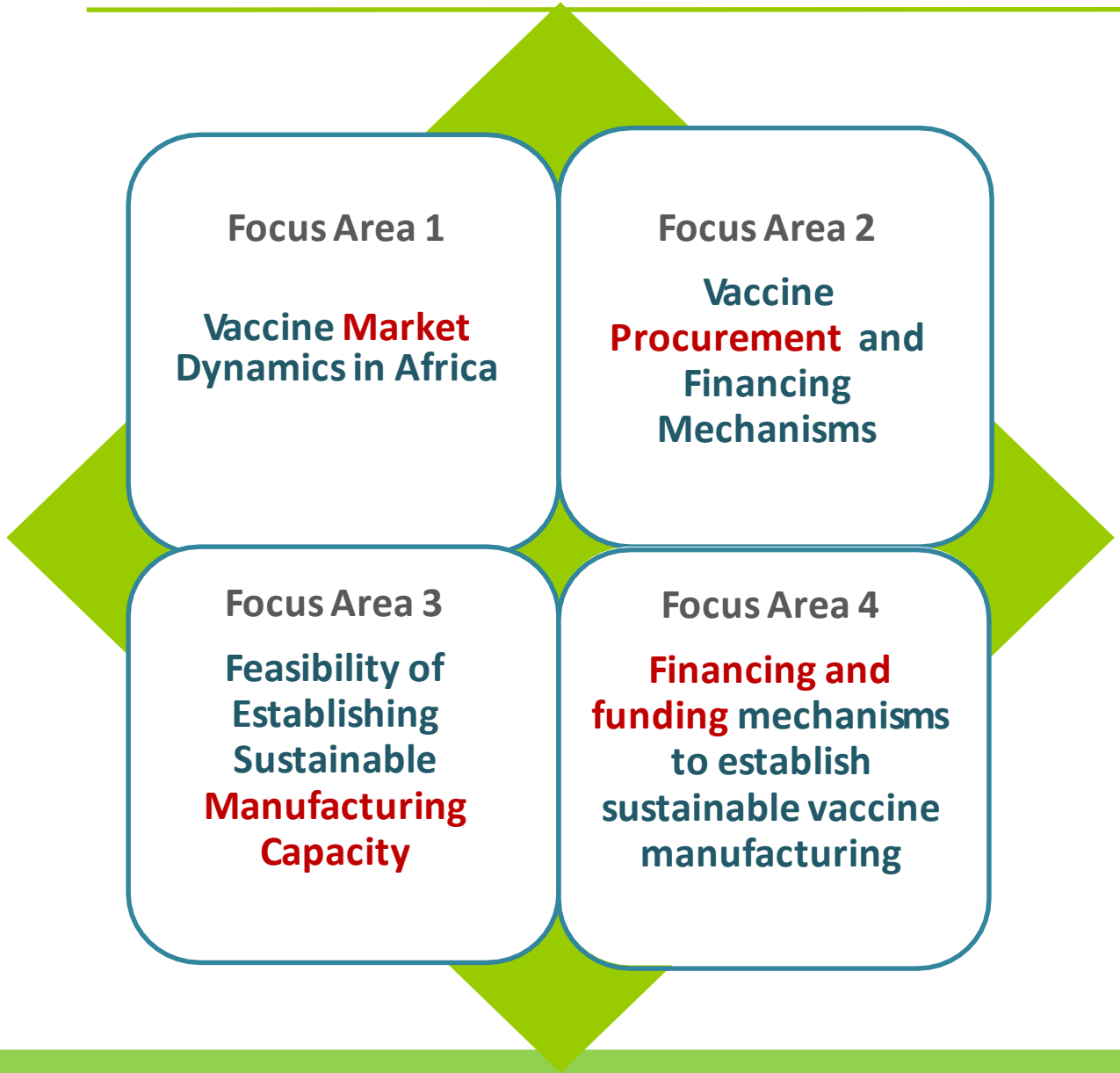
Key relationship

Manufacturing

Procurement

Sustainability

VMPA Study: Scope



- **Market**
- **Procurement**
- **Manufacturing**
- **Financing & Funding**

Key findings of the VMPA study

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Vaccine Market	• **African demand is booming:** vaccine doses, vaccine types, increased populations, immunization coverage & vaccine expenditure
Vaccine Procurement	• **Dominant procurement mechanism is Africa**: UNICEF SD 45 out of 54 countries use UNICEF SD
Vaccine Manufacturing	• **Heterogeneous levels of capacities and capabilities**
Vaccine Funding	• **Manufacturing facility cost :** between USD 60 – 130 million, with CAPEX at 60%

2016: Production capacity

THE BIOVAC INSTITUTE
The science of protecting life

GROUP 1: Companies with locally produced and marketed products: 3	GROUP 2: Companies at late stage of industrial development and manufacturing (no vaccines currently produced): 1	GROUP 3: Companies at very preliminary planning of vaccine development (no vaccines currently produced): 4
Pasteur Institute in Dakar, Senegal*	**Biovac**, South Africa	**Pasteur Institute**, Algeria
Pasteur Institute Tunis, Tunisia**		**Pasteur Institute**, Morocco
Egyvac-Vacsera, Egypt**		**EPHI**, Ethiopia
		Biovaccines, Nigeria

* Vaccines: Yellow Fever
** Vaccines: BCG
*** Vaccines: Tetanus toxoid, Cholera Typhoid, Cholera/typhoid, DT, DTP, DTP-Hib, Meningitis AC (polysaccharide)
Other products: Insulin, various antisera

Source: VMPA study

2016: Vaccine value chain assessment

THE BIOVAC INSTITUTE
The science of protecting life

African Companies / CAPABILITIES	GROUP 1: Companies with locally produced and marketed products			GROUP 2: Companies at late stage of vaccine development & manufacturing
	Institut Pasteur Dakar (Senegal)	Vacsera (Egypt)	Institut Pasteur (Tunisia)	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				

VMPA Study Conclusion

- Limited space for multiple major players in the vaccine production field in Africa
- A number of regional hubs could be established.
- Requires the right level of political and technical support
  - a clear, well-funded and coherent regional policymaking and planning approach,
  - development of the necessary ecosystem to establish a viable, competitive and sustainable vaccine manufacturing capability.

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A summary of key cost drivers and factors to consider when planning the establishment of a vaccine production facility.

An introduction to the manufacturing of human vaccines, providing information about the vaccine market, investment costs, project timelines and other factors to take into consideration.

Country Case Study

WHITE PAPER

Commercialising vaccines:

A methodology to identify potential market opportunities and conduct outline assessments

Case study: South Africa

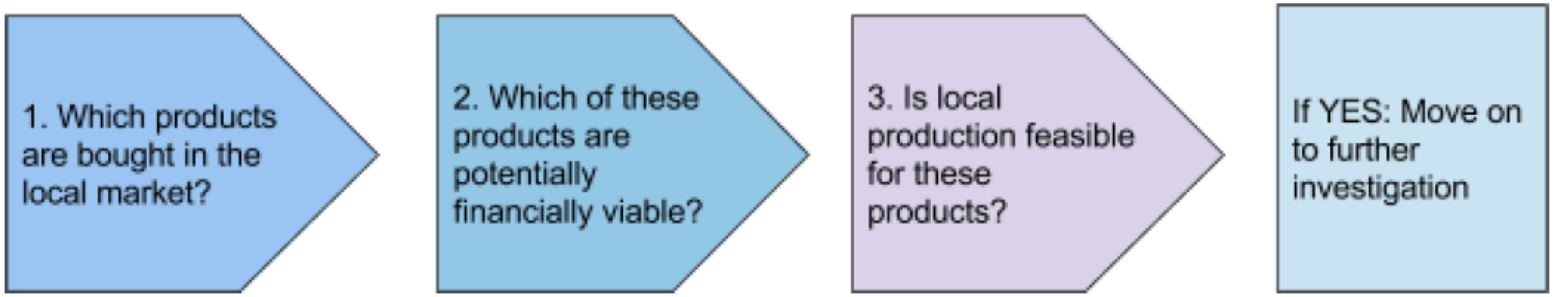
Global UNIDO Project:
Strengthening the local production
of essential medicines in developing countries
through advisory and capacity building support

2018

A methodology to identify potential commercially viable market opportunities and conduct outline assessments.

Country Case Study

- The study is to establish the initial evaluation to decide which vaccines may be worth manufacturing for a particular market.



- **First Phase:** Understanding the country's market for vaccines
- **Second Phase:** Identifying financially viable candidates for local production
- **Third Phase:** Assessing feasibility of local production

Profiling and Positioning

2016	• Ministerial Conference on Immunization in Africa • GVIRF
2017	• DCVMN • GET • Website
2018	• EAC Vaccine Forum • Dubai Vaccine Forum • Advac-Africa • 5th German-African Healthcare symposium

- Partnering with WHO, UNIDO, GIZ, HHS
- Studies and publications
- Meetings with presidents and ministers

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AVMI has developed an Advocacy document targeting priorities such as:

1. **Promoting the visibility of AVMI regionally and globally** as the voice for local vaccines and biologicals manufacturing in Africa.
2. **Promoting** the development and **adoption of a Pan-African** vaccines and biologicals **policy**.
3. **Leveraging** existing and new **partnerships** (public and private).
4. **Creating a network of advocates** across the region for vaccines and biologicals manufacturing in Africa.
5. **Promoting linkages** with other **infectious diseases area initiatives**

African Manufacturers

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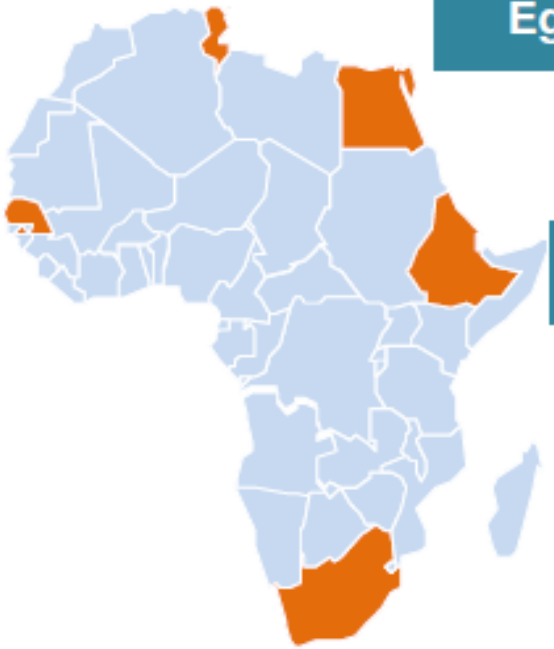
Institut Pasteur de Tunis

VACCINES, SERA & DRUGS
EGY VAC



Institut Pasteur de Dakar

Ethiopian Public Health Institute

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Prospective Manufacturers

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…establishing local vaccine manufacturing capacity

- **Nigeria**
  - BioVAccines
  - Innovative Biotech

BioVaccines NIGERIA LIMITED
RC 633335
Advancing health through Innovation

INNOVATIVE BIOTECH

- **Ghana**
  - AspirX

- **Zambia**
  - Biomedicalabs

Key challenges

- Secretariat needs to be better resourced with full time people.
- Lack of political support in Africa
- Funding
- Communication
- Mindset
  - Quality | Africa
  - Foreign dependency

Key Focus Areas ?

- Ministerial Conference on Vaccine Development and Manufacture
- REC vaccine fora
- Increasing membership – both in numbers and broader geographical spread throughout the continent
- Fundraising
- Gavi Graduation – AVMI support
- Secure government support
- “BRICS Vaccine R&D Centre”
- …

Agenda today and tomorrow

- *Session 2:* **Advancements**
- *Session 3:* **Regional Perspectives**
- *Session 4:* **Knowledge Café**
- *Session 5:* **Key Disease Challenges**
- *Session 6:* **Global Perspectives and Initiatives**
- *Session 8:* **A word from our sponsors**
- *Session 9:* **Key Messages, Decisions and Actions**

AVMI role is crucial …

Supporting country decision-making processes and business model evaluations

Contributing to capacity strengthening and building partnerships

Advocating for sustained access & viable vaccine development and production in the continent, building from the Heads of State Declaration on Immunization

African Vaccine Manufacturing Initiative (AVMI)

In summary…

- Africa has limited production capacity yet is the most in need of routine vaccines
- Africa has zero vaccine manufacturing capability to respond to pandemics
- A country needing to set up a vaccine manufacturer needs to have the right ecosystem in place (e.g. regulatory, skilled population, maintenance of sophisticated equipment, higher education system)
- Unless Africa procures its vaccines directly it will remain donor dependent and the cycle will not be broken.
- **It is possible to have more manufacturers provided that there is policy coherence within country and amongst the African states/regions.**

If this were easy… we would not be here.

We are here **because** it is difficult and challenging.

We are here because it is **necessary** and **possible**

Africa is the future: By 2050, Africa's population will number 2.5 billion. One in four people on earth will be African.

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- To speak of the future, one must speak of Africa – Europe's twin continent. *Jean-Claude Juncker*

- Universal health coverage is ultimately a political choice. It is the responsibility of every country and national government to pursue it. It takes vision courage and long term thinking

Dr Tedros Adhanom Ghebreyesus, Director-General of WHO

With thanks to…

AVMI
AFRICAN VACCINE MANUFACTURING INITIATIVE

Secretariat

Based in Cape Town, South Africa

Executive Director
Patrick Tippoo

Technical Officer
Dr Alex Ochem

Information Officer
Daria Kow

Legal Support
Charlie Nemugumoni

Technical Liason Officer
Ebrahim Mohamed

Administrative Support
Akhona Gura

Administrative Assitant
Melissa Schouw

…and…

AVMI
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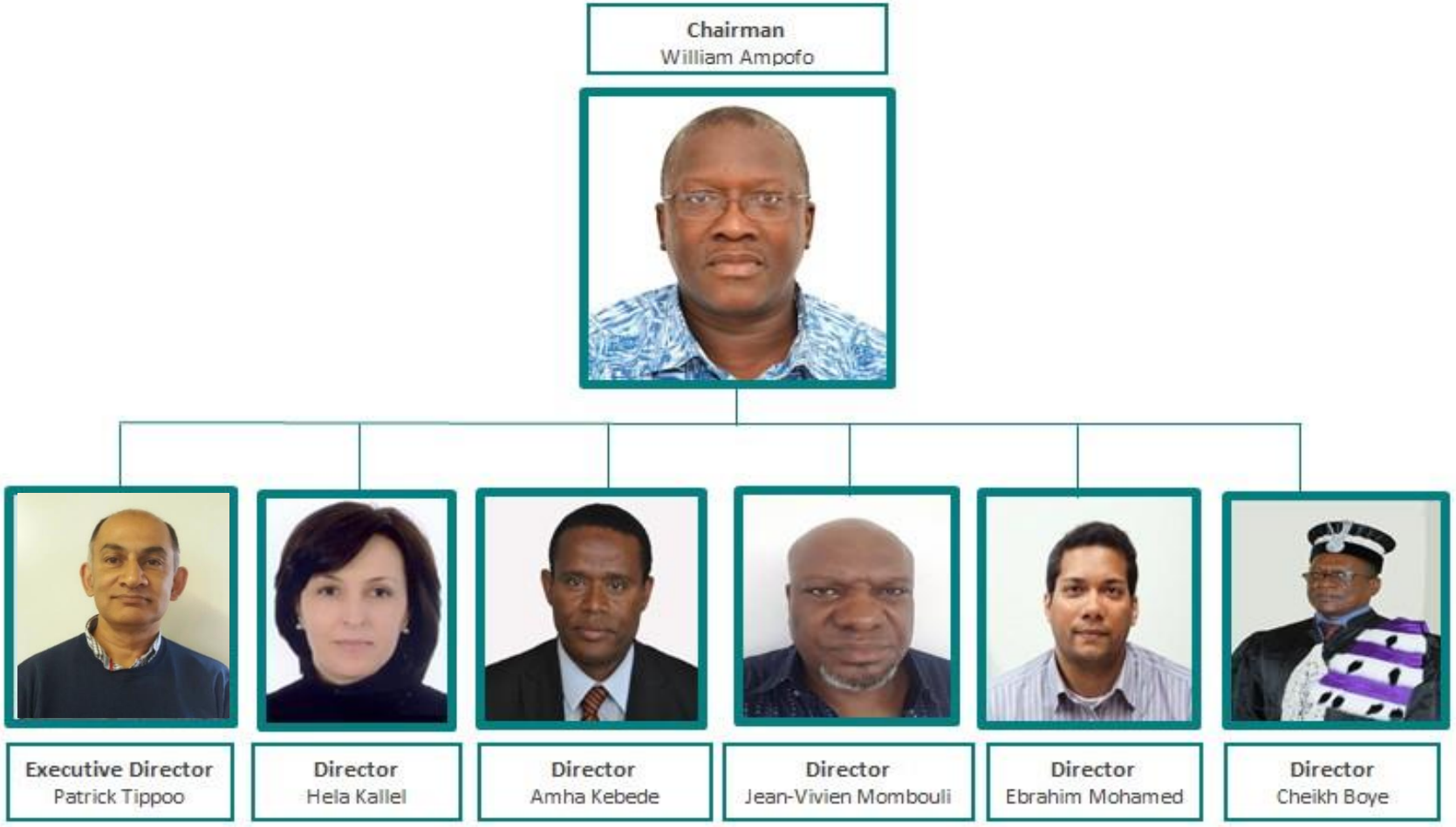
Board of Directors



Thank You

The best time to plant a tree was 20 years ago. The second best time is now.