



Members Meeting Updates

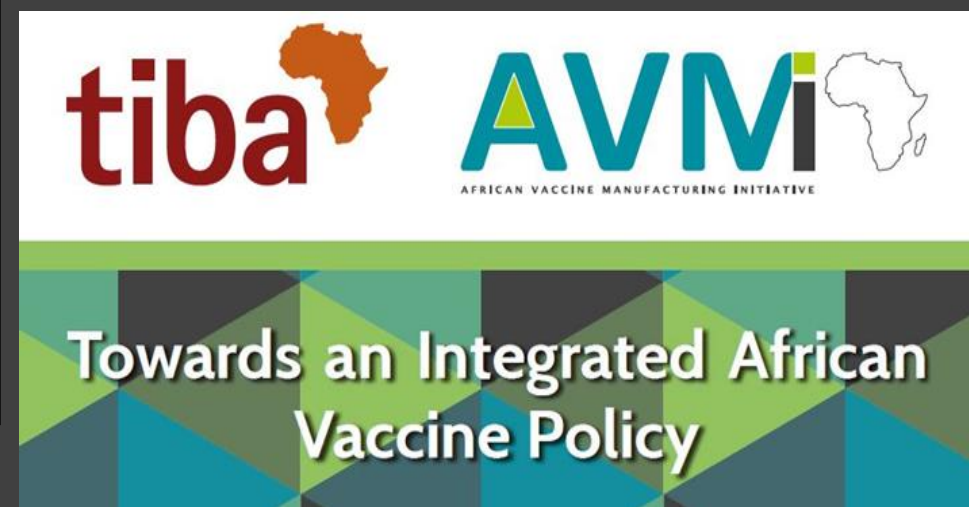
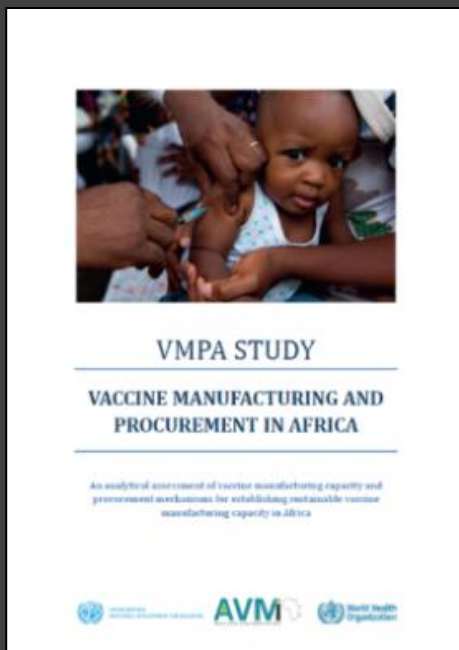
22 November 2022

Advance the establishment of
sustainable human vaccine
manufacturing capacity in Africa



MISSION





Some of the work done thus far...

Source: www.avmi-africa.org

2015 VMMPA Study Conclusion



VMMPA 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

- 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
 - ... to develop the necessary **ecosystem** to establish a viable, competitive and sustainable vaccine manufacturing capability.
- **Long-term vision** - tied to national (health) security and regional health security.

AU set goal to ensure 60% of vaccines administered in Africa by 2040 will be produced in Africa...

Context

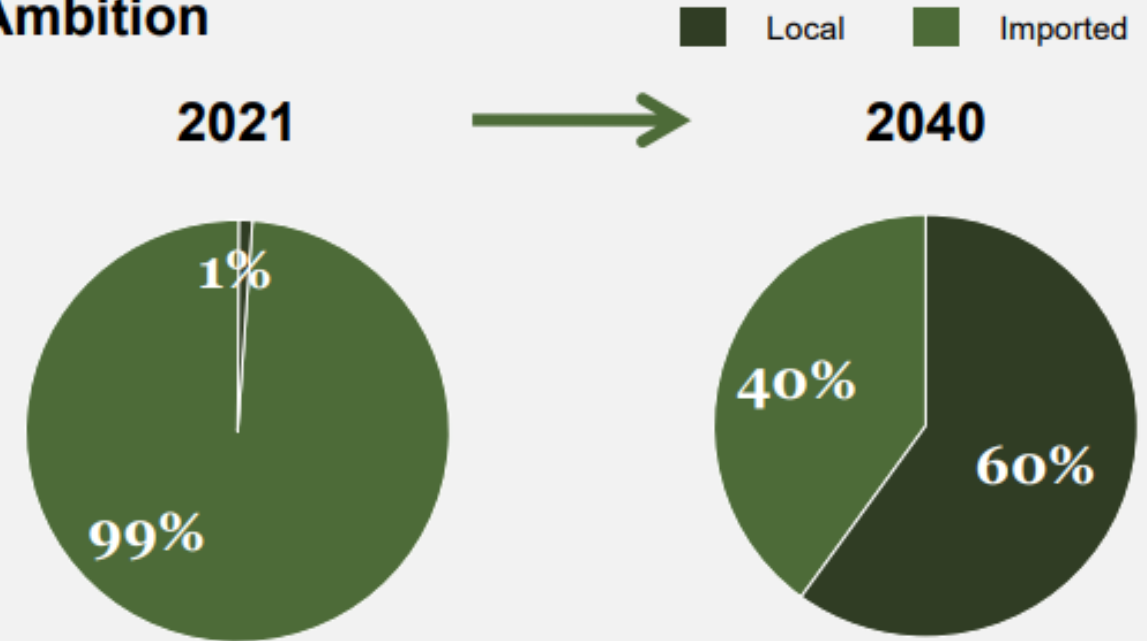


The African Union calls for a **New Public Health Order** aimed at safeguarding the health and economic security of the continent



The first pillar of the New Public Health Order is **expanded manufacturing of vaccines, diagnostics and therapeutics¹**

Ambition



The African Union has set a goal to **increase vaccine manufacturing on the African continent to meet 60% of the demand by 2040** and mandated the Partnerships for African Vaccine Manufacturing (PAVM) to **develop a framework for action to execute this**

...and mandated

PAVM

Partnership For African Vaccine Manufacturing

...to execute

Vision for African vaccine manufacturing

To ensure Africa has timely access to vaccines to protect public health security, by establishing a sustainable vaccine development and manufacturing ecosystem in Africa

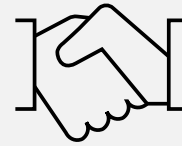
The PAVM was established under the Africa CDC with four broad objectives to guide its operations



PAVM's four broad objectives



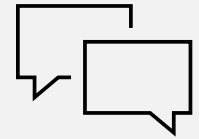
Steward a continental strategy that maintains scale and cost-competitiveness of local manufacturing and promotes equity and security for all



Support partnerships to **create a conducive business environment** that will encourage the emergence of a thriving manufacturing base



Play **intermediary and partner role between Member States and the global community of supporters** on an as-needed basis



Communicate updates and serve as the **central source of information for Africa Vx manufacturing**

The PAVM made significant progress since inception crossing many important milestones in 2021

Facilitated the **African Vaccine Manufacturing Summit** which mandated PAVM and set the target ambitions

12-13 April

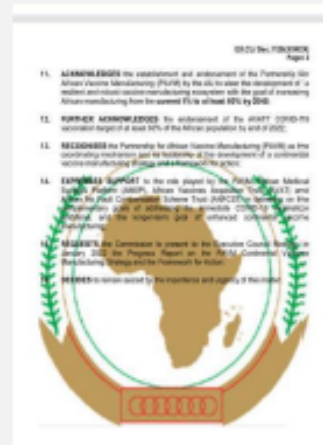


May

Operationalised the PAVM, setting up a task force of **7 workstreams** consisting **>60 members** which hosted **>30 hours of workshops** and **>100 hours of working sessions**

The PAVM was **approved by AU Executive Council** and will be presented to **AU Assembly of Heads of State** in February 2022

November



2021



6-7 December

Hosted a successful **Stakeholder Engagement Event** in Kigali where significant decisions were made on the FFA bold programs

Finalised Draft 1.0 of the FFA that was peer reviewed by independent experts and scientists

17 December



The PAVM has maintained its momentum into the implementation phase of the initiative into 2022

FFA has been endorsed by AU member states at the Heads of State Assembly



Framework for Action officially released to general public

Project Management Office (PMO) to oversee implementation of FFA set up

The PAVM developed Framework for Action which defines 8 bold programs that will support the momentum in vaccine manufacturing in Africa



Many implementation lead organisations for FFA bold programs identified



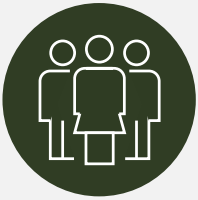
Bold program task-teams reconvened with weekly meetings to drive implementation

February 2022

March 2022

PAVM's journey has been structured in 3 phases

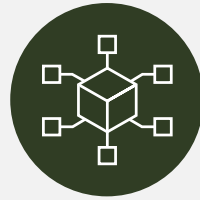
● Deep dives to follow



Phase 1

Getting the PAVM Task Force up and running

Definition and establishment of the PAVM Task Force and its workstreams



Phase 2

Developing a detailed Framework for Action (FFA)

Stand up the PMO
Operationalization of the PAVM Task Force
Lead the key analysis for each workstream in collaboration with the PAVM Task Force
Definition of action plans for each workstream and integrating them into a Continental Framework for Action (FFA)



Phase 3a

Developing FFA implementation plan and release support

Strengthen execution of the PMO
Onboard implementing partners and set up the bold program teams
Develop detailed FFA implementation plans
Initiate the first steps of the FFA's implementation plan



Phase 3b Implementation of the FFA

Ongoing implementation of the FFA bold programs

PAVM developed a continental strategy that outlines diseases, technology platforms and manufacturing value chain steps that Africa needs to prioritise

☐ Vaccine exists ☐ Vaccine does not yet exist

Potential disease prioritization



Prioritized 22 diseases...

Legacy				Expanding		Outbreak	
Diphtheria	Hepatitis B	Measles	Meningococcal	HPV	Pneumococcal	Ebola	Influenza
Whooping Cough	Yellow fever	Typhoid fever		HIV	COVID-19	Chikungunya	Lassa fever
Tetanus	Tuberculosis	Cholera		Malaria	Rotavirus	Rift valley fever	Disease X

Technology focus



... requiring a breadth of technology platforms...

Traditional			Innovative		
Live attenuated	Inactivated virus	Subunit	Virus-like particle	Viral vector	RNA/DNA

Potential value chain focus



... along the different steps of the value chain

Fill & Finish (F&F)

Fill & finish for all priority vaccines, enabling achievement of local production targets.

Drug Substance (DS)

Expand drug substance mostly in established platforms

R&D

Expand R&D activities to develop new vaccines for Africa, support more efficient manufacturing and improve vaccine characteristics

IPD is one of the anchor projects in the continental network funded fully through MCF but with strong collaboration through PAVM and in full alignment of the PAVM strategy

■ IPD's location

Key MADIBA Project Features (as in Madiba concept note)

Project Description

To build state-of-the-art manufacturing facilities to produce a portfolio of vaccines that are highly-relevant to the population of Africa

Total Cost

- ~\$ 222M of which SLL is requested to fund \$45M which will cover initial working capital including pre-revenue salary payments and CAPEX

Technology Supported

(current and planned)

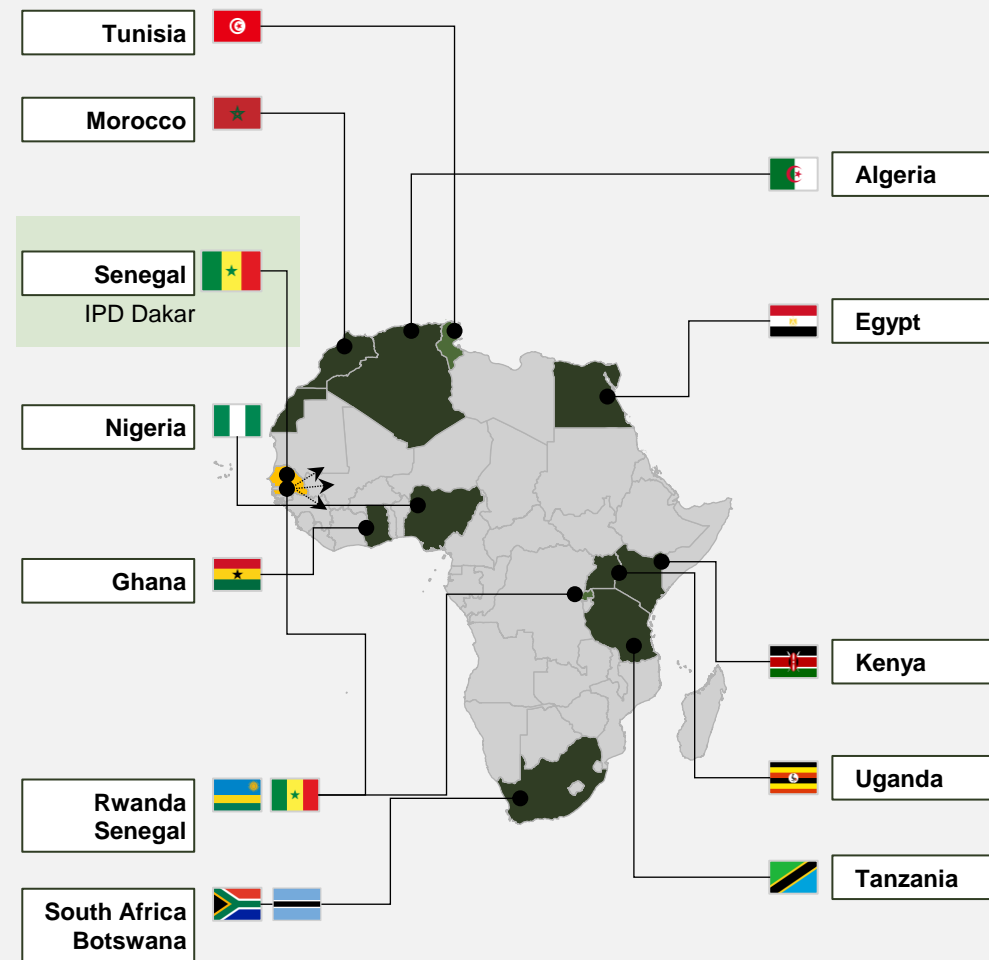
- Live attenuated vaccine, mRNA, viral vector

Trainings Provided

Customized training for MADIBA facility personnel in early phase

cGMP trainings for local manufacturers on the continent

Potential Benefiting Countries (frontrunner countries with industry/educational institutions)



Potential Benefits to Industry & Educational Institutions

Joint Mapping

- Collaboration between local manufacturers and IPD in mapping of talent needs
- Collaboration between local educational institutions and IPD on mapping of training needs

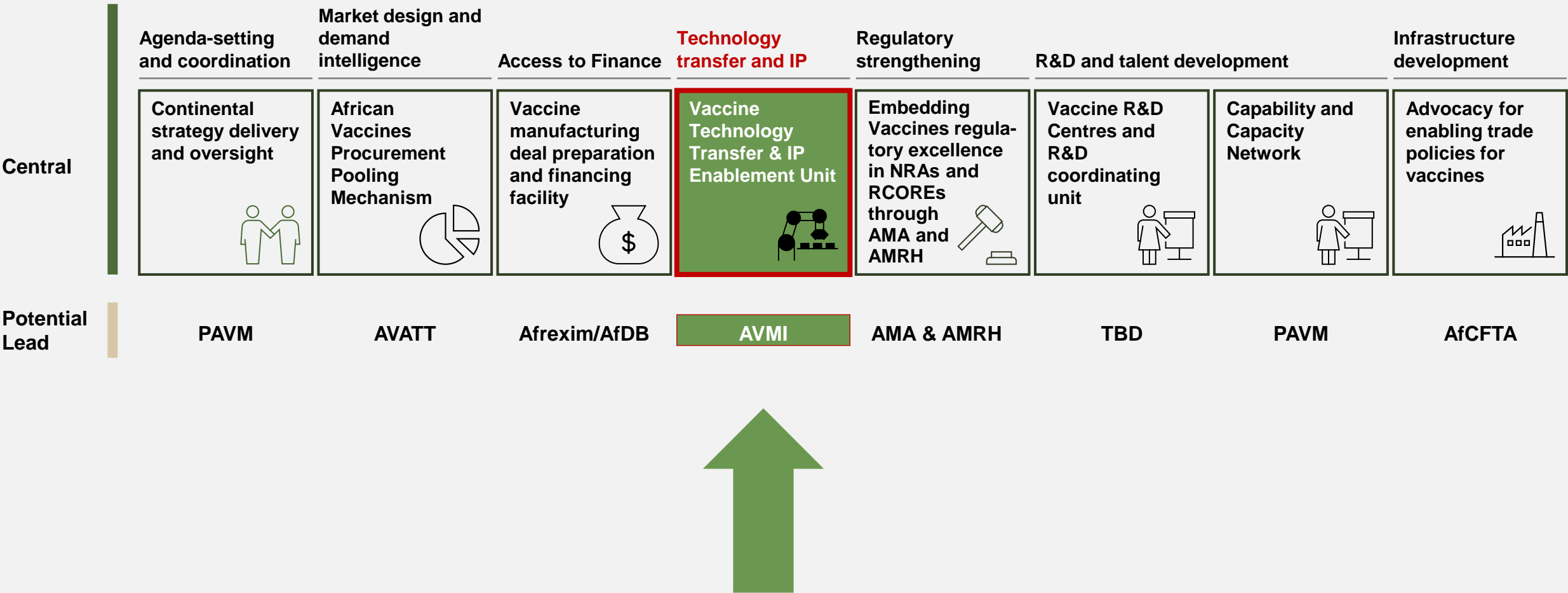
Training Development

- Co-creation between local manufacturers and IPD of customized training curriculum
- Support for local educational institutions on curriculum development, including expanding offering of hands-on training

Training Provision

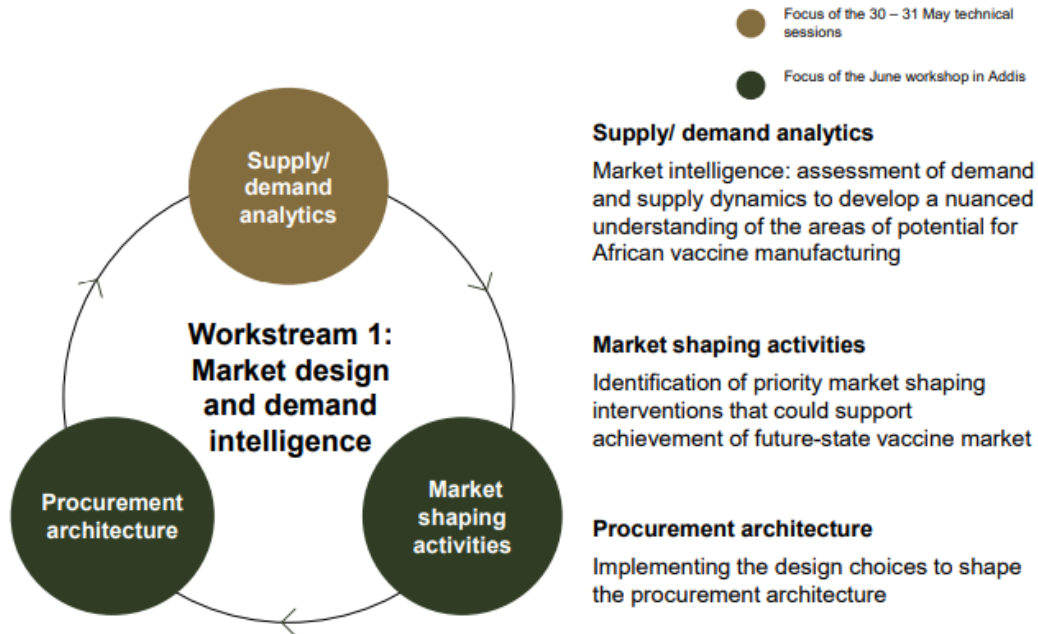
- Provision of affordable locally-relevant training to manufacturers
- Co-creation with institutions on training schedule and cohort size. Proposed by IPD to start at 50 persons annually and increase to ~200 per year when fully established

Partnerships will be key to implementing these bold programs and PAVM welcomes all stakeholders to play a role



Market Demand Developments

The Market Design and Demand Intelligence workstream is focussed around 3 areas



Supply/ demand analytics

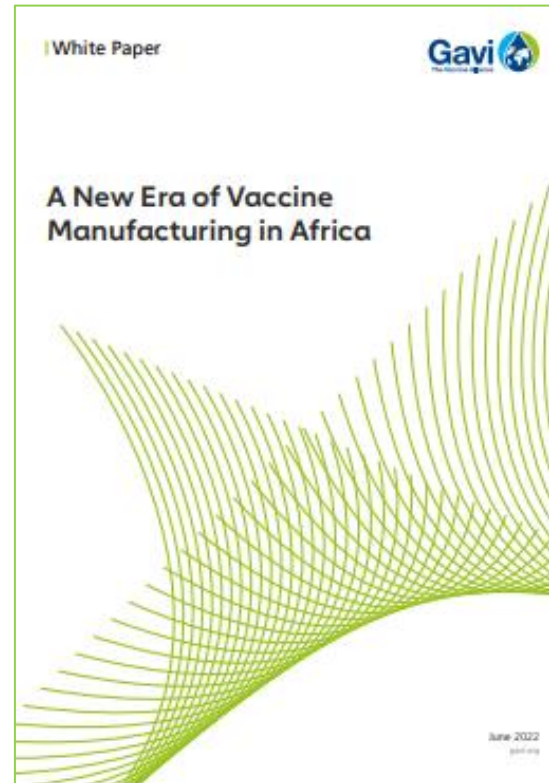
Market intelligence: assessment of demand and supply dynamics to develop a nuanced understanding of the areas of potential for African vaccine manufacturing

Market shaping activities

Identification of priority market shaping interventions that could support achievement of future-state vaccine market

Procurement architecture

Implementing the design choices to shape the procurement architecture



November 2022 | gavi.org



Expanding sustainable vaccine manufacturing in Africa: Priorities for Support

Delivered by Gavi and partners in response to a call from the African Union and G7 Development Ministers



Market Demand Developments



What is this plan?

- In response to the AU call to action for Gavi, the Vaccine Alliance and other stakeholders to **concretely support supply security on the continent, and the 2040 vision**, Gavi kicked off a process of wide consultation with the AUC, Africa CDC, and other supporting stakeholders.
- The plan proposes actions for Gavi, other international organizations, private sector, G7 Development Ministers, and African countries to contribute to a **new business model** for a **long term, sustainable full value chain African vaccine industry**.

Market Demand Developments



Overview of potential financing mechanism

- The plan also outlines a **potential framework** for a **time-limited financial instrument** that can help mitigate the high cost of vaccine production at market entry.
- Through this instrument, combined with strategic selection of antigens and a supportive Gavi market shaping framework, new African manufacturers can be supported to produce for the most commercially-viable vaccines, **helping to secure accelerated, competitive entry where there is unmet need**.
- This instrument would follow in the **footsteps of the Advanced Market Commitments (AMCs)** developed by Gavi for both the pneumococcal vaccine and the COVID-19 vaccines.

What are the next steps?

- Gavi Secretariat will be encouraging its Board and other parties to get behind and develop this concept in 2023



Regionalized Vaccine Manufacturing Collaborative



RVMC Mission

The RVCM aims to increase vaccine access for low- and middle-income countries through successful and sustainable establishment of a versatile global vaccine manufacturing network capable of producing vaccines during pandemic and non-pandemic times.



RVMC Objectives



Convene public and private stakeholders to facilitate dialogue, highlight critical issues, spur cross-sector collaborations, and drive collective action



Engage, build-on, and **strengthen ongoing regional efforts** for vaccine manufacturing (e.g. WHO, PAVM)



Identify barriers to the development of sustainable regional vaccine manufacturing capacity as well as **opportunities** for public-private collaboration to address such barriers



Develop a **landscape analysis** of existing and emerging vaccine manufacturing efforts to identify regions where additional vaccine manufacturing capacity is needed and opportunities for coordination



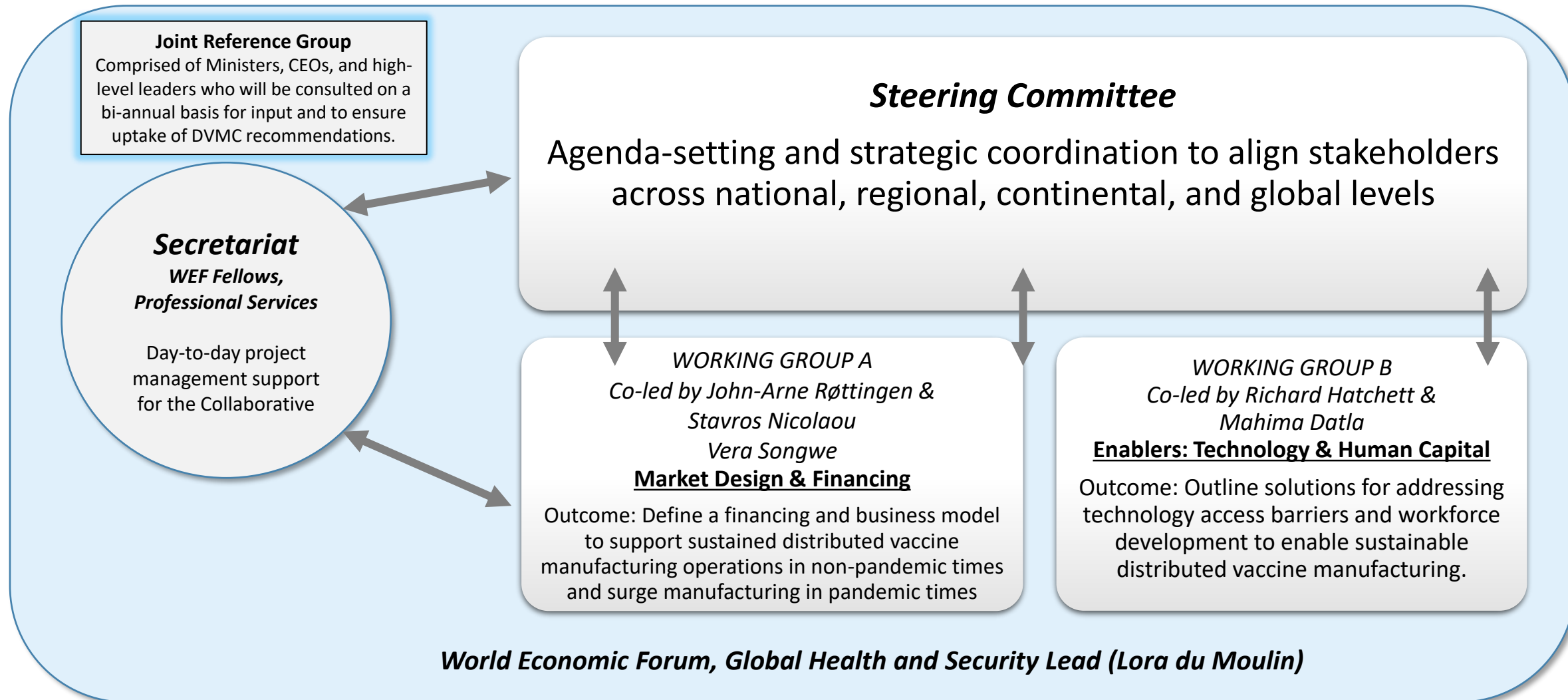
Define a set of recommendations expanding vaccine manufacturing capacity and ensuring sustainability of manufacturing facilities



Identify a pathway for RVMC members to advance recommendations



RVMC Structure





Steering Committee Structure

Co-Chairs

Richard Hatchett <i>(CEO, CEPI)</i> Victor Dzau <i>(President, US National Academy of Medicine)</i>
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Steering Committee

Budi Gunadi Sadikin, <i>(Minister of Health, Indonesia)</i>	Tharman Shanmugaratnam <i>(Senior Minister, Singapore)</i>	Soumya Swaminathan <i>(Chief Scientist, WHO)</i>	John Nkengasong <i>(U.S. Global AIDS Coordinator, USG)</i>	Seth Berkley <i>(CEO, Gavi)</i>	Ahmed Ogwell Ouma <i>(Acting Director, Africa CDC)</i>
Nísia Trindade Lima <i>(President, FioCruz)</i>	Paul Stoffels <i>(CEO, Galapagos)</i>	Ngozi Okonjo-Iweala <i>(Director General, WTO)</i>	Shyam Bishen <i>(Head of Health & Healthcare, WEF)</i>	Jeremy Farar <i>(Director, Wellcome Trust)</i>	Stephane Bancel <i>(CEO, Moderna)</i>

Business & Financing Models Co-Leads 1) John Arne Røttingen <i>(Ambassador for Global Health, Norwegian Ministry of Foreign Affairs)</i> 2) Stavros Nicolaou <i>(Sr. Executive, Aspen Pharmacare Group)</i> 3) Vera Songwe <i>(Executive Secretary of the UN Economic Commission for Africa)</i>			Technology & Human Capital Co-Leads 1) Richard Hatchett <i>(CEO, CEPI)</i> 2) Mahima Datla <i>(Managing Director, Biological E)</i>		
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Working Groups

Business & Financing Models Working Group	Technology & Human Capital Working Group
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RVMC Steering Committee



NATIONAL
ACADEMY
of MEDICINE



WORLD TRADE
ORGANIZATION



World Health
Organization



KEMENTERIAN
KESEHATAN
REPUBLIK
INDONESIA



FIOCRUZ
Fundação Oswaldo Cruz



Biological E. Limited
Celebrating Life Every Day



NORWEGIAN MINISTRY
OF FOREIGN AFFAIRS





Thank You



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

The NEXT best
time is **NOW!**

Advancing Vaccine
Manufacturing
Capacity in Africa

Breaking the
Cycle of
Dependency

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