



PAVM discussion with the African Vaccine Manufacturing Initiative (AVMI)

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Objectives of discussion between PAVM and AVMI

Discussion objectives



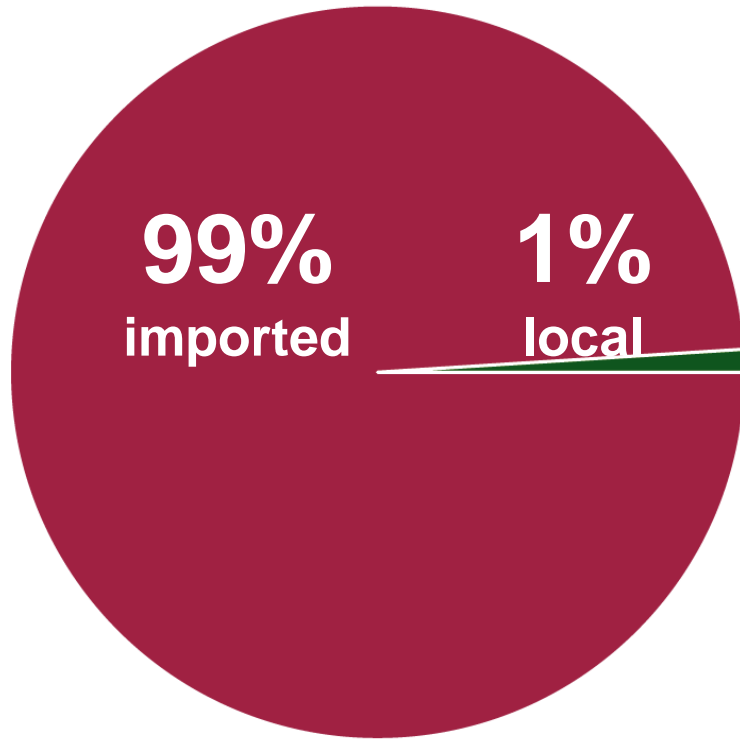
- 1 Update AVMI members on the **Partnerships for African Vaccine Manufacture's (PAVM's) progress to date**
- 2 Provide an **overview of 8 bold programs** that have been identified as part of the PAVM's Framework For Action (FFA)
- 3 Discuss how the **AVMI can support PAVM going forward, and the 8 bold programs**

Vision for African vaccine manufacturing

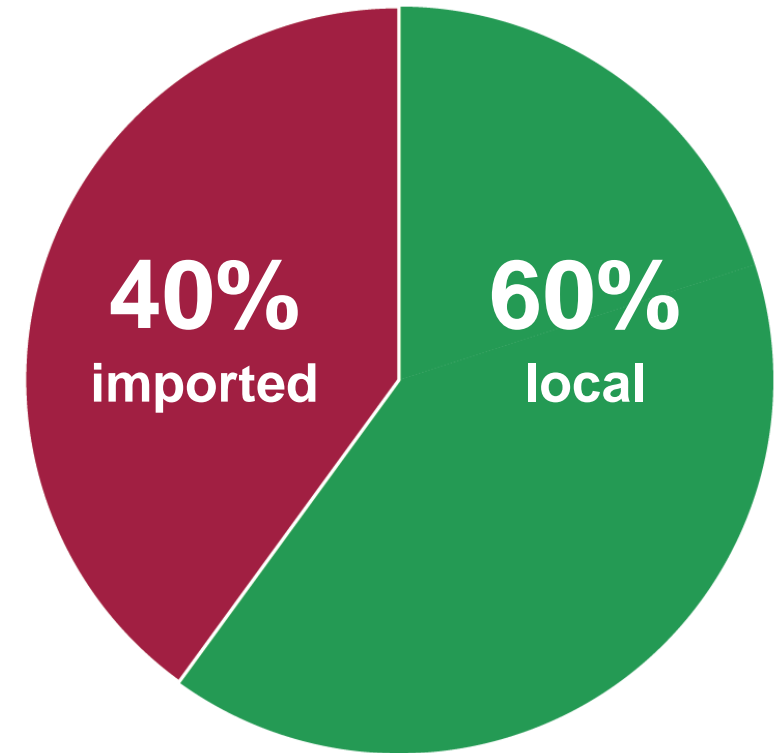
**To ensure Africa has timely access to vaccines to
protect public health security, by establishing a
sustainable vaccine development and manufacturing
ecosystem in Africa**

AFRICAN UNION / AFRICA CDC'S ASPIRATIONS FOR 2040

2021



2040



PARTNERSHIP FOR AFRICAN VACCINE MANUFACTURING (PAVM)

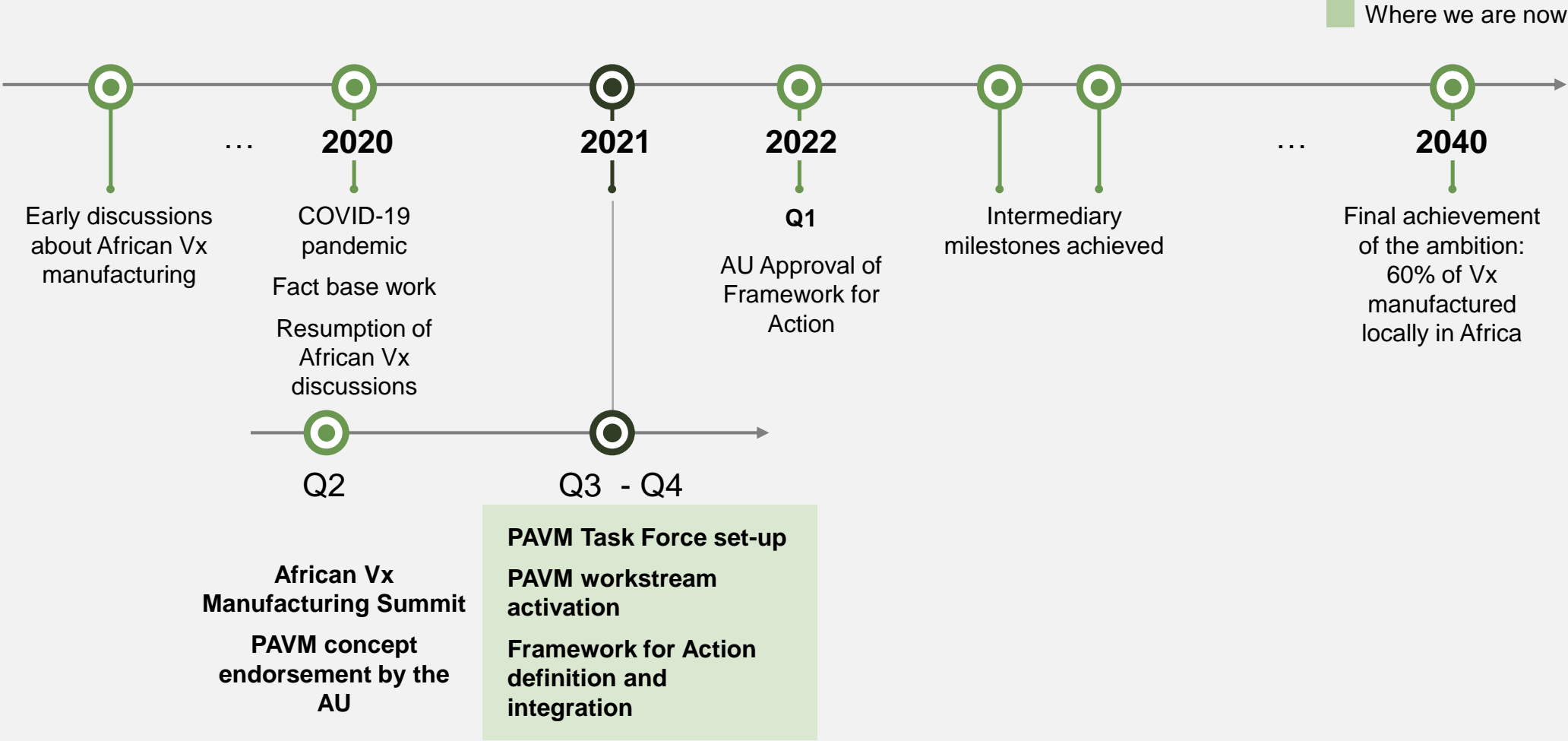
P Partnerships
A African
V Vaccine
M Manufacturing



The PAVM is working towards finalising Draft Zero of the Framework for Action, which outlines a plan to scale Africa's Vx manufacturing between now and 2040

Long-term journey...

...from an accelerated start



PAVM has four key mandates



PAVM mandates

Stewardship of the continental strategy

Develop a **continental strategy** (priority diseases, technology and value chain steps) to meet ambition



Set-up of an enabling environment

Develop a **Framework for Action** clearly articulating issues, strategic solutions, and implementation plan
Support of the implementation of the FFA



Intermediation and partnering

Connect **organizations offering support and Member States**
Support Member States in developing **meaningful partnerships with international institutions**



Communication and business intelligence

Gather **information on projects** on the continent on an ongoing basis
Proactively share with **Member States and the global Vx community** through several communications channels

Key achievements

Drafted and shared the **continental strategy** with the different workstreams, including the **prioritization of diseases and technology platforms** and potential strategic options



Activated **six workstreams with +40 workstream leads and members** actively engaged and meeting on a weekly basis

For each workstream, ran a **diagnostic, identified key challenges and pain points**, and started identifying **potential solutions**

Drafted the **first chapter of the Framework for Action**

Engaged in **several partnerships and intermediation activities** (e.g., COVAX WHO mRNA hub in South Africa, Manufacturing hub development with Team Europe)

Led multilateral engagement of Member States to share **PAVM value proposition** and have organized **eight countries** to present their current and ongoing **vaccine manufacturing projects**

Built a micro-website to be made available to public shortly

Developed a database regrouping ongoing and upcoming vaccine manufacturing projects on the continent

The PAVM has defined 8 Bold Programs required to achieve the 2040 ambition

Vision

Produce locally **60%** of the vaccines administered on the continent

Goal

Agenda-setting and coordination

Develop a fully integrated vaccines manufacturing ecosystem from R&D to Fill & Finish

1 **Continental strategy delivery and oversight :** Develop and execute the continental Vx manufacturing strategy and mobilizing the local and global Vx ecosystem to support its delivery

1 Prioritize 22 diseases

2 Invest in 7 technology platforms across traditional and novel ones

3 Research activities are scaled to support the ambition



Market design and demand intelligence

2 **African Vaccines Procurement Pooling Mechanism:** Organize public payers into a single purchasing entity that provides offtake certainty for Vx manufacturers



Access to finance

3 **Vaccines Manufacturing Fund:** Establish a commercial and non-commercial funding platform to support project financing for Vx manufacturers as well as financing for enablers (e.g., R&D, Talent, Regulatory)



Technology transfer and IP

4 **Vaccine Technology Transfer & IP Brokering Service:** Establish a service to link technology providers and recipients to an ecosystem of support across the technology transfer journey



Regulatory strengthening

5 **Support AMA and ongoing initiatives (AMRH) to build vaccine regulatory excellence:** Support the AMA to drive regulatory system strengthening for Vaccines among NRAs and RCOEs, leveraging existing institutions AMRH and AVAREF



R&D and talent development

6 **Vaccine R&D centres and R&D coordinating unit:** Coordinate the research on the continent and connect research institutions to the right resources and partners

7 **Regional Capability and Capacity centres:** Connect educational institutions with industry to enhance talent development



Infrastructure development

8 **Advocacy for enabling trade policies for Vaccines:** Advocate for trade policy within regions and member states to enable local vaccine manufacturing and trade, including AfCFTA

Bold Programs



The PAVM has started to see tangible impact from the intermediation and partnering initiatives

NON EXHAUSTIVE

COVAX



June 2021

mRNA hub

- Agreement to establish the first COVID-19 mRNA vaccine technology transfer hub in Africa
- Signed between Biovac, Afrigen Biologics & Vaccines, a network of universities, WHO, COVAX, and Africa CDC



mastercard foundation



Ongoing

Saving lives and livelihoods

- 1.3Bn \$ investment plan by the Mastercard Foundation focusing on 4 pillars
 - Purchasing Vaccines
 - Deploying Vaccines
 - Expanding Vaccine Manufacturing in Africa
 - Strengthening the Africa CDC

CEPI



Ongoing

CEPI-Africa CDC MoU

- Exchange of data on countries projects
- Strengthening of the Secretariat
- Ensuring pandemic and outbreak preparedness
- Leverage learnings from the COVID-19 and COVAX experience



Ongoing

Manufacturing hub development

- 1.2bn € investment to – among others – accelerate tech transfer and create vaccine manufacturing hubs across the continent
- In talks with South Africa, Senegal, Egypt, Morocco and Rwanda

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health



Ongoing

Coordination and support to Member States

- Member States meeting organization to build a thorough understanding of ongoing vaccine manufacturing projects
- On sites visit in South Africa, Morocco and Egypt

Engagements with member states

Frontrunner countries grouped by manufacturing maturity

Existing

Member States with **existing DS or F&F¹ capacity** and in the process of enhancing it

-  Egypt
-  Ethiopia³
-  Senegal
-  South Africa
-  Tunisia

Engaged

Member States that have **engaged in talks with international partners to establish DS or F&F capacity**

-  Algeria
-  Ghana
-  Morocco
-  Nigeria²
-  Rwanda
-  Uganda

Expressed interest

Member States that have **expressed interest** in entering the Vx manufacturing industry

-  Angola
-  Botswana
-  Kenya
-  Tanzania
-  Cameroon
-  Cote d'Ivoire

1. Drug substance manufacturing and Fill and finish
2. Nigeria has produced Yellow Fever vaccines in the past but production is currently stagnant and plants are not GMP qualified
3. Some production of Rabies using legacy Fermi technology

AVMI can support the implementation of the bold programs, making it a key partner for the PAVM

AVMI mission statement pillars



Potential areas of support for PAVM

High-level advocacy



Provide **financial and other resources to support with advocacy efforts** related to Vx manufacturing and trade



Support a **coordinated approach** towards scaling up Vx manufacturing in Africa, to minimize overlaps and meet diverse needs

Encourage partnerships



Provide **know-how** on carrying out successful tech transfers for manufacturers on the continent, through the proposed Technology Transfer and IP Brokering Service

Attract and secure resources



Provide **funding resources** to the Vaccine manufacturing Fund to fund both commercial and non-commercial projects
Encourage members to make use of the services to be provided by the Fund

Promote capacity building



Support proposed regional Capability and Capacity Centres (CCCs) by providing **on the job development programs** (e.g., internships, apprenticeships)
Avail resources (financial and expertise) to academic institutions to support the development of Vx-related programmes

We identified 22 priority diseases whose vaccines could be manufactured in Africa to reach the target set for 2040

PRELIMINARY :TO BE REVIEWED BY THE SCIENTIFIC PEER REVIEW GROUP

✓ Yes ✗ No

Archetype	Disease	Does a vaccine exist?	African doses volume by 2040 (Mn)	DALYS 2040 (Mn)
Legacy	Hep B, Diphtheria, Tetanus, Whooping Cough	✓	~370	6
	Tuberculosis	✓	~140	12
	Measles	✓	~240	2
	Yellow Fever	✓	~50	<1
	Cholera	✓	~30	1
	Typhoid	✓	~20	1
	Meningococcal ¹	✓	~60	5
Expanding	Papillomavirus	✓	~30	4
	Pneumococcal	✓	~140	13
	Rotavirus	✓	~120	9
	COVID-19	✓	~710	TBD
	Malaria	✓	~120	20
	HIV	✗	~110	10
Outbreak	Ebola	✓	~1	9
	Influenza ²	✓	~10	1
	Chikungunya	✗	~1	<1
	Rift Valley fever	✗	~1	<1
	Lassa fever	✗	~1	<1
	Disease X	✗	N/A	N/A
Total			~2,200	

Factors considered in prioritizing the diseases

- Building a sustainable vaccine manufacturing industry by prioritizing high-volume products
- Addressing Africa-specific infectious disease burden
- Preparing the African continent for potential outbreaks

Additional spare capacity is needed to support manufacturing for outbreak diseases when needed

1. Including key serogroups found in Africa (A, C, W and X)
 2. Considering here outbreak Influenza

Innovative technologies such as VV and RNA could significantly drive the production of Expanding and Outbreak vaccine archetypes

PRELIMINARY :TO BE REVIEWED BY THE SCIENTIFIC PEER REVIEW GROUP

✓ Yes ✗ No 🟢 Existing vaccine 🟡 Vaccine in clinical trial (from Phase I)

Archetype	Disease	Does a vaccine exist?	Traditional			Innovative		
			Virus-like Particle	Protein subunit	Inactivated virus	Live attenuated virus	Viral vector	mRNA
Legacy	Hep B, Diphtheria, Tetanus, Whooping Cough	✓		🟢	🟢			
	Tuberculosis	✓		🟡	🟡	🟢	🟡	
	Measles	✓				🟢		
	Yellow Fever	✓				🟢		
	Cholera	✓			🟢	🟢		
	Typhoid	✓				🟢		
	Meningococcal	✓		🟢				
Expanding	Papillomavirus	✓	🟢					
	Pneumococcal	✓		🟢				
	Rotavirus	✓				🟢		
	COVID-19	✓		🟢	🟢		🟢	🟢
	Malaria	✓	🟢				🟡	
	HIV	✗					🟡	
Outbreak	Ebola	✓					🟢	🟡
	Influenza	✓			🟢	🟢		
	Chikungunya	✗				🟡		🟡
	Rift Valley fever	✗		🟡		🟡	🟡	🟡
	Lassa fever	✗		🟡		🟡	🟡	🟡
	Disease X	✗					🟡	🟡

Legacy diseases mostly require investment into traditional technologies: in particular, **live attenuated, protein subunit and inactivated virus**

Expanding and Outbreak diseases are showing an **uptick in the role of novel technologies**, especially since the introduction of COVID-19 Vaccines

Africa could focus on Fill & Finish across all diseases, with a narrower focus on Drug Substance manufacturing and R&D

Yes
 Partially
 Yes
 No

Archetype	Disease	Does a vaccine exist?	Value-chain steps		
			R&D	DS + FF	FF only
Legacy	Hep B, Diphtheria, Tetanus, Whooping Cough	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Tuberculosis	✓	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Measles	✓		<input type="checkbox"/>	<input type="checkbox"/>
	Yellow Fever	✓	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Cholera	✓			<input checked="" type="checkbox"/>
	Typhoid	✓			<input checked="" type="checkbox"/>
	Meningococcal	✓			<input checked="" type="checkbox"/>
Expanding	Papillomavirus	✓			<input checked="" type="checkbox"/>
	Pneumococcal	✓		<input type="checkbox"/>	<input type="checkbox"/>
	Rotavirus	✓			<input checked="" type="checkbox"/>
	COVID-19	✓		<input type="checkbox"/>	<input type="checkbox"/>
	Malaria	✓	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	HIV	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Outbreak	Ebola	✓	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Influenza	✓	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Chikungunya	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Rift Valley fever	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Lassa fever	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Disease X	✗	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

Research and Development

Focus R&D activities on **under-developed vaccines** presenting substantial potential for the African continent- **primarily outbreak and neglected tropical diseases**

Drug Substance

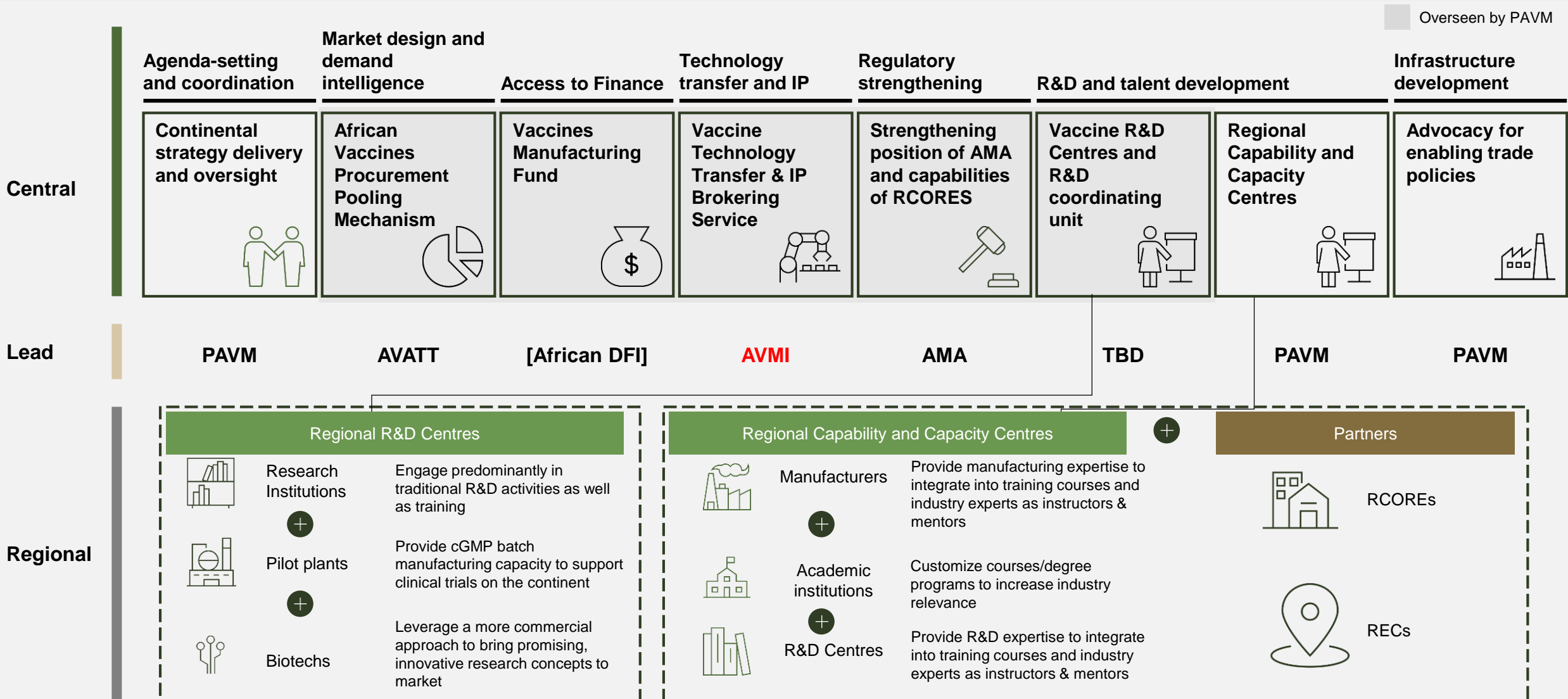
Drug Substance production should focus on Africa-specific diseases (i.e., Malaria, HIV and outbreak diseases). There is also an opportunity to target partial DS production for high-volume vaccines, which would enable production with economies of scale¹ (i.e., COVID-19, Penta, MMR, PCV and BCG) and to expand production for vaccines with ongoing DS production (Yellow Fever)

Fill and Finish

All prioritized vaccines will have, at the very least, **the Fill and Finish value-chain step localized on the continent**

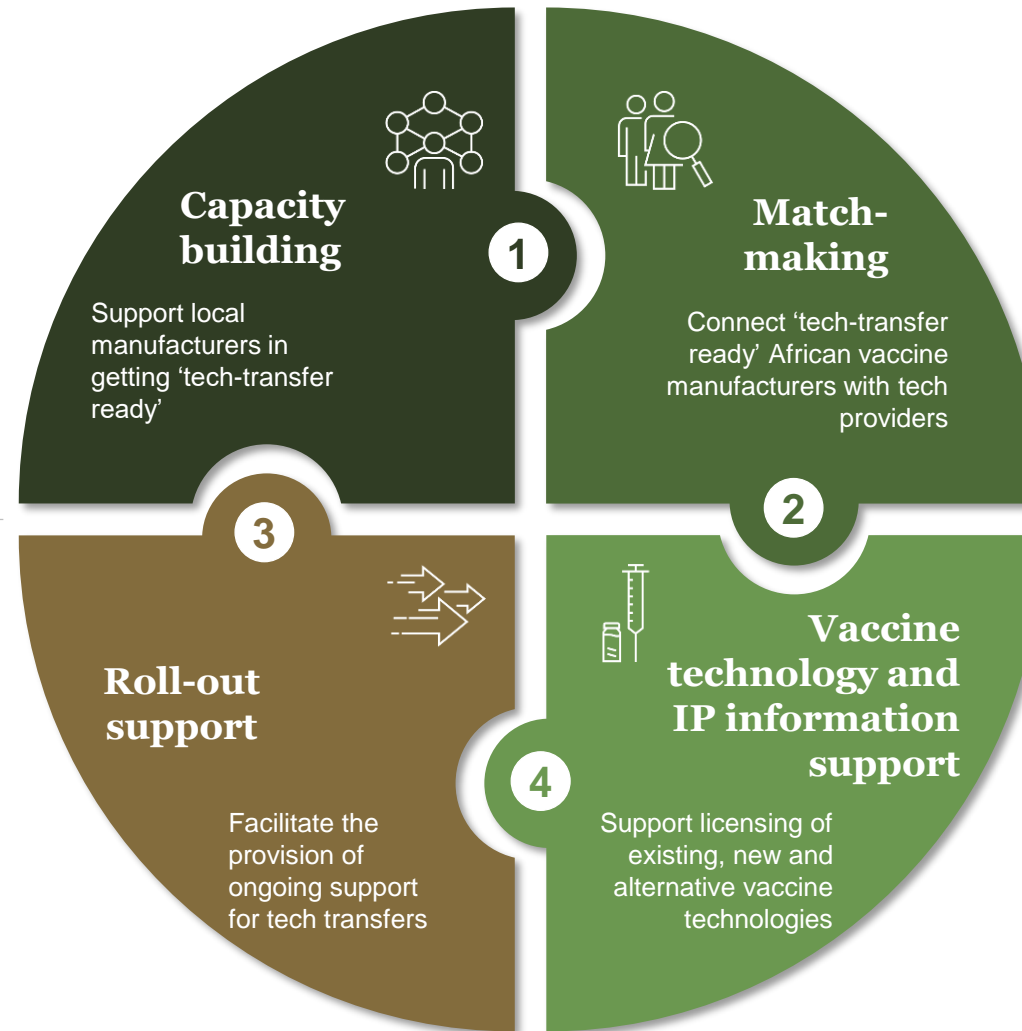
1. High volume vaccines were selected for partial DS production, based on whether or not partial production would have sufficient volumes to achieve minimum dosage requirements for economically viable plant set-up

PAVM will be responsible for overseeing the continental strategy delivery



The Vaccine Technology Transfer & IP Brokering Service could facilitate the transfer of technologies and IP to the continent through 4 primary roles

- **Collate playbook for local manufacturers** on how to get 'tech-transfer' ready
- **Conduct baseline assessments** to understand key capacity gaps across local manufacturers
- **Link manufacturers to potential partners and resources** to plug identified capacity gaps



- **Collate fact packs** to help 'tech-transfer ready' manufacturers adequately position their capabilities
- **Facilitate initial introductions** between the DCVM and MNC tech providers and local manufacturers

- **Facilitate access to ad-hoc support for tech providers and tech recipients**, including;
 - Funding
 - Partnerships
 - Talent
 - R&D capacity
 - Manufacturing and logistics capacity
 - Early NRA engagement
 - Incentives for Tech providers

- **Research and develop knowledge** on patent applications, vaccine technologies and emerging trends and technologies
- **Strengthen capabilities** of manufacturers and IP offices on IP and technology licensing and partnerships
- **Foster collaboration** between local manufacturers (i.e. pooled licensing) and with international partners and public research organizations
- Support the **review and strengthening of IP policy in Africa** as it relates to vaccines technology

Overall summary of the continental strategy

1 Potential disease prioritisation



Prioritized 22 diseases...

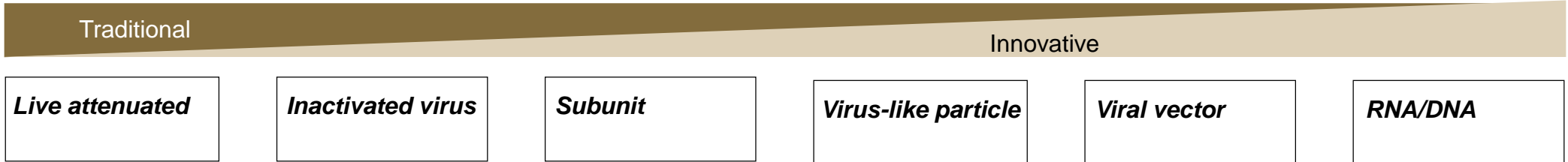
Vaccine exists

Vaccine does not yet exist

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

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

2 Technology focus



... along the different steps of the value chain

3 Potential value chain focus



Fill & Finish

Focus on highest volume vaccines (vaccine and modality agnostic) for economies of scale with potential for Africa to become cost-effective vis-à-vis other DCVM

Drug Substance

Expand drug Substance mostly in established platforms where tech transfers are readily available; manufacturing will likely require developing a local raw materials industry

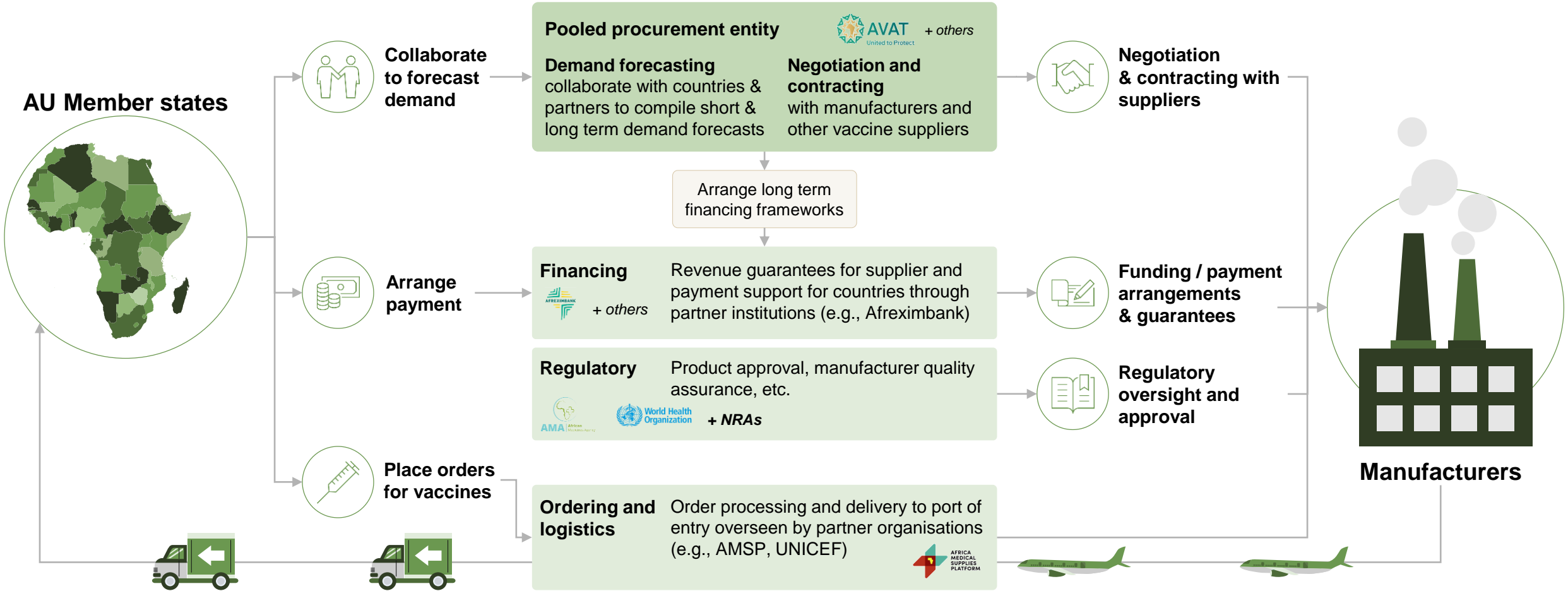
R&D

Create regional R&D hubs to support more efficient manufacturing, improve vaccine characteristics and consider research centers to develop new vaccines for Africa

What might the future state pooled procurement mechanism look like?

High level overview of emerging consensus

DRAFT FOR DISCUSSION – HIGHLY PRELIMINARY AND NON-EXHAUSTIVE



Talent challenges can be addressed by establishing a system of regional Capability and Capacity Centers with 5 key initiatives

Challenges



Scarcity of local talent development initiatives



Brain drain of local talent



Funding model



Program

Capability and Capacity Centers (CCC) program – PAVM to set up and support Capability and Capacity Centers in each region which will include a network of educational institutions and industry players to enhance the talent pipeline

Interdependencies with other programs

Initiatives

Create specializations in existing STEM degree programs by leveraging industry experts as additional lecturers and incorporating industry-specific nuances into course instruction

STEM program specializations will **increase local talent development** as it relates to vaccine specific expertise while **increasing student awareness of the industry**

Develop early internship options to raise awareness of vaccine career opportunities and provide students exposure to industry mentorship while they are still completing their degree

Internships will help students **convert from degree programs to vaccine careers potentially reducing brain drain**

Set up apprenticeship or other on the job development programs that provide recent graduates (of all education levels) a mix of hands-on job training, mentorship, and additional vaccine-specific classroom training over the course of multiple years

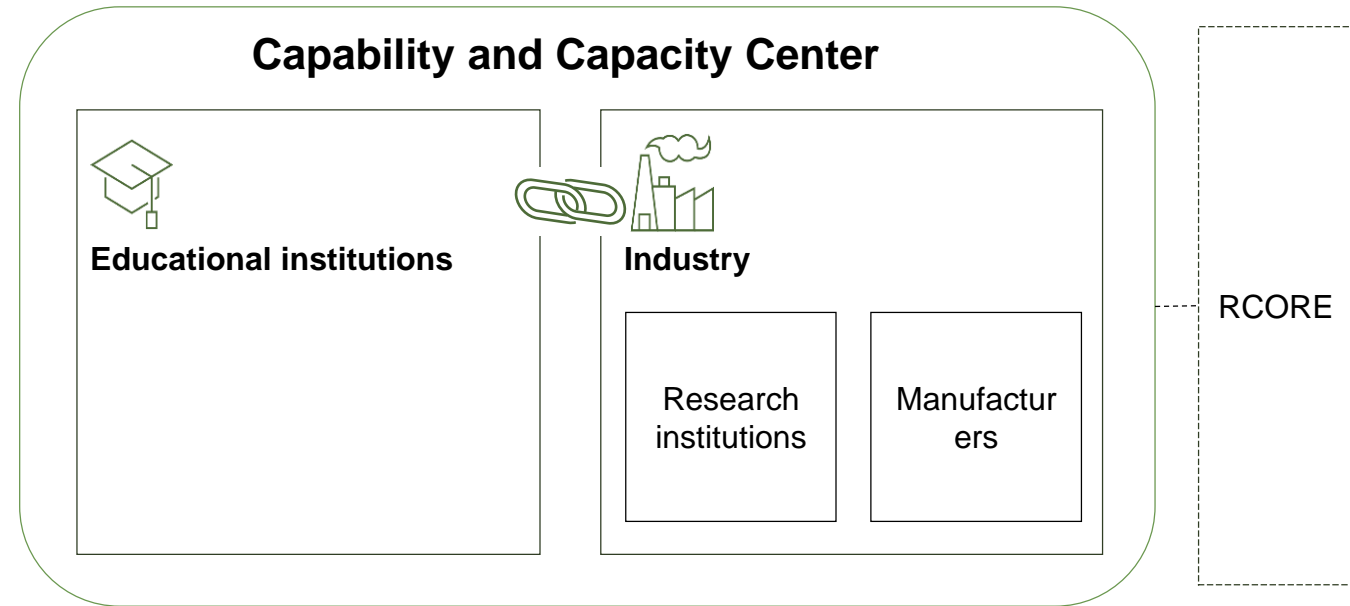
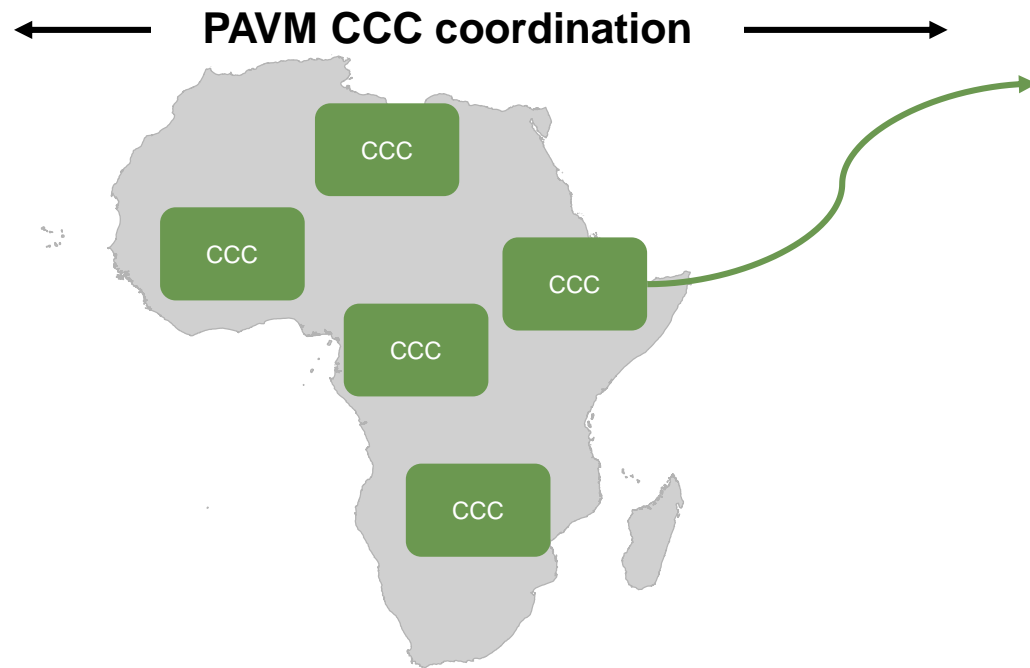
Programs can provide **custom training to develop a stronger local talent base**

Develop a playbook to support organizations in **defining and establishing a robust employee value proposition** to keep talent on the continent

Unlock access to funds for student scholarships, internship stipends, apprenticeship sponsorship, etc.

While initiatives are being developed and implemented, there will likely be a need to temporarily **leverage external experts, expat talent, international partners, etc.** to support immediate, urgent needs for talent development and training

The PAVM will create regional Capability and Capacity Centers comprised of regional educational institutions and industry players



PAVM will **coordinate regional CCCs including educational institutions and industry players**

This will include activities such as:

- **Manage program requirements** (e.g., expectations surrounding internships, on the job development programs, requirements on participation)
- Act as a **networking and communication platform**
- **Coordinate funding** for programs
- Track **needs and talent across the E2E ecosystem**
- **Facilitate partnerships with international players** as needed to pull in external expertise or expats to fill critical gaps

Capability and Capacity Centers will be located **regionally** (i.e., connecting local educational institutions in that region with local industry players in that region)

The CCC will **include industry players across manufacturing and research and each will be affiliated with one RCORE**

To participate in the CCC and thus receive key benefits, **all players must:**

- **Contribute to the continental strategy** which may require players to provide certain capabilities (i.e., coverage of a given technology or apprenticeship in a specific skill)
- **Agree to work with other players across the full Capability and Capacity Center** (i.e., no exclusive partnerships such as one university partnering with only one manufacturer)

