



HBV Forum11

Landscaping of HBV Clinical Research in Africa

Prof. Nicaise Ndembi, PhD MPH

Senior Strategy and Policy Adviser to Director General, Africa CDC
Africa Centres for Disease Control and Prevention

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The continental strategy calls for the production of 22 diseases across a range of technology platforms along all steps of the vaccine manufacturing value chain

PRELIMINARY

Vaccine exists Vaccine does not yet exist

1 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

2 Technology focus



... requiring a breadth of technology platforms¹...



3 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. Due to vaccine and modality agnostic nature, single plants could produce multiple vaccines, allowing for production of higher volumes that could lead to economies of scale, creating potential for Africa to become cost-effective against other DCVMs

Drug Substance (DS)

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

R&D

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

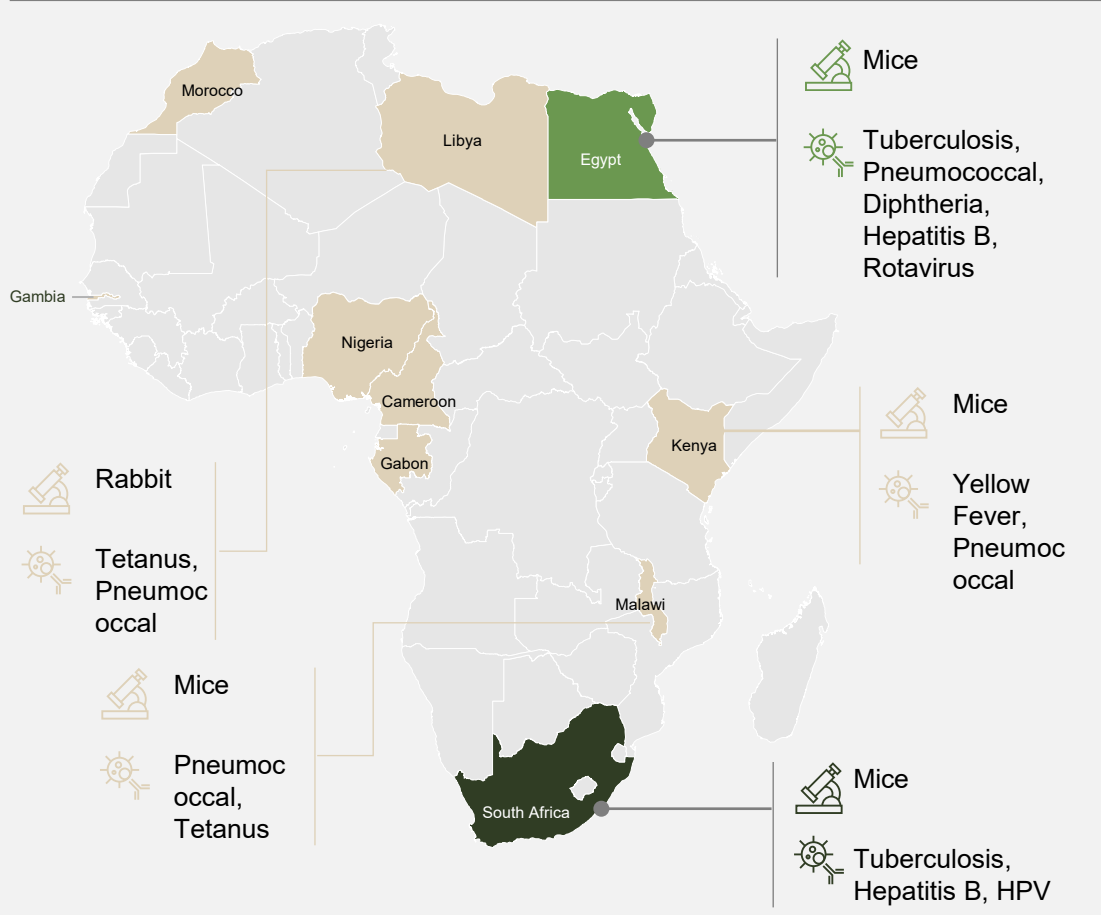
1. The FFA aims to balance both novel technologies with legacy technologies to ensure opportunities to grow and leverage newer technologies without risking putting too much reliance on new technologies that have not yet had long term experience built up. The continent could consider starting with these a sub-set of the technologies first: Inactivated virus, live attenuated, virus-like particle and RNA/DNA and then adding subunit and viral vector technologies later on.



Research activity on prioritized legacy and expanding diseases split in four clusters across continent

5 trials or less
 20 trials or less
 More than 20 trials
 Model organism
 Disease
 Legacy diseases
 Expanding diseases

Where studies are ongoing (2016 - 2021)



51 out of the 121 pre-clinical research papers focused on the prioritized legacy and expanding diseases in the past 5 years

Infectious diseases	Mice	Rabbit	Non-human primate	Total trials	Leading countries
Diphtheria	2	0	0	2	Egypt
Hepatitis B	4	0	0	4	South Africa, Egypt, Nigeria
Measles	0	0	0	0	-
Whooping Cough	0	0	0	0	-
Yellow Fever	1	1	0	2	Kenya
Typhoid fever	0	0	0	0	-
Tetanus	1	2	0	3	Libya, Malawi
Tuberculosis	20	1	3	24	South Africa, Egypt, Morocco, Cameroon
Cholera	0	0	0	0	-
HPV	2	0	0	2	South Africa, Morocco
Rotavirus	1	1	0	2	Egypt, Gabon
Pneumococcal	9	3	0	12	Egypt, Libya, Gambia, Malawi, Seychelles, Kenya

1. Includes tetanus, papillomavirus, rotavirus, yellow fever, papilloma virus and hepatitis A
 2. Including cattle, sheep, camel, horses, chicken, goats, rabbits, pigs, donkeys and mules



Clinical trials for prioritized legacy and expanding diseases mainly conducted in south, east and west of continent with gap in northern region

10 trials or less
More than 10
More than 20

 Trial Phase

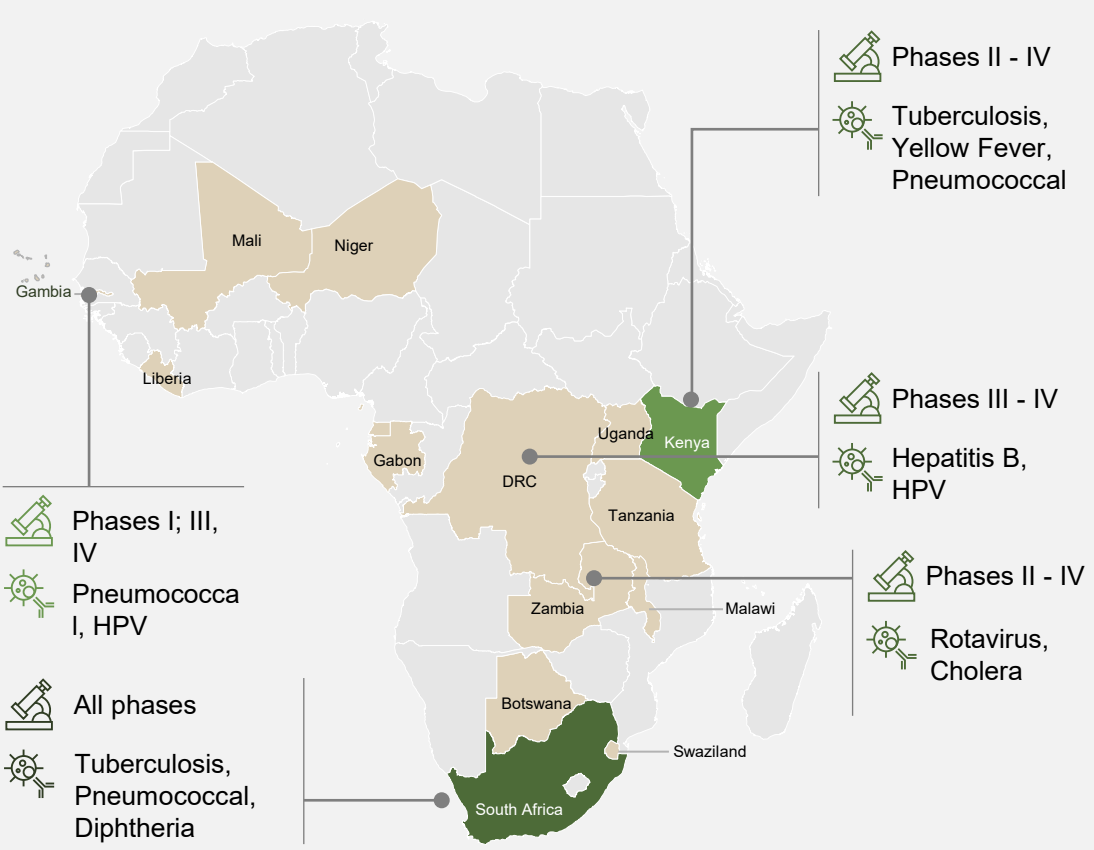
 Disease

Legacy diseases

 Expanding diseases

There are 68¹ clinical trials focused on the prioritized legacy and expanding diseases

Where studies are ongoing (2016 - 2021)



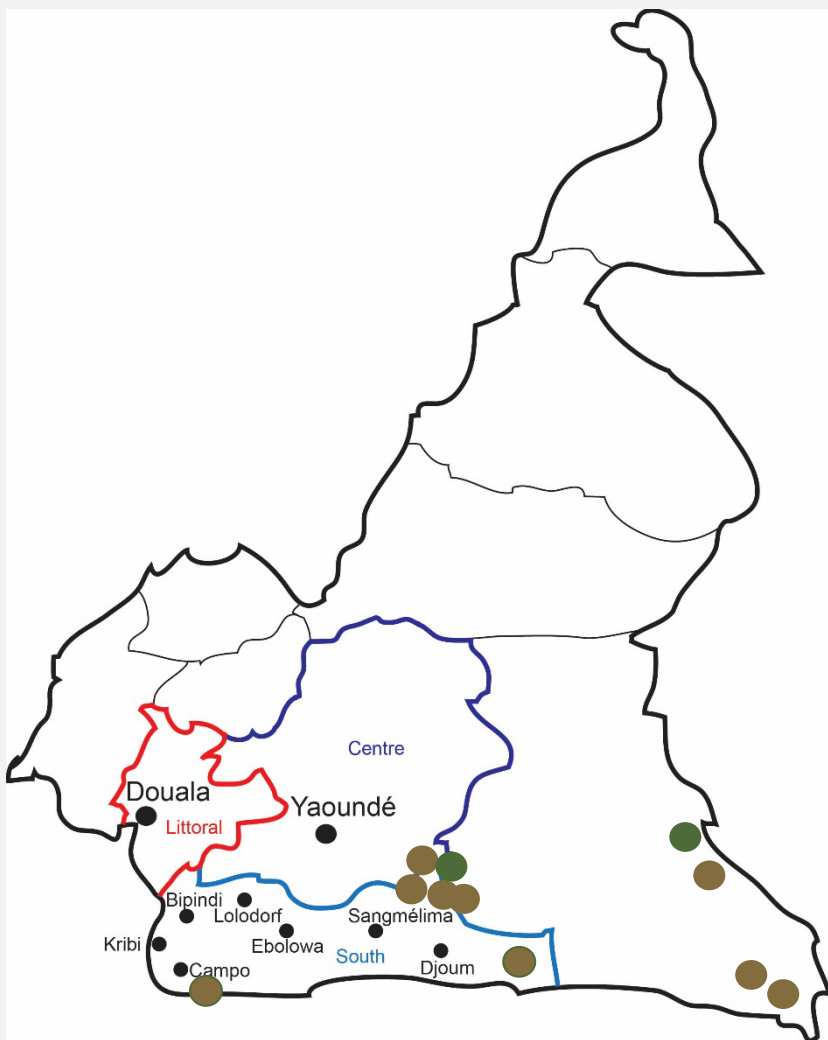
Note: This map does not in any way reflect our official positions in terms of international law

1. Currently over 3,000 clinical trials worldwide (African trials represent less than 3%)
 2. Includes cholera, yellow fever, HPV, whooping cough among others

Source: PubMed, ClinicalTrials.Gov, Press Searches, Scholarly Articles

Infectious diseases	Phase I	Phase II	Phase III	Phase IV	Total trials	Leading countries
Diphtheria	0	1	1	1	3	South Africa, Mali
Hepatitis B	0	0	0	5	5	DRC, Zambia
Measles	0	0	0	1	1	South Africa
Whooping Cough	0	1	0	1	2	Gambia, Uganda
Yellow Fever	1	0	0	4	5	Kenya, Uganda
Typhoid Fever	0	0	0	0	0	-
Tetanus	0	0	0	0	0	-
Tuberculosis	5	13	10	0	28	South Africa, Kenya, Botswana, Gabon, Uganda, Tanzania
Cholera	0	0	0	1	1	Zambia
HPV	0	0	4	3	7	Liberia, DRC, Gambia, Swaziland, Kenya
Rotavirus	0	4	3	0	7	Zambia, Malawi, South Africa, Kenya, Niger
Pneumococcal	1	0	6	2	9	Gambia, South Africa, Kenya

Longitudinal Surveillance of HIV and HBV in South Cameroon



SIVcpz ●; SIVgor ●; both SIVcpz and SIVgor ●;

Leftover blood collected from 22 sites:

- Voluntary testing campaigns
- Antenatal clinics
- Patients with illness of unknown etiology
- Door to door recruitment

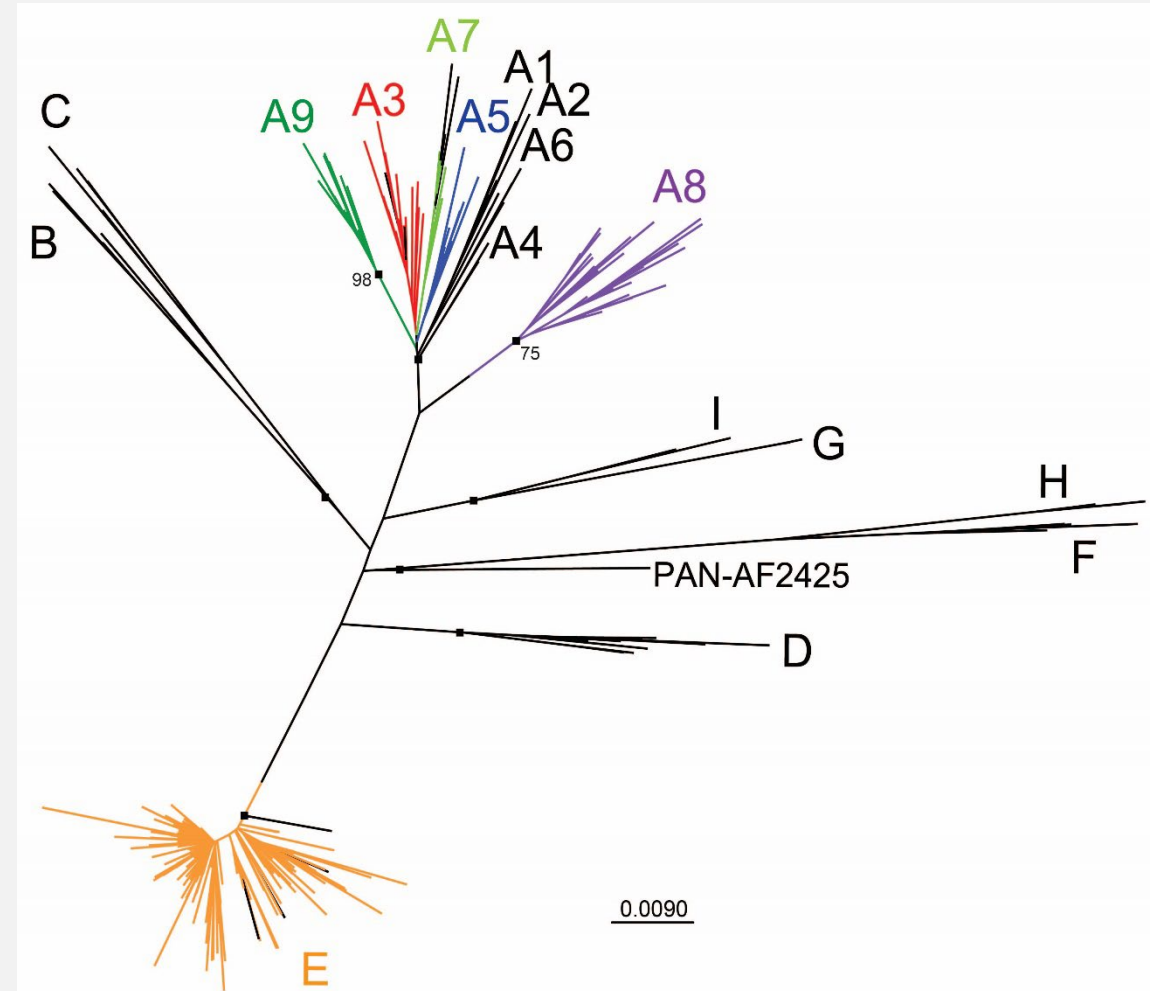
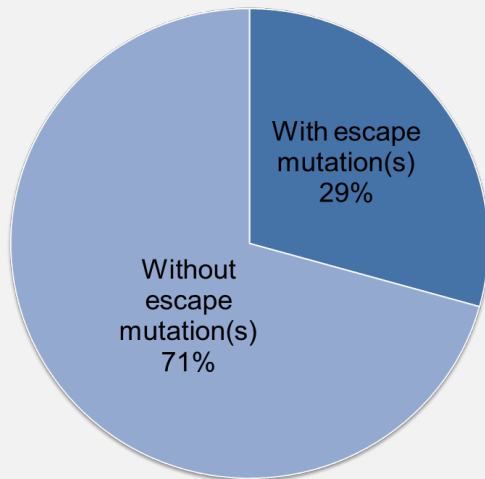
Annual shipments

~2000-3000 samples per shipment

- 1-3ml per sample received
- 13,700 total samples screened for HIV and HBV
- Prevalences are:
 - 40% HIV (prescreened) – Groups M, N, O
 - 10% HBV - 15% escape mutations
 - 1% HTLV – 1, 2, 3
- >1000 sequences deposited in Genbank

HBV Strains Identified in South Cameroon

Genotype	N	%
A	9	2.24
A3	26	6.48
A5	8	2.00
A7	5	1.25
A8	54	13.47
A9	24	5.99
AE	1	0.25
AE dual	3	0.75
E	271	67.58
Total	401	



N= 401 sequences

1 AE recombinant sequence, 84% genome coverage

Nigeria HIV-AIDS Indicator and Impact Survey 2018 – HBV and HCV

Indicator	Female		Male		Total		Unweighted sample size
	%	95%CI*	%	95%CI	%	95%CI	
HBV Prevalence							
15-49 years	6.1	5.1-7.0	11.1	9.6-12.5	8.6	7.8-9.5	8,682
15-64 years	5.8	4.9-6.6	10.3	9.0-11.6	8.1	7.3-8.9	10,438
HCV Prevalence†							
15-49 years	0.8	0.5-1.1	1.0	0.6-1.4	0.9	0.6-1.2	8,683
15-64 years	1.0	0.7-1.3	1.3	0.9-1.6	1.1	0.9-1.4	10,439
HIV/HBV Co-infection‡							
15-49 years	7.1	2.3-12.0	14.9	6.6-23.1	9.6	5.3-13.8	2,204
15-64 years	6.5	2.2-10.8	13.3	6.4-20.3	8.9	5.2-12.6	2,734
HIV/HCV Co-infection‡							
15-49 years	1.2	0.2-2.1	0.6	0.3-1.0	1.0	0.3-1.7	2,204
15-64 years	1.2	0.4-2.1	0.8	0.4-1.2	1.1	0.5-1.7	2,734

Abbreviations: HBV - hepatitis B virus, HCV - hepatitis C virus, HIV - human immunodeficiency virus

* The 95% CI (confidence interval) indicates the interval within which the true population parameter is expected to fall 95% of the time.

† The numerator for HBV and HCV prevalence is the number of people tested positive in each subgroup. The denominator is the number of eligible people tested in each age group who were tested for hepatitis.

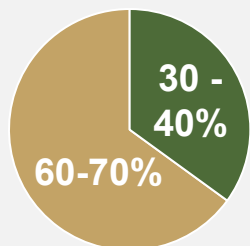
‡ Co-infection is defined as infected with HIV and either HBV or HCV. The denominator for co-infection is the number of eligible PLHIV in each age group.

Pharmaceutical and diagnostic manufacturing in Africa is still nascent, with heavy reliance on imports, and focus on upstream manufacturing



Therapeutics

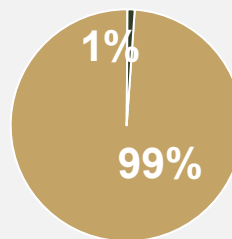
Total demand volume produced locally



Africa has limited manufacturing capacity, concentrated in a few countries, and low levels of integration along the value chain



Vaccines



The vaccines market is publicly driven and supply is concentrated to a small number of importers



Diagnostics Medical Devices



Investment is required to develop a clear overview of the diagnostics landscape on the continent

Supply	8	Countries contributing 80% of local production with over 600 manufacturers	5	Countries contributing 100% of local production with only 10 value chain players	~70	Local manufacturers with diagnostic manufacturing capabilities
	<20%	Manufacturers producing APIs operating in Africa	>80%	Manufacturers focus on fill and finish or packaging and labelling	>50%	Local diagnostic manufacturers focus test kits, with a strong focus on Covid-19, HIV/AIDS, Malaria, and TB
	<2%	Worldwide R&D projects in Africa				

Financing and procurement	~40%	Financed through private sector	~80%	Vaccines publicly financed and supplied through Gavi for 40 countries	Limited information available
	~25%	manufacturers belong to Multinationals	~70%	Gavi supported volume and ~40% self-financed volumes originate from a few established players in India	

EXPANDED MANUFACTURING OF VACCINES, DIAGNOSTICS, AND THERAPEUTICS

Africa CDC launched Partnership for African Vaccine Manufacturing (PAVM)

P Partnership for
A African
V Vaccine
M 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

RECAP - The Framework for Action defines 8 bold programs that will support the growing momentum of vaccine manufacturing in Africa

FFA Programs

Market design and demand intelligence

- 1 African Vaccines Procurement Pooling Mechanism

Access to finance

- 2 Vaccine manufacturing deal preparation and financing facility

Regulatory strengthening

- 3 Embedding Vaccines regulatory excellence in NRAs and RCOREs through AMA and AMRH

Technology transfer and IP

- 4 Vaccine Technology Transfer & IP Enablement Unit

R&D and talent development

- 5 Regional Capability and Capacity centres
- 6 Vaccine R&D centres and R&D coordinating unit

Infrastructure development

- 7 Advocacy for enabling trade policies for Vaccines



Human Capacity Development for Clinical Research in Africa

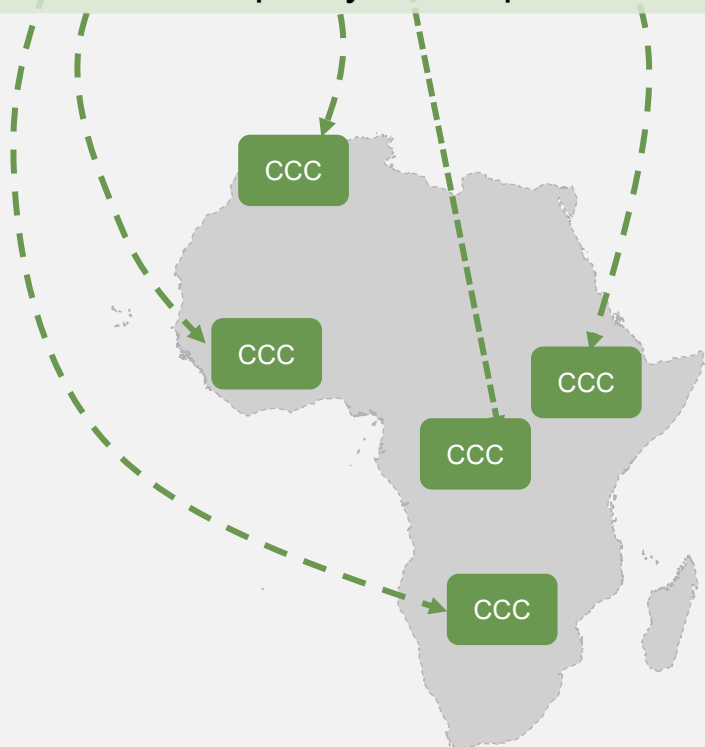
Partnerships for African
Vaccine Manufacturing

PAVM

From Aspiration to Action



Each Regional Hub will receive seed funding to the tune of US\$ 7.5 million for human capacity development.



Regional Hub Capacity Development Programmes



Academia

- Provide vaccine-specific classroom training for experienced hires
- Avail opportunity for training in graduate programmes
- Opportunities for trainings in vaccine-specific degree programmes



Pharma Industry

- Provide opportunity for mix of hands-on job training and mentorship
- Avail opportunity for internship programmes
- Provide opportunities for capacity building in R & D



Setting up Training Infrastructure at the Hub

- Set up on-the-job development programs that provide a mix of
 - hands-on job training, mentorship & internship
- Support academic institutions with industry experts as lecturers



THANK YOU



LEARN MORE AT

africacdc.org/covid-19

Safeguarding Africa's Health