The Advancing Vaccine End-to-end Capabilities in Africa Initiative

AVEC Africa

Jerome H. Kim, MD AVAC 3 June 2024



International Vaccine Institute

IVI: Who we are -- where we work -- what we do

Africa Office

Nairobi, Kenya, 2024

Africa Regional Office Kigali, Rwanda, 2024

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Other (COVID-19,

Chikungunya, AMR, etc).

KNUST-IVI

💡 Typhoid

Q Cholera

3 Collaborating Centers

In Ghana, Madagascar,

and Ethiopia

	IVI is an UN-chartered	Discover		Develop			Deliver		6 Ep	i. Surveillance
	international organization dedicated to accelerating vac R&D for global health		Material production, test & release for toxicology studies	Assay Validation & Clinical Samples Evaluation	Critical assay developr optimization Method validation acc			Field-based data collection incl. costing & willingness to pay		Protocol dev. incl. definition of endpoint, bio investigation, & database
			Protocol dev. CMO/CRO		guidelines			& willingness to pay		Prevalence & incidence est. of infection/disease severity
				Tech Transfer		andidates & process transfer to CMOs stability plan dev.	Health Economic Study	Global/country	Study Support	Data for decision on vaccine
			identification	Support	& stability plan dev.			analyses incl. invest., budget impact, cost- effectiveness, demand		Site preparedness for Ph.3 trial & effectiveness study
	evelo		Scalable & optimized processes for candidate Ag	Mfg. Support	Process scale-up & ens commercial-scale mfg. candidate supply	0		& disease burden	AMR Monitoring	AMR assessment & public database creation
Our mission	is to discover, develop and deliver safe, effective and affordable vaccines to enable the world's most vulnerable people to have full, productive lives		Analytical methods for qual. testing	Clinical Dev. & Regulatory Support	IPDP & CDP development Clinical trial implementation & management in HIC & LMIC		Policy & Advocacy Research		Vaccine Impact	Mass vaccination campaign
							Modeling	Vaccine impact & Modeling disease risk mapping		Vaccine intro through health authorities Real-life vaccine performance
			In vivo animal studies		Regulatory affairs cons	sultation	Modeling	etc.	· · · ·	assessment
Next step	is to expand our global presence and expand our (partnerships and innovative capabilities	 iNTS Group A s SFTSV Shigella Hepatitis Tuberculo 	• Hantavirus Pulmonary A, B • Syndrome	 Invasive Non-typhoidal Salmonella (iNTS) MERS-CoV Chikungunya Schistosomiasis Typhoid COVID-19 			 Human Papilloma Virus (HPV) Hepatitis E Cholera COVID-19 		 Typhoid Cholera COVID-19 RSV GAS Shigella 	
Together	we can achieve our <i>VISION</i> of developing countrie of suffering from infectious disease	 HAdV-55 COVID-19 	Lassa fever	Cholera	e array (MAP) Hep-B				• AMR	
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	Europe Regional Office Stockholm, Sweden, 2022	Argentina	a* Austria*	Bangladesh	Bhutan Brazi	China	Colo	mbia* Cote d'Ivoire*	Dominican Repub	olic* Ecuador
	10				-		\$	\mathbf{X}		
Country Office Vienna, Austria, 2022			El Salvador*	Ethiopia*	Finland Ghana		Indo	onesia Israel	Jamaica	Kazakhstan
			Kuwait*	Kyrgyzstan	k Lebanon Liberi		car* M	alta Mongolia	Myanmar	Nepal
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Pakistan

Sri Lanka

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Vietnam

Panama

Sudan*

WHO

Papua New Guinea

Sweden

Peru

<u>an</u>.

Tajikistan

Philippines

Thailand

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Tunisia*

Rwanda

C*

Turkey

Romania

UAE

*in-progress application

Oman

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Spain

Uzbekistan

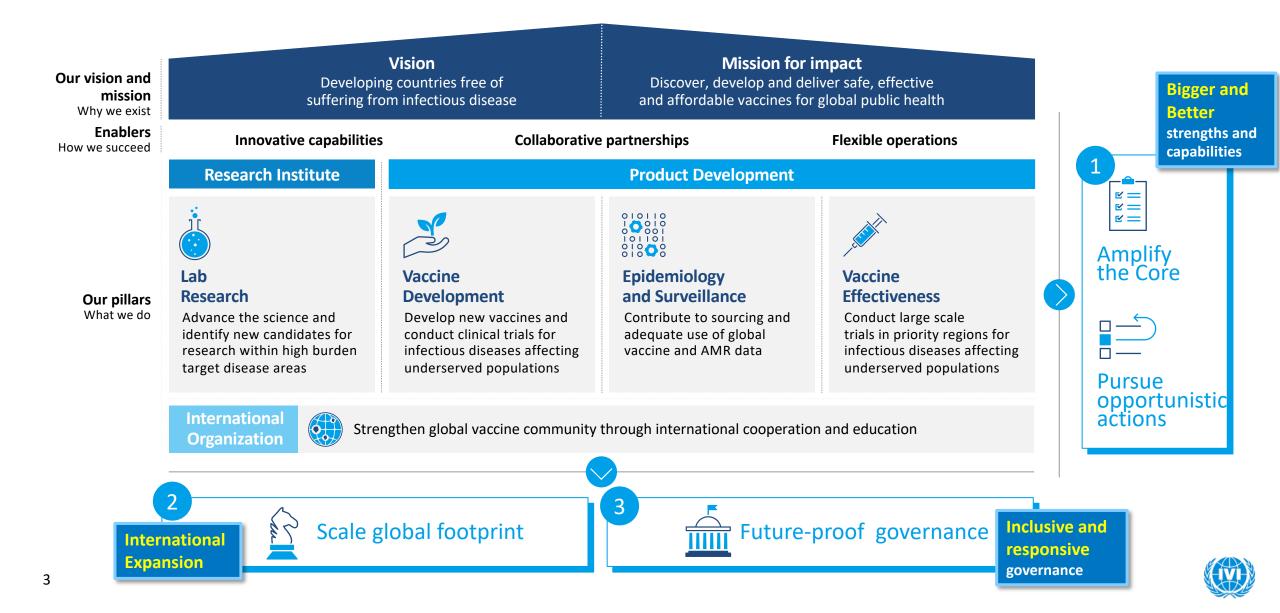
Netherlands

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Senegal

© Uganda*

Framework for IVI's strategic roadmap for 2022-2026



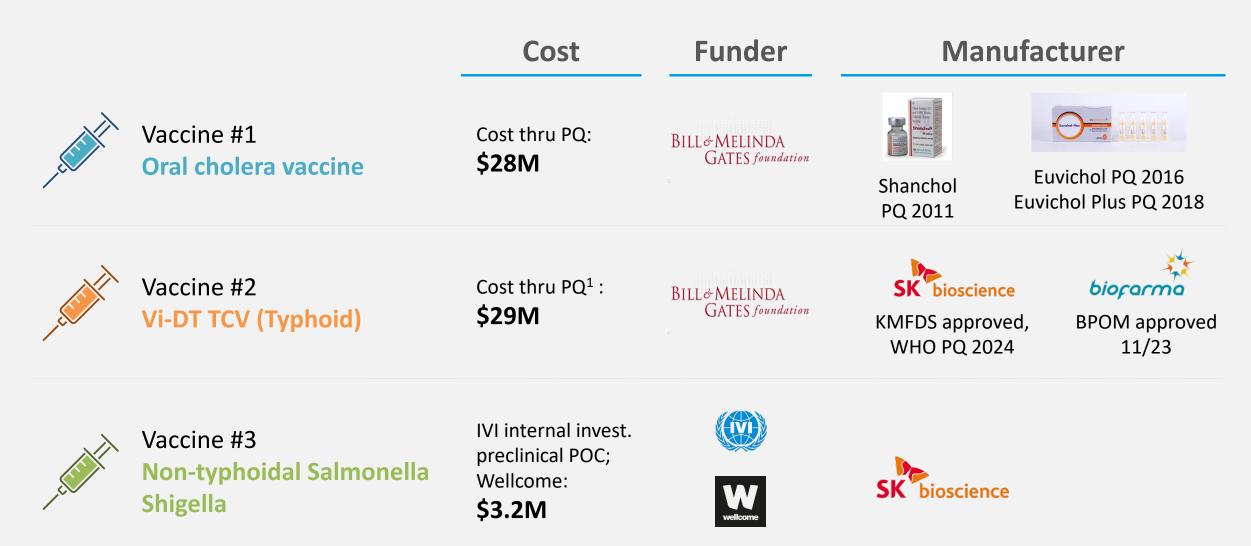


WHAT DO WE DO? Enhance vaccine manufacturing capacity (Korea)

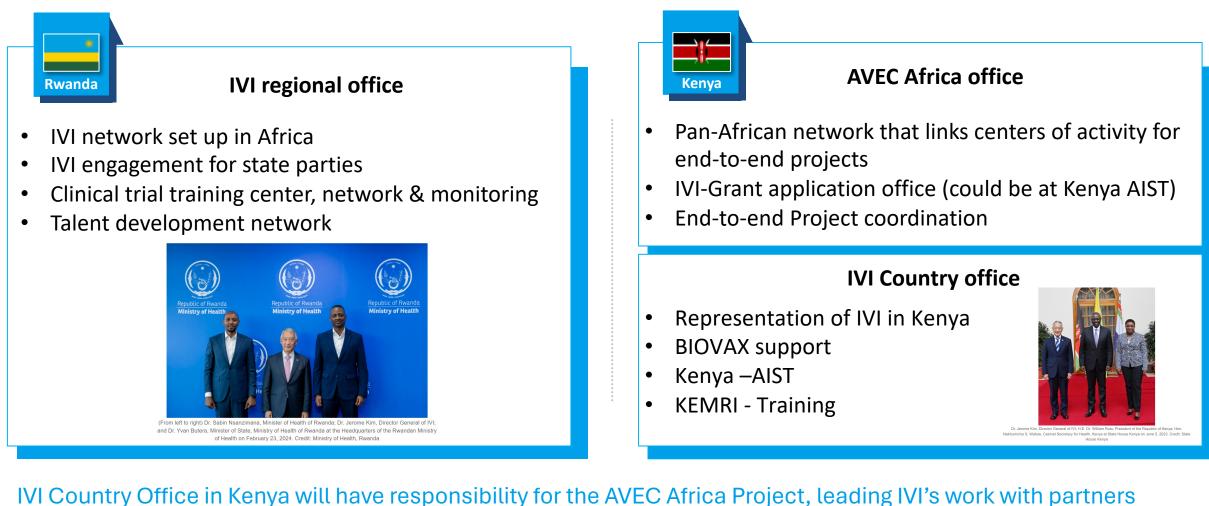




IVI Vaccines Bring Affordable Innovation to Global Health



1. Estimated



and stakeholders on end-to-end vaccine R&D projects in support of sustainable manufacturing in Africa



New Initiative: HKJC Global Health Institute (15 Nov 2023)

HKJC Global Health Institute

Objective

to strengthen the global pandemic preparedness system to rapidly identify new pathogens with pandemic potential and develop vaccines within an accelerated timeframe.

Global Health Institute

A transformational initiative led by HKU/IVI/UCAM leveraging the 5-year consortium formed between IVI* & CITIID*

Funding

From HKJC estimated at \$64M (IVI ~29.4M USD)

Governance

- Annual executive board IVI/UCAM/HKU & HKJC for high-level oversight
- Monthly executive committee meeting
 IVI/UCAM/HKU
- Administrative director
 Operational management of the GHI
- Functional unit

Staff members to work directly with their counterparts in Seoul, Cambridge & HKU

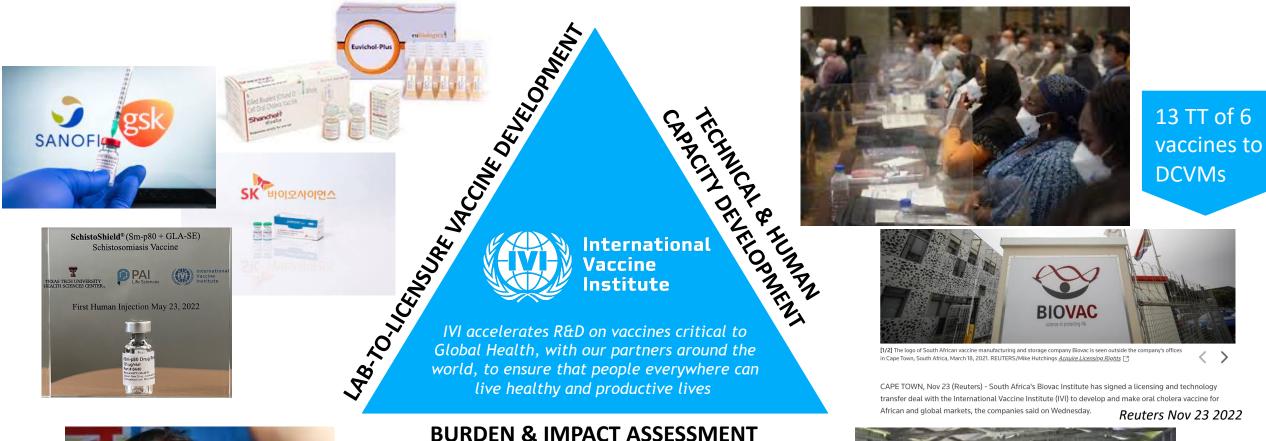


HKU : Hong Kong University

CITIID: Cambridge Institute of Therapeutic Immunology and Infectious Disease at the U Cambridge (UCAM) IVI: International Vaccine Institute



How we do it: end-to-end development > from innovation to impact









The 'Advancing Vaccine End-to-end Capabilities in Africa' initiative

AVEC Africa

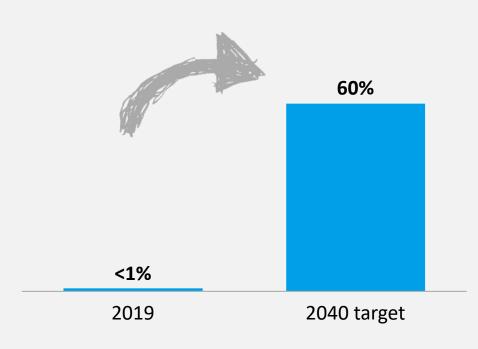




Ambitious objectives set for the continent by the Africa CDC / PHAHM¹

Strengthening of the African R&D and manufacturing system is required to:

Share of African vaccine demand produced on the continent





Strengthen pandemic preparedness Ensure Africa is ready to tackle the next pandemic, with appropriate clinical development and manufacturing capabilities and capacity

Tackle endemic diseases Develop & produce vaccines for local / regional and outbreak diseases that currently do not receive sufficient attention from global players



Establish a thriving vaccine manufacturing industry and reduce dependence to external supply for priority vaccines

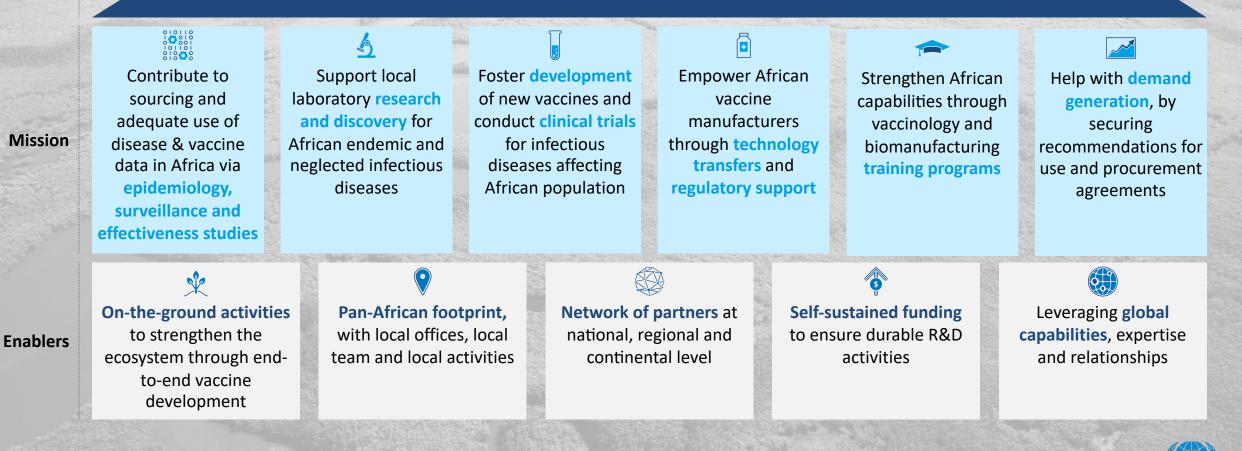


1. Platform for Harmonized African Health Products Manufacturing

The 'Advancing Vaccine End-to-end Capabilities in Africa' initiative (AVEC Africa) would build capacity and sustainability of the vaccine ecosystem

Vision

Accelerate the development of the African vaccine R&D ecosystem to make it the **powerhouse** of continental manufacturing via a **sustainable pan-African alliance executing** on the ground



Through projects, **AVEC Africa** will operationally support the implementation of 4 of the 8 programs identified in the Africa CDC - PHAHM Framework For Action

AFRICA CDC – PHAHM¹

Framework For Action



Program 1: Creating an African vaccines procurement pooling mechanism



- Program 2: Establishing a vaccine manufacturing deal preparation and financing facility
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Program 3: Strengthening NRAs and RCOREs² to build vaccine regulatory excellence





Program 4: Supporting technology transfer through an intellectual property enablement unit



Centres $\overline{\mathbf{M}}$

Program 5: Creating Regional Capability and Capacity



Program 6: Putting in place vaccine R&D centers and an R&D coordinating unit





Program 7: Undertaking advocacy for enabling trade policies for vaccines



Program 8: Ensuring effective continental strategy delivery and oversight

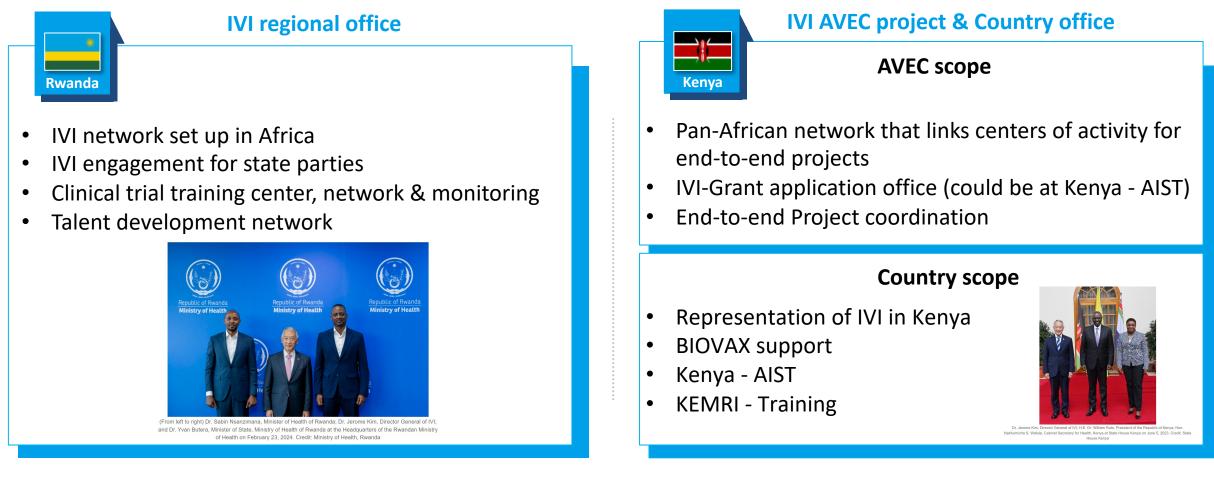


(Advancing Vaccine End-to-end Capabilities in Africa)

- AVEC Africa will execute end-to-end vaccine development **projects** identified in the Africa CDC/PHAHM Framework for Action to enable an R&D ecosystem that will support sustainable manufacturing
- Constant coordination and collaboration between Africa CDC/PHAHM and 'AVEC Africa' (progress update, information sharing, linking with stakeholders, etc.)

1. Platform for Harmonized African Health Products Manufacturing; 2. NRA: National regulatory Authority; RCORE: Regional Centre of Regulatory Excellence

Through the on-going establishment of its project/country office in Kenya and its regional Office in Rwanda, IVI will accelerate its global health support in Africa



IVI Country Office in Kenya will have responsibility for the AVEC Africa Project, leading IVI's work with partners and stakeholders on end-to-end vaccine R&D projects in support of sustainable manufacturing in Africa



IVI has developed a solid pipeline of projects and funding opportunities including partner-led collaboration in Africa



Manufacturer support

Select examples:

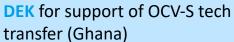
Institut Pasteur of Dakar: - MR vaccine clinical development - Biomanufacturing training (Senegal)



Afrigen support for developing mRNA capabilities (South Africa)

Biovac OCV-S tech transfer and clinical trial (South Africa)







Vaccine development / Clinical Trials

Select examples:

Advancing research capacity in West Africa (ARC-WA) starting with Lassa fever

mRNA Rift Valley Fever vaccine development with Afrigen (proposal in due diligence)

Phase 2b study for Hepatitis E vaccine in South Africa

Real-world Effectiveness of Oral Cholera Vaccines in Preventing Cholera in Mozambique (REOP).

Typhoid surveillance and effectiveness (Ghana, RD Congo, Mozambique, Madagascar)

Vaccine Against Schistosomiasis in Africa (VASA) (Burkina Faso, Madagascar)



Training programs

Select examples:



Global training hub biomanufacturing (GTH-B)



IVI Vaccinology course (including **Rwanda**)

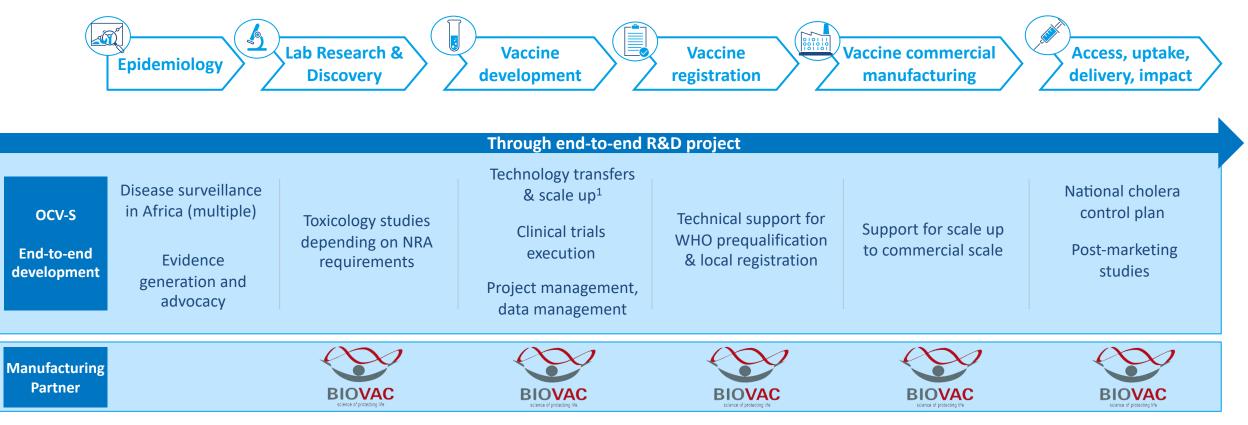


Kenya-AIST- Academic Programs

Advancing Partner-led Collaborations: application where the local partner is the grant recipient or co-lead

Example of end-to-end R&D project: The new Oral Cholera Vaccine-Simplified (OCV-S) has a lower cost, an increased yield, AND is easier to technology transfer

IVI's tailored support for partner R&D strengthening: Oral Cholera Vaccine-Simplified (OCV-S) Funder: BMGF & Wellcome Trust; Development Partner: EuBiologics; Tech transfer: to Biovac (S. Africa)



1. Prior to any technology transfer, source of IP and capacity of Sending and Receiving Unit must be assessed

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A response to the global shortage of cholera vaccine, OCV-S, allows greater production at a lower cost and makes technology transfer more accessible



AVEC Africa: strengthening end-to-end vaccine development capability for sustainable manufacturing and vaccine security





International Vaccine Institute

VACCINES FOR A HEALTHIER FUTURE

Thank You