



SUSTAINABLE VACCINE MANUFACTURING THROUGH END-TO-END VACCINE RESEARCH AND DEVELOPMENT PROJECTS IN AFRICA

A side event of the 37th Ordinary Session of the
Assembly of the African Union

18 February 2024 07.00 - 10.30 | Hyatt Regency Addis Ababa,
Regency Ballroom

Organized jointly by the Government of Kenya, the International Vaccine Institute, and Africa CDC



REPUBLIC OF KENYA



AfricaCDC
Centres for Disease Control
and Prevention



International
Vaccine
Institute

Introductions

Vaccines are crucial for global health, saving lives, and bolstering communities in the prevention and control of infectious diseases. While COVID-19 catalyzed swift advancements in vaccine innovation, the pandemic revealed disparities in access. By January 2022, the percentage of the population fully vaccinated against Sars-CoV-2 was 71% in the EU and 63% in the United States, but only 10% in Africa¹.

With Africa currently producing less than 1% of its vaccine needs, the imperative to invest in self-sufficient vaccine industries tailored to local needs is evident and urgently requires attention. One of the key enablers is to foster the vaccine ecosystem from capacity-building to access, delivery, and uptake, thereby accelerating relevant solutions for vaccine self-sufficiency in Africa. Self-sufficiency and self-reliance are even more urgent as climate change exacerbates the threat of outbreaks, further impacting resource-limited nations.

The Government of Kenya, the International Vaccine Institute (IVI), and the Africa CDC co-hosted a breakfast event on the margins of the 37th Ordinary Session of the Assembly of the African Union and to advocate for and discuss an integrated vaccine ecosystem in Africa executed through end-to-end vaccine research and development projects. The event, held on the 18th of February 2024, brought together key stakeholders including government officials, public health experts, pharmaceutical industry leaders, and international partners.

Participants

The event gathered leaders from national health agencies, regional vaccine manufacturing experts, and international partners. Over 150 participants from more than 30 countries registered for the event.

The following Heads of State were present at the event:

- H.E. Dr. William Ruto, President of Kenya,
- H.E. Mohamed al-Menfi, Chairman of the Presidential Council of Libya
- H.E. Brahim Ghali, President of the Sahrawi Arab Democratic Republic
- Hon. Ahmed Hachani, Prime Minister of Tunisia

¹ Our World in Data. Coronavirus (COVID-19) Vaccinations. <https://ourworldindata.org/covid-vaccinations>. Accessed March 1, 2024.

Session 1

Dr. Michael Lusiola, CEO / Director-General of the Kenya BioVax Institute opened the event and provided the aim - to discuss and agree on ways to work with sustainable vaccine manufacturing on the continent.

Welcome – Mr. George Bickerstaff, Chair of the International Vaccine Institute Board of Trustees

Mr. Bickerstaff thanked the co-organizers of the event, the Government of Kenya, and the African CDC. Vaccines are a pathway to healthier empowered communities. The COVID-19 pandemic highlighted the inequity in access to, and distribution of vaccines. Africa currently produces less than 1% of the vaccines used on the continent. However, Africa has chosen a pathway to self-sufficiency and self-sustainability through the development of a thriving vaccine ecosystem driven by end-to-end project initiatives. End-to-end project initiatives are a catalyst to action, bringing together expertise from governments, public health leaders, industry pioneers and international partners.

End-to-end project initiatives span from research and development to production and delivery of vaccines. They include regulatory frameworks that foster innovation while ensuring safety and accessibility of vaccines, and skilled workforces operating cutting-edge facilities. A strong vaccine ecosystem in Africa includes knowhow and products transcending borders, and robust markets ensuring affordable and equitable distribution.

It is hoped that this event will spur action and a commitment to share expertise and forge partnerships that will unlock the potential for end-to-end project partnerships and drive impactful change to a more healthy and resilient future for Africa.

Initiative for a sustainable vaccine manufacturing ecosystem through end-to-end vaccine research and development in Africa – Dr. Jerome Kim, Director General of the International Vaccine Institute

To realize the goal of the Partnership for African Vaccine Manufacturing (PAVM)², for 60% of Africa's vaccines to be produced on the African continent by 2040, end-to-end projects across the vaccine development process are needed. The International Vaccine Institute has a strong track record and an excellent reputation in the global health community for driving end-to-end projects. To date, IVI has

²Africa CDC. Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action. <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>. Accessed March 1, 2024.

technology transferred 12 vaccines and has supported the training of over 5,000 experts in vaccinology and biomanufacturing.

PAVM is critical in providing a framework for action and the IVI “AVEC Africa: Advancing Vaccine End-to-end Capabilities in Africa” can address four of the PAVM goals. The initiative covers the entire vaccine value chain and highlights the need to bring together laboratory knowhow, regulators, distributors, and others to train people and build capabilities in the ecosystem to sustain vaccine manufacturing. AVEC Africa works with African partners to enable the development of an end-to-end vaccine R&D ecosystem and has the capacity to address key gaps and challenges in epidemiology, laboratory R&D, vaccine development, registration and manufacturing, and vaccine access, uptake, delivery, and impact. Through AVEC Africa, IVI proposes to work with end-to-end coverage of the vaccine value chain and to facilitate partnerships across the continent.

Vision of local manufacturing as the second independence of Africa – Dr. Jean Kaseya, Director-General, Africa CDC

The Partnerships for African Vaccine Manufacturing (PAVM), established by the African Union Heads of State and Government in 2021, set an ambitious goal of locally manufacturing 60% of Africa’s vaccine needs by 2040. To achieve the goal, the Africa CDC is leveraging all the mechanisms (continental) to ensure sustainable vaccine manufacturing on the continent.

In the 37th AU Summit, the following important announcements that consolidate the Africa CDC’s work to ensure the continent’s second Independence i.e., manufacturing all health products were noted:

1. Establishment of the Pooled Procurement Mechanism (PPM) spearheaded by Africa CDC for medical products from African manufacturers.
2. Broadening the mandate of the PAVM to include manufacturing of medicines and diagnostics.
3. Appointment of H.E. Dr. William Ruto, President of the Republic of Kenya as African Union Champion for local manufacturing.

While being ambitious, Africa CDC is realistic about the challenges manufacturing faces. To mitigate these challenges, the Africa CDC is working on different aspect of the ecosystem – from R&D, clinical trials, capacity building, manufacturing, financing, regulatory process, and market access. One large step forward was the approval of the African Vaccine Manufacturing Accelerator – AVMA, set to be launched in June 2024. One billion USD has been committed by GAVI³ to support regional manufacturers.

³Gavi, the Vaccine Alliance. The African Vaccine Manufacturing Accelerator: what is it and why is it important? [https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important#:~:text=manufacturing%20in%20Africa.,The%20African%20Vaccine%20Manufacturing%20Accelerator%20\(AVMA\)%20is%20designed%20to%20make,also%20benefit%20outbreak%20and%20pandemic.](https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important#:~:text=manufacturing%20in%20Africa.,The%20African%20Vaccine%20Manufacturing%20Accelerator%20(AVMA)%20is%20designed%20to%20make,also%20benefit%20outbreak%20and%20pandemic.) Accessed March 1, 2024.

Africa CDC is committed to working with all like-minded stakeholders to ensure successful end-to-end vaccine projects, thus delivering on the New Public Health Order call to action strategic pillar: “Expanded manufacturing of vaccines, diagnostics and therapeutics

The AU Health Strategy – H.E. Amb Minata Samate Cessouma, Commissioner for Health, Humanitarian Affairs and Social Development, African Union

Vaccine manufacturing is important for the African continent and the African Union has a strong involvement in ensuring its realization. The African Health Strategy is a visionary framework to address sanitary problems that the African continent is facing - making the population more resilient and ensuring that every African citizen has access to quality health. The strategy will link education and health, leading to a reduction in poverty and drive sustainable economic development. As part of this strategy the key intervention areas include strengthening health systems, promoting prevention, primary health care, innovation, and research to support health. The African Union recognizes that partnership is critical to build capacity and to sustain the health infrastructure and ensure health sovereignty.

Africa was the last continent to benefit from the COVID-19 vaccines. Routine vaccination is important to achieve Africa’s sustainable development. People need easy access to quality vaccination and local manufacturing will help to achieve this. The AVMA has been particularly important for Africa and the collaboration is important for the African Union members states. Producing quality vaccines will help the people and reduce the use of counterfeit drugs. All member states are committed to support local vaccine manufacturing. There is a need to strengthen local capacity and dependence on exterior sources. Countries that are already producing vaccines should be congratulated and all parties are invited to continue to strengthen the partnership and support the collaboration to drive local vaccine manufacturing.

Hon Nakhumicha S Wafula, Cabinet Secretary for Health, Republic of Kenya

The presence of the Head of States at this event demonstrates their commitment to advancing the manufacturing of therapeutics and diagnostics on the African continent. There is a strong regional effort bringing together governments, R&D institutions, manufacturers, and others to protect the African people in times in need. Kenya has made strides forward, including the establishment of the Kenya BioVax Institute. The Kenya BioVax Institute will begin with fill and finish and with childhood vaccines. The institute is part of the effort to ensure manufacturing of local products, harmonization efforts in regulatory affairs, and workforce development.

H.E. Dr. William Ruto, President of Kenya

COVID-19 was an unacceptable situation with inequitable distribution of vaccines. In addition, it is also important to remember that the Mpox pandemic which received no international support until the disease spread beyond the African continent. Four years later, not one dose of the available Mpox vaccines have reached Africa. Africa needs to take steps to build a holistic ecosystem to support R&D, clinical trials, manufacturing, distribution, and delivery. Africa needs to sustain support for regulation and other frameworks and the building of human capacity to drive forward vaccine manufacturing.

Members of the African Union need to support the mobilization of adequate resources, sharing of knowledge, best practice and to translate the resources into concrete actions. Developing African vaccine capacity has the fundamental goal to achieve vaccine and healthcare sovereignty. Africa needs to remove dependence on external funding mechanisms and support African driven actions. African leaders need to mobilize resources and remove intellectual property difficulties. The focus should be on saving lives, and not greed for profit.

Kenya currently imports one billion USD of pharmaceutical commodities each year. This figure highlights the lost opportunities. Today we are discussing a reality we can make happen. The capacity needed for vaccine and pharmaceutical manufacture is already resident in Africa.

One example is [Revital](#), a Kenyan pharma company, that exports pharmaceutical products to Kenya and internationally. The African continent has the potential to manufacture for African consumption, but also for a global market. Kenya is ready on both fronts. Kenya has signed an agreement with Moderna, investing 500M USD, in the set up the first COVID-19 vaccine manufacturer in Kenya. The facility will also be used for other vaccines that are required. Kenya has established a special economic zone that will provide the necessary environment for pharmaceutical companies to set up and pharmaceutical companies are invited to establish themselves in Kenya. There exists an opportunity for a 1 billion USD market in Kenya and a 50 billion USD market in Africa.

Africa needs local production of vaccines – no one is safe until everyone is safe. Together, the African countries have a chance to face the challenges of today and for future generations. Today we will shift gears to go further, faster, to make manufacturing of vaccines in Africa a reality.

H.E. Mohamed al-Menfi, Chairman of the Presidential Council of Libya

H.E. Mohamed al-Menfi complimented the President of Kenya on the manufacturing plans for Africa and congratulated the countries that are already manufacturing vaccines and medicines. Libya will support the manufacture of vaccines and medicines with all means – technical and investment. It is of paramount importance to support independent facilities that can deal with epidemics and allow Africa to deal with future outbreaks. The COVID-19 pandemic highlighted the difficulties in vaccine

access, with Africa being the last to have access to vaccines. Africa needs to depend on their own endeavor and not wait for a donation from others. This meeting is hoped to be an inspiration for the continent to support those countries that are manufacturing medicines and vaccines. Libya has had a critical role in manufacturing medicine, but they are dependent on imported machinery, and as such have not yet been able to contribute.

Hon. Ahmed Hachani, Prime Minister of Tunisia

Tunisia has a rich past concerning vaccine manufacturing – since the first decade of the last century, Tunisia has been manufacturing vaccines. Therapeutics produced in Tunisia have been exported to other countries. Institute Pasteur, the only organization in Tunisia that is producing and manufacturing vaccines, has been producing vaccines and transferring knowledge to Korea, Turkey, Egypt, and others. Institute Pasteur has been chosen by the WHO to benefit from a technology transfer for mRNA vaccines. Africa can fully rely on the knowhow of Tunisia, which was acquired over a century ago.

Tunisia has invested in university institutions focused on health and pharmacy and has the potential to contribute to training (doctors, pharmacists, biologists etc.). However, it is important to ensure that trained personnel are retained in Africa and do not leave for Europe as part of the brain drain. Tunisia is steps ahead and has about 120 companies that participate in the technology value chain with more than 33 that manufacture medicines. There are multiple success stories – nationally or internationally – making Tunisia one of the top countries for manufacturing of medicines on the African continent. The market value in 2022 was more than 1 billion USD. Africa should rely on itself, and all African Union countries are partners and should help one another to ensure that Africa reaches its full potential. Tunisia is supportive to all its neighbors on the continent and together the African countries can make miracles.



Session 2

Dr. Anh Wartel, Deputy Director General, Europe Office / Regional Director, IVI Europe Regional Office opened the Session 2 and provided the aim – to receive PAVM's updates and have a robust panel discussion with experts on the pillars of the vaccine manufacturing ecosystem, fostering collaboration and coordination among stakeholders.

Dr. Abebe Genetu, Acting PAVM Coordinator, Africa CDC

The African Union strategy for local manufacturing should be seen as the second independence of Africa. In 2021, the African Union Heads of State supported the development of PAVM with the goal to manufacture 60% of the vaccines for Africa on the African continent. PAVM has since focused on the implementation of the strategy to ensure health markets for locally produced vaccines, secure the production of quality products, facilitate sustainable production, support capacity building, and drive R&D. The PAVM Framework of Action defined eight bold programs and the following is an update on the different programs:

Program 1: Creating an African vaccines procurement pooling mechanism

Africa CDC and GAVI are cohosting a manufacturing marketplace for African Union member states and manufacturers. They are mapping the manufacturing landscape to ensure alignment of manufacturers.

Program 2: Establishing a vaccine manufacturing deal preparation facility and fundraising for ecosystem enablers

Through collaboration of GAVI and Africa CDC, the African Vaccine Manufacturing Accelerator⁴ (AVMA) has been established. The AVMA will dedicate 1 billion USD over a 10-year period to support vaccines manufactured in Africa to be purchased by GAVI for use on the continent.

Program 3: Strengthening National Regulatory Agencies and Regional Centres of Regulatory Excellence to build vaccine regulatory excellence

Quality is not negotiable - vaccines need to be of a high standard. Once quality products are produced then Africa can enter the international market. One requirement for accessing the market is the need

⁴Gavi, the Vaccine Alliance. The African Vaccine Manufacturing Accelerator: what is it and why is it important? [https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important#:~:text=manufacturing%20in%20Africa.,The%20African%20Vaccine%20Manufacturing%20Accelerator%20\(AVMA\)%20is%20designed%20to%20make,also%20benefit%20outbreak%20and%20pandemic.](https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important#:~:text=manufacturing%20in%20Africa.,The%20African%20Vaccine%20Manufacturing%20Accelerator%20(AVMA)%20is%20designed%20to%20make,also%20benefit%20outbreak%20and%20pandemic.) Accessed March 1, 2024.

for high-quality vaccine standards. PAVM convened a meeting with Africa CDC, the African Union Development Agency-NEPAD and the WHO with the purpose of determining how to fast track the regulatory process on the continent. There is a need to ensure that products reach WHO PQ to enable GAVI to use the vaccines. National regulatory authorities need support, and acquisition of equipment for national control laboratories for vaccine quality testing is needed.

Program 4: Support the transfer of vaccine technologies and intellectual property through an enablement unit

There are 24 African manufacturers with production plants, of which only nine currently are installed. Six manufacturers are likely to commercialize in the short term with an additional three manufacturers prepared to receive technology transfers. Africa CDC has conducted an extensive mapping of the vaccine manufacturers, and this shows manufacturers working with multiple antigens, including yellow fever, which could enter the African market as early as 2024. The bulk of production of African produced vaccines will be from 2026 onwards. Vaccines that are in the pipeline include Hexavalent vaccine, Pneumococcal conjugate vaccine, Meningitis, Yellow fever, Rotavirus, IPV (Polio) and Measles/Rubella.

Program 5: Creating Regional Capability and Capacity Centres

A skilled workforce is needed to support regional manufacturing. Africa currently has around 1,500-3,000 full time equivalents (FTEs) working in vaccine R&D and manufacturing on the continent. To reach the goal of 60%, Africa needs at least 12,000 FTEs. A competency framework has been developed to determine how to reach the 12,000 people needed, and a needs assessment has been conducted to identify missing skills for manufacturing. The framework and needs assessment will support workforce development on the continent. The collaboration with IVI and other institutions has allowed the training of over 100 experts on vaccine manufacturing but this needs to be expanded. The final goal is to localize the training on the continent to ensure self-sufficiency.

Program 6: Putting in place vaccine research and development centres and a research and development coordinating platform

The development of R&D centers should not always be dependent on technology transfers. There is a need to invest in upstream discovery.

Program 7: Undertaking advocacy for enabling trade policies for vaccines

Under this, Africa CDC works with the African Continental Free Trade Area (AfCFTA Secretariat) to ensure favorable barriers are removed to ensure a conducive trade facilitation for locally produced health products.

Program 8: Ensuring an effective continental strategy for delivery and oversight

The vaccine value chain diagnostic has been completed and there are clear gaps. A draft strategy has been developed to ensure sustainable access and supply chain for input of raw materials. A forum of more than 150 people was recently held in Nairobi. This forum brought together suppliers and manufacturers, and potential solutions to sustainable access were discussed. All parts of the vaccine (vials, etc.) need to be produced in Africa for true self-sufficiency.

Panel Discussion: The pillars of the vaccine manufacturing ecosystem for fostering stakeholder's collaboration and coordination

Chaired by Dr. Anh Wartel, Deputy Director General of the International Vaccine Institute

Aligning with the goal set forth by the PAVM in its Framework for Action to meet 60% of Africa's vaccine demand by 2040, vaccine R&D projects are crucial for contributing to this objective and ensuring vaccine self-sufficiency across the continent. With this goal in mind, the panel discussion focused on strategies and insights on various aspects of the vaccine manufacturing ecosystem.

Prof. William Ampofo, Executive Director, African Vaccine Manufacturing Initiative (AVMI) / CEO of National Vaccine Institute (NVI), Ghana

After COVID-19, there has been a strong political commitment towards African vaccine manufacturing and the African Union has taken the issue very seriously. The discussion has even been expanded to include other pharmaceuticals. The African vaccine manufacturing scene has changed in the past years; however, the production of vaccines remains at 1%. At the African Vaccine Manufacturing Initiative (AVMI), which consists of scientists and manufacturers, there is excitement that there is a forum to move the idea of African vaccine manufacturing forward. The ecosystem is being defined and needs to include funding, technology transfers, a process for WHO PQ, a strong regulatory system, and a market to support a sustainable vaccine process. However, to be fully self-sustained, it is important to encourage R&D.

Capacity-building is essential for enhancing vaccine manufacturing capabilities, as the PAVM strategy has clearly identified. Africa CDC and others are supporting this training. There has been some progress, for example, surveys have been conducted to understand the current ecosystem and identify future needs, and models for training are being developed. IVI has already trained 5,000 people – and the Global Training Hub for Biomanufacturing is important to support African capacity-building needs. Regional training is also needed. In this regard, the University of Ghana, and other organizations, are developing courses in vaccinology and other related topics. To support capacity

building, there is a need to look at R&D and find gaps and then fill them – using a continuous process. Africa needs partnerships for knowledge sharing and training, and appropriate models of training and capacity building.

Dr. Michael Lusiola, CEO / Director-General - Kenya BioVax Institute

In Kenya today, animal vaccines are already being manufactured. However, it is now important to expand the focus on manufacturing on human vaccines. Kenya currently imports all vaccines included in their national vaccination program and were fully dependent on external vaccines and donations for COVID-19.

The Kenya BioVax Institute is focusing on downstream competencies – fill and finish - and will then connect with other institutes in Kenya and beyond, to build capacity in upstream vaccine manufacturing. The Kenya BioVax Institute is setting up the infrastructure needed for primary vaccines and for fill and finish of vaccines for outbreak diseases and expect to be ready to initiate manufacturing in 2026 or 2027.

The Kenya BioVax Institute is dependent on external expertise – including with PAVM, AVMI and IVI, and is a significant demonstration of the importance of partnerships. Specific focal areas include partnerships on the technical front for technology transfers from big manufacturers, workforce development for human vaccines and support for hands-on training in vaccine manufacturing, as well as support for the creation of a suitable regulatory board to ensure a quality product that is safe and effective.

There are challenges in developing the manufacturing system, but these can also be seen as opportunities. Setting up facilities is cost intensive, so Kenya has needed to think outside the box to determine how to obtain financing for fill and finish facilities, and to ensure an adequate budget for current and future development activities. For developing technical competencies, Kenya BioVax has aligned with global vaccine manufacturers. The Pharmacy and Poisons Board of Kenya is helping to achieve their goals in setting up a regulatory board for vaccines.

It is very costly to set up a manufacturing facility from scratch and partnerships are important to make the best use of existing expertise and avoid duplication of efforts. The Kenya BioVax Institute is already working with partners to set up manufacturing plants, including the machinery, and water and effluent treatment. They are hoping to set up two filling lines to support regional manufacturing and contribute to PAVM efforts.

Kenya is focusing efforts on supporting market shaping and to ensure the vaccines that are produced can be pushed out into the marketplace. They are working on their supply chain and distribution network, including cold chain in raw materials, and finished product. Kenya has a good understanding of the local demand, regional demand, and how they can support the East African community to set up their processes so there can be complementary activities between the countries to avoid

duplication. Kenya is working with GAVI for the AVM accelerator and contributing to the continental effort. Vaccines need to get into people's arms and not on the shelf.

Prof. Afework Kassu Gizaw, Director General - Armauer Hansen Research Institute (AHRI), Ethiopia

The Armauer Hansen Research Institute (AHRI) conducts biomedical and medical research from basic epidemiology to advanced vaccine studies. AHRI was established 54 years ago as a collaborative effort between different organizations and has diverse collaborative experience. AHRI works using a triple helix model – with higher education institutions, government bodies, and industry. AHRI also has many international collaborations, including with the Norwegian Institute of Public Health (meningococcal vaccines), Bactivac (gonococcal vaccine) and IVI (cholera vaccine development and implementation). IVI chose AHRI as the third IVI Collaborating Center in Africa where the focus is on R&D and talent development. Other international partners include BMGF/EPHI for genomic surveillance, WHO, and CEPI (Ethiopia was of the first African Union countries to be an investor in CEPI). Building on the expertise of AHRI, the Government of Ethiopia asked AHRI to provide strategies to implement their national priorities.

The ShieldVax enterprise⁵ is an enterprise to produce human vaccines. The National Vaccine Institute (NVI) has been working with over 20 animal vaccines. ShieldVax and NVI will collaborate under one umbrella to move the vaccine manufacturing forward in Ethiopia. ShieldVax will start with fill and finish and then move to the next level for R&D. AHRI is tasked to conduct the R&I activities of ShieldVax. The Government has prioritized up to six vaccines to be produced in Ethiopia.

In collaboration with other African countries, AHRI will support the PAVM strategy. AHRI has already decided to identify priority pathogens based on diseases in their own country, such as Rift Valley fever. The priority pathogens can be aligned with CEPI and GAVI. Ethiopia has also identified capacity building and regulatory as important aspects.

Dr. Edwin Nkansah, Vaccine, Vigilance and Clinical Trials Directorate, Food and Drugs Authority, Ghana

As a Maturity Level 3 national regulatory authority, Ghana's Food and Drugs Authority (FDA) demonstrates a well-established and defined regulatory framework with a systematic approach to regulatory processes and procedures. Commitment from leadership has been important to ensure that the policies developed at a national level by the Ministry of Health, were implemented to achieve MSL3. It is necessary to have laws and guidelines in place, and be able to adapt them as needed, for the national regulatory authority to work. It is important to establish quality management systems,

⁵“ShieldVax to Deliver Fill Finish Vaccine by 2026: Minister Lia.” Ethiopian News Agency, January 29, 2024, https://www.ena.et/web/eng/w/eng_3939515.

a capacity building framework and have finance to run the projects of the national regulatory authority. A risk-based approach to regulatory decision making is needed. When these aspects are in place regulatory systems can be strengthened and MSL3 or MSL4 can be achieved.

Ghana's FDA has a vision to become a global center for regulatory excellence. They are continually building the capacity of regulators and have offered support to be a training hub for Africa. They have developed training materials for clinical trials, pharmacovigilance etc. and have supported the training of 200 pharmacovigilance experts. Ghana's FDA aims to form strategic partnerships with regulatory authorities from other African countries and they have opened doors to sister agencies to observe what they do and transfer knowledge. There is a need to implement a specific program to retain trained people on the continent to achieve the goals of Africa to have an end-to-end vaccine system.



Summary of resources and actions necessary for end-to-end projects

Resources and actions needed to support end-to-end projects

Leadership, commitment and political will

- Governments need to support the development of policies that support R&D in vaccine end-to-end projects.
- Strategies need to be developed to move policies to action.

Financial resources

- Support for current activities as well as future activities
- Regional - Effective action needs resources for R&D. Countries need to invest 1% of their annual GDP into R&D.
- International – Continued commitment from international organizations is needed
- Key Financing mechanism in the horizon to support Africa (such as AVMA)

Human resources

- Investment into human resources for:
 - R&D
 - Manufacturing/Biomanufacturing
 - Clinical trial capacity
 - Regulatory
 - Epidemiology / disease surveillance
- Goal of reaching 12,000 FTEs trained within aspects of the vaccine manufacturing ecosystem

Infrastructure

- Lab testing
- Vaccine R&D
- Manufacturing/Technology
- Need to start with fill and finish and build infrastructure to support emerging needs
- Epidemiology/disease surveillance network
- Clinical trial network

Collaboration

- Private sector-Public sector collaboration
- Technology transfers
- National and regional collaboration to align different stakeholders

Research and development	<ul style="list-style-type: none"> ▪ Identify relevant pathogens based on national and regional needs ▪ Build educational systems to support vaccine R&D ▪ National and regional courses
Strong regulatory capacity	<ul style="list-style-type: none"> ▪ Pathway to strengthen the regulatory system through sharing capacity and expertise ▪ Legal framework to support regulatory activity ▪ Build framework to support production of quality vaccines: <ul style="list-style-type: none"> - Quality clinical data - Quality assured vaccine product - Quality management systems
Market	<ul style="list-style-type: none"> ▪ Cold chain for raw materials ▪ Access to the drug substance ▪ A strong process for WHO prequalification ▪ Empowered private sector to produce the vaccine ▪ Assured market for the output of the end-to-end R&D ▪ Continental free trade to allow vaccines to be provided where they are needed ▪ Pricing mechanism ▪ Market access agreement
Priorities	<ul style="list-style-type: none"> ▪ National priorities ▪ Continental priorities ▪ Demand Forecasting for an anticipated supply ▪ National program aligned with a regional program ▪ Target pathogens list relevant on the national and regional level
Communication strategy and mechanism	<ul style="list-style-type: none"> ▪ Communication to the public to explain about the vaccines that are going to be produced locally. Ensure the public that the vaccines made in Africa will be quality. Educate and communicate with the community against vaccine hesitancy.
Other topics	<ul style="list-style-type: none"> ▪ Common reagents ▪ Genomics/sequencing capabilities ▪ Continental mechanism for data sharing ▪ Stockpile management

Summary of key takeaways and remarks – Dr. Jerome Kim, Director General of the International Vaccine Institute

Dr Jerome Kim thanked President Ruto and the Government of Kenya. He highlighted that the discussion emphasized the need for moving the work of the leadership of PAVM and Africa CDC and others to ensure that Africa is not going to be in the same situation as they were for COVID-19. There is a clear pathway to vaccine manufacturing on the continent. Commitment has been made for successful African vaccine manufacturing. It is now time to put projects in place to support good health for all Africans.

IVI is establishing its regional and project offices in Africa and is committed to sharing what is needed to link the different aspects of the vaccine pathway and support end-to-end vaccine development and manufacturing. The next phase is to work with Africa CDC, PAVM, and different governments to create a way forward that is intrinsically African.

Hon. Susan Nakhumicha, Cabinet Secretary, Ministry of Health took the opportunity to thank the African CDC, IVI and participants. She highlighted that Kenya is committed to support African vaccine manufacturing, which will shield against disease and have a strong public health impact.

Acknowledgements

IVI is grateful to the Government of Kenya and Africa CDC for co-hosting this event as well as the Federal Democratic Republic of Ethiopia for their support of its organization. We also thank our panelists representing the Republic of Ghana, Partnerships for African Vaccine Manufacturing, and AHRI for lending their valuable expertise.



37TH ORDINARY SESSION OF THE ASSEMBLY OF THE AFRICAN UNION

SIDE EVENT ON SUSTAINABLE VACCINE MANUFACTURING THROUGH END-TO-END VACCINE RESEARCH AND DEVELOPMENT PROJECTS IN AFRICA

ANNEX 1. AGENDA

Session 1	
Host/MC introductory statement	Dr. Michael Lusiola, CEO/Director-General Kenya BioVax Institute
Remarks from IVI Board of Trustees Chairperson (pre-recorded video)	Mr. George Bickerstaff, Chairperson, IVI Board of Trustees
African Initiative for Vaccine Development to strengthen end-to-end research and development vaccine manufacturing ecosystem in Africa	Dr. Jerome Kim, Director General, IVI
Vision of local manufacturing as the second independence of Africa	H.E. Dr. Jean Kaseya, Director-General, Africa CDC
Remarks on AU Health Strategy	H.E. Amb. Minata SAMATE CESSOUMA, AU Commissioner for Health, Humanitarian & Social Development
Welcome Remarks	Hon. Nakhumicha S. Wafula, Cabinet Secretary for Health, Kenya
President of Kenya's Keynote Speech	H.E. the President of the Republic of Kenya
High-level Speech	H.E. Mohamed al-Menfi, Chairman of the Presidential Council of Libya
High-level speech	Hon. Ahmed Hachani, Prime Minister of Tunisia
Session 2	
Moderator introductory statement	Dr. Anh Wartel, Deputy Director General, Europe Office / Regional Director, IVI Europe Regional Office
PAVM Progress and Update To-Date	Dr. Abebe Genetu Bayih, Acting PAVM Coordinator
Moderated Panel Discussion with Q&A Session on the pillars of the vaccine manufacturing ecosystem for fostering stakeholder's collaboration and coordination:	Moderated by Dr. Anh Wartel
<ul style="list-style-type: none"> • Research & Development • Regulatory Affairs • Capacity Building and Technology Transfer • Access and Market Shaping • Financing 	<p>Dr. Michael Lusiola, CEO/Director-General, Kenya BioVax Institute</p> <p>Prof. William Ampofo, Executive Director, African Vaccine Manufacturing Initiative / CEO, National Vaccine Institute, Ghana</p> <p>Prof. Afework Kassu Gizaw, Director General, Armauer Hansen Research Institute (AHRI), Ethiopia</p> <p>Dr. Edwin Nkansah, Vaccine, Vigilance and Clinical Trials Directorate, Food and Drugs Authority, Ghana</p>
Summary of Key Takeaways and Closing Remarks	Dr. Jerome Kim, Director General, IVI
Cabinet Secretary concludes with vote of thanks	Hon. Nakhumicha S. Wafula, Cabinet Secretary for Health, Kenya



SPEAKERS' **BIOS**

(in the order of appearance)

A side event of the 37th
Ordinary Session of the
Assembly of the African Union



Dr. Michael Lusiola

CEO, Director-General, Kenya BioVax Institute

Dr. Michael Lusiola is a Pharmaceutical Research and Development expert with over 23 years experience working in Global Pharmaceutical Research and Development (Immunotherapies) and in Clinical Practice in the UK and USA.

Dr. Lusiola holds a Doctorate and Masters degrees in Global health (Harvard, US), MBA (Reading, UK), Lean Six Sigma, Yellow Belt (Project Management Institute, UK), Evidence-based medicine (Aston, UK), Clinical pharmacology and therapeutics (Queens, UK).

Dr. Lusiola has memberships at the Institute of Clinical Research (MICR) UK, the Royal Society of Medicine (MRSM) UK, the Royal Pharmaceutical Society (MRPS) UK, and the International Society for Vaccines.



George Bickerstaff

Chairperson, IVI Board of Trustees

Mr. Bickerstaff is a leader in business and philanthropy, with over 35 years of experience in healthcare and finance. He is currently Managing Director of M.M. Dillon & Co., a private investment bank which he co-founded, and previously held the position of Chief Financial Officer of Novartis Pharma AG. He has also worked at Dun & Bradstreet and General Electric.

Mr. Bickerstaff has served as a member of the board of multiple public, private and global foundations, including Gavi, the Vaccine Alliance. His philanthropic interests have focused on healthcare and child protection, serving on the board of non-profits including the International Center for Missing Children and Global Oncology. He is based in New York and holds degrees in business and engineering from Rutgers University.



Dr. Jerome Kim

Director General, IVI

Jerome H. Kim, M.D., is the Director General of IVI and an international expert on the development and evaluation of vaccines.

Prior to IVI, he served as the Principal Deputy, US Military HIV Research Program and the Chief, Laboratory of Molecular Virology and Pathogenesis at the Walter Reed Army Institute of Research; and the US Army Program Manager for HIV vaccines. He led the Army's RV144 Phase III HIV vaccine trial that showed efficacy in the prevention of HIV-1.

Dr. Kim is an Adjunct Professor, Department of Medicine, Uniformed Services University of the Health Sciences, Bethesda, USA; Adjunct Professor, Graduate School of Public Health, Yonsei University, Republic of Korea;

and an Honorary Professor, University of Rwanda. He was also named a Distinguished Visiting Professor, Seoul National University in 2022. He has authored over 350 publications.

Dr. Kim is a graduate of the University of Hawaii with high honors in History and highest honors in Biology, received his M.D. from the Yale University School of Medicine, and trained in Internal Medicine and Infectious Diseases at Duke University Medical Center.

Dr. Kim has received numerous awards: John Maher Award for Research Excellence, Uniformed Services University (2013); Department of the Army Research and Development Achievement Award for Technical Excellence (2013); Asia Pacific Vaccine Excellence Lifetime Achievement Award (2021); Medal of Honor for Civil Merit from the Government of the Republic of Korea (2022).



H.E. Dr. Jean Kaseya

Director-General, Africa CDC

H.E. Dr. Jean Kaseya was appointed Director-General of the Africa Centres for Disease Control and Prevention (Africa-CDC) during the thirty-sixth African Union Summit of Heads of State and Government in February 2023. Dr. Kaseya, a Congolese Medical Doctor with advanced degrees in Epidemiology and Community Health, brings to this position over 25 years of expertise in the field of public health, having held pivotal roles both at the national and international levels.

As the Director-General of Africa-CDC, Dr. Kaseya oversees the organisation's fundamental political, strategic, and technical functions. At the forefront of his agenda is his commitment to advancing a transformative "New Deal" for Africa CDC, with the primary objective of strengthening health security across the continent. This undertaking involves establishing sustainable and innovative financing mechanisms, enhancing robust governance structures, cultivating technical expertise, strengthening health systems, and efficient response to health crises.

Before assuming his role as Director-General of Africa CDC, Dr. Kaseya had a distinguished career, holding multiple significant roles. At the national level, Dr. Kaseya has been entrusted with significant responsibilities, contributing his expertise to the health initiatives of his home country. These roles have included serving as a Senior Adviser to President Laurent Desire Kabila at a ministerial level, where he played a vital role in shaping healthcare policies and strategies. Additionally, he has taken on roles such as the Head of Routine Immunization within the National Expanded Programme on Immunization, showcasing his dedication to enhancing healthcare delivery at the grassroots level.

On the international stage, he has worked with prominent organisations

such as UNICEF, Gavi, CHAI, and the World Health Organization, where he has been instrumental in driving forward various health initiatives of continental significance.



H.E. Amb Minata Samate Cessouma

Commissioner for Health, Humanitarian Affairs and Social Development, African Union

H.E. Amb Minata Samate Cessouma is the Commissioner for Health, Humanitarian Affairs and Social Development. She is a native of Burkina Faso with over thirty years of experience in international relations, Diplomacy, Governance and peace and security, humanitarian and social affairs.

At the international level, Her Excellency has served as Director of the United Nations and African Union Hybrid Mission in Darfur from June 2014 to July 2015, where she contributed through negotiations and mediation to strengthening peacekeeping operations, humanitarian affairs, and preventive diplomacy.



Hon. Nakhumicha S Wafula

Cabinet Secretary for Health, Republic of Kenya

Hon. Nakhumicha S Wafula is the Cabinet Secretary for Health of the Republic of Kenya. She is an alumnus of Jomo Kenyatta University (JKUAT) and holds a bachelor's degree in Procurement and Management, a master's degree in Logistics, Procurement, and Supply Chain Management, and a Ph.D. in Business Management at the same University. She also has a diploma in Pharmacy from Kenya Medical Training Institute (KMTI) and another Diploma in Healthcare Management from the Kenya Institute of Management. Until her appointment, she worked as Head of Supply at the University of California San Francisco (UCSF) Global Programs for Research and Training.



H.E. Dr. William Ruto

President of Kenya

H.E. Dr. William Ruto is the fifth and current president of Kenya since September 13, 2022. Before ascending to be President, Dr. Ruto served as the Deputy President of the Republic of Kenya from April 3, 2013 to September 12, 2022.

Dr. Ruto has held several leadership positions in Government.

He was appointed Minister for Agriculture in the Coalition Government that was formed in 2008 and served for three years. During his tenure, he revived irrigation schemes and provided affordable fertilizer to farmers while working

with maize, sugarcane, coffee and tea sectors to boost productivity and secure access to markets.

He was later appointed as the Minister of Higher Education where he sought to define education as acquisition of knowledge and skilling as well as elaborate policy on its value.

In 2008, he graduated with a Master of Science degree in Plant Ecology and in December 2018 graduated with a Ph.D. in Plant Ecology from the same university.



H.E. Mohamed al-Menfi

[Chairman of the Presidential Council of Libya](#)

H.E. Mohamed al-Menfi is the 16th Head of State of Libya. He is a graduate of Tobruk University in East Libya. From 2018 to 2019, he served as Libyan Ambassador to Greece.



Hon. Ahmed Hachani

[Prime Minister of Tunisia](#)

Hon. Ahmed Hachani is the Prime Minister of Tunisia since August 1, 2023. He holds a master's degree in law, specializing in public law from the Faculty of Law of Tunis in 1983. He joined the Central Bank of Tunisia in 1984.

From 2012 to 2017, Mr. Hachani worked as the General Manager of Human Resources and Training at the Central Bank of Tunisia and later served as Advisor for Legal Affairs and Human Resources at the same institution.

He has also represented the Central Bank of Tunisia on several boards of directors. He taught law and the banking environment for ten years at the Academy of Banking and Finance, which is part of the Tunisian Professional Association of Banks and Financial Institutions.



Dr. Anh Wartel

[Deputy Director General, Europe Office / Regional Director, IVI Europe Regional Office](#)

Anh Wartel, M.D., is the Deputy Director General, Regional Director of the IVI Europe Regional Office, overseeing IVI's operational, scientific, and technical activities in the Europe region, including the Europe Regional Office in Stockholm and a Country Office in Vienna. She is based in Stockholm, Sweden.

Dr. Wartel joined IVI in 2018 as the Head of Clinical Development and Regulatory, then the Deputy Director General of the Clinical, Assessment, Regulatory, Evaluation (CARE) unit. She has twenty-five years of experience in clinical research.

Before IVI, Dr. Wartel held various positions in epidemiology, clinical R&D, and medical affairs, overseeing multiple clinical developments (e.g., rabies, cholera, typhoid fever, hepatitis A, yellow fever, dengue, Japanese encephalitis vaccines) in pre- and post-licensure stages at Sanofi in Asia for 15 years. She initially started her research career with the French National Agency of Research on HIV/AIDS (ANRS), involved in drug trial projects as an investigator for five years in Paris.

Dr. Anh Wartel earned her M.D. at the Paris XII Medical School, France, and completed a post-graduate diploma in Public Health from the University of Liverpool, UK. She is an honorary Professor at the University of Rwanda.



Dr. Abebe Genetu

Acting PAVM Coordinator, Africa CDC

Dr. Abebe Genetu is the PAVM Coordinator at Africa CDC and has served as Africa Engagement Lead at CEPI since 2021. Before his appointment to CEPI, he served as Director General of the Armauer Hansen Research Institute (AHRI) and Chief Director for Research, Technology Transfer and Community Engagement at the College of Medicine and Health Sciences of the University of Gondar.

Dr. Genetu earned his Ph.D. in Molecular Microbiology at the University of Calgary and his master's degree in Microbiology at Addis Ababa University.



Prof. William Ampofo

Executive Director, African Vaccine Manufacturing Initiative (AVMI) /
CEO of National Vaccine Institute (NVI), Ghana

Prof. William Ampofo is a virologist and has a keen interest in the management of viral infections, teaches graduate student courses and conducts research projects on viral diseases as an Associate Professor of Virology at the University of Ghana, College of Health Sciences, Noguchi Memorial Institute for Medical Research / Department of Medical Laboratory Sciences.

Prof. Ampofo is the Chief Executive Officer of the National Vaccine Institute, Ghana, which coordinates and oversees research, development, and manufacturing of vaccines in Ghana. He serves on various national, regional, and global committees / bodies relating to vaccines and biologicals, viral diseases, and health security. He has also served on WHO advisory groups for influenza including global influenza vaccine production,

immunization, and pandemic influenza preparedness. He was also an advisor to the WHO International Health Regulations Emergency Committee on Ebola.

Prof. Ampofo chaired AVMI's Board of Directors from 2012 to 2023. He has been a passionate advocate for local vaccine manufacturing on the continent these past 11 years.



Prof. Afework Kassu Gizaw

Director General, Armauer Hansen Research Institute (AHRI), Ethiopia

Prof. Afework Kassu Gizaw is Director General of Armauer Hansen Research Institute (AHRI) of Ethiopia since January 2022.

Before joining AHRI, he served as State Minister of Ministry of Science and Higher Education from October 2018 to October 2021 where he led the Science, Linkage, and Higher Education Research and Community Service issues of the Ministry. He also served as State Minister of Ministry of Foreign Affairs (May 2018 – Oct 2018) where he led political diplomacy activities covering the Americas, Europe, Asia and Oceania, and International Organizations Affairs and International Legal Affairs. He also was State Minister of at Ministry of Science and Technology (Oct 2015 – May 2018) where he led Quality and Regulatory Affairs of the Ministry. He also served as Director General for Higher Education Research and Academic Affairs at the Federal Ministry of Education from January to October 2015 where he played a critical leadership role in higher education research and academic affairs.

Prof. Afework served University of Gondar in different capacities from May 1994 to September 2014, including as vice president for Research and Community Services. He has been transferred to the Department of Microbiology, Immunology and Parasitology, School of Medicine, College of Health Sciences of Addis Ababa University since October 2014 and serving as Professor of Medical Microbiology and Immunology.

Prof. Afework was trained as a biologist and an applied microbiologist at Addis Ababa University in Ethiopia and earned BSc and MSc degrees in 1993 and 2001, respectively. He holds Ph.D. in Biomedical Sciences from the University of Tokushima, Japan in 2007. He also conducted postdoctoral studies at University of Colorado Denver, USA from 2008 to 2010.



Dr. Edwin Nkansah

Vaccine, Vigilance and Clinical Trials Directorate, Food and Drugs Authority, Ghana

Edwin Nkansah (PhD) is a 45-year-old Ghanaian Director, and Head of the Vaccines, Vigilance and Clinical Trials Directorate at the Food and Drugs Authority (FDA), Ghana. Prior to his current role, he was the founding Head of the Vaccines and Biological Products Department, the Department responsible for the regulatory oversight for Biological Products, including vaccines. His current scope of regulatory oversight includes the clinical

trials, vaccine and biological products and safety monitoring regulatory functional areas.

Edwin has been a regulatory officer since November 2012, He led the establishment of the Department and oversaw its progression from a Unit to a Department with the responsibility of establishment the basic regulatory framework for authorizing the use of biological products, including vaccines in Ghana. Edwin's PhD was in Pharmaceutical and Biological Chemistry, specializing in molecular biology techniques and protein engineering, and a master's degree in Drug Discovery, all degrees from the University College London School of Pharmacy. He has been involved in 11 publications and abstracts,

Prior to joining the FDA, Edwin was a full-time lecturer at the School of Pharmacy, University of Ghana. He retains a part-time role at the school with the Department of Pharmacology and Toxicology.

On the global front, Edwin has consulted for the World Health Organization (WHO) and has participated in the drafting of WHO guidelines, including the revision of the WHO Biosimilar guidelines, which was developed to provide guidance to manufacturers and regulators. Further, he was one of the primary drafters for the Marketing Authorization and Clinical Trials Oversight factsheets of the WHO Global Benchmarking tool (GBT), the tool used to evaluate the maturity of National Regulatory Authorities.





H.E. Dr. William Ruto, President of the Republic of Kenya, gives a keynote speech during the side event “Sustainable vaccine manufacturing through end-to-end vaccine research and development projects in Africa” emphasizing the need for Africa to take steps to build a holistic ecosystem to support R&D, clinical trials, manufacturing, distribution, and delivery. Credit: IVI



Dr. Jerome Kim, Director General of IVI, gives a presentation titled “African Initiative for Vaccine Development to strengthen end-to-end research and development vaccine manufacturing ecosystem in Africa.” Credit: IVI



H.E. Dr. Jean Kaseya, Director-General of the Africa CDC, gives a presentation titled “Vision of local manufacturing as the second independence of Africa.” Credit: IVI



Four Heads of State and Government attended this side event on end-to-end vaccine research and development projects in Africa, including (left to right): H.E. Brahim Ghali, President of the Sahrawi Arab Democratic Republic; H.E. Dr. William Ruto, President of Kenya; H.E. Mohamed al-Menfi, Chairman of the Presidential Council of Libya; and Hon. Ahmed Hachani, Prime Minister of Tunisia. Credit: IVI



Dr. Anh Wartel, Deputy Director General at IVI (right), moderated a panel discussion covering the vaccine manufacturing ecosystem and engaging multi-sectoral collaboration and coordination, featuring (left to right): Prof. William Ampofo, Executive Director, African Vaccine Manufacturing Initiative; Dr. Michael Lusiola, CEO/Director-General, Kenya BioVax Institute; Dr. Edwin Nkansah, Food and Drugs Authority, Ghana; Prof. Afework Kassu Gizaw, Director General, Armauer Hansen Research Institute. Credit: IVI



The Government of Kenya, IVI, and Africa CDC co-hosted a side event emphasizing end-to-end vaccine research and development projects to achieve sustainable vaccine manufacturing in Africa. Kenya's Cabinet Secretary for Health, Hon. Nakhumicha S. Wafula, stands at the center of this group photo of event speakers and organizers. Credit: IVI



The Government of Kenya, IVI, and Africa CDC co-hosted an event on the sidelines of the 37th Ordinary Session of the Assembly of the African Union. Credit: IVI



SUSTAINABLE VACCINE MANUFACTURING THROUGH END-TO-END VACCINE RESEARCH AND DEVELOPMENT PROJECTS IN AFRICA

A side event of the 37th Ordinary Session of
the Assembly of the African Union



REPUBLIC OF KENYA



AfricaCDC
Centres for Disease Control
and Prevention



**International
Vaccine
Institute**