



# Kenya BioVax Institute

Presented at the Global event on enhancing the sustainability of  
investments for Vaccine Manufacturing in Africa

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# Kenya Biovax

- A State Corporation in the Ministry of Health, Government of Kenya ( Companies Act ,2015)
- Mandate to manufacture and commercialize vaccines, biotherapeutics and other HPTs.
- We are Kenyan spoke for the WHO mRNA Technology Transfer Programme

Our motto

*'...protecting health, promoting life...'*

# Situational analysis: Kenya today...

- Kenya requirement / market: >20m doses of 'routine' vaccines per year,
  - Valued at USD 30M (KES 4.2B).
  - (EAC regional requirement / market: >200m doses per year / USD 300M).
- Dependence on co-finance mechanism:
  - GoK 12% and UNICEF / GAVI 88%.
  - Accelerated withdrawal of GAVI support; stop in FY 2026/2027.
  - Sustainable self-sufficiency in vaccine needs; health commodity security
- ? Pandemic prevention, preparedness, response, resilience:
  - mRNA platform, continued R&D
- Local manufacturing (economic pillar):
  - Kenya as biotech hub in the region
  - Skilled jobs creation

# Strategy & roadmap:

- Fully-fledged , world-class, state-of-the-art **human vaccines manufacturing facility**, to incorporate upstream R&D activity (working with KEMRI), mid-stream formulation activity with vaccine antigens for drug substance, and to downstream ‘fill-and-finish’ for final drug product.
- Partners:
  - Establishment of ‘end-to-end’ vaccines and biopharmaceuticals manufacturing capability; USD 300M+.
  - Technology transfer
- Key vaccines, based on market and financial analyses, include:
  - Childhood immunisation vaccines for pneumonia, influenza, diphtheria, pertussis, tetanus, hepatitis;
  - Adolescent girls’ vaccine to prevent cervical cancers;
  - COVID-19, Malaria, HIV and Tuberculosis vaccines.
- Other products:
  - Insulin for diabetes, Monoclonal antibodies for cancer and other chronic inflammatory diseases, Antivenoms for snake bites and Diagnostic kits
- Target market: East African and ‘Great Lakes’ region;

# Ongoing works:



2021



Early 2022

# Where we want to be...



▣ PROPOSED 3D IMPRESSIONS

- **World-class, state-of-the-art vaccines production facility.**
- **Regional centre-of-excellence for biotech.**
- 100 million doses per year of range of human routine & outbreak vaccines and biopharmaceuticals
- **Local manufacturing, with >100s highly-skilled employees.**
- Biotherapeutics (insulin, mAB), diagnostics.
- **Gross margins >30%; FOREX earner.**

# Risks:

Risk:	Risk management plan:
Time-delays in construction - prolonged lead times	Pro-active planning with timely reporting. Applying project management principles from the start.
Market for product(s)	Market purchase guarantees for finished products, e.g. with GoK. Pooled procurement - UNICEF / GAVI; Africa CDC AVATT; Participate in market-shaping engagements for Africa. Justification for product selection based on critical analyses
Quality of product	Manufacturing machinery, equipment, processes are GMP-certified. Certification, Qualification, Validation (CQV), incl. WHO Pre-qualification process
Goodwill / stability - uncertainties.	Sustained communication and stakeholder engagements.

# What Kenya has to offer:

- Market.
  - Huge demand - local, regional.
  - Financials - incl support from exchequer
  - Portfolio of vaccines, biologicals, insulins, sera, anticancer agents, sterile products
- Location.
  - Facility - state of the art; GMP, WHO, ISO accreditations / pre-qualifications.
  - Hub for distribution / connectivity
- Skills
  - Efficient, lean and commercially-astute, focussed organisation
  - Biotechnology, biomedical science, R&D
  - Robust QMS and Biosafety protocols, supported by accreditations
- Well established R&D and National Regulatory Authority.

An investment opportunity with positive socioeconomic returns that could avert over 4 million deaths per year and over 206 million Disability Adjusted Life Years (DALYs) in the region



Thank you:

