KENYA BIOVAX INSTITUTE

Health Emergency Preparedness Response and Resilience (HEPRR) Project

Credit Number: 7405-KE

Project ID: P180127

TERMS OF REFERENCE

FOR

CONSULTING SERVICES FOR DEVELOPMENT OF A 20 YEAR INTEGRATED BUSINESS PLAN FOR THE KENYA BIOVAX INSTITUTE

(FIRMS SELECTION)

PROCUREMENT/CONTRACT REF NO.: KE-KBI-569948-CS-CQS

SEPTEMBER 2026

Client:

Kenya BioVax Institute

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1.0 Introduction

1.1 Project Background

The Government of Kenya, through the State Department of Medical Services, and with support from The World Bank, is implementing the Health Emergency Preparedness Response and Resilience Program (HEPRR) which aims to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Kenya. The Program, in part, seeks to reduce dependence on imports by supporting national and regional capacity for pharmaceutical and vaccine manufacturing. In this regard, the Program will specifically support Kenya, through the Kenya BioVax Institute (BioVax) to establish local vaccine manufacturing capacity through human resource development and operationalisation of a vaccine fill-finish facility in Nairobi, as part of efforts to strengthen pandemic preparedness and self-reliance in health commodities supply.

BioVax is a state-owned enterprise established in 2021 with the mandate to manufacture, commercialise, and distribute human vaccines and other specialised health products and technologies. It serves as the Government of Kenya's implementing agency for vaccine manufacturing under the HEPRR Program, leading efforts to ensure compliance with WHO Good Manufacturing Practice (GMP) standards and to strengthen the vaccines and biologics manufacturing ecosystem in the country.

BioVax is developing a vaccine fill-finish facility in Nairobi, with a planned/projected capacity of 72 million doses per year across two (2) production lines once completed. The facility is a brownfield development with a total floor area of approximately 3,024.5 m^2. The Institute has existing partnerships with local and regional universities and research institutions. The Consultant shall treat this baseline infrastructure and partnership landscape as the starting point for the 20-year roadmap and shall validate and update it during the inception phase. BioVax intends to develop a robust, market-informed, technically sound, evidence-based, and financially credible 20-year Integrated Business Plan covering vaccines, biologicals, biosimilars and other Health Product Technologies and selected health product technologies. The Plan will guide phased investments, operational pathways, and partnerships to ensure sustainable local manufacturing and regional market integration.

1.2 Rationale

Kenya and Africa remain heavily dependent on imports of vaccines, biologicals, biosimilars and other Health Product Technologies. This reliance exposes countries to global supply disruptions, foreign exchange volatility, price fluctuations, and limited access to essential therapies, particularly for non-communicable diseases such as diabetes, cancer, and autoimmune conditions.

In response, African Union Member States and continental institutions are advancing regulatory convergence and market-shaping reforms to support sustainable local manufacturing. Initiatives

such as the African Medicines Agency (AMA), the African Medicines Regulatory Harmonization (AMRH) program and demand-side mechanisms like the African Pooled Procurement Mechanism (APPM) are creating a predictable regulatory and market environment that facilitates investment, cross-border market access and long-term offtake arrangements for locally produced health products.

Within this context, BioVax seeks to be a platform-based biopharmaceutical manufacturing anchor for the region, progressively developing capabilities in vaccines, biologicals, biosimilars and other Health Product Technologies. Leveraging research outputs from bio-startups, universities and research institutions will enhance innovation, de-risk technology transfer and strengthen the long-term product and platform pipeline.

To guide this transition, BioVax requires a robust, market-informed, technically sound, evidence-based and financially credible 20-year Integrated Business Plan. This Plan will define strategic priorities, phased investments and operational pathways, ensuring the Institute's contribution to national, regional and global health security and support industrial upgrading in biopharmaceutical manufacturing.

2.0 Objective of the assignment

BioVax intends to engage a highly qualified Consulting Firm to develop a technically robust, market-validated, and financially grounded 20-Year Integrated Business Plan covering vaccines, biologicals, biosimilars and other prioritised Health Products and Technologies including gene/cell therapies, large and small volume parenterals, diagnostics, selected APIs and excipients. The assignment will define a phased implementation roadmap and develop an integrated financial model suitable for internal use and scenario testing. It will further provide recommendations on strategic business arrangements, including but not limited to joint ventures, public-private partnerships, and other structured collaboration mechanisms. The Plan will guide BioVax in establishing a sustainable and globally competitive biomanufacturing enterprise serving Kenya, the broader African region, and international markets.

2.1 Specific Objectives

The specific objectives of this assignment are to:

i. Undertake a comprehensive market, demand and value chain analysis to identify and quantify commercial opportunities for priority products, including biologicals, biosimilars, gene and cell therapies, and selected APIs and excipients;
ii. Determine and prioritise manufacturing platforms and product portfolios based on defined criteria, including market potential, technical feasibility, scalability, sustainability and regulatory requirements;

iii. Develop a regional commercialisation and market access strategy to facilitate market growth, and to establish BioVax's strategic positioning within national, regional, and global biopharmaceutical value chains. ,
iv. Develop a dynamic, afinancial model that will quantify costs, revenues and investment needs to support platform and product prioritisation, commercialisation strategies and phased implementation,
v. Prepare a phased 20-year business plan with an implementation roadmap supported by an integrated financial model, outlining investment sequencing, product rollout, and financial sustainability under different scenarios.

3.0 Scope of the consulting services and specific tasks

3.1 Scope of the consulting services

The scope of the Consulting Services will include provision of strategic, technical, market and financial analyses to support the development of a 20-year Integrated Business Plan for vaccines, biologicals, biosimilars and other prioritised health products and technologies including a financial model and implementation roadmap. This will require a phased approach covering institutional and market assessment, product and platform prioritisation and development of viable business, financing and partnership options.

The Consulting Firm will also provide strategic and technical support throughout the assignment, including the development of the commercialisation and market access strategy, integrated business plan, preparation of the financial model and delivery of implementation, commercialisation and partnership recommendations.

3.2 Specific tasks

3.2.1 Inception phase

The Consulting Firm will hold an inception meeting, which will serve as the formal starting point of the assignment and will establish a common understanding between BioVax and the Consulting Firm regarding the objectives, scope, deliverables, and implementation approach of the consultancy. This engagement will ensure strategic alignment, clarify roles and expectations, and confirm the pathways required to deliver a successful integrated business plan. In undertaking this task, the Consulting Firm will be expected to:

i. Familiarise themselves with all background documentation and preparatory work conducted to date, including but not limited to reports, studies, audits, and shall be responsible for carrying out initial technical, financial and market landscape reviews necessary for delivering a successful assignment;

ii. Undertake preliminary stakeholder mapping (local, regional and global) across key public and private sector actors, including governments ministries and agencies, regulators, procurement entities, development finance institutions (DFIs), industry players and potential investment and technology partners, conduct a targeted initial consultation with priority stakeholders, agreed with the Client to validate key assumptions and inform the overall approach, with an aim of developing a comprehensive Stakeholder Engagement Plan, including stakeholder identification, prioritisation, engagement methods and sequencing.
iii. Define a structured analytical framework for the development of the 20-year roadmap, including key analytical dimensions, assumptions, scenarios, and evaluation criteria to be applied in subsequent phases.
iv. Develop an inception report that clearly outlines the methodology, detailed implementation plan including the identification of key risks, dependencies and information gaps that may affect delivery of the assignment, a comprehensive stakeholder engagement plan, sequencing of tasks, timelines, deliverables, and key milestones. This report will provide a shared roadmap for the assignment and form the basis for monitoring progress and ensuring the timely and successful completion of the consultancy.

3.2.2 Market, Demand, and Value-Chain Analysis

The Consulting Firm will undertake a rigorous, evidence-based market, demand and value chain analysis for vaccines, biologicals, biosimilars and other prioritised health products and technologies to guide commercial and manufacturing decision making. The assessment will be conducted through desk-top reviews of published reports, and through structured interviews and workshops with key stakeholders at local, regional and international levels to validate assumptions, fill information gaps and provide operational and strategic insights.

The analysis shall utilise published research, industry reports, global market intelligence data from reputable and leading institutions such as the Africa CDC, AUDA – NEPAD, World Health Organization (WHO), Organisation for Economic Co-operation and Development (OECD), and the World Intellectual Property Organization (WIPO), World Trade Organization (WTO), CHAI, PATH, universities, public research institutions, and global R&D collaborations. This analysis shall include among others:

i. Landscape assessments and demand-supply analyses highlighting both existing capabilities and critical gaps in upstream and downstream production;
ii. Access, licensing and intellectual property-related landscape including analyses of voluntary licensing, technology transfer mechanisms, and their impact on accelerating generic competition and improving access in low- and middle-income countries;
iii. Innovation and pipeline intelligence from established pharmaceutical companies, biotechnology firms, and global R&D trackers, including data on biosimilars market expansion and gene and cell therapy pipelines.

3.2.3 Product Portfolio Prioritisation and Manufacturing Platform Optimisation

3.2.3.1 Regional demand analysis

The Consulting Firm shall utilise market, demand and value chain assessments from Kenya, EAC, COMESA, and the wider African region, to develop a regional demand analysis report detailing disease burden, market size, procurement dynamics, pricing and affordability and recommended priority products with high commercial and public health potential. The assessment dimensions will include among others:

i. Epidemiological Trends and Public Health Needs outlining:

   a. Disease burden and prevalence in priority therapeutic areas;
   b. Current treatment coverage gaps and emerging health challenges, with implications for product demand and priority setting.

ii. Procurement and Market Dynamics outlining:

   a. Public-sector demand: national health programs, pooled regional procurement mechanisms and other institutional buyers.
   b. Private-sector demand: hospitals, health insurers, and commercial distributors, assessing market scale, demand drivers and procurement practices using available data, surveys or expert inputs.
   c. Pricing and affordability: regional pricing, reimbursement mechanisms and affordability considerations, highlighting constraints and opportunities for locally manufactured products and sustainable pricing models.

iii. Market Potential and Growth Projections outlining:

   a. Estimation of current and projected demand volumes over the short-, medium-, and long-term, using scenario-based and directional approaches for years beyond year 10.
   b. Identification of high-demand products and therapies with strong regional market opportunities to inform platform and product prioritisation.

3.2.3.2 Prioritisation Framework

The Consulting Firm shall develop a transparent and evidence-based framework for product portfolio prioritisation and manufacturing platform optimisation strategies identified in the Regional Demand Analysis. The framework shall:

   i. Define clear evaluation criteria including market size and growth potential; public health impact and treatment coverage gaps; import substitution opportunities; technical

feasibility and manufacturing complexity; regulatory pathways and timelines; and scalability and platform synergies;

ii. Provide a structured scoring methodology or decision-support tool to rank products and platforms against the criteria; and

iii. Generate preliminary recommendations for anchor and follow-on products based on the analysis.

The Consulting Firm will be required to facilitate structured workshops with BioVax leadership and selected key stakeholders to review the portfolio prioritisation results; discuss trade-offs and strategic considerations; and validate and finalise the prioritised list of products and platforms.

3.2.3.3 Platform and Product Portfolio Strategy

The Consulting Firm shall translate the outputs of the regional demand assessment and prioritisation framework into a sequenced and actionable platform and product portfolio strategy to guide BioVax in selecting the most commercially viable, technically feasible, and strategically aligned products and manufacturing platforms for phased development. This task will include among others:

i. **Platform identification and Technical Assessment** that will define candidate manufacturing platforms that lead to development of the following priority portfolios: Vaccines, Biologicals and Biosimilars (e.g., insulin, monoclonal antibodies), Gene and cell therapies, Diagnostics, Large and Small Volume Parenterals, Selected APIs and excipients aligned with prioritised products. For each platform, the Consulting Firm will be required to assess the following dimensions including:
    a. Technical requirements (technology, infrastructure, utilities, quality systems)
    b. Regulatory feasibility and compliance requirements
    c. Capital and operating intensity
    d. Scalability and potential for modular expansion
    e. Personnel requirements for implementation

ii. **Product Portfolio Screening and Prioritisation** to map anchor (early-phase) and follow-on (mid- to long-term) products per platform, using the prioritisation framework and apply structured criteria, including regional market demand and growth potential, public health relevance, manufacturing and technical complexity, regulatory timelines and approvals, and revenue potential and affordability considerations. Identify sequencing logic and decision gates for phased product introduction, ensuring alignment with operational, financial, and partnership readiness.

iii. **Business Arrangements, Partnership and Collaboration Opportunities** through evaluation of potential business arrangements such as Public-Private Partnerships (PPP), joint ventures, or technology transfer collaborations to support platform scaling and de-risk implementation. Identification of strategic partners, including regional or international investors, technology providers, and research institutions, to strengthen BioVax's manufacturing capabilities and innovation pipeline.

iv. **Operational Readiness and Infrastructure assessment** to identify infrastructure, utilities and facility upgrade requirements necessary to implement prioritised platforms; define phased operational milestones and decision gates for platform readiness; and incorporate quality, regulatory, and compliance frameworks in operational planning.

3.2.4 Regional Commercialisation and Market Access Strategy

The Consulting Firm shall develop a practical, regionally focused commercialisation and market access strategy to guide BioVax in translating prioritised platforms and products into sustainable regional supply. The strategy shall focus on Kenya, the East African Community (EAC), COMESA and the wider African region, ensuring alignment with BioVax's mandate to manufacture, commercialise and supply essential vaccines, biologicals, biosimilars and other prioristised health product technologies.

The Consulting Firm shall define the following dimensions including:

i. **Market entry and distribution channels** to identify and define the market size for each product portfolio; identify and recommend realistic channels for reaching both public and private buyers, including: national health programs, regional pooled procurement mechanisms, hospitals, private insurers, and commercial distributors; and provide recommendations for strategic partnerships with distributors, logistics providers, and regional health systems to optimise product availability, reduce supply chain risks and ensure timely delivery.
ii. **Pricing Reimbursement, and Affordability models** that highlight constraints and opportunities for local manufacturing in the regional pricing environment. This will provide guidance on sustainable pricing models that balance cost recovery with regional affordability and assessments on reimbursement and procurement mechanisms, including public tenders, insurance coverage, and donor-funded programs, to inform market entry and adoption strategies.
iii. **Market Risks and Mitigation** to assess potential commercial risks, including competition, regulatory barriers, adoption challenges and distribution constraints, and propose mitigation strategies, such as phased rollouts, pilot programs, and targeted stakeholder advocacy to reduce entry barriers and accelerate uptake.

3.2.5 Integrated Financial Model

The Consulting Firm shall develop a dynamic, financial model with detailed five (5) year projections with directional fifteen (15) year extension. Directional projections beyond year ten (10) shall be clearly labeled as scenario-based to support strategic planning and shall not require precise forecasting. In undertaking this task, the Consulting Firm will be required to undertake systematic skills transfer to ensure BioVax staff can independently update assumptions, run scenarios and

interprate outputs through in-person trainings, a minimum of four weeks post-training support and development of a detailed user manual for the financial model.

The model will quantify costs, revenues and investment needs to support platform and product prioritisation, commercialisation strategies and phased implementation. The model will document all key assumptions including but not limited to:

i. Full CAPEX and OPEX estimates including tax implications taking in to consideration a phased implementation approach
ii. Pricing, Reimbursement and affordability with benchmarking of cost of goods sold (COGS) against global and regional manufacturers;
iii. Market uptake and demand-driven revenue projections, segmented by channel (public-sector, private-sector, and donor-funded/pooled procurement), with adoption curves, market share assumptions, and price elasticity considerations by product and phase;
iv. Capacity utilisation rates, including ramp-up curves from commissioning to steady-state operation by facility and platform, benchmarked against comparable regional and global manufacturers, and reflecting batch scheduling, changeover, and planned downtime assumptions;
v. Scenario analyses reflecting financing shifts, donor transitions, and programme switching;
vi. Resource mobilisation strategy for the capital and working capital needs identified in the model, evaluating the full range of options available to BioVax as a state-owned enterprise GoK budgetary allocation, concessional and commercial debt, donor/development-partner financing, and equity or PPP structures with an indicative, phase-by-phase financing plan and a recommended funding mix; and
vii. Evaluation of key investment metrics, including payback periods, internal rates of return, sensitivity to volume fluctuations, and exposure to market entry risks and macroeconomic variables such as currency, inflation, interest rates, supply chain, and procurement uncertainties.

The Consulting Firm will ensure that the model structure shall be presented in excel-based formats and other automated platforms and provide traceable calculations with no hard-coded assumptions; scenario toggles for base, upside, and downside cases; and linkages to commercial, operational, and technology transfer assumptions from other tasks.

3.2.6 Integrated 20-Year Business Plan

The Consulting Firm shall consolidate the outputs from preceding tasks into a coherent, phased 20-year business plan. The Plan will sequence product and platform introduction, market entry, technology transfer, capability building (infrastructure and personnel, including indicative staffing plans and organograms by phase) and investment implementation ensuring alignment with the regional demand, product prioritisation, commercialisation and operational strategies.

The Plan shall clearly indicate:

i. **Phase I (0–5 years):** Quick-win anchor products, early revenue generation, initial workforce and facility development, early business arrangement models and partnerships.
ii. **Phase II (5–10 years):** Platform scaling, mid-complexity products, expansion of technical and organisational capabilities, market deepening across the region.
iii. **Phase III (10–20 years):** Portfolio diversification, full capability maturation, backward integration where feasible and regional market anchoring.

The financial projections for each phase shall be drawn directly from the Integrated Financial Model, ensuring consistency between investment, operational, and revenue assumptions.

3.2.7 Legal, Regulatory and Fiscal Framework Analysis

The Consulting Firm shall assess the legislative, regulatory and fiscal framework required to support BioVax's growth as a state-owned biomanufacturing enterprise over the 20-year plan period. This shall be a cross-cutting workstream that shall commence during the inception phase and run in parallel with the tasks described in Sections 3.2.2 through 3.2.6, so that its findings inform product prioritisation, business arrangement and financial modelling decisions. This shall include, at a minimum:

i. An analysis of tax incentives, import duty exemptions, and local content/procurement preferences available or needed to support domestic vaccine and API manufacturing;
ii. Identification of legislative or policy reforms required to enable public-private partnership (PPP) structures, licensing, or technology transfer agreements; and
iii. Recommendations on the sequencing of any legal or regulatory reforms needed to support each phase of the roadmap.

3.2.8 Risk Analysis and Risk Management Plan

The Consulting Firm shall conduct a comprehensive risk analysis and develop a risk management plan covering the full assignment period, addressing at a minimum:

i. Identification and assessment of commercial, operational, financial, regulatory, technology and geopolitical risks to the successful implementation of the Business Plan across Phases I–III, including likelihood and potential impact ratings for each identified risk;
ii. Sensitivity and scenario analysis of key risk drivers against the Integrated Financial Model (Section 3.2.5), including downside cases and their implications for the phased implementation timeline;
iii. Proposed mitigation measures, ownership (Client, Consultant, or third party) and indicative timelines for each material risk; and

iv. A recommended risk monitoring framework (indicators, review frequency and escalation triggers) that the client can apply during implementation of the Business Plan beyond the life of this assignment.

3.2.9 Close-Out Phase

The Consulting Firm will hold a close-out meeting, to serve as the formal conclusion of the assignment and a critical governance milestone for BioVax. In the close-out meeting, the Consulting Firm will purpose to review, validate, and consolidate the assignment outputs, ensuring all agreed objectives are achieved and that BioVax is positioned to fully internalise and sustain the benefits of the engagement. The meeting will provide a structured forum for reflecting on implementation performance, confirming the completeness of deliverables, and facilitating institutional learning by capturing insights that will inform implementation of the business plan.

In undertaking this task, the Consulting Firm will be expected to complete the administrative close-out and handover of the assignment, including confirmation of completion of all agreed deliverables, handover of final documents, models, tools and supporting materials, and identification of any outstanding actions required to support implementation of the Business Plan.

4.0 Duration and Location of the Assignment

The consulting services will be implemented over a period of eight (8) months from contract commencement date.

The Consulting Services will generally be offered in Nairobi (Kenya) at the Kenya BioVax Institute offices. The Consultant's technical proposal shall describe their approach to delivering services, including any travel requirements.

5.0 Reporting Requirements and Timelines for submission of deliverables

5.1 Reporting

All reports and communications related to this assignment shall be in the English Language and all reports shall conform to an agreed format agreed with the Client, including an executive summary, a table of contents, standard cover sheet with date and project details, submission letter showing those copied and actual date of submission

The Consultant will deliver reports to the Chief Executive Officer. All reports shall be submitted to the:

Chief Executive Officer
Kenya BioVax Institute
KWFT Centre, Kiambere-Masaba Road Junction, Upperhill, Nairobi
P.O. Box 40779-00100. Nairobi. KENYA

Tel:+254775751639
Email: ceo@biovax.go.ke cc: heprr@biovax.go.ke

Upon submission of every report, the consultant may be asked to make a presentation of the submitted report to the Client in a scheduled meeting. The acceptance of the report shall be provided by the client to the consultant by e-mail and/or recorded in the minutes of the meeting.

5.2 Timelines for Submission of Deliverables

The consultant will be expected to deliver the following outputs as presented in Table 1:

Table 1: Reporting Requirements and Timelines for Submission of Deliverables

No	Deliverable / Report	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
1.	Inception Report	Detailed inception report (scope and tasks outlined in 3.2.1) comprising: i. Project work Plan ii. Methodology iii. Stakeholder Engagement Plan and preliminary engagement findings iv. Project implementation plan; analytical framework, sequencing of tasks; timelines; deliverables; key risk log with mitigation measures and key milestones.	1	2 printed copies & an electronic copy (Financial Models must be in excel format)
2.	Market, Demand and Value Chain Analysis Report	**2.1 Draft Market, Demand and Value Chain Analysis Report** (scope and tasks outlined in 3.2.2) comprising: , supply chain and market intelligence on prioritised portfolio, licensing and intellectual property related landscape for prioritized products,	2	2 printed copies & an electronic copy (Financial Models must be in excel format)

		2.2 Final Market, Demand and Value Chain Analysis Report (scope and tasks outlined in 3.2.2) comprising: supply chain and market intelligence on prioritised portfolio, licensing and intellectual property related landscape on prioritised portfolio	3	2 printed copies & an electronic copy (Financial Models must be in excel format)
3.	Product Portfolio Prioritisation and Manufacturing Platform Optimisation Report	**3.1 Draft Report** (scope and task outlined in 3.2.3) comprising: **3.1.1 Regional Demand Analysis Report** detailing disease burden, market size, procurement dynamics, pricing and affordability and recommended priority products with high commercial and public health potential **3.1.2 Prioritisation Framework** comprising of a decision-support tools and/or matrix and preliminary product and platform recommendations **3.1.3 Platform and Product Portfolio Strategy** including: i. Platform assessment framework detailing technical regulatory and operational requirements; ii. Portfolio screening and prioritisation matrix with anchor and follow-up product sequencing; iii. Recommendations for business arrangements, partnership and collaboration opportunities; v. Operational Readiness and Phased Infrastructure assessment Plan	4	2 printed copies & an electronic copy (Financial Models must be in excel format)

		3.2 Final Report (scope and task outlined in 3.2.3) incorporating feedback from BioVax and relevant stakeholders comprising: **3.2.1 Regional Demand Analysis Report** detailing disease burden, market size, procurement dynamics, pricing and affordability and recommended priority products with high commercial and public health potential **3.2.2 Prioritisation Framework** comprising of a decision-support tools and/or matrix and final product and platform recommendations **3.2.3 Platform and Product Portfolio Strategy** including: i. Platform assessment framework detailing technical regulatory and operational requirements; ii. Portfolio screening and prioritisation matrix with anchor and follow-up product sequencing; iii. Recommendations for business arrangements, partnership and collaboration opportunities; iv. v. Operational Readiness and Phased Infrastructure assessement	4.5	2 printed copies & an electronic copy (Financial Models must be in excel format)
4.	Regional Commercialisation & Market Access Strategy Report	**Draft Regional Commercialisation and Market Access Strategy** detailing recommended market entry and distribution channels, health technology assessment, pricing,	5	2 printed copies & an electronic copy (Financial Models must

		reimbursement and affordability models, market risks and mitigation.		be in excel format)
		Final Regional Commercialisation and Market Access Strategy detailing recommended market entry and distribution channels, health technology assessment, pricing, reimbursement and affordability models, market risks and mitigation.	5.5	2 printed copies & an electronic copy (Financial Models must be in excel format)
5.	Integrated Financial Model	**Draft Integrated Financial Model** report comprising: i. models quantifying costs, revenues and investment needs with scenario analysis, including the Resource Mobilisation Strategy (financing options and phased funding plan) ii. Scenario Testing report showing results of base, upside and downside cases iii. Financial Model user manual iv. Staff training materials	6	2 printed copies & an electronic copy (Financial Models must be in excel format; .word/PDF format for manuals and assumptions)
		Final Integrated Financial Model report comprising: i. Models quantifying costs, revenues and investment needs with scenario analysis, ii. Scenario Testing report showing results of base, upside and downside cases iii. Financial Model user manual iii. Staff training and post-training reports and user guides	6.5	2 printed copies & an electronic copy (Financial Models must be in excel format; .word/PDF format for manuals and assumptions)
6.	Integrated 20-Year Business Plan	**Draft Integrated 20-Year Business Plan** sequencing product/platform introduction, market entry, technology transfer,	7.5	2 printed copies & soft copy (Word/PDF)

		capability building (infrastructure and personnel) and phased investment; aligned with regional demand, product prioritisation, commercialisation and operational strategies		
		Final Integrated 20-Year Business Plan incorporating feedback from BioVax and relevant stakeholders and consolidating the final technical, commercial and financial outputs of the assignment, including the prioritised product and manufacturing platform strategy, commercialisation and market access strategy, business and partnership arrangements, legal and regulatory considerations, risk and sustainability recommendations, phased implementation roadmap, and financial projections derived from the Integrated Financial Model.	8	2 printed copies & soft copy (Word/PDF)

The Client shall review each submitted deliverable and provide consolidated written comments within ten (10) working days of receipt. The Consulting Firm shall submit a revised deliverable addressing the Client's consolidated comments within ten (10) working days of receiving them.

6.0 Payment Schedule

The proposed payment schedules based on satisfactory performance of the contract which will be negotiated with the successful consultant will be as presented in Table 2 below.

Upon submission of every report, the consultant is expected to make a presentation of the submitted report to the Client in a scheduled meeting. The acceptance of the report shall be recorded in the minutes of the meeting.

Table 2: Proposed Payment Schedule

S/No	Deliverable / Reports	Timelines for submission of deliverables after contract commencement (months)	Percentage of Contract Amount
1.	Submission and Acceptance of Inception Report	1	10%
2.	Submission and Acceptance of Draft Market, Demand and Value Chain Analysis Report	2	5%
	Submission and Acceptance of Final Market, Demand and Value Chain Analysis Report	3	5%
3.	Submission and Acceptance of Draft Product Potfolio Prioritisation and Manufacturing Platform Optimisation Report	4	5%
	Submission and Acceptance of Final Product Potfolio Prioritisation and Manufacturing Platform Optimisation Report	4.5	10%
4.	Submission and Acceptance of Draft Regional Commercialisation and Market Access Strategy	5	5%
	Submission and Acceptance of Final Regional Commercialisation & Market Access Strategy	5.5	10%
5.	Submission and Acceptance of Draft Integrated Financial Model	6	5%
	Submission and Acceptance of Final Integrated Financial Model	6.5	10%
6.	Submission and Acceptance of Draft Integrated 20-Year Business Plan	7.5	10%
7.	Submission and Acceptance of Final Integrated 20-Year Business Plan	8	25%

"Acceptance" of a deliverable shall mean written confirmation issued by the Chief Executive Officer or their designated representative, confirming that the deliverable meets the requirements set out in this Terms of Reference.

7.0 Minimum Requirements for Consultants Qualification and Experience

The consulting firm will comprise a team, headed by a team leader. The members of the team will have the skills and experience necessary to undertake the range of tasks set out in these terms of reference. Everyone on the team must be personally available to do the work as and when required.

7.1 Core business and years in business

The consulting firm shall be legally registered/incorporated as a consulting entity and shall have its core business providing business development, commercial strategy, and market entry support or related fields for Life Science companies, for a minimum period of five (5) years.

7.2 Relevant Experience

The consulting firm shall demonstrate as having successfully executed and completed at least two (2) assignments of similar nature, scope, and complexity, and in a similar operating environment within the last five (5) years.

Details of similar assignments shall be provided in the expression of interest, including the Client's name and address, scope of services, contract value, period of execution, and the consultant's role.

7.3 Technical and managerial capability of the firm

The consulting firm shall demonstrate adequate technical depth, financial and business advisory capacity, and managerial capability to undertake this assignment, supported by submitted company profiles, organisational structures, and availability of suitably qualified experts.

8.0 Team composition, Minimum Qualifications and Experience for Key Experts

The consulting firm shall have a multidisciplinary team of qualified and experienced professionals capable of delivering the full scope of this assignment, including business planning, sector strategy, market and commercial analysis, financial modelling, investment planning, and strategic advisory for biopharmaceuticals, biologics, vaccines, and related health products manufacturing value chains. The firm should possess the necessary resources, tools, and expertise required to undertake services of this nature.

The team shall comprise Key Experts (who provide leadership and accountability) and Supporting Experts (who provide specialised technical input).

Key Experts shall be available throughout the duration of the assignment, while Supporting Experts may be mobilised as required in accordance with the approved work plan.

All experts shall have relevant and verifiable experience in their respective areas of expertise, with the team collectively demonstrating extensive knowledge of business planning, sector strategy, and investment advisory for biopharmaceuticals, biologics, vaccines, or related health products manufacturing value chains, as well as working knowledge of regional and global frameworks affecting the pharmaceutical and vaccine manufacturing sectors.

8.1 Key Experts

The key experts to be provided for this assignment will include qualified personnel with extensive international, regional and national experience as follows: -

8.1.1 Team leader

The Team Leader shall provide overall leadership and coordination of the assignment and shall be responsible for the quality and timely delivery of all outputs, including the integrated business plan and financial model.

i. A minimum of a Master's degree in Business Administration, Economics, Finance, Life Sciences, or a related field from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in corporate strategy, business development, investment advisory, or related advisory services;
iii. A minimum of five (5) years of specific experience in developing business plans, sector strategies, or investment cases for the pharmaceutical, biotechnology, vaccines, biologics, or related life sciences sector;
iv. Demonstrated experience in leading multidisciplinary teams in similar assignments; and
v. Experience in stakeholder engagement and presentation of strategic, technical, or financial recommendations to senior-level stakeholders.

8.1.2 Life Sciences Business Development Expert

The Life Sciences Business Development Expert shall provide strategic and commercial expertise for the development of the Business Plan, including market assessment, demand forecasting, product portfolio strategy, market access, commercialisation, and assessment of relevant procurement and supply chain dynamics.

i. A minimum of a Master's degree in Pharmacy, Life Sciences, Biotechnology, Business Administration, Health Economics, or a related field from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in business development, commercial strategy, market access, market intelligence, portfolio strategy, or strategic business planning within the life sciences sector;
iii. A minimum of five (5) years of specific experience in market assessment, demand forecasting, product portfolio strategy, commercial opportunity assessment, or business case development for pharmaceuticals, vaccines, biologics, biotechnology, or related health products;
iv. Demonstrated experience in developing or contributing to business plans, feasibility studies, investment cases, or strategic plans within the pharmaceutical, vaccine, biotechnology, biologics, or related life sciences sector; and
v. Knowledge of pharmaceutical and vaccine markets, including procurement, supply chains, market access, and relevant regional and global market dynamics.

8.1.3 GMP and Biomanufacturing Expert

Biomanufacturing Expert will provide specialist manufacturing expertise to ensure product selection, manufacturing platform optimisation and technology transfer planning recommendations are aligned with facility capabilities and operational realities. This expert will serve as the manufacturing specialist ensuring deliverables are grounded in production feasibility.

i. Minimum of master's degree in biotechnology, Chemical Engineering, Pharmaceutical Sciences, or related discipline from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general experience in Pharmaceutical, vaccine or biologics manufacturing operations;
iii. A minimum of five (5) years specific experience in biologics, biosimilars, vaccines, or related production systems; with demonstrated ability in facility and equipment planning, manufacturing complexity assessments and scale up feasibility determination;
iv. Proven experience advising or working with life sciences companies on GMP-compliant manufacturing operations, quality systems strengthening, facility readiness, or production scale-up.
v. Must be validly registered and holding a current annual professional practicing license from

a relevant professional body in any country duly recognised in Kenya.

8.1.4 Financial Analyst

The Financial Analyst shall provide financial and investment analysis for the development of the Business Plan, including financial modelling, CAPEX/OPEX analysis, costing and pricing, investment appraisal, funding options, and scenario analysis.

i. A minimum of a Master's degree in Business Administration, Finance, Economics, Business Analytics, or a related field from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in financial analysis, business planning, investment analysis, or related advisory services;
iii. A minimum of five (5) years of specific experience in financial modelling, business case development, or investment analysis within the pharmaceutical, vaccine, biotechnology, biologics, or related life sciences sector;
iv. Demonstrated experience in developing financial models, including CAPEX/OPEX analysis, financial projections, cash-flow forecasting, investment appraisal, and scenario analysis; and
v. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.5 Risk Management specialist

The Risk Management Specialist shall identify, assess, and advise on the mitigation of operational, commercial, regulatory, and financial risks to support the development of a resilient and credible Business Plan.

i. A minimum of a Bachelor's degree in Risk Management, Finance, Business Administration, Engineering, or a related field from an academic institution in any country recognised in Kenya;
ii. A minimum of eight (8) years of general professional experience in enterprise or corporate risk management; and
iii. A minimum of four (4) years of specific experience in enterprise risk assessment, operational, commercial, financial, regulatory, or strategic risk management within the pharmaceutical, vaccine, biotechnology, biologics, or related life sciences sector.

8.2 Non-Key Experts

8.2.1 Regulatory Affairs & Product Registration Expert

The Regulatory Affairs and Product Registration Expert shall provide regulatory expertise for the identified product portfolio, including regulatory pathways, product registration, compliance strategies, and post-approval requirements.

i. A minimum of a Bachelor's degree in Pharmacy or Pharmaceutical Sciences from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in regulatory affairs for pharmaceuticals, human vaccines, biologics, or related health products;
iii. A minimum of seven (7) years of specific experience in regulatory submissions, including preparation or review of product registration dossiers, CMC documentation, GMP-related submissions, or WHO Prequalification requirements; and,
iv. Must hold a current annual professional practising licence from a relevant professional body in any country duly recognised in Kenya.

8.2.2 Legal and Intellectual Property Expert

The Legal and Intellectual Property Expert shall provide legal and intellectual property expertise for the Business Plan, including licensing, technology transfer, intellectual property, and structuring of strategic business arrangements.

i. A minimum of a Bachelor's degree in Law from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in legal advisory services, intellectual property, commercial law, or related legal practice;
iii. A minimum of five (5) years of specific experience in intellectual property, licensing, technology transfer, public-private partnerships, joint ventures, or other strategic business arrangements;
iv. Experience in providing legal advisory services to government entities, state-owned enterprises, or organisations within the pharmaceutical, biotechnology, life sciences, or related sectors; and
v. Must hold a current annual professional practising certificate from a relevant professional body in any country duly recognised in Kenya.

8.2.3 Sustainability specialist

The Sustainability Specialist shall provide environmental, social, and governance (ESG) expertise to support the integration of sustainability considerations into the Business Plan.

i. A minimum of a Bachelor's degree in Environmental Science, Environmental Engineering, Public Health, or a related field from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general professional experience in environmental and social impact assessment, environmental management, sustainability, or related advisory services;
iii. A minimum of five (5) years of specific experience in sustainability strategies, ESG compliance, or sustainable manufacturing within the pharmaceutical, biotechnology, life sciences, or related industrial sector; and
iv. Experience in ESG reporting, carbon accounting, life-cycle assessment, or other relevant sustainability frameworks.

9.0 Estimated Time Inputs for Key Experts

The number of key experts and the estimated time input for each key expert for the assignment are presented in Table 3.

Table 3: Estimated Time Inputs for Key and Non-Key Experts

S/No	Key and Non-Key Experts	No.	Time Inputs (person -months)
	Key Experts		
1.	Team Leader	1	8
2.	Life Science Business Development Expert	1	4
3.	GMP and Biomanufacturing Expert	1	3
4.	Financial Analyst	1	3
5.	Risk Management Specialist	1	2
	Non- Key Experts		
6.	Regulatory Affairs and Product Registration Expert	1	1
7.	Legal and Intellectual Property Expert	1	1
8.	Sustainability Specialist	1	1
	TOTAL		**23**

10.0 Management and Accountability of the Assignment

The Kenya BioVax Institute is the Client for these services. The consultant will report to the Chief Executive Officer. The Consultant will work closely with an assigned senior manager and the HEPRR focal officer to oversee the day-to-day running of the assignment.

The Consulting Firm may propose replacement of Key Experts via written notification to the Client. All replacements shall be subject to Client approval and must demonstrate equivalent or superior qualifications and experience as specified in the original proposal.

10.1 Monitoring of Quality and Performance

The Consultant's performance will be monitored against the following key performance indicators:

i. Timeliness of deliverable submission against the agreed schedule in *Table 1;*
ii. Responsiveness to Client comments, with revised deliverables submitted within ten (10) working days of receiving consolidated comments, in accordance with Section 5.2;
iii. Compliance of the integrated financial model with generally accepted modelling standards (e.g. FAST Standard principles), including clear separation of inputs, calculations, and outputs, and full transparency of assumptions; and
iv. Overall quality and completeness of deliverables as assessed by the Project Steering Committee.

11.0 Obligation of the Client

The Client will:

i. Provide all relevant information and documentation to the consultant that can assist in this assignment, including, at a minimum, an inventory of existing background documentation to be made available within ten (10) working days of contract signing: prior feasibility studies, market assessments, facility engineering reports, existing MOUs or partnership agreements referred to in Section 1.1, and any prior financial models developed for BioVax;
ii. Provide contacts of key stakeholders;
iii. Organise meetings with relevant stakeholders as may be required by the consultant;
iv. Facilitate liaison with other program-implementing partners;
v. Facilitate the Consultant's access to Government entities and respective stakeholders;
vi. Review and approve reports.

12.0 Obligations of the Consultant

i. The consultant shall be responsible for the provision of all the necessary resources to carry out the services including but not limited to appropriate qualified staff and shall make arrangements for the establishment of office, supporting office equipment and furniture, vehicles, utilities, communications, insurance, accommodation and any other required resources to ensure the assignment is carried on smoothly and seamlessly within the timeframe provided;
ii. BioVax shall second two (2) full-time staff members to support the Consultant's team throughout the assignment, including at a minimum one staff member with expertise in finance or regulatory affairs and one with expertise in technical/manufacturing operations, to facilitate data access, stakeholder coordination, and institutional knowledge transfer.
iii. The consulting firm will conduct stakeholder consultations and incorporate inputs from relevant actors at national, regional, and international levels to inform the technical,

commercial and strategic components of the assignment and the development of the Final Integrated 20-Year Business Plan;

iv. The Consultant and all members of its team shall treat all data, information, and materials obtained in the course of this assignment as strictly confidential and shall not disclose such information to any third party without the prior written consent of BioVax. Each member of the Consultant's team shall sign a Non-Disclosure Agreement (NDA), in a form acceptable to BioVax, prior to commencing work. The Consultant shall disclose any actual or potential conflicts of interest immediately upon becoming aware of them.

13.0 Proprietary Rights of Client in Reports and Records.

i. Unless otherwise indicated, all reports and relevant data and information such as databases, other documents and software, supporting records or material compiled or prepared by the Consultant for the Client in the course of the Services shall be confidential and become and remain the absolute property of the Client. The Consultant shall deliver all such documents to the Client, together with a detailed inventory thereof. The Consultant may retain a copy of such documents, data and/or software but shall not use the same for purposes unrelated to the Project without prior written approval of the Client; and

ii. If license agreements are necessary or appropriate between the Consultant and third parties for purposes of development of the plans, databases, other documents and software, the Consultant shall obtain the Client's prior written approval to such agreements, and the Client shall be entitled at its discretion to require recovering the expenses related to the development of the program(s) concerned.