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 TRANSACTION ADVISORY SERVICES ON ACQUISITION OF TECHNOLOGY TRANSFER CONTRACTS FOR THE KENYA BIOVAX INSTITUTE

(FIRMS SELECTION)

PROCUREMENT/CONTRACT REF NO.: KE-KBI-540009-CS-QCBS

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Client:
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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, thereby contributing to the African Union target of producing 60% of Africa's vaccine needs by 2040. 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 intends to acquire WHO prequalified vaccine drug substance/products and technologies, biologics and associated technical assistance from credible manufacturers.

1.2 Rationale

Kenya is strategically positioned to serve as the regional hub for manufacturing of specialised Health Products and Technologies, including vaccines for children, adolescents, and maternal populations. This potential is underpinned by an enabling business environment, a growing skilled workforce, the capacity to conduct relevant clinical research and trials, and a strategic role in regional health security initiatives. Evidence reveals that developing local manufacturing capacity for priority infectious diseases could avert over 4.44 million deaths and 206.27 million disability-adjusted life years across the African region, highlighting the transformative public health and economic benefits of domestic vaccine production.

However, global vaccine manufacturing is technologically complex and capital-intensive, requiring carefully structured partnerships for new entrants to succeed. For Kenya to enter and remain competitive in this landscape, the Kenya BioVax Institute (BioVax) must secure credible technology transfer arrangements that not only surpass manufacturing rights to include upstream technical

assistance, regulatory support, quality systems strengthening, and sustainable market access but also structured to ensure long-term viability, alignment with national health priorities, and compliance with international standards.

Under the HEPRR programme, BioVax is implementing the vaccine manufacturing component with an objective of establishing production capacities for human vaccines to strengthen health commodity security for Universal Health Coverage and self-reliance for pandemic preparedness captured in the Subcomponent 1.3: Strengthening of Local Pharmaceutical and Vaccine Manufacturing Capacity.

Given the technical, regulatory, intellectual property complexities, and investment risks involved, engaging a competent transaction advisor is essential to enable BioVax identify suitable partners, negotiate robust and bankable technology transfer agreements, mitigate risks, and ensure that partnerships are carefully structured to deliver sustainable capability development, regulatory compliance, and long-term value for Kenya's health security and industrial development.

2.0 Objective of the Assignment

BioVax intends to engage a highly experienced Transaction Advisor to guide the full lifecycle of technology transfer transactions, with the primary objective of supporting vaccines and biologics portfolio acquisition and successful transfer of identified technology and capabilities. The Transaction Advisor will also be required to ensure that the transactions are scientifically sound, legally compliant and commercially viable and will structure the deal to promote local capacity-building and implementation support, intellectual property protection and long-term sustainability.

2.1 Specific Objectives

The specific objectives of this assignment are to:

1. Review, validate and prioritise a strategic portfolio of vaccines and biologics suitable for technology transfer to BioVax through a rigorous assessment of project costs, incorporating robust financial modelling, affordability and sustainability analyses, and to recommend the optimal value-for-money options that best enable BioVax to achieve its strategic, public health, and commercial objectives;

2. Support the identification, evaluation, and selection of credible and capable technology transfer sending units with proven technical, regulatory, and operational capacity to transfer the identified antigens, in full compliance with the applicable laws and regulations;

3. Provide expert support to BioVax throughout the technology acquisition process, including the structuring, negotiation, and successful conclusion of legally sound and commercially viable technology transfer agreements with selected sending units, in accordance with the applicable laws and regulations; and

4. Advise BioVax and its appointed contractors on optimal planning and implementation strategies that ensure the effective and timely execution of technology transfer, while embedding project-based learning, knowledge management, policy development and systematic skills transfer mechanisms across the entire project life cycle to secure sustainable in-house capability development.

3.0 Scope of Consulting Services and Specific Tasks

3.1 Scope of the Consulting Services

The scope of the Consulting Services will include provision of the necessary technical, legal and financial analyses to enable identification and procurement of vaccine technology from a suitable partner in compliance with relevant laws and regulations, while ensuring commercial viability and long-term sustainability of the transaction. This will require transaction structuring options and analysis of the Technology Transfer Agreement components (services, IP/licensing, goods).
The Transaction Advisor will provide technical and commercial advisory support during Technology Transfer Agreement negotiations and execution with the Technology Transfer Partner. The Transaction advisor will also be expected to deliver comprehensive, technology transfer implementation support and capacity development that addresses all aspects of the technology transfer journey.

3.2 Specific Tasks

3.2.1 Inception Phase

The transaction advisor 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 Transaction Advisor regarding the objectives, scope, deliverables, and implementation approach of the consultancy. This engagement will ensure strategic alignment, clarify roles and expectations, and confirm the analytical and transactional pathways required to deliver successful technology transfer projects. In undertaking this task, the Transaction Advisor will be expected to:

a. 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 legal framework development and reviews necessary for delivering successful technology transfer projects.

b. Develop an inception report that clearly outlines the methodology, detailed implementation 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 Product Portfolio Prioritisation and Value Optimisation

The Transaction Advisor, in close liaison with BioVax, will undertake a comprehensive review of priority vaccines and biologics suitable for technology transfer. This will be supported by a detailed cost and market analysis that captures the national and regional vaccine and biologics landscape, necessary for the development of robust financial and commercial models to inform strategic decision-making. This assessment will include among others:

a. Review, validation and prioritisation of a strategic product portfolio suitable for technology transfer through a structured review of national and regional immunisation programmes and biologics markets, taking into account existing and projected funding arrangements; anticipated changes in immunisation schedules; UNICEF and Gavi, the Vaccine Alliance (Gavi) procurement mechanisms; and Gavi country transition and co-financing dynamics; and

b. Development of comprehensive financial and commercial models for each shortlisted vaccine technology, incorporating full CAPEX and OPEX estimates including tax implications; benchmarking of cost of goods sold (COGS) against global and regional manufacturers; demand-driven revenue projections; scenario analyses reflecting financing shifts, donor transitions, and programme switching; and evaluation of key investment metrics, including payback periods, internal rates of return, sensitivity to volume fluctuations, and exposure to market entry risks such as currency, supply chain, and procurement uncertainties.

c. Regulatory Pathway Assessment evaluating registration and WHO prequalification strategies, including: assessment of Kenya's Pharmacy and Poisons Board (PPB) WHO Maturity Level status and implications for prequalification eligibility; mapping of African National Regulatory Authorities at WHO Maturity Level 3 vaccine producing or above for potential regulatory reliance arrangements; and development of a regulatory strategy aligned with African Medicines Regulatory Harmonisation (AMRH) and EAC regional frameworks.

3.2.3 Selection of Technology Transfer Partners

The Transaction Advisor will support BioVax in the systematic identification, evaluation, and selection of suitable technology transfer partners (sending units) in accordance with World Bank Procurement Regulations, and will facilitate structured, transparent, and well-governed engagement with prospective partners. This task will be designed to ensure that selected partners possess not only the requisite technical and regulatory credentials, but also the strategic intent and institutional commitment to support long-term technology transfer, capacity building, and sustainable vaccine and biologics manufacturing in Africa. This task will include among others:

a. Preparation of comprehensive partner profiles and market intelligence briefs; development of formal outreach and expression-of-interest correspondence; drafting and execution of confidentiality and non-disclosure agreements; and preparation of structured introductory information packages to support informed and efficient engagement with potential technology partners;
b. Conducting rigorous due diligence assessments of prospective sending units, including evaluation of their technical capabilities and manufacturing track record; scope, ownership, and limitations of relevant intellectual property and licensing rights; financial strength, solvency, and corporate stability; historical regulatory performance, GMP compliance status, and quality management systems; and demonstrated willingness and capacity to support long-term partnerships, knowledge transfer, and capability development within the African context; technical assessment of each prospective partner's technology transfer capability, including evaluation of their technology transfer methodology, training programmes, technical documentation standards, and demonstrated track record of successful transfers to emerging market manufacturers;
c. Designing and recommending the most appropriate and bankable technology transfer transaction structures tailored to BioVax's strategic objectives and risk appetite. These may include, but are not limited to, licensing arrangements, joint ventures, white-label manufacturing, co-development and co-investment structures, and public–private partnership (PPP) arrangements. Each proposed structure will be systematically assessed against defined criteria, including ownership and transferability of intellectual property and know-how; freedom to operate; scope and duration of technology access rights (exclusive, non-exclusive, field- or territory-restricted); roles and obligations of the respective parties; allocation of technical, regulatory, commercial, and financial risks; performance milestones and deliverables; pricing, royalty, and long-term sustainability considerations;
d. Development of draft and final procurement documents incorporating at minimum appropriate qualification requirements and shall be based on applicable World Bank Procurement Regulations;
e. Development of the institutional Research, Intellectual Property and Technology Transfer Policy and implementation framework, including: (i) definitions and treatment of background intellectual property contributed by each party; (ii) patent landscape assessment for selected vaccine products to identify potential freedom to operate constraints; (iii) confidentiality and non-disclosure provisions appropriate for technology transfer documentation; (iv) licensing terms guidance including royalty structures, territorial rights, exclusivity provisions, and sublicensing arrangements; (v) provisions for improvements and innovations developed during technology transfer; and (vi) dispute resolution mechanisms for IP-related matters.

3.2.4 Technology Acquisition and Transaction Structuring

The Transaction Advisor will provide end-to-end support to BioVax in managing the vaccine and biologics technology acquisition process, from transaction design through negotiation and execution. The Technology Transfer Agreement shall be between the Client (as Receiving Unit) and the selected Technology Transfer Partner (Sending Unit). This support will ensure that all technology transfer arrangements are legally robust, commercially sound, and fully compliant with applicable national, regional, and international legal and regulatory frameworks, while safeguarding BioVax's long-term strategic, public health, and commercial interests. This task shall include, among others:

a. Providing comprehensive legal and contractual support through the drafting, review, harmonisation, and finalisation of all instruments required to formalise the technology transfer transaction. This will include, as applicable, administration of the bidding process including bid evaluation, master and framework agreements; technology transfer agreements; Heads of Terms; quality and GMP compliance agreements; material transfer agreements; facility use or services agreements; intellectual property license agreements; technical assistance and training agreements; cooperative research and development agreements; and confidentiality, data-sharing, and information security agreements; and

b. Leading and supporting BioVax throughout the negotiation process by developing structured negotiation strategies; preparing detailed negotiation briefing and decision packs; benchmarking proposed commercial and legal terms against industry and regional comparators; participating directly in negotiation sessions with sending units; and advising BioVax on the legal, financial, operational, and strategic implications of proposed terms and counterproposals.

3.2.5 Implementation Advisory and Capability Development

The Transaction Advisor will provide advice to BioVax and its appointed contractors on optimal implementation strategies that ensure the effective and timely execution of technology transfer, while embedding project-based learning, knowledge management, and systematic skills transfer mechanisms across the technology transfer project life cycle to secure sustainable in-house capability development. This task will include, among others:

a. Ensuring BioVax has timely and continuous access to all information necessary for effective implementation of the executed technology transfer agreements, including technical documentation, regulatory requirements, performance milestones, and compliance obligations provided by the technology transfer partner. The Advisor will identify, track, and advise on potential technical, regulatory, financial, and operational risks across the project life cycle, and support the development and application of appropriate mitigation measures to safeguard project timelines, quality, and outcomes;
b. Conducting capability-focused Gap Analysis covering: Process Gap Analysis, mapping existing production capabilities against sending unit manufacturing specifications and process parameters;

c. Development of Receiving Unit (RU) Readiness Framework including: organisational structure design for technology transfer operations with clear roles and reporting lines; competency framework and detailed job descriptions for key technical positions (Production Manager, QA Manager, QC Manager, Technical Services, etc.); and governance framework for technology transfer project management including steering committee structure and escalation protocols;
d. Strategic oversight and sending unit coordination during technology transfer execution phases including: Technology Transfer Master Plan and Validation Strategy with process transfer milestone tracking and acceptance verification, shipping validation and cold chain requirements specifications; and
e. Providing structured, practical, and on-the-job capacity building to BioVax and its contracted service providers through deliberate and well-defined knowledge and skills transfer mechanisms. This will include mentorship, joint working arrangements, targeted training sessions, Intellectual Property and Technology Transfer Policy implementation support, development of standard operating procedures and training modules, financial modelling and risk modelling training and hands-on support during critical implementation stages. The Transaction Advisor will be required to articulate a clear, intentional, and measurable approach for transferring both tacit and explicit knowledge to BioVax, ensuring that policies and capabilities are retained beyond the life of the consultancy.

3.2.6 Close-out Phase

The Transaction Advisor 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 Transaction Advisor will purpose to review, validate, and consolidate the outcomes of the technology acquisition and transfer process, 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 future technology transfer initiatives.

In undertaking this task, the Transaction Advisor will be expected to compile a comprehensive project final report that outlines technical, financial, and implementation performance assessments, documents lessons learned, residual risks, remaining actions from change control, sustainability interventions, transition arrangements and recommendations for future technology transfer initiatives. The report will incorporate any additional reporting requirements specified by BioVax and will serve as a reference for continuous improvement and future scaling efforts.

4.0 Duration and Location of the Assignment

The consulting services will be implemented over a cumulative period of eighteen (18) 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

i. 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

ii. 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

iii. 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 Transaction Advisor 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 / Reports	Deliverable Description	Timelines for submission of deliverables after contract commencement (months)	Submission Format
	PHASE 1 DELIVERABLES			
1	Inception Report	**Detailed inception report** (scope and tasks outlined in 3.2.1) comprising: i) Project work Plan ii) Project and methodology iii) detailed technical, financial, legal and regulatory framework review; iv) Project implementation plan; sequencing of tasks; timelines; deliverables; and key milestones.	0.5	2 printed copies & an electronic copy (Financial Models must be in excel format)
2	Product Portfolio Prioritisation and Value Optimisation Report	**2.1 Draft Comprehensive Product Portfolio Prioritisation and Value Optimisation report** (scope and tasks outlined in 3.2.2) comprising: i) Project cost estimates for each shortlisted product; ii) Financial models incorporating CAPEX, OPEX; pricing; and sustainability scenarios; iii) Value-for-money and affordability analysis with ranked recommendations.	1.5	2 printed copies & an electronic copy (Financial Models must be in excel format)

		Regulatory pathway assessment including: PPB WHO Maturity Level implications for prequalification eligibility; mapping of ML3/4 vaccine producing National Regulatory Authorities for regulatory reliance arrangements		
		2.2 Final Comprehensive Product Portfolio Prioritisation and Value Optimisation report (scope and tasks outlined in 3.2.2) comprising: i) Project cost estimates for each shortlisted product; ii) Financial models incorporating CAPEX, OPEX; pricing; and sustainability scenarios; iii) Value-for-money and affordability analysis with ranked recommendations. iv) Regulatory pathway assessment including: PPB WHO Maturity Level implications for prequalification eligibility; mapping of ML3/4 vaccine producing National Regulatory Authorities for regulatory reliance arrangements	2	2 printed copies & an electronic copy (Financial Models must be in excel format)
3	Selection of Technology Transfer Partners report	**3.1 Draft Technology Transfer partners selection report** (scope and tasks outlined in 3.2.3) comprising: i) Procurement documentation;	3.5	2 printed copies & an electronic copy (Financial Models must be in excel format)

		ii) Research and Intellectual Property and Technology Transfer policy and implementation framework;		
		3.2 Final Transfer partners selection report (scope and tasks outlined in 3.2.3) comprising: i) Technology partners comparison matrix with ranked recommendations to support partner selection and decision-making; ii) Procurement documentation; iii) Long and short lists of potential technology transfer partners; iv) Partner profiles v) Engagement documentation, including outreach letters, NDAs, and information packages; vi) Due diligence reports covering technical, IP, financial, regulatory, and strategic dimensions; vii) Research and Intellectual Property and Technology Transfer policy and implementation framework; viii) Technology transfer capability assessment for shortlisted partners covering transfer methodology, training	5	2 printed copies & an electronic copy (Financial Models must be in excel format)

		programmes, documentation standards, and demonstrated track record with emerging market manufacturers.		
4	Technology Acquisition and Transaction Structuring report	4.1 Draft report comprising: 4.1.1 Bid evaluation report 4.1.2Heads of Terms 4.1.3 Technology Transfer Agreement and Negotiation report including: i. transaction structuring options paper with comparative assessment and recommended deal structures; ii. negotiation strategy and briefing packs, including benchmarks and risk analyses; iii. suite of legal and contractual agreements governing technology transfer; with applicable laws and regulations; iv. risk allocation and governance framework embedded within transaction documentation	8	2 printed copies & an electronic copy
		4.2 Final report comprising: 4.2.1 Bid evaluation report	10	2 printed copies & an electronic copy

		4.2.2Heads of Terms 4.2.3 Technology Transfer Agreement and Negotiation report including: i. transaction structuring options paper with comparative assessment and recommended deal structures; ii. negotiation strategy and briefing packs, including benchmarks and risk analyses; iii. suite of legal and contractual agreements governing technology transfer; with applicable laws and regulations; iv. risk allocation and governance framework embedded within transaction documentation		

5	Implementation Advisory and Capability Development reports	5.1 Draft Technology Transfer Master Plan and Validation Strategy including i) Risk Management Framework and Risk-based Scenarios ii) Capability Gap Analysis including process gap analysis mapping production capabilities against sending unit specifications iii) Receiving Unit Readiness Framework including organizational structure design for technology transfer operations; competency framework and job descriptions for key technical positions; and governance framework for project management iv) Process transfer milestone tracking v) acceptance verification vi) Cold chain requirements specification	10	2 printed copies & an electronic copy (Financial models and Risk-based scenario models in Excel)
		5.2 Final Technology Transfer Plan and Validation Strategy including i)Risk Management Framework and Risk-based Scenarios ii) Capability Gap Analysis including process gap analysis mapping production capabilities against sending unit specifications iii) Receiving Unit Readiness Framework including organizational structure	16	

		design for technology transfer operations; competency framework and job descriptions for key technical positions; and governance framework for project management iv) Process transfer milestone tracking v) acceptance verification vi) Cold chain requirements specification		
		5.3 Development and deployment of Knowledge and skills transfer plan and implementation support report including: in-person training sessions (technical advisory on technology transfer, foundational financial modelling and risk modelling), training on modelling software utilisation, mentorship, and on-the-job learning activities, policy implementation support, seminars and workshops	12	
		5.4 Development and deployment of Capacity building tools and documentation report including SOPs, training modules, guidelines, and knowledge products/ software	16	
6	Final Report	**Comprehensive technical and financial final report** (scope and tasks outlined in 3.2.6) comprising:	18	2 printed copies & an electronic copy (Financial Models and Risk-Based

		i) summarised outcomes achieved, ii) performance and milestone achievement review iii) residual risk register with mitigation recommendations with relevant input from stakeholders iv) transition arrangements v) sustainability recommendations		Models must be in excel format)

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	0.5	5%
2	Submission and Acceptance of the Draft Product Portfolio Prioritisation and Value Optimisation report	1.5	0%
	Submission and Acceptance of Final Comprehensive Product Portfolio Prioritisation and Value Optimisation Report	2	10%
3	Submission and Acceptance of Draft (a) Technology Transfer Partners selection report	3.5	0%

	(b) research and intellectual property and technology transfer policy and implementation framework (c) procurement documentation		
	Submission and Acceptance of Final (a) Technology Transfer Partners selection report (b) research and intellectual property and technology transfer policy and implementation framework (c) procurement documentation	5	10%
4	Submission and Acceptance of Draft Technology Acquisition and Transaction Structuring report	8	0%
	Submission and Acceptance of Final Technology Acquisition and Transaction Structuring report	9	10%
5	Submission and Acceptance of Draft Technology Transfer Master Plan and Validation Strategy	10	10%
	Submission and Acceptance of Final Technology Transfer Master Plan and Validation Strategy	16	25%
	Submission and Acceptance of Knowledge and Skills Transfer Plan and Implementation support report	12	10%
	Submission and Acceptance of Capacity Building Tools and Documentation report	16	10%
6	Submission and Acceptance of Comprehensive Technical and Financial Final Report	18	10%

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 skill and experience necessary to undertake the range of tasks set out in these terms of reference. Each individual on the team must be personally available to do the work as and when required.

7.1 Core business and years in business

The firm shall be registered/incorporated as a consulting firm with core business in the field of transaction advisory for a minimum period of Eight (8) years.

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7.2 Relevant experience

The firm shall demonstrate as having successfully executed and completed at least one (1) vaccine technology transaction advisory assignment of a similar nature and complexity, and in a similar operating environment in the last eight (8) years. Details of similar assignments-Name and address of the client, scope, value, and period should be provided in the submitted proposal including enumeration of these similar past assignments.

7.3 Technical and managerial capability of the firm

The consulting firm shall demonstrate adequate technical 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 well-qualified and experienced professionals as required and appropriate for completion of the exercise. The key experts shall personally carry out (with assistance of other non-key staff deemed appropriate) the services described in these Terms of Reference.

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.

The key experts shall exhibit extensive knowledge of technology transfer transaction advisory, the African vaccine manufacturing sector and regulatory frameworks; and working knowledge of regional and global frameworks impacting 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 Lead

The Team Lead will provide overall leadership of the consulting engagement, ensuring strategic alignment with BioVax objectives, managing client relationships, and driving commercial and business case development. This expert will be accountable for all deliverables and team performance.

i. Minimum of a Master's degree in Business Administration (MBA), Finance, Economics or Life Sciences or related discipline from an academic institution in any country recognised in Kenya;
ii. Minimum of 15 years of experience in commercial strategy, business development, or technical advisory within the biologics/vaccine sectors;
iii. A minimum of 5 years working on African market entry, technology transfer negotiations, or manufacturing investment decisions;
iv. Experience in leading multidisciplinary teams in the design, negotiation, or execution of technology transfer agreements or strategic partnerships in the life sciences sector; and
v. Experience in engaging with National Regulatory Authority leadership on regulatory reliance pathways, preferably with African regulatory authorities in the context of vaccine or biologics manufacturing.

8.1.2 Global Health Specialist

The Global Health Specialist will support antigen selection and prioritisation through identification of platforms and manufacturing technologies and analyse the vaccine landscape ensuring long-term sustainability.

i. Minimum of a Master's degree in Medicine, Pharmacy, Vaccinology, Immunology, Biotechnology or related Life Sciences discipline from an academic institution in any country recognised in Kenya;
ii. Minimum of ten (10) years of general experience in pharmaceuticals or biologics/vaccine manufacturing environments;
iii. A minimum of four (4) years specific experience in policy and access analysis, market intelligence and forecasting and global procurement and financing; and
iv. Experience in product portfolio prioritisation and value optimisation planning with National Immunization Technical Advisory Groups (NITAGs), preferably with African NITAGs.

8.1.3 Technology Transfer Technical Lead

The Technology Transfer Technical Lead will be the principal technical expert responsible for overseeing the successful transfer of manufacturing processes, analytical methods, and quality systems from the sending unit to BioVax. This expert will serve as the technical bridge between the sending unit and BioVax's production and quality teams.

i. Minimum of Master's degree in Biotechnology, Pharmaceutical Sciences, Chemical Engineering, or related discipline from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general experience in biologics or vaccine manufacturing;
iii. A minimum of five (5) years specific experience leading or participating in technology transfer projects for biologics or vaccines, preferably involving fill-finish operations;
iv. Demonstrated expertise in process validation, analytical method transfer, and regulatory dossier preparation; and

v. Experience in working with WHO-prequalified or stringent regulatory authority-approved manufacturing facilities.

8.1.4 Senior Legal Expert

The Senior Legal Expert will lead all legal aspects of the technology transfer transaction, including intellectual property assessment, contract structuring, and negotiation support. This expert will ensure agreements protect BioVax interests while enabling effective technology transfer.

i. Minimum of Masters' degree in law from an academic institution in any country recognised in Kenya;
ii. A minimum of Eight (8) years of general experience in contract drafting and negotiations;
iii. A minimum of six (6) years specific experience working with intellectual property rights and freedom-to-operate in the pharmaceutical and vaccine industry;
iv. Must have executed a minimum of one successful vaccine technology transfer or intellectual property agreement; 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 Regulatory Expert

The Regulatory Expert will provide strategic guidance on regulatory pathways for product registration and WHO prequalification. This expert will lead engagement with national regulatory authorities and advise on regulatory reliance arrangements with African ML3/ML4 authorities.

i. A minimum of Bachelor of Pharmacy from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general experience in pharmaceutical and vaccine manufacturing;
iii. A minimum of five (5) years specific experience in pharmaceutical and vaccine technology transfer, including regulatory oversight of process transfer, preparation of regulatory dossiers, and ensuring compliance with GMP WHO guidelines;
iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.1.6 Financial Expert

The Financial Expert will develop financial models, conduct investment analysis, and support business case development. This expert will provide commercial viability assessments and advise on pricing, cost structures, and funding arrangements.

i. A minimum of Masters' degree in Business Administration (MBA) with specialisation in Business Analytics, Strategic Management/Planning, Finance, Economics, or related discipline from an academic institution in any country recognised in Kenya
ii. A minimum of ten (10) years of general experience in business planning;
iii. A minimum of six (6) years specific experience in pharmaceutical, vaccines and biologics business models development and analytics;

iv. Must hold a valid professional certification from a professional body in any country duly recognised in Kenya.

8.1.7 Bioprocess Expert

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

i. Minimum of Master's degree in Biotechnology, Biochemical 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 vaccine or biologics manufacturing operations;
iii. A minimum of five (5) years specific Experience in technology transfer from a receiving unit perspective, with demonstrated ability to assess manufacturing complexity and feasibility
iv. Demonstrated experience across multiple vaccine platforms (conjugate, recombinant, traditional) with specific fill-finish expertise; and
v. Strong knowledge of equipment and facility requirements for different vaccine products, including cleanroom classifications and HVAC specifications.

8.1.8 Procurement and Contracts Expert

i. Minimum of bachelors' degree in Supply Chain Management or Business Administration from or related discipline from an academic institution in any country recognised in Kenya;
ii. A minimum of ten (10) years of general experience in preparation of procurement documentation for projects, contract administration, claims management, and dispute resolution
iii. A minimum of five (5) years specific experience involving development of bidding documents and contract administration for pharmaceutical supply chain management;
iv. Must be validly registered and holding a current annual professional practicing license from a relevant professional body in any country duly recognised in Kenya.

8.2 Non-Key Experts

8.2.1 Legal Expert

The Legal Expert will support contract review, corporate governance compliance, and regulatory filings. This expert will assist the Senior Legal Expert with documentation and due diligence activities.

i. A minimum of bachelors' degree in law from an academic institution in any country recognised in Kenya;
ii. A minimum of six (6) years of general experience in contract drafting and negotiations;
iii. A minimum of four (4) years specific experience working with intellectual property rights;
iv. Must be validly registered and holding a current annual professional practicing license from

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

8.2.2 Quality Assurance (QA) / Quality Control (QC) specialist

The QA/QC Specialist will support quality systems development, analytical method transfer, and validation activities.

i. Minimum of Bachelor's degree in Chemistry, Biochemistry, Pharmaceutical Sciences, or related discipline from an academic institution in any country recognised in Kenya;
ii. A minimum of seven (7) years of experience in pharmaceutical or vaccine quality assurance and quality control;
iii. Experience in analytical methods validation and transfer per ICH Q2(R2) guidelines; and
iv. Strong knowledge of WHO GMP requirements, batch release procedures, deviation and CAPA management, and stability testing protocols.

8.2.3 Risk Analyst

i. Minimum of Masters' degree in Risk Management or related discipline from an academic institution in any country recognised in Kenya;
ii. A minimum of eight (8) years of general experience in corporate risk management; and
iii. A minimum of four (4) years specific experience in pharmaceutical, vaccines and biologics manufacturing environment.

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/ Non-Key Experts	No.	Time Inputs (person -months)
	Key Experts		
1	Team Lead	1	18
2	Global Health Specialist	1	8
3	Regulatory Expert	1	18
4	Technology Transfer Technical Lead	1	18
5	Financial Expert	1	12
6	Senior Legal Expert	1	10
7	Bioprocess Expert	1	12
8	Procurement and Contracts Expert	1	7
	Non-Key Experts		
6	Legal Expert	1	5
8	QA/QC Specialist	1	6
9	Risk Analyst	1	4

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.

11.0 Obligation of the Client

The Client will:

i. Provide all relevant information and documentation to the consultant relevant to the project for use for project purpose only and collaborate in obtaining additional required information;
ii. Facilitate the Consultant's access to Government entities and respective stakeholders;
iii. Review and approve reports.

12.0 Obligation 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. The Client, from time to time during the performance of the contract, may second to the Consultant BioVax staff and contracted service providers for training and capacity development;
iii. The consulting firm will consult and include inputs from the stakeholders and is responsible for organising and achieving the evaluation and delivering the final report.

13.0 Proprietary Rights of Client in Reports and Records

i. Unless otherwise indicated, all reports and relevant data and information such as diagrams, plans, 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, drawings, specifications, designs, 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.