Texila International Journal of Medicine
ISSN: 2520-3118
DOI: 10.21522/TIJMD.2013.08.02.Art002

Evaluating the Economic Viability of Vaccine Manufacturing in Nigeria: A 10-Year Return on Investment Simulation

Longe Sunday Anthony[1*], Rajendra Kumar B. C.[1], Abiodun Paul Olaiya[1,2], Kotila Olayinka[3]
[1]*School of Public Health, Texila American University, Georgetown, Guyana, South America*
[2]*School of Public Health, University of Central Nicaragua, Campus Central, Semoros del Zumen 3c. Abajo, 1C. al Lago, Telonos*
[3]*Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Ibadan, Nigeria*

Abstract

Nigeria's dependence on imported vaccines has exposed significant vulnerabilities, especially during global crises like the COVID-19 pandemic. With a population exceeding 200 million, local vaccine manufacturing is increasingly recognized as a strategic imperative. Regional initiatives, including GAVI's African Vaccine Manufacturing Accelerator (AVMA) and Africa CDC's 2040 target of 60% self-reliance, highlights the urgency for national investment. This study assesses the economic viability of establishing a vaccine production facility in Nigeria through a 10-year Return on Investment (ROI) simulation using semantic system dynamics for the *analysis. A mixed-methods approach was applied. Quantitative data from structured stakeholder questionnaires were analyzed alongside Cost-Benefit Analysis (CBA), Input-Output Multiplier Analysis, and Scenario-Based Sensitivity (SBS) modeling. Regression analysis was used to explore the relationship between vaccine manufacturing and public health outcomes, specifically Quality-Adjusted Life Years (QALYs) and Death-Adjusted Life Years (DALYs). Findings show that a $1 billion investment would break even by Year 6 and generate a 250% ROI by Year 10. Stakeholders identified major constraints in financial (mean = 23.1), technological (21.6), and infrastructural (21.8) domains. Infrastructure gaps included cold-chain systems (53.2%), quality control labs (48.6%), and GMP-compliant plants (47.7%). Technological challenges stemmed from limited technical expertise (61.3%) and high maintenance costs (18.9%). Public-private partnerships (PPPs), WHO prequalification alignment, donor funding, and domestic procurement policies were viewed as critical enablers. Therefore, local vaccine manufacturing in Nigeria is not only financially viable but also a strategic imperative for national and regional health security. To ensure sustainability, robust evidence-based planning, targeted regulatory reforms, and innovative funding models are essential.*

Keywords*: Cost-Benefit Analysis, Health Security, Nigeria, Public-Private Partnership, Return on investment, Vaccine Manufacturing.*

Introduction

The COVID-19 pandemic exposed global vulnerabilities in vaccine access, particularly in Africa, where local vaccine production remains minimal. With less than one percent of vaccines produced on the continent, African countries were disproportionately affected by global supply constraints and inequitable distribution [1]. Nigeria, with a population exceeding 200 million and a fragile healthcare system, is strategically positioned to benefit from localized vaccine manufacturing. Developing in-country vaccine production capabilities is not only critical for health security but also

Received: 30.06.2025 ***Accepted: 11.07.2025*** ***Published on: 31.07.2025***
****Corresponding Author: profsunny4life@yahoo.com***

offers long-term economic and strategic benefits. Globally, several case studies have demonstrated that local vaccine manufacturing is both financially viable and strategically advantageous [2]. For instance, South Africa's Biovac Institute, through a 15-year PPP with their National Department of Health, has successfully expanded R&D and production capabilities [3]. Similarly, in Ireland, WuXi Biologics' sale of a vaccine facility to Merck for $500 million highlights growing commercial interest in vaccine infrastructure [4].

In Nigeria, policy shifts and early-stage initiatives are paving the way for local vaccine production. A notable example is the Federal Executive Council's (FEC) approval of a partnership between Bio-Vaccine Nigeria Limited (BVNL) and the Serum Institute of India to establish a manufacturing plant in Ogun State, [5] with the aim of capturing 15 percent of UNICEF's vaccine procurement market. Efforts to build local technical capacity are underway through collaborations with regional and global partners. The African Pharmaceutical Technology Foundation (APTF), in partnering with the National Institute for Pharmaceutical Research and Development (NIPRD), seeks to close technology gaps and strengthen Nigeria's vaccine manufacturing ecosystem [6].

Nigeria's dependence on imported vaccines imposes a fiscal burden estimated ₦4–6 billion annually and heightens exposure to global supply disruptions. For example, during the 2017 cerebrospinal meningitis outbreak, delays in vaccine imports contributed to preventable morbidity and mortality [7]. Continental strategies are aligning to support African vaccine self-reliance. GAVI's African Vaccine Manufacturing Accelerator (AVMA), launched in 2023, will provide up to one billion dollars over ten years to support sustainable vaccine production [8], complementing the Africa CDC's 2040 target of achieving 60 percent vaccine self-sufficiency across the continent [9]. Despite current moment, Nigeria's previous attempts at local vaccine production have faced significant setbacks. Facilities like the Federal Vaccine Production Laboratory (FCPL) and the National Vaccine Production Facility (NVPF) failed to scale due to inadequate funding, poor governance, regulatory hurdles, and infrastructure deficits [10].

Global cost and revenue benchmarks provide a strong justification for investment in vaccine manufacturing. For instance, India's Serum Institute (SII) invested $500 million to expand operations and now earns $840 million annually [8]. South Africa's Aspen Pharmacare leveraged $700 million in public-private investments to achieve full production capacity within five years [9], while Rwanda's BioNTech-supported mRNA hub is projected to generate $1.2 billion over a decade with just $100 million in initial investment [9]. Cost analyses from developing nations show that the average vaccine production cost ranges from $0.98 to $4.85 per dose depending on technology and scale [11]. Nigeria's investment and revenue projections align closely with these international benchmarks, supporting the argument for financial and operational feasibility.

In summary, the literature indicates a strong precedent for successful local vaccine manufacturing through a mix of public-private partnerships, international collaborations, and sustained policy support. However, Nigeria must overcome historical inefficiencies and systemic barriers to fully capitalize on these opportunities.

Materials and Methods

Research Design

This study used a mixed-method approach to evaluate the economic viability of vaccine manufacturing in Nigeria. It integrated both quantitative and qualitative methods, including: structured questionnaire to assess stakeholder perspectives on the feasibility of investing in

vaccine manufacturing in Nigeria, as well as a Cost-Benefit Analysis (CBA) to compare investment expenses to predicted income and savings using a system dynamics tool to estimate a 10-year ROI cost breakdown and revenue growth over time. A Scenario-Based Sensitivity (SBS) simulation analysis was performed to determine market potential (profitability) by modeling financial outcomes under various investment scenarios. Also conducted was an Input-Output Multiplier Analysis to examine the broader economic impact of vaccine manufacturing on Nigeria's GDP, and used a regression analysis to establish the relationship between local vaccine production and public health outcomes, specifically (QALYs and DALY).

Sampling Strategy

A **stratified random sampling** technique was used to capture the perspectives of key sectors:

1. Government agencies (27.0 percent)
2. Pharmaceutical companies (50.5 percent)
3. Academic institutions (14.4 percent)
4. NGOs and community pharmacists (8.1 percent)

Sample Population

The target population included professionals working in the pharmaceutical and biotechnology sectors, public health institutions, research organizations, and government regulatory bodies in Nigeria. A purposive sampling technique was employed to select key informants and respondents with specific expertise in vaccine development, production, regulation, and distribution. In total, 111 participants participated in the study: Approximately 80 percent from public and private organizations (Government agencies and Pharmaceutical companies), 14 percent from academia, and six percent from healthcare-focused groups and NGOs.

Data Sources

Primary Data: Structured questionnaires administered to 111 stakeholders including government officials, pharmaceutical industry experts, academics, and healthcare professionals.

Secondary Data: Sourced from peer-reviewed literature, institutional reports (WHO, GAVI, Africa CDC), and comparable vaccine manufacturing case studies from countries such as India, South Africa, and Rwanda.

Data Collection Instruments

Data were collected using a structured questionnaire consisting of both closed-ended and open-ended questions. The instrument covered areas such as infrastructure, workforce capacity, regulatory environment, and technology transfer. The questionnaire targeted senior-level stakeholders to gain in-depth insights into operational and policy-level challenges based on their experience.

Validity and Reliability

To ensure content validity, the instruments were reviewed by experts in vaccine development and public health. A pilot study was conducted with 10 respondents not included in the main study, allowing for refinement of the instrument. The final tool yielded a Cronbach's alpha score of **0.945**, indicating excellent internal consistency and reliability.

Table 1. Analytical Framework

Analytical Tools	**Purpose**
Cost-Benefit Analysis (CBA)	Compare projected investment costs with estimated revenue and savings.
Input-Output Multiplier Analysis	Evaluate macroeconomic impact on Nigeria's GDP.

Scenario-Based Sensitivity (SBS) Analysis	Simulate financial outcomes under best-case, moderate, and worst-case investment scenarios using system dynamics open source modeling tool.
Regression Analysis	Assess impact of local vaccine production on health outcomes (QALYs and DALYs).

Data Analysis

Quantitative data were analyzed using IBM SPSS (Version 25)**.** Descriptive statistics such as frequencies, percentages, and mean ± standard deviation (SD) were used to summarize participant responses and highlight trends**.** A scenario-based financial analysis was conducted to estimate key economic indicators such as ROI, break-even timelines, and profitability under varied market and regulatory conditions using simantics system dynamics open source tool. In addition, qualitative data **obtained from a structured questionnaire were** analyzed using thematic analysis. Emerging themes were identified, categorized, and interpreted to provide contextual understanding. These qualitative findings were then used to triangulate and enrich the interpretation of the quantitative results.

Searched databases*: PubMed, Scopus, Google Scholar, and WHO archives.*

Ethical Considerations

This study adhered strictly to ethical research standards throughout its design, data collection, and analysis phases. Prior to participation, informed consent was obtained from all participants, ensuring they understood the purpose of the research, their voluntary involvement, and their right to withdraw at any stage. The structured questionnaire was designed to maintain confidentiality, prevent the collection of personally identifiable information, and protect the anonymity of participants.

Ethical approval was obtained from the University of Ibadan (UI)/UCH Ethics Committee, with Registration number NHREC/05/01/2008a. All primary data collected were anonymized and stored securely, in accordance with data protection guidelines. In addition, expert interviews and the use of secondary data adhered to academic ethical norms, ensuring proper citation, transparency and integrity in interpretation.

Limitations of the Study

While this study provides valuable insights into the feasibility of local vaccine production in Nigeria, certain limitations must be acknowledged:

Data Availability: Reliable, country-specific data, particularly on historical vaccine production costs and local market forecasts, were limited or inconsistently reported. Consequently, certain assumptions in the ROI model were derived from international benchmarks, which may not fully reflect the Nigerian context.

Survey Bias: The use of stakeholders expert opinion in completing the questionnaire, while valuable, may introduce subjective bias. Although the sample included stakeholders from diverse sectors, their responses may reflect institutional priorities or individual perspectives, which could affect the objectivity of findings.

Dynamic Policy Environment: Nigeria's regulatory and political climate is fluid [12]. Potential policy changes affecting local manufacturing, pharmaceutical investment, or trade regulations may influence feasibility projections after the study period.

Uncontrolled Variables in Modeling: The financial simulations did not fully incorporate macroeconomic shocks such as currency fluctuations, inflation, or political instability—

factors that could influence investment costs and returns over the 10-year period.

Despite these limitations, the study provides a strong evidence base and offers a strategic framework to inform future investments, policy formulation, and research in vaccine manufacturing within Nigeria and similar low- and middle income contexts.

Results

Socio-demographic Characteristics of Respondents

The study showed that the majority of respondents *(table 2)* were aged between 31-40 years, representing more than one-third participants (45 or 40.5 percent) of the total sample. This was followed by 36 respondents (32.4 percent) aged 41-50 years. In terms of work experience, one-quarter participants (23 or 20.7 percent) had between 1-5, years of experience. A slight majority, more than half participants (56 or 50.5 percent) were employed in pharmaceutical companies. Among the respondents, the most common job roles included: 27 operations managers (24.3 percent), 21 quality assurance officers (18.9%), 18 nurses (16.2 percent) and 16 lecturers (14.4 percent).

Table 2. Socio-demographic Characteristics

Variables	**Frequency (N=111)**	**Percentage (%)**
Age		
20-30	6	5.4
31-40	45	40.5
41-50	36	32.4
51-60	24	21.6
Years of experience		
1-5	23	20.7
6-10	18	16.2
11-15	22	19.8
16-20	21	18.9
Organization/Institutions		
Academia	16	14.4
Government agency	30	27.0
Pharmaceutical company	56	50.5
Community pharmacist	1	0.9
NGO	8	7.2
Role/Position		
Lecturer	16	14.4
Business Dev. Executives	8	7.2
Pharmacist	4	3.6
Quality assurance	21	18.9
Nurse	18	16.2
Regulatory/compliance officer	2	1.8
Technical officer	11	9.9
Laboratory scientists	4	3.6
Operations manager	27	24.3

The feasibility of establishing a vaccine manufacturing facility in Nigeria was assessed based on key requirements, including financial, technological, and infrastructural considerations.

Table 3. Frequency Distributions of Financial Requirements

Financial Requirements	Frequency	Percentage
i) What types of financial support are critical for establishing vaccine production in Nigeria?		
Government grants	38	34.2
Tax incentives	29	26.1
Low-interest loans	37	33.3
Private investment	14	12.6
Public-private partnerships	37	33.3
International funding	32	28.8
ii) What financial models would you consider most viable for sustaining vaccine production facilities in Nigeria?		
Government funding	30	27.0
Private funding	11	9.9
Public-private partnerships	40	36.0
International funding	23	20.7
Technological requirements	28	25.2
iii) What financial costs should be accounted for when selecting vaccine candidates?		
Research and development (R&D) costs	47	42.3
Manufacturing setup costs	46	41.4
Distribution and logistics costs	30	27.0
Funding and financing options	26	23.4
Licensing and intellectual property (IP) costs	16	14.4
Technology transfer costs	24	21.6

Table 4. Cumulative Score for Perceived Financial Requirements

Perceived financial requirements	Frequency	Percentage	Mean ±SD	Median	Min score	Max score
Low (<12.0)	55	45.5	23.1 ±13.6	12.0	0	50
High (≥12.0)	56	50.5				

This study showed a broad collection of finance mechanisms *(see table 3)* that stakeholders consider crucial to creating vaccine production capacity in Nigeria. These findings reflect an agreement on the necessity of mixed finance models, which combine local public investment with international donor support and private sector engagement to mitigate the inherent risks of vaccine manufacture. Overall, more than half of the participants (56 or 50.5 percent) perceived financial requirements as having a high impact

on the feasibility of vaccine production in the Nigeria (*see table 4*).

The importance of government grants and Public- Private Partnership (PPPs) in this study is consistent with the important work of Kaplan and Laing, who discovered that public-private financing models were critical for starting and maintaining pharmaceutical production in low- and middle-income countries (LMIC). Their findings underscored that local manufacturing efforts frequently lack immediate commercial viability and therefore rely on specific government incentives and risk-sharing mechanisms to be viable. Similarly, they emphasized the importance of international donor assistance in reducing initial costs and facilitating access to technical resources and markets [15].

When asked about viable financial models for sustaining vaccine production, PPP were identified by more than one-third respondents (40 or 36 percent) as the most viable approach. This was followed by government funding 30 (27 percent), Milstien showed how initial government-backed funding and co-investment initiatives facilitated the effective scale-up of vaccine production in countries such as Brazil and India. Their findings revealed that PPP frameworks, together with clear procurement strategies and technical partnerships, played an important role in enabling long-term vaccine supply in LMIC circumstances. This is especially so in Nigeria, where market fragmentation and irregularities in procurement continue to be substantial challenges to long-term investment in vaccine infrastructure [16]. The McKinsey & Co. strategy for African vaccine manufacturing supports the findings of this study. Their study emphasized the importance of a mixed finance model that includes concessional loans, government subsidies, and advanced market commitments (AMCs) to encourage private sector participation. They also highlighted the catalytic significance of international support from organizations such as GAVI, CEPI, and the Bill & Melinda Gates Foundation, while emphasizing the need of national policy alignment and fiscal commitment in ensuring sustainability [17]. This study's emphasis of international finance (28.8%) is consistent with this multi-pronged financing approach and demonstrates Nigerian stakeholders' increased knowledge of the importance of global-local financing synergies.

The current findings support the generally accepted view that no single financial model is sufficient; rather, a combination of financing alternatives, including grants, subsidized loans, PPPs, and donor contributions, is required to establish a viable and scalable vaccine manufacturing infrastructure in Nigeria. These findings not only confirm existing global evidence but also contextualize it within Nigeria's peculiar economic and institutional context.

Table 5. Frequency Distributions of Technology Requirements

Technology requirements	**Frequency**	**Percentage**
i) Which technologies are essential for local vaccine production		
Research and development technology	51	45.9
High-throughput production machinery	43	38.7
Cold-chain logistics and distribution technology	56	50.5
Quality assurance and testing technology	52	46.8
ii) Challenges of maintaining required technologies		
Technical know-how	68	61.3
Funding	18	16.2
Cost of maintenance	21	18.9
Insufficiently trained personnel	4	3.6

iii) What are the main challenges in acquiring or maintaining the required technologies for vaccine production		
Technical know-how	68	61.3
Funding	18	16.2
Cost of maintenance	21	18.9
Inadequately trained personnel	4	3.6

Table 6. Cumulative Score Perceived Technology Requirements

Perceived technology requirements	Frequency	Percentage	Mean ±SD	Median	Min score	Max score
Low (<4.0)	55	45.5	21.6±11.1	4.0	0	50
High (≥4.0)	56	50.5				

According to the findings of this study, technological capacity is an important factor in determining the feasibility of local vaccine production in Nigeria. The mean stakeholder score of 21.6 ± 11.1*(table 6)* indicates moderate but significant concern, with over half of respondents (50.5%) recognizing the strong influence of technological requirements on vaccine manufacturing performance. Cold-chain logistics and distribution technologies *(table 5)* had the highest rating (50.5%), followed by quality assurance/QC testing technology (46.8%) and research and development infrastructure (45.9%). These preferences show that important stakeholders value both downstream supply chain technologies and upstream innovation capacities. Milstien and Kaddar showed that LMICs frequently struggle to acquire and retain vaccine-specific technological skills, adding that access to cold-chain systems and validation platforms is critical for increasing vaccine manufacturing [16]. Similarly, a McKinsey & Co. research underlined that cold-chain infrastructure remains an ongoing challenge in Africa, more so than R&D, particularly in countries striving for WHO prequalification status [17].

Souza, observed that although many LMICs are capable of procuring manufacturing equipment, the primary barrier to sustainable use nevertheless remains a lack of local technical know-how and qualified personnel [18]. The most important obstacle to sustaining vaccine manufacturing infrastructure, according to 61.3% of respondents in this study, is a lack of technical capacity. This highlights the urgent need for technical capacity-building. Kaplan and Laing, further observed that a lack of technological investment in cleanroom validation, Quality control capacity, and quality management systems (QMS) is the main reason why many local producers in Africa fail to meet WHO standards rather than regulatory challenge [15]. This study's observations provide stakeholder-level reinforcement of the importance of quality system technologies, such as those for batch release and in-process control, in attaining and maintaining WHO prequalification status. This study also addressed the economic factor of technical sustainability. While only 18.9% identified maintenance costs and 16.2% indicated insufficient funds, these findings nonetheless imply considerable structural challenges. This is consistent with Reich's findings which, stated that without consistent government

financing or PPP-backed technological investment, many African manufacturing sectors get stuck in a cycle of under-capacity and over-regulation [19]. Evidence indicates an overall trend among LMICs: Technology is more than just access; it is about adaptation, application, and sustainability. This study supports this by identifying three cross-cutting needs: (1) Increased investment in essential technologies such as cold-chain and quality assurance systems, (2) staff development to close technical knowledge gaps, and (3) long-term planning for equipment maintenance and financing requirements.

These findings provide significant information for national policy development, donor programming, and the prioritization of WHO technology transfer projects in Nigeria. They also advocate that initiatives to improve local vaccine manufacture should not view technology as a single barrier, but rather as a multi-tiered ecosystem of skills, infrastructure, and systems that must be built concurrently.

Table 7. Frequency Distributions of Infrastructural Requirements

Infrastructural Requirements	**Frequency**	**Percentage**
Adequacy of Nigeria infrastructure to support local vaccine production. [scale of 1-5 (1 = Very poor, 5 = Excellent)]		
Laboratory facilities		
• Very poor	9	8.1
• Poor	18	16.2
• Good	31	27.9
• Very Good	4	3.6
• Excellent	0	0.0
Manufacturing facilities		
• Very poor	14	12.6
• Poor	25	22.5
• Good	21	18.9
• Very Good	2	1.8
• Excellent	0	0.0
Vaccine storage facilities		
• Very poor	14	12.6
• Poor	14	12.6
• Good	26	23.4
• Very Good	4	3.6
• Excellent	4	3.6
Vaccine transport facilities		
• Very poor	13	11.7
• Poor	23	20.7
• Good	20	18.0
• Very Good	4	3.6
• Excellent	4	3.6
What specific infrastructure improvements are most needed to support vaccine production in Nigeria?		
• Manufacturing plants	53	47.7

• Cold-chain logistics and distribution networks	59	53.2
• Quality control laboratories	54	48.6
• Waste management facilities	32	28.8
Which of local vaccine production models can be adopted in Nigeria?		
• India: Serum Institute of India (SII)	43	38.7
• Brazil: Bio-Manguinhos/FiocruzSouth Africa: Biovac Institute	18	16.2
• Indonesia: Bio Farma	34	30.6
• Cuba: Finlay Institute of Vaccines	22	19.8
How could local companies be incentivized to participate in vaccine production?		
• Subsidies and Grants for facility setup, equipment acquisition, and GMP certification processes.	47	42.3
• A 5–10 year tax holiday for vaccine manufacturers.	26	23.4
• Loans for infrastructure development and operational costs.	22	19.8
• Advance Market/procurement guarantees from the Nigerian Government to Mandate a percentage of government vaccine procurement sourced from local manufacturers.	38	34.2
• Establish expedited regulatory pathways for local vaccine manufacturers, reducing approval timelines without compromising quality.	24	21.5
• Broker technology transfer agreements to foster innovation and partnerships.	19	17.1
• Establish vaccine manufacturing clusters, offering benefits of shared facilities like cold storage, testing labs, and reliable utilities.	24	21.6
• Develop infrastructure through Public-Private Partnership (PPP) models, where the government provides land and basic utilities, and private companies invest in manufacturing facilities.	41	36.9

Table 8. Cumulative Score Perceived Infrastructural Requirements

Perceived infrastructural requirements	**Frequency**	**Percentage**	**Mean ±SD**	**Median**	**Min score**	**Max score**
Low (<24.0)	55	45.5	21.8±10.6	24.0	0	69
High (≥24.0)	56	50.5				

The results of this study show that infrastructure is a crucial enabler of local vaccine production in Nigeria. The mean stakeholder score of 21.8 ± 10.6 *(see table 8)* suggests significant worry, with 50.5% considering infrastructure readiness as having a

high impact on the feasibility of local vaccine manufacture. However, participants emphasized the critical importance of cold-chain logistics and distribution systems (53.2%), quality control laboratories (48.6%), and manufacturing plants (47.7%) in enabling sustainable production *(See table 7)*. These findings are consistent with more extensive studies which examine the infrastructure gap in LMIC vaccine production. The potential for producing vaccines on a large scale is severely limited by the absence of specialized facilities such as quality control units, cold-chain equipment, and bio-safety level laboratories, even in countries with basic pharmaceutical production capabilities [16].

Similar findings were drawn from the McKinsey & Co. study of the vaccine environment in Africa. According to their road-map, "physical infrastructure, particularly GMP-compliant plants, quality control labs, and regional cold-chain networks is the most significant barrier to scale," even though Africa has made progress in regional regulatory harmonization and policy alignment [17]. This study result, which determined that these exact elements were the most urgently required infrastructure upgrades, are directly consistent with these global findings.

UNICEF's report established that transportation and storage infrastructure, such as temperature-controlled logistics and last-mile delivery systems, are essential to vaccine efficacy and population reach, further confirming these findings [20]. Notwithstanding the lack of awareness among certain stakeholders (only 3.6% of respondents in this study identified storage and transportation facilities as having the greatest impact), this disparity might be the result of a lack of information rather than a lack of significance, indicating a need for advocacy and capacity-building.

The preference for vaccine production models such as the Serum Institute of India (SII) (38.7%) and Bio Farma in Indonesia (30.6%) reflects stakeholder awareness of successful LMIC-based vaccine manufacturers which have scaled effectively thanks to infrastructure-focused investment and government support.

These institutions serve as proven blueprints. SII, for example, used significant public-private investment in world-class factories, quality control labs, and vertically integrated logistics to become the world's leading vaccine supplier. Bio-Farma also increased regional industrial strength by focusing on infrastructure modernization, cold-chain independence, and WHO PQ-accredited facilities. These global insights combined with recent research support a significant finding: attempts to localize vaccine production in Nigeria will continue to be limited in the absence of intentional, well-funded investment in core infrastructure, such as laboratory capacity, manufacturing environment, and end-to-end cold-chain systems. In addition to limiting production volume, these infrastructural inadequacies impact WHO prequalification, regulatory compliance, and global procurement competitiveness.

B. Initial Investment Requirements from Global Benchmarks

To determine the feasibility of constructing a vaccine manufacturing facility in Nigeria, the cost structure was carefully estimated, analyzed, and compared with similar initiatives in other countries. The assessment includes a detailed breakdown of the estimated costs associated with establishing and operating such a facility in Nigeria, taking into account infrastructure, equipment, personnel, R&D, regulatory compliance, and operational expenses *(See table 9)*. This estimated cost structure is then bench-marked against global examples, specifically from India, South Africa, and Rwanda [8, 9] to provide comparative insights and highlight context-specific financial implications.

Table 9. Comparison Initial Investment Requirement with Global Case Studies for Vaccine Manufacturing Facilities in Nigeria

5 Major Cost Components	Nigeria ($1B Estimate)	India (Serum Institute)	South Africa (Aspen Pharmacare)	Rwanda (BioNTech mRNA Hub)
1. Infrastructure	$450M (45%)	$400M (40%)	$500M (50%)	$600M (60%)
2. Technology & Equipment	$300M (30%)	$350M (35%)	$300M (30%)	$250M (25%)
3. R&D Investment	$100M (10%)	$150M (15%)	$100M (10%)	$50M (5%)
4. Regulatory Costs	$50M (5%)	$50M (5%)	$40M (4%)	$30M (3%)
5. Operational Costs (first 3 years)	$100M (10%)	$50M (5%)	$60M (6%)	$70M (7%)
Total Investment	**$1 billion**	**$1 billion**	**$1 billion**	**$1 billion**

Nigeria's Projected Initial Investment in Comparison with Global and Africa's Investment Case Studies on All Five Major Cost Components

Nigeria's projected initial investment for establishing a vaccine manufacturing facility has been evaluated across five major cost components, in comparison with global African benchmark. On infrastructural development (*table 9*)**,** Nigeria's projected cost stands at $450 million, representing 45 percent of the initial investment. This figure **is** slightly higher than India's $400 million, but lower than South Africa and Rwanda**,** where higher labor and construction costs drive up infrastructure expenses. This suggests Nigeria's infrastructure development cost is competitive within the global context. For the initial investment in technology & equipment**,** Nigeria's allocation $300 million (30 percent) is aligned with international averages. India, for instance, allocates $350 million (35 percent), reflecting its investment in advanced vaccine production technologies. Nigeria's focus here is adequate but should anticipate future upgrades for technological advancement. As for regulatory compliance costs**,** Nigeria's estimated regulatory cost $50 million (five percent) aligned with international benchmarks. However, this cost could be reduced through streamlined and efficient approval pathways, accelerating facility setup and production roll-out**.** Nigeria's investment in R&D is projected at $100 million (10 percent), comparable to South Africa but lower than India's $150 million (15 percent). India's higher R&D allocation reflects its strategic focus on innovation, which in turn lowers production costs over time. For Nigeria, increasing R&D investment is essential for sustainable local manufacturing and long-term competitiveness. A gradual increase toward or beyond India's benchmark (15 percent) is recommended as profits accumulate annually**.** Operational costs for the first three years is critical and so Nigeria's allocation of $100 million (10 percent) is higher than India's, but comparable to South Africa and Rwanda. This highlights the importance of developing cost-effective workforce training and management strategies to optimize operational efficiency**.**

The total projected initial investment of $1 billion for Nigeria is consistent with global benchmarks. For example, India's Serum Institute of India (SII) invested $500 million to expand production and now generates $840 million in annual revenue [8]. South Africa's Aspen Pharmacare secured $700 million through PPPs and achieved full vaccine production within five years [9]. Furthermore, economies of scale and lower production costs indicate that Nigeria's venture into local vaccine production is both cost-effective and globally competitive. This also agrees with a

study which examined the local vaccine production costs in developing nations with an average production cost of $2.18 per dose, with costs ranging from $0.98 to $4.85 depending on the vaccine type and formulation [11].

Revenue Projections and Break-Even Analysis

Annual Revenue Estimates (Years 1-10):

ROI Calculation:

ROI= [Net Profit/Total cost of Investment×100]

Table 10. Simulation of a 10-Year ROI Breakdown and Break-even Point

Year	Cumulative Investment ($M)	Annual Revenue ($M)	Net Profit ($M)	ROI (%)	Break-even Status
Year 1	250	50	50	-80%	Not achieved
Year 2	400	100	150	-63%	Not achieved
Year 3	600	150	300	-50%	Not achieved
Year 4	800	250	550	-31%	Not achieved
Year 5	1,000	350	900	-10%	Not achieved
Year 6	1,000	450	1,350	35%	Break-even
Year 7	1,000	500	1,850	85%	Achieved
Year 8	1,000	500	2,350	135%	Achieved
Year 9	1,000	550	2,900	190%	Achieved
Year 10	1,000	600	3,500	250%	Achieved

Source: (GAVI, 2022)

The feasibility of local vaccine manufacturing in Nigeria is supported by empirical data from both global and African studies [21]. Nigeria's projected break-even period of six years *(table 10)* is slightly longer than South Africa and Rwanda's models but remains within a reasonable and acceptable range. Furthermore, the anticipated annual revenue of $500 million post-break-even demonstrates robust economic potential and the sustainability of establishing local vaccine production facilities (Figure 1).

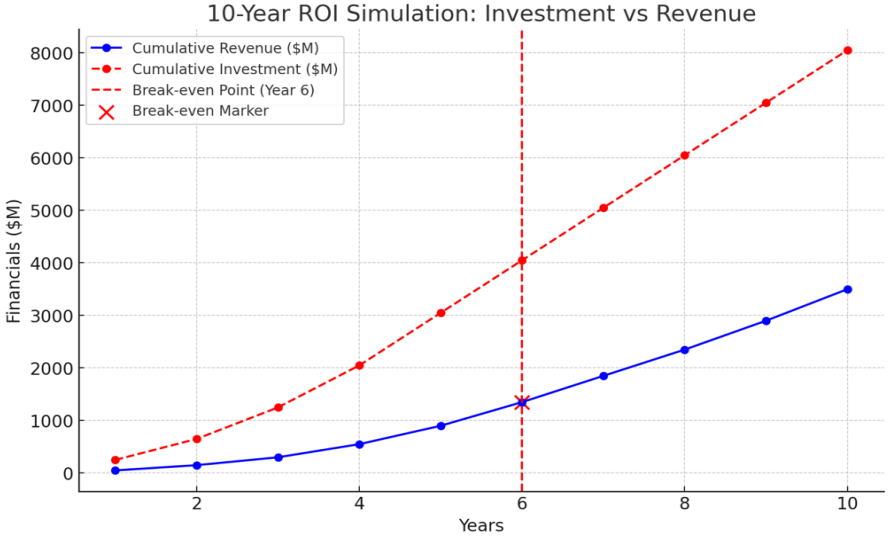

Figure 1. Graphical Representation of 10- year Revenue Projections and Break-Even Analysis

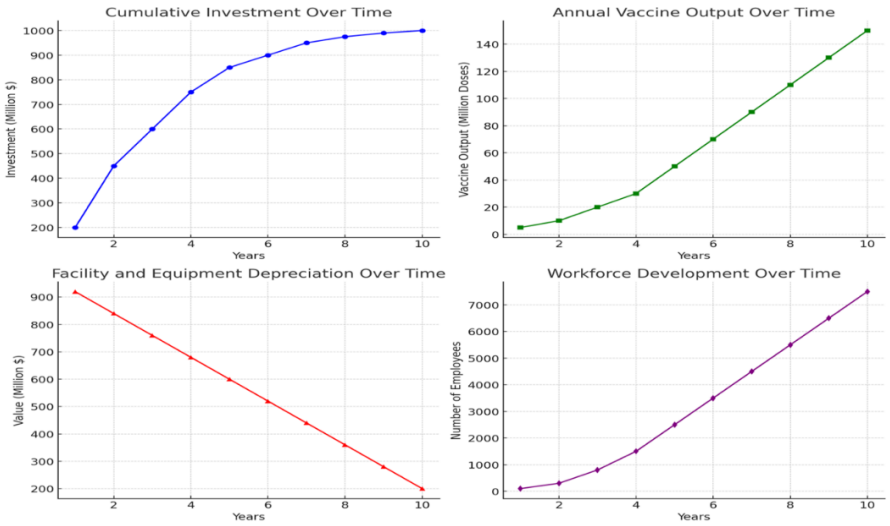

Figure 2. Graphical Representation of Key Financial Trends based on Projections

As illustrated in *(Figure 1)*, the cumulative revenue over time is shown by the blue line, while the cumulative investment is represented by the red dashed line. The break-even point is indicated by the red vertical line at Year 6, when revenue exceeds investment with a 15 percent yearly return on investment. After this point, revenue increases steadily, driven by expanded production capacity, export potential, and economies of scale. By Year 10, total revenue is projected to reach approximately $3.5 billion, yielding a 250 percent return on investment. The initial losses observed during years one to five are attributed to substantial upfront capital expenditures in technology & equipment, infrastructure development, R&D, and regulatory permissions. However, beginning in Year six, accelerated revenue growth reflects greater output, increased market share, and operational efficiency gains. In contrast, Rwanda's BioNTech-supported mRNA facility, which has received $100 million in initial investment and is anticipated to generate $1.2 billion over a ten-year period [9]. *(Figure 2)*, shows key financial trend taking into consideration four key factors/determinants i.e. cumulative investment, depreciation, cumulative output and workforce development over the time period. This projection underscores the financial viability and competitive advantage of Nigeria's vaccine manufacturing model when benchmarked against regional and global initiatives.

Table 11. Comparison of the Break-even Period/Revenue Growth with Global and African Case Studies and the Key Challenges Encountered.

Region	**Investment Cost**	**Break-even Period**	**Annual Revenue (Post Break-even)**	**Key Challenges**
Nigeria (Projected)	$1 billion	6 years	$500 million	Initial investment cost, Regulatory hurdles, and workforce development.
India (SII, 2022)	$500 million	5 years	$840 million	Export reliance, local demand fluctuations
South Africa (Aspen, 2023)	$700 million	5 years	$650 million	Intellectual property constraints
Rwanda (BioNTech, 2023)	$100 million	4 years	$150 million	Limited scale-up potential

Source: (WHO 2023)

As seen in (*figure 1*) above, Nigeria's projected break-even period of six years is slightly longer than that of South Africa and Rwanda, yet remains well within an acceptable range for large-scale pharmaceutical investments. The anticipated annual revenue of $500 million post-break-even reflects robust economic potential and underscores the viability of local vaccine manufacturing in Nigeria. However, an assessment of the primary challenges preventing the establishment of vaccine production facilities in Nigeria identified several barriers. These include financial constraints, technological limitations, regulatory challenges, Infrastructural inadequacies, and limited demand forecasting and market development. Despite these challenges, case studies from comparable countries demonstrate that such barriers can be effectively managed allowing them to achieve break-even within six years and realize high ROI. This indicates the viability of this investment in Nigeria, particularly as the projected ROI trajectory closely mirrors that of global counterparts *(table 11)*. The break-even point at Year six and subsequent revenue growth between Years 7 to 10 aligns with global trends and driven by increased domestic demand and growing export potential. A minimum projected annual ROI of 15 percent post-break-even **is** comparable to India's 17 percent, further affirming the competitiveness of Nigeria's vaccine manufacturing investment scenario [13].

Cost Saving Strategies to be Adopted Based on the Case Studies

To enhance the financial feasibility of local vaccine manufacturing, Nigeria can adopt several cost-saving strategies derived from successful international and regional case studies: Nigeria can reduce initial capital expenditure by adopting the PPP model, as demonstrated by the SII. This model facilitates shared financial risk and leverages private sector expertise. Additionally, bulk procurement of raw materials can lead to significant economies of scale, further reducing operational costs. To minimize the financial burden of R&D, Nigeria can collaborate with international research institutions and vaccine manufacturers, similar to the strategy employed by Aspen PharmaCare in South Africa. Such partnership can provide access to technical expertise, accelerate innovation, and reduce duplication of efforts, resulting in more efficient use of resources. Drawing lessons from Rwanda's BioNTech-supported vaccine hub, Nigeria can leverage government subsidies and secure grants from global health partners such as GAVI, WHO, and CEPI. These external funding sources can significantly offset infrastructure and regulatory compliance costs, easing the burden on domestic financing. Empirical data from GAVI (2022) and WHO (2023) underscore the economic feasibility of local vaccine production in Nigeria [7, 8]. Nigeria's estimated initial investment of $1 billion aligns with global benchmarks. For example, the SII in India increased its revenue by $840 million a year after investing $500 million to expand its manufacturing facilities [8]. Similar to this, Aspen Pharmacare of South Africa received a $700 million investment through a combination of PPPs. These precedents suggest that strategic financial planning and international cooperation can make local vaccine production in Nigeria both cost-effective and globally competitive [22].

Cost Savings of Local Production vs. Imports

One of the most significant advantages of establishing a local vaccine manufacturing facility in Nigeria is the significant cost savings that could be achieved by reducing dependency on imported vaccines. Currently, Nigeria spends over $400 million annually on vaccine imports [14]. By transitioning to local production, these costs can be drastically reduced over a 10-year period.

Table 12. Comparison of Local Production vs. Import Costs (Projected Savings Over 10 Years)

Cost Factor	**Imported Vaccines (10-Year Estimate)**	**Locally Manufactured Vaccines (10-Year Estimate)**	**Cost Savings (%)**
Procurement Costs	$4.2 billion	$2.1 billion	50%
Logistics & Import Tariffs	$800 million	$200 million	75%
Cold Chain & Storage Costs	$600 million	$400 million	33%
Regulatory & Quality Control	$300 million	$150 million	50%
Total Cost	$5.9 billion	$2.85 billion	52%

Over a 10-year period, Nigeria stands to achieve an estimated 52 percent overall cost savings by transitioning to local vaccine production *(table 12)*. Procurement costs is estimated to drop by half (50 percent) due to direct production and reduced dependence on global suppliers. Logistics & import tariffs will likely reduce by 75 percent**,** as local production eliminates international shipping, customs duties, and related import costs. Cold chain storage costs will decrease by 33 percent**,** since domestic supply chains require shorter transport times. Regulatory costs also likely to decrease by 50 percent, as approvals for locally produced vaccines can be streamlined and expedited. From similar global studies, transitions to local production have resulted in substantial cost savings in other countries, for example, India (SII) reduced import dependency which led to a 40 percent decrease in vaccine procurement costs [6]. South Africa (Aspen Pharmacare) **a**chieved $500 million in savings over five years through localized production initiatives [22]. Rwanda (BioNTech mRNA Facility) was expected to cut import costs by 45 percent over a decade [14]. By adopting similar strategies, Nigeria can replicate these cost efficiencies, enhancing vaccine affordability and national health security.

10-Year ROI Simulation using Scenario Based Sensitivity (SBS) Analysis

A comprehensive 10-year ROI simulation was conducted to evaluate the financial feasibility of establishing a vaccine manufacturing facility in Nigeria. This simulation integrates detailed revenue projections, capital and operational cost breakdowns, and incorporates SBS to evaluate the impact of key uncertainties on financial performance. The SBS analysis explores how variations in critical variables, such as production efficiency, regulatory approval timelines, input cost fluctuations, and market demand), may influence the facility's profitability and break-even timeline. This approach enables dynamic modeling of base-case, best-case, moderate case and worst-case scenarios, offering stakeholders a robust understanding of potential investment outcomes *(table 13)*.

Key Assumptions in the 10-Year ROI Model

1. ***Initial Investment****: $1 billion*
2. ***Annual Production Capacity****:*
   - *Year 1: 10 million doses*
   - *Year 5: 30 million doses (full capacity)*

- *Year 10: 50 million doses (expansion & exports)*

3. ***Average Vaccine Price per Dose****: $10 (based on global benchmark)*
4. ***Operational Costs Growth****: 5% annually*
5. ***Break-Even Point****: Year 6*

Table 13. 10-Year Financial Projection (Base Case Scenario)

Year	Investment ($M)	Revenue ($M)	Operating Costs ($M)	Net Profit ($M)	Cumulative ROI (%)
1	1,000	50	100	-50	-5.0%
2	1,000	100	120	-20	-2.0%
3	1,000	150	140	10	1.0%
4	1,000	250	160	90	9.0%
5	1,000	350	180	170	17.0%
6	1,000	450	200	250	25.0% (Break-Even)
7	1,000	500	210	290	29.0%
8	1,000	500	220	280	28.0%
9	1,000	500	230	270	27.0%
10	1,000	500	240	260	26.0%

Break-even occurs in Year 6 *when cumulative revenue surpasses the initial investment.* Net profit stabilizes from Year 7 onward, *allowing reinvestment in R&D and infrastructure.* By Year 10, the total ROI reaches 26%, *demonstrating long-term profitability.*

Sensitivity Analysis: Impact of Key Variables on ROI

The model was tested against three major scenarios**:**

Scenario 1: Delayed Regulatory Approvals (Worst Case Scenario)

1. Approval delays push production start to Year three
2. Operational costs increase by 10 percent due to inflation and delays
3. Break-even shifts from Year six to Year eight

Outcome: based on scenario 1- ROI drops to 18 percent by Year 10**,** making external funding more crucial.

Scenario 2: High Demand & International Partnerships (Best Case Scenario)

1. Export deals signed in Year four, increasing annual revenue by 30 percent
2. Technology transfer agreements reduce equipment costs by 15 percent
3. Break-even shifts earlier to Year 5

Outcome: based on scenario 2- ROI reaches 35 percent by Year 10**,** strengthening investment appeal.

Scenario 3: Increased Local Competition (Moderate Case Scenario)

1. Multiple facilities enter the market, reducing price per dose to $8
2. Revenue growth slows, but cost efficiencies keep margins stable
3. Break-even occurs in Year 7

Outcome: based on scenario 3- ROI stabilizes at 22 percent by Year 10**,** requiring adaptive pricing strategies.

Summary of Analysis & Discussion

This study showed the feasibility of establishing a vaccine manufacturing facility in Nigeria in terms of financial, technological, infrastructural, and regulatory challenges. The findings indicate that a majority of the participants perceived financial investment as

the most significant requirement for the successful establishment of local vaccine production. This aligns with the need for strong financial support, such as government grants, low-interest loans, PPP, and international funding, which are critical to overcome the high initial capital and operational costs.

In exploring viable financial models, over one-third of participants identified PPP as the most sustainable approach for vaccine production in Nigeria. This perception is consistent with global evidence. For example, the Serum Institute of India leveraged a PPP model in collaboration with GAVI to scale production and reduce costs effectively [8]. Similarly, Brazil's Bio-Manguinhos achieved achieved vaccine self-sufficiency within a decade through a PPP-driven initiative [14].

In the Nigerian context, PPPs offer a dual advantage, easing government fiscal burdens while mobilizing private sector innovation and efficiency. These models are particularly effective in low- and middle-income countries (LMICs) such as Nigeria, where financial and technological gaps pose significant constraints. PPPs combine government-backed regulatory frameworks with private sector operational expertise, thus fostering a robust and sustainable vaccine manufacturing ecosystem [14].

The feasibility of this model in Nigeria is further supported by successful case studies globally and across Africa. For instance, the SII, with backing from WHO, GAVI, and the Bill and Melinda Gates Foundation, has grown into the world's largest vaccine manufacturer, significantly reducing global vaccine prices through economies of scale and PPP-driven efficiencies. In Africa, South Africa's Biovac Institute, operating under a PPP with the South African government, successfully secured technology transfer agreements, including for Pfizer's COVID-19 vaccine, which enhanced local capacity and reduced import dependency [22].

The study also showed that more than half of the participants perceived that technology is a significant requirement for feasibility of establishing a vaccine manufacturing facility in Nigeria which is associated with cold-chain logistics and distribution technology, quality assurance and testing technology and development technology. The African Union and European Union facilitated Rwanda's partnership with BioNTech to build a local mRNA vaccine manufacturing facility is an example of how strategic international partnerships can attract foreign direct investment while enhancing Africa's pharmaceutical infrastructure [14]. Nigeria could adopt a similar approach by collaborating with GAVI, CEPI, and the Africa CDC to stimulate demand and technical assistance. South Africa's Aspen Pharmacare received $300 million in government-facilitated incentives, which accelerated vaccine production [22].

Government support are critical for reducing the risk of investments in the production of vaccines. Capital investment grants, which provide up to 50 percent of the initial capital investment cost, are one of the main policy interventions for infrastructure development [22]. Nigeria might follow the example of Brazil and India by implementing tax breaks, granting duty waivers on imported equipment and raw materials, and grants for research and development that could provide comparable benefits to reduce production costs [13]. The Nigerian government can implement advanced market commitments (AMCs), ensuring a stable demand for locally produced vaccines, reducing investor risk [14].

Conclusion

Using empirical data from similar programs in other countries, this analysis demonstrates that financing local vaccine manufacturing in Nigeria can have a major positive impact on the country's economic development and health security. The construction of a local vaccine

manufacturing facility is not only feasible but also strategically essential for reducing high dependency on imports, lowering long-term procurement costs, and strengthening national health security. With a six-year break-even point on a simulated 10-year ROI, the projected observations demonstrated that a $1 billion investment will have a significant economic impact.

Nigeria's cost structure is competitive, but it could potentially be made more efficient by using international best practices, especially in the areas of R&D funding, regulatory effectiveness, and technology transfer. Nigeria can produce vaccines at an affordable price while strengthening its healthcare system by aligning its strategy with successful international case studies. Nigeria can achieve financial long-term sustainability, lower the high initial vaccine investment cost, and establish itself as an African hub for vaccine manufacture by applying lessons from both international and African experiences. Implementing a well-structured PPP model with government-facilitated subsidies can accelerate the local manufacture of vaccines. In order to lower investment risk and assure long-term viability, PPP models and international collaborations will also be essential to encourage investment in vaccine production. Ultimately, this study provides actionable insights and practical policy recommendations for stakeholders, investors, and policymakers. By leveraging PPP frameworks and global collaborations, Nigeria can position itself as a regional hub for vaccine manufacturing, enhance health security, drive local economic growth, and contribute to Africa’s self-reliance in vaccine production.

Conflict of Interest

The authors declare that there is no conflict of interest related to this study.

Acknowledgement

I express my deepest gratitude to the Almighty God for the gift of good health and sound mind throughout this journey. I am sincerely thankful to my local guide, Dr. Paul Abiodun Olaiya, for his invaluable guidance, encouragement, and unwavering support during the course of this research. My heartfelt appreciation goes to my first co-guide, Prof. Dr. Rajendra Kumar BC, and Texila University faculty members especially Dr. Denis Mubiru, whose mentorship, critical insights, and constructive feedback significantly shaped the direction and quality of this work.

I would also like to extend my sincere thanks to Mr. Roobesh, my course coordinator, Mr. Harkrishnan R, my current student coordinator, and Mr. EZE, Francis Chukwuemeka, my friend and professional colleagues for their unwavering support and assistance during this academic journey. Special appreciation goes to Dr. Kotila Olayinka of the Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Ibadan, and Dr. Chinedu Nnaji, Senior Statistician and Research Ethics Administrator at the UI/UCH Health Research Ethics Committee Office, input and guidance. Rev. Olubunmi Idowu, Senior Pastor, Shining Light Family Church, Ota for His continued support and encouragements.

Finally, I extend my deepest appreciation to my beloved wife, LONGE, Abigail (Mrs.) and beautiful children, Bishop LONGE Samuel, Pastor David and Sister Osehon my steadfast friends, and greatest supporters. Your encouragement and belief in me were instrumental in bringing this work to completion.

Thank you all for being an integral part of this journey.

References

[1]. Osei, C. K., Nketiah-Amponsah, E., Fenny, A.P., Otchere, F., 2024. Vaccine pricing and production capacity in Africa: can Africa move beyond pooled procurement in the face of a future pandemic? *Global Health Journal*. 2024;8(4):172-180. Doi:10.1016/J.GLOHJ.2024.11.001.

[2]. Suri, R. K., Marini, A., 2024. Accelerating sustainable regional vaccine manufacturing through global partnerships – 24th DCVMN Annual General meeting 2023 report. *Vaccine X*. 2024; 19:100504. Doi:10.1016/J.JVACX.2024.100504.

[3]. Walwyn, D. R., & Gehl Sampath, P., 2021. South African case study sheds light on how vaccine manufacturing can be developed. *Down To Earth*. Retrieved from https://www.downtoearth.org.in/blog/africa/south-african-case-study-sheds-light-on-how-vaccine-manufacturing-can-be-developed-76427.

[4]. Roland, D., 2025. WuXi Biologics to Sell Irish Vaccine Facility to Merck for $500 Million. *The Wall Street Journal*. Retrieved from https://www.wsj.com/business/wuxi-biologics-to-sell-irish-vaccine-facility-to-merck-for-500-million-4d6684dc.

[5]. Ukpe, W., 2022. FEC approves process for indigenisation of vaccine production in Nigeria. *Nairametrics*. Retrieved from https://nairametrics.com/2022/09/15/fec-approves-process-for-indigenisation-of-vaccine-production-in-nigeria/.

[6]. Gavi., 2023. *The African Vaccine Manufacturing Accelerator: what is it and why is it important?*. Retrieved from https://www.gavi.org/vaccineswork/african-vaccine-manufacturing-accelerator-what-and-why-important.

[7]. Abubakar, Auwal Usman, Ismail Abdullateef Raji, Aminu Umar Kaoje, Umar Mohammed Ango, Mohammed Abdullahi Abdulkarim, Mohammad Danmadami Abdulaziz, Abubakar A., Danmafara, and Yahaya Mohammed., 2021, "Characteristics of Cerebrospinal Meningitis Cases in 2017 Outbreak, Sokoto State, Nigeria: A Secondary Data Analysis". *International Journal of TROPICAL DISEASE & Health* 42 (7):43-51. https://doi.org/10.9734/ijtdh/2021/v42i73047.

[8]. Africa CDC, 2023. *A Breakthrough for the African Vaccine Manufacturing*. Retrieved from https://africacdc.org/news-item/a-breakthrough-for-the-african-vaccine-manufacturing/.

[9]. Daily Trust, 2018. *Nigeria requires $1.63bn to fund immunisation in 10 years*. Retrieved from https://dailytrust.com/nigeria-requires-1-63-bn-to-fund-immunisation-in-10-years.

[10]. Nigeria's vaccine production centre remains comatose despite govt assurances | *Premium Times Nigeria*. Accessed June 19, 2025. https://www.premiumtimesng.com/news/headlines/253420-nigerias-vaccine-production-centre-remains-comatose-despite-govt-assurances.html.

[11]. African Development Bank Group, 2024. African Pharmaceutical Technology Foundation and Pharmaceutical Institute partner to strengthen Nigeria's pharmaceutical and vaccine manufacturing capacity. Retrieved from https://www.afdb.org/en/news-and-events/press-releases/african-pharmaceutical-technology-foundation-and-pharmaceutical-institute-partner-strengthen-nigerias-pharmaceutical-and-vaccine-manufacturing-capacity-69665.

[12]. Yagboyaju, D. A., Akinola, A.O., 2019. Nigerian State and the Crisis of Governance: A Critical Exposition. *Sage Open*. 2019;9(3). Doi:10.1177/2158244019865810.

[13]. GAVI, 2022. *India's Vaccine Leadership: The Role of Serum Institute of India.*

[14]. World Health Organization, 2023. *The Rwanda mRNA Hub Initiative: Expanding Vaccine Production in Africa.*

[15]. Kaplan, W., & Laing, R., 2005. Local production of pharmaceuticals: Industrial policy and access to medicines—An overview of key concepts, issues and opportunities for future research *(HNP Discussion Paper). The World Bank*. https://documents.worldbank.org/en/publication/documents-reports/documentdetail/551491468326174323/.

[16]. Milstien, J. B., & Kaddar, M., 2006. Managing the effect of TRIPS on availability of priority

vaccines. *Vaccine*, 24(2), 219–225. https://doi.org/10.1016/j.vaccine.2005.07.088.

[17]. McKinsey, & Co., 2021. Reimagining health systems: A roadmap for Africa's vaccine manufacturing. https://www.mckinsey.com/industries/public-and-social-sector/our-insights/a-blueprint-for-africas-vaccine-industry.

[18]. Souza, R. D., Azevedo, R., & Silva, F., 2020. Local vaccine production in developing countries: Technological barriers and policy responses. *Globalization and Health*, 16(1), 1–10. https://doi.org/10.1186/s12992-020-00618-9.

[19]. Reich, M. R., Gomez-Dantés, O., & Cash, R. A., 2021. Strengthening local production of essential vaccines: A public health imperative. *Health Affairs*, 40(3), 470–477. https://doi.org/10.1377/hlthaff.2020.01858.

[20]. UNICEF. 2022. Africa's Vaccine Logistics and Cold Chain Infrastructure: An Assessment of Gaps and Opportunities. https://www.unicef.org/documents/africa-vaccine-logistics-report.

[21]. African Union Development Agency – NEPAD. 2021. Pharmaceutical manufacturing plan for Africa: Business plan for the local production of vaccines in Africa. AUDA-NEPAD. https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-for-africa.

[22]. World Health Organization. 2022. Business case for establishing vaccine manufacturing capability in Africa. World Health Organization. https://www.who.int/publications/i/item/9789240059870.