Project Title:	**Innovation, Standardization, and Commercial Development of AISHAMIN (LEBAAIBU): A Novel Antidiabetic Phytodrug.**
Short title:	**ISCoDAL Project**
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Executive Summary

Background: Diabetes mellitus is a debilitating metabolic disease with a compounding prevalence of global public health concern. An estimated over eight million (8m) Nigerians suffer from the disease with high socioeconomic burden and low quality of life from catastrophic out-of-pocket health spending, social stigma, and lost manhours. Diabetes is a leading co-morbidity for many diseases. Management of the disease is highly dependent on conventional medicines that use imported drugs and expensive orthodox practices. This has worsened health accessibility and affordability, as well as heightened medicine insecurity for most sufferers. The abundance of Nigerian flora biodiversity and reliable ethnomedicinal knowledge of these flora present a vista of opportunity to harness our local resources for socioeconomic gains. Drawing from the above opportunity, AISHAMIN, a potential phytomedicine for the management of diabetes mellitus (DM), was developed from a Nigerian medicinal plant renowned for its ethnopharmacological uses. The preclinical data of AISHAMIN suggest that it has high potential for use in clinical management of DM.

Project Goal: The overall goal of the proposed project is to standardize the product for clinical use and commercial production.

Budget estimate and timeline: The project is estimated to cost one hundred and eighty-five million, fifty thousand, eight hundred and twelve naira, fifty kobo (**₦185,050,812.50**). The project will be implemented over a timeframe of fourteen months.

Project Justification and Expected Impact: The project aligns with the Presidential Initiative for unlocking the healthcare value chain (PVAC), which aims to promote local medicine security. The project will also directly impact five (5) of the pillars of the Renewed Hope Agenda, namely - Human Capital Development (specifically, health and social security sector), Economic Reform (specifically, youth and community empowerment), Agriculture (through raw material cultivation), Unlock Energy and Natural Resources for Sustainable Development (unlocking Nigeria's vast natural resources through sustainable management, increased investments, and environmental sustainability), and the Long-term vision of $1trillion (through investment and commercialization). The production of an affordable local phytodrug will save the country a cumulative estimate of $100m over 10 years.

1.0 Introduction

Diabetes mellitus (DM) is a debilitating metabolic disease characterized by a high blood glucose level, hyperglycemia[1]. The DM blood glucose level exceeds 7 millimoles per liter (126 mg/dL), and the body's cells are starved of energy because of the inability of the glucose to enter the cells from the blood. The WHO thresholds for DM diagnosis are ≥126 mg/dL (7.0 mmol/L) on two separate fasting blood sugar tests, or ≥200 mg/dL (11.1 mmol/L) on a random blood sugar test in a patient with classic symptoms, or a Hemoglobin A1c (HbA1c) level of ≥6.5%[2]. An estimated 8.02 million Nigerians, representing about 7% of adults, and 463 million adults worldwide suffer from DM. The major risk factors have been identified as genetic predisposition from family history, and high socioeconomic status resulting in sedentary lifestyles, poor diets, urban living, and abdominal obesity[3]. The disease leads to many health complications, huge out-of-pocket health spending, and a low quality of life. The rate of increase in DM prevalence and the associated socioeconomic burden have made it a major global public health concern[4].

Diabetes mellitus can result in acute conditions like diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS), which can be severe and life-threatening. Chronic health complications due to long-term damage to blood vessels and nerve cells by DM may arise and cause cardiovascular disease (CVD) or heart attack, nerve damage (neuropathy), kidney disease (nephropathy), eye damage (retinopathy), foot ulcers, mouth/gum infections, and slow wound healing. Slow wound healing is one of the common

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[1] Adigwe OP, Adzu B, Tarfa FD and **Egharevba HO** (2024). Antidiabetic phytodrug from *Maerua angolensis* DC: Formulation, standardization, in vitro and in vivo evaluations. *Scientific African (Elsevier)*, 23, e02026. https://doi.org/10.1016/j.sciaf.2023.e02026

[2] Richardson CR, Borgeson JR, Van Harrison R, et al. Management of Type 2 Diabetes Mellitus [Internet]. Ann Arbor (MI): Michigan Medicine University of Michigan; 2021 Oct. Table 1, Diagnosis of Diabetes: Diagnostic Tests and Glucose Values. Available from: https://www.ncbi.nlm.nih.gov/books/NBK579413/table/fm.s1.t1/

[3] Olamoyegun, M. A., Alare, K., Afolabi, S. A., Aderinto, N., & Adeyemi, T. (2024). A systematic review and meta-analysis of the prevalence and risk factors of type 2 diabetes mellitus in Nigeria. *Clinical diabetes and endocrinology*, *10*(1), 43. https://doi.org/10.1186/s40842-024-00209-1

[4] Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021. Results. Institute for Health Metrics and Evaluation. 2024 (https://vizhub.healthdata.org/gbd-results/).

complications of uncontrolled diabetes mellitus. Other complications may include hearing loss, musculoskeletal disorders, and depression[5].

The management of DM is expensive and includes lifestyle changes to improve diet and physical activity, and the use of conventional medicines such as insulin and Metformin to control blood glucose. Insulin and/or metformin use is known to be associated with several adverse events and patients' discomfort. Nigeria is estimated to spend $4.3 million annually on insulin and metformin importation[6]. Based on the rate of increase of DM prevalence and rising drug costs globally, this amount is expected to triple before the year 2030. Also, the catastrophic out-of-pocket expenses and socio-stigma associated with some of the complications of DM have confined most victims, especially those in the lower socioeconomic status bracket, to self-medication and unstandardized herbal medicine use, resulting in painful exploitation of unsuspecting Nigerians by unscrupulous charlatans. This was the basis for the development of AISHAMIN for the management of diabetes mellitus from a local plant codenamed "LEBAAIBU".

LEBAAIBU is ethnomedicinally renowned for its antidiabetic and wound-healing properties in Northern Nigeria. The development of the medicinal plant as a phytodrug for diabetes-related ailments began in 2020 when COVID-19 became a global pandemic, and DM was implicated as a leading co-morbidity[7]. The preclinical data covering (i) identification, authentication, and pharmacognostic and phytochemical characterization[8], (ii) Safety profile[9], and (iii) the antidiabetic property of the standardized formulation[10], have been well documented and published by my multidisciplinary research team.

This project aims to advance the development of AISAHMIN through a process of clinical standardization for Listing and Market Authorization with NAFDAC. The project will cover standardization of the formulation,

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[5] NHS (n.d.) Type 2 Diabetes. Available at: https://www.nhs.uk/conditions/type-2-diabetes/complications/#:~:text=damage%20to%20your%20blood%20vessels,gum%20disease [Accessed 30 Oct. 2025]

[6] WITS (World Integrated Trade Solution). Nigeria Medicaments of insulin, for retail sale imports by country in 2023. Available at: https://wits.worldbank.org/trade/comtrade/en/country/NGA/year/2023/tradeflow/Imports/partner/ALL/product/300431#:~:text=Nigeria%20imports%20of%20Medicaments%20of,5.51K%20%2C%20870%20Kg).&text=Egypt%2C%20Arab%20Rep.,-35.47

[7] Panja, A., Manna, S., Chatterjee, M., Ghosh, T., Bid, S., & Choudhury, S. M. (2025). Diabetes Mellitus, a Leading Comorbidity in COVID-19: an Insight on Pathophysiology, Molecular Interactions, and Comprehensive Management. *Current microbiology*, *82*(9), 388. https://doi.org/10.1007/s00284-025-04369-w

[8] Adigwe OP, Ibrahim JA, Buhari AH, Muhammed KA, Kirim RA, Danraka AM and **Egharevba HO*** (2021). Pharmacognostic and phytochemical characterization of *Maerua angolensis* DC.. African Journal of Plant Science, 15(4), 94-99. Available at; https://academicjournals.org/journal/AJPS/article-stat/D61398566588

[9] **Egharevba HO,** Buhari AH, Adigwe OP and Adzu B (2022). *Maerua angolensis* DC: evaluation of the oral acute and sub-chronic toxicity profile of its freeze-dried leaves infusion extract. *Int. J. Biol. Chem. Sci.*, 16(1): 242-250. doi: https://dx.doi.org/10.4314/ijbcs.v16i1.20

[10] Adigwe OP, Adzu B, Tarfa FD and **Egharevba HO** (2024). Antidiabetic phytodrug from *Maerua angolensis* DC: Formulation, standardization, in vitro and in vivo evaluations. *Scientific African (Elsevier)*, 23, e02026. https://doi.org/10.1016/j.sciaf.2023.e02026

optimization of the production process, generation of clinical safety and efficacy data, application for market authorization, social production, and commercialization.

1.1 Significance of (Justification for) the Study

Diabetes Mellitus is a debilitating metabolic disease that affects many Nigerians. It is a co-morbidity of many other ailments. The sufferer has a low quality of life, a huge economic burden, and high social stigma. Several people who could not afford the huge and catastrophic financial burden associated with imported drugs resort to patronage of unstandardized and unsafe galenical preparations. Furthermore, available conventional medicines are imported and unaffordable to many sufferers. The high cost of imported antidiabetic drugs leads to significant revenue losses for Nigeria, highlighting a strong economic case for local production. The supply chain disruption during the COVID-19 pandemic has reawakened the need for national and regional medicine security. This reawakening has led to the Presidential Initiative for unlocking the healthcare value chain (PVAC)[11], which aims to strengthen local manufacturing of essential medicines and to promote local medicine security. The project will directly impact five (5) of the pillars of the Renewed Hope Agenda[12], namely - Human Capital Development (specifically, health and social security sector), Economic Reform (specifically, youth and community empowerment), Agriculture (through raw material cultivation), Unlock Energy and Natural Resources for Sustainable Development (unlocking Nigeria's vast natural resources through sustainable management, increased investments, and environmental sustainability), and the Long-term vision of $1trillion (through investment and commercialization). The production of this affordable local phytodrug will save the country an estimated $100 million over 10 years.

1.2 Study Objectives

The Primary objective of ISCoDAL project/study is to standardize and obtain marketing authorization for AISHAMIN for the management of uncomplicated diabetes mellitus.

1.2.1 Specific Objectives 1: To standardize the formulation of AISHAMIN drug product for clinical use and generate clinical safety and efficacy data for Marketing Authorization.

1.2.1.1 Research Question 1: Will the standardized AISHAMIN formulation be suitable for clinical use?

1.2.1.2 Hypothesis 1: Standardized AISHAMIN formulation will meet all quality parameters for clinical management of diabetes mellitus.

[11] PVAC (The Presidential Initiative for Unlocking Healthcare Value Chain). Available at: https://pvac.gov.ng/ [Accessed 31 Oct 2025]

[12] CDCU (2025). 8 Priorities - The 8 Presidential Priority Areas. *Central Delivery Coordination Unit (CDCU)*. Available at: https://cdcu.ng/priority [Accessed 31 Oct 2025]

Explanation: The various standardized formulations and dosage forms will be developed and assessed for drug quality parameters. The clinical safety and efficacy data of the standardized formulations will be generated and included along with the preclinical data in the Drug Master File (DMF) or Common Technical Document (CTD) to be submitted to regulatory authorities (NAFDAC for Listing, and Federal Ministry of Industry, Trade and Investment (FMITI) for Trademark). Trademark registration and Marketing authorization will be obtained from the regulatory agencies.

1.2.2 Specific Objective 2: To scale up and optimize production for social and commercial mass production.

1.2.2.1 Research Question 2: Will the mass production of AISHAMIN be economically viable?

1.2.2.2 Hypothesis 2: The mass production of AISHAMIN will be commercially viable.

Explanation: The mass production of the standardized product will be optimized for commercial viability. This will make the product affordable and eliminate catastrophic spending on DM management. A mass production of 200,000 doses for social use will be undertaken to provide demonstrable economic viability of the product for the investment drive. The product will be licensed to a viable pharmaceutical company for commercial production.

2.0 Literature Review

The background literature review has been undertaken in our publications (see references 1, 7-9)

2.1 Published Reports

Aspects of the preclinical studies have been reported in published articles (see references 1, 7-9). The technical reports are available for sighting on request.

3.0 Research Approach

3.1 Theoretical and Conceptual Framework

The theoretical framework of the study is the drug development and marketing authorization process. The conceptual framework is as depicted in the flow chart below (Figure 1).

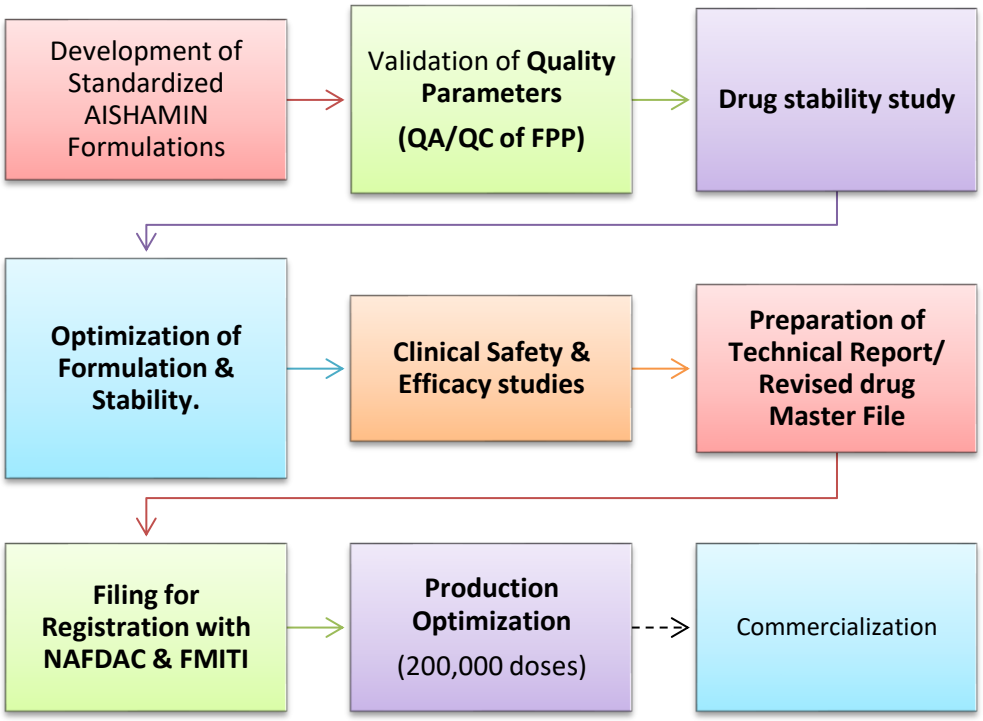

Figure 1: Conceptual Framework for the AISHAMIN Project with **key milestones in bold format**. (QA/QC = Quality Assurance/Quality Control; FPP = Finished Pharmaceutical Product; NAFDAC = National Agency for Food and Drug Administration and Control; FMITI = Federal Ministry of Industry, Trade and Investment)

3.2 Research Methodology

The project will fundamentally adopt NIPRD standard operating procedures (SOPs), which is ISO/IEC 17025:2017-based. The clinical safety and efficacy studies will follow ICH Good Clinical Practice (GCP) guidelines and specific regulatory guidance from NAFDAC which is the agency in charge of clinical trial study regulation. Specifically, the methods of Jung et al (2015)[13] and Kim et al. (2023)[14] will be adapted.

The major processes will include optimization of the laboratory- and pilot-scale processes including (i) raw material (RM) collection, extraction and drying standardization processes; (ii) formulation, stability, and optimization of quality assurance and control processes for the finished phytomedicinal product (FPP); (iii) evaluation of clinical safety and quality of finished product; (iv) and economic production for product

[13] Jung, C. H., Park, C. Y., Ahn, K. J., Kim, N. H., Jang, H. C., Lee, M. K., Park, J. Y., Chung, C. H., Min, K. W., Sung, Y. A., Park, J. H., Kim, S. J., Lee, H. J., & Park, S. W. (2015). A randomized, double-blind, placebo-controlled, phase II clinical trial to investigate the efficacy and safety of oral DA-1229 in patients with type 2 diabetes mellitus who have inadequate glycaemic control with diet and exercise. *Diabetes/metabolism research and reviews*, *31*(3), 295–306. https://doi.org/10.1002/dmrr.2613

[14] Kim, BH., Yim, SV., Hwang, S.D. *et al.* A clinical trial on anti-diabetic efficacy of submerged culture medium of *Ceriporia lacerata* mycelium. *BMC Complement Med Ther* **23**, 83 (2023). https://doi.org/10.1186/s12906-023-03895-z

investment viability and social availability.

A technical dossier for optimum manufacture or production of the FPP will be developed for technology transfers and/or commercialization.

Our Drug Manufacturing Unit (DMU) will be renovated and remodeled to GMP-compliant facilities for regulatory approval. Some equipment will be technically revamped and recalibrated for use in the project. These include extraction vessels, drying (freeze drying) chambers, a capsulation machine, and some analytical equipment.

7.0 Ethics Approval

Ethical approval for the clinical safety and efficacy studies will be obtained from the NIPRD Health Research Ethics Committee (NIPRD HREC) and the National Health Research Ethics Committee (NHREC). The ICH Good Clinical Practice (GCP) guidelines, including the procedures for obtaining participants' consent, will be followed.

8.0 Data interpretation

All primary data will be kept in accordance with NIPRD standard operating procedure (SOP) and as specified by its quality management system (QMS) and ICH Good Clinical Practice (GCP) guideline**s**. Laboratory data will be analyzed as provided in NIPRD SOP and as stipulated in the study protocol. Data analysis will be conducted by a statistician using a specified data analytic tool (GraphPad or SPSS).

9.0 Expected Outputs and Outcomes

The study will provide the relevant developmental/production data that will establish AISHAMIN use as an effective antidiabetic phytodrug, and its economic production and investment viability. It will provide a locally available, accessible and ready-to-use intervention for the management of diabetes mellitus.

As a product, it will add to the socioeconomic, health and social welfare developmental impact from the federal government. It will also contribute to the PVAC initiative for national medicine security, and the attainment of the Renewed Hope Agenda (RHA). This will also demonstrate a useful model for the development and commercialization of research outputs to meet prioritized national needs.

10.0 TimeLine

The project is expected to be implemented within 14 months. All compulsory information and data needed for a complete Dossier for NAFDAC registration have been considered in the research questions and methodology. The key activities and timeline are provided in the Gantt chart below (Figure 2).

S/N	Activities	Months													
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
1.	Preproject Activities (development of revised SOPs and Protocol, Ethical Approvals, Site Preparation)														
2.	Development of Standardized Formulations, Stability Study, QA/QC validations.														
3.	Clinical Safety & Efficacy Studies (Phase I&II)														
4.	Development of DMF														
5.	Application for Marketing Authorization														
6.	Production Optimization														
7.	Mass Production & Commercialization														
8.	Project Report														

Figure 2: Gantt chart for AISHAMIN Development and Commercialization

11.0 Study Budget

The estimated budget for the study is one hundred and eighty-five million, fifty thousand, eight hundred and twelve naira, fifty kobo (**₦185,050,812.50**). The summary is provided in Table 1. The budgeted fund is expected to be released in not more than two tranches. More details can be provided when required.

Table 1: Budget summary

S/N	Cost Heads	Justification	Multiplier	Rate (₦) (avr. cost)	Amount (₦)
1	Site Preparation	Meetings, SOPs and Protocol reviews/development: This will involve a lot of documentation, and physical and virtual communications.	1	5,000,000	5,000,000
2.	Ethical Approvals	NIPRD HREC, NHREC, NAFDAC, Clinicaltrial.gov, etc: This will involve a lot of documentation, and physical and virtual communications.	1	5,000,000	5,000,000
3	Raw Materials, Reagents and Chemicals, Reference	Development of formulation	35 items	755,250	26,433,750

	Standards, and consumables.				
4	Equipment and Apparatus	Purchase, Repairs, and Calibration	11 Items	3,080,000	33,880,000
5	Stability	Stability and shelf-life: This requires strict round-the-clock monitoring, extra-manhour and power supply.	1	5,000,000	5,000,000
6	Clinical studies for safety and Efficacy	Phase II clinical trial study: This involves the production of the investigational new drug (IND) to be used, participants' cost reimbursement, diagnostic tests, communication, personnel cost.	6 categories	5,600,000	33,600,000
7	Drug Master File	Documentation of drug information: This is also required for the registration process, further investigation, and commercialization.	2	6,500,000	6,500,000
8	Regulatory Approvals for Marketing Authorization	Trademarks by FMITI and NAFDAC Listing	2	3,000,000	6,000,000
9	Mass Production for Social availability and seeking investment	This is required for large or economic-scale production validation to woo potential investors for commercialization.	200,000 doses	100	20,000,000
10	Project Report and Dissemination of study outcomes	Final project report: This includes documentation of all activities, development of scientific papers and presentation of conference papers etc.		12,000,000	12,000,000
11	Project Supervision and Coordination	Professional coordination by the principal investigator and co-investigators, project monitors, inspectors, and regulators.	3	2,500,000	7,500,000
	Sub-Total				160,913,750
	Administrative charge (15%)	Provision of utilities, administrative support and enabling environment by institution.			24,137,062.5
	Grand-Total				**185,050,812.5**

12.0 Risk Management Plan

The Plan is to identify, assess, and mitigate potential risks associated with the development, manufacturing, and post-marketing phases of AISHAMIN, an antidiabetic phytomedicine. The Risk

Management Plan (RMP) will ensure compliance with regulatory expectations (e.g., NAFDAC) and promote patient safety, product quality, and regulatory readiness. The plan identifies and evaluates potential risks throughout the product lifecycle, implements proactive strategies to minimize or eliminate identified risks, and establishes continuous monitoring and corrective mechanisms post-authorization. The key risk and their mitigation strategy are outlined in Table 2.

Table 2: Risk Mitigation Strategy

S/N	Risk Category	Potential Risk	Mitigation / Control Strategy
1	Preclinical and Clinical Development	Incomplete safety or efficacy data, and adverse reactions during trials	Conduct GLP-compliant studies, implement a Data Safety Monitoring Board (DSMB), and a Robust pharmacovigilance plan
2	Manufacturing and Quality Control	Variability in raw plant materials, contamination or deviation from GMP	Source standardized raw materials, and implement validated GMP processes- Routine QC/QA checks
3	Regulatory compliance	Delays in dossier preparation or non-compliance with common technical document (CTD) requirements	Maintain a regulatory compliance checklist, commence early consultation with NAFDAC, and engage regulatory affairs experts.
4	Supply Chain and Logistics	Interruption in supply of raw materials or packaging components	Identify multiple qualified suppliers, maintain adequate safety stock, and establish supplier quality agreements.
5	Market & Commercialization	Low market acceptance or pricing pressure	Conduct market feasibility studies and implement patient and healthcare provider education programs
6	Post-Marketing Surveillance	Emergence of unforeseen adverse events	Establish a pharmacovigilance system, report adverse events per regulatory timelines, and conduct Phase IV / post-marketing studies in collaboration with the licensed producer.

The above RMP provides a structured framework for anticipating, managing, and mitigating potential risks across the product's development and commercialization phases. The approach ensures that AISHAMIN is developed, produced, and marketed in a manner that prioritizes patient safety, product integrity, and regulatory compliance.

13.0 References

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