Available online at *www.ujpronline.com*
Universal Journal of Pharmaceutical Research
An International Peer Reviewed Journal
ISSN: 2831-5235 (Print); 2456-8058 (Electronic)
Copyright©2026; The Author(s): This is an open-access article distributed under the terms of the CC BY-NC 4.0 which permits unrestricted use, distribution, and reproduction in any medium for non-commercial use provided the original author and source are credited

REVIEW ARTICLE

CLINICAL DRUG DEVELOPMENT IN AFRICA: MAPPING THE JOURNEY FROM DRUG DISCOVERY TO REGULATORY APPROVAL AND CLINICAL IMPLEMENTATION - A SYSTEMATIC REVIEW

Lambert Philipo Barugahale[1]*, Agape Philipo Barugahale[2]
[1] Kitete Regional referral Hospital, Pharmacy Department, Tabora, United Republic of Tanzania. [2]Department of internal Medicine, Bugisi Health Centre Didia, Shinyanga Region Tanzania.

Article Info:

Article History:
Received: 2 June 2026
Reviewed: 7 July 2026
Accepted: 4 August 2026
Published: 15 September 2026

Cite this article:
Barugahale LP, Barugahale AP. Clinical drug development in Africa: Mapping the journey from drug discovery to regulatory approval and clinical implementation - A systematic review. Universal Journal of Pharmaceutical Research 2026; 11(4): 85-92.
http://doi.org/10.22270/ujpr.v11i4.1634

***Address for Correspondence:**
Lambert Philipo Barugahale, Kitete Regional referral Hospital, Pharmacy Department, Tabora, United Republic of Tanzania.
Tel: +255-610997640
E-mail: *barugahalelambert@gmail.com*

Abstract

Background: A widening gap exists between Africa's share of the global disease burden and its participation in clinical pharmaceutical research. The continent shoulders approximately one quarter of all disease globally yet contributed fewer than two percent of clinical trials conducted worldwide in 2023. This review systematically examines each phase of pharmaceutical development in Africa, tracing the pathway from compound discovery and preclinical work through regulated human trials, national approval processes, and implementation in clinical settings, with the goal of identifying where progress has been made and where critical deficiencies persist.
Methods: Four electronic databases were searched - PubMed/MEDLINE, Scopus, Web of Science, and African Journals Online - covering publications from January 2015 to July 2025. Additional material was obtained from grey literature sources including official WHO documents, the Pan African Clinical Trials Registry, the African Union Commission, AUDA-NEPAD, SAHPRA, and the H3D Centre. Studies were eligible if they provided primary data or evidence synthesis on any phase of drug development, regulatory approval, or clinical implementation in Africa. All methods followed PRISMA 2020 reporting standards.
Results: The African pharmaceutical research landscape is dominated by three countries - South Africa, Egypt, and Nigeria - which collectively account for approximately 70% of all trials conducted on the continent. South Africa alone recorded over 4,000 trial initiations. Globally, Africa hosted just 845 of 76,331 newly initiated trials in 2023. The H3D Centre at the University of Cape Town achieved a historic milestone by advancing Africa's first internally developed antimalarial compound into Phase II human testing. The Pan African Clinical Trials Registry accumulated 2,998 registered studies by August 2021.
Conclusion: Africa holds substantial and largely unrealized potential as a driver of pharmaceutical innovation. Translating this potential requires coordinated investment in scientific training, laboratory infrastructure, regulatory capacity, and post-approval surveillance.
Keywords: AMRH, clinical trials sub-Saharan Africa, drug development Africa, H3D Centre, SAHPRA.

INTRODUCTION

Sub-Saharan Africa and the broader African continent face a paradox that defines modern global health: their populations bear a disproportionate share of infectious disease mortality and morbidity, yet they remain largely absent from the clinical research processes through which effective medicines are identified and validated. Of 76,331 clinical trials launched across the world in 2023, just 845 took place in Africa accounting for barely one percent of the global total despite the continent's outsized disease burden[1,2].

This exclusion from pharmaceutical research has practical consequences that extend well beyond scientific representation. When pivotal trials that underpin drug approvals are conducted in populations from North America, Europe, or East Asia, the resulting evidence may not accurately predict how those treatments perform in African patients who differ in genetic makeup, nutritional status, environmental exposures, and patterns of comorbidity[3]. A drug optimized through trials in one population does not automatically translate into equivalent safety and efficacy profiles for another, yet African health

systems routinely adopt therapies developed and validated almost entirely elsewhere[4].

The dependence on externally produced pharmaceutical products compounds this vulnerability. Africa currently relies on imports for more than 70% of the medicines it consumes, and local vaccine manufacturing capacity was so limited at the time of the COVID-19 pandemic that the continent was largely bypassed during early global distribution receiving initial doses months after rollout had begun in wealthier nations[5,6]. This pharmaceutical dependency is not a fixed condition but a consequence of historical decisions about where research funding flows, where manufacturing is located, and whose health needs are treated as primary drivers of innovation[7].

Drug development is an inherently difficult enterprise anywhere in the world. Globally, fewer than one in fifteen compounds entering Phase I human testing ultimately achieves market authorisation[8]. In Africa, every requirement for successful drug development faces additional obstacles that compound the already formidable challenge of bringing a new treatment to patients[9]. However, several genuine advances are visible. The H3D Centre at the University of Cape Town progressed an antimalarial compound to Phase II trials[10,11]; Kenya's Universal Corporation received WHO prequalification for TLD production in 2023[12]; and Rwanda inaugurated Africa's first mRNA vaccine manufacturing plant through BioNTech collaboration[13].

This systematic review maps the entirety of the drug development pathway as it exists in Africa today from discovery science through preclinical evaluation, clinical trial phases I to IV, regulatory processes, and post-authorisation surveillance to produce an integrated picture of where Africa stands, what is holding back progress, and what realistic opportunities exist for accelerating the development of medicines that serve African patients[14].

METHODS

Search strategy and database selection

A systematic literature search following PRISMA 2020 standards was performed across four indexed databases: PubMed/MEDLINE, Scopus, Web of Science, and African Journals Online[15]. The search window extended from January 2015 to July 2025, with earlier foundational publications included where necessary. Grey literature searches were conducted through the WHO Global Health Observatory, the Pan African Clinical Trials Registry, the AUDA-NEPAD AMRH repository, the SAHPRA clinical trials portal, and H3D Centre institutional publications.

Boolean search strings combined the following terms in various configurations: pharmaceutical development, drug discovery, clinical trials, Africa, sub-Saharan Africa, drug registration, regulatory harmonization, PACTR, AMRH, SAHPRA, medicine manufacturing, neglected tropical diseases, antimicrobial resistance, and national medicines regulatory authority. Country-specific terms were also applied including Kenya, South Africa, Nigeria, Tanzania, Uganda, Ethiopia, Rwanda, Ghana, and Senegal.

Study selection criteria

A study was eligible for inclusion if it:

i. Reported original data or evidence synthesis on pharmaceutical discovery, preclinical research, clinical trial activity, regulatory review, or post-market surveillance in Africa;
ii. Appeared in a peer-reviewed Scopus-indexed publication or constituted an official report from a recognized international or continental health authority; and
iii. Focused on human health interventions or pharmaceutical policy. Studies examining only veterinary pharmaceuticals, dietary supplements without pharmacological evidence, or clinical trials with no African site participation were excluded, as were non-English publications without English abstracts.

Data extraction and quality appraisal

Both authors independently extracted data from each eligible source using a standardized collection form capturing: publication year, country of focus, study design, clinical trial phase, relevant regulatory body, key quantitative findings, and documented limitations. Methodological quality was evaluated using the Newcastle-Ottawa Scale for non-randomized studies and the Cochrane Risk of Bias 2 tool for randomized trials[16]. Disagreements in data extraction were resolved through structured discussion.

Table 1: Africa's global position: Disease burden, population, and research participation (2023).

Indicator	Value (%)
Share of global disease burden	25
Share of global population	19
Share of clinical trials (WHO, 2023)	1.1
Late-stage R&D with ≥1 African site	27.5
Trials conducted only in Africa (2019–2024)	3.9
Vaccines produced locally (2023)	<1
Essential medicines imported	>70

Africa carries 25% of the global disease burden but hosts only 1.1% of clinical trials - a 22-fold gap between disease burden and research participation. Africa imports >70% of its medicines and produced <1% of its own vaccines as of 2023. AMI = Access to Medicine Index.

RESULTS

Any analysis of pharmaceutical development in Africa must begin with a frank acknowledgement of scale. The region shouldered 95% of global malaria deaths, accounts for the majority of new HIV infections worldwide, and records the highest tuberculosis mortality rates per capita of any world region[17]. To this longstanding burden of infectious disease, Africa is now adding a rapidly accelerating wave of non-

communicable illnesses cardiovascular disorders, cancers, and diabetes projected to become the primary driver of continental mortality by the end of this decade[18]. An analysis of five major medical journals published between 2019 and 2024 found that only 3.9% of clinical trials appearing in those publications were conducted exclusively within Africa[19]. A 2024 survey of R&D pipelines at the twenty largest pharmaceutical companies found that only 89 of 324 late-stage projects (27.5%) included at least one African trial site[1]. The implication is clear: medicines that reach approval without African trial data may perform unpredictably across the continent's diverse populations, since drug metabolism, dosing requirements, and disease phenotypes may differ in ways that were never measured[3].

Table 2: Principal African institutions contributing to drug discovery and clinical development.

Institution	Country	Research Focus	Significant Achievement
H3D Centre, UCT	South Africa	Malaria, TB, AMR, COVID-19	First African-developed compound to reach Phase II human trials (antimalarial kinase inhibitor)
KEMRI-Wellcome Trust	Kenya	Malaria, HIV, TB, Vaccines	Over 52 completed clinical studies; highest-ranked African health research institution (Scimago)
SAMRC	South Africa	HIV, TB, NCDs, Vaccines	Landmark HIV/TB Phase III trial sites; Wits RHI and PHRU major study hosts
MRC Unit The Gambia	The Gambia	Infectious diseases, Vaccines	Key site for malaria vaccine trials and pneumococcal conjugate vaccine evidence base
Makerere University	Uganda	HIV, TB, NTDs	More than 160 registered clinical trials; central to regional HIV treatment optimisation
DNDi East Africa	Multi-country	Sleeping sickness, Leishmaniasis, HCV	Oral single-dose treatment for African sleeping sickness demonstrated efficacious in clinical testing
Institut Pasteur Dakar	Senegal	Vaccines, Diagnostics, Arboviruses	diaTROPIX facility reached 75 million RDT/year production capacity in 2024
Universal Corporation Ltd	Kenya	ARV manufacturing	First African manufacturer granted WHO prequalification for TLD antiretroviral production (2023)

TB = Tuberculosis; AMR = Antimicrobial Resistance; NCD = Non-communicable Disease; NTD = Neglected Tropical Disease; HCV = Hepatitis C Virus; ARV = Antiretroviral; TLD = Tenofovir-Lamivudine-Dolutegravir; RDT = Rapid Diagnostic Test.

Table 3: Therapeutic area distribution of clinical trials in Sub-Saharan Africa (2012–2023).

Therapeutic area	Trials, n	Note
Infectious diseases	944	Malaria, HIV, TB dominant - well-developed research infrastructure
Oncology	132	Critically low given the rapidly rising cancer burden across Africa
Cardiovascular	118	Critically low given NCD projections; NCDs are projected to be the leading cause of death by 2030
Other areas	~731	Vaccines, nutrition, mental health, reproductive health, and others

NCD = Non-communicable Disease; SSA = Sub-Saharan Africa; N = 1,925 sub-Saharan African trials, Dec 2012–Mar 2023. South Africa alone accounts for 48.3% of all sub-Saharan African trial activity; the top 3 countries (South Africa, Nigeria, Kenya) together represent ~66% of all trials, while the remaining 40+ sub-Saharan countries share only 34%.

This review conceptualizes the drug development pathway in Africa as eight sequential stages, each shaped by distinct institutions, infrastructure gaps, and regulatory milestones: 1. target identification and drug discovery, led by centres such as H3D, KEMRI-Welcome Trust, DNDi, ANDI, and Institute Pasteur de Dakar; 2. preclinical research, constrained by scarce Biosafety Level 3 laboratories and the absence of a national pharmacopoeia in any African country; 3. ethics review and regulatory authorization, in which national ethics committees and 55 separate National Medicines Regulatory Authorities (NMRAs) historically operate largely independently; 4. Phase I first-in-human safety studies, concentrated in South Africa, Egypt, and Kenya the three countries hosting approximately 70% of Africa's trials against a global benchmark in which only 6.7% of Phase I compounds ultimately achieve market authorization; 5. Phase II preliminary efficacy assessment; 6. Phase III pivotal large-scale efficacy and safety trials; 7. regulatory submission and marketing authorization, historically undertaken separately for each of the continent's 55 NMRAs; and 8. post-market surveillance and clinical implementation, where pharmacovigilance capacity and rural healthcare access remain the principal constraints. Each of these stages is examined in turn in the sections that follow.

Stage 1 - Drug Discovery

Institutional landscape

Drug discovery encompassing molecular target identification, chemical library screening, and compound progression through hit identification, hit-to-lead optimization, and lead optimization remains largely concentrated in a small number of specialized African institutions[20].

The most advanced African drug discovery centre is the Holistic Drug Discovery and Development Centre (H3D), established at the University of Cape Town in 2010 under the direction of medicinal chemist Professor Kelly Chibale. With a multidisciplinary team of more than 75 scientists the overwhelming majority holding postgraduate qualifications the centre operates discovery programmes targeting malaria, tuberculosis, antimicrobial resistance, and COVID-19[10,11]. Its collaboration with the Medicines for Malaria Venture yielded a Plasmodium kinase inhibitor that became the first pharmaceutical candidate wholly developed in Africa to enter Phase II testing in human volunteers[10].

The Gates Foundation and LifeArc invested USD 7.2 million in 2023 to establish the Grand Challenges

African Drug Discovery Accelerator, a network connecting researchers across eight countries through four flagship research projects[14]. DNDi conducts research in East Africa targeting diseases including visceral leishmaniasis and African sleeping sickness, demonstrating an oral single-dose regimen effective against the latter[21,22]. The Institute Pasteur de Dakar expanded its diaTROPIX diagnostic manufacturing platform in 2024, lifting annual production of rapid diagnostic tests from five million to 75 million units[22].

Factors limiting discovery capacity

A rigorous assessment published in the Journal of Medicinal Chemistry in 2025 identified three systemic barriers constraining drug discovery across sub-Saharan Africa: inadequate hit-to-lead and lead optimization expertise, a chronic deficit of Africa-tailored funding mechanisms, and university curricula that do not routinely introduce students to pharmaceutical development workflows[23]. These gaps are exacerbated by the emigration of trained scientists to higher-income settings where laboratory facilities and salary levels are markedly superior[24-26].

Stage 2 - Preclinical research

Before any investigational compound can be administered to a human being, a comprehensive body of preclinical evidence must demonstrate sufficient safety and pharmacological activity to warrant the risk. This evidence- generated through *in vitro* assays, biochemical studies, and *in vivo* animal experiments - must characterise the compound's toxicity profile, pharmacokinetics, mechanism of action, and biological activity in disease models[27].

Table 4: Summary of clinical trial activity in Sub-Saharan Africa by country (2012-2023).

Country	Trial count	% of SSA	Primary therapeutic focus	Lead regulatory authority
South Africa	930	48.3%	HIV, TB, Oncology, Vaccines	SAHPRA
Nigeria	169	8.8%	Malaria, Infectious Diseases	NAFDAC
Kenya	163	8.5%	HIV, Malaria, Vaccines	Pharmacy and Poisons Board
Uganda	160	8.3%	HIV, TB, Malaria	National Drug Authority
Tanzania	~120	~6.2%	Malaria, HIV, NCDs	TMDA
Ethiopia	~86	~4.5%	HIV, TB, NTDs	EFDA
Ghana	~75	~3.9%	Malaria, NCDs	FDA Ghana
All other SSA	~222	~11.5%	Varied	Multiple NMRAs

SSA = Sub-Saharan Africa; NCD = Non-communicable Disease; NTD = Neglected Tropical Disease; TMDA = Tanzania Medicines and Medical Devices Authority; EFDA = Ethiopian Food and Drug Authority; NMRA = National Medicines Regulatory Authority.

Table 5: Barriers and corresponding strategic opportunities across the African drug development pipeline.

Stage	Key barriers	Available or emerging opportunities
Discovery	Limited medicinal chemistry capacity; scientist emigration; curricula misalignment; insufficient Africa-specific funding	H3D model replication; GC ADDA across 8 countries; USD 7.2M Gates+LifeArc investment (2023); ANDI continental coordination
Preclinical	Few certified GLP facilities; scarce BSL-3 labs; no African pharmacopoeia; heavy API import reliance	FuturePharma at CSIR; WHO GLP technical support; proposed regional BSL-3 hubs; continental pharmacopoeia discussions
Ethics Review	Approval timelines of 3-12 months; quarterly meetings; sequential national/institutional layers; understaffed secretariats	AMRH joint ethics harmonisation; digital submission portals; secretariat capacity-building; expedited pathways for priority diseases
Phase I-III Trials	Concentrated in 3 countries; few Phase I units; limited EHR infrastructure; economic dropout of participants	Expanding CRO partnerships (CCR-A 2024); EDCTP funding; 85-96% participant retention rates; large diverse eligible populations
Regulatory Review	55 separate NMRAs with divergent standards; SAHPRA former median 2,092 days; no continental pathway before AMA	AMA treaty ratification advancing; AMRH Green Book established (2023-2025); WHO CRP procedures; EMA-AMRH partnership
Post-Market Surveillance	Pharmacovigilance weak in most NMRAs; substandard medicines; rural access gaps over 3 hours; poverty-driven non-adherence	Kenya PPB quarterly digital reporting; Africa CDC 60% local production target by 2040; Global Fund local procurement; mRNA hubs operational in Rwanda and Senegal

GLP = Good Laboratory Practice; BSL = Biosafety Level; API = Active Pharmaceutical Ingredient; EHR = Electronic Health Record; EDCTP = European and Developing Countries Clinical Trials Partnership; CRO = Contract Research Organisation.

The infrastructure required is demanding and unevenly distributed across Africa. Biosafety Level 3 containment laboratories essential for pathogens such as Mycobacterium tuberculosis remain scarce outside South Africa and Kenya. Good Laboratory Practice certification has been achieved by only a fraction of African laboratories[27].

A systematic review found that 42% of global reports documenting substandard or falsified pharmaceutical products originate from Africa partly attributable to weakness of quality assurance systems at manufacturing and preclinical research levels[28]. Compounding this challenge, not a single African country has developed its own national pharmacopoeia, meaning quality standards used at the preclinical stage are borrowed from British, European, or US pharmacopoeias, which may not reflect profiles of African raw ingredients[29].

South Africa's Council for Scientific and Industrial Research recently opened FuturePharma, an open-access facility providing API synthesis and formulation development services across the continent[30]. Imported

active ingredients account for as much as 70% of total drug costs in South Africa, making this investment a meaningful step towards reducing upstream pharmaceutical dependency[31].

Stage 3 - Ethics review and regulatory authorization

Trial registration

The Pan African Clinical Trials Registry (PACTR), launched in 2007 under the WHO ICTRP, is the only WHO-recognized primary registry based within Africa. Analysis of its registration data documented 2,998 trials registered from founding through August 2021, with annual registrations reaching 606 in 2020 reflecting both greater research activity and improved compliance with prospective registration norms[32].

A comparative assessment of three registries covering sub-Saharan Africa from 2010 to mid-2020 found 2,622 registered trials in ClinicalTrials.gov, 1,501 in PACTR, and 507 in ISRCTN. Randomized controlled designs constituted over 80% of registrations across all three databases[33].

Ethics committee review

Across most of Africa, ethics committee approval before commencing a clinical trial requires between three and twelve months, compared to six to eight weeks in high-income research settings[34]. This disparity stems from several structural realities: many national ethics committees meet only quarterly, their secretariats are small teams with limited administrative support, and review processes at national and institutional levels are generally sequential rather than parallel. Some sponsors have opted for external IRBs to avoid delays raising legitimate concerns about community ownership of research[35].

National regulatory authorization

Each of Africa's 55 African Union member states maintains its own NMRA, and their capacity varies enormously. A 2024 review found that most African NMRAs operate under outdated legislative frameworks, conduct redundant assessments already evaluated by peer authorities, and lack sufficient scientific reviewers to process applications without protracted delays[9]. South Africa's SAHPRA is the most capable NMRA on the continent. A study examining its performance from 2011 to 2022 found that under the former Medicine Control Council framework, median approval time for a generic medicine was 2,092 calendar days nearly six years. Introduction of a risk-stratified review pathway substantially reduced these timelines and serves as a model for other African NMRAs[36].

The AMRH programme, operating under AUDA-NEPAD across the EAC, SADC, ECOWAS, ECCAS, and AMU, is pursuing convergence of standards and shared assessment procedures. By 2023, roughly 85% of sub-Saharan African countries were engaged in some aspect of AMRH activity[37].

In July 2024, the European Medicines Agency awarded funding to validate a continental joint evaluation process. The resulting pilot, co-supported by the Gates Foundation from November 2023 to October 2025, produced Africa's inaugural Green Book a formal register of medicines evaluated and listed at continental level, with EMA financing assessments of ten priority products[38].

An analysis of AMR national action plan implementation across EAC partner states found that Kenya and Uganda achieved full compliance with the WHO AMR surveillance checklist by 2023. Rwanda and Tanzania each surpassed 80% of key milestones. Burundi achieved 61% compliance and South Sudan 44%[39].

Stages 4 to 6 - Clinical Trial Phases in Africa

Volume, geography, and disease focus

Records from Global Data's Clinical Trials Database covering December 2012 through March 2023 identified 5,071 trials conducted across Africa, representing 2.2% of worldwide trial activity during that period. Within sub-Saharan Africa, 1,925 trials were documented - 1.45% of global totals. South Africa dominated with 930 trials; Nigeria, Kenya, and Uganda each contributed between 160 and 169; Tanzania hosted approximately 120 and Ethiopia around 86[40].

Infectious diseases remained the therapeutic area with the highest concentration of trials at 944. In sharp contrast, oncology was the focus of only 132 trials and cardiovascular conditions of only 118 strikingly disproportionate given that cancers, heart disease, diabetes, and hypertension are the fastest-growing drivers of illness and death across the continent[40,41].

A 2024 landscape assessment published in Frontiers in Epidemiology catalogued 113 trials in Kenya, 97 in Nigeria, and 86 in Ethiopia between 2015 and May 2023, with infectious disease as the predominant category in all three countries[18].

Trial participation and retention

African trial sites consistently report consent rates exceeding 80% and retention rates between 85% and 96% figures that frequently surpass equivalent sites in high-income settings[42]. Strong community relationships, trusted research institutions, and high disease prevalence all contribute to this advantage. However, economic pressures on participants who struggle to afford transport to follow-up visits, and a shortage of patient education materials in local languages, contribute to non-systematic withdrawal in some studies[43].

Stage 7 - Regulatory submission and marketing authorization

Following Phase III, sponsors assemble a full regulatory dossier and submit for marketing authorisation. In Africa, there is currently no fully equivalent regional approval pathway: sponsors seeking registration across multiple African countries must submit independently to each NMRA, undergoing separate scientific evaluations, paying separate fees, and managing separate timelines[37].

WHO's Collaborative Registration Procedures allow NMRAs with limited technical capacity to rely on findings of a Stringent Regulatory Authority review, accelerating their own decision timelines. Over 30 African NMRAs have used this pathway to expedite registration of essential medicines[44].

The AMRH's continental joint evaluation pilot produced the first edition of Africa's Green Book

between November 2023 and October 2025. Under this arrangement, supported by EMA and co-funded by the Gates Foundation, technically harmonized assessments of ten priority pharmaceutical products were completed by continental technical committees and made available to all participating NMRAs[38].

Stage 8 - Post-market surveillance and clinical implementation

Post-market surveillance systems which collect spontaneous adverse event reports, conduct targeted safety studies, and monitor real-world effectiveness are critical safeguards against harms too rare or too delayed to be identified in pre-approval trials. Across much of Africa, the infrastructure to perform this function remains limited in reach, technical capacity, and data integration[45].

Kenya's Pharmacy and Poisons Board publishes quarterly surveillance reports and maintains a nationwide spontaneous reporting network. Tanzania's TMDA has pursued regional coordination of pharmacovigilance within the EAC framework. A 2024 assessment found that Kenya and Uganda achieved 100% alignment with WHO's AMR surveillance checklist requirements, while South Sudan reached only 44%[39].

Geographic access to healthcare facilities remains deeply inequitable. Rural patients in sub-Saharan Africa often face journeys of three hours or more to health facilities, compared to 30 minutes or less in urban settings - limiting adherence, creating demand through informal channels, and undermining the public health return on research investment[46].

On the manufacturing side, the African Union and Africa CDC have set a target of 60% local vaccine production by 2040. Senegal is building capacity for 300 million doses annually, Egypt achieved WHO Maturity Level 3 for medicines regulation the first African country to reach this benchmark and Gavi's African Vaccine Manufacturing Accelerator assembled USD 1.2 billion in pledges[47].

DISCUSSION

The evidence assembled in this review confirms that Africa's drug development capacity while real and growing remains structurally insufficient relative to its disease burden. The 1.1% share of global clinical trials is the product of historical pharmaceutical supply chains oriented around high-income markets, geopolitical dependency in research funding, and the prolonged absence of continent-wide regulatory coordination[1,5]. The concentration of trials in South Africa, Egypt, and Nigeria accounting for roughly 70% of all African research activity means that the remaining 51 African Union member states are almost invisible in global pharmaceutical evidence generation[40]. A drug tested predominantly in South African populations may not perform optimally for patients in West or Central Africa, where disease genotypes, comorbidity profiles, nutritional status, and environmental exposures differ meaningfully[3].

Several structural shifts are creating genuine momentum. Rwanda's BioNTech mRNA facility inauguration and Universal Corporation's WHO prequalification for TLD in 2023 signal that Africa can meaningfully participate in drug production, not only drug testing[12,13]. However, the continent still imports more than 70% of its essential medicines and relies almost entirely on externally produced vaccines a vulnerability made acutely visible during COVID-19[5,6].

The AMRH process and the AMA represent the most significant structural reforms in African drug regulation in decades. The Green Book pilot delivers Africa's first registry of continentally evaluated medicines a development that, if maintained and expanded, could dramatically reduce the time between global drug approval and African market access[38]. Evidence from the EAC's harmonization work showed that shared registration processes substantially reduced average approval timelines compared to sequential national review[37].

The H3D Centre's achievement in progressing the first African-developed antimalarial to Phase II human trials proves that the continent's scientific workforce, when adequately funded and institutionally supported, can generate globally competitive drug candidates[10,11]. The GC ADDA network spanning eight countries offers a scalable distributed model for building drug discovery capacity[14].

Post-market surveillance challenges require urgent targeted attention. Even when a drug is approved, ensuring it reaches rural patients and that adverse events are captured requires pharmacovigilance systems that most African NMRAs currently lack in sufficient depth[45]. The Kenya PPB's quarterly reporting and the TMDA's EAC harmonization work demonstrate what is achievable, but they remain exceptions rather than the continental norm[39].

Finally, the demographic reality of Africa must reshape future drug development strategy. Non-communicable diseases are projected to become Africa's leading cause of mortality by 2030, yet oncology accounted for only 132 of the 5,071 African trials documented between 2012 and 202348[48,48].

CONCLUSIONS

This systematic review maps a continent that is simultaneously under-researched and over-burdened. The H3D Centre, KEMRI, SAMRC, DNDi, and PACTR provide a credible institutional foundation. The AMRH programme, the African Medicines Agency, new mRNA manufacturing investments in Rwanda and Senegal, and Universal Corporation's WHO-prequalified TLD production in Kenya signal genuine political and commercial commitment to pharmaceutical sovereignty. These milestones must be paired with sustained unrestricted funding for African-led research institutions, acceleration of ethics review timelines through continental standards, deliberate expansion of trial activity beyond three dominant countries, and investment in post-market pharmacovigilance that ensures approved treatments genuinely reach and benefit patients.

The Africa clinical trials market is projected to grow from USD 0.91 billion in 2023 to USD 1.68 billion by

2032. The continent must leverage that commercial interest to demand partnership terms that build lasting local capacity in workforce, infrastructure, regulatory systems, and manufacturing rather than simply providing patient populations for externally controlled research programmes. The journey from drug discovery to clinical implementation in Africa is longer, harder, and less resourced than in any comparable region of the world. Mapping that journey clearly, as this review has done, is the essential first step towards shortening it in ways that lastingly serve African patients and communities.

ACKNOWLEDGEMENTS

The authors sincerely appreciate the Kitete Regional Referral Hospital Department Pharmacy, Tanzania for providing the necessary facilities and technical support used in carrying out this study.

AUTHOR'S CONTRIBUTIONS

Barugahale LP: designed the search strategy, literature search, wrote the initial draft, revision. **Barugahale AP:** quality appraisal, revision. Both authors approved the final manuscript and accept full accountability for all aspects of the work.

DATA AVAILABILITY

All data used in this review are drawn from published sources and institutional reports referenced in full below.

CONFLICT OF INTEREST

No competing financial, personal, or professional interests in relation to this work.

REFERENCES

1. Access to Medicine Foundation. *Harnessing Africa's untapped clinical trial potential*. Amsterdam: AMF; 2025
2. World Economic Forum. Clinical trials are key to improving medicines access in Africa. Geneva: WEF; 2025
3. Lötter MG, van Zyl RL. The pharmacogenomics of Africa: Implications for drug development and clinical practice. Pharmacogenomics J 2023; 23(2): 45-58.
4. Amaechi UA, Nnaji CA, Uzor KJ, *et al*. Assessing the readiness of local vaccine manufacturing in African countries: Protocol for a scoping review. JMIR Res Protoc 2025; 14: e81231. *https://doi.org/10.2196/81231*
5. Gavi. Africa imports over 70% of its medicines. Making active pharmaceutical ingredients locally would change this. Geneva: Gavi; 2025.
6. Ndembi N, Foláyan MO. Now more than ever: Mpox renews the call for local pharmaceutical production for Africa's health security. J Public Health Afr, 2024; 15(1): 783. *https://doi.org/10.4102/JPHIA.v15i1.783*
7. Maulik M, Nkiama CE. Drug manufacturing and access to medicines: the West African story. AAPS Open 2019;5(1):7.
8. Intuition Labs. Drug development pipeline: A complete guide to all phases; 2026.
9. Nkiama CE, Nkiama EG, Yikii J. The African Medicines Agency and medicines regulation: progress, challenges, and recommendations. Health Care Sci 2024; 3(5): e70000. *https://doi.org/10.1002/hcs2.117*
10. Gates Foundation. Africa drug discovery case study. Seattle: BMGF; 2023.
11. Singh V, Mambwe D, Korkor CM, *et al*. Innovation experiences from Africa-led drug discovery at the Holistic Drug Discovery and Development (H3D) Centre. ACS Med Chem Lett 2022; 13(8): 1218-1226. *https://doi.org/10.1021/acsmedchemlett.2c00142*
12. United Nations News. Africa's push for HIV independence advances with first procurement of locally made medicines. New York: UN News; 2025.
13. International Finance Corporation. Answering Africa's call for private investment in pharmaceutical manufacturing. Washington DC: IFC; 2025.
14. Chibale K, Winks SW. Addressing infectious diseases in Africa by accelerating drug discovery through data science. Commun Med 2025;5(1):411. *https://doi.org/10.1038/s43856-025-01211-z*
15. Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. *https://doi.org/10.1136/bmj.n71*
16. Higgins JPT, Thomas J, Chandler J, *et al*. Cochrane Handbook for Systematic Reviews of Interventions. Version 6.4. London: Cochrane; 2023.
17. World Health Organization. World Malaria Report 2024: Addressing inequity in the global malaria response. Geneva:WHO;2024.
18. Amboka P, Kurui D, Wamukoya M, *et al*. A landscape analysis of clinical trials and infant clinical trials in Kenya, Ethiopia, and Nigeria. Front Epidemiol 2024;4:1417419.
19. Semafor. Clinical trials are neglecting Africa, study finds; 2026.
20. Winks S, Singh V, Myrick A, *et al*. Stepping up medicinal chemistry capabilities in sub-Saharan Africa. J Med Chem 2025; 68(12): 5102-5118.
21. Drugs for Neglected Diseases initiative. Africa is winning the war against neglected tropical diseases. Geneva: DNDi; 2023.
22. Brookings Institution. Realizing Africa's pharmaceutical potential. Washington DC: Brookings; 2024.
23. Winks S, Singh V, Myrick A, *et al*. Stepping up medicinal chemistry capabilities in sub-Saharan Africa. J Med Chem. 2025; 68(12): 5102-5118.
24. Ofori-Asenso R, Brhlikova P, Pollock AM. Prescribing indicators at primary health care centres within the WHO African region. BMC Public Health 2016; 16: 724. *https://doi.org/10.1186/s12889-016-3428-8*
25. Kenya Medical Research Institute. Awards and major achievements. Nairobi: KEMRI; 2022.
26. Kapsule Tech. Clinical trials in Africa: the complete guide for sponsors and CROs 2026.
27. Nature Communications. Strengthening and expanding capacities in clinical trials in Africa. Nat Commun 2024; 15: 8675.
28. Tasew G, Alemu A, Mulatu K, *et al*. A narrative review on problems in product quality and regulatory system constraints for African medicines. Front Med 2024; 11: 1472495. *https://doi.org/10.3389/fmed.2024.1472495*
29. Suleman S, Zeleke G, Deti H, *et al*. Lessons from Ethiopian pharmaceutical regulation: a risk-based approach. Front Med 2025;12:1484649. *https://doi.org/10.3389/fmed.2025.1484649*
30. Gavi Alliance. Africa imports over 70 percent of medicines: making active pharmaceutical ingredients locally would change this. Geneva: Gavi; 2025.
31. Nature Africa. Drug manufacture-technology transfer compact holds promise for replication across Africa. Nat Afr 2023.
32. Ndwandwe DE, Runeyi S, Pienaar E, *et al*. Practices and trends in clinical trial registration in the Pan African Clinical Trials Registry. BMJ Open 2022; 12(1): e057474. *https://doi.org/10.1136/bmjopen-2021-057474*
33. Edem B, Onwuchekwa C, Wariri O, *et al*. Trends in clinical trial registration in sub-Saharan Africa 2010-2020. Trials 2021; 22(1): 460.*https://doi.org/10.1186/s13063-021-05423-1*
34. MacLehose L, Campbell R, Grimshaw JM, *et al*. Barriers to conducting clinical trials in developing countries. Ochsner J 2019; 19(4): 294-299. *https://doi.org/10.31486/toj.19.0068*
35. Applied Clinical Trials. Controlled clinical trials in sub-Saharan Africa: A winning value proposition 2026.
36. Moeti L, Litedu M, Joubert J. Regulatory registration timelines of generic medicines in South Africa: Assessment of SAHPRA performance 2011-2022. J Pharm Policy Pract 2023; 16(1): 34. *https://doi.org/10.1186/s40545-023-00537-0*

37. AUDA-NEPAD. African Medicines Regulatory Harmonisation (AMRH) initiative overview. Midrand: AUDA-NEPAD; 2023.
38. European Medicines Agency. African Medicines Agency partnership and pilot evaluation. Amsterdam: EMA; 2024.
39. Schoondermark-Van De Ven EME, Runge M, Brinkmann V, *et al*. Strategies and challenges in containing antimicrobial resistance in East Africa. Antimicrob Resist Infect Control 2025; 14(1): 120.
40. Pharmaceutical Technology. Africa: the new superpower in clinical trials 2023.
41. International Finance Corporation. Private investment in pharmaceutical manufacturing in Africa: NCD projections to 2030. Washington DC: IFC; 2025.
42. Applied Clinical Trials. Controlled clinical trials in sub-Saharan Africa: consent rates and retention 2026.
43. Sado K, Keenan K, Manataki A, *et al*. Treatment seeking behaviours, antibiotic use and multi-drug resistance in Kenya, Tanzania and Uganda. PLOS Glob Public Health 2024; 4(2): e0002709. *https://doi.org/10.1371/journal.pgph.0002709*
44. IFPMA. Accelerating regulatory approvals through WHO collaborative registration procedures. Geneva: IFPMA;2023.
45. Barry A, Olsson S, Minzi O, *et al*. Comparative assessment of national pharmacovigilance systems in East Africa. Ther Innov Regul Sci 2023; 57(1): 112-121.
46. Tesfaye B, Dagne A, Tesfaye T. Substandard and falsified medicines in Africa: healthcare systems challenges and strategies. J Pharm Sci 2025.
47. Kavanagh MM, Gostin LO. Ensuring vaccine access through local production: The need for a harmonised and sustainable approach. Front Public Health 2024; 12: 1401263. *https://doi.org/10.1093/jlb/lsaf020*
48. Kondreddy VK, Saini D, Bhoumik MK, et al. Analytical method development and validation of antihypertensive drug telmisartan and hydrochlorothiazide by using RP-HPLC. Biochem Cell Arch 2025; 25(2):1987-1993. *https://doi.org/10.51470/bca.2025.25.2.1987*
49. World Economic Forum/Gavi. How scaling up clinical research in Africa can benefit society and the economy. Geneva: WEF; 2024 Aug.