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GLS INSIGHTS™

CLINICAL DEVELOPMENT AND GLOBAL HEALTH · BENCHMARK SERIES

The Future of Clinical Trials in Africa

The Scientific Imperative for Representative Evidence

Building the Research Ecosystems That Produce It

PART I OF III

GUIDING PRINCIPLES

REPRESENTATIVE SCIENCE

ECOSYSTEMS

HUMAN CAPITAL

TRUST

FUTURE PATIENTS

Guosa Life Sciences
Advancing Life Through Better Medicine

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About This Series

Conversations about clinical development in Africa have traditionally centered on access, disease burden, and operational complexity. Those issues remain real. They no longer capture the strategic question that matters most. The question is no longer whether Africa matters to the future of clinical development. It is how the continent's scientific institutions, demographic trajectory, and expanding healthcare systems will reshape the geography of healthcare itself.

This three-part benchmark series from GLS Institute examines that shift. It rests on a single premise: Africa should not be positioned only as a place to run trials, but as a contributor to more representative science, stronger evidence, future healthcare markets, and the next generation of global health innovation. Part I sets out the evidence and the framework. Part II turns to execution. Part III examines how research ecosystems evolve: artificial intelligence, precision medicine, regional manufacturing, and the future architecture of global clinical development.

A Note on Method and Sources

This report synthesizes publicly available data from intergovernmental and regulatory bodies, peer-reviewed literature, and industry analytics, current to mid-2026. Quantitative claims are referenced to their primary sources, listed at the end. Where figures are estimates or projections, they are identified as such. The country profiles draw on named institutions and documented programs rather than general impressions. Two categories of evidence anchor the analysis: representation data on where trials are conducted, drawn from the WHO International Clinical Trials Registry Platform, IQVIA, and the Access to Medicine Index; and institutional evidence on capability, drawn from the public records of the research organizations profiled.

Executive Summary

The most consequential shift in twenty-first-century healthcare is not technological. It is demographic. Africa is home to roughly 1.5 billion people, about 18% of the world's population, and is projected to reach close to 2.5 billion by 2050, about one in four people on earth[1]. The continent carries an estimated 25% of the global disease burden[2]. Yet it hosts a fraction of the research that defines how the world's medicines are developed and approved.

The scale of that gap is now measurable. Of the 20,825 trials that began globally in 2023, only about 819, roughly 4%, were hosted by African countries[3]. In 2025, the WHO's Western Pacific region registered more than thirty times as many new trials as the whole of Africa[4]. The 2024 Access to Medicine Index found that only 27.5% of late-stage R&D projects from twenty major pharmaceutical companies included even one African country[5]. This is the representation gap, and it is the central fact of this report.

GLS Institute reads this imbalance not primarily as a deficit but as one of the most significant under-priced opportunities in global health. The gap is a measure of evidence not yet generated, markets not yet served, and scientific capability not yet fully recognized. The organizations that close it will not simply expand a trial footprint; they will help determine the representativeness of the evidence base on which future medicine depends.

The strategic significance of Africa extends well beyond patient enrollment. Human capital, regulatory convergence, scientific partnerships, and digital transformation are producing research ecosystems whose value compounds across studies. The first continental regulator, the African Medicines Agency, has entered its expansion phase: still underfunded and partly donor-dependent, but real, and led by an African regulator of standing. African scientists are no longer only running other people's trials: they are designing and approving their own products, from the R21 malaria vaccine first licensed in Ghana[11] to the first-in-human HIV vaccine trial launched in Cape Town in January 2026[10]. The future leaders of life sciences will be distinguished less by where they ran trials in the past than by where they invested in talent, trust, and ecosystems. That trajectory is real but not inevitable: it is threatened by an acute 2025 funding shock and by structural headwinds examined candidly in Section V, which any organization acting on this analysis should weigh alongside the opportunity.

Key Findings

Representative Science Drives Better Medicine™

The quality of evidence depends on who contributes to it. Genetics, environment, and diet alter how patients respond to therapy; evidence drawn from narrow populations generalizes poorly. With Africa supplying under 2% of the genomic data used in research, representativeness is now a scientific requirement, not only an equity goal.

Ecosystems Outperform Sites™

Infrastructure can be built, technology acquired, capital mobilized. Trust, institutions, trained people, and durable partnerships cannot be replicated quickly. Competitiveness is determined by the interaction of these factors, the ecosystem, not by site counts alone.

Human Capital Is the Decisive Advantage™

A young, growing, and increasingly trained scientific workforce is the continent's least replicable asset. Global standards and local execution are complementary, not competing: context, relationships, and risk awareness held locally are decisive to delivery and cannot be imported. Institutions such as KEMRI-Wellcome and the South African Medical Research Council demonstrate that locally led science can reach the global frontier[12].

Trust Is Strategic Infrastructure™

Community trust shapes recruitment, retention, adherence, data quality, and resilience. It is built over years and lost in moments. Organizations that treat trust as an outcome under-invest; those that treat it as an asset compound returns.

Future Patients Are Future Markets™

The populations enrolled in trials today are among the most important healthcare markets of tomorrow. A continental pharmaceutical market projected to exceed USD 40 billion by the 2030s converges with the geography of future evidence.

SECTION I

Setting the Context: Why Conventional Thinking Is Incomplete

Much of the historical narrative about Africa has been written in the language of limitation, of what is missing. That framing obscures the more important development: the continent's growing capacity to contribute to representative science, stronger institutions, and the next generation of healthcare innovation. The most useful starting point is not the list of constraints but the size of the mismatch between burden and study.

The Representation Gap

Africa carries a disproportionate share of the world's disease and a minute share of the world's research. The continent holds about 18% of the global population and roughly a quarter of the global disease burden, yet hosts only around 3–4% of clinical trials[2][3]. The consequence is not abstract. When evidence is generated overwhelmingly in other populations, treatment guidelines and dosing are extrapolated to African patients rather than tested in them, and the continent contributes under 2% of the genetic data analyzed in genomics research[3].

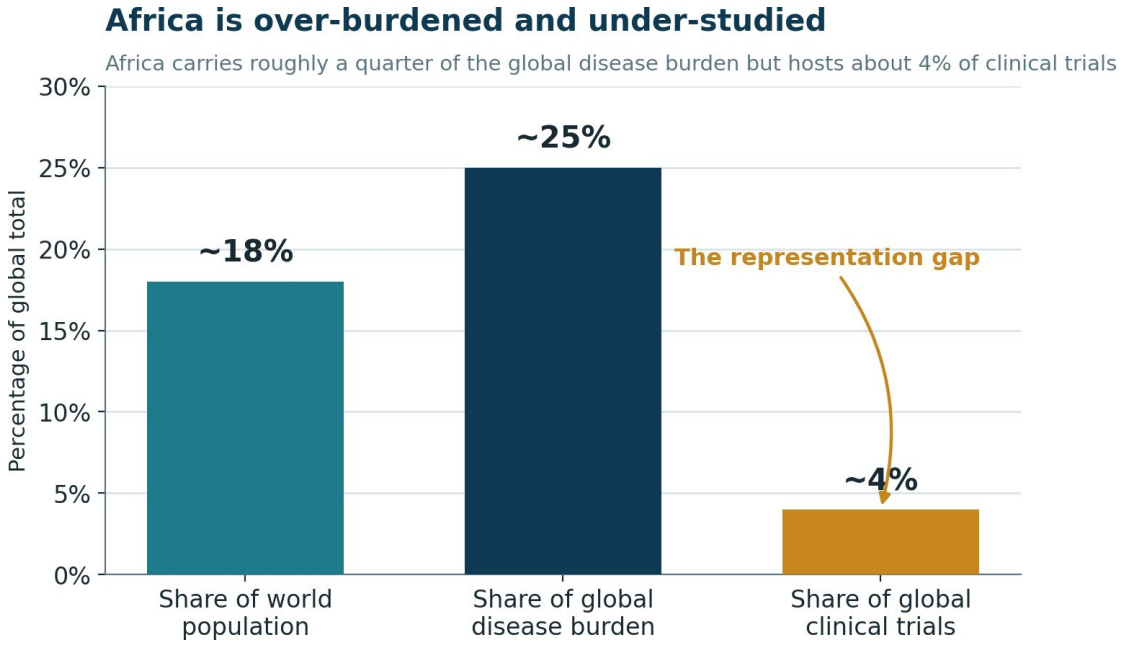

Figure 1. Africa's share of population, disease burden, and clinical trials. *Source: UN World Population Prospects 2024; IQVIA; Semafor analysis of five major journals, 2026.*

The gap is equally visible in raw counts, and it is widening rather than closing. WHO registry data show that in 2025 the Western Pacific region recorded 31,097 newly registered trials against 822 across all of Africa[4]. The same source shows the ratio growing over time: from roughly 24-to-1 in 2016 to 38-to-1 in 2025, as registrations in the Western Pacific and South-East Asia accelerated while Africa's remained broadly flat. The pattern holds at the level of corporate pipelines: the 2024 Access to Medicine Index found that only 27.5% of late-stage R&D projects from twenty leading companies, and only 16 of 80 candidate medicines for priority diseases, were being tested in any African

country[5].

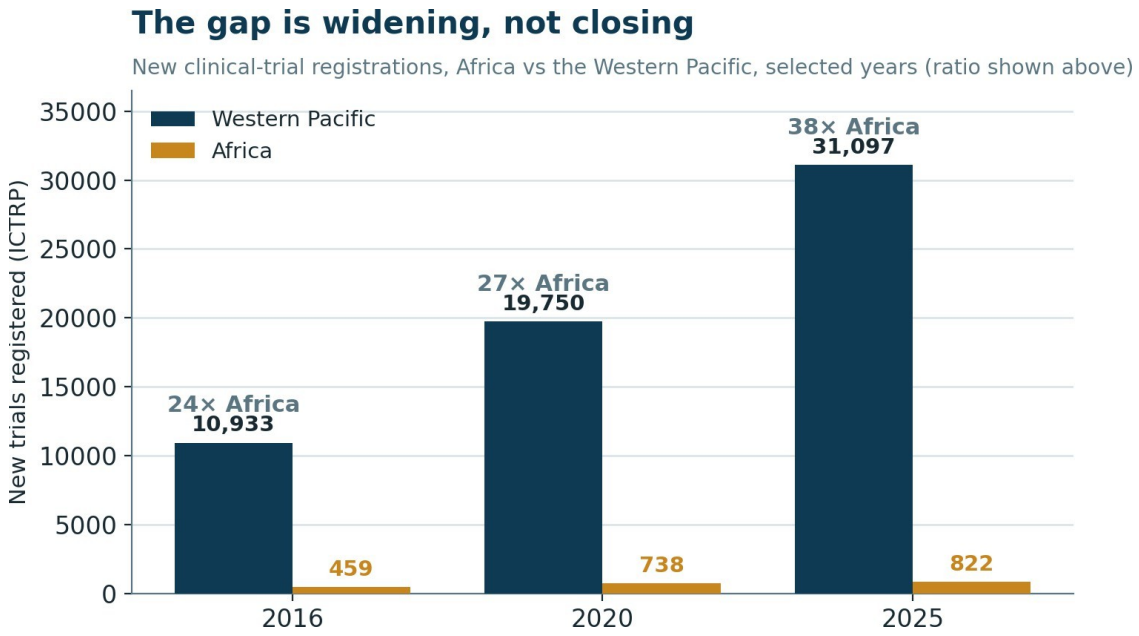

Figure 2. New clinical-trial registrations, Africa vs the Western Pacific, selected years. *Source: WHO International Clinical Trials Registry Platform (ICTRP), accessed 2026. All values are WHO-reported counts.*

Why Diversity Is a Scientific Imperative

Diversity in trials has historically been discussed as a matter of equity and inclusion. That framing is correct but incomplete. Representative evidence improves understanding of treatment response, strengthens the generalizability of findings, and underpins precision medicine. Where biology varies,
in drug metabolism, in disease subtype, in comorbidity, evidence drawn from unrepresentative samples is not merely unfair; it is less accurate. Scientific excellence and representativeness are mutually reinforcing. Diversity is becoming a prerequisite for better medicine, not an adjunct to it.

> **EXECUTIVE INSIGHT**
> *Representativeness is no longer a social objective layered onto science. It is a condition of scientific validity. Evidence is only as good as the populations that generate it.*

SECTION II

The GLS Research Ecosystem Framework

Discussion of clinical development in Africa has long focused on infrastructure gaps and site numbers. That lens is too narrow. The decisive question is not whether individual countries hold isolated capabilities, but whether interconnected ecosystems are emerging that can sustain scientific innovation. Infrastructure can be replicated, technology acquired, capital mobilized. Trust, institutions, human capital, and enduring partnerships are far harder to reproduce, and they are what ultimately determine resilience.

Eight Dimensions of Ecosystem Strength

GLS Institute evaluates research environments across eight interacting dimensions. No single dimension is sufficient; strength emerges from their interaction.

Table 1. The eight dimensions of the GLS Research Ecosystem Framework.

Dimension	What it measures
Regulatory readiness	Predictability, reliance mechanisms, and harmonization. Increasingly a strategic differentiator rather than an administrative function.
Scientific capability	The ability to generate meaningful evidence, support complex study designs, and contribute to global knowledge, a competitive advantage, not just an operational requirement.
Operational infrastructure	Sites, laboratories, and systems, essential, but valuable mainly as an enabler of collaboration rather than as an isolated asset.
Digital maturity	Connectivity, electronic data systems, decentralized methods, AI, and analytics that expand the possibilities for evidence generation.
Workforce capacity	The ability to attract, develop, and retain scientific talent, the least replicable asset of all.
Community engagement	Trust as the foundation of recruitment, retention, adherence, data quality, and resilience.
Data & IP governance	Privacy, intellectual-property protection, specimen and genomic governance, and responsible cross-border data flows.
Sustainability	The capacity to generate value beyond individual studies, institutions, careers, and capabilities that outlast a single program.

Regulatory Convergence: From Fragmentation to a Continental System

For decades, fragmented national regulation discouraged investment: a product approved in one country had to be re-registered, study by study, in the next. That is changing. The African Medicines Agency (AMA), established by treaty that entered into force in November 2021, had been ratified by 31 member states as of December 2025[6]. Its first Director General, Delese Mimi Darko, previously led Ghana's Food and Drugs Authority, the agency that became the first in the world to approve the R21 malaria vaccine[7]. The AMA is being implemented in phases, Foundation (2024–2025),

Expansion (2026–2030), and Maturity (2031 onward), building on regional work-sharing mechanisms such as the East African Community initiative and the SADC ZaZiBoNa program[6].

> **EXECUTIVE INSIGHT**
> *A harmonized system means approval in one country can be recognized across others. Regulatory readiness is shifting from a barrier toward a continental asset, though the AMA is only early in its expansion phase, underfunded and reliant in part on external support, and its promise is not yet fully realized.*

Human Capital Is the Decisive Advantage™

Infrastructure investments can be replicated; human-capital advantages cannot. The most under-appreciated implication of Africa's demographic transformation is its effect on scientific talent. Population growth, expanding educational investment, and maturing research communities are producing increasingly sophisticated workforces. Organizations that invest in people today are building assets whose value extends far beyond any single program. Talent, not infrastructure alone, is becoming the defining competitive advantage of future research ecosystems.

The GLS Research Ecosystem Maturity Model

Not all ecosystems evolve at the same pace, nor should they. The expectation that every environment converges on an identical model is itself a misconception; diversity is a strength of global science. GLS Institute describes ecosystem evolution across five levels, each defined by observable criteria rather than impression.

Table 2. The five levels of the GLS Research Ecosystem Maturity Model. Maturity is dynamic, not fixed, a country may sit at different levels by therapeutic area.

Level	Defining characteristics	Illustrative markers
Emerging	Early-stage capability; limited trial history; nascent regulatory function.	First dedicated trial sites; reliance on external sponsors.
Developing	Growing capacity and infrastructure; expanding investigator base.	Multiple active sites; regional collaboration begins.
Established	Strong scientific and operational foundations across several therapeutic areas.	Phase III capability; recognized regulator; trained workforce.
Advanced	Internationally integrated; capable of complex, multi-country programs.	First-in-human studies; reference laboratories; product approvals.
Strategic Innovation Hub	Shapes the direction of global science and product development.	Locally originated products; continental scientific leadership.

The Maturity Model describes stages of development. Part III introduces a companion instrument, the GLS Research Ecosystem Maturity Index™, which scores ecosystems numerically across five weighted dimensions. The two are related but not interchangeable: the Model is descriptive and has five levels; the Index is a 0–100 composite reported in four bands (Advanced, Established, Developing, Emerging) and does not yet score for the Strategic Innovation Hub level, which no ecosystem is judged to have reached. Where the Model and the Index differ for a given country, the Index is the more conservative reading, because it weights regulatory maturity at 25%.

Applying the Model: An Indicative Classification

A framework that classifies nothing is only a taxonomy. The table below places this report's profiled ecosystems on the model, with the basis for each judgment. These are directional assessments drawn from the documented evidence in Section III, trial-center counts, regulatory milestones, and demonstrated capability, not precise rankings, and they vary by therapeutic area. They are offered to be argued with.

Ecosystem	Indicative level	Basis
South Africa	Advanced	29 TB-capable centers; first-in-human capability; SAHPRA; reference laboratories. Approaching innovation-hub status in HIV and TB.
Kenya	Established → Advanced	KEMRI-Wellcome (est. 1989); strong vaccine and infectious-disease capability; regional anchor role.
Uganda	Established	Makerere programs; sustained HIV/TB trial record; BRILLIANT consortium member. Scores Developing on the Part III Index, which weights regulatory maturity heavily.

Ecosystem	Indicative level	Basis
Ghana	Established	Standard-setting regulator (first to approve R21); Noguchi Institute; emerging manufacturing.
Nigeria	Developing → Established	Large but concentrated capacity; second to approve R21; institutions such as NICRAT still maturing.
Tanzania	Developing	Five TB-capable centers; Muhimbili; R21 Phase III participation; active in EAC harmonization.
Mali	Developing (specialized)	Deep, focused malaria-research capability; contributed to R21 Phase III evidence base.
Ethiopia	Emerging → Developing	Significant demographic potential; comparatively thin documented trial infrastructure to date.

Scope note: This edition profiles sub-Saharan exemplars. North Africa, notably Egypt, one of the three countries that together host roughly 70% of African clinical research, sits outside these profiles and would, on trial volume, classify among the most active ecosystems on the continent. It is addressed in Part II.

From Transactional Relationships to Strategic Partnerships

The future of clinical development favors organizations that move beyond transactional models. Sponsors, governments, academic institutions, regulators, and communities increasingly operate within interconnected ecosystems. The most resilient of these are built not around individual projects but around enduring relationships. Transactional relationships create projects; strategic partnerships create ecosystems.

SECTION III

Country Ecosystem Profiles

Perhaps the greatest misconception about clinical development in Africa is that the continent can be read through a single narrative. It cannot. Fifty-four countries have evolved distinct strengths shaped by history, institutions, investment, and disease priorities. That diversity is not fragmentation; it is resilience. Just as diversified portfolios are less exposed to individual shocks, diverse research ecosystems create opportunities for specialization and complementary capability. The profiles below are illustrative, not exhaustive, and each names the institutions and programs that anchor its claim.

One structural fact frames them all: capacity is concentrated. Roughly 70% of African clinical research occurs in just three countries: Egypt, South Africa, and Nigeria[3], even as capability spreads steadily across the continent. The profiles that follow focus on sub-Saharan exemplars; Egypt and the wider North African ecosystem, though central to that 70%, are reserved for Part II and are not assessed here.

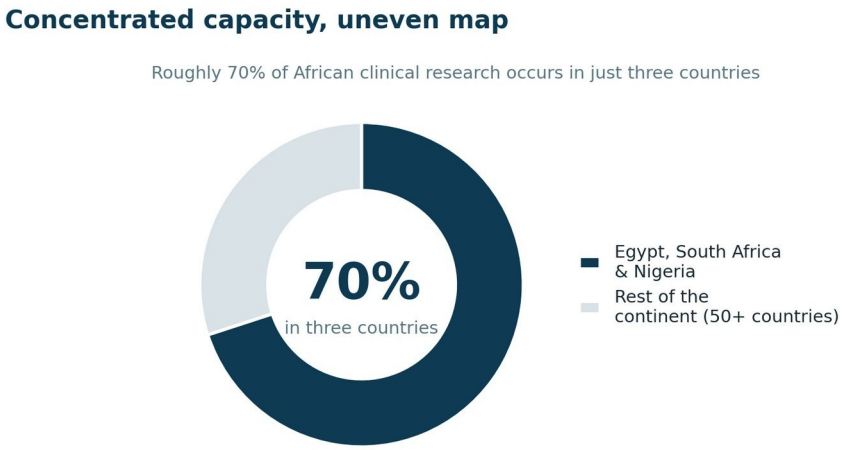

Figure 3. Geographic concentration of African clinical research. *Source: IQVIA, via World Economic Forum, 2024.*

South Africa — *Advanced Innovation Ecosystem*

South Africa has the continent's most developed research infrastructure, built over decades through the South African Medical Research Council (SAMRC), the University of the Witwatersrand (Wits RHI and Wits VIDA), and the Desmond Tutu HIV Centre at the University of Cape Town. Its regulator, SAHPRA, is among Africa's most capable. In January 2026 the country launched the BRILLIANT 011 first-in-human HIV vaccine trial in Cape Town, an African-led study, predominantly directed by African women scientists[10]. South Africa demonstrates how an execution platform becomes an innovation platform.

Strategic strengths: HIV · TB · oncology · precision medicine · cell and gene therapy

Kenya — *Regional Scientific Hub*

Kenya illustrates the power of institutions and long-term partnership. The Kenya Medical Research Institute (KEMRI) and the KEMRI-Wellcome Trust Research Program, founded in 1989 with the

University of Oxford and anchored at Kilifi: run world-class research in malaria, HIV, TB, and vaccines, supported by a multi-hospital clinical surveillance network[12]. Kenya's value lies not only in studies conducted today but in its role as a regional anchor for future collaboration.

Strategic strengths: vaccines · epidemiology · public health · implementation science

Ghana — *Standard-Setting Regulator*

Ghana shows that influence is not determined by scale. In 2023 its Food and Drugs Authority became the first regulator in the world to approve the R21/Matrix-M malaria vaccine, ahead of WHO prequalification[11], a decision later followed across the continent. The Noguchi Memorial Institute for Medical Research at the University of Ghana provides the scientific backbone[12], and the Serum Institute of India is establishing vaccine manufacturing in Accra. Ghana's regulatory leadership now extends continentally through the AMA.

Strategic strengths: vaccines · regulatory science · women's health · manufacturing

Nigeria — *Scale and Future-Market Potential*

Nigeria's importance lies in the intersection of demographics, urbanization, and future healthcare demand. As the continent's most populous country, it was the second in the world to approve the R21 vaccine[11] and is building dedicated capability such as the National Institute for Cancer Research and Treatment. Nigeria embodies the principle that future patients are future markets: the scale that makes it a research priority is the same scale that will make it a commercial one.

Strategic strengths: cardiometabolic disease · oncology · women's health · digital health

Uganda — *Global Health Leadership*

Uganda's strengths were shaped by decades of international partnership, with Makerere University's research programs contributing to major HIV and TB trials and to the BRILLIANT HIV vaccine consortium. Its experience underlines a recurring lesson: long-term relationships create capabilities that outlast individual projects.

Strategic strengths: vaccines · infectious disease · community-engaged research

Tanzania — *Growing Research Ecosystem*

Tanzania demonstrates the value of sustained investment and regional collaboration, anchored by Muhimbili and a regulator, TMDA, active in East African harmonization. It hosted part of the multi-country Phase III program for the R21 malaria vaccine, reflecting steady progression through the stages of maturity.

Strategic strengths: vaccines · oncology · infectious disease

Mali — *Research Collaboration Ecosystem*

Mali shows that scientific influence is not determined by economic scale. Through sustained malaria research partnerships, it contributed to the Phase III evidence base for the R21 vaccine, enrolling children alongside Burkina Faso, Kenya, and Tanzania[11]. Mali highlights the role of trust and focused specialization in ecosystem development.

Strategic strengths: malaria · vaccines · community-engaged research

Ethiopia — *Future Healthcare Market*

Ethiopia's long-term significance is driven by demographic scale and expanding healthcare systems. As one of Africa's most populous countries, its importance reflects the broader shift in the geography of healthcare demand more than its current trial footprint, making workforce and infrastructure development the strategic priorities.

Strategic strengths: public health · workforce development · healthcare infrastructure

Table 3. Illustrative ecosystem archetypes and anchor institutions.

Country	Archetype	Signature capability / anchor
South Africa	Advanced Innovation Ecosystem	SAMRC, Wits, UCT; first-in-human HIV vaccine trial (2026)
Kenya	Regional Scientific Hub	KEMRI-Wellcome Trust Program (est. 1989), Kilifi
Ghana	Standard-Setting Regulator	First worldwide to approve R21 vaccine; Noguchi Institute
Nigeria	Scale & Future-Market Potential	Largest population; second to approve R21; NICRAT
Uganda	Global Health Leadership	Makerere University HIV/TB research programs
Tanzania	Growing Research Ecosystem	Muhimbili; TMDA; R21 Phase III participation
Mali	Research Collaboration Ecosystem	Malaria research; R21 Phase III evidence base
Ethiopia	Future Healthcare Market	Demographic scale; expanding health systems

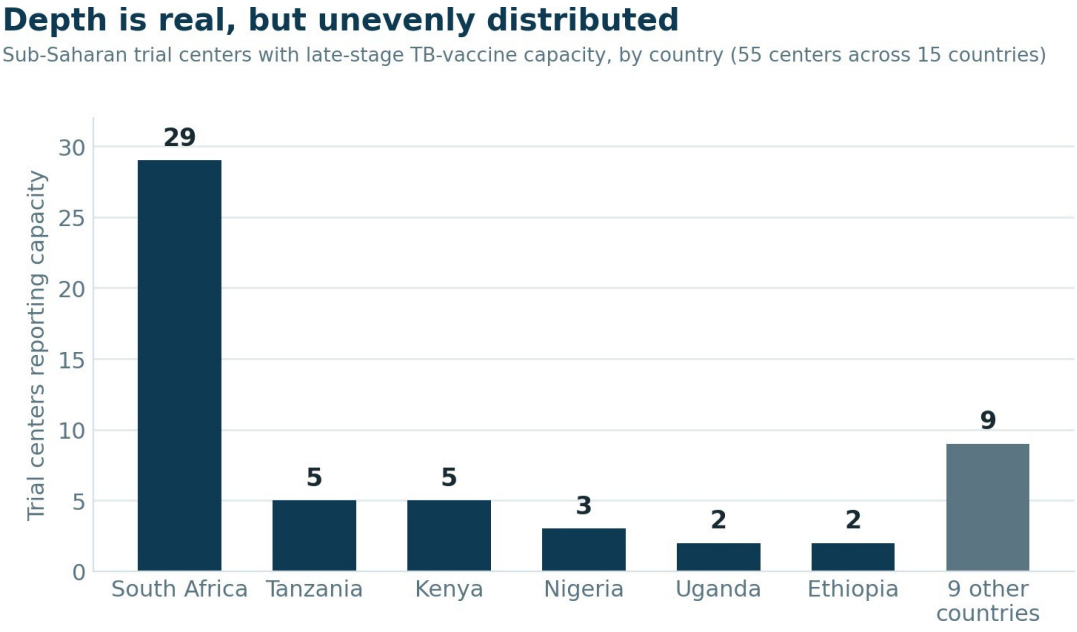

Figure 4. Late-stage TB-vaccine trial capacity by country (55 sub-Saharan centers with country attribution). *Source: TB Vaccine Clinical Trial Centre Directory, 2023.*

THE GLS PERSPECTIVE

Africa's strength lies not in any single country but in the complementarity of distinct ecosystems. The future favors organizations that integrate complementary capabilities rather than seeking uniformity. Diversity is resilience.

SECTION IV

The Future Geography of Healthcare

Market leadership in healthcare has historically followed established markets. History suggests it rarely stays still. Population growth, urbanization, and expanding healthcare systems are gradually relocating the center of gravity of healthcare demand, and the future geography of healthcare need not mirror the geography of historical pharmaceutical markets.

Future Patients Are Future Markets™

This is the central thesis of the series. The populations enrolling in trials today are among the most important healthcare consumers of tomorrow. The direction of travel is clear even where precise figures are not. Commercial market-research estimates put Africa's clinical-trials market near USD 0.96 billion in 2024, growing to roughly USD 1.68 billion by 2032, about 7.2% a year[8], while a peer-reviewed analysis projects the broader continental pharmaceutical market to exceed USD 40 billion by the 2030s as fragmented national markets consolidate under harmonized regulation[6]. A separate African Union and Africa CDC estimate, used in Parts II and III of this series, values the continental pharmaceutical market nearer USD 50 billion; the two figures rest on different scopes and methods and should be read as a range rather than a single number. These market figures should be read as directional: they originate largely with commercial vendors and institutional estimates, methodologies vary, and they are best treated as indicators of trajectory rather than precise values. The trajectory itself, a young, urbanizing population and expanding health systems, is well established. Organizations that invest early in ecosystems, talent, and partnerships are positioning themselves within future sources of demand, not only current sites of supply.

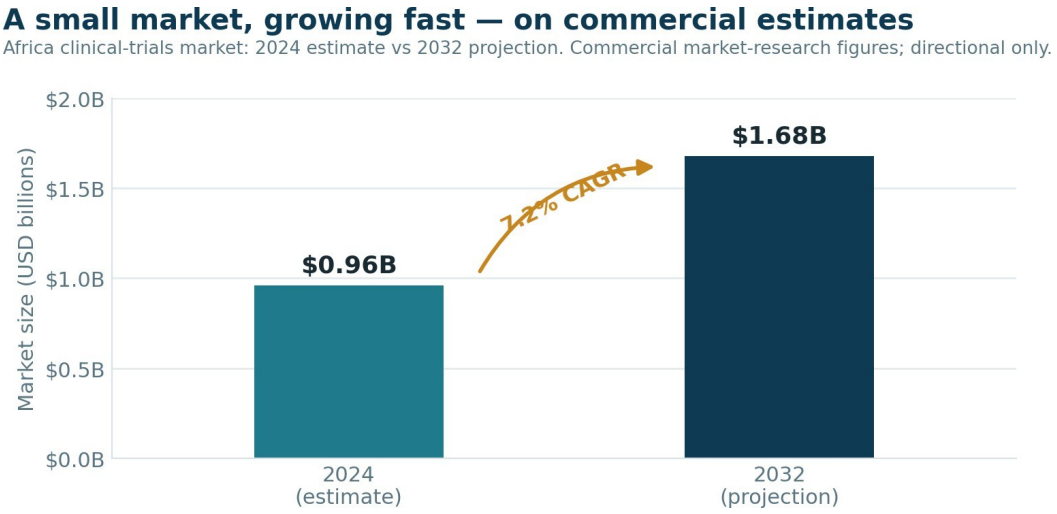

Figure 5. Africa clinical-trials market: 2024 estimate vs 2032 projection. *Source: Fortune Business Insights / Towards Healthcare, 2024–2025. Commercial estimates; directional only.*

The Convergence of Science and Commerce

Scientific and commercial strategies have often been treated separately. That distinction is eroding. Representative science produces stronger evidence; stronger evidence supports regulatory approval

and access; access drives adoption; adoption sustains growth and, ultimately, population-health impact. Each link depends on the one before it, and the chain begins with where evidence is generated.

Figure 6. The Future Healthcare Value Chain. *Source: GLS Institute. A descriptive device, not a separate mark.*

Beyond Trial Participation

Africa should not be positioned only as a place to conduct trials. Its greatest contribution may be to the substance of medicine itself. The R21 malaria vaccine, first approved by an African regulator and now deployed across multiple countries [11], and the first-in-human HIV vaccine trial launched in Cape Town in 2026[10] are early evidence that the continent is moving from hosting science to originating it. Representative evidence, future demand, digital transformation, and demographic change are converging into opportunities whose significance extends well beyond any single study.

> **THE GLS PERSPECTIVE**
> *The future of medicine may depend as much on where organizations invest in trust, talent, and partnerships as on the technologies they develop. The next generation of leaders will be distinguished by the ecosystems they helped build.*

SECTION V

Risks and Headwinds

A benchmark argument is only credible if it states the case against itself. The trajectory described in this report is real, but it is neither inevitable nor unthreatened. Several headwinds could slow or reverse it, and at least one is acute and current.

The Funding Shock

The most immediate threat is financial. In 2025, abrupt reductions in United States and NIH research funding struck African clinical research hard. South Africa, made a preferred research site precisely by its high HIV and TB burden and the strength of its scientific community, was disproportionately exposed. The South African Medical Research Council reported that universities had begun retrenchments at scale, leaving hundreds of master's, doctoral, and postdoctoral fellows whose stipends depended on these grants in acute precarity[13]. Cumulative NIH investment in South African HIV and TB research has been estimated at roughly USD 2 billion over twenty years[13], a dependency now exposed. Research leaders described the resulting transition as a regulatory and ethical challenge, and warned of a global loss of TB and HIV research capacity, not merely a national one.

The shock revealed a deeper structural fact: much of the continent's trial capacity was built on external funding and partnership rather than domestic finance. The goal had always been for local institutions to assume leadership and for domestic budgets to fund programs over time, but, as one long-standing HIV-vaccine partner put it, that handover is now happening far more abruptly than anyone had planned for[14]. An ecosystem that is scientifically capable but not yet financially self-sustaining is fragile in ways a site count does not reveal.

Structural Headwinds

Beyond the immediate funding shock, four structural constraints temper the optimistic case:

- **Concentration risk.** With roughly 70% of African research in just three countries, a shock to any one of them, such as the funding cuts in South Africa, distorts the entire continental picture. Diversity of ecosystems is a strength; concentration of capacity is a vulnerability.
- **Incomplete regulatory convergence.** The African Medicines Agency is only early in its expansion phase, underfunded and reliant in part on external support, with national legal harmonization, sustainable financing, and sovereignty questions unresolved. Recognition and reliance mechanisms are promising but not yet mature.
- **Workforce retention and brain drain.** Human capital is the continent's greatest advantage and its most mobile asset. Funding instability accelerates the loss of trained scientists to better-resourced systems, eroding precisely the capability that takes longest to build.
- **Data and infrastructure unevenness.** Trial registration, data systems, and laboratory infrastructure remain uneven across the continent, and registry data show meaningful rates of retrospective registration in some regions, a reminder that quality and transparency systems are still maturing.

THE GLS PERSPECTIVE

None of these headwinds argues for disengagement. If anything, the funding shock strengthens the case for diversified, locally anchored, and financially sustainable investment in place of donor-dependent project funding. But any organization acting on this report should price these risks in. The opportunity is real; so are the threats to it.

Strategic Implications for Sponsors

For organizations weighing where and how to engage, seven principles follow directly from the evidence in this report.

1. **Treat representativeness as a scientific requirement.** Build African participation into development plans early, where the science, not only the demographics, calls for it.
2. **Invest in ecosystems, not transactions.** Favor durable institutional partnerships over project-by-project site selection; the compounding asset is the relationship.
3. **Engage regulatory convergence early.** Align with the African Medicines Agency and regional harmonization mechanisms to benefit from reliance and recognition as they mature.
4. **Treat trust as an asset under management.** Resource community engagement as core infrastructure, with the same rigor applied to data systems or laboratories.
5. **Develop and retain local talent.** The least replicable advantage is people; invest in training, leadership, and careers, not only in sites.
6. **Build for financial sustainability.** The 2025 funding shock showed the fragility of donor-dependent capacity; favor models that move ecosystems toward diversified, locally anchored financing rather than single-source reliance.
7. **Read future patients as future markets.** Let evidence strategy and commercial strategy inform one another, recognizing where the two geographies converge.

Looking Ahead

Part I has established the evidence, the framework, and the headwinds: a measurable and widening representation gap, an ecosystem model applied to specific countries, and a candid account of the funding and structural risks that could derail the trajectory. Part II turns from opportunity to execution:
the operational, therapeutic, and partnership challenges of delivering high-quality clinical development at scale, the North African ecosystems reserved from this edition, the question of sustainable financing after the 2025 funding shock, and the strategic considerations that separate organizations that participate from those that lead.

Part II · From Opportunity to Execution: Challenges, Therapeutic Opportunities, and Strategic Considerations for Success.

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About the Author

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Charles Oviawe is a global clinical research executive and quality systems professional with more than two decades of experience supporting pharmaceutical, biotechnology, government, and global health organizations across the clinical development lifecycle.

His expertise spans Phase I through Phase IV clinical development, quality management systems, regulatory affairs, pharmacovigilance, laboratory quality, Good Clinical Practice, Good Laboratory Practice, Good Pharmacovigilance Practice, current Good Manufacturing Practice, and Computer System Validation.

Before founding Guosa Life Sciences, he held senior quality assurance and research and development leadership positions with Pfizer, Acadia, Shionogi Inc., BeyondSpring, and Forest Laboratories, supporting global clinical development programs across multiple therapeutic areas and contributing to inspection readiness, quality systems implementation, and global regulatory compliance.

Through Guosa Life Sciences he has advised pharmaceutical sponsors, biotechnology companies, contract research organizations, academic institutions, and public health organizations on clinical operations, quality systems, regulatory strategy, pharmacovigilance, and global research capacity development.

He is the architect of the GLS Clinical Development Network and the African Early Phase Clinical Research Network, initiatives designed to strengthen evidence-based institutional qualification, foster scientific collaboration, and expand sustainable Phase I clinical research capacity across Africa and other emerging markets.

About GLS Institute

GLS Institute is the clinical development and global health research division of Guosa Life Sciences. Its benchmark publications examine the forces reshaping where and how medicines are developed, with the aim of advancing better life through better medicine.

The Institute publishes independently of the commercial engagements of Guosa Life Sciences. Its benchmark studies are self-funded, and are not commissioned, sponsored, or subject to client review. Where the analysis touches on services the firm provides, that interest is disclosed rather than omitted. https://guosalifesciences.com/institute/index.html

About Guosa Life Sciences

Advancing Global Clinical Development Through Local Expertise

Guosa Life Sciences is a global contract research organization and strategic consulting firm supporting pharmaceutical, biotechnology, medical device, diagnostic, and global health organizations throughout the clinical development lifecycle.

GLS delivers integrated services spanning Phase I through Phase IV clinical research, regulatory affairs, quality assurance, pharmacovigilance, laboratory oversight, biometrics, medical writing, project management, logistics, and strategic advisory services.

With headquarters in the United States and an operational footprint across Sub-Saharan Africa and Asia, together with strategic partnerships in Europe, the Middle East, and other emerging markets, GLS combines global quality standards with in-country operational expertise.

Core service areas

- Clinical operations
- Quality assurance and compliance
- Regulatory affairs
- Pharmacovigilance
- Medical and scientific affairs
- Data management and biostatistics
- Laboratory services
- Supply chain and logistics
- Project management
- Global health research
- Strategic consulting

Strategic initiatives

GLS Clinical Development Network (GLS-CDN). A collaborative operational network connecting qualified research institutions, investigators, laboratories, and operational specialists to support evidence-based institutional qualification and multi-country clinical development.

African Early Phase Clinical Research Network (AE-PCRN). A scientific collaboration focused on strengthening Phase I clinical research readiness, institutional capacity, and sustainable early clinical development across Africa through collaboration, training, and evidence-based institutional qualification.

Guosa Life Sciences
Advancing Life Through Better Medicine