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A Shared Future

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GLS INSIGHTS™

CLINICAL DEVELOPMENT AND GLOBAL HEALTH · BENCHMARK SERIES

The Future of Clinical Trials in Africa

The Complete Series

Parts I–III and the Series Companion, in one volume

EDITION 2026.2 · CURRENT AS OF 22 JULY 2026

THE CANON AND ITS INSTRUMENTS

ARCHITECTURE

REPRESENTATIVE SCIENCE

ECOSYSTEMS

EARLY DEVELOPMENT

MATURITY INDEX

Guosa Life Sciences
Advancing Life Through Better Medicine

Charles Oviawe · GLS Institute

Published by GLS Institute · Founded by Guosa Life Sciences · 2026

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Section	Question it answers
Part I — The Scientific Imperative for Representative Evidence	Why does Africa matter? The representation gap, the ecosystem framework, the maturity model, eight country profiles, and the 2025 funding shock.
Part II — From Opportunity to Execution	How do ecosystems execute? Regulatory convergence, the Early Development Thesis, execution under pressure, therapeutic opportunity, and sustainable financing.
Part III, The Future Architecture	How do ecosystems evolve? Intelligent ecosystems, genomic sovereignty, manufacturing, the Maturity Index, and Outlook 2035.
Series Companion	How should the trilogy be read? The master architecture, the canon, full index methodology, and analytical standards.

This volume collects the three benchmark reports and the series companion as a single body of work. The reports are reproduced without abridgement; cross-references between them remain valid. Figures and tables are numbered within each part.

PART I

The Scientific Imperative for Representative Evidence

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].

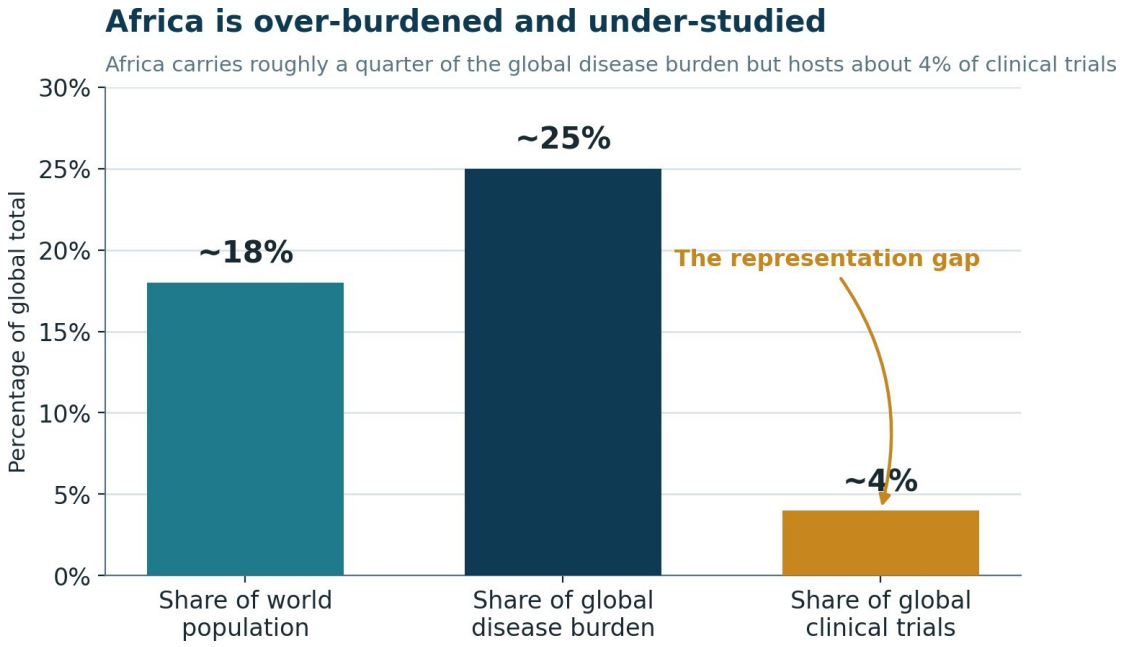

Figure 1. Africa's share of population, disease burden, and clinical trials. *Source: UN World Population Prospects 2024; IQVIA; Semafor analysis of five major journals, 2026.*

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].

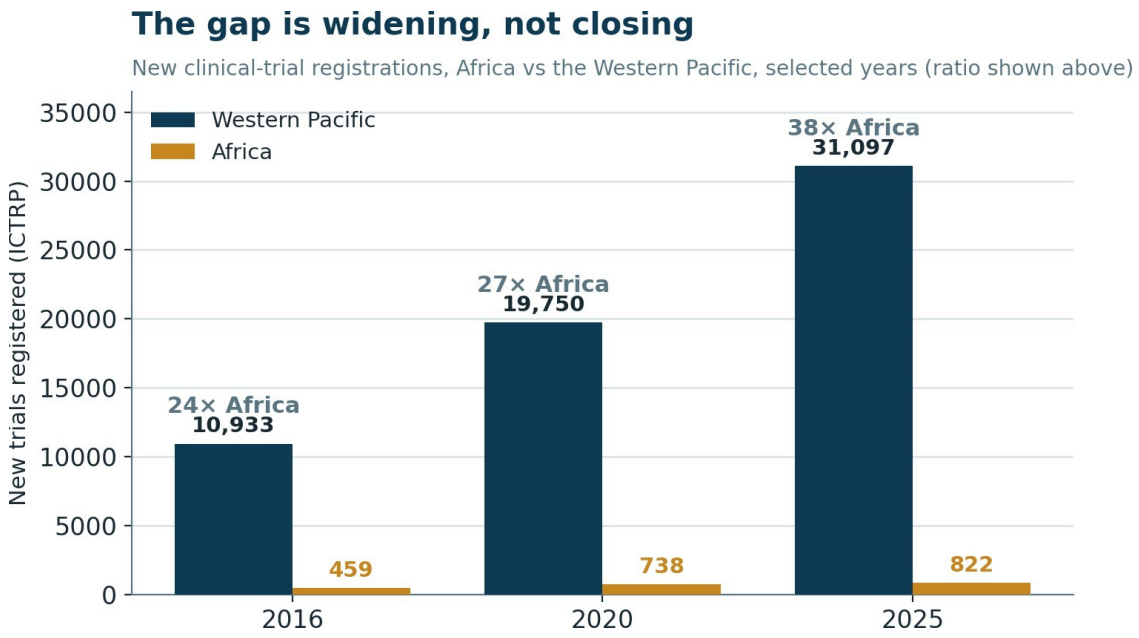

Figure 2. New clinical-trial registrations, Africa vs the Western Pacific, selected years. *Source: WHO International Clinical Trials Registry Platform (ICTRP), accessed 2026. All values are WHO-reported counts.*

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.

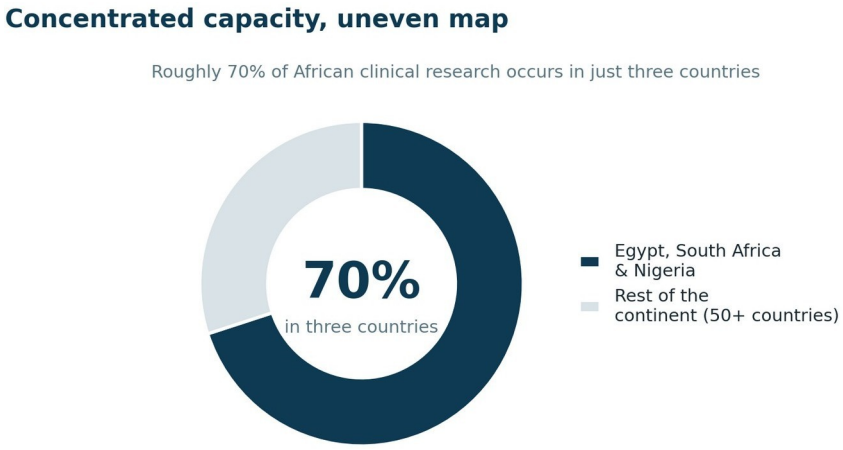

Figure 3. Geographic concentration of African clinical research. *Source: IQVIA, via World Economic Forum, 2024.*

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

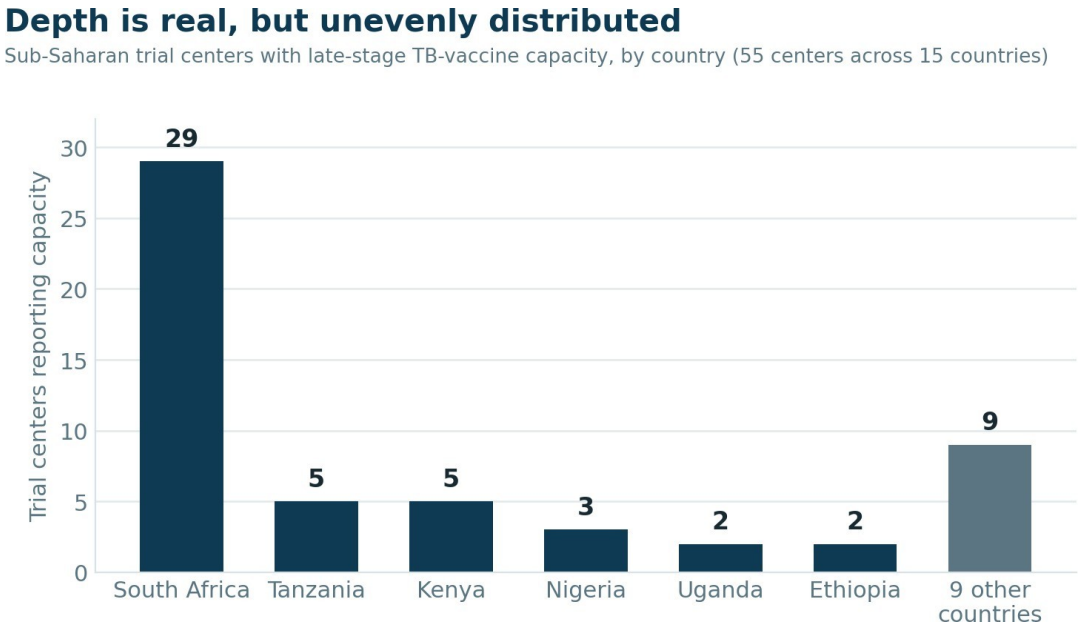

Figure 4. Late-stage TB-vaccine trial capacity by country (55 sub-Saharan centers with country attribution). *Source: TB Vaccine Clinical Trial Centre Directory, 2023.*

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.

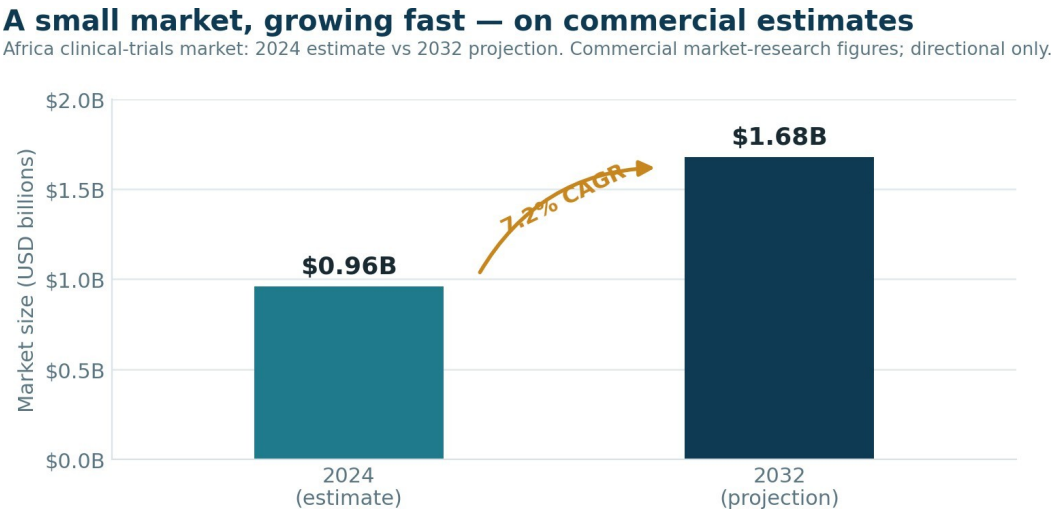

Figure 5. Africa clinical-trials market: 2024 estimate vs 2032 projection. *Source: Fortune Business Insights / Towards Healthcare, 2024–2025. Commercial estimates; directional only.*

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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PART II

From Opportunity to Execution

Where Part I Left Off

Part I made the strategic case for Africa. It documented a large and widening representation gap, a continent carrying roughly a quarter of the global disease burden while hosting about 4% of clinical trials, and argued that closing it is one of the most consequential opportunities in global health. It introduced the principles that anchor this series: that representative science drives better medicine, that ecosystems outperform sites, that human capital is the decisive advantage, that trust is strategic infrastructure, and that future patients are future markets. It also closed on a warning: the 2025 withdrawal of major external research funding exposed how much of the continent's capacity remains donor-dependent and financially fragile.

Part II turns from why to how. Recognizing Africa's importance is the first step; realizing it requires an operational discipline that goes beyond site selection and project management. This report addresses the execution questions Part I deferred: how regulatory convergence is reshaping the operating environment, where African science should sit in the development chain, how ecosystems perform under the pressure of a live health emergency, which therapeutic opportunities are emerging, and how to finance capacity that lasts. It carries Part I's threads forward rather than restating them: including the North African ecosystems, the therapeutic opportunities, and the sustainable-financing question reserved from the first report.

A Note on Method and Sources

As in Part I, quantitative claims are referenced to primary sources, intergovernmental and regulatory bodies, peer-reviewed literature, and named institutions, current to 22 July 2026. Forward-looking and commercial estimates are identified as such. Three developments that post-date Part I are integrated here because they materially change the execution picture: the WHO–AMA Framework Agreement for Collaboration signed at the Seventy-ninth World Health Assembly in May 2026, the June 2026 Statement of Cooperation between the African Medicines Agency and the United States FDA, and the 2026 Bundibugyo Ebola outbreak in the Democratic Republic of the Congo and Uganda.

Executive Summary

Execution in Africa has changed faster than most operating models have. Study performance is no longer determined primarily by selecting capable investigators and qualified sites; it is determined by the maturity of the surrounding ecosystem: regulatory collaboration, laboratory networks, referral pathways, digital readiness, workforce depth, community trust, and supply-chain resilience. Sponsors increasingly compete not for sites but for trusted ecosystems capable of delivering predictable quality.

Two structural facts define the execution agenda. First, African clinical research remains concentrated in late-phase studies and infectious disease: of the small share of global trials the continent hosts, most are in Phases III and IV[1], which means representativeness enters the evidence chain near its end rather than its source. GLS Institute argues that the next stage of maturity is to move upstream, into early-phase and first-in-human development, a position we set out as the GLS Early Development Thesis™. Second, regulatory convergence is rapidly becoming the backbone of predictable execution: the African Medicines Agency is operationalizing reliance mechanisms across the continent, signed a Framework Agreement for Collaboration with the WHO in May 2026, and in June 2026 signed a Statement of Cooperation with the United States FDA[2][14].

The stakes are not abstract. As this edition was finalized, a Bundibugyo Ebola outbreak in the DRC and Uganda: declared a public health emergency of international concern on 17 May 2026, with 2,473 confirmed cases and more than 1,000 confirmed deaths in the DRC as of 22 July 2026, and no licensed vaccine or treatment for the strain[7][8]: was being met with an emergency research response: a WHO-coordinated therapeutics protocol inside the outbreak zone, accelerated preparation of continental trial sites, and fast-tracked early-phase vaccine development beginning outside the continent. It is the clearest possible demonstration that trial-ready ecosystems are not a commercial luxury but a component of global health security.

Part II sets out how sponsors build and operate these ecosystems: through regulatory convergence, an early-development posture, designed-in quality, responsible data governance, a sharpened reading of therapeutic opportunity, and, the lesson of 2025, financing that is diversified and locally anchored rather than dependent on any single source. The organizations that master execution will not simply run more studies; they will help determine the representativeness, resilience, and reach of the evidence base itself.

Six Principles of Execution

Part I set out why Africa matters. These six principles govern how to execute there. They extend, rather than replace, the strategic principles of Part I.

Ecosystems Outperform Sites™

Performance follows the maturity of the surrounding ecosystem, regulators, laboratories, referral pathways, workforce, and trust, not the capability of any single site. Execution has evolved from site management to ecosystem management.

Regulatory Convergence Creates Predictability™

Reliance, recognition, and harmonization, now extending to cooperation with the WHO and the US FDA, are turning a fragmented approval landscape into a source of timeline predictability and a genuine competitive differentiator.

The GLS Early Development Thesis™

Africa's participation is concentrated in late-phase studies. The frontier of maturity is upstream: early-phase and first-in-human development that captures representativeness at the source of the evidence chain.

Quality Is Designed, Not Inspected™

Quality is most effective when embedded in study design, through risk-based quality management, centralized monitoring, and analytics, rather than assessed retrospectively through monitoring alone.

Trust Is Strategic Infrastructure™

Community trust is operational infrastructure. It governs recruitment, retention, adherence, data quality, and, as outbreak response shows, the speed at which an ecosystem can mobilize under pressure.

Sustainable Capacity Outlasts Single Studies™

The 2025 funding shock proved that donor-dependent capacity is fragile. Durable performance depends on diversified, locally anchored financing and capability that survives the end of any one program.

SECTION I

Why Execution Strategies Must Change

Traditional operating models assume that successful execution depends mainly on choosing capable investigators and qualified sites. That assumption is increasingly incomplete. Modern study performance is shaped by the maturity of the surrounding ecosystem, and successful sponsors now evaluate regional regulatory collaboration, laboratory networks, referral pathways, digital readiness, workforce depth, community engagement, and supply-chain resilience as a single interdependent system.

The implication is a shift in the unit of management. Execution has moved from site management to ecosystem management. A capable investigator embedded in a weak ecosystem will underperform; a strong ecosystem makes ordinary sites reliable. This is why sponsors increasingly compete less for individual sites and more for trusted ecosystems able to deliver predictable quality over time.

> **EXECUTIVE INSIGHT**
> *Sponsors no longer compete only for sites. They compete for trusted ecosystems capable of delivering predictable quality and enduring partnerships.*

The GLS Clinical Development Delivery Model

Delivery in this model flows from sponsor strategy through the ecosystem to impact, each stage dependent on the one before it. Operational excellence is the link in the middle, not the whole chain.

Figure 1. The GLS Clinical Development Delivery Model. *Source: GLS Institute. A descriptive device, not a separate mark.*

SECTION II

Regulatory Convergence as Execution Infrastructure

For sponsors, the single most consequential change in Africa's operating environment is regulatory. A landscape that once required separate, sequential approval in every country is consolidating into a system of reliance, recognition, and harmonization. This is not an administrative footnote; it is execution infrastructure that directly shapes timelines, cost, and predictability.

The Continental Backbone: the African Medicines Agency

The African Medicines Agency (AMA), whose treaty entered into force in November 2021 and had been ratified by 31 member states by the end of 2025, is being implemented in phases, Foundation (2024–2025), Expansion (2026–2030), and Maturity (2031 onward)[3]. Its design is deliberately suited to Africa's legal diversity: continental coordination combined with voluntary national implementation, enabling progressive convergence without overriding national sovereignty[3]. Its first Director-General, Delese Mimi Darko, previously led the Ghana FDA, the agency that became the first in the world to license the R21 malaria vaccine.

Two Bridges: the WHO–AMA and AMA–US FDA Agreements

In May 2026, at the Seventy-ninth World Health Assembly, the WHO and the AMA signed a Framework Agreement for Collaboration advancing harmonization, convergence, and reliance across African regulatory systems[14]. One month later, in June 2026, the AMA and the United States FDA signed a Statement of Cooperation establishing a formal framework for regulatory information exchange and convergence[2]. Signed by Director-General Darko and Mark Abdoo, the FDA's Associate Commissioner for Global Policy and Strategy, it builds on the FDA African Medicines Agency Liaison Office (AMALO) at the US Embassy in Kigali. For sponsors, the practical significance is direct: structured information-sharing and the prospect of African regulators relying on FDA assessments reduce duplication and improve predictability for programs spanning both jurisdictions. The agreements arrive as Africa's pharmaceutical market is projected to exceed USD 50 billion by 2030[2], underscoring why coordinated oversight matters commercially as well as scientifically.

Regional Blocs and Reliance in Practice

Beneath the continental layer, regional harmonization is already operational. In 2025, seven of Africa's leading national regulators, Ghana's FDA, Nigeria's NAFDAC, the Rwanda FDA, Senegal's ARP, South Africa's SAHPRA, Tanzania's TMDA, and Zimbabwe's MCAZ, signed a reliance memorandum committing to work-sharing and mutual recognition of assessment reports[4]. These are seven of the eight African authorities assessed at WHO maturity level 3; Egypt is the eighth. They build on established mechanisms such as the East African Community initiative and the SADC ZaZiBoNa program. External validation is visible too: Ghana attained WHO maturity level 3 and Regional Centre of Regulatory Excellence status, after which industry-sponsored trial participation in the country more than tripled[5].

North Africa: Completing the Map

Part I reserved North Africa from its profiles. It belongs here, because Egypt is one of the three countries that together host roughly 70% of African clinical research. Egypt regulates trials through the Egyptian Drug Authority under a modern legal framework, Clinical Trials Law No. 214/2020 and its executive regulations, applying ICH E6 Good Clinical Practice[12]. A large, partly treatment-naive population, a high cardiometabolic and oncology burden, and an experienced investigator base at academic hospitals such as Ain Shams, Cairo University, and Alexandria University make it one of the continent's most active environments, particularly in oncology. Egypt's maturity reinforces a central point: "Africa" is not one ecosystem, and execution strategy must read its regions distinctly.

Table 1. Africa's regulatory architecture for sponsors: layers of convergence.

Layer	Mechanism	What it means for execution
Continental	African Medicines Agency (AMA); WHO–AMA Framework Agreement (2026); AMA–US FDA cooperation (2026)	Reliance on FDA and peer assessments; information-sharing; reduced duplication across jurisdictions
Regional, East	EAC Medicines Regulatory Harmonization	Joint assessment and work-sharing across Kenya, Tanzania, Uganda, Rwanda and partners
Regional, West	ECOWAS / WA-MRH; NRA reliance MoU	Strengthening institutional capacity across Ghana, Nigeria, Senegal and others
Regional, South	SADC ZaZiBoNa	Collaborative registration anchored by SAHPRA and regional regulators
National (exemplars)	Ghana FDA (ML3 / RCORE); SAHPRA; NAFDAC; EDA (Egypt)	Mature national authorities applying ICH-GCP; reference points for reliance

> **EXECUTIVE INSIGHT**
> *Regulatory convergence should be read as a strategic opportunity, not an administrative development. The sponsors who engage it early: continental, regional, and now trans-Atlantic — convert a former barrier into predictability.*

SECTION III

The GLS Early Development Thesis™

Africa's clinical research is concentrated at the wrong end of the development chain. The studies the continent hosts are predominantly late-phase, Phases III and IV, and weighted toward infectious disease[1]. The consequence is structural: when African populations enter only at the late stage, representativeness is added near the end of the evidence chain rather than built in at its source. The continent that contributes under 2% of the genomic data in research[1] is largely absent from the early-phase work where dose, safety, and biology are first characterized.

GLS Institute's position is that the next stage of ecosystem maturity is to move upstream, into early-phase and first-in-human development. Early-development capability is the difference between an ecosystem that *executes other people's science* and one that *originates its own*. It is also where representativeness is most scientifically valuable: characterizing pharmacology and safety in the populations who will ultimately use a therapy, rather than extrapolating to them afterwards.

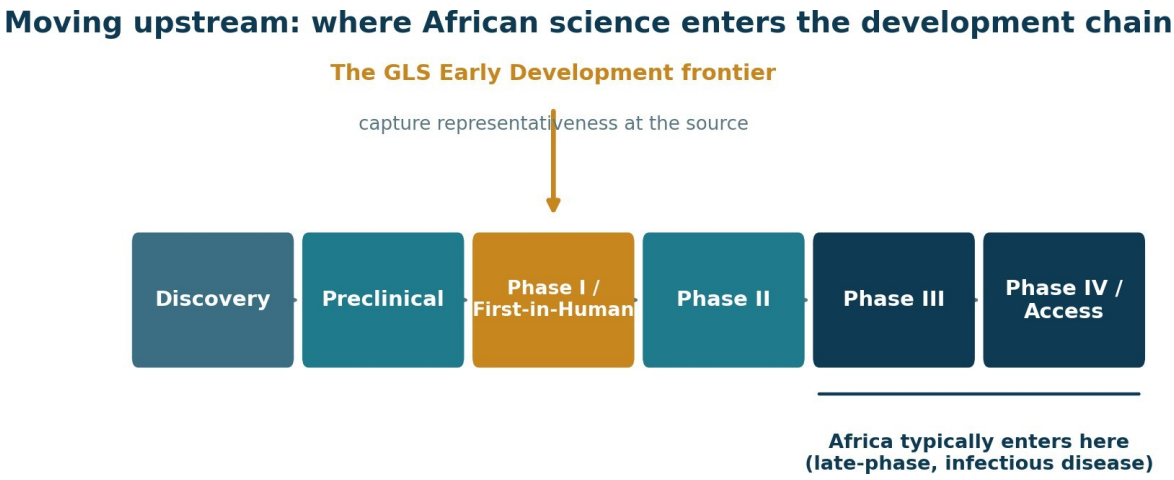

Figure 2. Where African science enters the development chain, and where the opportunity lies. *Source: GLS Institute.*

This is not aspiration without precedent. In January 2026, South Africa launched the BRILLIANT 011 first-in-human HIV vaccine trial in Cape Town: an African-led early-phase study, designed and run by African scientists and predominantly directed by African women, testing immunogens developed through international collaboration and first identified in African trial participants[6]. The 2026 Ebola response (Section IV) is a second test: it has accelerated trial-site preparation, GCP training and laboratory readiness on the continent, while the first Phase 1 vaccine studies for the outbreak strain began outside it, a precise illustration of the gap this thesis identifies. The capability exists; the thesis is that sponsors and ecosystems should treat early development as a deliberate strategy rather than an exception.

THE GLS PERSPECTIVE

An ecosystem that can only run Phase III is a destination for finished science. An ecosystem that can run first-in-human studies is a partner in creating it. Early development is where representativeness, and competitive advantage, begin.

SECTION IV

Execution Under Pressure: Health Security and the 2026 Ebola Outbreak

The clearest test of an ecosystem is an emergency. On 15 May 2026 the Democratic Republic of the Congo declared its seventeenth Ebola outbreak, caused by the Bundibugyo virus, a strain for which no licensed vaccine or specific treatment exists. The World Health Organization declared a public health emergency of international concern on 17 May, and Africa CDC declared a public health emergency of continental security the following day[7][8]. As of 22 July 2026, the DRC had confirmed 2,473 cases and more than 1,000 confirmed deaths; Uganda, which recorded a small cross-border cluster, discharged its final patient on 16 July and entered the 42-day countdown to declaring its outbreak over[8]. The DRC outbreak is unfolding in a conflict-affected region, and while contact tracing has reached roughly 82% of identified contacts, insecurity continues to constrain case-finding, a reminder that execution and context are inseparable.

What makes this relevant to clinical development is that the response is, in part, clinical development. With no approved countermeasures, the Coalition for Epidemic Preparedness Innovations fast-tracked vaccine candidates from IAVI, Moderna, and the University of Oxford, and a WHO-coordinated trial protocol was deployed in the DRC to evaluate therapeutics during the outbreak[7][8]. The first Phase 1 study of the Oxford candidate opened in the United Kingdom rather than in the affected region. Africa CDC and WHO launched a six-month continental response plan, and preparedness work explicitly included identifying clinical trial sites, training health workers in Good Clinical Practice, and strengthening laboratory diagnostic capacity[7].

The execution lesson is unambiguous. Outbreak response is early-phase clinical development conducted under the worst possible conditions, and it cannot be improvised. It depends on capabilities that must be pre-positioned: a GCP-trained workforce, laboratory and diagnostic capacity, agile regulatory pathways, resilient supply chains, and, decisively, community trust deep enough to support enrollment and follow-up during a crisis. Every one of these is an ecosystem asset built in peacetime. That the first-in-human work for this strain began offshore is not a criticism of the response; it is the measure of the gap that pre-positioned early-development capability would close. Trial-ready ecosystems are therefore not only a commercial proposition; they are infrastructure for global health security, and the case for building them is strongest precisely when they are hardest to build.

> **THE GLS PERSPECTIVE**
> *An outbreak is an audit of everything an ecosystem built before it arrived. Workforce, laboratories, regulatory agility, and trust cannot be created mid-emergency. The continent's trial-readiness is, increasingly, the world's health security.*

A note on sensitivity and currency: the figures above describe an active emergency affecting real communities. They are presented to make an operational point about preparedness, not to reduce a humanitarian crisis to a business case. They are current as of 22 July 2026 and will change; readers should confirm the latest WHO and Africa CDC situation reports.

SECTION V

Therapeutic Opportunities

Part I promised a closer look at where the therapeutic opportunities lie. They are being reshaped by an epidemiological transition: as life expectancy rises and lifestyles shift, the burden of non-communicable disease in sub-Saharan Africa rose by roughly 67% between 1990 and 2017. WHO's Regional Office for Africa estimates that illness of all kinds cost the region more than 2.4 trillion international dollars in lost output in 2015, of which non-communicable diseases accounted for about 37%, on the order of 0.9 trillion international dollars a year[10]. Yet African trials remain concentrated in infectious disease. The gap between disease burden and research focus is itself the opportunity.

Sickle Cell Disease: a Burden the World Under-Studies

No therapeutic area illustrates the mismatch better than sickle cell disease. Sub-Saharan Africa carries an estimated 75–80% of the global SCD burden[9], yet most therapeutic innovation has been developed and trialed elsewhere. The opportunity is concrete and already moving: after Ghana reached WHO maturity level 3, industry-sponsored trial participation in the country more than tripled, with a notable rise in sickle cell studies[5]. A disease defined by African genetics is precisely the kind of area where representative early-phase research is both a scientific necessity and a strategic opening.

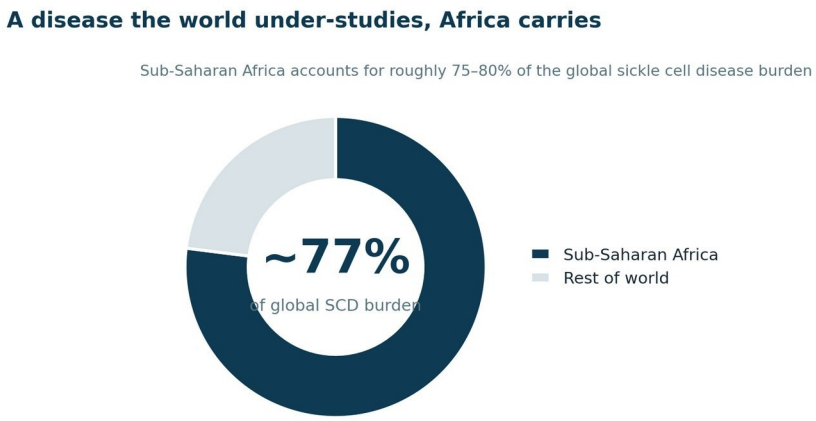

Figure 3. Sub-Saharan Africa's share of the global sickle cell disease burden. *Source: Global Burden of Disease 2021, via peer-reviewed analysis.*

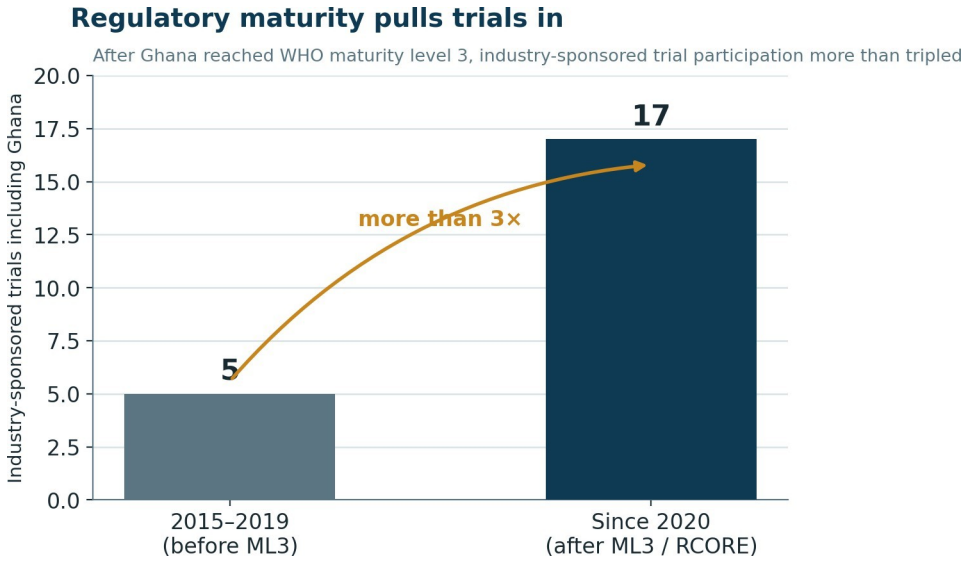

Figure 4. Industry-sponsored trials including Ghana, before and after WHO maturity level 3. *Source: Access to Medicine Foundation, 2025.*

Oncology, Cardiometabolic Disease, and Beyond

Cancer is now a formidable burden in sub-Saharan Africa, driven by rising incidence and longer life expectancy, and African patients more often present at later stages with poorer outcomes, a disparity that representative oncology trials could begin to close[11]. Cardiometabolic disease, women's health, and continued vaccine and infectious-disease leadership round out a diversifying opportunity set. The table below maps where Africa's burden and research interest are converging.

Table 2. Where therapeutic opportunity is concentrating.

Therapeutic area	Why Africa	Illustrative anchor
Sickle cell disease	~75–80% of global burden; defined by African genetics	Rising SCD trial activity in Ghana post-ML3
Oncology	Rising incidence; later-stage presentation; under-studied populations	AORTIC trial network; Egyptian oncology centers
Cardiometabolic	Large, partly treatment-naive populations; rapid NCD growth	Egypt, Nigeria diabetes/CVD burden
Vaccines & infectious disease	Established capability; health-security imperative	R21 malaria; BRILLIANT HIV; Ebola response
Women's & maternal health	High burden; strong community-engagement infrastructure	Noguchi and KEMRI-Wellcome programs

EXECUTIVE INSIGHT

The therapeutic opportunity is the inverse of the representation gap: the areas where Africa is most under-studied relative to its burden, sickle cell, oncology, cardiometabolic disease, are precisely where representative evidence is worth most.

SECTION VI

Quality, Data, and Digital Execution

Historically, monitoring was treated as the primary mechanism for ensuring study quality. Modern clinical development inverts that logic: quality is most effective when designed into a study rather than inspected after the fact. Risk-based quality management, centralized monitoring, digital oversight, analytics, and continuous improvement move quality assurance from a retrospective audit to a built-in property of the protocol.

Figure 5. Quality by Design. *Source: GLS Institute. A descriptive device, not a separate mark.*

Data and Genomic Governance

As development becomes more data-intensive, competitiveness will depend on the responsible stewardship of clinical data, genomic information, biospecimens, and intellectual property. This is not merely a compliance matter. Africa hosts the world's most genetically diverse populations yet contributes under 2% of genomic research data[1]; how that data is governed, with transparency, respect for national legislation and participant rights, and equitable benefit, will determine whether early-development science can be conducted on the continent at all. Responsible data governance is becoming a source of scientific credibility and competitive advantage, not a constraint on it.

Digital and AI as Complements, Not Substitutes

Electronic source documentation, remote and centralized monitoring, decentralized trial components, wearables, and AI-enabled analytics are expanding what is operationally possible. But digital transformation should complement, never replace, local expertise and community engagement. Technology extends the reach of a trusted ecosystem; it cannot manufacture trust where none has been built.

> **EXECUTIVE INSIGHT**
> *Designed-in quality and responsible data governance are not overheads. In an early-development ecosystem, they are the license to operate.*

SECTION VII

Sustainable Financing After the Funding Shock

Part I closed on the 2025 funding shock: the abrupt withdrawal of major external research funding, which hit South Africa hardest and exposed how much of the continent's capacity had been built on donor finance. Cumulative NIH investment in South African HIV and TB research alone had been estimated at roughly USD 2 billion over twenty years, and its withdrawal forced local institutions to assume leadership far faster than planned[13]. For an execution-focused report, the lesson is operational, not only financial: capability that depends on a single external source is not resilient capability.

The constructive response is a pivot toward diversified, locally anchored financing. Three levers are visible. Regulatory consolidation under the AMA is helping convert fragmented national markets into a continental one projected to exceed USD 50 billion by 2030[2], improving the economics of local investment. Local manufacturing is advancing, the Serum Institute of India is establishing vaccine production in Accra, shortening supply chains and retaining value on the continent. And reliance-based regulation reduces duplicative cost, freeing resources for capability rather than paperwork. None of this replaces external partnership; it rebalances it toward sustainability.

> **THE GLS PERSPECTIVE**
> *Sustainable capacity creates sustainable performance. The ecosystems that endure will be those financed to outlast any single sponsor, grant, or election, a lesson 2025 taught at considerable cost.*

SECTION VIII

Risks and Execution Headwinds

As in Part I, the case for execution is credible only if its obstacles are stated plainly. Four headwinds bear directly on delivery.

- **Financing fragility.** The 2025 shock is not fully resolved; capability built on narrow funding bases remains exposed, and the pivot to sustainable financing is early.
- **Instability and access.** The 2026 Ebola outbreak is unfolding in a conflict zone where insecurity has constrained case-finding and follow-up, a concrete illustration that security and humanitarian conditions can limit even well-designed execution.
- **Concentration and uneven maturity.** With roughly 70% of research in three countries and regulators at very different maturity levels, ecosystem strength is unevenly distributed; reliance mechanisms are promising but not yet uniformly mature.
- **Workforce retention.** Early-development ambition depends on specialized talent that is mobile and scarce; funding instability accelerates its loss.

THE GLS PERSPECTIVE

These headwinds do not weaken the execution case; they specify it. The advantage goes to sponsors who build for resilience, diversified financing, distributed capability, and trust, rather than for any single favorable condition.

The Sponsor Playbook

Translating the preceding sections into practice, organizations building long-term execution capability in Africa should:

1. **Evaluate ecosystems, not individual sites.** Assess regulatory maturity, laboratories, workforce, and trust as a system; site quality follows ecosystem strength.
2. **Engage regulatory convergence early.** Design for reliance, continental (AMA), regional (EAC, ECOWAS, ZaZiBoNa), and now trans-Atlantic (AMA–FDA), from the protocol stage.
3. **Build an early-development posture.** Where the science allows, bring first-in-human and early-phase work to African ecosystems to capture representativeness at the source.
4. **Design quality in.** Adopt risk-based quality management and centralized monitoring rather than relying on retrospective inspection.
5. **Govern data responsibly.** Treat genomic and specimen governance as a license to operate and a source of credibility, respecting national law and participant rights.
6. **Match therapeutic strategy to burden.** Prioritize areas: sickle cell, oncology, cardiometabolic — where Africa is most under-studied relative to its disease burden.
7. **Finance for sustainability.** Favor diversified, locally anchored funding and local capability over single-source, donor-dependent models.
8. **Treat trust as operational infrastructure.** Resource community engagement with the rigor applied to laboratories and data systems.

The GLS Sustainable Clinical Development Cycle

Done well, execution compounds: partnerships build trust, trust enables excellence, excellence produces representative evidence and impact, and the value generated is reinvested in the ecosystem that created it.

Figure 6. The GLS Sustainable Clinical Development Cycle. *Source: GLS Institute. A descriptive device, not a separate mark.*

Strategic Outlook and Looking Ahead

Africa's role in clinical development will be shaped not only by scientific capability but by the quality of partnerships, the depth of regulatory collaboration, the responsible adoption of digital tools, and sustained investment in people. Organizations that move from transactional execution to ecosystem stewardship, and that have the discipline to build early-development capability and finance it to last — will be best positioned to generate stronger evidence, improve predictability, and contribute to durable healthcare innovation.

Part III · The Future Architecture of Global Clinical Development: How Research Ecosystems Evolve — Outlook 2035.

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[2] African Medicines Agency & US Food and Drug Administration. Statement of Cooperation, June 2026, signed by Director-General Delese Mimi Darko and Associate Commissioner for Global Policy and Strategy Mark Abdoo; FDA African Medicines Agency Liaison Office (AMALO), Kigali. Africa’s pharmaceutical market projected to exceed USD 50 billion by 2030 (AMA).

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[5] Access to Medicine Foundation. “Harnessing Africa’s untapped clinical trial potential,” 2025 (Ghana WHO maturity level 3 and RCORE; industry-sponsored trials rose from 5 in 2015–2019 to 17 since 2020; rise in sickle cell trials).

[6] South African Medical Research Council. “Africa moves closer to an HIV vaccine as first-in-human BRILLIANT 011 clinical trial launches in Cape Town.” Press release, 22 January 2026.

[7] World Health Organization. “Ebola outbreak, DRC 2026” (Bundibugyo virus); outbreak declared by the DRC 15 May 2026; PHEIC declared 17 May 2026; Africa CDC public health emergency of continental security declared 18 May 2026; WHO-coordinated trial protocol; preparedness including clinical trial site identification, GCP training, and laboratory capacity. WHO Regional Office for Africa, 2026.

[8] US CDC, “Ebola Outbreak: Current Situation,” July 2026; WHO Disease Outbreak News and Africa CDC situation reports, 2026 (2,473 confirmed cases and more than 1,000 confirmed deaths in the DRC as of 22 July 2026; Uganda’s final patient discharged 16 July 2026 and 42-day countdown begun; no licensed vaccine or treatment for Bundibugyo; CEPI fast-tracking IAVI, Moderna, and Oxford candidates, with the first Phase 1 study of the Oxford candidate conducted in the United Kingdom; Africa CDC–WHO six-month continental response plan).

[9] Global Burden of Disease 2021, via comparative epidemiological analysis (Preprints.org, 2025): sub-Saharan Africa accounts for roughly 75–80% of the global sickle cell disease burden.

[10] WHO Regional Office for Africa, A Heavy Burden: The Productivity Cost of Illness in Africa (2019), based on 2015 data across 47 member states: total productivity loss in excess of 2.4 trillion international dollars, of which non-communicable diseases account for approximately 37%. Sub-Saharan NCD burden rose ~67% between 1990 and 2017 per comprehensive review of non-communicable disease burden on surgical services in Africa (2025).

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PART III

The Future Architecture of Global Clinical Development

The Series and Its Architecture

This is the final report in a three-part benchmark series. The series has a single argument, examined from three angles. Part I established why representative science and ecosystem development matter. Part II showed how operational excellence turns ecosystems into sustainable research capacity. Part III examines how those ecosystems evolve: how technological, regulatory, and geopolitical change is reshaping the architecture of global clinical development itself.

To keep the three parts intellectually unified rather than topically separate, the series rests on one master framework. Each report examines a different layer of the same architecture rather than introducing a new model.

The GLS Adaptive Clinical Development Ecosystem™

In this architecture, nine capabilities reinforce one another. People build trust; trust enables scientific capacity; capacity and convergence attract investment; digital intelligence multiplies their reach; together they generate representative evidence, healthcare innovation, commercial ecosystems, and ultimately population-health impact.

Figure 1. The GLS Adaptive Clinical Development Ecosystem™, the master architecture of the series. *Source: GLS Institute.*

Part I addressed the foundation of this architecture (people, trust, scientific capacity); Part II addressed its operation (convergence, quality, execution); Part III addresses its evolution: how digital intelligence, representative evidence, and commercial ecosystems are now reshaping the whole. The early-development argument introduced in Part II as the GLS Early Development Thesis™ recurs here as one mechanism of that evolution; the naming is deliberately consistent across the series.

A Note on Method, Evidence, and Foresight

This report distinguishes three kinds of content, and signals which is which. **Evidence** is observable fact: published data, regulatory developments, demographic trends, and market signals, referenced to primary sources current to 22 July 2026. **Interpretation** is what GLS Institute judges that evidence to mean. **Foresight**, concentrated in the scenarios and outlook, is explicitly probabilistic, identifying structural forces and uncertainties rather than predicting events. Where this report introduces an original measure, the GLS Research Ecosystem Maturity Index, it is presented as a transparent, illustrative prototype with its methodology and limitations stated[13], not as a definitive ranking.

Executive Summary

History rarely turns on a single breakthrough. It turns when several structural forces converge and reinforce one another. Clinical development is in such a period. Artificial intelligence is reshaping evidence generation; precision medicine is redefining disease classification; and regulatory systems, demographic shifts, manufacturing strategies, and geopolitics are together changing where innovation occurs and how medicines reach patients.

Africa is increasingly part of this transformation, not as an alternative venue for trials, but as a connected contributor to the global research enterprise. The change is measurable. Eight national regulators meet WHO maturity level 3 as of the most recent WHO benchmarking[4]; the African Medicines Agency has signed cooperation frameworks with both the US FDA and the WHO[2][3]; and a continental push aims to lift local vaccine manufacturing from under 1% today toward 60% by 2040[5]. These are not isolated developments. Together they are redefining the architecture of clinical development.

This report frames that change as five structural transitions: from fragmented regulation to convergence; from emergency response to permanent preparedness; from late-stage participation to contribution across the development lifecycle; from digital tools to intelligent research ecosystems; and from isolated markets to globally connected innovation ecosystems. Parts I and II examined the first three at length; this report concentrates on the two that define the future, intelligent ecosystems and connected innovation, and introduces the tools to measure the transition.

The Central Thesis — and How to Test It

> **GLS CENTRAL THESIS**
> *Global clinical development is shifting from geography-driven networks to ecosystem-driven networks. Africa is one of the clearest examples of this transition, but the underlying framework applies to every region. The future belongs not to isolated sites, but to connected ecosystems.*

This thesis is deliberately testable. Rather than asserting that Africa will simply become more important, it makes a claim that future evidence can confirm or weaken. GLS Institute will track the following indicators across editions:

- Growth in African trial participation and its phase distribution
- Expansion of regional regulatory harmonization and use of reliance pathways
- Growth in laboratory, genomic, and biobanking capacity
- Maturation of data-governance and benefit-sharing frameworks
- Increase in early-development and translational activity
- Growth in regional manufacturing and innovation ecosystems
- Investment in workforce and clinical-research training

WHAT WOULD CHANGE THIS THESIS

Intellectual honesty requires naming what would weaken the argument. The thesis is at risk if AMA implementation stalls, if reliance remains theoretical, if research funding contracts further after the 2025 shock[12], if workforce development fails to scale, if data governance becomes restrictive rather than enabling, or if instability disrupts key ecosystems. Each is tracked as an early-warning signal, not assumed away.

SECTION I

From Geography to Ecosystems: Africa in the Global Architecture

For three decades the question about Africa was “Can more trials be conducted there?” That question framed the continent as a destination for research activity. The more relevant question for the coming decade is different: “How will Africa influence the architecture of global clinical development?” That reframing is the heart of this report. Competitiveness will depend less on geographic expansion and more on ecosystem integration: the degree to which regulatory convergence, scientific capacity, digital intelligence, and trusted partnerships reinforce one another across regions.

Africa does not exist in a vacuum. It is one node in a diversified global development network that includes India, Southeast Asia, Latin America, Eastern Europe, the Middle East, and the established markets of the United States and Europe. The strategic question is not whether Africa replaces these regions, it will not, but where it offers differentiated value within a portfolio.

Table 1. Africa within the global development landscape: where it offers differentiated value.

Region	Established strength	Africa’s differentiated contribution
India & South-East Asia	Scale, cost-efficiency, large trial volumes	Genetic diversity and disease profiles absent elsewhere
Latin America	Mature oncology and cardiometabolic networks	Younger demographics; future demand growth
Eastern Europe	Fast recruitment, established sites	Infectious-disease and vaccine R&D depth
Middle East	Investment capacity; precision-medicine ambition	Regional harmonization momentum (AMA, RECs)
US & Europe	Innovation origin; regulatory reference	Representative evidence and emerging early-development capability

EVIDENCE Eight African regulators meet WHO maturity level 3 as of the most recent WHO benchmarking, and the AMA has signed cooperation frameworks with the US FDA and WHO[4][2][3].

GLS INTERPRETATION These are the institutional preconditions for ecosystem integration. A connected regulatory layer is what allows distributed national capabilities to function as a single network rather than a set of isolated sites.

STRATEGIC IMPLICATION Sponsors should evaluate regional regulatory ecosystems and reliance pathways, not only country-by-country requirements, when designing multi-country programs, and should position Africa for the value it uniquely adds rather than benchmarking it on cost alone.

> **GLS INSTITUTE PERSPECTIVE**
> *The future of clinical development is not a contest between regions. It is the construction of a connected architecture in which each region contributes differentiated value. Africa’s contribution, genetic diversity, representative evidence, and converging regulation, is becoming structural, not marginal.*

SECTION II

Intelligent Research Ecosystems: AI, Data, and Digital Evolution

The fourth structural transition is from digital tools to intelligent research ecosystems. Electronic data capture, decentralized trials, remote monitoring, and analytics are becoming embedded infrastructure; the frontier is now artificial intelligence applied to feasibility, protocol design, patient matching, pharmacovigilance, and evidence generation. For Africa, this transition carries both a singular opportunity and a singular risk.

The opportunity is leapfrogging: ecosystems that build digital infrastructure now can adopt intelligent methods without unwinding legacy systems. Pan-African initiatives are already laying the groundwork,
the Data Science for Health Discovery and Innovation in Africa program, the Africa CDC Pathogen Genomics Initiative, and the H3ABioNet bioinformatics network are building the data and analytic capacity on which intelligent research depends[7].

The risk is representational. Artificial intelligence trained predominantly on non-African data will generalize poorly to African patients, the same representation gap that defines the trial landscape, now encoded in algorithms. With Africa contributing under 2% of global genomic data[1], AI-enabled medicine built without African data risks widening, not closing, the equity gap. Digital transformation must therefore complement, never replace, local expertise, representative data, and community trust.

EVIDENCE Africa supplies under 2% of genomic research data even as decentralized and AI-enabled methods scale globally[1].

GLS INTERPRETATION Intelligent research ecosystems will only serve African populations if they are trained on representative data. The digital transition is inseparable from the representativeness argument that opened the series.

STRATEGIC IMPLICATION Sponsors and developers should treat African data generation and governance as a prerequisite for credible AI-enabled evidence, not an afterthought, and invest in local digital and analytic capacity as core infrastructure.

> **GLS INSTITUTE PERSPECTIVE**
> *Digital intelligence amplifies whatever data it is given. Built on representative African data, it can accelerate equitable medicine; built without it, it will automate the representation gap. The choice is being made now.*

SECTION III

Precision Medicine and Genomic Sovereignty

Precision medicine is redefining disease classification, and it depends on genomic diversity. Here Africa holds a paradox at the center of its strategic position: African populations are the most genetically diverse on Earth, yet contribute under 2% of global genomic research data[1][7]. The science cannot be completed without African genomes; the data to complete it barely exists.

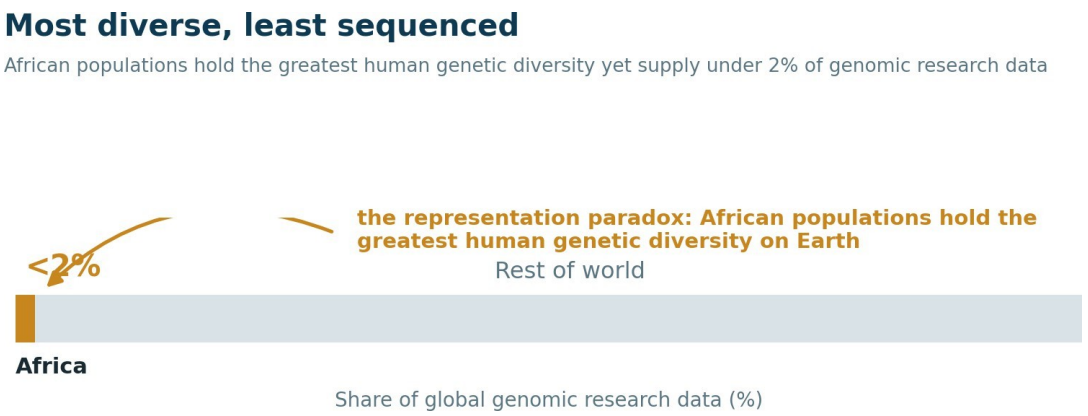

Figure 2. The genomic representation paradox. *Source: H3Africa and genomics-equity literature; GLS Institute.*

This is beginning to change through African-led science. The Human Heredity and Health in Africa consortium has built local genomic capacity and generated hundreds of publications and large biobank datasets, governed by an African data-and-biospecimen access framework[7]; SickleInAfrica and national genome initiatives are extending it. The strategic question is no longer only scientific but one of governance and sovereignty.

Governance, Ethics, and Scientific Sovereignty

Sophisticated readers expect a serious treatment of governance, because precision medicine in Africa raises questions that determine whether collaboration is sustainable: data protection and cross-border transfer, material transfer agreements for biospecimens, genomic-data and intellectual-property governance, benefit-sharing, responsible AI, community consent, and data sovereignty[8]. History makes these questions sharp, extractive research that removed samples and value without reciprocity is precisely what erodes the trust on which the whole architecture depends.

EVIDENCE African populations are the most genetically diverse yet most under-represented in genomic data, and governance frameworks for data, biospecimens, and benefit-sharing are still maturing[7][8].

GLS INTERPRETATION Genomic sovereignty is not an obstacle to precision medicine in Africa; it is its precondition. Trusted, reciprocal governance is what allows diverse data to be generated and shared at all.

STRATEGIC IMPLICATION Sponsors and research partners should build transparent data-governance, benefit-sharing, and trusted-research-environment models from the outset, treating scientific sovereignty as a foundation for collaboration rather than a barrier to it.

> **GLS INSTITUTE PERSPECTIVE**
> *Scientific collaboration is strongest when governance is transparent, ethical, reciprocal, and trusted. Africa's genetic diversity is a global scientific asset; whether the world can access it depends on whether the terms are sovereign and fair.*

SECTION IV

From Aid to Industry: Regional Manufacturing and Health Sovereignty

The fifth transition is from isolated markets to connected innovation ecosystems, and its most concrete expression is manufacturing. The COVID-19 pandemic exposed the cost of dependence: Africa imports roughly 95% of its medicines and 99% of its vaccines, and manufactures under 1% of the vaccines it uses[5]. The 2025 funding shock that closed Part I reinforced the lesson[12]. Sovereignty has become a strategic objective, not a slogan.

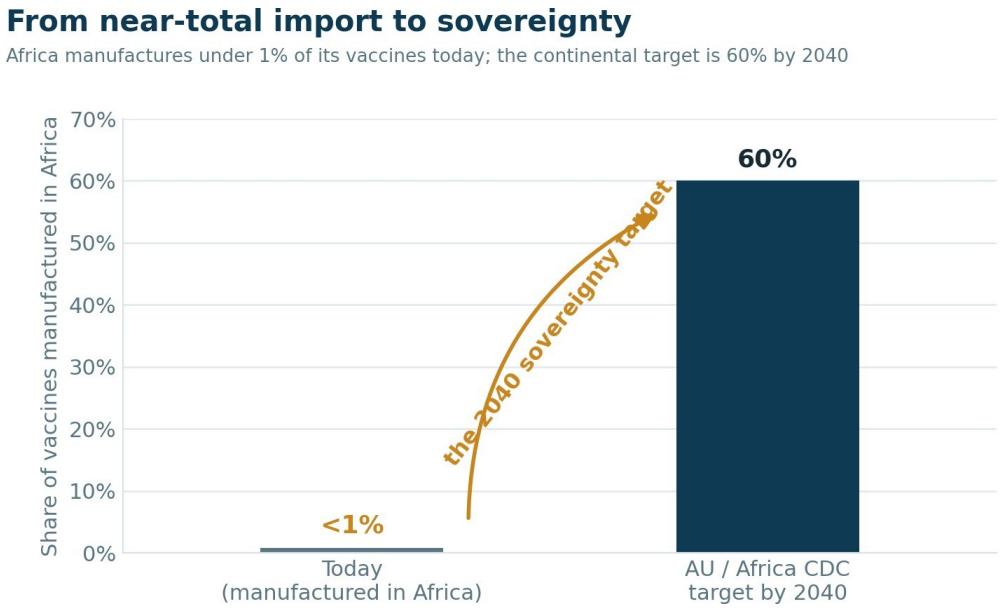

Figure 3. Africa's vaccine-manufacturing sovereignty gap. *Source: African Union / Africa CDC; Lancet Global Health, 2025.*

The response is an industrial build-out. The African Union and Africa CDC target 60% local manufacture of vaccines, medicines, and diagnostics by 2040, a goal tied to a continental market valued near USD 50 billion[5]. The institutions are emerging: the WHO mRNA technology-transfer hub at Afrigen in Cape Town; BioNTech's modular mRNA facility in Kigali; the Institut Pasteur de Dakar, long the only African producer of a WHO-prequalified vaccine, expanding through its MADIBA and VaxSen programs; and established players such as Biovac and Aspen in South Africa and Vacsera in Egypt[6]. Regulatory convergence is the enabler: only ecosystems with mature regulators can host production for prequalification, which is why the eight maturity-level-3 regulators and the AMA matter as much to manufacturing as to trials.

This is the link back to clinical development. Manufacturing and research co-locate: a continent that develops, tests, and makes its own medicines closes the loop from discovery to access on its own soil. The transition from aid to industry is also a transition from research destination to innovation partner.

EVIDENCE Africa manufactures under 1% of its vaccines but targets 60% by 2040, backed by a maturing regulatory layer and new facilities from Cape Town to Kigali to Dakar[5][6].

GLS INTERPRETATION Manufacturing sovereignty and research capability are two faces of the same ecosystem. Regulatory maturity, workforce, and trust serve both; investment in one strengthens the other.

STRATEGIC IMPLICATION Sponsors and investors should view regional manufacturing, regulatory maturity, and clinical-development capacity as an integrated opportunity, and recognize that the funding shock makes locally anchored, sovereignty-oriented models more resilient than donor-dependent ones.

> **GLS INSTITUTE PERSPECTIVE**
> *The most consequential shift of the coming decade may be Africa's move from importing finished science to producing it. A continent that makes its own medicines is no longer a venue for development; it is an author of it.*

SECTION V

Measuring the Transition: The GLS Research Ecosystem Maturity Index™

An institute is cited for its measures. To move the series beyond narrative, GLS Institute introduces the first of a planned family of benchmark indices: the GLS Research Ecosystem Maturity Index. It scores ecosystems across the dimensions that determine whether they can support modern clinical development, combining objective indicators with structured judgment. The version below is an illustrative prototype, its purpose is to demonstrate a transparent, repeatable method, not to issue a definitive ranking[13].

Table 2. Index construction: five weighted dimensions.

Dimension	Weight	Illustrative indicators
Regulatory maturity	25%	WHO maturity level (ML3); reliance-MoU participation; RCORE status
Scientific & trial capability	25%	Trial-center depth; first-in-human capability; anchor institutions
Manufacturing & sovereignty	20%	Vaccine/medicine production capability; WHO-prequalification readiness
Genomic & digital capability	15%	Genomic and bioinformatics capacity; data infrastructure
Convergence & sustainability	15%	Regional integration; financing diversification

The eleven ecosystems scored below comprise the eight profiled in Part I plus Egypt, Rwanda, and Senegal, which are central to the regulatory and manufacturing picture developed in Parts II and III. Zimbabwe, the eighth maturity-level-3 authority, is not yet scored because its documented trial-center and manufacturing indicators are too thin for a defensible composite; it is a candidate for the next edition. Coverage is a limitation of the prototype, not a judgment about the ecosystems omitted.

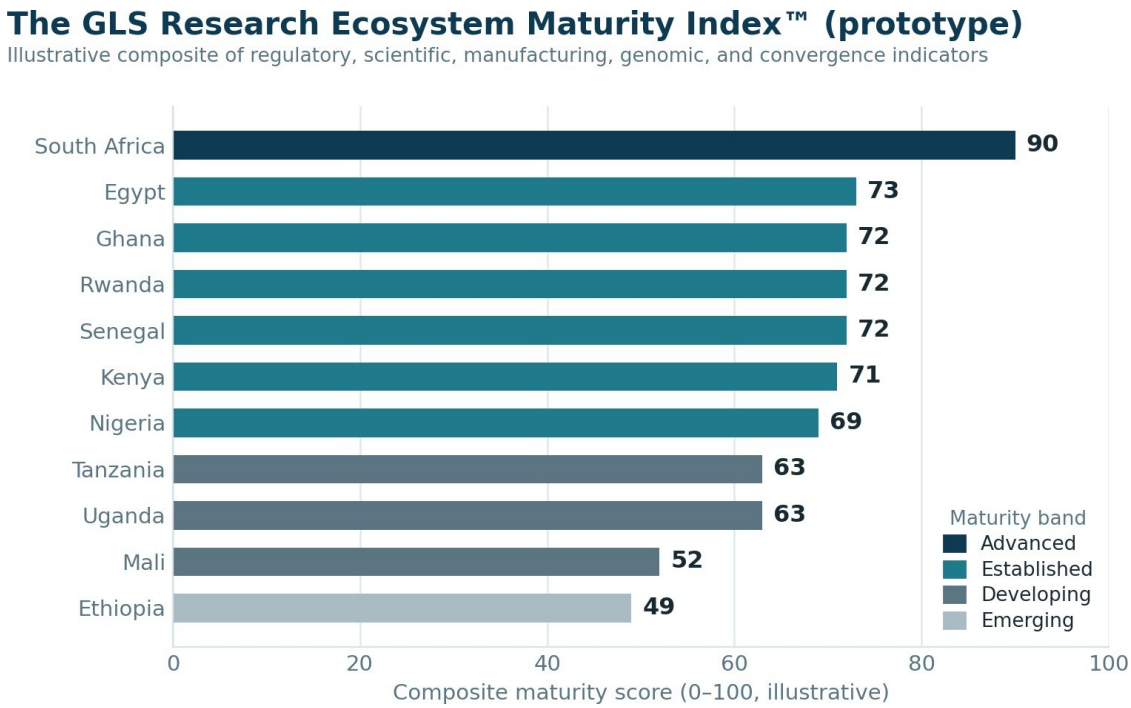

Figure 4. The GLS Research Ecosystem Maturity Index™ (illustrative prototype). *Source: GLS Institute analysis, 2026, drawing on WHO, Africa CDC, IQVIA, and institutional sources.*

The index does analytical work precisely because it is multi-dimensional. South Africa leads on the strength of regulatory maturity, scientific depth, manufacturing, and genomics together. But the rankings also reveal divergences a single measure would hide: Kenya and Uganda score high on scientific capability yet have not reached regulatory maturity level 3, while Rwanda and Senegal rise on regulatory and manufacturing strength despite a narrower trial base. Maturity is not one thing, and ecosystems advance unevenly across its dimensions. Where composite scores tie, ecosystems are listed alphabetically.

Table 3. Index readout: leading strengths and key gaps (illustrative).

Ecosystem	Score	Band	Leading strength	Key gap
South Africa	90	Advanced	Science, manufacturing, genomics	Funding resilience post-2025
Egypt	73	Established	Regulatory; oncology trial base	Genomic & digital depth
Ghana	72	Established	Standard-setting regulator (RCORE)	Manufacturing scale
Rwanda	72	Established	Regulatory; mRNA manufacturing	Scientific trial depth
Senegal	72	Established	Vaccine manufacturing (IPD)	Trial-base breadth
Kenya	71	Established	Scientific capability (KEMRI-Wellcome)	Regulatory maturity (not ML3)
Nigeria	69	Established	Scale; regulatory (NAFDAC)	Capacity concentration

Ecosystem	Score	Band	Leading strength	Key gap
Tanzania	63	Developing	Regulatory (ML3); EAC integration	Manufacturing & genomics
Uganda	63	Developing	HIV/TB science (Makerere)	Regulatory maturity
Mali	52	Developing	Malaria-research specialization	Breadth across dimensions
Ethiopia	49	Emerging	Demographic scale	Most dimensions early-stage

Methodology and Limitations

Scores combine objective indicators (WHO maturity level, documented trial-center counts, manufacturing capability, regulatory-reliance participation) with structured qualitative assessment, weighted as in Table 2 on a 0–100 scale; composites are rounded half-up and ties broken alphabetically. The prototype has real limitations, stated plainly: weights are judgment-based and would benefit from expert calibration; several indicators rest on partial public data; coverage is incomplete; the index measures ecosystem capability, not trial-conduct quality; and a single composite necessarily compresses genuine multi-dimensional difference. The Index should also be read alongside, not in place of, the five-level Maturity Model introduced in Part I: the Model is a descriptive ladder that includes a Strategic Innovation Hub level, while the Index reports four bands and does not yet score for that level, which no ecosystem is judged to have reached. It is offered as a transparent, improvable instrument, to be refined, challenged, and updated annually, not as a final verdict.

SECTION VI

Outlook 2035: Three Scenarios

Foresight is not prediction. A benchmark publication should not present a single inevitable future but a set of plausible ones, each driven by identifiable forces and watched through early-warning indicators. GLS Institute frames the decade to 2035 as three scenarios.

Table 4. Three scenarios for Africa's role in global clinical development to 2035.

Scenario	Key drivers	Principal risks	Early-warning indicators
1. Incremental Progress	Gradual trial growth; partial harmonization	Regulatory fragmentation and infrastructure variability persist	Reliance pathways stay theoretical; ML3 count stalls
2. Accelerated Integration	AMA operationalizes; reliance scales; digital and partnership investment	Funding instability; uneven regional progress	Rising reliance use; ML3 expansion; manufacturing facilities online
3. Innovation Leap	Africa contributes to platform trials, precision medicine, AI-enabled evidence, and regional manufacturing	Sovereignty and governance disputes; talent and capital constraints	First-in-human growth; local genomic data share rising; exports of African-made products

These scenarios are not equally likely, and the difference between them is largely a matter of choice and investment rather than fate. The same drivers, regulatory convergence, digital and genomic capacity, manufacturing, financing, and trust, appear in each; what varies is whether they are resourced and connected. The indicators in the final column are the signals GLS Institute will track to judge which path is unfolding.

> **GLS INSTITUTE PERSPECTIVE**
> *The decade to 2035 will not be decided by technology alone but by whether ecosystems are built to connect. Incremental progress is the default; accelerated integration and an innovation leap are choices, and the early-warning indicators will reveal which choice is being made long before the outcome is settled.*

SECTION VII

Counterarguments

A serious benchmark engages the strongest objections to its own thesis. Three credible counterarguments deserve direct answers.

Counterargument	GLS Institute response
“Africa remains too fragmented for large-scale clinical development.”	Fragmentation is real but no longer the whole story. Regional harmonization, AMA coordination, reliance pathways, and cross-border partnerships are creating more connected ecosystems; eight ML3 regulators and two continental cooperation frameworks signed in 2026 are evidence of convergence, not fragmentation.
“Infrastructure remains too variable.”	Variability matters, but mature development increasingly depends on ecosystem design, site selection, logistics, digital oversight, and quality-by-design rather than uniform physical infrastructure. The maturity index is precisely a tool for matching programs to demonstrated capability.
“Other regions are more competitive.”	India, Southeast Asia, Latin America, and Eastern Europe remain highly relevant. Africa is not a replacement but an increasingly strategic component of a diversified global architecture, differentiated by genetic diversity, young demographics, future demand, and infectious-disease and vaccine expertise.

GLS INSTITUTE PERSPECTIVE

Each objection contains a truth and stops short of the full picture. Fragmentation, variability, and competition are real constraints, and are precisely the conditions that ecosystem integration is designed to address. The thesis survives its strongest critics.

Closing: The Architecture of the Future

This trilogy is not, finally, a report about Africa. It is a report about the future architecture of global clinical development, using Africa as one of the clearest and most strategically important case studies of a transformation underway everywhere.

The future competitiveness of clinical development will increasingly be determined by the ability to build adaptive, trusted, and connected research ecosystems. Africa offers one of the most compelling demonstrations of that shift, a continent moving from research destination toward research author, from importer toward producer, from late-stage participant toward contributor across the development lifecycle. The first-in-human BRILLIANT 011 HIV vaccine trial launched in Cape Town in January 2026[9], and the emergency research response to the 2026 Bundibugyo Ebola outbreak[10], are early markers of that shift. But the underlying principles apply to every region seeking to strengthen scientific innovation, representative evidence, and long-term healthcare impact.

> **THE GLS INSTITUTE POSITION**
> *The next generation of clinical-development leadership will not be defined solely by where organizations conduct trials, but by where they invest in people, trust, regulatory capacity, digital intelligence, representative science, and sustainable healthcare ecosystems. This is the analytical foundation of the GLS Insights™ trilogy.*

Analytical Discipline of This Benchmark

For transparency, the elements below summarize the analytical structure applied across this report and the series.

Element	Purpose
Testable central thesis	Defines an argument future evidence can confirm or weaken
Evidence / interpretation / implication	Separates fact from judgment from recommendation
Master architecture	Gives the trilogy one intellectual backbone
Benchmark index	Makes ecosystem maturity measurable and improvable
Scenario analysis	Handles uncertainty without false prediction
Counterarguments	Engages the strongest objections directly
What would change the thesis	States the conditions that would weaken the argument
Methods & limitations	Supports citation and protects integrity

References

[1] IQVIA (2025) and WHO ICTRP (2026): Africa hosted ~4% of global clinical trials in 2023, supplies <2% of genomic research data, with participation concentrated in Phases III–IV.

[2] African Medicines Agency & US Food and Drug Administration. Statement of Cooperation, June 2026; FDA African Medicines Agency Liaison Office (AMALO), Kigali.

[3] World Health Organization & African Medicines Agency. Framework Agreement for Collaboration, signed at the 79th World Health Assembly (WHA79), May 2026: advancing harmonization, convergence, and reliance.

[4] WHO Global Benchmarking Tool (GBT). As of the most recent benchmarking (January 2025), eight African national regulatory authorities had attained Maturity Level 3: Egypt, Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, and Zimbabwe.

[5] African Union / Africa CDC. Target of 60% local manufacturing of vaccines, medicines, and diagnostics by 2040; Africa currently manufactures <1% of its vaccines and imports ~95% of medicines and ~99% of vaccines; continental market valued near USD 50 billion. (Africa CDC; Lancet Global Health, 2025.)

[6] Lancet Global Health (2025), “A landscape analysis of the vaccine ecosystem in Africa”; and African vaccine-manufacturing landscape: WHO mRNA hub at Afrigen (Cape Town), BioNTech (Kigali), Institut Pasteur de Dakar (MADIBA / VaxSen), Biovac and Aspen (South Africa), Vacsera (Egypt).

[7] H3Africa (Human Heredity and Health in Africa), H3ABioNet, Data Science for Health Discovery and Innovation in Africa (DS-I Africa), and the Africa CDC Pathogen Genomics Initiative; African genetic diversity and genomic underrepresentation (Nature Communications; Oxford Human Molecular Genetics, 2025).

[8] Munung N.S. et al. “Genomics and Health Data Governance in Africa.” Hastings Center Report, 2024, on data sovereignty, benefit-sharing, and ethical governance of African genomic data.

[9] South African Medical Research Council. BRILLIANT 011 first-in-human HIV vaccine trial, Cape Town, January 2026.

[10] World Health Organization. Ebola outbreak, DRC 2026 (Bundibugyo virus); PHEIC declared 17 May 2026; WHO–AMA and partner coordination on trial design during the response. Case and mortality figures as of 22 July 2026; see Part II, Section IV.

[11] Access to Medicine Foundation (2025): Ghana WHO maturity level 3 and Regional Centre of Regulatory Excellence; rise in industry-sponsored and sickle cell trials.

[12] Health Policy Watch and IAVI (2025): withdrawal of major external research funding and its impact on African research capacity (the “2025 funding shock”).

[13] GLS Institute analysis (2026): GLS Research Ecosystem Maturity Index prototype, methodology, weighting, and limitations as described in Section V. Illustrative; for refinement and annual update.

SERIES COMPANION & ANALYTICAL STANDARDS

Series Companion & Analytical Standards

The Series as One Work

The GLS Insights™ trilogy, *The Future of Clinical Trials in Africa*, is a single argument examined from three angles. Part I establishes why representative science and ecosystem development matter. Part II shows how operational excellence turns ecosystems into sustainable research capacity. Part III examines how those ecosystems evolve as technology, regulation, and geopolitics reshape the architecture of global clinical development.

Each part stands alone, but the three are designed to be read as one body of work. This companion is the connective tissue: it presents the master architecture that unifies the series, the disciplined canon of principles and terms the series uses, the full methodology behind its proprietary index, and the analytical standards, including currency and versioning, that govern the work. Its purpose is to let a reader navigate the trilogy as an institute benchmark rather than three separate papers, and to give sponsors, regulators, and researchers a transparent account of the methods behind the conclusions.

> **THE SERIES IN ONE SENTENCE**
> *Global clinical development is shifting from geography-driven networks to ecosystem-driven networks; Africa is the clearest example of that transition, and the trilogy maps its causes, its execution, and its future.*

How to Read the Series

The three parts follow a deliberate progression: foundation, execution, evolution. A reader new to the series should begin with Part I; a reader focused on operations can start with Part II; a reader concerned with strategy and the next decade can start with Part III and refer back.

Table 1. The trilogy at a glance.

Part	Question it answers	Signature deliverables
Part I	Why does Africa matter?	The representation gap (WHO/IQVIA data); the ecosystem framework; the maturity model; eight country profiles; the 2025 funding shock and risks.
Part II	How do ecosystems execute?	Regulatory convergence (AMA, WHO–AMA, AMA–FDA); the Early Development Thesis; execution under pressure (2026 Ebola); therapeutic opportunities; sustainable financing; the sponsor playbook.
Part III	How do ecosystems evolve?	The testable thesis; comparative global context; intelligent (AI) ecosystems; precision medicine and genomic sovereignty; manufacturing and sovereignty; the Maturity Index; Outlook 2035 scenarios; counterarguments.

Three threads run through all three parts and can be followed across them: the representation gap and the case for representative science; the 2025 funding shock and the turn toward sustainable, sovereign financing; and the move upstream into early-phase development. Each is introduced, advanced, and resolved across the series rather than confined to one report.

The Master Architecture

The trilogy rests on one model. Rather than introducing a separate framework in each report, every part examines a different layer of the same architecture, the GLS Adaptive Clinical Development Ecosystem™, in which nine capabilities reinforce one another, from people through to population-health impact.

Figure 1. The GLS Adaptive Clinical Development Ecosystem™, the single backbone of the series. *Source: GLS Institute.*

The table below maps each layer of the architecture to the part of the series that develops it most fully. Together they show that the three reports are not sequential topics but complementary views of one system.

Table 2. Where each layer of the architecture is developed.

Architecture layer	Developed primarily in	How
People	Part I	Human capital; institutional profiles; the workforce advantage
Trust	Parts I–II	Trust as a strategic and operational asset; community engagement
Scientific Capacity	Parts I–II	Named institutions; first-in-human and early-development capability
Regulatory Convergence	Part II	AMA; WHO–AMA and AMA–FDA frameworks; reliance pathways

Architecture layer	Developed primarily in	How
Digital Intelligence	Part III	AI-enabled evidence; data systems; genomic data capacity
Representative Evidence	Parts I, III	The representation gap; genomic diversity and sovereignty
Healthcare Innovation	Parts II–III	Therapeutic opportunity; precision medicine
Commercial Ecosystems	Part III	Regional manufacturing; market consolidation; sovereignty
Population Health Impact	Part III	Outlook 2035; sovereignty and health security

How the Instruments Relate

The series uses three analytical instruments, and readers should not confuse them. The **GLS Research Ecosystem Framework** (Part I) sets out eight dimensions of ecosystem strength and is diagnostic: it describes what to look at. The **GLS Research Ecosystem Maturity Model** (Part I) is a five-level descriptive ladder, Emerging, Developing, Established, Advanced, Strategic Innovation Hub, and describes where an ecosystem sits. The **GLS Research Ecosystem Maturity Index™** (Part III) operationalizes the Framework into five weighted, scorable dimensions and reports a 0–100 composite in four bands. The Index does not yet score for the Strategic Innovation Hub level, which no ecosystem is judged to have reached; where the Model and the Index disagree for a country, the Index is the more conservative reading, because it weights regulatory maturity at 25%.

The Series in Brief

The argument of the trilogy can be stated in a single page. Africa carries roughly a quarter of the global disease burden but hosts about 4% of clinical trials and supplies under 2% of genomic research data: a measurable, widening representation gap that is both an equity problem and a scientific one, since medicine tested in unrepresentative populations is less accurate[1]. Closing that gap is not a matter of running more trials in more places; it is a matter of building connected research ecosystems.

That shift, from geography-driven to ecosystem-driven development, is already underway and measurable. Eight national regulators meet WHO maturity level 3 as of the most recent WHO benchmarking[2]; the African Medicines Agency has signed cooperation frameworks with both the US FDA and the WHO[3]; first-in-human studies such as the BRILLIANT 011 HIV vaccine trial are being run on the continent; and a continental drive aims to lift local vaccine manufacturing from under 1% today toward 60% by 2040[4]. The trilogy frames this as five structural transitions: from fragmented regulation to convergence; from emergency response to permanent preparedness; from late-stage participation to contribution across the development lifecycle; from digital tools to intelligent research ecosystems; and from isolated markets to connected innovation ecosystems.

Two cautions discipline the optimism. The 2025 withdrawal of major external research funding exposed how much African capacity remained donor-dependent, making sustainable, locally anchored financing a strategic necessity[5]. And the gains are unevenly distributed, concentrated in a handful of ecosystems and contingent on regulatory maturity, workforce retention, data governance, and stability. The series' conclusion is therefore conditional: the future belongs to ecosystems built to connect, and whether that future arrives is a matter of investment and choice, not inevitability.

The GLS Canon

An institute is recognized by a disciplined vocabulary, not a proliferating one. The series therefore commits to a fixed canon: eight enduring principles, one signature thesis, one master architecture, and one family of indices. These, and only these, carry the GLS mark. Explanatory figures and models used within individual reports (delivery diagrams, value chains, quality cycles) are descriptive devices, not separate trademarks, and are presented as such throughout. Cover and promotional artwork uses the canon wording exactly as set out below.

The Eight Principles

Principle	What it asserts	Developed in
Representative Science Drives Better Medicine™	Better, more generalizable medicine requires evidence generated in the populations who will use it.	Part I
Ecosystems Outperform Sites™	Performance follows the maturity of the surrounding ecosystem, not the capability of any single site.	Parts I–II
Trust Is Strategic Infrastructure™	Trust governs recruitment, retention, data quality, and the speed of response under pressure.	Parts I–II
Human Capital Is the Decisive Advantage™	The least replicable asset is trained, retained, locally led people and expertise.	Part I
Regulatory Convergence Creates Predictability™	Reliance, recognition, and harmonization turn a fragmented approval landscape into predictability.	Part II
Quality Is Designed, Not Inspected™	Quality is most effective when built into study design rather than assessed retrospectively.	Part II
Sustainable Capacity Outlasts Single Studies™	Durable performance depends on diversified, locally anchored financing, not donor-dependent funding.	Part II
Future Patients Are Future Markets™	The populations enrolling today are among the most important healthcare consumers of tomorrow.	Part I

The signature analytical thesis of the series is **the GLS Early Development Thesis™** (Parts II–III): the frontier of ecosystem maturity is moving upstream, into early-phase and first-in-human development, where representativeness is captured at the source of the evidence chain. The master framework is **the GLS Adaptive Clinical Development Ecosystem™**, and the measurement family is **the GLS Research Ecosystem Maturity Index™**, the first of a planned set of benchmark indices.

> **A NOTE ON DISCIPLINE**
> *Earlier editions introduced several additional named models and figures, and some cover artwork carried variant wordings of the principles. These are consolidated under the canon above. From this edition forward, the GLS mark is reserved for the eight principles, the thesis, the architecture, and the index family, so that the vocabulary builds recognition rather than diluting it.*

The GLS Research Ecosystem Maturity Index™: Methodology and Data

The Maturity Index is the series' first proprietary benchmark. It scores research ecosystems across the dimensions that determine whether they can support modern clinical development. This companion publishes its full method and underlying scores so the index can be examined, challenged, replicated, and improved, the standard to which a citable institute measure should be held. The current version is an illustrative prototype; its purpose is to demonstrate a transparent, repeatable method, not to issue a definitive ranking.

Construction

Each ecosystem receives a score from 0 to 100 on five weighted dimensions. Dimension scores combine objective indicators (where available) with structured qualitative assessment; the weighted average is the composite, which is then placed in a maturity band. Composites are rounded half-up, and ties are broken alphabetically.

Table 3. The five dimensions, their weights, and their indicators.

Dimension	Weight	Illustrative indicators and sources
Regulatory maturity	25%	WHO Global Benchmarking Tool maturity level (ML3); reliance-MoU participation; RCORE status.
Scientific & trial capability	25%	Documented trial-center depth; first-in-human capability; anchor institutions.
Manufacturing & sovereignty	20%	Vaccine/medicine production capability; WHO-prequalification readiness.
Genomic & digital capability	15%	Genomic and bioinformatics capacity (e.g., H3Africa nodes); data infrastructure.
Convergence & sustainability	15%	Regional integration (RECs); diversification of financing.

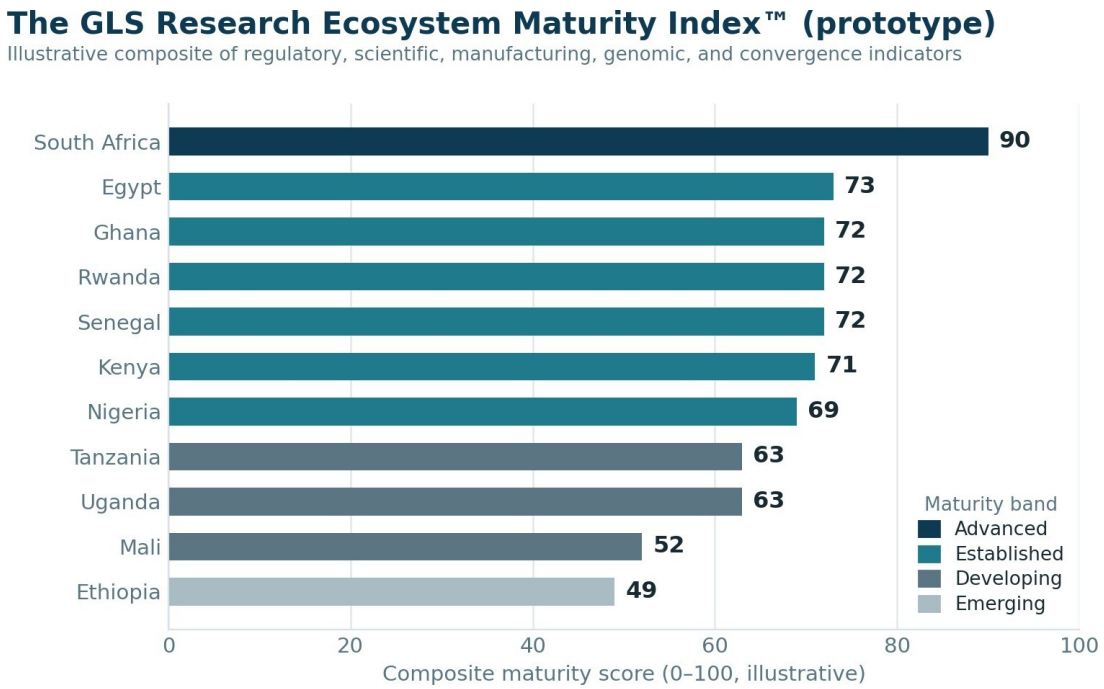

Figure 2. The GLS Research Ecosystem Maturity Index™ (illustrative prototype). *Source: GLS Institute analysis, 2026.*

The Underlying Scores

The full scoring matrix is published below. Bands: Advanced (80–100), Established (65–79), Developing (50–64), Emerging (below 50). The matrix is what allows the index to be interrogated rather than taken on trust, and it reveals divergences a single ranking would hide, such as ecosystems strong in science but not yet in regulatory maturity.

Table 4. Maturity Index scoring matrix (illustrative; 0–100 by dimension). Reg = regulatory maturity; Sci = scientific and trial capability; Mfg = manufacturing and sovereignty; Gen = genomic and digital capability; Conv = convergence and sustainability.

Ecosystem	Reg 25%	Sci 25%	Mfg 20%	Gen 15%	Conv 15%	Score	Band
South Africa	90	95	90	90	80	90	Advanced
Egypt	85	80	70	55	65	73	Established
Ghana	88	72	60	55	75	72	Established
Rwanda	85	60	75	55	80	72	Established
Senegal	82	65	80	55	72	72	Established
Kenya	60	88	55	75	75	71	Established
Nigeria	80	70	60	65	65	69	Established
Tanzania	80	60	45	50	75	63	Developing
Uganda	58	75	45	65	70	63	Developing

Ecosystem	Reg 25%	Sci 25%	Mfg 20%	Gen 15%	Conv 15%	Score	Band
Mali	50	62	35	50	60	52	Developing
Ethiopia	50	50	40	45	60	49	Emerging

Limitations and Update Cadence

The prototype's limitations are stated plainly. The weights are judgment-based and would benefit from expert calibration. Several indicators rest on partial public data. Coverage is incomplete: the eleven ecosystems scored are the eight profiled in Part I plus Egypt, Rwanda, and Senegal, and Zimbabwe,
the eighth maturity-level-3 authority, is not yet scored because its documented trial-center and manufacturing indicators are too thin for a defensible composite. The index measures ecosystem capability, not the quality of any individual trial. And a single composite necessarily compresses genuine multi-dimensional difference, which is why the full matrix, not only the composite, is published. The index is intended to be updated annually, with weights, indicators, and coverage refined as data improve and as external reviewers challenge them. It is offered as an improvable instrument, not a final verdict.

Analytical Standards and Currency

The series holds itself to a consistent analytical discipline, summarized below. Its purpose is to make the work citable and to keep the boundary between evidence, interpretation, and foresight visible to the reader.

Standard	What it requires
Testable thesis	A central argument that future evidence can confirm or weaken, with tracked indicators.
Evidence / interpretation / foresight	Observable fact, GLS interpretation, and probabilistic outlook are labeled and kept distinct.
Single architecture	Every part contributes to one master model rather than introducing new frameworks.
Benchmark indices	Original measures published with transparent method, data, and limitations.
Scenario analysis	Plural futures with drivers, risks, and early-warning indicators — not single predictions.
Counterarguments	The strongest objections engaged directly rather than avoided.
Risks and what would change the thesis	Headwinds and falsifying conditions stated explicitly in every part.
Methods and currency	Sources referenced; figures dated; time-sensitive facts flagged and refreshed.

Currency and Versioning

Several facts in the series are time-sensitive and will change: the 2026 Ebola case counts, the African Medicines Agency's implementation phase, the number of regulators at maturity level 3, and the commercial market estimates. This edition is current as of 22 July 2026 and is versioned accordingly (Edition 2026.2). Where two credible estimates of the continental pharmaceutical market circulate, a peer-reviewed figure above USD 40 billion by the 2030s and an African Union / Africa CDC figure near USD 50 billion, the series reports both and treats them as a range rather than a single number. The series is intended to be refreshed at least annually; readers acting on specific figures should confirm the latest status, and the indicator dashboard below is the mechanism for tracking change between editions.

The Indicator Dashboard

Because the central thesis is testable, the series commits to tracking a defined set of indicators across editions. These are the signals by which GLS Institute will judge whether the transition from geography-driven to ecosystem-driven development is accelerating, stalling, or reversing, and they form the basis of the series' longitudinal analysis.

Indicators of progress

- Growth in African trial participation and its phase distribution (especially early-phase activity)
- Expansion of regional harmonization and the practical use of reliance pathways
- Growth in laboratory, genomic, and biobanking capacity
- Maturation of data-governance, benefit-sharing, and sovereignty frameworks
- Growth in regional manufacturing toward the 2040 sovereignty target
- Investment in workforce development and clinical-research training

Early-warning signals (what would weaken the thesis)

- African Medicines Agency implementation stalls, or reliance remains theoretical rather than practiced
- Research funding contracts further after the 2025 shock
- Workforce development fails to scale, or talent loss accelerates
- Data governance becomes restrictive rather than enabling
- Instability disrupts key ecosystems, or sponsors retrench toward established regions

> **THE STANDARD THE SERIES SETS ITSELF**
> *A benchmark is judged not by how confidently it predicts, but by how honestly it can be tested. The dashboard is the series' commitment to be measured against its own argument, edition over edition.*

References and Sources

[1] IQVIA (2025) and WHO ICTRP (2026): Africa hosted ~4% of global clinical trials in 2023 and supplies <2% of genomic research data, with participation concentrated in Phases III–IV.

[2] WHO Global Benchmarking Tool: eight African national regulatory authorities at Maturity Level 3 as of the most recent benchmarking (January 2025): Egypt, Ghana, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Zimbabwe.

[3] African Medicines Agency – US FDA Statement of Cooperation (June 2026); WHO – AMA Framework Agreement for Collaboration (WHA79, May 2026).

[4] African Union / Africa CDC: target of 60% local manufacturing by 2040; Africa manufactures <1% of its vaccines today; continental market valued near USD 50 billion.

[5] Health Policy Watch and IAVI (2025): withdrawal of major external research funding and its impact on African research capacity (the “2025 funding shock”).

[6] Full primary sourcing for all figures appears in the reference lists of Parts I, II, and III. This companion summarizes and does not supersede them.

About the Author

Charles Oviawe — *Co-Founder and Managing Partner, Guosa Life Sciences*

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.

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