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GLS INSIGHTS™

CLINICAL DEVELOPMENT AND GLOBAL HEALTH · BENCHMARK SERIES

The Future of Clinical Trials in Africa

Executive Brief

The Trilogy in Brief — Evidence, Execution, and Outlook to 2035

SUMMARY OF PARTS I–III

WHAT THIS BRIEF COVERS

REPRESENTATIVE SCIENCE

ECOSYSTEMS

EARLY DEVELOPMENT

MATURITY INDEX

SUSTAINABILITY

Guosa Life Sciences
Advancing Life Through Better Medicine

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The Argument in One 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. That is a measurable, widening representation gap, and it is both an equity problem and a scientific one, because medicine tested in unrepresentative populations is less accurate[1]. Closing it 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[6]; and a continental drive aims to lift local vaccine manufacturing from under 1% today toward 60% by 2040[4].

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 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 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.*

The Representation Gap

Of the 20,825 trials that began globally in 2023, about 819, roughly 4%, were hosted by African countries[1]. The gap is widening rather than closing: WHO registry data show the Western Pacific recording 31,097 newly registered trials in 2025 against 822 across all of Africa, a ratio that has grown from roughly 24-to-1 in 2016 to 38-to-1 in 2025. Participation is also concentrated at the wrong end of the development chain, predominantly Phases III and IV, which means representativeness enters the evidence chain near its end rather than at its source.

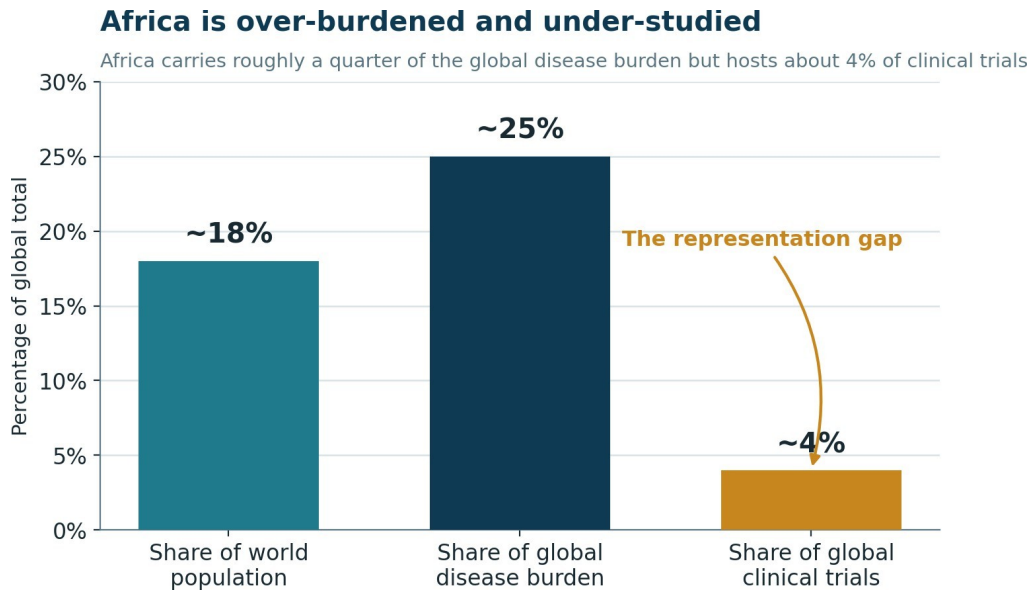

Figure 1. Africa's share of population, disease burden, and clinical trials. *Source: UN World Population Prospects 2024; IQVIA; Semafor analysis of five major journals, 2026.*

What the Trilogy Answers

Part	Question it answers	Signature deliverables
Part I	Why does Africa matter?	The representation gap; the ecosystem framework; the maturity model; eight country profiles; the 2025 funding shock and risks.
Part II	How do ecosystems execute?	Regulatory convergence (AMA, AMA–FDA, WHO–AMA); 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; counterarguments.

Where Ecosystems Stand Today

The GLS Research Ecosystem Maturity Index™ scores ecosystems across five weighted dimensions: regulatory maturity (25%), scientific and trial capability (25%), manufacturing and sovereignty (20%), genomic and digital capability (15%), and convergence and sustainability (15%). It is an illustrative prototype: its purpose is to demonstrate a transparent, repeatable method, not to issue a definitive ranking[7]. Where scores tie, ecosystems are listed alphabetically.

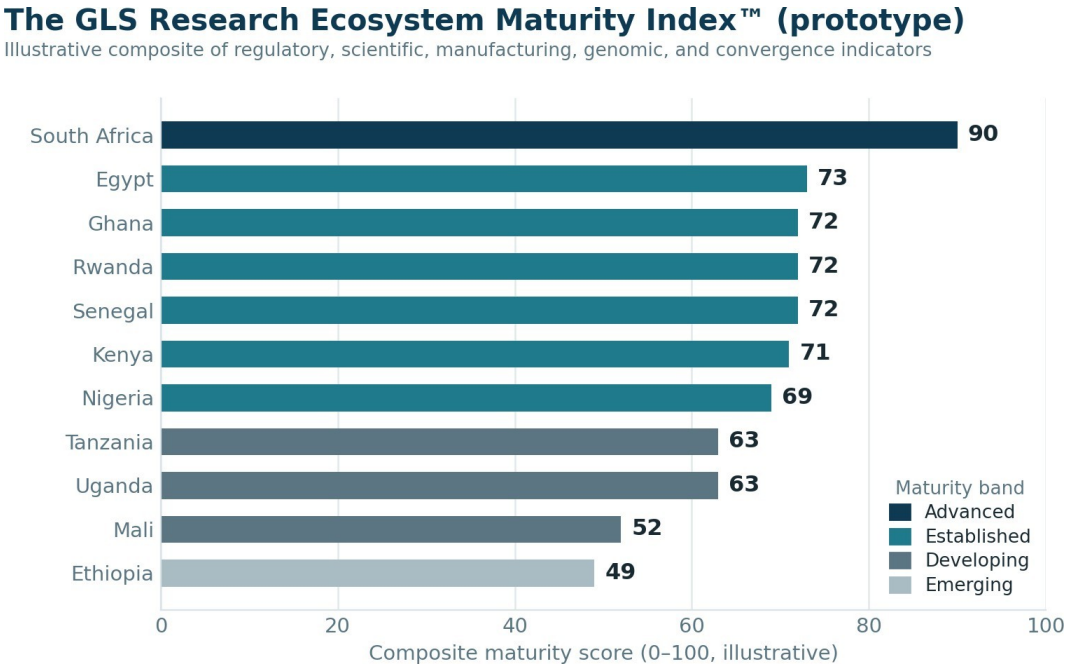

Figure 2. The GLS Research Ecosystem Maturity Index™ (illustrative prototype). *Source: GLS Institute analysis, 2026, drawing on WHO, Africa CDC, IQVIA, and institutional sources.*

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.

What Sponsors Should Do

Eight actions follow directly from the evidence across the three reports.

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 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.*

What Would Change the Thesis

Intellectual honesty requires naming what would weaken the argument. Each of the following is tracked as an early-warning signal, not assumed away.

- 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.

Currency and Versioning

Several facts in this 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). The series is refreshed at least annually; readers acting on specific figures should confirm the latest status.

References

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

[7] GLS Institute analysis (2026): GLS Research Ecosystem Maturity Index prototype, methodology, weighting, and limitations as described in Part III, Section V.

[8] Full primary sourcing for all figures appears in the reference lists of Parts I, II, and III. This brief 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
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- 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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