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GLS INSIGHTS™

CLINICAL DEVELOPMENT AND GLOBAL HEALTH · BENCHMARK SERIES

The Future of Clinical Trials in Africa

Series Companion & Analytical Standards

Reading the Trilogy as One Body of Work

COMPANION TO PARTS I–III

THE CANON AND ITS INSTRUMENTS

ARCHITECTURE

REPRESENTATIVE SCIENCE

ECOSYSTEMS

EARLY DEVELOPMENT

MATURITY INDEX

Guosa Life Sciences

Advancing Life Through Better Medicine

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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.

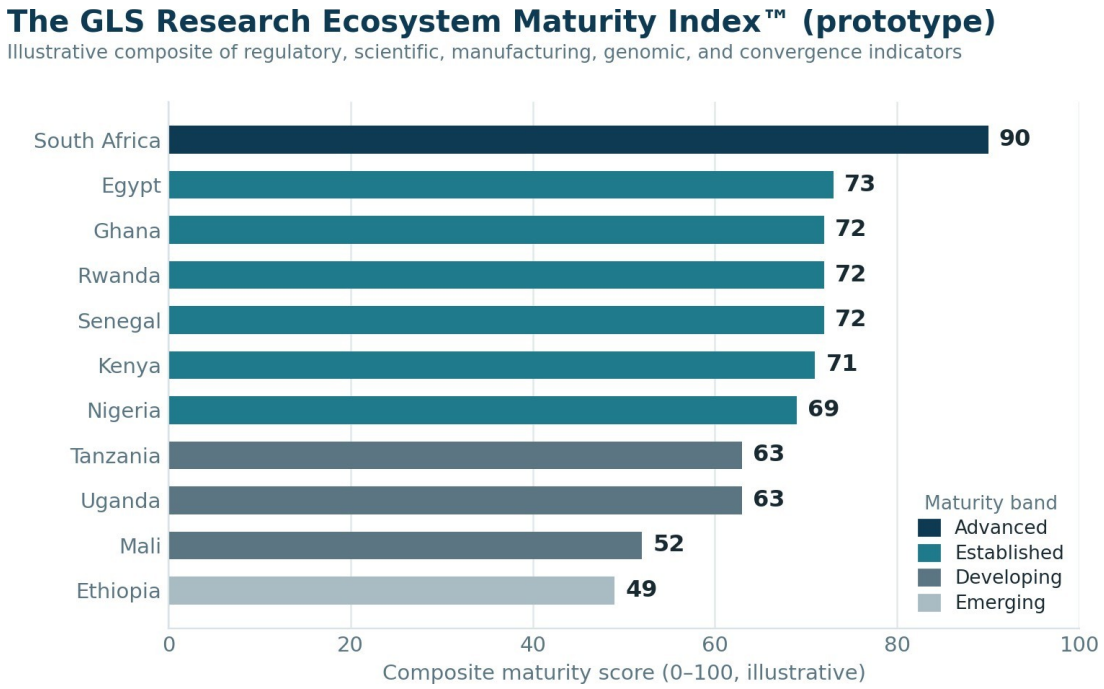

Figure 2. The GLS Research Ecosystem Maturity Index™ (illustrative prototype). *Source: GLS Institute analysis, 2026.*

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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