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Bridging the divide:

Technology, clinical research and patient outcomes in Africa's evolving health landscape

Enabling scalable, Africa-led clinical research through technology, partnerships and operating models

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Executive summary

Africa carries a disproportionate share (approximately 25%)[1,2] of the global disease burden while remaining underrepresented in clinical trials. This paper examines barriers and explores how integrated operating models—supported by appropriate technology, governance and workforce development—can improve research execution and patient outcomes.

Africa hosted only ~1% of global clinical trials in 2023,[2] contributing to clinical guidelines based on non-African populations and exposing the vulnerability of donor-dependent models.

Closing this gap requires an intentionally localized and execution-focused strategy. Scalable site network and Site Management Organization (SMO) models are emerging as critical enablers across Africa, allowing sites to operate within standardized frameworks while retaining local leadership. Continued capability development is needed in WHO Maturity Level 3 (ML3) and lower-income countries.

Technology embedded within coherent operating models, addressing data sovereignty, interoperability, workforce readiness and cross-border regulatory complexity, can enable a resilient, Africa-led research ecosystem capable of delivering high-quality, globally relevant evidence at scale.

Cognizant, with its deep expertise across Africa, is committed to supporting initiatives to promote clinical research and improve health outcomes for all communities across the region. Cognizant can play a key role in bringing together site networks, independent sites and sponsors on a shared collaboration platform—expanding equitable research opportunities for African sites, as well as helping sponsors identify, develop and reach their goals in Africa.

The research equity gap: Why it matters

Disparity in global health: Disease burden vs. research participation

The African continent carries approximately 25% of the global disease burden and is home to over 1.4 billion people, but just 3% of the global healthcare workforce;[1,17] this epidemiological reality remains significantly underrepresented in global R&D pipelines. However, 2023 data show very limited participation of African countries in global clinical trials. Africa's underrepresentation in clinical trials limits data generalizability and creates regulatory barriers, including labeling restrictions, refusal-to-file decisions and mandatory.

Phase IV postmarketing studies. Only 27.5% of late-stage R&D projects from top pharmaceutical companies included one or more African countries in 2024.[2] The continent hosted only 845 out of 76,331 clinical trials initiated globally in 2023 (approximately 1.1%), highlighting how trial activity remains concentrated in a few countries within Africa.[2]

This underrepresentation profoundly affects patient outcomes, as clinical trials are the gateway to generating safety and efficacy data across diverse populations. When African populations are excluded, disease management relies on non-African population data, potentially contributing to compromised healthcare quality and effectiveness on the continent.[2] Additionally, African nations miss the research and regulatory capacity-building benefits that trials can enable.[2]



Africa's dual disease burden and the expanding scope of health needs

While the continent continues to face high-priority infectious diseases such as Ebola, mpox, cholera, malaria, tuberculosis and HIV,[3] a rapid epidemiological transition is underway. Noncommunicable diseases (NCDs) such as cardiovascular disease, cancer, diabetes and neurological conditions are placing immense pressure on already strained African health systems.[4]

Recent analysis conducted in South Africa indicates that most new studies are related to cancer, followed by respiratory and infectious diseases (see adjacent Figure 1 below).[5] Similar patterns are emerging in other ML3 countries such as Egypt, Kenya, Ghana[35] and Rwanda.[36]

As an additional example, analysis of data (at the end of 2025) from Cognizant life sciences platforms such as Shared Investigator Platform (SIP),[32] shows more than 200 unique global, industry-sponsored studies that included sites in Africa (~50% oncology, ~70% Phase III) across more than 250 sites, led by South Africa, Egypt and Kenya, further illustrating the growth of NCD research activity across the continent.

However, despite recent progress, African populations remain underrepresented in much of the global NCD research landscape, meaning that treatment guidelines may not fully reflect African genetic profiles, comorbidities or lifestyle factors, potentially limiting therapeutic effectiveness.[6] Broadening Africa's clinical trial footprint beyond infectious disease silos to include NCDs is paramount for improving health outcomes and equitable medical access.[2]

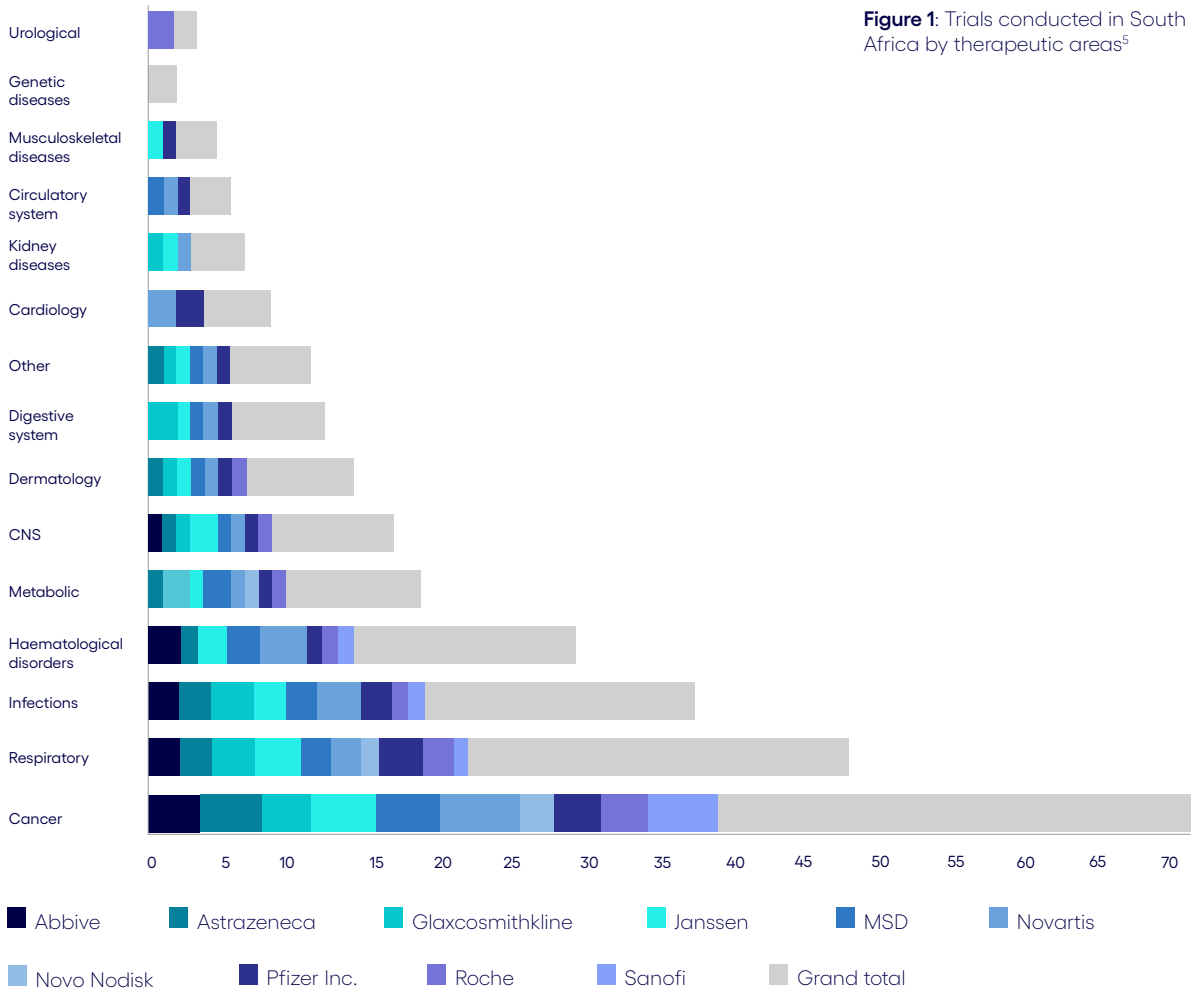


Figure 1: Trials conducted in South Africa by therapeutic areas[5]

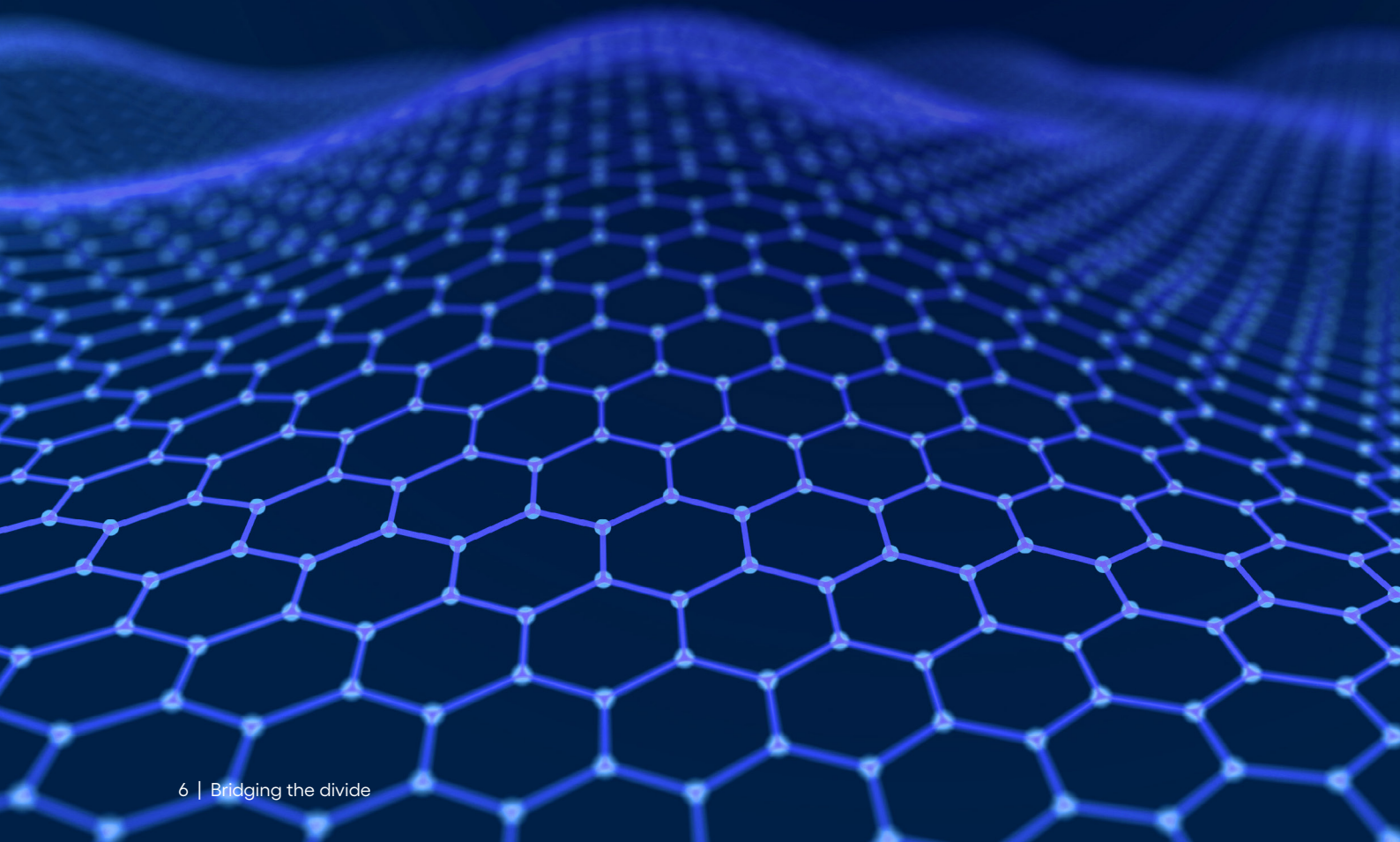
Uneven research capacity across Africa: Challenges in scale and compliance

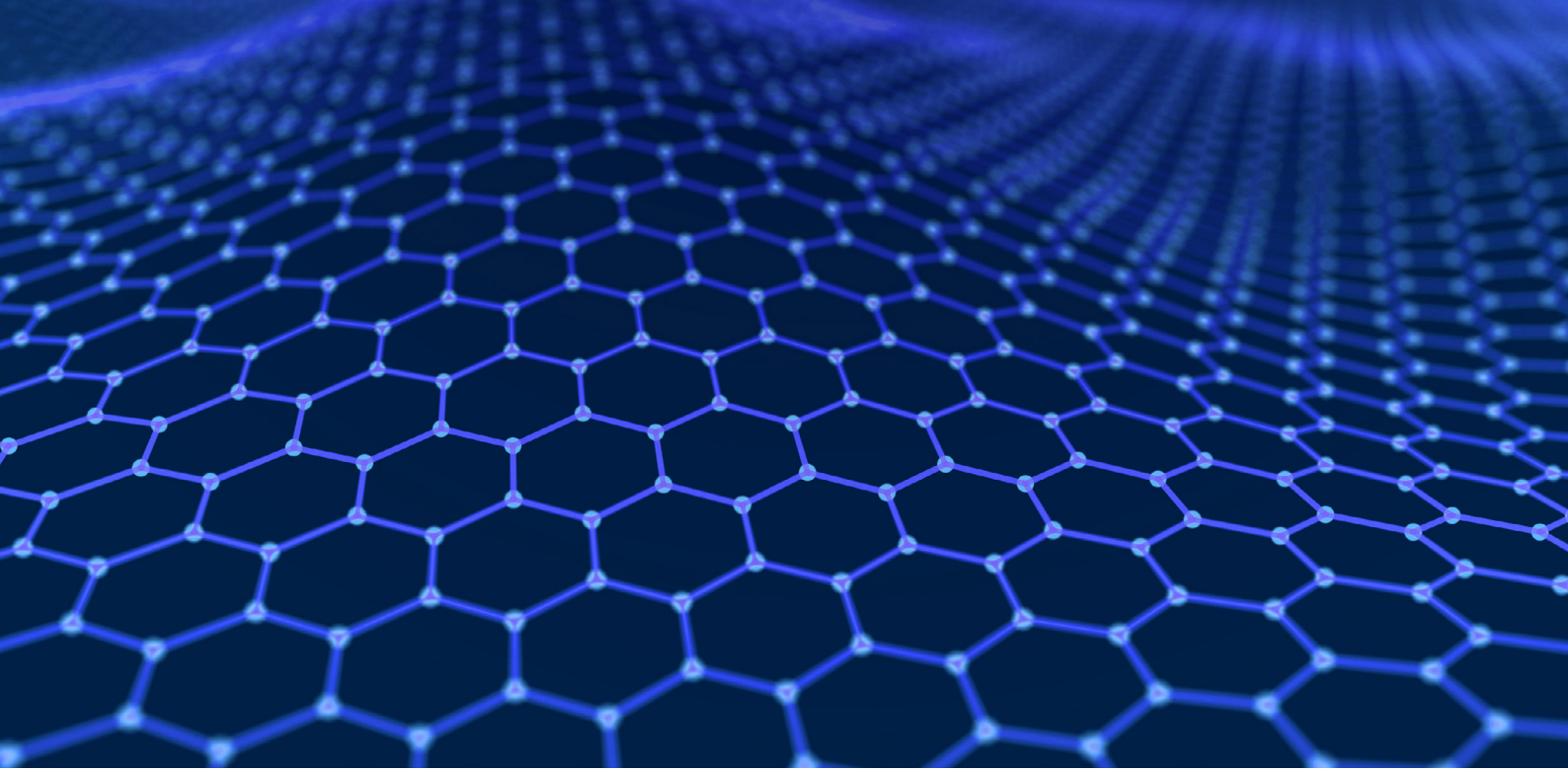
Current state of clinical trial capacity and concentration

Clinical trial activity remains concentrated, with 19 of all 54 countries (35%) not hosting a single industry-sponsored Phase II trial in the past decade.[2,6] Since 2015, 73% of Phase II–IV trials in Africa have enrolled participants exclusively from South Africa,[6] where trial activity is comparable to that of high-income countries. Similar capabilities are gradually emerging in other ML3 countries, including Egypt and Ghana. However, Central African countries remain underrepresented due to limited infrastructure and underinvestment.[6]

Newer models—embedded site networks, hub-and-spoke coordination and SMO-enabled execution—are helping ML3 countries expand trial capacity beyond traditional centers. Examples include the African Clinical Research Network's (ACRN) pan-Africa network of 35 sites, TASK-Parexel partnership in South Africa, IQVIA's embedded investigator network and Ghana's Good Clinical Practice (GCP)-driven SMO infrastructure.

Technology adoption readiness varies significantly across African subregions, requiring context-specific strategies. Emerging Africa-led site networks and contract research organization (CRO)/SMO models navigate these variations through shared, standardized Standard Operating Procedures (SOPs), harmonized training and collaborative operational infrastructure.





The table below compares the research infrastructure readiness, health data availability, clinical trial concentration and key highlights of the broad regions of Africa.

Table A: Trial concentration and regional readiness across African regions

Region	Trial concentration	Infrastructure maturity	Health data availability	Key aspects	Citations
Southern Africa	High (SA 73% of SSA trials)	Highest (established HIV/TB infrastructure)	Highest	Regulatory harmonization; NCD expansion; South Africa expertise	6
North Africa (MENA)	Low to moderate	Moderate to high (EHR focus)	Variable	Digital governance; social and cultural fit; conflict-sensitive implementation	8
East Africa	Low to moderate	Moderate (strong mHealth initiatives, training)	Variable; e.g., Uganda has high (~60%) availability since 2000; however high fragmentation across nations	Interoperability failure (Uganda case); limited standards; capacity building	7, 10–12
West Africa	Low	Low to moderate	Low	Connectivity constraints; public-private partnerships; outbreak response (Ebola case study)	9, 11
Central Africa	Critically low (almost no activity)	Extremely low	Extremely low; foundational investment required; large research gap	Lack of basic infrastructure	6

Note: mHealth=mobile health; EHR=electronic health records

Southern Africa (the regional hub)

Southern Africa exhibits the highest health system performance.[6] Zimbabwe, Botswana and Mozambique are expanding research capability.[6,26] The region, anchored by South Africa's regulatory infrastructure, serves as a springboard for continent-wide harmonization efforts through the Africa Medicines Agency (AMA).[27]

East Africa (maturity in mHealth, immaturity in standardization)

East Africa has scaled mHealth programs such as Jibu mLearning,[10] but faces technological fragmentation and inconsistent governance. Lack of standardization limits integration of research technologies.[17] Uganda, for instance, has multiple non-interoperable digital health interventions due to absent formal standards.[12] Emerging hubs in Kenya, Rwanda and Tanzania are developing stronger capabilities, with Kenya shifting to industry-sponsored trials and Rwanda building a health tech hub with high WHO maturity levels.



North Africa (MENA alignment and digital governance)

Northern Africa (MENA region) displays higher digital system sophistication, though this does not always translate into clinical research readiness. Many countries have enacted reforms focusing on national electronic health records (EHRs) and digital health training,[8] vital for research accessibility in fragile settings;[26] however, successful implementation requires social and cultural consideration.[8] Lessons learned (e.g., Uganda case[34]) underscore the need to align technology with workforce capability and governance.

West Africa (infrastructure and public-private partnership [PPP] dependence)

Western Africa faces infrastructural constraints with varying readiness.[11] Ghana's FDA serves as a Regional Centre for Regulatory Excellence (RCORE), and, alongside Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), has achieved WHO Medicines Regulatory Maturity Level [3], with Senegal actively participating in the West Africa Medicines Regulatory Harmonization (WA-MRH) initiative as part of broader ecosystem strengthening across ECOWAS member states.[37] mHealth has proven invaluable in outbreak management, as was witnessed during the Ebola epidemic in 2014–2015,[38] demonstrating the platform's value for rapid response. However, long-term sustainability requires continued government investment and multilateral technical support in regulatory systems and networks.[18]

Data governance, compliance and cross-border transfers

Africa's data governance remains fragmented with restrictive cross-border transfer conditions.[16,19] Regional harmonization initiatives, including the AMA, are creating compliance frameworks, though these remain in early stages.

Absent harmonized data frameworks and data localization[13] create compliance burdens for sponsors and CROs conducting multicountry trials, as each country imposes unique consent, jurisdiction adequacy and authorization requirements,[16] limiting expansion beyond established hubs. Researchers thus need country-by-country understanding of national legal frameworks.[19] Such challenges can be navigated through the expertise of site network models (e.g., SMOs) or CROs that have been operating in Africa for decades.

Strengthening Africa-led governance and compliance frameworks is essential for broader multicountry participation.

The table below highlights cross-border data transfer conditions and the lack of harmonization.



Table B: Cross-border data transfer requirements in selected African countries

Country	Primary condition for cross-border transfer	Regulatory/compliance hurdle
South Africa	Adequate protection (similar to Protection of Personal Information Act [POPIA]) or data subject consent	Prior authorization required for special personal information/children's data; extraterritorial application[15,16]
Nigeria	Adequate protection or binding corporate rules/contractual clauses	Recipient country must afford an equivalent protection level; complex legal assessment required[16]
Uganda	Recipient countries have adequate measures equivalent to local law and subject consent	Subject consent is required; checks on illegal transfers and abuse of data[16]
Kenya	Adequate levels of protection (same as Kenya's Data Protection Act, 2019) or proof of protective measures	Requires approvals from data controller/processor upon sufficient proof of data protection measures[16]

Africa's current path toward clinical trial success

African health systems have long relied on external aid.[20] However, recent shifts in global health financing have exposed this vulnerability, prompting countries to invest in domestic governance, data systems and regulatory capability.[19,21] This section discusses initiatives across Africa aimed at promoting clinical research by catalyzing domestic ownership and resilience.

Building indigenous site network models

Variations in local capacity—infrastructure, workforce, regulatory expertise—remain primary barriers for individual sites.[6]

Decades of investment have enabled research networks such as the HIV Vaccine Trials Network (HVTN), which enabled rapid COVID-19 trials via its existing infrastructure.[22] Region-led site networks and SMOs now provide scalable infrastructure and regulatory expertise beyond infectious diseases. These indigenous site networks are demonstrating operational scalability in ML3 countries, nonmetropolitan settings or upper-middle-income countries. For example:

- **ACRN** is building a first-of-its-kind pan-African ecosystem delivering globally competitive clinical research, trials-related training, regulatory and policy advocacy, and data management support, along with early-stage research services (including first-in-human studies) and analytics support[23]
- **Clinical Research Investigator Site Management Organization (CRISMO)** aims to bridge the capacity-building gap and provides site management and operational support[24]
- **Emin8** is a commercial SMO operating high-performance sites across South Africa, connecting global sponsors and CROs with diverse patient demographics[25]

Networks also contribute to improving quality through key mechanisms, including:

- Unified SOPs across sites enable consistent data quality and sponsor confidence
- Shared ethics/institutional review boards (IRBs) reduce bottlenecks and improve multicountry coordination
- Comprehensive support, including laboratory services, logistics and data management, ensure trials meet international GCP standards

Unified regulatory authority and data protection framework

Under the newly ratified AMA, the continent aims to consolidate regulations to improve standards and facilitate the regulation of medical products. AMA supports consistent standards and shared regulatory reviews, helping untangle the "spaghetti bowl" of regulations.[27]

AMA will coordinate trial reviews and joint Good Manufacturing Practice (GMP) inspections.[27] Assessments of "complex" products (like novel cancer drugs or mRNA vaccines) will help countries lacking technical expertise.

The transition is complex, with national processes continuing in parallel, but the continent-wide effort aims to promote local pharmaceutical production, accelerate approvals and ensure patient access to safe, effective and quality-assured medicines.

Additionally, there are ongoing efforts to address Africa's complex data transfer challenges and promote greater consistency across countries, led by the African Union (AU) and the Economic Community of West African States (ECOWAS), which are working to establish unified data protection frameworks.

Investigator capacity strengthening and certification

Clinical trial execution demands strict standards for patient protection and regulatory compliance[10]—hence, standardized, certified investigator training is critical.

The Clinical Investigator Certification (CLIC) course (PharmaTrain/European Clinical Research Infrastructures Network syllabus) has been implemented in South Africa,[14] with CROs actively expanding African networks into ML3 countries.[11] Hubs like Afrileadtech; TASK Research Academy; and Clinical Research, Education and Development (CREDE)[28,29,30] provide training on GCP and trials delivery expertise.

Cognizant's life sciences platforms, such as SIP,[32] enable mutual recognition of these GCP courses across all participating sponsors. This cross-sponsor transparency significantly reduces administrative burdens for local clinical trial sites.

Institutional partnerships

The Africa Centres for Disease Control and Prevention (Africa CDC), the European and Developing Countries Clinical Trials Partnership (EDCTP) and RCOREs have strengthened clinical research infrastructure, primarily for infectious diseases.[2]

Africa CDC plays a pivotal role as a continental public health institution by fostering strong intra-African and global partnerships that strengthen health systems, build workforce and regulatory capacity and promote collaborative research[18]. Through alliances with organizations such as WHO, UNICEF and regional networks, Africa CDC creates structured platforms for knowledge sharing, infrastructure development and coordinated responses to health priorities, including disease surveillance, emergency preparedness and clinical research expansion. By linking policy, funding and technical expertise across member states, Africa CDC not only strengthens research readiness but also advances Africa-led innovation and sustainable participation in global clinical development.

EDCTP funds clinical spaces across [229] institutions in 38 countries.[26] EDCTP's four regional networks of excellence provide infrastructure and human resources for trials:

- East African Consortium for Clinical Research (EACCR), East Africa
- West African Network for TB, AIDS, and Malaria (WANETAM), West Africa
- Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM), Central Africa
- Trials of Excellence in Southern Africa (TESA), Southern Africa

RCOREs serve as regional hubs for regulatory training and capability building in areas like pharmacovigilance, clinical trial oversight medicine evaluation and quality assurance. Key institutions include:

- Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe
- Food and Drugs Authority (FDA Ghana), Ghana
- Direction Générale de la Pharmacie, du Médicament et des Laboratoires (with University of Ouagadougou), Burkina Faso

These partnerships are essential for translating infrastructure into operational readiness.



A roadmap for a sustainable clinical research ecosystem

Cost-effective, user-friendly technology is pivotal for strengthening health systems in resource-constrained and emerging markets across Africa.17 These technologies improve access, track patient data and provide educational support.[8,17]

Key efficiency drivers include virtual interactions and paperless data management across healthcare, not just in clinical research.

Technology partners such as Cognizant have extensive experience supporting digital health and research initiatives across Africa, including an engagement with the African Medical and Research Foundation (AMREF) and Glaxo Smith Kline (GSK).[31] Cognizant developed an affordable, user-friendly centralized ("single pane of glass") reporting platform that integrates multiple data sources and generates meaningful and actionable insights to improve public health interventions in all 35 countries where AMREF operates.[31] This example illustrates how platform-enabled operating models can support large, multicountry health initiatives when aligned with local governance and workforce capacity. Reported outcomes included 100% of users finding the dashboard information useful, 100% rating their experience as good or very good and 89% saying they would recommend the dashboards to colleagues.[31]

The following recommendations aim to support the sustainable growth of the clinical research ecosystem in the region.

Site-centric platforms: Improving digital visibility and operational coordination

Global visibility to pharma companies and CROs is critical to ensuring that African sites are considered for inclusion in clinical trials. Clinical operations platforms such as SIP[32] improve global visibility via detailed facility profiles through which sites can highlight their capabilities and expertise, in addition to investigator profile data that can be joined with feasibility survey responses for data-driven site selection. Additionally, SIP profiles promote data reuse across sponsors, eliminating redundant requests for same site operational information and common documents such as CVs and medical licenses from study to study. Sponsor-site collaboration platforms like SIP and other Cognizant life sciences solutions ensure regulatory compliance (21CFR Part 11, ICH GCP E6 R3) and provide real-time document exchange and workflow tracking with full audit trails—significantly improving efficiency for sites and oversight by sponsors.

Africa's mobile-first digital landscape further strengthens the potential of site-centric platforms to expand access and participation. As of early January 2024, around 74% of web traffic in Africa was via mobile phones[39]—almost all African countries have higher web usage on mobile devices compared to other devices. In fact, many previously underserved regions in Africa are leapfrogging the desktop PC development phase and starting out as mobile-first societies—mostly due to lower cost and easy accessibility.

SIP's mobile application offers an intuitive, on-the-go solution for clinical sites and investigators, serving as a biometric-enabled mobile platform for clinical operations collaboration. This serves as a strong example of how the increasing penetration of mobile technologies across Africa can support adoption by enabling local practitioners to engage seamlessly with research operations platforms and with minimal barriers to entry.

Data sovereignty

Data sovereignty ensures that value generated from native populations serves national health and economic interests.

Strong data residency rules and informed consent can ensure research data remains protected, enabling locally led and investigator-initiated trials.

Otherwise, the paucity of health data can have serious implications in Africa's ambitions of implementing digital technology ecosystems and evidence-based practices.[11] Achieving this balance of data sovereignty and secure system interoperability within the continent requires coordinated policy, legal frameworks and operational models—not technology alone.

Technology interoperability and standardization

As regional hubs align with the AMA, the need for harmonized data transfer is increasing, even as national regulatory authorities continue to operate in parallel. While companies including Novartis, Roche, Pfizer and AstraZeneca conduct multicountry trials,[6] scaling these efforts requires secure, compliant cross-border data transfer. To support this, health ministries must enforce interoperability standards to enable seamless multicountry trials. This, in turn, should be supported by a common integration hub to facilitate systems integration and efficient data exchange.

Technology localization first

Technology implementation failure in Africa often stems from policy and cultural misalignment rather than technical capacity. In this context, site networks and SMOs play a critical role in operationalizing localization by embedding training and digital governance at the site level. To support this, a contextualized implementation approach is required, where all external technology developers must embed localization into their design, tailoring solutions to local languages, cultural factors and existing infrastructure. Ongoing training, mentoring and train-the-trainers programs are essential to support integration into clinical workflows and maintain data fidelity.

Site network maturity model

While we anticipate considerable benefits of the indigenous site network models as independent sites increasingly consolidate under a single organization or network, Cognizant recommends that the existing site network models further mature over time to become a "Center of Excellence" (Figure 2). Once at that stage, site networks work at a strategic level to influence national policies, improve standards of care and attract international investments.

Global models, such as the Australian teletrials model,[33] demonstrate how distributed trial delivery can expand access while maintaining quality. These principles can be adapted to the African context to support the development of a mature ecosystem, as represented by Stage 3 in Figure 2.

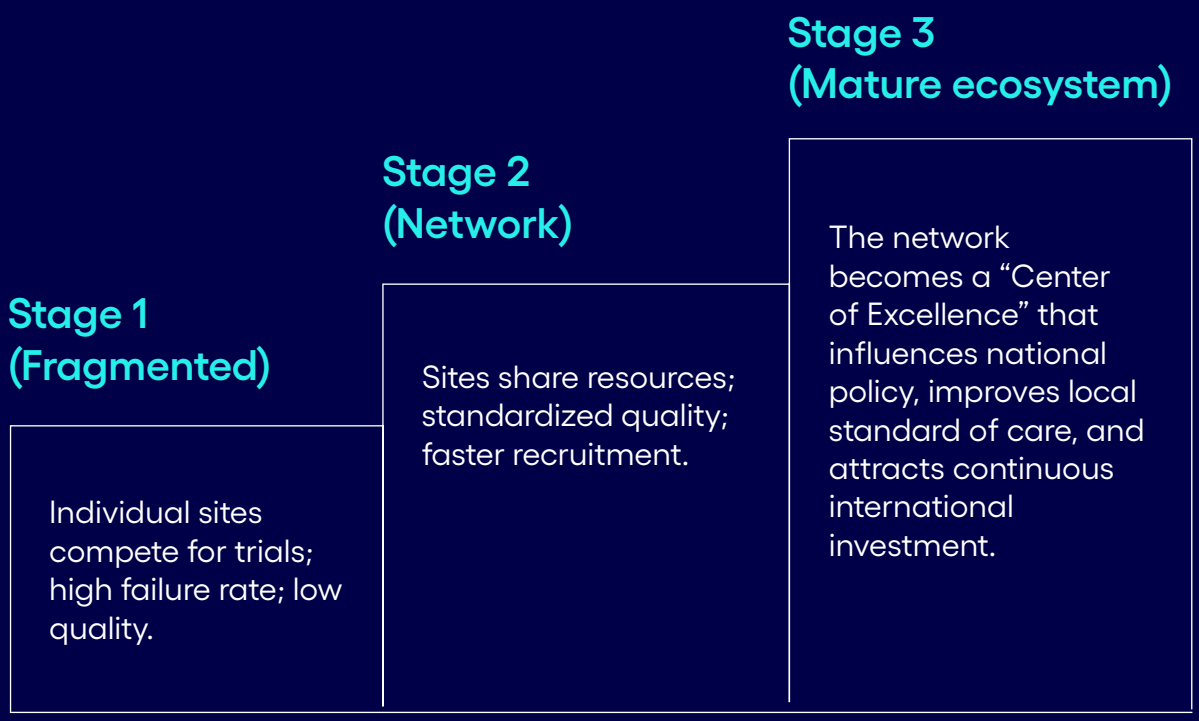


Figure 2: Cognizant's vision for a site network maturity model

Conclusion: Unlocking Africa's clinical research potential

The pathway forward lies in coordinated, Africa-led ecosystems integrating infrastructure, expertise, governance and technology to strengthen the continent's role in global clinical research.

Scalable operating models, strengthened regulatory coordination and fit-for-purpose technology can enable a resilient ecosystem aligned with the AMA's mandate and approach.

Technology partners such as Cognizant are well positioned as collaboration partners among site networks, sponsors and CROs.

For industry stakeholders, this represents both responsibility and opportunity—generating globally relevant evidence while expanding participation among diverse patient populations.

Working together, site networks, pharmaceutical companies and technology partners can build foundational infrastructure, supported by governments and continent-wide policies that advance data sovereignty and sustainability. Governments and regional bodies must foster enabling environments that encourage research, strengthen data governance, improve regulatory efficiency and support long-term sustainability.

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About the authors

The authors of this paper represent a convergence of visionary leadership, clinical research expertise and on-the-ground operational experience across Africa and the global health ecosystem.

The Cognizant authors are industry veterans with deep global experience in sponsor-site collaboration, medical affairs and life sciences technology platforms. They bring a unique lens on how technology can be the connective tissue of a resilient African research ecosystem. Their work sits at the intersection of clinical operations, digital health strategy and global stakeholder engagement.

The collaborating external authors are recognized Key Opinion Leaders (KOLs) and institution builders who are actively shaping the continent's clinical research landscape. As founders, executives and senior scientists within pioneering organizations, they bring direct experience in building and scaling site networks, training investigators, advocating for regulatory reform and generating locally led evidence. Their work reflects a shared commitment to translating scientific ambition into policy influence and sustainable research infrastructure across Africa.

Collectively, the authors are united by a conviction that Africa's moment in global clinical development is not a future aspiration—it is an active, accelerating reality that demands coordinated investment, trust-based partnerships and the kind of cross-sector collaboration this paper seeks to catalyze.

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