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COMMENTARY

Africa's Regulatory Revolution: How Harmonized Regulation Can Transform Global Clinical Trials

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Abstract: Africa bears a disproportionate share of the global disease burden yet remains underrepresented in global clinical research. Fragmented regulatory systems, variable approval timelines, and limited cross-border coordination have historically constrained multinational trials across the continent. Over the past decade, however, regional medicines regulatory harmonization initiatives and the establishment of the African Medicines Agency (AMA) have begun to transform Africa's regulatory environment. This Commentary reviews progress achieved through regional collaboration, assesses the early role of the AMA, and examines persistent structural and capacity-related barriers. We argue that regulatory harmonization represents a pivotal opportunity to reposition Africa as a central hub for global clinical research. Realizing this potential will require sustained political commitment, investment in regulatory capacity and digital infrastructure, and deeper engagement by global sponsors and funders. Nevertheless, substantial implementation gaps remain, particularly regarding uneven state adoption, sustainable financing, and post-market surveillance capacity. Strengthening Africa's regulatory ecosystem is not only a matter of efficiency, but also an ethical and scientific imperative for producing globally relevant and equitable clinical evidence.

Keywords: African Medicines Agency, National Medicines Regulatory Authority, regulatory convergence, clinical trial harmonization, health systems strengthening, health equity

Introduction

In 2020, as the world raced to develop COVID-19 vaccines, Africa, home to 17% of the global population, hosted less than 2% of registered clinical trials.[1] This stark disparity reflects a persistent paradox: while Africa bears roughly a quarter of the global disease burden, the continent remains largely excluded from the clinical research activity that shapes prevention and treatment strategies.[2,3] This underrepresentation is not simply a logistical challenge, it is also a legacy of historical exploitative and unethical research practices conducted in Africa, which have fostered institutional distrust and continue to shape how regulatory reform and sponsor engagement are perceived by African governments and communities.[4]

The drivers of this imbalance are well documented. Fragmented regulatory systems, variable approval timelines ranging from 60 days to over a year, and limited coordination across 54 countries have created structural barriers for researchers and pharmaceutical sponsors.[5,6] These challenges are compounded by Africa's linguistic diversity, encompassing Anglophone, Francophone, Lusophone, and Arabic-speaking regulatory environments, which creates additional complexity for harmonized documentation and cross-border trial protocols.[7] These challenges increase costs, delay trial initiation, and deter inclusion of African sites in multinational studies. Yet this narrative is beginning to shift, driven by regional harmonization initiatives and the establishment of the African Medicines Agency (AMA).[6,8]

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efficiency and accessibility, and limitations, including risks of bias propagation and reduced critical scrutiny, considerations that warrant transparency in academic reporting.[9,10]

Our Commentary examines Africa's evolving regulatory landscape, evaluates progress toward harmonization, and outlines policy actions needed to position the continent as a competitive and essential hub for global clinical research. To situate Africa's regulatory evolution, it is useful to note that other regions, including the European Union, whose European Medicines Agency facilitates centralized authorization across member states, and ASEAN, whose ACCSQ Pharmaceutical Product Working Group supports harmonized product registration, have demonstrated that regional harmonization can substantially accelerate approval timelines while maintaining regulatory rigor.[11] Africa's approach, driven by the AMA and regional bodies, is both informed by and distinct from these models, reflecting the continent's unique institutional landscape and capacity constraints.

Progress Through Regional Harmonization

Over the past decade, several African regions have demonstrated that collaborative regulatory approaches can substantially improve efficiency (Table 1). The East African Community Medicines Regulatory Harmonization (EAC-MRH) program has reduced median review times by 53%, from 553 days to 259 days.[5] The Southern African Development Community's ZaZiBoNa initiative enables joint assessments that participating countries can finalize in about 90 days, compared with 6–12 months for individual national reviews.[12]

These initiatives operate through joint scientific assessments in which participating National Medicines Regulatory Authorities (NMRAs) review clinical trial applications collaboratively. This model reduces duplicative reviews while maintaining regulatory rigor.[5,6] In West Africa, harmonization efforts under the Economic Community of West African States (ECOWAS) have similarly aimed to facilitate coordinated assessments and strengthen regulatory capacity across member states.[5,6]

The COVID-19 pandemic accelerated this momentum. The African Vaccine Regulatory Forum (AVAREF) coordinated parallel ethics and regulatory reviews across multiple countries to expedite clinical trial review.[13] These experiences demonstrated that African regulators can move rapidly without compromising safety or scientific integrity.[13]

The African Medicines Agency: A Continental Vision

Building on these regional successes, the African Medicines Agency represents a transformative continental initiative. The AMA was established in 2021, and its headquarters were inaugurated in Kigali, Rwanda in November 2024.[8,14] The agency's mandate includes harmonizing regulatory standards, supporting NMRAs, and enabling reliance mechanisms

Table 1 Major African Regional Regulatory Harmonization Initiatives

Initiative	Geographic Scope	Year Established	Participating Countries/Members	Median Approval Timeline & Key Achievements
EAC-MRH (East African Community Medicines Regulatory Harmonization)	East Africa	2009	Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda	Reduced median review time from 553 to 259 days; joint scientific assessment of clinical trial applications
ZaZiBoNa (SADC Collaborative Medicines Registration Initiative)	Southern Africa	2013	Zimbabwe, Zambia, Botswana, Namibia, and other SADC members	~90-day joint assessment vs. 6–12 months nationally; reduced duplication across NMRAs
ECOWAS Harmonization Framework	West Africa	Ongoing (2000s–present)	15 ECOWAS member states	Coordinated regulatory assessments; capacity-building across Anglophone and Francophone NMRAs
AMA (African Medicines Agency)	Continental (Africa)	Treaty adopted 2019; operational HQ inaugurated Nov 2024	African Union member states (55); ratification ongoing	Continental regulatory standards harmonization; reliance mechanisms; NMRA support. Full operations still developing.

that draw on assessments from trusted authorities like the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO).[8,15]

Despite its formal establishment, the AMA remains in an early operational phase. Core elements, including technical committees, staffing, regulatory workstreams, and sustainable financing mechanisms, are still developing, and the agency has not yet initiated full-scale continent-wide assessments.[8,14] Its near-term impact will depend on the speed with which member states operationalize commitments and integrate AMA processes into national regulatory pathways.[8]

Regulatory reliance pathways are already playing an important role in accelerating access to medicines and supporting regulatory efficiency.[15] Rather than conducting fully independent reviews, many African NMRAs increasingly leverage assessments from established regulators while focusing local review on context-specific considerations such as disease epidemiology and pharmacovigilance requirements.[15]

Several national regulators are also setting benchmarks for performance. South Africa's SAHPRA has documented clinical trial review processes and timelines and can move efficiently when submissions are complete.[16] Rwanda has likewise built a reputation for streamlined processes, reflected in its selection to host the AMA headquarters.[14]

Why Africa Matters for Global Clinical Research

Beyond regulatory reform, Africa offers compelling scientific, economic, and ethical rationales for expanded participation in global clinical trials.

Scientifically, Africa's genetic diversity is the greatest globally and offers unique value for pharmacogenomics and for understanding how genetic variation influences drug response and safety.[17] The continent's epidemiological profile, characterized by a dual burden of infectious diseases and rapidly rising non-communicable diseases, also makes African populations relevant to global therapeutic development.[3]

Economically, Africa's healthcare market is projected to expand substantially by 2030, and sponsors that build regulatory expertise and research infrastructure now may benefit as markets, health systems, and regulatory frameworks mature.[18]

Ethically, populations that bear a disproportionate share of disease burden should be represented in the studies that shape prevention and treatment strategies. Greater inclusion promotes equity and strengthens the generalizability of clinical evidence.[19] Therapies tested predominantly in high-income settings may not adequately reflect the genetic diversity, comorbidity patterns, and environmental exposures common in many African contexts.[17,19] Critically, expanding trial activity must be accompanied by clear frameworks governing data ownership, intellectual property, and benefit-sharing, to ensure that African populations and institutions equitably benefit from the research conducted on the continent.

Risks and Structural Challenges

Despite its promise, the AMA and broader harmonization efforts face substantial risks. Uneven political commitment across member states may result in fragmented adoption of AMA guidance, undermining continent-wide convergence.[8] Financial sustainability remains uncertain, with continued reliance on external partners for technical and operational support.[8] Capacity disparities between NMRAs could also create bottlenecks, particularly in countries with limited regulatory workforce, training programs, and digital infrastructure.[5,6,20]

At the national level, persistent structural challenges remain. Many regulators still lack electronic submission systems, relying on paper-based processes that slow reviews and limit transparency.[20] Resource constraints restrict capacity in specialized areas such as advanced biologics and complex trial designs.[20] In some jurisdictions, sequential rather than parallel review by ethics committees and regulators further extends timelines.[13,20]

Approval time variability continues to complicate multinational trial coordination. While leading countries can complete reviews within 60–90 days, other jurisdictions may require many months or longer, increasing operational complexity and deterring sponsors from including a broader range of African sites.[5,6,20]

A further structural gap concerns post-approval regulatory functions. The current harmonization discourse focuses primarily on trial initiation and approval timelines; however, harmonized post-market surveillance systems have received comparatively little attention. This is a critical regulatory function where most African NMRAs face significant capacity

gaps and addressing it will be essential for the long-term sustainability and credibility of expanded clinical research activity on the continent.

Digital infrastructure and technological capacity also warrant closer examination. Beyond the general need for electronic submission systems, there is growing potential for artificial intelligence and machine learning tools to support regulatory review, adverse event detection, and trial monitoring in resource-limited settings. Integrating such tools into regulatory capacity-building strategies could accelerate review timelines while reducing the human resource burden on understaffed NMRAs.

The Path Forward

Realizing Africa's potential as a global clinical research hub will require coordinated action across stakeholders.

African research institutions must continue aligning with international standards, including ICH-GCP principles, and actively leverage regional harmonization mechanisms.[5,6] Investments in institutional digital infrastructure, including professional websites, trial registries, and research databases, can improve visibility and facilitate partnerships.[19] The Africa Centers for Disease Control and Prevention (Africa CDC) has emerged as a central actor in clinical research coordination and epidemic preparedness; its institutional mandate and continental reach make it a critical partner for regulatory harmonization initiatives and should be explicitly integrated into national and regional research strategies.

Pharmaceutical sponsors and contract research organizations should engage early with the AMA and regional bodies, adopt pan-African regulatory strategies, and invest in local capacity building.[8,19] Engagement must be accompanied by equitable partnership models that address data ownership, intellectual property arrangements, and benefit-sharing with African institutions and governments. These investments can yield long-term returns through faster trial initiation, stronger partnerships, and improved data quality.[19]

Policy makers and funders should prioritize regulatory strengthening through sustained technical assistance, workforce training, and digital infrastructure support, including investment in AI-enabled regulatory tools.[5–7,20] The AMA, in particular, will require predictable and durable financing to transition from a symbolic continental institution to a fully functional regulator capable of driving convergence at scale.[8]

Conclusion

Africa stands at a pivotal moment in its integration into global clinical research. Regional harmonization initiatives, including the EAC-MRH, ZaZiBoNa, and ECOWAS frameworks, and the establishment of the AMA have laid the foundations for meaningful participation. While progress has been substantial, the conditions for Africa's full emergence as a global clinical research hub are not yet fully in place. Uneven state adoption, financing uncertainties, and persistent capacity gaps must be addressed concurrently with the opportunities that harmonization creates.

Every clinical trial conducted in Africa strengthens regulatory systems, builds workforce capacity, and advances health equity. Achieving this vision will require regulators to sustain harmonization momentum and expand pharmacovigilance capacity; sponsors to commit to equitable, benefit-sharing partnerships; funders to provide predictable financing for the AMA and national regulatory authorities; and policymakers to prioritize digital infrastructure and workforce development. As regulatory pathways continue to converge, those engaging now, with transparency, equity, and long-term commitment, will be positioned as leaders in one of the world's most consequential research and healthcare markets.

Declaration of Generative AI and AI-Assisted Technologies in the Manuscript Preparation Process

During the preparation of this manuscript, the authors used an AI-assisted language tool (ChatGPT, OpenAI) to support language editing, structural refinement, and clarity of expression. All content was reviewed, edited, and validated by the authors, who take full responsibility for the accuracy, originality, and integrity of the work.

Disclosure

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