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## Review Article

Open  Access**Between Statutes and Practice: Regulatory Capacity for Clinical Trials in The Gambia within the ECOWAS Regional Context**Bojang Abdoulie <sup>a,b,c,\*</sup><sup>a</sup>Student, Advanced Postgraduate Diploma in Clinical Research and Regulatory Affairs, James Lind Institute, Switzerland<sup>b</sup>National Chairperson, Dental Care Professionals Association, The Gambia<sup>c</sup>Founder and Director, Kabboumb Academy, The Gambia.**Abstract**

The global expansion of clinical research has heightened the importance of strong national regulatory systems capable of ensuring ethical conduct, scientific validity, and participant safety. While West Africa has become an increasingly important region for clinical trials, regulatory capacity across the region remains uneven, and small states such as The Gambia are underrepresented in regulatory scholarship. This desk-based review assesses the regulatory capacity for clinical trial oversight in The Gambia through a comparative analysis within the ECOWAS region. Drawing on national legislation, regulatory guidelines, regional harmonisation frameworks, and international benchmarking tools, the study examines legal authority, institutional capacity, approval processes, ethics oversight, and pharmacovigilance systems. Comparative insights from Ghana, Nigeria, and Senegal highlight both shared challenges and divergent regulatory trajectories. The analysis shows that although The Gambia has established foundational regulatory frameworks aligned with international standards, significant operational and capacity-related gaps persist. The study underscores the importance of regulatory reliance, regional harmonisation, and targeted capacity strengthening in advancing regulatory readiness in small regulatory systems.

**Conclusion:** This review demonstrates that strengthening regulatory readiness in The Gambia will depend less on new legislation and more on institutional capacity development, regional collaboration, and effective use of reliance mechanisms. Addressing these priorities is essential to safeguarding research participants and enhancing the country's role in global clinical research.

**Keywords:** Clinical trials; Regulatory capacity; Medicines Control Agency (The Gambia); Ethics review; Pharmacovigilance; ECOWAS; Small regulatory systems

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**DOI:** 10.22270/ijdra.v14i1.843\*Corresponding author. E-mail address: [kabboumbacademy@gmail.com](mailto:kabboumbacademy@gmail.com) (B. Abdoulie)**1. Introduction**

Clinical trials are essential to the development and evaluation of medicines, vaccines, and medical devices, and their globalisation has increasingly shifted research activity toward low- and middle-income countries. This expansion has brought new opportunities for addressing region-specific health priorities, particularly in Africa, but has also intensified demands on national regulatory authorities responsible for ensuring ethical conduct, scientific integrity, and participant protection. Within West Africa, regulatory capacity for clinical trial oversight varies widely, reflecting differences in institutional maturity, technical expertise, and engagement with regional harmonisation initiatives. While countries such as Ghana and Nigeria have made sustained investments in regulatory systems, smaller states continue to face structural constraints that limit regulatory readiness. The Gambia represents a

particularly important yet underexamined case, having hosted internationally funded clinical research for decades without corresponding scholarly analysis of its regulatory capacity. This review addresses that gap by assessing The Gambia's clinical trial regulatory framework through a comparative ECOWAS lens, with the aim of identifying capacity gaps, contextual strengths, and policy-relevant pathways for strengthening regulatory oversight

**2. Conceptual Framework: Regulatory Capacity and Readiness in Clinical Research**

Regulatory capacity in clinical research refers to the ability of a national regulatory system to authorise, monitor, and enforce compliance in the conduct of clinical trials in accordance with legal mandates and international standards. (1) Closely related is the concept of regulatory readiness, which emphasises not only the

presence of regulatory structures but also their functionality, sustainability, and performance in practice.

Internationally, regulatory capacity is increasingly assessed through structured benchmarking frameworks. The World Health Organization (WHO) Global Benchmarking Tool provides a systematic approach for evaluating national regulatory systems across key functions, including clinical trial oversight, medicines authorisation, pharmacovigilance, and regulatory inspection. (1) These frameworks focus on system maturity and continuous improvement rather than formal compliance alone.

In the context of clinical research, regulatory readiness is closely linked to adherence to internationally recognised standards such as the International Council for Harmonisation Good Clinical Practice guidelines. (2) These standards emphasise participant protection, scientific validity, data integrity, and effective safety monitoring throughout the clinical trial lifecycle.

A functional clinical trial regulatory system typically comprises several interrelated domains. These include clear legal authority, adequate institutional capacity, efficient and transparent approval processes, independent ethics review mechanisms, and integrated pharmacovigilance systems. (1,2) Weakness in any of these domains can undermine the overall effectiveness of regulatory oversight.

For small states, regulatory readiness is shaped by additional structural factors. Limited economies of scale can constrain the availability of specialised expertise, while reliance on external funding and technical assistance may affect long-term sustainability. (1) At the same time, regional harmonisation and regulatory reliance mechanisms offer opportunities to strengthen oversight by leveraging the assessments and experience of more mature regulatory authorities. This conceptual framework informs the analysis of The Gambia's clinical trial regulatory system by emphasising both statutory foundations and functional implementation within a regional context.

### 3. Methodology

This study adopted a qualitative desk-based review design to assess regulatory capacity for clinical trial oversight in The Gambia. Desk-based regulatory analyses are widely used in regulatory science and health policy research to evaluate legal frameworks, institutional arrangements, and policy instruments using secondary data sources. (1) This approach is particularly appropriate for comparative regulatory studies and aligns with ethical standards for research that does not involve human participants.

The review drew on authoritative and publicly available sources, including national medicines legislation, regulatory authority guidelines, ethics committee procedures, regional harmonisation frameworks, and international policy and benchmarking reports. (1–12) These materials provided insight into both the formal regulatory framework and the operational features of clinical trial oversight systems.

Analytical focus was structured around five domains derived from WHO benchmarking frameworks and international regulatory guidance: legal and institutional framework, clinical trial authorisation processes, ethics review and governance, pharmacovigilance and safety oversight, and regional harmonisation and regulatory reliance mechanisms. (1,2) These domains were applied systematically to The Gambia and comparator countries to support structured comparative analysis.

Ghana, Nigeria, and Senegal were selected as comparator countries due to their relative regulatory maturity, active engagement in international clinical research, and leadership roles within ECOWAS regulatory harmonisation initiatives. (8–12) While desk-based analysis has inherent limitations, including reliance on available documentation, it enables transparent and replicable assessment of regulatory capacity grounded in official and policy-relevant sources.

## 4. The Gambian Clinical Trial Regulatory Framework

### 4.1 Legal and Institutional Basis

Clinical trial regulation in The Gambia is anchored in the Medicines and Related Products Act, 2014, supported by subsidiary legislation under the Medicines and Related Products Regulations, 2020. (4,5) These instruments provide the statutory basis for the regulation of medicinal products, including investigational medicinal products used in clinical trials. Regulatory authority is exercised by the Medicines Control Agency (MCA), which functions as the national medicines regulatory authority and is mandated to ensure the quality, safety, and efficacy of medicines circulating within the country. (8)

The MCA's mandate explicitly includes oversight of clinical trials involving medicinal products, encompassing authorisation of trials, regulation of importation of investigational products, and post-approval safety monitoring. (8) The Agency operates within a public health-oriented regulatory model, balancing facilitation of research with protection of research participants and the wider population.

Ethical oversight of research involving human participants is provided through national ethics review mechanisms operating independently of the MCA. This separation between regulatory authorisation and ethical review reflects internationally recognised best practice and aligns with ICH Good Clinical Practice principles. (9) However, the effectiveness of this dual-authority model depends on clarity of institutional roles, coordination between bodies, and consistency in procedural requirements.

While the legal framework establishes clear authority for clinical trial regulation, operationalisation remains constrained by limited specialised personnel and evolving regulatory systems. As with many small regulatory authorities, the MCA faces challenges related to sustaining technical expertise across the full clinical trial lifecycle, particularly for complex or multi-centre studies. (1)

## 4.2 Clinical Trial Authorisation Process

Sponsors intending to conduct clinical trials in The Gambia are required to obtain both ethical approval and regulatory authorisation prior to trial initiation. Ethical approval must be secured from a recognised ethics committee, while regulatory authorisation is granted by the Medicines Control Agency. (6) This two-step process ensures independent ethical and scientific oversight of proposed research.

**Table 1.** Overview of Clinical Trial Approval Requirements in The Gambia

Component	Responsible Authority	Key Requirements
<b>Ethical review</b>	National ethics committee	Protocol review, informed consent, risk–benefit assessment
<b>Regulatory authorisation</b>	Medicines Control Agency	Investigational product data, GCP compliance, safety reporting
<b>Import authorisation</b>	Medicines Control Agency	Product quality documentation and regulatory clearance

While this framework provides structured oversight, the absence of integrated or joint review mechanisms may result in procedural duplication and extended approval timelines. Defined regulatory timelines for clinical trial authorisation are limited, reducing predictability for sponsors and potentially affecting the attractiveness of The Gambia as a clinical trial destination. (6)

## 4.3 Pharmacovigilance and Safety Oversight

Safety monitoring during clinical trials is a core regulatory responsibility and a critical determinant of regulatory readiness. In The Gambia, pharmacovigilance functions are overseen by the Medicines Control Agency in accordance with national pharmacovigilance guidelines. (7) These guidelines outline requirements for adverse event reporting, safety signal detection, and post-authorisation surveillance.

Although pharmacovigilance systems are established, integration between routine pharmacovigilance activities and active clinical trial safety monitoring remains limited. Reporting of serious adverse events and suspected unexpected serious adverse reactions relies heavily on sponsor compliance and external monitoring mechanisms. (7) Strengthening linkages between clinical trial oversight and national pharmacovigilance systems would enhance regulatory visibility of safety issues and contribute to system maturity.

## 5. Comparative ECOWAS Analysis

### 5.1 Ghana

Ghana represents one of the most advanced clinical trial regulatory systems within the ECOWAS region. Clinical trial oversight is exercised by the Food and Drugs Authority (FDA Ghana), which operates under a comprehensive legal and regulatory framework. (2,3) The Authority has developed detailed clinical trial guidelines, defined regulatory timelines, and increasingly digitalised submission and tracking processes. (2)

The MCA's Guideline for Clinical Trials in Humans sets out the documentation and procedural requirements for clinical trial applications, including protocol submission, investigator qualifications, investigational product information, and compliance with Good Clinical Practice standards. (6) In addition, sponsors must obtain import authorisation for investigational products, ensuring regulatory oversight of product quality and supply chain integrity. (6)

Ghana has undergone WHO Global Benchmarking and actively participates in regional and continental regulatory harmonisation initiatives, positioning it as a reference authority within West Africa. (1,12) Joint review procedures and reliance mechanisms are increasingly integrated into its regulatory practice, contributing to efficiency and predictability for sponsors. (11)

### 5.2 Nigeria

Nigeria's regulatory authority, the National Agency for Food and Drug Administration and Control (NAFDAC), oversees one of the largest and most complex regulatory environments in Africa. (10) NAFDAC has issued Good Clinical Practice guidelines and maintains dedicated structures for clinical trial oversight, including inspection and pharmacovigilance units. (10)

While administrative scale can introduce procedural complexity, Nigeria has invested substantially in regulatory science capacity, safety monitoring systems, and international collaboration. Active engagement in ECOWAS and African Union regulatory initiatives reflects Nigeria's leadership role in regional medicines regulation. (11)

### 5.3 Senegal

Senegal benefits from strong academic institutions and a long history of participation in international clinical research. Regulatory oversight is exercised by the national medicines regulatory authority, with coordination between regulatory and ethics review bodies relatively streamlined compared to smaller systems. (12)

Although formal reliance mechanisms are less institutionalised than in Ghana or Nigeria, Senegal's regulatory system demonstrates effective coordination and functional capacity for trial oversight, supported by sustained engagement with international research partners. (12)

## 5.4 Comparative Regulatory Features

**Table 2.** Comparative Regulatory Features Across Selected ECOWAS Countries

Feature	The Gambia	Ghana	Nigeria	Senegal
Legal mandate for clinical trial oversight	Established in primary legislation with supporting regulations	Well-established and periodically updated	Well-established with detailed subsidiary instruments	Established with clear statutory authority
Dedicated clinical trial guidelines	Emerging and evolving guidance	Established, comprehensive, and regularly updated	Established with detailed GCP-aligned guidance	Established and consistently applied
Defined approval timelines	Limited and not consistently codified	Clearly defined and publicly communicated	Partially defined; timelines vary by study type and regulatory pathway	Defined and generally predictable
Ethics–regulatory coordination	Sequential review with limited formal coordination	Increasing use of coordinated or parallel review mechanisms	Parallel structures with improving inter-agency coordination	Relatively streamlined coordination between bodies
WHO Global Benchmarking status	Not yet formally benchmarked	Successfully benchmarked	Benchmarking ongoing	Preparatory or partial benchmarking activities
Pharmacovigilance integration during trials	Functional but weakly integrated with trial oversight	Strong integration with active safety monitoring systems	Established systems with dedicated pharmacovigilance units	Functional integration supported by academic and research institutions
GCP inspection capacity	Limited and largely ad hoc	Established, risk-based, and routine	Established with regular inspections	Moderate capacity with targeted inspections
Use of regulatory reliance mechanisms	Minimal and largely informal	Active use of reliance and joint review procedures	Active engagement in reliance initiatives	Limited and case-dependent
Participation in ECOWAS joint reviews	Minimal participation	Active participation and leadership role	Active participation	Limited participation
Overall regulatory maturity for clinical trials	Foundational, with operational gaps	High and regionally influential	Advanced but administratively complex	Moderate to high and functionally effective

## 6. Key Regulatory Gaps Identified

Comparative analysis highlights several structural gaps in The Gambia's regulatory readiness for clinical trial oversight. These include limited availability of specialised regulatory personnel, particularly in clinical evaluation and pharmacovigilance, and the absence of formalised regulatory reliance mechanisms. (1,6)

Integration between clinical trial oversight and national pharmacovigilance systems remains underdeveloped, constraining proactive safety monitoring during trials. (7) In addition, limited participation in ECOWAS joint review procedures reduces opportunities to leverage regional expertise and streamline regulatory decision-making. (11)

Importantly, these gaps are primarily operational rather than normative. The legal and policy foundations for effective clinical trial regulation are in place, but sustained investment in institutional capacity, regional collaboration, and system integration is required to translate statutory authority into mature regulatory performance.

## 7. Implications for Clinical Research Governance in Small Regulatory Systems

The findings of this review have important implications for clinical research governance in small regulatory systems such as The Gambia. While statutory authority and formal guidelines are necessary components of regulatory readiness, they are insufficient in isolation. Effective clinical trial oversight depends on the translation of legal mandates into operational capacity, supported by skilled personnel, sustainable financing, and institutional learning. (1)

Small regulatory authorities face persistent challenges in maintaining specialised expertise across all regulatory functions, particularly in clinical evaluation, biostatistics, and pharmacovigilance. (1,9) In such contexts, rigid replication of regulatory models from larger jurisdictions may not be feasible or efficient. Instead, adaptive governance approaches that prioritise risk-based oversight and regulatory reliance are increasingly recognised as appropriate strategies for small and resource-constrained systems. (11)

The Gambian case illustrates how long-standing engagement in international research does not automatically translate into regulatory maturity. Without structured mechanisms to capture regulatory learning and institutionalise best practices, experience gained through individual trials may remain fragmented. (6) Strengthening internal coordination between regulatory and ethics review bodies, clarifying procedural timelines, and enhancing post-authorisation safety monitoring are therefore central to improving governance outcomes.

From a sponsor perspective, predictability and transparency in regulatory processes are critical determinants of site selection. Limited clarity on approval timelines and safety reporting pathways may discourage trial placement, even where scientific capacity and disease relevance are strong. (2) Addressing these governance gaps would enhance The Gambia's credibility as a clinical research partner while reinforcing participant protection.

### 8. Regional Harmonisation and Regulatory Reliance Opportunities

Regional harmonisation initiatives within ECOWAS and the African Union present significant opportunities to strengthen clinical trial oversight in The Gambia. Regulatory harmonisation aims to align technical requirements, procedures, and decision-making processes across countries, thereby reducing duplication and enhancing efficiency. (11)

Ghana and Nigeria have demonstrated how participation in joint reviews and reliance mechanisms can accelerate regulatory decisions while maintaining oversight quality. (2,10) Reliance allows a national regulatory authority to leverage assessments conducted by trusted reference authorities or regional bodies, particularly for clinical trial authorisation and safety evaluation. (11) For small regulators, such mechanisms offer a pragmatic pathway to compensate for limited internal capacity.

At the continental level, collaborative initiatives facilitated by Africa CDC and WHO Regional Office for Africa underscore the growing recognition of regulatory convergence as a public health priority. (1,12) Participation in regional workshops, joint inspections, and information-sharing platforms enables regulators to build technical competence while contributing to collective regulatory intelligence.

For the Gambia, formalising participation in ECOWAS joint review procedures and establishing clear reliance pathways could significantly enhance regulatory efficiency and consistency. Such engagement would not diminish national sovereignty but rather strengthen regulatory decision-making through shared expertise and mutual trust. (11)

Importantly, reliance and harmonisation mechanisms must be embedded within a clear national legal framework and supported by internal standard operating procedures to ensure accountability and transparency. (4,5) When strategically implemented, these approaches offer a sustainable model for advancing regulatory readiness in small states while aligning with international best practice.

### 9. Recommendations for Strengthening Regulatory Readiness

Strengthening regulatory readiness for clinical trials in The Gambia requires targeted, context-sensitive interventions that build on existing legal foundations while addressing operational constraints. Given the structural realities of a small regulatory system, reforms should prioritise efficiency, sustainability, and regional integration rather than expansive institutional duplication. (1)

First, institutional capacity within the Medicines Control Agency should be strengthened through focused investment in specialised regulatory competencies, particularly clinical evaluation, pharmacovigilance, and Good Clinical Practice inspection. (1,6) This may be achieved through structured training programmes, staff secondments with more mature regulatory authorities, and participation in regional regulatory networks. (11,12)

Second, the formal adoption of regulatory reliance mechanisms should be prioritised. By leveraging assessments conducted by trusted reference authorities within ECOWAS, The Gambia can improve regulatory efficiency while maintaining oversight quality. (11) Reliance frameworks should be codified through internal standard operating procedures to ensure transparency, accountability, and consistency in decision-making. (4,5)

Third, greater integration between clinical trial oversight and national pharmacovigilance systems is essential. Establishing clearer pathways for adverse event reporting, safety signal review, and regulatory action during trials would strengthen participant protection and enhance system maturity. (7)

Finally, increased engagement in ECOWAS joint review processes and regional harmonisation initiatives would enable The Gambia to contribute to, and benefit from, collective regulatory expertise. (11) Such engagement supports regulatory convergence while preserving national authority and public health priorities.

### 10. Study Limitations and Future Research Directions

This review is subject to several limitations inherent to desk-based regulatory analysis. The study relied exclusively on publicly available legislation, guidelines, and policy documents, which may not fully capture informal practices, operational bottlenecks, or recent procedural adaptations within regulatory institutions. (1) As a result, some aspects of regulatory performance may be under- or over-represented.

In addition, comparative analysis was limited to selected ECOWAS countries with relatively mature regulatory systems. While this approach facilitated meaningful benchmarking, it does not reflect the full diversity of regulatory capacity across the region. (11)

Future research would benefit from empirical studies incorporating stakeholder interviews, regulatory performance metrics, and case analyses of completed clinical trials. Such work could provide deeper insight into approval timelines, inspection practices, and safety monitoring effectiveness. Longitudinal assessment using

WHO benchmarking tools would also support evidence-based tracking of regulatory system maturation over time. (1)

## 11. Conclusion

This desk-based comparative analysis examined regulatory capacity for clinical trial oversight in The Gambia within the broader ECOWAS regional context. The findings indicate that The Gambia has established essential legal and institutional foundations aligned with international regulatory norms, including statutory authority, dedicated guidelines, and ethical oversight mechanisms. (4–7,9)

However, when assessed against more mature regulatory systems in the region, significant operational gaps remain. These gaps are primarily structural, reflecting constraints in specialised expertise, pharmacovigilance integration, and participation in regional harmonisation initiatives rather than deficiencies in regulatory intent. (1,11)

Addressing these challenges will require strategic adoption of regulatory reliance mechanisms, sustained capacity development, and deeper engagement with ECOWAS and continental regulatory frameworks. (11,12) By pursuing these pathways, The Gambia can enhance regulatory readiness, strengthen participant protection, and position itself as a credible and trusted partner in global clinical research.

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## Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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The author have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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