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OPEN LETTER

Collaborative clinical research ethics and regulatory governance in Sub-Saharan Africa: Gaps, challenges and implications

[version 1; peer review: 1 approved with reservations]

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Abstract

Although some countries in sub-Saharan Africa have strengthened their systems and reached WHO GBT Maturity Level 3, important gaps remain. Addressing these gaps is critical for strengthening clinical research oversight and preparedness. This open letter highlights that ethics and regulatory systems are often fragmented. National ethics committees, regulatory authorities, and institutional review boards do not always have clear roles or strong coordination. Reviews can therefore be slow and inconsistent, especially for multi-site and multi-country trials. Joint inspections because there are few shared procedures, common guidelines, or formal agreement between regulators. Limited staff and funding worsen these problems and weaken oversight of complex, multi-site trials.

Many clinical research sites are not well prepared for emergencies.

Open Peer Review

Approval Status ?

	1
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1. **Raymond De Vries**, University of Michigan, Ann Arbor, USA

Any reports and responses or comments on the article can be found at the end of the article.

They may struggle to quickly adapt their work and maintain safety and compliance when a public health crisis occurs, putting ongoing trials at risk. Digital systems for review and follow-up are also underdeveloped. Many committees and authorities lack integrated online submission platforms, linked databases, and pharmacovigilance e-portals. Safety reporting systems are often weak and scattered, and there is too little expertise in detecting and analysing safety signals. Links between ethics review, regulatory inspections, and safety monitoring are limited, making it harder to manage risks across the trial lifecycle.

Information on the distribution and capacity of clinical trial sites is patchy, hindering rapid mobilisation during outbreaks. Training efforts are typically short term, fragmented, and poorly coordinated regionally, with insufficient emphasis on twinning and long-term mentorship to sustain skills. This affects the quality and timeliness of reviews, especially for complex, innovative, or multi-country protocols. Practical mechanisms to implement post-trial access commitments are often absent, which can erode participants' trust. In response, this letter sets out recommendations and proposed actions for policymakers, regulators, research institutions, and ethics bodies to strengthen policies, systems, and day to day practices.

Keywords
Clinical Research Ethics, Framework, Regulator, Governance, Sustainability, Training, Research ethics committees, Sub-Saharan Africa, Research ecosystem, Collaboration, Harmonization, Digital infrastructure, Pharmacovigilance, Post-trial access



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Introduction

The escalating burden of infectious diseases, emerging global health threats, and the rising prevalence of non-communicable diseases (NCDs) underscore the urgent need for robust, ethically governed clinical research systems in low- and middle-income countries (LMICs), particularly across sub-Saharan Africa (SSA) (Akanmori et al., 2018; Global Observatory, 2026). Despite growing international investment in health research, approximately only 1.1% of global clinical trials are hosted across the entire African continent, with the vast majority concentrated in just three countries: Egypt, South Africa, and Nigeria; SSA excluding South Africa accounts for well under 1% (Global Observatory, 2026), limiting the region's contribution to biomedical innovations and access to context-relevant therapeutics advances (Saleh et al., 2024).

Clearly, clinical trials are scientific undertakings that require effective ethical oversight, regulatory predictability, and institutional legitimacy. Strong governance systems (including post-trial access frameworks) (Bernabe, 2024) are essential to protect research participants, build participants trust, ensure scientific validity, preserve public trust, and facilitate timely translation of evidence into policy and clinical practice (Belaynehe et al., 2024). The literature on offshoring of clinical trials demonstrates the need not only for infrastructure but for robust ethical and regulatory oversight to ensure not only that clinical trials take place, but that these clinical trials in fact benefit the population of the host country (Glickman et al., 2009; Osei, 2012; Petryna, 2009; Shah, 2012).

This Open Letter is particularly timely because persistent regulatory fragmentation, weak institutional capacity (specifically the lack of digital submission platforms, interoperable databases, and pharmacovigilance e-portals), and inadequate ethics governance continue to delay trial activation, constrain the conduct of complex and early-phase studies, and reduce regional competitiveness (EDCTP, 2023, 2024; WMA, 2013a). At the same time, global and regional bodies including WHO, African Vaccine Regulatory Forum (AVAREF), and European and Developing Countries Clinical Trials Partnership (EDCTP) are actively promoting harmonization, joint reviews, and regulatory strengthening, creating a critical policy window for coordinated reform (Akanmori et al., 2018; COHRED, 2010; EDCTP, 2023, 2024). The letter seeks to contribute constructively to ongoing debates by highlighting systemic gaps and proposing actionable, evidence-informed solutions, setting out recommendations and proposed actions for policymakers, regulators, research institutions, and ethics bodies to strengthen policies, systems, and day to day practices.

The wicked problem of clinical trial governance in SSA

Clinical trial governance across SSA may be undermined by multiple, interrelated legal, institutional, technical, and ethical weaknesses. Using the language of Complexity Theory, the issues of clinical trial governance in Africa may be considered a "wicked problem"[1] because fragmented and under-resourced institutions must navigate contested norms around equity, exploitation, and access, making it impossible for any single actor or reform to produce a stable, widely accepted "solution" (Foundation, 2025; Taylor-Robinson et al., 2021; Yilma, 2024). At the same time, governance is deeply entangled with global industry strategies, neocolonial power asymmetries, regulatory capacity gaps, and broader health-system weaknesses, so each intervention reshapes rather than resolves the problem, mirroring the core criteria of wicked problems identified in African policy scholarship (Foundation, 2025; Saleh et al., 2024; Taylor-Robinson et al., 2021).

Practically, fragmented regulatory pathways, overlapping mandates between Research Ethics Committees (RECs) and National Regulatory Authorities (NRAs), and non-harmonised administrative frameworks frequently result in sequential reviews, duplication of effort, and prolonged approval timelines (COHRED, 2010; Nabyonga-Orem et al., 2021; Thomas Bollyky, 2011). Although several countries formally permit parallel submission to RECs and NRAs, scientific review by NRAs often begins only after REC approval, thereby preserving de facto sequential review and extending activation timeline (Cavaleri et al., 2025). Institutional capacity constraints such as inadequate training, lack of specialized manpower, underfunding, weak local ownership further compound these inefficiencies. RECs and NRAs in Uganda, Malawi, Rwanda, and the Central African Republic, for example, frequently operate with limited financial, technical, and human resources, restricting their ability to evaluate complex protocols—such as adaptive designs, genomic research, and Phase I trials (EDCPT, 2023; Ouma et al., 2025). Weak digital infrastructure, including unreliable internet connectivity, limited access to scientific databases, interoperability issues of submission platforms, pharmacovigilance databases and e-portals, and lack of integrated digital systems hamper real-time monitoring, data sharing, and enforcement of compliance (Jjagwe et al., 2024).

[1]«Wicked problem» can be understood as complex, contested social and socio-ecological issues that are difficult to formulate, involve multiple stakeholders, and whose proposed solutions have uncertain and emergent effects (Reference: Niskanen VP, Rask M, Raisio H. "Wicked Problems in Africa: A Systematic Literature Review." SAGE Open. 2021;11(3):1–19.)

Regional harmonization efforts under EDCTP-funded initiatives advocate standardized obligations, to ensure that investigational products with proven efficacy are made available to participants and, where feasible, to broader patient populations (EDCPT, 2023). Institutional mechanisms, such as Memoranda of Understanding (MoUs) between hospitals, ministries of health, and sponsors, are being piloted to guarantee continuity of care and supply chains beyond trial completion (Akanmori et al., 2015). Embedding these frameworks into regulatory governance not only safeguards participant welfare but also strengthens public trust in clinical research. EDCTP and WHO emphasize the need for standardized inspection guidelines, strengthened ethics review, and harmonized regulatory pathways (EDCTP, 2023, 2024). Yet in Uganda, Ethiopia and other SSA countries specifically, the absence of comprehensive standard operating procedures (SOPs) for joint GCP inspections and the lack of a national clinical trial site accreditation framework limit standardization, quality assurance, and compliance with international Good Clinical Practice (GCP) standards (COHRED, 2010).

More broadly, ethics governance systems across the region remain under-resourced and technically immature, with REC members often insufficiently trained in ethical theory, deliberative reasoning, and substantive scientific review (Belaynehe et al., 2024; Seralegne et al., 2023)). Weak ethics oversight systems further increase the risk of poorly managed adverse events, (Kass et al., 2025), undermine regulatory credibility, constrains the ability of to design and implement high-quality, multi-site, and early-phase trials, increases vulnerability to exploitation of research participants and communities (Alsulmi, 2025; Kass et al., 2025).

Ensuring equitable post-trial access remains a cornerstone of ethical clinical research governance in SSA. Post-trial access refers to the benefit-sharing obligation of sponsors and researchers, in coordination with host governments and other stakeholders including research ethics committees, clinical trial regulators, and the relevant community, to make available as soon as possible any intervention or product developed, associated medical care and infrastructure, as well as the knowledge generated, to the clinical trial participants and the population or community where the research is conducted after a trial concludes (Bernabe de La Cruz & Hellmann, 2025; CIOMs, 2016). International guidelines, including the Declaration of Helsinki (WMA, 2013b) and the Council for International Organizations of Medical Sciences (CIOMs, 2016), emphasize the importance of post-trial access, though differ in terms of scope. Previous studies demonstrate the need for PTA guidance and training for REC members and other stakeholders. (Gebrehanna, 2024; Seralegne et al., 2024; Tucho et al., 2025). To address the need for a SSA guidelines on PTA, the EDCTP-funded project co-created the *AccessAfrica Guidelines on Post-Trial Access for International Clinical Trials in Sub-Saharan Africa* (Bernabe, 2024). However, having guidelines is just the starting point. Within the regional context, gaps persist in establishing national guidelines, though there have been appreciable strides since the publication of the AccessAfrica Guidelines, including moves to incorporate and operationalize post-trial responsibilities in Uganda (UNCST, 2025). Some national RECs are requiring trial sponsors to submit clear PTA plans during protocol review (Silaigwana & Wassenaar, 2019). However, the fact remains that the gargantuan task of continuous adaptation and operationalization of post-trial access principles in the various SSA countries remains a challenge compounded by the wicked problem of clinical trial governance.

There are, however, signs of progress. Countries as Rwanda and Ethiopia have attained WHO Global Benchmarking Tool (GBT) Maturity Level 3, demonstrating that regulatory system strengthening is achievable through sustained investment, institutional commitment, and political will (Chaudhry et al., 2022). Yet even within these advancing systems, gaps persist, including limited availability of systematically trained REC members with robust grounding in ethical theories, deliberation methodologies, and harmonized review standards (COHRED, 2010; Silaigwana & Wassenaar, 2015).

Recommendations and proposed actions

The recommendations in this section directly address the gaps outlined in Table 1, particularly the need for clearer mandates, harmonised procedures for joint review and inspection, and stronger regional guidance on post-trial access.

For Policymakers and Regulators

- Develop and institutionalize national Standard Operating Procedures (SOPs) for joint clinical trial inspections ensuring that these procedures are fully aligned with international Good Clinical Practice Standards (EDCPT, 2023; ICH, 2025). Establishing national frameworks for clinical trial sites with accreditation will help promote standardisation, accountability, and compliance.

- Legally delineate the respective roles of RECs and NRAs to reduce duplication of efforts and enable genuinely parallel and coordinated reviews.

Table 1. Summary gaps and implications in collaborative research ethics governance in SSA.

Prioritized Areas	Gaps	Challenges
Systemic fragmentation	• Absence of coherent, unified regulatory pathways across SSA. • Lack of clear division of roles between RECs and NRAs (overlapping mandates). • Non-harmonized administrative and regulatory frameworks. • Formal provisions for parallel review that are not fully implemented in practice	• Sequential reviews and duplication of effort prolong approval timelines and delay trial activation. • Difficult coordination among multiple institutions and levels of governance. • Governance is embedded in global industry strategies and neocolonial power asymmetries, making structural reform politically and practically difficult. • Each intervention tends to reshape rather than resolve governance problems, reflecting the "wicked problem" nature and complicating long-term, stable solutions.
Capacity and resource deficits	• Insufficient technical, financial, and human resources in RECs and NRAs. • Lack of specialized experts to review complex protocols (adaptive designs, genomics, Phase I). • Inadequate training and skills development for regulators and ethics committee members. • Weak local ownership and institutional investment in regulatory and ethics bodies.	• Limited capacity to rigorously assess and monitor complex or innovative trials. • Difficulty sustaining improvements due to chronic underfunding and resource instability. • Reliance on external support or consultants, which can constrain local autonomy and continuity. • Inability to scale up to high-quality, multi-site, early-phase trials, reducing competitiveness and scientific output.
Weak ethics and digital infrastructure	*a) Ethics infrastructure* • Underdeveloped ethics governance systems at national and institutional levels. • REC members often lack training in ethical theory, deliberative reasoning, and substantive scientific review. • Incomplete systems for adverse event oversight and response. *b) Digital infrastructure* • Unreliable or low-quality internet connectivity. • Limited access to scientific and regulatory databases. • Non-interoperable or fragmented submission platforms, pharmacovigilance databases, and e-portals. • Lack of integrated digital systems linking ethics, regulatory, and monitoring functions.	*a)* • Higher risk of poorly managed adverse events, harming participants and eroding trust. • Limited ability to identify and address exploitation, inequities, and contextual justice issues. • Weakened regulatory credibility and reduced attractiveness for sponsors and global collaborations. • Difficulty embedding robust ethical deliberation in routine practice, even when guidelines exist. *b)* • Inability to perform real-time monitoring and rapid data-driven decision-making. • Barriers to efficient data sharing across institutions and borders. • Difficulty enforcing compliance and tracking trial performance systematically. • Increased administrative burden and slower processes for sponsors, regulators, and researchers.
Incomplete harmonization and inspection standards	• Partial or uneven implementation of harmonized regulatory pathways despite EDCTP/WHO guidance. • Lack of comprehensive SOPs for joint GCP inspections in many countries. • Absence of national clinical trial site accreditation frameworks. • Incomplete integration of regional mechanisms (e.g., AVAREF joint reviews) into national systems.	• Inconsistent quality and oversight standards across sites and countries. • Difficulty ensuring uniform compliance with international GCP norms. • Reliance on episodic, externally coordinated reviews that may not build sustainable local capacity. • Complex coordination demands for joint inspections and cross-country harmonization, given varied legal and institutional contexts

Table 1. *Continued*

Prioritized Areas	Gaps	Challenges
Major implementation barriers around post-trial access (PTA)	• Limited or absent national PTA guidelines in many SSA countries. • Inadequate training and guidance for RECs, regulators, and other stakeholders on PTA obligations. • PTA plans not consistently required or standardized in trial protocols. • Incomplete translation of regional frameworks into binding national policy and practice.	• Complex coordination among sponsors, researchers, regulators, governments, and communities to deliver post-trial benefits (products, care, infrastructure, knowledge). • Need for continuous adaptation of PTA principles to diverse health systems, legal environments, and resource settings. • Financial and logistical constraints in ensuring sustained post-trial access, especially for expensive or specialized interventions. • The overall "wicked" governance environment (fragmentation, capacity deficits, power asymmetries) makes the operationalization of PTA uneven, slow, and politically sensitive.

- Invest in sustainable digital submission, tracking, and monitoring platforms with offline functionality for low-connectivity settings.

- Develop robust pharmacovigilance systems that support safety monitoring and early signal detection during the conduct of clinical trials.

- Develop interoperable databases and pharmacovigilance e-portals as a core component of digital readiness.

- Establish structured mentorship pipelines alongside MSc-level training programs to ensure long-term capacity and sustainability.

- Clearly establish the post-trial responsibilities of policymakers and regulators in accordance with the principles of the AccessAfrica Guidelines.

- Institutionalize clinical trial emergency preparedness plans (including rapid protocol adaptation, contingency oversight procedures, and continuity of care arrangements) within national regulatory and ethics frameworks.

- Strengthen regional collaboration through platforms such as AVAREF, EDCTP, and African Union structures to support joint reviews, mutual recognition of inspections, and shared PTA standards.

For Research Institutions and Ethics Bodies

- Implement comprehensive, adapted, and applied real-world ethics training programs for RECs that integrate ethical theory, deliberative reasoning, evaluation of actual cases, substantive scientific review, and administrative compliance.

- Establish mechanisms for REC evaluation and accreditation in accordance with international and African research ethics principles as well as GCP.

- Establish and strengthen institutional RECs and promote mentorship and twinning arrangements with more advanced peers to accelerate capacity building (EDCTP, 2023, 2024).

- Establish the PTA responsibilities of RECs and research institutions in accordance with the principles of the AccessAfrica Guidelines.

- Register and certify research institutions and accredit trial sites to improve quality assurance and accountability.

- Support the formation of research volunteer associations within institutions to enhance awareness of participant rights, strengthen informed consent processes, and foster dialogue among volunteers, researchers, and regulators.

- Prioritize long-term, locally owned capacity-building initiatives and twinning networks over short-term, donor-driven programs to ensure sustainability and knowledge retention (EDCPT, 2023).

- Institutionalize mechanisms for meaningful community and civil society participation in protocol review and PTA planning, including community advisory boards and co-designed communication strategies.

- Develop institutional registries of clinical trial sites, their capacities, and oversight histories, and share this information with national authorities to support rapid response during outbreaks and multi-country trials.

Call to engagement

Strengthening clinical research ethics and regulatory systems in East and Central Africa requires coordinated, sustained, and locally owned action. This Open Letter calls for renewed dialogue among policymakers, regulators, ethics committees, researchers, and funders to advance harmonized GCP inspection guidelines, clinical trial site accreditation mechanisms, and comprehensive ethics training frameworks. Regional collaboration through platforms such as AVAREF, coupled with peer learning and mentorship from countries with more mature regulatory systems, offers a practical and scalable pathway toward convergence and sustainability. By positioning ethics governance as both a scientific and moral imperative, this Open Letter seeks to contribute to ongoing scholarly and policy discourse while catalyzing actionable reforms. Ultimately, it calls for a collective commitment to building resilient, transparent, and trusted systems that will enable the region to participate safely, ethically, and competitively in the global clinical research landscape.

Use of generative AI

During the preparation of this document, the authors utilized Grammarly, an artificial intelligence-based editing tool, to review the text for grammatical correctness, and spelling errors. After using this tool, the authors reviewed and edited the content as necessary and take full responsibility for the final formatting and overall accuracy of the text.

Ethics and consent

Ethical approval and consent were not required.

Disclaimer

The views expressed in this article are those of the author(s). Publication in Open Research Europe does not imply endorsement by Horizon Europe and Global Health EDCPT3.

Data availability

No data are associated with this article.

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References

Akanmori B, Bellah A, Ward M, *et al.*: **The African vaccine regulatory forum (AVAREF): A platform for collaboration in a public health emergency.** *WHO Drug Information.* 2015; **29**: 127–132.

Akanmori BD, Mukanga D, Bellah A, *et al.*: **The Role of The African Vaccine Regulatory Forum (AVAREF) in The Accelerated Clinical Evaluation of Ebola Vaccine Candidates During the Large West Africa Epidemic.** *J Immunol Sci.* 2018; **2**(Si1): 75–79.
Publisher Full Text

Alsulmi E: **Building Clinical Trials Capacity in a Developing Research Ecosystem.** 2025.

Belaynehe KM, Nguta JM, Lopez M, *et al.*: **One Health research ethics review processes in African countries: Challenges and opportunities.** *One Health.* 2024; **18**: 100716.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

de La Cruz B, Hellmann F: **Glossary of Terms and Explanatory Document on Terms Related to Access to Drugs and Interventions in Public Health Emergency Research.** 2025.
Publisher Full Text

Bernabe R d l C, terefe TG: **AccessAfrica Guidelines on Post-Trial Access for International Clinical Trials in Sub-Saharan Africa (D3.4).** 2024.
Publisher Full Text

Cavaleri M, de Sousa CMA, Hacker A, *et al.*: **A roadmap for fostering timely regulatory and ethics approvals of international clinical trials in support of global health research systems.** *Lancet Glob. Health.* 2025; **13**(4): e769–e777.
Publisher Full Text

Chaudhry I, Thurtle V, Foday E, *et al.*: **Strengthening ethics committees for health-related research in sub-Saharan Africa: a scoping review.** *BMJ Open.* 2022; **12**(11): e062847.
Publisher Full Text

CIOMs: **International Ethical Guidelines for Health-related Research Involving Human.** 2016.
Reference Source

COHRED: **Strengthening Pharmaceutical Innovation in Africa: Designing strategies for national pharmaceutical innovation: choices for decision makers and countries.** 2010.
Reference Source

EDCPT: **Annual Report.** 2023; **2023**.

EDCTP: **Annual Reports and CCRREEA Project Updates.** 2023; **2024**.
Reference Source | **Reference Source**

Foundation, a. t. m: **Harnessing Africa's untapped clinical trial potential.** 2025.
Reference Source

Gebrehanna E: **Post-trial access trends in Sub-Saharan Africa.** 2024.
Publisher Full Text

Glickman SW, McHutchison JG, Peterson ED, *et al.*: **Ethical and scientific implications of the globalization of clinical research.** *Mass Medical Soc.* 2009; **360**: 816–823.

Global Observatory, W: **Number of clinical trials by year, country, WHO region and income group (1999-2025).** 2026.
Reference Source

ICH: **ICH HARMONISED GUIDELINE GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3).** 2025.
Reference Source

Jjagwe R, Kirabira JB, Mukasa N, *et al.*: **The drivers and barriers influencing the commercialization of innovations at research and innovation institutions in Uganda: A systemic, infrastructural, and financial approach.** *J. Innov. Entrep.* 2024; **13**(1): 78.
Publisher Full Text

Kass NE, Faden RR, Angus DC, *et al.*: **Making the ethical oversight of all clinical trials fit for purpose.** *JAMA.* 2025; **333**(1): 75–80.
PubMed Abstract | **Publisher Full Text**

Nabyonga-Orem J, Asamani JA, Makanga M: **The state of health research governance in Africa: what do we know and how can we improve?.** *Health Research Policy and Systems.* 2021; **19**(1): 11.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Osei A: **Challenges of clinical trials in low-and middle-income countries.** *International Psychiatry.* 2012; **9**(2): 30–31.
Publisher Full Text

Ouma LO, Al-Ashmori S, Sarkodie S, *et al.*: **Master protocols in low- and middle-income countries: a review of current use, limitations and opportunities for precision medicine.** *BMJ Glob. Health.* 2025; **10**(7): e018561.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Petryna A: **When experiments travel: clinical trials and the global search for human subjects.** 2009.
Publisher Full Text

Saleh M, Sharma K, Shamshudin A, *et al.*: **Regulatory approval of clinical trials: is it time to reinvent the wheel?.** *BMJ Glob. Health.* 2024; **9**(1): e013727.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Seralegne Y, Wangamati CK, Bernabe RC, *et al.*: **Post-trial access practices in conducted clinical trials for Malaria, Tuberculosis, and Neglected Tropical Diseases (NTDs) across Sub-Saharan African countries: A quantitative study.** *Open Res Eur.* 2024; **4**: 212.
Publisher Full Text

Seralegne YZ, Wangamati CK, Bernabe RD, *et al.*: **Composition and capacity of Institutional Review Boards, and challenges experienced by members in ethics review processes in Addis Ababa, Ethiopia: An exploratory qualitative study.** *Dev. World Bioeth.* 2023; **23**(1): 50–58.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Shah S: *The Body Hunters: Testing new drugs on the world's poorest patients.* New Press, The; 2012.

Silaigwana B, Wassenaar D: **Biomedical research ethics committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes.** *J. Empir. Res. Hum. Res. Ethics.* 2015; **10**(2): 169–184.
Publisher Full Text

Silaigwana B, Wassenaar D: **Research Ethics Committees' Oversight of Biomedical Research in South Africa: A Thematic Analysis of Ethical Issues Raised During Ethics Review of Non-Expedited Protocols.** *J. Empir. Res. Hum. Res. Ethics.* 2019; **14**(2): 107–116.
Publisher Full Text

Taylor-Robinson SD, Spearman CW, Suliman AA: **Why is there a paucity of clinical trials in Africa?.** *QJM: An International Journal of Medicine.* 2021; **114**(6): 357–358.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

Thomas Bollyky JAA, Makanga M: ***Safer,* Faster, Cheaper: Improving Clinical Trials and Regulatory Pathways to Fight Neglected Diseases.** *Report of the Center for Global Development's Working Group on Clinical Trials and Regulatory Pathways.* 2011.
Reference Source .

Tucho GT, Wangamati CK, Kumsa DM, *et al.*: **Perspectives of stakeholders on post-trial access arrangements in Ethiopia: a qualitative study.** *Glob Bioeth.* 2025; **36**(1): 2497599.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**

UNCST: **National Guidelines for Research Involving Humans as Resaerch Participants.** 2025.
Reference Source

WMA: **WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants.** 2013a.
Reference Source

WMA: **World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.** *JAMA.* 2013b; **310**(20): 2191–2194.
Publisher Full Text

Yilma D: **Breaking the barriers for conducting clinical trials in Africa: A need for higher commitment and collaborations.** *Ethiop. J. Health Sci.* 2024; **34**(3).

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Raymond De Vries
University of Michigan, Ann Arbor, Michigan, USA

This an important and well documented article. The authors make an important contribution by bringing together the literature describing the regulatory gaps in ethical oversight of clinical trials in Sub-Sharan Africa (although in some cases the citations are a bit dated). Based on their summary, they offer appropriate recommendations for addressing these gaps.

I recommend indexation with one important caveat. The summary of the gaps is well done, the recommendations follow from the gaps identified, but if this letter is to do more than paint a picture of the current situation, the authors must address the cultural and structural roadblocks to the implementation of their recommendation.

This need not add too many words to the letter, but they must specify which policymakers and regulators. which departments at research institutions, which ethical bodies (local, regional, national, or international). And they need to suggest where the funds for this work will come from.

Another issue that merits mention is the need to address cultural variation moral ideas and reasoning.

Lacking these specifics this will be no more than another "white paper" to be discussed and then ignored.

In sum, it needs to be indexed, but it must be more directive about how to put the fine recommendations into practice.

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Yes

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social and cultural science; bioethics; medical ethics; ethical regulation.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.