REPUBLIC OF KENYA

National Commission for Science, Technology and Innovation

POLICY BRIEF

Strengthening Clinical Trials Ecosystems in Kenya



NACOSTI Policy Brief No. 3/ 2025-2026

JUNE 2026

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BACKGROUND

A clinical trial has been defined as any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, to discover or verify the effects of, identify any adverse reactions to investigational products, to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (MoH, 2026). Clinical trials are essential for generating evidence on the safety, efficacy, and effectiveness of health products, including drugs, vaccines, diagnostics, and medical devices. They underpin access to innovative therapies and are critical for achieving Universal Health Care and improving health outcomes.

Africa carries almost a quarter of the world's disease burden, yet it runs only about 2% of global clinical trials and receives less than 2% of global health research funding (Simpkin et al., 2019). This gap in resources is alarming, but the problem goes deeper. The continent is also experiencing a disproportionate number of disease outbreaks, so it urgently needs a strong, transparent, and fast clinical research system to protect people. This can be done through better diagnostics, evidence-based treatments, new vaccines, and improved health outcomes. The 2022 World Health Organization World Health Assembly resolution (WHA 75.8), called for stronger clinical trials worldwide (World Health Organisation, 2022a). The resolution urges member states to produce high-quality evidence about health interventions and to improve research quality, coordination, and accountability. These include strengthening national clinical trial capacity to ensure compliance with international standards for trial design, supporting ethics committees and regulatory authorities to strengthen efficient, risk-based governance of clinical trials, uphold scientific and ethical standards, protect participants, data, and enhance preparedness for high-quality national and multi-country trials, including during public health emergencies (World Health Organisation, 2022b).

RATIONALE

Kenya has a growing clinical research ecosystem, with established regulatory authorities, active research institutions, and increasing interest from international sponsors. However, gaps in regulatory and governance efficiency, coordination and national strategy, infrastructural limitations, human resource constraints, limited data systems capabilities, unequitable partnerships, funding and sustainability challenges as well as community engagement and participant protection limit Kenya's ability to attract, conduct, and benefit optimally from high-quality clinical trials.

Recent global calls, including the World Health Assembly resolution on strengthening clinical trials (World Health Organization, 2025), emphasize the need for countries to develop efficient, transparent, and high-quality clinical research systems. Aligning Kenya's clinical trial environment with these principles will enhance research quality, improve participant protection, and strengthen national preparedness for public health emergencies. This policy brief outlines priority policy actions to strengthen the clinical trials environment in Kenya, enhance participant protection, and position the country as a regional centre of excellence.

METHODOLOGICAL APPROACH

This policy brief was developed through a desk review and synthesis of evidence on the clinical trials ecosystem at global, regional, and national levels. The review aimed to identify key challenges, gaps, opportunities, and policy options required to strengthen clinical trial capacity and governance in Kenya.

Evidence from the desk review was analyzed thematically across key components of a functional clinical trials ecosystem, including regulatory systems, ethics oversight, clinical research capacity, quality management systems, data governance, financing, infrastructure, innovation, and stakeholder coordination.

SITUATIONAL ANALYSIS

The Current National Governance and Institutional Landscape

The clinical trial regulatory environment in Kenya is anchored within the national legal and policy framework governing research, medicines regulation, data protection, and human subject protection.

National Commission for Science, Technology, and Innovation: The National Commission for Science, Technology, and Innovation (NACOSTI) is the statutory body mandated to regulate and oversee research activities in the country across all scientific disciplines. Its core role includes registering research institutions and licensing research activities by institutions, individual investigators, and foreign collaborators to ensure that research is conducted in line with national priorities and scientific standards. In addition to granting research approvals, NACOSTI oversees all research activities to ensure they adhere to ethical and legal requirements. The Commission accredits Institutional Scientific Ethics Reviews Committees in research and academics institutions to review projects and proposals before granting research licenses. NACOSTI further monitors compliance by conducting field visits, requiring periodic reporting, reviewing research outputs, and conducting institutional inspections.

Pharmacy and Poisons Board: The Pharmacy and Poisons Board (PPB) is Kenya's National Regulatory Authority with the legal mandate to oversee medical products and health technologies, as well as investigational products used in clinical trials. The PPB assesses investigational products for safety, efficacy, and quality before authorizing clinical trials. In addition, it monitors compliance by inspecting clinical trial sites to ensure adherence to Good Clinical Practice, Kenya's regulatory requirements, and other international guidelines. The Board further oversees pharmacovigilance activities, including tracking and reviewing safety reports, serious adverse events, and suspected unexpected serious adverse reactions during and after the trial. By fulfilling these roles, the PPB not only safeguards research participants but also protects public health and fosters confidence in the country's clinical trial ecosystem.

Office of the Data Protection Commissioner: The Office of the Data Protection Commissioner (ODPC) plays an

important role in the governance of clinical trials in Kenya by overseeing compliance with data protection and privacy requirements in health research. Clinical trials involve, prior-informed consent, data collection, processing, storage, transfer, and analysis of sensitive personal and health-related information from participants, including medical histories, biological data, and trial outcomes. Under Kenya's data protection framework, the ODPC provides regulatory oversight to ensure that clinical trial sponsors, researchers, institutions, and other data controllers/processors handle participant data lawfully, transparently, and securely. Within the clinical trials ecosystem, the ODPC therefore complements the roles of research ethics committees and regulatory authorities by strengthening trust, protecting research participants' privacy, and ensuring that Kenya's clinical research environment aligns with national data governance requirements and international standards for ethical health research

Research institutions and investigators: Kenya's clinical research activities are conducted through a diverse range of institutions, including public and private universities, research institutes, hospitals, and specialized clinical research centres. These institutions provide platforms for investigator-led research as well as externally sponsored clinical trials. Universities, hospitals, and research organizations conduct clinical trials in collaboration with regulatory authorities and ethics committees. Researchers design and implement trials, monitor outcomes, and ensure compliance with both regulatory and ethical standards.

Sponsors: Clinical trials are often sponsored by pharmaceutical companies, academic institutions, non-governmental organizations, and international research organizations. These sponsors provide financial and technical support and rely on the regulatory and ethics framework to ensure that trials are conducted safely and efficiently.

FINDINGS

Despite an established regulatory and ethics oversight framework, Kenya's clinical trials governance system faces several structural and operational constraints that affect efficiency, consistency, and responsiveness.

Fragmented and multi-layered approval processes: Clinical trials undergo multiple sequential reviews and approvals, delaying trial initiation. These include reviews by the institution's scientific/research boards, PPB, and NACOSTI, as well as, in some cases, additional sector-specific approvals. This issue is exacerbated in multisite clinical trials, where the same protocol undergoes separate reviews by multiple institutional committees rather than relying on a single accredited ethics review that has already assessed the study's scientific and ethical aspects. The absence of a formal and operational reliance mechanism limits efficiency lengthens trial initiation timelines, and may discourage participation in large-scale, multicentre research. This multi-step system, while strengthening oversight, often results in prolonged timelines, particularly for multicentre and multicounty studies.

Unequitable international partnerships and limited local value capture in clinical trials

Although Kenya participates in multinational and externally sponsored clinical trials, many partnerships remain largely sponsor-driven. Local research institutions function primarily as recruitment and implementation sites rather than scientific partners. There is therefore a need to shift from transactional trial participation toward equitable research partnerships that promote shared leadership, strengthen local capabilities, support local innovation, and ensure that clinical research contributes to national health priorities.

Limited harmonization and coordination of oversight functions: Although accreditation procedures for scientific and ethics review exists, the capacity and maturity of the committees vary widely, leading to variability in review quality and timelines. Variability exists in reviewing standards, submission requirements such as pre-submission meetings, and operational procedures across institutions. This lack of full harmonization can lead to inconsistent decisions, repeated protocol revisions, and delays in trial initiation and amendments.

Capacity constraints within regulatory and ethics oversight bodies: Regulatory authorities and ethics committees face shortages of adequately trained personnel, particularly in specialized areas such as complex trial designs (adaptive/platform trials), advanced therapeutics, genomics, and digital health research. This limits the ability to efficiently review increasingly sophisticated clinical trial applications.

Weak adoption of risk-based and proportionate oversight models: Current oversight systems are still largely process-heavy rather than risk-tiered. Limited implementation of risk-based review approaches can lead to disproportionate scrutiny of low-risk studies while constraining resources needed for high-risk or novel trials.

Limited digitalization and regulatory information systems: Many regulatory and ethics review processes remain partially manual or fragmented across platforms. Limited interoperability also constrains real-time oversight and monitoring by organizations.

Funding and Sustainability: High dependence on external sponsors and funders; limited domestic funding for investigator-initiated trials; Few incentives for local industry or public institutions to invest in trial infrastructure and capacity.

Public and Community Engagement: Misconceptions and fears around clinical trials; inadequate, inconsistent community engagement approaches and materials; Limited availability and use of patient and community voices in priority-setting and oversight.

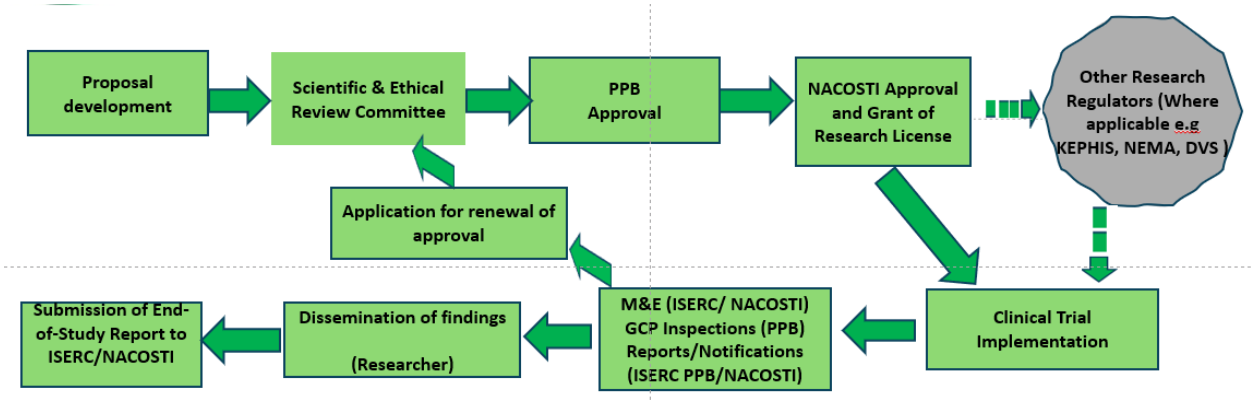


Figure 1: Clinical Trials Authorization and Implementation Pathway in Kenya

POLICY RECOMMENDATIONS

#	Theme	Specific Action
1	**Improve efficiency, transparency and coordination of regulatory and ethics oversight**	Develop and implement a harmonized clinical trial workflow that integrates regulatory agencies.
		Promote parallel (rather than sequential) reviews while maintaining quality;
		Establish a national clinical trials coordination mechanism to align regulatory decisions and reduce duplication of review processes
		Develop joint review mechanisms and a reliance model for efficient approval and oversight of multi-site trials
		Strengthen clinical trials regulatory guidelines to promote equity of post-trial benefits and participant protection.
		Publish clear requirements, timelines and procedures for approvals.
		Strengthen monitoring capacity to ensure compliance with international standards.
		Develop a National Clinical Trials Research Agenda aligned with Kenya's disease burden and health priorities, including.
2	**Promote equitable international partnerships**	Develop partnership guidelines that include, among other things, support for knowledge transfer and ensure access to relevant trial outcomes.
		Encourage South–South collaborations with other African countries
3	**Strengthen community and patient involvement throughout the trial lifecycle**	Establish mechanisms to meaningfully engage patients, communities, and civil society in trial design, recruitment strategies, and the dissemination of findings.
		Develop community engagement standards/guidelines for clinical trials
4	**Standardize ethics and regulatory review processes through national harmonization and accreditation strengthening.**	Review regulations and guidelines for SOPs development, templates, and review checklists for clinical trials. Strengthen accreditation and continuous quality assurance systems for scientific and ethics review committees.
		Promote shared training programmes and peer-review systems across ethics committees to improve consistency and quality.
5	**Invest in specialized human resource development and institutional capacity strengthening.**	Develop a national clinical trials regulatory and ethics training curriculum
		Establish specialist technical advisory pools for genomics, adaptive trials, digital health, and advanced therapeutics.
		Support mechanisms to retain skilled reviewers through competitive career structures and continuous professional development programmes.
		Support capacity-building of staff in regulatory authorities with Good Clinical Practice (GCP), research ethics, and clinical trial management training
		Encourage mentorship schemes linking high-experience and emerging trial sites.
		Leverage existing research platforms by building on capabilities within research institutions, universities, and major hospitals to train and support county-level sites.
6	**Support/Implement risk-based regulatory and ethics oversight framework.**	Develop risk classification system for clinical trials to guide differentiated levels of review and oversight intensity.

#	Theme	Specific Action
6	**Support/Implement risk-based regulatory and ethics oversight framework.**	Introduce expedited review pathways for low-risk studies and streamlined amendment procedures.
7	**Develop an integrated national digital clinical trial regulatory platform**	Enable end-to-end digital submission, tracking, approvals, and monitoring of clinical trials.
		Ensure interoperability across institutional systems to allow real-time sharing of regulatory and ethics decisions.
		Create or enhance a national clinical trials inventory: Ensure all trials approved and conducted in the country are registered with basic, public-facing information (title, sponsor, disease area, status, sites); Allow policymakers and the public to track trials and avoid duplication.
		Promote dissemination and uptake of results: Require timely sharing of trial results with regulatory agencies; establish processes to integrate high-quality trial evidence into guidelines, formularies, and policy decisions.
8	**Diversify and strengthen domestic financing and sustainability mechanisms for clinical research.**	Provide fiscal and tax incentives to encourage private sector and pharmaceutical investment in local trials.
		Promote public–private partnerships for the development and maintenance of clinical trial infrastructure.
		Establish mechanisms for funding clinical trials in Kenya through National Clinical Research Fund or window. Earmark domestic funding to support priority investigator-initiated trials and early-phase research.
		Incentivize local investment: Encourage joint ventures and co-funding models between government, development partners, and industry.
		Leverage international partnerships: Position Kenya to participate actively in regional and global research consortia (e.g. vaccine trials networks, NCD trial platforms), with a focus on fair site funding and capacity transfer.
9	**Institutionalize structured and meaningful community engagement in clinical research.**	Establish mechanisms to meaningfully engage patients, communities, and civil society in trial design, recruitment strategies, and the dissemination of findings.
		Develop national guidelines for community engagement in clinical trials, including minimum standards and practices.
		Support establishment of community advisory boards within major research institutions and trial sites.
		Implement public awareness campaigns to address misconceptions and improve understanding of clinical trials.
		Protect participants' rights and welfare: Reinforce clear standards for informed consent, insurance for trial-related injury, and complaint/redress mechanisms.
		Close monitoring of clinical trials to avoid misconduct or exploitation.

ACKNOWLEDGEMENT

The development of this policy brief was undertaken under the guidance and support of **Dr. David Ngigi, Ag. Director General, NACOSTI**.

This policy brief was prepared through the collective efforts and valuable contributions of the following NACOSTI officers:

Dr. Benson Mburu, Godfrey Kalerwa, Julius Mwangi, Carolyne Nekesa, Teresia Nyawira, Ezekiah Gatheru, Lilian Awala, Njuguna Kiuna, Lourine Auma, and Mitchell Gakii.

Their expertise and commitment in the development of this policy brief are acknowledged and appreciated.

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