

**ETHICAL AND REGULATORY COMPLIANCE IN THE EVALUATION OF CLINICAL
RESEARCH INVOLVING ARTIFICIAL INTELLIGENCE IN SUB SAHARAN AFRICA**

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Department of Pharmacotoxicology and Pharmacokinetics, Faculty of Medicine and Biomedical Sciences, University of Yaoundé 1, Cameroon. DOI: <https://doi.org/10.5281/zenodo.23798841>

How to cite this Article: Charles Ntungwen Fokunang^{1*}, Abondo Rose Ngono Mballa², Marceline Djuidje Ngounou³, Joseph Fokam⁴, Edit Lum Abongwa⁵, Estella Achick Tembe-Fokunang¹, Wilfred Fon Mbacham⁶, Charles Okechukwu Esimone⁷, Vincent Pryde Kehdingha Titanji⁷. (2026). Ethical and Regulatory Compliance In The Evaluation of Clinical Research Involving Artificial Intelligence In Sub Saharan Africa. European Journal of Pharmaceutical and Medical Research, 13(11), 1–16.

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Article Received on 01/10/2026

Article Revised on 22/10/2026

Article Published on 01/11/2026

ABSTRACT

In recent years, the use of artificial intelligence (AI) in research involving human participants has gained popularity in clinical and biomedical research domains, more so in advance economies than in low medium income countries (LMIC) like Cameroon. AI is transformative in its ability to perform faster repetitive tasks, analyze large amounts of data, and potentially leading to enhance clinical research decision-making. As with all research involving human participants, research using AI should be in compliance with ethical principles and subject to regulatory guidelines for better protection of volunteering research participants. The use of AI in research involving human participants presents new ethical and regulatory challenges, including those related to privacy and data confidentiality, transparency, amplification of bias, and implications for maintaining human autonomy and oversight. Existing guidelines of most research ethics committees relating to digital health technology evaluation for human research are not up-to-date to address AI evaluation in clinical research. In view of providing a regulatory compliant structure that protects the human participant's privacy and mitigation of bias Sub-Saharan African countries have an obligation to update their standard operating procedures to integrate aspects for evaluating AI research. There are however, a few existing guidelines from developed countries like the US and Canada that provide the ethical foundations for the use of AI in clinical research. Tools are still required to enhance the protocol review process by the research ethics committees charged with ensuring consistency, efficiency and sustainability across institutions, to reflect accepted standards of ethical research review oversight. This document aims to focus on AI contributions in clinical research, challenges and adopted guidelines for evaluation of AI-driven clinical research. This is in view of providing support for Institutional Review Boards (IRBs) and other ethics advocacy institutions with the awareness and practical friendly user steps to identify, assess, and mitigate potential risks to participants in an AI-driven research, during the ethical review process.

KEYWORD: Artificial intelligence, Ethical Challenges and Evaluation Procedures, IRBs, clinical research, Sub Saharan Africa.

INTRODUCTION

The ethical evaluation of artificial intelligence (AI) technology involved in clinical research requires adapting traditional research ethics to address unique challenges, such as algorithmic "black box" opacity, data bias, and the shifting role of human oversight.^[1,2] Key frameworks, notably the European Union (EU) AI Act of 2024, and guidance from bodies like the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University, advocate for a risk-based, transparent, and systematic review process throughout the AI. It also requires the responsible management of risks in global clinical research, aiming to strengthen participant protection while enforcing scientific innovation.^[2] Ethics committees and Institutional Review Boards (IRBs) mandatorily should focus on the following key areas:

Transparency and Explainability ("Black Box")

AI systems often lack transparency, making it hard to interpret how they arrive at a decision. Evaluators must mandate "explainable AI" and compel researchers to document the model's training data, decision-making logic, and its limitations.^[3]

Data Governance and Privacy

AI research involves massive datasets, increasing risks of re-identification. Ethical procedures must encourage secure handling, including techniques like differential privacy and federated learning, ensuring compliance with laws like the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA). Both regulations share the unilateral goals of placing obligations upon organizations to appropriately manage, store, and protect users' personal data.^[4]

Informed Consent and Autonomy

Informed consent and participants' autonomy have a strong consideration given that participants must be informed how their data will be used to train AI technologies, and consent must be very specific and understandable by participants, what is known as Specific, Informed, and Unambiguous (SIU).^[5]

Algorithmic Bias and Fairness

Ethical evaluation must verify that AI models are trained on representative, diverse datasets to prevent discriminatory outcomes, especially for underrepresented or special/minority populations. Procedures include reviewing pre-screening of datasets and implementing bias checks during development.^[6]

Human Oversight and Accountability

AI should add value, not replace, human judgment and mental capacity to reason. Ethical approval depends on defining clear accountability for AI-driven decisions and ensuring researchers maintain control over clinical decision-making.^[1,7]

Ethical evaluation should follow the development stage of the AI system: **Phase 1 (Training/Development)**: This focuses on data sourcing, privacy, and informed consent.

Phase 2 (Testing/Real-world Evaluation): The focus is on safety, performance, and validation, ensuring that the AI is tested on new, unseen data.

Phase 3 (Post-marketing Monitoring): The focus is on ongoing performance, bias detection, and accountability after its application.

ETHICAL REGULATION OF CLINICAL RESEARCH INVOLVING HUMANS IN CAMEROON

Ethical regulation of clinical research involving humans in Cameroon is primarily governed by Law No. 2022/008 of 27 April 2022, which provides a comprehensive legal framework for protecting participants' rights and safety. This law is likely to transform the clinical research landscape from a reliance on international standards to a robust national system of accountability and oversight.^[7]

Key Regulatory Frameworks in Cameroon

In Cameroon on clinical research oversight is split between ethical review and administrative approval. The structure is presented as follows:

National Ethics Committee for Human Health Research (CNERSH): Evaluates national-scale projects, clinical trials, and projects with international funding and collaborations.

Regional Ethics Committees: Oversee projects confined to specific regions of Cameroon. Regional ethics committees are functional, for example, in some regions like the Centre, West, Littoral, Southwest and Northwest.^[8]

Institutional Ethics Committees: These review studies conducted entirely within specific academic or health institutions. Cameroon also authorizes private non-governmental organization to function as advocacy groups for the promotion and capacity building in health research ethics.^[8]

The Ministry of Public Health under the Directorate of Operational Health Research with the French acronym (DROS), Issues the mandatory Administrative Authorization of Research (AAR) after ethical clearance is obtained.

Core Ethical Requirements in Cameroon

Under the 2022 Law and existing guidelines, researchers must adhere to several strict standards:

Informed Consent: Must be obtained in writing and in a language/format understood by the participant.

Participants must have a clear understanding of the study, and they retain the right to withdraw at any time.

Protection of Vulnerable Groups: Specific safeguards are required for minors, pregnant women, embryos, and incapacitated adults.

Confidentiality: Unauthorized disclosure of participant data is a criminal offense punishable by imprisonment (3 months to 3 years) and fines.

Scientific Validity: Protocols must be reviewed for their relevance to local health needs and methodological soundness. Institutional Review Board (IRB).

Risk-Benefit Analysis: Research must prove a favorable risk-benefit ratio.

Beneficence and Justice: Fair selection of subjects, avoiding exploitation, and sharing benefits with the community.

Compliance and Sanctions

Approval Sequence: Ethical clearance from a committee is a prerequisite, but it does not authorize research on its own; the administrative research Authorization (ARA) from the Ministry of Public Health is the final legal requirement.^[9]

Sanctions: The 2022 law introduced clear penalties for non-compliance, including fines and imprisonment for ethical breaches or conducting research without proper authorization.

Monitoring: The Ministry and ethics committees have the authority to conduct unannounced checks and site investigations to ensure ongoing compliance.

Major Challenges in conducting clinical research in Cameroon

Implementation Gaps: While the law is robust, some studies indicate a lack of awareness among medical students and researchers regarding specific national regulations.

Decentralization: Regional coverage is still expanding, with the goal of reaching all ten regions of Cameroon to better serve local needs. The National Ethics Committee (CNERSH) operates under the Ministry of Public Health, reviewing projects to ensure ethical standards.

Regulatory Structure: A 2012 order reorganized the ethics system into national, regional, and institutional levels, although resources for regional committees are limited.

Core Principles: Mandatory adherence to informed consent, ensuring voluntary participation, confidentiality, and beneficence.

Specific Protections: Regulations restrict the sale of human body parts for research, protect vulnerable

populations, and regulate research in emergency situations.^[7,8]

Requirements for Ethics review Approval

Independent Review: All trials require approval from a certified Ethics Review Board (ERB) or *Ethical Violations and Enforcement:* Non-compliance with ethical principles can lead to the shutdown of trials and sanctions. There has been great advancement in building capacity for clinical research like the Building Capacity for Research Ethics Evaluation and Drugs Safety Monitoring (BREEDSAFCA) project implemented in Cameroon from 2018 to 2022 with funding from The European & Developing Countries Clinical Trials Partnership (EDCTP), a public-public partnership between countries in Europe and sub-Saharan Africa, supported by the European Union. This project has contributed to the strengthening of the regulatory framework of Cameroon's ethical and administrative evaluation of clinical research, and the improvement of the national coverage of Research Ethics Committees (RECs). The BREEDSAFCA has enhanced the ethical review process of clinical research and drugs safety monitoring in Cameroon with the mission of strengthening the protection of research participants and pharmacovigilance within the regulatory frameworks in research ethics.^[9]

The Role of AI in Clinical Research

AI plays a pivotal role in clinical research by streamlining processes that traditionally required extensive human intervention. By evaluating historical data and identifying trends, AI systems can assist researchers in designing protocols that maximize patient enrollment and retention while ensuring regulatory compliance. This capability is particularly valuable in rare disease studies or trials with stringent eligibility criteria, where finding suitable participants can be a significant hurdle.^[9]

Moreover, AI can automate repetitive tasks such as data entry and analysis, allowing clinical researchers to focus on more strategic aspects of trial management, thus enhancing overall productivity. For instance, natural language processing (NLP) can be employed to extract relevant information from unstructured data sources like clinical notes or patient feedback, further enriching the dataset available for analysis. This not only reduces the likelihood of human error but also accelerates the timeline for data processing, enabling quicker insights and adjustments to trial protocols as needed.^[10]

The Impact of AI on Clinical Trials

The integration of AI technologies is not only reshaping how clinical trials are conducted but also creating far-reaching impacts that can benefit researchers, sponsors, and patients alike. The main advantages of AI in clinical trials include enhanced efficiency, improved accuracy, and broader applicability of findings.^[11]

Enhancing Efficiency in Clinical Trials

One of the key benefits of AI in clinical trials is its ability to significantly enhance efficiency. AI algorithms can analyze eligibility criteria much faster than traditional manual processes, enabling quicker patient recruitment. As a result, trials can begin sooner and reach completion more efficiently, thereby accelerating the pace at which new therapies are brought to the market. Furthermore, AI can streamline data collection and management processes, reducing the burden on clinical staff and allowing them to focus on patient care rather than administrative tasks. This not only improves the overall workflow but also minimizes the risk of human error, which can compromise the integrity of trial results.^[3,12]

Improving Accuracy and Precision

Beyond mere efficiency, the application of AI can also lead to remarkable improvements in the accuracy and precision of trial results. By using predictive modeling, researchers can identify suitable populations and tailor interventions to meet specific patient needs. This precision medicine approach can ultimately lead to more effective outcomes and reduced adverse effects during treatment. Additionally, AI can assist in real-time monitoring of patient responses, enabling researchers to make data-driven adjustments to trial protocols on-the-fly. This dynamic adaptability ensures that the trials remain relevant and aligned with the evolving understanding of patient responses, thereby enhancing the overall quality of the research.^[5]

Furthermore, the use of AI can facilitate the analysis of vast datasets, including genomic information, electronic health records, and patient-reported outcomes. By integrating these diverse data sources, AI can uncover hidden patterns and correlations that may not be apparent through conventional analysis methods. This comprehensive approach not only enriches the data landscape but also opens new avenues for hypothesis generation and exploration, ultimately leading to more innovative therapeutic strategies. As AI continues to evolve, its role in clinical trials is expected to expand, potentially transforming the landscape of medical research and patient care.^[7,13]

Clinical research involving Artificial Intelligence (AI) in resource-limited settings faces significant hurdles. These include data scarcity and quality issues, lack of infrastructure and expertise, ethical concerns, and regulatory uncertainties. Additionally, ensuring equitable access to and appropriate use of AI technologies in these settings is crucial.^[6,14]

Technical Challenges in AI Integration

One of the most significant hurdles is the technical complexity involved in implementing AI systems. Researchers may encounter difficulties in data interoperability, scalability of algorithms, and integration with existing clinical systems. To address these

challenges, a collaborative approach involving IT specialists, data scientists, and clinical professionals is essential.^[15]

Overcoming Resistance to AI Adoption in Clinical Trials

Resistance from stakeholders can also impede AI adoption. Mistrust towards automated systems, fear of job displacement, and a lack of understanding about AI's benefits can create barriers. Engaging stakeholders through education, demonstrating successful case studies, and fostering an inclusive environment can encourage buy-in and drive the transition to AI-enabled clinical trials.^[16]

Data Quality and Availability

AI algorithms thrive on data, but clinical research data is often fragmented, incomplete, and inconsistent. Clinical trials and observational studies generate vast amounts of data, but much of this data exists in silos across multiple institutions, systems, and formats. Inconsistent coding, missing data, and low-quality datasets can impair the ability of AI algorithms to function effectively. Moreover, clinical data often contains personal health information, which raises concerns about data privacy and the security of sensitive data.^[18]

To overcome this, data cleaning, standardization, and the creation of interoperable systems for data sharing are essential. However, these tasks are time-consuming and require substantial investment in infrastructure, both of which present barriers to successful AI deployment.

Bias and Generalization in AI research

AI algorithms are only as good as the data they are trained on. If the data used to train these models is biased, the AI will learn and perpetuate these biases, leading to inaccurate predictions or outcomes. For example, clinical trials historically underrepresent certain demographics, including racial minorities, women, and elderly patients. As a result, AI models trained on this incomplete data may fail to generalize to broader populations, leading to health inequities.^[19]

Addressing bias in AI requires diverse and representative datasets. Ensuring that clinical trials and observational studies include underrepresented populations will help develop more accurate and fair AI models. Moreover, creating algorithms that can detect and correct biases in data will be crucial for improving AI's applicability across all patient groups.^[20]

Interpretability and Transparency

One of the most significant challenges of AI in clinical research is the "black box" nature of many AI models, especially deep learning algorithms. These models are often complex and difficult to interpret, making it challenging for clinicians and researchers to understand how the model arrived at a particular decision or prediction. In clinical research, this lack of transparency

can be problematic, particularly when AI recommendations impact patient outcomes.^[10]

Regulatory bodies, such as the FDA, are increasingly demanding transparency in AI decision-making processes. There is a growing emphasis on developing explainable AI (XAI), where the algorithms can provide interpretable results that clinicians can understand, trust, and act upon. Researchers are also focusing on developing AI models that are inherently more transparent, offering insights into the factors influencing their predictions.^[21]

AI Integration into Clinical Practice

Integrating AI into clinical research workflows can be a significant challenge. Clinicians, researchers, and healthcare providers are often resistant to adopting new technologies, especially when they disrupt existing practices. The transition from traditional research methods to AI-driven approaches requires not only technological infrastructure but also a cultural shift within organizations.^[22] Training researchers and clinicians to work with AI tools is another hurdle. Clinicians may lack the necessary expertise to interpret AI outputs effectively, and researchers may need to develop new skill sets to design studies that fully leverage AI capabilities. Building trust in AI requires time and a proven track record of success, making it a gradual process.^[23]

Data Privacy and Security

Given the sensitive nature of health data, AI applications in clinical research must comply with stringent data privacy regulations such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States, or the General Data Protection Regulation (GDPR) in Europe. AI systems must be designed to safeguard patient privacy and ensure that personal health information is not exposed to unauthorized parties.^[24] The growing volume of health data presents challenges

in maintaining secure systems capable of preventing cyberattacks or data breaches. Researchers and AI developers must collaborate closely with cybersecurity experts to create robust protections against data vulnerabilities.

Cost and Resource Constraints

The development and implementation of AI in clinical research are costly. Building and maintaining AI systems require significant investment in infrastructure, computational power, and human resources. Small research institutions or organizations with limited budgets may find it challenging to adopt AI technologies. Additionally, AI algorithms need continuous updates and monitoring to ensure they remain accurate and reliable, further adding to the cost.^[25] The financial burden of AI integration can be mitigated through public-private partnerships, shared research initiatives, and grants, but the expense remains a significant challenge for many organizations, particularly in resource-limited settings.

Regulatory Approval and Validation

AI-based tools must undergo rigorous validation before they can be used in clinical research. This process can be lengthy and complex, as regulatory bodies such as the FDA and EMA assess the safety and efficacy of AI tools. Given the rapid evolution of AI technology, traditional validation methods may need to be adapted to accommodate new models and approaches.^[23,25] There is a need for standardized validation processes for AI systems, ensuring that they meet the same rigorous standards as other clinical research tools. Regulatory bodies must establish frameworks that account for the unique characteristics of AI, including its ability to learn and evolve over time.

AI models can inherit biases from training data, leading to unfair treatment recommendations or participant exclusions. There are challenges and possible solutions as summarized in table 1.

Table 1: Challenges and solutions on Bias and fairness in AI models.^[15]

The Challenges include: Underrepresentation of diverse populations. Algorithmic bias affecting treatment decisions. Lack of transparency in model training data.	Solutions: Ensure diverse datasets to eliminate bias. Conduct regular audits and recalibrate AI models. Promote collaboration between AI experts and clinical researchers to refine algorithms.
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3. Transparency and Explainability

Many AI models operate as “black boxes,” making it difficult to understand how decisions are made. This lack

of transparency can undermine trust in AI-driven clinical trials. The AI transparency and explainability challenges and possible solutions can be summarized in table 2.

Table 2: The AI transparency and explainability challenges and possible solutions.^[15]

Challenges: Difficulty in explaining AI-based patient selection. Lack of clear reasoning behind AI-generated treatment recommendations. Regulatory uncertainties regarding AI-based decision-making in trials.	Solutions: Utilize Explainable AI (XAI) to provide clear insights. Ensure human oversight in AI-assisted decision-making. Establish regulatory guidelines for AI explainability in clinical research
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4-Informed Consent and Patient Autonomy

Participants must understand how AI influences trial processes and outcomes. The informed consent and

patient autonomy challenges and proposed solutions can be summarized in table 3.

Table 3: The informed consent and patient autonomy challenges and proposed solutions.^[15]

Challenges: Patients may not fully grasp AI's role in their treatment. AI-driven changes to the trial process might not be communicated effectively. Ethical concerns regarding dynamic consent updates.	Solutions: Offer simplified explanations about AI's involvement. Implement dynamic consent models that update patients on AI-driven changes. Use digital platforms to ensure ongoing patient engagement and consent tracking
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5. Regulatory Compliance and Accountability

AI in clinical trials must align with regulatory frameworks and Good Clinical Practice (GCP) standards

to ensure ethical conduct^[15], The challenges and possible solution to regulatory compliance and solution is outlined in table 4.

Table 4: The challenges and possible solution to regulatory compliance and accountability.^[15]

Challenges: Rapid AI advancements outpacing regulations. Global disparities in AI-related clinical trial guidelines. Lack of harmonization in AI compliance across different regulatory bodies	Solutions: Collaborate with regulatory bodies to establish AI compliance frameworks. Develop standardized ethical guidelines for AI use in trials. Encourage cross-border collaborations to streamline AI regulations for global clinical trials.
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AI RESEARCH FOCUS IN SUB SAHARAN AFRICA

AI is transforming clinical research in Sub-Saharan Africa through improving diagnostic accuracy, enhance disease surveillance, and improved drug discovery, with special focus poverty related diseases like malaria and infectious diseases. Key applications include AI-driven medical imaging (TB screening), and mobile-based telemedicine, targeting enclaved zones in Africa. Key challenges however, include limited digital infrastructure, lack of localized data, and ethical concerns.^[21-23]

Key Impacts of AI in Clinical Research in African Countries

Diagnostics and Screening: AI-powered software such as CAD4TB, is used in South Africa and Kenya for TB screening via chest X-rays, enabling faster diagnosis. AI is also being explored for cervical cancer screening using smartphone imaging.^[26]

AI in Disease Surveillance and Outbreak Prediction

AI algorithms predict outbreaks by analyzing health records and environmental data. For example, during the COVID-19 pandemic, AI models were used to predict spread patterns and manage resources.

Precision Medicine and Drug Development

AI aids in analyzing high genetic diversity for personalized healthcare, particularly in genomic studies. It also assists in analyzing malaria parasite resistance patterns to improve treatment strategies.^[26]

Task Shifting and Resource Management. In areas with few radiologists, AI tools in medical laboratories can enhance diagnostic capabilities.

Key Challenges for AI Adoption in Africa

Data Privacy and Security: AI systems require vast datasets, increasing risks of data breaches, unauthorized access, and re-identification of anonymized data. Sophisticated AI algorithms can re-identify individuals by linking supposedly anonymous health data with external datasets.^[28]

Data Availability and Quality

Limited, inconsistent local data and lack of standardization hinder effective AI model training. Ethical and Regulatory Frameworks issues deal with lack of clear policies on data privacy and AI ethics raises concerns about data security and algorithmic bias. We have setbacks from limited Digital Literacy as a result of the shortages in trained personnel to develop, manage, and use AI technologies effectively.^[29]

Privacy-Preserving Solutions: Advanced techniques are being developed to mitigate these risks, including federated learning (training models on local data without sharing it), differential privacy (adding noise to data), and synthetic data generation.

Infrastructure Limitations

Many health institutions rely on legacy systems that cannot handle the large-scale data analysis required by AI. Limited internet connectivity, unstable power supplies, and lack of interoperable, standardized data formats are major barriers. Infrastructure and Connectivity due to poor internet access and unstable electricity hinder the implementation of AI solutions.^[30]

Algorithmic Bias

If training data is non-representative (e.g., underrepresenting minorities), AI tools can amplify

inequalities, providing less accurate diagnostic performance for certain populations.^[30]

Key Impact Areas of AI in Clinical Research

Precision Medicine & Genomics: AI facilitates a shift from "one-size-fits-all" treatments to personalized care tailored to the specific genetic profiles of African populations. Initiatives like **H3Africa** utilize AI to analyze vast genomic datasets to identify markers for diseases such as sickle cell anemia and cancer.^[32]

Drug Discovery & Development AI platforms like AlphaFold can rapidly process protein structures, significantly shortening the timeline for discovering new drug candidates for diseases like malaria and tuberculosis. Local organizations like the African Drug Discovery Foundation (ADDF) that use AI to accelerate these processes.^[33-34]

Clinical Trial Optimization, Infectious Disease Surveillance and Implementation Challenges

AI tools are increasingly used to optimize trial protocols and improve site selection by analyzing historical data to predict recruitment success and identify high-performing investigators. During the COVID-19 pandemic, AI-powered predictive models helped forecast outbreak patterns and track viral variants across several SSA countries. Despite its promise, several barriers hinder the widespread adoption of AI in clinical research across the

region within the areas of Data Scarcity & Quality, algorithmic bias, infrastructure Deficits and Regulatory & Ethical Gaps. Many countries lack comprehensive frameworks for data privacy and liability for AI-driven clinical errors. As of 2024, only a few countries like Mauritius, Rwanda and South Africa have finalized national AI strategies.^[35-36]

Since the emergence of COVID-19 pandemic, there has been great initiatives for AI research in Africa as illustrated in table.... South Africa, Nigeria, Ghana, and Egypt have a lead in malaria and tuberculosis research. For Rwanda there are evidence of effective precision medicine initiatives. For Zambia the use of AI-trained telemedicine for remote patient monitoring has been reported. American robotics firm Zipline uses its life-saving drone delivery network throughout Africa following a US\$150m commitment from the US State Department. The US Government has pledged up to US\$150m to support the expansion of Zipline International's operations across the African continent. This move has increased access to medical supplies for health facilities and communities by improving the scale and reliability of autonomous delivery systems.^[37-38] To maximize the impact, future efforts need to focus on strengthening data infrastructure, increasing funding, and fostering local, context-specific AI development as indicated in table 5.

Table 5: Some Key Regions and Initiatives of AI research in Africa.^[14]

Country	AI Application	Key Benefit
Zambia	Screening of Diabetic retinopathy	Achieves 99.4% sensitivity in vision-threatening cases, more than human experts
Nigeria	Ubenwa startup	Uses machine Learning to detect birth asphyxia in resource limited countries
Kenya	Path LLM-based	Supports clinicians in diagnosis and treatment recommendations
South Africa	Lelapa AI	Focuses on building language models for under represented African dialects to improves research inclusion
Cameroon	EMERGENTS PROJECT, University of Dschang	Tracking urban Malaria with AI-enabled smart traps specifically to track <i>Anopheles stephensi</i> mosquito species invading Africa that spreads malaria in urban environments.
Rwanda		Precision Medicine

INTEGRATION OF AI RESEARCH INTO NATIONAL HEALTH POLICIES

Regulatory Frameworks

Countries are moving beyond general data laws like the EU general data protection regulation (GDPR), which is the strongest privacy and security law in the world. This regulation updated and modernized the principles of the 1995 data protection directive. It was adopted in 2016 and entered into application on 25 May 2018. The GDPR law to AI-specific regulations is essential and the EU Artificial Intelligence Act classifies many AI health tools as "high risk," mandating strict conformity assessments. The GDPR law will help African countries draw inspiration to develop their legal frame work on AI research.^[40-41]

National Digital Strategies

Governments are creating national health accounts (e.g., India's ABHA number) and digital infrastructure to create "findable" and "accessible" data, which is essential for training AI.

Health Technology Assessment (HTA): AI is being integrated into HTA processes to evaluate technology worth, optimize resource allocation, and ensure cost-effectiveness, especially for non-communicable disease management.

Global Collaborations

Organizations like the World Health organization (WHO) and the Organization for Economic Community

and development (OECD) guidelines are establishing frameworks to guide the development and implementation of AI in health, emphasizing safety, transparency, and equity, particularly for low- and middle-income countries.^[42-43]

Key Principles for Evaluating AI-Driven Interventional Trials

The evolution of artificial intelligence (AI) in the dynamic landscape of medical health care and technologies have introduced dynamics of possibilities in healthcare. By the OECD definition, an AI system is a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment. AI-based tools integration into the healthcare system is on a steady increase, and more submissions for clinical trials using these tools.^[37] In light of this increase, there is also a need to present guidelines for reviewing and approving applications, while ensuring safety, efficiency and observance of ethical rules.

Machine Learning Practice for Medical Device Development

At the core of the approach is the recognition of the unique characteristics of AI-based products, such as: data reliance, algorithmic complexity, and the ability to continuously learn and autonomously update over time. As a result, evaluating these products requires disclosure and transparency of the sources and databases used in its training, training techniques, model limitations, data on past performance and information on existing control pathways.^[42]

Recognizing that not all AI applications are equal in risk or clinical benefit profiles provides a support for an approach that matches the complexity and novelty of the technology being evaluated, and the clinical context in which it will be applied.^[43] The Helsinki Committees exercise discretion in implementing the fundamental ethical principles, in consultation with experts in the field, and to examine the applications that deals with perceived risk and benefit. To identify and classify risks in the Machine learning tool, it is recommended to use the International Medical Device Regulators Forum (IMDRF) documents related to risk management.^[45]

ETHICAL CONSIDERATIONS IN AI PROTOCOL DESIGN

AI protocol design refers to the methodical process of incorporating artificial intelligence technologies into the preparation and execution of clinical trials. This encompasses a range of applications, from improving patient selection to optimizing the operational aspects of trial management. As the landscape of clinical research evolves, the integration of AI not only promises to

accelerate the pace of trials but also aims to enhance the quality of the data collected, ultimately leading to more reliable outcomes.^[11,46] The revolutionary potential of AI in clinical trials comes with significant ethical considerations that must not be overlooked. Balancing innovation with ethical responsibility is paramount to ensuring the integrity and safety of clinical research endeavors. As we navigate this rapidly evolving landscape, it is essential to engage in ongoing dialogue among stakeholders, including ethicists, researchers, and patient advocates, to foster a collaborative approach to ethical AI deployment in healthcare.^[47-49]

Balancing AI Innovation and Patient Safety

As the reliance on AI grows, it is critical that researchers prioritize patient safety. Systems should be designed with robust safeguards, ensuring that AI-driven decisions do not compromise the well-being of participants. This calls for comprehensive testing of AI algorithms and continuous monitoring during trials to mitigate risks. Furthermore, it is essential to involve diverse patient populations in the development and validation of AI systems to ensure that the algorithms are equitable and do not inadvertently perpetuate biases that could affect patient outcomes.^[5-53]

Data Privacy and Security in AI-Driven Research

Data privacy remains a crucial issue, particularly when dealing with sensitive patient information. Researchers must implement stringent security measures and adhere to international regulations to protect personal data.^[50] Clear protocols need to be established for data handling, storage, and sharing to maintain participant trust and comply with legal frameworks. Additionally, the use of anonymization techniques and secure data-sharing platforms can help mitigate risks associated with data breaches.^[51] Engaging patients in discussions about how their data will be used and the measures in place to protect their privacy can further enhance transparency and foster a sense of partnership in the research process.^[52,55]

Consideration of AI Protocol Design

The AI protocol design leverages algorithms that analyze big data to identify patterns and predict outcomes. The goal is to enhance the efficiency and effectiveness of clinical trials by ensuring that the right patients are enrolled while minimizing risks.^[56] Key elements include data analytics, machine learning models, and statistical methods that inform decision-making processes. These technologies can sift through electronic health records, genetic information, and even social determinants of health, providing a comprehensive view of potential participants and their suitability for specific trials. In light of the rapid pace of development of AI technologies, the continues unrevealing of ethical and safety aspects, as well as the development of the international regulatory infrastructure, we consider this document to be an adaptive document subject to updates to address context and specificity of different users.^[52]

Table 5: Focus on Evaluating the AI Protocol Design in Clinical Trials to revolutionize and enhance Research Methodologies. Aspects of AI protocol evaluation consideration.^[51,52]

Number	Question	Significant issues
1	Does the title of the study state that the clinical intervention is based on AI, machine learning or an algorithmic model?	It is important to consider the degree of autonomy/automation of the tool (fully autonomous, partially autonomous or nonautonomous).
2	Does the informed consent form state that the technology being tested in the clinical trial is based on AI?	Make sure that the wording in the informed consent form is in understandable language and that there is a concise explanation of the significance of using AI in the context of the study.
3	What is the version of the model/tool used?	In the intended use/purpose, the following points should be addressed: <ul style="list-style-type: none"> • The medical purpose. • Intended users (clinicians, patients, the general public, etc.).
5	What is the intended use/purpose of the AI tool?	<ul style="list-style-type: none"> • The intended clinical environment. • The role of outcomes in the clinical process. • Mode of use (including the degree of autonomy of the tool). • Characteristics of learning and update of the model (proactive or continuous).
6	What are the inclusion and exclusion criteria at the participant and input data level? What is the reasoning for these criteria? - Do these criteria correspond to the designated population for the tool?	<ul style="list-style-type: none"> • The reasoning for the criteria can relate to the limitations of the model, risk management of bias, etc. <p>The entrepreneur should justify the sample size with the ability to reach statistical significance, and take into account the possible risk to patients.</p>
7	Are there any previous regulatory approvals for the tool?	If there are previous approvals: <ul style="list-style-type: none"> • Do the approvals include the AI component in the product? • Have there been any changes to the product or model since approval? • What is the indication indicated in the certificate?
8	Are there prior information and evidence of intervention using the specific AI tool or other AI tool for the same clinical indication/purpose?	Response required.
9	What is the process of collecting/acquiring input data?	Response required
10	What mechanisms and tools exist to maintain data privacy?	<ul style="list-style-type: none"> • Processes of de-identifying data should be addressed, and cybersecurity principles should be upheld. • If external tools are used for preserving privacy, it is necessary to specify which tools.
11	Is there reference to analyzing the model's performance in subpopulations (e.g., gender, age, ethnicity, etc.)?	It is necessary to consider whether the comparison is made to human best practice, and/or to the accepted professional practice for the clinical procedure.
12	What are the factors to which the AI tool is compared to in the study?	<ul style="list-style-type: none"> • Training process: what data was used and how they were chosen, the algorithm and techniques chosen and the optimization process. • Human involvement: who developed the model, their expertise and their role in the process. • Model evaluation: how the model's

		performance was evaluated (performance on different sets of data/comparison with other models/expert evaluation/other). The training process should be considered with an emphasis on the data sets and their contents, and how they were chosen.
13	How was the model trained?	<ul style="list-style-type: none"> The limitations of the model must be addressed, inter alia, in relation to biases, sub-populations, sensitivities, etc. There is room to attach basic statistics as well. It is important to address, inter alia, who is responsible for examining the performance of the model, and to address performance in subpopulations as applicable.
14	Does the tool require integration with other systems in the clinical environment?	<ul style="list-style-type: none"> It is essential to specify which systems are interacting with the AI tools. If there are specific versions of these systems, this should be noted. Consideration must be given to the structure of the information, the types of information transmitted, the frequency of updating/online updating. In addition, consideration should be given to the level of risk to the ongoing functioning of the systems, including the issue of information security.
15	Is there an interaction between a human and the AI tools in handling the input data? - If so, is a level of expertise required from the participants?	Consideration must be given to the involvement of the human factor in entering the data into the AI system, and the expertise required for this purpose.
16	Is there a program for evaluating and handling poor-quality, inaccessible, or incorrectly entered input data?	Response required
17	Is there a risk management plan to prevent biases in the input data, information discontinuity (problems with availability and flow of information), etc.?	Response required
18	What does the output of the AI intervention look like?	Results should be defined in two ways: model performance, and model and human joint performance.
19	Does the tool have autonomy?	<ul style="list-style-type: none"> How does the degree of autonomy of the tool affect the clinical process? Emphasis should be placed on the form of interpretability and analysis of the output. <p>Whenever possible, a breakdown of the rationale and an explanation of the model's output (explainability) should be incorporated, as well as an indication of the level of security.</p>
20	How does the output contribute to the decision-making process or any other clinical activity?	<ul style="list-style-type: none"> Within the framework of the results of the model, metrics should be defined in various aspects: accuracy relative to the equator, saving time/resources, user satisfaction (medical staff, patients, etc.) and the rate of user intervention in system decisions
21	Is there any reference to reporting substantial changes to the model to the Committee?	Response required
22	What is the training process for the	<ul style="list-style-type: none"> Is there a reference to how usability is tested?

	interface of the AI tools?	<ul style="list-style-type: none"> It is important to indicate whether digital literacy is required on the part of the participants in the experiment.
23	What are the criteria for stopping the experiment?	Emphasis should be placed on these criteria from the perspective of the risk management plan, for example: difficulty in translating the outputs into proper clinical activity, gaps in input data.
24	What are the anticipated point of change in software model	<ul style="list-style-type: none"> Anticipated points for changes in versions of the model (including third-party software used), usage label or research environment should be noted. It should be made clear if these are material changes that will require reconsideration by the institutional committee.
25	How can errors in model performance be identified and analyzed? - How is the risk around these errors managed?	<ul style="list-style-type: none"> The risk of low performance of the model (as well as alarm fatigue) and the responses to these risks should be assessed. Processes should be defined to identify and document errors in the model (for example, discrepancies between the user's decision and the system), processes that will allow recording the performance of the system for reverse investigation (for example, keeping a history of the prediction that performs the model with all the data (snapshot) for investigation or rerun if required.

CONSIDERATION OF RISK IN ARTIFICIAL INTELLIGENCE EVALUATION IN DIGITAL HEALTH TECHNOLOGY CLINICAL RESEARCH

Consideration of risk in AI study evaluation is a critical, ongoing, and multi-dimensional process that has evolved from a voluntary best practice to a regulatory necessity within the framework of the European AI Act. Effective risk evaluation transcends basic accuracy metrics to involve safety, fairness, transparency, and accountability throughout the AI lifecycle.^[14,58]

The core Components of AI Risk Assessment

The core components include a structured risk assessment framework, such as the National Institute of Standard and technology (NIST). AI Risk Management Framework (AI RMF), has developed a framework to better manage risks to individuals, organizations, and society associated with artificial intelligence (AI). The risk is also to identify Map System Context that highlights identified stakeholders, the intended use case, data sources, and potential impact areas.^[34,59]

Identify Risks: Cataloging technical (malfunction, security), ethical (bias, discrimination), and operational risks.

Measure Likelihood and Severity: Assessing the probability of a risk event occurring and the magnitude of its consequences.

Mitigate and Manage: Implementing safeguards such as adversarial training, human-in-the-loop overrides, and regular bias audits.^[34,59]

Key Risk Categories in AI Evaluation

Data Risks: Insufficient data quality, lack of diversity (leading to bias), and training data poisoning. **The Model Risks** which are linked to performance degradation (model drift), adversarial attacks (prompt injection), and lack of interpretability (the "black box" problem). **The Operational Risks** which signal system failures in real-world environments that differ from testing environments. **The Ethical & Legal Risks** that deals with privacy violations, discriminatory outcomes, and non-compliance with regulations.^[34,60]

Risk in AI-Assisted Research

Using AI in research (e.g., literature review, data analysis) introduces unique risks that can jeopardize scientific integrity (CGIAR),

Responsibility Gaps: When AI agents act autonomously, attributing liability for errors or unethical outcomes becomes difficult.

Deskilling: Over-reliance on AI may lead to a loss of critical thinking and foundational skills among researchers.

Unverifiable Knowledge: Advanced AI may produce results (e.g., complex models) that are too difficult for human researchers to verify or understand,

Best Practices for Risk Mitigation

Human-in-the-Loop (HITL): Maintaining human oversight to validate AI outputs and provide override capabilities.

Continuous Monitoring: Since AI systems evolve, risk assessment must be an iterative, continuous process rather than a one-time, pre-deployment task.

Multidisciplinary Teams: Involving data scientists, legal experts, ethicists, and end-users to identify varied perspectives on risk (University of California, Berkeley)

Essential Steps for Evaluating Risk in AI studies

1. *Risk Identification*: Catalog all AI systems, including "shadow" projects, and map stakeholders affected by them.
2. *Risk Analysis*: Assess the likelihood of a threat occurring and the severity of its impact on people, the organization, and society.
3. *Risk Treatment*: Decide whether to avoid, mitigate (apply controls), transfer (through insurance/contracts), or accept the risk based on the organization's tolerance.
4. *Continuous Monitoring*: Since AI systems are dynamic and can learn new behaviors, periodic reassessments are necessary to catch model drift or new vulnerabilities.

THE REVOLUTION IN AI RESEARCH METHODOLOGIES

The shift from traditional methodologies to AI-driven approaches marks a revolutionary change within the clinical research landscape. This transition is not just about the tools but also about redefining the framework within which research is conducted.^[9,61]

Transition from Traditional to AI-Driven Methods

Historically, clinical trials have followed strict protocols dictated by time-consuming manual processes. The introduction of AI techniques has disrupted these norms, allowing researchers to adopt more flexible and adaptive study designs. This new paradigm facilitates real-time data gathering and analysis, enabling responsive adjustments throughout the study period. As a result, researchers are finding new ways to engage with participants, ensure adherence, and monitor outcomes, all while keeping operational costs in check. The flexibility offered by AI approaches could be the catalyst for the next generation of clinical trial methodologies. Moreover, the integration of machine learning algorithms allows for the identification of patterns and trends that were previously overlooked, thus enhancing the predictive power of research findings. This capability not only accelerates the pace of discovery but also ensures that trials are more aligned with the actual needs and responses of participants, creating a more dynamic and responsive research environment.^[24]

The revolution in AI research methodologies represents a shift from traditional, human-driven hypothesis testing to **hybrid systems where artificial intelligence actively partners in data collection, pattern recognition, and scientific discovery**. This paradigm shift leverages machine learning, large-scale data analysis, and automation to enhance research speed, objectivity, and capacity to handle high-dimensional, complex datasets, essentially moving from simple automation to "co-intelligence."

Breakdown of the key elements of this revolution

1. From Data Collection to "Data Generation"

- **AI-Generated Simulations**: Instead of only collecting physical data, AI generates virtual experiments, reducing costs and mitigating ethical risks (e.g., in behavioral psychology).
- **Automated Data Gathering**: Natural language processing (NLP) tools and AI agents harvest, scrape, and label massive datasets from literature or online environments automatically.

2. The Rise of "Hypothesis-Free" Discovery

- **Pattern Recognition in Large Data**: Traditional methods start with a hypothesis. AI enables **data-driven exploration**, where systems identify hidden patterns or anomalies in massive datasets that humans cannot see, forming new hypotheses.
- **Predictive Modeling**: AI models are used to simulate outcomes, allowing researchers to explore numerous variables before running physical experiments.

3. Key Methodological Transformations

- **Automated Experimentation**: AI is integrated with laboratory robotics to run iterative tests, optimize parameters, and analyze results without human intervention.
- **Simulation & Digital Twins**: Creating virtual simulations of complex systems (e.g., climate change models, city traffic, biological systems) to test scenarios safely.
- **Natural Language Processing (NLP)**: Extracting insights from decades of unstructured scientific literature to identify trends or gaps in knowledge.

4. New Research Paradigms

- **Research 5.0 (Hybrid Research)**: A human-AI partnership blending human intuition with digital cognition (hybrid scientist model).
- **AI-Enhanced Qualitative Analysis**: Using AI to analyze emotional patterns, themes, and nuances in massive text or video data.

Science revolution is transforming AI from a specialized tool into a foundational research infrastructure across engineering, physical sciences, health, and social sciences. The summary of impact of traditional methods and AI driven methodologies is outlined in table 6.

Table 6: Summary of Impact of traditional methods and AI driven methodologies.^[35]

Feature	Traditional Methods	AI-Driven Methodologies
Workflow	Linear & Slow	Iterative & Dynamic
Role of Human	Investigator	Curator & Strategist
Data Volume	Small to Medium	Massive (Big Data)
Core Method	Hypothesis Testing	Pattern Detection & Simulation

Future Predictions for AI in Clinical Research

Looking ahead, the landscape of clinical research seems poised for radical transformation facilitated by AI. Predictions suggest an increasing reliance on AI to handle complex data challenges, enabling personalized treatment approaches and facilitating patient-centric trials. Furthermore, as AI technologies evolve, we foresee enhanced collaborations among stakeholders across the research ecosystem, leading to more robust study designs and richer data sets that can improve patient outcomes on a global scale. The potential for AI to streamline the recruitment process is particularly noteworthy; algorithms can analyze vast amounts of data to identify suitable candidates more efficiently than traditional methods. This not only shortens the timeline for trials but also ensures a more diverse participant pool, which is crucial for the generalizability of research findings. As these innovations continue to unfold, the synergy between AI and clinical research is likely to yield breakthroughs that could redefine standards of care and treatment efficacy in the years to come.^[7,8]

Recommendations for Ethics Committees of AI Review consideration

Some general recommendations should be considered to build a solid review process on AI as indicated.

Multidisciplinary Review: This involves data scientists, ethicists, clinicians, and patient representatives in the review process.

AI clinical research Continuous Monitoring: Require ongoing, iterative monitoring rather than a one-time approval, as adaptive algorithms learn and change over time.

Risk-Based Approach: Scientist must apply efforts to classify AI applications based on their risk to participants, with higher scrutiny for diagnostic and therapeutic interventions within our settings.

CONCLUSION

The integration of artificial intelligence (AI) into clinical trials is a great innovative breakthrough in the field of medical and biomedical research. This review explores the major challenges of AI protocol design, its transformative impact on clinical trials, and the ethical and regulatory challenges that associated with this technological advancement. AI holds the future potential in the field of clinical research, enhancing the potential to revolutionize drug discovery and development while exploiting the African rich pharmacopoeia, personalized medicine, and healthcare delivery. There are however, significant challenges and impediments to AI-Driven research such as data quality, bias, interpretability, ethical issues, integration barriers, and regulatory

complexities. Addressing these challenges requires a collaborative effort between researchers, healthcare providers, policymakers, and AI developers. By overcoming these hurdles, AI can become a powerful tool in advancing clinical research and improving patient care in Sub Saharan Africa to meet worldwide competition. As we advance, continuous dialogue among researchers, patients, and regulators will be vital in navigating the complexities of AI in clinical research responsibly for the African sub regions. The National ethics committees need capacity building on procedure and technicalities for evaluating AI-Driven clinical research protocols.

Authors Contribution

This work was carried out in collaboration among all authors. MDN, CNF, EATF conceive the project, ARNB, JF ELF, COE, VPPT did data mining, critical analysis of study. All authors reviewed and approved manuscript for publication.

Disclaimer (Artificial Intelligence)

Author(s) hereby declares that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

ACKNOWLEDGEMENTS

The authors are grateful to all the participants dedicated time to contribute to this review paper. We acknowledge financial and technical support of the project from the laboratory for preclinical animal and pharmacotoxicology research. The Ministry of Higher Education (MINESUP) for modernization grant that funded this study. Accessible documents for the generation of the manuscripts has been gladly acknowledged.

Competing Interests: Authors have declared that no competing interests exist.

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