



Navigating AI Regulation and Innovation In Nigeria's Health and Pharmaceutical Sector



Introduction

Artificial intelligence (AI) is reshaping the global healthcare landscape, enhancing efficiency, diagnostics, and patient outcomes. With Nigeria witnessing a surge in AI-driven healthcare innovations, businesses must navigate an evolving regulatory framework to mitigate legal risks

and harness AI's full potential.

The global AI healthcare market, valued at over \$16 billion in 2022, is projected to reach \$150 billion by 2026. Nigeria's AI healthcare sector is also on an upward trajectory, expected to grow from \$0.01 billion in 2022 to

\$0.13 billion by 2030.¹ As AI adoption accelerates, stakeholders—including hospitals, tech firms, and investors—must align with emerging regulations to safeguard patient data, ensure compliance, and build trust.

AI in Nigerian Healthcare: Key Developments

AI-driven solutions are transforming Nigeria's healthcare sector, from early disease detection to telemedicine and counterfeit drug prevention.

Diagnostics & Disease Detection:

Machine learning algorithms at Lagos University Teaching Hospital now facilitate early breast cancer detection through AI-assisted mammogram analysis.

Telemedicine & Remote Access:

Startups like Wellvis are leveraging AI-powered telemedicine platforms to extend healthcare to underserved communities, while drone delivery services by Zipline have improved medicine distribution.

Combatting

Counterfeit Drugs: AI applications, such as ZMP Inc.'s barcode scanning technology, help verify drug authenticity, reducing the prevalence of fake pharmaceuticals in the market.

These innovations present lucrative opportunities for tech companies and investors. However, the legal and regulatory environment must evolve to support responsible AI deployment.

Legal & Regulatory Considerations for AI in Healthcare

While AI adoption grows, Nigeria's fragmented regulatory framework presents compliance challenges. Key legal considerations include:

1. Data Privacy & Protection

AI-driven healthcare systems require vast amounts of patient data, necessitating stringent compliance with data protection laws:

- The Nigerian Data Protection Act (NDPA) 2023 mandates lawful processing, transparency, and security of patient data.
- Gaps remain concerning AI-driven profiling, data exploitation risks, and algorithmic transparency, therefore ensuring that data is de-identified and securely stored is crucial.

2. Cybersecurity & AI-related Threats

As AI adoption rises, so do cybersecurity threats. The Cybercrime (Prohibition, Prevention, etc.) Amendment Act 2024 provides some legal safeguards, but existing frameworks lack specific provisions addressing AI-driven cyberattacks, such as deepfake fraud and AI-powered phishing schemes.

3. Product Liability & Consumer Protection

AI-powered medical devices and software must adhere to the Federal Competition and Consumer Protection Act (FCCPA) 2018. However, AI-based healthcare solutions do not fit neatly into traditional product liability definitions, creating legal uncertainty regarding accountability in cases of harm or data breaches.

Global AI Regulatory Insights

To navigate regulatory gaps, Nigeria can draw lessons from global AI governance frameworks:

European Union

The European Union Artificial Intelligence Act (EU AI Act), which came into force on 1 August 2024,² establishes a comprehensive regulatory framework for the development, deployment, and use of artificial intelligence systems

within the EU. Central to the Act is a risk-based classification system, which categorizes AI systems into four tiers of risk: unacceptable, high, limited, and minimal. Each category is subject to varying degrees of regulatory oversight,

with high-risk applications—particularly those used in healthcare—subject to the most stringent

requirements.³

Under the AI Act, AI systems employed in medical diagnostics, clinical decision support, patient monitoring, and other health-related functions are deemed high-risk due to their potential impact on human life and well-being.

As such, these systems must comply with a range of obligations, including robust risk management procedures, the use of high-quality and representative datasets, clear documentation and transparency, human oversight, and the assurance of accuracy, reliability, and cybersecurity throughout the system's lifecycle.

In parallel, the

General Data Protection Regulation (GDPR) imposes strict requirements on the processing of health-related personal data, classifying it as sensitive data that warrants enhanced protection. AI systems that process such data must ensure full compliance with GDPR principles, including lawfulness, fairness, transparency, purpose limitation, data minimization, accuracy, and accountability. Additionally, appropriate technical and organizational safeguards must be implemented to protect data subjects' rights and freedoms.

United States

In the United States, an Executive Order was recently issued by President Donald J. Trump to rescind the 2023 Executive Order on “Safe, Secure and Trustworthy Development and Use of Artificial Intelligence”. The rescission of the 2023 Executive Order on AI safety could have significant implications for the global health sector, particularly in the areas of AI-driven medical research, diagnostics, and regulatory

frameworks.

The removal of strict AI governance policies could lead to faster development and deployment of AI-powered medical technologies, such as diagnostic

algorithms, robotic-assisted surgeries, and AI-driven drug discovery. Given this development, pharmaceutical companies are likely to push forward on AI applications in healthcare with fewer regulatory hurdles, leading to more rapid advancements.

This action by the

United States government seeks to strike a balance between regulating artificial intelligence (AI) and fostering innovation, particularly by key private sector stakeholders driving advancements in the field. However, there are legitimate concerns that AI models used in healthcare may lack oversight, potentially leading to biased diagnostics, misinterpretations in patient care, and ethical concerns in AI-driven treatment recommendations.





United Kingdom (UK)

The Medicines and Healthcare products Regulatory Agency (MHRA) oversees the regulation of artificial intelligence as a medical device (AlaMD) in the United Kingdom, ensuring that AI-powered medical technologies meet rigorous safety and performance standards. To support innovation while maintaining regulatory oversight,⁴ the MHRA launched the AI Airlock initiative in May 2024, a regulatory sandbox aimed at assisting manufacturers in

gathering the necessary evidence for product approvals. As part of this pilot program, five AI-driven medical technologies were selected for evaluation, with the initiative set to run until April 2025.⁵

Beyond safety and efficacy, data privacy and protection remain critical considerations for AlaMDs. These aspects are governed separately under the Data Protection Act 2018, which incorporates the principles of the General Data Protection Regulation (GDPR). Manufacturers of AI-

driven medical devices must adhere to these data protection laws to ensure compliance with privacy and security standards.⁶

By refining its regulatory framework and aligning with data protection laws, the MHRA seeks to establish a balanced approach that fosters both public health protection and technological innovation in AI-driven medical solution.

Strategic Considerations for Nigerian Businesses

To ensure the responsible and effective deployment of artificial intelligence (AI) in Nigeria's healthcare sector, stakeholders must adopt comprehensive governance and compliance strategies tailored to the country's legal and regulatory landscape. Nigerian healthcare stakeholders must adopt the following measures:

Develop Comprehensive AI Governance Frameworks:

Organizations must establish robust internal governance structures to ensure that AI deployment in healthcare aligns with global best practices and ethical standards. This may require a clear definition of accountability measures for AI-driven medical decision-making and implementing AI compliance policies that adhere to frameworks such as the World Health Organization (WHO) AI Ethics Guidelines and the EU AI Act.

Strengthen Data Security and Privacy Measures:

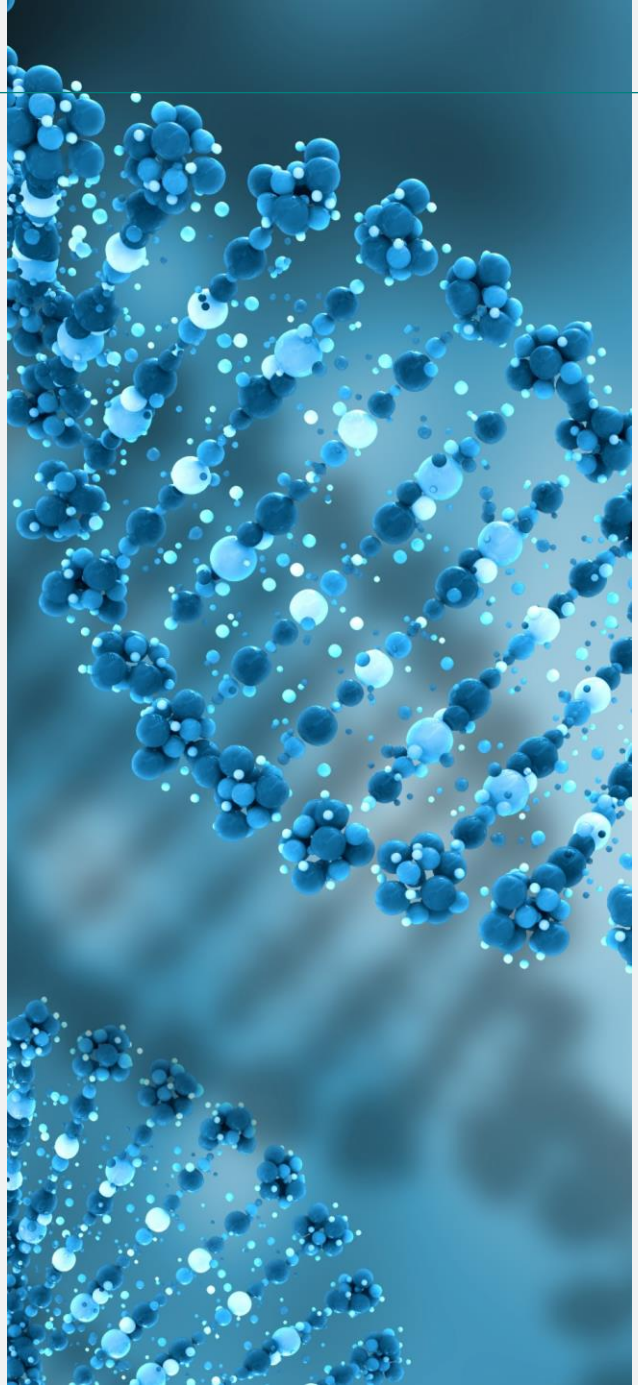
Given the sensitive nature of health data, investing in advanced cybersecurity protocols is critical to protect patient information from breaches, unauthorized access, and cyber threats. Organizations must constantly ensure compliance with the Nigeria Data Protection Act 2023 and other global data protection regulations.

Proactively Engage with Regulators and Policymakers:

To ensure AI applications in healthcare remain compliant and beneficial, organizations should actively collaborate with regulatory bodies, health ministries, and industry associations. This can be achieved by participating in policy discussions and AI regulatory sandboxes to shape practical and effective AI governance frameworks.

Conduct Comprehensive AI Impact and Risk Assessments:

Before deploying AI in healthcare settings, organizations must evaluate potential risks and legal liabilities associated with AI-driven decision-making. This would necessitate conducting bias and fairness audits to ensure AI models do not disproportionately disadvantage certain patient groups. Additionally, it will require a thorough assessment of the reliability and accuracy of AI diagnostic tools through clinical validation studies.



Conclusion

AI presents transformative opportunities for healthcare in Nigeria and globally, but regulatory uncertainties pose

challenges in Nigeria. Learning from international best practices, Nigeria must proactively develop a comprehensive AI

regulation strategy to ensure AI's safe and effective integration into the healthcare industry without hampering innovation.

Endnote

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Authors



Francisca Igboanugo

Team Lead

FranciscaIgboanugo
@strenandblan.com



Emmanuel Ughanze

Associate

Emmanuel Ughanze
@strenandblan.com



Oluchukwu Nwakor

Associate

OluchukwuNwakor
@strenandblan.com



www.strenandblan.com
contact@strenandblan.com
[@strenandblan](https://www.instagram.com/strenandblan)

+234 (0)702 558 0053
3 Theophilus Orji Street, Off Fola Osibo
Road, Lekki Phase 1, Lagos, Nigeria