

Digital Regulatory Pathways for Medical Devices: A Comparative Documentary Analysis of Nigeria's NAPAMS Environment and Germany's EUDAMED-Based Framework

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Abstract

As technical advancements, software-driven healthcare, and international trade broaden the spectrum of products requiring evaluation for safety, efficacy, and post-market responsibility, the regulation of medical devices has grown increasingly intricate. Digital medical devices now encompass independent software, clinical tools based on apps, algorithmic systems, and software integrated with hardware devices, posing challenges to regulatory frameworks initially crafted for more static physical products. This article conducts a qualitative documentary comparative analysis of the regulatory pathways for digital medical devices in Nigeria and Germany, emphasizing the legal and institutional functions of Nigeria's NAPAMS framework and Germany's implementation of the EU MDR-EUDAMED system. The comparison explores aspects such as regulatory authority, the logic of submission and registration, software classification, evidentiary requirements, traceability, and issues related to post-market information management. The primary conclusion is that NAPAMS and EUDAMED should not be considered identical, as they represent distinct regulatory tools: one being a national electronic application management system and the other a supranational lifecycle data infrastructure. Germany's pathway, which is based on EUDAMED, functions within a well-established yet decentralized MDR framework that incorporates notified bodies, risk-based classification, and a six-module database designed to unify actors, devices, certificates, vigilance, and market surveillance. In contrast, Nigeria's digital pathway is more accurately described as a developing national administrative framework that facilitates electronic submissions and modernization but still encounters widespread challenges typical of many LMIC regulatory systems, such as limited specific pathways for medical software, infrastructure limitations, and weaker transparency in post-market activities. The analysis suggests that digital regulatory modernization should be assessed as a comprehensive pathway from submission to lifecycle surveillance, with future reforms focusing on interoperable registries, clearer governance for software, and structured post-market feedback, rather than merely digitizing documents. **Keywords:** medical device regulation; digital medical devices; software as a medical device; Nigeria; Germany; EUDAMED; NAPAMS; post-market surveillance; harmonization; documentary analysis

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Introduction

Regulation of medical devices now occupies a crucial position at the crossroads of patient safety, industrial strategy, digital innovation, and international market oversight.^{31,36,37} Recent studies frequently highlight a regulatory landscape that has become increasingly intricate due to the inclusion of traditional hardware, embedded software, standalone software, networked diagnostic tools, and progressively adaptive AI-driven systems in product portfolios. This growing complexity is significant because regulatory frameworks must address more than just market entry decisions. They are required to assess risk levels, establish evidence criteria, confirm intended applications, ensure traceability, oversee post-launch safety and performance, and uphold public confidence in technologies that are progressively involved in the collection, creation, and distribution of sensitive health information. While older frameworks centered on relatively stable hardware devices provide a valuable base, numerous reviews suggest they do not adequately address the iterative, data-reliant, and frequently updated nature of modern digital medical devices.^{31,35,36}

In Europe, the Medical Device Regulation and associated measures have shifted regulation towards more robust lifecycle management. The MDR has

heightened evidence requirements, further integrated risk-based classification, and made transparency and surveillance core aspects of compliance rather than secondary considerations. EUDAMED exemplifies this transformation as a comprehensive six-module information system that manages registration and surveillance throughout the device lifecycle. Its policy aims focus on enhancing transparency, ensuring traceability, and facilitating coordination among member states. However, the literature indicates that implementing ambitious digital governance is challenging. The complete deployment of EUDAMED has been postponed, its surveillance modules are being introduced gradually, and scholars frequently highlight that high-level ambitions do not negate the challenges of implementation, interpretation discrepancies, or fragmentation among decentralized entities.

Germany stands out in Europe because it doesn't just follow MDR requirements and it's also built its own well-defined digital health pathways and ways to generate evidence. The country has made a name for

itself when it comes to assessing and reimbursing digital medical devices.^{28,30} Just look at the DiGA Fast-Track program: it lets certain lower-risk digital tools be evaluated using real-world data and even provisional evidence. But Germany still has to deal with all the challenges that come with the wider EU system, like the decentralized setup with notified bodies, the stricter rules after software up-classification under Rule 11, and the ongoing struggle to balance innovation with tough compliance standards. Researchers often describe Germany's market as one where digital health companies can succeed, but only if they provide stronger evidence, follow clearer rules, and commit to rigorous monitoring over time.

Germany is a useful case within this European architecture because it combines MDR obligations with nationally visible digital-health pathways and evidence-generation mechanisms.^{28,30} The German policy environment has been prominent in the assessment and reimbursement of digital medical devices, particularly through initiatives such as the DiGA Fast-Track, which explicitly accommodates real-world data and provisional evidence-generation concepts for some lower-risk digital tools.^{20,28} At the same time, Germany is subject to the broader EU system's structural tensions: decentralized oversight through notified bodies, software up-classification under Rule 11, and growing pressure to reconcile innovation with demanding compliance obligations. Several studies describe this as a setting in which digital market access is possible but increasingly dependent on more rigorous evidence, clearer guidance, and stronger lifecycle monitoring.^{18,20,27,30}

Nigeria presents a different but equally policy-relevant context.^{10,31} Although the supplied corpus does not contain a Nigeria-specific operational paper on NAPAMS itself, it provides a strong evidence base on the broader regulatory conditions faced by LMICs that are modernizing device governance. Reviews of LMIC and emerging-market digital regulation show recurring constraints: tailored pathways for medical software are often absent, administrative processes remain too dependent on manual workflows originally designed for physical devices, and legal modernization frequently outpaces data infrastructure and surveillance capacity.^{1,3,8} Emerging systems can make real progress through centralized electronic intake and phased modernization, as comparative work on India's SUGAM platform suggests, but transparency and post-market data accessibility still tend to lag behind front-end submission digitization.^{5,6} For that reason, a comparison between Nigeria's NAPAMS environment and Germany's EUDAMED-based framework should not ask which website is better. The analytically useful question is how each jurisdiction organizes the full pathway linking application handling, regulatory judgment, traceability, and post-market control.^{1,3,7,32}

Medical device regulation has moved from a narrow focus on market entry toward a broader lifecycle governance model that links pre-market review, traceability, post-market surveillance, and public accountability. This shift has become more urgent as device markets now include conventional hardware, embedded software, standalone software, connected diagnostics, and increasingly AI-enabled tools whose performance can depend on data quality, intended use, and post-deployment updates.⁴⁹ Across jurisdictions, regulators are under pressure to ensure that innovation does not outpace safety oversight, especially where older approval models were designed for relatively stable physical products rather than adaptive or software-driven systems.

The policy challenge is not simply whether a country has an online registration portal, but whether its regulatory system can organize a coherent digital pathway from submission and classification to evidence review, identification, vigilance, and corrective action.⁴⁹ Comparative literature from Africa, Europe, and other low- and middle-income settings shows that many regulatory systems still struggle to connect front-end digitization with strong post-market controls, interoperable registries, and technical capacity for software review.⁴¹

Background Context

Digital health innovation has rapidly expanded the scope of what counts as a medical device. Software as a medical device now includes products intended for diagnosis, treatment, mitigation, prevention, and clinical management without being part of a hardware device, creating regulatory questions that do not fit neatly within older hardware-oriented pathways.⁵¹ The same trend is visible in Europe, where regulators have had to respond to software-intensive technologies and to growing demands for stronger clinical evidence, traceability, and transparency across the device lifecycle.⁴⁷

In the European Union, the MDR was introduced to address weaknesses in earlier frameworks, including inconsistent clinical evidence requirements, limited post-market surveillance, and uneven oversight among notified bodies. The MDR therefore increased clinical evidence expectations, strengthened surveillance duties, expanded the role of notified bodies, and embedded traceability tools such as UDI and EUDAMED into the regulatory architecture.⁴⁷

Germany and The EU Pathway

Germany is a useful case for studying this system because it is a major EU market for medical device software and operates within the MDR-EUDAMED structure rather than through a purely national approval model. In one recent analysis of IVDR-approved medical device software, Germany accounted for 38.2% of market placement among listed products, making it the dominant national market in that sample.⁴⁸ EUDAMED is intended to provide public information on devices, manufacturers,

and certificates, while UDI is intended to support device identification through distribution and use.⁴²

At the same time, the European framework is not fully centralized in practice. Higher-risk devices are assessed by notified bodies rather than a single EU regulator, and manufacturers must continuously generate and report clinical and post-market data under the MDR. The formal architecture is therefore comparatively mature, but implementation remains incomplete because EUDAMED rollout has been delayed, reporting practices remain variable, and some critical modules are not yet fully operational.⁵²

Nigeria and Emerging Digital Regulation

Nigeria presents a different regulatory setting, where the key question is not only modernization but also institutional capacity. NAFDAC is the main statutory authority for medical devices, and recent analysis suggests that Nigeria has made progress in strengthening regulation but still faces persistent problems in enforcement, compliance, trained personnel, and alignment with international standards.¹⁰ Nigeria's regulatory environment also appears more focused on import control than on a full lifecycle approach that integrates pre-market assessment, local validation, and strong post-market surveillance.¹⁰

These challenges are consistent with broader African evidence. A scoping review of 39 documents found that regulatory processes in African countries were often characterized by limited pre-market testing, reliance on international certifications, and weak processes for adverse-event monitoring and reporting.⁴¹ More recent comparative work also describes Nigeria as an emerging digital health ecosystem with fragmented records, limited implementation of privacy protections, and no specialized internal sub-units dedicated to evaluating software as a medical device or AI-driven regulatory tools.⁵⁰

Why This Comparison Matters

For that reason, a comparison between Nigeria's NAPAMS environment and Germany's EUDAMED-based framework should not treat the two systems as direct institutional equivalents. EUDAMED is a supranational lifecycle database embedded within a multi-actor MDR conformity and surveillance regime, whereas a national platform such as NAPAMS is better understood as part of a domestic administrative and registration environment. The more useful analytical comparison is therefore between complete regulatory pathways: how each jurisdiction handles classification, evidence, software governance, traceability, and post-market learning.

This distinction matters especially for digital medical devices. Reviews of SaMD oversight in LMICs show that reliance on manual processes designed for physical products creates inconsistent decisions and patient-safety risks, while the absence of dedicated digital health units limits the ability of regulators to assess software, algorithms, and system updates

effectively.⁵⁷ In Europe, by contrast, the challenge is less the absence of regulation than the complexity of coordinating multiple legal frameworks, actors, nomenclatures, and post-market obligations for software-driven products.

Study Rationale

This article therefore examines digital regulatory pathways, not merely digital portals. It compares how Nigeria and Germany structure the movement of medical devices through submission, classification, evidence generation, registration, traceability, and post-market surveillance, with particular attention to software-enabled and digitally regulated products. The goal is to clarify where digitalization supports genuine regulatory strengthening and where it risks remaining limited to document handling without corresponding advances in interoperability, transparency, or lifecycle oversight.⁵

A pathway-based comparison is especially relevant for policy reform. Across African and LMIC settings, harmonization, standardized dossiers, stronger registries, and targeted capacity building are repeatedly identified as priorities for safer and more efficient medical device governance. In the EU context, the same literature shows that transparency, UDI-based traceability, centralized data infrastructures, and structured post-market clinical follow-up are central to the modern regulatory model, even though implementation remains uneven.^{5,13,17}

Methods

This study uses a qualitative documentary comparative design. That approach is appropriate because the relevant evidence concerns legal frameworks, regulator guidance, policy analyses, review articles, and documentary descriptions of digital regulatory systems rather than linked administrative datasets or prospective observational audits. Documentary analysis is common in comparative work on medical-device regulation, especially when the object of study is the structure of regulatory pathways, classification rules, evidence requirements, and post-market obligations. The focus here is comparative interpretation rather than causal estimation.^{11,31,35}

The source base for the manuscript consists of peer-reviewed papers and documentary analyses addressing digital medical devices, software as a medical device, AI-enabled medical-device software, EU MDR implementation, EUDAMED, European digital-health assessment pathways, and regulatory modernization in emerging-market settings. The corpus includes comparative studies of EU and non-EU regulatory frameworks, scoping and narrative reviews of AIaMD and SaMD oversight, and policy analyses of digital-device assessment, reimbursement, and lifecycle governance. Several papers draw explicitly on regulator documentation from the EU, FDA, IMDRF, WHO, and national agencies, which strengthens the documentary basis for comparing legal authority,

evidence expectations, and data-infrastructure design.^{11,13,17}

The comparative framework used in this manuscript examines six analytical domains: institutional authority, submission and registration logic, software classification, evidentiary standards, lifecycle data and traceability, and post-market surveillance.^{11,18,19} These domains recur across the supplied literature and capture the functions most relevant to digital regulation. Institutional authority addresses whether oversight is centralized in a single regulator or distributed across notified bodies and national authorities.^{22,35} Submission and registration logic addresses whether digitization primarily supports administrative intake or broader lifecycle, information integration. Software classification and evidentiary standards matter because digital devices increasingly sit at the edge of traditional risk models and often require additional guidance on intended use, change control, and real-world performance monitoring.^{13,19,22} Germany is analysed as an EU member state operating inside the MDR-EUDAMED environment, while Nigeria is analysed as a national regulator using a domestic digital application environment in an LMIC context. This is not a limitation of design so much as the object of inquiry itself.^{1,5} The purpose is to compare how different legal and institutional architectures solve similar regulatory problems, not to pretend that both jurisdictions rely on equivalent instruments. The analysis is therefore interpretive and synthetic. It does not attempt to measure approval speed, portal usability, staff workload, or manufacturer burden quantitatively because those outcomes are not directly established in the available Nigeria-specific evidence base.^{11,13}

Comparative Analysis

The first major difference between Nigeria's NAPAMS environment and Germany's EUDAMED-based framework lies in the level at which digital regulation is organized.¹ The European model is structurally multi-layered. Oversight of device compliance is decentralized across notified bodies and national authorities, while EUDAMED is designed as a shared supranational data infrastructure that connects multiple lifecycle functions. The EU system is principle-based rather than centrally rule-administered in the FDA sense, and it delegates substantial interpretive work to technical standards, notified bodies, and implementing guidance. Germany operates within this arrangement. Its device pathway is therefore not reducible to a single national submission site. Rather, it is a pathway that links CE-marking logic, decentralized conformity assessment, MDR software rules, national access mechanisms such as DiGA, and the gradual incorporation of data into EUDAMED.^{1,5,13}

A national system such as NAPAMS serves a different function. In emerging-market settings, digital platforms often first appear as centralized intake and administrative management tools used to structure

submission workflows, reduce manual inconsistency, and create a basis for phased modernization.^{1,5} Comparative evidence from other national systems, particularly India's SUGAM and the Bangladesh roadmap, suggests that such platforms can improve the front end of regulation by centralizing oversight and clarifying workflow, but they do not by themselves create mature post-market transparency or robust lifecycle interoperability.^{10,13} In this sense, the most important conceptual distinction is that NAPAMS should be understood as part of a national administrative environment, whereas EUDAMED is a cross-border regulatory infrastructure intended to support a larger legal order.^{5,17}

The second major difference concerns software classification. Europe has moved toward stricter risk positioning of medical-device software under MDR Rule 11.^{18,19} Three years after MDR implementation, the distribution of software classifications shifted markedly away from Class I, with the largest share of entries falling into Class IIa under the new regime. This matters because reclassification expands third-party review, documentation burdens, and the need for notified-body involvement for products that previously sat lower in the risk hierarchy. Additional European literature emphasizes that the guidance supporting practical implementation has not always kept pace with the strictness of the framework, leaving manufacturers, especially software developers, exposed to uncertainty in interpretation and compliance strategy. The burden is especially visible for smaller firms, which may struggle to access MDR-designated notified bodies and may face delays created by the EU's decentralized approval structure.^{18,19}

By contrast, LMIC-oriented papers repeatedly note that many lower-resource systems still lack tailored pathways for software and AI-enabled devices.^{31,32} Manual processes designed for physical devices remain common, and this creates inefficiency, inconsistent decisions, and avoidable patient-safety risk when software products are forced through workflows not designed for them.^{35,36} The absence of tailored software pathways is not merely a technical omission; it shapes what kinds of evidence can be assessed, how change management is handled, and whether intended use can be evaluated in a repeatable way. For a Nigerian digital regulatory environment, this implies that even a functioning electronic portal does not resolve the deeper challenge of software governance unless classification rules, reviewer guidance, and post-market monitoring standards are adapted for SaMD and AIaMD.^{32,36}

The third difference lies in evidentiary philosophy. Germany's broader digital-health environment has experimented with flexible evidence-generation pathways that combine formal clinical studies with real-world data.^{26,27} The DiGA Fast-Track explicitly permits a range of study designs and allows provisional listing based on early evidence plus a

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manufacturer-independent evaluation plan for evidence generation during the first year on the market.^{29,30} Newer methodological work within Europe proposes formal frameworks that integrate interim clinical results with post-launch real-world data, showing how temporary access and final decision-making can be linked statistically rather than treated as disconnected stages. This orientation reflects a broader European debate: digital devices evolve quickly, but regulators still need structured evidence, predefined monitoring, and post-market evaluation that resembles phase IV thinking.^{27,36}

Across jurisdictions, evidence expectations remain heterogeneous, but the recurring themes are clear: change management, versioning, transparency, bias evaluation, cybersecurity, and ongoing performance monitoring are essential for defensible regulation of adaptive systems. Traditional one-time validation is increasingly seen as inadequate for products whose clinical behaviour can shift with software updates, changing datasets, or altered contexts of use. In that respect, Germany's EUDAMED-based pathway has a potential long-term advantage: it sits within a regulatory ecosystem already moving toward explicit lifecycle data infrastructures, even if practical implementation remains incomplete. Nigeria's NAPAMS environment may support intake and file management, but unless it becomes linked to structured post-market information systems, it cannot provide equivalent support for continuous oversight of adaptive digital tools.^{39,40}

Traceability and lifecycle data infrastructure form the fourth major contrast. EUDAMED is intended to function as a central hub for information on devices, manufacturers, certificates, and post-market activities, and this design is directly tied to EU goals of transparency, traceability, and patient safety.^{13,15} The wider literature on digital and software-based devices supports this trajectory. Full-stack governance for digital medical devices requires more than premarket authorization; it requires patient-access infrastructure, evidence management, interoperability, and feedback loops that extend beyond first approval. More general digital-health analyses likewise argue that trust in regulation depends on making it legible to users whether a product is regulated and what evidentiary threshold it has met.^{17,22}

Yet the same European evidence base shows that building such infrastructure is difficult. EUDAMED modules have been phased and delayed, and important functions, especially in vigilance and surveillance, have taken longer than planned because of technical challenges tied to scale and cross-member-state coordination.^{13,16} Studies of diabetes devices in Europe also show that, during transitional periods, actual registration coverage may remain incomplete, with some equipment and software not appearing in EUDAMED because registration is not yet fully mandatory for all relevant categories. This matters for comparison because it shows that even a sophisticated

lifecycle database is not automatically synonymous with full practical visibility. Still, the architecture is explicitly designed for lifecycle integration in a way that national intake systems generally are not.^{23,24}

Comparative Regulatory Features

Domain	Nigeria / NAPAMS Environment	Germany / MDR- EUDAMED Environment
Institutional level	National, centered on NAFDAC and domestic oversight functions	EU plus national, combining MDR obligations, competent authorities, notified bodies, and EUDAMED
Digital role	Electronic submission and administration under a national framework	Multi- module lifecycle database linking actors, devices, certificates, and surveillance
Market-access logic	More dependent on import controls and documentary oversight	CE marking is the main route to the EU single market
Post-market maturity	Underdeveloped reporting and	Stronger formal lifecycle PMS, though implementa

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Domain	Nigeria / NAPAMS Environment	Germany / MDR- EUDAMED Environment
	repository functions	tion remains incomplete
Software readiness	Limited specialized SaMD capacity and fragmented registries	Formal software classification, but stricter Rule 11 burden

Figure 1 Comparative regulatory features of Nigeria's NAPAMS environment and Germany's MDR-EUDAMED pathway.

Results

The comparison showed that Nigeria's NAPAMS environment and Germany's EUDAMED-based framework are not equivalent digital instruments, because NAPAMS is best understood as a national administrative environment for regulatory handling, whereas EUDAMED is a supranational lifecycle database embedded in the MDR architecture for registration, vigilance, and market surveillance.^{1,11} Across the European evidence base, MDR 2017/745 strengthened classification, revised approval processes, and expanded post-marketing oversight, with manufacturers now expected to generate stronger clinical evidence and maintain active post-market systems throughout the device lifecycle.^{16,17} In Germany's broader EU pathway, high-risk devices are expected to carry public safety and clinical summaries and be traceable through UDI-linked recording systems, reflecting a more explicit lifecycle model than a submission-only platform.^{22,23}

The European digital pathway remains only partially realized in practice because EUDAMED delays have limited full unification of reporting, registration, and surveillance. Full implementation has been postponed, some reporting still routes through member-state competent authorities, and parallel national and EU-level obligations have increased rather than reduced administrative burden in the transition period.^{11,13} Reviews of EU regulation also found that delayed database functionality restricts access to clinical evidence and slows the intended strengthening of post-market surveillance and conformity assessment transparency.^{16,23} The current European transition is

therefore best characterized as high formal convergence with incomplete operational integration. The implementation bottlenecks and duplicated obligations across member-state and EU levels are illustrated in a convergence-complexity flow figure. Software regulation emerged as one of the clearest points of divergence. Under MDR Rule 11, European medical device software has shifted sharply upward in risk class, with legacy Class I software frequently reclassified into Class IIa, and about three quarters of legacy German patient apps projected to require Class IIa status by the end of transition.¹³ This reclassification matters because it expands documentation, notified-body involvement, and evidence demands for software developers, while recent survey data indicate that manufacturers experience substantial financial burden, delays, and cancelled launches under the new MDR environment.¹⁶ For software-driven and AI-enabled devices more broadly, post-market systems remain strained by missing data, inconsistent adverse-event reporting, and persistent difficulty tracking software-specific failure modes.^{38,40}

Evidence from African and Nigeria-focused studies showed a different pattern: the dominant constraints are weaker lifecycle governance, reliance on imported devices and external certifications, and limited post-market capacity. Across African countries, post-market surveillance was often described as inadequate, reactive, and weak in field testing, recall mechanisms, and routine inspection capacity.^{6,7} African regulatory systems commonly rely on foreign pre-market evaluations or WHO prequalification, which simplifies import approval but does not fully solve local oversight gaps.^{9,10} Nigeria-specific literature similarly described progress in regulation, but also emphasized that the system remains largely reactive, more focused on import controls than on a full device-lifecycle approach, with underdeveloped post-market surveillance increasing the risk that adverse effects go unreported.^{5,6}

Nigeria nonetheless appears somewhat more visible than many African settings in adverse-event feedback mechanisms. A continent-wide scoping review identified only Tanzania and Nigeria as having reported mechanisms for collecting feedback on adverse events and communicating recall of substandard products, although the same review stressed that overall African feedback systems remain limited.^{6,7} More broadly across eastern, central, and southern Africa, many countries have some post-market controls, but they are uneven in depth and often restricted to inspection, labelling, or advertising rather than comprehensive vigilance and registry-based monitoring.^{9,10}

Post-market surveillance was the strongest cross-cutting theme in both settings. International reviews describe PMS as central to ensuring safety, quality, and performance after market entry, yet also note that PMS remains poorly harmonized and too dependent

on passive or ad hoc reporting in many jurisdictions.^{35,36} In Europe, MDR formally requires proactive manufacturer PMS plans integrating real-world data, trend analysis, and field safety corrective actions, but public-facing implementation remains incomplete because EUDAMED is not fully operational and field safety notices are still fragmented across national competent-authority websites.^{35,36} The fragmentation of field safety notice reporting across countries, and the predominance of electrical and software problems in implantable devices, are shown in a multinational safety-notice dataset.

The study also showed that stronger PMS depends on standardized identifiers, registries, and nomenclature. EUDAMED is intended to operate with common nomenclature and centralized lifecycle information, but incomplete mapping between nomenclatures can weaken traceability and undermine PMS performance.^{6,7} UDI and EUDAMED are widely framed as tools to improve transparency and market traceability, yet European implementation studies repeatedly note that these tools must fit into complex, poorly interoperable information ecosystems.^{15,17} This is the strongest systems-level contrast with Nigeria, where recent scholarship calls instead for creation of a national repository for approved devices, adverse-event reporting, and manufacturer compliance status as a prerequisite for transparency and oversight.^{22,25}

Discussion

Germany's EUDAMED-based framework is not simply "more digital" than Nigeria's NAPAMS environment. It is embedded in a regulatory philosophy that treats traceability, public summaries, UDI, and post-market obligations as parts of a connected lifecycle model.^{10,11} Nigeria's pathway, by contrast, is earlier in the modernization sequence, where digitization improves administration but has not yet matured into integrated surveillance, software-specific oversight, or broad public evidence visibility.^{15,17}

A key implication is that portal digitization alone is insufficient. The attached paper argues that digital modernization should be evaluated as a complete pathway from submission through lifecycle surveillance, not as front-end document handling alone.^{35,36} That view is strongly supported across the wider corpus. The substance-based device PMS platform paper describes active PMCF and passive vigilance as dual pillars of post-market evidence generation. The general PMS review concludes that PMS remains insufficiently harmonized internationally and that conformity assessment is often not managed in a traceable, evidence-based way.^{22,25} The registry commentary likewise argues for coordinated and transparent post-market data collection as a condition for safe and durable access to innovation.^{5,13}

The European evidence also shows that formal sophistication brings trade-offs. The EU system

appears stronger than the Nigerian system in traceability architecture, software classification, and legal articulation of PMS obligations.^{24,25} But it also imposes higher costs, longer timelines, and heavier evidence burdens, especially for digital-health manufacturers and smaller firms.^{19,23} The attached paper already notes that software developers face uncertainty because practical guidance has not fully kept pace with stricter regulation. That claim is echoed by studies of digital manufacturers, implementation reviews, and software-specific analyses that describe delayed rollout, incomplete databases, and uncertain operational pathways as persistent frictions inside the EU framework.^{11,16}

- Europe's advantage is a clearer formal architecture for traceability, UDI, PMS, and public documentation.
- Europe's weakness is incomplete implementation and higher compliance burden during transition.
- Nigeria's advantage is that administrative digitization can be phased and targeted to local needs.
- Nigeria's weakness is institutional incompleteness in surveillance, software oversight, and evidence integration.

The software and AI dimension sharpens this contrast further. The attached paper argues that both systems are stressed by software-driven devices, but for different reasons.^{18,19} In Europe, the problem is not absence of software regulation but the combination of up-classification, ambiguity, and implementation burden.^{25,31} In lower-resource settings, the problem is the absence of tailored software pathways, which forces adaptive products into hardware-era frameworks that inadequately address updates, bias, cybersecurity, and continuous performance monitoring.^{31,32} The AI/ML governance study strengthens this point by showing that even the FDA's central adverse-event system is insufficient for properly assessing the safety and effectiveness of marketed AI/ML device.^{36,37} The implication is that Nigeria cannot safely regulate future digital devices by merely digitizing paperwork, and Europe cannot rely on classification alone without stronger operational data flows.^{38,40}

Post-market evidence is where the comparison converges most strongly. That is well supported by the field safety notice study, which shows that FSNs remain essential but are difficult for clinicians to interpret because reporting practices vary and centralized access is lacking while EUDAMED remains delayed.^{13,16} The same study found that among 121 unique FSNs from 20 countries, the most frequent problem classes were electrical/electronic issues and manufacturing problems, with many "no apparent event" notices later reclassified into electrical and software issues.²² The broader empirical PMS study similarly finds that software-driven devices exhibit persistent issues despite corrective actions and

therefore require differentiated regulatory approaches.²⁵

For Nigeria, the main issue is less over-complexity than institutional incompleteness. The African evidence base consistently identifies inadequate funding, limited technical expertise, reactive reporting, and weak recall and testing capacity as structural barriers to effective device oversight.^{16,23} Nigeria-specific work adds that imported-device dependence and insufficient local validation can leave international approvals poorly matched to local infrastructural and environmental realities.^{10,18} That makes simple imitation of the EU model less useful than context-sensitive harmonization built around feasible surveillance functions, trained personnel, and national repositories.^{6,9}

A further implication is that software and AI devices expose weaknesses in both systems, though in different ways. In Europe, Rule 11 and AI-related ambiguity have tightened oversight but also increased uncertainty, cost, and the need for clearer guidance for clinicians and developers.^{10,18} In lower-resource settings, the absence of tailored software pathways means that digital tools risk being processed through frameworks designed for conventional hardware, which limits appropriate evaluation of updates, bias, cybersecurity, and real-world performance.^{35,36} Across both settings, the literature points toward the same destination: continuous, data-linked, and clinically interpretable post-market oversight rather than one-time approval alone.^{1,2,6}

Conclusion

Nigeria's NAPAMS environment and Germany's EUDAMED-based framework represent different stages and scales of digital medical-device regulation. The evidence supports describing Germany's pathway as a partially implemented lifecycle-governance system with stronger traceability, software classification, and post-market architecture, while Nigeria's pathway remains more administrative and reactive, with its main gaps in surveillance capacity, local validation, and integrated device information systems.^{25,35}

The main comparative lesson is that digitizing submissions is not enough. Effective digital regulation requires interoperable registries, standardized nomenclature, clearer software rules, and active post-market data flows that can detect safety signals early and support corrective action across the device lifecycle.^{17,18} For this Nigeria-Germany comparison, the literature therefore supports a conclusion of asymmetric convergence: Nigeria can learn from the EU model's emphasis on traceability and lifecycle surveillance, but the more realistic policy path is phased, context-sensitive strengthening rather than direct institutional transplantation.^{13,15}

The documentary comparison shows that Nigeria's NAPAMS environment and Germany's EUDAMED-based framework operate at different institutional levels and perform different regulatory functions.^{1,5}

The attached paper states that the European model is structurally multi-layered, with device oversight distributed across notified bodies and national authorities while EUDAMED serves as a shared supranational infrastructure linking registration and surveillance functions.^{10,13} It also states that NAPAMS is better understood as part of a national administrative environment, where digitalization primarily supports electronic intake, workflow structuring, and phased modernization rather than full lifecycle interoperability.^{11,17} This distinction is consistent with the broader literature on emerging-market regulatory digitization, which shows that centralized digital portals can improve front-end submission management without automatically delivering mature post-market transparency or integrated vigilance systems.^{1,5}

The European side of the comparison is defined by the MDR's shift toward lifecycle governance. The attached paper reports that MDR tightened evidence expectations, deepened risk-based classification, and repositioned transparency and surveillance as central features of compliance.^{30,35} Supporting studies describe MDR 2017/745 as having revised approval processes and post-marketing evaluation, with manufacturers now expected to provide sufficient clinical evidence and maintain active systems for benefit-risk confirmation after market entry.^{15,16} In high-risk fields, the EU framework also requires public clinical documentation and device traceability through the Summary of Safety and Clinical Performance and Unique Device Identification systems.^{19,20} The attached paper therefore characterizes Germany's pathway not as a single submission site, but as a combination of CE-marking logic, decentralized conformity assessment, software rules under MDR, national access routes such as DiGA, and gradual incorporation into EUDAMED.^{25,26}

A major empirical result concerns software classification. The attached paper identifies MDR Rule 11 as one of the clearest points of divergence between the European and Nigerian contexts.¹⁹ The supporting Rule 11 study reports that legacy software classified mostly as Class I under the MDD shifted under MDR so that the largest share of entries became Class IIa, with 55% of entries in Class IIa and only a narrow residual Class I space.²⁵ The same study projects that roughly three quarters of legacy German patient apps will require reclassification to Class IIa by the end of the transition period.¹⁹ The attached manuscript correctly interprets this shift as materially important because reclassification expands third-party review, documentation burdens, and notified-body dependence for software developers. Survey evidence from digital-health manufacturers supports that interpretation, finding that 88.6% of respondents reported a significant or severe financial burden, 23.1% cancelled planned launches, and 34.8%

discontinued existing products under the new MDR environment.²⁵

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