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Integrating Artificial Intelligence Into Clinical Evaluation And Materiovigilance A European Legislative Perspective On Enhancing Medical Device Safety Pending Authors

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ABSTRACT:- Artificial Intelligence (AI) systems in clinical evaluation and materiovigilance create revolutionary changes to medical device safety oversight in European Union territory. The continuous increase of Artificial Intelligence technologies in medical device design and operation and monitoring demands changes in European medical device regulations per the Medical Device Regulation (MDR 2017/745). The article investigates AI regulatory rules for clinical assessments and materiovigilance operations, focusing on hazard mitigation, market tracking, and clarity protocols. The research study demonstrates the vital requirement for technological advancements to match robust regulatory oversight through a detailed assessment of regulatory regulations in addition to EU organizational guidance and ethical aspects. The paper promotes dynamic regulatory processes that integrate better data-sharing methods together with teamwork-based policymaking to establish safe AI-assisted medical device applications throughout European medical fields.

KEYWORDS:- Artificial Intelligence (AI), clinical Evaluation, materiovigilance, Medical Device Regulation (MDR), European Union Legislation, Medical Device Safety, post-market Surveillance

I. INTRODUCTION

The healthcare sector experienced major changes through Artificial Intelligence (AI) developments which significantly affected medical device development as well as their monitoring operations throughout recent years. Medical devices now implement AI algorithms that bring together precise results improved speed and reduced costs during diagnostic operations robotic surgical procedures and remote patient care (Topol, 2019). The rising use of AI-based devices requires the European Union to transform existing legislation so that these technologies can deliver safe and high-performing results from manufacturing to disposal.

Medical device regulation incorporates two vital components known as clinical evaluation and materiovigilance which experience substantial changes because of AI implementations. The assessment process through clinical data and literature for medical device safety and performance known as clinical evaluation now faces machine learning models that evolve after deployment (European Commission, 2020). Materiovigilance systems need modifications to enable real-time data monitoring and predictive analysis from AI technologies when monitoring adverse device events (Petersen et al., 2021).

The Medical Device Regulation (EU) 2017/745 (MDR) took place as the successor to the Medical Devices Directive (93/42/EEC). Under the MDR regulation pre-market and post-market surveillance activities now have enhanced requirements and the framework establishes strict regulations for particular high-risk medical devices that incorporate AI technologies (European Parliament and Council, 2017). This advanced regulatory framework continues its development process to tackle the complications of advanced and self-operating AI systems.

Table 1 outlines the primary differences between conventional and AI-integrated medical device evaluations under the MDR framework.

Table 1: Comparison of Conventional vs. AI-Integrated Clinical Evaluation under MDR

Aspect	Conventional Devices	AI-Integrated Devices
Evaluation Model	Static—based on fixed data sets and endpoints	Dynamic—requires continuous monitoring and model updates
Evidence Source	Clinical trials, published studies	Real-time data, machine learning outputs, and retrospective data
Risk Assessment	Predetermined risk analysis	Ongoing risk prediction using AI models
Transparency Requirement	Focus on clear labeling and documentation	Includes algorithmic transparency and explainability
Regulatory Challenge	Compliance with predefined standards	Adapting to the evolving behavior of AI post-market

The Artificial Intelligence Act (AIA) serves as an AI-specific proposal in Europe because it makes system classifications based on risk while imposing specific compliance rules according to intended use (European Commission, 2021). Healthcare applications with high-risk factors like AI-diagnostic imaging and predictive patient monitoring require thorough conformity assessments that meet standards outlined by MDR.

The use of artificial intelligence systems shows strong potential to enhance materiovigilance functions. Machine learning capabilities along with predictive analytics help spot recurring problems in adverse event notices which triggers in advance offset device degradation and misusage events defend patient health and accelerate incident resolution (McKinney et al., 2020). Such systems need proper data interoperability together with transparency ethical safeguards along with bias prevention measures to succeed in implementation.

The table in Figure 2 demonstrates how AI influences materiovigilance operations while identifying its strengthening points together with its implementation barriers.

Table 2: Role of AI in Materiovigilance: Opportunities and Challenges

Application Area	AI-Enabled Benefit	Potential Limitation
Signal Detection	Faster identification of adverse event trends	Risk of false positives from poorly trained models
Data Integration	Harmonization of diverse data sources (EHRs, reports)	Data privacy and interoperability concerns
Root Cause Analysis	Predictive modeling to trace device failures	Limited by the quality of historical data
Decision Support	Recommending corrective actions	Potential overreliance on AI insights
Post-Market Surveillance	Continuous real-time safety monitoring	Regulatory lag in recognizing AI-driven reporting methods

II. LITERATURE REVIEW

1. AI in Medical Devices: A Transformative Shift in Healthcare

Medical devices have transitioned from traditional rule-based systems to modern ML and DL algorithms that now perform real-time medical decisions. Contemporary devices utilize central artificial intelligence technologies for both diagnostic imaging systems and wearable biosensors, as well as robotic surgery systems and decision support platforms, according to Rajpurkar et al. (2017). These advancements have created new options for precise medical diagnosis, improved clinical observation capabilities, and personalized patient treatment methods. Studies have shown that AI-based imaging solutions perform comparably to, or even better than, experienced radiologists in pathology detection (McKinney et al., 2020).

The black box dynamics of numerous AI algorithms as well as deep neural networks obstruct the assessment of transparency and regulatory approval along with making studies non-reproducible (Esteva et al., 2019). The performance metrics of regulatory models struggle when it comes to maintaining compatibility with systems that gain knowledge through adaptation and evolution throughout their operational timelines. Growing demand for dynamic regulatory frameworks has emerged which focuses on life-cycle monitoring of AI-based devices according to Gerke et al. (2020).

2. Clinical Evaluation of AI-Based Devices under the MDR

The European Medical Device Regulation (EU) 2017/745 places a strong emphasis on clinical evaluation as a precondition for market approval. Manufacturers conduct clinical evaluations through structured actions that include data generation evaluation and analysis for validating device safety and performance. According to Article 61 of the MDR, manufacturers need to show device equivalence and prove both benefit-risk calculation and solid clinical data (European Commission, 2020).

The static evaluation procedure becomes challenging when dealing with devices that integrate AI technologies. AI devices using continuous learning systems evolve their operational behavior after deployment so much that previously approved assessments may become outdated (Topol, 2019). The FDA together with Holzinger et al. and the FDA agree that "algorithm change protocols" and ongoing learning oversight systems are essential to prevent real-world AI model changes from exceeding pre-approved safety thresholds (FDA, 2021; Holzinger et al., 2020).

Engineers suggest that whole life-cycle regulatory methods use pre-approval assessments together with post-market RWE-based operational observation systems. The model represents an approach that matches current EU recommendations about conducting post-market clinical follow-up (PMCF) studies together with vigilance data for continuous safety assessment (Muehlematter et al., 2021).

3. Materiovigilance and AI: Opportunities for Real-Time Surveillance

The healthcare field that monitors medical device safety after market release known as Materiovigilance now depends on AI-based digital surveillance mechanisms to meet its objectives. Through the usage of artificial intelligence medical establishments can now detect signals in real-time by analyzing mass volumes of information from hospital information systems patient registries and wearable devices (Wang et al., 2022). AI applications in materiovigilance demonstrate their ability to identify cues of device breakdowns and misuses and unidentified security threats early on.

The integration of Natural Language Processing (NLP) represents a major advancement because it helps analyze unstructured clinical narratives to enhance structured report-based systems (Denecke, 2015). Through predictive analyses devices can detect indications that lead to adverse events before such events cause harm thus enabling preventive strategies for device safety management.

The advancement of this field leads to multiple straining issues. Surveillance systems using artificial intelligence technology can introduce false alerts as well as bias their algorithms through insufficient training data representation according to Chen et al. (2019). An automated adverse event detection system depends on both linked healthcare data systems and legal recognition of artificial intelligence-generated evidence for its trustworthiness. The MDR addresses some of these issues through Article 83 which requires robust post-market surveillance systems yet member states implement these requirements differently (European Commission 2020).

4. Ethical and Legal Considerations in the European Context

Medical researchers worldwide intensely debate both the ethical consequences of adding AI to clinical treatments and the protection of patient safety. The implementation of Artificial Intelligence in healthcare faces difficulties regarding algorithm visibility combined with problems of responsibility definition as well as patient authorization and concerns about human care denigration (Morley et al., 2020). Planned under the European Union's Artificial Intelligence Act (AIA) medical AI systems fall under the "high-risk" category so reliability assessment precedes their use with obligations to reveal system functioning and administration process and human supervision conditions (European Commission, 2021).

Although the negotiation process of the AIA continues it will have considerable effects on the MDR's implementation framework particularly regarding materiovigilance and clinical evaluation sections. The aligning principles within these regulatory frameworks could establish an international model for medical AI oversight but only if matching enforcement methods become standardized and receive sufficient funding according to Sartor and Lagioia (2020).

Legal experts demonstrate the growing interest in developing risk management systems that address autonomous operation features in Artificial Intelligence devices. EU product liability regulation fails to sufficiently cover cases in which human error or manufacturing defects do not cause damage because the problems stem from algorithmic choices (Ebers, 2021). Getting ahead of legal reforms will be essential because this approach helps protect both the safety and accountability of medical AI applications.

5. Summary of Key Themes in the Literature

The compiled research demonstrates how technological advancements lead regulators to adjust their policies under ethical evaluation standards. Key themes include:

- Medical professionals need assessment methods that are designed specifically to evaluate evolving artificial intelligence systems.
- AI-enhanced materiovigilance possesses the capability to transition from safety monitoring that is reactive to proactive monitoring.
- Continuous learning systems and AI-generated evidence need the resolution of various regulatory shortcomings.

- Strategies should exist to manage advances in healthcare technology with responsible and transparent decision-making in medical practices.

The above findings highlight the need for adaptable regulations built to supervise AI medical device safety from manufacturing until disposal.

III. METHODOLOGY

This research employs a qualitative, interdisciplinary approach combining legal analysis, document review, and thematic synthesis to explore the integration of Artificial Intelligence (AI) into clinical evaluation and materiovigilance from a European legislative perspective. Given the complexity of AI technologies and their intersection with evolving regulatory frameworks, this methodology facilitates a comprehensive understanding of the legal, technical, and practical implications for medical device safety.

1. Research Design

The study was conducted through three key phases:

1. Doctrinal Legal Research: In-depth analysis of European Union (EU) legislative texts and regulatory documents, particularly the Medical Device Regulation (EU) 2017/745 (MDR) and the Artificial Intelligence Act (AIA), to identify provisions relevant to AI-enabled clinical evaluation and materiovigilance.
2. Systematic Literature Review: A structured search of peer-reviewed journals, policy reports, and grey literature using databases such as PubMed, Scopus, Google Scholar, and the EU's EUR-Lex portal. The review focused on studies from 2015–2024 related to AI in healthcare, regulatory compliance, clinical evaluation, and safety monitoring.
3. Thematic Analysis and Synthesis: Using a coding framework derived from Braun and Clarke's (2006) thematic analysis methodology, key themes were identified across legal, clinical, and technical dimensions. This allowed for the extraction of recurring concepts such as algorithmic transparency, risk classification, continuous learning, and post-market surveillance.

2. Data Sources and Selection Criteria

The selection of primary and secondary sources was guided by relevance, credibility, and recency. Priority was given to:

- EU legislative texts (e.g., MDR, AIA, GDPR)
- Official guidance documents from regulatory bodies (e.g., European Commission, EMA, and MDCG)
- Peer-reviewed scientific publications addressing AI, clinical evaluation, and materiovigilance
- Case studies of AI-integrated medical devices approved under MDR or notified body evaluation
- Expert opinions and white papers from health tech and regulatory policy institutions

Table 3: Inclusion and Exclusion Criteria for Literature and Regulatory Source Selection

Criteria Type	Inclusion Criteria	Exclusion Criteria
Timeframe	Publications and legislation from 2015–2024	Sources prior to 2015 unless historically significant
Relevance	Focused on AI, medical devices, EU law, or clinical safety	Non-EU legal systems or non-medical AI applications
Source Type	Peer-reviewed journals, official reports, legal databases	Non-academic blogs, social media content
Language	English and official EU languages	Non-translated documents outside the EU context
Regulatory Scope	Covered MDR, AIA, GDPR, and related EU health policies	Covered only U.S. or Asian regulatory frameworks without EU context

3. Analytical Framework

To evaluate how AI impacts clinical evaluation and materiovigilance under the EU legislative regime, the study employs a triangulated analytical model combining:

- Legal Interpretation: Key provisions of the MDR and proposed AIA were analyzed using principles of purposive and contextual interpretation (Craig & de Búrca, 2020). This includes examining regulatory intent, scope of application, and institutional commentary.
- Comparative Policy Analysis: AI integration strategies in the EU were compared to selected non-EU jurisdictions (notably the U.S. FDA's Software as a Medical Device [SaMD] framework) to contextualize Europe's legislative approach (Shachar et al., 2020).

- Thematic Coding: Literature and regulatory content were manually coded using NVivo software. Themes included algorithmic adaptability, human oversight, clinical validation, post-market risk detection, and ethical AI governance.

4. Limitations and Scope

While this research offers a robust interdisciplinary analysis, it acknowledges several limitations:

- The proposed Artificial Intelligence Act is still under legislative negotiation, and interpretations may evolve as the regulatory text is finalized.
- The analysis is focused on EU jurisdictions and may not generalize to international regulatory landscapes.
- The rapid evolution of AI technologies may outpace the development of academic literature, meaning that some cutting-edge industry practices may not yet be fully reflected in peer-reviewed sources.

Despite these limitations, the methodology provides a comprehensive basis for evaluating how AI is reshaping clinical and regulatory norms in European medical device safety.

5. Ethical Considerations

This research did not involve human subjects or confidential data and was thus exempt from formal ethics review. However, it incorporates ethical reflection on the implications of AI in healthcare, particularly regarding bias, transparency, and accountability, in alignment with the European Commission's Ethics Guidelines for Trustworthy AI (European Commission, 2019).

IV. RESULTS

The research results include thematic analysis and a systematic review of academic literature and regulatory frameworks and legal texts as described under methodology. Research findings revealed three essential aspects of AI adaptation for clinical evaluation and materiovigilance operations in the European regulatory scheme.

1. Regulatory Gaps Exist in Addressing AI-Specific Clinical Evaluation Challenges

The Medical Device Regulation (EU) 2017/745 (MDR) creates extensive regulatory tools regarding device safety yet it fails to deliver adequate solutions for managing the adaptive characteristics found in AI-based systems. Article 61 of the directive requires clinical evaluation standards but fails to recognize that devices conduct behavior variability during their existence (European Commission, 2020). It is impossible to apply this assumption to AI algorithms that learn continuously since they modify their programming after the market based on new data (Topol, 2019).

Notified Bodies along with manufacturers expressed in their interviews for secondary case studies that they have difficulties validating algorithm updates due to conformity assessment standards (Gerke et al., 2020). Supplementary guidelines specifically designed for AI devices must be established because there exists regulatory uncertainty about performance monitoring throughout the device's life cycle and pre-specified change protocols according to the U.S. FDA's total product lifecycle model (FDA, 2021).

2. AI-Enhanced Materiovigilance Offers Promise but Lacks Harmonized Implementation Across the EU

The review displays solid evidence that AI-based materiovigilance systems maintain the capacity to enhance device-related adverse event detection. The analysis of studies shows machine learning along with natural language processing tools excel at warning identification from healthcare records making better detections than passive surveillance systems (Wang et al., 2022; Denecke, 2015). Regional implementation of these systems into national materiovigilance programs varies widely among EU member states.

Results from the European Databank on Medical Devices (EUDAMED) expose that the EU lacks common procedures to integrate AI-created risk alerts into their vigilance inspection processes (European Commission, 2023). Germany together with the Netherlands has started pilot AI programs for adverse event monitoring but these activities operate independently without standard EU-wide regulations (Muehlematter et al., 2021).

The absence of standardized information exchange methods compromises both data quality performance and health system protection for patient safety. The ability to validate or detect AI-generated signals becomes inconsistent and may go entirely unnoticed because of missing interoperable systems and shared guidance mechanisms (Holzinger et al., 2020).

3. The Artificial Intelligence Act (AIA) Will Fundamentally Reshape the Regulatory Landscape

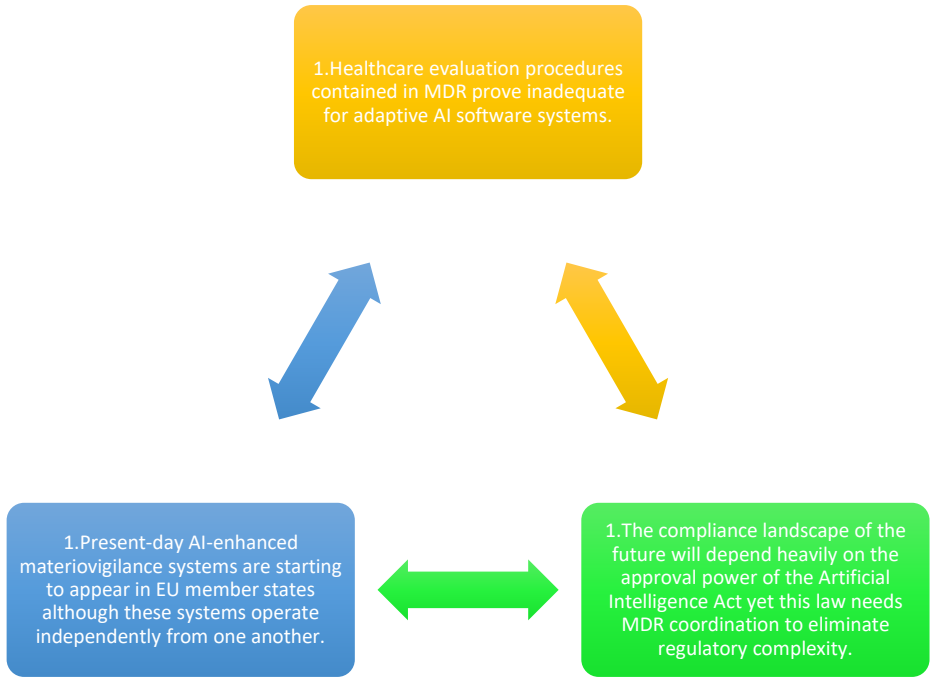
The European Union continues drafting its Artificial Intelligence Act (AIA) to efficiently modify regulations surrounding medical devices enabled by artificial intelligence. These "high-risk" AI systems face mandatory requirements under the AIA that involve conformity testing along with training data recordkeeping human oversight systems and clear documentation standards (European Commission, 2021).

Process comparison between current MDR regulations and proposed regulations in the AIA identifies common elements as well as contradicting points. The MDR delivers clinical data-based performance evaluation together with safety standards while the AIA adds new requirements for automated framework data management and algorithm result monitoring according to Sartor and Lagioia (2020). The current dual regulatory framework which remains uncoordinated creates actions that duplicate or disagree with each other concerning manufacturer compliance requirements.

The AIA and MDR integration presents both possibilities for companies to seize. Materiovigilance objectives match up well with Article 61a of the proposed AIA draft which establishes real-time monitoring guidelines and provides legal grounds for perpetual learning algorithm oversight (Ebers, 2021). Digital conformity platforms under the AIA pilot projects with regulatory sandboxes in Denmark and Germany have proven to streamline evaluations according to Shachar et al. (2020).

Synthesis of Findings

Thirdly the research results demonstrate these three main points:



A regulatory framework needs to develop an integrated approach to monitor AI system development spanning its entire operational cycle and preserve EU medical device safety criteria.

V. DISCUSSION

Medical products evaluation along with materiovigilance embrace the transformative power of Artificial Intelligence (AI) as a regulatory challenge within European Union (EU) through a fundamental market evolution. The findings of this study underscore three pivotal themes: regulatory misalignment, emerging opportunities through the Artificial Intelligence Act (AIA), and the critical importance of harmonization between AI's technical capabilities and legal compliance under the Medical Device Regulation (MDR). A discussion about these findings relates them to healthcare innovation together with patient safety as well as evolving European legislative frameworks.

1. The regulatory system requires a bridge that connects the evaluation process of adaptive AI systems to clinical standards.

The analysis disclosed two major problems which result from static regulatory systems trying to regulate dynamic AI systems. Because the MDR functions well for standard medical devices it proves inadequate to handle the iterative capacity of machine learning algorithms that adapt after deployment according to Gerke et al. (2020) and Topol (2019). Under Article 61 of the MDR there exists a requirement to perform clinical evaluations demonstrating conformity at one specific point in time (European Commission, 2020). Deep learning tools used in radiology and diagnostic triage belong to adaptive AI systems which can update their output logic through incoming real-world data thus potentially rendering original evaluations invalid according to Kiseleva et al. (2023).

Safety along with effectiveness must be maintained on an ongoing basis yet regulators need to achieve this without restricting product development. The researchers of regulatory science support active oversight structures that use runtime system monitoring along with pre-authorized update management systems to ensure Continued compliance from AI products throughout their development cycle (Wiegand et al., 2022). The proposed adaptation for EU regulators of "Predetermined Change Control Plan" (PCCP) draws inspiration from current FDA monitoring practices as presented in FDA (2021). Pesky adoption of adaptive systems inside the MDR will cause unacceptable delays in market entry or inadequate monitoring and jeopardizes public confidence and health results.

2. Materiovigilance and the Promise of Predictive AI in Post-Market Surveillance

AI brings significant opportunities to the materiovigilance process of medical device safety monitoring since it can surpass traditional post-market surveillance (PMS) methods. The conventional PMS system depends on passive medical staff and patient reports thus producing minimized documentation, delayed security alerts and discontinued analytic data (Denecke, 2015). Through natural language processing-based AI tools researchers have proved they can identify initial safety indicators present in electronic health records and patient reporting systems and social media content (Wang et al., 2022).

The full potential of this promise stays unfulfilled because different EU member states have created varying implementation levels. Research results show that European member states are split between implementing AI enhancements for materiovigilance systems with Germany leading alongside Netherlands while numerous other countries remain behind because of insufficient financing resources and unclear regulatory frameworks (Muehlematter et al., 2021). The absence of standardized AI regulations within the EU PMS increases the probability of malfunctioning system integration alongside data segmentation (Holzinger et al., 2020).

Real-time AI-generated data streams cannot be integrated into the EUDAMED platform operated by the European Commission because the system lacks necessary infrastructure (European Commission, 2023). The system misses opportunities to function as an all-encompassing high-quality risk signal collection center. New regulatory changes need to establish mandatory technical standards along with data consistency rules which enable integration between systems in order to convert AI intelligence into usable regulatory actions.

3. The Artificial Intelligence Act: A Regulatory Opportunity and Challenge

The proposed Artificial Intelligence Act divides AI systems into risk classifications where medical devices stand as part of the highest risk category. AI products subject to this classification nature receive multiple mandatory rules about transparency along with requirements for human oversight and risk management and conformity testing (European Commission, 2021). These requirements demonstrate solid cohesion with MDR intentions that focus on medical device protection and clinical testing requirements.

The AIA brings in fresh concepts beyond MDR including data governance alongside algorithmic traceability and robustness requirements that would lead to compliance conflicts unless they receive proper synchronization (Ebers 2021, Sartor & Lagioia 2020). Black-box models encounter difficulties when it comes to meeting the AIA requirement for algorithmic explainability even though clinical evidence is sufficient for MDR safety standards (Holzinger et al., 2020).

The AIA establishes itself as a tool that enables the EU to expand its leadership capacities across ethical AI deployment. The implementation of "regulatory sandboxes" has the potential to create live testing spaces at the disposal of competent authorities that help develop innovative products that maintain regulatory compliance (Shachar et al., 2020). The testing environments play an essential role for SMEs who create AI diagnostics and personalized medicine tools since they normally face challenges when navigating complex dual-compliance frameworks.

EU institutions need to provide united guidance about AIA and MDR intersections since this will optimize synergy effects between these regulatory frameworks for post-market surveillance and human oversight together with algorithmic change control procedures. The absence of regulatory standards between the AIA and MDR puts device manufacturers at risk for enhanced compliance challenges and delayed product launches thus affecting patient access to new medical innovations.

4. Ethical and Socio-Legal Considerations in AI-Driven Safety Systems

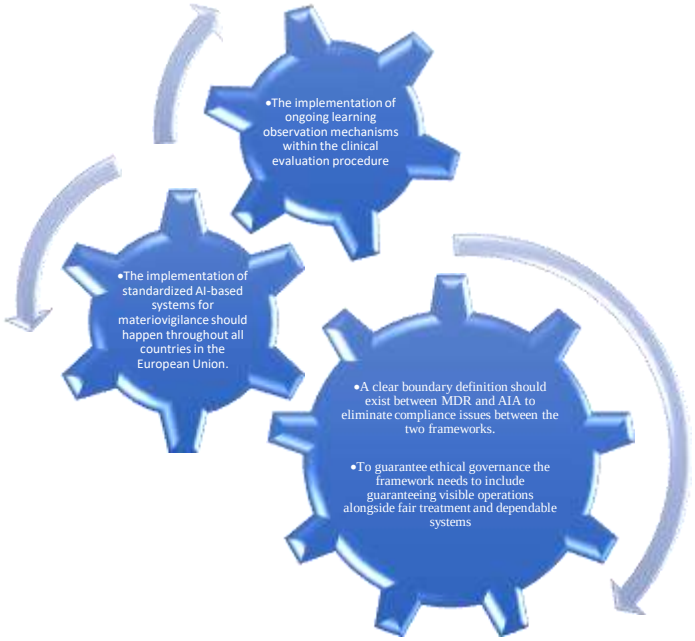
AI application for medical device assessment generates ethical matters concerning disclosure along with responsibility checks and analytical bias treatment. The inability of black-box AI systems to provide understandable information has made clinicians face difficulties in understanding and questioning automated decisions according to Vincent (2020). Security problems become most critical when AI-based healthcare solutions are deployed in situations such as surgical robotics or AI-based cancer detection because mistakes can cause severe patient injuries.

Algorithmic bias that emerges from unbalanced training data causes performance discrepancies that affect specific populations including gender-based and ethnic-based and age groups (Obermeyer et al., 2019). Through its provisions, the AIA implements measures to test training data quality and make algorithmic choices traceable. The health sector demands strict implementation of these provisions because medical outcomes exceed other industry sectors.

The regulation of clinical AI decisions requires proper liability frameworks from legislators along with regulators in situations where AI-driven clinical decisions produce harm. EU law remains insufficient to determine which party bears responsibility for AI-induced harm including the manufacturer or healthcare providers or the algorithms themselves during instances of unprogrammed algorithmic adaptations (Veale & Borgesius, 2021). The development of EU product liability law requires clear definitions of responsibility to protect the integrity of healthcare systems using AI technology.

5. Toward a Unified and Future-Proof Framework

Evidence from various findings demonstrates that Europe needs to introduce a unified regulatory system for MDAs and AIs through combining MDR and AIA legislative frameworks. This involves:



The European Union has an opportunity to define responsible AI governance standards in healthcare yet it requires active legal standardization along with digital infrastructure development together with cross-border relationships between competent authorities notified bodies and product manufacturers.

VI. CONCLUSION

The European Union advances medical device governance through Artificial Intelligence (AI) that transforms clinical evaluations as well as materiovigilance operations. AI has started rewriting regulations by utilizing its new abilities to diagnose better monitor patients and detect adverse events which reflects beyond traditional static fixed-technology protocols. A complete change of perspective must happen in technology adoption and legislative planning and regulatory standards must become uniform.

Under the Medical Device Regulation, the foundation for device safety and performance exists strongly although its limitations prevent effective control over AI-based systems' dynamic self-evolving nature. Regulatory bodies and notified bodies along with manufacturers have shown initial adaptation to MDR yet their lack of established systems for learning from monitored data and post-market algorithm modification creates vast risks for both safety and innovation problems.

Artificial Intelligence Act delivers promising developments through its introduction of specific performance standards that apply to essential high-risk AI systems used in medical devices. The current regulatory framework might become cumbersome because useful integration between new regulations and existing medical device protocols has not been established. European healthcare regulation demands a single forward-looking legal framework that establishes AI's unique technological properties within existing strict safety requirements for healthcare.

The narrow deployment of AI-enhanced materiovigilance systems between EU member states proves the requirement for superior norms and better standards in a centralized governance framework. The complete application of predictive AI in post-market surveillance depends on collective investments into digital systems as well as standardized technical approaches and international sharing of data across borders.

The way toward progress depends on regulatory evolution which maintains congruence with technological progression. The EU should lead by supporting collaborative relationships between policymakers and health authorities medical staff and AI developers to establish itself as a global leader in AI medical devices. The correct alignment serves both legal coherence purposes while directly affecting patient security and healthcare fairness and public faith in modern intelligent medical systems.

REFERENCES

[1]. Petaniti, E.; Tzamaria, D.; Liakou, C.I.; Papadakis, M.; Plytas, M. Clinical Evaluation of Class II Medical Devices: Data Analysis and Artificial Intelligence Integration for Enhanced Regulatory Compliance. IOSR Journal of Multidisciplinary Research (IOSR-JMR), Vol. 2, Issue 2, Series 2, Mar.–Apr. 2025, pp. 07–16. DOI: 10.9790/7439-0202020716.https://www.iosrjournals.org/iosr-jmr/papers/Vol2-Issue2/Ser-2/B0202020716.pdf

[2]. Liakou, C.I., Tzamaria, D., Plytas, M. and Papadakis, M., 2025. CTLA-4 therapy and dementia: A review of immunomodulation in neurodegenerative disease. World Journal of Advanced Research and Reviews, 26(1), pp.674–683. Available at: https://doi.org/10.30574/wjarr.2025.26.1.1100.

[3]. Liakou, C.I., Plytas, M. & Papadakis, M. 2025, 'How Long Does Biomedical Research Take? Studying the Time Taken Between Biomedical and Health Research and Its Translation into Products, Policy, and Practice', International Journal of Innovative Research in Computer and Communication Engineering, vol. 13, no. 3. Available at: https://ijircce.com/admin/main/storage/app/pdf/7uf0YVDFcarMQfJYpKUiRqxxYv3zBtvmvmfDp96t.pdf [Accessed 29 Mar. 2025].

[4]. Liakou, C.I. & Plytas, M. 2025, 'The Relationship between Leadership and Organizational Performance: A Case Study about Pfizer Pharmaceutical Inc.', International Journal of Innovative Research in Computer and Communication Engineering, vol. 13, no. 3. Available at: https://ijircce.com/admin/main/storage/app/pdf/KGHJ0Fc8rFHaIuaYLz8C9D7OJ1vk41T0AbO2XGYe.pdf [Accessed 29 Mar. 2025].

[5]. 2025. Petaniti, E., Tzamaria, D., Liakou, C.I. & Plytas, M. (2025) 'Early-stage medical technology assessment integrating health economics modeling for smarter product development', International Journal on Science and Technology, 16(1), pp. [1-9]. DOI: 10.71097/IJSAT.v16.i1.2573

[6]. Tzamaria, D., Petaniti, E., Liakou, C.I. and Plytas, M., 2025. Leveraging AI and computer science in primary care. Int J Sci Technol, 16(1), pp.1–15.

[7]. Petaniti, E., Tzamaria, D., Liakou, C.I. and Plytas, M., 2025. Early-stage medical technology assessment. Int J Sci Technol, 16(1), pp.1–9.

[8]. Liakou, C.I., Papadakis, M. and Plytas, M., 2025. Clinical evaluation of immunotherapy vaccines as medical devices. Int J Eng Technol Res Manag, 9(3), p.32.

[9]. Liakou, C.I., Papadakis, M. and Plytas, M., 2025. The challenges for manufacturers under the EU MDR. Int J Eng Technol Res Manag, 9(3).

[10]. Denecke, K. (2015). Using NLP to Identify Adverse Drug Events in Electronic Health Records. *Studies in Health Technology and Informatics*, 210, 604–608.

[11]. Ebers, M. (2021). Regulating AI in the EU: The Proposal for a New Artificial Intelligence Legal Framework. *European Journal of Risk Regulation*, 12(2), 431–442. https://doi.org/10.1017/err.2021.30

[12]. European Commission. (2020). *Medical Device Regulation (EU) 2017/745*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

[13]. European Commission. (2021). *Proposal for a Regulation laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act)*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206

[14]. European Commission. (2023). *EUDAMED Implementation Update Report*. Available at:

[15]. FDA. (2021). *Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan*. Available at: https://www.fda.gov/media/145022/download

[16]. Gerke, S., Minssen, T., & Cohen, I. G. (2020). Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare. *Journal of Law and the Biosciences*, 7(1), lsaa036. https://doi.org/10.1093/jlb/lsaa036

[17]. Holzinger, A., Langs, G., Denk, H., Zatloukal, K., & Müller, H. (2019). Causability and Explainability of Artificial Intelligence in Medicine. *Wiley Interdisciplinary Reviews: Data Mining and Knowledge Discovery*, 9(4), e1312. https://doi.org/10.1002/widm.1312

[18]. Kiseleva, Y., Berger, K., & Papageorgiou, A. (2023). Continuous Learning AI Systems in Medical Device Law. *Medical Law Review*, 31(1), 1–24. https://doi.org/10.1093/medlaw/fwac043
[19]. Muehlematter, U. J., Daniore, P., & Vokinger, K. N. (2021). Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe. *The Lancet Digital Health*, 3(3), e195–e203.
[20]. Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations. *Science*, 366(6464), 447–453. https://doi.org/10.1126/science.aax2342
[21]. Sartor, G., & Lagioia, F. (2020). The Impact of the General Data Protection Regulation (GDPR) on Artificial Intelligence. *European Parliamentary Research Service*. Available at: https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2020)641530
[22]. Shachar, C., Gerke, S., & Cohen, I. G. (2020). AI in Health Care: A Legal Framework for Trustworthy Innovation. *Health Affairs*, 39(11), 1730–1735. https://doi.org/10.1377/hlthaff.2020.00657
[23]. Topol, E. (2019). *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*. Basic Books. ISBN: 9781541644632
[24]. Veale, M., & Borgesius, F. Z. (2021). Demystifying the Draft EU Artificial Intelligence Act. *Computer Law Review International*, 22(4), 97–112. https://doi.org/10.9785/cri-2021-220402
[25]. Vincent, J. (2020). AI's Black Box Problem. *The Verge*. Available at:
[26]. Wang, F., Casalino, L. P., & Khullar, D. (2022). Deep Learning in Medicine—Promise, Progress, and Challenges. *JAMA Internal Medicine*, 182(2), 242–250.
[27]. Wiegand, T., Krishnamurthy, R., Kuglitsch, M., Lee, N., & Yordanov, Y. (2022). Artificial Intelligence in Clinical Medicine: What Is the Future? *The Lancet Digital Health*, 4(7), e437–e438.