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Original Article

Civil Liability in the Use of Digital Therapeutics and AI-Based Software: A Comparative and Narrative Review

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Abstract:

Introduction: The rapid advancement of digital health technologies, particularly artificial intelligence (AI) and digital therapeutics (DTx), has created challenges for existing regulatory and civil liability frameworks. This study compared regulatory approaches and civil liability models across the European Union (EU), the United States (US), and the Asia–Pacific region to identify governance strategies that balance patient safety and innovation.

Methods: A comparative narrative review was conducted. Literature was searched in PubMed, Google Scholar, and Google without time restrictions using terms related to DTx, AI, software as a medical device (SaMD), civil liability, and legal responsibility. English-language publications addressing regulatory frameworks or liability issues for DTx and AI-based medical software were included. Duplicates, non-English publications, conference abstracts without full text, and studies lacking regulatory or legal relevance were excluded. Official reports and websites from regulatory authorities and international organizations were also reviewed.

Results: The search identified 640 records, with 58 duplicates removed. After screening and full-text review, 13 peer-reviewed articles and 7 authoritative websites were included. The EU follows a comprehensive risk-based framework based on the MDR, AI Act, and strict product liability. The US combines flexible FDA pathways with a hybrid tort-based liability model, whereas the Asia–Pacific region demonstrates diverse approaches involving product liability, negligence, and data protection frameworks.

Conclusion: Regulatory systems are increasingly adopting risk-based governance; however, civil liability frameworks remain fragmented and insufficiently adapted to AI-enabled medical software. A lifecycle-based liability model integrating oversight, transparency, post-market monitoring, and adaptive accountability may strengthen future digital health governance.

Keywords: Artificial Intelligence; Digital Health; Digital Therapeutics; Liability; Legal.

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Introduction

In recent years, healthcare has undergone a profound transformation, driven largely by the integration of artificial intelligence (AI)-based technologies and digital therapeutics (DTx) into clinical practice (1). These technologies have enabled the development of software-based interventions that are increasingly used for disease prevention, treatment optimization, and long-term disease management. Their ability to deliver personalized, evidence-informed care at scale has created new opportunities to improve treatment adherence, enhance chronic disease management, and support clinical decision-making (2,3).

However, the rapid adoption of AI-based medical software and digital therapeutics has also introduced complex regulatory and legal

challenges. AI-based medical software, especially systems that provide autonomous or semi-autonomous support for clinical decision-making, may generate inaccurate outputs, diagnostic errors, or inappropriate recommendations, potentially resulting in patient harm. In such circumstances, determining legal responsibility becomes increasingly challenging. Liability may involve multiple actors, including healthcare professionals, healthcare organizations, software developers, and manufacturers, depending on the circumstances of the harm and the applicable legal framework. The interaction among these stakeholders creates uncertainty regarding the application of traditional civil liability principles, which were primarily developed for more linear models of healthcare delivery and product responsibility (4–7).

Recent medico-legal research has highlighted these challenges, demonstrating that the increasing use of digital health technologies has expanded the complexity of medical malpractice and accountability frameworks (8). Furthermore, concerns regarding responsibility allocation, algorithmic transparency, and the establishment of appropriate safety standards indicate persistent regulatory uncertainties surrounding AI-enabled healthcare technologies (9,10). The global expansion of these technologies, with parallel regulatory developments across Europe, North America, and Asia, emphasizes the importance of understanding how different jurisdictions address liability and governance challenges (11).

Despite increasing attention to these issues, comparative evidence examining the relationship between regulatory approaches and civil liability frameworks for digital therapeutics and AI-based medical software remains limited. Therefore, this study aims to compare the regulatory and civil liability frameworks governing digital therapeutics and AI-based medical software across Europe, North America, and East Asia. By analyzing similarities and differences among jurisdictions, this review seeks to identify existing legal challenges and regulatory gaps and to provide insights for developing balanced governance approaches that promote patient safety while enabling responsible digital health innovation.

Materials and Methods

Study design

This study employed a comparative narrative review to examine regulatory frameworks and civil liability regimes for Digital Therapeutics (DTx) and AI-based medical software across Europe, North America, and the Asia–Pacific region. Narrative review methodology enables the integration of heterogeneous evidence from legal, regulatory, clinical, and technological domains, providing flexibility to synthesize complex, multidisciplinary information. Unlike systematic reviews, narrative reviews support iterative literature assessment and interpretive analysis, offering conceptual insights into evolving and heterogeneous research areas (12–14)

Research Question

Based on the objectives of this comparative narrative review, the central research question guiding this study was:

How do regulatory frameworks and civil liability regimes governing DTx and AI-based medical software differ across the European Union, the United States, and the Asia–Pacific region?

To address this primary question, the review further examined the following sub-questions:

- What are the principal regulatory approaches used for the approval, classification, and oversight of DTx and AI-based medical software across different jurisdictions?
- How is civil liability distributed among developers, healthcare providers, and other relevant stakeholders in cases involving DTx and AI-driven clinical decision-making tools?
- What similarities, differences, and emerging trends can be identified in the governance of legal responsibility for AI-enabled medical technologies across the selected regions?

These questions were developed iteratively to guide the identification, selection, and synthesis of heterogeneous evidence drawn from legal, regulatory, clinical, and technological domains.

Data Sources

Peer-reviewed Literature

Peer-reviewed academic literature was retrieved from PubMed, Google Scholar, and Google. These sources were searched to identify studies addressing regulatory frameworks and civil liability related to Digital Therapeutics (DTx) and AI-based medical software.

Official Websites

Official websites were included to complement the academic evidence base. This approach reflects the rapidly evolving nature of Digital Therapeutics (DTx) and AI-based healthcare software, where important regulatory and policy developments are frequently published by regulatory authorities and international organizations before appearing in peer-reviewed literature. Accordingly, seven authoritative websites from recognized regulatory agencies and international organizations were included.

Previous Evidence

Part of the evidence informing the regulatory framework analysis was also derived from a previously conducted scoping review by the authors on digital health reimbursement across 15 countries (15).

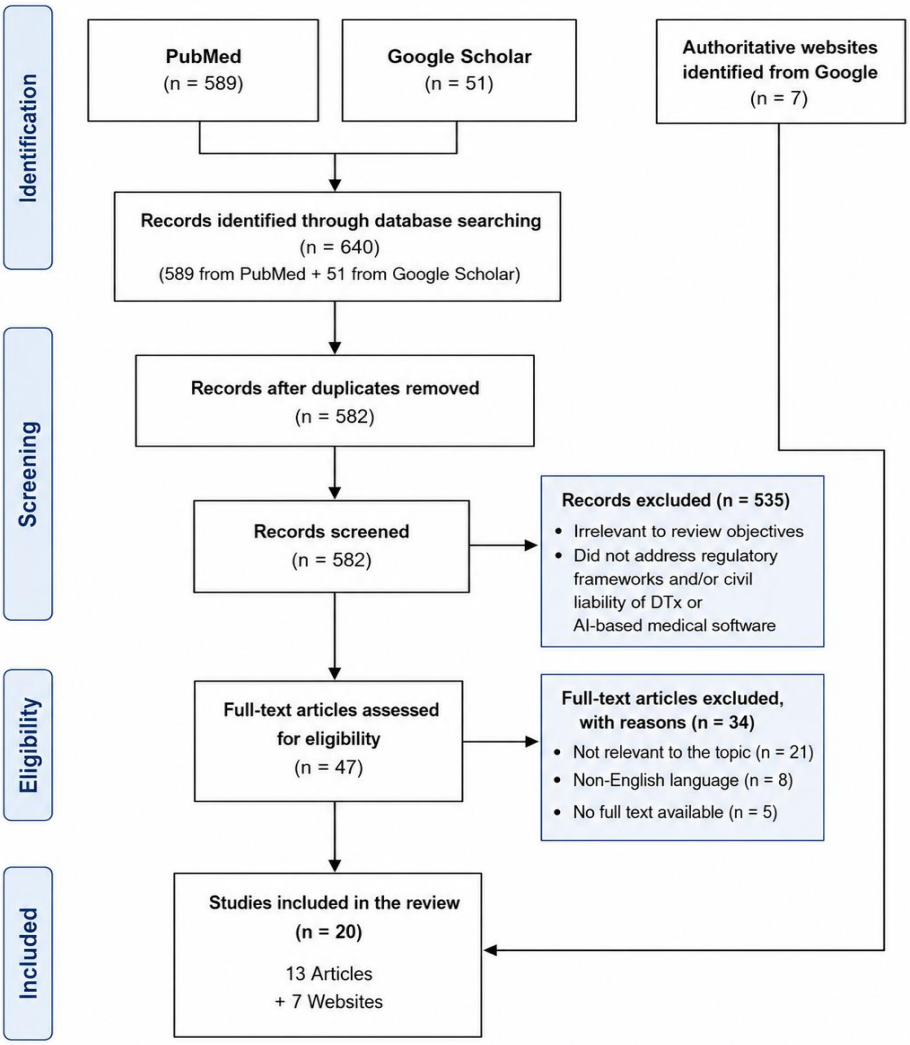

Fig 1: Flow diagram of conducting searches, filtering and paper selection

Search strategy

The literature search was conducted between February and March 2026. No time restrictions were applied to the publication year. The search strategy was based on a combination of keywords related to digital health and civil liability: (("Digital Health" OR "Digital Healthcare" OR "Digital Medicine" OR "Digital Therapeutics" OR "eHealth" OR "mHealth" OR "Mobile Health" OR "Health Technology" OR "Digital Treatment" OR "Digital Therapy" OR "Digital Intervention" OR "Software as a Medical Device" OR "SaMD" OR "Medical Software" OR "Digital Therapeutic Software" OR

"Regulated Health Software") AND ("Liability" OR "Civil Liability" OR "Medical Liability" OR "Legal Responsibility" OR "Accountability")).

Selection of an Article

No time restrictions were applied, and only English-language articles and documents were included. The inclusion criteria comprised studies addressing regulatory frameworks governing market authorization and pre-market evaluation of Digital Therapeutics (DTx) and AI-based medical software, as well as civil liability frameworks associated with their use. The exclusion criteria were as follows: (1) documents published in languages other than English; (2) conference abstracts without full-text availability; (3) studies lacking empirical or legal relevance to regulatory or liability frameworks; and (4) duplicate publications reporting identical data. A total of 640 records were identified through database searches in PubMed and Google Scholar. After removal of duplicates (n = 58), 582 records remained for title and abstract screening. Following title and abstract screening, 535 records were excluded because they were not relevant to the review topic or did not address the regulatory or civil liability frameworks of Digital Therapeutics or AI-based medical software. Consequently, 47 articles were considered potentially eligible and were retrieved for full-text assessment. Of these, 34 articles were excluded for the following reasons: not relevant to the study topic (n = 21), non-English language (n = 8), and lack of access to full-text articles (n = 5). Ultimately, 13 peer-reviewed articles and 7 authoritative websites met the inclusion criteria and were included in the final review. No industry reports or commercial resources were included. Figure 1 presents the study selection process from identification through to final inclusion.

Data synthesis

Data were analyzed using a narrative synthesis approach, which enables the interpretation of findings through structured descriptive analysis (16,17). Information from each region was systematically categorized and examined across two core domains: (1) pre-market regulatory frameworks and (2) civil liability frameworks applicable to Digital Therapeutics (DTx) and AI-based medical software. A comparative summary of regulatory frameworks across the selected regions is presented in Table 1, while key differences in the allocation of civil liability among stakeholders are outlined in Table 2. To ensure accuracy and validity, all analyses were conducted independently by two researchers. Any discrepancies were resolved through discussion and consensus, thereby enhancing the reliability and robustness of the findings.

primary report, and the review contributed contextual information only.

Results

Regulatory Frameworks for Digital Therapeutics and AI-Based Medical Software

European Union

In the European Union, the regulatory framework for digital therapeutics is grounded in a comprehensive set of laws and regulations, ranging from the 1993 Medical Devices Directive to the more recent Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). These regulations categorize medical devices and therapeutic software into risk-based classes (I–III), with higher-risk devices subject to more stringent clinical evaluation and approval requirements. Low-risk software that provides limited diagnostic support is generally classified as Class I or IIa, whereas systems that measure critical physiological parameters or directly influence clinical decisions may fall into higher-risk categories (IIb or III) (18). The MDR requires manufacturers to provide clinical evaluation evidence and obtain CE marking through conformity assessment procedures before market access.

The EU Artificial Intelligence Act further establishes a risk-based governance model for AI systems, introducing requirements related to risk management, data governance, transparency, and human oversight. In parallel, the General Data Protection Regulation (GDPR) provides requirements for data protection, accountability, and responsible processing of health information (19). In Germany, the Digital Healthcare Act and the DiGA pathway provide a structured mechanism for reimbursing approved digital health applications through statutory health insurance. The possibility of temporary reimbursement based on preliminary evidence has contributed to faster market access for digital therapeutics (20). Other European countries,

including Belgium, France, and the United Kingdom, are developing their own assessment and reimbursement approaches, although challenges remain regarding evidence generation, clinical effectiveness, and integration into routine healthcare systems (21).

Asia–Pacific

Regulatory approaches in the Asia–Pacific region demonstrate considerable variation in terms of classification, approval requirements, and reimbursement mechanisms. In South Korea, digital therapeutics are regulated as Software as a Medical Device (SaMD) under the guidance of the Ministry of Food and Drug Safety. Depending on their intended use and clinical application, some products require physician involvement and are regulated under the Medical Device Act (22). In Japan, therapeutic software is classified into four SaMD categories (I–IV) and is generally required to operate under appropriate medical supervision (23). Australia regulates digital therapeutics through the Therapeutic Goods Act and SaMD-related guidance, applying risk-based classification principles similar to international medical device frameworks (24). Despite differences among countries, regulatory authorities in the region increasingly emphasize clinical evidence, safety evaluation, performance verification, and alignment with international standards (25).

United States

In the United States, oversight of digital health technologies is primarily conducted by the Center for Devices and Radiological Health (CDRH) within the U.S. Food and Drug Administration (FDA). The Digital Health Center of Excellence (DHCoE) supports digital health innovation by developing regulatory policies, addressing cybersecurity challenges, providing guidance for AI-enabled medical devices, and promoting the use of real-world evidence in regulatory decision-making (26).

Digital therapeutics are generally regulated as Software as a Medical Device (SaMD), with FDA review pathways including the 510(k), De Novo, and, when applicable, Premarket Approval (PMA) pathways (27). Most prescription digital therapeutics have been classified as Class II devices. However, AI-based medical software presents additional regulatory challenges because machine learning systems may change their performance over time and generate outputs based on complex computational processes.

To address these challenges, the FDA has introduced AI/ML-specific regulatory initiatives, including guidance on adaptive artificial intelligence-enabled devices, lifecycle management, transparency, cybersecurity, and predetermined change control plans (PCCPs). In addition, broader U.S. AI governance initiatives, such as the National Institute of Standards and Technology (NIST) Artificial Intelligence Risk Management Framework (AI RMF), provide recommendations for risk management, accountability, reliability, and trustworthy AI implementation. These initiatives represent an emerging governance approach that complements existing medical device regulations.

The FDA continues to apply a risk-based regulatory model. Class I devices are subject to limited regulatory controls, Class II devices commonly follow the 510(k) pathway, and Class III devices require Premarket Approval (PMA). Novel low- or moderate-risk devices without an appropriate predicate may be reviewed through the De Novo pathway (29,30). Under the Federal Food, Drug, and Cosmetic Act, software may be considered a medical device when it is intended for diagnosis, treatment, or influencing physiological functions. However, certain categories of software, including some low-risk wellness and administrative applications, are excluded from device regulation under the 21st Century Cures Act.

FDA requirements include establishment registration, quality management, risk assessment, labeling, cybersecurity considerations, and software lifecycle management, with reference to international standards such as ISO 13485 and IEC 62304 (27). The selection of an appropriate regulatory pathway depends on the intended use, level of risk, technological characteristics, and available evidence demonstrating safety and effectiveness (31).

Despite regulatory progress, reimbursement remains a persistent barrier to the adoption of digital therapeutics in the United States. Unlike Germany's DiGA model, the U.S. healthcare system does not currently have a dedicated national reimbursement pathway for digital therapeutics. Coverage decisions are largely

determined by individual payers, employer-based programs, research funding mechanisms, or other healthcare financing arrangements. Although some private insurers have started covering selected products, the lack of standardized reimbursement mechanisms continues to restrict broader implementation (28).

Comparative Overview of Regulatory Frameworks

Across the European Union, the United States, and the Asia–Pacific region, regulatory approaches for DTx and AI-based medical software are increasingly based on risk assessment principles. However, these jurisdictions differ in their regulatory structures, approval mechanisms, AI governance approaches, and reimbursement arrangements. The European Union has established a comprehensive regulatory model through the Medical Device Regulation (MDR), Artificial Intelligence Act, and General Data Protection Regulation (GDPR), emphasizing risk management, data governance, transparency, and post-market oversight.

The United States adopts a more flexible, pathway-based approach centered on FDA medical device regulations, including 510(k), De Novo, and Premarket Approval pathways. This approach is increasingly complemented by AI-specific initiatives, such as FDA guidance on AI/ML-enabled medical devices, predetermined change control plans, and the NIST Artificial Intelligence Risk Management Framework, which aim to support safe and trustworthy AI implementation. Nevertheless, the U.S. currently lacks a comprehensive AI-specific healthcare regulation and a standardized reimbursement pathway for digital therapeutics.

In contrast, the Asia–Pacific region represents a more diverse regulatory landscape. Countries such as Japan, South Korea, and Australia have developed SaMD-oriented regulatory systems aligned with international standards; however, differences remain in regulatory maturity, evidence requirements, and reimbursement mechanisms across countries. A comparative summary of these regulatory frameworks is presented in Table 1.

Table 1: Comparative Regulatory Frameworks for Digital Therapeutics and AI-Based Medical Software

Region	Regulatory Authority	Classification System	Approval Pathways	AI-Specific Regulation / Governance	Reimbursement Status
European Union	EMA / National Competent Authorities	Class I–III (MDR)	CE marking, clinical evaluation	EU AI Act (risk-based framework), GDPR, MDR requirements for AI-enabled medical devices	Limited; advanced in Germany (DiGA)
United States	FDA (CDRH, DHCoE)	Class I–III	510(k), De Novo, PMA	Emerging AI governance frameworks (FDA AI/ML-SaMD guidance, NIST AI RMF, federal AI policy initiatives)	Limited; no standardized national reimbursement pathway
Asia–Pacific	National agencies (PMDA, MFDS, TGA, etc.)	SaMD-based classification (Class I–IV / I–III)	National approval pathways	Developing AI regulatory frameworks aligned with international standards	Fragmented and evolving

Abbreviations: DTx, Digital Therapeutics; AI, Artificial Intelligence; EMA, European Medicines Agency; MDR, Medical Device Regulation; FDA, Food and Drug Administration; CDRH, Center for Devices and Radiological Health; DHCoE, Digital Health Center of Excellence; PMA, Premarket Approval; SaMD, Software as a Medical Device; PMDA, Pharmaceuticals and Medical Devices Agency (Japan); MFDS, Ministry of Food and Drug Safety (South Korea); TGA, Therapeutic Goods Administration (Australia).

Civil Liability in the Use of Digital Therapeutics and AI-Based Medical Software

European Union

In the European Union, civil liability for digital therapeutics and AI-based medical software is shaped by a combination of product liability rules, professional liability principles, and emerging AI governance requirements. The Revised Product Liability Directive (Directive (EU) 2024/2853), which will require transposition into national law by December 2026, expands the scope of product liability by recognizing software and certain AI-enabled systems as products. Under this framework, manufacturers may be subject to strict liability when a defective product causes harm, without requiring proof of negligence. The injured party must demonstrate that the product was defective, that damage occurred, and that a causal relationship exists between the defect and the harm (32).

Liability may arise from design deficiencies, manufacturing defects, insufficient safety information, or inadequate warnings regarding product limitations. Therefore, manufacturers are expected to maintain appropriate documentation, ensure transparency regarding system performance, and implement adequate risk management measures throughout the product lifecycle (33). Healthcare professionals and institutions, in contrast, remain subject to professional liability rules established under national legislation. Their responsibility generally relates to appropriate clinical decision-making, adherence to accepted standards of care, adequate documentation, and appropriate oversight when using digital health technologies. Healthcare organizations may also be responsible for institutional failures, including inadequate training or improper implementation of digital systems.

The EU Artificial Intelligence Act (Regulation (EU) 2024/1689) introduces additional obligations for high-risk AI systems used in healthcare, including requirements related to risk management, transparency, human oversight, and data governance. These obligations do not replace existing liability mechanisms but provide additional regulatory requirements that may influence future liability assessments. Although regulatory authorities do not generally assume direct civil liability, non-compliance with regulatory obligations may result in administrative sanctions and indirectly contribute to liability assessments.

Furthermore, the Medical Device Regulation and the AI Act emphasize transparency-related requirements, including information on intended use, system performance, limitations, and risk controls. These requirements may help reduce uncertainty regarding accountability and support safer implementation of AI-based medical technologies (34).

United States

The U.S. civil liability framework for digital therapeutics and AI-based medical software follows a hybrid tort-based approach that distinguishes between products and services while attempting to balance technological innovation with patient protection. Manufacturers of standalone clinical software may face product liability claims related to design defects, manufacturing defects, or inadequate warnings under principles reflected in the Restatement (Third) of Torts: Products Liability. Potential defenses include the state-of-the-art doctrine, the unavoidable unsafe product doctrine, and the learned intermediary doctrine, under which appropriate warnings provided to prescribing physicians may, in certain circumstances, satisfy manufacturers' duty to warn.

Regulatory authorization by the FDA through pathways such as 510(k), De Novo, or Premarket Approval does not generally eliminate the possibility of state-level tort claims, although limited exceptions may apply. In contrast, digital health technologies delivered through cloud-based platforms or subscription models may be interpreted as services rather than products, shifting liability analysis toward negligence-based claims. In such cases, plaintiffs must generally demonstrate the existence of a duty of care, breach of that duty, causation, and compensable harm.

Healthcare professionals are typically evaluated under negligence standards, while comparative fault principles may allow responsibility to be distributed among clinicians, manufacturers, and other involved parties depending on the circumstances of the harm. Healthcare institutions may also face vicarious liability related to issues such as staff training, technology implementation, supervision, and

system validation (30). Although FDA authorization provides evidence of regulatory compliance, it does not remove the need for appropriate clinical oversight, clear instructions for use, and disclosure of relevant algorithmic limitations. In addition, violations of health information privacy requirements may contribute to negligence assessments but do not independently establish strict liability (32).

Asia–Pacific

Civil liability approaches in the Asia–Pacific region remain diverse due to differences in legal traditions, regulatory maturity, and healthcare systems. Japan and South Korea have developed frameworks that share similarities with the European model, combining manufacturer responsibility under product liability principles with negligence-based liability for healthcare professionals. In China, manufacturers may face strict product liability, and AI-enabled healthcare applications are increasingly being considered within existing product safety frameworks, while physicians continue to be evaluated primarily under professional negligence standards (35).

Other jurisdictions, including India and Singapore, rely mainly on negligence-based liability models. However, regulatory developments in these countries indicate a gradual expansion of expectations regarding manufacturer responsibility, particularly concerning software safety, transparency, and risk management. In these systems, comparative or contributory fault principles may influence the allocation of responsibility among manufacturers, healthcare providers, and users.

Regulatory authorities across the region, including the National Medical Products Administration in China, the Pharmaceuticals and Medical Devices Agency in Japan, the Health Sciences Authority in Singapore, the Ministry of Food and Drug Safety in South Korea, and the Central Drugs Standard Control Organization in India, increasingly emphasize requirements related to algorithm transparency, performance evaluation, and disclosure of system limitations. Compliance with these requirements may affect subsequent liability assessments (36).

Furthermore, data protection legislation, including China's Personal Information Protection Law, Singapore's Personal Data Protection Act, South Korea's Personal Information Protection Act, and Japan's Act on the Protection of Personal Information, creates additional obligations for organizations handling health data. Breaches of these requirements may result in parallel regulatory or civil consequences, requiring manufacturers and healthcare providers to address both data protection and technology safety throughout the lifecycle of AI-based healthcare systems (37).

Comparative Overview of Civil Liability Frameworks

Civil liability frameworks governing DTx and AI-based medical software demonstrate important differences across jurisdictions, although most systems attempt to distribute responsibility between technology developers, healthcare providers, and other stakeholders. The European Union has developed a relatively structured liability model that combines manufacturer responsibility under product liability rules with professional liability obligations for healthcare providers. This approach is further influenced by emerging regulatory instruments, including the revised Product Liability Directive and the AI Act, which introduce additional requirements related to transparency, risk management, and accountability.

The United States follows a more flexible tort-based approach in which liability depends largely on whether a digital health technology is considered a product or a service. This distinction allows claims based on both strict product liability and negligence principles, while legal doctrines and state-level variations continue to shape the allocation of responsibility among manufacturers, clinicians, and healthcare organizations.

In the Asia–Pacific region, liability approaches remain heterogeneous, reflecting differences in legal systems and regulatory development. Nevertheless, many jurisdictions share common elements with the European and U.S. models by combining manufacturer obligations with professional liability standards for healthcare providers. In addition, the increasing role of data protection regulations introduces further considerations regarding accountability for privacy breaches and technology-related harms.

A comparative summary of civil liability frameworks across the selected regions is presented in Table 2.

Table 2: Comparative Civil Liability Frameworks for Digital Therapeutics and AI-Based Medical Software

Region	Manufacturer Liability	Healthcare Provider Liability	Legal Model	Key Legal Instruments	Special Features
European Union	Strict liability	Fault-based	Hybrid	Product Liability Directive (EU) 2024/2853; AI Act	National liability laws; data protection laws
United States	Strict (products) / Negligence (services)	Negligence	Hybrid tort system	Restatement (Third) of Torts; FDA framework	Learned intermediary doctrine; product vs service distinction
Asia–Pacific	Predominantly strict (manufacturers)	Negligence	Mixed systems	National liability laws; data protection laws	High variability; strong link to data protection regulations

Abbreviations: DTx, Digital Therapeutics; AI, Artificial Intelligence; FDA, Food and Drug Administration

Discussion

This comparative review identified important differences in the regulatory governance of DTx and AI-based medical software across the European Union, the United States, and the Asia–Pacific region. Although all examined jurisdictions increasingly rely on risk-based regulatory principles, the analysis demonstrates variation in regulatory maturity, AI governance mechanisms, approval pathways, and reimbursement structures. These differences suggest that while regulatory systems have advanced rapidly, mechanisms for accountability, reimbursement, and long-term integration of digital health technologies have developed more gradually.

In the European Union, the analysis indicates the most comprehensive regulatory approach among the reviewed regions through the combined application of the Medical Device Regulation (MDR), the Artificial Intelligence Act (AI Act), the General Data Protection Regulation (GDPR), and emerging liability reforms. The MDR establishes a structured risk classification and conformity assessment pathway for medical software, whereas the AI Act introduces additional requirements related to risk management, transparency, human oversight, and governance of high-risk AI systems (38,39). Together, these instruments represent a shift from traditional device-focused regulation toward a broader governance model that considers the entire lifecycle of AI-enabled healthcare technologies. However, challenges remain regarding the application of existing liability principles to systems involving multiple actors, including developers, healthcare providers, and users (40).

The United States follows a different regulatory pathway, with oversight primarily centered on FDA medical device regulations, including 510(k), De Novo, and Premarket Approval (PMA) pathways. Unlike the European Union, the United States does not currently have a comprehensive AI-specific healthcare law. Instead, AI governance is developing through FDA initiatives related to AI/ML-based Software as a Medical Device (SaMD), lifecycle management approaches, predetermined change control plans, and broader frameworks such as the National Institute of Standards and Technology (NIST) Artificial Intelligence Risk Management Framework (AI RMF) (41,42). These approaches emphasize risk management, transparency, cybersecurity, and continuous monitoring. However, the absence of a unified AI regulatory framework may lead to variability in

oversight practices and accountability expectations across different clinical applications.

In the Asia–Pacific region, the regulatory landscape remains more diverse, reflecting differences in legal systems, healthcare infrastructures, and digital health development. Countries such as Japan, South Korea, and Australia have established SaMD-related regulatory pathways that align with international standards; however, differences persist in classification approaches, evidence requirements, and reimbursement mechanisms. This variation highlights the influence of national policy priorities and healthcare system characteristics on the development of digital health governance. Similar observations have been reported in previous comparative studies emphasizing the need for greater regulatory coordination and international collaboration (43).

Beyond regulatory approval, our findings indicate that reimbursement remains a critical determinant of successful adoption of DTx and AI-based medical software. Germany's DiGA pathway represents one of the most advanced reimbursement models by linking regulatory assessment with statutory health insurance coverage (44). In contrast, the United States and several Asia–Pacific countries continue to rely on fragmented reimbursement approaches, in which coverage decisions depend on payer requirements, available clinical evidence, and existing healthcare financing structures. These findings suggest that future regulatory strategies should be developed alongside evidence-generation frameworks and sustainable reimbursement mechanisms.

Another important finding concerns the challenge of assigning responsibility for AI-enabled medical technologies. Traditional liability systems were largely developed for technologies with identifiable manufacturers, predictable performance characteristics, and relatively stable modes of operation. However, AI-based medical systems introduce additional complexity because outcomes may depend on interactions among algorithms, training data, healthcare professionals, and end users. This complexity may complicate the identification of responsible parties when harm occurs (45). Previous research has highlighted related challenges, including algorithmic opacity and difficulties in attributing responsibility within multi-actor systems (46,47). Therefore, future governance models may need to incorporate lifecycle-based accountability, with clearly defined responsibilities during development, validation, deployment, monitoring, and post-market adaptation.

Overall, this review suggests that effective governance of DTx and AI-based medical software requires alignment among regulatory approval processes, AI oversight mechanisms, liability frameworks, and reimbursement policies. Although current regulatory models are moving toward more adaptive approaches, further refinement is needed to ensure that legal and policy systems can address rapidly evolving digital health technologies while maintaining patient safety, accountability, and equitable access.

Strengths and Limitations

This study has several strengths. First, it provides a comprehensive comparative analysis of regulatory frameworks and civil liability approaches for DTx and AI-based medical software across three major regions, including the European Union, the United States, and the Asia–Pacific region. By integrating evidence from legal documents, regulatory frameworks, and peer-reviewed literature, this review offers a multidisciplinary perspective on the evolving governance of digital health technologies. Second, the inclusion of both regulatory approval mechanisms and liability frameworks enables a broader understanding of the challenges associated with the adoption and accountability of AI-enabled healthcare technologies. Furthermore, the use of authoritative regulatory sources complements the academic literature and enhances the relevance of the findings for policymakers and stakeholders.

However, several limitations should be considered. First, as a narrative review, this study does not follow the systematic review methodology, and therefore potential selection bias cannot be completely excluded. Although multiple sources were considered and the selection process was conducted systematically, the interpretation of heterogeneous legal and regulatory evidence may involve a degree of subjectivity. Second, regulatory frameworks for AI-based medical software and digital therapeutics are rapidly evolving; therefore,

some recently introduced policies or future regulatory changes may not be fully captured. Third, this review focused on selected jurisdictions with relatively advanced digital health regulatory systems, and the findings may not be directly generalizable to low- and middle-income countries with different regulatory capacities and healthcare infrastructures. Future research should consider broader geographic coverage and conduct longitudinal assessments to evaluate how emerging regulatory and liability frameworks evolve.

Conclusion

This study demonstrates that although regulatory frameworks for DTx and AI-based medical software are converging toward risk-based governance models, civil liability regimes remain conceptually fragmented and doctrinally inconsistent across jurisdictions. The European Union is moving toward an integrated model in which regulatory compliance, transparency obligations, and product liability are increasingly interlinked. However, unresolved tensions persist regarding the legal characterization of adaptive AI systems, particularly in defining defectiveness over the lifecycle of the product. The United States maintains a highly flexible but structurally fragmented tort-based system, where liability outcomes are heavily dependent on doctrinal classification and judicial interpretation. This creates adaptability but at the cost of legal predictability, especially for AI systems that blur the distinction between product and service.

The Asia–Pacific region reflects an evolving hybrid structure in which multiple liability logics coexist, including product liability, negligence, and data protection-based responsibility. While this pluralism allows contextual adaptation, it also generates doctrinal fragmentation and regulatory inconsistency.

A key finding of this study is that existing liability frameworks are fundamentally constrained by their reliance on static notions of causation, fault, and product integrity, which are increasingly misaligned with the dynamic, adaptive, and distributed nature of AI systems. This mismatch creates accountability gaps that incremental legal reform alone cannot resolve.

To address these challenges, this study supports developing a lifecycle-based liability model in which legal responsibility is distributed dynamically across design, development, deployment, and post-market phases. Such an approach would better align liability with functional control and risk exposure across the AI system lifecycle. From a policy perspective, stronger integration between regulatory compliance mechanisms and civil liability standards is required to reduce legal uncertainty and ensure coherent accountability structures. In particular, transparency obligations, auditability requirements, and real-world performance monitoring should be explicitly linked to liability allocation mechanisms. Future research should focus on operationalizing adaptive liability frameworks for AI systems, evaluating the legal implications of emerging EU instruments such as the AI Act and AI Liability Directive, and developing comparative models that integrate regulatory governance with tort law evolution in digital health ecosystems.

Authors' Contribution

Zahra Bagheri: Writing – original draft, Validation, Methodology, Investigation, Formal analysis, Conceptualization.
Ali Ansari: Writing – review & editing, Writing – original draft, Methodology,
Sohrab Almasi: Writing – original draft, Visualization, Validation, Methodology, Investigation, Formal analysis, Conceptualization

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Data Availability

The study is based on extracting data from published articles; all data are included in the report.

Ethics Approval

This is not applicable as the study is based on extracting data from published articles.

Conflict of Interest

There are no conflicts of interest

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