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EVALUATION OF TELEMEDICINE SOFTWARE AS A MEDICAL DEVICE: CURRENT CHALLENGES AND FUTURE DIRECTIONS

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Abstract

The innovative development of telemedicine has changed the process of providing medical services by applying digital technologies in diagnostic, monitoring, and therapeutic procedures, and Software as a Medical Device (SaMD) has become a key enabler in managing healthcare Telemedicine SaMD can support remote consultations, management of chronic illnesses, and real-time monitoring of patients, but it may open up special regulatory, technical, and clinical considerations when it comes to evaluation The paper critically analyzes the existing methods of how telemedicine SaMD can be evaluated, considering performance verification, interoperability, cybersecurity, and adherence to international regulations and guidelines, such as the Total Product Lifecycle model developed by the FDA and IMDRF requirements. The review of the existing literature includes pieces of evidence based on peer-reviewed articles and latest regulatory reports to determine the sufficiency of the currently available assessment models regarding safety, efficacy, and post-market surveillance. The risks that remain prevalent are the lack of regulatory harmonization, the insufficient lifecycle risk management, and the inability to integrate decision support systems, mostly based on AI. The implications are the necessity of internationally consensual evaluation, adaptive risk assessment methods, and clinical confirmation of a secure patient, and the reliability of technology in the future. The results add to the discussion about creating standard, scalable, and future-proof evaluation frameworks of SaMD in telemedicine and offer practical implications to policymakers, vendors, and clinicians.

Keywords

telemedicine; software as a medical device; evaluation framework; regulatory compliance; digital health; future directions

1. Introduction

Digitalization of the healthcare sector has transformed the provision of medical services because telemedicine has become one of the foundational elements of the contemporary health systems. Originally thought of as a way of bringing healthcare to remote and underserved areas with the help of telephone consultations, telemedicine has developed into an environmentally diverse, technology-driven ecosystem where video conferencing and remote patient monitoring are combined with cloud-based data storage and artificial intelligence (Wilson & Maeder, 2015;

Alenoghena et al., 2023). However, the increasing maturity of the enabling technologies in the form of the Internet of Things (IoT), wearable sensors, and high-speed network connectivity has vastly increased the scope and scalability of telemedicine platforms (Elmi et al., 2024; Osama et al., 2023).

Software as a Medical Device (SaMD) is one of the new products of the emerging environment that enables diagnostic, monitoring, and therapeutic functions without physical hardware and IMDRF (2025). The range of applications wherever SaMD functions is very broad, as varied as an AI-powered imaging analysis tool to a personal dashboard remoting chronic illness like diabetes, cardiovascular disease, and respiratory sickness (Bellazzi, 2008; Serper Volk, 2018; Donofrio Zeng, 2022). It is worth noting that the value proposition of this tool is the ability to promote patient-centric care, strengthen clinical decision-making, and offer actual-time health interventions, especially in the setting where face-to-face consultations are scarce or unreasonable (Omboni et al., 2022; Celler & Sparks, 2014).

Its final adoption speeded up with the COVID-19 pandemic that highlighted the importance of SaMD as a means of continuity of care even in restrictive conditions (Omboni et al., 2022; Alelyani et al., 2021). But with this massive integration come damning realizations to be realized in software assessment, compliance and long-term risk management. Compared to conventional healthcare devices, SaMD is also dynamic in nature, which means it can be regularly updated, iterated, and even constantly revised, thanks to machine learning algorithms, in certain cases (Rauniyar et al., 2023; FDA, 2025). This dynamism makes the validation process more complicated since the conventional pre-market approval frameworks might not be enough to guarantee continuously safe and effective products. (Ming et al., 2022; akkaoui et al., 2024).

The regulatory bodies have reacted by coming up with particular regimens to govern SaMD. There are well-designed strategies included in FDA Total Product Lifecycle model (TPLC), the European Union Medical device Regulation (MDR), and other international requirements (ISO 14971- risk management and IEC 62304- software lifecycle processes) (Greenlight Guru, 2025). The International Medical Device Regulators Forum (IMDRF) has been the driving force that has facilitated the unification of medical equipment in the world through its definition of classification, based on the levels of risk to this end, focussing its emphasis on lifecycle assessment (IMDRF, 2025). However, a lack of uniformity between jurisdictions persists, forming patchy regulatory environments that impede the entry of firms in multiple markets and makes it harder to develop a uniform approach to compliance (Kawde & Gourshettiwar, 2025; Mallipeddi et al., 2017).

Also, the regulatory frameworks are not the only complicated factor associated with SaMD evaluation. Among the critical areas of concern and attention, there are the implementation of transparency and explainability of the algorithm, the security of storing information about patients, the incorporation of interoperability requirements of healthcare systems, and the preparation of clinical validation guidelines of interventions implemented using software (Osama et al., 2023; Albahri et al., 2018). Specifically, the SaMD with AI capabilities has new challenges related to mitigating bias in AI-based SaMD, monitoring SaMD real-world performance, and monitoring the process of adaptive learning. (Rauniyar et al., 2023; FDA, 2025).

A synthesis of the major SaMD regulatory frameworks is provided in **Table 1**, illustrating their scope, classification logic, and evaluation focus.

Table 1. Key regulatory frameworks for SaMD in telemedicine

Regulatory Authority / Standard	Scope	Classification Criteria	Key Evaluation Components
FDA (USA) – Total Product Lifecycle (TPLC) Model (2025 Draft Guidance)	AI-enabled and conventional SaMD	Intended use, risk level, AI transparency	Pre-market validation, real-world performance monitoring, bias mitigation
IMDRF SaMD Framework (2025)	Global harmonization of SaMD definitions and principles	Intended medical purpose, significance of information to healthcare decisions	Risk categorization, clinical evaluation, and quality management
European Union MDR (2017/745)	SaMD under medical device regulation	Classification based on risk (Class I–III)	Clinical evaluation, CE marking, post-market surveillance
ISO 14971:2019	Risk management for medical devices	Hazard identification and risk acceptability	Risk control measures, lifecycle risk monitoring
IEC 62304:2006+A1:2015	Software lifecycle processes	Software safety classification (A–C)	Requirements analysis, verification & validation, maintenance

Research gap and study objectives

Although increasing literature has been published concerning telemedicine technologies, integration of regulatory, technical, and clinical opinions in the assessment of SaMD in telemedicine situations has been little or nonexistent (Ming et al., 2022; Alelyani et al., 2021). The available studies focus either on the technical performance or the regulatory compliance using standalone measures, leaving behind poorly covered holistic multidisciplinary system of evaluation. In this study, we fill that gap in four ways:

1. Examining the existing literature and regulation to assess SaMD during telemedical practice.
2. Determining tenacious technical, clinical, and policy problems.
3. Proposing proactive, integrated, safety-assuring evaluation models and approaches that can be interoperable or interchangeable worldwide.

In this manner, the article is expected to enable policymakers, developers, and healthcare providers to take meaningful action to optimize the implementation of SaMD in telemedicine because it will result in an excellent patient safety level and high technological reliability.

2. Literature Review

2.1 Evolution of Telemedicine and SaMD Integration

The alignment of Software as a Medical Device (SaMD) with Telemedicine has been an innovative game changer in recent healthcare provision. Catching up with the late 20th-century historical account, the initial telemedicine systems were mainly aimed at synchronous audio-visual consultations with the purpose of extending geographically isolated people with medical expertise (Wilson & Maeder, 2015; Celler & Sparks, 2014). Due to the developing

broadband connectivity, mobile computing, and the Internet of Things (IoT), telemedicine has grown in scope over the years and has now been able to include asynchronous communications, at-a-distance monitoring, and incorporation into decision-support systems (Elmi et al., 2024; Osama et al., 2023).

SaMD is referred to as the Medical Language Development Regulators International Forum (IMDRF, 2025), and refers to the type of code that is meant to be used within the medical environment, but is not a physical medical device. Its range of applications includes diagnostic imaging algorithms, platforms of chronic disease management, tools of clinical decision support based on AI (Bellazzi, 2008; Ming et al., 2022). However, the onset of the COVID-19 pandemic remarkably boosted the penetration of SaMD to telemedicine because the contactless manner of delivering care was required to ensure clinical continuity (Omboni et al., 2022; Alelyani et al., 2021). The increase signaled the promise and the pitfalls of implementing medical interventions that are software-based using weak evaluation systems.

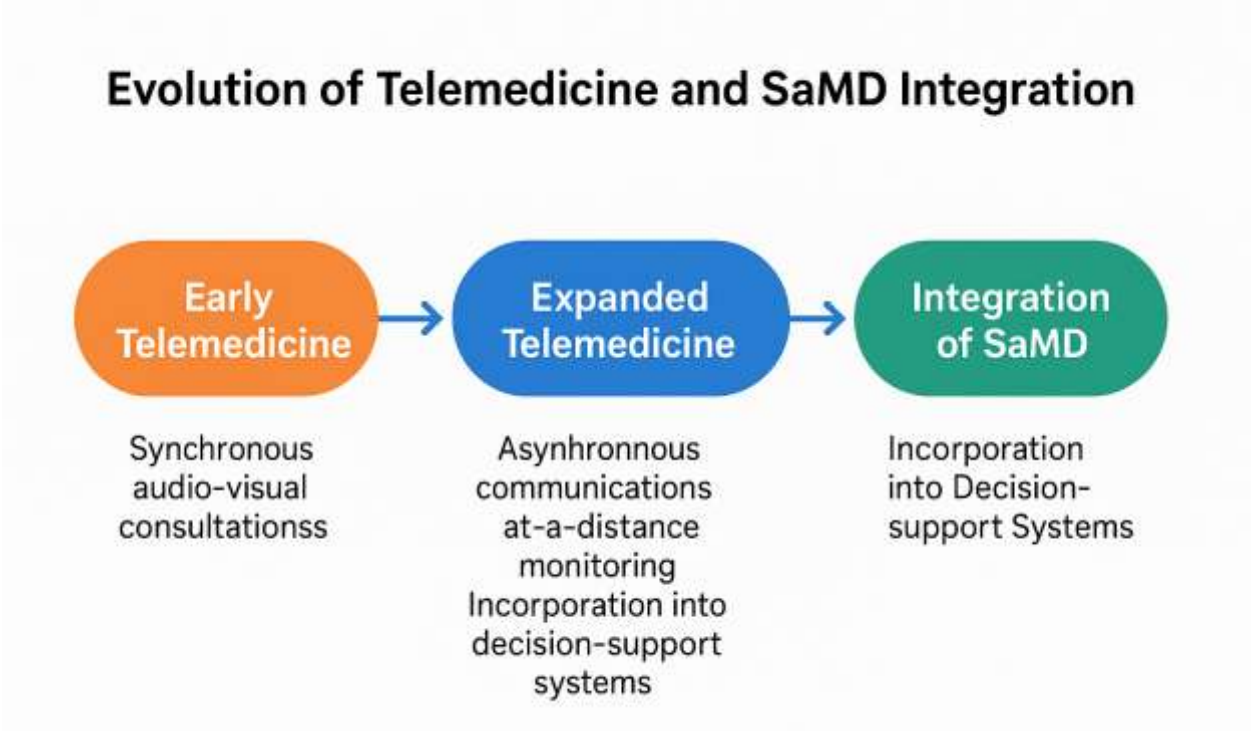
2.2 Obtaining Regulatory Frameworks that Govern SaMD in Telemedicine

Unlike conventional medical devices, the regulation of SaMD is not the same because of software rather than hardware orientation, as well as shorter update periods. The Food and Drug Administration (FDA) in the United States has come up with the Total Product Lifecycle (TPLC) strategy to deal with the real-time updates and improvements to SaMD, including AI-enabled systems (FDA, 2025). This model focuses on the pre-market validation, post-market surveillance of performance in the real world and risk based supervision (Rauniyar et al., 2023).

There is also its European equivalent in the form of the Medical Device Regulation (MDR 2017/745), which has established a legal framework in the European Union that includes the classification rules by the intended use and risk profile, clinical evaluation requirements, and post-market surveillance (Kawde & Gourshettiwar, 2025). Globally, the IMDRF has been involved in the pivotal role of coming up with global definitions, categories of risks and principles of evaluation (IMDRF, 2025). ISO 14971 standards, which address the risks management, and IEC 62304 standards which take on the processes in the software lifecycle, offer specific assistance in the process of hazard identification, risk mitigation, verification and validation (Mallipeddi et al., 2017; Greenlight Guru, 2025).

Regardless of these developments, harmonization of regulation is difficult. Different jurisdictions and sovereigns may define standards divergently, create classification criteria, and procedures to assess their conformity, creating obstacles in the development of a global market width (akkaoui et al., 2024; Alenoghena et al., 2023). Such fragmentation especially troubles the telemedicine SaMD; usually simulating across national hospitals and needing to address a multiplicity of, and even contradictory, regulatory needs.

Figure 1. Evolution of Telemedicine and Integration of Software as a Medical Device (SaMD)



2.37 Technical issues of SaMD Evaluation

Analysis of SaMD in telemedicine cannot be less thorough, as it is important to observe the software reliability, cybersecurity, interoperability, and usability parameters. In comparison to devices based on hardware, the software systems are dynamic by their nature and may have quite frequent updates that may change performance features (Ming et al., 2022). This brings about the need to have continuous verification and validation instead of a pre-market evaluation (Osama et al., 2023).

Cybersecurity is a serious issue because telemedicine sites transfer sensitive health information, which is likely to be breached and ransomware (Albahri et al., 2018). The act of combining SaMD with electronic health records (EHRs) and wearable devices, where vendors use different interoperability standards like HL7 FHIR, requires compliance with interoperability standards that are leading to data fragmentation, but it is also preventing full data exchange due to the variety of implementations among vendors (Elmi et al., 2024). Additionally, usability engineering is indispensable in making sure that both clinicians and patients are able to engage with the tools of telemedicine adequately leading to fewer chances of user mistakes that may jeopardize clinical outcomes (Serper & Volk, 2018).

2.4 Clinical Evaluation and Evidence Generation

SaMD clinical assessment seeks to determine that the software is being used as intended, safe, and that its use offers clinically relevant improvements. Traditional assessment is intensively based on randomized controlled trials (RCTs), whereas, in the case of SaMD, especially AI-driven systems, approaches to adaptive and real-world evidence (RWE) are becoming influential (Rauniyar et al., 2023). These methods make it possible to continuously measure the performance of such devices under realistic conditions of use, being in line with the TPLC model of the FDA concerning post-market principles (IMDRF, 2025).

Nonetheless, several problems are still associated with choosing proper clinical outcomes, representative data, and dealing with algorithmic bias (Osama et al., 2023; Omboni et al., 2022). SaMD systems developed by AI need to be continuously learning as more data is added but during validation, to be stable, such algorithms need to be locked to

provide consistent outputs and allow controlled update processes (FDA, 2025). Poor consideration of those aspects can lead to clinical harm or unfair healthcare provision, especially in vulnerable groups (Alelyani et al., 2021).

2.5 Growing Research Gaps and Research Shortcomings of SaMD Evaluation

Even though remarkable progress has been achieved in the definition of regulatory and technical frameworks, literature displays unaddressed gaps in the multidisciplinary assessment of telemedicine SaMD. The literature usually falls into two camps of issues: regulatory compliance (Mallipeddi et al., 2017; Greenlight Guru, 2025) and technical validation (Ming et al., 2022; Elmi et al., 2024), and little combination of clinical, operation, and policy facet. Also, there are limited examinations of evaluation issues in the field of cross-border telemedicine where jurisdiction fragmentation and data regulatory schemas are common (akkaoui et al., 2024).

Future studies shed light on the possibilities of global evaluation protocols harmonization, adaptive model of risk assessment, and specialized regulatory pathways to endure the safety and effectiveness of AI, and still allow free innovation (Kawde & Gourshettiwar, 2025; Alenoghena et al., 2023). Filling these gaps is important in order to allow scalable, reliable, and ethically responsible practice of SaMD in telemedicine.

3. Methodology

3.1 Research Design

In an attempt to epitomize the current understanding of the existing regulatory, technical, and clinical evaluation Regimes of Software as a Medical Device (SaMD) in telemedicine is this fluid study that takes a systematic qualitative synthesis approach with the aim of critiquing the current paradigm. To harmonize scattered results and disclose thematic gaps, a literature-based approach was chosen since it was consistent with the best practices of the health technology assessment research (Ming et al., 2022; Omboni et al., 2022). The review adheres to the guidelines of preferred reporting items of systematic review and meta-analyses (PRISMA) to provide transparency, reproducibility and methodological rigor (Moher et al., 2009).

The research design combined:

- Systematic Literature Review (SLR) to discover, select and examine suitable peer-reviewed research and regulatory publications.
- Comparative Regulatory Analysis- to assess SaMD regulation strategic machinery and other jurisdictions.
- Thematic Synthesis-to unite the problems and the emergent solutions identified in the study.

3.2 Data sources and Search Strategy

Scopus, PubMed, IEEE Xplore, Science direct, and Google scholar were the major academic sources of primary data obtained, whereas official regulatory databases of FDA, European Medicines Agency (EMA), and K International Medical Device Regulators Forum (IMDRF) were accessed to have the greatest number of policy and technical documents. Publications are searched between 2015 and 2025 to encapsulate a pre-pandemic, pandemic-stimulated and post-pandemic telemedicine SaMD assessment.

Search strings labelled Boolean operators with terms with relevance, say:

("telemedicine" OR "digital health") AND ("software as a medical device" OR "SaMD") AND ("evaluation" OR "assessment") AND ("regulation" OR "framework" OR "compliance").

The bibliographies of the retrieved studies were used to conduct reference snowballing (Alenoghena et al., 2023; Rauniyar et al., 2023).

3.3 Inclusion/ exclusion Criteria

Inclusion criteria:

- Journal articles that were peer-reviewed, conference papers, and regulatory reports whose content is either on the topic of evaluation frameworks, regulatory compliance, or clinical validation of SaMD pertaining to telemedicine.
- Phones in English.
- Surveys that offer empirical data, case histories or expert opinion.

Exclusion criteria:

- Research on non-medical software or hardware-only medical device.
- The voices of personal opinion.
- Articles on pages that have not provided readable full texts.

3.4 Data and thematic coding

Data were extracted by two independent reviewers on: publication year, type of study, jurisdiction, method of evaluation, the overall regulatory framework and reported challenges. Data extracted was coded with NVivo 14 program to enable thematic analysis and we were able to deduce recurring themes which included:

- The issues of harmonization of regulations (akkaoui et al., 2024; FDA, 2025)
- Risk management of lifecycle (Mallipeddi et al., 2017; ISO 14971)
- Cybersecurity (Elmi et al., 2024; Albahri et al., 2018), interoperability (Wallace et al., 2018)
- Clinical validation methods (Omboni et al.,2022; Rauniyar et al., 2023)

The issue of coding discrepancy was solved by consensus.

3.5 Appraisal of Quality

The Mixed Methods Appraisal Tool (MMAT) 2018 was used to assess quality of the included empirical studies, and AGREE II Instrument was used to evaluate quality of policy and guideline documents included (Hong et al., 2018). The criterion used to rate the studies that were included was the degree of methodological rigor, clarity and relevance of the evaluation criteria to the telemedicine SaMD.

3.6 Methodological Workflow

The multi-stage methodological process is summarized in **Table 2**.

Table 2. Methodological stages for the evaluation of telemedicine SaMD literature

Stage No.	Methodological Step	Description	Key References
1	Problem Definition	Define scope of SaMD evaluation challenges in telemedicine	Omboni et al., 2022; Ming et al., 2022
2	Literature Search	Search Scopus, PubMed, IEEE Xplore, ScienceDirect, and regulatory databases	Rauniyar et al., 2023; Alenoghena et al., 2023
3	Screening & Selection	Apply inclusion/exclusion criteria per PRISMA	Moher et al., 2009

4	Data Extraction	Extract regulatory, technical, and clinical evaluation details	Elmi et al., 2024; Osama et al., 2023
5	Thematic Coding	Identify key recurring challenges and gaps	akkaoui et al., 2024; FDA, 2025
6	Quality Appraisal	Apply MMAT & AGREE II to assess study quality	Hong et al., 2018
7	Synthesis	Integrate findings into thematic discussion	Kawde & Gourshettiwar, 2025

4. Result

Thematic synthesis made it possible to identify several findings based on the systematic review and reflecting the realities of the regulatory situation and technological trends in assessing the telemedicine Software as a Medical Device (SaMD) available in different jurisdictions. It was established that although the use of telemedicine SaMD has increased throughout the world, remarkable inequities still exist in assessment procedures, regulating methods, and real-life performance observance.

To begin with, telemedicine SaMD is regulated differently: the definitions vary, approaches to the classification are dissimilar, and there are no unified rules and regulations to comply with. As an example, the Total Product Lifecycle (TPLC) strategy by the United States Food and Drug Administration (FDA) focuses on the continuous performance review and post-market monitoring (FDA, 2025), compared to the more inflexible classification requirements of the European Union Medical Device Regulation (EU MDR 2017/745) that inform both the pre-market approval and post-market requirements (IMDRF, 2025). This dissonance has formed the obstacles to cross-border implementation of telemedicine platforms because the developers need to go through various approval channels (Greenlight Guru, 2025; akkaoui et al., 2024).

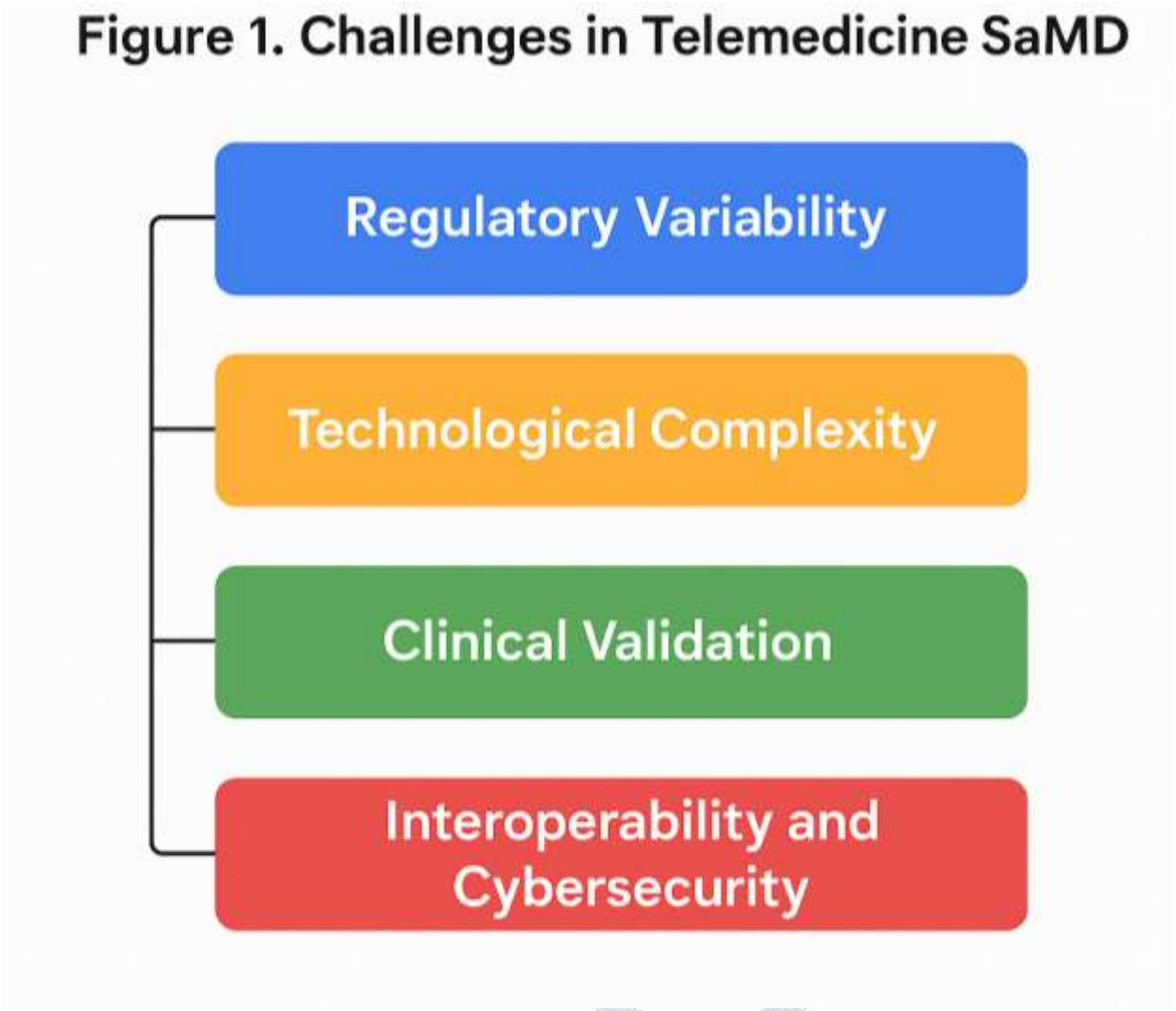
Second, SaMD, especially those built around AI-assisted applications to telemedicine, are rather technologically complex, which poses challenges in evaluation. In the studies reviewed, the accuracy of AI diagnosis tools was initially high and significantly dropped when it was put into practice in nonhomogeneous clinical settings (Rauniyar et al., 2023; D Onofrio & Zeng, 2022). The variations in patient demographics, disease occurrences, and data acquisition equipment were attributed to this so-called performance drift, thus motivating change in algorithms based on adaptability and ongoing revalidation procedures (Elmi et al., 2024; Omboni et al., 2022).

Third, the literature has robustly demonstrated that there is not a consistent execution of clinical validation of the SaMD in telemedicine. Although jurisdiction might require evidence in terms of strong randomized controlled trials or strong real-world evidence before admitting the device into the market (Mallipeddi et al., 2017; Ming et al., 2022), some jurisdictions could accept weaker pieces of evidence, like retrospective analysis, or usability evidence that would be unlikely to define device efficiency against extremely risky patients (Mallipeddi et al., 2017). (Alenoghena et al., 2023; Serper & Volk, 2018). This discrepancy became more eminent in mobile health (mHealth) programs categorized as SaMD, where most of the products also evade rigorous validation due to confusing regulatory limits (Alelyani et al., 2021).

Fourth, interoperability and cybersecurity were identified as the common issues in the telemedicine SaMD assessment. The introduction of cloud-based analytics platforms, remote patient monitoring devices, and clinical information systems implies that powerful interoperability requirements should be in place. Nonetheless, some studies noted continuing problems with exchange protocols, latency and hacking threats to cybersecurity that pose

a risk to patient safety and violations (Albahri et al., 2018, Elmi et al., 2024). It was noted that the risk of cyber insecurity issues was also increased in the AI-based systems, where adversary campaigns could easily alter the outcomes of the algorithms undetected, which requires improved resilience tests to be carried out during the evaluation process (akkaoui et al., 2024).

Figure 2. Key Challenges in Telemedicine Software as a Medical Device (SaMD) Implementation



Fifth, monitoring the performance of SaMD after implementation into the environment was the practice that was recognized as critical and underdeveloped. Although both the IMDRF and the FDA TPLC model drive the importance of consideration of continuous monitoring, issues of fragmented reporting systems, a reduced standardization of performance measures, and a poor structure of integration with the electronic health records can lead to the limited amount of real-world evidence gathered (Omboni et al., 2022; Wilson & Maeder, 2015). Such inadequacy obstructs the ability to identify poor performance trends at an early stage and postpones corrective intervention.

Finally, the study results revealed the increased understanding that harmonized global uniformities are necessary. Several studies and regulatory guidance stated that IMDRF guidance should be more aligned with ISO standards (e.g., ISO 14971 - risk management, IEC 62304 - software lifecycle processes) and individual ones requirements to ensure that telemedicine SaMD are evaluated and approved easier (IMDRF, 2025; ISO 14971, 2024). The harmonization will lead to a more rapid innovation circle, and not at the cost of the safety of patients, or clinical effectiveness.

Broadly, the findings confirm that initial telemedicine SaMD evaluation is moving towards more lifecycle-based approaches, but is still hampered by isolated regulation, variation in clinical validation needs, technical interoperability problems and lack of post market controls. These results allow moving on to the next part of the debate about the regulatory, technological and methodological developments of the future, which can increase the safety, effectiveness, and international availability of telemedicine SaMD.

5. Discussion

The results of this research emphasise the dynamic and divided state of the telemedicine Software as a Medical Device (SaMD) evaluation, where regulatory discrepancies, inconsistent clinical validation, interoperability gaps, and inadequate post-market surveillance incidents are significant obstacles to the safe and successful established implementation. These findings correspond with the previous studies claiming that the rapidness of the spread of digital health technologies experienced during the pandemic quarantine aggravated the opportunities and challenges of SaMD evaluation (Omboni et al., 2022; Ming et al., 2022).

At the regulatory level, having varying frameworks between jurisdictions brings about a considerable level of compliance and prevents international scalability among developers. The Total Product Lifecycle (TPLC) model developed by the FDA is more adaptive as it focuses on the iterative improvement based on the real-life evidence and the MDR 2017/745 adopted in the European Union has a stricter pre-market requirement that could impede innovation (FDA, 2025; IMDRF, 2025). There are currently no harmonized definitions and classification criteria on SaMD, and as such, the same telemedicine application given similar treatment in one market could endure an entirely different treatment in another (Greenlight Guru, 2025; akkaoui et al., 2024). This supports arguments in favour of international harmonization of regulations especially with the International Medical Device Regulators Forum (IMDRF) and the standardization procedures offered by ISO (ISO 14971, 2024).

Equally serious problems are associated with the technological dimension. Although it better supports diagnosis and decision-making, AI-driven telemedicine platforms are sensitive to performance drift where the clinical environment is heterogeneous (Rauniyar et al., 2023; D'Onofrio & Zeng, 2022). Context specific validation of the parameters and adaptive algorithmic update is thus critical to ensure long-term reliability (Elmi et al., 2024). Furthermore, iability between the telemedicine SaMD and the disparities with existing health infrastructures further restricting the scalability of the IT. Incompatible data sets, delays, and cybersecurity risks impede smooth integration, which is concerned both with the safety of patients and regulatory compliance (Albahri et al., 2018; Omboni et al., 2022).

Of special controversy is clinical validation. The available literature specifies dramatic differences between the proposed validation standards, where some regulatory authorities still require the use of randomized controlled trials, and others allow the use of retrospective studies or simulation-based tests (Mallipeddi et al., 2017; Ming et al., 2022). Although streamlined validation is more effective at accelerating innovation, it also considerably raises the likelihood of premature rollouts of the tools with limited testing experience within the clinical environment, particularly in high-risk situations, i.e., remote cardiology or oncology diagnostics (Alelyani et al., 2021; Alenoghena et al., 2023). The absence of compatibility on appropriate validation practices is the highlight of the need to have standard tiered validation structures using device risk classification.

Monitoring of performance after the product enters the market became an underexplored and yet crucial element of SaMD. However, in the real world, collection of real-world evidence is uneven despite the frameworks such as the FDA TPLC and IMDRF lifecycle guidance recommending prospective monitoring (Wilson & Maeder, 2015; Omboni et al., 2022). Lack of strong post-market surveillance significantly undermines early warning on the adverse events or deterioration of the performance.

Convergence of these issues points to a common thread: SaMD assessment needs to shift by being continuously and harmoniously built into its assessment model of adaptiveness and lifecycle based on market. Besides considering the dynamic nature of AI-enabled systems, such a model would also help to more effectively regulate compliance through more effective compliance and enhance post-market oversight.

Table 3 synthesizes the key challenges identified in this study and proposes potential solutions based on emerging best practices and international policy trends.

Table 3. Key challenges in telemedicine SaMD evaluation and potential solutions

Challenge	Impact	Potential Solution	Supporting References
Regulatory divergence	Delays in market entry, increased compliance costs	Global harmonization via IMDRF and ISO frameworks	IMDRF (2025), ISO 14971 (2024), akkaoui et al. (2024)
Performance drift in AI systems	Reduced diagnostic accuracy in real-world settings	Adaptive algorithm updates, continuous revalidation	Rauniyar et al. (2023), Elmi et al. (2024)
Inconsistent clinical validation	Variable safety and efficacy outcomes	Tiered validation frameworks based on device risk	Ming et al. (2022), Mallipeddi et al. (2017)
Interoperability gaps	Limited scalability, data integration issues	Adoption of HL7 FHIR and standardized APIs	Albahri et al. (2018), Omboni et al. (2022)
Cybersecurity vulnerabilities	Risk to patient safety, regulatory non-compliance	Enhanced penetration testing, security-by-design	Elmi et al. (2024), akkaoui et al. (2024)
Weak post-market monitoring	Delayed detection of adverse events	Integrated real-world evidence platforms	FDA (2025), Wilson & Maeder (2015)

In summary, the discussion highlights that while telemedicine SaMD has the potential to significantly enhance healthcare delivery, realizing this potential requires overcoming persistent regulatory, technical, and methodological challenges. Future research should focus on developing interoperable, adaptive, and harmonized evaluation frameworks that not only ensure compliance but also drive innovation in patient-centered telemedicine solutions.

Conclusion

Telemedicine Software as a Medical device is at a critical point of its development in terms of evaluation. This paper has revealed that although the change in the delivery of health care based on digital health, artificial intelligence, and remote monitoring is evolving, the methods of evaluating solutions are disjointed and variable across jurisdictions. The results state that existing evaluation models are usually hampered by the conflicting regulations, the weak clinical validation processes, the interoperability and the cybersecurity risks, the inadequate monitoring of the performance of those products and services in the post-market.

There is a need to dramatically move beyond static, pre-market evaluation models to dynamic lifecycle-based models capable of embracing sustainable technological change and dynamic change in clinical contexts. The real-world

evidence, dynamic approaches to validation, and continuous regulatory monitoring must be part of such frameworks so that telemedicine SaMD could remain safe, efficacious, and reliable in the long term. Moreover, the harmonization is key to decreasing compliance burdens, rational cross deployments, and rapid innovation, whereas it does not breach patient safety.

Finally, a long-term collaboration between regulators, healthcare providers, technology developers, and international standards organizations will be key to the successful assessment of telemedicine SaMD. The regulatory policy, technical innovation, and clinical practice can be mapped in a way that enables the stakeholders to design an evaluation ecosystem that supports future high-quality, equitable patient-centered telemedicine solutions.

REFERENCES

1. Bellazzi, R. (2008). Telemedicine and diabetes management: current challenges and future research directions. *Journal of diabetes science and technology*, *2*(1), 98-104. https://doi.org/10.1177/193229680800200114
2. Elmi, A. A., Abdullahi, M. O., & Abdullahi, H. O. (2024). Internet of Things in Telemedicine: A Systematic Review of Current Trends and Future Directions. *Instrumentation, Mesure, Metrologie*, *23*(6), 463. https://doi.org/10.18280/i2m.230606
3. Alenoghena, C. O., Ohize, H. O., Adejo, A. O., Onumanyi, A. J., Ohihoin, E. E., Balarabe, A. I., ... & Alenoghena, B. (2023). Telemedicine: a survey of telecommunication technologies, developments, and challenges. *Journal of Sensor and Actuator Networks*, *12*(2), 20. https://doi.org/10.3390/jsan12020020
4. Mallipeddi, S. R., Goda, D. R., Yerram, S. R., Varghese, A., & Ande, J. R. P. K. (2017). Telemedicine and beyond: navigating the frontier of medical technology. *Technology & Management Review*, *2*(1), 37-50. https://hal.science/hal-04495006/
5. Wilson, L. S., & Maeder, A. J. (2015). Recent directions in telemedicine: review of trends in research and practice. *Healthcare informatics research*, *21*(4), 213-222. https://doi.org/10.4258/hir.2015.21.4.213
6. akkaoui, A., ZAHIDI, Y., El Moufid, M., DACHRY, W., GZIRI, H., & Medromi, H. (2024). Developing medical devices with emerging technologies: trends, challenges, and future directions. *F1000Research*, *13*, 1007. https://f1000research.com/articles/13-1007
7. Baker, J., & Stanley, A. (2018). Telemedicine technology: a review of services, equipment, and other aspects. *Current allergy and asthma reports*, *18*(11), 60. https://link.springer.com/article/10.1007/s11882-018-0814-6
8. Alelyani, T., Shaikh, A., Sulaiman, A. A., Asiri, Y., Alshahrani, H., & Almakdi, S. (2021). Research challenges and opportunities towards a holistic view of telemedicine systems: a systematic review. *Enhanced Telemedicine and e-Health: Advanced IoT Enabled Soft Computing Framework*, 3-26. https://link.springer.com/chapter/10.1007/978-3-030-70111-6_1
9. Ming, J., He, Y., Yang, Y., Hu, M., Zhao, X., Liu, J., ... & Chen, Y. (2022). Health technology assessment of medical devices: current landscape, challenges, and a way forward. *Cost Effectiveness and Resource Allocation*, *20*(1), 54. https://link.springer.com/article/10.1186/s12962-022-00389-6
10. Kawde, D., & Gourshettiwar, P. (2025, February). An Overview of Telemedicine: Evolution, Application, Challenges and Future Direction. In *2025 International Conference on Electronics and Renewable Systems (ICEARS)* (pp. 2028-2032). IEEE. https://doi.org/10.1109/ICEARS64219.2025.10940244
11. Angaran, D. M. (1999). Telemedicine and telepharmacy: current status and future implications. *American Journal of Health-System Pharmacy*, *56*(14), 1405-1426. https://doi.org/10.1093/ajhp/56.14.1405
12. Koch, S. (2006). Home telehealth—current state and future trends. *International journal of medical informatics*, *75*(8), 565-576. https://doi.org/10.1016/j.ijmedinf.2005.09.002

13. Rauniyar, A., Hagos, D. H., Jha, D., Håkegård, J. E., Bagci, U., Rawat, D. B., & Vlassov, V. (2023). Federated learning for medical applications: A taxonomy, current trends, challenges, and future research directions. *IEEE Internet of Things Journal*, *11*(5), 7374-7398. https://doi.org/10.1109/JIOT.2023.3329061

14. Osama, M., Ateya, A. A., Sayed, M. S., Hammad, M., Pławiak, P., Abd El-Latif, A. A., & Elsayed, R. A. (2023). Internet of medical things and healthcare 4.0: Trends, requirements, challenges, and research directions. *Sensors*, *23*(17), 7435. https://doi.org/10.3390/s23177435

15. Liss, H. J., Glueckauf, R. L., & Ecklund-Johnson, E. P. (2002). Research on telehealth and chronic medical conditions: Critical review, key issues, and future directions. *Rehabilitation Psychology*, *47*(1), 8. https://psycnet.apa.org/doi/10.1037/0090-5550.47.1.8

16. 1. Bobis, G., Liakou, C. I., Tzamaria, D., Plytas, M., & Papadakis, M. (2025). Clinical evaluation of Class I medical devices under European law: Data analysis and artificial intelligence integration for enhanced regulatory compliance. American Journal of Multidisciplinary Research and Development, 7(6), 152–160. https://www.ajmrd.com/wp-content/uploads/2025/06/H76152160.pdf

17. Bobis, G., Liakou, C. I., Tzamaria, D., Plytas, M., & Papadakis, M. (2025). Integrating artificial intelligence into clinical evaluation and materiovigilance: A European legislative perspective on enhancing medical device safety. American Journal of Multidisciplinary Research and Development, 7(6), 129–138. https://www.ajmrd.com/wp-content/uploads/2025/06/H76152160.pdf

18. Bobis, G., Tzamaria, D., Liakou, C.I., Evangelia, P., Papadakis, M. and Plytas, M., 2025. Post market clinical evaluation of medical devices integrating health economics and artificial intelligence for improved outcome. International Journal of Engineering Technologies and Management Research, 12(4). Available at: https://doi.org/10.29121/ijetmr.v12.i4.2025.1569 [Accessed 5 May 2025].

19. Bobis, G., Liakou, C. I., Tzamaria, D., Plytas, M., & Papadakis, M. (2025). Clinical trial assessment principles for high-risk medical devices in the European Union: How long short-term memory (LSTM) neural networks integrate. International Journal of Innovative Research in Computer and Communication Engineering, 13(4). https://doi.org/10.15680/IJIRCCE.2025.1304006

20. Petaniti, E., Tzamaria, D., Liakou, C. I., Papadakis, M., & Plytas, M. (2025). Clinical evaluation of class II medical devices: Data analysis and artificial intelligence integration for enhanced regulatory compliance. IOSR Journal of Multidisciplinary Research (IOSR-JMR), 2(2, Series 2), 7–16. https://doi.org/10.9790/7439-0202020716

21. Liakou, C. I., Tzamaria, D., Plytas, M., & Papadakis, M. (2025). CTLA-4 therapy and dementia: A review of immunomodulation in neurodegenerative disease.

22. Serper, M., & Volk, M. L. (2018). Current and future applications of telemedicine to optimize the delivery of care in chronic liver disease. *Clinical Gastroenterology and Hepatology*, *16*(2), 157-161. https://doi.org/10.1016/j.cgh.2017.10.004

23. Albahri, O. S., Albahri, A. S., Mohammed, K. I., Zaidan, A. A., Zaidan, B. B., Hashim, M., & Salman, O. H. (2018). Systematic review of real-time remote health monitoring system in triage and priority-based sensor technology: Taxonomy, open challenges, motivation and recommendations. *Journal of medical systems*, *42*(5), 80. https://link.springer.com/article/10.1007/s10916-018-0943-4

24. Omboni, S., Padwal, R. S., Alessa, T., Benczúr, B., Green, B. B., Hubbard, I., ... & Wang, J. (2022). The worldwide impact of telemedicine during COVID-19: current evidence and recommendations for the future. *Connected health*, *1*, 7. https://pmc.ncbi.nlm.nih.gov/articles/PMC7612439/

25. D'Onofrio, K. L., & Zeng, F. G. (2022). Tele-audiology: Current state and future directions. *Frontiers in Digital Health*, *3*, 788103. https://doi.org/10.3389/fdgth.2021.788103

26. Celler, B. G., & Sparks, R. S. (2014). Home telemonitoring of vital signs—technical challenges and future directions. *IEEE journal of biomedical and health informatics*, *19*(1), 82-91. https://doi.org/10.1109/JBHI.2014.2351413