Improving Regulatory Compliance in AI Software as a Medical Device: A Mixed-Methods Analysis of Stakeholder Perspectives and Design Strategies

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Abstract

Background: AI integration into medical devices is an inevitable trend, poised to redefine the healthcare landscape. These AI-driven devices can process vast amounts of patient data with unparalleled speed, enabling more accurate diagnostics and tailored treatment approaches. With AI at the core, medical devices are becoming smarter and more responsive, providing real-time insights that support clinicians in making precise, data-backed decisions. As this technology advances, it will drive greater efficiency, reduce medical errors, and enhance the quality of patient care, marking a new era where AI is essential in modern medicine. However, the commercialization of AI SaMD may face significant challenges due to insufficient regulatory frameworks, inadequate design processes, and poor collaboration among stakeholders. Failure to address these development challenges may lead to wasted resources and ultimately unsuccessful outcomes.

Objective: This study aims to guide medical device manufacturers in effectively adapting to this trend and understanding strategies for complying with medical regulations in the AI device design process. Manufacturers must stay updated on regulatory changes, particularly in specialized training and regulatory review processes. This will help balance innovation with compliance, enabling a smooth advancement of AI-driven technology in medical devices.

Methods: This study constructs an analytical framework based on a comprehensive literature review and interviews with key stakeholders involved in AI SaMD development, including academics, researchers, manufacturers, clinical participants, and regulatory consultants. Following the framework's establishment, the Imperative-External Assistance Analysis (IEA) and the Decision-Making Trial and Evaluation Laboratory (DEMATEL) methods were utilized to identify the interaction structures among the identified factors. This approach facilitates the determination of effective coping strategies that enhance the efficacy of AI SaMD development and implementation.

Results: This study collected data from interviews with 16 stakeholders and analyzed 68 questionnaire responses. It proposes an AI design process evaluation framework comprising 17 factors across four stages: Pre-processing, Model Establishment, Clinical Evaluation, and Registration. This framework was applied to assess AI SaMD design and development and identify improvement strategies. Specifically, it emphasizes strengthening internal management during the Pre-processing stage, retaining the current practices in Model Establishment, and seeking external expertise for the Registration and Clinical Evaluation stages. Tailored recommendations for each development stage are also provided to support effective AI SaMD development.

Conclusions: This study examines the design and development of AI-based Software as a Medical Device (SaMD) and introduces a feasibility analysis model that integrates regulatory requirements. It underscores the critical role of collaboration among software engineers, medical professionals, and regulatory experts for successful AI SaMD development. Additionally, this study serves as a practical guide for stakeholders in the AI SaMD industry, fostering collaboration and building consensus. By adopting effective strategies early in the design and development process, stakeholders can accelerate AI SaMD innovation, achieve regulatory compliance more efficiently, and ultimately enhance healthcare quality. Clinical Trial: not applicable

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Keywords: Digital Health, Artificial Intelligence, Medical Devices, Medical Software, Artificial Intelligence-based Software as Medical Devices, Decision-Making Trial and Evaluation Laboratory, Management Strategies.

Introduction

Based on the existing ICT (Information and Communications Technology) with the help of emerging technologies, such as the Internet of Things (IoT), big data(BD), artificial intelligence (AI), remote and mobile platforms, and wearable devices, which lead to a super- connected society where healthcare industry can get an enormous benefits for diverse purposes, such as for storing electronic health records as well as medical records, patient remote monitoring, medical education, physician-patient communication, and real-time behavioral tracking [1]. Therefore, various countries began to focus and promote Digital health development, hoping to improve the efficiency and quality of healthcare services and achieve the purpose of reducing medical burden.

In recent years, the independent functionality of medical software has even surpassed that of traditional medical devices or hardware. Coupled with the expansion of medical big data (MBD), generated from vast amounts of EHRs, EMRs, and other medical information, this development facilitates the application of AI technology in the healthcare field. Integrating AI into medical devices, known as AI SaMD (Artificial Intelligence-based Software as a Medical Device), has become an inevitable trend to enhance healthcare benefits. AI SaMD enables medical software to analyze large volumes of MBD and generate diagnostic insights, assisting healthcare professionals in performing efficient medical analysis and decision-making. Furthermore, it helps reduce medical errors and saves time in healthcare workflows [2].

However, The AI SaMD requires extensive clinical data combined with machine learning techniques to create algorithms that aid in disease diagnosis and monitoring. These algorithms must align with the intended use and meet user expectations, particularly healthcare professionals. This highlights the importance of accurate data collection and annotation during AI model training to ensure precise clinical outputs [3]. The innovation and implementation of such digital health applications demand significant resource investments, the integration of professional medical expertise, and the consideration of patient safety, further complicating the process [4, 5]. Previous research indicates that failure to address development challenges can lead to wasted resources and unsuccessful innovation [6-9] . Resistance from various stakeholders can also hinder innovation acceptance,

necessitating strategies to identify and mitigate such resistance[7, 10].

Furthermore, the adaptability and variability of AI amplify the challenges in regulatory oversight. The U.S. Food and Drug Administration (FDA) has proposed amendments to its regulatory framework for medical devices that incorporate AI and machine learning algorithms. Thus, the AI SaMD needs to be supervised with the safety and effectiveness evaluation in the process of commercialization [11-13]. Additionally, coordination with clinical resources and integration of unmet clinical needs are crucial, requiring the involvement of multiple stakeholders from various disciplines [14, 15]. Ultimately, the commercialization of AI SaMD may encounter significant challenges due to insufficient regulatory frameworks sense, inadequate design processes, and poor collaboration among stakeholders [11, 15-17].

Countries around the world have been actively adopting Digital Health solutions to alleviate the healthcare burden and improve the quality of care. Taiwan, with its strong ICT capabilities and advanced 4G/5G network and healthcare infrastructure, holds significant potential for Digital Health development. Moreover, the Ministry of Health and Welfare (MOHW) has been proactive in promoting the National Health Insurance (NHI) system, which has facilitated the widespread adoption of Electronic Medical Records (EMR) and Electronic Health Records (EHR). This system now represents a comprehensive medical database covering nearly the entire population of Taiwan. The vast amount of medical data accumulated over decades has formed a robust foundation of MBD, which enables extensive data analysis and exploration by researchers and medical institutions. This wealth of data and ICT capabilities has created a solid foundation for digital health innovation in Taiwan, positioning the country as a key indicator for the future development of the digital health industry [18-20], which could further accelerate the progress of the technological and commercialization of Digital Health industry.

Consequently, this study investigates the challenges and barriers encountered during the design and development of AI SaMD in Taiwan. We identify and clarify these obstacles, constructing an analysis framework based on the development process. By employing analytical methods such as Content Analysis, Imperative-External Assistance Analysis (IEA), and Decision-Making Trial and Evaluation Laboratory (DEMATEL), We transform qualitative research into quantitative insights and, furthermore, propose effective solutions and managerial strategies. The goal is to provide a valuable reference for stakeholders, including healthcare institutions and industries, to enhance the success rate of AI SaMD implementation and improve the efficiency of resource allocation.

Literature review

The Development and regulatory supervision of AI SaMD

The Medical Big Data formed by the hospital’s large number of records enables AI to analyze and propose judgment results based on a large amount of medical data to assist medical staff. At the same time, to carry out efficient analysis and decision-making through quick and precise image interpretation, AI technology in conjunction with a medically assisted diagnosis system can be used to diagnose a wide range of diseases [15]. Jha and Topol [21] pointed out in the early years that AI could effectively improve the accuracy, speed, and consistency of results by analyzing large amounts of clinical data, medical records, and medical management systems in terms of medical imaging and disease control mechanisms. Allen Jr, Seltzer [14] introduce the roadmap for AI translational research in the medical field and mention that translational research and implementation of AI in the medical field can help physicians, nurses, and other medical personnel to simplify their work and reduce the loading. Additionally, academic institutions and industry are contributing to the rapid

development of machine learning in medical imaging and the potential benefits of using AI in medical imaging, it could also quickly integrate, and process scientific literature and electronic medical records, further providing precise treatment methods and reducing medical errors. They also propose some suggestions for promoting the development of AI medical applications, such as strengthening education and training, establishing better data-sharing platforms, and formulating stricter regulatory policies, but also face some technical and ethical issues that need to be addressed.

Some of the research discusses the current state and role of AI in healthcare and explores the pros and cons of relying on AI to analyze medical data. The AI implementation could improve accuracy, efficiency, and workflow, while the disadvantages include potential biases, privacy and security issues, and a lack of transparency [3, 13]. Topol [3] highlights the challenges faced by the healthcare industry and the potential of data-driven solutions to improve patient outcomes. Furthermore, Yaeger, Martini [13] mention the evolution of regulatory oversight for medical devices and software applications in response to changing technology, as well as the need for regulatory bodies to rapidly respond to new technologies such as AI. And through the challenges and opportunities associated with adopting AI in healthcare from a regulatory perspective, including balancing innovation with safety concerns.

In short, AI is widely used in the medical field, mainly for recording, and storing medical data, clinical testing and analysis, patient monitoring and management, medical diagnosis and treatment, drug research and development, personalized medicine, and hospital service system decision-making and management. In addition to the algorithms involved in AI itself, the developers must also pay attention to issues such as data monitoring, personal data privacy, and data usage restrictions [3, 22]. However, the adaptive nature of the AI SaMD algorithm can continue to learn independently and further change the software performance based on the large amount of information received, such as disease characteristics, ethnic distribution, and medical care status. Such characteristics and developments have brought great challenges to both regulators and developers. The past researches indicated that the existing regulatory paradigms are not well-suited to balancing patient safety with furthering the growth of this new sector due to the unique characteristics and novelty of AI SaMD [11].

However, AI biomedical technology-related innovations have flourished under the encouragement of governments, but have rarely been successfully commercialized. Different from medical devices that have been approved in the past, AI SaMD is difficult to apply for listing in a substantially equivalent process due to the "black box" algorithm for declared indications and intended use. Furthermore, the summary documents from the approved product z that the submitted for marketing are mostly approved through the De Novo procedure and the relevant clinical evaluation report must still be included to prove the claimed efficacy of the product. According to the USFDA database and past research, only about 230 AI SaMD algorithms have been approved by the end of November 2022, and there are still a lot of recall problems to work on [23]. Furthermore, in a study exploring the deployment of AI-enabled wearable medical devices, Some researchers pointed out that lack of collaboration between stakeholders is the most critical barrier to the development of AI medical devices which includes technical, clinical, legal, and managerial reasons [17].

Thus, the collaboration between technical, clinical, legal, and managerial experts for effective quality management, creating a well-established machine learning system through safety and effectiveness verification, and transparent data performance monitoring could become the most significant challenges for AI SaMD development. [3, 11, 13, 17, 24]. Developers may encounter numerous obstacles when addressing regulatory requirements during the design and development of AI SaMD [11].

Therefore, focusing on the regulatory perspective of AI SaMD design and development, we extract the factors that affect the AI SaMD development and commercialization and provide the frameworks and strategy for stakeholders in the AI SaMD industry through clear quantitative figures and concrete development strategies.

Design and development of AI SaMD

The past research indicated that the design and development process of AI SaMD started with the purpose of clinical application which is to fill the unmet need. It needs to integrate a large amount of clinical data and machine learning technology to construct an algorithm model; besides, AI SaMD focuses on data collection and processing to train the AI algorithm model and ensure that the software can output clinical diagnostic evidence [3, 13]. In earlier research Park and Han [12] provide valuable insights into the methodology involved in using AI technology for diagnostic or predictive analysis in the medical field, and further discuss the use of statistical methods to evaluate the performance of high-dimensional or overparameterized diagnostic or predictive models, as well as the use of reporting guidelines to achieve better reporting. Chassagnon, Vakalopoulou [25] also mention a few challenges associated with developing algorithms such as data collection and construction during an overview of the applications of AI in thoracic imaging. In addition, Gerke, Babic [24] mention that medical AI products need to be reviewed by regulatory agencies before they can be marketed, and relevant evidence needs to be provided to demonstrate their safety and efficacy. Additionally, they emphasize that regulatory agencies need to shift their focus from evaluating individual products to evaluating entire systems to ensure the long-term safety and efficacy of medical AI systems. Consequently, In the case of ensuring the safety and effectiveness of diagnosis and treatment, the development of AI SaMD faces many regulatory problems and technical challenges.

This study reviewed the development process and key aspects of AI SaMD based on existing literature and outlined the commercialization process into several main developmental stages: Pre-processing, Model Establishment, Clinical Evaluation, and Registration. Based on the four key stages of AI SaMD development, this research also references the regulatory process of medical software. It identifies the regulatory requirements at each development stage to create an analysis model for design and development.

Pre-processing

At the beginning of AI SaMD product design, serious consideration must be given to addressing unmet clinical needs (e.g., assisting in diagnosis or informing clinical management) to ensure the safety and effectiveness of the product for patients. Developers should set software development goals based on market demand (clinical needs, clear intended use, and clinical application scope), the technical requirements for product development (design control and risk management systems), and the regulatory requirements of the target market (varying by nation) [14]. Subsequently, product development plans should be formulated, utility indicators established for each stage of development, and a design and quality control system put in place [24, 26, 27].

Additionally, developers must confirm the product's risk classification and the applicable evaluation standards for safety and effectiveness based on the intended use and the regulations of the target countries [13, 24]. AI SaMD requires large amounts of clinical data to build algorithms, and the collaboration and participation of medical professionals, particularly physicians and clinicians, are essential [14, 15]. Their role includes defining the required conditions and scope of clinical data, data

characteristics and annotations, as well as planning and executing clinical trials [25].

Given concerns regarding access to medical information and patient privacy, the acquisition of clinical data must be approved by Institutional Review Boards (IRB) before labeling and inputting it into the algorithm [28].

Model Establishment

At the algorithm development stage, it is essential to conduct design control planning and clarify risk considerations and assessment criteria to ensure safety and effectiveness [24]. The design of AI SaMD algorithms can be summarized in three key steps: data input, algorithm training, and data output. Developers must build machine learning models, perform system training, and iteratively refine the algorithms to establish their design principles and processing sequences [14].

During the construction process, the performance of the AI algorithm must be evaluated by assessing false negatives and positives, repeatability, reproducibility, and stability to ensure it meets the design requirements [15, 16, 29].

Additionally, the potential impact of accessing patient medical information on privacy should be carefully considered. Developers must evaluate network security capabilities and vulnerabilities according to regulatory requirements and develop systems to address issues such as cyberattacks and network security threats [3, 11, 22].

Clinical Evaluation

To finalize the model prototype, the AI SaMD product should be deployed in the medical field for further testing using real-time clinical data, assessing whether the product meets expected indicators such as accuracy, sensitivity, and specificity requirements [3, 14]. Additionally, the clinical evaluation environment (e.g., hospital information systems like picture archiving and communication systems, PACS) must be designed to accommodate various test requirements as the foundation for clinical trials [29]. By observing, recording, and analyzing user behavior and feedback, developers can further refine the product design [15].

Given the diversity of disease states and the complexity of real-world clinical settings, a thorough clinical study and evaluation of AI SaMD is crucial, particularly in support of Premarket Approval (PMA) [12]. However, all AI SaMD products must have an approved Investigational Device Exemption (IDE) to allow deployment in clinical studies for collecting safety and effectiveness data. Additionally, clinical evaluations should comply with Good Clinical Practice (GCP), including an investigational plan approved by an IRB, informed consent from patients, and the proper conduct of clinical studies.

The objectives of the trials and the implementation of clinical indicators should be clearly defined and documented, including sensitivity, accuracy, recruitment criteria, sample size, and statistical methods [12-14]. Furthermore, the progress and outcomes of clinical trials—including hospital and physician evaluations, informed consent collection, trial execution, data collection, and statistical analysis—must be recorded in accordance with regulatory requirements [3, 12].

Registration

After sufficient data and evidence are collected, the relevant administrative and technical documents

from the AI SaMD development process must be submitted to the regulatory authority. These include design control, quality management, and risk management documents that demonstrate the software's quality evaluation system [24, 27], the software data specifications [14], the software development plan [26], and, most importantly, the safety and effectiveness test report [3, 12]. Once approved, the product can be certified and enter the market, accompanied by post-market surveillance activities [11, 13].

Methods

Research Design

This study identified the design and development factors of AI-based Software as a Medical Device (AI SaMD) by collecting information from literature reviews, the AI SaMD regulatory discussion paper, and the action plan, which were then used to develop a semi-structured interview outline. Through face-to-face interviews with stakeholders, the research further explored important issues, extracted critical factors through content analysis, and developed a questionnaire for distribution to stakeholders. The qualitative data were then transformed into quantitative data using data analysis methods such as Imperative-External Assistance Analysis (IEA) and Decision-Making Trial and Evaluation Laboratory (DEMATEL), which helped to illustrate the development strategies (Figure 1).

Additionally, based on the literature review and preliminary interview results, it was recognized that the development of AI SaMD should involve collaboration and interaction among cross-disciplinary professionals, including experts in technical engineering, clinical medicine, and regulatory affairs. Therefore, the stakeholders interviewed and surveyed in this research included AI SaMD manufacturers and operators, clinical personnel involved in AI SaMD development, academics and researchers working on AI SaMD-related technologies, and regulatory consultants experienced in AI SaMD certification. These experts helped confirm the accuracy and completeness of the design and development factors.

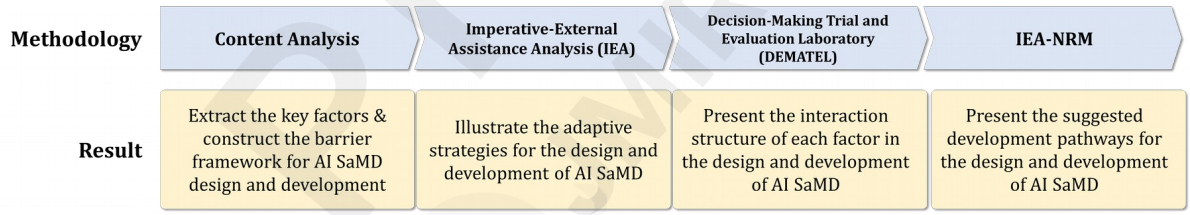

Figure 1. Framework of hybrid methodologies applied in the research process

The content of the questionnaire is divided into three parts. The first part gathers basic information, including the personal details of the respondent and their role and position in the development of AI medical devices. The second and third parts focus on constructing the IEA-NRM analysis model for the regulatory design and development process dimensions and factors of AI SaMD. This model comprises two main phases.

Imperative-External Assistance Analysis (IEA): This phase helps to identify the urgency and assistance needed of the design and development processes. It is implemented using a graph with an XY axis that plots normalized values for Imperative and External Assistance. The Imperative and External Assistance values determine the strategic actions needed to address each key factor.
DEMATEL Method for Network-Relationship Map (NRM): In this phase, the DEMATEL method is used to construct a Network-Relationship Map (NRM), which helps understand the mutual

influences between various aspects and factors. It calculates the relative importance of each factor, aiding in the development of a resource allocation strategy and the selection of an appropriate development strategy.

The questionnaire was distributed across various regions of Taiwan. Participants included 10 AI SaMD-related developers, including 3 listed companies; 5 medical institutions, comprising 3 medical centers and 2 regional hospitals; 8 academic and research institutions, including AI technology R&D centers, national research institutes, and technical research institutions; and 4 regulatory-related consultants and management organizations, such as a regulatory certification company, a contract research organization (CRO), and the government agency responsible for medical device regulations in Taiwan.

Analysis tool

Content Analysis

Content analysis is an established research methodology used to interpret textual data by systematically coding and analyzing themes. As described by Neuendorf [30], it involves describing and explaining the state or development of a phenomenon at a given time. The purpose is to gain insights and explanations on a subject by categorizing data and refining the research themes throughout the process. This approach supports the creation of both descriptive and explanatory knowledge [31].

The process of content analysis relies on a systematic coding approach where data is categorized based on relevance and frequency, leading to inferences from small but meaningful units of text, such as phrases or sentences. Categories are continuously refined by "confirming back and forth" between conceptualization, data gathering, analysis, and interpretation, which ensures that interpretations remain grounded in the data and context of the study [32].

For reliability, content analysis often involves calculating inter-coder reliability, which measures the consistency among different coders in categorizing the data. Kassarjian and Kassarjian [33] indicate that a reliability coefficient above 0.85 is generally considered satisfactory, suggesting high agreement and thus a reliable coding result.

Imperative-External Assistance Analysis (IEA)

Chen [34], based on the Important-Performance Analysis (IPA) proposed by Martilla and James [35], proposed the Important-Resistance Analysis (IRA). Taking importance and resistance as the dual axes, we divided the four quadrants into resource investing, suspension, maintaining status, and priority processing and used them to explore the resource allocation strategy of medical big data applications. This research further extends and proposes the Imperative-External Assistance Analysis (IEA) model and applies it to the AI SaMD development process. The method could analyze the factors and place them in a two-dimensional matrix according to urgency and external assistance demand; thus, improvement strategies could be developed accordingly.

For further explanation, as shown in Figure 2, the horizontal axis is the Imperative Index (II), which indicates the level of urgency of the factors for the organization in developing AI SaMD; The vertical axis is the External Assistance Index (EAI), which indicates the level of external assistance demand for AI SaMD developers, such as outsourcing or consultation. The 4 quadrants would show the location of factors identified by the high (H) and low (L) values of the index and further provide the

strategies as 1) *priority in seeking external assistance*; 2) *temporarily postpone external assistance*; 3) *retain the internal status*; and 4) *priority internal management*, for decision-makers to make development decisions.

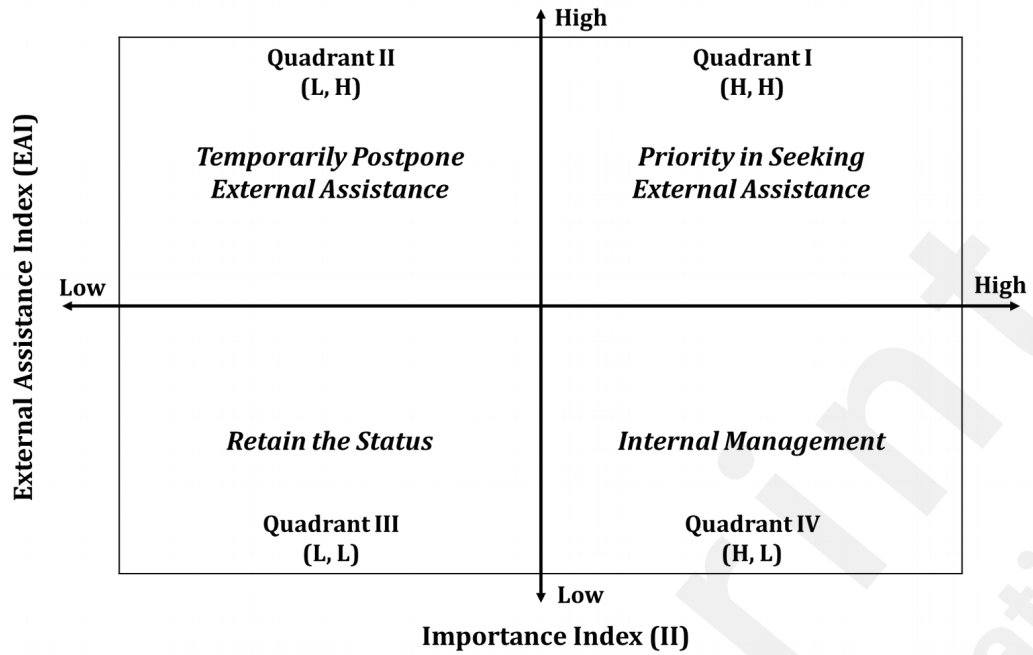

Figure 2. Framework of Imperative-External Assistance Analysis (IEA)

Decision-Making Trial and Evaluation Laboratory (DEMATEL)

From 1972 to 1976, within these 4 years, Decision-making trial and evaluation laboratory method (DEMATEL) was originally developed by the Science and Human Affairs Program of the Battelle Memorial Institute of Geneva. The major characteristic of DEMATEL method is that it can confirm the interdependence among the elements of a system through a causal diagram to describe the basic concept of contextual relationships and the strengths of influence among the elements by a hierarchical structure[36]. The DEMATEL method can recognizes the interdependence among the elements of a system through a causal diagram, in which diagraphs are utilized instead of graphs to portray the basic concept of contextual relationships and the strengths of influence among the elements [37]. The procedure of this method is divided into six steps:

Step 1. Compute the average matrix.
Step 2. Initial-influence matrix.
Step 3. Establish normalized direct-influence matrix.
Step 4. Calculate the indirect influence matrix.
Step 5. Calculate the total- relation matrix.
Step 6: Performing the structure association analysis.

As for the calculations, the causal degree (d-r) value indicates the impact relationship between factors when the value is positive and negative, respectively, if the difference is higher than 0, it means the degree that this indicator influences other indicators is higher than being affected; if the difference is less than 0, it means that the degree that this indicator is affected by other indicators is higher than it influences others. Besides that, the level of significance (d+r) value expresses the strength of the connection of factors. If the degree of (d+r) is higher, it means the relationship between indicators is stronger, otherwise, it is smaller. Take the (d+r) as the X axis and (d-r) as the Y

axis, and then draw the Network Relationship Map (NRM). NRM can be obtained by mapping all coordinate indicators to visualize the complex interrelationship as well as provide information to judge which the most important factors are and how the inter-influence of factors.

IEA/ IAA-NRM Model

Wang, Lin [38] extended Martilla and James [35] Importance-Performance Analysis (IPA) to Satisfaction-Importance Analysis (SIA) to evaluate the performance of each department in manufacturing, with the DEMATEL, the results were integrated into the SIA-NRM model to identify factors that may contribute to underperformance. Later, Chen (2018) established an Importance-Resistance Analysis (IRA)-NRM model to analyze the main applications of medical big data and formulate a strategic path for the development of medical big data. This study introduces the IEA-NRM and IAA-NRM models, and sorts according to the degree of the Imperative, External Assistance, Importance, and Acceptance index on the axes with NRM to determine the relevant optimal solution pathway.

Practical study and results

This research included a total of 9.05 hours of interviews with 16 stakeholders involved in the development of AI SaMD. The participants consisted of 5 academics and researchers (31.3%), 3 clinic participants (18.8%), 6 AI SaMD manufacturers and operators (37.5%), and 2 regulatory consultants and experts (12.5%). The study discussed and identified the regulatory and commercialization challenges faced during the design and development of AI SaMD, with participants providing consent for the interview recordings to be transcribed, organized, and coded.

Three PhD students served as coders for this study, analyzing the verbatim transcripts of the interviews. The coding was based on various stages of AI SaMD development, categorized into four main aspects: pre-processing, model building, clinical trials, and registration. The transcripts were coded according to these stages. Through mutual agreement among the coders and reliability testing, the study achieved a reliability score of 0.962, which is above the accepted standard of 0.8.

The analytical frameworks of AI SaMD design and development

Drawing on the literature review and interview findings, this research identified four key aspects critical to the regulatory design and development of AI SaMD.

Pre-processing (PP): This stage involves acquiring medical data and performing data preprocessing, which is essential for product development.
Model Establishment (ME): In this stage, a machine learning model is constructed, followed by system training and necessary adjustments.
Clinical Evaluation (CE): This phase requires completing the model and conducting clinical trials, including developing and refining the trial plan and evaluation metrics.
Registration (RT): The final stage involves preparing and submitting the required documents to the regulatory agency (such as the FDA) for medical review and registration.

Each of these aspects, along with their definitions and operational details, is presented in Table 1.

Table 1. The description of the key factors to the design and development AI SaMD

Aspect/ Factor	Description	Literature	Inter.

Pre-processing (PP)		In the early stage of product development, the acquisition and preprocessing of medical data		
PP1	Quality Management System	Build up the design and quality control system to ensure the intended use set by the manufacturer meets the regulatory requirements.	Niel and Bastard [27]; Gerke, Babic [24]	□
PP2	Development requirements planning	To setting the software development goals, specifications, and performance criteria for each stage based on market demand, the technical threshold for product development, and the regulatory requirements of the target market.	Liu, Zhou [26]; Allen Jr, Seltzer [14]	□
PP3	Regulatory pathway planning	To confirm the classification of products with applicable evaluation standards on safety and effectiveness of regulation for targeted countries.	Yaeger, Martini [13]; Gerke, Babic [24]	□
PP4	Medical personnel involvement	The intended use requires medical personnel (physician/ clinician) to be involved and provide clinical expertise to assist in product development. (including defining clinical needs, data characteristics and annotations, clinical trial planning, and execution).	Chassagnon, Vakalopoulou [25]; Currie, Hawk [15]; Allen Jr, Seltzer [14]; Gerke, Babic [24]	□
PP5	Clinical data define and accepting	Define the required conditions and scope of clinical data collection for the intended use plan the quality and quantity of data for AI training to be approved by the IRB for further labeling and input to the algorithm.	Chassagnon, Vakalopoulou [25]; Bahado-Singh, Vishweswaraiah [28]	□
PP6	Data preprocessing and classify	Collaborate with medical personnel to label quality data that meets the specification requirements and perform grouping of data sets.	Chassagnon, Vakalopoulou [25]	□
Model Establishment (ME)		Establish a machine learning model, and conduct further system training and adjustment		
ME1	Algorithm design	Identify the principles, methods, and risk considerations of algorithm design.	Park and Han [12]; Allen Jr, Seltzer [14]	□
ME2	Algorithm performance evaluation	Evaluating and clarifying the performance of the algorithm meets the design requirements.	Currie, Hawk [15]; Toh, Dondelinger [16]	□

ME3	Cyber security protection consideration	Analyze network security capabilities and vulnerabilities, and construct the ability to deal with network threats.	Carter, Rogers [22]; Topol [3];	□
Clinical Evaluation (CE)		Complete the model and conduct clinical trials, establish a complete trial plan and evaluation indicators		
CE1	Clinical trial design and preparation	Confirm the purpose and expected results of the clinical trial, determine relevant clinical indicators, and further discuss and confirm the evaluation plan.	Park and Han [12]; Yaeger, Martini [13]; Allen Jr, Seltzer [14]	□
CE2	Clinical trial IDE application	Preparing IDE submission and correspondence for IDE review comments.	Yaeger, Martini [13]	□
CE3	Clinical trial IRB application	Preparing IRB review documentation for clinical investigation and correspondence for IRB review comments.	Bahado-Singh, Vishweswaraiah [28]	□
CE4	Clinical trial execution	Collaborate with medical institutions and physicians to implement clinical trials for data collection, evaluation, and analysis followed by the GCP.	Park and Han [12]; Yaeger, Martini [13]; Allen Jr, Seltzer [14]	□
CE5	Clinical trial report composing	Complete the evaluation report according to the clinical trial results and fit the regulatory requirements.	Park and Han [12]; Topol [3]	□
Registration (RT)		Complete the relevant documents and send them to the authorities for inspection and registration		
RT1	Administrative registration process Confirmation	Confirmation of the completeness of administrative processes and documents to facilitate inspection and registration	Yaeger, Martini [13]; Harvey and Gowda [11]; Gerke, Babic [24]	□
RT2	Technical registration documents preparation	Preparation of the technical documents to meet the regulatory requirements of the listed countries.	Yaeger, Martini [13]; Harvey and Gowda [11]	□
RT3	Registration review response	Clarify the submission specification and manage the reply to the review.	-	□

Inter.: Mention through the interview

Result of IEA-NRM model

In the data collecting period, a total of 68 questionnaire responses were obtained in this study (Table 2), including 28 academics and researchers (41.18%), 16 AI SaMD manufacturers and operators (23.53%), and 17 clinic participants (25.00%) and 7 AI SaMD regulatory consultants and experts (10.29%). In addition, the respondents in this research are all AI SaMD professionals. They have relevant development experience and knowledge (27.90% of 0-5 years, 13.2% of 5-10 years, 17.60% of 10-15 years, 19.1% of 15-20 years, and 16.2% of those who are more than 20 years, and the average service years is 13.04 years), with a considerable proportion of middle-level and senior/executive managers and administrators (20.59% of junior managers, 16.18% of middle-level managers, and 38.24% of senior/executive managers) included.

Table 2. The descriptive statistics of respondents

Background	Number of samples	Ratio
Academics and Researchers	28	41.18%
Manufacturers and Operators	16	23.53%
Clinic Participants	17	25.00%
Regulatory Consultants and Experts	7	10.29%
Total	68	100%

The general aspects of the AI SaMD design and development

In the 4 development aspects of the AI SaMD design and development, the result shows that the “Registration (RT)” aspect and the “Clinical Evaluation (CE)” aspect are highly urgent and require an immediate search for external support, and would adopt the strategy of “priority in seeking external assistance”; The “Model Establishment (ME)” aspect stated as low urgency and requires low level of external assistance, would adopt the “Retain the internal status” strategy; the “Pre-processing (PP)” aspect is urgent but requires less external assistance, adopt the “Priority internal management” strategy.

As shown in the NRM (Table 3 and Figure 3), “Pre-processing (PP)” is the primary and dominant aspect, and “Clinical Evaluation (CE)” is the last aspect dominated by others. From the total-influence matrix (Table 4) and diagram (Figure 3), we can find that the “Pre-processing (PP)” aspect influences the “Model Establishment (ME)”, “Registration (RT)”, and “Clinical Evaluation (CE)” aspect; the “Model Establishment (ME)” aspect influences the “Registration (RT)” and “Clinical Evaluation (CE)” aspect while the “Registration (RT)” aspect influences the “Clinical Evaluation (CE)” aspect.

Table 3. Imperative-External Assistance index, Interdependent Direct, and total impact of

General Aspects	**IEA**			**NRM**	
	II	EAI	(II, EAI)	d_i+r_i	d_i-r_i
Pre-processing (PP)	0.764	-0.238	(H, L)	20.7854	1.4873
Model Establishment (ME)	-1.277	-1.435	(L, L)	21.7588	0.5100
Clinical Evaluation (CE)	1.093	0.483	(H, H)	22.0169	-1.0049

Registration (RT)	0.171	1.281	(H, H)	20.3305	-0.6602
II: Imperative Index; EAI: External Assistance Index; L: Low; H: High.					

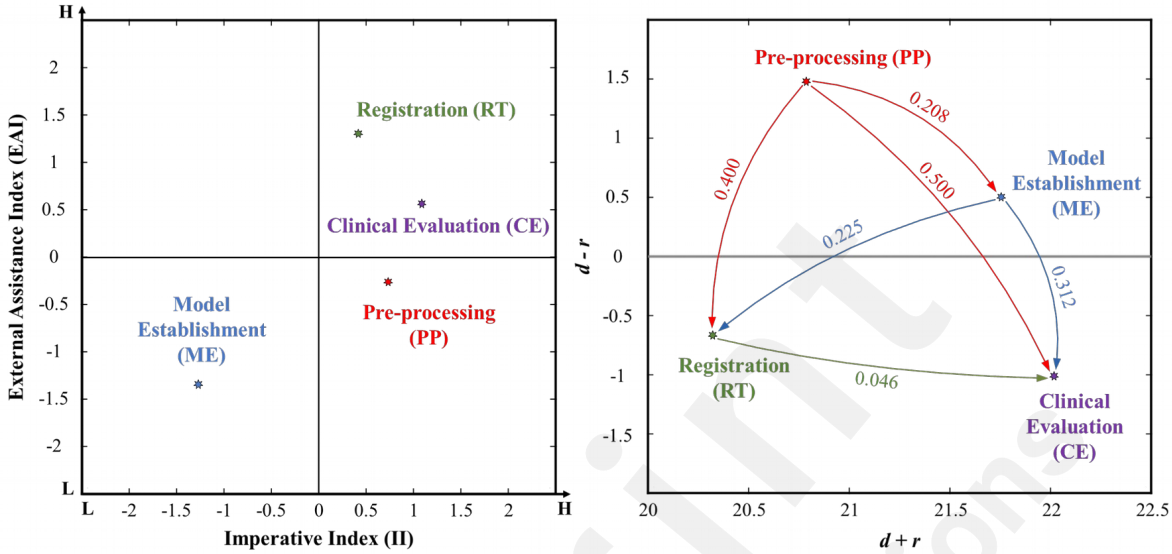

Figure 3. The IEA-NRM analysis diagram of the general aspects of AI SaMD design and development

Table 4. total-influence matrix of General aspects

Influence matrix	**PP**	**ME**	**CE**	**RT**
PP	-			
ME	-0.208	-		
CE	-0.500	-0.312	-	
RT	-0.400	-0.225	0.046	-

In the following sections, we analyze and explain the factors of each aspect based on the 4 aspects.

Pre-processing aspect

In the pre-processing aspect (Table 5 and Figure 4), “Medical personnel involvement (PP4)” is highly urgent and requires an immediate search for external support, which would adopt a “priority in seeking external assistance” strategy; “Quality Management System (PP1)”, “Development requirements planning (PP2)”, and “Regulatory pathway planning (PP3)” have high external assistant demand but not urgent, which adopt the strategy of “temporarily postpone external assistance”; “Clinical data define and accepting (PP5)” and “Data preprocessing and classify (PP6)” are urgent but requires less external assistance, adopting the strategy of “Priority internal management”.

As shown in the NRM, “Medical personnel involvement (PP4)” is the primary and dominant factor, and “Data preprocessing and classify (PP6)” is the last factor dominated by others. From the total-influence matrix (Table 6) and diagram (Figure 4), we can find that “Medical personnel involvement (PP4)” influence “Regulatory pathway planning

(PP3)", "Quality Management System (PP1)", "Development requirements planning (PP2) ", "Clinical data define and accepting (PP5)", and "Data preprocessing and classify (PP6)"; and "Regulatory pathway planning (PP3)" influence "Quality Management System (PP1)", "Development requirements planning (PP2)", "Clinical data define and accepting (PP5)", and "Data preprocessing and classify (PP6)"; "Quality Management System (PP1)" influence "Development requirements planning (PP2)", "Clinical data define and accepting (PP5)", and "Data preprocessing and classify (PP6)"; "Development requirements planning (PP2)" influence "Clinical data define and accepting (PP5)" and "Data preprocessing and classify (PP6)"; "Clinical data define and accepting (PP5)" influence "Data preprocessing and classify (PP6)".

Table 5. Summary of Imperative-External Assistance index, Interdependent Direct, and total impact of Pre-processing aspect.

Pre-processing (PP)	**IEA**			**NRM**	
	II	EAI	(II, EAI)	$d_i + r_i$	$d_i - r_i$
Quality Management System (PP1)	-0.467	0.770	(L, H)	20.9530	0.3060
Development requirements planning (PP2)	-1.045	0.846	(L, H)	22.7822	-0.3609
Regulatory pathway planning (PP3)	-0.756	1.349	(L, H)	20.3610	0.4540
Medical personnel involvement (PP4)	2.130	0.997	(H, H)	20.7333	0.4936
Clinical data define and accepting (PP5)	0.275	-0.692	(H, L)	23.0283	-0.4388
Data preprocessing and classify (PP6)	0.852	-0.414	(H, L)	22.5383	-0.4539
II: Imperative Index; EAI: External Assistance Index; L: Low; H: High.					

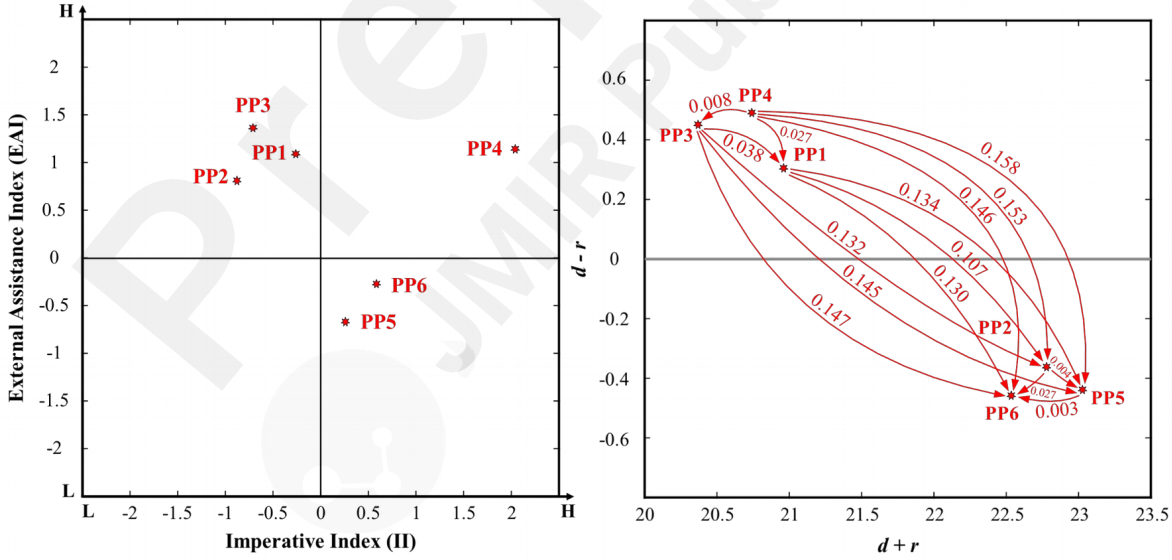

Figure 4. The IEA-NRM analysis diagram of Pre-processing aspect of AI SaMD design and development

Table 6. total-influence matrix of Pre-processing aspect

Influence matrix	**PP1**	**PP2**	**PP3**	**PP4**	**PP5**	**PP6**
PP1	-					
PP2	-0.107	-				

PP3	0.038	0.132	-			
PP4	0.027	0.153	0.008	-		
PP5	-0.134	-0.004	-0.145	-0.158	-	
PP6	-0.130	-0.027	-0.147	-0.146	-0.003	-

Model establishment aspect

In the model establishment aspect (Table 7 and Figure 5), “Cyber security protection consideration (ME3)” have high external assistant demand but not urgent, which adopt the strategy of “temporarily postpone external assistance”; “Algorithm design (ME1)” and “Algorithm performance evaluation (ME2)” are urgent but requires less external assistance, adopting the strategy of “Priority internal management”.

As shown in the NRM, “Cyber security protection consideration (ME3)” is the primary and dominant factor, and “Algorithm performance evaluation (ME2)” is the last factor dominated by others. From the total-influence matrix (Table 8) and diagram (Figure 5), we can find that “Cyber security protection consideration (ME3)” influence “Algorithm design (ME1)”, “Algorithm performance evaluation (ME2)”; “Algorithm design (ME1)” influence “Algorithm performance evaluation (ME2)”.

Table 7. Summary of Imperative-External Assistance index, Interdependent Direct, and total impact of Model Establishment aspects.

Model Establishment (ME)	**IEA**			**NRM**	
	II	EAI	(II, EAI)	$d_i + r_i$	$d_i - r_i$
Algorithm design (ME1)	0.726	-0.934	(H, L)	28.8303	0.0040
Algorithm performance evaluation (ME2)	0.415	-0.121	(H, L)	28.7015	-0.3704
Cyber security protection consideration (ME3)	-1.141	1.055	(L, H)	24.9354	0.3663
II: Imperative Index; EAI: External Assistance Index; L: Low; H: High.					

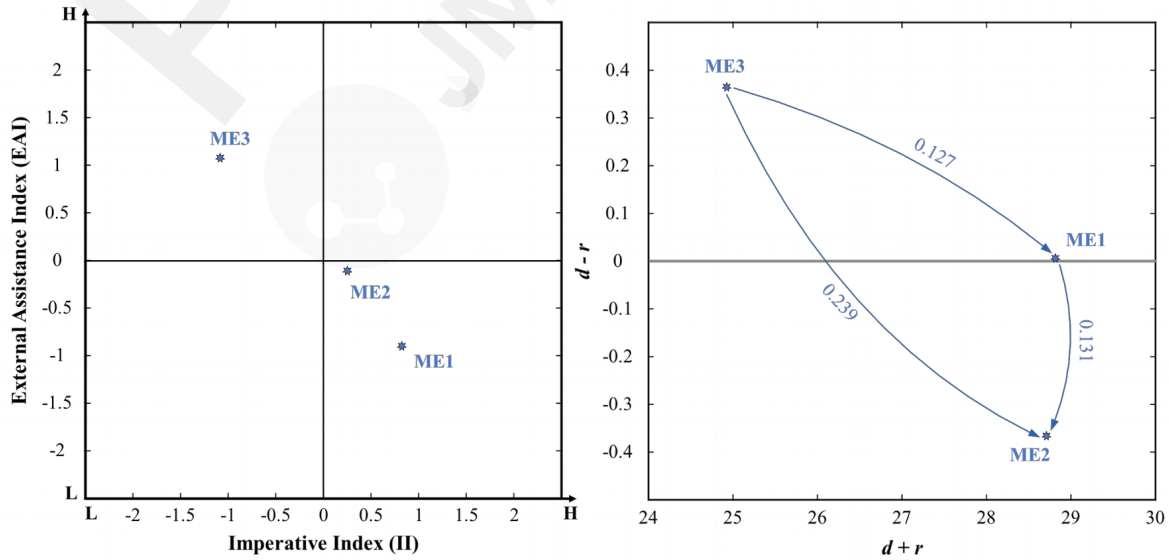

Figure 5. The IEA-NRM analysis diagram of Model Establishment aspect of AI SaMD

design and development

Table 8. total-influence matrix of Model Establishment aspect

Influence matrix	ME1	ME2	ME3
ME1	-		
ME2	-0.131	-	
ME3	0.127	0.239	-

Clinical evaluation aspect

In the clinical evaluation aspect (Table 9 and Figure 6), “Clinical trial design and preparation (CE1)” is highly urgent and requires an immediate search for external support, which would adopt a “priority in seeking external assistance” strategy; “Clinical trial IDE application (CE2)” have high external assistant demand but not urgent, which adopt the strategy of “temporarily postpone external assistance”; “Clinical trial IRB application (CE3)” and “Clinical trial report composing (CE5)” state as low urgency and low external assistance required, would adopt the “Retain the internal status” strategy; and “Clinical trial execution (CE4)” are urgent but requires less external assistance, adopting the strategy of “Priority internal management”.

As shown in the NRM, “Clinical trial design and preparation (CE1)” is the primary and dominant factor, and “Clinical trial report composing (CE5)” is the last factor dominated by others. From the total-influence matrix (Table 10) and diagram (Figure 6), we can find that “Clinical trial design and preparation (CE1)” influence “Clinical trial IRB application (CE3)”, “Clinical trial IDE application (CE2)”, “Clinical trial execution (CE4)”, and “Clinical trial report composing (CE5)”; the factor “Clinical trial IRB application (CE3)” influence “Clinical trial IDE application (CE2)”, “Clinical trial execution (CE4)”, and “Clinical trial report composing (CE5)”; “Clinical trial IRB application (CE3)” influence “Clinical trial IDE application (CE2)”, “Clinical trial execution (CE4)”, and “Clinical trial report composing (CE5)”; “Clinical trial IDE application (CE2)” influence “Clinical trial execution (CE4)” and “Clinical trial report composing (CE5)”; “Clinical trial execution (CE4)” influence “Clinical trial report composing (CE5)”.

Table 9. Summary of Imperative-External Assistance index, Interdependent Direct, and total impact of Clinical Evaluation aspects.

Clinical Evaluation (CE)	IEA			NRM	
	II	EAI	(II, EAI)	$d_i + r_i$	$d_i - r_i$
Clinical trial design and preparation (CE1)	0.224	0.787	(H, H)	59.235	1.197
Clinical trial IDE application (CE2)	-1.133	1.809	(L, H)	58.390	-0.235
Clinical trial IRB application (CE3)	-1.347	-0.873	(L, L)	58.837	0.544
Clinical trial execution (CE4)	1.295	-0.298	(H, L)	60.027	0.172
Clinical trial report composing (CE5)	-0.062	-0.745	(L, L)	57.518	-1.678
II: Imperative Index; EAI: External Assistance Index; L: Low; H: High.					

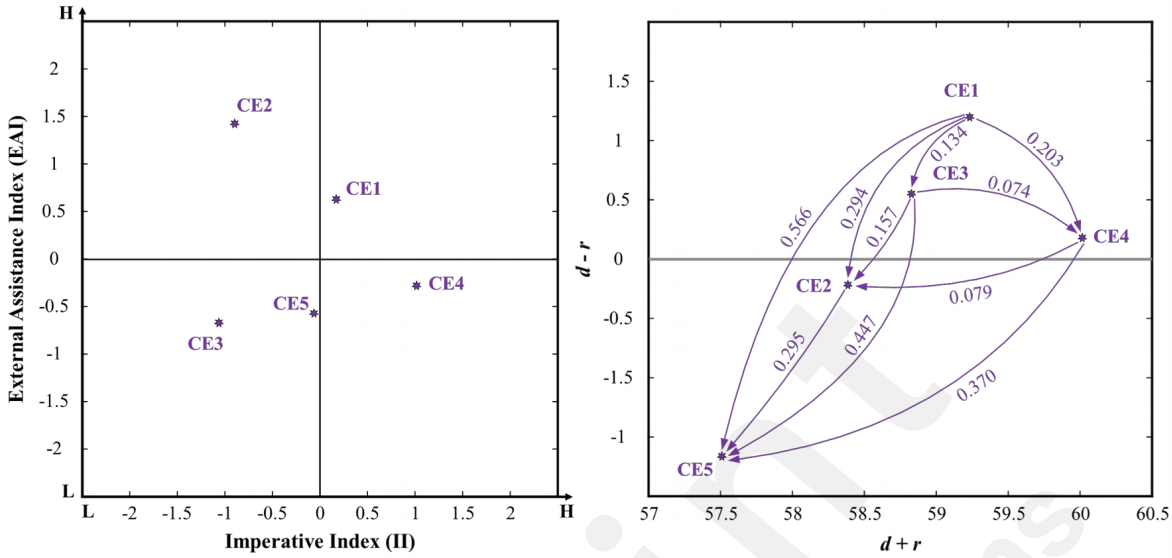

Figure 6. The IEA-NRM analysis diagram of Clinical Evaluation aspect of AI SaMD design and development

Table 10. total-influence matrix of Clinical Evaluation aspect

Influence matrix	CE1	CE2	CE3	CE4	CE5
CE1	-				
CE2	-0.294	-			
CE3	-0.134	0.157	-		
CE4	-0.203	0.079	-0.074	-	
CE5	-0.566	-0.295	-0.447	-0.370	-

Registration aspect

In the registration aspect (Table 11 and Figure 7), “Technical registration documents preparation (RT2)” and “Registration review response guidance (RT3)” has high external assistant demand but not urgent, which adopt the strategy of “temporarily postpone external assistance”; “Administrative registration process confirmation (RT1)” is urgent but requires less external assistance, adopting the strategy of “Priority internal management”.

As shown in the NRM, “Technical registration documents preparation (RT2)” is the primary and dominant factor, and “Administrative registration process confirmation (RT1)” is the last factor dominated by others. From the total-influence matrix (Table 12) and diagram (Figure 7), we can find that “Technical registration documents preparation (RT2)” influence “Registration review response guidance (RT3)” and “Administrative registration process confirmation (RT1)”; and “Registration review response guidance (RT3)” influence “Administrative registration process confirmation (RT1)”.

Table 11. Summary of Imperative-External Assistance index, Interdependent Direct, and total impact of Registration aspects.

Registration (RT)	IEA			NRM	
	II	EAI	(II, EAI)	$d_i + r_i$	$d_i - r_i$
Administrative registration process confirmation (RT1)	1.072	-1.044	(H, L)	117.7574	-0.3323
Technical registration documents preparation (RT2)	-0.165	0.095	(L, H)	120.0163	0.5602
Registration review response (RT3)	-0.907	0.949	(L, H)	120.5691	-0.2280

II: Imperative Index; EAI: External Assistance Index; L: Low; H: High.

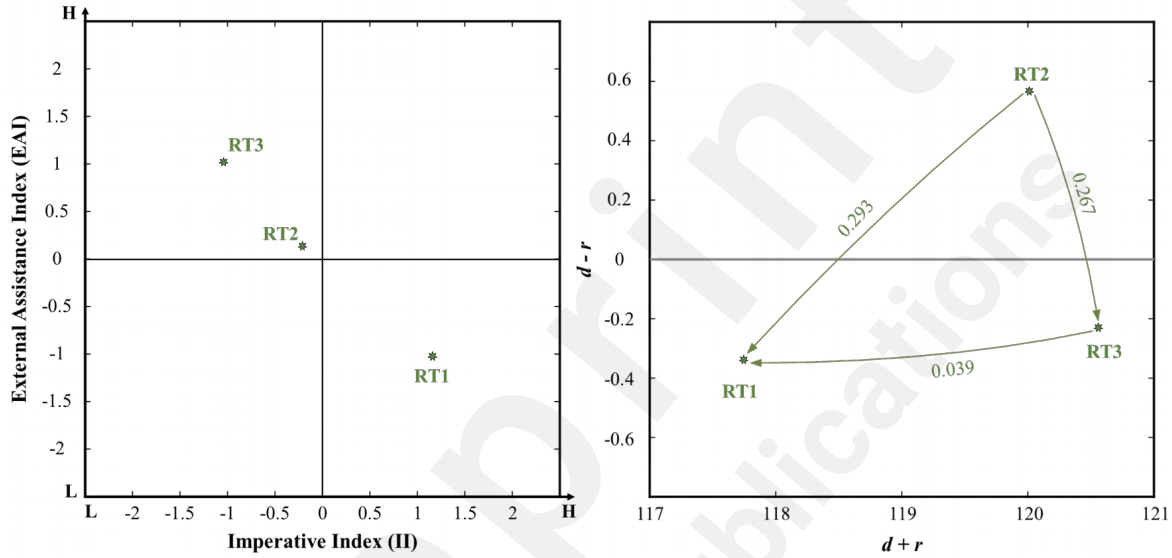

Figure 7. The IEA-NRM analysis diagram of Registration aspect of AI SaMD design and development

Table 12. total-influence matrix of Registration aspect

Influence matrix	RT1	RT2	RT3
RT1	-		
RT2	0.293	-	
RT3	0.039	-0.267	-

The summary and strategy of AI SaMD design and development

To provide a clearer and more detailed representation of the design and development process for AI SaMD, we have summarized the IEA-NRM results for all aspects in a diagram (Figure 8). In the diagram, color blocks identify the factors associated with each aspect. The yellow circles, marked with Roman numerals, indicate the quadrant location and corresponding management strategy for each factor. Additionally, the lines with arrows illustrate the interrelationships and direction of impact between the factors.

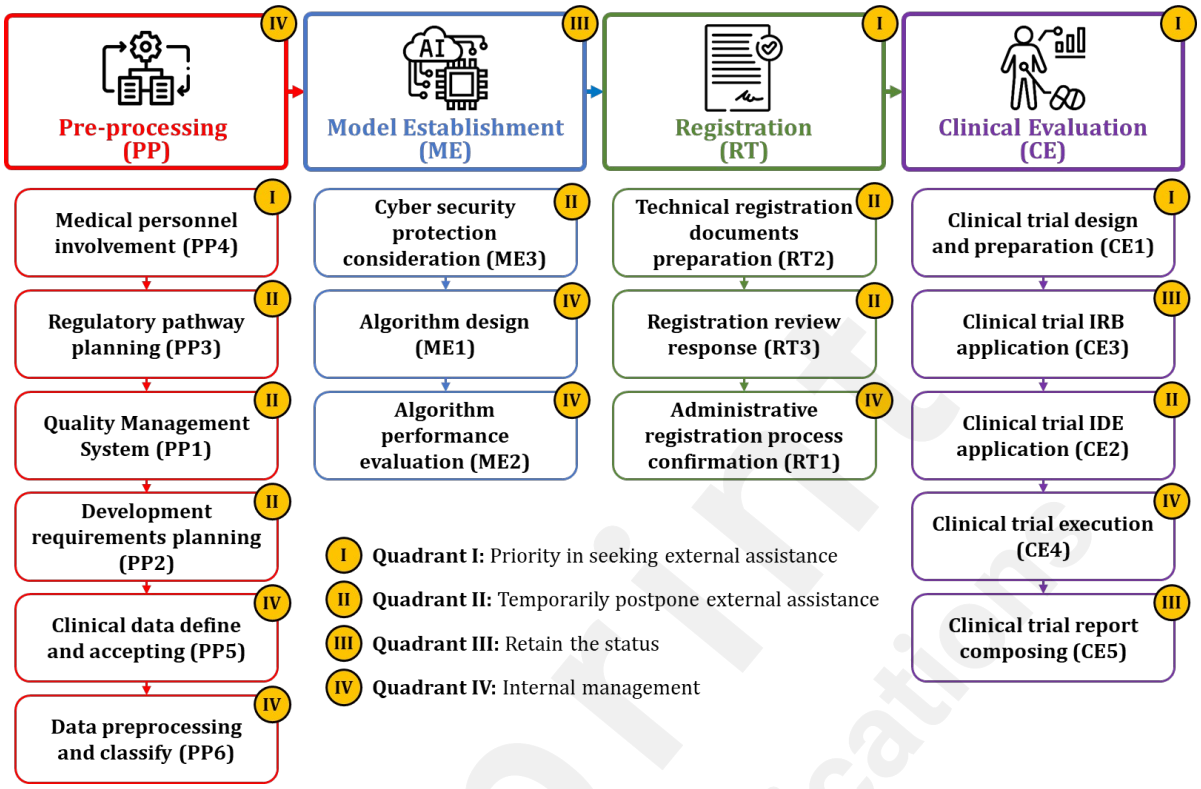

Figure 8. Summary of the IEA-NRM analysis diagram of AI SaMD design and development process

In summary, AI SaMD developer could improve the design and development process by overcoming obstacles mainly through the following pathways.

[PP→ME→RT→CE]: AI SaMD developers should prioritize internal management during the Pre-processing stage. The current approach to Model Establishment can be maintained, while external assistance should be sought for the Registration and Clinical Evaluation stages.

[PP4→PP3→PP1→PP2→PP5→PP6]: AI SaMD developers should prioritize seeking external assistance for involving medical personnel. Meanwhile, they can temporarily postpone external assistance for regulatory pathway planning, quality management systems, and development requirements planning. Additionally, they should focus on internally managing tasks such as defining clinical data, data acceptance, preprocessing, and classification.

[ME3→ME1→ME2]: AI SaMD developers should temporarily postpone seeking external assistance for cybersecurity protection considerations. Additionally, they should focus on internal management of algorithm design and performance evaluation.

[CE1→CE3→CE2→CE4→CE5]: AI SaMD developers should prioritize seeking external assistance for clinical trial design and preparation. The current approach to the clinical trial IRB application can be maintained, while seeking external assistance for the clinical trial IDE application can be temporarily postponed. Additionally, developers

should focus on internally managing the execution of clinical trials and maintain the current process for composing clinical trial reports.

[RT2→RT3→RT1]: AI SaMD developers should temporarily postpone seeking external assistance for the preparation of technical registration documents and responses to registration reviews. Meanwhile, they should focus on internally managing the confirmation of the administrative registration process.

Discussion

The process of AI SaMD design and development

AI SaMD developers need to perform pre-processing and build a complete AI algorithm model before proceeding with evaluation and AI model testing. This is necessary to continue refining and updating prototype products, ensuring that the AI model is perfected and ready to serve as the basis for clinical trials [3, 14, 22]. However, the results of this study indicate that the registration and listing processes should precede clinical trials. For developers, both registration/listing and clinical trials require coordination with other units, such as medical institutions and regulatory bodies. Therefore, it is important to organize these components before proceeding with development [11, 13].

According to the IEA results, although the Registration aspect has the highest demand for external assistance, it is relatively less urgent compared to the Clinical Evaluation aspect. Developers should allocate resources based on the strength of partnerships and the availability of external support. In cases where external resources are limited, it is more appropriate to prioritize investments in the Clinical Evaluation aspect.

The process of each aspect of AI SaMD design and development

The results of the pre-processing aspect align with previous literature and the insights gathered from interviews [14, 15]. The involvement of medical personnel in the AI SaMD development process is highly urgent and serves as a primary and dominant factor requiring external support. As highlighted by Allen Jr, Seltzer [14] and [15], clinician participation is crucial to AI SaMD development. Their expertise influences multiple factors throughout both the early stages and the entire development process. Medical personnel assist developers in defining clinical requirements (unmet needs), labeling model input data, and collaborating on case acceptance, clinical trial planning, and execution.

Additionally, developers need to integrate the professional opinions of regulatory experts and collaborate with medical personnel to ensure compliance with national regulations, based on the clinical intended use or indications. A common challenge, however, is that many developers underestimate the importance of clinical data acquisition and relevant norms in constructing algorithms. This oversight can lead to violations of research ethics, often tied to the development team's lack of familiarity with regulations.

At this stage, developers can confirm the risk level and establish safety and effectiveness evaluation conditions based on the clinical indications and the country where the product will be marketed [27]. This process ensures the product meets both inspection and registration pathways, as well as user needs. Therefore, developers must collaborate with medical personnel to plan effectiveness indicators for each development stage and define the scope, conditions, quality, and quantity of data used for model training [25].

In the model establishment phase, IEA analysis shows no urgent need for external resistance. However, Network Relationship Map (NRM) results indicate that cybersecurity protection is the most critical and urgent factor to address. In software design and development, especially for AI SaMD, the protection of programming is crucial due to the handling of extensive clinical data, including sensitive patient information and labeling results. Developers must prioritize strategies to prevent cyberattacks and data breaches [3, 11, 22].

Once security measures are well established, the evaluation of AI SaMD algorithm performance can be conducted [14]. Algorithm performance assessment includes evaluating the completeness of quality management, which impacts subsequent clinical evaluations. Therefore, it is essential to establish requirements for software repeatability, reproducibility, and stability [15, 16]. For developers, having a core algorithmic technology is foundational to AI SaMD development, and many involve professional software development and technical personnel early in the process to ensure smooth progress.

The clinical evaluation phase is critical in AI SaMD development due to its medical implications. The entire process must follow regulatory pathways and classifications based on safety and effectiveness considerations [11, 12, 24]. IEA results indicate that developers urgently need external assistance for clinical trial design consultation. Close collaboration with medical personnel, particularly clinicians, is essential in this phase. Clinicians play a key role in trial design, case enrollment criteria, and execution. Developers may also need external support, such as contract research organizations (CROs) and regulatory experts.

Moreover, IDE submission and review are critical steps in conducting clinical evaluations. Once the FDA approves the IDE application, the clinical trial can commence, with case acceptance based on the resolutions of the Institutional Review Board (IRB) and the FDA committee. This ensures that data sources are used legally and that privacy and security are maintained [28]. With regulatory and medical personnel support, developers can conduct clinical trials in line with evaluation criteria and produce trial reports that record safety and effectiveness evaluations.

In the registration phase, design and quality control documentation, along with software test reports, must be thoroughly prepared throughout the design and development process [11, 24]. Although document preparation and responding to registration reviews have lower urgency, there is a high demand for external support.

This need is consistent with the pre-processing phase, as AI SaMD development involves collaboration among experts from diverse fields. Technical and management documentation should be carefully planned and established early in the development process. It is, therefore, necessary to involve regulatory experts or consultants to clarify administrative procedures and guidance for registration to ensure that the review process and document preparation do not delay the product's market entry.

Limitations

This research faced limitations, particularly in establishing contact with AI SaMD development teams and manufacturers. The complexity of the questionnaire, designed to align with the research structure and analysis model, made it difficult to administer without supervision and support. Additionally, the research content often involved confidential information from manufacturers or teams, making it challenging to secure participation and candid responses from selected experts.

Given the cross-disciplinary nature of AI SaMD development, the stakeholders involved in interviews and questionnaires came from diverse fields, including technical, medical, regulatory, and other professional backgrounds. Although the questionnaire was distributed as widely as possible, differences in respondents' background knowledge, status, and representation could influence the weight and ranking of the factors in the analysis. To improve the balance and effectiveness of future research, increasing the data sample from each stakeholder group is essential.

Finally, there are many potential factors that could impact the development and commercialization of AI SaMD, and this research addresses only a portion of these, focusing on key aspects related to product design. Future studies could explore specific criteria in greater depth for individual stages of development or challenges. By narrowing the focus, researchers can better align with real-world development situations and identify the most critical factors for improvement. The findings from this study can serve as a foundation for future research, helping to explore more detailed strategies related to relevant regulations and development processes.

Conclusions

This study provides a foundation from the regulatory perspective, systematically discussing and clarifying factors related to the design and development of AI SaMD, while establishing a feasibility analysis model framework. We found that AI SaMD development relies heavily on strong collaboration between software technicians, medical personnel, and regulatory experts. By using clear quantitative data and network structures, this research identifies the interactive influence of various factors and their relative importance, offering insights for developing resource allocation strategies.

Our analysis highlights that during the AI SaMD design and development process, the *Registration* and *Clinical Evaluation* phases have an urgent need for external assistance.

However, resource investment should initially focus on the *Pre-processing* phases, as this will allow subsequent phases—*Model Establishment*, *Clinical Evaluation*, and *Registration*—to proceed more efficiently. We also provide resource allocation recommendations tailored to the factors in each development phase.

This study offers guidance for stakeholders in the AI SaMD industry, fostering consensus and enhancing the effectiveness of collaboration. By adopting responsive strategies early in the product design and development process, stakeholders can accelerate AI SaMD development and ensure regulatory approval. Ultimately, this will help overcome barriers to innovation, improve hospital application development, enhance medical efficiency, and strengthen the overall quality of healthcare.

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Conflicts of Interest

None declared.

Abbreviations

AI SaMD: Artificial Intelligence-based Software as Medical Device
ICT: Information and Communications Technology
IoT: Internet of Things
IEA: Imperative-External Assistance Analysis
DMATEL: Decision-Making Trial and Evaluation Laboratory
MBD: Medical Big Data
FDA: Food and Drug Administration
MOHW: Ministry of Health and Welfare
NHI: National Health Insurance
EMR: Electronic Medical Records
HER: Electronic Health Records
II: Imperative Index
EAI: External Assistance Index
Inter.: Mention through the interview
PP: Pre-processing
ME: Model Establishment
CE: Clinical Evaluation
RT: Registration

PP1: Quality Management System
PP2: Development requirements planning
PP3: Regulatory pathway planning
PP4: Medical personnel involvement
PP5: Clinical data define and accepting
PP6: Data preprocessing and classify
ME1: Algorithm design
ME2: Algorithm performance evaluation
ME3: Cyber security protection consideration
CE1: Clinical trial design and preparation
CE2: Clinical trial IDE application
CE3: Clinical trial IRB application
CE4: Clinical trial execution
CE5: Clinical trial report composing
RT1: Administrative registration process Confirmation
RT2: Technical registration documents preparation
RT3: Registration review response

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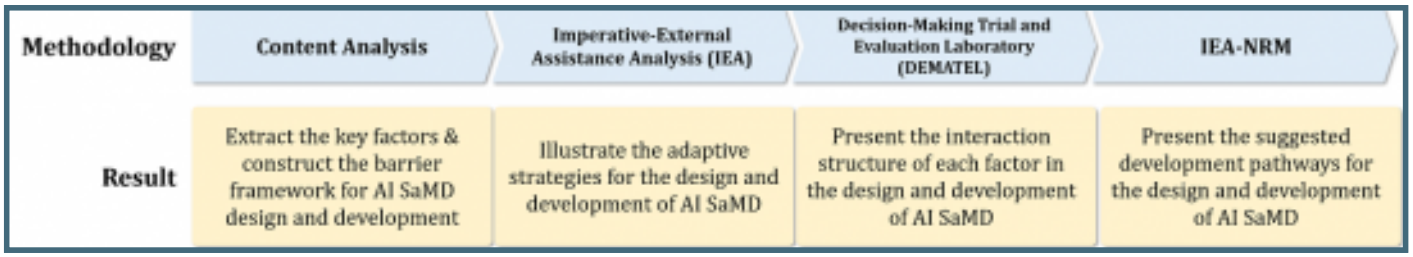
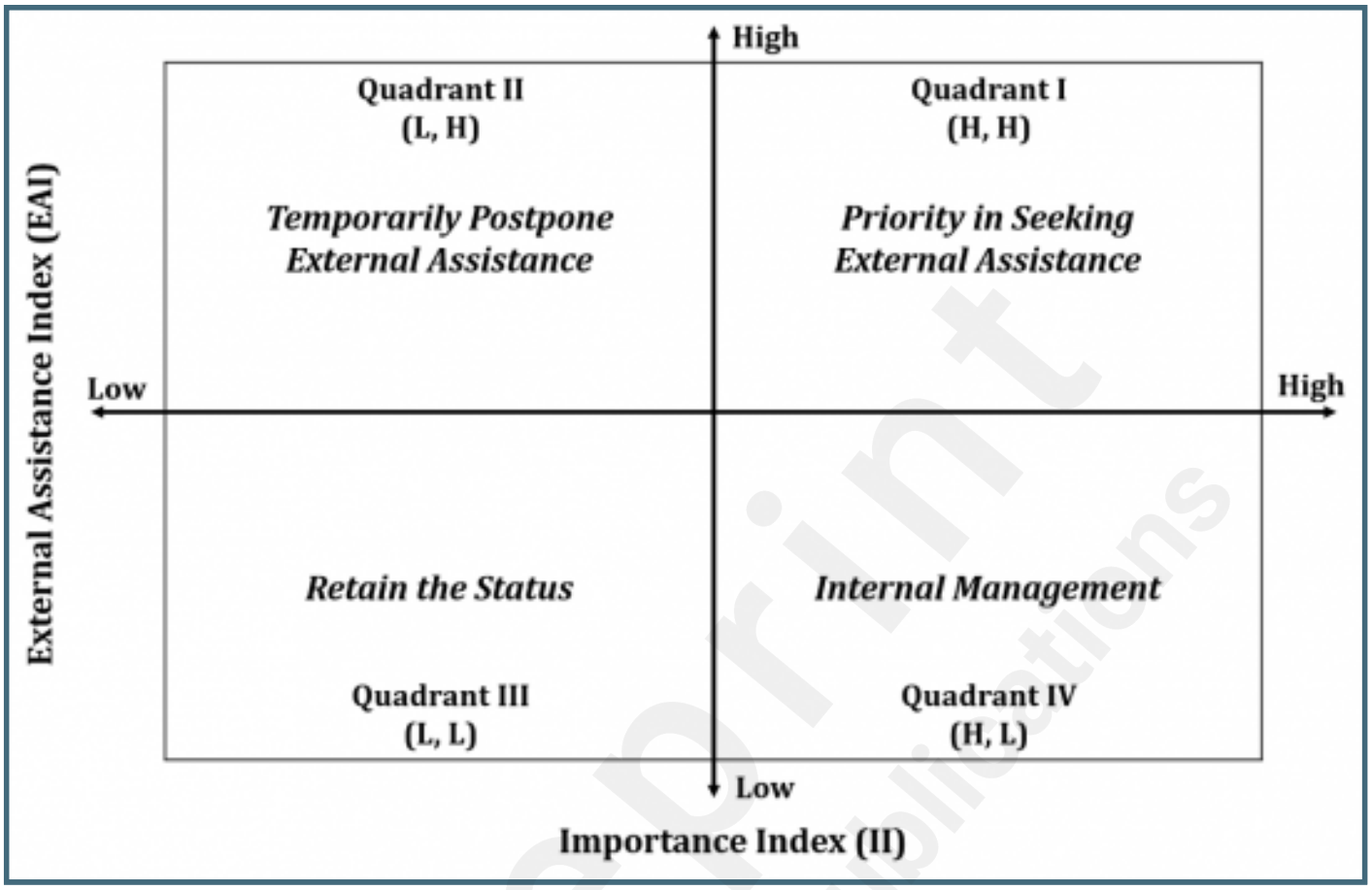
Supplementary Files

Figures

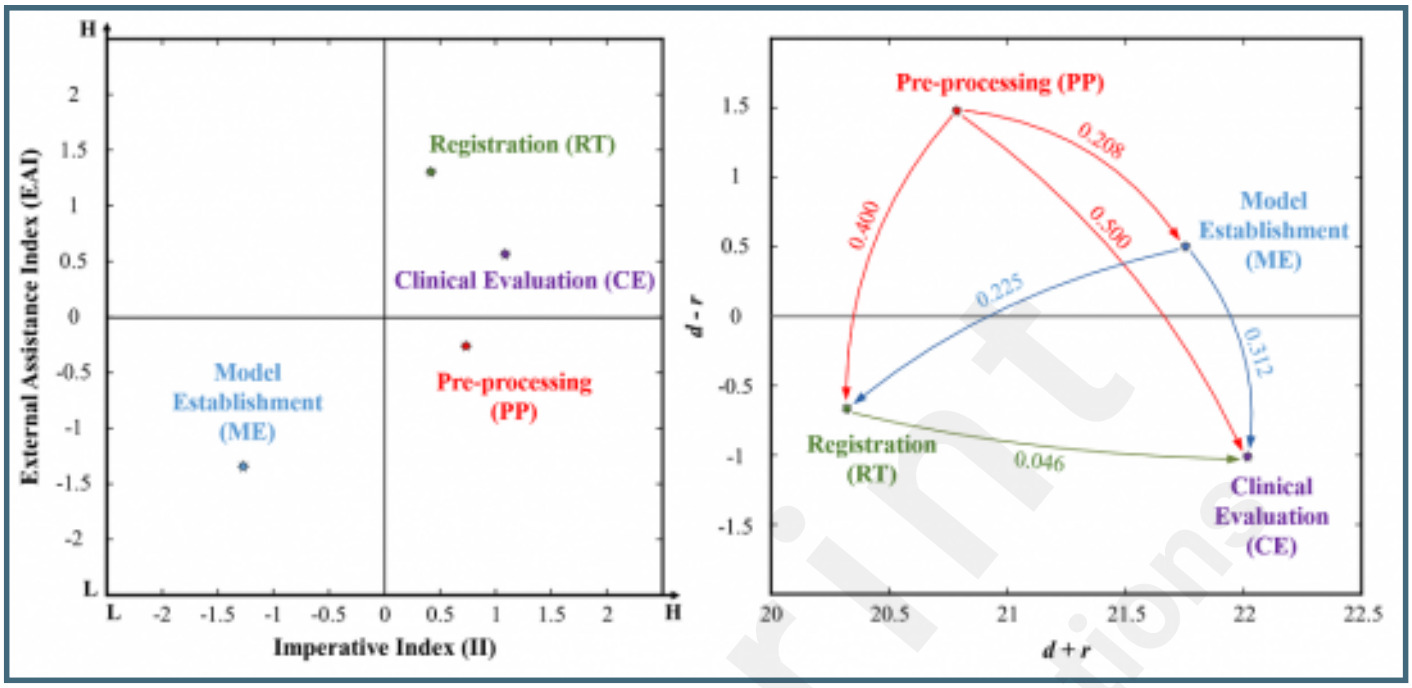
Framework of hybrid methodologies applied in the research process.



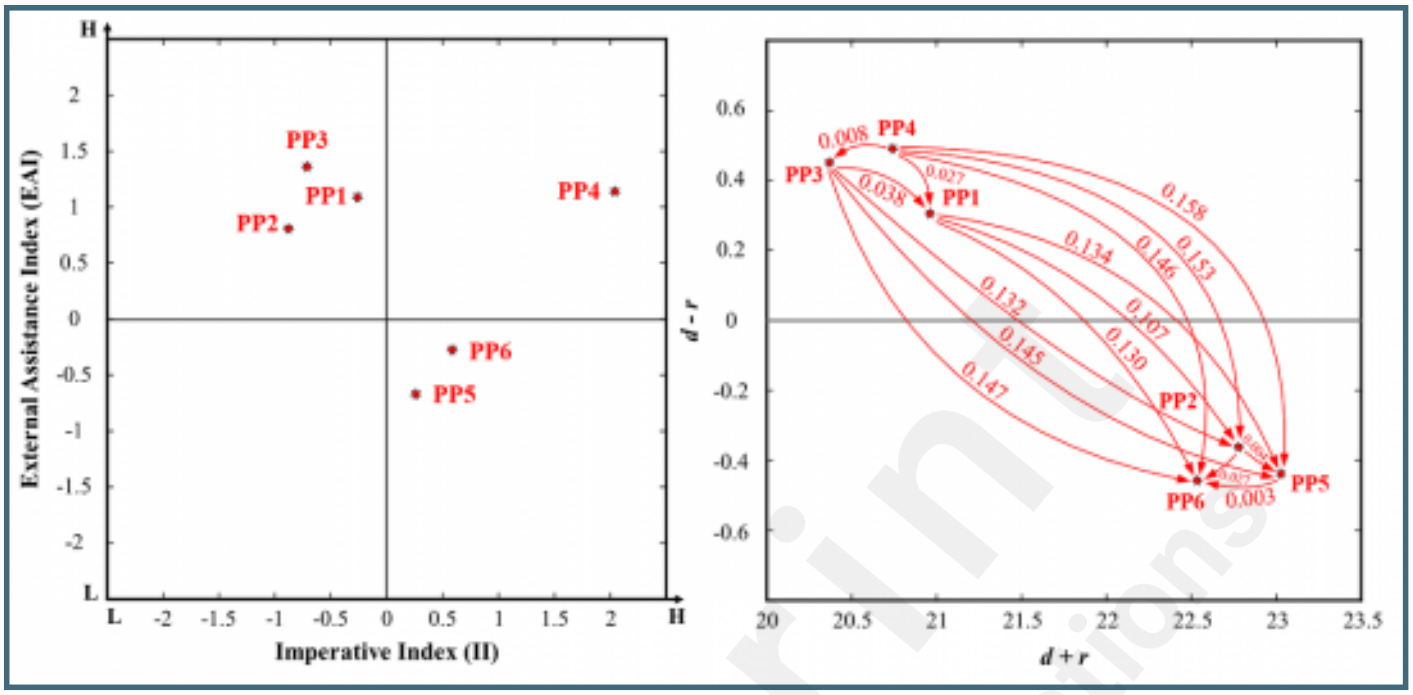
Framework of Imperative-External Assistance Analysis (IEA).



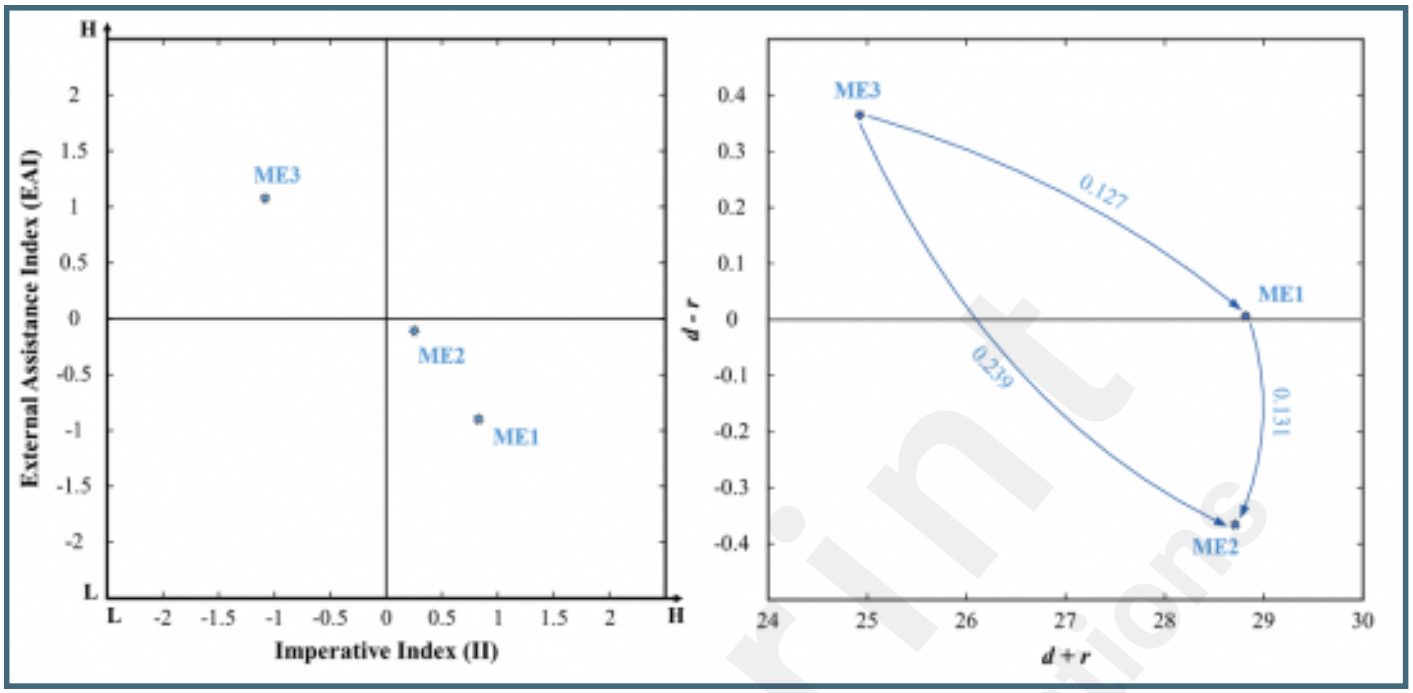
The IEA-NRM analysis diagram of the general aspects of AI SaMD design and development.



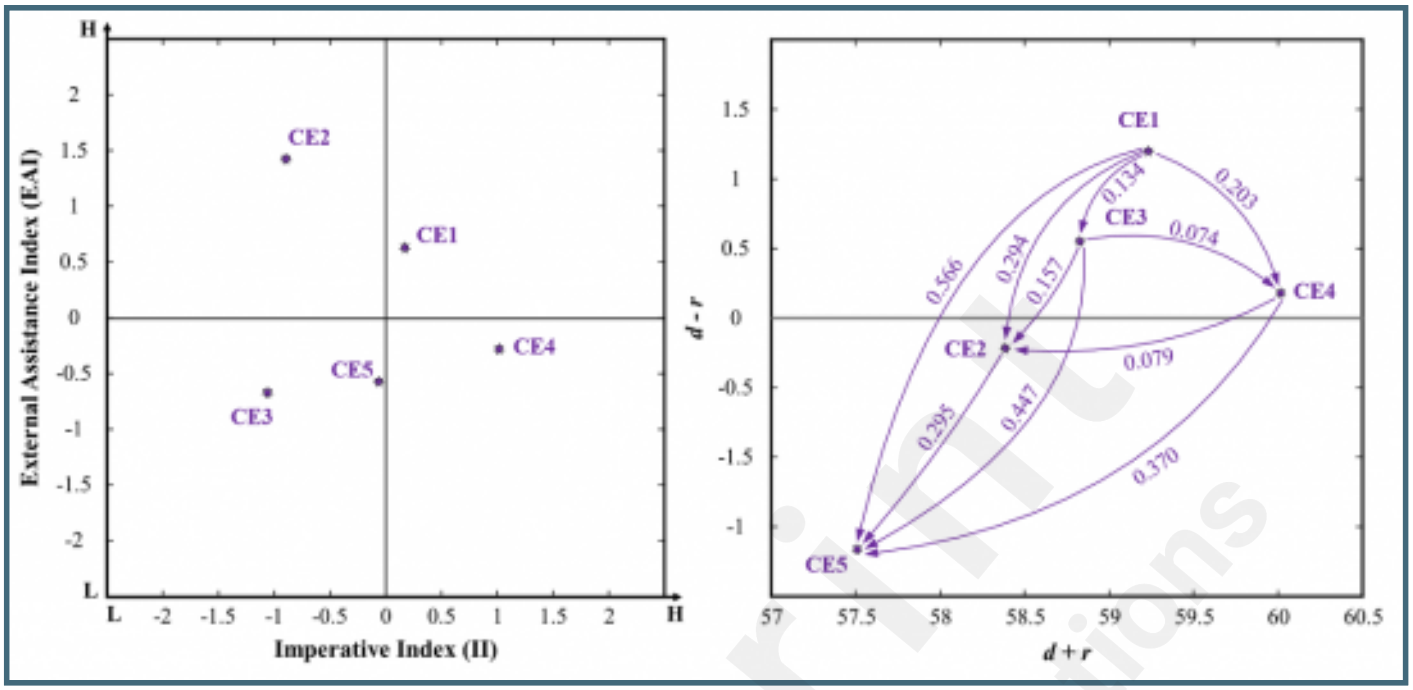
The IEA-NRM analysis diagram of Pre-processing aspect of AI SaMD design and development.



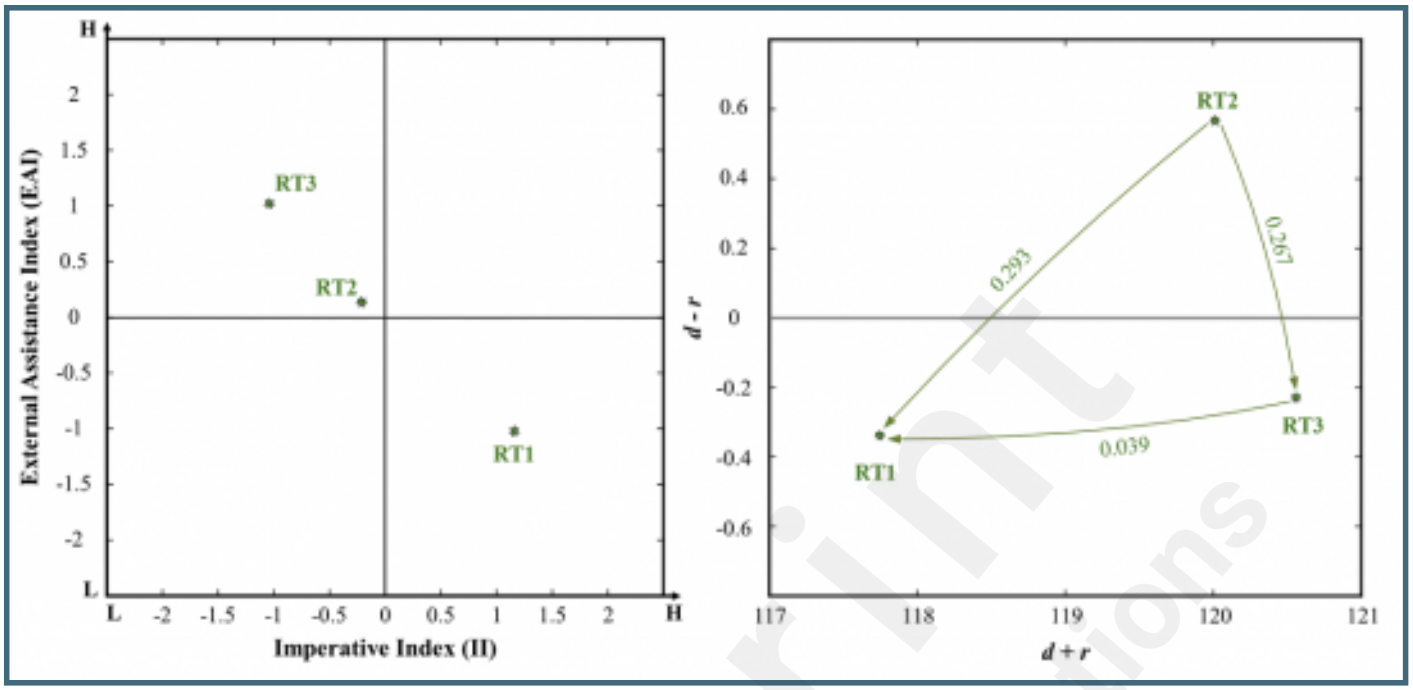
The IEA-NRM analysis diagram of Model Establishment aspect of AI SaMD design and development.



The IEA-NRM analysis diagram of Clinical Evaluation aspect of AI SaMD design and development.



The IEA-NRM analysis diagram of Registration aspect of AI SaMD design and development.



Summary of the IEA-NRM analysis diagram of AI SaMD design and development process.