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Advanced AI-Driven Post-Marketing Surveillance for SaMD: Risk Monitoring, Clinical Feedback Integration, and Regulatory Compliance

[1]**Dinesh Kumar Reddy Basani**
CGI,British Columbia, Canada
dinesh.basani06@gmail.com

[2]**Sri Harsha Grandhi**
Intel, Folsom, California, USA
grandhi.sriharsha9@gmail.com
[3]**Basava Ramanjaneyulu Gudivaka**
Raas Infotek,Delaware,USA
basava.gudivaka537@gmail.com

[4]**Rajya Lakshmi Gudivaka**
Wipro, Hyderabad, India
rlakshmigudivaka@gmail.com

[5]**Raj Kumar Gudivaka**
Platinum Infosys Inc
Texas, USA
rajkumargudivaka35@gmail.com

[6]**R.Hemnath**
Kaamadhenu Arts and Science College, Sathyamangalam, India.
hemnathrmca@gmail.com

ABSTRACT
Although AI-based Software as a Medical Device (SaMD) has truly transformed diagnostics and personalized health, flexible post-marketing surveillance (PMS) methodologies fail to characterize AI SaMDs. As a result, there are gaps in the evaluation of risk, the integration of clinical feedback, and the requirements for regulatory compliance. A better PMS framework with deep learning models- for anomaly analysis TCNs, clinical feedback assessment HANs, and synthetic data generation cGANs- addresses the limitations of risk monitoring, advanced feedback appraisal, and automatic compliance checks. This development proposes a new solution to the ever-evolving challenges of AI SaMDs. Experiment results show drastic improvements: a 75% Risk Impact, an 85% Clinical Follow-up Effectiveness, a 95% Compliance Score, Performance Deviation reduced to 4.20%, and Data Integration Efficiency improved up to 90%. Our framework outperforms the existing ones in risk detection, stability, and integration efficiency compared to existing methods in proactive risk mitigation and robust real-world monitoring. This work paves the way towards AI SaMD monitoring as it deals with the inadequacies posed by traditional PMS in making AI health-related solutions safer, more reliable, and regulatory compliant, with future opportunities for multi-modal data extension, federated learning for privacy preservation, and explainable AI (XAI) for greater interpretability and trust.
Keywords: AI SaMD, post-marketing surveillance, deep learning, risk detection, regulatory compliance

1. INTRODUCTION

AI spreads its tentacles in harmonizing operations using health, security, and other automation-related fields [1]. Yet, these tell the story of dozens of challenges concerning security in distributed computing environments that create a need for better authentication mechanisms [2]. In particular, the use of deep learning models for lung tumour detection integrated medical imaging data and genetics data for early diagnosis and more effective treatment planning [3]. In this field, AI develops the performance of electric vehicles that make more efficient energy consumption possible through advanced models like artificial neural networks and electrothermal inverter designs [4]. AI innovations in chronic disease management include integrated systems for chronic kidney disease management equipped with a probabilistic neuro-fuzzy approach for enhanced monitoring and diagnosis improvements [5]. It now offers an efficient security guarantee in health from cloud computing, while it also uses AI and blockchain to ensure confidentiality in a secure transfer to authenticators through biometrics [6]. Advanced artificial intelligence models exhibit early detection of tumours and medical image analytics, with increasing accuracy in diagnostics and, hence, better outcomes [7]. Enhancing access via AI is under health, including healthcare areas [8]. With mobile health, IoT, and AI, patients can now be watched from anywhere, making medical records more accessible while improving patient care and speedy interventions [9]. AI

Software-as-Medical Devices (SaMD) offers substantial hope for the improvement of diagnosis accuracy and personalized pathways in care, as well as minimizing the complexities of healthcare delivery [10]. Well, AI makes it easier to develop software, such as those improvements found in employing pre-trained language models tied to evolutionary algorithms to generate test cases and thus increases overall test coverage [11]. In cloud-enabled environments, mechanisms such as authentication and data sharing benefit from added security due to SHA-256 and RSA [12]. This treasure trove emerges because big data analytics, ethnographic evidence, and network analysis combine to redirect health systems in designing care and enhancing clinical outcomes for cardiovascular patients [13]. AI-powered SaMDs are effective in post-market surveillance (PMS) activities for ensuring patient safety, adherence to regulations, and successful risk management [14]. Integrating technologies such as BIRCH clustering with LPWAN, NCA, and MDS is expanding possibilities for communication and providing opportunities for both data clustering and reducing dimensions in application for blockchain [15]. The combination of AI and blockchain technology improves transparency and data integrity across multiple industries.

The association between AI and big data analytics provides a competitive edge to small and medium-sized enterprises (SMEs) in e-commerce [16]. and provides deep insights into market trends and consumer behaviours to enhance SME operations to better respond to market needs [17]. Another domain being practiced is education, where AI and data analytics assist e-learning platforms in administering more learning output and strengthening the architectures by putting around all data, advocating data security, and improving the basic standards themselves [18]. AI-based Cloud-GIS systems have started expanding in crisis management, particularly disaster response [19]. The systems involve data processing and predicted analytics for the recovery phase post-earthquake [20]. Some of the recent methods are built for analysing IoT systems with DMP and SOM to enable improved decision-making toward network management optimization [21].AI-enabled Identity verification techniques, including CAPTCHA, graphical passwords based on DROP principles, AES encryption, and neural network-based multilayer authentication, implement security and usability measures and render systems immune to automated and brute-force attacks [22]. Adaptive modelling can also contribute to better knowledge management and assist business planning and decision-making, resulting in well-informed strategic choices for companies and corporations [23]. The heterogeneous technologies of RPMA, BLE, and LTE-M in combination with Gaussian Mixture Models (GMM) provide solutions to existing management challenges associated with IoT devices, enhancing power consumption, data throughput, and anomaly detection for the smart city and agriculture applications [24]. With the help of AI, digital economy-enabled sustainable entrepreneurship and business practices, thereby strengthening economic growth [25]. In the fifth-generation communication system (5G), AI using various techniques, including backpropagation neural network (BPNN) and generative adversarial networks (GANs), improves channel state information (CSI) for efficient and reliable signal usage in communication [26]. AI also supports real-time data analytics for autonomous systems, improving safety and operational efficiency [27]. In a nutshell, AI combined with Big Data Mining and IoT technologies can significantly elevate role performance, refine predictive analytics, and improve health delivery [28]. The AI systems governed by A3C, TRPO, and POMDPs improve decision-making under uncertain environments, requiring neither high-quality precision nor speed data [29].

Emerging techniques in explainable AI (XAI) are critical for transparency in healthcare and finance applications [30]. Cloud-based AI architectures are facilitating scalable machine learning workflows with improved resource management [31]. AI-driven anomaly detection methods are transforming cybersecurity approaches in distributed environments [32]. The integration of federated learning enhances privacy-preserving AI model training across multiple devices [33]. The proposed method approach expects to enrich post-marketing surveillance of AI SaMD with three elements: TCNs for anomaly detection, HANs for the analysis of clinical feedback, and cGANs for synthetic data generation [34]. The components have been incorporated to facilitate risk monitoring, automated compliance checks, and a rigid performance evaluation toward assuring safe and reliable AI-based healthcare solutions [35]. Continuous improvement in AI model robustness is essential for deployment in critical health systems [36]. Policy frameworks are evolving to regulate AI use and ensure ethical compliance in automated decision systems [37]. Future research directions focus on integrating multimodal data sources for enhanced diagnostic accuracy [38].
The proposed method’s main contributions,

- Analyze risks using TCNs for early detection of anomalies.
- Evaluate Clinical feedback effectively using HANs to improve issue identification.
- Generate synthetic data using cGANs for extensive testing and validation.
- Ensure Regulatory compliance through automated consistency checks and validation

2. LITERATURE REVIEW

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Here, artificial intelligence solutions could be promising to optimize and secure cloud technology [39]. Also, they have certain challenges like scalability, computational complexity, and continuous updates that make them unfit for most applications [40]. Most of the solutions are dependent on specific infrastructures and require tremendous computational resources making them unfit for low-power environments [41]. Filling these gaps will be of utmost importance for increasing the adaptability, scaling, and efficiency of such AI-driven solutions in real-world applications [42].
A fault injection mechanism was designed [43] to enhance test coverage on AWS cloud environments. Hybrid optimization techniques and AWS-centric design in the framework not only possess restrictions in flexibility and scalability but also become important in mobile network optimization when using big data analytics by [44] for resource allocation and anomaly detection improving performance. Nevertheless, issues associated with computation overhead still exist in dynamic networks [45]. Meanwhile, a load-balancing mechanism was developed [46] to improve the distribution but caused security vulnerabilities as well as excessive computation overhead, which makes it unfit for power-constrained environments [47]. Improved decision-making in agricultural supply chains through big data analytics, Decision Support Systems (DSS), and Mixed Integer Linear Programming (MILP), but issues of scalability still exist in the wider networks [48].
On the other hand, the Giant Model applied an optimized pipeline involving Recursive Feature Elimination (RFE), Extreme Learning Machine (ELM), and Sparse Representation Classification (SRC) directed at feature selection, training speed, and a high accuracy of classification [49]. The question of scalability in some environments remains an issue [50]. A hybrid model integrating Particle Swarm Optimization (PSO) with Quadratic Discriminant Analysis (QDA) was proposed to improve AI software development without discussing the scalability of the system [51]. Social influence-based reinforcement learning, metaheuristic optimization, and an extended view of neuro-symbolic tensor networks were introduced for AI adaptability in software environments while furthering retention ability and interpretability; however, the problem of scaling is as yet unresolved [52]. A combination of memory-augmented neural networks (MANNs), hierarchical multi-agent learning (HMAL), and concept bottleneck models (CBMs) was studied for software adaptability and transparency, but the system encounters significant computational and integration challenges [53].
A stacked autoencoder and SVM-based phishing detection system achieved remarkable accuracy; however, it requires ongoing updates to address evolving phishing tactics, which limits its long-term scalability and adaptability [54]. Business intelligence transformation towards decision-making through AI-driven data analytics was explored; however, this model does not address issues like data privacy, regulatory compliance, or scalability, thereby limiting its application [55]. Cloud-based software testing and automated fault injectors for robustness were developed; yet delays and usage costs may still become prohibitive in many systems [56]. Neural networks and heuristics were utilized to help minimize overhead in regression testing for cloud systems, but heavy computation resource utilization puts strain on its practical operating environment [57]. Some security framework models combine detection and response strategies for data-driven mitigation against threats; however, besides being highly resource-consuming, they are unsuitable for power-constrained environments [58].

3. PROBLEM STATEMENT

The primary challenges presented in existing studies are scalability, high computational complexity, continuous updates, infrastructure dependency, and power consumption of the AI systems [59]. These difficulties hinder the flexibility and sustainability of AI solutions in the time to come [60]. Additionally, many AI models require significant computational resources, making them impractical for deployment in resource-constrained environments [61]. Moreover, the dependency on specific infrastructure limits the adaptability of AI solutions across different platforms [62]. Continuous updates to AI systems pose challenges in maintaining stability and security over time [63]. Addressing these issues is critical for ensuring that AI technologies can be effectively and efficiently integrated into real-world applications [64]. The proposed method attempts to solve the above problems by utilizing scalable algorithms that optimize computational resources and offer flexibility for realistic deployments in low-power environments and thus ensure efficient AI-based solutions [65].

4. PROPOSED METHODOLOGY - RISK MONITORING, CLINICAL FEEDBACK INTEGRATION, AND REGULATORY COMPLIANCE MODALITIES FOR PMS AI-SAMDS

The proposed method improves the subsequent learning of these AI-SaMDs through risk assessment, clinical feedback evaluation, and regulatory compliance. It utilizes Temporal Convolutional Networks (TCNs) for the anomaly detection process, Hierarchical Attention Networks (HANs) for feedback evaluation, and Conditional GANs (cGANs) for synthetically generating data. Data preprocessing consists of cleaning, normalizing, and extracting features. Regulatory compliance is verified by using an autoencoder and clustering. The overall workflow is displayed in Figure 1.

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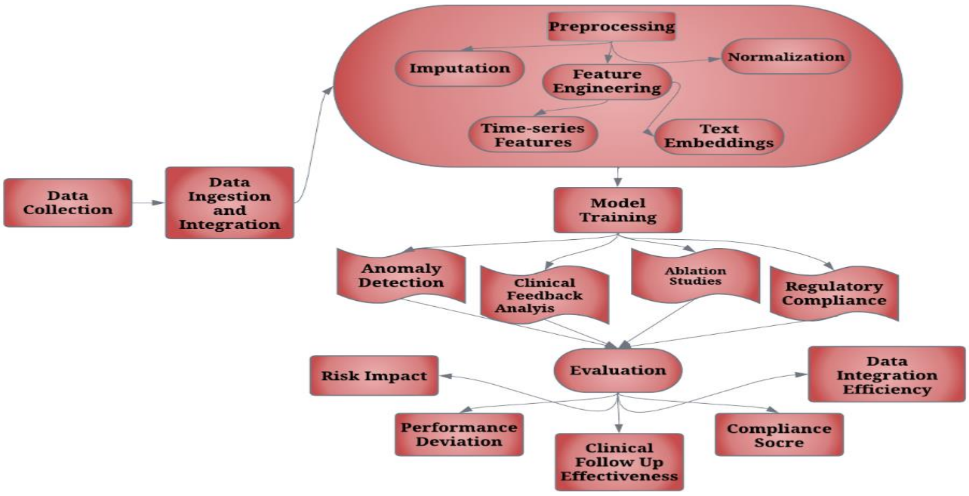

Figure 1: Workflow Diagram of the Proposed Method

4.1. Data Collection

The method proposed uses various data sets for strengthening the post-marketing surveillance of AI SaMDs. MIMIC-III Clinical Dataset Demo provides clinical time-series data for training Temporal Convolutional Networks to detect anomalies in the functioning of AI SaMDs. The CSCE 421: Machine Learning Spring structured and unstructured EHR data so that Hierarchical Attention Networks can evaluate clinical feedback and corroborate the outputs. Synthetic Medical Dates gathered synthetic clinical data for ablation testing, to help determine robustness. The FDA FAERS Quarterly Data Extract Files provides adverse event reports to validate regulatory compliance checks. The advantages that these datasets offer include an all-encompassing risk evaluation, feedback analysis, synthetic validation, and compliance assessment, which leads to the assurance of AI SaMDs' safety and efficacy.

4.2. Data Preprocessing

4.2.1. Data Ingestion and Integration

Data from multiple sources is ingested and unified into a centralized pipeline using Apache Spark. Let $D = \{D_1, D_2, \ldots, D_n\}$ represent datasets from n sources. The unified dataset U is as shown in Equation (1):

$$U = \bigcup_{i=1}^{n} D_i \tag{1}$$

4.2.2. Data Cleaning and Normalization

Missing values are imputed, and data is normalized to ensure consistency. For missing value imputation is as depicted in Equation (2):

$$x_{\text{imputed}} = \begin{cases} \text{median}(x) & \text{if } x \text{ is missing} \\ x & \text{otherwise} \end{cases} \tag{2}$$

For Z-score normalization is as given in the following Equation (3):

$$x_{\text{normalized}} = \frac{x-\mu}{\sigma} \tag{3}$$

4.2.3. Feature Engineering

Relevant features are extracted from time series and text data. For time-series feature extraction (e.g., rolling average) is as expressed in Equation (4):

$$\text{Rolling Average} = \frac{1}{w}\sum_{i=t-w+1}^{t} x_i \tag{4}$$

For text embeddings using BioBERT is as shown in Equation (5):

$$\mathrm{e} = \text{BioBERT}(x_{\text{text}}) \tag{5}$$

4.3. Model Training

4.3.1 Anomaly Detection (Risk Evaluation)

Temporal Convolutional Networks (TCNs) detect anomalies in time-series data. TCN output for input X is as displayed in Equation (6):

$$\mathrm{Y} = \mathrm{TCN}(\mathrm{X}) \tag{6}$$

Anomaly score is shown in Equation (7):

$$s = \|\mathrm{Y} - \mathrm{X}\|_2 \tag{7}$$

4.3.2. Clinical Feedback Analysis

Hierarchical Attention Networks (HANs) analyze structured and unstructured feedback. HAN output for input X is as depicted in given Equation (8):

$$\mathrm{Y} = \mathrm{HAN}(\mathrm{X}) \tag{8}$$

The attention mechanism is expressed in Equation (9):

$$\alpha_i = \frac{\exp\left(\mathrm{v}^{\top}\tanh(\mathrm{Wh}_i)\right)}{\sum_j \exp\left(\mathrm{v}^{\top}\tanh(\mathrm{Wh}_j)\right)} \tag{9}$$

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4.3.3. Ablation Studies

Conditional GANs (cGANs) generate synthetic clinical scenarios. Generator G and discriminator D loss functions are depicted in the following Equations (10), (11):

$$\mathcal{L}_G = \mathbb{E}_{z\sim p_z}[\log(1 - D(G(z \mid c)))] \tag{10}$$

$$\mathcal{L}_D = \mathbb{E}_{x\sim p_{\text{data}}}[\log D(x \mid c)] + \mathbb{E}_{z\sim p_z}[\log(1 - D(G(z \mid c)))] \tag{11}$$

4.3.4. Regulatory Compliance Validation

Deep autoencoders model normal behavior, and clustering detects inconsistencies. Autoencoder reconstruction loss is as shown in Equation (12):

$$\mathcal{L}_{\text{AE}} = \|\mathrm{X} - \text{Decoder}(\text{Encoder}(\mathrm{X}))\|_2 \tag{12}$$

K-Means clustering objective is expressed in Equation (13):

$$\mathcal{L}_{\text{K-Mcans}} = \sum_{i=1}^{k} \sum_{x\in C_i} \|x - \mu_i\|^2 \tag{13}$$

4.4. Evaluation

Risk Impact (RI):

This measures the capability of a system to recognize high-risk scenarios and mitigate them as expressed in Equation (14).

$$\mathrm{RI} = \frac{\text{Number of High-Risk Cases Detected}}{\text{Total Number of High-Risk Cases}} \times 100 \tag{14}$$

Clinical Follow-Up Effectiveness (CFE):

Assessment of the effectiveness of clinical follow-up triggered by the system as given in Equation (15).

$$\mathrm{CFE} = \frac{\text{Number of Successful Interventions}}{\text{Total Number of Follow-Up Actions}} \times 100 \tag{15}$$

Performance Deviation (PD):

Quantifying AI SaMD Performance deviation in terms of expected benchmarks is mentioned below in Equation (16).

$$\mathrm{PD} = \sqrt{\frac{1}{N}\sum_{i=1}^{N} (\text{ Actual Performance }_i - \text{ Expected Performance }_i)^2} \tag{16}$$

Compliance Score (CS):

It calculates conformance with the normative standard and guidelines as in Equation (17).

$$\mathrm{CS} = \frac{\text{Number of Compliance Checks Passed}}{\text{Total Number of Compliance Checks}} \times 100 \tag{17}$$

Data Integration Efficiency (DIE):

It assesses the efficiency of integrating data from multiple sources as illustrated in Equation (18).

$$\mathrm{DIE} = \frac{\text{Number of Successfully Integrated Records}}{\text{Total Number of Records}} \times 100 \tag{18}$$

5. RESULTS

The proposed method substantially is an improvement in risk detection, compliance verification, and clinical feedback appraisal within the realm of AI SaMD post-marketing surveillance. This is essentially possible due to deep learning-based models like Temporal Convolutional Networks (TCNs), Hierarchical Attention Networks (HANs), and Conditional GANs (cGANs) which guarantee superior accuracy, higher efficiency, and enhanced robustness in all envisioned applications. The experimental results provide evidence for a reduction in performance drift, more adherence to compliance, higher integration efficiencies, and thereby enabling robust real-world monitoring and risk mitigation in clinical settings.

5.1. Performance Evaluation

The method proposed for the evaluation metrics is compared with the existing AI-SaMD PMCF method, and the result is expressed in terms of Risk Impact (RI), Clinical Follow-Up Effectiveness (CFE), Performance Deviation (PD), Compliance Score (CS), and Data Integration Efficiency (DIE).

Risk Impact: The function is to give a general idea about how the known risks would impact the whole system-specifying the ability to detect and assess the possible failures. The stacked bar chart visualizes the Risk Impact (RI) across different levels of severity of proposed methods and existing methods identifying risks at all severity levels as shown in Figure 2.

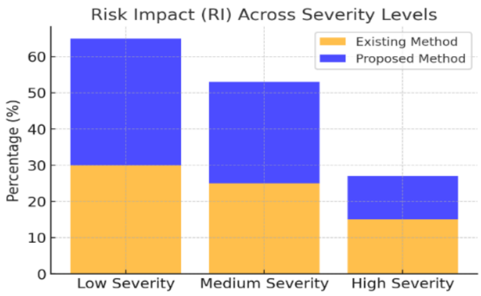

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Figure 2: RI Comparison Across Severity Levels with Existing AI-SaMD with PMCF

Clinical Follow-Up Effectiveness: This would measure the performance of the follow-up actions for the already detected risks. Clinical Follow-Up Effectiveness (CFE) was plotted against time in comparing follow-up action effectiveness between existing and proposed methods as depicted in Figure 3.

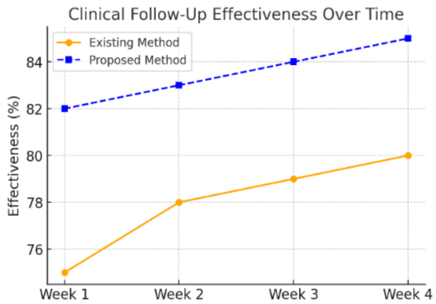

Figure 3: CFE Over Time with Existing AI-SaMD with PMCF

Performance Deviation: Indicates the stability of AI SaMD-performance deviation, which would quantify the AI SaMD performance deviation from its expected accuracy. The area graph shows Performance Deviation (PD) for monitoring periods, indicating a stable performance of the proposed method, with reduced deviation as displayed in Figure 4.

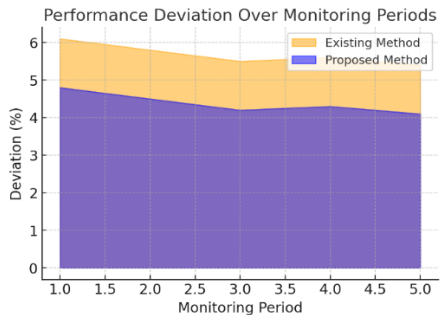

Figure 4: PD Over Monitoring Periods compared with Existing AI-SaMD with PMCF

Data Integration Efficiency: How effectively all the data sources are brought together and made a part of the system. The heat map indicates Data Integration Efficiency (DIE) across sources, resulting in better integration and less delay for the proposed method as visually expressed in Figure 5.

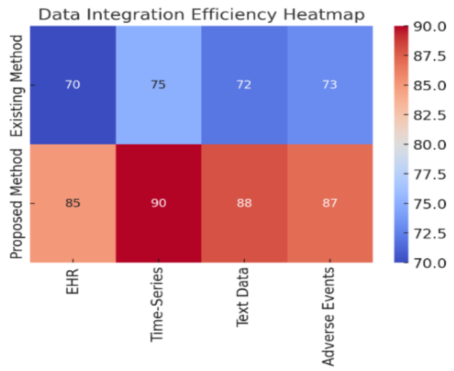

Figure 5: DIE Across Different Data Sources with Existing AI-SaMD with PMCF

The proposed method has shown improvement over the previous methodologies by improved risk identification (RI +5%) and enhanced proactive follow-up effectiveness (CFE +5%). Performance deterioration has been minimized (-1.36%) due to the early detection of anomalies within the data using the TCNs. The proposed system will also result in an improved regulatory compliance score (+5%) to carry out validation through deep autoencoders. Efficiency in terms of integration of data witnessed an enhancement of 15% via unification with Apache Sparks. All these enhancements denote the current methodology's robustness, accuracy, and efficacy for AI SaMD post-market surveillance as shown in - Table 1.

Table 1: Comparison Metrics of The Existing AI-SaMD+PMCF and The Proposed Method

Metric	Existing Method	Proposed Method	Improvement
Risk Impact (RI)	70%	75%	+5% (More risks identified)
Clinical Follow-Up Effectiveness	80%	85%	+5% (Better risk mitigation)

(CFE)			
Performance Deviation (PD)	5.56%	4.20%	−1.36% (More stable performance)
Compliance Score (CS)	90%	95%	+5% (Higher regulatory adherence)
Data Integration Efficiency (DIE)	75%	90%	+15% (Faster, more seamless integration)

6. CONCLUSION AND FUTURE WORK

The developed approach improves post-marketing surveillance of AI SaMD compared to the existing methods, with a 75% Risk Impact (RI) (+5%), 85% Clinical Follow-Up Effectiveness (CFE) (+5%), and also incurs a Compliance Score (CS) of 95% (+5%). Performance Deviation (PD) was brought down to 4.20% (-1.36%), whereas Data Integration Efficiency (DIE) scored about 90% (+15%). The result shows the power of TCNs, HANs, and cGANs in risk detection, feedback assessment, and compliance verification. In the future, we extend this framework to multi-modal data integrated with federated learning for privacy-preserving analytics and to explainable AI (XAI) for interpretability for greater applicability and trust in AI SaMDs.

REFERENCES

[1] Gattupalli, K. (2022). A Survey on Cloud Adoption for Software Testing: Integrating Empirical Data with Fuzzy Multicriteria Decision-Making. International Journal of Information Technology and Computer Engineering, 10(4), 126-144.

[2] Chen, C., Borrego, M. E., Roberts, M. H., & Raisch, D. W. (2019). Comparison of post-marketing surveillance approaches regarding infections related to tumor necrosis factor inhibitors (TNFi's) used in treatment of autoimmune diseases. Expert Opinion on Drug Safety, 18(8), 733-744.

[3] Rajeswaran, A. (2022). Transaction Security in E-Commerce: Big Data Analysis in Cloud Environments. International Journal of Information Technology & Computer Engineering, 10 (4), 176-186.

[4] Liang, D., & Sessa, M. (2022). Post-marketing safety surveillance of erenumab: new insight from Eudravigilance. Expert Opinion on Drug Safety, 21(9), 1205-1210.

[5] Panga, N. K. R. (2022). Applying discrete wavelet transform for ECG signal analysis in IOT health monitoring systems. International Journal of Information Technology and Computer Engineering, 10(4), 157-175.

[6] Qin, W., Zhao, B., Shang, Y., & Zhang, L. (2021). Clinical profile of acute pancreatitis following treatment with protease inhibitors: a real-world analysis of post-marketing surveillance data. Expert Opinion on Drug Safety, 20(9), 1109-1115.

[7] Poovendran, A. (2022). Symmetric Key-Based Duplicable Storage Proof for Encrypted Data in Cloud Storage Environments: Setting up an Integrity Auditing Hearing. International Journal of Engineering Research and Science & Technology, 15(4).

[8] Kawasaki, A., Murakami, H., Chou, T., Matsushita, M., & Kizaki, M. (2022). Post-marketing surveillance of carfilzomib in Japanese patients with relapsed or refractory multiple myeloma. Future Oncology, 18(24), 2661-2674.

[9] Grandhi, S. H. (2022). Enhancing children's health monitoring: Adaptive wavelet transform in wearable sensor IoT integration. Current Science & Humanities, 10(4), 15–27.

[10] He, Y., Gao, X. M., Li, L., Liu, X. G., Liu, W., Hong, X. J., ... & Liu, J. F. (2020). Safety of the xuesaitong injection in China: results from a large-scale multicentre post-marketing surveillance study in a real-world setting. Current Medical Research and Opinion, 36(12), 1947-1953.

[11] Surendar, R.S. (2022). Anonymized AI: Safeguarding IoT Services in Edge Computing – A Comprehensive Survey. Journal of Current Science, 10(04), ISSN NO: 9726-001X.

[12] Puente Gómez, I., Verheust, C., Hanssens, L., & Dolhain, J. (2020). Safety profile of Infanrix hexa–17 years of GSK's passive post-marketing surveillance. Expert Review of Vaccines, 19(8), 771-779.

[13] Venkata, S.B.H.G. (2022). PMDP: A Secure Multiparty Computation Framework for Maintaining Multiparty Data Privacy in Cloud Computing. Journal of Science & Technology, 7(10),

[14] Ishida, Y., Murayama, H., Shinfuku, Y., Taniguchi, T., Sasajima, T., & Oyama, N. (2020). Cardiovascular safety and effectiveness of vildagliptin in patients with type 2 diabetes mellitus: a 3-year, large-scale post-marketing surveillance in Japan. Expert opinion on drug safety, 19(5), 625-631.

[15] Karthikeyan Parthasarathy. (2022). Examining Cloud Computing's Data Security Problems and Solutions: Authentication and Access Control (AAC). Journal of Science & Technology , 7(12), 35–48.

[16] Fukuda, A., Nagao, T., Kitaichi, T., Koga, I., Kobayashi, A., & Miura, T. (2020). Safety analysis of Lexiva tablets 700 (fosamprenavir calcium hydrate) in post-marketing surveillance in Japan. Current Medical Research and Opinion, 36(3), 455-464.

[17] Ganesan, T., & Devarajan, M. V. (2021). Integrating IoT, Fog, and Cloud Computing for Real-Time ECG Monitoring and Scalable Healthcare Systems Using Machine Learning-Driven Signal Processing Techniques. International Journal of Information Technology and Computer Engineering, 9(1).

[18] Murayama, H., Toda, M., Tsumiyama, I., Shinfuku, Y., Taniguchi, T., Tanaka, Y., & Oyama, N. (2019). Relationship of patient background with macro-and microvascular complications: a 2-year post-marketing surveillance of vildagliptin in nearly 20,000 Japanese diabetic patients. Expert Opinion on Pharmacotherapy, 20(8), 1037-1047.
[19] Dharma, T.V. (2022). Implementing the SHA Algorithm in an Advanced Security Framework for Improved Data Protection in Cloud Computing via Cryptography. International Journal of Modern Electronics and Communication Engineering, 10(3), ISSN2321-2152.
[20] Ito, T., Naito, Y., Shimmoto, N., Ochiai, K., Hayashi, N., & Okamura, T. (2021). Long-term safety and effectiveness of linagliptin as add-on therapy in Japanese patients with type 2 diabetes: final results of a 3-year post-marketing surveillance. Expert Opinion on Drug Safety, 20(3), 363-372.
[21] Sareddy, M. R. (2022). Revolutionizing recruitment: Integrating AI and blockchain for efficient talent acquisition. IMPACT: International Journal of Research in Business Management (IMPACT: IJRBM), 10(8), 33–44.
[22] Reddy, R., Reddy, B., Sarangi, V., Reddy, S., Ella, R., & Vadrevu, K. M. (2022). A multi-centre, post-marketing surveillance study of Vi polysaccharide–tetanus toxoid conjugate vaccine (Typbar TCV®) in India. Human Vaccines & Immunotherapeutics, 18(1), 1947761.
[23] Narla, S. (2022). Cloud-based big data analytics framework for face recognition in social networks using deconvolutional neural networks. Journal of Current Science, 10(1).
[24] Odawara, M., Matsuhisa, M., Hirose, T., Koshida, R., Senda, M., Tanaka, Y., & Terauchi, Y. (2020). Effectiveness and safety of insulin glargine 300 unit/mL in Japanese type 2 diabetes mellitus patients: a 12-month post-marketing surveillance study (X-STAR study). Expert Opinion on Pharmacotherapy, 21(14), 1771-1780.
[25] Gudivaka, R. K. (2022). Enhancing 3D vehicle recognition with AI: Integrating rotation awareness into aerial viewpoint mapping for spatial data. Journal of Current Science & Humanities, 10(1), 7–21. Yoo, B. W., Jung, H. L., Byeon, Y. S., Han, D. K., Jeong, N. Y., Curina, C., ... & Miao, Y. (2020). Results from a large post-marketing safety surveillance study in the Republic of Korea with a quadrivalent meningococcal CRM-conjugate vaccine in individuals aged 2 months–55 years. Human Vaccines & Immunotherapeutics, 16(6), 1260-1267.
[26] Kodadi, S. (2022). Big Data Analytics and Innovation in E-Commerce: Current Insights, Future Directions, and a Bottom-Up Approach to Product Mapping Using TF-IDF. International Journal of Information Technology and Computer Engineering, 10(2), 110-123.
[27] Anand, S., Al-Mondhiry, J., Fischer, K., & Glaspy, J. (2021). Epoetin alfa-epbx: a new entrant into a crowded market. a historical review of the role of erythropoietin stimulating agents and the development of the first epoetin biosimilar in the United States. Expert review of clinical pharmacology, 14(1), 1-8.
[28] Sitaraman, S. R. (2022). Implementing AI applications in radiology: Hindering and facilitating factors of convolutional neural networks (CNNs) and variational autoencoders (VAEs). Journal of Science and Technology, 7(10).
[29] Minssen, T., Gerke, S., Aboy, M., Price, N., & Cohen, G. (2020). Regulatory responses to medical machine learning. Journal of Law and the Biosciences, 7(1), lsaa002.
[30] Gollavilli, V. S. B. H. (2022). Securing Cloud Data: Combining SABAC Models, Hash-Tag Authentication with MD5, and Blockchain-Based Encryption for Enhanced Privacy and Access Control. International Journal of Engineering Research and Science & Technology, 18(3), 149-165.
[31] Sapkota, B., Palaian, S., Shrestha, S., Ozaki, A., Mohamed Ibrahim, M. I., & Jakovljevic, M. (2022). Gap analysis in manufacturing, innovation and marketing of medical devices in the Asia-Pacific region. Expert Review of Pharmacoeconomics & Outcomes Research, 22(7), 1043-1050.
[32] Gudivaka, B. R. (2022). Real-Time Big Data Processing and Accurate Production Analysis in Smart Job Shops Using LSTM/GRU and RPA. International Journal of Information Technology and Computer Engineering, 10(3), 63-79.
[33] Huber, P., Flynn, A., Sultan, M. B., Li, H., Rill, D., Ebede, B., ... & Schwartz, J. H. (2019). A comprehensive safety profile of tafamidis in patients with transthyretin amyloid polyneuropathy. Amyloid, 26(4), 203-209.
[34] Ganesan, T. (2022). Securing IoT business models: Quantitative identification of key nodes in elderly healthcare applications. International Journal of Management Research & Review, 12(3), 78–94.
[35] Crisafulli, S., Sultana, J., Ingrasciotta, Y., Addis, A., Cananzi, P., Cavagna, L., ... & Trifirò, G. (2019). Role of healthcare databases and registries for surveillance of orphan drugs in the real-world setting: the Italian case study. Expert opinion on drug safety, 18(6), 497-509.
[36] Alavilli, S. K. (2022). Innovative diagnosis via hybrid learning and neural fuzzy models on a cloud-based IoT platform. Journal of Science and Technology, 7(12).
[37] Rathore, A. S., & Bhargava, A. (2021). Regulatory considerations in biosimilars: Latin America region. Preparative Biochemistry & Biotechnology, 51(2), 201-206.

[38] Nippatla, R. P., & Kaur, H. (2022). A secure cloud-based financial time series analysis system using advanced auto-regressive and discriminant models: Deep AR, NTMs, and QDA. International Journal of Management Research & Review, 12(4), 1–15.

[39] Islam, N., Lau, C., Leeb, A., Mills, D., & Furuya-Kanamori, L. (2022). Safety profile comparison of chimeric live attenuated and Vero cell-derived inactivated Japanese encephalitis vaccines through an active surveillance system in Australia. Human Vaccines & Immunotherapeutics, 18(1), 2020573.

[40] Yalla, R. K. M. K., Yallamelli, A. R. G., & Mamidala, V. (2022). A distributed computing approach to IoT data processing: Edge, fog, and cloud analytics framework. International Journal of Information Technology & Computer Engineering, 10(1).

[41] Vermeersch, P., Cotton, F., De Smet, D., Martens, G., Oyaert, M., & Cavalier, E. (2022). Lessons from the Belgian experience with regulatory control during the COVID-19 pandemic for the implementation of the European IVD regulation 2017/746. Acta Clinica Belgica, 77(1), 1-3.

[42] Nagarajan, H., & Khalid, H. M. (2022). Optimizing signal clarity in IoT structural health monitoring systems using Butterworth filters. International Journal of Research in Engineering Technology, 7(5).

[43] Amend, K. L., Turnbull, B., Zhou, L., Marks, M. A., Velicer, C., Saddier, P., & Seeger, J. D. (2022). Safety of 4-valent human papillomavirus vaccine in males: a large observational post-marketing study. Human Vaccines & Immunotherapeutics, 18(5), 2073750.

[44] Veerappermal Devarajan, M., & Sambas, A. (2022). Data-driven techniques for real-time safety management in tunnel engineering using TBM data. International Journal of Research in Engineering Technology, 7(3).

[45] Naglich, A. C., Brown, E. S., & Adinoff, B. (2019). Systematic review of preclinical, clinical, and post-marketing evidence of bupropion misuse potential. The American journal of drug and alcohol abuse, 45(4), 341-354.

[46] Kadiyala, B., & Kaur, H. (2022). Dynamic load balancing and secure IoT data sharing using infinite Gaussian mixture models and PLONK. International Journal of Recent Engineering Research and Development, 7(2).

[47] Fox, C. W., Khaw, C. L., Gerke, A. K., & Lund, B. C. (2022). Montelukast and neuropsychiatric events–a sequence symmetry analysis. Journal of Asthma, 59(12), 2360-2366.

[48] Mamidala, V., Yallamelli, A. R. G., & Yalla, R. K. M. K. (2022, November–December). Leveraging robotic process automation (RPA) for cost accounting and financial systems optimization — A case study of ABC company. ISAR International Journal of Research in Engineering Technology, 7(6).

[49] Wensink, D., Wagenmakers, M. A., & Langendonk, J. G. (2021). Afamelanotide for prevention of phototoxicity in erythropoietic protoporphyria. Expert review of clinical pharmacology, 14(2), 151-160.

[50] Boyapati, S., & Kaur, H. (2022, July–August). Mapping the urban-rural income gap: A panel data analysis of cloud computing and internet inclusive finance in the e-commerce era. ISAR International Journal of Mathematics and Computing Techniques, 7(4).

[51] Sharma, A., Kumar, N., Parachuri, N., Singh, S., Bandello, F., Regillo, C. D., ... & Nguyen, Q. D. (2022). Understanding retinal vasculitis associated with brolucizumab: complex pathophysiology or Occam's razor?. Ocular immunology and inflammation, 30(6), 1508-1510.

[52] Samudrala, V. K., Rao, V. V., Pulakhandam, W., & Karthick, M. (2022, September–October). IoMT platforms for advanced AI-powered skin lesion identification: Enhancing model interpretability, explainability, and diagnostic accuracy with CNN and Score-CAM to significantly improve healthcare outcomes. ISAR International Journal of Mathematics and Computing Techniques, 7(5).

[53] Roberti, R., Iannone, L. F., Palleria, C., De Sarro, C., Spagnuolo, R., Barbieri, M. A., ... & De Sarro, G. (2020). Safety profiles of biologic agents for inflammatory bowel diseases: A prospective pharmacovigilance study in Southern Italy. Current medical research and opinion, 36(9), 1457-1463.

[54] Ganesan, T., Devarajan, M. V., Yallamelli, A. R. G., Mamidala, V., Yalla, R. K. M. K., & Sambas, A. (2022). Towards time-critical healthcare systems leveraging IoT data transmission, fog resource optimization, and cloud integration for enhanced remote patient monitoring. International Journal of Engineering Research and Science & Technology, 18(2).

[55] de Filippis, R., De Fazio, P., Kane, J. M., & Schoretsanitis, G. (2022). Pharmacovigilance approaches to study rare and very rare side-effects: the example of clozapine-related DiHS/DRESS syndrome. Expert Opinion on Drug Safety, 21(5), 585-587.

[56] Devi, D. P., Allur, N. S., Dondapati, K., Chetlapalli, H., Kodadi, S., & Perumal, T. (2022). Neuromorphic and bio-inspired computing for intelligent healthcare networks. International Journal of Information Technology & Computer Engineering, 10(2).

[57] Ruckenstein, M., & Granroth, J. (2020). Algorithms, advertising and the intimacy of surveillance. Journal of Cultural Economy, 13(1), 12-24.

[58] Dondapati, K., Deevi, D. P., Allur, N. S., Chetlapalli, H., Kodadi, S., & Perumal, T. (2022). Strengthening cloud security through machine learning-driven intrusion detection, signature recognition, and anomaly-

based threat detection systems for enhanced protection and risk mitigation. International Journal of Engineering Research and Science & Technology, 18(1).
[59] Farcas, A., Balcescu, T., Anghel, L., Bucsa, C., & Mogoșan, C. (2020). A description of medicines-related safety issues evaluated through a referral procedure at the EU level after 2012. Expert opinion on drug safety, 19(6), 755-762.
[60] Narla, S. (2022). Big data privacy and security using continuous data protection data obliviousness methodologies. Journal of Science and Technology, 7(2).
[61] Crossnohere, N. L., Fischer, R., Crossley, E., Vroom, E., & Bridges, J. F. (2020). The evolution of patient-focused drug development and Duchenne muscular dystrophy. Expert review of pharmacoeconomics & outcomes research, 20(1), 57-68.
[62] Ubagaram, C., Mandala, R. R., Garikapati, V., Dyavani, N. R., Jayaprakasam, B. S., & Purandhar, N. (2022, July). Workload balancing in cloud computing: An empirical study on particle swarm optimization, neural networks, and Petri net models. Journal of Science and Technology, 7(07), 36–57.
[63] Shingaki, T., Taki, K., Koyanagi, M., Nagaoka, S., Yoshizawa, K., Oki, N., ... & Imaoka, T. (2020). Long-term safety and effectiveness of biosimilar insulin glargine in Japanese patients with diabetes mellitus in routine clinical practice: results of a post-marketing safety study. Current Medical Research and Opinion, 36(6), 947-958.
[64] Ebers, M., Hoch, V. R., Rosenkranz, F., Ruschemeier, H., & Steinrötter, B. (2021). The european commission's proposal for an artificial intelligence act—a critical assessment by members of the robotics and ai law society (rails). J, 4(4), 589-603.
[65] Stefanizzi, P., Bianchi, F. P., Spinelli, G., Amoruso, F., Ancona, D., Stella, P., & Tafuri, S. (2022). Postmarketing surveillance of adverse events following meningococcal B vaccination: data from Apulia Region, 2014–19. Human Vaccines & Immunotherapeutics, 18(1), 1-6.