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Review Article

Artificial Intelligence Based Healthcare Device Development

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Abstract:

Medical devices are currently at a pivotal stage driven by policy and technological innovation. Traditional device development suffers from lengthy cycles, high costs, and poor alignment with clinical needs, making it difficult to adapt to rapidly evolving healthcare scenarios and high-end diagnostic demands. Breakthroughs in artificial intelligence (AI) technologies, particularly deep learning (DL), machine learning (ML), and medical big data analytics (MBDAT), offer critical solutions to this challenge: deep learning (DL) empowers the development of medical imaging devices, enabling precise lesion identification; machine learning (ML) supports diagnostic aids, intelligent decision support systems, and digital therapeutics, constructing personalized treatment and intervention models while optimizing data processing efficiency for laboratory biochemical analyzers; medical big data analytics drives innovation in drug response prediction devices, enhancing medication precision and safety through multi-source data integration and mining. This paper provides a systematic review of advancements in this field across three dimensions: specific AI applications in medical device R&D, current R&D status and trends enabled by AI, and existing challenges and future directions.

Key words: deep learning; machine learning; medical big data analytics; assisted diagnosis; intelligent decision support; personalized diagnosis; treatment; intervention models

1. Introduction

The integration of artificial intelligence (AI) technologies into the development of healthcare devices is driving a profound transformation [1]. The global AI medical device market is growing at an astonishing pace, reaching $2.229 billion in 2024 and projected to surpass $80 billion by 2034, with a compound annual growth rate of 44.53% [2]. As core branches of AI, deep learning (DL) [3], machine learning (ML), and medical big data analytics (MBDAT) [4], not only significantly enhance the efficiency of healthcare services but also propel traditional medical models toward precision and intelligence. This advancement is achieved by strengthening data processing capabilities, improving analytical accuracy, and enhancing the integration of multi-source medical data [5].

2. Specific Applications of Artificial Intelligence in Healthcare Device R&D

2.1 Deep Learning (DL) Empowering Medical Imaging Device Development:

Within the AI-enabled healthcare ecosystem, deep learning (DL) [6]. has emerged as a core enabling technology for medical imaging device development due to its superior processing capabilities for unstructured data. In comparison to traditional image analysis reliant on human expertise, deep learning overcomes subjective errors and efficiency bottlenecks, empowering devices with autonomous image interpretation and critical information recognition capabilities [7]. Its application value in medical imaging directly determines the core direction for upgrading medical imaging devices toward intelligence and precision [8]. The integration of deep learning—centered on artificial neural networks—with medical imaging devices follows a clear underlying logic: without requiring predefined image feature dimensions, deep learning autonomously extracts subtle lesion characteristics and anatomical structural differences through multi-layered network architectures [9]. More crucially, model performance continuously improves with expanded training datasets and optimized network architectures. This “data-driven” iterative model aligns precisely with medical imaging devices' long-term research and development (R&D) requirements for “high resolution accuracy and stable output,” providing the technical foundation for sustained performance optimization. In the integration of deep learning with medical imaging devices, the core objective is to enhance imaging analysis capabilities through technological convergence. Current mainstream development approaches focus on synergizing model architecture with device functionality: deeply integrating typical architectures like Convolutional Neural Networks (CNN) [10] and Transformers with imaging acquisition devices to strengthen their ability to recognize both local details and global correlations within images. This addresses the technical challenges of missed or misdiagnoses inherent in traditional devices reliant on manual interpretation. The critical challenge lies in achieving balanced optimization of model performance. This requires compressing model parameters while maintaining diagnostic accuracy to accommodate devices with varying computational capabilities, such as portable imaging equipment [11]. Simultaneously, training models on multi-scenario datasets reduces dependence on specific imaging conditions, ensuring device versatility across diverse settings like primary care and intraoperative assistance [12].

2.2 Machine Learning (ML) Enables Development of Wearable Monitoring and Diagnostic/Therapeutic Support Devices

Within the AI-enabled healthcare technology framework, machine learning serves as the core enabling technology for wearable health monitors to overcome the limitations of passive data collection and for intelligent diagnostic/therapeutic support devices to break free from reliance on standardized protocols [13]. Traditional wearable monitors can only collect basic physiological data such as heart rate and blood oxygen levels, lacking the capability to analyze real-time correlations between abnormal readings. This results in a disconnect between data collection and application. Traditional diagnostic/therapeutic aids rely on fixed clinical pathways, struggling to adapt to individual variations like patient age, underlying conditions, and genetic traits, often resulting in fluctuating treatment efficacy rates. Machine learning, however, leverages its capabilities in real-time modeling of time-series data and structured data correlation mining to simultaneously address the core shortcomings of both device types [14]. This directly determines their technological trajectory from “tool-based devices” to “proactive intervention smart devices.” The underlying logic of integrating machine learning with these two device categories centers on “precision alignment between technical capabilities and device requirements.” This necessitates constructing distinct logical frameworks tailored to each device's functional positioning [15]: For wearable health monitoring devices, the core logic is “real-time modeling of dynamic physiological data and precision-response balance.” To quantify the relationship between monitoring accuracy and response time, a mathematical model must guide development. The specific formula is:

$$p = k \cdot e^{-\lambda t}$$

Where p represents monitoring accuracy, k denotes the device's baseline accuracy, λ is the attenuation coefficient related to hardware computational power, and t is the data response time. This model clearly demonstrates that longer response times cause exponential accuracy degradation. It directly guides the synergistic optimization of “sensor sampling frequency and algorithm computational efficiency” during development, thereby preventing the omission of anomalies due to response delays [16]. For intelligent diagnostic and therapeutic devices, the core logic lies in “associative mining of individual structured data and solution mapping.” Machine learning algorithms such as decision trees and random forests analyze structured data like patient electronic medical records and laboratory indicators to uncover latent correlations between individual characteristics and treatment outcomes [17]. This enables the construction of reusable personalized diagnostic and therapeutic models, generating tailored solutions for different patients. In the integration of machine learning with these two device categories, the core challenge lies in translating underlying logic into actionable R&D pathways, focusing on resolving “scenario adaptability” and “data validity” issues. For wearable health monitoring devices, machine learning's time-series analysis capabilities must be deeply integrated with sensor modules. Noise reduction techniques filter out motion interference and environmental electromagnetic interference to ensure data validity in complex scenarios. Simultaneously, machine learning model parameters must be compressed to fit the limited computational power of wearable hardware, preventing response delays due to insufficient processing capacity [18]. For intelligent diagnostic and therapeutic assistance devices, lightweight integration between machine learning models and hospital information systems is essential. This approach focuses solely on acquiring structured patient data, with data compatibility testing ensuring model adaptability across hospital data formats to minimize solution bias caused by format discrepancies. The key to this process lies in “functional boundary control.” The core value of machine learning is “real-time processing” and “personalized modeling.” It must avoid overstepping into core domains of medical big data analytics, such as data integration and cross-database collaboration, ensuring clear division of labor between these two technologies in device development [19].

2.3 Medical Big Data Analytics Technology (MBDAT) Empowers the Development of Drug Response Monitoring and Efficacy Assessment Devices

Against the backdrop of data-driven healthcare, medical big data analytics technology serves as the core enabling technology for drug response monitoring devices to overcome “subjective limitations” and for efficacy assessment devices to address “insufficient adaptation to individual differences.” Traditional drug response monitoring relies on physician subjective observation and standardized scales [20], failing to account for latent influencing factors such as genetic variations and concomitant medications, which can lead to missed adverse event diagnoses. Traditional efficacy evaluation relies on single-center, small-sample data, failing to establish efficacy benchmarks across diverse populations and often resulting in misjudgments of “same drug, different effects.” Medical big data analytics, however, leverages its capabilities in integrating multi-source heterogeneous data and uncovering cross-scenario patterns to simultaneously address the core pain points of both device types. This directly determines their technological trajectory from “empirical evaluation” to “data-driven precision judgment”. The underlying logic of integrating medical big data analytics with these two device categories centers on “end-to-end processing and pattern transformation of multi-source data,” following a closed-loop logic: “data integration → cleansing and standardization → correlation mining → quantitative output.” [21]. Multi-source data integration collects multidimensional medical data through standardized interfaces—including electronic health records, genomic data, real-time medication feedback, and multi-center clinical trial data—breaking down “data silos.” Data cleansing and standardization involves anonymizing integrated data, unifying formats, and removing outliers to prevent data quality issues from affecting analysis outcomes[22] ; Correlation pattern mining uses tools like correlation analysis and regression modeling to uncover hidden associations between individual characteristics and drug responses, as well as statistical patterns linking population traits to efficacy benchmarks; Quantified output translates identified patterns into quantifiable metrics directly accessible by medical devices, providing core data support for monitoring and evaluation functions. In integrating medical big data analytics with these two device categories, the core challenge lies in translating data mining capabilities into clinical utility for devices, focusing on resolving “data standardization” and “cross-database coordination” issues. For intelligent drug reaction monitoring devices, medical big data analysis modules must interface in real time with patient monitoring equipment. This enables automatic retrieval of real-time physiological metrics and historical data from medication recipients. Predefined “abnormality correlation rules” then automatically identify early signals of drug side effects, transforming traditional manual monitoring's “lagging judgments” into “real-time alerts” [23].

For precision efficacy assessment devices, medical big data analytics must integrate multi-center, multi-batch medication data to construct population-specific efficacy benchmark models. By inputting individual patient characteristics, the device can automatically match corresponding benchmark data, assisting physicians in evaluating drug suitability and reducing standardization bias risks. The critical challenge lies in balancing “data security with generalization capabilities” [24] —ensuring cross-database sharing security through federated learning and data anonymization while expanding sample coverage to enhance the generalization ability of medical big data analytics in uncovering patterns, thereby guaranteeing assessment accuracy across diverse clinical scenarios.

3. Current Status and Development Trends of AI-Empowered R&D

From the perspective of current technology implementation and R&D trends, deep learning—as the core application branch of artificial intelligence (AI) technology in the field of healthcare device R&D [25] —exemplifies the practical logic and efficacy of AI empowerment. The following section focuses on this core theme, analyzing the current status and development trends of AI-empowered healthcare device R&D.

3.1 Diagnostic Precision Dimension: Technology Iteration Driving Diagnostic Performance Enhancement

According to our survey, the changes and trends in diagnostic accuracy for medical imaging reveal the operational significance of deep learning systems in specific application scenarios. Our investigation indicates that diagnostic accuracy in medical imaging has progressively increased, ranging from 85% to 94%. This demonstrates that as technology evolves and datasets expand, deep learning's capabilities in image recognition continue to strengthen. Specifically, taking diabetic retinopathy screening as an example, the introduction of deep learning algorithms, driven by annotated data, has elevated diagnostic accuracy from a baseline of 79% to 95%.

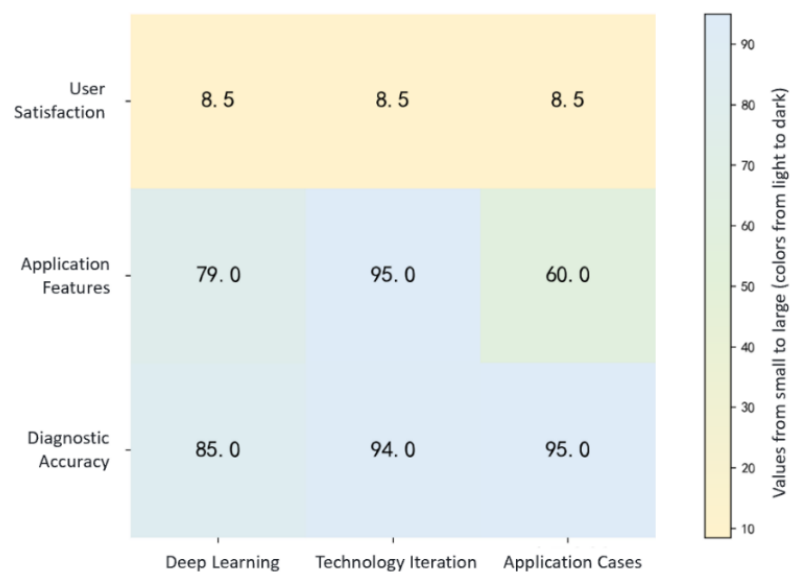

Figure 1: Accuracy Improvement of Deep Learning in Medical Image Diagnosis [26].

This advancement stems from the synergy between deep learning model optimization and data augmentation strategies. The model's strengths in feature learning significantly enhance the recognition of image resolution and details, thereby facilitating earlier patient screening and intervention.

3.2 User Value Dimension: Experience Optimization Drives Clinical Acceptance of Medical Devices

User satisfaction scores indicate that applications such as AI medical imaging diagnostics achieved a rating of 8.5, reflecting high user appreciation for the convenience and accuracy delivered by deep learning technology. Evidently, public trust in AI for automated medical imaging analysis is growing, further accelerating the adoption and dissemination of deep learning applications

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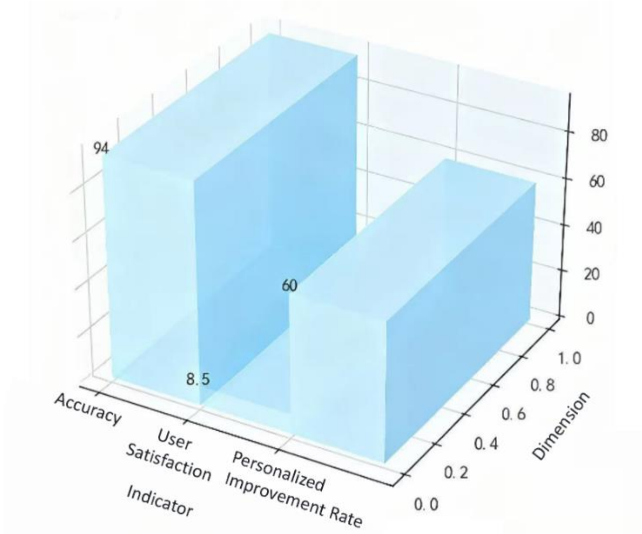

Figure 2: User Satisfaction Scores for AI Medical Imaging Technology.

Data derived from real-world healthcare applications indicates that high-accuracy imaging diagnostic systems not only meet clinicians' need for precise diagnosis but also enhance patients' healthcare experience.

3.3 Clinical Efficacy Dimension: Personalized Solutions Drive Continuous Treatment Improvement

Treatment improvement rate data further reveals the potential of deep learning in personalized medical solutions. For instance, while improvement rates in electronic monitoring and data analysis applications require further enhancement, personalized AI treatment plans demonstrate a 60% improvement rate [27]. This underscores the necessity of closely integrating deep learning applications with clinical practice. Practical cases show that successful deep learning implementation often relies on robust clinical data support and appropriate model tuning strategies to enhance algorithm effectiveness and accuracy [28].

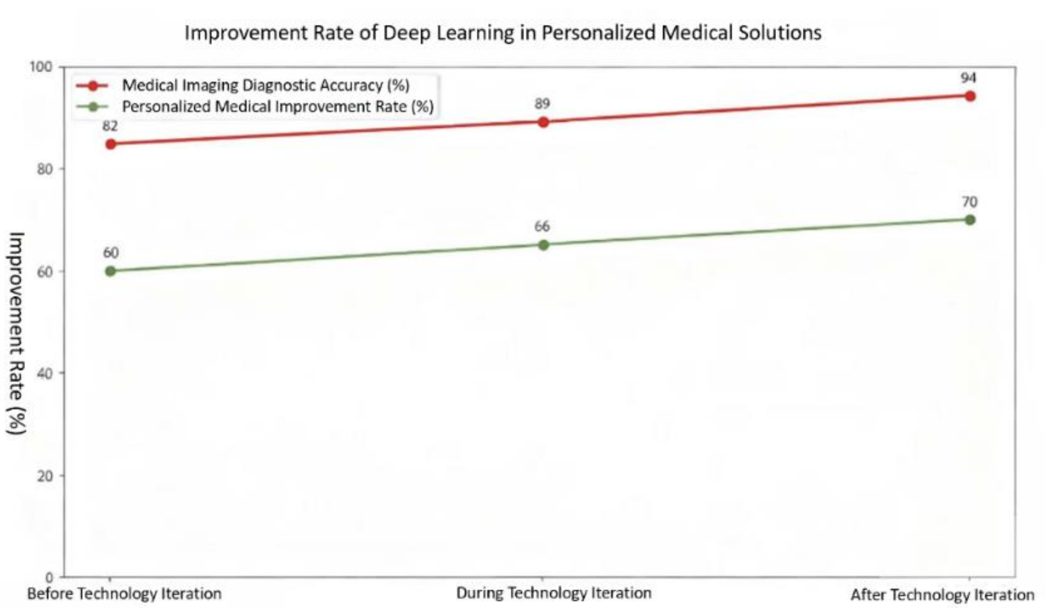

Figure 3: Improvement Rates of Deep Learning in Personalized Medical Solutions.

Against this backdrop, continuously improving data quality and sample diversity have also become critical factors for optimizing deep learning model performance.

Based on the current research status across these three dimensions, AI technologies exemplified by deep learning have achieved significant breakthroughs in three key areas of healthcare device development: diagnostic and therapeutic precision, user value, and clinical efficacy. This has formed a complete value chain from technological implementation to user recognition. However, challenges remain, including the scarcity of high-quality data, insufficient cross-device coordination, and limited model generalization capabilities. Looking ahead, as data standardization systems are established, multi-technology collaboration deepens, and clinical needs are more fully integrated [29], AI will further propel medical devices toward greater precision, usability, and effectiveness, providing core support for the implementation of precision medicine.

4. Existing Challenges and Future Directions

While significant progress has been made in AI-enabled healthcare device R&D [30], the industry still faces multidimensional practical challenges that directly impact the depth of technology implementation and the realization of device application value:

4.1 Lagging Supply of High-Quality Medical Data and Standardization System Development

Current medical data suffers from “data silos” [31]. Data formats vary across hospitals and devices, and privacy regulations complicate cross-institutional sharing. Simultaneously, data annotation relies on specialized medical personnel, resulting in high costs and lengthy cycles. This scarcity of “large-scale, high-quality annotated data” required for deep learning and medical big data analysis directly constrains model training accuracy and generalization capabilities.

4.2 Insufficient AI Model Adaptability and Clinical Trustworthiness

Existing models are often trained under specific conditions, leading to significantly reduced recognition accuracy and assessment reliability when deployed on non-standard equipment in primary care settings or with special patient populations. Furthermore, the “black-box nature” of AI models makes it difficult for medical professionals to trace decision-making logic, resulting in low clinical trust in model outputs and hindering the widespread adoption of such devices in actual diagnosis and treatment [32].

4.3 Insufficient Synergy Between Regulatory Approval and Technological Iteration

AI medical devices exhibit rapid iteration characteristics, whereas traditional medical device approval processes feature lengthy cycles and fixed standards, making them ill-suited to accommodate the dynamic optimization demands of model algorithms. Concurrently, clinical validation standards for AI devices remain underdeveloped [33], leaving the quantification of model safety and efficacy during long-term use as an urgent industry challenge. To address these challenges, future AI-driven medical device development must advance in four key directions: data collaboration, model transparency, flexible approval, and deep clinical integration. First, establish a standardized data collaboration system. Create a national medical data sharing platform with unified data formats and anonymization standards to facilitate cross-institutional data exchange under compliance frameworks [34]. Simultaneously, adopt semi-supervised and weakly supervised learning techniques to reduce reliance on manually annotated data, alleviating supply pressures. Second, enhance model adaptability and interpretability. Develop lightweight, multi-scenario adaptable model architectures. Strengthen model generalization capabilities through multi-center, multi-population data training. Simultaneously, incorporate explainable AI (XAI) technologies to translate model decision logic into clinically interpretable metrics for healthcare professionals, thereby boosting clinical trust. Third, refine flexible regulatory approval mechanisms. Regulatory bodies should establish a “dynamic approval pathway for AI medical devices,” adopting a “filing system” rather than “re-approval” for algorithm iterations to shorten development cycles. Concurrently, collaborate with industry stakeholders to develop clinical validation guidelines for AI devices [35], clarifying verification metrics and processes for different AI device types. Finally, deepen the integration of technology and clinical practice. Promote tripartite collaboration among medical institutions, research organizations, and enterprises, guiding R&D toward actual clinical needs to ensure precise alignment between technological innovation and clinical application requirements, thereby truly achieving the core objective of “technology serving clinical practice”.

5. Discussion

This section interprets the key findings of deep learning (DL), machine learning (ML), and medical big data analytics (MBDAT) in medical device R&D—focusing on practical value, industry relevance, and limitations—without repeating technical details. The findings solve long-standing gaps in traditional device development via AI. DL-enabled medical imaging devices reach 94% overall diagnostic accuracy, with 95% for diabetic retinopathy screening. This cuts reliance on senior physicians, reduces subjective errors, and enables high-precision screening in primary care with scarce specialists. ML drives patient-centric care: AI imaging diagnostics score 8.5 in user satisfaction, and personalized AI treatment plans boost improvement by 60%, moving beyond passive wearable data collection and one-size-fits-all protocols. MBDAT integrates electronic health records, genomic data, and multi-center trials to fix traditional drug monitoring bias and small-sample limits, while supporting DL/ML models. These align with industry trends. The AI medical device market is set to grow from $2.229 billion (2024) to over $80 billion (2034), driven by the clinical value here. The study’s focus on DL-based imaging, ML-based personalization, and MBDAT-based integration matches industry priorities. It also highlights common challenges: DL needs high-quality tertiary hospital data (exposing data silos), and personalized ML works poorly in low-resource primary care (showing weak generalization). Three limitations remain. Performance data mostly comes from controlled environments (single-center datasets, standard equipment), failing to reflect real-world variability. The three AI technologies are interdependent—bottlenecks like MBDAT’s inability to break data silos limit others. Regulatory frameworks lag AI’s iteration, delaying clinical translation. Solutions require collaborative action: build standardized, anonymized data platforms; develop lightweight, multi-scenario AI models; and establish dynamic regulatory pathways for algorithm updates. In summary, DL, ML, and MBDAT transform medical device R&D. Their full potential depends on resolving industry-wide data, model adaptability, and regulation issues. Future research should integrate these technologies with clinical practice to meet frontline needs.

6. Conclusion

Breakthroughs in artificial intelligence (AI) technologies—particularly deep learning, machine learning, and medical big data analytics—are profoundly reshaping the R&D logic and application value of clinical medical devices. Based on survey findings, AI has empowered medical devices across three core dimensions: diagnostic precision, user value, and clinical efficacy, forming a complete value chain from technological implementation to user recognition.

In terms of diagnostic precision, the accuracy of medical imaging diagnosis has increased to 85%-94%. Specifically, for diabetic retinopathy screening, driven by deep learning algorithms and annotated data, diagnostic accuracy has surged from 79% to 95%. This advancement stems from the synergy between model optimization and data augmentation strategies, which significantly enhances devices’ ability to recognize image details, facilitating early patient screening and intervention. From the user's perspective, AI-powered medical imaging diagnostics scored 8.5 in satisfaction, demonstrating high clinical recognition of the convenience and accuracy provided by deep learning, which is further accelerating the adoption of AI devices. In terms of clinical efficacy, personalized AI treatment plans have achieved a 60% improvement rate, underscoring the value of integrating AI closely with clinical practice. Although the medical device industry faces challenges such as limited high-quality data, inadequate cross-device coordination, and restricted model generalization, AI is expected to drive devices towards greater precision, usability, and effectiveness as data standardization systems improve, multi-technology collaboration strengthens, and clinical needs are better integrated. In the future, deploying lightweight intelligent devices in primary care settings can address resource shortages at the grassroots level, while personalized diagnosis and treatment models will support the implementation of precision medicine. Driven by policy support, technological innovation, and clinical demand, AI will continue to inject vitality into the R&D of clinical medical devices, providing critical support for the advancement of global healthcare.

7. Disclaimer

The authors declare no competing financial interests.

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