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AI-Enabled Medical Devices for Precision Immunology

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ABSTRACT

AI-enabled medical devices are revolutionizing precision immunology through enabling personalized strategies for diagnosis, monitoring, and treatment of immune-mediated diseases. The integration of AI with medical technologies has emerged as a convergence of breakthrough capability to combine clinical, immunological, genomic, multi-omic, and real-time physiological signals, offering unprecedented opportunities to enhance disease stratification, anticipate treatment response, and tailor individualized healthcare. This review summarizes recent progress in AI-enabled medical devices and their broadening applications in precision immunology as leveraging tumor immunology, autoimmune diseases, allergic conditions, infectious diseases, cardiovascular immunology, lupus nephritis, rheumatoid arthritis, sepsis, and more. The review further discusses the enablement of precision medicine by integration of wearable biosensors, intelligent diagnostic platforms, connected health systems, adaptive therapeutic devices, and multi-omic analytics. Additionally, the review addresses current barriers to clinical translatability of these technologies including data acquisition quality and standardization, system interoperability, algorithm transparency, regulatory oversight, cybersecurity, and ethical concerns. We also highlight future innovations including intelligent biosensors, explainable immuno-AI, adaptive responsive drug delivery systems, and connected digital health systems.

1. Introduction

Precision immunology has been positioned as the new paradigm of modern medicine by acknowledging the complex, high-dimensional heterogeneity of immune response across individual patients, and utilizing its knowledge to implement precision detection, prevention, and treatment. Unlike traditional immunology that often immunotherapies broadly targeted the population, today's precision immunology combines a wealth of molecular, genetic, immunological, and clinical data to understand the immune profile of each individual patient for diagnosing and predicting clinical outcomes. The rapid progression of artificial intelligence (AI) now facilitates this transition by deciphering multidimensional biomedical information that is otherwise overwhelming for classic statistical methods, allowing us to accelerate disease sub-classification, predict biomarker response, and adopt precision medicine strategy(Ali et al., 2025; Chen et al., 2025; Wang et al., n.d.).

The exponential growth of EHRs, next-generation sequencing (NGS) technologies, multi-omics platforms and digital health data sets has opened up unprecedent opportunities for AI-based precision medicine. Machine learning and deep learning algorithms can explore complex, indirect correlations between related genomic, transcriptomic, proteomic, metabolomic and immunologic parameters providing for earlier diagnosis, disease subclassification and optimal treatment selection. These heterogeneous data sets have enhanced definitions especially for immune-mediated diseases, given the intrinsic disease heterogeneity and evolving nature of immune responses encountered in most cases (Chen et al., 2025; Shen et al., 2026; Chao et al., 2025).

AI has shown great promise in many immunological diseases such as autoimmune diseases, allergy, infection diseases, cancer immunotherapy, and inflammatory disease. AI-enabled tools have been used for some applications such as improved prediction

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on immune responses and disease-specific diagnostic or prognostic markers, optimized immunotherapeutic regimens and courses, and timely tracking of disease progression through continuous assessment of clinical and biological data to achieve more accurate, personalized healthcare and less delays and limitations in diagnostic workup and treatment (Afzal et al., 2024; Alshorman et al., 2026; Mane et al., 2024; Sah et al., 2025; Shang et al., 2025; van Breugel et al., 2025).

Alongside these virtual improvements in computing, medical devices are increasingly transforming from traditional monitoring tools to smart clinical devices, able to generate, interpret and communicate physiologic or immunologic information in real-time. AI-powered medical devices such as wearable biosensors, connected monitoring systems, imaging tools, implantable devices, or flexible therapeutic devices are facilitating precision immunology by allowing continuous patient monitoring, early immunological decompensation detection, prediction of disease flares, and flexible therapies personalization (Konstantinou et al., 2025; Dinc & Ardic, 2026; Qoronfleh, 2026; Zapotoczny et al., 2026).

As AI-enabled medical devices gain wider acceptance, regulatory oversight and attention to issues regarding device safety, clinical validation, transparency and performance in real-world use has increased. As AI moves from "a black box" to an integrated part of decision support for clinicians and autonomous medical devices being incorporated into machinery, regulators and clinicians will face a time of new challenges in technology validation, algorithm adaptation, cybersecurity, ethical oversight, data protection and other for effective and sustainable clinical use (Derraz et al., 2024; Qoronfleh, 2026; Zapotoczny et al., 2026).

While technological advancement continues to accelerate rapidly, many clinically important barriers persist that hinder integration of AI-enabled medical devices into the workflow of precision immunology. Inconsistent data quality, lack of interoperability, underrepresentation of minority groups in training datasets, bias of algorithms, explainability, and the challenge of transitioning newly developed AI models into everyday patient care have all been identified as major barriers to implementation (Negut & Vidan, 2025; Prema et al., 2026; Van Breugel et al., 2025; Derraz et al., 2024).

This review discusses the rising role of intelligent and AI-enabled medical devices in enabling precision immunology. It covers the intersection between artificial intelligence, immunological sciences and medical device innovation; covers existing clinical applications for immune-mediated conditions; discusses recent innovations; dives into regulatory and practical adoption considerations; and discusses future prospects for intelligent medical devices to revolutionize disease diagnosis and management in a more precise manner. These combined progresses promise to revolutionize healthcare across disease diagnoses, monitoring and management in a more personalized, precise manner (Alshorman et al., 2026; Chen et al., 2025; Dinc & Ardic, 2026; Konstantinou et al., 2025; Qoronfleh, 2026).

2. Literature Review

2.1. Precision Immunology: Evolution toward Personalized Immune Care

For example, precision immunology, which was derived from a broad concept of precision medicine, involves the precision assessment of individual immune functions toward more accurate management of disease diagnosis, prognosis, and treatment (Ali et al., 2025). In traditional immunology disciplines, the treatments were mostly standardized and not specifically tailored to individual needs. The concept of precision immunology mainly harbored the biological heterogeneity across patients, such as more our more in-depth understanding of the variability of optimal gene combinations, immune cell populations, cytokine levels, environmental influences and all relevant clinical features for specific states, coalesced with the rapid development of artificial intelligence (AI), this paradigm was more robust with development of integrating large clinical, immunological and molecular data through AI during patient endotyping and therapeutic strategies decision in a high-dimensional fashion (Chen et al., 2025; Ali et al., 2025; Wang et al., n.d.).

However, with the emerging availability of high throughput sequencing, multi-omics, digital health platform, more immunome relevant datasets have been generated for clinical and research application. AI algorithms were evolved that can be utilized to find out complex nonlinear inter-relationships of the multi-faceted datasets that were not revealed by traditional statistical tools. Meanwhile, AI-supported precision immunology approach has promoted biomarker discovery, disease stratification, therapy response prediction, and disease evolution monitoring for countless immune-mediated diseases (Chen et al., 2025; Shen et al., 2026; Chao et al., 2025).

The clinical implications of precision immunology are especially apparent in diseases with complex and variable immune pathways, such as autoimmune diseases, allergies, infectious diseases, and malignancies. AI-based analytical approaches allow clinicians to pinpoint patient-specific immunological endotypes to help tailor therapy with fewer provisions of non-beneficial therapies and related adverse events, thus yielding better clinical outcomes and more efficient use of healthcare resources (Afzal et al., 2024; Mane et al., 2024; Alshorman et al., 2026; Shang et al., 2025; Sah et al., 2025).

2.2. Artificial Intelligence Technologies Driving Precision Immunology

Artificial intelligence is a set of algorithms that use computer processing systems to power a range of sophisticated analytical capabilities; by examining big data sets, computer learning algorithms can accurately identify patterns that are the foundation of AI. In the field of precision immunology, machine learning, deep learning, natural language processing, and predictive analytics are now across all imitative applications to personalize insights derived from EHRs, imaging, labs, genomic, proteomic, metabolomic, and immunophenotyping data to enable precision (Ali et al., 2025; Chen et al., 2025, Wang et al., n.d.).

Machine-learning techniques have proven useful for discovering diagnostic biomarkers, predicting disease susceptibility and therapeutic response in immune-mediated diseases. Supervised machine learning learning predicts the disease phenotypes or therapeutic outcomes based on labeled, clinical data-sets, while unsupervised learning can reveal novel immunological subgroups by revealing hidden relations between multimodal data sets. Deep learning would help improve the accuracy of prediction by automatic feature extraction from complex biological data (Negut & Visan, 2025; Chao et al., 2025; Shen et al., 2026).

Recently, AI innovations have been recognized for its use predicting T-cell-mediated immunity, an essential factor governing the level of immune protection, response to vaccination, as well as responsiveness to immunotherapeutics. With the capability of analyzing immunological, molecular, and genomic information, AI models can accurately predict antibody and immune response, vaccine reaction, and treatment response, which can facilitate tailored immunotherapies and optimize recipients for targeted treatment approaches (Chao et al., 2025; Alshorman et al., 2026).

2.3. AI-Enabled Medical Devices in Precision Immunology

With the integration of AI and medical device technologies, traditional monitoring and clinical diagnostic systems have evolved into intelligent clinical platforms that enable personalized immunological care and interventions. AI-enabled medical devices are defined as computer algorithms loaded within medical hardware systems for ongoing collection, interpretation, and analysis of physiological and immunological signals. These devices foray into earlier disease detection, deep longitudinal monitoring, risk prediction, and dynamic therapeutic intervention, thus expanding the scope of precision medicine beyond episodic clinic visits (Qoronfleh, 2026; Dinc & Ardic, 2026).

The use of wearable and connected medical devices is one of the fastest growing in the application of AI in immunology. Wearable sensors and connected medical devices are able to collate real-time information on physiological levels, environmental factors and self-reported symptoms, and use of AI algorithms can identify patterns that precede allergic symptoms and asthma exacerbation or other immune responses. Furthermore, the ability to provide real-time information can facilitate personalized, near-to-life disease tracking and immune management with a clinical response even before the disease manifests (Konstantinou et al., 2025; van Breugel et al., 2025).

The regulatory landscape for AI-enabled medical devices continues to evolve as technology advances. Growing regulatory approval for many different AI-based medical devices for a variety of clinical applications including pediatric medicine highlights increasing confidence in the clinical usefulness of this new technology. The required continuous algorithm adaptation, software updates, cybersecurity considerations and post-market surveillance for this technology however pose distinct regulatory hurdles compared to traditional medical devices (Zapotoczny et al., 2026; Derraz et al., 2024; Qoronfleh, 2026).

2.4. Clinical Applications of AI in Immune-Mediated Diseases

Another area where AI has been a boon is the diagnosis and management of autoimmune disorders, by the incorporation of clinical features with molecular and immunological markers for early diagnosis and personalized treatments, using the predictive algorithms AI can help clinicians define subtypes of diseases and anticipated disease outcomes and determine optimal therapies for each individual patient based on immune system features (Afzal etal., 2024, Mane etal., 2024, Negut & Visan, 2025).

Cancer immunotherapy is an additional important field in which AI has enhanced the field of precision immunology. The use of AI allows for the optimization of immunotherapeutics, patient stratification and prediction of treatment response by integrative analysis of genomic, transcriptomic and immunological data sets leading to improved immunotherapeutics and less patient exposure to ineffective treatments (Alshorman et al., 2026).

AI has also shown to be of notable utility in infectious disease through enabling tailored therapies and predicting treatment outcomes. For instance, in HIV medicine, artificial intelligence is enabling precision medicine to combine clinical, behavioral, and molecular data to guide treatment selection, monitor disease and improve long-term patient results.3 AI-facilitated multi-omics analysis has been similarly characterized in sepsis to deploy early diagnosis, risk stratification, and tailored therapeutics in acutely ill patients.

Correspondingly, AI-based precision medicine has advanced the care of lupus nephritis through biomarker identification, prediction of treatment responses, and personalized treatment selection. With the modeling of clinical data with molecular biomarkers, the use of AI-enabled tools enable earlier intervention and more precise monitoring of disease course to better inform personalized clinical decision-making for complex autoimmune conditions (Shang et al., 2025).

2.5. Challenges and Future Perspectives

While much progress has been achieved, there still remains a number of challenges that need to be overcome before AI-enabled medical devices can be widely incorporated into precision immunology in the clinical setting. The strong performance of AI algorithms is significantly limited by the access to high quality diverse data sources that are representative to the inherent biological heterogeneity occurring in clinical patient populations. The management of data heterogeneity, breaks in interoperability, and lag in standardization further limit the generalizability of AI algorithms in different clinical applications. (Prema et al. 2026; van Breugel et al. 2025).

Further concerns around algorithm transparency and explainability are also not to be overlooked for real-world clinical translation. As many models of high performance tend to operate as "black box" decision systems with lower interpretability levels, clinicians will require incremental optimal levels of understanding of the prediction or recommendation responsible by these models in order to provide optimal and confident use within healthcare (Negut & Visan, 2025; Derraz et al., 2024).

Furthermore, regulatory and ethical issues have become more prominent as the scope of AI-enabled devices takes on an increasing role in guiding clinical decisions in immunology. Novel challenges posed by ongoing software development, cybersecurity threats, patient data confidentiality, algorithmic bias, and post-market surveillance necessitate updated regulatory infrastructure capable of fulfilling the demands for both innovation and patient safety in the future (Derraz et al., 2024; Zapotoczny et al., 2026; Qoronfleh, 2026).

3. AI-Enabled Medical Devices for Precision Immunology

3.1. Overview of AI-Enabled Medical Devices

AI-enabled medical devices are in the process of becoming part of our fields by embedding increasingly sophisticated forms of computational intelligence into diagnostic, monitoring, and therapeutic medical devices. While traditional medical devices are designed to observe, log, or provide visual representations of physiological information, AI-enabled devices can use machine learning, image recognition, and deep learning neural networks to take in clinical and biological big data and provide outputs that are useful for decision making predicting and classifying disease states or immune responses, or recommending specific courses of treatment. They are especially useful for precision immunology where immune responses are diverse and change rapidly over time (Qoronfleh, 2026; Ali et al., 2025).

The advancement of these types of devices has been made possible through exponential progress in biosensor technology, cloud computing, high performance computing processors, wireless communication, and interoperable healthcare systems over the last few decades. Embedded in these medical devices are AI algorithms that utilize large scale data streams of physiological signals, immunological, genomic, and environmental data to help clinicians better understand the precise course of a disease or condition and how it is responding to therapy. This confluence of digital technologies has transformed the traditional medical device from a passive diagnostic tool into a personalized system to manage individual patient care over the course of treatment (Chen et al., 2025; Qoronfleh, 2026; Wang et al., n.d.).

In immunology, the use of AI-enabled medical devices are especially valuable because immune mediated diseases can be dynamic in presentation with substantial biological heterogeneity. Continuous monitoring afford clinicians the ability to identify early immune changes that are clinically silent, thereby pre-empting clinical exacerbation and its potentially severe consequences (such as tissues degradation) (Konstantinou et al., 2025; Van Breugel et al., 2025).

3.2. AI-Enabled Diagnostic Devices

Diagnostic accuracy, which are a core factor of precision immunology, is also enhanced by the use of AI, with AI-empowered diagnostic tools that incorporate multiple laboratory biomarkers, radiological images, immune-phenotypes, molecular profiling data, and clinical information that advanced diagnosis development and classification of diseases (Negut & Visan, 2025; Chen et al., 2025).

AIs with these developments utilize all comprehensive and integrated diagnostic pathways and allow including many other types of diagnostic markers that automatically integrates and interprets the immunological findings, including autoantibodies, risk gene/alleles, immune cell subsets, and clinical features in order to differentiate diseases with similar clinical presentations (Mane et al., 2024; Afzal et al., 2024; Negut & Visan, 2025).

Such advances in personalized cancer immunotherapy have been aided by the development of AI-reliant diagnostic techniques. AI-based monitoring of genomic, transcriptomic, and immune markers can more accurately determine which patients are most likely to respond to immunotherapeutic strategies. More precise tumor-immune profiling allows for personalization of treatment options, increased accuracy in predicting therapy response, and improved clinical management of immunotherapy patients (Alshorman et al., 2026).

In infectious disease, AI-enabled diagnosis systems were been used to blend laboratory information with molecular and clinical data, for early detection and personalized therapeutic choice. Systems utilized for diagnostic purposes as of today with promising results in HIV treatment and sepsis occurred where early diagnosis and accurate choice of therapy significantly affected the outcome (Sah et al., 2025; Shen et al., 2026).

3.3. AI-Driven Wearable and Connected Medical Devices

Wearable medical devices are increasingly important in precision immunology because they provide a clinical out-of-clinic platform to measure physiologic and environmental variables and generate longitudinal measurements. For example, artificial intelligence (AI) wearable devices utilize continual monitoring of heart rate, respiratory rate, skin temperature, oxygen saturation, physical activity level, sleep pattern, and environment to identify patient physiologic trends that signal the emergence or escalation of immune abnormalities(Konstantinou et al., 2025).

3.4. AI-Enabled Therapeutic and Drug Delivery Devices

Intelligent drug delivery systems are a unique example of this paradigm shift to advanced therapeutic, where AI algorithms facilitate the rationalized control of drug release using physiological patient parameters, disease benchmarking, and treatment response history for improved efficacy and without unwanted side effects. In the case of rheumatoid arthritis, AI-enabled drug delivery techniques integrated with stimuliresponsive biomaterials provide avenues for site-specific release of therapeutic molecules at inflamed joints thus improving the clinical effectiveness and reducing systemic toxicity (Thakur et al., 2026).

In the same way, there is an increasing level of incorporation of immunological knowledge into the management of cardiovascular devices that are using artificial intelligence. Adaptive endovascular devices assess the thrombo-inflammatory profile dynamically, so that tailored management of vascular procedures occurs in relation to the dynamic fluctuating biologic conditions. Such technologies show how AI-enabled medical devices can incorporate both the biotechnology of biomaterials and the science of immunology with computational intelligence to maximize patient-specific therapy (Dinc & Ardic, 2026).

3.5. Integration of Multi-Omics and AI-Enabled Devices

A hallmark of precision immunology is the use of multiple datasets leading to a rich patient profiling. AI-enabled medical devices are transforming this task by acting as portals that provide the conduits for the convergence of real-time monitoring with multi-omics framework including genomic, transcriptomic, proteomic, metabolomic, and immunophenotypic datasets. These multidimensional analyses have the advantage of spatiotemporal resolution to reveal dimensions of immune status and disease pathophysiology not captured by each set separately. (Chen et al., 2025; Shen et al., 2026).

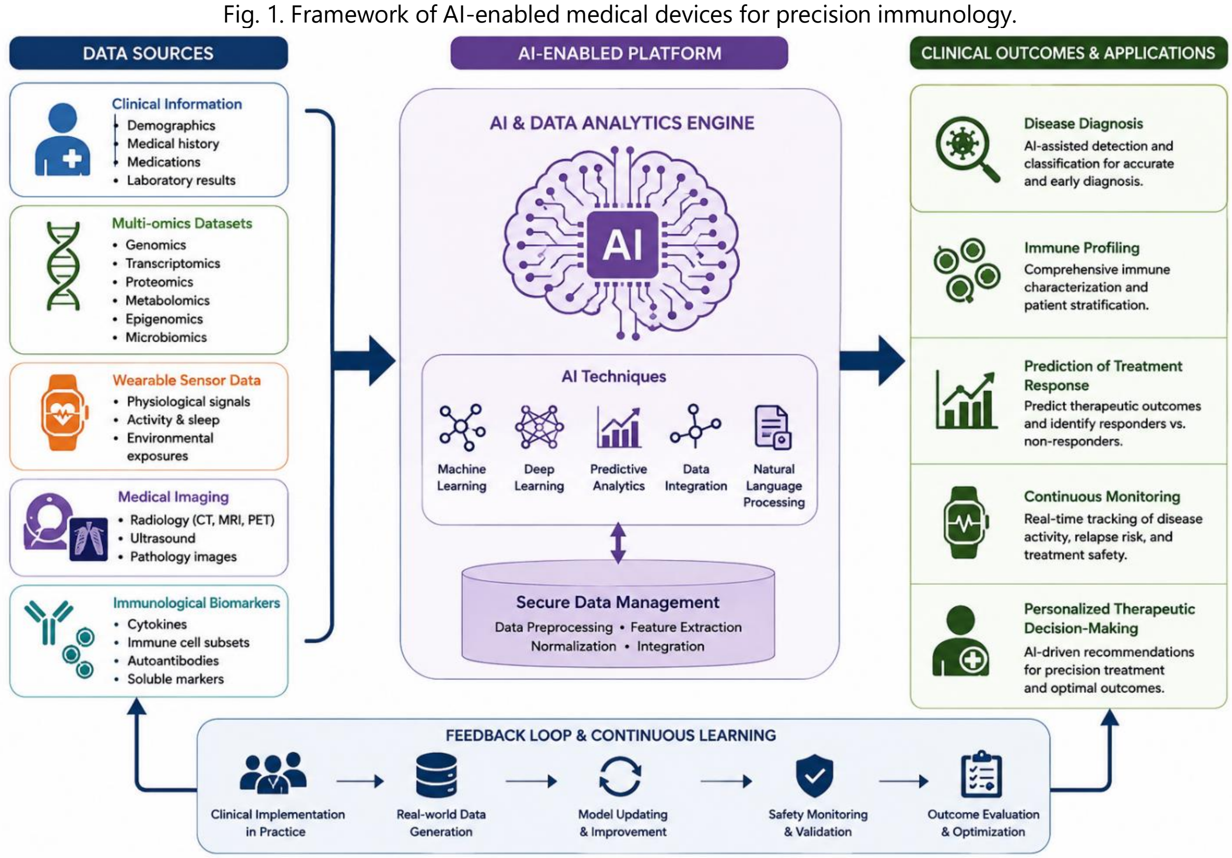
AI algorithms allow us to make sense of these extremely complex data in a clinically meaningful way by connecting molecular biomarkers, immune pathways and clinical features. By comprehensively analyzing these multidimensional data, we can improve disease classification, predict responses to therapy and discover novel biomarkers that help tailor treatment decisions to the individual patient. This skill of integrative analysis is very pertinent in immune-mediated diseases – with their high variability of molecular mechanisms and clinical presentation (Chao et al., 2025; Shang et al., 2025).

Table 1
Categories of AI-enabled medical devices and their applications in precision immunology.

Device category	AI technology	Immunological application	Clinical significance	Representative references
AI-enabled wearable biosensors	Machine learning, predictive analytics	Continuous monitoring of allergic responses and immune-related physiological changes	Early detection of disease exacerbation, personalized monitoring, remote patient management	Konstantinou et al. (2025); van Breugel et al. (2025)
AI-assisted diagnostic platforms	Machine learning, deep learning	Diagnosis of autoimmune diseases, immune profiling, biomarker identification	Improved diagnostic accuracy and patient stratification	Negut & Visan (2025); Mane et al. (2024); Afzal et al. (2024)
AI-integrated multi-omics platforms	Deep learning, data integration	Integration of genomic, transcriptomic, proteomic, metabolomic, and immunological data	Precision diagnosis and prediction of therapeutic response	Chen et al. (2025); Shen et al. (2026); Chao et al. (2025)
Intelligent therapeutic and drug delivery systems	Adaptive AI algorithms	Personalized drug administration and treatment optimization	Improved treatment efficacy with reduced adverse effects	Thakur et al. (2026); Dinc & Ardic (2026)
Connected clinical decision support systems	Machine learning, predictive modeling	Integration of electronic health records with immunological data	Personalized treatment planning and continuous clinical monitoring	Chen et al. (2025); Ali et al. (2025)

Abbreviations: AI, artificial intelligence.

Fig. 1. Framework of AI-enabled medical devices for precision immunology.



Artificial intelligence enabled medical devices amalgamation of clinical patient data, multi-omics studies, wearable data, imaging and immune-biomarkers are coalesced by AI algorithms that use this heterogenous information to aid or assist in targeting disease diagnosis, immune profiling, prediction of therapy response, post-therapy surveillance, and individual TDM.

4. Clinical Applications of AI-Enabled Medical Devices in Precision Immunology

The application of AI in medical devices has broadened the opportunities of precision immunology by facilitating disease-specific diagnostics, monitoring, and therapeutics tailored to individual immune profiles. Equipped with computational intelligence, the AI-enabled medical devices incorporated continuous physiological and molecular sensing information to tailor the clinical decision-making across the vast domain of immune-mediated diseases. Their capacity of fusing heterogenous data, making predictive insights, and providing personalized interventions has boosted their utilization for cancer, autoimmune diseases, allergic disorders, infectious diseases, cardiovascular immunology, and inflammatory conditions (Chen et al., 2025; Qoronfleh, 2026).

4.1. Cancer Immunotherapy

An essential aspect of cancer immunotherapy is the detailed understanding of tumor-immune interactions so as to tailor treatment strategies to ensure optimal treatment efficiency and reduced adverse effects. There are however, significant inter-patient variations in immune cell infiltration, tumor antigen presentation, tumor mutational load and response to immunotherapeutics. AI-driven medical devices enable precision immunotherapy via the amalgamation of medical data with new imaging modalities, molecular biomarkers and immunological databanks in order to inform personalized intervention schemes (Alshorman et al., 2026).

AI-based diagnostics further improves patient stratification by defining predictive biomarkers of response to therapeutics. Machine learning models can analyze complex multi-parametric data to determine those patients most likely to respond to immune checkpoint inhibitors, other immunotherapies while minimizing administration of costly, ineffective treatments. However, AI-based monitoring devices allow for the ongoing monitoring of treatment response to quickly identify the onset of either immune-related adverse events or the emergence of resistance and adapt the treatment plan accordingly. (Alshorman et al., 2026)

Another area where the combination of AI and precision oncology could offer significant benefits is through adaptiveclinical decision-making integrating feedback into the process by iteratively all-owing newly obtained patient data to be assimilated into predictive models to inform therapeutic adjustments without delay. These systems can enhance personalized treatment optimization and disease outcomes by adapting evidence-based approaches over the duration of immunotherapies (Derraz et al., 2024; Wang et al., n.d.).

4.2. Autoimmune Diseases

Autoimmune pathologies are complicated by immune dysregulation, overlapping clinical presentations, and distinct disease courses (autoimmune glomerulopathies, neuromuscular syndromes, inflammatory arthropathies), even at early stages (Al-Achi et al., 2014), which impede early diagnosis and patient-specific therapeutic intervention. AI-powered medical devices have been harnessed to revolutionize disease assessments, bringing together lab test data, genomics, history, scans, and immune profile in comprehensive analytical views (Afzal et al., 2024; Mane et al., 2024).

Application of AI subtyping diagnostic tools in autoimmune disease offers the ability to select the accurate disease diagnostic subgroups based on complex association of a range of biomarkers that may not be recognized with traditional analysis methods; thus making disease diagnosis at an earlier point in disease pathway possible, and allowing earlier application of disease-specific treatment regimes leading to decreased tissue damage and better clinical prognosis. (Negut & Visan, 2025; Mane et al., 2024).

4.3. Allergy and Hypersensitivity Disorders

As a consequence, clinical management of allergic diseases has evolved to require ongoing monitoring of environmental exposures, physiological responses, and clinical manifestation courses. AI-powered wearable medical devices allow clinicians to utilize physiological and environmental data, sensed in real time, to proactively prevent allergic impairment prior to clinically significant sensory presentation (Konstantinou et al., 2025).

Wearable biosensors amass ongoing data streams pertaining to respiratory metrics, cardiovascular indices, activity levels, and allergen exposures. Artificial intelligence models analyze these multidimensional data arrays to derive personal risk scores, forecast alerts, and enable early treatment initiation, all of which improve quality of life and individual productivity while alleviating the need for urgent healthcare visits caused by severe allergic responses (Konstantinou et al., 2025).

Integrated healthcare platforms enhance allergy management by linking wearable sensor outputs into other health information technologies including electronic health records and decision-support platforms. A on-going link with patients enhances disease control and quality of life through real-time communication between patient and clinician and timely modification to treatment regiments in response to disease activity (van Breugel et al., 2025; Chen et al., 2025).

4.4. Infectious Diseases

The growing demand of precision immunology in infectious disease management stems from the fact that host immune responses vary significantly, leading to differences in disease severity and treatment response. AI-enabled medical devices enable personalized healthcare by providing consistent surveillance, early diagnosis, and prognostic prediction of disease course through integration of clinical and molecular data (Sah et al., 2025).

E.g., In treatment of infectious disease: AI-based precision therapy used various patient data including demographic data, laboratory biomarkers, past medical and treatment history, and immunological markers for personalized treatment strategy. Intelligent clinical decision-support systems guided clinicians in selection of therapy, effective monitoring of therapeutic response, and prediction of long-term clinical outcomes. Personalized therapeutic strategy for optimized viral suppression helped in better management of patient (Sah et al., 2025).

AI-supported medical technologies are also showing promising utility in the management of sepsis. For example, multi-omics integration with AI-enabled predictive models has the potential for early detection of some patients heading toward more severe conditions, facilitating earlier therapeutic intervention before permanent tissue and organ damage ensues. Monitor and alarm systems provide additional support to clinicians monitoring the progression of the disease and its response to treatment (Shen et al., 2026).

4.5. Cardiovascular Immunology

Inflammation constitutes a fundamental component in the underlying pathogenesis and progression of multiple cardiovascular disease states, including after various vascular interventions. AI-enabled medical devices have enabled the creation of immunologically adaptive endovascular devices that can perpetually monitor thrombo-inflammatory changes pre-, intra and post-cardiovascular intervention (Dinc & Ardic, 2026).

These smart devices combine advanced biosensing system with AI algorithms to allows real-time monitoring of inflammatory biomarkers, interactions between biomaterials and living tissue, and rehabilitation of vasculature. With the benefit of continuous monitoring, physicians can tailor therapeutic interventions according to individual biological responses which enhances the function of implanted devices and maintains have a better long-term outcome with less rate of thrombosis and hyperflammatory response (Dinc & Ardic, 2026).

In addition to the extensive use of computing intelligence in diagnostic devices, the coalescence of computational intelligence with biomaterials engineering is exemplified in the use of AI-enabled medical devices to implement precision immunology in therapeutic modalities to improve individualized patient outcomes (Qoronfleh, 2026; Dinc & Ardic, 2026).

Table 2
Clinical applications of AI-enabled medical devices across immune-mediated diseases.

Disease area	AI-enabled medical device/application	Clinical contribution	Key references
Cancer immunotherapy	AI-assisted diagnostic and treatment support systems	Biomarker identification, patient stratification, prediction of immunotherapy response	Alshorman et al. (2026); Derraz et al. (2024)
Autoimmune diseases	AI-assisted diagnostic platforms and monitoring devices	Early diagnosis, disease classification, prediction of disease activity, treatment optimization	Afzal et al. (2024); Mane et al. (2024); Negut & Visan (2025)
Allergy	Wearable biosensors and connected monitoring systems	Continuous monitoring, prediction of allergic exacerbations, personalized disease management	Konstantinou et al. (2025); van Breugel et al. (2025)
HIV	AI-enabled clinical decision-support systems	Individualized treatment planning and monitoring of therapeutic outcomes	Sah et al. (2025)
Sepsis	AI-integrated multi-omics diagnostic platforms	Early diagnosis, risk stratification, prediction of disease progression	Shen et al. (2026)
Lupus nephritis	AI-guided biomarker and monitoring platforms	Prediction of treatment response and personalized therapeutic management	Shang et al. (2025)
Rheumatoid arthritis	AI-enabled intelligent drug delivery systems	Precision drug delivery and adaptive therapeutic optimization	Thakur et al. (2026)
Cardiovascular immunology	Immunologically adaptive endovascular devices	Personalized vascular intervention and thrombo-inflammatory monitoring	Dinc & Ardic (2026)

5. Challenges, Regulatory Considerations, and Future Perspectives

5.1. Technical Challenges in AI-Enabled Medical Devices

While AI-enabled medical devices are increasingly used in precision immunology, there are still several technical obstacles that prevent more widespread implementation of these technologies in clinics. One challenge is the need for AI algorithms to be trained on large, high-quality datasets with sufficient representative diversity of patient populations. Immunological diseases are highly heterogeneous, with dramatic variations in genetic background, exposure history, immune phenotype, disease course, and response to therapy. AI models trained on limited datasets or naive to disease heterogeneity may have poorer generalizability when used in different clinically relevant contexts (Chen et al., 2025; Prema et al., 2026).

Data integration is yet another challenge. Precision immunology depends heavily on the fusion of electronic health information, laboratory diagnostic tests, medical imaging, genome sequencing, proteomics and metabolomics, immunophenotyping, and continuous physiological monitoring, whose data may be captured with distinct devices and protocols, thus forming disparate data sources that hinder the development and deployment of AI models. To ensure confidence in clinical decision support, the interoperability of healthcare systems and AI-empowered medical devices is vital (Chen et al., 2025; Shen et al., 2026; Wang et al., n.d.).

Algorithm interpretability is also still a prominent concern; many highly skilled deep learning techniques operate as a type of complicated computer, which have a demonstrated ability to generate accurate predictions but offer no insight or explanation. Lack of explainability can impact confidence in a model by clinicians, pose barriers to clinical validation and adoption into daily healthcare activities, particularly in immunology where much of the therapy selection decision making process possesses high clinical complexities (Negut & Visan, 2025; Derraz et al., 2024).

A further technical issue is the ongoing development of AI algorithms. While traditional medical devices retain roughly the same operation after regulatory approval, AI enabled devices may regularly update software, retrain, or learn continuously as new clinical evidence becomes available. While continuous learning enhances algorithm performance, it raises reproducibility difficulties with regards to the maintenance of the accuracy, validation of updates, and reproducibility of clinical performance across the device lifecycle (Derraz et al., 2024; Zapotoczny et al., 2026).

5.2. Regulatory Considerations

In response to the rapid development of AI-enabled medical devices (AIMD), regulatory institutions begin to review the existing standards in assessing the safety of medical devices. Unlike the conventional hardware-based device which provides fixed functions and features, AIMD updates through the evolving software usage and the additional experience learned from long-term real-world application, requiring the regulatory procedures to focus on balancing safety and innovation risk (Derraz et al., 2024; Zapotoczny et al., 2026).

Clinical validation is currently one of the most important regulatory requirement for AI-enabled medical devices. Regulatory approval is more and more relying on data proving analytical validity, clinical validity, and clinical utility in representative patient populations. Strong validation studies are required to prove how AI algorithms run reliably in terms of diagnosis and prediction performance in the clinical setting but not only in research environment (Zapotoczny et al., 2026).

Post-market surveillance has become more critical because of potential ongoing development of AI-enabled medical devices once approved by regulatory agencies. Ongoing algorithm performance monitoring helps detect software errors, diminishing predictive utility, unanticipated clinical consequences, and cybersecurity issues early on. For this reason, regulatory bodies require lifecycle oversight from years after initial market release (Derraz, et al., 2024; Zapotoczny, et al., 2026).

Recent advances show growing regulatory acceptance of AI-enabled medical devices. The growing list of approved AI-enabled medical devices, including the approval of some designed for pediatrics clinical use, indicates growing confidence in the Clinical Utility of AI healthcare technologies, while also highlighting on healthcare technology validation and lifecycle regulation(Zapotoczny et al., 2026).

5.3. Ethical and Data Governance Challenges

The incorporation of AI-enabled devices into the paradigm of precision immunology will also have to contend with ethical standards such as privacy, fairness and transparency (Prema et al., 2026). Because precision immunology involves the pervasive use of sensitive health records, such as genomic, immunological and physiological data, a capable data governance system will be necessary for the safe implementation of AI-enabled devices.

The privacy and security of the data is a paramount issue which deals with an evolving AI powered medical devices continuously collecting data related to individual health via wearable sensors, invasive devices, networked healthcare networks, and electronic medical records while safeguarding these data from intrusion and secure data sharing between healthcare experts is a niche area in order to secure the platforms (Konstantinou et al., 2025; Qoronfleh, 2026).

Another key ethical concern is algorithm bias. When created from biased data sets that insufficiently capture demographic diversity, AI algorithms could produce differential diagnostic or treatment recommendations between patient groups, thus, perpetuating healthcare gaps and undermining science-based equitable access to precision immunology. Constructing representative data sets and ongoing bias evaluation are therefore critical for safe AI application (Prema et al., 2026; van Breugel et al., 2025).

Both are vital. Clinicians need to know the reason for an AI-recommendation before applying it clinically for complex immunological diseases where decisions are likely to carry significant clinical weight. Approaches within 'explainable AI' that can generate clear explanations with feasible outputs, will likely increase clinician trust in the system leading to wider adoption (Negut & Visan, 2025; Derraz et al., 2024).

5.4. Future Perspectives

The future use of AI-enabled devices in precision immunology will be driven by ongoing developments in computational intelligence, health-digital infrastructure, multi-omics platforms and biomedical engineering; as further integration of genomics, transcriptomics, proteomics, metabolomics, immune-phenotyping and physiologic monitoring continues, the individual patient will be characterized by more complete immune profiles guiding individualized diagnostics and treatment (Chen et al., 2025; Shen et al., 2026).

Additional useful applications of wearable and connected devices that are predicted to emerge will relate to the measurement of immune-relevant parameters in a continuous, real-time fashion, with enhanced sensitivity of biosensors, improvements in wireless data transfer, cloud computing, and forecasting analytics. This would enable earlier detection of disease progression, prediction of therapeutic efficacy, and personalized long-term disease management in many if not most immune-mediated diseases (Konstantinou et al. 2025; van Breugel et al. 2025).

Anticipated advances in therapeutic devices include smarter, more adaptive AI algorithms that can alter the course of treatment in real-time based on patient physiology. Novel intelligent drug delivery platforms, stimuli responsive biomaterials and immune morphing implantable devices could potentially allow optimized dosing schedules for patients with reduced side effects (Dinc & Ardic, 2026; Thakur et al., 2026).

As precision immunology continues to grow, collaboration among multidisciplinary teams, including clinicians, immunologists, biomedical engineers, computer scientists, regulatory agencies, and health policy makers will become more important. the design of standardized data formats, interoperable health information systems, open frameworks for validation, and flexible regulatory policy will be necessary to make the practical use of AI-enabled devices a reality in clinical settings. (Derraz et al., 2024; Qoronfleh, 2026; Prema et al., 2026).

As AI evolves, implementation will likely advance from clinical decision support to more comprehensive and actively learning healthcare ecosystems where real-time patient data is harnessed to generate predictions of disease pathogenesis and inform individualized therapies, from prevention and disease management to individualized treatment of complex immunological conditions (Alshorman et al., 2026; Ali et al., 2025; Qoronfleh, 2026).

Table 3
Major challenges, regulatory considerations, and future opportunities for AI-enabled medical devices in precision immunology.

Aspect	Current challenge	Potential strategy	Representative references
Data quality	Heterogeneous and incomplete clinical and immunological datasets	Standardized data collection and integration of multi-center datasets	Chen et al. (2025); Prema et al. (2026)
Multi-omics integration	Interoperability among diverse biological data platforms	Development of interoperable healthcare infrastructures and AI integration frameworks	Shen et al. (2026); Chen et al. (2025)
Algorithm transparency	Limited interpretability of complex AI models	Development of explainable AI approaches and transparent clinical validation	Negut & Visan (2025); Derraz et al. (2024)
Regulatory oversight	Continuous software evolution and adaptive learning algorithms	Lifecycle-based regulatory evaluation and continuous post-market surveillance	Derraz et al. (2024); Zapotoczny et al. (2026)
Data privacy and cybersecurity	Protection of sensitive patient health information	Robust cybersecurity measures and secure health data governance	Qoronfleh (2026); Konstantinou et al. (2025)
Algorithmic bias	Underrepresentation of diverse patient populations	Inclusive datasets and continuous bias assessment	Prema et al. (2026); van Breugel et al. (2025)
Clinical implementation	Limited integration into routine healthcare workflows	Multidisciplinary collaboration, clinician training, and standardized validation pathways	Derraz et al. (2024); Qoronfleh (2026)

6. Conclusion

The existence of AI-enabled medical device is a paradigm shift towards the era of precision immunology as it allows us to conceptualize a transition from population-based commonly utilized methods to personalized disease diagnosis, monitoring, and treatment. Through integration of computational intelligence with clinical/laboratory molecular/immunological/physiological information, AI-enabled medical devices have helped to extend the boundaries of precision healthcare by providing tools with which to profile complicated immune responses for optimal clinical decision-making and tailored therapeutic interventions.

Despite the significant headway made, multiple hindrances still hinder the general clinical use of AI-enabled medical devices. Tackling bottlenecks concerning data quality, interoperability, algorithm interpretability, cybersecurity, regulatory control and ethical governance must be focused on to create AI-enabled medical devices that are safe, trustworthy and generalizable across clinical settings. This will need standardized validation mechanisms, resilient digital health infrastructure and partnership with clinicians, immunologists, biomedical engineers, data scientists and regulatory boards.

Another contributing factor that will promote the strengthening of AI-enabled medical devices will be the future evolution of intelligent biosensors, multi-omics integration, adaptive therapeutic systems and connected healthcare ecosystem. With such development, AI-enabled medical devices could be the key to enable a more proactive, preventive and personalized management of immunology, leading to better clinical prognosis and more cost-effective healthcare system. For this, ongoing and future translational research, responsible innovation and evidence- based implementation of the AI-enabled medical devices will be imperative.

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