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Clinical Validation of AI-Based Medical Devices for Immune-Related Applications

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ABSTRACT

Artificial intelligence (AI)-enabled medical devices, particularly those based on image analysis and biomarkers, are transforming immune-related healthcare by enabling deeper insights into disease pathophysiology, increased diagnostic precision, patients' stratification, personalized therapy selection, and improved monitoring of disease and treatment responses. The advent of the capability for AI-enabled medical devices to combine, analyze, and interpret multidimensional data, such as genomic, proteomic, radiomic, immunologic, and electronic health records data, has been key to the adoption of precision medicine approaches in cancer immunotherapy, autoimmune disease, and cellular immunotherapies. To fully realize the benefits of AI-enabled medical devices for immune-related healthcare, clinical validation of reliable and reproducible diagnostic and therapeutic performance must prove their clinical meaningfulness and generalizability to different clinical and demographic scenarios. In this review, we explore clinical validation concepts and systems, including analytical validation, clinical validation, external validation, prospective evaluation, and performance monitoring, as well as criteria used to evaluate diagnostic performance, clinical utility, model robustness, and interpretability. We further review the applications of clinically validated AI-enabled medical devices in cancer immunotherapy, autoimmune disease, chimeric antigen receptor T-cell therapy, and immune biomarker-guided precision medicine. In addition, the key challenges for their clinical translation, including data heterogeneity, generalizability, algorithmic bias, lack of explainability, workflow integration, and ethics, are critically evaluated.

1. Introduction

AI technology has revolutionized the healthcare industry by providing the ability to develop medical devices that can aid disease diagnosis, therapeutic practices, prognosis, and overall clinical decision-making. In the context of immunology, the use of AI has transformed the potential of conventional medical devices by enhancing their analytical capabilities with combinations of machine learning, deep learning, and predictive analytics to extract insights from large and complex immunological data sets and facilitate disease biomarker detection and therapeutic selection. This is particularly important in immune-related disease where the complex interactions of multiple genetic, molecular, cellular, and environmental components of the immune response are frequently impossible to decipher intuitively (Alshorman et al., 2026; Basha & Hanirex, 2024; Negut & Visan, 2025).

Driven by the growing burden of malignant and autoimmune disease, as well as other chronic inflammatory and infectious diseases, use of information technology and AI-based applications in clinical immunology continues to evolve. Device development is increasingly focused on providing immune profiling, response prediction, disease stratification, and customization of therapy. AI-based tools are being incorporated into clinical decision support platforms in oncology for the determination of tumor-immune interactions, discovery of predictive markers, and stratification of responders to immunotherapy. Also, in autoimmune disease, use of machine learning to create AI-enabled autoimmune detection applications

are beginning to integrating multiple sources of data (electronic health records, laboratory data, biomarkers, and imaging) (Alshorman et al., 2026, Nosa-Ihaza et al., 2026, Olawade et al., 2025, Shiwlaniya et al., 2025).

More recently, using the rapidity of AI to identify subtle but precisely-behaving signals, we expect that advanced AI may find further application in the development of highly specialized immune related clinical devices. Contributing to precision immunotherapy, various machine learning-based tools are successfully used to finetune the process of targeted chimeric antigen receptor (CAR)-T cell therapy by predicting efficacy, optimizing antibody-antigen combinations, reducing its toxicity, and improving its manufacturing protocols, distribution, and reaction-based co-treatment (Shahzadi et al., 2024; Alshorman et al., 2026; Olawade et al., 2025).

However, despite the technological innovations, a successful clinical translation of machine learning based medical devices has been shown to be paramount on thorough validation in the clinical setting. The algorithm performance that was manifest during model development, is not a predictor of the safe, reliable, or outcome-beneficial performance of the model in diverse healthcare settings (Zimmerman et al., 2022). Therefore, various validation schemes such as analytical performance, clinical performance, external validation, prospective validation, and post-implementation monitoring have been necessary criteria to establish the safety and effectiveness of a machine learning based medical device (Oisakede et al., 2026; Rajchenberg et al., 2025; Negut & Visan, 2025).

This is especially important for immune-related applications, given the heterogeneity of immunological diseases and dynamic host immune responses over time that need to be captured on the AI platform (Oisakede et al., 2026; Rajchenberg et al., 2025). In such cases, the reliability of AI solutions as immunological decision support tools will need to be established across different patient populations, disease type and progress, health systems, and diagnostic platforms.Validation should not only be restricted to statistical performance, but clinical utility, interpretability, reproducibility, robustness, and impact on patient outcome without undue harm or bias in clinical decision making (Basha & Hanirex, 2024).

Clinician trust and regulatory acceptance of AI-aided medical devices are also affecting factors to consider. Despite various AI models surpassing the state-of-the-art predictive performance under a strictly experimental setting, issues surrounding limited transparency, low levels of external validation, dataset bias, and low explainability are barriers to clinical adoption. These challenges are particularly significant in the context of immunology, where clinicians use risky treatment options such as immune checkpoint inhibitors, biologic therapies, and cellular immunotherapies for long-term management of immune-related diseases. Better clinical validation evidence is a crucial step for clinicians, patients, and regulators to develop confidence with AI and enable adoption into real-world clinical practice (Oisakede et al., 2026; Rajchenberg et al., 2025; Alshorman et al., 2026).

This review focuses on clinical validation of AI-enabled medical devices for immune-related diseases, addressing validation methods, assessment of clinical utility, and challenges for clinical translation. It discusses the application of AI in the domain of cancer immunotherapy, autoimmune diseases, immune biomarker characterization, and cell-based immunotherapy, while describing the current challenges for clinical translation and the future outlook to realize trustworthy, clinically effective, and regulatory-approved AI-enabled medical devices in immunology. (Alshorman et al., 2026; Olawade et al., 2025; Oisakede et al., 2026; Shahzadi et al., 2024).

2. AI-Based Medical Devices for Immune-Related Applications

The use of artificial intelligence has revolutionized the diagnosis, monitoring, and management of immune-related diseases by enabling the access and analysis of multi-dimensional large-scale clinical and biological datasets. AI-based medical devices are defined as systems that can be made to produce a diagnostic, prognostic, or therapeutic output with an appropriate clinical decision support system to aid medical decisions by combining a computational algorithm with the clinical data acquisition system. For immune-related applications of AI-enabled medical devices, ML, DL, and generative AI models increasingly rely on the analysis of immunological biomarkers, genomic data, medical images, histopathology, and EHRs to provide the tools necessary to implement precision medicine practices that are also challenging to implement using traditional methods (Alshorman et al., 2026; Basha & Hanirex, 2024; Negut & Visan, 2025).

The clinical application of artificial intelligence (AI) based diagnostics lies in their ability to combine heterogeneous datasets and detect high order patterns that emerge from complex immune function and disease processes. Diseases of the immune system often involve interactions between flow of genetic information, temperature, cytokine kinetics, immune cell subpopulations, and pathogen interactions that are too complex for statistical algorithms to effectively model for meaningful diagnostic purposes. AI algorithms can to analyze multiple correlated variables concomitantly, allowing for earlier recognition of disease, disease subclassification, risk analysis, and prediction of therapeutic response and remission. Thus AI powered diagnostic devices are becoming increasingly incorporated into clinical practice (Basha & Hanirex, 2024; Negut & Visan, 2025; Alshorman et al., 2026).

2.1 AI-Based Medical Devices in Cancer Immunotherapy

Immunotherapy approaches for the treatment of cancer is among the most advanced applications ofAI-aided development of medical devices. The effectiveness of immune checkpoint inhibitors, adoptive cell therapies, and cancer vaccines is largely dependent on selecting the appropriate patients and discovering biomarkers that can indicate likelihood of response to a given treatment. AI-enabled medical devices help to expedite this process by combining radiological imaging, histopathological characteristics, genomic and transcriptomic signatures, as well as immune biomarker measurements into cost-effective, noninvasive diagnostic tests to identify potential responders to immunotherapy and spare others from unnecessary adverse effects (Olawade et al., 2025; Nosa-Ihaza et al., 2026; Alshorman et al., 2026).

Using tumor microenvironment characteristics, immune cell infiltration, expression of programmed death-ligand 1 (PD-L1), tumor mutational burden, among other immunological biomarkers, cancer-related ML algorithms incorporated into clinical decision-support systems have proven effective in profiling tumors on an individual level, assessing likelihood of responsiveness, identifying adverse immune-related events, detecting resistance to treatment, and providing oncologists with personalize and precise treatment approaches (Nosa-Ihaza, et al. 2026; Olawade et al., 2025; Alshorman et al., 2026).

2.2 AI in Autoimmune and Inflammatory Disorders

Because of prototypic clinical similarities, unpredictable fluctuations in disease severity, and diverse immune responses, autoimmune diseases can be particularly challenging to accurately diagnosis. Several AI-enabled medical devices have been employed more prevalently for assisting autoimmune disease diagnosis and management; a number of devices utilize combinations of laboratory tests, immune indicators, imaging modalities, genetics, and clinical information to help the practitioner differentiate various diseases, or to predict clinical evolution or responsiveness of autoimmune diseases to specific immune suppressive drugs (Negut & Visan, 2025; Basha & Hanirex, 2024).

However, recent developments in generative AI and machine learning have enabled even greater scope for AI-enabled clinical platforms to analyze longitudinal EHRs with immune biomarker data. Utilizing this information derived from structured and unstructured healthcare records can support the early detection of disease flares and progression, improve patient stratification and inform personalized treatment approaches in autoimmune and inflammatory disease (Shiwlani et al., 2025; Basha & Hanirex, 2024; Negut & Visan, 2025).

2.3 AI-Assisted Medical Devices for Cellular Immunotherapy

Ultimately, certain cell-based immunotherapies, such as chimeric antigen receptor T-cell (CAR-T) therapy, necessitate highly customized treatment regimens and comprise the manufacturing, quality control assessment, and clinical monitoring in of a complex series of steps. As such, AI-based medical devices have been utilized to enhance some of these factors, including antigen target selection, efficacy prediction, toxicity assessment, manufacturing optimization, and post-treatment surveillance. These predictive systems delineate huge quantities of genomic, proteomic, and immunological data that factor into therapeutic responses (Shahzadi et al., 2024; Alshorman et al., 2026).

Additionally, AI algorithms play a role in the detection of biomarkers linked to cytokine release syndrome, immune-related toxicities and treatment resistance, allowing for earlier intervention and more efficient patient care. As AI-enabled medical devices can enhance predictive precision at each stage of therapy, they could enhance safety of cellular immunotherapies while optimizing clinical responses. However, validity of the devices still needs extensive validation in different patient populations and clinical environments (Shahzadi et al., 2024; Oisakede et al., 2026).

2.4 Emerging Trends in AI-Enabled Immunological Medical Devices

However, developments in AI-based medical devices are moving towards multimodal data integration where data from various sources such as genomic, transcriptomics, proteomics, digital pathology, radiology, wearable sensors and EHRs are integrated in order to produce a holistic assessment of immune activity. Such multimodal tools have the potential to improve diagnostic accuracy and offer customized therapeutic solutions by reflecting the multifaceted interplay of immune mediators more closely than single modalities (Alshorman et al., 2026; Shiwlani et al., 2025).

Conversely, another developing area appears to be a shift from practical AI applications in a predictive setting toward explainable and clinically interpretable models. Explainability is crucial, especially for immune-related applications, where clinicians require an understanding of the reasoning behind any AI recommendations before integrating this knowledge into a treatment strategy. Improving model interpretability, robustness and integration with current healthcare infrastructure are identified as prerequisite steps to ensuring clinician trust and device approval in this realm. For their part, however, algorithmic bias, patient data heterogeneity and representativity, clinical generalizability and patient privacy considerations remain also

relevant issues for the translation of AI-enabled hardware into clinical settings (Rajchenberg et al., 2025; Oisakede et al., 2026; Alshorman et al., 2026).

3. Clinical Validation Frameworks for AI-Based Medical Devices

The translation from a computational innovation into a clinically used AI-enabled medicine requires more than the design of a sensitive and accurate algorithm. Prior to clinical use, an AI-enabled device must also be shown to be producing meaningful and consistent clinical results that result in improved health outcomes in the targeting clinical scenarios. As such, clinical validation acts as an essential step in the life cycle of a medical device, displaying that the device produces consistent results in the targeted time- and patient-specific circumstances and in a safe manner that minimizes patient risk while supplying data appropriately to inform ICDAS. This role is especially crucial in immune-centered applications where the breadth of disease presentation and individual variation in immune response is broad (Oisakede et al., 2026; Rajchenberg et al., 2025; Alshorman et al., 2026).

It should be understood that clinical validation is not a one-time event performed prior to market introduction, instead, it is a continuous process. AI diarmaceutical devices may vary in their performance as a function of different patient populations, healthcare institutions, laboratory procedures and imaging techniques, as well as changing disease phenotypes. Thus validation processes needs to monitor AI device performance in the entire life time, from validation during the development and wide clinical use and real-time post-deployment testing, and to ensure the stability of clinical predictive performance and utility. This concept is pertinent in the orientation of immunology, where growing knowledge and innovation in clinical trialla and therapies, push clinical practice to progress (Oisakede et al., 2026; Rajchenberg et al., 2025).

3.1 Analytical Validation

Analytical validation is used to determine if the product's input receives the expectation of a reproducible output under a wellcontrolled operating range. This stage tests the technical performance of the computational model in terms of its heterogeneity, missingness, computation stability, and reproducibility across experiments. In immune-domain applications, the majority of analytical validation was conducted on data quality, prior to inputting the data into AI algorithms, of immunological biomarkers, sequencing, transcriptomics, digital pathology, imaging, and electronic health records (Negut & Visan, 2025; Basha & Hanirex, 2024; Alshorman et al., 2026).

Moreover, the analysis evaluates the strength of the feature extraction techniques, data pre-processing workflows and model tuning processes. The source of weaknesses are inferior quality data sets, heterogenous laboratory procedures and different data collecting instrumentation which altogether can significantly alter the algorithmic results and thus negatively impact the dependability of AI-enabled medical devices. Standardized data gathering practices, suitable quality assurance procedures and automated second-party technological controls must be therefore considered as requirements prior to clinical trial (Basha & Hanirex, 2024; Rajchenberg et al., 2025).

3.2 Clinical Validation

Clinical validation evaluates whether an AI-driven medical device delivers clinically relevant information that enhances health service quality for the target patient group. Clinical validation is the only type of validation that establishes a correlation between what the AI produces and a clinical outcome, such as whether the device provides support for diagnosis, forecast of disease growth or response to therapy, or guidance of application of a treat (Oisakede et al., 2026; Alshorman et al., 2026).

For immune-related diseases, clinical validation should compare performance across the different disease phenotypes, patient populations and healthcare systems, as immune responses are affected by many biological and environmental variables. Devices used for cancer immunotherapy, autoimmune diseases or infectious diseases should progress to demonstrate robust clinical behavior across multiple institutions and patient populations, not just results based on a single development dataset. Multi-centric validation enhances the external validity of the AI model, such that performance is not merely reflective of local disease manifestations or regional practices (Nosa-Ihaza et al., 2026; Olawade et al., 2025; Oisakede et al., 2026).

The clinical validation can also explore if AI-supported guidance enhances clinicians' ultimate decision making, without the AI technology stand as sole decision-makers. The primary goal for the AI-based medical devices would be to supplement a clinician's knowledge and experience by giving data-driven, evidence-based suggestions on diagnosis, patient stratification, management plans and disease progression. Showing improvements on levels of diagnostic certainty and found etiology, and outcomes is a key requiring evidence, nonetheless (Rajchenberg et al., 2025; Oisakede et al., 2026).

3.3 External Validation and Generalizability

External validation is arguably the most important aspect of clinical validation because it tests the efficacy of a model on an entirely separate, prospective dataset that was not utilized in model (algorithm) development. AI systems tend to perform very well, often with high accuracy, during internal testing but suffer performance decline when applied to new cohorts of patients with clinically different demographics, risk factors, disease prevalence, laboratory techniques or health systems. Independent validation thus provides a more accurate picture of clinical utility and reveals the breadth of applicable patient cohorts prior to deployment (Oisakede et al, 2026; Rajchenberg et al, 2025).

For immune-related applications, external validation is especially critical as immunological biomarkers and responses to treatment may vary between groups of differing ethnicity, genetics, exposure to environment and clinical disease subgroup. Medical devices with AI for deployment to a general healthcare environment trained on homogenous geographically or klinikally populations, are likely to exhibit inconsistent clinical performance. Validation with data from multiple institutions and ethnic groups is needed to eliminate bias and ensure equitable clinical performance (Alshorman et al., 2026; Nosa-Ihaza et al., 2026; Rajchenberg et al., 2025).

3.4 Prospective Clinical Evaluation and Real-World Validation

While retrospective studies offer important evidence in the development of a model, prospective clinical validation strengthens evidence of the utility of AI-based medical devices in routine health care. In prospective validation, in the context of clinical workflows, investigators also assess the impact of AI recommendations on clinician guidance, treatment plans, speed of diagnosis, and patient outcomes (Oisakede et al., 2026).

External validation is particularly important for immune-focused medical devices as patient populations, therapies, and systems of care differ significantly across institutions. Ongoing assessment after clinical deployment allows developers and practitioners to detect alterations in algorithm performance due to changing disease epidemiology, new therapies, or changes in clinical practice (Rajchenberg et al., 2025; Alshorman et al., 2026).

3.5 Post-Market Performance Monitoring

Clinical validation, however, is a process that extends beyond the time of the introduction of the AI based medical device to practice. The AI technology must be observed using post-market monitoring throughout the life of the device in order to assess the long-term safety, performance, and efficacy. AI algorithms in turn may also perform less efficiently in light of shifting patient populations, more advanced technological developments in diagnostic tools, or standards of care having been changed. This phenomenon, known asperformance driftcan be observed in an ongoing fashion such that any changes to performance can be corrected pre-emptively to uninformed patient care (Rajchenberg et al., 2025; Oisakede et al., 2026).

In addition to implementation, post-market monitoring should include ongoing monitoring of clinical performance, adverse events, modification of the algorithms and feedback from the end-users. This is especially crucial for immune-related indications as rapid progress in both immunotherapy and biomarker discovery can quickly make prediction models established at an earlier point in time more and more obsolete in the context of current clinical evidence. Continuous validation can prevent this and ensure the continually good match between AI-based recommendations and current clinical knowledge and practices, which is also important for creating health professionals' trust in the longevity of these devices (Alshorman et al., 2026; Olawade et al., 2025; Rajchenberg et al., 2025).

3.6 Building Clinical Trust Through Robust Validation

Ultimately though, the goal for clinical validation is not just to prove statistically valid performance, but to earn the trust of clinicians, patients, healthcare organizations, and regulatory stakeholders. A trustworthy AI-based medical device should perform with accuracy, reproducibility, transparency, robustness, equity, and clinical utility while being interpretable in the context of integrated, day-to-day medicine. In immune-related healthcare in which treatment choices often rely on relatively high-risk intervention such as immune checkpoint inhibitors and cellular immunotherapies, confidence in a recommended AI outcomes is built on the foundation of quality and diverse clinical evidence (Oisakede, et al., 2026; Rajchenberg, et al., 2025; Alshorman, et al., 2026).

4. Validation Metrics and Clinical Performance Assessment

Acceptance of AI-enabled medical devices in the clinic is contingent on not just accurate predictions but should also establish robust performance in clinically relevant evaluation metrics. Clinical performance evaluation in this context serves to provide quantitative evidence that an AI-enabled medical device can aid in decision making such as diagnosis, prognosis, therapeutic guidance, or monitoring with dependable performance in the relevant clinical settings. In this regard, immune-related diseases where the biological heterogeneity as well as the complexity of the immune system interact to play a decisive role in clinical

outcomes demand further criteria from the performance evaluation process in addition to benchmark measures of model accuracy; it should include clinical utility, stability, interpretability and reproducibility (Oisakede et al., 2026; Rajchenberg et al., 2025).

4.1 Diagnostic Performance Metrics

The performance of AI-based medical devices in their first reports usually concentrates on the evaluation of the discrimination capacity (or the ability to distinguished patients with and without a specific disease or clinical condition). Sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) are a critical set of measures in diagnosis because they provide information on the ability of the algorithm to correctly classify true disease cases and inadvertently avoid false positive and false negative diagnoses (Negut & Visan, 2025; Basha & Hanirex, 2024; Oisakede et al., 2026).

Receiver operating characteristic (ROC) curves and their area under the curve (AUC) are routinely employed to assess discriminative ability across a range of thresholds. In general, larger AUC values signal that an AI algorithm has robust ability to distinguish between clinical outcomes over a wide range of operating conditions, so such discriminatory information is pertinent to the evaluation of preditions generated within those applications, such as immune-based diagnostic and therapeutic decision support. However, while a high AUC is indicative of excellent discrimination, the clinical usefulness of a medical prediction model depends on both its discriminatory capacity and its performance in real-world healthcare environments (Oisakede et al., 2026; Rajchenberg et al., 2025).

4.2 Predictive Performance in Therapeutic Decision-Making

Numerous AI-powered immunology-specific medical devices have been created to prediction rather than diagnose. For example, many tools risk stratify existing patients to predict what fraction may be immune checkpoint inhibitors, biologic therapies, CAR-T cell therapies, or other immunotherapies likely to be successful based on given molecular, genomic, histologic, and clinical input values. Therefore, validation tests if the AI predictions/assessments realistically reflect therapeutic results on procedures on new, unseen patient cohorts (Nosa-Ihaza et al., 2026; Olawade et al., 2025; Shahzadi et al., 2024).

Assessment of predictive accuracy needs also to evaluate whether AI-enabled devices can stratify patients at higher risk of treatment failure, irAE, or disease recurrence. An accurate forecast of these states is crucial for personalized therapy, guiding clinicians in fine tuning treatment selection, predicting side effects, and when necessary initiating a timely clinical response. Such capacity for forecast can be established on general and longitudinally collected clinical data that capture the heterogeneity of irAEs measured in routine everyday practice (Alshorman et al., 2026; Nosa-Ihaza et al., 2026; Oisakede et al., 2026).

4.3 Reproducibility and Robustness

Clinical performance of AI-enabled medical devices has to be reproducible across similar clinical data obtained under a variety of operating conditions and robust against changes in data quality, hospital infrastructure, imaging camera, lab protocols, and patient factors to be dependable for clinical applications. Reproducibility refers to the consistency of the result over identical sample analysis, whereas robustness refers to the consistency of algorithm performance against variations in image quality, healthcare infrastructure, laboratory protocols, and patient factors. Both are critical for clinical application due to immune-related datasets of multiple hospital sources, platforms and data acquisition workflows (Rajchenberg et al., 2025 ; Basha & Hanirex,2024).

Validation should consequently involve testing across different geographical cohorts, various hospitals and heterogeneous clinical data sets. This testing can reveal potential faults related to overfitting, narrow clinical data sets, or bias introduced by the development hospital, while providing additional rationale that an AI-enabled medical device can perform acceptably in contexts outside of where the system was originally developed. This is especially relevant for immunological applications because fluctuations in biology and disease prevalence can affect algorithm behaviors (Oisakede et al., 2026; Alshorman et al., 2026; Rajchenberg et al., 2025).

4.4 Clinical Utility and Decision Impact

Good statistical results may not lead to better patient care; clinical validation is therefore needed to establish if a machine learning generated output has an impact in the context of diagnostic accuracy, therapeutic decision making, workflows, and patient outcomes. Clinical utility is the degree to which an AI-based medical device can provide clinically relevant information that offers an improvement in patient care without adding unnecessary complexity to the process or compromising patient safety (Oisakede, et al., 2026; Rajchenberg, et al., 2025).

In immune-mediated medicine, AI-powered clinical decision-support tools will need to show improvements in patient categorization, interpretation of immune biomarkers, therapy choice, and disease tracking that outperform established clinical standards. Data that AI suggestions would increase IIM confidence and diminish diagnostic or treatment uncertainty will weigh

more heavily in favor of direct-to-physician utilization than an AI application's algorithmic precision alone. Hence, direct-to-physician use cases as well as prospective clinical trial and observational rate-of-use studies are important aspects of IIM AI application performance analysis (Olawade et al., 2025; Nosa-Ihaza et al., 2026; Oisakede et al., 2026).

5. Clinical Applications of Clinically Validated AI-Based Medical Devices

The clinical utility of AI-driven medical devices remains predicated on their effectiveness in delivering tangible benefit to patients within operational healthcare environments. In the wake of comprehensive validation, clinical benefit in terms of enhanced immune-related health outcomes has been observed to be progressively abstracted namely in the fields of cancer immunotherapy, autoimmune disorders, cellular immunotherapy and immune marker analysis. In addition, by harnessing and extracting the integrative insight from clinical, molecular, imaging and immune-centric datasets, validated AI-powered medical devices support earlier detection, greater risk stratification, phenotypic accuracy, treatment individualization/monitoring, easing impact of precision medicine on clinicians through improved decision-making (Alshorman et al., 2026; Olawade et al., 2025; Oisakede et al., 2026).

5.1 Autoimmune Diseases

Autoimmune disease diagnosis and management can be considered exceedingly difficult considering the commonality of overlapping clinical presentation, variation in disease status and considerable biological heterogeneity. Established AI-enabled medical devices have enhanced healthcare decision-making between autoimmune diseases by incorporating laboratory tests, immunological and genetic markers, imaging results and prior histories in order to more accurately discriminate autoimmune disease, in comparison to traditional diagnostic methods (Negut & Visan, 2025; Basha & Hanirex, 2024).

In the clinical setting, these diagnosis tools can also be used for disease prognosis, monitoring disease activity, and finding more effective treatments. The machine learning algorithms embedded in validated medical devices can detect immunological signs of worsening or remission, thus guiding doctor to apply patient-specific treatment plan (Basha & Hanirex, 2024; Negut & Visan, 2025; Shiwlani et al., 2025).

More recently though, the integration of generative AI into immune related clinical platforms has again improved upon EHR interpretation by allowing extraction of clinically significant data from structured and unstructured medical reports. This combined profile of immune biomarkers and long-term clinical history provides information useful for personalized treatment plans and continuity of patient care across multiple hospitals (Shiwlaniya et al., 2025; Negut & Visan, 2025).

5.2 Chimeric Antigen Receptor (CAR)-T Cell Therapy and Cellular Immunotherapy

Introduced through the development of chimeric antigen receptor T (CAR-T) cell therapy, novel, highly individualized treatment strategies have been devised for hematologic malignancies and other immune conditions. Yet, the challenges posed by patient selection, target antigen discovery, manufacturing procedures, and management of toxicity have opened new avenues for AI-supported clinical decision support. Validated AI-supported medical devices support all steps in the care of patients with CAR-T treatment by unifying data from numerous sources such as genome, transcriptome, proteome, and immunome to guide therapeutic planning and clinical outcomes; (Shahzadi et al., 2024; Alshorman et al., 2026).

AI-enabled medical devices can help expedite selection of suitable antigen targets, predict treatment response, and predict the risk of side-effects including cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome. These predictions can assist patients with risk stratification to receive therapy and allow for more frequent and intense clinical monitoring with treatment. This can help mitigate side effect complications associated with therapies and help optimize the use of cellular immunotherapies (Shahzadi et al., 2024; Alshorman et al., 2026).

AI is also relevant to how manufacturing can be optimized for the production of CAR-T cells. Optimizing the manufacturing process with the help of AI can improve quality control measures and identify determinants of successful manufacturing. Computational analysis of manufacturing parameters can help standardize product quality and minimize sources of variability that could affect the therapeutic efficacy. These examples further exemplify the emerging application of validated AI-driven medical devices far beyond direct clinical decision making and into more comprehensive areas of advanced immunotherapeutic management (Shahzadi et al., 2024).

6. Future Perspectives

Future progress in AI-momedical device clinical validation for immune therapies will also rely heavily on the creation of more rigorous, transparent and clinically meaningful validation schemes. This would call for multicenter collaborations, conformed validation protocols, broad patient datasets as well as prospective clinical trials, which are all crucial for model generalization and evidence based clinical application. Increasing focuses on explainable AI, post-marketing real-world data analysis, as well as

multi-disciplinary synergy will better foster the robustness and clinical translation of the AI systems for immune disease management (Alshorman et al., 2026; Oisakede et al., 2026; Rajchenberg et al., 2025).

Newer technologies that can synthesize genomics, proteomics, transcriptomics, imaging, and longitudinal clinical data are anticipated to push the boundaries of precision immunology even further. Yet, a challenge with the realization of the clinical value of such advances will be the development of validation pathways that emphasize safety, clinical utility, equity, and reproducibility alongside algorithmic performance. By bolstering these facets of clinical validation pathways, the promise of the safe, reliable application of AI-enabled medical devices in immune-centered medical care from research to clinical settings can be systematically achieved to improve diagnostics, therapeutics, and outcomes.

7. Conclusion

As artificial intelligence (AI) becomes more prevalent in medical devices, researchers are exploring new ways these innovative technologies can improve the diagnosis, monitoring and treatment of immune-related diseases. These emerging technological innovations offer great promise in advancing a precision approach to medication by better informing immune profiling, giving insight into likely treatment response, facilitating patient stratification and improving clinical decisions for all facets of immune medicine, such as tumor immunology, autoimmunity and cellular immunotherapy. Yet, there remains a need for clinical evidence to substantiate that AI-based medical devices are not only computationally feasible but are also safe, reproducible, reproducible and clinically-effective.

None the less, clinical validation is the foundation for the successful transition from algorithm development to routine adoption. In-practice validation of medical devices should include rigorous analytical validation, validation in different patient cohorts with the use of prospective clinical validation, external validation, and ongoing monitoring of device performance throughout the device lifecycle.

Although substantial advancements have been achieved, significant hurdles still need to be overcome. Data heterogeneity, concerns on model generalizability, algorithmic bias, lack of interpretability, and standardized validation approaches should all be tackled before these solutions can be implemented into everyday clinical practice. This may involve multidisciplinary team work, improved data standards, transparent model building, as well as tight clinical validation and evidence.

However, future studies should focus on multicenter validation studies of large sample sizes, creation of standardized clinical assessment frameworks, as well as ongoing post-deployment assessment for long term safety and efficacy. As validation strategies improve in tandem with the progression of artificial intelligence, clinically validated AI-based medical devices will undoubtedly become a greater part of providing accurate, personalized, evidence-based care in patients with immune-related conditions.

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