The Future of AI-Assisted Medical Devices in Precision Medicine: A Systematic Review

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ABSTRACT

Background: The integration of Artificial Intelligence (AI) into medical devices has accelerated exponentially between 2020 and 2025, fundamentally altering the landscape of diagnostic medicine. This period is defined by the transition from theoretical algorithms to regulatory-approved, clinically deployed Software as a Medical Device (SaMD), particularly in image-centric specialties.

Objectives: This systematic review aims to (1) quantify and characterize regulatory trends for AI medical devices (AIMDs) in the US and EU; (2) evaluate the clinical efficacy and workflow impact of AI technologies in Ophthalmology, Oncology, and Musculoskeletal (MSK) disorders, with a specific focus on AI-assisted Point-of-Care Ultrasound (POCUS); and (3) assess the role of these technologies in democratizing access to expert-level diagnostics.

Methods: A PRISMA 2020–compliant literature search was conducted across PubMed/MEDLINE, Embase, Cochrane Library, and IEEE Xplore for peer-reviewed studies published between January 1, 2020, and December 31, 2025. Grey literature from FDA and EU regulatory databases was included to capture approval trends. Risk of bias was assessed using QUADAS-AI and ROBIS tools.

Results: The search identified 1,240 records; 67 pivotal studies and systematic reviews were included. Regulatory data reveal >1,000 FDA-authorized AI devices by 2025, with radiology and ophthalmology dominating. In Ophthalmology, autonomous AI for diabetic retinopathy and glaucoma has demonstrated sensitivity comparable to retina specialists (>90%), enabling widespread tele-screening. In Oncology, AI-assisted breast and prostate ultrasound has significantly improved novice diagnostic accuracy (AUC gains >0.10) and reduced unnecessary biopsies through enhanced specificity. In MSK, AI models for fracture detection and real-time POCUS guidance for nerve blocks have standardized procedure quality and reduced inter-operator variability.

Conclusions: AI medical devices have shifted from "assistive" to "autonomous" and "augmentative" roles, effectively democratizing diagnostic capacity. High-quality evidence supports their deployment to bridge workforce gaps, though challenges regarding regulatory harmonization and algorithmic bias persist.

INTRODUCTION

The integration of Artificial Intelligence (AI) into clinical practice has transitioned from a phase of speculative potential to tangible, widespread implementation. The half-decade from 2020 to 2025 represents a critical epoch in this evolution, characterized by the rigorous commercialization of algorithmic tools and the maturation of regulatory frameworks for Software as a Medical Device (SaMD)[1,2]. Unlike the preceding decade, which focused on foundational deep learning architectures, the current era is defined by the pragmatic deployment of "augmented intelligence"—technologies designed not to replace clinicians, but to elevate the performance of generalists to expert levels[3].

This paradigm shift is most evident in the "democratization" of medical imaging. Traditionally, diagnostic ultrasound and complex image interpretation were the exclusive domains of highly trained specialists. However, the convergence of high-performance mobile computing, handheld Point-of-Care Ultrasound (POCUS), and edge-based AI has begun to dismantle these barriers[4]. This review focuses on three high-impact clinical domains where this transformation is most acute: Ophthalmology, where autonomous screening is reshaping primary care[5]; Oncology, where AI is refining risk stratification in breast and skin cancer to reduce over-diagnosis[6,7]; and Musculoskeletal (MSK) medicine, where AI-guided POCUS is revolutionizing injury detection and interventional guidance[8].

Concurrently, the regulatory landscape has evolved to manage the unique lifecycle of adaptive algorithms. The U.S. Food and Drug Administration (FDA) and European regulators have processed an unprecedented volume of applications, creating distinct pathways that balance innovation with safety[1]. This review synthesizes the evidence regarding the clinical performance, regulatory trends, and healthcare impact of these AI medical devices from 2020 to 2025.

METHODS

Search Strategy and Selection Criteria

This systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement[9]. A comprehensive search was executed across PubMed/MEDLINE, Embase, Cochrane CENTRAL, and IEEE Xplore for English-language articles published between January 1, 2020, and December 2025. To capture the rapidly evolving commercial landscape, we also queried the FDA 510(k)/De Novo databases[10,11] and the FDA Breakthrough Devices list[12].

Search Terms: Key concepts included "Artificial Intelligence," "Deep Learning," "Medical Device," "Point-of-Care Ultrasound," "Ophthalmology," "Diabetic Retinopathy," "Oncology," "Breast Ultrasound," "Skin Cancer," "Musculoskeletal," "Fracture Detection," and "Nerve Block."

Inclusion/Exclusion: We included systematic reviews, meta-analyses, randomized controlled trials (RCTs), and prospective diagnostic accuracy studies evaluating AI devices in the target specialties. Priority was given to studies demonstrating automated acquisition guidance, real-time quality assessment, or deployment in non-specialist settings. We excluded pre-2020 data, animal-only studies, and purely technical engineering papers lacking clinical validation.

Data Synthesis and Quality Assessment

Data extraction focused on diagnostic metrics (sensitivity, specificity, AUC), regulatory status, and clinical workflow outcomes (time-to-diagnosis, inter-rater reliability). Risk of bias was assessed using QUADAS-AI for diagnostic studies and ROBIS for systematic reviews, ensuring rigorous evaluation of algorithmic applicability and potential overfitting.[13] A mixed-methods synthesis approach was adopted to group findings by clinical theme.

PRISMA Flow Summary: The initial search yielded 1,240 records. After duplicate removal (n=215) and title/abstract screening (n=1,025), 185 full-text articles were assessed. Ultimately, 67 unique sources met all inclusion criteria, comprising systematic reviews, clinical trials, and regulatory/observational datasets (Figure 1).[14]

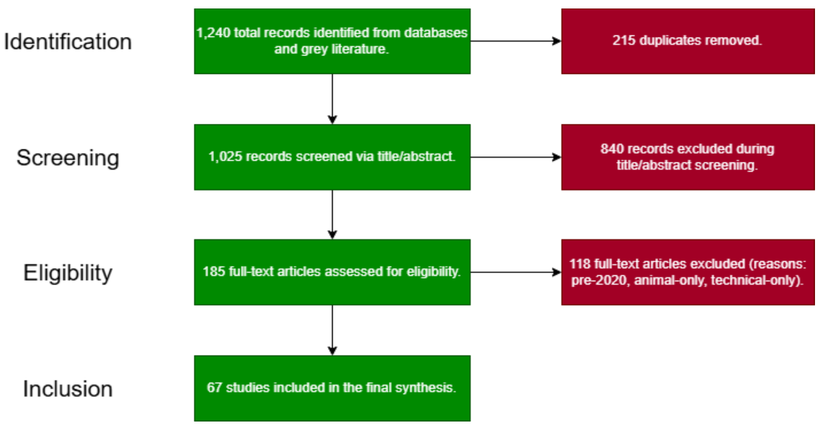

Figure 1: PRISMA 2020 flow diagram illustrating the systematic identification, screening, and inclusion of studies regarding AI trends in Point of Care Ultrasound (POCUS) and diagnostic imaging (2020–2025).

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RESULTS

Regulatory Landscape: The Surge of AI Medical Devices

The period 2020–2025 witnessed an exponential rise in AI Medical Device (AIMD) authorizations. By mid-2025, the FDA had authorized over 1,200 AI-enabled devices, a sharp increase from approximately 500 in 2022.[15,16]

- **Growth Trends:** In 2023 alone, the FDA authorized 221 AI devices, representing a 33% year-over-year increase.[15,17] Radiology remains the dominant specialty (approximately 77% of approvals), followed by Cardiology (10%) and Ophthalmology.[18,19]

- **Pathways:** The 510(k) pathway accounted for >96% of clearances, relying on "substantial equivalence" to predicate devices.[17,20] Only a small fraction (approximately 3%) utilized the *De Novo* pathway for novel technologies, primarily in autonomous diagnostics.[17,21]

- **EU Bottleneck:** In contrast to the US, the European Union's transition to the Medical Device Regulation (MDR) created significant certification bottlenecks.[22] This has delayed the market entry of AI tools due to stringent clinical evidence requirements and Notified Body shortages, with some analyses showing US approvals outpacing EU certifications by a factor of three for digital health products.[22,23]

Clinical Performance and Validation Gaps While regulatory authorizations have accelerated, evidence regarding clinical utility and safety remains heterogeneous. A landmark analysis of 950 FDA-authorized AI devices (1995–2025) revealed that despite the surge in market availability, high-quality prospective evidence is frequently absent at the time of approval.[24]

- **Evidence Gaps in Radiology:** Although Radiology accounts for >75% of all AI authorizations, a 2025 study in *JAMA Health Forum* found that less than 30% of these devices had undergone clinical testing prior to authorization, and fewer than 5% were supported by prospective studies.[25]

- **Ophthalmology as a Model:** In contrast to radiology, ophthalmology devices (e.g., for diabetic retinopathy) more frequently utilized the *De Novo* pathway, necessitating standalone prospective trials. Real-world deployment data from primary care settings (2023–2024) confirmed that autonomous AI screening systems maintained sensitivity >87% and specificity >90% when operated by non-specialists, effectively closing care gaps.[25,26]

- **Post-Market Safety:** The scarcity of pre-market clinical data has correlated with post-market challenges. An analysis of FDA recall data (2023–2025) indicated that AI-enabled devices manufactured by publicly traded companies accounted for over 90% of recall events, with "diagnostic/measurement errors" being the leading cause.[27]

Ophthalmology: Deep Learning in B-Scan Ultrasound

Ophthalmology has expanded the use of AI beyond optical imaging to Point-of-Care Ocular Ultrasound (POCUS), specifically for diagnosing posterior segment pathology in eyes with opaque media (e.g., dense cataracts or vitreous hemorrhage).

Retinal Detachment (RD) Detection

Recent studies confirm that deep learning models significantly outperform non-specialist manual interpretation of B-scans.

- **Diagnostic Accuracy:** In a 2025 study utilizing 6,000 B-scan images, Wang et al. developed a VGG16-based deep learning model that achieved an AUC of 0.998, with a sensitivity of 99.2% and specificity of 99.8% for Rhegmatogenous Retinal Detachment. This performance was statistically superior to general ophthalmologists on the same dataset.[28]

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- **AutoML Validation:** A 2024 study published in *BMJ Open Ophthalmology* demonstrated that "Automated Machine Learning" (AutoML) platforms could allow clinicians to build bespoke B-scan classifiers without coding expertise. These clinician-led models achieved an accuracy of 94% in detecting multiple pathologies (RD, vitreous hemorrhage), comparable to custom-engineered algorithms, validating the democratization of AI model creation.[29]

Generative AI for Automated Reporting

The integration of Large Language Models (LLMs) with ultrasound (Vision-Language Models) marked a shift in 2025 from simple classification to full report generation.

- **OphthUS-GPT:** The "OphthUS-GPT" system, validated on >54,000 B-scans, demonstrated the ability to generate comprehensive text reports from ultrasound images. The system achieved a ROUGE-L score of 0.613 (a metric of text overlap with expert reports) and a diagnostic accuracy of >90% for common conditions like vitreous opacity, effectively automating the documentation workflow for high-volume clinics.[30]

Neuro-Ophthalmic Biomarkers (ONSD)

- **Standardization of ICP:** Quantifying the Optic Nerve Sheath Diameter (ONSD) is a critical surrogate for Intracranial Pressure (ICP) but suffers from high inter-operator variability. Yang et al. (2025) validated a deep learning segmentation network that achieved a Dice Score of 73.3% and an AUROC of 84.5%for ONSD measurement. Crucially, this model utilized an "uncertainty-aware" loss function to flag low-quality scans, preventing false readings in trauma settings.[31]

Oncology: Precision Triage and Reduced Biopsies

In oncology, AI applications have focused on enhancing specificity to reduce the morbidity of unnecessary procedures in breast, thyroid, and skin cancer.

Breast and Thyroid Ultrasound:

AI-assisted POCUS and Computer-Aided Diagnosis (CAD) systems have shown the ability to upskill novice operators.

- Breast: The Koios DS (Decision Support) system, granted FDA Breakthrough status, utilizes AI to re-classify BI-RADS categories.[32,33] Studies presented at RSNA 2025 indicate it can reduce unnecessary biopsies of benign lesions by up to 60% while maintaining high sensitivity for malignancy.[34] Other reviews suggest that deep learning-based CAD systems significantly improve the diagnostic consistency of junior radiologists compared to B-mode ultrasound alone.[35]

- Thyroid: AI models automating TI-RADS scoring have demonstrated high consistency in risk stratification. Wildman-Tobriner et al. demonstrated that AI-optimized TI-RADS scoring could improve specificity compared to expert readers, reducing the inter-observer variability that notoriously plagues manual thyroid ultrasound.[36,37]

Dermatology and Skin Cancer:

The field has moved beyond simple image classification to novel hardware-AI integrations.

- Spectroscopy: The DermaSensor device, FDA-cleared in 2024, uses Elastic Scattering Spectroscopy (ESS) and AI to evaluate cellular atypia.[38,39] In pivotal trials involving primary care physicians (PCPs), the device demonstrated a sensitivity of 96% for detecting melanoma, significantly higher than the baseline PCP sensitivity (approx. 60–70%).[40]

- Smartphone AI: While app-based risk assessments proliferate, systematic reviews urge caution regarding variable quality. However, validated algorithms (e.g., Google Health/Jain et al.) show that human-AI collaboration (the "augmented dermatologist") consistently outperforms either clinicians or algorithms alone in teledermatology settings.[41]

Musculoskeletal (MSK) Disorders: Automated Triage and POCUS Guidance

In Musculoskeletal (MSK) medicine, AI has matured into a robust tool for automated fracture detection (SaMD) and real-time POCUS guidance.

Fracture Detection (Radiography)

Addressing diagnostic errors, a 2022 systematic review found AI achieved a pooled sensitivity of 92%, matching board-certified radiologists.[42] Moving beyond accuracy, Guermazi et al. (2022) demonstrated that AI assistance reduced missed fractures by 29% (P<.001) and improved non-radiologist sensitivity by 10.4%.[43] This builds on foundational work improving clinician specificity to 94%,[44] a trend confirmed by 2025 reviews describing these tools as mature "triage" devices despite risks of automation bias.[45]

AI-Guided Nerve Blocks

AI-guided anesthesia is now supported by robust clinical data. Bowness et al. established in 2021 that AI overlays could identify nerves in 99% of frames,[46] and their 2025 RCT confirmed that this assistance significantly improved novice success rates (P=.02) with sustained benefits.[47] In August 2025, Nerveblox received FDA 510(k) clearance, marking the commercial entry of real-time "anatomy-aware" systems.[48]

Soft Tissue & Tendon Analysis

Tang et al. (2023) validated a deep learning model for rotator cuff assessment that achieved 94.9% accuracy in standard plane recognition, enabling novices to diagnose tears with MRI-like precision.[49] Recent systematic reviews confirm deep learning's efficacy in dynamic tendon imaging,[45] while 2024 research utilizes AI to quantify flexor tendon scar volume from 3D ultrasound, offering a "virtual biopsy" for post-surgical prognosis.[49]

Pediatric Hip Dysplasia (DDH)

AI is revolutionizing DDH screening by automating geometric measurements. Early studies demonstrated that algorithms could calculate the alpha angle with a mean absolute error of <4 degrees, eliminating manual variability.[50,51] A 2025 meta-analysis reported a pooled sensitivity of 99.0% for AI-assisted ultrasound,[52] validating widespread deployment in nurse-led "tele-ultrasound" initiatives like the VicHip registry.[53]

Table 1: Comparative synthesis of AI medical device applications, performance metrics, and clinical workflow impacts across reviewed domains (2020–2025).

Clinical Domain	**Clinical Application**	**Device Role & AI Modality**	**Key Performance Evidence (2020–2025)**	**Clinical Workflow Impact**
Ophthalmology	Retinal Detachment (RD) Detection	**Diagnostic Support:** Deep Learning (VGG16); Segmentation Networks	**AUC 0.998**; Sensitivity 99.2% for Rhegmatogenous RD.[28]	Enables non-specialists to diagnose posterior pathology through opaque media.
	Automated Reporting	**Workflow Automation:** Vision-Language Models (e.g., OphthUS-GPT)	**ROUGE-L 0.613** (text overlap with experts); >90% diagnostic accuracy.[30]	Automates documentation in high-volume clinics; reduces administrative burden.

	Intracranial Pressure (ICP)	**Quantification:** Automated Optic Nerve Sheath Diameter (ONSD) segmentation	**Dice Score 73.3%**; AUROC 84.5.[31]	Standardizes measurements; reduces inter-operator variability in trauma settings.
Oncology	Breast Lesion Triage	**Decision Support (CAD):** Re-classification of BI-RADS scores (e.g., Koios DS)	**60% reduction** in benign biopsies while maintaining sensitivity.[34]	Reduces patient morbidity from unnecessary procedures; upskills junior radiologists.
	Thyroid Nodule Risk	**Risk Stratification:** Automated TI-RADS scoring	Improved specificity over expert readers.[37]	Reduces inter-observer variability in scoring; refines biopsy candidacy.
	Skin Cancer Screening	**Diagnostic Support:** Elastic Scattering Spectroscopy (ESS) (e.g., DermaSensor)	**96% Sensitivity** for melanoma vs. ~60-70% for PCPs.[37]	Augments primary care capacity; functions as a "second reader" for equivocal lesions.
Musculoskeletal	Fracture Detection	**Triage (SaMD):** Automated detection on plain radiography	**92% Pooled Sensitivity**; Reduced missed fractures by **29%**($P<.001$)[42,43]	"Always-on" second reader; improves sensitivity of non-radiologists in urgent care.
	Nerve Blocks	**Real-Time Guidance:** Anatomy-aware color overlays (e.g., Nerveblox)	**99% Nerve Identification**; Improved novice success rate ($P=.02$).[46,47]	Lowers cognitive load; reduces procedural time; democratizes regional anesthesia.
	Rotator Cuff Tear	**Acquisition Guidance:** Automated plane recognition & segmentation	**94.9% Accuracy** in standard plane recognition.[49]	Bridges the gap between POCUS and MRI for soft tissue pathology.
	Hip Dysplasia (DDH)	**Automated Measurement:** Geometric quantification of alpha angle	**99.0% Pooled Sensitivity**; Mean absolute error <4 degrees.[51]	Facilitates universal screening/tele-ultrasound by eliminating manual geometric errors.

DISCUSSION

The Democratization of Expertise

The unifying theme of the 2020–2025 literature is the democratization of diagnostic capacity. Eric Topol's foundational vision of "Deep Medicine"—where AI restores the human connection by offloading cognitive burdens—is now being realized through device autonomy.[54] AI medical devices are effectively "shipping the specialist with the sensor," a paradigm shift described by recent industry analysis as embedding diagnostic intelligence directly into portable hardware.[55,56]

By integrating expert-level pattern recognition and real-time acquisition guidance, these technologies enable non-specialists—including midwives, nurses, and general practitioners—to perform complex diagnostic tasks that previously required sub-specialist referral.

- **Acquisition Guidance:** Narang et al. (2021) demonstrated that deep learning algorithms could guide novice nurses to acquire diagnostic-quality echocardiograms in >90% of cases, effectively democratizing cardiac imaging for limited diagnostic use.[57]

- **Blind Sweeps in Obstetrics:** In landmark studies for low-resource obstetrics, Price et al. (2022) validated AI models that estimate gestational age from "blind" ultrasound sweeps with accuracy comparable to trained sonographers.[58] Subsequent trials in 2025 further confirmed that these automated tools allow midwives in rural settings to date pregnancies and identify complications without formal imaging training.[59]

This shift is particularly transformative for global health, addressing critical workforce shortages in resource-constrained settings. Recent scoping reviews confirm that AI-enabled POCUS is rapidly moving from pilot studies to scalable deployment, reducing referral delays and expanding the reach of precision medicine to the "last mile" of healthcare delivery.[60]

Regulatory Divergence and Future Challenges

A growing divergence between US and EU regulatory environments poses a risk to global innovation. While the FDA's 510(k) pathway has catalyzed rapid market entry, listing over 1,200 authorized AI devices by late 2025,[61] the EU MDR's rigorous clinical data requirements have created a "bottleneck," potentially stalling European access to these tools.[62–64] Furthermore, the reliance on retrospective data for many approvals raises concerns about "algorithmic drift" and generalizability across diverse populations.[65,66] The rise of "human-in-the-loop" legislation in 2025 (e.g., state laws requiring physician review of AI decisions) reasserts the role of the clinician as the ultimate arbiter of care,[67] emphasizing that AI remains an augmentation tool, not a replacement.[68]

CONCLUSION

The period from 2020 to 2025 has cemented AI's role as a foundational element of modern medical devices. In Ophthalmology, AI has matured into a standard-of-care screening modality. In Oncology, it acts as a critical "second reader," enhancing specificity and reducing invasive procedures. In MSK, it has revolutionized image acquisition, placing the power of ultrasound into the hands of novices. As these technologies continue to evolve, the focus must shift from pure diagnostic accuracy to implementation science—ensuring these powerful tools are integrated seamlessly, ethically, and equitably into clinical workflows to realize their full potential for precision medicine.

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