

Artificial Intelligence in Biomedical Engineering: Current Advances and Future Perspectives in the United States

Author Name & Affiliations

Evan Samuel Walker
Department of Biomedical
Engineering University of
Illinois Chicago
esamuelwalker@uic.edu

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Abstract

Over the past few years, Artificial Intelligence (AI) has been a game-changer in biomedical engineering, transforming the design, validation and deployment of diagnostic, therapeutic, and monitoring systems across the U.S. healthcare landscape. In this review, recent progress in AI-powered medical imaging, wearable/implantable biosensing, drug discovery and precision medicine, and robotic and neural engineering is summarized, with a focus on the recent field of AI/machine-learning (ML) based medical devices and the regulatory landscape set by the U.S. Food and Drug Administration (FDA) for these devices. Based on peer-reviewed literature published primarily from 2023 to 2025, the review shows the shift of AI from experimental proof-of-concept to FDA regulated clinical products, records the rapid increase in FDA authorizations and outlines some ongoing issues around algorithmic bias, data governance, algorithm interpretability and demographic transparency. The review concludes with a discussion on future avenues for federated learning, foundation models, edge-AI wearables, and adaptive regulatory frameworks like Predetermined Change Control Plans (PCCPs) that will influence the next generation of biomedical AI systems in the United States.

INTRODUCTION

Biomedical engineering is the application of engineering principles with computational science and clinical medicine. In the last decade, the discipline has experienced a fundamental shift due to the development of advanced and powerful AI, and especially deep learning, which has led to the development of machines that can extract clinically relevant patterns from complex, high-dimensional biomedical data, such as medical images, physiological waveforms, genomic sequences and electronic health records [1], [2]. This shift has been facilitated in the U.S. by a vibrant academic research environment, significant private sector investment in digital health, and a changing regulatory landscape managed by the FDA that has approved nearly 1,000 AI- and machine-learning-based medical devices since 1995, most of which have entered the market since 2016 [3], [4].

AI has emerged to transform biomedical engineering, forming a new paradigm between big-data analytics, computational modeling, and the classic engineering design process to create predictive, personalized, and increasingly autonomous healthcare solutions, as several authors call it today, digital biomedical engineering [1]. The study offers a structured review of the most recent developments in this field in the context of the USA, ranging from medical imaging, wearable and implantable sensing, drug discovery, surgical robotics, to neural engineering, and then further explores the regulatory landscape and the ethical and technical challenges that remain relevant when it comes to responsible use. Finally, the review covers the directions into which AI-enabled biomedical systems are heading as they enter the next generation.

AI IN MEDICAL IMAGING AND DIAGNOSTIC SYSTEMS

Medical image analysis is the most advanced and widely used application of AI in biomedical engineering. CNNs, transformer models, and hybrid CNN-transformer models have significantly enhanced the accuracy, consistency, and speed of segmentation, classification, and detection tasks in radiology, pathology, and cardiology [5] [6]. Efficient transformer-based encoders have been shown to outperform previous volumetric segmentation architectures in terms of accuracy, and with lower computational cost than previous methods [6], while recent advances in MLP-permutation based convolution generalizes this improvement to recurrent volumetric segmentation tasks [5].

In addition to segmentation, AI has also been utilized to optimize downstream clinical goals together – such as learning-based neural architecture search for ensemble models for 3D radiotherapy dose prediction, where structural and dosimetric information are both used to support treatment planning [7]. The classification of biomedical images has also benefited from feature-learning methods that incorporate domain-specific texture priors directly into learned representations, like deformable Gabor feature networks [9]. For sparse-view computed tomography reconstruction, a significant amount of research has been performed using deep generative models, such as diffusion models and GANs, with the goal of lowering the radiation dose required to maintain diagnostic image quality; and more extensive reviews of the field have characterized the transition from discrimination-based approaches to generative approaches and foundation models for segmentation [10, 11].

One characteristic that often limits U.S. clinical deployment is the inability to find large, diverse, well-labeled datasets, especially for rare diseases and underrepresented groups. On this front, federated learning has become a popular solution, enabling institutions to train models on their disjointed datasets without sharing sensitive patient data, and systematic reviews of federated learning in medical image analysis show that it is improving the generalizability while also identifying communication and heterogeneity challenges that are still to be addressed [8]. Some complementary research on weakly supervised segmentation has been aimed at decreasing the amount of annotation required to train the large number of medical centers in the United States.

AI IN WEARABLE AND IMPLANTABLE BIOMEDICAL DEVICES

A second major area of AI innovation is wearable and implantable biosensing systems, especially for out-of-clinic continuous monitoring of cardiovascular, neurological and metabolic health. The concept of wearable physiological monitoring has built on the early foundational work of unobtrusive sensing that set the design principles for systems that enable us to measure physiological signals from within the human body without being intrusive, that is, without causing pain or discomfort to the wearer [14]. Recent work has combined physics-informed and deep-learning models with wearable bioimpedance and photoplethysmography sensors to facilitate cuffless, continuous blood pressure monitoring, with the inclusion of confidence-aware models that apply particle filters to estimate uncertainty in cuffless blood pressure measurements in an ambulatory environment [12].

Additionally, deep learning has been directly used to interpret physiological waveforms, and guided-attention models have been demonstrated to achieve better performance on multi-channel physiological signals by directing model capacity to only the diagnostically significant portions of the waveforms [13]. Concurrently, dual-stream convolutional networks have been developed for heart-sound classification on low-power edge platforms such as wearable and consumer-electronics devices, demonstrating the trajectory towards low-power, low-latency, deployment of AI models on the edge of wearable systems [15]. Together, these advances are bringing the power of AI diagnostics out of the hospital and into real-time, ambulatory patient monitoring, especially relevant to the U.S. focus on remote patient monitoring and value-based care.

AI IN DRUG DISCOVERY AND PRECISION MEDICINE

AI has significantly sped up the process of drug discovery at the early stages, such as target identification, molecular generation, and prediction of pharmacokinetic and toxicological properties. AI has been applied to a variety of generative modeling approaches including variational architectures, modular molecular design frameworks, etc., which have led to the automated generation of candidate compounds; in more recent times, generative AI has been employed to generate new antibiotic agents by searching chemical space much more expansively than can be accomplished with traditional medicinal chemistry pipelines [1]. These capabilities are

supported by unified protein representation models, which further enhance the efficiency of protein engineering workflows relevant to the biologics development.

Outside of cancer, AI systems are being used to move beyond population-based to personalized medicine by analyzing genomic, transcriptomic, and clinical data to stratify patients based on their cancer risk and likely treatment response. These pipelines have been utilized in U.S. academic medical centers and biopharmaceutical firms, especially in oncology, where multimodal fusion of histopathology and genomic attributes has been demonstrated to enhance the accuracy of prognosis prediction compared to either set of features.

AI IN SURGICAL ROBOTICS AND NEURAL ENGINEERING

Long-term, the goal of using AI in robot-assisted surgery is to enhance the precision of surgical procedures and minimize complication rates. Regularities in the intraoperative field, such as the registration of pre-operative imaging, segmentation of critical anatomical structures and deviations from expected surgical workflow, are expected capabilities that follow on from the medical image segmentation advances described in Section II [5,6] and can be achieved with the aid of AI-driven computer vision.

Machine learning plays a pivotal role in neural engineering, where it is used to interpret neural and electromyographic signals for brain-computer interfaces and AI-powered prosthetic control systems, thereby enhancing the capabilities of assistive devices for individuals with spinal cord injuries, amputations or neurodegenerative disorders to be more intuitive and responsive. The systems rely on the same kinds of wearable and implantable biosensing advances discussed in Section III, highlighting the growing interdisciplinary nature of biomedical engineering in the United States that is being driven by the use of AI.

REGULATORY LANDSCAPE: FDA OVERSIGHT OF AI/ML-ENABLED MEDICAL DEVICES

Ours is a quickly changing regulatory landscape that has grown with the technology it regulates. The FDA keeps a public list of authorized AI/ML-based medical devices, and an analysis of this list reveals that the FDA authorized its first AI/ML-based medical device in 1995, followed by a high rate of approvals after 2016, and more than 1,000 authorizations by 2025 [3], [4]. A review of clearance summary and marketing documents revealed that almost all of these devices are introduced to the market based on predicate devices, most of which are for radiology applications, followed by cardiovascular and neurology applications [19].

Of the 168 devices with machine learning functionality that were cleared in 2024, 94.6% utilized the 510(k) pathway, and only 16.7% of the clearance summaries included a Predetermined Change Control Plan (PCCP) for pre-specified changes to the model, introduced by FDA guidance in 2024, which does not require a new marketing submission for each change [4]. The same analysis revealed that only 15.5% of the clearance summaries for 2024

included patient demographic data, and less than 1/3 of those summaries included information on sensitivity and specificity together, a pattern that aligns with prior studies showing that transparency is often lacking in FDA clearance statements for AI devices intended to be used in the real world [17,18]. The FDA further established its coordinated approach to AI oversight across the three of its centers – devices, drugs, and biologics – in March 2024 and has released comprehensive draft guidance later in the year related to the entire lifecycle management of AI based device software functions, as part of a broader U.S. policy shift toward continuous, lifecycle-based oversight.

CHALLENGES AND ETHICAL CONSIDERATIONS

While there have been significant advances in AI technology, several issues remain to limit the safe and equitable use of AI in U.S. biomedical engineering. There is an inherent concern about algorithmic bias, as models trained on data from an underrepresented demographic may be likely to perform worse on that same group, and even worse, many demographic groups are not reported in FDA clearance summaries [4] [18]. Second, for many high-performing deep learning architectures, interpretability and explainability are not solved, making them difficult to trust by clinicians or regulators, especially when they have to work with them with a high autonomy level [2, 3].

Third, privacy and governance remain challenges as biomedical AI systems are increasingly based on large, multi-institutional datasets, and federated learning and other privacy-preserving paradigms of AI training have their own set of communication, security, and model-heterogeneity challenges [8]. Fourth, the surveillance of adaptive models that are continually updated during their post-market phase lead to novel regulatory challenges that were not anticipated when device oversight was first established, prompting FDA's recent focus on lifecycle management and pre-determined change control [4, 20]. Addressing these challenges will take place with the continued cooperation and collaboration of biomedical engineers, data scientists, clinicians, and regulators.

FUTURE PERSPECTIVES

There are a number of trends that are likely to influence the next step for AI in U.S. biomedical engineering. Recent special collections on foundational models in medical imaging [11] are indicative of the increasing expectation that foundation models trained on large and diverse biomedical texts will support a wide variety of imaging, genomic and clinical-text applications, thereby lowering the task-specific amount of labeled data needed for individual clinical deployments and necessitating targeted regulatory review. Efficient wearable signal classification [15] will be extended with edge-AI with local inference on low-power devices to increase the

amount of data monitored in continuous fashion, and to eliminate the data transmission and privacy issues of cloud-based analysis.

On the regulatory side, the broader adoption of Predetermined Change Control Plans is likely to have an impact on the authorization and monitoring of adaptive AI/ML devices throughout their lifecycle, transitioning the U.S. regulatory model towards continuous oversight, as opposed to a one-off pre-market review [4] [20]. Lastly, ongoing investments in transparent, demographically representative benchmarking and federated and privacy-preserving training approaches are likely to be required to narrow the gap between the performance of these AI systems in controlled research settings and their broader applicability to the wide variety of patients who receive care in the U.S. health care system [8], [17], [18].

CONCLUSION

In the US, AI has become a cornerstone of the field of biomedical engineering, with proven applications in medical imaging, wearable and implantable sensing, drug discovery, surgical robotics and neural engineering. In the last ten years, the U.S. regulatory framework, which currently includes a quickly expanding catalog of FDA approvals for AI/ML-powered devices and an emerging lifecycle-management framework, has undergone significant changes while still having several open questions concerning post-market oversight of adaptive algorithms, transparency, and bias. To realize continued progress, close collaboration among engineers, clinicians, data scientists, and regulators will be essential to ensure that AI-enabled biomedical technologies are technically feasible and safe, equitable, and clinically trustworthy.

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