The Role of Artificial Intelligence (AI) in Healthcare

Executive Summary

Artificial intelligence (AI) applied to healthcare, driven by innovative medical technology, has and will continue to transform patient care. These advancements can enable clinicians to better understand diseases, achieve faster and more accurate diagnostic results and leverage significant amounts of information to develop appropriate treatment options and care plans. AI-enabled technologies can also streamline workflows and other administrative tasks, bringing efficiencies to health care practices facing resource constraints and clinician burn out.

AI is being utilized across the healthcare continuum; this paper predominantly focuses on AI and AI/ML-driven products that are regulated by the Food and Drug Administration (FDA) as medical devices. We also include a snapshot of AI utilization that is currently unregulated. With AI-enabled medical technology, these products fit into the category of medical device software.

FDA has a comprehensive regulatory framework that ensures the safety and effectiveness of many different types of medical technologies, including AI/ML-enabled medical devices, throughout their lifecycle. This framework utilizes a well-established risk-based framework for premarket authorization and postmarket oversight. As of August 2024, FDA has authorized more than 950 AI/ML enabled devices.

It is important to note that there are many AI products utilized in healthcare that are not FDA-regulated. Many of these non-medical products are regulated by other federal bodies (e.g. decision support interventions (DSIs), which are governed by the Office of the National Coordinator (ONC). All these products, including FDA-regulated products, are subject to additional requirements such as Federal Trade Commission (FTC), consumer protection and privacy and state laws.

This white paper provides an overview of the current landscape of AI-based applications and products in the healthcare sector. It highlights the benefits of AI and provides examples of how AI is being leveraged to transform healthcare. This document highlights a range of AI technologies utilized in healthcare, with a specific focus on AI technologies that are regulated by FDA. It describes the major categories of AI and the roles that these technologies can play, including a summary of AI's strengths and limitations, and provides a summary of how FDA is approaching AI regulation under its existing authorities. This paper also provides an overview of steps that can be taken to accelerate the adoption and use of AI in medical technologies.

Current Application Areas for AI in Healthcare

AI has numerous applications in healthcare. There are two main types of problems that AI is uniquely applicable to solving. First, AI can help surface details, including patterns and insights, that human practitioners could miss under a heavy workload or potentially minute details within a patient's charts. Second, AI can automate repetitive routine tasks within healthcare workflows or narrow down a large set of viable solutions to help determine the most efficient path to an optimal solution. By leveraging these two key strengths, AI solutions have been developed for diagnostic, therapeutic, and workflow optimization, with the vast majority being in medical imaging analysis. While many of these applications are FDA-regulated, others are not.

This section describes some of the ways that AI is currently being deployed in the healthcare sector and highlights several examples of technologies that has received FDA approval or clearance.

Diagnostics

Medical Imaging Analysis (87% of new AI/ML device FDA clearances in 2023 and 79% in the first half of 2024): Deep learning models can accurately detect and classify abnormalities, tumors, polyps, or other pathologies from medical images or videos such as X-rays, CT scans, MRI scans or during procedures such as colonoscopies, often outperforming human clinicians regarding accuracy and consistency. AI significantly streamlines radiology imaging workflows. Pre-scan, AI auto-positioning uses 3D cameras for patient setup, reducing manual effort and improving image accuracy. During scans, AI guidance for ultrasound advises on transducer placement and captures quality images, minimizing operator dependency. Post-scan, AI analyzes and prioritizes images, quickly identifying urgent cases like strokes for immediate attention, aiding in rapid diagnosis and prioritization for radiologists. This results in a faster, more efficient imaging process with improved patient outcomes.

1. **Disease Diagnosis**: ML models can be trained to analyze patient medical records, laboratory results, and other clinical data to make accurate diagnoses, aiding in early detection and personalized treatment planning.
2. **Genomic and Biomarker Analysis**: ML techniques can analyze complex genomic data, identify genetic markers, and uncover patterns associated with specific diseases or treatment responses, leading to more personalized and targeted therapies.
3. **Clinical Decision Support Systems**: AI-powered decision support systems can assist healthcare professionals in making informed treatment decisions by analyzing patient data, medical literature, and treatment guidelines, reducing errors, managing data burden, and improving overall clinical decision-making.
4. **Predictive Analytics and Risk Stratification**: These ML models are a type of CDS that can analyze patient data and identify patterns that predict the risk of developing certain conditions or complications. This enables the implementation of preventive measures, optimizing resource allocation, and prioritizing high-risk patients for early intervention.

Examples of FDA approved or cleared devices in this category include:

1. **Paige Prostate Detection System by Paige.AI, Inc. DEN200080**

Intended Use: AI-based software assists in the detection of foci suspicious for prostate cancer in digital images of H&E-stained prostate core needle biopsy specimens acquired from patients with known or suspected prostate cancer.

2. **Aidoc Pulmonary PE AI Software by Aidoc Medical Ltd. K222277**

Intended Use: AI-based software aids in the detection and triage of acute pulmonary embolism in CT angiography images. It identifies and highlights regions of interest, alerting radiologists to suspected positive cases.

3. **GI Genius System by Cosmo Artificial Intelligence Ltd., Distributed by Medtronic K211951**

Intended Use: AI-based reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. It identifies and highlights regions of interest, alerting endoscopists to suspected lesions.

4. **IDx-DR AI System by Digital Diagnostics Inc. K203629**

Intended Use: Autonomous AI system is designed to detect diabetic retinopathy, including macular edema, in adults diagnosed with diabetes. It analyzes retinal images and provides a screening decision without the need for a clinician to interpret the image or results.

5. **SimpleSense-BP by Nanowear Inc. K232053**

Intended Use: AI-Diagnostic software-as-a-medical-device for self-administered, continuous, non-invasive, and cuffless blood pressure monitoring at-home. It uses a wearable and proprietary nanotechnology that collects millisecond-by-millisecond dynamically changing physiological data - ECG, heart sounds, and thoracic impedance as inputs to the AI, which passively delivers systolic and diastolic blood pressure every 60 seconds.

These devices leverage AI and machine learning to enhance the accuracy, efficiency, and consistency of diagnostic and treatment decision making by clinicians.

Therapeutic

1. **Personalized Medicine and Treatment Optimization**: By analyzing patient-specific data, such as genetic information, medical history, and lifestyle factors, ML models can help develop personalized treatment plans tailored to individual patients, optimizing treatment outcomes, and minimizing adverse effects.
2. **Robotic Surgery and Assistive Technologies**: AI and ML are being integrated into robotic surgical systems, providing enhanced precision, stability, and control during complex procedures. Additionally, AI-powered assistive technologies, such as exoskeletons and prosthetics, can aid in rehabilitation and improve the quality of life for patients with disabilities.

Some recent FDA-cleared examples of devices in this category are as follows:

1. **da Vinci 5 Robotic System by Intuitive Surgical**

Intended Use: The da Vinci 5 is a fifth-generation multiport robotic system designed to enhance surgical precision and efficiency. It includes over 150 enhancements such as improved accuracy, next-generation 3D display and image processing, and first-of-its-kind force-sensing technology.

2. **VELYS Robotic-Assisted Solution by DePuy Synthes**

Intended Use: This system is used for uncompartmentalized knee arthroplasty procedures. It builds upon the VELYS platform used in Total Knee Arthroplasty (TKA), providing robotic assistance to improve surgical outcomes.

3. **UNiD Spine Analyzer by Medtronic**

Intended Use: Intended for assisting healthcare professionals in viewing and measuring spine related CT images as well as planning orthopedic spine surgical procedures. The device also includes tools for measuring anatomical component for placement of surgical implants. (FDA cleared AI features as part of UNiD Spine Analyzer via K212005).

Workflow Optimization and Care Coordination

Many AI-enabled products in this category are not FDA-regulated. Categories include:

1. **Predictive Analytics for Patient Flow and Resource Management**: AI algorithms analyze inpatient admissions, discharges, and transfers patterns to optimize patient flow and resource allocation. This involves predicting high-demand periods and adjusting staffing levels and bed availability to reduce bottlenecks and wait times.
2. **Electronic Health Records (EHR) Management**: AI systems manage and organize extensive patient and provider data, including electronic health records, appointments, and treatment histories. These systems can extract pertinent information from unstructured data, improving data management and retrieval efficiency and accuracy.
3. **Automated Billing and Claims Processing**: AI algorithms automate billing and insurance claims processing by rapidly analyzing and processing claims data, identifying errors or inconsistencies, and ensuring compliance with relevant regulations.
4. **Automated Scheduling Systems**: AI-driven scheduling systems optimize the organization of appointments and procedures by analyzing variables such as provider availability, patient preferences, and urgency of care. These systems minimize no-shows and cancellations, maximizing the utilization of healthcare professionals' time and enhancing patient flow.

Examples for Workflow Optimization

1. **Reveal LINQ and LINQ II Insertable Cardiac Monitors AccuRhythm AI platform by Medtronic Ltd. K223630 and K210484 (FDA regulated)**

Description: Insertable cardiac monitors, with embedded algorithms for arrhythmia monitoring and detection, that leverage two cloud-based AI algorithms to improve diagnostic specificity by rejecting false atrial fibrillation and pause episodes from patient ECGs, reducing clinical data review burden.

2. **Nuance Dragon Ambient eXperience (DAX) by Nuance Communications**

Description: This ambient clinical intelligence solution uses AI to securely capture and contextualize physician-patient conversations during virtual or in-person visits. It automatically creates detailed clinical notes, reducing the administrative burden on providers and improving data capture accuracy.

Types of AI - Traditional AI vs. Generative AI and General-Purpose AI (Foundation model)

AI is a broad category of technologies that spans many sub-specialties and disciplines, like machine learning (and its subfield of deep learning), computer vision, natural language processing, and more recently generative AI and foundational models. For the purposes of this effort, we will confine the scope to the most common and generalized concepts, namely Traditional AI, Generative AI and foundational models, since they are the most relevant and referenced. They each offer unique contributions in healthcare applications.

Traditional AI in healthcare typically involves rule-based systems and machine learning/deep learning models designed for specific tasks such as diagnostic imaging, patient monitoring, and predictive analytics. These systems can rely on structured data and predefined algorithms to classify patient data, to detect anomalies in medical images or predict patient outcomes based on historical data. Also known as "classic" or "narrow" AI, traditional AI approaches operate within predefined parameters and are typically designed to perform specific tasks or solve particular problems. This type of AI relies heavily on structured data. Traditional AI excels in tasks such as image recognition, natural language processing, and predictive analytics, where the input data is well-defined, and the desired output is clear. All the FDA-authorized medical devices that leverage AI have been traditional AI models.

For Traditional AI, two primary types of learning paradigms are commonly used: supervised learning and unsupervised learning. Both play crucial roles in AI model development, each with its unique methodologies and applications. Supervised learning involves training a model on a labeled dataset, meaning each training example is paired with an output label, usually by credentialed and qualified medical professionals. The goal is for the model to learn a mapping from inputs to outputs. This type of learning is widely used in applications such as classification, regression, and predictions. The advantages of supervised learning include high accuracy and strong predictive power. Supervised learning models are also often more explainable because the relationship between input features and output labels is explicitly learned from expert labeled medical data. However, supervised learning also requires a large amount of labeled data, which can be expensive and time-consuming to obtain.

In contrast, unsupervised learning deals with training a model on a dataset without labeled responses. The purpose is to infer the natural structure present within a set of data points. Common applications include clustering (e.g., patient segmentation, and anomaly detection) and dimensionality reduction

(e.g., principal component analysis to reduce the number of variables in the data). Unsupervised learning has the advantage of working with unlabeled data, which is often more readily available, and is useful for discovering hidden patterns or intrinsic structures in data. However, it generally achieves less accuracy compared to supervised learning models for prediction tasks, and the results can be harder to interpret.

Generative AI and General-purpose AI (GPAI) or Foundation Models.

Generative AI and GPAI (aka foundation models) are very closely related solutions with some unique distinctions. Importantly, there are no FDA-cleared generative AI products specifically for healthcare applications.

Generative AI is designed to create new content by leveraging a large corpus of data used for its training. These models learn the underlying distribution of the input data and can produce novel outputs such as images, text, or audio. Common applications include image generation, text generation, and music or speech synthesis. In healthcare applications, this includes generating synthetic medical data, creating personalized treatment plans, and simulating patient responses to different healthcare therapies.

Foundation models are trained on extensive datasets and designed to perform a wide range of tasks without task-specific training. These models serve as versatile bases that can be fine-tuned for specific applications. Most commonly, these models are widely used in natural language processing (e.g., translation, summarization), computer vision (e.g., object detection, image classification), and general AI tasks (e.g., question answering, recommendation systems). In healthcare applications, these models can be used for various applications from providing medical information and recommendations to assisting in medical decision-making.

In terms of explainability and interpretability, especially for healthcare applications, generative AI and foundational models often pose challenges in explainability due to their complexity. Understanding why a model generated a specific output can be difficult, especially with deep generative models, and the responses are not deterministic. This means that if you ask the same question multiple times, you might get different answers each time. Moreover, the open-ended nature of evaluating the potential harm to patients with different outputs provided by Generative AI for the same inputs at different times makes it challenging from a risk assessment perspective. Foundational models also face challenges in explainability due to their large size and inherent complexity. In terms of interpretability, both generative AI and foundational models are generally less interpretable; they can create new data, extract unstructured data into a structured format, and provide predictions, rather than making decisions based on input features.

Therefore, while the distinction could be academic, Generative AI and Foundational models have unique strengths and limitations, with generative AI exceling in creating new content and augmenting data, while foundational models offer versatility and efficiency across diverse tasks. Methods are under development within the industry to address some of the challenges raised by foundation models and Generative AI. Adoption of these technologies in healthcare applications should anticipate and mitigate potential pitfalls of these new technologies.

Strengths and Limitations

The different AI models offer distinct benefits and limitations, making them suitable for different healthcare applications. These characteristics are usually a major factor in healthcare applications and need to be considered into the risk profile and regulatory framework.

To date, all AI/ML-enabled medical devices are FDA cleared or approved with "locked" algorithms, which means that the algorithms are not continuously learning or automatically evolving in the field.

Traditional AI solutions developed through either supervised and unsupervised learning each have their unique strengths and limitations. As mentioned in the previous section, supervised learning excels in predictive accuracy and explainability when expertly labeled medical data is available, while unsupervised learning is invaluable for discovering hidden patterns in unlabeled medical data. Furthermore, locked AI modes, the most common in medical applications, provide consistency and predictability. However, there is the potential risk that locked algorithms can become less clinically valuable over time due to evolutions in clinical practice, changes in patient populations, and other factors that contribute to 'drift'. Human-in-the-loop AI can help to ensure accuracy and ethical oversight but can slow down decision-making processes or intervention.

On the other hand, traditional AI that is adaptive in its operation offers the advantage of evolution and personalization to match the needs of patients, especially for chronic conditions and progressive diseases. Adaptive algorithms continuously improve by learning from new data but require careful management to avoid unintended consequences. The safety and efficacy of these AI algorithms can be controlled and mitigated against unwanted drift that may compromise the algorithms performance and jeopardize patient safety.

Despite the significant interest in in Generative AI and GPAI technologies, the FDA has not yet authorized devices that incorporate foundation models or those powered by large language models (LLM)s. Because of the dynamic and adaptive nature of Generative AI and GPAI or foundation models, the current regulatory framework may need to further evolve.

To illustrate this point, recent studies have shown that LLMs can significantly enhance diagnostic accuracy compared to physicians in specific scenarios. A study by Google DeepMind found that an LLM achieved a top-10 accuracy of 59.1% in generating differential diagnoses (DDx) from complex cases, compared to 33.6% for unaided clinicians[1]. Another study highlighted that GPT-4 performed above the median physician in internal medicine and psychiatry on the 2022 Israeli board residency examinations[2]. Additionally, a meta-analysis revealed that generative AI models had an overall diagnostic accuracy of 56.9%, with physicians outperforming these models by 14.4% on average[3].

However, some AI models like GPT-4 performed comparable to non-expert physicians in non-expert settings. These findings suggest that while LLMs can aid in complex diagnostic tasks and improve

[1] Towards Conversational Diagnostic AI Tu, T. et al. Preprint at https://arxiv.org/abs/2401.05654 (2024)
[2] Katz. U. et al. GPT versus Resident Physicians — A Benchmark Based on Official Board Scores. N Engl J Med AI. 2024;1(5): Doi: https://doi.org/10.1056/AIdbp2300192
[3] Diagnostic Performance Comparison between Generative AI and Physicians: A Systematic Review and Meta-Analysis, Takita, H. et al. Preprint at https://www.medrxiv.org/content/10.1101/2024.01.20.24301563v2.full

accuracy, they are not a replacement for expert physicians and require further refinement and evaluation in real-world clinical settings.

FDA's regulation of AI-enabled medical products

FDA's regulatory framework is robust and intentionally flexible to ensure the safe and effective use of many different types of technologies, including AI/ML-enabled devices, across the product lifecycle. As of August 2024, FDA has authorized more than 950 AI/ML enabled devices.[4] The majority of the FDA authorized AI/ML-enabled devices to-date are for medical imaging software, however utilization of this technology continues to expand to other medical device specialties, including, among others, cardiovascular, neurology, hematology, and GI.

FDA's regulatory framework includes a well-established risk-based framework for the premarket authorization and oversight of medical devices. Existing mechanisms for supervising and ensuring compliance, including pre-market review, post-market surveillance, and regular inspections and audits. For AI-based medical devices that have obtained FDA marketing authorization, there is substantial evidence demonstrating their safety and efficacy through the FDA premarket review process. Medical device manufacturers (MDMs) have ongoing post-market requirements to monitor the performance and safety of their AI-driven solutions, including implementing robust quality management systems, conducting post-market surveillance studies, and actively monitoring user feedback and adverse event reports. MDMs also engage in improvement of their AI algorithms throughout the product lifecycle, refining and updating their AI models as new clinical data becomes available and real-world evidence is collected.

FDA has issued multiple guidances addressing various aspects of regulating AI-enabled devices. Examples include FDA's released guidance on Clinical Decision Software that is excluded from the definition of medical device. This authority, which was provided by Congress in the 21st Century Cures Act of 2016, provides for access to software products that are not devices, if specific requirements are met. In addition, FDA recently released Predetermined Change Control Plan (PCCP) guidance, for which Congress provided statutory authority in the Food and Drug Omnibus Reform Act of 2022 (FDORA).

PCCP is an innovative concept that provides a voluntary pathway for industry to obtain review and authorization from FDA of pre-specified changes to a device in a premarket submission. This permits a manufacturer to make controlled changes to existing AI algorithms without an additional submission to FDA. This innovative concept enables manufacturers to innovate more efficiently and rapidly to help improve patient health while still ensuring the safety and effectiveness of the device. This authority applies to all medical devices but has great applicability to AI/ML-enabled devices because it enables the regulatory framework to keep better paces with the rapid change nature inherent to AI/ML technologies. FDA has authorized PCCPs for locked algorithms.

For further information related to FDA guidances that address AI-enabled devices, see the reference section.

[4] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Considerations to accelerate adoption and use of AI/ML-enabled devices

As discussed above, FDA has a robust regulatory framework to oversee all medical devices, including AI/ML devices. FDA's oversight is guided by a framework that includes a rigorous pre- market review process that assesses medical device performance, reliability, and safety, as well as extensive monitoring and surveillance requirements after devices are authorized for sale. These ensure continued safety and effectiveness throughout the device lifecycle.

As the use of AI continues to expand in healthcare, the existing FDA policies for AI in medical devices will likely need to evolve to keep pace with the pending growth in AI based submissions from medical device companies. FDA development of guidance related to best practices in the development of different types of AI (e.g., adaptive models) and premarket review practices for these technologies (e.g., mitigating unwanted bias) will help drive predictability and consistency for AI submissions. As AI continues to evolve and AI/ML-enabled devices are developed with adaptive algorithms, the PCCP framework could be further evolved to allow for appropriate guardrails to be set within the premarket authorization to allow for post-market modifications for adaptive algorithms.

FDA's regulatory framework is only part of the challenge medical device innovators must address to bring their products to market. To get AI and software technologies deployed for use in healthcare delivery, they must also be reimbursed by payers, including Medicare and private insurance plans. A more comprehensive and systematic solution is needed across and within Medicare's benefit categories to address coverage, coding and payment issues if patients are to benefit from AI's promise of personalized treatments, improved diagnostics and screening, and more accurate procedures. In addition, improved policies for access to data sets necessary to develop effective AI algorithms and promote AI innovation. For example, privacy requirements may limit the collection and use of these demographic variables, making it challenging to conduct comprehensive bias analyses.

Domestic and International harmonization

Global alignment of AI regulation plays a crucial role in facilitating international collaboration, building public trust, and managing risks. It is important to continue to develop and promote common AI standards to advance the safe, secure and trustworthy AI development and use. Standards play a crucial role in the development and adoption of new and emerging technologies. They are especially important in the field of AI, where policymakers and regulators in the United States and abroad are looking to the standards ecosystem to guide AI actors on how to implement high-level principles and policies. In addition, there are many currently available standards for AI, e.g., ISO/IEC 42001:2023 Information technology -Artificial intelligence - Management system, as well as additional standards that apply to medical devices (e.g., IEC 62304- Medical device software: Software life cycle processes).

Conclusion

AI is a transformational tool with the potential to improve health outcomes, enhance efficiency of patient care, lower costs, and make advancements in health care. The potential for AI to transform healthcare in the US is immense, with many of its benefits already being realized in healthcare.

Public discussion regarding AI/ML has increased in recent years as the utilization of AI/ML technology has expanded in all sectors of society. However, the utilization of AI/ML technology is not new for the medical device industry. The FDA has been reviewing and authorizing AI/ML enabled medical devices for

over 25 years. As state and federal legislators seek to ensure AI/ML-enabled technologies in all industries are used safely, FDA should continue to maintain regulatory oversight of medical devices.

While pace of innovation is rapid, FDA's existing regulatory authorities are robust and adaptable to keep up with the advancements in AI/ML technology and to ensure the safe and effective use of AI/ML technology in medical devices. As the complexity and sophistication of AI algorithms increase, the FDA will need to adapt its policies, such as the PCCP framework, to specifically address unique considerations associated with AI. Further, FDA should continue to promote global alignment of AI regulation, including the continued emphasis on AI standards, to continue to further the development of AI technologies globally.

Leveraging its extensive repository of AI validation methods from cleared devices, the FDA is uniquely positioned to implement a robust framework for MDMs. Such a framework would ensure that validation requirements are clearly defined before MDMs embark on clinical studies to develop and validate their AI products. This guidance is accessible to MDMs through the FDA's generic pre-submission mechanism. However, by creating explicit guidelines for AI-focused pre-submission requests, the FDA can streamline the data collection process necessary to demonstrate the safety and effectiveness of pre-market devices. This not only promotes resource and time efficiency in developing AI-based methods but also accelerates the early availability and adoption of transformative technologies in clinical settings, ultimately benefiting both patients and clinicians.

FDA Resources

FDA has issued many guidances and other resources related to FDA's regulation of software products, including AI/ML-enabled devices. For the complete list of digital health guidances, see here and here. FDA also maintains a list of the AI/ML-enabled devices that the Agency has authorized, see here. We provide below a subset of the documents related to AI/ML-enabled devices.

FDA Guidance Documents and Other Documents

- FDA Guidance "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions"
- FDA Guidance "Clinical Decision Support Software"
- FDA Guidance "Policy for Device Software Functions and Mobile Medical Applications"
- FDA Guidance "Multiple Function Device Products: Policy and Considerations"
- FDA Guidance "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act"
- FDA Guidance "General Wellness: Policy for Low Risk Devices"
- FDA Guidance "Off-The-Shelf Software Use in Medical Devices"
- FDA Guidance "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices"
- FDA Guidance "Content of Premarket Submission for Device Software Functions"
- FDA Guidance "Deciding When to Submit a 510(k) for a Software Change to an Existing Device"
- FDA Draft Guidance "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations"

Guiding Principles and International Documents

- IMDRF/AIMD WG/N67 "Machine Learning-enabled Medical Devices: Key Terms and Definitions"
- FDA, Health Canada, and UK MHRA "Good Machine Learning Practice for Medical Device Development: Guiding Principles"
- FDA, Health Canada, and UK MHRA "Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles"
- FDA, Health Canada, and UK MHRA "Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles"