AI is a Starting Point, Not a Magic Wand

Five key considerations for harnessing the potential of AI in medtech operations

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Executive Summary

➔ **Understanding the difference between regulated device AI that's related to clinical care and operational AI is critical to drive progress on overall AI objectives.**

➔ **Medtech organizations should consider several success factors for AI including clear business objectives, appropriate risk controls to maintain compliance, a technical platform strategy, a data strategy for provisioning model data, plus the right team, partners, and governance.**

There is no shortage of hype or promise regarding artificial intelligence (AI) and machine learning (ML). In the medtech industry, this is especially true. As of October 2023, the FDA approved over 700 AI/ML-enabled medical devices.[1] All of these approvals are for products labeled as software-as-a-medical device (SaMD),[2] which have a distinct regulatory process from software in a medical device.

While the clinical care benefits of AI in medtech are clear, executives need to understand the benefits of AI in operations and approach adoption deliberately, with optimism, and with some caution. An important first step toward establishing an AI strategy that delivers value is knowing how the technology is applied for clinical and operations.

[1] FDA, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," 2023
[2] FDA, "Software as a Medical Device (SaMD)," 2018

Understanding AI in medtech clinical and operational settings

None of the 700 FDA-approved AI- and ML-enabled devices use generative AI or large language models (LLMs).[3] Instead, SaMD devices rely primarily on ML, a technology that uses large-scale statistical prediction and pattern recognition algorithms to process data sets and identify trends. We can see the reality of this pattern with the prevalence of radiology SaMDs in today's market. Radiology has a vast "corpus" of images with relatively high consistency, which lends itself to the type of analytical pattern recognition where ML excels.

On the clinical care side, AI and ML thus have the potential to transform the industry by deriving novel insights from the vast troves of data generated during healthcare delivery. For example, global healthcare technology leader Medtronic uses AI and ML to find polyps during colonoscopies, process surgical videos, and improve the accuracy of atrial fibrillation detection.[4]

Even with the success of using AI for clinical care, many medtech companies have not yet mastered leveraging AI to improve their internal processes. Device and diagnostic manufacturers often struggle to manage vast quantities of enterprise and third-party operational data across disparate systems.

While some software vendors position AI applications as cure-alls, many organizations don't have a foundation of structured data and documents to derive valuable insights from the technology. With so many differing messages, here are five questions to help determine AI and ML readiness and evaluate technologies.

[3] MedTech Dive, "5 takeaways from the FDA's updated list of cleared AI/ML medical devices," 2023
[4] MDDI Online, "Why Medtronic Is Bullish on the AI Opportunity in Medtech," 2024

1

How can the technology fit potential use cases?

Since each functional area has different opportunities and pain points, an internal assessment should distinguish between clinical and operational use cases. As a rule, patient-interacting software technology teams are separate organizations from the CIO's office. They will have their own tech stacks, tools, and clinical use case priorities based on R&D funnels that are essentially therapeutic area specific. These have a clear regulatory approval path with a growing set of SaMDs already in the market.[5]

Operational use cases are usually broader and – despite medtech companies' continued investments in data lakes – frequently struggle with data availability, interoperability, and quality. It's equally as important to evaluate the risk level of different applications. For example, given the state of LLMs, which are known to have "hallucinations,"[6] it's not appropriate to use them to create regulated content.

More fundamental (and straightforward) AI and ML models focused on pattern recognition can deliver a reasonable risk balance for tasks like document classification and metadata creation, where the risk of an error is "just" a false positive or false negative. These models – trained on high-quality, consistent data – can often produce results at over a 95% confidence level, and we can then choose sampling and verification protocols appropriate to the risk level of the task.

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Do we have high-quality data available to train AI models?

AI requires data at significant volumes to obtain insights or automate tasks. Medtech companies typically have the necessary quantities of clinical data to train AI models in key domains, such as radiology abnormality detection.

In others, like electro-physiology, the data can be more complex or require synthesizing from various sources to produce useful or novel outputs. This challenge is compounded by statutory and provider PHI requirements for handling patient data. Thus, a clear strategy to clean, aggregate, harmonize, and deidentify clinical patient data, including data from multiple sources, is crucial for creating downstream analytics and modeling to drive better clinical outcomes.

A data strategy to centralize and govern enterprise operational data in a single source of truth provides a foundation to gain value from AI applications. The process can help to streamline processes, improve quality, and foster collaboration across siloed teams. But without a consistent data model and governance in place, it will be challenging, if not impossible, for companies to leverage their operational data.

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[5] FDA, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," 2023

[6] Stanford University Human-Centered Artificial Intelligence, Hallucinating Law: Legal Mistakes with Large Language Models are Pervasive, 2024

After laying this groundwork, medtech companies can use AI to optimize tasks and workflows that are highly inefficient today. However, the typical data variability across most organizations will be a barrier to getting there.

3

Can AI reduce manual processes in operations?

In evaluating how best to drive efficiencies, it's important to assess whether digital enablement through process/software application-based automation or AI/ML is the better technology choice. For example, from a regulatory perspective, ML models could enhance internal intelligence by identifying trends across health authority interactions and suggesting responses to common questions ahead of time. Through continued use, the models improve, allowing organizations to make more proactive, informed decisions while reducing manual steps. Yet the success of the ML models depends on the level of workflow automation and on available, useful associated data assets to feed the model. Thus, foundational investments in automation—especially for technologically underserved areas like regulatory—are often an excellent starting point to reduce manual processes.

Once medtech organizations speed up and automate workflow approvals and reduce repetitive steps by connecting the right data and content to stakeholders across multiple processes and systems, there are certainly opportunities for further intelligence and AI efficiencies.

Ensuring appropriate risk controls are applied is critical given the regulatory and GxP sensitivity of product development processes. There is no direct guidance from health authorities on how to leverage AI/ML tools for operations, and the burden will be on medtech companies to ensure compliance and determine an acceptable level of risk. This suggests that for the foreseeable future, medtech organizations will need to have human review (human-in-the-loop)[7] and that the development and cost of these added controls needs to factor into the return on investment of potential AI/ML efficiencies.

[7] EMA, Quality Innovation Group (QIG), October 2023

4

What risks does AI introduce?

Adopting new technologies always carries risks, and AI is no exception. These risks are often poorly understood because of the technology's complexity and marketing hype. On the clinical side, AI may pose challenges like re-identifying individuals and increasing exposure to data breaches.[8]

The ML component of AI "trains" on data sets, so it's susceptible to inaccurate outputs based on overrepresentation or data sparsity, like the lack of healthcare data for women and minority populations. It amplifies any statistical bias inherent in the data set upon which training occurs. ML is generally good in pattern recognition, where it has large volumes of data, but notoriously bad at understanding rare or "long tail" scenarios.

Proofs-of-concept (POCs) are common for companies to test AI value propositions. This is a tried and solid approach to identify and further develop the most promising use case. Yet, industrializing these POCs into compliant, production-ready applications requires a different approach and skillset. This point in the process introduces scaling risks for operational AI.

Another area where risk can increase is complaint handling. AI can automate repetitive tasks to free up skilled clinical complaint staff for higher-value work, but a misclassified adverse event by the algorithm can be catastrophic.

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This type of risk is material, given that rare adverse events, by definition, fall into the long tail that AI and ML models are not good at classifying and predicting. This is the same data sparsity and overrepresentation risk if models train on "critical" or "well-processed" documents only, and the selection that goes into that results in a training set not representative of actual data the model must process once implemented.

[8] Thompson Reuters, Understanding the advantages and risks of AI usage in healthcare, 2023

5

How can we use AI and ML to spark further innovation?

The current state of AI is a starting point, not a magic wand. Medtech companies should be cautiously optimistic about incorporating AI into their technology strategy. We are still in the early stages, and these areas will grow significantly in the coming years.

The FDA has expressed its goal to provide the "least burdensome approach to support iterative improvement through modifications to an AI and ML-enabled device while continuing to provide a reasonable assurance of device safety and effectiveness."[9]

Together with Health Canada and the MHRA, they have defined 10 guiding principles for good ML practice. They also developed robust plans to help align regulatory processes with a streamlined change management approach for these devices[10] that allows the software to evolve and "learn" within predefined boundaries, maximizing patient benefits while containing the change control risks.

The guidance aims to foster engagement and collaboration, providing a starting point for medtech companies looking to use AI for clinical purposes. The industry is moving positively with AI and ML, but more work lies ahead. Ultimately, the advancements that AI and ML will enable can benefit patients through earlier access to innovative technologies, more accurate diagnoses, and real-time monitoring of devices.

[9] Medtech Dive, FDA drafts guidance to ease path to updates for AI-enabled devices, 2023

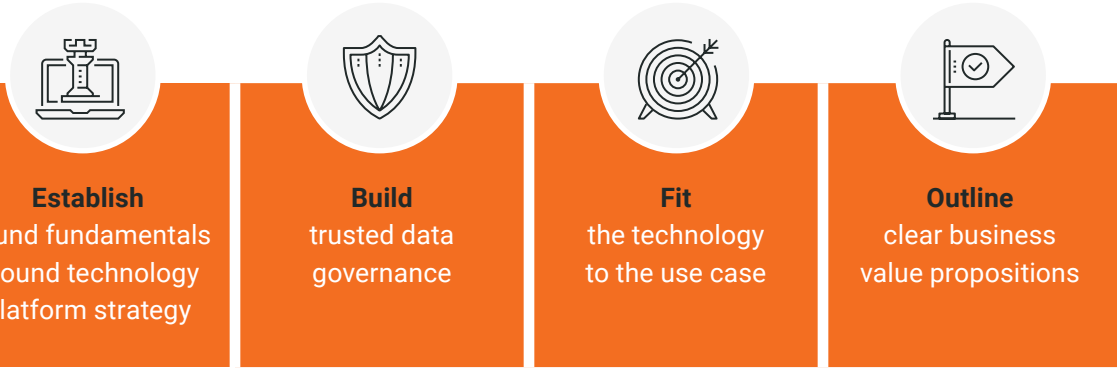
[10] FDA, Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles, 2023

Establishing a strategy for AI

The path to adopting AI and ML that incorporates appropriate, compliant controls can be complex. Start by establishing sound fundamentals with a technology platform strategy, trusted data governance, a fitting use case supported by technology, and clear business value propositions. Together, these are an excellent foundation for medtech IT and operational leaders to take advantage of the growth and cost efficiency AI can support while driving digital automation and improving teams' effectiveness.

In the end, tapping into the potential of clinical care AI and operational AI will unlock significant value and innovation for medtech companies. Before jumping into the deep end, it is critical to understand the use cases and risks associated with these applications. With answers to these five questions, medtechs can adopt AI for new ways of working that drive operational excellence.

THE RIGHT STARTING POINT



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