AI IN HEALTHCARE: PANACEA OR PIPE DREAM?

Artificial intelligence, Augmented Intelligence, Augmented Reality, and Machine Learning (collectively referred to as AI technologies) are revolutionizing the healthcare industry.

AI technologies, whether in Software as a Medical Device (SaMD) or Software in a Medical Device (SiMD), are rapidly advancing, promising enhanced patient care, improved efficiency, better outcomes, fewer adverse events, and reduced costs. For all of the potential upsides, AI technologies do not necessarily represent a panacea, or do they? Before incorporating AI technologies into your medical product some key considerations should be explored and assessed.

AI Technologies: Promises and Pitfalls

The first consideration is the technology itself. While the use of AI technologies in healthcare is not new, recent advancements in software and algorithm development platforms are accelerating the adoption of machine learning, natural language processing, and computer vision. Therefore, some pressing questions come to mind. What AI technologies might be appropriate for the intended application? What types of sensors and data acquisition elements will be needed to support the technology stacks selected? Can the targeted medical system support the compute resources and signal processing needs to support the intended use?

The next factors to consider are data training sets and model bias. Training sets are intended to be a representative cross section of the demographic groups the model will serve, and the model algorithms tend to be accurate when their application falls within the model training set. However, the reality is that a training set is biased toward the demographic groups providing the input data to be used for model training. A cardiac intervention model, for instance, is likely trained to numerous annotated data sets in which most of the data is likely to represent white males over 50 years of age. This isn't intentional bias but rather a fallout from the fact that this group had the largest representation

of the medical condition, had access to healthcare, and provided the earliest sets of data. This effect is known as model bias. Since AI models will always contain some amount of bias, especially in the early stages of model development, the consideration is to use ongoing machine learning to expand the model's knowledge and efficacy by constantly introducing new datasets to the model to improve the model's knowledge and understanding while retaining the efficacy and safety of the original model.

Another important aspect and one of the more challenging tasks of real-time learning is model validation. As the model learns and expands, how do we determine what effects the new data sets and expanded demographics have in diagnosis? What are the effects on accuracy and efficacy of the model? Is the new model as effective as the previous model? Does the new model perform as well as before with the legacy data set? Does the model perform to the expected standard with the new data sets? These questions and many others are now front and center with the FDA. Addressing these questions is also of utmost importance to our clients who are actively pursuing the integration of AI technologies into their next-generation therapies.

Regulatory

To support the evolving use of AI, the FDA released the agency's first Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. This action plan outlines a multi-pronged approach aimed at advancing the Agency's oversight of AI/ML-based medical software. Seeking input and guidance from industry subject matter experts and device manufacturers, the FDA aims to achieve several goals including:

- Developing an update to the proposed regulatory framework presented in the AI/ML-based SaMD discussion paper, including the issuance of a draft guidance on the Predetermined Change Control Plan (PCCP).

- Strengthening the FDA's encouragement of the harmonized development of good machine learning practice through additional FDA participation in collaborative communities and consensus standards development efforts.

- Supporting a patient-centered approach by continuing to host discussions on the role of transparency to users of AI/ML-based devices. Building upon the October 2020 Patient Engagement Advisory Committee (PEAC) meeting focused on patient trust in AI/ML technologies, the FDA proposes to hold a public workshop on medical device labeling to support transparency to users of AI/ML-based devices.

- Supporting regulatory science efforts on the development of methodology for the evaluation and improvement of machine learning algorithms, including for the identification and elimination of model bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions.

- Advancing real-world performance monitoring pilots in coordination with stakeholders and other FDA programs, to provide additional clarity on what a real-world evidence generation program could look like for AI/ML-based SaMD.

By collaborating with industry and researchers, the FDA desires to facilitate the development and role of AI technologies in medical products while creating a process framework that enables the industry to develop and evolve safe and effective products. The goal is that models can evolve and increase in efficacy, avoiding the need to put model updates through months and years of testing and validation before incremental improvements can be implemented for clinical use.

Conclusion

While AI technologies hold immense promise for healthcare, there are still crucial questions to address regarding their efficacy and implementation. Continual assessment of these technologies will be required to ensure that they incrementally yield the expected benefits—enhanced patient care, improved efficiency, better outcomes with fewer adverse events, and reduced costs. This is a very tall order with a diverse set of stakeholders who can all contribute to accelerating the development and role of AI technologies in medical products while ensuring the delivery of safe and effective AI-enabled products and solutions to the marketplace.

The potential of AI technologies to transform healthcare is undeniable. Nevertheless, as we have explored in this article, a multitude of essential considerations and complex challenges require careful assessment. In our next INSIGHTS article, we will delve into the value proposition of AI technologies in healthcare, exploring their impact on medtech OEMs, clinicians and patients. Stay tuned as we continue this exploration to uncover the true potential of AI technologies to revolutionize healthcare.

ABOUT THE AUTHOR

Norm Martel | *Senior Solutions Architect*

Norm is an experienced hands-on software architect with an extensive background in hardware and software components. He specializes in systems engineering, safety critical embedded systems, signal processing, wireless, and cybersecurity across the full product lifecycle.

Contact MedAcuity - info@medacuitysoftware.com

REFERENCES

1. *FDA News Release; January 21, 2021 - https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan*

ABOUT MEDACUITY

MedAcuity, a software engineering firm, partners with companies to address the business and technical challenges inherent in developing complex software-intensive solutions. Offering a combination of strategic consulting services focused on aligning product technology strategy with business goals and full lifecycle software development expertise, we accelerate the pace of innovation for leading companies and innovators in the MedTech, Life Sciences and Robotics industries. With over a decade of experience in software design and development methodologies for highly regulated and compliance-driven environments, our technical capabilities span all levels of software from embedded systems to mobile devices, the cloud and enterprise technologies. Contact us at **medacuitysoftware.com**