As artificial intelligence (AI) continues to expand into various aspects of our lives, from social media to computational data analysis, it comes to no surprise the capabilities these algorithms and models can impact the healthcare industry, such as medical devices. And at PQE, we believe that the future of healthcare is connected medicine. The potential for integrated pharmaceutical/biotech products and medical devices is infinite.

As of January 2023, the FDA has approved over 520 artificial intelligence (AI) and machine learning (ML) algorithms for medical use. Most of these are related to medical imaging and healthcare image and video analyses and diagnoses, so in the majority of use cases, these are computer vision (CV) models. Connected medicine examples include innovations such as knee implants that connect to a phone to track pH and degradation that can notify the patient or doctor of a possible infection or complication. Other examples are heart valves that can provide diagnostic feedback to a doctor that could help optimize pharmacological treatment or a chip implanted under the skin that could report if a cancer patient in remission is showing diagnostic signs that cancer may have returned. Or daily monitoring of the activity of multiple sclerosis patients for earlier detection of MS attacks, and the investigation of skin appearance features with image analysis algorithms to provide continuous, non-invasive blood pressure monitoring.

A common thread between the aforementioned medical devices is that they would be highly dependent on appropriate software and IT communication and could potentially benefit from increased efficiency and capacity that AI and ML bring to the industry. Capitalizing on available resources and opportunities for improvement that AI can offer is critical, especially in a time where the demand for healthcare services is ever increasing and many countries are experiencing a shortage of healthcare providers [1].

For these reasons, it is critical to understand evolving perspectives provided from various international communities and organizations to understand and implement best practices moving forward, as we integrate complex computer systems into healthcare. For instance, the FDA has issued Guiding Principles for Good Machine Learning Practice for Medical Device Development [2], as well as Change Control Plans for Machine Learning-Enabled Medical Devices [3] to provide insight to the development and life cycle process for these integrated devices. The FDA has even gone as far as issuing an “Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device” Action Plan [4] to outline five actions intended to be taken from the FDA, helping outline how the Agency intends to consider the regulation of AI and ML Medical Devices.
Furthermore, US President Biden has issued an Executive Order (EO) On the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence [5] to further strengthen the power of relevant departments to ensure appropriate measures are considered and taken when implementing AI. In this Executive Order, a commonly identified concern surrounds privacy and the ethics that follow the use of a less human-centered approach to the development and life cycle of the devices.

It is equally as important to consider the ethical implications of utilizing these expansive AI and ML capabilities. An article from the University of Rochester explains that “AI medical devices could also harm patients and worsen health inequities if they are not designed, tested, and used with care” [6]. Incorporating a strong sense of transparency about the accuracy and limits of AI, as well as ensuring that everyone has access to these AI advancements is a good step forward ensuring that the negative possibilities of this technology do not become the norm.

With the vast possibilities that continue to become reality thanks to the help of AI and ML progressions in science, it is important to understand the full ramifications of such technology. Moving healthcare forward in a positive direction is completely possible with the tools provided from these advancements, but checks and balances must be carefully maintained to ensure an equitable approach for all of healthcare.

References:


[6] Keeping a Human in the Loop: Managing the Ethics of AI in Medicine, 2023