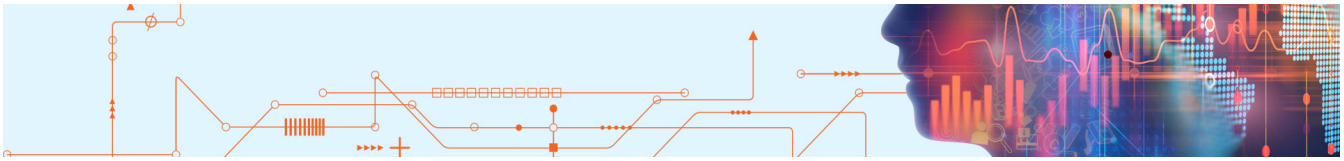

Regulating Artificial Intelligence in Medical Devices: A Global Perspective

November 5, 2021

By Tony Orsi and Nicole LaBerge

Artificial intelligence (AI)-based medical devices are revolutionizing healthcare across the globe. From increasing diagnosis accuracy, to improving hospital workflow, to early disease detection, AI and machine learning (ML) are transforming healthcare practice by interpreting vast amounts of data on a daily basis. Despite these improvements to healthcare delivery, the regulation of AI-based medical devices is still in its developmental stages.

The innovation in this space is also reflected in the number of issued patents and patent filings. A recent GlobalData report on global trends in AI-based medical devices found that in the last five years, the number of issued patents has increased over 200% and the number of filed patent applications has increased over 300%.[1] Leading countries include the United States and China who have together filed over 18,000 patent applications between 2011 and 2020. The United Kingdom and Germany have filed approximately 500 applications, while Canada was reported to have filed roughly 600 applications during this time[1] The Canadian Intellectual Property Office (CIPO) has also reported that Canadian researchers fare well against Americans in various applications of AI including medical based technologies. [2]

Despite the rapid innovation in AI-based medical devices, current medical device regulatory pathways such as those pertaining to software as a medical device (SaMD) do not account for technologies that change in real-time as is the case with some software-based medical devices that utilize AI. Thus, many countries have begun developing new regulatory protocols that account for highly iterative, autonomous, and adaptive technologies to ensure effectiveness and patient safety. Since such technologies are novel, there is a need for countries around the world to revamp their medical device regulatory approval processes to account for AI-based medical devices.

Regulation of AI-based medical devices in the United States

For instance, in the United States, manufacturers of medical devices that utilize AI or ML algorithms must obtain premarket clearance (510(k)),[3] a De Novo classification,[4] and premarket approval[5] through the Food and Drug Administration (FDA). Premarket clearance is granted when the algorithm has been shown to be at least as safe and effective as another similar, legally marketed algorithm. Obtaining a De Novo classification involves assessing the device's risk before it is marketed and obtaining premarket approval clearance requires scientific evidence to support the device's effectiveness.

However, the current US regulatory framework does not account for AI/ML algorithms that are "unlocked" or "adaptive", since some of these algorithms can change with new data. To address this issue, in 2019 the FDA released a proposed regulatory framework [6] for AI and ML based SaMD products outlining a potential approach for premarket review of AI- and ML-driven real-time software modifications. The proposed framework outlines a "predetermined change control plan" that anticipates different types of modifications termed "Software as a Medical Device Pre-Specifications" and the associated methods used to implement those changes in a controlled manner which are referred to as "Algorithm Change Protocols". Following public consultation on the proposed framework, the FDA has since released its first AI/ML-Based SaMD Action Plan[7] that outlines a holistic approach based on total product lifecycle oversight to further the beneficial impact these technologies can have on patient care while delivering safe and effective software functionality.

In light of the recently released action plan, it is expected that manufacturers seeking approval will have to commit to transparency and real-world performance monitoring of their AI/ML SaMD products. These manufacturers will also have to provide the FDA with routine updates on software changes as part of the pre-specifications and algorithm change protocols.

Regulation of AI-based medical devices in Europe

Regulation of AI-based medical devices in Europe is also in its developmental stages. The European Commission recently published proposed harmonized rules[8] on commercialized AI devices that states that high-risk AI systems, such as those used in some medical devices, should only be released in the EU market "if they comply with certain mandatory requirements" that ensure they do not pose unacceptable risks to the public. The proposal is largely based on feedback gathered on the European Commission's White Paper on AI that was released in February 2020. There, the European Commission proposed that high-risk AI applications undergo a conformity assessment for approval. [9]

The conformity assessment proposed by the European Commission involves a total product lifestyle approach involving a pre-market assessment along with on-going reviews in which manufacturers would be expected to meet several legal requirements. Firstly, data used to train the AI-based medical device must be broad and representative of all relevant scenarios to avoid dangerous situations. Secondly, manufacturers must also accurately record data used to train, build, test, and validate the AI-based medical device. Thirdly, with regard to transparency, manufacturers would be required to provide information on the AI-based medical device's capabilities, limitations, and purposes for its intended use along with conditions under which it should function and expected levels of accuracy. Fourthly, manufacturers would be required to show that the AI-based medical device system is robust, accurate, and is able to be correct errors and inconsistencies at all phases of the life cycle. Lastly, manufacturers must ensure their AI-based medical device system has an appropriate level of human oversight.

The European commission envisions that the AI conformity assessment will be added to current pre-market conformity assessment requirements. Under the proposed guidelines, those who fail to comply could face fines up to €30 million, or if the offender is a company, 6% of its total worldwide annual turnover.

Regulation of AI-based medical devices in China

China is also extremely active in AI-based medical devices. The Centre for Medical Device Evaluation (CMDE) of the National Medical Products Administration (NMPA) has established an AI working group to evaluate performance and safety of upcoming medical devices.[10] The CMDE is also planning to implement technical review guidelines for AI medical devices sometime this year. These guidelines will likely build upon the NMPA's Technical Guidelines on AI-Aided Software. [11] Under these guidelines, Chinese regulators evaluate AI-based medical devices on how the software controls data and the ability of the system's algorithms to generalize (i.e., this involves evaluating how well an algorithm makes predications based on inputted data). The guidelines, also consider associated clinical risks of late or missed diagnoses. Chinese Regulators also consider algorithm selection, training, and performance, as well as routinely re-assess algorithm-driven software updates to ensure safety. To obtain approval, manufacturers must submit clinical data representative of the Chinese population to show that the software used by the AI-based medical device is safe for use in China. Manufacturers that cannot ensure safety and efficacy must conduct clinical trials in China to obtain regulatory approval.

Regulation of AI-based medical devices in Canada

Presently, Canada does not have a proposed regulatory framework covering AI-based medical devices. However, in late 2019, Health Canada created the Medical Device Directorate in response to the increasing number of regulatory issues with medical devices.[12] The Directorate consists of six offices and bureaus whose activities focus on evaluating medical device effectiveness and quality, assessing benefits and risks of medical devices, as well as monitoring evolving safety of medical devices in development.[13] Based on the Medical Device Directorate, those seeking approval of AI-based medical devices in Canada are subject to current medical device approval protocols and should be prepared to provide additional data in support of their device's efficacy and safety similar to the requirements proposed by Europe and the United States. However, recently Health Canada along with the US FDA and the UK's Medicines and Healthcare products Regulatory Agency, have proposed some guiding principles for the development of safe, effective and high-quality medical devices that use AI[14].

Conclusion

AI-based medical devices are being developed at an increasing rate transforming healthcare as we know it. Countries around the world are also rapidly adapting their regulatory pathways to

keep up with AI-based medical device development. As such, manufacturers of AI-based based medical devices, should familiarize themselves with the regulatory protocols in the various jurisdictions in which they intend to commercialize in order to ensure that their AI-based medical devices do not get held back by red tape.

For more information, or if you have questions about protecting and obtaining regulatory protection for an AI-Based Medical Devices, please feel free to contact our medical device[15], artificial intelligence[16], or regulatory practice groups[17].

---

[1] https://www.medicaldevice-network.com/wp-content/uploads/sites/11/2021/07/MedicalAIPatentsMay2021.pdf

[2] https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr04776.html

[3] https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

[4] https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request

[5] https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

[6] https://www.fda.gov/media/122535/download

[7] https://www.fda.gov/media/145022/download

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623335154975&uri=CELEX%3A52021PC0206

[9] https://ec.europa.eu/info/sites/default/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf

[10] http://english.nmpa.gov.cn/NMPAorganizations.html

[11] https://chinameddevice.com/china-nmpa-cfda-ai-software/

[12] https://www.regdesk.co/health-canada-creates-the-medical-device-directorate/

[13] https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/medical-devices-directorate.html#_Bureau_of_Medical

[14] https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/good-machine-learning-practice-medical-device-development.html

[15] https://www.bereskinparr.com/practicearea/medical-devices

[16] https://www.bereskinparr.com/practicearea/artificial-intelligence-ai

[17] https://www.bereskinparr.com/practicearea/regulatory-advertising-marketing

Content shared on Bereskin & Parr's website is for information purposes only. It should not be taken as legal or professional advice. To obtain such advice, please contact a Bereskin & Parr LLP professional. We will be pleased to help you.