Artificial Intelligence Software as a Medical Device: Regulatory Approvals and Post-Deployment Evaluation Frameworks in North America and Europe

Zaim R[1], Ramos IC[2], Thielen FW[3], Shaw JA[4]

[1]University of Toronto, Dalla Lana School of Public Health, Toronto, ON, Canada, [2]Erasmus University Rotterdam, Institute for Medical Technology Assessment, Rotterdam, Netherlands, [3]Erasmus University Rotterdam, Erasmus School of Health Policy & Management, Rotterdam, Netherlands, [4]University of Toronto, Temerty Faculty of Medicine, Toronto, ON, Canada.

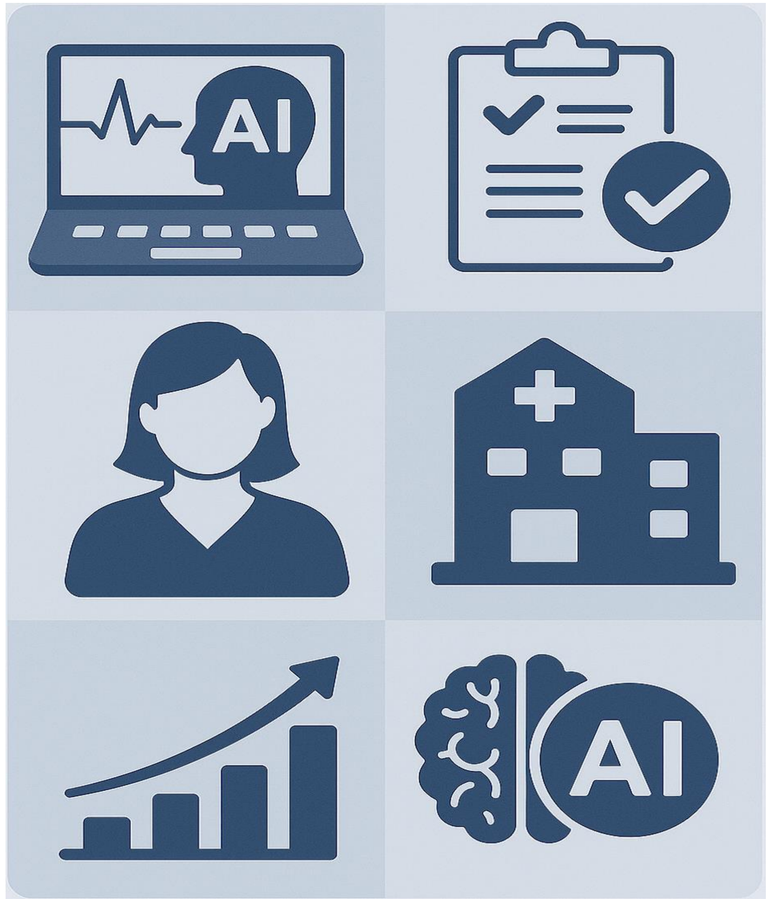
Objectives

Artificial Intelligence (AI) software classified as a medical device (SaMD) is governed by regulatory agencies globally. This study aims to compare the regulatory approvals of SaMDs across North America and Europe and explore Health Technology Assessment (HTA) frameworks related to the post-deployment evaluation of SaMDs within healthcare systems.

Methods

We searched SaMD regulatory approvals using databases from the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the United Kingdom (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA). We then examined HTA guidance from the U.K. National Institute for Health and Care Excellence (NICE) and Canada's Drug Agency (CDA) databases, specifically for the SaMD classification.

Results



**AI assisted technologies were used in the creation of this schematic diagram.*

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Conclusions

This study examines the regulation of AI-enabled medical devices in North America and Europe, focusing on SaMDs. It underscores the need for publicly accessible registries of regulated AI-enabled medical devices and adaptive HTA frameworks to guide continuous monitoring and ethical governance of AI for responsible integration into health systems.

The FDA's Digital Health Center of Excellence authorized a total of 1016 SaMDs. The most common medical specialties were radiology (777 [76.48%]), cardiovascular use (104 [10.24%]), and neurology (42 [4.13%]). Unlike the FDA's searchable database, the MHRA, Health Canada, and the EMA do not maintain a publicly accessible registry dedicated to approved SaMDs. While the MHRA, FDA, and Health Canada have jointly established guiding principles for the transparency of AI-enabled devices, EU regulations require manufacturers to undergo a conformity assessment process to demonstrate that their devices meet safety and performance requirements. Final approval and CE ("Conformite Europeenne") markings are granted by Notified Bodies—independent organizations designated by EU member states—not by the EMA. HTA frameworks from the NICE and CDA do not yet provide specific guidance on the post-deployment evaluation processes of SaMDs.