UK, USA and Canadian regulators identify 10 guiding principles to be addressed when medical devices use AI or machine learning software

News story

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Through international regulatory collaboration we have identified and co-published 10 guiding principles that should be addressed when medical devices use artificial intelligence or machine learning software. These principles are intended to lay the foundation for developing good machine learning practices (GMLP) and will help guide future growth in this rapidly progressing field.

They cover key elements of GMLP, for example: having an in-depth understanding of a model's intended integration into clinical workflow, and the desired benefits and associated patient risks as well as selecting and maintaining training and datasets to be appropriately independent of each other. We envision these guiding principles may be used to:

- adopt good practices that have been proven in other sectors
- tailor practices from other sectors so they are applicable to medical technology and the health care sector
- create new practices specific for medical technology and the health care sector

These guiding principles further identify areas where the International Medical Device Regulators Forum (IMDRF), international standards organizations and other collaborative bodies could work together to advance GMLP. Areas of collaboration include research; creating educational tools and resources; regulatory policies and regulatory guidelines; international

harmonization; and consensus standards.

We know that strong international partnerships will be essential part of empowering the wider sector to advance responsible innovations. We look forward to our continued collaborative work and engagement with the FDA and Health Canada and wider international health partners in this area.

Read the 10 guiding principles in full.

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