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Regulatory challenges of AI products
A pre-market perspective

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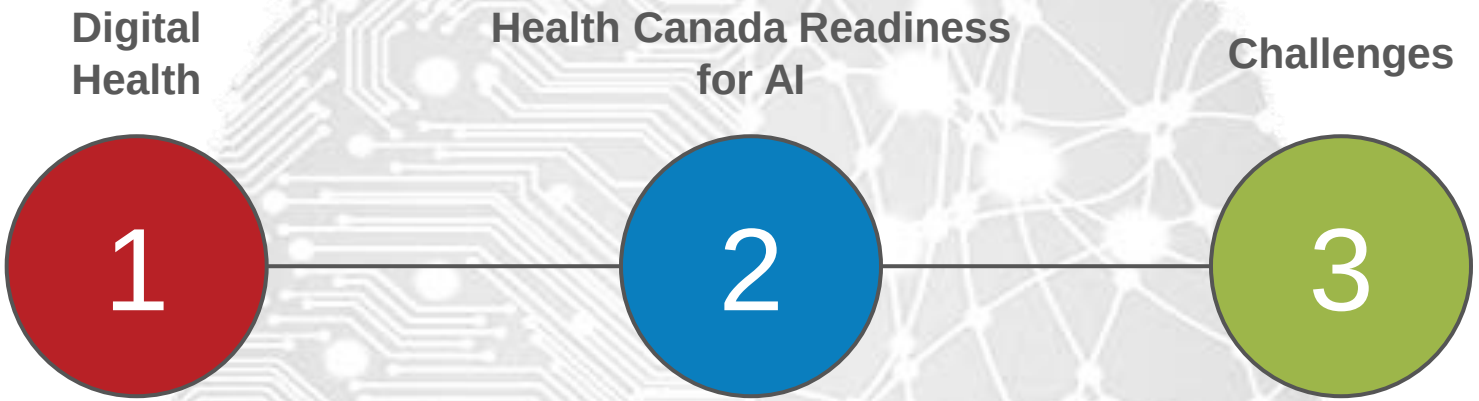
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Agenda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Digital Health

Digital Health Division - Objectives

Digital Health is intended to:

- Make health information more accessible
- Improve and facilitate more timely diagnosis
- Provide access to care for patients at home, at other health care facilities, and in rural and remote communities

OBJECTIVE: To advance and adapt regulatory approach to respond to system needs by:

- Building expert review capacity in Digital Health
- Developing a targeted review process for large volumes of digital health products (e.g., wireless medical devices, mobile medical apps, telemedicine, software as a medical device, etc.)
- Being better positioned for regulating innovative technologies (e.g. AI)
- Engaging with internal and external stakeholders to map challenges and opportunities
- Continue to be a key international player in regulating digital health devices

Newly Created Digital Health Division

Established on March 28, 2018

Priorities

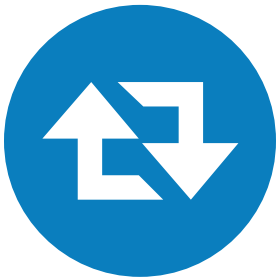
- Build a workforce of reviewers (pre-market) in the digital health field, including engineers
- Develop work tools and guidance documents
- Engage with stakeholders to better understand trends and needs, and identify areas for collaboration

Current Activities

- In addition to > 250 Class III and Class IV applications…

Cybersecurity

- Guidance Finalization
- Co-chair IMDRF WG with FDA
- Collaboration with NRC and Canadian Centre for Cybersecurity
- Participation in cybersecurity standards development



AI / Machine Learning

- Training
- Scientific Advisory Committee: May 9
- Best Brains Exchange on AI
- Continue to review devices that employ machine learning

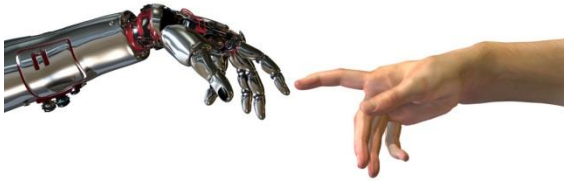
Software

- Guidance Finalization
- Continued classification on SaMD
- Continue to develop a targeted review process

3D Printing

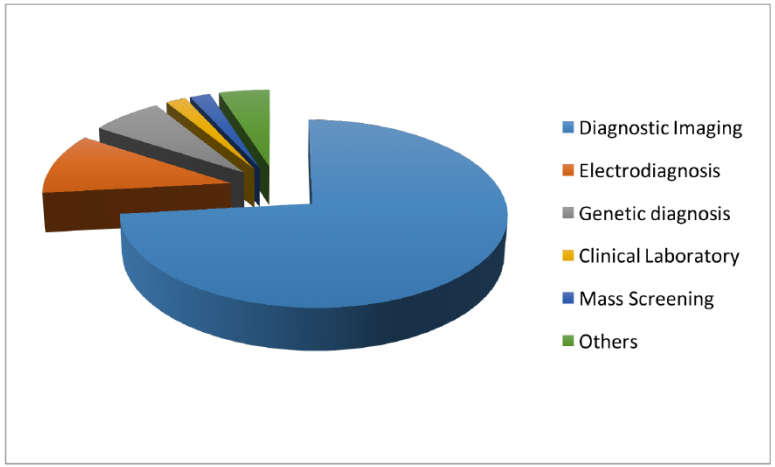
- Guidance Finalization
- Participating in regulatory review activities on point-of-care manufacturing
- Participating in policy development on software for 3D printing

Health Canada Readiness for AI



Emergence of Machine Learning in Devices

- Health Canada is seeing the emergence of machine learning predominantly in image-based healthcare applications (e.g. diagnostic imaging/radiology)
- Several licences already issued that employ machine learning



Digital Health Expertise

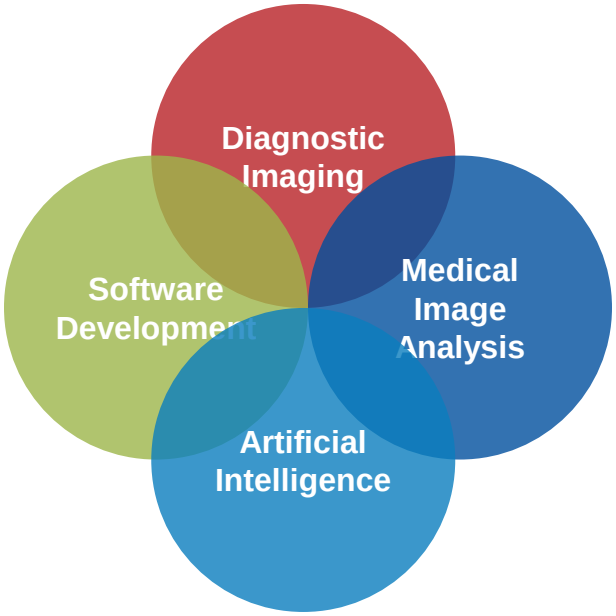


Figure 11 The data sources for deep learning. The data are generated through searching deep learning in combination with the diagnosis techniques on PubMed.

Jiang F, Jiang Y, Zhi H, *et al*. Artificial intelligence in healthcare: past, present and future. *Stroke and Vascular Neurology* 2017;2: e000101.

Readiness for AI

Health Canada is well-positioned to deepen its support of AI advancements in digital health by:

1. Building in-house Expertise

- Digital Health Division with a specialized training plan for AI for existing staff.

2. Deepening Dialogue with Industry & Key External Experts

- HC stakeholder engagement (national/international government, industry, etc.)
- Canadian Institutes of Health Research / Health Canada co-hosted BBE (*Best Brains Exchange*) on AI and Machine Learning in Medical Devices.
- A *Scientific Advisory Committee on Digital Health Technologies (SAC-DHT)* has been convened. Future meeting to seek input on the regulatory approach to AI and Machine Learning (May 9, 2019)

3. Modernizing Medical Device Software Authorizations

- Software as a Medical Device Guidance Document
- Considering drafting Guidance Document for medical devices that use AI
- The inclusion of web-based/cloud-based software products under the term “sale”.
- The potential for new regulatory models (new classification rules, establishment oversight vs product oversight) that are more conducive to software products and their lifecycle.

4. Continue to Review Devices that use AI to get more experience

Regulatory Challenges with Artificial Intelligence and Machine Learning

Challenges - Introduction

- Artificial intelligence has the potential to revolutionize the health care sector, including advancements in diagnosis, disease onset prediction, prognosis, and more
- There is currently no established regulatory framework for AI in medical devices
  - Require further experience to develop manageable framework
  - Currently managing AI submissions on a case-by-case basis
- Health Canada is faced with several challenges for developing a regulatory framework to regulate AI devices

Challenges

FOSTERING INNOVATION

- How do we balance safety and effectiveness while facilitating market access to innovative products?

EFFECTIVE REGULATION

- What are the requirements for the manufacturer to get pre-market authorization?
- Do we regulate manufacturer's process instead of the product itself?

TRAINING DATA

- How reliable and representative is the training data?
  - Representative patient population, multi-centre, disease prevalence, accuracy, data curation, simulated data, data imputation, etc.

Challenges

VERIFICIATION AND VALIDATION

- How can the AI algorithms be assured to be generalizable and transferable?
- What are the best verification/validation approaches to ensure algorithms generate correct and predictable results?
- Do we recommended third-party verification/validation?

PERFORMANCE METRICS

- What are the ideal performance metrics to assess performance of an AI algorithm?
  - Receiver operator characteristics may not be accurate predictors of algorithm performance

INTEROPERABILITY

- How can we ensure that AI is integrated appropriately into the end user environment without any unintended consequences?

Challenges

CONTINUOUS/ ACTIVE LEARNING

- How do we approach continuous learning algorithms where results can vary in time and between institutions?

POST-MARKET

- How can we develop an effective post-market regulation framework?
- What are the key elements for post-market?

RESPONSIBILITY

- Who is accountable for mistakes made by the software?

Challenges

STANDARDS

- No current standards for regulation of medical devices that use AI algorithms. How do we proceed without standards?

ETHICS

- Do underlying ethics concerns impact the effective regulation of medical devices in terms of safety and effectiveness?

Conclusion

Conclusion

- AI will likely become a standard technology in medical devices in the future
  - There are already some licensed products in Canada that use AI
- Health Canada is well-situated to deal with the emerging technology
- Health Canada has several planned activities to address the new technology to overcome the potential challenges
  - Engage with stakeholders
  - Develop more in-house expertise through training and experience
  - Consider developing a guidance document for industry to help communicate our expectations for pre-market submissions of devices that employ AI
  - Consider adapting our regulatory framework for the regulation of AI-enabled medical devices