Health Canada Santé Canada

Canada

Health Canada's Digital Health Division: A Year in Review and Future Directions

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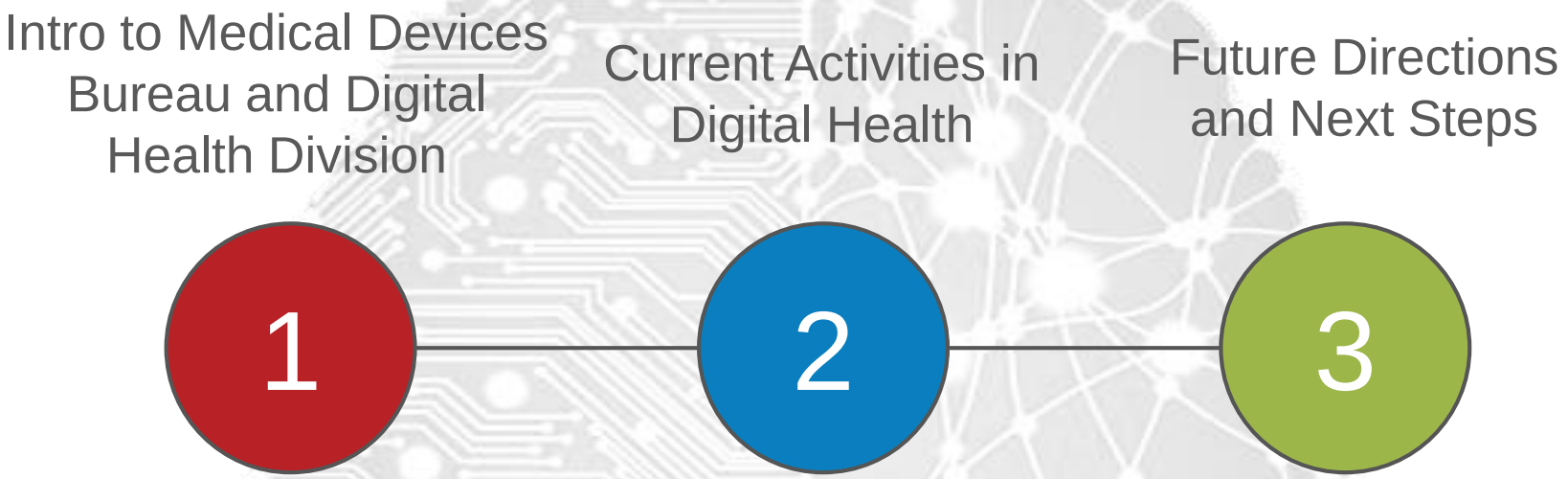
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Agenda


Intro to Medical Devices Bureau and Digital Health Division
Current Activities in Digital Health
Future Directions and Next Steps
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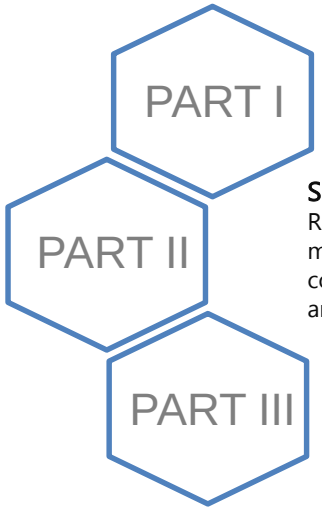
REGULATING MEDICAL DEVICES

Ensuring the safety, quality, and effectiveness of medical devices in Canada

MEDICAL DEVICES REGULATIONS (MDR)

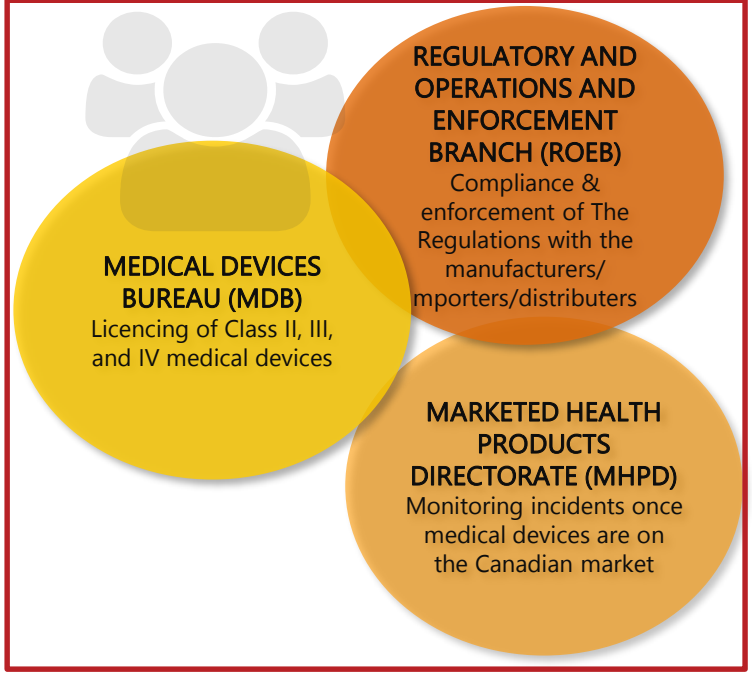


LICENSING
Requirements to meet Canadian safety and effectiveness requirements

SPECIAL ACCESS
Requirements to access to custom-made devices or unlicensed devices if conventional therapies have failed or are unavailable/ unsuitable

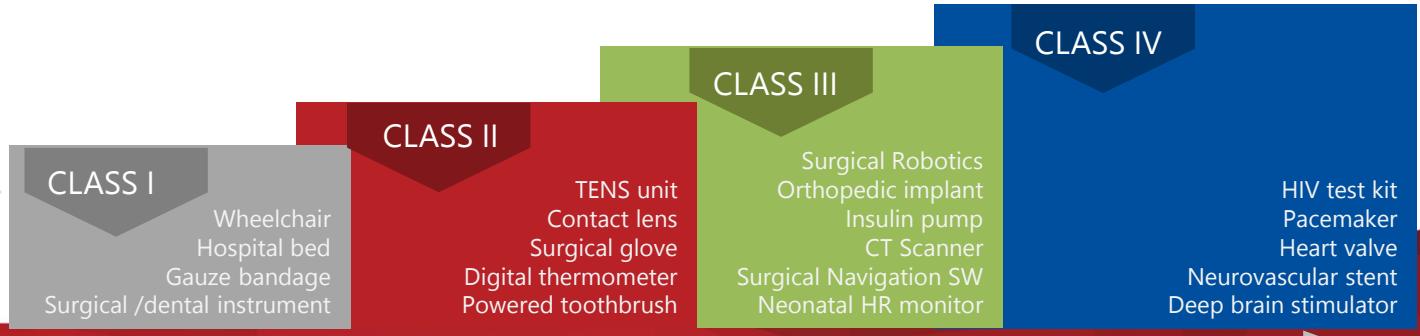
INVESTIGATIONAL TESTING
Requirements to access a device for clinical trials involving human subjects

MEDICAL DEVICE PROGRAM



RISK-BASED MEDICAL DEVICES CLASSIFICATION

Classification Indicators
Duration of contact • Potential for transmission of infection • Impact of results on the person/public • Invasiveness • Importance of information for diagnosis • Energy exposure • etc.



Digital Health - Resources and Objectives

RESOURCES

For the Digital Health project only: $4.6 M over five years (2017-2022)

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

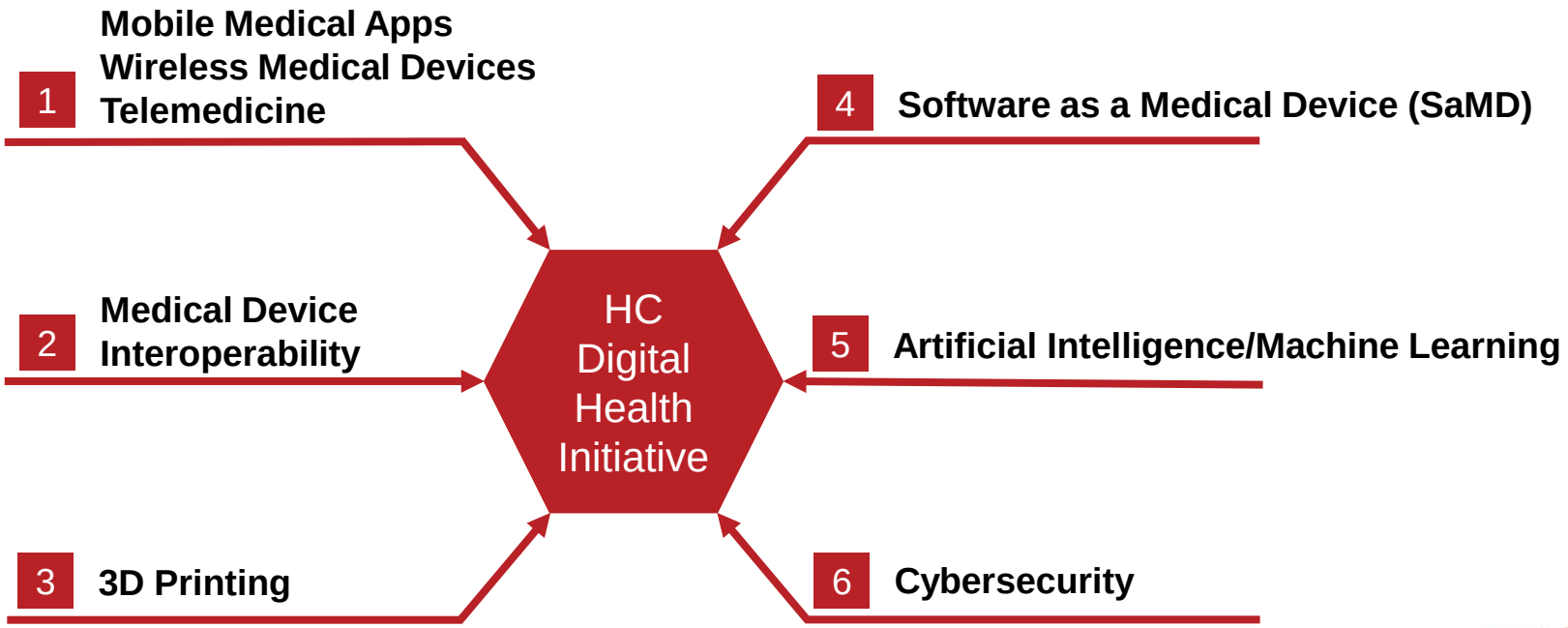
- Building expert review capacity in Digital Health
- Developing a targeted review process for large volumes of digital health products
- Being better positioned for innovative and disruptive technologies (e.g. AI)
- Aligning and engaging with other regulatory agencies, HTAs, and other stakeholders
- Continue to be a key international player in regulating digital health devices

Digital Health-enabled Medical Devices

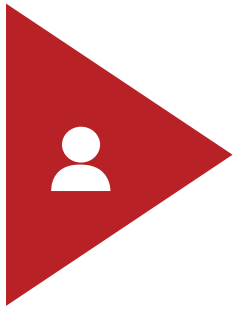
Digital Health is intended to:

- 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

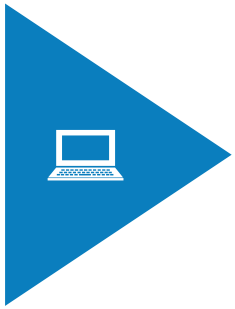
Key areas of focus:



Digital Health: A year in review…



Recruitment and Training



Stakeholder Engagement

Work Tools and Guidance Documents

Notables from the last 12 months…

Workload

- Over 250 Class III and Class IV applications completed primarily in diagnostic imaging, radiotherapy, and cosmetic devices

Key Engagements

- Scientific Advisory Committee – Cyber
- Best Brains Exchange – AI
- Scientific Advisory Committee - AI

Support

- Supported classification, review, industry meetings, and investigational testing activities in software, cybersecurity, and AI

Guidance Documents

- Involved in 4 guidance documents

Current Activities

Cybersecurity

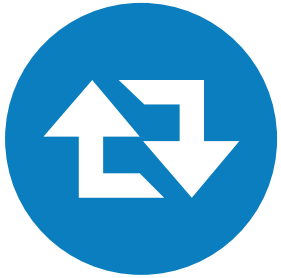
- Guidance Finalization
- Co-chair IMDRF WG with FDA
- Collaboration with NRC and Canadian Centre for Cybersecurity
- Participation in cybersecurity standards development

3D Printing

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

Software

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

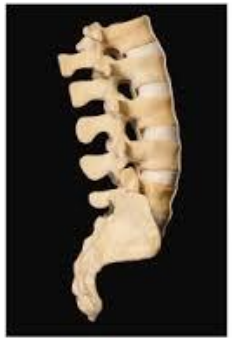


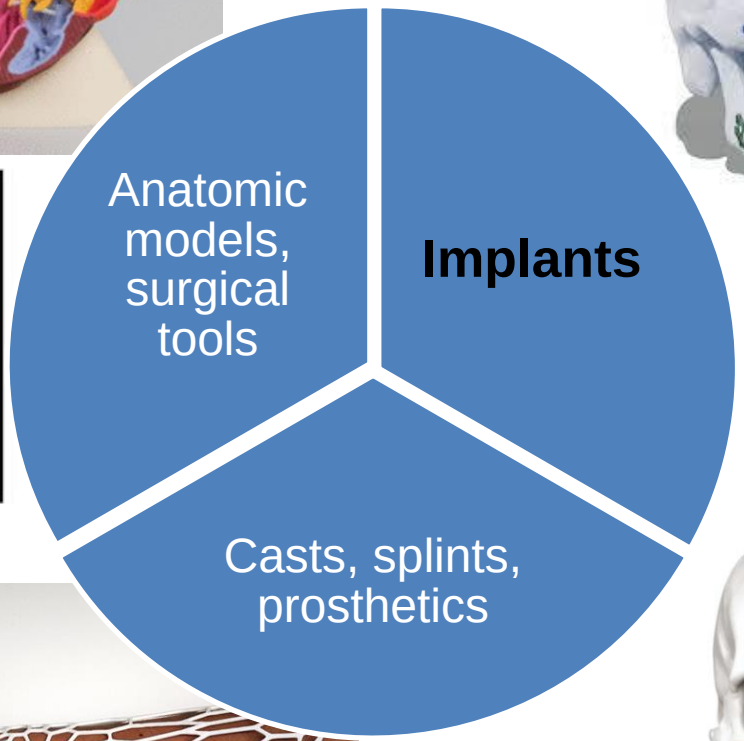
AI / Machine Learning

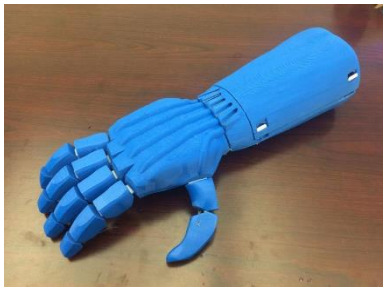
- Training
- Scientific Advisory Committee: May 9
- Generating Report from Best Brains Exchange
- Continue to review devices that employ machine learning

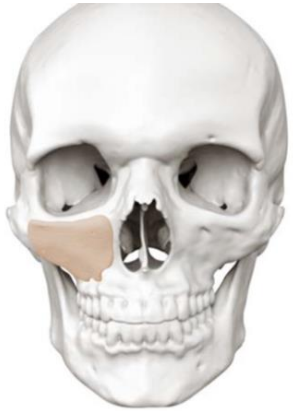
3D PRINTING

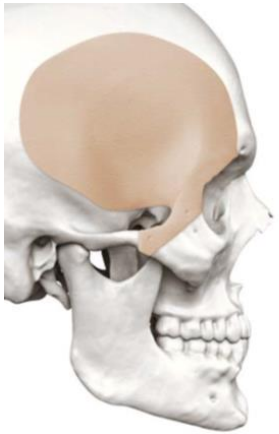
Medical Applications of 3D Printing











3D Printing Guidance Document: Timeline

AUGUST 2018 → **FALL 2018** → **APRIL 2019**

Publication of the online notice for 3D Printing

Final publication of guidance document posted

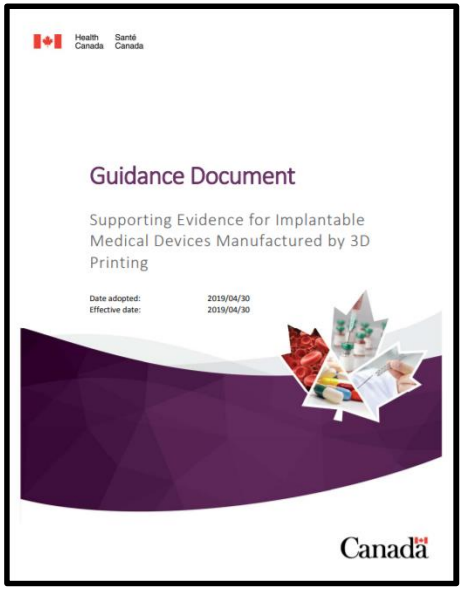
Notice: Upcoming Guidance Development on the Licensing Requirements for 3D-Printed Devices

August 28, 2018

Our file number: 18-110417-534

Health Canada is pleased to announce that it is currently developing a draft guidance document to assist medical device manufacturers seeking to license 3D-printed devices.

Draft publication of guidance document posted for comment



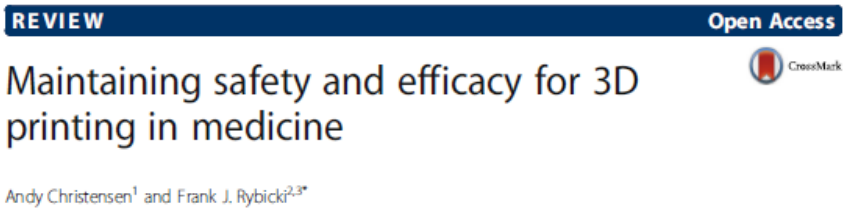
3D Printing Guidance Document: Key Messages

- The document provides guidance for manufacturers regarding specific evidence required to support pre-market Class III and Class IV licence applications for implantable medical devices manufactured by 3D printing processes.

- Considerations related to the design and manufacturing process, material controls, device testing, and labelling of 3D printed devices are included in this document, including considerations for patient-matched devices.

- This document does not provide guidance on standalone software, custom-made devices, anatomical models or products made through bio-printing which incorporate viable living cells.

Regulation of Software?


REVIEW Open Access

Maintaining safety and efficacy for 3D printing in medicine

Andy Christensen[1] and Frank J. Rybicki[2,3*]

- *"The authors recognize an important shift towards point-of-care manufacturing for medical models in a hospital environment."*

Anatomical Models	Model printed from anatomical images
Modified Anatomical Models	Digitally modified model of anatomy for enhanced surgical planning
Virtual Surgical Planning	Use of models and templates during surgery

Opportunity

To further develop positions on:

- Anatomical Models
- Software used in 3D Printing
- Point-of-Care manufacturing in these cases of anatomical models

SOFTWARE

SaMD Challenges

Only a small percentage of software products used in the healthcare industry are medical devices. Software developers are uncertain whether their products are subject to Canada's Medical Devices Regulations (MDR)

The device risk classification system in the MDR does not clearly define how software is categorized.

Health Canada must protect Canadians from unsafe software while creating an environment that fosters innovation.

Solution: Draft SaMD Guidance Document

The US FDA developed certain criteria to exclude certain device functions from the medical device definition and these criteria are referenced in the Health Canada document.

Harmonized

The guidance leverages US FDA & IMDRF software categorization principles.

The IMDRF established software labelling expectations and software risk categorization factors.

The same criteria are used in the SaMD Guidance to assist stakeholders in determining whether their SaMD is Class I, II, III or IV.

FDA

Health Canada

IMDRF

SaMD Guidance: A foundation for further work

It is Health Canada's intention is to use the SaMD Guidance as an interim policy while appropriate legislative and regulatory amendments are developed to address:

Software as Service

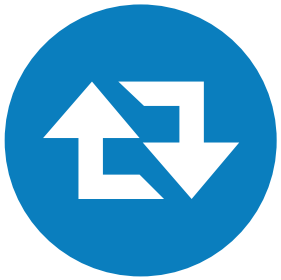
The document remains mainly silent on this complex issue

Classification Rules

Current classification rules are not well designed for SaMD

1. The inclusion of web-based/cloud-based software products under the term "sale",

2. The potential for new regulatory models (new classification rules, establishment oversight vs product oversight) that are more conducive to software products and their lifecycle.



ARTIFICIAL INTELLIGENCE / MACHINE LEARNING

Machine Learning – Challenges

- Artificial intelligence has the potential to revolutionize the health care sector, including advancements in diagnosis, disease onset prediction, prognosis, and more.

FOSTERING INNOVATION

- How to 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?
- What does effective post-market regulation look like?

TRAINING DATA / BIAS

- How reliable and representative is the training data?

Challenges

VERIFICIATION AND VALIDATION

- What are the best testing approaches for these software products?

PERFORMANCE METRICS

- What are the ideal performance metrics to assess performance of an AI algorithm?
- How can algorithms be shown to be generalizable between populations?

INTEROPERABILITY

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

Challenges

CONTINUOUS LEARNING

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

ETHICS

- Do underlying ethics concerns impact the regulation of these medical devices?

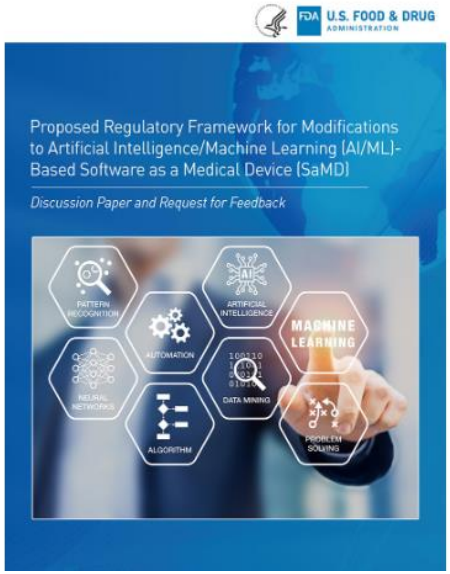
STANDARDS

- There are no current standards for regulation of medical devices that use AI algorithms.

International Context

- United States

  - The FDA's Digital Health Innovation Action Plan outlines a new regulatory framework for the safe and effective regulation of rapidly advancing digital products.
  - FDA's 2018 *Software Precertification (Pre-Cert) Pilot Program* aims to investigate the idea of regulating the manufacturer and their organizational excellence, rather than the product itself
  - Discussion Paper: *Proposed Regulatory Framework for Modifications to AI/ML-Based Software as a Medical Device (SaMD)*



- European Union

  - New regulations come into effect on May 26, 2020, that will broaden the scope of the regulatory oversight of AI products.
  - The regulations address the issue of software as medical devices, including software that provides "prediction and prognosis" capabilities.

Regulatory Readiness for AI/ML

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

1. Building in-house Expertise

2. Deepening Dialogue with Industry & Key External Experts

3. Modernizing Medical Device Software Authorizations

Current Challenges in Digital Health

DISTRIBUTION METHOD

The definition of “sale” hinders Health Canada’s oversight in cloud-based software products.

CLASSIFICATION

Existing classification rules for SaMD are outdated and are increasingly not able to adequately classify novel SaMD.

PACE OF INNOVATION

SaMD are developed and updated at a rate inconsistent with the current regulatory process for traditional medical devices.

NEW REGULATORY CHALLENGES

Machine learning algorithms present new regulatory challenges (training sets, continuous learning, etc.)

Future Directions and Next Steps

Cybersecurity: Post-market

Leveraging the IMDRF WG and consultation, Digital Health is poised to actively participate in guidance development in the post-market space

Business Process Improvements

Continue to develop a targeted review process to be able to dynamically shift technical review focus to where it is needed and contribute technical expertise to agile regulatory models.

3D Printing

Contribute to policy positions on anatomical models and software used for 3D Printing

Machine Learning

Develop initial notice or guidance to industry of Health Canada's requirements for pre-market submissions

Goal

Continue to make **sound, evidence-based** decisions that benefit all Canadians by fostering and facilitating innovative products onto the market while maintaining our already **high standard** for quality, safety, and effectiveness.