



**IMDRF**

International Medical  
Device Regulators Forum

# **Regulatory and Policy Updates**

## **Medical Devices Directorate**

### **Health Canada**

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**Director General**



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## Overview

- COVID-19
- Regulatory Consultations
- Guidances



## COVID-19

- The *Interim Order No. 2 Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19* was signed on March 1, 2021
- HC is developing transitional regulations that will migrate IO authorizations to medical device licences



## COVID-19

- The *Interim Order No. 2 Respecting the Clinical Trials For Medical Devices and Drugs Relating to COVID-19* was signed on May 3, 2021
- HC is working on transitional regulations that will migrate IO authorized clinical trials to our standard frameworks



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## COVID-19

- As of August 26, Health Canada has issued Interim Order authorizations for 78 testing devices and 640 non-testing devices



## Open Consultations

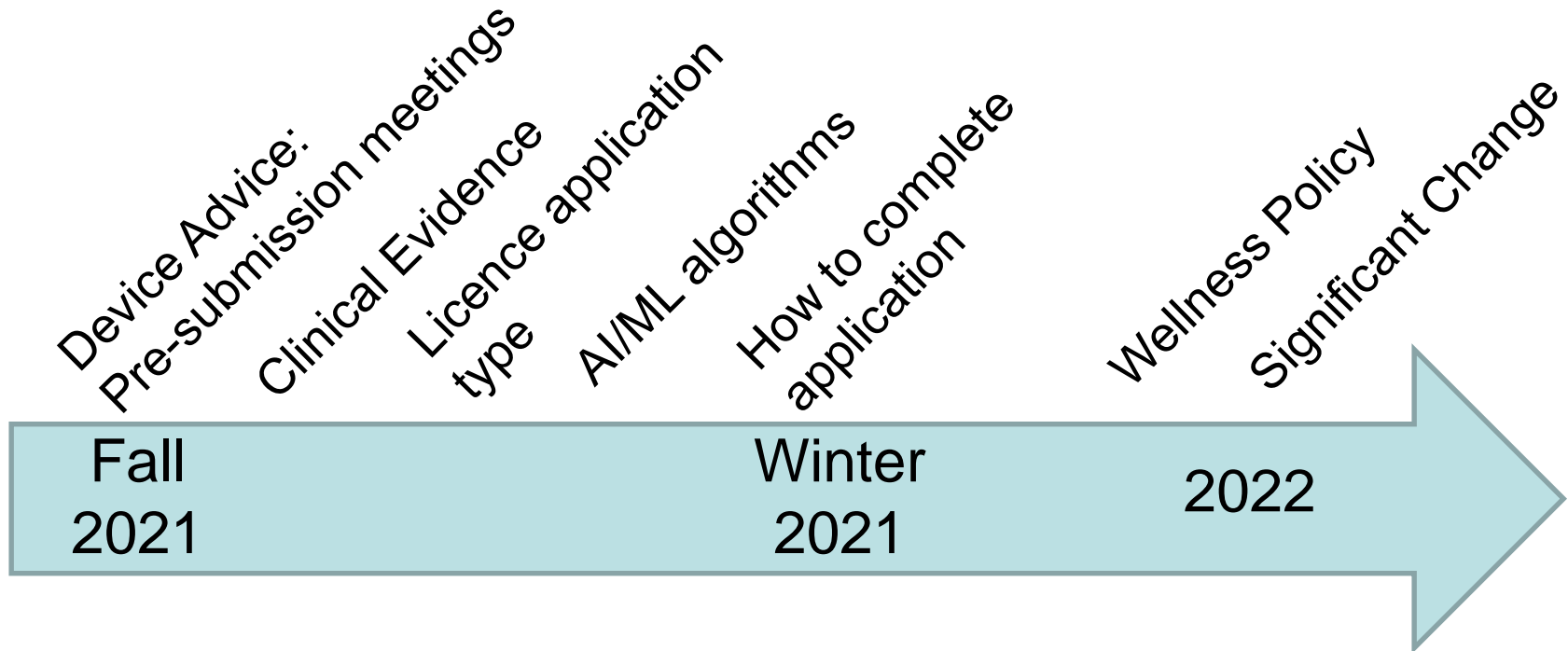
- Clinical Trial modernization
  - Will provide a risk-based, flexible framework for drugs, biologics, vaccines, natural health products, and medical devices
- Unique Device Identifiers
  - Exploration of introducing UDI system in Canada



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## Planned Guidance Documents for Consultation





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## **Questions/comments**

Thank you!