IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Medical Devices Directorate
Health Canada

David Boudreau

Director General

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

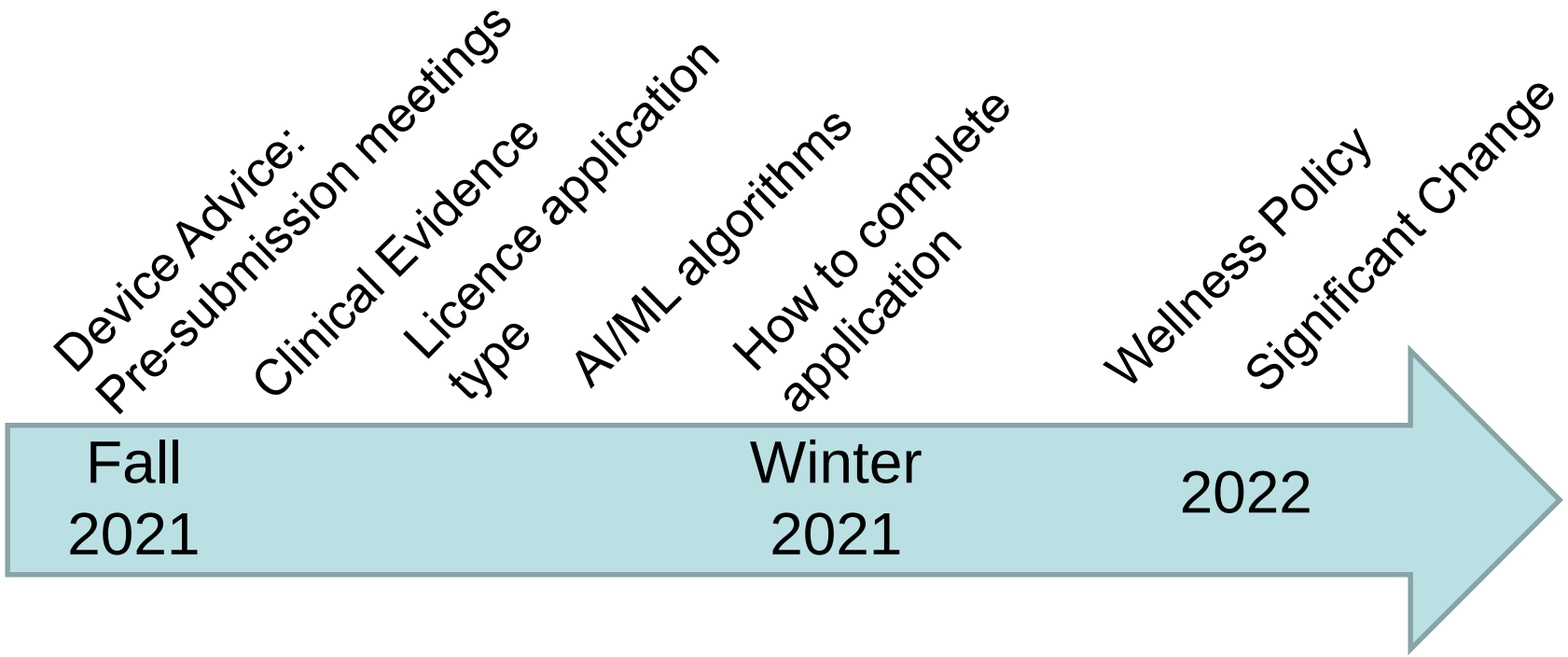
COVID-19

- 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

Planned Guidance Documents for Consultation



Questions/comments

Thank you!