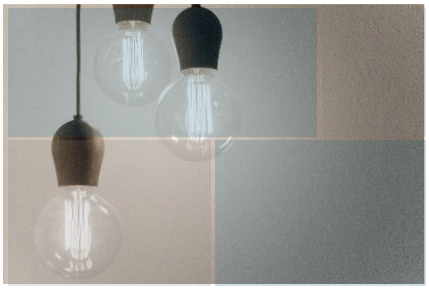


CRI

Centre for Regulatory Innovation

Regulatory Experimentation Expense Fund

Adaptive machine learning-enabled medical devices

OVERVIEW

Organization:
Health Canada (HC)

Timeline:
Nov 2022 – Mar 2023

Funding:
$73,733

ABOUT THE REEF

CRI's Regulatory Experimentation Expense Fund (REEF) helps federal regulators conduct regulatory experiments and pilot projects, enabling them to test new approaches and technologies in real-world scenarios.

PURPOSE

The purpose of this pre-experiment was to explore and develop a regulatory sandbox for adaptive Machine Learning-enabled Medical Devices (aMLMDs) under Health Canada's Advanced Therapeutic Products (ATP) Framework, enabling these devices to update their models without requiring repeated regulatory authorizations.

Context:

The rapid evolution of medical devices incorporating artificial intelligence (AI) and machine learning (ML) challenges existing regulatory frameworks.

Current requirements mandate that algorithm updates for aMLMDs trigger new submissions, delaying patient access to improved technologies and increasing regulatory burdens.

The ATP Framework allows Health Canada to test flexible regulatory approaches, balancing timely market access with safety and efficacy/effectiveness through a lifecycle-based sandbox model.

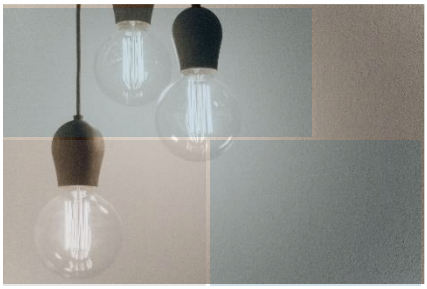
Learning objective:

The experiment sought to determine:

- How regulatory sandboxes can balance innovation, market access, and safety.
- The viability of a tailored regulatory pathway for adaptive MLMD.
- Best practices for stakeholder engagement, project management, and communication strategies.

Pre-Experimental design:

- Develop internal processes, guidance, and licensing schemes
- Consult stakeholders to refine oversight mechanisms
- Align with international regulators (U.S., EU) when possible
- Collect data via stakeholder feedback, reporting, and internal consultations



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Outcomes:

Key achievements and results included:

- A draft guidance document and Notice of Intent were drafted, clarifying Health Canada's approach to regulating adaptive MLMDs.
- The process for adding adaptive MLMDs to the regulatory schedule was initiated, meeting early milestones.
- An implementation plan was developed to address operational changes, such as revising procedures, templates, and application forms.
- Key insights were gained on the potential for existing regulations to address oversight through updated interpretations rather than new frameworks.
- The ATP analysis process successfully identified a regulatory pathway forward and led to the publication of a new guidance on MLMDs on February 2025.

Lessons learned:

Stakeholder Engagement:

Effective engagement requires ongoing updates and better integration of stakeholder input into policy decisions.

Governance:

A centralized governance model with clear roles and accountabilities greatly improved efficiency and clarity.

Adaptability:

Frequent reassessment of the regulatory approach is critical as new legal and international developments arise.

Operational Planning:

Detailed project planning, including templates, standard operating procedures, and consultation strategies, is essential for implementation.

Pre-experiments serve as valuable exploratory tools for identifying potential research gaps and refining hypotheses before committing resources to full-scale regulatory experiments