CAPT Conference Workshop

Defining "Decision-Grade" RWE and its Role in the Canadian Context: A Design Sprint

Lightning Talk: Health Canada

Rhonda Kropp

Health Canada Santé Canada

CADTH

CAPT ACTP

IHE INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

October 21, 2018
Toronto, Ontario

Objectives

1. Provide the context in which Health Canada is exploring optimizing the use of RWD/RWE across the life cycle

2. Describe the desired state for the use of RWE from Health Canada's perspective and our timelines to get there

3. Outline what we are hoping to get out of our session today

Regulatory Context

- **January 2016 Health Ministers Meeting:**
  - Commitment to improve **the affordability, accessibility and appropriate use** of therapeutic products
  - Health Canada's Health Products and Food Branch (HPFB) launches Regulatory Review of Drugs and Devices (R2D2)

- **Enhanced Use of Real World Evidence (RWE) for 1. Drugs and 2. Devices**

Goal
- To improve Canada's ability to assess and **monitor safety and effectiveness** across the health product life cycle by optimizing the use of RWE through engagement with key stakeholders

Objectives
- Understand the **key information gaps** across the product life cycle
- Understand how RWE can be used to **inform regulatory decision making**
- Determine potential **return on investment for use of existing/new RWE sources**
- To implement the **strategic use of RWE** across the product life cycle
- **Collaborate with partners** to explore access to, and use of, RWE

Desired Outcomes
- The health-related risks to Canadians associated with use of drugs and devices are minimized, while the benefits are maximized
- Accessibility, affordability & appropriate use of drugs & devices are improved

Current State: We Already Use RWE

Health Canada is committed to optimizing the use of RWE across the entire product life cycle

- Pre-Market:
  - Where a **conventional RCT was unfeasible or unethica**l & RWE was therefore submitted and assessed in lieu
  - Where a **product was previously approved and marketed in a foreign jurisdiction** and RWE from clinical registries in the foreign jurisdiction was used in the Canadian submission

- Post-Market:
  - Submitted to address requirements in the **Risk Management Plans (RMP)** to address residual risks
  - **Monitor for adverse reactions and signals** domestically and internationally
  - **To inform change in indications, monograph or label revisions** for products already marketed in Canada

– Can **ask/compel MAH to develop the evidence, for drugs:**
  - Minister of Health can require holders of drug product (and establishment) licenses to perform tests or other monitoring related to their products (but not NHPs) where…
    – Significant uncertainties exist about the drug's harms or benefits (or activities of license holders)
    – Company is unable to provide the needed information & it is not available through other regulatory powers

– Can undertake or solicit **research, for drugs:** Drug Safety and Effectiveness Network **(DSEN)**
  - CIHR and Health Canada have partnered to establish the DSEN to increase..
    » …evidence on drug safety and effectiveness available
    » …capacity within Canada to undertake high-quality post-market research in this area.
  - Health Canada, and others, work with DSEN to formulate research questions and gather information on safety & effectiveness of pharmaceuticals used by diverse patient populations outside of clinical trials.

But…there is room to optimize….

Health Canada Santé Canada CADTH CAPT ACTP IHE INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

Desired State

- RWE is used appropriately across the entire product life cycle, improving timely access for Canadians to health products

- RWD and RWE submitted to Health Canada is of sufficient quality to be considered for decision making

- Assessment of quality of evidence is, where possible, aligned with domestic and international partners; assessment of sufficiency of evidence to support a decision will, by necessity, be a case by case decision
  - Optimizing RWE use across the life cycle in no way means HC will lower its regulatory decision making bar, rather that the bar will be adapted to fit the circumstances.

- Health Canada and Industry partners work collaboratively and early on for a given submission to determine the potential use of RWE for a given decision

How will we get there…..

Health Canada Santé Canada

CADTH

CAPT ACTP

IHE INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

Planned Approach

Moving forward, HC will publish a strategy outlining how we will optimize the use of RWD/RWE across the product life cycle. Snapshot of the approach….

1. Developing Guidance for Industry and Data Partners
   - Publishing principles and guidance for industry and data partners on the key data elements needed for decision points across the product life cycle and how HC and Industry can work together to optimize RWE use early on in submission discussions

2. Developing and Implementing a Transparent Approach to Assessing Quality of Evidence
   - Documenting the approach to assessing quality of evidence submitted across the life cycle.
   - Aim is to support data producers in collecting the right data of sufficient quality to inform regulatory decision making

3. A Phased Approach to Implementation
   - Health Canada already accepts RWE as part of submissions across the life cycle, however, with the Guidance and Quality of Evidence (QoE) approach clarified, we will work with willing partners to phase in deliberate use of RWE starting with product lines for which use of RWE provides clear value-add to the health system and to Canadians. Lessons learned will be used to optimize the approach for future phases.

4. Working with Partners to Optimize Data Availability
   - Collaborating with partners to support the development/sharing/optimization of sources with greatest Return on Investment (RoI) for Canadians.
   - Monitoring the safety and effectiveness of medical devices on the market requires data, both to identify signals and proactively assess for potential issues
     - Regulatory and non-regulatory solutions will be assessed

How Will Today Help?

- This session provides an excellent opportunity for partners in RWE generation and use to discuss key challenges and opportunities in a concrete way

- As we aim to move from talking to doing, HC will need to understand:
  - The guidance and processes that will best support Industry in working with HC to use RWE in submissions across the life cycle
  - Where there is and is not quality real world data/evidence in Canada to inform decision making along the life cycle, and where there is insufficient data, where are the most important gaps from the perspective of the health of Canadians?
  - Where are the opportunities in Canada to better use existing data/evidence sources (low hanging fruit) to inform regulatory and HTA decision making?
  - What are the greatest risks associated with decision making based on or supplemented by RWE and how do we mitigate those risks?

Key Take Home Messages

- Health Canada is committed to working with partners to optimize the use of RWE at all points in the health product life cycle for both drugs and devices
  - Aiming to have a strategy in place by end of this fiscal year (April 2019), with as much alignment as possible with our CADTH colleagues

- Today's workshop is not an isolated opportunity for partnership on this topic; success on this journey will require many partners working together, understanding each others' needs and how we can support one another with the aim of optimizing access to safe and effective products in Canada

- A phased approach where HC, CADTH, Industry and other partners use RWE in decision making outside our current 'comfort zone' and continue to refine our approach will be useful
  - These are not 'pilot projects': We are already committed to RWE use.
  - Aim is to get moving and use the lessons learned to refine as we collectively mature

- We are delighted to be moving from talking to doing with our partners in regards to optimizing RWE use and thank everyone for their thoughtful input as the day progresses