A Draft Reassessment Framework
Developed by the CanREValue Collaboration

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CanREValue Goal

Overall Purpose
To develop a framework for Canadian provinces to generate and use RWE for cancer drug funding decisions in a consistent and integrated manner

Potential System Impact

- Reassessment of cancer drugs by recommendation-makers
- Refinement of funding decisions or re-negotiations/re-investment by decision-makers/payers across Canada
## CanREValue Objectives

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<tr>
<th>No.</th>
<th>Objective</th>
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<tbody>
<tr>
<td>1</td>
<td>To develop a comprehensive understanding of the current state of RWE in cancer drug reimbursement in Canada</td>
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<td>2</td>
<td>To establish formal national working groups dedicated to policy and methodological applications of RWE, and collaboratively/iteratively develop working framework for the generation and use of RWE</td>
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<td>3</td>
<td>To validate the developed framework through the completion of multi-province RWE projects</td>
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<td>4</td>
<td>To employ knowledge translation (KT) strategies to establish and integrate the final RWE framework into official practice of participating provinces and on a national level</td>
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National Working Groups (WG)

Drug selection

Collection of Data

Reassessment

Funding Decision

RWE Methods WG

RWE Data WG

RWE Planning and Drug Selection WG

Stakeholder Engagement WG

RWE Uptake and Reassessment WG
Reassessment WG Membership

- PMPRB
- Cancer Agencies
- HTA (CADTH, INESSS)
- Ministry of Health
- Reassessment WG
- Health Canada
- Applied Researchers
- Patients & Family
- pCPA

Value-based decisions from Real World Evidence
Objectives:

1. to propose a high-level process for how the reassessment of currently funded drugs could work within the Canadian health system

2. to recommend processes and factors required to revisit negotiations and funding decisions
Scope of the Reassessment WG

**In Scope**
- Define a high-level process for reassessments
- How to initiate reassessment of drugs
- How/who will conduct reassessments
- What information is required to revise a funding decision?

**Out of Scope**
- Guidance on the critical appraisal of RWE
- Triggers for selecting drugs for RWE data collection
- How RWE data are going to be collected
- How RWE analysis will be conducted
- Provincial infrastructure for RWE
Methods

• A modified Delphi approach was used to inform the reassessment and uptake component of the framework.

• Series of surveys/teleconferences to seek areas of agreement on how a reassessment framework could be conceptualized.
DRAFT Reassessment Process

**Trigger and RWE Data Collection**
- Province initiated
- Industry initiated
- Industry needs to be incentivized to submit a reassessment
- Out of scope for this WG

**Transparency**
- CADTH* review
- Review data to address uncertainty
- Type/source of data may be different than initial review
- Similar deliberative framework as pERC, with differences in adoption/feasibility.

**Patient and Clinician Engagement**
- Committee Recommendation
- Revisit negotiation or price ceiling
- Do not recommend/De-list
- Committee rec categories

**Outcomes**
- Status quo
- Revisit negotiation or price ceiling
- Do not recommend/De-list
- Committee rec categories

**Funding decision**
- No change

**Timeline ~6 months**

* CADTH or another national group
Current Status and Next Steps

• Draft report on draft reassessment framework that has been reviewed by the Working Group
• Explore draft reassessment framework with other working groups, in particular the stakeholder working group
• Conduct a ‘mock reassessment’ to see how the draft reassessment framework performs—identifying gaps and opportunities
Thank you