

Developing a framework for the incorporation of real-world evidence into cancer drug funding decisions in Canada: An update from the Canadian Real-world Evidence for Value of Cancer Drugs (CanREValue) Collaboration

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Objective

The **Canadian Real-world Evidence for Value** of Cancer Drugs (CanREValue) collaboration brings key stakeholders (Table 1) to develop a framework for the generation and use of real-world evidence (RWE) for cancer drugs. The framework will assist decision-makers in:

- Refining funding decisions, or renegotiations/reinvestment by Canadian decision-makers/payers
- Reassessing recommendations previously made

Table 1. Stakeholders working with the CanREValue Collaboration

Applied Researchers	Patients & Family Members
Canadian Association of Provincial Cancer Agencies (CAPCA)	pan-Canadian Pharmaceutical Alliance (pCPA)
Canadian Partnership Against Cancer (CPAC)	Patented Medicine Prices Review Board (PMPRB)
Health Canada	Provincial Cancer Agencies
Health Technology Assessment (CADTH/pCODR, INESSS, OSCCD)	Provincial Ministries of Health

The CanREValue Working Groups

- The CanREValue collaboration established 5 working groups (WGs)
- The members of the WGs consist of:
 - Cancer drug recommendation and decision makers (Health Canada, provincial health ministries/departments, provincial cancer agencies, HTA organizations (CADTH/pCODR and INESSS))
 - Research and experts in HTA, methods and data
 - Clinicians
 - Patients and patient representatives
- The objectives of the WGs are:

RWE planning and drug selection WG:

Recommend criteria to identify potential candidates for real-world evaluation and advise on the necessary provincial infrastructure needed for RWE.

RWE Data WG:

Explore options for data access and recommend strategies for harmonization of data

RWE Methods WG:

Recommend methods to analyze real-world data with methodological rigor. The

RWE Reassessment and Uptake WG:

Develop process to undertake HTA reassessment and advise on strategies to incorporate RWE results into policy-making.

RWE Engagement WG:

Establish mechanisms to inform key stakeholders on the draft recommendations from the WGs and elicit stakeholder feedback for consideration by the WGs as recommendations are developed in an iterative process.

Progress

- In addition to the establishment of the WGs, the CanREValue collaboration has made important progress over the past years:

Environmental Scan

- The environmental scan was conducted to obtain a better understanding of the current state of RWE in healthcare decision-making across Canada and in international jurisdictions
- The study found that there are multiple sources for RWD and study designs for RWE and various benefits of the application of the RWE for multiple stakeholders

Qualitative Study

- The qualitative study was conducted to explore stakeholders' views regarding the creation and implementation of a framework to incorporate RWE in cancer drugs funding decisions in Canada
- Participants included Canadian policy-makers (provincial and federal), industry representatives, researchers, and patient advisors as well as international experts
- Draft manuscript is in preparation for publication

Framework development

- Regular teleconferences and two annual in-person meetings were held
- All WGs participated and worked together to develop and refine the recommendations for the framework
- The framework will be revised iteratively through conducting RWE evaluations and qualitative interviews

Draft reports

- The WGs have developed interim reports to engage stakeholders on the development, and implementation of a framework for the incorporation and use of RWE

Knowledge Translation and Engagement

- The CanREValue collaboration presented at CCSN webinar and CAMO conference
- An introductory manuscript about the CanREValue Collaboration was submitted for publication
- The CanREValue website was launched to share updates and progresses of the CanREValue collaboration

First RWE Evaluation

- The first RWE evaluation of a funded cancer drug is in progress with participation all provinces

Conclusions & Next Steps

- The CanREValue is a multi-stakeholder initiative, which will provide recommendation- and decision-makers with a framework that is expected to enable the generation and use of RWE for oncology drugs
- The RWE framework is expected to enable the reassessment of funded cancer drugs to ensure that patients have access to safe and effective treatment choices contribute to a sustainable health care system.
- The CanREValue will work closely with clinicians, patient groups, payers and industry to ensure that all key stakeholders are given a voice in the development and implementation of the RWE framework.

Table 2. Expected deliverables for each of the WG

Working Group (WG)	Expected deliverables
Planning and drug selection	<ul style="list-style-type: none"> Criteria for selecting and prioritizing RWE evaluation Policy framework for drug selection for RWE evaluation Process for selecting drugs for conducting RWE evaluation
Data	<ul style="list-style-type: none"> Report on the availability of relevant databases and process to access real-world data in each province Minimum dataset to conduct real-world evaluation of cancer drugs
Methods	<ul style="list-style-type: none"> Papers on methodological/analytical challenges in conducting RWE evaluations including various methods to consider as options
Reassessment and Uptake	<ul style="list-style-type: none"> Development of process for reassessment of funding process Recommendation on strategies for the uptake of the RWE framework
Engagement	<ul style="list-style-type: none"> Collect feedback from patient groups, clinician groups, industry and payers

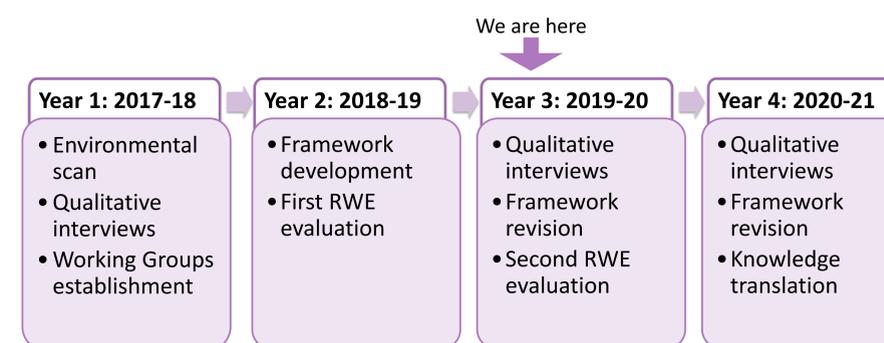


Figure 1. CanREValue Collaboration Project Timeline

