

RWE Steering Committee Meeting Summary

September 14, 2022 2:00-3:00 p.m. ET

Agenda – September 14, 2022



Time	Topic / Discussion Item	Facilitator
2:00 p.m. 5 min	Welcome and Opening remarks	CADTH Chair
2:05 p.m. 15 min	RWE for Rare Disease Update	CADTH RWE Team
2:20 p.m. 10 min	ICMRA Statement (see attached document) Update on NOC/c Non-Oncology Project	Health Canada
2:30 p.m. 10 min	CADTH Launch of Post-Market Drug Evaluation Program	CADTH CoLab Team
2:40 p.m. 10 min	CADTH Scientific Advice for RWE	CADTH Scientific Advice
2:50 p.m. 20 min	Update: RWE Guidance Project	RWE Guidance Working Group
3:10 p.m. 10 min	Discussion: Addition of New Members to Steering Committee Membership	CADTH Chair
3:20 p.m. 10 min	Discussion: Public Posting of Meeting Summaries	CADTH Chair
3:30 p.m.	Meeting Close	CADTH Chair



Meeting Summary

- The Real-World Evidence (RWE) Steering Committee convened virtually for a meeting on Wednesday, September 14, 2022, to discuss and provide updates on the work of the Committee, its Working Groups, and its members. In accordance with action items from the previous meeting, the meeting was extended from 60 to 90 minutes.
- The CADTH RWE Team provided an update on the status of several of its learning projects in the area of rare diseases, including for spinal muscular atrophy, pediatric glioma, and amyotrophic lateral sclerosis. An updated list of recent RWE team publications was also shared (links are provided on the following slide).
- Members of Health Canada presented a recent <u>statement</u> published by the International Coalition of Medicines Regulatory Authorities (ICMRA) concerning international collaboration to enable use of RWE to support regulatory decision-making. An update on the status of a joint Health Canada—CADTH learning project focusing on potential value of RWE for decision-making about non-oncology drugs for rare disease listed with a Notice of Compliance with conditions (NOC/c) was also provided.



Meeting Summary

- The CADTH <u>Post-Market Drug Evaluation</u> (PMDE) Program members provided an overview of their activities leading up to the September 1 program launch, as well as the newly formed <u>CoLab</u> research network supporting this work.
- CADTH Scientific Advice <u>announced</u> plans in April 2022 to expand scientific advice services over a 1-year learning period to include advice on RWE generation plans after finalization of pivotal trial protocols and members provided an update on their expanded program and their early learnings. Additional information on Scientific Advice and the expansion can be found at <u>www.cadth.ca/scientific-advice</u>.
- The RWE Guidance working group provided an update of their ongoing efforts. There was a joint <u>CADTH-CAPT workshop</u> where a preliminary draft of the RWE guidance document was presented to key stakeholder groups.



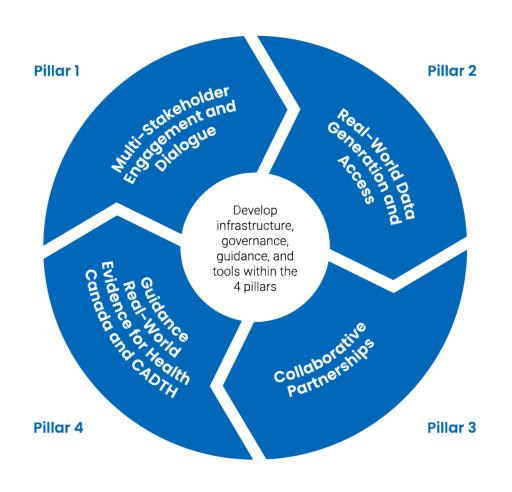
Action Items

The following actionable items were discussed at the September RWE Steering Committee meeting:

- A group discussion will be held at the next Steering Committee meeting on the potential addition of other pan-Canadian organizations to the Committee.
- The process for drafting and posting RWE Steering Committee meeting summaries was discussed and approved by Steering Committee members.

Recent CADTH RWE Publications





Optimizing the Use of RWE for Decision-Making for Drugs for Rare Diseases

- Best Brains Exchange: Optimizing the Use of RWE as Part of Decision-Making for Drugs for Rare Diseases: Report on a Best Brains Exchange: Optimizing the Use of Real-World Evidence as Part of Decision-Making for Drugs for Rare Diseases (cadth.ca)
- RWE for Rare Disease: <u>Optimizing the Integration of Real-World Evidence as Part of Decision-Making for Drugs for Rare Diseases:</u> <u>What We Learned (cadth.ca)</u>

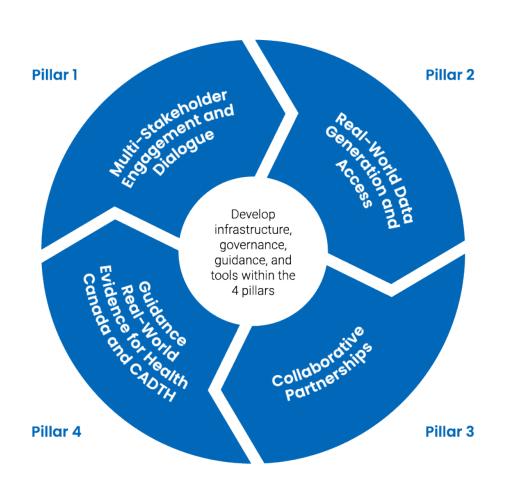
RWD Generation and Access

- Reflections on Canadian Bleeding Disorders Registry: Lessons Learned and Future Perspectives: <u>Peer-Reviewed Article on</u> <u>Reflections on the Canadian Bleeding Disorders Registry:</u> Lessons Learned and Future Perspectives (cadth.ca)
- The Value of Patient Registries: Common Needs for Rare Diseases Editorial: <u>View of the Value of Patient Registries:</u>

 <u>Common Needs for Rare Diseases | Canadian Journal of Health Technologies (canjhealthtechnol.ca)</u>

Recent CADTH RWE Publications





Portraits of Care and System Readiness

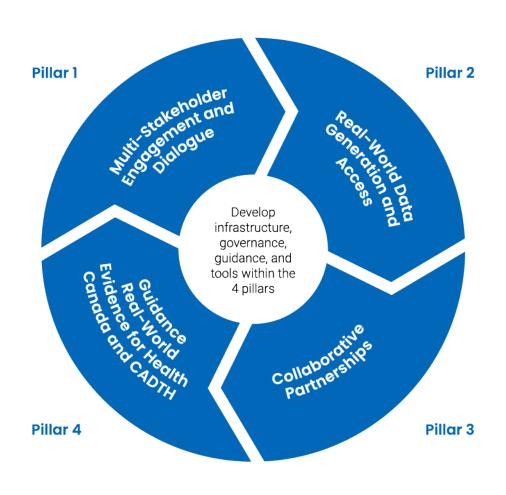
Understanding the Portrait of Care for Dementia in Canada: Panel of Clinical Experts: <u>Understanding the Portrait of Dementia Care in Canada: A CADTH Panel of Experts | CADTH</u>

Dementia RWF Evidence Bundle:

- Patient Panel <u>Dementia Concerns and Considerations: A CADTH</u>
 Panel of People With Lived Experience
- Canadian Medical Imaging Inventory <u>The Role of PET-CT in Drugs Targeting Amyloid-Beta in Alzheimer Disease: Part 2 (cadth.ca)</u>
- Devices <u>View of An Overview of New and Emerging Technologies</u> for Early <u>Diagnosis of Alzheimer Disease</u> | <u>Canadian Journal of</u> <u>Health Technologies</u> (canjhealthtechnol.ca)
- Pharmaceuticals <u>View of Utilization of Cholinesterase Inhibitors</u> for Alzheimer <u>Disease in Canada | Canadian Journal of Health</u> <u>Technologies (canjhealthtechnol.ca)</u>
- Infusion Clinics <u>View of Health System Readiness Report: The Availability of Privately Funded IV Infusion Clinics in Canada | Canadian Journal of Health Technologies</u> (canjhealthtechnol.ca)

Recent CADTH RWE Publications





Collaborative Partnerships

CADTH-CIHI Partnership: <u>CADTH and the Canadian Institute for Health Information (CIHI) Real-World Evidence Feasibility Collaboration | CADTH</u>

Formulary Management

• Utilization of Glucagon-Like Peptide-1 Receptor Agonists: Utilization of Glucagon-Like Peptide-1 Receptor Agonists | CADTH



Next Steering Committee Meeting

December 15, 2022, 2:00-3:30 p.m. ET

For more information on CADTH RWE Team activities, please visit the <u>RWE landing page</u> or contact us at rwe@cadth.ca



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