

RWE and CADTH

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CADTH

Disclosure

- CADTH is funded by contributions from the Canadian federal, provincial, and territorial ministries of health, with the exception of Quebec.
- CADTH receives application fees from the pharmaceutical industry for:
 - CADTH Pharmaceutical Reviews, including the Common Drug Review, the pan-Canadian Oncology Drug Review, and the Interim Plasma Protein Product Review
 - CADTH Scientific Advice

Agenda

- Past
- Present
- Future



Past



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Past

CAPT 2018 launched RWE-CAT

- Membership
- Deliverables
 - Paper (Tadros et al, *HEALTHCARE POLICY* Vol. 15 No.4, 2020) (Health Canada, Institute for Health Economics, CADTH, CAPT)
 - White paper (Health Canada, Institute for Health Economics, CADTH, CAPT)

Developing a Canadian Real-World Evidence Action Plan across the Drug Life Cycle

Développement d'un plan d'action canadien fondé sur les données probantes du monde réel tout au long du cycle de vie des médicaments



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Files

 [CADTH CAPT HC IHE workshop summary report Oct 21 2018](#)
PUBLISHED: December 6, 2018

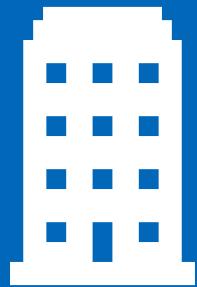
Defining "Decision-Grade Real World Evidence" and its Role in the Canadian Context: A Design Sprint – Pre-Conference Workshop / CAPT Annual Conference

Event Date: October 21, 2018

Present



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Present

- CAT RWE
- -3 working groups (Guidance/guidelines, Oncology, Non-oncology)
- Terms of Reference
- Inventory of databases
- Understanding of RWD sources and strategies across Canada
- Improved dialogue between regulators, HTA, data holders/producers, and industry
- Building criteria for choosing RWE demonstration projects
- Building criteria for evaluating RWE submitted as evidence to regulators
- Optimal time points to assess the need for RWE
- Best practices and strategies to understand funding models

Future



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Case Studies

- Non-oncology
- Oncology
- Question
- How to choose case study
- What questions are we trying to address

Proposed CADTH-RWE Strategy



CADTH-RWE Future Strategy: Guidance

- Guidelines
 - When is RWE acceptable?
 - Guidance on acceptable RWE methodology
 - Should it be for post-market only?
 - Standards and guideline development
- Criteria for submissions?
- Collaboration with HC, INESSS
 - To promote alignment and improve efficiencies
 - Better identify appropriateness of RWE across the product lifecycle
 - Strategy documents



CADTH-RWE Future Strategy: Advice

- Provide early scientific advice of RWE plan;
- Early design concepts;
- Methods advice?
- Link to recommendation?

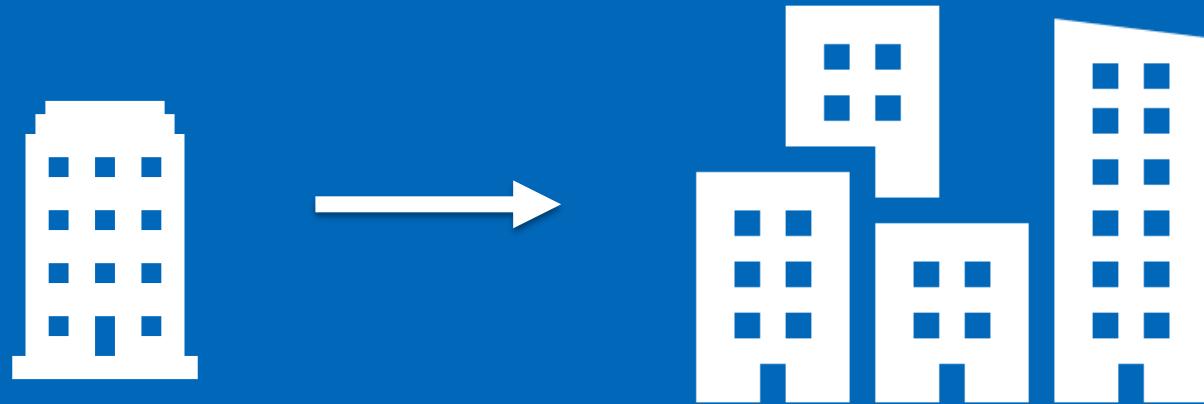
CADTH-RWE Future Strategy: Evaluation

- Methods development
- Need to stipulate the outcome;
- Threshold
- Deliverable
- Re-assessment
- Collaborative panel/expert panel who can review and recommend study design [patients, HC, industry, methods (IHE, CanReValue), payer, etc?]



CADTH-RWE Future Strategy: Collaboration

- Link to Health Canada/pan Canadian health Organizations (e.g., CIHI);
- RWE-Core Action Team (HC, CADTH, INESSS, Industry, Academia)
 - 3 Working groups
- Network of independent methodologists/academics who have access to data (e.g., IHE, DSEN, CanReValue, O2, P/Ts)
- Link to data
- Retrospective vs. Prospective
- Responsive to payers and stakeholders



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Thank You

CADTH Evidence
Driven.
—
ACMITS Preuves
à l'appui.