Building the RWE Blueprint: A Coordinated Approach to RWE Use in Pharmaceutical Regulatory and Reimbursement Decisions in Canada

CADTH Symposium  Concurrent Session F1
Dr. Tarry Ahuja, CADTH
Dr. Gayatri Jayaraman, Health Canada
Ms. Sylvie Bouchard, INESSS
Dr. Kelvin Chan, ARCC
Panelists

Dr. Tarry Ahuja – CADTH
Manager, Program Development & RWE Lead

Dr. Gayatri Jayaraman – Health Canada
Director, Marketed Health Products Directorate at Health Canada

Ms. Sylvie Bouchard – INESSS
Director of Medication

Dr. Kelvin Chan – ARCC, CanREValue
Director, ARCC
Overview of joint-RWE Workshop

Defining “Decision-Grade” Real World Evidence and its Role in the Canadian Context: A Design Sprint
Joint-RWE Workshop

- held in Toronto October 2018 at the CAPT conference
- joint collaboration between Health Canada/CADTH/IHE/CAPT
- a total of 87 participants including representation from:
  - regulators
  - public payers
  - academia
  - patient advocates
  - HTA
  - clinicians/HCPs
  - industry
Joint-RWE Workshop

- the objectives of the workshop were to:
  - identify the value and applications of RWE in supporting pharmaceutical regulatory and reimbursement decision-making
  - identify the conditions upon which RWE will be considered of sufficient quality to inform decision-making
Joint-RWE Workshop

- participants were divided into two groups by case studies:
  - one scenario in the oncology space
  - another in the rare disease domain
Joint-RWE Workshop

• summary of key points:
  - current evidentiary requirements are challenging and potentially not feasible for drugs used in the treatment of rare diseases and in oncology
  - RWE should be used as a supplement or complement to current evidence standards and not “in lieu of”
  - regulatory and HTA bodies should engage with manufacturers pre- and post market for RWE initiatives as appropriate
Joint-RWE Workshop

• summary of key points:
  
  o  prescriptive guidance is challenging so instead articulate good process and guidance on quality of evidence to ensure useful RWE

  o  Health Canada and CADTH expressed commitment to working with all stakeholders across a product’s full life cycle and to ensure a consistent and transparent approach
Development of RWE Core Action Team (CAT)
RWE Core Action Team

- established in November 2018 after RWE workshop
RWE Core Action Team

- the RWE Core Action Team (CAT) comprises representatives from:
  - CADTH
  - Health Canada
  - Institut national d’excellence en santé et en services sociaux (INESSS)
  - pan-Canadian Pharmaceutical Alliance (pCPA)
  - Canadian Institutes of Health Research (CIHR)
  - Canadian Institute for Health Information (CIHI)
  - Canadian Pharmaceutical Industry (1 with expertise in regulatory issues and 1 with expertise in market access/HTA)
  - Canadian health research sector (2 representatives with expertise in RWE)
RWE Core Action Team

- **objectives** of the RWE CAT include:
  - create a forum for stakeholders to have dialogue and awareness of initiatives nationally
  - form an advisory body that will help guide and support the development of a pan-Canadian approach to the use of RWE
  - identify where RWE can add value to regulatory and reimbursement decision-makers throughout a technology’s lifecycle
RWE Core Action Team

- **Action Teams** or Working Groups will be established to work on priority areas

- membership will include some CAT members along with appropriate key external stakeholders/representatives

- **priority areas** of the RWE CAT _could_ include:
  - define and address data gaps – across the product lifecycle
  - methodological capacity and standards
  - optimize data sharing – among partners in Canada
RWE CAT

- Data Gaps
- Methods
- Data Sharing
- TBD
- TBD
Use of RWE by CADTH
Current State of RWE

- CADTH **continues** to use RWE throughout the product lifecycle

  - continue to accept RWE in CDR drug submission as part of evidence bundle (*hierarchy of evidence*)
Hierarchy of Evidence

LEVEL 1
Systematic Reviews

LEVEL 2
Randomized Control Trials
Quasi-Experimental Studies

LEVEL 3
Realist Reviews
- Case Studies with Evidence of Effectiveness
  External evaluation with scientific rigour
- Case Studies with Encouraging Results
  Internal or external evaluator that lacks scientific rigour

LEVEL 4
Program Descriptions or reports with limited data or evidence
Opinions, ideas, policies, editorials

BEST PRACTICES
PROMISING PRACTICES
EMERGING PRACTICES
Current State of RWE

- CADTH continues to use RWE throughout the product lifecycle

- Continue to accept RWE in CDR drug submission as part of evidence bundle (hierarchy of evidence)
- Continue to utilize in pharmacoeconomic modeling
- Used to inform policy/research question within HTA
- Continue to use RWE for rapid response & OU/HTA
- pERC has issued conditional coverage recommendations
- Development of reassessment framework
Reassessment

- a key goal of CADTH’s Strategic Plan is to adopt a **life-cycle approach** to HTA
  - a key component to life-cycle approach is re-assessment

- CADTH is developing a **Reassessment Framework**

- will need to consider “**Health Canada Notice of Compliance**”
Reassessment

pCPA
Cancer agencies
Drug plans
Manufacturer

Reassessment (CADTH review)

New Recommendation

Conditional recommendation/listing agreement
Future Considerations

• use of RWE for long-term comparative effectiveness and safety

• better understanding of subpopulations and patient reported outcomes

• improved access to therapies
Next Steps

- continue collaborative development of a joint-RWE action plan and framework

- improve transparency and consistency

- continue dialogue and development to improve system readiness for RWE across the product lifecycle
Use of RWE by Health Canada

Presented by
Dr. Gayatri Jayaraman, Health Canada
Introduction

• Health Canada already considers RWE during the pre- and post-market drug regulatory process to inform decision-making.

• The market authorization of new drugs for some of our most vulnerable patient populations present some unique challenges, due to for example:
  - small populations, e.g., pediatrics
  - small subgroups, e.g., rare diseases or patients with rare genomic markers making it difficult to register in formal trials.

• The Health Canada commitment to ‘Strengthening the use of RWE for Drugs’, an initiative under the Regulatory Review of Drugs and Devices, aims to optimize the consideration of RWE across the drug life cycle.
  - A key goal of the project is to work with partners to develop a systematic and transparent approach to using RWE across the drug life cycle.

So how does Health Canada already use RWE?
Current Use of RWE at Health Canada

*Consideration in extending an indication to rare subsets of patients not included in the original approval (dependent on data quality)

*Labelling changes in special populations for post market safety concerns

*Registries to investigate long-term effectiveness and safety

*Review of studies in signal detection for hypothesis generation

*Drug Safety and Effectiveness Network studies

Diagram: Neil Yeates et al. CMAJ 2007;176:1845-1847

But we are committed to doing more……
New Initiatives at Health Canada

• Health Canada is working with its partners, including CADTH and INESSS, to optimize the use of RWE for regulatory decisions in order to improve the extent and rate of access to prescription drugs in Canada.
  o A joint action plan is being developed as a first step to outline how the organizations will work together to accomplish this goal (anticipated to be published this fall).
  o Linkages with the HTA/Payer Pathways for early parallel scientific advice.

• Health Canada is expanding internal capacity to evaluate the place and appropriate use and scope of RWE as supportive and pivotal evidence (in rare cases) for regulatory decision making.
  o A key goal of the project is to work with partners to develop a systematic and transparent approach to using RWE across the drug life cycle.

• “Elements of Real World Data/ Evidence Quality throughout the Prescription Drug Product Life Cycle” will be published by Health Canada to provide overarching principles on the quality of RWD/RWE
  o Outlines elements of protocol development and characterizes key elements of RWD quality

• Notice to Industry to be issued by Health Canada indicating that high quality RWE submissions are welcome.
RWE Notice to Industry

• While not limiting to any particular area, Health Canada is encouraging submissions:
  o that aim to expand evidence-based indications for populations often excluded from clinical trials
  o for drugs/diseases where clinical trials are unfeasible
  o where clinical trials are unethical

• The quality of the RWE will inform the extent to which Health Canada considers such information sources in regulatory decision-making
  o An iterative, ‘learning-by-doing’ approach which will build capacity and enable the development of guidance documents for industry

• Sponsors considering using RWE in a drug submission to Health Canada should consult the Quality of Evidence document. As usual, Health Canada has offered to provide pre-submission consultations to facilitate the process.
Use of RWE by INESSS

Presented by
Ms. Sylvie Bouchard, INESSS
Real World Evidence

RWD or RWE  Assessment  RWD or RWE
Real Word Evidence at INESSS

- RWE is complex and associated with potential bias
- INESSS has initiated discussion & activities internally on RWE
- INESSS has not yet published orientations on RWE
  - expected later in 2019
- Notice to industry published in January 2019:
  - currently possible to include real word data in the submission (registry data or observational study)
  - however real-world evidence approach can’t replace methodologically sound randomized double-blind clinical trials
- Recent examples: Spinraza$^{MC}$ & Galafold$^{MC}$ recommendations associated with clinical monitoring and potential reassessment.
RWE in our process

More than economic concern

- exposure to « bad drugs »
- more harm than asset in accordance with patient preferences

Not always a regulator’s concern

- efficacy
- innocuity
- uncertainty on long term outcomes… OS

Must we deny the patients of treatments potentially safe and effective during the time the evidence is coming?
RWE and purpose

Are we ready to live and accept the results issued by RWE?

- what if the results are not what expected?
  - re-negotiate?
  - desinvest?
Are we conscious than while we collect RWD, the environment changes

- more experienced clinicians
- new therapies, new sequencing
- will we find what we are looking for?
RWE and purpose

Does HTA have the ability to do that?

• access to data
RWE and purpose

Does the government want and have the ability to receive that?

- in HTA recommendations
- in signed agreement
- in managing this information
Why RWE

A way to ↓ uncertainties
- confirm long term outcomes
- reassessment
  - review recommendation/sequencing
- re-negotiate prices according to efficiency

A way to identify best responders
- when results are fantastic in small number
From the past into the future

The unmet need is big but the actual data do not give us confidence that the medication can fulfill that need.

In the past
- therapeutic value not assessed

In the future
- refusal of listing?
- positive recommendation with condition?
  - clinical monitoring
Areas under development and collaboration with Health Canada/CADTH

- Currently working in collaboration with HC to ensure consistency between upcoming regulations/guidance on RWE
- Currently, RWE can be submitted during the pre- and post-market drug regulatory process of HC
- Any changes to the HC guidance on RWE during the drugs life cycle could impact the INESSS evaluation
  - Minimal alignment between INESSS and HC: RWE requirements to maintain the fast access of medications to the population
  - Transparency on similarities & differences between HC and INESSS: requirements will have to be known to manufacturers to properly design/conduct clinical trials and submission

April 16th, 2019
Areas under development and collaboration with Health Canada/CADTH

- As per the Quebec’s Life Science Strategy, INESSS and CADTH recommendations need to be synchronized so that the average difference time between the two organizations is 1-month or less.
  - Consistency between HTAs upcoming requirements on RWE will be important to maintain this goal

- Source of RWD : INESSS is interested in collaboration with HC & CADTH to access to international & pan-canadian data
  - The population from Québec must be represented in the RWD, included in registries,…..
Overview of CanREValue

Presented by
Dr. Kelvin Chan, ARCC
Canadian Real-world Evidence for Value of Cancer Drugs (CanREValue) Collaboration

Developing a Framework for the Incorporation of Real-World Evidence (RWE) into Cancer Drug Funding Decisions in Canada

CADTH Symposium 2019

Kelvin Chan, MD FRCPC MSc (Clin Epi) MSc (Biostats) PhD
Canadian Centre for Applied Research in Cancer Control
Sunnybrook Odette Cancer Centre
Introduction
### Acknowledgements – Working Group Members

#### Planning & Drug Selection
- **Chair:** Scott Gavura
- Angie Wong
- Helen Anderson
- Danica Wasney
- Alicia Wall
- Tarry Ahuja
- Maureen Trudeau
- Marianne Taylor
- Anne Newman
- Sang Mi Lee
- Tanya Potashnik
- Elena Lungu
- Nevzeta Bosnic
- Don Husereau
- Basanti Ghosh
- Melissa Hunt
- France Hall
- Michele De Guise
- Sylvie Bouchard
- Erika Brown

#### Data
- **Chair:** Claire de Oliveira
- Reka Pataky (BC)
- Paulos Teckle (BC)
- Winson Cheung (AB)
- Riaz Alvi (SK)
- David Tran (SK)
- Donna Turner (MB)
- Zeb Aurangzeb (MB)
- Nicole Mittmann (ON)
- Erin Strumpf (QB)
- Robin Urquhart (NS)
- Farah McCrate (NFL)
- Ted McDonald (NB)
- Phillip Champion (PEI)
- Carol McClure (PEI)
- Kim Vriends (PEI)

#### Methods
- **Chair:** Jeff Hoch
- Miguel Hernan (USA)
- Luke Keele (USA)
- Richard Grieve (UK)
- Nicholas Latimer (UK)
- Kelvin Chan
- Jaclyn Beca
- Rinku Sutraddhar
- Petros Pechlivanoglou
- Eleanor Pullenayegum
- Wanrudee Isaranuwatchai
- Michelle Ross
- Lisa Currie
- David Griess

#### Reassessment & Uptake
- **Chair:** Alex Chambers
- Suzanne McGurnn
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- Helen Anderson
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- Carole Chambers
- Erica Craig
- Helen Mai
- Maureen Trudeau
- Anthony Reiman
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- Daniel Sperber
- Tanya Potashnik
- Elena Lungu
- Nevzeta Bosnic
- Basanti Ghosh
- Melissa Hunt
- France Hall
- Michele De Guise
- Sylvie Bouchard
- Erika Brown

#### Engagement WG
- **Chair:** Bill Evans
- Tarry Ahuja
- Michelle Mujoomadar
- Brendalynn Ens
- Marjorie Morrison
- Scott Gavura
- Alex Chambers
- Carol McMahon
<table>
<thead>
<tr>
<th>Acknowledgement – Grant Members</th>
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<tr>
<td>Kelvin Chan (Principal Investigator)</td>
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<td>Michael Sherar (Principal Knowledge User)</td>
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<td>Brent Fraser</td>
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<td>Corrinne Daly</td>
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<td>Michele DeGuise</td>
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<td>Brian Mckee</td>
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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
Value-based decisions from Real World Evidence
Timeline & Next Steps

Year 1: 2017-18
- Environmental scan
- Qualitative interviews
- Develop Working Groups

Year 2: 2018-19
- Framework development
- RWE evaluation 1

Year 3: 2019-20
- Qualitative interviews
- Framework revision
- RWE evaluation 2

Year 4: 2020-21
- Qualitative interviews
- Framework revision
- Knowledge translation

We are here
Objective 2

WORKING GROUPS
Chair: Scott Gavura

RWE PLANNING AND DRUG SELECTION WORKING GROUP
To develop criteria to identify potential drug candidates for real world evaluation and establish provincial infrastructure for RWE
## Proposed Criteria to Identify RWE projects

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>1. Uncertainty in the clinical benefit and/or alignment with patient values</td>
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<td>2. Uncertainty in value for money or feasibility of adoption</td>
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<tr>
<td>3. The identified uncertainties in criteria 1 &amp; 2 are not expected to be resolved by evidence from future planned studies</td>
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<tr>
<td>4. The identified uncertainties in criteria 1 &amp; 2 are not expected to be managed through listing agreements</td>
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</table>
Draft Framework

Step 1: Identification Process

Horizon Scanning

Identification Criteria

Health Canada

HTA (PCCDR/INESSS)

Pricing

Step 2: Prioritization Process

RWE Structure

△ = High Priority

△ = Medium Priority

△ = Potential RWE Question

△ = Selected RWE Question

△ = Dropped out RWE Question

Step 3: Initiate RWE Project

RWE Co.

Project 'A'

Project 'B'

Project 'C'

Stop

Step 4: Re-evaluate Priorities

Payer Co.

△

△

Step 5: Conduct RWE Analysis

RWE Co.

△

△

Step 6: Reassessment

HTA

CanREValue

Value-based decisions from Real World Evidence
Chair: Dr. Claire de Oliveira

DATA WORKING GROUP
To identify strategies for data access across provinces and harmonize data elements relevant for RWE studies

Data Working Group

RWE Planning and Drug Selection WG

RWE Data WG

RWE Methods WG

Drug selection

Collection of Data

Reassessment

Funding Decision

RWE Uptake and Reassessment WG
• Data experts from each province
• Survey to identify databases and data elements needed to conduct RWE studies for each province
• BC, SK and ON also have completed the CPAC-ARCC Avastin project (so their data readiness and feasibilities have been assessed through this work)
## Overall Summary (for Oral drugs)

<table>
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<th>Analysis</th>
<th>BC</th>
<th>AB</th>
<th>SK</th>
<th>MB</th>
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<th>NS</th>
<th>NS</th>
<th>NFL</th>
<th>PEI</th>
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<td>Effectiveness (Survival)</td>
<td>&gt; 12 months</td>
<td>3 – 6 months</td>
<td>6 – 12 months</td>
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<td>&gt; 12 months</td>
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<td>Safety &amp; Toxicity</td>
<td>&gt; 12 months</td>
<td>6 – 12 months</td>
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<td>Budget Impact (payer’s persp)</td>
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<td>Cost-Effectiveness Analysis</td>
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<td>PROs/QOL (e.g. ESAS)</td>
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- **Analysis Can be Completed**
- **Analysis Can be Completed with Caveat**
- **Analysis Cannot be Completed**

*Colors based on current assessment of the data holdings & availability*
Historical Control: Can these analyses be completed in 3 months (to fit pCODR timeline for planning when drug initially being assessed) based on currently available resources?

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<td>Number of patients per year</td>
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<td>At CCMB</td>
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<td>Overall Survival (KM curve)</td>
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<td>At CCMB</td>
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<td>Maybe</td>
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- Analysis Can be Completed in 3 months
- Analysis Can be Completed in 3 months with Caveats
- Analysis Cannot be Completed in 3 months

*Colors based on current assessment of the data holdings & availability*
Chair: Dr. Jeffrey Hoch

METHODS WORKING GROUP
To recommend methods to analyze real world data with methodological rigor (minimal bias).
## Key Methods

<table>
<thead>
<tr>
<th>Problem</th>
<th>Method</th>
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<tr>
<td><strong>Observable confounders</strong></td>
<td>• Regression adjustment</td>
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<td>• Inverse probability weighting</td>
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<td></td>
<td>• Double robust methods</td>
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<td></td>
<td>• Regression on the propensity score</td>
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<td>• Matching</td>
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<td>• Parametric regression on a matched sample</td>
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<tr>
<td><strong>Unobservable confounders</strong></td>
<td>• Instrumental variable</td>
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<td>• Panel data models</td>
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<td></td>
<td>• Structural models</td>
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<td></td>
<td>• Control function</td>
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<td></td>
<td>• Correction approach</td>
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<tr>
<td><strong>Balance treated and control groups</strong></td>
<td>• Inverse probability weighting</td>
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<tr>
<td></td>
<td>• Matching</td>
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<tr>
<td><strong>Natural Experiments</strong></td>
<td>• Difference-in-differences</td>
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<td></td>
<td>• Regression Discontinuity</td>
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</table>
Chair: Alex Chambers

UPTAKE AND REASSESSMENT WORKING GROUP
Uptake and Reassessment WG

RWE Methods WG

RWE Data WG

Drug selection

Collection of Data

Reassessment

Funding Decision

RWE Planning and Drug Selection WG

To develop strategies for implementing RWE results for HTA reassessment and policy making decisions
DRAFT Reassessment Process

Trigger and RWE Data Collection

- Other triggers or pERC rec outlining uncertainty

Out of scope for this WG

Transparency

- Patient and Clinician Engagement

- F/P/T initiated
- Cancer agency or tumour group initiated
- Industry initiated

Industry needs to be incentivized to submit a reassessment

CADTH/INESSS review

Review data to address uncertainty

Type/source of data may be different than initial review

Committee Recommendation

Similar deliberative framework as pERC, with differences in adoption/feasibility.

Committee rec categories

Timeline ~6 months

- Status quo
- Revisit negotiation
- Do not recommend/De-list
- Committee rec categories
- No change

Funding decision

pCPA
Chair: Dr Bill Evans

ENGAGEMENT WORKING GROUP
Engagement Working Group

Chair: **Dr. Bill Evans**, Medical Oncologist, Professor Emeritus, McMaster University

To ensure appropriate input from key stakeholders throughout the framework development
Approach

• Working with CADTH engagement experts
• Initial contacts each of the key stakeholder groups
  – Patient groups (e.g. CCSN webinar)
  – Clinicians (e.g. CAMO executives, CAMO conference)
  – Industry (e.g. JOPT)
  – Payers (e.g. briefing note, CADTH board, PAG, CAPCA)
Timeline & Next Steps

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- Framework development
- RWE evaluation 1

Year 3: 2019-20
- Qualitative interviews
- Framework revision
- RWE evaluation 2

Year 4: 2020-21
- Qualitative interviews
- Framework revision
- Knowledge translation

We are here
Next Steps

• Initiation of Objective 3
• Year 2 In-Person meeting May 29 in Halifax after the ARCC conference
  • Conduct a Mock Reassessment of a RWE case
  • Develop a Protocol for a Multi-Province RWE study
• Develop draft framework recommendations and surveys to seek input/feedback from stakeholders
Ongoing Collaboration and Coordination through CAT

- Regular CAT teleconference to optimize coordination and collaboration
- Multiple members from different agencies and organizations are on both CAT and CanREValue to enhance synergism and coordination
Thank you!

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