Stakeholder Consultation Webinar

Presenters: CanREValue Collaboration

Date: November 6th, 2019

Ontario

CanREValue
Value-based decisions from Real World Evidence

CIHR IRSC
Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

ARCC
Canadian Centre for Applied Research in Cancer Control

CanREValue
Value-based decisions from Real World Evidence

Welcome

Agenda

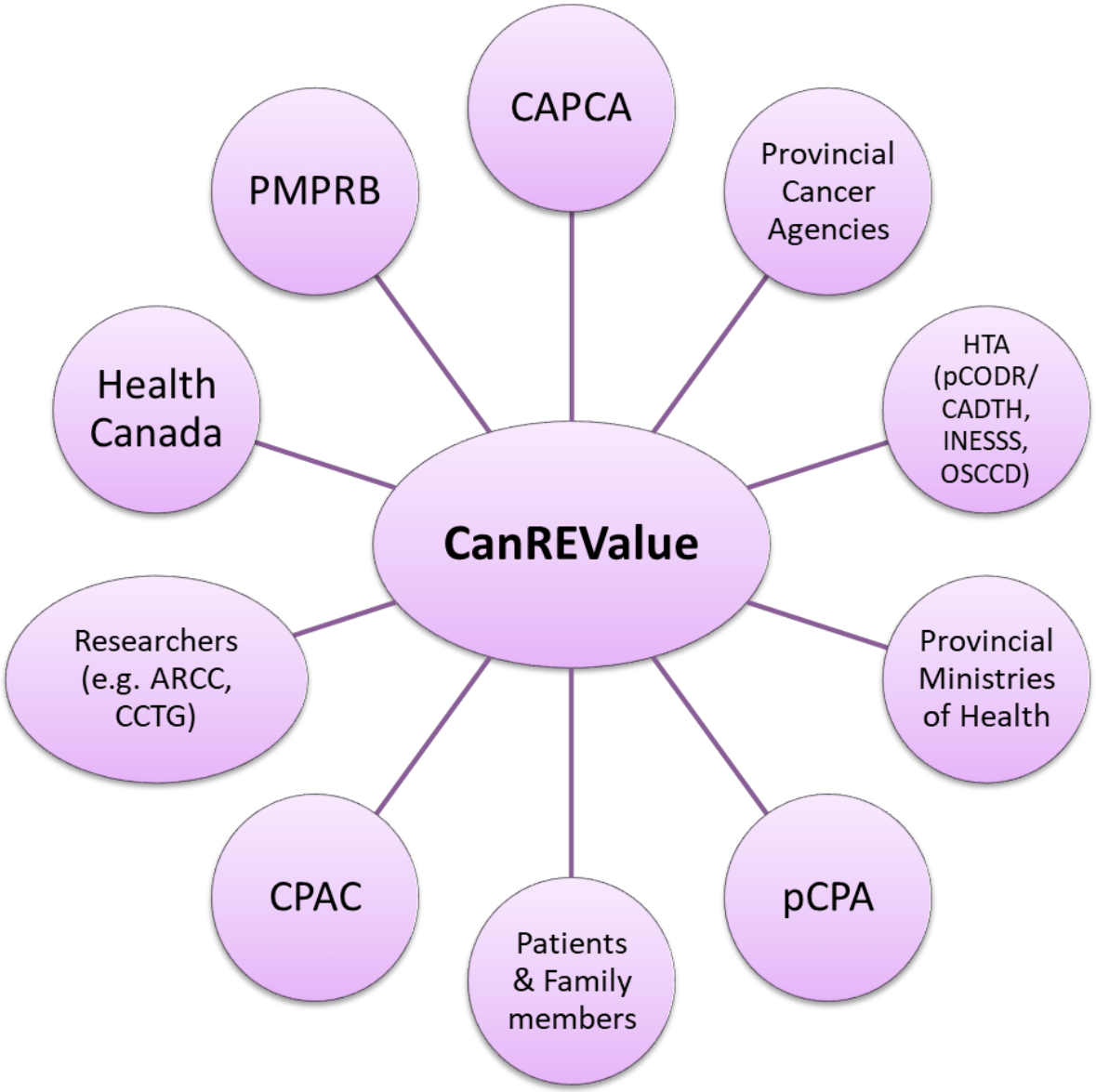
1. Introduction of CanREValue Collaboration
2. Introduction of preliminary framework
3. Stakeholder Consultation process
4. Questions

CanREValue Collaboration

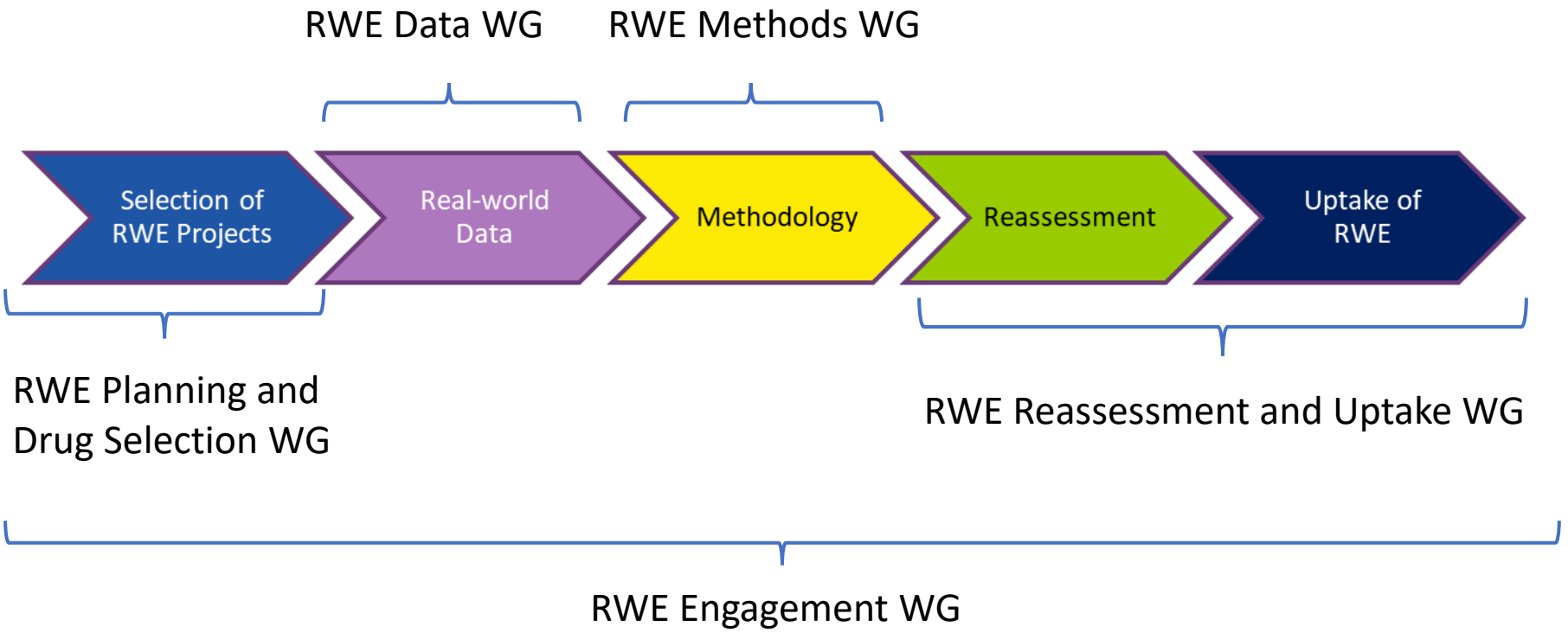
Purpose: To develop a framework for Canadian provinces to generate and use RWE for cancer drug funding decisions in a consistent and integrated manner

- Reassessment of cancer drugs by recommendation-makers
- Refinement of funding decisions or renegotiations/disinvestment by decision-makers/payers across Canada

CanREValue Members



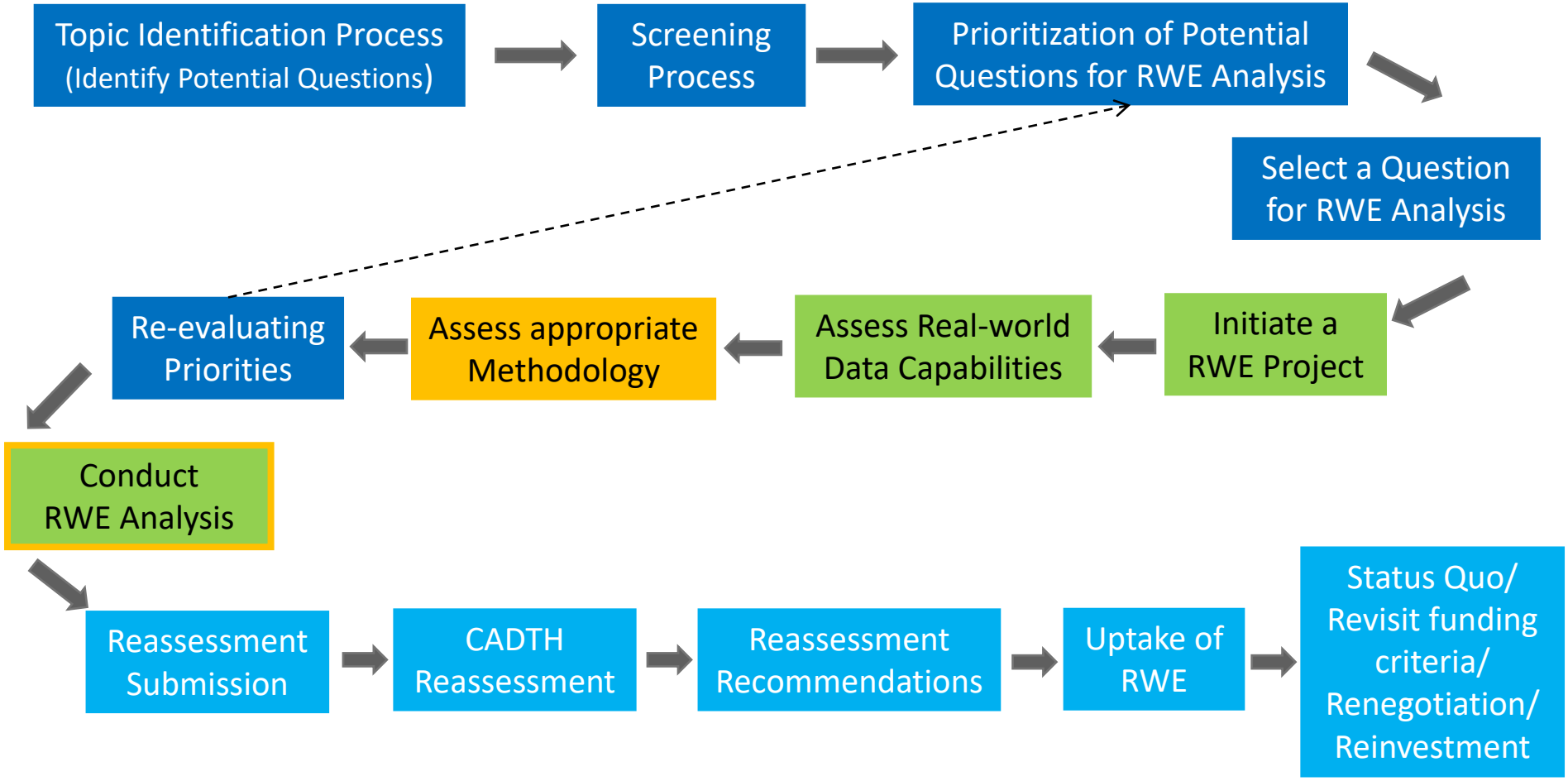
CanREValue Working Groups



Framework Development

- The five Working Groups are tasked with developing the framework
- Through multiple teleconferences and two in-person meetings, the Working Group members have drafted a preliminary framework
- The findings from each Working Group are summarized in interim reports for stakeholders consultation
- Based on the inputs from the stakeholders, the Working Groups will update the preliminary framework through an iterative process

CanREValue Preliminary Framework



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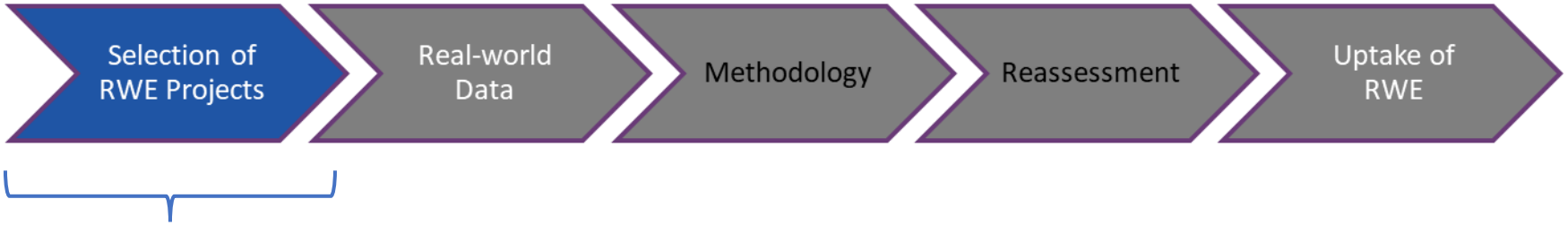
Value-based decisions from Real World Evidence

Planning & Drug Selection Working Group

Chair**: Scott Gavura,** Director, Provincial Drug Reimbursement Programs (Cancer Care Ontario)

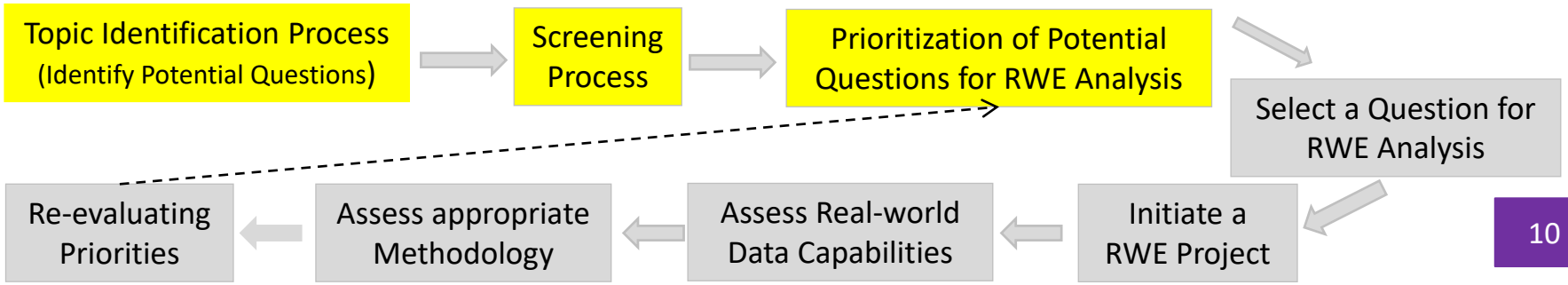


RWE Planning and Drug Selection WG

To develop criteria to identify potential drug candidates for real world evaluation and establish provincial infrastructure for RWE

Developing the framework component

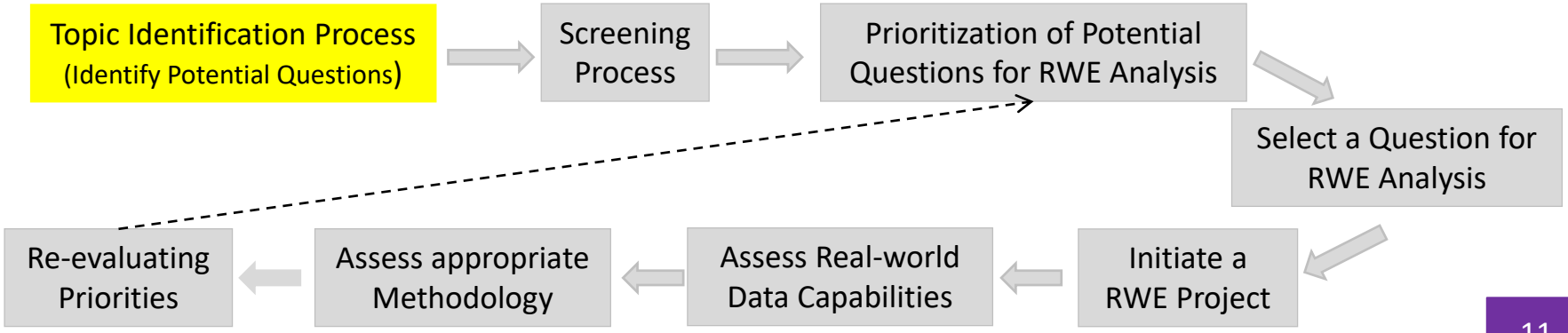
- From Jan 2018 to Oct 2019, the WG members have completed:
  - 5 teleconferences
  - 2 annual in-person meetings
  - 6 surveys
- The working group members have
  - Developed a topic identification process
    - Applied it to identify 3 potential candidate drugs for RWE evaluation
  - Consulted with experts regarding prioritization process development
    - Identified multi-criteria decision analysis (MCDA) approach to priority-setting
    - Established a plan to develop and incorporate an MCDA based tool



Topic Identification Process

Triggers of potential RWE questions:

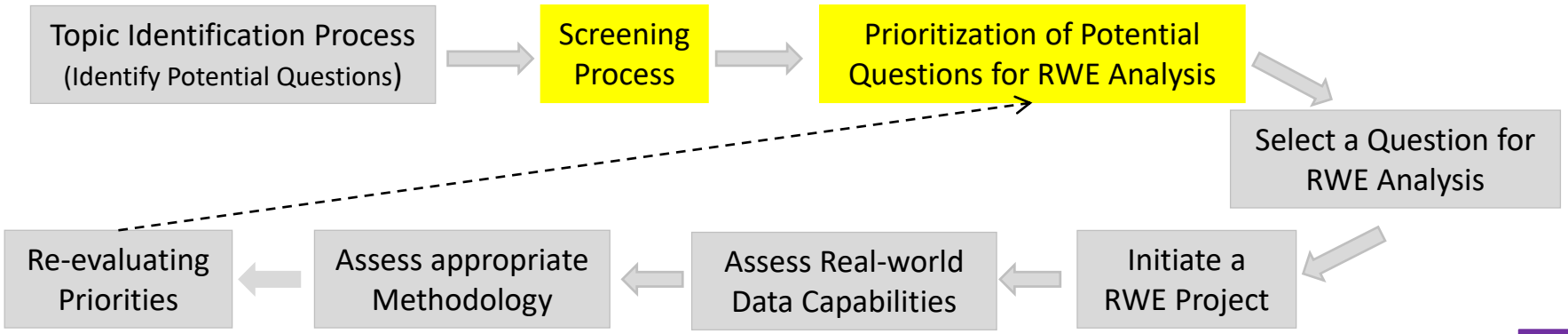
- Trigger 1: Uncertainties in the clinical benefit and/or alignment with patient values.
- Trigger 2: Uncertainties in value for money or feasibility of adoption of the drug
- Trigger 3: The uncertainties identified in triggers 1 & 2 are not expected to be resolved by evidence from future planned studies



Screening & Prioritization Process

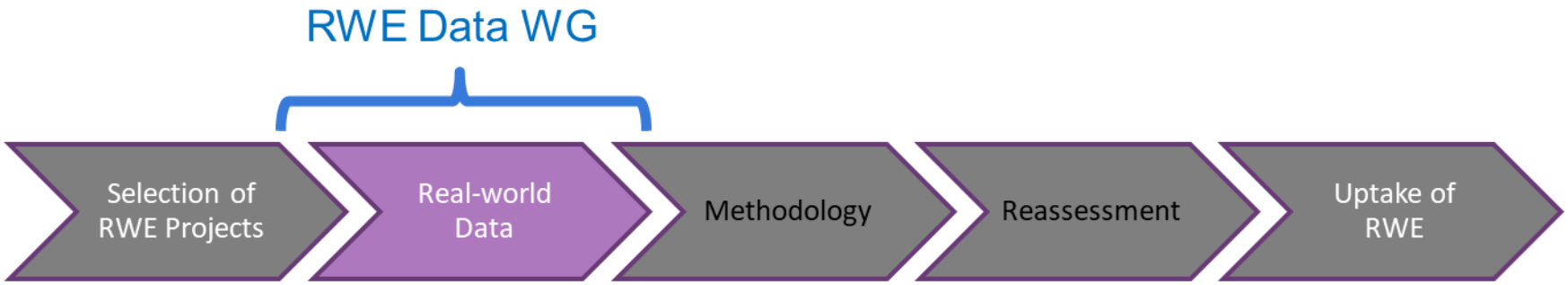
Screening & Prioritization Process – under development

- WG members will develop a multi-criteria decision analysis based rating tool for prioritizing RWE questions
- Two sets of criteria are being considered for prioritization:
  - ✓The importance of the uncertainty identified
  - ✓The likelihood of resolving the uncertainty identified using administrative data

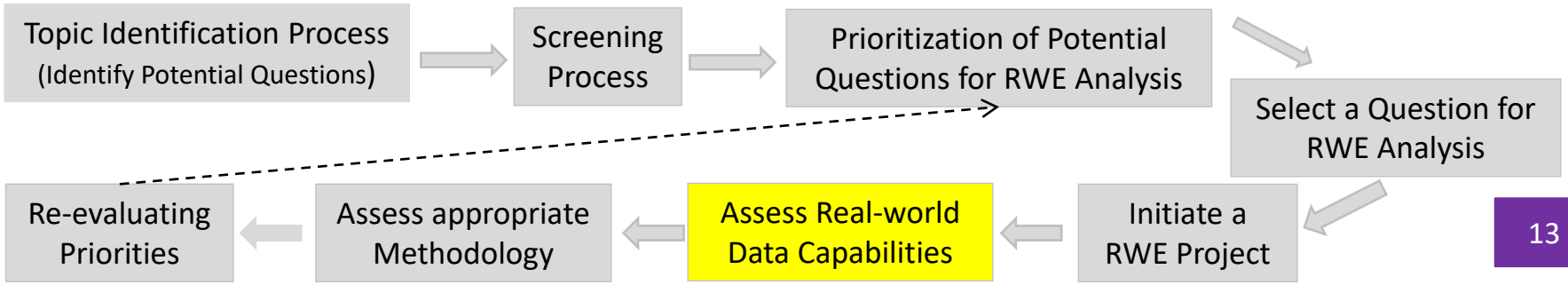


Data Working Group

Chair**: Dr. Claire de Oliveira,** Associate Professor, University of Toronto; Health Economist, Centre for Addiction and Mental Health



To identify strategies to access data across provinces and harmonize data elements relevant for RWE studies



Data holding across provinces

- Data experts from the ten provinces were iteratively consulted from March 2018 to September 2019 to complete the asset review via
  - 4 teleconferences
  - 2 in-person meetings
  - Two surveys
  - Multiple iterative exchanges via emails
- A survey was circulated to identify the main data custodians in each province and the available databases held by each jurisdiction.

Example: Survey on Data Holding

Province	Data Holder	Databases	Date Range	Update Frequency	Notes
Province	Custodian name	Database name	Year – Mar 2019	E.g. annual	
		Database name	Year – to date	E.g. real time	

Data elements held in databases

- Within each database, we requested information on the name of each data element and descriptions.
- Data experts were asked to assess whether the data elements were available and linkable, and any limitations in coverage and/or completeness.

Example: Survey on Data element

Province	Data Element	Description	Database Name	Available & Linkable	Notes
Province	Age	Patient age	Cancer Registry	Green	
Province	Drug cost	Cost of drug	Treatment database	Yellow	

Data available and linkable

Data available and linkable with caveat

Data not available or linkable

Capability to conduct real-world analyses

- Data experts from each province was asked to assess their capability to conduct a real-world study on different outcomes of interest
- Capability for conducting a RWE study varies by:
  - Type of outcome examined
  - Type of oncology drug (based on route of administration)
  - Province

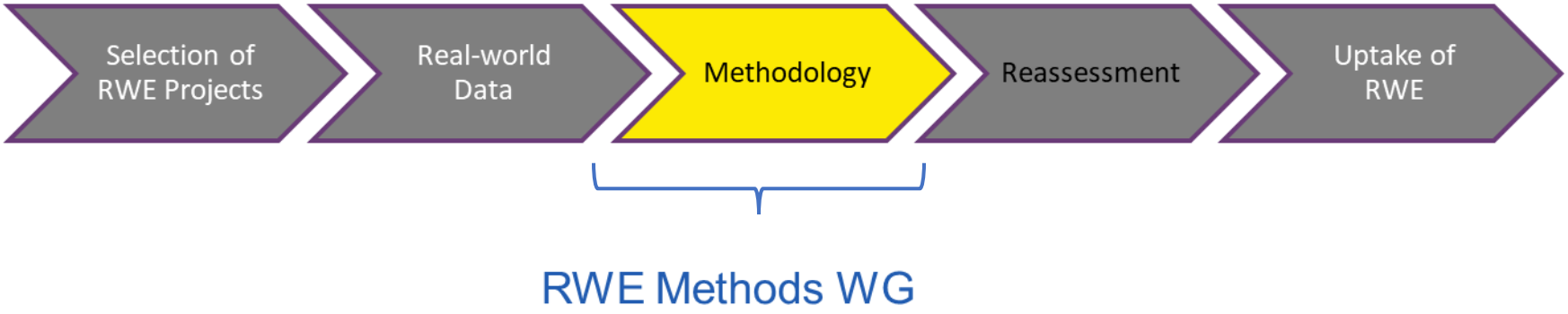
Intravenous Cancer Drug Analysis	BC	AB	SK	MB	ON	QB	NB	NS	NL	PEI
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (payer's perspective)										
Cost-Effectiveness Analysis										
PROs/QOL (e.g. ESAS)										

Oral Cancer Drug Analysis	BC	AB	SK	MB	ON	QB	NB	NS	NL	PEI
Effectiveness (survival)										
Safety & Toxicity										
Budget Impact (payer's perspective)										
Cost-Effectiveness Analysis										
PROs/QOL (e.g. ESAS score)										

Analysis can be completed
Analysis can be completed with caveat
Analysis cannot be completed

Method Working Group

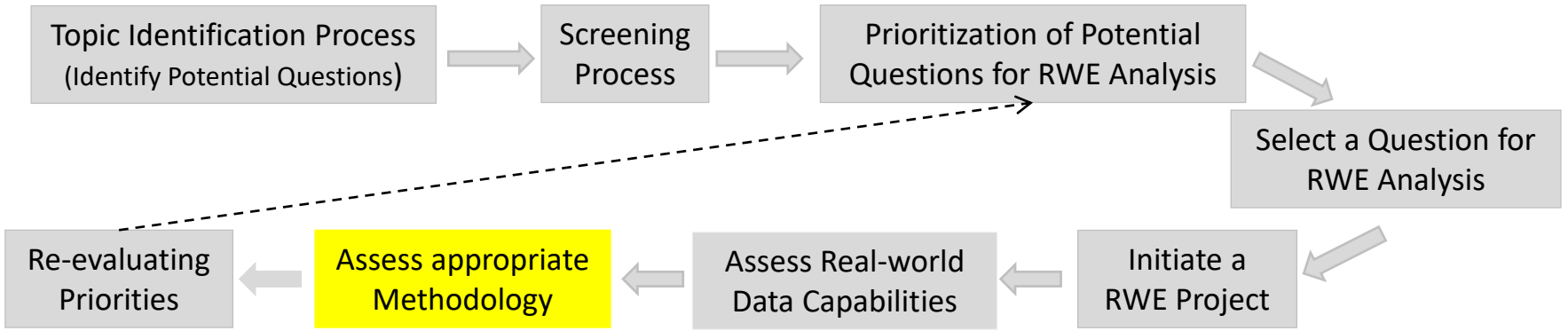
Chair**: Dr. Jeffrey Hoch,** Professor and Chief, Division of Health Policy and Management, Department of Public Health Sciences, UC Davis; Associate Director, Center for Healthcare Policy and Research



Generating RWE from RWD

Two stages of analysis must be conducted to generate RWE from RWD

1. Adjusting for biases between exposure and controls
2. Statistical analysis to examine associations between exposure and outcome



Identifying the appropriate methods

- The WG has held 2 teleconferences and 2 in-person meetings
- The group has adopted an outcomes-focused approach
  - Papers will focused on methods to evaluate different outcomes (e.g. survival)
- We have a paper exploring different approaches for survival analysis

Adjusting for biases – checklist of methods

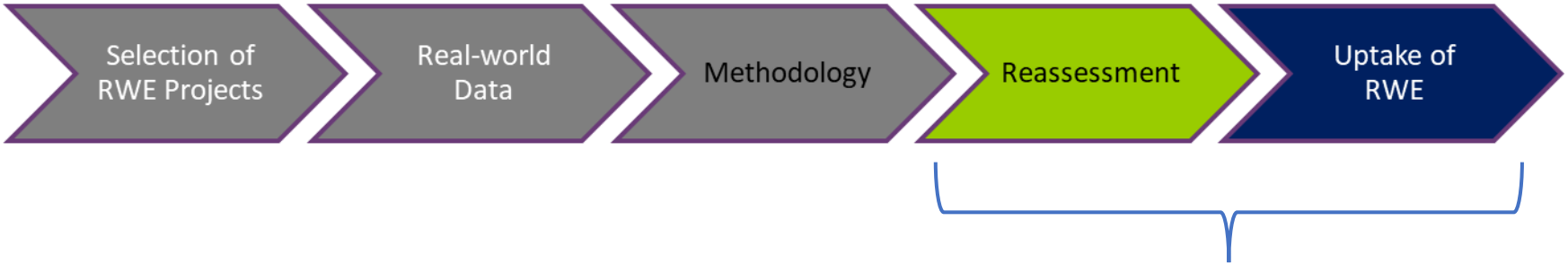
- ❑ Multivariable-based regression
- ❑ Propensity score related analysis
- ❑ Instrumental variable methods
- ❑ Other methods

Reassessment & Uptake Working Group

Co-Chairs:

Erica Craig, Provincial Pharmacy Director, New Brunswick Cancer Network

Brent Fraser, Vice President of Pharmaceutical Reviews, Canadian Agency for Drug and Technologies in Health



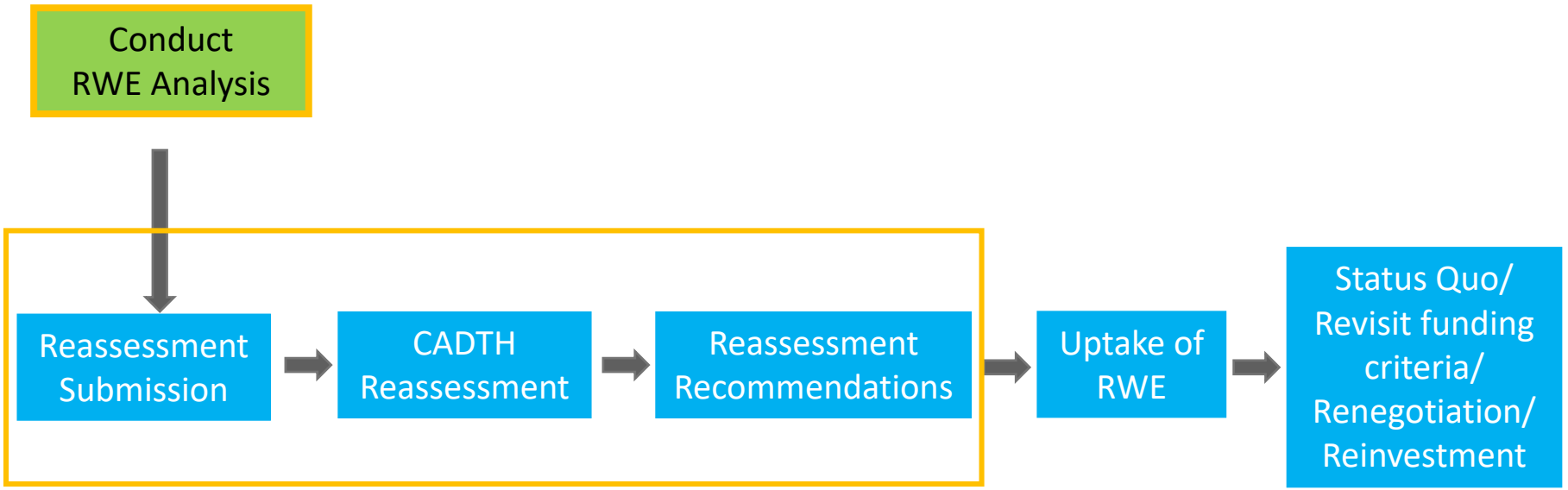
RWE Reassessment and Uptake WG

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

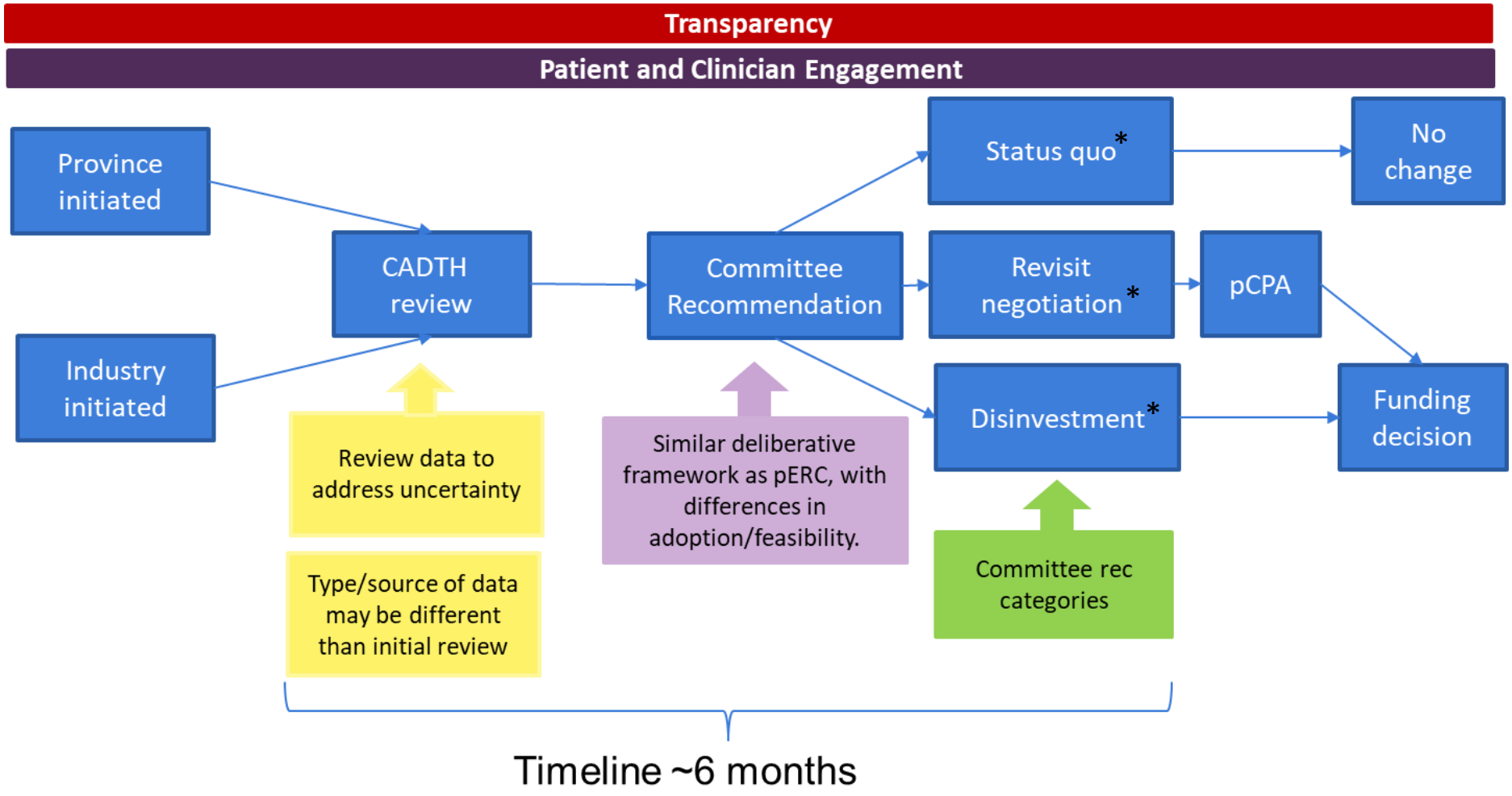
Developing the framework component

- Between Jan 2018 to October 2019, the working group members have completed:
  - 4 teleconferences
  - 2 annual in-person meetings
  - 4 surveys
  - 1 mock reassessment session
- The working group members have
  - Developed a draft reassessment process
  - Evaluated the process by conducting a mock reassessment session
    - Members were presented with real-world evidence from a funded cancer drug and were asked to
      I. Deliberate upon the evidence presented and make a recommendation
      II. Evaluate the reassessment process (e.g. what type of evidence is needed during a reassessment)

Reassessment Process

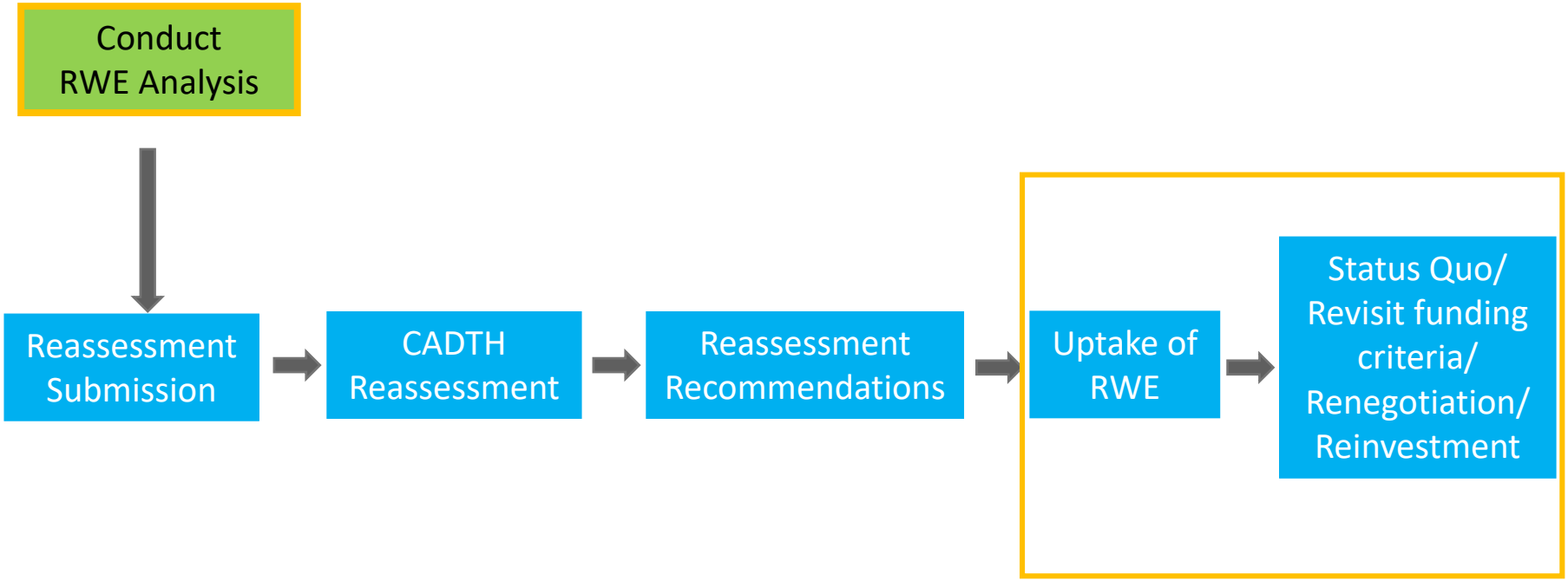


Reassessment Process



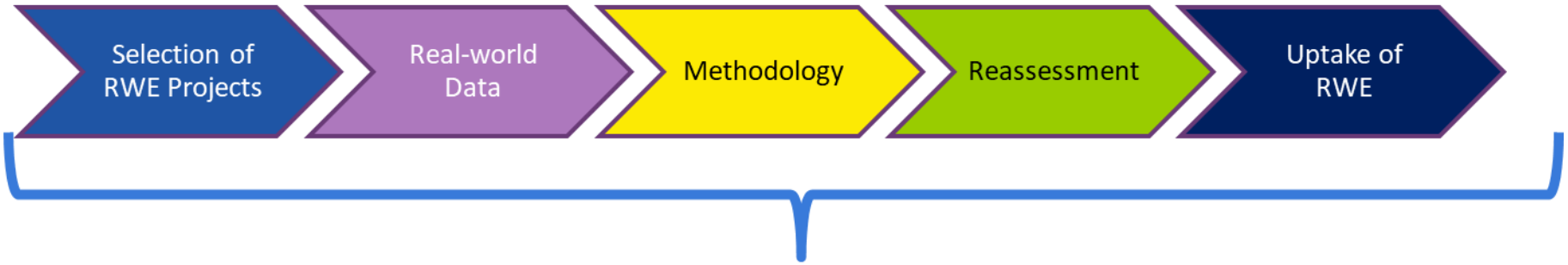
*Based on the learnings from the mock reassessment, the WG members are working revising the recommendation categories

Uptake of RWE



RWE Engagement Working Group

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



To ensure appropriate input from key stakeholders cross-jurisdictionally, at all steps of the framework development

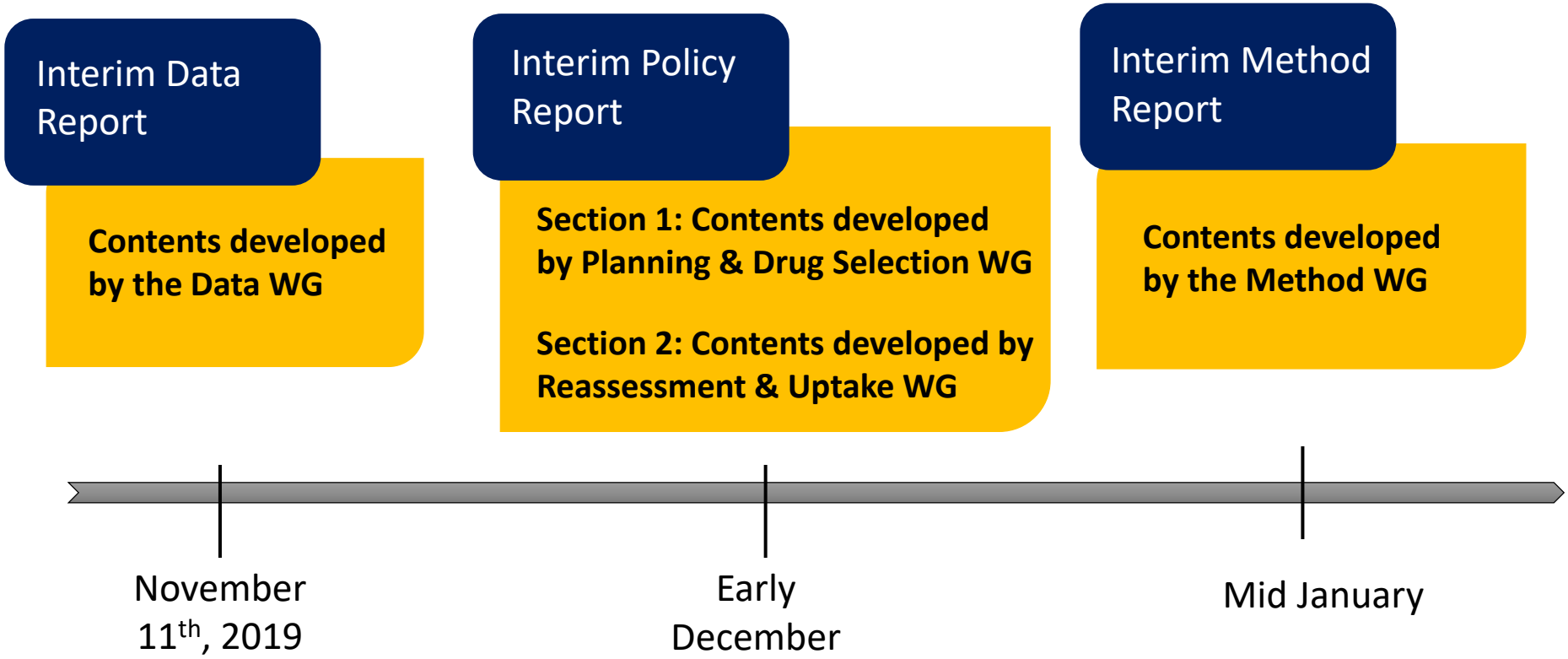
Stakeholder Consultation

- We aim to seek inputs from the public and all stakeholders on the preliminary framework process
- A series of interim reports were drafted to outline the different components of the framework
  - ❑Report 1: Interim Data Report
  - ❑Report 2: Interim Policy Report
  - ❑Report 3: Interim Method Report

Feedback Process

- Interim Report can be accessed via:
  - I. CanREValue Website
    - ❖Reports will be posted on the website: https://cc-arcc.ca/canrevalue-kt
    - ❖Under the tab labelled "CanREValue Working Group Reports"
  - II. Register with CanREValue mailing list
    - ❖Sign up at: CanREValue@cc-arcc.ca or follow @CanREValue
    - ❖Reports will be send out to the mailing list
- Feedback can be provided in the feedback form
  - ➢ Feedback forms will be included with the report
  - ➢ Accept feedback from all stakeholders through written submission
  - ➢ Feedback (maximum 5 pages) will be accepted for 1 month after release of draft report
- Updated report will be released with reply to all feedback
  - ➢ All replies and comments may be made public

Timeline for report release



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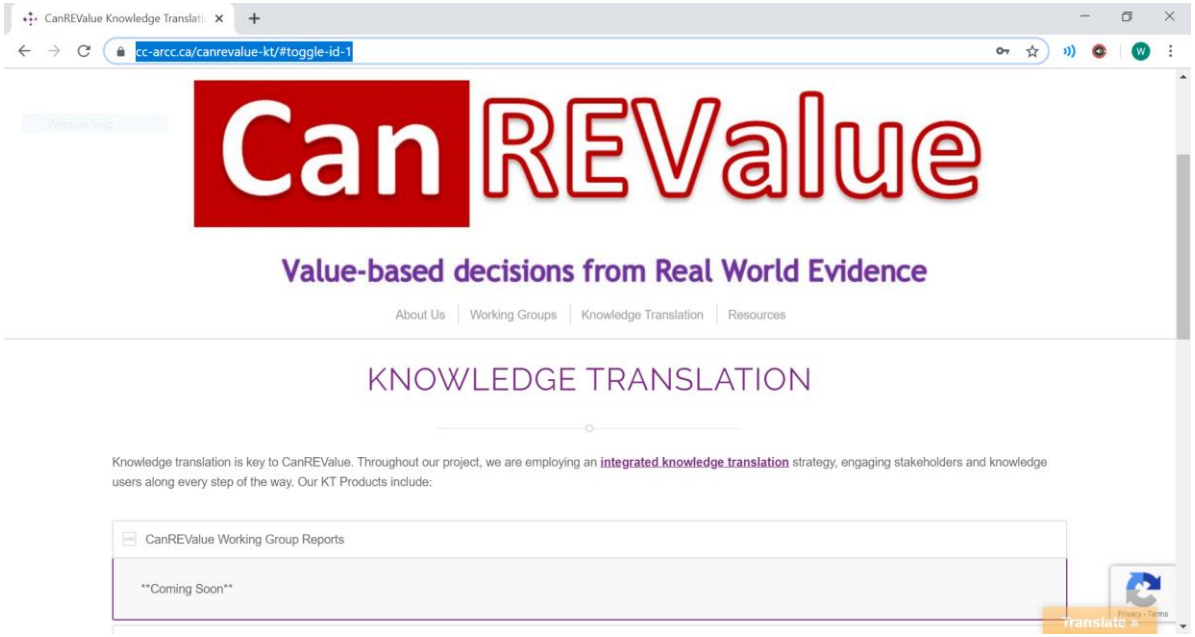
Questions?

Reports can be accessed one of the following ways:

- Register for the CanREValue mailing list (CanREValue@cc-arcc.ca)
- Visit the CanREValue website (https://cc-arcc.ca/canrevalue-kt)



Next steps

- Access the Interim reports
- Provide feedback to the Interim reports
- If you have any questions, please email us at CanREValue@cc-arcc.ca