CADTH Drug Portfolio Information Session
Patient Groups and Clinicians
OCTOBER 26, 2016
Welcome

DR. BRIAN O’ROURKE
PRESIDENT AND CHIEF EXECUTIVE OFFICER
Session Objectives

• CADTH is committed to ongoing, two-way communication with stakeholders
• Today is an opportunity to:
  o Share program updates from the CADTH Drug Portfolio
  o Introduce new initiatives
  o Answer questions and discuss key issues
CADTH Pharmaceutical Reviews: VP and Directors

- Mr. Brent Fraser  
  Vice-President, Pharmaceutical Reviews, CADTH

- Dr. Trevor Richter  
  Director, CADTH Common Drug Review and Optimal Use

- Ms. Alexandra Chambers  
  Director, CADTH pan-Canadian Oncology Drug Review
## Overview of the Agenda

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>LEAD</th>
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<tbody>
<tr>
<td>Welcome</td>
<td>Brian O’Rourke</td>
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<tr>
<td>CADTH Drug Portfolio – Overview and Updates</td>
<td>Alexandra Chambers</td>
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<tr>
<td></td>
<td>Brent Fraser</td>
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<td>Trevor Richter</td>
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<tr>
<td>CADTH Scientific Advice Program</td>
<td>Amy Sood</td>
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<tr>
<td>Update on Patient Engagement Processes</td>
<td>Ken Bond</td>
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<tr>
<td>Update on Health Economic Guidelines</td>
<td>Karen Lee</td>
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<tr>
<td>Companion Diagnostics</td>
<td>Sohail Mulla</td>
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<tr>
<td>Health Technology Management</td>
<td>Brian O’Rourke</td>
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<tr>
<td>Open Forum</td>
<td>CADTH Team</td>
</tr>
<tr>
<td>Wrap Up</td>
<td>Brian O’Rourke</td>
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</table>
CADTH Drug Portfolio: Overview and Updates

BRENT FRASER
VP, PHARMACEUTICAL REVIEWS

ALEXANDRA CHAMBERS
DIRECTOR, pCODR

TREVOR RICHTER, PhD
DIRECTOR, CDR AND OPTIMAL USE
CDR / pCODR update

• Notices issued in March 2016 regarding procedural changes:
  • Revised Recommendation Framework
    • Effectively aligned pCODR and CDR frameworks
    • No immediate plans for changes, but the framework may continue to evolve as a result of changing environments
    • Unmet need scenario
**CDR / pCODR update**

- **Unmet Need**

  - If available evidence reasonably suggests that a drug could substantially reduce morbidity and/or mortality associated with the disease, and there are practical challenges in conducting robust clinical trials and pharmaco-economic evaluations, and in the presence of significant unmet medical need, the committees may issue a recommendation to reimburse with clinical criteria and/or conditions despite uncertainty regarding the clinical and/or economic evidence.

  - Significant unmet clinical need is identified on a population or subpopulation basis (i.e., not on an individual basis) through the CDR and pCODR processes, including the opinion of clinical experts and patients.
Unmet Need

The ‘unmet need’ scenario may address issues common to drugs for rare and ultra-rare diseases.

Although there is uncertainty with the clinical evidence, the available evidence must reasonably suggest that the drug could substantially reduce morbidity and/or mortality associated with the disease.

If there are no organized patient groups that could represent the interests of patients, submissions from individual patients can be considered eligible for consideration by the committee.
CDR / pCODR update

• 120 day notification period
  • Compliance at 100%
  • Allows for better planning and efficient resource use
  • Potential issues with changes in dates due to NOC changes

CDR / pCODR alignment

• Ongoing operational changes
  • Conflict of interest
  • Consistent communications on website
  • IT processes
CDR / pCODR update

Biosimilars:

- Ongoing discussions with drug plan and cancer agency representatives regarding the current review process
  - Want to ensure the current review process provides the greatest value
  - Information regarding “switching” data and timeliness of recommendations are very important
  - If changes made to the existing framework, there will be opportunities to comment as per usual process
- Developing general information pamphlet for clinicians and patients regarding biosimilars
CDR / pCODR update

Engagement with pCPA

• Increased efficiencies with HTA / Payer processes
• pCPA invited to attend pre-submission meetings and operational meetings
• Opportunity to identify potential implementation issues for consideration in developing recommendations
• Opportunity for CADTH to provide additional support to pCPA processes as required
• Important for committee members to have feedback from the negotiations
• CADTH does not have access to non-public agreement terms
CDR update

- Provision of CDR Review Team’s Responses
- Revised Procedure for Voluntary Withdrawal
pCODR update

- Pipeline information
  - Increasingly important for planning for CADTH as well as drug plans
  - Thank you for responding to survey
## CDR Reviews Completed

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Business Plan Range</th>
<th># Reviews Conducted</th>
<th>% Increase in reviews conducted over previous year</th>
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<tbody>
<tr>
<td>2011-2012</td>
<td>30-35</td>
<td>27</td>
<td>N/A</td>
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<tr>
<td>2012-2013</td>
<td>30-35</td>
<td>25</td>
<td>-7%</td>
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<tr>
<td>2013-2014</td>
<td>30-35</td>
<td>30</td>
<td>20%</td>
</tr>
<tr>
<td>2014-2015</td>
<td>30-35</td>
<td>37</td>
<td>23%</td>
</tr>
<tr>
<td>2015-2016</td>
<td>40-45</td>
<td>49</td>
<td>32%</td>
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</table>
# pCODR Reviews Completed

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Business Plan Range</th>
<th># Reviews Conducted</th>
<th>% Increase in reviews conducted over previous year</th>
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<tr>
<td>2011-2012</td>
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<td>N/A</td>
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<tr>
<td>2012-2013</td>
<td>N/A</td>
<td>12</td>
<td>1100%</td>
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<tr>
<td>2013-2014</td>
<td>N/A</td>
<td>19</td>
<td>58%</td>
</tr>
<tr>
<td>2014-2015</td>
<td>15-20</td>
<td>9</td>
<td>-53%</td>
</tr>
<tr>
<td>2015-2016</td>
<td>20-25</td>
<td>22</td>
<td>144%</td>
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# CDR and pCODR Performance Metrics

<table>
<thead>
<tr>
<th>Performance Metric</th>
<th>Target</th>
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<tbody>
<tr>
<td><strong>CDR Performance metrics</strong></td>
<td></td>
</tr>
<tr>
<td>• 10 business day screening metric</td>
<td>100%</td>
</tr>
<tr>
<td>• 180 calendar days review metric</td>
<td>100%</td>
</tr>
<tr>
<td><strong>pCODR Performance Metrics</strong></td>
<td></td>
</tr>
<tr>
<td>• 5 business day screening metric for submissions</td>
<td>100%</td>
</tr>
<tr>
<td>• 10 business day screening metric for re-submissions</td>
<td>100%</td>
</tr>
<tr>
<td>• 180 calendar day review metric</td>
<td>100%</td>
</tr>
</tbody>
</table>
pERC Final Recommendation

pCODR has issued 72 notification to implement as of September 30, 2016

- 9 (13%) recommend to reimburse
- 50 (69%) recommend to reimburse with clinical criteria and/or conditions
- 13 (18%) do not recommend to reimburse
CDEC Final Recommendation

CDR has issued 389 Recommendations as of September 30, 2016

- 39 (10%) recommend to reimburse
- 198 (51%) recommend to reimburse with clinical criteria and/or conditions
- 142 (36%) do not recommend to reimburse
- 10 (3%) do not list at the submitted price
CDEC Final Recommendation

CDR has issued 91 Recommendations between January 2015 and September 30, 2016

- 3 (3%) recommend to reimburse
- 74 (82%) recommend to reimburse with clinical criteria and/or conditions
- 13 (14%) do not recommend to reimburse
- 1 (1%) do not list at the submitted price
Therapeutic Reviews

CADTH
Therapeutic Reviews

Therapeutic Reviews are undertaken to address the following:

• Issues regarding effectiveness, either of the class as a whole or of the relative effectiveness of agents within the class
• Issues regarding safety, either of the class as a whole or of the relative effectiveness of agents within the class
• Issues that affect resource use concerns regarding inappropriate utilization of agents within a class.

To inform drug listing and drug policy decisions and to encourage optimization of drug therapy.
CADTH Therapeutic Reviews

- A review of the most recent, publicly-available evidence on:
  - A drug class (e.g. biologics for rheumatoid arthritis)
  - A therapeutic category (e.g., drug therapies for RRMS)

- Perspective of the review: public policy and population health

- Multiple opportunities for stakeholder input throughout the process

- Outputs:
  - Clinical and economic review reports
  - Recommendations (system-level recommendations)
  - Knowledge Mobilization Tools
Cadth Therapeutic Reviews

- Off label use
  - Will continue to be included in TRs where appropriate
  - Use will be confirmed through clinical evidence, information provided by clinical experts and information from drug plans e.g., claims information
CADTH Therapeutic Reviews

• Proposed change
  • CADTH will issue an Update, with opportunity for feedback noting that the recommendations for TRs will supersede CDEC recommendations for individual drugs
    • Usual process for requiring a Request for Advice from the drug plans to update individual recommendations will not be required
    • For complicated TRs, drug plans may require clarification for some individual drug product recommendations as needed
Identification of Topics for Therapeutic Reviews

CADTH Staff (PDOs, LOs)
Policy Makers, Government
CDEC, CDR
Environmental Scans, Horizon Scans

Topic Identification
Topic Selection Criteria

- **Relevance**
  - Jurisdictional need

- **Timeliness**
  - Meet requested timelines
  - If required to be aligned with CDR review
  - Partnerships available

- **Impact**
  - Clinical practice
  - Population
  - Cost impact on healthcare system
  - Duplication of effort
  - Scope and extent of customer base
  - Anticipated uptake of recommendations
Priority Areas

• Project themes (Drug Portfolio):
  • Cardiovascular & Cerebrovascular Diseases
  • Metabolic and Endocrine Disorders (including Diabetes Mellitus)
  • Infectious Diseases
  • Mental Health
  • Neurological Diseases
  • Emerging Issues (e.g., prescription drug abuse, anti-VEGF drugs for retinal conditions)
## Examples of Projects Under Consideration

<table>
<thead>
<tr>
<th>Priority Area</th>
<th>Topics for Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular &amp; Cerebrovascular Diseases</td>
<td>PCSK9 Inhibitors for the treatment of hypercholesterolemia</td>
</tr>
<tr>
<td>Mental Health</td>
<td>Treatments for alcohol dependence, ADHD, Antipsychotics</td>
</tr>
<tr>
<td>Neurological Diseases</td>
<td>Peripheral Neuropathic Pain</td>
</tr>
<tr>
<td>Emerging Issues (e.g., inflammatory conditions)</td>
<td>Rheumatoid Arthritis, Crohn’s Disease, COPD</td>
</tr>
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Clinician Input Pilot
Pilot for Clinician Input & Feedback

• Objective
  • To provide an opportunity for more oncologists to provide input and feedback on pCODR drug submissions

• Why?
  • To expand participation in the pCODR process to involve oncologists in the community
  • Enable cancer specialists to provide input on the value or a drug and its place in therapy
Overview of pCODR Review Process

INPUT
- Provincial Advisory Group
  - Patient Advocacy Group
    - Registered Clinician

REVIEW
- Review Team
  - pERC
    - Initial Recommendation

DELIBERATIONS
- pERC
  - Final Recommendation

FEEDBACK
- Provincial Advisory Group
  - Patient Advocacy Group
    - Registered Clinician
      - Submitter
Pilot for Clinician Input & Feedback

• Who is eligible to participate?
  • Actively practicing oncologists, who are members of a provincial cancer agency or similar body or a national cancer organization

• How do clinicians participate?
  • Similar to patient groups, registered clinicians have 10 business days after pCODR receives a drug submissions to submit input following a standard template
  • Input received from clinicians is summarized in pCODR reports
How is clinician input used?

- Economic re-analysis considers factors identified in clinician input.
- Clinical Guidance Panel incorporates clinician input into their interpretation.
- Considered in systematic review protocol.
- pERC reviews clinician input alongside other review information during their deliberations.
What we’ve learned so far

• There has been a lot of interest by many stakeholders groups in the clinician input pilot
  • Outreach through presentations to groups, social media, promotion through patient groups and jurisdictions
    • We welcome your support to promote clinician input, send any questions to us

• Clinicians have formed networks to provide joint group input
# Clinician Input as of September 2016

<table>
<thead>
<tr>
<th>Registered Clinicians</th>
<th>74</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual clinician input received</td>
<td>8</td>
</tr>
<tr>
<td>Group clinician input received</td>
<td>7</td>
</tr>
<tr>
<td>Reviews with clinician input</td>
<td>10 (out of 15 possible)</td>
</tr>
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CADTH Scientific Advice Program

AMY SOOD, PharmD.
SCIENTIFIC ADVISOR
CADTH Scientific Advice Program

- Established January 2015

- Advice on early drug development plans from a Canadian health technology assessment (HTA) perspective

- Voluntary, fee-for-service, confidential, non-binding
Why CADTH Scientific Advice?

Help generate complete and relevant evidence for a reimbursement recommendation → Reduce uncertainty

Opportunity for CADTH to influence evidence generated for Canadians and worldwide → Recommendations based on better evidence

Timely access for patients
Why CADTH Scientific Advice?

Key strengths of our program:

- Advice is presented at the 3 hour face-to-face meeting allowing for meaningful 2-way dialogue

- Timeframe of 14 weeks from Briefing Book submission to presentation of advice; flexibility to customize timelines

- Advice is well researched and actionable
## Current Experience

### Scientific Advice Meetings

<table>
<thead>
<tr>
<th>Completed</th>
<th>Scheduled</th>
</tr>
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<tbody>
<tr>
<td>July 23, 2015</td>
<td>December 14, 2016</td>
</tr>
<tr>
<td>November 17, 2015</td>
<td>June 2017</td>
</tr>
<tr>
<td>March 31, 2016</td>
<td></td>
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<tr>
<td>May 4, 2016</td>
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Feedback to date has been overwhelmingly positive
Eligibility

- New drug products
- Existing drug products with new indications
- Drugs for rare diseases
- Oncology products
Types of questions

• Trial population; subgroups
• Trial design
• Comparators
• Outcomes
• Health-related quality of life measures
• Economic analysis
Patient Involvement

- Individual patient is identified through patient groups
- 1 hour interview; standardized questions
- Written summary of interview included in the record of scientific advice

Experience to date:
- Patient perspectives have been most important in the development of advice regarding outcomes and quality of life measures
Expert Involvement

- 3 Teleconference team meetings
- Multiple time points for written feedback on draft responses
- Participation in open dialogue at face-to-face meeting
- Agreement on final written record of scientific advice
Future Directions

Exploring Broader Service Offerings:

• Expanding scope

• Parallel Scientific Advice (Regulatory/HTA)
  • Preliminary discussions with Health Canada

• Joint HTA advice
  • Interest from NICE
www.cadth.ca/scientificadvice

scientificadvice@cadth.ca

requests@cadth.ca
Update on Patient Engagement Processes

KEN BOND
DIRECTOR, PATIENT ENGAGEMENT AND INTERNATIONAL AFFAIRS
Overview

- Therapeutic Review Process
- CCAN HTA Patient Engagement Navigator Project
- Patient Group Input Template Revisions
- Collaboration and Outreach
Therapeutic Review Process

*Patient Group Input*
- Tailored templates with specific prompts related to policy / research question asked by Therapeutic Review
- 1 month to complete

*Patient groups provide feedback on*
- Proposed project scope
- Included studies
- Draft science report
- Draft recommendations
CCAN Patient Engagement Navigator

• Collaborative initiative with in-kind support from CADTH
• Engage and inform patient groups about the pCODR process
• Help patient groups prepare drug review submissions
• Provide opportunity for patients to understand how their input are used in pERC recommendations
Input and Feedback

• Identify the outcomes upfront that are most important to patients
• Understand insights and information unavailable through other sources
• Help CADTH reviewers interpret and apply clinical trial data
• Offer specific ways that current therapies may fall short to help potential value of new therapies
• Offer real world scenarios about the drug under review
Patient Input to Pharmaceutical Reviews

532 patient input submissions from 137 patient groups

Many groups answer multiple calls for patient input

June 2010 – June 2016
Patient Input Template Revisions

- Based on analysis how input is used, comments from patient groups, CADTH reviewers and committee members
- Common wording and expectations
- Greater focus on potential benefits and risks of treatment than on description of condition
- Caregivers perspectives more consistently collected
- Identical conflict of interest declaration
Collaboration and Outreach

- CCAN Workshop: Role of Health Technology Assessment in Cancer Drug Funding Decisions, October 25, 2016
- HTAi Patient and Citizen Involvement Interest Group Meeting Manchester, UK, October 19-21, 2016
- International Perspectives on Patient Involvement in HTA published by Springer (2 chapters)
- CADTH 2017 Symposium
Updating the Guidelines for the Economic Evaluation of Health Technologies: Canada

KAREN LEE
DIRECTOR, HEALTH ECONOMICS

CADTH
Guidelines for the Economic Evaluation of Health Technologies

• Provide best practices for conducting economic evaluations.
• Used to standardize and facilitate economic evaluations.
• Help promote the use of high-quality economic evaluations.
Guidelines for the Economic Evaluation of Health Technologies

Updating the Guidelines has been a priority for CADTH:

- Convened Health Economic Working Group.
- Reviewed topic areas.
- Commissioned technical reports.
- Conducted stakeholder-input survey.
Guidelines for the Economic Evaluation of Health Technologies

- Updated topics.
- Consolidated draft.
- Received peer review feedback.
- Discussed proposed revisions with Health Economic Working Group.
- Posted draft for stakeholder feedback, Oct 28, 2016

4th edition expected spring 2017
Stay Informed

• Subscribe to our Health Economic Update e-newsletter
  • www.cadth.ca/subscribe

• Follow CADTH on social media

• Attend health economic education session:
  • Introduction to Health Economics (Nov 2016)
  • Health Economics: Basic Concepts (Spring 2017)
  • Health Economic Technical Workshops (CADTH Symposium)
Introduction to Health Economics
Scott Klarenbach, M.D.
November 28, 2016, Ottawa, ON
1:00 p.m. to 2:30 p.m. EST
Attend in person or via the web
Proposed Process for the Assessment of Companion Diagnostic Tests at CADTH

SOHAIL MULLA, PhD
SCIENTIFIC ADVISOR
Personalized medicine

“Tailoring of... interventions to the characteristics of an individual...”

1Personalized Medicine Working Group (Health Canada)
Companion diagnostic (CDx) tests

- Likely to benefit from a specific therapy
  - Biomarker present
    - Happy face
  - Biomarker absent
    - Sad face
- Unlikely to benefit from a specific therapy
CDx test market

Value of global CDx test market

Projected CAGR ~20%

New oncology drugs with CDx tests

Various sources
2015 pCODR survey
Public reimbursement of CDx tests in Canada

• Not well-defined

• Funding mechanisms vary by jurisdictions

• Important need for pan-Canadian leadership

• CADTH stakeholders support centralized structure
Objective

To provide evidence-based advice on the public reimbursement of a CDx test associated with a given drug.
Work to date

2014
- CADTH Environmental Scan

2015
- Policy Forum Wider Table on Personalized Medicine

2016
- Consultations:
  - Australia
  - Canadian jurisdictional representatives
  - CADTH drug portfolio committees
<table>
<thead>
<tr>
<th>Questions arising from consultations</th>
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<tbody>
<tr>
<td><strong>WHO</strong></td>
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<td><strong>WHAT</strong></td>
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<td><strong>WHEN</strong></td>
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<td><strong>WHERE</strong></td>
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<td><strong>WHY</strong></td>
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Approach to proposed process

• Guided by consultations with stakeholders

• Builds on existing CADTH programs and services

• **Dynamic** and **adaptable** to jurisdictional needs over time
Current process

Recommendation on drug by CDEC or pERC

*From:
- Clinicians
- Participating jurisdictions
Proposed process

- Clinical evidence
- Economic evidence
- Patients & additional input*

*From:
- Clinicians
- Participating jurisdictions

Recommendation on drug + evidence-based advice on CDx test by CDEC or pERC
Evidence-based advice

Formal recommendation

Informal consideration
Proposed process: overview

- One application (drug + CDx test) to be submitted
- Drug + CDx test manufacturers (if different) will need to collaborate
Proposed process: overview

120 days

- Mandatory advanced notification
- Application submitted
- Application accepted for review
- CDR or pCODR review
- CDEC or pERC deliberation
- Initial rec. issued

Target ≤180 days

- Indicate presence of CDx test
- Engagement of additional stakeholders
Proposed process: eligibility

New drug

- New CDx test
- Existing CDx test

Existing drug

- New indication
  - New CDx test
  - Existing CDx test
  - Existing indication
    - New CDx test
    - Existing CDx test
    - New CDx test
Proposed process: clinical evidence

• Submitter:
  • Analytic validity
  • Clinical validity
  • Clinical utility

• CADTH will appraise submitted evidence and conduct Rapid Response
Proposed process: economic evidence

• Submitter:
  • Cost-effectiveness analysis
  • Budget impact analysis*

• CADTH will appraise submitted evidence

*CDR: provided to jurisdictions; pCODR: critiqued for discussion at pERC
Proposed process: patients & additional input

- **Patients:**
  - Experience and/or expectations

- **Clinicians:**
  - Experts in pathology and/or laboratory testing

- **Participating jurisdictions:**
  - Implementation issues

(CADTH)
Next steps

2014
- CADTH Environmental Scan

2015
- Policy Forum Wider Table on Personalized Medicine

2016
- Consultations:
  - Australia
  - Canadian jurisdictional representatives
  - CADTH drug portfolio committees
  - Drug portfolio information sessions
  - Stakeholder feedback

2017
- Planned implementation
Health Technology Management

DR. BRIAN O’ROURKE
PRESIDENT AND CHIEF EXECUTIVE OFFICER

CADTH

TRANSFORMING HOW WE MANAGE HEALTH TECHNOLOGIES IN CANADA IN SUPPORT OF THE TRIPLE AIM
Transforming How we Manage Health Technologies in Canada in Support of the Triple Aim

1. Governance and Priority Setting
2. Assessment and Evaluation Throughout the Technology Lifecycle
3. Strengthening the Evidence to Action Connection
4. Measuring Impact and Improving Value for Money
Open Forum
Wrap Up
Stay Connected

requests@cadth.ca   @cadth_acmts

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