



Session 9

RWE to support outcomes-based agreements in Canada: A case study using patient support program data

This session is supported by research conducted by the Real-World Evidence and Outcomes-Based Agreements Working Group

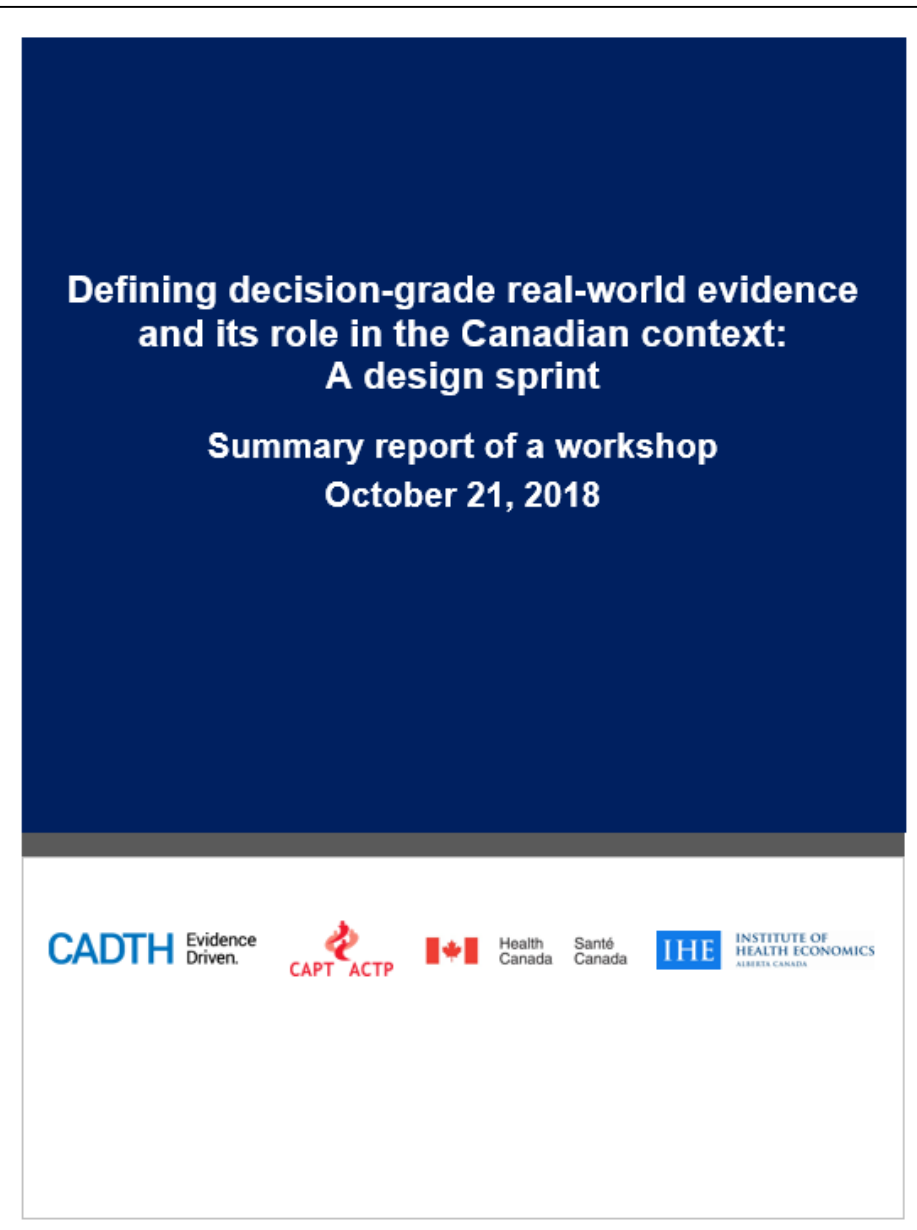
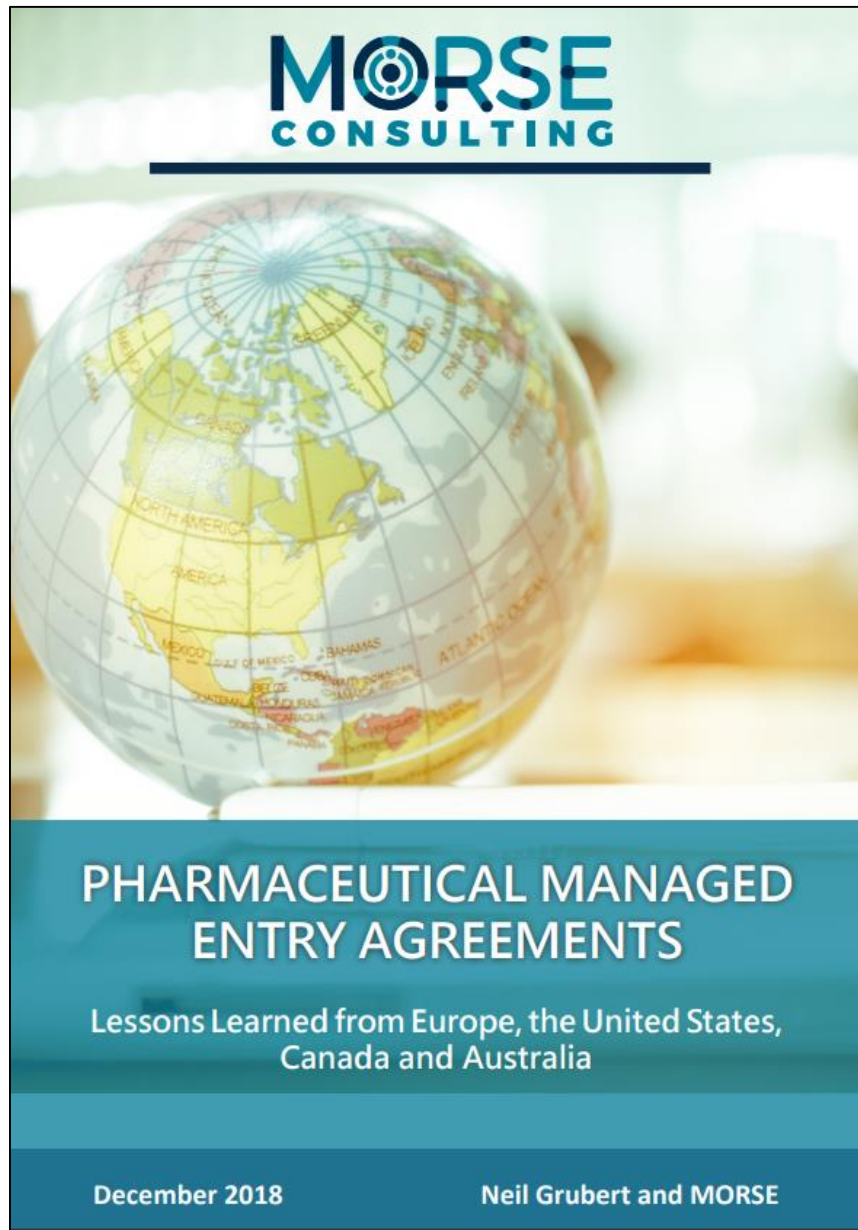
CAPT Conference October 22, 2019 | Toronto, Canada
2:00PM – 3:00PM

Working Group Mission Statement

The Real-World Evidence and Outcomes-Based Agreements Working Group will **advance the opportunity for the use of outcomes-based agreements in Canada.**



Why a working group on RWE and OBAs?



Value-Based Health Care

Based on the research of Professor Michael Porter, **Value-Based Health Care** is a framework for restructuring health care systems around the globe with the overarching goal of value for patients.



Defining VALUE as the outcomes that matter to patients and the costs to achieve those outcomes.¹

I say outcomes-based agreements...

**I say outcomes-based
agreements...**

you say CHALLENGES!

Challenges



Is it the right product?

- How long does it take for the drug to demonstrate clinically meaningful outcomes? Can control for non-treatment factors? Are there consistently and accurately measurable outcomes?



Who does the analysis?

- Need to ensure that data collection and evaluation are independent of manufacturer



Who takes on the up-front risk?

- How to share risk if high uncertainty around clinical value and cost-effectiveness



Timelines?

- RWE-incorporated negotiations are complex; pCPA is willing to have early discussions



What should the price be if drug performs as expected? What if drug does not perform?

- List price is not often reasonable and removing funding still a very difficult conversation



Do all jurisdictions have to participate? Best proxy?

- Different jurisdictions have different data infrastructure, capacity to mine data



Source: *Presentation: Outcome Based Agreements*, Sang Mi Lee, pCPA Office, Oct 2, 2019.

Why a working group on RWE and OBAs?

To bring clarity to and advance OBA implementation in Canada.

2019 Working Group Research Objectives

Research and analysis to bring clarity on the opportunity for OBAs in Canada, and to develop a framework for OBA implementation in Canada, including:

1.

Developing clarity on when it is appropriate to use an OBA, the benefits of an OBA for payers and manufacturers, and how to evaluate when a drug is a good fit for an OBA.

2.

Developing a process for the monitoring and reporting on outcomes, and the creation of implementation framework to support OBAs, through simple and complex drug case studies.

3.

Exploring the use of patient support program (PSP) and specialty pharmacy infrastructures to support outcomes data collection for OBAs.



STAKEHOLDER COLLABORATION

Case Study: PSP infrastructure and data

Product launch with the intent of establishing an OBA: drug with single endpoint

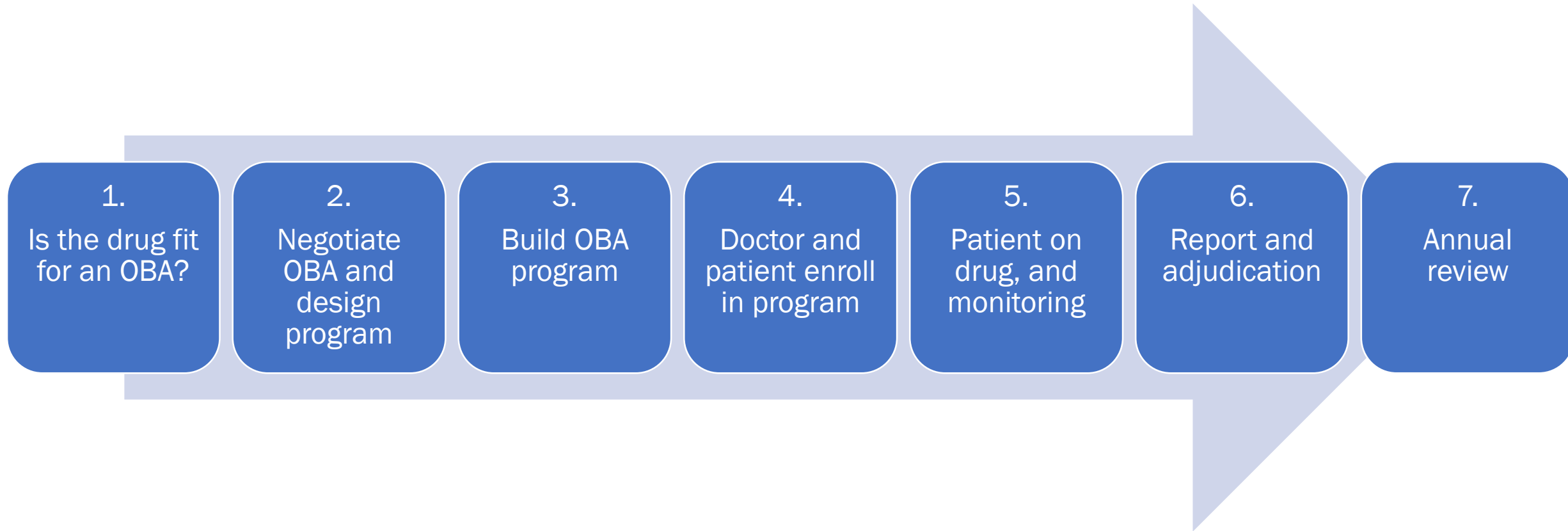
Case Objectives:

- Work through the end-to-end process elements to evaluate how an OBA Program using PSP infrastructure could work.
- This case uses a simple health outcome measurement to monitor with the objective of using this as a base exercise to work through the various elements of the outcomes-based agreement program process.

Case Parameters:

- Therapy with single endpoint for health outcome: Oral solid for Hepatitis C
- First cure
- Dosing: 4-month treatment
- Treatment Cost: \$80K/patient
- RCT efficacy results: 80% effective
- RCT data complete
- Intent to establish an OBA
- Health outcome data source: PSP infrastructure for OBA Program

7-Step OBA Implementation Framework





Panel Discussion on OBA Implementation

PANEL MODERATOR:

**Allison
Wills**

Partner
**20Sense Specialty
Pharmaceutical
Consulting**

PANELISTS:

**Sang Mi
Lee**

BScPhm, RPh
Senior Manager
**pan-Canadian
Pharmaceutical
Alliance Office**

**Janey
Shin**

Director, RWE
Janssen Inc.

**Chris
Dalseg**

Vice President,
Strategy and Industry
Relations
BioScript Solutions