
**REAL-WORLD EVIDENCE AND
OUTCOMES-BASED AGREEMENTS
WORKING GROUP**
2021 RESEARCH AND OUTPUTS
EXECUTIVE SUMMARY

DECEMBER 10, 2021



REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS WORKING GROUP

2021 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

RWE AND OBA
WORKING GROUP

BACKGROUND

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

Established in 2019, the working group brings together organizations inspired by the opportunity for real-world evidence (RWE) generation to support outcomes-based agreements (OBAs) in Canada. The scope of the working group includes all therapeutic areas and both public and private payer markets.

The working group values inclusion, knowledge sharing and collaboration, and invites input and participation from all relevant parties, with the objective of advancing opportunities for OBAs to the benefit of all stakeholders in the Canadian healthcare system.

It is recognized that there are many challenges to overcome with the development and implementation of OBAs in Canada, and that the landscape is constantly evolving. The working group's method is to actively address these challenges and to find potential solutions and approaches that will provide value to all stakeholders.

The 2021 RWE & OBA Working Group Members include AstraZeneca, Bayer, BioScript Solutions, Janssen, Novartis, Pfizer, and 20Sense.

For further information, resources, and past publication from the RWE & OBA Working Group, please consult <https://www.20sense.ca/the-rwe-oba-working-group>. Inquiries may be directed to info@20sense.ca.

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RESEARCH OBJECTIVES

By building on the research conducted and tools developed to support OBA implementation by the working group in 2019 and 2020, in 2021 there was a continued focus on **research and analysis to bring clarity on the opportunity for OBAs in Canada**, while developing expertise and knowledge in key areas to ensure **readiness for OBA implementation**.

There were two primary areas of research in 2021, including:

1.

Investigating the feasibility and current infrastructure readiness to collect real-world data to support an outcomes-based agreement in Canada.

In Canada, OBAs are confidential and there are no publicly available examples for stakeholders to learn from. Providing examples of how an OBA can be done in Canada, specifically focusing on the health outcome data/RWD part of the OBA, is critical for shared learnings to help advance the opportunity for OBAs.

Therefore, in 2021 the group chose to carry out a demonstration project on operationalizing an OBA, focusing on RWD. For this initiative the working group collaborated with Dr. Winson Cheung, MD, MPH, senior medical oncologist, and Principal Director of the Oncology Outcomes (O2) Program that focuses on enriching data sources and leveraging new technologies to facilitate “fit-for-purpose” cancer RWE generation, and Chris Cameron, Senior Vice President, Value and Evidence at EVERSANA. In scope was oncology, Alberta, O2, and patient support programs (PSP). Out of scope was actual patient or drug-specific data, and drug examples.

The project had two objectives:

1. Evaluate which health outcomes are suitable for OBAs; and determine if health outcomes can be tracked with existing databases (O2 and PSPs).
2. Determine how data tracking can be operationalized for the purpose of an OBA, by designing an OBA data process.

2.

Further investigating the current state of OBAs in Canada, by conducting a Canadian Outcomes-Based Agreement Experience and Perceptions Survey with key stakeholders.

In 2021, the working group conducted a survey to understand Canadian stakeholders’ positions and knowledge of OBAs, current experience with OBAs, and future plans for OBAs.

Participation was open to individuals from the following organizations, current or past: Patients and patient organizations; Regulatory; HTA; pCPA; Public Payers; Private Payers; Physicians/HCPs; Academics/Researchers. Research was conducted from August to September 2021. It included an online self-serve survey and qualitative follow-up interviews.

The objective of this this research was to provide deeper insights into the current state of OBAs in Canada.

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OUTPUTS AND FINDINGS

1.

An outcomes-based agreement in oncology can be operationalized using Alberta administrative health data. It is feasible to collect the RWD with existing data infrastructure.

Key Findings:

[1] Two health outcomes, overall survival (OS) and time to next treatment (TTNT), were deemed to be suitable for OBAs and can be tracked with existing data infrastructure.

Figure 1: Health outcomes data suitable to support outcomes-based agreements, using Alberta data

Health Outcome	Suitable for an OBA?	Data Readiness Accessible for an OBA, complete and accurate.	Data Interpretation Health outcome is clear and simple.	Data Timeframe Can be collected in a reasonable timeframe.
1 Overall Survival (OS)	Yes	Yes	Yes	Yes
2 Time to Next Treatment (TTNT)	Yes	Yes	Yes	Yes
3 Progression Free Survival (PFS)	No	No	No	N/A
4 Patient-Reported Outcomes (PROs)	No – future potential	No	No	N/A
5 Return to Work	No	No	No	N/A

Figure 2: Health outcomes data readiness, interpretation, and timeframes

Health Outcome	Suitable for an OBA?	Data Readiness Accessible for an OBA, complete and accurate.	Data Interpretation Health outcome is clear and simple.	Data Timeframe Can be collected in a reasonable timeframe.
1 Overall Survival (OS)	Yes	<ul style="list-style-type: none"> AB Cancer Registry Data has been used in published studies 	<ul style="list-style-type: none"> Binary data point, easy to interpret 	<ul style="list-style-type: none"> 6-month time lag in AB (12 months or longer in other provinces)
2 Time to Next Treatment (TTNT)	Yes	<ul style="list-style-type: none"> AB PIN database contains all Rx's dispensed in AB (all payers) Data has been used in published studies 	<ul style="list-style-type: none"> Algorithm required for specific treatment pattern 	<ul style="list-style-type: none"> 1-month time lag in AB
3 Progression Free Survival (PFS)	No	<ul style="list-style-type: none"> AB Administrative data Incomplete: Timing of tests are not standardized 	<ul style="list-style-type: none"> Interpretation of results recorded in data are not standardized 	<ul style="list-style-type: none"> N/A
4 Patient-Reported Outcomes (PROs)	No – future potential	<ul style="list-style-type: none"> AB administrative data: ESAS, EQ5D surveys. Incomplete: Not administered to all patients. No published studies. 	<ul style="list-style-type: none"> EQ5D and ESAS frequently included in HTA submissions 	<ul style="list-style-type: none"> N/A
5 Return to Work	No	<ul style="list-style-type: none"> Data not available 	<ul style="list-style-type: none"> Patient may choose not to return to work 	<ul style="list-style-type: none"> N/A

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Key Findings:

continued

[2] Three OBA data processes have been identified, using administrative data, patient support program infrastructure, and a combination of both.

Figure 3: Process design for data collection to support outcomes-based agreements in Canada

		PROCESS 1 Administrative Data	PROCESS 2 Administrative Data with PSP Support	PROCESS 3 PSP Data
Data Planning	Feasibility Study	O2	O2	O2
Data Capture	Patient Registry	Administrative Data	PSP	PSP
	Drug Distribution	Administrative Data	PSP	PSP
	Health Outcome Data Source	Administrative Data	Administrative Data	PSP
Data Analysis	Analysis	O2	O2	O2

For additional details, please consult the following:

CADTH Symposium Panel Session presentation slides: [Building infrastructure to support outcomes-based agreements in Canada: Can an outcomes-based agreement in oncology be operationalized using administrative health data?](#), November 3, 2021. [DOWNLOAD THE PRESENTATION](#)

OUTPUTS AND FINDINGS

2.

Canadian Outcomes-Based Agreement Experience and Perceptions Survey

Methods:

The survey consisted of 27 questions and was conducted from August to September 2021. Questions addressed themes on OBAs including general OBA knowledge, OBA readiness, data to support OBAs, and the future of OBAs. Online surveys were completed by 38 individuals with affiliations as follows: Academic & HTA (10), Patient organization & Physician/HCP (15), and Public & Private payers (13). Respondents were invited to collaborate in follow-up interviews to validate survey responses and collect additional input. Qualitative interviews were conducted with 5 individuals.

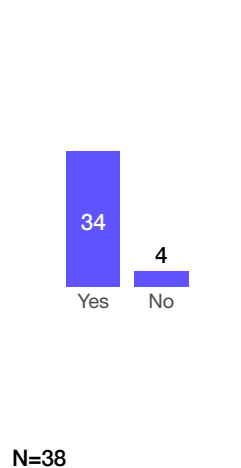
Survey themes included: [1] Infrastructure & Data Collection, [2] Usability of Data (Quality and Capture Rate), [3] Data Usage, [4] Roadblocks & Challenges, [5] Future Plans.

Key Findings:

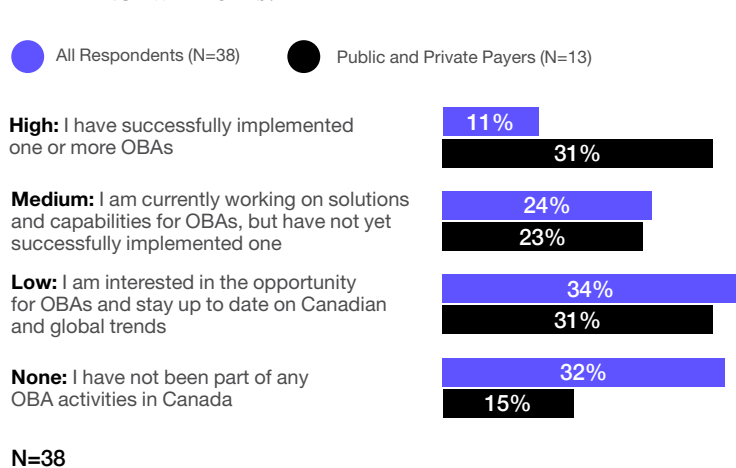
[1] There is a need for outcomes-based agreements in Canada and leading payers have successfully implemented one or more OBAs.

Figure 1: Need for and experience with OBAs in Canada

DO YOU SEE A NEED FOR OBAS IN CANADA?



WHAT BEST DESCRIBES YOUR EXPERIENCE WITH OBAS?



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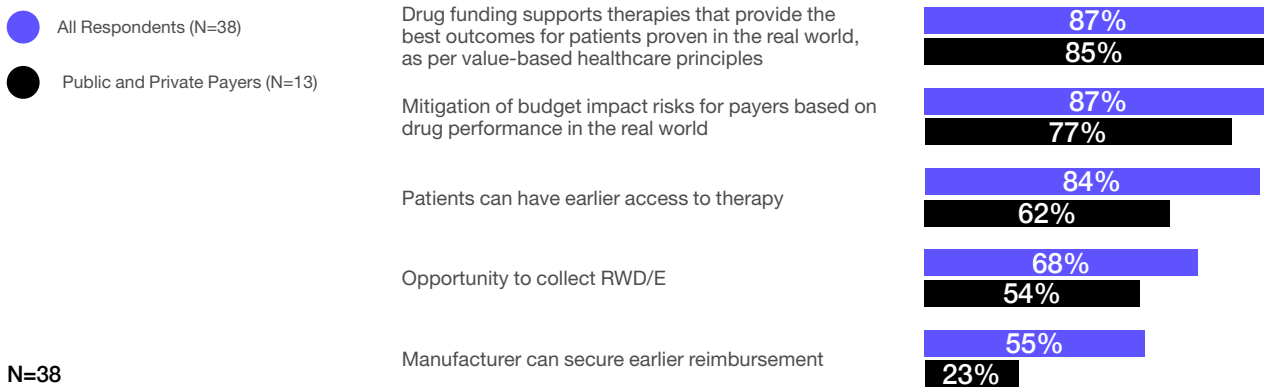
Key findings:

continued

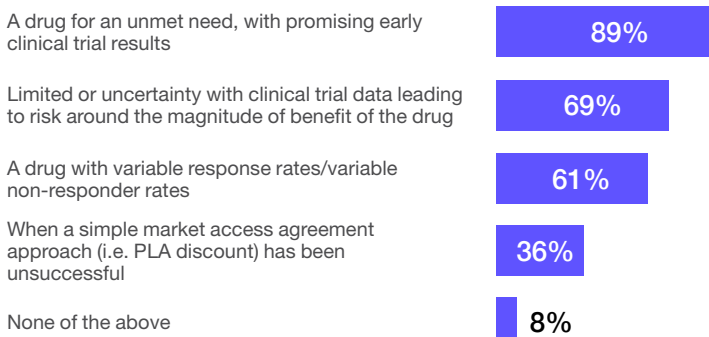
[2] Respondents are aligned on core principles for outcomes-based agreements, including their benefits, appropriateness, and areas of most need.

Figure 2: Benefits, appropriateness, and areas of need for OBAs

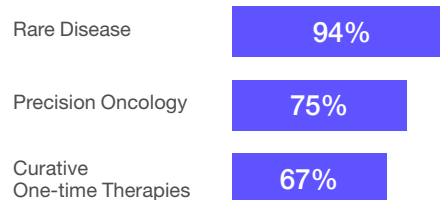
WHAT ARE THE POTENTIAL BENEFITS OF USING OBAS?



IN WHICH SITUATIONS WOULD IT BE APPROPRIATE TO CONSIDER USING AN OBA?



WHICH AREAS DO YOU FEEL HAVE THE MOST URGENCY FOR OBAS?



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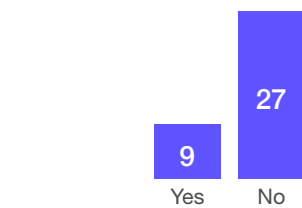
Key findings:

continued

[3] Respondents noted that some key elements to support successful OBA implementation are already in place in Canada.

Figure 3: Pathway for OBA discussions; payer willingness and readiness for OBAs; data management qualities for OBAs.

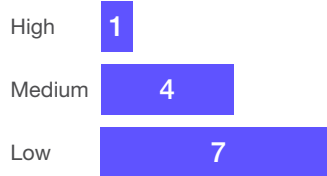
DOES THE CURRENT DRUG LISTING PROCESS HAVE AN APPROPRIATE PATHWAY TO ENTERTAIN DISCUSSIONS ABOUT THE POTENTIAL USE OF AN OBA FOR A SPECIFIC DRUG?



N=36

PAYERS: HOW WOULD YOU RANK YOUR ORGANIZATION'S IMPLEMENTATION READINESS AND WILLINGNESS TO DO AN OBA TODAY?

Payer Readiness (N=12)



N=12

Payer Willingness (N=11)

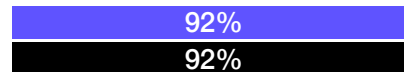


WHAT DATA MANAGEMENT QUALITIES ARE IMPORTANT FOR OBAS?

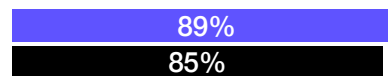
- All Respondents (N=37)
- Public and Private Payers (N=13)

N=37

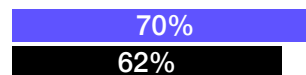
A transparent process for collecting and aggregating data, and analyzing results



Data sources must be agreed upon by the payer, the manufacturer, and the parties responsible for data collection



An independent and credible third-party managing the data collection, aggregation, and analysis



I'm not sure



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Conclusions:

Survey findings suggest that there is a need for OBAs in Canada and that leading stakeholders are already using OBAs today.

For OBAs to be available as an option to a broader set of stakeholders, there is a need to increase overall understanding and expertise of how to do an OBA. Transparency and sharing of learnings from OBAs implemented in Canada, as well as increasing knowledge on RWE generation for OBAs, can help support this. Willingness of most stakeholders is already medium-high, but readiness is not. Gaining alignment between HTA, pCPA, public and private payers, patients, and industry on an approach will be important.

The rate of adoption and use of OBAs to support timely market access for patients in Canada is only expected to increase in the coming years. This includes the further development of capabilities and expertise to support OBAs.

For additional details, please consult the following:

- Survey Results: [Canadian Outcomes-Based Agreement Experience and Perceptions Survey](#), October 12, 2021. [DOWNLOAD SURVEY RESULTS](#)
- Poster: [A Survey of Canadian Stakeholders on Outcomes-Based Agreements](#), RWE & OBA Working Group, as presented as the Canadian Association for Population Therapeutics Conference, October 25, 2021. [DOWNLOAD PDF POSTER](#)