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**REAL-WORLD EVIDENCE AND  
OUTCOMES-BASED AGREEMENTS  
WORKING GROUP**  
**2020 RESEARCH AND OUTPUTS**  
EXECUTIVE SUMMARY

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NOVEMBER 10, 2020



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# REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS WORKING GROUP

## 2020 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

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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 2020 RWE & OBA Working Group Members include AstraZeneca, Bayer, BioScript Solutions, Janssen, Novartis 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](mailto:info@20sense.ca).

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## 2020 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

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## RESEARCH OBJECTIVES

By building on the OBA implementation framework developed by the working group in 2019, in 2020 the working group had 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 2020, including:

1.

**Investigating the value of an outcomes-based agreement by creating a Decision Modelling Tool: Outcomes-Based Agreement vs. Price Discount Contract Model.**

In 2019, the working group created a *qualitative* guideline to help stakeholders evaluate when it is appropriate for an OBA to be used, based on member input and discussion, and supported by a global literature review.

To advance this work, in 2020 the group chose to carry out a *quantitative* analysis, which led to the creation of a modelling tool to compare a traditional price discount agreement with an outcomes-based agreement. The resulting modelling tool has 9 variables in total, that pertain to real-world outcomes, patients, treatment duration, pricing, and OBA administration costs.

For this initiative, the working group collaborated with our affiliated subject-matter expert EVERSANA (formerly Cornerstone Research Group, Inc.).

2.

**Further investigating the patient support program data and infrastructure opportunity for RWD generation and usage in OBAs, by conducting a Canadian Patient Support Program Data Capabilities Survey.**

In 2019, the working group's research found that the patient support program infrastructure is increasingly recognized as a valid source to collect outcomes data for RWE generation, and the existing PSP infrastructure contains many of the necessary requirements to enable the OBA data collection process.

To advance this work, in 2020 the group chose to investigate the current state of PSP data in the Canadian market, including such areas as: PSP infrastructure, capture rate of patients in PSP data for a given drug, types of data captured, quality of the data, use of data by stakeholders, and purpose of data collection.

# REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS WORKING GROUP

## 2020 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

## OUTPUTS AND FINDINGS

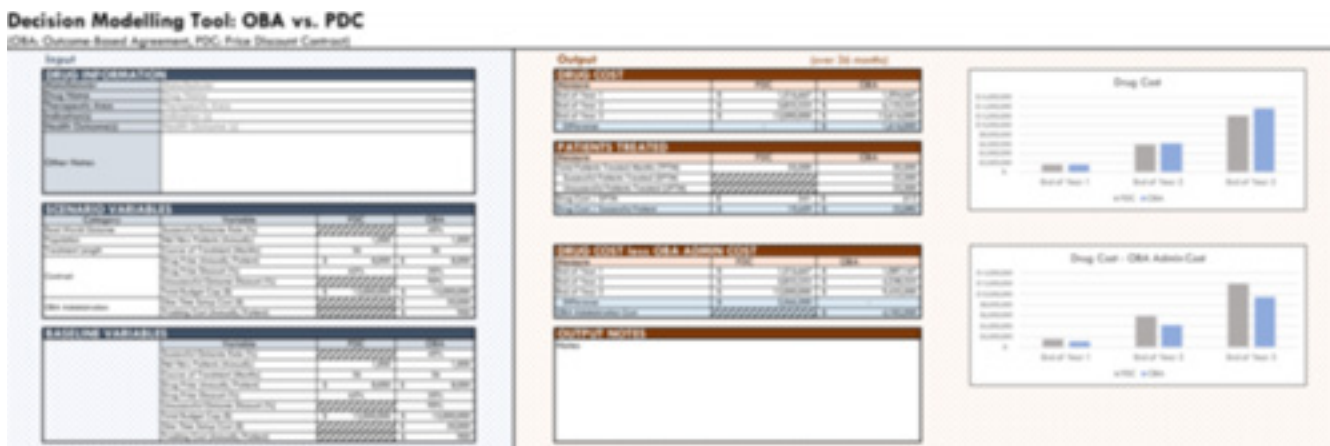
### 1.

#### Decision Modelling Tool: Outcomes-Based Agreement vs. Price Discount Contract Model

##### Overview:

- The modelling tool has 9 variables in total. Traditional variables include drug price, discount and budget cap, number of patients and treatment length. For the OBA evaluation, variables include price and/or discount for successful and unsuccessful outcomes, and OBA administration.
- The model is divided into two sections: *input* and *output*. As variables are changed on the *input* side, the *output* metrics are updated, allowing for the user to model various scenarios and view the results instantly.
- The outputs are in three sections: drug costs, patients, and OBA administration cost. Each metric is calculated for the price discount contract, and the OBA, so they can be compared simultaneously.
- The model was tested with various drug scenarios, with modifications made to price, patient population and treatment length.

Figure 1: Layout of the Decision Modelling Tool: OBA vs PDC Pricing Model



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### Decision Modelling Tool: Outcomes-Based Agreement vs. Price Discount Contract Model

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#### Scenario modelling exercise:

The model was tested with multiple scenarios, varying by price, patient population, and treatment length, on 3 different product types:

PRODUCT TYPE	NET NEW PATIENTS (ANNUALLY)	DRUG PRICE (ANNUALLY / PATIENT)	OBA ADMINISTRATION TRACKING COST (ANNUALLY / PATIENT)
1. Chronic	Large: 1,000/year	\$8,000	\$900
2. Oncology	Medium: 180/year	\$42,000	\$600
3. Rare Disease	Small: 80/year	\$185,000	\$300

All scenarios for this exercise assumed that outcomes data was collected via a patient support program infrastructure, and OBA administration and tracking costs were inputted accordingly.

#### Preliminary findings:

Based on the scenario modelling exercise, the characteristics that made a significant impact on model results were:

- Number of patients on drug
- Drug price
- OBA tracking cost

Patient support program OBA administration costs (the set up of the outcomes tracking) were low, and leveraging an existing PSP infrastructure to collect outcomes data was shown to be a cost-effective option. Data collected via the PSP infrastructure was a good fit with scenarios that has lower patient numbers. Other outcome data sources (such as administrative data sets) may be used for input into the model, and may be better-suited to support scenarios with high patient numbers.

#### Next steps:

The working group will continue work on the decision modelling tool, including:

- Conducting additional scenario testing and refining insights.
- Conducting an external consultation on the decision modelling tool, notably with payers, HTA, prescribers, and patients. Timing for consultations is early 2021.  
**Interested parties are invited to contact the working group for additional information.**
- Journal publication of findings.

# REAL-WORLD EVIDENCE AND OUTCOMES-BASED AGREEMENTS WORKING GROUP

## 2020 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

### OUTPUTS AND FINDINGS

# 2.

## Canadian Patient Support Program Data Capabilities Survey

The working group continued its research on the patient support program data and infrastructure opportunity for RWD generation and usage in OBAs, by conducting a *Canadian Patient Support Program Data Capabilities Survey*.

### Methods:

The survey was conducted in July 2020 and consisted of 40 questions, to understand the baseline state of PSP data, PSP data capabilities, and future plans for PSP data collection as it pertains to generating RWD to support OBAs. Online surveys were completed by 59 respondents, including 15 pharmaceutical manufacturers (32 unique respondents), 10 PSP service providers (21 unique respondents), and 6 'other' respondents. Respondents were invited to collaborate in follow-up qualitative interviews to validate survey responses and collect additional input. Qualitative interviews were conducted with 9 companies in August and September 2020.

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

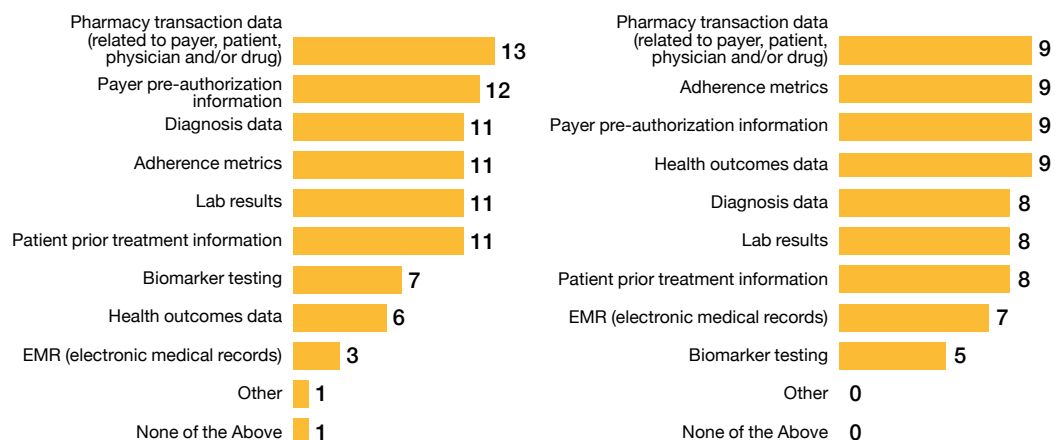
### Key findings:

Figure 1: Types of Data Collected within PSPs

**[1] Broad data collection is occurring today within PSPs, including RWD.**

14 out of 15 manufacturers are currently receiving data from their PSP vendors

All PSP vendors are collecting data within their PSP infrastructure



N = 15; MANUFACTURERS ONLY

N = 9; PSP VENDORS ONLY

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## 2020 RESEARCH AND OUTPUTS EXECUTIVE SUMMARY

### Key findings:

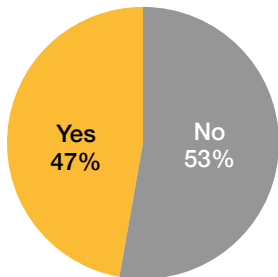
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[2] PSP data are increasingly being leveraged for formal research and analyses.

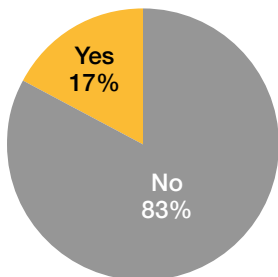
Figure 2: PSP Data Use in Research, Registries, HTA Analysis and Publications

Q31: HAVE YOU LEVERAGED YOUR PSP DATA TO SUPPORT HTA ANALYSIS?  
N = 33; ALL RESPONDENTS

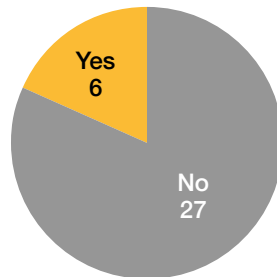
Pharmaceutical manufacturers



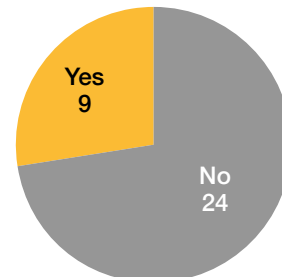
PSP vendors



Q29: HAVE YOU SHARED YOUR PSP DATA OR MADE IT AVAILABLE TO THIRD-PARTY RESEARCHERS?  
N = 33; ALL RESPONDENTS

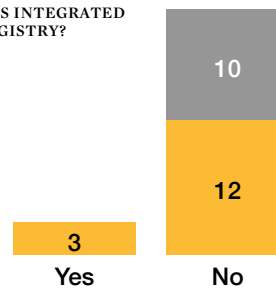


Q30: HAVE YOU PUBLISHED RESULTS FROM YOUR PSP DATA?  
N = 33; ALL RESPONDENTS



Q16: IS YOUR PSP COLLECTING DATA THAT IS INTEGRATED WITH A CANADIAN OR GLOBAL PATIENT REGISTRY?  
N = 25; ALL RESPONDENTS

● Pharmaceutical manufacturer  
● PSP vendor



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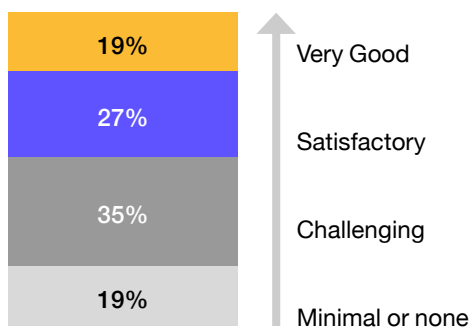
### Key findings:

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**[3] Canadian stakeholders are gaining experience with PSP data use, and will continue to invest in PSP data capabilities and applications.**

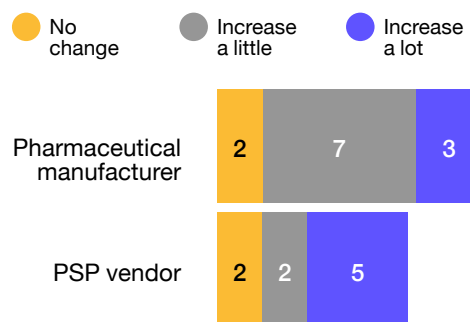
Figure 3: PSP Data Experience and Investment Plans

HOW WOULD YOU DESCRIBE YOUR EXPERIENCE COLLECTING DATA VIA THE PSP INFRASTRUCTURE TO DATE?



N = 37

HOW DO YOU ANTICIPATE YOUR ORGANIZATION'S INVESTMENT IN CAPTURING AND UTILIZING PSP DATA CHANGING, IF AT ALL, IN THE NEXT YEAR?



N = 21

### Conclusions:

Survey findings suggest that Canada's patient support program infrastructure is readying itself to be able to support the collection of real-world data for use in outcomes-based agreements.

There is a notable evolution in capabilities and expansion of PSP data usage among Canadian stakeholders, with some currently extracting significant value, as others continue to develop their expertise. All PSP vendors and manufacturers have a level of interest and investment in PSP data with initiatives underway, at varying levels of sophistication, and varying levels of success.

The pace of evolution in PSP data sophistication, and the associated PSP infrastructure, is expected to increase. This includes the further development of capabilities to support outcomes-based agreements.

For additional details from the survey results, please consult the following documents:

- Survey Results: [The Canadian Patient Support Program Data Capabilities Survey Executive Summary Report](#), October 15, 2020. [REQUEST A COPY OF THE REPORT](#)
- Poster: [Canada's patient support program infrastructure support the collection of real-world data for use in outcomes-based agreements?](#) RWE & OBA Working Group, as presented at the Canadian Association for Population Therapeutics Conference, October 26, 2020. [DOWNLOAD PDF POSTER](#)



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## 2020 CONCLUDING REMARKS AND KEY ACTION AREAS FOR CONSIDERATION

The working group is committed to advancing the opportunity for the use of OBAs, to the benefit of all stakeholders in the Canadian healthcare system. From the work conducted in 2020, the working group identified the following key action areas for consideration:

1.

There is a need to further develop the details of OBA appropriateness and implementation processes to continue to remove barriers to OBAs, with input from all relevant stakeholders.

Further research into the OBA opportunity in Canada, with the support of the OBA Decision Modelling Tool, and with the continued investigation of the PSP infrastructure to generate RWD, will allow the advancement of OBA implementation readiness.

2.

There is a need for greater collaboration at the upstream decision-making level with HTA evaluators on adaptive pathways, and specifically to identify appropriate drugs for OBAs and to provide support to downstream parties (pCPA, payers) on their suitability. The potential to discuss OBA appropriateness for a drug during Early Parallel Scientific Advice (Health Canada, CADTH) has been identified as an area to investigate.

3.

Connecting with other related initiatives is required to ensure collaboration on work being conducted on RWE and OBAs. The working group will ensure that findings are shared appropriately with stakeholders to support the advancement of the opportunity for OBAs in Canada.

FOR INQUIRIES ABOUT  
THE RWE & OBA WORKING GROUP,  
PLEASE CONTACT  
INFO@20SENSE.CA.