THE CANADIAN PATIENT SUPPORT PROGRAM DATA CAPABILITIES SURVEY
RESULTS

EXECUTIVE SUMMARY REPORT

OCTOBER 15, 2020

The following report contains the findings of research conducted by The 2020 RWE & OBA Working Group.
Please contact **info@20sense.ca** for all inquiries.

ABOUT THE RWE & OBA WORKING GROUP

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.

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. Affiliated subject-matter experts include MORSE Consulting and Eversana.

The 2019 RWE & OBA Working Group Executive Summary Report can be found **here**. The 2020 Executive Summary Report will be published late 2020. Please contact **info@20sense.ca** for details

RESEARCH OBJECTIVES

The Canadian Patient Support Program Data Capabilities Survey was conducted on behalf of the 2020 RWE & OBA Working Group.

The group's research includes investigating the opportunity for patient support program (PSP) infrastructure use for the collection of real-world data to support outcomes-based agreements (OBA). The objective of this survey is to understand the baseline state of PSP data, PSP data capabilities, and future plans for PSP data collection in Canada.

The survey was conducted from July-September 2020, and open to all individuals from all Canadian-based pharmaceutical manufacturers who have patient support programs, and Canadian-based patient support program vendors.

SURVEY PARTICIPATION

There were 59 individual respondents to the online survey, including:

- 15 pharmaceutical manufacturers (32 unique respondents)
- 10 patient support program service providers (21 unique respondents)
- 6 in the ‘other’ category (including patient support program technology companies, specialty pharmacies, and consultants)

Follow-up qualitative interviews were conducted with 9 companies to validate survey responses and collect additional input.

SURVEY RESULTS

Survey results are presented at the individual response level, or aggregated to the company level.

Each result includes a legend indicating the original question, the number of responses, and the respondents represented *(All respondents; Manufacturer only; PSP Vendor only)*.

The survey results are grouped into four categories:

Section 1: Infrastructure and Data Collection
Section 2: Usability of Data (Quality and Capture Rate)
Section 3: Data Usage
Section 4: Future Plans

The way the industry collects, uses, and shares the data from PSPs is changing across multiple areas including:

- An increased use of PSP data to generate RWE to support market access and reimbursement
- An increased focus on consent, privacy, ethics, compliance, audits and data security practices
- A continued overall increase and expansion of PSP data capabilities
- The ability to share PSP data across stakeholders
- An increase in patient involvement with data collection, ownership and use

"PSP data will support outcomes-based agreements with public and private payers."

"Payers and regulators may mandate patient data to negotiate agreements."

"Use data in a more predictive manner to adjust services to those that need it most."

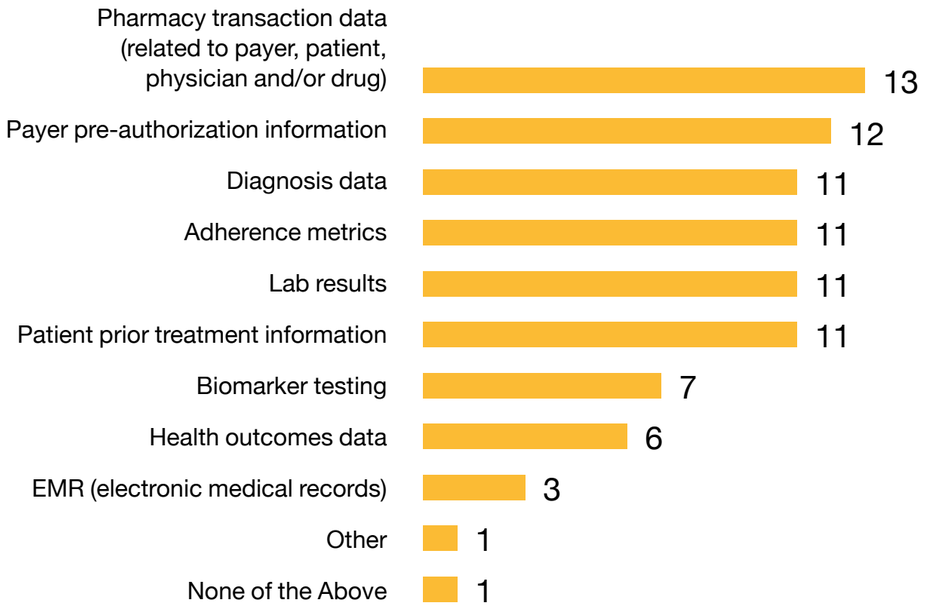
"More comprehensive patient consent language to allow for the use of data for other than supporting therapy access at the patient level."

"Incorporation of RWE studies with PSP, whether in whole or in part."

Q5: IN YOUR OPINION, WHAT DO YOU THINK WILL BE THE BIGGEST CHANGE(S) TO THE WAY OUR INDUSTRY COLLECTS, USES, AND SHARES THE DATA FROM PSPS? (LIST TOP 3)
N = 114; ALL RESPONDENTS

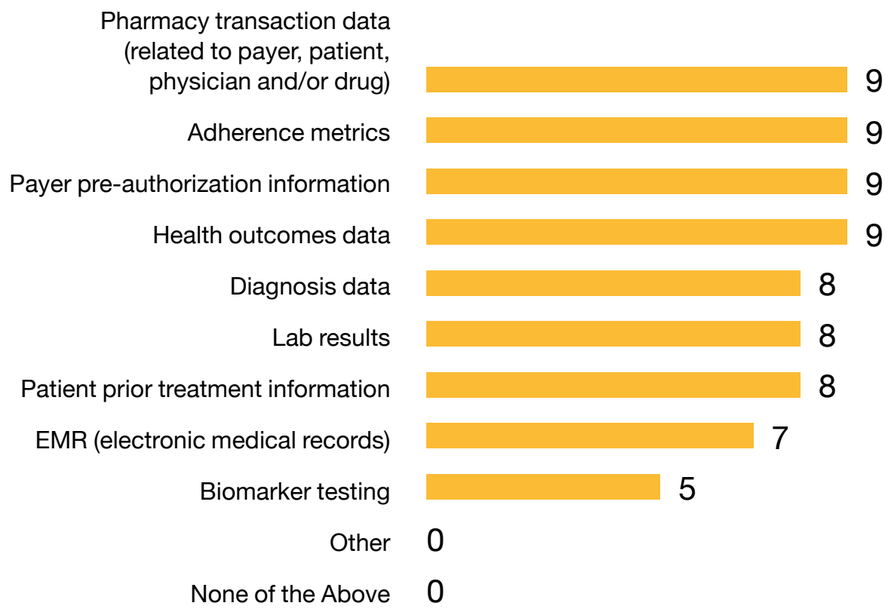
Broad data collection is occurring today within PSPs, including health outcomes

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



Q6: WHICH OF THE FOLLOWING TYPES OF DATA HAVE YOU RECEIVED FROM YOUR PSP VENDOR(S)? PLEASE SELECT ALL THAT APPLY.
N = 15; MANUFACTURERS ONLY

All PSP vendors are collecting data within their PSP infrastructure

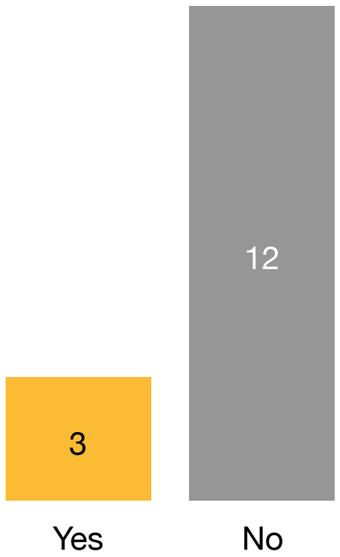


Q8: WHICH OF THE FOLLOWING TYPES OF DATA HAS YOUR ORGANIZATION COLLECTED WITHIN THE PSP INFRASTRUCTURE? PLEASE SELECT ALL THAT APPLY.
N = 9; PSP VENDORS ONLY

Patient Reported Outcomes (PROs)

Question to manufacturers:

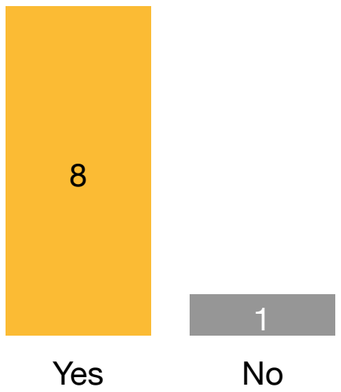
Have you collected or received patient reported outcomes (PROs) from your PSP and/or PSP vendor(s)?



Q7: HAVE YOU COLLECTED OR RECEIVED PATIENT REPORTED OUTCOMES (PROS) FROM YOUR PSP AND/OR PSP VENDOR(S)?
N = 15; MANUFACTURERS ONLY

Question to PSP vendors:

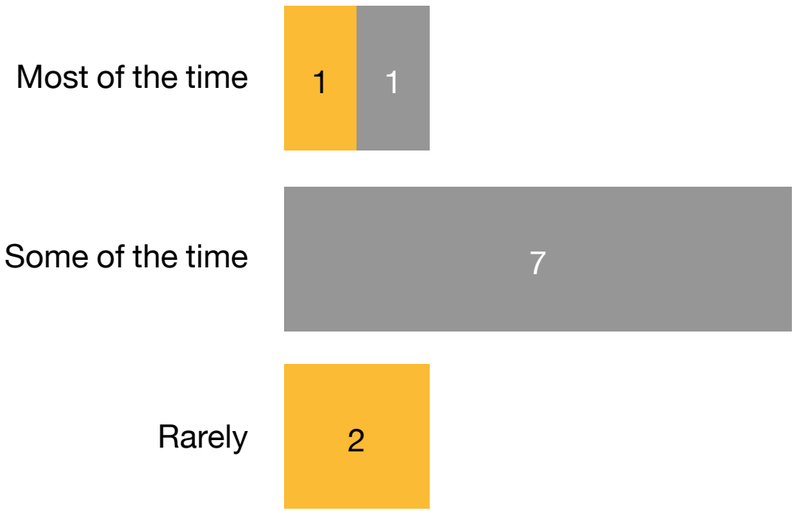
Have you or your organization collected patient reported outcomes (PROs) within the PSP infrastructure?



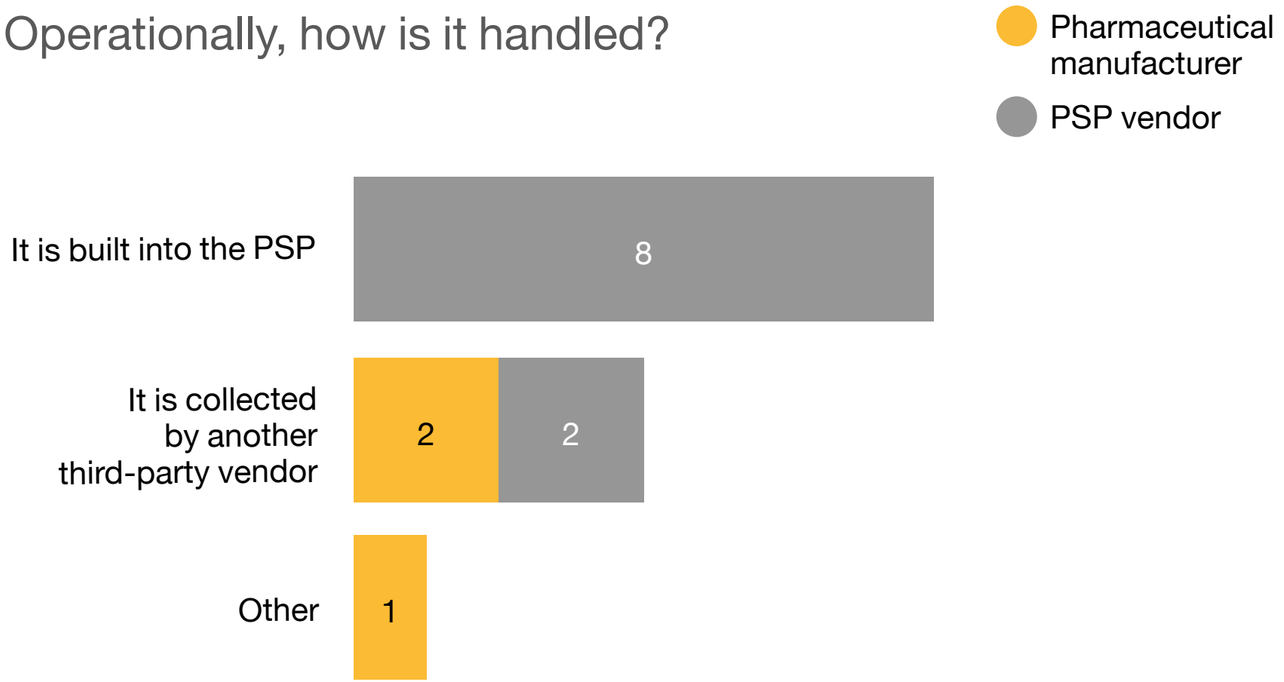
Q9: HAVE YOU OR YOUR ORGANIZATION COLLECTED PATIENT REPORTED OUTCOMES (PROS) WITHIN THE PSP INFRASTRUCTURE?
N = 9; PSP VENDORS ONLY

For those who indicated that they collect or receive Patient Reported Outcomes (PROs):

How commonly is this done within your PSPs?



Operationally, how is it handled?



Q10: YOU SAID YOU COLLECT OR RECEIVE PATIENT REPORTED OUTCOMES (PROS). HOW COMMONLY IS THIS DONE WITHIN YOUR PSPS?
N = 11; ALL RESPONDENTS

Q11: YOU SAID YOU COLLECT OR RECEIVE PATIENT REPORTED OUTCOMES (PROS). OPERATIONALLY, HOW IS IT HANDLED? (MULTI-OPTION)
N = 13; ALL RESPONDENTS

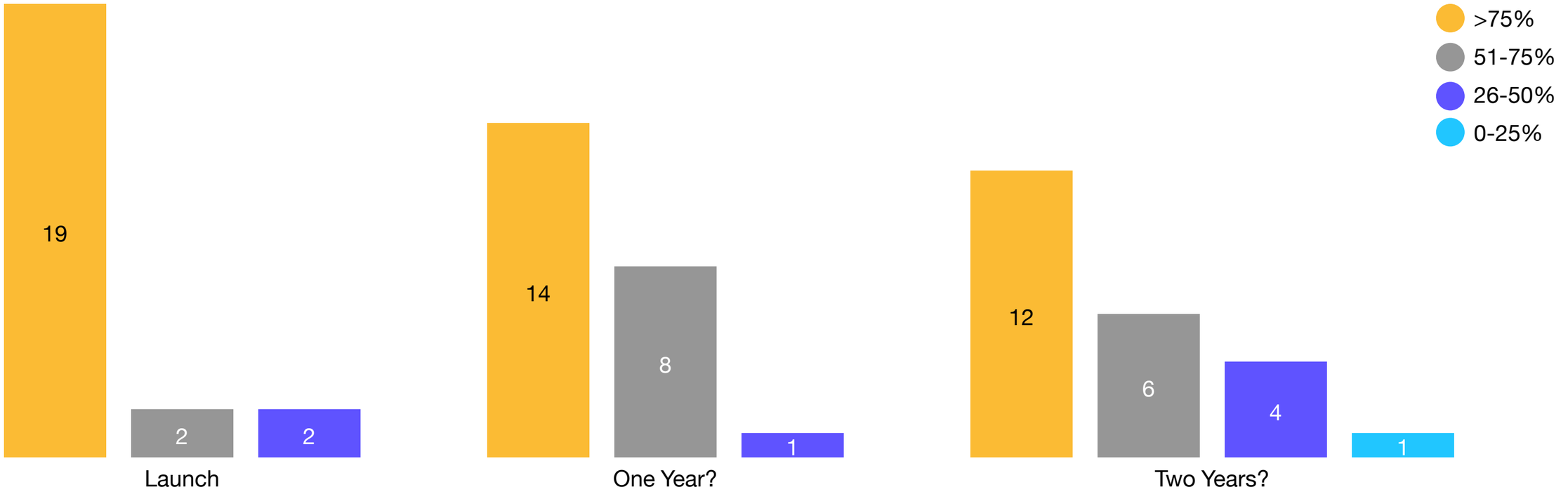
40% of stakeholders are using a validated system for their PSP data

Q14: ARE YOU USING A VALIDATED SYSTEM FOR YOUR PSP DATA?
N = 24; ALL RESPONDENTS

Is your PSP collecting data that is integrated with a Canadian or global patient registry?

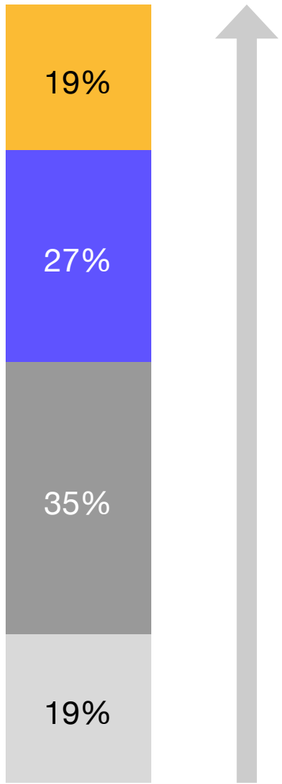
Q16: IS YOUR PSP COLLECTING DATA THAT IS INTEGRATED WITH A CANADIAN OR GLOBAL PATIENT REGISTRY?
N = 25; ALL RESPONDENTS

In many programs, >75% of patients remain within PSPs after two years post drug launch



Q17: IN GENERAL, APPROXIMATELY WHAT PORTION OF TOTAL PATIENTS FOR A GIVEN DRUG ARE PART OF YOUR PSPS
N = 23; ALL RESPONDENTS

How would you describe your experience collecting data via the PSP infrastructure to date?



Very Good

Satisfactory

Challenging

Minimal or none

Very good

"We have been successful in engaging HCPs and patients with the [PSP data collection] software which has significantly reduced admin time, reduced data entry errors and increased PSP efficiency."

"Very efficient processes in place as an in-house data solution is being used across the globe."

Satisfactory

"Our experience has improved with increasing investment in PSP infra-structure, including consolidating disconnected and fragmented data sources."

"A good first step but has a lot more potential and think it's being underutilized. With the appropriate structure, guidance and governance it can be leveraged to support various initiatives to benefit manufacturer, customer and ultimately the patient."

"Automated data capture or drop down options help with data validity and reduce errors or redundancy within the data set. Typically self-reported data can be unreliable versus claims data or physician/ pharmacy level data."

Challenging

"Challenging in that the data is not always consistently reliable."

"Significant challenges with data integrity and ability to analyze/generate insights by outsourced PSP vendors. As a result, we have in-sourced the CRM platform for some of our PSPs, and this has greatly improved our ability to do this."

"Data is a mix of structured and unstructured and is generated by teams (HCPs and PSPs) with little understanding of data management best practices or how it will be used."

Minimal or none

"Limited ability due to company restrictions around collecting any data beyond that which is strictly required to operate the PSP."

"We are not taking advantage of the wealth of data that resides in the PSP.

Q24 HOW WOULD YOU DESCRIBE YOUR EXPERIENCE COLLECTING DATA VIA THE PSP INFRASTRUCTURE TO DATE? PLEASE BE AS SPECIFIC AS POSSIBLE.
N = 37; ALL RESPONDENTS

18% of respondents have shared their PSP data or made it available to third-party researchers

What type of data was provided?
What type of initiative was data provided for?

"Data has been provided to primary lead researchers as part of studies when patients within the specific PSP were involved in the study. In one example, patients and physicians involved in the study originated from the PSP."

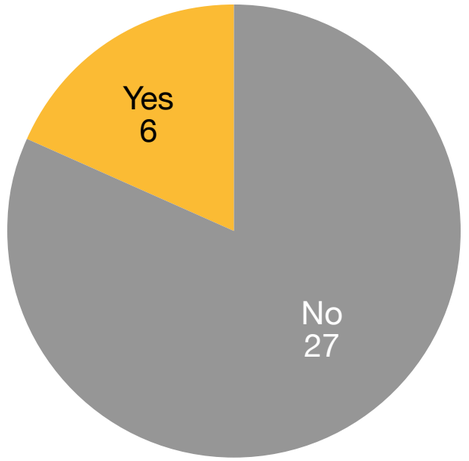
"Data has been provided to support a retrospective adherence analysis for a PSP-associated product."

"Data has been made available to HCPs for presentations and posters."

"Data has been provided to a private payer, based on their request."

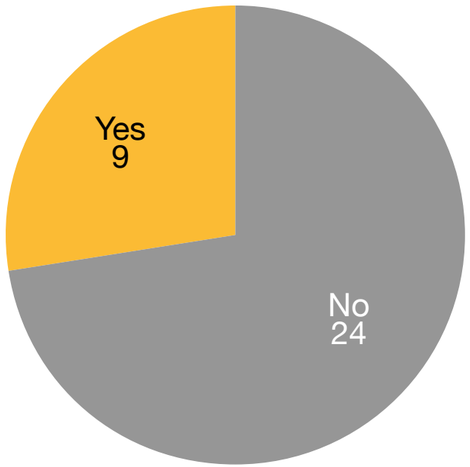
"Data is provided as per a partnership with IQVIA, for some manufacturers."

"Aggregated claims data from the PSP."



Q25: HOW WOULD YOU DESCRIBE YOUR EXPERIENCE WORKING WITH PSP VENDORS ON THE DESIGN OF THE DATA COLLECTION?
N = 23 MANUFACTURERS ONLY

27% of respondents have published results from their PSP data



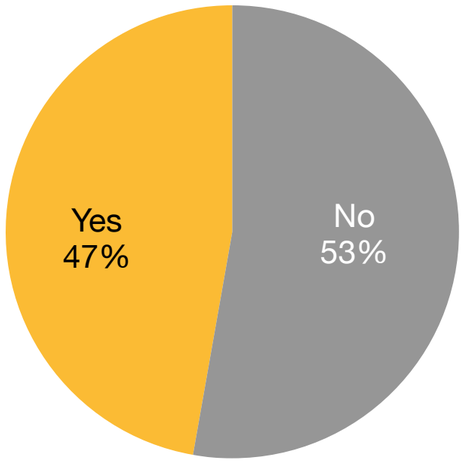
Examples of publications using PSP data:

- Prognosis of patients with hepatocellular carcinoma treated with sorafenib: a comparison of five models in a large Canadian database **https://bit.ly/2RipcTw**
- The Effects of Noncompliance to Prolia (Denosumab) on the Changes in Bone Mineral Density: A Retrospective Review **https://bit.ly/2Zp9pXx**
- Canadian Experience with Fingolimod: Adherence to Treatment and Monitoring **https://bit.ly/3inK6MY**
- Real-world use of trifluridine/tipiracil for patients with metastatic colorectal cancer in Canada **https://bit.ly/3bQaNHz**
- Impact of Adalimumab Patient Support Program's Care Coach Calls on Clinical Outcomes in Patients with Crohn's Disease in Canada: An Observational Retrospective Cohort Study **https://bit.ly/2GLKG9e**
- BioAdvance Patient Support Program Survey: Positive Perception of Intravenous Infusions of Infliximab **https://bit.ly/3kdLJxj**

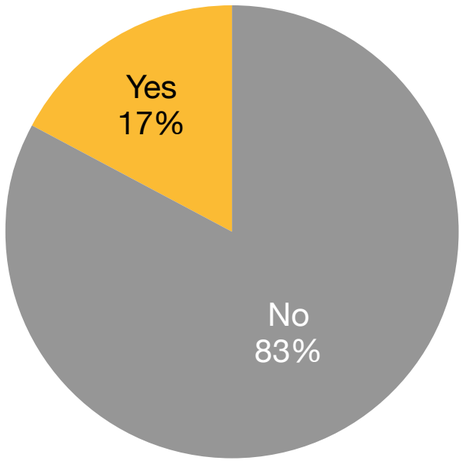
Q30: HAVE YOU PUBLISHED RESULTS FROM YOUR PSP DATA?
N = 33; ALL RESPONDENTS

47% of pharmaceutical manufacturers and 17% of PSP vendors have leveraged PSP data to support HTA analysis

Pharmaceutical manufacturers



PSP vendors



When or how was PSP data used to support HTA analysis?

"To validate assumptions."

"PSP data was cited in HTA submissions."

"To validate the treatment journey and duration of response."

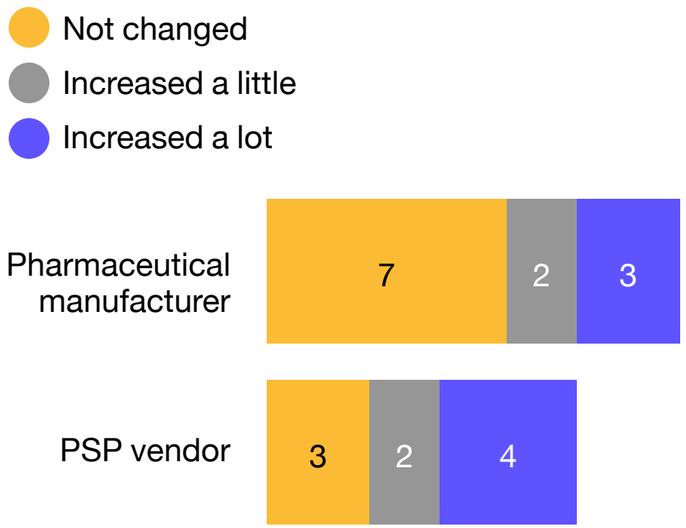
"Provided the number of patients enrolled and the outcomes of our patients."

"Used to determine the number of patients currently on treatment that would be transitioned to public payers."

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

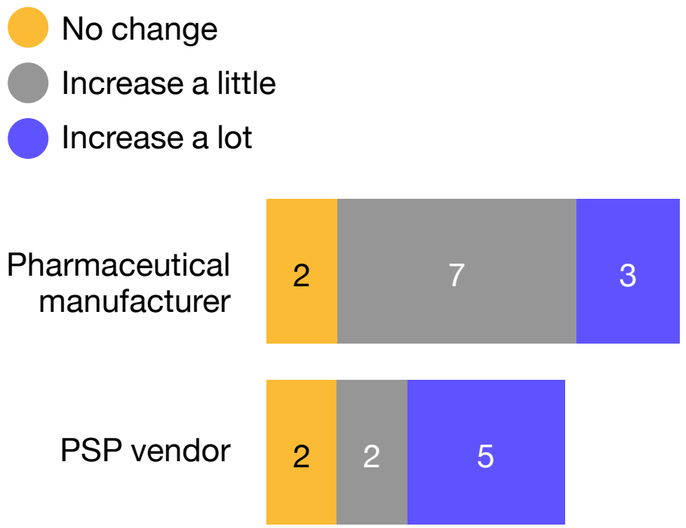
Investment in capturing and utilizing PSP data

How has your organization's investment in capturing and utilizing PSP data changed, if at all, **versus one year ago**?



Q38: HOW HAS YOUR ORGANIZATION'S INVESTMENT IN CAPTURING AND UTILIZING PSP DATA CHANGED, IF AT ALL, VERSUS ONE YEAR AGO?
N = 21; ALL RESPONDENTS

How do you anticipate your organization's investment in capturing and utilizing PSP data changing, if at all, **in the next year**?



Q39: HOW DO YOU ANTICIPATE YOUR ORGANIZATION'S INVESTMENT IN CAPTURING AND UTILIZING PSP DATA CHANGING, IF AT ALL, IN THE NEXT YEAR?
N = 21; ALL RESPONDENTS

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