

CAN CANADA'S PATIENT SUPPORT PROGRAM INFRASTRUCTURE SUPPORT THE COLLECTION OF REAL-WORLD DATA FOR USE IN OUTCOMES-BASED AGREEMENTS?

THE REAL-WORLD EVIDENCE & OUTCOMES-BASED AGREEMENTS WORKING GROUP

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BACKGROUND

The 2020 Real-World Evidence & Outcomes-Based Agreement Working Group is conducting research on the use and capabilities of patient support program (PSP) data in Canada, with the purpose of **investigating the opportunity for PSP infrastructure use for the collection of real-world data to support outcomes-based agreements (OBA).**

METHODS

The **Canadian Patient Support Program Data Capabilities Survey** consisted of 40 questions and was conducted from July 1 to 31, 2020, to understand the baseline state of PSP data, PSP data capabilities, and future plans for PSP data collection as it pertains to generating real-world data to support outcomes-based agreements. Online surveys were completed by 59 individual respondents, including 15 pharmaceutical manufacturers (32 unique respondents), 10 patient support program service providers (21 unique respondents), and 6 'other' respondents (including patient support program technology companies, specialty pharmacies, and consultants). 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.

RESULTS

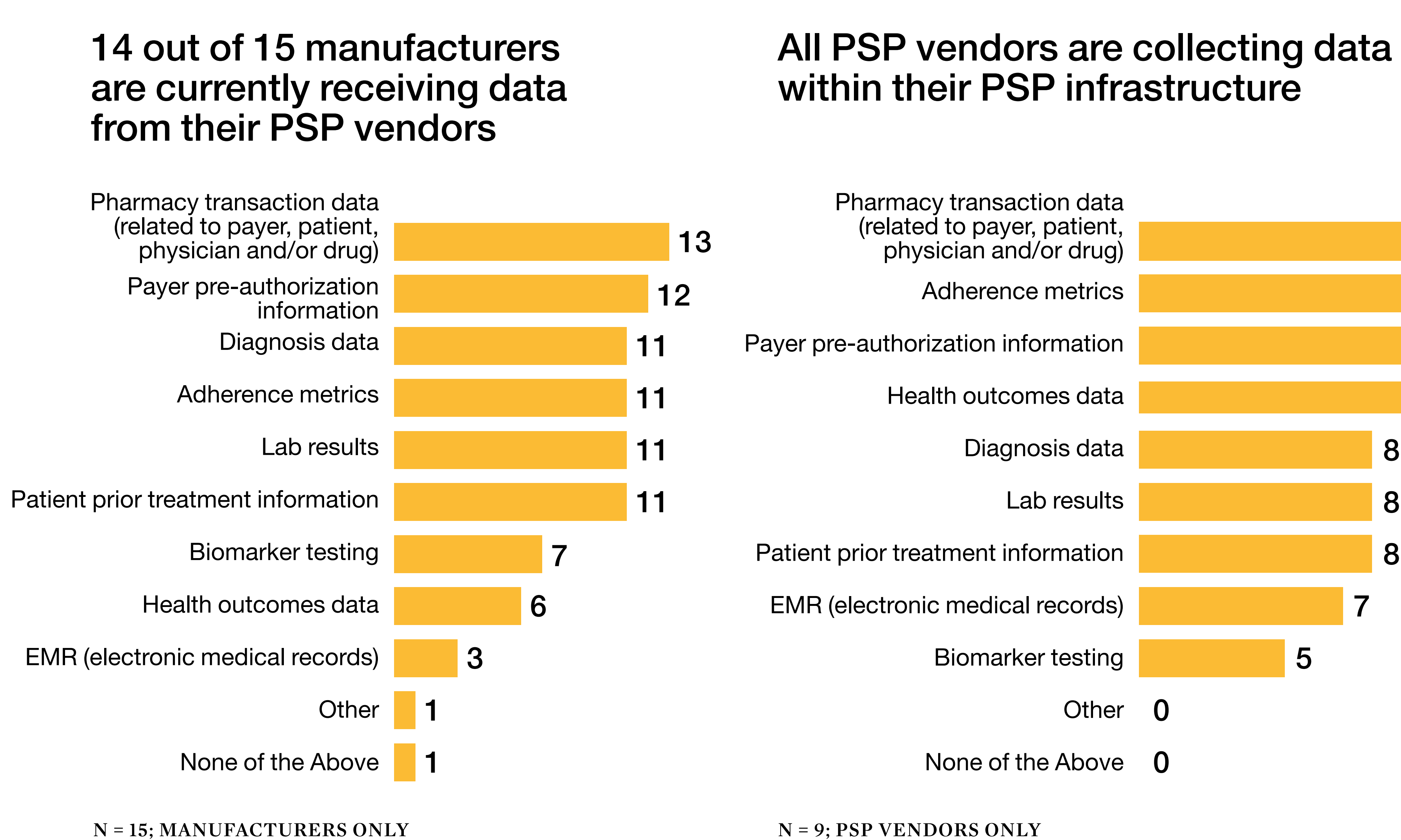
Key findings from the survey include:

1.

Broad data collection is occurring today within patient support programs, including real-world data (RWD)

- The majority of manufacturers receive data from their PSP vendors, and all PSP vendors are actively working in data collection, including advanced data, such as biomarker testing and health outcomes data. Advanced data are being received by half of the manufacturers surveyed, and increasingly collected within PSPs.
- Patient reported outcomes are also being routinely collected, as 8 out of 9 PSP vendors are collecting PROs, with all 8 indicating that the PRO data collection is built into the PSP.
- The survey found that in many programs, >75% of patients remain within their PSPs after two years post drug launch. Additionally, 40% of stakeholders are currently using a validated system for their PSP data.

Figure 1: Types of Data Collected within PSPs

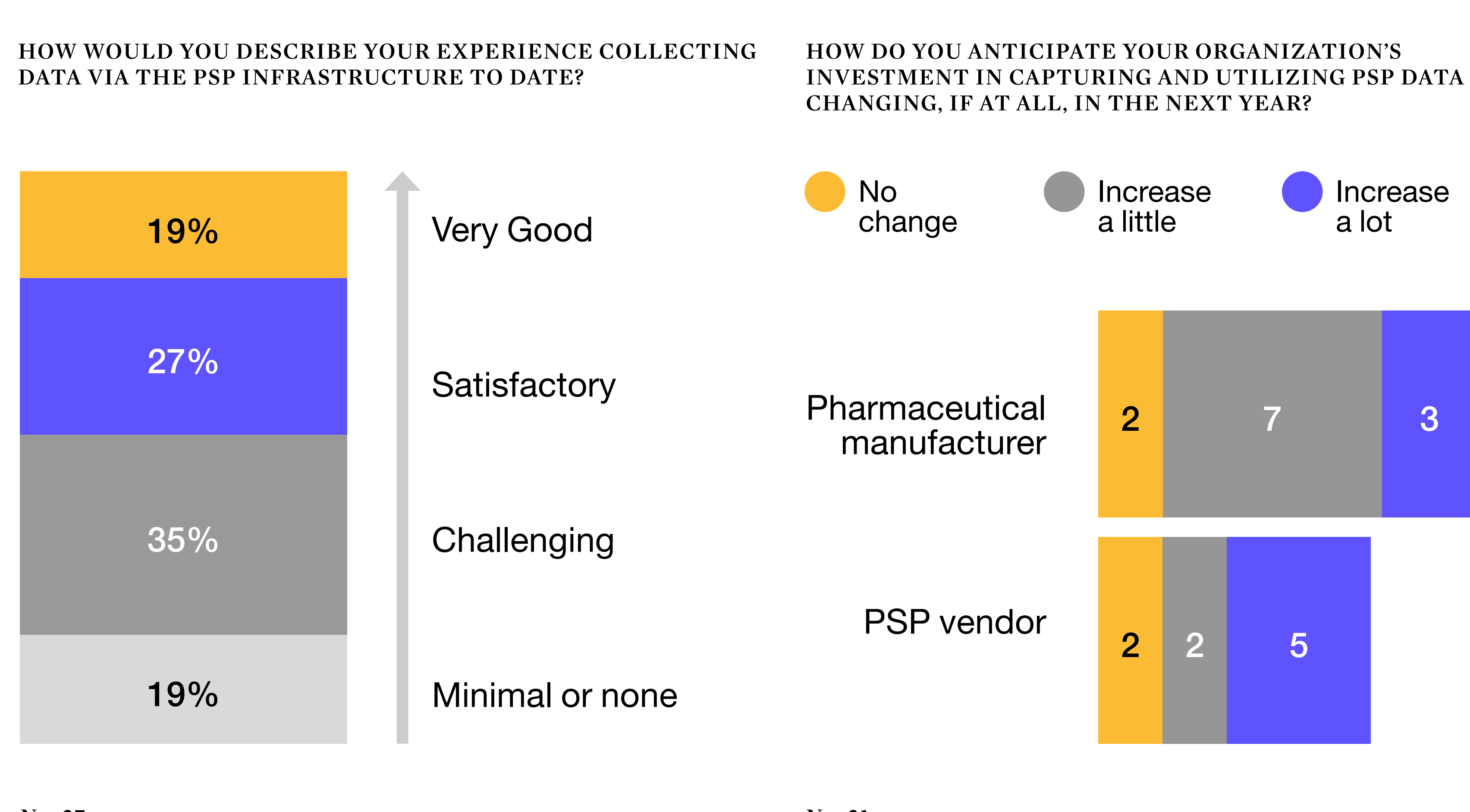


3.

Canadian stakeholders are gaining experience with PSP data use, and will continue to invest in PSP data capabilities and applications

- Survey respondents indicated that the biggest changes to the way our industry collects, uses, and shares the data from PSPs includes an increased use of PSP data to generate RWE to support market access and reimbursement, and a continued overall increase and expansion of PSP data capabilities.
- The experience collecting data to-date via the PSP infrastructure has been varied, with the majority of stakeholders indicating that they will increase their investment in PSP data in the coming year

Figure 3: PSP Data Experience and Investment Plans



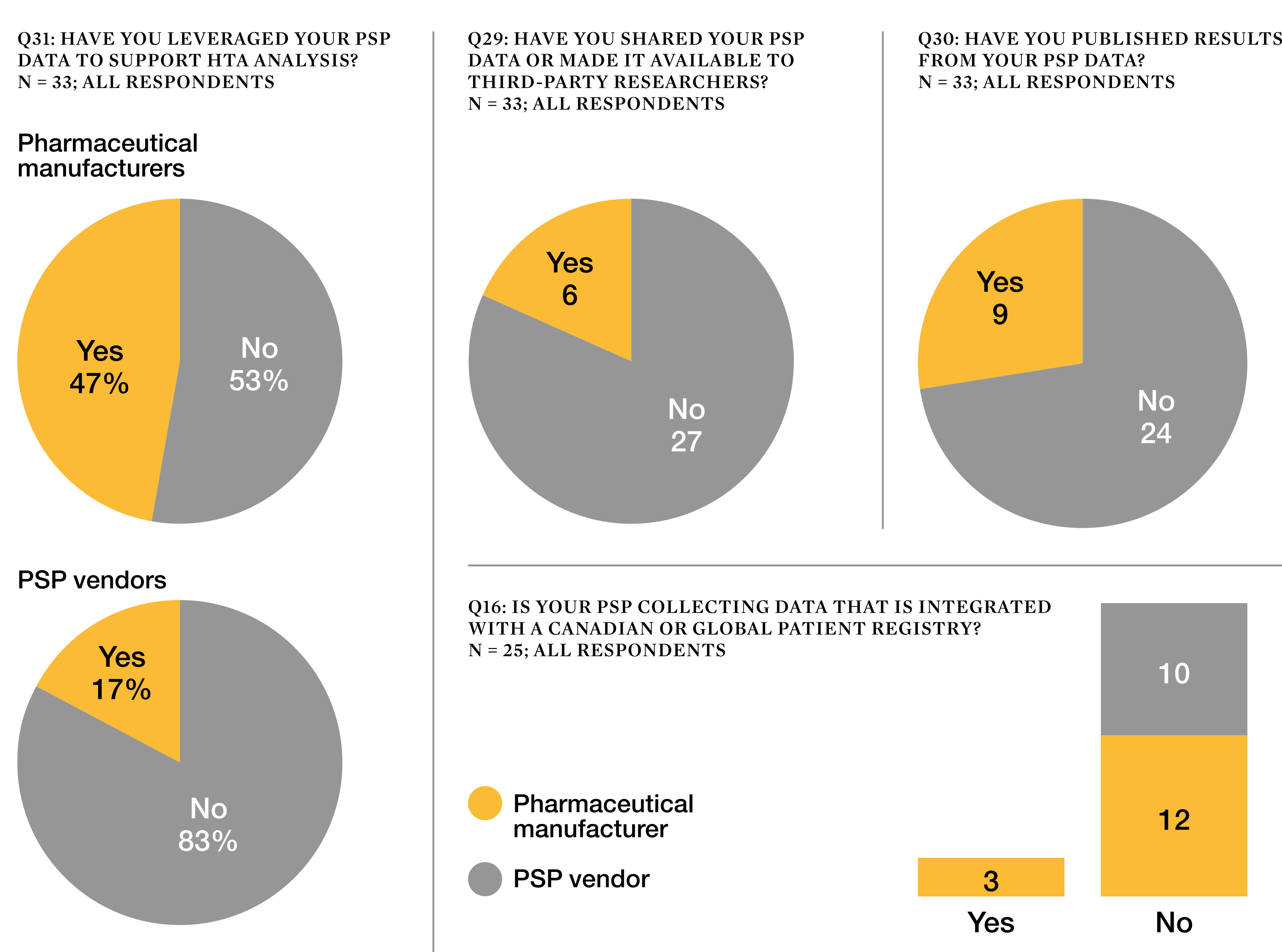
2.

Patient support program data are increasingly being leveraged for formal research and analyses

The survey found that:

- 47% of pharmaceutical manufacturers and 17% of PSP vendors have leveraged PSP data to support HTA analysis;
- 27% of respondents have published results from their PSP data;
- 18% of respondents have shared their PSP data or made it available to third-party researchers;
- 3 PSPs have data integrated with a Canadian or global patient registry.

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



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/2GLKC9e>
- BioAdvance Patient Support Program Survey: Positive Perception of Intravenous Infusions of Infliximab <https://bit.ly/3kdLJxj>

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.