

Spotlight on the Canadian Specialty Pharmaceutical Market



**Real-World
Data** *from*
**Patient
Support
Programs
in Canada**

*Where We Are Today,
and What's Next*

**PSP data: The story
behind the numbers**

**A distinctly
Canadian approach to
evidence collection**

**Dr. Aastha Dolley of
Taiho Canada powers up
PSP data**



Patient Support Programs are *Reaching New Heights*

For Canadians living with complex diseases, patient support programs (PSPs) meet critical care needs.

They also serve as a source of real-world data.

This information can reveal insights to healthcare providers, support academic research, and ultimately improve long-term patient care and access to therapies.

What Are Patient Support Programs?

PSPs exist to help patients move through the steps required to initiate and continue treatment with specialty pharmaceuticals. These medicines often treat chronic, serious, and rare diseases, require special handling, and generally have a high cost – which makes them more complex for patients to manage than traditional medications. Funded by drug

manufacturers, PSPs address critical gaps in the Canadian health care system for patients: working with payers to secure drug reimbursement, providing drug infusion and injection services and, in some cases, providing financial assistance or compassionate drug. Along the way, PSPs gather important data.

By the Numbers

PATIENT SUPPORT PROGRAMS

More than
400

Number of PSPs in Canada.¹

175

Number of PSPs for oncology drugs alone.²

10

Major specialty service providers running PSPs in Canada.³

> 600,000

Canadian patients currently enrolled in PSPs.⁴

PSP DATA IN ACTION

75%

Percentage of Canadian patients who remain in a PSP for at least two years – which results in large patient populations for real-world data collection.⁷

30,000

Estimated highest number of patients enrolled in any one PSP.⁵

Less than
500

An estimated one-third of PSPs have fewer than 500 patients enrolled.⁶

100%

Of Canada's major specialty service providers are using their PSP infrastructure to collect data.⁷

86%

Percentage of manufacturers and specialty service providers who say they're expanding or enhancing their PSP data collection capabilities.⁷

8

Number of published peer-reviewed journal articles that include Canadian PSP data.⁷

Making Headlines: Patient Support Program Data

Wondering what kind of real-world evidence PSPs can generate?

Here are five examples of studies that used PSP data.

PRODUCT & THERAPEUTIC AREA	STUDY	HOW PSP DATA AND INFRASTRUCTURE WAS USED
<p>GILENYA (fingolimod)</p> <p>Relapsing remitting multiple sclerosis (RRMS)</p>	<p><u>Canadian experience with fingolimod: Adherence to treatment and monitoring</u></p> <p>The Canadian Journal of Neurological Sciences Inc. (2016)</p>	<p>Fingolimod was the first oral therapy to be approved in Canada for RRMS. Virtually all Canadian patients taking the drug (about 2,000) were enrolled in the PSP, making it an especially representative dataset. Data collected by the PSP included drug continuation rates at 12 and 24 months, as well as reasons for therapy discontinuation such as side effects and physician requests.⁸</p>
<p>ENTYVIO (vedolizumab)</p> <p>Inflammatory bowel disease (IBD)</p>	<p><u>The relationship between vedolizumab therapeutic drug monitoring, biomarkers of inflammation, and clinical outcomes in inflammatory bowel disease in the real-world setting</u></p> <p>Journal of Crohn's and Colitis (2021)</p>	<p>This study followed patients enrolled in the PSP between 2018 and 2020 and treated with vedolizumab for Crohn's disease and ulcerative colitis. The PSP collected data from lab tests including trough concentrations of post-induction vedolizumab, albumin, fecal calprotectin, and C-reactive protein, as well as disease scores such as the Harvey-Bradshaw Index, at defined time points.⁹</p>
<p>OCREVUS (ocrelizumab)</p> <p>Multiple sclerosis (MS)</p>	<p><u>Pregnancy outcomes of women with multiple sclerosis treated with ocrelizumab in Canada: A descriptive analysis of real-world data</u></p> <p>Multiple Sclerosis and Related Disorders (2022)</p>	<p>Combining data from the PSP and a global safety database made it possible to study the safety of ocrelizumab before and during pregnancy in patients with MS – a subpopulation for whom clinical studies may not be feasible. The combined data set collected estimated conception dates and dates of ocrelizumab infusions before and during pregnancy, among other data.¹⁰</p>
<p>LORBRENA (lorlatinib)</p> <p>Non-small cell lung cancer (NSCLC)</p>	<p><u>Leveraging patient support program infrastructure to gather data to supplement HTA for rare tumors: What constitutes quality real-world evidence?</u></p> <p>Canadian Association for Population Therapeutics (2022)</p>	<p>This study followed 59 anaplastic lymphoma kinase-positive NSCLC patients on lorlatinib over a 20-month period. For this rare condition with a high unmet patient need, the PSP enabled the collection of data including ECOG status, prior therapy, and time-to discontinuation. The PSP also captured quality-of-life scores at baseline and at three, six- and twelve-months post-initiation.¹¹</p>
<p>LONSURF Trifluridine/tipiracil (FTD/TPI)</p> <p>Metastatic gastric and gastroesophageal cancer</p>	<p><u>Trifluridine/tipiracil in the real-world management of metastatic gastric and gastroesophageal junction cancers in Canada</u></p> <p>Current Oncology (2022)</p>	<p>This study followed 123 patients on FTD/TPI over 2 years, with the PSP collecting baseline data including age, primary diagnosis, HER2 status, and prior therapies, and treatment data including therapy start and stop dates, doses, dose adjustments, and reasons for discontinuing treatment. The PSP also enabled the assessment of patients' reimbursement status, including compassionate access to therapy, and compared time-to-reimbursement for public and private plans.¹²</p>

Patient Support
Program Data:
A Uniquely
Canadian Source
of Evidence

Like everything else in healthcare, patient support programs are changing.

First introduced a couple of decades ago, these programs have become a mainstay for hundreds of thousands of Canadian patients taking specialty drugs.⁴ They help patients access financial support, learn about their medication, and navigate complex health systems to get the care they need. In the process, PSPs gather data – and this is where the most exciting changes are happening. PSP data collection, research, and evidence-generating capabilities continue to evolve. With over 400 PSPs in place in Canada,¹ each with data collection infrastructure and capabilities, stakeholders across the specialty healthcare spectrum are taking notice.

What makes PSP data unique

Many patient support programs support the majority of – and sometimes all – patients who begin therapy on any given specialty drug. A large percentage of patients who are still on therapy after two years remain active in the associated PSP,⁷ and some programs are supporting patients beyond the five-year mark. As such, PSPs provide a major opportunity for longitudinal data collection.

PSPs have the added advantage of design flexibility, offering the opportunity to customize both patient services and data collection. Manufacturers can set up the PSP to collect data that will help fill evidence gaps and generate insights that can improve patient care. IQVIA Canada's real-world evidence expert Brad Millson agrees: "patient support program data can enrich our understanding of product-specific health outcomes."

Data collected through PSPs runs the gamut from patient demographics and prior therapies to lab results and treatment outcomes. Duration of treatment, dosing changes, reasons for discontinuation and quality of life: the PSP infrastructure can be employed to capture all these metrics and more. Data collection tools may include PSP enrolment forms, information captured in post-infusion reports and patient questionnaires, among others.

This breadth of data, coupled with the PSP infrastructure in place in Canada, has led Canada's health care and research vanguards to recognize PSP data's potential to not only enhance care for patients within a PSP, but to improve health care more broadly. After all, PSPs facilitate large real-world datasets of Canadian patients, presenting an excellent opportunity to fill evidence gaps and generate insights to support better health outcomes in this country.

THE CHANGING FACE OF PSP DATA

One criticism levied against PSP data, common to all observational databases, is that it lacks the rigour of controlled clinical trial data.¹³ Another is that an industry-funded data source may have a bias. Tackling these challenges head on, the research community has been working hard to elevate the quality of PSP data by engaging independent academic researchers to analyze and validate it. In some instances, these researchers are linking PSP data to other datasets, such as Health Canada's SAP data¹⁴ and global safety databases.¹⁰ A few are even using advanced research methods, like predictive analytics, to arrive at key safety and efficacy outcomes – including overall survival.¹² The data has been gaining further legitimacy as it finds its way into peer-reviewed journals.

New paradigms for PSP data collection and usage

Leading the charge, manufacturers are investing more in PSP data collection capabilities, often bringing in data scientists and engineers to ensure their PSPs have the expertise to collect the best data. Recent years have also seen extensive efforts to increase PSP data quality, including focusing on privacy, ethics, compliance, audits, and data security practices.¹⁵ "Appropriate patient-centric data governance and consents, in addition to refined statistical models are increasing the ability to use PSP data," notes Rana Qadeer, Senior Manager of the Patient Center of Excellence at AstraZeneca Canada, adding that "data quality initiatives like automated checks have made PSP data increasingly comprehensive. It's an exciting time."

Appropriate patient-centric data governance and consents, and refined statistical models are increasing the ability to use PSP data.

Manufacturers are also collaborating with PSP vendors to set data collection goals “way before setting up the PSP,” says Kelly Isaacs, Vice President of Patient Programs at BioScript’s NavieGo. The conversation “should be based on what clinical trials are doing now and will be doing in the future,” she says. Dr. Winson Cheung, a professor of medicine at the University of Calgary and principal director of the Oncology Outcomes (O2) research program, has experienced this approach first-hand, with “more frequent data-focused meetings and earlier coordination between the manufacturer, PSP vendors, and data experts.” These extra investments have yielded a big dividend: higher-quality data. For example, one PSP service provider moved from recording blood pressure as “normal, high and low” to tracking of the actual numbers, recognizing that more granular data would mitigate bias and categorization errors. With data a priority from the get-go, PSP enrolment forms are being harnessed to gather comprehensive baseline data that can inform both current and future research activities. To ensure cleaner and more complete datasets, many PSPs have moved to fillable enrolment forms, including tick boxes and drop-down menus, which also take less time to fill out.¹⁵

In tandem with these structural changes, many research organizations are developing expertise in analyzing PSP data, as they increasingly conduct PSP data studies. They may start small – for example, using deidentified patient data to gain insight into how calls from nurses impact patient adherence.¹⁶ Building from there, they may gather data that could be helpful to inform discussions between physicians and patients, such as quality-of-life data.¹⁷

Engaging patients in PSP data

It goes without saying that PSP data collection and research depends on patient consent, and manufacturers have been working diligently with their service providers and patients to improve the consent process. As noted by Isaacs at NavieGo, PSPs should ideally have “a single-consent process for research for every patient from the beginning of the program.” In fact, such one-stop consent processes are gaining ground as more PSPs are being set up to enable data collection for research. To reassure patients that the research won’t compromise their privacy, consent forms specify that the data will be deidentified, anonymized, or aggregated.¹⁵ PSP service providers and manufacturers are also working to involve patients in decisions around data collection, governance, and use.¹⁵

Patient representatives, for their part, largely support the use of PSP data for research with the right protections in place. “The patient voice is integral to improving patient care,” says Ursula Mann, Principal and Chief Patient Officer of Patient Voice Partners, which helps organizations work with patients. “Patient experts value sharing their insights while having their privacy maintained, providing PSPs the opportunity to better understand the patient experience.”

Lisa Machado, founder of the Canadian CML Network, which represents Canadian chronic myelogenous leukemia patients and their healthcare providers, sees PSPs as “a natural vehicle for data collection,” with an important caveat: “Industry needs to work with patients to ensure the outcomes collected matter to them.”

Some companies are doing just that. As Anne Marie Hayes, Director of Patient Experience at Hoffmann-La Roche, explains, the company’s Patient Co-creation Councils help them design patient support programs “through the lens of the experts – those living with the condition.” Involving patients “not only unlocks more value from research, but also builds credibility as real-world data plays an increasingly important role in informing access decisions.”

PSP research is getting published and talked about

With all this energy poured into PSP data research, it’s hardly surprising that we’re seeing such data appear in more and more published studies.¹⁵ 8 peer-reviewed published studies have used Canadian PSP data and infrastructure as part of the research,¹⁵ and the number increases further if we include posters and abstracts presented at conferences.

The fact is, PSP-driven studies can generate real-world evidence (RWE) at a relatively low cost – an opportunity that forward-thinking stakeholders don’t want to miss. These studies, which go through the rigour of ethics research board approvals,¹² can provide important RWE that help deliver insights to physicians. In a study published earlier this year, for example, Taiho Canada used its PSP to collect baseline and treatment data. By tracking start dates to treatment discontinuation due to death or disease progression, study investigators were able to estimate progression-free survival in over 100 patients taking LONSURF for metastatic gastric or gastroesophageal cancer.¹²

In another recent study, IQVIA Solutions used PSP data to gain insights on the benefits of lorlatinib therapy in a group of patients with non-small cell lung cancer – specifically, to understand time to discontinuation and quality of life at various time points during treatment.¹¹ In a poster presentation about these study findings, attendees had the opportunity to weigh in on what might lead health technology assessors (HTAs) to accept this RWE in their decisions about the therapy’s efficacy and value.¹¹ Such information gathering goes beyond a thought experiment: it’s only by sharing and critiquing PSP data that its quality can continue its rise to the level of informing broader healthcare decision making.

The patient voice is integral
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Ursula Mann, Principal and Chief Patient Officer, Patient Voice Partners

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WHAT'S NEXT FOR PSP DATA?

If current trends are any indication, future PSPs will align more closely with value-based healthcare principles: tracking and sharing the outcomes that matter most to patients, using data to drive efficiencies in their programs, and customizing patients' experiences. PSP service provider Sentrex Health Solutions is already working in this direction. In collaboration with experts at an academic institution, the group is building algorithms using retrospective ophthalmology data from their PSPs, with the goal of generating insights that will allow PSP interventions to be fine-tuned accordingly, so the right services can reach the right patients at the right time, and helping them to optimize treatment.¹⁵

The top rung for PSP data

In the next logical step, PSP data would join the fold of datasets that inform healthcare decision making about a drug's efficacy and value. As Canada continues to adopt value-based healthcare principles and innovative market access approaches, PSP data could even help expedite patient access to medications. With CADTH hard at work on a framework for the use of RWE to support decision making, we can expect to see some exciting movement in this regard.¹⁸ Dr. Nicole Mittmann, Vice-President, Scientific Evidence, Methodologies, and Resources at CADTH, confirms that "PSPs are definitely on our radar. We're having a lot of discussion around them."¹⁹ While alert to the "potential bias in using a data source developed and funded by industry," she notes that "independent analyses to ensure the reliability of the data can help overcome the issue."

Three big ideas to push PSP data forward

So where can we expect to go from here? Stakeholders looking to take PSP data to the next level can set their sights on three tangible goals:

- 1. Continue to improve data quality.** Manufacturers, PSP service providers, and data experts can work together to increase data quality, which will generate trust that the datasets reflect real-world scenarios. The "practice makes perfect" adage applies here: the more stakeholders use PSP data to generate insights, the better they can identify and fix data quality issues that arise.
- 2. Continue to use PSP data for academic research and publications.** This will increase both the industry and research communities' expertise in using PSP data, as well as HTAs' and payers' acceptance of the data as a legitimate source of RWE. Manufacturers are already

investing in the PSP data capabilities needed to generate publishable data; it's now a matter of keeping up these efforts.

3. Prepare PSP data for value-based healthcare.

Determine how to make PSP data robust enough to meet HTAs' and payers' standards. Once the data rises to the required standard, it also has the potential to support innovative market access agreements such as outcomes-based agreements. This vision feeds into a larger movement toward value-based healthcare – a philosophy that prioritizes health outcomes that matter to patients and judicious use of resources to allocate healthcare services humanely and equitably. To start the conversation: Could a registry of real-world evidence from PSPs raise the profile of PSP research and inspire conversations about standards and best practices? Would more widespread use of third-party analyses of PSP data allay stakeholders' concerns about bias? To be continued.

The Canadian way

Multifunctional, comprehensive PSPs are a uniquely Canadian phenomenon, and PSP data offers a Canadian-made opportunity to generate evidence to further improve patient outcomes. The immense opportunity for PSP data – specifically, its potential to support real-world research, clinical decisions, more responsive healthcare services, and earlier access to life-changing medications – gives us all the motivation we need to capitalize on this unique data source. Patients, who have the most to gain from RWE generation, are counting on us.

FIVE KEY ADVANTAGES OF COLLECTING DATA THROUGH A PSP

1. The data comes from Canadian patients in the real-world setting.
2. Can tailor data collection to fill evidence gaps.
3. Can capture a large percentage of patients within PSP datasets.
4. Can collect and analyze data in subpopulations for whom clinical studies may not be feasible.
5. Can add data collection at minimal cost compared to other forms of evidence generation.

Powering Up Patient Support Program Data

To create meaningful data from patient support programs, Dr. Aastha Dolley needed the right partnerships, efficient review and approval processes, and robust predictive analytics.

Dr. Aastha Dolley, Senior Director, Medical at Taiho Canada, first saw the opportunity of patient support program (PSP) data over a decade ago. Three peer-reviewed publications later (and counting), Dr. Dolley shares what led to her team's success, and the barriers and opportunities in harnessing PSP data to improve patient care.

How did you come to view PSP data as a potential source of actionable real-world evidence (RWE)?

I started looking at how patient support programs could help generate data that would not only be helpful to health care providers, but would also address local reimbursement and publication needs, which would ultimately impact clinical research in Canada. I spoke about this concept with Dr. Winson Cheung, a professor of medicine at the University of Calgary and principal director at Oncology Outcomes. With his guidance, we first published an article using PSP data in 2018 in *Current Oncology*, on duration of therapy and dose reductions in metastatic colorectal cancer patients. This paper was very well received. Since then, we've published two more papers in the journal, one on quality-of-life data for metastatic colorectal cancer patients and the other on understanding metastatic gastric/gastroesophageal cancer treatment outcomes in a real-world setting.

What endpoints did you measure with PSP data for these studies?

My PSP data journey began with analysis of readily available data. At first, we focused on treatment duration and reasons for discontinuation – the data available at the time. We also gathered data on dose delay, to understand if there was a specific group of patients who were more likely to have delays in receiving their next dose. We then progressed to using data to predict which patients might respond better to a particular therapy, and most recently to generating overall survival and progression-free survival data in a real-world setting.

In 2019, we decided to look at quality-of-life and overall survival data, because we knew these datasets would be valuable to the research community. I met with Dr. Cheung and asked if he could estimate these endpoints with predictive modelling, based on data extrapolated from the PSP. The answer was yes: Dr. Cheung was able to match data from US and European clinical trial programs to real-world PSP data. That's how, in our most recent publication, we were able to take the revolutionary step of including predicted overall survival and progression-free survival data.

We are extremely selective in what we include in our PSP data collection plans, to ensure we get all the information we need to conduct robust research.

Has anything changed in the operational set-up of the PSP, now that you know you are using it to collect data?

The data components have largely remained the same, but we have become extremely selective in what we include in our data collection plans, to ensure we get all the information we need to conduct robust research. We have also made it easier to for physicians to fill out the patient enrolment form by replacing some open-ended questions with checklists.

We're currently working on a fourth manuscript involving PSP data. This time, we requested that physicians complete a reenrolment form at six months, to ensure continued access for patients that responded well to therapy. Approximately two-thirds of the enrolled physicians sent us back completed forms, which gave us an appropriate study sample size. As a result, our upcoming manuscript has more robust baseline and 6-month-post-treatment data, along with progression-free and overall survival data.

Did the studies meet their goals?

Yes, especially in the big-picture sense. We wanted to help grow the clinical research footprint in Canada and to contribute to the conversation about when and how to use PSP data to support decision making, and I think we've achieved that. In one of the studies, we wanted to generate evidence that would help us understand the nuances between a clinical trial program and real-world data, and give physicians a snapshot of what is actually happening in Canada. The study gave us some new insights, and some of the data that we included in our paper had never been published before.

Do you think PSP data should be accepted as RWE for healthcare decision making with, for example, HTA bodies?

Yes, I do. PSPs can provide such a wealth of information, it's a shame not to use them in this way. One current problem is that, while HTAs will consider RWE data in resubmissions, they use the same criteria to evaluate the robustness of RWE data as they do for clinical trial data. I think HTAs need to be more open to indirect comparisons, because it's often not possible to do an RWE study with a comparator arm.

What are the largest advances in the use of PSP data for evidence generation in recent years?

PSP data has the potential to help predict outcomes and quality of life parameters. That's powerful information! For example, PSP datasets can give predictive insights into treatment outcomes for subsets of cancer patients in the real world compared to clinical trials. We now have predictive analytic tools that were not available even five years ago, with even more opportunities to mine the data using AI technology.

PSP data has the potential to help predict outcomes and quality of life parameters — *that's powerful information.*

What are some critical factors in the successful use of PSP data?

It's crucial to develop the PSP enrolment form with an eye to obtaining high-quality data. Success also depends on partnerships with researchers and PSP vendors. In Taiho's case, Bayshore Specialty Rx, our patient support program provider, has been critical to ensuring the data we collect is accurate and complete. Dr. Cheung and the team at Oncology Outcomes, who run the data analytics part of the program, have raised the bar for PSP research.

Will you continue to use PSP data to support additional evidence generation?

In anticipation of the additional indications we'll be launching, we are prepping our PSP programs to collect even more and better data. The real-world Canadian evidence we can generate from our PSPs is a rich vein of information that, used judiciously, helps us improve care for Canadian patients.

To date, Taiho Canada has published the following three studies, thanks to data collected within its patient support program. A fourth study will be coming shortly.

Real-world use of trifluridine/tipiracil for patients with metastatic colorectal cancer in Canada Samawi, H.H. et al. (2019). *Current Oncology*.

Quality of life in a real-world study of patients with metastatic colorectal cancer treated with trifluridine/tipiracil Cheung, W. Kavan, P. and Dolley, A. (2020). *Current Oncology*.

Trifluridine/Tipiracil in the Real-World Management of Metastatic Gastric and Gastroesophageal Junction Cancers in Canada Ding, P., Dolley, A. and Cheung, W. (2022). *Current Oncology*.

On the reading list

[Global healthcare fairness: We should be sharing more, not less, data](#)

[The role of health data in evolving our healthcare systems](#)

[Can Canada's patient support program infrastructure support the collection of RWD for use in outcomes-based agreements?](#)

[Patient support program insights can inform payer programs](#)

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Spotlight on the Canadian Specialty Pharmaceutical Market

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