THE 20SENSE REPORT

SPOTLIGHT ON THE CANADIAN SPECIALTY PHARMACEUTICAL MARKET

JULY 2019_ISSUE 9

20 SENSE
Making sense of Canada's specialty pharmaceutical market

Are We Ready to Put Health Outcomes Data to Work?

Health Outcomes Data: When, Where, and How to Collect It

Let's throw a pie in the sky and imagine that all healthcare providers have ready access to data on a medication's real-world performance, so they know whether to prescribe it to the patient across their desk; that payers can use health outcomes data to decide whether to list or delist a drug, or how to price it; and that manufacturers of high-performing medications can leverage data to reach patients more efficiently and expand their global presence.

Why is this so hard to imagine, let alone implement?

Real-world data, real-world challenges

Capturing data is one thing, using and sharing it quite another. Within a specific therapeutic area – leukemia or multiple sclerosis, for example – an academic institution may launch a database, a manufacturer may support a registry, and a hospital or clinic may gather internal data. But can a physician at the hospital access the registry? Can the academic database mine the clinic's data? Without effective cross-talk between the databanks, they stagnate in their respective siloes and their power remains limited.

Adding a further layer of complexity, the technologies used to capture data are constantly evolving, leading to glitches along the way. Take artificial intelligence (AI), for example. In theory, AI systems can crunch a vast number of data points from previous patients and use the information to predict how a new patient will respond to treatment X, Y or Z. The problem: AI algorithms are only as good as the inputs from which they learn. If the inputs contain biases, the algorithms will carry these biases forward. As an example, an AI algorithm that learns from previous images of moles in fair-skinned individuals may accurately identify a cancerous mole in a patient with fair skin, but miss the mark in a darker-skinned patient.[1]

Bias can lurk in the most unexpected places. In one instance, a Toronto-based start-up discovered the AI technology they were using to identify patients with neurologic disorder only worked for native speakers of Canadian English.[2] When applied to people with different accents, the technology was liable to misinterpret speech patterns and identify a disease where none existed.[2]

Creating the infrastructure to enable such data communication takes time, money and resources, not to mention agreement from several parties. Concerns about privacy and data integrity can easily derail the process. And with development budgets under constant scrutiny, the vision of a "data highway" may seem a distant mirage.

Moving in the right direction

For all these obstacles, interest in generating and using real-world data has ballooned in recent years. This is a welcome development, →

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as real-world data offers two important advantages over clinical-trial data: there is a lot more of it, and it reflects the experience of real-world patients in all their complexity, rather than the narrowly defined cohorts in clinical trials.[3]

Not surprisingly, clinical trial data and real-world data do not always align – as exemplified in an analysis of lung cancer patients on PD-1 inhibitors, which found that real-world patients had shorter survival times than their clinical-trial counterparts.[3] Such discrepancies drive home the point that real-world evidence can – and should – supplement clinical-trial results. In support of this principle, the FDA based its 2016 decision to approve a new indication for an aortic valve replacement on real-world data from a product registry.[4]

Real-world data can also help contain costs by shining a lens on treatments that work – and those that don't. According an American Society of Clinical Oncology (ASCO) study, fewer than one out of five recently approved cancer drugs significantly improve survival outcomes, making it more urgent than ever to link payment to value.[5] With this objective in mind, some Canadian preferred provider networks (PPNs) are mining health outcomes data to substantiate pay-for-performance agreements between payers and manufacturers.

The wider the data net, the greater its strength. The next big step in data capture will be to link databases throughout the country – and beyond – to create a data highway that prescribers, payers and manufacturers can use to improve the patient experience. A number of countries have taken significant steps in this direction– notably the United Kingdom, where pharmaceutical companies can purchase access to an EMR family-physician database.[6]

Canada is not so far behind. Throughout the country, initiatives in health-outcomes data are already bringing the dream of "health data connectivity" to our corner of the world.

Real-world data drivers

- **Patient registry:**[7] A collection of standardized information about a group of patients who share a condition or experience.
- **Specialty medication data:** Data that reveals how a specialty medication performs in different patient groups.
- **Patient support program (PSP):** These programs provide educational and logistical support to patients taking specialty medications. PSPs can also be harnessed to capture health outcomes data. In recognition of the data's strategic importance, more and more PSPs are weaving data-collection capabilities into their upfront design.

References

1. Cuttler M. Transforming healthcare: how artificial intelligence is reshaping the medical landscape. CBC.ca. April 26, 2018. http://bit.ly/2x1T1xr
2. Gershgorn D. If AI is going to be the world's doctor, it needs better textbooks. Quartz. September 6, 2018. http://bit.ly/2XSBAve
3. A study showing real world use of "real world data." Datavant 2018. http://bit.ly/2XW4R85
4. Panner M. Real-world health data push brings challenges and opportunities. Forbes Community Voice. December 12, 2018. http://bit.ly/2MWayBV
5. Value-based contracting for oncology drugs. A NEHI white paper. http://bit.ly/2KVLfxr
6. Cavlan O et al. Real-world evidence: From activity to impact in healthcare decision making. McKinsey & Co. https://mck.co/2L0Xfxp
7. Workman TA. Engaging Patients in Information Sharing and Data Collection: The Role of Patient-Powered Registries and Research Networks. Agency for Healthcare Research and Quality, 2013. http://bit.ly/2KrbCfc
8. Pennic J. Canadian Government Awards $49M Grant to Establish Canada-wide AI Health Data Platform. Canada.ai. http://bit.ly/2IpmQOT
9. Real-World Evidence and Outcomes-Based Agreements Working Group for Specialty Pharmaceuticals. Meeting #1 synopsis, March 9, 2019.
10. Lun E. Managing the "Expense" in Expensive Drugs for Rare Diseases (EDRD). Panel discussion, CADTH symposium, April 15, 2019. http://bit.ly/2L00ntA
11. Value-based decisions from real-world evidence. CanREValue. https://cc-arcc.ca/canrevalue-about/
12. ConnectingOntario ClinicalViewer. eHealth Ontario. http://bit.ly/2IPZd0X
13. Québec Health Record, Québec. http://bit.ly/2xxORxO
14. Defining decision-grade real-world evidence and its role in the Canadian context: A design sprint. Summary report of an October 21, 2018 workshop.
15. Driving Health Innovation: Harnessing the Power and Value of Real-World Evidence. CAPT conference Oct. 21-22, 2019. https://www.capt-actp.ca/conference/

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Grand and Grounded: Real-World Ideas and Initiatives in Canada

Recognizing the power of real-world data, Canadian governments, private institutions and academic centres are finding new ways to generate it, collect it, and connect data points across the country. Here's a taste of what's happening.

AI-powered national data platform

Earlier this year, the Government of Canada pledged up to $49 million toward the creation of a nationwide AI-based health data platform to accelerate cancer research (and eventually, research in other therapeutic areas).[8] A network of close to 100 partners across Canada, including health care institutions, research foundations, and AI research labs in Canada, will collaborate to create the platform. If the grand vision bears out, the platform will enable cancer clinics and hospitals to quickly share data to develop more personalized and effective treatments for aggressive cancers.[8]

Realistic planning for rare-disease treatment

Earlier this year, the Standing Committee on Health made several forward-thinking recommendations: adding transparency to the review process for rare-disease drugs, funding research to generate real-world data on these drugs, and using the data to inform decisions about coverage.[10] Along similar lines, the Provincial/Territorial EDRD Working Group's proposed supplemental process for complex/specialized drugs, outlined in 2018 with stakeholder consultations completed early 2019, involves the collection and assessment of real-world evidence (RWE).[10]

Keeping oncology treatment accountable

Backed by a Canadian Institutes of Health Research (CIHR) grant of almost $1 million, Dr. Kelvin Chan at the Sunnybrook Research Institute in Toronto is heading a multidisciplinary study titled "Developing a framework for the incorporation of real-world evidence into cancer drug funding decisions in Canada." The study seeks to determine how best to generate and use RWE in the assessment of cancer medications and to refine funding models for these medications.[11] The study group will assemble a national panel of clinical, methodological, and policy experts to create flexible RWE-based frameworks for cancer-drug funding decisions.[11]

Connected provinces: Ontario and Quebec

Life has just gotten easier for Ontario physicians and pharmacists. A new web-based portal, developed by eHealth Ontario, gives health providers a comprehensive view of their patients' health journey within the province.[12] Called **ConnectingOntario ClinicalViewer**, the portal provides secure access to lab results, dispensed medications, diagnostic imaging reports, visits to hospitals, and mental health care information, among other data.[12] In Quebec, the Québec Health Record (QHR) allows physicians and other authorized health and social services professionals centralized access to lab results, medical images and medication information, with plans to soon integrate information on hospital stays.[13]

Evidence with teeth

Last October, Health Canada, the Canadian Association for Population Therapeutics (CAPT), the Canadian Agency for Drugs and Technologies in Health (CADTH), and Institute of Health Economics (IHE) jointly developed and delivered a "design sprint" workshop on RWE.[14] In addition to exploring opportunities to use RWE across the drug life cycle, the workshop sought to establish standards for "decision-grade" RWE. The group identified a structured decision-making process, end-to-end stakeholder involvement, and trust between stakeholders as crucial factors in the generation of high-quality RWE.[14] Building on this theme, the CAPT's upcoming October 2019 conference will tackle tough issues such as privacy and data sharing, RWE to inform reimbursement, and RWE to drive policy change.[15]

Paying for performance

Spiralling drug-spend, cash-strapped health system, payers stretched to their limits… We've all heard these alarm bells. The Real-World Evidence and Outcomes-Based Agreements Working Group is exploring ways to advance the opportunity for outcomes-based agreements (OBA) in Canada, so that a drug's real-world performance determines when it's paid for.[9] The group's 2019 priorities include defining the OBA value proposition, identifying scenarios for drugs in which OBAs make the most sense, and examining health outcomes data within patient support programs and at specialty pharmacy.[9]

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Smart Data: Interview with Tazmin Merali

As co-founder and partner at Drug Intelligence, **Tazmin Merali** has helped numerous innovative pharma companies break through to commercial success. A pharmacist by trade and graduate of Harvard Business School, Tazmin has worked in every corner of the industry – as a pharmaceutical sales representative, advisor to private payers, health informatics specialist, at CHUM in Montreal and UHN in Toronto, among other positions – and brings a unique and powerful skill set to Drug Intelligence. Her current role has Tazmin leading the charge on the collection and analysis of Canadian health outcomes data. In this discussion with 20Sense, she shares her expert opinions about the role of data for specialty pharmaceuticals and gives us an inside look at Drug Intelligence.

Q: What led you to start your own data company, and what does Drug Intelligence do?

When I was working within the hospital system, we had reports telling us how much drug was purchased and who was using it, but we didn't know if the drugs were being used for the right patients at the right time. We also didn't fully understand how clinicians were making treatment decisions. So, we started to collect holistic clinical data on drug use, which allowed us quantify the impact of our initiatives over time. Drug Intelligence was a natural outgrowth of this process: we started the company to capture, analyze and interpret real-world treatment data that can be used to inform clinicians, industry and payers.

Q: What kind of data do you collect and how do you use it?

We collect real-world clinical data, data on treatments used and their outcomes, data on health resource use, and patient-reported data such as the impact of treatment on their everyday activities. We continuously track the treatment of specific diseases – which for some we've been doing over a 25-year period – and use scientifically validated methods across all sites and update our data on a regular basis. We don't just collect the data, we connect it. By linking clinical data to patient-reported data, we gain insights into why patients start or discontinue treatment, or what clinicians who keep them on treatment are doing differently. We may also use our data to demonstrate a gap in current treatment and highlight a need for innovation.

Q: How do you obtain your clinical data?

We get it from physicians who treat patients in the real world. In oncology, for example, a panel of about 100 oncologists across the country, representing two-thirds of tier-one and tier-two cancer centres in C anada, provides us with anonymized patient data across a variety of cancers. We also work with physicians in other specialties to obtain curated data about the conditions they treat.

Q: How does data benefit manufacturers, payers, prescribers, and patients?

Here's a simple metric: What proportion of patients eligible for a treatment are receiving treatment? The answer gives manufacturers a world of insight into market size, gaps, needs, and opportunities. Payers need data on patients and anticipated uptake over time, so they can allocate their budgets to the right treatments. Prescribers can use the data to adjust treatment decisions. →

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Patients themselves want access to treatments that will make a real difference in their lives, and the data can help them decide if a treatment makes sense for them.

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Q: Are pharmaceutical manufacturers using data to its full potential? How could the industry improve its use of data?

Some forward-thinking companies are using local data the way it should be: to inform decisions, monitor performance and now also to support HTA and payer submissions. For this to happen, traditional silos need to break down. The information needs to flow between the people within the organization who capture or buy the data and those who deal with commercialization and access. With drug submissions, you get one kick at the can and need to put your best foot forward. Good data is critical to good submissions.

Ideally, data should lead to an action – think of it as a lever. Let's say the benefit of a particular specialty treatment depends on testing positive for a biomarker. If the data reveals a low rate of testing, the manufacturer can work with clinicians and laboratories to ensure the testing gets done. That's the lever.

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Q: How have you seen the data needs of the industry change over the years?

We now have treatments for more advanced stages of disease, especially in oncology. Let's say you've launched a third-line colorectal cancer treatment, suitable for those with relapsed disease. You'll need data on time to relapse, proportion of patients who relapse, and biomarkers that correlate with relapse, among other parameters. Today, we also have opportunities to capture data from multiple distribution channels – from hospitals to infusion clinics, pharmacies to patient support programs.

Q: How has Drug Intelligence evolved to serve the changing industry?

When we started out, we did chart audits for individual companies that needed real-world data. With the proliferation of specialty drugs, we began collecting our own comprehensive data on a range of diseases and making it available to all our clients.

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Q: Could health outcomes data be used to support outcomes-based agreements (OBAs)?

Yes, for some treatments. With so many transformative but costly treatments being developed, we really have no choice. The challenge is to decide on what constitutes a good outcome. People also need to trust that the data is reliable and objective. To make OBAs a reality, we need to think creatively and keep our focus on the patient.

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Q: Do you have any advice to give manufacturers about harnessing the power of data?

Data can help match the right treatments to the right patients at the right time, resulting in better outcomes. What's more, the commercial success of a specialty brand depends heavily on data. Become familiar with, and leverage, multiple data sources. Frame the right data to meet payer needs. Base your decisions on robust, reliable and credible data and monitor the impact of your strategies over time. At the same time, be comfortable with less than perfect data, and harness the power of predictive analytics to plot a longer-term strategy.

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Q: What is a "typical" workday for you at Drug Intelligence, if there is such a thing?

A typical day involves reviewing analyses of databases to address specific business questions, digging further to uncover relevant insights, and talking to clinicians and clients across the country. Having said that, every disease is different, and I am constantly learning. I have never been bored! That's what I love about this work.

Pushing the levers

Tazmin is passionate about data-driven decisions—what she calls levers. Here, from Tazmin's files, are two examples of how data helped pharma companies push the right levers and get results.

A manufacturer with a novel treatment for metastatic prostate cancer gathered data to put the costs of treatment in perspective (for example, cost savings from avoiding or delaying hospitalizations) and used the data in their market access submissions. As a result, the company was able to secure access on the earliest timeline after the treatment entered the market.

In a case involving a drug that raised payers' concerns about budget impact due to its proposed broad use, the manufacturer used outcomes data and predictive analytics to build an argument to fund the medication for patients at highest risk. Over time, as more people started using the medication, outcomes data confirmed and quantified its benefits to patients, supporting further dialogue about broader access and pricing between the manufacturer and payers.

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The Specialty Data Mine: What Canadian Industry Leaders are Doing

To get a pulse on the role of health outcomes data in the industry, 20Sense surveyed four Canadian specialty pharmaceutical leaders. As captured in the table below, these leaders collect data on a spectrum of treatment parameters – and use the information to gain strategic insights for the benefit of stakeholders across the country.

WALKING THE DATA TALK: DATA SERVICES PROVIDED BY CANADIAN SPECIALTY LEADERS

	Bayshore Specialty Rx	BioScript Solutions	Specialty Health Network (Shoppers Drug Mart)	sti reach assist discover
OWNERSHIP	🍁	🍁	🍁	🍁
CANADIAN HEAD OFFICE	Mississauga, ON	Oakville, ON & Moncton, NB	Mississauga, ON	Halifax, NS
PATIENT SUPPORT PROGRAM MANAGEMENT DIVISION	Bayshore Specialty Rx	NavieGo Patient Programs	SHN Patient Assistance Solutions	STI assist
THERAPEUTIC AREA EXPERTISE	Oncology, neurology, rheumatology, immunology, rare diseases.	Multiple sclerosis, HCV, immunology, oncology, rare diseases and more.	Immunology, oncology, neurology, endocrinology, rare diseases.	Oncology, GI disorders, infectious diseases, organ transplant, eating disorders, neurology, multiple sclerosis, inflammation, hormonal disorders.
DATA AND ANALYTICS SERVICES PROVIDED TO MANUFACTURERS	Reporting, surveys, portals, dashboards.	Data visualization, transformation, aggregation; predictive analytics, dynamic performance dashboards, therapy utilization, payer insights.	Comprehensive raw data, analytics and insight generation.	Analytics to support, measure and manage: program design, program performance, patient engagement and journey, prescriber & pharmacy engagement in programs
HEALTH OUTCOMES DATA COLLECTION	Developing and publishing real-world data; using real-world evidence to advocate for drug coverage. Supporting pay-for-performance models through nursing and pharmacy services that facilitate adherence.	Validated clinical scales and lab values; chief complaint, indication, adherence, persistence, treatment pathway, dose escalation, comorbidities, concomitant therapies, quality of life.	Patient clinical surveys; validated questionnaires (quality of life, work productivity, activity impairment, etc.).	Measurement of program effectiveness and impact on clinical outcomes.

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Data forecasts

20Sense was curious about how industry leaders see the role of data evolving in the future. So we asked them: "What do you see as the next innovation or opportunity in health outcomes data collection for the Canadian specialty pharmaceutical industry?" **Here's what they told us.**

"Our integrated technology platforms have propelled us into a data-rich world. Within specialty medicine, the high-touch treatment model allows us to capture data at every point along a patient's journey.

The next frontier will be to contextualize and combine disparate data sets to gain deeper insights into the value and drivers of specialty therapies."

Chris Dalseg
Vice President, Strategy and Industry Relations,
BioScript Solutions

"Health outcomes data facilitates market access and pay-for-performance models, which are becoming increasingly important for specialty pharmaceuticals, and enables us to respond to patient concerns that could lead them to drop off treatment.

We are working on finding creative and efficient ways to capture this data directly from patients – for example, through Bluetooth-enabled wearables and medical apps."

Karl Frank
Divisional Director,
Bayshore Specialty Rx

"Health outcomes data only has meaning if it influences decisions. That will be the next big step: connecting the dots between data and decision-making.

Clinicians will harness real-world data to guide new patient starts and improve their clinical decision making, and the data will support a rationale for coverage and patient access."

Tony Volpe
Senior Director, Business Development,
Shoppers Drug Mart Specialty Health Network

"There are no limits to the creative ways we can collect and use health outcomes data. As just one example, community and specialty pharmacists can enrol patients in support programs, help them stay engaged in program services, and collect clinical and experiential data.

This model will gain further traction as more specialty products are launched."

Paul Cowley, Sr.
Director Patient Engagement Solutions,
STI Technologies Limited

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What We're Reading

We find that the following articles provide great insight into the specialty pharmaceuticals market. Follow us on **LinkedIn** where we're sharing our thoughts on these topics and many more.

- Real-world health data push brings challenges and opportunities
- Real-world evidence: From activity to impact in healthcare decision making
- Closing our data gap will be good for our health
- Canadian Government Awards $49M Grant to Establish Canada-wide AI Health Data Platform
- No Miracle Drug Should Cost $2.1 Million
- Defining decision-grade real-world evidence and its role in the Canadian context: A design sprint summary report of a workshop
- Use of real-world data sources for Canadian drug pricing and reimbursement decisions: stakeholder views and lessons for other countries

Upcoming Issues

In upcoming issues of The *20Sense Report*, we'll take a deeper dive into:

- The patient perspective on specialty pharmaceuticals
- Exploring opportunities for outcomes-based agreements

Is there an issue you'd like us to address? Do you have a question you'd like us to answer?

We welcome your suggestions for topics you'd like *The 20Sense Report* to cover.

THANK YOU TO OUR SPONSORS, SUPPORTING INDEPENDENTLY RESEARCHED CONTENT AND WORKING TOGETHER TO PROVIDE VALUE AND TRANSPARENCY WITHIN CANADA'S SPECIALTY PHARMACEUTICAL INDUSTRY.

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