



REAL-WORLD EVIDENCE (RWE)
Let's Talk Manitoba

FORUM REPORT²⁰¹⁶



EXECUTIVE SUMMARY

The concept of Real-world Evidence (RWE) continues to grow in importance among health care delivery stakeholders, and it is critical that the Life Science Association of Manitoba (LSAM) help its members better understand the benefits of RWE and how and where to access the data.

Manitoba is considered to be unique in its depth of available data and is home to organizations that offer solutions and services relating to research, data acquisition, knowledge translation, health care delivery and an innovative life science sector. However, despite the clear and demonstrated benefit of RWE, it is felt that access to this data is excessively onerous.

One of LSAM's main goals is to assess and assist in building a research environment in Manitoba. By bringing stakeholders together, we aim to uncover new opportunities for partnership and strengthen relationships between industry, researchers and Manitoba research organizations.

As such, LSAM surveyed its members to determine if they are accessing Manitoba data and to better understand their experiences when attempting to acquire this data. These survey results were used to shape the RWE Forum, which took place on May 17, 2016 and which discussed the opportunities and issues surrounding the use and access of RWE (data) in Manitoba.

As the voice of the organizational nucleus of the life science industry in Manitoba, LSAM is providing this report, which contains a summary of the presentations and discussions at the Forum, and a set of recommendations to further build a clinical research environment in Manitoba.



THE SURVEY

An online questionnaire was developed and distributed to LSAM members and stakeholders in December of 2015, with follow up in March of 2016. A total of 26 companies completed the survey.

Results showed that **79% attempted to obtain data** from a researcher or organization for a health related project. The remaining **17% did not attempt to obtain data** because the process was unclear or they weren't aware that the data was available.

Of the respondents who attempted to obtain data, **53% (10) were able to access the data** they sought by working with their first point of contact. In most cases, they were able to obtain the data in a one week to two months.

The other **47% were unable to access the data** for a variety of reasons, including being re-directed from their first point of contact, misunderstanding the process, privacy and security concerns, and issues with documentation.

Those who were seeking data anticipated outcomes that including improved efficiencies in health care delivery, better patient outcomes, benefit to health care provider and cost savings.

Whether those surveyed were successful or not in obtaining data, all respondents reported incurring work delays, lost salaries and additional paperwork. Comments received in the survey indicated that the process was "slow", "time consuming" and even "painful and frustrating".

Members indicated the process could be improved by reducing red tape, lessening the amount of paperwork required, creating an easier and more transparent process, speeding up the decision making process, and responding with the data that was required. They also suggested that a better evaluation of the privacy concerns was required.

When asked if they would be willing to pay for the data, 83% said they would be willing.

THE FORUM

LSAM hosted the Real-World Evidence Forum on May 17, 2016. The intent of the Forum was to initiate a constructive dialogue regarding RWE in Manitoba. Why Manitoba is unique? What opportunities exist here and how do we capture them? What are the challenges and how do we overcome them? A broad array of stakeholders attended the conference.

The first presenter was **Dr. Adrian Levy** from the Department of Epidemiology and Community Health at Dalhousie University. He focused on the framework of data, information and knowledge and touched on the following points:

1. That the concept of RWE is not recent, but is growing in recognition among healthcare stakeholders and policy makers;
2. Generating RWE requires multi-disciplinary expertise from health and social sciences and other areas;
3. Innovations in data sciences and information processing have the potential to ensure more evidence-based policy and decision-making.

Dr. Levy provided an overview of what RWE is and the various advantages and disadvantages of observational and experimental study designs. He explained that Randomized Controlled Trials (RCT) are the basis of regulatory approval worldwide and that regulators have a strong belief that RCTs are the ultimate form of evidence for both intended and unintended effects, citing the JUPITER trial as an example. Dr. Levy suggested we should move beyond the notion that RCTs are the single highest form of evidence, as even regulators treat the same pieces of evidence very differently depending on the region.

He further explained that while the concept of RWE isn't new, there have been numerous advances in terms of data processing, such as the way we use information and generate knowledge. In the hierarchy of data, information and knowledge, he suggests that one can think about going from data to information as a processing issue; unorganized facts and figures can be processed to contextualize information and gain improved understanding of the data. This has generated renewed and growing interest in RWE.

Dr. Levy highlighted some of the major data gathering agencies in Canada including the Canadian Institute for Health Information (CIHI), as well as the Manitoba Centre for Health Policy, which was one of the first repositories to introduce data on non-medical determinants of health including family services, justice and social housing. He also discussed the advances in computing software, including networked information systems, which allow for faster database manipulation. He encouraged the audience to begin sharing their data so other researchers can access and build further understanding.

Dr. Levy finished his presentation by discussing the importance of outcomes and end-points. He indicated that there is a significant data collection gap relating to the impact a surgery or device has on a patient, i.e. have we helped them walk, reduced their pain, returned them to normal levels of activity? The Canadian Institute of Health Research (CIHR) has begun looking into this through its Strategy for Patient-Oriented Research (SPOR), which is a patient-oriented research effort that refers to a continuum of research that engages patients as partners, focuses on patient-identified priorities and improves patient outcomes.

PANEL DISCUSSION #1 – *Why?*

A panel discussion followed Dr. Levy's presentation. Four guests comprised the panel – **Marshall Ring** of ASI Inc., **Dr. Salah Mahmud**, from the Vaccine and Drug Evaluation Centre at the University of Manitoba and the George and Fay Yee Centre for Healthcare Innovation, **Dr. Alan Katz**, from the Manitoba Centre for Health Policy, Department of Community Health Sciences, College of Medicine, Faculty of Health Sciences at the University of Manitoba, and **Ed Gudaitis**, General Manager at the Gilead Sciences Canada Inc. and Prairies Chair, Innovative Medicines Canada.

Questions and discussion were moderated by **Doug McCartney**, Senior Executive Director, Science, Innovation and Business Development at Province of Manitoba.

The Panel Discussion focused on “Why” Manitoba is unique and what opportunities and challenges exist here.

Panelists discussed how data is required in a more robust way now than ever before. They agreed there is an increased need to validate decisions, which can lead to new inventions and the introduction of better devices/treatments into the market. The panelists agreed that more data means more informed decisions, which leads to more knowledge.

Panelists were asked to express what they believe are the opportunities and challenges facing Manitoba relating to RWE. Panelists saw the following opportunities for RWE:

1. RWE supports improved decision making, allowing for new inventions, faster access to better products and services at lower costs. Practical access to RWE would open new paths for industry in Manitoba;
2. RWE efficiency could be found with the integration of the administrative database management at Manitoba hospitals, which are currently managed by two separate entities which are large and have their own distinct protocols;
3. RWE presents an entirely new field of academic study and offers potential for the industry and academic community to discover the potential from cooperation;
4. RWE could reduce the percentage of error rate currently accounted for in studies;
5. Manitoba has the opportunity to take a leadership position in the field of RWE;
6. The academic community and private industry could better recognize the potential of working together.

Panelists saw the following challenges for Manitoba with regard to RWE:

- Access to data itself is challenging from both a technical and regulatory standpoint. Access is heavily regulated with inconsistent processes, and once navigated the data can be difficult to analyze due to a lack of resources and funding;
- Manitoba has had policies in place for 25 years. In that time, other jurisdictions have caught up so we need to do something to remain our leadership position;
- These issues also touch on the value of the data. Government needs to understand this and approach this data as a valuable resource for Manitobans

Accessibility to the data was an important aspect of the discussion for the panelists. They agreed that a unique advantage exists in Manitoba in terms of our ability to collect data from multiple sources in one place (Manitoba Center for Health Policy). Other Provinces/regions don't have this ability and the panel felt there was an opportunity to build on the current system that is already in place and well supported. It was suggested that research/clinical trial data could also

be leveraged to be part of the available RWE pool as it is a very rich source of data.

It was noted, however, that in Manitoba there is an issue with capacity. While there is an enormous amount of data that exists across multiple organizations, accessing that data and obtaining approval to use it is difficult. Panelists identified an opportunity for Manitoba to attract skilled people who can manage and analyze the data in an efficient way and determine a more central way to create access to the data.

The discussion concluded with panelists expressing the need for action - to **“quit talking about doing something and take action” before the rest of the world catches up.** We need to treat our data like a resource and determine how to carefully manage and use it.

PANEL DISCUSSION #2 – *How?*

The second panel welcomed five more guests, **Dr. Paul Komenda** from Seven Oaks General Hospital & Chronic Disease Innovation Centre, **Dr. Ryan Zarychanski** from CancerCare Manitoba & the University of Manitoba, **Janey Shin** from Janssen, **Heather Medwick** from the International Centre for Infectious Diseases, and **Dr. Paul Terry**, President and CEO at PHEMI (Vancouver).

The Panel Discussion focused on “How” to capture the opportunity that exists in Manitoba. Questions and discussion were moderated by **Christina Weise** from Research Manitoba.

Panelists agreed that data is growing in significance and that the industry is looking at it through a different lens. However, in order to realize the opportunity it was felt Manitoba must:

- Establish better and more collaborative partnerships with stakeholders;
- Determine ways to tap the money and expertise needed to access the data;
- Harness clinical data that already exists and make it more accessible.

Progress in these areas would offer important benefits – for example, panelists noted it would allow small companies to run trials at a reduced cost and avoid spending millions to collect data that already exists.

During the discussion, real-time clinical data was described as an “unstoppable force in Canada and the world.” Panelists discussed the common theme that Manitoba has the unique opportunity to stay ahead in this context because of its defined catchment area for collecting data.

Panelists agreed that Canada is sitting on a wealth of data that is, for the most part, inaccessible. They further suggested that we can’t afford to ignore this significant opportunity, or to keep spending billions of dollars gathering data that already exists. Panelists agreed that even if a user fee model was required, funds would be better used to access existing data.

PANEL DISCUSSION #3 – *Next Steps?*

The third panel welcomed back **Dr. Alan Katz**, **Ed Gudaitis**, **Dr. Adrian Levy** and **Dr. Paul Terry**.

Questions and discussion were moderated by **Tracey Maconachie**, President, Life Science Association of Manitoba.

The Panel Discussion focused on the “Next Steps”.

Panelists shared a variety of recommendations on what the next steps should be, which included:

- A **change in culture** to make people better appreciate existing data, specifically demonstrating to them through experience how data can benefit them;
- A **better understanding of the process for accessing data**; specifically, what data is available and where to find it;
- The need to **engage other stakeholders** (for instance, from the fields of computer science and mathematics) in order to turn clinical data into a more useable form;
- **Improve the timeliness of access to data**, ensuring that data is available on a timely basis. This can be achieved incrementally by starting with three or four data sets, and adding to it over time.

Dr. Katz referred to RWE (data) as a ‘resource’ and likened it to water – we have the water, now we need to build the bottling plan to export the water and invest in the process to make it happen. It was also noted by panelists that we should not be afraid to leverage opportunities outside of Manitoba; the process can be “designed in Manitoba” but built by others with experience building similar processes.

RECOMMENDATIONS

Based on feedback from the survey and the discussions with panelists and participants in LSAM's Real World Evidence Forum, it is clear RWE is at once growing materially in importance within our industry and that Manitoba has both a unique advantage and a unique challenge with regard to medical data. Based on this, LSAM has three broad recommendations for RWE policy in Manitoba.

1. Manitoba needs to understand its data opportunity

Participants in the event agree Manitoba has had, and continues to have, a unique opportunity with regard to the strength and breadth of data available to stakeholders in the industry. The systems and processes underpinning Manitoba's data advantage were not developed with an eye to facilitating access and leverage by private industry, but as RWE has increased in prominence and importance to all stakeholders, including LSAM members, Manitoba needs to understand the unique opportunity it has in this area. Evidence from discussions at the Forum is clear – **RWE can lead to more innovation, more development in the industry and ultimately better outcomes for the people of Manitoba** who count on all players to deliver products and services they rely on.

2. Manitoba needs to embrace its data opportunity

With a "data opportunity" defined, a **change of culture and policy** is required to bring forward systems and processes, which regulate and accommodate reasonable and efficient access to Manitoba's data. The balkanized landscape of policies, procedures and processes leads to uneven access to data in Manitoba. The stewards of RWE data in Manitoba acknowledge the opportunities and benefits access to RWE offers stakeholders but **do not have a clear direction or framework** to make this access consistent, clear, reliable and predictable. This needs to change – Manitoba needs to embrace its opportunity.

3. Manitoba needs to promote its data opportunity

With an opportunity defined and embraced, the logical next step is to **promote this advantage in an increasingly globalized world**. Different RWE panelists noted at different points during the event that other jurisdictions are catching up to Manitoba with regard to data. These are jurisdictions with larger populations, and therefore larger pools of potential data. A larger pool of data holds a larger potential value to users, and the steady pace of improvements in data management tools makes these larger jurisdictions more potentially attractive every day.

With its "data opportunity" understood and embraced, Manitoba should then promote this advantage to position its life sciences sector for continued growth and success in a competitive global economy.

As policymakers consider the issues and opportunities relating to RWE and the data used to develop it, LSAM is well positioned to assist with a continued dialogue for development of policy and exploration of this opportunity and potential competitive advantage for the province of Manitoba. As participants noted, Manitoba is at the cutting edge of a critical component of the life sciences industry. This edge should not be lost.

Thank you to our Event Partners

