



CASE STUDY

9 months of data. A lifetime of insights.

How longitudinal real-world data is helping CHU Sainte-Justine safely and effectively study the associations of medications with pregnancy outcomes before, during, and after pregnancy.



There are a lot of factors to consider before, during, and after pregnancy. While the expecting family mentally and physically prepares for a new baby, the information overload – or lack thereof – can be overwhelming. For many moms-to-be, it can be hard knowing when you should or should not take certain medications. Unfortunately, most clinical drug trials exclude pregnant women due to safety and ethical concerns, leaving potential risks and benefits unknown.

In our data-rich world, we know some of these insights are right under our nose, we just need the right datasets and tools to uncover them.

For years, institutions like the CHU Sainte– Justine Research Center, have been using realworld data (RWD) to look at patient experiences before, during, and after pregnancy to inform future drug development and improve care for pregnant women and their families. But insights are only as powerful as the data they are built on, and without a large sample size, research is limited. Anick Bérard, PhD, FCAHS, FISPE, a professor at the Faculty of Pharmacy of the University of Montreal and a Senior Scientist at CHU Sainte-Justine, has been working on medications in pregnancy for over 20 years. Having primarily worked with Canadian administrative data, her team wanted to grow their sample size and decided to look across the border to the United States for representative RWD. But health data is messy and complex, especially when you're dealing with different healthcare systems and federal regulations. Before the team could begin research, they first had to harmonize their Canadian data with MarketScan to speak the same language and define the variables of interest. After cleaning the data, they got to work building cohorts and analyzing trends.

"A vast majority of Canadian and US pregnant women will use medications for which we have very little data on risks, and even less on benefits.

Real-world data sources, like MarketScan, are extremely valuable in safely identifying risks and signals."



Gain a better view of population health with MarketScan

To better understand pregnancy and the medication associations with adverse outcomes, you need to look beyond just those nine months of data. Fortunately for Sainte-Justine, Canada's universal healthcare system makes it easier to drill down to the patient-level and track specific trends over their lifetime. The team relies on the Canadian Mother-Child Cohort (CAMCCO) because it has over 10 million pregnancies and up to 25 years of patient-level data, helping look at pre-existing conditions and treatments that took place during or around the time of pregnancy.

However, with their focus being on rare adverse outcomes, the team realized they needed many more patient lives to be conclusive. MarketScan was the boost Sainte-Justine needed, gaining access to over 293 million fully-adjudicated patient lives across the United States. Now with the Canadian cohort and the American MarketScan cohort, they could start looking at the data differently and conducting bigger studies with more confidence.

"With MarketScan, we can make comparisons that we would not be able to make with just our Canadian data. Having the two cohorts lets us look at variables like access to medication at different socioeconomic status levels."



Stay ahead of the trends with diverse sources

When Sainte-Justine began their journey with MarketScan, their focus was mainly on growing their sample sizes. Since then, they have seen other unanticipated benefits. For example, in August 2023, the US Food and Drug Administration (FDA) approved the first oral treatment for postpartum depression.¹ As an epidemiologist, Anick initially felt limited because the medication was not yet available in Canada. Fortunately, the MarketScan data gives her the ability to further study postpartum depression using the American cohort as new data becomes available.

The FDA often approves treatments before other international regulatory bodies, so organizations with MarketScan gain a distinct advantage – early access to data on treatments and drugs that are not yet available in their region. This allows them to prepare for the introduction of the drug, refine their methodologies, identify trends, and provide better treatment within their communities.

This creates a positive example for other global organizations contemplating similar research endeavors. By leveraging American RWD such as MarketScan to study FDA approvals, they can potentially expedite their own research and development processes, bridging the gap between innovation and application in their home markets.

What's next for Sainte-Justine?

The future is bright for Sainte-Justine as they continue to find innovative ways to combine data and technology to drive discovery for the mothers and children of Canada. The team has a wide variety of studies planned where MarketScan is playing a crucial role. but one area stood out among the rest accelerating the identification of safety signals, such as fetal toxicity. Studies often take 10 years to conclusively identify if a drug is toxic to fetal development, which is far too long to put women and children at risk. To expedite the process, Sainte Justine is exploring how MarketScan data and machine learning (artificial intelligence and predictive models) can work together to accelerate the identification of signals. The faster they can identify potential toxicity signals, the faster they can begin to assess whether the signals are valid.

"Because we now have access to such a large amount of clean data and we're confident in the variables, we are hopeful that identifying fetal toxicities will go from 10 years to less than five years."

Explore more success stories

Talk to the MarketScan team







About Sainte-Justine Research Center

Driven by a passion for excellence, the CHU Sainte-Justine Research Center is committed to making Quebec into a place where the health of mothers-to-be, children and youth ranks among the best in the world. With this in mind, they are intent on advancing knowledge and applying new research findings in order to translate new discoveries into more efficient and less invasive methods and devices aimed at disease prevention, diagnosis, prognosis, treatment and long-term follow-up starting at conception and continuing throughout the journey to adulthood.

About Merative

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References

 https://www.fda.gov/news-events/press-announcements/ fda-approves-first-oral-treatment-postpartum-depression @ Merative US L.P. 2023. All Rights Reserved.

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