



Direct access to real-time, real-world data



## Let's define our terms

Since there are no unanimous definitions of the terms "real-world data" and "real-world evidence," we use the definitions established by the Canadian Agency for Drugs and Technologies in Health (CADTH).

#### What is real-world data?

"Real-world data (RWD) includes information about the health of individuals or the delivery and/or outcomes of health care that is collected outside of traditional clinical trials and thus reflects results within the context of the particular health care system."

### What is real-world evidence?

"Real-world evidence (RWE) is evidence about the use, safety, and effectiveness of a medical product, technology, or drug that is based on or derived from analysis of data generated in a real-world health care setting."  $^2$ 

"Vigilance Santé is proud to have contributed to the Paxlovid project by developing the CURO forms, which support structured data collection thanks to ECo, our standard for documenting clinical events. We believe that pharmacists can play a key role in data collection by obtaining valuable information during their consultations with patients."



# Direct access to real-time, real-world data made possible by Curo<sup>TM</sup> and the community pharmacy network

## Quality real-world data collection: Lessons learned from the Paxlovid project

Faced with the increasing complexity and cost of specialty drugs, both the pharmaceutical industry and government now have access to real-world data to support their decision-making.

Accessa<sup>™</sup> can collect reliable, neutral and structured real-world data in real-time using its state-of-theart Curo platform and direct access to a broad network of community pharmacies. Accessa's innovative Paxlovid pilot project successfully demonstrated both the feasibility and relevance of collecting data from the field, as information was collected from 1,004 patients at 306 community pharmacies, achieving a compliance rate of 87.5%. All this in one year.





**ACCESSA™** is a trademark of 9408 -6758 Québec Inc.

**CURO™** is a trademark of 9408 -6758 Québec Inc. (Accessa)

## A critical need for quality real-world data

Decision-makers and clinicians recognize that the clinical data that is currently available to them is insufficient to guide them in selecting optimal treatments.<sup>3</sup> Insurers want access to RWD to support their decisions on whether or not to cover certain treatments. Patients ask for this data so that they can better understand how a given therapy can meet their needs<sup>4</sup> and gain faster access to medicines. With such widespread interest in assessing treatment efficacy, there is a critical need for quality data.

Most regulatory agencies believe that RWD and RWE should be taken into account when evaluating drug marketing and coverage.<sup>5</sup> By filling gaps in information, RWD supports analysis and decision-making.

"However, RWD can only serve as evidence for decision-making if it is considered to be relevant and reliable information."

## Accessa offers a practical solution backed by a solid network of pharmaceutical experts

The Quebec Association of Owner Pharmacists (AQPP) created Accessa in the hopes of delivering a one-of-a-kind solution that would meet market needs. Accessa provides reliable, neutral and structured data available in real time. The data is collected by healthcare professionals in community pharmacies members of the AQPP. This ensures that Accessa meets Health Canada and the Institut national d'excellence en santé et services sociaux (INESSS) requirements for the provision of data.

"STI is proud of the unique technology we provided, helping make the CURO platform more effective and efficient. Our contribution lays the foundation for secure and robust data collection and sharing between various stakeholders, allowing for better treatment decisions or analyses."



## **JOSÉE ST-MARTIN**

General Manager at STI Technologies Limited, a subsidiary of IQVIA

## The Accessa Advantage: Real-world data at your fingertips

- DIRECT ACCESS
  - A flow of data, accessible quickly, continuously and in real time.
- RELIABLE TECHNOLOGY AND STRUCTURED DATA

A cutting-edge platform that supports the collection of structured, reliable, neutral, and transparent data.

BROAD NETWORK

An extensive network of data collection points staffed by qualified healthcare professionals.

CUSTOMIZABLE INFORMATION
 Data that reflects your specific needs.



## **PAXLOVID PILOT PROJECT**

# Speed and agility: The keys to success





The Paxlovid pilot project was an ambitious undertaking prepared in record time. The Accessa team could count on its Curo platform to make it possible, but the company still had to create a RWD collection program and consult with its partners and ensure buy-in from the pharmacist-owners within the AQPP's broad network of community pharmacies. Jean Bourcier, Accessa's President, and Nadia Khassassi, Vice-President - Operations, shared how the project was conceived, developed and executed.

## HOW DID YOU COME UP WITH THE IDEA FOR THE PAXLOVID PILOT PROJECT?

#### **Jean Bourcier**

It all began in January 2022, when Health Canada approved Paxlovid<sup>™</sup>, the first oral treatment against COVID-19 marketed in Canada for at-home use. INESSS determined that treatment would be reserved to individuals at very high risk of an unfavourable outcome.<sup>7</sup> However, the organization felt that more research and data on this new treatment was needed. Following a suggestion from a pharmacist, the AQPP, our sole shareholder, recognized that we had an interesting opportunity to participate in RWD collection and decided to invest in this innovative project. Since Accessa manages patient support programs (PSPs), we already had the Curo platform, which works very well for collecting this type of data.

"The AQPP is always on the lookout for innovative initiatives that can be implemented in community pharmacies to benefit patients. Naturally, we're very interested in real-world data collection. We have every confidence in Accessa and the strength of our network, and we fully support their efforts to revolutionize the collection of quality data."



## SO YOU JUMPED AT THE OPPORTUNITY?

#### **Jean Bourcier**

Yes, absolutely. We wanted to help fill the gaps in data, so we set out to create a unique RWD collection program through our far-reaching network of community pharmacies.

#### **HOW DID YOU PROCEED?**

#### Nadia Khassassi

We quickly contacted our partners and stakeholders, including the INESSS, to discuss the project and start designing it. We got everything prepared in four weeks! Our team successfully designed the program, determined which data would be collected, finished the configuration of Curo by working with STI<sup>8</sup>, and created data collection forms in collaboration with Vigilance Santé<sup>9</sup>. Then, with support from the AQPP, we provided pharmacist-owners with information and training. The first patient record was created on February 26, 2022.

## HOW DID THE ROLL-OUT IN PHARMACIES PLAY OUT?

#### Nadia Khassassi

The program was destined to be successful because it's so simple. There were three steps. The first involved creating the patient file. When the pharmacist dispensed Paxlovid™ to a patient, they let the patient know about the program, requested their consent, and created a file in the Curo platform. From the outset, each patient profile contained information that would allow them to be identified with a personal identification number and anonymize their data.

The next step involved filling out a form to collect basic information about the patient before treatment began. Lastly, 14 days after the start of the treatment, the pharmacist filled out a second form to record information about efficacy, safety and compliance.

## HOW LONG WAS THE DATA COLLECTION PERIOD?

#### Nadia Khassassi

We collected data on Paxlovid<sup>™</sup> for a full year, from February 2022 to January 2023. Some 933 pharmacists from 306 pharmacies across Quebec took part in the training provided by Accessa and participated in the Paxlovid program. We wouldn't have been able to collect quality data without their help.

#### WHAT WERE THE RESULTS?

#### Nadia Khassassi

A total of 1,189 unique records were created using the Curo platform and 1,004 were selected for analysis. This indicates a compliance rate of 87.5%. Three data extractions were carried out. The first two provided us with the information needed to follow up with pharmacists so we could optimize the data collection and ensure the program's inclusion criteria were met. Anonymized data from the final extraction was shared with INESSS.

## WHAT WERE THE CONCLUSIONS FROM THE PAXLOVID PILOT PROJECT?

## **Jean Bourcier**

It was very positive! The Paxlovid RWD program was a groundbreaking pilot project for Accessa, and the results go far beyond advancing knowledge about Paxlovid™. We confirmed that Accessa is capable of collecting real-world data simply and reliably in real time at community pharmacies. This data can also be shared with government organizations so that they can make use of it.

## Pharmacists and patients helping advance knowledge

## Pharmacists' point of view

As stated by Ms. Khassassi, the widespread participation of community pharmacists was key to the pilot project's success. Without their buy-in, the results would not have been the same. From the outset, they responded positively to the project and welcomed the opportunity to support a cause close to their hearts: helping patients and society by advancing knowledge about a new drug. In fact, this is how most pharmacists presented the project to their patients.

By participating, pharmacists underscored the importance of their role in monitoring and supporting patients undergoing complex treatments. They also contributed to the advancement of knowledge about Paxlovid<sup>™</sup> by collecting essential information from the field.

Patients also felt that they were doing something useful. The pandemic affected everyone so profoundly that people were excited to be part of a group that could help demonstrate the effectiveness of a treatment.

"Patients are very open and trusting. Once we present the Paxlovid project, explain where the data will be sent and who will benefit from the information, patients are quite open to it. I'm very motivated, and so are the patients, because the information will be useful at the clinical level in the future. It's very exciting."



Pharmacist-owner, Master's student in Health and Politics.

## Conclusions from the Paxlovid pilot project

The Paxlovid pilot project allowed Accessa to demonstrate that it is both feasible and relevant to collect real-world data from community pharmacies using its Curo platform and the extensive network of pharmacies. The project also demonstrated that Curo is well suited for this type of data collection.

The project led to some interesting findings. It showed that community pharmacists and other stakeholders like INESSS are interested in participating in studies aimed at improving knowledge about new therapies. It also demonstrated that the Curo platform is highly effective. Not only can it securely compile and store patient records, but it is easy for pharmacists to use. In addition, the data was structured in a common format to facilitate interoperability with other databases. Finally, the project highlighted the importance of working jointly with key stakeholders early on, as it led to closer and more effective cooperation in designing the data collection process and anticipating potential biases. It also ensured that everyone's perspectives were proactively taken into account.

"By enabling real-world data to be recorded and tracked, the proposed platform will allow us to gain a better understanding of the effectiveness of pharmaceutical treatments offered to Quebecers. These insights will be highly valuable, particularly to INESSS, in areas where there is a regrettable lack of evidence in the available scientific literature."



Director of Drug Evaluation and Technologies for Reimbursement at the INESSS

## **Quality data in real time**

Accessa offers an additional source of high-quality, reliable and structured data in real time. This invaluable contribution helps meet a growing demand for RWD. Meanwhile, contributing Canadian community pharmacists and their extensive network of pharmacies have become effective providers of RWD. They have the ability to collect data on the real use of medications. Finally, Curo has proved to be a dynamic platform that meets recognized security standards, an important consideration in today's world.

The concept is innovative and can be replicated in a variety of fields. It opens up a number of possibilities in other therapeutic areas, such as oncology and rare diseases. Curo is designed in such a way that it can be adapted to different Canadian markets, across all provinces. With all these advantages, the solution meets the needs of both provincial and federal decision-makers.

Ultimately, the collected data will help advance knowledge and support health outcomes through improved care and access to better treatments.

For more information, contact: info@accessa.ca or 1-438-800-6609.

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## ACCESSA.

# Democratizing access to specialty drugs by placing pharmacists at the heart of patient support programs

In 2019, the Quebec Association of Owner Pharmacists (AQPP) saw an opportunity to participate in the revolution of the specialty drugs market, which has been ongoing for several years. As more of these drugs are prescribed, patients are requiring closer monitoring and follow-up to ensure health benefits are maximized. Consequently, we can expect to see an increase in patient support programs (PSPs) over the next few years.

However, these programs are traditionally managed by individuals who aren't core members of the patient's usual healthcare team and therefore have limited access to the patient's medical history. By establishing Accessa, a patient-focused solution, the AQPP is paving the way for more accessible, effective and ethical PSPs that democratize access to specialty drugs.

The members of the AQPP, Accessa's sole shareholder, approved the project in 2019, and the company's operations began in February 2020. The team was undeterred by the pandemic and worked hard to develop Curo, its program management platform. Curo enables proactive follow-up planning and the collection of relevant and reliable clinical data. Accessa has therefore developed a decentralized model that promotes transparency and collaboration while maximizing existing care pathways and expertise.

Since its creation, Accessa has signed a number of PSP management agreements with various pharmaceutical companies. This underscores the interest in Accessa's unique model and the tremendous added value provided by community pharmacists.

In 2022, Accessaresponded to pandemic-driven stakeholder needs by collecting and processing data on the Paxlovid project. To do so, it used its intelligent and reliable technological infrastructure and mobilized the entire community pharmacy network. Accessa's RWD component took off as the company demonstrated its ability to collate real-time data in an efficient and detailed manner that benefitted all stakeholders in the healthcare system.



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