

BIOQUÉBEC

Le réseau québécois des bio-industries et des sciences de la vie
The Quebec Bio-Industries and Life Sciences Business Network

Accessing Quebecers' Medical Data: Increasing Research and Discovery While Establishing a Strong Regulatory Framework

The Ministry of Economy and Innovation recently indicated the government's interest in making RAMQ medical data accessible to pharmaceutical companies. While the idea has been criticized by many, Quebec's life sciences industry, its biotechs and clinical and contract research organizations in particular, welcomes this announcement.

Better Health Data Management Means:

- ✓ Being able to improve predictive, clinical, and therapeutic healthcare delivery outcomes.
- ✓ Accelerating public and private scientific research.
- ✓ Positioning ourselves as a knowledge-based society using knowledge that is based on generating and using data.

Accessing the RAMQ data is one of the [Quebec Life Sciences Strategy](#)'s recommendations; this strategy was established with the help of our leading health research thinkers and decision-makers and has resulted in a consensus developed over time between all life sciences sector stakeholders.

Quebec's Advantage

- ✓ The existence of a universal public healthcare plan provides Quebec with the advantage of having a critical mass of real-world data.
- ✓ Quebec has unquestionable expertise in data processing and artificial intelligence.
- ✓ Our life sciences sector is integrated - research is carried out through multiple **collaborations** between **academic researchers, public research centres, biotechs, clinical and contract research organizations, and pharmas.**

Having Access to Medical Data Drives Research and Discovery

Public research centres, biotechnology firms, and pharmaceutical companies are working to discover new treatments, drugs, and vaccines to meet current health needs and improve the health of various populations.

- ✓ Obtaining information from health databases helps accelerate research and discovery.
- ✓ High-quality research helps to **attract investment** and allows for more research to be conducted, which in turn helps Quebec to **develop our life sciences sector** and **strengthen local companies**.

What Is Citizens' Health Data Used For?

- ✓ To better understand the **factors which contribute to a disease** or health condition.
- ✓ To find new biological targets for **new drugs**.
- ✓ To develop **highly-targeted therapies and vaccines** that produce fewer side effects.
- ✓ To more easily identify patients who could **participate in innovative clinical trials** that could improve their health.
- ✓ To attract more **major international clinical studies**: numerous projects cannot be conducted in Quebec because of the lack of timely access to data.
- ✓ To ensure **better use of drugs** by patients and clinicians, which will ultimately lead to better clinical results.
- ✓ To monitor clinical results, treatment compliance, and patient care pathways so that **care can be optimized**.
- ✓ To access real-world clinical data to **prove the validity of a particular treatment**, especially for rare diseases.
- ✓ **To submit drug approval applications** in Quebec using data collected in the province, as this better represents our population, rather than using data from Ontario or the U.S.

A Sophisticated Ethical Framework: A *Sine Qua Non* for the Use of Data

If Quebec is to benefit from the advantages of having access to medical data, it must **rely on a sophisticated and crucial ethical framework** inspired by the best practices being used around the world. These fundamental conditions must be in place:

- ✓ The public and private research world does not want access to the actual data, but rather to the **anonymized or depersonalized results** from data banks. They can get this information through the banks' third-party managers without having access to the raw data.
- ✓ The transparent implementation of a **strong regulatory framework that will protect confidential data**.
- ✓ Researchers, whether from the public or private sector, must explain the scope of their research projects and be contractually obligated to comply with all the conditions set

forth by the governments.

- ✓ Any government decision on this matter must include **a regulatory framework, clear guidelines, and strict conditions** that do not allow confidential data to be passed on to the public or private research community.
- ✓ Only **anonymized and aggregated data** can be provided.

Quebec's legislative framework, developed in the 1980s, needs to be updated to include the life sciences sector as an integrated one:

- ✓ The **sharing of data** is crucial for facilitating and accelerating research.
- ✓ Such reform would provide a **better ethical framework**, reassure the public, and allow Quebec to reach its full potential, **which would ultimately benefit patients**.
- ✓ **Several countries have adopted efficient and secure processes** for better data management for research purposes, including France, Denmark, the United Kingdom, and Singapore. Moreover, Ontario's framework is newer than Quebec's, while Alberta is currently developing its own strategy and approach.
- ✓ Countries with the strongest and clearest legislative, regulatory, and ethical frameworks are the **most successful in attracting** research (e.g. Britain's National Institute for Health Research).

In the end, it isn't a question of using this information to extract details about people's private lives; it is about aggregating the data to learn more about Quebecers' medical needs, with the goal of developing drugs that perfectly meet those needs. This would also undoubtedly help Quebec to attract additional investments in research and clinical research.