



CROs

**PILLARS IN DRUG
DEVELOPMENT**

2022

PREPARED BY

BIOQUÉBEC

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CROs, PILLARS IN DRUG DEVELOPMENT

CROs, SPECIALIZED RESEARCH ORGANIZATIONS

A CRO, or contract research organization, is a company that provides, on a contractual basis, services in the biomedical research field.

The discovery of new medical treatments is a long and costly process that requires extensive expertise. Pharmaceutical companies used to carry out the vast majority of drug development studies, but a change to their business model in the 2000s led to them closing their large laboratories, both here in Quebec and elsewhere in the world. This transformation forced research to be structured differently, and it is now mainly done by external partners. While contract research organizations (CROs) had generally focused on the phases of clinical research, they have diversified to now offer more specialized research services, which allows for research projects to continue to be carried out.

CROs are an integral part of the innovation chain as they support biopharmaceutical sector companies in all phases of the development of a new drug, vaccine, or medical device. They have the expertise to develop drugs, which helps to accelerate discovery and reduce costs.

Given their crucial role in the development of new treatments and technologies, as well as their economic importance, BIOQuébec and CATALIS, with financial support from the Ministry of Economy and Innovation, conducted a study of Quebec CROs to chart the sector's impact and measure its growth, strengths, and needs.

A [similar study conducted by BIOQuébec in 2016](#) validated CROs' significant importance within the life sciences industry from both economic and innovation standpoints. CROs export their services internationally, which generates substantial foreign revenue, and create a substantial number of quality jobs.

Following the update of the Quebec Life Sciences Strategy (QLSS) in May 2022, BIOQuébec felt that the time was right to measure the evolution of CROs within Quebec's life sciences sector over the past few years. This study provides an overview of the results of the efforts made since the first QLSS was launched in 2017, particularly with respect to CROs and their development in Quebec.



STUDY SUMMARY

There are eighty-one active CROs in Quebec. Fifty-three of them (65.4%) answered our questionnaire, which allowed us to update our profile of the industry and provide an accurate representation of this sector's businesses. The companies surveyed for this study include all those offering research services to a third party, whether or not they are a main component of the company's offerings. Our data also included the services of academic research institutes and non-profit organizations (NPOs). Regulatory affairs consultants, companies providing services only to academic laboratories, and those providing other related services (e.g., legal, financial, market access, IT, etc.) were not part of this study.

CROs SUPPORT INNOVATION

CROs' Contributions to R&D

CROs are an important link in the innovation chain, and they support research in many ways:

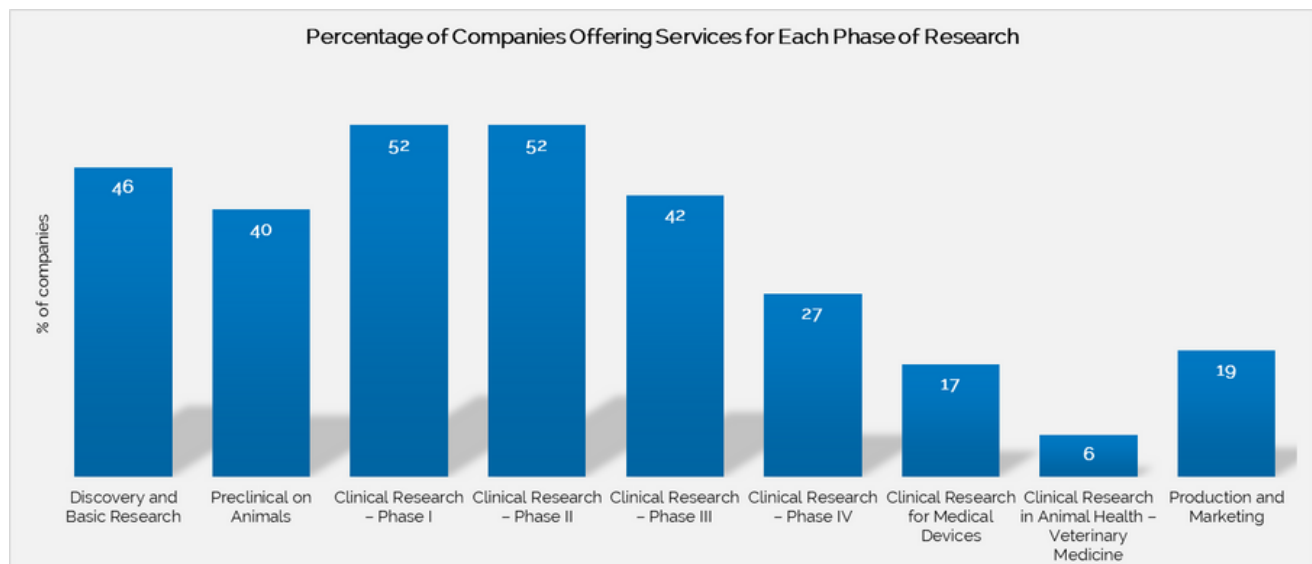
- By specializing in specific activities
- By optimizing the drug development cycle time to reach the market
- By allowing biopharmaceutical sector companies to optimize their discoveries and their human and material resources
- By improving drug development support processes and creating new technologies to facilitate the conduct of research projects
- By supporting and guiding biopharmaceutical companies in their growth and development of health innovations
- By helping to keep expertise in Quebec and expand its reach internationally
- By ensuring the integrity of results and meeting the highest levels of standards and regulations
- By offering innovative care to Quebec patients and taking over patient care, while reducing costs to the health system

CROs are crucial partners in the development of biopharmaceutical and medical technology companies' products!

CROs Support All Phases of Innovation

CROs provide life sciences companies with specialized services allowing them to accelerate their research in all phases of the process, from basic research to commercialization.

Quebec's CROs offer research services for all phases of drug development. The majority (75%) offer services for more than one phase of development.



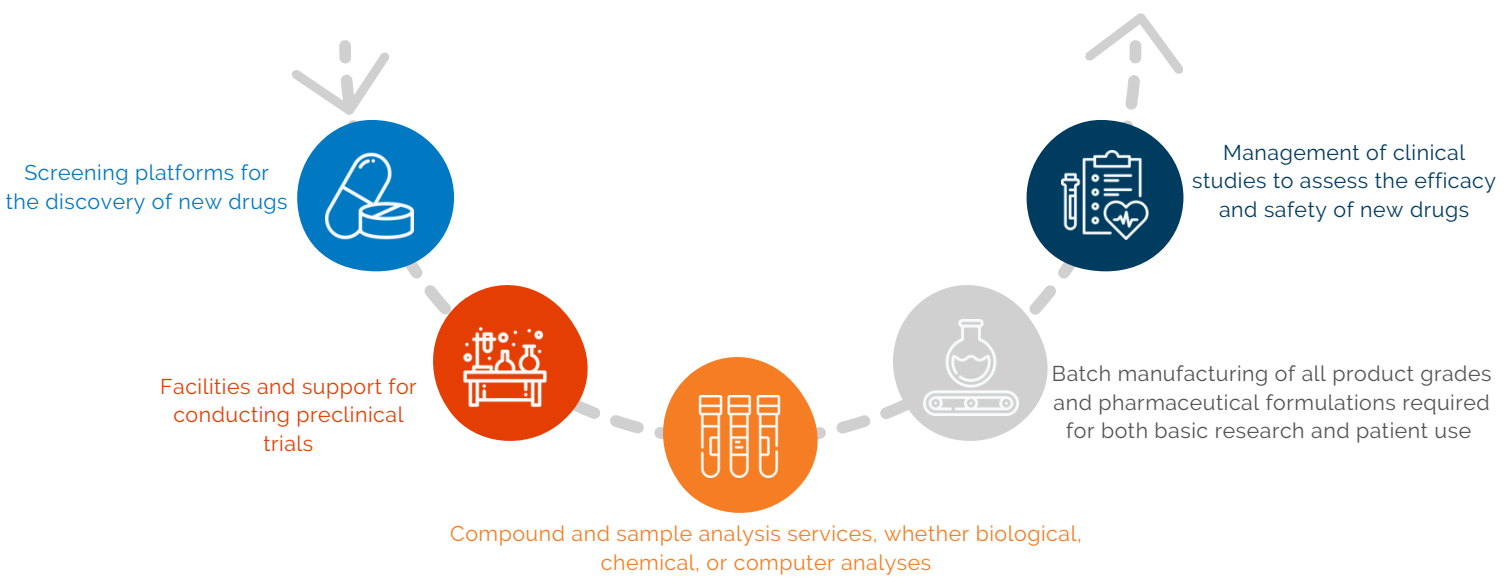


"The concentration of pre-clinical research in Quebec's CROs is unique in the world. Quebec should be very proud of what it has built over the years and the expertise offered here."

- Michel Provence, Corporate Vice President,
Charles River Laboratories

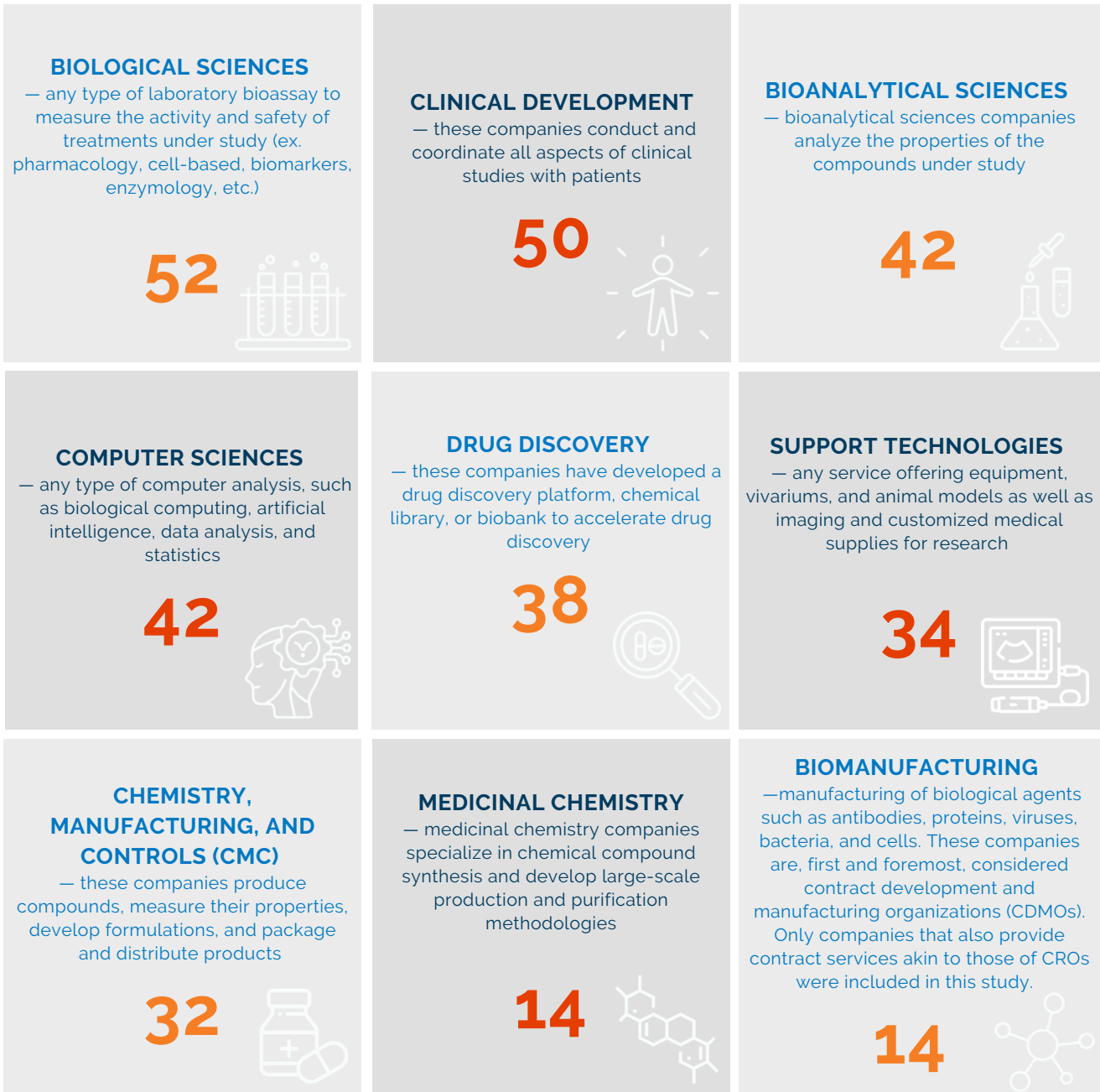
Varied and Specialized Service Offerings by Quebec's CROs

Quebec's CROs offer all the services needed to complete all phases of a research project, including:



Proportion of companies offering a certain type of service

The majority of companies offer more than one type of service (78%).



Quebec's Expertise

Many of Quebec's CROs offer ultra-specialized services:

- **12** CROs offer **services related to artificial intelligence**
- **10** CROs have developed a **drug discovery screening platform**
- **13** CROs specialize in **mass spectrometry and omics technologies**
- **18** CROs are **clinical study management experts**



“Quebec has everything it takes to be a “turn-key” for all stages of drug development. The many partnerships between the province’s various drug development chain stakeholders are a definite advantage for companies looking to carry out their research projects here.”

- Suzie Talbot, President, Diex Recherche

CROs Provide Services Across All Therapeutic Areas

Nearly half (48%) of the CROs provide research services across all therapeutic areas, while others specialize in specific ones.

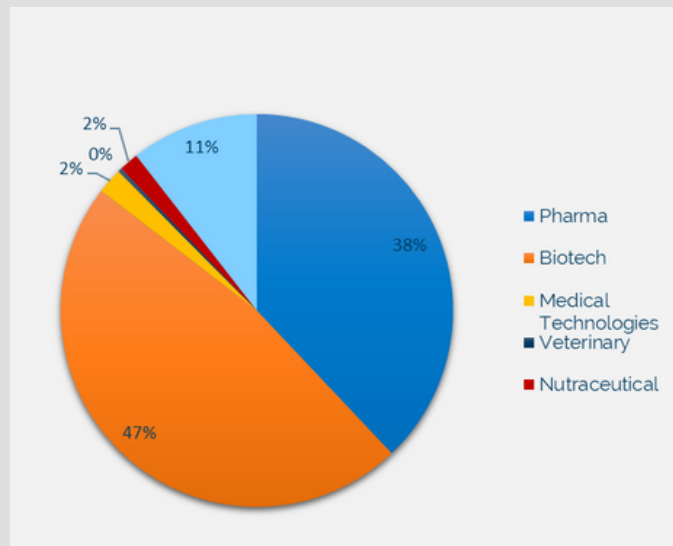
The most prevalent areas are oncology, infectious diseases, respiratory diseases, and neurology. In comparison to 2016, infectiology and genetics are areas whose prevalence has increased, most likely due to COVID-19 and the QLSS's efforts to make Quebec a hub for genetics and precision medicine.

More on Quebec's CROs

CROs' Clients

CROs' other clients are companies in the following fields:

- Medical technology
- Nutraceuticals
- Academic institutions
- Animal health
- Cosmetics
- Human sciences
- Other CROs



Accreditation

Fifty-three percent of CROs surveyed have at least one accreditation or certification. This is less than in 2016 (66%), but this change can be attributed to the fact that more companies are involved in basic research, a sector that requires fewer accreditations because its companies are upstream of development.

Quebec's CROs have the following accreditations and certifications:

- AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care - 18%)
- GMP (Good Manufacturing Practices - 16%)
- CAP (College of American Pathologists - 13%)
- CCAC (Canadian Council on Animal Care - 4%)
- HRA Canada (Human Research Accreditation Canada - 4%)
- CLIA (Clinical Laboratory Improvement Amendments)
- ISO9001 (Quality Management Systems)
- LSPQ (Quebec public health laboratory)
- HACCP (Hazard Analysis and Critical Control Points) by Health Canada or the FDA
- CNSC (Canadian Nuclear Safety Commission) license
- Health Canada controlled substances and cannabis licenses
- SCC (Standards Council of Canada)
- GCP (Good Clinical Practices) of the International Health Council E-14



Types of Companies

Eighty percent of CROs are private companies, whereas 8% are publicly-listed companies and 12% are associated with a public agency (8% of which are not-for-profit and 4% are for-profit).



Intellectual Property

CROs' role is to support companies that develop products; as a result, they generate less intellectual property and are less likely to register patents, given that their clients own the rights. However, this study found that at least ten Quebec CROs hold a patent for an innovation they developed to better serve their clients.

While they do not hold patents for drugs, they specialize in their areas of expertise and improve processes, create new technologies, and use state-of-the-art equipment, all of which contribute to the collective wealth.

Whether it be the development of imaging-labeling molecules, biomarker identification platforms, an artificial intelligence platform, a CRISPR production platform, or specialized services for new drug formulations, CROs also drive innovation!



COVID-19

Thirty-two percent of companies surveyed shifted their operations in response to COVID-19.

CROs put their expertise and know-how to use in the fight against the coronavirus!



THE ST. LAWRENCE VALLEY, FERTILE GROUND FOR DRUG DISCOVERY

A total of 81 CROs are active in Quebec, most of which are located in the St. Lawrence Valley.

The head offices of these 81 CROs with facilities in Quebec are in:



Seventy-eight percent of CROs with facilities in Quebec are Quebec-based and have their head offices in the province, whereas 93% of them did in 2016. One of the QLSS's objectives is to attract businesses, and this data suggests that the Strategy is succeeding, as it indicates that more companies from outside the province have been investing in Quebec by choosing to operate here.

The Internationalization of CROs

Multinationals Establish Operations in Quebec

There are several companies with international profiles that now have facilities in Quebec in addition to their facilities elsewhere in the world. The following companies have at least 10 facilities, with one of them in Quebec:

- o Allucent (Cato SMS)
- o Banook
- o ICON Recherche clinique
- o IQVIA
- o LabCorp
- o Les laboratoires Charles River
- o Medisca
- o Precision for Medicine
- o Syneos Health



Quebec-Based CROs Export Their Knowledge Internationally

Several Quebec-based CROs have expanded their operations outside the province, making them jewels in the province's crown.

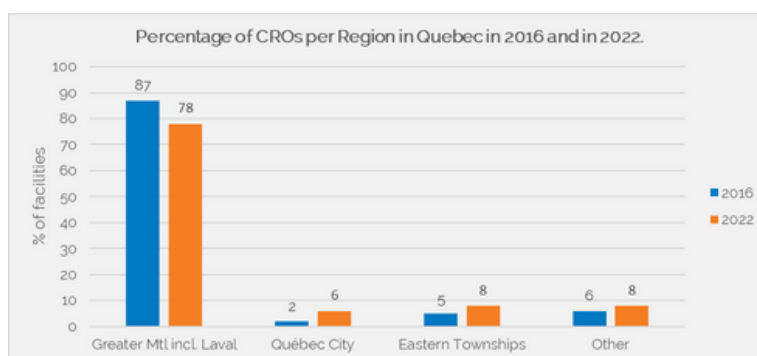
Company	Number of Facilities	Locations
CellCarta Biosciences	10	Canada, United States, Belgium, Australie, China
Mispro Biotech Services Inc.	8	United States
Altasciences	7	United States
JSS —Recherche Médicale	3	Colombia, India, Poland
Innovaderm Recherches Inc.	2	United States, Spain
Neopharm Labs Inc.	1	United States
Imeka	1	United States
PhInC. Modeling	1	France

Growing, Multicentre CROs

Several CROs are expanding and have opened more than one facility in Quebec. Of the 81 CROs, 14 have more than one facility in the province, bringing the total number of facilities to 107.



In comparison to the data from 2016, the current total contains a higher percentage of CROs outside the greater Montréal area (87% in 2016 and 78% in 2022). A review of these companies indicates that research activities have expanded to other regions in Quebec, allowing them to benefit from the life sciences sector's growth.



“The area between Québec City, Montréal, and Sherbrooke is now Drug Discovery Valley: it holds an extremely high concentration of scientists in this field and is unique in North America.”

- Marc LeBel, President, NuChem Sciences Inc.

CROs, A GROWTH SECTOR

Rising Revenues

Thirty of the CROs who completed this survey agreed to share their revenues for the last fiscal year. They reported total revenues of \$691 million, with a median revenue of \$1.8 million. Based on this data, we can estimate that the 81 CROs in Quebec bring in around \$1.2 billion annually.

It is difficult to know the sector's exact economic impact. We do note, however, that the revenues reported this year are significantly higher than those reported in the 2016 study, in which participating companies reported revenues of \$550 million.

In 2016, 46% of companies had less than \$1 million in revenues. The ratio has remained relatively stable at 40%. One-third of companies earn more than \$5 million per year.

A Sector with Greater Maturity

In 2022, 65% of CROs had been in operation for at least 10 years vs. only 47% in 2016, which highlights the increasing development, sustainability and diversity of the sector.



Growing Companies

Growth Over the Last Three Years

Seventy-one percent of companies surveyed reported an increase in their revenues over the last three years, with median growth of 45%.

In 2016, 76% of participating businesses reported growth. This slight decrease could be attributed to COVID-19, which greatly affected the operations of many companies around the world. However, the data suggests that Quebec CROs were not overly affected by the pandemic and have been able to continue their operations. The assumption can be made that CROs operating in areas other than infectious diseases may have been more affected.

Growth Projection

Ninety-three percent of companies surveyed expect to grow over the next three years, with a median expected growth of 50%.



“Our services are in high demand. The challenge is to find solutions to operationalize this growth, support it by obtaining relevant certification, and find the resources needed to meet the demand.”

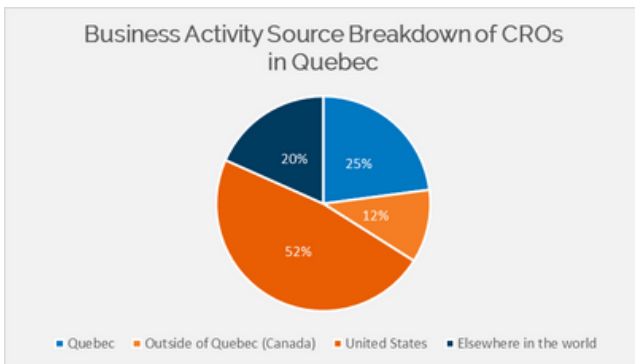
-Hugo Gagnon, Chief Scientific Officer, PhenoSwitch Biosciences

CROs ATTRACT REVENUE FROM AROUND THE WORLD

The expertise of Quebec's CROs is internationally recognized, and these companies do business with companies across the globe.

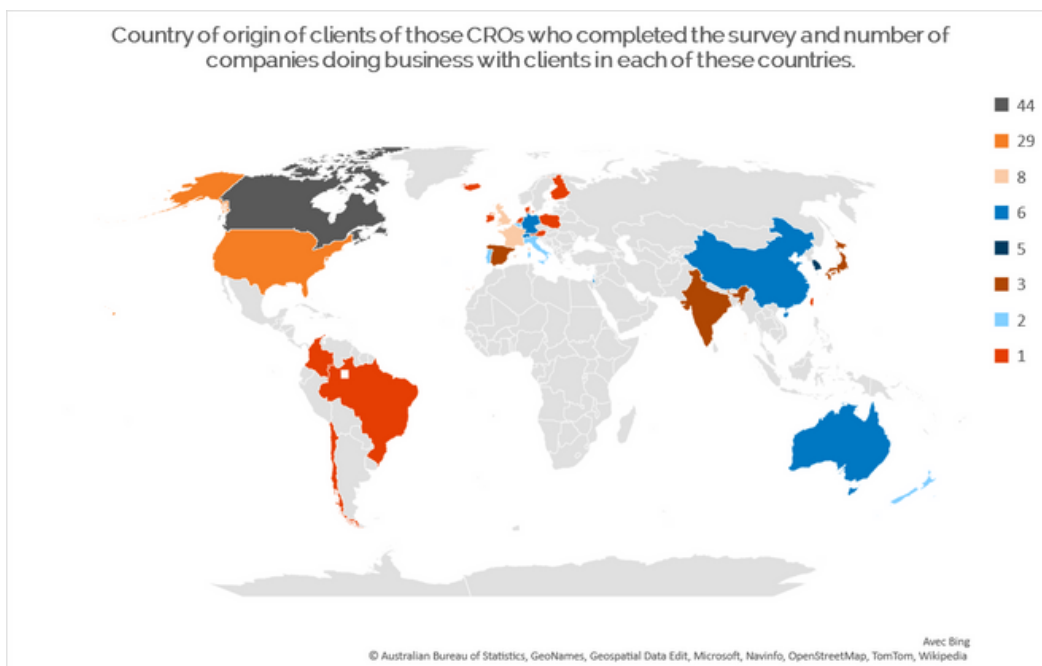
On average, 77% of the revenues of companies who completed the survey originate outside of Quebec.

It is important to note that 88% of the companies who completed the survey have clients outside of Quebec.



It is interesting to note that in 2016, a bigger share of the revenues (91%) reported by participating CROs came from outside Quebec. The larger share of CROs' revenues now earned here could be due to an increase in the operations of Quebec's biotechnology companies and pharmaceutical companies, a sign that the life sciences industry is growing. Since the QLSS' implementation (from 2017 to 2021), the Ministry of Economy and Innovation has identified more than \$3 billion in private life sciences investment, thanks in part to various economic development initiatives. This increase could also be explained by the fact that more international companies have opened facilities in Quebec.

Quebec's CROs do business with many countries around the world.



CROs CREATE QUALITY JOBS

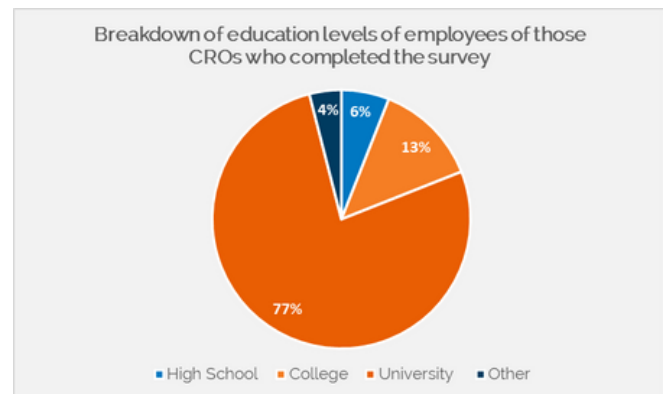
Large Number of Employees

According to BIOQuébec's records, Quebec's CROs employ 7,363 people (including at least 465 in part-time positions). In 2016, that number stood at 4,300, an impressive increase in the number of jobs in CRO companies.

In addition, 59% of CROs have fewer than 25 employees (it was 65% in 2016), which also indicates that the CRO sector is growing.

High Levels of Education

CROs employ people with a variety of levels of education, but a majority (77%) have university degrees, which indicates that the sector generates high-quality, high-paying jobs.



CROs' NEEDS

To discover ways to offer better support to the CRO sector, BIOQuébec asked the companies who completed the survey to describe their main concerns and issues.

Labour Force Requirements to Support CROs' Growth

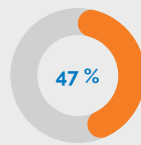
Its labour force is the cornerstone of a company's growth. In fact, 91% of the responding companies expect their need for additional workers to grow over the next three years. CROs' labour force requirements will increase in the coming years and are vital to their growth.

Labour force issues are a top concern for the growth of 84% of the companies who completed the survey. CROs' employees are highly specialized, which limits the pool of candidates. Research assistants, laboratory technicians, and animal health technicians are in high demand. Offering training adapted to CRO employees is crucial to maintaining the sector's growth and competitiveness.

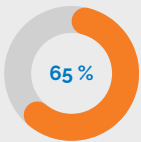
CROs face these major labour force challenges:



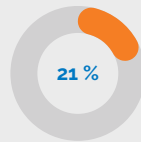
The high demand for workers has increased competition and salary demands



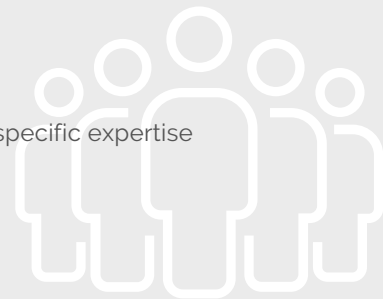
Applicants with specific expertise are rare



The shortage of qualified applicants



Immigration limitations



The demand for qualified employees is greater than their availability in the marketplace, significantly raising employee wage expectations and making retention difficult. This change is particularly challenging for small CROs that may not have the same means as larger companies.

Large CROs are more affected by immigration issues than smaller ones, which suggests that international recruitment is an option more often considered by larger companies.

Several companies mentioned that the number of clinical research projects has exploded because of COVID and that demand is not currently an issue for them. However, the employee shortage has forced CROs to postpone projects and slowed their growth. Many CROs have growth challenges due to the shortage of employees. The current conditions make expanding facilities to meet demand and obtaining the necessary certifications more challenging and complicate the growth of some CROs.

Attracting New Clients to Stimulate the Market

The second major challenge reported by the CROs surveyed is client attraction (43%).

Initiatives to highlight the sector are welcome. Trade missions, technology showcases, and company registers are good ways to advertise Quebec's CROs.



"Quebec is a great place to conduct clinical research. Let's be proud and work together to promote it around the world."

-Vatche Bartekian, President, Vantage Biotrials

Financing CROs

Half of the CROs surveyed are currently looking for financing.

Of those who reported having received financing:

- 55% received some type of financing from the Quebec government (including Investissement Québec) for expansion, working capital, training support or other
- Half the companies received financial support from a bank
- 28% obtained assistance from other organizations such as industrial research sectoral groups (RSRIs) or Mitacs

The way CROs are financed is different from the way biotech companies are financed. Only 8% of companies surveyed reported that a mutual fund or venture capital firm was one of its main shareholders. Unlike biotechs, CROs have their own source of revenue (their clients) which supports their growth. They also use other financial vehicles such as loans.

SR&ED Credits Support CROs' Development

A majority (76%) of companies surveyed reported income from a scientific research and experimental development (SR&ED) tax credit, with a median of 30% of reported expenditures. R&D expenditures have increased for 34% percent of respondents over the past three years.

In comparison, 61% of CROs had reported such income in 2016. It is difficult to know whether this increase is due to the fact that companies have higher R&D expenses or whether they are more aware of the availability of this financial assistance.

According to the companies surveyed, SR&ED credits' main benefits are:



- Helping to increase investments in research and innovation (59%)
- Allowing for increased hiring (50%)
- Improving company stability (43%)
- Increasing capital investments (32%)
- Positively impacting the company's value (32%)
- Reducing layoffs (16%)

These comments confirm that SR&ED credits are vital in supporting drug discovery and clinical research in Quebec and must continue to be available to encourage research and innovation, given that CROs strongly support drug development.

SR&ED credits support the development of Quebec businesses and promote their competitiveness. They help CROs to offer competitive prices to their clients, thereby promoting access to quality services and the advancement of many research projects. This government support is especially beneficial for small biotech companies, which often have limited budgets. By supporting life sciences businesses, SR&ED credits support innovation, a basic component of Quebec's economic growth. Companies that invest in R&D develop expertise and become more productive, competitive, and innovative.

However, credit eligibility creates limitations. The unpredictability of credit approvals is a major concern for companies, given that when they commit funds to a research project, they need to know in advance if and when they will receive their credits.

Eligibility criteria are also limited: credits are not available for certain activities essential to developing a drug, such as clinical batching and phase I studies. It may take a long time to obtain the credits, or the application for a project may be accepted one year and refused the next. A lack of funds can hinder drug development.

Ideally, eligibility standards would be more predictable. Increasing awareness and educating application assessment officials on companies' research activities would help them better understand which activities are related to R&D and accept projects essential to drug development.

Cybersecurity

Seventy-eight percent of CROs surveyed will invest in cybersecurity within the next two years.

CONCLUSION


With the restructuring of Quebec's life sciences' ecosystem in the late 2000s and early 2010s, CROs clearly became essential to carrying out drug research activities in Quebec. More than a dozen years later, it is evident that the industry is strong and continues to grow, that the validity of the CRO model has been confirmed, and that it attracts significant interest from international biopharmaceutical companies.

CROs support the development of new health innovations such as drugs and vaccines. By being experts in their field of activity, CROs are actively involved in enhancing their services by innovating their expertise, improving their techniques, and optimizing their equipment. These specialists support life sciences companies in their product development, help accelerate the development cycle, and significantly reduce the time leading to commercialization. CROs could be renamed "health innovation services companies." Our data shows that Quebec's CROs are growing rapidly and are a solid economic sector that attracts international investment. Quebec CROs offer diversified and specialized services which help companies to develop innovations that improve the health of the general population.

Clinical research is essential for developing new drugs and improving patient care. Many patients have access to the most innovative treatments and receive high-quality care and monitoring through clinical trials. The sector's vitality is unequivocal; companies worldwide do business with Quebec CROs, which offer the full range of services needed to conduct studies here in Quebec, from discovery to commercialization. CROs contribute a great deal to Quebec by generating technological wealth, allowing research activities to continue in Quebec, and creating many high-quality jobs.

CROs support Quebec research at all levels, from university laboratories to biotechnology, pharmaceutical, and medical technology companies. They bridge the gap between research and business and connect the various sectors: they are our industry's backbone.

The CRO sector is a pillar of research in Quebec and a high-value industrial sector: it must continue to be supported and valued by government bodies. Research and development credits contribute to its growth and to advancing research. They must be preserved and made more accessible because they help strengthen our industry. We must acknowledge the value Quebec's CROs bring to drug development and promote them throughout the life sciences industry.



"Quebec's CROs are an important economic driver for our industrial life sciences cluster. A large majority of their revenues come from foreign companies, which brings new money to Quebec and keeps us collectively among the best in the world."

-Yves Roy, President, Corealis Pharma