

# CLINICAL TRIALS IN CANADA

RESEARCH NOTE APRIL 2023





## ISSUE

The innovative pharmaceutical industry has sponsored over two-thirds of clinical trials initiated in Canada in the last 5 years and contributed over <u>\$15 billion to the Canadian economy annually</u>.<sup>1</sup> The industry sponsored an even larger share of clinical trials for oncology products (over 70%),<sup>2</sup> and for drugs for rare diseases (over 70%).<sup>3</sup>

While the number of clinical trials initiated in Canada has been relatively steady over the past decade, its share of worldwide trials initiated has been decreasing. Only 3.1% of clinical trials initiated worldwide in 2022 had sites in Canada, compared to 6% in 2010. This highlights the need to better position Canada as an attractive destination for pharmaceutical R&D and clinical trials. This could be encouraged through initiatives such as a National Ethics Approval with one informed consent, national contract language, and increased support for infrastructure at clinical trial sites, particularly in smaller centres.

In addition, Health Canada is working on modernizing the clinical trials' regulatory framework by proposing, among others, the establishment of a single authorization of a trial involving multiple health products, the use of a risk-based approach to regulate clinical trials, the use of terms and conditions on a clinical trial authorization and the approval of decentralized/hybrid trials which would increase diversity and inclusion in clinical trials.<sup>4</sup> It is expected that this potential modernization would better serve the needs of stakeholders while continuing to protect the safety of patients.

A challenge relates to availability of medicines and Canada's <u>lengthy and onerous pharmaceutical funding pathway</u>.<sup>5</sup> Companies provide patient access to medicines through clinical trials, but once approved, those medicines are not made available to patients insured through public drug plans in a timely manner. This impacts Canada's international reputation during a period of high global competition for clinical trials development. Governments across Canada can help to attract pharmaceutical investment by addressing these pressing patient access gaps.

1 Statistics Canada. (2020). The Canadian Research and Development Pharmaceutical Sector : Reference Year 2020.

2 Industry sponsored, on average, 70% to 80% of oncology clinical trials initiated every quarter since 2018.

3 Industry sponsored, on average, 70% to 90% of drugs for rare diseases clinical trials initiated every quarter since 2018.

4 Health Canada. (2022). <u>Clinical Trials Modernization: Consultation Paper</u>.

5 Canadian patients wait 834 days following Health Canada approval to access medicines through public plans, twice as long as patients in peer countries and ranking Canada last among G7 countries.



# **KEY INSIGHTS**

- The pharmaceutical industry leads in clinical trial initiation in Canada, especially in trials for drugs for rare diseases and trials for oncology products.
  - The industry sponsored between 64% and 76% of all clinical trials initiated in Canada every quarter since 2018. (Chart 1 and Chart 2)
  - Approximately one-third of clinical trials initiated since 2018 were for oncology products, and approximately 70-80% of these trials were industry-sponsored. (Chart 3)
  - Clinical trials for drugs for rare diseases represented about 30% to 40% of all trials initiated in Canada every quarter since 2018, and the majority of these trials were sponsored by industry (70% to 90%) compared to non-DRD trials (57% to 72%). (Chart 4)
  - There was a 28% decrease in clinical trials initiated in 2022 compared to 2021, and also a significant decrease in the number of clinical trials completed each quarter in 2022 when compared to previous years. (Chart 1 and Chart 5)
- The majority of clinical trial activities in Canada took place in Ontario and Quebec. (Chart 6)
- Oncology was the main therapeutic area accounting for 38% of ongoing trials, followed by trials for central nervous system drugs (15%), cardiovascular drugs (8%), and infectious disease drugs (6%). (Chart 7)
- Most of the clinical trials initiated in Canada were multinational trials, and industry sponsored the majority of multinational trials.
  - On average, 88% of multinational trials initiated since 2018 were industry sponsored, compared to 21% of single-country trials being sponsored by industry. (Chart 8)
- While the number of clinical trials initiated in Canada since 2010 has been relatively steady, the share of worldwide trials initiated in Canada has been decreasing.
  - 3.1% of clinical trials initiated worldwide in 2022 had sites in Canada, compared to 6% in 2010. (Chart 9)
  - Similarly, 3.5% of oncology trials initiated in 2022 had Canadian sites, compared to 7% in 2010.
  - Canada fares relatively better in the share of trials for rare diseases, with 4.9% of these trials having Canadian sites in 2022 compared to 6.9% in 2010.
- The Asia-Pacific region has emerged as a hub for clinical trials over the past decade. From 20,036 clinical trials initiated worldwide in 2022 (Chart 10):
  - 56% were in the Asia-Pacific region (increase from 35% in 2010),
  - 23% were in North America (decrease from 35% in 2010),
  - 19% were in Europe (decrease from 30% in 2010).

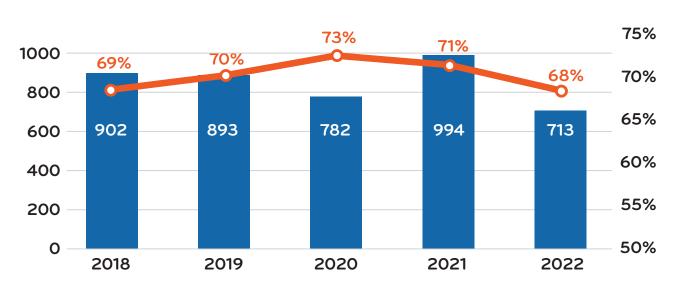
🛑 % Industry-Sponsored



## **DATA CHARTS**

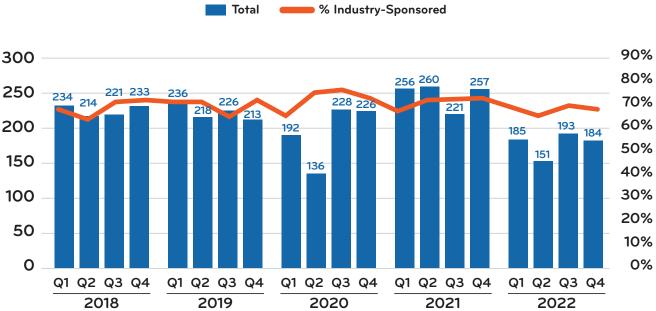
### Chart 1: Clinical Trials Initiated in Canada, 2018 - 2022

Total



Source: GlobalData. Clinical trials initiated since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.

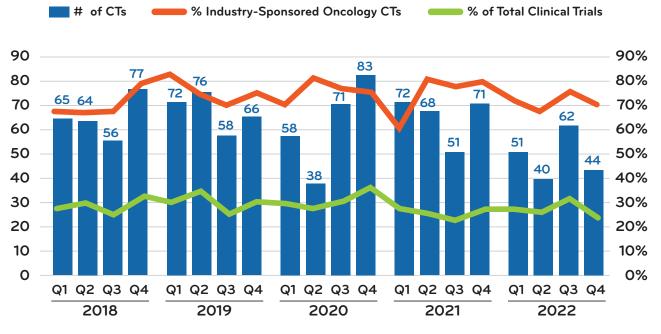
Chart 2: Clinical Trials Initiated in Canada, 2018Q1 - 2022Q4



Source: GlobalData. Clinical trials initiated since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.



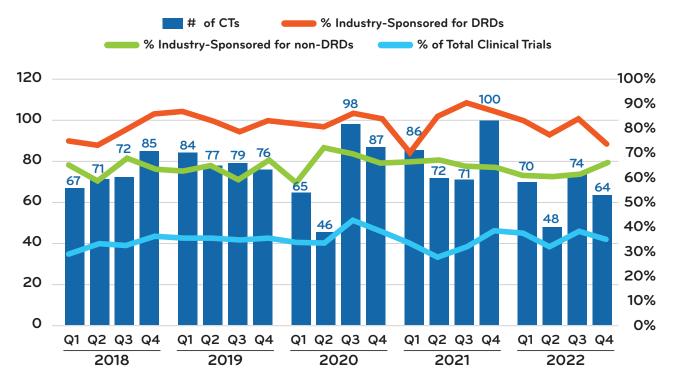




#### Chart 3: Clinical Trials for Oncology Initiated in Canada

Source: GlobalData. Clinical trials initiated since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.

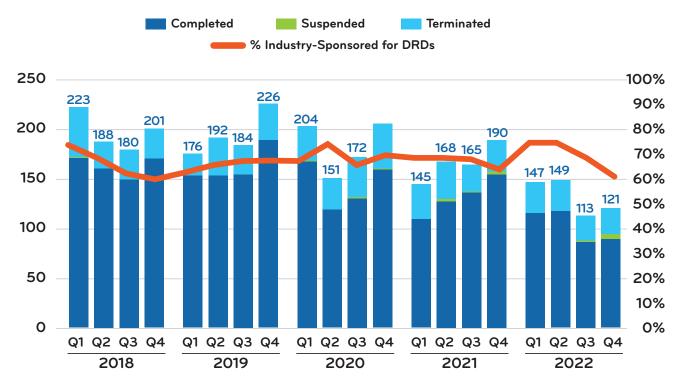
#### Chart 4: Clinical Trials for Rare Diseases Initiatied in Canada



Source: GlobalData. Clinical trials initiated since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.

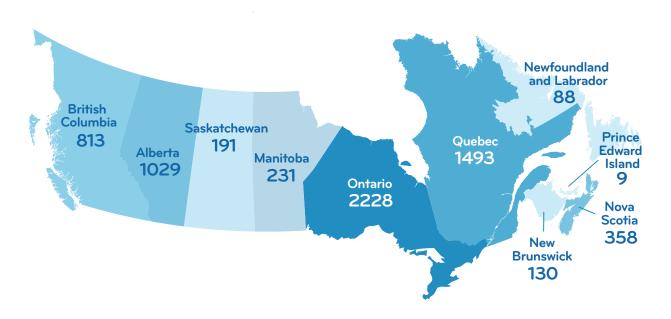


#### Chart 5: Clinical Trials Completed in Canada, by Status



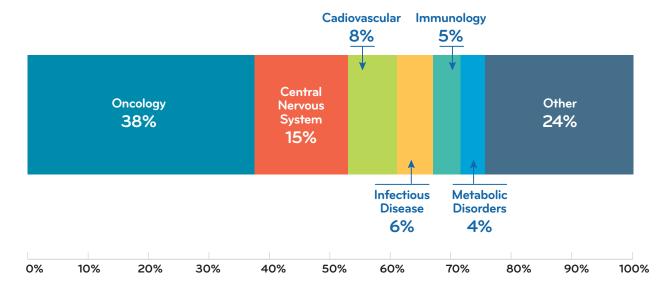
Source: GlobalData. Clinical trials ended since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.





Source: GlobalData. Total ongoing clinical trials = 3,313. Provincial totals add up to more than Canadian total due to trials having multiple sites in multiple provinces. 346 trials had no specified sites and are not included on the map. Clinical trials ongoing on the date of January 13, 2023. Includes Phase 0 to phase IV interventional studies for drugs but does not include trials for medical devices, observational, or behavioural studies.

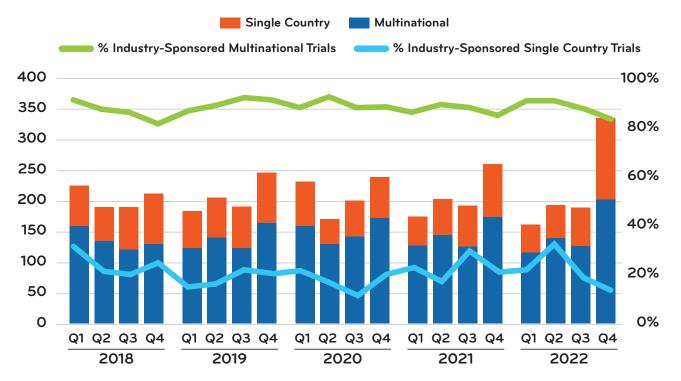




## Chart 7: Ongoing Clinical Trials by Therapeutic Area

Source: GlobalData. Clinical trials ongoing on the date of January 13, 2023. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural, or observational studies.

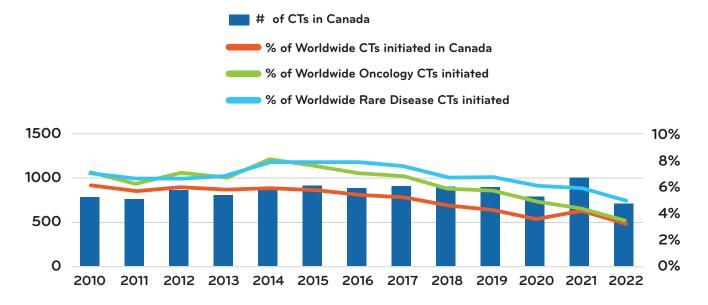




Source: GlobalData. Clinical trials initiated since January 1, 2018; industry-sponsored was either sole- or joint- sponsorship by a company. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.



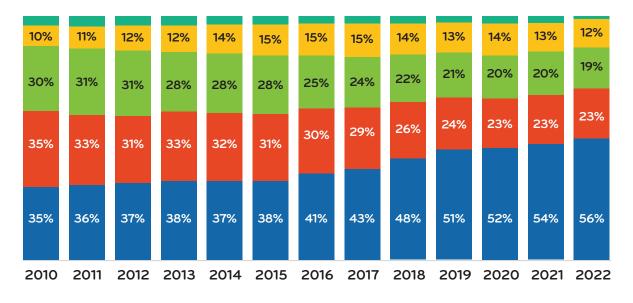
#### Chart 9: Share of Worldwide Clinical Trials Conducted in Canada



Source: GlobalData. Clinical trials initiated between January 1, 2010, and December 31, 2022. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.

## Chart 10: Worldwide Clinical Trials Initiated, by Region





Source: GlobalData. Clinical trials initiated between January 1, 2010, and December 31, 2022. Totals add up to more than 100% due to some trials having multiple sites in different regions. Includes Phase 0 to phase IV interventional studies for drugs. Does not include trials for medical devices, behavioural studies, or observational studies.



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