

# ***Gaps and Gains A Global Look at Clinical Trials***

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# About Tufts CSDD

**Center History:** 50-year-old Independent, globally-focused, academic research center based within Tufts University School of Medicine (Boston).

**Mission:** Conduct robust, data-driven assessments and analyses to inform drug development stakeholders committed to optimizing quality, performance, efficiency and economics.

**Communities Served:** Congress, the National Academies of Science, foundations, industry, government and regulatory agencies, public-private partnerships, trade associations, professional societies, consultants, capital market analysts.

**Output:** 12 – 15 empirical studies annually; averaging 19 peer-reviewed publications and 29 articles in the trade press; presentations at 3 conference/meetings monthly; 6 professional development programs.



# AGENDA

- **Overview of the Global Clinical Research Landscape**
- **Focus on Canada's Clinical Research Landscape**
- **Closing Comments**



# AGENDA

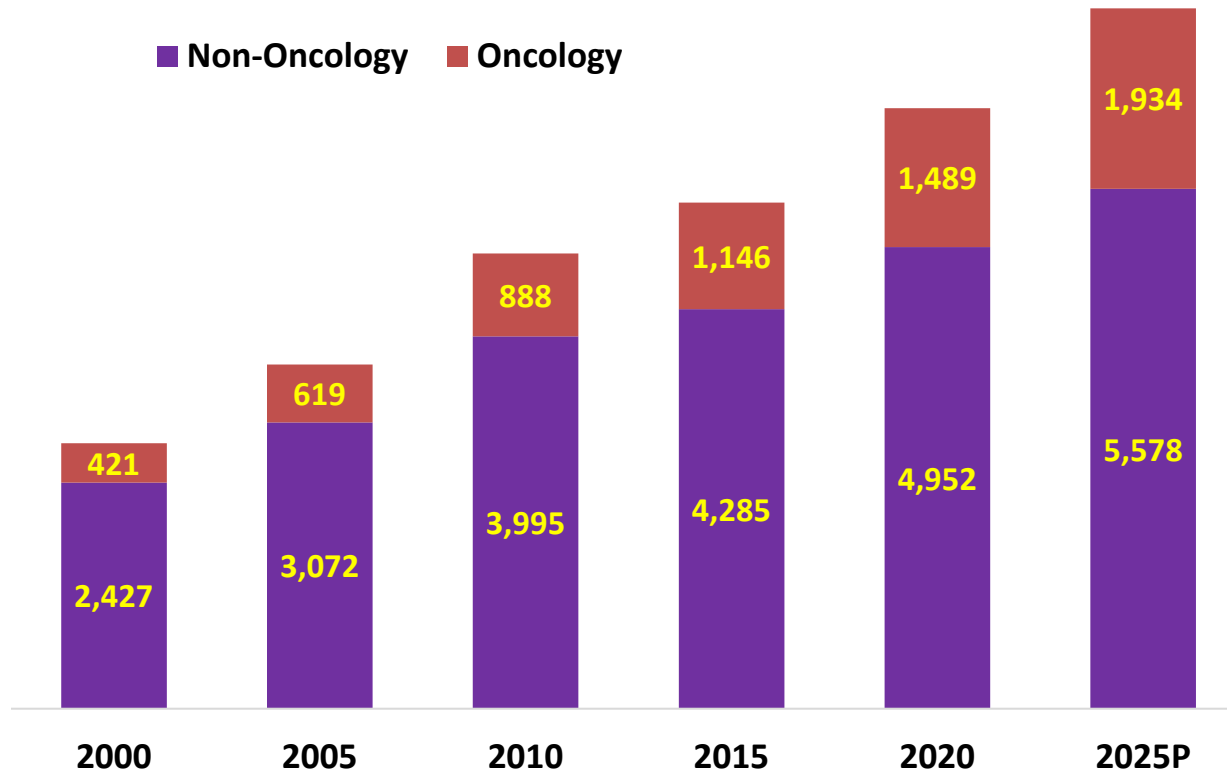
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# Changing Global Pipeline Composition

## Total Drugs and Biologics in the Pipeline



## Pipeline Composition

|       | Percent of Drugs in R&D that are Personalized Therapies | Percent of Drugs in R&D Targeting Rare Diseases |
|-------|---|---|
| 2010  | 19%   | 14%   |
| 2015  | 21%   | 25%   |
| 2020  | 26%   | 34%   |
| 2025E | 38%   | 41%   |

Source: PharmaProjects; Evaluate Pharma, Statista, Tufts CSDD

# Declining Return on Development Investment

|       | Total Capitalized Investment to Develop a Successful Drug | Mean Peak Sales post Approval | Return on R&D Investment |
|-------|---|-------------------------------|--------------------------|
| 2000s | \$ .8 billion   | \$757 million                 | 12–15%                   |
| 2010s | \$2.6 billion   | \$816 million                 | 9-11%                    |
| 2020s | \$4.4 billion   | \$396 million                 | 3-5%                     |

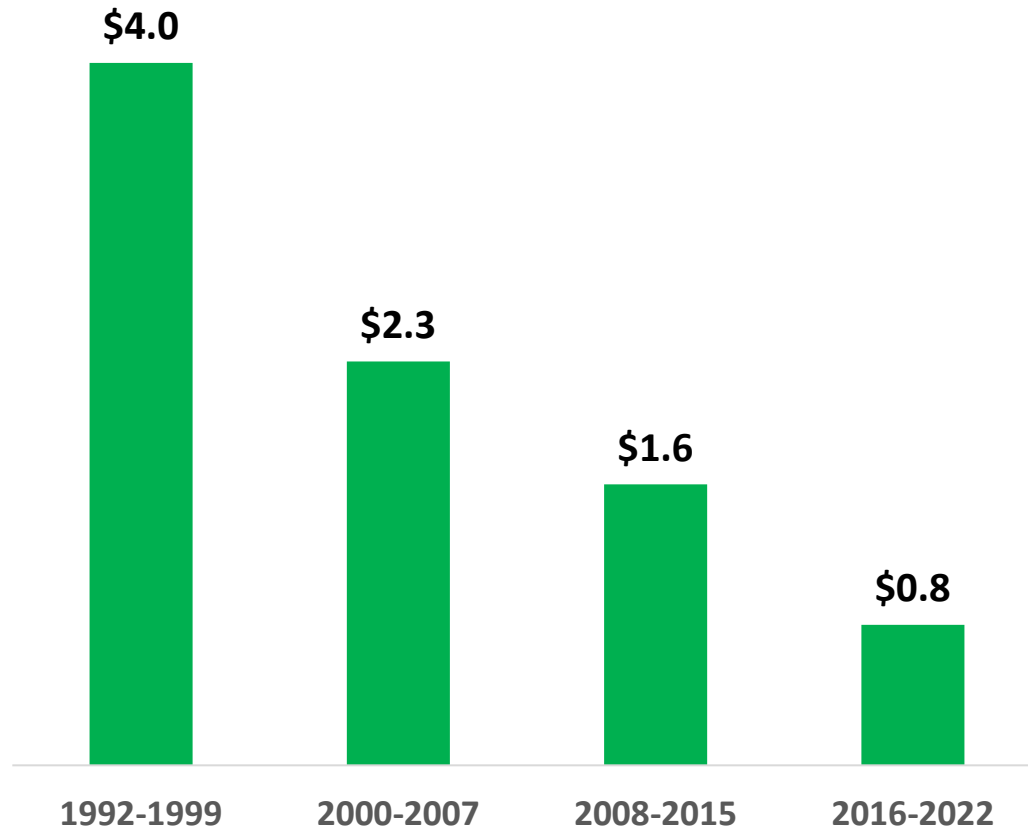
Sources: Statista, Evaluate Pharma, Deloitte, Oliver Wyman, Tufts CSDD



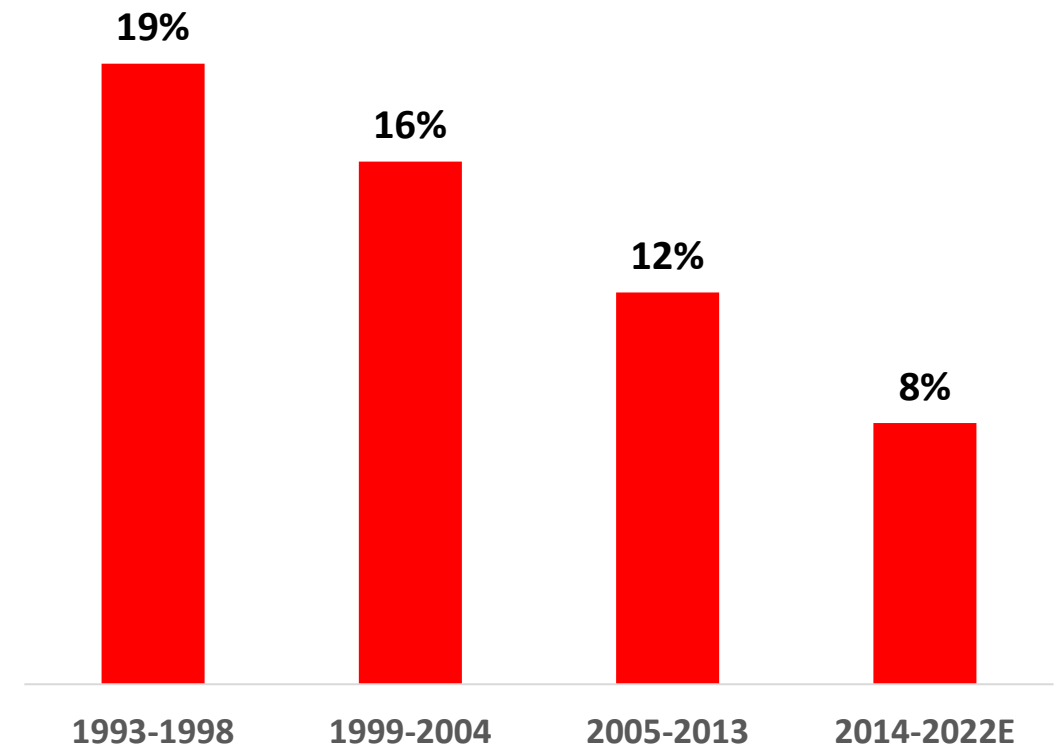


# The Value of a Development Day

Mean Daily Sales by Launch Year



Drug Development Success Rates  
(Percent of IND Filings receiving FDA Approval)

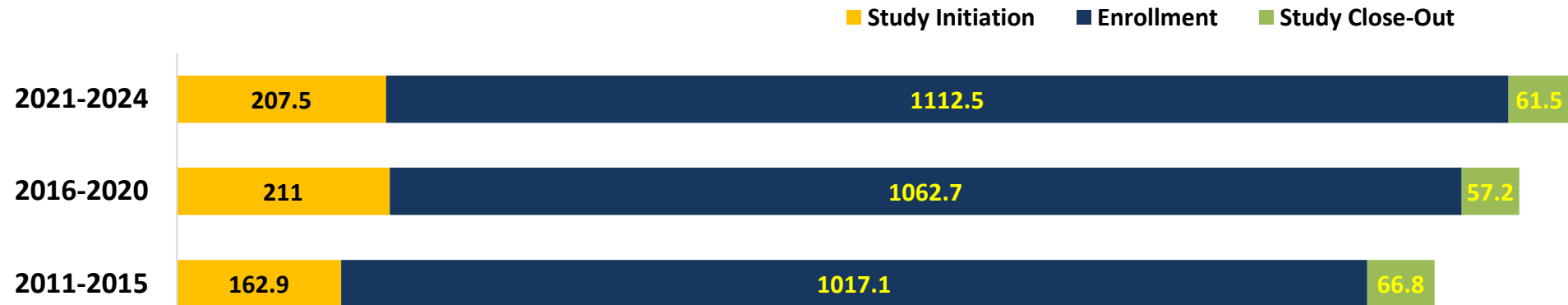




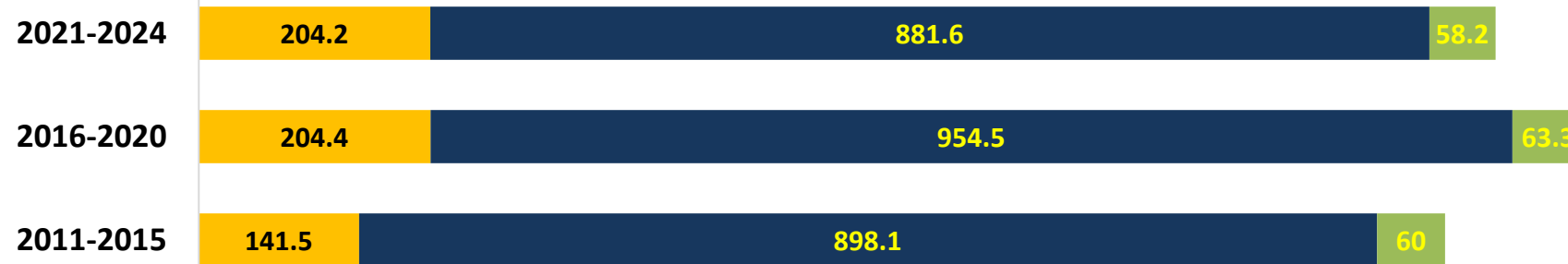
# Overall Clinical Trial Durations

Duration (in days) across three time periods

## Phase III



## Phase II



Source: Tufts CSDD

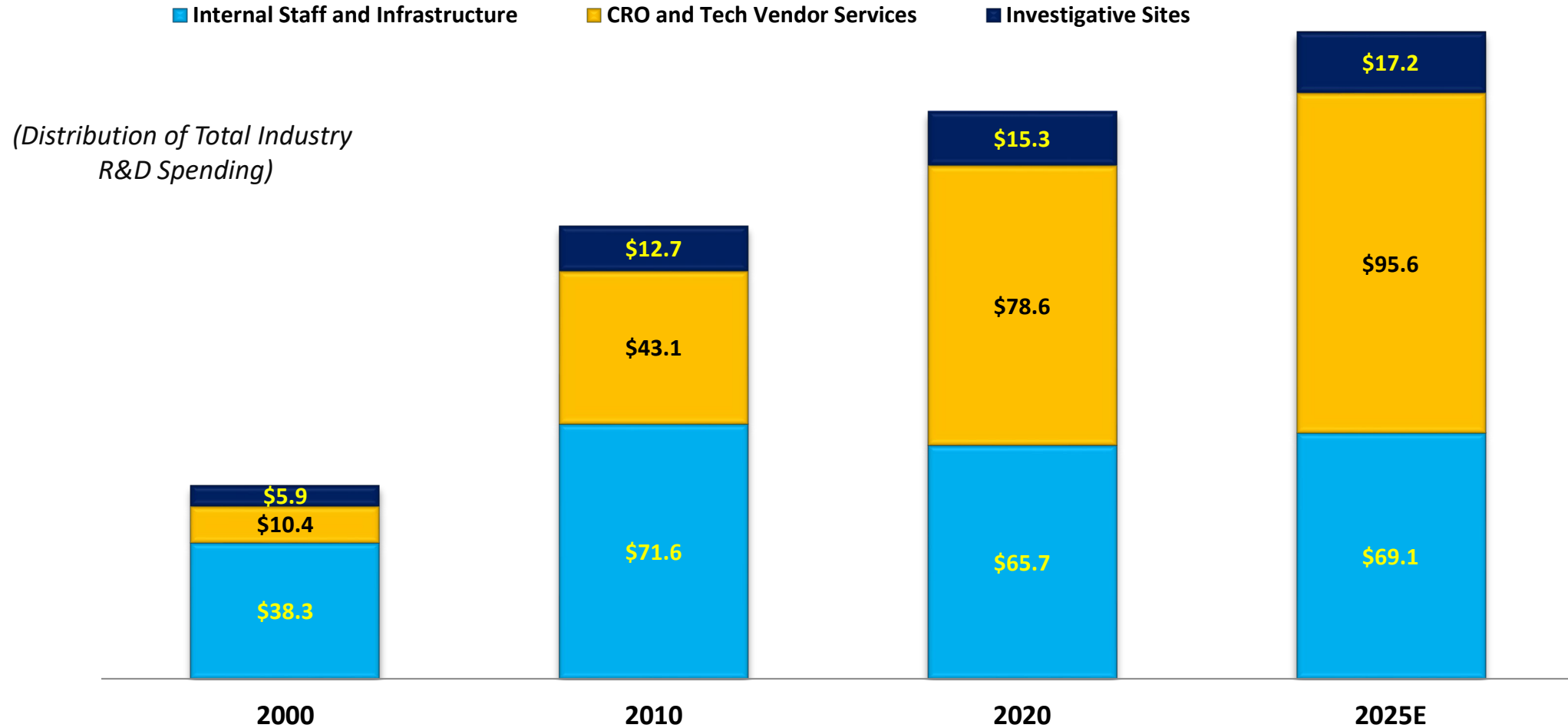




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# Underlying Conditions: Collaboration Complexity

## *(Executional Fragmentation)*



Source: Tufts CSDD

# Underlying Conditions: Protocol Complexity

## *(Design and Executional Customization)*

| Phase III Pivotal Trials<br><i>(Means per Protocol)</i> | 2013-2015 | 2023-2025 | Increase |
|---|-----------|-----------|----------|
| Total Endpoints   | 19.9      | 25.8      | 29.6%    |
| Total Eligibility Criteria                              | 31.7      | 33.3      | 5.1%     |
| Total Procedures  | 187.6     | 301.2     | 60.6%    |
| Total Countries   | 9.4       | 15.8      | 68.1%    |
| Total Investigative Sites                               | 87.0      | 135.4     | 55.6%    |
| Number of Planned Visits                                | 15.4      | 17.1      | 11.1%    |
| Total Patients Randomized                               | 632.3     | 689.8     | 9.1%     |

Source: Tufts CSDD

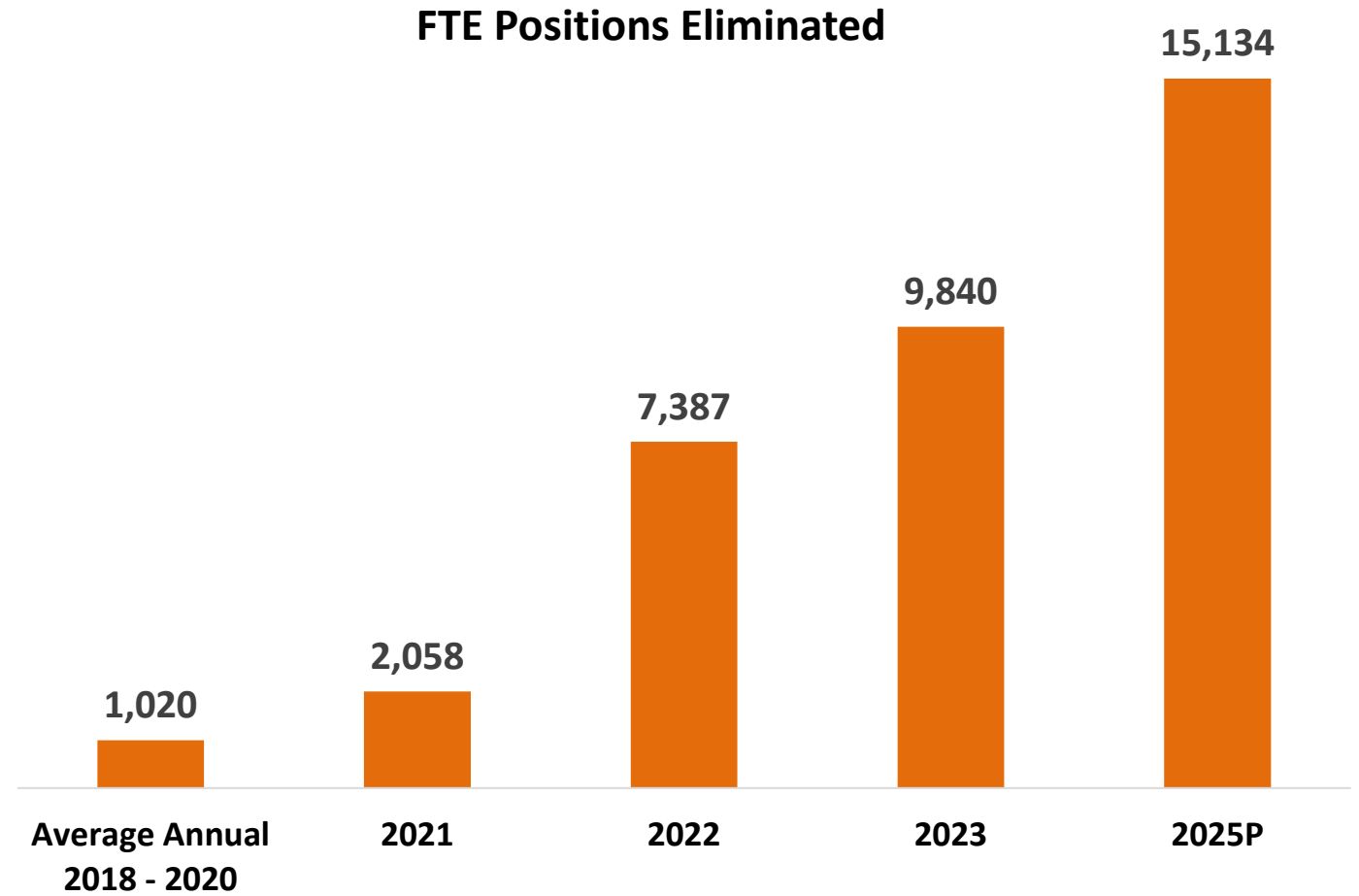
# The Impact of Customization and Fragmentation

| Per Phase III Pivotal Trial     | 10-year Change |
|---------------------------------|----------------|
| Protocol Deviations             | 184.6%         |
| Overall Duration                | 47.0%          |
| Total Substantial Amendments    | 52.2%          |
| Drop-Out Rates                  | 105.1%         |
| Data Volume (Total Data Points) | 418.5%         |

Source: Tufts CSDD

# More Recent 'Challenges': Patent Expirations and Industry Layoffs

| Global Sales at Risk Due to Patent Expirations (\$US Billions) |      |
|--|------|
| 2018   | \$31 |
| 2019   | \$46 |
| 2020   | \$16 |
| 2021   | \$12 |
| 2022   | \$36 |
| 2023   | \$63 |
| 2024   | \$21 |
| 2025   | \$50 |
| 2026   | \$54 |
| 2027   | \$39 |



Source: Evaluate Pharma, Fierce Biotech

# Other 'Recent' Operating Realities...



| Actions and Announcements  | Actual and Expected Responses   |
|--|---|
| <ul style="list-style-type: none"> <li>• Intense scrutiny of government programs</li> <li>• Federal funding cuts and NIH Overhead rate caps</li> <li>• Federal health services staffing reductions</li> <li>• Increased trade regulation and tariffs</li> <li>• Favored Nation requirements</li> <li>• Drug pricing pressures</li> </ul> | <ul style="list-style-type: none"> <li>• Tighter budgets and margin pressure</li> <li>• Longer delays and decision cycles</li> <li>• More limited interaction with government representatives; increased private sector involvement</li> <li>• Unprecedented pressure on academic research institutions</li> <li>• Volatile and uncertain environment for emerging and small companies; capital market retrenchment</li> <li>• Global isolation and alienation</li> </ul> |

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# Clinical Trial Implementation Trends in Canada

|                            |                     | Study Start Year |              |              |              |              |                  |
|----------------------------|---------------------|------------------|--------------|--------------|--------------|--------------|------------------|
| Province                   | 2024 Population (%) | 2020 (%)         | 2021 (%)     | 2022 (%)     | 2023 (%)     | 2024 (%)     | Period Total (%) |
| Alberta                    | 11.9                | 7.2              | 8.4          | 8.4          | 6.6          | 6.9          | 7.6              |
| British Columbia           | 13.8                | 5.6              | 6.4          | 6.2          | 6            | 7.3          | 6.3              |
| Manitoba                   | 3.6                 | 1.8              | 1.9          | 2.4          | 2.1          | 2.1          | 2.1              |
| New Brunswick              | 2.1                 | 0.6              | 0.5          | 0.5          | 0.4          | 0.3          | 0.5              |
| Newfoundland               | 1.3                 | 0.1              | 0.3          | 0.2          | 0.1          | 0.1          | 0.2              |
| Nova Scotia                | 2.6                 | 1.3              | 1.7          | 1.7          | 1.9          | 1.8          | 1.7              |
| <b>Ontario</b>             | <b>39.1</b>         | <b>62.9</b>      | <b>59.8</b>  | <b>59.8</b>  | <b>63.2</b>  | <b>58.8</b>  | <b>60.9</b>      |
| Quebec                     | 22.1                | 16.5             | 17.3         | 17           | 16.8         | 19.3         | 17.3             |
| Saskatchewan               | 3                   | 1.5              | 1.2          | 1.3          | 0.5          | 1.3          | 1.2              |
| Unspecified                | --                  | 2.5              | 2.5          | 2.4          | 2.4          | 2.1          | 2.4              |
| <b>Total Trials Starts</b> | <b>--</b>           | <b>1,386</b>     | <b>1,812</b> | <b>1,602</b> | <b>1,513</b> | <b>1,342</b> | <b>7,655</b>     |

Data are number of unique NCT ID associated with a Start Date from [www.clinicaltrials.gov](http://www.clinicaltrials.gov) expressed as a percentage of the total number of trials that year. Data downloaded on July 3, 2025, from [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Source: Statistics Canada (Canadian Census Population Data). Data downloaded on July 29, 2025, from <https://www12.statcan.gc.ca/>

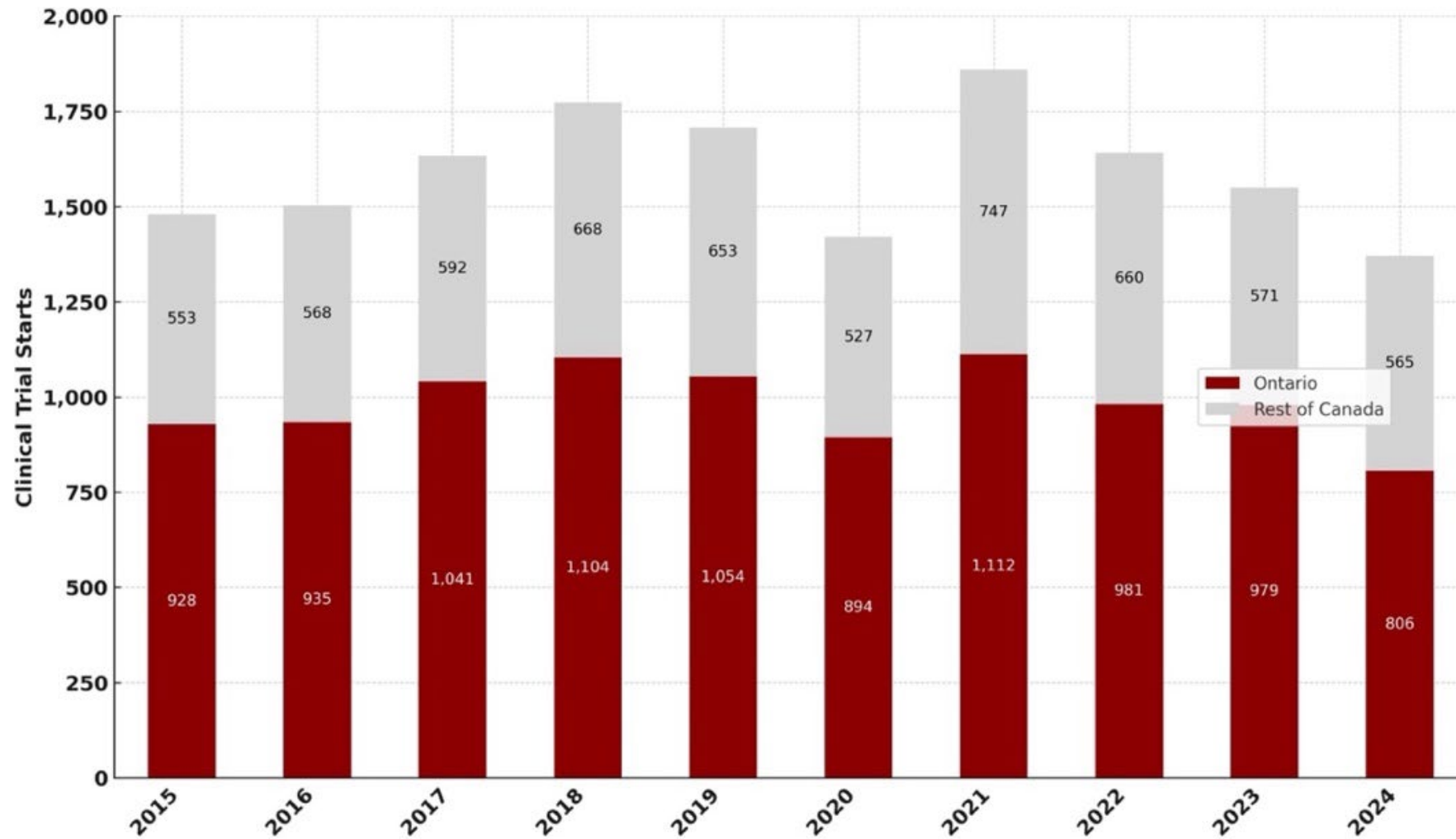
Unspecified province in [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.



# Clinical Trial Starts 2015-2024

## Ontario vs. Rest of Canada

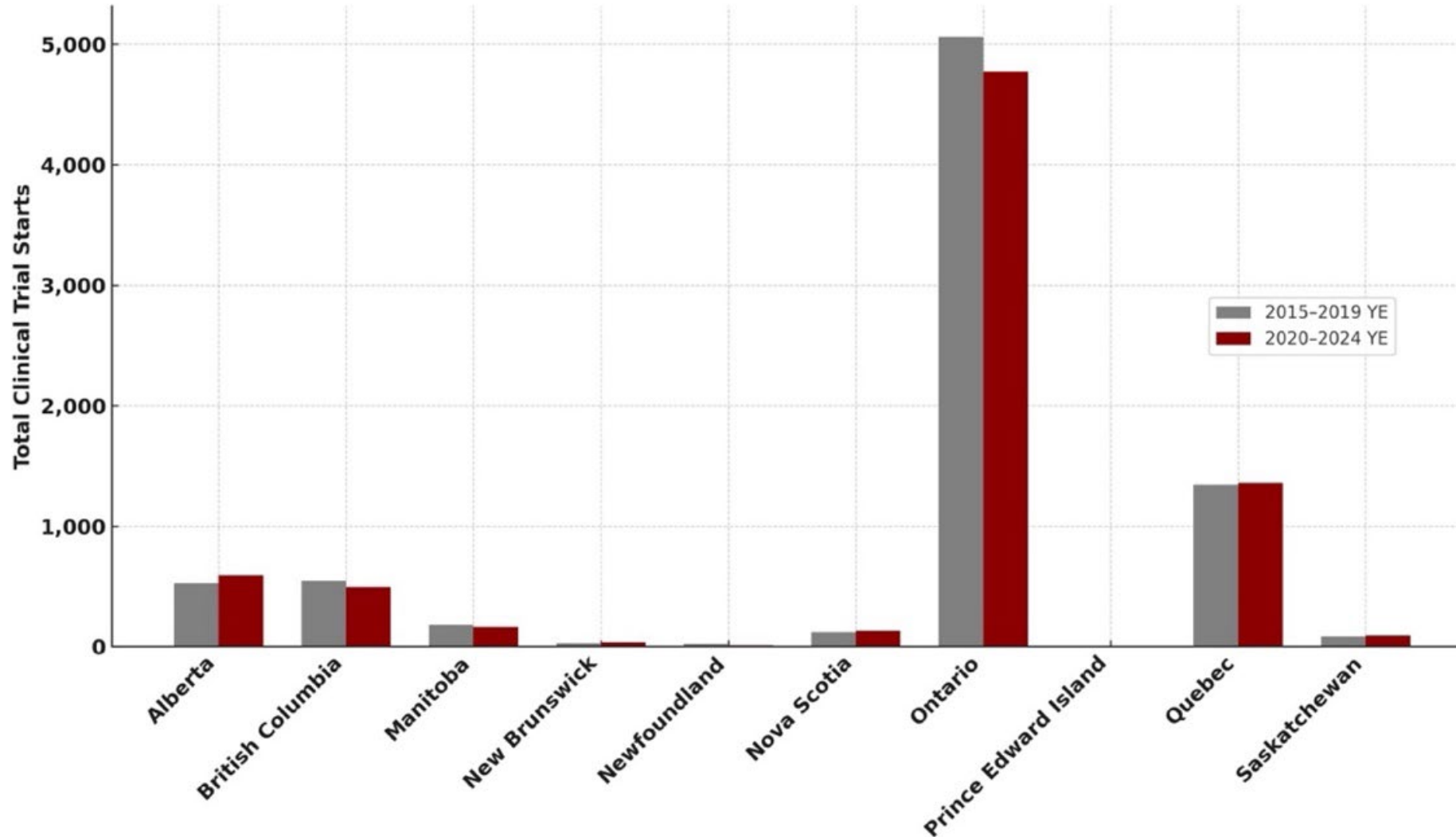


Source: Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

Note: Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.

# Number of Clinical Trial Starts by Province

2015-2019 vs. 2020-2024



Source: Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

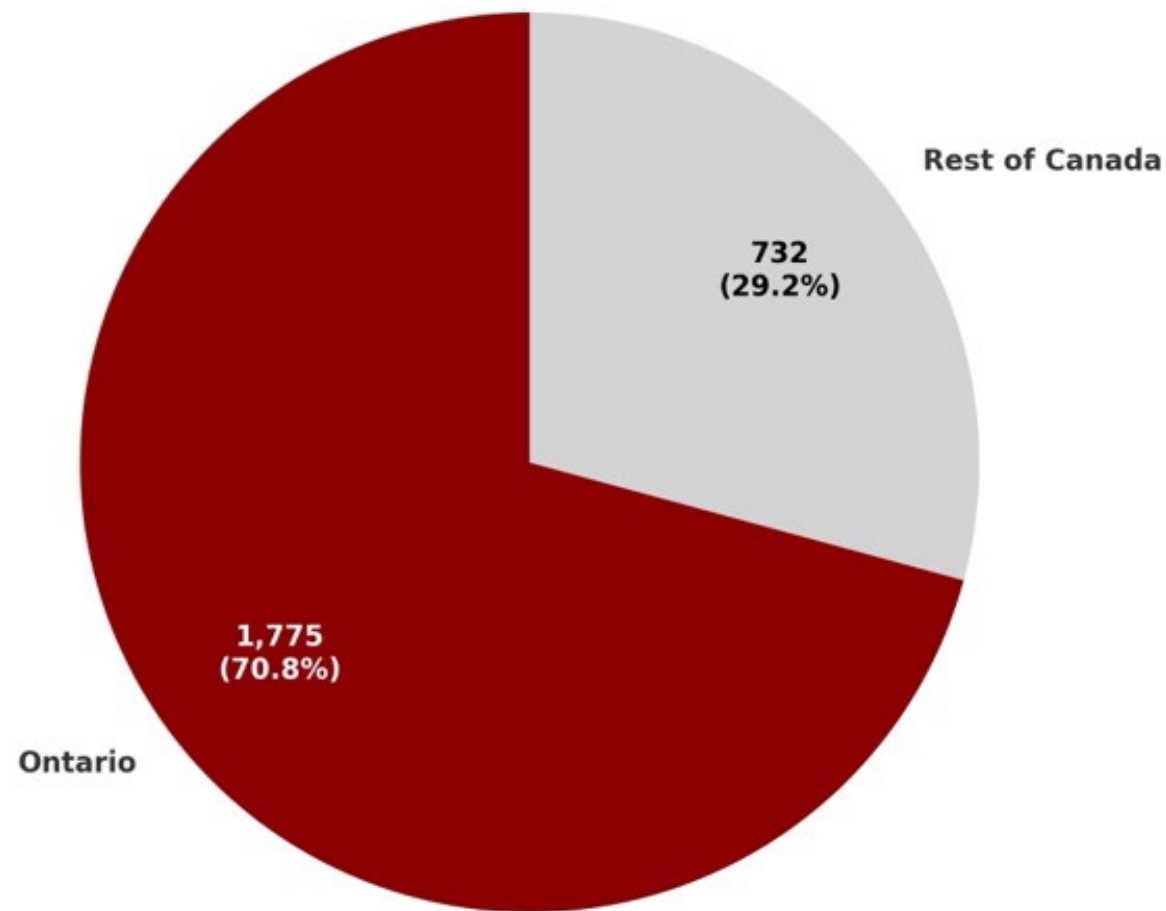
Note: Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.



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# Oncology Trials Initiated 2020-2024

## Ontario vs. Rest of Canada

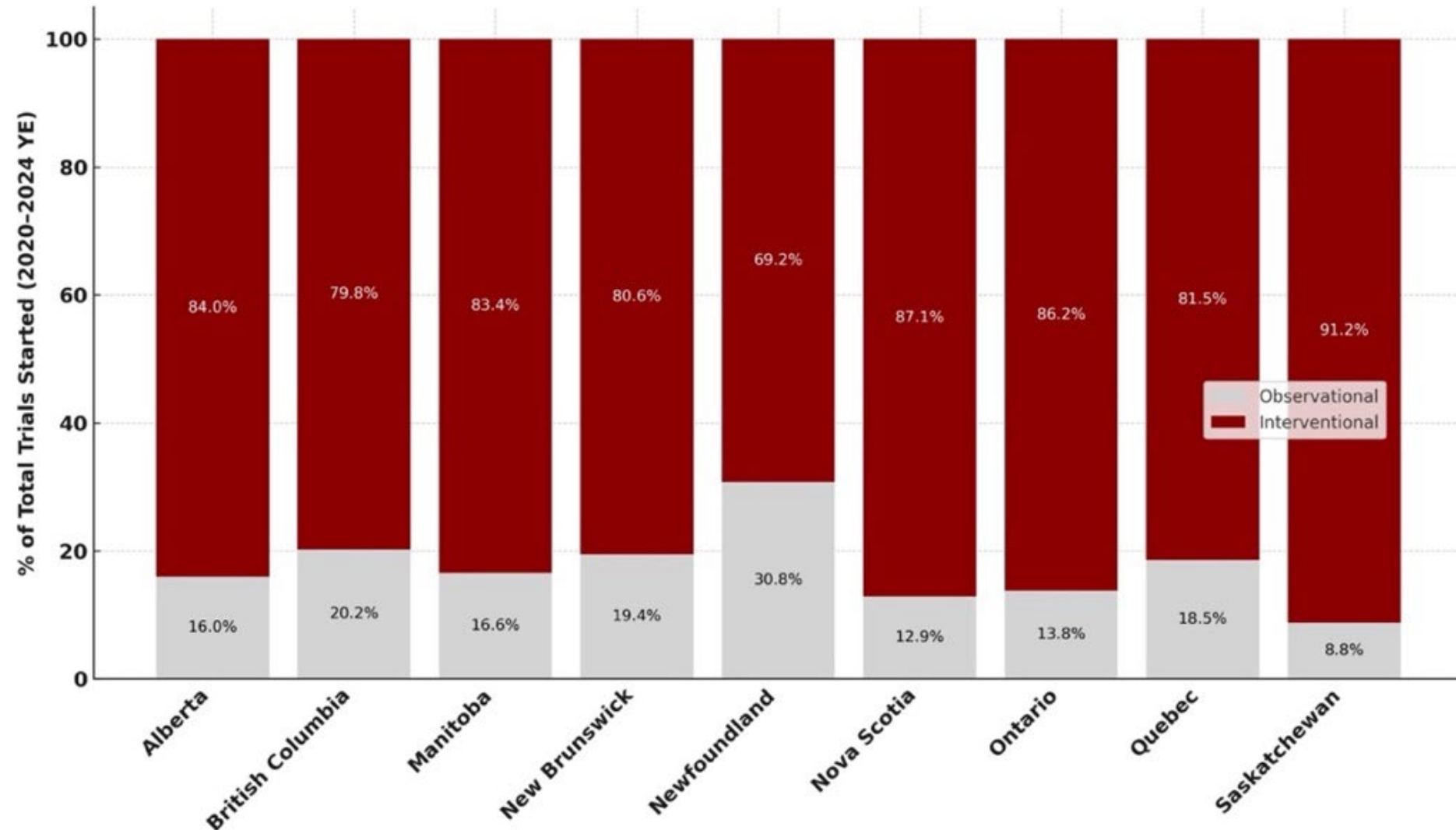


Source: Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

Note: The sample of studies initiated includes industry-sponsored and academia-sponsored, and single-site and multi-site trials.

# Observational vs. Interventional Studies

2020-2024 by Province

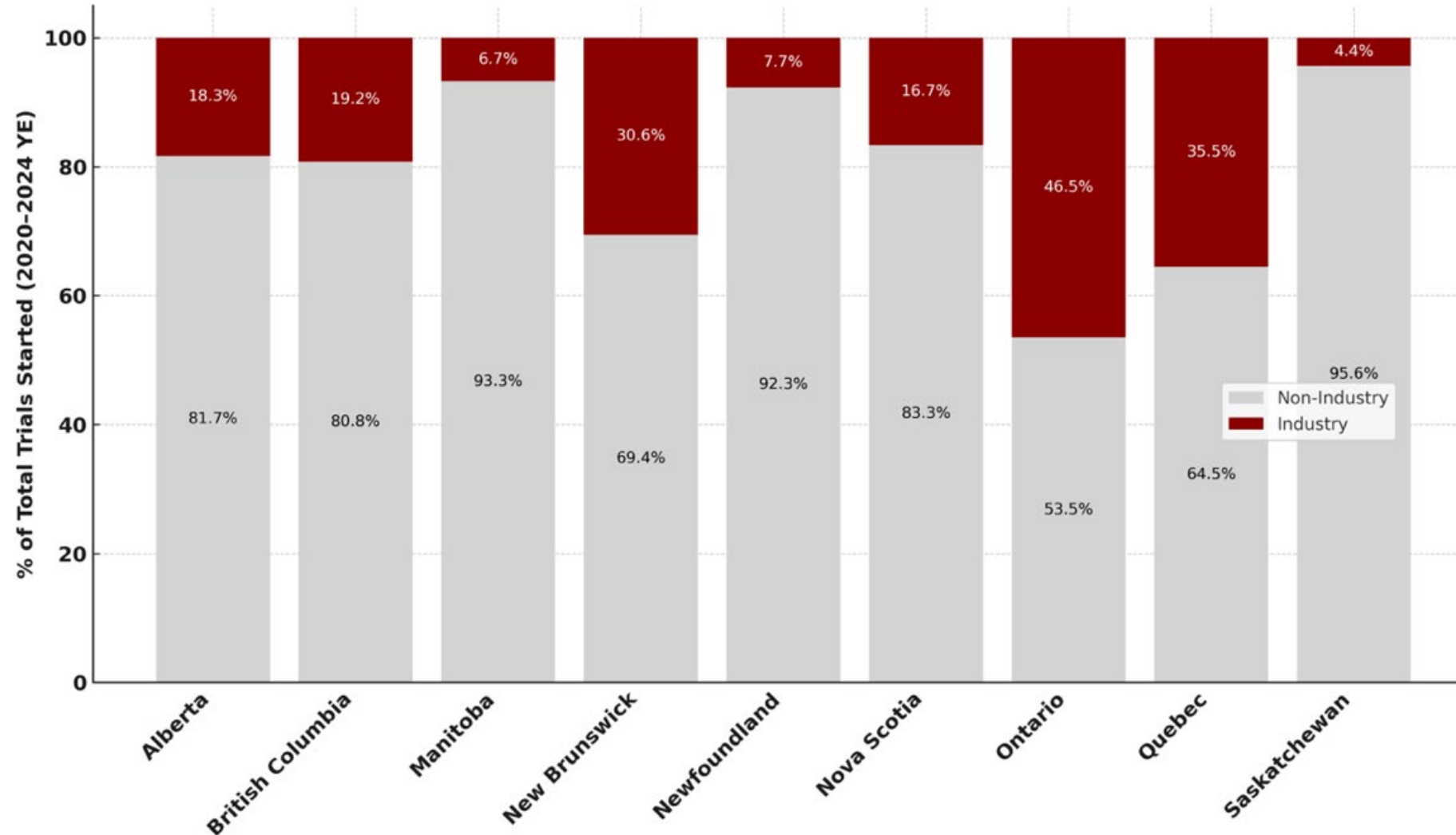


Source: Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

Note: Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.

# Trends in Industry Sponsored Trials

## 2020-2024 by Province

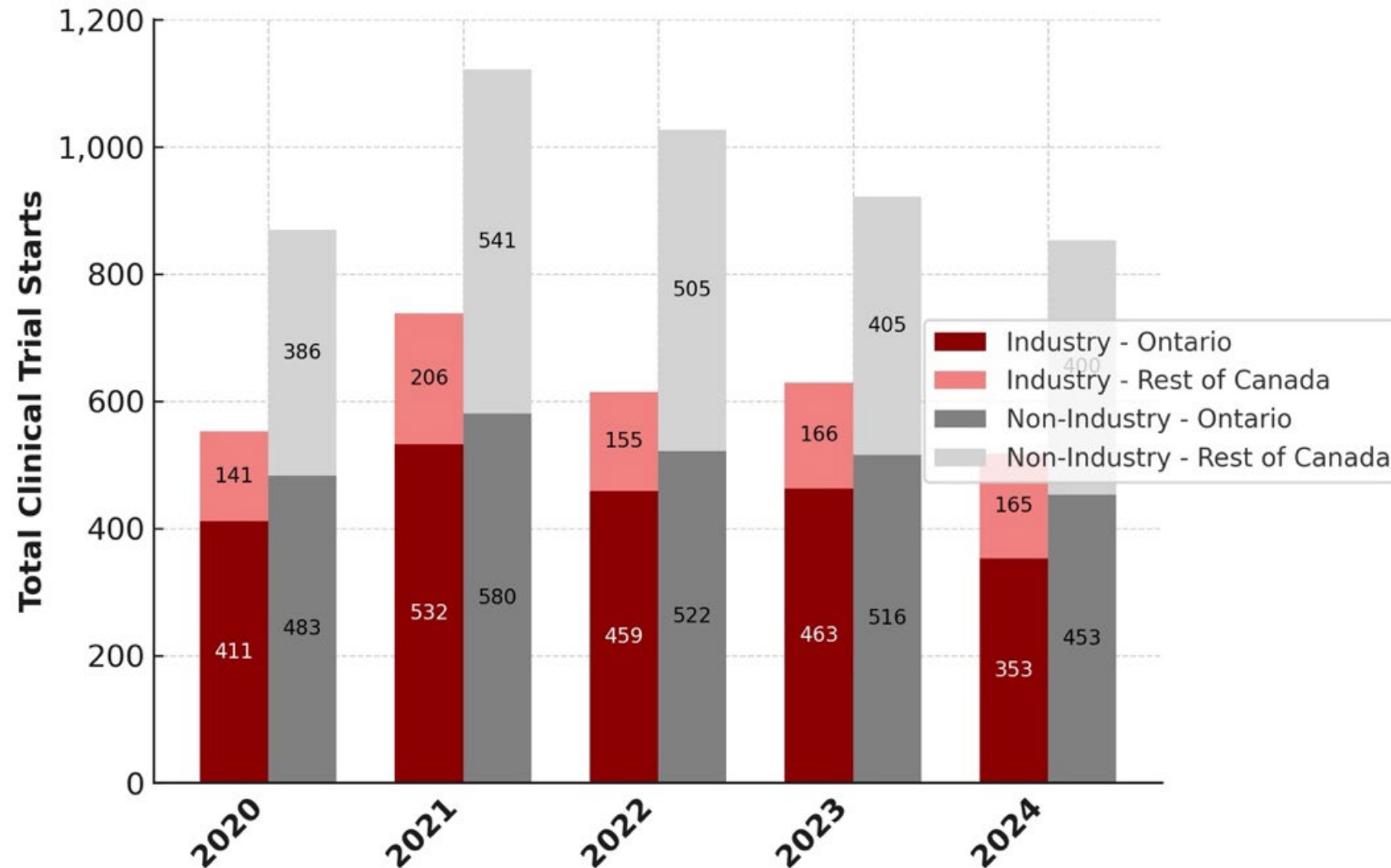


Source: Data from [www.clinicaltrials.gov](https://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

Note: Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.

# Industry Sponsored vs. Non-Industry Sponsored

## 2020-2024 – Ontario vs. Rest of Canada

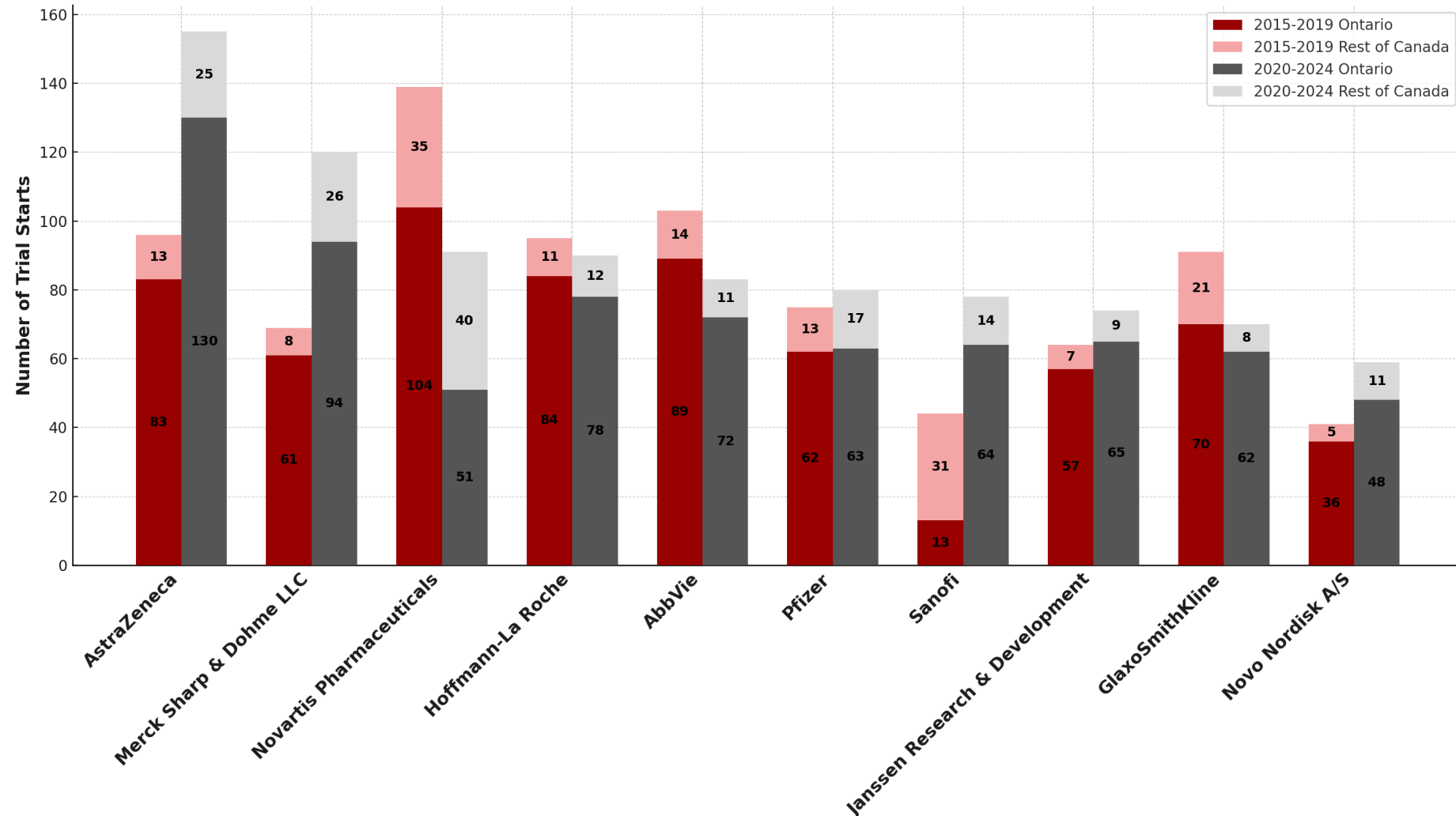


Source: Data from [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Data downloaded by Tufts CSDD on July 3, 2025.

Note: Study starts includes industry-sponsored and academia-sponsored, as well as single-site and multi-site trials.

# Top 10 Industry Sponsors In Canada

## By Number of Clinical Trials



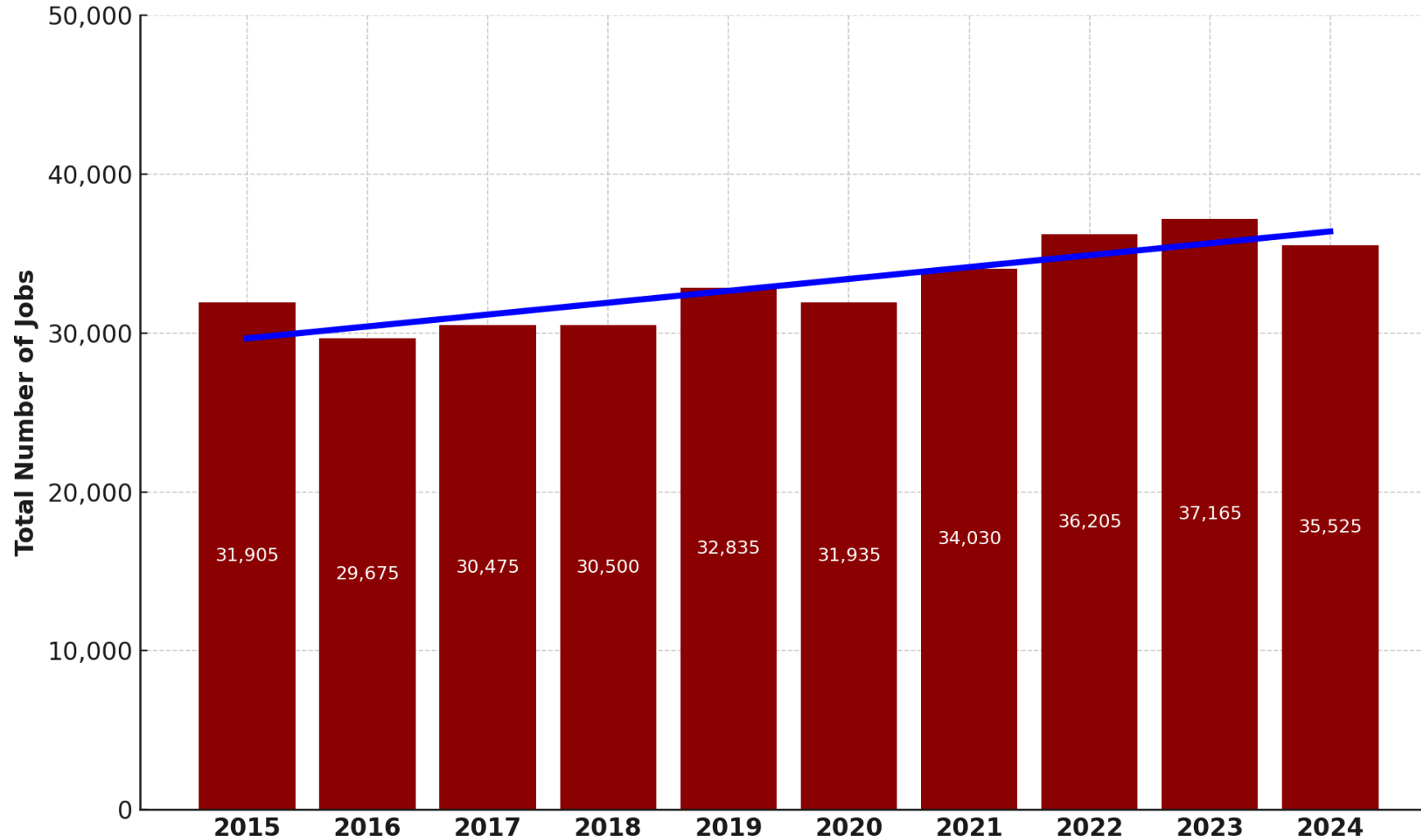
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# Trends in Canadian Pharmaceutical Labor Market

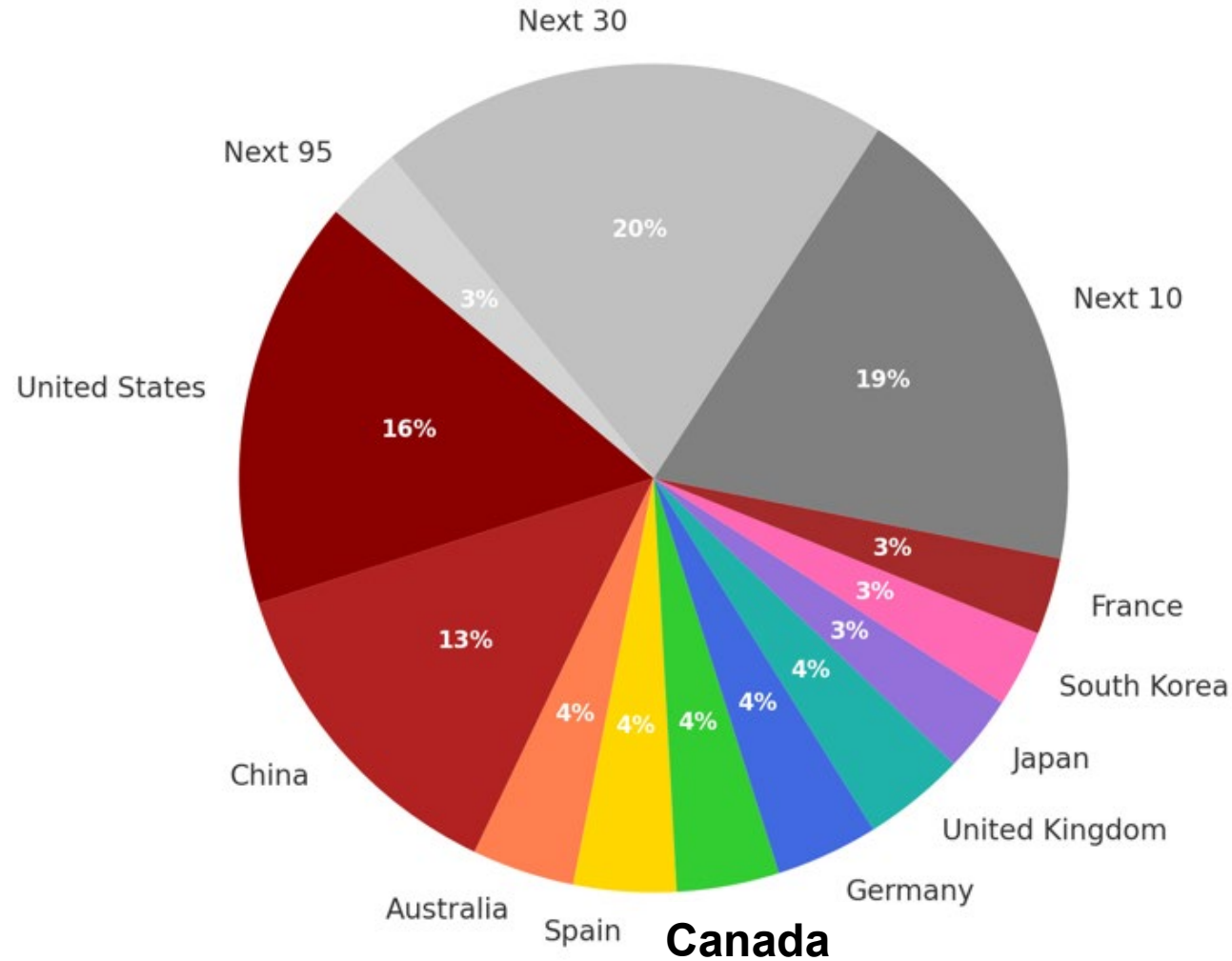
## 2015-2024



Source: Labor data from Statistics Canada / Statistique Canada (Census Data).  
 Downloaded by Tufts CSDD on July 29, 2025. <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=3610048901>

# Ongoing Clinical Trials by Country

## 2020-2024



Source: Citeline Trialtrave Jan 2024. IQVIA Research Institute June 2024. Global Observatory on Health Research. Retrieved by Tufts CSDD on August 12, 2025.

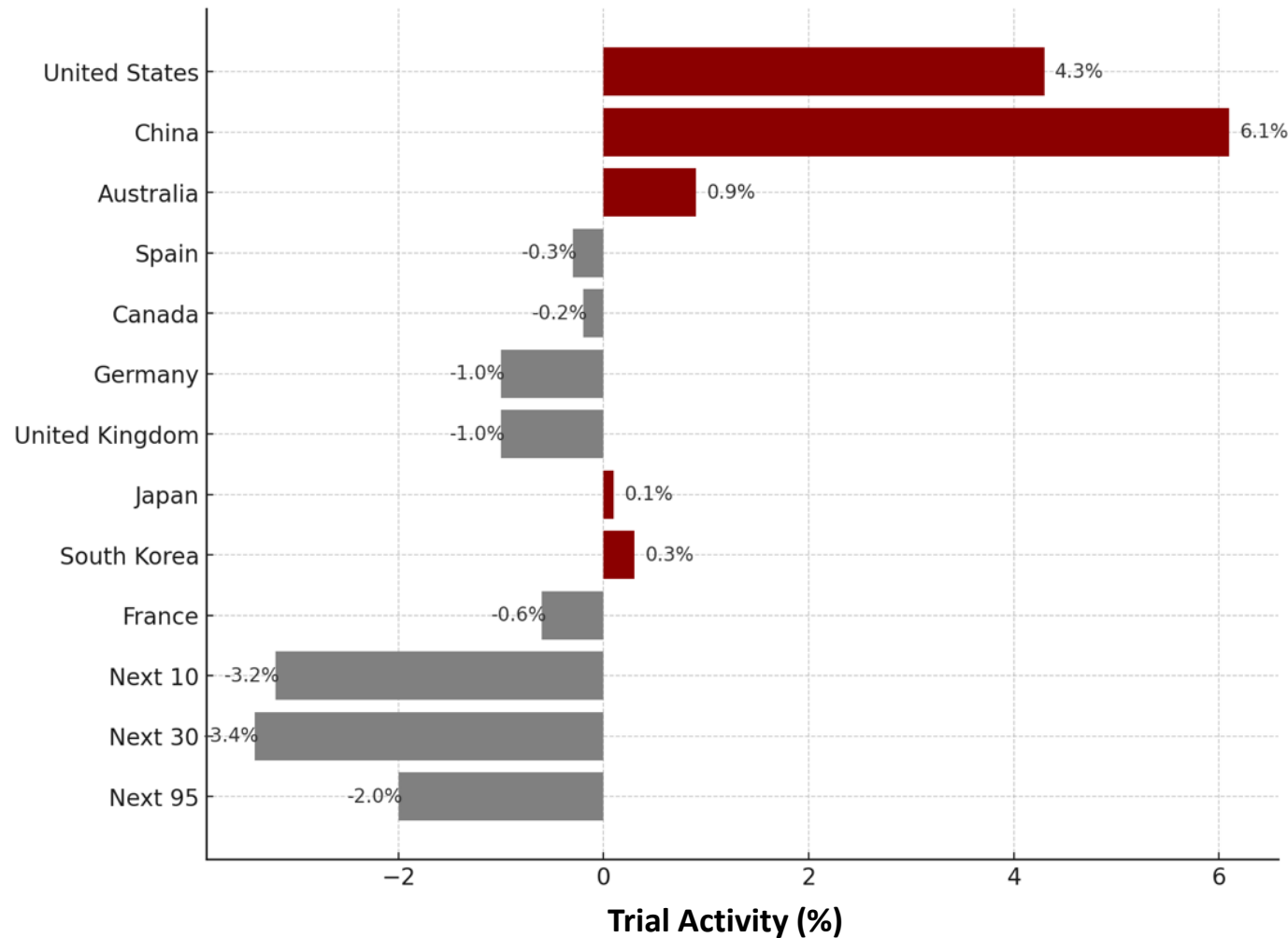
<https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group>

Note: Clinical trial activity (trial-use share) is total trials per country divided by the total number of trial-uses globally. Trials exclude diagnostics, behavioral therapies, supplements, devices, and medical procedures. Analysis excludes trials with no country reporting.

Report: Rethinking Clinical Trial Country Prioritization: Enabling Agility through global Diversification

# Changes in Clinical Trial Activity by Country

## 2019-2023



Source: CitelineTrialtrove Jan 2024. IQVIA Research Institute June 2024. Global Observatory on Health Research. Retrieved by Tufts CSDD on August 12, 2025. <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group>

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# Closing Comments

- **The current global clinical trial operating environment is facing intensifying operational and economic challenges.**
- **The current US political environment is expected to drive major shifts in the global clinical trial landscape.**
- **Ontario continues to lead Canada's clinical research landscape, accounting for over 60% of national trial starts and demonstrating strength across both oncology and non-oncology studies.**
- **Nearly half of Ontario's trials are industry-sponsored and most are interventional, reflecting strong private-sector engagement and growing confidence in Canada's clinical research environment.**
- **With a steadily expanding pharmaceutical workforce and global industry sponsors investing in Canada, the country remains a vital hub for innovation and growth in clinical development.**



**Thank You!**

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