

CANADA: A WORLD LEADING LOCATION TO CONDUCT CLINICAL TRIALS





Foreign Affairs, Trade and Development Canada Affaires étrangères, Commerce et Développement Canada





Canada is a world leading location for pharmaceutical and medical device companies to conduct their clinical trials. Both publicly available information and testimonials from leading global companies doing research in Canada show why many companies choose Canada for their clinical development projects based on its unique combination of quality and efficiency.

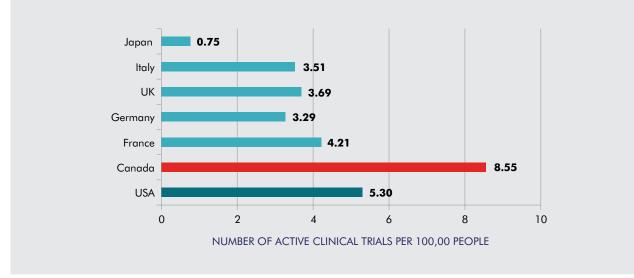
A clinical trials investment in Canada provides the greatest returns by producing high quality, timely research that generates a robust evidence package in support of new product commercialization. In addition, the prospects of the clinical trials industry in Canada hold the promise of continued growth, as its main players continue to innovate and cooperate in various collective ways and therapeutic areas to maintain this competitive edge.

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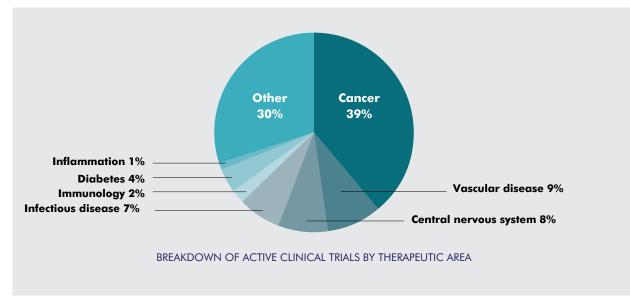
THE FACTS

As of October 2014, there were 2,971 active clinical trials in Canada. Canada has the highest number of active clinical trials per capita among G7 nations.



Source: clinicaltrials.gov (accessed 6 October 2014)

2 Canadian clinicians are conducting clinical trials across all major therapeutic areas.



Source: clinicaltrials.gov (accessed 6 October 2014)

GLOBAL LEADER IN QUALITY

The quality of Canadian clinical research is outstanding, thanks to several unique assets stemming from its population demographics, labour force and health care system. These assets include Canada's ethnically diverse population, universal healthcare coverage, leading universities, and major hospitals and health research centres staffed with highly qualified investigators, as well as national centres of excellence in specific therapeutic areas for commercialization.

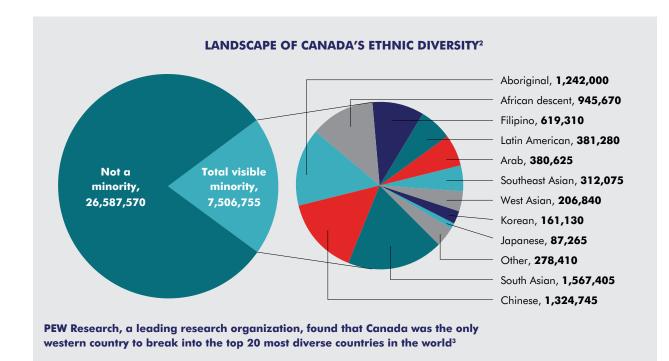
"Within Roche, Canada has a strong reputation for clinical trials based on the quality of data generated by our Canadian sites."

> - Nita Arora Vice President, Country Clinical Operations Roche Canada



DIVERSE POPULATION SUPPORTS BETTER CLINICAL TRIALS

- Canada, with a population of almost 35 million people, has one of the most ethnically diverse populations, which greatly assist with studies that require large, genetically diverse pools of patients.
- Having a greater diversity of patients enrolled in clinical trials can lead to enhanced drug development outcomes¹ and Canada has the diversity to support enrollment goals.



Source: 1 - Lechleiter J. Closing the Diversity Gap in Clinical Trials. Forbes; 2 - Statistics Canada – 2011 Census data; 3 - PEW Research. Fact tank 2013 Report, Most and least culturally diverse countries in the world (accessed 15 October 2014)

UNIVERSAL HEALTHCARE SYSTEM

• Canada's universal healthcare system provides quality and cost advantages for conducting clinical trials. The quality of care received by patients is world class and largely uniform across the country, with a per capita spending of \$4,676¹. On average, there are 2.1 doctors² and 7.9 nurses³ per 1,000 people. This high level of spending and universal medical coverage ensures that a common and high standard of care is being delivered to patients before, during and after the clinical trial, resulting in superior data accuracy and quality from all trial sites.

GLOBALLY RECOGNIZED UNIVERSITIES AND WORLD-CLASS RESEARCH HOSPITALS

- Canada is regarded as a leader in scientific research. The Council of Canadian Academics published findings in 2012 that Canada was ranked fourth in the world in terms of scientific expertise⁴, based on a survey of topcited international researchers. These researchers ranked Canada highly for originality, impact and scientific rigor, demonstrating that Canada is internationally recognized for the integrity and importance of its scientific research. Additionally, Canadian universities consistently rank among the top in the world. In 2014, QS World Rankings placed the University of Toronto, McGill University, University of British Columbia and McMaster University in the top 50 Universities in the world for medical research.
- Canada is home to many world-class research hospitals, including Princess Margaret Hospital, which ranks in the top five hospitals in the world supporting cancer research and is an indispensable site for any cancer clinical trial, as well as the Ottawa Heart Institute, The Hospital for Sick Children, The IWK Health Centre, Peter Munk Cardiac Centre and Toronto Western Hospital, to name just a few.
- Canadian health research centres are world-renowned for being on the cutting edge of research and development, bringing in high levels of government grants and private research dollars, and staffed by some of the top talent globally. These include Sunnybrook Research Institute, the Montreal Neurological Institute, the Montreal Heart Institute and the BC Cancer Agency.



"We conduct clinical trials in Canada because of the quality of research."

- Christine Robeson

Director, GCO Country Head, Global Clinical Operations Janssen Inc., Canada

¹ World Health Organization website. http://www.who.int/countries/can/en/ (accessed 9 October 2014).

² Globe and Mail article. Canada has more doctors, making more money than ever. Published Sept 26th, 2013.

³ Canadian Federation of Nurses unions. https://nursesunions.ca/sites/default/files/2012.backgrounder.nursing_workforce.e_0.pdf Report published Feb 2012 (accessed 9 October 2014).

⁴ The state of Science and Technology in Canada, 2012 report. The Canadian Council of Academics. http://www.scienceadvice. ca/63B65C5C-D7E3-4E27-BA6E-C56B3F34A736/FinalDownload/DownloadId-4C05522FE2DE2AD5F50BA502A1692116/ 63B65C5C-D7E3-4E27-BA6E-C56B3F34A736/uploads/eng/assessments%20and%20publications%20and%20news%20releases/ sandt_ii/stateofst2012_fullreporten.pdf (accessed 23 September 2014).

EFFICIENT CLINICAL TRIAL ENVIRONMENT

Canada offers an efficient and responsive regulatory system for clinical trials that is also cost competitive. Canada has multiple mechanisms in place to expedite clinical trial set-up time. These include efficient regulatory review processes, a patient enrollment process aided by numerous Canadian research networks, efficient clinical trial monitoring, and collaborative industry, government and academic partners.

"Canada enjoys a strong history of world-class clinical research. We continue to enhance the clinical trials landscape and highlight Canada's outstanding global reputation as the place to conduct clinical trials."

- Belinda Vandersluis

Director of Implementation, Canadian Clinical Trials Coordination Centre

EFFICIENT CLINICAL TRIAL SET-UP AND PATIENT ENROLLMENT

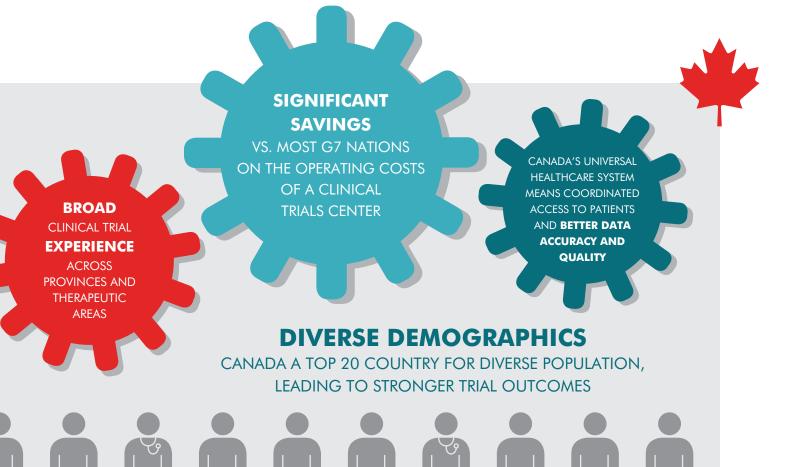
- Canada has an efficient regulatory process that fosters the prompt launch of clinical trials. Set-up times are among the best in the world. Health Canada targets a 30-day review of clinical trial applications. In 2013, Health Canada achieved 99% of their target for all applications received.
- Canada has several large research networks that provide an effective way to rapidly access investigators, sites and
 patients across the country via a coordinated approach. These include NCIC Clinical Trials Group, Canadian HIV
 Trials Network, Maternal Infant Child & Youth Research Network, Canadian Neuromuscular Disease Network,
 Canadian Cardiovascular Research Network, Network of Networks, BC Clinical Research Infrastructure Network, and
 Alberta Clinical Research Consortium.
- Trial sites are close to Canada's major population areas as well as to most of those in the US. The Canadian population is clustered around the Canada/US border, with 75% of Canadians living within 160 km of the border, and 90% of the population living within 200 km of the border¹. Similarly, many if not most of the largest population centers in the US are located near the Canadian border². This mutual proximity leads to more efficient trial management by significantly reducing the travel burden and cost when monitoring and inspecting multiple sites for trials conducted in both countries.

RANKED NUMBER 1 PER CAPITA IN ACTIVE CLINICAL TRIALS AMONG THE G7 NATIONS GLOBAL LEADER IN QUALITY STEMMING FROM ITS WORLD-CLASS UNIVERSITIES AND RESEARCH CENTRES R&D TAX CREDITS OF 15 TO 32%

THE WORLD'S TOP 10 PHARMACEUTICAL COMPANIES REGULARLY CONDUCT CLINICAL TRIALS IN CANADA

COST-COMPETITIVE ENVIRONMENT FOR THE DESIGN AND MANAGEMENT OF CLINICAL TRIALS

- Given the large expense of designing and managing global clinical trials, an important consideration are the annual operating costs of administrating clinical trials centers, both for those business costs relating to real estate and personnel. On this, two independent sources point to Canada's strong competitive environment as a location in which to establish such centers:
 - The Financial Times' fDi Benchmark database³, an FDI tracking tool that can assess the relative competitiveness of more than 600 locations across over 65 sectors for hundreds of data points, reveals that most major Canadian cities are significantly more affordable to establish and run clinical trials centers than their American and European key counterparts.
 - As well, KPMG's 'Competitive Alternatives 2014'⁴, an annual report that compares business costs and other competitiveness factors in more than 100 cities in ten major countries and over a 10-year horizon, puts Canada as 15.9 points ahead of the U.S. on business costs engaged by a representative operation modeled on a clinical trials management firm.
- Building on already competitive labour and facility costs, the Canadian government has established major grants that support companies who perform their research and development activities in Canada. These grants are administered through major government granting agencies such as the Canadian Institutes of Health Research (CIHR), Canadian Foundation for Innovation (CFI) and the National Research Council (NRC).
- The Canadian government has established tax credits which are awarded to companies that conduct research and development activities. The Scientific Research and Experimental Development (SRED) tax incentive program can amount to tax credits of 15% to 20%, and/or refund for a company's expenditures spent on eligible research and development work conducted in Canada⁵. Additionally, Canadian provinces also provide additional tax credits specific to research and development conducted in their territory. The overall tax savings of the SRED program is between 15% and 32% (includes federal and provincial tax credits) depending on the province.
- ¹ National Geographic website, http://travel.nationalgeographic.com/travel/countries/canada-facts/ (accessed 9 October 2014).
- ² BBC website. http://news.bbc.co.uk/2/hi/americas/country_profiles/1198865.stm (accessed 9 October 2014).
- ³ fDi Benchmark from the Financial Times Ltd 2014, http://www.fdibenchmark.com/)
- ⁴ KPMG Source: http://www.competitivealternatives.com/highlights/indsummary.aspx?id=886)
- ⁵ Canadian Revenue Agency website, http://www.cra-arc.gc.ca/txcrdt/sred-rsde/menu-eng.html (accessed 22 September 2014).



TAKE ADVANTAGE OF BUSINESS OPPORTUNITIES IN CANADA TODAY.

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