

Did you know...

The 12 Facts Before Christmas



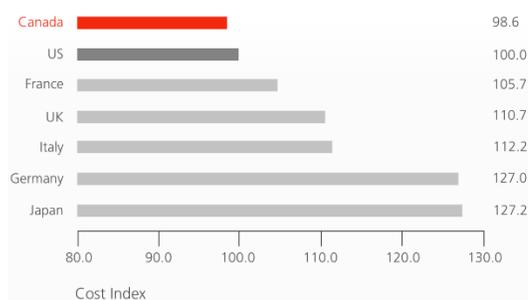
With the holidays right around the corner, it will soon be time to spend quality time with family and friends. If you have started (or will soon start) gift shopping, you will most probably start hearing Christmas carols that put us in the spirit. The *12 days of Christmas* is one of these famous carols and in line with this song, we thought we could provide you with 12 “Did you know” facts related to clinical research in Canada as our gift to you for the holidays. We could also have prepared a YouTube video with all Vantage BioTrials’ team singing this carol but...unfortunately for us, our true talent is only in clinical trial management, not singing. Happy holidays!

Fact 1: In North America 1/3 of all beds available for phase I clinical studies are located in the province of Quebec¹.

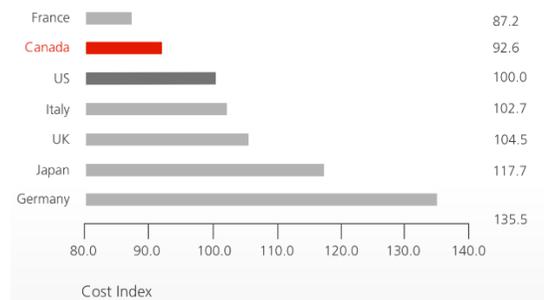
Fact 2: Canada has highly competitive cost advantages. It is ranked as having the lowest Biomedical R&D costs among the G7 nations and the second lowest clinical trial management costs².

Biomedical R&D Costs

G7 Results (US = 100.0)



Clinical Trials Management Costs



Images Source: Competitive Alternatives, KPMG LLP (Canada), 2014

¹ Biopolis Quebec

² KPMG LLP, 2014

- Fact 3:** Over the last 3 decades, Canada has developed an extensive and generous program of tax incentives for scientific research and development. The federal incentives have been generously strengthened by provincial R&D tax incentives. The tax credits significantly reduce the net cost of doing R&D in Canada and are designed to encourage innovation³.
- Fact 4:** The medical device sector is the second largest in Canada’s life sciences industry, accounting for 13.5% of total life science foreign direct investment⁴.
- Fact 5:** Canada is a world leader in biotechnology. Over the past twenty years, the Canadian economy has experienced a 77.2% growth in the number of biotechnology companies⁵.
- Fact 6:** The estimated average timeline for Clinical Trial Approval in Canada is short compared to other jurisdictions⁶:

Clinical Trial Application (or equivalent) Decision Timing by Jurisdiction

Source: Clinipace Worldwide, Webcast: *The Joys and Woes of Clinical Trial Start-Up: A Global Perspective*

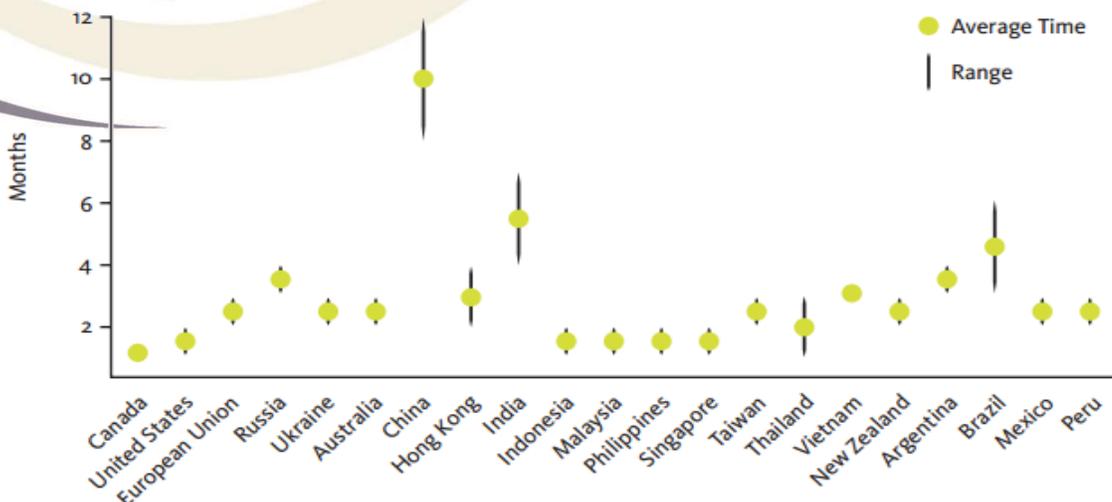


Image Source: Clinical Trials Ontario

In Canada, Phase I to Phase III studies must be submitted to Health Canada via a Clinical Trial Application (CTA) and the full review is completed within a 30-day default period. For bioequivalence studies, the review can be completed within 7 days. Unlike other jurisdictions where clinical trials are regulated at the state/territorial/provincial level, the review process is heterogenic in Canada. Health Canada has prepared [documents](#) to help sponsors understand the application process for initiating clinical trials in Canada.

³ Invest In Canada, 2013-2014

⁴ Invest in Canada, Medical Device, 2012

⁵ Government of Canada, sector information

⁶ Clinical Trials Ontario

Fact 7: Canada's competitiveness in clinical trials is supported by strong government support within the public research infrastructure including over \$750 million worth of investment by the Canadian Institutes of Health Research (CIHR) in health research funding. Canada's extensive network of academic health institutions and research centers which support clinical research includes 16 medical schools, over 45 academic health care organizations and approximately 13,600 researchers⁷.

Fact 8: Canada's ethnic diversity, coupled with defined and special populations, serves as an opportunity for clinical studies⁸.

Fact 9: Canada possesses world-class clinical research talent. Its researchers are Recognize for their expertise in designing and managing complex clinical trials. The Canadian Institutes of Health Research (CIHR) aims to train more clinician-investigators to design and direct international trials in order to further strengthen Canadian clinical research. CIHR has launched a "Randomized Controlled Trial Mentoring Program" and a "Strategy for Patient-Oriented Research" to mentor future leaders in clinical research. CIHR has also partnered with the Canada Foundation for Innovation to support clinical infrastructure, high quality research, research personnel, and training and research programs in clinical research. In addition, Canada's contract research industry has thrived through a strong base of local and international clients that are drawn to Canada's clinical research environment⁹. Canadian headquartered CROs have been making a name for themselves both at home and internationally. Examples include: Vantage BioTrials, NewLab Clinical Research, Genizon Biosciences, the Beaulieu-Saucier Pharmacogenomics Centre, CitOx LAB, and Phase I Clinical Research Units such as Biopharma Services, Algorithm Pharma and GCP Trials.

Fact 10: The Consolidated Standard of Reporting Trials (CONSORT), used by more than 400 healthcare journals internationally, was lead and initially developed by Dr. David Moher, an Ottawa-based epidemiologist, a world recognized scientific leader in the methodology of systematic reviews and the development of reporting guidelines for health research studies.^{10,11}

Fact 11: Strong collaborative research and clinical linkages have been built by the Canadian research community to facilitate and optimize clinical research in Canada. To name a few:

 Canada's Strength in Cancer Research, apart from the quality of its researchers, is also due to initiatives like the Canadian Cancer Clinical Trials Network (www.3ctn.ca), which aims to support researchers conducting clinical trials to provide patients with better access to clinical trial centers across the nation. There

⁷ Industry Canada

⁸ Canadian Institutes of Health Research, 2012

⁹ Industry Canada

¹⁰ CONSORT

¹¹ University of Ottawa

is also the support of specialized cancer centers like the Canadian Cancer Society Research Institute (representing 90 institutions across Canada participating in cancer trials), the BC Cancer Research Centre and the Ontario Institute for Cancer Research.

 Canada's Networks of Centers of Excellence (NCE) program (www.nce.gc.ca) promotes partnerships between universities, government and industry in specific therapeutic areas like arthritis, genetic diseases, obesity, allergy and stem cells. These networks are powerful tools in advancing clinical research in specific therapeutic areas. For example, the Canadian Arthritis Network was instrumental in establishing the Canadian Rheumatology Consortium (www.rheumtrials.ca) to conduct clinical trials in new therapies for rheumatoid arthritis.

 Networks of Networks (N2) (www.n2canada.ca) is a national Canadian initiative bringing together over 16 existing disease networks representing more than 200 clinical research sites and other stakeholders including academic institutions and the Canadian Institutes of Health Research. N2 and its members provide tools, resources and best practices, including an updated set of Standard Operating Procedures to promote quality and consistency in the conduct of clinical trials for research networks.

Fact 12: Eleven (11) blockbuster drugs have been discovered in Québec over the last 100 years such as Premarin, Singulair, Fluvarix and Egrifta¹².



About the Author:

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With over 14 years of pharmaceutical, generic and clinical research experience, Reginald is a professional with an excellent overview of both the management and scientific aspect of drug and clinical development.

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¹² Biopolis Quebec

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12. Biopolis Quebec, <http://www.quebeclifesciences.com/biopolisQuebec/contentQuebec.asp?p=dyk>

About Vantage BioTrials Inc.

Vantage BioTrials Inc. is a privately owned Clinical Trial Management Organization (CTMO) based in Montréal, Canada, that provides superior trial management services and combines a precise blend of clinical development knowledge, talent and resources that will ensure a clinical study's full potential. By servicing our global Pharmaceutical, Biotech, Medical Device and Generic clients who perform Phase I, II-IV clinical trials, our goal is to exceed their expectations by offering outstanding monitoring, project management and clinical operation services.

To learn more about Vantage BioTrials, please visit us at www.vantagebiotrials.com.