



Getting Started: Conducting Clinical Trials in Ontario

Ontario offers compelling advantages as a location for conducting clinical trials. From world-class leadership in research to globally recognized excellence in health care stewardship, Ontario's clinical research community makes the province an attractive destination for global clinical trials.

This *Introductory Guide* serves as a reference document for companies new to initiating and conducting clinical trials in Ontario. It highlights important resources that can help sponsors and investigators to understand the clinical trials environment. It covers several key topics:

Regulatory Approval

Access to Funds

Tax Incentives

Regional Economic Development

Accessing Key Assets

Additional Sources of Information in Ontario & Canada

**CLINICAL
TRIALS
ONTARIO**

ABOUT CLINICAL TRIALS ONTARIO

Clinical Trials Ontario is an independent not-for-profit organization established by the Government of Ontario. Our mandate is to provide a streamlined approach to conducting multi-centre clinical trials in Ontario, while maintaining the highest ethical standards for participant protection.

REGULATORY APPROVAL

In Canada, all regulatory and enforcement activities—and most policy activities—pertaining to health products are carried out by the Health Products and Food Branch (HPFB) of Health Canada. The type of health product determines which Directorate or Bureau within the HPFB will review and authorize the product's sale or import in Canada:

Therapeutic Products Directorate (TPD)

<http://bit.ly/therapeutic-products-directorate>

The HPFB Directorate that regulates pharmaceutical drugs and medical devices for human use.

Medical Devices Bureau

<http://bit.ly/medical-devices-bureau>

The office within the TPD that regulates medical devices.

Biologics and Genetic Therapies Directorate

<http://bit.ly/biologics-and-genetic-therapies-directorate>

The HPFB Directorate that regulates biological drugs and radiopharmaceuticals for human use in Canada.

Natural Health Products Directorate

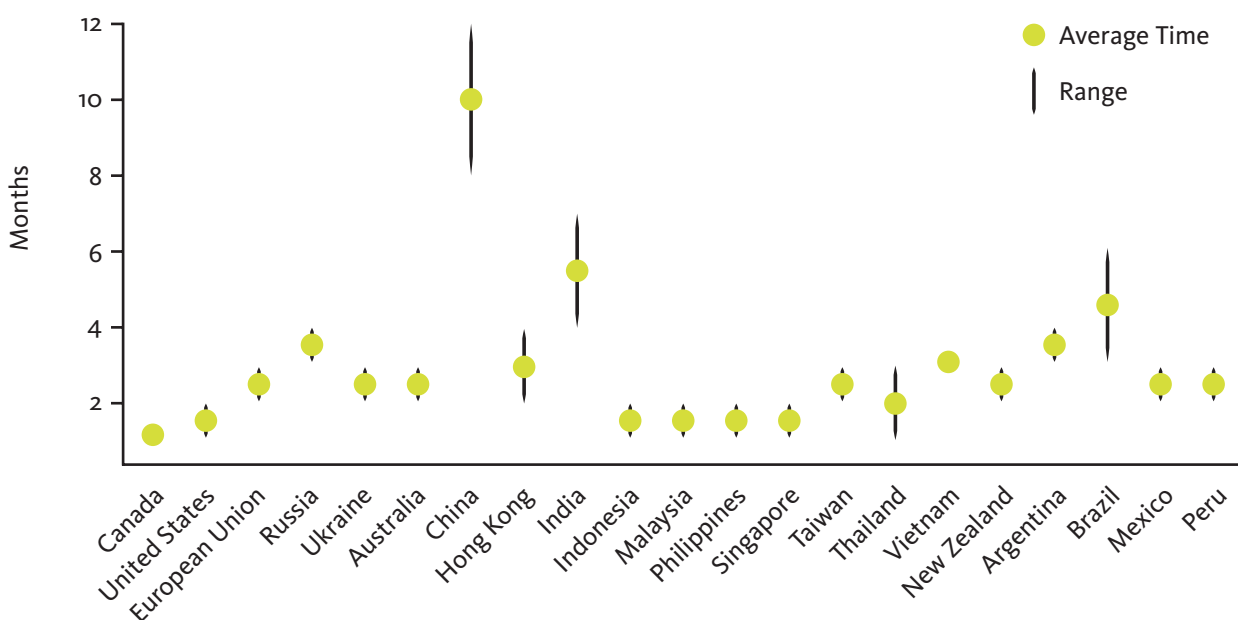
<http://bit.ly/natural-health-products-directorate>

The HPFB Directorate that regulates natural health products for sale in Canada.

Health Canada normally takes 30 days to review clinical trials applications for Phase I to Phase III protocols, and 7 days to review applications for Phase I bioequivalence trials.

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*



Health Canada has produced documents to help sponsors navigate the regulatory framework and to understand the application process for initiating clinical trials in Canada:

Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications (CTAs)

<http://bit.ly/health-canada-guidance-for-ct-sponsors-cta>

Provides guidance to all sponsors (e.g. industry, academic, contract research organization) seeking authorization to sell or import a drug for the purpose of a clinical trial in Canada.

Safe Medical Devices in Canada Fact Sheet

<http://bit.ly/safe-medical-devices-in-canada>

Offers information on how medical devices are approved and authorized in Canada.

Biologics, Radiopharmaceuticals, and Genetic Therapies Fact Sheets

<http://bit.ly/biologics-radiopharmaceuticals-genetic-therapies-fact-sheets>

Offers guidance for organizations looking to conduct a clinical trial for a health product in biologics, radiopharmaceuticals, and genetic therapies.

Guidance Document for Clinical Trials For Natural Health Products

<http://bit.ly/guidance-for-clinical-trials-for-natural-health-products>

Assists organizations in applying for authorization to conduct a clinical trial for a natural health product in Canada.

Health Canada invites sponsors to request a pre-CTA consultation meeting. These meetings are particularly useful for applications that may include new or complex issues that require further guidance from Health Canada.

ACCESS TO FUNDS

Ontario and Canada offer a number of financing opportunities for research and development activities:

Ontario Capital Growth Corporation

<http://bit.ly/ontario-capital-growth>

Ontario Network of Entrepreneurs

<http://bit.ly/ontario-network-entrepreneurs>

Investment Accelerator Fund

<http://bit.ly/investment-accelerator-fund>

The Funding Portal

<http://thefundingportal.com>

Southwestern Ontario Development Fund

<http://bit.ly/sw-ontario-development-fund>

Eastern Ontario Development Fund

<http://bit.ly/e-ontario-development-fund>

TAX INCENTIVES

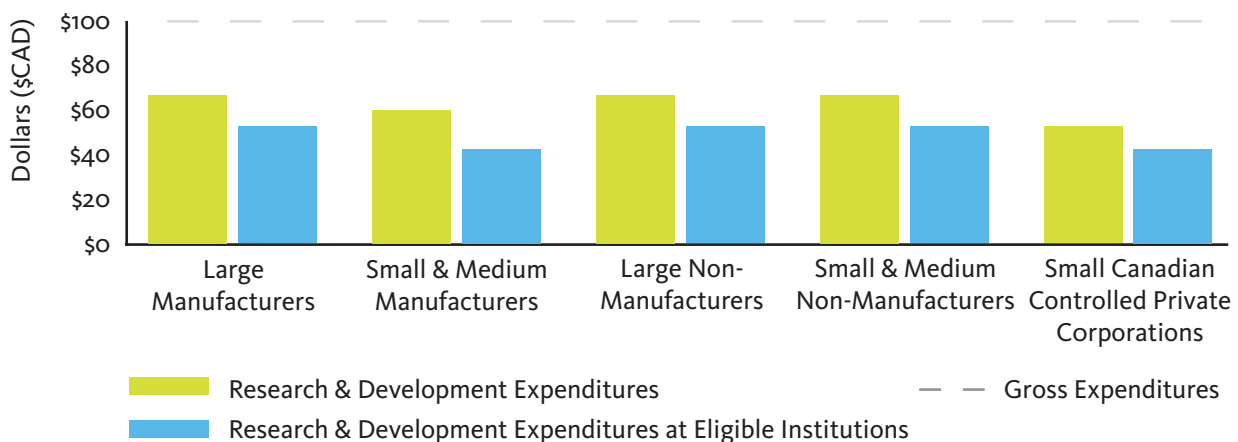
A variety of tax incentives offered in Ontario help businesses reduce costs and remain competitive:

Federal Investment Tax Credit for R&D: Scientific Research &
Experimental Development Incentive Program (SRED)
Ontario Business Research Institute Tax Credit (OBRI)
Ontario Research and Development Tax Credit (ORDTC)
Ontario Innovation Tax Credit (OITC)

<http://bit.ly/sred-canada>
<http://bit.ly/obritc>
<http://bit.ly/ordtc>
<http://bit.ly/oitc-ontario>

After-tax Costs of Research & Development Spending in Ontario

Source: Invest in Ontario, *Ontario's R&D Tax Program*



REGIONAL ECONOMIC DEVELOPMENT

Connect with professionals involved in regional economic development to understand how to operate and grow your business in Ontario:

Invest in Ontario

<http://bit.ly/invest-in-ontario>

Open for Business

<http://bit.ly/open-for-business-medical-technology>

Invest Toronto

<http://bit.ly/invest-toronto>

Doing Business in Toronto

<http://bit.ly/doing-business-toronto>

Mississauga Win The Human Race

<http://bit.ly/win-the-human-race-life-sciences>

London Life Sciences

<http://bit.ly/london-life-sciences>

Hamilton Life Sciences

<http://bit.ly/hamilton-life-sciences>

Kingston R&D

<http://bit.ly/kingston-r-and-d>

Windsor-Essex

<http://bit.ly/windsor-essex-health-life-sciences>

Kitchener-Waterloo

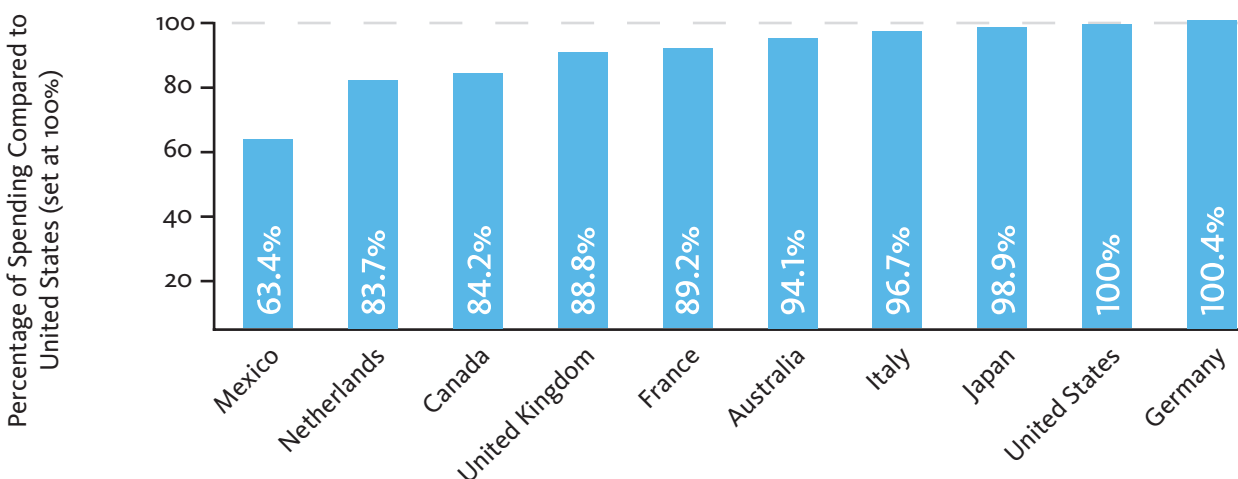
<http://bit.ly/kw-life-sciences>

Ottawa

<http://bit.ly/ottawa-life-sciences>

Research & Development Cost Advantages by Jurisdiction (2014)

Source: KPMG, *Competitive Alternatives: KPMG's Guide to International Business Location Costs*, 2014 Edition



ACCESSING KEY ASSETS

The following directories, registries, and databases can help locate appropriate assets to help with your clinical trials:

Contact Canada

<http://contactcanada.com>

A directory that collects and publishes up-to-date company profiles in various industries.

ClinicalTrials.gov

<http://clinicaltrials.gov>

A registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Canadian Cancer Trials

<http://canadiancancertrials.ca>

Search for a clinical trial by cancer type, province, drug, keyword or phrase.

Ontario Life Sciences Asset Map

<http://bit.ly/ontario-life-sciences-asset-map>

An interactive directory and information platform for life sciences organizations from across Ontario.

Canadian Medtech Asset Map (HTX)

<http://bit.ly/canadian-medtech-asset-map>

A database of registered Canadian medical technology organizations.

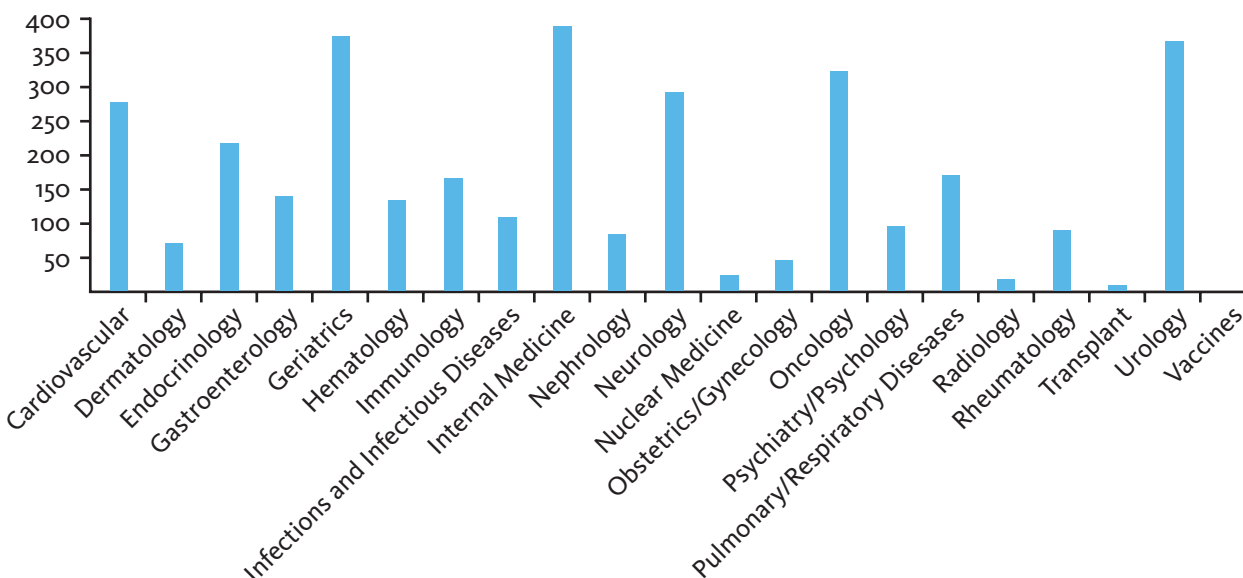
Medtech RISE (HTX)

<http://bit.ly/medtech-rise>

A registry of innovators, suppliers, and exporters of medical technology companies in Canada, along with other industry statistics.

Number of Principal Investigators in Canada by Therapy Area

Source: DrugDev.org



ADDITIONAL SOURCES OF INFORMATION IN ONTARIO & CANADA

If the resources in this *Introductory Guide* have not answered your questions, several organizations can help:

BIOTECCanada

<http://biotech.ca>

BIOTECCanada is the national industry association with nearly 250 members located nationwide, reflecting the diverse nature of Canada's health, industrial and agricultural biotechnology sectors.

Canadian Association for Independent Clinical Research (CAICR)

<http://caicr-acrci.net>

CAICR is a non-profit association that promotes the development of independent clinical research in Canada.

Health Technology Exchange (HTX)

<http://htx.ca>

HTX supports and accelerates the growth of the medical and assistive technology sector in Ontario, and nationally. Funding is available for approved programs.

Life Sciences Ontario (LSO)

<http://lifesciencesontario.ca>

LSO is a member-driven organization that represents and promotes Ontario's vibrant and diverse life sciences sector.

MaRS EXCITE

<http://bit.ly/mars-excite>

MaRS EXCITE is a collaborative initiative between a range of stakeholders in Ontario's health care system that work together to help innovative health technologies get to market faster and improve patient outcomes.

MEDEC

<http://medec.org>

MEDEC is the national association created by and for the Canadian medical technology industry.

Network of Networks (N2)

<http://n2canada.ca>

N2 is a not-for-profit incorporated organization and an alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity.

Ontario Bioscience Innovation Organization (OBIO)

<http://obio.ca>

OBIO is a not-for-profit, membership-based organization engaged in the development of an integrated health innovation economy for Ontario and one that will become a global leader in providing health technology products and services to the international marketplace.

Ontario Brain Institute (OBI)

<http://braininstitute.ca>

OBI is a provincially-funded, not-for-profit research centre seeking to maximize the impact of neuroscience and establish Ontario as a world leader in brain discovery, commercialization and care.

Ontario Institute for Cancer Research (OICR)

<http://oicr.on.ca>

OICR is an innovative cancer research and development institute dedicated to prevention, early detection, diagnosis and treatment of cancer.

Ontario Network of Entrepreneurs (ONE)

<http://bit.ly/ontario-network-entrepreneurs>

The ONE is a collaborative network of organizations across Ontario, designed to help entrepreneurs, businesses and researchers commercialize their ideas by providing a comprehensive suite of programs and services across the full commercialization continuum from idea to market.

Rx&D

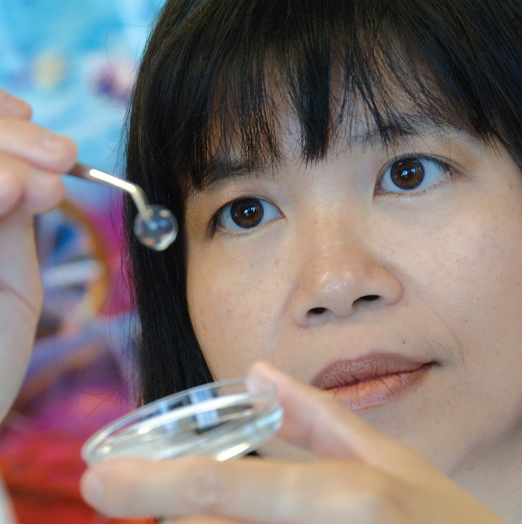
<http://canadapharma.org>

Canada's Research-Based Pharmaceutical Companies (Rx&D) is the national association representing the men and women who work for 50 research-based pharmaceutical companies in Canada.

The HUB – Health Research Solutions

<http://hubresearch.ca>

The HUB is a unified clinical research methods and services group at the Li Ka Shing Knowledge Institute of St. Michael's Hospital in Toronto.



Making Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

To stay up to date with the latest conversations, follow us on Twitter and LinkedIn, or visit our website at <http://ctontario.ca>



@clinicaltrialON



<http://www.linkedin.com/company/clinical-trials-ontario>

This *Introductory Guide* is not a comprehensive listing of all resources available in Ontario and is intended to be a living reference document. For more information please contact info@ctontario.ca.

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