

Industry Resource Guide

Conducting
Clinical Trials
in Ontario





This Resource Guide acts as a reference document for companies new to initiating and conducting clinical trials in Ontario. You will find important resources that can help companies understand the clinical trials environment and leverage the many financial incentives and clinical trial assets available in Ontario.

Clinical Trials Ontario offers a Concierge Service that can walk you through these and other resources, including identifying key resources and investigator contacts.

CTO's Industry Concierge

The Industry Concierge service is for any person or company looking to connect into Ontario's clinical research ecosystem to conduct a clinical or observational research study. Whether you are a large multinational pharmaceutical company or a local start-up, we can help connect you to the relevant people or resources to get your trial off the ground. Once CTO knows about your needs and your technology, we can create a plan for next steps, whether that's performing a feasibility analysis, adding sites to your clinical trial, finding a key opinion or business partner in Ontario, or connecting you to resources and funding opportunities to start your trial.

Trial Site Network

The Trial Site Network enables industry to connect directly with Ontario's research ecosystem. The Network is comprised of highly engaged clinical research personnel representing sites from across Ontario. Through the Trial Site Network, CTO can provide any company or start-up looking to conduct a clinical or observational study in Ontario with a warm introduction to clinical trial representatives from trial sites participating in the Network that align with the study's objectives. Participating sites can use the Network to expand their clinical trials activities.

Please contact info@ctontario.ca for more information.



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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 HPFB's mandate is to manage health-related risks and benefits of health products and food offered in Canada.



**Health Canada
Governance**



**Pharmaceutical, Biologics,
Genetics and Natural Health
Products**



**Medical
Devices**

Health Canada Governance

Pharmaceutical Drugs Directorate (PDD)

The PDD is the HPFB Directorate that regulates pharmaceutical drugs and medical devices for human use. It contains 9 offices and bureaus and is responsible for assessing the benefits and risks of prescription drugs and medical devices. The PDD also reviews Clinical Trial Applications for prescription drugs and some natural health products and monitors their safety while they are being used in clinical trials.



Health Canada Guidance Documents

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 documents are meant to provide assistance to industry and health care professionals on how to comply with the governing statutes and regulations. Health Canada invites sponsors to request a pre-CTA/ pre-ITA consultation meeting. These meetings are particularly useful for applications that may include new or complex issues that require further guidance from Health Canada.

Pharmaceutical, Biologics, Genetics & Natural Health Products

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

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Biologic and Radiopharmaceutical Drugs Directorate

Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD) regulates biological drugs (products made from living sources, including vaccines), radiopharmaceuticals (drugs that have radioactivity), and cells, tissues and organs for human use in Canada.

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Natural and Non-Prescription Health Products Directorate

This HPFB Directorate regulates and authorizes natural health products and non-prescription drugs for sale in Canada.

Pharmaceutical, Biologics, Genetics & Natural Health Products: Clinical Trials Applications

This section outlines the requirements for a Clinical Trial Application (CTA) involving the use of pharmaceutical, biological, and radiopharmaceutical drugs.

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Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications

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.

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Guidance Document 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.

Medical Devices

This section outlines the requirements for clinical trials involving pre-market medical devices in Canada.

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**Medical Devices
Directorate**

The office within the TPD that regulates medical devices including applications for Investigational Testing Authorizations (ITA's). An ITA is required when a non-approved medical device is being used in a clinical trial in Canada.

Medical Device: Investigational Testing Applications

This section outlines the requirements for clinical trials involving a non-approved medical device in Canada.

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**Guidance Document:
Applications for
Medical Device
Investigational Testing
Authorizations**

Provides assistance to manufacturers and importers in organizing and submitting an investigational testing application (ITA) to perform a clinical trial in Canada with a pre-approved medical device Class II, III and IV (Non-IVDD).

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**Preparation of an
Application for
Investigational Testing
- In Vitro Diagnostic
Devices (IVDD)**

This guidance document is to assist manufacturers and/or device sponsors in their preparation of the necessary documentation that is required to obtain an authorization for the sale of an in vitro diagnostic device for investigational testing, under the Medical Devices Regulations.

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**Guidance Document:
Software as a Medical
Device (SaMD)**

This document is intended to clarify how SaMD fits into Health Canada's regulatory framework for medical devices, based on current interpretation of the definitions of "device" and "medical device" in the Act and Regulations.

Research and Development Support

Here you will find resources on government grants, loans, tax credits and support services for Ontario businesses, grants to cover hiring and training, and regional specific funding.

Tax Incentives

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

ONTARIO BUSINESS AND RESEARCH INSTITUTE TAX CREDIT

Eligible corporations can claim a 20% refundable tax credit for qualified expenditures on scientific research and experimental development work performed in Ontario under contract with eligible research institutes.

ONTARIO INNOVATION TAX CREDIT

Qualifying corporations can claim a refundable tax credit for qualified expenditures on scientific research and experimental development performed in Ontario.

ONTARIO RESEARCH AND DEVELOPMENT TAX CREDIT

Qualifying corporations can claim a non-refundable tax credit on eligible scientific research and experimental development expenditures performed in Ontario to reduce their Ontario corporate income tax payable.

ONTARIO TAX EXEMPTION FOR COMMERCIALIZATION

If you are a newly established corporation in certain sectors, you could be eligible for a refund of the corporate income tax and corporate minimum tax your business paid in its first 10 taxation years.

SCIENTIFIC RESEARCH AND EXPERIMENTAL DEVELOPMENT (SR&ED)

Information about the Scientific Research and Experimental Development (SR&ED) Program, including what you need to know to claim SR&ED tax incentives.

Research and Development Support

Funding Organizations

There are a number of organizations that have funding opportunities available for research within the specific therapeutic areas. Here are some key organizations that may be helpful. Please check their website for more information on specific calls for proposals.

	ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
<p>AGE-WELL AGE-WELL is Canada's technology and aging network. AGE-WELL is dedicated to the creation of technologies and services that benefit older adults and caregivers.</p>	✓		✓	
<p>BioCanRX BioCanRx is a network of scientists, clinicians, cancer stakeholders, academic institutions, NGOs and industry partners working together to accelerate the development of leading edge immune oncology therapies for the benefit of patients.</p>	✓	✓		
<p>Centre for Aging and Brain Health Innovation (CABHI) The Centre for Aging & Brain Health Innovation is a unique collaboration of health care, science, industry, not-for-profit and government partners whose aim is to help improve quality of life for the world's aging population, allowing older adults to age safely in the setting of their choice while maintaining their cognitive, emotional, and physical well-being.</p>	✓		✓	
<p>Canadian Institutes of Health Research As the Government of Canada's health research investment agency, the Canadian Institutes of Health Research (CIHR) supports excellence across all four pillars of health research: biomedical; clinical; health systems services; and population health.</p>	✓			
<p>Fight Against Cancer Innovation Trust (FACIT) Fight Against Cancer Innovation Trust (FACIT) is the gateway to the cancer research pipeline in Ontario. As a bridge between the public and private sectors, they apply an entrepreneurial approach, along with strong business expertise and industry connections, to continuously identify and advance breakthroughs in science and technology.</p>	✓	✓	✓	
<p>GlycoNet The vision of GlycoNet is to deliver solutions to important health issues and improve quality of life of Canadians through glycomics.</p>	✓			
<p>Canada Health Infoway Infoway helps to improve the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health solutions across Canada. Through our investments, we help deliver better quality and access to care and more efficient delivery of health services for patients and clinicians.</p>			✓	✓

Academic: Organizations who support university research and academic/industry collaborations.
Biotech: Organizations who support the development of pharmaceutical, immuno-oncology, biologics, and regenerative medicine R & D.
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Health Care: Organizations who support improving efficiencies in the delivery of healthcare, procurement, and logistics.

Research and Development Support

Funding Organizations

	ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
<p>MaRS Investment Accelerator Fund Investment arm of MaRS Discovery District. IAF is the leading seed stage investor in Ontario, investing in IT, health and cleantech companies and acts as a catalyst for attracting the follow-on funding and talent that companies need to grow and thrive.</p>		✓	✓	
<p>Mitacs Mitacs is a national, not-for-profit organization that has designed and delivered research and training programs in Canada for 18 years. Working with 60 universities, thousands of companies, and both federal and provincial governments, we build partnerships that support industrial and social innovation in Canada.</p>		✓	✓	
<p>National Research Council The National Research Council (NRC) is the Government of Canada's premier research and technology organization (RTO). Working with clients and partners, we provide innovation support, strategic research, and scientific and technical services.</p>		✓	✓	
<p>NSERC NSERC aims to make Canada a country of discoverers and innovators for the benefit of all Canadians. The agency supports university students in advanced studies, promotes and supports discovery research, and fosters innovation by encouraging Canadian companies to participate and invest in postsecondary research. NSERC researchers are on the vanguard of science, building on Canada's long tradition of scientific excellence.</p>				
<p>The Ontario Brain Institute The Ontario Brain Institute 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 research, commercialization and care. Convergent partnerships are created between researchers, clinicians, industry, patients, and their advocates to foster discovery and deliver innovative products and services that improve the lives of those living with brain disorders.</p>	✓			
<p>Ontario Centre of Innovation OCI's mandate is to develop and deliver programs that accelerate the development, commercialization, and adoption of advanced technologies to drive job creation.</p>	✓	✓	✓	
<p>Office of the Chief Health Innovation Strategist The Office of the Chief Health Innovation Strategist (OCHIS) is a catalyst to help accelerate health technology commercialization efforts in Ontario. OCHIS works on behalf of health technology innovators to remove barriers and improve access to Ontario's health care system. Our goal is to grow businesses and build a health innovation ecosystem in Ontario.</p>			✓	✓

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Research and Development Support

Funding Organizations

	ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
<p>Ontario Institute for Cancer Research (OICR) The OICR is a collaborative, not-for-profit research institute focused on accelerating the translation of new cancer research discoveries to patients around the world while maximizing the economic benefit of this research for the people of Ontario.</p>	✓	✓		
<p>Ontario Institute for Regenerative Medicine The Ontario Institute for Regenerative Medicine merged from a partnership between OSCI and CCRM. The vision of OIRM is to revolutionize the treatment of degenerative diseases, making Ontario a global leader in the development of stem cell-based products and therapies.</p>	✓	✓		
<p>Venture Ontario Venture Ontario is the venture capital agency of the Government of Ontario. Venture Ontario was created to promote and develop the venture capital sector in Ontario, so that more innovative, high potential funds and companies have access to the capital needed to grow and prosper. The principal business of the Venture Ontario is to invest in venture capital funds and manage the venture capital investment portfolio on behalf of the Government of Ontario.</p>			✓	✓
<p>Ontario Genomics Ontario Genomics is a not-for-profit intermediary organization funded by the Ontario government and the federal research funding agency Genome Canada. The only entity focused solely on stimulating, enabling and nurturing genomics innovation in the province of Ontario, we act as a catalyst for developing and applying genomic technologies across seven key sectors – agriculture, bioproducts, energy, forestry, health, mining, and water.</p>	✓		✓	
<p>Weston Family Foundation The Weston Family Foundation invests in innovation and learning to deliver measurable impacts to the well-being of Canadians. We take a collaborative approach to philanthropy, working alongside forward-thinking partners to advance Canada and create lasting benefits. One of their goals is to catalyze and scale science-based approaches to significantly improve the health and well-being of Canadians as they age.</p>	✓	✓		
<p>The Biomedical Zone The Biomedical Zone was founded in 2015, with the goal of fostering and growing early-stage health technology companies. Two years prior, the Toronto Metropolitan University and St. Michael’s Hospital founded the Institute for Biomedical Engineering, Science and Technology, a 20-year partnership for conducting biomedical research to advance healthcare.</p>			✓	✓

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Research and Development Support

Incubators and Accelerators

Below find a list of organizations who can support your startup and build a company around your innovation. They provide mentorship and advisory services around topics such as investment, market access, regulatory, and business strategy.

ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
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MaRS Discovery District

MaRS Discovery District experienced advisors support you at every stage of your company's development, providing in-depth advice in a range of areas, including: intellectual property protection; medical product discovery, design and development; regulatory affairs; clinical trials design /conduct; partnering and business development; and marketing and sales.



Ontario Bioscience Innovation Organization

The Ontario Bioscience Innovation Organization (OBIO®) founded in 2009, is a not-for profit, membership-based organization engaged in strategy, programming, policy development and advocacy to further the commercialization of Ontario's human health technologies positioning Ontario as a leader in the international marketplace. OBIO advances this goal through collaborative partnerships.



ONE Network

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.



Techna

Techna offers a full range of productization services to advance your research from discovery to application and commercialization. We leverage the resources of Canada's largest research hospital and a team of highly trained professionals including engineers, project managers, operations specialists, physicists, human factors specialists, and developers to help mature, validate, and accelerate the implementation of medical technologies.



VentureLAB

VentureLAB is where talented entrepreneurs get help bringing their innovations to market. We apply a unique combination of mentoring, partnering, and connecting to help pioneering entrepreneurs turn their great ideas into globally competitive businesses with successful start-up business training.



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



CANADIAN CANCER TRIALS

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



THE CANADIAN CLINICAL TRIALS ASSET MAP

A database of registered Canadian medical technology organizations.



CLINICALTRIALS.GOV

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



CONTACT CANADA

Collects and publishes up-to-date company profiles in various industries.



THE FUNDING PORTAL

Canada's bilingual one-window gateway to improve access to 7,000+ sources of government funding and private financing for business, hospitals, universities, and research.



INVEST ONTARIO

Provides a searchable map of a variety of life science companies across Ontario including consultants, CROs, biotechs, pharmas, and medical device companies bought to you by the province of Ontario.



ONTARIO LIFE SCIENCES ASSET MAP

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



TORONTO'S CLUSTER CONNECT

Toronto's Health Science Cluster portal.

Member Organizations

Canada has a number of member organizations that may be helpful to explore. They may serve as a helpful support service to your organization or as a reference point to an important audience.

ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
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BIOTECCanada

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



Canadian Society for Clinical Investigation

CSCI promotes clinical and basic research in the field of human health throughout Canada, lobbies for adequate research funding at the federal, regional and local levels, and supports Canadian researchers in their endeavours and at all stages of their careers.



OHA

The Ontario Hospital Association (OHA) is the voice of Ontario's hospitals and a key partner in the health system.



Digital Health Canada

Members are dedicated to realizing their full potential as professionals and advancing Health Informatics through access to information, talent, credentials, recognition, programs, and a broad range of services and specialized resources.



Innovative Medicines Canada

Innovative Medicines Canada represents Canada's innovative pharmaceutical industry. We help our members discover, develop, and deliver innovative medicines and vaccines. Our membership consists of more than 45 companies, from established organizations to fledgling startups, all of whom are revolutionizing healthcare through the discovery and development of new medicines and vaccines.



Life Sciences Ontario (LSO)

Life Sciences Ontario (LSO) is a member-driven organization that represents and promotes the province's vibrant and diverse life sciences sector. LSO collaborates with governments, academia, industry and other life science organizations in Ontario and across Canada to promote and encourage commercial success throughout this diverse sector.



MedTech Canada

Medtech Canada is the national association leading the effort to develop and advance Canada's innovative medical technology industry, representing approximately 120 medtech companies (ranging from Canadian-owned to multinationals).



N2 Canada

Network of Networks (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.



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Service and Support

The following are examples of organizations that provide services to help advance your technology to the next level.

	ACADEMIC	BIOTECH	MEDICAL DEVICES	HEALTH CARE
<p>Centre for the Commercialization of Regenerative Medicine (CCRM) Center for the Commercialization of regenerative Medicine's mission is to generate sustainable health and economic benefits through global collaboration in cell and gene therapy, and regenerative medicine.</p>	✓	✓		
<p>CIMTEC CIMTEC exists to facilitate the commercialization of important and world-leading medical imaging technology, so that Canadians can reap the health and economic benefits of these innovations.</p>			✓	✓
<p>Clinical Trials Ontario (CTO) Clinical Trials Ontario is a leading organization in the clinical trials community dedicated to strengthening, promoting and capitalizing on Ontario's competitive advantages for conducting high-quality clinical trials.</p>	✓	✓	✓	✓
<p>The HUB – Health Research Solutions The HUB integrates health economics expertise from the Centre for excellence in Economic Analysis Research (CLEAR), clinical research methods and operations infrastructure of the Applied Health Research Centre (AHRC) and knowledge translation expertise from BreakThrough Knowledge Translation (KT) Services.</p>	✓	✓	✓	✓
<p>MaRS Excite The MaRS Excellence in Clinical Innovation Technology Evaluation (EXCITE) program is a part of the MaRS Health portfolio. We work to break down the barriers between the health system and technology innovators to effect health system change.</p>			✓	
<p>Structural Genomics Consortium Led from Toronto, the SGC is a pre-competitive public-private partnership in the areas of structural and chemical biology, and drug discovery. Their mission is to understand the function(s) of all proteins encoded by the human genome and accelerate the discovery of new medicines.</p>	✓	✓		
<p>STARR The STARR Innovation Centre brings together products, services, and technologies to accelerate cutting-edge and multidisciplinary research in oncology, cardiology, metabolic diseases, and many other fields. STARR offers the services and facilities needed for translational drug development and preclinical research.</p>			✓	✓
<p>Toronto Global Toronto Global forges meaningful connections between business, government, industry and academia, fostering a network that amplifies your business potential and propels you to new heights.</p>		✓	✓	
<p>Women's College Hospital Institute for Health System Solutions and Virtual Care (WHV) Working with stakeholders inside the health system and innovators from other sectors, WHV identifies and evaluates ground-breaking approaches that address gaps in our healthcare system. Our work supports solutions that make care more convenient, more effective, and less costly to deliver.</p>			✓	✓



About CTO

Clinical Trials Ontario is a leading organization in the clinical trials community dedicated to strengthening, promoting and capitalizing on Ontario's competitive advantages for conducting high-quality clinical trials. We work collaboratively with industry, research institutes, patients and the public and other health innovation organizations to improve the clinical trials environment and attract investment to the province, while supporting the highest ethical and quality standards.

Contact

MaRS Centre, West Tower
661 University Avenue, Suite 460
Toronto, Ontario M5G 1M1
Canada

416-673-6684

info@ctontario.ca



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