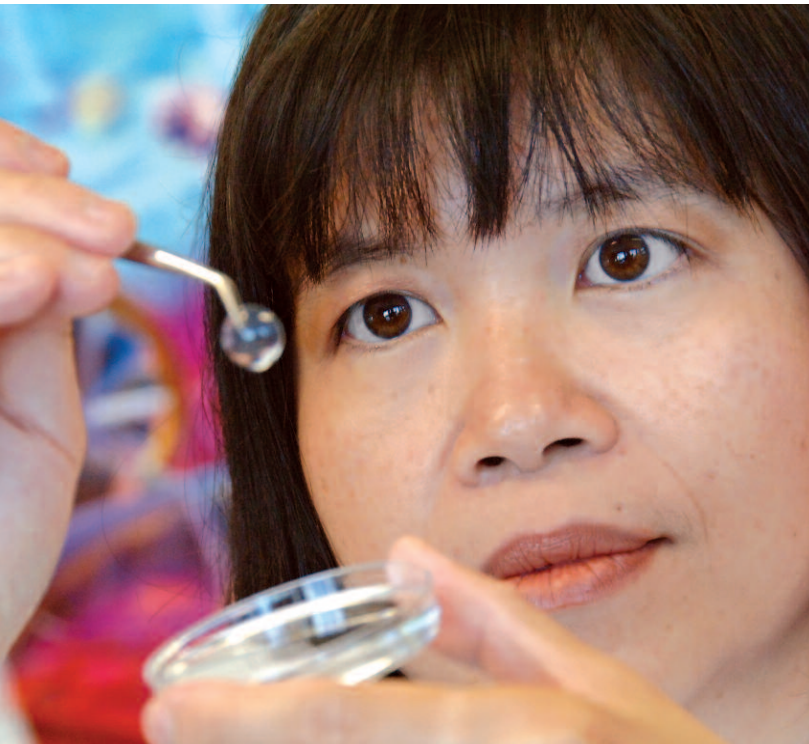


CLINICAL
TRIALS
ONTARIO

This is the place for
GLOBAL CLINICAL TRIALS



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

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.

THE VISION OF CLINICAL TRIALS ONTARIO (CTO) IS BEING ADVANCED UPON THREE STRATEGIC PILLARS:

1

Improving speed and reducing costs of multi-centre clinical trials by streamlining the research ethics approval process and harmonizing other administrative processes and platforms.



2

Attracting clinical trial investments to Ontario based on CTO's success in streamlining activities and by leveraging strategic partnerships with investigators, industry and government to access global decision makers.



3

Improving participant recruitment and retention through education, and by engaging participants and the public in recognizing the benefits of clinical trials.



CLINICAL TRIALS: THE ONTARIO ADVANTAGE

The pace of medical discovery is accelerating, increasing the pressure on life sciences researchers to complete clinical trials quickly, efficiently and with the high-quality data that regulators demand, while maintaining the highest ethical standards for participant protection.

In Ontario, life sciences leaders break new ground every day. Clinical trials help health care leaders to bring life-saving solutions to global markets. These solutions provide positive patient outcomes, affordable medicines, shorter hospital stays and high-quality jobs.

Our trials put participant safety first and address every aspect of patient care. We deliver treatment, diagnostic, prevention and quality-of-life trials. Research areas of excellence for Phase I to Phase IV clinical trials in Ontario include:

- oncology – all types
- heart and blood diseases – e.g. coronary artery disease, arrhythmias, stroke
- rheumatology – e.g. arthritis
- infectious diseases – e.g. HIV/AIDS, hepatitis
- digestive system diseases – e.g. Inflammatory Bowel Disease
- nervous system diseases – e.g. Alzheimer's, Parkinson's, autism, epilepsy
- mental health – e.g. depression, addiction
- ophthalmology



ONTARIO – A HISTORY OF INNOVATION

For close to a century, our researchers have been at the forefront of major breakthroughs in nearly every area of medicine. Ontario is where insulin was discovered. It is where the pacemaker was developed. It is where the first successful lung transplant was performed. It is also where a system for automatic and inexpensive DNA sequencing was developed. It is where L-DOPA for the treatment of Parkinson's disease originated. It is no accident that so many life-changing discoveries have taken place here.

TOP 5 REASONS FOR CHOOSING ONTARIO AND CANADA FOR CONDUCTING GLOBAL CLINICAL TRIALS

World-class excellence in research and clinical trial experience, from bench to bedside

Ontario is renowned for outstanding clinical research in virtually every area of health care. Our researchers excel at designing and managing complex clinical trials. A unique collaborative research environment contributes to Ontario's tremendous success in biomedical discovery. Major international medical authorities recognize the validity of data from clinical trials conducted in Ontario.

Vibrant collaborations and networks, both nationally and internationally

Ontario has well-established clinical trials networks, contract research organizations and a thriving independent clinical research community, all highly experienced in managing trials across Canada and worldwide. We share North American practices in terms of medicine, regulatory frameworks, culture and language. This makes for successful partnerships with U.S. firms. At the same time, our cultural, scientific and trade ties with Europe and Asia provide a solid foundation for multi-centre international research collaborations.

Strong commitment to improving clinical trial infrastructure both regionally and nationally

Ontario and Canada are constantly working to improve funding support and service delivery. A number of financing opportunities exist for research and development activities. Tax incentives in Ontario help businesses reduce costs and stay competitive. We have a highly-efficient regulatory environment overseen by Health Canada. It takes just 30 days to review clinical trial applications for Phase I to Phase III protocols, and 7 days to review applications for Phase I bioequivalence trials. The Government of Ontario has established Clinical Trials Ontario to streamline the research ethics review process for multi-centre clinical trials.

Access to Canada's public health care system and a diverse population

Ontario has a centrally managed public health care system. This makes it easy to access a population of more than 13 million that is demographically and ethnically diverse, a critical advantage that can accelerate the understanding of treatment effects in different population subgroups.

Globally recognized excellence in health care stewardship

Health policy decisions are increasingly important as the opportunity costs from making wrong decisions continue to grow. Ontario's excellence in clinical epidemiology has brought it international recognition as a leader in health economics and health technology assessment, bridging the worlds of research and health care decision-making.

We have the people and the resources that today's leaders in life sciences need to efficiently test promising innovations. Ontario is ready to welcome your organization and to host your next clinical trial.

STREAMLINING THE RESEARCH ETHICS REVIEW SYSTEM IN ONTARIO

Implementing a streamlined research ethics review system for Ontario is an immediate priority for Clinical Trials Ontario (CTO). We are moving to a single ethics review for multi-centre clinical trials. This new approach will improve the speed and reduce the costs of these trials. Typically, in many jurisdictions including Ontario, the practice has been to conduct a research ethics review at each and every public institution participating in the same clinical trial. This has resulted in multiple ethics reviews. It's time to streamline the process.

The **CTO Streamlined Research Ethics Review System** will support the timely, efficient and effective review of multi-centre clinical research in Ontario. This system will enable any single 'Qualified' Research Ethics Board (REB) to provide ethics review and oversight of clinical trials being conducted in multiple institutions across the province.

The CTO System is expected to provide significant benefits to sponsors, investigators, institutions and REBs conducting multi-centre clinical research by harmonizing processes and reducing the time and effort required to initiate research across multiple sites in Ontario.

HOW THE CTO STREAMLINED RESEARCH ETHICS REVIEW SYSTEM WORKS:

All REBs participating in the Streamlined System are 'CTO Qualified.' The CTO REB Qualification Program provides REBs in Ontario with an external review of their governance, membership, operations and review procedures. The qualification process is important as it promotes a high level of trust and allows institutions and REBs to feel confident delegating ethics review and oversight to each other.



KEY FEATURES OF THE CTO STREAMLINED RESEARCH ETHICS REVIEW SYSTEM:

- supports a single REB in providing research ethics review and oversight to multiple research sites
- can be used for any multi-site clinical research – i.e. industry sponsored or investigator initiated
- offers a web-based information technology system that will enable research ethics review, document management and communication between multiple institutions and REBs
- ensures that all REB reviews done through the CTO System are conducted by high-quality REBs that have achieved Qualification status
- investigators/applicants will use the same interface and REB application forms, irrespective of which REB is providing oversight
- consistency in submission requirements
- timely and reliable distribution of study events (such as safety updates and amendments) between the REB and multiple institutions
- transparent and timely information to applicants regarding REB review status.

FAST FACTS

- More than 3,200 clinical trials are underway in Ontario at any given time with over 800 clinical trials newly registered in 2013.¹
- Ontario has 580 clinical trial sites, placing it on par with other jurisdictions that are showing rapid growth in trial activity.²
- In 2012 alone, pharmaceutical companies spent over \$250 million on clinical trials in Ontario.³
- Canada is one of the top three countries in terms of cost of clinical trials administration, and has an almost 16% cost advantage over the U.S., according to a KPMG survey of 10 countries.⁴



1 www.ClinicalTrials.gov

2 www.DrugDev.org

3 Patented Medicine Prices Review Board. Annual Report 2012.

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

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