2022

A Decade of Impact



Improving
Ontario's
Clinical Trials
Environment



Better Trials for a Brighter Future

Ten years ago, clinical trial investment and activity was in decline in Ontario and around the world. The Government of Ontario, along with hospitals, universities, industry, research ethics boards and other leaders in Ontario's clinical trials community saw the opportunity to make this province a world-leader in conducting clinical trials. They came together to establish Clinical Trials Ontario (CTO), one of Canada's first dedicated, non-profit clinical trials organizations with a goal of strengthening, promoting and capitalizing on Ontario's competitive advantages for conducting high-quality clinical trials.

Our first step was to establish CTO Stream, an Ontario-made online system to enable a single research ethics review for multisite trials. It was designed with our clinical trials community, and its success is owed to the Research Ethics Boards, institutions, industry colleagues and investigators who continue to support this collaborative effort to work efficiently and to make trials available to participants sooner.

With support from our partners, we leveraged the success of CTO Stream to launch other leading programs, including CTO QuickSTART, Research Ready, our patient and public engagement activities, our annual CTO Conference, our Industry Concierge and Trial Site Network, and more.

Today, CTO plays an essential role in fueling Ontario's now thriving clinical trials sector. Within the last decade, the

number of active clinical trials in Ontario has increased by over 160%, with more than 4,000 trials underway in Ontario at any given time. Our collective efforts have allowed us to attract trials, investment, talent and jobs. And they have put Ontario at the forefront of determining better treatments for future patients here at home, and contributed globally to the development of preventive and therapeutic options.

As we reflect on the achievements in this report, we thank the Government of Ontario for its recognition of the vital role that clinical trials play in this province and for its continued support of our community's work. We also thank our dedicated CTO team, our Board of Directors, and the members of our clinical trials community, who are tireless in their efforts and inspiring in their dedication.

In the decade ahead, we are motivated by the opportunity for future collaborations with our community in Ontario, across Canada and beyond to continue improving the environment for conducting high-quality research and clinical trials.

A better clinical trials environment means a brighter future for everyone.

Susan Marlin, President & CEO

Raphael Hofstein, Chair of the Board

About CTO

Vision

Our vision is to make Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

Mission

Our mission is to strengthen, promote and capitalize on Ontario's competitive advantages to conduct highquality clinical trials.

Strategic Priorities



Streamline

Streamline processes to help make high-quality clinical trials more timely, efficient and cost-effective.



Engage

Engage with patients and the public to increase awareness, foster collaboration and improve how clinical trials are conducted.



Promote

Promote Ontario's competitive advantages and clinical trial capacities to attract more trials and industry investment to the province.

CTO's 10th anniversary represents 10 years of working together and building a better environment for conducting high-quality, efficient and effective clinical trials in Ontario.

Watch the video at: www.ctontario.ca/decadeofimpact



2012-2022

"Congratulations to Clinical Trials Ontario for 10 years of contributing to improving Ontario's research landscape. Your work directly benefits the future of our province and reflects the spirit of innovation and desire to overcome challenges that have always been at the heart of Ontario's researchers."

The Honourable Jill Dunlop
Ontario's Minister of Colleges and Universities



Ontario's Clinical Trials Environment

Over the past ten years, Ontario's clinical trials community has built a strong environment for conducting clinical trials in the province. This work has helped to put Ontario – and Canada – on the map, attracting not only more clinical trials, but also global investment, talent and jobs. These high-impact numbers reflect the dedication, excellence and collaboration of the tens of thousands of people who support clinical trials in Ontario.

By-the-Numbers Snapshot

160%

increase in the number of active clinical trials since 2012¹

2.5 x more

industry-sponsored trials compared to 2012¹

2x more

active clinical trials per capita compared to the United States¹

500+

government-sponsored clinical trials in Ontario – the highest number in Canada¹

The most common diseases with active clinical trials in Ontario are cancers followed by non-specified pathological conditions signs and symptoms, nervous system disorders, cardiovascular disease and immunological illnesses¹

4,600+

active clinical trials in Ontario

- the highest number in

Canada¹

\$466M

in industry investment in Ontario clinical trials²

2,300+

industry sponsored clinical trials in Ontario¹

Ontario is Canada's leading trials sector Ontario has world-class clinical trials assets

19 of Canada's top 40 research hospitals³

140 hospitals with over 200 unique sites⁴

14 acute academic hospitals

46 community hospitals

complex continuing care & rehabilitation hospitals

62 small hospitals

5 mental health & addiction hospitals

22,000+

\$1.73B

2,200+

30,000+

26,000+

employed researchers/staff in academic hospitals⁴

invested in health research at Ontario hospitals⁴

biotechnology, medical device and digital health companies⁵

jobs in drugs and pharmaceuticals⁵

jobs in medical devices⁵

Total number of active clinical trials among G7 nations in 2021¹

USA 42,312 France 10,340 Canada 6,946 UK 5,852 Germany 5,744 Italy 5,380 Japan 2,099

All major pharmaceutical companies conduct clinical trials in Canada¹

Canada is a globally competitive trials jurisdiction

Ranked 1st

in active clinical trials per capita among G7 nations¹

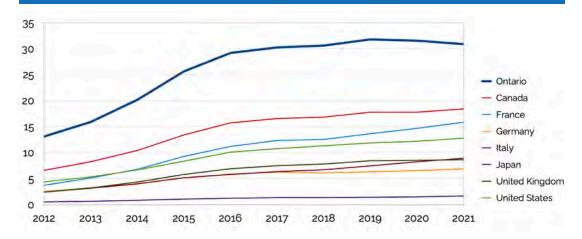
Ranked 3rd

among G7 nations for total number of clinical trials¹

2nd lowest cost

among G7 nations for managing clinical trials⁶

Active Studies per 100k Population — G7 Nations & Ontario¹



¹Based on <u>clinicaltrials.gov</u> data provided by the <u>Clinical Trials Transformation Initiative AACT</u>
<u>Database</u> between 2012-2021 and analyzed by Clinical Trials Ontario

²Data from 2021 Patented Medicines Pricing Review Board Annual Report

³Data from 2021 RE\$EARCH INFOSOURCE list of Canada's Top 40 Research Hospitals

⁴Data from <u>Ontario Hospital Association (oha. com)</u>; article: <u>Ontario's Research Hospitals</u>: <u>A Key Strategic Resource for Canada</u>

⁵Data from LSO 2019 Report: <u>Accelerating</u> <u>Prosperity: The Life Sciences Sector in Ontario</u>

⁶Data from McDougall Scientific (mcdougallscientific.com) based on KPMG's Competitive Alternatives 2016 study



Achievements

A Decade of Improving the Environment for Clinical Trials At CTO, we are focused on improving Ontario's environment for conducting high-quality clinical trials, making them more efficient, effective and accessible for everyone – researchers and healthcare professionals, patients and families, and members of industry.

Our impact over the past decade is the result of the clinical trials community's tireless and strong collaborative efforts to continue streamlining processes, engaging with patients and the public, and promoting our province's advantages to attract more trials to Ontario.



2012

Streamlined research ethics review system designed by CTO collaboratively with over 100 members of the clinical trials community

2014

CTO Stream launched, establishing a single research ethics review for multi-site trials in Ontario; CTO hosts its first clinical trials conference

2016

CTO Patient & Public Advisory Group and Industry Concierge program established

2018

QuickSTART, Research Ready, Trial Site Network and Clinical Trial Finder search tool officially launched; 1,000th study submitted through CTO Stream

2020

ACT initiative launched Resource Guide for Decentralized Clinical Trial Approaches; Participant Experience Toolkit published; 1,500th study submitted through CTO Stream CTO established with support from the Government of Ontario and a cross-section of stakeholders

2013

CTO REB Qualification Program implemented after successful pilot with Ontario Cancer Research Ethics Board

2015

CTO REB Council established to improve and gain input on CTO Stream's research ethics approval process

2017

100th site joins CTO Stream; Key resources published, including guide for companies looking to conduct trials in Ontario and education modules for people interested in trial participation

2019

CTO Stream leveraged for COVID-19 studies; CIHR-funded CHEER initiative launched; CTO College of Lived Experience established

2021

2022 CTO celebrates a decade of impact



Strategic Priority
Streamline

Streamline processes to support the timely, efficient and costeffective conduct of highquality clinical trials

By creating coordinated systems and facilitating collaborations that improve the timeliness, quality and cost of clinical trials, CTO has helped Ontario to capitalize on our many research strengths and attract the attention of industry and talent around the world. For the people of Ontario, streamlining clinical trials means we are able to advance critical health research quickly so that more clinical trial opportunities are available and new medicines and devices can reach patients faster.

"The CTO stream process has been extremely helpful in launching province wide, multi-site research initiatives. It has allowed the elimination of a significant amount of duplication and overall allows for quicker, and more efficient approvals process."

Dr. Stephen Choi

Staff Anesthesiologist, Sunnybrook Health Sciences Centre; Associate Professor, Department of Anesthesia, University of Toronto

"CTO has assumed a vital role in expediting and facilitating clinical research." Dr. John Marshall Professor of Surgery, University of Toronto; Trauma Surgeon and Intensivist, St. Michael's Hospital, Unity Health Toronto; Professor of Surgery, University of Toronto

CTO Stream

The gold standard for efficient, multi-site research ethics review

High-quality ethical review is critical to protecting the rights and welfare of people participating in clinical research studies. Up until 2015, each hospital or research site in Ontario participating in a study typically acquired its own local review, spending significant time and public resources on an inefficient process duplicated across participating sites. CTO Stream has transformed how research ethics review is done in Ontario, enabling a single ethics review for multiple research sites participating on the same study.

Ontario is leading the country with its engagement and expertise around streamlining research ethics review. The impact of CTO Stream has been demonstrated year over year with increased uptake and savings of time and money. During the pandemic, CTO Stream fully realized its potential by quickly advancing clinical trials related to COVID-19. CTO Stream is now firmly embedded within Ontario's clinical trials ecosystem as the default for conducting efficient, high-quality multi-centre health research.

CTO Stream By the Numbers



COST SAVINGS

\$17.5M

in estimated cost savings to Ontario



PARTNERS

7,700+ users of CTO Stream

110

participating hospitals and research sites, including Ontario's most active trial sites

120+

pharmaceutical and medical device companies

19

qualified Ontario research ethics boards provide multi-site ethics review



RESEARCH STUDIES

1,850+

research studies

5,500+

applications for research ethics approval received

10 days

to approval for participating research sites (average)



COVID-19

122

COVID-19 studies through CTO Stream

400+

sites submitted applications to CTO Stream to join open COVID-19 studies

7 days

to approval for participating research sites (average)

CTO QuickSTART

Giving Canada a formula for efficient trial start-up times

Researchers and sponsors spend years developing potential therapies and preparing to launch clinical trials. Once protocols and clinical trial supplies are ready to go, the pressure to activate research sites and begin recruiting participants is immense. CTO QuickSTART relieves pressure by enabling trial sites to get studies up and running within 90 days. The program uses a custom-built digital platform and focuses on streamlining trial activation processes, such as budgets and contracts, identified as common hurdles by industry and institutions. Launched as a pilot in 2019, CTO QuickSTART has become a key part of Ontario's efforts to make trials more effective and efficient.







Reduced trial start-up times from 5+ months to just 90 days

More than **10 institutions** and more than **10 industry sponsors** are QuickSTART Ready

Adoption of QuickSTART tools in the N2 Clinical Research Coordinators Training

Leveraged to support investigatorinitiated trials in **response to COVID-19**

Expanded tools to support medical device trials and contract research organizations

Expanding tools to **support institutions** as a study project management platform

Collaboration on the Ontario/ Quebec common NDA template

Research Ready

Facilitating learning, growth and mentorship

Research teams across Ontario are on the front lines of making clinical trials happen. They help design studies, recruit and support participants, and ensure all requirements are met to deliver high-quality clinical trials. Our community has often commented on the erosion of education and training opportunities for Ontario's investigators and research coordinators. CTO's Research Ready fills this gap by providing Ontario research teams with high-quality training, education and mentoring resources that are relevant to the evolving needs of the community.



150 participants in our online community of practice

Monthly Community of Practice newsletter to share best practices, upcoming events and updates of interest to research staff

Established Mentor Spotlight Webinar series on key topics including patient consent, clinical trial budgets, REDCap, privacy and remote monitoring strategies

Established Advisory Group to help direct educational content for the research community

CHEER

Streamlining research ethics approval across Canada

The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER) is a Canada-wide initiative on a mission to improve child health by streamlining research ethics review for child health research across Canada. CHEER is led by Clinical Trials Ontario and the Maternal Infant Child and Youth Research Network, in partnership with the Queen's University Faculty of Health Sciences, Office for Professional Development and Educational Scholarship, and investigators and collaborators across the country.



Launched in 2020 with funding from the CIHR Institute of Human Development, Child and Youth Health and the CIHR Institute of Genetics

Leveraged experience with CTO Stream to launch a web-based collaborative research ethics review platform

6 REBs have been CHEER qualified

6 multi-site studies have been submitted through the CHEER system





Engage with patients and the public to increase awareness, foster collaboration and improve how clinical trials are conducted

Helping Ontarians make informed decisions about clinical trials and improving the clinical trials experience.

CTO is committed to better engaging patients and the public with clinical trials and improving the clinical trial experience. Over the past decade, we have collaborated with patients, patient organizations and health charities to co-develop resources and tools that help patients and the public engage make informed decisions about participation in clinical trials and help them be members of clinical trial teams.

Learning from the lived experience of patients and participants

Working with patient and public partners brings a diversity of lived experiences to our initiatives, and we have developed unique models of engagement. It's thanks to the support of the two groups below that we have been able to reach broad communities and have impact.

CTO'S COLLEGE OF LIVED EXPERIENCE

Established in 2019, CTO's College of Lived Experience has 25 members from across Ontario including patients, caregivers, and members of the public. Members of the College provide input on numerous key CTO projects, including our work on decentralized trials, and collaborate with external research community partners to improve proposed resources, research projects and clinical trials.

CTO'S HEALTH CHARITIES AND PATIENT ORGANIZATIONS GROUP

Since 2015, CTO has been working closely with nearly 40 health charities and patient organizations from across Canada to co-develop and distribute clinical trials resources to their communities and raise awareness to improve patient and public engagement with clinical trials. This group also facilitates collaboration and works with CTO to provide input to regulators and others on clinical trial topics.



TOP CTO TOOLS & RESOURCES SUPPORTING PATIENT & PUBLIC ENGAGEMENT

CTO Clinical Trials Finder, the first web-based search tool of its kind in Canada that connects patients and the public with active clinical trials across Canada, used by over 30,000 site visitors

Online education modules that walk people through the process of what to expect when participating in a clinical trial so that they can make informed choices

Clinical trial terms glossary, co-developed by patients and participants to define clinical trials terms in accessible language

Participant Experience Toolkit that includes resources, templates and videos to help researchers ensure trial participants feel valued and informed, developed by a multistakeholder group

Interactive decision aids for patients and investigators to support patient partner engagement with trial design

#TalkClinicalTrials public awareness campaign that gives space for trial participants, researchers and others to share their experiences with clinical trials



Be flexible.

Think about creating opportunities to meet outside of regular business hours, allow for different meeting time options or host the same meeting twice so there are more options to contribute. Meet one on one with those who can't make times that work for the majority, facilitate meetings to encourage everyone to engage in ways that work for them.

Have resources including a budget to support engagement.

Resources may include a point person for all engagement activities, offering honoraria (individuals may or may not wish to receive it), covering travel and other expenses and more.

Communicate clearly.

Set context and timelines for project engagement, offer tailored information to patient partners at a level that makes sense for them (which may not be the same information and materials you would provide others such as researchers or clinicians), and create online, closed message boards to keep communication accessible.

Engage a large group so there isn't pressure to participate.

This allows more perspectives and allows individuals to step back if their health or life require them to, or if they're simply not as interested in the topic at hand.

Close the loop.

Let partners know about project results, outcomes and next steps based on their generous input and insights.

"As a member of the College of Lived Experience, I had the opportunity to collaborate with like minded patients and caregivers and provide impactful input on a variety of initiatives that will help to elevate the clinical trial experience and outcomes of patients and their families during this stressful period."

Terry HawryshMember of CTO's College of Lived Experience



Strategic Priority
Promote

Promote Ontario's competitive advantages and clinical trial capacities and attract more trials and industry investment to the province

Global investment attracts more global investment, and our worldclass clinical trials sector plays an essential role in fueling Ontario's economy. Since 2012, we have seen 2.5 times more industry-sponsored trials come to Ontario. CTO has been encouraging this positive trend by promoting Ontario as an attractive site for companies to set up shop and conduct R&D, including clinical trials. Over the past decade, we have been making it easier for biopharma and medical device companies to do business here by providing expert advice, navigational support and warm introductions to sites and other partners.



"When CTO introduced us to Impact Clinical Trials through the Trial Site Network, we immediately connected and knew they were the right fit."

Nazanin Hosseinkhah

Research Scientist and Physicist at Vielight Inc.

Industry Concierge

Connecting companies to clinical trials in Ontario

Since its launch in 2017, CTO's Industry Concierge service has been connecting industry sponsors with resources and research sites in Ontario's clinical trials ecosystem. In 2019, we formally established our Trial Site Network, which now includes more than 200 academic hospitals, community hospitals and private research networks across the province. The network has proven to be a win-win: companies and start-ups connect directly with potential partners, and sites expand their research activities.



200+ trial sites participating in CTO's Trial Site Network

120+ companies have used the Industry Concierge service to connect directly with clinical trials sites

Connected 100+ incoming clinical trials/validation studies to potential site partners in areas such as COVID-19, autism, hemophilia, PTSD, early-stage Parkinson's disease and more

ACT

Advancing approaches to decentralized trials

During the COVID-19 pandemic, Ontario's clinical trials community was forced to pivot, putting in place new digital and virtual solutions to maintain trials safely and at a distance. These measures opened the door to conducting decentralized clinical trials, which can help to expand trials to reach underserved, rural and remote communities. Launched in 2021, CTO's ACT (Advancing Clinical Trials) initiative is helping the clinical trials community move toward a decentralized trial approach. ACT is driven by stakeholders from industry, institutions, REBs and participants who have come together to share ideas and create tools for increased alignment and transparency.



Established three subgroups: a Privacy and IT Subgroup, a Site Self-Governance Subgroup and a Principal Investigator Oversight Subgroup

Published the Resource Guide for Decentralized Clinical Trial Approaches, which aims to provide a common framework of best practices for conducting decentralized clinical trials

Launched a survey for patients and caregivers to share input on decentralized clinical trial preferences

Draft Site Self-Governance Framework has received positive feedback from institutions and industry



CTO Conference

Hosting Canada's leading interdisciplinary forum for clinical trials

What started as a modest meeting of 200 people is today one of the most important knowledge exchange and networking opportunities in Canada's clinical trials ecosystem. The CTO Clinical Trials Conference draws 400-500 people each year from all corners of the clinical trials community, including hospitals and universities, industry, research ethics

boards, health charities, patient groups, government and more. In 2020, we introduced an Innovation Showcase for emerging organizations to profile their innovations for Ontario's clinical trials community. Hosting the annual conference is just one of the ways that CTO improves the climate for clinical trials in Ontario and attracts business to the province.

CTO Conference by the numbers

8th
Annual Conference

400+ Registrants

11 Exhibitors

38 Speaker



Putting a spotlight on Ontario's clinical trials community

Concert Fairs Corts

Service Trains Corts

S

CTO works to promote
Ontario's world-class research
talent and infrastructure to
attract more clinical trials
investment to the province.
Over the past decade, we've
developed new tools and
resources, highlighted Ontario
successes, participated in
key events and more.

Showcasing the Ontario-Quebec clinical trials corridor at the 2019 BIO International Convention in Philadelphia.

Partnering with Healthing.ca, a Postmedia publication to share stories from Ontario's clinical trials community. Opinion: Clinical trials happening globally to halt COVID-19

National Post

Opinion: How two hospitals and a pharma company are coming together to improve clinical research

Healthing.ca

'Hope, optimism, a better quality of life': Clinical trials save lives while moving science forward. Here's how you can be a part of it

Healthing.ca

Susan Marlin presenting Ontario's clinical trial advantages to a delegation from Brazil.





Industry Resource
Guide to Conducting
Clinical Trials in Ontario

Creating and curating data, regulatory guides and resources to help companies do business in Ontario

E / BIENVENUE

Collaborating with Health Insight to share stories from Ontario's clinical trials community.



WELCOME / BIEN

Québec ##

Leadership

CTO Board of Directors

Raphael Hofstein (Chair)

Bradly Wouters (Vice Chair and Secretary)

Bev Heim-Myers (Treasurer)

Tina Ceroni (Member)

Anne Ellis (Member)

Mark Lundie (Member)

Clive Ward-Able (Member)

James Wilson (Member)

Kym Boycott (Member)

Former President and Chief Executive Officer, Toronto Innovation Acceleration Partners (TIAP)

Executive VP, Science & Research, University Health Network

Chair, Canadian Coalition for Genetic Fairness; Chair, Board of Directors for Dying with Dignity Canada, Former CEO, Huntington's Canada

Clinical Trial Participant

Associate Professor and Chair, Division of Allergy & Immunology, Department of Medicine, Queen's University

Global Medical Affairs Lead, Rare Neurology, Pfizer Canada

President, Clintell Inc., Pharmaceutical Industry Consultant

Retired Commercial, Consultant, Medical Devices, Orthopaedic Trauma & Extremities

Clinician Scientist, CHEO Research Institute; Professor of Pediatrics, University of Ottawa; Tier 1 Canada Research Chair in Rare Disease Precision Health

Founding Institutions

Ontario Hospital Association

Innovative Medicines Canada

Medtech Canada

BIOTECanada

Council of Ontario Faculties of Medicine (COFM)
Ontario Council on University Research (OCUR)

CTO Team

Susan Marlin

President & CEO

Elena Trebinjac

Director, Operations and Outreach

Emily Di Giovanni

Program Coordinator

Craig Proulx

Operations Coordinator

Cindy Lee

Accounting Specialist

Matthew D'Ascanio

Director, Research Ethics Review Program

Scott Tomlinson

CTO Stream and Support Lead

Michelle Lee

Administrative Coordinator, Streamlined Research Ethics Review

Dawn Richards

Director, Patient and Public Engagement

Lam Pho

Director of IT

lan Stewart

Senior Web Application Developer

Elise Johnson

Communications Lead

Emily Edwards

Communications Officer

Special Thanks

The growth and success of CTO over the past decade is thanks to the support, dedication and collaborative spirit of our clinical trials community and sector partners in Ontario, across Canada and internationally.

We thank CTO's past board members and founding institution leaders for collaborating on a vision for Ontario's clinical trials community. We also recognize the vital contributions of CTO's inaugural Board Chair, Art Slutsky, and first Executive Director, Ron Heslegrave, who together set out a path for this organization and contributed much to Ontario's health and life sciences sector.

We thank the thousands of voluntary participants, as well as Canada's patient groups and health charities, who generously give their time and energy to supporting trials and research in this province.

We thank the research ethics boards members and teams across the province for their trust and commitment to supporting what is now the gold standard for streamlined research ethics review in this country, and we thank the over 7,000 users, 110 institutions and 120 industry partners who participate in this program.

We thank the Government of Ontario for seizing the opportunity to make this province a destination for clinical trials, and for its ongoing support of Clinical Trials Ontario thereby advancing the health care opportunities and well-being of Ontarians.

Thank you – all of you – for what we have achieved together in these past ten years. We look forward to collaborating over the coming decade to continue advancing clinical trials for a brighter future for everyone.



Clinical Trials Ontario offers a wide variety of programs to the clinical trials community to help collectively improve the environment for clinical trials in Ontario. Contact our team to learn more about how you can get involved with our services and programs.

416.673.6684 www.ctontario.ca info@ctontario.ca







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