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# About Clinical Trials Ontario

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

## Our vision is to make Ontario

Vision

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.





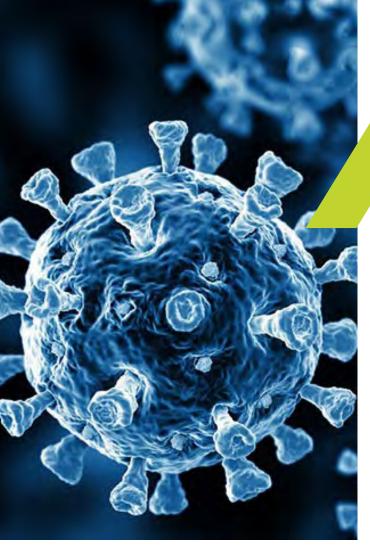
# A New Era for Clinical Trials in Ontario

Joint message from Susan Marlin, President & CEO, and Rafi Hofstein, Board Chair

COVID-19 has had a deep impact on how we conduct clinical trials here in Ontario and around the world. Our community has faced extraordinary challenges requiring new ways of thinking and working together to advance science safely and deliver care. Now, as we are coming out on the other side of this pandemic, we are entering into a new era of clinical trials in Ontario. We are using technology to innovate processes and connect more effectively, prioritizing patients and the participant experience and advancing decentralized approaches to clinical trials.

Ontario's clinical trials community has shown incredible resilience and innovation by implementing digital, virtual, and decentralized clinical trial processes in order to keep clinical trials moving forward in a safe and socially distant manner. These decentralized approaches, once seen as an immediate risk mitigation tactic during the pandemic, are now recognized as a highly effective and participant-centric option for conducting clinical trials.

Clinical Trials Ontario's latest initiative, ACT: Advancing Clinical Trials, is helping to harness lessons learned by bringing together representatives from industry, institutions, Research Ethics Boards and trial participants to address considerations and create tools for increased alignment in approaches to decentralized trials.



Adopting these approaches when appropriate will strengthen Ontario's competitive edge, reaffirm our place as a top jurisdiction for conducting clinical trials, reduce barriers to trial participation and offer greater access and equity.

While the ACT initiative works on bringing clinical trial conduct into the future, our flagship program, CTO Stream, continues to grow and move research forward as quickly as possible. Since 2015, this visionary program, built by the clinical trials community, makes trials faster, less resource-intensive and more efficient by allowing a single ethics review for multi-site clinical trials. Today, the program supports over 1,550 research studies, with participation from 19 CTO-Qualified REBs, 110 trials sites and more than 120 pharmaceutical and medical device companies. Throughout the pandemic, CTO Stream has supported over 115 Ontario-led COVID-19 studies, enabling ethics approvals across 403 research sites.

Working alongside patient groups and health charities, we are continually working to improve the clinical trial participant experience and make it easier for patients and the public to engage with clinical trials. Our new Participant Experience Toolkit – co-created with participants, health charities, patient organizations, REB representatives, industry and researchers – includes useful resources, templates and engaging videos with the aim of making trial participants feel more valued and informed.

Reflecting on these and other shared achievements, 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 team and our Board of Directors. As we enter a new era of clinical trials in Ontario, we are motivated by our community's spirit of innovation and collaboration, embracing new opportunities in the face of hardship and advancing health research forward, faster, for an even brighter future in this province.

Susan Marlin | President & CEO

Raphael (Rafi) Hofstein | Board Chair

# **Ontario Snapshot**

Ontario is Canada's largest and fastest growing clinical trials community and among the top jurisdictions in North America. Over the past year, COVID-19 has urged us to think differently about clinical trials. Our community has not only adapted, it has innovated by adopting digital, virtual and decentralized processes to conduct safe, socially distant, high-quality trials. These efficient and participant-centric decentralized trial strategies, together with our world-class environment, make Ontario even more competitive in attracting investment, jobs and talent.

> "Clinical research needs to move towards an electronic world, and the COVID-19 pandemic has given us a push to get there. It's been exciting to be part of discussions across Ontario and Canada to see how we can work together to come up with solutions in order to conduct good quality research in our new reality."

 Janet Knechtel, Senior Quality Assurance & Education Officer, Lawson Health Research Institute

#### ONTARIO CLINICAL TRIALS

# By the Numbers

4,500+

more trials than other provinces in Canada

72% of all clinical trials conducted in Canada

of all oncology trials conducted in Canada

in industry investment in Ontario clinical trials\* 2,000+ industry sponsored clinical trials

\*Data from 2019 Patented Medicines Pricing Review Board Annual Report. All other data in this infographic retrieved from clinicaltrials.gov.



We have worked really hard with our clinical trial sites in a very short period of time to get remote solutions going. Moving forward, we will enhance these and have more sustainable long-term solutions. I think what we are looking at is the future of clinical trials."

- Nessrine Hanna, Associate Director, Clinical Research, Merck Canada Inc.

# Ontario is Home to Top Talent



\*Data from 2020 list of Canada's Top 40 Research Hospitals, released by RE\$EARCH Infosource Inc.

\*\* 2019 data from Ontario Hospital Association \*\*\*LSO Annual Report 2019 6



# CTO's Impact & Achievements

# Bringing clinical trials into the future

At CTO, were laser-focused on improving Ontario's environment for conducting high-quality clinical trials, making them more efficient and effective for everyone – researchers and healthcare professionals, patients and families, and members of industry.

Throughout the pandemic, we have worked alongside the clinical trials community to strengthen and leverage our existing programs – and develop new ones. We are streamlining clinical trials processes, engaging with more patients and members of the public, improving clinical trial conduct through digital strategies, and promoting our province's advantages and assets. The future of clinical research is here, and we are ready for it.

# Streamline

### Facilitating faster, more efficient clinical trials



#### **CTO STREAM**

CTO Stream enables research sites participating in a clinical trial to undergo a single ethics review rather than separately applying to their local research ethics boards, reducing the time and effort required to obtain research ethics approval. Today, CTO Stream is the gold standard for supporting efficient, high-quality multi-site studies and has become integral to Ontario's clinical trial ecosystem.

**\$13M** 7,000+ 110 120 +19 1,600+ 4,700+ 11 days

in estimated cost savings to Ontario

users of CTO Stream

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

pharmaceutical & medical device companies

Qualified Ontario research ethics boards provide multi-site ethics review

research studies

applications for research ethics approval received

to approval for participating research sites (average)

nitted applications to

COVID-19 studies

## **ACCELERATING COVID-19 RESEARCH**

115	400+
COVID-19 studies	sites subm

7 days

Learn more about COVID-19 studies in CTO Stream

to approval for participating research sites (average)

**Join CTO Stream** 

## **Streamline**

#### Facilitating faster, more efficient clinical trials

#### QUICKSTART

A typical clinical trial can take more than five months to get started. Our QuickSTART program helps sites and sponsors achieve activation within just 90 days by developing authentic partnerships, setting targets and enhancing existing procedures without disrupting them.

Join QuickSTART

#### **RESEARCH READY**

The Research Ready program is strengthening Ontario's world-class health research infrastructure by helping to ensure that Ontario research institution staff have the skills and knowledge to conduct effective and efficient clinical trials. Over the past year, 50 participants have joined our online community of practice sharing best practices in key areas including patient consent, clinical trial budgets, RedCap, privacy and remote monitoring strategies.

Join Research Ready

## **QuickSTART Highlights**

10+ institutions & 10+ industry sponsors are research ready Reduced trial start-up times from 5+ months to 90 days

Adoption of QuickSTART tools in the N2 CRC Training Leveraged QuickSTART to support investigator-initiated trials

in response to COVID-19

Expanded QuickSTART tools to support medical device trials and contract research organizations Collaboration on the ON/QC common NDA template

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

# Engage

#### Improving patient and public engagement with clinical trials

"I was thrilled to help co-design the Participant Experience Toolkit. After participating in several clinical trials over a period of 54 years, this is the first time that anyone has asked me about my experiences and gave me a voice to say how I think the experience of participants could be improved."

 Maureen Smith, Clinical Trial Participant, Member of CTO's College of Lived Experience and Contributor to the Participant Experience Toolkit

Hear Maureen Smith discuss her participation in the Toolkit

#### PARTICIPANT EXPERIENCE TOOLKIT

CTO's Participant Experience Toolkit, co-created with our community, aims to help improve the experience of trial participants. The toolkit contains useful resources and engaging videos. Templates for thanking participants and plain language summaries, available in English and French, are also included in the toolkit. Thanks to the many collaborators who helped build this toolkit with the goal of making trial participants feel more valued and informed. Since its launch in fall 2020, the digital toolkit has been viewed over 7,400 times.

#### EDUCATION MODULES TO LEARN MORE ABOUT CLINICAL TRIALS

CTO's education modules, which consist of information to walk an individual through the process of participating in a clinical trial, now include helpful videos from members of the community available in English and French. The modules are intended to help people make informed decisions about clinical trials and reflect what we have learned from clinical trial participants, patient organizations and health charities.

#### Improving patient and public engagement with clinical trials



#### **COLLEGE OF LIVED EXPERIENCE**

The College of Lived Experience has 25 members from across Ontario including patients, caregivers, and members of the public. This past year, the College has provided input on CTO projects including the Participant Experience Toolkit, the Clinical Trial Restart Toolkit, the Resource Guide for Decentralized Trial Approaches, and the Clinical Trial Finder. The College has also collaborated with external research community partners to improve proposed resources, research projects and clinical trials.

### INTERACTIVE DECISION AIDS FOR PATIENT PARTNER ENGAGEMENT

CTO, in partnership with patients and researchers at the University of Toronto, Queen's University, and the University of Ottawa, continued to enhance and promote two online <u>decision aid tools</u> – one for patients and one for investigators/sponsors – designed to assess readiness for and help with patient partner engagement as part of patientoriented research teams.

#### ENHANCING THE CLINICAL TRIALS FINDER

CTO's <u>Clinical Trials Finder</u> search tool is helping connect patients and the public with clinical trials. Users can now watch a video tutorial narrated by a member of CTO's College of Lived Experience to learn how to use the tool. They can also receive alerts when new trials that meet their criteria become available. With more than 9,900 users, engagement with CTO's Clinical Trial Finder app increased by 90% in 2021.

Engage

#### RAISING AWARENESS AS A COMMUNITY

CTO works closely with <u>health charities and</u> <u>patient organizations</u> to co-develop and distribute informative clinical trials resources to their communities and raise awareness to improve patient and public engagement with clinical trials. We thank this community for its ongoing support.

#### Let's #TalkClinicalTrials

Help spread the word about why clinical trials matter on social media or on our #TalkClinicalTrials blog series, where trial participants, researchers and others share their experiences.

Learn More



### **Promoting Ontario's competitive advantages**

Promote



# Highlights

400+ 120+ 100+

Trial sites participating in CTO's Trial Site Network

Companies have used the Industry Concierge service to connect directly with clinical trials sites

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

### INDUSTRY CONCIERGE & TRIAL SITE NETWORK

CTO's Industry Concierge service continues to connect industry sponsors with resources and research sites in Ontario's clinical trials ecosystem through our Trial Site Network. It's a win-win: Companies and start-ups are connecting directly with potential partners, and sites are expanding their research activities.

**Connect with our Industry Concierge** 

# Ontario light therapy clinical trial aims to accelerate recovery from COVID-19

A clinical trial testing whether the recovery of COVID-19 patients may be accelerated by the use of a specialized light therapy device was made possible in part by CTO's Trial Site Network.

**Read the Story** 

## Promote

### Promoting Ontario's competitive advantages

#### **ACT: ADVANCING CLINICAL TRIALS**

CTO's ACT initiative is helping Ontario's clinical trials community build on the digital and virtual solutions put in place during the COVID-19 pandemic and 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.

#### Learn more about ACT

"It is our social responsibility as a research community to rethink our approach to clinical trials to allow more choice and opportunities for participants and caregivers. We must embrace change and break free from the status quo to compete on a global stage."

 George Memari, Clinical Trials Operations, Novartis Pharmaceuticals Canada Inc.



## **ACT Highlights**

## Launched the ACT initiative

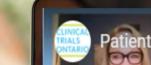
# Established 3 subgroups

- Privacy and IT Subgroup
- Site Self Governance Subgroup
- Principal Investigator Oversight
  Subgroup

Published the <u>Resource Guide</u> for Decentralized Clinical Trial <u>Approaches</u>, which provides best practices and key considerations for conducting decentralized clinical trials. The aim of this guide is to form a common framework of practices

Work has begun on a survey of patients and caregivers on decentralized clinical trial preferences

Site Self Governance Framework is being drafted



### **Promoting Ontario's competitive advantages**

# **Promote**



#### **CTO CONFERENCE 2021**

As one of the largest conferences of its kind in Canada, the CTO conference is among Ontario's most important knowledge exchanges within our clinical trials ecosystem. Due to the COVID-19 pandemic, CTO's 2021 Clinical Trials Conference was held virtually on March 23, 24, and 25, 2021.

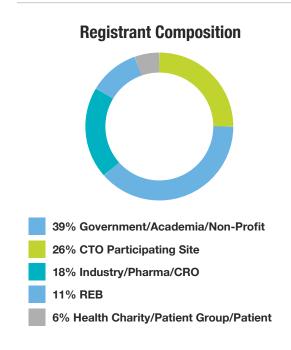
Speakers at the 2021 conference discussed the impact of COVID-19, the changing nature of clinical trials and moving clinical trials

#### Watch the CTO 2021 Session Recordings

closer to participants through decentralized approaches. Clinical trial participants shared what it's really like to participate in a clinical trial and presented on patient preferences in clinical trial design. Clinical data infrastructure in Canada and research ethics and machine learning were other key topics at this year's conference.

CTO also offered virtual exhibitor booths to 27 companies and organizations in the clinical trials ecosystem, allowing opportunities to network and generate partnerships.





# **Financials**

## ASSETS

	2021	2020
Cash	\$1,610,364	\$1,094,682
Guaranteed investment certificates	\$20,000	\$20,000
Accounts receivable	\$452,672	\$318,698
HST receivable	\$33,878	\$57,884
Prepaid software costs	\$150,161	\$134,736
Prepaid insurance and deposits	\$128,404	\$113,890
Prepaid rent	\$20,729	\$3,326
	\$2,416,208	\$1,743,216

## **LIABILITIES & NET ASSETS**

	2021	2020
Accounts payable and accrued liabilities	\$567,480	\$412,054
Deferred contributions	\$385,952	\$226,449
Net assets (unrestricted)	\$1,418,687	\$1,104,713

# **CTO Board of Directors**

We have strong governance and oversight from a skills-based Board of Directors dedicated to advancing patient care by attracting and improving the quality of clinical trials in Ontario.

#### Dr. Raphael Hofstein I Chair

Former, President & Chief Executive Officer, Toronto Innovation Acceleration Partners, TIAP

#### Dr. Bradly Wouters | Vice Chair & Secretary

Executive VP, Science & Research, University Health Network

#### **Bev Heim-Myers | Treasurer**

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

#### Tina Ceroni I Member

**Clinical Trial Participant** 

#### Dr. Anne Ellis | Member

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

#### Dr. Mark Lundie | Member

Director, Medical Affairs, Rare Diseases, Pfizer Canada

#### Dr. Clive Ward-Able | Member

President, Clintell Inc., Pharmaceutical Industry Consultant

#### **James Wilson | Member**

Commercial, Consultant, Trauma & Extremities, Stryker

# **Contact**

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.

Ontario 😵

Clinical Trials Ontario is supported by the Ontario Ministry of Colleges and Universities 416.673.6684 <u>www.ctontario.ca</u> info@ctontario.ca

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