CLINICAL TRIALS ONTARIO

Annual Report

2016/2017

Positioning Ontario as the preferred place for global clinical trials

OUR Vision

To make Ontario a preferred location for global clinical trials while maintaining the highest ethical standards.

OUR Mission

To strengthen, promote and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.

OUR Strategic Priorities

Streamline

Streamline processes to support the timely, efficient and cost-effective conduct of high-quality clinical trials.

Engage

Support and promote public and patient engagement with clinical trials.

Promote

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

Moving Ahead

Building on the foundation for an improved clinical trials environment in Ontario.

In 2012 the Province of Ontario took a bold step in investing in the health research sector by establishing Clinical Trials Ontario. Mandated to establish the province as a preferred destination for global clinical trials, CTO has focused its efforts on working with the clinical trials community to develop programs to streamline clinical trial conduct, engage patients and the public, and raise awareness of the advantages Ontario brings to the clinical trials space.

With renewed support from the government and the basic building blocks in place CTO is positioned to maximize the impact of current programs and collaborate with the clinical trials community to broaden its scope and develop new ways to support high-quality and ethical clinical trials. CTO will increase its efforts to engage patients and the public with clinical trials and promote Ontario's tremendous clinical trial capabilities.

We look forward to continued collaboration with the clinical trials community in positioning Ontario as a preferred location for clinical trials.

MESSAGE FROM THE

Board Chair and President & CEO

As we look back to 2012 when CTO was established, and where we are now, we cannot help but be excited about the future of clinical trials in Ontario. This past year was about strengthening the foundation created to support a thriving clinical trials community. Together with our partners in the health and life sciences sectors we have been successful in establishing core programs, and positioning CTO to expand in engagement and impact.

CTO Stream – our unique online system that supports a single ethics review for multi-site studies – is now fully operational with new features being added continuously. Our objectives moving forward are to optimize the program, maximize institution as well as sponsor participation, and proactively promote the benefits of CTO Stream locally, nationally and globally.

Participants in clinical trials help make safe and effective treatments available to all Canadians. CTO has learned through its outreach that patients have a desire for improved access to trials, as well as supports that empower them to make informed decisions about participation. By establishing the Patient and Public Advisory Group and engaging with

> “This past year was about strengthening the foundation created to support a thriving clinical trials community.”

> With world-class research facilities, over 200 hospitals, and 50% of Canada's pharmaceutical investment in R&D, Ontario is one of the world's ideal locations for clinical trials.

patient organizations and health charities, CTO will identify strategies to support the development of better clinical trials, and improve access to clinical trials, thus enhancing patient involvement with trials.

Over the past year CTO has actively participated in various meetings and conferences, exchanging knowledge and best practices, and fostering connections with a diverse network of research, business and healthcare professionals. We continue to raise the profile of CTO while promoting Ontario's infrastructure to support efficient clinical trials. With world-class research facilities, over 200 hospitals, and 50% of Canada's pharmaceutical investment in R&D, Ontario is one of the world's ideal locations for clinical trials. With the building blocks in place, we will now pursue a new phase of enhancements to support the efficient conduct of clinical trials, and respond to the evolving needs of the research community. Together with our clinical trials community we will continue to drive improvements and ensure that Ontario remains a dynamic and sought after clinical trials environment.

Sincerely,

Arthur Slutsky, Chair, Board of Directors and
Susan Marlin, President & CEO

STRATEGIC PRIORITY 1

Streamline

OBJECTIVE: Streamline processes to support the timely, efficient and cost-effective conduct of high-quality clinical trials

PROGRESS HIGHLIGHTS

1 More Institutions Adopting the Single Ethics Review Model

Engagement in CTO's Streamlined Research Ethics Review System has been increasing as we intensify our efforts to reduce the administrative burden and shorten the time associated with ethics reviews for multi-centre studies. The number of CTO Stream users is growing. This has enabled CTO to collect valuable feedback on the efficiency of the system and how it can be enhanced to support institutions and REBs. CTO aims to maximize participation and develop additional tools and resources that support the conduct of efficient and high-quality clinical trials.

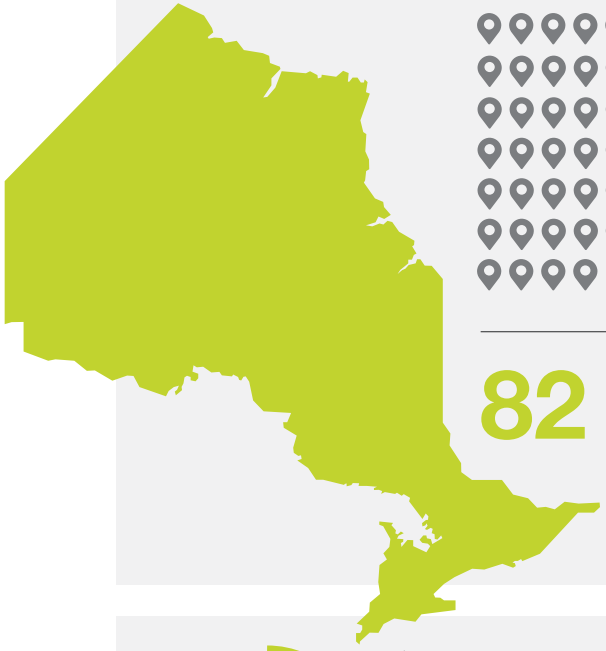
2 Streamlined Ethics Review will expand to Include Observational Research Studies

CTO consulted with institutions, REBs, and researchers as they plan for the expansion of CTO Stream to accommodate multi-site observational health research studies. Feedback from stakeholders will inform the creation of new ethics application forms and consent form templates for observational studies. This effort will help further streamline operations for multi-site research studies in Ontario.

3 Ethics Reviews for Cancer Studies now Facilitated Through CTO Stream

A major operational initiative of CTO was the transition of the Ontario Cancer Research Ethics Board (OCREB) to CTO Stream. The process was a major step towards a single system for ethics reviews for all multi-centre research in Ontario. Ethics applications for multi-site clinical trials in oncology, which would have been previously reviewed by OCREB using their former online system, will now be submitted to CTO Stream. By having one system in place, CTO and OCREB have partnered to create efficiencies and cost savings across the province.

CTO STREAM BY THE NUMBERS



82 Total number of participating research sites

16 Total number of CTO Qualified REBs

Percentage of sites receiving ethics approval to join a provincially approved study within one month

Median number of days to REB approval of provincial-wide application

CTO QUALIFIED REBs

- Baycrest Research Ethics Board
- Centre for Addiction & Mental Health Research Ethics Board
- Comité d'éthique de la recherche de l'Hôpital Montfort
- Children's Hospital of Eastern Ontario Research Ethics Board
- Hamilton Integrated Research Ethics Board
- Holland Bloorview Research Ethics Board
- Mount Sinai Hospital Research Ethics Board
- North York General Hospital Research Ethics Board
- Ontario Cancer Research Ethics Board
- Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board
- Southlake Regional Health Centre Research Ethics Board
- St. Michael's Research Ethics Board
- Sunnybrook Health Sciences Centre Research Ethics Board
- University Health Network Research Ethics Board
- Western University Health Sciences Research Ethics Board
- Ottawa Health Science Network Research Ethics Board/Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa

STRATEGIC PRIORITY 2

Engage

OBJECTIVE: Support and promote public and patient engagement with clinical trials

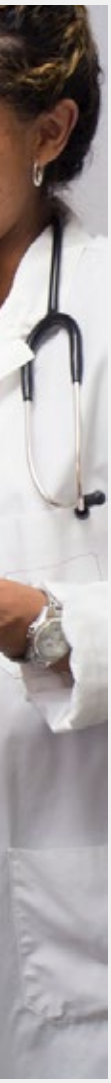
PROGRESS HIGHLIGHTS

1 Harnessing the Patient Voice

A committee of seven individuals who are interested in and impacted by clinical trials was formed in early 2017 with the objective of advising CTO on current topics and issues regarding clinical trials for which patient and public input would be valuable. The Patient and Public Advisory Group, also known as the P2AG, will ensure that the patient and public perspectives are incorporated into relevant CTO activities, and will also be ambassadors for clinical trials and for CTO.

2 Forming Linkages with Health Charities and Patient Groups

Another way to increase patient and public engagement is by collaborating with and learning from health charities and patient organizations. Through interactions with their stakeholders, these organizations have insight into the needs of individuals who are considering participating in a trial. They have shared their desire for more clinical trials in Ontario and resources in place that help individuals connect to trials andunderstand what participation entails. Representatives from a number of these organizations participated in CTO's 2017 conference and we look forward to more collaboration.



3 Understanding the Needs of Healthcare Providers

Data from a 2015 survey conducted by CTO and Clinical Trials BC (formerly the BC Clinical Research Infrastructure Network) is being prepared for publication. Results indicate that healthcare providers are perceived by the public to be one of the top sources for information about clinical trials. CTO will explore the knowledge and attitudes of healthcare providers to inform the development of programs to support their needs with respect to clinical trials.

4 Reaching out to New Partners

We are starting to identify the resources and tools we can build to improve patient and public engagement in clinical trials. For example, CTO has become an active member of Patient Focused Medicines Development, an independent global initiative committed to meaningful patient engagement throughout the development of new treatments. Building relationships with stakeholders across the clinical trials continuum is important to help guide us in developing meaningful and useful tools and resources.

5 Patient Engagement Discussion at CTO Conference

At CTO's 2017 conference a panel comprised of representatives from patient groups, industry and academic institutions discussed approaches to learning from patient and participant experiences to improve clinical trials and research. The session focused on patient input in clinical trial design, strategies to improve participant recruitment, and the role of healthcare providers in patient engagement. It inspired attendees and led to fruitful discussions about meaningful patient engagement with research.

STRATEGIC PRIORITY 3

Promote

OBJECTIVE: Promote Ontario's competitive advantages and clinical trial capacities to attract more industry and investment

PROGRESS HIGHLIGHTS

1 Increasing CTO's Visibility

CTO engaged with the international business and research communities at the annual BIO Conference in San Francisco in June 2016. CTO hosted a panel discussion with their life sciences partner Montreal InVivo, as well as Montreal Goes Clinic and Life Sciences Ontario. An esteemed group of experts including Dr. Dominick Amato, Mr. Bert Bruce, Ms. Margaret Horner, Dr. Jacques Michaud and Mr. Marc LePage was convened to discuss clinical trials and rare diseases. CTO's presence in the Ontario Pavilion promoted Ontario as a leading location for research and trials. CTO leveraged this and other events to strengthen relationships with industry and highlight Ontario's capacity to support clinical trials.

2 Industry – a Key Player in Clinical Trials

Working with industry is key to increasing the number of trials in Ontario. CTO conducted in-depth interviews with industry representatives to better understand the challenges and how we can help place more studies in the province. We will work with industry and institutions to develop tools and resources to improve the planning and execution of trials. Additionally, we will compile case studies from sites that have improved research outcomes and timelines and will use these examples to help form best practices for Ontario's research community.

> “The CTO Conference was the best clinical trials-focused conference I have attended in 20 years.”

3 Bringing Together Experts in Clinical Trials for Collaboration and Knowledge Exchange

CTO’s third annual conference welcomed over 300 delegates from government, academia, healthcare, industry, life sciences, health charities and patient advocacy groups for a two-day program that included diverse and interactive presentations, speakers and discussions. We heard from world-renowned experts including Jeffrey Simpson, former National Affairs Columnist, Globe and Mail, Greg Simon, Director of the Biden Cancer Initiative with The Biden Foundation and former Executive Director, The White House Cancer Taskforce (Moonshot Program) and Timothy Caulfield, Canada Research Chair in Health and Law Policy and Professor in the Faculty of Law and School of Public Health, University of Alberta.

Focused on the theme of Building Momentum: Ideas into Action, conference participants discussed opportunities to strengthen the environment for clinical trials in Ontario and across Canada, the health and economic benefits they bring to Ontarians and the ideas that will help us attract more trials to the province. Other topics that were touched on include policy and regulatory frameworks, patient and public education strategies, streamlining processes to facilitate efficient, high-quality and ethical conduct of clinical trials, and the infrastructure and investment needed to support clinical trials.

Conference presentations, videos and the Conference Digest – which provides a summary of the presentations and discussions – can be found on **ctontario.ca**.

2017 CONFERENCE BY THE NUMBERS

311 Registered Delegates

33 Speakers

11 Sessions

7700 Twitter Impressions

Delegate Makeup

34.5%	Institution (Academic, Hospital)
15.1%	Research Ethics Office/Board Member
14%	Researcher/Research Staff
4.3%	Research Network
7.5%	Health Charity/Patient Advocacy Group
5.4%	Independent Clinical Research Service Provider
9.7%	Industry
1.1%	Association
3.2%	Government/Publicly-funded Organization
2.2%	Professional Service
2.2%	Other

> "A valuable event in the clinical research sector."

Organizational Profile

THE TEAM

Matthew D'Ascanio	Program Manager, Systems Development and Support
Erin Bell	Program Manager, Streamlined Research Ethics Review
Todd Leach	Senior Communications Specialist
Susan Marlin	President and CEO
Lam Pho	Director, IT
Craig Proulx	Administrative Assistant
Dawn Richards	Associate Director, Patient and Public Engagement
Ranuka Srinivasan	Program Manager, Clinical Trials Outreach
Ian Stewart	Web Application Developer
Scott Tomlinson	CTO Stream Navigator
Elena Trebinjac	Operations Manager

BOARD OF DIRECTORS

Arthur Slutsky (Chair)	Vice President, Research, St. Michael's Hospital
Mark Lundie	Director, Medical Affairs, Rare Diseases, Pfizer Canada Inc.
Michael Owen	Vice-President, Research, Innovation & International, University of Ontario Institute of Technology
Tina Ceroni	Clinical Trial Participant
Anne Ellis	Associate Professor and Chair, Division of Allergy & Immunology, Department of Medicine, Queen's University
Raphael Hofstein	President and Chief Executive Officer, MaRS Innovation
Raphael Saginur	Chair, Ottawa Health Sciences Research Ethics Board, Associate Professor of Medicine, University of Ottawa, and Infectious Diseases Physician, The Ottawa Hospital
Clive Ward-Able	Executive Director, R&D, Amgen
James Wilson	President, Brancorth Medical Inc.

Financial Statement

As at April 30th, 2016 and April 30th, 2017.

ASSETS	2017	2016
Current Assets		
Cash	$ 663,238	$ 331,461
Guaranteed Investment Certificates	10,000	10,000
Accounts receivable	105,870	6,780
HST recoverable	22,748	24,431
Prepaid rent	69,354	66,028
Prepaid software costs	117,620	60,232
Prepaid insurance and deposits	43,731	22,198
	$ 1,032,561	$ 521,130

LIABILITIES AND NET ASSETS	2017	2016
Current Liabilities		
Accounts payable and accrued liabilities	$ 155,930	$ 66,682
Deferred contributions	731,679	440,239
	887,609	506,921
Net assets (Unrestricted)	144,952	14,209
	$ 1,032,561	$ 521,130

Contact Information

Clinical Trials Ontario

661 University Avenue | Suite 460
MaRS West Tower
Toronto | ON
M5G 1M1

416.673.6684
ctontario.ca | info@ctontario.ca

ClinicalTrialsOntario
@clinicaltrialON

Local, Provincial, National & International Partners & Collaborators

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Clinical Trials Ontario is supported by the Ontario Ministry of Research, Innovation and Science