CLINICAL TRIALS ONTARIO

ANNUAL REPORT 2014-15

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

Clinical Trials Ontario (CTO) is an independent not-for-profit organization established with support from the Government of Ontario. Our mandate is to work collaboratively with the clinical trials community, the public and strategic partners to improve Ontario's clinical trials environment and attract clinical trial investment to the province, while supporting the highest ethical and quality standards.

OUR STRATEGIES THE VISION OF CLINICAL TRIALS ONTARIO IS BEING ADVANCED THROUGH THESE KEY STRATEGIES:

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

2 Supporting and promoting public and patient engagement in clinical trials.

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

AS A GLOBAL LEADER IN CLINICAL TRIALS

This was a landmark year for Clinical Trials Ontario (CTO). Working closely with the clinical research community, we accomplished something that was just an idea three years ago. CTO officially launched a new 'streamlined' approach to research ethics review in this province. Ontario now stands out even more as an excellent location for clinical trials.

The new CTO Streamlined Research Ethics Review System offers a highly-efficient approach to obtaining ethics review across multiple research sites in Ontario, while maintaining the highest ethical standards. It benefits everyone involved in clinical trials by harmonizing processes and reducing the time and administrative burden involved in multi-centre clinical trials.

As you will read in this report, multiple trials are already flowing through the new system. At the time of writing, 10 research ethics boards (REBs) are 'CTO Qualified' to review studies, and several others are expected to qualify soon. Over 40 research sites have signed on and are ready to recruit patients to trials reviewed through the system.

The CTO Streamlined System significantly enhances the clinical trials climate in Ontario. Clinical trials are crucial to our health and well-being. They assess the safety and effectiveness of therapies and support the development of new drugs, devices and vaccines. They offer access to novel treatments and generate evidence to inform health care delivery. Clinical trials also create high-paying jobs and attract world-class researchers and clinicians.

The Ontario advantage

In Ontario, we are fortunate to have many advantages to build on—world-class research facilities and investigators, research-intensive academic and community hospitals, a thriving private research community, a reputation for high-quality data, and a population that is demographically and ethnically diverse.

And now, Ontario can boast a unique and efficient research ethics review process. As you will see on these pages, stakeholders are recognizing the importance of the CTO Streamlined System. In fact, it was one of the initiatives featured in a 2015 report on the Government of Ontario's burden reduction activities.

Building the CTO Streamlined System has truly been a community effort and success. A stakeholder-led organization, CTO has received extraordinary support from the clinical trials community in advancing our programming and other initiatives to streamline clinical trials, engage patients and the public in clinical trials, and promote Ontario as the preferred location for clinical trials.

Building on success

Now, CTO has an opportunity to build on this success and further enhance the clinical trials environment in Ontario. Maximizing engagement in the Streamlined System is paramount. CTO is also actively working on other streamlining measures, such as processes to support efficient contract review for multi-centre clinical research. We are deeply committed to increasing public awareness of clinical trials, and to supporting research site performance. Front and centre to all of our activities will be partnering and promoting Ontario as *the place* for global clinical trials.

In three short years, CTO has earned recognition as an essential component of the life sciences sector in Ontario. Thanks to the Ontario government's investment in CTO, we now have the infrastructure to advance Ontario as a global leader in clinical trials. CTO is also grateful to the CTO Board of Directors, our staff, member organizations, stakeholders and wider community for their involvement, contribution and support.

We have succeeded in bringing together the talent, drive and commitment that exists in Ontario, and focusing it on a common goal: a high-quality and efficient clinical trials environment which offers cutting-edge therapies to Ontarians.

Arthur Slutsky
Chair, Board of Directors

Susan Marlin
President and CEO

We are proud of what the clinical trials community has achieved in partnership with CTO over the past year. We have made significant progress in advancing our mission: to strengthen, promote and capitalize on Ontario's competitive advantages for conducting high-quality clinical trials.

KEY SUCCESSES FROM THE PAST YEAR INCLUDE:

- Officially launching the CTO Streamlined Research Ethics Review System and CTO Stream, with impressive uptake:
  - 10 fully qualified research ethics boards and others undergoing the CTO REB Qualification process
  - Over 40 research sites signed on to participate
  - Multiple studies reviewed or pending review through the System
- Developing additional streamlined supports and tools
- Hosting the CTO 2015 Clinical Trials Conference, and releasing a Conference Digest
- Establishing CTO as a vital resource for information on the clinical trials sector in Ontario
- Building partnerships and collaborations to enhance the clinical trials climate in Ontario and Canada
- Engaging with health charities and advocacy groups
- Undertaking a landscape review of participant recruitment and retention strategies
- Conducting a public opinion survey on perceptions and knowledge of clinical trials
- Producing a high-quality video to showcase Ontario's advantages as a location for clinical trials.

1 STREAMLINING PROCESSES

THE NEW CTO STREAMLINED SYSTEM

This is the year that we officially rolled out the CTO Streamlined Research Ethics Review System and reviewed the first clinical trials through the new System.

Ontario now has a unique and efficient approach to research ethics review that reduces the time and effort involved in launching multi-centre clinical trials.

The new CTO Streamlined System allows any single 'CTO Qualified' research ethics board (REB) in Ontario to provide ethics review and oversight for multiple research sites participating in the same clinical trial.

This means, for example, that a trial with 10 participating sites no longer has to go through 10 separate research ethics board reviews for the same study protocol.

What used to take months can now take days. Instead of each research site submitting a full research ethics review application to their local REB—a process that can take up to six months—a site can join an approved protocol in just days.

It's a timely and effective approach that will improve the speed and reduce the costs of doing multi-centre clinical trials in Ontario, while maintaining the highest ethical standards for participant protection.

This streamlined approach was conceived, designed and built as a community effort with hospital, university, REB, industry, private provider and other communities supporting clinical research across Ontario.

The CTO Streamlined System can be used for both industry-sponsored and investigator-initiated multi-centre clinical trials, and for any multi-centre health research project, including health systems research and epidemiologic studies.

Qualification Program in full swing

A centrepiece of the CTO Streamlined System is a rigorous qualification process. It ensures that all participating REBs are 'CTO Qualified'.

The unique program provides REBs with an external review of their governance, membership, operations and review procedures to ensure that a certain standard is met to deliver on high-quality reviews.

The CTO REB Qualification Program was finalized in 2015 and 10 research ethics boards became fully qualified (see list on page 6). More are in the midst of the qualification process, or preparing for it.

Any fully qualified REB can officially provide ethical review and oversight of multi-centre research on behalf of multiple research sites across Ontario. It becomes known as the 'board of record' for that study.

Within a year, CTO expects to have qualified research ethics boards serving most of the academic hospitals in Ontario, as well as qualified REBs in the community hospital and private research sectors.

FIRST INDUSTRY TRIAL RECEIVES ETHICS APPROVAL

Over a dozen others moving through System

In spring 2015, GlaxoSmithKline (GSK) became the first industry clinical trial sponsor to use the CTO Streamlined Research Ethics Review System.

GSK's global multi-centre clinical trial received province-wide ethics approval of the study protocol in Ontario just two months from the time of submission.

With ethics approval in place, the study can add on sites in Ontario. This will take days to approve instead of months.

"GSK is very happy to work with CTO and to participate in the Streamlined System. It will make timelines for our trials faster, it will simplify things and it will make Ontario a lot more competitive. Congratulations to CTO, and thank you for helping to make Ontario more competitive, and helping all of us to make Canada a lot more competitive when it comes to clinical trials," said Dr. Rav Kumar, Vice President, R&D, GSK.

Since June 2015, when CTO announced GSK's successful use of the CTO Streamlined System, 16 other clinical studies have been reviewed or are pending review through the System.

From left to right: Rav Kumar, Vice President, R&D, GlaxoSmithKline (GSK); Daiene Vernile, MPP and Parliamentary Assistant to the Ontario Minister of Research and Innovation; Susan Marlin, President and CEO, CTO; Leslee Thompson, then-Chair, Council of Academic Hospitals of Ontario; Arthur Slutsky, Chair, Board of Directors, CTO.

THE LAUNCH

The province-wide CTO Streamlined System was formally launched before an audience of over 400 members of the clinical research community at the CTO 2015 Clinical Trials Conference in Toronto on March 4, 2015.

The announcement was made by Daiene Vernile, Member of Provincial Parliament (MPP) and Parliamentary Assistant to The Honourable Reza Moridi, Ontario Minister of Research and Innovation.

"The new CTO Streamlined System is a more nimble, efficient approach, while maintaining the highest ethical standards for participant protection," said Parliamentary Assistant Vernile. "Streamlining ensures more trials will come to Ontario, and that's a good thing."

Taking the podium to support the announcement were Dr. Rav Kumar, Vice President, R&D, GlaxoSmithKline (GSK), and Leslee Thompson, then-Chair, Council of Academic Hospitals of Ontario (CAHO).

"By improving speed and reducing costs of clinical trials in multiple locations, streamlining will enhance the environment for clinical trials and ensure that more trials come to Ontario," said Ms. Thompson. She said CAHO's 24 member hospitals intend to use the System.

GOING GLOBAL

The Ontario launch of the CTO Streamlined System was followed by an international announcement at the 2015 BIO International Convention in Philadelphia on June 16, 2015.

In making the announcement, Susan Marlin, President and CEO, CTO, shared news that GSK had successfully used the new system to receive ethics approval for a multi-centre study (see page 4 for details).

Pfizer Canada is also embracing the CTO Streamlined System. Dr. Ghislain Boudreau, Vice President, Public Affairs, Pfizer Canada, called it an important day for clinical trials in Ontario.

"The CTO Streamlined System is going to enrich the clinical trials environment in Ontario and open the door to more clinical trial activity in this province. We would like to express our support for the new system among the many advantages that Ontario offers as a location to conduct clinical trials."

The launch of the CTO Streamlined System generated national and international media coverage. Many clinical research organizations posted the news on their websites. Social media was buzzing with partner support.

Building the CTO College of Reviewers

Volunteer reviewers play an essential role in the CTO REB Qualification process. This past year, 12 experienced members of Ontario's research ethics community joined the CTO College of Reviewers.

Qualification reviews are carried out by two reviewers, an auditor and CTO staff. The review team spends two days on site with REB personnel, reviewing documents and conducting interviews to assess the REB and its operations against the CTO REB Qualification Checklist.

We thank the dedicated members of the College of Reviewers for participating in site visits and contributing their expertise. With each visit, CTO learns more about the remarkable commitment and capabilities that exist to protect research participants in Ontario.

CTO Stream goes live

Core to the CTO Streamlined System is CTO Stream, a web-based electronic platform for coordinating research ethics reviews. CTO Stream was tested and finalized early this year and launched in March 2015.

Developed in partnership with Infonetica Ltd, CTO Stream enables research ethics review, document management, and communication between multiple institutions and REBs. All studies employ the same user-friendly interface and REB application forms.

CTO Stream is designed for any multi-site clinical research. We also offer local use of the system on a fee recovery basis. Having a common system across Ontario for local reviews will further harmonize processes.

Signing on research sites

Once a study protocol is approved through the CTO Streamlined System, sites wishing to take part in the trial can get going—provided they have a participation agreement with CTO. So far, more than 40 research sites have signed agreements and can join studies approved through CTO. A list of participating sites can be found on our website.

Common forms, policies and procedures

CTO continues to develop policies, procedures, tools and education to support the CTO Streamlined System. We have created a common set of application forms for research ethics review, based on common elements identified through a national survey of forms, and advice from the CTO Forms Working Group composed of REB operations experts from across Ontario.

CTO has also developed a standard informed consent form for clinical trials. This template can be used by researchers submitting studies to the CTO Streamlined System. It is a broader version of a harmonized consent form for oncology trials that was created by the Ontario Cancer Research Ethics Board, NCIC-Clinical Trials Group and British Columbia Cancer Agency. CTO is grateful to the 'CTO Qualified' REBs and CTO advisory groups that provided their expertise and feedback on this template.

Training and information

To date, CTO has hosted 11 webinars introducing the CTO Streamlined System and providing essential information to the clinical research community. More than 400 people from industry, REBs and institutions have attended these sessions. We have also created informational handouts describing key components of the System. User manuals and training for CTO Stream are being developed, as are standard operating procedures for REBs using the web platform.

CONGRATULATIONS TO 'CTO QUALIFIED' REBs

Baycrest Research Ethics Board
Hamilton Integrated Research Ethics Board
Holland Bloorview Research Ethics Board
Ontario Cancer Research Ethics Board
Ottawa Health Science Network Research Ethics Board
Queen's University Health Sciences and Affiliated Teaching Hospitals 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

STREAMLINING AND HARMONIZING OTHER PROCESSES AND PLATFORMS

CTO worked on a number of other initiatives this past year that will also help to streamline, harmonize and improve the clinical trials environment.

1 Model Clinical Trials Agreement

CTO has continued to follow this important issue and remains supportive of national efforts to create a model agreement for use across studies. In addition to tools like the model contract, CTO will be exploring mechanisms to streamline the contract finalization process across multiple institutions.

2 REB Standard Operating Procedures

The Canadian REB standard operating procedures (SOPs) developed by the Network of Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB) are a critical resource to REBs in Ontario and to the CTO REB Qualification process. CTO provided direct support to finalize the SOPs, and for translation into French. Making these SOPs available will contribute to the adoption and maintenance of best practices across multiple REBs.

FUTURE ACTIVITIES INCLUDE:

- Maximizing engagement in the CTO Streamlined System to make Ontario a leading jurisdiction for efficient and high-quality ethical review
- Streamlining clinical trial agreements and other processes to support efficient contract review for multi-centre clinical research
- Working with research sites to identify and implement programs to support improved site performance
- Continuing to develop best practices, toolkits and education/training resources to support efficient start-up and conduct of clinical trials in Ontario
- Developing user manuals and training for using CTO Stream.

2 ENGAGING PARTICIPANTS AND THE PUBLIC

Clinical trials could not exist without volunteer participants. It is crucial for patients and the public to be informed about the benefits of participating in clinical trials, as well as the social value of clinical trials. This past year saw an increased focus at CTO on participant and public engagement.

Why do we see this as a key part of our mission? Patients need to be aware that clinical trials are an option so that they can make informed decisions about participating. Additionally, greater public

engagement can enrich clinical trials. Patients and the public can serve an important role in advising how to do trials better, how to communicate information about trials, and how to design trials in a way that supports participant recruitment and retention.

In recent months, CTO has been working to identify areas where we can make a meaningful contribution to the participant engagement process. A number of steps have helped to lay the groundwork for future activities.

Learning more, sharing ideas

At the CTO 2015 Clinical Trials Conference in March, participant engagement was the topic of a special session and a highly-productive workshop, with panelists offering professional and personal perspectives about the roles of participants and the public in clinical trials.

In May 2015, we organized a one-day workshop on patient and participant engagement. Attended by representatives from patient organizations and health charities, the event was aimed at understanding perceptions of clinical research and trials. Another goal was to learn more about the tools and resources that are available—and what else may be helpful. Attendees shared ideas and examples of engagement in clinical research that are being used to inform CTO programming.

Engaging experts, conducting research

This year, CTO hired two patient engagement advisors to help us develop a framework for participant engagement. A landscape review of strategies for recruitment and retention of clinical trial participants was completed in May 2015. This review indicated the need to take into account the perspective of both the research participant and the health care provider. It also showed the importance of tailoring approaches to specific trials and participant populations.

CTO is delighted to have formed a partnership this year with the British Columbia Clinical Research Infrastructure Network (BCCRIN). Together, we are working on an opinion survey to gain insight into public perceptions and knowledge of clinical trials. The survey was carried out in Ontario and B.C. in summer 2015 by Ipsos Reid. Results will provide valuable information to guide CTO's activities.

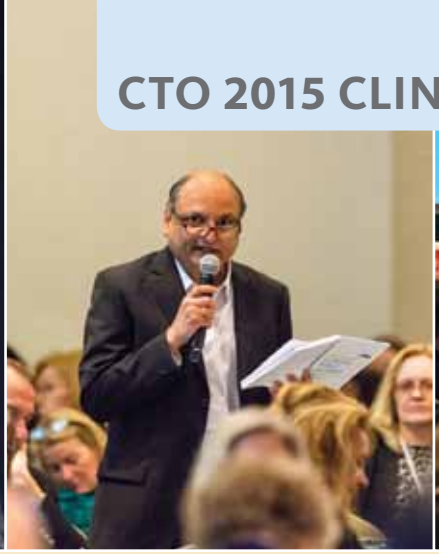
Raising public awareness about trials

CTO continues to spotlight different members of the community who make clinical trials happen. Our Community Spotlight website series profiled a renowned clinician-researcher, a senior research administrator, and a member of the research ethics community. We also featured volunteers, who play such an indispensable role in clinical trials. One story profiled a mother who reflected on her young son's experience in clinical trials. Another featured a breast cancer survivor who took part in a clinical trial 26 years ago.

FUTURE ACTIVITIES INCLUDE:

- Implementing programming to support public engagement in clinical trials
- Actively involving patients and the public in CTO activities
- Increasing public awareness of clinical trials
- Supporting health care providers.

CTO 2015 CLINICAL TRIALS CONFERENCE



Our annual conference, held in Toronto on March 4-5, 2015, attracted more than 400 members of the clinical research community. The focus was on ways to enhance the clinical trials environment in Ontario and in Canada. Once again, this event was an opportunity to hear from a wide range of stakeholders. Some of the topics covered:

- Building a global system for excellence in clinical research
- Developments in the clinical trials environment in Canada and Ontario
- From the frontlines—investigator and investigative site experiences
- Participant engagement in clinical trials.

Kicking off the plenary day was the announcement of the new CTO Streamlined Research Ethics Review System. Daiene Vernile, Member of Provincial Parliament (MPP) and Parliamentary Assistant to The Honourable Reza Moridi, Ontario Minister of Research and Innovation, officially launched the CTO Streamlined System. Leslee Thompson, then-Chair, Council of Academic Hospitals of Ontario (CAHO), and Dr. Rav Kumar, Vice President, R&D, GlaxoSmithKline (GSK), supported the announcement.

As the conference got underway, Dr. Robert Bell, Ontario Deputy Minister of Health and Long-Term Care, delivered opening remarks. There were then lively roundtable discussions and presentations about opportunities for making Ontario a more attractive place for world-leading clinical research. Also on the agenda were two focused workshops; one explored opportunities and challenges in recruiting patients and using patient data, while the other covered the new CTO Streamlined System and looked at streamlining experiences elsewhere.

CTO published a Conference Digest which captures key discussions and themes from the event.

WHAT PEOPLE SAID

"An opportunity to see research leaders working collaboratively towards solving the biggest problems facing clinical research."

"One of the first conferences I have attended where I felt every single topic was relevant to my line of work."

"Probably the best, most organized, timely conference I have ever attended."

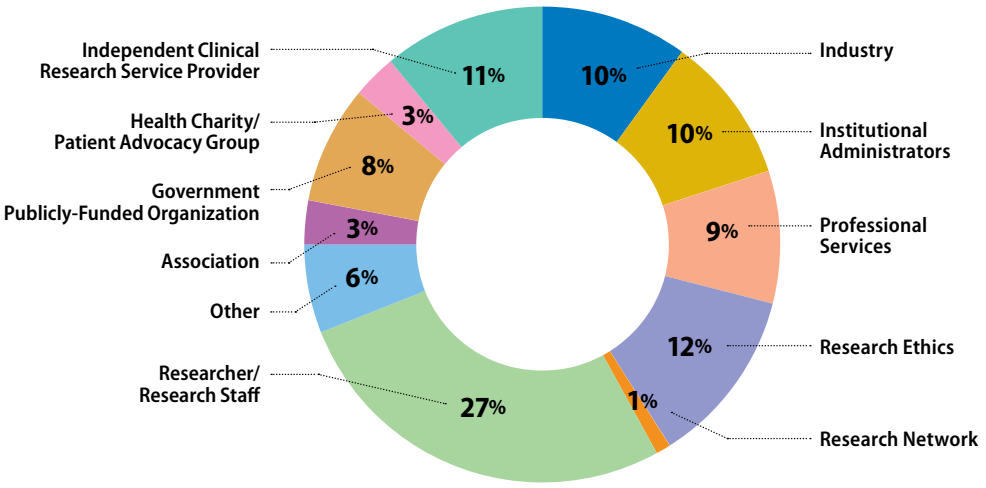
AT A GLANCE

400+
attendees

40
speakers

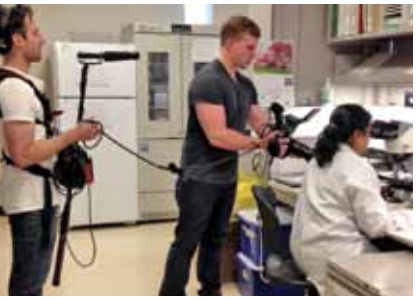
5,136
website visits

WHO ATTENDED



3 PROMOTING ONTARIO AND ATTRACTING INVESTMENT

Ontario has tremendous clinical research strengths, including top researchers, established networks and high-quality research infrastructure. We have a centrally-managed public health care system, competitive regulatory environment and diverse population. And now, Ontario has something new to offer: CTO's Streamlined Research Ethics Review System. These advantages need to be showcased to attract more clinical trials—bringing the benefits of new treatments, investment and high-quality employment. And that's exactly what CTO is doing.



CTO video shoot

CTO is working hard to promote Ontario's clinical trial capacities and to engage with decision-makers investing in clinical trials to help them understand the strategic opportunities that Ontario offers to their business. We interact with industry, private providers and companies new to conducting clinical trials in Ontario. Our industry advisory group, chaired by Dr. Rafi Hofstein, provides expertise and advises on clinical trials activity in Ontario. CTO is also finalizing a metrics and evaluation program that will help us keep abreast of trends in Ontario's clinical trials environment. Listed below are some of CTO's activities in 2014-15 that are increasing awareness of Ontario's clinical trial strengths.

Hosting a clinical trials conference

CTO hosted its second Clinical Trials Conference on March 4-5, 2015. The conference is a setting for vibrant discussion about challenges and opportunities faced by the clinical trial sector. It engages stakeholders in strengthening and promoting Ontario as a location for clinical trials. For more about the conference, see page 9. A Conference Digest, published after the event, shows the opportunities that exist to make Ontario a preferred location to conduct clinical trials and attract more investments.

Getting industry support and buy-in

CTO's launch of the Streamlined System has received high-profile industry support. Dr. Rav Kumar, Vice President, R&D, GlaxoSmithKline (GSK), was an early and enthusiastic supporter of the new 'streamlined' approach at the Ontario launch. GSK was the first industry sponsor to use the system to receive ethics approval. The international launch of the Streamlined System was supported by Dr. Ghislain Boudreau, Vice President, Public Affairs, Pfizer Canada. Dr. Boudreau took part in the announcement.

News of the System's launch received widespread media coverage. CTO's press release captured interest from the U.S., U.K., Japan, Germany, India, Australia and Hong Kong, to name a few places. CTO was featured in numerous trade and specialty media outlets, including Biotechnology Focus, PharmaIQ, Applied Clinical Trials, BioPortfolio.com, PharmExec.com, Drug Today Online, and the Toronto Region Board of Trade's OnBoard Magazine.

CTO's new Streamlined System was highlighted in Ontario's 2015 Burden Reduction Report. The Building a Better Business Climate for Ontario: 2015 Burden Reduction Report featured 28 initiatives across government that are "modernizing services and making it easier for businesses to succeed."

Showcasing Ontario's strengths

In 2015, CTO promoted Ontario's clinical trial advantages at various national and international conferences. For instance, CTO was an exhibiting partner in the Ontario Pavilion at the BIO 2015 International Convention. This was an amazing opportunity to explain and promote the advantages of the new CTO Streamlined System and to reach out to companies not yet conducting clinical trials in Ontario. As a participant in the Ontario Pavilion, CTO was seen as a valuable part of the pipeline that brings innovations and investments to Ontario.

CTO presented in 2015 to Ontario's International Investment Development Representatives (IIDR). These representatives promote Ontario in the U.S., European Union (U.K., Germany and France) and Asia (China, India, Japan and Korea).

We also added to our collection of promotional materials. At BIO 2015, CTO released our new video, Why Ontario for Clinical Trials. This high-quality video informs industry about the advantages of conducting clinical trials in Ontario. It features interviews with industry leaders, clinician-researchers and other experts. Also in 2015, CTO created a new brochure, Clinical Trials: The Ontario Advantage, which lists top reasons for doing clinical trials here. Finally, CTO has redesigned its website to better meet the needs of different audiences and promote Ontario. We increasingly use social media to interact with audiences and enhance awareness of Ontario's clinical trial capabilities.

FUTURE ACTIVITIES INCLUDE:

- Informing industry about the advantages of conducting clinical trials in Ontario and in Canada
- Building recognition and support for CTO's vision, mandate and value
- Explaining and promoting the benefits of CTO initiatives to improve the clinical trials climate
- Hosting a third annual clinical trials conference.

"Ontario is an ideal location for clinical trials because of our leading researchers and clinicians, established networks and high-quality research infrastructure. Now, with a new streamlined approach for ethical review and oversight, Ontario will be an even more globally attractive place to conduct clinical trials."

The Honourable Reza Moridi
Ontario Minister of Research and Innovation

"The CTO Streamlined System is going to enrich the clinical trials environment in Ontario and open the door to more clinical trial activity in this province. We would like to express our support for the new system among the many advantages that Ontario offers as a location to conduct clinical trials."

Ghislain Boudreau
Vice President, Public Affairs, Pfizer Canada

"I've been in research administration for a long time, so I've seen lots of initiatives to harmonize clinical research processes start and stop. The CTO Streamlined Research Ethics Review System is one that has actually come to fruition. The fact that we now have a province-wide streamlined ethics review system is impressive. It's a positive thing for research in Ontario."

Katie Porter
Director, Research Administration, Hamilton Health Sciences

"By improving the speed and reducing the costs of clinical trials in multiple locations, the CTO Streamlined Research Ethics Review System will enhance the environment for clinical trials and ensure that more trials come to Ontario. Clinical trials are integral to the research discovery process and play a key part in the scientific and business models in many of our member hospitals. The Council of Academic Hospitals of Ontario (CAHO) recognizes the importance of having a streamlined review system to not only expedite reviews but also to provide a harmonized process."

Catherine Zahn
Chair, Council of Academic Hospitals of Ontario (CAHO) and President and CEO, Centre for Addiction and Mental Health

"GSK is very happy to work with CTO and to participate in the Streamlined System. It will make timelines for our trials faster, it will simplify things and it will make Ontario a lot more competitive. Congratulations to CTO, and thank you for helping to make Ontario more competitive, and helping all of us to make Canada a lot more competitive when it comes to clinical trials."

Rav Kumar
Vice President, R&D, GlaxoSmithKline (GSK)

"As one of Ontario's research-intensive hospitals, we thought we should be part of the CTO Streamlined System and be involved in reviewing studies province-wide. I'm pleased that we took part in the CTO Qualification process. It's a good review of your own operation. It makes you think about how you are doing things and are you doing the best job possible. It ensures that you have procedures that are appropriate in relation to standards and guidelines in Ontario, Canada and the U.S."

Albert Clark
Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

Ontario's investment in CTO has provided a focal point and catalyst for our stakeholder communities to actively engage in improving the clinical trials environment in Ontario.

Over the past year, CTO has continuously connected with the community and increased the number of partnerships and collaborations.

CTO is now an important component of the life sciences sector in Ontario. Collaborating with Ontario-based organizations to strengthen and promote this sector is critical to attracting more investment to the province. CTO has developed a close working relationship with Life Sciences Ontario (LSO). We are also part of a new initiative on the scene called TO Health! which is focused on creating a single voice for the Toronto Region Human Health & Science cluster.

Another way CTO interacts with the life sciences sector is through the new CTO Streamlined System. Several organizations in the sector are now using and benefiting from this ethics review process. The system will be employed for projects funded through MaRS EXCITE and the Ontario SPOR SUPPORT Unit's (OSSU) IMPACT Awards. Additionally, multi-centre evaluation projects funded through the HTX "REACH" program are being reviewed through the CTO System.

CTO is also one of the Ontario SPOR SUPPORT Unit's 12 research centres—another way in which we are supporting clinical trial conduct and patient engagement.

Connecting provincially, nationally and internationally

We partner with national organizations and with other provinces in Canada. These partnerships strengthen the clinical trials environment across the country and bring additional benefits to Ontario. This past year, CTO was excited to begin a partnership with the BC Clinical Research Infrastructure Network (BCCRIN). It is off to a strong start with a collaboration involving a public opinion survey about clinical trials, conducted in summer 2015 in Ontario and B.C.

CTO continues to collaborate with national organizations such as Canada's Research-Based Pharmaceutical Companies (Rx&D) and Canada's Medical Technology Companies (MEDEC) to enhance the clinical trials environment. Ms. Marlin serves as a member of the advisory committee of the Canadian Clinical Trials Coordinating Centre (CCTCC), which was created to implement an action plan to strengthen and improve clinical trials in Canada and to streamline processes for companies and researchers.

CTO IS PLEASED TO BE PARTNERING AND WORKING WITH THESE AND OTHER ORGANIZATIONS:

Alliance for Clinical Research Excellence and Safety (ACRES)
BC Clinical Research Infrastructure Network (BCCRIN)
Canada's Medical Technology Companies (MEDEC)
Canada's Research-Based Pharmaceutical Companies (Rx&D)
Canadian Association of Research Ethics Boards (CAREB)
Canadian Clinical Trials Coordinating Centre (CCTCC)
Council of Academic Hospitals of Ontario (CAHO)
Council of Ontario Faculties of Medicine (COFM)
HealthCareCAN
Health Charities Coalition of Canada
Health Technology Exchange (HTX)
Industrial Biotechnology Association of Canada (BIOTECanada)
Institute for Clinical Evaluative Sciences (ICES)
Life Sciences Ontario (LSO)
MaRS EXCITE
Network of Networks (N2)
Ontario Brain Institute (OBI)
Ontario Cancer Research Ethics Board (OCREB)
Ontario Council on University Research (OCUR)
Ontario Institute for Regenerative Medicine (OIRM)
Ontario SPOR SUPPORT Unit (OSSU)
TO Health!

From left to right: Rob McMaster, Chair, BCCRIN; Heather Harris, Director, Operations, BCCRIN; Susan Marlin, President and CEO, CTO; Arthur Slutsky, Chair, Board of Directors, CTO.

In the past year, CTO has also worked closely with the Canadian Association of Research Ethics Boards (CAREB) and the Network of Networks (N2) to support excellent initiatives already underway in the community that help clinical research. CTO was involved in the review of the CAREB and N2 REB standard operating procedures, released in fall 2014. Translation of the English-language documents into French was funded by CTO. The Canadian REB SOPs are specific to ethics boards that review health sciences research and are compliant with applicable Canadian and U.S. regulatory and ethics guidance criteria.

Beyond our borders, CTO recently entered into an international relationship with the U.S.-based Alliance for Clinical Research Excellence and Safety (ACRES), a multi-sector non-profit dedicated to excellence in clinical research. Our cross-border partnership with ACRES focuses on working together to address the global challenges facing the conduct of clinical trials and the development of global therapies and health-related research endeavours. It is the first time that ACRES has entered into a strategic alliance with a provincial organization in Canada. CTO and ACRES have a common interest in advancing clinical research to improve the development and delivery of medical therapies. We will share information and collaborate in areas of mutual interest that may include streamlining global ethical review processes and regulatory innovations, site performance, and patient and public engagement in research.

Interacting in person and online

Community engagement also takes place through hosting of the CTO conference. This event, held in March 2015, advanced discussions about the changing clinical research ecosystem and Ontario's place in it. (See page 9 for more details.) CTO also interacts with the community at other conferences and events, including BIO 2015. Ms. Marlin presented at the Canadian Association of Research Ethics Board's CAREB-ACCER 2015 National Conference and AGM, and at the CARA 2015 Annual Conference, hosted by the Canadian Association of Research Administrators. CTO had meetings throughout the year with institutions, industry, clinical trial service providers, investigators/investigator networks, government, innovation partners, participant/patient groups, and provincial, national and international initiatives.

CTO has also increased its engagement with stakeholders on social media, including with groups such as MEDEC, Rx&D, MaRS EXCITE and companies that interact with CTO. Readership is increasing for our e-newsletter, Phase Next, which promotes CTO activities and continued stakeholder engagement.

As a stakeholder-led organization, collaborations and community engagement come naturally to CTO. Our flagship program, the CTO Streamlined System, was built as a collaborative effort with our hospital, university, REB, industry, private provider and other communities supporting clinical research. The clinical research community continues to make extraordinary contributions to CTO programming.

CTO's e-newsletter, Phase Next.

WE THANK THE MEMBERS OF THE FOLLOWING CTO GROUPS AND

Research Ethics Review Advisory Group

Nancy Camack	*Director, Clinical Research Administration, Ottawa Hospital Research Institute*
Albert Clark	*Chair, Health Sciences & Affiliated Teaching Hospitals Research Ethics Board, Queen's University*
Michael Coughlin	*Chair, Tri-Hospital Research Ethics Board*
Sharon Freitag	*Director, Research Ethics Office, St. Michael's Hospital*
Dianne Godkin	*Senior Ethicist, Trillium Health Partners*
Dario Kuzmanović	*Research Ethics Manager & Analyst, Office of Research Ethics, University of Toronto*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
David Mazer	*Professor of Anesthesia, University of Toronto, St. Michael's Hospital*
Keitha McMurray	*Executive Director, Research Integrity & Clinical Research Operations, Sunnybrook Health Sciences Centre*
Kelly Morris	*Manager, Research Ethics, St. Joseph's Care Group*
Anita Sengar	*Operations Manager, Research Ethics Board, University Health Network*

College of Reviewers

Erika Basile	*Director, Research Ethics, Western University*
Albert Clark	*Chair, Health Sciences & Affiliated Teaching Hospitals Research Ethics Board, Queen's University*
Alison M. Collins-Mrakas	*Senior Manager & Policy Advisor, Office of Research Ethics, York University*
Padraig Darby	*Chair, Research Ethics Board, Centre for Addiction and Mental Health*
Sharon Freitag	*Director, Research Ethics Office, St. Michael's Hospital*
Joseph Gilbert	*Chair, Health Sciences Research Ethics Board, Western University*
Jack Holland	*Chair, Oncology REB Review Panel, University Health Network*
Alexander Karabanow	*Manager, Clinical Research Services, University Health Network*
Dario Kuzmanović	*Research Ethics Manager & Analyst, Office of Research Ethics, University of Toronto*
Ilde Lepore	*Ethics Officer, Faculty of Medicine, Research, Graduate Studies and IRB, McGill University*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Raphael Saginur	*Chair, Ottawa Health Science Network Research Ethics Board*
Suzette Salama	*Associate Clinical Professor, Department of Medicine, McMaster University and Chair, Hamilton Integrated Research Ethics Board*
Francine Sarazin	*Vice-Chair, Ottawa Health Science Network Research Ethics Board*
Richard Sugarman	*Chair, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Alison van Nie	*Research Ethics Officer, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*

COMMITTEES FOR THEIR DEDICATION AND CONTRIBUTION:

Participation Agreement Working Group

Tamara Birkenheier	*Senior Legal Counsel, Sunnybrook Health Sciences Centre, Sunnybrook Research Institute*
David Bruce	*Legal Counsel & Associate Director (Research Contracts), Industry Partnerships & Innovation Park, Queen's University*
Cheryl Litchfield	*Manager, Grants and Contracts, Lawson Health Research Institute*
Cindy Lu	*Counsel, Research, St. Michael's Hospital*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Keitha McMurray	*Executive Director, Research Integrity & Clinical Research Operations, Sunnybrook Health Sciences Centre*
Paul McPherson	*Director, Grants, Contracts and Ethics Review Services, University Health Network*
Katie Porter	*Director of Research Administration, Hamilton Health Sciences Corporation*
Howard Simkevitz	*General Counsel & Privacy Officer, Ontario Institute for Cancer Research*

Non-Clinical Trials Forms Working Group

Erika Basile	*Director, Research Ethics, Western University*
Albert Clark	*Chair, Health Sciences & Affiliated Teaching Hospitals Research Ethics Board, Queen's University*
Dianne Godkin	*Senior Ethicist, Trillium Health Partners*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Lorelei Nardi	*REB Program Manager, The Hospital for Sick Children (formerly)*

Industry Advisory Group

Tracey Allin	*Regional Research Manager, Medicines Development Unit, Diabetes & Biomedicines, Eli Lilly Canada Inc.*
Nita Arora	*Regional Head, Clinical Operations North America, Hoffmann-La Roche*
Shurjeel Choudhri	*Senior Vice President and Head, Medical and Scientific Affairs, Bayer Inc.*
Wendy Gibson	*Director, Site Management & Monitoring Canada, AstraZeneca*
Raphael Hofstein	*President and Chief Executive Officer, MaRS Innovation*
Chantal Lacasse	*Senior Clinical Operations Manager, Medical Division, Chef Principale, Operations cliniques, Division Medicale, AbbVie Corporation/Corporation AbbVie*
Brian Lewis	*President and Chief Executive Officer, MEDEC*
Mark Lundie	*Director, Medical Affairs, Rare Diseases, Pfizer Canada Inc.*
Neil Maresky	*Vice President, Scientific Affairs, AstraZeneca*
Barbara Nicholls	*Director, Clinical Development - Therapy Area/Respiratory, ID, CV/MET, GlaxoSmithKline (GSK)*
Stephanie Ounpuu	*Director, Clinical Operations, Boehringer Ingelheim (Canada) Ltd./Ltée*
Doron Sagman	*Senior Medical Director, Eli Lilly*
Clive Ward-Able	*Executive Director, R&D, Amgen*
James Wilson	*President, Brancorth Medical Inc.*

STATEMENT OF FINANCIAL POSITION

as at April 30, 2014 and April 30, 2015

	2015	2014
ASSETS		
Current assets		
Cash	**$ 264,754**	$ 281,710
Guaranteed investment certificates	**10,014**	10,021
HST rebate recoverable	**39,465**	46,481
Amounts receivable	**221**	7,035
Prepaid software costs	**160,543**	395,712
Prepaid rent	**58,225**	120,051
Prepaid insurance and other costs	**24,671**	11,060
	$ 557,893	$ 872,070
LIABILITIES AND NET ASSETS		
Current liabilities		
Accounts payable and accrued liabilities	**$ 64,242**	$ 55,611
Deferred contributions	**485,278**	807,189
	549,520	862,800
Net assets		
Unrestricted	**8,373**	9,270
	$ 557,893	$ 872,070

CTO Team

OUR TEAM

Susan Marlin *President and CEO*
Manal Siddiqui *Manager*
Erin Bell *Program Coordinator*
Matthew D'Ascanio *Program Coordinator*
Elena Trebinjac *Program Administrator*
Jessa Gill *Project Manager, e-REB IT System*
Gwen Penvern *Web Application Developer*
Margaret Polanyi *Senior Communications Specialist (Part-time)*
Sean Power *Communications Specialist (Part-time)*
Anita Sengar *Lead Auditor, REB Qualification Program*
Sheri Webb *Auditor, REB Qualification Program*
Chris Riddle *Governance Support (Part-time)*

COMMUNITY EXPERTS

Multi-Centre Research Ethics Review
Janet Manzo *Executive Director, Ontario Cancer Research Ethics Board*

IT Infrastructure
Lam Pho *Director of Information Technology, NCIC Clinical Trials Group/ Director of Information Technology, Canadian Cancer Clinical Trials Network*

Legal Agreements and Contracts
Cheryl Litchfield *Manager, Grants and Contracts, Lawson Health Research Institute*

FORMER TEAM MEMBERS

Dawn Richards *Participant Engagement Advisor (Part-time)*
Don Willison *Participant Engagement Advisor (Part-time)*
Levan Khutsishvili *Web Application Developer*
Delilah Ofosu-Barko *Auditor, REB Qualification Program*
Kim Riley *Executive Assistant (Part-time)*
Kim Brown *Administrative Assistant (Part-time)*

BOARD OF DIRECTORS

Arthur Slutsky *(Chair) Vice-President, Research, St. Michael's Hospital*

Mark Lundie *(Vice-Chair and Secretary) Director, Medical Affairs, Rare Diseases, Pfizer Canada Inc.*

Michael Owen *(Treasurer) Vice-President, Research, Innovation & International, University of Ontario Institute of Technology*

Raphael Saginur *Chair, Ottawa Health Science Network REB*

James Wilson *President, Brancorth Medical Inc.*

Clive Ward-Able *Executive Director, R&D, Amgen*

Raphael Hofstein *President and Chief Executive Officer, MaRS Innovation*

Michael Wood *Director, Research & Innovation, North York General Hospital*

Anne Ellis *Associate Professor & Chair, Division of Allergy & Immunology, Department of Medicine, Queen's University*

MEMBER REPRESENTATIVES

Council of Academic Hospitals of Ontario (CAHO)
Karen Michell *Executive Director*

Canada's Medical Technology Companies (MEDEC)
James Wilson *President, Brancorth Medical Inc.*

Canada's Research-Based Pharmaceutical Companies (Rx&D)
Alison Sargent *Executive Director, The Rx&D Health Research Foundation*

Industrial Biotechnology Association of Canada (BIOTECanada)
Alison Vanlerberghe *Director, Market Access, Celgene Corporation*

Council of Ontario Faculties of Medicine (COFM)
Alison Buchan *Vice-Dean, Research and International Relations, Faculty of Medicine, University of Toronto*

Ontario Council on University Research (OCUR)
Michael Owen *Vice-President, Research, Innovation & International, University of Ontario Institute of Technology*

CLINICAL TRIALS ONTARIO

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