CLINICAL TRIALS ONTARIO

ANNUAL REPORT 2013-14

CONTENTS

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Hard copies are available upon requests directed to **info@ctontario.ca**.
The report in its entirety can be downloaded by visiting **www.ctontario.ca**.

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WHO WE ARE

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 by the Government of Ontario. Our mandate is to provide a streamlined approach to conducting multi-centre clinical trials in Ontario, while maintaining the highest ethical standards for participant protection.

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

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

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

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

EXECUTIVE MESSAGE

Arthur Slutsky
Chair, Board of Directors

Susan Marlin
President and CEO

Ontario is rich with expertise and experience when it comes to clinical research—and now, this province is about to become an even more attractive place to conduct clinical trials.

The reasons to do trials in Ontario and Canada are many; world-class researchers, established networks, high-quality research infrastructure. Clinical trial sponsors are also drawn by our centrally managed public health care system and diverse population.

Clinical Trials Ontario (CTO) is implementing a new approach that will make Ontario all the more appealing. We are streamlining the research ethics review process to improve the speed and reduce the costs of doing multi-centre clinical trials, while maintaining the highest ethical standards.

The benefits of clinical trials are indisputable. They improve people's health and quality of life through new treatments and devices, and enhanced diagnostic tools. Clinical trials also stimulate the economy through direct investments in research facilities, job creation and attracting top talent.

CTO is led and supported by the community of stakeholders involved in Ontario's clinical trials sector. We are dedicated to making this province a preferred location for global clinical trials. Ontario has the capacity to take on more clinical research. CTO's streamlined approach and programs can help Ontario to better compete for global trials.

The new CTO Streamlined Research Ethics Review System will support a single ethical review for multi-centre clinical trials. The single review can be done by any 'CTO Qualified' research ethics board (REB) in Ontario, on behalf of multiple institutions participating in the same research study. This approach is expected to provide significant benefits to sponsors, investigators, institutions and REBs by harmonizing processes and reducing the time and effort required to initiate research across multiple sites.

We are delighted to report that the Streamlined System is coming on-line. Institutions and REBs are coming forward to 'qualify' to take part in the system. This fall, CTO will be piloting a web-based information technology platform —called CTO Stream—that is core to the streamlined approach. In just a few months, the first clinical trials will be reviewed through the Streamlined System.

As you will read in this report, CTO is also moving forward with other initiatives that will help Ontario and Canada to attract more clinical trial investment.

The progress we are making is thanks to the cooperation and commitment of the clinical research and research ethics communities, both public and private. The entire sector is coming together to advance clinical trial activity, provincially and across the country. Only two years after the official launch of CTO, we are well on the way to achieving our goals.

We thank the Government of Ontario for supporting the work of CTO. We recognize and appreciate the significant investment Ontario has made in the clinical trials environment and in advancing our innovation economy and health care for Ontarians. We are also grateful to the CTO Board of Directors, our staff, member organizations, stakeholders and wider community for their passion, their determination and their many contributions.

Together, we can help Ontario to capitalize on its clinical research strengths and capture more of the global clinical trials activity—for the benefit of all Ontarians, now and in the future.

YEAR IN REVIEW

Over the past year, CTO has made tremendous progress in advancing its mandate. There were many significant achievements as CTO began to implement core programming that will enable Ontario to leverage its clinical research strengths to attract more clinical trial investment.

KEY ACHIEVEMENTS FROM THE LAST YEAR INCLUDE:

- Developing the CTO Streamlined Research Ethics Review System to support the timely, efficient and effective review of multi-centre clinical research in Ontario
- Implementing the CTO REB Qualification Program to provide an independent review of Ontario REBs planning to participate in the Streamlined System
- Launching the College of Reviewers, made up of experienced volunteers from the REB community who participate in REB Qualification reviews
- Entering a partnership with research software specialist Infonetica Ltd to build a web-based platform that will support the Streamlined System
- Hosting the first-ever CTO 2014 Clinical Trials Conference, and releasing a Conference Digest
- Creating new resources to promote Ontario as an attractive destination for global clinical trials and assist companies looking to conduct clinical trials in Ontario
- Coordinating Ontario's response to the national model Clinical Trials Agreement initiative.

PROGRAMMING

Created in 2012, CTO concentrated in the first year on planning its programming and bringing together stakeholders to discuss opportunities and challenges facing clinical trials in Ontario. Last year, CTO began to put programming in place.

A key focus has been the design and implementation of a Streamlined Research Ethics Review System. This is a more efficient way to provide ethics review and oversight of multi-centre clinical trials in Ontario. CTO has also made strides with other initiatives. Central to everything we do is the crucial input of the clinical research and research ethics communities in Ontario.

STRATEGIC PILLAR 1

Improving the Speed and Reducing the Costs of Multi-Centre Clinical Trials

STREAMLINED RESEARCH ETHICS REVIEW SYSTEM

Streamlining the research ethics review process in Ontario is the immediate priority for CTO. The current approach in Ontario has been to conduct a research ethics review at each and every public institution participating in the same clinical trial. This process can be inefficient and CTO is working to change it.

Over the past year, implementation of a Streamlined Research Ethics Review System has advanced significantly. Several developments have moved us closer to a more efficient, nimble approach that will support any single 'CTO Qualified' Research Ethics Board (REB) in Ontario in providing ethical review and oversight for multiple research sites. It's all part of enhancing the climate for clinical research in Ontario.

Thanks to the expertise and dedication of the clinical research community in Ontario, we have made excellent progress with the two key components of the Streamlined System:

1 REB Qualification Program

We are excited to report that the CTO REB Qualification Program is now open for business and institutions and REBs are coming forward to request qualification reviews. The Qualification Program provides REBs planning to participate in the Streamlined System with an external review of their governance, membership, operations and review procedures. The process is important because it promotes a high level of trust and allows institutions and REBs to feel confident delegating ethical review and oversight.

Launching the Qualification Program

CTO has completed development of the Qualification Program, with expert advice from the CTO Research Ethics Review Advisory Group comprised of REB Chairs and REB Administrators. A successful pilot of the Qualification process was conducted with the Ontario Cancer Research Ethics Board (OCREB) in late 2013. Feedback from OCREB and the Qualification Review Team helped to further develop the Qualification Program.

The Qualification Program uses the CTO REB Qualification Manual as a guide for the review and qualification of REBs. The manual was developed using the

Toronto Academic Health Science Network (TAHSN) REB qualification manual as a starting point. An REB that is to be 'qualified' by the CTO process will be assessed against the CTO REB Qualification Review Checklist, contained in the manual. The requirements reflected in the checklist are informed by regulations, policies and standards applicable to the conduct of clinical trials and health research in Ontario and Canada.

Establishing the CTO College of Reviewers

Qualification reviews are conducted by a team of reviewers who spend up to 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. The CTO Qualification Review Team is comprised of a CTO auditor and members of our newly-established College of Reviewers. Two auditors have been hired to lead the qualification visits. CTO is delighted that a number of experienced members of the REB community have joined the College and we invite others to do so. The College is an excellent example of the community involvement that is so important to the success of CTO activities.

Putting an eREB in place: the CTO staff developing the new platform

With the Qualification Program in place, CTO is reaching out to institutions and REBs across Ontario to participate in the Streamlined System. Qualification reviews are scheduled for the months ahead and CTO looks forward to announcing new 'qualified' REBs. REBs that achieve Qualification status are presented with the new CTO Seal of Qualification, which was created at the request of the community.

2 Delegated Board of Record Review System

CTO has finalized the framework for a delegated board of record model. This model will enable any 'CTO Qualified' REB in Ontario to conduct an ethical review of a multi-centre clinical trial on behalf of multiple research sites across the province.

CTO Stream: a web-based electronic platform

A web-based electronic platform called CTO Stream will support the board of record in providing ethical oversight for multiple research sites across the province, and assist investigators and sponsors conducting multi-centre research in Ontario.

CTO is pleased to be working with Infonetica Ltd, a UK-based research software specialist, to build this eREB platform. Infonetica was chosen after a public request for proposals (RFP) and a rigorous evaluation process that included REB and IT professionals from institutions across the province. CTO Stream will enable research ethics review, document management, and communication between multiple institutions and REBs.

Recognizing the possibility that local REBs and institutions may have an interest in using CTO Stream for single-site reviews, arrangements have been negotiated with Infonetica to enable local REB use.

The CTO eREB Implementation team has worked closely with Infonetica to develop and test the eREB. We thank the researchers and REBs across Ontario who provided feedback. The eREB will be rolled out in Fall 2014.

The CTO registry

Work is underway on the other major component of our IT infrastructure: a registry that will collect and house information relating to REBs/REB offices, research sites and personnel, and sponsors and clinical trials across Ontario. This secure web-based system will link to the CTO Stream, providing functionality beyond what the Infonetica system offers. Personnel from sites and REBs will be able to maintain and access up-to-date information contained in the registry (see page 8 for more).

Common forms, policies and procedures

As the CTO Streamlined System moves forward, thorough consideration is being given to every detail and every step in this new approach.

The REB Application Forms Working Group has worked tirelessly to develop REB application forms for CTO Stream. Building on the work of the Strategy for Patient-Oriented Research (SPOR) – Streamlining

Health Research Ethics Review (SHRER) Committee and the review of multiple forms across Ontario, the CTO Working Group created a set of REB application forms that reflect best-of-class standards. These forms will be further reviewed and tested as CTO Stream develops.

CTO will continue to work with the community in developing policies and procedures that will govern the board of record model. We invited the community to participate in a survey of REB operational practices across Ontario. Information shared in the responses is helping CTO staff and the Research Ethics Review Advisory Group to make key decisions.

Community guidance has been essential in finalizing and implementing the Streamlined System. Three experts from the community have provided leadership: Janet Manzo, Executive Director of the Ontario Cancer Research Ethics Board; Lam Pho, Director of Information Technology at the NCIC Clinical Trials Group; and Anita Sengar, Manager of Research Ethics Board Operations at the University Health Network. They have worked closely with the CTO team, three key advisory groups (Technical/Operations Committee; eREB RFP Evaluation Committee; Research Ethics Review Advisory Group) and others from the research ethics review and clinical trials community in Ontario (see pages 13 and 14 for a listing of committee members).

CTO recognizes the pivotal role that REBs and research teams play in protecting the rights, safety and well-being of research participants. The CTO Streamlined System harnesses the excellent research ethics review and administration capacity across our institutions.

Following completion of the pilot phase over the next months, CTO will formally announce the launch of the Streamlined System.

STREAMLINING AND HARMONIZATION OF ADMINISTRATIVE PROCESSES AND PLATFORMS

CTO continues to engage with others on important initiatives that will improve the clinical trials environment, both nationally and provincially.

1 Model Clinical Trials Agreement

CTO provided support in developing an Ontario response to the model Clinical Trials Agreement (mCTA). This was done in collaboration with the Ontario Council on University Research (OCUR) and the Council of Academic Hospitals of Ontario (CAHO). We were pleased to give input to the national initiative, led by the Association of Canadian Academic Healthcare Organizations (ACAHO), now known as HealthCareCAN. This initiative represents a significant opportunity to reduce the time it takes to finalize clinical trial agreements with sites in the academic sector.

Model Clinical Trials Agreement – Ontario Team

CTO continues to work with others to further identify barriers to the efficient start-up and conduct of clinical trials, and to define areas in which CTO can make an impact.

2 Developing Best Practices, Toolkits and Educational/Training Resources

CTO enthusiastically supports the development of policies, procedures, tools and education to enhance REB review and operational efficiencies. Our first priority has been the creation of standard operating procedures (SOPs) for research ethics review activities at clinical trial sites. REBs must have SOPs in place in order to undergo a CTO Qualification Review. We welcome the recent release of the first set of collaboratively developed, standardized, Canadian REB SOPs, developed by the Network of Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB). CTO reviewed these SOPs during their development. They will be an excellent resource for the REB community.

Opportunities for supporting the continued advancement of quality in research ethics review in Ontario will be sought through the development of a 'community of practice' amongst REBs and REB offices participating in the CTO Streamlined System.

STRATEGIC PILLAR 2

Attracting Clinical Trial Investments to Ontario

An important part of fulfilling our mandate involves drawing on the expertise of CTO's many stakeholders to get a 360 degree view of the clinical trials environment.

CTO connects regularly with sponsors, hospitals, investigator groups, private providers and others to identify ways to support Ontario's clinical research sector and position the province as a preferred location for global clinical trials. To that end, CTO established an industry advisory group in 2014 that allows us to access vital expertise.

Described below are several CTO initiatives that will help Ontario to showcase and leverage its clinical research strengths and attract more clinical trial investments.

Clinical Trials Ontario booth: 2014 BIO International Convention

Creating an asset registry

Work is progressing well on the creation of a CTO registry. This will be a repository for information relating to clinical trials, research sites/institutions, research site personnel, REBs and offices in Ontario. CTO has been consulting closely with stakeholders to determine how best to leverage the registry so that it can help Ontario to capture more clinical trials.

CTO is partnering with others in the development of a national clinical trials asset map.

Tracking clinical trial activity

Earlier this year, CTO formalized an initial set of metrics to be collected to reflect Ontario's current and recent clinical trials activity. CTO engaged SHI Consulting and the Applied Health Research Centre (AHRC) at St. Michael's Hospital to develop a Metrics and Evaluation (M&E) program to track clinical trial activity in Ontario and Canada and benchmark our performance against comparator jurisdictions. The M&E program builds on the work of the CTO Working Group on IT and Performance Metrics as well as an initial framework of metrics that took into consideration a number of metrics initiatives currently underway in the clinical research community (e.g. CAHO, N2, MEDEC, and Rx&D).

CTO's M&E program relies on publicly available data and data provided by organizations outside of CTO. More than 100 external sources of information were considered to capture data on Canada and other jurisdictions. As CTO programming comes on-line, operational metrics will be generated and tracked to assess the success and impact of the programs. CTO intends to communicate the outputs of its data collection with the broader clinical research community.

Promoting clinical trial capabilities

CTO is working hard to increase awareness of Ontario's clinical trial capabilities. This year, we updated and produced new materials promoting Ontario as an excellent location for multi-centre clinical trials. Our new brochure, *This is the Place for Global Clinical Trials*, makes a compelling case for Ontario and Canada as an attractive destination for global clinical trials.

CTO also developed an introductory guide for companies new to conducting clinical trials in Ontario. *Getting Started: Conducting Clinical Trials in Ontario* highlights important resources that can help sponsors and investigators to understand the clinical trials environment. This practical guide points to resources on key topics such as regulatory approval, tax incentives and regional economic development. It was prepared with input from members of the clinical trials community. CTO will be developing additional materials for companies.

The BIO 2014 International Convention, which draws industry leaders from over 60 countries, was a tremendous opportunity for CTO to promote Ontario's clinical trial assets. The CTO Exhibitor Booth in the Ontario Pavilion attracted considerable interest from conference attendees. We also participated in the DIA 2014 50th Annual Meeting, a great place to network and spotlight the advantages that Ontario offers as a clinical trials location.

CTO 2014 CLINICAL TRIALS CONFERENCE

Challenges, Opportunities and Next Steps

Held on February 27, 2014 in Toronto, CTO's first annual Clinical Trials Conference brought together over 200 members of the clinical research community to advance discussions about improving the clinical trials environment in Ontario and in Canada.

The conference was an opportunity to hear perspectives from a wide variety of stakeholders, including industry, hospitals, universities, research ethics, consumer, public and private research communities, and to discuss common concerns. Sessions included:

- Evolving Challenges and Opportunities for Clinical Trials
- Developments in the Clinical Trials Environment: Canada and Ontario
- Challenges and Opportunities in Streamlining Research Ethics Review
- Clinical Trials Participant Engagement and Retention.

In response to overwhelming interest in the conference content, CTO published a *Clinical Trials Conference Digest*. The Digest recalls conversations and highlights key themes from the conference. It is intended to extend the reach of the conference to include members of the community who were unable to attend.

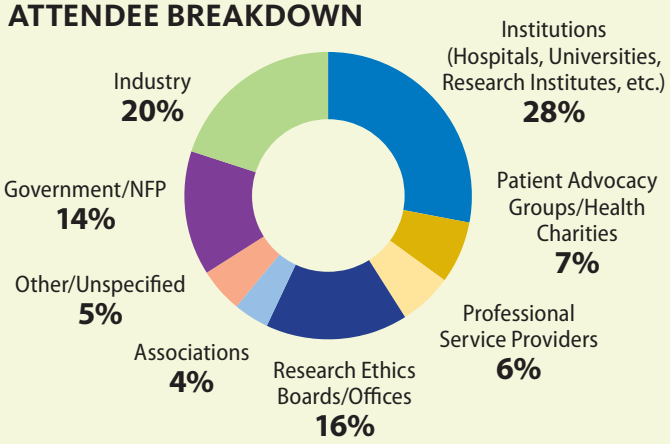
CTO is now planning for the CTO 2015 Clinical Trials Conference on March 4-5, 2015 in Toronto. This two-day event will focus on what's next, and how clinical research continues to evolve. It will include sessions about the Streamlined Research Ethics Review System and participant engagement. Once again, this will be a time for cross-stakeholder conversations. More details and registration information can be found at www.ctoconference.ca.

THE CONFERENCE AT A GLANCE

200+ Attendees **22** Speakers

50 expressions of interest received to become or stay involved in CTO activities after the conference

ATTENDEE BREAKDOWN



COMMENTS FROM ATTENDEES

"A great opportunity to learn about clinical trials in Ontario and the challenges."

"Finally seeing Ontario waking up to the issues that impact on research in Canada."

"The conference was wonderfully organized and the content was very interesting. It was great to be able to learn more about CTO and the progress they have made in the past year."

In February 2014, CTO was proud to host its own conference—a sold-out event with more than 200 participants from industry, research sites, REBs, government and other trials-related organizations (see article on page 9). The enthusiasm of stakeholder communities was clearly evident at this conference, which generated important discussion about how to improve the clinical trial environment in Ontario and in Canada.

Building on the success of this event, CTO will host its second annual conference in Toronto on March 4-5, 2015. This meeting will bring together all of us who care deeply about advancing clinical research in Ontario to focus on what's next, and what else we can do to realize Ontario as a preferred location for clinical trials. The agenda will include sessions dedicated to the Streamlined Research Ethics Review System, and patient engagement and retention.

Efforts to promote Ontario as the place for global clinical trials will intensify in the months ahead as CTO programming evolves. Work has also started on refreshing CTO's website to reflect advancements in our programming and to provide portals for specific audiences.

More broadly, CTO continues to connect with organizations working to advance clinical trial activity, both provincially and nationally.

CTO has played a role, as a member organization, in developing the Ontario SPOR SUPPORT Unit (OSSU), which is implementing Canada's strategy for patient-oriented research to transform Ontario's health system through high-impact, patient-oriented research. We are excited about this new opportunity to further build Ontario's research capacity. Canada's Strategy for Patient-Oriented Research (SPOR) is a collaboration of federal, provincial, and territorial partners dedicated to the integration of research into care.

CTO is also pleased to be working with organizations such as the Network of Networks (N2), HealthCareCAN, Canada's Research-Based Pharmaceutical Companies (Rx&D), the Canadian Institutes of Health Research (CIHR), Health Canada and Industry Canada.

Last spring, CTO was delighted to be on the agenda at meetings of the Canadian Association of Research Ethics Boards (CAREB) and the Canadian Association of University Research Administrators (CAURA). Additionally, CTO was pleased to have our President and CEO, Susan Marlin, invited to join the advisory committee for the newly-formed Canadian Clinical Trials Coordinating Centre (CCTCC), which is a welcome addition to the clinical trials landscape. We look forward to collaborating with the CCTCC, and to continued involvement with organizations in other provinces that are advancing efforts to support clinical trials.

STRATEGIC PILLAR 3

Improving Participant Recruitment and Retention

Volunteers play an indispensable role in clinical research. Clinical trials provide information about effectiveness and safety of new interventions. Successful trials lead to new drugs, devices and procedures that can save lives, enhance quality of life, reduce health care costs and generate more investment in health care.

Many organizations are working to enhance public awareness of the benefits of clinical trials. CTO is identifying ways in which we can make a unique contribution to the overall effort. For instance, this past year, CTO engaged with key patient advocacy groups and other organizations and individuals to begin discussions about approaches to improving participation rates. This has helped to inform a strategy, being developed by CTO, to support the recruitment and retention of research participants.

The issue of participant recruitment and retention was the focus of a full session at the CTO 2014 Clinical Trials Conference. This served as an excellent framing exercise for participant engagement. There was a focus on bringing trials to participants—instead of participants to trials—and educating, informing and empowering patients to understand clinical trials and what it means to be an active participant.

In advance of the conference, CTO convened a Patient Engagement advisory team with representatives from the health charities, patient advocacy groups, and clinical research and industry communities. The team advised on conference content and is contributing to discussions about CTO's strategy for supporting participant recruitment.

In the months ahead, CTO will also be working with partners on other initiatives that advance participant engagement.

"Clinical Trials Ontario (CTO) seeks to find the best care and cures for patients, to attract the best and brightest scientific and clinical talent to Ontario, and to make this province a leading jurisdiction to invest in clinical trials. These trials are a vital part of the health research and discovery process; they ensure that novel therapies are tested in safe and controlled settings, and that the promise of benefit to patients is evaluated and tested. CAHO will continue to support the success of CTO and the advancement of initiatives to improve the clinical research environment in Ontario."

Leslee Thompson *Chair, Council of Academic Hospitals of Ontario (CAHO)*
President and CEO, Kingston General Hospital

"Going through the CTO Qualification process with the Ontario Cancer Research Ethics Board (OCREB) was both eye-opening and stimulating. It is truly two days of walking the walk. On the other side, it has been a delight to be able to give back as a Reviewer within the Qualification process. The Qualification process supports using the diverse expertise and capacity of the research regulatory system to establish a streamlined ethical review process to aid in the rapid deployment of high-quality research activities throughout Ontario. The whole can be greater than the simple sum of the parts."

Richard Sugarman *Chair, Ontario Cancer Research Ethics Board*

"We believe CTO's efforts to streamline the ethics review process into a single provincial process for institutions will ultimately benefit both pharma and institutions, by saving the resources and time that are necessary when there are multiple submissions for the same study. CTO's collaborative approach with industry will ensure that Ontario avoids the pitfalls of other provincial IRBs, and create an environment that will be attractive to more research in Ontario."

Rav Kumar *Vice President, R&D Operations/Business Development, GlaxoSmithKline (GSK)*

"Ontario and Canada have a sophisticated understanding of clinical trials and a public health system that makes it easier to do clinical trials than in many other countries. I think it's a welcome development that there is an initiative to streamline the ethics review process for initiating multi-centre clinical trials in Ontario. It would certainly help to cut down on the administrative work you have to do to get a trial going. This would enhance Ontario's appeal as a place to do multi-centre clinical trials."

Douglas Bradley *Senior Scientist and Clifford Nordal Chair in Sleep Apnea and Rehabilitation Research, Toronto Rehab-University Health Network, and Professor of Medicine and Director of the Division of Respirology, University of Toronto*

"The CTO REB Qualification Program facilitates a consistently high standard of REB review processes across the province; a critically important factor in the development of trust among institutions entering into the delegated REB review model. Researchers and institutions are eager for the implementation of the CTO Streamlined Research Ethics Review System for multi-centre clinical research in Ontario."

Keitha McMurray *Director, Human Research Protections Program, Sunnybrook Health Sciences Centre*

"It is essential that Ontario restore its competitive advantage and be in a position to attract global clinical trials. Having an organization which dedicates itself to that vision is vitally important to our province. CTO has done a terrific job, in a short period of time, of addressing the critical elements of competitiveness. They have also done a terrific job of integrating with and aligning themselves with the life sciences community. CTO has been a valuable resource for LSO, especially when we receive leads for potential clinical trial investments. And Life Sciences Ontario will continue to partner with CTO to position and promote Ontario as a global centre for clinical trials."

Paul Lucas *President and Chair, Life Sciences Ontario (LSO)*

COMMUNITY SUPPORT AND ENGAGEMENT

The momentum we are seeing could not have been achieved without the continued support and engagement of our stakeholder communities. CTO is grateful to the clinical research and research ethics communities who are building and advancing our programming by contributing their expertise, experience and ideas.

Community engagement is an essential thrust for CTO. We draw heavily on expert working groups and committees to provide advice on our evolving programming. Last year, we had 7 working groups and committees, with 57 members from our stakeholder communities serving on these groups. Their participation underlines the dedication that exists in the community to advance programming that will enhance the clinical trials environment in Ontario. CTO thanks all members of these groups (listed below) for their enormous contributions.

The CTO 2014 Clinical Trials Conference was a prime example of CTO's community engagement (see story on page 9). The conference attracted more than 200 members of the clinical research community for a day of discussions about the challenges and opportunities that exist for clinical trials in Ontario and in Canada. We plan to do it again next year.

CTO connects frequently and in a meaningful way with other organizations that represent key stakeholders and share common interests. These include the Canadian Association of Research Ethics Boards (CAREB), Canadian Association of University Research Administrators (CAURA), Life Sciences Ontario (LSO), MaRS Innovation, Ontario Bioscience Innovation Organization and HTX.

In total, CTO conducted over 250 meetings last year (2013-14) with associations; investigators/investigator networks; clinical trial service providers; institutions; industry; government; innovation partners; provincial, national and international initiatives; and participant/patient groups.

Only by working together can we truly improve the clinical trials climate in Ontario and Canada.

We extend our grateful thanks to the members of the following CTO groups and committees for their hard work and huge contributions:

Research Ethics Review Advisory Group

Nancy Camack	*Director, Clinical Research Administration, Ottawa Hospital Research Institute*
Albert Clark	*Chair, Health Sciences and Affiliated Teaching Hospitals REB, 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 Kuzmanovic	*Research Ethics Analyst & Manager, University of Toronto*
C. David Mazer	*Chair, Research Ethics Board, St. Michael's Hospital*
Keitha McMurray	*Director, Human Research Protections Program, Sunnybrook Health Sciences Centre*
Kelly Morris	*Manager, Research Ethics, St. Joseph's Care Group*
Anita Sengar	*Manager, Operations, University Health Network Research Ethics Board*

College of Reviewers

Alison M. Collins-Mrakas	*Senior Manager & Policy Advisor, Research Ethics, Office of Research Ethics, York University*
Sharon Freitag	*Director, Research Ethics Office, St. Michael's Hospital*
Raphael Saginur	*Chair, Ottawa Health Science Network REB*
Suzette Salama	*Chair, Hamilton Integrated Research Ethics Board (HiREB)/Associate Clinical Professor, Department of Medicine, McMaster University*
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*

Technical/Operations Committee

Nancy Camack	*Director, Clinical Research Administration, Ottawa Hospital Research Institute*
Michael Hendley	*Manager, Business Systems Integration, Ottawa Hospital Research Institute*
Tom Herra	*Senior Business Analyst, University Research Services, Queen's University*
Alexander Karabanow	*Manager, Research Ethics Education & Coordinated Approval Process for Clinical Research, University Health Network*
Deborah Mazzetti	*Manager, Hamilton Integrated Research Ethics Board (HiREB), Hamilton Health Sciences*
Kathy Reed	*Ethics Coordinator, Queen's University Health Sciences and Affiliated Teaching Hospitals*
Anita Sengar	*Manager, Operations, University Health Network Research Ethics Board*
Janice Sutherland	*Research & Graduate Program Coordinator, Department of Surgery, Schulich School of Medicine & Dentistry, Western University*
Simon Wong	*Senior Business Analyst, Ontario Cancer Research Ethics Board (formerly)*

E-REB RFP Evaluation Committee

Koralee Berghout	*Clinical Research Program Manager, Ottawa Hospital Cancer Centre*
Kevin Cheung	*Project Leader II, Sunnybrook Health Sciences Centre*
Mary Jane Dykeman	*Partner, Dykeman Dewhirst O'Brien LLP*
Michael Hendley	*Manager, Business Systems Integration, Ottawa Hospital Research Institute*
Mary Beth Husson	*Ethics Regulatory Coordinator, London Regional Cancer Program, Lawson Health Research Institute*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Suzanne McGovern	*Program Manager, Pain Centre, The Hospital for Sick Children*
Keitha McMurray	*Director, Human Research Protections Program, Sunnybrook Health Sciences Centre*
Lam Pho	*Director of Information Technology, NCIC Clinical Trials Group*
Andy Scotter	*Procurement Specialist, Queen's University*
Anita Sengar	*Manager, Operations, University Health Network Research Ethics Board*

Electronic Forms (E-Forms) Working Group

Erika Basile	*Director, Research Ethics, Western University*
Nancy Camack	*Director, Clinical Research Administration, Ottawa Hospital Research Institute*
Alexander Karabanow	*Manager, Research Ethics Education & Coordinated Approval Process for Clinical Research, University Health Network*
Dario Kuzmanovic	*Research Ethics Analyst & Manager, University of Toronto*
Janet Manzo	*Executive Director, Ontario Cancer Research Ethics Board, Ontario Institute for Cancer Research*
Deborah Mazzetti	*Manager, Hamilton Integrated Research Ethics Board (HiREB), Hamilton Health Sciences*
Kathy Reed	*Ethics Coordinator, Queen's University Health Sciences and Affiliated Teaching Hospitals*
Tiffany Tassopoulos	*Manager, Research Ethics, Sunnybrook Health Sciences Centre*

Model Clinical Trial Agreement (mCTA) – Ontario Team

David Bruce	*Legal Counsel, Industry Partnerships & Innovation Park, Queen's University*
Aaron Leahy	*Legal Counsel, The Hospital for Sick Children*
Cheryl Litchfield	*Manager, Grants and Contracts, Lawson Health Research Institute*
Douglas Meneilley	*Senior Contracts Officer, Ottawa Hospital Research Institute*
Bruno Toneguzzi	*Contracts Officer, Ottawa Hospital Research Institute*
Karen Wilkes	*Contracts Officer, Children's Hospital of Eastern Ontario Research Institute*

Participant Engagement Advisory Group

Linda Bennett	*Executive Director, Canadian Rheumatology Research Consortium (formerly)*
Gale Carey	*Chief Executive Officer, Alzheimer Society of Ontario*
Larry Chambers	*Scientific Advisor, Alzheimer Society of Canada*
Sandra Gazel	*Senior Manager, PROGRESS Patient Support Program, Patient Engagement, AbbVie Corporation, Canada*
Barry Greenberg	*Director of Strategy, Toronto Dementia Research Alliance*
Robert Reinhard	*Public/Global Health Consultant, Immunology, University of Toronto*

Industry Advisory Group

Tracey M. Allin	*Regional Research Manager, Medicines Development Unit, Biomedicines & Diabetes, Eli Lilly Canada Inc.*
Nita Arora	*Regional Head, North America, Hoffmann-La Roche Limited*
Bruce Beamer	*Director Government and External Affairs, Bayer*
Steve Dmytrasz	*Oncology Clinical Operations Manager, Amgen Canada Inc.*
Raphael Hofstein	*Chief Executive Officer & President, MaRS Innovation*
Mark Lundie	*Regional Director, Research & Development, Pfizer Canada*
Trinh Luong	*Director, Health Technology Assessment & Pricing Regulation, Novartis Pharmaceuticals Canada Inc.*
Neil Maresky	*Vice President, Scientific Affairs, AstraZeneca*
Barbara Nicholls	*Director, Clinical Development Therapy Area, RESPIRATORY, ID, CV/MET, GlaxoSmithKline*
Stephanie Ounpuu	*Director, Clinical Operations, Boehringer Ingeheim (Canada) Ltd.*
Clive Ward-Able	*Executive Director, Research & Development, Amgen*
James Wilson	*President, Brancorth Medical Inc.*

THE WAY FORWARD

The next year will see continued progress as CTO moves forward with core programming and other important initiatives.

KEY OBJECTIVES FOR THE UPCOMING YEAR INCLUDE:

- Officially launch the Streamlined Research Ethics Review System and pilot the first trials
- Fully operationalize the delegated board of record model and CTO Stream platform
- Increase the number of 'CTO Qualified' REBs in Ontario
- Host an expanded CTO Clinical Trials Conference
- Launch the CTO registry and develop its asset promotion facility
- Partner with a national initiative to develop a Canada-wide asset map
- Implement the Metrics and Evaluation program
- Aggressively promote Ontario as a preferred location for global clinical trials
- Implement strategies for participant recruitment and retention
- Stabilize the CTO operational environment and initiate sustainability measures.

STATEMENT OF FINANCIAL POSITION

as at April 30, 2013 and April 30, 2014

	2014	2013
ASSETS		
Current assets		
Cash	**$ 281,710**	$ 318,693
HST rebate recoverable	**53,516**	48,504
Guaranteed investment certificates	**10,021**	10,012
Prepaid software costs	**395,712**	
Prepaid rent	**120,051**	
Prepaid insurance and other costs	**11,060**	8,072
	$ 872,070	$ 385,281
LIABILITIES AND NET ASSETS		
Current liabilities		
Accounts payable and accrued liabilities	**$ 55,611**	$ 51,502
Deferred revenue	**807,189**	323,840
	862,800	375,342
Net assets		
Unrestricted	**9,270**	9,939
	$ 872,070	$ 385,281

ORGANIZATIONAL PROFILE

OUR TEAM

Susan Marlin *President and CEO*
Manal Siddiqui *Manager*
Erin Bell *Program Coordinator*
Matthew D'Ascanio *Program Coordinator*
Anita Sengar *Lead Auditor, REB Qualification Program*
Delilah Ofosu-Barko *Auditor, REB Qualification Program*
Jessa Gill *Project Manager, eREB IT System*
Terry Liu *Senior Business Systems Analyst (Part-time)*
Levan Khutsishvili *Web Application Developer*
Margaret Polanyi *Senior Communications Specialist (Part-time)*
Sean Power *Communications Specialist (Part-time)*
Chris Riddle *Governance Support (Part-time)*
Kim Brown *Administrative Assistant (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*

REB Operations
Erika Basile *Director (Research Ethics), Western University*
Lorelei Nardi *REB Program Manager, The Hospital for Sick Children (formerly)*

FORMER TEAM MEMBERS

Linda Bennett *Executive Director, Canadian Rheumatology Research Consortium (formerly)*
Andrew Milroy *Program Coordinator*
Suzanne McGovern *Program Coordinator*


CTO Team


CTO Directors and Member Representatives

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., Head, Strategic Research Partnerships, Ontario, External R&D Innovations, Pfizer 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 *Chief Executive Officer and President, MaRS Innovation*

Michael Wood *Director, Office of 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)
Jared Rhines *Vice President, Scientific and Strategic Affairs*

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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