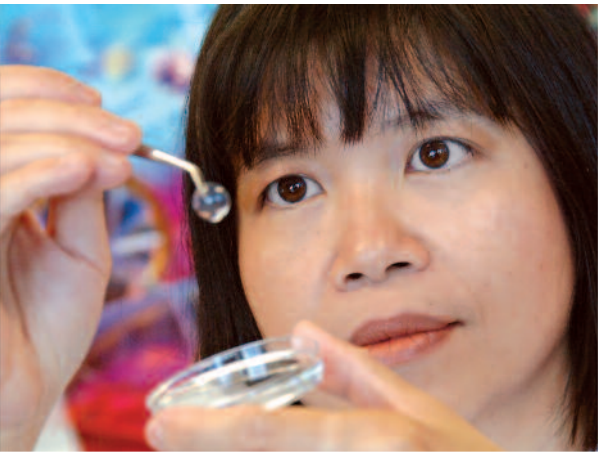
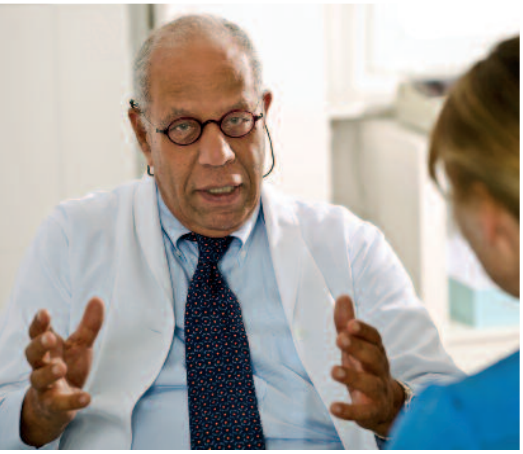
ANNUAL REPORT | 2012.2013

CLINICAL TRIALS ONTARIO



CONTENTS

This report reflects the work completed or in progress between **June 2012** and **April 2013**.

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

CREDITS

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CLINICAL TRIALS ONTARIO

is an independent not-for-profit corporation supported by the Government of Ontario through the Ministry of Research and Innovation. Our mandate is to provide the life sciences industry with a streamlined approach to conducting multi-centre clinical trials in Ontario while ensuring the highest ethical standards for participant safety.

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

1 Improving the speed and reducing the costs of multi-centre clinical trials by streamlining the research ethics approval process and harmonizing other 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; and

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

Message from the President and Chairman of the Board of Directors

ARTHUR SLUTSKY

I am delighted to be writing this message to all stakeholders of Clinical Trials Ontario (CTO) as we celebrate some impressive achievements and issue our first Annual Report.

Following the signing of a multi-year funding agreement between CTO and the government of Ontario in June 2012, CTO hosted an inaugural meeting to provide relevant stakeholders with information on the strategic approach being adopted by the organization for streamlining the conduct of multi-centre clinical trials in Ontario.

Since then, CTO has undertaken a series of outreach activities and has tapped into a rich and varied pool of talent and expertise that will enable CTO to move forward with confidence under the leadership of Susan Marlin, our Executive Director. The nine-member skills-based Board of Directors for CTO has demonstrated tremendous commitment to shaping the organization and under their stewardship CTO is advancing its mandate as envisioned.

I want to take this opportunity to acknowledge the dedication and generous volunteer efforts of members of our clinical research and research ethics community who have stepped forward to provide expert advice and to help build a firm foundation for CTO programming.

I believe that Ontario's clinical trials enterprise now has the ability to make Ontario the preferred location for global clinical trials while maintaining the highest ethical standards.

On behalf of our Member institutions and my fellow Directors, I want to thank all those who have contributed to getting CTO to where it is today. In particular, I want to make special mention of our provincial funding partner for their ongoing support to help Ontario realize the potential of its outstanding clinical trials' expertise.

Message from the Executive Director

SUSAN MARLIN

The enthusiasm and commitment across Ontario for improving the environment for conducting clinical trials continues. Over this past year we have focused on developing a strong foundation for CTO programming that will support the conduct of high-quality clinical trials and provide health and economic value to Ontarians into the future.

Core to the development of CTO programming is our understanding that the actual work — the design, conduct, ethical oversight and quality management of clinical trials — is done by our clinical research and research ethics communities, both public and private. Our focus at CTO is in understanding how we can best support you in accomplishing your goals. Key to this has been, and will continue to be, working with you to develop resources to support and promote our clinical research capabilities in Ontario.

As national efforts to support clinical trials advance and the clinical trials environment continues to evolve, CTO will collaborate with our stakeholders in Ontario and our national and international colleagues to ensure that our efforts will contribute meaningfully to improving the clinical trials environment.

As core CTO programming comes on-line over this next year we look forward to your continued engagement. On behalf of CTO, I would like to acknowledge members of our stakeholder communities who continue to engage with us, keep the community informed of our progress at different levels and reach out to us as an important resource for the conduct of clinical trials in Ontario.

Only in working together will the opportunity for Ontario to be a preferred location for clinical trials be fully realized.

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

Clinical trials contribute valuable information about the effectiveness and safety of new and existing therapies. They serve an important role in the evaluation of medical treatments and in providing treatment options to Ontarians for both today and in the future. Many breakthroughs in disease prevention and treatment in the last half-century have depended on the willing involvement of research participants and their families in clinical trials.

In Ontario, the safety of clinical trial participants is paramount. We pride ourselves on the leading medical and clinical trials expertise in the province, and on the excellent quality of ethical oversight provided by our Research Ethics Boards (REBs). We recognize the pivotal role our research teams and REBs play in protecting the rights, safety and well-being of research participants.

For close to a century, Ontario's researchers have been at the forefront of major breakthroughs in nearly every area of medicine. With rapid improvements in detecting disease, understanding the root causes of acute and chronic illnesses, and in developing medical innovations, clinical trials will continue to play a critical role in advancing medical knowledge and improving the quality of care received by Ontarians, by Canadians, and by patients around the world.

Clinical trials are supported by various means in Ontario including federal and provincial research funding and health care charities. They are also supported by the pharmaceutical, biotechnology, and medical device companies that actively collaborate with Ontario's publicly funded research institutions, independent clinical research organizations and medical care providers. All of these entities contribute to a robust and increasingly important clinical research environment in Ontario.

PROGRAMMING

Since its official launch in June 2012, CTO has invested in building a strong foundation for future improvements in the clinical trials environment in Ontario.

The design and planning stages for CTO programming have been guided by expert input from the clinical research and research ethics communities in Ontario. The development of CTO programming has provided a focal point for colleagues from industry, institutions, research ethics boards and others to discuss opportunities and challenges associated with conducting clinical trials in Ontario.

STRATEGIC PILLAR 1:
Improving the Speed and Reducing the Costs of Multi-Centre Clinical Trials

STREAMLINED RESEARCH ETHICS REVIEW SYSTEM

Before participants can be enrolled in a clinical trial, the research must be approved by a Research Ethics Board (REB) — an independent body composed of medical and scientific experts, ethicists, researchers, healthcare professionals, legal and privacy experts and other non-scientific and community members.

Clinical trials often engage participants from many institutions and locations across Ontario and beyond. When multiple public institutions participate in the same clinical trial, the current practice is for an REB from each and every one of the participating institutions to review the trial and provide ethical oversight for the participants from their institution. This results in multiple ethical reviews for the same clinical trial.

An immediate priority for CTO is the development of a province-wide streamlined research ethics review system that will support a single ethical review for multi-centre clinical trials. This single review can be done by any *qualified* REB in Ontario, on behalf of multiple institutions participating on the same clinical trial. This necessitates ensuring a quality of ethics review and promoting a high level of trust such that institutions are comfortable delegating ethics review to each other.

The streamlined ethics review system has two primary components:

1) REB Qualification Program

Members of the CTO REB Streamlining Working Group reviewed several models for assessing the quality of REBs and recommended that the Toronto Area Health Sciences Network (TAHSN) REB qualification manual be used as a starting point for the qualification program. The program is being developed with experts from the research ethics review community. The qualification process will be offered to REBs in Ontario in January 2014.

National discussions continue with respect to the accreditation of REBs and the streamlining of research ethics. Decisions made at a national level may impact the CTO REB Qualification Program in future. However, the planning and execution of the program will continue as it is a key component in the Streamlined Research Ethics Review System and important in establishing trust amongst institutions and REBs. Continued efforts will be made to stay apprised of national and provincial developments, and to engage in these discussions as related programs develop.

2) Delegated Board of Record Review System

A delegated board of record model will be implemented in Ontario and will support any *qualified* REB in conducting an ethics review of a multi-centre clinical trial on behalf of multiple research sites across the province. Implementation of the model will be heavily dependent on information technology (IT) infrastructure that will support research ethics activities, document flow and communication capabilities across multiple REBs and institutions.

The design and development of the streamlined ethics review system has been informed by the reports and recommendations of CTO Working Groups. Additionally, CTO has reviewed a number of research administration and REB management systems in Ontario as well as in the US, United Kingdom and Australia. The research ethics harmonization efforts in British Columbia, Alberta, Quebec and Newfoundland have also provided valuable information for advancing the CTO streamlined ethics review system.

Two experts from the community were formally engaged by CTO and contributed substantially to the development of the system: Janet Manzo, the Executive Director of the Ontario Cancer Research Ethics Board and Lam Pho, the Director of Information Technology at the NCIC Clinical Trials Group and the Director of Information Technology at the Canadian Cancer Clinical Trials Network.

The target date for the implementation of the streamlined ethics review system is June 2014.

STREAMLINING AND HARMONIZATION OF OTHER ADMINISTRATIVE PROCESSES AND PLATFORMS

Discussions with clinical research sites, industry and others over the past months have highlighted opportunities for improving clinical trial processes beyond research ethics (e.g. negotiating and finalizing budgets and clinical trials contracts). While continuing these conversations and identifying opportunities for CTO to contribute to practical solutions, CTO is currently focussing its efforts on the following initiatives:

1) Model Clinical Trials Agreement

CTO is engaging with the Association of Canadian Academic Health Care Organizations (ACAHO) to advance the model clinical trials agreement (mCTA) per the National CT Summit Action Plan and the plan described in the first year Communique. CTO, along with the Council of Academic Hospitals of Ontario (CAHO) and the Ontario Council of University Research (OCUR), will help to provide coordinated input from Ontario and engage with leaders in other provinces.

2) Developing Best Practices, Toolkits and Educational/Training Resources

Engagement in the development of best practices, toolkits and educational/training resources and programs will be an ongoing activity for CTO. The first priority is the development of supports for the streamlined research ethics review system. Directly relevant to the REB Qualification Program is the development of standard operating procedures as a resource for research ethics boards. The Networks for Networks (N2) and the Canadian Association of Research Ethics Boards (CAREB) are currently drafting standard operating procedures for research ethics review activities at clinical trial sites. CTO is a member of both organizations and participates in the committee overseeing this activity.

STRATEGIC PILLAR 2:
Attracting Clinical Trial Investments to Ontario

CTO is committed to continually reaching out to our multiple stakeholders in Ontario to understand the challenges and opportunities for Ontario to become the preferred location for global clinical trials.

Ontario is home to leading clinical research expertise and facilities, as well as to excellent health care and research institutions which provide the foundation to many of our clinical research programs. CTO formally connects with the hospital and university research communities in Ontario through the Council of Academic Hospitals of Ontario (CAHO) and the Ontario Council of University Research (OCUR). These organizations have been critical in the establishment of CTO and provide a bridge between CTO programming and the adoption of these programs in institutions across Ontario.

CTO continues to learn about the breadth and depth of clinical research capacities across Ontario and has connected with several investigator networks expressing a significant interest in engaging with CTO. Additionally, Ontario has a thriving independent clinical research community that contributes significantly to the success of Ontario's clinical research environment. We are reaching out to them, both individually and through organizations like the newly formed Canadian Association for Independent Clinical Research (CAICR), headquartered in Ontario.

CTO will intensify its efforts to promote Ontario's clinical research capabilities and interests as CTO's programming and the understanding of Ontario's strategic advantages advance. The creation of a CTO registry over the next year, which will collect and manage information regarding clinical trials, investigators and sites, research ethics boards and private providers, will facilitate this effort. Additionally, CTO will collaborate with national efforts led by Rx&D and others to create a national clinical trials asset map.

Ontario Pavillion, 2013 BIO International Convention

Engaging with industry is an important and continuing activity as CTO builds its knowledge base and promotion capabilities for Ontario's clinical trial assets. Understanding how clinical trial investments are prioritized in a global context and how Ontario can advance its position as a preferred location is paramount. CTO frequently interacts with industry, ranging from major pharmaceutical companies to start-up medical device companies. Participation by CTO at key events such as BIO 2013 provide an opportunity to promote Ontario as a preferred location for clinical trials. Partnerships and collaborations with Life Sciences Ontario, MaRS Innovation, Ontario Bioscience Innovation Organization (OBIO) and The Health Technology Exchange (HTX) are developing well and collaboration with these organizations will be key in supporting industry's engagement with clinical trials in Ontario.

CTO engages frequently with organizations interested in advancing clinical trial activity on a national basis including the Association of Canadian Academic Healthcare Organizations (ACAHO), Canada's Research-Based Pharmaceutical Companies (Rx&D), the Canadian Institutes for Health Research (CIHR), Health Canada and Industry Canada.

Additionally, CTO has become a member of the national clinical trials Network of Networks (N2), and has active memberships with the Canadian Association of Research Ethics Boards (CAREB) and Canadian Association of University Research Administrators (CAURA). CTO was pleased to be invited to present at the national meetings for both CAREB and CAURA. Where opportunities exist to advance CTO's agenda, collaborative partnerships are being developed.

Clinical Trials Ontario Booth, 2013 BIO International Convention

STRATEGIC PILLAR 3:
Improving Participant Recruitment and Retention

In addition to establishing the safety and efficiency of health care interventions, clinical trials provide the opportunity for Ontarians, both participants and health care providers, to have access to cutting-edge therapies. Clinical research contributes not only to advancing health care in Ontario but also to advancing our health research capacity and our economy through direct investments in research facilities and highly qualified personnel.

At CTO we recognize that clinical research in this province could not be done without the voluntary participation of Ontarians. It is crucial for Ontarians to be informed about the value of clinical trials in advancing the quality of health care and improving social well-being, as well as the contributions of our voluntary participants in improving lives across Ontario and beyond.

Industry partners, health care providers and many community-based volunteer associations already have educational materials and formal processes for enhancing public awareness of clinical trials. CTO will work with a network of partners to enhance the recruitment and retention of research participants.

Patient Advocacy Zone, 2013 BIO International Convention

COMMUNITY SUPPORT AND ENGAGEMENT

At CTO we are excited to see that our industry, hospital, university, research, and research ethics communities are keen to collaborate with us in the development and implementation of our programming.

CTO was officially launched with an inaugural meeting in July 2012 to provide the REB and institutional communities with information on the strategic approach being adopted for a streamlined approach to conducting multi-centre clinical trials in Ontario. Following the inaugural meeting, CTO issued a call to a broad cross-section of stakeholders to join three expert Working Groups to provide advice on key aspects of the organization's programming.

The response from the clinical trials community was gratifying and by September 2012 three working groups were formed: Research Ethics Board Streamlining, Information Technology and Metrics, and Legal and Liability Issues. The Working groups met several times during a six month period, and in February 2013 the final recommendations were reviewed by the CTO Board of Directors. The reports of the Working Groups provided CTO with an important framework for moving forward with planning the streamlined ethics review system.

Since then two additional advisory groups have been formed. The Technical/Operational Advisory Group is composed of information technology (IT) and operational experts from institutions and REBs and has provided CTO with expert advice in designing and planning the IT intrastructure to support the streamlined ethics review system. The Research Ethics Review Advisory Group is composed of REB Chairs and Directors/Administrators, and is advising on policy and procedures to support the streamlined ethics review process.

The significant contributions of the CTO working groups and committee members are gratefully acknowledged by CTO.

The membership of these groups is provided here:

WORKING GROUPS

REB STREAMLINING

Michael Borrie
Director, Geriatric Clinical Trials Group, UWO/Lawson Research Institute, Parkwood Hospital

Jack Corman
President, IRB Services

Padraig Darby
Chair, Research Ethics Board, Centre for Addiction and Mental Health

Paul MacPherson
Director, Grants, Contracts and Ethics Review Services, University Health Network

Janet Manzo
Executive Director, Ontario Cancer Research Ethics Board

Nicole McLean
Manager, Global Clinical Operations – Site Activation Management, Eli Lilly Canada Inc.

Keitha McMurray
Director, Clinical Studies Resource Centre and Research Ethics Office, Sunnybrook Health Sciences Centre

Frank Naus
Director, Research Administration, Hamilton Health Sciences Corporation

Suzette Salama
Chair, Hamilton Integrated Research Ethics Board, McMaster University

IT HARMONIZATION AND PERFORMANCE METRICS

Adam Cole
CIO, Liberate Health

Joe Downey
Financial and Regulatory Administrator, Centre for Applied Urological Research, Department of Urology, Queen's University

Wendy Fiander
Director, Medical Clinical Operations, Hoffmann-La Roche Limited

Femida Gwadry-Sridhar
Director, Health Informatics, Lawson Health Research Institute

Mike Hendley
Manager, Business Systems Integration, Ottawa Hospital Research Institute

Jack Holland
Chair, Research Ethics Board, Oncology, University Health Network

Trinh Luong
Director, Health Technology Assessment and Pricing Regulation, Novartis Pharmaceuticals Canada Inc.

Simon Wong
(former) Senior Business Analyst, Ontario Cancer Research Ethics Board

LEGAL AND LIABILITY ISSUES

Kelly Clark
Clinical Research Manager, Vaccines and Early Stage Development, Global Clinical Trial Operations (North America – Canada), Merck Research Laboratories

Beena Cracknell
Director of Finance and Contracts, Population Health Research Institute

Jennifer Horton
Legal Counsel, The Hospital for Sick Children

Tricia Houston
Associate Director, Clinical Development, Regulatory and Medical Affairs, Novo Nordisk Canada Inc.

Cheryl Litchfield
Manager, Grants and Contracts, Lawson Health Research Institute

Douglas Meneilley
Senior Contracts Officer, Ottawa Hospital Research Institute

Kelly Morris
Manager, Shared Research Ethics Office, St. Joseph's Care Group & Thunder Bay Regional Health Sciences Centre

Delilah Ofosu-Barko
Research Consultant, Research Operations – Research & Innovation Office, Trillium Health Partners

TECHNICAL/OPERATIONAL ADVISORY GROUP

Nancy Camack
Director of Clinical and Translational Research Administration, Ottawa Hospital Research Institute

Michael Hendley
Manager, Business Systems Integration, Ottawa Hospital Research Institute

Tom Herra
Senior Business Analyst, TRAQ Project, Queen's University

Alexander Karabanow
Manager, Research Ethics Education and Coordinated Approval Process for Clinical Research (CAPCR), University Health Network

Deborah Mazzetti
Coordinator, Hamilton Integrated Research Ethics Board, McMaster University

Kathy Reed
Ethics Coordinator, Queen's University and Affiliated Teaching Hospitals REB

Anita Sengar
REB Operations Manager, University Health Network

Janice Sutherland
Research and Graduate Program Coordinator, Department of Surgery, Schulich School of Medicine & Dentistry, Western University

Simon Wong
(former) Senior Business Analyst, Ontario Cancer Research Ethics Board

RESEARCH ETHICS REVIEW ADVISORY GROUP

Nancy Camack
Director of Clinical and Translational Research Administration, Ottawa Hospital Research Institute

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

Michael D. Coughlin
Chair, Tri-Hospital REB, Kitchener/Cambridge

Sharon Freitag
Director, Research Ethics Office, St. Michael's Hospital

Dianne Godkin
Senior Ethicist, Trillium Health Partners

Dario Kuzmanović
Research Ethics Manager & Analyst, University of Toronto

C. David Mazer
Chair, Research Ethics Board, St. Michael's Hospital

Keitha McMurray
Director, Clinical Studies Resource Centre and Research Ethics Office, Sunnybrook Health Sciences Centre

Kelly Morris
Manager, Shared Research Ethics Office, St. Joseph's Care Group & Thunder Bay Regional Health Sciences Centre

THE WAY FORWARD

The next year will be a challenging and exciting one for CTO as core programming comes on-line and other initiatives advance.

KEY OBJECTIVES FOR THE UPCOMING YEAR INCLUDE:

- Implementing an REB qualification program in Ontario.
- Implementing the delegated board of record model.
- Creation of a CTO registry to manage information required to support the streamlined research ethics review system and to promote Ontario's clinical trials assets.
- Providing coordinated input from Ontario and supporting the development of a national model clinical trials contract.
- Working with stakeholders and partner organizations to further refine barriers to efficient clinical trials conduct and to identify areas where CTO can make an impact.
- Formalizing industry engagement with CTO.
- Developing resources and promotional materials to showcase Ontario's clinical trials assets.
- Engaging with key patient advocacy groups and stakeholders to discuss approaches to improving participant recruitment and retention.
- Developing strategies for partnerships and collaborations to support participant engagement.
- Formalizing a plan for metrics collection.
- Enhancing outreach to our community.

Clinical Trials Ontario's new home in 2014: MaRS Centre Phase 2

STATEMENT OF FINANCIAL POSITION

as at April 30, 2013 and April 30, 2012

Currency in Canadian dollars	**2013**	2012
ASSETS		
Current assets		
Cash	**$ 318,693**	$ 431,777
HST rebate recoverable	**48,504**	17,854
Guaranteed investment certificates	**10,012**	10,031
Prepaid expenses	**8,072**	2,359
	$ 385,281	$ 462,021
LIABILITIES AND NET ASSETS		
Current liabilities		
Accounts payable and accrued liabilities	**$ 51,502**	$ 77,853
Deferred revenue (restricted grant funds remaining)	**323,840**	374,411
	$ 375,342	$ 452,264
Net assets		
Unrestricted	**9,939**	9,757
	$ 385,281	$ 462,021

ORGANIZATIONAL PROFILE

OUR TEAM

Susan Marlin, *Executive Director*

Manal Siddiqui, *Project Manager*

Anita Sengar, *Associate Director, Research Ethics Review Program (Part-time)*

Suzanne McGovern, *Program Coordinator*

Andrew Milroy, *Program Coordinator*

MULTI-CENTRE CLINICAL TRIALS COMMUNITY EXPERTS

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

FORMER TEAM MEMBERS

Ronald J. Heslegrave, *Interim Executive Director*

Erin Menzies, *Research Analyst*

BOARD OF DIRECTORS

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

Mark Lundie (Vice-Chair and Secretary)
Regional Director, R&D, Pfizer Canada

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

Raphael Saginur
Chair, Research Ethics Board, Ottawa Hospital

James Wilson
Chair, MEDEC

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

Raphael Hofstein
Chief Executive Officer and President, MaRS Innovation

Michael Wood
Professor, Northern Ontario School of Medicine

Anne Snowdon (resigned June 2013)
Chair, International Centre for Health Innovation, Richard Ivey School of Business, University of Western Ontario

MEMBER REPRESENTATIVES

COUNCIL OF ACADEMIC HOSPITALS OF ONTARIO (CAHO)

Karen Michell, *Executive Director*

CANADA'S MEDICAL TECHNOLOGY COMPANIES (MEDEC)

James Wilson, *Chair*

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*

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
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