Clinical Trials Ontario

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

Susan Marlin, Executive Director
February 27, 2014
CTO Clinical Trials Conference
ABOUT CLINICAL TRIALS ONTARIO

■ Clinical Trials Ontario is an independent, not-for-profit organization

■ Established with seed funding from the Province of Ontario—$4.5 million over 3 years in response to:
  ▪ Significant decline in clinical research in Ontario
    ▪ 2009: $550m | 2010: $500m | 2011: $438m (pharma investment)
  ▪ Stakeholder recommendations regarding what would help

■ Mandate for CTO – support a **streamlined approach to conducting multi-centre clinical trials** in Ontario while ensuring the highest ethical standards for patient safety.
Streamlining REB and other CT Admin processes

Promoting Ontario and Attracting Investments

Improving Participant Recruitment and Retention

Corporate Projects

Operations & Governance

Engagement of the Clinical Trials Community in Ontario
STREAMLINED ETHICS REVIEW SYSTEM

Supports any “qualified” REB in Ontario in providing ethical review/oversight for a study conducted in multiple research sites in the province

Two Primary Components:

Research Ethics Board (REB) Qualification Program

- Offers external review and qualification of REBs against a standard (i.e. checklist) informed by regulations/guidelines etc. applicable to the ethics review of clinical/health research
- Required for any REBs participating in the CTO Streamlined Ethics Review System

Streamlined Ethics Review Process (Implementation Date: June 2014)

- Based on 'delegated board of record model'; a qualified REB is delegated by participating institutions the responsibility to provide ethical oversight for a clinical research study conducted across multiple institutions – “one study, one REB”
DELEGATED BOARD OF RECORD MODEL – INITIAL APPROVAL

**New multi-centre clinical trial**

- REB application submitted by any registered investigator/site, i.e. “Provincial Applicant”
- CTO assigns Board of Record (any qualified REB in Ontario) and advances application
- Board of Record reviews application and resolves any issues with applicant
- Once issues are resolved Board of Record approves study
- Participating sites are notified and given access to REB materials in CTO system

**New Investigator/Research Site**

- Site adopts approved ICF. Submits site application focused on site specific information
- Site application advances to Board of Record
- Board of Record reviews application (usually expedited) and resolves any issues with site applicant
- Board of Record issues approval for site to participate
DELEGATED BOR MODEL – CONTINUING OVERSIGHT AND APPROVAL

New overall (study-level) event, e.g., amendment, DSMB report, safety update

Documentation submitted by “Provincial Applicant”

Board of Record reviews submission and resolves issues with prov. applicant

Once issues are resolved, approval or acknowledgement is issued by Board of Record and sent simultaneously to all approved participating sites

New site level event, e.g., continuing (annual) review, local SAE, protocol deviation

Documentation submitted by research site

Board of Record reviews submission and resolves issues with research site

Approval or acknowledgement issued by Board of Record
## PILLAR 1: STREAMLINING - RESEARCH ETHICS REVIEW STREAMLINING SYSTEM

<table>
<thead>
<tr>
<th>Component</th>
<th>Progress</th>
<th>Planned</th>
<th>Opportunities</th>
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<tbody>
<tr>
<td>REB Qualification Program</td>
<td>✓ Manual drafted; based on TAHSN manual as recommended by WG</td>
<td>• Incorporate expert reviews</td>
<td>• Ontario recognized as a jurisdiction in which most REBs are qualified – unique in Canada</td>
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<tr>
<td></td>
<td>✓ Pilot conducted November 2013</td>
<td>• Post for public consultation</td>
<td>• To provide a model for a national REB qualification/accreditation. process</td>
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<td></td>
<td>✓ Auditing/monitoring capacity hired</td>
<td>• Stay abreast of national discussions re: REB accred.</td>
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<td></td>
<td></td>
<td>• Qualify up to 20 REBs next year</td>
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<td></td>
<td>• Continue to revise and refine program</td>
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<td>Delegated Board of Record</td>
<td>✓ E-REB system design complete</td>
<td>• Obtain feedback on the REB application forms</td>
<td>• Ontario recognized as a leading jurisdiction in North America for high quality, efficient REB review of multi-centre trials</td>
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<tr>
<td>Model</td>
<td>✓ RFP/contract negotiation for e-REB system near complete</td>
<td>• Develop training/education modules</td>
<td>• Develop community of practice for REBs in Ontario</td>
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<td></td>
<td>✓ REB application forms developed (Prov. &amp; Site) considered SPOR-SHER, multiple REB examples</td>
<td>• Several policy issues to be resolved</td>
<td>• Develop e-REB system for CTs that can be used for local reviews</td>
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<tr>
<td></td>
<td>✓ Several policy issues under discussion</td>
<td>• Implement model June 2014</td>
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# PILLAR 1: ADDITIONAL STREAMLINING INITIATIVES

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<tr>
<th>Activity</th>
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<tbody>
<tr>
<td><strong>Model Clinical Trials Contract</strong></td>
<td>✓ Distributed to Ontario Institutions summer 2013</td>
<td>• Support continued national efforts</td>
<td>• If this can be accomplished it will reduce start-up time for industry sponsored clinical trials in the academic/public hospital setting</td>
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<td></td>
<td>✓ CTO, CAHO &amp; OCUR coordinated the development of an Ontario response November 2013</td>
<td></td>
<td>• CTO to provide a “start-up” package to interested sites including the model contract for the trial and REB review</td>
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<td>National Initiative led by ACAHO, RX&amp;D and CIHR</td>
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<tr>
<td><strong>Developing Opportunities</strong></td>
<td>✓ Preliminary discussions re: standard clinical trial costing, indirect costs and investigator recognition and training/development</td>
<td>• Continue discussions to determine future priorities</td>
<td>• The development of standard costing/budgets could allow an enhanced CTO Clinical Trial “Start-Up Package”</td>
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<td></td>
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<td>• Increasing the engagement of new investigators in clinical research</td>
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<tr>
<td>Activity</td>
<td>Progress</td>
<td>Planned</td>
<td>Opportunities</td>
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<td><strong>Industry Outreach</strong></td>
<td>✓ Attend industry meetings/events and 1-1’s</td>
<td>• Industry Advisory Committees: Sustainability &amp; CTO Operations</td>
<td>• Promote Ontario as a preferred location for clinical trials through programming advancements</td>
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<td></td>
<td>✓ CTO Newsletter</td>
<td>• Marketing and communications strategy</td>
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<td>✓ First conference (today!)</td>
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<td><strong>Registry and Asset Map</strong></td>
<td>✓ Member of RX&amp;D National Asset Map development committee</td>
<td>• Design and program Registry spring/summer 2014</td>
<td>• Tool to promote Ontario Assets</td>
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<td></td>
<td>✓ CTO broad plans for “Registry”</td>
<td>• Partner with other organizations to define data to be collected</td>
<td>• Centralize/standardize data collection relating to clinical trials and improve data availability and lessen the data submission burden on stakeholders</td>
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<tr>
<td><strong>Metrics</strong></td>
<td>✓ IT/Metrics Working Group report completed; Issued RFP Nov 2013 for the design and implementation of metrics and evaluation program</td>
<td>• Primary data collection and benchmarking to be complete by March 2014</td>
<td>• Availability of data to position Ontario as a preferred location for clinical trials; ability to benchmark and track Ontario and CTO’s performance</td>
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**PILLAR 3: PARTICIPANT RECRUITMENT AND RETENTION**

<table>
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</table>
| Plan for CTO’s Engagement in Participant Recruitment and Retention efforts | ✓ Initial environmental scan completed  
✓ Informal working group convened including research site, industry, charity, Best Medicines Coalition | • CTO Conference– session to focus on recruitment/retention and planning next steps           | • Develop partnerships and determine how CTO can best provide value in recruitment/retention efforts in Ontario |
Streamlining REB and other CT Admin processes

Promoting Ontario and Attracting Investments

Improving Participant Recruitment and Retention

Corporate Projects

Operations & Governance

Engagement of the Clinical Trials Community in Ontario
IT TAKES A VILLAGE
CTO TEAM

In-House Team
- Manal Siddiqui, Project Manager
- Suzanne McGovern, Program Coordinator
- Andrew Milroy, Program Coordinator
- Sean Power, Communications Specialist (part-time)

Community Expertise:
- Janet Manzo, Executive Director OCREB (Multi-centre ethics review expertise)
- Lam Pho, Director of IT, NCIC CTG (IT & Multi-centre clinical trials expertise)
- Anita Sengar, UHN REB Manager (REB operations/qualification expertise)
- Linda Bennett, Executive Director, Cdn Rheumatology Research Consortium (Participant Engagement/Asset Map)
- Chris Riddle, Governance/Board Support
- Andy Scotter, Procurement Specialist, Queen’s University
- Kevin Cheung, Sunnybrook Health Sciences Centre (IT/RFP expertise)
Board of Directors

Arthur Slutsky (President and 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, UOIT

Raphael Saginur
Chair, Ottawa Health Science Network Research Ethics Board

James Wilson
President, Brancorth Medical Inc.

Anne Ellis
Associate Professor and Chair, Department of Medicine, Queen’s University

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

Institutional 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

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
REB STREAMLINING WORKING GROUP

MEMBERS

- **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** - Centre Director, Human Research Protections Program, 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 WORKING GROUP

MEMBERS

- **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 WORKING GROUP

MEMBERS

- **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
RESEARCH ETHICS REVIEW ADVISORY GROUP

MANDATE
Provide expert advice regarding the optimal processes and supports for the provincial streamlined ethics review system for multi-centre studies.

MEMBERS
- Nancy Camack – Director, Clinical and Translational Research Administration, Ottawa Hospital Research Institute
- Michael D. Coughlin – Chair, Tri-Hospital REB; Associate Professor, Department of Psychiatry and Behavioural Neurosciences, McMaster University
- Albert Clark – Chair, Research Ethics Board, Health Sciences and Affiliated Hospitals Research Ethics Board, Queens University
- Sharon Freitag – Director, Research Ethics Office, St. Michael’s Hospital
- Dianne Godkin – Senior Ethicist, Trillium Health Partners
- Dario Kuzmanović – Research Ethics Analyst, University of Toronto
- David Mazer – Professor and Acting-Chair, Department of Anesthesia, University of Toronto; Vice-Chair for Research, St. Michael's Hospital
- Janet Manzo – Executive Director, Ontario Cancer Research Ethics Board
- Keitha McMurray – Centre Director, Human Research Protections Program, Sunnybrook Health Sciences Centre Director, Human Research Protections Program
- Kelly Morris – Manager, Research Services/Research Ethics, St. Joseph’s Care Group/Thunder Bay Regional Health Sciences Centre
TECHNICAL AND REB OPERATIONS COMMITTEE

MANDATE
Provide expert advice regarding technical solutions for research ethics review administrative processes.

MEMBERS
• Nancy Camack – Director, 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, Queens University
• Alexander Karabanow – Manager, Research Ethics Education and CAPCR, University Health Network
• Janet Manzo – Executive Director, Ontario Cancer Research Ethics Board
• Deborah Mazzetti – Research Ethics Board Coordinator, Hamilton Health Sciences
• Lam Pho – Director, Information Technology, NCIC - Clinical Trials Group, Queens University
• Kathy Reed – Ethics Coordinator, Queens University
• Anita Sengar – Research Ethics Board Operations Manager, University Health Network
• Janice Sutherland – Ethics Officer, Health Sciences Research Ethics Board Full Board, University of Western Ontario
• Simon Wong – Senior Business Analyst, Ontario Cancer Research Ethics Board
E-REB SYSTEM RFP EVALUATION COMMITTEE

MEMBERS

• Koralee Berghout – Clinical Research Program Manager, The Ottawa Hospital Cancer Centre
• Mary Jane Dykeman – Partner Dykeman Dewhirst O'Brien LLP
• Mike Hendley – Manager, Business Systems Integration, Ottawa Hospital Research Institute
• Mary Beth Husson – Ethics Regulatory Coordinator, Lawson Health Research Institute
• Janet Manzo - Executive Director, Ontario Cancer Research Ethics Board (OCREB)
• Suzanne McGovern - Program Coordinator, Clinical Trials Ontario
• Keitha McMurray – Director, Human Research Protections Program, Sunnybrook Health Sciences Centre
• Lam Pho – Director of Information Technology, NCIC Clinical Trials Group, Director of Information Technology, Canadian Cancer Clinical Trials Network
• Anita Sengar – Manager, Operations, University Health Network Research Ethics Board
ELECTRONIC FORMS (E-FORMS) WORKING GROUP

MANDATE
To provide REB expert advice in the development of CTO application forms for REB review

MEMBERS

• Erika Basile, Ethics Officer, University of Western Ontario
• Nancy Camack, Director, Clinical and Translational Research Administration, Ottawa Hospital Research Institute
• Alexander Karabanow, Manager, Research Ethics Education and CAPCR, University Health Network
• Dario Kuzmanović, Research Ethics Analyst, University of Toronto
• Janet Manzo, Executive Director, Ontario Cancer Research Ethics Board
• Deborah Mazzetti, Coordinator HIREB, Hamilton Health Sciences
• Kathleen Reed, Ethics Coordinator, Health Sciences Research Ethics Board, Queen's University
• Tiffany Tassopoulos, Manager, Research Ethics, Human Research Protections Program, Sunnybrook Health Sciences Centre
MODEL CLINICAL TRIAL AGREEMENT (MCTA) – ONTARIO TEAM

MANDATE
Provided legal expert advice in coordinating a single response from Ontario Institutions to the draft national model Clinical Trial Agreement (mCTA).

MEMBERS
• David Bruce – Legal Counsel, Industry Partnerships, Queen’s University
• Cheryl Litchfield - Manager, Grants and Contracts, Lawson Health Research Institute
• Aaron Leahy - Legal Counsel, SickKids (representing the Toronto Academic Health Sciences Network)
• Douglas Meneilley - Senior Contracts Officer and Bruno Toneguzzi, Contracts Officer (each participating in one of the two sessions), Ottawa Hospital Research Institute
• Karen Wilkes - Contract Officer, Children’s Hospital of Eastern Ontario (CHEO) Research Institute
PARTICIPANT ENGAGEMENT / RECRUITMENT ADVISORY TEAM

MANDATE
To provide expert advice around issues and current programs where CTO might be able to partner and add value in addressing participant recruitment and retention in clinical trials.

MEMBERS
• Linda Bennett – Executive Director, Canadian Rheumatology Research Consortium
• Gale Carey - Chief Executive Officer, Alzheimer Society of Ontario
• Larry Chambers - Scientific Advisor, Alzheimer Society of Canada
• Sandra Gazel - Associate Director, Clinical Operations, AbbVie
• Barry Greenberg - Director of Strategy, Toronto Dementia Research Alliance
• Robert Reinhard - Public/Global Health Consultant
# ORGANIZATIONS

**Provincial**

- Council of Academic Hospitals of Ontario
- Ontario Council of University Research
- Ontario Cancer Research Ethics Board
- Ontario Brain Institute
- Life Sciences Ontario
- MaRS Innovation
- Health Technology Exchange
- Ontario Bioscience Innovation Organization
- Council of Ontario Faculties of Medicine

**National**

- Association of Canadian Academic Health Organizations
- Rx&D
- MEDEC
- N2 (Networks of Networks)
- Canadian Association of Research Ethics Boards
- Canadian Association of University Research Administrators
- Canadian Association of Independent Clinical Research
- Health Canada
- Canadian Institutes of Health Research
CONCLUDING REMARKS

• Over the past year the focus has been on planning and building a strong foundation for CTO operations and programming

• The contributions and the commitment from our stakeholder community towards building CTO and improving the clinical trials environment are absolutely necessary, and have been extraordinary

• The environment keeps changing, partnerships evolving. CTO programming will be impacted and will need to evolve as well

• THANK YOU!!