Clinical Trials Ontario

Priorities for Transforming the Clinical Trials Environment

Ontario's Ambition to Accelerate Timely Access to Trials and New Therapies

Ontario Leadership Table for Clinical Trials

Introduction

Clinical trials are critical to Ontario's robust life sciences sector and world-class health research infrastructure. They provide a pathway to more effective therapies and hospitals and health care teams rely on clinical trials to generate evidence-based data to inform medical decisions. The strength of our economy depends on clinical trials to attract new investments and bring highly skilled jobs to the province.

With over 4,600 active clinical trials[i], and a 160% increase in the number of trials over the past decade[ii], Ontario leads the country in clinical trial activity. Ontario's research-intensive hospitals and institutions have invested $1.73 billion in research and development[iii], and we are home to 19 of Canada's top 40 research hospitals[iv]. With access to a vast health research talent hub and over 65,000 annual STEM graduates, we have the people and the infrastructure to support world-class research, innovation and training. According to the 2021 Canadian census, 38% of Ontarians report multiple ethnic origins[v] giving researchers access to one of the most ethnically diverse populations amongst Western nations. Through our universal health care system, patients receive a high standard of care before, during and well after participation in a clinical trial. These reasons highlight why global companies and start-ups choose Ontario to conduct clinical trials.

But more needs to be done. Countries increasingly recognize the critical importance of a healthy clinical trials environment in bolstering their capacity to rapidly scale up and respond to local/global health emergencies and the ongoing health care needs of their citizens. They also understand that economic growth and health care system capacity is dependent on the ability to attract and efficiently deliver clinical trials in the most effective and resource conscious way. To maintain its attractiveness in a highly competitive global market, Ontario needs a vision that reflects the significance of clinical trials as a driver of economic prosperity and healthcare innovation.

Ontario benefits from leading research hospitals, a strong industry presence and highly engaged thought leaders committed to supporting patients and researchers in our province. The province's hospital and industry leaders have come together to form the **Ontario Leadership Table for Clinical Trials**. The engagement of three provincial ministries (Colleges and Universities, Economic Development, Job Creation and Trade and Health) as observers on the Ontario Leadership Table represents the holistic collaboration across these stakeholders. With a focus on bringing more clinical trial opportunities to Ontario and new therapies to patients as quickly as possible, the Ontario Leadership Table will develop a vision for transformative change in how we conduct clinical trials.

This document reflects the priorities and opinions of the Ontario Leadership Table which includes senior leaders from the top research-intensive hospitals and global pharmaceutical companies investing in Ontario. These individuals are confident we have the people and enthusiasm to address Ontario's challenges head-on. The Ontario Leadership Table has identified key opportunities to improve access to clinical trials and new therapies in Ontario. By addressing challenges collaboratively, we can improve healthcare options, and achieve our bold ambition to secure Ontario's position as one of the most important and innovative clinical trial jurisdictions in the world.

Opportunities and Priorities for Transformative Change

New approaches to improve access to and participation in clinical trials are important to the future success of all trials.

Activating Trials Sites in 45 Days - Priority #1

A significant opportunity for improving access to clinical trials is reducing administrative overhead and activating trial sites faster. How quickly we activate new clinical trials is a metric is used to compare jurisdictions globally when clinical trial sponsors make critical decisions regarding which sites to select for a new clinical trial. This directly impacts patients and investigators waiting for new therapies. To stand out as a world leading jurisdiction for clinical trials we must do better.

Clinical trials are most efficient when they enroll patients quickly enough to support research and development goals in a timely manner. Study data from a trial is often used to inform treatment decisions and the design and conduct of further clinical trials. A site that can activate a clinical trial quickly, will be able to start recruiting patients sooner, providing patients timely access to the trial.

Opening a new clinical trial is an extremely time sensitive and resource intensive process for both sites and sponsors. This clinical trial site activation process often takes six months or more. Ontario is in competition with sites around the world for a limited number of enrollment spots on trials. Once a clinical trial has met its enrollment target, no further patients can be enrolled. Sites

that are slow to activate a trial often miss out on the chance to enroll patients after having expended significant costs and resources in the trial activation process.

When making critical business decisions on where to invest future clinical trial resources, sponsors carefully assess sites' track records for timely site activation and consistent, reliable patient enrollment. Sites that cannot compete and deliver in these key areas are not selected for future clinical trials. This represents a significant loss to our patients and researchers who will miss out on opportunities to access novel therapies. It represents a loss to our life sciences economy as industry moves those investments and jobs to more competitive jurisdictions. A thriving clinical trials environment with activity and investment that allows us to compete with the best in the world is essential to retaining and attracting leading researchers and healthcare talent to the province.

As a first priority, the members have set an ambitious and global leading target of 45 days for new study activations in Ontario to help address the issue of timely access to clinical trials. Members have appointed an **Operational Leadership Committee** consisting of experts in clinical trial operations from hospital sites and industry. This Operational Leadership Committee will advise on the development of new programming and supports to accelerate trial activation timelines. This includes enhancements to programs such as CTO QuickSTART which was conceived to enable 90-day clinical trial activations through enhanced transparency, document management and communication features built into a bespoke digital platform. The work of this committee is underway and enhancements to CTO QuickSTART and other programming are planned for implementation within one year.

Recruitment

The ability to engage, recruit and retain a sufficient number of eligible trial participants that properly reflects the diversity of the study population is key to the success of a clinical trial. Lack of enrollment can negatively impact timely completion of a trial, advancement of scientific knowledge and reporting of study outcomes. It can also result in wasted time, resources and research funds when trials are prolonged or closed due to lack of recruitment. Even more importantly, there are often many individuals in the province that lack access to clinical trials due to socioeconomic and geographic circumstances. With the release of the FDA's draft guidance for industry, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials",[vi] sponsors have been anticipating the operational strategies that need to be implemented if we are to achieve diversity objectives in clinical trials.

Ensuring more broad access to clinical trials within the community is one way to help achieve recruitment targets across all trials, and bring trials to where patients live and receive care. Fifty-two percent of Ontarians reside outside of the GTA[vii] where most clinical trial activity is currently focused. Patients located outside of such large urban centres should have the same opportunities

to benefit from clinical trial access. This could be supported by implementing decentralization in various aspects of trial conduct, beginning with recruitment. By adopting tools such as eConsent, virtual study visits and development of centralized registries, we can make it easier for patients to participate in trials and help researchers to find eligible patients no matter where they are in the province.

Finally, we need to embrace patient centric pathways that allow individuals to easily find trials and connect with researchers who are looking for participants. Supporting patients who are seeking healthcare options, offering simple ways to come forward when they wish to participate in a trial and making the process of getting onto a clinical trial clear and simple. These are the ways in which we can bring more trials to more citizens and broaden representation in clinical trial participants.

Health Data Access

Healthcare providers and organizations supporting and/or operating within the healthcare system routinely collect high quality heath data. This information, stored in registries and databases (such as the Ontario Health Data Platform), can include evaluations of treatments for disease, health status, mortality information, data on the use of healthcare resources, hospital visits, follow-up care and medication use to name a few. The data from these different sources is vast but through technological supports, can be securely and effectively linked and used in ways that facilitate decision-making about and throughout the healthcare system, enhance patient care and make clinical trials more efficient and cost-effective. By incorporating the use of various sources of high-quality health data, researchers and sponsors can supplement or replace some of the data collection required for clinical trials with real world data. Accessing such data helps to understand the value and application of new therapies as they are used in the real world.

Leveraging data to support the future of clinical trials is critical, but access and novel applications in the use of patient health data present ongoing challenges. We need to better understand and embrace AI applications to facilitate research. AI tools have been effective in rapidly assessing eligible patient pools for clinical trials. Jurisdictions that have a clear process to allow for such access to health data have a significant advantage when it comes to addressing patient recruitment and broadening clinical trial access.

Collaborative thinking on ways to inform and update regulations and policies governing our healthcare, privacy and IT environments is a key priority. Unless we find ways to support more broad research access to health data, a key asset in Ontario, adoption of new technologies and innovations that improve efficiencies in trial conduct, decision-making and the delivery of quality care will not be possible.

Rare Disease

The Government of Canada recently announced its National Strategy for Drugs for Rare Diseases with funding of up to $1.5 billion to help support access to drugs for rare diseases. This includes support to advance rare disease research and the establishment of a Canadian rare disease clinical trials network. This presents a unique opportunity for the clinical trials community in Ontario to lead the way in improving access to therapies in rare diseases by addressing the issues around trial start-up, recruitment and health data access outlined above. Clinical trials in rare diseases provide opportunities to access new therapies and need to be implemented efficiently and quickly if they are to reach these patients where they are, and when they need them the most. We can do this by using health data and technological tools to identify patients, making it easier for them to find and enroll in rare disease trials and activating these trials as quickly as possible anywhere in the province. Additionally, when it comes to accessing tested rare disease therapies, we must look at international best practices for timely regulatory submission and approval requirements, and processes for timely access to these life-changing therapies.

Collaborative Advocacy

As innovative therapies are shown to be effective and move out of clinical trials into the real world, patients expect they will be able to access them in a timely way. However, the current regulatory and drug reimbursement pathway in Canada is complex with multiple layers of review processes which encompass safety, reimbursement and real-world value assessments at both provincial and federal levels. With an average timeline of two years, Canada is far behind comparator jurisdictions with respect to the time it takes for a new drug to be made available to patients through the public reimbursement system. This is due to lengthy procedures for health technology assessments, pricing review/negotiation and provincial drug listing processes. This severely limits access to innovative new therapies, and notably impacts rare disease populations. It is a fact that investment from the pharmaceutical industry (which encompasses investments in clinical trials) is linked to early adoption of innovation. Demonstrating that we can quickly review and grant access to new therapies is directly linked to our attractiveness as a leading jurisdiction able to translate clinical trial results into real world access for patients and establishment of new standards of care.

Maintaining a globally competitive clinical trials environment, advocating for streamlined access pathways, leadership in development of rare disease policies, and collaboration with government partners. These are the important ways in which we can work together to ensure timely access to therapies for all our patients and continue the positive cycle of investments in our province’s research sector.

Looking Forward

Achieving a 45-day clinical trial activation target is only the beginning. The clinical trials community continues to adapt and innovate in the post-pandemic environment. Finding ways to manage resources, maintain infrastructure, grow research talent, adopt rapidly evolving technologies while navigating regulatory frameworks will require innovative thinking and collaboration.

Our patients want rapid access to innovative new therapies. Our researchers and intuitions want better integration of research and healthcare. Stakeholders across the community want to strengthen and attract investment in the life sciences sector and foster relationships with global sponsors. Through the Ontario Leadership Table, we have access to thought leaders who understand the complexities of the evolving clinical trials landscape and what it will take to ensure Ontario remains at the top.

Looking ahead, improving timely access to trials and therapies will require implementation of patient-centric models for clinical trial conduct that make trials more convenient and accessible to Ontarians regardless of their geographic location. Thoughtful adoption of technology and artificial intelligence will need to inform and support broader, rapid access to clinical trials. Over the next year, the Ontario Leadership Table will guide and inform strategies to support educating and advocating for strategic policies and investments that will create the environment necessary to maintain a world-class environment for clinical trials conduct in the province.

About the Ontario Leadership Table for Clinical Trials

Led by Clinical Trials Ontario in collaboration with executive leaders from Ontario's top research-intensive hospitals and global pharmaceutical companies, the Ontario Leadership Table has come together to drive better processes that will speed up patient access to trials and new therapies in Ontario. Engagement of multiple stakeholders from within the provincial government is an important feature of the Ontario Leadership Table. The membership includes Assistant Deputy Ministers from the Ministries of Economic Development, Job Creation and Trade, Health and Colleges and Universities as observers. Their engagement facilitates information sharing amongst hospitals, industry and government with a clear flow of communication to leaders and decision makers who are well placed to inform thoughtful updates to government policy, regulations and investment priorities.

Members of the Ontario Leadership Table are aligned in their commitment to achieving transformative improvements in clinical trial activation processes. In examining ways to collaboratively explore and advance new approaches, the Leadership Table aims to vastly improve access to and participation in clinical trials more broadly. Informing the short and long-term strategic considerations to position Ontario/Canada as a leading jurisdiction for clinical trials is key to establishing a long-term vision for growth and innovation.

Current Membership

Industry:

AbbVie	**Christina Pelizon**, Country Medical Director, AbbVie
AstraZeneca Canada	**Kiersten Combs**, President, AstraZeneca Canada
Bayer Inc.	**Shurjeel Choudhri**, Senior Vice President and Head, Medical and Scientific Affairs, Bayer Inc.
Bristol Myers Squibb	**Elaine Phillips**, General Manager, Bristol Myers Squibb
Janssen Inc Canada	**Ebele Ola**, Vice-President, Medical Affairs, Janssen Inc Canada
Merck Canada	**Marwan Akar**, President and Managing Director, Merck Canada
Pfizer Canada	**Vratislav Hadrava**, Vice President & Medical Director, Pfizer Canada
Roche Canada	**Brigitte Nolet**, President and CEO, Roche Canada
Sanofi	**Stephanie Veyrun-Manetti**, General Manager Specialty Care and Canada Country Lead, Sanofi
Takeda Canada	**Jefferson Tea**, Vice President Medical & Scientific Affairs, Takeda Canada
Eli Lilly Canada	
Novartis	

Institutions:

Children's Hospital of Eastern Ontario	**Jason Berman**, CEO and Scientific Director, Children's Hospital of Eastern Ontario Research Institute, and Vice-President, Research, Children's Hospital of Eastern Ontario
Hamilton Health Sciences	**Marc Jeschke**, Vice President Research and Chief Scientific Officer, Hamilton Health Sciences
Hospital for Sick Children	**Padmaja Subbarao**, Associate Chief, Clinical Research, Hospital for Sick Children
Kingston General Health Research Institute	**Steven Smith**, President & CEO, Kingston General Health Research Institute, and Vice President, Health Sciences Research, Kingston Health Sciences Centre
Lawson Health Research Institute	**David Hill**, Scientific Director, Lawson Health Research Institute and Integrated Vice President, Research, London Health Sciences Centre and St. Joseph's Health Care London
Ontario Hospital Association	**Melissa Prokopy**, Vice President, Policy and Advocacy, Ontario Hospital Association
Ottawa Hospital	**Duncan Stewart**, CEO & Scientific Director, Ottawa Hospital Research Institute and Vice-President, Research, The Ottawa Hospital
Sinai Health	**Anne-Claude Gingras**, Director, Lunenfeld-Tanenbaum Research Institute and VP Research, Sinai Health
Sunnybrook Health Sciences Centre	**Kullervo Hynynen**, Vice-President, Research and Innovation, Sunnybrook Research Institute, Sunnybrook Health Sciences Centre
Unity Health Toronto	**Ori Rotstein**, Vice-President, Research and Innovation, Unity Health Toronto
University Health Network	**Brad Wouters (Chair)**, Executive Vice-President, Science and Research, University Health Network

[i] clinicaltrials.gov data, accessed July 19, 2023.
[ii] Based on clinicaltrials.gov data provided by the Clinical Trials Transformation Initiative AACT Database between 2012-2021 and analyzed by Clinical Trials Ontario
[iii] "An R&D powerhouse", Invest Ontario, last modified June 1, 2023, https://www.investontario.ca/pharmaceuticals#rd.
[iv] Data from 2022 RE$EARCH INFOSOURCE list of Canada's Top 40 Research Hospitals, accessed July 19, 2023, https://researchinfosource.com/top-40-research-hospitals/2022/list.
[v] Table 98-10-0337-01 Visible minority by ethnic or cultural origin: Canada, provinces and territories, census metropolitan areas and census agglomerations with parts, Statistics Canada, October 26, 2022, https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=9810033701&pickMembers%5B0%5D=1.56&pickMembers%5B1%5D=2.1&pickMembers%5B2%5D=3.1&pickMembers%5B3%5D=4.1&pickMembers%5B4%5D=5.1
[vi] Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Guidance for Industry, Draft Guidance, April 2022, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations.
[vii] Ontario Demographic Quarterly: Highlights of first quarter, March 22, 2023, https://www.ontario.ca/page/ontario-demographic-quarterly-highlights-first-quarter.