CLINICAL TRIALS ONTARIO

Frequently Asked Questions about the CTO Streamlined Research Ethics Review System

1. What is Clinical Trials Ontario?

Clinical Trials Ontario (CTO) is an independent not-for-profit organization established with support from the Government of Ontario in 2012. Its mandate is to provide a streamlined approach to conducting multi-centre clinical trials in the province. The vision of CTO is to make Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards for participant protection.

CTO programming is organized into three strategic pillars:

1) Improving the speed and reducing the cost of multi-centre clinical trials by streamlining the research ethics process and harmonizing other processes.
2) Attracting clinical trial investment to Ontario.
3) Improving participant recruitment and retention.

CTO is led and supported by the community of stakeholders involved in clinical trials in Ontario.

2. What is a research ethics review?

A research ethics review is a critical and necessary step in initiating a clinical trial. A research ethics board (REB) reviews the research study to ensure that it meets the highest scientific and ethical standards and provides the greatest level of protection to patients.

3. What is the new CTO Streamlined Research Ethics Review System? How does it differ from the current system?

The current approach in Ontario has been to conduct a research ethics review at each and every public research institution that is participating in the same clinical trial. The new CTO Streamlined System is a more nimble, efficient approach that allows one single ethical review to be conducted for a clinical trial taking place at multiple research institutions. That single review can be done by any ‘CTO Qualified’ research ethics board in Ontario, on behalf of all of the institutions that are participating in the clinical trial.

4. How was the CTO Streamlined System developed?

CTO has been working with Ontario's clinical trials and research ethics community over the past two years to design and create the CTO Streamlined System. Developing the new system has required the cooperation and commitment of the clinical research and research ethics communities. The entire sector has come together to advance clinical trial activity, provincially and across the country.

5. When was the CTO Streamlined System introduced and implemented?

Through the expertise and dedication of the clinical research and research ethics communities in Ontario, the CTO Streamlined System is now up and running. It was offically launched on March 4, 2015 at the CTO 2015 Clinical Trials Conference in Toronto. The System was launched internationally on June 16, 2015 at the 2015 BIO International Convention in Philadelphia, PA with the announcement that the first industry sponsor has received ethics approval through the CTO Streamlined System.

6. Who is using the CTO Streamlined System?

Although the CTO Streamlined System was finalized only a few months ago, 9 research ethics review boards in Ontario have become ‘CTO Qualified’ and 23 research sites have already signed on to participate in the CTO Streamlined System.

In recent months, a number of clinical trials have been piloted through the CTO Streamlined System. GlaxoSmithKline (GSK) is the first industry clinical trial sponsor to successfully use the Streamlined System to receive province-wide ethics approval. GSK’s global multi-centre clinical trial is now ready to add on sites in Ontario that will take days to approve instead of months, which can be the case in jurisdictions where studies may need to undergo an ethics review at each site.

7. How does the CTO Streamlined System work?

The system has two main components:

1) The CTO REB Qualification Program provides research ethics boards planning to participate in the CTO Streamlined System with an external review of their governance, membership, operations and review procedures.

2) The CTO model allows any ‘CTO Qualified’ research ethics board in Ontario to provide ethical review and oversight on behalf of multiple institutions participating

in the same clinical trial. Facilitating the system is **CTO Stream**, a web-based electronic platform used to coordinate research ethics reviews.

8. What are the advantages of the new system to sponsors, investigators, institutions and research ethics boards?

The new system is expected to provide significant benefits to sponsors, investigators, institutions and research ethics boards by harmonizing processes and reducing the time and effort required to initiate research across multiple sites in Ontario. For sponsors, it will reduce the cost and improve the speed of conducting multi-centre clinical trials in the province. The system will ease the burden on investigators by moving to a single ethics review. It will enhance efficiency, while supporting high-quality reviews and maintaining the highest standards for participant protection.

9. Why is it important to streamline research ethics review?

Many jurisdictions have seen a decline in global clinical trial activity in recent years. Competitiveness in the field of industry-sponsored clinical research is impacted by speed, quality and cost. As Ontario is widely recognized as a jurisdiction that generates high-quality data, gains in competitiveness can be achieved by making structural changes to improve the speed and efficiency of clinical trials, while maintaining the highest ethical standards.

10. Is the new system safe?

The ethics review process is all about protecting the rights, safety and well-being of research participants. Patient safety and oversight is paramount in the CTO Streamlined System. It allows research ethics boards to do the important work they have always done – just more efficiently.

11. Does the new system cover all types of clinical research?

The CTO Streamlined System can be used for both industry-sponsored and investigator-initiated multi-centre clinical trials and health research.

12. Why do we need clinical trials?

Clinical trials provide information about the effectiveness and safety of new treatments. Successful trials lead to new drugs, devices and other interventions that can save lives, enhance our quality of life, reduce health-care costs and generate more investment in research facilities. Clinical trials also attract top clinicians and scientists, create high-quality jobs and stimulate Ontario's economy.

A 2012 report by the Standing Senate Committee on Social Affairs, Science and Technology noted that “the financial investment made by drug companies when operating clinical trial sites in Canada puts money back into the research environment and helps to train and retain investigators and other skilled professionals associated with conducting trials.” It added that conducting clinical trials “provides early access to promising therapies and familiarizes health professionals with new treatments.”

13. What impact will the system have on clinical trials conducted in Ontario?

The CTO Streamlined System will improve the climate for conducting clinical trials in Ontario. It will allow the province to capitalize on its tremendous clinical research strengths and capture more global clinical trials activity.

14. Have other places streamlined research ethics reviews?

A number of jurisdictions have streamlined or are in the process of streamlining research ethics reviews. The CTO Streamlined System is unique in that it combines an REB Qualification Program with a customized web-based system for managing ethics review across the province. This supports any ‘CTO Qualified’ REB in providing ethical review and oversight on behalf of multiple sites involved in the same trial.