Clinical Trials Ontario

Overview and Implementation Guideline for Ontario Universal Agreement for Clinical Trials

Agreement Between Pharmaceutical Sponsors and Institutions

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Background

The top focus of the Ontario Leadership Table, convened by Clinical Trials Ontario (CTO), is improving timely access to trials by reducing trial start-up timelines to 45 days. Achieving this ambitious target requires transformational change and investment in common processes and tools to minimize the time and effort required to start up a trial. Earlier this year, CTO and the Ontario Leadership Table legal/contracts administration teams were tasked with developing a single clinical trials agreement (CTA) for the province of Ontario. We are pleased to announce the Ontario Universal Agreement for Clinical Trials is now ready for implementation. Use of the Ontario Universal Agreement for Clinical Trials is the first step in achieving the 45-day target.

What is the Ontario Universal Agreement for Clinical Trials?

The Ontario Universal Agreement for Clinical Trials (UACT) and the appended Clinical Trial Specific Agreement (CTSA) template have been developed by consensus with contract and legal representatives from organizations represented by the Leadership Table. It is designed for use by sponsors and institutions for clinical trials of drug products. The Ontario UACT has been vetted by experienced representatives from sponsors and institutions who have determined it to be fair and balanced, representing each party's significant interests and reflecting applicable regulations. The Ontario UACT is intended to be used as the standard CTA between institutions and sponsors for pharmaceutical drug trials in Ontario.

Why Do We Need the Ontario Universal Agreement for Clinical Trials?

Negotiation of individual CTAs is a time and resource-intensive process. To achieve the 45-day target for trial activation, we must adopt tools and processes that improve efficiency, reduce workload and allow for greater predictability for all parties involved in the start-up process in order to speed up the delivery of research outcomes and patient treatments.

When Does Implementation Begin?

Any contracting parties who are ready to implement and execute the agreement may proceed. Each organization represented by the Leadership Table will be asked to designate 1-2 individuals to prepare their local and/or global teams and support the process within their organization.

Implementation Process

Organizations represented by the Leadership Table will implement the agreement between Ontario institutions and industry sponsors that are conducting pharmaceutical drug trials.

- CTO will contact Leadership Table organizations to confirm:
    - Intention to adopt the Ontario UACT
    - Name and contact information for the individual(s) who will facilitate communications and prepare local and/or global teams for implementation of the Ontario UACT
- CTO will maintain the list of organizations who have agreed to adopt the Ontario UACT and make this available on the CTO website.
- Leadership Table member organizations can begin work on any internal processes needed to facilitate implementation within their organizations.
- Any organization ready to use the Ontario UACT can begin offering/executing the agreement with other contracting parties. The UACT Agreement will be executed "as-is", and amended **only** to insert administrative details such as the parties' legal names, addresses and contact / signatory information. Essential trial-specific details will be set out in each CTSA executed under the UACT.
- If parties cannot use the UACT (i.e., they cannot execute the agreement "as-is", notify CTO to facilitate collection of feedback on updates or revisions that may be required.

Implementation of the Ontario Universal Agreement for Clinical Trials (UACT)

For new trials without a CTA currently under negotiation	Once the UACT is executed between a sponsor and institution, sponsor will insert study-specific information for new studies in a Schedule B (CTSA) and submit to the study site as part of the start-up package or other mutually agreed upon CTA submission process.
For new trials with a CTA other than the Ontario UACT in active review/negotiation	Parties can discuss and mutually decide whether to switch over to use the UACT / CTSA in lieu of continuing to negotiate the previous CTA template.

Ongoing, active studies will continue to operate under the terms of their existing CTA or universal agreement. Ongoing, active studies are not expected to be amended or switched to the UACT.

To support implementation and maintenance of the UACT and reducing clinical trial start up times, CTO will follow-up with institutions and sponsors to track the use of the Ontario UACT and CTSAs. CTO will gather information from members such as: which parties have executed the agreement, timelines for negotiation and execution of subsequent CTSAs, feedback for improvements.

Additional Implementation Notes to Consider:

Once parties have adopted the Ontario UACT, any previous CTA templates, agreements and/or associated study-specific schedules/Statement of Work templates they have previously used will be retired and no longer executed for new pharmaceutical drug studies.

Frequently Asked Questions

Is the Ontario UACT only for CTO studies?

No. Any institution and sponsor who implements the Ontario UACT can use it for their industry sponsored pharmaceutical drug trials.

Can the Ontario UACT be used for studies that are led by a CRO? What about medical device studies?

At this time, the UACT has been specifically designed and intended for use in pharmaceutical company sponsored drug trials. Additional agreements for other types of studies may be developed based on needs and feedback from the community.

Do we have to commit to activating a study in 45 days if we want to use the Ontario UACT?

No. While it has been developed as a tool to help achieve the 45-day trial activation target, the Ontario UACT will support streamlining the overall contracting process for all parties once it is implemented.

Can changes be made to the Ontario UACT main agreement?

As the agreement was subject to lengthy discussion and negotiation with representatives from the Ontario Leadership Table member organizations, the expectation is that the UACT will be implemented / executed "as is", with no revisions. Minimal administrative details are to be added where noted in the agreement. Study specific additions related to study protocols may be made in the CTSA document. Organizations are encouraged to keep negotiation of such CTSA revisions to a minimum in keeping with the Ontario Leadership Table goal of meeting a 45-day start-up timeframe. If parties are not able to accept and execute the UACT, please notify CTO so that we may collect feedback on revisions or updates that may be considered when the agreement is revisited in the future.

Will a detailed budget template be provided for the CTSA?

A budget template is not being provided. Sponsors will continue to provide sites with a budget template for the purposes of negotiation.

Who will update/maintain the UACT if changes are agreed upon in the future?

CTO is committed to revisiting the agreement and collecting/coordinating feedback on updates or revisions for future consideration.

Who can we contact with questions or suggestions?

Questions or suggestions can be sent to: *quickstart@ctontario.ca*