Clinical Trials Ontario

Ontario Universal Agreement for Clinical Trials

Implementation Guideline for Pharmaceutical Sponsors and Research Institutions

Ontario Universal Agreement for Clinical Trials (Agreement Between Pharmaceutical Sponsors and Institutions)

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. To support this effort, CTO and the Ontario Leadership Table legal/contracts administration teams were tasked with developing a single, province-wide clinical trials agreement (CTA). This work led to the launch and implementation of the Ontario Universal Agreement for Clinical Trials. Its adoption marks a key first step in achieving the 45-day activation target.

What is the Ontario Universal Agreement for Clinical Trials?

The Universal Agreement for Clinical Trials (UACT) and the appended Clinical Trial Specific Agreement (CTSA) were developed through extensive consultations with contract and legal representatives from institutions and sponsor organizations represented on the Leadership Table. The UACT is intended to be used as the standard CTA between institutions and sponsors for pharmaceutical drug trials in Ontario.

The UACT must be used for studies being activated through QuickSTART, Ontario's accelerated clinical trials star-up pathway.

Why Do We Need the UACT?

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.

UACT Adoption Process

Each organization adopting the UACT will be asked to designate 1-2 individuals as their "UACT Contact" who will prepare their local and/or global teams to support the process within their organization.

CTO will support the UACT initiative in the following ways:

- Maintain the list of organizations who have agreed to adopt the UACT and make this available on the CTO website.
- Collect the name(s) and contact information of UACT Key Contacts. CTO will provide this contact information to adopter organizations wishing to connect with other UACT partners.

- Follow-up with institutions and sponsors to track the use of the UACT and CTSAs. CTO will gather information including which parties have executed the UACT and details of the timelines for negotiation / execution of the UACT and subsequent CTSAs.
- Engage in individual conversations with any organization wishing to consider implementing the UACT.
- Actively promote awareness of the UACT to increase its use amongst a wide range of sponsor and research organizations through various outreach activities, including presentations at meetings and conferences.
- Provide updates about implementation to the Ontario Leadership Table.

Organizations adopting the UACT can support implementation in the following ways:

- Work on any internal processes needed to facilitate implementation within their organization.
- Offer / execute the agreement with other contracting parties.
- Execute the UACT "as-is" and amend **only** to insert administrative details such as the parties' legal names, addresses and contact / signatory information, or as provided for in the various footnotes. Essential and unique trial-specific details can be set out in each CTSA executed under the UACT.
- Assist CTO in tracking the success of the UACT initiative by providing feedback when requested.
- Announce their adoption of the UACT and promote use of the UACT using internal and external communications tools, such as in newsletters and social media posts. Contact CTO for helpful communications templates.

Implementation of the UACT

For new trials without a CTA currently under negotiation	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.
For new trials being undertaken by parties with a pre-existing universal CTA in place.	Once an organization has adopted the UACT, any previous CTA templates, agreements and/or associated study-specific schedules/Statement of Work templates will be retired and no longer used for **new** pharmaceutical drug studies.

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.

When should the UACT be signed?

The main UACT agreement may be signed at any time when parties acknowledge that they intend to work together undertaking clinical trials, even if activating a study is not currently contemplated. Once the main UACT agreement is executed, only a study-specific CTSA will need to be signed when a new study is being planned.

Alternatively, the main UACT agreement and the CTSA including the study-specific details may be signed at the same time, once a study is being planned for imminent start-up.

Sponsors participating in QuickSTART

For sponsors planning to participate in the QuickSTART program, it is recommended that they approach their research site(s) to sign the UACT before a QuickSTART study is contemplated. This ensures the parties will be positioned to sign the study-specific CTSA within the QuickSTART timelines.

Questions?

Please click here for answers to Frequently Asked Questions or to download a copy of the Universal Agreement for Clinical Trials.

Contact us via email: quickstart@ctontario.ca.