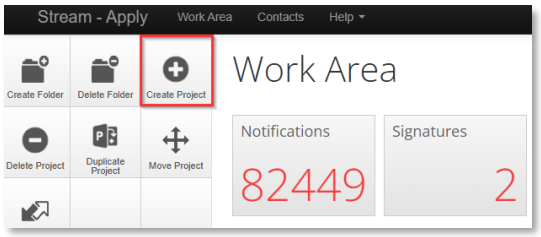
QuickGuide: Submitting a new study in CTO Stream

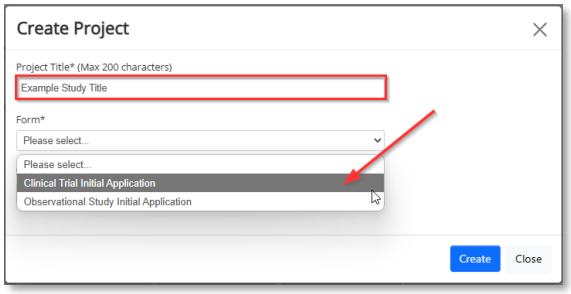
The initial study-wide application, called the Clinical Trial Initial Application (CTIA) or the Observational Study Initial Application (OSIA) is created by a member of the lead study team (or the sponsor/CRO) within CTO Stream.

The user who creates the new project automatically becomes the **Project Owner**. Once the project has been created, the project owner is the only user who can access the study in the system and therefore, it is their responsibility to give any other members of the research team a **Role** on the study, as necessary. The project owner should grant a role to the Lead Applicant, Lead Co-Applicant (if applicable), Sponsor/CRO, and any other research staff responsible for study-wide ethics submissions for the project.

1. Login to CTO Stream at apply.ctostream.ca and click the 'Create Project' button in the Actions Menu on the left-hand side of the page.



2. Enter the study short title or nickname (this will be used throughout the system) and indicate the type of forms you wish to use for the project by selecting either **Clinical Trial Initial Application** or **Observational Study Initial Application** in the drop-down menu.



3. Once the new study has been created, you will automatically be taken into it where the CTIA/OSIA is ready for you to begin working on.

4. Once all mandatory questions of the form have been completed, navigate to the last section of the form called, "Agreement & Approval" and request signatures from the Lead Applicant (and Lead Co-Applicant, if applicable). The form will automatically submit once the signature has been applied (or once the final signature has been applied if the form requires multiple signatures).

5. To confirm the application was submitted successfully, an email notification will be sent to the Lead Applicant, Lead Co-Applicant, and Lead Administrative Contact using the email provided for these individuals in section 1.0. The notification is also sent to anyone with the following role for the study: Lead Applicant, Lead Co-Applicant, Lead Site Study Staff, or Sponsor/CRO (full access).

6. Download the DIER and/or SRERS Administration form for your site from the Participating Sites page of the CTO website. The Streamlined Research Ethics Review System (SRERS) Administration Form contains details about a site's research administration processes and identifies the contact details of the institution representative(s) which you will need when completing the application.

7. Participating Site Initial Applications (PSIAs) can be created for each site at any point (i.e., you do not need to wait until the initial study-wide application (CTIA/OSIA) has been approved). More information on how to create a PSIA can be found in the QuickGuide, "Creating a PSIA" which can be downloaded from the Manuals & Guides page of the CTO website.

Tips:

1. View the list of CTO Participating Sites on the CTO website to ensure there are at least two or more sites that will be participating on your study. If you don't see a site on the list contact CTO by submitting a support ticket at support.ctontario.ca and we can give you an update.
2. Make sure to use the mandatory CTO Informed Consent Form template when drafting the study-wide consent form template (for oncology studies, please use the OCREB consent templates). This template has been accepted by the CTO Qualified REBs and contains language and elements required by CTO participating institutions. You can find the consent form template on the Tools and Resources page of the CTO website.
3. Share access to the new project with the other collaborators at your site by using the 'Roles' button. Instructions on how to give roles can be found in the Adding new study team members using Roles Quick Guide. Note: Users must have a CTO Stream account to be given a role.

Questions? Submit a support ticket at support.ctontario.ca