

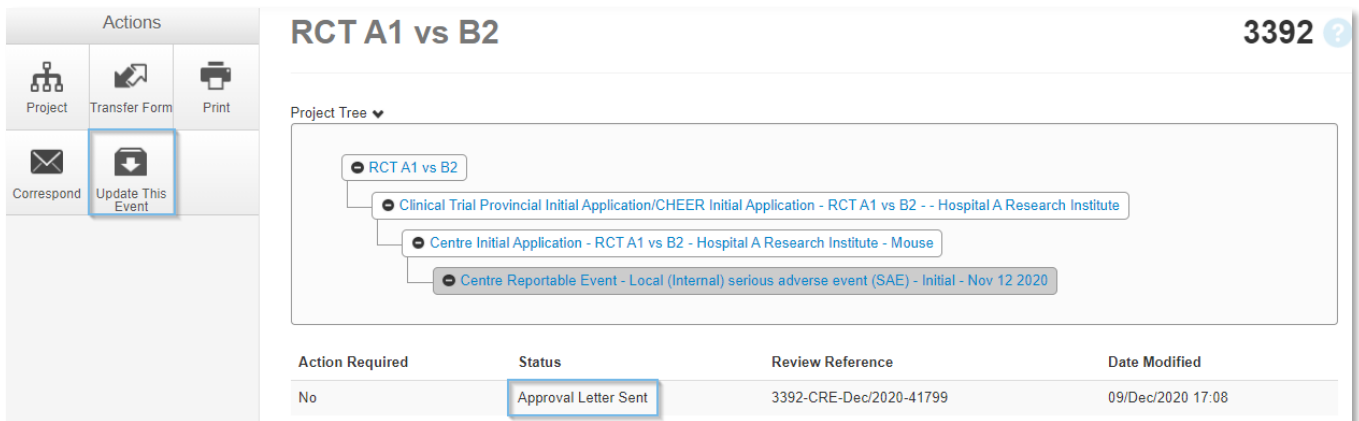
QuickGuide: Updating a Reportable Event Application

Reportable Event applications (both centre-level and provincial) can be updated to include additional details about the event after the original submission has been approved or acknowledged. Once the REB sends the approval or acknowledgement letter for a reportable event submission the ‘Update Reportable Event’ button will become visible under the Action Menu on the left-hand side of the screen from the Project Tree Page (*Figure 1*). It is also visible in the Action Menu from inside any section of the form. Once the updated reportable event form is submitted the previous version of the application is automatically archived, similar to when a form is re-submitted.

To update a Reportable Event:

1. Login to CTO Stream and open the study containing the reportable event application from the Projects list of the Work Area.
2. In the Project Tree, select the Reportable Event form that need to be updated
3. Press ‘Update Reportable Event’ from the Actions Menu on the left-hand side of the screen (*Figure 1*).

Note: The button will only be visible when the form status is “Approval Letter Sent” or “Acknowledgement Sent.”



The screenshot shows the CTO Stream interface for a study titled 'RCT A1 vs B2' with ID 3392. On the left, the 'Actions' menu is visible, with the 'Update This Event' button highlighted. The main area shows a 'Project Tree' with a hierarchy of items, including 'Centre Reportable Event - Local (Internal) serious adverse event (SAE) - Initial - Nov 12 2020'. Below the Project Tree is a table with the following data:

Action Required	Status	Review Reference	Date Modified
No	Approval Letter Sent	3392-CRE-Dec/2020-41799	09/Dec/2020 17:08

Figure 1

4. Once the button is pressed, the application will become unlocked (editable) and the form status will change to “Reportable Event Unlocked” (*Figure 2*)
5. The form can now be updated and submitted to the REB of Record.

RCT A1 vs B2 3392

Project Tree ▼

- RCT A1 vs B2
 - Clinical Trial Provincial Initial Application/CHEER Initial Application - RCT A1 vs B2 - - Hospital A Research Institute
 - Centre Initial Application - RCT A1 vs B2 - Hospital A Research Institute - Mouse
 - Centre Reportable Event - Local (Internal) serious adverse event (SAE) - Initial - Nov 12 2020

Action Required	Status	Review Reference	Date Modified
Yes	Reportable Event Unlocked	3392-CRE-Dec2020-41799	09/Dec/2020 17:08

Figure 2

Tips:

- Only reportable events which have been 'Approved' or Acknowledged can be updated in this manner.
- Once the updated reportable event is submitted the previous reportable event submission will be archived and available to download under the 'Submissions' tab.
- Reporting requirements are posted on the website of the REB of Record.

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