QuickSTART Digital Platform User Manual

Version 1.3

March 2020

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CTO Stream, CTO Registry and the QuickSTART Platform

Stakeholders may already be familiar with CTO Stream, the online streamlined ethics platform offered by CTO. CTO Stream provides an online environment to facilitate multi-site ethics reviews. CTO has developed a companion system, the CTO Registry, to accompany CTO Stream and provide an environment for CTO programs outside of the direct scope of ethics reviews. The first of these programs is the QuickSTART digital platform.

User Accounts

All stakeholders who will have a role assigned to them in the QuickSTART digital platform must have a user account in CTO Registry. Existing CTO Stream users will already have a CTO Registry account for use with QuickSTART. However, users must go to: https://ctoregistry.com/ and use the 'Reset your password' link to verify the account and set the password. For ease of use, this password may be the same as Stream.

New users to CTO's systems can contact CTO for a user account. You will need to provide CTO with your name, company/institution, role within QuickSTART and email address.

After CTO creates your user account, you will receive an account set up email from the system prompting you to verify and change your password. This link will be valid for 24 hours, after which you may reset by selecting 'Reset your password' (at https://ctoregistry.com/).

Roles

There are three different parties represented on the QuickSTART digital platform: the Sponsor, CRO and the Institution. Within these parties there are specific roles that can be assigned. User access is as follows:

Sponsor

- **Full access –** Users can make changes to the form/forms for which they have access, including uploading documents when creating applications and making changes on the status of the application

Sponsor Roles

- Study Sponsor Contact
- Sponsor Contract Contact
- Sponsor Budget Contact

Contract Research Organization (CRO)

- **Full access –** Users can make changes to the form/forms for which they have access, including uploading documents when creating applications and making changes on the status of the application

CRO Roles

- Study CRO Contact
- CRO Contract Contact
- CRO Budget Contact

Institution

- **Full access–** Users can make changes to the form/forms for which they have access, including uploading documents, adding users and assigning approvers, as well as making changes on the status of the application
- **Read-Only –** 'Read-Only Users' have read only access and can view the documents as well as view the status of the application

Institutional Roles

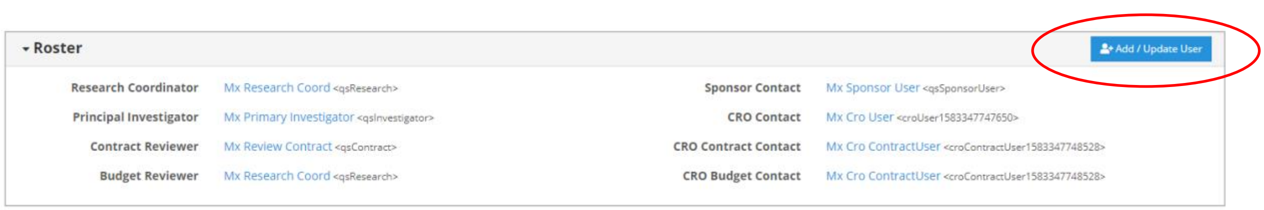
- Research Coordinator (RC)
- Investigator
- Contract Reviewer
- Budget Reviewer
- Approver
- Read-only

Notifications

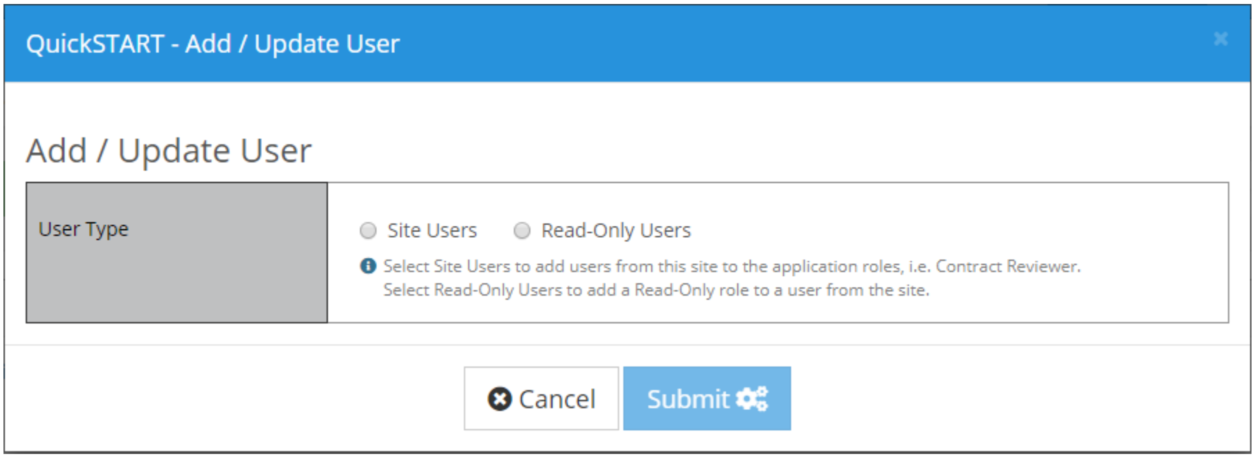
Users will receive notifications based on what type of role and responsibility they have been assigned. See Appendix A to review the type and timing of notifications for each role. Read-only roles only receive the final completion notifications.

Assigning a Role

To assign a person a role in the QuickSTART engagement screen, the RC would select 'Add/Update User' in the Roster section.

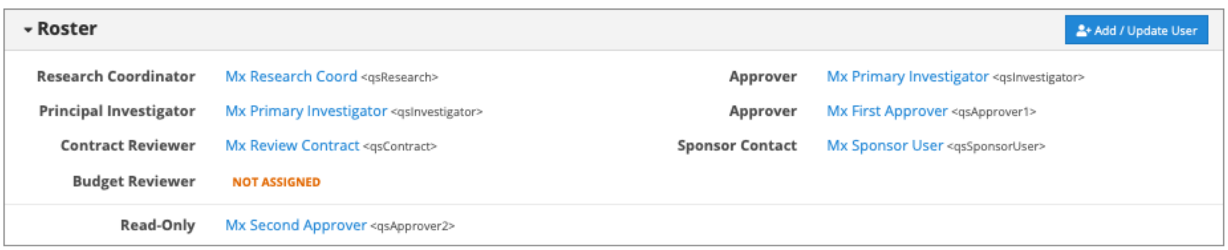


A pop-up screen will ask you to identify the person as a 'Site User' (has a responsibility and write access) or 'Read-Only Users' (read access). If the person is identified as a Site User, a prompt for role and name will follow.



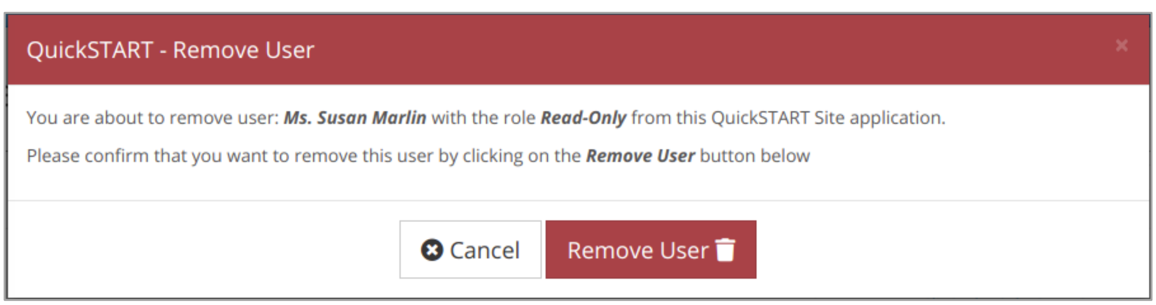
Once you select Site User, you will then be able to assign a role from the list: Investigator, Research Coordinator, Budget Reviewer, and Contract Reviewer.

A list of all users for an application will be visible in the ‘Roster’ section.



Removing a Read-Only User’s Role

The garbage can icon at the end of a Read-Only user’s name will allow you to remove the user’s access. You will receive a prompt to confirm this action. Confirm by selecting ‘Remove User’.



Who Gets What Role?

Appendix A outlines the notifications that will be associated with each role. There are a number of ways to determine who should receive a role. The following section describes the nature of each role.

Study Sponsor User

The Sponsor user has full access. There may be multiple Study Sponsors for a QuickSTART application. This user is considered the main sponsor contact for the QuickSTART application. The Study Sponsor User can perform all Sponsor actions, receives all Sponsor notifications and can assign other Sponsor Users. They also create the QuickSTART application.

Sponsor Contract User

The Sponsor Contract User is assigned by the Study Sponsor User and has full access. The Sponsor contract user can upload the contract information into the application before it is complete. The Sponsor Contract user can respond to comments on the contract portion of applications and edit the contract information. The Sponsor Contract User will only receive notifications related to the contract review.

Sponsor Budget User

The Sponsor Budget User is assigned by the Study Sponsor User and has full access. The Sponsor contract user can upload the contract information into the application before it is complete. The Sponsor Budget user can respond to comments on the budget portion of applications and edit the budget information. The Sponsor Budget User will only receive notifications related to the budget review.

Study CRO User

The CRO user has full access. There may be multiple Study CRO users for a QuickSTART application. This user is considered one of the main study contacts (along with the Sponsor contact) for the QuickSTART application. The Study CRO User can perform all Sponsor actions, receives all Sponsor notifications and can assign other Sponsor Users. They also can assist the Sponsor in creating the QuickSTART application.

CRO Contract User

The CRO Contract User is assigned by the Study Sponsor User or Study CRO User and has full access. The CRO contract user can upload the contract information into the application before it is complete. The CRO Contract user can respond to comments on the contract portion of applications and edit the contract information. The CRO Contract User will only receive notifications related to the contract review.

CRO Budget User

The CRO Budget User is assigned by the Study Sponsor User or Study CRO User and has full access. The CRO contract user can upload the budget information into the application before it is complete. The CRO Budget user can respond to comments on the budget portion of applications and edit the budget information. The CRO Budget User will only receive notifications related to the budget review.

Research Coordinator

The Research Coordinator (RC) will act as the primary contact (quarterback) from the site for the given QuickSTART application. This person may be the RC at the departmental level or may be the primary contact in a clinical services team. The RC may also assign themselves other Reviewer and Approver roles if they do not wish to have the individuals receiving notifications from the QuickSTART platform.

Investigator

The investigator is one of the *engaged parties* in QuickSTART, and therefore must be identified on the QuickSTART application. The investigator will have full view of the engagement screen and status screen, and may also be assigned as a reviewer or approver. If timelines are not being met during the QuickSTART process, the investigator will receive additional notifications in order to inform and escalate.

Contract Reviewer

A Contract Reviewer is the user responsible to review and approve the contract. Documents in the 'Study Documents' Section will be available to the reviewer for additional information that may be required during contract review. The user who is assigned this role will receive notifications on the timeline and status of this activity.

Budget Reviewer

A Budget Reviewer is the user responsible to review and approve the budget. Documents in the 'Study Documents' Section will be available to the reviewer for additional information that may be required during budget review. The user who is assigned this role will receive notifications on the timeline and status of this activity.

Approver

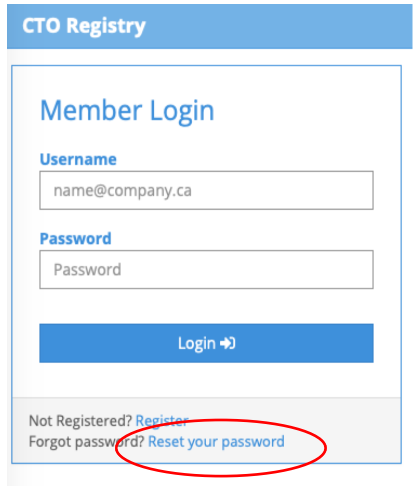
The Approver role is a broad role that can be assigned to any user who must approve resources, final documentation or any other activity that is established at the institution. When an Approver is added, the Type and Task details can be used to identify the impact on other activities and the timeframe that this approval takes place within.

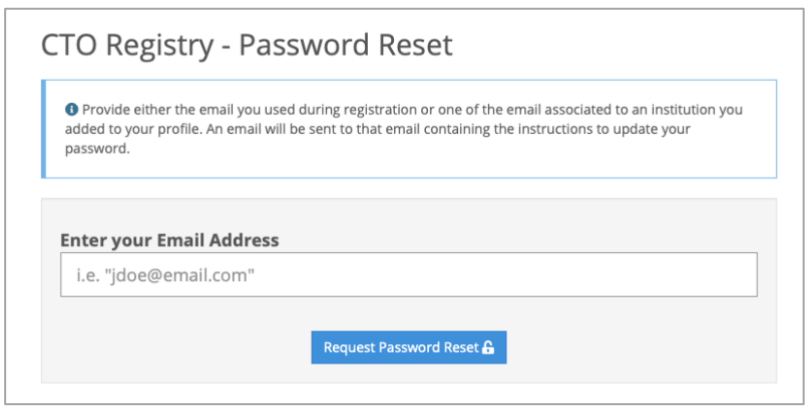
Setting up a User Account

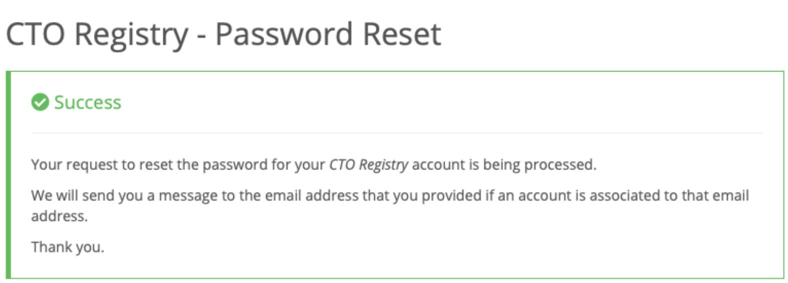
The QuickSTART platform can be accessed at: https://ctoregistry.com

The Sponsor contact or CRO contact is responsible for starting a QuickSTART application and will need to have a User Account before starting a QuickSTART application. All additional contacts will also require a verified account before they can be added to a QuickSTART application.

For existing CTO Stream users, on first use, the user will need to reset their CTO Registry password by selecting 'Reset your password' and then following the onscreen instructions:



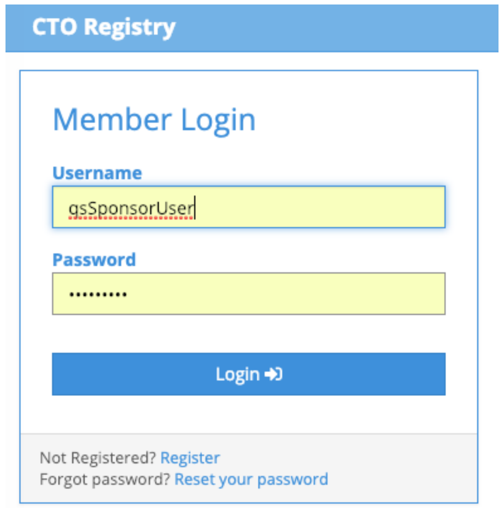




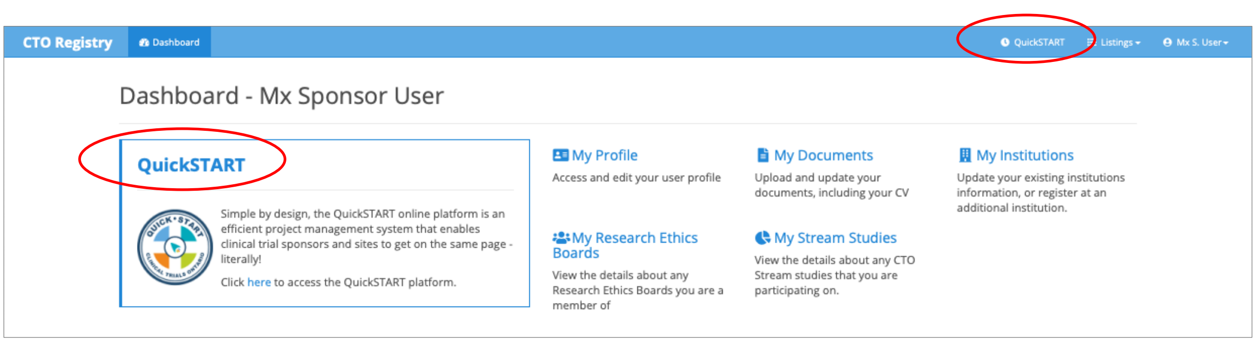
A password reset email will be sent to the email indicated for you to set up your new password and finalize your account creation.

Creating a QuickSTART application

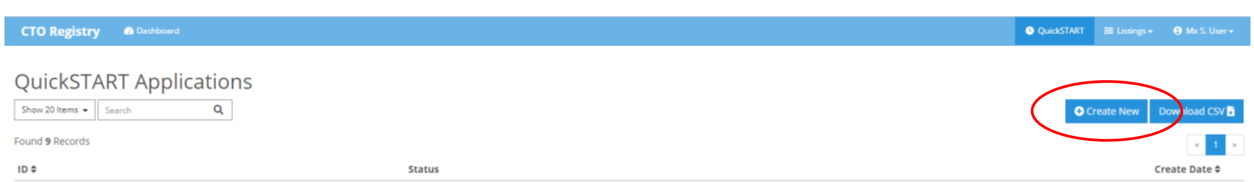
To start a QuickSTART application, the Sponsor contact or CRO contact will login to the QuickSTART digital platform at: https://ctoregistry.com



QuickSTART can be selected on the menu bar or by the QuickSTART link. If you do not see QuickSTART link displayed, please contact CTO to have your account settings reviewed.



To start a new application, select "Create New" button.



This will open a new application screen where the Sponsor/ CRO contact may enter all the study information including: Short title, Sponsor name, Study Sponsor contact(s), Study type/phase, therapeutic area and if available the Stream Project ID (this may be added later also), CRO contact(s) (if applicable).

Study Details

The information entered on this page will be used for all the site applications created for this QuickSTART study. After the study has been created, you can update these values at any time from this same screen if needed. (See this section for more details: Adding New QuickSTART Site Engagements to an Existing QuickSTART Study)

Study Details

Study Short Title	Enter the Study Short Title
Study Type	Select the Study Type
Therapeutic Area	Enter the Therapeutic Area
Is this a Single Site Study using local REB?	Yes No
Stream Project Id Number	Enter the Stream Project Id Number If the study has already been created in CTO Stream, you can record the Project ID Number (ie 1010). If the application has not been created in CTO Stream at this point you can leave this field empty and CTO will populate it during the QuickSTART pre-screen process.
QuickSTART ID	Enter the QuickSTART ID If you would like this QuickSTART application to have a specific ID you can enter it here. If this field is left blank, then an ID will be automatically generated for this application.

The Stream Project ID Number can be entered if this is already available at the time of the application creation. The QuickSTART ID can be entered by the sponsor, otherwise it will be generated by the system.

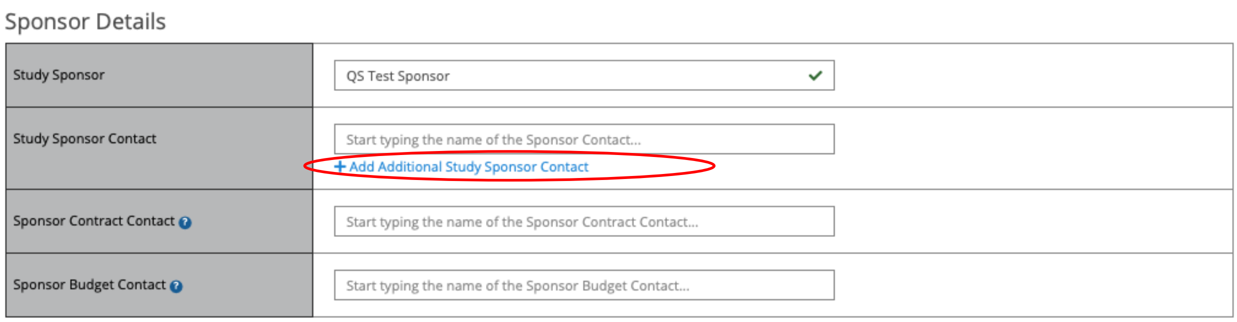
If the REB will be a single site application, select 'yes' and then enter the name of the REB who will review this study. In this case, The Stream Project ID number will not be required.

Is this a Single Site Study using local REB?	Yes No
Study REB	Start typing the name of the REB... × Study REB is required.
QuickSTART ID	Enter the QuickSTART ID If you would like this QuickSTART application to have a specific ID you can enter it here. If this field is left blank, then an ID will be automatically generated for this application.

Sponsor Details

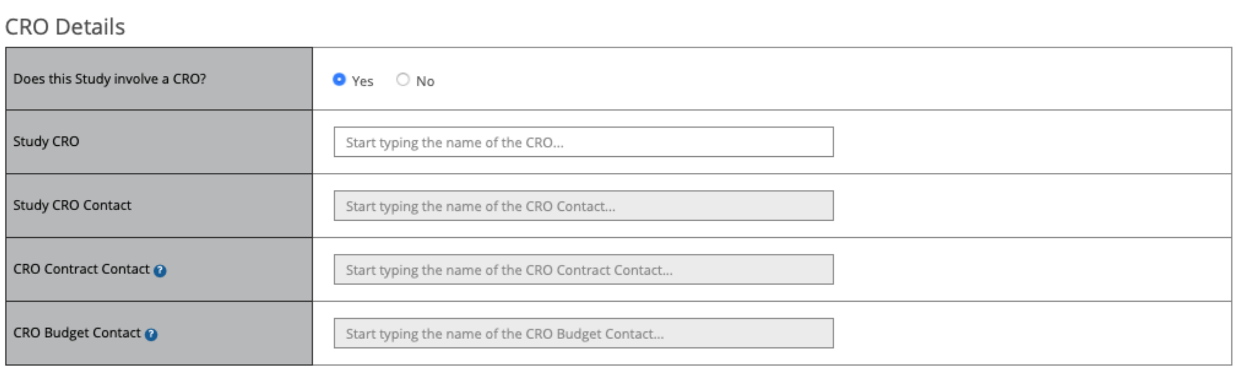
Sponsor contacts can be specified by specific responsibilities, such as contract and budget, or can be generalized (i.e., Study Sponsor Contact). At least one Study Sponsor contact will be required. Additional Study Sponsor Contacts can be added also. These users will receive all sponsor notifications.

Note: *If there are more than one users who will interact with contacts or budget during start-up, consider adding the additional Study Sponsor contacts here.*



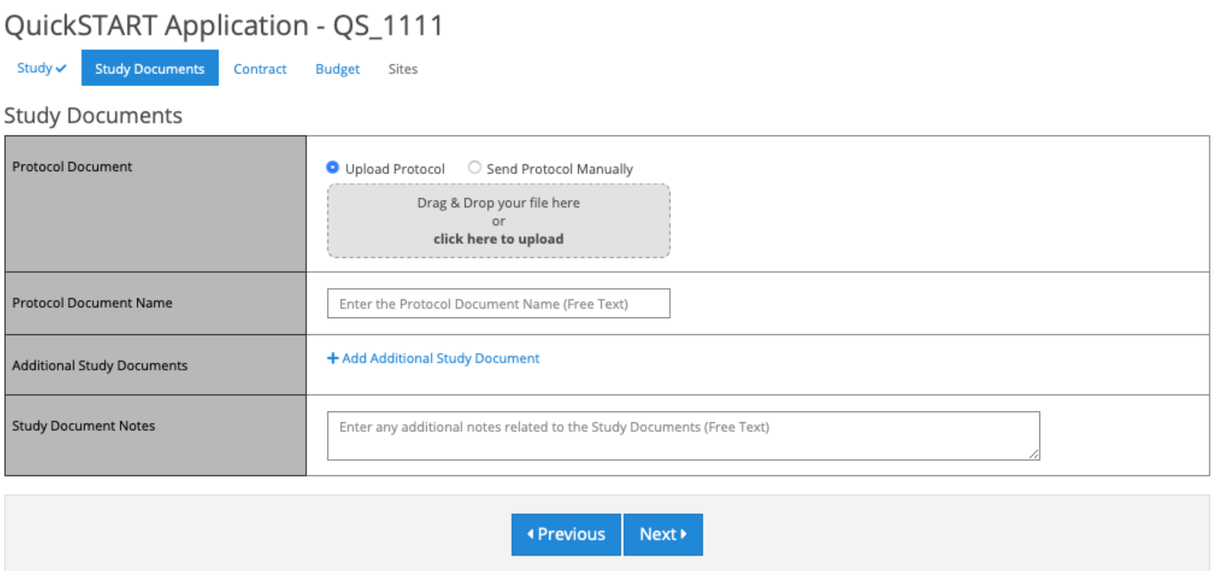
If a CRO will be involved in the study start-up and QuickSTART engagement, select 'yes' in the CRO Details section and assign users accordingly using the same logic as described for sponsor users.

Note: *If a CRO is included, it is required to identify one Study Sponsor Contact on the QuickSTART application to ensure full engagement.*



Study Documents

Study documents may be uploaded to the platform at this time, or can be indicated as 'sent manually' outside of the platform. In order to benefit most from the QuickSTART process, it is encouraged that documents be uploaded to the platform. Documents may be password protected for additional security. See the CTO *Electronic System Compliance Review* for additional information on security.



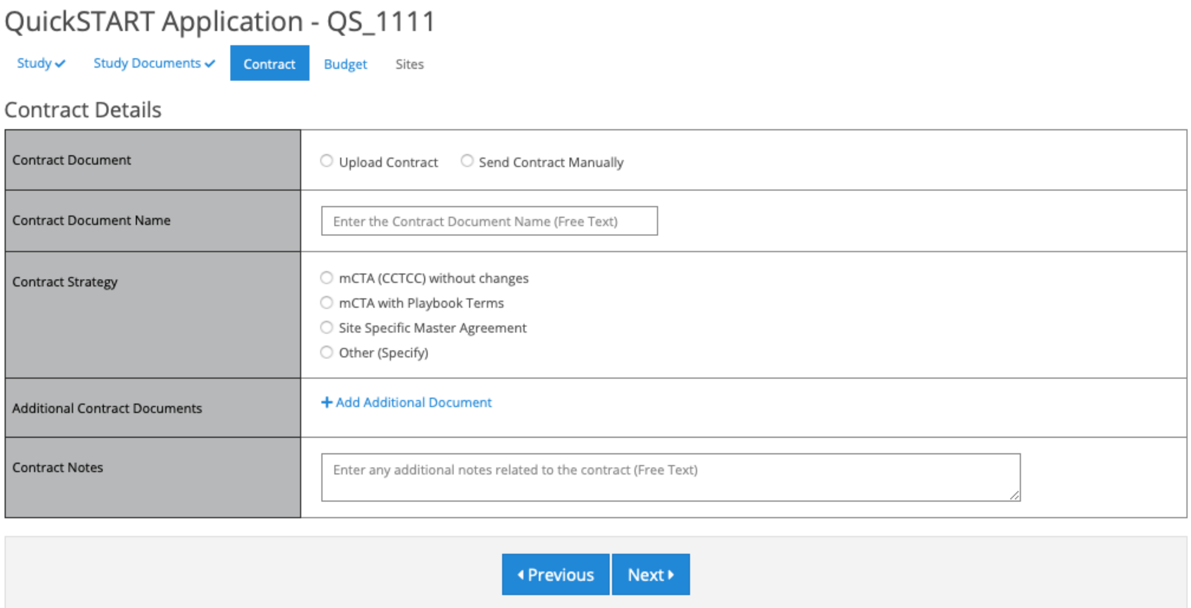
Additional study documents may include informed consent form, investigator brochure, sub-study protocols, letter of intent, etc. Many additional documents may be added. All documents that are added here will be available on the QuickSTART engagement screen for assigned users.

Note: *For additional document security, you may upload password protected documents. If you choose to use password protected documents, it will be up to you to communicate the document password(s) separate from the QuickSTART platform.*

Contract

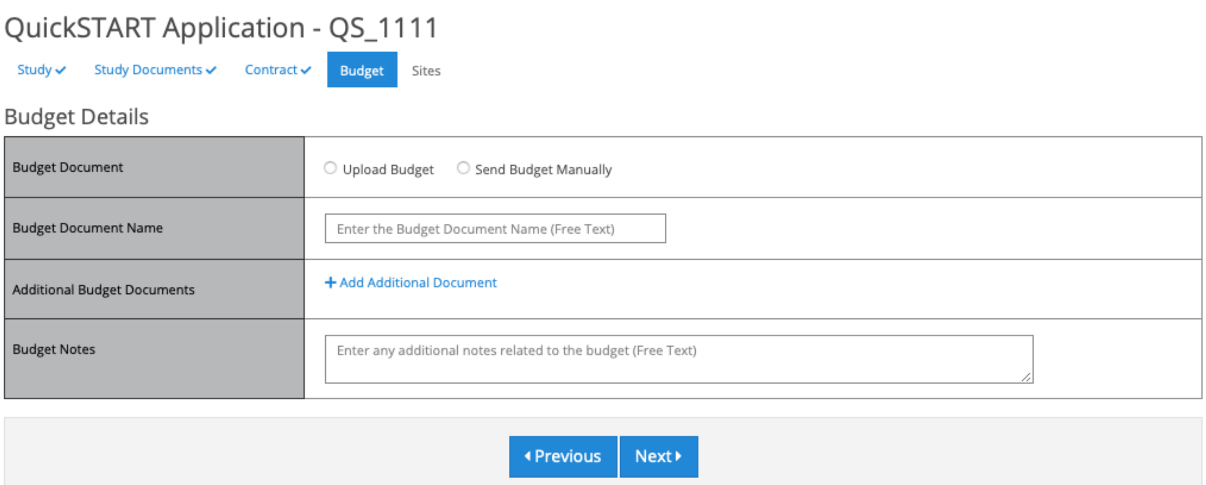
As part of QuickSTART, a streamlined contract strategy is required. The Sponsor contact may select from a number of streamlined contract strategies including the CCTCC model CTA (without changes or with playbook terms) or a site specific master agreement. ‘Other’ may include previously used contract with playbook terms addressed.

The contract can be uploaded to the application or sent manually.



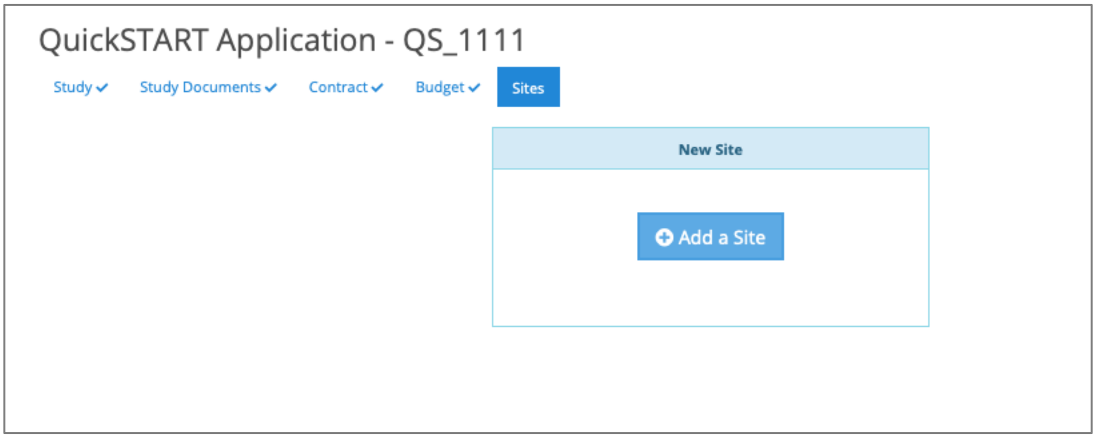
Budget

The study budget may be uploaded to the application or sent manually. Any additional documents to support the budget review may also be uploaded on this screen.



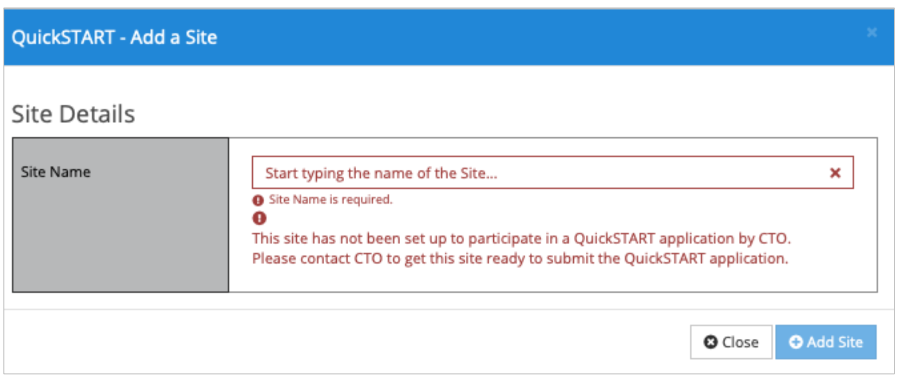
Adding Sites

On this tab, the Sponsor can add a new site to the application. If this is a new QuickSTART application, 'New Site' will be the only available option. If the Sponsor contact is adding an additional site to an existing QuickSTART application, all site engagements for this study will be available here.

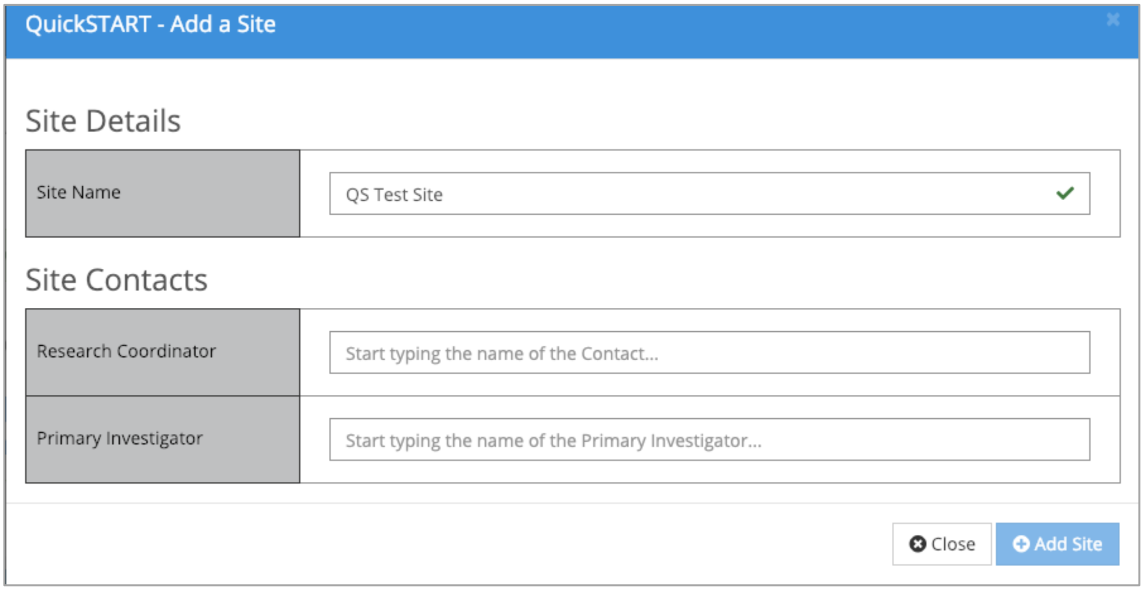


To add a new site click on the blue 'Add a Site' button within the 'New Site' box. On the next screen, you will be prompted to input the site name.

If the site is not yet QuickSTART Ready you will receive this message. Please contact CTO to ensure that the site is ready to proceed with a QuickSTART study application.



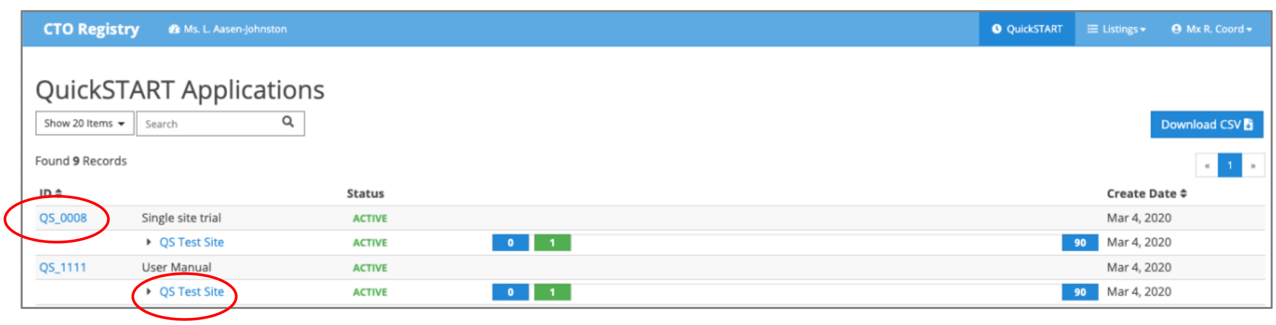
If a site is QuickSTART Ready, it will be available to select. Next, add the names of the Primary Investigator and Research Coordinator that will be working on this study.



QuickSTART Applications

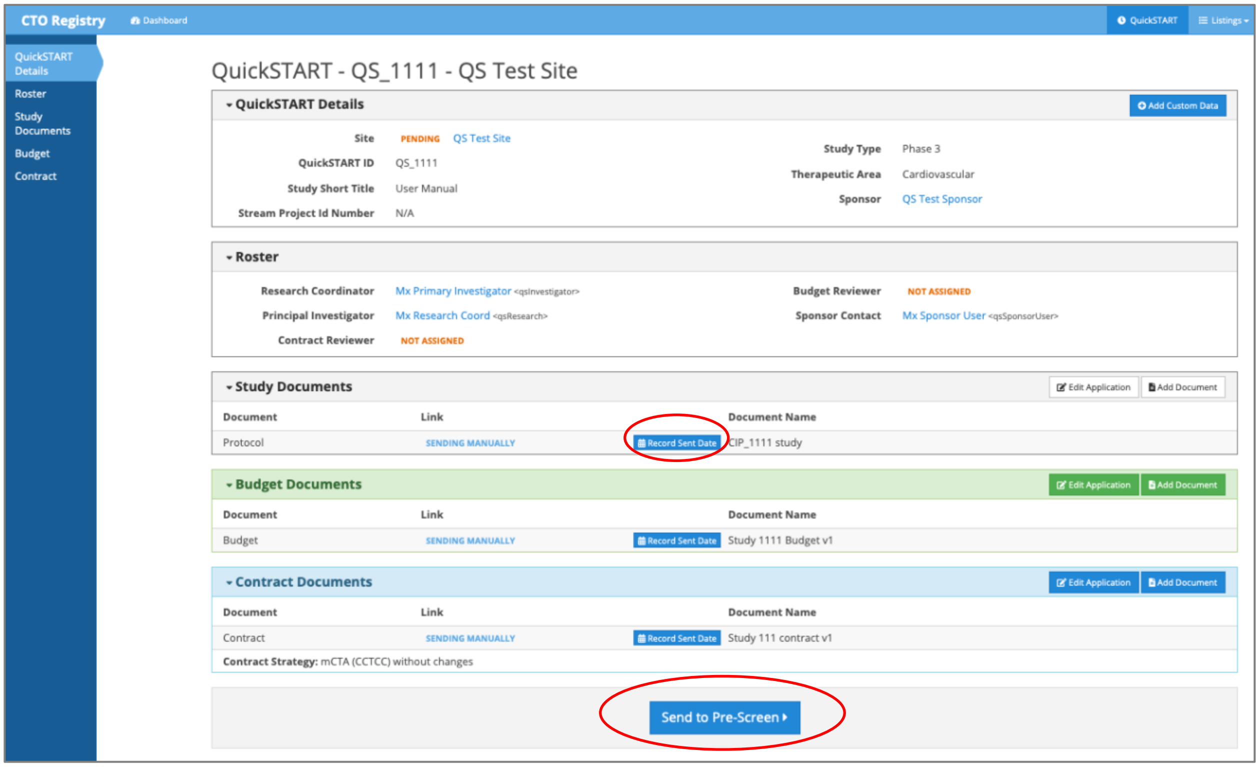
Any time a QuickSTART application is assigned to a user, the user will be able to see and access the QuickSTART engagement page from the QuickSTART applications list. The QS_ID will take Sponsor User to the QuickSTART application page for that study. Selecting the site name in the study list, will bring all users to the respective engagement page.

The QuickSTART timer is visible on this page for each engagement.

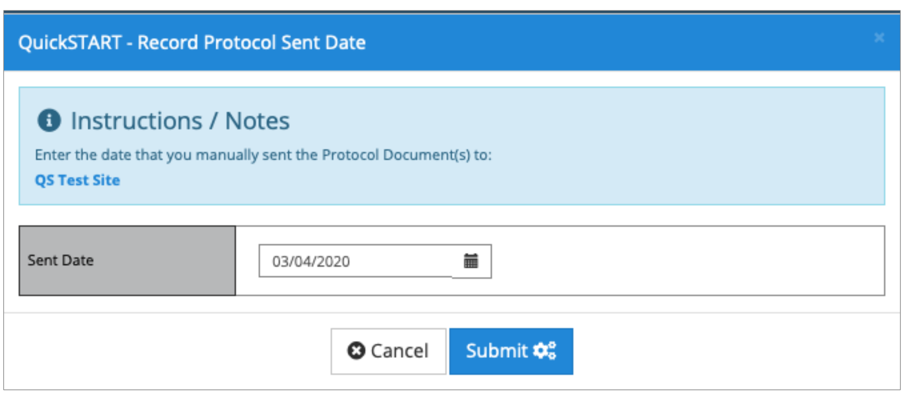


Pre-Screen

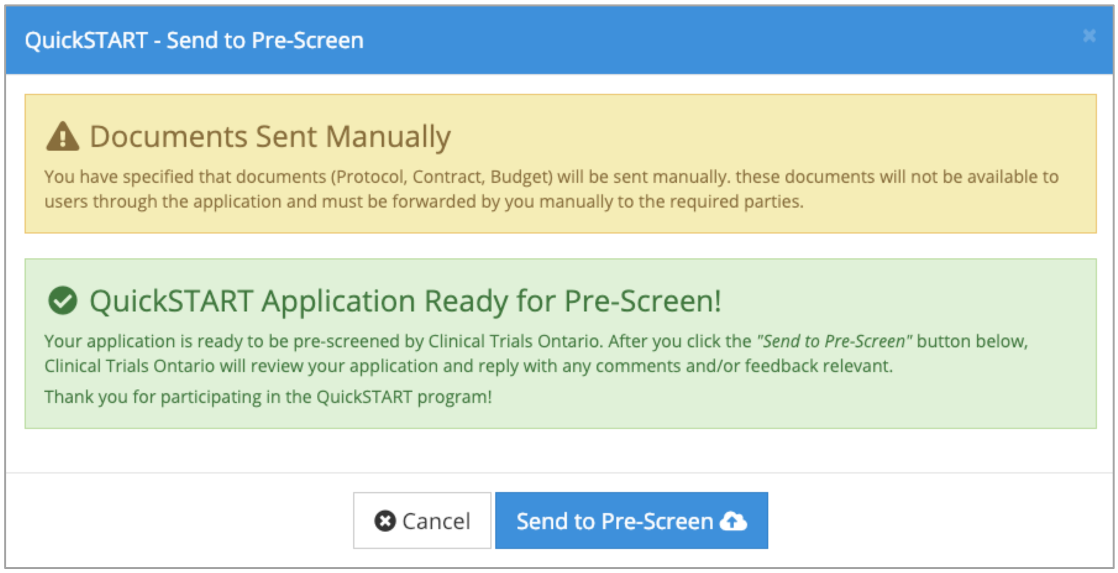
Once this is complete, you will have an opportunity to review the application and make changes as you wish. If you are satisfied with the application, select ‘Send to Pre-Screen’ to have CTO review the application prior to sending to the site.



If you have identified any documents as being sent manually, you may enter the 'sent date' at this time by selecting the 'Record sent date' button for each section as applicable. A pop-up screen will appear and allow you to select the date (this may also be back dated to ensure accurate records).



If a document is identified as being sent manually and you have not entered a date, you will receive a reminder about this before confirming that the application is being sent to pre-screen.

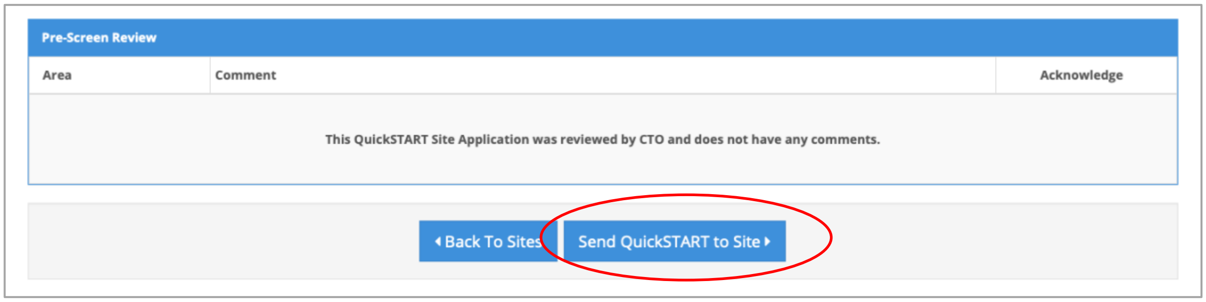


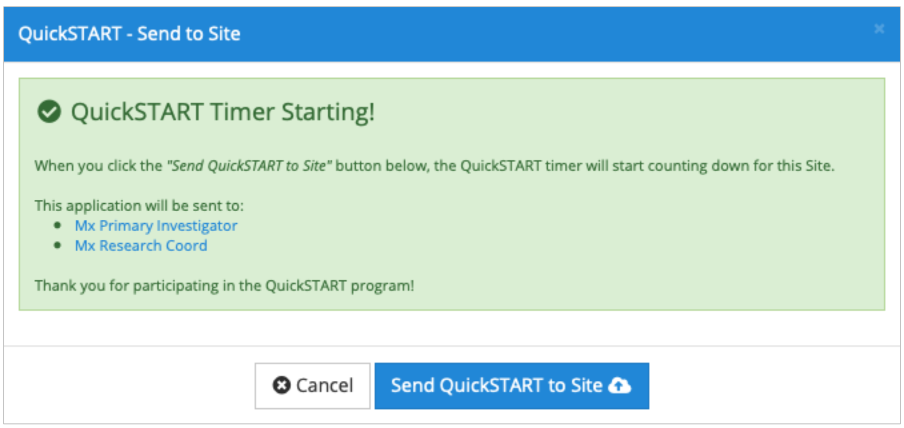
The application status for each site is indicated at the top of the engagement screen as well as on the QuickSTART Applications page.

CTO will review the pending QuickSTART application for completeness and to ensure streamlined strategies are in place. CTO will not review the content of the study documents, contracts, budgets, etc.

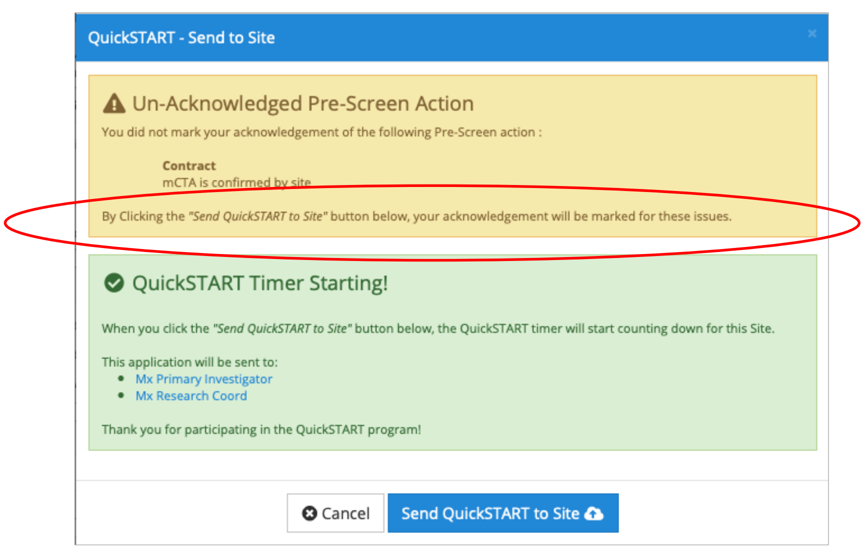
Once pre-screen is complete, the Sponsor user will be notified. The pre-screen review section will alert the Sponsor to any comments. If there is nothing outstanding, the Sponsor user can begin the QuickSTART engagement by selecting 'Send QuickSTART to Site'. This will start the QuickSTART Timer and the Site contact will be notified.

Submitting an application

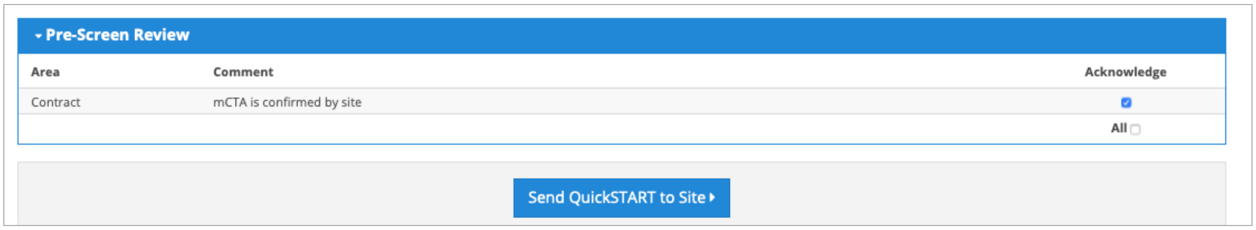




If there are comments from the CTO pre-screen, the Sponsor/CRO user will need to acknowledge the comment before the QuickSTART application can be sent to the site. A pop-up screen will alert you to the default acknowledgement of these comments.

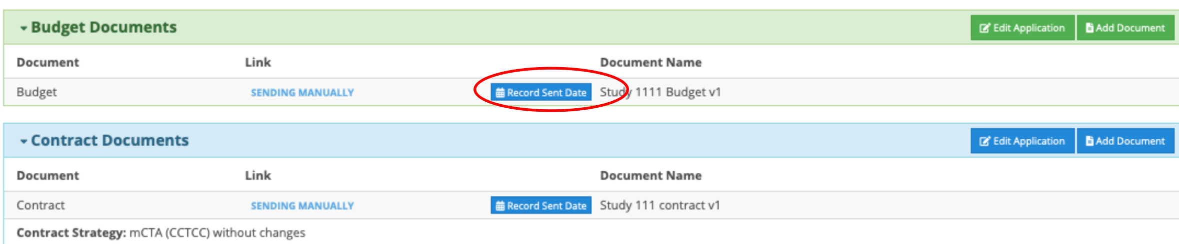


Pre-screen comments can be reviewed and acknowledged in the 'Pre-Screen Review' section.



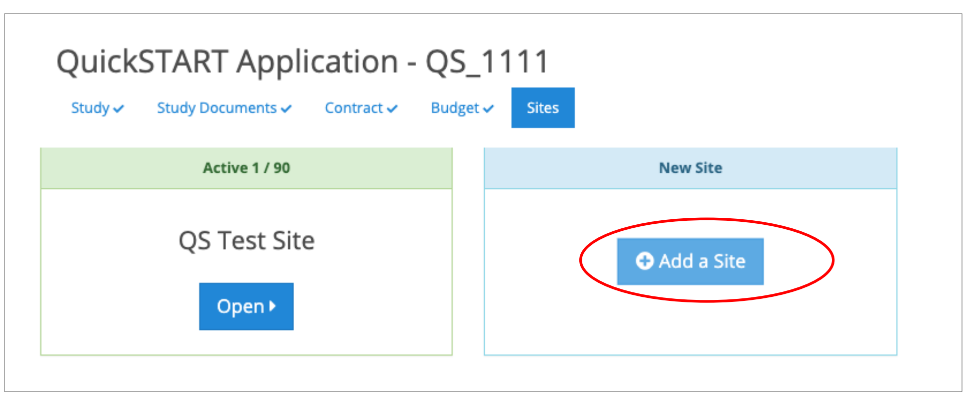
Reminder: *Submitting a QuickSTART application will start the timer for that engagement. In order to best utilize the QuickSTART platform, it is important that the site and sponsor have agreed to this timing.*

If you chose to send any documents manually, you will need to ensure all documents are sent by the time a QuickSTART application begins, and record this on the QuickSTART engagement page. Only the Sponsor can record or edit this date and it should reflect the date that the documents were sent to the site.

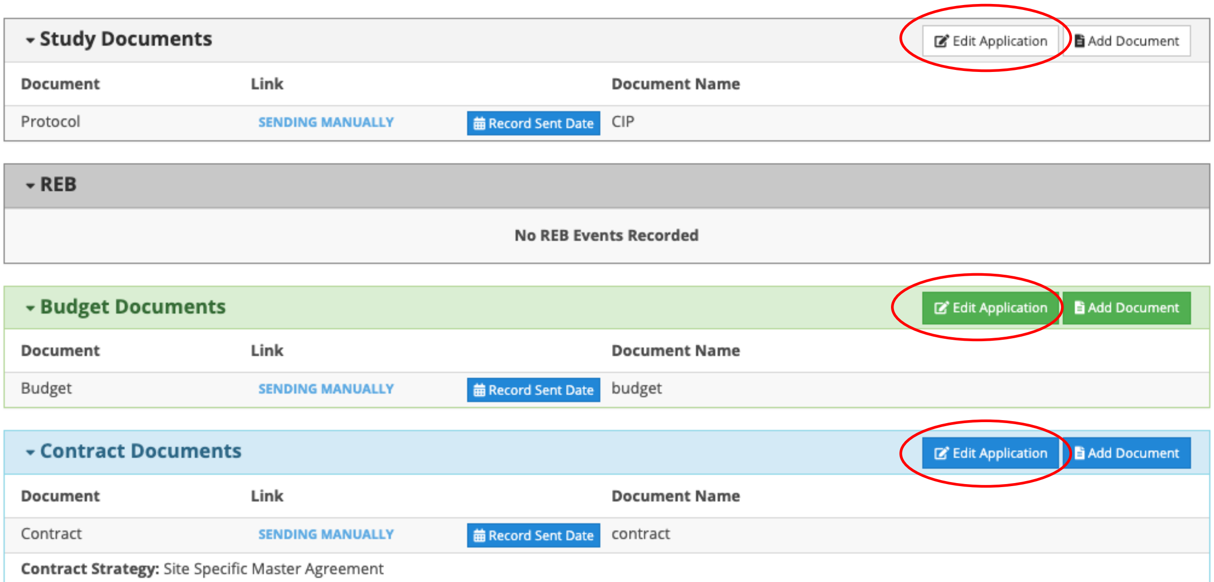


Adding New QuickSTART Site Engagements to an Existing QuickSTART Study

Once a QuickSTART engagement has been created for one site, a second site may be added very easily. The sponsor user can access the QuickSTART application for the study of choice and then select the 'Sites' tab. This will bring the sponsor user to this screen and the user can select 'Add a Site'.

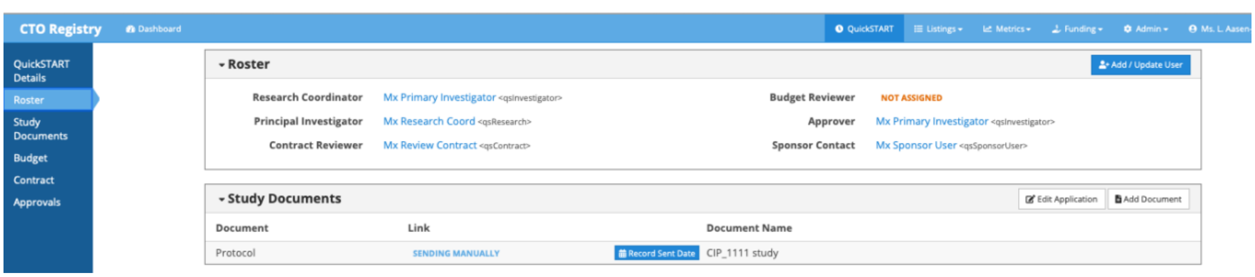


The user can then enter the new site name, investigator and research coordinator (RC) and submit. The contract and budget strategies will automatically default to the options that were utilized in the application for the first QuickSTART site in that study. However, if this is different for the new site, the sponsor user can customize these by selecting 'Edit Application' in any of the sections of the engagement screen prior to sending for pre-screen.



QuickSTART Engagement Screen

Quick Tabs along the left side of the screen will allow a user to jump to the area of interest on the engagement screen.



The QuickSTART Engagement screen is shared by the Sponsor/ CRO (if applicable) and Institution. The Roster will display all the users who are engaged on this page and have visibility to the study documents and approval status.

It documents were sent manually, they will not be available from this engagement page.

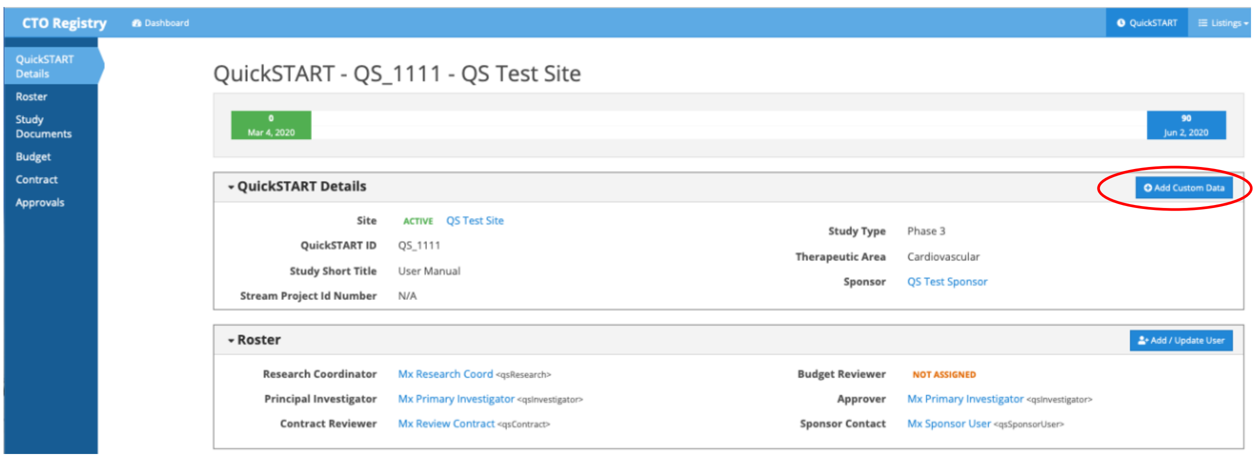
Research Coordinator assignments

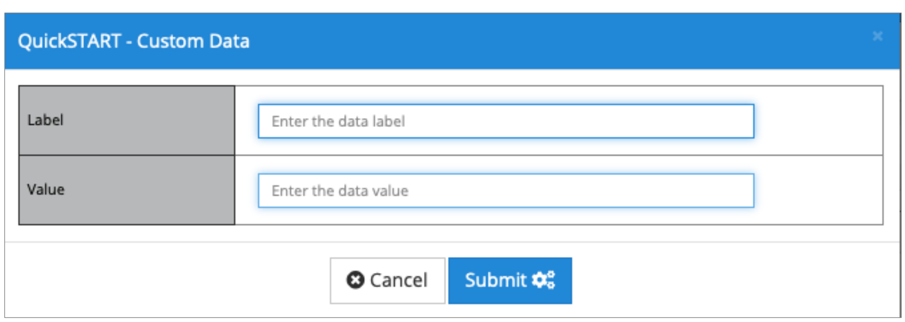
Once an application is sent to the site, the assigned Investigator and Research Coordinator (RC) will be notified from the digital platform. The timer also starts at **Day 0** upon submission.

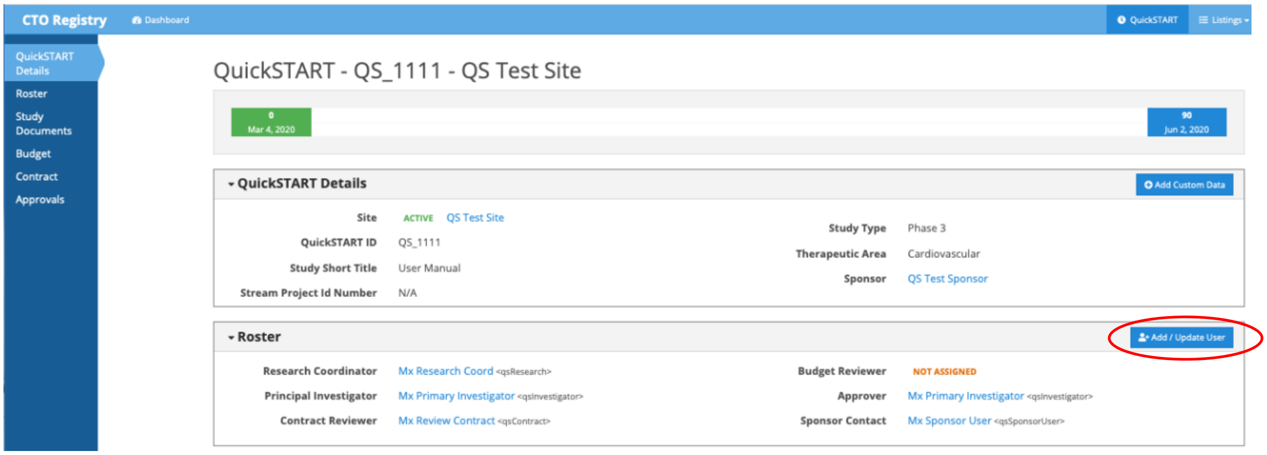
The RC will be able to access the engagement screen from the notification email or by logging into the QuickSTART digital platform. Upon receiving a new QuickSTART engagement, the RC may need to enter a number of details. The RC will need to assign the reviewer and approver roles from this screen (see Assigning a Role section).

Custom Data

This optional field may be utilized by the site to identify any internal ID that may be linked to this study and approval processes. Select 'Add Custom Data', then the Label name and ID.



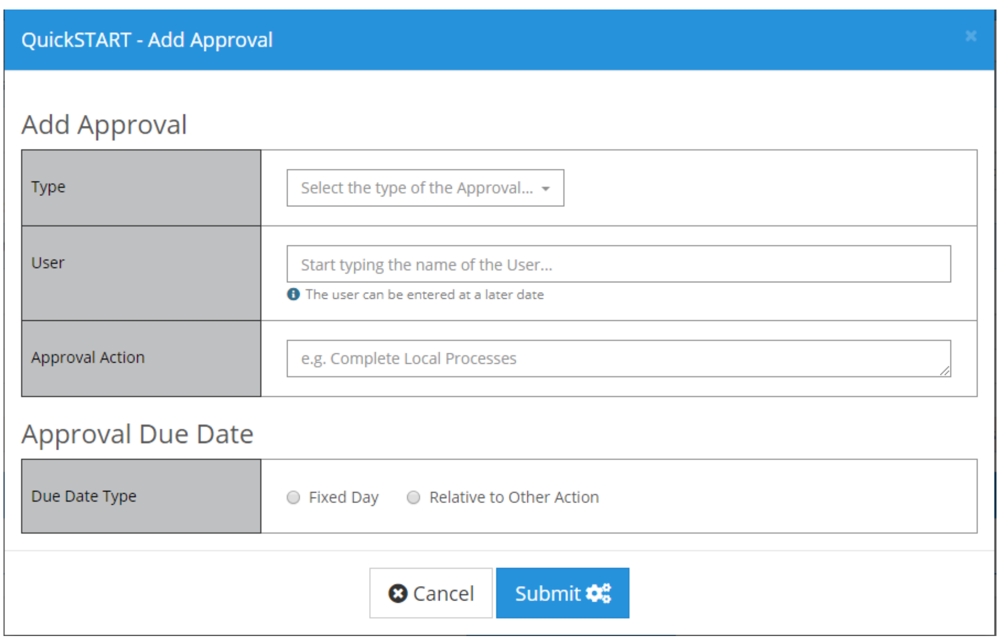




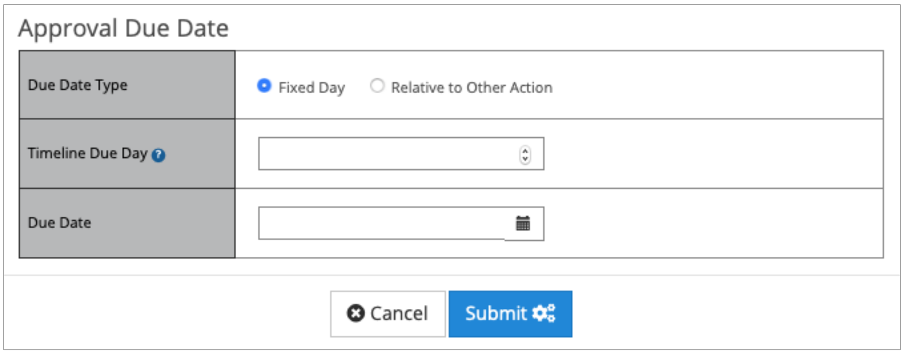
Adding Approvals

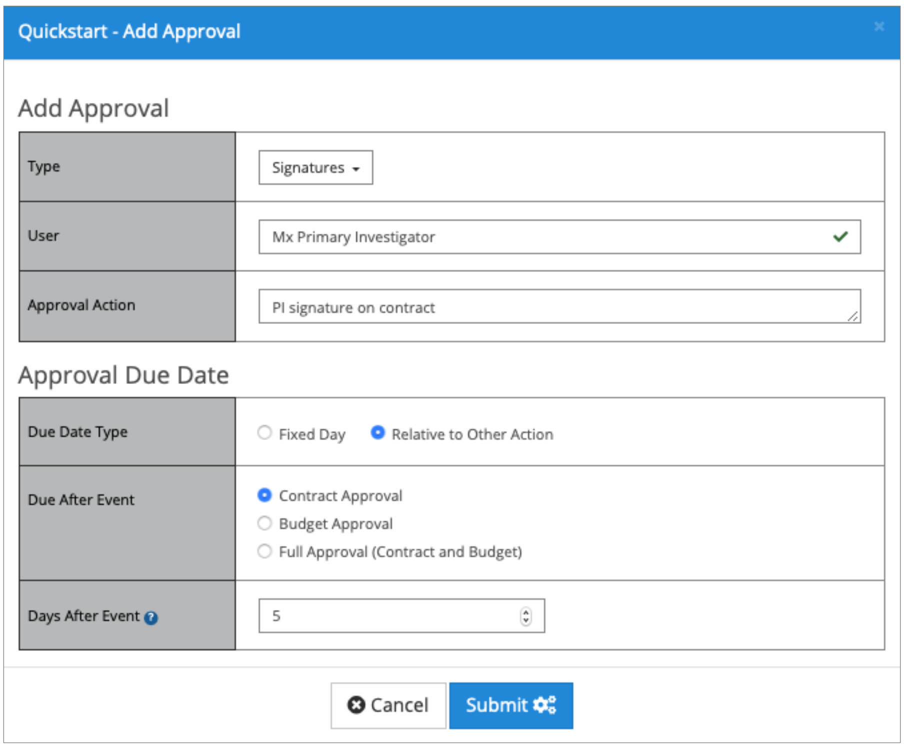
Select the 'Add Approval' button to enter details in the pop-up screen.

Approvals may only be assigned to QuickSTART users (i.e., verified account) and should be agreed upon in advance of assignment.



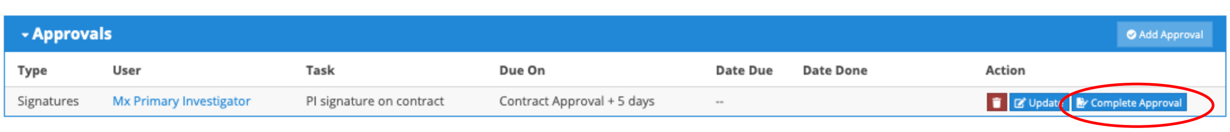
Approval dates can be fixed (either number of days from Day 0 or date) or relative to another action. The latter may be considered in scenarios where the current approval cannot be completed without a previous approval, as in the case of a contract signature (see example below).





When adding approvals, the user can be left blank and added a later time if it is not known who will be responsible for the approval.

Once approval items have been added to the application, type of approval, the assigned reviewer, the task details and due date will be visible in this section. The assigned reviewer will receive notifications on this item and can select 'Complete Approval' when the task is complete. After this is complete, the approval line will turn green with a completion date recorded and no further edits will be allowed on this item. Due dates can be set according to institutional guidance for each item in this section.



Institution Approval Templates

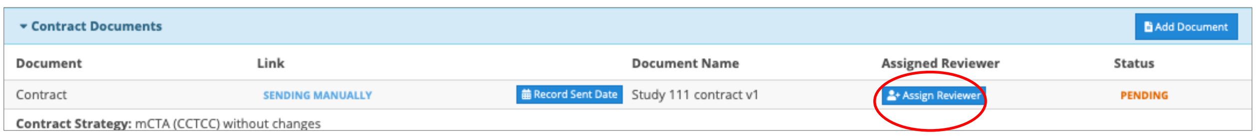
If an institution has a standard set of Approvals that will always be added to their QuickSTART site engagements, these approvals can be added to the institution as templates, and will then be added to any future QuickSTART site engagements started for that institution.

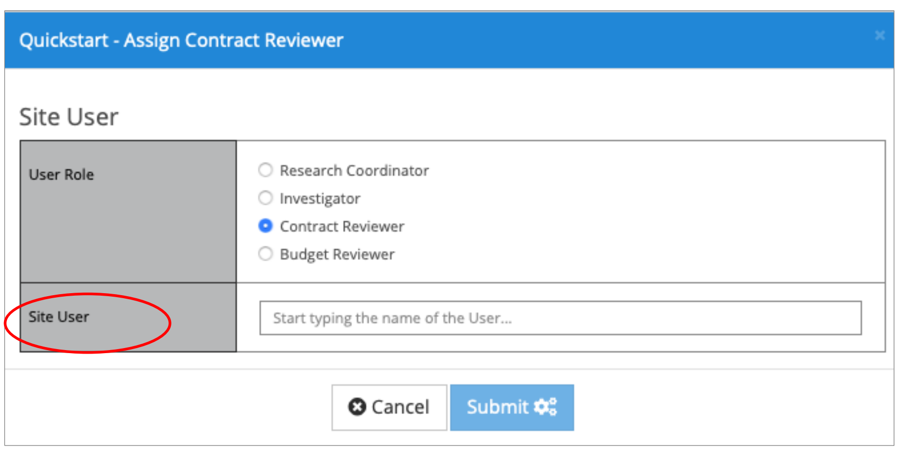
These templates are created in exactly the same way as approvals, but instead of adding them to each individual site engagement, they are added to the institution.

Access to this feature is controlled by CTO. To add institution approval templates to your institution, contact CTO to gain access to this feature, or CTO can you in set up the templates on your behalf.

Contracts

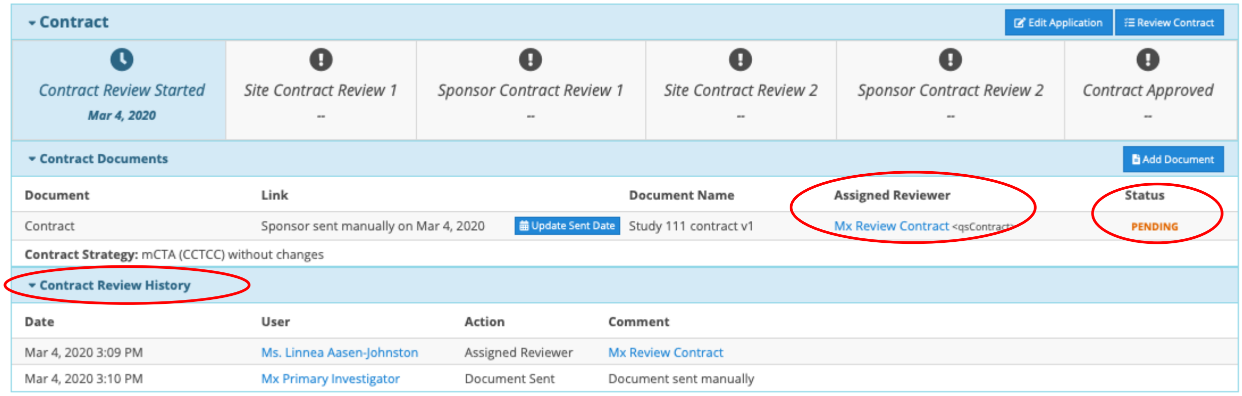
A contract reviewer must be assigned in the contract section.





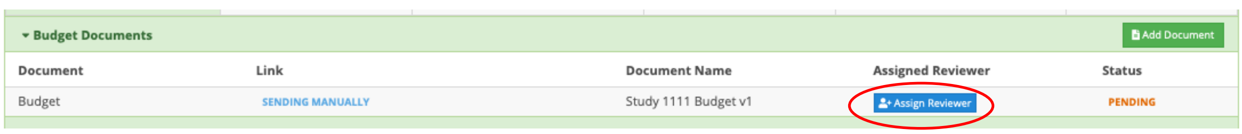
Once a contract reviewer has been assigned, they will be visible in this section of the engagement screen. The current status of the contract review is displayed under the status column at the right of the table. Additionally, the 'Contract Review History' will document the movement and current status of the review. The status bar will update automatically as the review is documented.

All sections of the contract can be minimized using the arrows to the left to allow the user to focus on their particular area of interest.



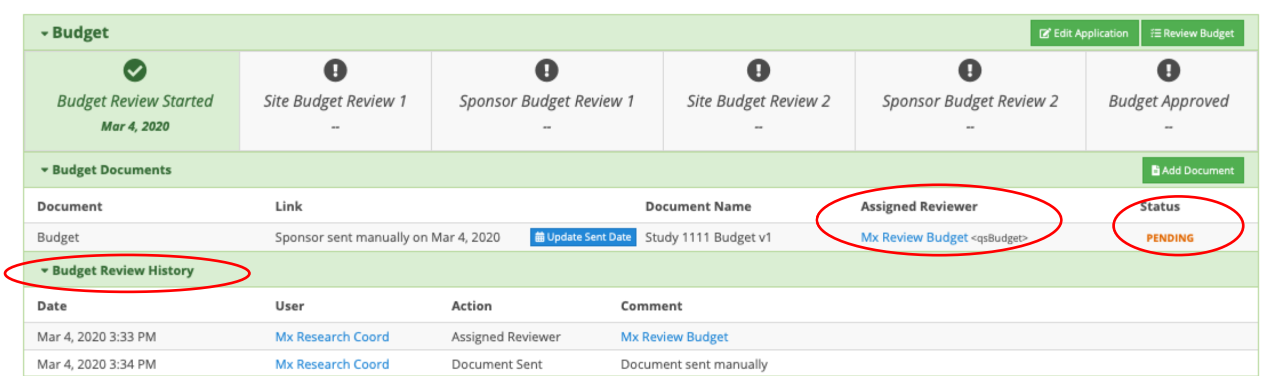
Budgets

A budget reviewer must be assigned in the budget section.



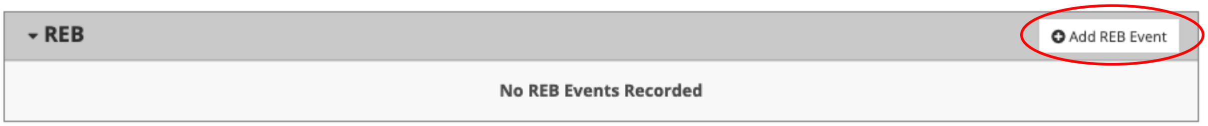
Once a budget reviewer has been assigned, they will be visible in this section. The current status of the budget review is displayed under the status column at the right of the table. Additionally, the 'Review History' will document the movement and current status of the review. Additionally, the 'Contract Review History' will document the movement and current status of the review. The status bar will update automatically as the review is documented.

All sections of the contract can be minimized using the arrows to the left to allow the user to focus on their particular area of interest.

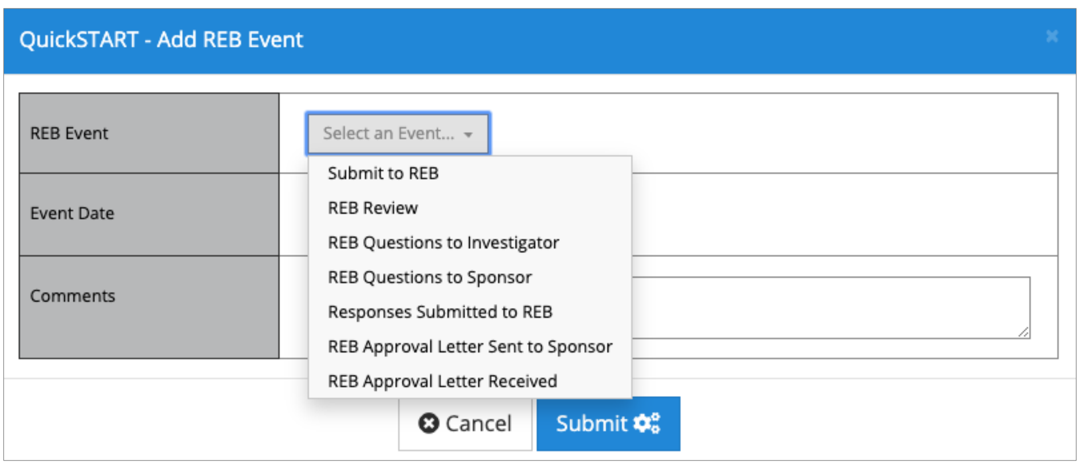


Single Site REB

If a QuickSTART study is a single site trial and Stream will not be utilized for the ethics review portion, the Sponsor will indicate this on the QuickSTART application, allowing the RC to enter information on the REB status.



Status updates can be made as they occur, or can be entered as a planned date in the future (e.g., REB review date).

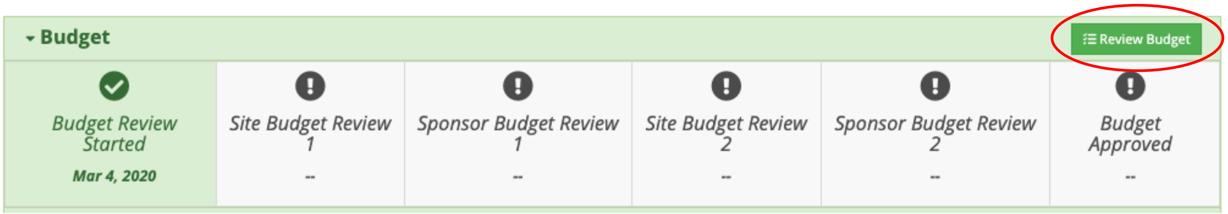


As the events are completed, they can be checked off by the RC and this will be logged.

Reviewing a Document in the QuickSTART Engagement Screen

Site Reviewer

The user who is assigned to review the Contract or Budget can do so by selecting the 'Review' button in that section. The QuickSTART timelines and notifications are based on two rounds of review in order to encourage a full review within the associated timelines (see Appendix B for QuickSTART Timelines).



A pop-up screen will appear with the choices ‘Comment’ or ‘Send to Sponsor’ along with the date associated with the comment/action.

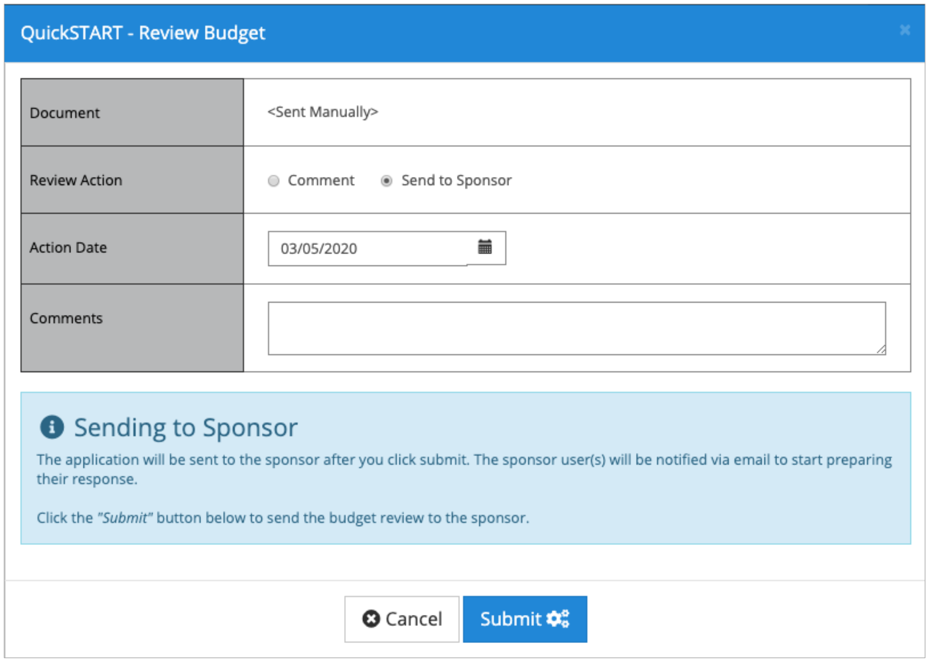
A comments section is available to add in notes for the other party or for the other department within an organization. These notes will appear in the Review History table. A comment <u>will not</u> end the review round, reset the status /timer, or send a notification to the other party.

In order to log the end of the given review round and send notification to the other party that the timer has begun for their review, you must select ‘Send to Sponsor’. A notice will pop up to ensure that this is your intention. Select ‘Submit’ to proceed.

This will be logged in the Review History section.

Budget Review History

Date	User	Action	Comment
Mar 4, 2020 3:33 PM	Mx Research Coord	Assigned Reviewer	Mx Review Budget
Mar 4, 2020 3:34 PM	Mx Sponsor User	Document Sent	Document sent manually
Mar 5, 2020 2:29 PM	Mx Review Budget	Reviewer Comment	final changes requested
Mar 5, 2020 2:29 PM	Mx Review Budget	→ *Sent To Sponsor*	

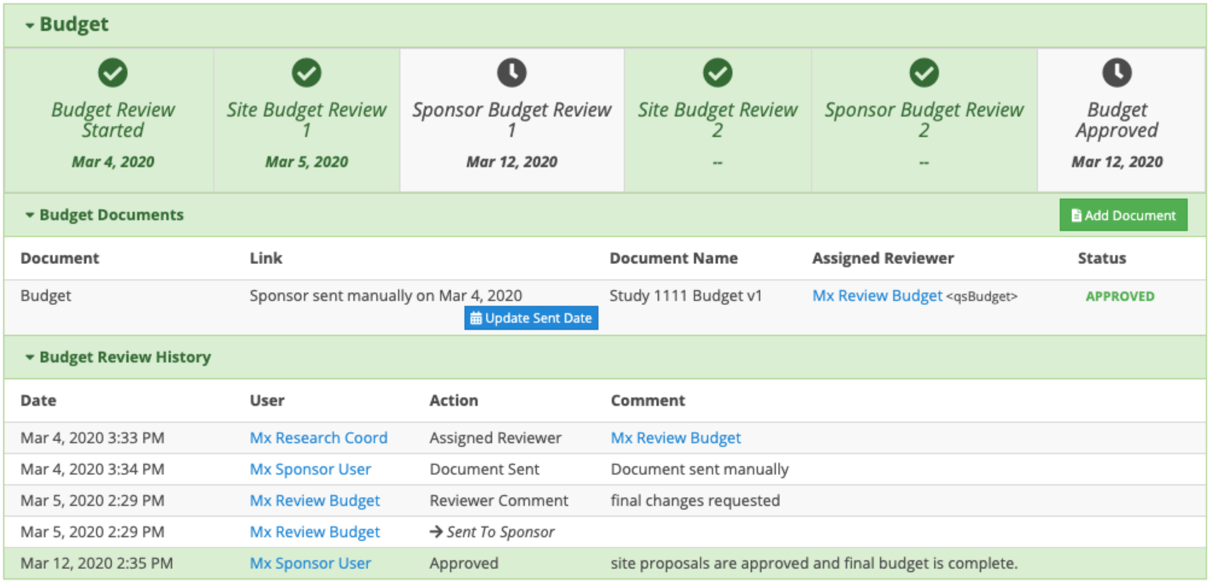


If the document has been uploaded to the platform by the sponsor, the reviewer may upload a revised version of the document upon review by selecting the ‘Add Document’ button. For more information about the ‘Add Document’ feature, see The Sponsor user can ‘Comment’, ‘Send to Site’ or ‘Approve’. If the document was initially uploaded to the platform, the Sponsor can also upload a revised document using the ‘Add Document’ button.

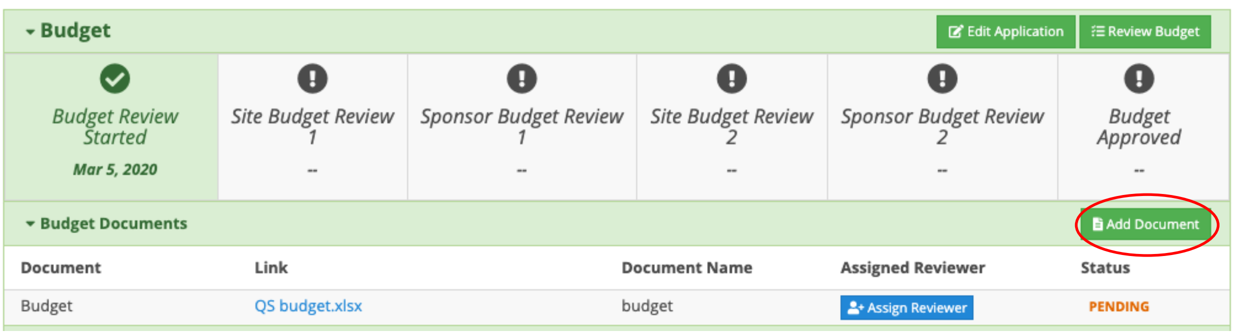
As with the site review, ‘Comment’ will only log a comment for that date, however the review timer will continue for the sponsor review cycle and no notification of change in status will be send to the site reviewer. ‘Send to Site’ will end the sponsor review cycle, notify the site reviewer and restart the timer for the site review.

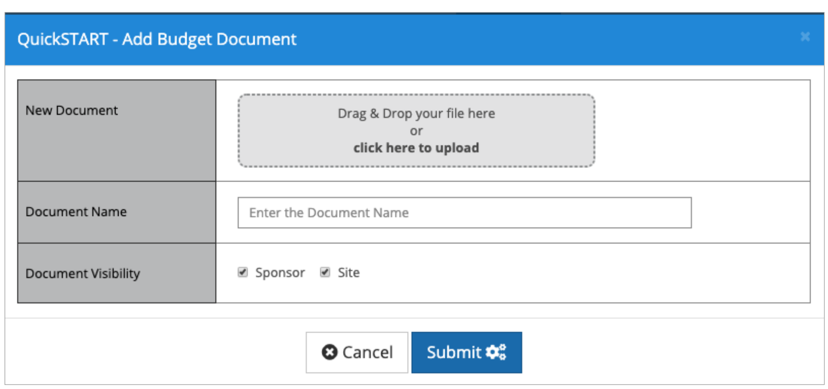
‘Approve’ is an action exclusively available to the sponsor reviewer and would signify that the item is approved and negotiations for that section are complete. This should only be completed after the site has indicated that they are approved this from their side and the sponsor is ready to accept this final version.

Once a section has been approved, no additional information can be added to this section. The status will be updated automatically.



Adding an Additional Document to a QuickSTART Application.



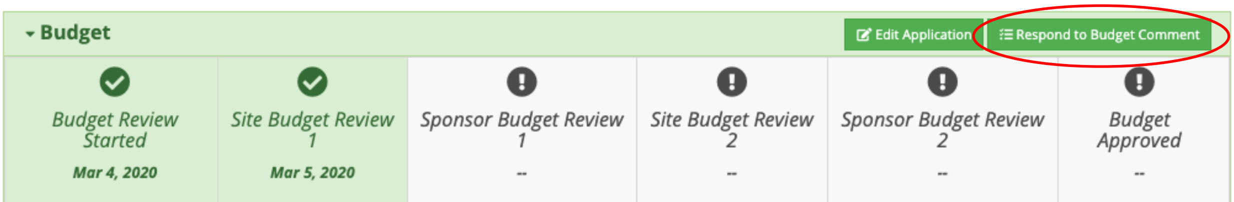


Sponsor Review

When the Reviewer at the site submits their review (i.e., 'Send to Sponsor'), the QuickSTART platform will notify the applicable Sponsor users to alert them to the change of status and to indicate the next timers have begun for the sponsor's review cycle.

The Sponsor user can access this QuickSTART engagement screen by clicking the link in the email notification or by logging onto the QuickSTART platform and selecting the appropriate study and site.

The Sponsor user can review and respond to the document review by selecting 'Respond to Comments' button.

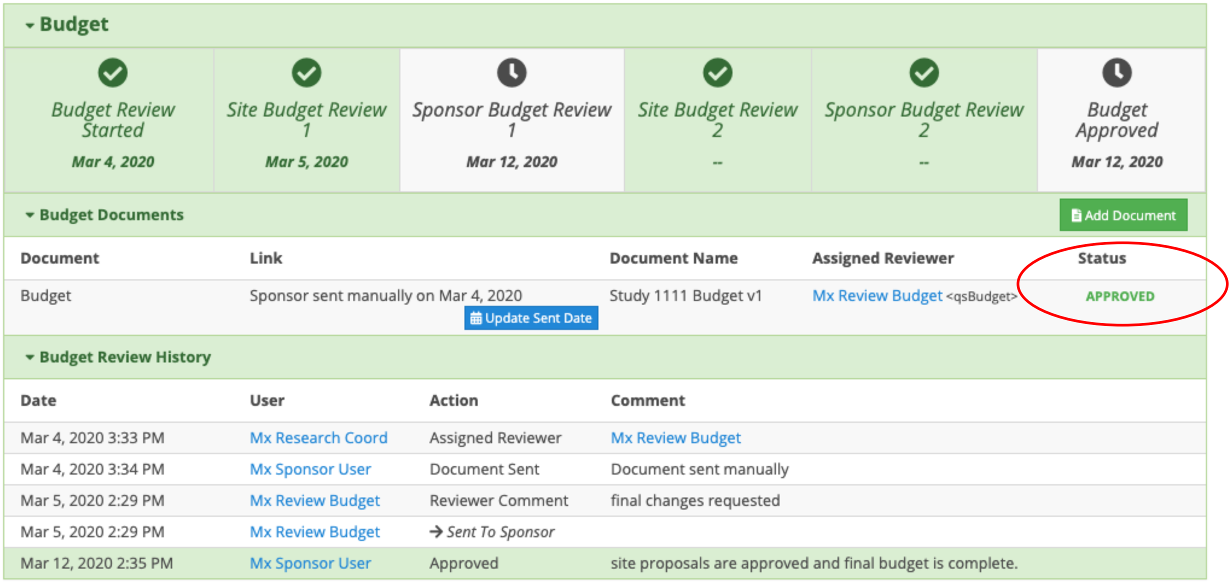


The Sponsor user can 'Comment', 'Send to Site' or 'Approve'. If the document was initially uploaded to the platform, the Sponsor can also upload a revised document using the 'Add Document' button.

As with the site review, 'Comment' will only log a comment for that date, however the review timer will continue for the sponsor review cycle and no notification of change in status will be send to the site reviewer. 'Send to Site' will end the sponsor review cycle, notify the site reviewer and restart the timer for the site review.

'Approve' is an action exclusively available to the sponsor reviewer and would signify that the item is approved and negotiations for that section are complete. This should only be completed after the site has indicated that they are approved this from their side and the sponsor is ready to accept this final version.

Once a section has been approved, no additional information can be added to this section. The status will be updated automatically.



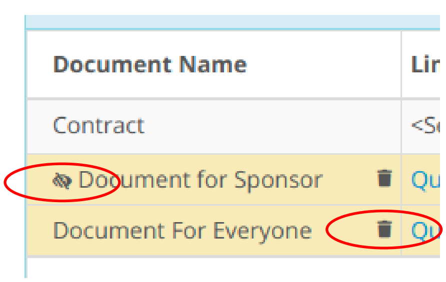
Adding an Additional Document to a QuickSTART Application

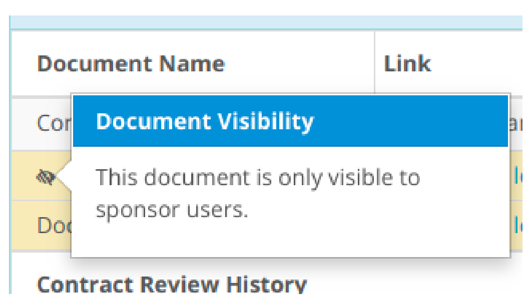
In addition to uploading revised documents after review, the 'Add Document' feature can be used to add any additional documents to the application for any purpose.

When adding documents you can select the visibility, which will control who from the QuickSTART application can see the uploaded document. The options for document visibility are 'Sponsor' and 'Site'.

- **Sponsor** and **Site**: all users can see this document
- **Sponsor**: all Sponsor and CRO users can see this document
- **Site** : only site users can see this document
- ***<None>***: Only visible to the user that uploaded the document

Note*: If an additional document was added neither the sponsor and site selected as visible, then a small "eye" icon will be displayed to show the visibility restrictions.*





Additional documents can be removed at any time by the uploading user or by the RC for the QuickSTART site application by clicking on the garbage can icon next to the document name.

***Note**: Sponsor users have the ability to update the original documents that are part of the application. It is up to the sponsor whether they would like to update the original document using the 'Edit Application' feature, or upload a new revised document using the 'Add Document' feature.*

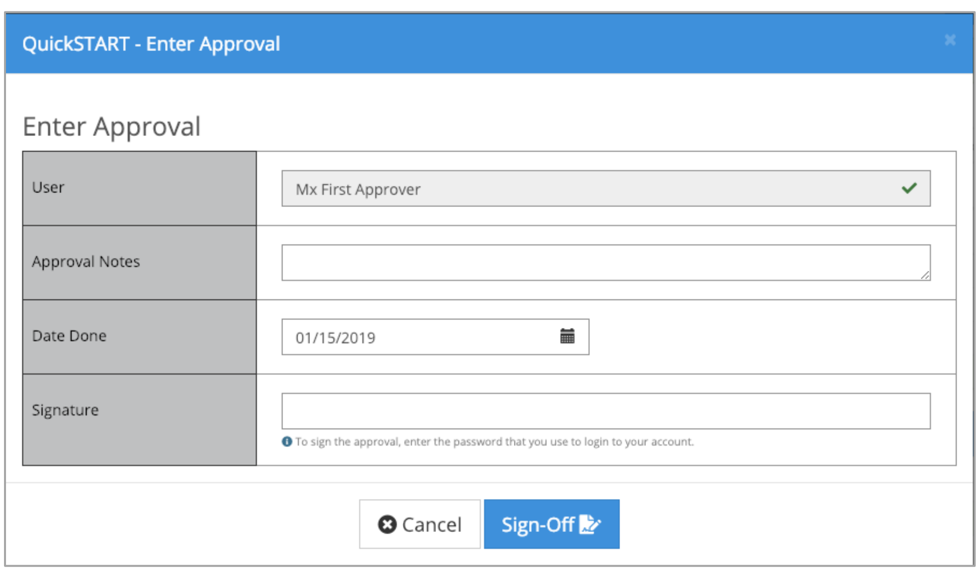
Examples of Extra Documents

- Investigator Brochure
- Final approved Informed Consent form
- Training manual

Entering an Approval Item in the QuickSTART Engagement Screen

Site Approver

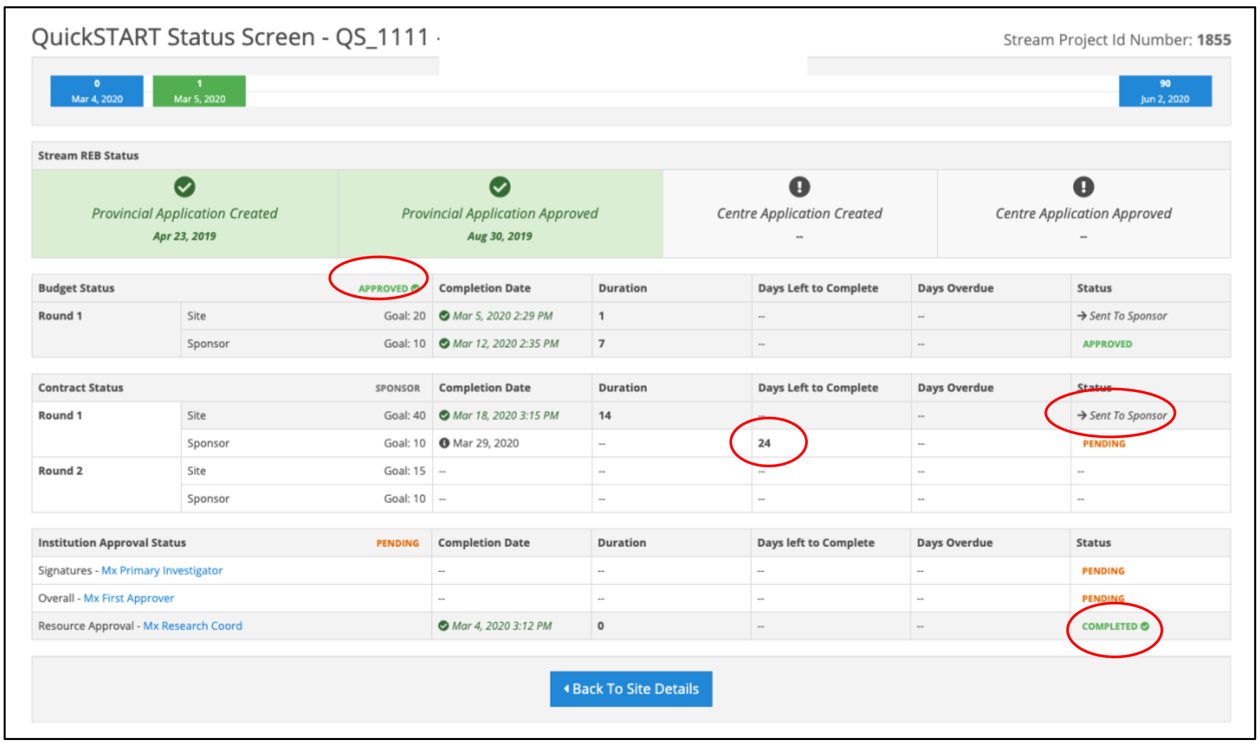
The user who is assigned as an Approver can easily do so by selecting the 'Complete Approval' button in the Approvals section for the assigned approval. Selecting this button will open a pop-up screen where the Approval Notes can be entered as well as the date. The approvers signature is required- this is the password for the account of that approver. The final step is to select 'Sign off'.



QuickSTART Status Screen

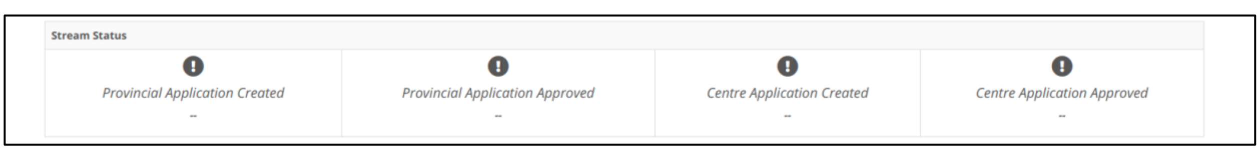
The QuickSTART Status screen is shared by the Sponsor/CRO and Institution users. There is full visibility to both parties and all users that are included on the 'Roster'. This screen acts as a visual overview of each activity status.

The overall timeline is shown at the top of the screen. The status of each section is noted at the top and bottom of the section. For each review cycle, the review cycle goal is noted in days, the completion date and duration of review (once complete), and the days left to complete or days overdue are displayed when the review is pending.

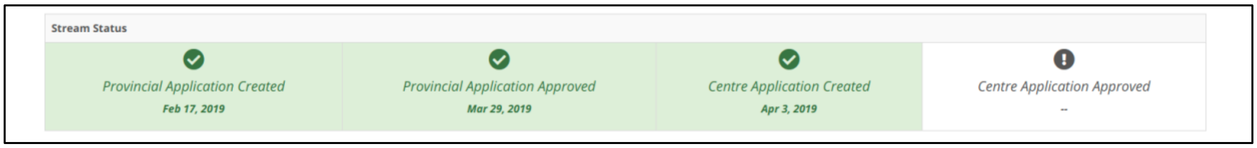


Stream Status

If the QuickSTART application has a Stream Project ID Number, then the status screen will also show a summary of the Stream review for the related provincial and centre applications.



As review are completed this section will update to show the dates that the events took place on.



***Note**: This information is updated from CTO Stream in CTO Registry hourly. Due to this, it may take up to one hour for approvals entered in CTO Stream to be displayed in the QuickSTART application.*

QuickSTART Completion and Metrics

A QuickSTART application and engagement is considered complete once all activities and approvals are indicated as 'Approved'. For non-single site applications that have provided a Stream ID, this includes the REB approval.

When a QuickSTART application is complete, metrics will be collected and logged for that site, sponsor and study engagement. Metrics can be further analysed to identify areas of improvement after the completion.

QuickSTART Extension

If a QuickSTART study is determined to be more complex in nature either at the start of the engagement or during the engagement, parties may collectively decide to extend the completion goal. This will still allow the start-up status to be tracked and supported by the QuickSTART platform while maintaining realistic targets.

QuickSTART Termination

If a QuickSTART application is not being actively maintained by the Sponsor and / or the Institution, the engagement may be terminated. The QuickSTART program is built on the agreement of all parties that they are engaged and willing to meet the timelines within the QuickSTART process. If this is no longer true, the application may be deemed as no longer QuickSTART eligible and will be removed from the system.

Appendix A- QuickSTART Notifications

Timepoint/ Action	Message	User Receiving Message
Create Application	New application created	CTO, Sponsor, Research Coordinator
Pre-Screen	Status of pre-screen	CTO, Sponsor
Application submitted	QuickSTART timer has started	Investigator, Research Coordinator, Sponsor
Reviewer/ Approver is added to application	Notification- Added to a QuickSTART application	Site Reviewer/ Site Approver (newly assigned only)
Review is submitted by Site Reviewer	Notification of change in status	Sponsor
Review is submitted by Sponsor	Notification of change in status	Site Reviewer
Approval entered	Notification of change in status	Research Coordinator
Last Approval/ Review complete	Site Start-up completed	ALL assigned users
Last Approval/ Review complete + Stream PIA and CIA approved	Site is ready	ALL assigned users
Reviewer reminders	Review due in 7 days	Site Reviewer, Research Coordinator
Sponsor reminders	Review due in 4 days	Sponsor
Timeline reminders (45, 70, 80 days)	XX days left	Sponsor, Research Coordinator
Timeline reminders (85, 90 days and past due)	5 days left; Due Today; Past Due	Sponsor, Research Coordinator, Investigator

Note: *CRO Users will receive all Sponsor emails*

Appendix B- QuickSTART Timelines