

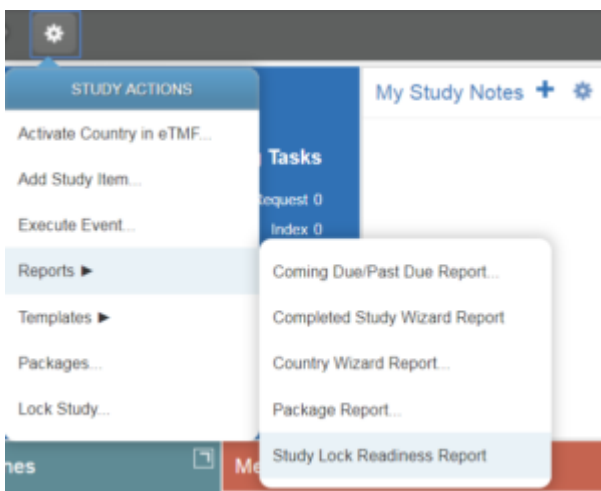
Study Lock

A study can be locked as a way to both prevent the study from modification and prepare it for [archiving](#). Locking a study inhibits a user from making any changes for a study, including: [Uploading](#) content, deleting study items, fulfilling study items, obsoleting study items, and running wizards for the study that is locked. Users with Check Lock Preparedness permission can lock a study.

Review the Lock Readiness Report

Before locking a study, review the Lock Readiness report. Generate the report by executing the following steps:

1. Navigate to the Study Home page of the study you want to lock.
2. Click on the Actions menu icon and select **Reports >Study Lock Readiness Report**.



The report downloads to either your default download location or to a location you specify. The exact behavior is based on the browser used.

The report contains a summary page that displays counts of issues in the following categories:

- Unfulfilled Study Items
- Documents in Work Area
- Documents in Workflow
- In-process Wizards
- Countries with No Sites
- Sites not in TMF
- Unaddressed Acknowledgements

The report also shows the breakdown of issues within each category.

| Study Lock Preparedness Report | |
|---|---------------|
| Study A0350125 | |
| Study Owner Study Owner 0 | |
| Generated 02-Jul-2013 1:39:41 PM by Business Administrator 1 | |
| Summary | |
| Category | Issues |
| Unfulfilled Placeholders | 12 |
| Uploaded/Transmittal Documents | 2 |
| In QC Documents | |
| In-process Wizards | 1 |
| Countries Without Sites | 2 |

| Unfulfilled Study Items | | | | | | |
|--|---------|------------------|---------|------|-------------|--------------|
| Study Item Name | Is Core | Study Item Level | Country | Site | Site Status | Organization |
| This study has more than 100 issues identified when compared against the Unfulfilled Study Items lock criteria. This section will only display the first 100 identified issues. | | | | | | |
| Accountability Documentation (Site Level) | true | Site | CANADA | 8245 | ONGOING | ClinOps |
| Audit Certificate (Site Level) | true | Site | CANADA | 8245 | ONGOING | QA |
| Clinical Trial Agreement | true | Site | CANADA | 8245 | ONGOING | Legal |
| Documentation of Corrections to Entered Data (Paper) | true | Site | CANADA | 8245 | ONGOING | Data |
| Final Trial Close Out Monitoring Report | true | Site | CANADA | 8245 | ONGOING | ClinOps |
| Financial Disclosure Form - Joanne O. Dalrymple | false | Site | CANADA | 8245 | ONGOING | ClinOps |
| Investigator Regulatory Agreement | true | Site | CANADA | 8245 | ONGOING | ClinOps |
| IP Shipment Documentation (Site Level) | true | Site | CANADA | 8245 | ONGOING | ClinOps |
| IP Shipment Documentation (Site Level) | true | Site | CANADA | 8245 | ONGOING | ClinOps |

Complete all required and desired remediation

If there are issues outlined in the Study Lock Readiness Report, complete all required and recommended remediation based on the following guidance:

| Issue | Action | Must be Addressed? |
|--------------------------------|--|---------------------------|
| Unfulfilled Study Items | Determine why they are empty and perform one of the following options: * Obtain Content * Mark as Fulfilled without Content * Delete | No |
| Uploaded/Transmittal Documents | Determine if content is needed. * If not needed, delete using Advanced Search * If needed, contact contributors to release the documents to QC | Yes |
| In QC Documents | Contact task owners to expedite the completion of tasks. | Yes |
| In-Process Wizards | Determine if the wizard needs to be finished and if the resulting content is needed in the eTMF * If needed, complete the wizard and address missing documents * If not, delete the wizard | Yes |

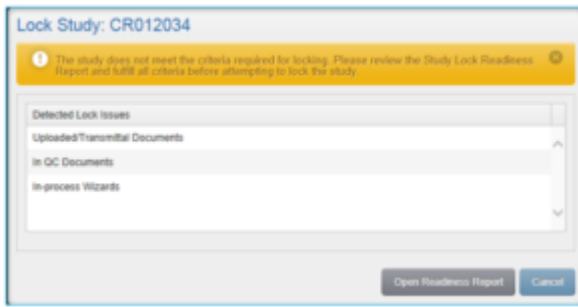
| Issue | Action | Must be Addressed? |
|---------------------------|--|--------------------|
| Countries Without Sites | Determine if content is needed for sites * If it is not needed, no action is necessary * If it is necessary, complete the site wizard(s) and address the missing documents | No |
| CTMS Sites Not in the TMF | Determine if content is needed for the sites * If not needed, no action is necessary * If it is needed, complete the site wizard(s) and address missing documents | No |

All essential issues must be addressed in order to lock the study.

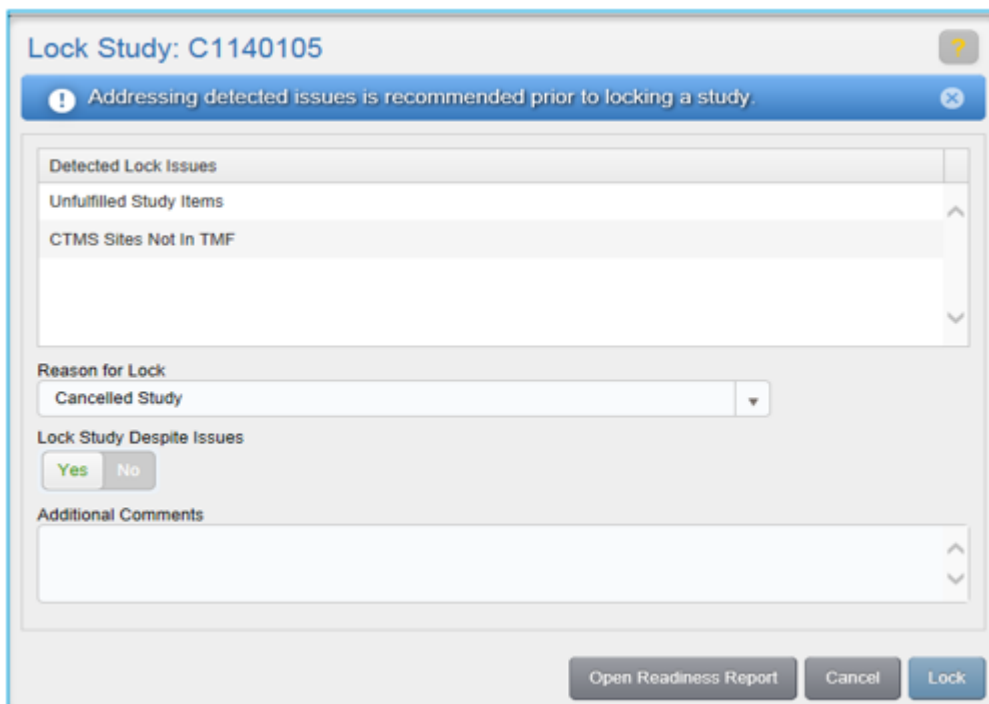
Lock Study

To lock the study, navigate to the Study Home page of the study you want to lock. Click on the Actions menu icon and select "Lock Study."

If the required criteria for locking has not been met, a warning message will display, stating that you must review the Lock Readiness Report and fulfill all criteria before you can lock the study. Click **Open Readiness Report** to view the report immediately or **Cancel** to generate the report at a later time.



If only non-essential issues remain, you can proceed with locking the study by acknowledging that you are aware of the issues and providing a reason for the lock. Select a reason from the **Reason for Lock** drop-down, and select “Yes” in the **Lock Study Despite Issues** field. Enter any **Additional Comments** you might have and click **Lock**.



Unlock a Study

Once a study has been locked, it can be unlocked if you need to add additional study items or fulfill study items. To unlock a study, you must have Study Unlock permission.

1. Navigate to the Study Home page of the study you want to lock.

2. Click on the Actions menu icon and select “Unlock Study.”
3. Select a **Reason for Unlock**, enter **Additional Comments** if necessary, and click **Unlock**.



Unlock Study: C1140105

Reason for Unlock

Please select a reason for unlocking the study

Additional Comments

Cancel Unlock