How to Create a Study

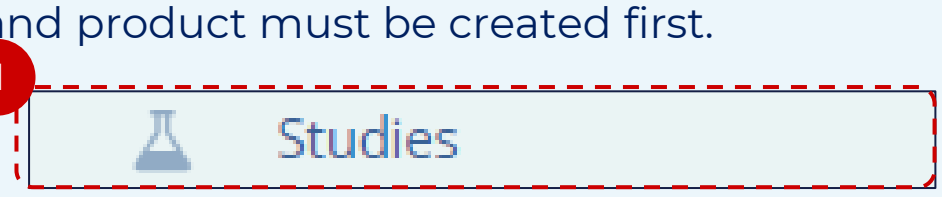
CTMS version 2.0

APPLICABLE TO:

- ● **Company Admin**
- ● **Study Manager**
- ○ **CRA**

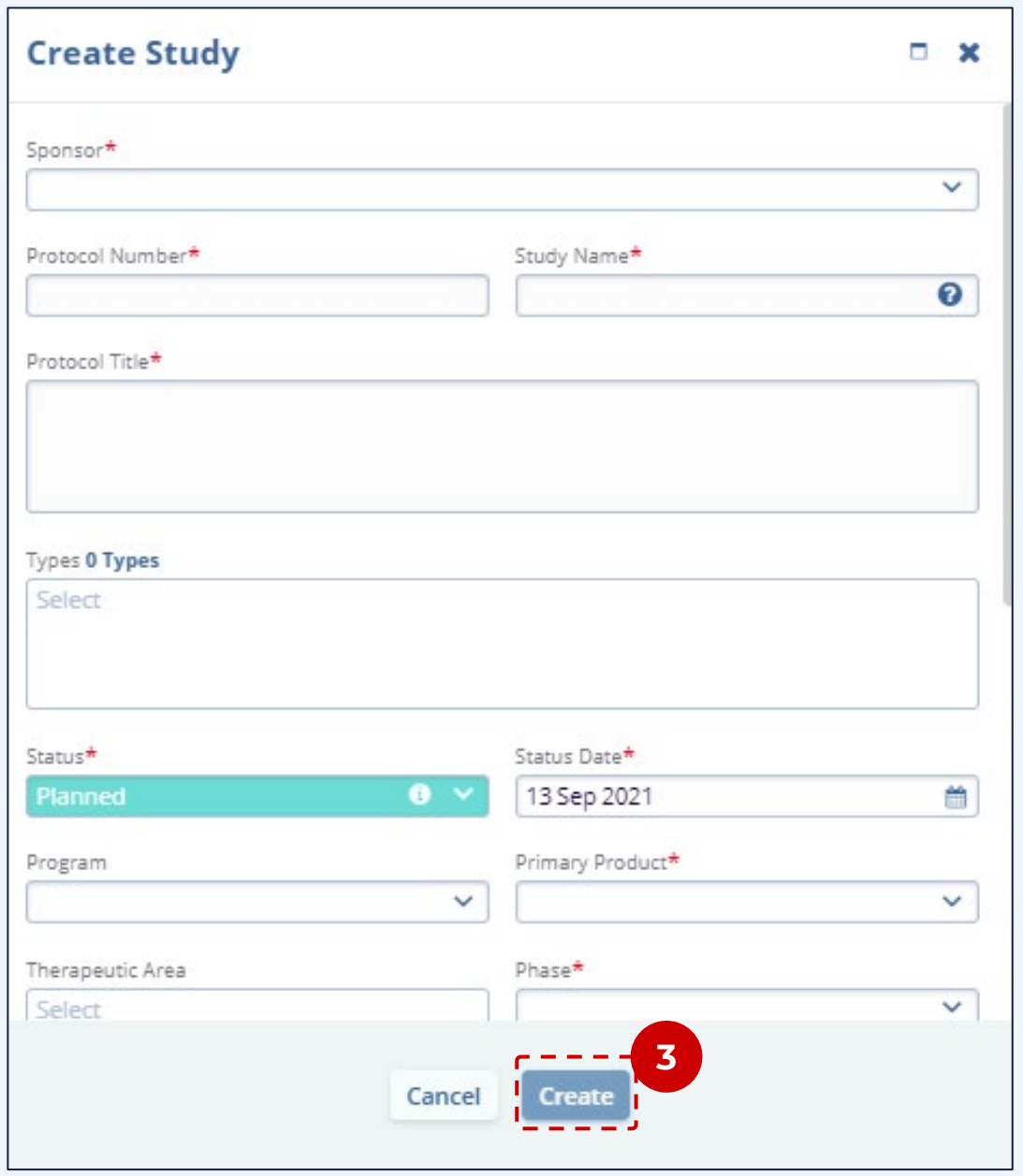
Note: In order to successfully create a study, the sponsor and product must be created first.

1 Log into the CTMS and click on **Studies** on the left.



2 To add a new study, click **Add.**

3 Enter the study details, then click **Create** to save.



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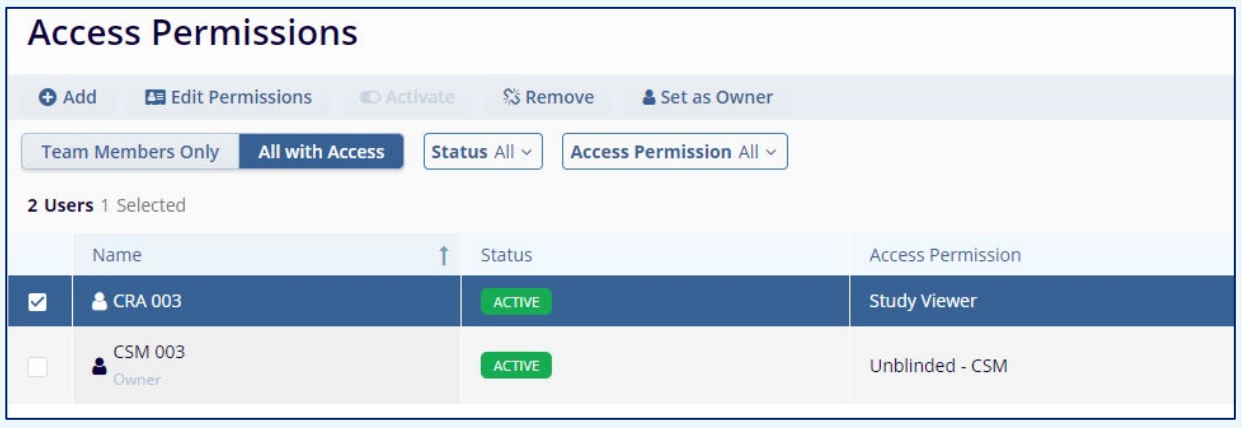
Note: At this point, the study itself has been created. The following are recommendations for additional steps in order to complete the setup of the study in the CTMS.

4 Navigate to the **Study Details** area to manage Study Settings.

5 Navigate to the **Access Permissions** area and indicate the members of your study team and their study-level access level.

- All non-CSM users who will play a part in the study should be added with a view-only level of access.
- If the study is blinded, you will need to reach out to the Trial Interactive Service Desk at help@trialinteractive.com to have an Unblinded CSM created so that that user can manage unblinded aspects of the study including designating unblinded CRAs.
- For additional information, please see the related job aid and video regarding how to manage study access permissions.



6 In the **Settings** Area:

- If applicable to your study, indicate which users are to be tasked with reviewing site visit reports. This list comes from those with access to the study. Please note that Blinded and Unblinded Reviewers need to be indicated separately, even if the same people will be performing both functions.
  - If this is not done, the Visit Report workflow will not function as expected, leading to delays and potential document rejections.