# How to Create a Study

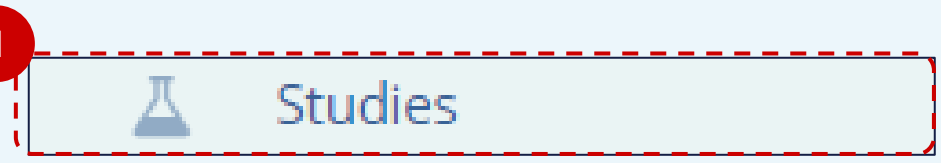
**CTMS version 3.1**

**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.

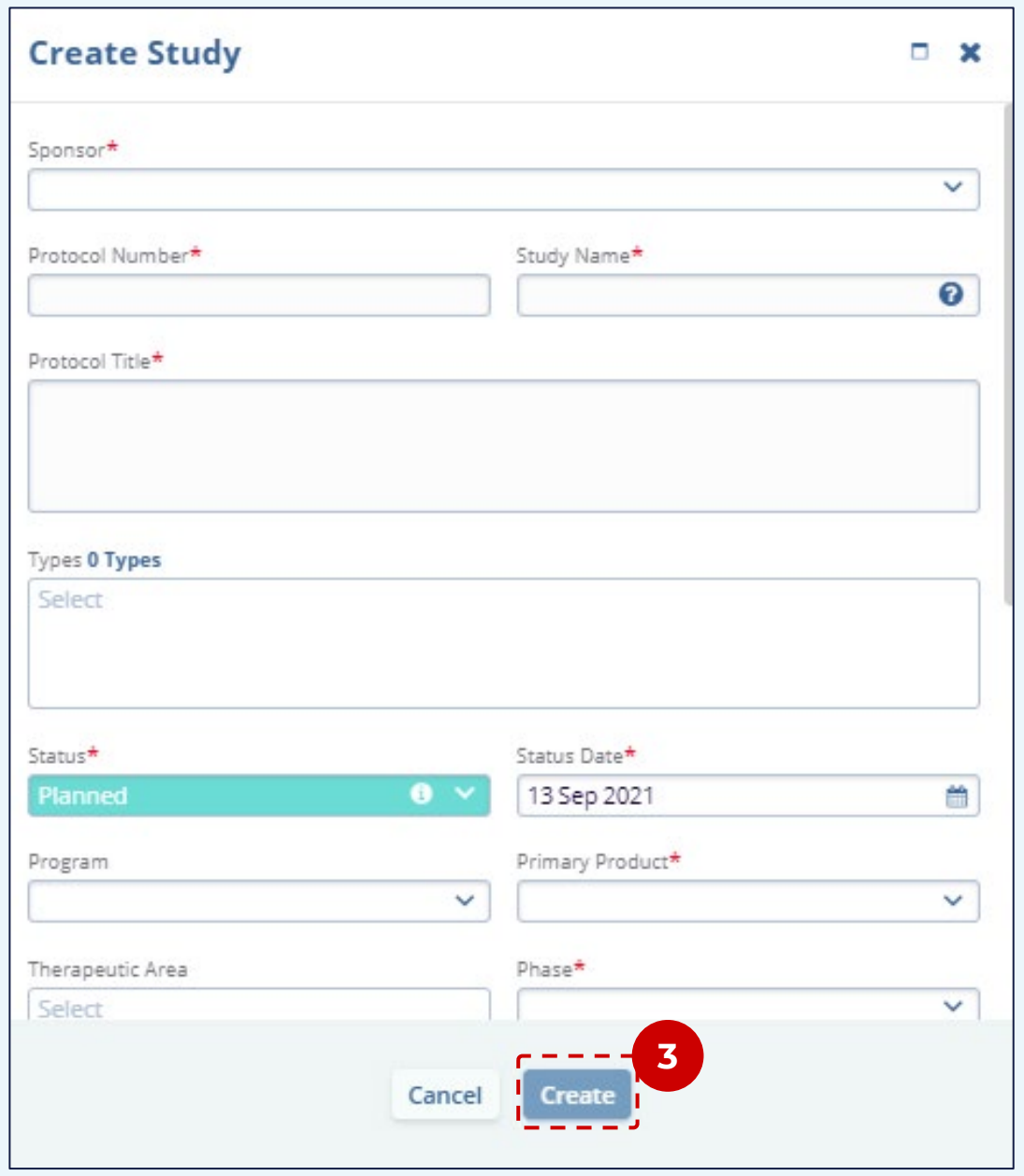



**2** To add a new study, click **Add.**


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

The CTMS is optimized so that the task can be accomplished with minimal information but inputting as much information as possible ensures both accurate recordkeeping as well as accuracy of reporting.

The **Status** field is of particular importance as it allows users to report on study readiness. Creating Planned studies in the system in a Draft status allows for accurate forecasting of resources and timelines.



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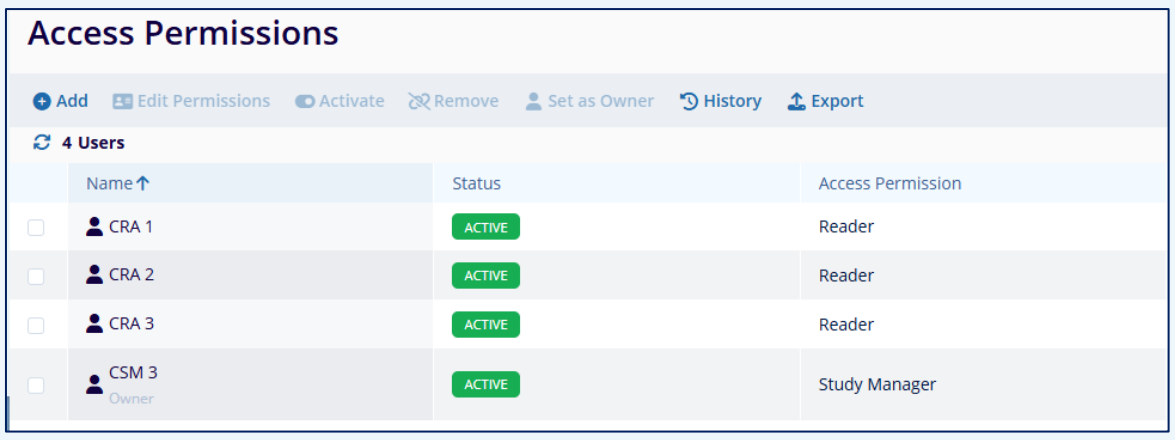
**Note**: At this point, the study itself has been created. The following are recommendations for additional steps in order to complete the setup of the study in the CTMS.

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

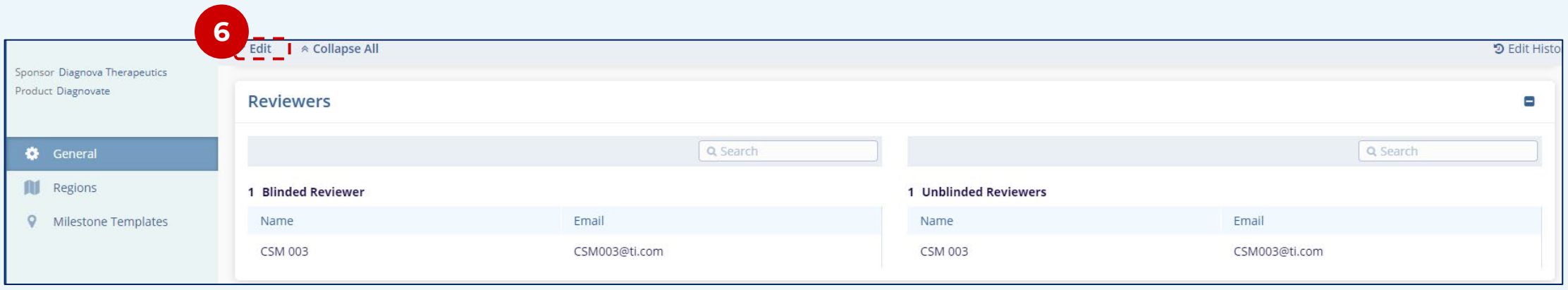

**5** Navigate to the **Access Permissions** area and indicate the members of your study team and their study-level access level.

- 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.



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In order to ensure that your study has the greatest chance of a successful launch, we recommend reviewing the following study-related items:

- **Study Settings/General Settings:** Review all available options

- **Study Settings/Monitoring Information:** SVR Submission Days and Approval Days

- **Study Settings/Reviewers:** Reviewers are selected from the list of people granted Access Permissions to your study. If you have not added anybody to your Access Permissions list, you will not be able to select Reviewers. Reviewers must be assigned prior to review of any site visit report.

- **Study Access Permissions:** There is a separate set of supporting materials for this but it's of vital importance to ensure that all users have the appropriate level of access at each level of the study. For example, a CRA should have 'Reader' access at the Study and Country levels, but should be assigned 'Site and Visit Editor' rights for any site to which they are assigned. This will need to be done after the site has been created in the study.

- **Milestone Templates:** Any milestone that needs to be tracked over the course of this study needs to be added here. Ideally, the list of milestones would be imported from the Sponsor record, but any milestones unique to this study can be created in this area for tracking purposes.

- **Fields, Site Visit Types, Site Visit Cancellation Reasons, and Subjects:** These areas represent your chance to change these default values. For example, it is possible that a Site Visit Type which exists in the system is inappropriate for your study, by making changes in this area, you are able to remove it from the study options entirely, thereby ensuring that it cannot be used at all. Making no changes in these areas means that Global-level default options will be applied instead.