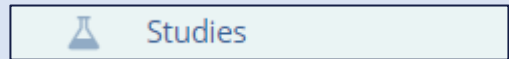


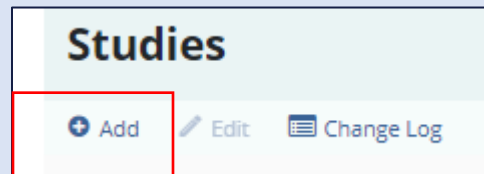
- APPLICABLE TO:
- Company Administrator
 - CTMS
 - Study Manager
 - CRA

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.

A screenshot of the 'Create Study' form. The form contains several fields: 'Sponsor*' (dropdown), 'Protocol Number*' (text), 'Study Name*' (text with a help icon), 'Protocol Title*' (text), 'Types 0 Types' (dropdown with 'Select'), 'Status*' (dropdown with 'Planned' selected), 'Status Date*' (calendar icon with '13 Sep 2021'), 'Program' (dropdown), 'Primary Product*' (dropdown), 'Therapeutic Area' (dropdown with 'Select'), and 'Phase*' (dropdown). At the bottom right, there are two buttons: 'Cancel' and 'Create'. The 'Create' button is highlighted with a red rectangular box.



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.

Diagnova DT11-B PLANNED

Diagnova Therapeutics

Edit Collapse All Edit History

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 the “Study Viewer” role.
 - 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 the study team.

Access Permissions

➕ Add ✎ Edit Permissions 🔴 Activate 🗑 Remove 👤 Set as Owner

Team Members Only All with Access Status All ▾ Access Permission All ▾

2 Users 1 Selected

	Name	Status	Access Permission
<input checked="" type="checkbox"/>	👤 CRA 003	ACTIVE	Study Viewer
<input type="checkbox"/>	👤 CSM 003 <small>Owner</small>	ACTIVE	Unblinded - CSM

6. In the **Settings** Area:
- If applicable to your study, indicate which members of the Study Team are to be tasked with reviewing site visit reports. 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.

Sponsor: Diagnova Therapeutics
Product: Diagnovate

Edit Collapse All Edit History

Reviewers

1 **Blinded Reviewer**

Name	Email
CSM 003	CSM003@ti.com

1 **Unblinded Reviewers**

Name	Email
CSM 003	CSM003@ti.com