

8.1.1 Create a Study

To create a new Study:

- Select Tasks > Studies. The Administer Studies page opens.
- Click Create a New Study (located near the top of the page). The Create a New Study page opens, showing the fields in Section A: Study Description.

Create a New S	itudy	
Enter the Study and Protocol Information requested below to create the study. The data element definitions used here are based on ClinicalTrials.gov. Please consult		
the website for descriptions		and an entranning of these contain
SECTION A: Study Descri	iption	
 indicates required field. 		
Unique Protocol ID:	·	
Brief Title:	· ·	
Official Title:		
Secondary IDs:		
(separate by commas)		
Principal Investigator:	·	
Protocol Type:	⊙ Interventional ⊖ Observational *	
Brief Summary:		
	h	
Detailed Description:		
	4	
Sponsor:	n.a ·	
Collaborators:		
(separate by commas)		
	R_	
Please select a user who will later edit or update the Study.		
Select User : -Select-		
Save	Cancel	

- 3. Complete at least the required fields. Click any field name that is a link if you want to view its definition at the <u>clinicaltrials.gov</u> website, or you can view descriptions in <u>Create Study Edit</u> <u>Details</u>. Information you enter now can be modified later. While only users with certain permissions can create a Study, additional user Roles and Types typically have permission to complete the fields or modify the information once the Study exists. As part of this step, you can provide access to an existing user who has a Data Manager or Study Director Role in OpenClinica; later you can change that user's access to the Study.
- Click the Save button. The Administer Studies page opens, and the table now includes the Study you added. The

Study Status reported in the table is "pending" because the Study is in the Design state; the Status will be changed to Available as part of the <u>Study Setup process</u>.

This page is not approved for publication.

8.1.1.1 Re-Using Elements from One Study in Another Study

You cannot replicate an existing Study and just customize the items for the new Study. However, there are some ways to leverage what you've already done for other Studies when you create a new Study.

- You can use CRFs in multiple Studies. You can utilize CRFs for an existing Study as is, or make new versions with customizations for the new Study.
- You can assign existing users to multiple Studies. The user's Role in the new Study can be different than in existing Studies.
- You can use Rules in multiple Studies.
- You can refer to the Study Metadata from a Study to help ensure you are creating all the elements you want from it in the new Study.