

# How to Track Amendment Completion

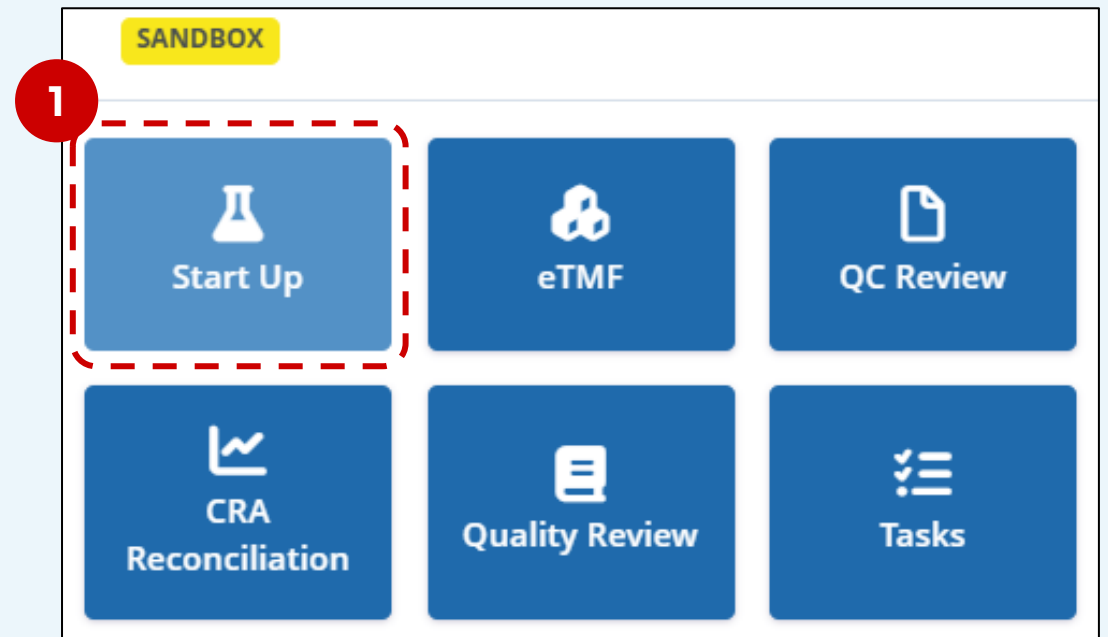
TI version 10.8

## APPLICABLE TO:

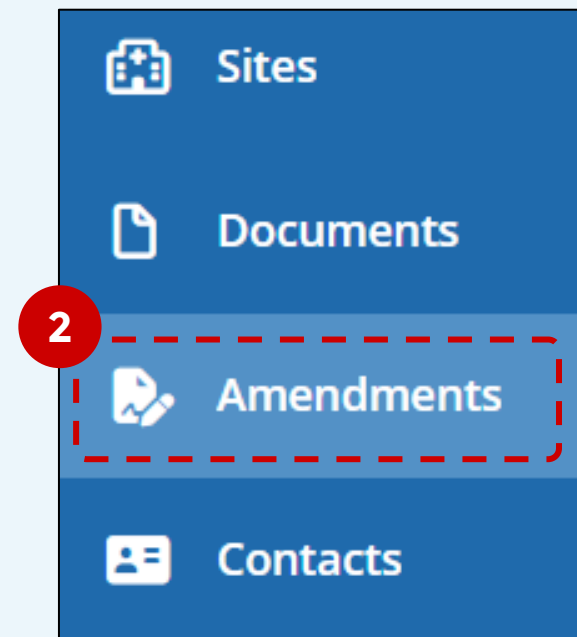
- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

Amendments in Study Start-up formalize crucial changes to Protocols, Informed Consent Forms, etc., ensuring Regulatory Compliance, safety, and operational feasibility. Amendments can be created and monitored for completion using the Study Start-Up Module.

**1** Enter a room and navigate to the **Start-Up** area.



**2** Select the **Amendments** section from the Navigation Bar. This will display all amendments, which can be filtered by various criteria.



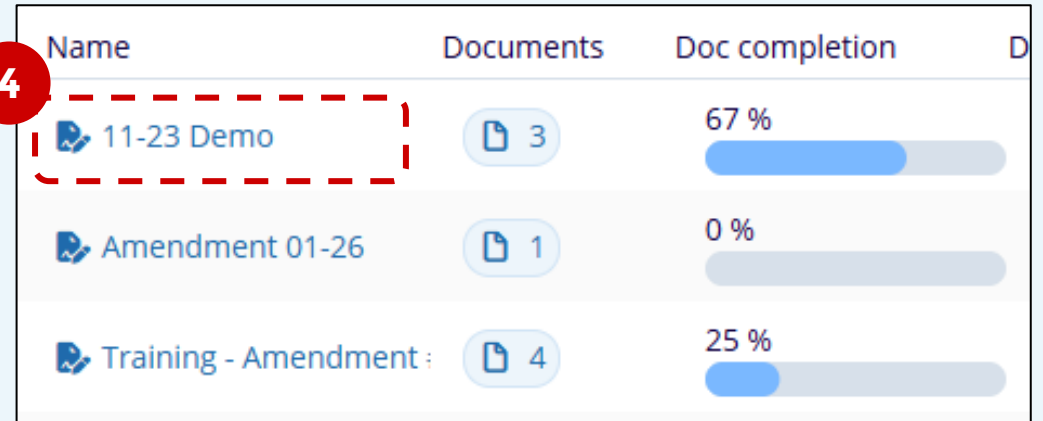
**3** Each amendment in the list is shown with a **Progress Bar**, which displays what percentage of needed documents has been collected and approved.

Name	Documents	Doc completion	D
11-23 Demo	3	67 %	
Amendment 01-26	1	0 %	
Training - Amendment :	4	25 %	

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**4** Click on and **Amendment's name** to display its full page and details.

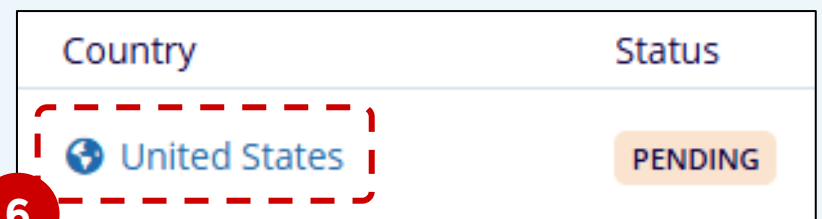


Name	Documents	Doc completion	D
11-23 Demo	3	67 %	
Amendment 01-26	1	0 %	
Training - Amendment :	4	25 %	

**5** Amendments may contain documents provided by/for different entities. Click on an entity type in the panel on the left to display entities involved with the amendment.

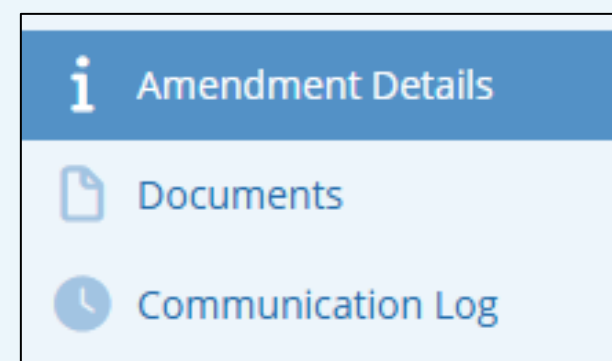



**6** Click on the **entity name** to display related amendment information, documents, and communications log (use the panel on the left to navigate).



Country	Status
United States	PENDING

**7** You can use the **Documents** space to Add Requirements, download or mail documents, or submit a document for a placeholder. You can use the **Communication Log** space to review, add, edit, or delete, history of relevant communications.



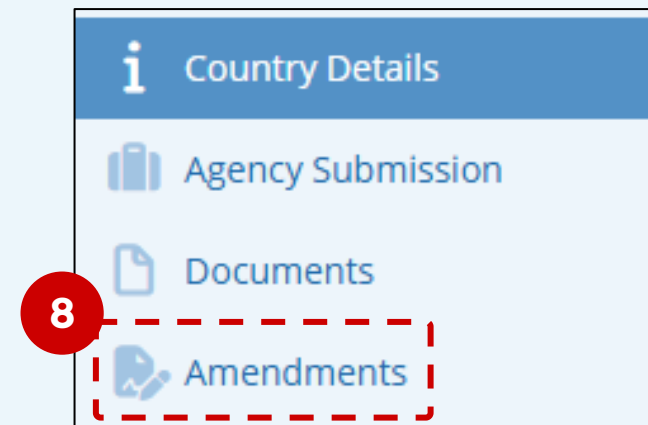
 The Amendments area is not meant for review of documents, which has to be carried out by the appropriate reviewers. If you are looking for information about performing document review, which may be needed to complete amendment requirements, please refer to the **SSU\_How to Approve or Reject Documents** job aid.

**7** Once an amendment's requirements have been collected and approved, the progress bar will display **100%** completion.

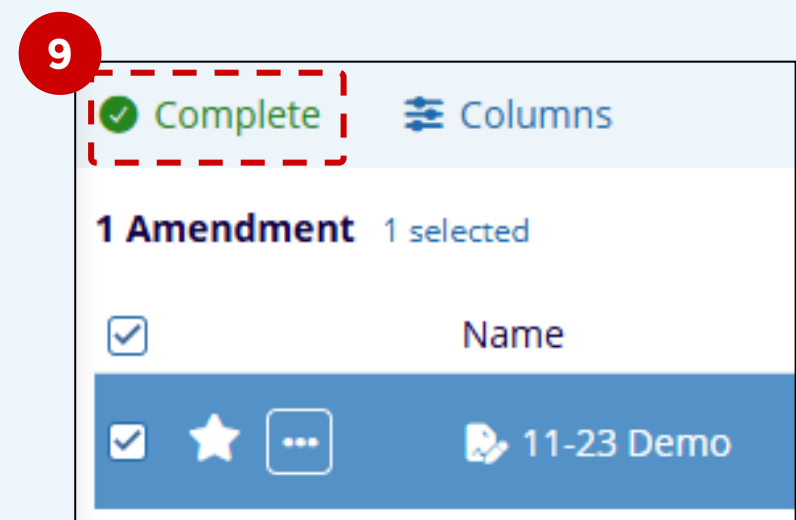
Name	Documents	Doc completion
11-23 Demo	3	100 % 
Training - Amendment	4	25 % 

**8** Room Admins / Start-up Specialists may wish to mark the amendment complete for a specific entity.

Select an entity within the Amendment or navigate to a County, Site, or IRB then select the **Amendments** space from the panel on the left.



**9** Select the amendment via checkbox and click on **Complete/Complete Amendment** in the menu bar.



**10** Select your preferred option for moving documents to eTMF, then click **Complete Amendment (Next if you choose to select documents manually)**.

To complete the Amendment please select which option needs to be applied to amendment documents

Do not Publish Documents

Publish All documents

Select Documents to be Published

**10**

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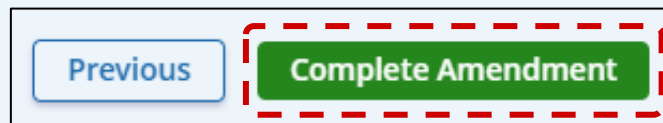
**10b** If **Select Documents to be Published** has been chosen, the next page will allow you to **check-select** those documents you wish moved to the eTMF. After selection click Next, review information and click **Complete Amendment** to finalize.

3 Documents 1 selected

<input type="checkbox"/>	Submitted Name	Document Type
<input type="checkbox"/> *	Protocol Amendment...	Protocol Amendment
<input type="checkbox"/> *	PROTOCOL 11-23 Ad...	Protocol Amendment A
<input checked="" type="checkbox"/> *	Synopsis Amendmen...	Protocol Amendment S

10b

Cancel Next



**11** The amendment status will show as **Completed**.

Name	Status
11-23 Demo	COMPLETED

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