

# How to Approve or Reject Documents for Study Start-Up

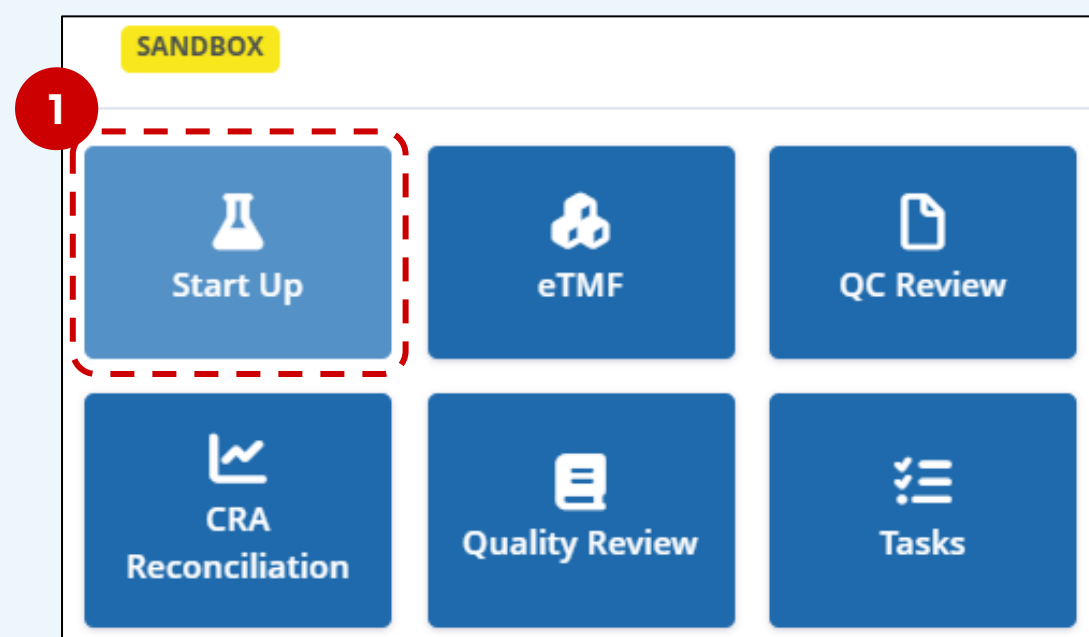
TI version 10.8

## APPLICABLE TO:

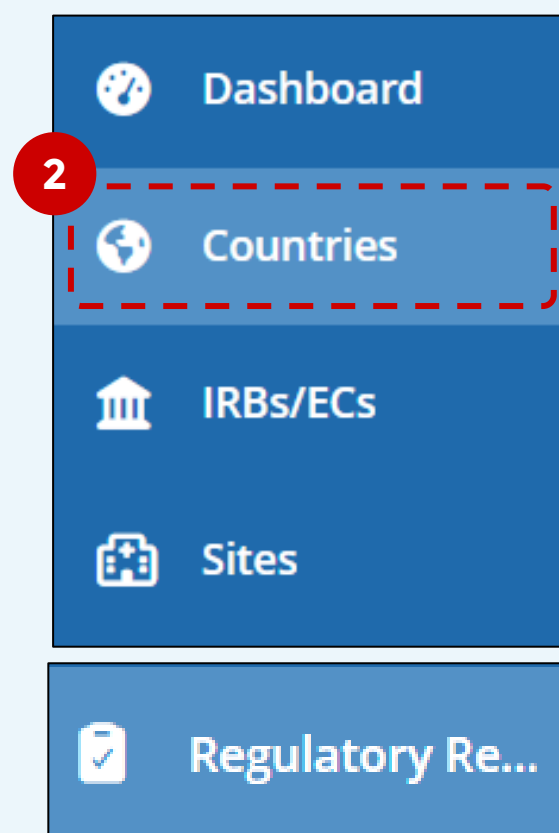
- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

Users designated as Start-Up Specialists are required review essential documents that are needed for Countries, IRB/EC's, and Sites. The review of these documents is critical, as it ensures that each document goes through a quality check before an entity can be activated. Regulatory Reviewers can be assigned for additional oversight, ensuring a second quality check review. Additionally, if enabled, Sponsors can also review and approve/reject documents that are assigned to them.

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



- 2** Select an entity type containing documents to review (for ex. **Countries**) from the Navigation Bar. Documents can be reviewed at Countries, IRBs, and Sites.

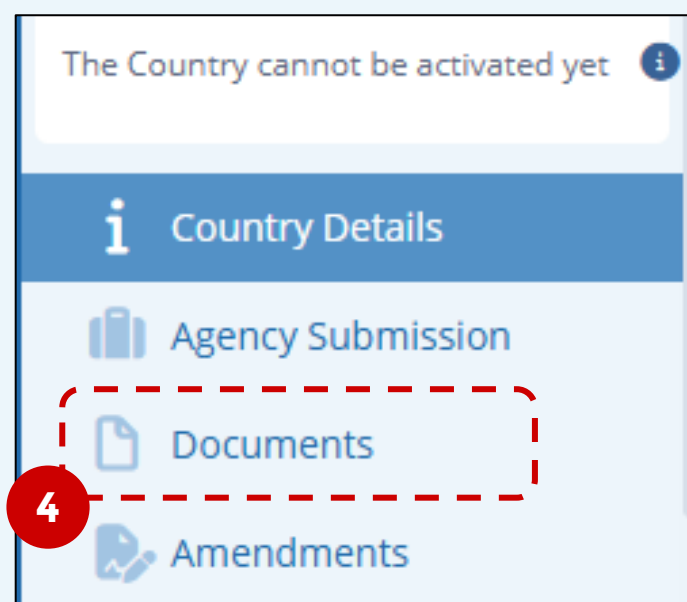


A Regulatory Reviewer can select the Regulatory Review section instead, and skip to step 5 of this guide.

- 3** Select an entity (Site, Country, or IRB) from the list, by clicking on its name.



- 4 Click on the **Documents** option in the left-hand panel.



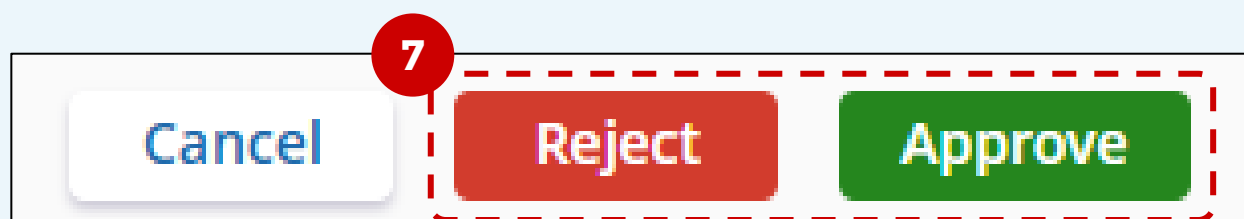
- 5 Identify any document where the *Essential Document Status* (if you are an SSU Specialist) or *Reg Review status* is listed as **Pending**. Select the document by clicking on the **checkbox** to the left.

<input type="checkbox"/>	Submitted Name	Essential Document Stat...	Regulatory Approval Stat...
<input type="checkbox"/>	Training Test Document	APPROVED 23 Mar 2022	APPROVED 02 Jun 2023
<input checked="" type="checkbox"/>	Training-Evidence_V02-27-20...	PENDING	

- 6 With the document selected, click on the **Approve/Reject** button in the menu bar.



- 7 Use the window to review the document. Click on the **Approve** button (or **Reject** button) to designate the relevant document status.

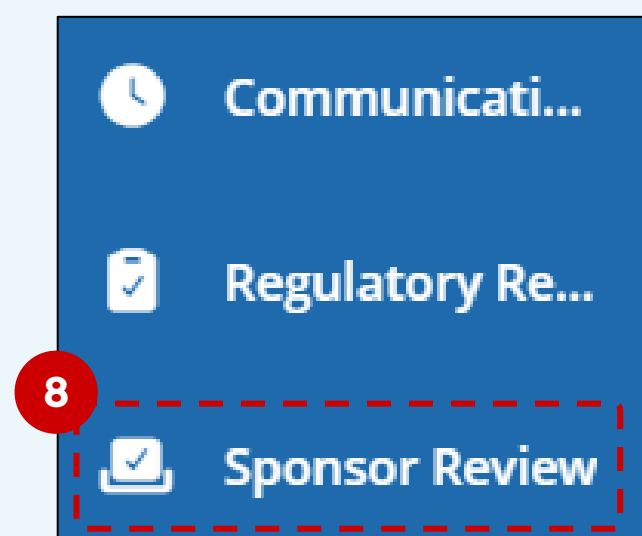


A rejected document will need to be corrected and/or resubmitted for approval.

## Sponsor Review

Rooms can be configured to have an additional layer of review for Sponsor Oversight. If activated, document or process owners can send approved documents over for Sponsor Review. Any user designated can then review the documents in a manner similar to the above.

- 8 As a Sponsor Reviewer, access the **Sponsor Review** section in the left panel.



- 9 Select and review a document in the section, as shown in steps 5-7. When the review is completed the **Pending** indicator will change to Approved with the date of approval.

<input type="checkbox"/>		Submitted Name	Essential Docum...	Regulatory Approv...	Sponsor Approval Stat...
<input type="checkbox"/>	★	<input type="checkbox"/> Demo 123.xlsx	APPROVED 10 Sep 2025	APPROVED 10 Sep 2025	APPROVED 03 Feb 2026
<input type="checkbox"/>	★	<input type="checkbox"/> Confidentiality Agreement...	APPROVED 19 Nov 2025	APPROVED 19 Nov 2025	<b>9</b> PENDING