

How to Activate Entities in Study Start-Up

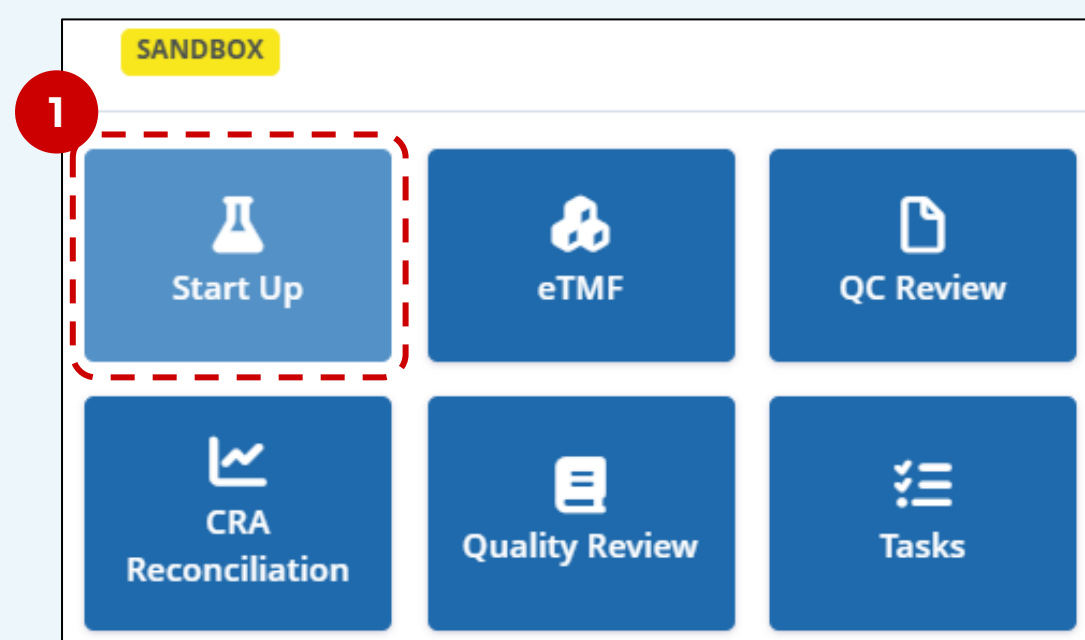
TI version 10.8

APPLICABLE TO:

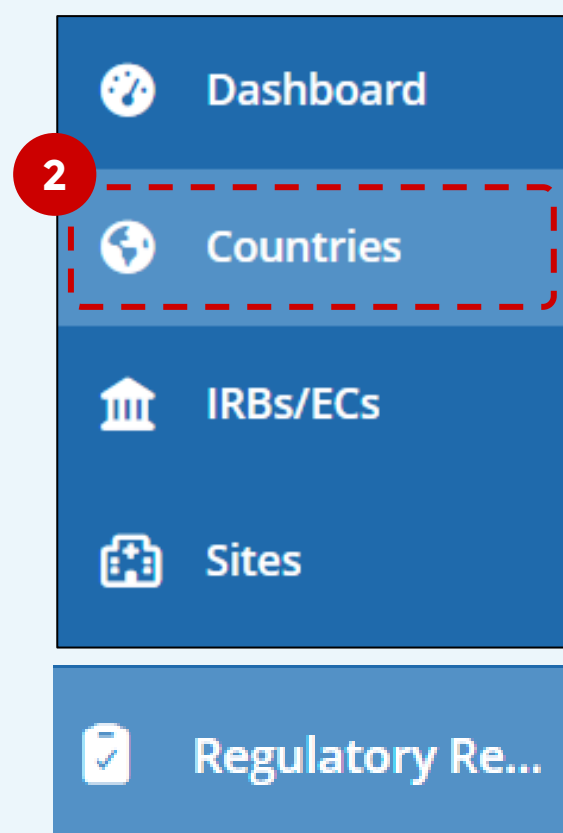
- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

Study Start-Up is used to collect all essential documents that are required for Site Activation. The essential documents come from the Country, IRB/EC, and Site entities. These entities can be activated **only** when the essential required documents are collected and approved in their entirety. Countries and IRB/EC's **must** be activated first in order to activate the Site.

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



2 Select an entity type subject to activation from the Navigation Bar. These are Countries, IRBs/ECs, and Sites.



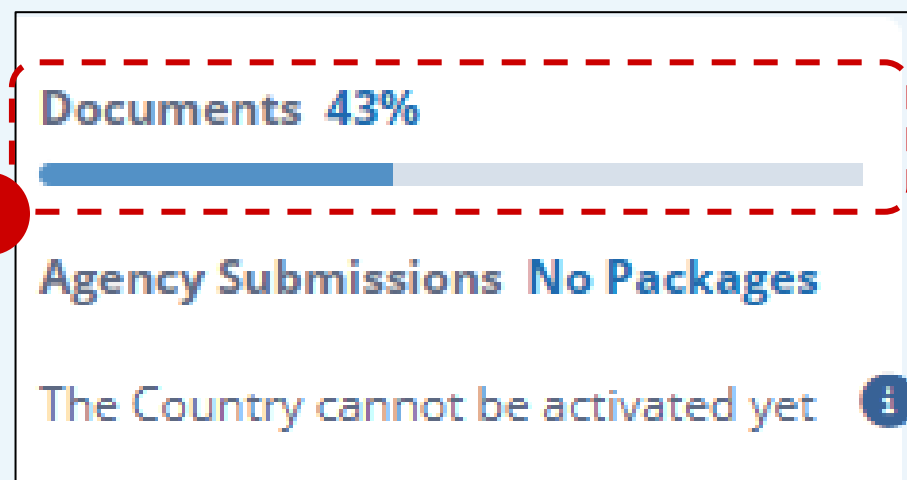
3 Select a specific entity (Site, Country, or IRB) from the list, by clicking on its name.




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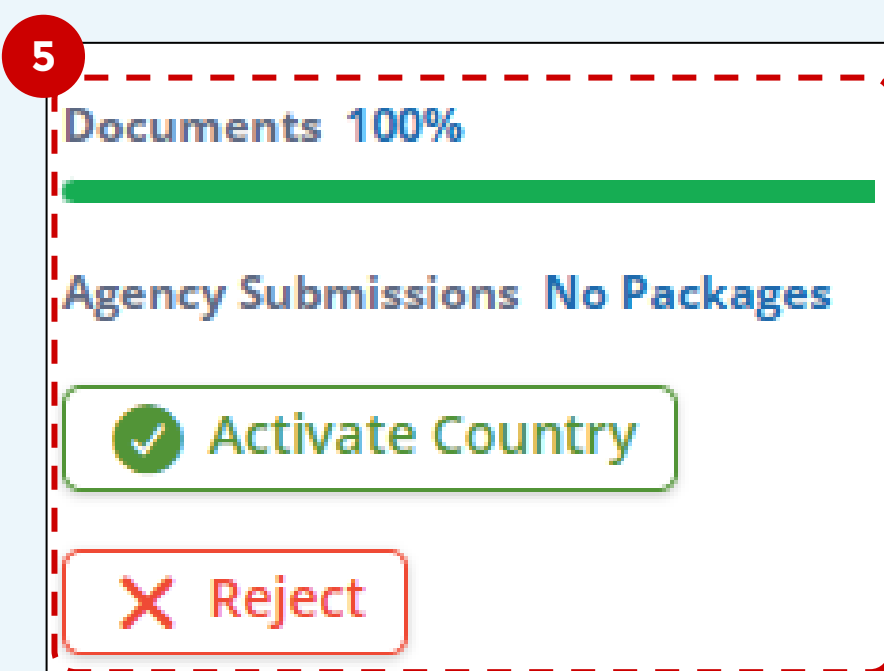
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- 4 Check the panel on the left for the activation progress status. Entities cannot be activated until all documents have been collected and (if review is enabled) approved.

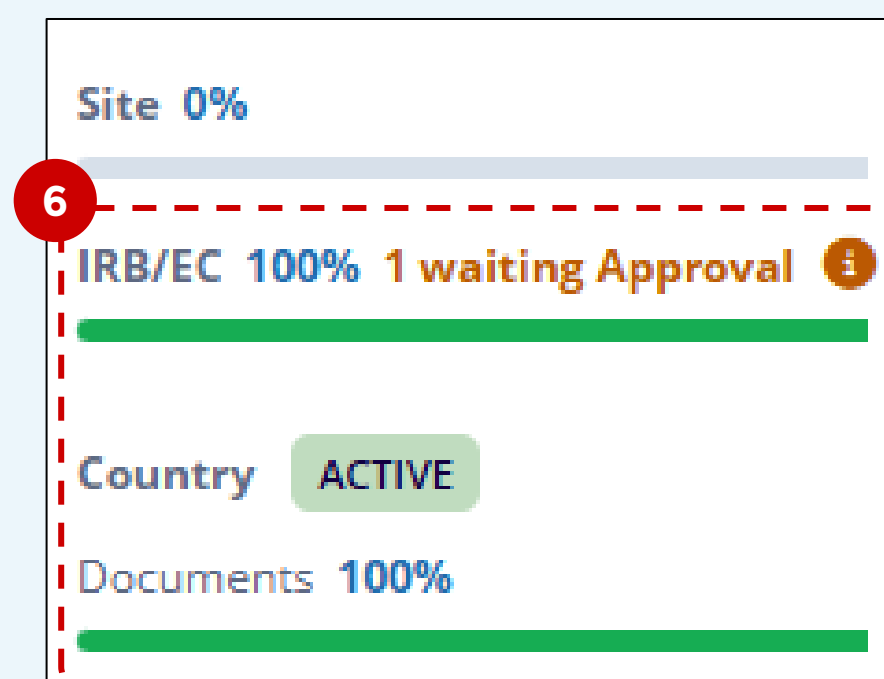


- 5 When the work of collecting and approving documents is completed, the same area will look different:
 - the Progress bar displays 100% completion
 - buttons appear to Activate or Reject.

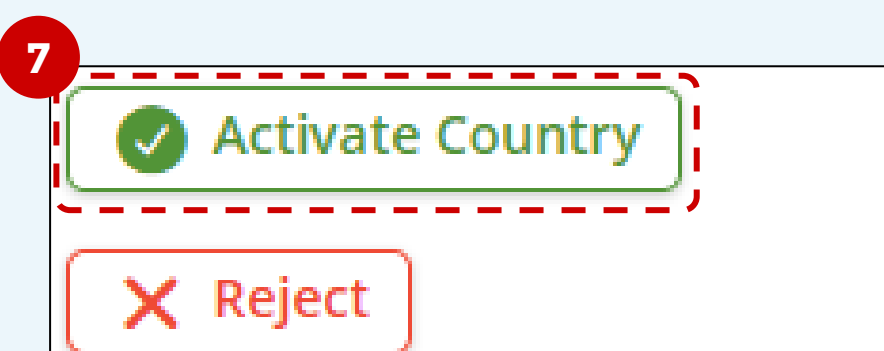
 **Notice:** Should an entity have no document requirements, the bar will display 100% immediately after creation.



- 6 While the activation process is similar for all entity types, Sites in particular can only be activated if the respective Country and IRB are activated. The progress tracker takes this into account, displaying the document collection progress and activation status for related entities.



- 7 To start activation, click on the **Activate [Entity]** button also displayed in step 5.



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8 The Approval window will open, requiring user to set an **Approval Date**;
add any **Comments**;
and determine the manner of moving documents to eTMF (no publishing, automatic -all documents, or manual - select documents).

9 If the option to **Select Documents** is chosen in step #8, new pages will appear in the window, where the user can **make a selection** for documents to be copied into the eTMF.

- Activation Info
- Select Site Docs
- Select Country Docs
- Review And Confirm

10 After setting Activation Info and (if applicable) selecting documents, review the information and click on **Activate [Entity]** to conclude the process.



Use Previous or click any of the pages headers on the left to go back and change information when needed.