

How to Resubmit Documents not Approved for Study Start-Up

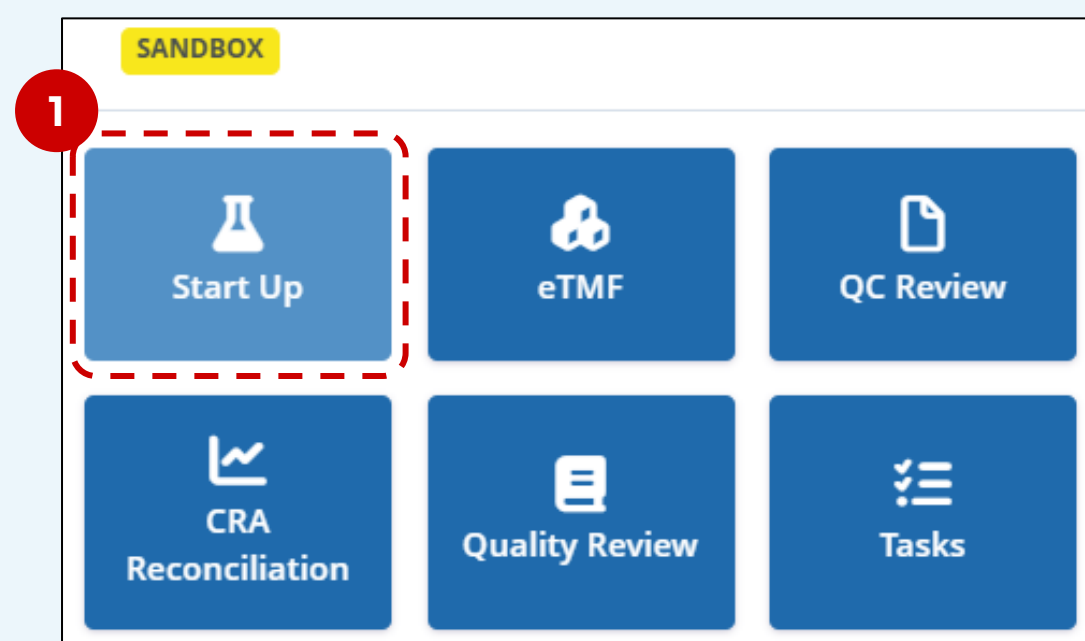
TI version 10.8

APPLICABLE TO:

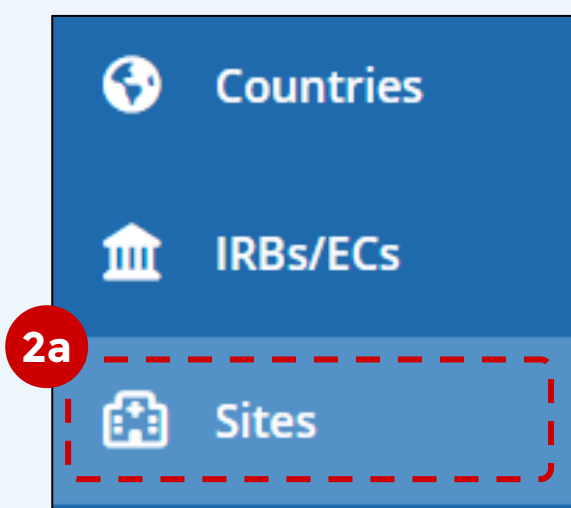
- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

The Start-Up module in TI rooms is designed with approval cycles in mind. It is possible that a document may be rejected because of timeliness, content, or authoring issues (e.g., missing signatures). When that happens, a new submission of the document, aptly updated, can be made. This job aid demonstrates how to resubmit a rejected document in Study Start-up.

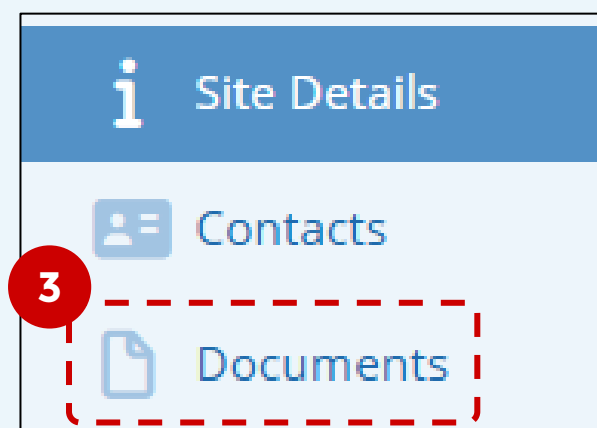
- 1** Enter a room and navigate to the **Start-Up** area with the module selector.



- 2** Select the entity type containing the document that was rejected (for ex. **Sites**) from the Navigation Bar. Select an entity by clicking on its name.



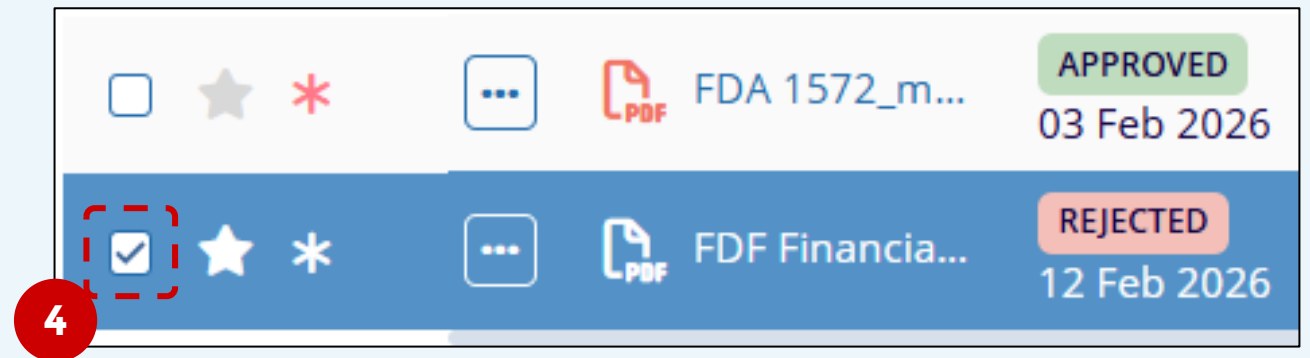
- 3** Click on the **Documents** option in the left-hand panel to display documents and their status.



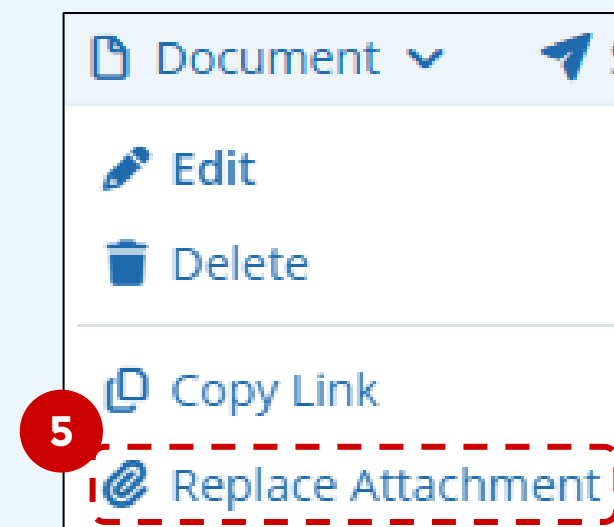
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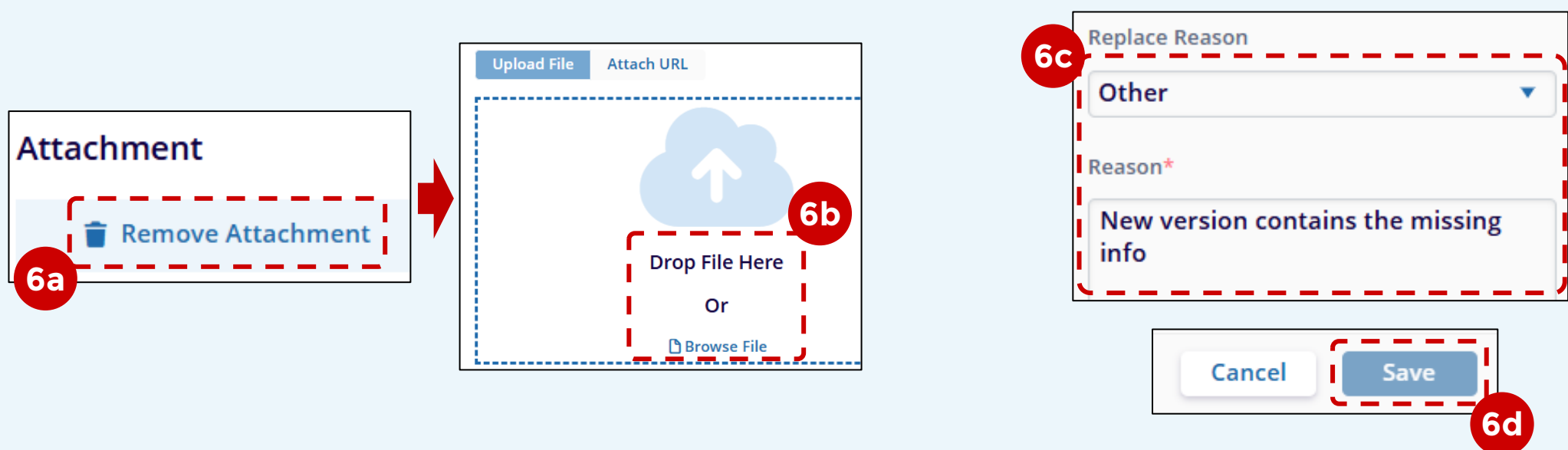
- 4** Locate and **select** (click on checkbox) the document to be resubmitted.



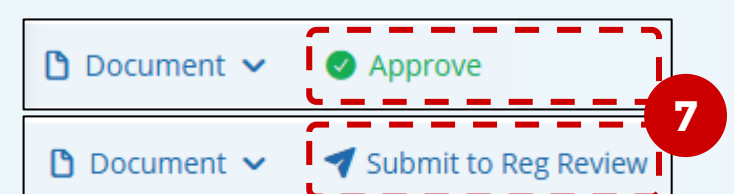
- 5** Expand the Document menu item and select **Replace Attachment**.



- 6** In the upload menu, first **Remove** the current attachment; the window changes into the standard upload window. **Upload a file** (6b) and complete the information on the right-hand panel (6c). Click **Save** to complete (6d).



- 7** Once the item is updated, click on the **'Approve/Submit to Regulatory Review'** button on the menu bar (changes based on document review stage).



- 8** If selecting 'Approve', the current user can perform the required review to approve the document (this does not replace the second stage if there is one). Simply confirm document and metadata are complete&correct, then click **Approve**. Click Cancel if you're not ready to complete the review.

