

How to Add a Required Document for SSU within Sites

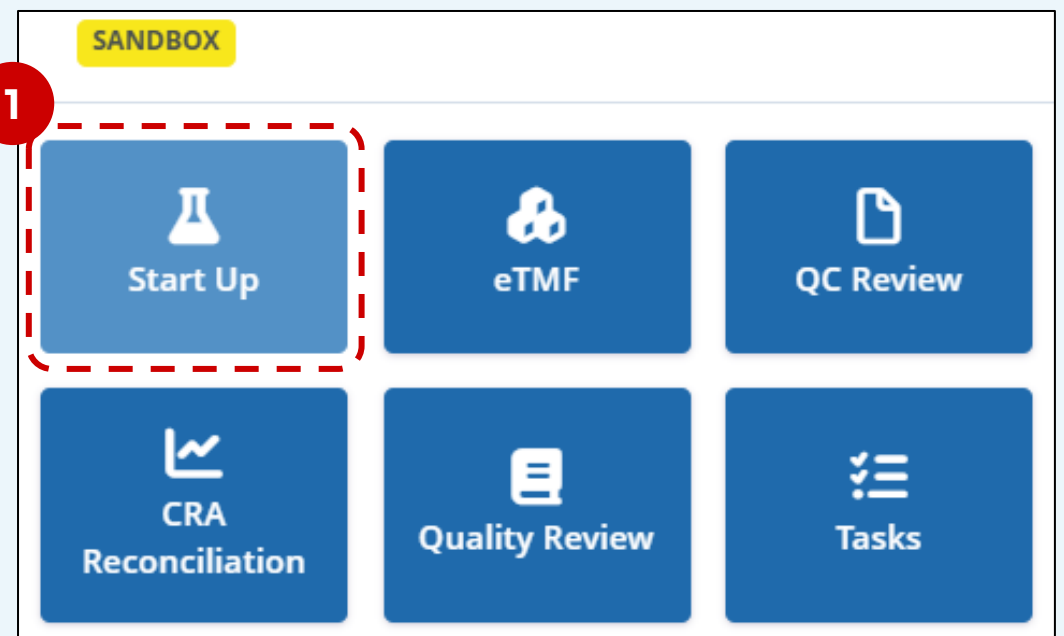
TI version 10.8

APPLICABLE TO:

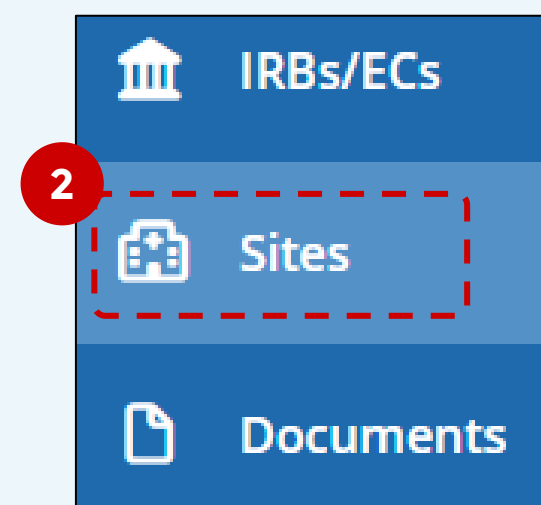
- Admin
- Manager
- Editor
- Reader
- SSU
- eTMF

Start-Up Specialists or Room Administrators are able to make additions to the list of required documents for a Site. This feature is used to accommodate for changes requested by Sponsors or IRBs, and, to ensure all essential documents are collected before activation.

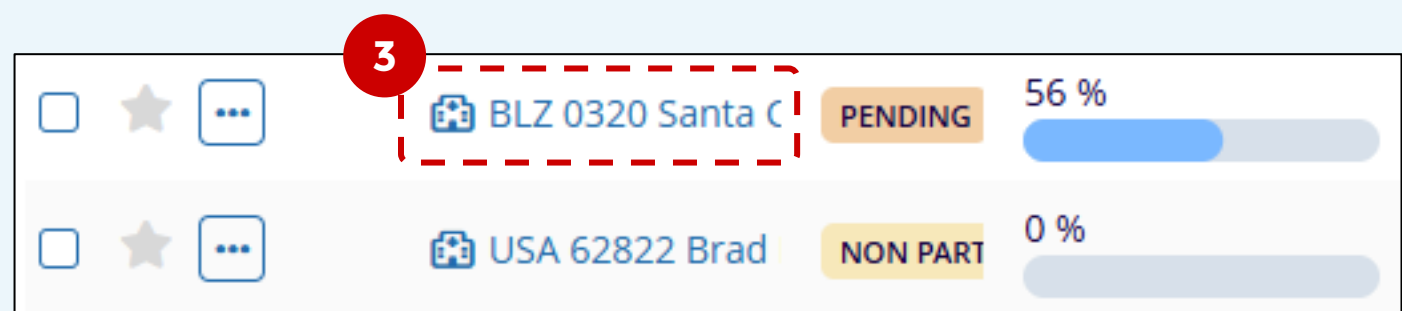
- 1 Enter a room and navigate to the **Start-Up** area.



- 2 Select **Sites** from the Navigation Bar.



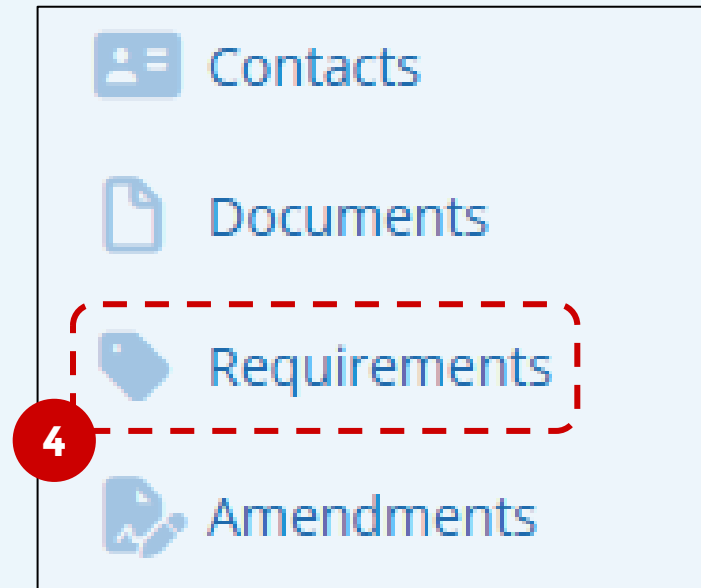
- 3 Select a **Site** from the list, by clicking on its name.



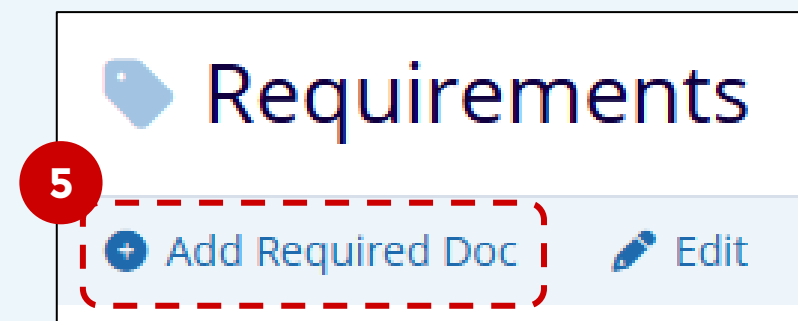
How to Add a Required Document for SSU within Sites

TI version 10.8

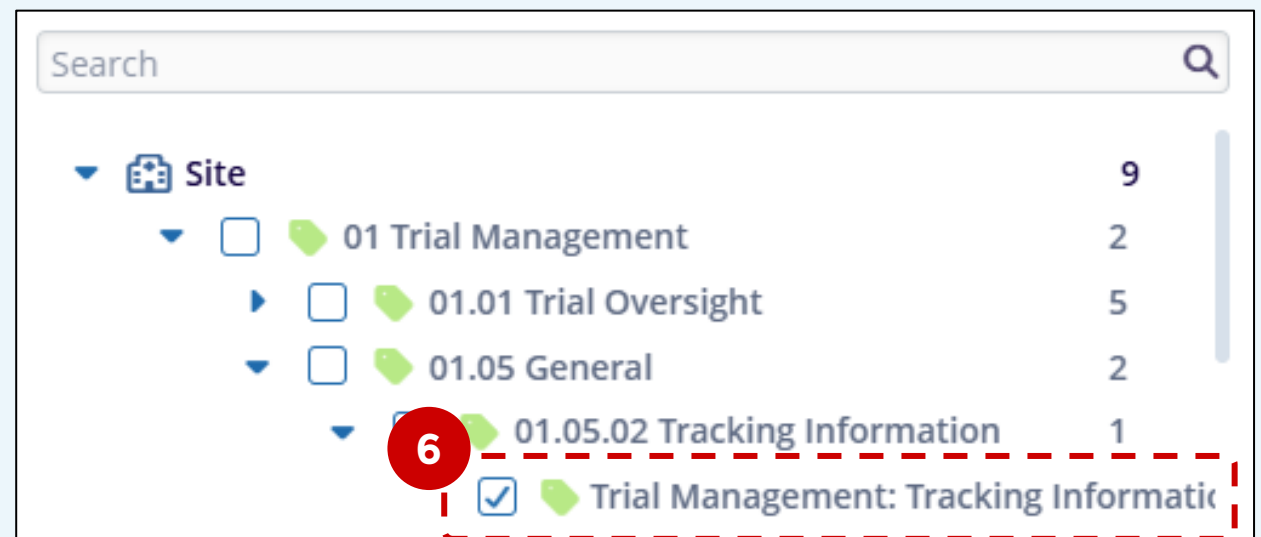
- 4 Click on the **Requirements** option in the left-hand panel.



- 5 Click on **Add Required Doc.**



- 6 Use the search bar, or **select** from the tree, the type of document to be collected (this can be done for multiple documents at the same time).



- 7 In the area to the right, select the **Site Activation** checkbox.



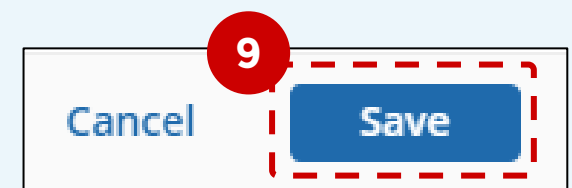
- 8 Consider the other options: **To Be Submitted By** (select responsible contact types) and **Languages** (creates multiple placeholders if multiple languages selected).

Event Driven cannot be chosen at this step for placeholders that are not already setup with it.



The screenshot shows a form with two input fields. The first field is labeled 'To be submitted by' and the second is labeled 'Languages'. A red dashed box highlights both fields, and a red circle with the number 8 is positioned to the left of the 'Event Driven' checkbox, which is also highlighted by the dashed box.

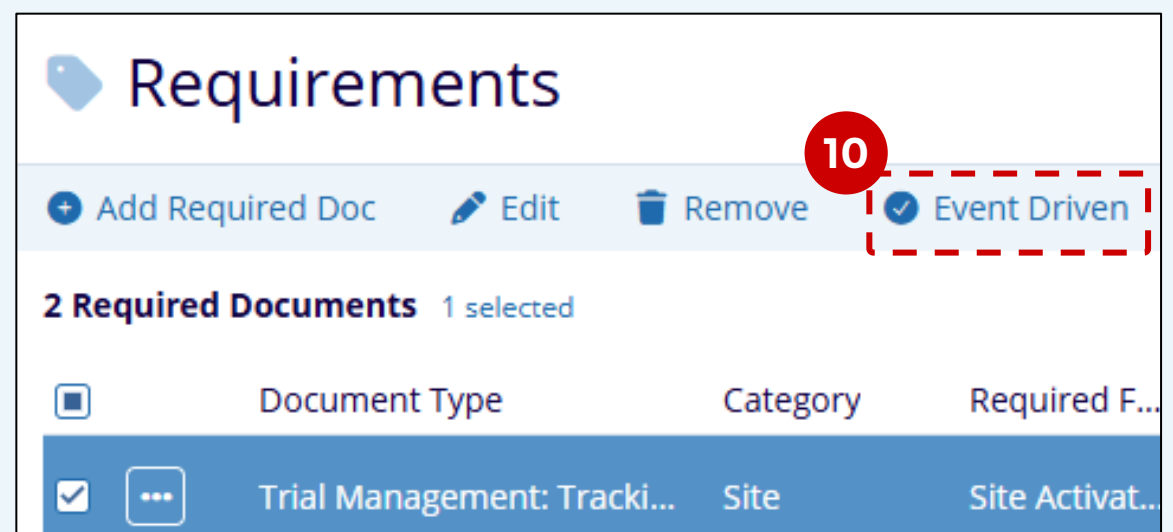
- 9 Click **Save** at the bottom of the window to add the new requirement(s).




The screenshot shows two buttons: 'Cancel' and 'Save'. A red dashed box highlights the 'Save' button, and a red circle with the number 9 is positioned above it.

- 10 Once a requirement is set, it will generate a placeholder. The requirement can be edited or deleted.

[Optional] If you need the placeholder to not be generated immediately, you may select the requirement and click on **Event Driven**. Requirements that are Event Driven will only generate placeholders when an event that contains the requirement is completed.



The screenshot shows the 'Requirements' interface. At the top, there are buttons for 'Add Required Doc', 'Edit', 'Remove', and 'Event Driven'. A red dashed box highlights the 'Event Driven' checkbox, and a red circle with the number 10 is positioned above it. Below the buttons, there is a table with columns for 'Document Type', 'Category', and 'Required F...'. The table contains one row with a checked checkbox, a menu icon, and the text 'Trial Management: Tracki...', 'Site', and 'Site Activat..'

 Placeholders added by these requirements can be tracked the same way as all others, in the Documents space within a Site or the Documents area accessed via the navigation bar.