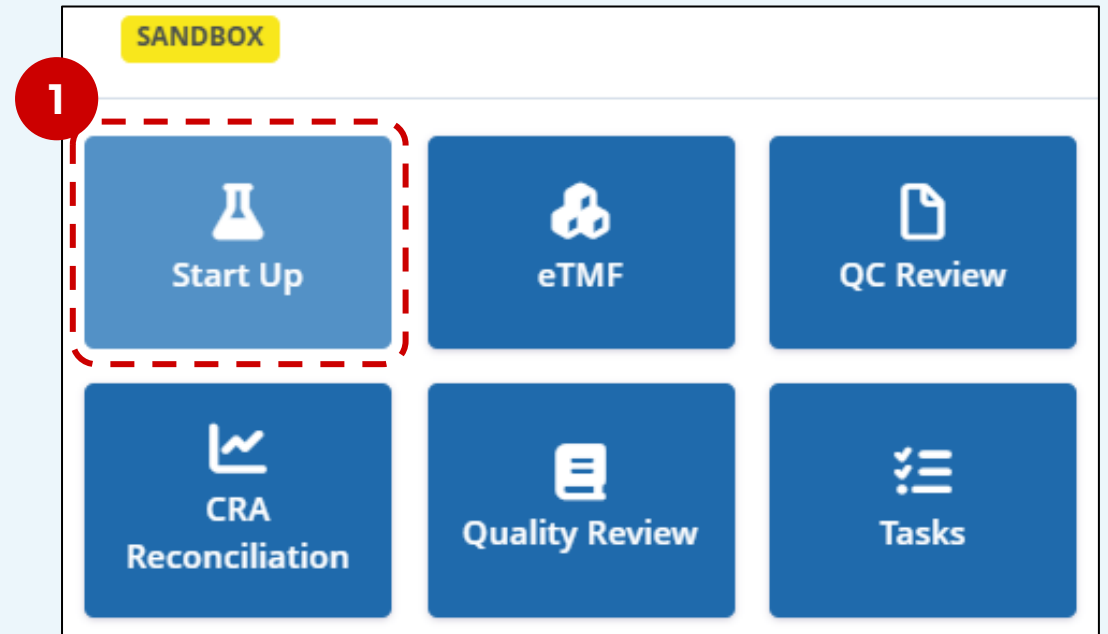


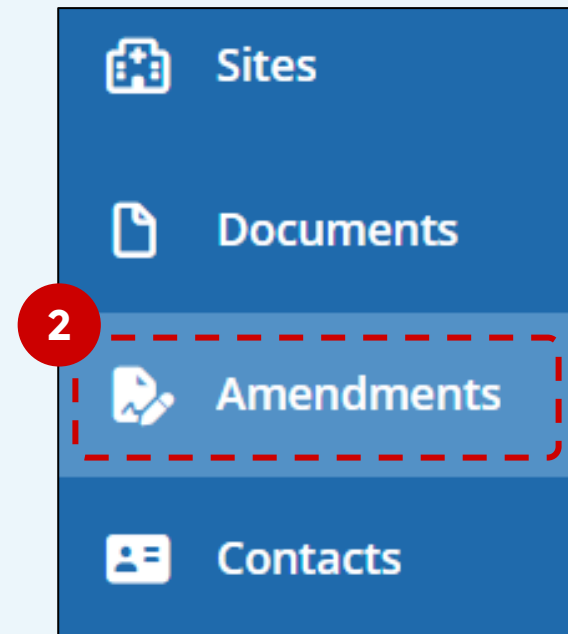
APPLICABLE TO:

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

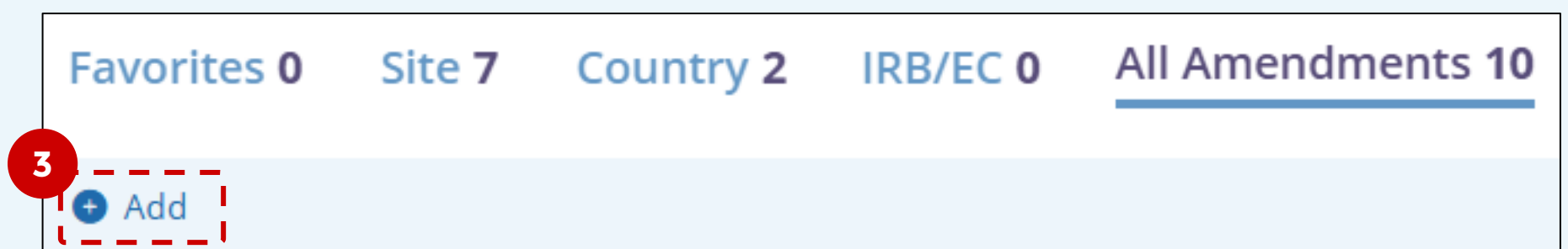
1 Enter a room and navigate to the **Start-Up** area.



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



3 Click on the **Add** button to begin creating a new amendment.



- 4** In the new window, enter the Amendment information: **Title** and **Date**. Optionally, you can add a description, which is recommended. Move to the Next step (controls are at the bottom of the window).

Amendment Information

Amendment Information

Title *

Rewrite of Randomization Method for Protocol A1D25

Amendment Date *

05 Jan 2026

Description

- 5** Click **Add Required Doc** to start adding the documents that will need to be collected.

Amendment Information

Required Documents

Review & Confirm

Required Documents

+ Add Required Doc Remove

0 Document Types

Document Type

- 6** In the document selection window, select the applicable entity type for your requirement(s). If you select an option beginning with “specific”, proceed to click the relevant Sites/IRBs/Countries.

Amendment to be Required for

All Sites Specific Sites Specific IRB/EC **Specific Countries**

Search

15 Countries

Country

Albania

Argentina

- 7** Search for the document type(s) you require, and **select** them. You may repeat the process as many times as needed. Use the dropdowns at the bottom to generate multiple requirements for different contacts and or/languages.

Documents to be submitted by all the Sites from selected Countries

Provided by **Site** Study

Q agreement

- All 487
- Site 9
 - 05 Site Management 5
 - 05.01 Site Selection 4
 - 05.01.02 Confidentiality Agreement 1
 - Confidentiality Agreement
 - 05.02 Site Set-up 17
 - 05.02.09 Investigator Regulatory Agreement 3
 - Investigator Regulatory Agreement

To be submitted by Languages

Select Select

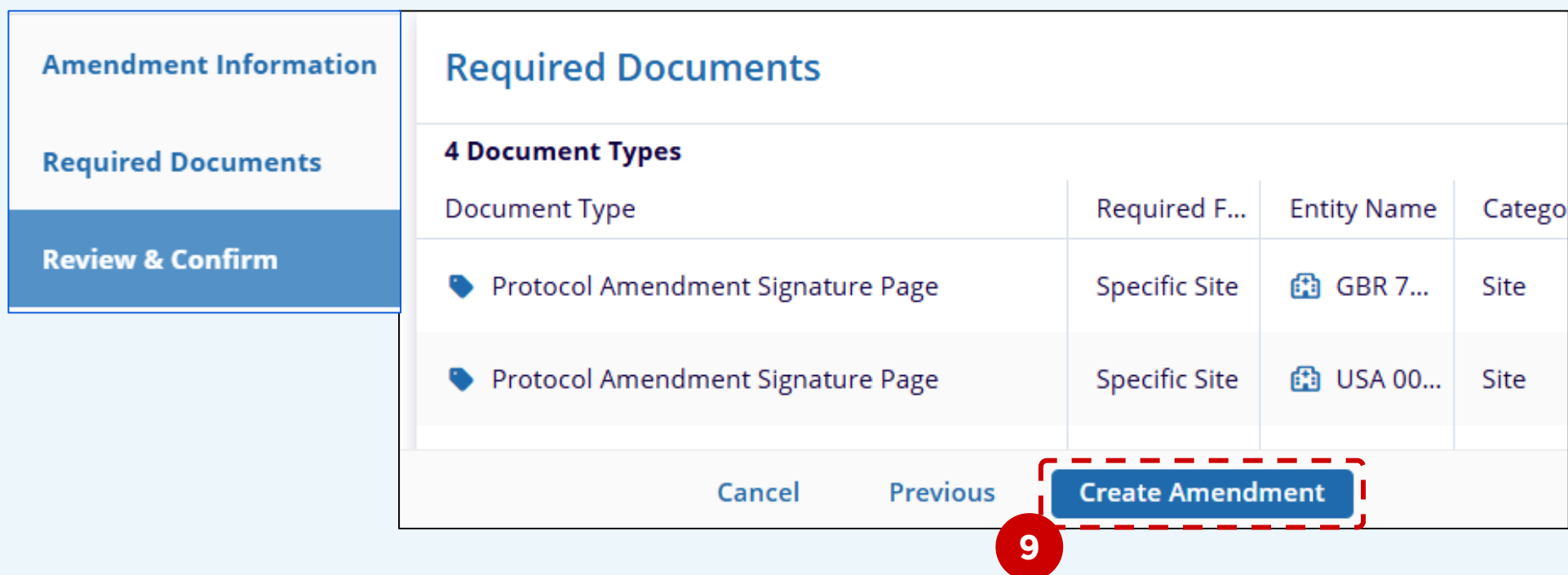
More Save & Close

- 8** Once you have selected all document types you need, click on **Save & Close**.

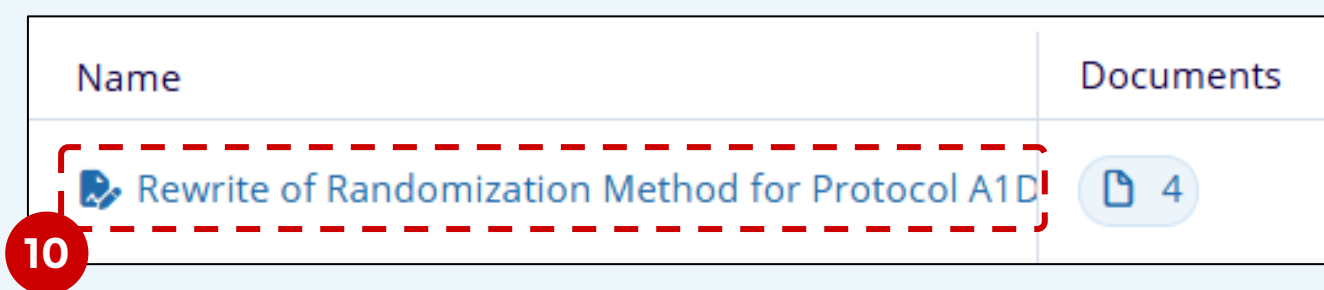
Save & Add More Save & Close

Use **Save & Add More** to select documents for a different entity type, e.g. select *Specific Sites* after adding for *Specific Country*.

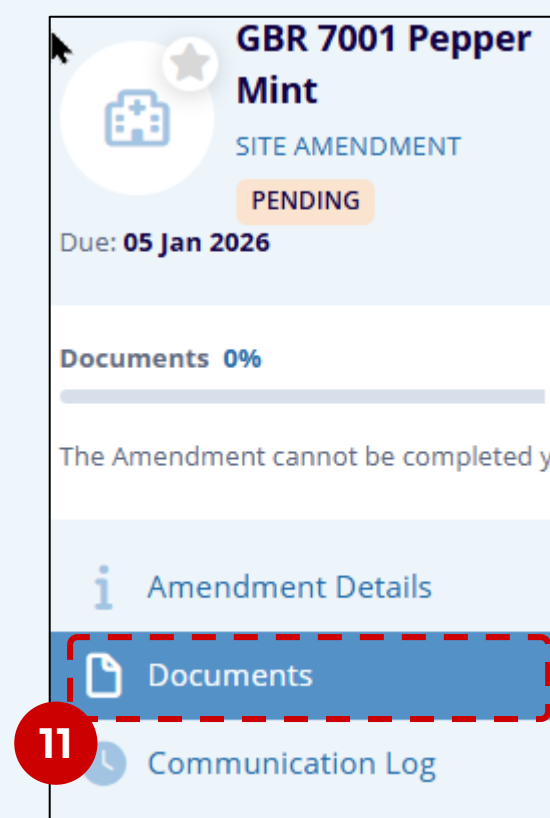
- 9 The last step, **Review & Confirm**, is a non-interactive panel. Verify the info is correct and if not, go back to a previous step to edit it. When all information is correct, click on **Create Amendment** to finalize the process.



- 10 Once the Amendment is created, click on its **Title** to enter and track its progress and required documents.



- 11 User can enter Sites, Countries, or IRB listed in the amendment (use left-side panel) and head to the respective **Documents** section to review, upload, edit, or (for limited roles only) approve the required documents.



- 12** Once all documents are collected, the Admin/Manager can use the **Complete Amendment** button to close the Amendment document collection process.

