

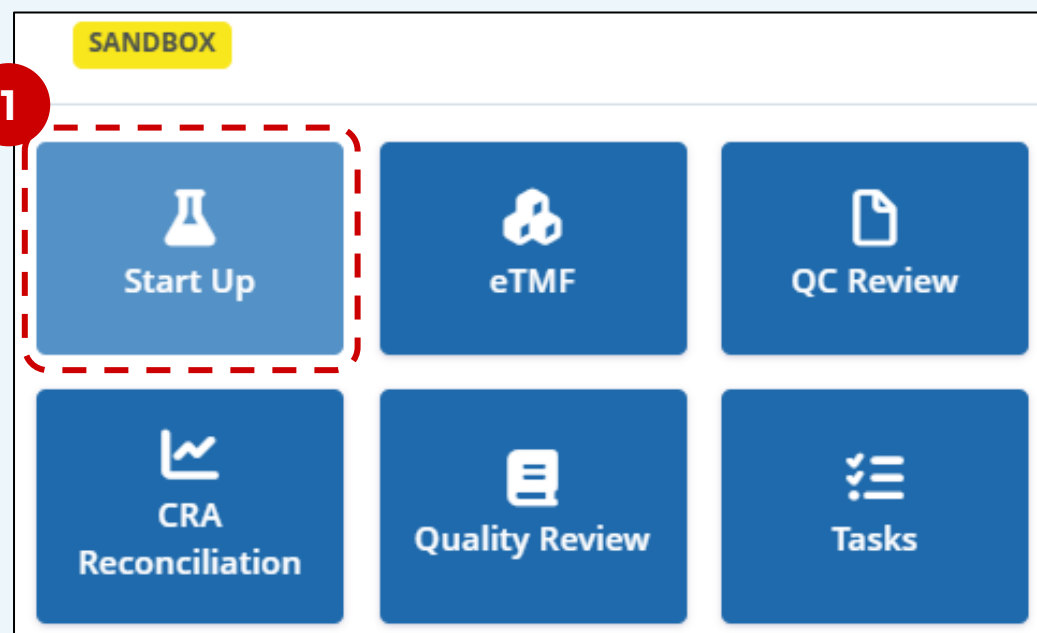
How to Create a Submission Package

TI version 10.8

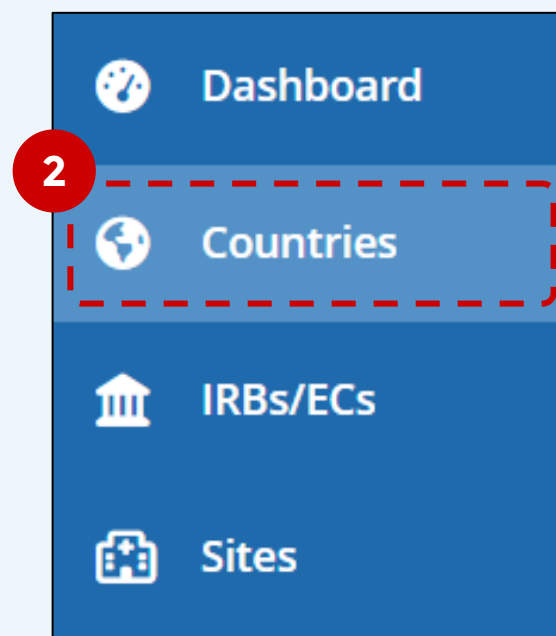
APPLICABLE TO:

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

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



2 Select the **Countries** section from the Navigation Bar. This will display the list of Countries for the study.



3 Select a country by clicking on its name.

A screenshot of a table with the following structure:

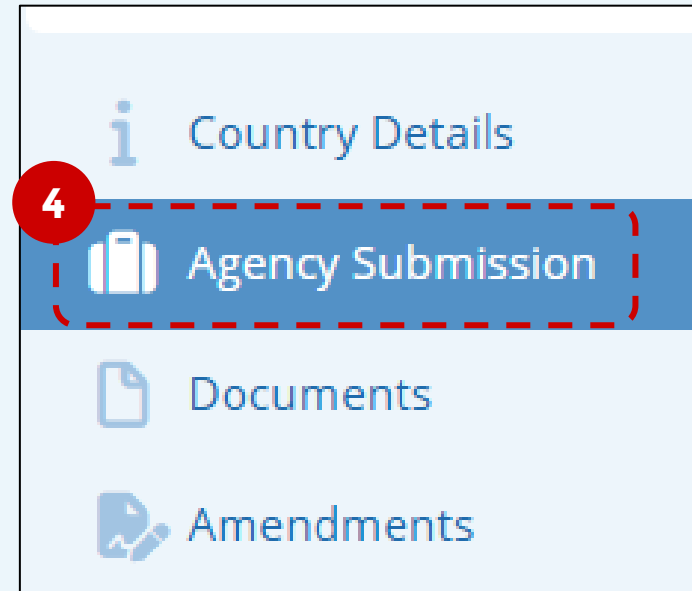
			Country	Status
<input type="checkbox"/>				
<input type="checkbox"/>	★	...	Albania	ACTIVE
<input type="checkbox"/>	★	...	Argentina	PLANNED
<input type="checkbox"/>	★	...	Australia	PLANNED

The table has a header '15 Countries' and a toolbar with 'Edit', 'Columns', and 'Export' icons. A red dashed box highlights the 'Argentina' row, and a red circle with the number '3' is next to it.

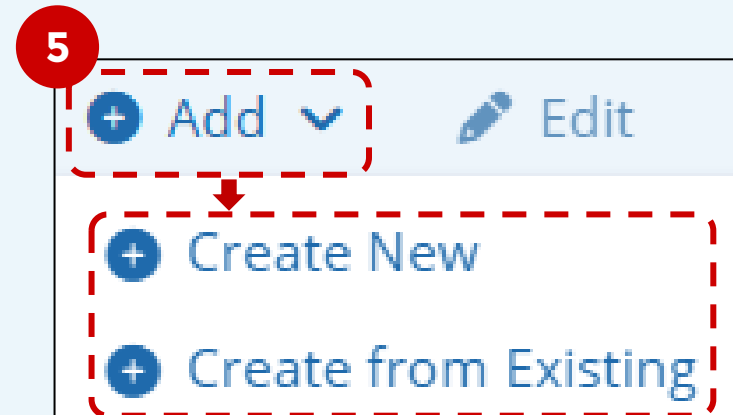
How to Create a Submission Package

TI version 10.8

- 4 Select **Agency Submission** in the left-hand panel.

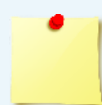


- 5 Click on the **Add** button in the ribbon and then choose from **Create New** or **Create from Existing**. The latter duplicates an existing submission package, but allows the user to make edits before committing.



- 6 In Step 1, add the **name of the package** and any comments.

If creating from existing, the name will be pre-filled; we recommend changing it to avoid confusion.

 The *Agency* selector field comes pre-filled, and in most cases will not contain a different selection if opened.



A screenshot of a 'Package Details' form. A red circle with the number '6' is to the left of the 'Package Name' field. The form includes the following fields: 'Package Name *' (a text input field with a red dashed box around it and the text 'This field is required' below it), 'Submission Status' (a dropdown menu with 'PENDING' selected), 'Agency *' (a dropdown menu with 'Agencia de Calidad del Farmaco' selected), and 'Submission Comments' (a text area). A red dashed box also highlights the 'Submission Status' and 'Agency' fields.

How to Create a Submission Package

TI version 10.8

7 In the second step, select or add the **Country(ies)** that the submission will cover. If the IRB selected is local to a country, as in this example, no selection will be needed.

Countries

Please add countries within which this package will operate

[+ Add](#) [Remove](#)

1 Country

<input type="checkbox"/>	Name	Status	Sites	Language
<input type="checkbox"/>	Argentina Current	PLANNED	1	Spanish

8 In the last step, **drag, browse, or search** the current room for the documents to include in the submission. Click on **Create Package** to finalize.

You may edit the documents you select, using the options in the ribbon (see image below).

Select Documents

[Browse File](#) [Search Documents](#) [Edit Doc Name](#) [Delete](#)

2 Documents 1 selected

8

Drag & Drop

or

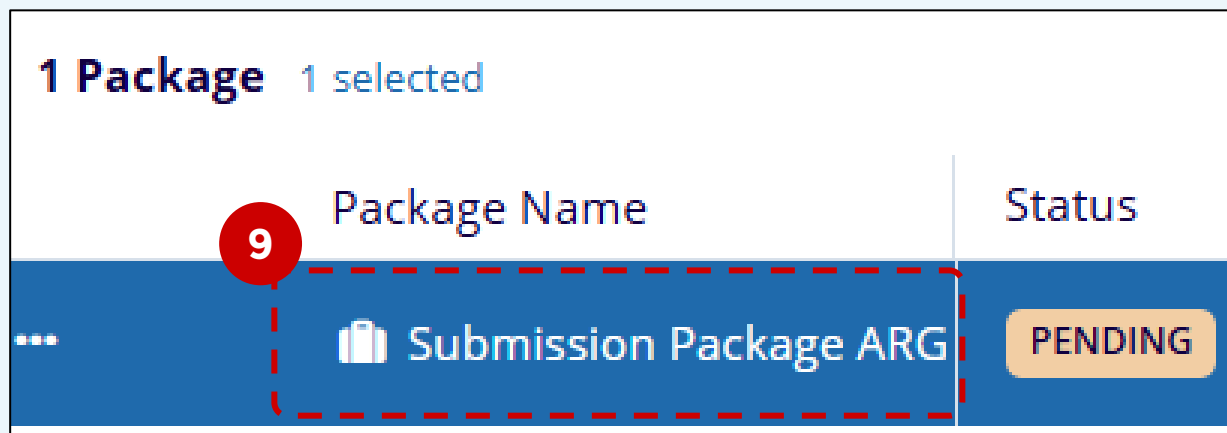
Browse File Search Documents

[Previous](#) [Create Package](#)

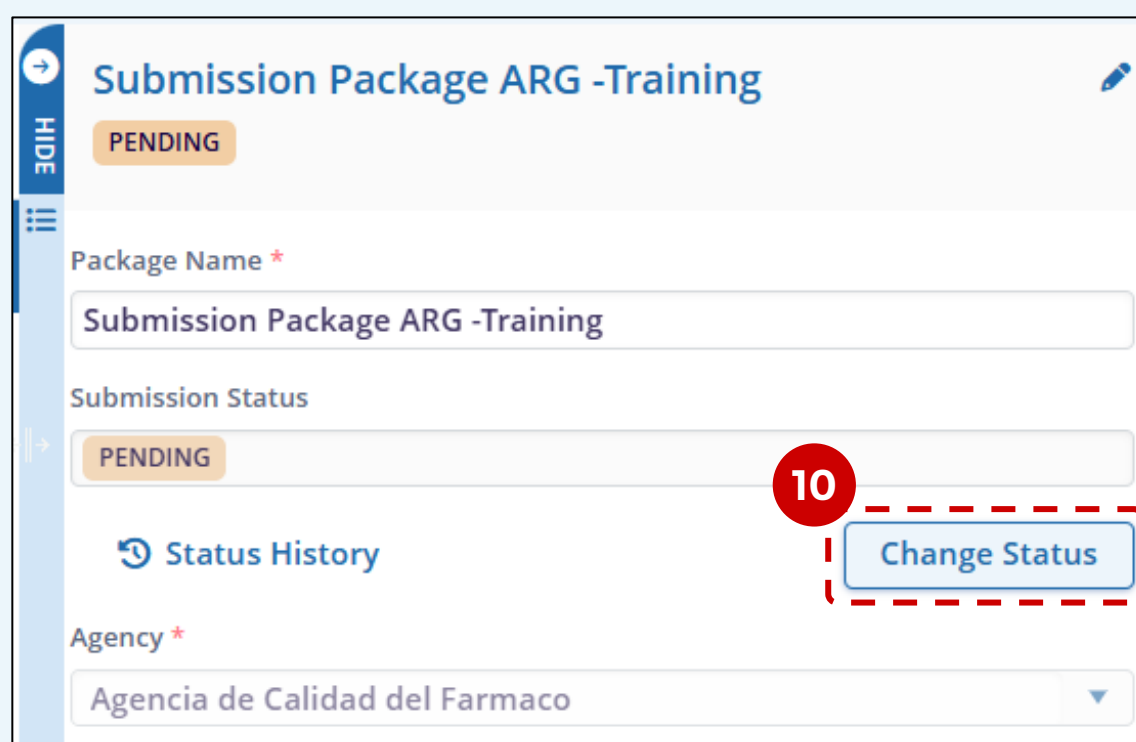
How to Create a Submission Package

TI version 10.8

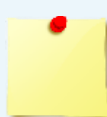
- 9** The submission package is listed with all others relevant for the selected Country. It can be Edited or Downloaded. Once the submission is ready, **Select** a package to call up the side panel.



- 10** In the side panel, click on **Change Status**.



- 11** Once the package has been received, the user should update the status to **Submitted**. Use the selector to change the status, then click **Save**.



After the status is saved as **Submitted**, users can operate the selector again to update to the appropriate status at the time (ex. Approved, Rejected, Withdrawn).

