

Creating a Package

A Document Package can be created within a study to track a subset of documents for a specific purpose (e.g., drug shipment).

Prerequisites: To create a package, you must be a member of the **TMF Create Packages** security group and you must be a member of a Creator Group for at least one Package Definition.

1. Navigate to the Study Item List of the study for which you want to create the package.
2. From the Study Items Breadcrumb Menu, select “Packages List.” The Packages List Page is displayed.
3. Select the gear icon above the list and select “Create New Package” from the Actions Menu. The Create Package screen appears.
4. In the **Package Definition** field, select the definition on which the package will be based. The list of definitions available to you includes those for which you are a member of a Creator Group. Once the definition is selected, several other fields on the screen automatically fill in:
 - Package Type –based on the definition selected
 - Study–based on the selected study
 - Status – is automatically “Draft” for a new package
5. In the **Name** field, enter the name used to identify the package.
6. If the definition is country-level or site-level, select the country for which the package applies in the **Country** field’s drop-down.
7. If the definition is site-level, select the site for which the package applies from the **Site** field’s drop-down.
8. In the Initiation Date field, select the start date of the package.

9. In the Package Due Date field, select the end date of the package. The Due Date cannot be before the Initiation Date.
10. Select "Create." The screen updates to display the list of Study Items for Document Types included in the Document Package, along with an indication as to whether or not the Study Item has been fulfilled. The name of each Study Item is displayed a hyperlink that opens the corresponding document details page. If no matching Study Item was found, and the Document Type is milestone based, an entry is included with a blank status.
11. (Optional) Add any additional Study Items that are needed by selecting "Select Study Items" and following the sub-steps below.
 - On the Select Study Items screen, select the check box for each Study Item to add. Use the Search and filter fields on the left to reduce the list of Study Items as needed.
 - Select "Select." The selected items are added to the list on the Create Package screen.
12. Remove any Study Items that are not needed by selecting the X next to the Study Item.
13. Re-order as desired by dragging and dropping.
14. Select "Save."