

Creating a Package Definition

A Package Definition defines the scope for a specific type of package, including the types of documents to include, the level of documents to include and the users who can create and/or approve packages.

Prerequisites: To create a Package Definition, you must be a member of the **TMF Manage Package Definitions** security group.

1. On the User Home Page, select **More** within the Global Header. From the Actions menu, select "View eTMF Configurations."
2. Select the Breadcrumb. From the Actions menu, select "Package Definitions." The Package Definitions List Page is displayed.
3. Select the gear icon above the list. From the Actions menu, select "Create New Package Definition." The Create Package Definition screen is displayed.
4. In the Package Type field, select the type of package from the drop-down list. Values available are provided from the Package Type dictionary.
5. In the **Name** field, enter a name for the definition.
6. (Optional) In the **Description** field, enter a description of the definition and/or when it should be used.
7. In the **Level** field, select either "Study," "Country," or "Site" from the drop-down to indicate the level of documents to include.
8. If "Country" or "Site" was selected in the previous step, the **Country** field is displayed. Select the country for the package from the drop-down list.
9. Specify the groups of users who can create and manage packages from this definition:
 - Under the **Creator Groups** field, select "Select Groups."
 - In the Groups & Roles screen, select the check box for each group to specify as a Creator Group. Use

the search and filter fields on the left to reduce the list as needed.

- Select “Apply.” The groups are displayed in the **Creator Groups** field on the Create Package Definition screen.

10. Specify the groups of users who can evaluate and approve packages created from this definition:

- Under the **Approval Group Names** field, select “Select Groups.”
- In the Groups & Roles screen, select the check box for each group to specify as an Approval Group. Use the search and filter fields on the left to reduce the list as needed.
- Select “Apply.” The groups are displayed in the **Approval Group Names** field on the Create Package Definition screen.

11. (Optional) To limit the documents included in packages created from this definition, do the following:

- In the **Document Types** field, select “Select Master Items.”
- In the Select Document Types screen, select the check box for each type of document that must be included in packages created from the definition. Use the search and filter fields on the left to reduce the list as needed.
- Select “Select.” The Document Types are added to the **Document Types** field on the Create Package Definition screen*.

12. In the **Approval Type** field, indicate whether internal approval of packages created from this definition require eSignature. Select “Approval With Signature” to require an eSignature, or select “Approval Without Signature” if the signature is not required.

13. In the **Approval Meaning** field, select the meaning of the approval. The list of available values is provided from the Package Approval Meanings dictionary.

14. Select “Create.”

***Note:** Ad hoc or event based Document Types will be included only if a matching Study Item is found when the package is created (e.g., a Protocol Amendment will be added if one is actually found, but otherwise will not appear in the package). Milestone based documents will be added to the package whether or not a matching Study Item is found