

Package Definitions

Before packages can be created, one or more Package Definitions must be configured by a Business Administrator or other user with **TMF Manage Package Definitions** permissions. A Package Definition defines the characteristics for a particular type of package, including the following:

- The level of Document Types to include (Study, Country, or Site)
- Specific Document Types to include
- The groups of users who can create and manage or approve packages
- Whether or not approval requires eSignature and the meaning of the eSignature

Once package definitions have been created, authorized users can create new packages based on those definitions.*

***Note:** A Package Definition must be made effective for it to be available for use during package creation.

You can create a new Package Definition on the Package Definitions List Page. The Package Definitions List Page displays a list of existing Package Definitions and options for managing those definitions. To access the Package Definitions List Page, select “View Configurations” from the More Actions Menu in the Global Header and select “Package Definitions” from the Breadcrumb Menu.

A newly created Package Definition is assigned a *Draft* status and a minor version number of “.1”. A definition with a *Draft* status can be edited if needed to make changes to the Document Types/Study Items or dates. To edit a *Draft* definition, select “Edit Metadata” from the definition’s Actions Menu. On the Edit Metadata screen, make changes as desired and select “Save.”

You can make a definition in *Draft* status “Effective” to make it available for use during package creation. To make a *Draft* definition effective, select “Make Effective” from the definition’s Actions Menu. An *Effective* definition is assigned the next major version number (e.g., 1.0). Once a definition is *Effective*, changes can no longer be made. To make changes, you must return to the definition to *Draft* status by selecting “Revise” from the definition’s Actions Menu. This action increases the version number by .1 (e.g., 1.1)

If you want to retire the definition from use, select “Make Obsolete” from the definition’s Actions Menu. An *Obsolete* definition is not available during package creation, nor can it be edited. An *Obsolete* definition can be made *Effective* if needed.