

Packages

Packages provide a way to tag and track a set of documents in a study for a specific purpose, such as IRB submissions, IP Green Light/drug shipments, etc.

Organizations can create Package Definitions that define the rules for a particular type of package. These rules include the level of package (e.g., Study, Country, or Site), necessary Document Types, the user roles that can create and/or approve packages, and the need for electronic signature during approval. Users with the appropriate permissions can then create new packages based on Package Definitions.

When a package is created, eTMF determines which Study Items to include based on the package definition and lists them on the Create/Edit Package screen along with their status (fulfilled or unfulfilled). Package Creators can add or remove items from this list and track their fulfillment. Once all applicable Study Items have been fulfilled and finalized, Package Approvers can review for completeness and approve.

eTMF also provides a Package Dashboard to monitor and document package progress.