

# Approving a Package

A package in *Draft* status for which all required Document Types/Study Items have been finalized can be internally approved to indicate that the package is complete and is ready for submission, audit, etc.

Certain types of packages may also require external approval (or rejection). For example, IRB/IEC submissions are typically sent outside of the organization for approval. If a package requires external approval, you can mark the package to indicate that the outside organization has either approved or rejected the documents. Documentation supporting the external approval or rejection of the packages can be linked to the package if Study Items exist for that documentation on the Study Item List.

## Internally Approve a Package

**Prerequisites:** To approve a package, you must be a member of the **TMF Create Packages** security group and a member of an Approval Group for the Package Definition.

1. Navigate to the Study Item List of the study to which the package is related.
2. From the Study Items Breadcrumb Menu, select "Package List." The Package List Page is displayed.
3. Locate the package you want to approve and select "Approve Package" from the package's Actions Menu.
4. If the package requires an approval with signature, enter your eTMF User Name and Password credentials in the corresponding fields.
5. On the Approval screen, select "Approve."

The status of the package changes to *Internally Approved*.

## Record External Approval

**Prerequisite:** A package can be marked as externally approved only after it's been internally approved. In addition, the External Approve action can be performed only by users within Approval Groups for the Package Definition.

1. Navigate to the Study Item List of the study to which the package is related.
2. From the Study Items Breadcrumb Menu, select "Package List." The Package List Page is displayed.
3. Locate the package you want to approve and select "Record External Package Approval or Rejection" from the Actions Menu. The Package Approval (External) screen is displayed.
4. In the **External Approval or Rejection Date** field, select the date.
5. (Optional) to attach supporting documents, do the following:
  - Select "Select External Support Documents." The Select Study Items screen appears.
  - Select the check box for each Study Item to add as a supporting document. Use the Search and filters fields to the left to reduce the list of Study Items as needed.
  - Select "Select." The items are displayed in the External Approval or Rejection Support Documents grid.
6. To approve the package, select "Approve Package (External)." The status of the package changes to Externally Approved.
7. To reject the package, select "Reject Package (External)." The status of the package changes to Externally Rejected.