

Creating a File Review

A File Review can be created within a study to initiate a secondary review process, such as a sponsor review or a pre-inspection review.

Prerequisites: To create a File Review, you must be a member of the **TMF Create File Reviews** feature group and you must be a member of a Review Manager Group for at least one File Review Template.

1. Navigate to the Study Item List of the study for which you want to create the File Review.
2. From the Study Items Breadcrumb Menu, select “File Reviews.” The File Reviews List Page is displayed.
3. Select the gear icon above the list and select “Create New File Review” from the Actions Menu. The Create File Review screen appears. If an error message stating that you have exceeded the maximum number of open File Reviews is displayed, contact your System Administrator.
4. In the **File Review Template** field, select the template on which the File Review will be based. The list of templates available to you includes those for which you are a member of a Review Manager Group. Once the template is selected, several other fields on the screen automatically fill in.
5. (Optional) In the **Description** field, enter a description for the File Review. If entered, the description will be used within the File Review name. Therefore, we recommend entering a short but meaningful description.
6. The following fields are automatically populated with values from the selected template and are disabled:
 - File Review Template Description
 - Minimum Sampling Percentage
 - Calculated Sample Size Percentage
7. The **Sampling Percentage** field displays the sampling percentage that the system will use to determine the

number of Study Items included as Review Items. This percentage is the higher of the percentages in the two previous fields (or, if only the **Minimum Sampling Percentage** field is populated, then that value is displayed here). If you want to specify a different sampling percentage, enter the desired value.

8. If the File Review is based on a template that limits Review Items based on dates, the **Review Start Date** and **Review End Date** fields are enabled. Select the dates that define the range of Study Items to include. For example, if you're creating a File Review for Quarter 1 2018 documents, enter 01-Jan-2018 as the Review Start Date and 31-Mar-2018 as the Review End Date.
9. In the **Review Manager** field, enter the user who is responsible for managing the File Review (i.e., adding or removing Review Items, reviewing Action Items, etc.).
10. Select "Create."

The system begins creating the File Review with the appropriate Study Items. When File Review creation is complete, an email is sent to the Review Manager.