

File Review Template Fields

Use the following table when creating a File Review Template.

Field

Description

Action

Name	The name of your File Review Template. Note: This will display each time you create a file review from this template.	Enter a name in the field.
Review Type	The type of file review provided from the File Review Types Data Dictionary.	Select one of the File Review Types.
Description	(Optional) A description of the template purpose.	Enter a description.
Minimum Sampling Percentage	The minimum percentage of study items to include as review items in file reviews created from this template.	Enter the minimum percentage.

<p>Apply Sampling Percentage Before or After All Filtering</p>	<p>Filtering mechanism to determine the number of review items for reach file review.</p>	<p>Select one of the following: Before: Mandatory items are counted towards the sample size. After: Mandatory items are not counted towards the sample size.</p>
<p>Sample Size Parameters</p>	<p>Parameters for calculating the sample size percentage for your file review template.</p>	<p>Select the button and enter your calculation. For more information on sample size calculation, see here.</p>
<p>Review Manager Groups</p>	<p>The group of users who can create and manage File Reviews of this template.</p>	<p>Click Select Groups. In the Groups & Roles screen, select the check box for each group to specify. Use the search and filter fields on the left to reduce the list as needed.</p>
<p>Review Participant Groups</p>	<p>The group of users who can evaluate review items for this template.</p>	<p>See Above.</p>
<p>Review Reader Groups</p>	<p>The group of users who can view File Reviews created from this template.</p>	<p>See Above.</p>

<p>Risk Level</p>	<p>The specified document type risk level.</p>	<p>Set the risk level between 1 (low) to 10 (high).</p>
<p>Mandatory Document Types</p>	<p>The required document types that are added to the file review. Note: These documents can not be deleted during a review.</p>	<p>Click Select Document Types, then choose the documents from the TMF Master List. Use the search and filter fields on the left to reduce the list as needed.</p>
<p>Excluded Document Types</p>	<p>The document types to exclude when performing the file review.</p>	<p>See Above.</p>

<p style="text-align: center;">Document Selection</p>	<p>All Documents – Includes all finalized documents that satisfy other conditions for the template.</p> <p>All Unreviewed Documents – Includes all documents that satisfy other conditions for the template AND that have not been included in another File Review of the same type.</p> <p>All Unreviewed Documents Within Specified Period – Includes all finalized documents that satisfy other conditions for the template, have not been included in another File Review of the same type, AND have a Finalization Date that falls within the dates of the File Review.</p> <p>Note: The dates of the File Review are specified during File Review creation.</p>	<p style="text-align: center;">Select All Documents, All Unreviewed Documents, or All Unreviewed Documents Within Specified Period.</p>
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<p>Include all Study Items satisfied without content</p>	<p>No Empty Study Items – Excludes all empty Study Items from File Reviews</p> <p>All Empty Study Items – Includes all empty Study Items that satisfy other conditions for the template.</p> <p>All Unreviewed Empty Study Items – Includes all empty Study Items that satisfy other conditions for the template AND that have not been included in another File Review of the same type.</p> <p>All Unreviewed Empty Study Items Within Specified Period – Includes all empty Study Items that satisfy other conditions for the template, have not been included in another File Review of the same type, AND have a Creation Date that falls within the dates of the File Review.</p> <p>Note: Available if All Unreviewed Documents Within Specified Period was selected in the Document Selection field.</p>	<p>Select No Empty Study Items, All Empty Study Items, All Unreviewed Empty Study Items, or All Unreviewed Empty Study Items within a Specified Date.</p>
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<p>Country</p>	<p>Used to control selection of country and site level study items.</p> <p>Note: Using a country filter does not prevent selection of enterprise, program, or study level study items</p>	<p>Select one or multiple countries.</p>
<p>Site Status</p>	<p>Used to control the selection of site level study items by status.</p>	<p>Select a site status from the dropdown.</p>
<p>Site</p>	<p>Used to control the selection of site level study items by site.</p>	<p>Select your site from the dropdown.</p>
<p>Document Owner</p>	<p>Filter study items by document owner.</p>	<p>Select one or multiple document owners from the dropdown.</p>
<p>Document Submitter</p>	<p>Filter study items by document submitter.</p>	<p>Select one or multiple document submitters from the dropdown.</p>
<p>Exclude Unblinded</p>	<p>The option to exclude unblinded documents from the file review.</p>	<p>Select Yes or No.</p>
<p>Non Document Items</p>	<p>Review Items that are not related to specific documents (e.g., Check Correspondence). The list of non-document review items is provided from the File Review Non Document Review Items dictionary.</p>	<p>Select one or more non-document items.</p>