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.

Apply Sampling Percentage Before or After All Filtering	Filtering mechanism to determine the number of review items for reach file review.	Select one of the following: Before : Mandatory items are counted towards the sample size. After: Mandatory items are not counted towards the sample size.
Sample Size Parameters	Parameters for calculating the sample size percentage for your file review template.	Select the button and enter your calculation. For more information on sample size calculation, see <u>here</u> .
Review Manager Groups	The group of users who can create and manage File Reviews of this template.	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.
Review Participant Groups	The group of users who can evaluate review items for this template.	See Above.
Review Reader Groups	The group of users who can view File Reviews created from this template.	See Above.

Risk Level	The specified document type risk level.	Set the risk level between 1 (low) to 10 (high).
Mandatory Document Types	The required document types that are added to the file review. Note: These documents can not be deleted during a review.	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.
Excluded Document	The document types to exclude when performing	See Above.
Types	the file review.	

	No Empty Study Items —	
	Excludes all empty Study	
	Items from File Reviews	
	All Empty Study Items –	
	Includes all empty Study	
	Items that satisfy other	
	conditions for the	
	template.	
	All Unreviewed Empty Study	
	Items – Includes all empty	
	Study Items that satisfy	
	other conditions for the	Select No Empty
	template AND that have not	Study Items. All
Include all	been included in another	Empty Study Items.
Study Items	File Review of the same	All Unreviewed
satisfied	type.	Empty Study Items.
without	All Unreviewed Empty Study	or All Unreviewed
content	Items Within Specified	Emptv Studv Items
	Period – Includes all	
		within a Specified
	empty Study Items that	Date.
	empty Study Items that satisfy other conditions	Date.
	empty Study Items that satisfy other conditions for the template, have not	within a Specified Date.
	empty Study Items that satisfy other conditions for the template, have not been included in another	within a Specified Date.
	empty Study Items that satisfy other conditions for the template, have not been included in another File Review of the same	within a Specified Date.
	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	Within a Specified Date.
	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	within a Specified Date.
	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.	within a Specified Date.
	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. Note: Available if All	within a Specified Date.
	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. Note: Available if All Unreviewed Documents	within a Specified Date.
	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. Note: Available if All Unreviewed Documents Within Specified Period	within a Specified Date.
	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. Note: Available if All Unreviewed Documents Within Specified Period was selected in the	within a Specified Date.

Country	Used to control selection of country and site level study items. Note: Using a country filter does not prevent selection of enterprise, program, or study level study items	Select one or multiple countries.
Site Status	Used to control the selection of site level study items by status.	Select a site status from the dropdown.
Site	Used to control the selection of site level study items by site.	Select your site from the dropdown.
Document Owner	Filter study items by document owner.	Select one or multiple document owners from the dropdown.
Document Submitter	Filter study items by document submitter.	Select one or multiple document submitters from the dropdown.
Exclude Unblinded	The option to exclude unblinded documents from the file review.	Select Yes or No .
Non Document Items	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.	Select one or more non-document items.