Outcomes of an Action Item Workflow Task

The following table lists outcomes available when handling an <u>Action Item workflow task</u>.

Option	Tasks Option is Available for…	When and How to Use	What Happens
Ask	• Rework	You are not sure how to proceed and you need to ask a question. Select a reason code, enter a comment, and select "Send Request."	 Task appears in QC group Inbox. Action Item status remains Open. Task status remains Active.
Delegate	• All	You determine that you are not the right person to handle the task. Enter the name or email of the correct person and select "Delegate."	 Task appears in new recipient's Inbox. Action Item status remains <i>Open</i>. Task status remains <i>Active</i>.
Delete *Available only if the Study Item is not a Core Study Item and the user has TMF Virtual Delete Permissions	 Delete or Mark Study Item as Fulfilled Obsolete or Delete Document 	You have been instructed to delete the Study Item. Select "Delete."	 Study Item remains visible only to administrators. Review Item changes to a Non-Document Review Item. Action Item status changes to Addressed. Task status changes to Completed.

		You have been	
Mark as Fulfilled	• Delete or Mark Study Item as Fulfilled	<pre>instructed to mark the study item as fulfilled without content. Select the reason the document cannot be obtained, enter a comment, and (optionally) specify the URL where the document can be accessed. Then select "Mark Fulfilled."</pre>	 Action Item is available to Review Manager for approval. Action item status changes to Addressed. Task status changes to <i>Completed</i>.
Mark as Unfulfilled	• Correct Study Item Incorrectly Marked as Fulfilled	You have been advised that an empty Study Item was marked as fulfilled in error and instructed to correct. Select the reason the document cannot be obtained, enter a comment, and specify the URL where the document can be accessed. Then select "Mark Fulfilled."	 Action Item is available to the Review Manager for approval. Study Item status changes to Unfulfilled, and the Finalization Date is removed. Action Item status changes to Addressed. Task status changes to <i>Completed</i>.
Obsolete and Retire	• Obsolete or Delete Document	You have been informed that the Study Item is no longer valid and instructed to obsolete the item. Select a reason code, enter a comment, and select "Make Obsolete and Retire."	 Action Item is available to Review Manager for approval. Document status changes to Obsolete. Action Item status changes to Addressed. Task status changes to <i>Completed</i>.
Reject	• All	You do not think a correction is necessary. Enter an explanatory comment and select "Action will not be taken".	 Action Item is available to Review Manager for approval. Action Item status changes to Addressed. Task status changes to <i>Completed</i>.

Resolve	• Add Study Item • Generic	<pre>For a Generic task, this indicates that you have taken corrective action outside of the task. Enter a comment and select "Action Completed." For an Add Study Item task, this indicates that you have added the new Study Item outside of the task (or will do so within the task) and want to mark the task as complete. To add the Study Item within the task, select "Add Study Item" and follow the prompts for selecting a document type. To mark the task as complete, enter a comment and select "Action Completed."</pre>	 Action Item is available to the Review Manager for approval. For an Add Study Item task, a new Study Item is created. Action Item status changes to Addressed. Task status changes to <i>Completed</i>.
Submit	• Rework • Upload Document	You have corrected the issue (e.g., metadata) or uploaded the necessary document. Enter a comment and select "QC."	 Task appears in QC group Inbox. Action Item status remains Open. Task status remains Active.