

Reviewing Addressed Action Items

All Action Items that have been addressed in a File Review must be reviewed by the Review Manager to ensure that they were handled correctly.

1. Navigate to the Study Item List of the study for the File Review.
2. From the Study Items Breadcrumb Menu, select “File Reviews.” The File Reviews List Page is displayed.
3. Locate the File Review you want to work with within the list and select the name hyperlink. The File Review Items List Page is displayed.
4. In the Filters Panel, select the “In Review, AIs Addressed” facet under the Review Item status category to filter the list of Review Items to those with addressed Action Items.
5. Select the hyperlink for a Review Item to view the details.
6. Expand the Action Items tab on the right. Review the metadata and comments.
7. Select one of the following options based on your review:
 - **Close** –If you think that the Action Item was handled correction, use this option to close the Action Item. If there are no other open Action Items associated with the Review Item, the status of the Review Item changes to *Review Completed*.
 - **Reopen**–If you think that the Action Item was not handled correctly, use this option to reopen the Action Item. The Reopen Action Item screen is displayed. Proceed to the next step.
8. If you chose to reopen the Action Item in the previous step, complete the following sub-steps on the Reopen

Action Item screen:

- In the **Reason** field, select the appropriate reason from a list of those applicable for the Review Item.
- In the **Recipient** field, select a recipient for the workflow task from those listed or enter the name or email address of the desired recipient.
- In the **Issue Category** field, select the specific issue. The issues available are based on the Reason.
- In the **Action Item** Comment field, enter an explanation or instructions.
- Select "Save."