

File Reviews Overview

File Review provides a tracked and documented secondary QC process in addition to normal document QC. This process may involve sampled document QC, completeness checks, consistency checks, etc., on a combination of Study Items and Non Document Review Items (e.g., Check for Health Authority Correspondence). It may be used for periodic review, pre-inspection review, sponsor oversight, review prior to study lock, or other purposes.

Organizations can create File Review Templates which define the rules for a particular type of review. These include sampling percentages or algorithms, mandatory and excluded Document Types, user roles, rules for review of empty placeholders, and the creation of Non-Document Review Items.

When a File Review is created, eTMF determines which Study Items are in the scope of the review and provides the list of those Study Items on a File Review Items List Page. Review Participants can access this list and begin conducting the review on a self-serve basis. As users complete the review, they will either indicate that there are no Action Items or they will create one or more Action Items. Action Items result in workflow tasks. When tasks are complete, a Review Manager can review the results and close or re-open the Action Items.

eTMF provides reports and dashboards to monitor and document the File Review process. When all Action Items have been addressed, the File Review can be closed.