

IQVIA™ eTMF - eUpload Feature

Expedite upload and processing of ad hoc documents such as emails with automatic system indexing and integration.

ENHANCE EFFICIENCY AND PROMOTE ONGOING ETMF COMPLIANCE

eUpload allows your entire team to upload unplanned but relevant documents into your eTMF to remain compliant. The system automatically indexes each document uploaded to the appropriate document type and level and creates the associated study item(s).



Simplify eMail Integration

Email correspondence is even easier using integration to current versions of Outlook, including Office 365.

The system captures the email string, subject, date, and all attachments, consolidating everything into inspectable artifacts properly filed in your eTMF.



Everyone Adds to the Workflow

There are a lot of documents that are not planned for in the eTMF that regulatory authorities want to see, but there are no placeholders waiting for correspondence such as emails and memos. This is made even more challenging because the Reference Model has multiple locations where correspondence can be filed.

In the past, it has been difficult to include these artifacts into the eTMF. The IQVIA eTMF eUpload feature provides all users with a portal to upload supporting ad hoc documentation relevant to the study.

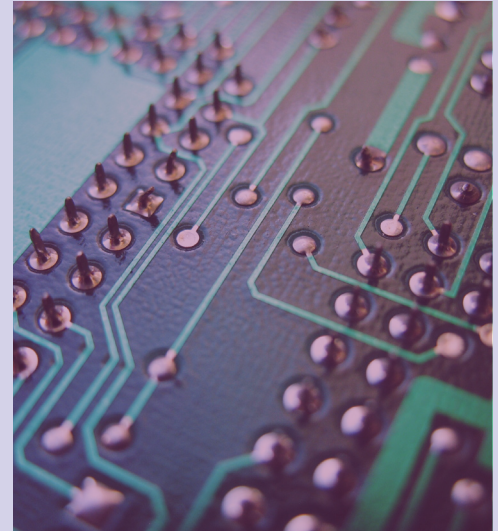
Now all related information can be included like conduct of study, side effects, correspondence from sites to CROs, services delivered from other vendors, or other relevant documentation - all filed properly in the eTMF and easily reviewable in the event of an inspection.

Complete - Consistent - Compliant

The eUpload feature streamlines document submission and helps to ensure all relevant artifacts are correctly documented and accurately filed within the eTMF, resulting in a more complete, consistent, and compliant trial master file.

The eUpload feature allows you to:

- Upload files individually or in batches
- Review uploaded files and specify missing metadata
- Index uploaded documents automatically to ad hoc document types
- Extract metadata from Outlook .msg files and match with existing email threads
- Submit in only one click with configurable submission workflow routes



Make Document Submission Easier

Extract, Populate and Auto-Update

If an unplanned study item already exists, you can upload a document directly to that study item as a newer version. During the upload, special handling is provided for Outlook .msg files, automating several steps of the process and adding to your overall time savings - all while maintaining the integrity of the correspondence. Key metadata such as Subject (if applicable), Document Date, Receipt Date, and Language are automatically extracted from the file and used to populate the corresponding fields on the document.

Thread identification is used to match the uploaded content to existing email threads in the study, automatically adding future correspondence to

the email chains and eliminating unnecessary duplication. Related content from attachments can also be accessed and is automatically linked from email threads, providing inspectors with the ability to easily browse them as needed.

Maintain Accuracy and Viability

eUpload provides a simplified review screen that allows you to ensure that the appropriate documents were accurately uploaded and to apply missing metadata before submitting them. Documents can be reviewed and submitted on an individual basis, or submitted all at once.