Upload Program & Enterprise Study Item

Use the steps described on this page to <u>Upload</u> a <u>Program Level</u> <u>Document</u> or an <u>Enterprise Level Document</u> so that it can be finalized and associated with studies. See <u>Program and Enterprise Documents</u> for an overview of how these types of documents work in the eTMF.

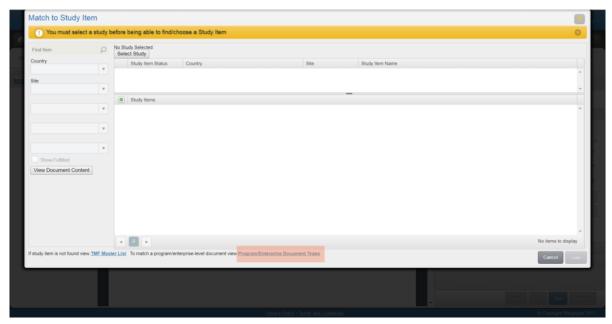
Each <u>Enterprise Level Document</u> and <u>Program Level Document</u> must first be uploaded independent of a study and finalized before it can be associated with specific study items.

NOTE: Not all users can upload Program or Enterprise documents. Permissions depend on your eTMF configuration.

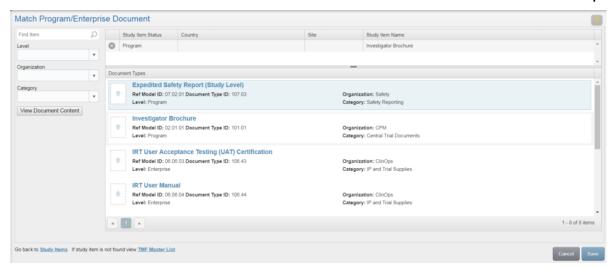
 Upload one or more documents using the Upload Document(s) button in your Work Area.



- 2. On the Upload to Work Area screen, click **Add Files** and select one or more files from your local network. Do **NOT** assign a study, country or site value on the Upload to Work Area screen.
- 3. Click **Upload**. The files are uploaded to your Work Area.
- 4. Select the hyperlink for one of the uploaded files in your Work Area to open the Details view.
- 5. Click **Edit** in the Index area of the Workspace panel. The Match to Study Item screen appears.
- 6. Click the **Program/Enterprise Document Types** link at the bottom of the screen.



- 7. Use the Search field and/or Level, Organization, or Category fields to locate the correct document type. Select the document type from the list and click **Save**.
- 8. On the New Program/Enterprise Document screen, complete any required fields (i.e., those outlined in red).
- 9. Click **Save** to return to the Match Program/Enterprise Document screen. The program/enterprise level study item is listed at the top.



- 10. Click **Save** on the Match Program/Enterprise Document screen. You are returned to the Details view for the study item.
- 11. Proceed as normal with indexing and submit to QC. Once the document has been finalized, it can be associated with study items in individual studies.