

Business Documents

What are Business Documents?

Business Documents are trial-related documents that are not required in the official TMF but can be managed and stored in the eTMF.

Who can see Business Documents?

Neither the study items nor documents are visible to users without the appropriate permissions (TMF View Business Documents). This differs from the way Restricted or Unblinded documents work, where all users can see the Study Item and metadata but only users with additional permissions can see content. This means that:

- For a Sponsor organization, business documents are not visible to CRO partners (users in the global or trial-specific Partner groups).
- For a CRO, business documents are not visible to any associated Sponsor users (users in the global or trial-specific Regulatory groups).
- For both Sponsor and CRO systems, business documents are not visible to inspectors (users in the global or trial-specific Regulatory groups).

How to Set Up Business Documents

A Business Administrator must specify the appropriate master items in the Master List as Business Documents using the setting shown below.

Is Business Document:

Yes

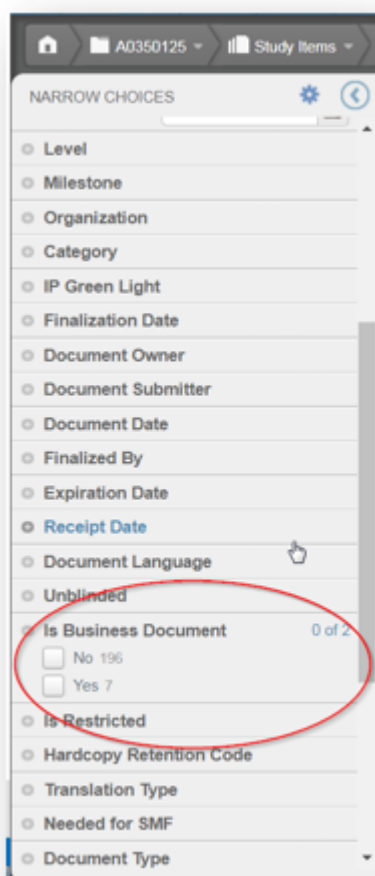


The Business Administration must also add the desired users to the TMF View Business Documents group. This should include any user who may need to index content files to business documents study items, perform QC on business documents, or view business document study item metadata and content.

How to Use Business Documents

Business Document study items can be created, QCed, and finalized the same way as other study items, but only by users with the TMF View Business Documents group permissions.

On the study item list, users can filter for business documents using the “Is Business Document” Category.



Business Documents in File Reviews

If your system uses the File Review feature, business documents may be included as review items in a file review. Note that business documents in a file review *will be visible to all users with access to the file review*. However, only those users with TMF View Business Documents group permissions will be able to open the associated review items to view the content and metadata.

Business Documents in Metrics

In version 2.9 (yet to be released), business documents will no longer be reflected in metrics.