

About Unblinded Documents

In eTMF, documents indexed to study items can be marked as Unblinded to control the visibility of both metadata and content to unintended audiences. With the sensitive nature of unblinded documents, security measures are in place to prevent unnecessary unblinding of documents.

To implement unblinded security, eTMF provides the following features:

Document types in the master list can be defined to allow unblinded content

A setting in the definition of each document type, **Can Be Unblinded**, indicates whether documents of this type may contain content that could potentially unblind a study. This setting must be **Yes** to allow a user to mark uploaded documents of this type as Unblinded.

Study can be defined to Allow Unblinded Documents

When a study wizard is executed to create a study and its study item list in eTMF, the user indicates if the study can contain unblinded documents. The answer to this question must be **Yes** to allow a user to mark uploaded documents of types that **Can Be Unblinded** as being unblinded.

To manually change the unblinded documents setting for a study:

1. Go to your **Study Homepage**.
2. Click the **Study Roles** tab.
3. In the **Study Contains Unblinded Documents** section, click **Yes** or **No**.

Note: Selecting **Yes** indicates that users will be prompted to confirm unblinded status of specific types of documents. Selecting **No** indicates no documents in your study will be

considered unblinded. Making changes to this setting applies to new documents going forward.

User can mark a document containing unblinded content

If a study can contain unblinded documents, and a user uploads a document to a study item of a document type that **Can Be Unblinded**, the user must indicate whether the content is unblinded during indexing.

The image shows a screenshot of a document form. At the top, there is a grey header bar with a minus sign and the word "Document". Below this, there are several form fields:

- Additional Information**: A large text input field with a blue information icon and a pencil icon.
- Document Date**: A date input field showing "03-Mar-2022" with a calendar icon and a pin icon.
- Receipt Date**: A date input field showing "03-Mar-2022" with a calendar icon and a pin icon.
- Document Language**: A dropdown menu showing "English - US" with a pin icon.
- Document Owner**: A text input field containing "Rob Bell".
- Document Submitter**: A text input field containing "System Administrator 2".
- Unblinded**: A radio button group with "Yes" selected (indicated by a blue dot) and "No" unselected.
- Is Restricted**: A radio button group with "Yes" unselected and "No" selected (indicated by a grey dot).

If the user chooses **Yes** for Unblinded, then both the metadata and content will be visible **ONLY** to users with specific security group membership.

Note: This setting is No and is disabled if the logged-in user does not have the necessary group membership.

Unblinded Security Groups

The following permission groups have access to unblinded documents:

- TMF Global Unblinded
- TMF Program Unblinded
- TMF Study Level Unblinded

TMF Global Unblinded

Group Type: Group

Group Sub Type: Global Groups

TMF Program ABT-199 Unblinded

Group Type: Group

Group Sub Type: Program Groups

TMF Study ES-101 Unblinded

Group Type: Group

Group Sub Type: Study Groups

The Global Unblinded group provides users access to unblinded documents across all studies the user has access to, while study specific Unblinded groups provide users access to the Unblinded documents within a specific study.

Generally, a study-specific user (e.g., study-specific study owner) should be provided with study-specific Unblinded access rather than Global Unblinded access.

The program-specific unblinded groups provide users access to program unblinded documents that are not yet associated with study items in a specific study. For example, to view a QC task for a program Unblinded document, the user must have membership in the program specific Unblinded group.

The default group nestings provided with eTMF provide optimal access:

- The Global Unblinded group is a member of each study-specific unblinded group and each program specific unblinded group
- Each study-specific Unblinded group is a member of the program-specific unblinded group for the associated program

If these default group nestings are modified, Unblinded security may not work as expected.

To set unblinded security settings for a user as a business administrator:

1. Click the **More** actions icon in the global header, then select **View eTMF Configurations**.
2. Click the breadcrumbs, then select **User Administration**.
3. Go to your user, then click the **Actions** icon > **Edit Metadata**.
4. In Direct Group Memberships, click **Select Groups**.
5. In the **Search** field, enter **TMF Unblinded**.
6. Select the checkbox of each permission group to assign to the user.
7. Click **Apply**.
8. In the Edit User dialog box, click **Save**.

To set unblinded security settings for a user as a study owner:

1. Go to your Study Homepage.
2. Click the **Study Roles** tab, then go to your study unblinded role.
3. Click the **Add/Remove Members** plus icon.
4. In the Edit Group dialog box, click **Select User**, then select the checkbox of each user.
5. Click **Apply**.
6. In the Edit Group dialog box, click **Save**.

Replacement of uploaded file name with Chronicle ID

When a document is uploaded directly to the Work Area without being indexed, the file name is displayed in the Work Area and in the audit trail. This behavior may be undesirable if the file name typically contains information that can Unblind a study.

As an added security measure, you can set unindexed documents (uploaded documents not associated to a study item) to display a chronicle ID until they are indexed. The chronicle ID replaces the file name of the document with a series of

numbers. This could prevent any sensitive information from potentially being viewed in the document title.



1000AAAA0000000021F3C00

Ref Model ID: Document Type ID:

Level:

Document Status: Uploaded

Due Date:

Milestone:

To enable this feature, please contact the IQVIA Help Desk. The steps below are for IQVIA Help Desk use:

1. Click **More** actions in the global header then select **System Administration**.
2. Click the breadcrumbs, then select **Work Area Upload Settings**.
3. On the Replace file name with chronicle ID for uploaded documents setting, select **Yes**

Replace file name with chronicle ID for uploaded documents

Yes No

Remove Unblinded Security Job

The Remove Unblinded Security job removes unblinded security from all documents within studies containing unblinded documents when a specified milestone date is achieved.

For more information, please contact the IQVIA Help Desk.