Document Upload Feature User Manual

For eTMF

Version 1.0

Smart IMS India Pvt Ltd

**Revision History**

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# Introduction

The electronic Trial Master File (eTMF) is an application designed to assist in the setup, collection, storage, tracking, and archival of essential clinical study documents. This user manual provides instructions for using the Document Upload feature in the eTMF application.

# Overview

<Provide a brief overview of the project. >

## Scope of this Document

<Describe here briefly the scope of the document and it’s purpose. Purpose of this document typically is to do the high level design by identifying the different modules and their interfaces. Here you can describe with respect to the component architecture document, which are the modules that you’re planning to describe in this document and which are out of the scope of this document. >

## Definitions and Acronyms

The terms in use in the document are explained below.

|  |  |
| --- | --- |
| Acronym | Description |
|  |  |

## Platform and Tools

<Can optionally list out any of the third party tools being used and the platform on which the system is being designed for. >

|  |  |
| --- | --- |
| Tool Name | Purpose for which the Tool is proposed to be used |
|  |  |
|  |  |

## References

The documents referred to in the preparation of this document or those on which this document is based, are as follows: <specify the documents referred to and also the relevant documents, such as SRS, any customer supplied documents, etc. >

## Assumptions

The following assumptions are made during this design:

<This gives the assumptions being made in the design of the system. These assumptions may be made due to limited functionality or may be because of implementation issues. Reasons for the assumptions must be indicated, where relevant. >

## Design Constraints

The following are the Constraints taken into account while preparing this document:

< Specify the design constraints. Design constraints could be:

External integration requirement (for open architecture)

Customer specific architecture. >

# Document Upload

The Document Upload feature in the eTMF application enables you to upload various document formats in a structured manner. You have three sources available for document upload: manual upload, CTMS upload, and ISF upload.

To access the Document Upload feature, follow these steps:

* Log in to the eTMF application with your credentials.
* Navigate to the Document Upload section of the application.

## Drag and Drop Functionality:

Drag-and-drop functionality is designed to simplify and expedite the document upload process. It offers a more intuitive way to add documents to the eTMF application. However, it's crucial to ensure that the dragged document is in a supported format by the application.

1. **Locate the document on your computer:** Open the folder or location where the document is saved on your computer.
2. **Click and hold the document:** Left click on the document and continue holding the mouse button.
3. **Drag the document to the designated area:** While holding the mouse button, drag the document over to the designated area within the eTMF application. This area is usually indicated by a dashed or highlighted box or a clear indication of a drop zone.

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Description automatically generated with medium confidence

1. **Release the mouse button to drop the document:** Once the document is positioned over the designated area, release the mouse button to drop the document into the application. The eTMF application will start processing the uploaded document.

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**If a non-supported document is drag-and-dropped:**

When a non-supported document is drag-and-dropped into the eTMF application, the system may display an error message or notification to alert the user that the document format is not compatible.

In such cases, it's recommended to review the list of supported document formats provided by the application. It includes file types such as Word documents (e.g., .doc, .docx), PDF files, Excel spreadsheets (e.g., .xls, .xlsx), and other common formats. If the dragged document is in an unsupported format, the user will need to convert it to a supported format before uploading it to the eTMF application.

## Manual Upload:

With the manual upload option, you can select and upload documents directly from your local repository. Supported document formats includes, but are not limited to:

* Word documents (.doc, .docx)
* PDF files
* Excel spreadsheets (.xls, .xlsx)
* Image files (.jpg, .png, .gif)
* Text files (.txt)

The ETMF application imposes certain size restrictions on uploaded documents. Presently, the maximum file size allowed for uploads is 5MB. To ensure a successful upload, please ensure that the size of your document does not surpass this specified limit.

When utilizing any of the upload options mentioned above, it is crucial to ensure that the uploaded documents contain accurate and relevant information. This ensures the integrity and compliance of the eTMF system.

## Upload Document (Choose File):

1. Click on the **Upload** button.
2. Select the document from your local repository or use the drag-and-drop functionality.
   1. Drag and drop file.

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* 1. Choose file from the local folder.

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* 1. Successfully Uploaded Document

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## Metadata Entry

The eTMF application ensures that Metadata fields are presented in a specific order and format based on the **eTMF Metadata Definition** provided. Following are the details regarding metadata entry:

### Order and Indent Level:

The eTMF application follows the ordinal and indent level column in the **eTMF Metadata Definition** to determine the order and hierarchy of the metadata fields. It ensures consistency and organization when entering metadata for documents.

### Data Type:

The system incorporates the data type column specified in the **eTMF Metadata Definition** for each field. The data type determines the format in which the data should be entered. It may include text, date, number, or other data formats.

### Predefined Data Types and Code Lists:

The eTMF application provides data types for the metadata fields. These predefined types ensure uniformity and standardization across the system. Code lists may be associated with specific fields, allowing users to select values from a dropdown list. It streamlines data entry and maintains consistency in capturing information.

### Text Fields:

Users can directly enter the relevant data for fields that accept textual information. These fields may include document names, study titles, investigator names, or other textual details.

### Dropdown Selection:

Specific fields are associated with code lists that provide a predefined set of values. When such fields are encountered, the eTMF application presents a dropdown list of values for the user to choose from. It ensures accuracy and standardization in capturing metadata.

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The eTMF Metadata Definition is based on industry best practices and standards, such as the Drug Information Association (DIA) Reference Model. The DIA Reference Model provides a comprehensive framework for organizing and categorizing TMF content, including metadata fields.

The metadata fields capture important details about the document, such as the document name, artifact number, study country, site, and other relevant information. These fields help categorize, organize, and search for documents within the eTMF application.

* **Document Name:** Enter the name of the document.
* **TMF Level:** Select the appropriate TMF level (study, country, or site).
* **Study:** Select the study associated with the document.
* **Country:** Select the country associated with the document.
* **Site:** Select the site associated with the document.
* **Artifact Name:** Select the artifact (document) based on the selected "TMF Level".
* Once the user selects an **Artifact Name**, the system automatically updates the related fields such as **Type**, **Subtype**, **Milestones**, and **Artefact Number**.
* **Version Number:** The Version Number field is automatically updated with a default value of “1.0“by the system.
* **Upload Date:** This field is automatically updated with the current date.

**Note:**

* **Study** and **Country** fields in the TMF application vary based on the selected TMF level.
* Users must choose the appropriate study and country associated with the document based on the TMF level.
* The dropdown menu for **Study** and **Country** will be filtered to display only relevant options for the TMF level.
* Filtering options ensure metadata entry aligns with the eTMF system's context and hierarchy.
* Accurate categorization and organization of documents are facilitated by selecting the appropriate study and country.

1. After entering all the metadata, click the **Submit** button. The system will validate the form and display a confirmation message to confirm that the document has been successfully uploaded. If there are any validation errors, the system will display the corresponding validation message.

## View Uploaded Documents

The View Uploaded Documents lets users keep track of all the documents successfully uploaded in the eTMF application. Users can quickly review and access their uploaded documents in a convenient list view, providing a comprehensive record of their document management activities within the eTMF application.

### Accessing the Uploaded Documents:

After completing the document upload process, users can access the uploaded documents in the upload screen.

### Displayed Information:

The uploaded documents are presented in a list format, providing key details for each document. The following information is shown:

* **Document Name:** The name entered by the user during the metadata entry process is displayed and highlighted for easy identification.
* **Artefact Name:** The name selected during the metadata entry process represents the document's type or category.
* **Uploaded Date and Time:** This reflects the date and time the documents were uploaded.
* **Document Status:** By default, the document's status is "Uploaded" to indicate that it has been successfully uploaded.

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### Sorting and Presentation:

The uploaded documents are organized based on the uploaded date and time, with the most recently uploaded documents appearing at the top. This ensures that users can quickly locate and access the most recent documents. The list of documents is sorted in descending order (DESC) based on the uploaded date and time.

### Pagination:

If there are many uploaded documents, pagination functionality is available. It allows users to navigate through multiple pages of documents and view them in a manageable manner.

### Record Keeping:

The View Uploaded Documents feature serves as a record of all the documents that have been uploaded. Users can refer to this list to track the history of uploaded documents and retrieve any necessary information.

## Document Upload Versioning

Document versioning functionality allows you to easily upload new versions of existing documents while maintaining proper version control. It ensures that the latest updates and changes are accurately reflected and accessible within the eTMF application.

As a document owner, viewer, or reviewer, you can upload a new version of an existing document in the eTMF application. The document versioning process work as follows:

### Accessing the Document Upload Area:

Navigate to the document upload area within the application. It can be done by following the designated pathway or accessing the relevant section.

### Uploading a New Version:

You can upload a new document version by dragging and dropping the file or choosing it from your local repository. Ensure that the file you are uploading contains the desired updates or changes.

### Metadata Entry:

Enter the necessary metadata fields associated with the document. It may include information such as the Artefact Name, TMF Level, Study, Country, and Site. Provide accurate and relevant details to facilitate proper document identification.

### Identifying Existing Document:

The system assesses if a document with the same parameter values already exists. Specifically, it looks at the Artefact Name, TMF Level, Study, Country, and Site fields. If a document with identical values is found, the system recognizes the uploaded document as a new version of the existing document.

### Version Control Popup:

A version control popup is displayed upon identifying the uploading document as a new version. This popup, titled "Version Control," provides the following information:

* **Document Name:** The name of the existing document that matches the parameters of the uploading document.
* **Update Prompt:** A message informs you that the artifact already exists and asks if you want to update the version number.

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### Version Control Options:

The version control popup presents several options, allowing you to manage the versioning process. The options include:

* **Update as Version <X.Y> (Major Change):** Selecting this option signifies that the new version introduces significant changes to the document. The following major version number is displayed based on the current version.
* **Update as Version <X.Y> (Minor Change):** This option indicates that the new version includes minor changes or updates. The following version number is shown based on the current version.
* **Overwrite Current Version:** If you choose this option, the new version overwrites the current version of the document.

### Creating the New Version:

After selecting the appropriate version control option, the system creates a new document version. The chosen option determines the version number assigned to the new version. The updated document is then available in both the document upload and document viewer list view sections of the application.