



## eTMF

on Documentum / Alfresco / Oracle WebCenter



**DIA**

### DIA EDM Reference Model

Document and metadata set – starting from the reference model



### Template-based Approach

Create documents, full eTMF structure and add sites, all from templates – all fully configurable



### Portal / Cloud

Simple and secure access for external contributors  
Cloud-enabled for both internal and external users



### CTMS and other Integrations

Integrate with multiple CTMS systems within the CARA UI and push documents to submissions or pull from Quality (SOP)

# CARA for eTMF

CARA for electronic Trial Master Files is a configuration package of the standard CARA product to provide functionality required for managing all Clinical Trial Master File documentation and related information. This package is based on the EDM Reference Model.

The CARA Portal for Investigators and Clinical Trial Sites to upload data to your repository. Additionally, the CARA Hub functionality allows you to display and update information from third party systems (e.g. CTMS, submission management, master data management) using web services, JSP or other easy integration points.

## CARA eTMF features

- Based on the **EDM Reference Model** for metadata model
- **eTMF template structures** included
- Ability to create **contexts** so that documents included in multiple studies can have different metadata (e.g. Investigator CVs)
- **De-duplication** of data – manage and report on duplicate files
- Wizard for creation of content based on **templates**
- Integration with simultaneous authoring / review tools e.g. from PleaseTech, i4i and Brava
- Full **cycle** of creation, authoring, review and approval including eSignature
- Easy **drag-and-drop** to create and manage Trial Master Files
- Use metadata and CARA **dashboards** to manage TMF information
- Ability to have external CROs and Investigators or Trial Sites contribute documents directly into your database via the **CARA Portal** – uploading to a staging area where files can then be fully tagged
- **Study Tagging** information for the CTD
- Ability to tie TMF documents into **submissions** (see separate CARA Regulatory Affairs package)
- Fully **multi-lingual** including many European languages as well as Japanese, Chinese and multiple European languages

## General CARA features

### **DIMENSIONS**

CARA has a unique ability to allow users to build their own navigation tree view (“Dimensions”) based on metadata.

### **WIDGETS**

Extensible panel showing widgets – choose from core set (e.g. properties, renditions) or create your own, linking in any web service / JSP or query as a widget. Rearrange the widgets pane with drag & drop.

### **VIEW MANAGEMENT**

Define different views for different user groups / usage scenarios. Specify different properties, widgets, filters, SnapLists, Dimensions and other options, allowing users to work in the way that best supports their individual processes.

### **DASHBOARDS**

Dashboards provide a strong reporting capability for data both inside CARA and accessible externally via web services, and results can be shown as tables, charts or graphs, exported to Excel.

### **USER PREFERENCES**

All settings that users choose to personalize are saved as their preferences, so that the user can login from another machine and will have the same preferences applied.

### **CONFIGURABILITY**

CARA has a full configuration and customization layer built in to allow faster deployment and easier validation.