



# End to End for Life Sciences: CARA for eTMF

CARA uses the DIA Reference Model for Electronic Trial Master File documents, which provides a structure for all metadata configurations. It includes new site handling, reporting of missing documents, integration with multiple CTMS systems and an Investigator Portal.



#### DIA Reference Model

Data structure based on the DIA EDM reference model.



#### Template Based Approach

Fully configurable templates for document creation, eTMF structures and additional sites.



#### Portal

CARA Portal enables third party viewing for simple and secure access by CROs, investigators and trial sites.



#### E-signatures

Our eSignature capabilities apply user information into a signature page that can be added to documents automatically depending on business processes.

## Looking for an Intelligent RIM Platform?

The **Alliance of Experts** was founded to provide a deeply integrated family of applications from best of breed providers for an End to End platform. As part of the Alliance of Experts, CARA's integration with PhlexGlobal's eTMF system provides a comprehensive eTMF solution for users.



## CARA eTMF Features

- eTMF template structures included as standard
- Reduced data duplication
- Content creation based on templates in CARA
- Simultaneous authoring
- eTMF lifecycle managed from cradle to grave, with drag and drop functionality for rapid and efficient TMF creation
- Dashboards and reporting based on metadata to manage TMF information.
- Use of the CARA portal for third party access, including CROs and Investigators, who can directly contribute documents to the staging area where files can be classified.
- Used in conjunction with the CARA regulatory affairs package, eTMF documents can be linked to the submission process.
- Multi-lingual support

Connect your Landscape  
New CARA is the most interoperable ECM platform for Life Sciences.

## Pure SaaS

All our of New CARA solutions are cloud-first, providing the simplicity and security of a fully-managed service. Backed by global content storage leaders, you can be safe in the knowledge that your content and information is protected by cutting-edge technology in a private cloud.

