AMEDON eTMF

EVERYTHING IN ITS PLACE

Our eTMF solution supports you in receiving, allocating and tracking essential and other study documents, e.g. according to the TMF reference model of the DIA. The structure of documentation and study setup can be completely setup at start or grow throughout the project.

ONE APPLICATION - ALL STUDIES

Our eTMF application supports the administration of any number of studies. Benefit from reusable profile templates according to standards such as the DIA reference model and your established TMF structures when setting up each new study. The circle of users can also be taken from existing studies or be completely independent of them.

Within the eTMF application it is possible to represent any study type and structure. You are independent of whether it is a study in the field of medical devices, medicinal products, a combination or a study according to professional law. In addition, you can depict monocentric as well as multinational, multicentric studies. This is ensured by profile sets that can be freely created and combined with each other as desired on the one hand and a free creation of the protocol and trial centre structure on the other.

INSPECTION READINESS

Timely delivery by document holders

- Document delivery can be facilitated by simply giving providing access to any document holder within your clinical trial setup.

Document review and access possibilities

- Access every document and its history at any moment directly within the eTMF application.

Overview and audit preparation

- Create filtered overview tables at any time to list missing and/or available documents for the overall study or single sites.
- Create *ad hoc* TMF archives for audit and inspection purposes. For better overview during interim analyses the created file structure overview shows placeholders for already expected documents not yet available.

DAILY DOCUMENT HANDLING

STRUCTURED PROCESSES AND ACCESSIBLE DOCUMENTS

TMF

It is possible to create and download a TMF document package at any time. The package contains all documents and their revisions in a freely definable folder structure that always meets your needs. In addition, an interactive and printable content file is included, showing the individual documents, their revisions and their status.

ISF

The eTMF application takes advantage of the fact that a large part of the documents to be maintained in the TMF are identical to the documents provided to the trial sites for their ISF. It is possible at any time to export the ISF documents stored in the application for each site involved in a study in a structure predefined similarly to the TMF. This ensures that only your reviewed versions of the documents provided are included in the ISF.

OVERVIEW AND WORKFLOW

Within a study, it is possible to make tailored workspaces accessible to different groups of users and to assign associated privileges. To this end, simple processes are also deliberately kept simple on the user interface. This avoids frustration and increases compliance.

EXAMPLE

Site staff can be granted access to upload CVs etc. with minimal training only. This allows you to receive documents quickly and securely and also avoids redundant efforts.

EXAMPLE

Read only access can be granted individually for each study in your eTMF application. This enables auditors, inspectors or sponsor staff to access the application independently without any risk of disclosure.

COMPATIBLE & ADAPTABLE

Clinical trial documentation has to comply with certain standards such as the DIA eTMF reference model. AMEDON provides a basis structure according to the DIA if desired. This or any other profile package is 100% adaptable to suit your diverse studies and other obligations such as Sponsor company rules.

DIA Drug Information Association — Trial Master File TMF Reference Model

EVERYTHING IS ARCHIVABLE

State of the art clinical trials combine data of different instruments such as ePRO results, wearables records, app outcome as well as imaging of classical approaches like MRI, CT, X-ray etc. The AMEDON eTMF is able to archive every digital file independent of its size or type.

SECURITY AND STANDARDS

- Data stored in Germany – German Data Protection standards
- Data security: Data center ISO/IEC 27001 certified
- Total Quality Management system
- Validation processes based on GAMP guideline
- Applications prepared to be compliant to FDA 21 CFR part 11

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