FACT SHEET

eTMF by Octalsoft

Electronic Trial Master File

- Seamless integration with CTMS application
- Interactive reporting system
- Customized workflows for quality reviews & documents
- Multi-layered security for data & application

To know more, email us at
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ELECTRONIC TRIAL MASTER FILE BENEFITS

Aligns with the Drug Information Association (DIA) Reference Model

- The eTMF filing structure uses standardized terminologies, modules and sections as per DIA model for managing filing of trial documents.
- Octalsoft's eTMF complies with the principles and standards of the DIA Reference Model by providing real-time tracking and monitoring of document completeness, accuracy, and timeliness, and enabling efficient communication, collaboration, and coordination among various stakeholders involved in the trial.
- Octasoft's eTMF supports the 'DIA Exchange Mechanism Standard' to export data from one filing system to another (for e.g CRO to Sponsor).

eTMF Integration

- Deploy as a standalone application
  - Single Study
  - Multi-study
- Integrate with Octalsoft CTMS
- Integrate eISF of Octalsoft rSDV with eTMF
- Integrate Octalsoft eTMF with any third party CTMS through API

Personalized Email Alerts & Quick Access Links

- Contextual and real-time notifications for users to complete tasks within the system through email alerts and to-do-lists with hyperlinks for quick access such as for
  - Expired Artifacts
  - Artifact Workflow
    - Uploaded
    - Sent for Review
    - Sent for Rework
    - Approved
    - Published
    - Un-published
    - Status reports on defined frequency

Online Collaboration & Audit Readiness

- Easy access, retrieval, and sharing of documents among different stakeholders
- Real-time tracking and monitoring of document completeness, accuracy, and timeliness helps in being audit ready

Customizable Table of Content & Access

- Flexible wizard-driven process for setting up eTMF- Table Of Contents (TOC)
- TOC can be customized as per project requirement
- Controlled Access to Upload, Retrieve & Review artifacts
  - Create Blinded & Unblined user roles and provide access at document level and folder level
- Document preview feature allows users to view documents online without the need to download

Easy Upload & Scalability

- Drag & drop option to upload documents
- Easy upload from any mobile device
- Scalability to handle large volumes of documents and records associated with the size and scope of your project

Dynamic & Intuitive Workflows for Publishing Artifacts

- Clear and intuitive menus, icons, and buttons
- Define user roles and levels of access for performing various tasks
- Review and approve artifacts with eSignature
  - Auto-version control of the documents during the review and approval process
- Function to publish & un-publish artifacts
- Withdraw and delete artifacts if required (with deletion audit trail)

File Nomenclature & Smart Search

- Centralized document repository with automated filing nomenclature
- Smart search and filtering capabilities using metadata attributes of the file such as author name, document name, document type, date of creation etc.

Real-time Reports & Graphs for Decision Making

- Track completeness of eTMF in real-time with a dynamic report
- Check artifact statuses
- Monitor TAT for publishing artifacts
- View TOC & Audit Trail report

OUR UNIQUE CUSTOMER SUPPORT STRUCTURE

Detailed User Manuals/Guides

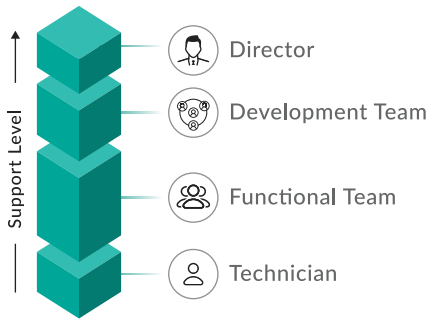
One Stop-Hassle Free Support

- Detailed user guides & training sheets for every product module
- Guided video tutorial sessions to address user queries
- Exhaustive FAQ sheets per product module

24 X 7 Help Desk Support

Our Specialists are Always Available to Resolve Your Queries

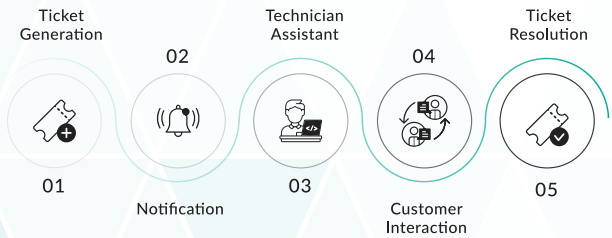
1. Customized screen for every user
2. Integrated online & offline support
3. Comprehensive repository of common queries
4. Module embedded chatbot



Embedded Agile Ticketing Feedback System

Your Query is Our Priority

Issue based (bug, enhancement, data rectification & others) ticket resolution system to address urgent queries on priority



AI Powered Module Specific Chatbot

Personalized Just for You!

1. Specific phone key number allocation to every client
2. Local & international support
3. Integrated online & offline support

Meet **Rohan**,

Clinical Research Associate

He works at a leading pharmaceutical company. With over 10 years of experience in clinical research, Rohan is responsible for managing multiple clinical trials across various therapeutic areas. His primary responsibilities include monitoring study progress,ensuring compliance with regulatory requirements, and maintaining effective communication with study sites and vendors.

Despite having experience in managing clinical trials, Rohan faced several challenges in managing paper-based Trial Master Files (TMFs) such as tracking study documents, ensuring document completeness and accuracy, and managing document version control.

To tackle these challenges, Rohan adopted Octalsoft Electronic Trial Master File (eTMF) solution. Our solution provided Rohan with a centralized platform for managing all study documents, including regulatory documents, study protocols, and case report forms. It also offered advanced document management capabilities, including version control, audit trails, and real-time document access.

By adopting our eTMF solution, Rohan has been able to manage his clinical trials more efficiently. He can quickly access study documents, ensure document completeness and accuracy, and track document versions with ease.

WHY CONSIDER OUR ECLINICAL SOLUTION?

Single Unified Mobile-Enabled Platform

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Regulatory Compliant

Compliant with all current & highest regulatory guidelines:

GDPR | FDA 21 CFR Part 11 | EU COMPLIANT Annex 11 | GAMP 5 | cdisc | HIPAA COMPLIANT | GxP | ICH GCP

Patient Centric

Integrated ePRO & eConsent enables you to conduct patient-centric virtual trials to access diverse population all over the world for smarter and faster trials

Audit Ready Database

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Global Mega Trials in Multiple Languages

Experience conducting global trials for all types of studies and trial phases with US FDA Submission | EMA Submission | DCGI Submission

Fast Study Startup

Shortest build times with over 90% of studies deployed within 2-4 weeks. Easy-to-use trial builder allows quicker configuration of eCRFs

Configurable, Customizable, Cost Effective & Easy to Use

The platform can easily integrate with your existing system and can also get designed as per your requirements for increased flexibility, mobility and scalability

Unparalleled Global Customer Support

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Our Values

For 15+ years, we've mastered the art of Simplifying Technology so that greater discoveries can happen sooner. As a leading eClinical Solution provider, we've always invested in the right expertise, experts, and technology that keeps us, and you at the forefront of science and medicine. As a trusted tech partner for some of the world's leading clinical trial initiatives, our values of innovation, reliability, and client satisfaction guide everything we do.

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