FACT SHEET

eDOCS by Octalsoft

Electronic Documents Management System

Instant Document Availability

Centralized Document Repository

Easy Document Review

Version Control

To know more, email us at info@octalsoft.com inquiry@octalsoft.com

+1 (240) 547-4400
+91 (760) 098-3010

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ELECTRONIC DOCUMENT MANAGEMENT SYSTEM BENEFITS

Enhanced Patient Understanding

- eDOCS provides a centralized platform for managing and organizing clinical trial documents.
- It ensures that all trial-related documents are easily accessible, reducing the risk of misplaced or lost documents.

Regulatory Compliance

- The system helps ensure compliance with regulatory requirements.
- It allows users to track and maintain compliance with Good Clinical Practice (GCP) guidelines, helping to avoid compliance issues and potential regulatory setbacks.

Version Control

- eDOCS enables version control for trial documents.
- It ensures that the most up-to-date and accurate information is always available, reducing the risk of errors and ensuring data integrity.

Collaboration and Communication

- The system facilitates collaboration among research teams, sponsors, and other stakeholders.
- It offers communication tools to streamline discussions and document reviews, fostering a more efficient working environment.

Real-Time Data Access

- eDOCS provides real-time access to trial data and documents.
- The system ensures that all team members can access the information they need when they need it, improving decision-making and overall trial efficiency.

> Octalsoft eDocs is a cloud-based solution that is specifically developed keeping in mind the requirements of a document-intensive clinical trial development phase. Octalsoft eDocs eliminates “content chaos” and allows the user to cost-effectively manage the complete lifecycle of content, from draft to final approval.

Krunal Bhatt
Technical Manager | Octalsoft

Secure Data Storage

- The system offers robust security features to protect sensitive clinical trial data.
- It includes user access controls, encryption, and audit trails to safeguard data from unauthorized access or breaches.
- eDOCS simplifies and automates various workflows related to clinical trial management, including document creation, review, approval, and archiving. This streamlines processes and reduces administrative overhead.
- Octalsoft's eDOCS system helps maintain patient data privacy and confidentiality by controlling access to sensitive information and ensuring compliance with data protection regulations.

Efficient Reporting and Reduced Administrative Burden

- The system offers reporting and analytics tools to generate real-time reports on trial progress, document status, and other key metrics. This helps sponsors and investigators make informed decisions.
- eDOCS reduces the administrative burden associated with managing clinical trial documents and data. This frees up research staff to focus on critical tasks, such as patient recruitment and data analysis

Time and Cost Savings with Data Integrity

- By automating document management, streamlining workflows, and reducing the risk of compliance issues, eDOCS can lead to significant time and cost savings throughout the clinical trial lifecycle.
- The system helps ensure data integrity by reducing the risk of errors and discrepancies in trial documents. This is crucial for maintaining the reliability of trial results.
- eDOCS maintains comprehensive audit trails, allowing for the tracking of document revisions and user actions. This can be invaluable for quality assurance and regulatory purposes.

Remote Access and Scalability

- In an increasingly globalized world, eDOCS supports remote access, enabling collaboration among geographically dispersed teams and facilitating remote monitoring of clinical trials.
- The system is scalable, making it suitable for small to large-scale clinical trials. It can adapt to the specific needs of each trial, whether it's a small, single-site study or a large, multi-site, international trial.

OUR UNIQUE CUSTOMER SUPPORT STRUCTURE

Detailed User Manuals/Guides

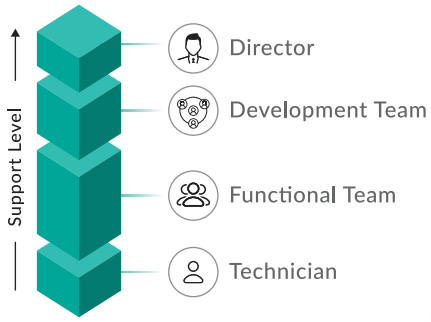
One Stop-Hassle Free Support

- 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

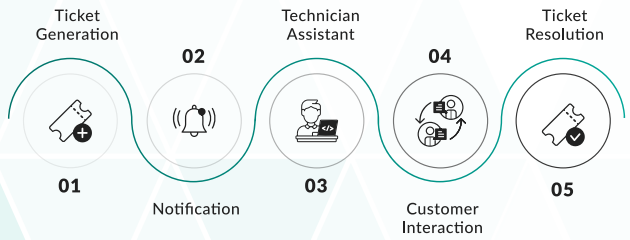
1. Customized screen for every user
2. Integrated online & offline support
3. Comprehensive repository of common queries
4. Module embedded chatbot



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 **Rhea,**

Clinical Trial Operation Mgr.

She works at a Mid -Size Pharmaceutical research company. Rhea's primary goal is to efficiently manage all aspects of clinical trials, from study startup to closeout. She wants to ensure that her team has the right tools to optimize processes and reduce administrative overhead. As a seasoned professional in the clinical research field, Rhea understands the importance of regulatory compliance. She is constantly seeking ways to minimize the risk of compliance issues and regulatory setbacks.

Octalsoft's eDOCs system automates workflows, saving time and reducing administrative burden. eDOCs helps Rhea maintain compliance with GCP guidelines and data protection regulations. The system's robust security features, including user access controls and encryption, align with Rhea's need to protect sensitive clinical trial data.

By addressing these needs and pain points, Octalsoft's eDOCs system is well-suited to help Rhea efficiently manage clinical trials, maintain compliance, and achieve her goals.

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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