FACT SHEET

EDC by Octalsoft

Electronic Data Capture

- Capture Subject Data with Speed & Accuracy
- Reduce Cost
- Reduce Deployment Time
- Secured Online Hosting

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

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+91 (760) 098-3010

Schedule a **Demo** with our Product Specialist today!

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ELECTRONIC DATA CAPTURE BENEFITS

Rapid Study Deployments

- Reduce study start up & close-out time by leveraging:
  - Robust study designer that enables setting up complex studies in a limited time period
  - Global library of generic eCRFs and edit checks allows reuse of study components across trials, and simplifies study configuration
  - Automation in defining null value edit checks
- Supports adaptive trial and mid-study CRF changes

Real Time Data Collection & Monitoring

- Simple UI for quick data entry, minimal data entry errors and end-user training
- Inbuilt validation logic to prevent common data entry errors resulting in clean data

Online Collaboration

- Multi-study platform with single sign-in
- Online collaboration among CRC's, PIs, CRAs and DMs for data collection & review process to ensure data discrepancies are addressed promptly
- Integrated query management process to ensure closure of queries quickly

Reports & Data Extraction

- Customized data extraction capabilities
- Lab data upload with lab range configuration & integration with CRFs
- SAS ready & CDISC compliant reports
- Dynamic & real time eCRF report creation for ready regulatory submission
- Robust reporting capability to speed up the data review and clean-up activities

Integrated Medical Dictionary

- Online integration of complex, multi-axial, hierarchical medical dictionaries facilitates coding and data accuracy
- Supports mid-trial dictionary upgrades
- MedDRA® and WHO-DD intelligent search functionality with a robust search engine featuring bulk auto-coding capabilities

Seamless Integration

- End-to-end system integration with IWRS, Medical Image Transfer, ePRO, and CTMS
- API integration with third-party applications/systems

> We needed a centralized web-based database to manage the large amounts of healthcare data associated with the operation of global clinical trials. We approached Octalsoft with our high level system requirements and they developed comprehensive CTMS & EDC solutions for us that met all our business requirements. They finished the project on time and within our budget constraints. We will hire Octalsoft without hesitation for any of our future IT requirements
>
> CEO, Oncology Services Inc.
> (Now Lambda Therapeutic Research)

OUR UNIQUE CUSTOMER SUPPORT STRUCTURE

Detailed User Manuals/Guides

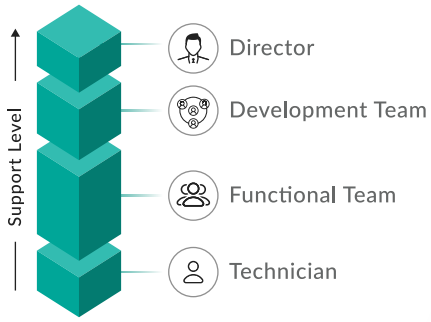
One Stop-Hassle Free Support

- 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

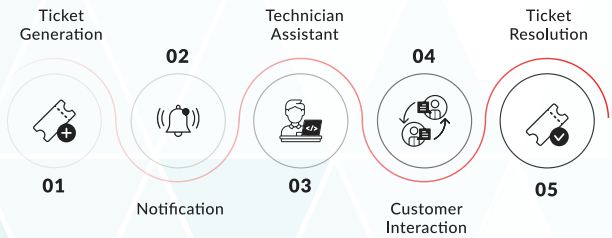
1. Customized screen for every user
2. Integrated online & offline support
3. Comprehensive repository of common queries
4. Module embedded chatbot



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 **Sarah,**

Data Manager

She works at a large clinical research organization. With more than 8 years of experience in data management, Sarah is responsible for overseeing the collection, cleaning, and analysis of data from multiple clinical trials. Sarah's key responsibilities include ensuring data quality and accuracy, managing study timelines, and communicating effectively with study teams and external stakeholders.

However, Sarah faces several challenges in managing clinical trial data, such as tracking data queries and resolutions, monitoring data entry and query response rates, and ensuring timely and accurate data transfer from various sources.

To avoid such time-consuming hurdles, Sarah adopted the Octalsoft EDC system. Our solution provided Sarah with real-time visibility into data entry and query resolution rates, allowing her to quickly identify areas that need attention and take corrective actions. It also offered advanced data cleaning capabilities, enabling Sarah to identify and resolve data discrepancies more efficiently. Our solution also helped Sarah to manage study timelines, track data transfers, and generate automated reports.

Overall, by adopting our EDC solution, Sarah has been able to streamline data management processes and improve data quality, allowing for more accurate and timely analysis of clinical trial data.

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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