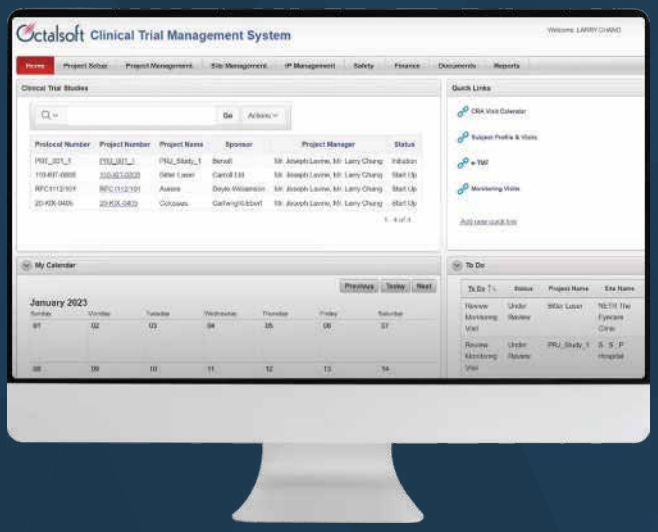
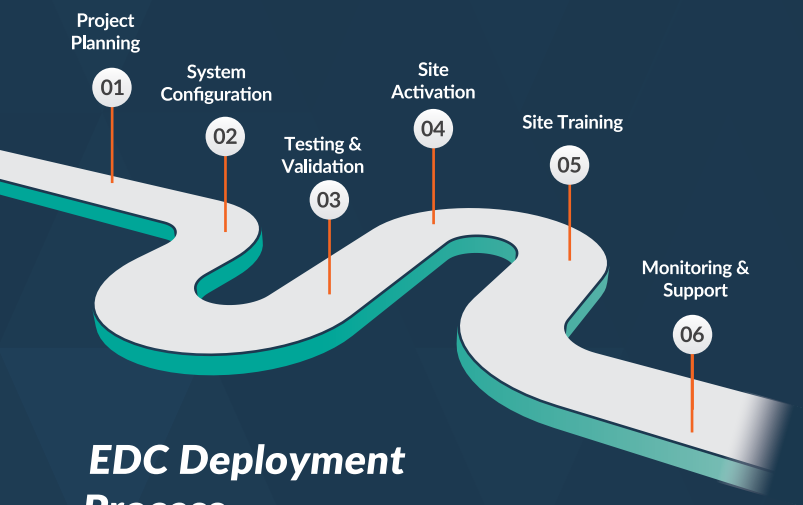
Octalsoft
TECHNOLOGY SIMPLIFIED

EDC CASE STUDY

Module Features

- Designed with User Experience (UX) always at the forefront
- Smart study designer to set up the most complex studies with flair
- Captures high-quality data over a secured network
- Multi-platform and multi-device enabled
- Comes with an integrated medical dictionary (MedDRA, WHO Drug, and More)
- CDISC compliant
- Query management and streamlined communication





EDC Deployment Process

Goals Achieved

The implementation of our EDC solution yielded significant achievements for the Global Contract Research Organization:

- Dynamic study database design.
- Reduced Go-LIVE time through automation.
- Regulatory submission-ready reports.

Our Key Platform Benefits

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

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EDC by Octalsoft

EDC CASE STUDY

CONTRACT RESEARCH ORGANIZATION
Industry

INDIA
Location

30+
Clinical Trial Projects

Client Requirement

- Streamline the study setup process and facilitate efficient database designing for multiple therapeutic areas.
- Develop a unified **EDC** platform enabling seamless integration with Interactive Web Response Systems **(IWRS),** Risk-Based Source Data Verification **(rSDV)**, and electronic Patient-Reported Outcomes **(ePRO).**
- Configure dynamic data management functionalities with minimal vendor support to adapt to changing study requirements.
- Implement an automated system for setting up edit checks for mandatory fields, enhancing data quality.
- Integrate Medical Dictionary for Regulatory Activities **(MedDRA)** and World Health Organization Drug Dictionary **(WHODD)** for standardized coding.

Our Solution

In response to the client's requirements, our team implemented a comprehensive EDC solution encompassing the following key components:

- ✔ Created a specialized module dedicated to data management, allowing for dynamic adjustments and modifications.
- ✔ Built an efficient study database design process that reduces manual efforts and expedites study initiation.
- ✔ Designed new Case Report Forms (CRFs) effortlessly, copying entire study designs or selective CRFs from a central repository.
- ✔ Facilitated automatic creation of edit checks for mandatory fields, ensuring data quality and compliance.
- ✔ Implemented audit trails to track study design changes, enhancing transparency and accountability.
- ✔ Built a robust reporting system for data analysis and decision-making.

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