Octalsoft
TECHNOLOGY SIMPLIFIED

ECLINICAL SUITE **CASE STUDY**

PHARMA Industry

MULTIPLE Therapeutic Area

INDIA Location

MULTIPLE Regulatory Submission

Client Requirement

- Required an **integrated platform** (EDC, IWRS, rSDV, CTMS and eTMF, Mobile application) to deploy **multiple projects** across **different therapeutic areas and locations** for submission to **various regulatory bodies**.
- **Mobile enabled dashboard** collating critical data points in **real-time** from the eClinical suite for strategic **insights to the top management**.
- Improve Document Management and Quality Processes through **eTMF solution**
- **Facilitate mid-study changes** to accommodate protocol amendments after go-live and a highly responsive customer support system.
- **Robust IWRS system** for complex randomization and dispensation logics.
- Perform **remote source data verification** and centralize monitoring efforts.
- Extraction of Statistical Analysis System (SAS) ready and **CDISC compliant subject data listings** from the application in excel,csv, PDF, and **xpt file format**

Our Solution

Octalsoft was able to:

- ✔ Achieve the client project objectives in the given timeframe using an agile development methodology
- ✔ Reduce on-site monitoring time, costs and efforts by utilizing the rSDV module.
- ✔ Provide a standardized repository of generic eCRF designs for rapid study startup, and re-usability across various newly added studies.
- ✔ Enhance user experience by providing a single sign-in functionality to access the unified eClinical suite.
- ✔ Integrate coding of medical dictionaries for standard classification of medicinal products and medical conditions/events.
- ✔ Provide a cost-effective and highly efficient integrated solution within the given timeframe

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

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

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

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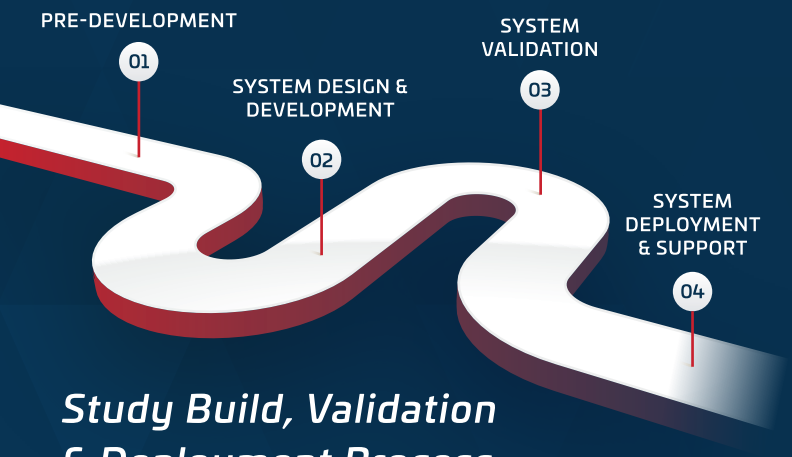
Module Features

- Better UI with simple & intuitive navigation with logical input controls
- Integration with central lab data and normal reference ranges
- Graphical representation of study status and subject data
- Dynamic & real time eCRF report creation for ready regulatory submission



Study Build, Validation & Deployment Process

- Bulk coding functionality for medical dictionaries
- Automation in study designer module, such as defining null value edit checks
- Configurable eTMF with color-coded dashboard

Our Key Platform Benefits

- Unparalleled Customer Support
- Modularized & Integrated Platform With Single Sign In
- Easily Configurable
- Cost Effective
- Compliant With Highest Regulatory Standards
- Simple & Intuitive User Interface

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