



**PHARMA**  
Industry



**MULTIPLE**  
Therapeutic Area



**INDIA**  
Location



**MULTIPLE**  
Regulatory Submission

## Client Requirement

- Required an **integrated platform** (EDC, IWRS, SDV, 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





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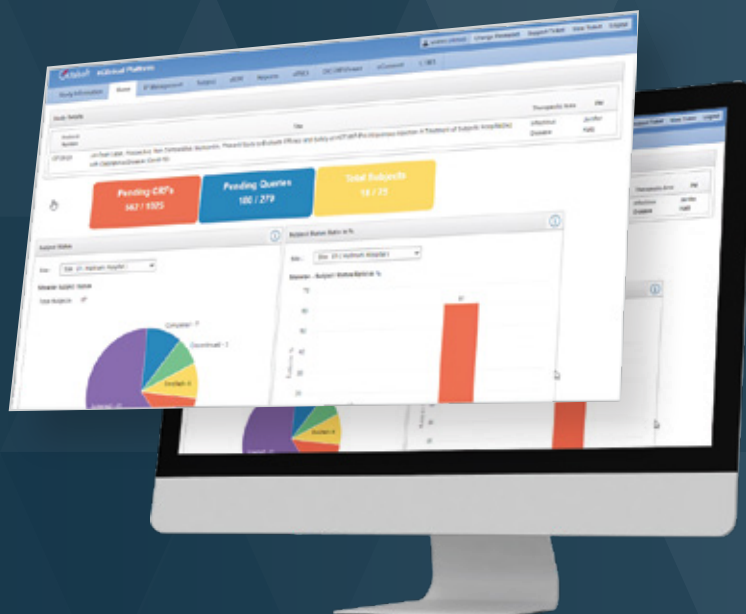
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Schedule a **Demo** with  
our Product Specialist  
today!



## 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



PRE-DEVELOPMENT

01

SYSTEM DESIGN & DEVELOPMENT

02




SYSTEM VALIDATION

03

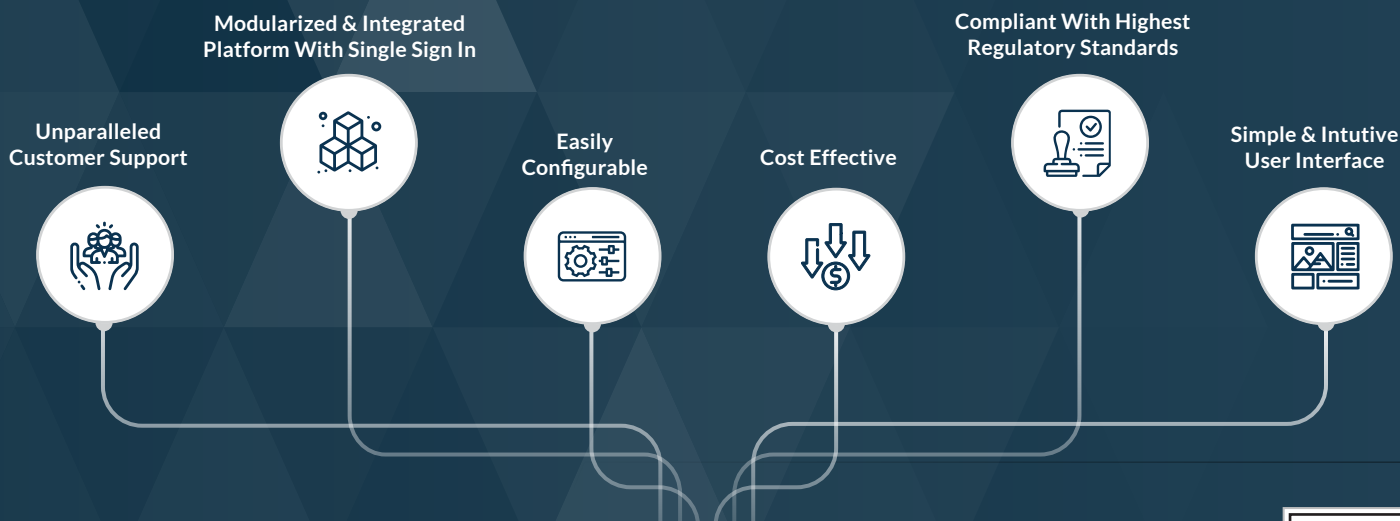
SYSTEM DEPLOYMENT & SUPPORT

04

## 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



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