PHARMA
Industry

CANADA
Location

> $2B
Investment in R&D

> 100
Clinical Trial Projects

Client Requirement

- Manage and monitor **multiple clinical trials** across the **globe** with the highest level of accuracy and precision.

- Ensure patient safety, accurately assess and report outcomes, and **comply with global regulatory requirements**.

- Organize and store documents in a **CDISC-compliant eTMF structure**.

- Customize **country-specific** finance budget sheets.

- Convert **labor-intensive** clinical operations management into an **effortless and seamless** process by deploying CTMS.

Our Solution

Octalsoft provided a customized & centralized system for capturing trial data, monitoring trial progress, generating reports, and addressing open action items. We currently **host a database of 1000+ trials**, which help maintain clinical operations and subject-specific data in **compliance with the highest regulatory standards**. With Octalsoft CTMS, the client:

- ✓ Made real-time, data-driven decisions, increased the efficiency of the business processes, and contained costs, resulting in timely trial completion and license filings.

- ✓ Increased productivity of the CRAs by automating tasks, allowing real-time information sharing, and effective time management.

- ✓ Generated an intensive database of verified Clinical Trial Sites and Principal Investigators, giving it a sustainable competitive edge

- ✓ Enabled integration of IWRS & EDC for subject-specific critical data points. The data points included but were not limited to subject statuses & visit progression, recruitment efforts, and subject safety.

- ✓ Accessed flexible exports, smart reports, dashboards, and multiple reporting tools as per the management requirement.

- ✓ Improved document management and quality processes through Octalsoft eTMF.

- ✓ CTMS Finance Module helped with online tracking of pass-through and non-pass-through study costs and investigator milestone payments, and claim management in case of SAEs
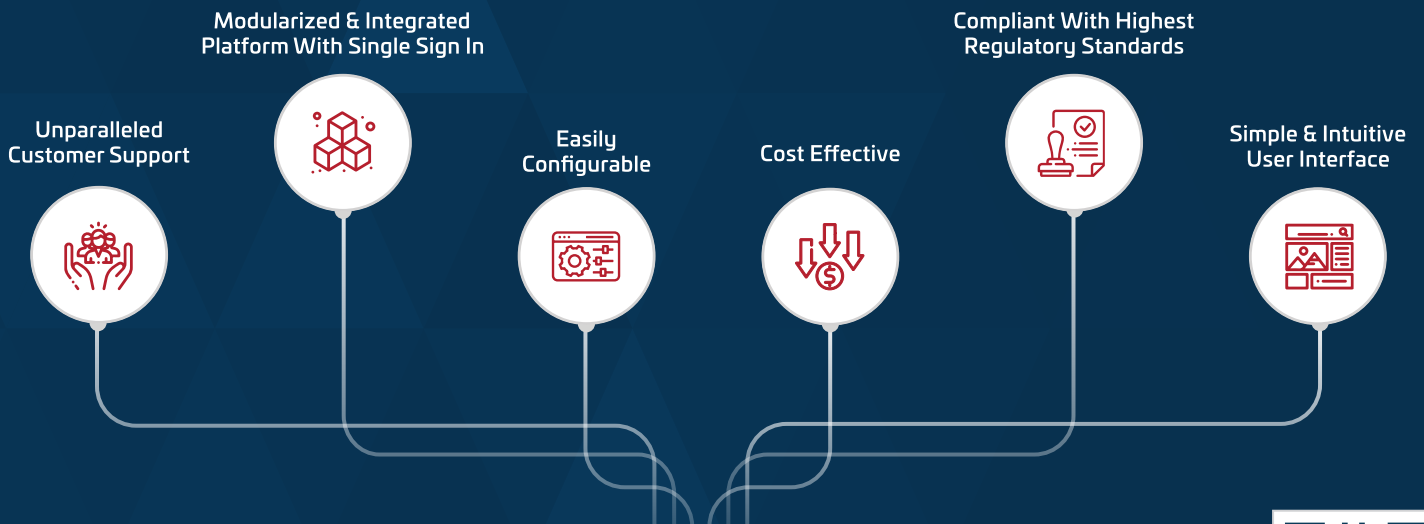
Module Features

- Clinical Site Visit Reports
- Milestones Planning and Tracking
- Resource Planning and Tracking
- Action Items & Deviations
- Finance Management for Trial Budgeting and Payments
- Site Budget and Payments

PRE-DEVELOPMENT
01

SYSTEM DESIGN & DEVELOPMENT
02

SYSTEM VALIDATION
03

SYSTEM DEPLOYMENT & SUPPORT
04
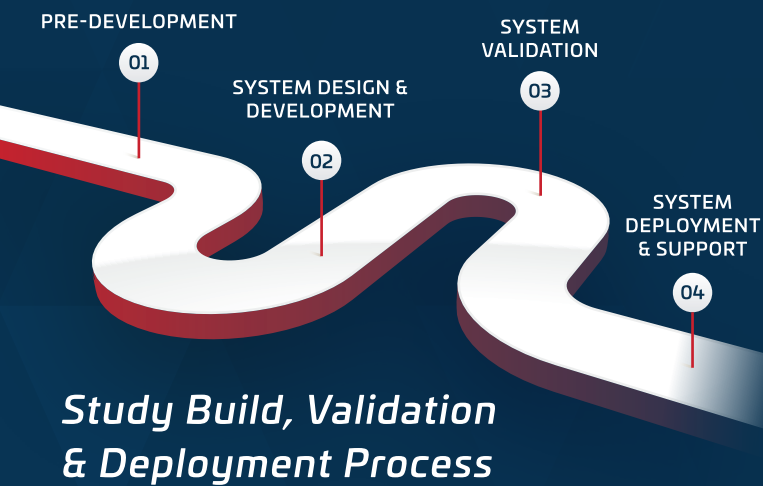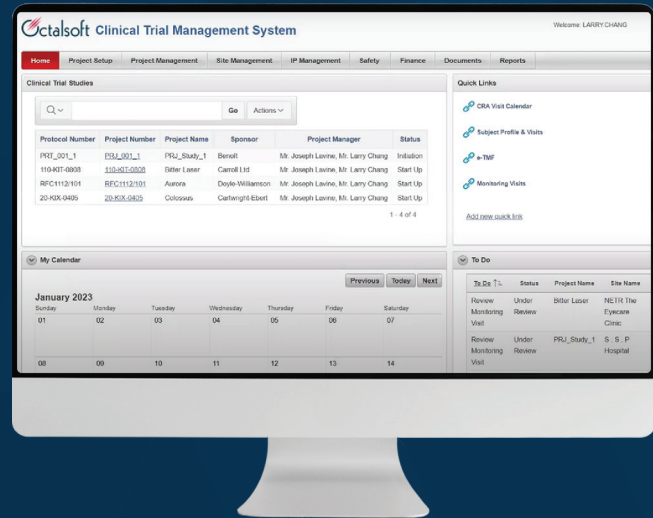
Study Build, Validation & Deployment Process

- Site Monitoring (Site Qualification, Selection, Initiation, and Closure)
- Travel Expenses & Timesheet Tracking
- Regulatory Documents & Compliance Tracking
- Training Management
- Adverse Event Tracking
- Integration with Other eClinical Solutions

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