Oracle Siebel CTMS

A comprehensive, enterprise-grade Clinical Trial Management System (CTMS) for pharmaceutical, biotech, and CRO organizations.

https://www.oracle.com/life-sciences/clinical-trials/clinical-trial-management/

Overview

Oracle Siebel Clinical Trial Management System (CTMS) is a robust, scalable, and integrated trial management suite designed for large-scale operations in pharmaceutical companies, biotechnology firms, and Contract Research Organizations (CROs). Built on the foundational Siebel CRM platform, it offers end-to-end capabilities to streamline, automate, and report on clinical trial operations, enhancing operational efficiency and ensuring regulatory compliance.

Key Capabilities The system provides a comprehensive set of tools for Clinical Research Associates (CRAs), clinical investigators, and site coordinators. Key functionalities include support for full clinical trial hierarchies (Subject-Site-Region-Protocol-Program), management of global trials across multiple countries, languages, and currencies, and support for complex trial designs (randomized, multi-arm, epoch, and adaptive trials).

It centralizes critical trial data, offering features such as investigator and site profiling, document tracking, and integrated payment tracking for sites and investigators. CRAs benefit from site management tools like a site calendar, clinical trip report templates, and mobile disconnected capabilities for offline work during site visits.

Target Users & Benefits Siebel CTMS is primarily targeted at medium to large-scale enterprises with complex clinical trial needs. It is used by trial sponsors (pharma/biotech) and CROs to increase productivity, make better decisions with real-time data visibility, and accelerate time to market by automating repetitive tasks and enforcing organizational processes.

Key Features

- End-to-End Clinical Trial Management
- Global Trial Support (multi-language, multi-currency)
- Investigator and Site Management Portal
- Integrated Payment Tracking and Budget Control
- Clinical Trip Report Management with Audit Trail
- Source Data Verification (SDV)
- Project and Resource Management
- Mobile Offline Capabilities for CRAs
- Flexible Audit Trail Engine

Pricing

Model: enterprise

Enterprise-level licensing model. Pricing is not publicly disclosed and requires licensing a Siebel CRM Base Application and the Siebel Life Sciences CRM Base Option per user, available upon contact with Oracle Sales.

Target Company Size: medium, enterprise

Integrations

Oracle Clinical One Platform, Oracle Clinical, Oracle Remote Data Capture (RDC), Oracle Argus Safety (AERS), eTMF Systems (via web service), Microsoft Project, Siebel Pharma Sales & Service, Oracle Health PowerTrials

Compliance & Certifications

FDA 21 CFR Part 11, GCP