



Siebel CRM Strategy & Customer Success for Clinical Trials

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September, 2020

Oracle Health Sciences. **For life.**



Presenters



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What is Siebel CTMS's role in Clinical Trials

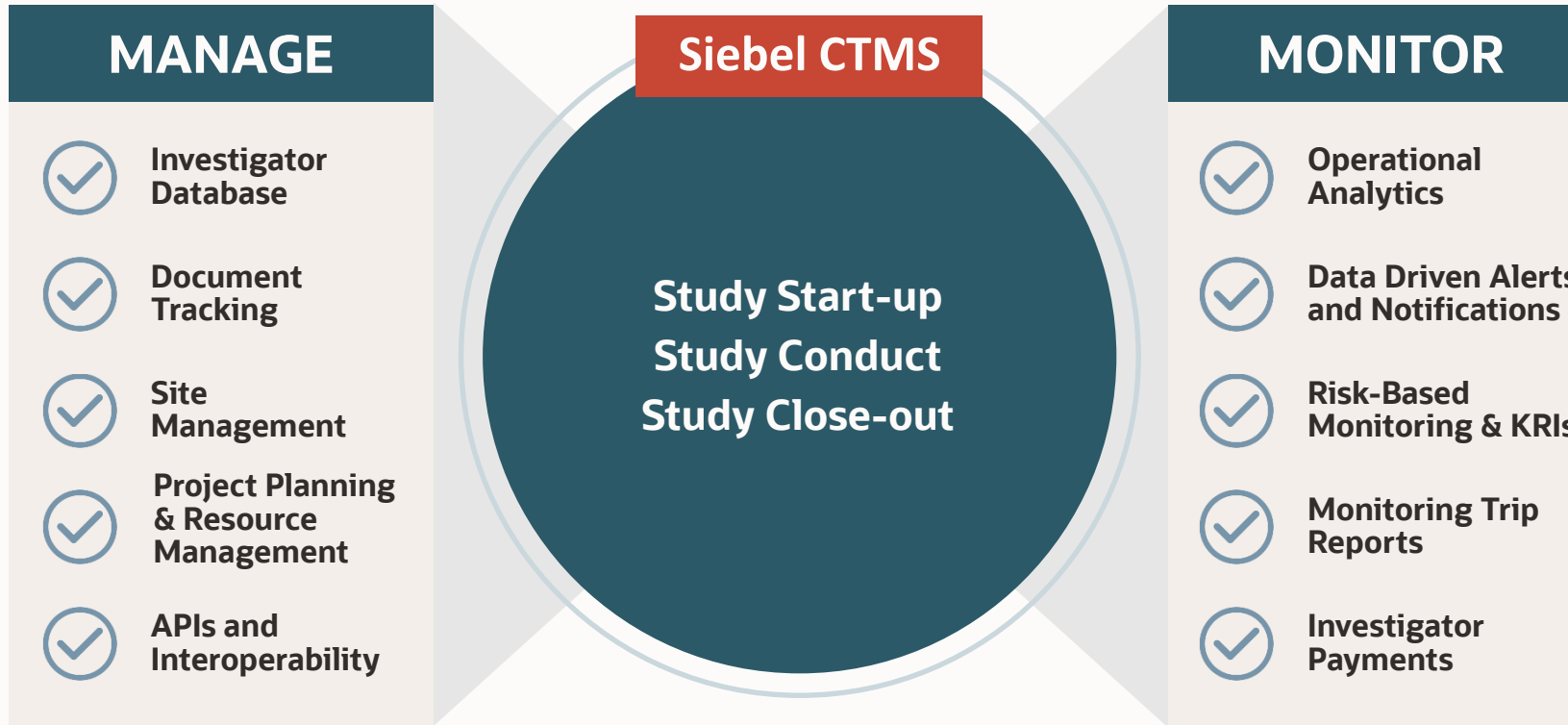


Oversight/management of operations for clinical trials - ensures that both safety of patients and that efficacy of study are monitored and cannot be questioned

Siebel Clinical Trials Management System (CTMS) is used to manage **60 to 80% of Clinical Trials** (Primary tool for CRO's)

Trial Management and Monitoring

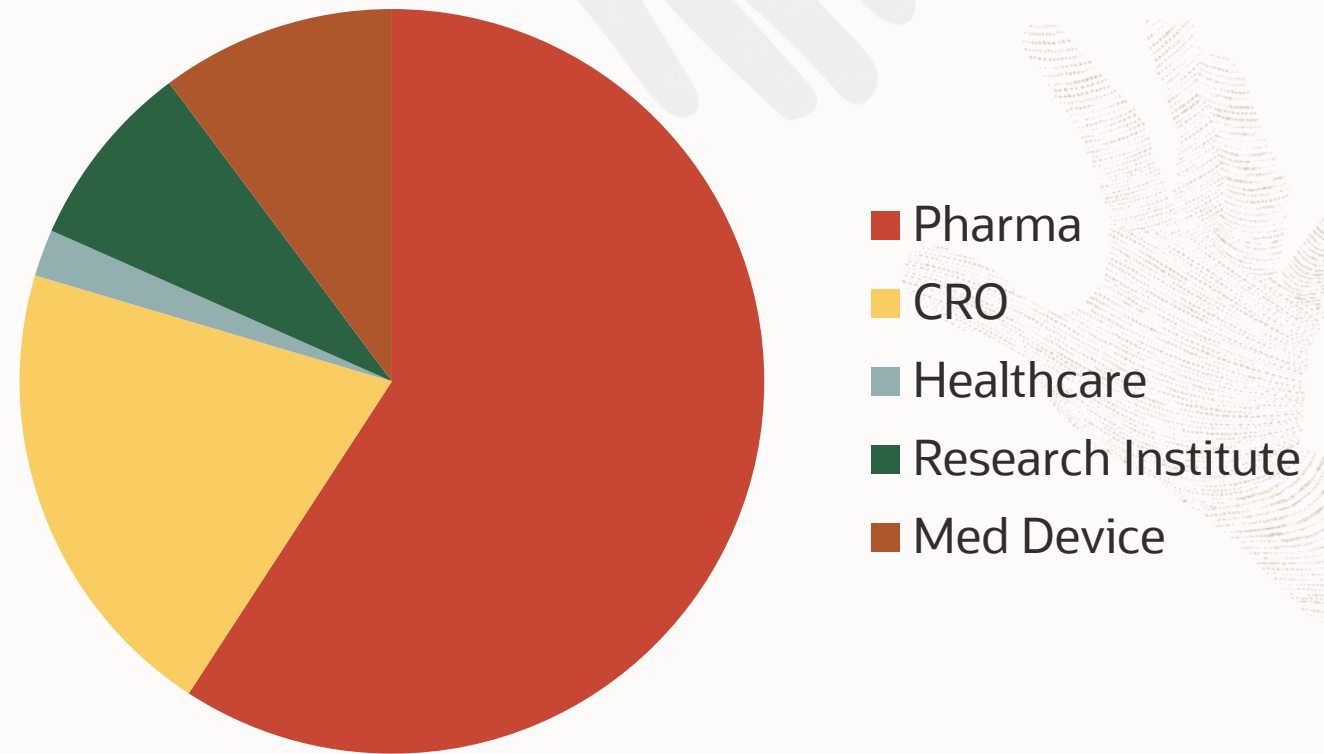
Oracle Health Sciences **Siebel CTMS** is an integrated, purpose-built trial planning & management solution for today's complex trial environment



Key Benefits	
End-to-End Trial Management	<ul style="list-style-type: none">Investigator Database streamlines site selectionSeamless integration with InForm, CDA, eTMF and available REST APIsRisk Based Monitoring embedded
Gain Business Efficiencies	<ul style="list-style-type: none">Workflows and Templates for data collection and approvalsMulti-Lingual enabled for global study supportOffline capabilities for monitors at sitesSimple checklist based monitoring trip reports
Improved Visibility	<ul style="list-style-type: none">Built in hierarchy simplifies viewing of data from program to study levelCentralized risk management to track risks and actionsIntegrated with CDA and external analytics

CTMS Customer Distribution

- Over 60 active customers, on-premise and cloud
- Pharma, CRO, Med-Device (SMB to Large Customers)



Oracle Siebel CTMS Delivers Key Benefits to Stakeholders

Program Managers

Improves Data Visibility

- Clinical hierarchy from program to subject level provides easy visibility
- Spot trends and identify anomalies
- Easily compare studies with CDA dashboards

Establish and track key performance and operational metrics

- Data entry
- Enrollment
- Aging and cycle times

Global Network of Investigators

- Leverage investigator history and performance data to select sites

Study Managers

Global Visibility

- Immediate access to protocol, regional and site views
- Easy access to overall study payments

Automated Workflows

- Simple workflows for approvals (trip reports, payments)

Manage by Exception

- Integration with CDA to quickly see outstanding site or monitor actions
- View site and monitor performance across sites or study

Monitors

Improves Status Visibility

- Easily track clinical documents
- Quickly record and manage site issues and finding

Simplifies Site Management

- Achieve more productive visits
- Subjects and visits imported automatically from InForm
- Checklist based trip reporting templates with branching
- Centralized SDV/SDR views
- Quickly generate & track payments

Manage by exception

- Identify open issues or missing documents
- Integrated with CDA

Centralized Monitoring

Manage Study Risks

- Identify risks at program, study and site level
- Systematic implementation of RACT

Targeted SDV

- Partial SDV fed from InForm

Centralized RBM Tracking

- All issues recorded and tracked in single system
- Fully audit trailed
- Simplified visibility and reporting through CDA
- KRIs integrated to CDA

Challenges With Current Processes & Systems at Pharma

Key Themes

Data is highly fragmented, with no single source of truth



To get the full answer, you need to go to multiple spreadsheets.



We are highly dependent on pockets of information within teams, vs. a centralized source of data.



Being able to see key metrics and data at a program level is a huge need for me and we don't have that today.



We lack the analysis to understand where we are losing or making money.



It takes me 2 weeks to generate the bi-weekly KPI report with my current tools.



At least half their time is spent tracking and managing documents.



We have a different spreadsheet for every study.



Automating this [site payment management] could save 80 hours of work per quarter.

Lack of KPI's and analytics to manage operations and profitability

Highly manual, duplicative processes, lack of process automation; high reliance on "tribal knowledge"

Siebel CTMS Vision

Enhanced & Simplified User Interface



Task Based UI, iHelp, User Specific Links

Configuration Based Implementation



Simple, upgradeable configurations
(Workflows, Approvals, etc.)

Seamless Integration Capabilities



Out of box integrations, RESTful & SOAP APIs

Out of Box Implementation



Reusable configuration packs for common
workflows, business views, etc.

Siebel Mobile Disconnected



Offline capabilities for CRAs

Key Benefits of Oracle Siebel CTMS



Enterprise-wide, proven, scalable CTMS system



Out of the box/simple configuration only implementation



Pre-built templates



Automated workflows



Simple, checklist-based trip report capabilities



Easily implement strategic risk-based monitoring



Multi-lingual enabled



Integrated Suite – CDA & InForm

Key Differentiators of Oracle CTMS



Enterprise-wide,
proven, scalable CTMS
system



Configuration based
implementation for
easy upgrades



Pre-built templates to
enable fast study
builds



Automated workflows



Simple, checklist-
based trip report
capabilities



Integrated risk based
monitoring capabilities



Multi-lingual enabled



Integrated Suite – CDA
& InForm



Flexible cloud
upgrades

Oracle Health Sciences Trial Management & Monitoring Suite

Siebel CTMS Core Modules

Siebel CTMS Base for Clinical Trial Management

Siebel Trip Reports

Siebel Document Tracking

Siebel Protocol Builder

Siebel Payments

Siebel Project Planning & Resource Mgmt.

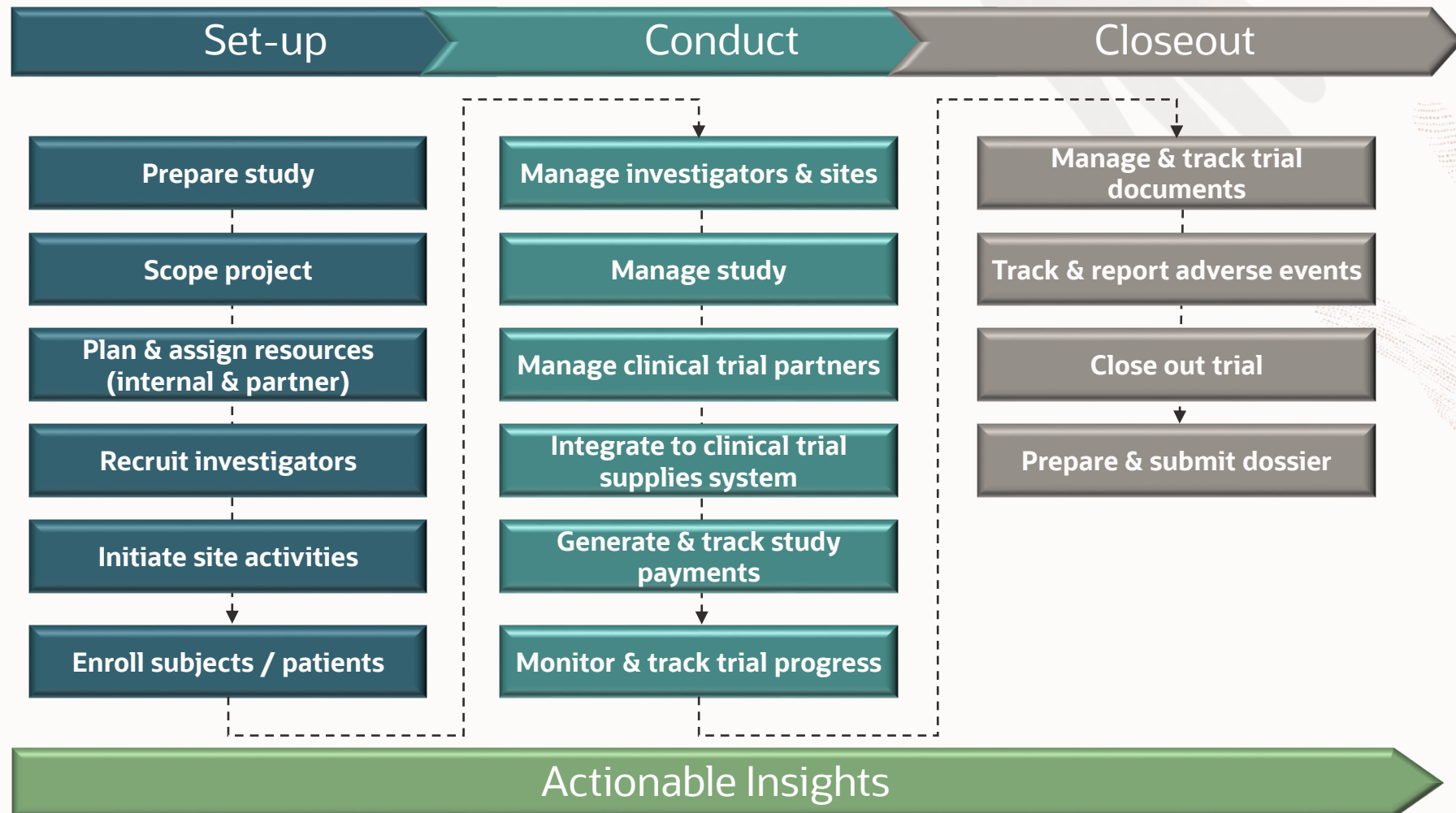
Siebel Project Costing

Siebel Clinical Contracts

Key Clinical Trials Business Processes

Value Chain

Key Siebel Clinical Process Steps



Trial Management Cloud Overview

Core Benefits

- Agile CTMS Solution with best-of-breed approach
- Modular implementation
- Oracle hosted, maintained and supported
- Integrated Suite (InForm, CDA)

Siebel CTMS Cloud

CTMS: Flexible & Configurable Industry Leading Solution

Contacts

Contracts

Protocol
Mgmt.

Payments

Trip
Reports

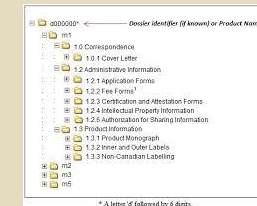
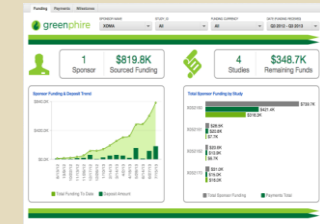
Resource
Allocation

Cost
Tracking

Document
Tracking

Application Monitoring, DR, Support

Seamless Integrations



“We are delighted to be able to implement Novotech’s vision of next generation trial management”

“Oracle’s cloud technology provides a centralized trial database enabling **improved access, control and governance** of clinical data. The system is **highly configurable** allowing us to tailor process flows and alerts to client needs, as well as ensuring effective control on deviations. **Advanced functionalities** like eSignatures, and tools for swift approvals and submissions help us accelerate trial implementation.”

Dr. John Moller, CEO – Novotech

December 2018

Novotech CRO Launches Largest Oracle Trial Management and Monitoring Cloud Service Implementation in Asia-Pacific

Siebel CTMS Cloud Customer Implementation Case Studies

Large CRO

- ~120 studies moved from on-premise Siebel CTMS to Oracle Cloud Siebel CTMS implementation
- Largely out of the box configuration, including use of Clinical Development Analytics (CDA)

Completed in 6 weeks

Small Pharma

- Moved from Excel based CTMS to Oracle Cloud Siebel CTMS implementation
- Out of the box CTMS use – zero configurations or customizations
- Utilized out of the box integration to InForm EDC

Completed in 10 weeks

Large Pharma

- Move to a single cloud CTMS across organization, to be accessed by Pharma and CRO partners
- Multiple integrations (warehouse, EDC, etc.)
- Redefined business processes and workflows, support all study types

Completed Phase 1 in 5 months

Case Study: Large Pharma moves to Siebel CTMS Cloud

CTMS Goals

- Single cloud CTMS across organization
- Accessed by both Pharma and CRO contractors
- Support all study types
- Retire existing CTMS system (not cloud)
- Core Platform to optimize study execution

CTMS Cloud Implementation

- Implemented in 2 major releases, additional functionality added in each release
 - Release 1: 5 months
 - Release 2: 4 months
- Included multiple integrations, redefined business processes and workflows
- Fully supports all study types
- All new studies starting in CTMS Cloud

Case Study: Why a Pharma chose Oracle Siebel CTMS Cloud over others in the marketplace

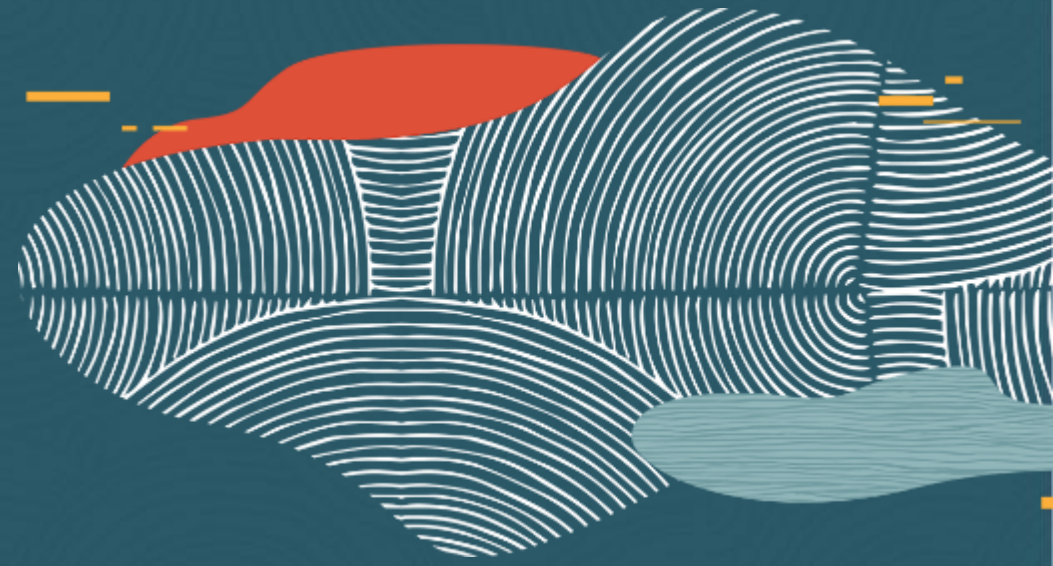
- Pharma conducted a thorough evaluation of the CTMS marketplace, including new entrants and determined that Siebel CTMS was the best choice for their organization due to the following benefits:
 - Pharma could not afford to sacrifice any of the capabilities they had grown accustomed to and relied upon to support their business requirements; other vendors did not have the thorough set of capabilities available and could only promise they were on the way.
 - The Siebel CTMS suite is by far the market leader and is the only CTMS Cloud solution ready today to support the requirements of the organization and allowed for an easy path to the cloud and re-purposing of much of their existing capabilities that needed to persist in the new next gen platform
 - Control over upgrades and ease of validation was important to them, other “multi-tenant” vendors force three or more major releases a year, causing clients to run continuous validation cycles
 - Siebel CTMS cloud delivers the benefits of SaaS, without sacrificing control
 - No data migration is necessary, resulting in reduced costs and risks for the upgrade to Cloud
 - The new Siebel **Open UI** and other capabilities planned for 20.7 were of interest to Pharma (outlined in following slides)
 - Significant cost savings realized by moving to the cloud and transitioning from a user based metric to a site based metric.

Thank You





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Let us help you kickstart your
Siebel CRM transformation

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[CAB portal](#)

[LinkedIn Customer Connect](#)

Newsletter Email Distribution list
([Customer](#)) & ([Partner](#))

[Virtual CAB replays](#)