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Leading the Way in the dynamic Clinical Trials Industry with Siebel CTMS

Oracle Siebel CTMS

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Safe harbor statement

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Presenters

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Siebel Strategy

Cost-savings (reuse), agility, industry applications

Cloud

Industry

Siebel CRM Core & Cloud Platform

Benefits:

- No functional changes
- Minimal technical changes
- Agility – Siebel, Database, OS, hardware
- Cost savings – Better performance, elastic infrastructure
- Managed services option

Functionality :

- Cloud Manager – Automating developer and technical operations
- Exposing more capabilities via REST API's
- Redwood UX with Open UI
- Incorporate OCI PaaS Capabilities

Siebel CRM Customer Experience

Benefits:

- Best-of-breed front-office applications
- Rapid assembly with Cloud Apps
- Reuse best of Siebel applications, including all your customization
- Incremental migration on your schedule

Functionality:

- Cross-channel digital Marketing
- Loyalty, transactional & behavioral
- Customer Data Platform
- Sales Planning, Advanced Order Capture & eCommerce

Siebel CRM for Industries

Benefits:

- Introducing CX Industry Framework – Foundation for Industries enabling Business and IT Agility
- Industry specific experiences (minimize customization)
- Externalize capabilities to Industry apps with pre-built components for Siebel (Catalog, Service, Order Capture, etc)
- Co-exist with Industry apps with pre-built integration with Siebel modules
- Introducing DX4C – Oracle's End-to-End (front & back-office) solutions for Telco

How does Siebel CTMS Lead the Way in Clinical Trials?

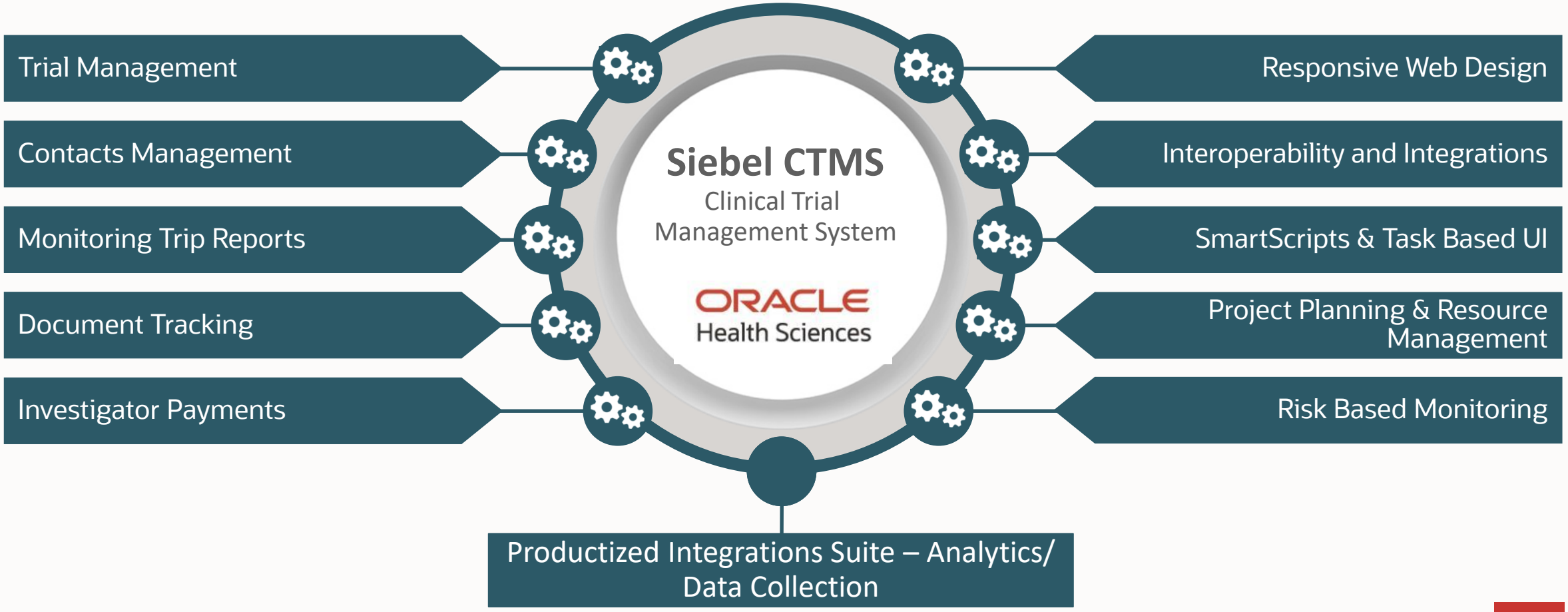
Provides Oversight:
Management and oversight of operations for clinical trials in the pharmaceutical industry

Enables Monitoring and Compliance:
Ensures alignment with Industry Standards, ensures safety of trial subjects and reliability and quality of data

Siebel Clinical Trial Management System (CTMS) is used to manage 60-80% of Clinical Trials (primary tool for CROs)

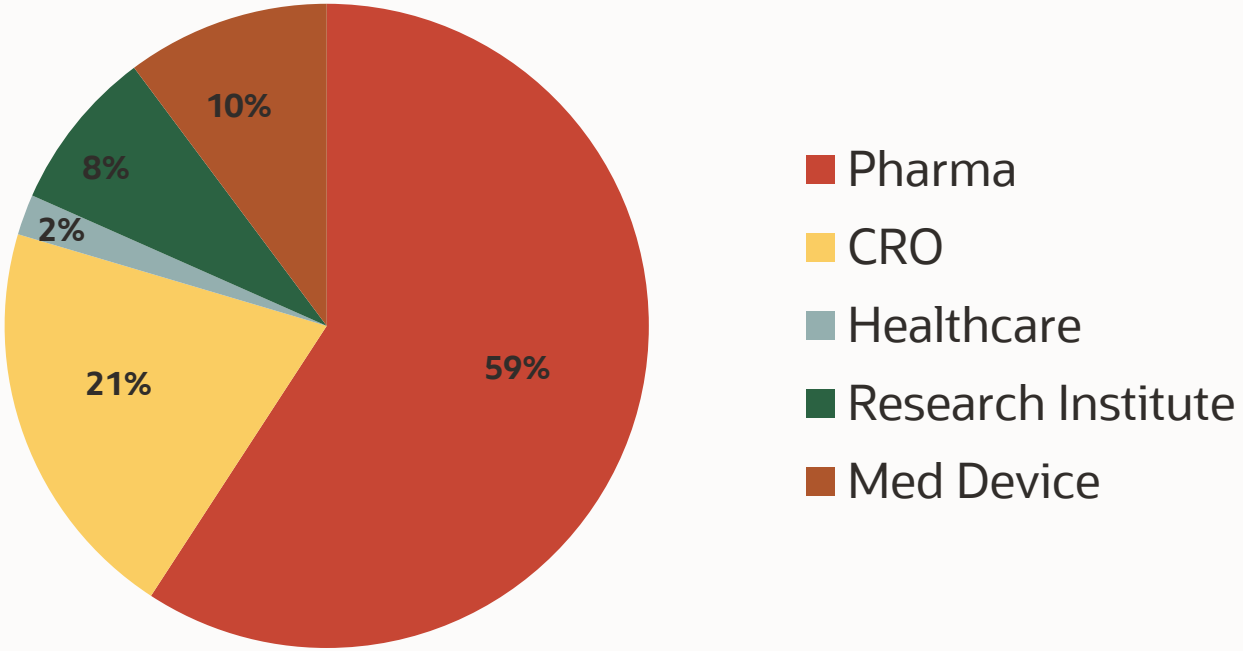
Leading the Way…
Siebel CTMS Cloud Platform Delivers High-Quality Data & Drives Efficiencies

Integrated, purpose-built trial management solution for today's complex trial environment



Siebel CTMS Customer Base

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



Siebel CTMS Delivers Key Benefits to Stakeholders

Program Managers

- Improves Data Visibility
- Establish and track key performance and operational metrics
- Global Network of Investigators

Study Managers

- Global Study Visibility
- Automated Workflows
- Manage by Exception

CRA Monitors

- Improves Study Status Visibility
- Simplifies Site Management
- Manage by exception

Central Monitors

- Manage Study Risks
- Targeted source document verification
- Centralized RBM Tracking

Siebel CTMS – Strategic Vision

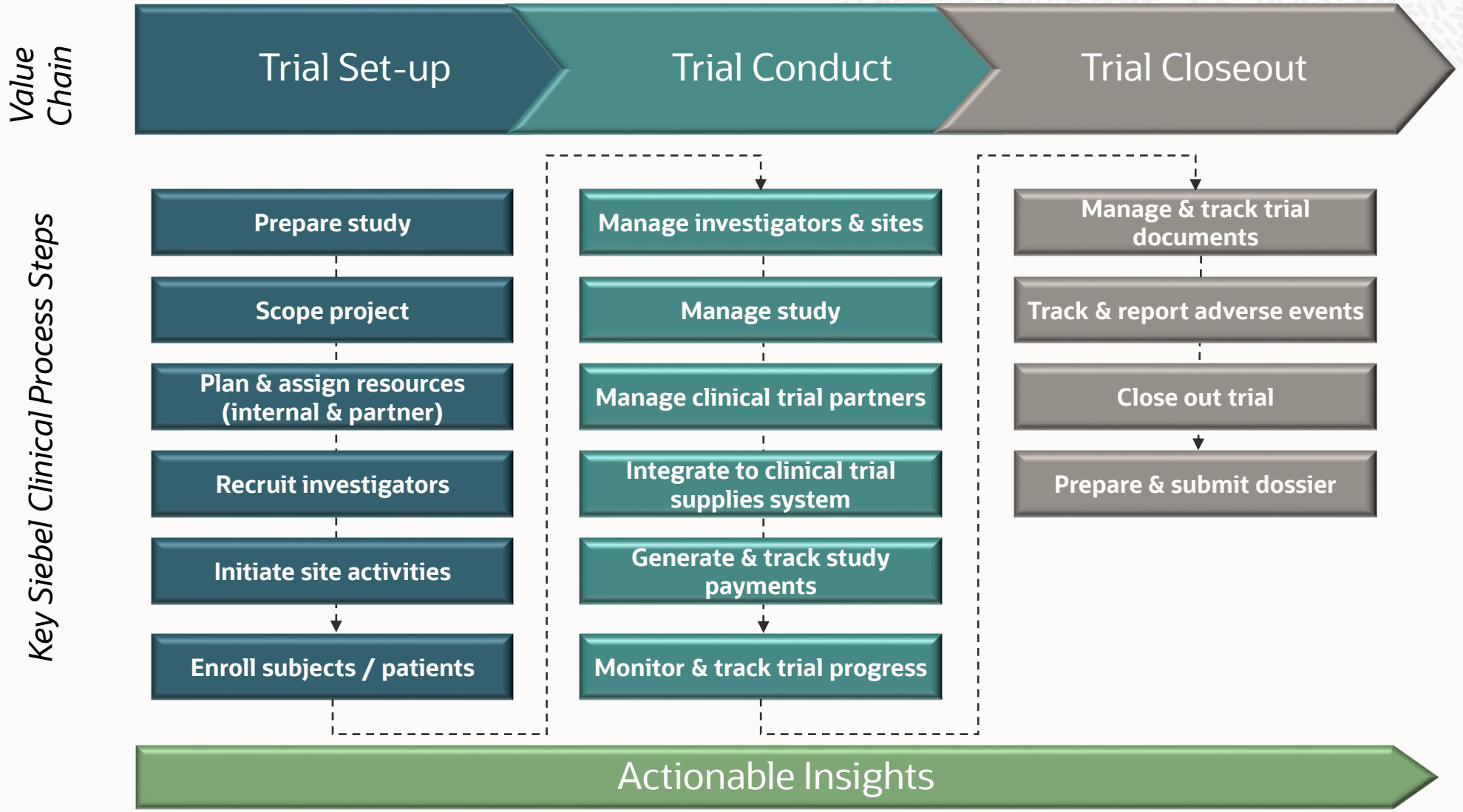
Aligned with Industry Trends		Continued expansion of core functionality
Enhanced & Simplified User Interface		Task Based UI, iHelp, User Specific Links
Configuration Based Implementation		Simple, upgradeable configurations (Workflows, Approvals, etc.)
Seamless Integration Capabilities		Out of box integrations, RESTful & SOAP APIs
Out of Box Implementation		Reusable configuration packs for common workflows, business views, etc.
Siebel Mobile Disconnected		Offline capabilities for CRAs

Leading Benefits of Siebel CTMS

Benefits result from:

- Built in hierarchy simplifies viewing of data from program to trial level
- Investigator Database – site selection/ contact management
- Automated Workflows and Templates – process/ data
- Seamless Integration – available REST APIs
- Risk Management/ Risk Based Monitoring embedded
- Adaptable monitoring trip reports
- Multi-lingual – global study support
- Easy configuration
- Integrated suite – Analytics and Data Collection Tools

Key Clinical Trial Business Processes



Process Management as Circumstances Change

Managing trial conduct during the **COVID-19 pandemic**

Major impact on conducting clinical trials

- Travel restrictions, lockdowns, and increased health risks
- Investigative sites and patients have been unable to maintain compliance to study process
- Regulatory agencies issued guidance to addressing impacted studies
- Regulatory Guidance
  - USA Food & Drug Administration
  - EU European Medicines Agency (EMA)
  - UK Medicines and Healthcare products Regulatory Agency (MHRA)
  - Japan - Pharmaceuticals and Medical Devices Agency (PMDA)

Regulator Guidance – Trial Monitoring

FDA

- If on-site monitoring visits are no longer possible, sponsors should consider centralized and remote monitoring programs and document inability to access or delayed monitoring of a site”

EMA

- “…measures include cancellation/postponement of on-site monitoring visits, implementing phone and video visits, and centralized monitoring and review of data”

MHRA

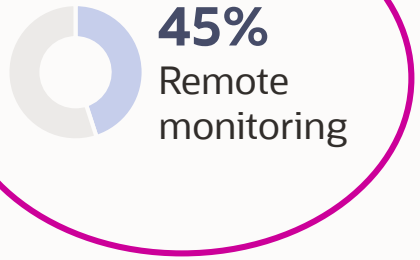
- “…The use of alternative means of oversight such as teleconferences /videoconferences is encouraged”.

PMDA

- “..If on-site monitoring is not possible, alternative monitoring methods should be considered”

State of industry direction/transformation/advancing strategies

Which new approaches did your organization implement during the pandemic?*



45% Remote monitoring

37% Video visits

35% Phone visits

28% eConsent

26% Electronic health records (EHR)

23% Patient apps

20% Home healthcare

19% Mobile health/ wearables

19% Central monitoring

19% Central labs

18% eCOA (health professional)

18% ePRO (patient)

18% Local labs

15% eSource

10% We have not implemented any new approaches

*Data from a current industry-wide survey conducted by Informa Intelligence sponsored by Oracle Health Sciences released October 25, 2021 .

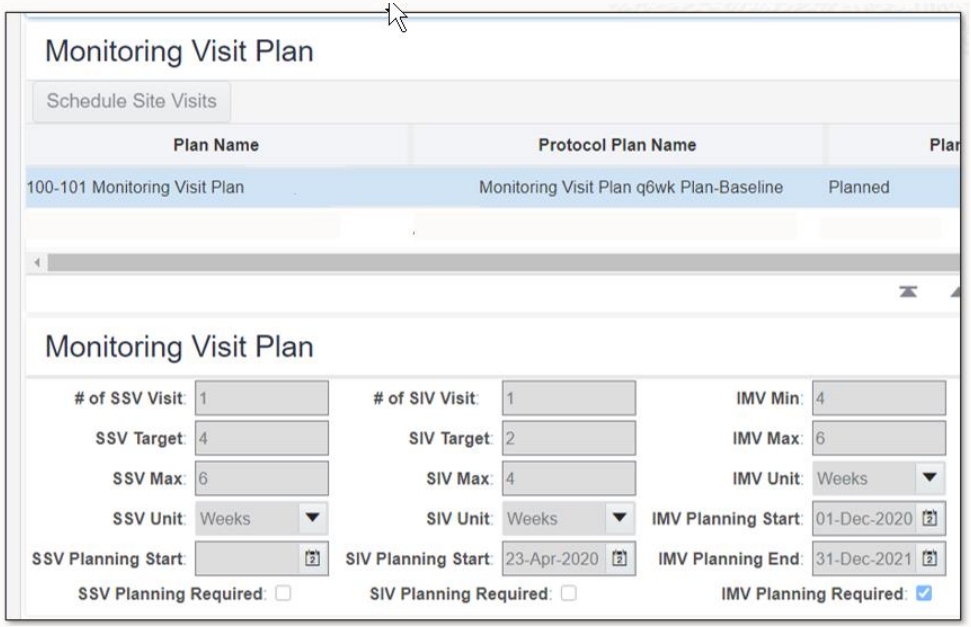
Siebel CTMS - Leading with easy adoption of new business process…

Create Monitoring Plan
Trial or Country

Set the Monitoring Visit Type

Selection
Initiation
Remote
Central
On Site

Approve the
Monitoring Plan



Siebel CTMS - Trial Management Cloud Overview

Core Benefits

- Agile CTMS solution with best-of-breed approach
- Rapid implementation
- Oracle hosted, maintained and supported
- Integrated Suite

CTMS Cloud

CTMS: Flexible & Configurable Industry Leading Solution

- Site Contacts
- Trial Mgmt.
- Document Tracking
- Trip Reports
- Contracts
- Payments
- Resource Allocation
- Cost Tracking

Application Monitoring, 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

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

December 2018

“Oracle's Siebel CTMS helps Rho to mine data, remove Excel Trackers, and more”

"Our top benefit with Oracle CTMS is related to trip reports.

What we have seen since we have rolled it out is that our CRAs have a much more efficient turnaround time in being able to write their trip reports. So that’s a huge efficiency that we can see.”

Nick Poulson, Sr. Project Manager - Rho
2019

Leading with Cloud Implementation

Siebel CTMS Cloud Customer Case Studies

Large CRO

- ~120 studies moved from on-premise Siebel CTMS to Oracle Cloud 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 CTMS implementation
- Out of the box CTMS use – zero configurations or customizations
- Utilized out of the box integration to InForm EDC

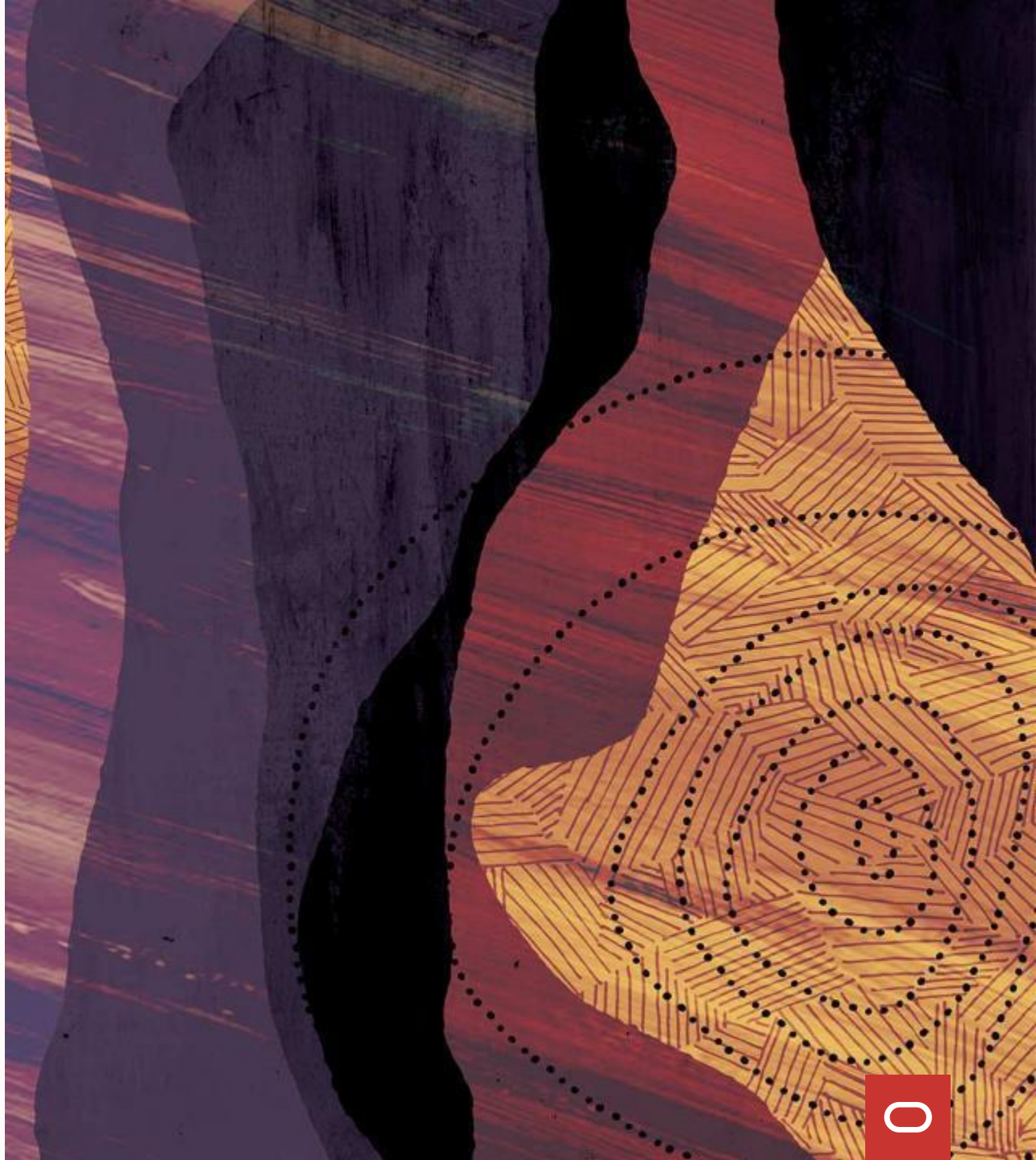
Completed in 10 weeks

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

Thank You

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