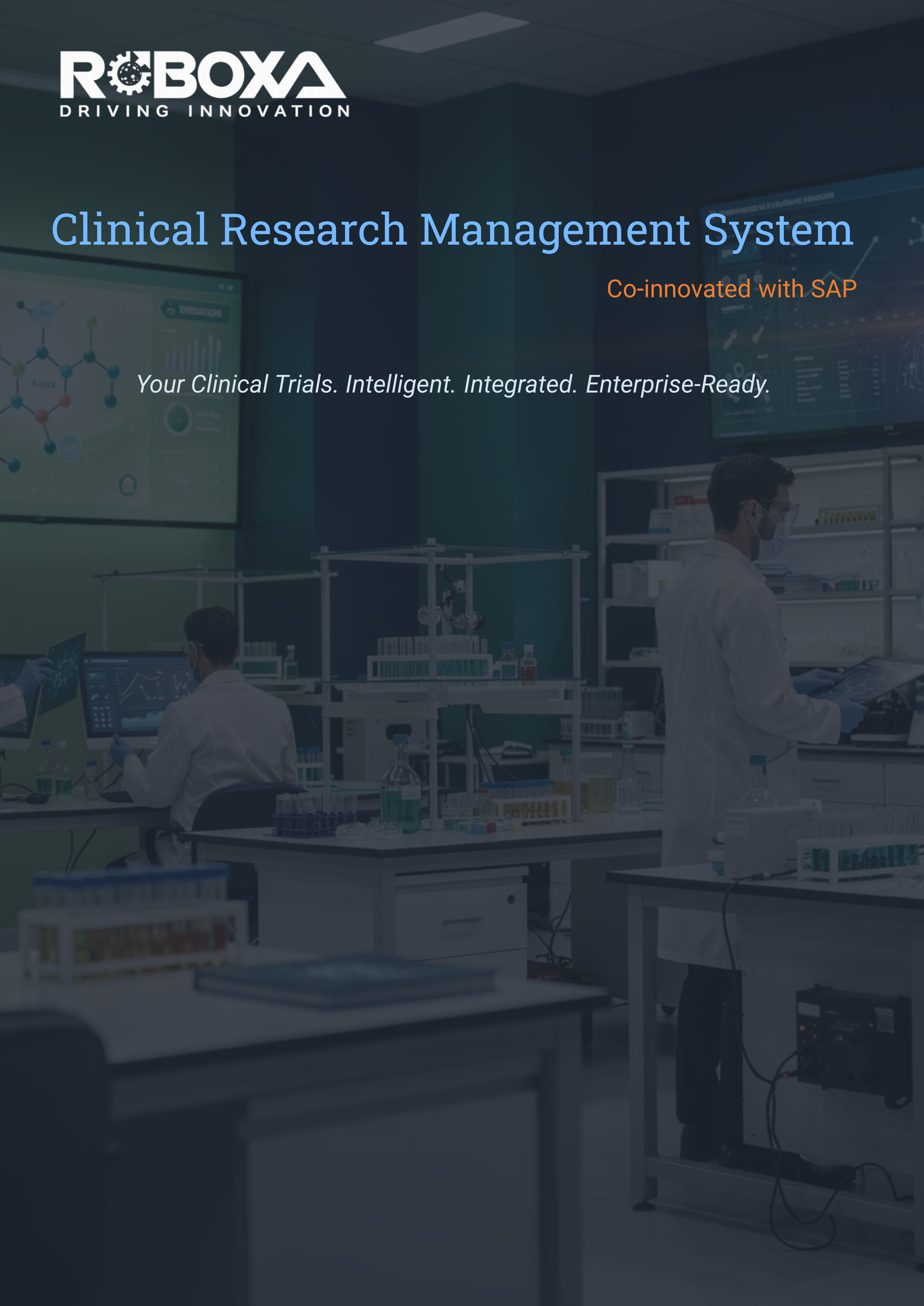
Clinical Research Management System

Co-innovated with SAP

Your Clinical Trials. Intelligent. Integrated. Enterprise-Ready.



Understanding the Clinical Research Challenge

2.6B	10-15	30%
Avg. Cost per Drug	Avg. Development Time	Cost Reduction
average cost to develop a new drug	*years for new drug development*	*potential with better CRMS*

Key Challenges in Clinical Research

- Rising R&D costs and long timelines for drug development
- Complex regulatory landscape – USFDA, EMA, CDSCO
- Multi-geography clinical trials and patient recruitment challenges
- Limited real-time visibility into trial performance
- Increasing need for collaboration with stakeholders

Objectives by Role

Sponsor Objectives

- Accelerate drug development timelines
- Reduce overall trial costs
- Ensure regulatory compliance globally
- Improve data quality and integrity
- Enhance patient safety and engagement

CRO Objectives

- Deliver trials on time and within budget
- Optimize operational efficiency
- Meet sponsor expectations for data and reporting
- Manage global study complexities effectively
- Leverage technology for streamlined processes

CRMS delivers a unified, SAP-native platform that transforms clinical trial management into an integrated enterprise capability, connecting research operations directly to financial systems and strategic decision-making.

CRMS – Unified Clinical Research Platform

Key Highlights

- Integrated solution for Sponsors, CROs, Sites & Investigators
- End-to-end clinical trial lifecycle management
- Real-time data and faster trial execution
- Regulatory compliant (21CFR Part11, GCP, ISO 9001, CDISC)
- Infrastructure compliant (ISO 27001, SOC 2 certifications)

Quantitative Benefits

50%
Reduction in site qualification time

40%
Faster study startup times

60%
Improvement in data quality

Effort Reduction Metrics

50%
Monitoring Efforts

48%
Automated Data Flow

40%
Sponsor Visibility

25%
Site Communication

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CRMS Modules Overview

Site Management

Comprehensive site qualification, selection, and performance tracking.

Patient Management

End-to-end patient lifecycle management, from recruitment to study completion.

Clinical Operations

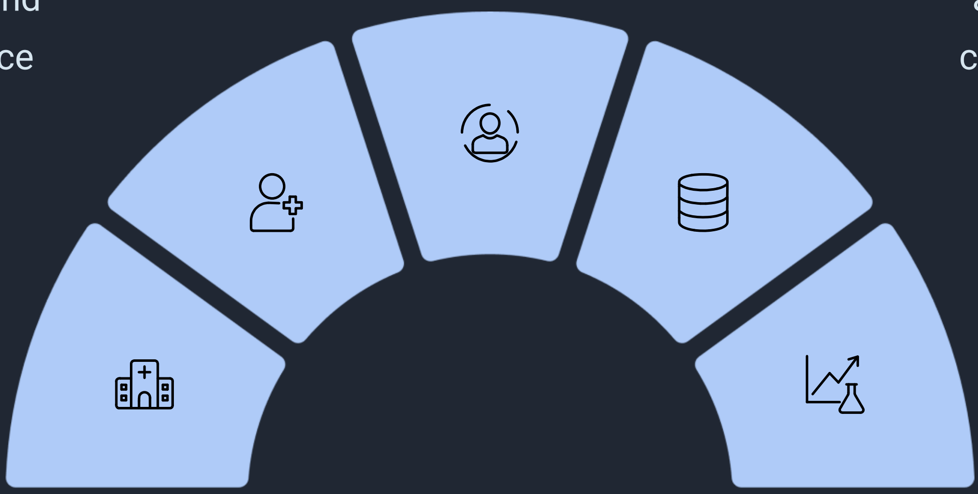
Streamlined study execution, milestone tracking, and automated workflows.

Data Management

Integrated EDC/eCRF with CDISC compliance and real-time data quality.

Analytics & Governance

Executive dashboards, predictive analytics, and comprehensive audit trails.



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Quantified Business Value

CRMS delivers measurable value across operational efficiency, data quality, and financial performance, transforming clinical research into a strategic enterprise capability.

Operational Efficiency*

50%

Site Qualification

Reduction in site qualification time through automated workflows.

40%

Study Startup

Faster study startup enabling earlier patient enrollment.

60%

Data Quality

Improvement in data quality via real-time validation.

50%

Monitoring Efforts

Reduction in monitoring efforts and resource allocation.

48%

Automated Data Flow

Increased automation for seamless data exchange.

Strategic Benefits

Unified Data

Single source of truth for all research data.

End-to-End Visibility

Comprehensive oversight across all operations.

Real-time Analytics

Faster decision-making with immediate insights.

Regulatory Confidence

Ensured audit readiness and compliance.

SAP Integration

Seamless integration with existing SAP ecosystem.

Cost Optimization

- 30% Potential Cost Reduction
- Optimized resource utilization
- Reduced clinical trial cycle time
- Lower total cost of ownership

**Operational Efficiency is based on CRMS pilot run with a CRO*

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Enterprise Integration Architecture

CRMS leverages native SAP technology stack, ensuring seamless integration with existing enterprise systems and eliminating costly middleware solutions.

This architecture delivers enterprise-grade scalability, security, and performance while maintaining the flexibility to adapt to evolving business requirements. Native integration reduces implementation time, lowers total cost of ownership, and provides a future-proof foundation for clinical research innovation.

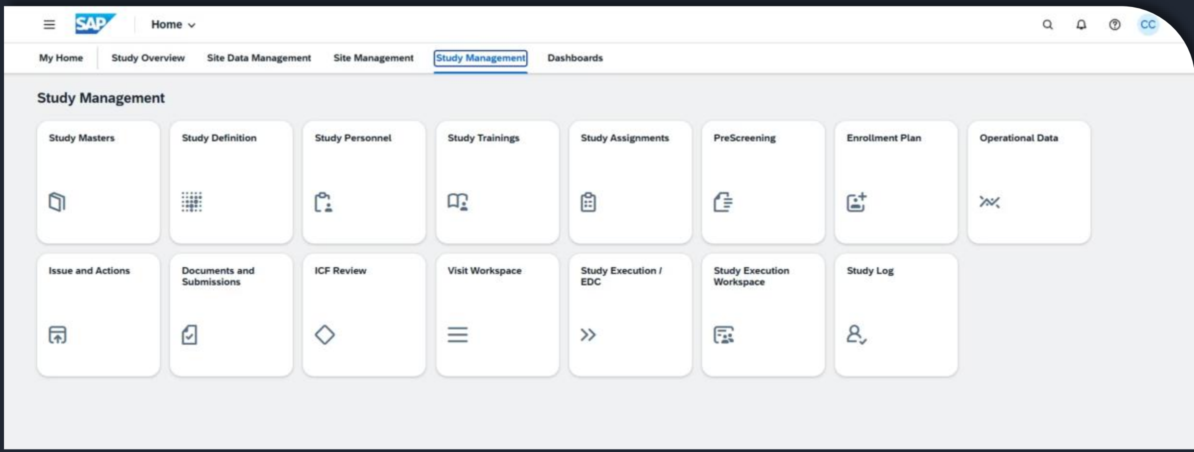
SAP S/4HANA Integration

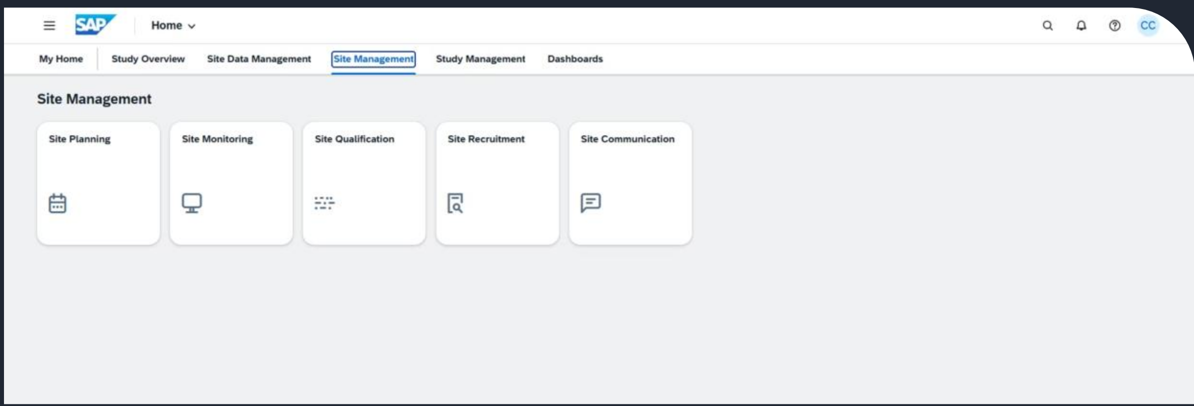
- Master Data (Business Partner, Materials)
- Project Systems (Study Milestones)
- Sales Order Management (Study Contracts)
- Accounts Payable (Study Payments)

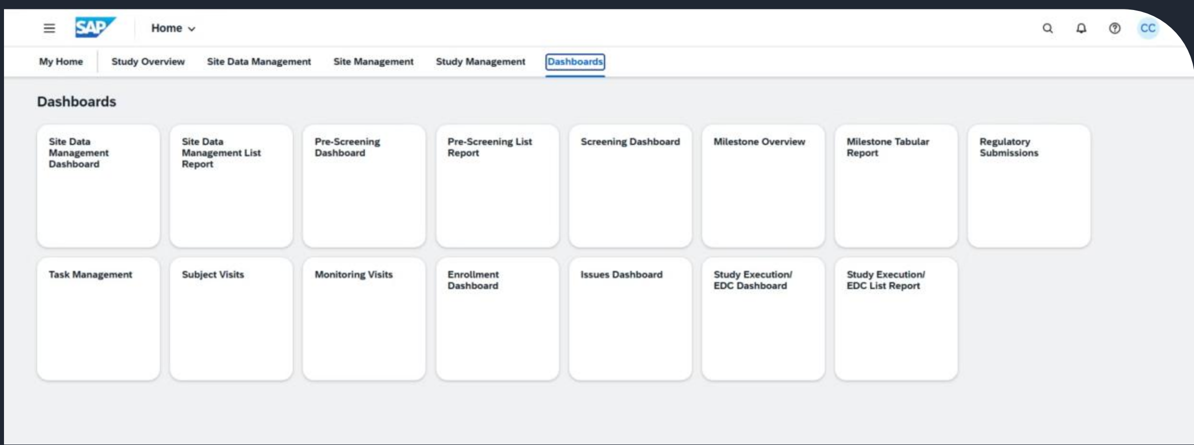
SAP ICSM Integration

- Study Master (Protocol Data, Study Parameters)
- Planning & Forecasting (Drug Demand)
- Distribution (KIT Info, Inventory)
- Patient Enrollments

CRMS User Experience







Key UX Highlights:

- SAP Fiori-based modern interface
- Role-based dashboards for all stakeholders
- Real-time visibility into trial performance
- Mobile-responsive design
- Intuitive navigation across all modules

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REGULATORY & SECURITY

Security & Regulatory Compliance

Enterprise-Grade Protection for Clinical Research Data

***CRMS is architected for regulatory confidence.** Built on enterprise-grade security architecture, CRMS protects sensitive clinical trial data while ensuring global regulatory adherence across the entire study lifecycle.*

🔒 Data Protection by Design

- End-to-end encryption (data in transit/at rest)
- Role-based access control with granular authorization
- Secure Single Sign-On integration
- Segregation of duties enforcement
- Controlled third-party integrations

🏅 Embedded Regulatory Framework

- 21 CFR Part 11
- ICH GCP
- CDISC
- EU Annex 11
- ISO 9001
- ISO 27001
- SOC 2
- Electronic signatures, audit trails, validated workflows, document lifecycle control, and data freeze governance ensure inspection readiness.

🔍 Complete Audit Transparency

Automated Audit Logs
Continuous, tamper-proof records

Version Control
Protocol amendments with full history

SDV Workflows
Source Data Verification embedded

Discrepancy Tracking
Structured resolution & data quality

DB Lock & Freeze
Controlled database lock governance

☁️ Enterprise Infrastructure Assurance

Deployed in secure enterprise-grade environments with **continuous monitoring**, high availability architecture, **disaster recovery protocols**, and operational resilience for global trials. Aligned with US FDA, EMA, PMDA, and ANVISA requirements.

- 24/7 Monitoring
- High Availability
- DR Protocols
- Global Regulator Ready

"CRMS is not merely compliant. It is built to sustain regulatory trust across global clinical operations."

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AI-Powered Innovation Roadmap

CRMS incorporates artificial intelligence and machine learning to transform clinical operations from reactive to predictive, enabling proactive decision-making and continuous optimization.

AI Site Selection

Machine learning algorithms analyze historical performance, patient demographics, and operational capacity to recommend optimal site selection strategies.

Predictive Patient Recruitment

Advanced analytics forecast enrollment trends, identify recruitment bottlenecks, and recommend targeted interventions to accelerate patient accrual.

Regulatory Intelligence

Natural language processing monitors regulatory changes across jurisdictions, automatically flagging potential impacts on ongoing trials.

SAP Certified Solution


Co-Innovated with SAP®

Partner Innovation Lifecycle Services (PILS)

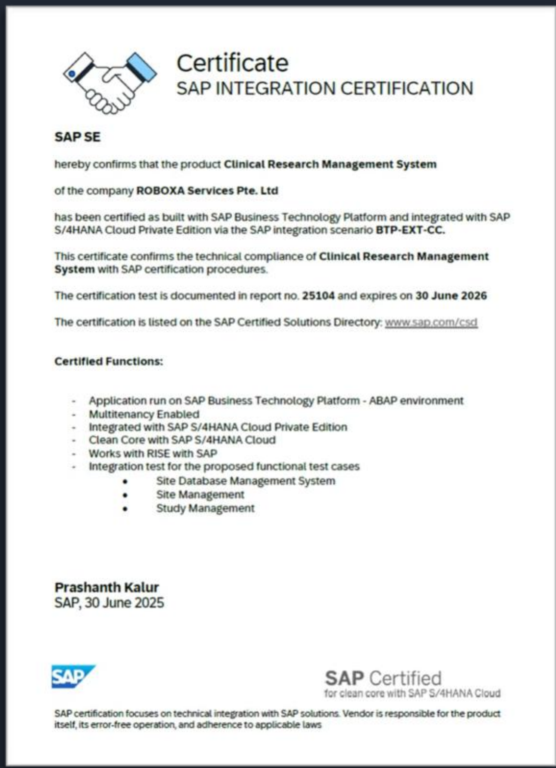
Congratulations! On behalf of SAP SE, we are excited to recognize that **ROBOXA Services Pte. Ltd** has successfully completed the end to end service engagement with Partner Innovation Lifecycle Services (PILS) team for your product **"Clinical Research Management System"**.

We hereby grant you the usage of the **"Co-Innovated with SAP"** font treatment in connection with **"Clinical Research Management System"** from June 17, 2024 to June 16, 2025. Congratulations again on this achievement.

Best Regards,

Nandagopal B Prasad
Senior Vice President
Head, Partner Innovation Lifecycle Services (PILS)
SAP Labs India Pvt. Ltd.
June 17, 2024

THE BEST RUN SAP


Certificate
SAP INTEGRATION CERTIFICATION

SAP SE

hereby confirms that the product **Clinical Research Management System**

of the company **ROBOXA Services Pte. Ltd**

has been certified as built with SAP Business Technology Platform and integrated with SAP S/4HANA Cloud Private Edition via the SAP integration scenario **BTP-EXT-CC.**

This certificate confirms the technical compliance of **Clinical Research Management System** with SAP certification procedures.

The certification test is documented in report no. **25104** and expires on **30 June 2026**

The certification is listed on the SAP Certified Solutions Directory: www.sap.com/csd

Certified Functions:

- Application run on SAP Business Technology Platform - ABAP environment
- Multitenancy Enabled
- Integrated with SAP S/4HANA Cloud Private Edition
- Clean Core with SAP S/4HANA Cloud
- Works with RISE with SAP
- Integration test for the proposed functional test cases
    - Site Database Management System
    - Site Management
    - Study Management

Prashanth Kalur
SAP, 30 June 2025

SAP Certified
for clean core with SAP S/4HANA Cloud

SAP certification focuses on technical integration with SAP solutions. Vendor is responsible for the product itself, its error-free operation, and adherence to applicable laws

- Co-Innovated with SAP designation
- SAP Integration Certification (BTP-EXT-CC)
- Built on SAP Business Technology Platform

This validates the enterprise-grade quality and SAP partnership.

Customer Success & Value Proposition

Use Case Example: Global Pharma Sponsor

A leading global pharmaceutical sponsor leveraging SAP S/4HANA across their enterprise deployed CRMS to unify clinical operations with corporate financial systems.

Key Results

Seamless Integration

with existing SAP landscape

Real-Time Financial Visibility

across trials

Reduced System Complexity

Improved Compliance

and audit readiness

Why SAP Customers Choose CRMS

Native SAP Integration (no middleware needed)	Consistent User Experience across SAP ecosystem	Leverages Existing SAP Infrastructure
Enterprise-Grade Scalability and Security	Single Vendor Relationship	Unified Support Model

ROBOXA DRIVING INNOVATION

Transform Your Clinical Enterprise

Unify clinical operations with enterprise systems through SAP-native technology

Enterprise Integration

Seamlessly connect clinical research with finance, procurement, and HR systems

Accelerated Innovation

Reduce time-to-market with streamlined workflows and real-time collaboration

Regulatory Confidence

Built-in compliance frameworks ensure inspection readiness across global trials

Data-Driven Decisions

Real-time insights and predictive analytics optimize trial performance

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Ready to modernize your clinical operations?

Take the next step toward enterprise-grade clinical transformation.

Schedule a personalized Demo

Speak with our Clinical Technology Expert

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Experience CRMS

Live Demo

Explore the CRMS platform with an interactive demo

See how CRMS can transform your clinical research operations with a personalized walkthrough of the Study Management interface.

Next Steps

Schedule a personalized demo

Discuss your specific requirements

Conduct fitment assessment

Review implementation roadmap

Begin your digital transformation journey

Contact Information

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