Enterprise Architecture Decision Record (ADR)

# 1. General Information

• Decision ID: ADR-2025-001  
• Decision Title: Selection of Clinical Trial Management System (CTMS)  
• Author: EA Team  
• Date Created: 2025-09-02  
• Last Updated: 2025-09-02  
• Status: Accepted

# 2. Context

Our existing CTMS is nearing end-of-life and is not compliant with updated EMA Clinical Trial Regulation (CTR). We require a system that supports global studies, integrates with EDC, and ensures data integrity.

# 3. Decision Statement

Adopt Vendor X’s cloud-based CTMS as the enterprise standard.

# 4. Options Considered

- Option A: Upgrade existing on-prem CTMS (Cons: limited scalability, costly validation).  
- Option B: Vendor X’s cloud CTMS (Pros: validated SaaS, integrations, GxP compliance; Cons: subscription costs).  
- Option C: Build custom CTMS (Cons: high validation cost, long delivery time).

# 5. Rationale

Vendor X provides a validated SaaS CTMS with proven regulatory compliance and strong industry adoption. It reduces maintenance overhead and accelerates study start-up.

# 6. Consequences

- Positive: Faster deployment, compliance ensured, global access.  
- Negative: Vendor lock-in, recurring costs.  
- Mitigation: Negotiate multi-year pricing and exit clauses.

# 7. Related Artifacts

• Architecture Principle: AP-01 Data Integrity  
• Linked Workflows: Clinical Data Integration Pipeline

# 8. Review & Approval

• Reviewed By: Clinical IT Director, QA Head  
• Approval Date: 2025-09-01  
• Next Review: 2026-09-01