CASE STUDY

Real-time CRO oversight across disconnected eClinical systems

Overview

A medium-size biotech with several FDA approved products in-market and 40 development projects in-flight and multiple CRO partners faced an all too familiar problem: each CRO operated in a different eClinical environment, and the sponsor needed timely access to progress and milestone data to maintain proper oversight. With no system-to-system integration in place, data exchange was manual, error-prone, and expensive, creating delays and limiting visibility.

In practice, this meant the same operational questions kept taking too long to answer: Are sites hitting milestones? Are key regulatory activities on track? Are timelines slipping—and if so, where and why? Instead of a consistent, trusted source of truth, teams were forced into repeated cycles of chasing updates, reconciling mismatched fields, and validating "which version is correct" across CRO deliveries. The cost wasn't just time, it was reduced confidence in oversight, slower decisions, and more risk as programs scaled.

Adaptive Clinical Systems implemented its vendor-agnostic AI enabled interoperability layer to automate data exchange, improve data quality, and enable near real-time oversight across the sponsor's complicated trial ecosystem.

The Challenge

This biotech worked with multiple CROs and multiple eClinical systems. They needed timely access to those systems to monitor study progress, milestones, and operational health. But because the systems were not integrated, data exchange required manual effort, introduced errors, increased cost, and delayed decision-making, ultimately reducing the effectiveness of their CRO oversight.

A key pain point was that even when data arrived "on time," it often arrived in different shapes: different structures, different naming conventions, and different delivery methods depending on the CRO and the study. That variability created a constant burden on sponsor teams—manual handling, repeated validation, and downstream reporting disruption whenever CRO delivery methods changed without notice. Oversight became reactive instead of real-time and continuous.

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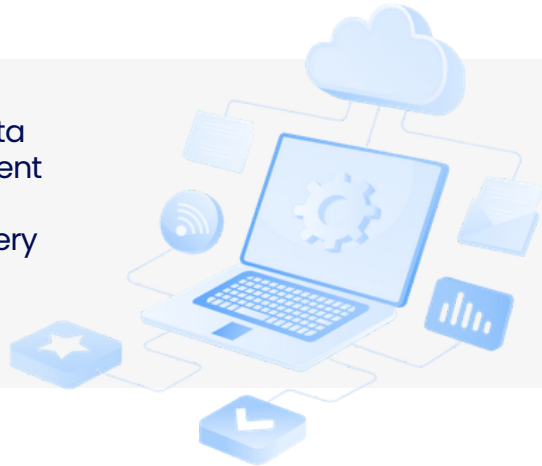


Objectives

1. Enable CRO systems to interoperate seamlessly with the sponsor's Veeva Vault-CTMS, including systems operated by key CRO partners (PPD and PAREXEL) and 4G Clinical IRT
2. Completely eliminate manual data handling
3. Improve data quality and timeliness of updates to near-real-time
4. Automate the exchange of data between systems

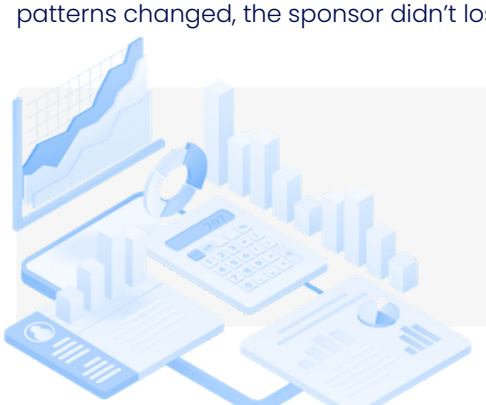
Adaptive's Clinical Solution's Approach

Adaptive configured the Adaptive eClinical Bus® as the interoperability hub connecting CRO-managed systems with the sponsor's environment.

Implementation Highlights

• Configured the Adaptive eClinical Bus® to connect CRO systems, the sponsor's Vault-CTMS, and 4G Clinical IRT without requiring any changes to their systems
• Used the Smart Mapping Wizard to automate field-level data transformations using Adaptive's integrated Rules Engine.
• Enabled real-time data exchange across systems
• Insulate the sponsor's CTMS reporting by accommodating variations in data content and flows as CROs changed their delivery methods
• Implemented quality control using confidence scoring with human-in-the-loop (HITL) review for exceptions
• Established ongoing monitoring and adjustment using Adaptive's operational Dashboards with its integrated Adaptive DataVIEW®

A key design principle was resilience: the goal wasn't just to "connect systems once," but to keep the sponsor's oversight stable as studies evolved and CRO processes shifted. Adaptive's approach focused on governed transformations, exception-based review, and monitored flows—so when upstream delivery patterns changed, the sponsor didn't lose reporting continuity or spend weeks reworking integrations.



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Deliverables

- Production integration flows connecting CRO systems to the sponsor's Vault CTMS
- Automated, reusable field mappings via Smart Mapping Wizard
- Real-time exchange configuration (near-continuous updates vs batch/manual)
- QC workflow: confidence scoring + HITL exception handling
- Fully Validate the interconnects into the validated Veeva Vault platform to include formal Functional Requirements Specification (FRS) generation, Operational Qualification (OQ) and formal User Acceptance Testing (UAT)
- Monitoring + operational rules to detect changes, disruptions, and data drift

Results Key outcomes are many and highlighted below:

Eliminated all manual data transcriptions thus reducing data entry by up to 90%, lowering management overhead

Increased operational capacity 25% without increasing staff

Reduced data flow Validation and Process Quality activities by 80% (Automated FRS, OQ and IQ document generation)

Improved compliance and reduced risks by reducing manual errors, enhancing operational response to protocol deviations

Direct Integration of CTMS from sources resulted in easy construction of comprehensive dashboards for 100% accurate and near-real-time tracking of study KPIs tracking of study KPIs

Reduced feed source change maintenance and validation and compliance burden from weeks to days

Retired antiquated and batch oriented ETL systems with no new IT footprint

Stronger CRO oversight by enabling full transparency into CRO-managed execution

Takeaway

Multi-CRO oversight breaks down when trial data is trapped in disconnected systems and stitched together manually. Data transfer agreements are prone to unannounced changes and data corruption during transfer . By implementing a vendor-agnostic AI enabled interoperability layer, this biotech replaced brittle handoffs with governed, monitored, near real-time data exchange—where oversight becomes a capability, not a recurring fire drill.