

# Clinical Data Remediation

## Is your clinical data holding your digital transformation hostage?

Clinical organizations face persistent data quality crises driven by legacy systems, manual reconciliations, and siloed functions that prevent accurate reporting and timely decision-making. The reality: fragmented data across your clinical ecosystem is blocking every strategic initiative you're trying to execute.



### Legacy integration chaos

Manual reconciliations across EDC, eTMF, and CTMS create inconsistent reporting and unreliable metrics



### Failed digital initiatives

CTMS migrations, AI platforms, and cross-functional dashboards stall because poor data quality breaks everything



### Inspection readiness panic

Last-minute TMF completeness scrambles before every audit because you can't see the full picture



### Siloed operations

Outdated operating models create misalignment between functions, compounding data inconsistencies



### Unclear data status

Teams spend months overanalyzing instead of fixing because they don't know where to start

The cost of standing still is too high. You can't implement next-generation clinical systems, enable AI-driven insights, or achieve continuous inspection readiness without fixing your data foundations first.

The root cause? Unmastered data objects, inconsistent hierarchies, unreliable metadata, and governance gaps stemming from human factors, organizational silos, and technical debt accumulated over years.

Data is a strategic asset - instill your data foundations, organize and use data wisely to gain the competitive insights you need to accelerate your digital transformation journey with AI & ML.

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# Strategic Data Remediation That Actually Works

Clinical data remediation isn't a one-time cleanup project – it's about improving data quality AND establishing governance to maintain that quality over time. We combine proven methodology with intelligent technology to transform your clinical data landscape.

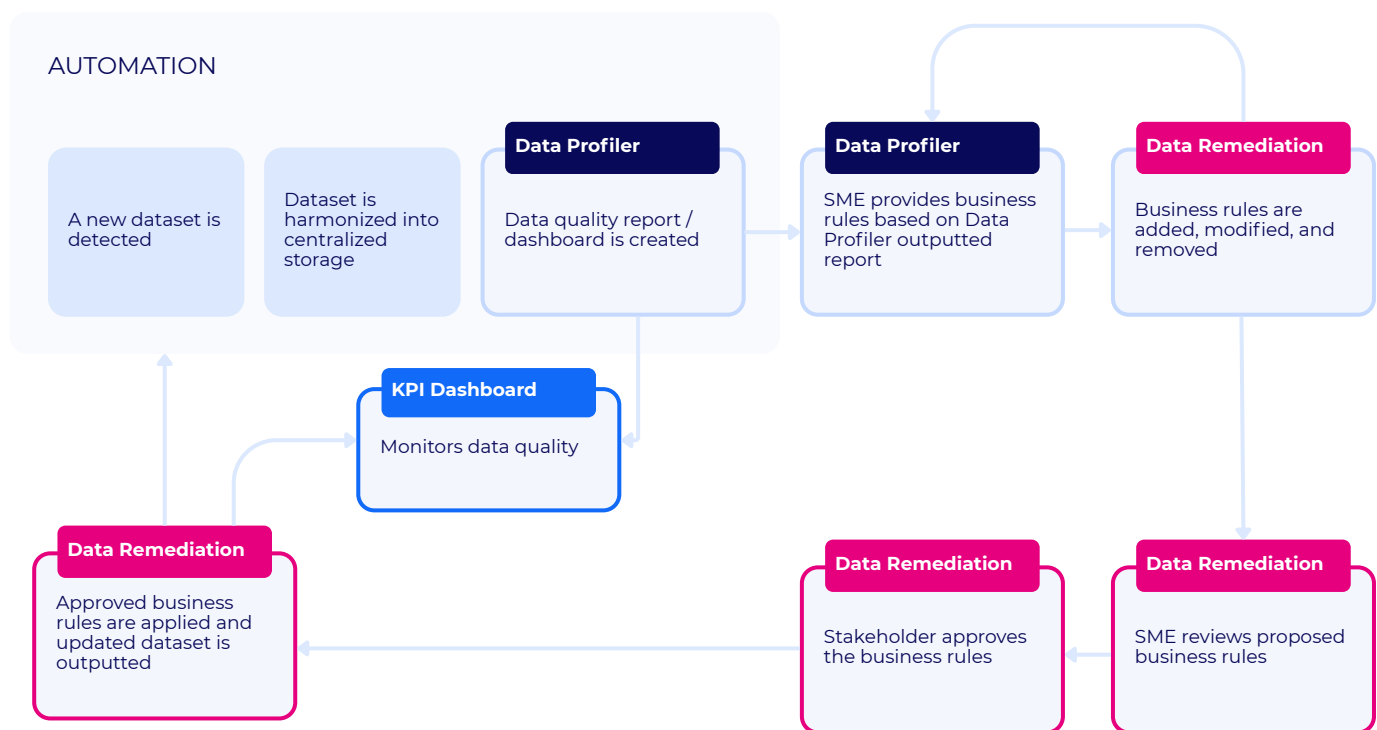
## 1 Data Quality Assessment & Profiling

Before remediation begins, you need to understand the full scope of your data quality challenges. Our assessment analyzes your entire clinical ecosystem to identify quality issues and their root causes, ensuring you're fixing the right problems in the right order.

- Comprehensive data quality analysis across CTMS, eTMF, EDC, and source systems
- Interactive dashboards that identify root causes across human, governance, organizational, and technical dimensions
- Prioritized remediation roadmap based on business impact and system dependencies

## 2 Intelligent Data Remediation Execution

Data-centric (not system-centric) approach using scalable, automated remediation platforms. Agile wave-based execution with sandbox validation ensures compliance and auditability before applying changes.



### Key process elements:

- Automated Data Profiling: Continuous quality monitoring with interactive dashboards
- SME-Driven Business Rules: Subject matter experts define remediation logic based on profiler outputs
- Sandbox Validation: Dry runs ensure changes are tested before production application
- Stakeholder Approval: Governance checkpoints maintain compliance and auditability
- Continuous Monitoring: KPI dashboards track quality improvements over time

### 3 Governance & Future State Enablement

Remediation only delivers lasting value when governance prevents quality degradation and your data foundations enable future innovation.

We establish sustainable governance frameworks with object-based ownership, continuous monitoring via KPI dashboards, and standards injected at the system level (CDISC, Veeva Vault Clinical Data Model) - positioning you for AI, advanced analytics, and next-generation digital initiatives.

#### Data Quality Activities

- **Issue Resolution** - Resolve priority issues post remediation. Monitor and investigate root cause for data discrepancies identified during operations.
- **Technical Support** - Provide technical support for Continuous Data Monitoring data pipelines, reporting, and dashboards.
- **Metrics Tracking** - Ensure data quality trends above KPI targets and escalate quality issues.
- **Ad Hoc Remediation** - Define rules, logic, workflows to remediate data.
  - Build transformational data pipelines for bulk updates.
  - Manually resolve issues in source systems for 'one off' issues.

#### Deliverables

Data Change Controls, Data Remediation Documentation (Plans, Logs, Reports), Supporting Tool Documentation (As needed)

#### Governance Activities

- **Implement** - Execution of future state governance structure & processes.
- **Business Support** - Support Data Governance stakeholders with newly defined governance processes, tools, and operational reporting.

#### Deliverables

Maintain Data Governance Framework & SOPs, Maintain Data Quality Monitoring Dashboard, Supporting Governance Documentation

## Data Remediation is the Gateway to Other Outcomes

Poor data quality isn't just a compliance problem - it's blocking revenue growth, operational efficiency, and competitive advantage. Our approach delivers measurable improvements in compliance, efficiency, and decision-making.

### Accelerated Inspection Readiness

No more last-minute scrambling. Real-time TMF completeness visibility at every milestone keeps you continuously audit-ready.

### CTMS Migration Success

Fully remediated, standardized data guarantees seamless next-generation system implementations with zero legacy data issues carrying forward.

### Digital Transformation Enablement

Enterprise-wide governance standards position you to leverage AI platforms, cross-functional insights, and advanced analytics - finally.

### Operational Excellence

High-quality data transforms day-to-day operations. Reduced study startup times, eliminated manual reconciliations, faster decision-making with trustworthy metrics, and minimized inspection risk through proactive compliance.

### Competitive Advantage

Company growth requires data quality. Remediation becomes your digital accelerator, giving you an edge competitors don't have.

# Why partner with Epista for Data Remediation?

Most consultancies offer point solutions or generic data services. We're different: we bring the technology, the strategy to implement it, and the domain expertise to make it work in your clinical reality.

## Deep Clinical Expertise

20+ years in clinical trial execution, operations data, and compliance. Our specialized consultants understand your reality across clinical operations, data governance, and regulatory requirements - not just data management theory.

## Solution Architect & Provider

We don't just consult - we design, build, and implement complete remediation solutions. Strategic partnership with leading platforms provide enterprise-grade automation, validation capabilities, and scalable architecture designed for regulated environments.

## Integrated Approach

We bridge process, technology, and governance into a cohesive solution. Our remediation programs address not just the technical fixes, but the organizational and governance changes needed to sustain quality improvements over time.

## Industry Alignment

Active members of CDISC, DIA, and other standards bodies. We embed industry standards and best practices - including CDISC and Veeva Vault Clinical Data Model - rather than force-fitting point solutions that don't align with how clinical operations actually work.

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## Proven Track Record

Successfully delivered one of pharma's largest clinical data remediation programs - 800+ studies, 43K sites, 4M+ documents - for a global biopharmaceutical leader. We've executed successful data migrations and remediations across top 10 pharma companies.



## Ready to transform your data?

Let's discuss your Data Remediation needs.

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