

# Driving Data Integrity and Operational Excellence in Clinical Operations

## Introduction:

In the fast-evolving landscape of life sciences, the integrity and reliability of clinical data are paramount. Executive decision-makers in large pharmaceutical companies are increasingly recognizing that robust data remediation strategies are not just about compliance but about unlocking the full potential of their clinical operations. This solution brief outlines a comprehensive approach to address the complexities of clinical data quality, ensuring that your organization is equipped to make informed decisions, mitigate risks, and accelerate the delivery of life-changing therapies.

## The Problem:

In today's complex pharmaceutical landscape, clinical operations are generating vast amounts of data across diverse systems. Maintaining the integrity, consistency, and completeness of this data is a significant challenge. Data quality issues, such as legacy integrations, inconsistent reporting, inability to track vendor performance, and manual data checks, can lead to delayed decision-making, inspection readiness scrambles, and non-compliance. Often, by the time issues are recognized during the implementation phase of new technologies, it is a difficult task to retroactively plan a strategy to rectify critical data quality issues. These issues ultimately hinder the successful implementation of critical systems like Clinical Trial Management Systems (CTMS) and impact overall operational efficiency. Organizations often face fragmented data, inconsistent naming conventions, and a lack of unified data governance, resulting in manual remediation efforts that are time-consuming and prone to errors.

## The Solution:

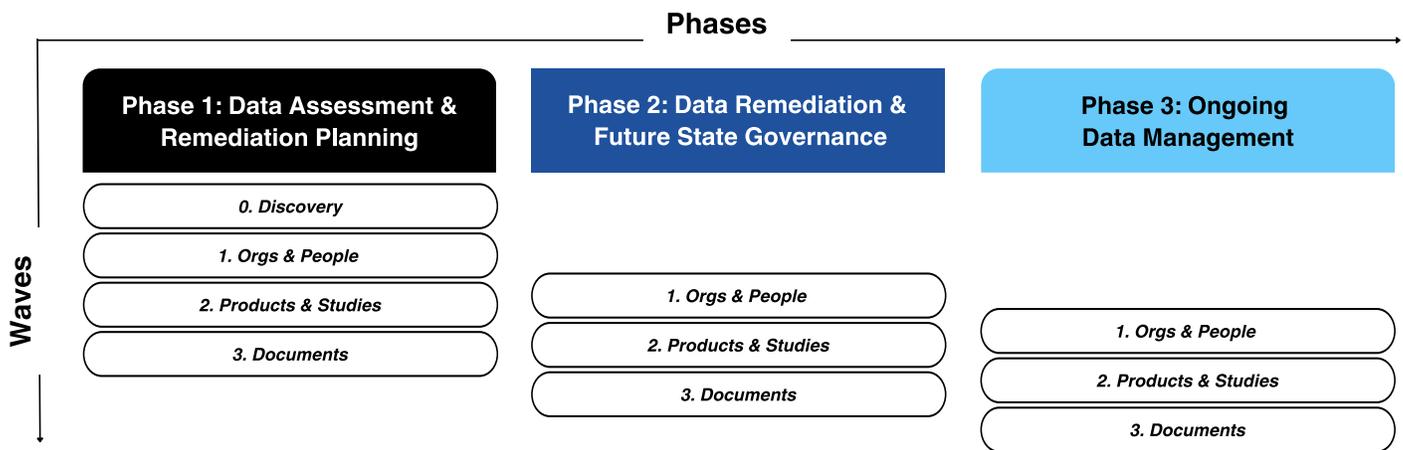
Addressing these challenges requires a multi-faceted approach that combines deep industry expertise with cutting-edge technology, focusing on improving data quality and establishing governance to maintain it.

## Key Takeaways:

- **Proactive Data Remediation:** Essential for ensuring accuracy and reliability of clinical data.
- **Strategic Partnerships:** Leverage specialized expertise and advanced technology for comprehensive solutions.
- **Sustainable Governance:** Establish frameworks for continuous data quality monitoring and long-term operational reliability.
- **Enhanced Decision-Making:** Improve reporting, compliance, and strategic insights through high-quality data.

# Epista Life Science: The Business Solution

Data is at the intersection of Business and IT – Epista  
*A proven “Phases to Wave” methodology to Assess, Remediate & Monitor Data Quality*



Success requires equal parts clinical operations expertise, technical architecture knowledge, and organizational change management. Epista SME, PMO, and OCM.

**Technical SMEs:**

- Identify source of truth systems for key data objects coming into CTMS & eTMF

**Clinical Operations SMEs:**

- Profile, Root Cause Analysis, Remediation Decisions
- Evaluate current state governance practices

**Clinical Operations SMEs:**

- Identify target repository for remediated data
- Define future-state data flow, process, and governance framework

**Technical SMEs:**

- Configure remediation decisions & execute (iterative until data quality KPI is reached)

**Data Stewards:**

- Monitor data quality and act per governance

**Clinical Operations SMEs:**

- Implement & drive governance

Data remediation fails when it’s treated as purely a technical exercise. Success requires equal parts clinical operations expertise, technical architecture knowledge, and organizational change management.

Epista Life Science provides a strategic framework and execution discipline to make remediation programs work in the real world of pharmaceutical operations.



## A Proven Methodology:

The Epista Life Science approach is built on a foundation of successful remediation programs. We use a structured "Phases to Waves" methodology to assess, remediate, and monitor clinical operations data quality. This includes:

### PHASE 1:

**Data Assessment & Remediation Planning:** Before fixing anything, we establish the ground truth. This phase delivers a complete understanding of your data landscape: Identifying and defining source systems, data profiling, categorizing data discrepancies, root cause analysis, standardizing data models, and defining remediation rules.

### PHASE 2:

**Data Remediation & Future State Governance:** This is where most programs either succeed or stall. Epista teams execute the technical cleanup while simultaneously building the governance infrastructure that prevents recurrence. Configuring remediation logic, monitoring results at each stage and validating outcomes against success criteria.

### PHASE 3:

**Ongoing Data Management:** Remediation programs create value over time, not just at go live. This phase transitions from project mode to operational excellence. Implementing technical and business governance elements, resolving priority issues, providing technical support for continuous data monitoring, and tracking metrics.

## Why this approach works?

**We understand both sides of the house:** Epista teams combine clinical expertise with technical architecture knowledge. Speaking the same language of study managers and data engineers creates a fluency that is critical for data remediation project success.

**Governance isn't an afterthought:** Many remediation efforts focus exclusively on the cleanup and treat governance as a future-state concern. We build governance in parallel with remediation because we know that cleaned data degrades quickly without proper stewardship. Our frameworks define not just what good data looks like, but who owns it, how it's maintained, and what happens when issues arise.

**Change management is integrated, not separate:** Technology and processes fail when people don't adopt them. We design change management into the program from day one (including Prosci ADKAR principles) to ensure teams understand why, know the how, and actually maintain new practices over time.

**Accelerators based on real programs:** We don't just start from scratch on every engagement. Our remediation frameworks include solution accelerators built from previous programs: common data quality rules, governance templates, stakeholder communications plans, and training materials.

# DNAnexus: The Technical Solution

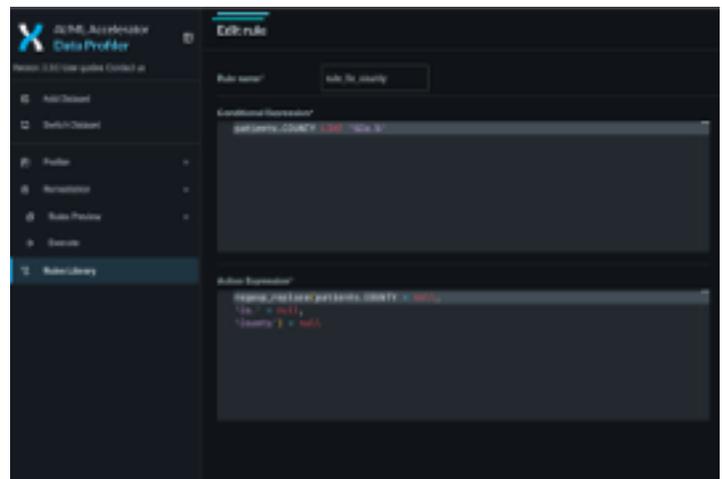
DNAnexus provides the underlying technical platform and tools that accelerate and sustain the data remediation efforts. *Their contribution includes:*

**Data Profiler:** A user-friendly tool to assess the state of data and data quality, generating comprehensive data quality analysis (DQA) reports based on standards and business rules. It provides consistent visualizations of datasets, identifies discrepancies, and supports root cause analysis.

**Remediation Tool:** A configurable tool to create and modify business rules for cleaning and harmonizing datasets. It includes an approval workflow, version control, logging for auditability, and the ability to execute new business rules in a sandbox (dry-run) environment.

**Data Quality Dashboard:** A "live stream" dashboard to monitor data quality over time, automatically refreshing with new data versions and business rules. It provides aggregated metrics at various levels (e.g., studies, sites) and serves as the primary interface for data stewards to monitor and maintain data quality, providing alerts and notifications for discrepancies.

**Automation Capabilities:** The platform, tools, and automation capabilities make the cleanup effort faster, smarter, reusable, and sustainable, ensuring long-lasting value beyond a one-time fix. It enables secure regulatory data exchange and streamlines operations by automating repetitive processes.



## Key Outcomes and Organizational Benefits:

By implementing this integrated solution, pharmaceutical organizations can achieve:

- 1. Improved Data Integrity:** Achieve trusted, high-quality, and FAIR (Findable, Achievable, Interoperable, Reusable) operational data across the ecosystem, addressing common data quality issues like inconsistent hierarchies, varying milestone dates, and unmastered user/organization data.
- 2. Accurate Metrics Reporting:** Technology capabilities to provide near real-time reports and dashboards for data quality metrics, enabling enhanced decision-making based on reliable source data.
- 3. Improved Governance & Reliability:** Establish a robust governance framework to continuously monitor data pipelines and resolve issues as they arise in operations, reducing manual remediation efforts and ensuring proactive compliance.
- 4. Enhanced Decision Making:** Gather automated AI/ML insights from technology to streamline and support decision-making based on accurate source data, leading to cross-functional, enterprise-wide insights and competitive advantage.
- 5. Reduced Risk and Cost:** Minimize regulatory misreporting risks, avoid failed audits, and reduce operational costs associated with poor data quality and manual processes.
- 6. Accelerated Deployment:** Leverage proven accelerators and an experienced team to achieve faster deployment and reduced manual effort, with a structured approach to transition from hypercare to managed operations.
- 7. Clinical Trial-Ready Operational Reliability:** Ensure clinical trial data is inspection-ready, reliable, and future-proof, supporting the entire data lifecycle from ingestion and remediation to modeling and analysis in one integrated environment.



**DNAexus**

**To learn more** about how a comprehensive data remediation strategy can transform your clinical operations and drive sustained data quality, contact us for a detailed consultation. **[dnanexus.com](https://dnanexus.com)**