

Staying Out of the Ditch – How Governance Can Provide Your Team Guardrails

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ABSTRACT

Regulatory expectations for data integrity, quality control (QC), and governance in clinical trials continue to intensify. As trials increase in complexity, developers face heightened scrutiny under guidelines such as the FDA's 21 CFR Part 11 and ICH E6 R3, which call for transparent audit trails, robust risk management, and verifiable compliance. Traditional approaches - spreadsheets, disjointed software tools, and labor-intensive manual reviews—are no longer adequate for ensuring quality at scale.

This paper presents a next-generation governance framework that integrates automated policy enforcement, real-time audit trails, and risk-based QC tracking within Statistical Computing Environments (SCEs). By weaving compliance checks into SAS, R, and Python workflows, organizations can elevate QC from an afterthought to a continuous, data-driven process. The discussion includes strategies for adoption, covering the roles of people, process, and technology in modernization efforts, and concludes with a scenario demonstrating how AI-driven automation and predictive analytics form an audit-ready, proactive QC environment.

INTRODUCTION

Governance in clinical trial programming goes beyond mere box-checking. It is a proactive discipline designed to uphold data integrity, ensure audit readiness, and streamline regulatory submissions. Despite this, governance has historically been a final-stage activity—programmers complete their work, then hand off deliverables for QC reviews tracked in spreadsheets or emails. This siloed approach undermines both efficiency and compliance.

For clinical programming teams - especially using SAS and R - several governance challenges are prevalent:

- **Manual QC Tracking:** Activities are often logged in Excel, email threads, or unstructured repositories. This scattered documentation complicates version alignment and makes it easy for errors to slip through.
- **Limited Automated Auditability:** Without dedicated version control and automated logs, it is difficult to prove compliance to regulators. Spreadsheets seldom capture timestamps or detailed histories of who changed what and why.
- **Fragmented Policies:** Governance rules may exist, but if they are not embedded within the development environment, enforcement is inconsistent. Critical reviews can be overlooked, or executed only at the end of a project, increasing regulatory risk.
- **Regulatory Uncertainty:** As agencies refine guidelines around data integrity and AI oversight, organizations must strengthen traceability for code, analyses, and datasets to avoid scrutiny.

As modern trials incorporate a growing volume and variety of data, the need for dynamic, real-time governance becomes more pronounced. QC must move from passive oversight to an active strategy that embraces automation and continuous improvement.

THE IMPORTANCE OF GOVERNANCE IN QC TRACKING

Despite investments in advanced clinical trial tools, many teams still default to manual QC processes, risking misalignment between the development environment and the QC tracking mechanism. Several core issues persist:

Separation of Development and QC

In a fragmented model, clinical programmers work within SAS or R while reviews happen offline, often in Excel or standalone systems. This increases the likelihood of version mismatches and can delay issue detection. Any unresolved discrepancy—like a missing validation step for an ADaM dataset—can escalate into a larger regulatory concern later.

Inadequate Audit Trails

Traditional spreadsheet-based tracking typically lacks detailed revision histories. Teams may know who submitted the last update, but not necessarily what changed, when it changed, or the rationale behind it. In an audit, the inability to demonstrate a fully transparent lineage of code, data, and QC reviews can raise questions about overall data integrity.

Weak Policy Visibility

A policy requiring independent peer review of critical outputs may be well-documented, but if it is not enforced in real time, it could be easily bypassed. Without real-time checks in place, some teams might skip this step under tight timelines, unaware of the regulatory repercussions.

Given these concerns, robust governance is not optional. It is a cornerstone of regulatory compliance, ensuring every dataset modification or programming script update is accountable, traceable, and aligned to established standards.

KEY DRIVERS FOR GOVERNANCE TRANSFORMATION

With growing regulatory scrutiny and increasing trial complexity, governance must evolve to become an active, embedded function within Statistical Computing Environments (SCEs). Several industry trends are driving this transformation:

Stricter governance regulations are reshaping compliance requirements. The FDA's enforcement of 21 CFR Part 11 now extends to electronic records, AI/ML-generated analyses, and remote compliance validation. The introduction of ICH E6 R3 emphasizes risk-based governance and real-time QC tracking, requiring organizations to adopt more proactive compliance strategies. Regulatory agencies are also increasing their focus on AI governance oversight, requiring that machine learning models and automation-driven decisions are transparent, auditable, and bias-free.

As clinical trials grow in scale and complexity, governance frameworks must be flexible, automated, and scalable. Traditional governance models, which rely on manual validation and static compliance logs, are no longer sustainable for large-scale, global trials. Organizations must transition to AI-powered governance monitoring, automated risk assessments, and real-time compliance dashboards.

Governance transformation also enables faster insights and competitive advantages. With automated governance workflows, sponsors can accelerate regulatory submission timelines and ensure that compliance bottlenecks do not delay trial execution. AI-driven compliance tracking reduces the burden of manual validation, allowing teams to focus on scientific insights and trial execution rather than regulatory troubleshooting.

VISION AND PRINCIPLES FOR NEXT-GEN GOVERNANCE IN QC

A successful governance model is characterized by *proactivity*, *automation*, and *seamless integration* with daily programming tasks. Historically, QC tracking often lived outside of the coding environment, but next-gen governance merges these elements to form a continuous feedback loop.

1. Embedded Governance

Instead of treating governance as a separate step, QC checks must be incorporated directly into SAS, R, and Python workflows. For instance, any time a code script is updated, the governance system captures that change in real time, triggering automated validation rules. This eliminates the lag between development and QC, minimizing errors that arise from waiting until the end of the process.

2. **Risk-Based Automation**

Automation is not just about saving time; it ensures consistency and scalability. By leveraging AI or rule-based engines, teams can define risk thresholds for different datasets and automatically prioritize certain QC tasks accordingly. A critical output for a pivotal Phase III trial might demand more rigorous peer review, whereas simpler outputs could follow a streamlined workflow.

3. **Comprehensive Audit Trails**

Next-gen systems automatically record granular change logs, including timestamps, user IDs, and detailed commentary. This transparency is invaluable when regulators request evidence of how and why decisions were made. Automated audit trails also aid in internal knowledge transfer and root cause analysis when investigating issues.

4. **AI-Augmented Monitoring**

AI-driven governance tools can proactively scan statistical outputs for anomalies or deviations from historical norms. These insights become especially powerful when combined with predictive models that anticipate where compliance issues might arise in future data cycles. Human oversight remains critical, but AI offers an additional layer of protective foresight.

5. **Continuous Improvement**

Successful governance includes feedback loops. Each QC cycle generates data that can be analyzed to optimize governance rules. If recurring errors are detected, the system can recommend policy revisions or prompt user training, fueling a cycle of ongoing enhancement.

By converging these principles, organizations can embed governance as a living, dynamic element of their clinical programming infrastructure, boosting both compliance and operational effectiveness.

GOVERNANCE IN ACTION

An effective governance model must go beyond theoretical principles and translate into tangible, real-world workflows. Consider a scenario where a clinical programmer updates an ADaM dataset as part of an ongoing statistical analysis. In a traditional setting, this update would trigger a manual QC process, requiring a separate spreadsheet entry, an email request for peer review, and a final validation step that may take hours or even days to complete. The disconnect between development and governance introduces inefficiencies and increases the likelihood of errors slipping through the cracks.

In a next-generation governance framework, this process is fully integrated and automated. When the programmer commits the dataset update in SAS or R, the system automatically flags the change for review. Instead of relying on manual coordination, an AI-driven governance engine detects the modification and initiates the appropriate QC workflow. This includes automated validation steps, risk assessments based on study-specific criteria, and an audit trail entry capturing the details of the modification. If the update introduces a potential compliance issue—such as an unexpected deviation from predefined data patterns—the AI system escalates the alert to study leads for further investigation.

As the QC workflow progresses, governance dashboards provide real-time visibility into the review process. Study leads receive automated alerts summarizing governance risk scores, pending compliance tasks, and overall QC completion metrics. If additional validation is required, the governance system enforces role-based approval workflows, ensuring that all necessary signoffs occur before the dataset is finalized. Once the QC process is complete, the governance platform updates the compliance status and documents the results in an auditable format, creating a transparent, traceable record that is readily available for regulatory submission.

By embedding governance into the development workflow, this approach eliminates the delays, inconsistencies, and manual dependencies associated with traditional QC tracking. The ability to detect compliance risks in real-time and proactively address them ensures that statistical analyses always remain audit ready. Governance no longer serves as a bottleneck in clinical trial execution but rather as an enabler of faster, more efficient, and more reliable QC tracking. With AI-driven compliance monitoring and automated workflows, organizations can shift from a reactive governance model to a predictive and proactive framework that enhances both regulatory confidence and operational efficiency.

KEY TO GOVERNANCE ADOPTION: PEOPLE, PROCESS, TECHNOLOGY

Achieving modernized governance is a multi-dimensional effort that requires cohesive action across human resources, operational workflows, and technical solutions.

1. People

- **Training & Awareness:** Empower statisticians, data managers, and programmers to understand *why* governance matters. Host regular workshops and refreshers on emerging regulations.
- **Governance Champions:** Identify internal experts who can evangelize best practices, lead pilot implementations, and guide teams through tool integrations.
- **Cross-Functional Collaboration:** Governance should not be the sole responsibility of QA or compliance teams. Encourage joint initiatives with IT, data science, and clinical operations to maintain alignment.

2. Process

- **Risk-Based SOPs:** Traditional SOPs often outline uniform QC steps for all deliverables. Update these documents to reflect a risk-based approach, ensuring higher scrutiny where the stakes are higher.
- **Early Integration:** Introduce governance and QC checklists at project inception, not merely before a regulatory submission deadline. This fosters a “compliance by design” mindset.
- **Continuous Monitoring:** Move away from end-stage audits to ongoing reviews. Distribute smaller, more frequent checkpoints throughout the development cycle to spot issues early.

3. Technology

- **Unified SCE:** Invest in platforms that combine development, version control, and QC tracking under one roof. A single source of truth minimizes confusion around dataset versions or code branches.
- **Automation & AI:** Use rule-based engines for routine checks and advanced AI modules for anomaly detection, predictive risk scoring, and real-time alerts.
- **Scalable Architecture:** As data volumes grow, your SCE should be able to handle increased activity without sacrificing performance. Cloud-based solutions often offer elasticity and robust security.

By balancing these three pillars, organizations can lay the groundwork for sustainable governance that evolves in tandem with regulatory changes and scientific advances.

CONCLUSION

Effective governance in QC tracking is both a requirement and an opportunity—an opportunity to reduce operational costs, improve data reliability, and expedite regulatory submissions. By embedding governance principles directly into daily programming tasks, clinical teams can move beyond reactive reviews and create a culture of continuous compliance. As regulators become more vigilant in assessing data lineage, automation and AI-driven checks offer a robust defense against both inadvertent and intentional non-compliance. The alignment of people, process, and technology ensures that governance itself becomes an integral, value-added dimension of clinical trial execution.

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