

Leading Through the Fog: Resilient Technical Leadership in a BANI Clinical World

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ABSTRACT

The clinical research landscape is no longer just volatile—it is brittle, anxious, nonlinear, and incomprehensible (BANI). Technical teams across clinical programming, biostatistics, and data management are facing growing challenges: fragile systems, shifting timelines, AI-driven complexity, and rising team fatigue. This session offers a reflective leadership perspective to help navigate these conditions with clarity and resilience. Through relatable real-world scenarios and current industry trends, we'll explore how individuals in technical roles are adapting to constant change. Grounded in the CLEAR leadership model—Courage, Listening, Empathy, Adaptability, and Resilience—this session presents practical insights for leading teams, managing uncertainty, and staying grounded amid complexity. By connecting leadership mindsets with everyday challenges in clinical development, the session aims to spark meaningful reflection and equip professionals with new ways to think about resilience, influence, and sustainable performance in a high-pressure, high-impact industry.

INTRODUCTION

Clinical trials today face unprecedented pressures: frequent protocol amendments, evolving regulatory expectations, parallel timelines, and rapid technological change. These factors create a landscape where change is not the exception but the environment itself. Leaders must develop new routines and mindsets to thrive.

Why This Matters Now

Recent years have seen a dramatic increase in protocol amendments and operational complexity:

- ~76% of Phase I–IV protocols now include at least one amendment (up from ~57% in 2015).
- Completed protocols average ~3.3 amendments—a 60% increase over earlier benchmarks.
- Phase III trials average ~3.5 amendments per protocol.

These changes are compounded by regulatory updates during studies, new system implementations, and the growing use of automation and AI. Teams are often exhausted, yet delivery expectations remain unchanged.

The BANI Framework

The BANI model describes the current environment:

- Brittle: Systems fail under small stress.
- Anxious: Pressure to deliver without stable ground.
- Nonlinear: Minor changes create major delays.
- Incomprehensible: Outcomes are harder to predict or explain.

Where Complexity Shows Up

Complexity in clinical trials manifests in several ways:

- Design decisions have far-reaching impacts.
- Change often arrives after work is stabilized.
- Interdependencies multiply faster than plans adapt.
- Effort increases without proportional progress.

Case Study: A Small Change, Outsized Impact

Background

During a pivotal oncology trial, the protocol initially specified:

‘Patients must have received no more than one prior line of systemic therapy.’

This criterion was designed to ensure a homogeneous patient population and streamline statistical analysis.

The Amendment

Midway through the study, new external data and evolving regulatory guidance prompted a protocol amendment:

‘Patients may have received up to two prior lines of systemic therapy, provided the most recent therapy was

completed at least 6 months prior to screening.’

Immediate Impacts

- Data Review: All previously collected patient data had to be re-examined to identify newly eligible subjects and ensure compliance with the revised criteria.
- SDTM and ADaM Derivations: The data management team created 18 new SDTM derivations and revised 11 ADaM datasets to accommodate the expanded eligibility.
- Output Rework: Seven tables, listings, and figures (TLFs) previously considered final were reworked to reflect the new patient cohort and analysis populations.
- Submission Readiness: The timeline for regulatory submission shifted, as the biostatistics and medical writing teams needed additional time to incorporate the changes and re-run analyses.

Team and Leadership Challenges

- Resource Strain: Increased workload for data managers, programmers, statisticians, and medical writers.
- Communication Complexity: Cross-functional teams had to rapidly align on new definitions and communicate changes to external partners.
- Risk of Burnout: Pressure to deliver on unchanged timelines led to fatigue and risk of errors.

Leadership Response

Applying the CLEAR framework:

- Courage: Named the impact early, communicating scope and risks.
- Listen: Solicited team feedback to surface concerns.
- Empathy: Acknowledged cost and provided support, including resource augmentation.
- Adapt: Reworked project plan with new milestones and buffers.
- Resilient: Maintained quality standards despite disruption.

Lessons Learned

- Minor protocol changes can have major downstream effects.
- Early impact assessment and transparent communication are critical.
- Resilient leadership stabilizes teams and maintains delivery standards under shifting conditions.

Environment Shift: Industry Benchmarks and Operational Signals

Benchmarks:

- Protocol amendments are now routine.
- Regulatory guideline updates occur during study conduct.
- New systems and platform implementations are common.
- Parallel timelines and evolving submission expectations are the norm.
- Increased use of automation and AI tools.

Sources: Tufts CSDD; TransCelerate

Leadership Response: The CLEAR Model

To navigate this environment, leaders must demonstrate CLEAR behaviors:

- Courage: Decide early and name the impact.
- Listen: Hear the team and stakeholders.
- Empathy: Acknowledge the cost of change.
- Adapt: Re-plan intentionally and deliberately.
- Resilient: Hold the line and stabilize the team.

CLEAR in Action

A single protocol amendment can be a leadership moment:

- C: Name the impact.
- L: Hear the team.
- E: Acknowledge the cost.
- A: Re-plan intentionally.
- R: Hold the line.

Implications for Leaders

Leaders must:

- Surface assumptions, risks, and triggers early (Brittle).
- Listen and empathize to manage pace and capacity (Anxious).
- Adapt deliberately, triggering replans at defined thresholds (Nonlinear).
- Stabilize quality, focus, and morale (Incomprehensible).

Key Takeaways

- Change isn't the exception—it's the environment.
- Leadership is what stabilizes teams and enables delivery.
- Adopt routines that anticipate, listen, adapt, and stabilize.

Q&A and Reflection

- What's one leadership routine you'll adopt after today?
- Which BANI pressure is most acute in your current projects?

References

- [New Benchmarks on Protocol Amendment Practices, Trends and their Impact on Clinical Trial Performance | Therapeutic Innovation & Regulatory Science](#)

CONTACT INFORMATION

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