

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

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Agenda

- Today's clinical environment
- Where Complexity shows up
- Leadership behaviours that matter
- Closing reflections

Why This Matters Now



Late protocol amendments reset weeks of programming.

Regulatory expectations are evolving during ongoing studies.

Evolving systems and faster submissions - improve patient access

Advancing disease landscapes demand faster treatment delivery



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



DESIGN DECISIONS
TRAVEL FAR.



CHANGE OFTEN ARRIVES
AFTER WORK IS
STABILIZED.



INTERDEPENDENCIES
MULTIPLY FASTER THAN
PLANS ADAPT



EFFORT INCREASES
WITHOUT PROPORTIONAL
PROGRESS

A Small Change, Outsized Impact

Change

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



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.

What Followed:

- ✓ Review of data already collected
- ⚙ Additional derivations across SDTM and ADaM
- 📅 Rework of outputs already considered complete
- 🔄 Submission readiness shifted

Environment Shift

Protocol Amendments are now routine

~76% of Phase I – IV protocols include at least one amendment (up from ~57% in 2015)

Completed protocols average ~3.3 amendments (~60% increase over earlier benchmarks)

Phase III trials average ~3.5 amendments per protocol

Regulatory guideline updates during study conduct

New systems and platform implementations

Parallel timelines and evolving submission expectations

Increased use of automation and AI tools

Leadership Response



CLEAR behaviours that matter in a
changed environment

C – Courage

L – Listen

E –Empathy

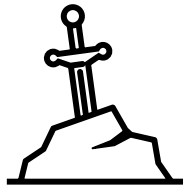
A – Adapt

R – Resilient



CLEAR in Action

A single protocol amendment – five leadership moments



C

Name
the impact



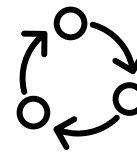
L

Hear
the team



E

Acknowledge
the cost



A

Re-plan
intentionally



R

Hold
the line

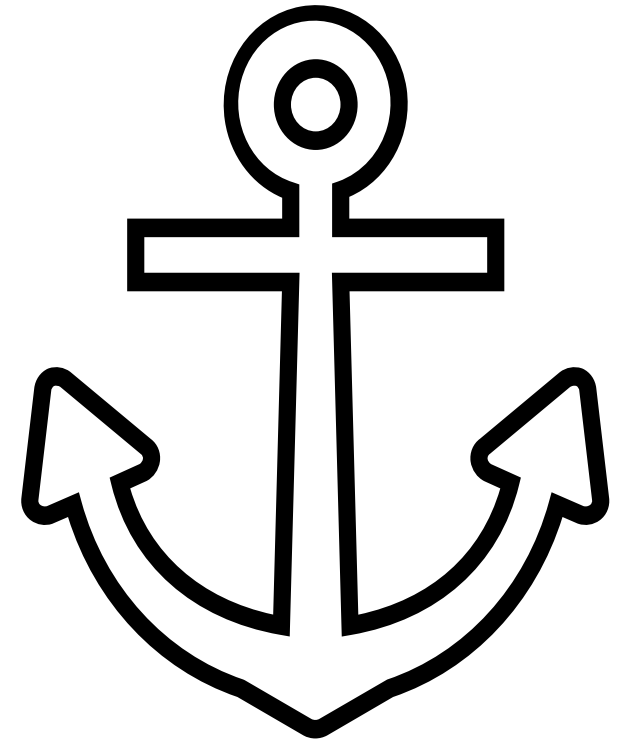
Implications for Leaders

Pressure	Impact on teams	Leadership Levers(CLEAR)
Brittle	Small shocks break workflows	C — Anticipate: Surface assumptions, risks and triggers early
Anxious	Uncertainty drives rework & burnout	L/E — Listen & empathize: pace checks, capacity buffers
Nonlinear	Minor changes → major delays	A — Adapt deliberately: trigger replans at amendment risk $\geq X$
Incomprehensible	Outcomes hard to predict/explain	R — Stabilize: Protect quality, focus and morale



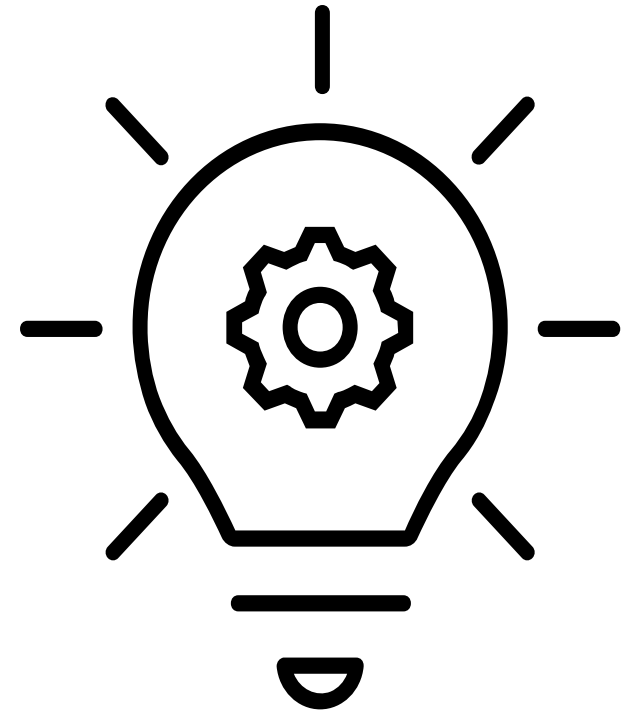
Key Takeaways

- ✓ Change isn't the exception – it's the environment
- ✓ Teams can handle complexity when leadership provides clarity and steadiness.
- ✓ In a shifting system, leadership becomes the stabilizer.



Q&A

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





Thank you