



CRO Team Continuity: A Strategic Advantage in Early Phase Development



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Full-Service CRO Specializing in Phase I-II Clinical Studies

100-Bed Phase I Unit

- On-site cGMP pharmacy
- In-house clinical laboratory



- First-in-Human through NDA-enabling
- Global network of strategic partner sites
- Normal healthy volunteers and special populations
- Protocol design through CSR publishing



The Scientist's Perspective

Success from a team perspective

Your trial operations team is your team

- Experience pays off in cost and outcomes
- A program approach works for investors, vendors and regulators
 - Builds relationships
 - Drives quality
 - Contains costs



Continuity in Project Leadership

The hidden multiplier

Program continuity is not a “nice to have.”
It is a delivery infrastructure.

- Continuity compounds learning
- Handoffs compound risk
- Continuity is risk management



Anita Phillips

Senior Project Manager

Dr. Vince Clinical Research



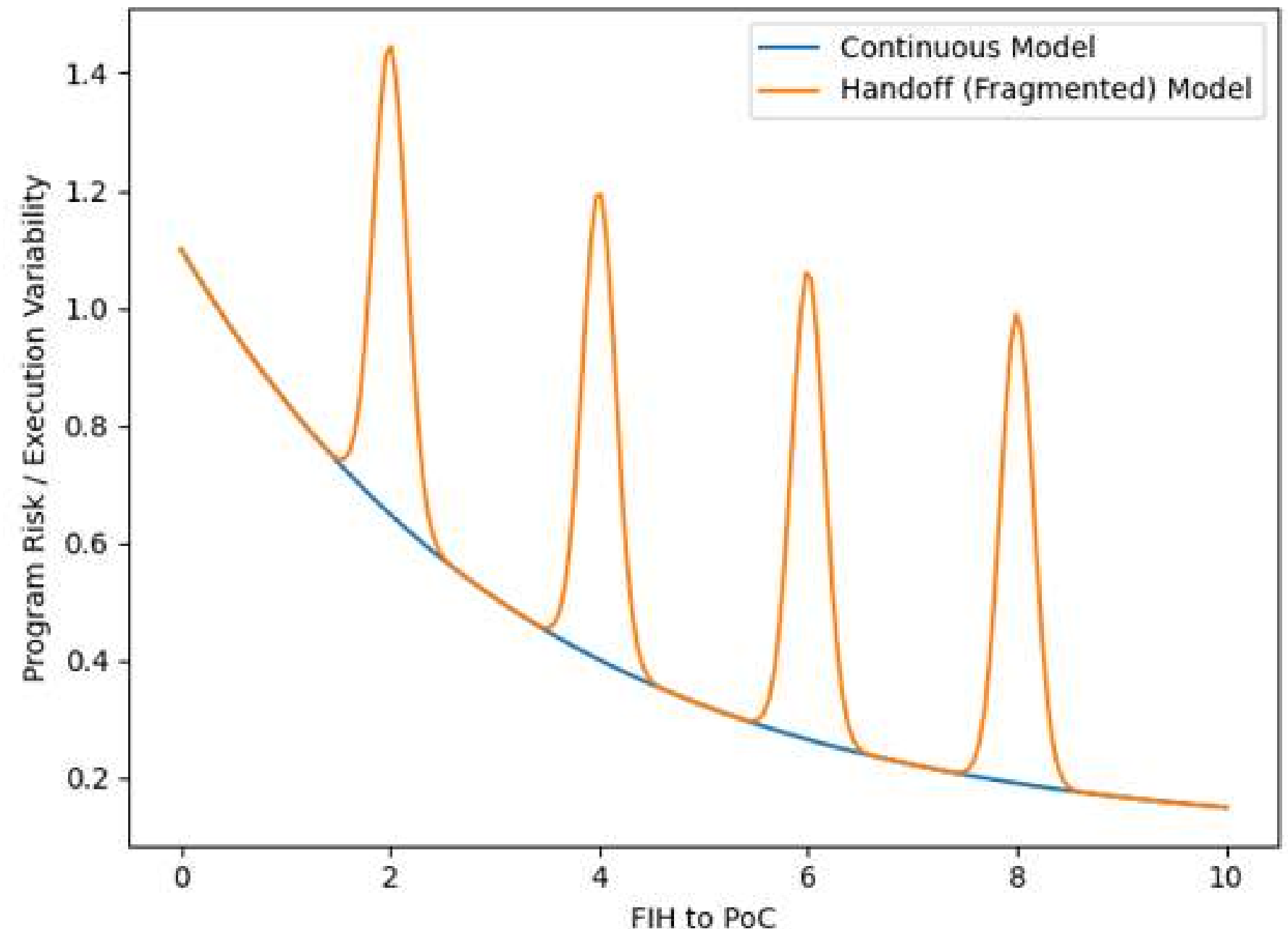
Continuity as an Execution Strategy

Program A (Continuity)	Program B (Reset)
FIH completed	FIH completed
Phase 1b start - accelerated	Phase 1b start - slower
Faster decisions	Reconstructed context
Momentum builds	Momentum slows

The difference is rarely the molecule it is continuity

The Sponsor Reality: Early Phase Is Not Modular

- FIH → SAD/MAD → Phase 1b → PoC is a continuous scientific narrative
- Decisions in Study 1 directly shape Study 2 and 3
 - Operational
 - Regulatory
- Typical experience:
 - New PMs
 - New operational leads
 - New governance structures
- Path from FIH → phase 2 enables funding and regulatory pathway



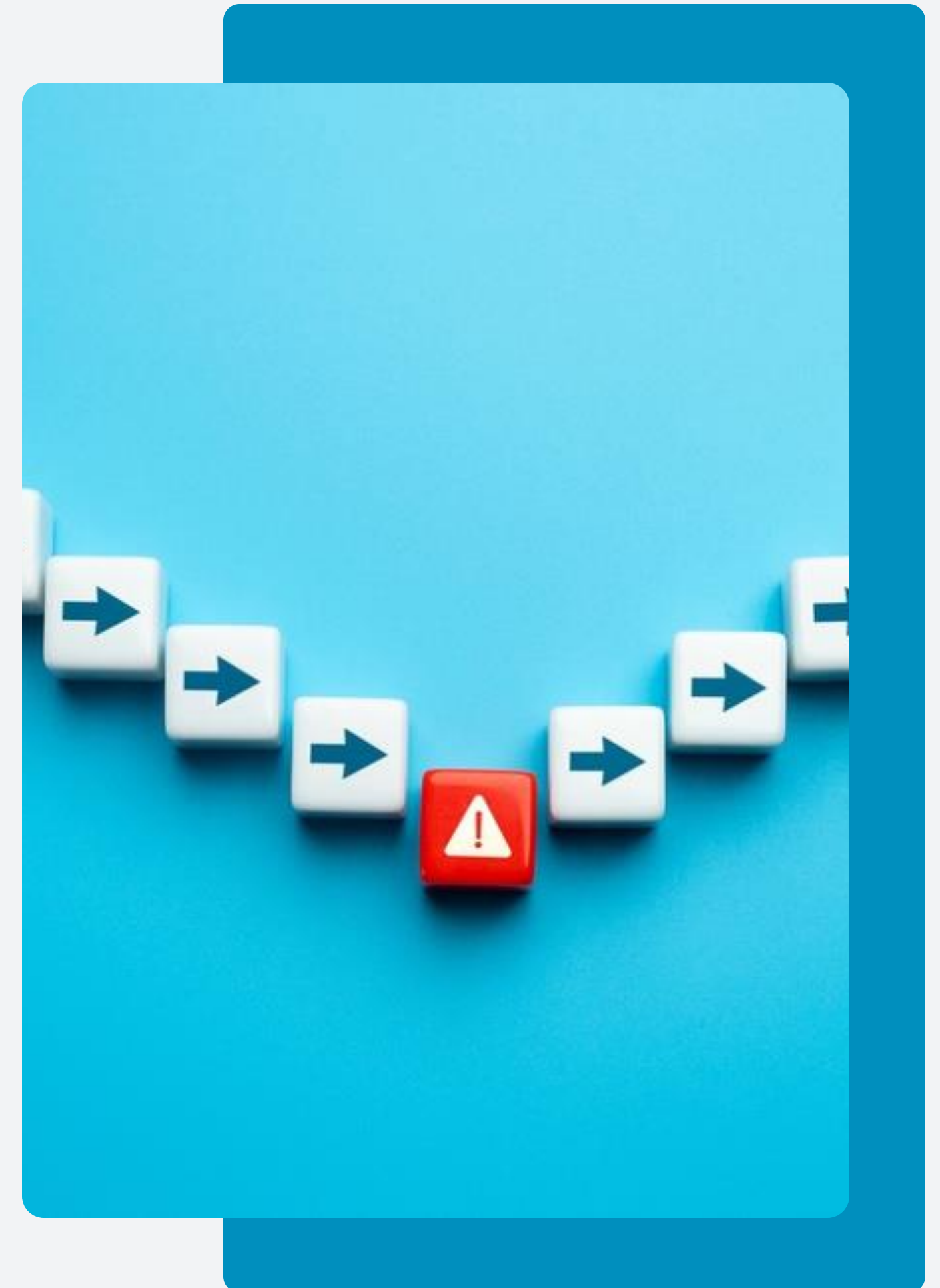
What Gets Lost in a Reset

What gets lost

- Design rationale
- Escalation history
- Risk tolerance calibration
- Cohort pattern recognition
- Sponsor decision logic

Result

- Re-litigation of decisions
- Conservative re-planning
- Slower decision cycles





Two Common Continuity Breakpoints

Internal Reset

- PM transition between phases
- No sustained program lead
- Context reconstruction required

External Reset

- CRO transition between phases
- New oversight frameworks
- Historical reinterpretation required

Impact

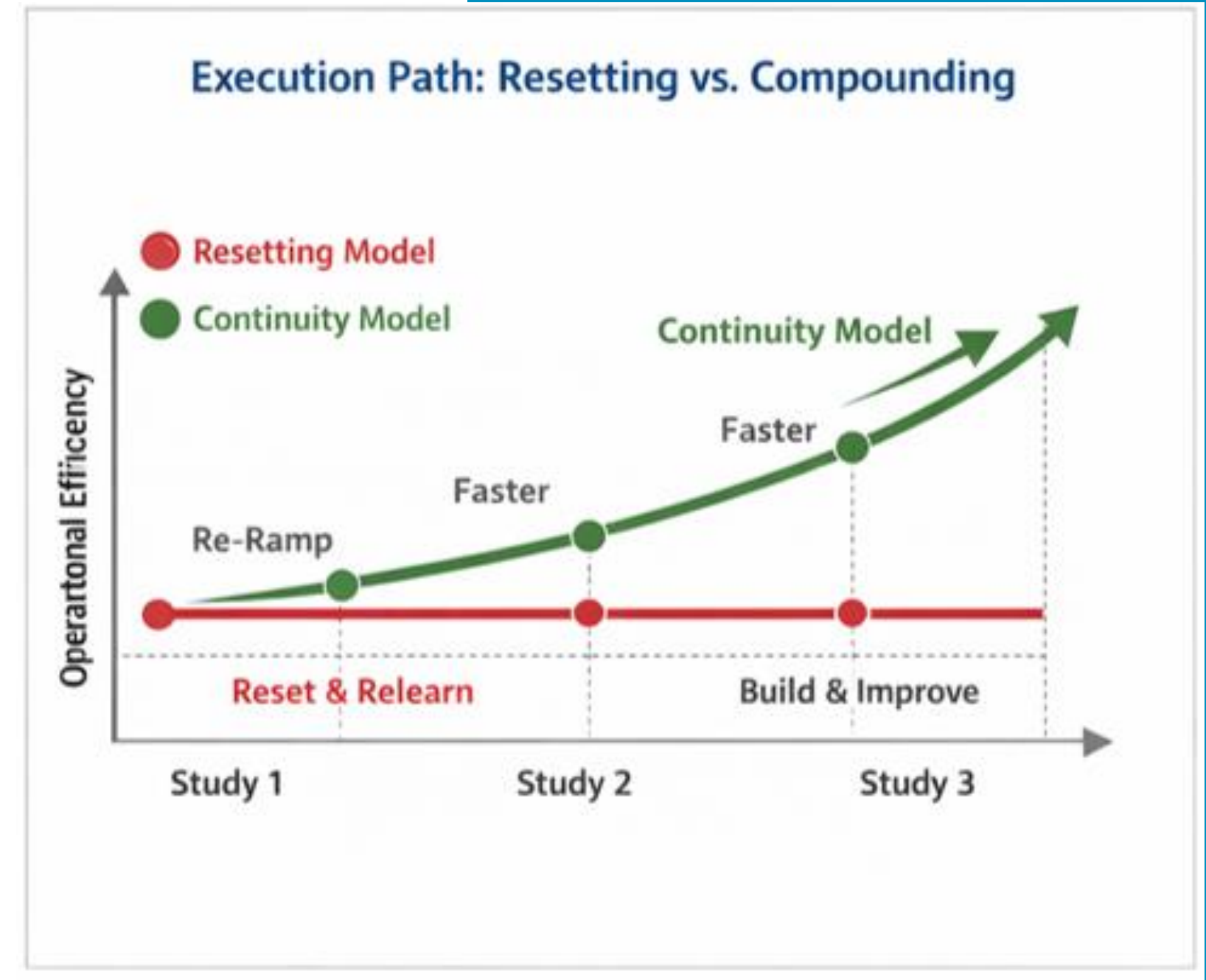
- Decision velocity slows
- Risk calibration resets
- Historical context must be rebuilt

Continuity Compounds Execution Efficiency

Each phase starts from a higher baseline

- Protocol development accelerates
- Sites and vendors start faster
- Pattern recognition improves
- Governance becomes lighter
- Decisions require less reconstruction

Execution improves as the program progresses



Phase 1b/2a: The Continuity Infection Point

Program complexity increases

- Adaptive designs
- Multiple cohorts
- Expanded operational scope
- Higher governance visibility

Team continuity often resets

- New CRO engagement
- New leadership structure
- New monitoring teams
- Reinterpretation of prior decisions

Programs scale at Phase 1b/2a

The question is whether continuity scales with them

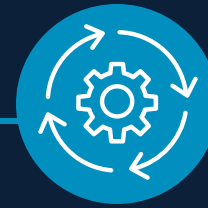


Designing Continuity into Early Phase Execution

Three Structural Layers of Program Continuity



Interpretive Leadership
(Program Lead / PM)



Operational Execution
(Study Management)



Data Oversight
(Clinical Monitoring)

Study Management Continuity

- Preserves clinic execution rhythm
- Maintains protocol intent across cohorts
- Anticipates operational friction
- Reduces cohort-to-cohort noise



Monitoring Continuity

- Cohort-to-cohort pattern recognition
- Consistent deviation interpretation
- Early signal sensitivity
- Preserved escalation logic



Inspection Readiness as Structural Proof

- Stable oversight narrative
- Consistent escalation logic
- Coherent interpretive history
- Reduced late-stage regulatory surprises



Traditional Question:

“Can you run this study?”

Evolving Question:

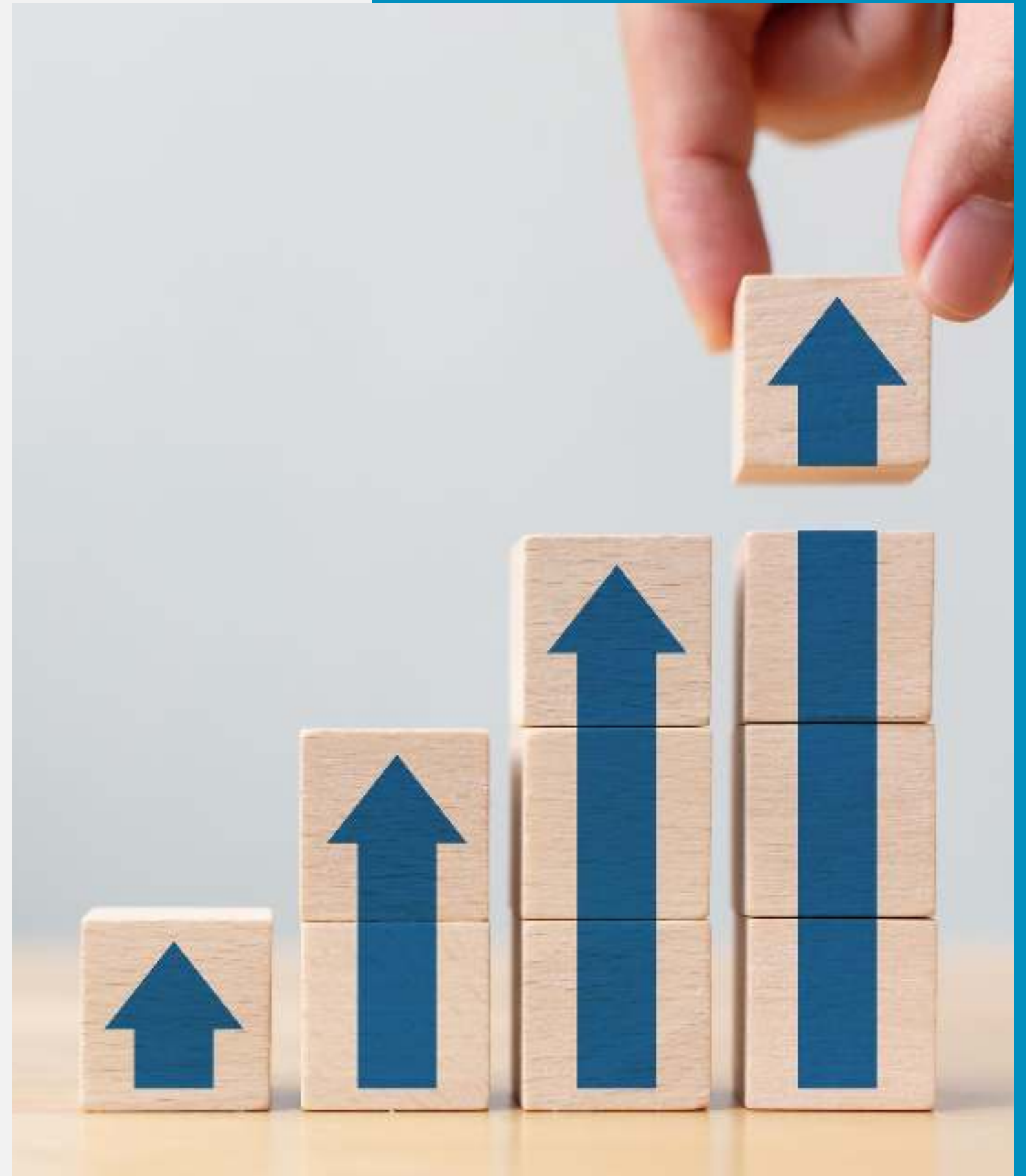
“**Will the same leadership and oversight framework own this molecule at Proof of Concept?**”



Leadership Engagement

- You should have engagement:
 - Project level (tactics)
 - Corporate level (strategy)
- Corporate level leaders focus on long-term success
- Together, sponsor, project, and executive stakeholders will deliver program success

**We are in it for the program,
not just for the project**





Thank you



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