



Thriving in Change: Building People, Process, and Technology Capabilities in Statistical Programming

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Industry Transformation – Why Now?

- AI, automation, and digital transformation reshaping clinical development
- Growing data complexity and regulatory expectations
- Shorter timelines with higher quality requirements



The Capability Framework

Thriving requires three connected capabilities

- People: resilience & mindset
- Process: structured adoption
- Technology: AI & automation



People Capability

Why Resilience Matters

- Hybrid and global teams
- Constant technology change
- Regulatory pressure and tight timelines
- Without resilience: burnout, resistance, slow adoption



People Capability

Building Psychological Safety

- Anonymous pulse surveys
- Open forums and idea sharing
- Safe-to-fail experimentation
- Innovation happened when people feel safe to speak up



People Capability

Practical Actions

- Peer mentoring programs
- Micro-learning modules
- Scenario-based workshops
- Knowledge-sharing communities
- Outcome: faster adoption and higher engagement



Process Capability

From Innovation to Adoption

- Good tools fail without adoption
- Agile-Lean hybrid methodologies
- Iterative delivery and feedback loops
- Shift from task-based to strategic programming



Process Capability

Adoption methods

- Structured change management¹
 - Embed tools into real deliverables
 - Engage stakeholders early
- Minimum Viable Product (MVP) Pilots
 - Test small, measure impact, scale what works
- Agile-Lean Integration



Process Capability

Compliance by design

- CDISC standards and validation
- Metadata-driven automation
- Digital audit trails and reproducibility
- Innovation must strengthen compliance



Technology Capability

The Engine of Scale

- AI copilots and automation
- Open-source ecosystems
- Containerized pipelines
- Benefits: speed, accuracy, scalability



Technology Capability

Technology examples in statistical programming

- AI-assisted code generation
- Automated dataset validation
- Reproducible pipelines
- Low-code workflow orchestration
- Time- savings on repetitive tasks



Technology Capability

Responsible AI & governance

- Human oversight and accountability
- Traceability and version control
- Explainable and reproducible results
- Align with FDA AI/ML guidance



Bringing It Together

- Tech only -> underutilized tools
- Process only -> rigidity and slow delivery
- People only -> inconsistent execution
- All three together -> sustainable performance



Key Takeaways & Call to Action

- Build psychological safety
- Pilot before scaling
- Automate responsibly
- Invest in upskilling
- Resilient people + adaptive process + smart tech = thriving teams



Thank You –
Questions?

