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Single Day Events

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Smarter, Not Faster

Reimagining Efficiency in
Statistical Programming

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The Efficiency Paradox

THE PROBLEM



The Efficiency Paradox

Are we solving the right problem?

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- **More tools, yet efficiency feels harder**
 - Faster execution alone is not enough
 - Efficiency now emphasizes smart decision-making
- **Rework and QC cycles increasing**
 - Automations focus on optimizing isolated workflow steps
 - Integrated approaches bring upstream clarity and prevent downstream rework
- **Speed vs quality misalignment**
 - Faster initial delivery can result in higher rework
 - Late-stage quality checks frequently extend overall timelines



Where Efficiency is Lost

- **Increasing Protocol Complexity**
 - Innovative study designs and analyses
 - More endpoints and intercurrent events
- **Limitations of Automation**
 - Optimizes individual steps with tools and macros
 - Automates execution, not decision-making or analytical intent
- **Regulatory and Quality Demands**
 - Regulatory expectations demand transparency and reproducibility
 - Excessive QC adds effort without improving outcomes
- **Outdated Efficiency Models**
 - Output-focused metrics ignore rework and true cycle time
 - QC-heavy models cannot scale with trial complexity





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Redefine Efficiency

THE SHIFT



Efficiency Beyond Speed

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- **Balanced Approach to Speed**
 - Prioritize quality, consistency, and regulatory confidence in clinical trials
- **First-Time-Right Delivery**
 - Deliver correct and defensible results aligned with trial objectives
- **Focus on Outcomes Not Activity**
 - Assessing process value through outcomes enhances inspection readiness and shifts accountability to quality delivery
- **Embedding Quality Early**
 - Early quality embedding, transparent intent, and lifecycle traceability align with regulations and support productivity gains





From Automation To Augmented Intelligence

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Automation

Automation handles predefined tasks efficiently but cannot resolve ambiguity or make contextual decisions.

Repetition of Workflow Steps

Augmented Intelligence

Augmented intelligence combines human expertise with computational power to enhance decision-making

Generation and Validation

Human in the Loop

Experienced professionals review and validate augmented intelligence outcomes to maintain scientific rigor and compliance.

Judgment and Decisions

Together

Augmented intelligence shifts focus from execution to decision support, boosting productivity and responsibility

Scalable Efficiency

Working Smarter, Not Faster



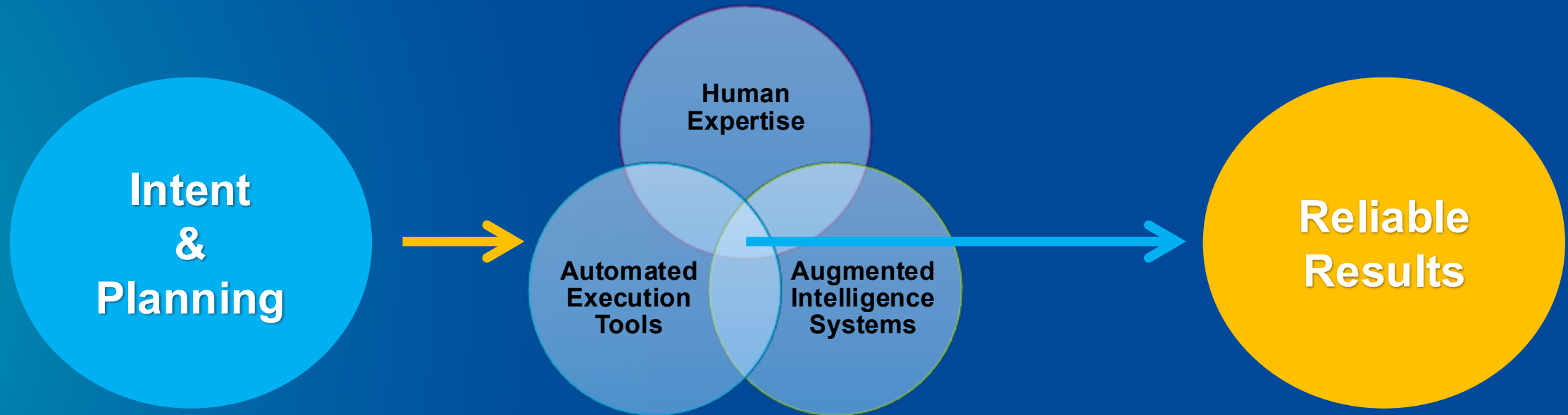


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Augmented Intelligence

THE MODEL

Augmented Intelligence Model





Smart QC

Through Risk-based Validation

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Limitations of Traditional QC

- Exhaustive methods like universal dual programming are unsustainable with increasing complexity and tight timelines

Risk-based, Targeted Checks

- Validation efforts prioritize high-risk analyses impacting patient safety, trial results, and regulatory decisions

Quality-by-Design Integration

- Embedding quality into trial processes reduces reliance on end-stage inspections and improves efficiency

Benefits & Implementation

- Risk-based approaches cut QC effort, boost critical output confidence, and require cultural and procedural shifts



Traceability by Design

Embed Early in the Lifecycle

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Regulatory Expectation for Traceability

- Traceability is required by regulations and must be established proactively, not retrospectively.

Alignment of Trial Components

- Early traceability aligns objectives, endpoints, data collection, analysis, and reporting transparently.

Benefits of Early Traceability

- Embedding traceability early reduces ambiguity, supports reproducibility, and eases health authority responses.

Efficiency Through Proactive Approach

- Although time-consuming upfront, early traceability decreases rework and enables inspection-ready outputs.



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Role Evolution & Roadmap

THE FUTURE



Evolving Roles

Biostatisticians & Statistical Programmers

- **Shifting Responsibilities**
 - Roles are moving upstream to include trial design, estimand framework, and risk assessment responsibilities.
- **Scientific Partnership**
 - Biostatisticians and programmers act as scientific partners, applying expert judgment supported by intelligent tools.
- **New Skill Demands**
 - New skills include systems thinking, cross-platform data literacy, and understanding AI capabilities and limits
- **Augmented Intelligence Impact**
 - Augmented intelligence amplifies human expertise, increasing the importance of biostatisticians and programmers





A Pragmatic Roadmap *For Implementation*

- **Level 1: Immediate Term Actions**
 - Adopt risk-based QC frameworks, standardize analysis patterns, and pilot AI tools in low-risk areas to start transformation
- **Level 2: Near-Term Process Enhancements**
 - Develop metadata-driven workflows, embed traceability across processes, and establish governance for intelligent tools
- **Level 3: Team Upskilling and Governance**
 - Upskill teams for augmented intelligence and implement governance to manage risks during transformation
- **Maturity Level: Sustainable Improvement Strategy**
 - Align strategy, process, and capabilities to achieve steady improvements without disrupting delivery commitments





What Success Looks Like



Outcome-Focused Efficiency

- Success means consistent first-time-right delivery and faster submissions without quality compromise.



Confident and Empowered Teams

- Teams operate with confidence, using clear traceability and validation frameworks for smoother inspections.



Technology Enhances Impact

- Professionals feel empowered by intelligent tools that enhance their productivity and impact.



Organizational Resilience

- Success leads to resilience, scalability, and sustained relevance in complex clinical research environments.





Key Take Aways

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- **Redefining Efficiency**
 - Efficiency now includes quality, traceability, and confidence beyond just speed in statistical programming
- **Role of Augmented Intelligence**
 - Augmented intelligence complements automation to handle today's complex challenges effectively
- **Risk-Based Quality Control**
 - Implementing risk-based QC, early traceability, and connected standards drives practical improvements in processes
- **Elevated Professional Roles**
 - Biostatisticians and programmers remain central, with technology elevating their impact in clinical development

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