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Single Day Events

Mumbai, India

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The Human Edge in an Automated World

Keynote - 3
Deven Babre – Fresh Gravity
18th April 2026
10:15 – 10:45 Hours

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Disclaimer

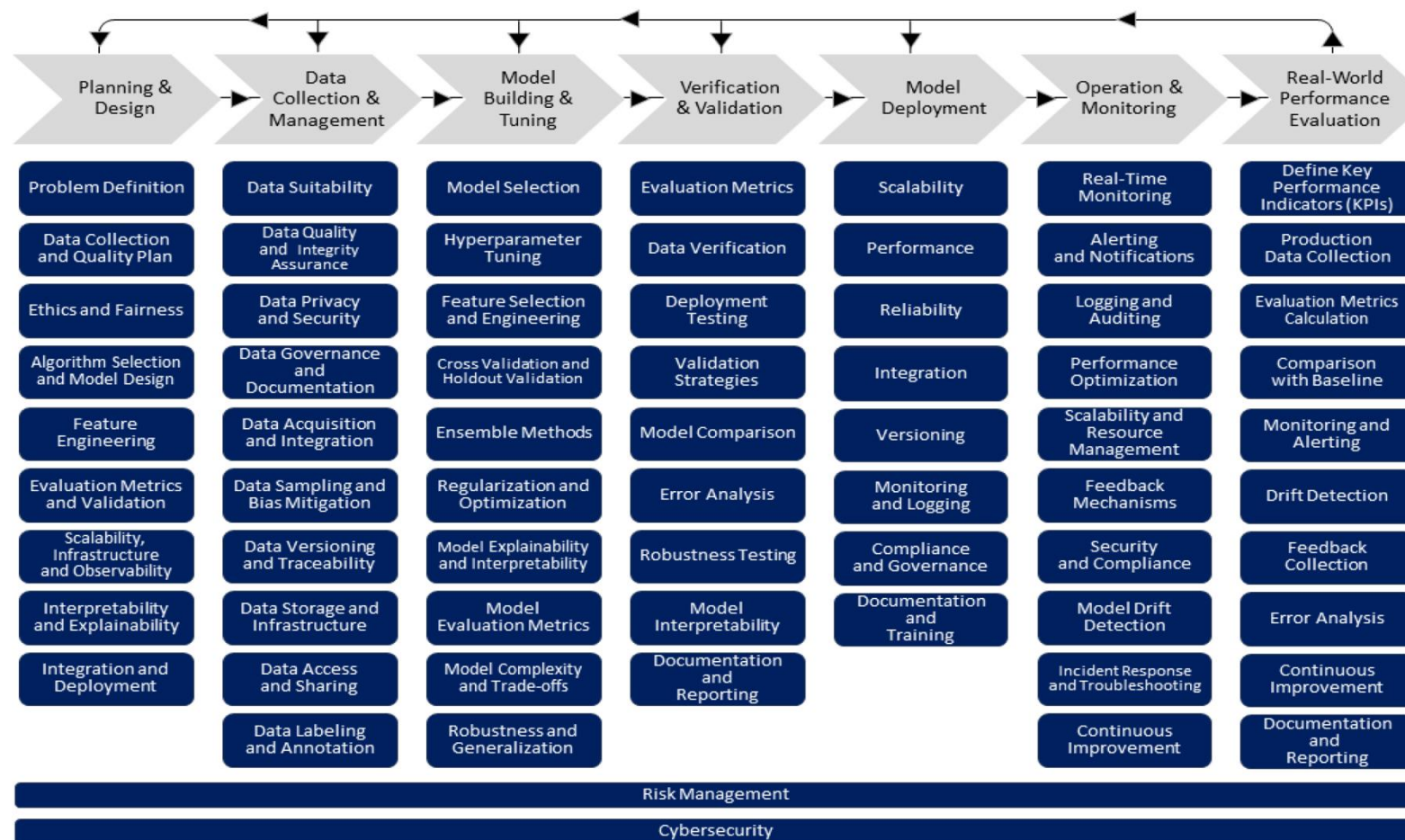
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- **This presentation includes perspectives on artificial intelligence and automation in clinical trials. AI-generated insights may have limitations, and human oversight remains essential. The content should not be solely relied upon for critical decision-making without appropriate validation and expert review.**

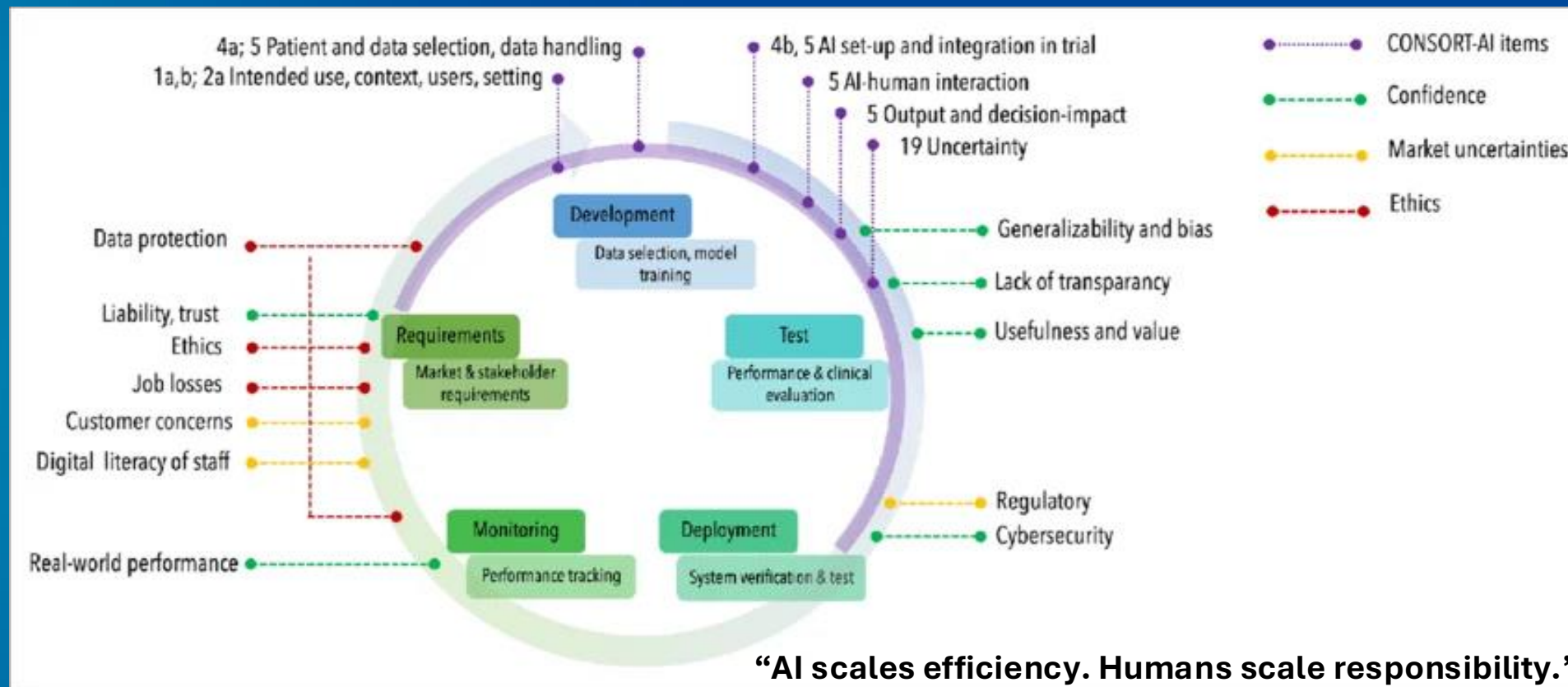


Lifecycle of (AI)

**“But here’s the truth—AI
doesn’t own outcomes...
humans do.”**



Lifecycle of (AI) applications





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AI Application – Clinical Trial Data Lifecycle

Digital Biomarkers & Continuous Monitoring



- Smartwatches, wearables, voice sleep, HR sensors
- AI detects changes in patient status

Risk-Based Monitoring



- Site-level AI risk scores and deviation detection
- AI automates issue detection

Automated Data Cleaning & Standardization



- NLP standardizes free text
- ML imputes missing values

“But when a regulatory authority asks—‘*Why did this data change?*’

AI doesn’t answer... **we do.**”



Check Point

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**Domains /
Divisions**

**# of
Documents /
Trial**

**# of Units
Programming**

“It’s not inefficient because people are slow...
It’s inefficient because systems were never designed for intelligence.”



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In AI We Trust... But Humans Sign Off

1 “The Judgment Layer” – Where Science Meets Responsibility

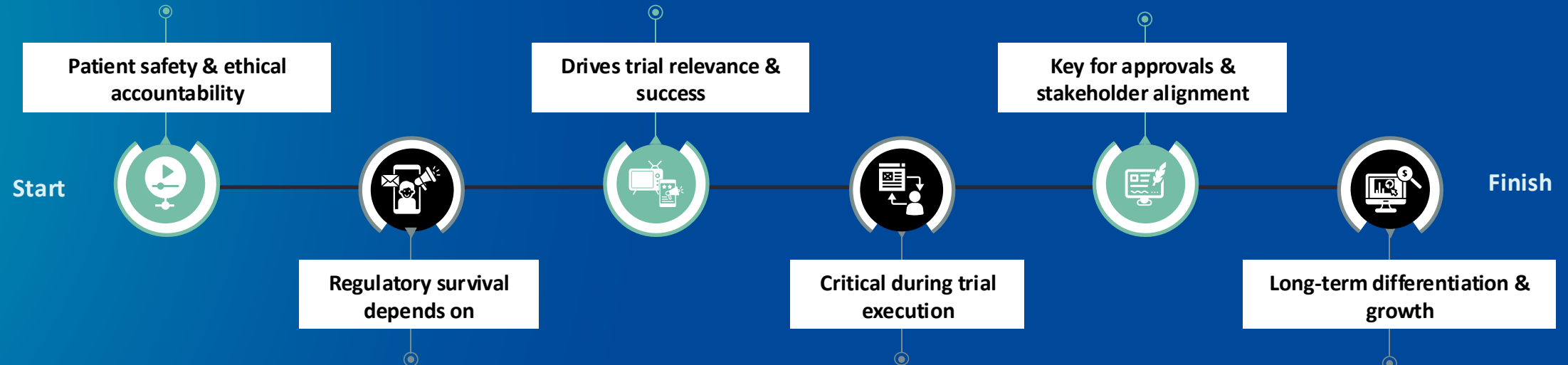
- AI supports—but humans make final clinical and ethical decisions on benefit-risk.

3 “The Patient Pulse” – Beyond Data, Into Human Experience

- Human understanding ensures patient-centric design, diversity, and retention.

5 “The Story Engine” – Turning Data into Decisions

- Transforms complex data into clear regulatory narratives and insights.



2 “The Trust Anchor” – Compliance with Confidence

- Ensures GxP compliance, audit readiness, and trustworthy, explainable outputs.

4 “The Navigator” – Thriving in Uncertainty

- Humans manage ambiguity, protocol deviations, and emerging risks.

6 “The Innovation Spark” – Powering What Machines Can’t Imagine

- Humans drive new trial models, hypotheses, and scientific breakthroughs.

➤ TRUST
➤ INTEGRATION
➤ GOVERNANCE



The Human Edge Framework



Automation	Human Judgement	Collaboration	Leadership
			
Consistent	Pattern-Based	Rule Driven	
Contextual	Integrated	Accountable	Transparency
Critical Thinking			
Continuous Improvement			
Anticipated	Shared	Mitigated	Departmental requirements
Risk Alignment			
Rule-Driven	Interpreted		Transparent
Governed			
Meaningful	Connected	Transformational	Scalable
Efficiency Gain (Tangible & Non-Tangible)			
Stakeholder Impact			

“AI suggests. Humans certify.”



Use cases

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Clinical Data Management

- AI-driven data cleaning & anomaly detection
- Auto query generation & resolution
- Real-time data review dashboards

Impact

- 30–50% cycle time reduction
- Improved data quality
- Continuous monitoring vs periodic review

Biostatistics & Statistical Programming

- Auto-generation of TFLs (Tables, Listings, Figures) Natural language → Statistical code
- Adaptive trial simulations

Shift

- From coding → Statistical strategy
- From outputs → Insights

Risk Based Quality Management

- Predictive risk modelling
- Site performance analytics
- AI-driven monitoring triggers

Outcome

- Proactive risk mitigation
- Reduced monitoring cost
- Better inspection readiness

Pharmacovigilance (Clinical Trials)

- AI-based case intake & triage
- Signal detection using ML models
- Automated aggregate reporting

Impact

- Faster safety insights
- Improved compliance
- Enhanced patient safety

“The future is not AI vs Humans...
It is AI *with* Humans—designed intentionally.”

Traditional Model

- Manual programming (SDTM/ADaM/TLF)
- Reactive operations (issue resolution, data cleaning)
- Effort-driven delivery

Human Edge Model - **Focus on**

Study design optimization, Endpoint relevance, Data interpretability

- Automation generates output
- Humans define what matters

With Automation (AI/GenAI)

Auto-generation of:

- SDTM/ADaM datasets
- TLF shells & outputs
- QC checks

Shift in Statistical Programming

Traditional Role	Human Edge Role
Writing SAS/R scripts	Designing reusable analytical frameworks
Dataset conversion	Ensuring scientific integrity of data
TLF generation	Insight-driven outputs for decision-making

Human Edge in Programming

- Define analysis strategy
- Validate clinical relevance of outputs
- Interpret anomalies vs blindly flagging them
- Ensure regulatory defensibility

Code can be automated, judgment cannot

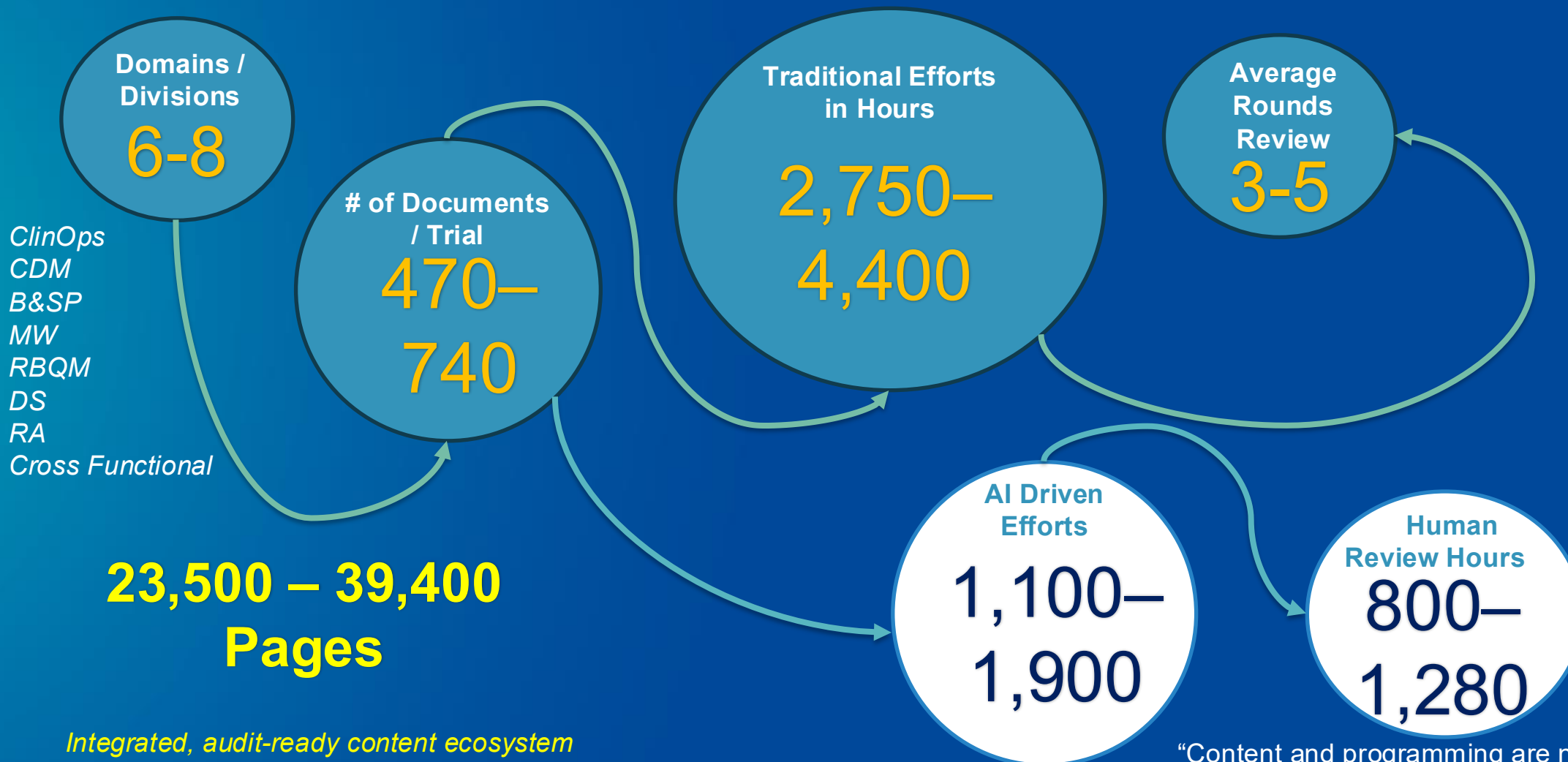
“Human-in-the-loop is not a control...

It’s a **compliance necessity.**”



Modern way

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Integrated, audit-ready content ecosystem

“Content and programming are no longer separate... They are part of a **unified intelligence layer**.”



AI Strategy for Clinical Data & Risk Excellence: Scaled for Pharma

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Function	Small Pharma (Agile / Cost-Conscious)	Mid Pharma (Scaling / Standardizing)	Large Pharma (Enterprise / Transformational)
Clinical Data Management (CDM)	Focus: Automation Lite • EDC-based auto edit checks • Basic anomaly detection • Outsource-heavy model AI Strategy: Plug-and-play tools Implementation: 1–2 studies	Focus: Standardization • AI-driven data cleaning • Central data review dashboards • Reduced manual queries AI Strategy: Integrated platforms Implementation: Portfolio-level rollout	Focus: Intelligent Data Ecosystem • End-to-end automation (ingestion → cleaning → review) • Real-time data pipelines • AI-assisted medical review AI Strategy: Custom AI models + data lake Implementation: Enterprise-wide CDM transformation
Risk-Based Quality Management (RBQM)	Focus: Risk Identification • Rule-based risk indicators • Basic dashboards AI Strategy: Pre-built risk models Implementation: Study-level monitoring	Focus: Predictive Risk Management • AI risk scoring (site/patient) • Central monitoring teams • KRIs/KPIs tracking AI Strategy: Configurable AI tools Implementation: Multi-study integration	Focus: Proactive Quality Engine • Predictive + prescriptive analytics • Cross-study risk intelligence • Automated CAPA triggers AI Strategy: Advanced ML + integrated QMS Implementation: Enterprise RBQM framework
Statistical Programming & Content Automation	Focus: Efficiency Gains • Code libraries, macros • Basic TLF automation AI Strategy: Assisted coding tools Implementation: Programmer-led adoption	Focus: Semi-Automation • Metadata-driven programming • Automated TLF generation • Reusable standards (CDISC) AI Strategy: Workflow automation + AI copilots Implementation: Standard pipelines	Focus: Autonomous Analytics Layer • End-to-end automation (SDTM → ADaM → TLFs) • AI-generated outputs & narratives • Integrated submission-ready systems AI Strategy: GenAI + enterprise metadata repository Implementation: Fully integrated analytics ecosystem

“AI maturity is not about how much you automate... It’s about how well you **control what you automate.**”



From Execution to Strategic Leadership

From → To

- Doing Programming → Analytics Architecture
- Data Processing → Insight Generation
- Following Protocols → Shaping Decisions
- Manual Effort → Intelligent Oversight
- Tool Usage → Technology Governance

Leadership Capabilities Required

- Balance Speed vs Compliance
- Balance Innovation vs Risk
- Balance Efficiency vs Accountability

“Automation amplifies capability—but only human intelligence can define direction, trust, and scientific meaning.”



“AI will write the future of clinical trials...But humans will sign it.”

“In the future, two companies will run clinical trials with AI...”

- One will automate everything
- The other will automate intelligently

“Only one will succeed.”

- AI will redefine speed — but humans define success
- Programming will evolve — but validation will remain critical
- Operations will automate — but judgment will differentiate
- Trust will be the ultimate currency

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