Sycamore Informatics

Sycamore Clinical Agentic Framework™

SPD PROTOCOL | MDR METADATA | DTM TRANSFORM | DSW OPEN-SOURCE | SCE ANALYSIS | CDR REPOSITORY

Breaking Silos with Agentic AI and Standards: Orchestrating End-to-End Digital Data Flow

KALA SHIVALI AND DIVYA KAPOOR

About the Presenters

Kala Shivali, MBA
Executive Director, Services

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Kala.Shivali@

Kala Shivali is a seasoned leader with over 30 years of experience across BioPharma, Biotechnology, and IT. Her career includes leadership roles in statistical programming, program management, customer engagement, and strategic delivery. Holding a degree in Computer Science and an MBA in Biosciences, Kala excels at bridging the gap between technology, operations, and clinical development.

Currently, at Sycamore Informatics, she focuses on modernizing clinical development through AI, automation, and next-generation data analytics. Kala is passionate about leading global teams, driving large-scale transformations, and shifting the industry from managing data to enabling faster, data-driven decisions.

Divya Kapoor, Ph.D.
Director, Services

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Divya.Kapoor@

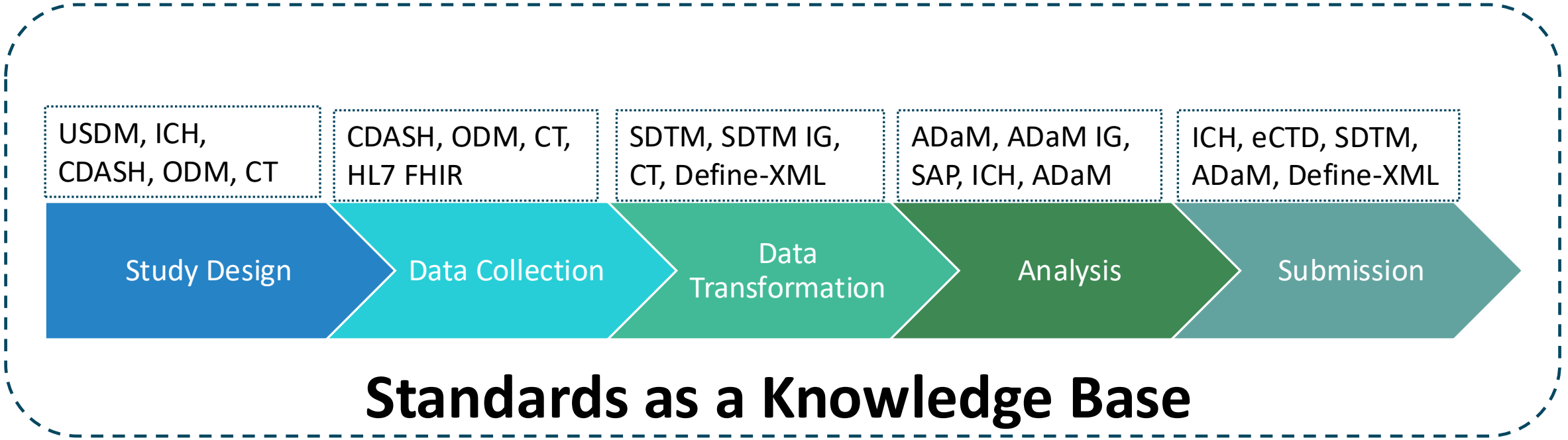
Divya Kapoor is Director of Services at Sycamore Informatics, where she leverages over a decade of pharmaceutical industry experience to lead the deployment of cloud-native clinical trial data science solutions for global biotech and pharma leaders.

With a PhD in Life Sciences from Jawaharlal Nehru University, Divya bridges the gap between complex technical innovation and practical clinical strategy. She champions product innovation, transforming feedback from pilot programs and proof-of-concept workshops into scalable business solutions that streamline operations, enhance efficiency and expedite clinical development timelines.

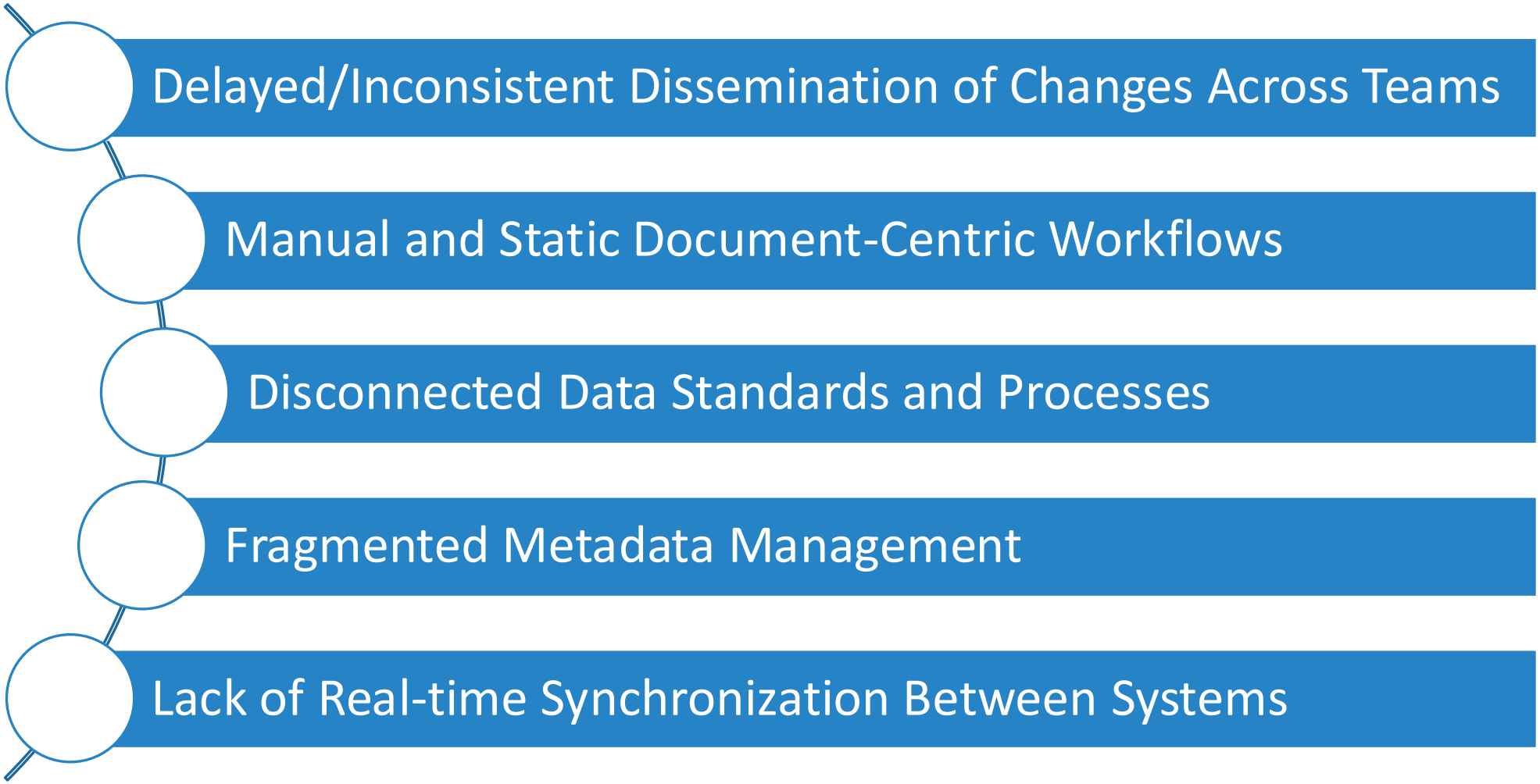
Agenda

- Digital Data Flow: The Current State
- Seamless Digital Data Flow through Agentic AI
- Agentic Framework
  - Risks
  - Foundation
  - Real-world example
- Agentic AI in Digital Data Flow: ROI Drivers
- Conclusion

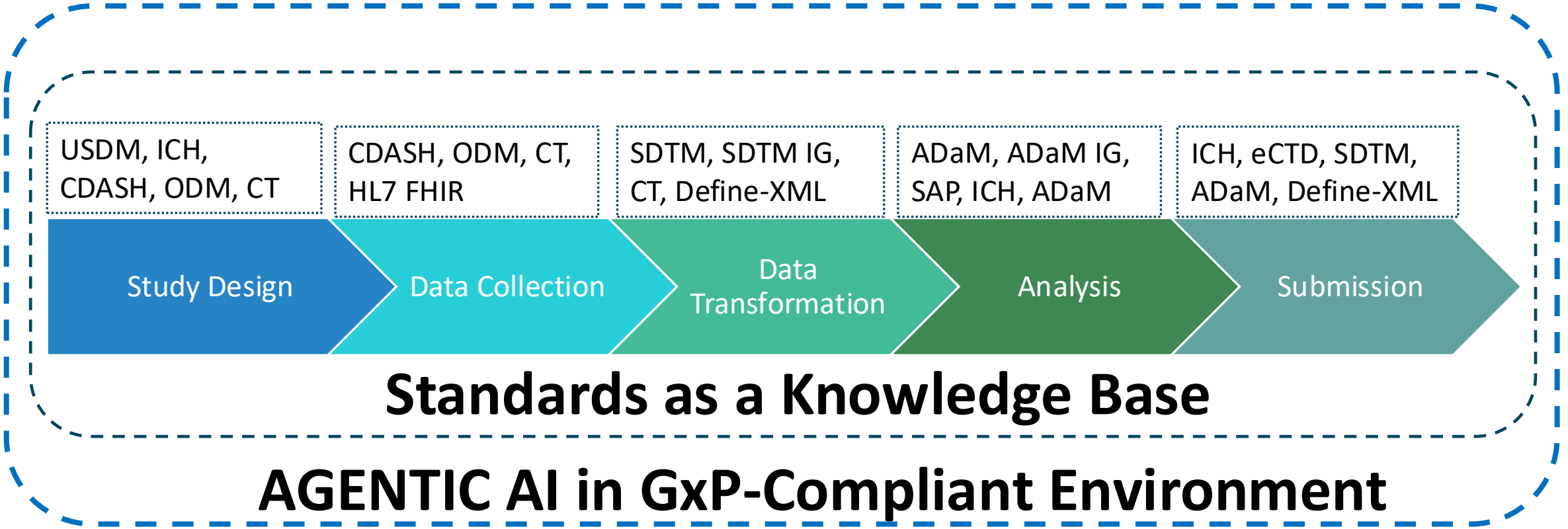
Standards-Driven Digital Data Flow: From Protocol to Submission



The Need for Interoperability to Break Down Silos



Transforming Silos into Connected Data Ecosystem through Agentic AI



Achieving Compliance With Agentic AI in Clinical Trials

- Data Leakage
- Data Integrity Risks
- Agent Autonomy Risks
- Prompt Injection
- Unauthorized Actions
- Auditability & Explainability Challenges
- Regulatory Non-Compliance

21CFR Part11, EU Annex 11 Compliant

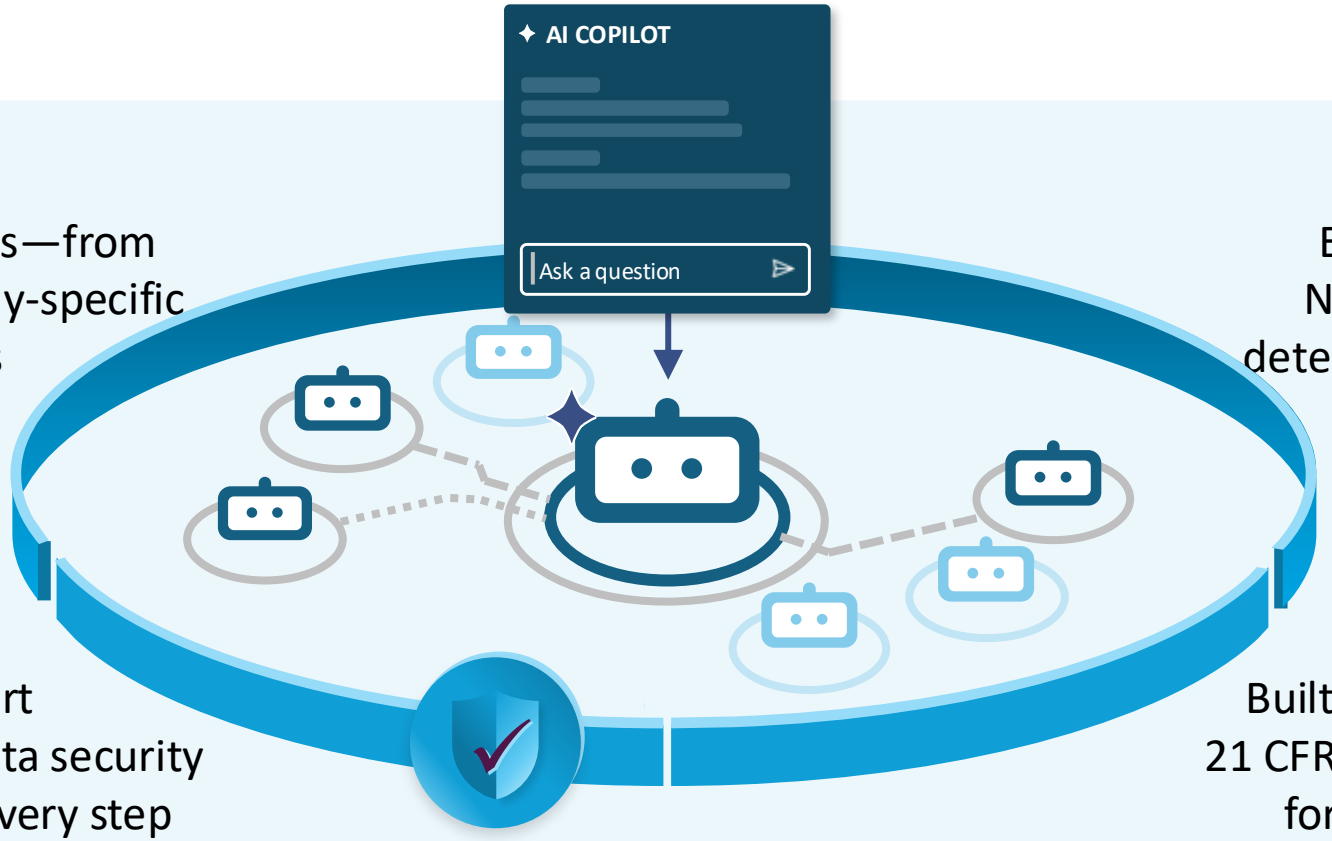
Agentic AI Framework: Deterministic Outputs with Unparalleled Acceleration & Efficiency

Context

Deep domain awareness—from CDISC standards to study-specific metadata and protocols

Constraints

Eliminating hallucinations. Non-LLM primitives ensure deterministic, reliable outputs



Control

Human-in-control. Expert oversight, enterprise data security with access control at every step

Compliance

Built-in GxP rigor—supporting 21 CFR Part 11 and EU Annex 11 for regulatory-grade quality.

End-to-End Clinical Trials Data Lifecycle

Design ***Protocols*** representing Standard of Care

Clinical Scientists

Design studies with content re-use, evaluate cost and burden, generate protocols

Clinical Scientists
Biostatisticians
Clinical Operations
Medical Writers

Generate ***eCRF and Data Transfer Specifications*** using a protocol & standards

Data Managers

Build studies in ***EDC*** with integrations

EDC Programmer

Generate SDTM Specifications and Programs for study data sources

SDTM Spec Author

ADaM & TFL Code Generator referring SAP, Protocol and other study documents

Statistical Programmer

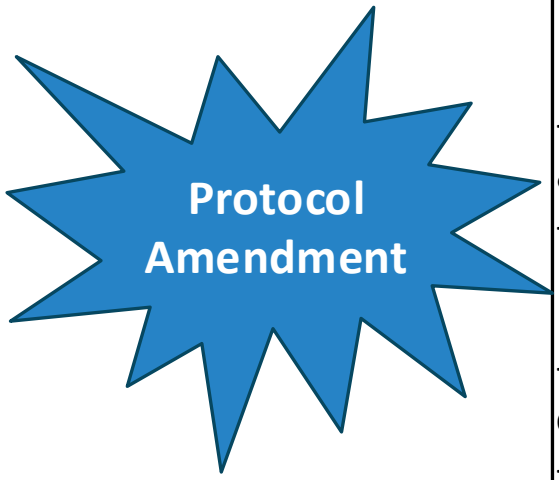
Reuse clinical content to ***produce a draft CSR*** from protocol, Analysis Results,

Generate ***in-text Summary Tables*** and their ***Narrative Description***

Biostatisticians
Medical Writers
Regulatory Affairs

Real-World Example - Protocol Amendment

The Ripple Effect: A single amendment in protocol triggers a cascade of updates, reviews, alignments and rework across the trial ecosystem.

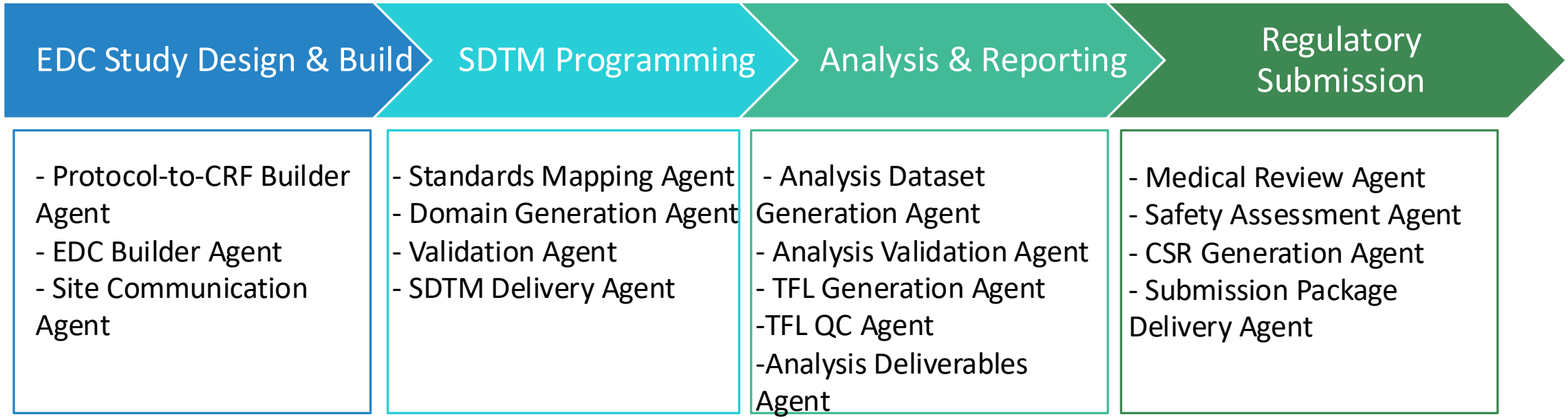


Protocol Store & Design	EDC Study Design & Build	SDTM Programming	Analysis & Reporting	Regulatory Submission
	Data Manager - Update CRF Forms **EDC Programmer** - Modify visit structures & edit checks - Rebuild EDC database **Site Coordinators** - Implement changes at every active site - Collect updated raw data	**SDTM Programmer** - Update SDTM specs - Modify mapping programs - Update Define.xml metadata -Run P21 validation -Resolve validation issues, and deliver updated SDTM datasets	**Statistical Programmer** - Update ADaM specs - Rewrite derivations - Regenerate Analysis datasets - Update Tables, Figures & Listings (TFLs)	**Medical Monitor** - Review medical rationale - Update safety assessments **Medical Writer** - Update CSR **Regulatory Affairs** - Update submission package

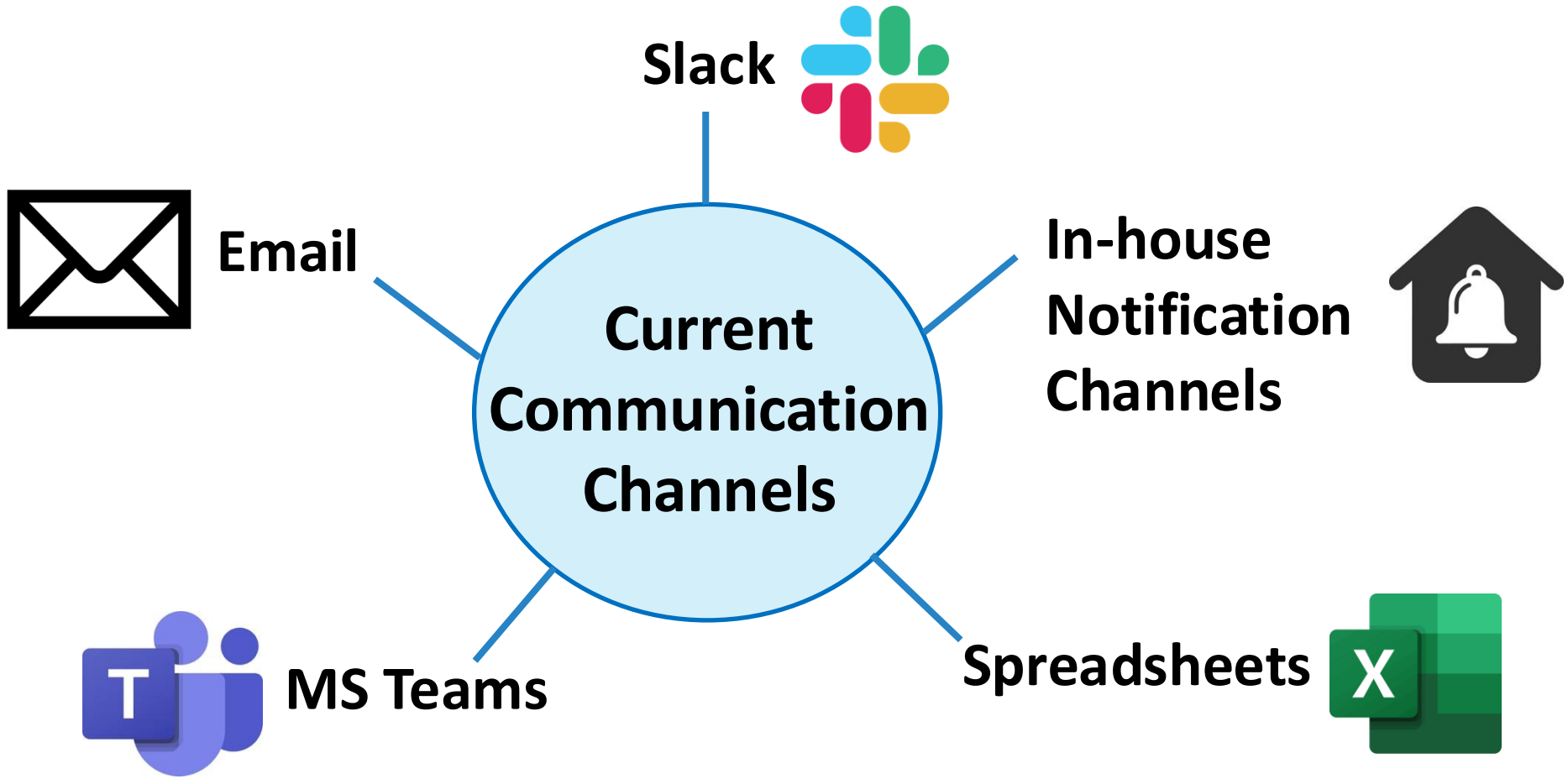
Agentic AI-Powered Protocol Amendment Lifecycle

AI AGENTS ASSIST EVERY TEAM

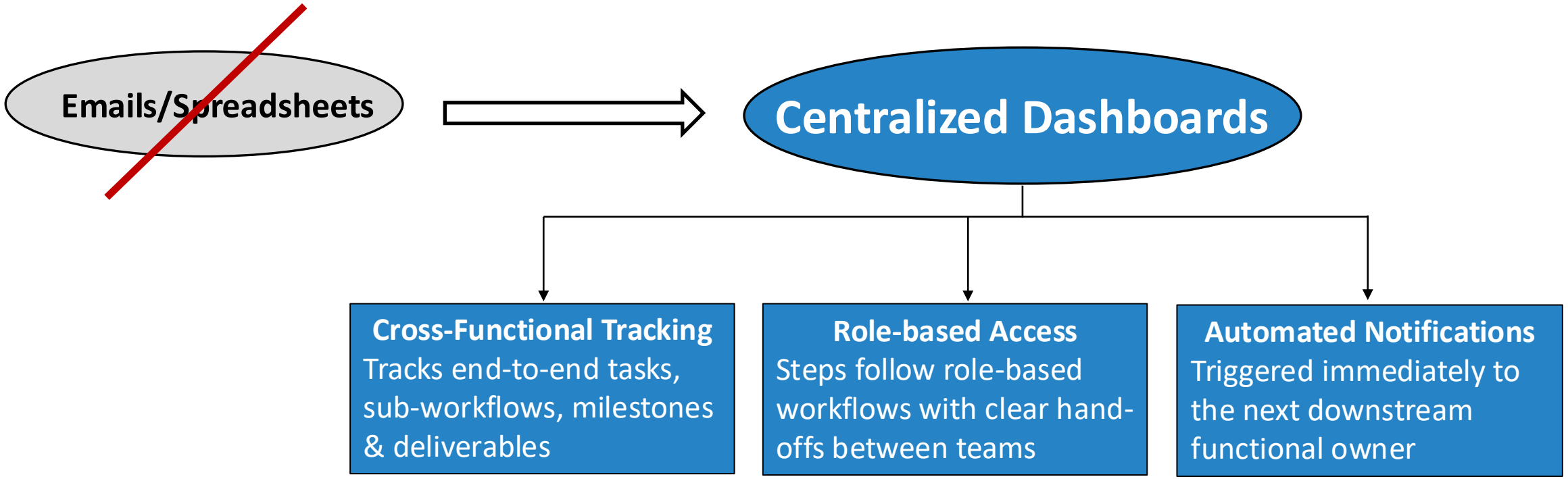
Domain-specific agents |Task automation |Intelligent, auditable recommendations with human oversight



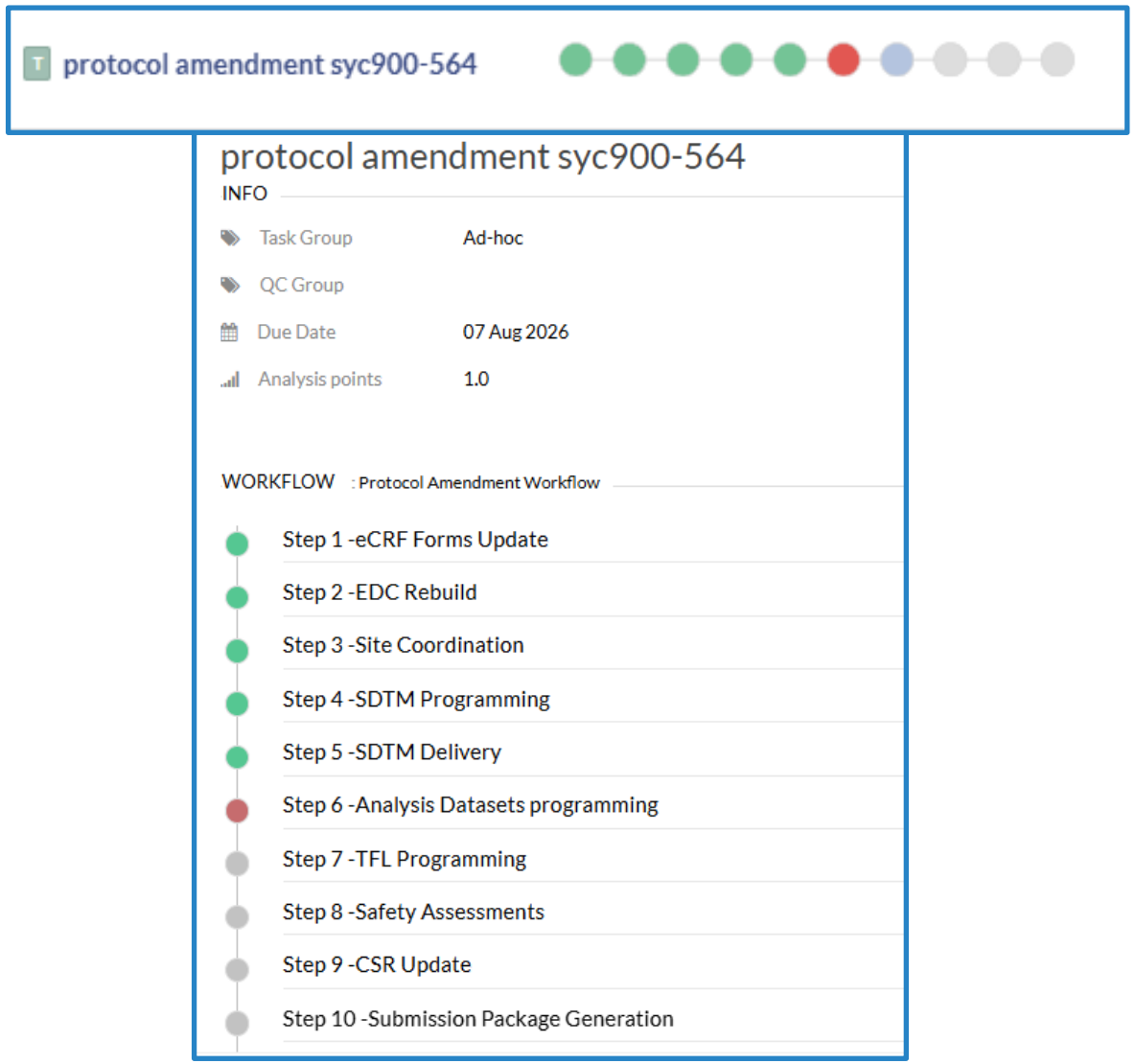
Why Protocol Amendments Break Down Across Teams

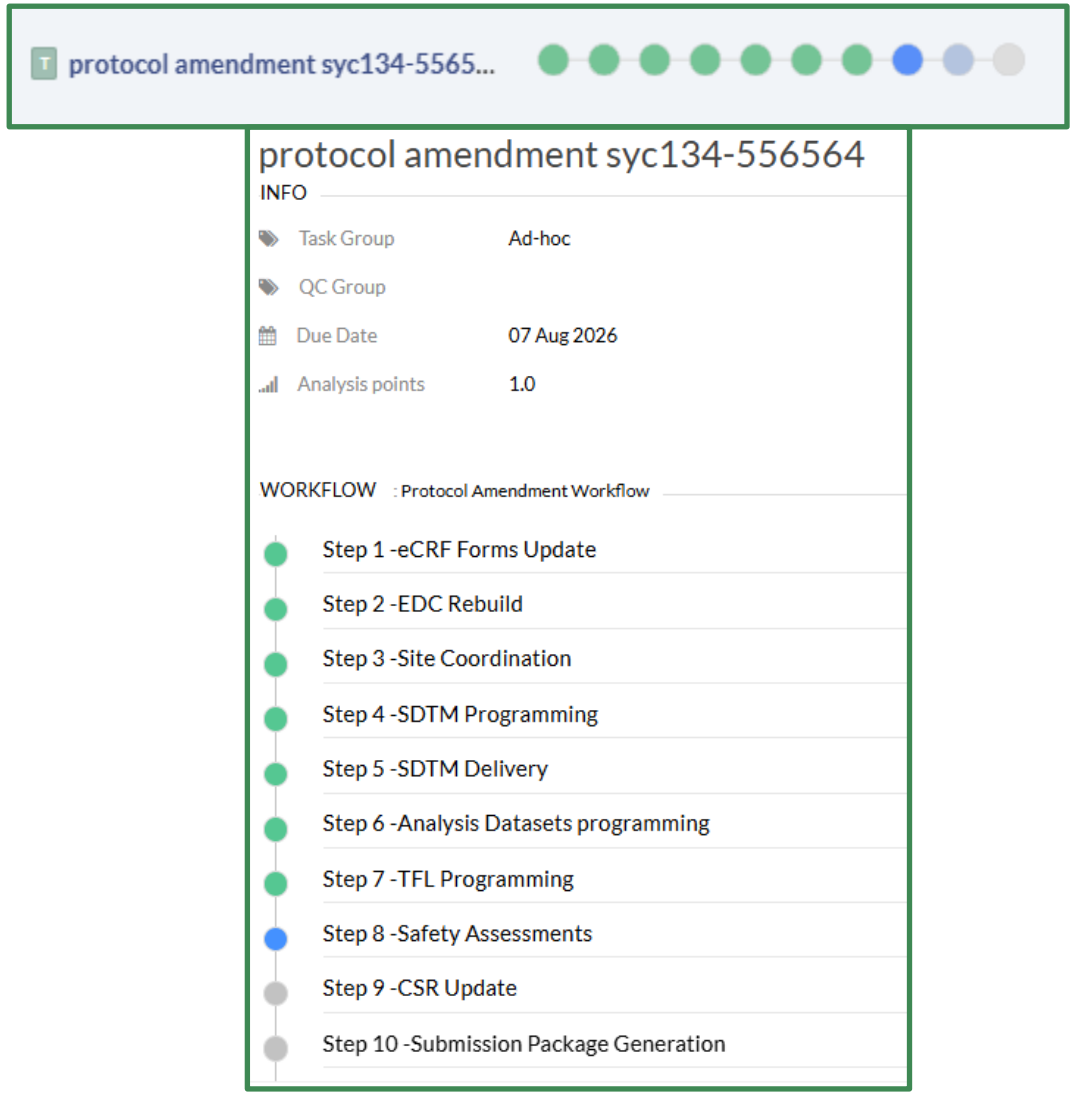


One Platform : End-to-End Clinical Trial Visibility

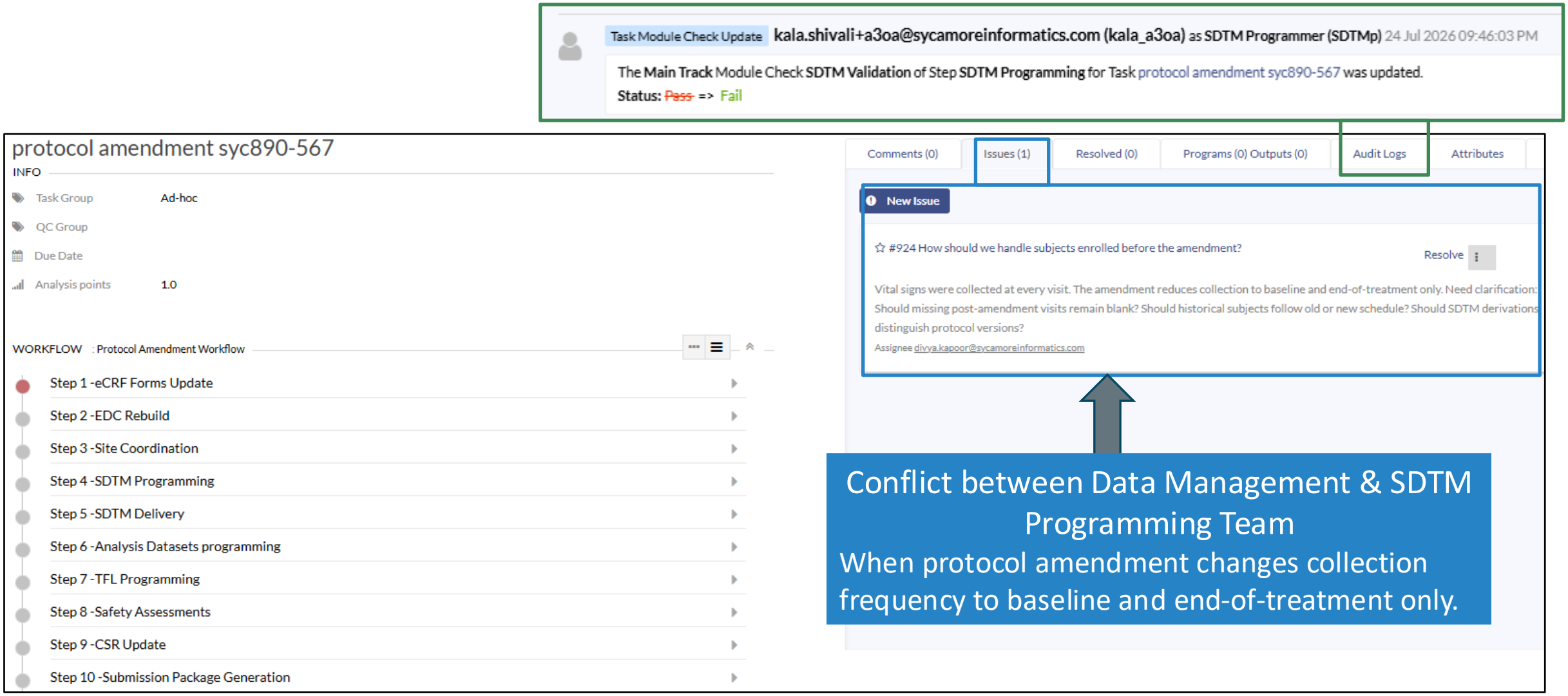


Protocol Amendment Impact Tracking Workflow Examples

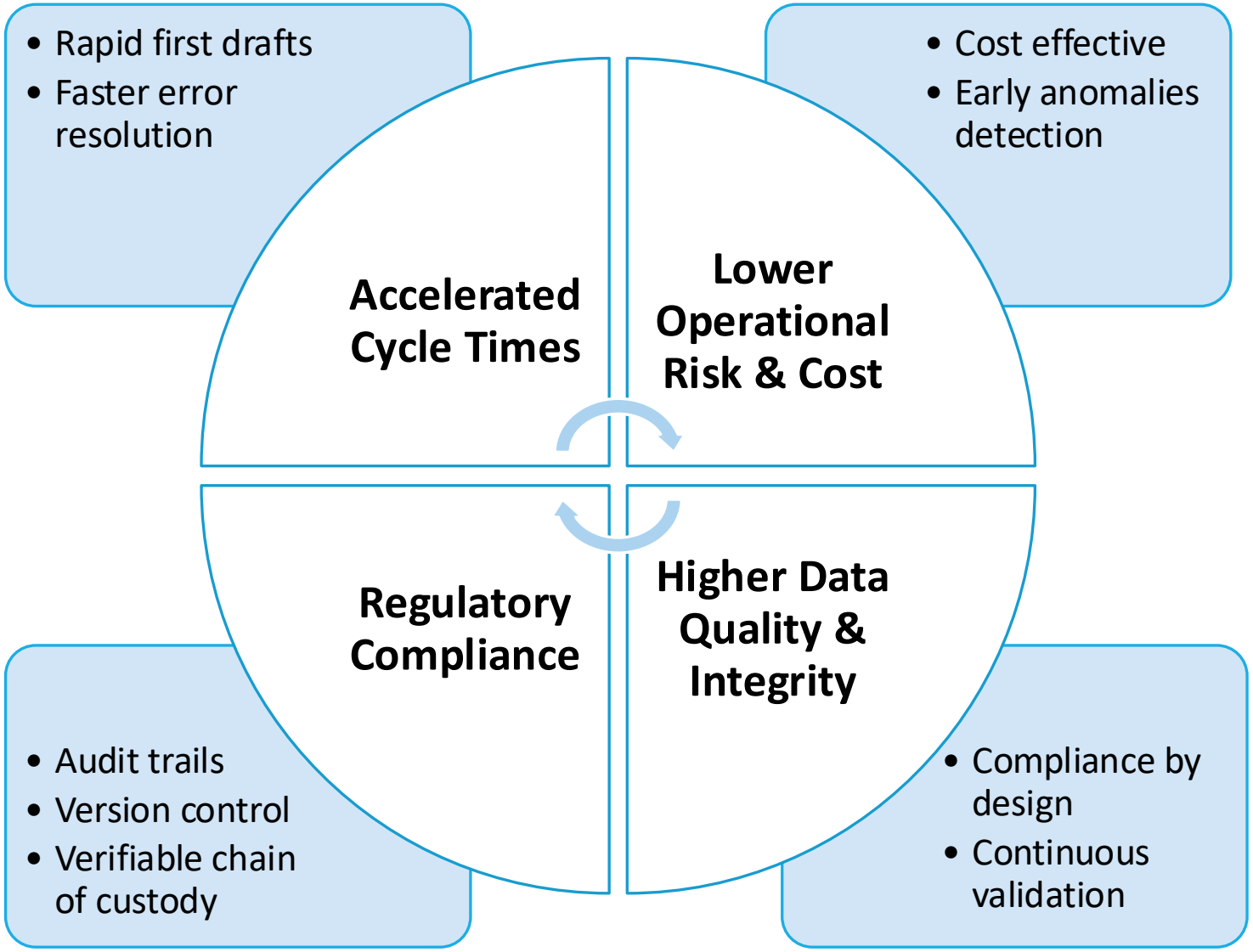




A Trusted GxP-Compliant Platform for Holistic Clinical Trial Visibility



Agentic AI in Digital Data Flow: ROI Drivers



Agentic AI Orchestrates End-to-End Digital Data Flow in GxP-Compliant Ecosystem

Human Oversight

Data Security, Role-Based Access Control

Traceability & Auditability

Regulatory Compliance

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Thank You

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