



SPA MDR CDR SCE

From Tables to Text: Revolutionizing CSR Development with Generative AI

Kala Shivali & Eric Zloty



Agenda

- Challenges of Clinical Study Reports (CSR)
- Generative AI Enabled CSR Framework
- CSR Generation Workflow and AI
- GxP Considerations
- Benefits, Impact, Next Steps (aka adoption roadmap)
- Future Outlook



CSR Development Today: High Effort, High Risk

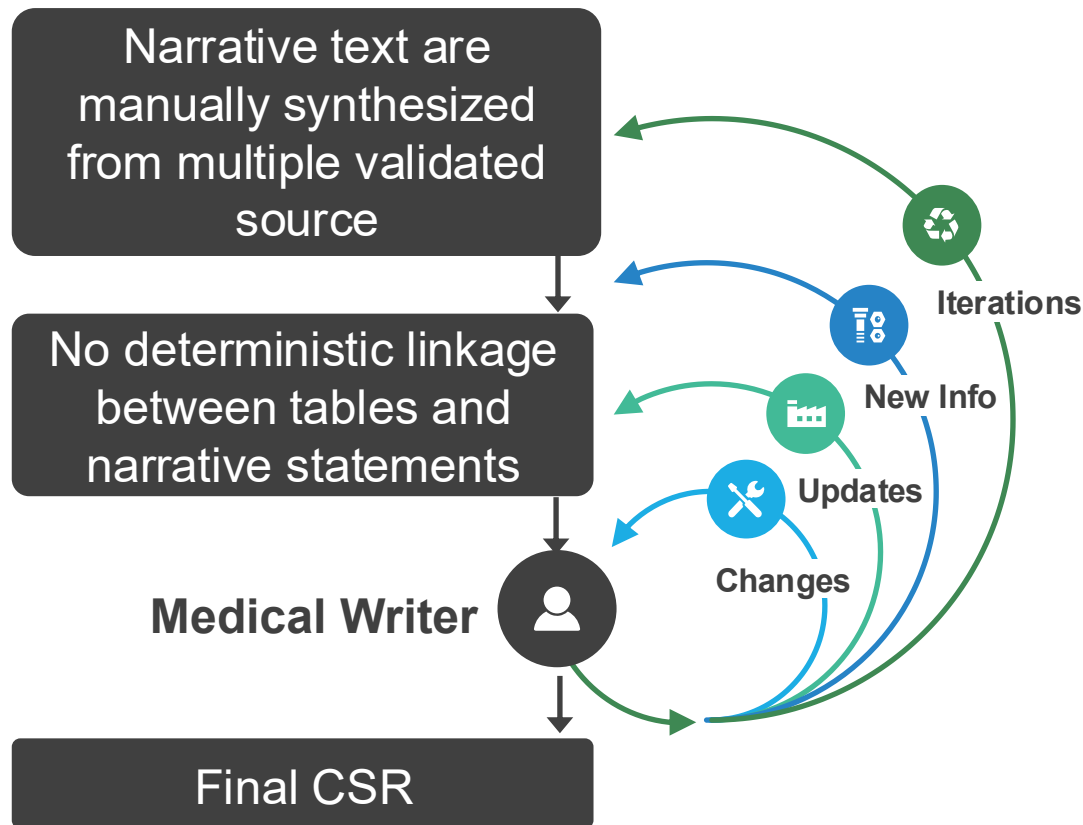
Despite advances in standards, analytics, and automation:

- CSR narrative development remains largely manual
- Late-stage data changes drive extensive rework
- Traceability and reproducibility are difficult to enforce

How do you ensure accuracy, traceability, and inspection-readiness?



Where CSR Narrative Development Breaks Down

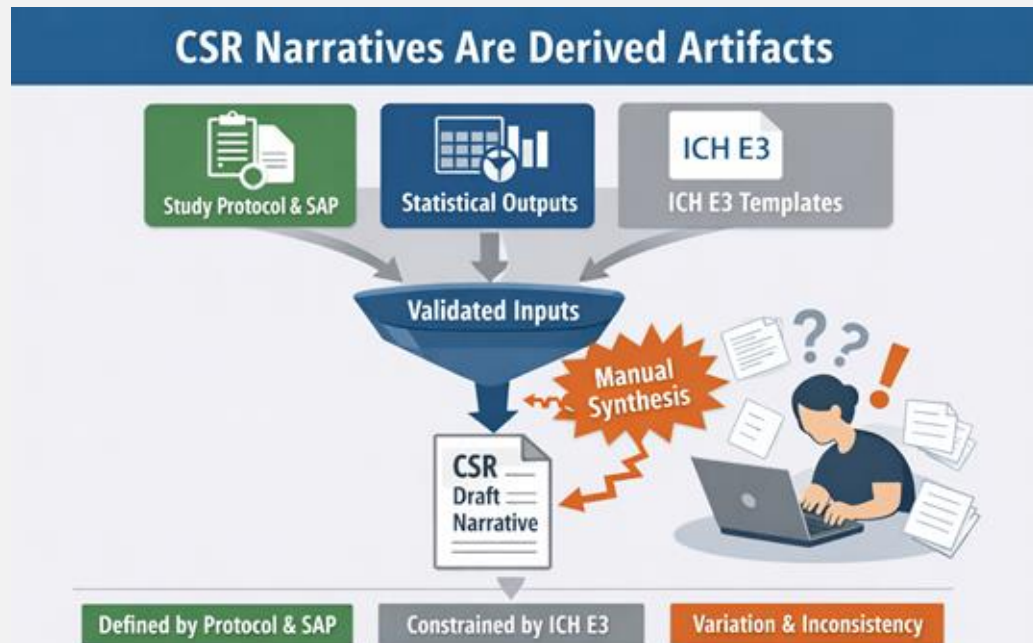


Statistical output (TFLs) updates propagate manual rework across sections



CSR Narrative Generation Can Be Systematized

- CSR text is derived from validated, structured inputs
- Narrative intent is defined by protocol and SAP
- Content structure is constrained by ICH E3
- Narrative intent and structure are predefined
- Variability enters during manual synthesis
- Draft narratives can be generated deterministically



A Governed, Metadata-Driven Approach to CSR Narratives

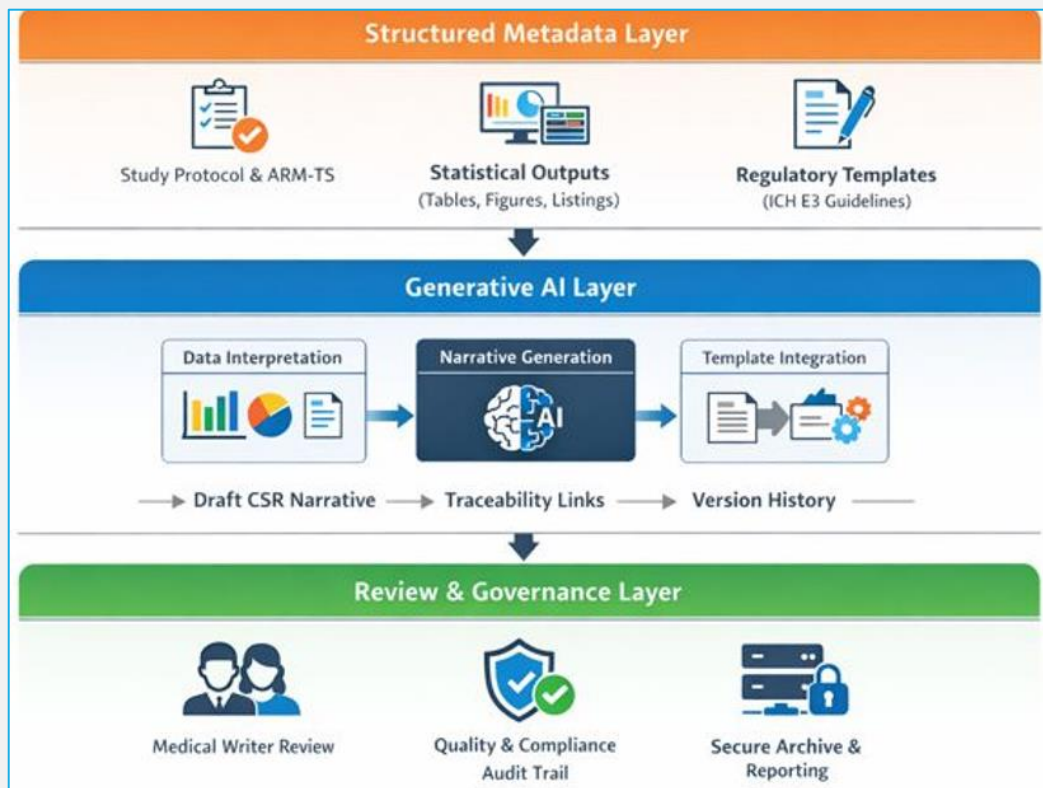
- CSR narratives generated from structured study metadata
- Statistical outputs used as primary evidence sources
- Regulatory templates (ICH E3) constrain content and tone
- Governance embedded for traceability and reproducibility

The focus remains on governance and compliance



Framework Architecture: Three Integrated Layers

- **Input Layer:** Protocol, SAP, tables, figures, listings (validated sources)
- **Generation Layer:** Narrative drafting aligned to intent and structure
- **Governance Layer:** Traceability, consistency checks, regulatory constraints

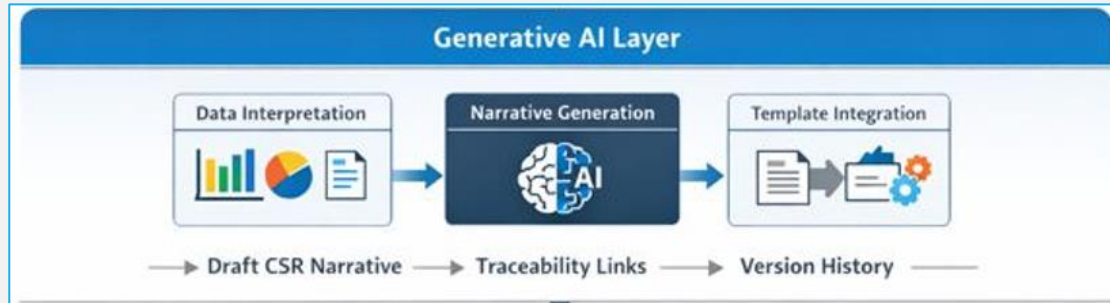


Structured Inputs: Authoritative Sources of Truth



- Study protocol and amendments define narrative intent
 - SAP and analysis metadata define populations and endpoints
 - Finalized tables, figures, and listings (TFLs) serve as evidence
- All inputs are validated, version-controlled, and traceable**

AI Interpretation and Controlled Narrative Generation



- Section-specific context assembled from prot, SAP, & TFLs
- Tables interpreted to identify key trends and outcomes
- Narrative generated within ICH E3–aligned templates
- Generation constrained to ensure consistency and low variability



Human-in-the-Loop Review and Quality Control



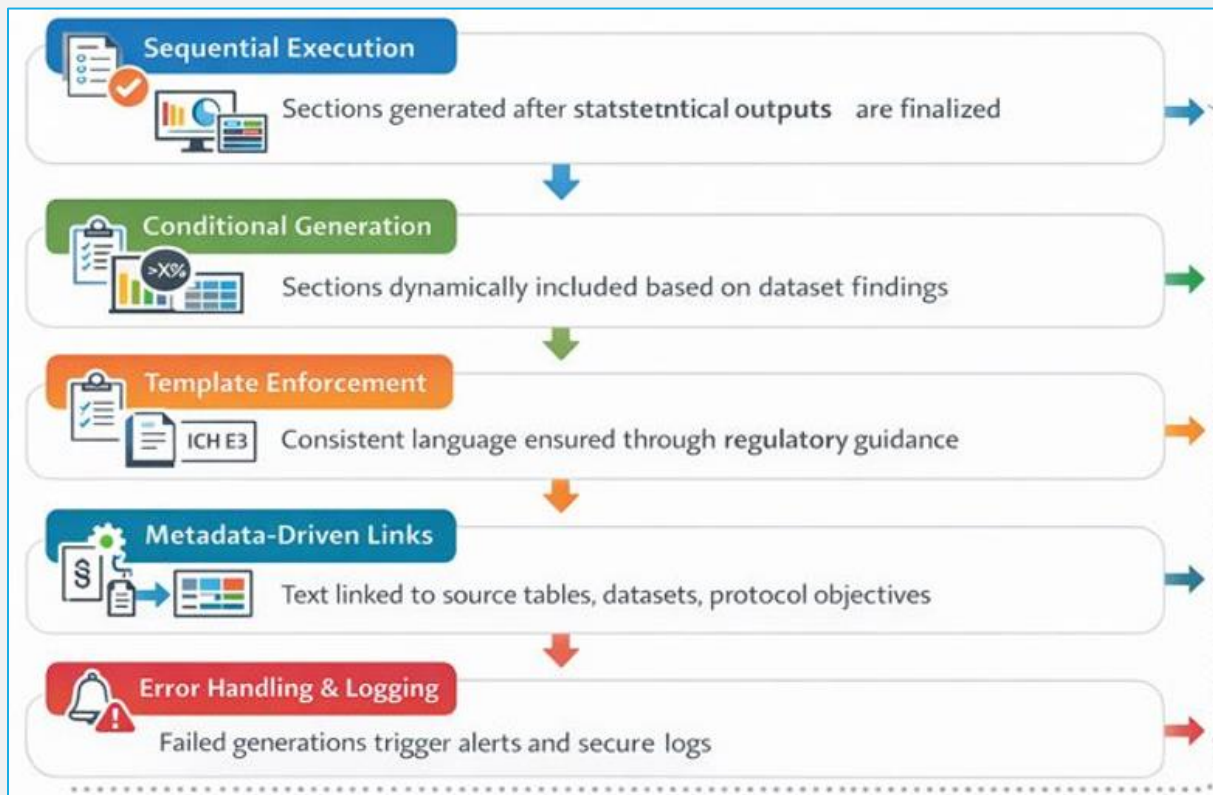
- AI generates first-pass draft narratives only
- Medical writers review with full source attribution
- Scientific interpretation and messaging refined by humans
- Explicit human approval required before finalization

Governance, Traceability, and Audit Readiness



- End-to-end traceability from inputs to final narrative text
- Version control across data, prompts, and outputs
- Full audit trails for review, edits, and approvals
- Alignment with GxP expectations and inspection readiness

High-Level Workflow in CSR Automation



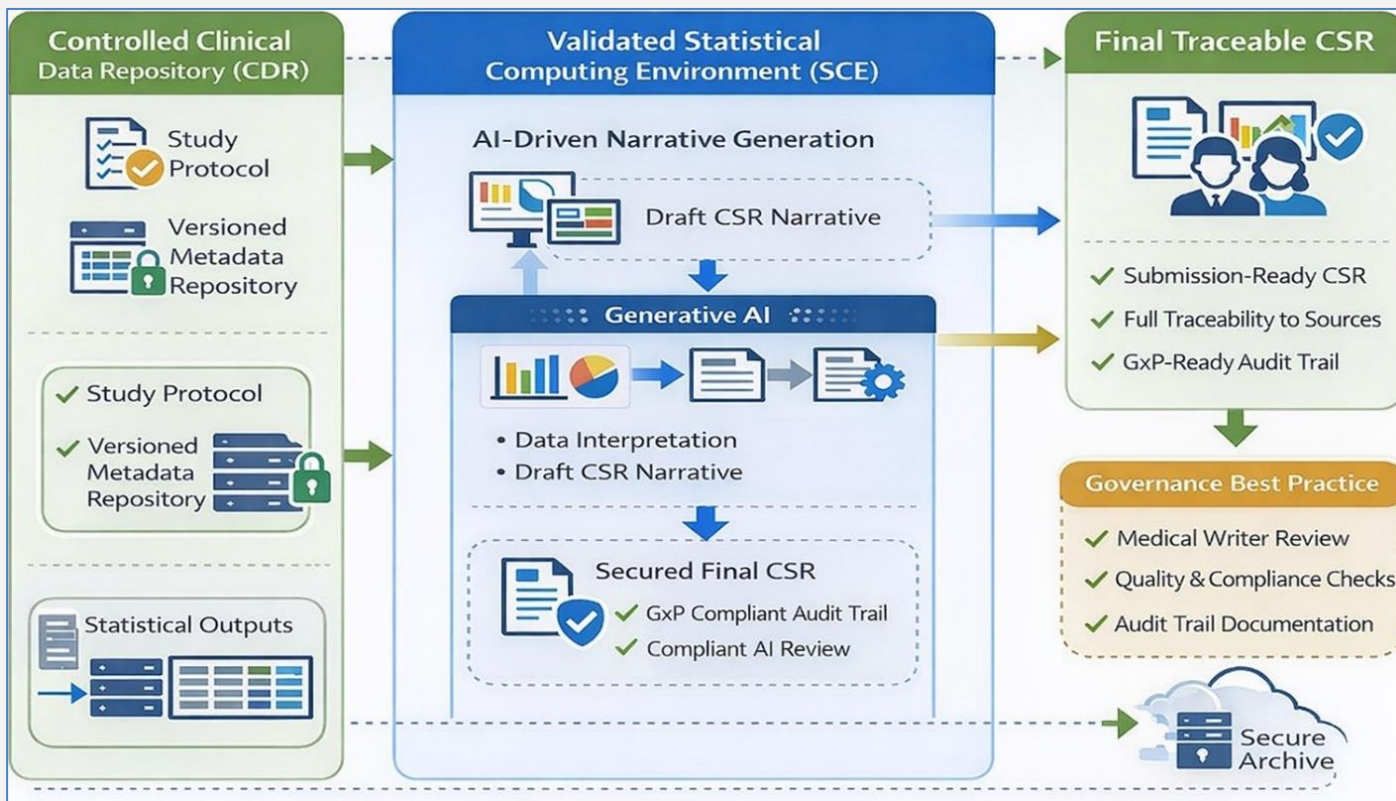
GxP Implementation Considerations



- Risk-based validation aligned with intended use
- AI treated as a configurable tool, not an autonomous system
- Separation of model logic, prompts, and content
- Qualification within existing document authoring workflows



AI Driven CSR Generation in a GxP Environment



Benefits and Impact



01

Complex clinical interpretation still requires expert judgment



02

Edge cases may fall outside template-based generation



03

Ongoing refinement needed for evolving regulatory expectations

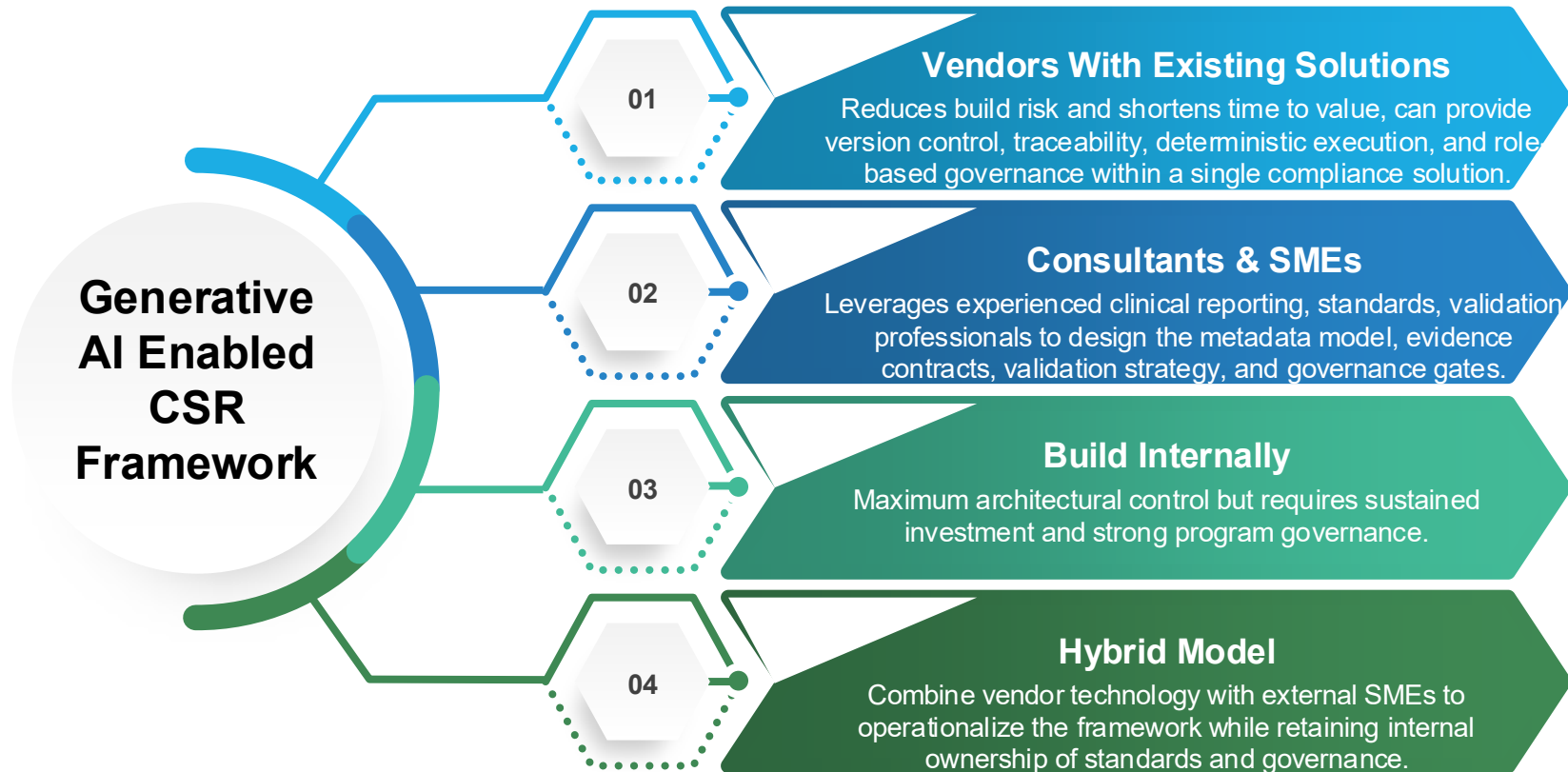


04

Future work includes broader section coverage and adaptive learning



Recommended Adoption Roadmap: Start Pragmatically



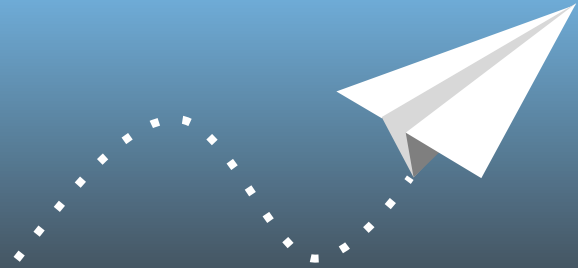
Key Takeaways

- CSR narratives are derived, constrained artifacts
- Narrative generation can be systematized without loss of control
- AI enables scalable drafting within regulatory boundaries
- Human oversight and governance remain essential



Thank You

<https://www.sycamoreinformatics.com>



Kala Shivali

kala.shivali@SycamoreInformatics.com
<https://www.linkedin.com/in/williamqubeck/>

Eric Zloty

eric.zloty@SycamoreInformatics.com
<https://www.linkedin.com/in/suhasgiriraj/>