



SPA MDR CDR SCE

PD10

Disruption in Clinical Trials: How Conventional Roles Are Set to Change

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About the Presenters



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 [Kala Shivali](#)

Professional with experience across BioPharma, Biotech, CRO, CRM, finance, and IT. Holds a B.E. in Computer Science from Bangalore University and an MBA in Bioscience from NC State University. Currently leading the Service team at a SaaS company for BioPharma and Biotech, with a focus on leadership and structured problem-solving. Outside work, enjoys reading, podcasts, marathons, and hiking.



Amit Javkhedkar

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 [Amit Javkhedkar](#)

Amit brings with him a wealth of experience in the clinical domain, totaling 16 years. Throughout his career, he has traversed multiple roles within various CROs and product companies. These roles encompass EDC programming, team leadership and mentoring, people management, and customer relationship management.

Amit's recent professional journey has seen him take on the role of a Customer Success Manager at Sycamore, contributing to several product implementations.



The Core Disruption



Key Message

Emerging technologies
and standards reshaping
execution.



Deeper Disruption

Silos are breaking; roles
evolving.



Goal

Key functions (ClinOps,
DM etc) are being
redefined.



What will you see today?



01

What?

What led us
to the
current
state?



02

What?

What do we
mean by
roles
evolving?



03

What?

What can
organizations
and individuals
do to adapt
and thrive?



04

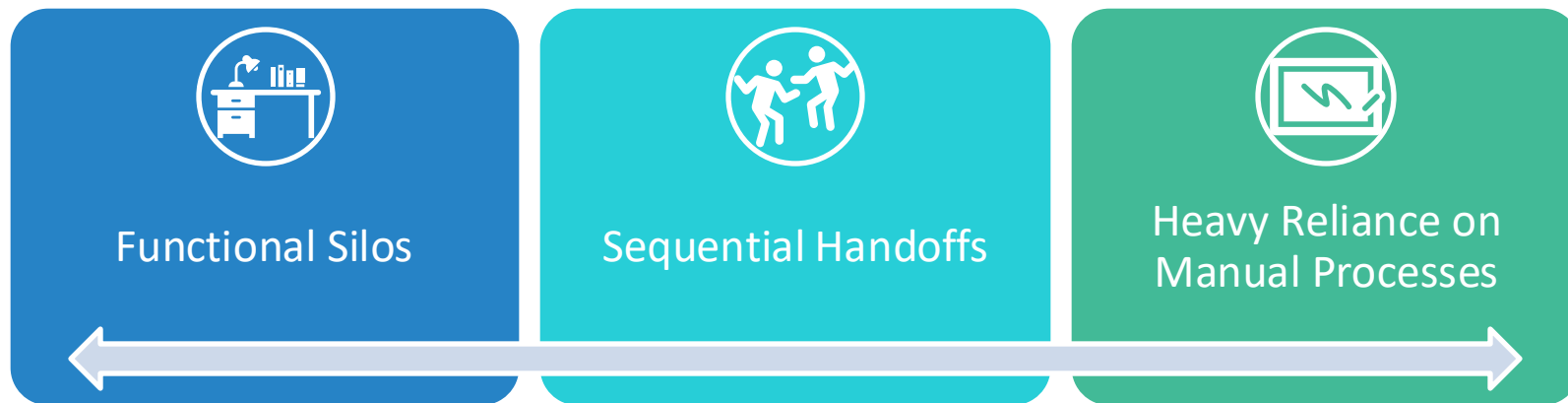
Case Study

Real life
example of
how
technology can
assist.



The Traditional Model: Triad of Inefficiencies

The prevailing model, while robust for safety and compliance, is characterized by:



Result: Duplicated efforts, rework, and significant delays in drug development.



A Seismic Shift

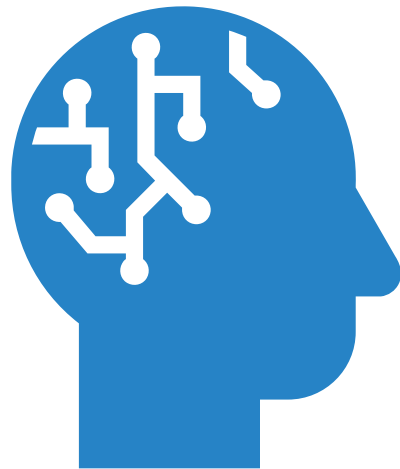
Forces of change: The **COVID-19 pandemic accelerated**

- AI Adoption
- Led to standards evolution like TransCelerate's DDF and CDISC USDM



Driving Force 1: Artificial Intelligence & Agentic AI

- Agentic AI is capable of **autonomous task completion**
- Protocol Design:
 - LLMs read past protocols, CT.gov: **Skeleton of Protocol**
- Human focus **Execution** ➡ **Governance, quality and compliance**



Driving Force 2: Digital Standards & Interoperability

- Frameworks like TransCelerate's DDF and CDISC USDM.
- Automate metadata management and hence
 - study setup, dataset creation, is faster
- DM/programmers shift to **governance**, pipeline **automation**, and **metadata**-driven analytics.



Evolution of Key Traditional Roles

Function	Then (Traditional)	Next (Future)
Protocol Authors	FROM narrative endpoints TO structured, interoperable design	AI maps endpoints to CDISC CT; flags ambiguities early
Study Build	FROM form creation TO metadata governance	AI auto-builds CDASH forms, enforces SDTM alignment
ClinOps	FROM reactive query mgmt TO proactive data quality	AI predicts query patterns; guides sites via chatbots
Stats Prgm	FROM code execution TO insight acceleration	AI validates traceability; help generate programs, analyses



Evolution of Key Traditional Roles

Function	Then (Traditional)	Next (Future)
Safety & PV	FROM manual review TO predictive signal detection	AI mines SDTM AEs/Labs; automates MedDRA coding
Medical Writers	From manual CSR writing → assisted storytelling	AI drafts narratives from ADaM; flags inconsistencies
Regulatory Affairs	From post-hoc checks → continuous compliance	AI runs live conformance checks; pre-empts submission issues



The Skills That Will Define Tomorrow's Workforce



Digital Fluency

Proficiency with EDC, DCT platforms, and AI-assisted applications; critical thinking to evaluate new technologies.



Data Literacy

Ability to read, interpret, and critically evaluate diverse, high-volume data (RWD, digital biomarkers).



Systems Thinking

Capacity to see beyond isolated tasks and understand how decisions in one function impact the entire trial lifecycle.



Metadata-Driven Approaches

Mastery of how metadata underpins study design, data transformation, and reporting to maximize automation.



Organizational Evolution: Changes for Leadership



Flexible and Cross-Functional Team Models: Shift from rigid, siloed teams to agile structures for faster decision-making and problem-centric collaboration



Continuous Learning and Upskilling: Embed continuous training in digital fluency, AI oversight, and data standards to develop T-Shaped Professionals



Choosing the Right Technology Partner: Select a partner for strategic collaboration to guide digital transformation, ensure GxP integrity, and support digital standards like USDM



Right Technology Partner



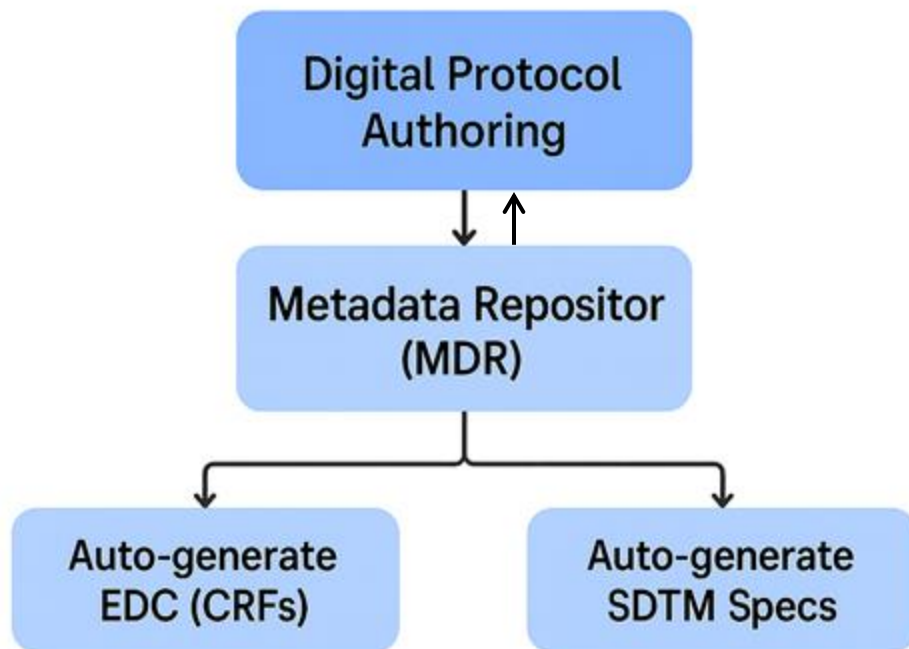
Teamwork
Reproducibility
Elastic resources
Agility
Governance
Automation *Insights*

ONE single comprehensive application that is GxP, 21CFR11, and EUAnnex11 compliant with audit trails, granular access control, version control, chain of custody, traceability, and reproducibility for regulated polyglot execution, and high-performance storage



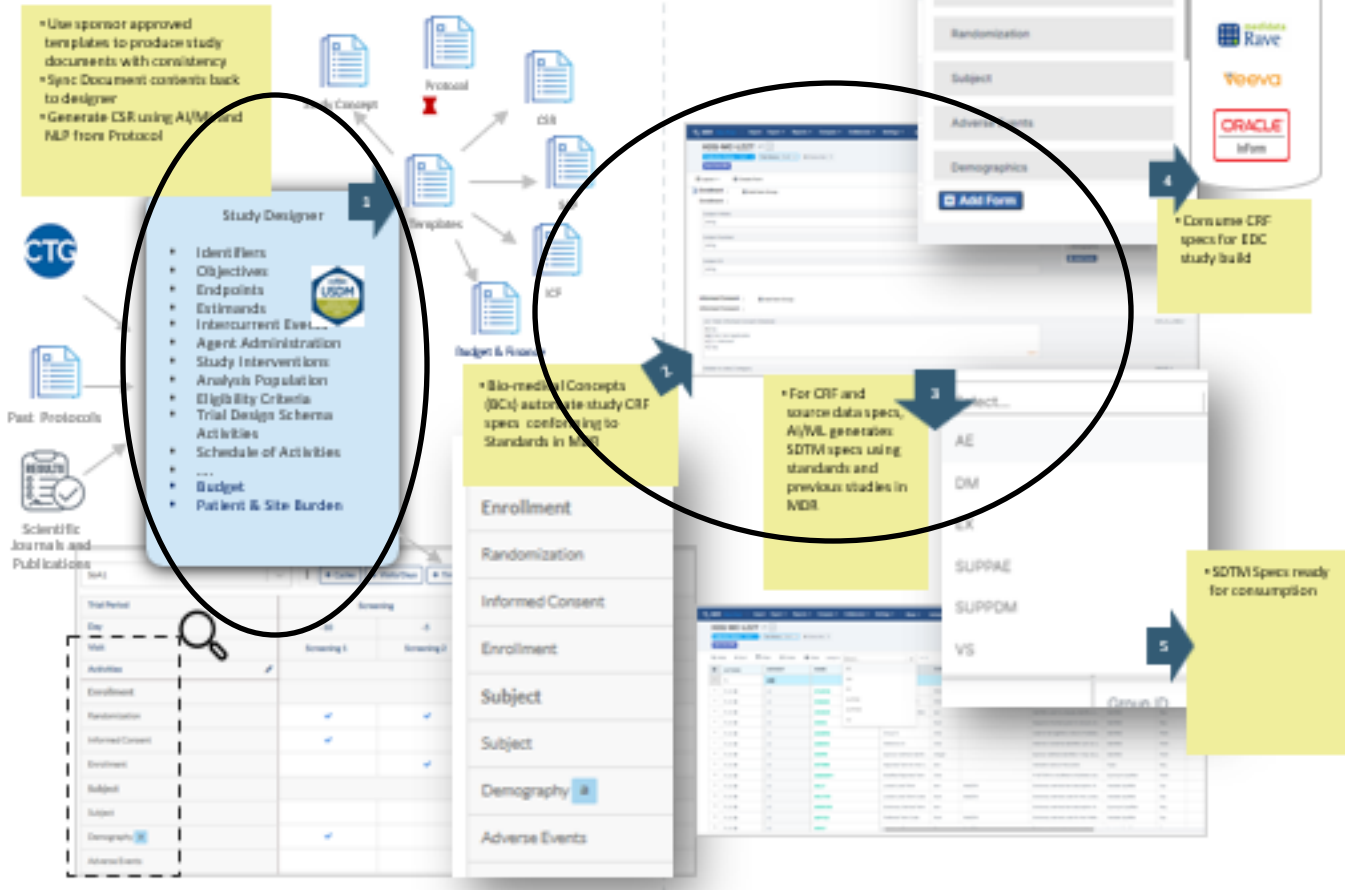
Case Study – Automating EDC and SDTM specification generation





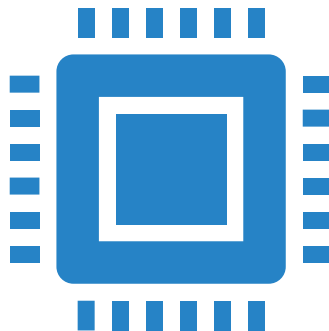
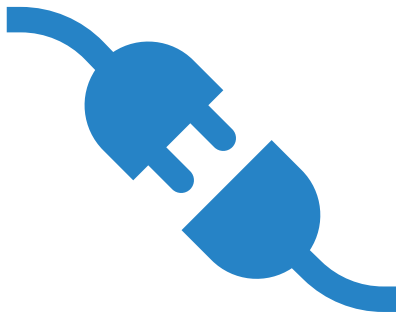
**Automated synchronization →
reduced timelines → improved quality**





Conclusion

Future success hinges on embracing agility and adapting the human element.



LET HAMBURG *surprise* YOU!

Thank you!

