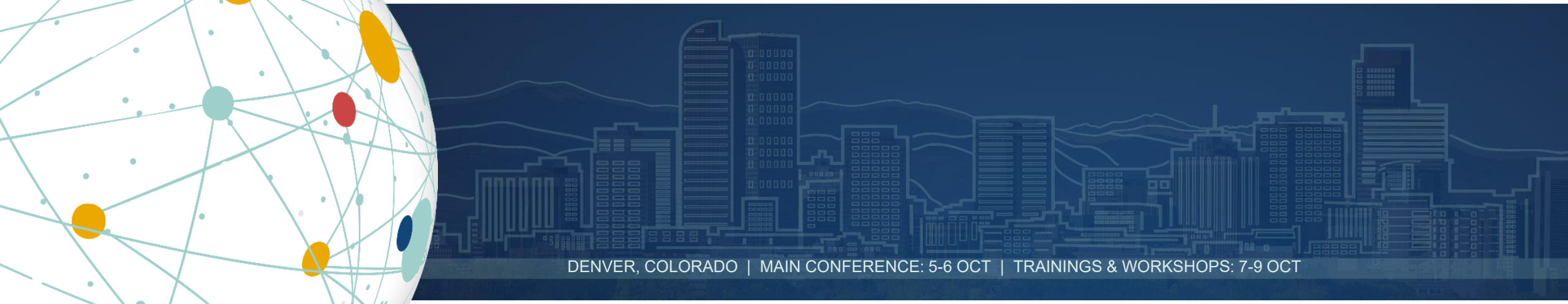


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



What Breaks First When You Go DDF?

Real-World DDF Adoption for Structured Protocols,
ICH M11 Alignment, and Automated Study Builds

Udiksha Jaiswal
Project Manager | Sycamore Informatics

Agenda

1. THE CHALLENGE
2. APPROACH
3. RESULTS
4. LESSON LEARND
5. MEASURED OUTCOMES
6. TAKEAWAY
7. READY NOW v/s STILL EVOLVING
8. YOUR TURN

Speakers



Udiksha Jaiswal
Project Manager
Sycamore Informatics

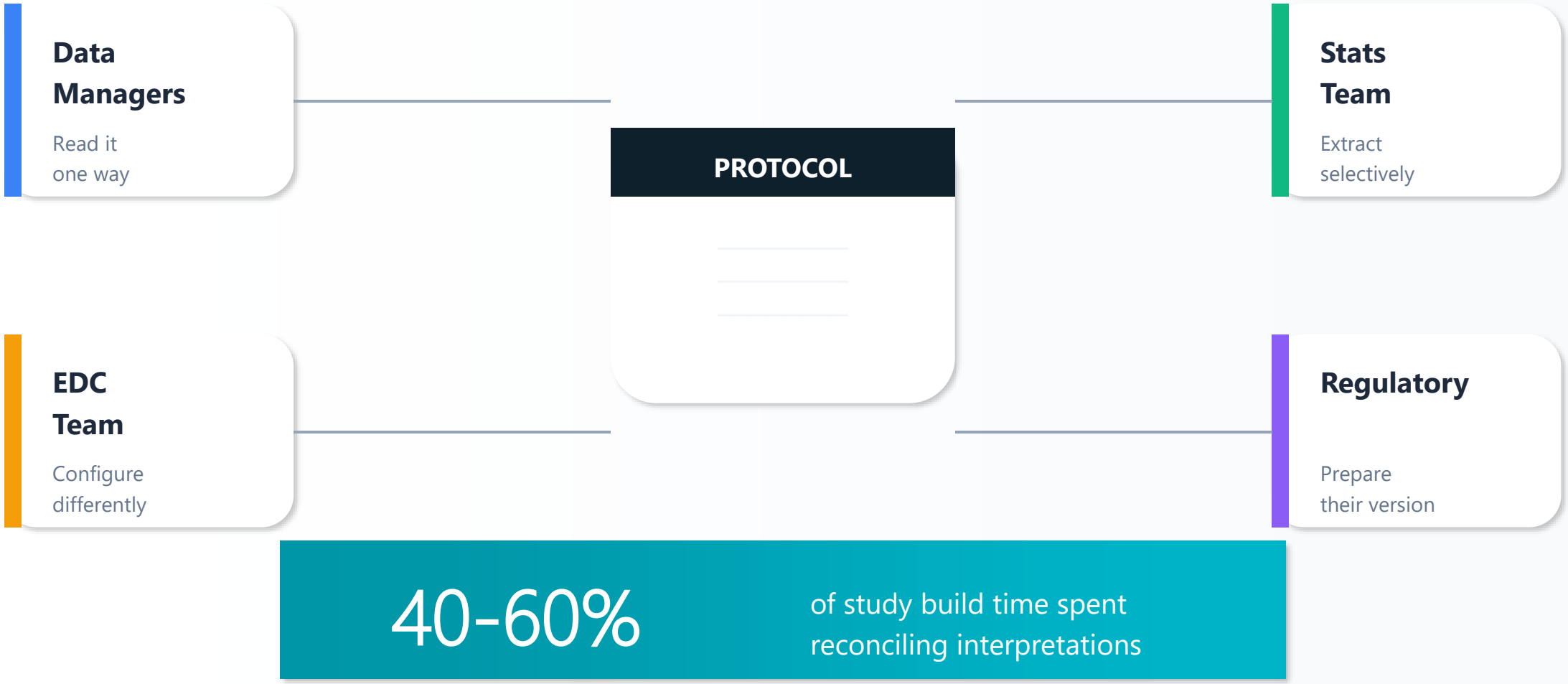
I am Udiksha Jaiswal, Project Manager at Sycamore Informatics Pvt Ltd, having 12 years of experience, including in clinical trials and specialized expertise digital health transformation. I am CDISC USDM certified and active CDISC USDM volunteer, contributing to the advancement of data standards, interoperability, and regulatory compliance.

My work focuses on Digital Data Flow, metadata-driven automation, and AI-enabled validation to streamline the clinical data lifecycle. I have led global teams in delivering innovative, standards-based healthcare solutions using open-source tools and automation frameworks. I am passionate about accelerating clinical research through scalable, intelligent, and compliant data ecosystems.

THE CHALLENGE

One Protocol. Four Interpretations

The same document gets reinterpreted at every handoff



APPROACH

Three Interconnected Capabilities

01

Syntax Templates

Structured Authoring

- Controlled vocabulary fields
- Real-time USDM validation
- CDISC terminology integration

02

Semantic Search

Protocol Intelligence

- Historical protocol lookup
- Element-level similarity
- One-click prior art adoption

03

Auto Pipelines

Study Build

- API-driven data flow
- EDC auto-configuration
- Change propagation

Protocol Authors → USDM Structure → EDC/CDMS → Regulatory Submission

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RESULTS

Three Immediate Wins

17
issues caught

Ambiguity Surfaced

Templates flagged vague terms like 'clinically significant' instantly

100%
adoption

Search Transformed Authoring

Became the default starting point for all protocol elements

90%
time saved

Propagation Automated

Amendment changes flow without manual rework

KEY INSIGHT: Upstream structure investment delivers massive downstream dividends

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LESSON LEARND

What Required Iteration

Honest lessons from an implementation still evolving

TECHNICAL

- **Integration complexity**

  Each system had its own data model and validation rules

- **Validation rethinking**

  Traditional review processes assumed narrative documents

- **Dual maintenance**

  Preparing both narrative + structured during transition

HUMAN

- **Uneven adoption**

  Some authors experienced structure as constraint, not guidance

- **Change management**

  New skills and mental models required across teams

- **Regulatory uncertainty**

  Practical acceptance experience still limited

Start with felt pain, not technology. Teams who experienced the problem embraced the solution.

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MEASURED OUTCOMES

The Numbers That Matter

Single pilot study — interpret with appropriate caution

4-5
WEEKS

Protocol → EDC

Down from 8-10 weeks

~50%

2-3
DAYS

Amendment Propagation

Down from 3-4 weeks

~90%

8-12
QUERIES

Clarifications/Study

Down from 45-60

~80%

15-30
MINUTES

Prior Study Research

Down from 2-3 days

~95%

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TAKEAWAY

Four Lessons for Your Journey

01 Start with Genuine Pain

Select a study where protocol ambiguity caused documented issues

02 Invest in Semantic Infrastructure

Structured authoring without reuse means more work for invisible benefits

03 Plan for Coexistence

Narrative and structured protocols will coexist for years during transition

04 Engage Regulators Early

Regulatory acceptance is the critical enabler for full DDF value realization

Which lesson resonates most with your organization's situation?

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READY NOW

The technology is mature

- ✓ USDM v4.0 expressiveness
- ✓ ICH M11 regulatory pathway
- ✓ Semantic search capability
- ✓ API-driven integrations

STILL EVOLVING

The ecosystem is maturing

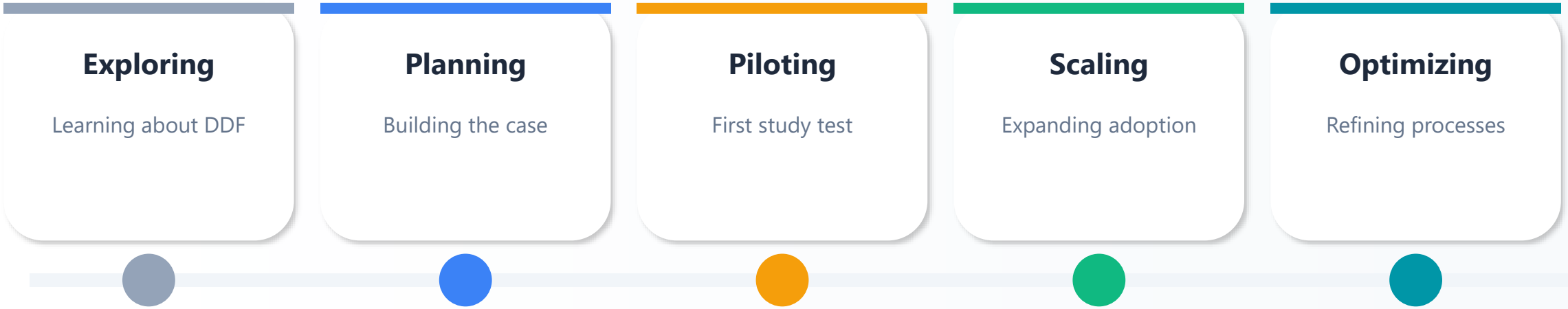
- → Author change management
- → Integration investment
- → Regulatory clarity
- → Industry-wide adoption

The remaining challenges are organizational, not technical

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YOUR TURN

Where Are You on the Journey?



DISCUSSION

- What's your biggest barrier to DDF adoption?
- What would make structured authoring easier for your authors?

Thank You!



"We go through life reasoning by analogy, which essentially means copying what other people do with slight variations. But ***first principles means boiling things down to the most fundamental truths****... and reasoning up from there.“-* ***Elon Musk***



Questions?

