



cdisc[®] 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

BRING YOUR OWN MODEL
A Plug-and-Play Framework for Flexible Clinical Data Flow

Presented By Sanket Patnaik, Product Consultant, ADD Platform, TCS

Speakers



Sanket Patnaik
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Sanket leads the Research and Development Team in the Advanced Drug Development (ADD) platform at TCS with over 5 years of experience in the Life Sciences and Healthcare domain, specializing in advanced clinical data architectures and scalable digital solutions. He is Based in New Delhi, focused on enabling organizations to transition from legacy systems to modern, metadata-driven, and flexible data ecosystems.



Agenda

1. Problem: The Limitations of Traditional Clinical Data Architectures
2. Solution: An Autonomous Flexible Data Fabric (AFDF) with BYOM
3. Impact: Business Value & Scalable Transformation Roadmap



THE BURDEN OF FIXED LEGACY MODELS



STRUCTURAL LOCK-IN

- Most organizations depend on traditional fixed data models and transformation pipelines for handling heterogeneous data from EDC, Labs, Controlled Terminologies, Safety Systems, etc.
- Any clinical protocol modification requires weeks of manual reconfiguration, creating severe bottlenecks.





LACK OF SCALABILITY

- Global trials require:
 - Adaptive Data Containers
 - Audit-ready traceability
 - Faster study startup
- Frequent protocol amendments force expensive remapping and revalidation cycles.
- CDISC compliance often becomes a downstream activity.

The future of clinical data is in the autonomy of the organizations to define their own data destiny.

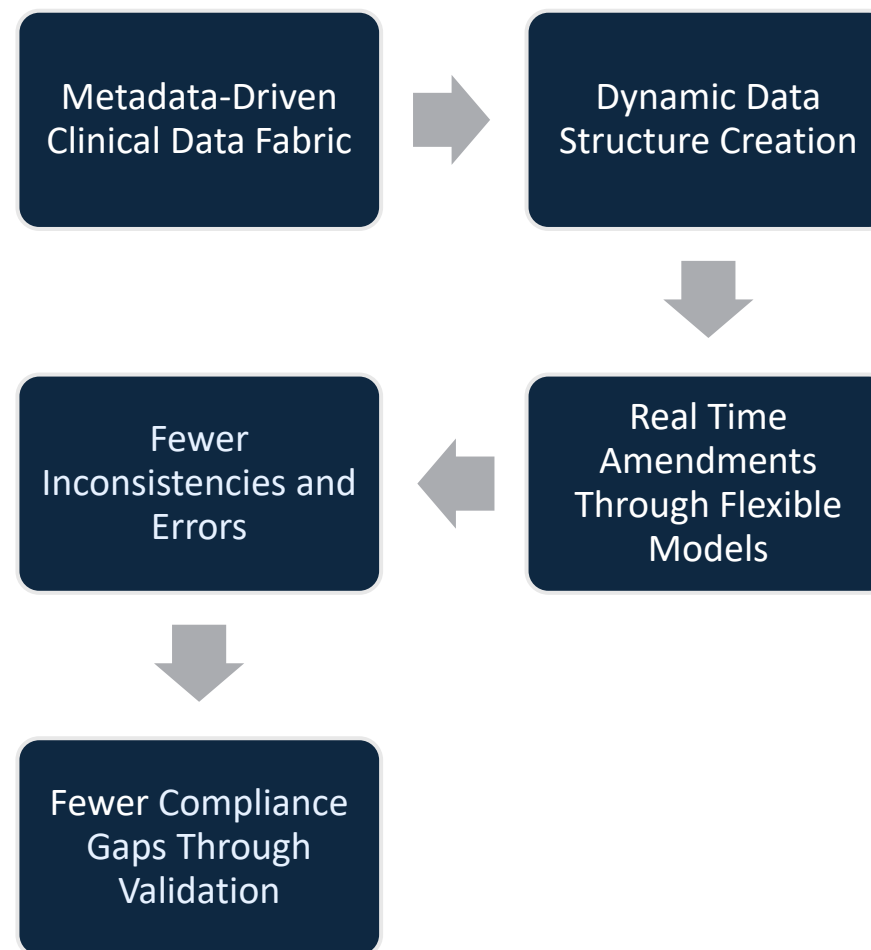


AUTONOMOUS FLEXIBLE DATA FABRIC (AFDF)

Breaking the Chains of Static Data Processing

ORGANIZATION-CENTRIC DATA SOVEREIGNTY

- A single metadata-driven Clinical Trial Data Fabric replacing all the hardcoded data models.
- Organizations define their own semantic data structures dynamically.
- By internalizing the data model, organizations reclaim control over their clinical assets.
- Instant model updates enables teams to adjust data structures in real-time as protocol amendments occur, ensuring cross-study standardization is maintained without external intervention.



METADATA-DRIVEN CLINICAL DATA FABRIC



Logic Engine

Create attribute properties and let the system generate the model.



Schema Sync

Automatic adaptation to future structure changes.



Automated Mapping

Built-in Transformation tool for conversion to submission domains.



Rule Engine

Define a rule once and apply the validation across models and standards.

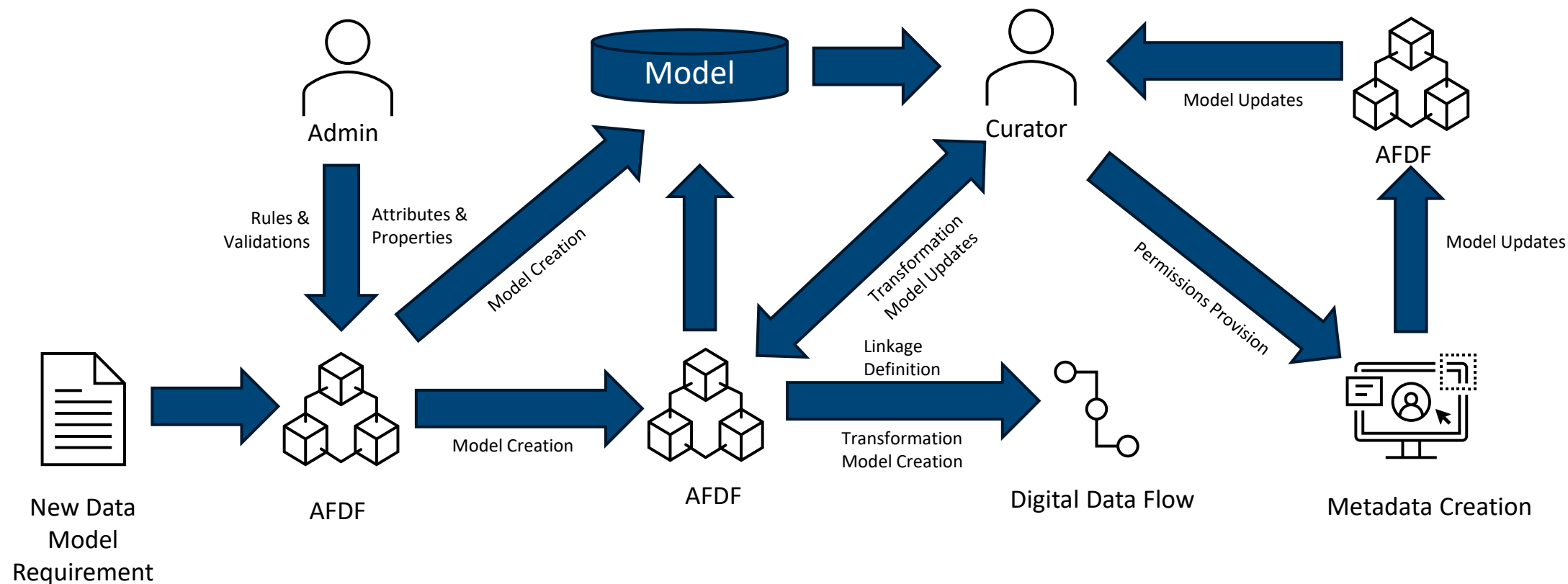


FLEXIBLE DATA IN ACTION

- Business users configure domains, variables, mappings and validation logic visually.
- Every data object is defined through these configurations rather than fixed database tables.
- Transformation pipelines interpret metadata and generate compliant structures automatically.
- Study-specific and therapeutic-area-specific variations are supported without redevelopment.
- A single system-driven infrastructure ensures organization-wide consistency and leads to fewer errors.

Clinical data complexity is increasing faster than the systems can adapt. Flexible data offers an opportunity to accelerate innovation, compliance, and patient outcomes.

FROM METADATA TO MODEL: THE OPERATIONAL FLOW



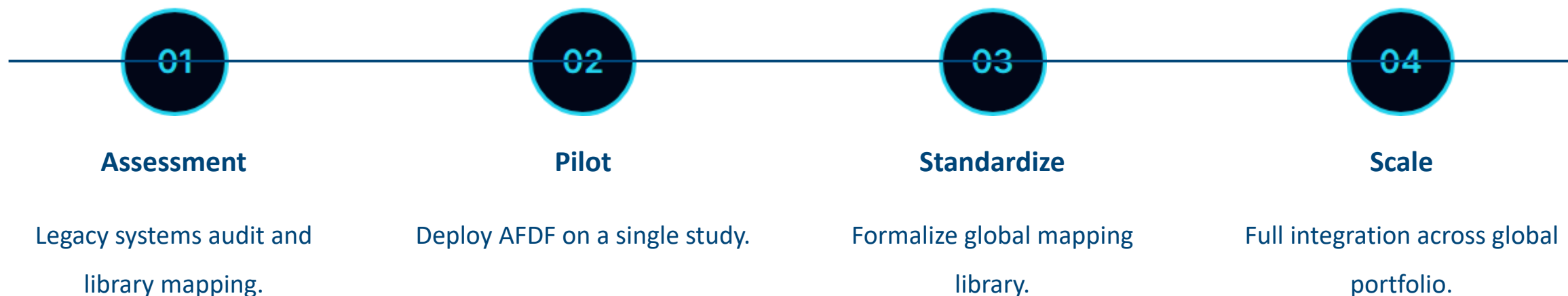


WHAT SETS THIS APPROACH APART

- ✔ **Supports Any Kind of Standard:** Unlike rigid traditional platforms, this approach is schema-fluid and metadata-first.
- ⚡ **Agile Solution to the Fixed Model Problem:** Supports evolving regulatory standards without rebuilding infrastructure. Designed for global scalability across therapeutic areas and regional regulations
- 🔄 **Living Traceability:** Keeps a clear lineage from raw data points to final statistical outputs for regulatory audits.
- 🌐 **Global Standards Sync:** Automatic updates to the latest CDISC versions without rewriting core study logic. Transforms CDISC compliance into a strategic operational capability.

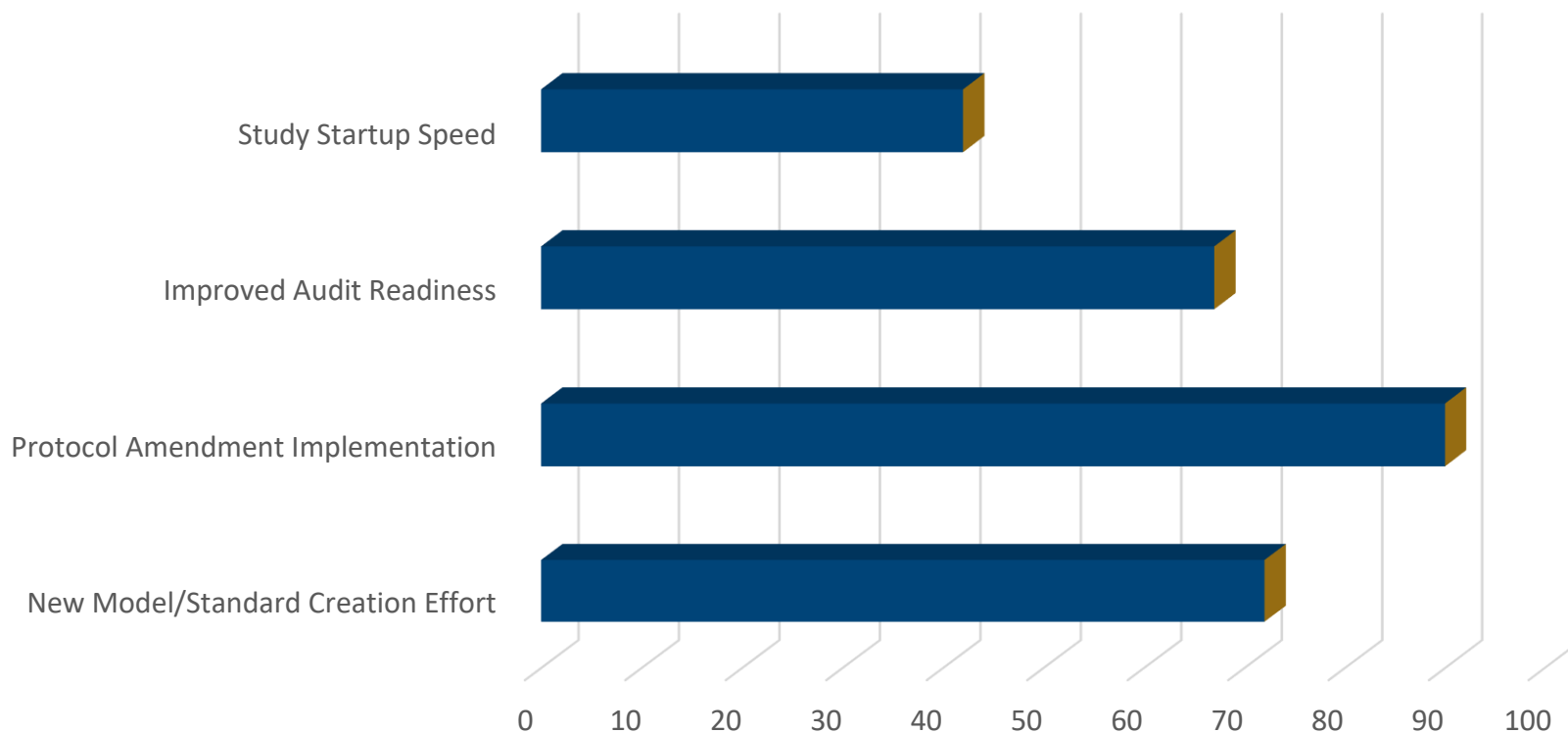
True agility comes from owning your data architecture.

ENTERPRISE DEPLOYMENT ROADMAP



STRATEGIC EFFICIENCY BENCHMARKS

The Numbers Behind the Transformation



**Results based on internal enterprise deployments and metadata driven automation benchmarks*



Thank You!





Questions?





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your data architecture.*

