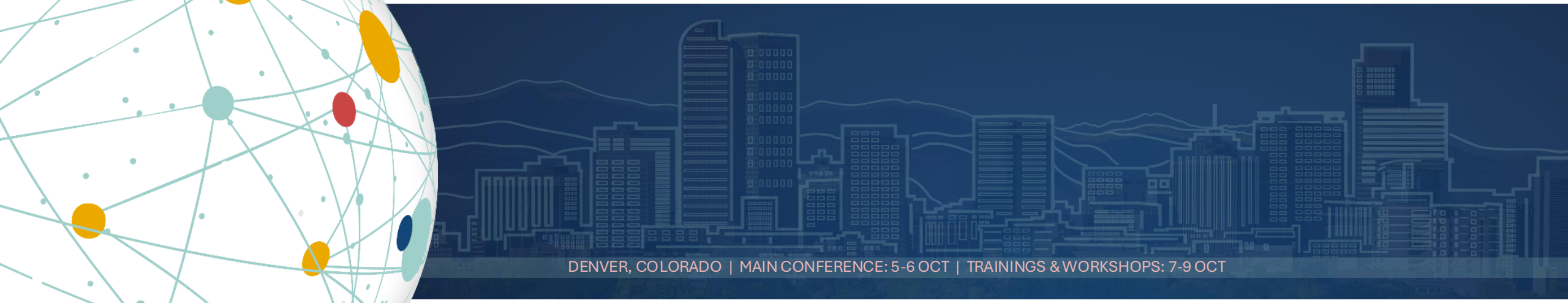


2026 US Interchange

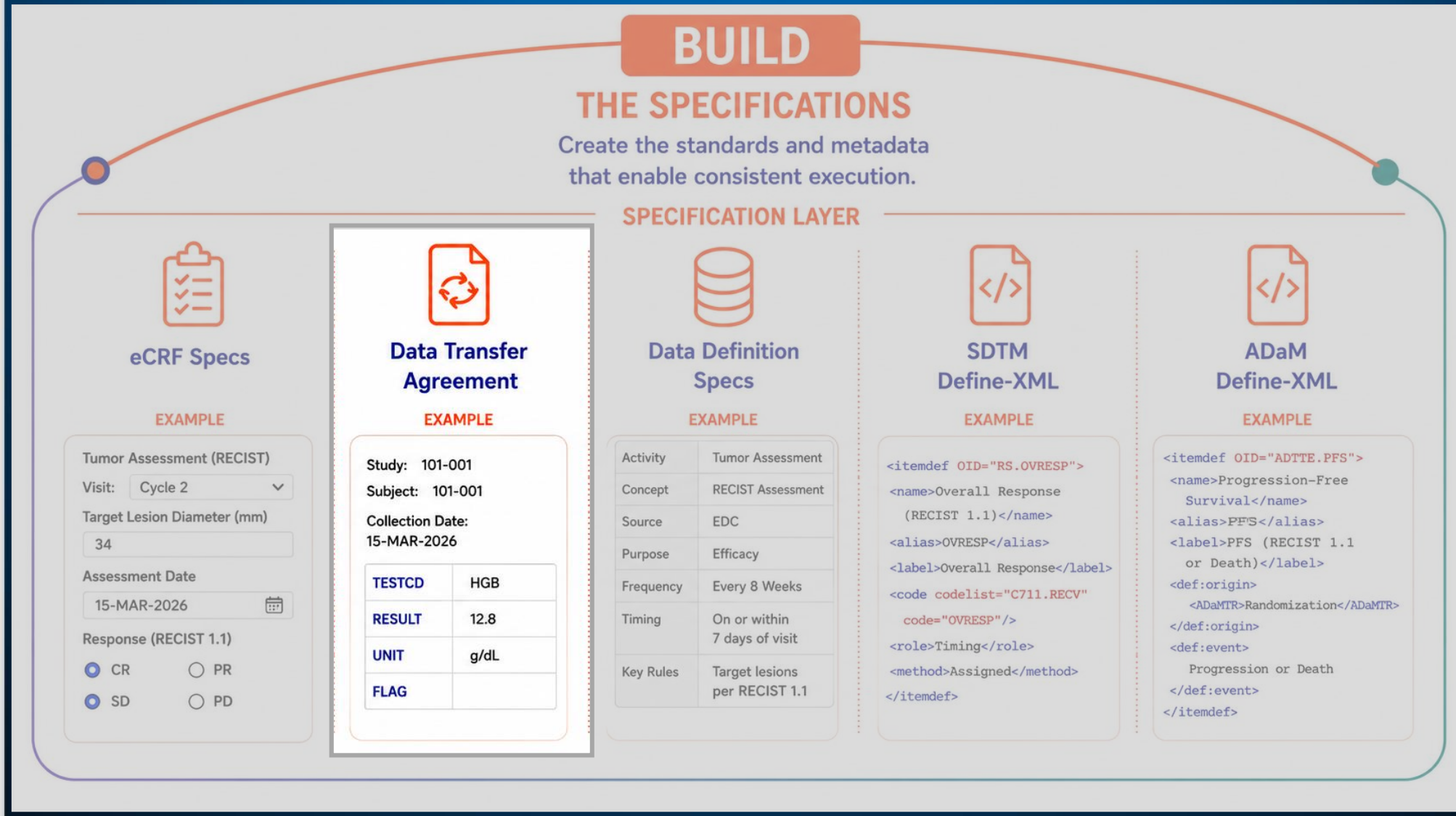
THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



From Fragmentation to Interoperability: The Digital DTA Transformation

Valerie Sheft, Operations Manager, Merck

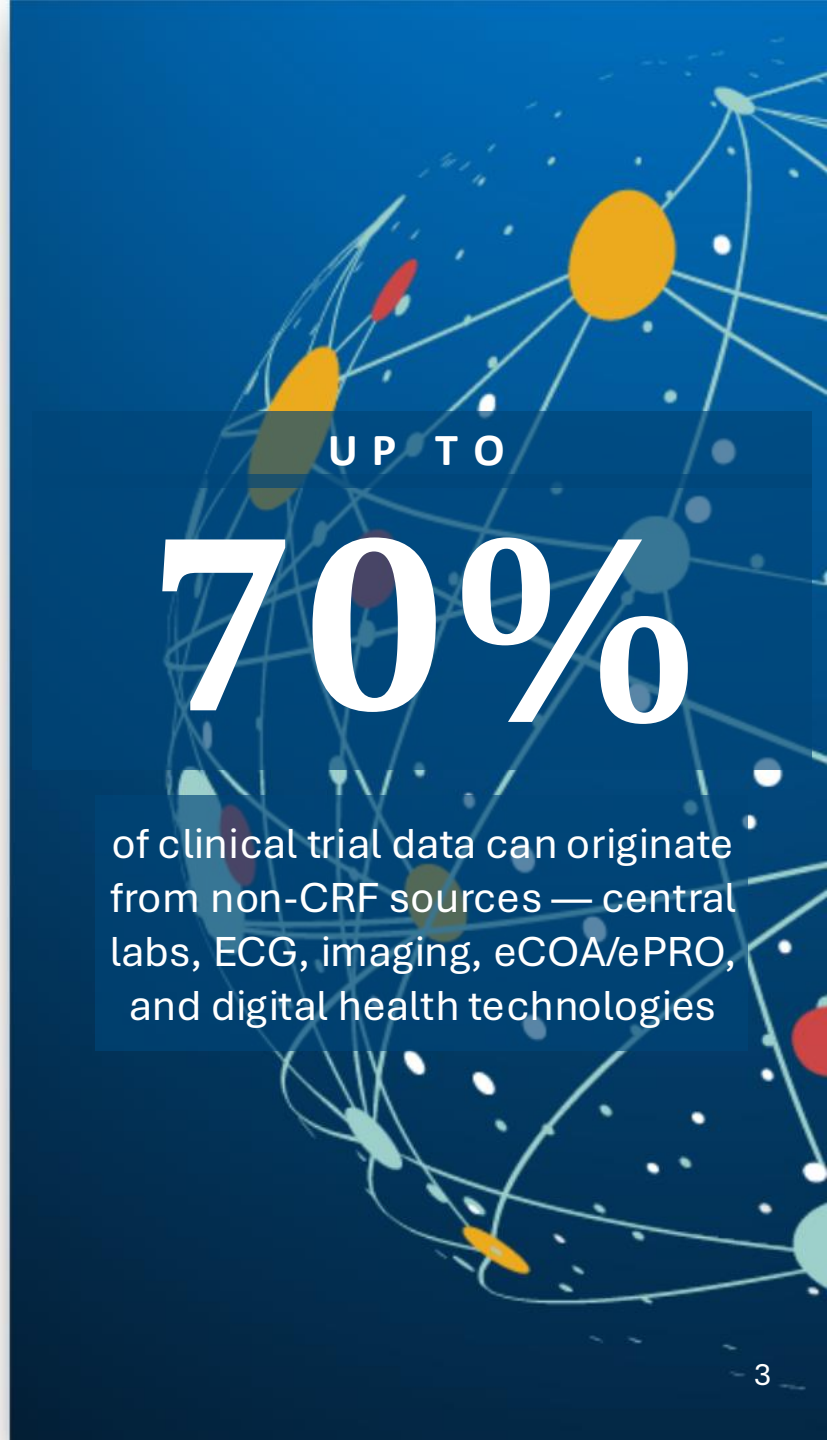
In Focus: Data Transfer Agreement



Problem Statement

No non-proprietary standard links the protocol to how data is transferred and what is delivered

- **No Protocol Linkage**
- **Unstructured Agreements**
- **Fragmented Specifications**
- **Repeated Work**



Solution: Digitizing the DTA

GOAL

Use CDISC standards to automate the Data Transfer Agreement process, end to end.

BENEFITS



Faster, clearer agreements

Standardized templates and language eliminate ambiguity and speed finalization.



Less negotiation effort

A common industry framework minimizes back-and-forth between parties.



Automated specifications

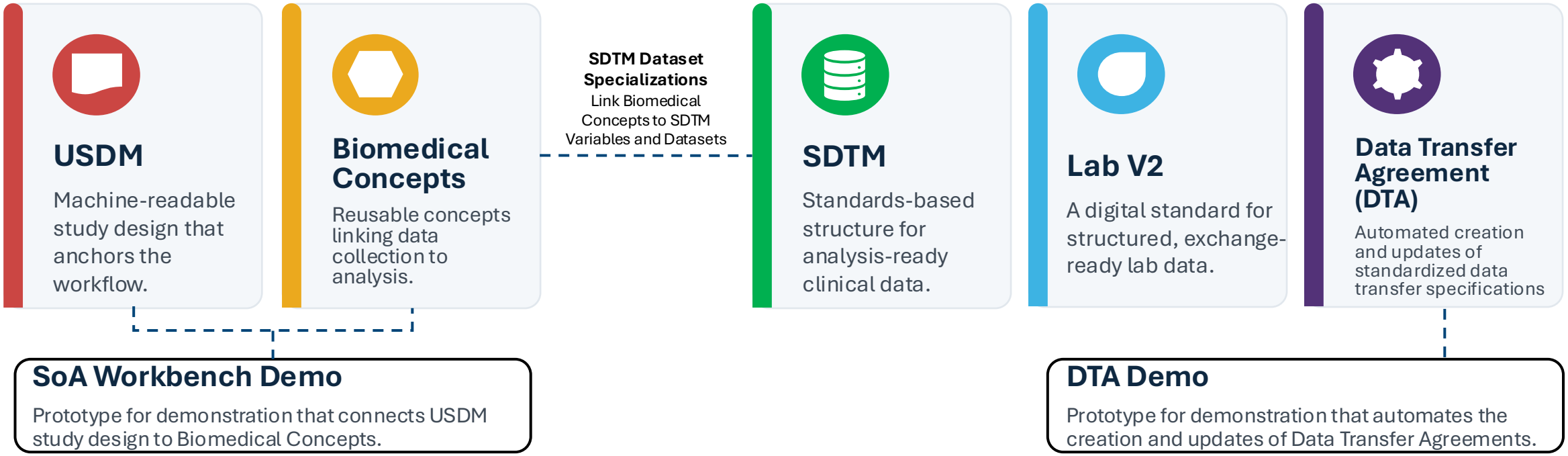
Study-specific specs generate automatically from standardized components.

Benefits: Automating the DTA Workflow

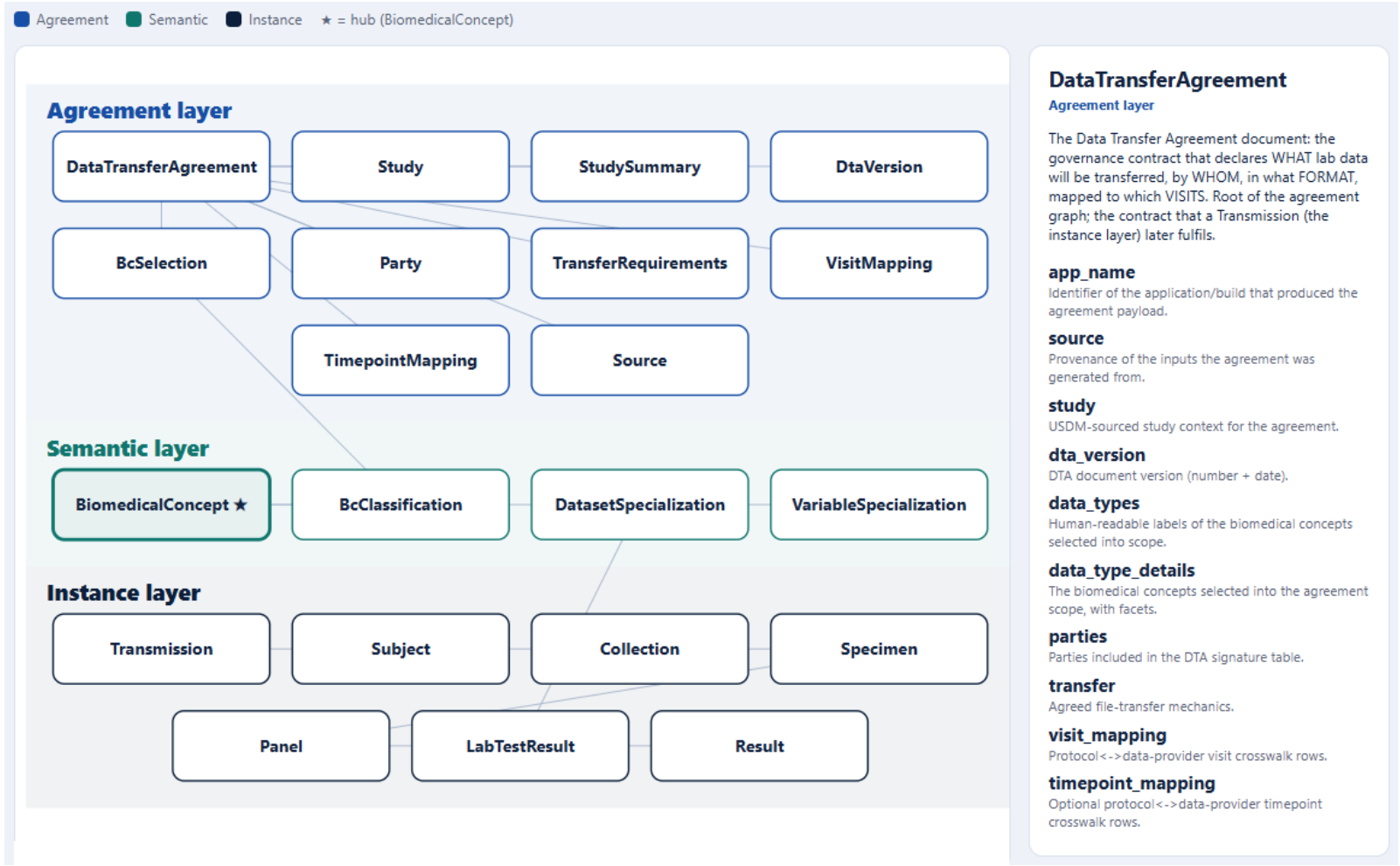
APPROACH

Connect CDISC standards into an integrated workflow that automates DTA creation and updates.

CONNECTED COMPONENTS



Model: DTA Logical Data Model



Participant Engagement: DTA Logical Data Model

- If you'd like to explore the technical details of the DTA Logical Data Model, scan the QR code to view the model in the 360i GitHub repository.

Digital DTA Demo

Showcasing how CDISC Standards enable automation in the DTA Workflow.

Demo Takeaway: Before/After the DTA Model

BEFORE

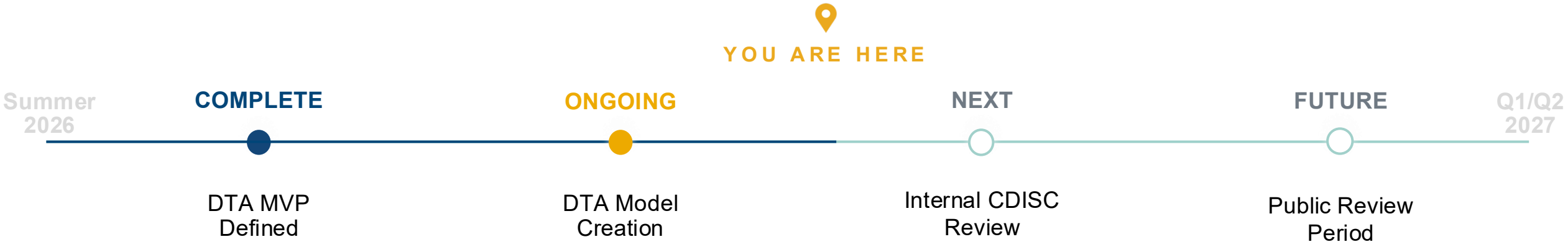
- DTA Specifications created manually with no direct link to the protocol
- Agreements vary by vendor without common structure
- Specifications are fragmented and require manual updates
- Repeated work across similar study and transfer types

AFTER

- Standards-driven DTA, with both human- and machine-readable outputs
- Biomedical Concepts drive automation; USDM links that automation to the protocol
- Bridges the gap between standards and the signable agreement sponsors and vendors use

Looking Ahead

- Minimum Viable Product (MVP) for DTA release identified and defined
- DTA Model development continues
- DTA specific Biomedical Concept Groupings development
- Internal review will follow, with a subsequent 60-day public review period
- Initial DTA model published



Thank You!

