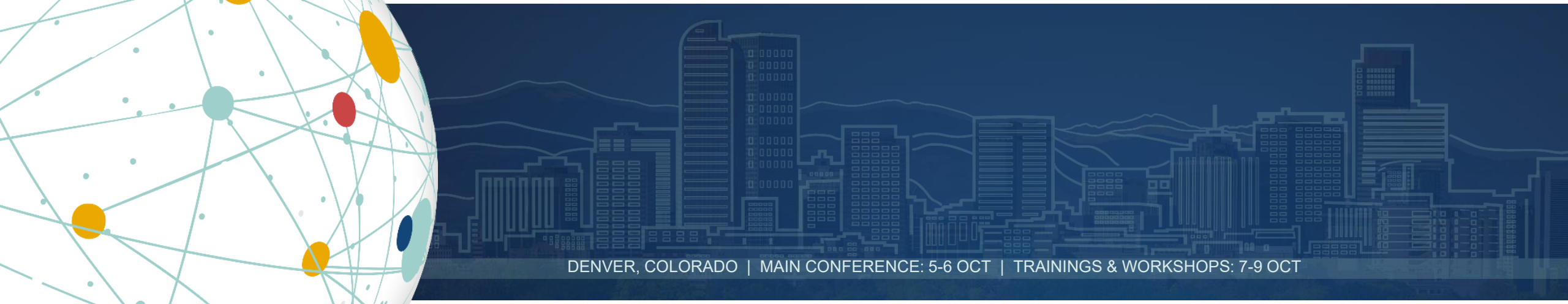


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



360i Phase 2: Journey of an Endpoint

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The Journey of an Endpoint

Progression Free Survival (PFS)

Hi, I'm PFS. Come take a journey with me.



IMPACT ANALYSIS
(Protocol Amendment)

When something changes, we know what it impacts.

- Trace the change
- Assess downstream impact
- Identify affected data, analysis and outputs
- Accelerate decisions with confidence

Affected Areas

- Schedule of Activities (SoA)
- Biomedical Concepts (BC)
- Analysis Concepts (AC)
- Derivation Concepts (DC)
- Data Acquition (EDC / eDT / DHT)
- Specifications
- SDTM / ADaM / ARS / TFLs

Changes feed back to design

DESIGN
THE ENDPOINT

STUDY DESIGN
Define the trial purpose, population and key decisions.

OBJECTIVE
Define study objectives and the questions the study will answer.

ENDPOINT (PFS)
Define PFS using estimand (ICH E9(R1)) and Analysis Concept Model.

SCHEDULE OF ACTIVITIES (SoA)
Define activities, timepoints and link to Biomedical Concept (BC) groupings.

BUILD
THE SPECIFICATIONS

Create the standards and metadata that enable consistent execution.

SPECIFICATION LAYER

- eCRF Specs
- Data Transfer Agreement
- Data Definition Specs
- SDTM Define-XML
- ADaM Define-XML

SEMANTIC BACKBONE
The stable meaning that everything connects to.



PFS
(Primary Endpoint)
Meaning preserved throughout the lifecycle.

BC BIOMEDICAL CONCEPTS
Define the clinical meaning and context.

AC ANALYSIS CONCEPTS
Define how the endpoint is analyzed.

DC DERIVATION CONCEPTS
Define how data is derived and transformed.

RUN
THE DATA PIPELINE TO GENERATE THE EVIDENCE

ACQUIRE
Capture data at the source.

TABULATE
Harmonize and integrate data into a trusted, analysis-ready dataset.

ANALYZE
Generate insights and answer the study question.

ANSWER
Answer the study question and support decisions with trusted evidence.

- **EDC** Electronic Data Capture
- **eDT** Electronic Data Transfers
- **DHT** Digital Health Technologies
- **SDTM** Standardized observed data
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ONE ENDPOINT. ONE THREAD. ENDLESS IMPACT.

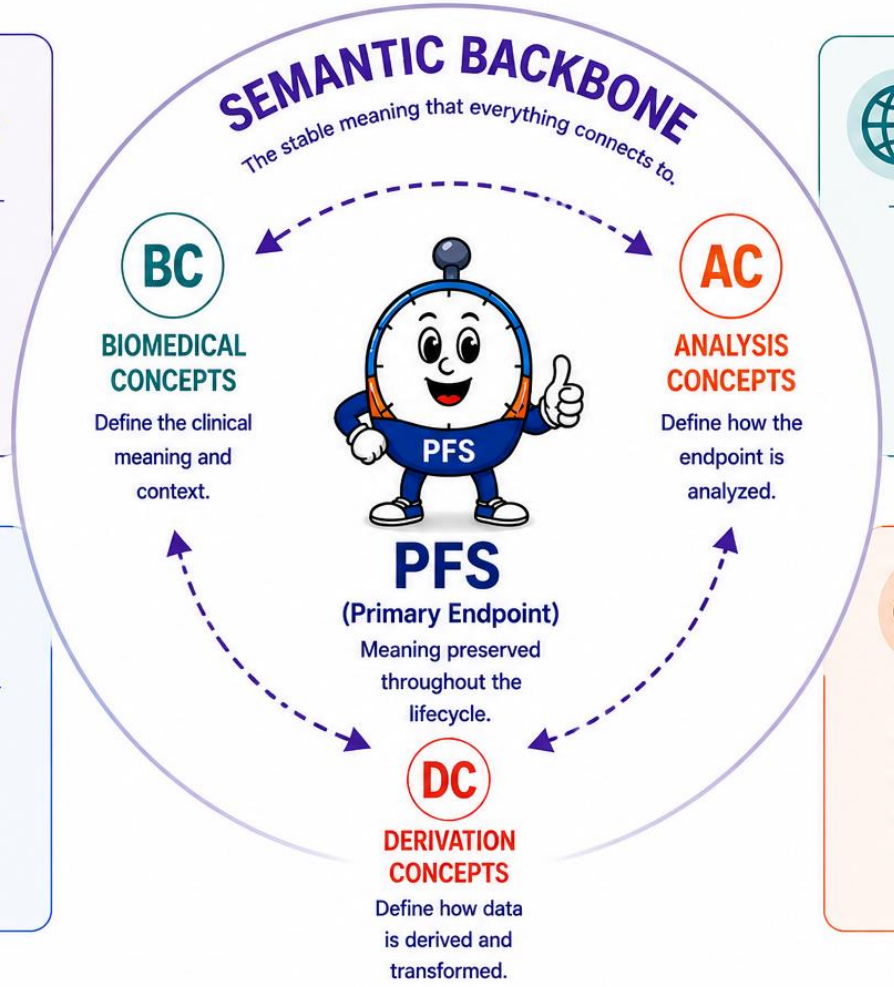
The Semantic Backbone

TRACEABILITY

Ability to follow an endpoint from study intent through collection, analysis, and results.

REUSE

Definitions created once and reused across studies, programs, and therapeutic areas.

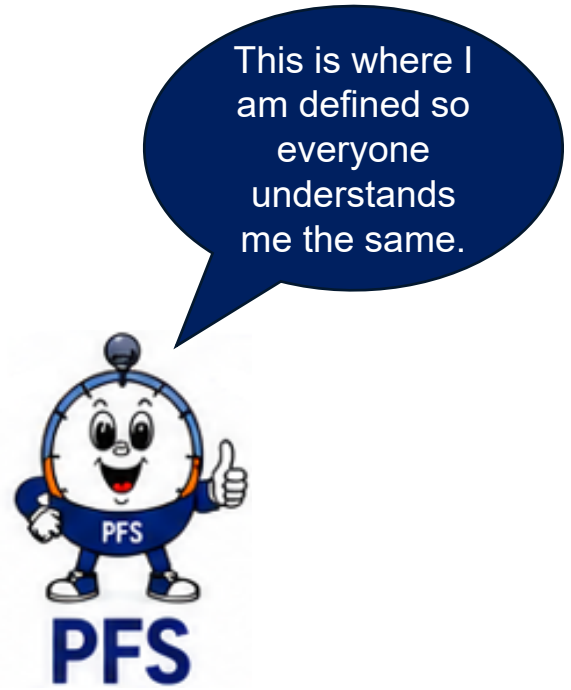


CONSISTENCY

Shared meaning across standards, systems, organizations, and studies.

AI-READY

Structured semantics that enable automation, impact analysis, and AI-driven workflows.



ONE ENDPOINT. ONE THREAD. ENDLESS IMPACT.

Design the Endpoint

To answer my question, the study must specify exactly what information needs to be collected.



DESIGN THE ENDPOINT

STUDY DESIGN

Phase III Breast Cancer Study

Compare Drug A *versus* Standard of Care in patients with metastatic breast cancer.

OBJECTIVE

Determine whether Drug A improves Progression-Free Survival compared with Standard of Care.

ENDPOINT (USDM)

Progression-Free Survival (PFS)

Time from randomization to first documented disease progression per RECIST 1.1 or death from any cause, whichever occurs first.

USDM

Primary Endpoint

Progression-Free Survival (PFS)

Definition (RECIST 1.1)

Time from randomization to the first documented disease progression per RECIST 1.1 or death from any cause, whichever occurs first.

SCHEDULE OF ACTIVITIES (SoA)

Activity	Screening	Cycle 1	Cycle 2	...	Follow-up
Tumor Assessment (RECIST)	●	●	●		●
Survival Status	●	●	●		●
Subsequent Therapy		●	●		●
Adverse Events	●	●	●		●

The endpoint drives the activities. Biomedical Concepts define the information collected at each activity.

Build the Specifications

BUILD

THE SPECIFICATIONS

Create the standards and metadata that enable consistent execution.

SPECIFICATION LAYER

eCRF Specs

EXAMPLE

Tumor Assessment (RECIST)

Visit: Cycle 2

Target Lesion Diameter (mm)

34

Assessment Date

15-MAR-2026

Response (RECIST 1.1)

CR PR

SD PD

Data Transfer Agreement

EXAMPLE

Study: 101-001

Subject: 101-001

Collection Date: 15-MAR-2026

TESTCD	HGB
RESULT	12.8
UNIT	g/dL
FLAG	

Data Definition Specs

EXAMPLE

Activity	Tumor Assessment
Concept	RECIST Assessment
Source	EDC
Purpose	Efficacy
Frequency	Every 8 Weeks
Timing	On or within 7 days of visit
Key Rules	Target lesions per RECIST 1.1

SDTM Define-XML

EXAMPLE

```
<itemdef OID="RS.OVRESP">
 <name>Overall Response
   (RECIST 1.1)</name>
 <alias>OVRESP</alias>
 <label>Overall Response</label>
 <code codelist="C711.RECV"
   code="OVRESP"/>
 <role>Timing</role>
 <method>Assigned</method>
</itemdef>
```

ADaM Define-XML

EXAMPLE

```
<itemdef OID="ADTTE.PFS">
 <name>Progression-Free
   Survival</name>
 <alias>PFS</alias>
 <label>PFS (RECIST 1.1
   or Death)</label>
 <def:origin>
   <ADaMTR>Randomization</ADaMTR>
 </def:origin>
 <def:event>
   Progression or Death
 </def:event>
</itemdef>
```

Now the blueprint for collecting and analyzing me gets created.



PFS

Run the Data Pipeline

This is where I become evidence



PFS EXAMPLE: FROM OBSERVATION TO EVIDENCE

EDC (Electronic Data Capture)

eDT (Electronic Data Transfer)

DHT (Digital Health Technologies)

1 ACQUIRE (RECIST Assessment)

Example

Tumor Assessment

Subject: 101-001

Visit: Cycle 2

Target Lesion
Diameter: 34 mm

Overall Response
SD

Assessment Date:
15-MAR-2026

Tumor assessments collected at scheduled visits per protocol.

2 TABULATE (SDTM RS Dataset)

Example

Standardized Observation

Tumor Assessment → Overall Response (RECIST 1.1) → SD

SDTM
Standardize responses into SDTM.

3 ANALYZE (ADaMTE Dataset)

Example

Derive Progression-Free Survival

Randomization (0) — Assessments Over Time — Progression or Death

PFS = 11.8 months

Time from randomization to the first documented progression or death.

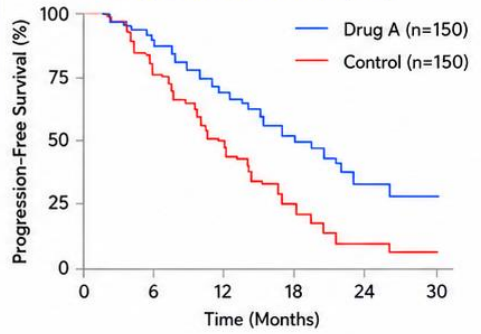
ADaM
Derive analysis variables and subject-level datasets.

ARS
Analysis results standardized.

4 ANSWER (Kaplan–Meier Curve)

Example

Progression-Free Survival (PFS)

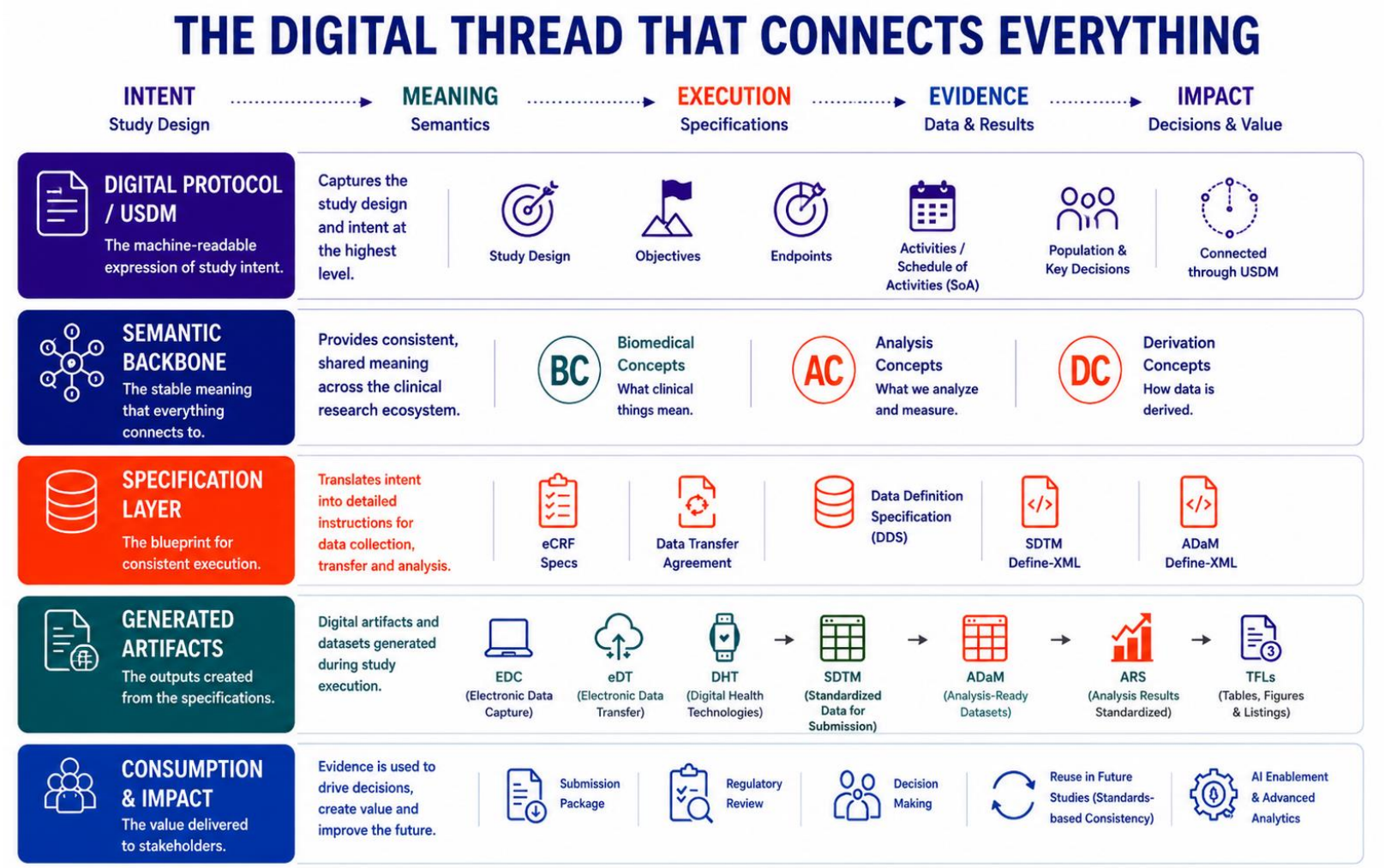


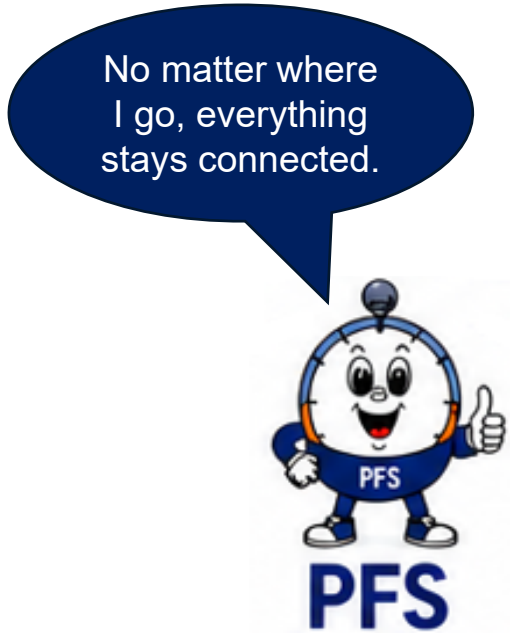
TFLs (Tables, Figures and Listings)

Median PFS (Months)	
Drug A	11.8
Control	8.3
Hazard Ratio (95% CI)	0.71 (0.52, 0.97)

Results reported in Tables, Figures and Listings.

The Digital Thread





ONE ENDPOINT. ONE THREAD. ENDLESS IMPACT.

Impact Analysis



IMPACT ANALYSIS
(Protocol Amendment)

When something changes, we know what it impacts.

PROTOCOL AMENDMENT
Version 2.0

CHANGE
PFS assessment frequency changes

Every 12 weeks → Every 8 weeks

IMPACT ANALYSIS ENGINE

WHAT IS IMPACTED?

DESIGN (CONCEPTS)	BUILD (SPECIFICATIONS)	RUN (IMPLEMENTATION)	OUTPUTS (EVIDENCE)
SoA Schedule of Activities (SoA) Updated	eCRF Specs Updated	EDC Updated	ARS Dataset Updated
BC Biomedical Concepts (BC) Updated	DTA Updated	eDT Updated	TFLs Updated
AC Analysis Concepts (AC) Updated	DDS Updated	DHT Updated	
DC Derivation Concepts (DC) Updated	SDTM Define-XML Updated	SDTM Dataset Updated	
	ADaM Define-XML Updated	ADaM Dataset Updated	

AFFECTED AREAS AUTOMATICALLY IDENTIFIED | Design (Concepts) | Build (Specifications) | Run (Implementation) | Outputs (Evidence) | Updated = impacted by the change

Endless Impact

My journey doesn't end with one study.



PFS

ENDLESS IMPACT

- Traceable
- Transparent
- Reusable
- Standards-based
- AI-ready
- Future-proof

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cdisc 360i

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ONE ENDPOINT. ONE THREAD. ENDLESS IMPACT.

What we will Demonstrate

Here's what my journey will demonstrate today.



360i Phase 2: What We Will Demonstrate

1 CONNECT INTENT TO EXECUTION

Carry study intent and meaning from the Digital Protocol and Biomedical Concepts into executable specifications.

Digital Protocol (USDM) + Biomedical Concepts (BCs)

DDS → eCRF Specs + SDTM Define-XML

Data Definition Specification (DDS)

Define the study purpose, objectives, endpoints, populations, and activities using standardized meaning.

Translate intent and meaning into structured metadata that drives data capture and submission.

2 STANDARDIZE DATA EXCHANGE

Carry defined meaning into consistent, machine-readable data transfer specifications.

Data Transfer Agreement (DTA) + Data Transfer Specifications

Ensure aligned, repeatable, and transparent exchange of study data.

3 CONNECT INTENT TO ANALYSIS

Preserve the meaning of the endpoint through analysis and into evidence.

Analysis Concepts → Derivations (Logic) → ADaM Datasets → TFLs (Tables, Figures & Listings)

Link analysis back to intent and semantics to produce trustworthy, traceable analysis results.

4 SCALE & REUSE THE DIGITAL THREAD

Bring connected standards together into reusable, end-to-end therapeutic area guidance.

Digital TAUGs (Therapeutic Area User Guides)

Enable consistent implementation, reuse, and continuous improvement across studies and programs.

One connected thread across the lifecycle: Intent → Meaning → Specifications → Exchange → Analysis → Evidence → Impact

Standards. Connected. Consistent. Trusted.

ONE ENDPOINT. ONE THREAD. ENDLESS IMPACT.