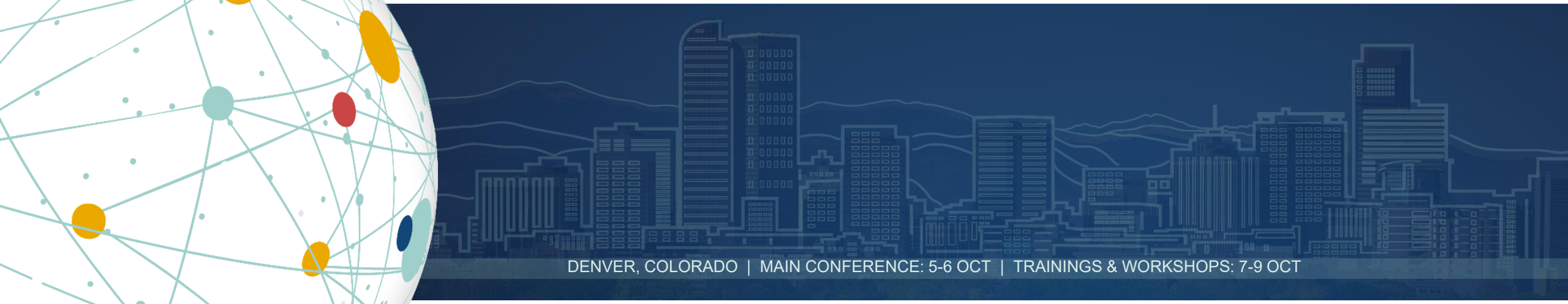
2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION





CDISC 360i and the State of the Standards

What Worked, What Didn't, and What Comes Next

Peter Van Reusel, Chief Standards Officer, CDISC

Opening plenary, Monday 5 October 2026

Agenda

1. State of the Standards
2. 360i Phase 2 Scope & Approach
3. Phase 2 Results & Challenges
4. Phase 3 What's next
5. Building Digital Therapeutic Area Standards, One Endpoint at a Time

Session 2 at 11:00 shows the Phase 2 work in detail: 360i Phase 2 – The Journey of an Endpoint.

State of the Standards

Digital Protocol, TMF Standard Model, CDISC Open Rules

CDISC Standards Across the Study Data Lifecycle

PLAN Protocol and study design	COLLECT Data collection	EXCHANGE Data transfer	TABULATE Organising study data	ANALYZE Analysis-ready data	REPORT Submission
EXISTING	EXISTING	EXISTING	EXISTING	EXISTING	EXISTING
USDM v4.0	CDASH · ODM	LAB Model v1 · Dataset-JSON	SDTM · SDTMIG · SEND	ADaM · ARS v1.0	Define-XML
CURRENT INITIATIVES	CURRENT INITIATIVES	CURRENT INITIATIVES	CURRENT INITIATIVES	CURRENT INITIATIVES	CURRENT INITIATIVES
DDF Phase 5	eCRF and QRS portals	LAB Model v2	SDTM v3.0	ARS v2.0: project launch	CDISC Open Rules SDTMIG 3.2, 3.3, 3.4
USDM governance	DHT portal	Digital DTA / DTS	SDTMIG v4.0	ADaMIG v4.0	FDA Business Rules (Clinical, SDTMIG)
USDM SoA implementation guide		Data Definition Specification (DDS)	SENDIG v4.0		CORE v1.0
USDM v4.1: public review Nov 2026					RWD Lineage

Cross-foundational projects: Tobacco Implementation Guide v1.1 · Polycystic Kidney Disease v2.0

Digital Foundation: Controlled Terminology · Biomedical Concepts (1,475, July 2026) · Analysis Concepts · CDISC Library

TMF Standard Model v1: community review from mid-October 2026 · release with implementation guide April 2027

cdisc®

Digital Protocol: USDM, DDF and the SoA Implementation Guide

USDM

- USDM v4.0: the published model for a digital protocol and study design
- USDM v4.1: alignment with ICH M11, plus a small set of critical updates
- USDM governance: formal USDM/DDF governance being put in place

Digital Data Flow

- Focus moves to accelerating adoption and community engagement
- USDM Implementation Handbooks, trial design domains, SoA and Define-XML
- Support for the Vulcan UDP Project

SoA Implementation Guide

- Standardises how the Schedule of Activities is represented: fewer footnotes, more structure and automation
- Timing constructs, visit windows and anchors; minimum viable metadata
- Worked examples for cyclic and non-cyclic studies and event-driven activities

USDM v4.1 TIMELINE

Under development · public review opens end of November 2026 · publication early 2027

Session 2, 11:10: the SoA Workbench builds study designs as USDM JSON — Darren Moreland

TMF Standard Model v1 Update

Goals

- A framework for controlling the evidence of compliance with ICH E6(R3)
- A standard designed for the digital era: the record is the evidence, not necessarily a document

Five Perspectives, One Model

- Drug / biologic clinical trials
- Real-world evidence and non-interventional studies
- Medical device clinical investigations
- In-vitro diagnostic studies
- Investigator site file

Timeline

- July 2026: early draft of zones, record groups and record types shared with vendors
- Mid-October 2026: community review of the TMF structure
- End October 2026: community review of the implementation guide
- April 2027: release of TMF Standard Model v1 with implementation guide

"We are not simply updating the TMF Reference Model. We are building the foundation for how our industry controls study evidence in a digital era."

TMF plenary: 11:00, Evergreen D–E · TMF closing plenary: Tuesday 15:30

cdisc®

CDISC Open Rules Update

Release, October 2026

- First SDTMIG Open Rules packages in production: SDTMIG v3.2, v3.3 and v3.4
- First FDA Business Rules package (Clinical / SDTM IG) in production
- CORE v1.0 open-source reference engine, rebuilt on PostgreSQL
- Engine-agnostic by design; ADaM and SEND rule development continues

Next Steps

- Q4 2026: Open Rules governance group, aligned with the USDM governance structure
- Q1 2027: industry pilot — organisations run Open Rules against production study data and compare with existing validation tools
- 2027 and beyond: machine-readable rule model, form-based rule authoring, certified engines

Partners

- Verisian: engine development, SDTM and FDA rule migration
- SGS: rule authoring, CORE training and onboarding
- Accelerator Program: GSK, Medpace, Novartis, Pfizer, Sanofi
- Open Rules volunteer community: hundreds of hours of rule authoring and review

The rules are the product; CORE is a reference engine. CDISC develops and governs the rules and certifies engines.

Tuesday 13:30, Track B: CDISC Open Rules — Progress, Performance, and Foundations for the Future, Tomás Sabat Stöfsel, Verisian

cdisc®

360i Phase 2 Scope & Approach

Five Year Vision: CDISC 2030

By end of 2030, all CDISC standards are digital, linked, and easily consumable by users and systems.

- Digital, connected standards create the trusted foundation required for scalable automation and responsible AI.
- Digital standards empower experts across the clinical research ecosystem, reducing manual burden, increasing transparency, and enabling better, faster decisions for patients



Digital

Structured, machine-readable standards that reduce manual effort



Linked

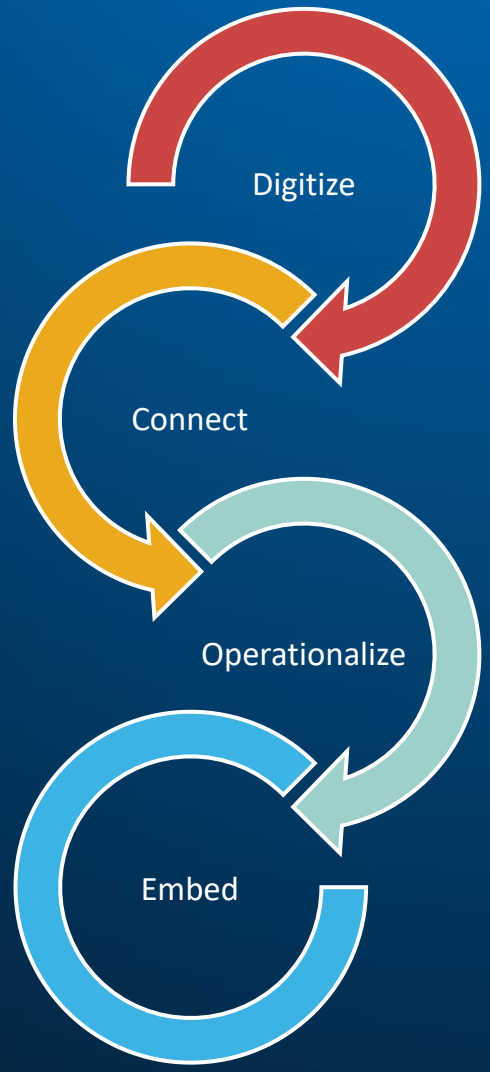
Unified semantic backbone that provides clarity and context



Accessible

Embedded in workflows to support informed, confident decisions

Path to 2030



360i Phase 2: Operationalizing the Vision

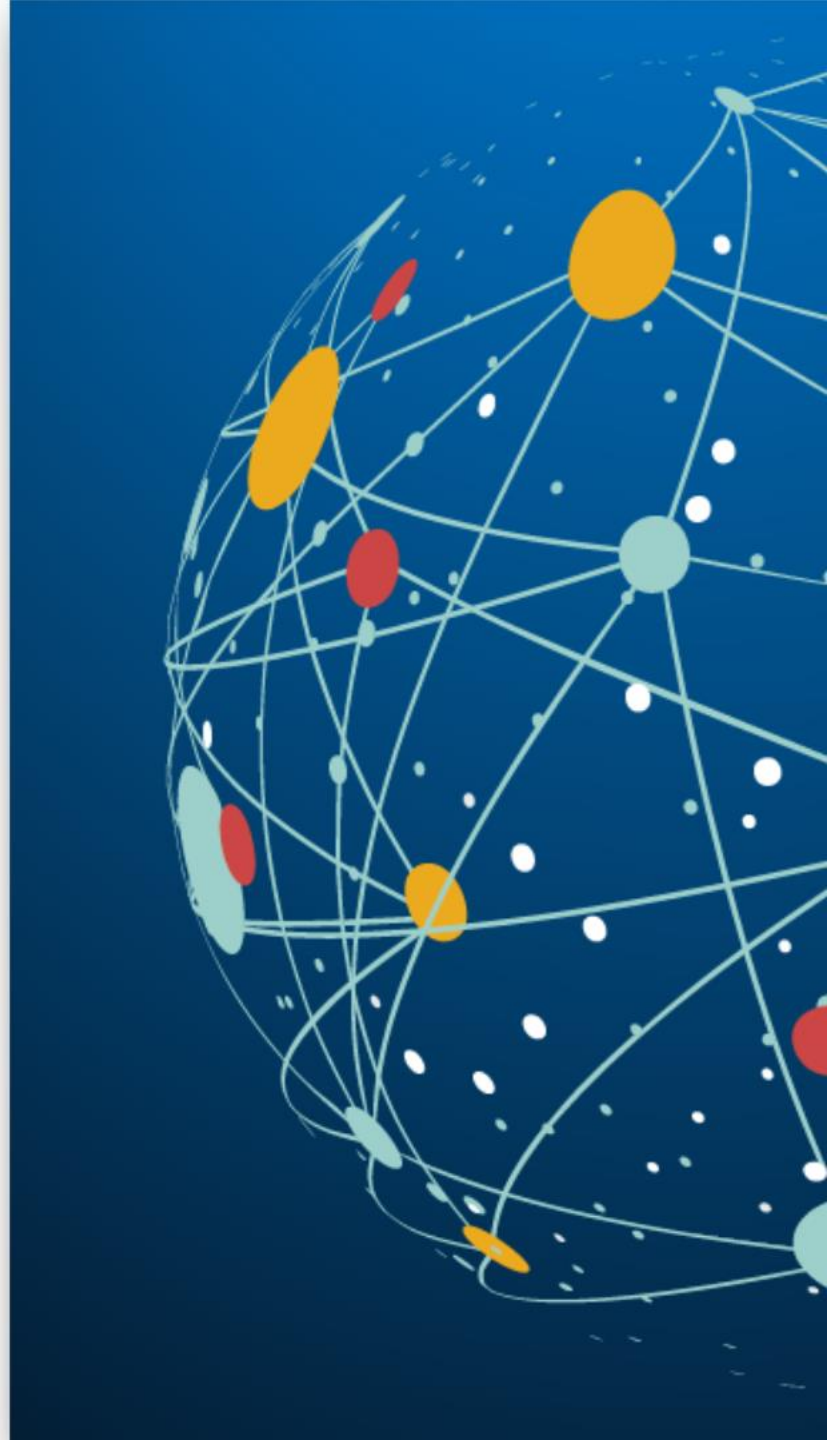
Key Deliverables

Digital Protocol & Impact Analysis Reporting: Machine-readable protocol model with automated amendment and impact analysis

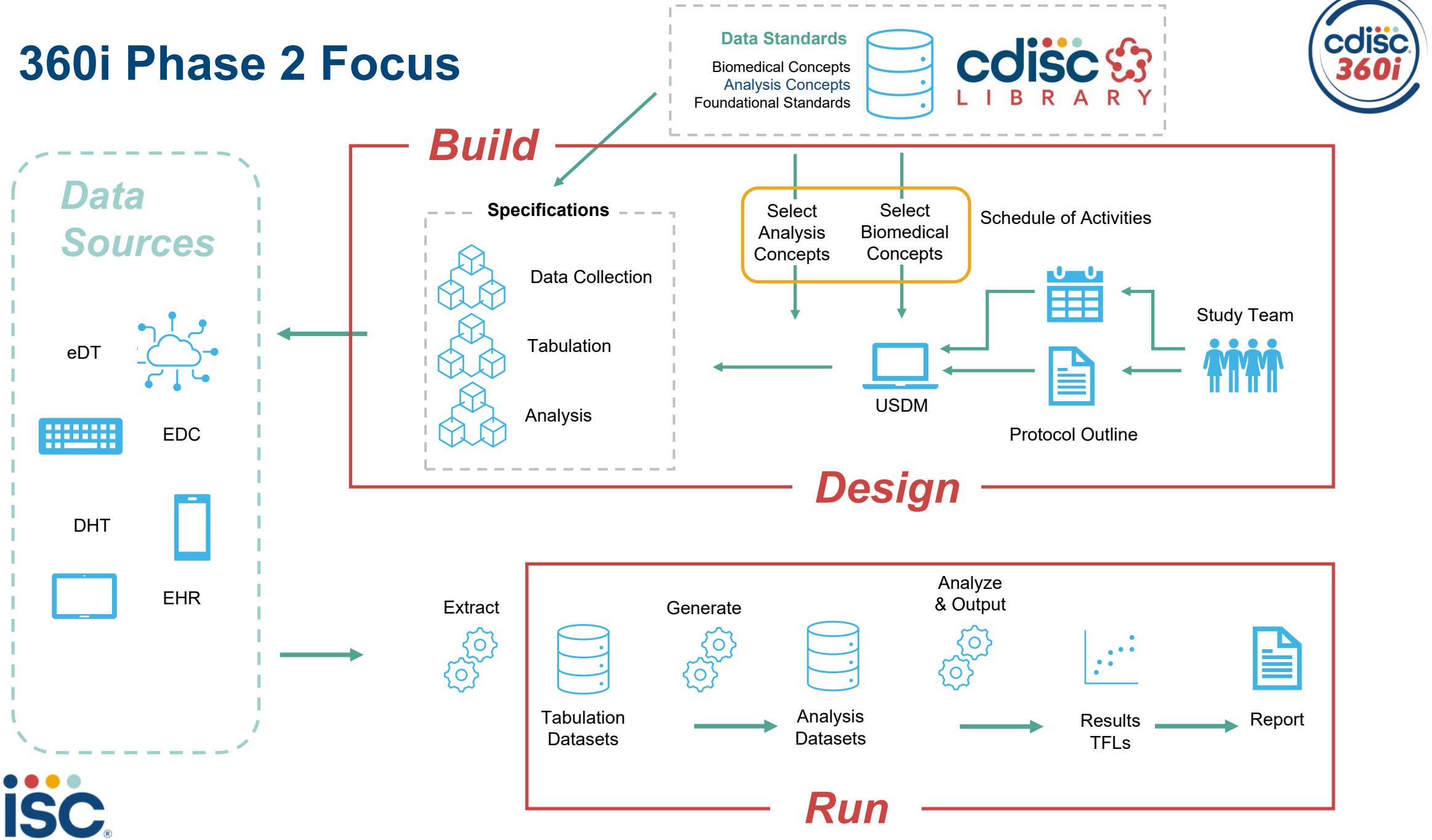
Automated eCRFs, Define & Dataset Generation: Generation of eCRFs, Define.xml and datasets integrated with study workflows

Digital Data Transfer Agreement Model: Technical DTA model and standardized template aligned with the digital protocol

Standardized Analysis Concept Model: Configurable, machine-readable analysis concepts driving automated analysis artifacts



360i Phase 2 Focus



Phase 2 Results & Challenges

Phase 2 Results at a Glance

Phase 2 moved 360i from vision to working software: four workstreams, fifty volunteers, one breast-cancer study.



Study Design

Study designs authored as USDM-conformant JSON, mapped to Biomedical Concepts, integrated with the CDISC Library



Define-XML and eCRF

Define-XML v2.1 generated end to end; Data Definition Specification (DDS) drafted as a shared, reusable model



Data Transfer Agreements

Automation proven through USDM and Biomedical Concept lookups



Analysis Concepts

Methods model drafted and demonstrated; controlled-terminology work started

Study Design

Workstream leads: Darren Moreland, Bess LeRoy

Successes

- Biomedical Concepts and specializations mapped to activities
- Versioning with impact analysis across versions
- SoA Workbench: study design authored end to end as USDM JSON

Available under COSA

Challenges

- Additional Biomedical Concepts required to support the breast cancer study
- Curating and releasing new concepts takes time
- Groupings and CRF specializations not yet published in the Library

Planning for Phase 3

- USDM v4.1 and the remaining entity classes
- Terminology and groupings published in the Library
- One complex study, start to finish

Define-XML and eCRF

Workstream lead: Sam Hume

Successes

- eCRFs and Define-XML v2.1 generated end to end through Biomedical Concepts in USDM
- Data Definition Specification drafted, with a reusable profile per use case
- Reference tools generate, validate and visualise the output

Challenges

- The DDS is too broad to populate and validate efficiently for one use case
- Value-level metadata and variable origins still need manual post-processing

Planning for Phase 3

- DDS v0.1 and its profiles released
- ADaM Define-XML generation
- Modular architecture: the pipeline split into standalone services

Data Transfer Agreements

Workstream lead: Tony Rios

Successes

- MVP logical data model completed
- Demonstrated automation from USDM and Biomedical Concepts to DTA creation
- Publication of the model initiated, planned for internal review by end of year

Challenges

- MVP scope narrowed: no protocol versioning, item-level blinding, or multi-file transfers
- Biomedical Concepts do not cover every common DTA pattern
- Public review pending

Planning for Phase 3

- Public review, then v1 release
- Maturation of BC groupings for labs, oncology imaging and ECG
- Industry feedback for model progression

Analysis Concepts

Workstream lead: Edwin van Stein

Successes

- Components agreed and a draft model for analysis methods
- Demonstration videos show the model works
- Controlled-terminology discussions started

Challenges

- Complex content first, so the model takes longer to build
- Modelling capacity lost late in the phase
- Linked standards need the teams linked too
- More example data needed across therapeutic areas

Planning for Phase 3

- Finish and validate the model
- Mature the concept layer
- The eSAP model, estimands and intercurrent events

Session 2 at 11:00: The Journey of an Endpoint

Evergreen A–C, chair Julie Smiley · joint Q&A at 12:45

11:10

Endpoint by Design: SoA Workbench and Data Definition Specifications

Darren Moreland, CDISC

11:35

From Fragmentation to Interoperability: The Digital DTA Transformation

Valerie Sheft, Merck

11:55

Analysis Concepts: A Standard for Executable Clinical Analysis

Edwin van Stein, CDISC

12:25

Digital Therapeutic Area User Guides

Bess LeRoy, CDISC

Also:

Monday 13:00 Poster, Atrium: Analysis Concepts: Framework in a Nutshell — Edwin van Stein, Kirsten Langendorf
Monday 14:00 AI Innovation Challenge: the winners present their solutions — Session 3, Track C, Evergreen C
Tuesday 13:30 CDISC Open Rules: Progress, Performance, and Foundations for the Future — Tomás Sabat Stöfsel, Verisian
2 December Webinar: CDISC 360i — Phase 2 Outcomes and the Road to Phase 3

Phase 3 What's next

Phase 3 preview

Define

- Select the therapeutic area and its most-used endpoints
- Define each endpoint in USDM and Biomedical Concepts

Specify

- Analysis Concepts and derivations; tabulation, collection and DTA layers
- Every layer machine-readable and traceable to the endpoint

Prove

- Test and validate with synthetic data through the whole chain
- Test packages sponsors can run in their own environments and report back on

ACROSS ALL WORKSTREAMS

Synthetic test data facility NEW!

synthetic data generated for each endpoint, used to test every layer, and shipped with the package

Working method: AI drafts, experts validate; specialists join for their stage

Foundations continuing in Phase 3

- **DDS v0.1 and DDS Profiles**
- **Analysis Concepts and eSAP model**
- **DTA v1.0**
- **USDM v4.1**
- **BC groupings and CRF specialisations in the CDISC Library**

cdisc®

Building Digital Therapeutic Area Standards, One Endpoint at a Time

Why We Are Changing How We Develop TA Content

One gate — at the very end

All endpoints at once
One 18-month-plus engagement

One large, standing group
Cross-company SMEs on recurring calls throughout

Heavy upfront ask
No visible output until the end

CURRENT PRACTICE

A gate — and an output — at every stage

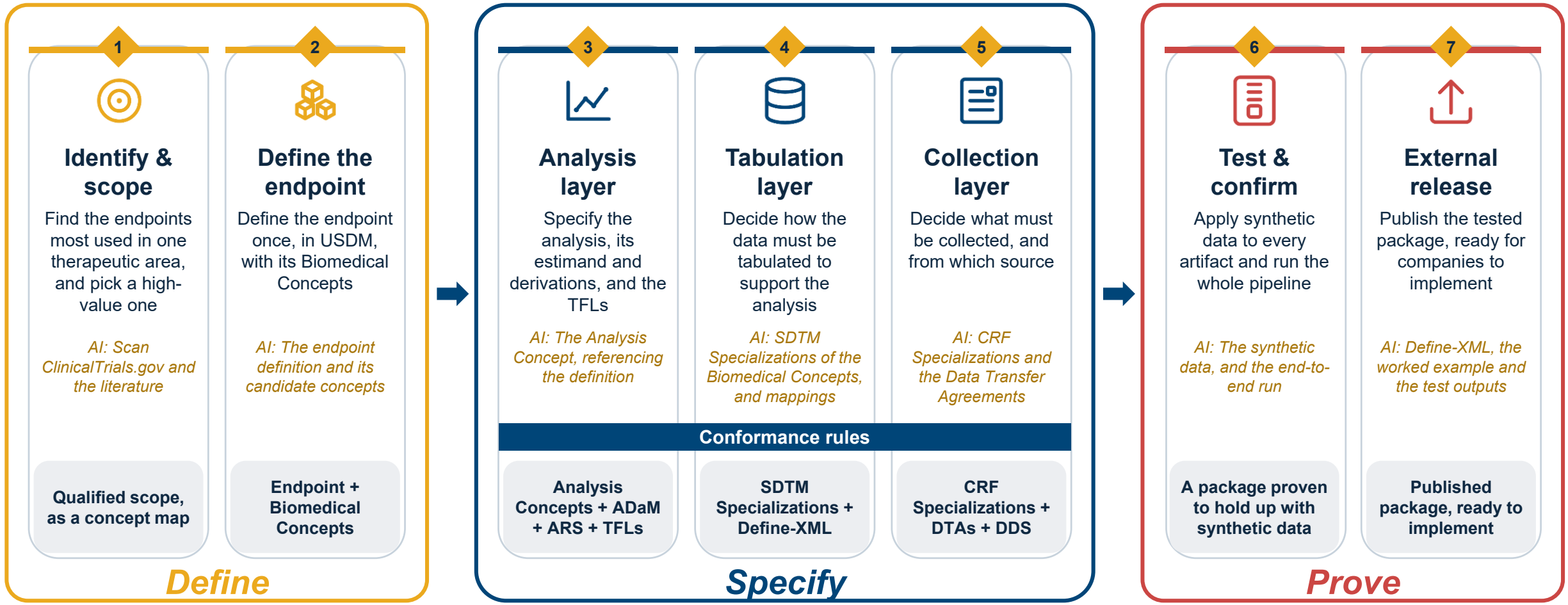
One endpoint at a time
Built end to end before moving to the next

Small, stage-specific experts
Engaged only for the stage that needs them

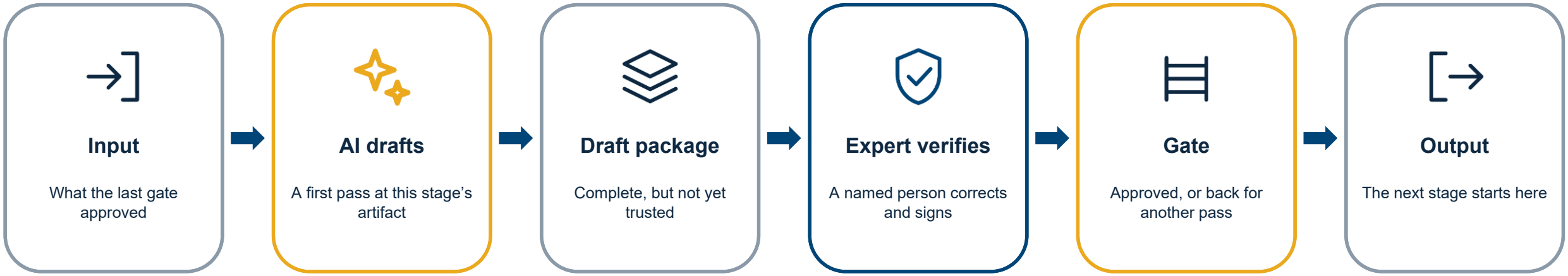
AI drafts, experts verify
Sign-off required before anything publishes

THE NEW MODEL

The Seven Gates, End to End



AI Drafts, a Named Expert Signs



Where the acceleration comes from: AI proposes at every gate, so expert time goes into checking rather than drafting; experts are called only for the gate that needs them, not held on a standing call; and each endpoint reuses what the last one established, so every pass is faster than the one before.



We Need You!



Relentless Collaboration

How you can take part in Phase 3

- Bring your expertise to one stage — specialists join only where they are needed
- Run our test packages in your own environment and tell us what holds up
- Tell us which endpoints matter most in your therapeutic area

2 DECEMBER WEBINAR

CDISC 360i: Phase 2 Outcomes and the Road to Phase 3

More on the Phase 3 plans — and how you can take part

cdisc®

Thank You!

Session 2, 11:00: 360i Phase 2 – The Journey of an Endpoint
2 December: webinar CDISC 360i – Phase 2 Outcomes and the Road to Phase 3

