2026 Korea CDISC Day

29 October 2026 · Seoul, Korea

Building the Digital Foundation for Clinical Research Innovation

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Session 1 · Thursday 29 October 2026 · Woobong Hall, Seoul



Agenda

1. Where clinical research is heading
2. 360i Phase 2: scope, approach and what we achieved
3. The next step: Digitalizing the end-to-end User Guides
4. CDISC 360i Phase 3 preview

Where clinical research is heading

From digitized paper to a digital thread

One connected flow from the protocol to the submission, with no re-keying in between

AI orchestration powered by process knowledge



AI data flow and transformations powered by digital standards

The shift Today every hand-off is a copy, a re-key or a re-interpretation. The thread removes the hand-offs.

Defined once, used everywhere: that is what makes automation and AI safe to use.

A digital protocol makes review easier

The thread starts at the protocol, and ICH M11 gives the world one structure for it

ICH M11

- One harmonized protocol structure
- Template + technical specification
- CDISC maintains ICH terminology

USDM

- The protocol as structured data
- Born in TransCelerate DDF
- M11-conformant, and wider

For the reviewer

- Endpoint traced to result
- Data in a standard they know
- Less reconciling, more reviewing

Next in this session Ron Fitzmartin on ICH M11 and CDISC adoption, then Dr Huh on M11 in Korea, and MFDS.

A connected protocol is the first link in the thread, and the one reviewers see first.

What connected data unlocks

Better data, better AI, and therapies that reach patients sooner

AI you can rely on

Connected data is the prerequisite for AI agents, not an afterthought

Speed and quality

Faster studies, better data, far less rework

Smoother review

Consistent, traceable submissions, checked automatically

Patients sooner

Every hour saved moves a therapy closer to patients

“Clinical development is no longer constrained by science, but by our ability to connect data, people and processes.”

Five-Year Vision: CDISC 2030

By the 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

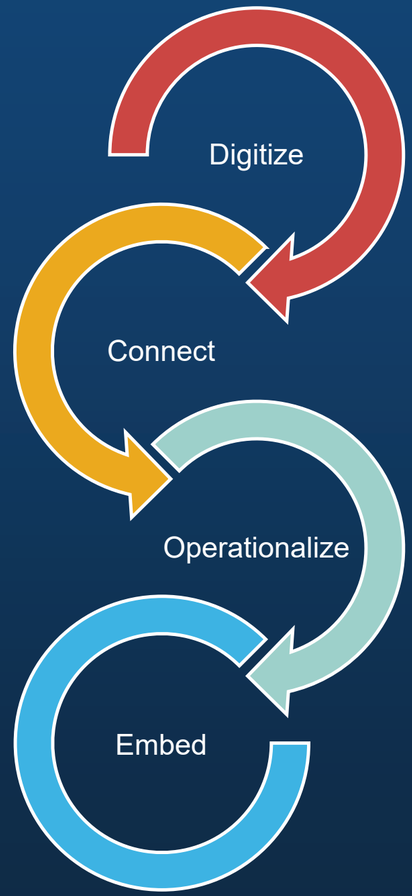
Linked

Unified semantic backbone that provides clarity and context

Accessible

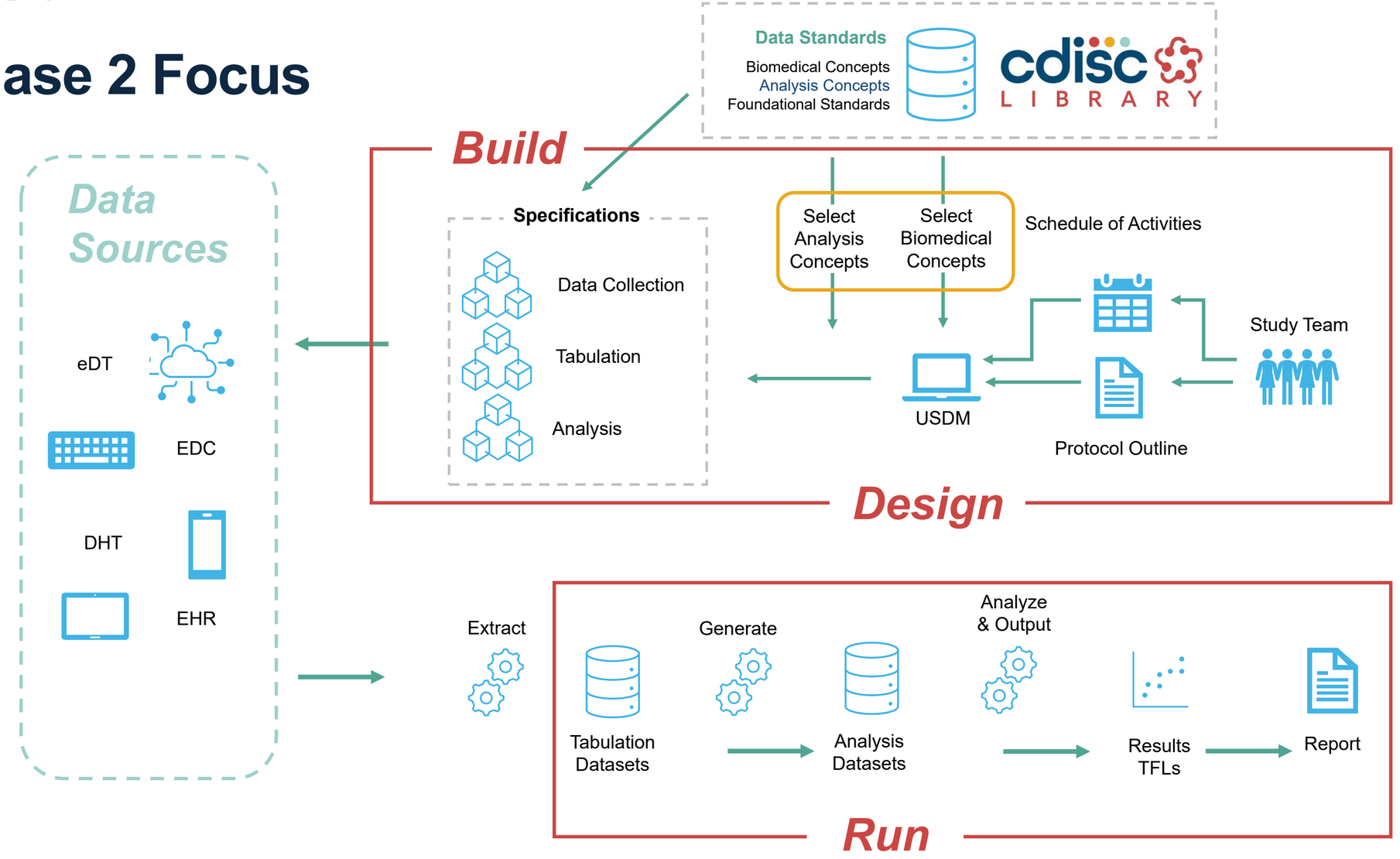
Embedded in workflows to support informed, confident decisions

Path to 2030



360i Phase 2: scope, approach and what we achieved

360i Phase 2 Focus



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



Workstream 1: Study design

Workstream leads: Darren Moreland, Bess LeRoy

What we built

The SoA Workbench authors the study design end to end as USDM, with every activity linked to its Biomedical Concepts.

What was hard

The breast cancer study needed more Biomedical Concepts than we had, and curating new ones takes time.

What comes next

USDM v4.1, the groupings published in the Library, and one complex study from start to finish.

Available under COSA: you can use the SoA Workbench today

Workstream 2: Define-XML and eCRF

Workstream lead: Sam Hume

What we built	What was hard	What comes next
eCRFs and Define-XML v2.1 generated end to end from the Biomedical Concepts in USDM.	Our new Data Definition Specification is still too broad to fill and validate for one use case.	Release DDS v0.1 with its profiles, and add ADaM Define-XML.

Data Definition Specification will become the CDISC Standards operational metadata model

Workstream 3: Data transfer agreements

Workstream lead: Tony Rios

What we built	What was hard	What comes next
A logical data model for data transfer agreements, and a DTA created automatically from USDM and the Biomedical Concepts.	We narrowed the scope to get there: no protocol versioning, item-level blinding or multi-file transfers yet.	Internal review by the end of the year, then public review and version 1.

Data Transfer Agreements can be generated at the time of study design

Workstream 4: Analysis Concepts

Workstream lead: Edwin van Stein

What we built	What was hard	What comes next
The components are agreed, and the draft model for analysis methods works in our demonstrations.	We started with complex content, so the model takes longer, and we need an experienced information modeler.	Finish and validate the model, and add the eSAP model with estimands and intercurrent events.

Phase 3 will finish and validate the model

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

The next step: Digitalizing the end-to-end User Guides

What a digital TAUG looks like

TODAY

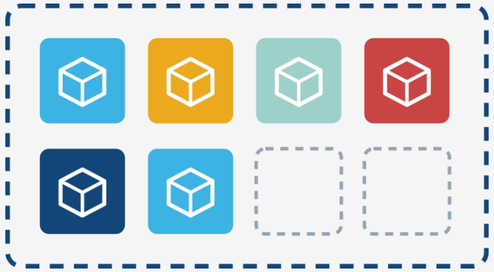
A document



- Static examples to read
- Re-interpreted by every organization
- Released for the whole area at once

DIGITAL TAUG

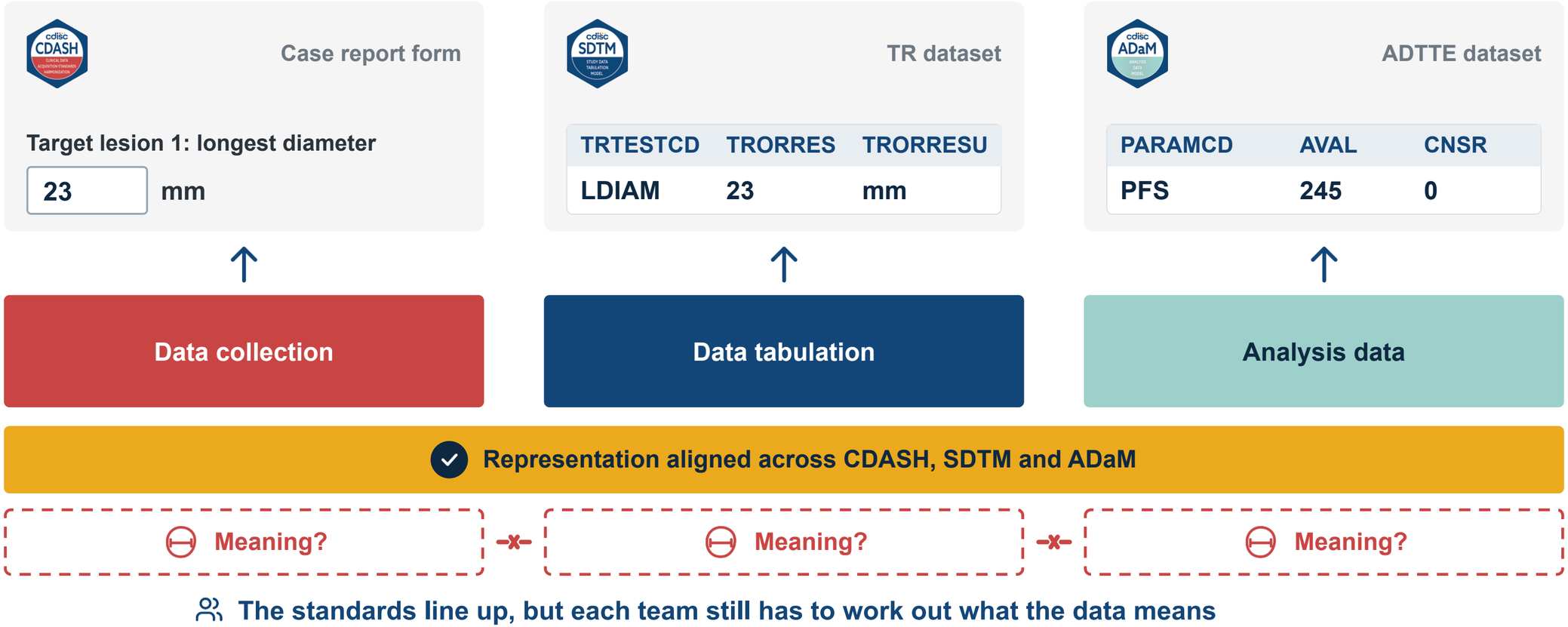
Assembled from endpoint packages



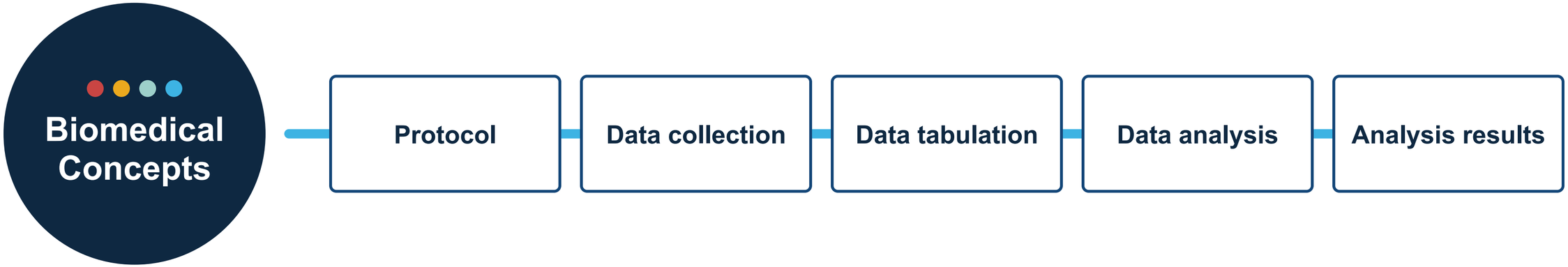
- Machine-readable, ready for tools
- Tested with synthetic data
- Grows one endpoint at a time
- Published in the next-generation CDISC Library

TAUGs align representation, but not meaning

One breast cancer tumor measurement, from case report form to progression-free survival



Biomedical Concepts define meaning once



CONCEPTUAL LAYER

Clinical meaning

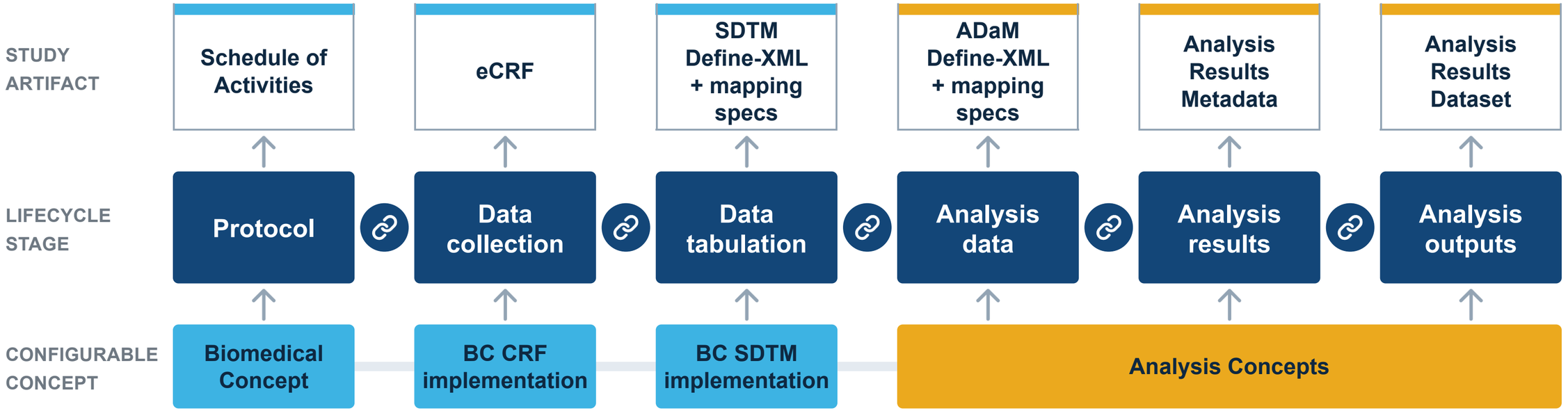
The concept in the real world, independent of any study or data standard

IMPLEMENTATION LAYER

Representation in a standard

CDASH SDTM FHIR OMOP

Digital assets link meaning through every stage



We define the meaning once and generate each stage's artifacts from it.

How we are changing the way we build therapeutic area content

CURRENT PRACTICE

One gate, at the very end



THE NEW MODEL

A gate and an output at every stage



One large, standing group

→ **Small, stage-specific experts**

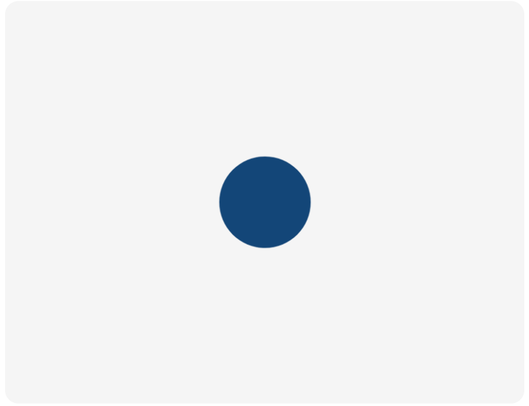
Heavy upfront ask

→ **AI drafts, experts verify**

No visible output until the end

→ **Sign-off before anything publishes**

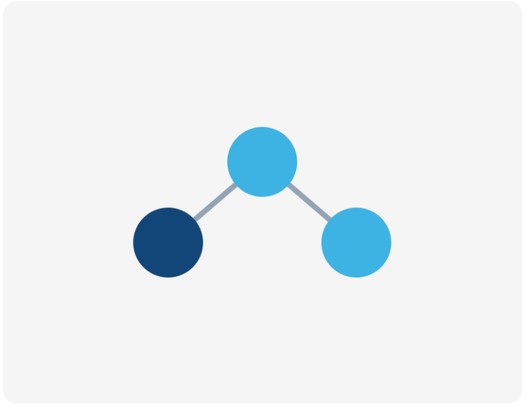
From one endpoint to a therapeutic area



01 Prove it

One endpoint, end to end

We publish one endpoint and test the method



02 Repeat it

Next endpoints reuse shared concepts

Each endpoint takes less time than the last



03 Complete it

Enough endpoints to assemble the TAUG

The first fully digital TAUG

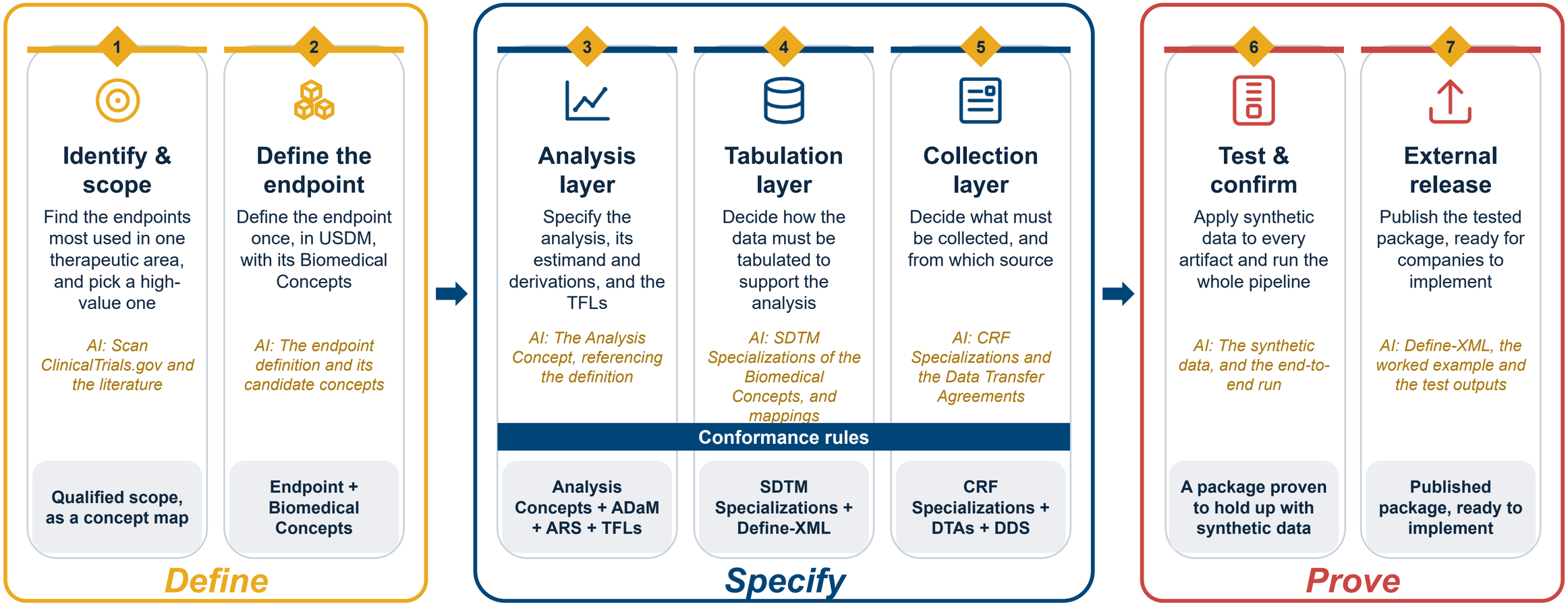


04 Extend it

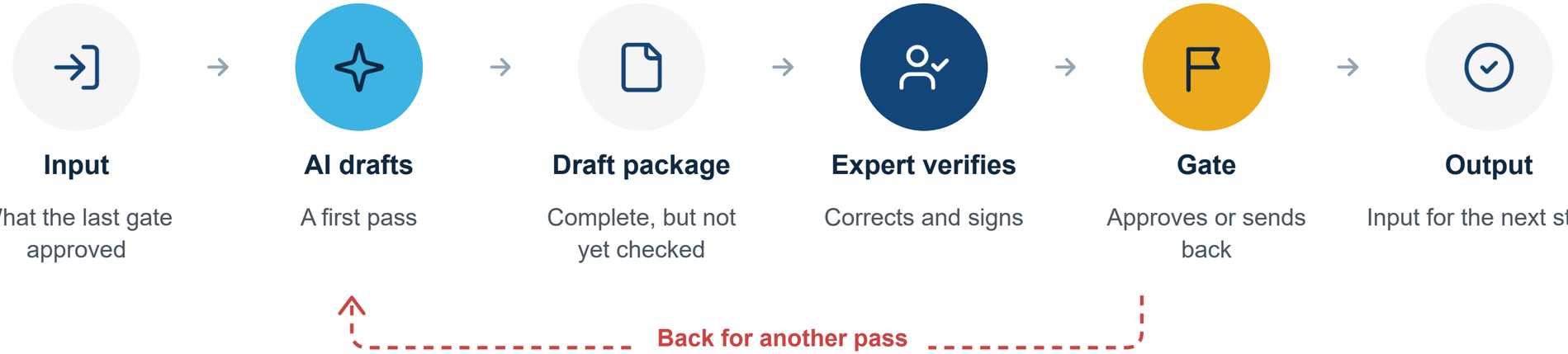
Shared concepts carry to the next area

New areas reuse what we already built

The Seven Gates, End to End



AI drafts, then a named expert checks and signs



WHY THIS IS FASTER

- Experts check rather than draft
- Experts called only for the gate that needs them
- Each endpoint reuses work from the one before

What a Published Package Contains (Work In Progress)

Gate 7 output · the same for every endpoint package

Define · Gates 1–2

What the endpoint means

- Objective and endpoint, as USDM entities
- Biomedical Concepts, with NCI codes
- Concept map of the endpoint scope

Specify · Gates 3–5

How it is analyzed, tabulated and collected

- Analysis Concepts, Derivation Concepts, ARS metadata and TFL shells
- Estimand, derived from the Analysis Concepts
- ADaM specifications for the analysis datasets
- SDTM Specializations
- CRF Specializations and the Data Transfer Agreement
- Data Definition Specification (DDS)
- Define-XML for SDTM and ADaM, with value-level metadata and controlled terminology
- Conformance rules for every artifact

Prove · Gates 6–7

Evidence that it holds up

- Synthetic test data
- The results of our own end-to-end run, to compare against
- A worked example

CDISC 360i Phase 3 preview

Phase 3 plan (draft)

From one study to digital therapeutic area standards

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

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 specializations in the CDISC Library**

How you can participate in Phase 3

We got here by working together, and Phase 3 works the same way



Relentless collaboration

01 Bring your expertise where it's needed most
Specialists join only for the gate that needs them

02 Help us shape the future
Tell us which endpoints and therapeutic areas matter to you

03 Run our test packages
Run them in your own environment, and tell us what breaks

DATES TO KEEP

End Nov 2026
USDM v4.1 public review

2 Dec 2026
Webinar: 360i Phase 2 outcomes and the road to Phase 3

Feb–Mar 2027
Phase 3 volunteering opens

Any time
Work with K3C in Korea

Thank You!

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

