From Digital Protocols to Executable Trials

Neuro-Symbolic Intelligence Enabling CDISC Digital Data Flow

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Agenda

Why execution matters

01 The promise of Digital Data Flow, and where value leaks

02 What “executable” has to mean

How it works

03 Neuro-symbolic: learned vs. computed decisions

04 Architecture: from USDM to standards-executable logic

05 Downstream in practice: study build, biometrics, monitoring

What it takes

06 Implementation realities: ambiguity, interoperability, governance

07 Takeaways

About this session

WHO IS SPEAKING

Jian Chen

President · EDETEK, Inc.

Brings a clinical data platform perspective to connecting CDISC standards with study design and biometrics workflows, with an emphasis on governed automation and traceability across the study lifecycle.

SESSION FRAME

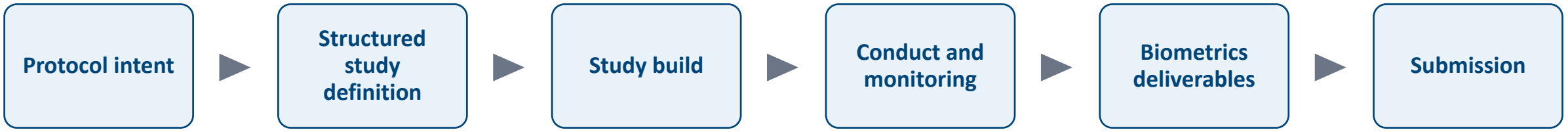
What you will and will not hear

- This is an implementation report, not a product demonstration.
- Where the approach worked, where it did not, and what we changed.
- Figures and timelines quoted are from our own delivery experience; we flag clearly where something is still a target rather than a measured result.

The promise of Digital Data Flow

Capture study intent once, in structured and standards-aware form, and let downstream processes consume it.

Author once → consume many times



The expectation

Fewer manual reinterpretations
One authored definition, not a protocol re-read by every function.

Faster, more consistent build
Study set-up driven by structured study definitions rather than repeated document review.

Traceability by construction
A path from protocol intent to the value in the submission dataset.

CDISC Digital Data Flow (DDF) and the USDM provide the structured representation. This talk is about what must happen next.

Where the value leaks

A digital protocol is a document that a machine can read. That is necessary, and it is not sufficient.

01 Structured, but not semantic

An activity named “Blood pressure” is text in a field. Nothing yet ties it to a Biomedical Concept, a CDASH item, a codelist, or an SDTM variable.

02 Read once, then re-keyed

Downstream teams still open the protocol PDF. EDC build, SDTM specs and monitoring plans are authored independently, and drift apart from the day they are written.

03 No executable consequence

The digital protocol defines what should happen, but downstream systems do not automatically enforce it. If the build deviates from the study definition, no validation is triggered by default.

04 Traceability asserted, not evidenced

Lineage is reconstructed at submission time from specs and memory, rather than emitted as a by-product of execution.

The gap is not representation. It is execution.

What “executable” must mean

Three properties, in order. Each one is a precondition for the next.

1 Resolvable
MEANING RESOLVED

Every study concept resolves to a governed standards object: a Biomedical Concept, a controlled terminology code, a CDASH item, an SDTM variable. No free text left carrying meaning.

2 Computable
LOGIC RUNNABLE

The definition can be evaluated, not just displayed. Schedule of activities becomes a visit×assessment matrix; eligibility and derivations become expressions a machine can run.

3 Consequential
SYSTEMS GOVERNED

Downstream artifacts are generated from it and validated against it. If build and definition disagree, something visible fails.

Most digital protocol programs stop after the first property.

Neuro-symbolic: which decisions are learned, which are computed

The division of labor is the design decision. Everything else follows from it.

NEURAL · PROPOSES

Interpretation and authoring

- Reads narrative protocol text and ICH M11 sections
- Proposes concept matches from the CDISC Library
- Drafts derivations, edit checks and mapping candidates
- Flags ambiguity instead of resolving it silently

HUMAN APPROVAL

A qualified reviewer

Accept · revise · reject

Owner and version recorded on acceptance.

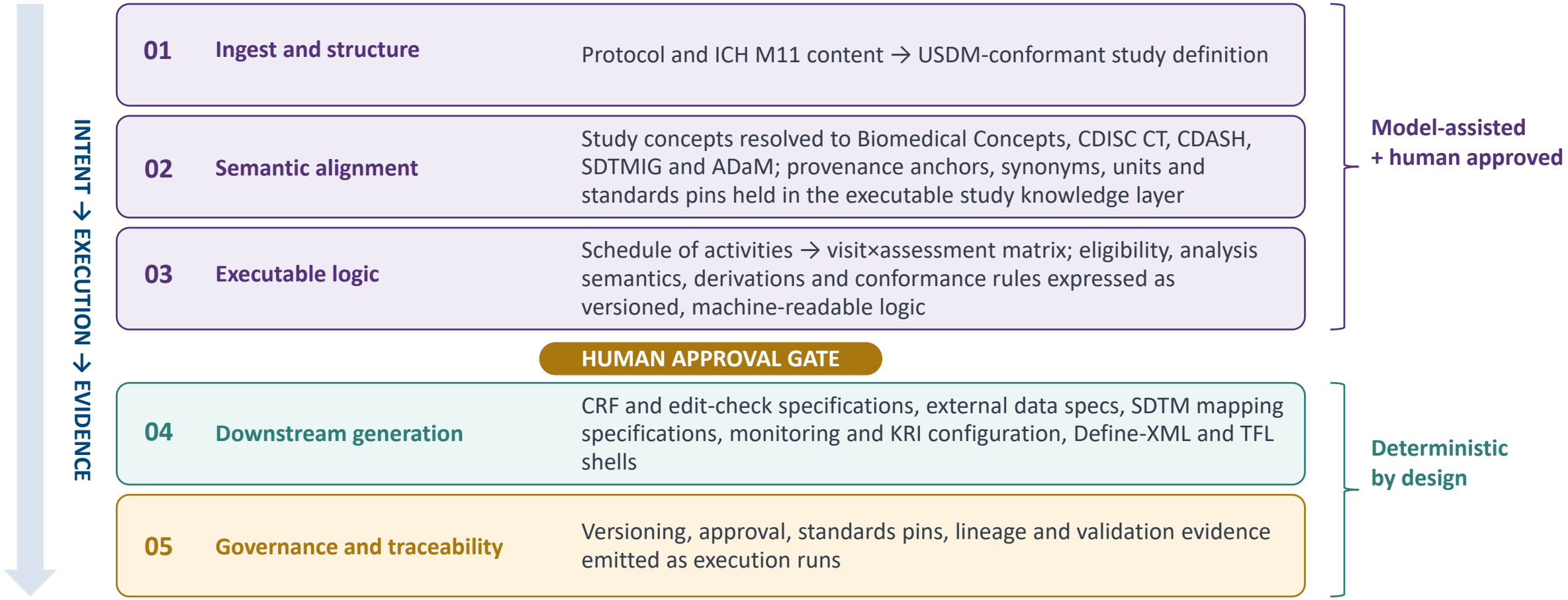
SYMBOLIC · EXECUTES

Deterministic, standards-governed execution

- Resolves intent against version-controlled standards, study definitions (e.g., CDISC USDM) and controlled terminology
- Executes approved rules deterministically - the same inputs produce the same outputs
- Validates conformance and emits the evidence
- Produces the controlled artifacts; a model proposal becomes a deliverable only by passing the gate

Propose → Approve → Execute

Architecture: five layers, one direction of travel



From study definition to standards-executable logic



What it holds
- Narrative text
- Sections, tables
- Human-authored

What it adds
- Study design
- Schedule of activities
- Eligibility, endpoints

What it adds
- Biomedical Concepts
- Controlled terminology
- CDASH / SDTM / ADaM

What it adds
- Visit × assessment matrix
- Derivation expressions
- CORE + study rules

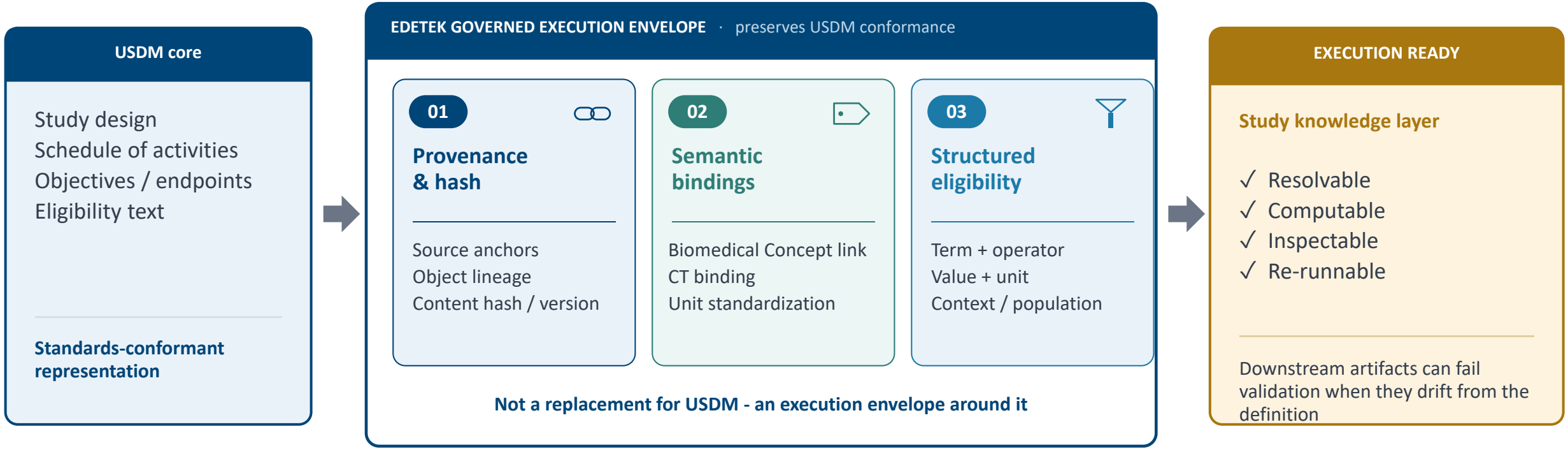
What comes out
- CRF and edit-check specs
- SDTM mapping specs
- DDS, Define-XML, TFL shells

Every arrow is a versioned transformation with an owner, an approval and an audit record.

Standards touchpoints: OpenStudyBuilder and the DDF Study Definitions Repository; CDISC CORE; Dataset-JSON.

USDM + governed execution envelope

USDM gives the structured study definition. The execution envelope adds governed metadata that makes it traceable, normalized and computable without changing USDM itself.



Extension principle: preserve USDM conformance; add execution-layer metadata beyond the native representation where deterministic downstream use requires it.

Downstream, in practice

What actually changes for study build, biometrics and monitoring

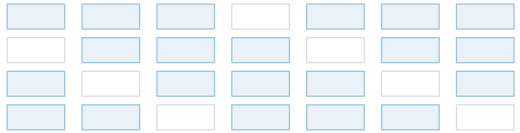
Study build and CRF alignment

The schedule of activities is one of the highest-value objects in the study definition, because every downstream function needs it.

SHARED SOURCE

Schedule of activities

visit × assessment, authored once



What the definition drives

- Which CRFs exist, and which visits they appear at, from the visit×assessment matrix.
- CDASH-conformant item selection from the Biomedical Concept where one is published, rather than from a library search.
- Codelists bound at build time from CDISC CT, with the version recorded.
- Edit checks generated from the same expressions that define the assessment.

What it does not drive

- Anything requiring clinical judgment at the site. Investigator assessment stays with the investigator.
- Sponsor-specific design conventions that are not expressed in the standard.
- Legacy study conventions carried forward for comparability. These are declared, not inferred.

Deliberate boundaries, not failures.

The build is not faster because a model wrote it. It is faster because it stopped being authored twice.

SDTM mapping and biometrics deliverables

UPSTREAM · Semantic resolution + governed study definition

SDTM specifications

Generated from the concept resolution, so origin and role are known at authoring time rather than reconstructed at Define-XML generation.

Define-XML

Emitted from the same metadata that drove the build. Origin types reflect how each value was actually collected or derived.

Conformance

CDISC CORE-compatible rules run inside the workflow, not only as a separate pre-submission exercise.

ADaM and TFL shells

Endpoint definitions in the study definition seed the analysis specifications. Shells are drafted from approved study and analysis metadata, then reviewed by the statistician who owns them.

The goal is not unattended biometrics. It is one specification a human approves, and a deterministic path after it.

1 GENERATED

Specifications emitted from the resolved study metadata, with origin and role already known.

2 APPROVED · POINT OF NO RETURN

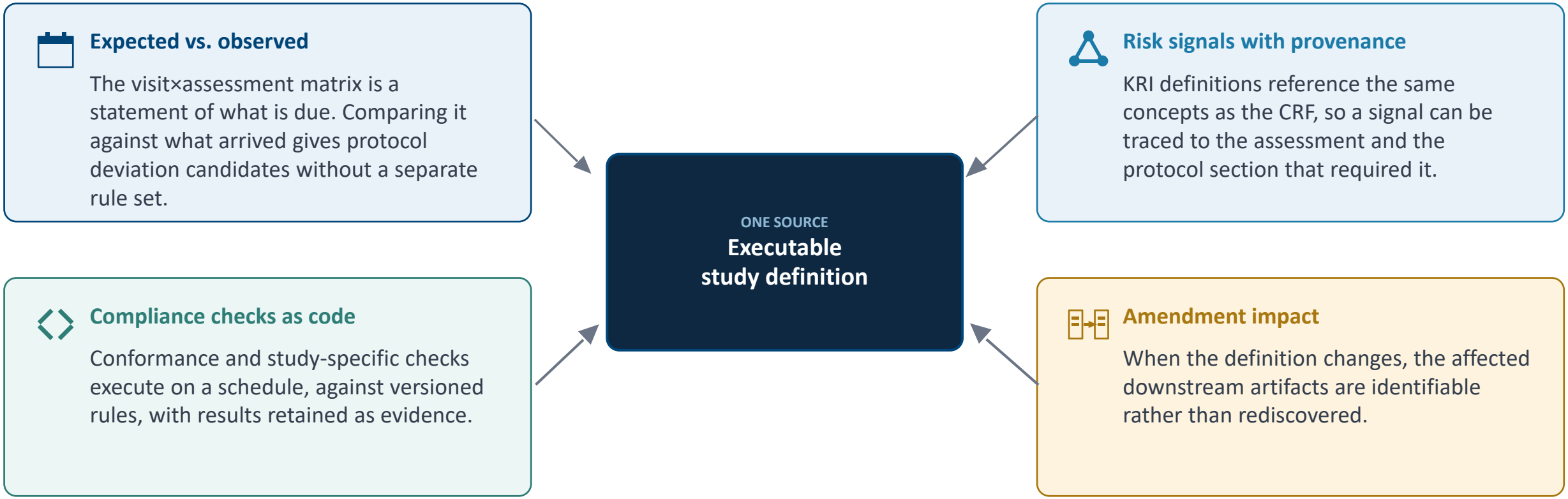
Statisticians and programmers approve the specification - they do not rebuild it.

3 DETERMINISTIC EXECUTION

Every downstream deliverable is then generated deterministically from the approved specification.

Monitoring readiness and compliance checks

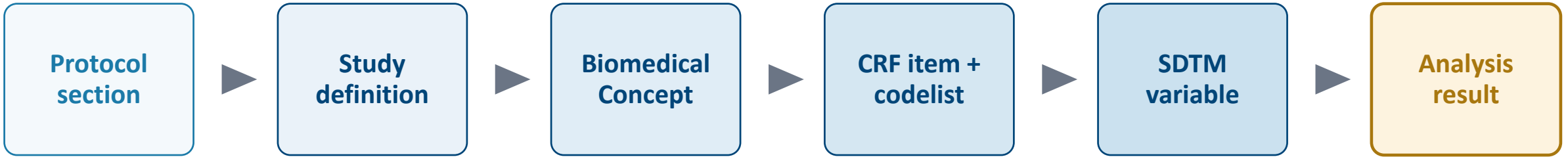
The same executable definition that builds the study also tells you what should have happened.



Four consumers. One definition.

Why determinism is the point

For inspection, the critical question is not simply whether a model was accurate; it is how a value came to be in the dataset.



Each link is a stored relationship, not a reconstruction.

Deterministic execution

Same inputs, same approved rules, same pinned versions → same output. Re-runnable at any point, including after the study closes.

Versioned everything

Standards version, terminology package, rule version, source hash, approval and execution ID recorded on every run.

Model output is not the artifact

Models propose; approved rules produce what ships. Proposals are retained as proposals.

Implementation realities

The four things that decided whether this worked

Four realities that decide the outcome

Content ambiguity

SURFACE IT

- Protocols are written for humans and are legitimately imprecise.
- “Every 8 weeks (±7 days) from C1D1 until progression” carries at least three decisions a machine cannot make alone.
- Our rule: ambiguity is surfaced and assigned, never auto-resolved.

Interoperability

PIN THE VERSIONS

- The seams are between standards versions, not between systems.
- USDM version, CT package, SDTMIG version and EDC capability rarely move together.
- Every artifact records the version set it was produced under.

Governance

NAME THE OWNER

- Who may approve a concept resolution? Who owns a rule once approved?
- Without named ownership, the knowledge graph degrades into a second uncontrolled spec.
- Approval is a role, not a person, and it is audited.

Cross-functional reach

DESIGN WITH CONSUMERS

- Digital Data Flow stalls when treated only as a standards-team project.
- Biometrics, data management, monitoring and regulatory have to be in the design from the first study, not consulted at handover.
- The downstream consumer defines what “done” means.

Ambiguity, concretely

From the protocol: *"Tumor assessment every 8 weeks (±7 days) from C1D1 until radiographic progression or start of new anticancer therapy."*

	Decision	Why ambiguous	Governed resolution	Owner
01	**Is the window calendar days or business days?**	The protocol does not say. Convention varies by sponsor and by region.	Flagged as an open decision; default proposed from sponsor standards, approved explicitly.	*not yet named*
02	**Does the 8-week clock reset after a delay?**	Two defensible readings, with different deviation counts and different exposure denominators.	Escalated to medical and biometrics jointly; the resolution is recorded in the study definition.	**Medical + biometrics**
03	**What ends the schedule when both events occur?**	Ordering matters for the analysis population and for censoring.	Resolved with the statistician; encoded once and reused by monitoring and analysis.	**Statistician**
04	**Is "radiographic progression" investigator or central read?**	Determines which data object closes the schedule and which is authoritative.	Declared in the definition; both are represented where the study collects both.	*not yet named*

The value of the system is not that it answered these. It is that it found them before first patient in, and recorded who decided.

Governance: what must be true to be inspectable

01	**Named ownership per object**	Study definition, concept resolution, rule set and generated artifact each have an accountable owner and an approver role.
02	**Approval before execution**	No proposal reaches a downstream artifact without recorded acceptance. The proposal itself is retained, accepted or not.
03	**Version pinning**	Every run records USDM, CT, SDTMIG, rule version, source hash, approval and execution ID. Re-execution reproduces the original result.
04	**Change control across the seam**	A protocol amendment, a CT package update and a rule change all trigger the same impact assessment path.
05	**Evidence as output**	Validation results, lineage and approvals are emitted by the run, not assembled for the inspection.

What we would tell a team starting now

01

Start from the downstream end

Pick what hurts most, and work backward.

02

Resolve concepts before automating

Automating unresolved text compounds it.

03

Put biometrics in the room early

Whoever consumes it should shape it.

04

Budget for terminology drift

Pin the release; assess changes first.

05

Draft output is attributable

A proposal is reviewable; an answer is not.

Start with one painful artifact → prove the execution loop → scale deliberately

Key takeaways

01

Structured representation alone is not enough

Value appears when study intent becomes executable across downstream processes. Representation is the start of the work, not the end of it.

02

Neuro-symbolic connects definition to execution

Models interpret and draft. Standards-aware, deterministic logic executes. The approval gate between them is what makes the result defensible.

03

Digital Data Flow is an enterprise program

It succeeds when biometrics, monitoring, compliance and submissions are in the design from the outset, and it stalls when it stays inside the standards team.

Representation → Governed execution → Enterprise adoption

Questions?



Thank You!

