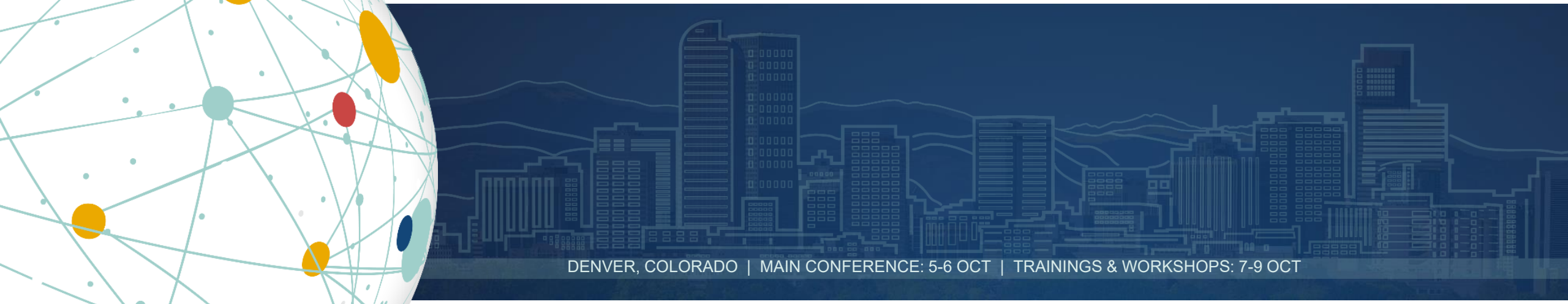


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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Operationalizing CDISC Biomedical Concepts as the Semantic Layer of an eSource Platform

EHR-to-EDC data transfer, AI-grounded extraction and metadata-driven study configuration from one concept library

Paradigm Health

Three problems we had to solve

Paradigm sought to build its eSource capability from the ground up with biomedical concepts at the core – solving these problems were key to making this possible

PROBLEM 01 Semantics

CRFs are not machine-readable

Fields are string identifiers. Nothing tells a system that SYSBP on one form and VS_SYS_1 on another are the same measurement, or what unit it expects.

WHAT PARADIGM BUILT

Biomedical Concepts as the semantic layer: every field is bound to a BC and a Data Element Concept, so the pipeline knows where EHR data goes and how to normalize it.

PROBLEM 02 Structure

Sponsor CRFs arrive as they are

Repeating item groups, single groups, tables, free-form logs. Sponsors will not redesign their casebook to fit our data model, so the model has to fit theirs.

WHAT PARADIGM BUILT

A study builder that applies BCs and DECs to any form structure, and a digital protocol that tells the pipeline which instance belongs in which visit.

PROBLEM 03 Scale

Perfect definitions do not scale

Waiting for a complete, agreed definition of every activity and concept is a bottleneck. Studies start before the standards catch up.

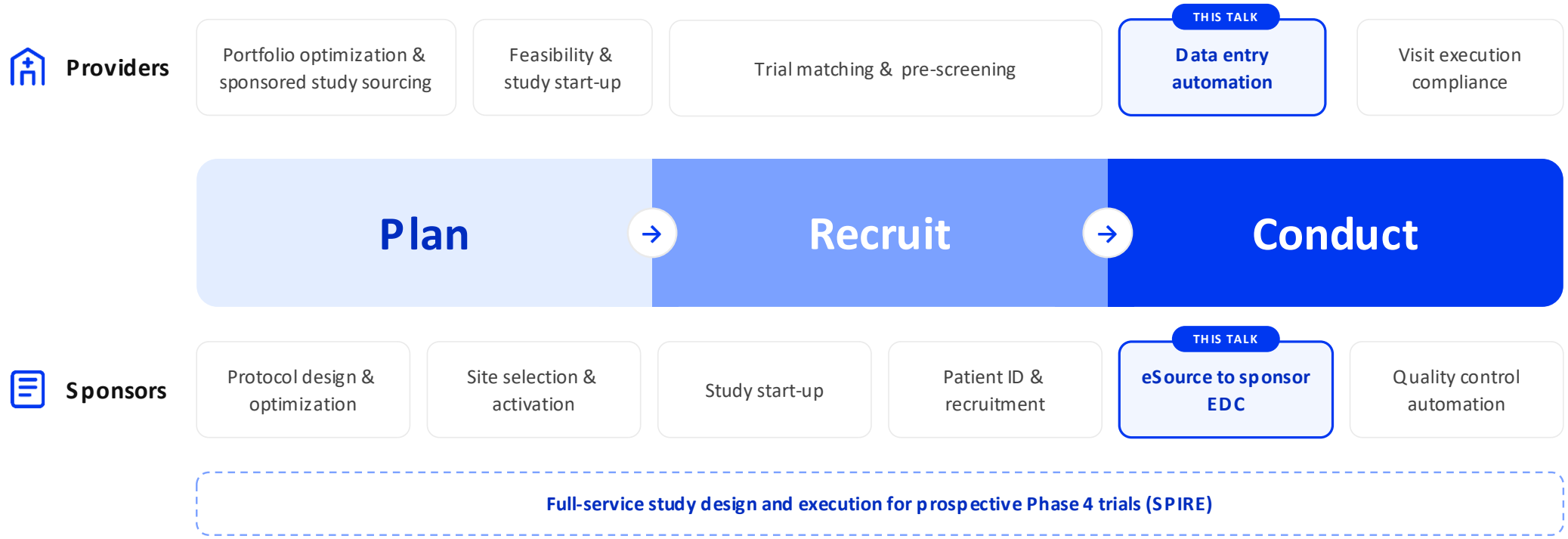
WHAT PARADIGM BUILT

Composable modeling: canonical domains and DECs compose into BC classes, BCs are printed from classes, and activities are supersets rather than exact lists.

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Paradigm connects providers and sponsors across the trial lifecycle

This talk lives in the Conduct phase: eSource auto-population of case report forms from EHR data



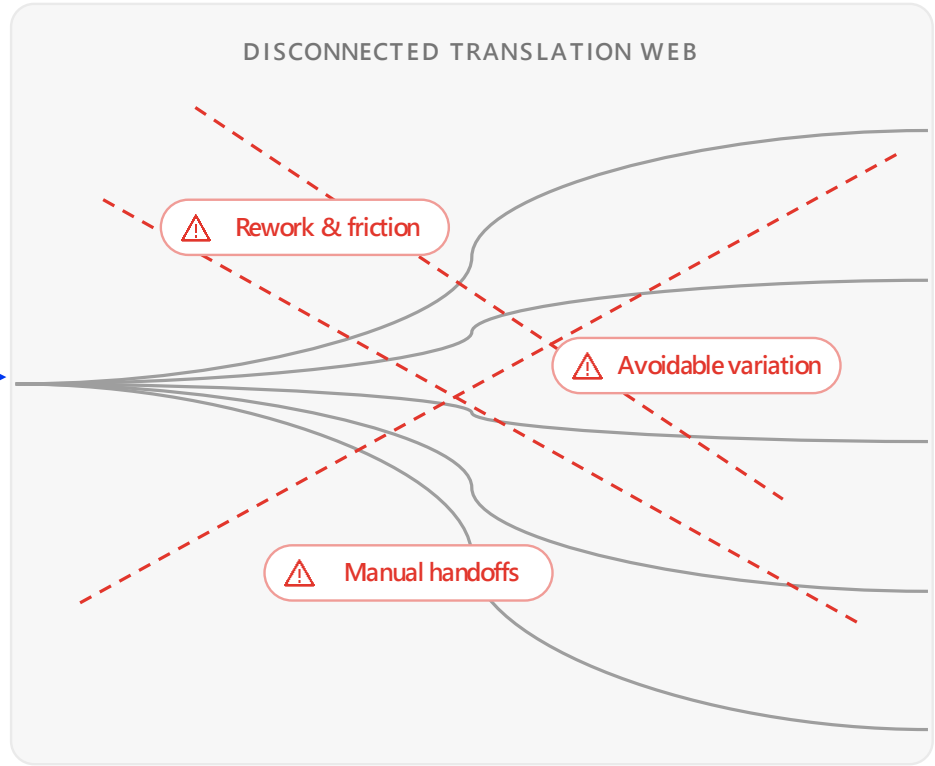
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We are trapped in interpretation-driven operations

One protocol, five independent translations, and every handoff is manual

Protocol intent

One unstructured document, read five different ways



Study design
Interpreted by clinical ops

EDC configuration
Interpreted by data management

External data transfers
Interpreted per vendor

SDTM mapping
Interpreted by programming

Analysis
Interpreted by biostatistics

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Semantics, defined once, replace documents read many times

What Digital Data Flow and Biomedical Concepts change

	Document-driven	Semantic-driven
Source material	PDF and text documents	**Digital Data Flow (DDF) protocol**
Clinical intent	Re-interpreted by each silo	**Defined once, reused consistently**
System set-up	Manual configuration	**Metadata-driven configuration**
Data output	Fragmented outputs	**Machine-readable, submission-ready**

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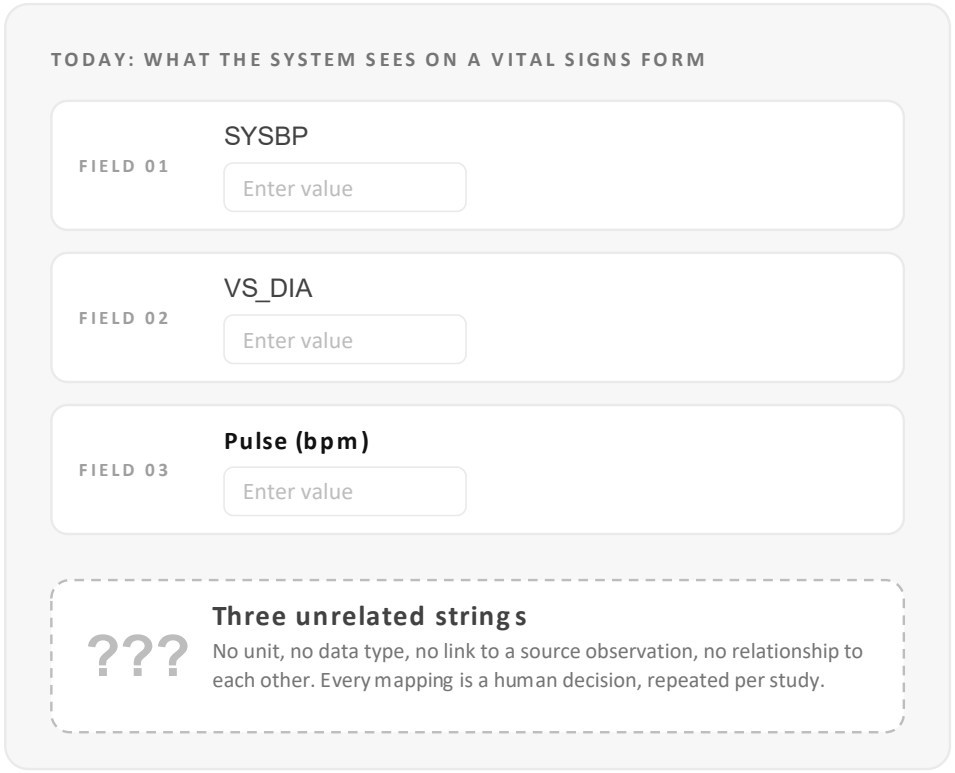
PROBLEM 01 · SEMANTICS

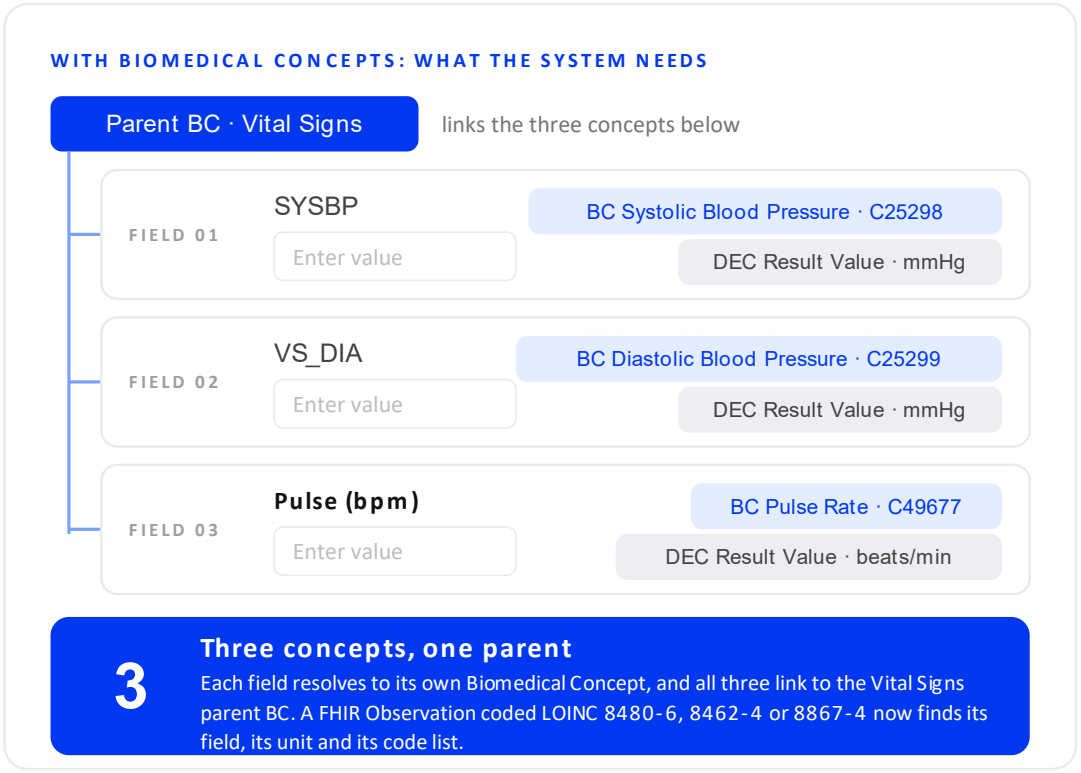
Case report forms are not machine-readable

What Paradigm built: Biomedical Concepts as the semantic layer, so every field carries meaning a pipeline can act on.

Within an EDC, a CRF field is just a string

Field identifiers carry no semantics, so nothing tells a pipeline which concept a field captures, where an EHR observation belongs, or how to normalize it





Coding the form is what lets structured FHIR data find its way onto the right form, the right field, in the right unit.

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Three metadata layers make a form machine-readable

Each layer is the foundation for the next; Paradigm required this architecture to make BC management scalable

Operational layer

Study-specific configuration and outputs

Conceptual layer

Reusable, study-agnostic clinical meaning

Terminology layer

Codes and crosswalks everything else resolves to

OPERATIONAL

eCRF configuration | Casebook versions | SDTM | ADaM | define-xml

Printed from the layers below. Rebuilt per study, never hand-mapped.

CONCEPTUAL

Activity Concepts | Biomedical Concepts | BC Class templates | Canonical Domains | Data Element Concepts

Where this talk lives. A knowledge graph of what should be observed and how the pieces relate.

TERMINOLOGY

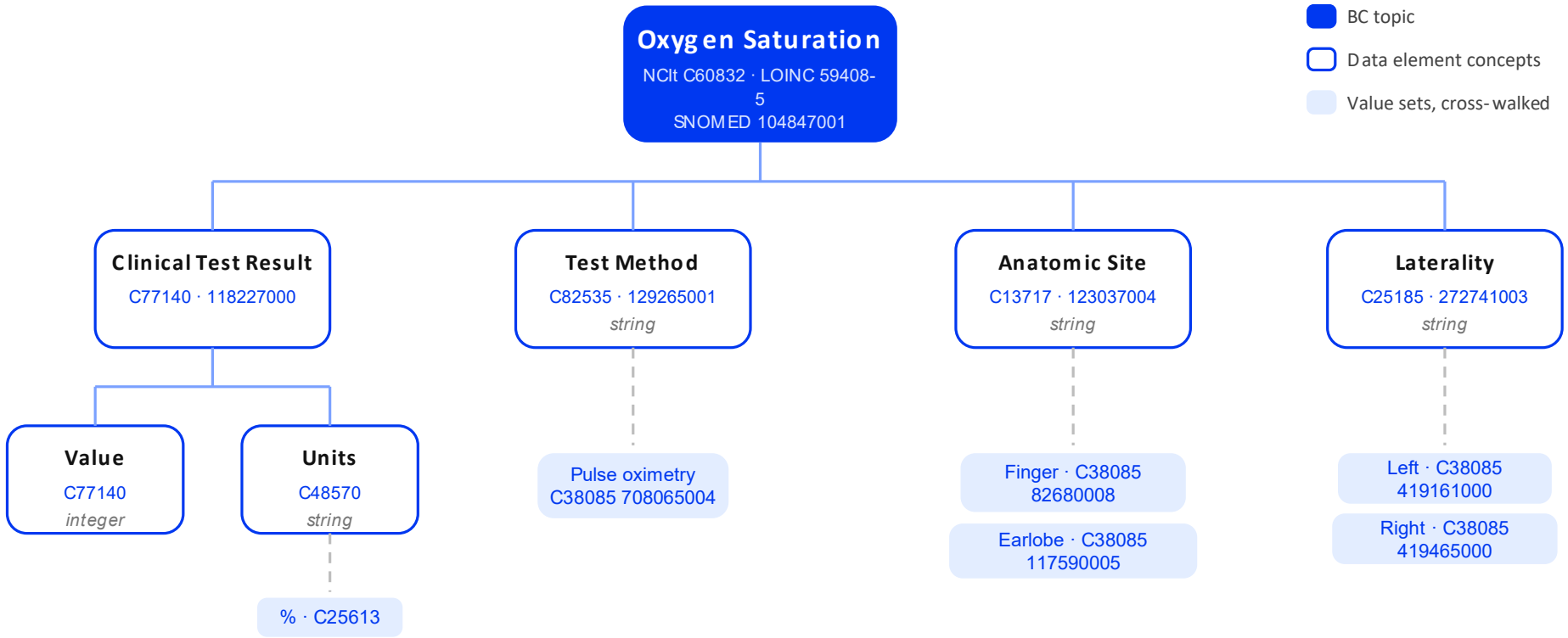
Base terms | Crosswalks | Value sets

NCIt, LOINC, SNOMED CT, UCUM, RxNorm and sponsor code lists, linked so any code can be resolved to any other.

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A Biomedical Concept is a unit of knowledge: what should be observed, and how

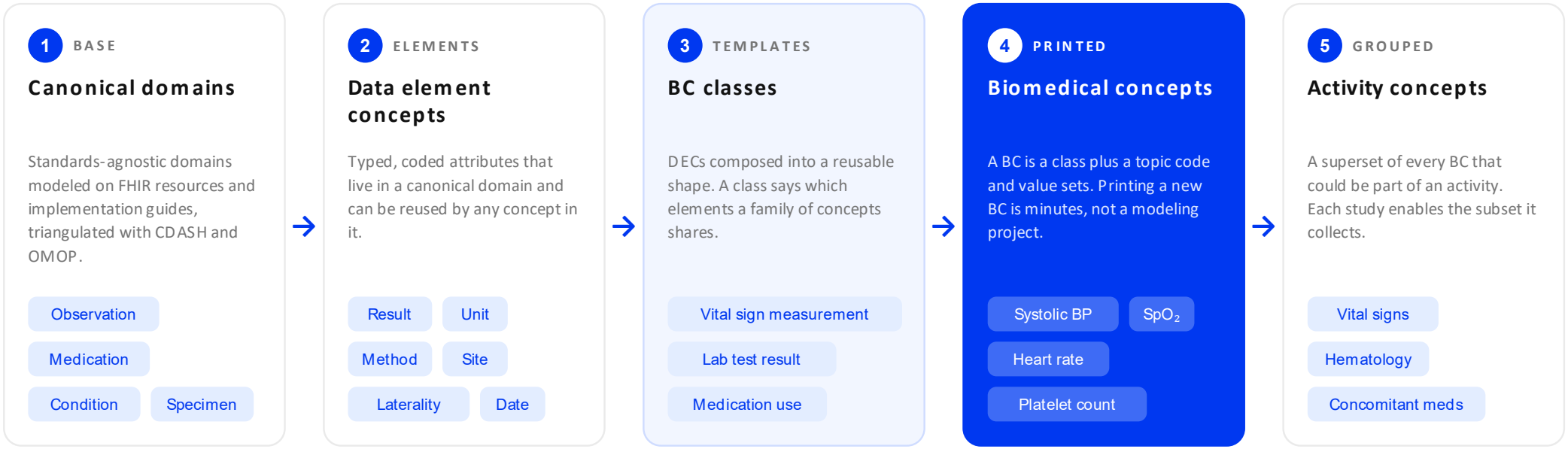
Oxygen Saturation as a graph of data element concepts, each coded and cross-walked, with value sets at the leaves



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How Paradigm builds BCs: compose from a canonical base, then print

Canonical domains and data element concepts compose into BC classes; BCs are printed from classes; activity concepts group them



REFERENCE MODELS TRIANGULATED

FHIR R4 · US Core & IPS guides · CDASH · OMOP CDM

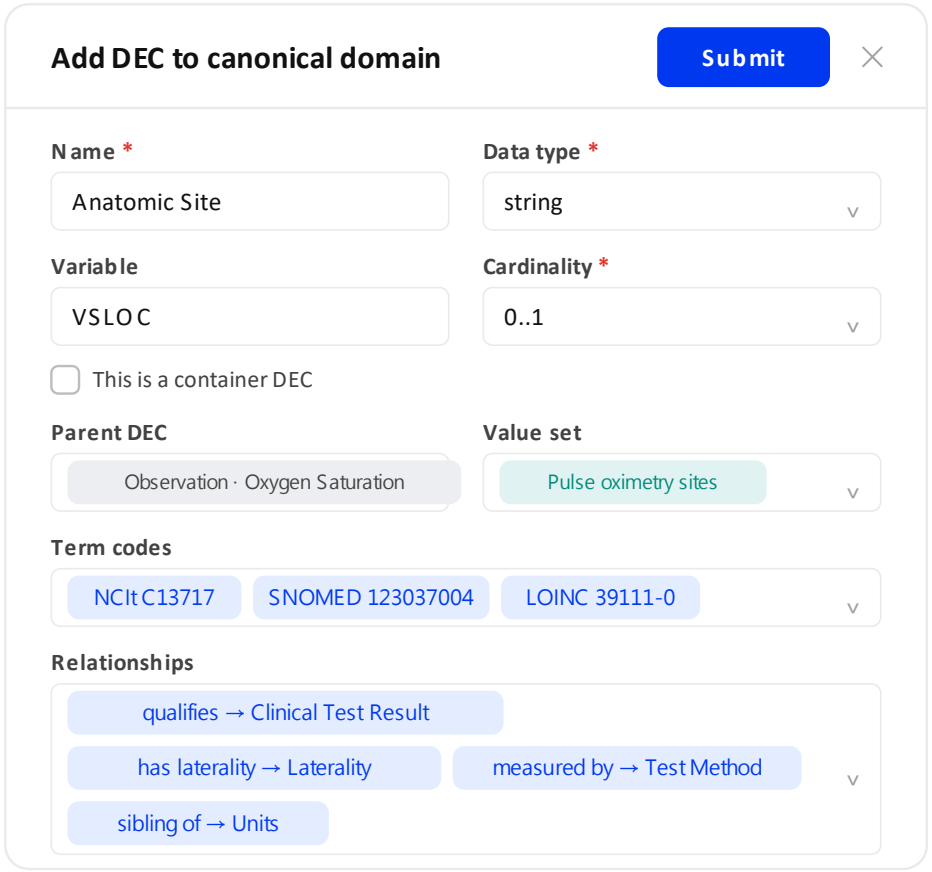
TERMINOLOGIES CROSS-WALKED

NCIt · LOINC · SNOMED CT · UCUM · RxNorm · Sponsor code lists

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The anatomy of a Data Element Concept

Every attribute is something the pipeline or the study builder acts on



Name & term codes	**Meaning the graph can resolve.** The codes are the join key to FHIR, CDASH and OMOP through crosswalks, so an EHR value finds this element by concept, not by label.
Data type	**Typed extraction and validation.** Integers, strings, dates and codeable concepts are parsed differently from FHIR and validated before they land on a form.
Variable	**A path to SDTM.** The CDASH or SDTM variable this element feeds, so submission datasets are derived rather than mapped by hand.
Cardinality	**Single value or repeating.** Tells the study builder whether an element can populate a log or a table row.
Container & parent	**Nesting.** A result is a container for value and unit; the hierarchy is what makes the BC a graph rather than a flat list.
Relationships	**Edges in the knowledge graph.** What this element qualifies and what qualifies it, so a pipeline can traverse from a result to its site, method and laterality.
Value set	**Controlled terms with crosswalks.** Allowed answers, each coded, so sponsor code lists can be normalized to and from them.

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BCs are metadata, not data

Paradigm's data platform instantiates BCs into BC instances from FHIR resources

Conceptual layer

Metadata. Defined once in the concept library, study-agnostic.

ACTIVITY CONCEPT

Vital Signs

Superset of the BCs a vital-signs activity may collect.

→

BIOMEDICAL CONCEPT

Oxygen Saturation

Topic code plus the data elements that describe one measurement.

Topic LOINC 59408-5

→

DATA ELEMENT CONCEPTS

Result · Units · Method · Site · Laterality

Result	integer, 0..1
Units	value set: %
Site	value set: finger, earlobe

↓ Instantiated by the data platform from FHIR resources, one BC instance per qualifying observation

Data layer

Study data. One instance per subject, visit and observation.

ACTIVITY INSTANCE

Vital Signs · Cycle 1 Day 8

Subject	PD-1042
Collected	2024-12-23 10:30

→

BC INSTANCE

Oxygen Saturation

Source	FHIR Observation/8f2c…
Effective	2024-12-23 10:31

→

DATA ELEMENT VALUES

97 · % · Pulse oximetry · Finger · Left

Result	97
Units	% · C25613
Site	Finger · 82680008

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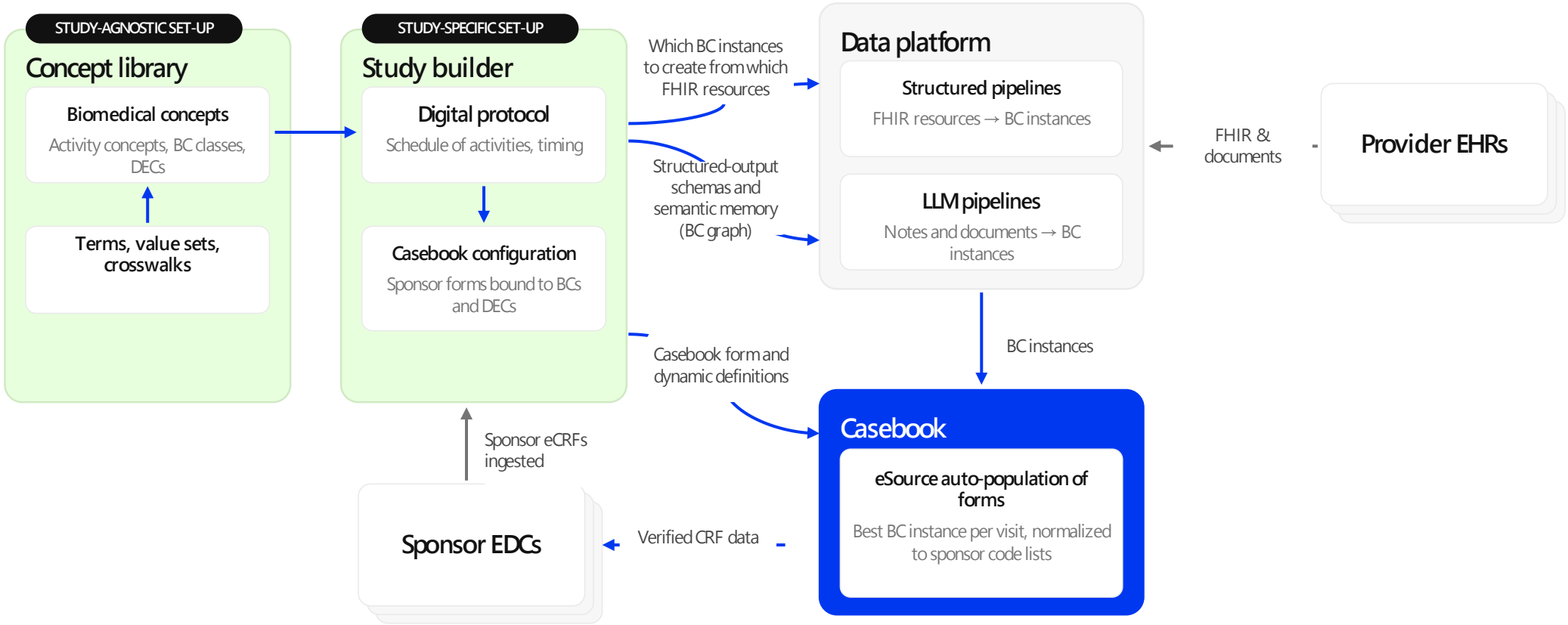
PROBLEM 02 · STRUCTURE

Sponsor case report forms arrive as they are

What we built: a study builder that applies BCs and DECs to any form structure, and a digital protocol that tells the pipeline which instance belongs in which visit.

Paradigm's Digital Data Flow-aligned architecture

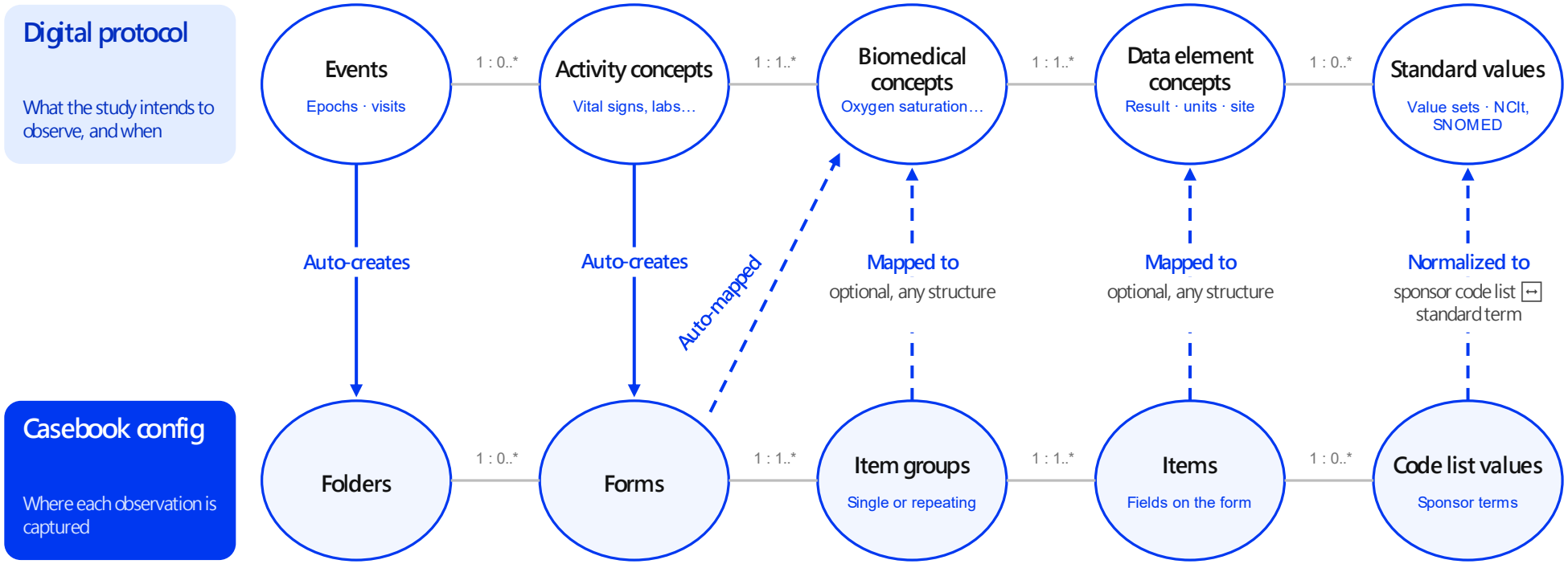
Study-agnostic concepts, study-specific configuration, and a data platform that reads both



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From digital protocol to casebook: forms inherit their concepts

A casebook version pulls in the digital protocol, then adds fine-grained data collection metadata on top



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Study Builder maps concepts onto any form structure

Single item groups, repeating item groups, tables and mixed layouts, all bound to the same BCs and DECs

SINGLE ITEM GROUP 1 : 1

Vital Signs

Activity · Vital signs

Systolic BP	118	C25298
Diastolic BP	76	C25299
Pulse	68	C49677
SpO_2	97	C60832

One record per visit

REPEATING ITEM GROUP 1 : 0..*

Concomitant Meds

Activity · Con meds

#	Medication		Dose	Route
1	Metformin	RxNorm	500 mg	Oral
2	Lisinopril	RxNorm	10 mg	Oral
3	Atorvastatin	RxNorm	20 mg	Oral

+ Add row · one BC instance per row

TABLE LAYOUT rows × columns

Hematology

Activity · Hematology

Test		Result	Unit	Date
Hematocrit	C64796	42.3	%	23 Dec
Leukocytes	C51948	7.8	$10^3/\mu L$	23 Dec
Platelets	C51951	245	$10^3/\mu L$	23 Dec

Each row is a BC; each column a DEC

Same concepts, different structures

The pipeline routes data by BC and DEC, not by field position or label, so the sponsor's form stays as the sponsor designed it.

Single group · Repeating group · Table · Mixed

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The digital protocol plus BCs find the data most likely to be study-specific

Protocol timing narrows the record to a visit window; the BC graph narrows the codes; the best instance pre-populates the eCRF

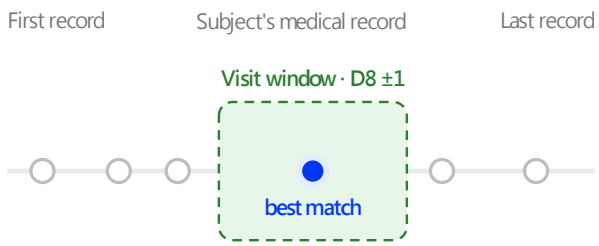
1 The digital protocol says when

Schedule of Activities

	Epoch	Screening		
	Visit Parent		Cycles 1-2	
	Visit	D1	D1	D8, D15, D22
Activities	Window	±3	±3	±1
Vital Signs		☑	☑	☑
Height		☑	☐	☐
Weight		☑	☑	☐
12-lead ECG		☑	As clinically indicated	
Hepatitis Serology Testing		☑	☐	☐
HBV DNA		☑	If indicated, every 12 weeks	

Schedule of activities: Vital Signs at Cycles 1–2, Day 8, window ±1 day.

2 The BC says what qualifies



Filter Observations coded to the BC topic (LOINC 59408-5 and crosswalks)

Rank Inside the window, then closest to the target date

Protocol timing narrows the record; the BC graph narrows the codes.

3 The eCRF is pre-populated

Vital Signs · C1D8 Auto-filled

SpO_2	97 % ✓
Method	Pulse oximetry ✓
Site	Finger ✓
Laterality	Left ✓
Date	23 Dec 2024 ✓

Source-linked to the FHIR observation for review and audit.

Site staff verify rather than transcribe.

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Pipeline example: hematology from FHIR to eCRF

Ingest, extract BC instances, group into activity instances, import

1 Ingest EMR FHIR data

- **Observation**
- **DiagnosticReport**
- **Specimen**

Pulled per subject, per visit window, from the provider's FHIR API.

2 Extract BC instances

BC	Collected	Value	Unit
Hematocrit	23 Dec 10:30	42.3	%
Leukocyte count	23 Dec 10:30	7.8	10^3/µL
Leukocyte count	23 Dec 11:25	6.4	10^3/µL
Platelet count	23 Dec 11:25	245	10^3/µL

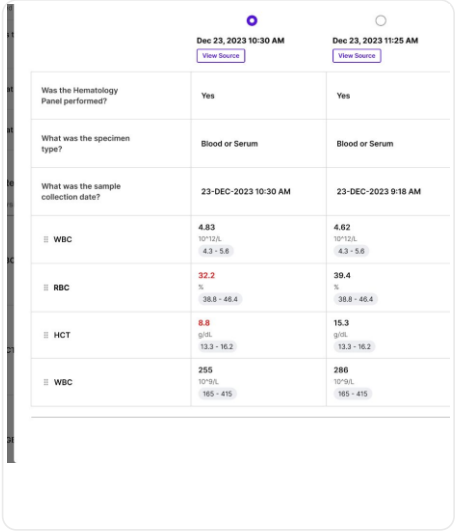
Each LOINC-coded observation resolves to its own BC through the crosswalk; units are normalized to the BC's value set.

3 Group into activity instances


```
{ "activityConcepts": [
  { "name": "Hematology",
    "instanceDate": "2024-12-23T10:30",
    "biomedicalConceptInstances": [
      { "test": "Hematocrit",
        "value": 42.3, "unit": "%" },
      { "test": "Hemoglobin",
        "value": 13.9, "unit": "g/dL" },
      { "test": "Leukocyte Count",
        "value": 7.8, "unit": "10³/µL" },
      { "test": "Erythrocyte Count",
        "value": 4.6, "unit": "10⁶/µL" } ] },
  { "name": "Hematology",
    "instanceDate": "2024-12-23T11:25",
    "biomedicalConceptInstances": [
      { "test": "Leukocyte Count",
        "value": 6.4, "unit": "10³/µL" },
      { "test": "Platelet Count",
        "value": 245, "unit": "10³/µL" },
      { "test": "Neutrophil Count",
        "value": 3.9, "unit": "10³/µL" } ] } ] }
```


Grouped by specimen collection time into activity instances.

4 Site imports into the eCRF

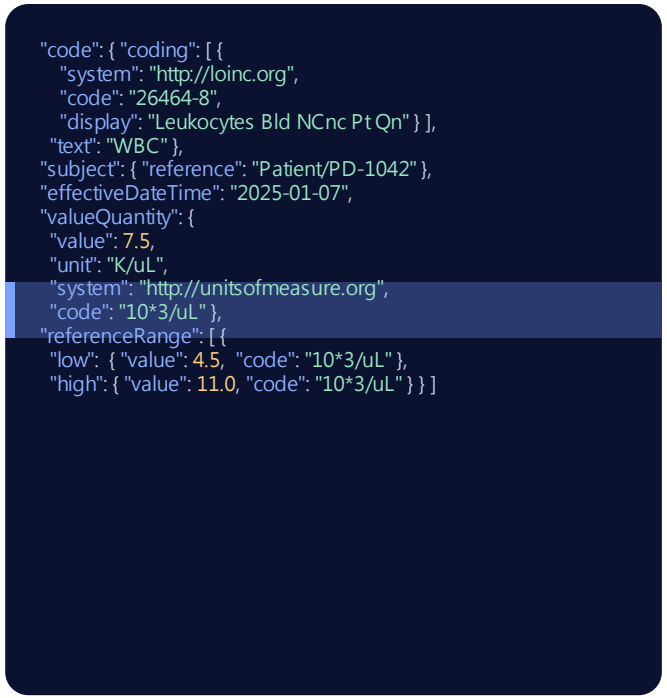


Candidate instances side by side; one click imports the chosen one.

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From codeable concept to sponsor code list

Normalization happens twice: once to the canonical term, once to the sponsor's controlled terminology



```
"code": { "coding": [ {
    "system": "http://loinc.org",
    "code": "26464-8",
    "display": "Leukocytes Bld NCnc Pt Qn" } ],
  "text": "WBC" },
"subject": { "reference": "Patient/PD-1042" },
"effectiveDateTime": "2025-01-07",
"valueQuantity": {
  "value": 7.5,
  "unit": "K/uL",
  "system": "http://unitsofmeasure.org",
  "code": "10*3/uL" },
"referenceRange": [ {
  "low":  { "value": 4.5,  "code": "10*3/uL" },
  "high": { "value": 11.0, "code": "10*3/uL" } } ]
```

EHR CODEABLE CONCEPT

10*3/uL

UCUM code as sent by the provider's FHIR server. Another site may send "K/uL" or "thou/mm3".

CANONICAL TERM

Billion per liter

Curated semantic crosswalk to the CDISC / NCIt unit the BC's value set expects.

SPONSOR CODE LIST

X10³/µL

Sponsor-specific mapping applied at the form, so the EDC receives its own controlled term.

INFORMATICS-MANAGED NORMALIZATION

Terminology & crosswalks

- Curate canonical terms, value sets and aliases
- Map EHR and local codes to CDISC / NCIt once, reuse everywhere

Sponsor delivery

- Maintain sponsor code-list and unit mappings per study
- Review exceptions, then version and publish reusable maps

Crosswalks are curated once by informatics and reused across every study and sponsor.

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PROBLEM 03 · SCALE

Perfect definitions do not scale

What we built: composable modeling with supersets and generic concepts, so studies never wait on a finished library.

Paradigm’s activity concepts are supersets, not definitions

Define everything a vital-signs activity could collect once; each study enables the subset it needs

Activity concept · Vital Signs

13 BCs

- Systolic blood pressure
- Diastolic blood pressure
- Pulse
- Body mass index
- Frame size
- Heart rate
- Temperature
- Waist circumference
- Respiratory rate
- Oxygen saturation
- Head circumference
- Lean tissue mass
- Total body water

Defined once as everything a vital-signs activity could collect. Adding a BC later never breaks an existing study.

Study A · Oncology

7 enabled

- [x] Systolic BP
- [x] Diastolic BP
- [x] Pulse
- [ ] Body mass index
- [ ] Frame size
- [x] Heart rate
- [x] Temperature
- [ ] Waist circ.
- [x] Respiratory rate
- [x] Oxygen saturation
- [ ] Head circ.
- [ ] Lean tissue mass
- [ ] Total body water

Configured in minutes from the superset. The pipeline only extracts what is enabled.

Study B · Cardiology

6 enabled

- [x] Systolic BP
- [x] Diastolic BP
- [ ] Pulse
- [x] Body mass index
- [ ] Frame size
- [x] Heart rate
- [ ] Temperature
- [x] Waist circ.
- [ ] Respiratory rate
- [ ] Oxygen saturation
- [ ] Head circ.
- [ ] Lean tissue mass
- [x] Total body water

Same activity concept, different subset. No debate about the "correct" definition of Vital Signs.

No study is blocked on agreeing the one correct definition of an activity.

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Generic BCs: model the shape, not every instance

One Concomitant Medication BC covers every medication the EHR can send

ONE BC PER DRUG?

- BC ~~Metformin use~~
- BC ~~Lisinopril use~~
- BC ~~Atorvastatin use~~
- BC ~~Pembrolizumab use~~
- BC ~~Ondansetron use~~

… × every product in RxNorm

Modeling at the level of the individual medication means the library is never finished, and every new study waits on new definitions.

Generic BC · Concomitant Medication

BC class · Medication use

Medication RxNorm · NCIt *codeable concept*	**Dose** CMDOSE *decimal*	**Dose unit** CMDOSU · UCUM *value set*	**Route** CMROUTE *value set*
Frequency CMDOSFRQ *value set*	**Start date** CMSTDTC *date*	**End date** CMENDTC *date*	**Indication** CMINDC · SNOMED *codeable concept*

Instance	Medication	Dose	Route	Frequency	Start	Source
1	Metformin · RxNorm 6809	500 mg	Oral	BID	2023-04-02	MedicationStatement
2	Lisinopril · RxNorm 29046	10 mg	Oral	QD	2022-11-15	MedicationRequest
3	Ondansetron · RxNorm 7804	8 mg	IV	PRN	2024-12-23	MedicationAdministration

The drug itself is a value of the Medication element, resolved through RxNorm, not a concept to be modeled. One BC covers every medication the EHR can send.

Generic concepts absorb variation the library never has to model explicitly.

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The same semantic layer powers more than eSource

Paradigm’s eSource Casebook capability can leverage BC-linked eCRFs to drive value beyond data entry automation

AI-grounded extraction

BC value-level metadata becomes the structured-output schema for LLM pipelines over notes and documents. The model can only answer in coded terms the graph already knows, and the BC graph doubles as its semantic memory.

Structured outputs | Semantic memory | Coded, not free text

Semantically aware forms

Because every field knows its concept, the casebook can render a subject's data as timelines and trends across visits, navigate by concept instead of by page, and flag out-of-range or inconsistent values at entry.

Cross-visit trends | Concept navigation | Entry-time checks

Standards-driven outputs

Each DEC carries its CDASH and SDTM variable, so datasets, define-xml and visualizations are derived from the same concept library that configured the study. One definition, every downstream use.

SDTM | define-xml | Visualization

Every capability reads the same library. None needs its own mapping layer.

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Three problems, three design decisions

01 · SEMANTICS

CRFs were strings a system could not interpret.

Bind every field to a BC and DEC, resolved through a terminology graph.

EHR data now knows which form, which field, and which unit or code list it must become.

02 · STRUCTURE

Sponsor forms could not be redesigned to fit a model.

A study builder that maps concepts onto any form structure, timed by the digital protocol.

Single groups, repeating logs and tables all route by concept, and the protocol picks the right instance per visit.

03 · SCALE

Perfect definitions would have stalled every study.

Compose from canonical domains, print BCs from classes, and treat activities as supersets.

New concepts take minutes; generic BCs and supersets absorb variation without re-modeling.

One concept library. Every downstream use.

CDISC BCs | DDF-aligned | FHIR-native

EHR-to-EDC transfer, AI-grounded extraction, standards-driven outputs and study configuration, all from the same Biomedical Concepts.

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Thank you

Questions and discussion

- CRFs made machine-readable with BCs
- Any sponsor form, mapped by concept
- Composable modeling that scales

