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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



DENVER, COLORADO | MAIN CONFERENCE: 5-6 OCT | TRAININGS & WORKSHOPS: 7-9 OCT

AI-Driven Study Orchestration and Implementation: Powered by CDISC Biomedical Concepts

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Agenda

1. Introduction to the BC Paradigm
2. Downstream Orchestration
3. Live Demonstration
4. Q&A & Forward Vision

Speakers



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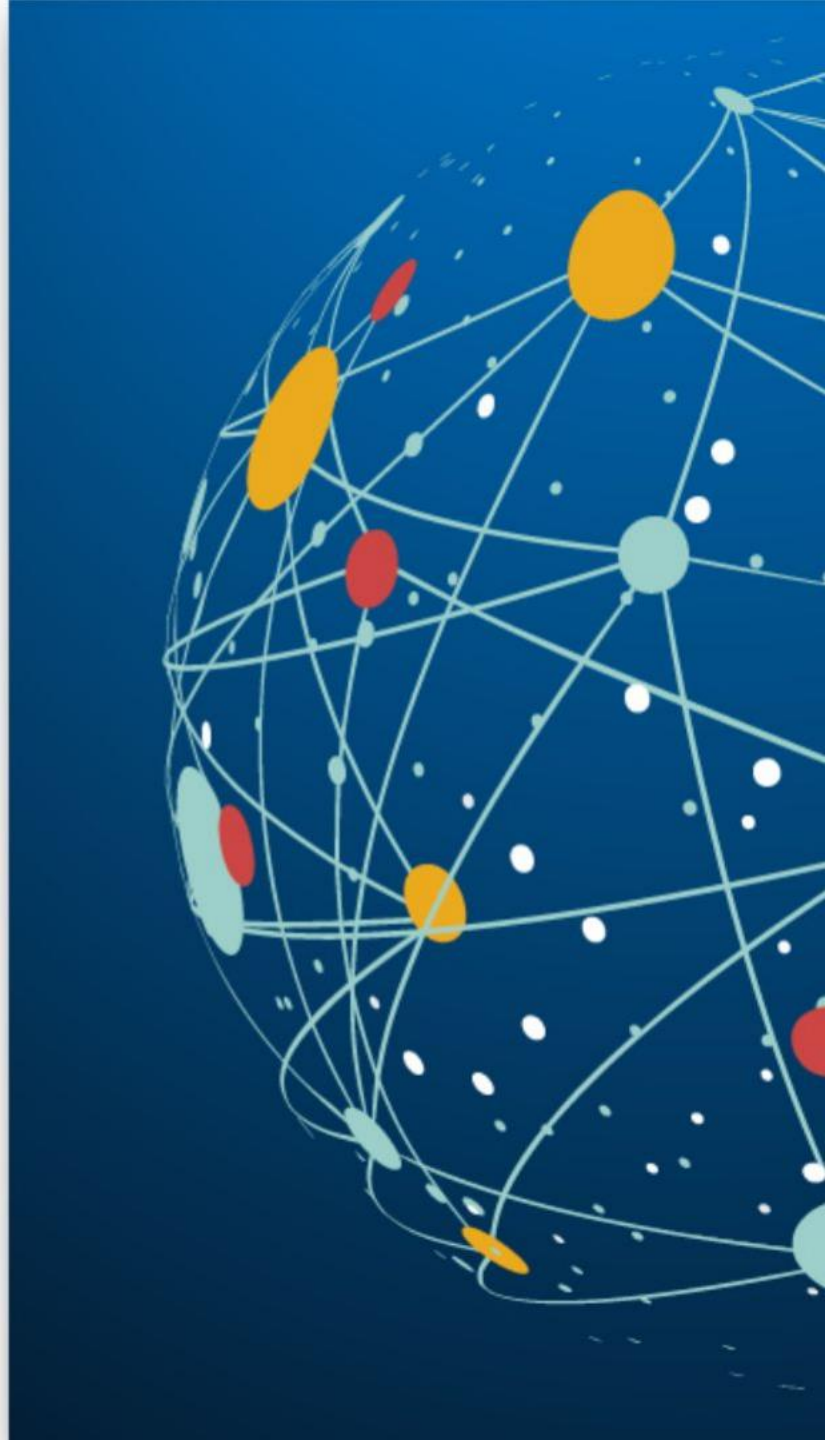
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Smart Biomedical Concepts Suite

CDISC AI Innovation Challenge 2025 Use Case 2 Winner

Our Foundation:
The Previous Hackathon

- **The Starting Point**
  - Built a successful BC extraction solution in the previous hackathon
- **The Pivot**
  - Shifted focus away from the extraction process itself
- **The New Objective**
  - Now focused entirely on downstream capabilities and achievements.

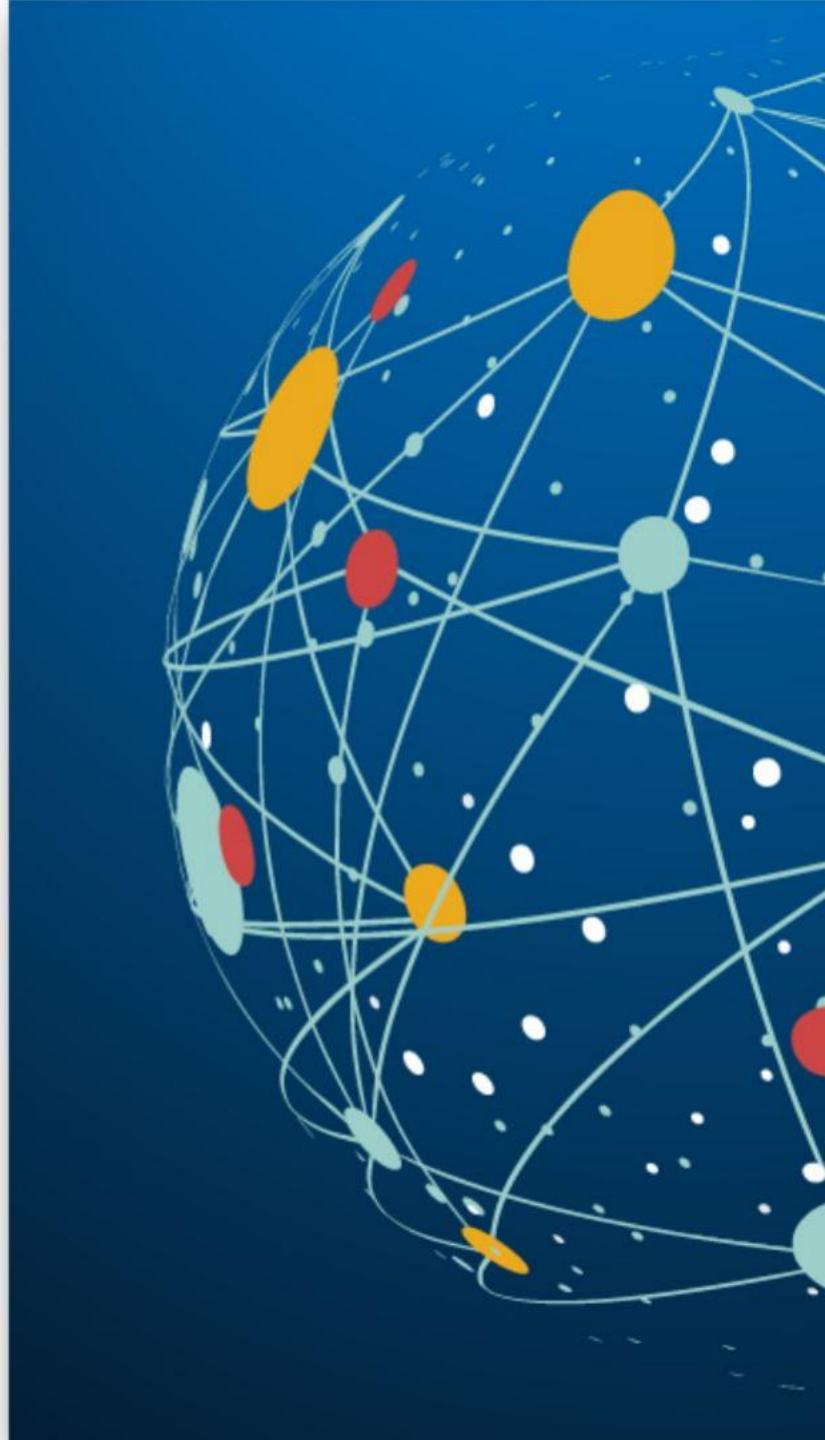


The Biomedical Concept Paradigm

Why Extraction is Just the Tip of the Iceberg?

Tip of the Iceberg

- **Agnostic Ground Truth:** The BC Library is independent of downstream systems.
- **The Gap:** Raw extraction alone lacks necessary contextual enrichment.
- **The Execution:** We split, select, and enrich BCs based on specific downstream use cases.



USDM Semantic Enrichment

Injecting the "Atomic Unit of Truth"

USDM Enrichment

- **The Opportunity**
  - Most LLM-generated USDMs overlook embedding extracted BCs directly into the JSON
- **Value of Enrichment**
  - Injecting BCs restores schedule granularity and accessibility for downstream tasks
- **Working Within USDM v4**
  - BCs sit in Activities and Conditions; the full library is kept alongside

Mapping what USDM supports today, while preserving the full BC library for tomorrow…

Inside the Enriched USDM

One Biomedical Concept, as generated for the lymphoma study (abridged)

```
1 { "instanceType": "BiomedicalConcept",
    "id": "BC-039",
    "name": "Pregnancy Test",
    "synonyms": ["Serum Pregnancy Test", "hCG Test"],
2   "code": { "standardCode": {
        "code": "C64851",
        "decode": "Choriogonadotropin Beta Measurement" } },
3   "properties": [
4     { "name": "Collection Date Time", "isRequired": true },
      { "name": "Biospecimen Type",     "isRequired": true },
5     { "name": "Observation Result",   "isRequired": true,
        "responseCodes": ["Negative", "Positive"] } ],
6   "notes": ["Protocol term: serum pregnancy test"] }

  // Linked from the schedule activity "Pregnancy testing"
```

What to look at

1. **A standard USDM concept**
   Pregnancy Test, with its own ID inside the study.
2. **Shared meaning**
   NCIt code C64851: the same code every system and standard uses.
3. **What gets collected**
   Date and time, specimen type and the result.
4. **What is mandatory**
   isRequired marks the items a site cannot skip.
5. **Allowed answers**
   Negative or positive, nothing free-text.
6. **Back to the protocol**
   Kept with the concept, so every item traces to its source.

Dynamic eCRF Generation

Eliminating Form Bloat with Targeted BCs

Dynamic eCRF Generation

- **The Burden of "Form Bloat”**
  - Reusing templates causes over-collection, inflating costs and burdening sites.
- **The BC Solution**
  - AI analyzes the BC library to identify exact collection needs and automates CDASH tagging
- **Intelligent Refinement**
  - "Required" variables are added automatically
  - AI uses historical sponsor ontologies to dynamically assign "Expected" and "Permissible" qualifiers. .

Eliminate form bloat. Collect exactly what is scientifically necessary, and nothing more

Inside the Generated CRF

One field of the ODM 1.3.2 form definition for the lymphoma study (abridged)

```
1 <ItemDef OID="IT.LB.LBSPEC" Name="LBSPEC"
2          DataType="text" SDSVarName="LBSPEC">
3   <Question>
      What is the specimen material type?
    </Question>
4   <CodeListRef CodeListOID="CL.SPECTYPE"/>
5   <Alias Context="CDASH" Name="LBSPEC"/>
    <Alias Context="SDTM"  Name="LBSPEC"/>
6   <Alias Context="CORE"  Name="R/C"/>
7   <Alias Context="BC"    Name="... BC-039 ..."/>
8   <Alias Context="RATIONALE" Name="Identifies the
       specimen behind haematology, chemistry,
       serology and pregnancy results"/>
    <Alias Context="ControlType" Name="dropdown"/>
  </ItemDef>
```

What to look at

1. **One field on the form**
   The specimen-type field of the Laboratory form.
2. **How it is stored**
   Text, landing in the SDTM variable LBSPEC.
3. **What the site sees**
   The question as it appears on screen.
4. **Controlled answers**
   Picked from a standard list (serum, urine and so on).
5. **Standard names**
   Named as CDASH for collection and SDTM for submission.
6. **Why it is included**
   CDASH rates it Recommended/Conditional; the protocol needs it.
7. **Traced to the concept**
   Linked back to the Pregnancy Test concept, BC-039.
8. **Explained for reviewers**
   A plain-language reason the field is on the form.

Data Quality (DQ) Checks

The Condition-Bound Projection: Automating Golden Rules

Data Quality (DQ) Checks

- **The Manual Burden**
  - Data Managers still manually translate complex protocol rules into edit checks.
- **Contextual Enrichment**
  - AI assigns specific DQ tags (across 22 categories) based on BC context and operators.
- **Intelligent Tiering**
  - Proprietary system grades checks as Bronze, Silver, or "Golden" (high-impact).



Inside a Data Quality Check

One generated check for the lymphoma study, as simple pseudo-code

```
1 CHECK DQC-052
    "Required serum pregnancy tests are negative and dated"
2   CONCEPT   BC-039 Pregnancy Test     TIER  GOLDEN
3   TYPE      Time-window validation    SEVERITY  critical
4   SOURCE    Protocol section 5.1, Inclusion Criteria, p.48

5   FOR EACH participant who could become pregnant:
      tests = lab records where test = "serum pregnancy test"
      EXPECT result = "NEGATIVE"
      EXPECT screening test 10 to 14 days before Day 1
      EXPECT pre-dose test within 24 h of first lenalidomide
6     FLAG missing test, non-negative result, missing date,
           or a date outside the window
```

What to look at

1. **One generated check**
   Unique ID and a plain-language title.
2. **Concept and tier**
   Built on BC-039. Golden: it protects patient safety, so it is reviewed first.
3. **Kind of rule**
   A time-window check, rated critical.
4. **Where it came from**
   The exact protocol section and page.
5. **The rule itself**
   Who it applies to and what must be true.
6. **What gets flagged**
   Each failure becomes a query for the site.

Live Demo

“From Unstructured Protocol to Executable Artifacts”

Click to play the demo · 2:39



Thank You!

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Questions?

Smart Biomedical Concepts Suite

smartbc.airesearch.lsac-dev.com

Explore the demo site (view-only)

