



CDISC India Day

## **CDISC 360i Vision in Practice: Open Source Tools from USDM to SDTM**

Chaitanya Repaka & Koushik Grandhi



# Speakers



## Chaitanya Repaka

Founder & CEO  
AI LENS | CDISC I3C

- Founder & CEO of AI LENS, building agentic AI systems for clinical data operations — from protocol digitization and AI-assisted CRF annotation to end-to-end SDTM automation.
- Member of the CDISC I3C, contributor to the CDISC 360i initiative, and lead of the DTA2SDTM subteam on automating SDTM with dataset specializations and [sdm.oak](https://sdm.oak).
- Open-source work featured in the CDISC COSA Spotlight; speaker at PharmaSUG and PHUSE APAC Connect.
- 15+ years building end-to-end analytics platforms and ML models. M.Pharmacy (JNTUH); Advanced Management Programme in AI, ISB.

# Speakers



**Koushik Grandhi**

Presenter  
AI LENS

- Engineer at AI LENS working on clinical data standards and open source tooling for the CDISC 360i initiative.
- Contributes to the USDM Viewer, Biomedical Concept Mapper and USDM OSB Uploader.
- Focuses on reliable, standards-native automation — carrying study definitions from USDM through Biomedical Concepts into SDTM.

# Agenda

1. The CDISC 360i Vision
2. USDM – the protocol as data
3. Demo: USDM Viewer
4. Biomedical Concepts & Specializations
5. Demo: Biomedical Concept Mapper
6. Conclusion





# The CDISC 360i Vision





## The Study Lifecycle Today

Connected on paper — disconnected in practice



### Fragmented handoffs

Protocol, SoA, CRFs and dataset specs live in separate documents, re-authored at every step



### Repeated re-specification

The same clinical concept is redefined by hand in each artifact, study after study



### Inconsistent representation

One concept ends up shaped differently across datasets, breaking traceability



### Late quality control

Issues surface at submission time — long after the design decisions that caused them

### THE 360i ANSWER

## One connected, machine-readable model from protocol to submission

Study information is captured once as standards-based metadata and flows forward — instead of being re-transcribed at every stage.

Protocol (**USDM**) → Concepts (**BC**) →  
Datasets (**SDTM**) → Submission





# USDM – the protocol as data



# USDM

The Unified Study Data Model (USDM) is a CDISC & TransCelerate DDF standard that captures the entire study design as one machine-readable JSON document.

## What USDM captures:

- **Study design** – arms, epochs, elements and encounters
- **Schedule of Activities** – visits linked to activities
- **Objectives & eligibility** – endpoints, estimands and criteria as structured, reusable objects
- **Biomedical Concepts** embedded as references to CDISC concept definitions — the hook for everything downstream

## USDM Viewer

- **Tree view**: expand / collapse the full JSON hierarchy, filter by key study objects
- **Mind-map view**: hierarchical drill-down of study objects with breadcrumb navigation
- **Display modes**: all fields, or name / description / text only

# USDM Viewer — Tree view of the CDISC Pilot Study (USDM v4.0)

USDM Viewer

TreeMind-map

RepositoryOpen JSONReset to full

Filter key study objects

1. Search for specific keys:

Filter by key (e.g., arms)Apply

2. Or click common study elements:

armsstudyDesignsepochs

encountersactivitieselements

endpointsbiomedicalConcepts

eligibilityCriteriaobjectives

Hierarchical Mind-map

Display mode:

All Fields

 Name/Description/Text Only

 Navigation

- Level 1: Click + to expand children
- Level 2: Click node to drill down
- Level 3: Click to navigate deeper
- Use breadcrumbs to navigate back
- Home button returns to root

Viewer

- {4}

- "study" : {7}

"id" : null

"name" : "CDISC PILOT - LZZT"

"description" : null

"label" : null

+ "versions" : [1]

+ "documentedBy" : [2]

"instanceType" : "Study"

"usdmVersion" : "4.0.0"

"systemName" : "CDISC USDM E2J"

"systemVersion" : "0.62.0"



# USDM Viewer — Mind-map view: drill down through the study hierarchy

### USDM Viewer

Tree

Mind-map

Repository

Open JSON

Reset to full

#### Filter key study objects

1. Search for specific keys:

Filter by key (e.g., arms)

Apply

2. Or click common study elements:

arms

studyDesigns

epochs

encounters

activities

elements

endpoints

biomedicalConcepts

eligibilityCriteria

objectives

#### Hierarchical Mind-map

Display mode:

All Fields

 Name/Description/Text Only

##### Navigation

- Level 1: Click + to expand children
- Level 2: Click node to drill down
- Level 3: Click to navigate deeper
- Use breadcrumbs to navigate back
- Home button returns to root

### Viewer

Home

← Back

Root

- 100% +

Click nodes with → to drill down

Study Data {4}

study {7}

usdmVersion : 4.0.0

systemName : CDISC USDM E2J

systemVer... : 0.62.0

name : CDISC PILOT - L...

instanceType : Study

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# USDM Viewer — Filtered to study arms: Placebo and Xanomeline groups

### USDM Viewer

Tree

Mind-map

Repository

Open JSON

Reset to full

#### Filter key study objects

1. Search for specific keys:

Apply

2. Or click common study elements:

arms

studyDesigns

epochs

encounters

activities

elements

endpoints

biomedicalConcepts

eligibilityCriteria

objectives

#### Hierarchical Mind-map

Display mode:

All Fields

Name/Description/Text Only

##### Navigation

- Level 1: Click + to expand children
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- Level 3: Click to navigate deeper
- Use breadcrumbs to navigate back
- Home button returns to root

### Viewer

Home

← Back

Root

100%

Click nodes with → to drill down

Study Data [3]

0 {11}

1 {11}

2 {11}

id : StudyArm\_1

name : Placebo

label : Placebo

description : Placebo

dataOrig... : Data collected ...

instanceType : StudyArm

id : StudyArm\_2

name : Xanomeline Low ...

label : Xanomeline Low ...

description : Active Substanc...

dataOrig... : Data collected ...

instanceType : StudyArm

id : StudyArm\_3

name : Xanomeline High...

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# Biomedical Concepts & Dataset Specializations



# Biomedical Concepts & Dataset Specializations

A Biomedical Concept defines a clinical observation once, in machine-readable form. Dataset specializations bind each concept to concrete SDTM variables — so the same concept looks the same in every dataset.

- **Biomedical Concept (BC):**

- A standardized, machine-readable definition of a clinical observation
- Properties, data types and controlled terminology — e.g. Sex (C28421) with responses Male / Female
- Dataset-agnostic: defined once, reused everywhere

- **SDTM Dataset Specialization:**

- Binds a concept to a target domain — e.g. Systolic Blood Pressure to VS
- Variable-level metadata: VSTESTCD, VSORRES, VSORRESU
- Value-level constraints, ready for define.xml

- **Why it matters:**

- One concept is represented the same way in every dataset
- Metadata-driven transformation replaces per-study hand mapping
- Standard terminology at the point of definition — better data quality

- **Where they live:**

- CDISC Biomedical Concepts (COSMoS) — latest exports on GitHub
- SDTM Dataset Specializations — CSV / Excel, also via CDISC Library API

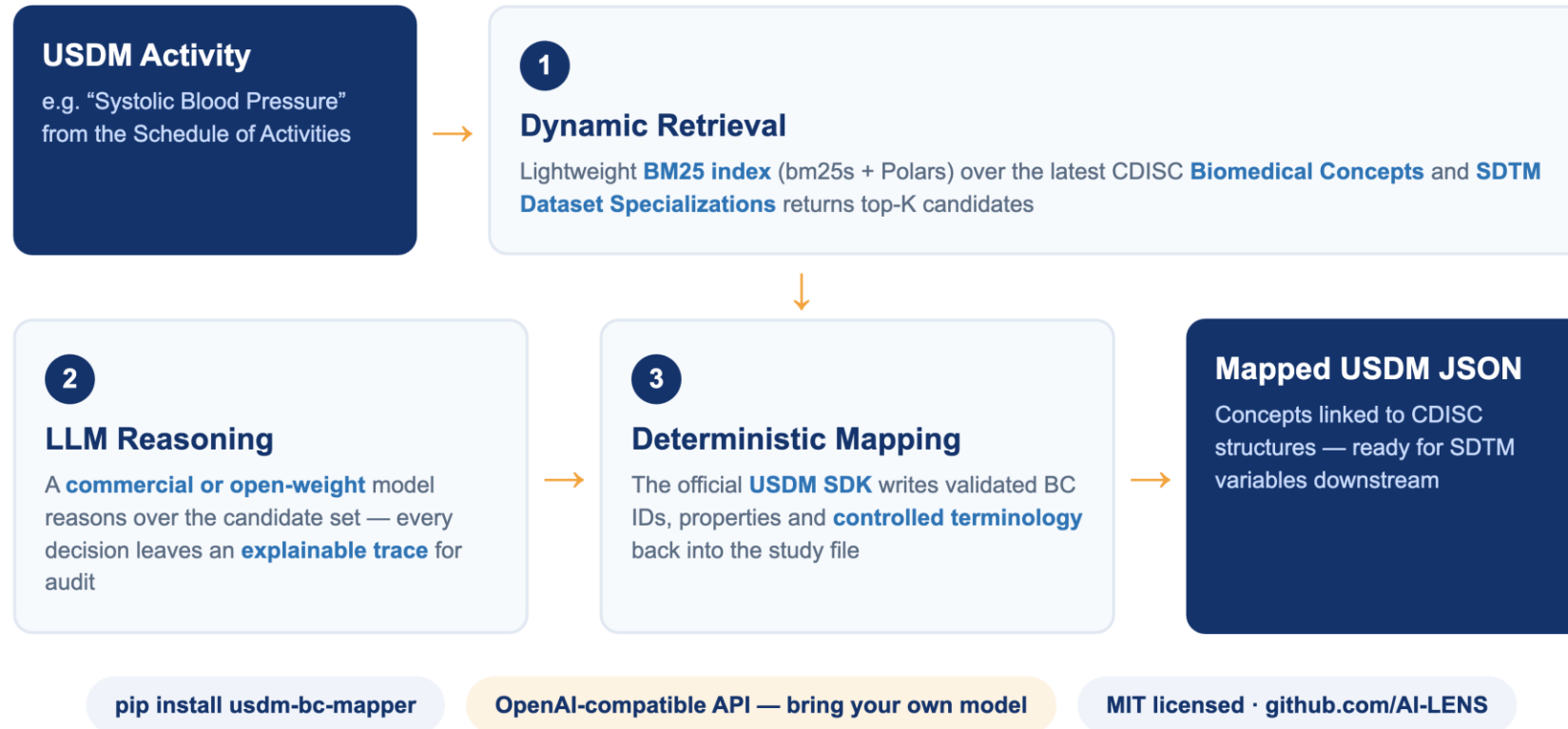


# Biomedical Concept Mapper



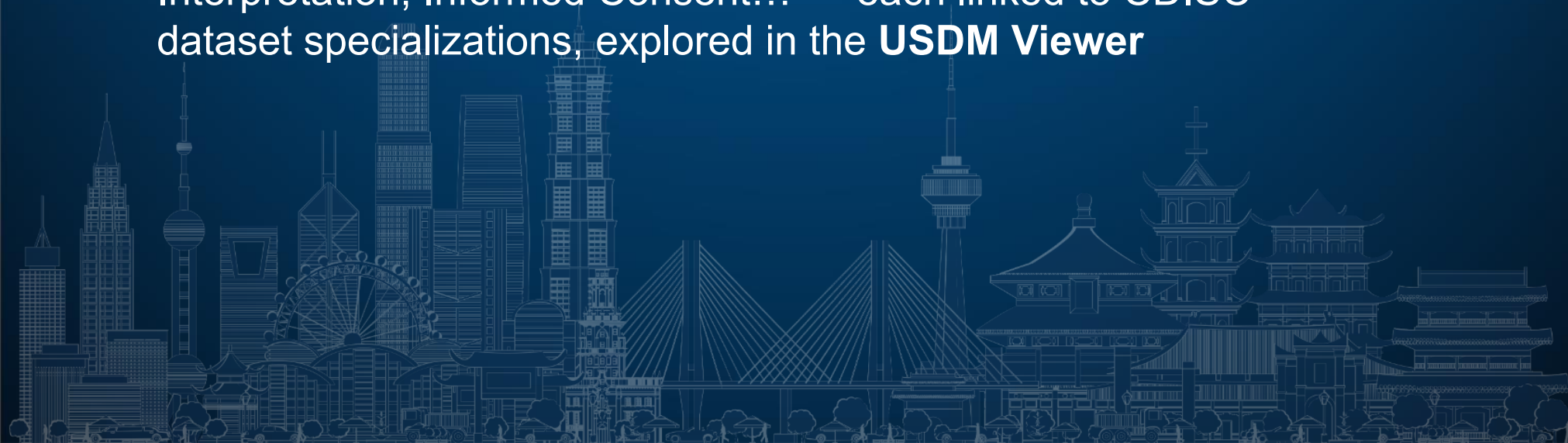
# Biomedical Concept Mapper — How It Works

A retrieval-grounded agent: three explainable steps, no black-box pipeline



# Demo: Mapping the CDISC Pilot Study

- One command maps the study's 36 activities to CDISC Biomedical Concepts: **bcm usdm CDISC\_Pilot\_Study.json**
- 11 missing concepts added — Chest X-Ray, ECG Interpretation, Informed Consent... — each linked to CDISC dataset specializations, explored in the **USDM Viewer**



## The result: an enriched study file — 43 Biomedical Concept entries with CDISC Library references

**USDM Viewer**

TreeMind-map

RepositoryOpen JSONReset to full

**Filter key study objects**

1. Search for specific keys:

biomedicalConceptsApply

2. Or click common study elements:

armsstudyDesignsepochsencounterselementsactivitiesendpointsbiomedicalConceptseligibilityCriteriaobjectives

**Hierarchical Mind-map**

Display mode:

All Fields

Name/Description/Text Only

**Navigation**

- Level 1: Click + to expand children
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**Viewer**

- [43]

- 0 : {10}

"id" : "BiomedicalConcept\_20"

"extensionAttributes" : [0]

"name" : "Sex"

"label" : "Sex"

"synonyms" : [0]

"reference" : "/mdr/bc/packages/2025-04-01/biomedicalconcepts/C28421"

- "properties" : [2]

- 0 : {11}

"id" : "BiomedicalConceptProperty\_130"

"extensionAttributes" : [0]

"name" : "Sex"

"label" : "Sex"

"isRequired" : true

"isEnabled" : true

"datatype" : "string"

- "responseCodes" : [2]

+ 0 : {7}

+ 1 : {7}

+ "code" : {5}

"notes" : [0]

"instanceType" : "BiomedicalConceptProperty"

+ 1 : {11}

# Onward: USDM into OpenStudyBuilder

The same study file flows onward: the USDM OSB Uploader loads it into OpenStudyBuilder, completing an open, reproducible 360i path from protocol to SDTM-ready metadata.

- **USDM OSB Uploader:**

- Uploads a complete USDM study into OpenStudyBuilder
- Arms, epochs, visits, populations and criteria — one CLI command
- Schema-validated, retry-aware, type-safe API operations

- **Open source (MIT):**

- [github.com/AI-LENS](https://github.com/AI-LENS) — viewer, mapper and uploader
- `pip install usdm-bc-mapper`

- **Recognized by CDISC COSA:**

- `usdm-bc-mapper` — listed by the CDISC Open Source Alliance
- `usdm-osb-uploader` — listed by the CDISC Open Source Alliance

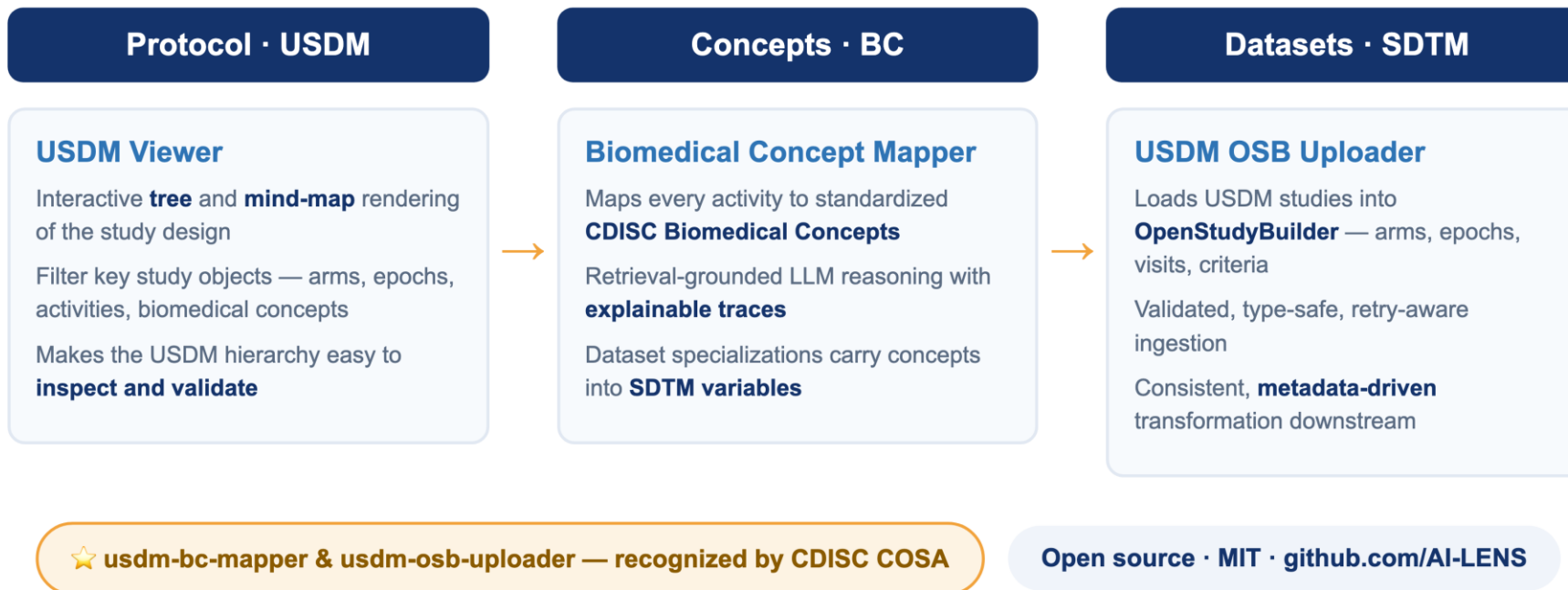
- **Why it matters:**

- Community-vetted building blocks for the 360i data lifecycle
- Anyone can reproduce this protocol-to-SDTM pipeline today

# Conclusion



## CDISC 360i in Practice — One Connected, Open Source Path





**Thank You!**





**Questions?**

