

TT06: From **SDTM** to a Graph-Based, Multi-Purpose Interface for Data

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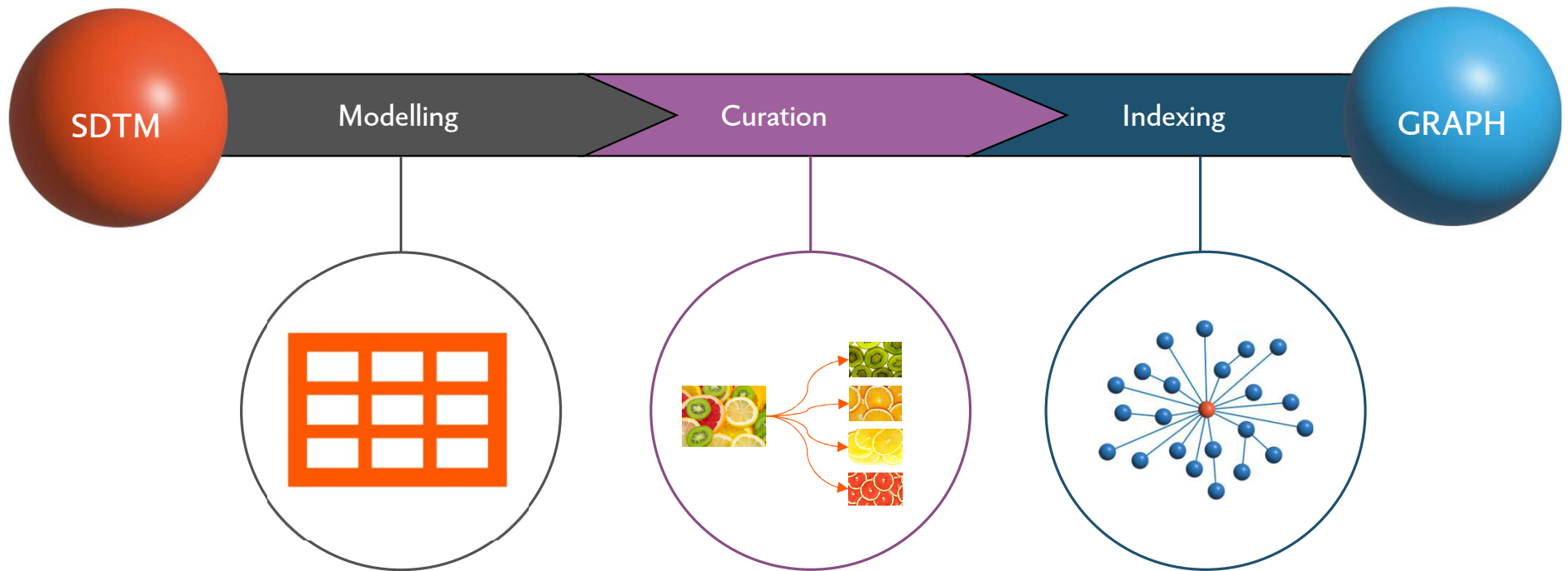


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Introduction

We've mastered structure, now it's time to master connection.

SDTM has given us order and consistency; now we need to make the relationships it holds come alive.



Relational Database – The Current Reality

- **A RELIABLE FRAMEWORK**

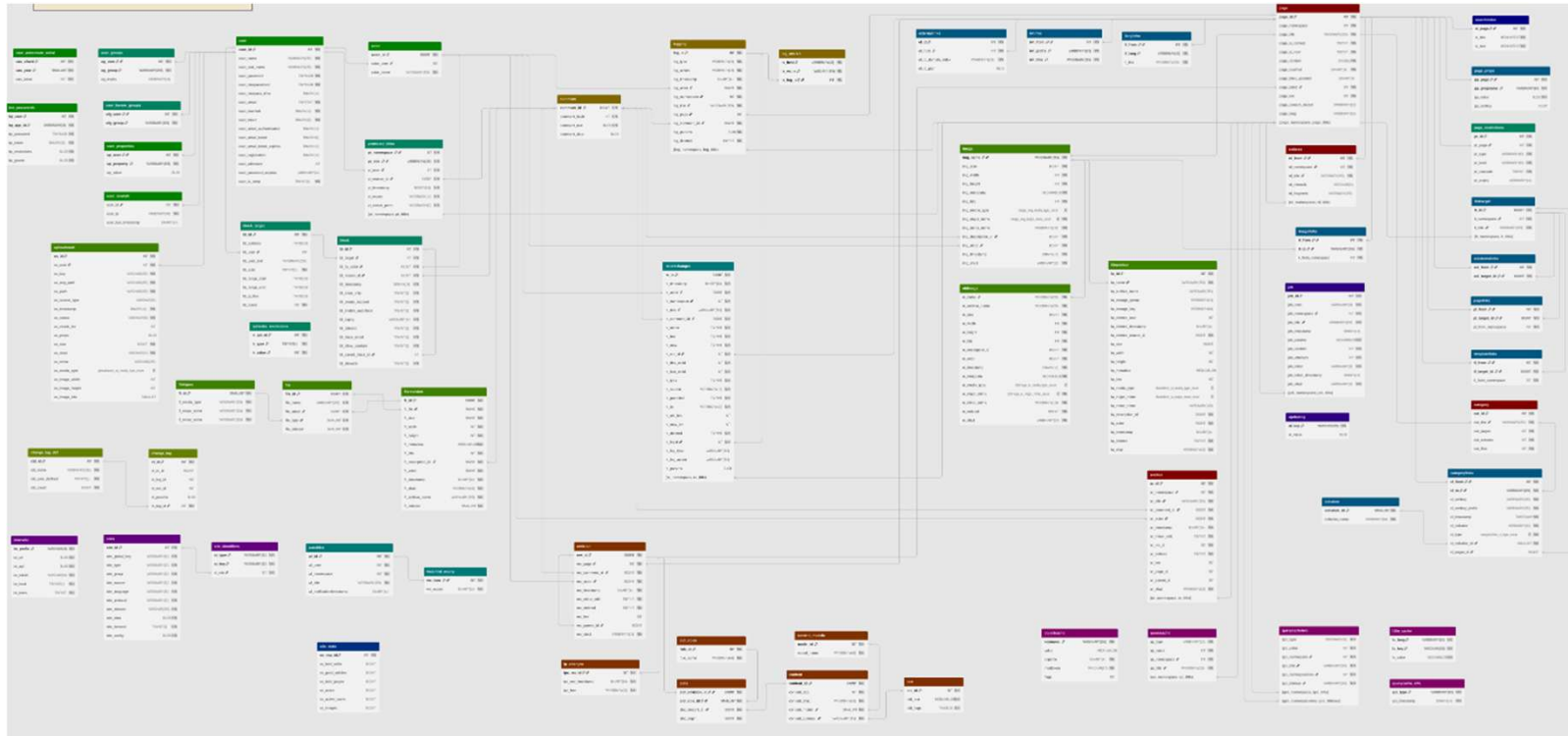
SDTM structures data into defined domains - AE, LB, EX, DM - making it standardized, compliant, and ready for analysis.

- **THE HIDDEN COMPLEXITY**

Relationships live behind identifiers like USUBJID and VISITNUM; context is revealed only through joins and programs.

- **WHAT THIS MEANS**

Every question requires reconstruction - data is complete, but the story is fragmented.



Source: https://upload.wikimedia.org/wikipedia/commons/thumb/b/b3/ER_diagram_of_schema_ENWIKI_with_foreign_keys.svg/5730px-ER_diagram_of_schema_ENWIKI_with_foreign_keys.svg.png

Graph Database – A New Way to See Data

- **FROM TABLES TO CONNECTIONS**

Instead of separating information into domains, a graph links patients, visits, events, and outcomes directly.

- **HOW IT WORKS**

Data becomes a network of nodes and relationships - each connection tells part of the story, and together they reveal the full picture.

- **WHY IT MATTERS**

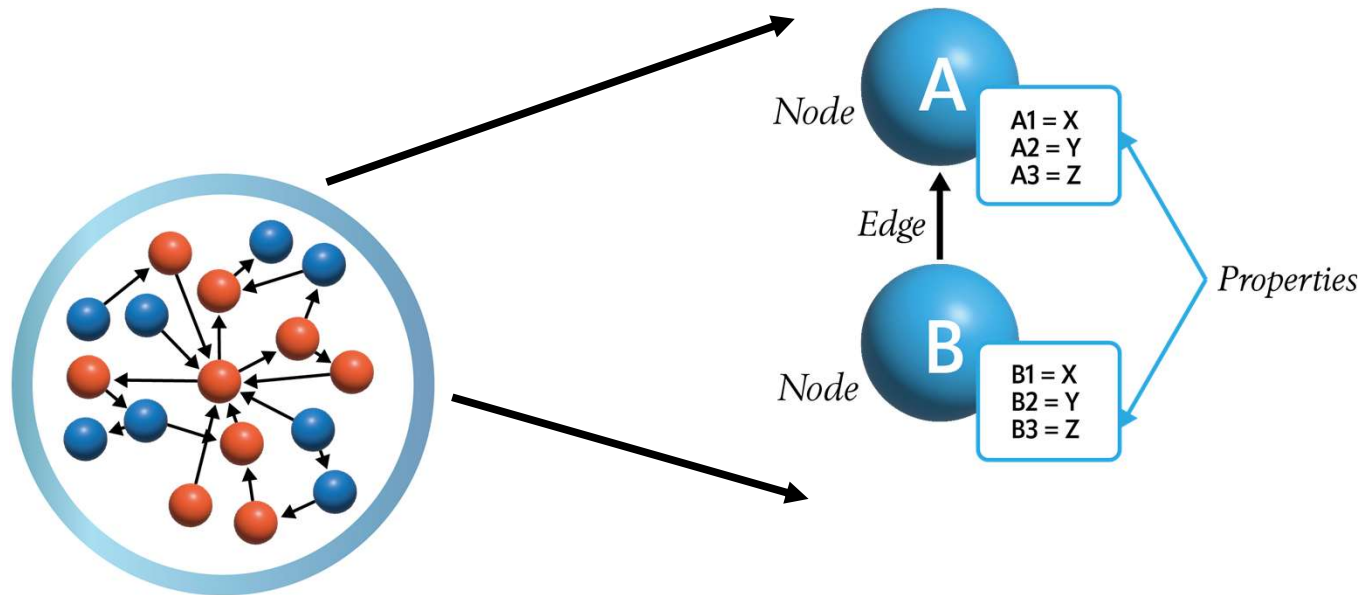
Exploration becomes intuitive and dynamic - teams can trace patterns, relationships, and insights in real time.



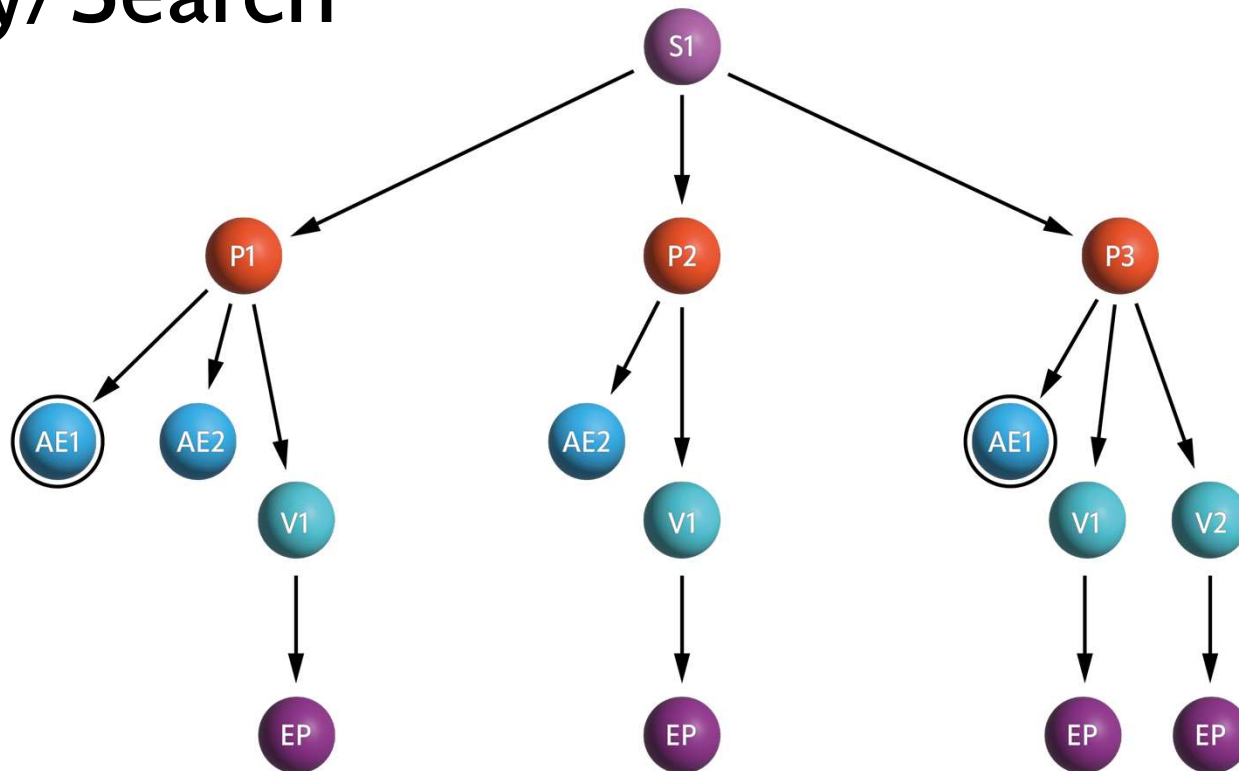
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Property Graph Databases



Query/Search



Relational Databases		Graph Databases
<i>Tables with columns and rows</i>	Format & Model	<i>Graphs with nodes and edges</i>
<i>Implicit relations using table keys</i>		<i>Explicit relations using edges</i>
<i>Rigid data model (each row has the same columns)</i>		<i>Flexible data model (each node can contain different properties)</i>
<i>Complex joins between tables required</i>		<i>No joins are required</i>
<i>Predefined and flat data (e.g., financial data)</i>	Use Cases	<i>Varying and interconnected data (e.g., medical data)</i>
<i>Data entry (with transactions)</i>		<i>Integration and harmonization</i>
<i>Predefined analysis</i>		<i>Data science (exploration)</i>

SDTM vs Graph Application

- **STRUCTURED FOR COMPLIANCE**

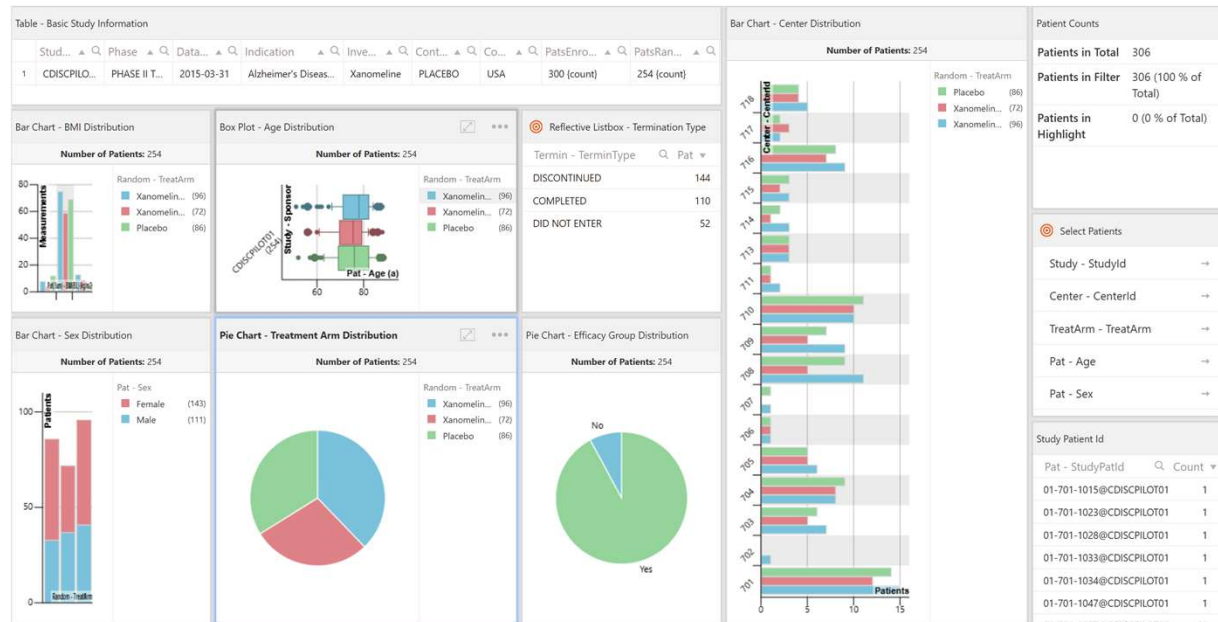
SDTM ensures regulatory readiness and consistency, with data neatly organized into relational domains.

- **BUILT FOR CONNECTION**

A graph model keeps that structure but makes relationships explicit, connecting patients, visits, events, and outcomes.

Teams can explore data contextually, follow relationships in real time, and uncover insights without heavy programming.

PHUSE project



Access the data:

<https://github.com/phuse-org/TestDataFactory/tree/main/Updated>



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SDTM tables

ae	relrec	suppae
cm	sc	suppdm
dm	se	suppds
ds	sv	supplbch
ex	ta	supplbhe
lbch	te	supplbur
lbhe	ti	
lbur	ts	
mh	tv	
qsco	vs	
qsda		
qsgi		
qshi		
qsmm		
qsni		

Challenges

- **GENERIC TABLE DESIGN**

Mapping flexible SDTM domains into graph nodes requires careful design to retain meaning and traceability.

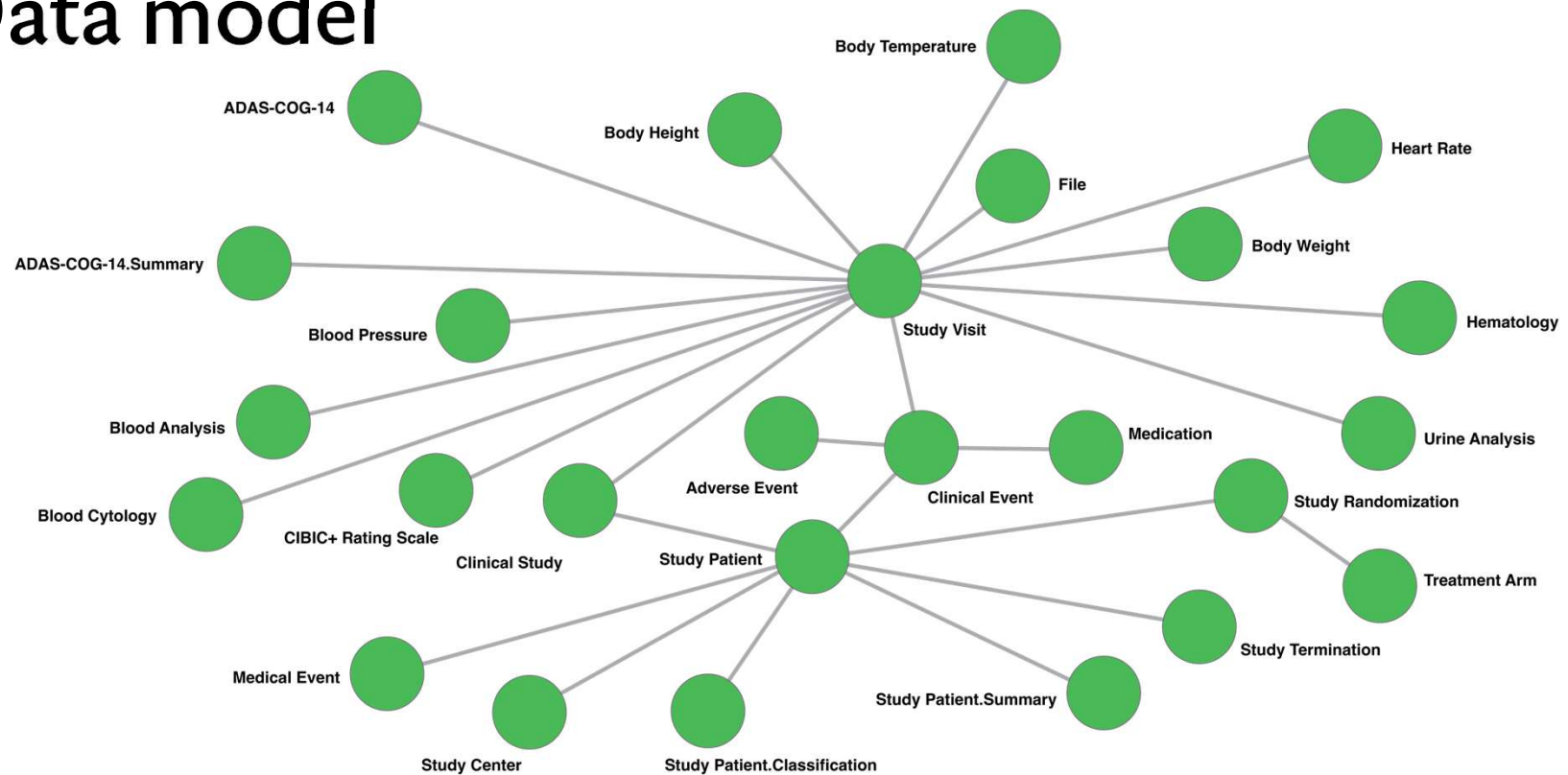
- **CONSISTENCY ACROSS VISITS**

Aligning visit numbers, days, and timing across domains is complex, especially when planned and actual visits differ.

- **VISITS VS DATE**

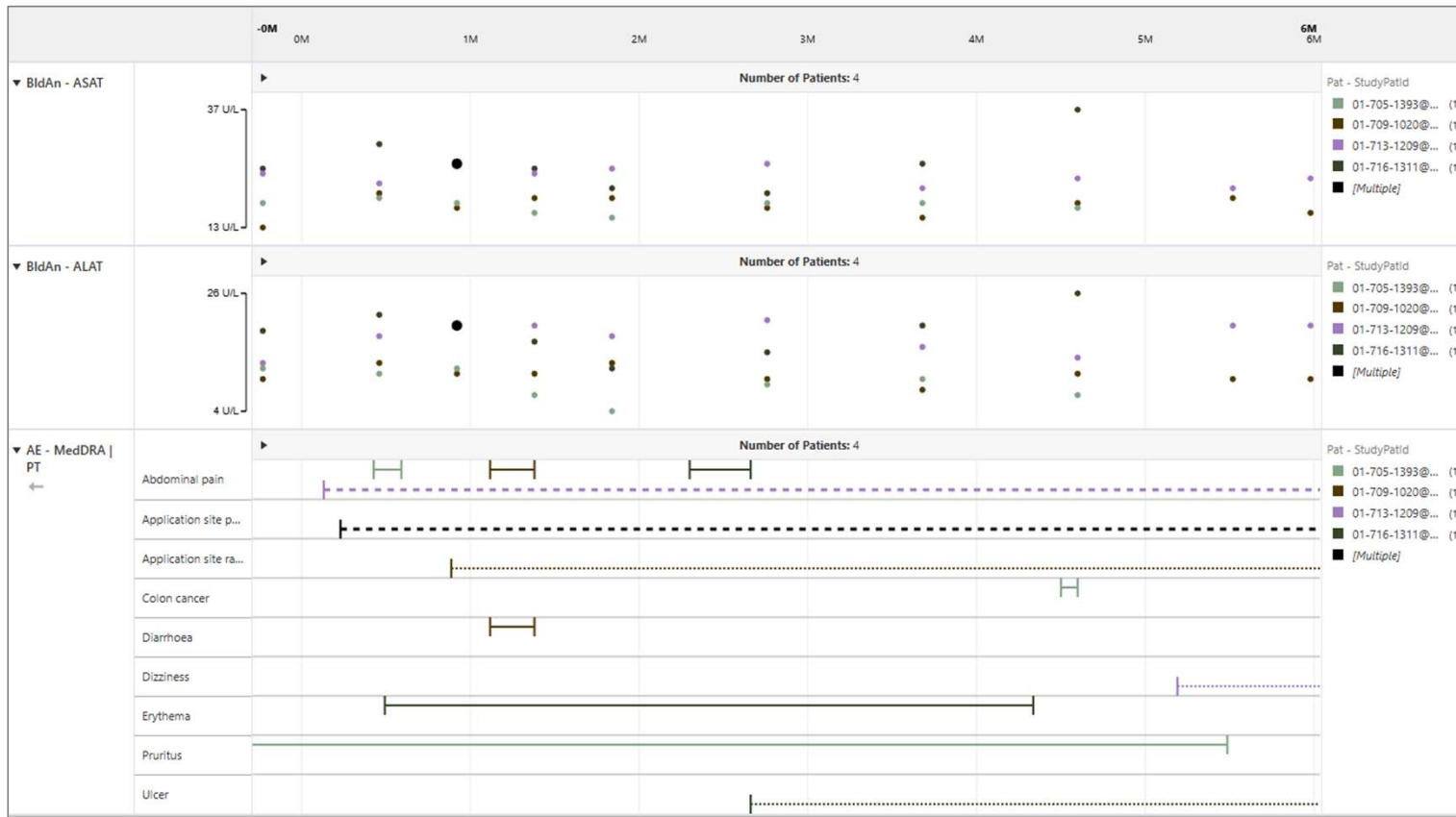
Determining which reference to use, scheduled visit or real-world date, can change how relationships are interpreted.

Data model

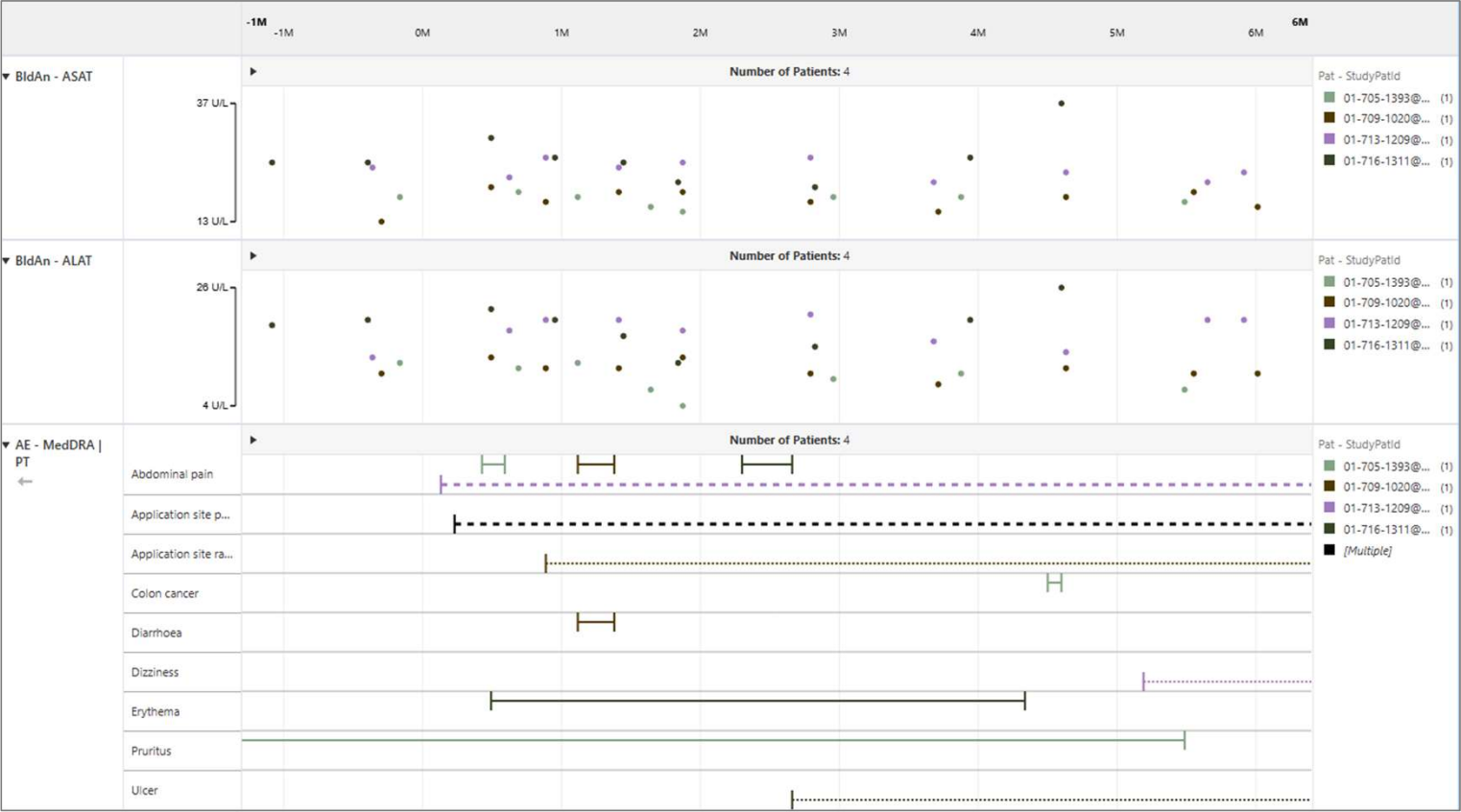


Variable	Scheduled Visit	Time Interval (label on output)	Time Interval (Day)	Target Time Point (Day)
ADAS-Cog CIBIC+	3	Baseline	≤ 1	1
	8	Week 8	2-84	56
	10	Week 16	85-140	112
	12	Week 24	>140	168
NPI-X	3	Baseline	≤ 1	1
	4	Week 2	2-21	14
	5	Week 4	22-35	28
	7	Week 6	36-49	42
	8	Week 8	50-63	56
	8.1	Week 10 (Tel)	64-77	70
	9	Week 12	78-91	84
	9.1	Week 14 (Tel)	92-105	98
	10	Week 16	106-119	112
	10.1	Week 18 (Tel)	120-133	126
	11	Week 20	134-147	140
	11.1	Week 22 (Tel)	148-161	154
	12	Week 24	162-175	168
	13	Week 26	>175	182

Visit

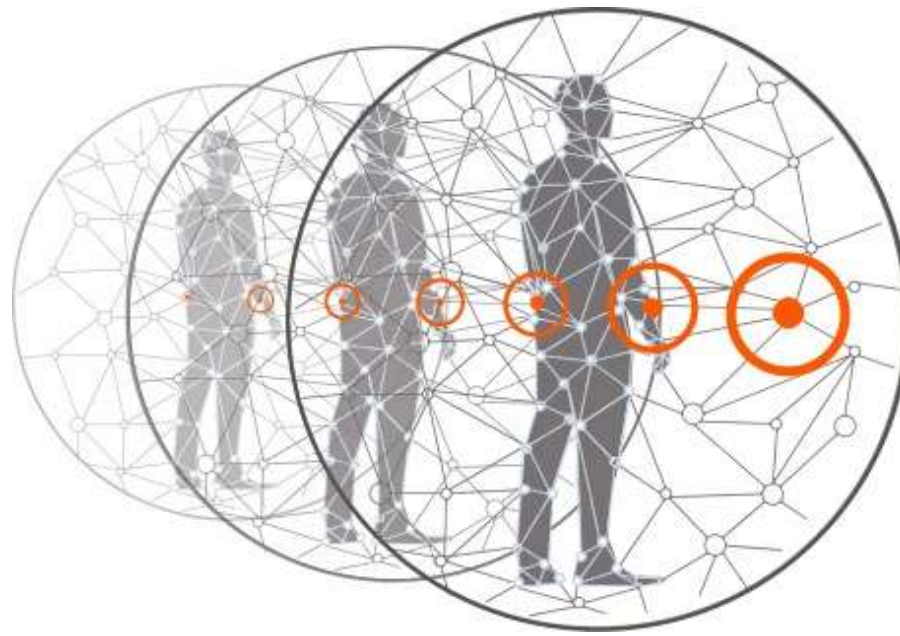


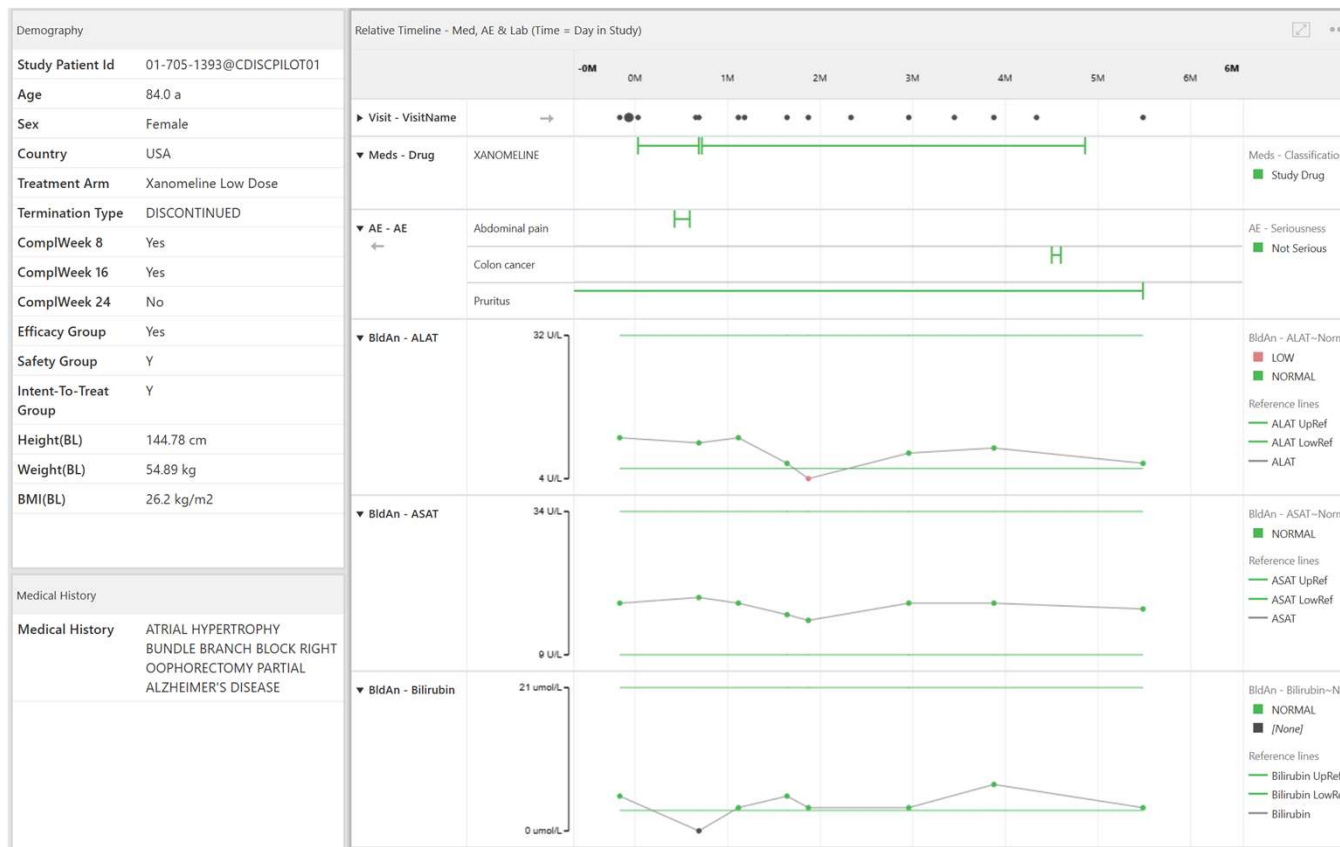
Day



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Example – Patient centricity





Examples – Exploring Clinical Relationships

- **ALL DATA FOR ONE PATIENT**

View a complete patient profile, demographics, dosing, labs, and events, connected through one continuous story.

- **MEDICATIONS DURING AN EVENT**

Identify which treatments overlap with an adverse event to better understand timing and potential causality.

- **DRUG-DRUG INTERACTIONS**

Detect overlapping treatments and visualize how co-administered drugs relate to specific outcomes.

- **TREND DETECTION ACROSS VISITS**

See how lab results, vitals, or event frequency evolve across visits, patterns that may not be visible in listings.

- **SIGNAL CLUSTERING**

Spot clusters of related adverse events across patients or treatment groups to identify emerging safety signals.

- **CROSS-DOMAIN EXPLORATION**

Move seamlessly between domains, from exposure to lab results to outcomes, following relationships instead of merging tables.



Difficult to attract investors?

Can you **compare data** from different studies?

Want to easily **share findings**?

High individual treatment response in a **cohort**?

What **endpoints** were used in the phase II program?

Waiting for response from the **statistician**?

What **version of data** are you working with?

Looking for drug-drug **interaction**?

Have abnormal **lab values** been reported as AEs?

Need to handle many different **data sources**?

Can you identify **outliers**?

Worried about questions from **authorities**?

Concerned with data **consistency** across sites?

Difficult to recruit **patients**?

Is your data **future proof** and interoperable?

Do you have **data access 24/7**?

Conclusion

- **FROM STRUCTURE TO CONNECTION**

SDTM gives us the foundation; graphs bring that foundation to life through relationships.

- **FROM DATA REVIEW TO DATA EXPLORATION**

A connected model turns static listings into dynamic insights, faster, visual, and collaborative.

- **FROM INFORMATION TO UNDERSTANDING**

When data is connected, patterns emerge naturally, helping us make better, safer decisions.

Thank you!

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Software for **yousers.**