

A New Approach to Visualize Adverse Events

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Introduction

Current challenges in Adverse Event (AE) analysis.

- Data is fragmented, making it difficult to track relationships.

The importance of better visualization in AE monitoring.

- Improves decision-making, enhances regulatory compliance, and identifies hidden patterns.

Introduction to Graph-Based Visualization.

- How property graphs provide a structured approach to understanding AE data.

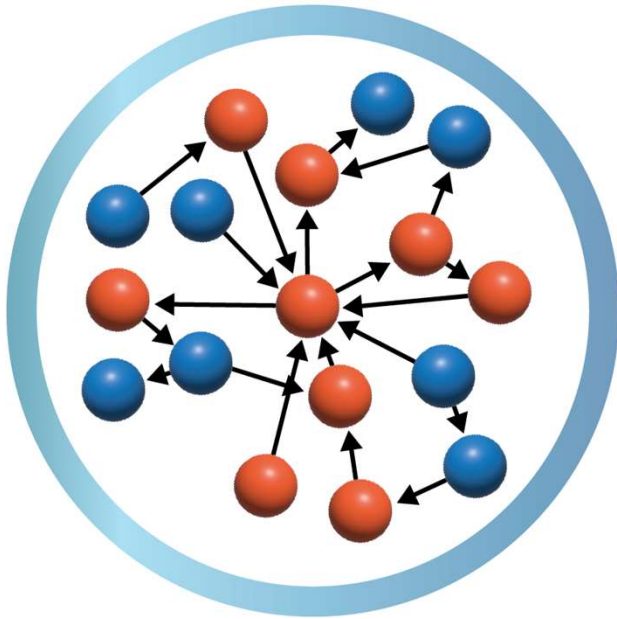
What?



What: Property Graphs in AE Analysis

- A property graph is a structured way to represent data.
 - It consists of nodes (entities), edges (relationships), and properties (metadata).
- Example: Representing an AE term (e.g., Headache) in a graph model.
 - Nodes represent events, patients, or drugs; edges show connections between them.
- Traditional tabular methods are insufficient for complex relationships.
 - Graphs allow for dynamic linking and easier exploration of data.

Property Graph Databases

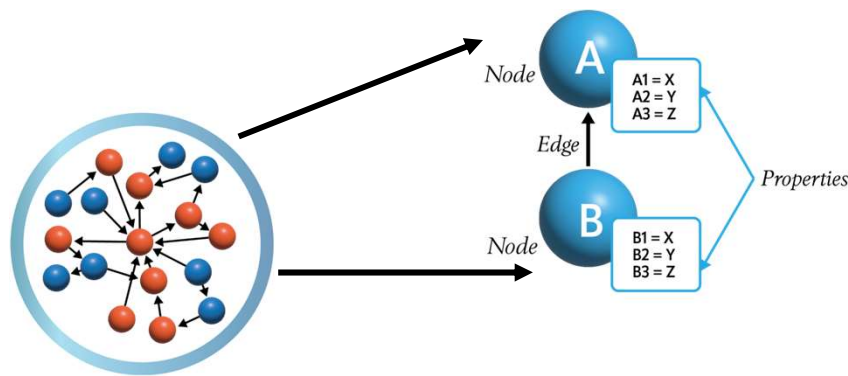


A collection of data with focus on the relations.

Real-world structures/scenarios.

Performance and flexibility.

Property Graph Databases



Nodes store data objects.

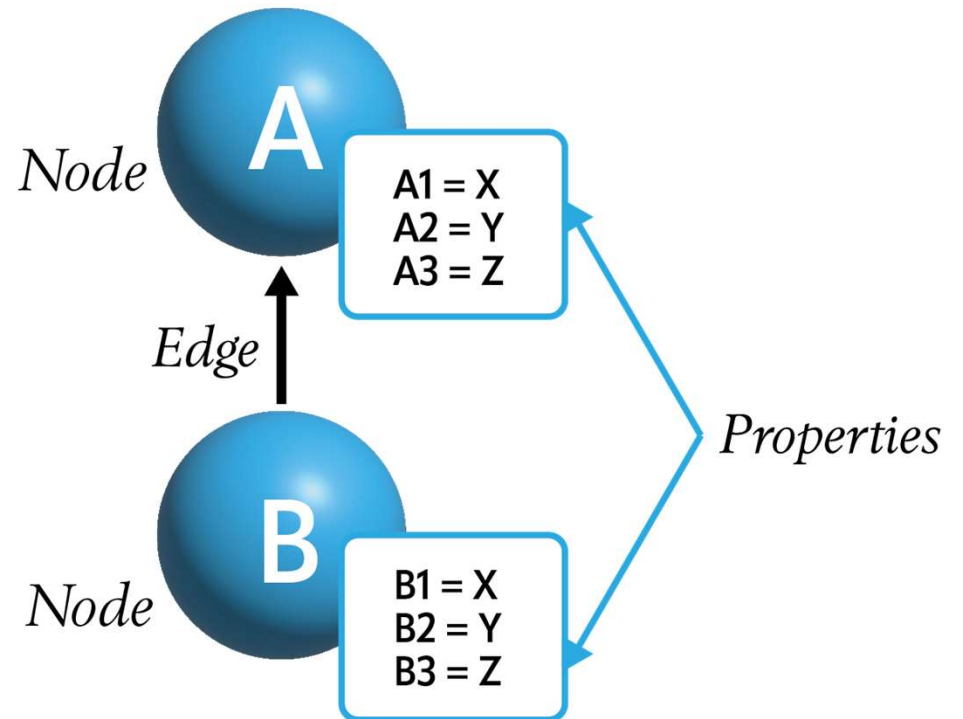
Properties describe each node.

Edges are the relationships between nodes.

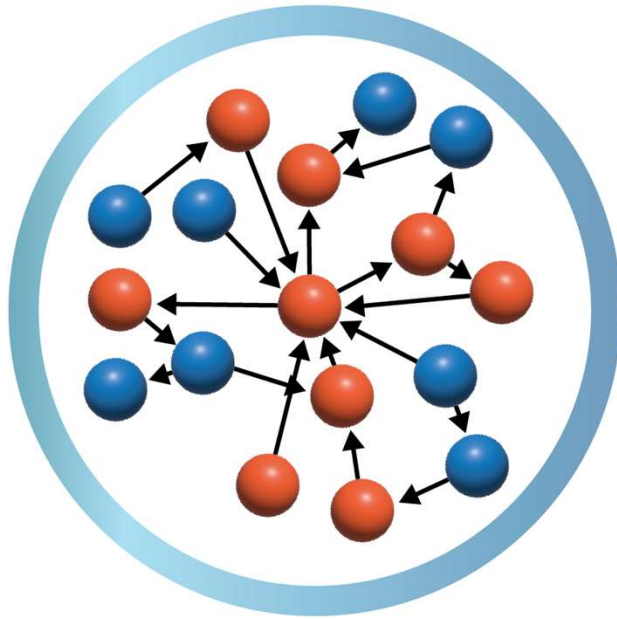
Property Graph Databases

Example: AE term=Headache
Start date=2023-12-24
Stop date=2023-12-26

Patient ID=16-001
Age=45
Sex=Female



Property Graph Databases



Flexibility – modify graph structure

Performance – data volume

Efficiency – utilizing linked nodes

How?



How: Implementing a Graph-Based AE Approach

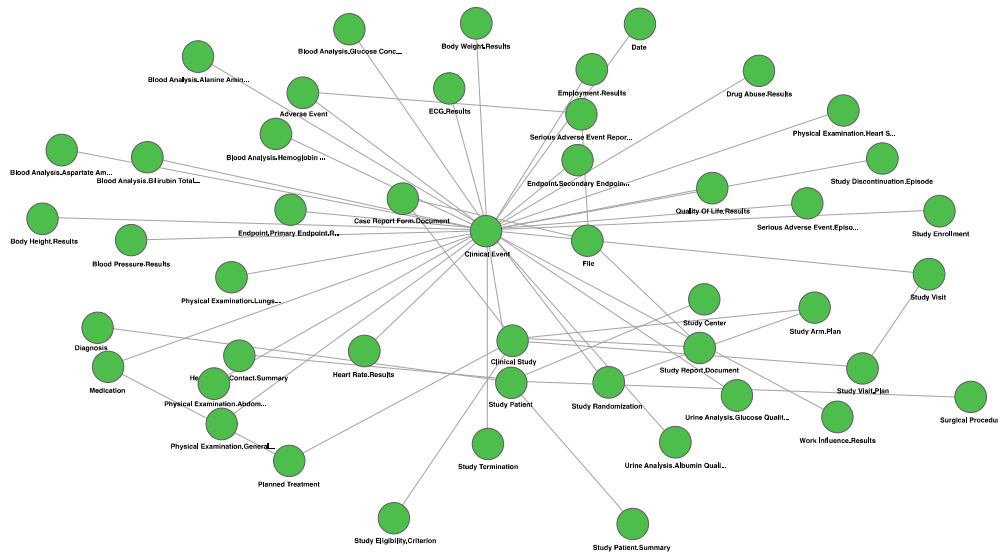
- Key factors in adopting a graph-based AE visualization approach.
 - Standardization, ontology integration, and data curation.
- A step-by-step approach to curating and organizing AE data.
 - Define key entities, establish relationships, and validate data accuracy.
- Ensuring consistency and reliability in AE analysis.
 - Structured data leads to better insights and regulatory alignment.



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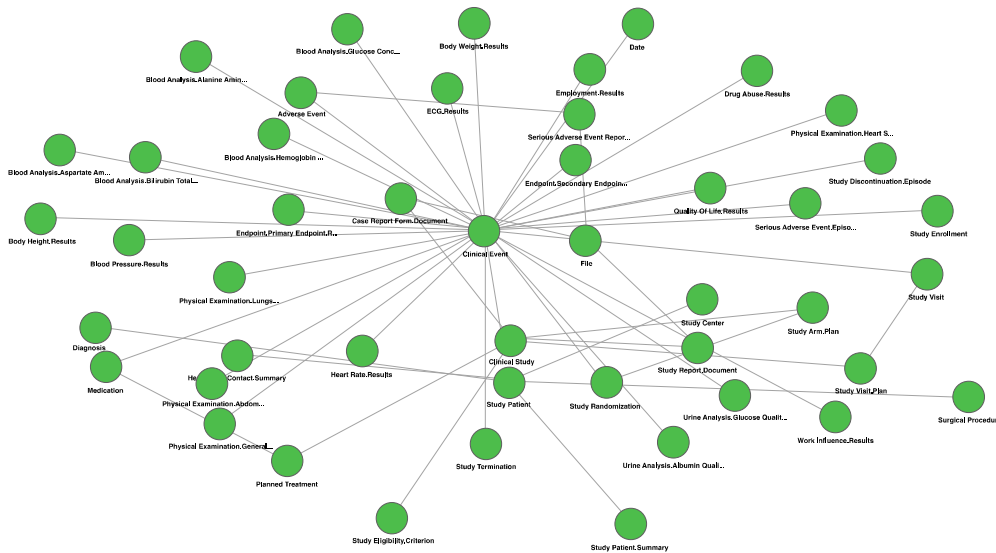
Structure



A common understanding of the structure of information, reuse domain knowledge and make domain knowledge explicit.

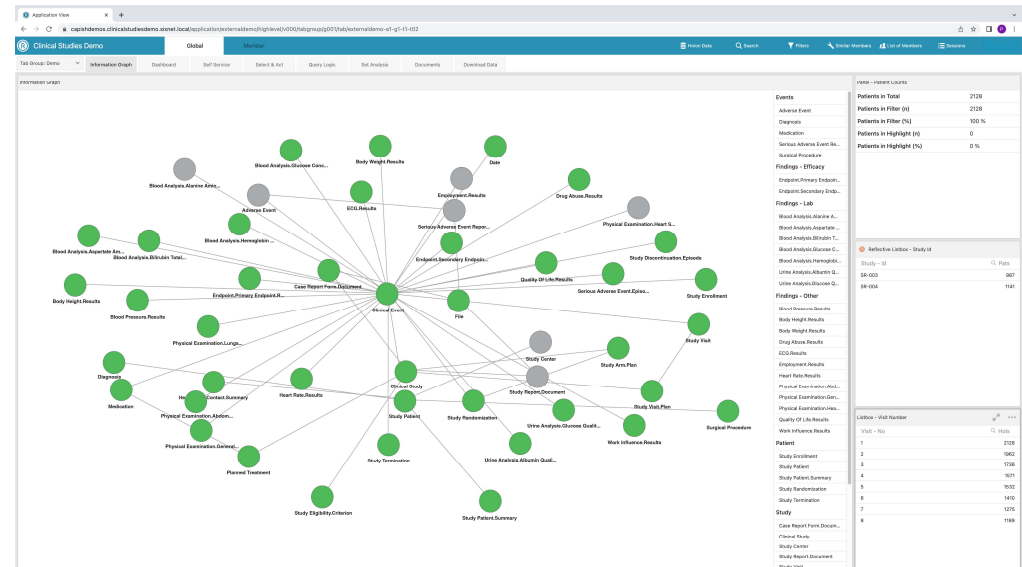
Ontology

Ontological entities and relationships can be represented in a graph database, where data and metadata are kept together.



Content

A representation, formal naming, and definition of the categories, properties, and relations between the concepts, data, and entities that substantiate a domain.



Curation

Process	Methodology	Impact
Describing Data	Establishing Terminology	Ensures standardization and consistency
Enhancing Data	Utilizing Metadata	Improves data understanding and insights
Providing Structure	Implementing an Information Model	Enables efficient and effective data use

Why?



Why: Benefits and Use Cases

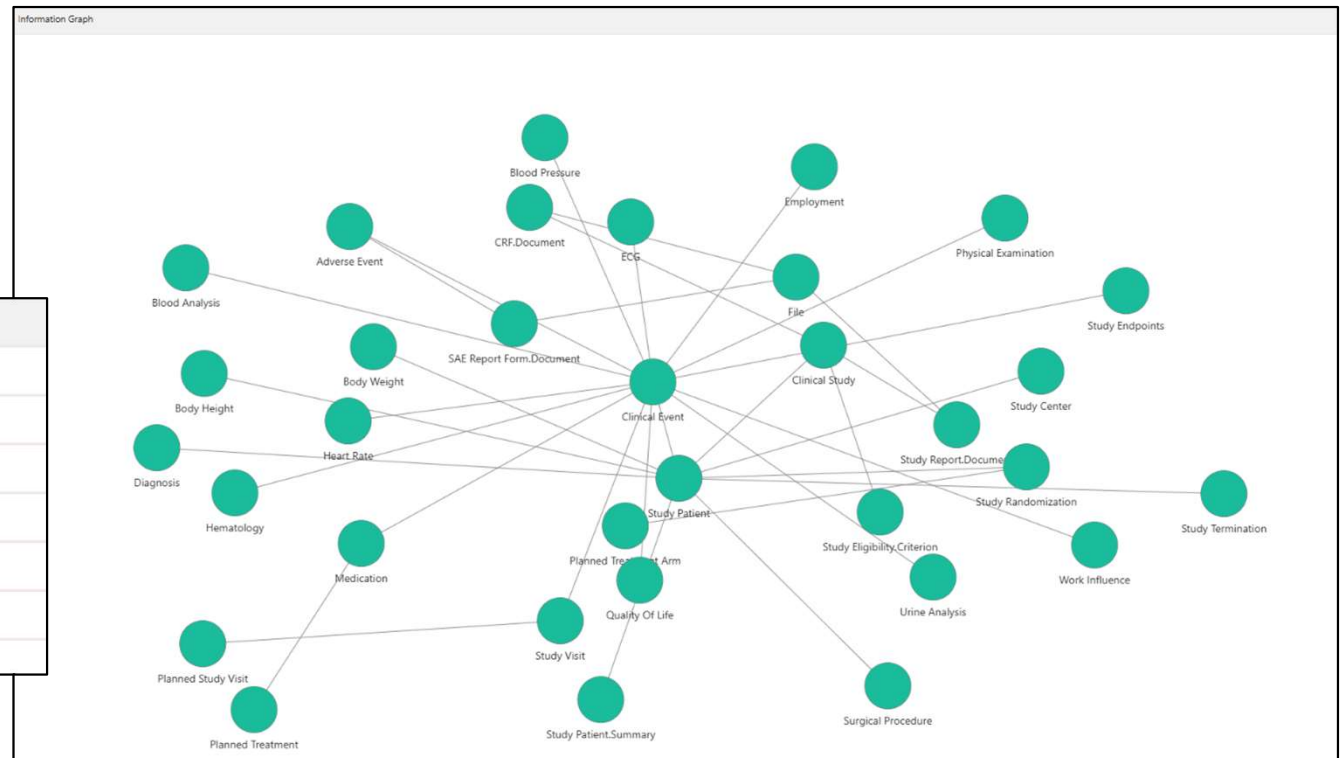
- Major advantages of using property graphs for AE monitoring.
 - Real-time trend analysis, improved AE tracking, and predictive modeling.
- Examples of real-world applications.
 - Identifying trends over time, holistic AE monitoring, and pre-disposition analysis.
- Traditional methods struggle with large and evolving datasets.
 - Graphs facilitate easier identification of emerging safety signals.

Examples

Utilizing a dataset made available at the phuse-scripts repository.
https://github.com/phuse-org/phuse-scripts/tree/master/data/sdtm/TDF_SDTM_v1.0

Inventory

AE Overview	
Studies with AE data	1
AEs in total	961
SAEs	3
Patients with AEs	225 (74 %)
Patients with SAEs	3 (1 %)
Patients without any AE	81 (26 %)



Examples

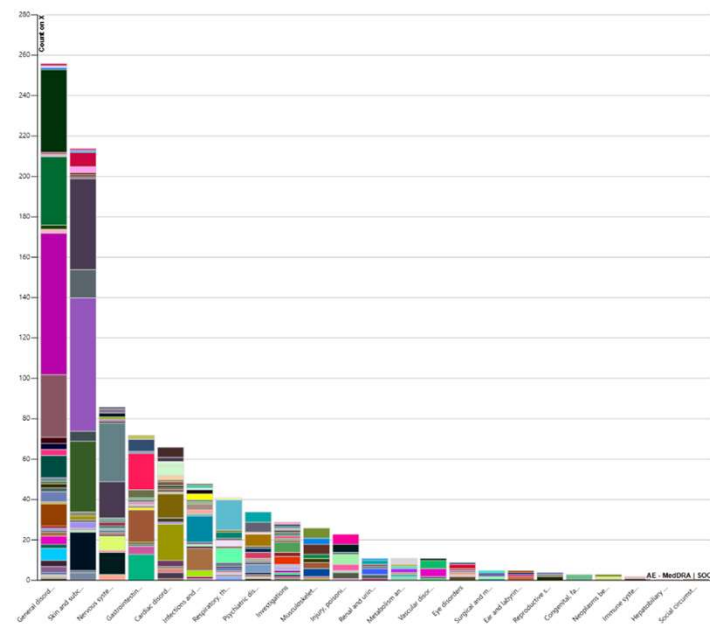
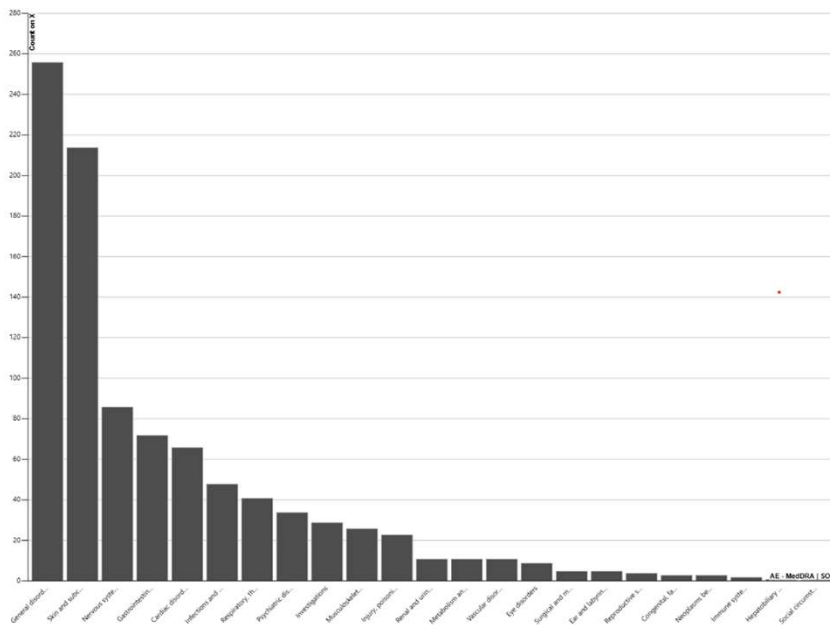
Inventory

	AE - MedDRA SOC	Count
1	General disorders and administration site conditions	256
2	Gastrointestinal disorders	72
3	Skin and subcutaneous tissue disorders	214
4	Cardiac disorders	66
5	Infections and infestations	48
6	Respiratory, thoracic and mediastinal disorders	41
7	Renal and urinary disorders	11
8	Musculoskeletal and connective tissue disorders	26
9	Eye disorders	9
10	Psychiatric disorders	34
11	Metabolism and nutrition disorders	11
12	Nervous system disorders	86
13	Investigations	29
14	Surgical and medical procedures	5
15	Injury, poisoning and procedural complications	23
16	Reproductive system and breast disorders	4
17	Vascular disorders	11
18	Congenital, familial and genetic disorders	3
19	Ear and labyrinth disorders	5

AE - MedDRA SOC	AE - MedDRA PT	Count
General disorders and administration site conditions	Application site erythema	41
General disorders and administration site conditions	Application site pruritus	70
General disorders and administration site conditions	Fatigue	11
General disorders and administration site conditions	Application site vesicles	11
General disorders and administration site conditions	Application site irritation	34
General disorders and administration site conditions	Application site rash	31
General disorders and administration site conditions	Pyrexia	3
General disorders and administration site conditions	Application site pain	2
General disorders and administration site conditions	Application site urticaria	3
General disorders and administration site conditions	Secretion discharge	1
General disorders and administration site conditions	Sudden death	1
General disorders and administration site conditions	Application site perspiration	2
General disorders and administration site conditions	Pain	3
General disorders and administration site conditions	Malaise	4
General disorders and administration site conditions	Feeling abnormal	1
General disorders and administration site conditions	Cyst	1
General disorders and administration site conditions	Chest discomfort	2
General disorders and administration site conditions	Chills	5
General disorders and administration site conditions	Oedema peripheral	6
General disorders and administration site conditions	Oedema	2
General disorders and administration site conditions	Irritability	2
General disorders and administration site conditions	Application site swelling	3
General disorders and administration site conditions	Application site warmth	2
General disorders and administration site conditions	Application site discharge	1
General disorders and administration site conditions	Feeling cold	1
General disorders and administration site conditions	Application site bleeding	1
General disorders and administration site conditions	Chest pain	2
General disorders and administration site conditions	Application site induration	1
General disorders and administration site conditions	Application site exfoliation	1
General disorders and administration site conditions	Asthenia	1

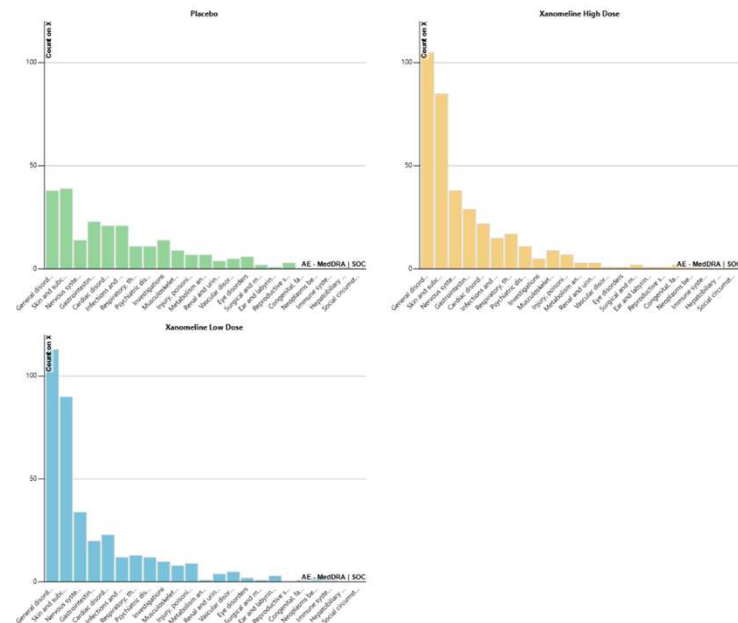
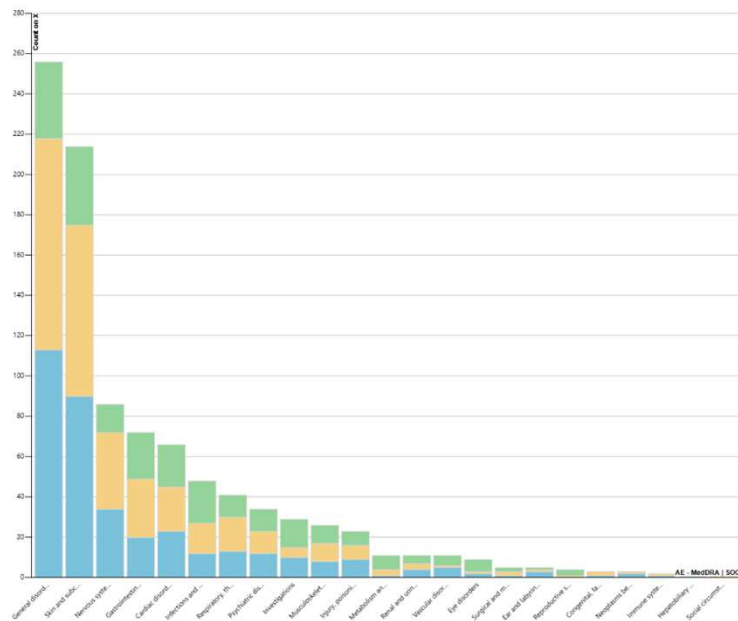
Examples

Inventory



Examples

Inventory



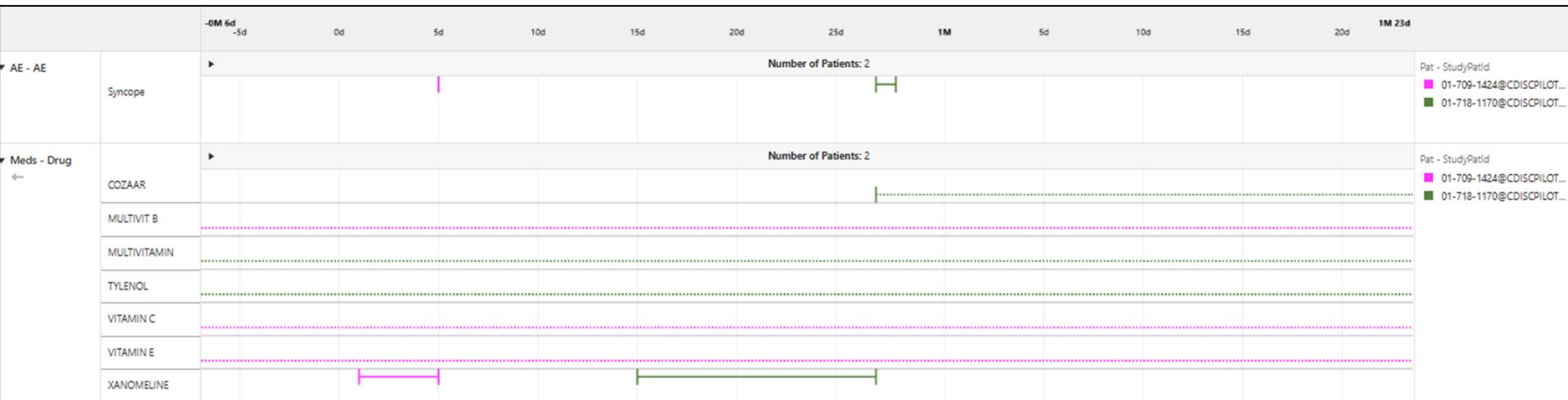
Examples - Exploring AEs over time



Examples - Exploring AEs over time



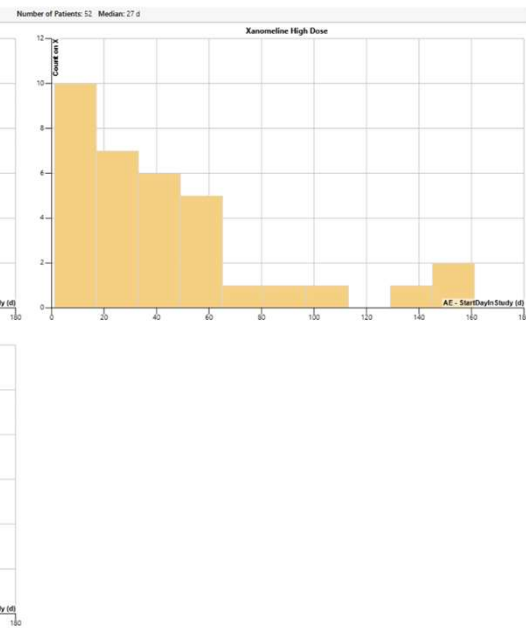
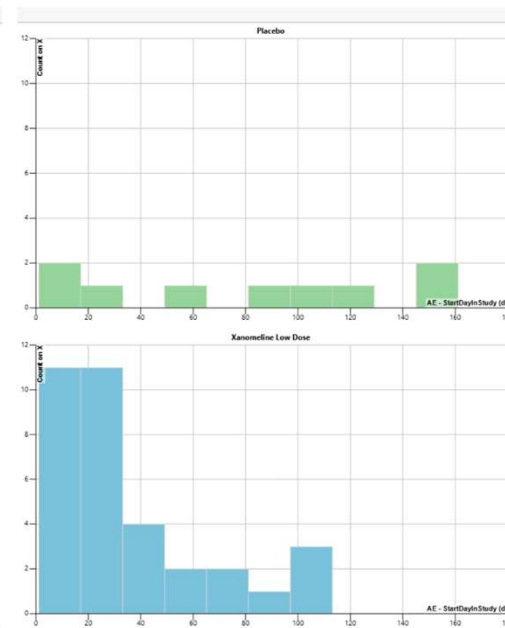
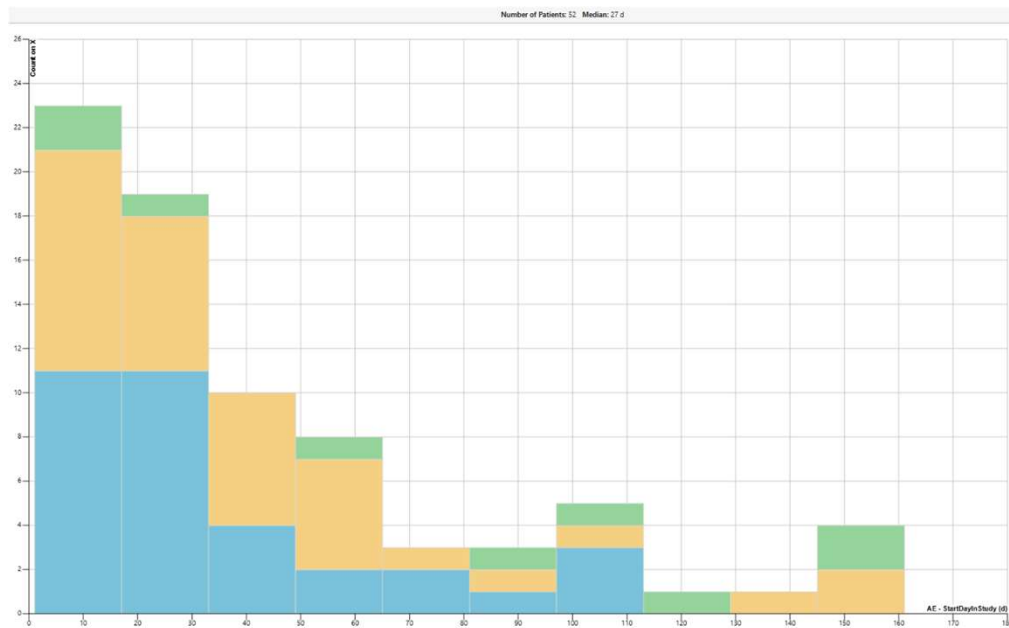
Examples - Exploring AEs over time



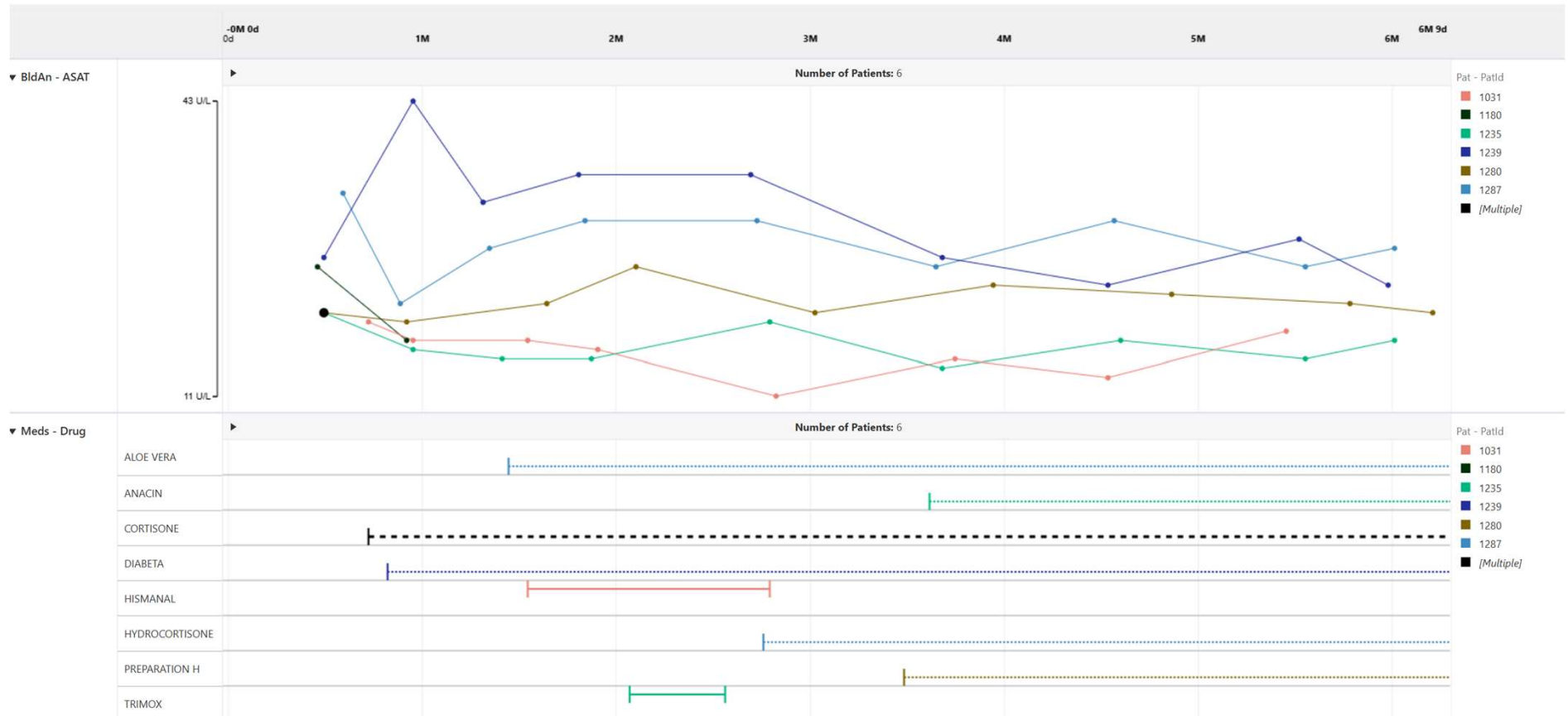
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Examples - Exploring AEs over time



Examples – Biomarkers and Medications



Examples - Subgroups/Cohorts

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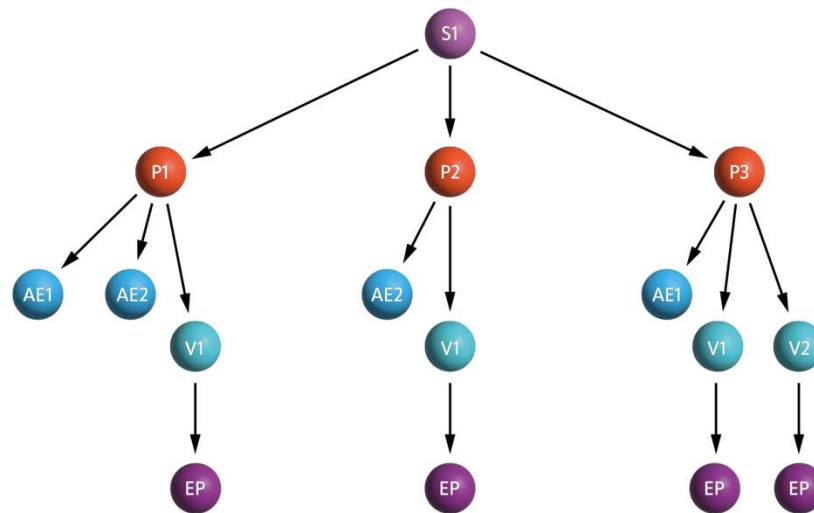


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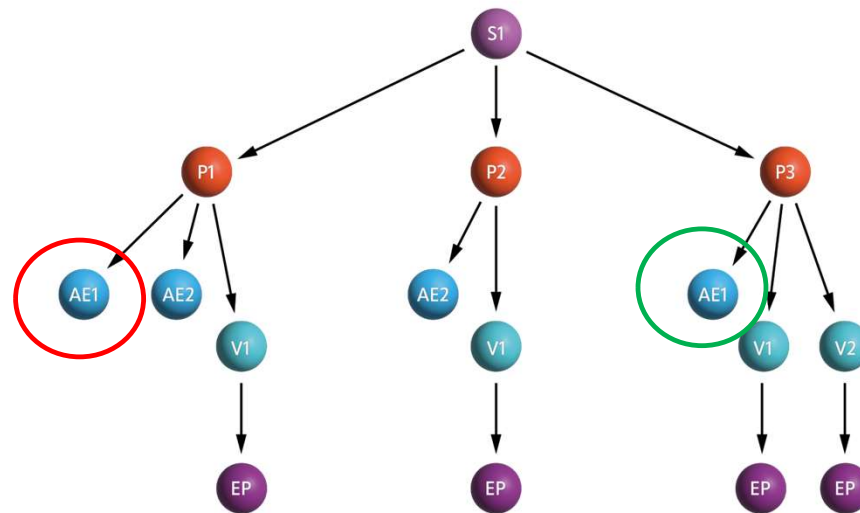
Reflect your data

Example of patient cohorts



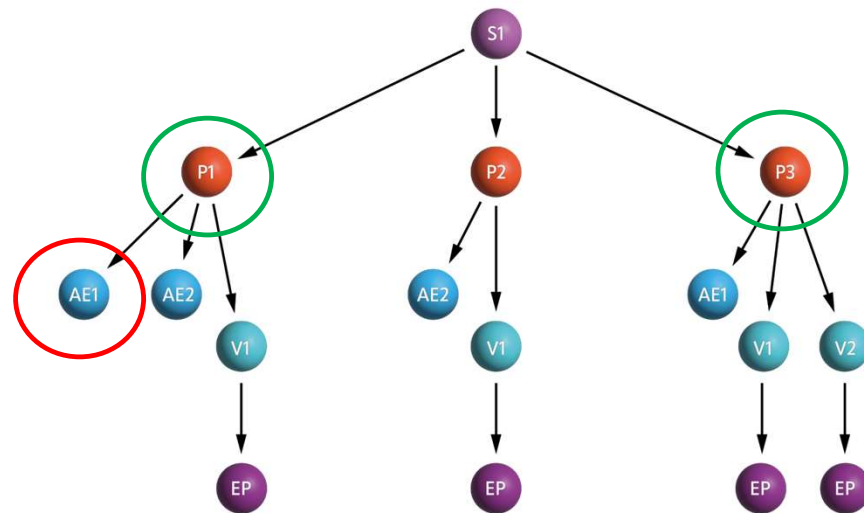
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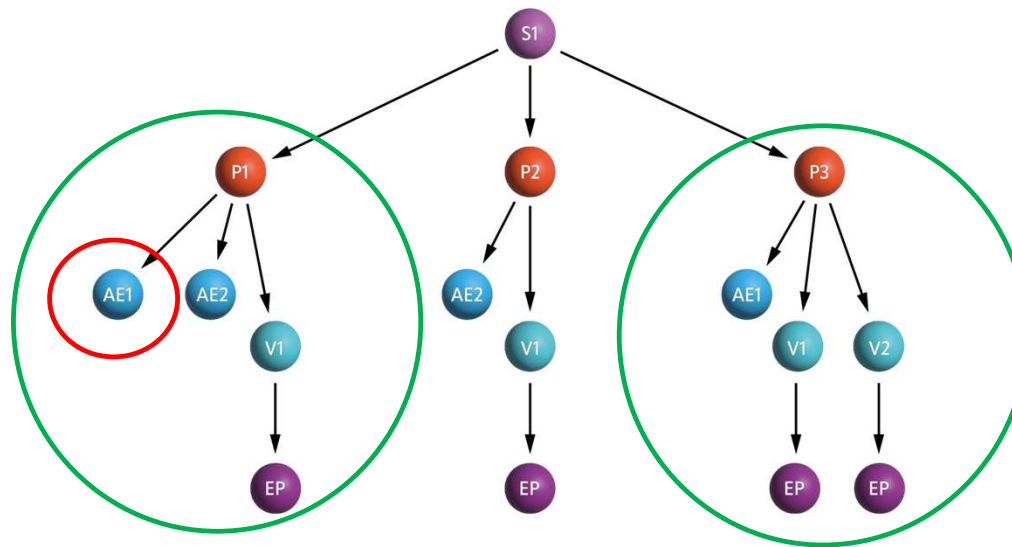
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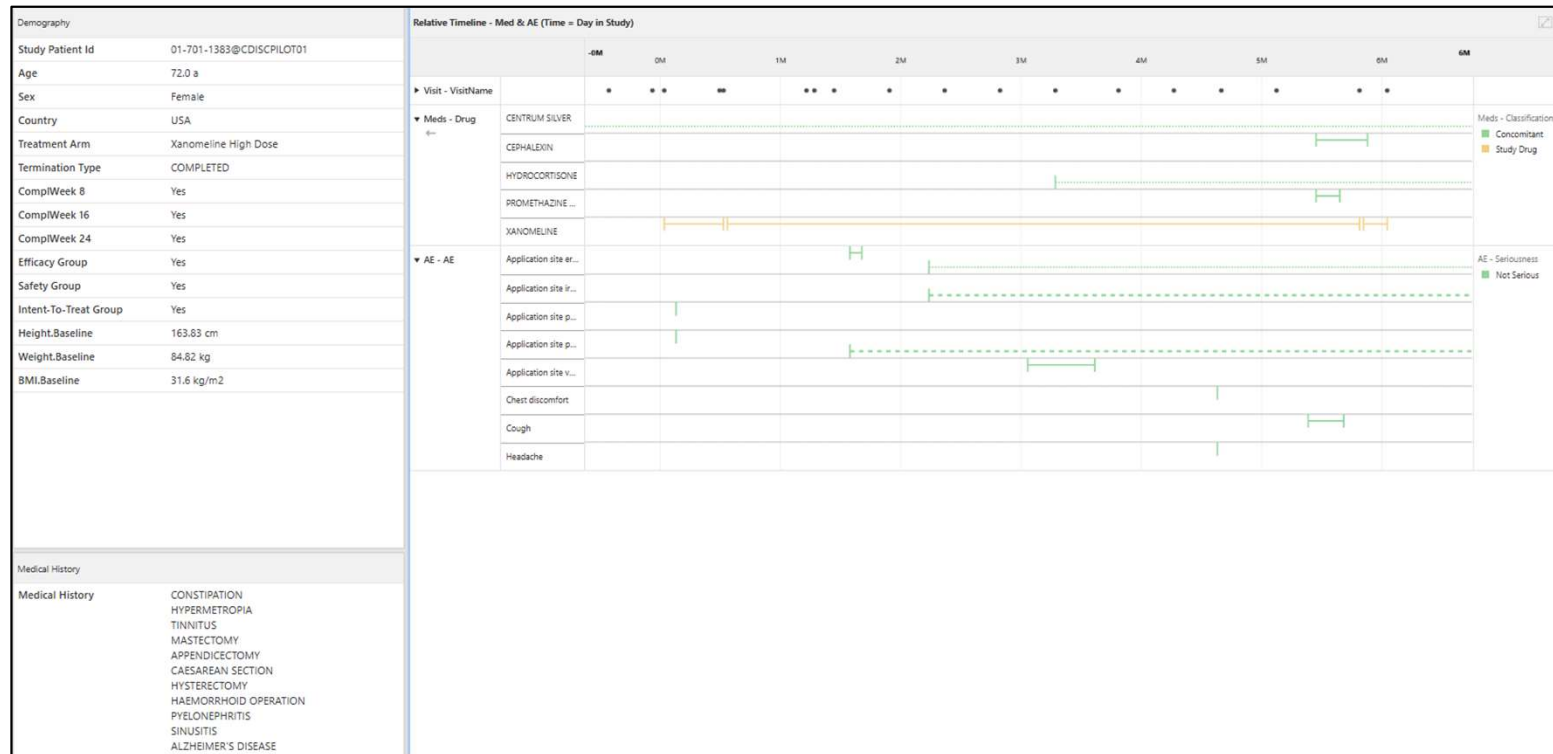


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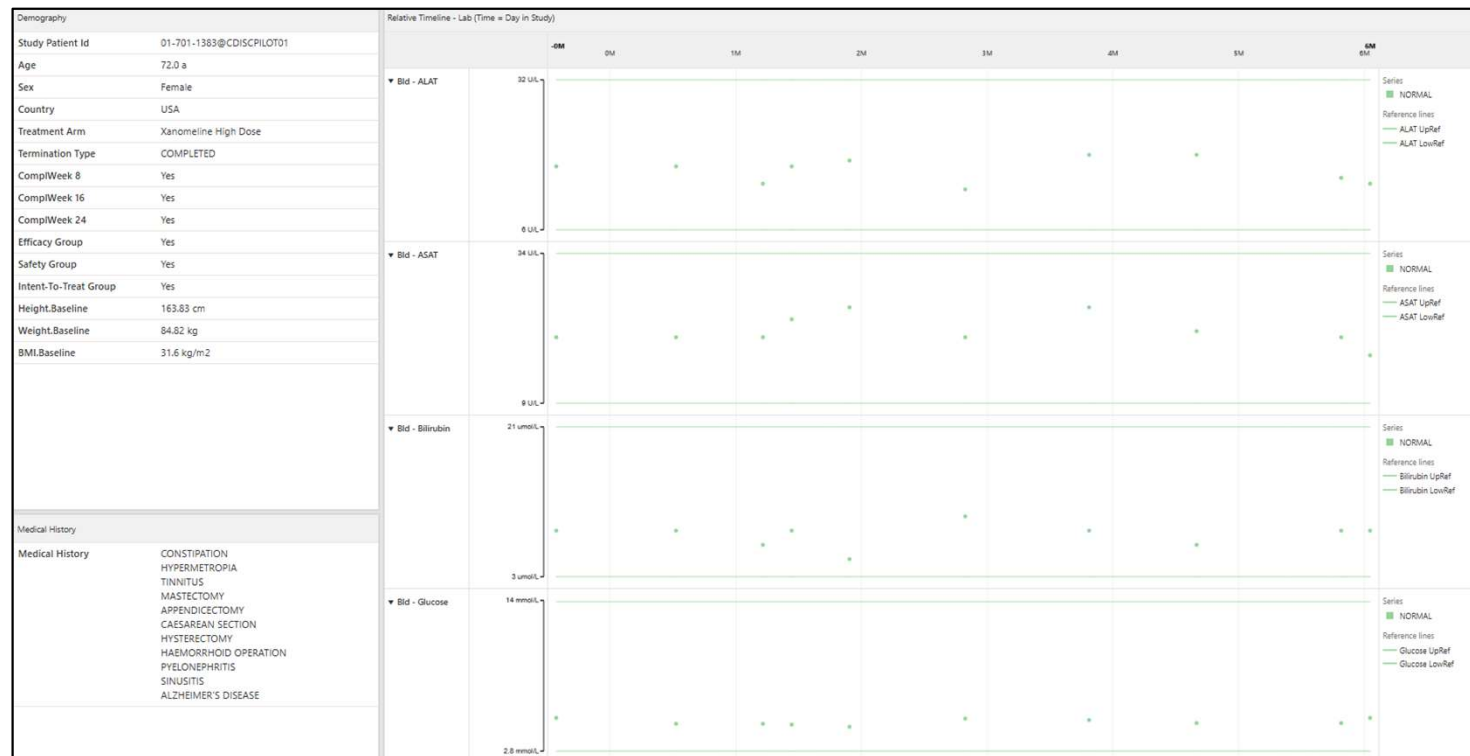
Example of patient cohorts



Examples – Patient-Centric Understanding of AE



Examples – Patient-Centric Understanding of AE



Examples – Patient-Centric Understanding of AE

Match Member data

Search

☐ Show only selected fields

Events

☒ Diag - Diagnosis

☐ AE - AE

☐ Meds - Drug

Findings

☐ EP - PrimEndpoint.Baseline

☐ EP - SecEndpoint.Baseline

☐ EP - SecEndpoint-Diff%(BL)

☐ Bld - ALAT.Baseline

☐ Bld - ASAT.Baseline

☐ Bld - Bilirubin.Baseline

☐ Bld - Glucose.Baseline

☐ Hemat - Hemoglobin.Baseline

☐ Height - Height

☐ Weight - Weight

☐ HR - HeartRate.Baseline

☐ BP - SBP.Baseline

☐ BP - DBP.Baseline

☐ EP - PrimEndpoint-Diff%(BL)

Patient

☒ Pat - Age(V1)

☒ Pat - Gender

☐ Pat - Race

Study

☐ Center - Country

Events

Diag - Diagnosis: 1 selected

Dyspepsia and other specified disorders of function of stomach

Phlebitis and thrombophlebitis of unspecified site

Study indication

Unspecified essential hypertension

Abdominal pain, unspecified site

Patient

Pat - Age(V1): 65.3

Upper limit 2

Lower limit -2

Pat - Gender: 1 selected

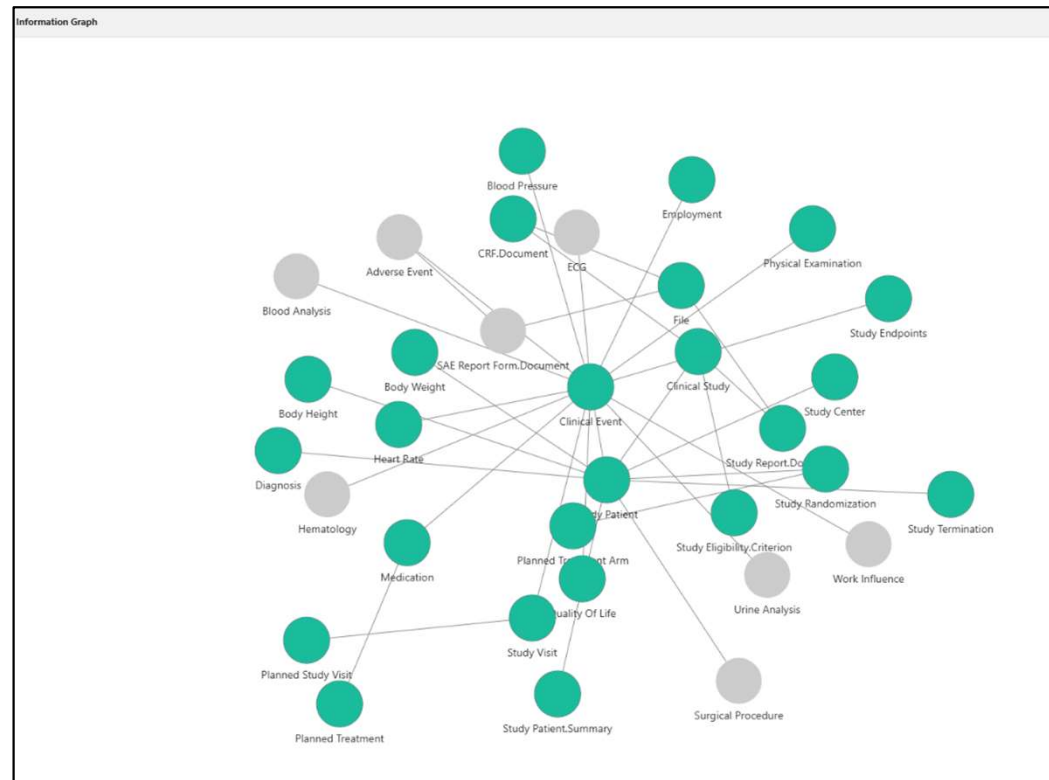
Male

Female

Match

The applied filter resulted in 9 similar Members. Use the action menu to create highlight or to add to the List of Members.

Examples – Patient-Centric Understanding of AE



Wrapping Up

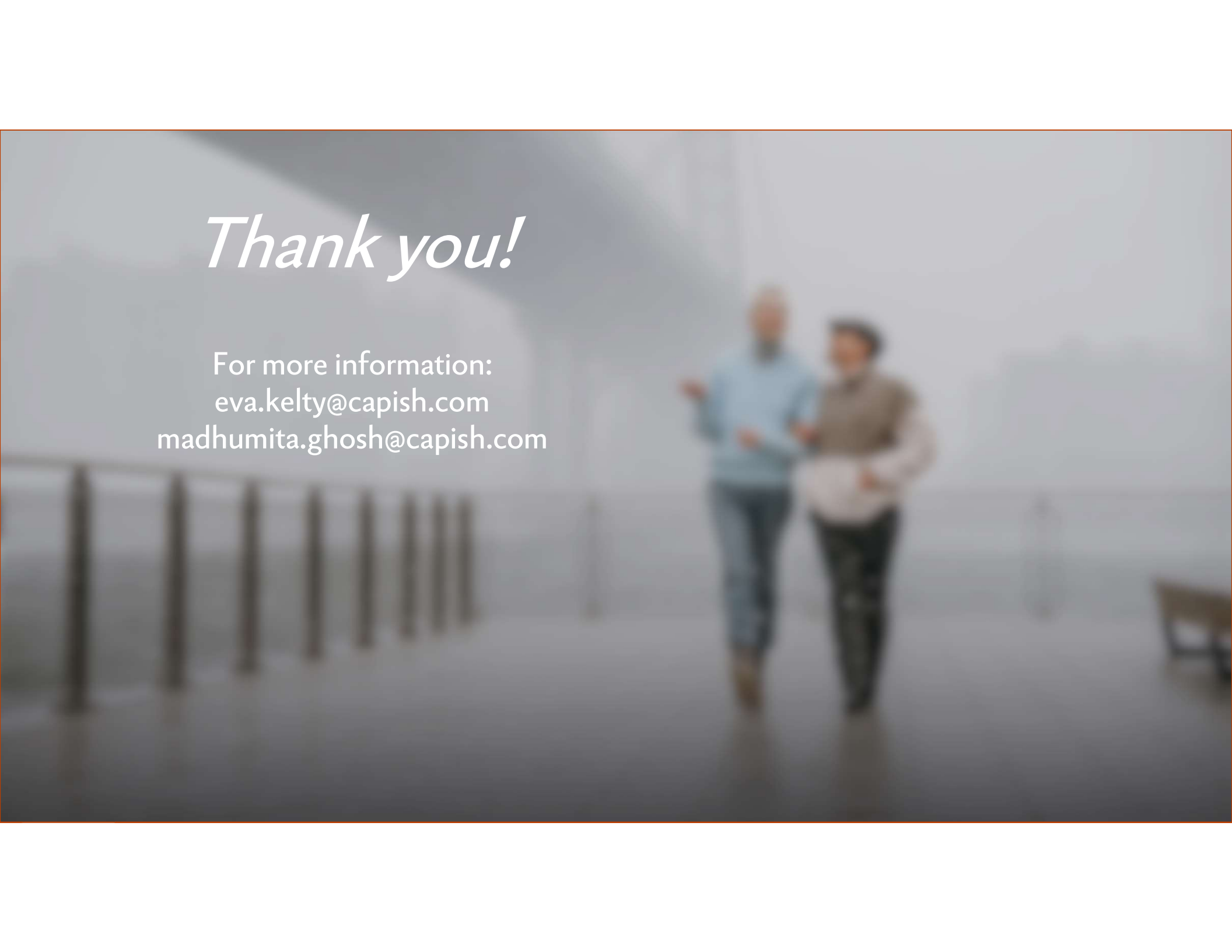
Possibilities → Opportunities

Possibilities:

- SMQ/FMQ: Enhancing AE detection through standardized queries.
- Integration with other sources: Connecting safety databases for a more comprehensive view.
- Prepare DSUR: Streamlining Development Safety Update Reports with structured data.

Opportunities:

- Improved signal detection with graph-based insights.
- Better regulatory compliance through integrated safety data.
- Efficient reporting with flexible data exploration.



Thank you!

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