

CDISC Tech Webinar – Leveraging CDISC Standards to Drive Cross- trial Analytics; Graph Technology and A3 Informatics

26 OCT 2017



Strength through Collaboration

Panelists

- Jim LaPointe – Managing Director, Cambridge Semantics
- Patrick Jackson – Senior Architect & Solutions Engineer, Cambridge Semantics
- Kirsten Walther Langendorf – Subject Matter Expert, A3 Informatics, Principal Consultant, S-Cubed and
- Dave Ibersen-Hurst – Managing Director, A3 Informatics and Assero
- Dr. Lauren Becnel, VP, Strategy and Innovation, CDISC

Agenda

- Leveraging CDISC Standards to Drive Cross-trial Analytics
 - Jim LaPointe and Patrick Jackson, Cambridge Semantics
- Graph Technology and A3 Informatics
 - Kirsten Langendorf and Dave Ibersen-Hurst, A3 Informatics
- Q&A Session
 - All Panelists

***Leveraging CDISC Standards to
Drive Cross-trial Analytics
An Anzo Smart Data Lake® Enterprise Solution***

Jim LaPointe – Managing Director, Life Sciences & Healthcare

Patrick Jackson – Senior Architect & Solutions Engineer

Cross-trial Advanced Analytics Example

ANZO ON THE WEB

Search Dashboard Lenses Filters Refresh Designer Help

ICDB *Q1 SV *Q2 SV *Q3 SV *Q4 SV *Q5 - AE SV *Q5 - AE time of onset SV

Study Identifier

Search...
[+] show sort details

- CA209063 (135)
- CA209057 (784)
- CA209017 (375)

3 choices

Unique Subject Identifier

Best Overall Response

Search...
[+] show sort details
[+] show filters

- SD (1552)
- PR (1294)
- PD (818)
- NE (143)
- CR (91)

5 choices

Overall Survival

Min: 0.033
Max: 26.48

Linked Data Sets

Accelerated
ANZOSVLD5

Percent Change (Subjects on MAXIDAMPA 3 mg / kg)

Change from Baseline (%)

Visit Number

Percent Change (Subjects on DOCETAXEL)

Change from Baseline (%)

Visit Number

CA209017-106-17055
X: 87
Y: -44

Tumor Measurements by Visit

Unique Subj...	Visit Num...	Sum of R...	Treatment	Percent ...	Best
CA209017-100-17065	-1	105		0	PR
CA209017-100-17065	43	60		-42.857	PR
CA209017-100-17065	62	51		-51.429	PR
CA209017-100-17065	74	48		-54.286	PR
CA209017-100-17065	50	55		-47.619	PR
CA209017-100-17065	56	51		-51.429	PR
CA209017-100-17065	82	48		-54.286	PR
CA209017-100-17065	37	59		-43.81	PR
CA209017-100-17065	26	73		-30.476	PR
CA209017-100-17065	68	51		-51.429	PR
CA209017-100-17065	20	72		-31.429	PR
CA209017-100-17065	31	61		-41.905	PR
CA209017-100-17065	14	72		-31.429	PR
CA209017-100-17065	8	82		-21.905	PR
CA209017-106-17055	-1	50	DOCETAXEL	0	PR
CA209017-106-17055	39	30	DOCETAXEL	-40	PR
CA209017-106-17055	69	28	DOCETAXEL	-44	PR
CA209017-106-17055	33	30	DOCETAXEL	-40	PR
CA209017-106-17055	51	28	DOCETAXEL	-44	PR
CA209017-106-17055	27	30	DOCETAXEL	-40	PR
CA209017-106-17055	63	28	DOCETAXEL	-44	PR
CA209017-106-17055	21	30	DOCETAXEL	-40	PR
CA209017-106-17055	45	28	DOCETAXEL	-44	PR
CA209017-106-17055	9	50	DOCETAXEL	0	PR
CA209017-106-17055	75	28	DOCETAXEL	-44	PR
CA209017-106-17055	15	45	DOCETAXEL	-10	PR

Page 1 of 13 | Page Size: 100

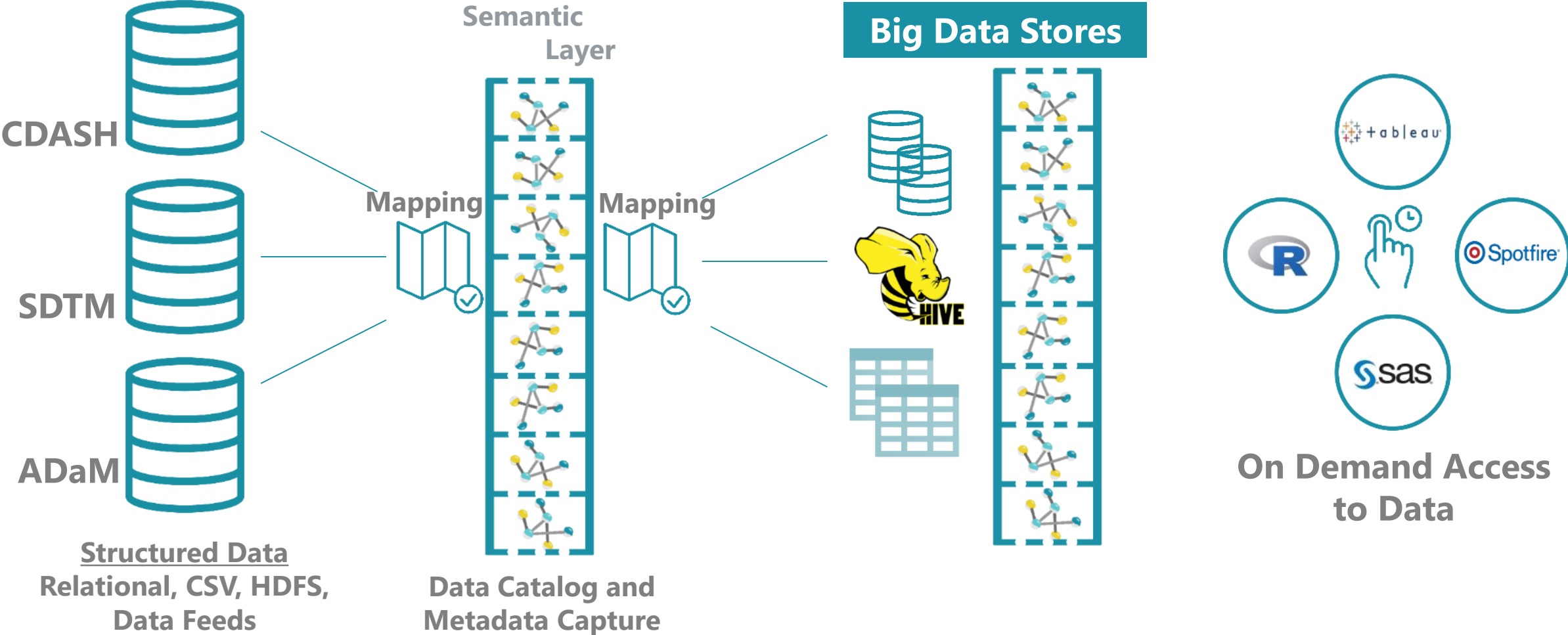
CDISC Driven Semantic Layer

Ingest

Catalog

Prepare

Access



External and Internal

Creating the Semantic Layer

Product

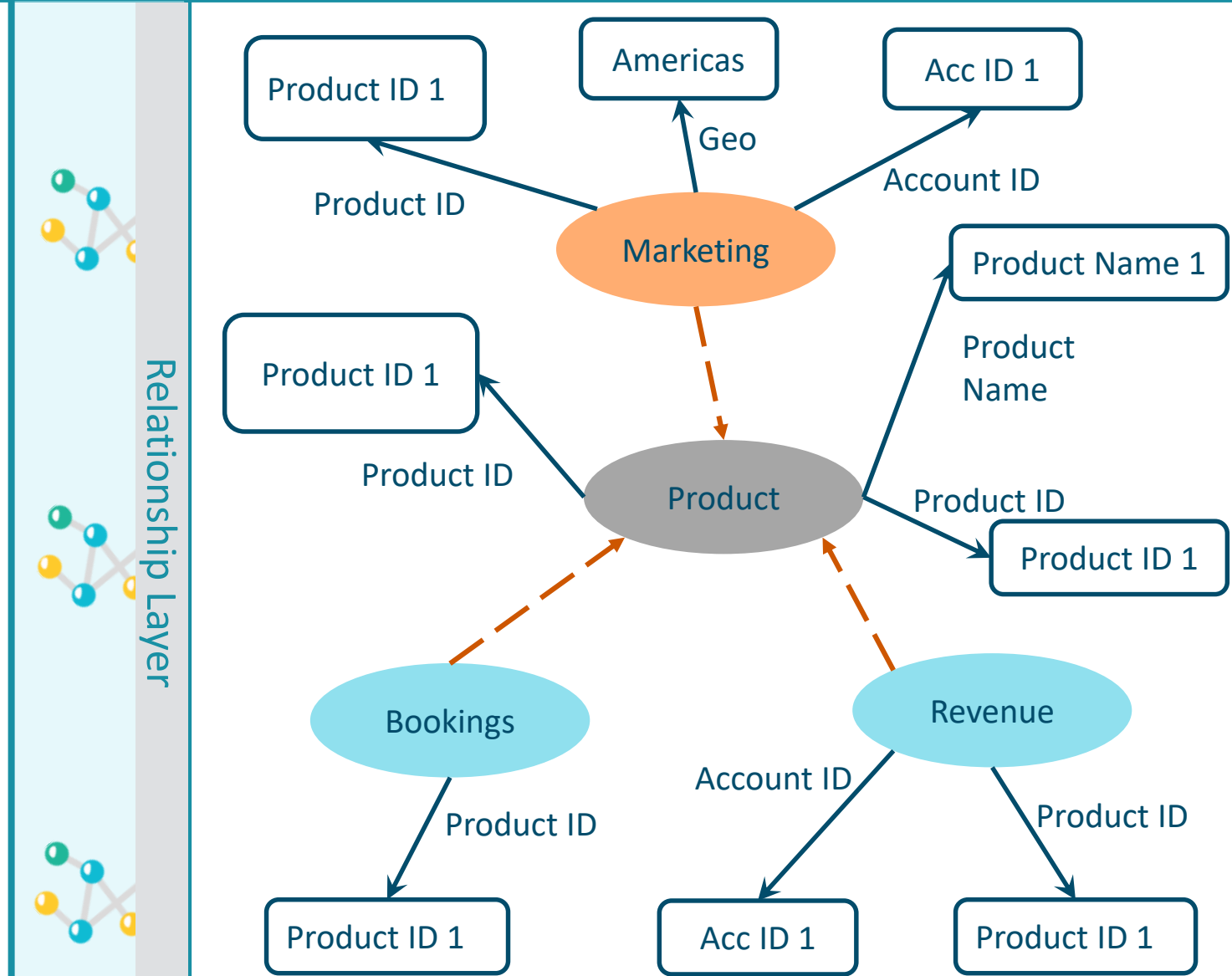
Product Name	Product ID	Opportunity Product ID
Product Name 1	Product ID 1	Product ID 1
Product Name 2	Product ID 2	Product ID 2
...

Revenue

Product ID	Account ID	Geo
Product ID 1	Acc ID 1	Americas
...

Marketing

Opportunity Product ID	Account ID	Geo
Product ID 1	Acc ID 1	Americas
...



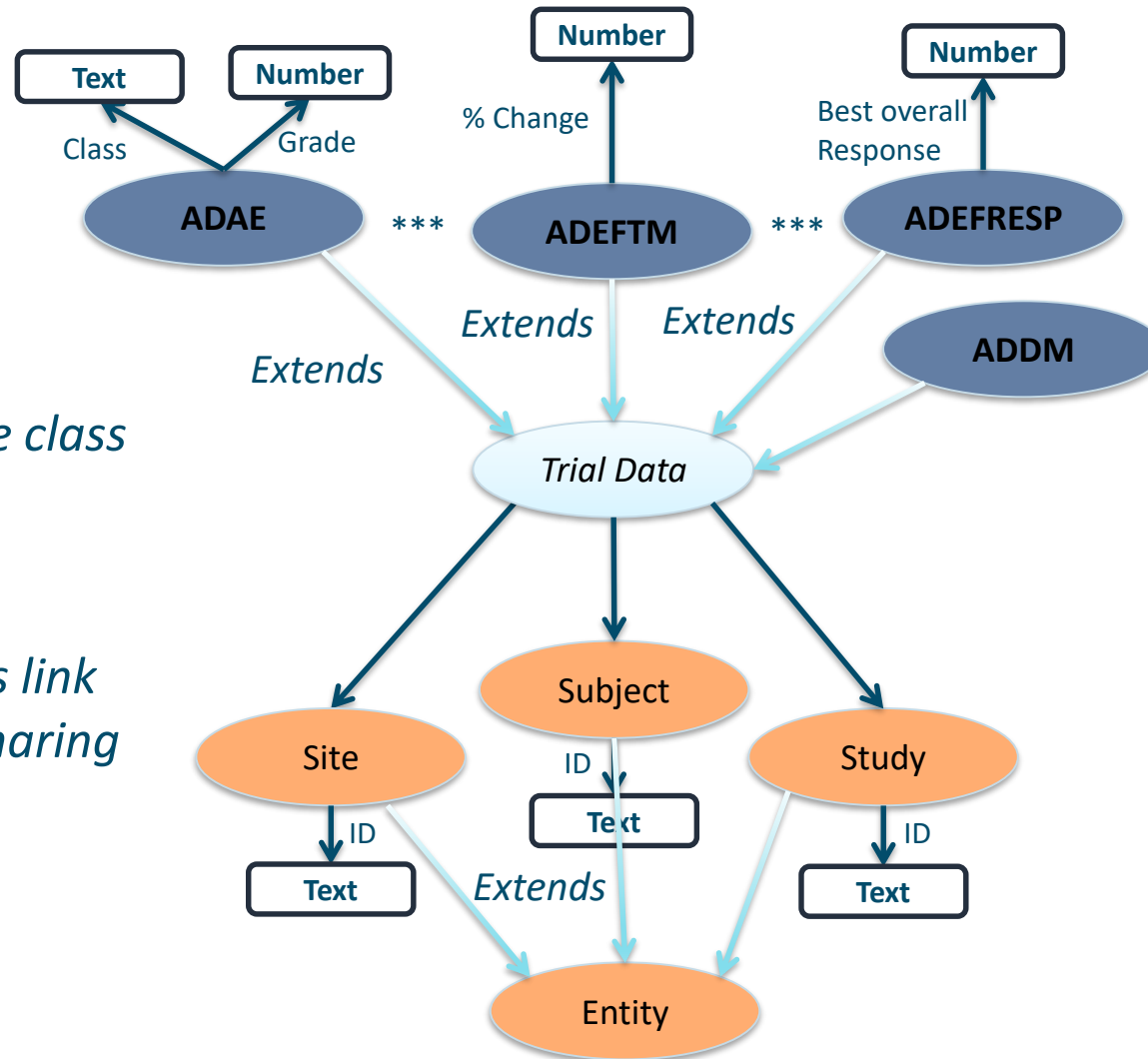
Relationship Layer

ADaM Domain Driven Semantic Layer Example

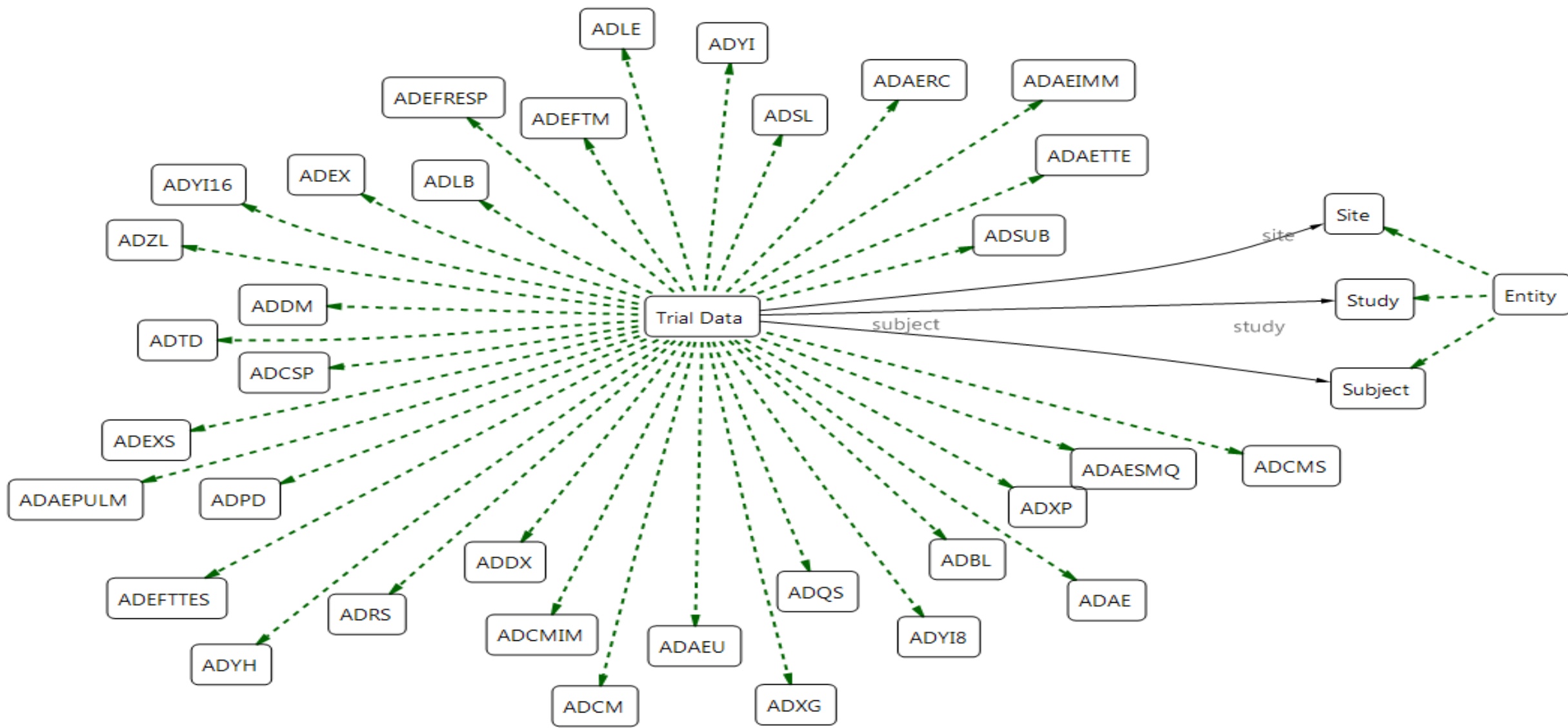
Each domain is modeled with a “Class” with attributes and relationships

Trial Data is the common base class for all domain classes

Subject, Site and Study classes link all domain classes together sharing a common Entity class



Full ADaM Driven Semantic Layer Example



Sample Auto-generated Mapping for ADAE Domain Data

Book6 - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Anzo for Excel Acrobat

From Access From Web From Text From Other Sources Existing Connections Refresh All Connections Sort & Filter Filter Clear Reapply Advanced Text to Columns Remove Duplicates Data Validation Consolidate What-If Analysis Group Ungroup Subtotal Outline Data Analysis Show Detail Hide Detail Analysis

CA209063-1-63001

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	USUBJID	AESEQ	ASTDT	STUDYID	SITEID	SUBJID	COUNTRY	AREGION	SEX	AGE	RACE	SUBINFO1	DSSTAGE	ECOGPS	TRTP	TRTPN
2	CA209063-1-63001	1		CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
3	CA209063-1-63001	2		CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
4	CA209063-1-63001	3		CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
5	CA209063-1-63001	4		CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
6	CA209063-1-63001	5		CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
7	CA209063-1-63001	6	1/27/2013	CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
8	CA209063-1-63001	7	2/14/2013	CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
9	CA209063-1-63001	8	12/12/2012	CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
10	CA209063-1-63001	9	1/27/2013	CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
11	CA209063-1-63001	10	12/22/2012	CA209063	1	63001	USA	US	M	69	WHITE	(69/M/C)	STAGE IV	1	3 mg/kg	1
12	CA209063-1-63018	1		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
13	CA209063-1-63018	2		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
14	CA209063-1-63018	3		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
15	CA209063-1-63018	4		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
16	CA209063-1-63018	5		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
17	CA209063-1-63018	6		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
18	CA209063-1-63018	7		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
19	CA209063-1-63018	8		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
20	CA209063-1-63018	9		CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
21	CA209063-1-63018	10	7/3/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
22	CA209063-1-63018	11	5/1/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
23	CA209063-1-63018	12	3/6/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
24	CA209063-1-63018	13	3/11/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
25	CA209063-1-63018	14	7/3/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
26	CA209063-1-63018	15	3/6/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
27	CA209063-1-63018	16	5/21/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
28	CA209063-1-63018	17	4/24/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
29	CA209063-1-63018	18	3/20/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
30	CA209063-1-63018	19	5/21/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
31	CA209063-1-63018	20	4/10/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
32	CA209063-1-63018	21	3/6/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1

Link Workbook

Link the active workbook to the Anzo Data Collaboration Server.

Open Save Options

Data Set

XXXXXXXXXX

Type

ADAE

Properties

- no comments -

ASTDT Date

- no comments -

1/27/2013

ASTDTF String

- no comments -

D

ASTDTM Literal

- no comments -

2013-01-27T16:07:00

Search on ASTDT

Orientation

Row Selection contains headers

Column

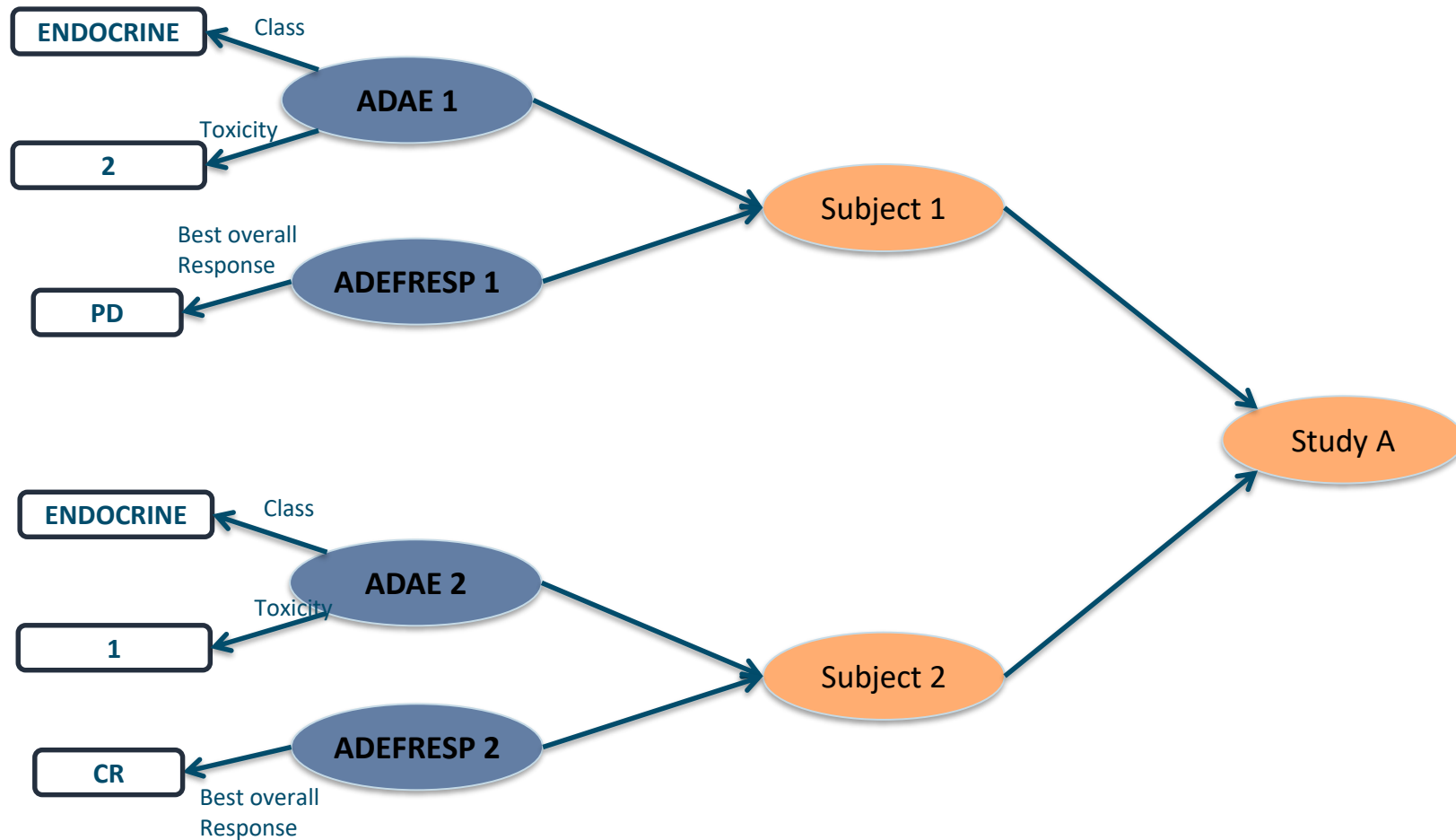
Link Upload

Evaluation Use Only - This copy of Anzo For Microsoft Excel is license...

Average: 110147.4349 Count: 115054 Sum: 4523975446 100%

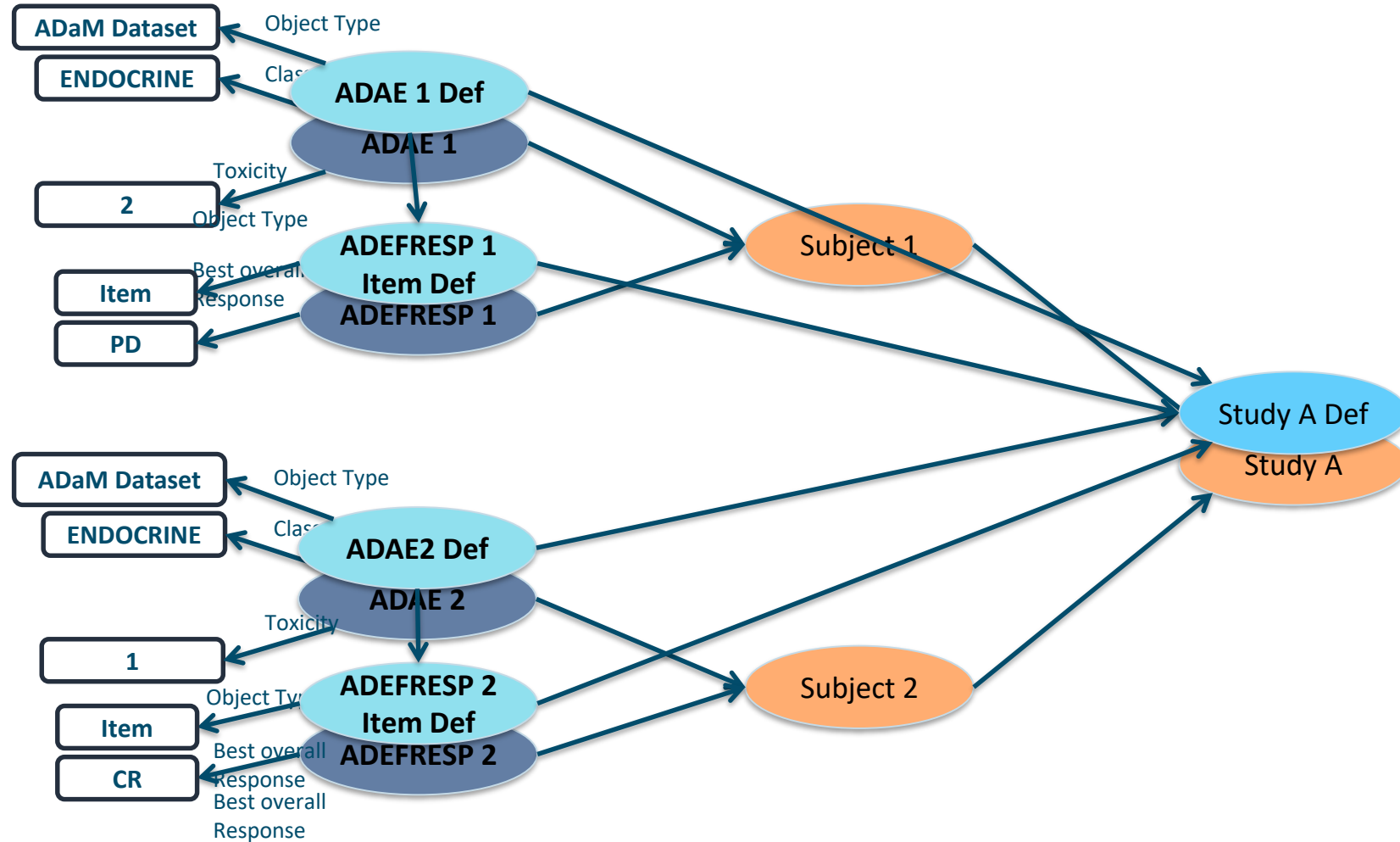
Driving Advanced Analytics by the Semantics Layer

Explore the relationship between AE Toxicity and Overall Response.

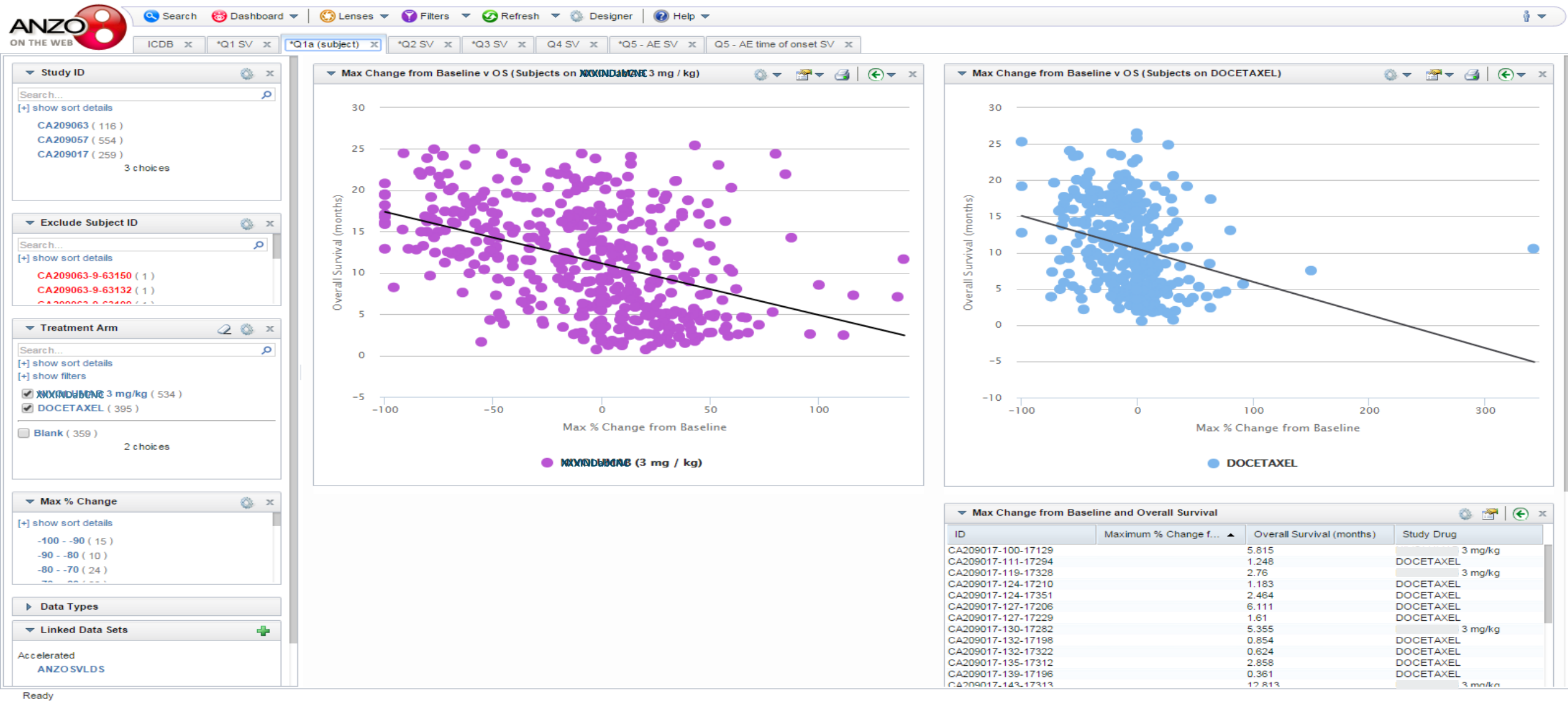


Driving Advanced Analytics by the Semantics Layer

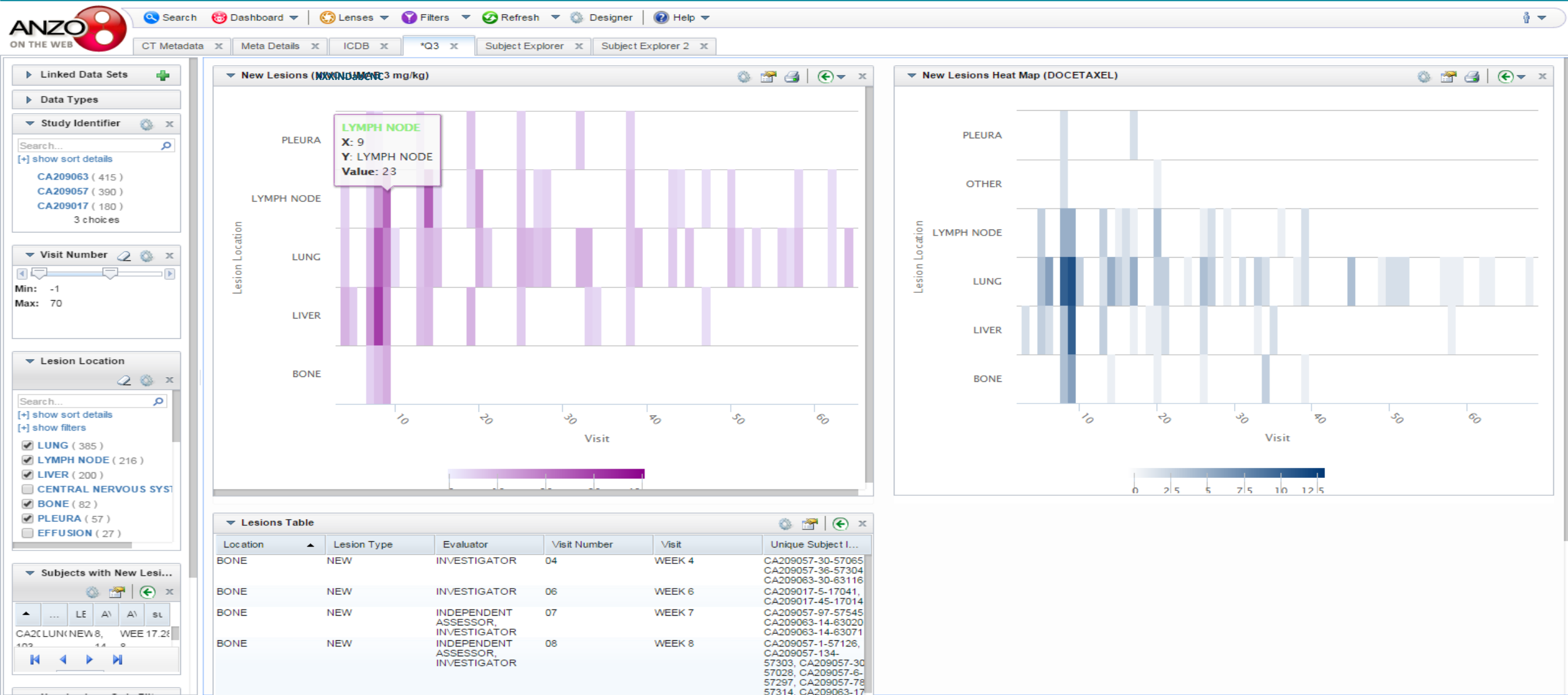
Explore the relationship between AE Toxicity and Overall Response.



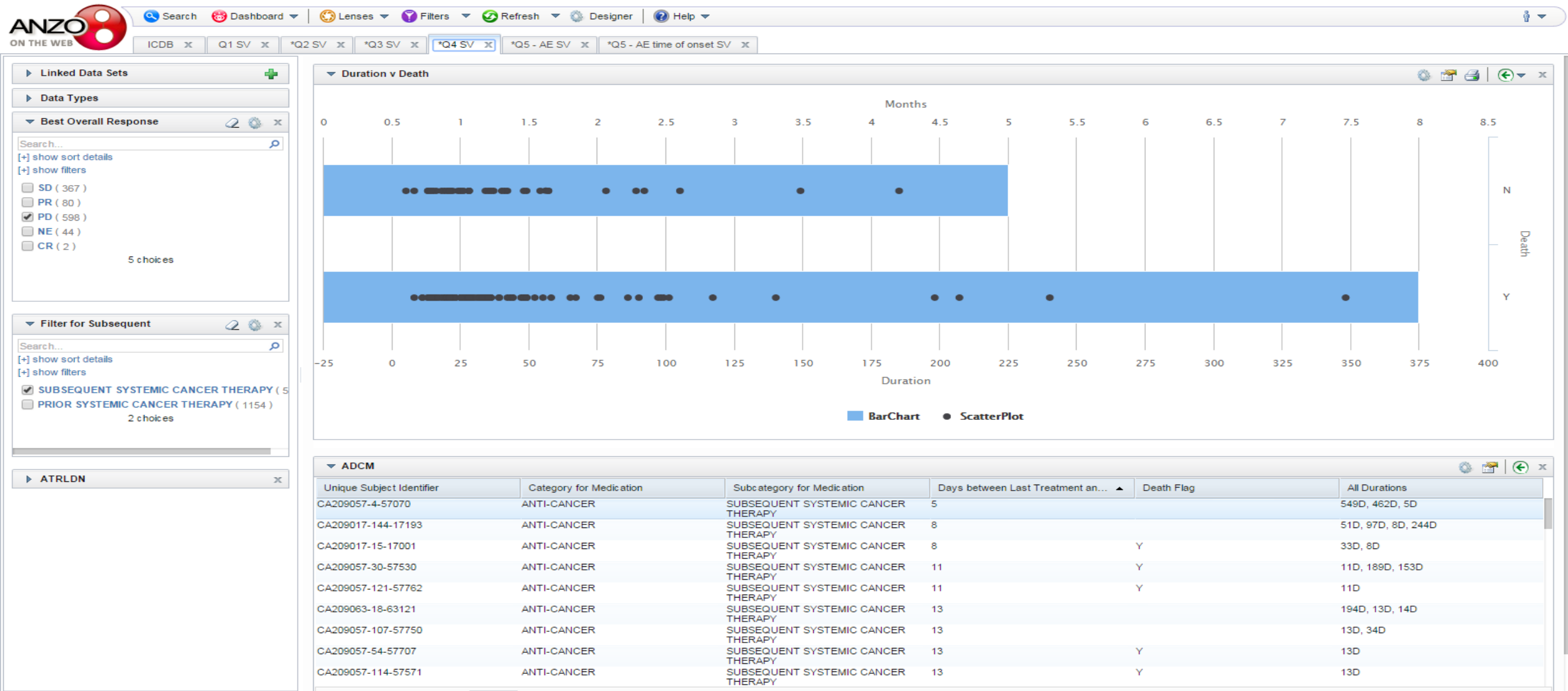
Cross-trial Advanced Analytics Example



Cross-trial Advanced Analytics Example



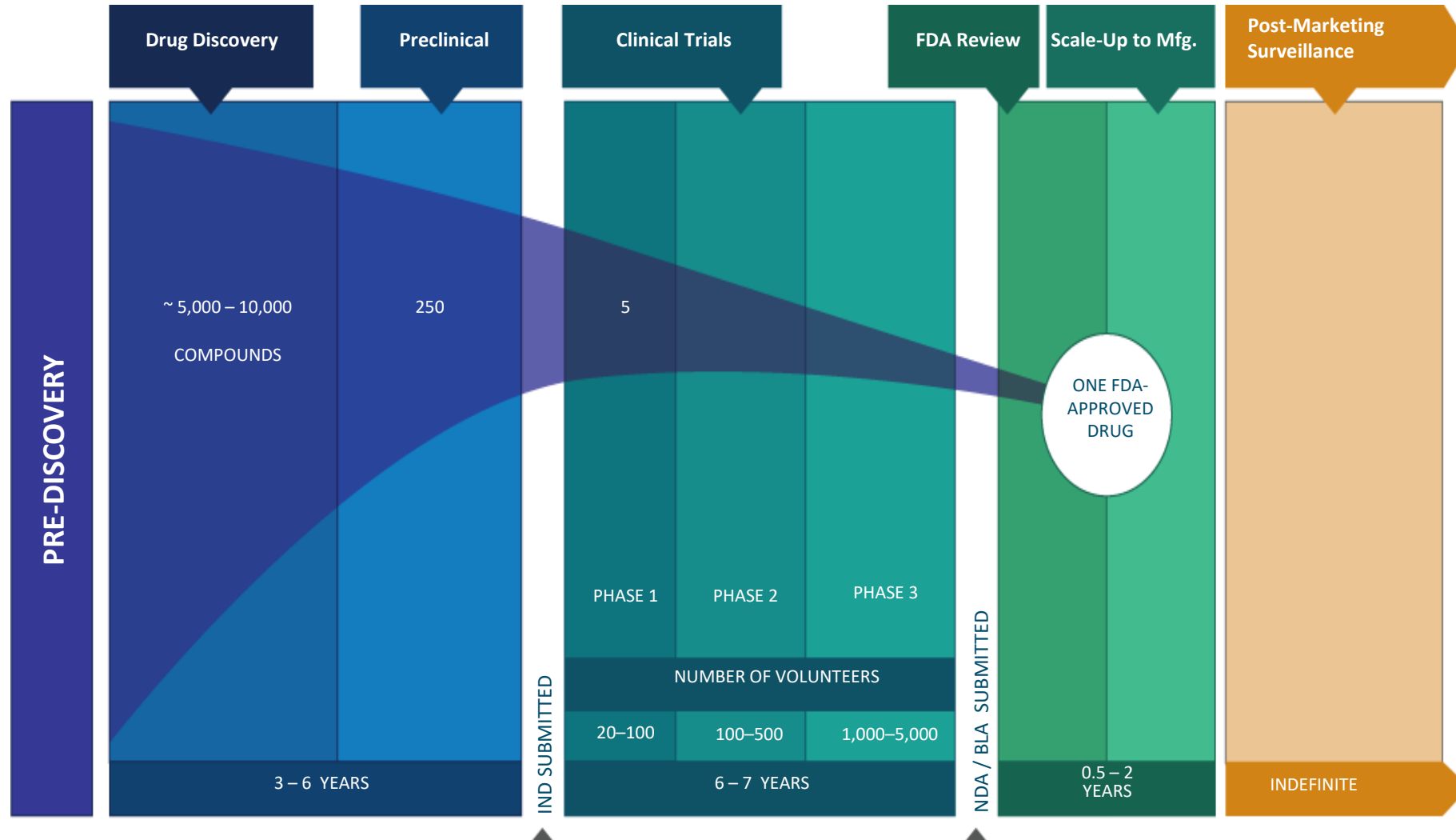
Cross-trial Advanced Analytics Example



Ready

The Metadata View of the World

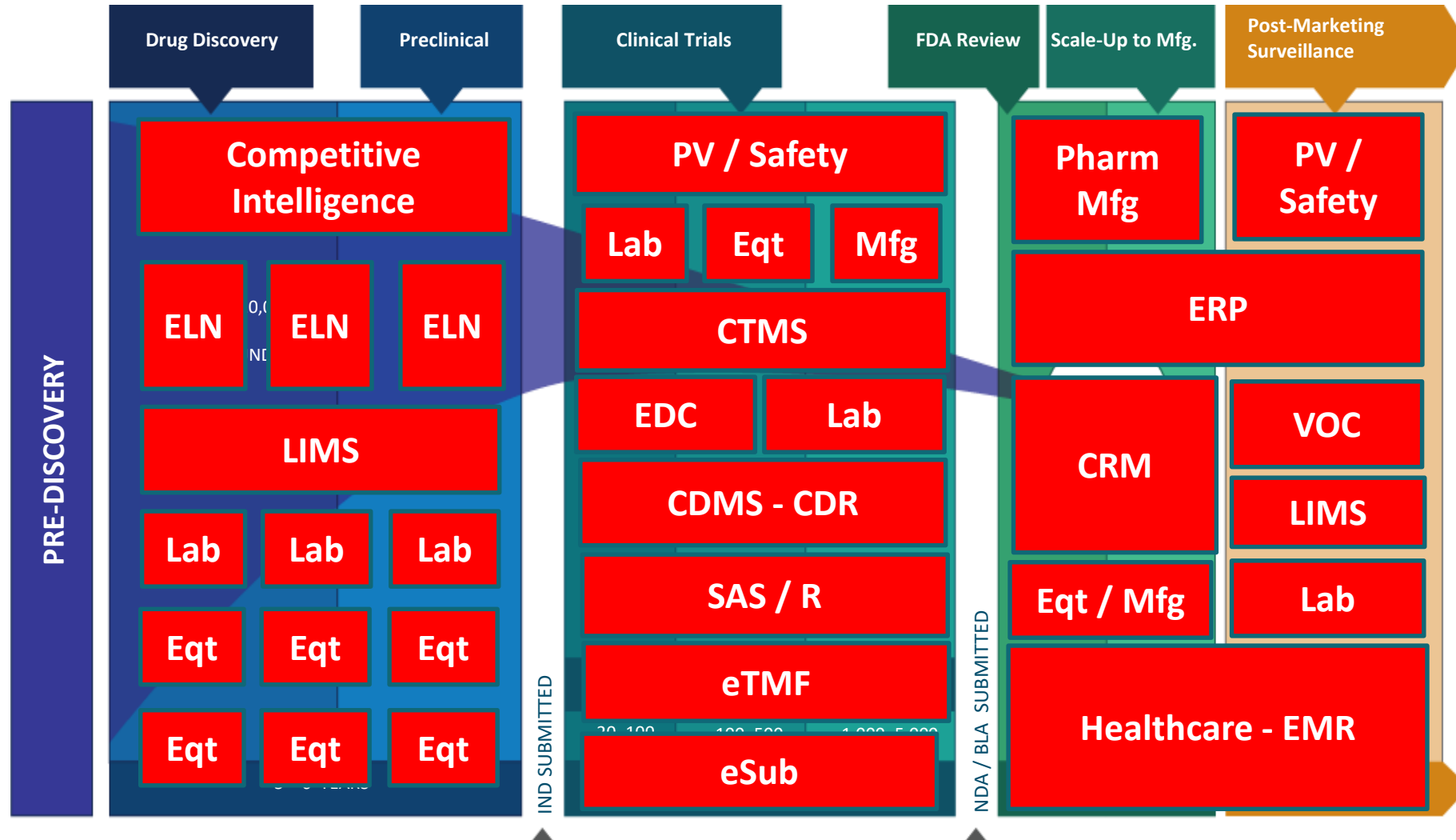
Anzo Smart Data Lake© Enterprise Solutions



Source: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org

The Metadata View of the World

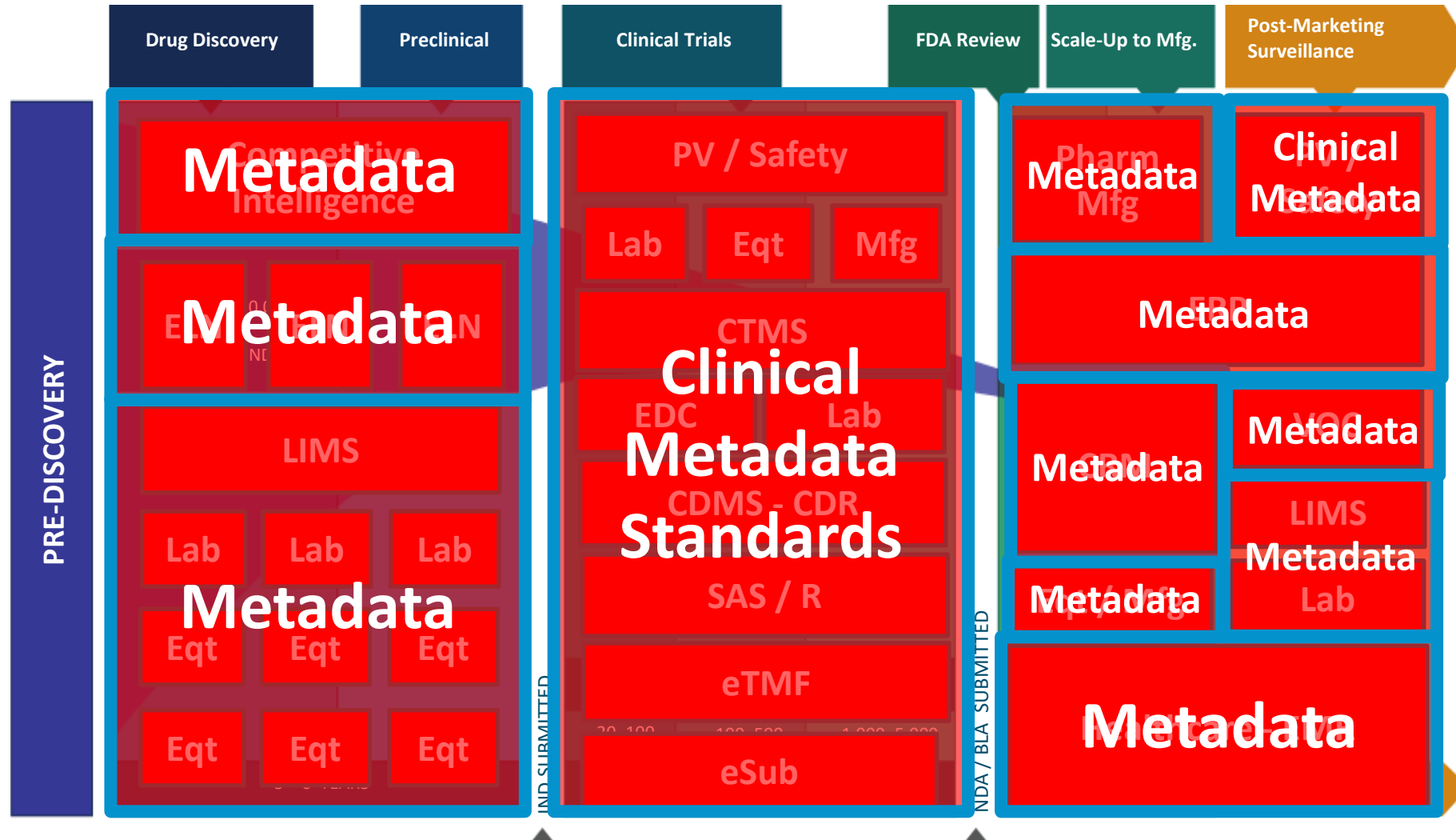
Anzo Smart Data Lake© Enterprise Solutions



Source: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org

The Metadata View of the World

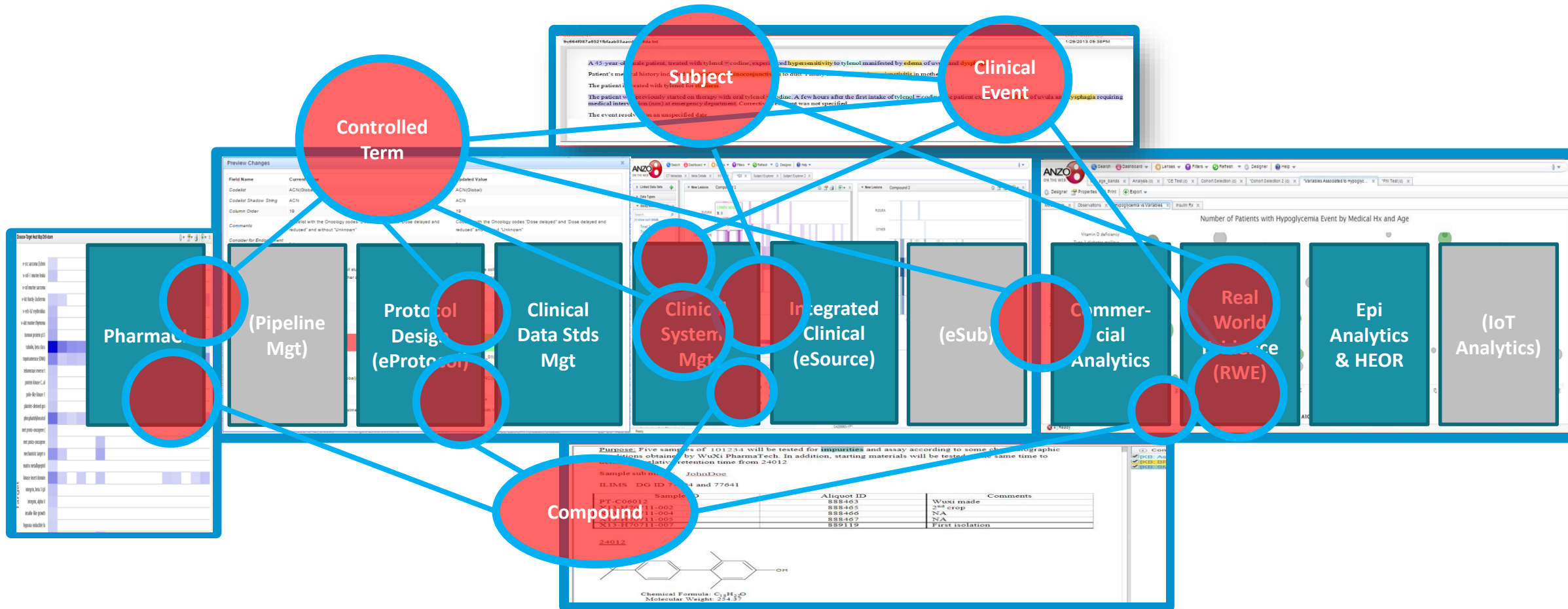
Anzo Smart Data Lake© Enterprise Solutions



Source: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org

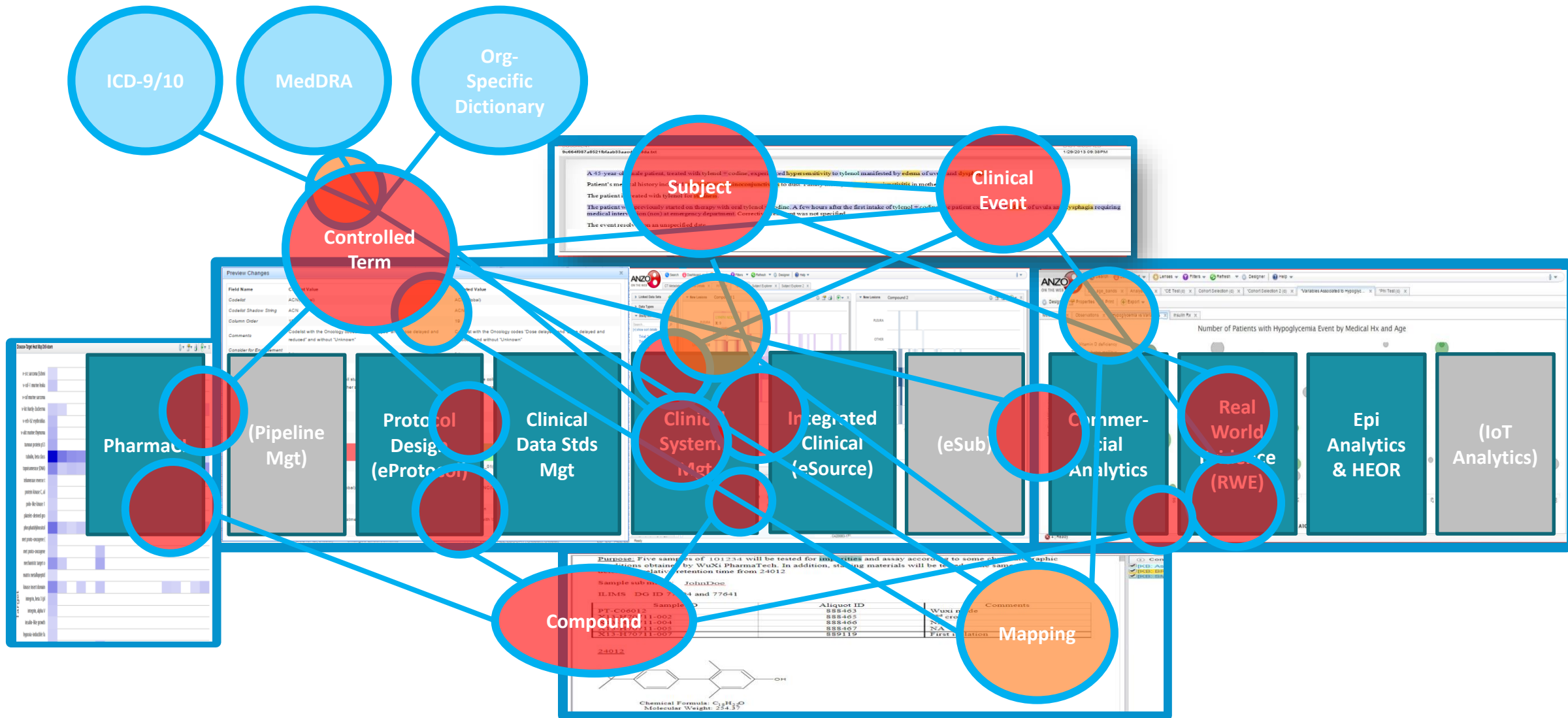
Global Definitions of Concepts

Anzo Smart Data Lake© Enterprise Solutions

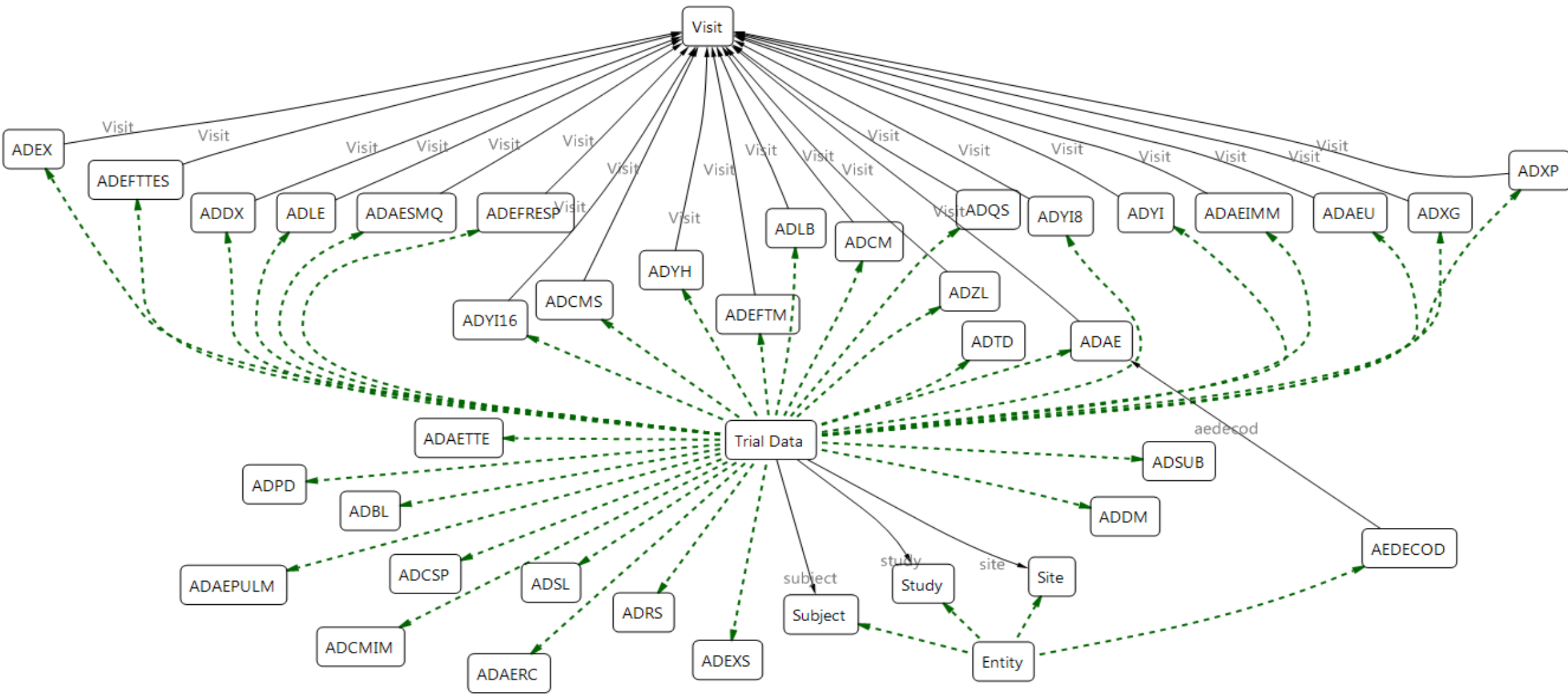


Global Definitions of Concepts

Anzo Smart Data Lake© Enterprise Solutions



Semantic Layer Enhancements to Driven More Analytics



CDISC Driven Advanced Analytics Value Proposition (Business Case)

Benefits of an on-demand Clinical Smart Data Lake

- Single, unified & trusted source of clinical trial data
- Empower rapid data discovery (meta-analysis) for business-driven analytics & visualizations
- Reuse & control high value business 'answer sets'
- Extensible platform to add future data sources

Time to value (for a single 'answer set')

BioStats Method	Estimated \$ @ \$120 / hr.	Clinical Smart Data Lake	Estimated \$ @ 120 / hr.	Estimated \$ Savings	Comment
1 day	\$ 960	1 day	\$960	\$ 0	
1 week	\$4,800	1 day	\$960	\$ 3,840	Typical case?
1 month	\$19,200	1 day	\$960	\$18,240	
3 months	\$57,600	1 day	\$960	\$56,640	
Never	Infinite	1 week	\$4,800	Infinite	Value for these?

Typical case: 1 week → 1 day X 250 times = \$960,000 savings per year!



The Semantic Layer

"Semantic approaches are the future of the enterprise information fabric"

Michele Goetz - Principal Analyst - Forrester Research

Anzo Smart Data Lake®

The industry leading platform for building a Semantic Layer



End-To-End



Open Standards



Enterprise Scale

CDISC Technical Webinar Series

Kirsten Walther Langendorf
S-Cubed & A3 Informatics

Dave Iberson-Hurst
Assero Ltd & A3 Informatics

26th October 2017



Strength *through Collaboration*

Abstract

At the recent PhUSE conference, there were many mentions of 'graph technology'. CDISC itself generates exports from SHARE in RDF formats. But people ask if it a practical solution. This presentation will provide an overview of a toolset based on graph and semantic technologies designed to enhance and improve current processes, in particular impact analysis.

A3 INFORMATICS

A3 Informatics is a new joint venture by Assero Ltd and S-cubed ApS.



Assero is based in the UK and provides consultancy services to the pharmaceutical industry in the field of CDISC data standards and their use in improving the clinical trial process with a particular emphasis on the use of metadata.

www.assero.co.uk

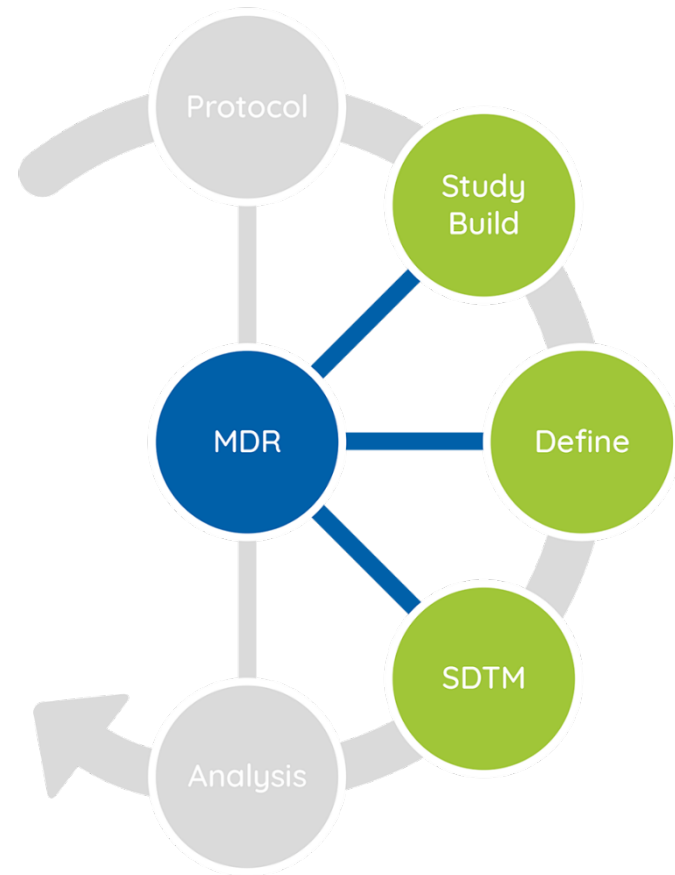


S-cubed is a European company based in Denmark and the United Kingdom offering flexible solutions, consultancy, in house support, and full-service CRO capabilities. S-cubed specialize in Biometrics, CDISC Standards (implementation and conversion), Regulatory Affairs, Business Intelligence, Quality Assurance, and highly experienced Project Managers. www.s-cubed.global.com

Glandon - Overview

A suite of tools

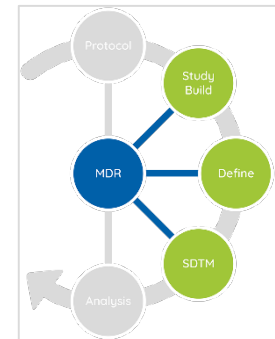
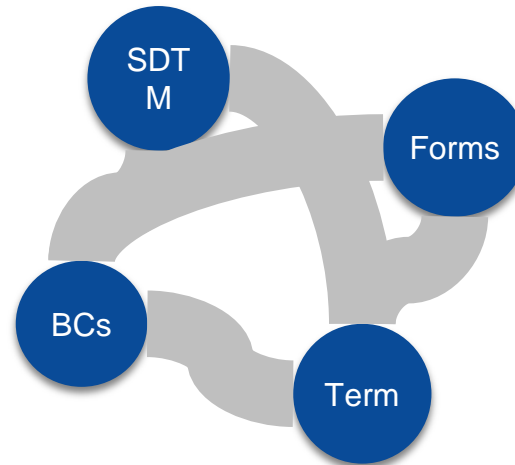
- An MDR at the centre providing a single source of knowledge
- A study build tool to construct clinical studies
- A define tool to build a define (in development, beta evaluation available)
- A tool to generate SDTM datasets (planned)
- Then expand across lifecycle
- Also, not shown, an experimental tool linking healthcare and clinical research prototyping the SDTM auto generation



MDR

Content

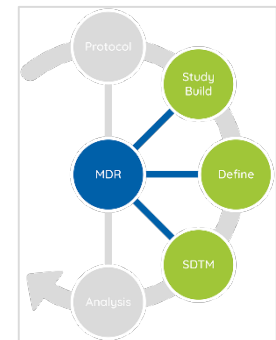
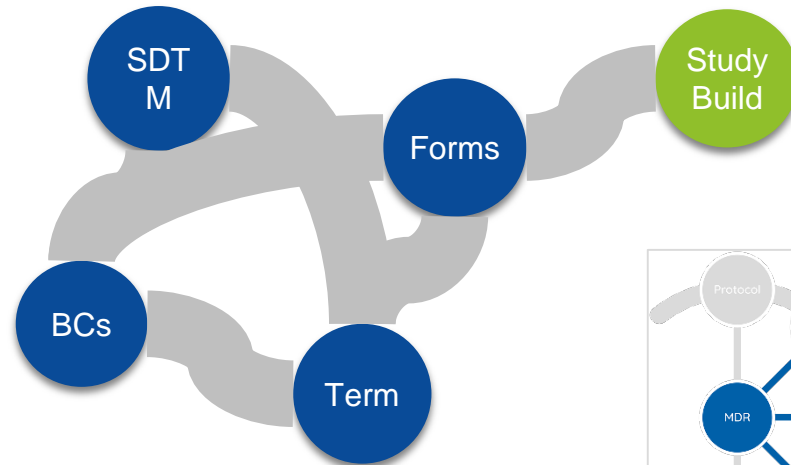
- Stores the standards providing version control
 - Terminology
 - Biomedical Concepts (BCs)
 - Forms
 - SDTM (Model, IG etc)
- Provides an API to other tools
- Provides control to the user
 - Visibility of changes
 - When did it change
 - What is the impact of change



Study Build

Use MDR Content

- Uses the MDR API to allow access to the curated content
- Select forms to build schedule of assessments
- Forms bring with them the associated definitions



Glandon - demo

Graph-based repository of standards and studies

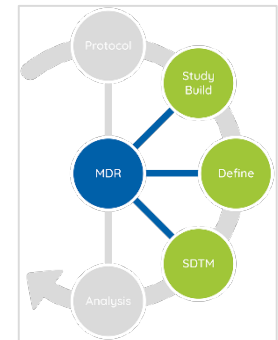
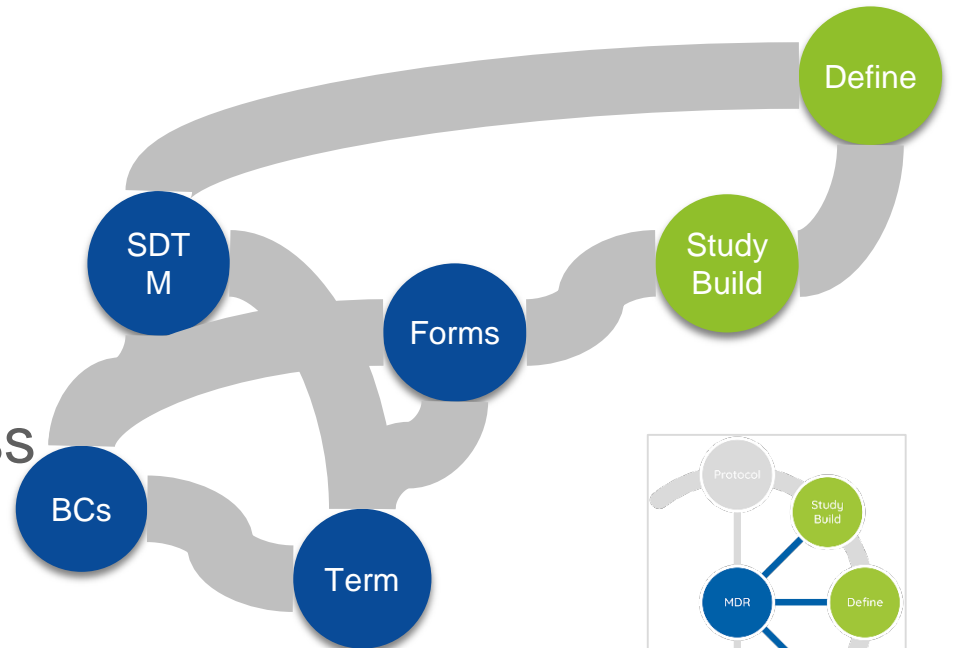
- MDR
 - Managing Controlled terminology
 - Managing models
 - Defining assessments on patients – Biomedical Concepts
 - Building Standard Forms – what's being collected together on 'logical pieces of papers'
- Study Builder
 - Specifying CRF/data collection for study

Demo

Define.xml

Automate Generation

- Uses the Study Build API to access study definitions
- Use MDR API to access content definitions
- Allow for the generation of a define.xml
 - Based on Study Definition
 - From scratch
 - From existing define.xml



Define.xml

- Present information in a more friendly manner that all users can understand
- Hide define structure and XML
- Automate as much as possible using study build and MDR definitions

Study Information

Name	Demonstration 1
Description	To be set.
Protocol Name	To be set.
SDTM Version	3.1.2
Define.xml Version	2.1.0

← ↗ ⬇️ 😊 📄

Study Documents

Annotated CRF: ✓

Reviewers Guide: ✗

Name	Location
Another report	ar.pdf

← ↗

Study Terminologies

Name	Version
QS TERM	2.0.0
LOINC	18.0.0
CDISC Terminology	43.0.0

← ↗

Study Domains

Show 15 entries

Prefix	Name		
MS	Microbiology Susceptibility	✗	🔗
PC	Pharmacokinetic Concentration	✗	🔗
PE	Physical Exam	✗	🔗
PP	Pharmacokinetic Parameters	✗	🔗
QS	Questionnaires	✓	🔗
SC	Subject Characteristics	✗	🔗
SE	Subject Element	✗	🔗
SU	Substance Use	✗	🔗
SV	Subject Visits	✗	🔗
TA	Trial Arms	✓	🔗
TE	Trial Elements	✓	🔗
TI	Trial Inclusion/Exclusion Criteria	✓	🔗
TS	Trial Summary	✓	🔗
TV	Trial Visits	✓	🔗
VS	Vital Signs	✗	🔗

Showing 16 to 30 of 30 entries

←

Previous 1 2 Next

Define.xml

Variable Information

Name	QSORRES
Label	Finding in Original Units
Key Position	
Datatype	Char
Length	
Format	
Origin	CRF

←

Value Level Metadata

Format	Terms	When
string 20	Y N	QSCAT = EQ-5D-3L QSTESTCD = EQ5D0101
float 6.2		QSCAT = EQ-5D-3L QSTESTCD = EQ5D0102


←

Terminology



Identifier	Submission	Preferred Term	Synonym(s)	Definition
C49488	Y	Yes	Yes	The affirmative response to a question. (NCI)
C49487	N	No	No	The non-affirmative response to a question. (NCI)

←

Comment

Current comment:
This is a direct copy or converted depending on the units 2. 

Show 15 entries Search:

Comment  

No data available in table



Showing 0 to 0 of 0 entries Previous Next

← +

Methods

Current method:
None set

Show 15 entries Search:

Method  

No data available in table

Showing 0 to 0 of 0 entries Previous Next

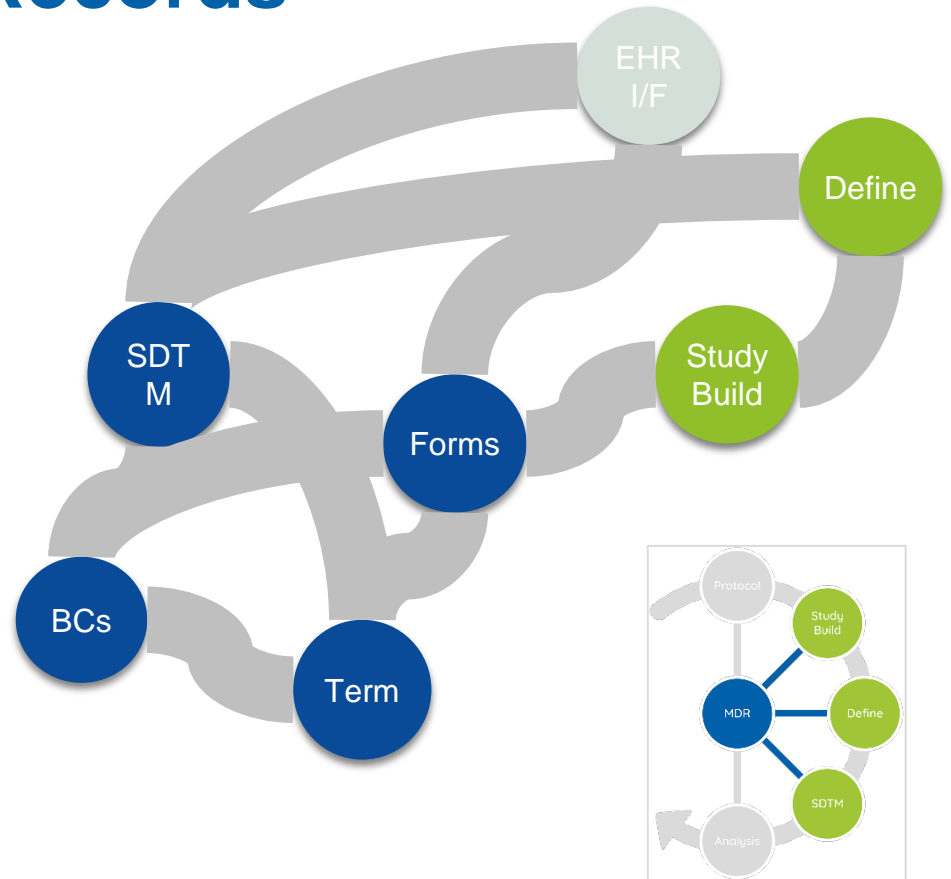
← +

- Automate VLM generation
- Use MDR definitions to assist users in creating VLM

Electronic Health Records

An Experiment

- Test application to test and demonstrate some of these ideas.
- Use HL7 FHIR to obtain patient data (map LOINC/UCUM -> CDISC Terminology mapping).
- Map to form selected from Glandon MDR built using Biomedical Concepts. Can build form on the fly and populate.
- Put into graph (in effect a simple data warehouse) for multiple subjects.
- Extract a presentation of the data (SDTM) using domain definition from Glandon MDR.



EHR Data

Full Description: <https://www.a3informatics.com/graphs-fhir-cdisc/>

- Select form from the MDR
- Add patients/subjects from the EHR
- Create SDTM domain

Current Form

Vital Signs BC Demo 2

Group

Question Group

Question text

Height (BC 03547)

Result value?

Result unit?

Height (BC 03548)

Result value?

Result unit?

CR F

Patients

EHR Patient List

Show 10 entries

Search:

Identifier	Name	Show	Add
SMART-1288992	Adams	Show	Add
SMART-1291938	Young	Show	Add
SMART-1482713	Clark	Show	Add
SMART-1520204	James	Show	Add
SMART-1540505	Clark	Show	Add
SMART-1551992	Coleman	Show	Add
SMART-1557780	Thomas	Show	Add
SMART-1577780	Allen	Show	Add
SMART-1614502	Williams	Show	Add
SMART-1627321	Taylor	Show	Add

Showing 11 to 20 of 68 entries

Previous 1 2 3 4 5 6 7 Next



SDTM Domain

Tabulation

STUDYID	DOMAIN	USUBJID	VSEQ	VSORFID	VSPID	VSTRTCD	VSTEST	VICAT	VISCAT	VSPOS	VSORRESU	VSTRESC	VSTRTRESM	VSTRESU	VSTRT	VREAINO	VLOC	VBLFL	VDIRPL	VSTNUM	VST	VSTIDY	VSETC	VSDY	VSTPT	VSTPTNUM	VSLTM	VS
VSB02	VS	VSB02-SMART-1288992	1			HEIGHT	HGTN			174.344	cm												1997-05-18T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1291938	2			HEIGHT	HGTN			89.74496	kg												1997-10-27T00:00:00-07:00					
VSB02	VS	VSB02-SMART-1288992	3			HEIGHT	HGTN			103.368	cm												2009-04-24T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1288992	4			HEIGHT	HGTN			86.53006	kg												2008-04-22T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1291938	5			HEIGHT	HGTN			161.205	cm												2008-09-11T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1291938	6			HEIGHT	HGTN			114.21456	kg												2008-09-03T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1275431	7			HEIGHT	HGTN			174.732	cm												2002-05-26T00:00:00-05:00					
VSB02	VS	VSB02-SMART-1275431	8			HEIGHT	HGTN			75.47772	kg												2008-05-28T00:00:00-05:00					



Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

- 1) What should be supported by ADaM datasets?
- 2) Is there a limit to the number of variables that can be in ADSL?

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Q&A



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London (Reading), United Kingdom	22-26 Jan 2018	SDTM, ADaM Primer, ADaM T&A, CDASH, Define-XML	22 Oct 2017	22 Dec 2017	

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Seoul, South Korea	5-14 Mar 2018	Standards from the Start, SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	5 Dec 2017	5 Feb 2018	

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Any more questions?

Thank you for attending this webinar.

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