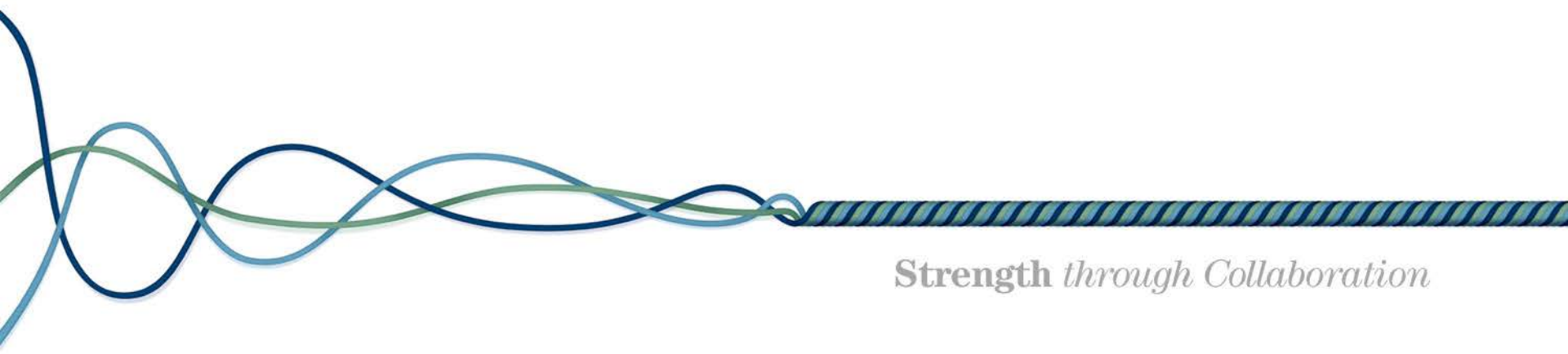
CDISC Tech Webinar –
Leveraging CDISC Standards to Drive Cross-trial Analytics; Graph Technology and A3 Informatics

26 OCT 2017



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 Iberson-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 Iberson-Hurst, A3 Informatics
- Q&A Session
  - All Panelists

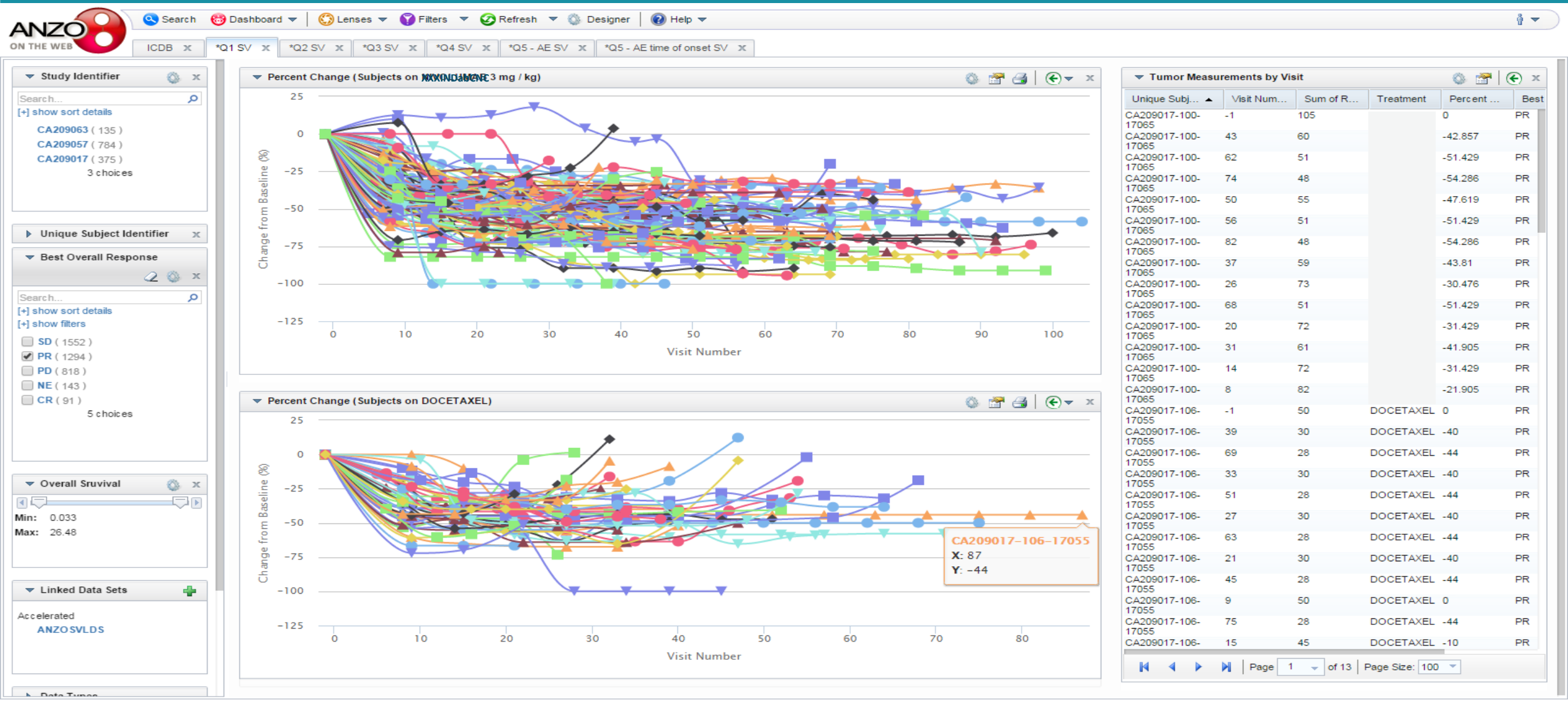
CAMBRIDGE SEMANTICS
THE SMART DATA COMPANY®

Leveraging CDISC Standards to Drive Cross-trial Analytics

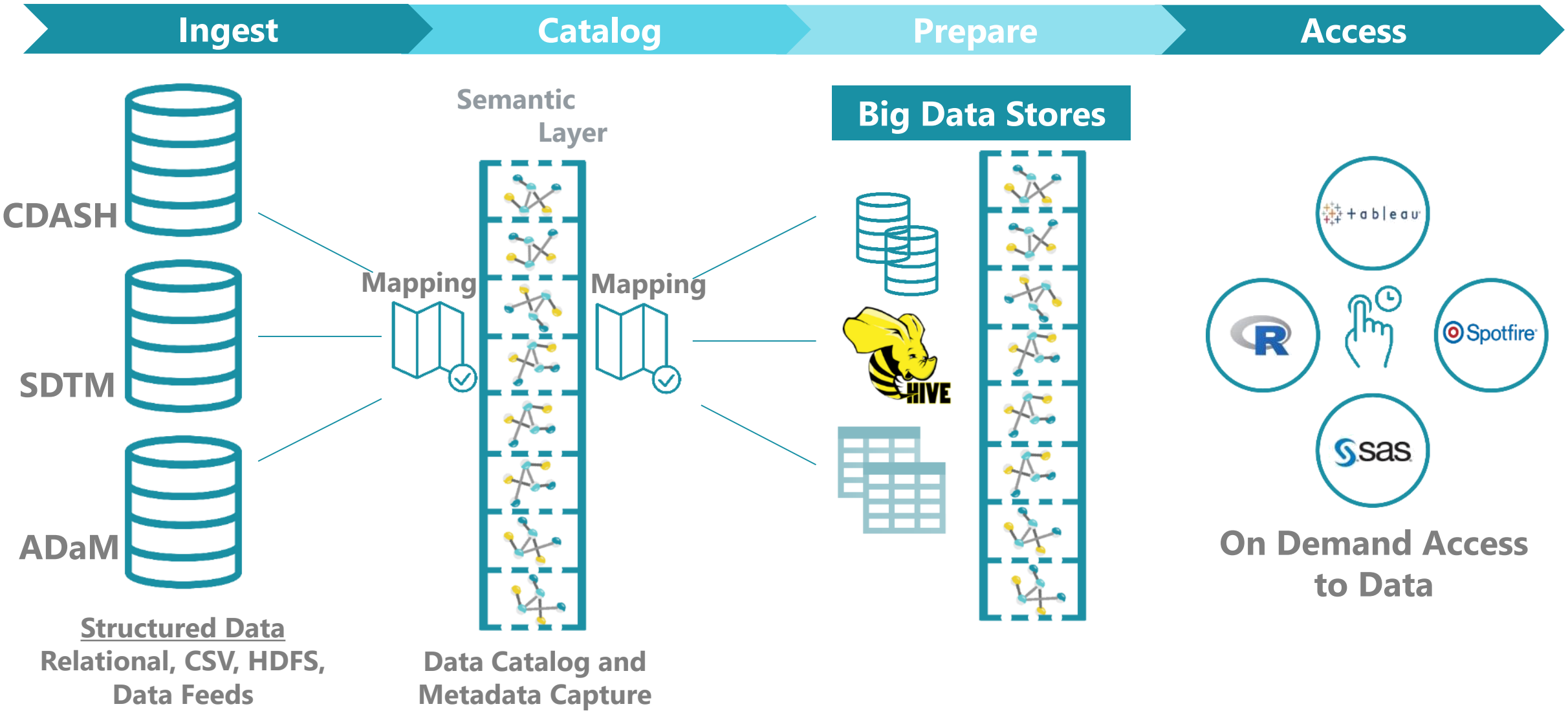
An Anzo Smart Data Lake® Enterprise Solution

Jim LaPointe – Managing Director, Life Sciences & Healthcare
Patrick Jackson – Senior Architect & Solutions Engineer

Cross-trial Advanced Analytics Example



CDISC Driven Semantic Layer



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
…	…	…

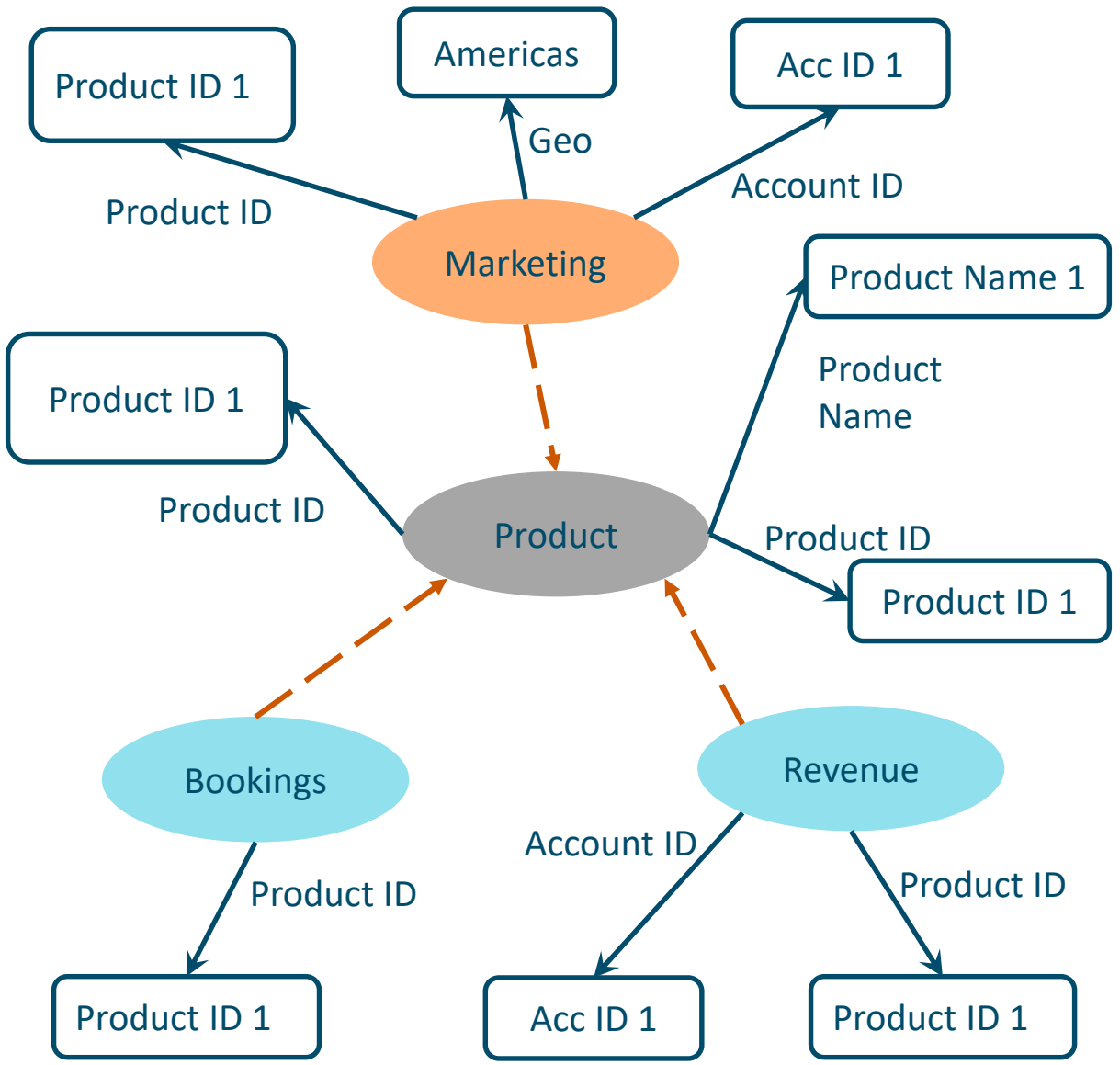
Revenue

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

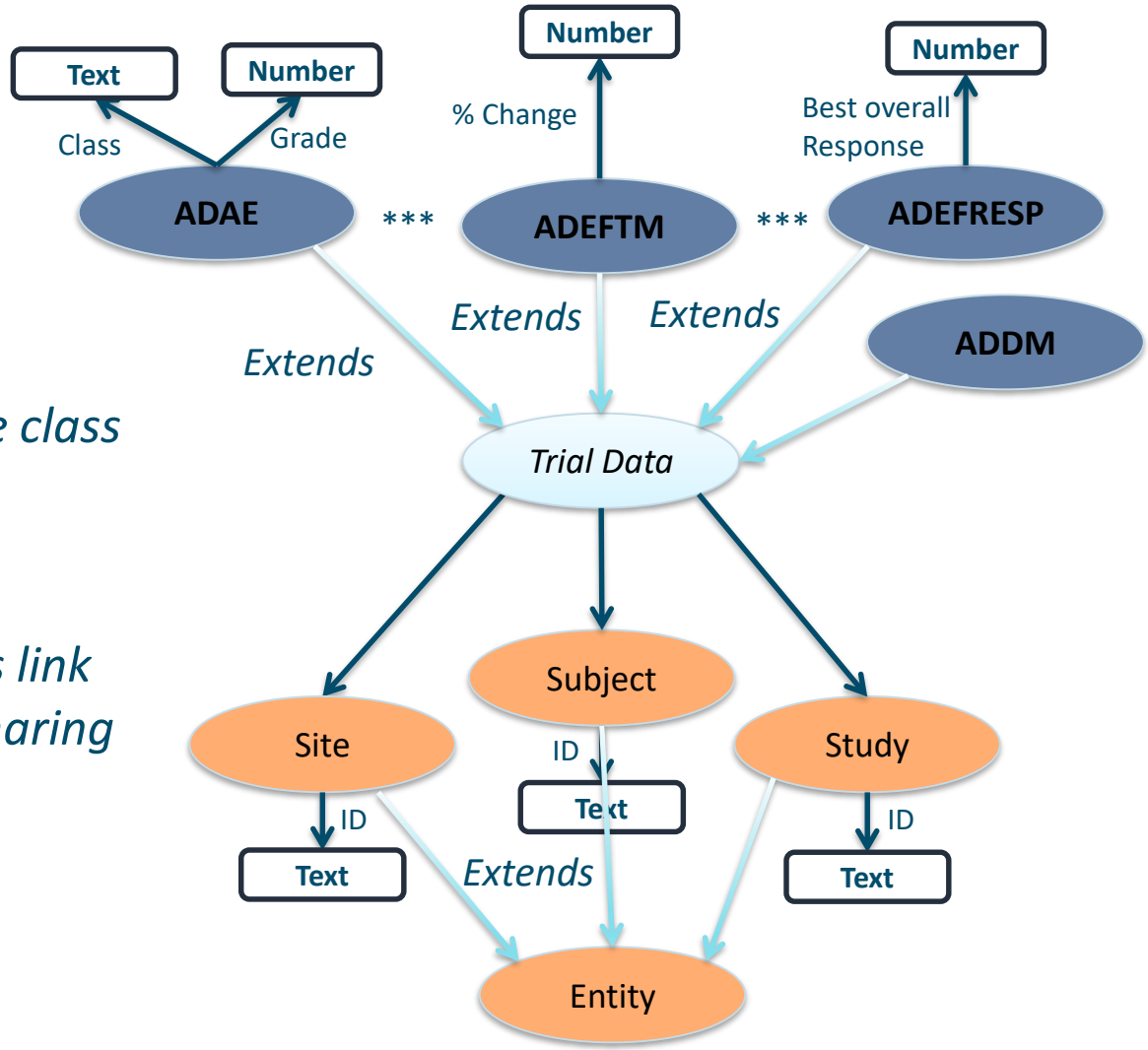


ADaM Domain Driven Semantic Layer Example

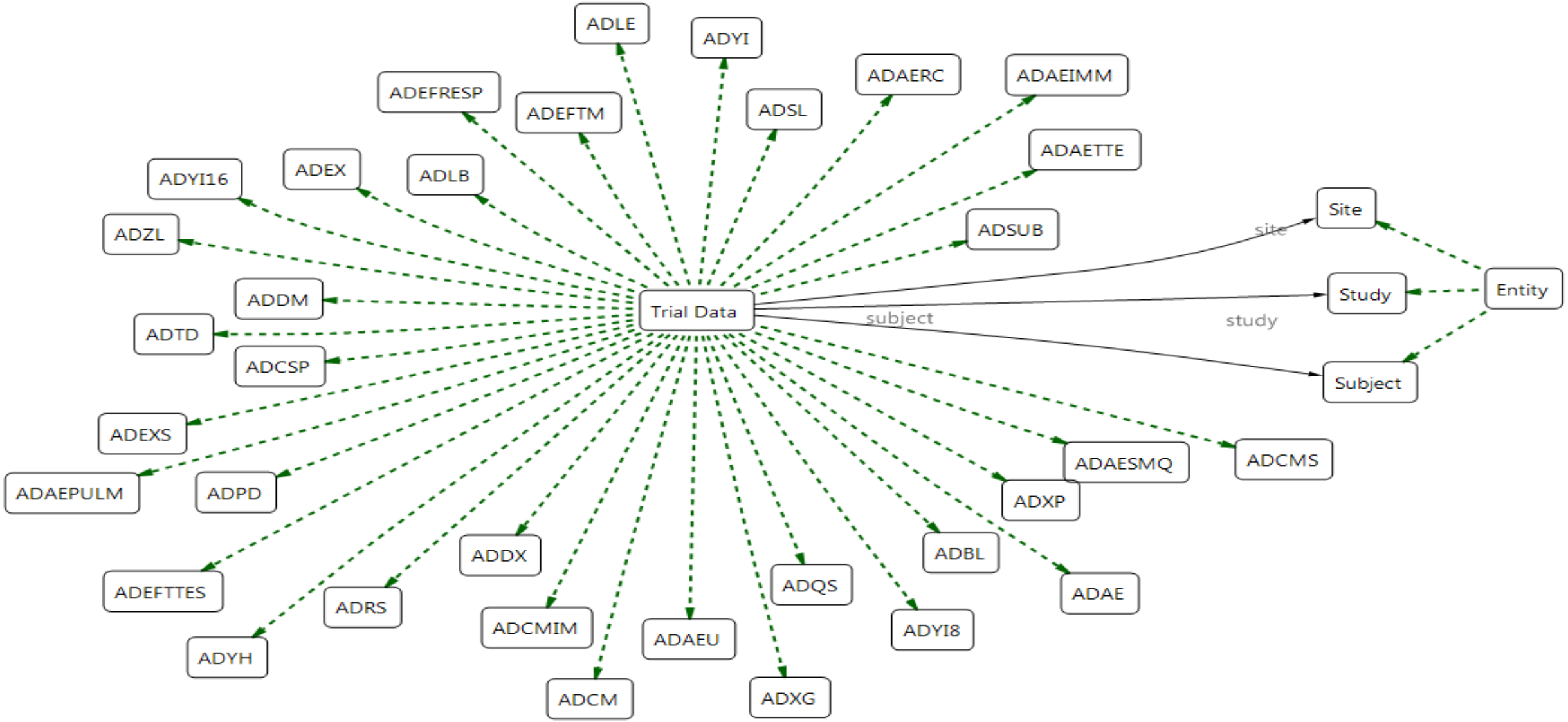
Each domain is modeled with a "Class" with attributes and relationships

Trial Data is the common base class for all domain classes

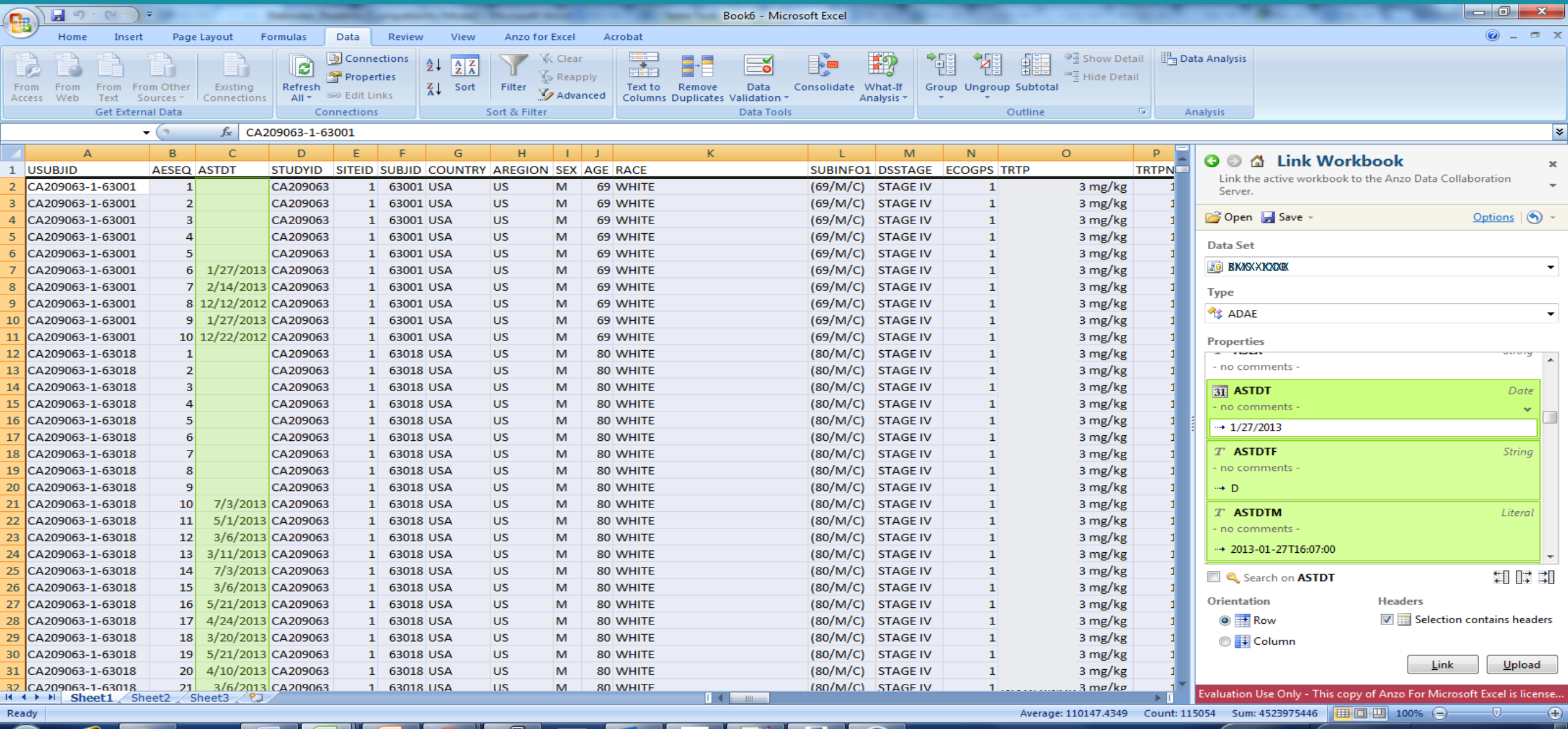
Subject, Site and Study classes link all domain classes together sharing a common Entity class



Full ADaM Driven Semantic Layer Example



Sample Auto-generated Mapping for ADAE Domain Data



	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
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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
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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
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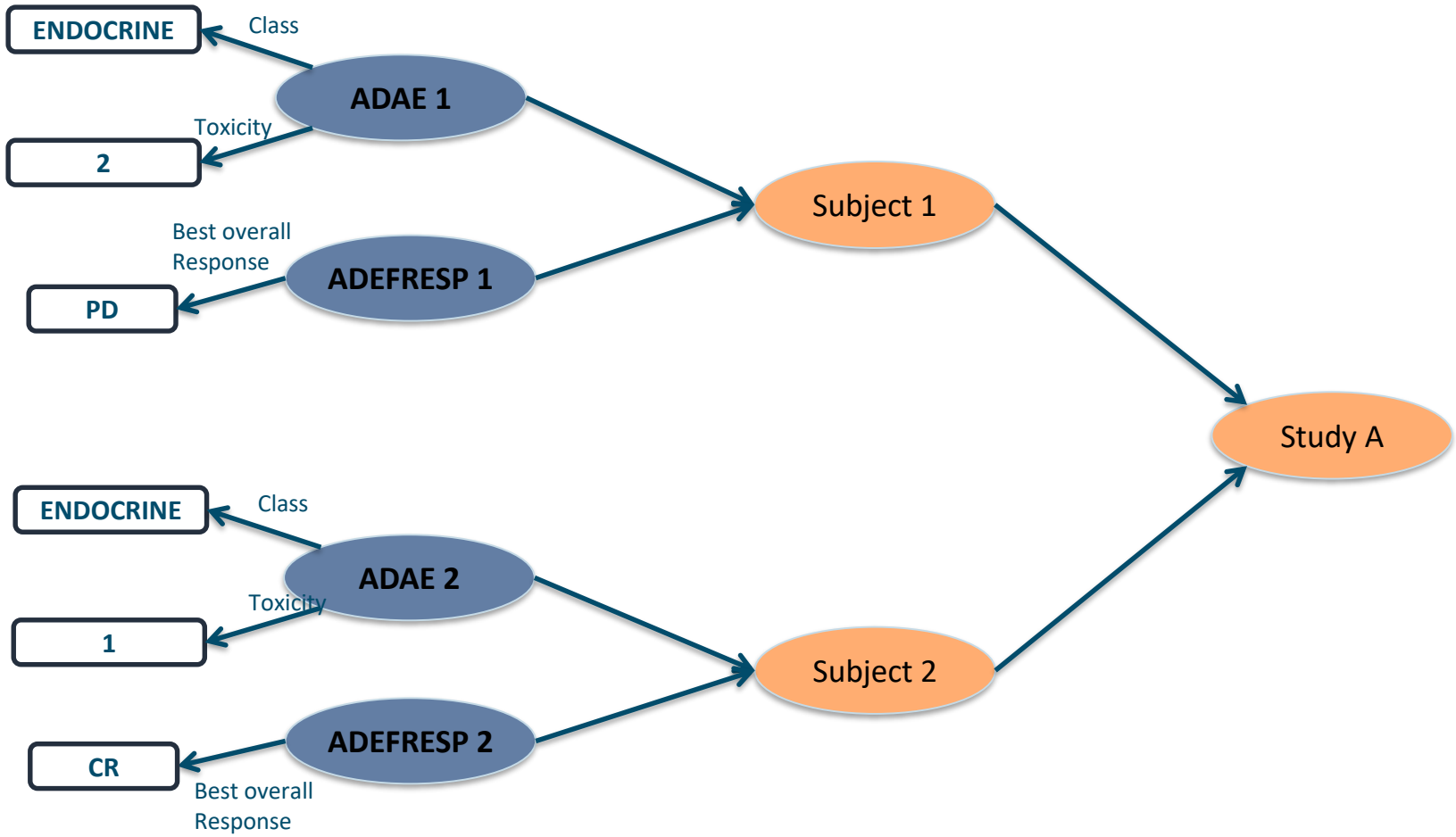
31	CA209063-1-63018	20	4/10/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1
32	CA209063-1-63018	21	3/6/2013	CA209063	1	63018	USA	US	M	80	WHITE	(80/M/C)	STAGE IV	1	3 mg/kg	1

Driving Advanced Analytics by the Semantics Layer

Explore the relationship between AE Toxicity and Overall Response.



Driving Advanced Analytics by the Semantics Layer

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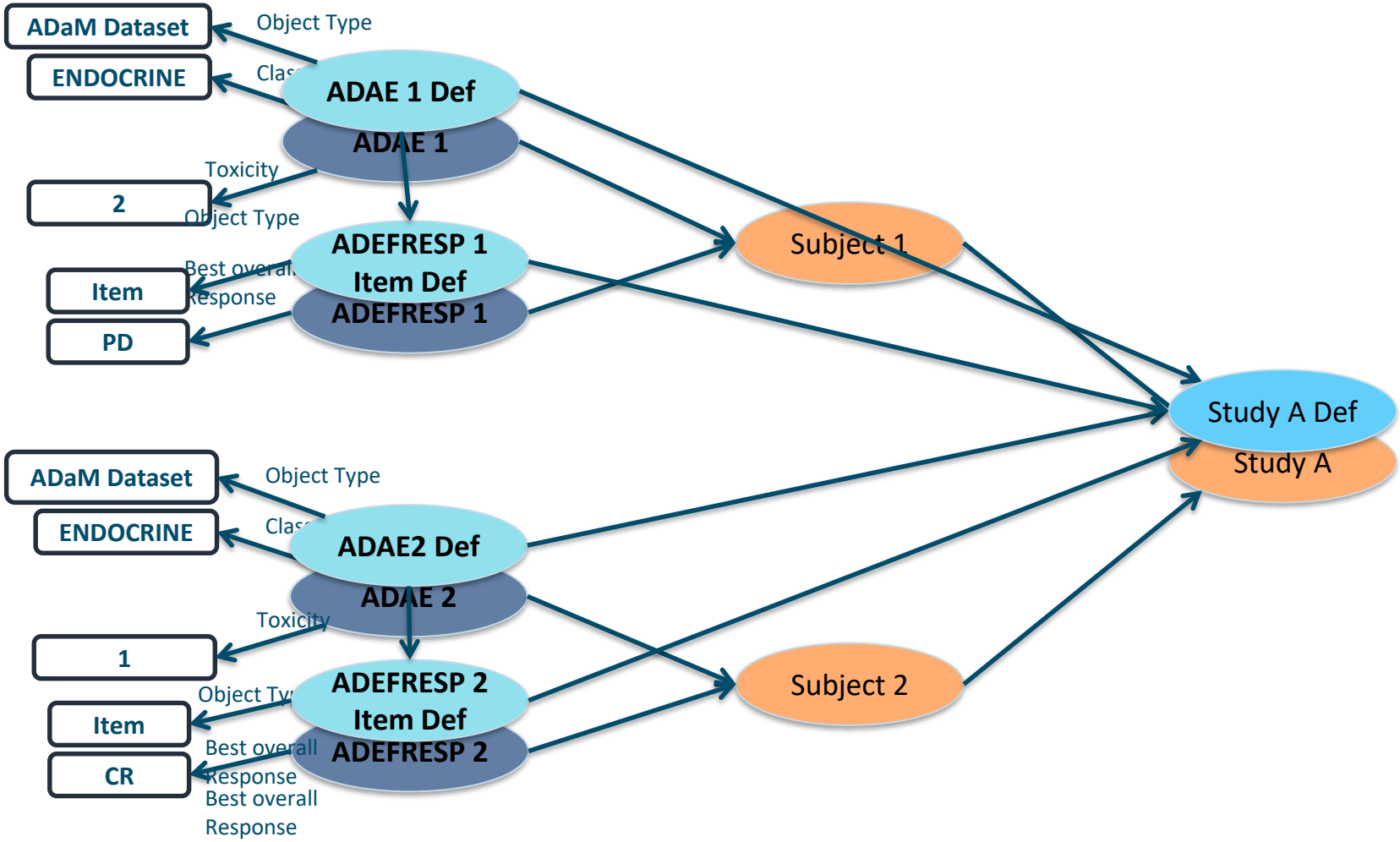
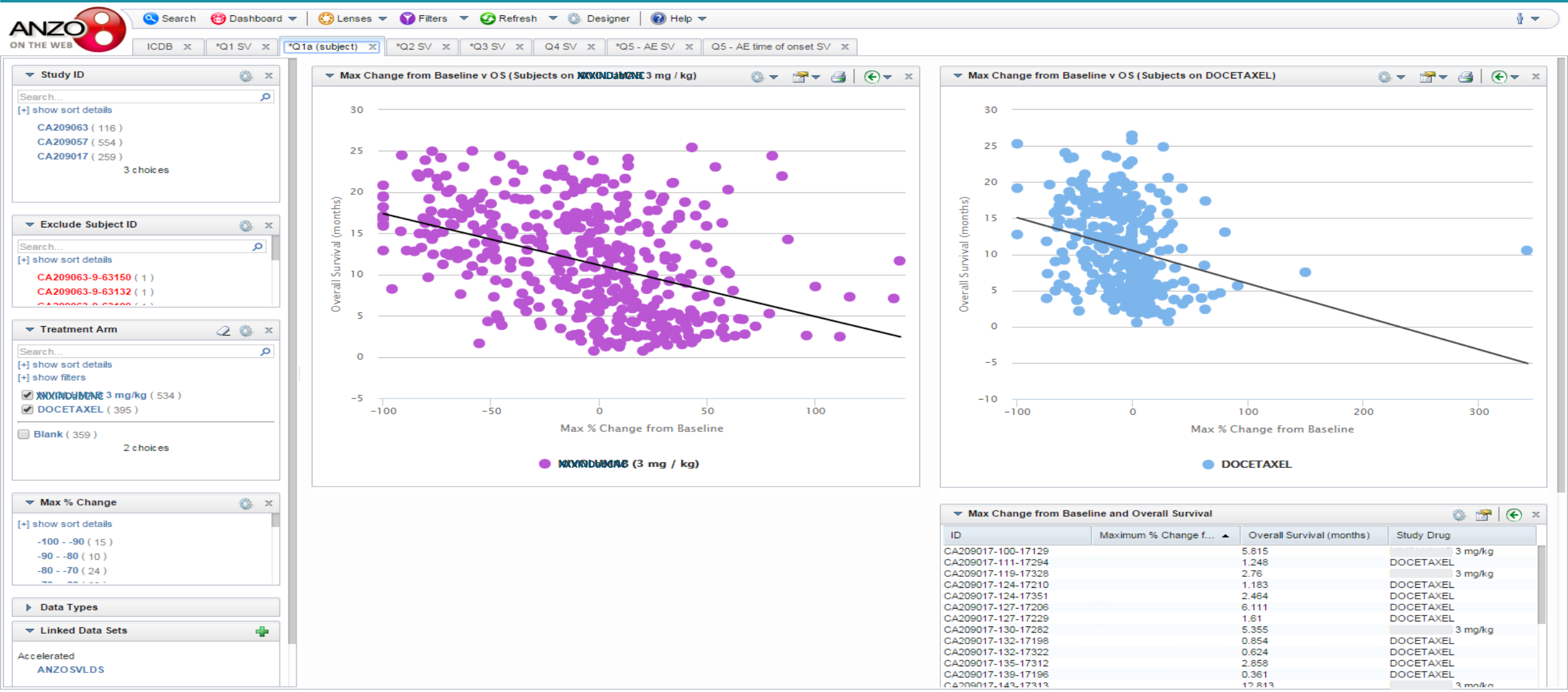
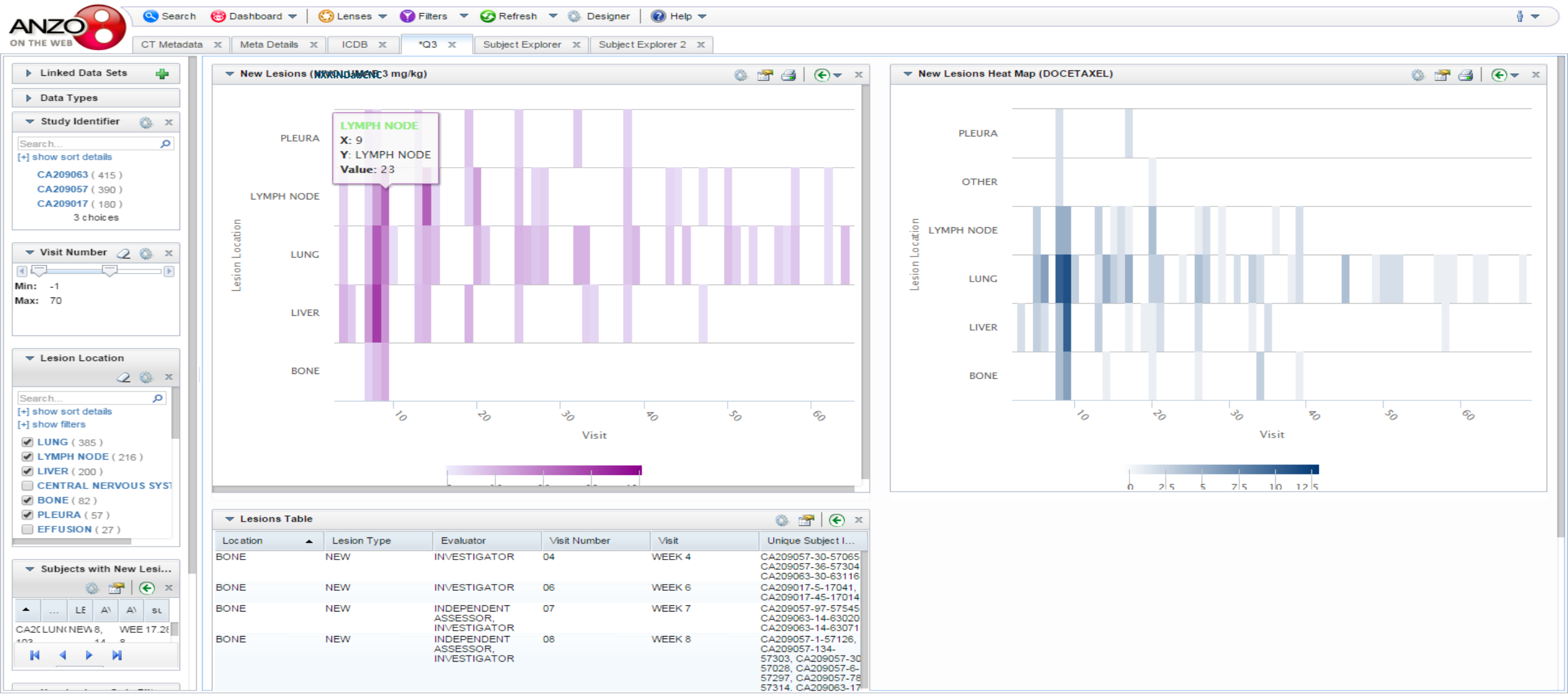


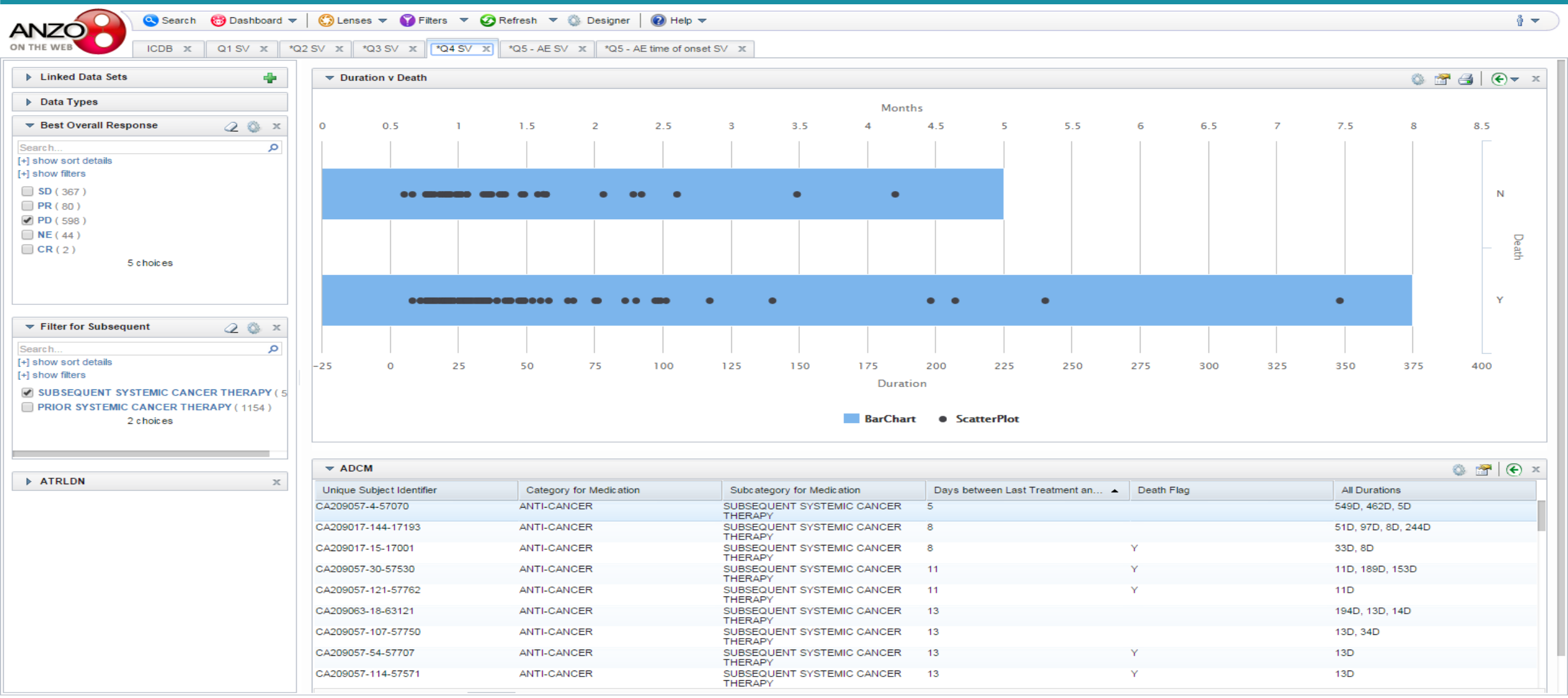
Cross-trial Advanced Analytics Example



Cross-trial Advanced Analytics Example

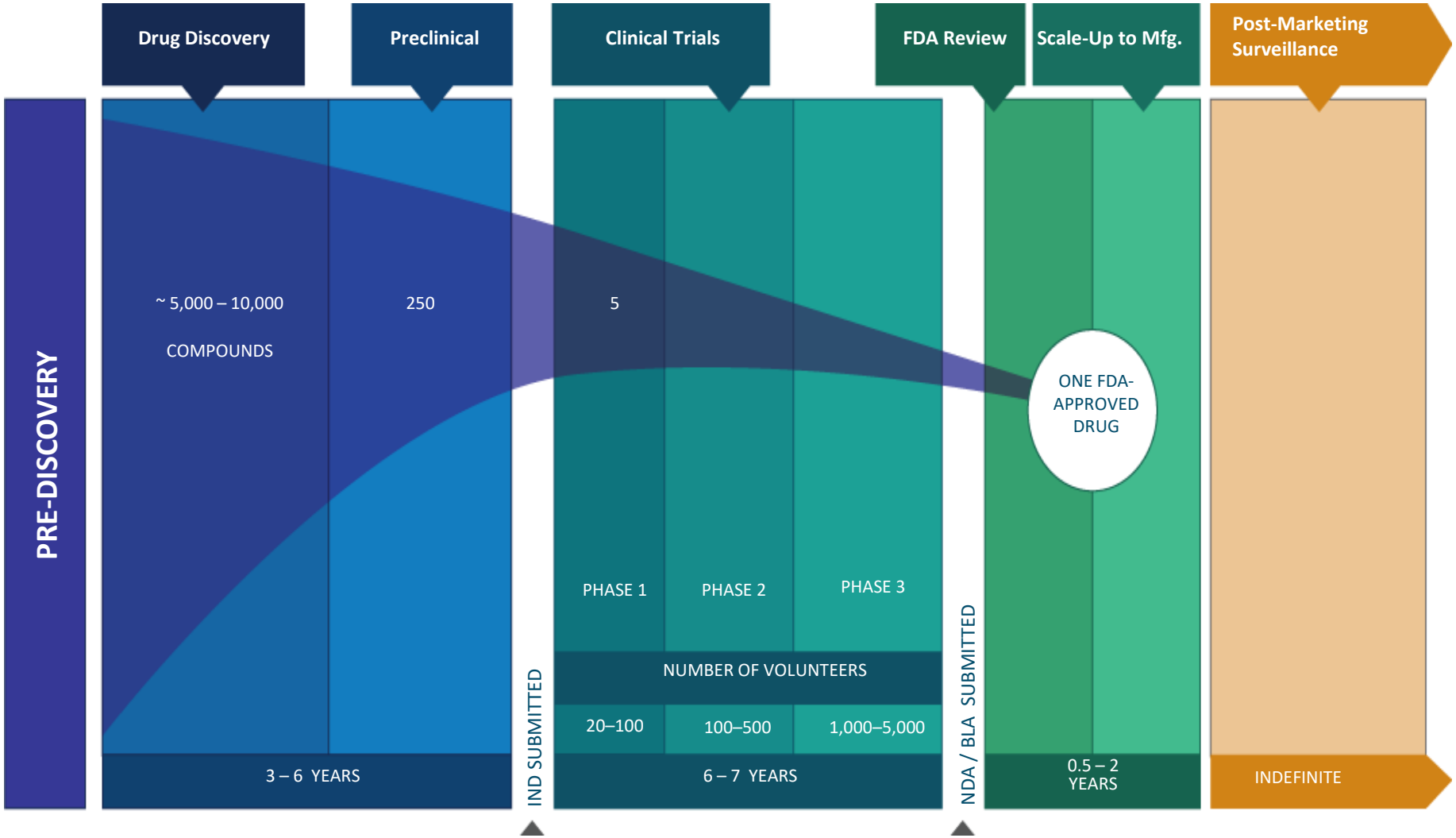


Cross-trial Advanced Analytics Example



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

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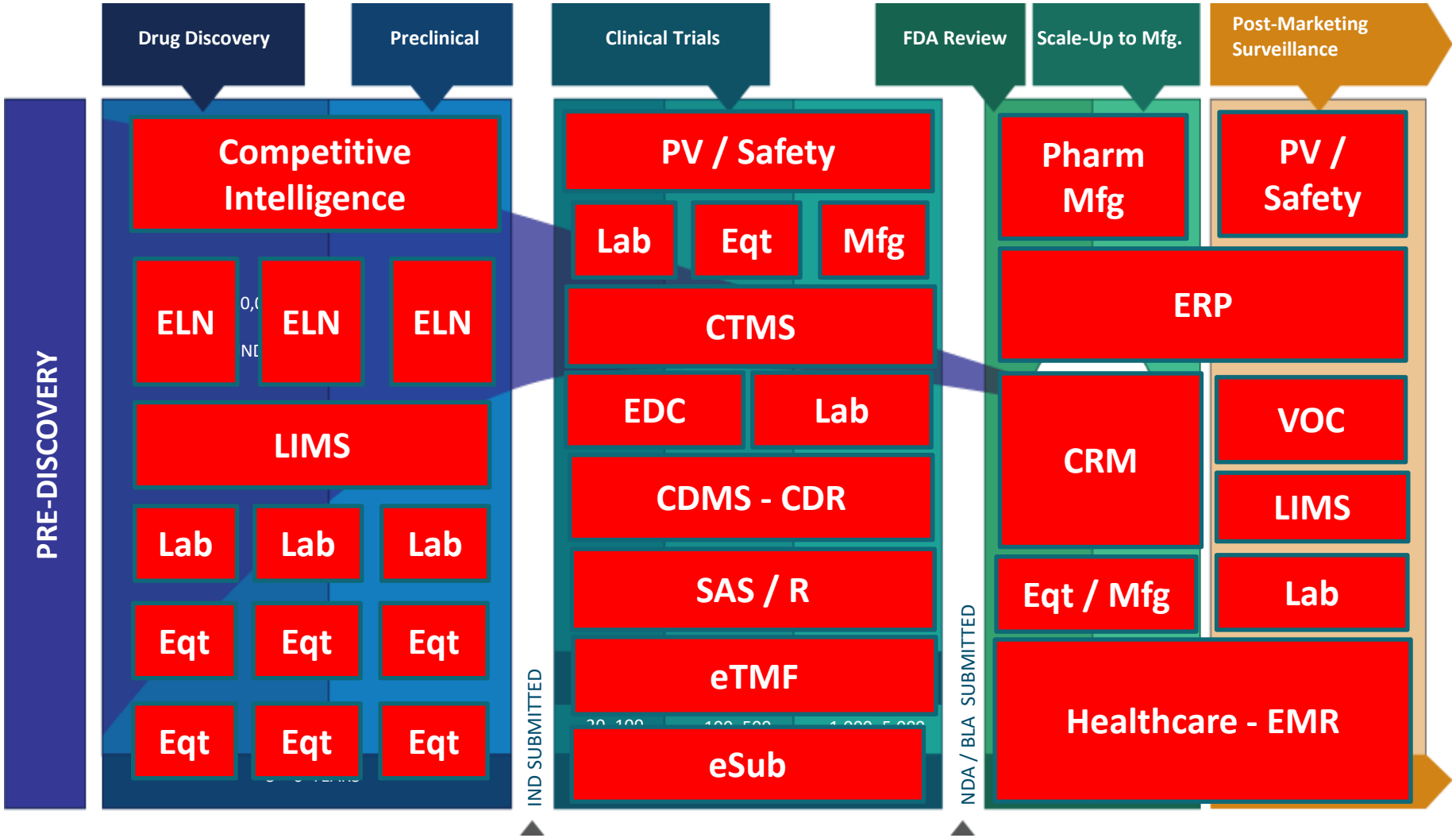

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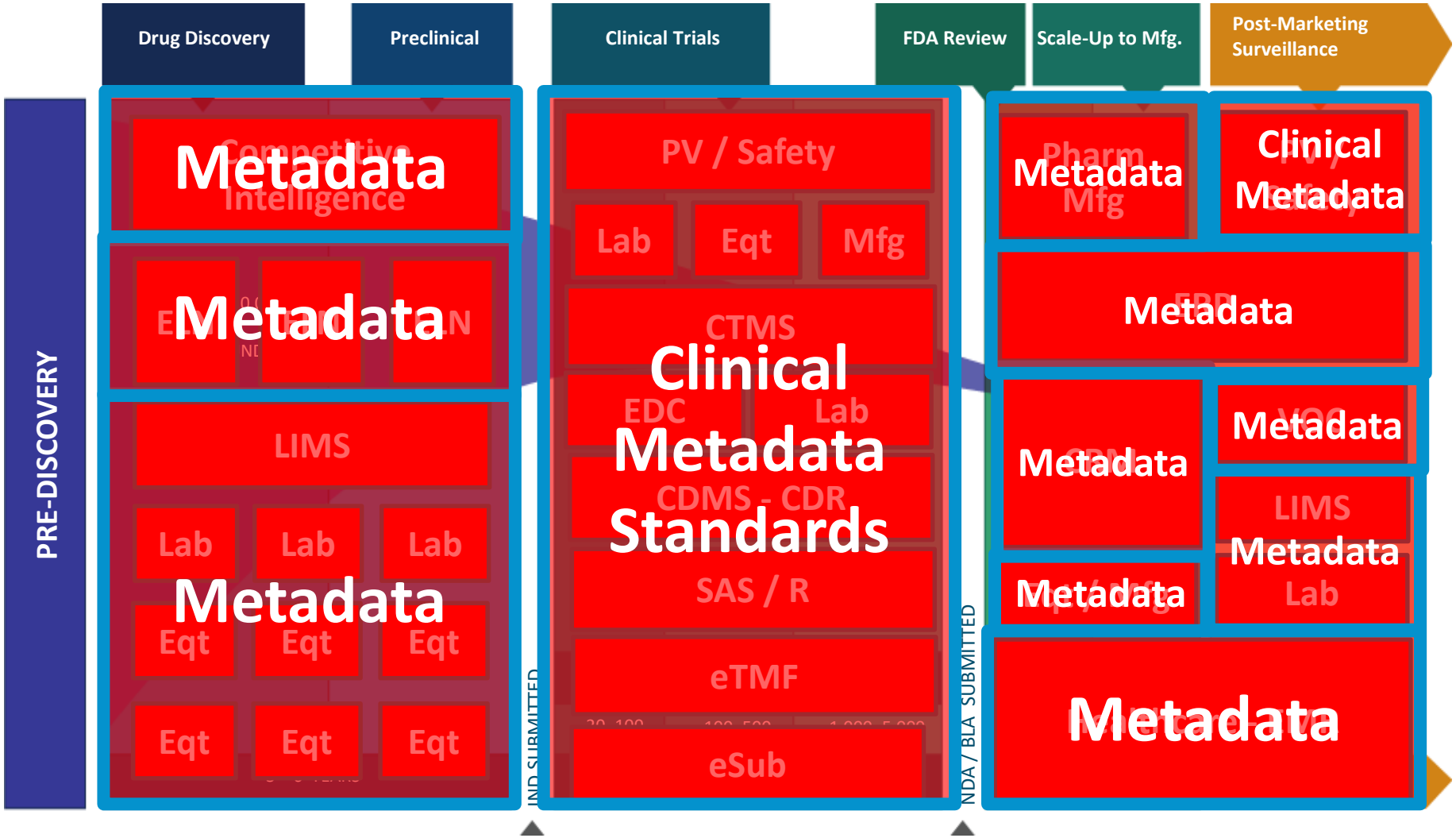

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Global Definitions of Concepts

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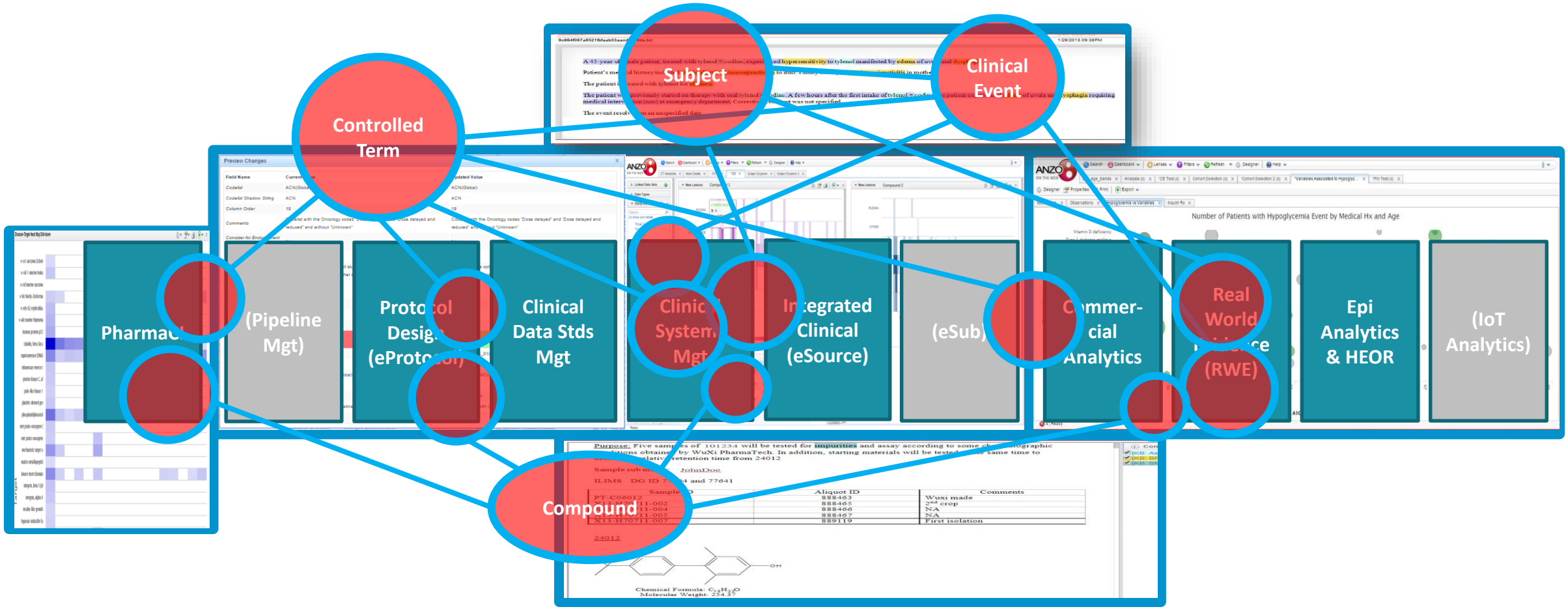

Global Definitions of Concepts

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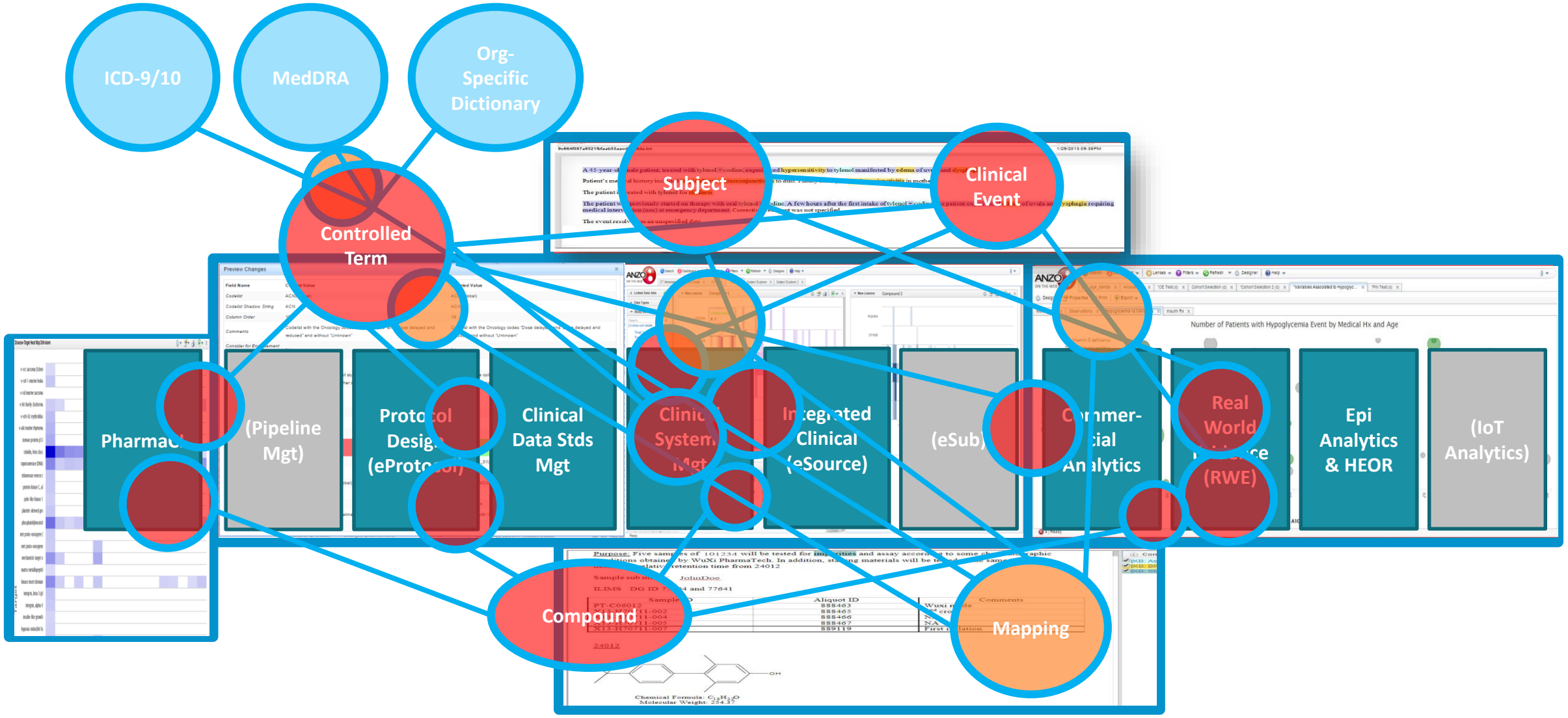
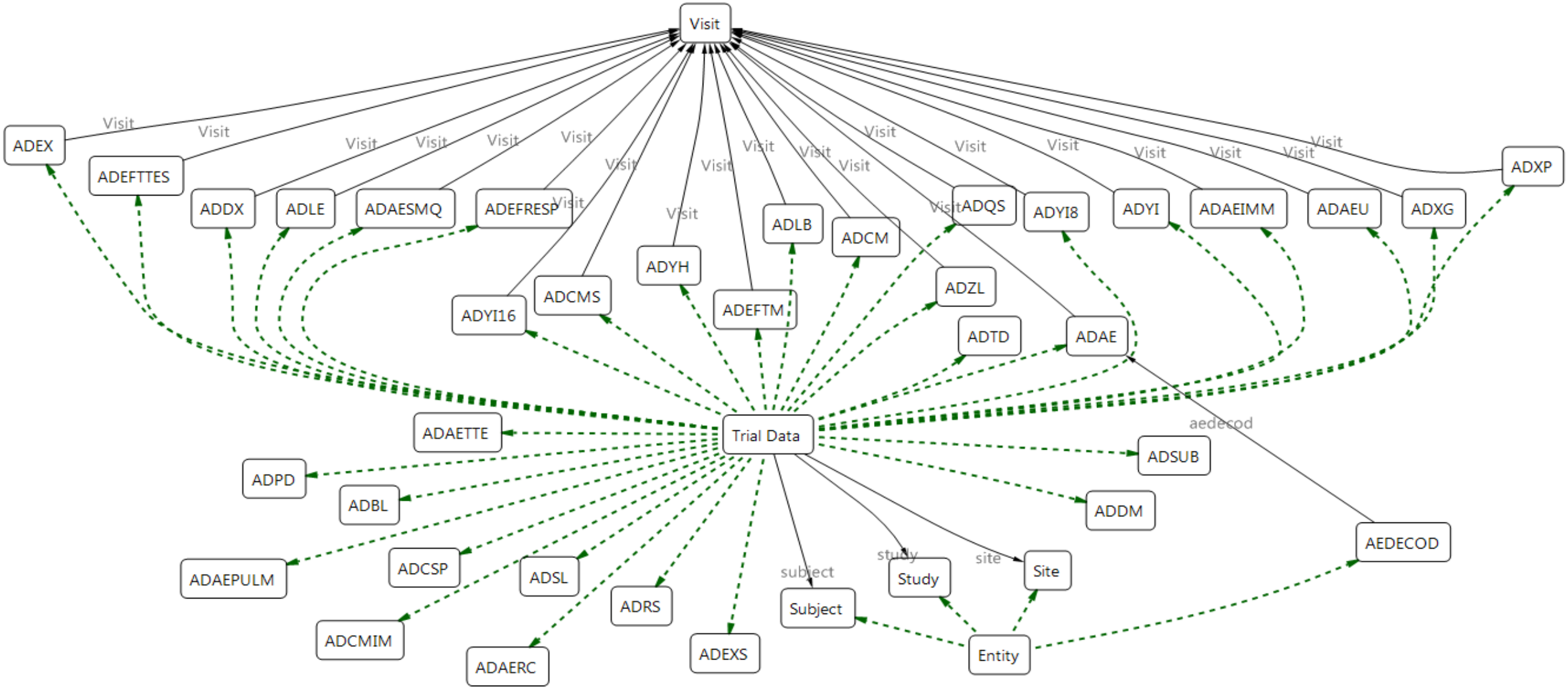


Semantic Layer Enhancements to Driven More Analytics



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

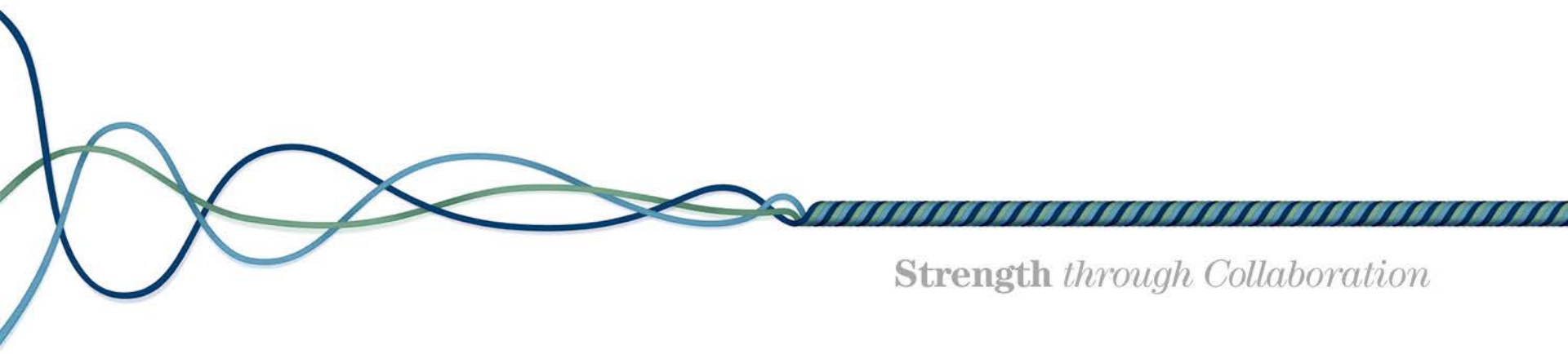
Enterprise Scale

CDISC Technical Webinar Series

Kirsten Walther Langendorf
S-Cubed & A3 Informatics

Dave Iberson-Hurst
Assero Ltd & A3 Informatics

26th October 2017



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

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

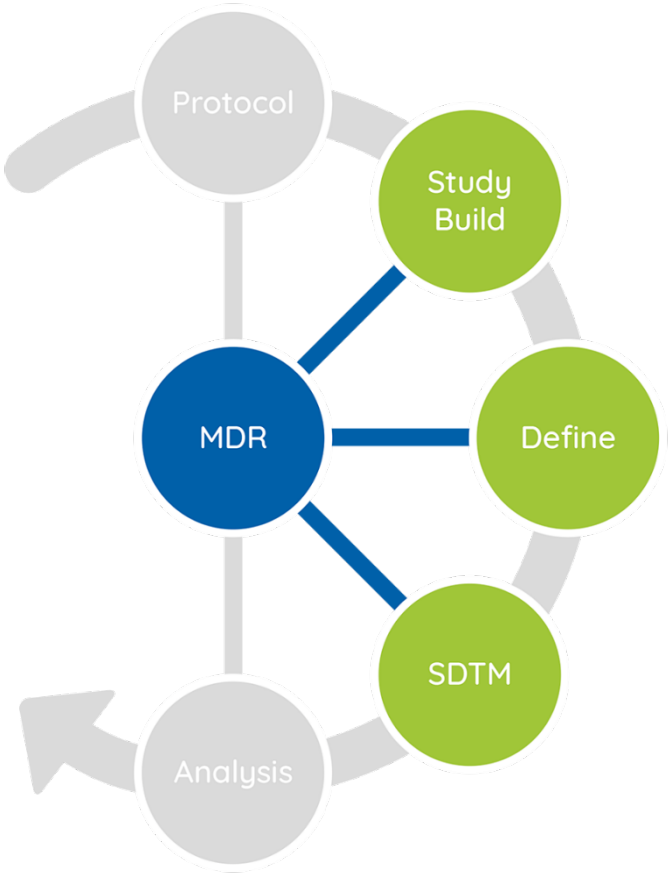
S-CUBED

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

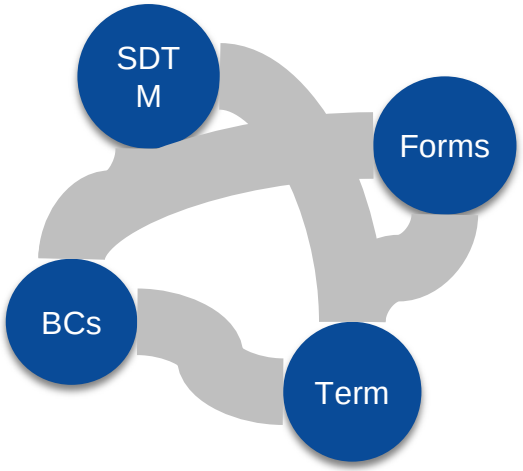
- An MDR at the centre providing a single source of knowledge
- A study build tool to construct clinical studies
- A define tool to build a define (in development, beta evaluation available)
- A tool to generate SDTM datasets (planned)
- Then expand across lifecycle
- Also, not shown, an experimental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

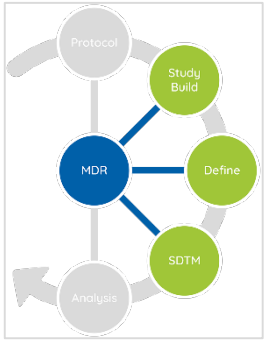


MDR

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

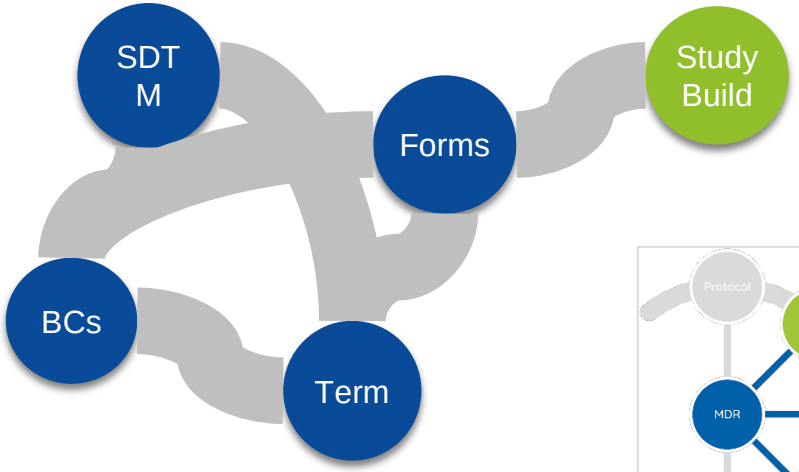


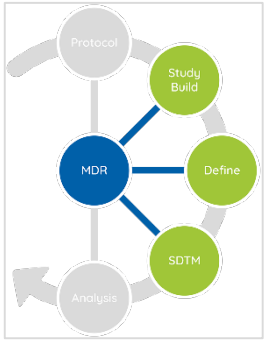


Study Build

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

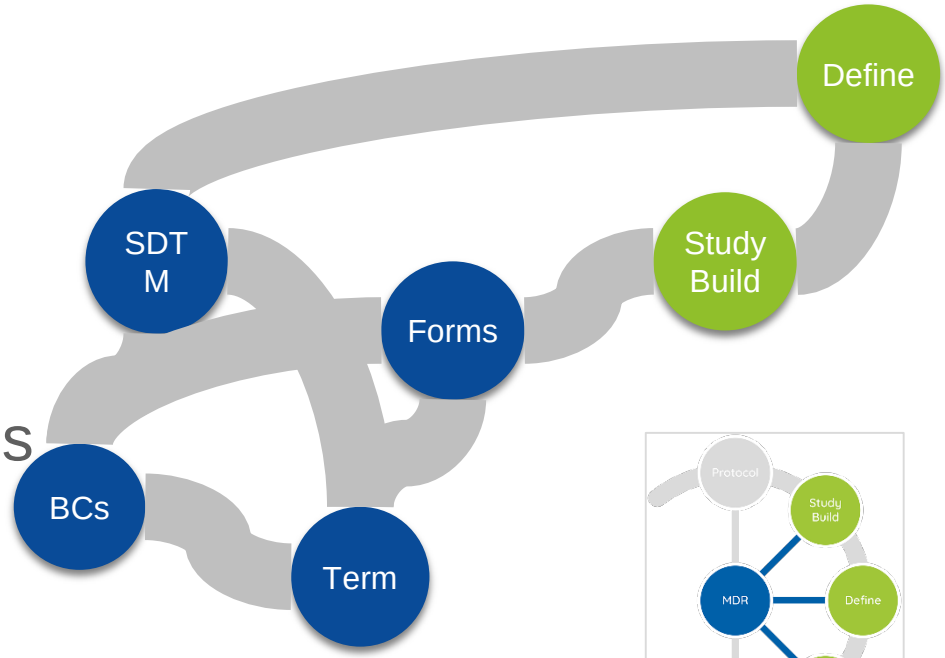
- MDR
  - Managing Controlled terminology
  - Managing models
  - Defining assessments on patients – Biomedical Concepts
  - Building Standard Forms – what's being collected together on 'logical pieces of papers'
- Study Builder
  - Specifying CRF/data collection for study

Demo

Define.xml

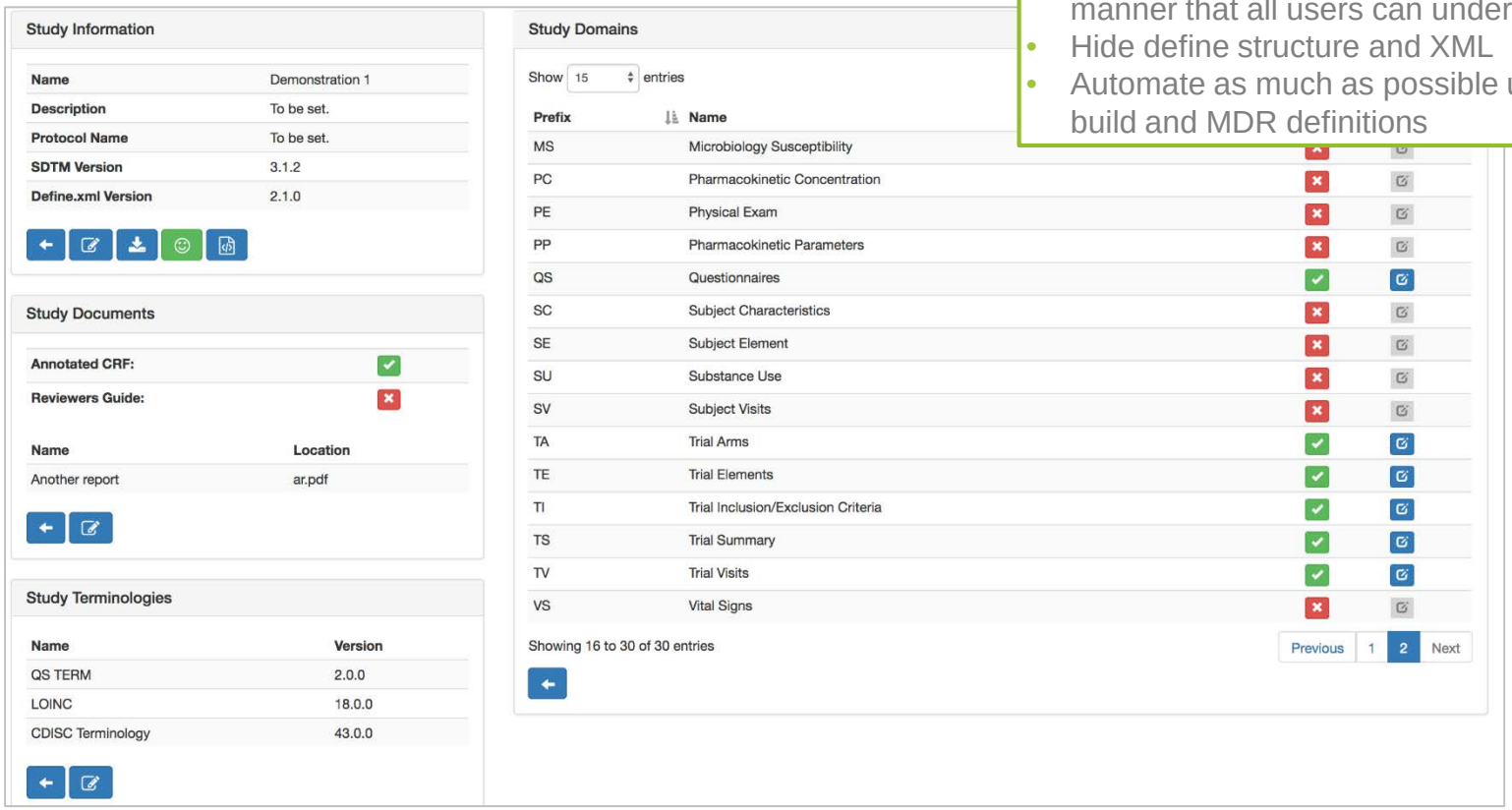
Automate Generation

- 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

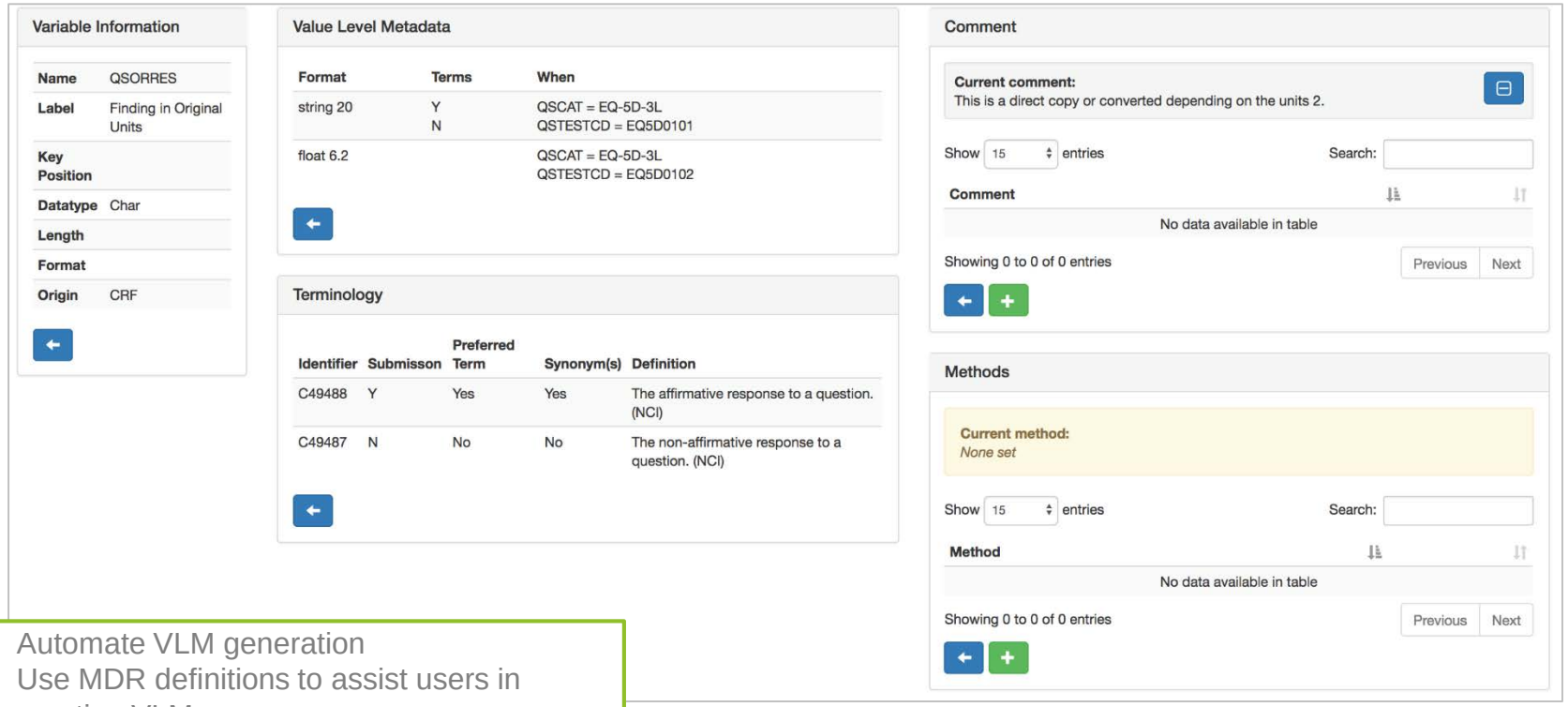


Define.xml

- 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



Define.xml

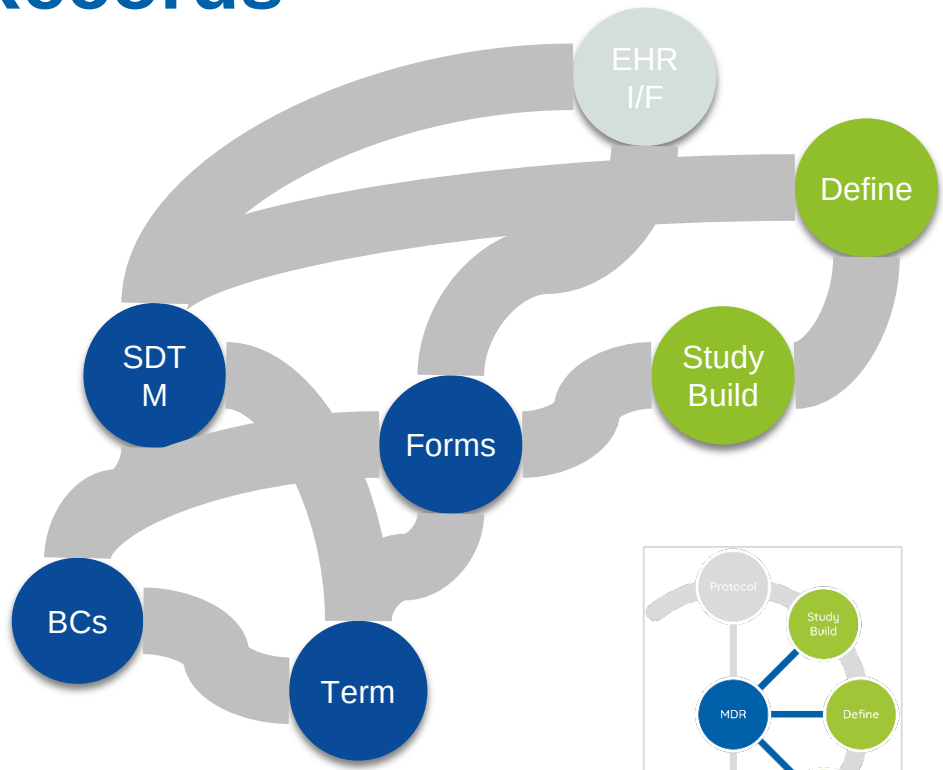


- Automate VLM generation
- Use MDR definitions to assist users in creating VLM

Electronic Health Records

An Experiment

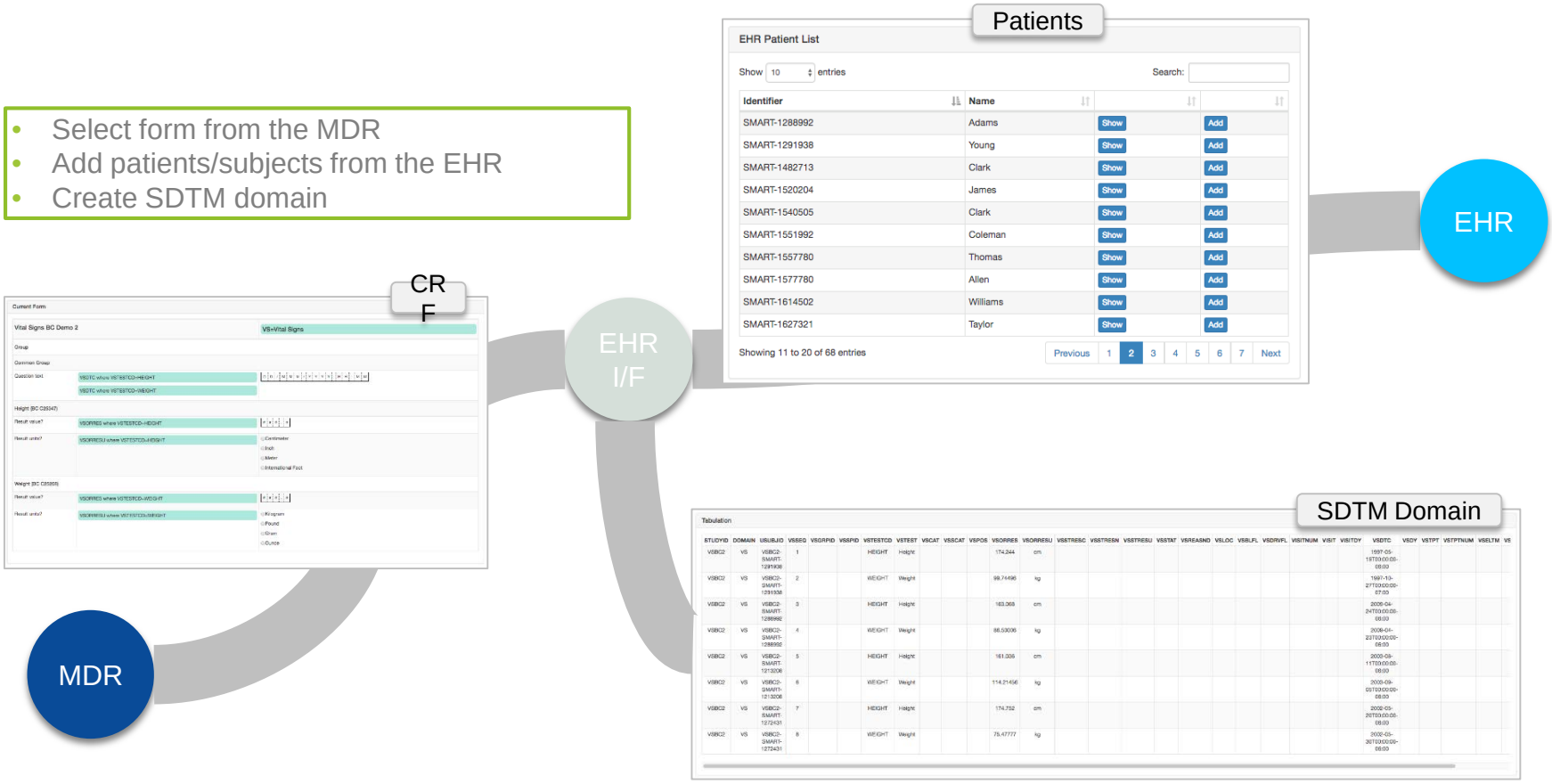
- Test application to test and demonstrate some of these ideas.
- Use HL7 FHIR to obtain patient data (map LOINC/UCUM -> CDISC Terminology mapping).
- Map to form selected from Glandon MDR built using Biomedical Concepts. Can build form on the fly and populate.
- Put into graph (in effect a simple data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



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?

Content Disclaimer

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Q&A

CDISC is IACET Accredited!

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- CDASH Implementation Classroom Course currently offering CEUs
- ADaM classroom, CDASH, SDTM and newly published TA online course modules will offer CEUs by end of 2017

For more info on IACET and CEUs, visit www.iacet.org

For more info on CEUs, email training@cdisc.org

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- Credit amount is based on membership level:
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UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Austin, TX	13-17 Nov 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML, Controlled Terminology, SEND, Standards from the Start, ODM, SDTM for Medical Device	13 Aug 2017	3 Nov 2017	CDISC

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UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
Copenhagen, Denmark	2-10 Nov 2017	SEND, SDTM, ADaM Primer, ADaM T&A, Define-XML	2 Aug 2017	3 Oct 2017	
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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UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Tokyo, Japan	4-8 Dec 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	4 Oct	4 Nov	Croit
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	C&R RESEARCH

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Any more questions?

Thank you for attending this webinar.

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