

innovation

Metadata Driven Yet Another Cliché in Our Industry PhUSE 2015 – DH02

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Ian Fleming

October 29, 2015

Outline

- What is metadata driven mean...
- Current World is Flat
 - Challenges with standards
 - Multidimensionality of clinical data
 - Siloed people and processes
- The World Needs to be Round
 - What do other industries do
 - Relationships
 - Really building a metadata driven approach

What is metadata driven?

■ What is not metadata driven...

- Reading an excel spreadsheet and applying a SAS label
- Writing pseudo code in an algorithm metadata field
- Creating empty data set shells

■ What is metadata driven...

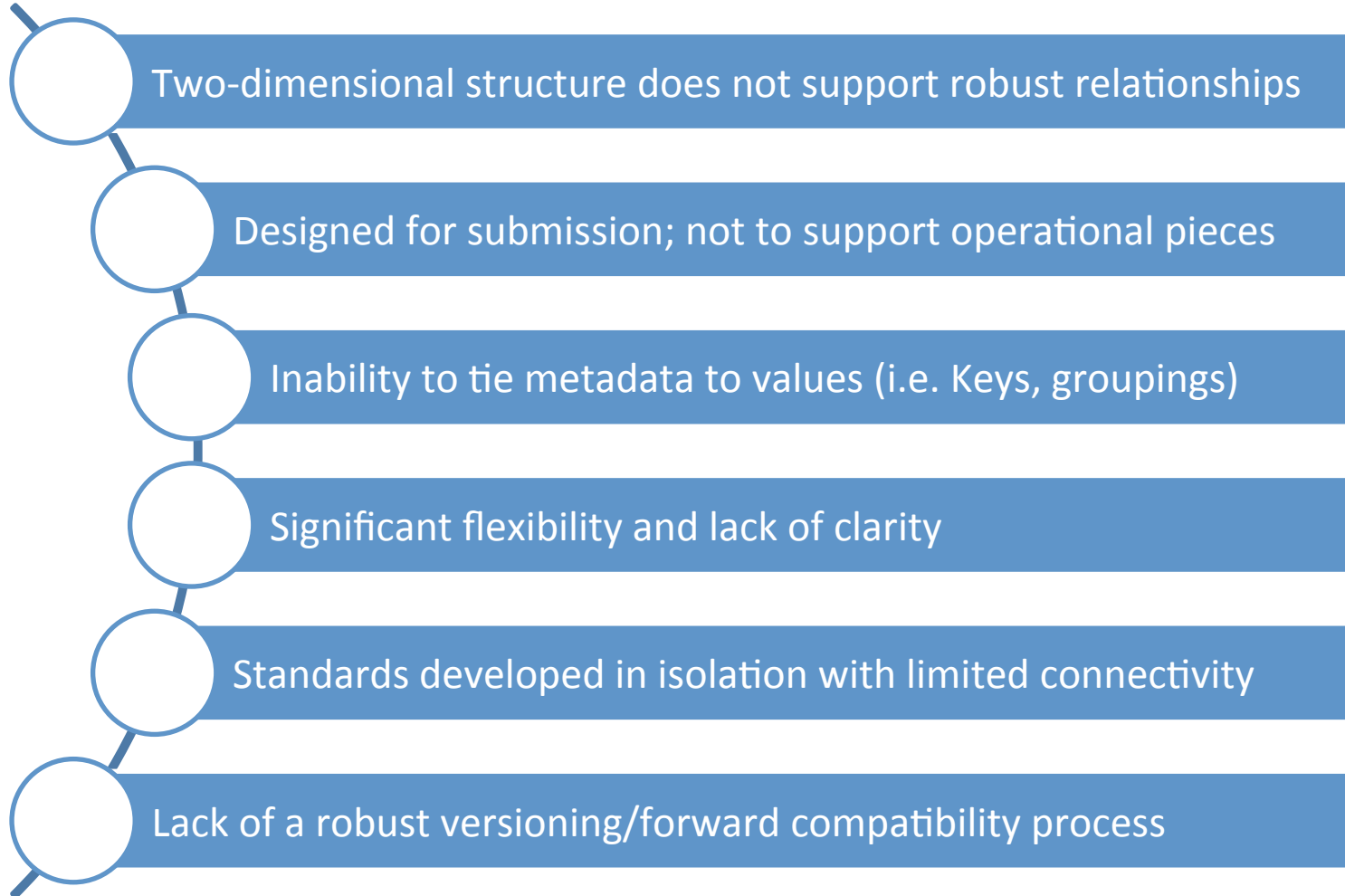
- Dynamically running different modules of code based on user input
- Having metadata and data tightly integrated
- Information that drives process





THE WORLD IS FLAT

Gaps in Standards



Multidimensionality

Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number	Vital Signs Test Short Name	Vital Signs Test Name	Vital Signs Position of Subject	Result or Finding in Original Units	Original Units	Character Result/Finding in Std Format	Numeric Result/Finding in Standard Units	Standard Units	Completion Status	Location of Vital Signs Measurement	Baseline Flag	Visit Number	Visit Name	Planned Study Day of Visit	Date/Time of Measurements	Study Day of Vital Signs	Planned Time Point Name	Planned Time Point Number	Planned Elapsed Time from Time Point Ref	Time Point Reference
CDISCPLOT01	VS	01-701-1023	64	SYSBP	Systolic Blood Pressure	STANDING	130	mmHg	130	130 mmHg					201	RETRIEVAL	168	2013-02-18	198	AFTER STANDING FOR 3 MINUTES	817	PT3M	PATIENT STANDING
CDISCPLOT01	VS	01-701-1023	65	TEMP	Temperature		097.8	F	36.56	36.56 C			ORAL CAVITY		1	SCREENING 1	-7	2012-07-22	-14				
CDISCPLOT01	VS	01-701-1023	72	WEIGHT	Weight		173.0	LB	78.47	78.47 kg					1	SCREENING 1	-7	2012-07-22	-14				
CDISCPLOT01	VS	01-701-1028	1	DIABP	Diastolic Blood Pressure	SUPINE	76	mmHg	76	76 mmHg					1	SCREENING 1	-7	2013-07-11	-8	AFTER LYING DOWN FOR 5 MINUTES	815	PT5M	PATIENT SUPINE

Data point(s)
of interest:

Who:

What:

Where (from DM):

VSSTRESN
130
36.56
78.47
76

USUBJID
01-701-1023
01-701-1023
01-701-1023
01-701-1028

VSTESTCD	VSTEST
SYSBP	Systolic Blood Pressure
TEMP	Temperature
WEIGHT	Weight
DIABP	Diastolic Blood Pressure

DOMAIN	USUBJID	SITEID	COUNTRY
DM	01-701-1023	701	USA
DM	01-701-1028	701	USA

Why:

When:

How:

STUDYID
CDISCPLOT01
CDISCPLOT01
CDISCPLOT01
CDISCPLOT01

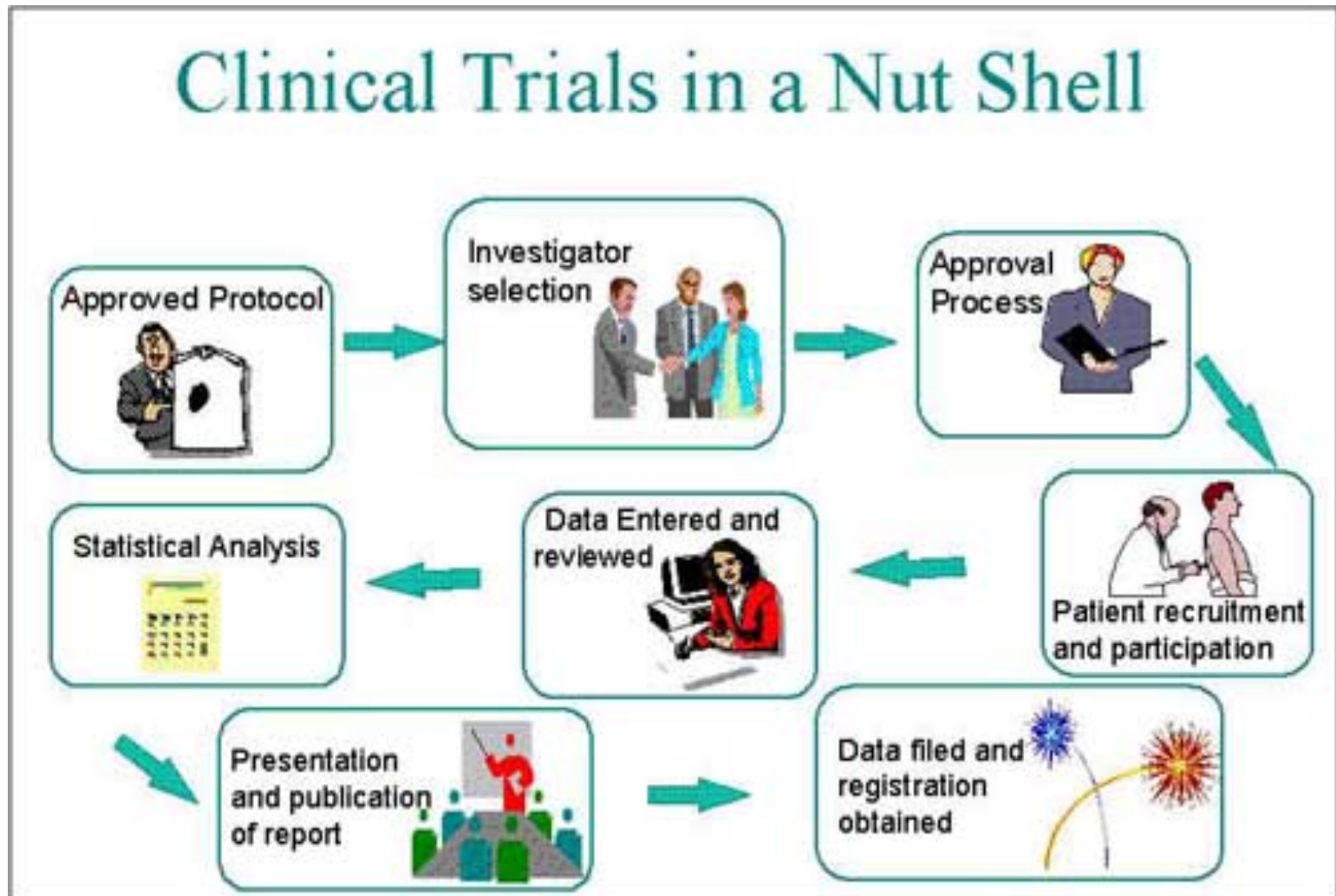
VISITNUM	VISIT	VISITDY	VSDTC	VSDY
201	RETRIEVAL	168	2013-02-18	198
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VSPOS	VSSTRESU	VSLOC
STANDING	mmHg	
	C	ORAL CAVITY
	kg	
SUPINE	mmHg	

TSVAL
Mild to Moderate Alzheimers Disease

VSTPT
AFTER STANDING FOR 3 MINUTES
AFTER LYING DOWN FOR 5 MINUTES

World of Silos



The world is
round and the
place which
may seem like
the end may
also be only
the **beginning**.

- IVY BAKER PRIEST

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THE WORLD IS ACTUALLY
ROUND



Simon Weston

Simon Weston OBE is a veteran of the British Army who has become well known throughout the United Kingdom for his recovery and charity work after suffering severe burn injuries during the Falklands War.
[Wikipedia](#)

Born: August 8, 1961 (age 54), [Caerphilly, United Kingdom](#)

Battles and wars: [Falklands War](#)

Service/branch: [British Army](#)

Unit: [Welsh Guards](#)

Parents: [Pauline Weston, Lofty](#)

Books

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[A Nod from Nelson](#)
2008



[Get Fit with Nelson](#)
2013



[Walking Tall: An Autobiography...](#)
1989



[Nelson at Sea](#)
2011



[Moving on](#)
2003

Multidimensionality

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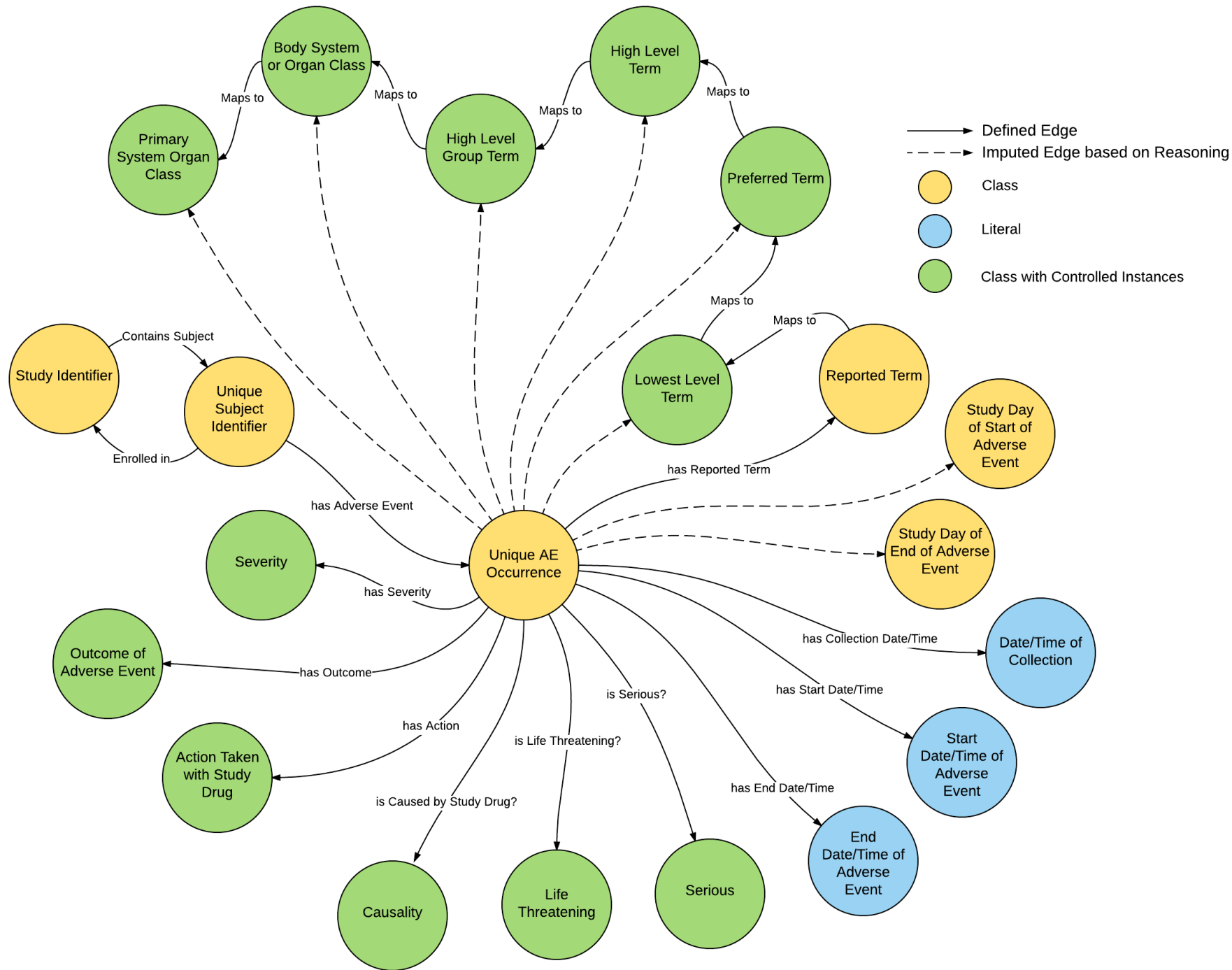
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STANDING	mmHg	
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	kg	
SUPINE	mmHg	

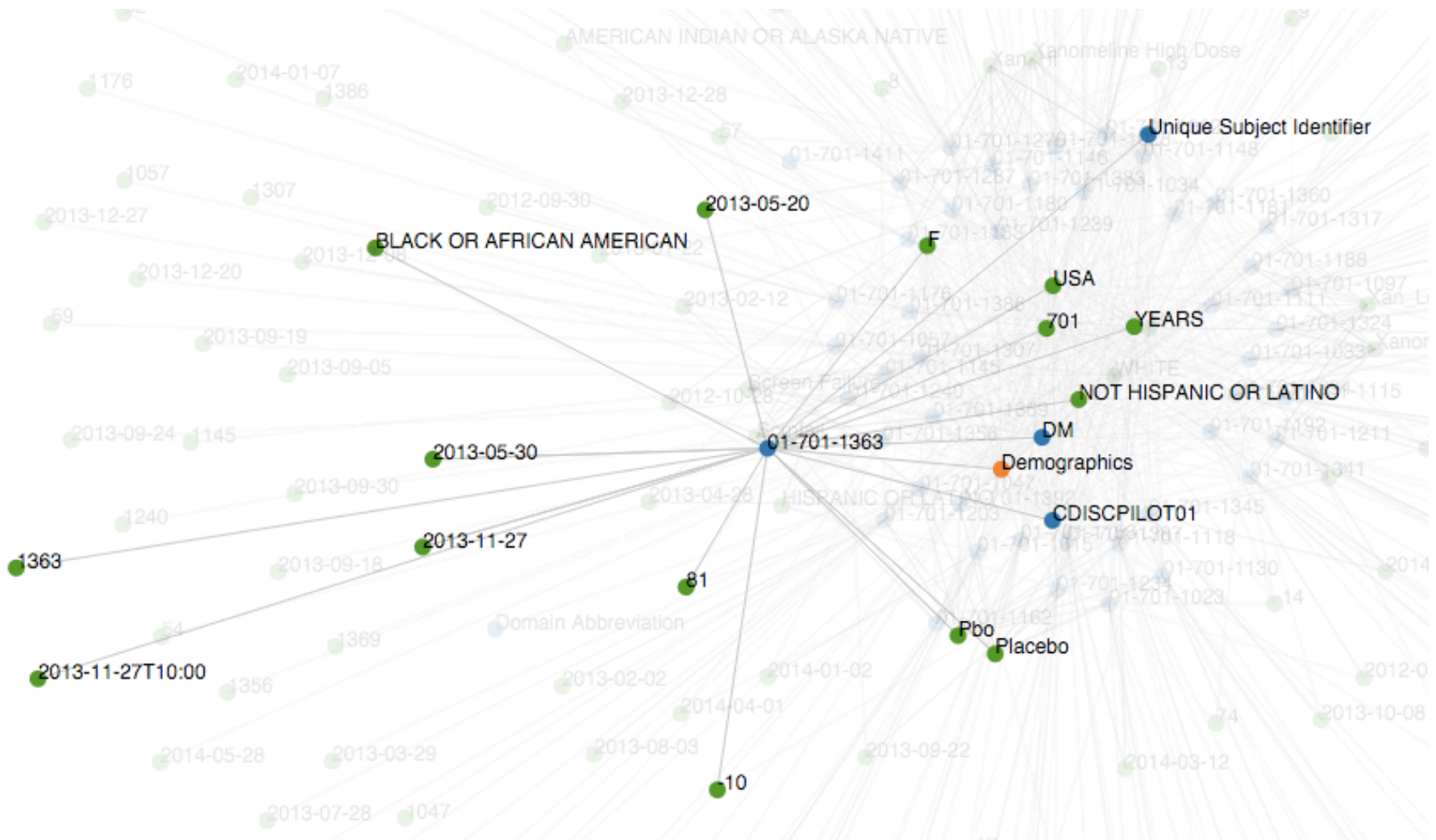
TSVAL

Mild to Moderate Alzheimers Disease

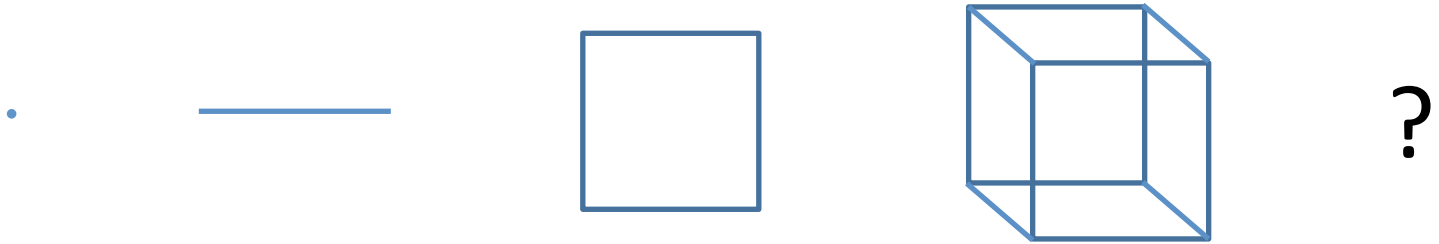
VSTPT
AFTER STANDING FOR 3 MINUTES
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Ontology with Data



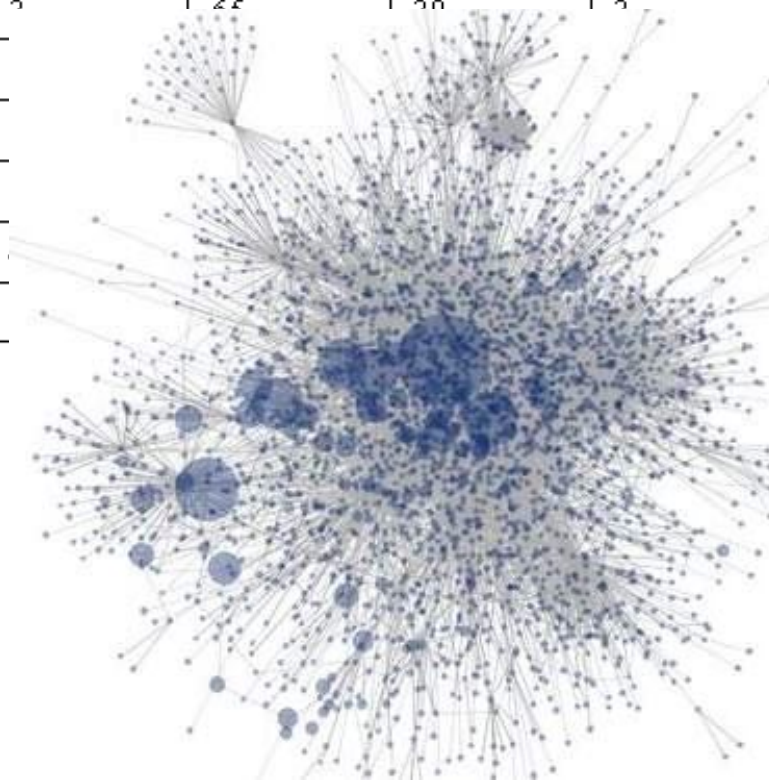
Physical Dimensions



- String theory and M theory are only feasible in 11 dimensional physical space
- This is very difficult for humans to comprehend

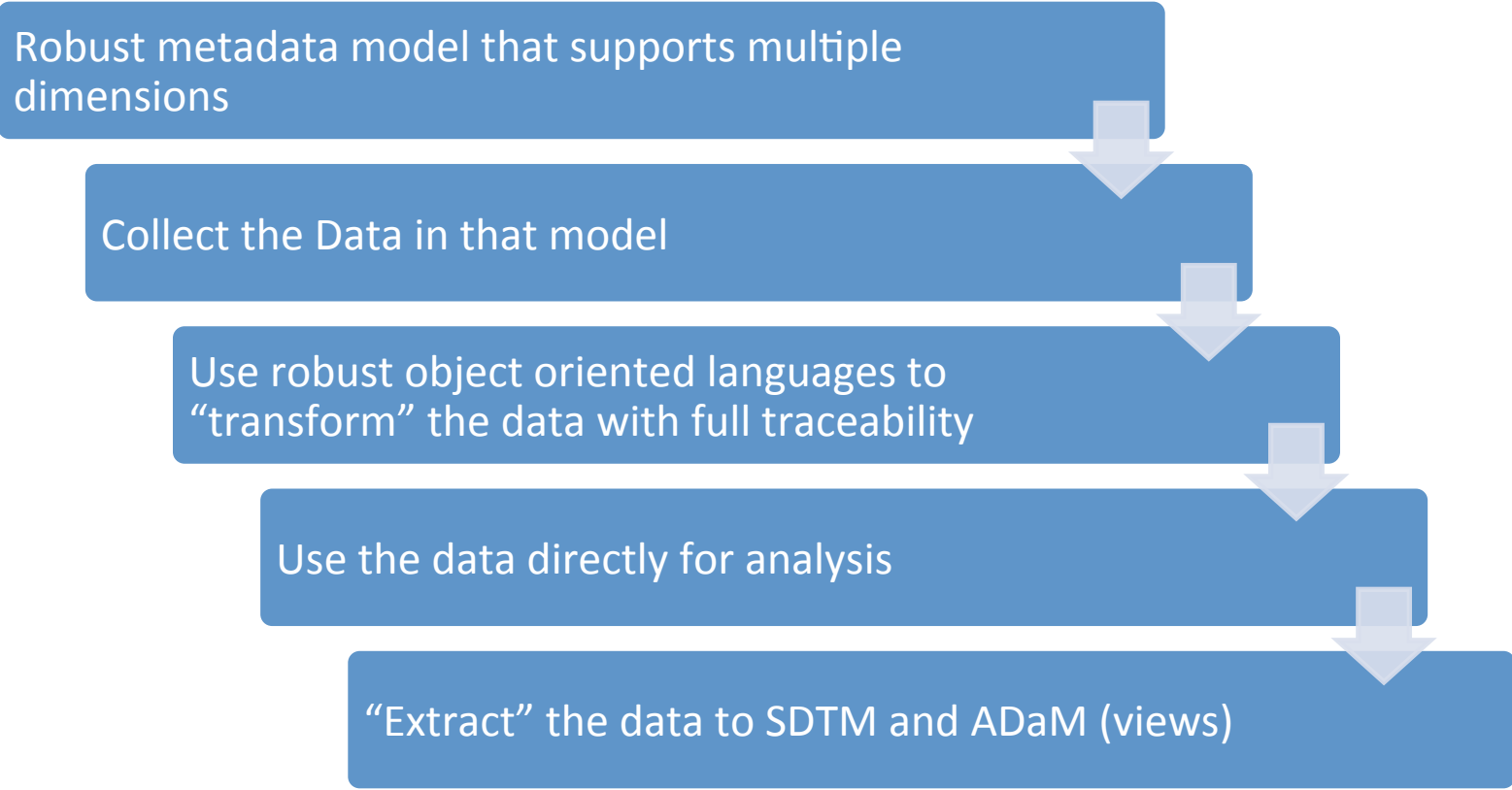
Data Dimensions

	Sex	Race	Height	Income	Marital Status	Years of Educ.	Liberal-ness
R1001	M	1	70	50	1	12	1.73
R1002	M	2	72	100	2	20	4.53
R1003	F	1	55	250	1	16	2.99
R1004	M	2	65	20	2	16	1.13
R1005	F					12	3.81
R1006	M					9	4.76
R1007	F					21	2.01
R1008	F					18	1.27
R1009	M					12	3.25



How do we make it real?

Robust metadata model that supports multiple dimensions



```
graph TD; A[Robust metadata model that supports multiple dimensions] --> B[Collect the Data in that model]; B --> C[Use robust object oriented languages to "transform" the data with full traceability]; C --> D[Use the data directly for analysis]; D --> E["Extract" the data to SDTM and ADaM (views)];
```

Collect the Data in that model

Use robust object oriented languages to “transform” the data with full traceability

Use the data directly for analysis

“Extract” the data to SDTM and ADaM (views)

Summary

- The current flat world creates severe limitations
- The Standards are not currently robust enough to support the dimensionality of clinical data
- We should learn from other industries
- Must integrate information and metadata
- It's not an academic exercise

Join us in believing the world is round!