

The Chicken and Egg Dilemma: Why Metadata Solutions have Struggled

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Outline

- Metadata or Data or both
- Why do you need an MDR?
- User Needs versus System Requirements
- Challenging the implementation approach

Metadata Definition

met·a·da·ta

/ˈmedəˌdādə, ˈmedəˌdadə/

noun

noun: metadata; noun: meta-data

a set of data that describes and gives information about other data.

It's all Data! Stop separating metadata and data...

What is Metadata? What is Data?

Char 1 to many AEDECODE

AEBODSYS Cardiovascular No

Nausea AE Preferred term

Yes MEDDRA V10.0

ADAE frequency

Adverse Events

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	
CDISCPILOT01	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
CDISCPILOT01	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				
CDISCPILOT01	VS	01-701-1023	72	WEIGHT	Weight		173.0	LB	78.47	78.47	kg				1	SCREENING 1	-7	2012-07-22		-14				
CDISCPILOT01	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
CDISCIPILOT01
CDISCIPILOT01
CDISCIPILOT01
CDISCIPILOT01

VISITNUM	VISIT	VISITDY	VSDTC	VSDY
201	RETRIEVAL	168	2013-02-18	198
1	SCREENING 1	-7	2012-07-22	-14
1	SCREENING 1	-7	2012-07-22	-14
1	SCREENING 1	-7	2013-07-11	-8

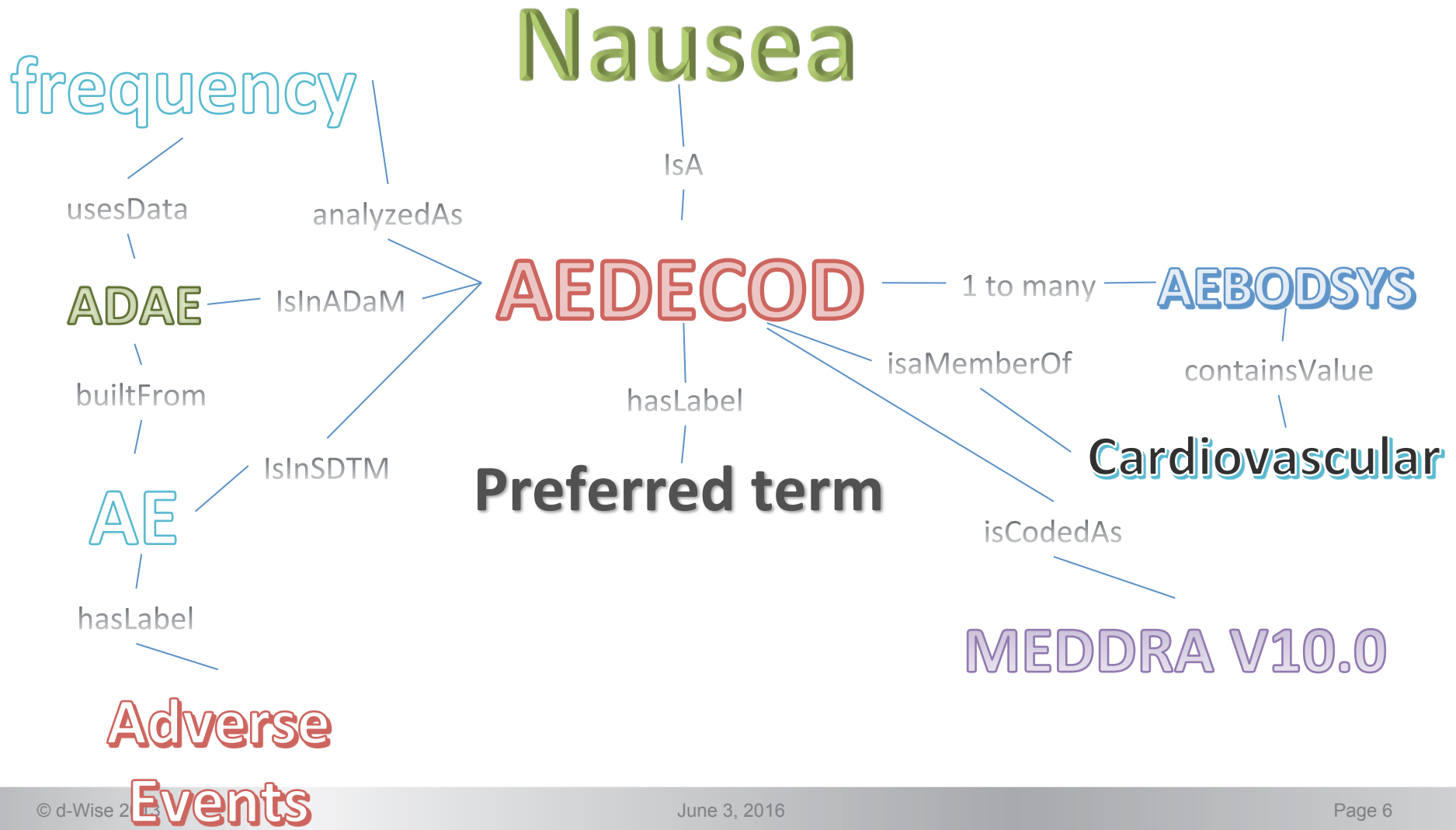
VSPOS	VSSTRESU	VSLOC
STANDING	mmHg	
	C	ORAL CAVITY
	kg	
SUPINE	mmHg	

TSVAL

Mild to Moderate Alzheimers Disease

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

Putting it all together...



Gaps in Standards



Two-dimensional structure does not support robust relationships

Designed for submission; not to support operational pieces

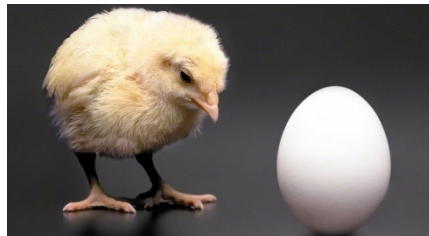
Inability to tie data together (i.e. Keys, relationships)

Standards developed in isolation with limited connectivity

Lack of a robust versioning/forward compatibility process

Setting Expectations

- "End to End Traceability of all metadata to support push button automation and versioning and governance of all standards"
- What you really need is "controlled spreadsheets"
 - Existing Standards limited in robust traceability
 - Relational databases don't support multidimensional relationships
 - Crawl before you can walk
- What comes first? The model to support the multidimensionality of clinical information or the tools to support it...



WHY DO YOU NEED AN MDR?

Why?

- This is a surprisingly difficult question for many organizations
- Variety of different pressures has led to inclusion of MDRs in the clinical toolset
- Uncertainty around standards complicates this question
- The MDR market in clinical development is still fairly new (~5 years)

How do YOU answer that question?



Regulatory compliance



Operational Control



Part of standards implementation



Process efficiency



Automation



Something else

Move on to the what

- What are the things that you expect the system to do?
 - Stick to business tasks
 - Keep it simple
 - Be specific and avoid ambiguity
- Don't get caught up in the how
 - New systems should be seen as an opportunity for innovation
 - Focusing on how reinforces current ways of working

USER NEEDS VERSUS SYSTEM REQUIREMENTS

Traditional Requirements



How the customer explained it



How the project leader understood it



How the engineer designed it



How the programmer wrote it



How the sales executive described it



How the project was documented



What operations installed



How the customer was billed



How the helpdesk supported it

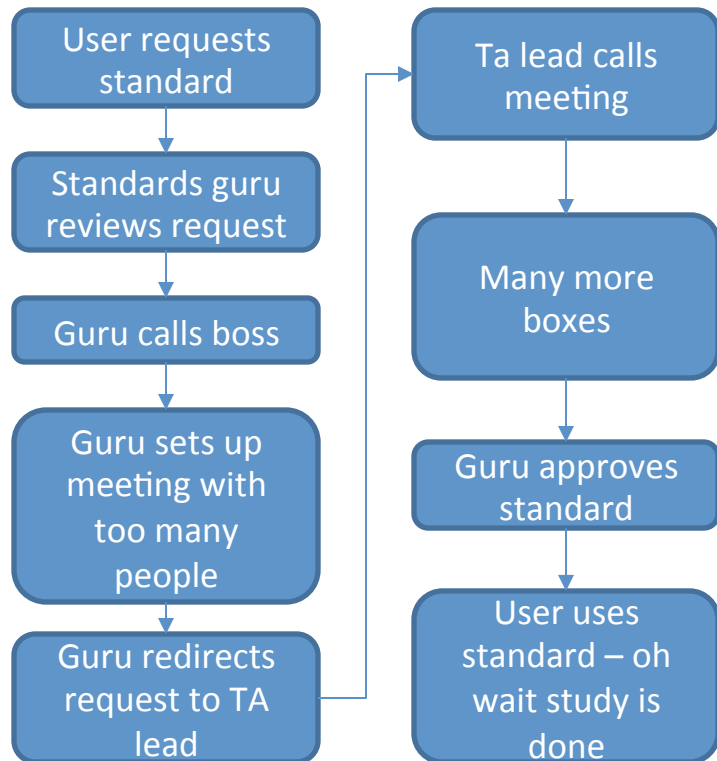


What the customer really needed

Problem with 'system' Reqs

- The system isn't important! It's the people using the system...
- "The system shall manage standards..."

Option 1:



Option 2:



Option 3...N:

Understanding the User



Need to change the mindset
and focus on the user need

Rewrite your 'Requirements'

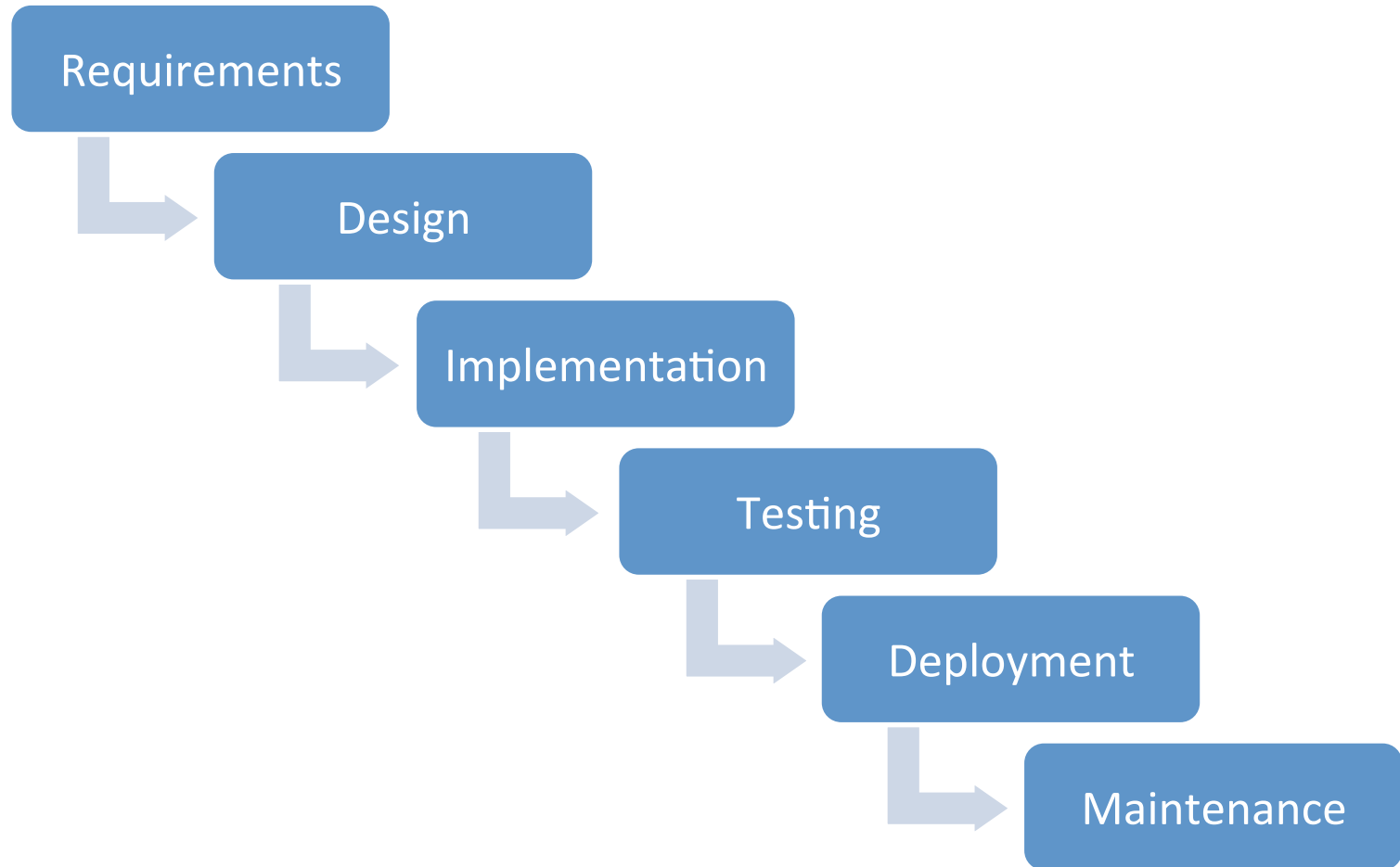
- As a standards manager I want to import the new version of SDTM so my study teams can use it in their studies
- As a study user I want to easily pull the standards metadata into my study so I can be aligned with the components required and meet regulatory requirements
- As a quality manager I need to compare my existing study specification to the company standard to make sure I submit data/metadata that is accurate
- As a Dad I want to get my son to clean his room so I don't kill him

CHALLENGING THE EVALUATION AND IMPLEMENTATION STATUS QUO

A Little Bit of History

- Pharma has been developing their own systems for 30-40 years
- Commercial tools were not available for such a highly specialized application
- At the time, software was developed mostly using waterfall methodology
- Waterfall methodology is perceived as being low-risk
 - We would challenge that it is actually high risk

Waterfall



Ongoing Issues

- Waterfall is a bad way to develop useful software
 - Agile and continuous delivery are ubiquitous now
- Software development methodology is not intended to evaluate software
 - Requirements tell software vendors how software should function rather than the problem the software needs to solve
 - This results in highly configurable software that is customized for each customer
- Enormous projects
- Bundled risk

So what then?

- Think small
- Focus on user needs driven by business tasks rather than specific system details
 - Seek out naïve individuals and experts
- Iterate
- Stay flexible
 - Essential when the problem space isn't well known
 - Ensure software you are evaluating allows for changes based on user feedback