



STRATEGY



DATA



CLOUD



PRIVACY



ANALYTICS

d-wise

Empowering innovation
for a healthier world

#KiITFLs

Chris Decker

d-wise

VP, Life Science

Chris.Decker@d-wise.com

March 11, 2019

Agenda

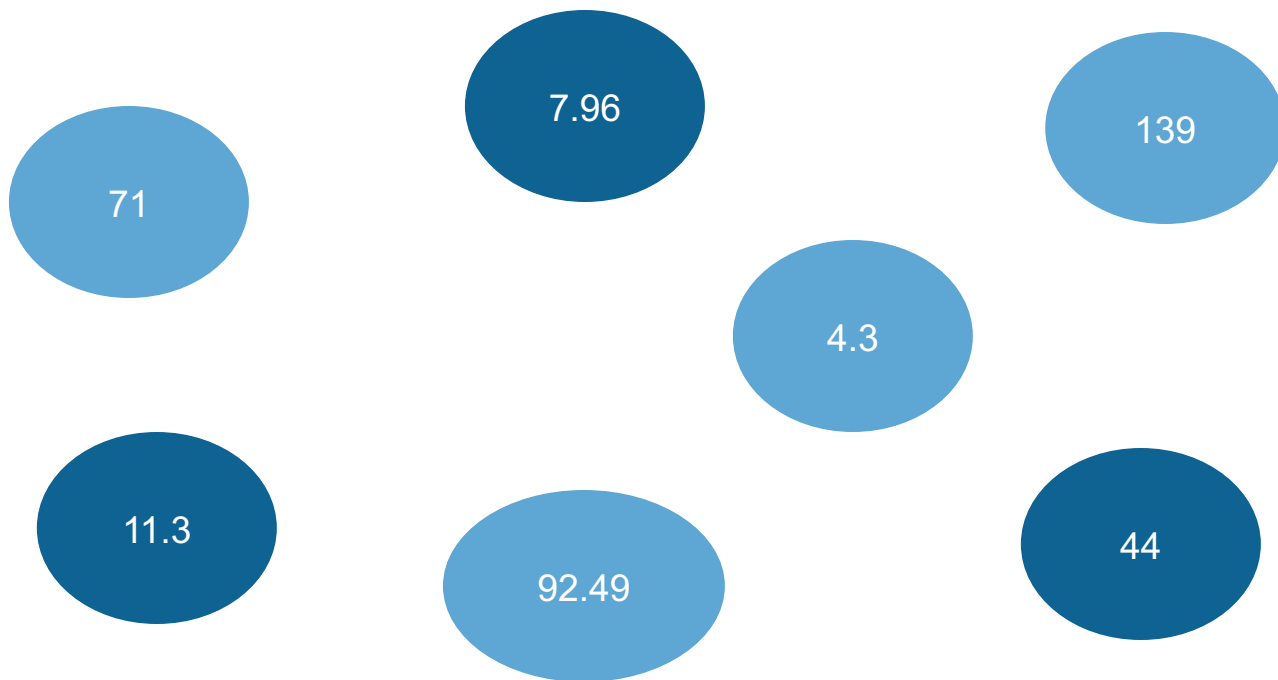
- 40 Years of the same thing
- What really defines an analysis
- Advantages of defining context
- Who is exploring this space
- How do we make it real?

Produce this same thing for 40 years

Demographic Summary		Page 1 of 2	
Intent-to-Treat Population		9:15 11JAN2018	
		DDDM	
Demographic Parameter		drug c (N=69)	drug b (N=71)
Sex	n*a	69	71
	F	31 (44.9)	39 (54.9)
	M	38 (55.1)	32 (45.1)
Age (yrs)	n*a	69	71
	Mean	56.49	58.24
	Std. Dev.	7.96	9.90
	Median	57.00	59.00
	Min	38.00	30.00
	Max	71.00	77.00
Race	n	69	71
	AMERICAN INDIAN OR ALASKA NATIVE	3 (4.3)	8 (11.3)
	ASIAN	2 (2.9)	0 (0.0)
	BLACK OR AFRICAN AMERICAN	6 (8.7)	7 (9.9)
	WHITE	55 (79.7)	55 (77.5)
	MULTIPLE	3 (4.3)	1 (1.4)
Ethnicity	n*a	69	71
	HISPANIC OR LATINO	20 (29.0)	23 (32.4)
	NOT APPLICABLE	5 (7.2)	4 (5.6)
	NOT HISPANIC OR LATINO	44 (63.8)	44 (62.0)
Weight (kg)	n*a	69	71
	Mean	93.27	92.49
	Std. Dev.	18.32	18.20
	Median	92.80	93.10
	Min	52.20	57.30
	Max	139.00	130.40
Abbreviations: N = number of subjects in population; n = number of subjects;			
NC = not calculable;			
*a = number of subjects with non-missing data, used as denominator			
Program Execution Location: [REDACTED]			
Output Execution Location: [REDACTED]			
Data Set Execution Location: [REDACTED]			



What do these numbers mean?



Context is Everything

	71	7.96	11.3	4.3	139	92.49	44
Is the number a count?	✓						✓
Is the number for drug C?		✓			✓		✓
Is the number in the ITT population?	✓	✓	✓	✓	✓	✓	✓
Is the number a statistic?		✓			✓	✓	
Is the number a percentage?			✓	✓			
Is the number for the Weight parameter?					✓	✓	

How can we leverage this information?

Summary of Demographics

Analyses in Display: [+ Add](#)

- See by Planned Treatment for Randomized Subjects w/ Non-Missing
- Age by Planned Treatment for Randomized Subjects
- Race by Planned Treatment for Randomized Subjects w/ Non-Missing
- Gender Weighted (Planned Treatment)

Tables: Demographic Summary, Randomized Population, N/A, N/A, 100%

Demographic Parameter	TREATMENT A (N=1000)	TREATMENT B (N=1000)
Sex n(%)	n/a	xx
	F	xx(100.0)
	M	xx(100.0)
	U	xx(100.0)
Age (years)	n/a	xx
	Mean	xx.x
	Median	xx.x
	Minimum	xx.x
	Standard Deviation	xx.x
Race n(%)	n/a	xx
	AMERICAN INDIAN OR ALASKA NATIVE	xx(100.0)
	ASIAN	xx(100.0)
	BLACK OR AFRICAN AMERICAN	xx(100.0)
	MULTIPLE	xx(100.0)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	xx(100.0)
	WHITE	xx(100.0)

Automating the Clinical Study Report

Dynamic Reports with Better Reporting Tools

11.2.2.2 Concomitant Medications and Concurrent Procedures

During the 12 months of followup, 9 patients (23.7%) had a concurrent procedure for treatment of AK: 8 (21.1%) had cryotherapy and 1 (2.6%) had micrographic skin surgery (Table 7 and Appendix 16.2, Listing 16.2.8.2.1). One patient (No. [REDACTED]) received a concomitant medication (oral prednisolone for polymyalgia rheumatica) that had immunosuppressant potential (Table 7 and Appendix 16.2, Listing 16.2.8.1.1).

Table 7 Summary of Concomitant Medications and Concurrent Procedures (CC57 Population)

PEP005 Gel, 0.05%	
Any Concurrent Procedures, n (%)	9 (23.7)
Cryotherapy, n (%)	8 (21.1)
Micrographic skin surgery, n (%)	1 (2.6)
Any Concomitant Medication, n (%)	1 (2.6%)
Prednisolone	1 (2.6%)

	Study1	Study2	Study3	Study4	Study5	Study6	Study7	Study8
Which studies analyzed blood pressure for females and display those analyses?	✓		✓	✓		✓		✓
Which of my studies collected a LOCF pain score analysis at week 8 and combine those analyses?	✓	✓	✓		✓		✓	
How many subjects were in my safety population across these 3 pivotal studies?	42	38	121	26	98	34	61	432

Simple and Powerful Cross Study Analyses

The Industry is dabbling - PhUSE

PhUSE 2015
Paper TT07

'Dude, where's my graph?' RDF Data Cubes for Clinical Trials Data.

Marc Andersen, StatGroup ApS, Denmark
Tim Williams, UCB BioSciences Inc, USA

ABSTRACT
The concept of Linked Data conjures images of effortlessly traversing from one data point to the next on a web of discovery. Contrast this with the seemingly countless number of subject-predicate-object triples and relationships in a Resource Description Framework (RDF) data source and comprehension of even familiar data becomes challenging. The added value of RDF can appear elusive without tools to facilitate data exploration and display.

This paper introduces approaches to visualizing RDF as Linked Data networks and presenting summary results. Visualization is a powerful tool for designing, exploring, and validating data models like the RDF Data Cubes. Tabular display enables presentation of the data and metadata. RDF provides traceability from source to result between visualization and tabular display allows new forms of data exploration. The suitability of RDF demonstrated by representing and displaying results for disposition, efficacy and adverse event data.

This paper is presented in support of the PhUSE Analysis Results & Metadata project.

Navigation trail: Statistics Ontologies for representing Analysis Results Model » ARMPublications » Analysis Results Model

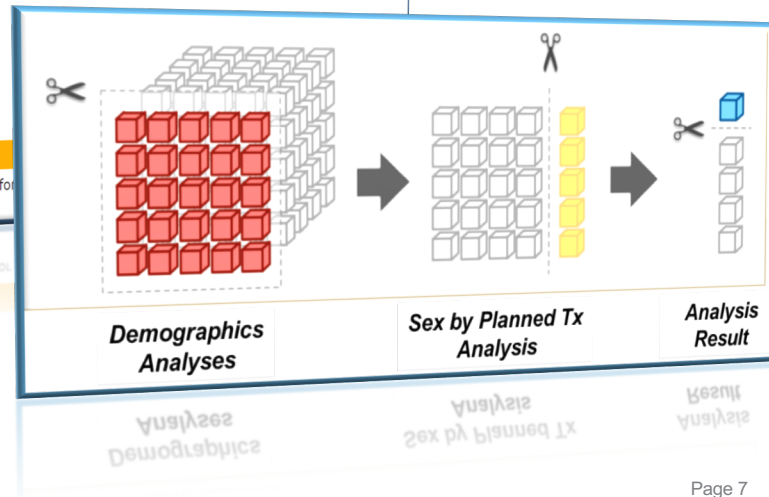
Analysis Results Model

Contents [hide]

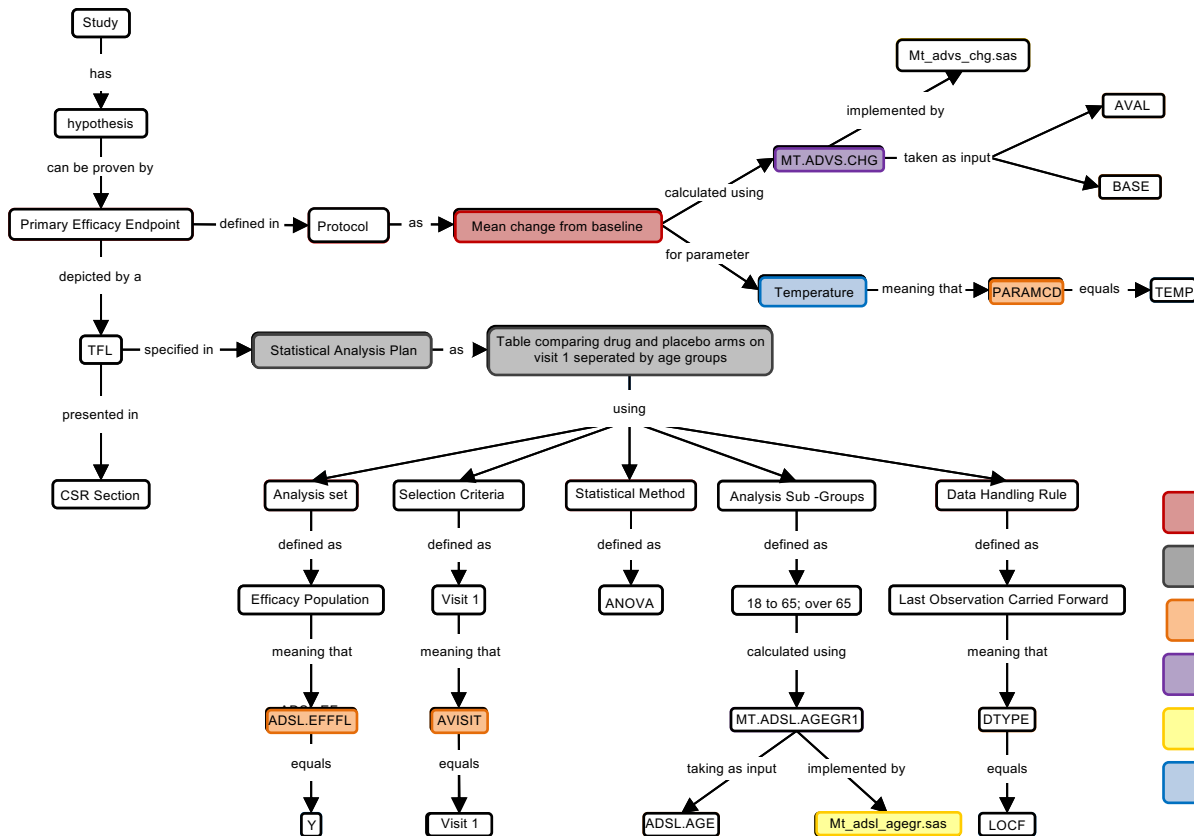
- 1 Project Overview
- 2 Project Leads
- 3 Project Participants
- 4 Project Rationale
- 5 Project Deliverables
- 6 Project Related Documents

Project Overview

- Development of standard models and technical standards for support clinical and non-clinical applications.



CDISC 360: Analysis Implementation Layer





STRATEGY



DATA



CLOUD



PRIVACY



ANALYTICS

d-wise

Empowering innovation
for a healthier world

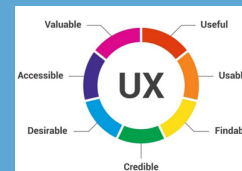
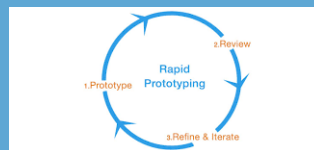
How do we Make this Happen?

d-wise Innovation Lab

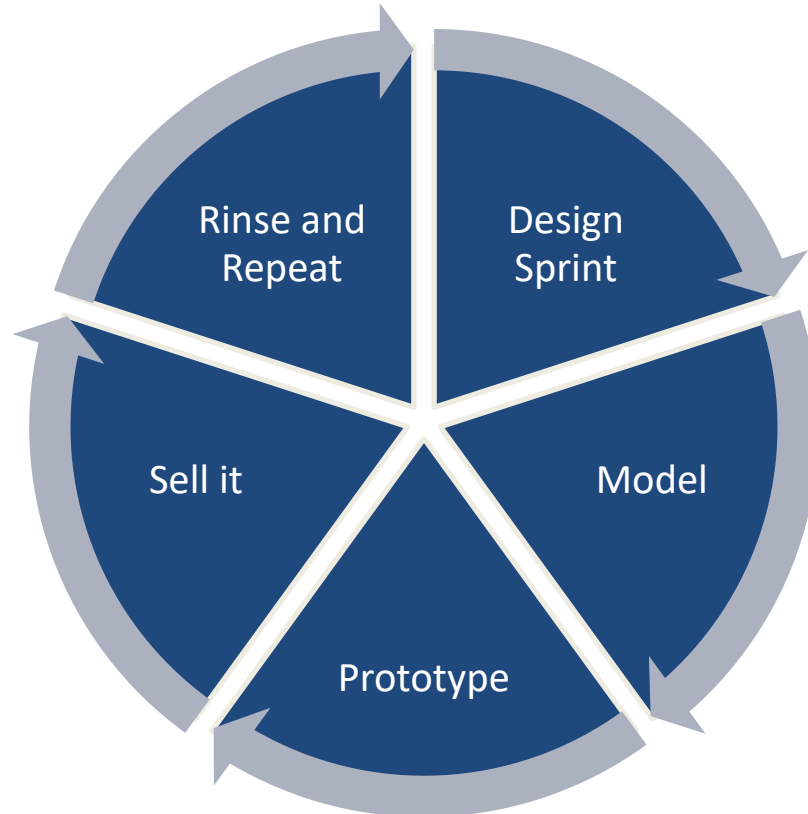
Tools



Methodologies



How do we approach the problem



For example...

Dimension	Label
<u>sponsorqb:dim.population</u>	Population
<u>sponsorqb:dim.treatment</u>	Treatment
<u>sponsorqb:dim.parameter</u>	Analysis Parameter
<u>sponsorqb:dim.visit</u>	Visit
<u>sponsorqb:dim.baseline</u>	Baseline Indicator
<u>sponsorqb:dim.statistic</u>	Statistic
<u>sponsorqb:dim.sex</u>	Sex
<u>sponsorqb:dim.agecat</u>	Age Category
<u>sponsorqb:dim.soc</u>	System Organ Class
<u>sponsorqb:dim.pt</u>	Preferred Term

qb: Observation	qb: Table	dim.population	dim.treatment	dim.parameter	dim.sex	dim.agecat	dim.statistic	analysisResult
1001	dm.summary	enrolled	Treatment.A	param.subjects	sex.ALL	agecat.ALL	stat.freq	100
1002	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.freq	60
1003	dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.percent	60
1004	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.freq	40
1005	dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.percent	40
1006	dm.summary	enrolled	Treatment.B	param.subjects	sex.ALL	agecat.ALL	stat.freq	50
1007	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.freq	30
1008	dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.percent	60
1009	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.freq	20
1010	dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.percent	40
1011	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.ALL	agecat.ALL	stat.freq	150
1012	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.freq	90
1013	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.percent	60
1014	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.freq	60
1015	dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.percent	40
1016	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.freq	100
1017	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.mean	40.7
1018	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.stdev	10.7
1019	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.median	37.0
1020	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.min	21.0
1021	dm.summary	tt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.max	66.0
1022	dm.summary	tt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.freq	50
1023	dm.summary	tt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.mean	41.2
1024	dm.summary	tt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.stdev	10.3
1025	dm.summary	tt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.median	36.0
1026	dm.summary	tt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.min	23.0

How do we make it real...



Let's get out of the ~~stone~~ paper age...



QUESTIONS