

d-wise

Empowering innovation for a healthier world



STRATEGY



DATA



CLOUD



PRIVACY



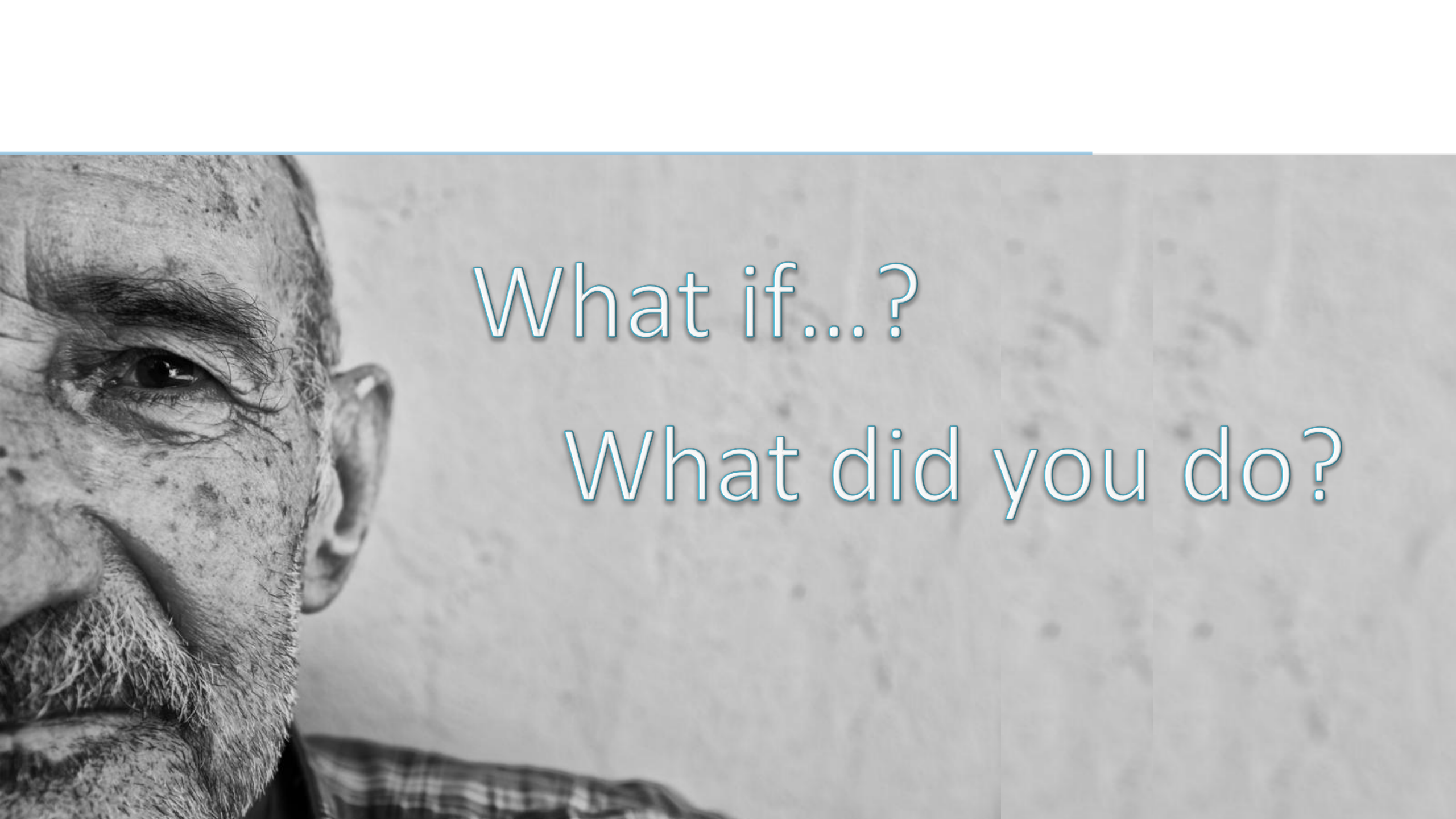
ANALYTICS

Moving Towards a Round World

PhUSE SDE: Crossing the Technical Frontier

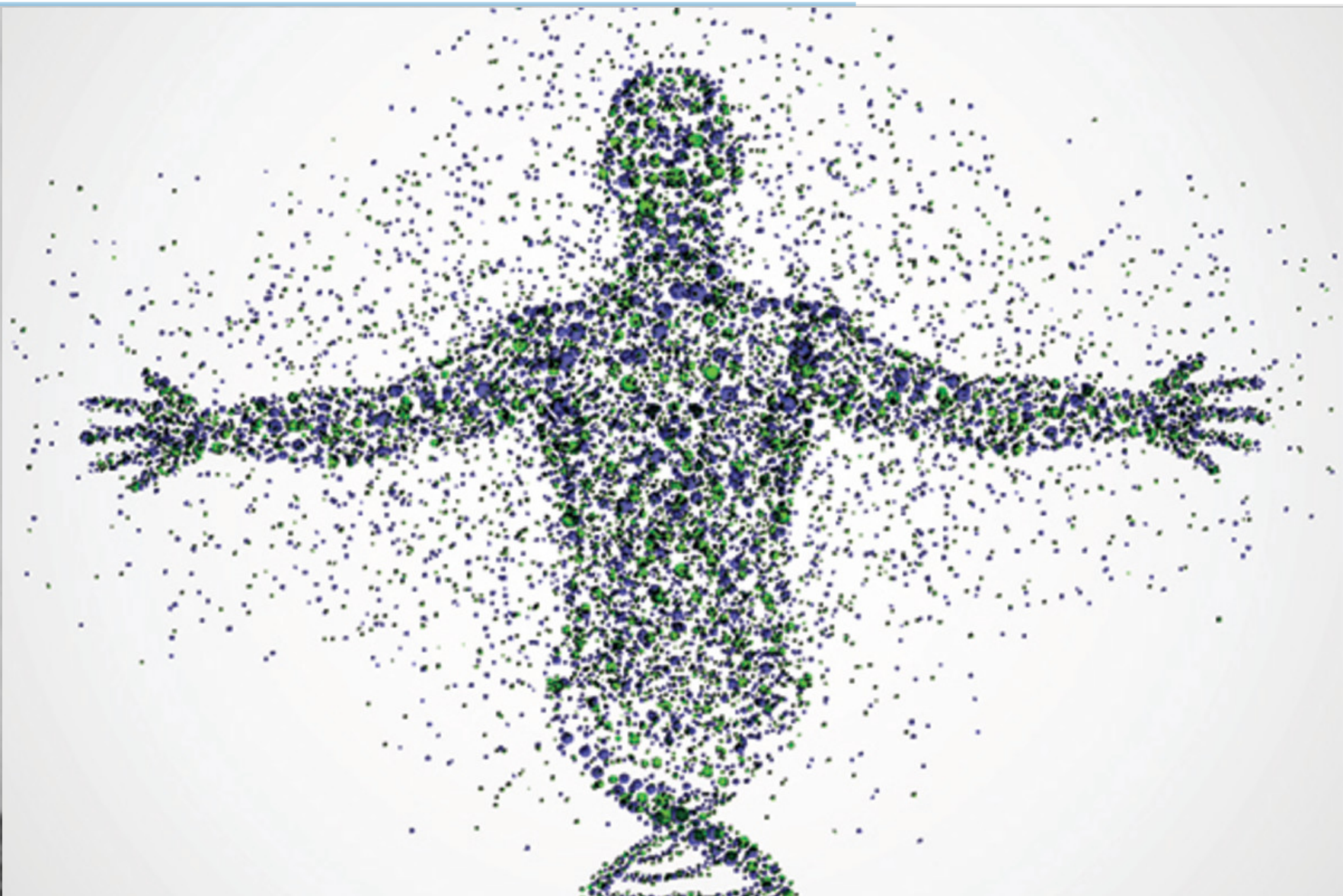
Agenda

- What is the problem?
- Connecting the dots
- Proving a concept
- Conclusion



What if...?

What did you do?



POC: More “Pleasurable” Specifications

Daffy

Study: h8a_je_lzak

+

AnalysisDisplaysData

Summary of Demographics

Edit Display DetailsExport Display

Analyses in Display

+ Add

Sex 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

Titles

Demographic Summary

Randomized Population

h8a_je_lzak

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

Ethnicity by Plan...

Planned Treatment for Ra...

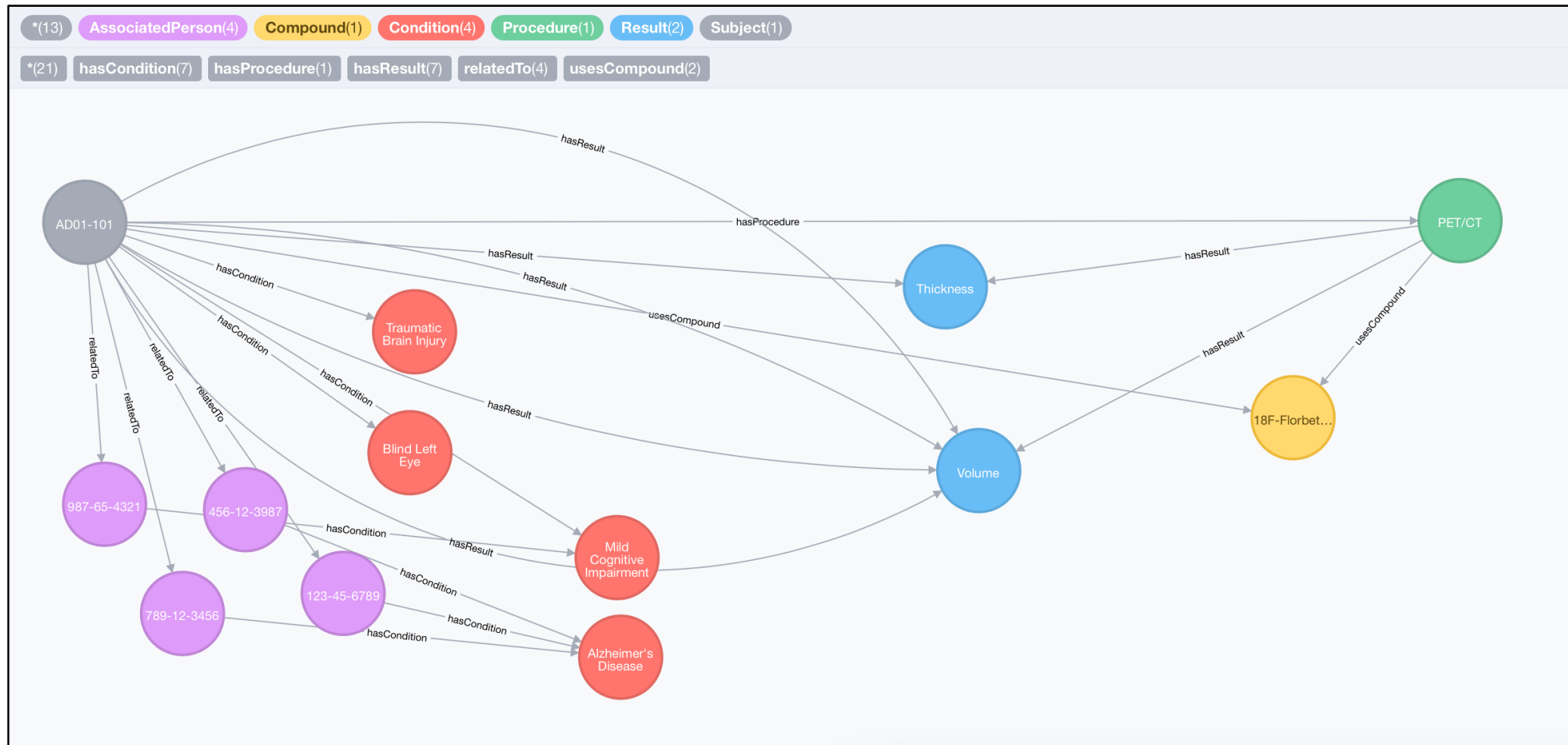
Race by Planned Tre...

Country by Planned

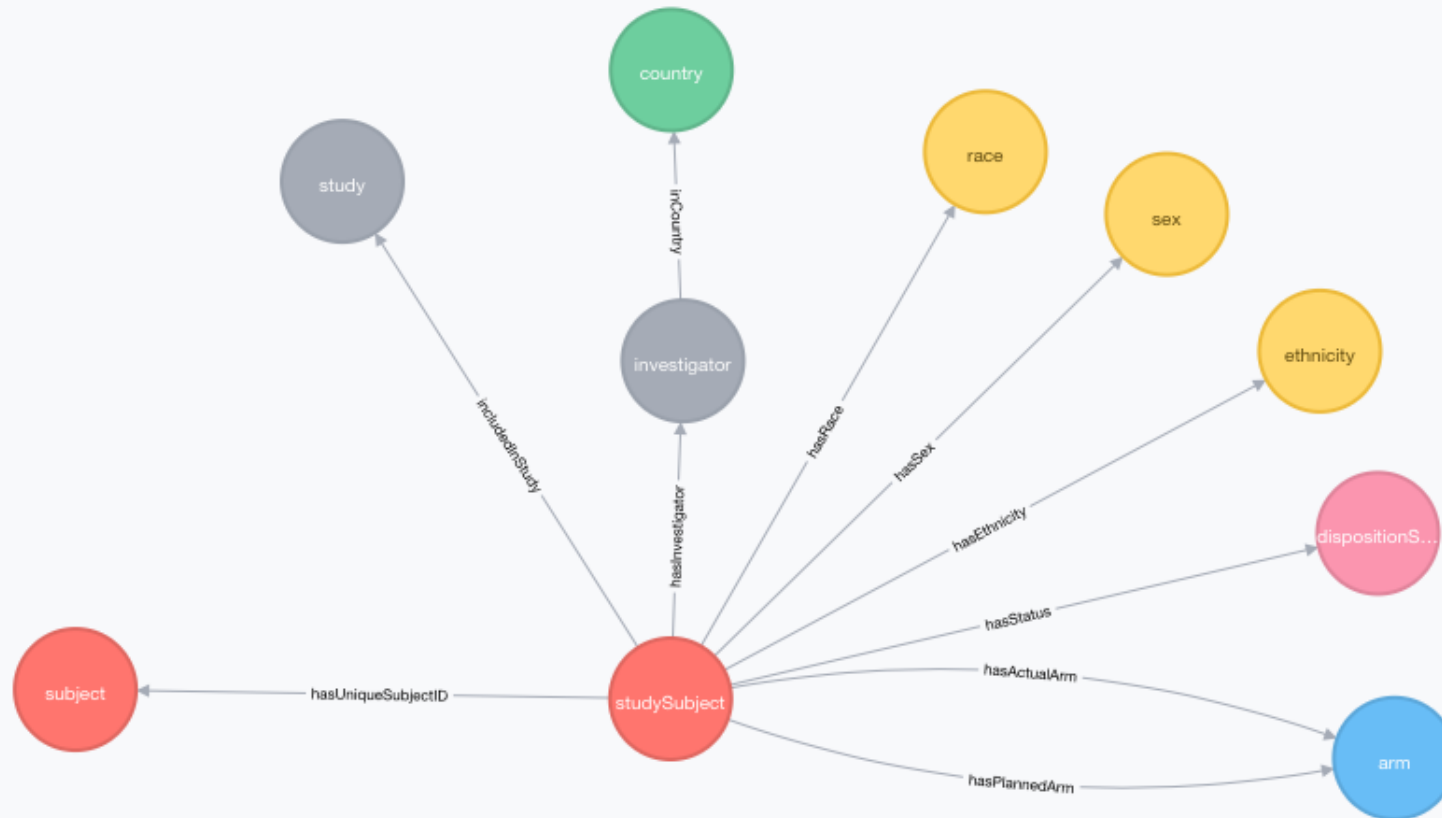
Metadata is not...



It's the data...



2017 PhUSE CSS Link-a-thon



Use Case 1: Extracting Data to SDTM

SDTM DM domain conformant to CDISC/PMDA rules

STUDYID	USUBJID	SUBJID	RFSTDT	RFENDTC	RFXSTDT	RFXENDTC	RFXPDTC	SITEID	AGE	AGEU	SEX	RACE	ETHNICITY	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY	DMDTC	DMDY
CDISCPLOT01	01-701-1015	1015	1/2/14	7/2/14	1/2/14	7/2/14	2014-07-02T11:45	701	63	YEARS	F	WHITE	HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	12/26/13	-7
CDISCPLOT01	01-701-1028	1028	7/19/13	1/14/14	7/19/13	1/14/14	2014-01-14T11:10	701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	7/11/13	-8
CDISCPLOT01	01-701-1047	1047	2/12/13	3/29/13	2/12/13	3/9/13	7/28/13	701	85	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	1/22/13	-21
CDISCPLOT01	01-701-1118	1118	3/12/14	9/9/14	3/12/14	9/9/14	2014-09-09T13:28	701	52	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/27/14	-13
CDISCPLOT01	01-701-1130	1130	2/15/14	8/16/14	2/15/14	8/16/14	2014-08-16T13:10	701	84	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/9/14	-6
CDISCPLOT01	01-701-1133	1133	10/28/12	4/29/13	10/28/12	4/28/13	2013-04-29T10:13	701	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	10/23/12	-5
CDISCPLOT01	01-701-1153	1153	9/23/13	4/1/14	9/23/13	3/16/14	2014-04-01T14:25	701	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/6/13	-17
CDISCPLOT01	01-701-1180	1180	2/12/13	3/23/13	2/12/13	3/18/13	4/7/13	701	56	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/28/13	-15
CDISCPLOT01	01-701-1181	1181	12/5/13	12/12/13	12/5/13	12/9/13	5/23/14	701	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Lo	Xanomeline Low Dose	USA	11/26/13	-9
CDISCPLOT01	01-701-1188	1188	2/15/13	3/25/13	2/15/13	3/24/13	8/4/13	701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	2/3/13	-12
CDISCPLOT01	01-701-1234	1234	3/30/13	9/22/13	3/30/13	9/22/13	2013-09-22T09:25	701	69	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	3/20/13	-10
CDISCPLOT01	01-701-1239	1239	1/11/14	7/11/14	1/11/14	7/10/14	2014-07-11T15:40	701	56	YEARS	M	WHITE	HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	12/28/13	-14
CDISCPLOT01	01-701-1275	1275	2/7/14	6/14/14	2/7/14	5/31/14	2014-06-14T12:35	701	61	YEARS	M	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/25/14	-13
CDISCPLOT01	01-701-1345	1345	10/8/13	3/18/14	10/8/13	3/18/14	2014-03-18T14:12	701	63	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	10/1/13	-7
CDISCPLOT01	01-701-1386	1386				1/7/14		701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	SCRNFAIL	Screen Failure			USA	12/28/13	

SDTM DM domain conformant to FDA rules

STUDYID	USUBJID	SUBJID	RFSTDT	RFENDTC	RFXSTDT	RFXENDTC	RFXPDTC	SITEID	AGE	AGEU	SEX	RACE	ETHNICITY	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY	DMDTC	DMDY
CDISCPLOT01	01-701-1015	1015	1/2/14	7/2/14	1/2/14	7/2/14	2014-07-02T11:45	701	63	YEARS	F	WHITE	HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	12/26/13	-7
CDISCPLOT01	01-701-1028	1028	7/19/13	1/14/14	7/19/13	1/14/14	2014-01-14T11:10	701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	7/11/13	-8
CDISCPLOT01	01-701-1047	1047	2/12/13	3/29/13	2/12/13	3/9/13	7/28/13	701	85	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	1/22/13	-21
CDISCPLOT01	01-701-1118	1118	3/12/14	9/9/14	3/12/14	9/9/14	2014-09-09T13:28	701	52	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/27/14	-13
CDISCPLOT01	01-701-1130	1130	2/15/14	8/16/14	2/15/14	8/16/14	2014-08-16T13:10	701	84	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/9/14	-6
CDISCPLOT01	01-701-1133	1133	10/28/12	4/29/13	10/28/12	4/28/13	2013-04-29T10:13	701	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	10/23/12	-5
CDISCPLOT01	01-701-1153	1153	9/23/13	4/1/14	9/23/13	3/16/14	2014-04-01T14:25	701	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/6/13	-17
CDISCPLOT01	01-701-1180	1180	2/12/13	3/23/13	2/12/13	3/18/13	4/7/13	701	56	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/28/13	-15
CDISCPLOT01	01-701-1181	1181	12/5/13	12/12/13	12/5/13	12/9/13	5/23/14	701	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Lo	Xanomeline Low Dose	USA	11/26/13	-9
CDISCPLOT01	01-701-1188	1188	2/15/13	3/25/13	2/15/13	3/24/13	8/4/13	701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	2/3/13	-12
CDISCPLOT01	01-701-1234	1234	3/30/13	9/22/13	3/30/13	9/22/13	2013-09-22T09:25	701	69	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	3/20/13	-10
CDISCPLOT01	01-701-1239	1239	1/11/14	7/11/14	1/11/14	7/10/14	2014-07-11T15:40	701	56	YEARS	M	WHITE	HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	12/28/13	-14
CDISCPLOT01	01-701-1275	1275	2/7/14	6/14/14	2/7/14	5/31/14	2014-06-14T12:35	701	61	YEARS	M	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/25/14	-13
CDISCPLOT01	01-701-1345	1345	10/8/13	3/18/14	10/8/13	3/18/14	2014-03-18T14:12	701	63	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	10/1/13	-7
CDISCPLOT01	01-701-1386	1386				1/7/14		701	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	SCRNFAIL				USA	12/28/13	

Use Case 2: Exploring Integrated Data

■ Which studies contain a placebo arm?

- match (s:study)-[*1..4]-(a:arm) where a.value contains "Placebo" return distinct s.studyNumber order by s.studyNumber

■ How many subjects are participating in multiples studies?

- match (s:subject)-[]-(ss:studySubject) with s, count(*) as nstudy where nstudy > 1 with s match (s)-[]-(ss:studySubject)-[]-(stdy:study) return s.uniqueSubjectID,stdy.studyNumber order by s.uniqueSubjectID,stdy.studyNumber ;

Use Case 3: Adding New Information to the Graph

■ I need to add a new indicator that a sites 701, 703, and 707 have violated best practices

- `match (n:investigator) where n.siteID in ['701', '703', '707'] set n.violation='Y' return n ;`



Use Case 3: Extracting to SDTM

■ SDTM DM domain with Site Deviation Flag

STUDYID	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFXPDTCT	SITEID	SITEDV	AGE	AGEU	SEX	RACE	ETHNICITY	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY	DMDTC	DMDY
CDISCP10T01	01-701-1015	1015	1/2/14	7/2/14	1/2/14	7/2/14	2014-07-02T11:45	701	Y	63	YEARS	F	WHITE	HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	12/26/13	-7
CDISCP10T01	01-701-1028	1028	7/19/13	1/14/14	7/19/13	1/14/14	2014-01-14T11:10	701	Y	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	7/11/13	-8
CDISCP10T01	01-701-1047	1047	2/12/13	3/29/13	2/12/13	3/9/13	7/28/13	701	Y	85	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	1/22/13	-21
CDISCP10T01	01-701-1118	1118	3/12/14	9/9/14	3/12/14	9/9/14	2014-09-09T13:28	701	Y	52	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/27/14	-13
CDISCP10T01	01-701-1130	1130	2/15/14	8/16/14	2/15/14	8/16/14	2014-08-16T13:10	701	Y	84	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	2/9/14	-6
CDISCP10T01	01-701-1133	1133	10/28/12	4/29/13	10/28/12	4/28/13	2013-04-29T10:13	701	Y	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	10/23/12	-5
CDISCP10T01	01-701-1153	1153	9/23/13	4/1/14	9/23/13	3/16/14	2014-04-01T14:25	701	Y	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/6/13	-17
CDISCP10T01	01-701-1180	1180	2/12/13	3/23/13	2/12/13	3/18/13	4/7/13	701	Y	56	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/28/13	-15
CDISCP10T01	01-701-1181	1181	12/5/13	12/12/13	12/5/13	12/9/13	5/23/14	701	Y	79	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Lo	Xanomeline Low Dose	USA	11/26/13	-9
CDISCP10T01	01-701-1188	1188	2/15/13	3/25/13	2/15/13	3/24/13	8/4/13	701	Y	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	2/3/13	-12
CDISCP10T01	01-701-1234	1234	3/30/13	9/22/13	3/30/13	9/22/13	2013-09-22T09:25	701	Y	69	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	3/20/13	-10
CDISCP10T01	01-701-1239	1239	1/11/14	7/11/14	1/11/14	7/10/14	2014-07-11T15:40	701	Y	56	YEARS	M	WHITE	HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	12/28/13	-14
CDISCP10T01	01-701-1275	1275	2/7/14	6/14/14	2/7/14	5/31/14	2014-06-14T12:35	701	Y	61	YEARS	M	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/25/14	-13
CDISCP10T01	01-701-1345	1345	10/8/13	3/18/14	10/8/13	3/18/14	2014-03-18T14:12	701	Y	63	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	10/1/13	-7
CDISCP10T01	01-701-1386	1386					1/7/14	701	Y	71	YEARS	M	WHITE	NOT HISPANIC OR LATINO	SCRNFAL	Screen Failure			USA	12/28/13	
CDISCP10T01	01-701-1392	1392	10/28/12	4/28/13	10/28/12	4/28/13	2013-04-28T11:30	701	Y	78	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	10/17/12	-11
CDISCP10T01	01-701-1440	1440	8/8/13	2/5/14	8/8/13	2/5/14	2014-02-05T11:25	701	Y	70	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	7/24/13	-15
CDISCP10T01	01-703-1096	1096	1/25/13	3/29/13	1/25/13	3/16/13	3/29/13	703	Y	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	12/19/12	-37
CDISCP10T01	01-703-1119	1119	2/20/13	6/13/13	2/20/13	6/13/13	8/24/13	703	Y	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	2/2/13	-18
CDISCP10T01	01-703-1295	1295	11/21/13	5/19/14	11/21/13	4/19/14	2014-05-19T14:45	703	Y	88	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	10/24/13	-28
CDISCP10T01	01-703-1299	1299	9/12/12	3/13/13	9/12/12	3/13/13	3/27/13	703	Y	81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/7/12	-5
CDISCP10T01	01-703-1335	1335	3/17/14	5/24/14	3/17/14	5/7/14	2014-05-24T12:15	703	Y	67	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	2/28/14	-17
CDISCP10T01	01-704-1065	1065	10/24/13	12/24/13	10/24/13	12/22/13	2/17/14	704		75	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	10/17/13	-7
CDISCP10T01	01-704-1074	1074	1/22/14	3/31/14	1/22/14	3/20/14	2014-03-31T10:30	704		80	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	1/19/14	-3
CDISCP10T01	01-704-1114	1114	1/23/13	7/8/13	1/23/13	7/7/13	2013-07-08T09:56	704		77	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	1/9/13	-14
CDISCP10T01	01-704-1127	1127	10/2/13	3/31/14	10/2/13	3/31/14	2014-03-31T11:30	704		84	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/16/13	-16
CDISCP10T01	01-704-1164	1164	9/19/12	4/4/13	9/19/12	4/4/13	4/4/13	704		67	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/11/12	-8
CDISCP10T01	01-704-1218	1218	11/19/12	5/27/13	11/19/12	5/27/13	2013-05-27T11:20	704		81	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	11/11/12	-8
CDISCP10T01	01-704-1260	1260	8/30/12	1/18/13	8/30/12	11/4/12	1/18/13	704		71	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	8/23/12	-7
CDISCP10T01	01-704-1323	1323	7/8/13	8/8/13	7/8/13	8/5/13	10/1/13	704		68	YEARS	F	WHITE	NOT HISPANIC OR LATINO	Xan_Lo	Xanomeline Low Dose	Xan_Lo	Xanomeline Low Dose	USA	6/13/13	-25
CDISCP10T01	01-704-1332	1332	12/9/13	2/16/14	12/9/13	2/14/14	2/24/14	704		80	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Xan_Hi	Xanomeline High Dose	Xan_Hi	Xanomeline High Dose	USA	11/24/13	-15
CDISCP10T01	01-704-1351	1351	10/12/13	4/18/14	10/12/13	4/18/14	2014-04-18T10:30	704		70	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	9/26/13	-16
CDISCP10T01	01-704-1435	1435	11/17/12	1/12/13	11/17/12	1/9/13	2013-01-12T12:00	704		74	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	11/1/12	-16
CDISCP10T01	01-704-1445	1445	5/11/14	11/1/14	5/11/14	11/1/14	11/1/14	704		75	YEARS	M	WHITE	NOT HISPANIC OR LATINO	Pbo	Placebo	Pbo	Placebo	USA	5/1/14	-10

Food for thought...



Scott Bahlavooni
Sr. Consultant d-wise
scott.bahlavooni@d-wise.com

THANK YOU!

“This is just an Academic exercise”

- Actually it's not! Other industries are leveraging these technologies to store and leverage relationships
- CDISC (based on 2-dimension SAS data structure) in it's current incarnation is outdated and needs to be retired
- Need to focus on the next generation data standards
- Customer are exploring and building solutions using these tools
- Time to be dragged into the 21st century and pick up new tools!