



2024 CDISC KOREA
INTERCHANGE

SEOUL

12-13 NOVEMBER: CONFERENCE & EXPO | 11, 14, 15 NOVEMBER: TRAININGS

USDM in Action: From Protocol to SDTM

Dave Iberson-Hurst
data4knowledge ApS



Meet the Speaker

Dave Iberson-Hurst

Title: Partner

Organization: data4knowledge ApS

40+ years' experience across several industries with the last 20 years spent in the pharmaceutical industry combining his technology and software development experience with clinical data standards. During this time, he has served as the CDISC CTO, worked on, and led, several CDISC teams, presented in many forums in Europe, the US, and elsewhere across the globe.

He has worked closely with the FDA, EMA, HL7, ISO, and other standards organizations and was a member of CDISC's Blue Ribbon commission. He is currently the CDISC Product Owner for the Digital Data Flow project.

He is a partner at data4knoweldge in Copenhagen and is focused on getting greater value and utility from clinical trial data



Meet the Contributors

Kirsten Walther Langendorf

Title: Partner

Organization: data4knowledge ApS

20+ years' experience in the pharmaceutical industry within programming, IT implementation & validation, process improvement, CDISC standards implementation, and statistics.

As partner at data4knowledge in Copenhagen, she has been involved in implementing various e2e metadata driven systems based on linked data technologies.



Johannes Ulander

Title: Partner

Organization: data4knowledge ApS

20+ years' experience in standardizing clinical data and have been involved in implementing CDISC standards from an end-to-end perspective for the last 15 years. For the last 7 years by using linked data and graph databases.

He is a partner at data4knowledge in Umeå and an authorized CDISC SDTM instructor.

Disclaimer and Disclosures

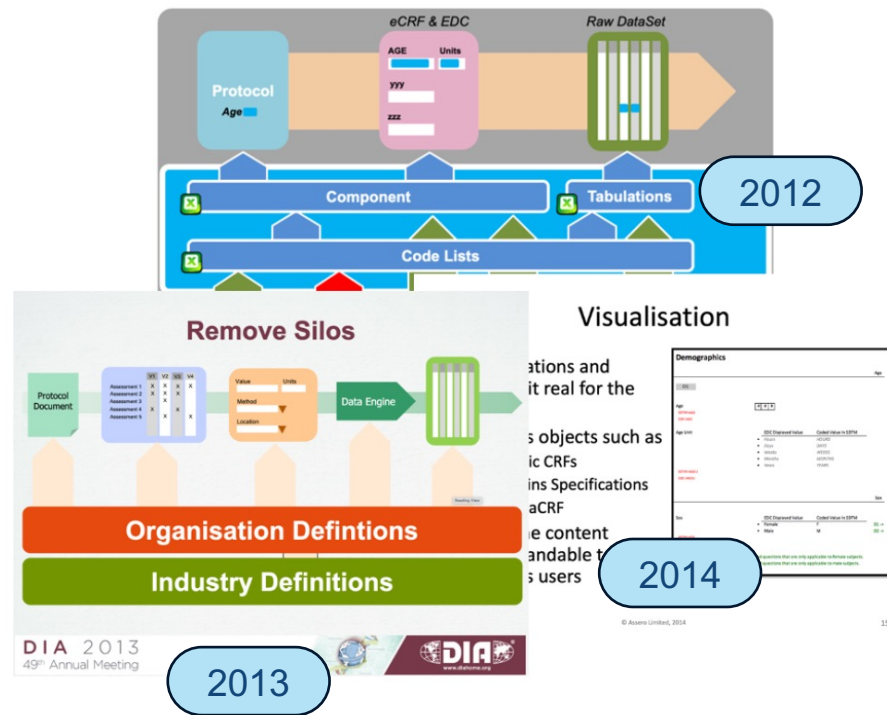
- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *I am a contractor to CDISC as the DDF USDM Product Owner*

IMPORTANT

This talk is presented on behalf of data4knowledge ApS and is about using the USDM as the foundation for much of what we do and the potential for the removal of silos and automation. It is about the sharing of ideas.

Old Ideas Whose Time Has Come

- We [industry] have been looking at removing silos for a decade or more
- We have been looking at “eProtocol” for probably two decades or more
- DDF, USDM, ICH M11, precisionFDA ... all these initiatives / standards are making it a reality





We help our customers make better use of their primary asset, the clinical data.

Contact

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Overview

Over the past few years, the partners at d4k have worked on ways in which the handling of data can be improved, silos removed, and automation increased. But showing these ideas in action requires more than a few slides. To this end, we at d4k have built a demonstrator to illustrate the potential of using the Unified Study Definitions Model (USDM) with Biomedical Concepts (BCs) providing the foundation for the automation of downstream processes that industry has been lacking.

The demonstrator implements USDM version 3, CDISC Biomedical Concepts, CDISC Controlled Terminology, CDISC SDTM, and the emerging ICH M11 CeSHARP eProtocol standards to illustrate how the detailed study definition provides the foundation to link subject data to the study design thus allowing the automated generation of SDTM without the need for any programming. This same design can also be used for the generation of submission artefacts and this poster discusses how an implementation based upon the USDM can serve multiple purposes.

Key Takeaways:

- USDM is the foundation industry has been missing
- USDM opens the door to multiple new innovations and approaches
- The TransCelerate end-to-end Digital Data Flow vision is achievable today

One Model: USDM at the Centre

Study Design

The technology demonstrator implements a single linked model. The heart of the model is provided by the USDM.

The USDM provides the ability to define the overall study design and logic and provides the foundation for everything that follows.



Study Detail

Biomedical Concepts are already linked into the USDM and provide the necessary detail and precision not normally found in existing, paper, protocols. BCs define the data to be collected and provide the basis for the data contract, the data needed to meet the study's needs



Operational Data

The USDM contains some site information, but this is related to amendments and recruitment. This information is expanded to include more details needed to link subject data into the model.



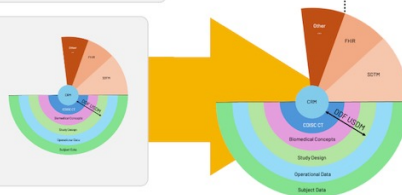
Subject Data

We now have a full study definition to which subject data can be linked. This then creates a single linked graph containing both the study design plus the data; no more silos!



SDTM & Other Exports

We can now link SDTM to the data. The SDTM is linked to a small model (the CRM) that models the intricacies of observations. This model is also linked to the BCs (in fact BCs should be based on this model) such that there is a link from data to BC to SDTM. A similar approach can be taken with other data exports



Technology Demonstrator

The technology demonstrator implements the model described here and then populates it with data to show the concepts working.

We have leveraged the test data provided by the TransCelerate / CDISC DDF project taking the LZ27 protocol and associated raw data and loading these data into a single model. From that we can automatically extract SDTM, aCRF and define.xml. Data capture instruments can also be driven from the metadata

Future work will look at such topics as subject and site burden, study risk and study cost.

Scan the QR code to see a video of the demonstrator in action



Views

The expanded USDM model can serve many purposes. Many of the artefacts required within clinical development are simply extracts, exports or views, of one consistent and linked set of data.

Protocol: The entire protocol can be extracted, either in a sponsor template or the M11 template.

Specific Views: Tailored views for specific roles, e.g. EDC build, data monitoring, can be accommodated.

EDC: Machine and human readable exports for EDC configuration.

CRF & Define: Data capture specifications, aCRFs and Define.xml can be generated from the model prior to a single data point being captured.

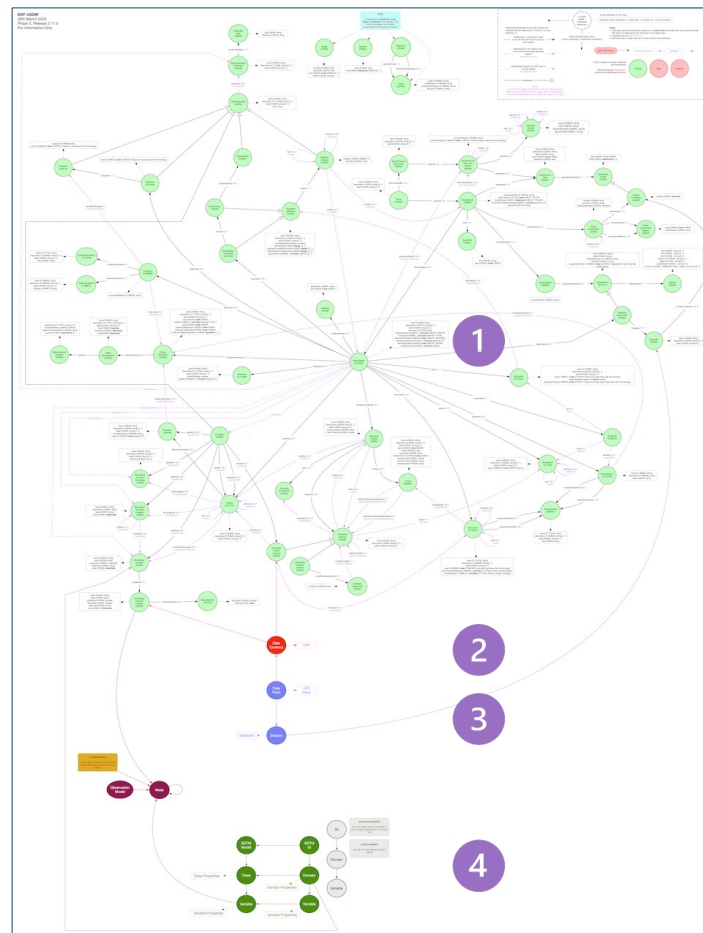
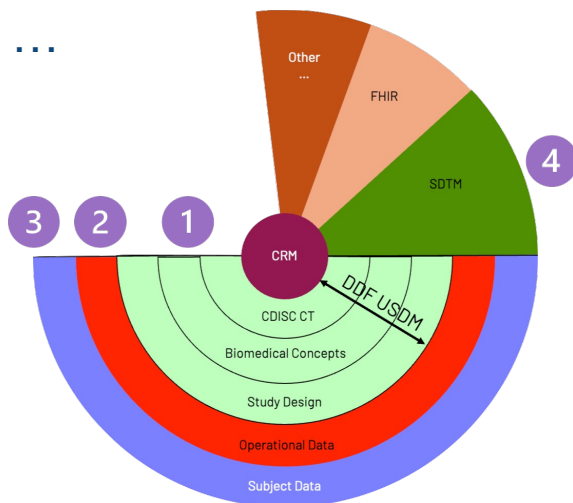
SDTM: As already noted the model supports the automated generation of SDTM datasets capable of supporting multiple versions of SDTMIG.

And many more: The expanded USDM model is not limited to the above exports or views. Many other use cases and exports could be envisaged such as subject journey, site risk, TMF and CTMS.

USDM as the Foundation

1. USDM is the foundation
2. Add the “data contract”
3. Attach subjects and their data
4. Link to SDTM

... and use ...



Technology Demonstrator

- A Powerpoint just doesn't do the job
- Need to see the ideas in action
- Implemented in Python, FastAPI with a Neo4j database
- Has a basic User Interface (UI)
- We are continuing to work on it



DM Domain Data

Data queried from the database for the Demographics domain

CDISC ID	DOMAIN	USUBJID	SUBJID	RFXSTDTC	RFXENDTC	RFICDTC	DTHDTC	DTHFL	SITEID	INVID	INVNAM
R2Q-MC-001	DM	702-1	02-1			2024-10-18T09:12			702		
R2Q-MC-002	DM	CDISC001	C001	2012-11-30	2012-12-13	2012-11-23			701		
R2Q-MC-003	DM	CDISC002	C002	2012-11-15	2012-11-28	2012-10-30			701		
R2Q-MC-004	DM	CDISC003	C003	2013-08-29	2013-09-11	2013-08-20			701		
R2Q-MC-005	DM	CDISC004	C004	2013-10-08	2013-10-21	2013-10-01			701		
R2Q-MC-006	DM	CDISC005	C005	2013-02-04	2013-08-04	2013-01-22			701		
R2Q-MC-007	DM	CDISC006	C006	2013-03-19	2013-04-01	2013-02-25			701		
R2Q-MC-008	DM	CDISC007	C007	2013-01-05	2013-01-18	2012-12-31			701		
R2Q-MC-009	DM	CDISC008	C008	2014-05-11	2014-05-24	2014-05-01			701		
R2Q-MC-010	DM	CDISC009	C009	2012-10-22	2013-04-21	2012-10-06			701		
R2Q-MC-011	DM	CDISC010	C010	2013-09-01	2013-09-01	2013-09-01			701		

Paper to eProtocol using USDM

2. Objectives

2.1. Primary Objectives

The primary objectives of this study are

- To determine if there is a statistically significant relationship (overall Type 1 error rate, $\alpha=0.05$) between the change in both ADAS-Cog (see Attachment LZTZ.2) and CIBIC+ (see Attachment LZTZ.3) scores, and drug dose (0, 50 cm² [54 mg], and 75 cm² [81 mg]).
- To document the safety profile of the xanomeline TTS.

2.2. Secondary Objectives

The secondary objectives of this study are

- To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas (see Attachment LZTZ.4).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will

Protocol Attachment LZTZ.1
Schedule of Events for Protocol H2Q-MC-LZTZ(c)

ACTIVITY	VISIT	1	2	3	4	5	7	8
	WEEK	-2	-3	0	2	4	6	8
Informed consent		X						
Patient number assigned		X						
Hachinski 54		X						
MMSE 10-23		X						
Physical examination		X						
Medical History		X						
Habits		X						
Chest x-ray		X						
Apo E genotyping					X			
Patient randomized				X				
Vital Signs/Temperature		X	X	X	X	X	X	X
Ambulatory ECG placed			X					
Ambulatory ECG removed				X				
ECG		X			X	X	X	X
Placebo TTS test		X						

cdisc USDM
UNIFIED STUDY DEFINITIONS MODEL (DDF)

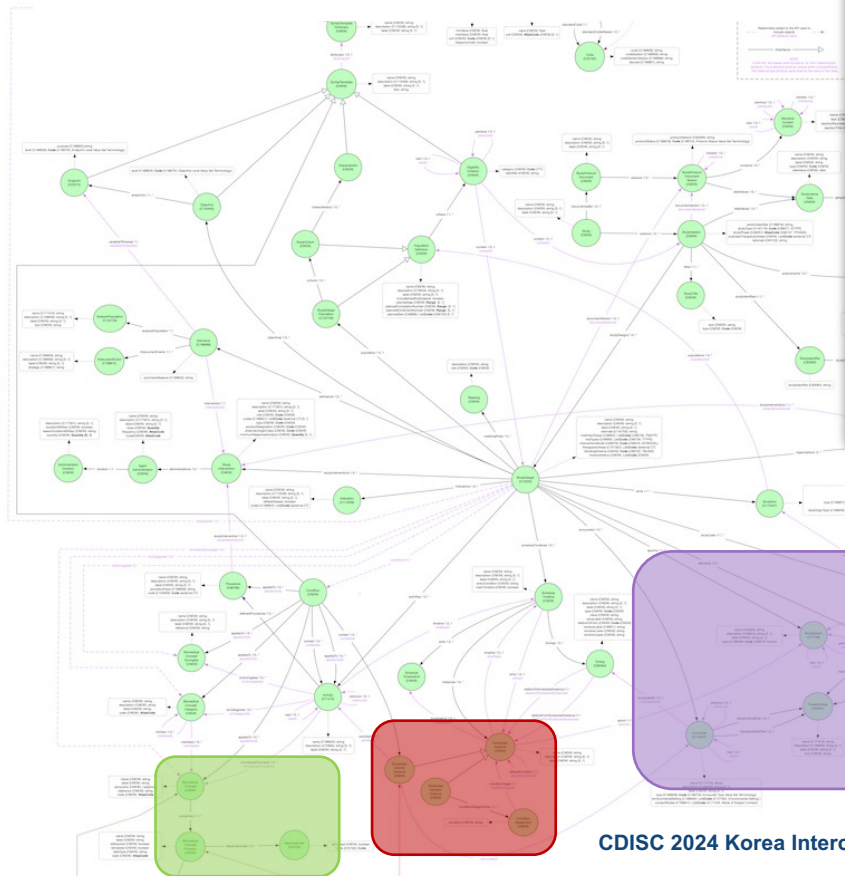
Screening	Screening	Treatment One	Treatment One	Treatment Two	Treatment Two	Treatment Two	Treatment Two	Treatment Two	Treatment Two	Treatment Two	Treatment Two	Treatment Two
1	2	1	2	1	2	3	4	5	6	7	8	9
None	-4.0 hours	None	-3.3 days	-3.3 days	-3.3 days	-3.3 days	-3.3 days	-3.3 days	-4.4 days	-4.4 days	-4.4 days	-4.4 days

Notes

- Reusing the work from the CDISC DDF / USDM project and the Microsoft Excel load files
- Using the CDISC Pilot Study LZTZ
- Using USDM v3.0

The Detailed Design

DDF USDM
2018 March
Phase 2.0a
For Review



d4k Study Browser STUDIES STATUS

Study Details

	Screening 1	Screening 2	Treatment One Baseline	Treatment One Week 2	Treatment Two Week 4	Treatment Two Week 6	Treatment Two Week 8
	None	-4.0 hours	None	-3.3 days	-3.3 days	-3.3 days	-3.3 days

Informed consent X

Inclusion and exclusion criteria X

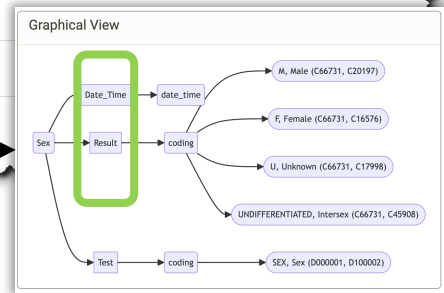
Patient number assigned X

Demographics X

BiomedicalConcept: Race

BiomedicalConcept: Sex

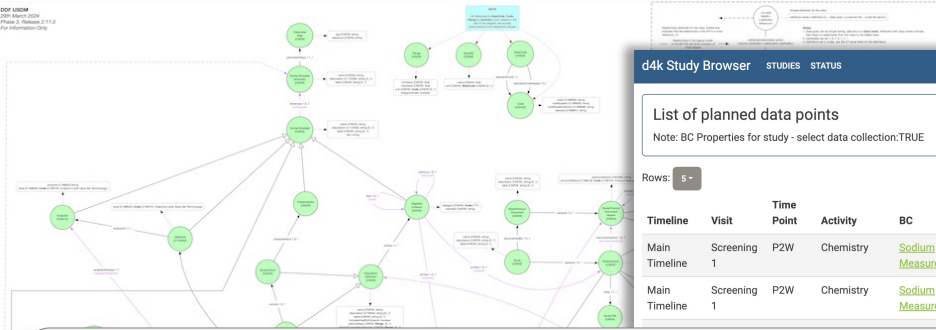
Demographics
BiomedicalConcept: Race
BiomedicalConcept: Sex



- Notes
- USDM provides the solid foundation
 - Provides the SoA
 - Provides the SoA+ (SoA plus observations)

Add in a "Data Contract"

SDS USDP
20th March 2024
Please do not reuse this ID
For Information Only



d4k Study Browser STUDIES STATUS

List of planned data points
Note: BC Properties for study - select data collection:TRUE

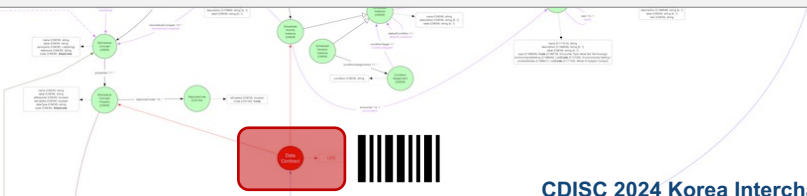
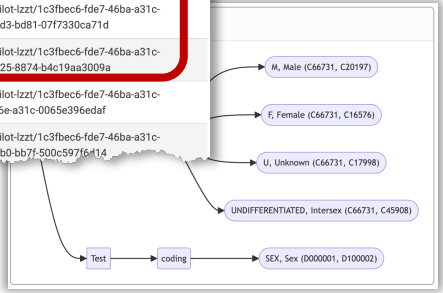
Rows: 5 -

Begin typing to search ...

Timeline	Visit	Time Point	Activity	BC	Property	Data Contract URI
Main Timeline	Screening	P2W	Chemistry	Sodium Measurement	Laboratory Test Fasting Status	https://study.d4k.dk/study-cdisc-pilot-lztt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/04f1ee66-aa3d-4f6f-8cf9-5dece3dc05e2
Main Timeline	Screening	P2W	Chemistry	Sodium Measurement	Laboratory Test Result	https://study.d4k.dk/study-cdisc-pilot-lztt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/a268e144-e432-44d3-bd81-077f330ca71d
					Molarity Unit	https://study.d4k.dk/study-cdisc-pilot-lztt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/04c930d3-1ada-4725-8874-b4c19aa3009a
						https://study.d4k.dk/study-cdisc-pilot-lztt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/c1436f0d-6d37-496e-a31c-0065e396daf
						https://study.d4k.dk/study-cdisc-pilot-lztt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/3b240e92-3dc6-42b0-bb7f-500c597f6f14

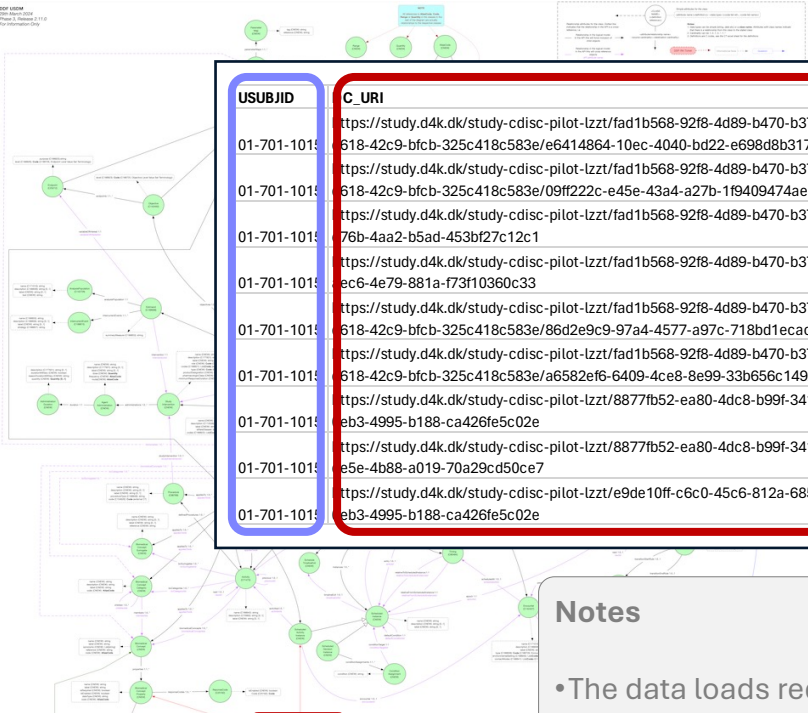
Notes

- The data contract is the set of data points needed to meet the needs of the study.
- Expands the SoA+ (e.g. observations repeated across visits)
- The URI is the barcode for a single atomic data point, a unique identifier that persists forever.
- Can be used for multiple purposes: external data providers, long term retention of data ...



Link the Subject Data

SDP USDM
 2024-08-08
 11:10
 11/11/2024



USUBJID	C_URI	DATAPOINT_URI	VALUE
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/e6414864-10ec-4040-bd22-e698d8b31790	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/e6414864-10ec-4040-bd22-e698d8b31790/01-701-1015	64
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/09ff222c-e45e-43a4-a27b-1f9409474ae8	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/09ff222c-e45e-43a4-a27b-1f9409474ae8/01-701-1015	mmHg
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/15ece647-e76b-4aa2-b5ad-453bf27c12c1	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/15ece647-e76b-4aa2-b5ad-453bf27c12c1/01-701-1015	58.00.00
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01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/86d2e9c9-97a4-4577-a97c-718bd1ecac5a	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/86d2e9c9-97a4-4577-a97c-718bd1ecac5a/01-701-1015	57
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/a6582ef6-6409-4ce8-8e99-33b656c1492b	https://study.d4k.dk/study-cdisc-pilot-lztt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/eed3c040-d618-42c9-bfcb-325c418c583e/a6582ef6-6409-4ce8-8e99-33b656c1492b/01-701-1015	BEATS/MIN
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e	https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015	41
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/1b2e1fa0-de5e-4b88-a019-70a29cd50ce7	https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/1b2e1fa0-de5e-4b88-a019-70a29cd50ce7/01-701-1015	U/L
01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lztt/e9de10ff-c6c0-45c6-812a-685d20747ce7/4b7708f0-0eb3-4995-b188-ca426fe5c02e	https://study.d4k.dk/study-cdisc-pilot-lztt/e9de10ff-c6c0-45c6-812a-685d20747ce7/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015	45

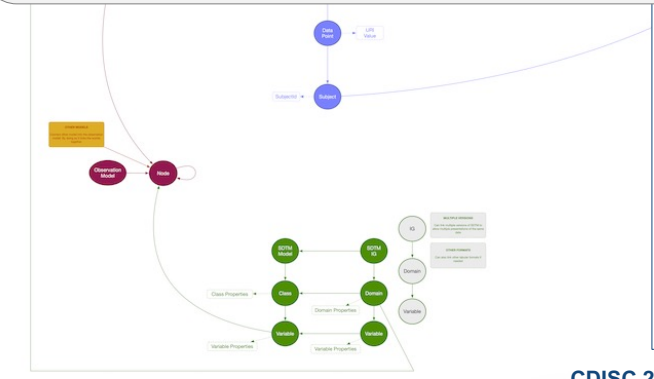
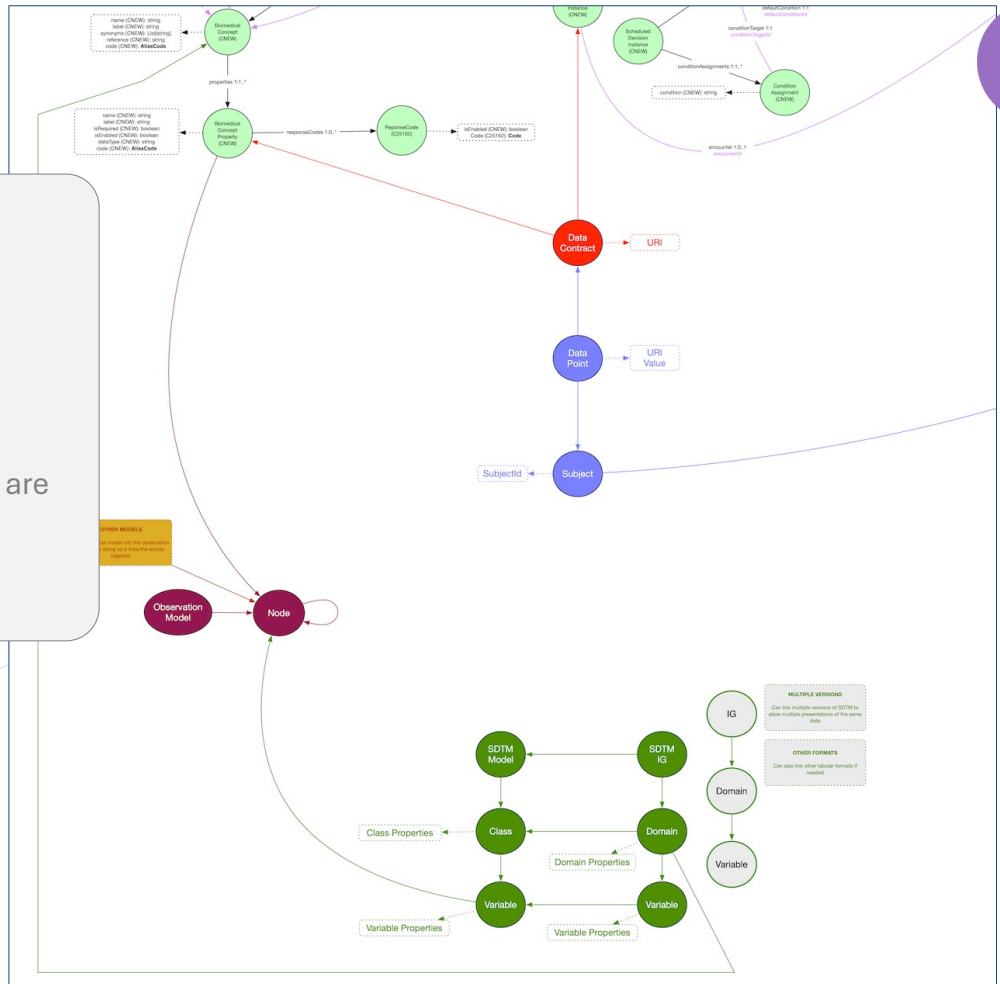
Notes

- The data loads require a triple of the subject identifier, the data contract URI and the data value
- This allows for data to be linked into the overall data, in bulk or individually

Link SDTM

Notes

- We have a small model that models what an observation is
- Link the SDTM IG via the SDTM Model to the observation model
- Link BCs to the same observation model
- We take this further in that all the BCs we use are based on that same observation model
- Can link to multiple versions of the IG
- Can link to other models other than SDTM



And so ...

2. Objectives

2.1. Primary Objectives

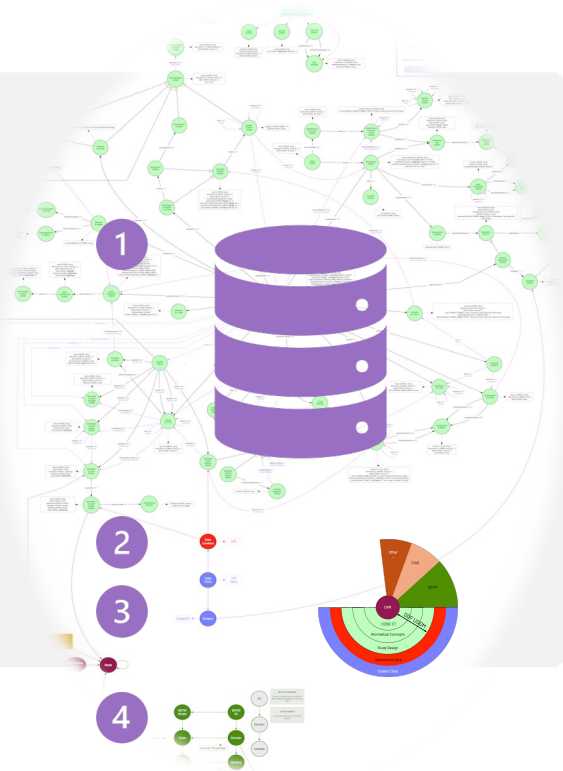
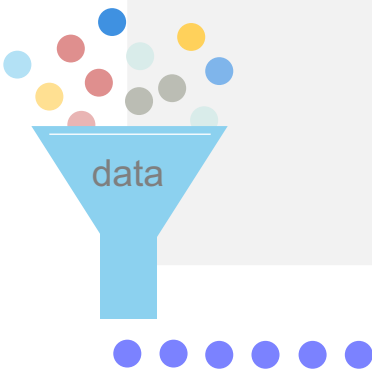
The primary objectives of this study are

- To determine if there is a statistically significant relationship (overall Type I error rate, $\alpha = .05$) between the change in both ADAS-Cog (see Attachment LZT.2) and CIBC+ (see Attachment LZT.3) scores, and drug dose (0, 50, 100, 154 mg, and 175 mg).
- To document the safety profile of the axamidine TTS.

2.2. Secondary Objectives

The secondary objectives of this study are

- To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-20) will indicate improvement in these areas (see Attachment LZT.4).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will indicate improvement in these areas (see Attachment LZT.5).
- To assess the dose-dependent improvements in an extended assessment of cognition that integrates attention/concentration tasks. The Alzheimer's Disease Assessment Scale-14 item Cognitive Subscale, hereafter referred to as ADAS-Cog (14), will be used for this assessment (see Attachment LZT.2).
- To assess the treatment response as a function of Apo E genotype.



Subject Data

ID	Subject ID	Property	Value	DefaultID
101	01-101	Active Anamnesis/Screening Test Result	1	101
101	101	Active Anamnesis/Screening Test Result	1	101
101	01-101	Active Anamnesis/Screening Test Result	1	101
101	101	Active Anamnesis/Screening Test Result	1	101

Raw Data

SDTM LB Domain Data

STUDYID	DOMAIN	UNBLIND	LBSEID	LBTESTCD	LBTEST	LBSEQ	LBSTAT	LBORRES
H02MAC	LB	01-101	1015	ALP	50	34		
H02MAC	LB	01-101	1015	ALP	50	34		
H02MAC	LB	01-101	1015	ALP	50	34		
H02MAC	LB	01-101	1015	ALP	50	34		

SDTM Data

Admin data entry

Subject ID: [input field]

Test Result: [input field]

Submit

Data entry

Subject ID: [input field]

Test Result: [input field]

Submit

Data Capture

Admin data entry

Subject ID: [input field]

Test Result: [input field]

Submit

Data entry

Subject ID: [input field]

Test Result: [input field]

Submit

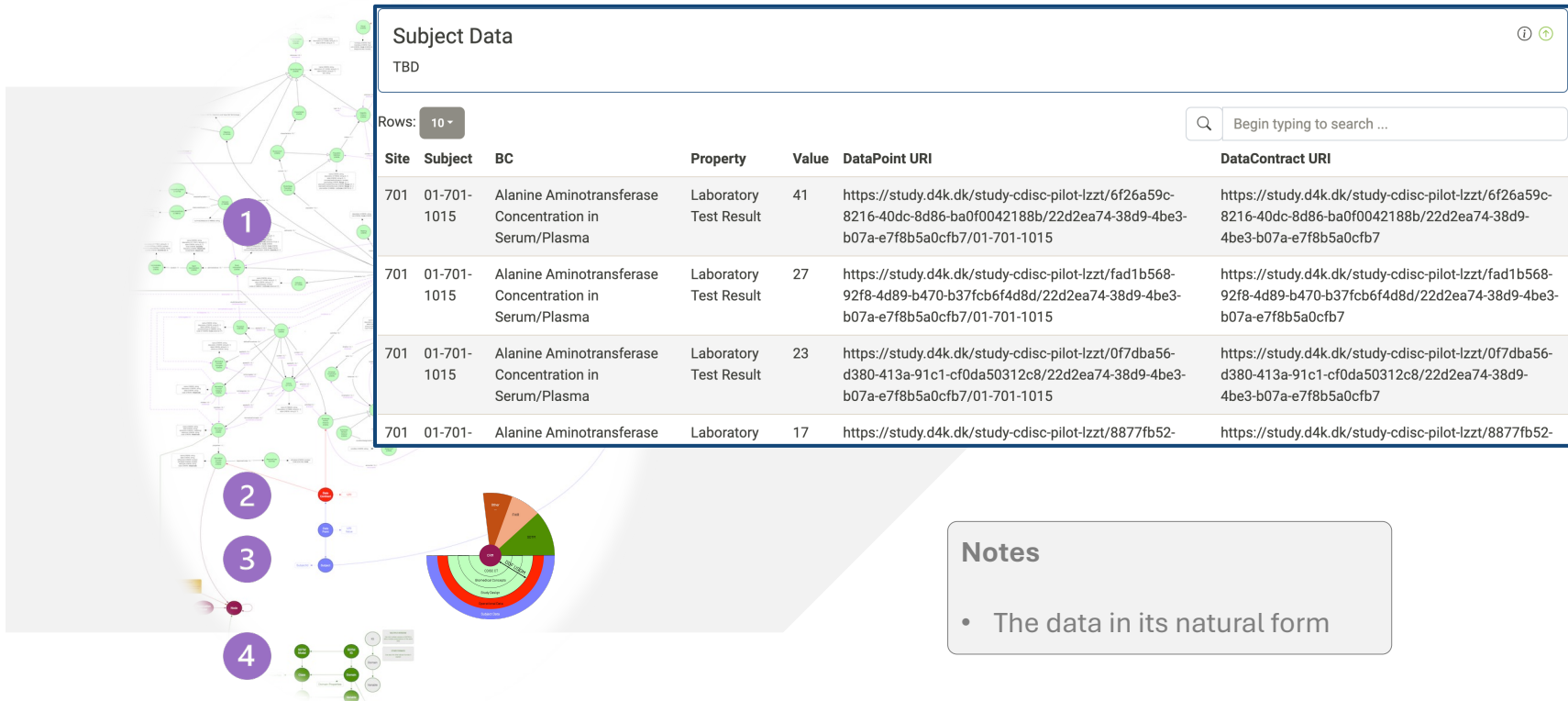
aCRF

define.xml

Element	Value
STUDYID	H02MAC
DOMAIN	LB
UNBLIND	01-101
LBSEID	1015
LBTESTCD	ALP
LBTEST	50
LBSEQ	34
LBSTAT	
LBORRES	

define.xml

Present Raw Data



Subject Data ⓘ ↻

TBD

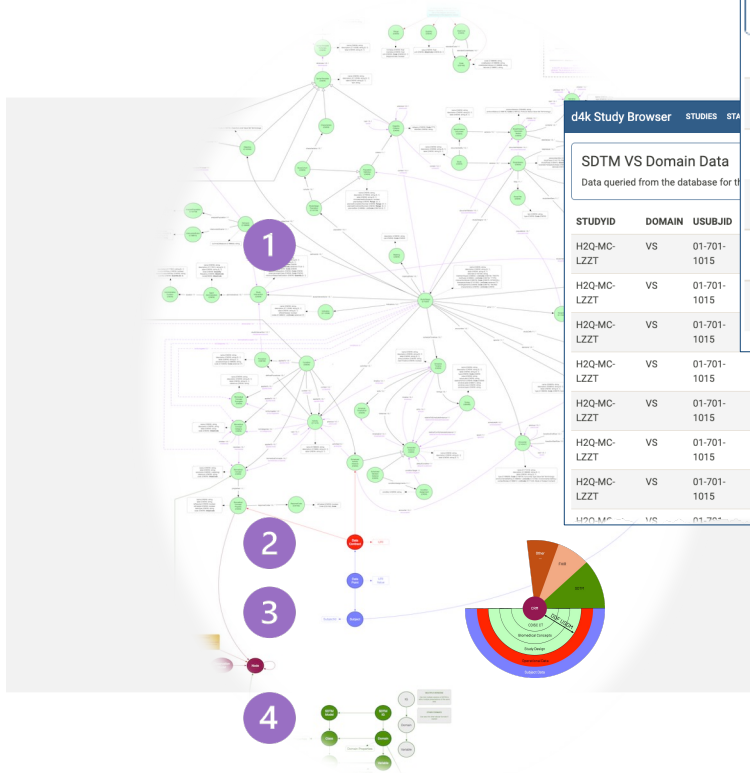
Rows: 10 ▾

Site	Subject	BC	Property	Value	DataPoint URI	DataContract URI
701	01-701-1015	Alanine Aminotransferase Concentration in Serum/Plasma	Laboratory Test Result	41	https://study.d4k.dk/study-cdisc-pilot-lzzt/6f26a59c-8216-40dc-8d86-ba0f0042188b/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7/01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lzzt/6f26a59c-8216-40dc-8d86-ba0f0042188b/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7
701	01-701-1015	Alanine Aminotransferase Concentration in Serum/Plasma	Laboratory Test Result	27	https://study.d4k.dk/study-cdisc-pilot-lzzt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7/01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lzzt/fad1b568-92f8-4d89-b470-b37fcb6f4d8d/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7
701	01-701-1015	Alanine Aminotransferase Concentration in Serum/Plasma	Laboratory Test Result	23	https://study.d4k.dk/study-cdisc-pilot-lzzt/0f7dba56-d380-413a-91c1-cf0da50312c8/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7/01-701-1015	https://study.d4k.dk/study-cdisc-pilot-lzzt/0f7dba56-d380-413a-91c1-cf0da50312c8/22d2ea74-38d9-4be3-b07a-e7f8b5a0cfb7
701	01-701-	Alanine Aminotransferase	Laboratory	17	https://study.d4k.dk/study-cdisc-pilot-lzzt/8877fb52-	https://study.d4k.dk/study-cdisc-pilot-lzzt/8877fb52-

Notes

- The data in its natural form

Present SDTM Data



d4k Study Browser STUDIES STATUS

SDTM LB Domain Data

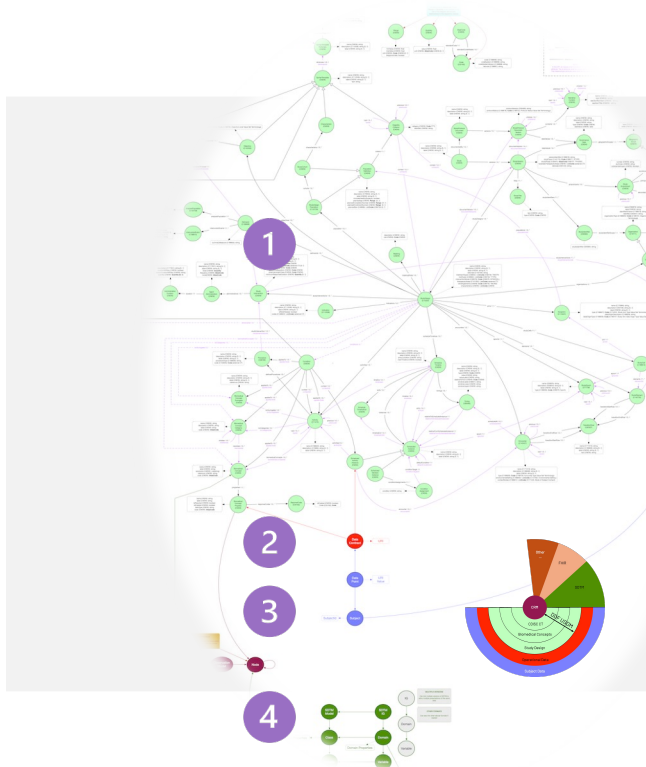
Data queried from the database for the Laboratory Test Results domain

STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBSCAT	LBORRES	LBORRESU	LBRESSCL	LBRESTYP	LBCOLSRT	LBORNRO	LBORNR
H2Q-MC-LZZT	LB	01-701-1015		ALP				34	U/L					
H2Q-MC-LZZT	LB	01-701-1015		ALP				50	U/L					
H2Q-MC-LZZT	LB	01-701-1015		ALP				41	U/L					
H2Q-MC-LZZT	LB	01-701-1015		ALP				43	U/L					
H2Q-MC-LZZT	LB	01-701-1015		ALP				47	U/L					
H2Q-MC-LZZT	LB	01-701-1015		ALP				53	U/L					
H2Q-MC-LZZT	VS	01-701-1015	DIABP		59	mmHg				Screening 2	Screening			PT1M
H2Q-MC-LZZT	VS	01-701-1015	DIABP		71	mmHg				Screening 2	Screening			PT2M
H2Q-MC-LZZT	VS	01-701-1015	DIABP		68	mmHg				Screening 2	Screening			PT5M
H2Q-MC-LZZT	VS	01-701-1015	DIABP		51	mmHg				Baseline	Treatment 1			PT1M

Notes

- Can export the data into SDTM via query
- Derived data is handled
- The solution can handle the “unexpected”
- Think about the data, not how it is presented
- It works in ‘real time’

Configure Domains



d4k Study Browser STUDIES STATUS

SDTM LB Domain BC Links

Set set of BCs linked with the SDTM Laboratory Test Re

Biomedical Concepts Linked with LB Domain

Rows: 10 -

Name	
Alanine Aminotransferase Concentration in Serum/Plasma	✕
Albumin Presence in Urine	
Alkaline Phosphatase Concentration in Serum/Plasma	
Aspartate Aminotransferase in Serum/Plasma	✕
Creatinine Concentration in Urine	✕
Hemoglobin A1C Concentration in Blood	✕
Potassium Concentration in Urine	✕
Sodium Concentration in Urine	

d4k Study Browser STUDIES STATUS

SDTM VS Domain BC Links

Set set of BCs linked with the SDTM Vital Signs Domain

Biomedical Concepts Linked with VS Domain

Rows: 10 -

Begin typing to search

Name	
Diastolic Blood Pressure	✕
Heart Rate	✕
Height	✕
Systolic Blood Pressure	✕
Temperature	✕
Weight	✕

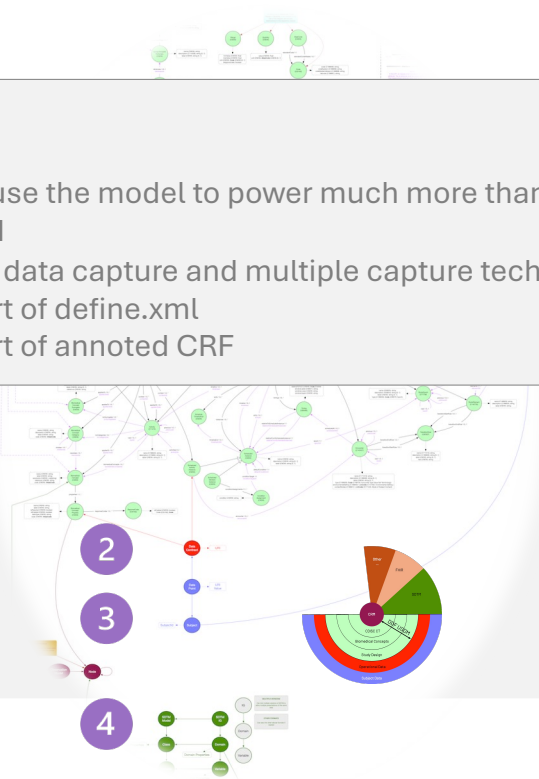
Notes

- Allows for observations to be “assigned” to domains
- Allows for custom domains etc
- Allows for data to be repeated across domains

Data Collection, aCRF and Define.xml

Notes

- Can use the model to power much more than just SDTM
- Drive data capture and multiple capture technologies
- Export of define.xml
- Export of annotated CRF



2

3

4

Standard	Type	Status	Recommendation
SDTM01.A1	DR	Final	From CDISC, Legacy SDTM
SDTM02.D02.10.00	CT	Final	From CDISC, Legacy Controlled Terminology

Standard	Element	Recommendation	Location
SDTM01.A1	INFORMED CONSENT OBSERVED	Final	Table DT
SDTM02.D02.10.00	DIASTOLIC BLOOD PRESSURE	Final	Table DT
SDTM02.D02.10.00	BLOOD PRESSURE	Final	Table DT
SDTM02.D02.10.00	BLOOD PRESSURE OBSERVED	Final	Table DT
SDTM02.D02.10.00	BLOOD PRESSURE OBSERVED PER PATIENT	Final	Table DT
SDTM02.D02.10.00	BLOOD PRESSURE OBSERVED PER PATIENT	Final	Table DT

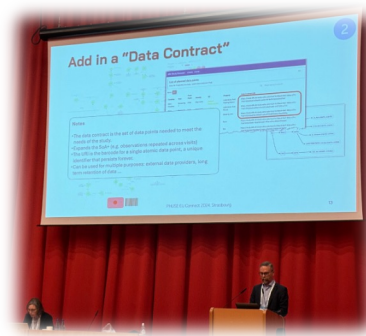
Technology Demonstrator @ PHUSE EU Connect

d4k Study Browser STUDIES CDISC PILOT NEODASH NEODASH DETAILS JOIN MEETING STATUS

Existing SDTM

SDTM DM Domain Data
Data queried from the database for the Demographics domain

STUDYID	DOMAIN	USUBJID	SUBJID	RFXSTDTC	RFXENDTC	RFICDTC	DTHDTC	DTHFL	SITEID	INVID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM
H2Q-MC-LZZT	DM	101-DIH	DIH			2024-11-11T12:47			101			2000-11-11	24		M	WHITE			
H2Q-MC-LZZT	DM	101-Peter	Peter			2024-11-11T13:16			101			N/A			M				
H2Q-MC-LZZT	DM	701-1087	1087	2012-10-22	2013-04-21	2012-10-06			701			1938	73		E	WHITE			
H2Q-MC-LZZT	DM	701-1115	1115	2012-11-30	2012-12-13	2012-11-23			701			1928	84		M	WHITE			
H2Q-MC-LZZT	DM	701-1211	1211	2012-11-15	2012-11-28	2012-10-30			701			1936	75		E	WHITE			
H2Q-MC-LZZT	DM	701-1236	1236	2013-09-21	2013-09-21	2013-09-08			701			1927	85		E	WHITE			
H2Q-MC-LZZT	DM	701-1302	1302	2013-08-22	2013-09-11	2013-08-20			701			1951	61		M	WHITE			



d4k Study Browser

Subject Site:101

Subject identifier: Dave

Sex: Date of collection: 2024-11-11 Encounter: Screening 1

Self Reported Sex: Male Female

Next activity: Collection of BC Race

SHOW ACTIVITIES

d4k Study Browser

Subject Site:101

Subject identifier: Dave

Date of Birth: Date of collection: 2024-11-11 Encounter: Screening 1

Birthdate: 2000-11-11
Age of subject is 24.
Remember that subjects need to be older than 50 to be included in study

Next activity: Collection of BC Temperature

SHOW ACTIVITIES

New Data

=

d4k Study Browser STUDIES CDISC PILOT NEODASH NEODASH DETAILS JOIN MEETING STATUS

SDTM DM Domain Data
Data queried from the database for the Demographics domain

STUDYID	DOMAIN	USUBJID	SUBJID	RFXSTDTC	RFXENDTC	RFICDTC	DTHDTC	DTHFL	SITEID	INVID	INVNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD	ARM
H2Q-MC-LZZT	DM	101-DIH	DIH			2024-11-11T12:47			101			2000-11-11	24		M	WHITE			
H2Q-MC-LZZT	DM	101-Dave	Dave			2024-11-11T15:29			101			2000-11-11	24		M	WHITE			
H2Q-MC-LZZT	DM	101-Peter	Peter			2024-11-11T13:16			101			N/A			M				
H2Q-MC-LZZT	DM	701-1087	1087	2012-10-22	2013-04-21	2012-10-06			701			1938	73		E	WHITE			
H2Q-MC-LZZT	DM	701-1115	1115	2012-11-30	2012-12-13	2012-11-23			701			1928	84		M	WHITE			
H2Q-MC-LZZT	DM	701-1211	1211	2012-11-15	2012-11-28	2012-10-30			701			1936	75		E	WHITE			
H2Q-MC-LZZT	DM	701-1236	1236	2013-09-21	2013-09-21	2013-09-08			701			1927	85		E	WHITE			

Real time update of SDTM

Summary

- USDM provides the strong foundation
- We extended USDM ...
 - Established the data contract
 - Linked in the subject data
 - Linked in SDTM
 - Allows for data capture
 - Extracted SDTM, aCRF and define.xml
- And more to come ...

