



2024 CDISC + TMF  
EUROPE INTERCHANGE

BERLIN

24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

## Demonstrating e2e study data automation using extended USDM model

Presented by Partners at data4knowledge ApS:

Kirsten Walther Langendorf

Johannes Ulander

Dave Iberson-Hurst

# Meet the Speakers



**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.



**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 data4knowledge in Copenhagen and is focused on getting greater value and utility from clinical trial data



# 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.*
- *Disclosure of financial relationship or conflict of interest relevant to this presentation:*
  - *Dave Ibersen-Hurst is Product Owner of CDISC USDM*

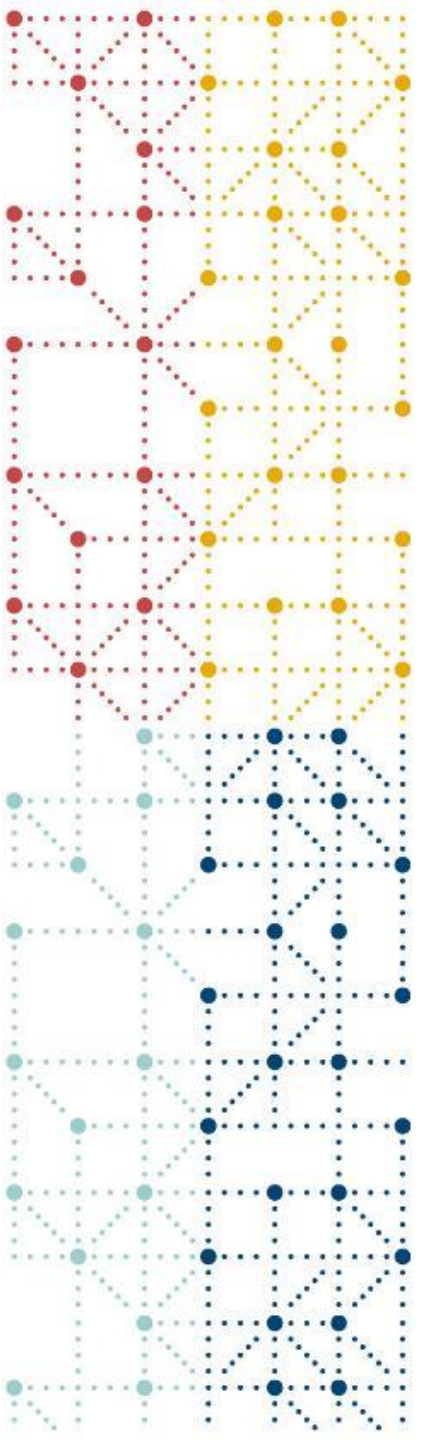




# From abstract

To make the USDM vision tangible, we will demonstrate

1. Create a digital study protocol including the study design and the schedule of assessments (SoA)
2. Drive data capture artefacts from the SoA
3. Load data: bulk loads, human entered and from EHR sources (FHIR)
4. Demonstrate the automated generation of SDTM
5. Show how submission ready artefacts (aCRFs and define.xml) can be generated
6. Touch upon how data anonymisation to allow for data sharing (FAIR data) can be accommodated



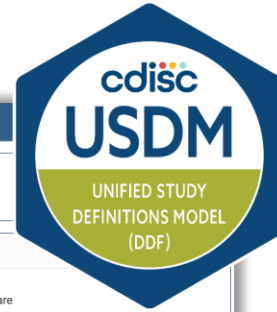
# Agenda

1. Introduction to e2e study data automation and demonstration
2. The demonstration - video
3. Summary

# Background

- Input
  - Using CDISC Pilot study protocol and data
  - Study metadata excel example of that study developed as part of CDISC DDF
  - Built upon the prototype tooling Dave has made as part of the CDISC DDF
- Prototype
  - Using USDM, BC and extending that model to facilitate automation
- Work in progress
  - Due to time limitations, we have not covered all aspects listed in the abstract
  - Will extend over the coming months through a set of webinars to show the progress

# Paper protocol into USDM electronic representation\*



## 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 LZTT.2) and CIBIC+ (see Attachment LZTT.3) scores, and drug dose (0, 50 cm<sup>2</sup> [54 mg], and 75 cm<sup>2</sup> [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 LZTT.4).
- To assess the dose-dependent improvements in activities of daily living. Improved scores on the Disability Assessment for Dementia (DAD) will

**Protocol Attachment LZTT.1  
Schedule of Events for Protocol H2Q-MC-LZZT(c)**

	VISIT	1	2	3	4	5	7	8
ACTIVITY	WEEK	-2	-3	0	2	4	6	8
Informed consent		X						
Patient number assigned		X						
Hachinski $\leq 4$		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						



Study Design SoA

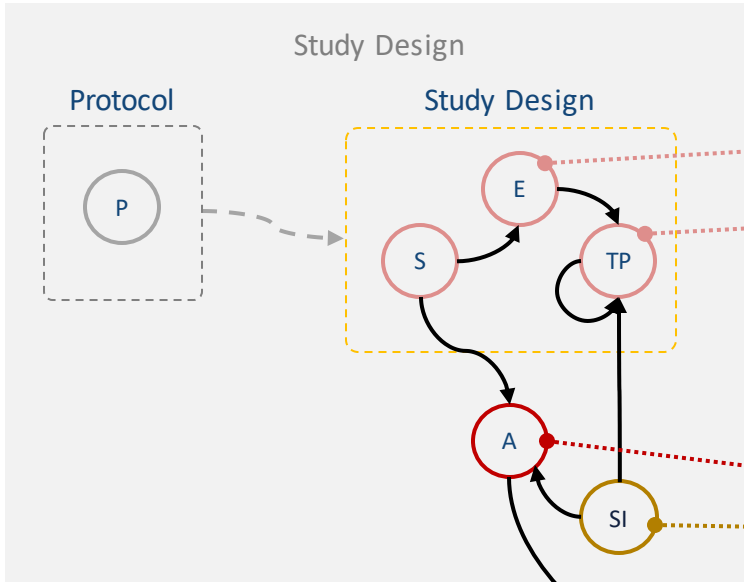
	Screening	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	1	2	Baseline	Week 2	Week 4	Week 6	Week 8	Week 8	Week 12	Week 16	Week 16	Week 16
Informed consent	X											
Inclusion and exclusion criteria	X											
Patient number assigned	X											
Demographics	X											
Hachinski Ischemic Scale	X											
MMSE	X											
Physical examination	X											
Medical history	X											
Habits	X											
Chest X-ray	X											
Apo E genotyping						X						
Patient randomised					X							
Vital Signs and Temperature	X	X	X	X	X	X	X	X	X	X	X	X

\* Developed as part of the CDISC DDF project

Source: CDISC Pilot Study(H2Q-MC-LZZT(c))



# USDM behind the scenes\*



**d4k Study Browser** STUDIES STATUS

**Study Details**

Screening 1	Screening 2	Treatment One	Treatment One	Treatment Two	Treatment Two	Treatment Two	Treatment Two
		Baseline	Week 2	Week 4	Week 6	Week 8	Week 8
◇ None	-4..0 hours	None	-3..3 days	-3..3 days	-3..3 days	-3..3 days	-3..3 days

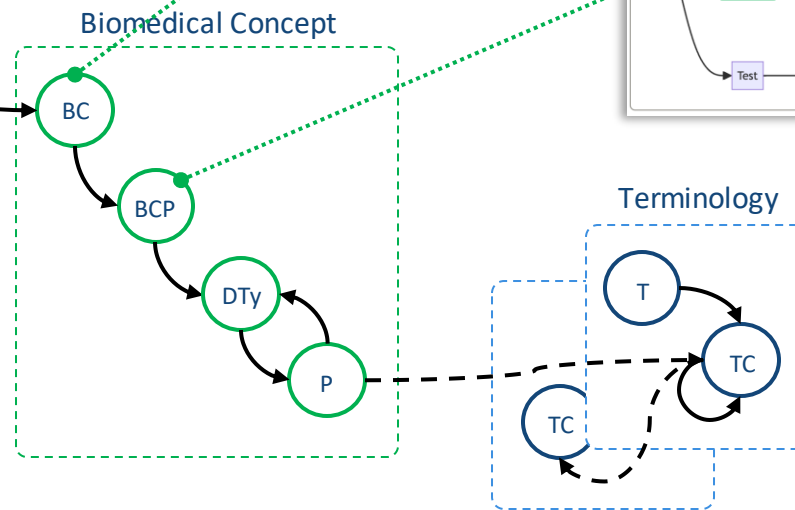
Informed consent ◇ X  
 Inclusion and exclusion criteria ◇ X  
 Patient number assigned ◇ X  
 Demographics X X  
 BiomedicalConcept: Race X  
 BiomedicalConcept: Sex X

**Graphical View**

```

    graph LR
    Sex --> Date_Time
    Sex --> Result
    Sex --> Test
    Date_Time --> date_time
    Result --> coding
    Test --> coding
    date_time --> M["M, Male (C66731, C20197)"]
    date_time --> F["F, Female (C66731, C16576)"]
    date_time --> U["U, Unknown (C66731, C17998)"]
    coding --> UN["UNDIFFERENTIATED, Intersex (C66731, C45908)"]
    coding --> SEX["SEX, Sex (D000001, D100002)"]
    
```

- P protocol
- S study
- E epoch
- TP time point
- A activity
- SI scheduled activity instance



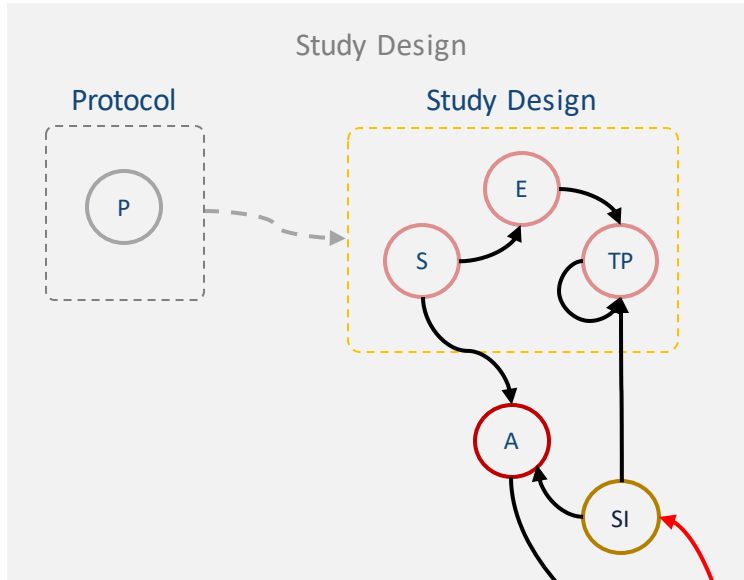
- BC Biomedical concept
- BCP BC Property
- DTy Data Type
- P property
- T terminology



\* Conceptual view



# Extending USDM with DataContract



d4k Study Browser STUDIES STATUS

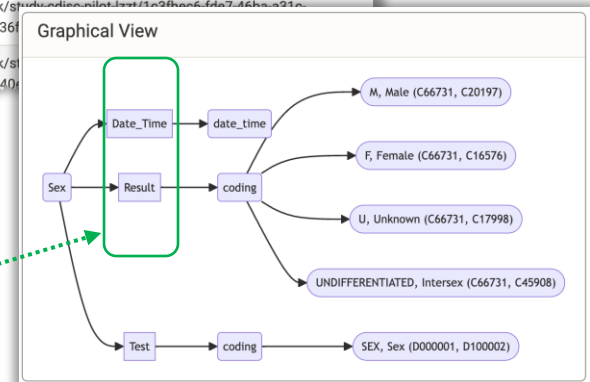
List of planned data points  
Note: BC Properties for study - select data collection:TRUE

Rows: 5

Timeline	Visit	Time Point	Activity	BC	Property	Data Contract URI
Main Timeline	Screening 1	P2W	Chemistry	Sodium Measurement	Laboratory Test Fasting Status	https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-7fa41032a9ad/04ffee66-aa3d-4f6f-8cf9-5dece3dc05e2
Main Timeline	Screening 1	P2W	Chemistry	Sodium Measurement	Laboratory Test Result	https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/a268e144-e432-44d3-bd81-07f7330ca71d
Main Timeline	Screening 1	P2W	Chemistry	Sodium Measurement	Molarity Unit	https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/04c930d3-1ada-4725-8874-b4c19aa3009a
Main Timeline	Screening 1	P2W	Demographics	Race	Race	https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/c1436f...
Main Timeline	Screening 1	P2W	Demographics	Sex	Sex	https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/3b240...



Like a barcode – a unique identifier

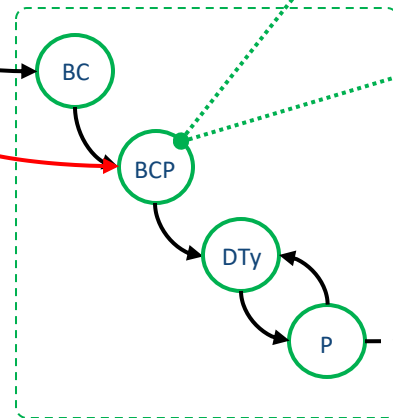


- BC Biomedical concept
- BCP BC Property
- DTy Data Type
- P property
- T terminology

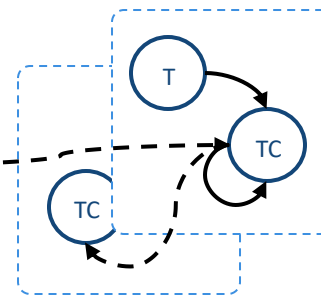
- P protocol
- S study
- E epoch
- TP time point
- A activity
- SI scheduled activity instance
- DC data contract

Data contract URI for every BC property at all the X's in the SoA of the study

## Biomedical Concept



## Terminology



# Requesting data from Data Provider

Please deliver the following data  
- When returning, include the Data Contract URI



## Data Contract

[Data Contract](#) ⓘ

Total number of planned data points: 1108

d4k Study Browser STUDIES STATUS

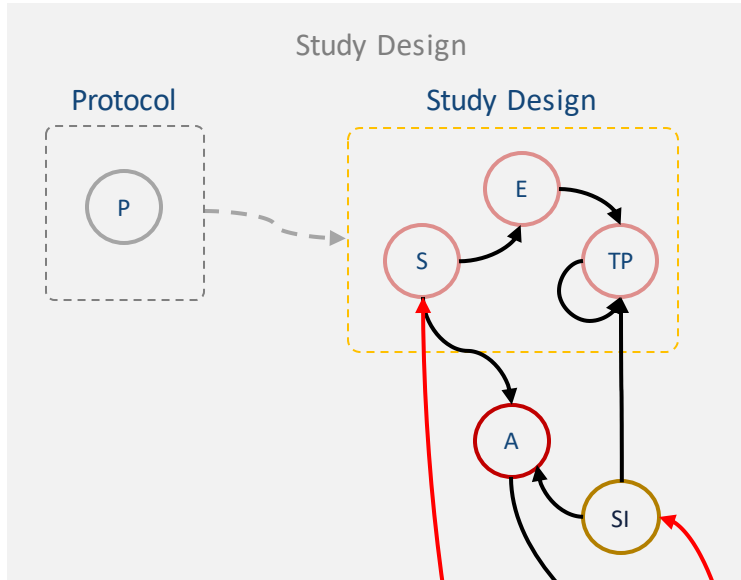
List of planned data points ⓘ ⓘ

Note: BC Properties for study - select data collection:TRUE

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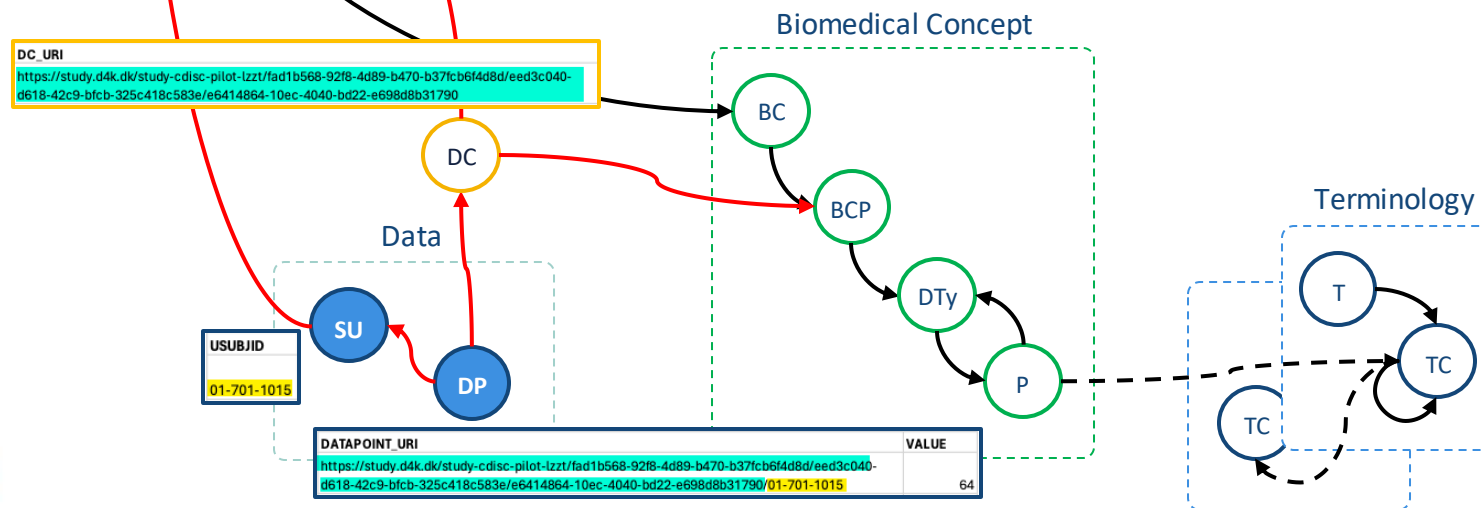
Timeline	Visit	Time Point	Activity	BC	Property	Data Contract URI
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Height</a>	Clinical Test Result	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/d26fd49d-32e0-4406-8d1f-3c5a26a09c76">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/d26fd49d-32e0-4406-8d1f-3c5a26a09c76</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Height</a>	Unit of Height	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/c7592222-7cc0-4531-86d6-f01036300003">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/c7592222-7cc0-4531-86d6-f01036300003</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Temperature</a>	Anatomic Site	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/eeff1e95-9728-4900-a34a-68b860b418c3">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/eeff1e95-9728-4900-a34a-68b860b418c3</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Temperature</a>	Clinical Test Result	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/738ae21e-ec1c-4262-8f8b-8a08a89ed884">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/738ae21e-ec1c-4262-8f8b-8a08a89ed884</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Temperature</a>	Unit of Temperature	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/036b72aa-40cb-4756-aac7-01a75e6bdd74">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/036b72aa-40cb-4756-aac7-01a75e6bdd74</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Weight</a>	Clinical Test Result	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/4ec46cad-7b04-4092-9cf0-17060cc82d5b">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/4ec46cad-7b04-4092-9cf0-17060cc82d5b</a>
Main Timeline	Screening 1	P2W	Vital Signs and Temperature	<a href="#">Body_Weight</a>	Unit of Weight	<a href="https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/854ddc9a-5460-4faf-8bec-6a8d6a554145">https://study.d4k.dk/study-cdisc-pilot-lzzt/1c3fbec6-fde7-46ba-a31c-7fa41032a9ad/854ddc9a-5460-4faf-8bec-6a8d6a554145</a>

# Adding Data – bulk load of LB and VS data



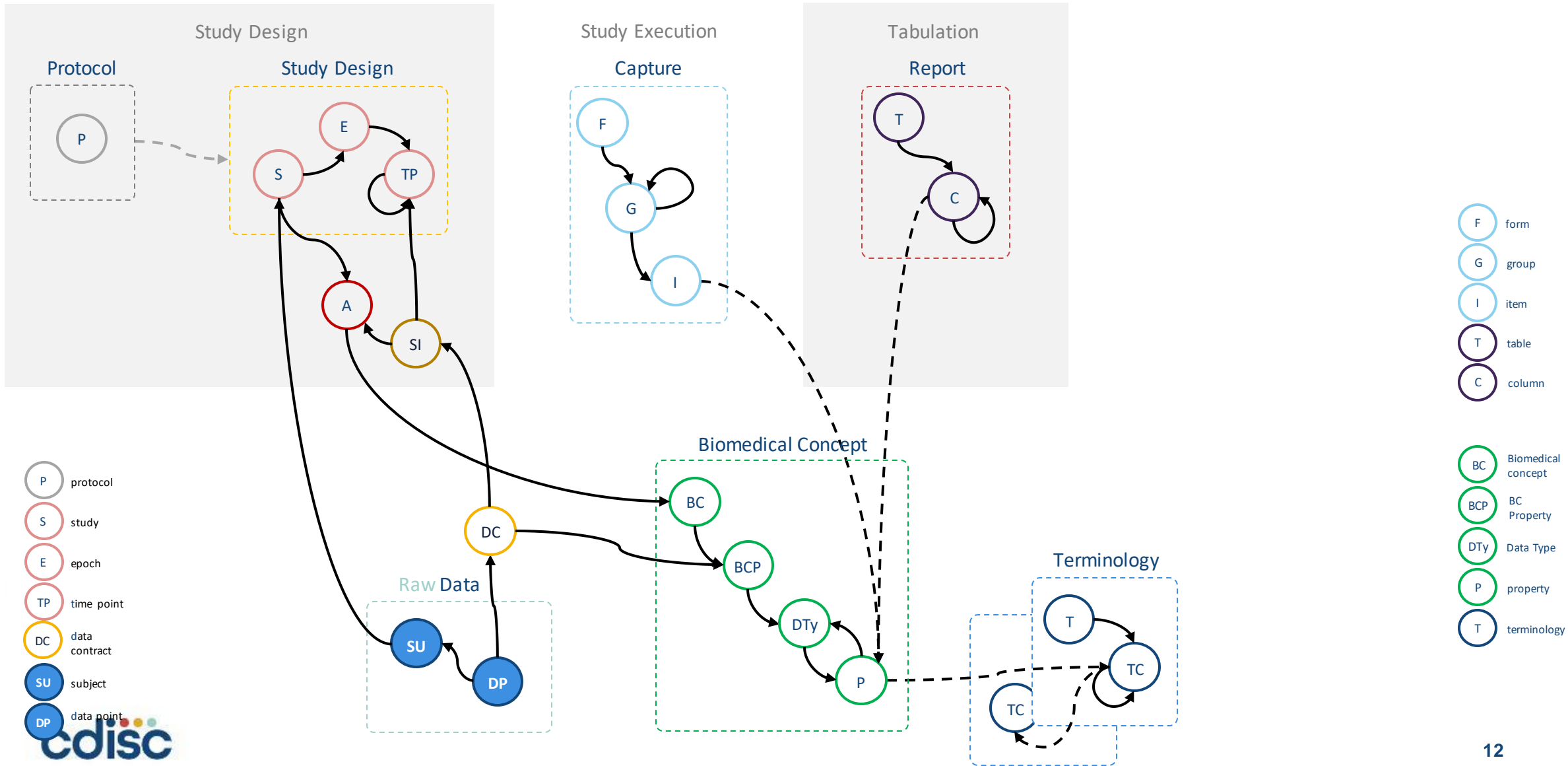
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01-701-1015	<a href="https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e">https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e</a>	<a href="https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015">https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015</a>	41
01-701-1015	<a href="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</a>	<a href="https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/1b2e1fa0-de5e-4b88-a019-70a29cd50ce7/01-701-1015">https://study.d4k.dk/study-cdisc-pilot-lztt/8877fb52-ea80-4dc8-b99f-341d70c5a796/1b2e1fa0-de5e-4b88-a019-70a29cd50ce7/01-701-1015</a>	U/L
01-701-1015	<a href="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</a>	<a href="https://study.d4k.dk/study-cdisc-pilot-lztt/e9de10ff-c6c0-45c6-812a-685d20747ce7/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015">https://study.d4k.dk/study-cdisc-pilot-lztt/e9de10ff-c6c0-45c6-812a-685d20747ce7/4b7708f0-0eb3-4995-b188-ca426fe5c02e/01-701-1015</a>	45

- P protocol
- S study
- E epoch
- TP time point
- A activity
- SI scheduled activity instance
- DC data contract
- SU subject
- DP data point



- BC Biomedical concept
- BCP BC Property
- DTy Data Type
- P property
- T terminology

# Tabulating data in RAW and SDTM – query the data!





# Tabulating data in RAW and SDTM – query the data!

**d4k Study Browser** STUDIES STATUS

SDTM LB Domain  
Set set of BCs linked with the SDTM Vital Signs Domain

Biomedical Concepts Linked with VS Domain

Rows: 10 -

Name

Diastolic Blood Pressure

Heart Rate

Height

Systolic Blood Pressure

Temperature

Weight

**Subject Data**

TBD

Rows: 10 -

Begin typing to search ...

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-cdi	

Adding metadata from USDM – puts context to URI

Relating BCs to domains

**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
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	

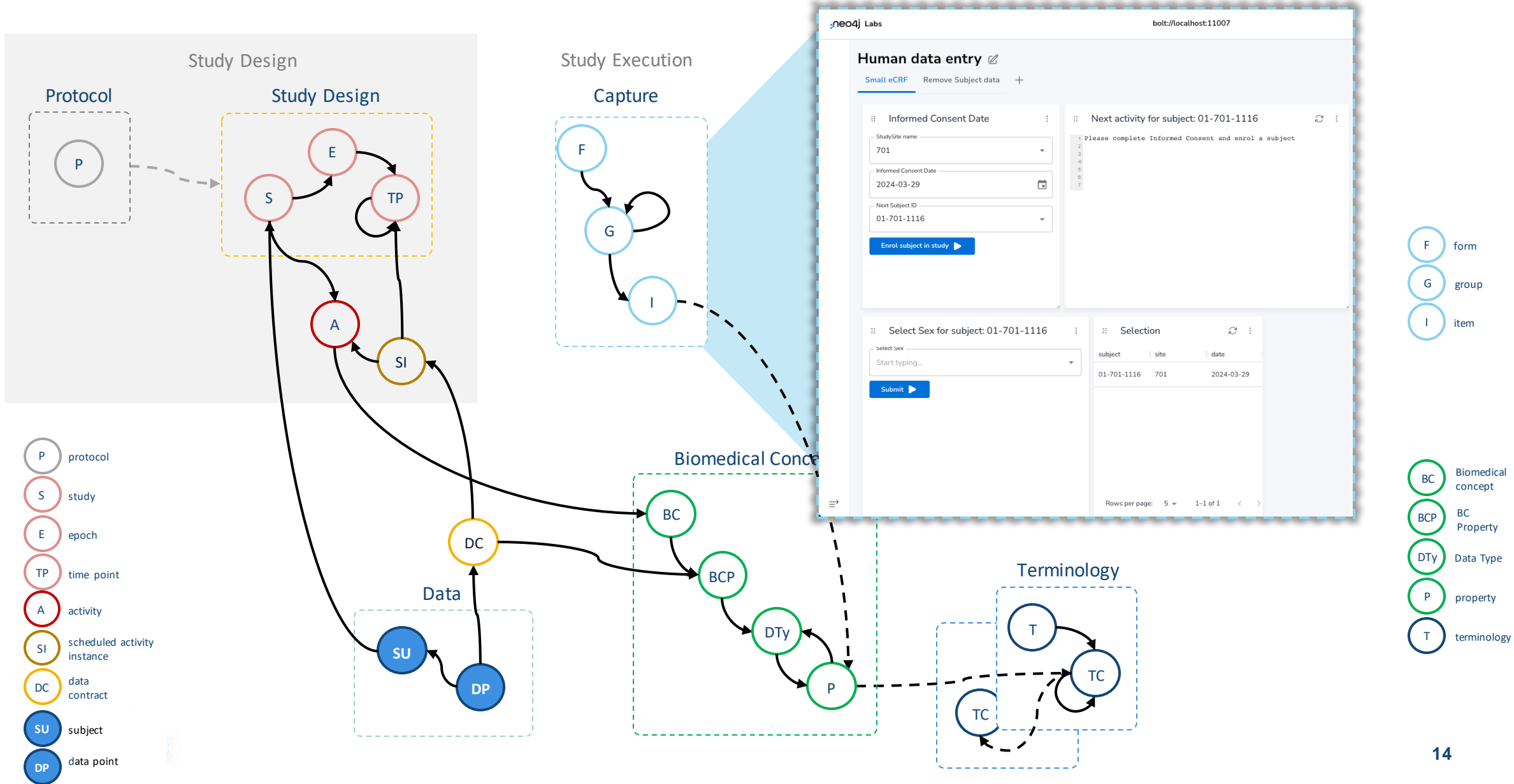
**d4k Study Browser** STUDIES STATUS

SDTM VS Domain Data

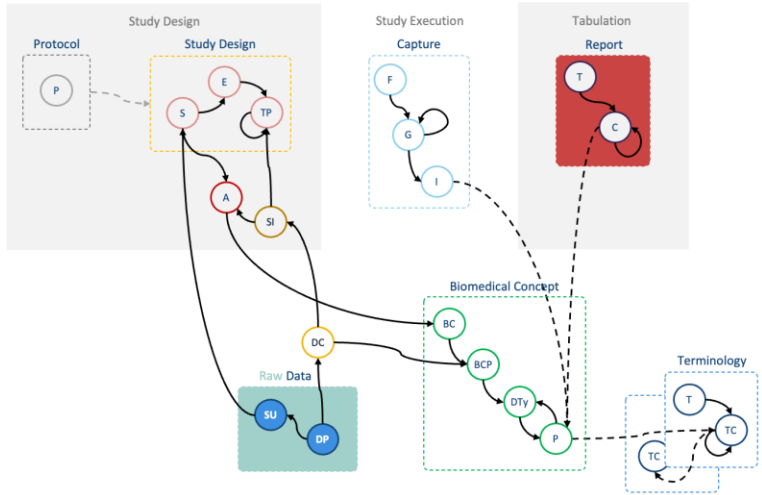
Data queried from the database for the Vital Signs domain

STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSCAT	VSSCAT	VSPPOS	VSORRES	VSORRESU	VSSTAT	VSREASND	VSLOC	VSLAT	VSBLFL	VISITNUM	VISIT	VISITDY	EPOCH	VSDTC	VSDY	VSTPT
H2Q-MC-LZZT	VS	01-701-1015		DIABP					83	mmHg						Screening 1	Screening				PT1M	
H2Q-MC-LZZT	VS	01-701-1015		DIABP					57	mmHg						Screening 1	Screening				PT2M	
H2Q-MC-LZZT	VS	01-701-1015		DIABP					64	mmHg						Screening 1	Screening				PT5M	
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	

# Collecting in eCRF – human entered data



# Update data in RAW and SDTM



d4k Study Browser STUDIES STATUS

**Subject Data**  
Raw subject data as held within the database

Rows: 10

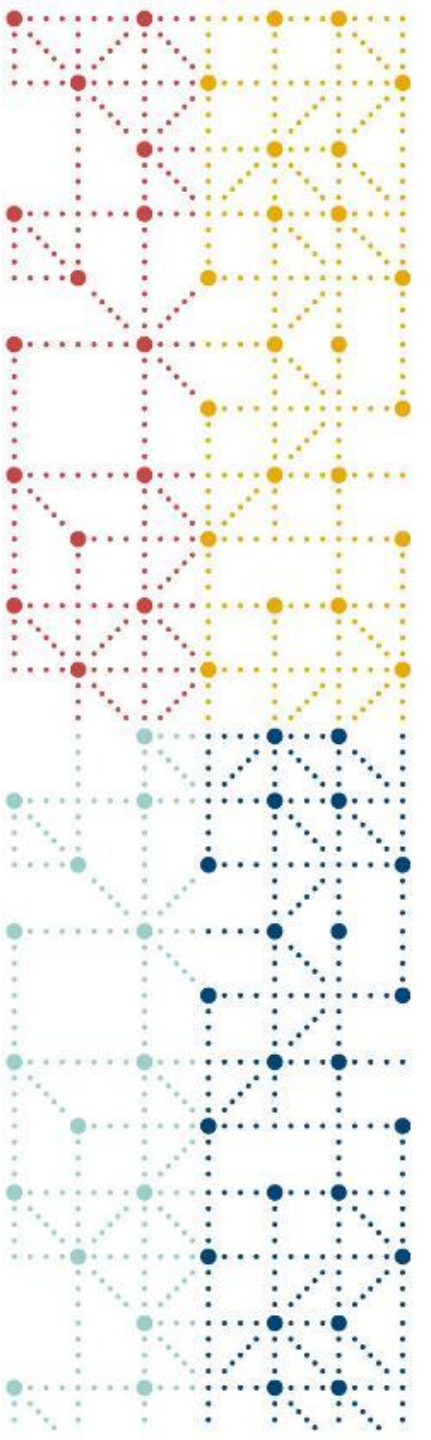
Begin typing to search ...

Site	Subject	BC	Property	Value	DataPoint URI	DataContract URI
701	01-701-1115	Weight	Unit of Weight	LB	https://study.d4k.dk/study-cdisc-pilot-lzzt/98c25a33-94a0-4620-87cf-f83a85b7a2c/b0b0e79a-e8f5-4df0-b017-0e68e356deef/01-701-1115	https://study.d4k.dk/study-cdisc-pilot-lzzt/98c25a33-94a0-4620-87cf-f83a85b7a2c/b0b0e79a-e8f5-4df0-b017-0e68e356deef
701	01-701-1115	Weight	Unit of Weight	LB	https://study.d4k.dk/study-cdisc-pilot-lzzt/c5df6be8-f351-47a6-b2b7-b4a4643a5bd6/b0b0e79a-e8f5-4df0-b017-0e68e356deef/01-701-1115	https://study.d4k.dk/study-cdisc-pilot-lzzt/c5df6be8-f351-47a6-b2b7-b4a4643a5bd6/b0b0e79a-e8f5-4df0-b017-0e68e356deef
701	01-701-1116	Informed Consent Obtained	tbd	2024-04-14	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/fda48814-cc3f-485a-9316-912ce272254e/01-701-1116	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/fda48814-cc3f-485a-9316-912ce272254e
701	01-701-1116	Informed Consent Obtained	Dictionary-derived Term	INFORMED CONSENT OBTAINED	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/757e0264-f9bd-4273-9fd4-727553e99f05/01-701-1116	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/757e0264-f9bd-4273-9fd4-727553e99f05
701	01-701-1116	Informed Consent Obtained	Observation Start Date Time	2024-04-14	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/d21a82df-8761-4bfb-86fc-d28137db4abe/01-701-1116	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/d21a82df-8761-4bfb-86fc-d28137db4abe
701	01-701-1116	Informed Consent Obtained	Reported Event Term	Informed Consent Obtained	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/2afb7fa5-a88f-462d-b5a0-73b2bf1ac8bc/01-701-1116	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/2afb7fa5-a88f-462d-b5a0-73b2bf1ac8bc
701	01-701-1116	Sex	Sex	F	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/96d9783b-e3a4-4966-a971-1d29c4ac2982/01-701-1116	https://study.d4k.dk/study-cdisc-pilot-lzzt/c894e88b-1236-47e7-a361-690566e694cb/96d9783b-e3a4-4966-a971-1d29c4ac2982

d4k Study Browser STUDIES STATUS

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

STUDYID	DOMAIN	USUBJID	SUBJID	DTHDTC	DTHFL	SITEID	INVID	INVMNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC	ARMCD
H2Q-MC-LZZT	DM	01-701-1015	1-1015			701						F	WHITE		
H2Q-MC-LZZT	DM	01-701-1034	1-1034			701						F	WHITE		
H2Q-MC-LZZT	DM	01-701-1057	1-1057			701						F	WHITE		
H2Q-MC-LZZT	DM	01-701-1028	1-1028			701						M	WHITE		
H2Q-MC-LZZT	DM	01-701-1023	1-1023			701						M	WHITE		
H2Q-MC-LZZT	DM	01-701-1097	1-1097			701						M	WHITE		
H2Q-MC-LZZT	DM	01-701-1115	1-1115			701						M	WHITE		
H2Q-MC-LZZT	DM	01-701-1111	1-1111			701						F	WHITE		
H2Q-MC-LZZT	DM	01-701-1033	1-1033			701						M	WHITE		
H2Q-MC-LZZT	DM	01-701-1047	1-1047			701						F	WHITE		
H2Q-MC-LZZT	DM	01-701-1116	1-1116			701						F			



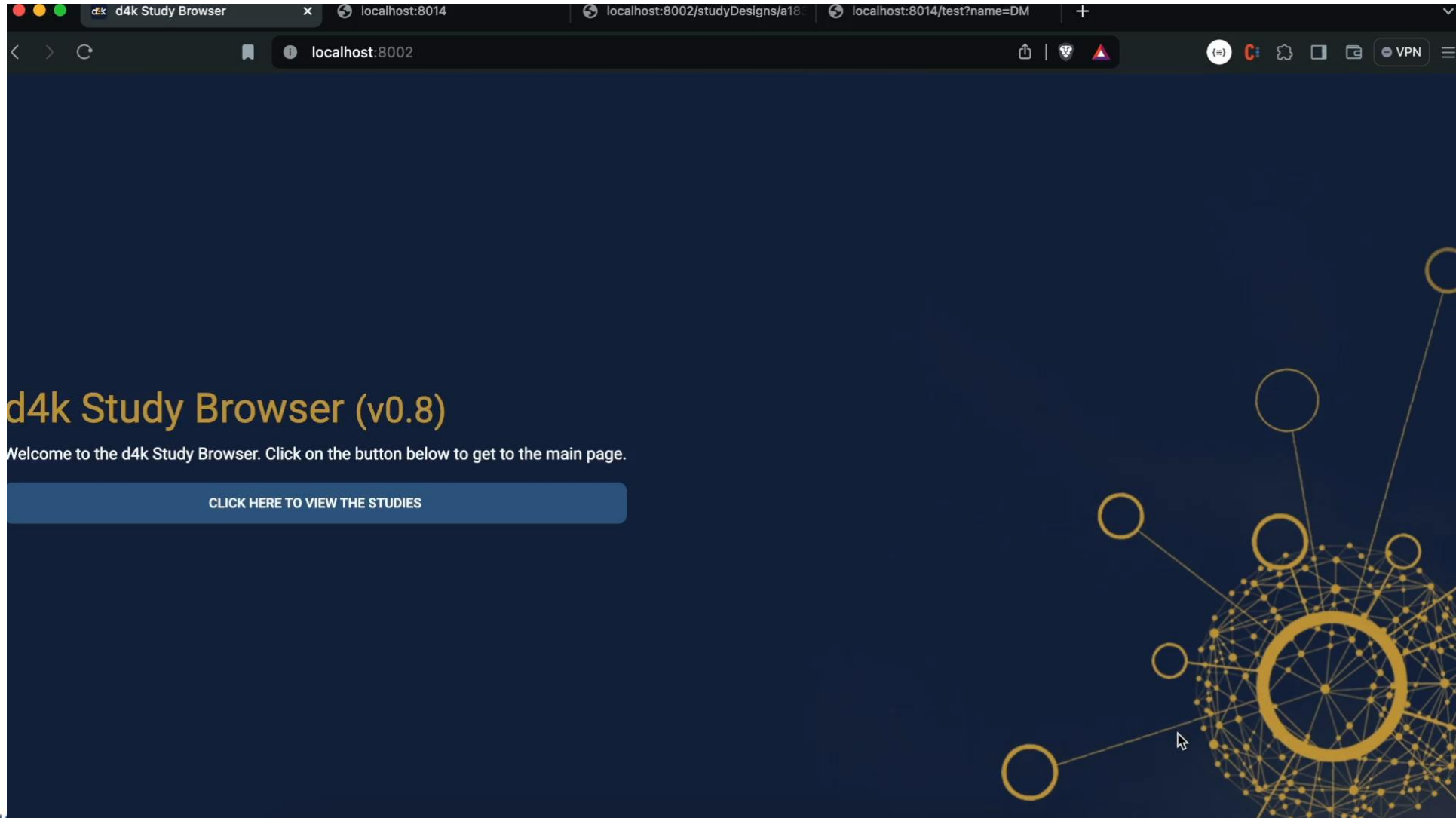
# Video

Demonstrating the experiment



# Video

- Demonstrating e2e study data automation using extended USDM model



# d4k Study Browser (v0.8)

Welcome to the d4k Study Browser. Click on the button below to get to the main page.

[CLICK HERE TO VIEW THE STUDIES](#)



# Video

- CRF flow driven by USDM

# Study Design

A single study design

## Timelines

Name	Description	Label	Condition	Main Timeline
Adverse Event Timeline	This is the adverse event timeline	Adverse Event Timeline	Subject suffers an adverse event	False
Early Termination Timeline	This is the early termination processing	Early Termination Timeline	Subject terminates the study early	False
Main Timeline	This is the main timeline for the study design.	Main Timeline	Potential subject identified	True
Vital Sign Blood Pressure Timeline	BP Profile	Vital Sign Blood Pressure Timeline	Automatic execution	False

## Data Contract

[Data Contract](#)

Total number of planned data points: 1477

## Subject Data

[Subject Data](#)

Total number of actual data points: 1982

## SDTM Data

[SDTM Data](#)



# Video

- Experimenting with protocol editing

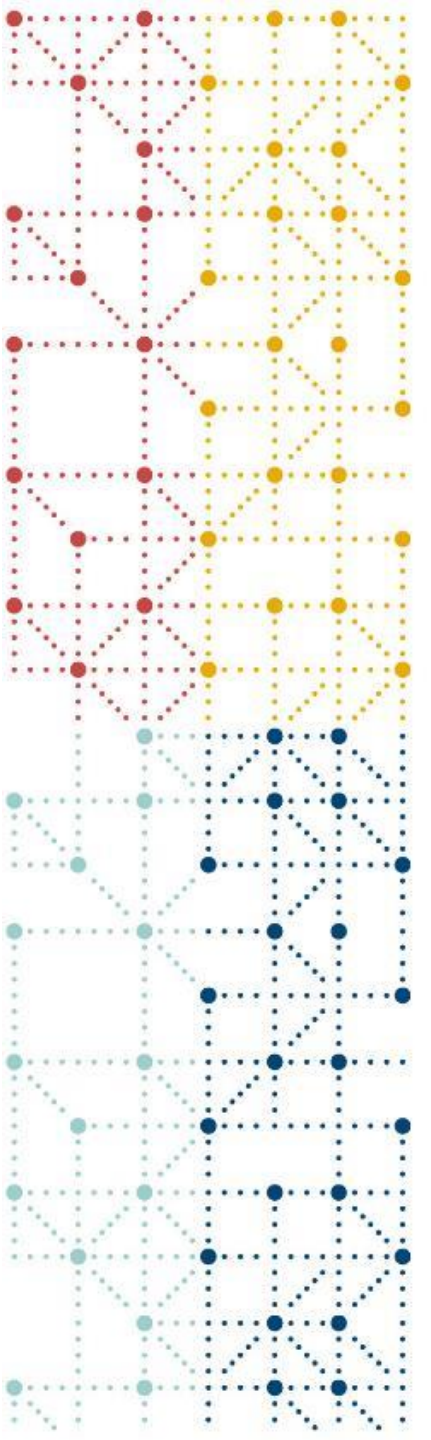
# Studies

The set of studies held within the system.

Info, Add, Edit, Delete, Refresh icons

Rows: 10 ▾

Name
Study_CDISC PILOT - LZTZ 



# Summary

# Summary

- ✓ Created a digital study protocol including the study design and the schedule of assessments (SoA)
- ✓ Made data contract: Drive data capture artefacts from the SoA
- ✓ Loaded DM, VS and LB as bulk load
- ✓ Showed human entered via small CRF (could also be from EHR sources (FHIR)) <https://d4k.dk/2022/03/03/into-the-fire-linking-cdisc-fhir/>
- ✓ SDTM query: Demonstrated the automated generation of SDTM



# If we had more time...

- Show how submission ready artefacts (aCRFs and define.xml) can be generated

### Study CRF/aCRF book

Autogenerated - full book or distinct forms

Study: SoA, Detail, CRF, aCRF, Domains, Documents, Terminologies

Study Annotated CRF: Demo study - 1. gen tool (auto create) - 1.ans

Schedule of Assessments

SoA	SCREEN	V1	V2	V3	V5
Demographics	✓				
Vital Signs					✓
Adverse Events Log					
Tumor Identification / Results New Lesion			✓	✓	
Laboratory Tests - demo form					✓

Demographics

DM=Demographics

DEMOGRAPHICS

Age (Years)  [x|x]

Date of Birth  [d|/|m|/|y|v|v|y|v]

Ethnicity   Hispanic or Latino  Not Hispanic or Latino

### Study Exports

Export Study

File exports: The study version can be exported in a variety of formats.

[Export ALS](#) [Export JSON](#) [Export ODM](#) [Export Define](#)

PDF exports: The study version can be exported as a CRF or Annotated CRF. The full case book format will be used.

[CRF Report](#) [aCRF Report](#)

Define.xml Stylesheets

Define.xml Version:

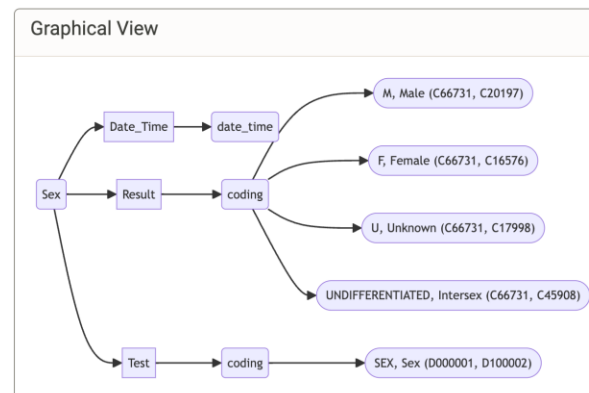
Define-XML v2.0 stylesheet as published by PHUSE 2018-1

[Submit](#) [History](#)

- Touch upon how data anonymisation to allow for data sharing (FAIR data) can be accommodated

- Information on BC/BC Properties

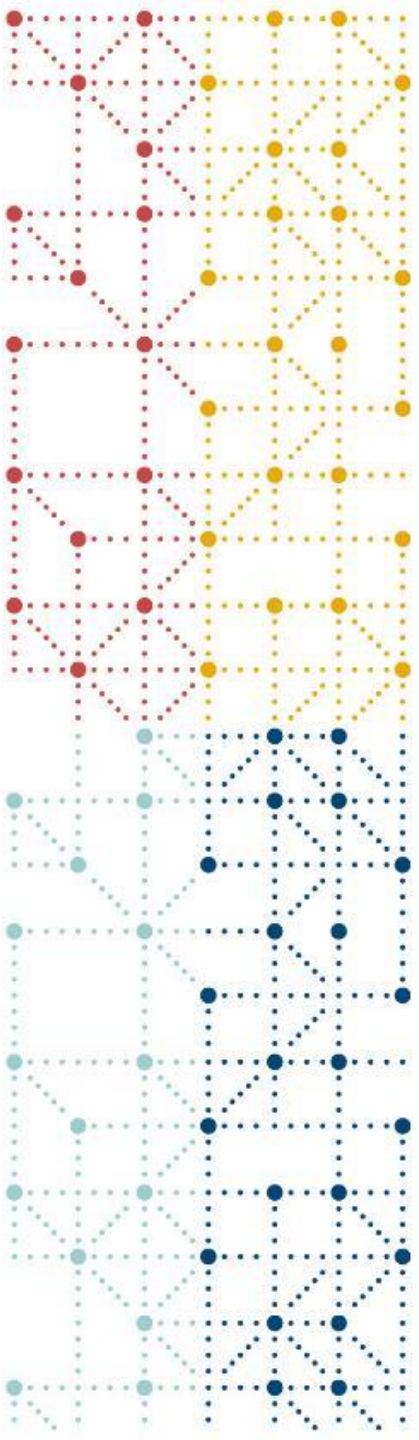
- dataSharing:true/false



### Tabular View

Item Name	Identifier	Data Type	Terms
Date Time		date_time	
Result		coding	M, Male (C66731, C20197) F, Female (C66731, C16576) U, Unknown (C66731, C17998) UNDIFFERENTIATED, Intersex (C66731, C45908)
Test	✓	coding	SEX, Sex (D000001, D100002)





# Thank You!

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info@data4knowledge.dk

[www.d4k.dk](http://www.d4k.dk)

**cdisc**

**data4knowledge**

# EPOCH not part of data – from the protocol

SAS System Viewer - [vs.xpt]

File Edit View Window Help

	VSORRESU	VSTRESC	VSTRESN	VSTRESU	VSSTAT	VSLOC	VSBLFL	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT	VSTPTNUM	VSELTM	VSTPTREF
1	mmHg	64	64	mmHg				1	SCREENING	-7	2013-12-2	-7	AFTER LYI	815	PT5M	PATIENT S
2	mmHg	83	83	mmHg				1	SCREENING	-7	2013-12-2	-7	AFTER STA	816	PT1M	PATIENT S
3	mmHg	57	57	mmHg				1	SCREENING	-7	2013-12-2	-7	AFTER STA	817	PT3M	PATIENT S

d4k Study Browser STUDIES STATUS

SDTM VS Domain Data

Data queried from the database for the Vital Signs domain

TCD	VSTEST	VSCAT	VSSCAT	VSPOS	VSORRES	VSORRESU	VSSTAT	VSREASND	VSLOC	VSLAT	VSBLFL	VISITNUM	VISIT	VISITDY	EPOCH
					83	mmHg							Screening 1		Screening
					57	mmHg							Screening 1		Screening