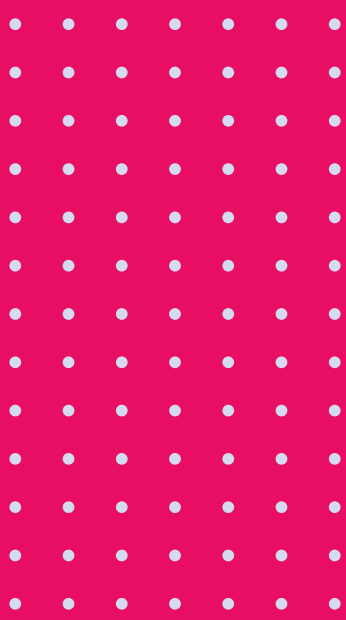




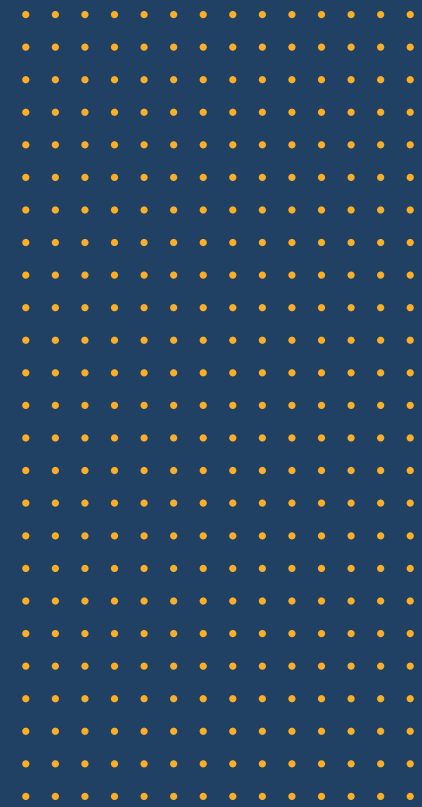
Biomedical Concepts

What are they, and why should I care?

DS04 PHUSE US Connect 2025

Stuart Malcolm,
Head of Standards, Efficiency and Automation
Veramed





What's the problem we are solving?

How do we go from this...

Subject: 12031402
 Page: Vital Signs at Screening

Weight (xxx.xx) ... ☐ ☐ ☐

Height (xxx) ... ☐ ☐ ☐

Pulse beats/min ☐ ☐ ☐

#	Systolic BP	Diastolic BP	Position	
1	mmHg	mmHg	SITTING	☐ ☐ ☐
2	mmHg	mmHg	SITTING	☐ ☐ ☐
3	mmHg	mmHg	SITTING	☐ ☐ ☐

...to this?

CDISC Pilot - eTFL Library

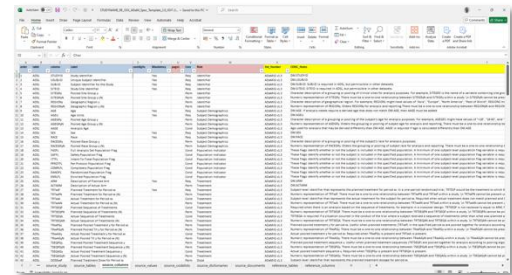
Generated using TFL Designer (Community, v1.0)

Page 1 of 30

ARS-VS-T01

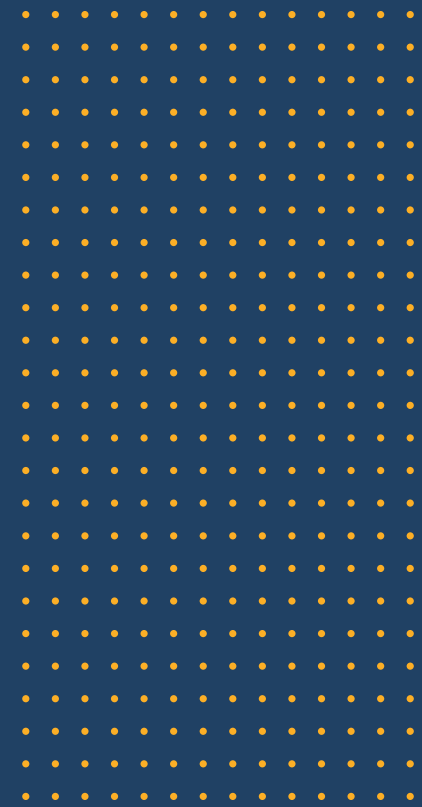
 Summary of Observed and Change from Baseline by Scheduled Visits - Vital Signs
 Safety Population

Parameter (Unit)	Xanomeline Low Dose (N=84)	Xanomeline High Dose (N=84)	Placebo (N=86)
Visit	n (%)	n (%)	n (%)
Diastolic Blood Pressure (mmHg)			
Baseline			
n	252	252	255
Mean (SD)	76.4 (10.25)	78.3 (10.27)	77.1 (10.91)
Median	76.0	79.5	78.0
Min, Max	48, 108	51, 108	40, 110
Week 2			
n	251	243	252
Mean (SD)	76.2 (9.89)	76.4 (10.78)	74.5 (10.42)
Median	76.0	77.0	74.0
Min, Max	45, 102	43, 118	45, 100
Week 2 Change from Baseline			
n	212	215	223
Mean (SD)	-0.2 (9.53)	-2.0 (11.54)	-2.9 (10.27)
Median	1.0	-2.0	-3.0
Min, Max	-28, 32	-38, 28	-34, 30



	ETHNIC_STD	SUCORR	SUCORR_STD	SUBJECT	BLACK	WHITE	JAPANESE
1	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-001			
2	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-001			
3	NOT HISPANIC OR LATINO	Current Scanner	Y Ongoing	45-05-100-002			
4	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-003			
5	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-004			
6	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-005			
7	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-006			
8	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-007			
9	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-008			
10	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-009			
11	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-010			
12	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-011			
13	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-012			
14	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-013			
15	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-014			
16	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-015			
17	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-016			
18	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-017			
19	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-018			
20	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-019			
21	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-020			
22	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-021			
23	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-022			
24	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-023			
25	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-024			
26	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-025			
27	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-026			
28	NOT HISPANIC OR LATINO	Uniform Non-Scanner	N	45-05-100-027			
29	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-028			
30	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-029			
31	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-030			
32	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-031			
33	NOT HISPANIC OR LATINO	Fast Scanner	Y Favor	45-05-100-032			

DD-MMM-YYYY 5



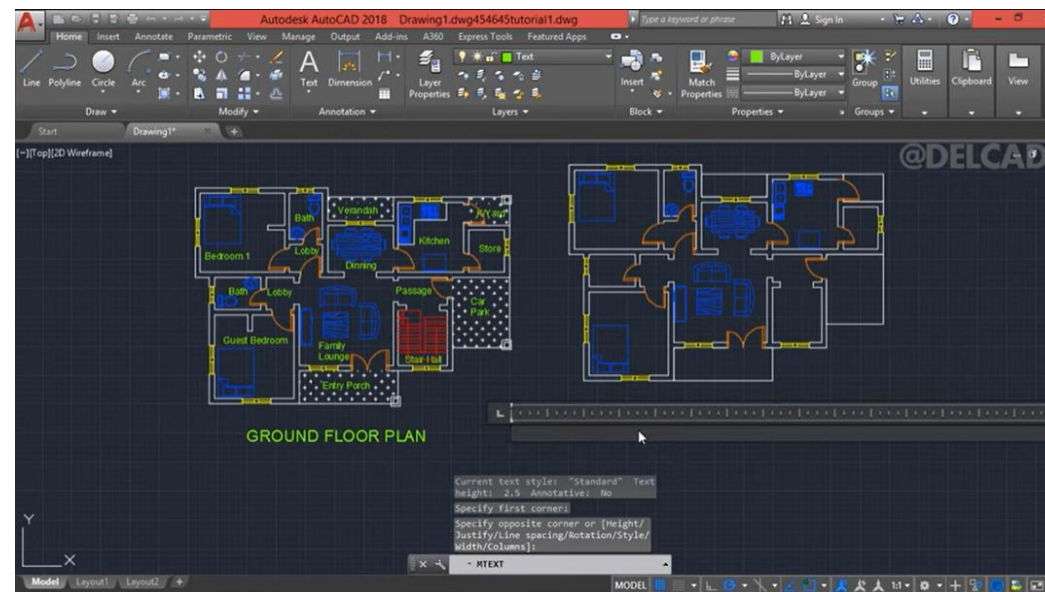
Why do we do it this way?

Moving from electronic to digital

Electronic



Digital



Moving from electronic to digital

Electronic



Study Data Tabulation Model
Implementation Guide: Human Clinical Trials
Version 3.4 (Final)

Developed by the
CDISC Submission Data Standards Team

Notes to Readers

- This is the implementation guide for human clinical trials corresponding to Version 2.0 of the CDISC Study Data Tabulation Model.

Revision History

Date	Version
2021-11-29	3.4 Final
2018-02-20	3.3 Final
2013-11-28	3.2 Final
2012-07-16	3.1.3 Final
2008-11-12	3.1.2 Final
2005-08-26	3.1.1 Final
2004-07-14	3.1

See [Appendix F](#) for representations and warranties, limitations of liability, and disclaimers.

Digital

```

id: https://www.cdisc.org/cosmos/1-0
name: COSMoS-Biomedical-Concepts-Schema

imports:
  - linkml:types

prefixes:
  linkml: https://w3id.org/linkml/
  cosmos: https://www.cdisc.org/cosmos/1-0
  NCIT: http://purl.obolibrary.org/obo/NCIT_

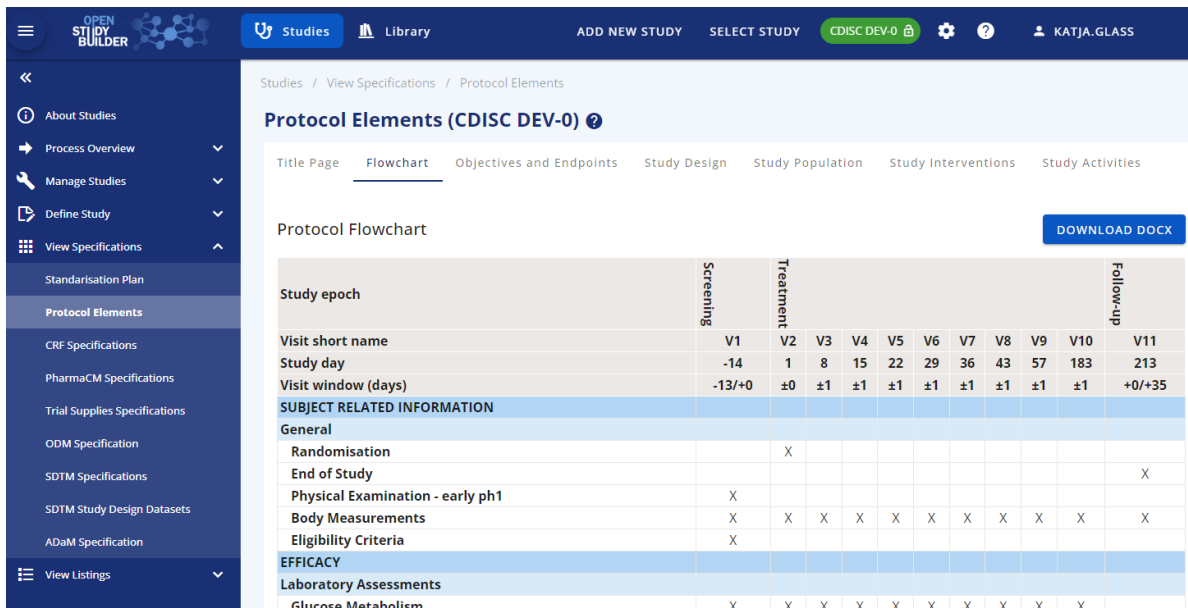
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default_range: string

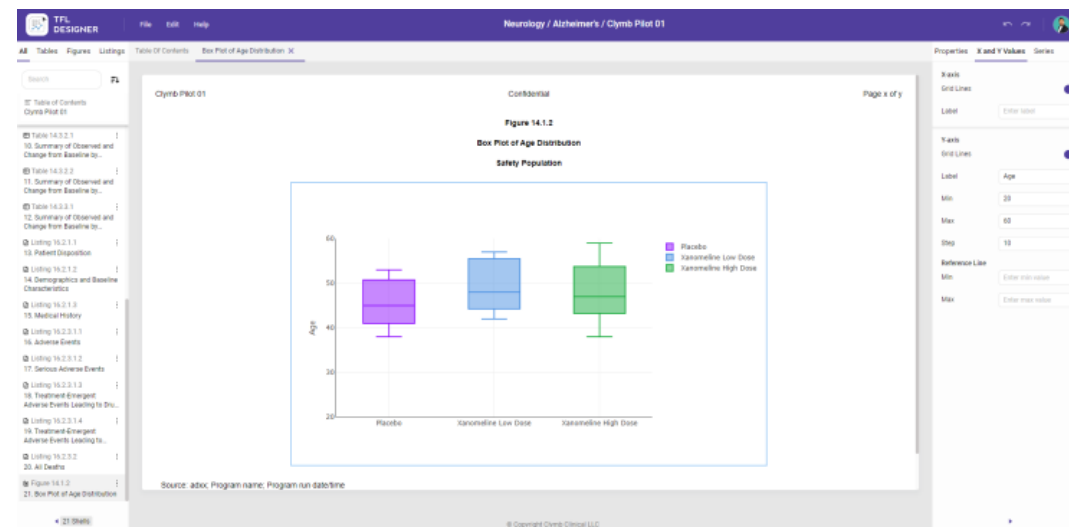
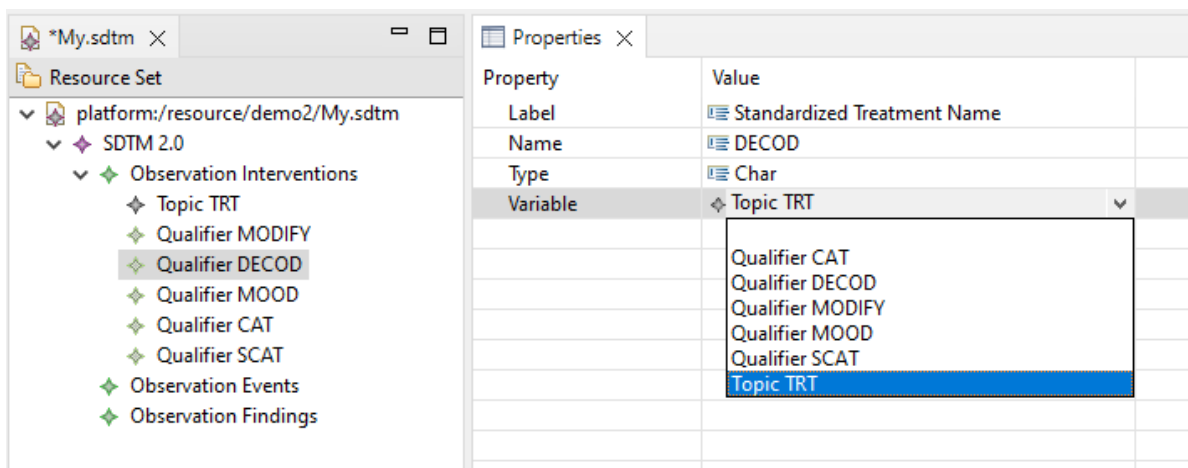
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      - packageType
      - domain
      - shortName
  
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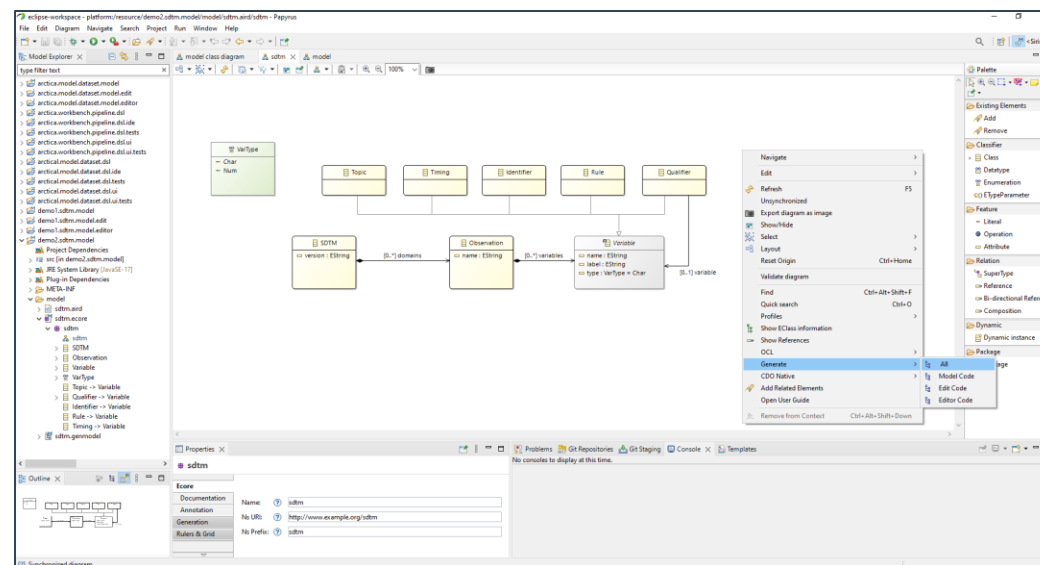
Enabling tool-based biometrics

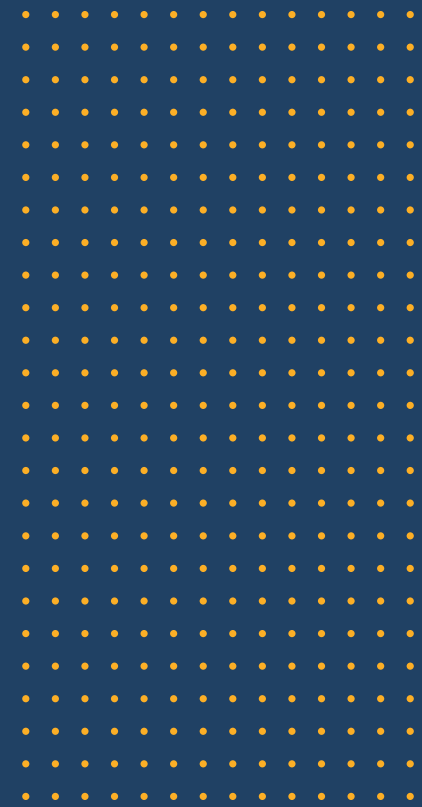


Study epoch	Screening	Treatment	Follow-up
Visit short name	V1	V2 V3 V4 V5 V6 V7 V8 V9 V10	V11
Study day	-14	1 8 15 22 29 36 43 57 183	213
Visit window (days)	-13/+0	±0 ±1 ±1 ±1 ±1 ±1 ±1 ±1 ±1 ±1	+0/+35
SUBJECT RELATED INFORMATION			
General			
Randomisation		X	
End of Study			X
Physical Examination - early ph1	X		
Body Measurements	X	X X X X X X X X X X	X
Eligibility Criteria	X		
EFFICACY			
Laboratory Assessments			
Glucose Metabolism	X	X X X X X X X X X X	

Property	Value
Label	Standardized Treatment Name
Name	DECOD
Type	Char
Variable	Topic TRT





What are Biomedical Concepts?

CDISC Biomedical Concepts and SDTM Dataset Specializations

3 Key pieces

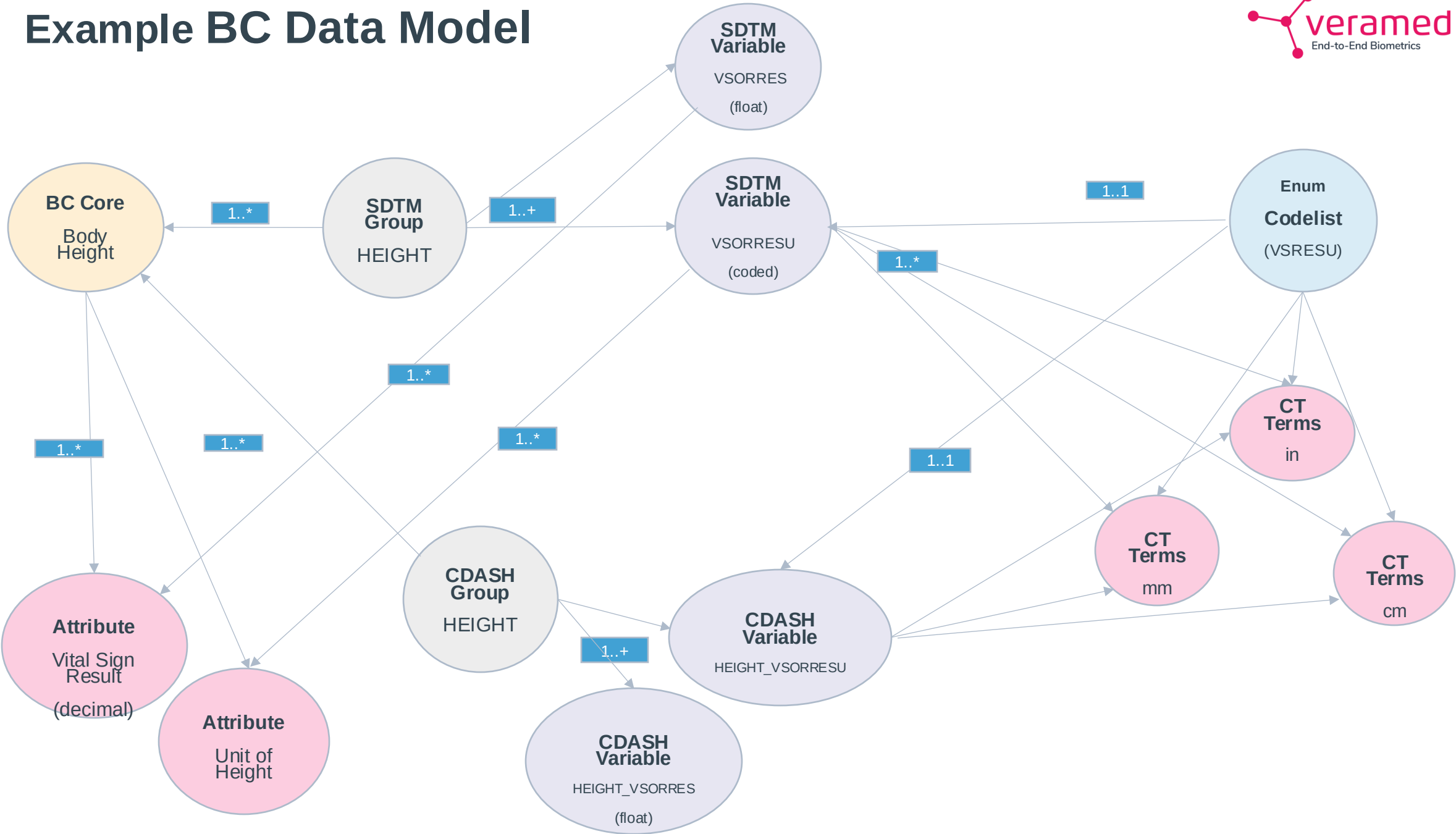
- Conceptual Layer – standards agnostic BC's
 - Provides semantics - aligned with NCI terminology
 - Supports study design, Schedule of Activities (SOA)
- Implementation Layer - Dataset Specializations aligned with standards
 - Dataset specializations as an extended dataset structure
 - Value level data supports programmers
 - Pre-configured building blocks for Define-XML
 - Tailored to BCs to link with unambiguous semantics & definitions
- Extend foundational standards
 - Add explicit relationships between variables
 - Additional operational metadata, e.g., data type, etc.

Each BC has a unique ID

USDM,
CDASH, SDTM

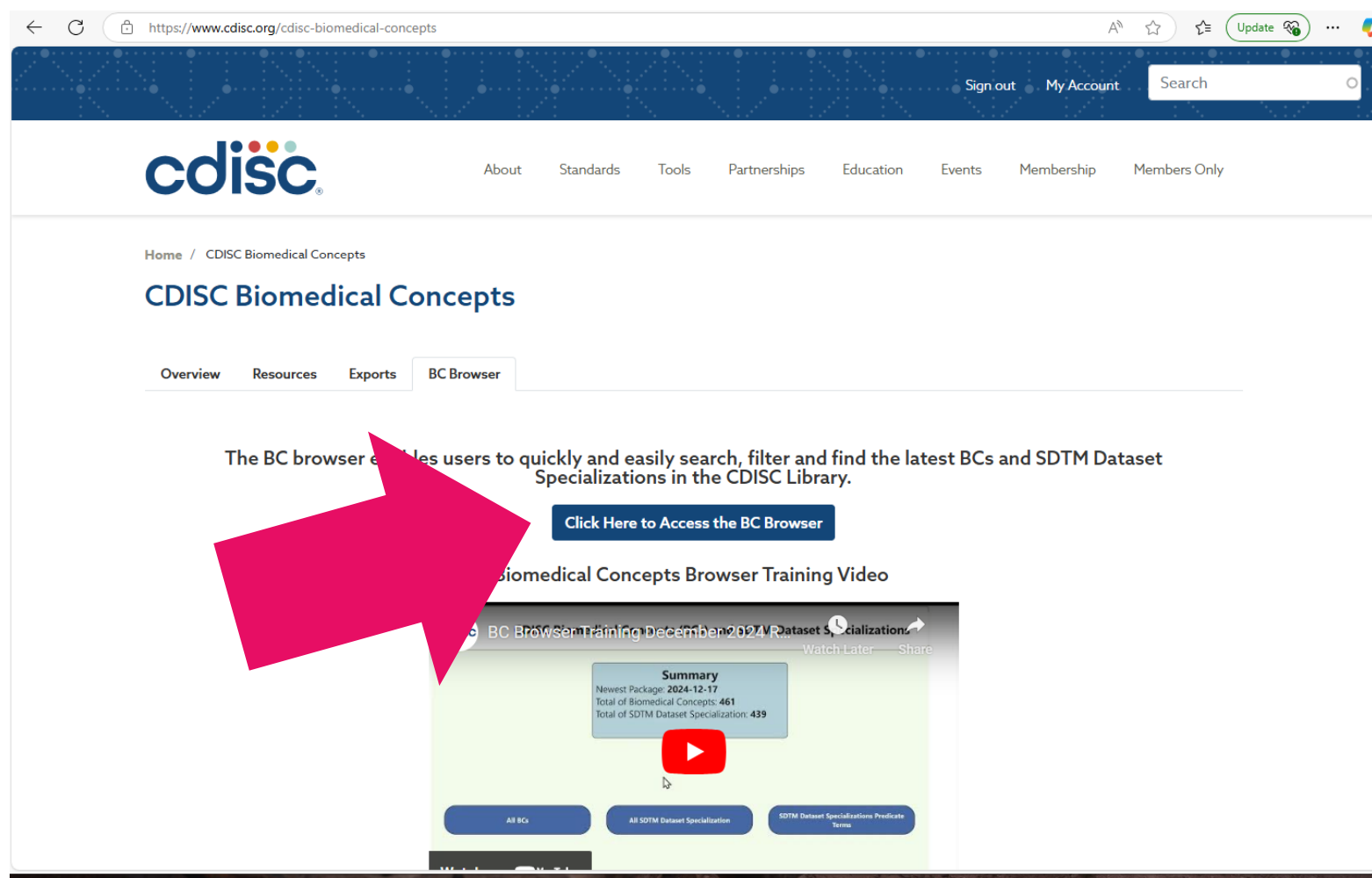
Eventually all
CDISC standards

Example BC Data Model



The BC Browser

<https://www.cdisc.org/cdisc-biomedical-concepts>



The screenshot shows the CDISC Biomedical Concepts BC Browser page. The page has a dark blue header with the CDISC logo and navigation links: About, Standards, Tools, Partnerships, Education, Events, Membership, and Members Only. A search bar is also present. Below the header, the page title is "CDISC Biomedical Concepts" with a breadcrumb "Home / CDISC Biomedical Concepts". A tabbed interface shows "Overview", "Resources", "Exports", and "BC Browser" (which is selected). The main content area states: "The BC browser enables users to quickly and easily search, filter and find the latest BCs and SDTM Dataset Specializations in the CDISC Library." Below this text is a button labeled "Click Here to Access the BC Browser". A video player overlay is positioned in the lower half of the page, titled "CDISC Biomedical Concepts Browser Training Video". The video player shows a summary box with the following information: "Summary", "Newest Package: 2024-12-17", "Total of Biomedical Concepts: 461", and "Total of SDTM Dataset Specialization: 439". The video player also has a red play button and a progress bar.

Search by word

Search

🔍 ✕

SDTM Short Name

BC Short Name

Domain

Domain

VS

▼

SDTM Short Name

Height

▼

SDTM Variable

All

▼

More
Dropdowns



Note: When applying one filter, it applies to the other dropdowns.
Use ctrl + click to do multiple selections in the same filter.



Package Date	BC ID	SDTMIG Start Version	SDTMIG End Version	Domain	VLM Source	VLM Group ID	SDTM Short Name	SDTM Variable
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSDTC
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSORRES
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSORRESU
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSSTRESC
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSSTRESN
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSSTRESU
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSTEST
2024-12-16	C164634	3-2		VS	VS.VSTESTCD	HEIGHT	Height	VSTESTCD

SDTM Dataset Specializations

Search by word

Search



SDTM Short Name

BC Short Name

Domain

Domain

VS



SDTM Short Name

Height



SDTM Variable

All

More
Dropdowns

Note: When applying one filter, it applies to the other dropdowns.
Use ctrl + click to do multiple selections in the same filter.

SDTM Short Name	Assigned Value	Role	Subject	Linking Phrase	Predicate Term	Object	Data Type	Length	Format	Significant Digits	Mandatory Variable
		Timing	VSDTC	is the date of occurrence for	IS_TIMING_FOR	VSTESTCD					Y
		Qualifier	VSORRES	is the result of the test in	IS_RESULT_OF	VSTESTCD	float	8	8.3	3	Y
		Qualifier	VSORRESU	is the unit for the value in	IS_UNIT_FOR	VSORRES					Y
		Qualifier	VSSTRESN	is the result of the test in	IS_RESULT_OF	VSTESTCD	float	8	8.3	3	N
		Qualifier	VSSTRESU	is the result of the test in	IS_RESULT_OF	VSTESTCD	float	8	8.3	3	N
		Qualifier	VSSTRESU	is the unit for the value in	IS_UNIT_FOR	VSSTRESN					N
HEIGHT		Qualifier	VSTEST	decodes the value in	DECODES	VSTESTCD					Y
HEIGHT		Topic	VSTESTCD	is the code for the value in	IS_DECODED_BY	VSTEST					Y

Takeaway

- Move from electronic to digital
 - Machine readable standards
 - Enable tool-based workflow
- Codelists + Relationships + Dataset Specializations
 - Currently CDASH and SDTM
 - BC used in USDM
- Coming to all CDISC standards

Thanks!

Questions?

Stuart.Malcolm@Veramed.co.uk

<https://www.linkedin.com/in/stuart-malcolm/>

