

From Schedule of Activities to SDTM: Automating Data Standards with USDM and BCs

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PHUSE SDE SAN MARCOS, TX 2026

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Introductions

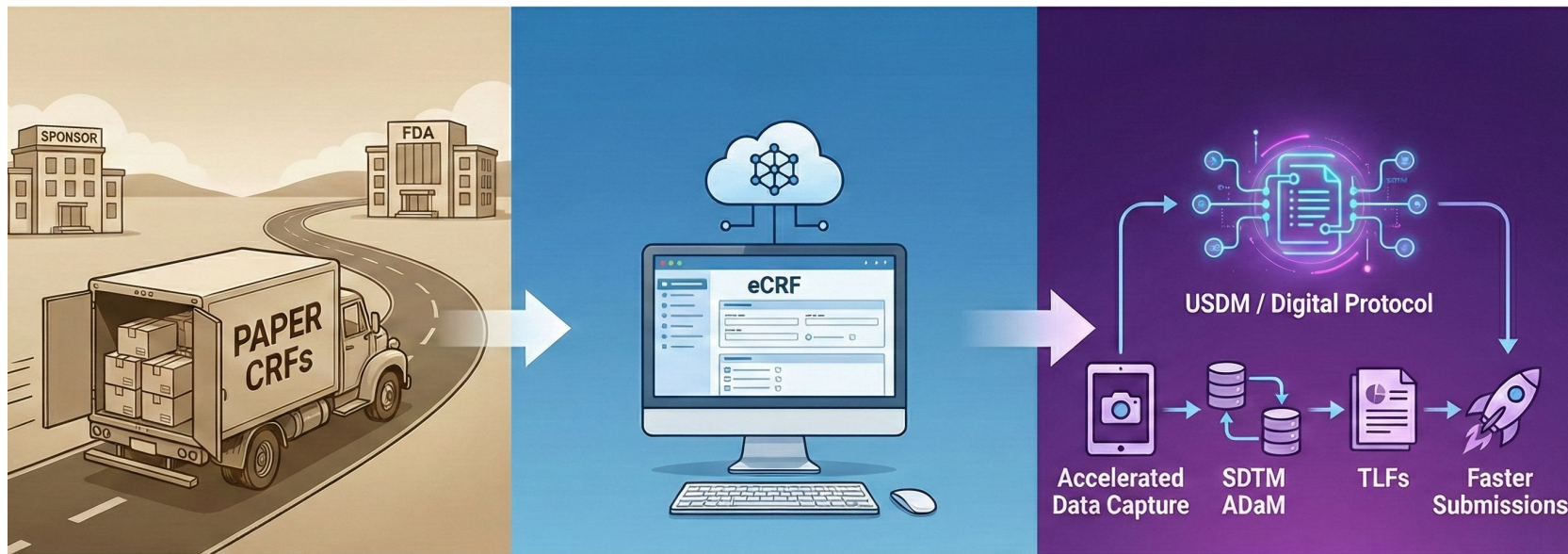


Bhargav Koduru

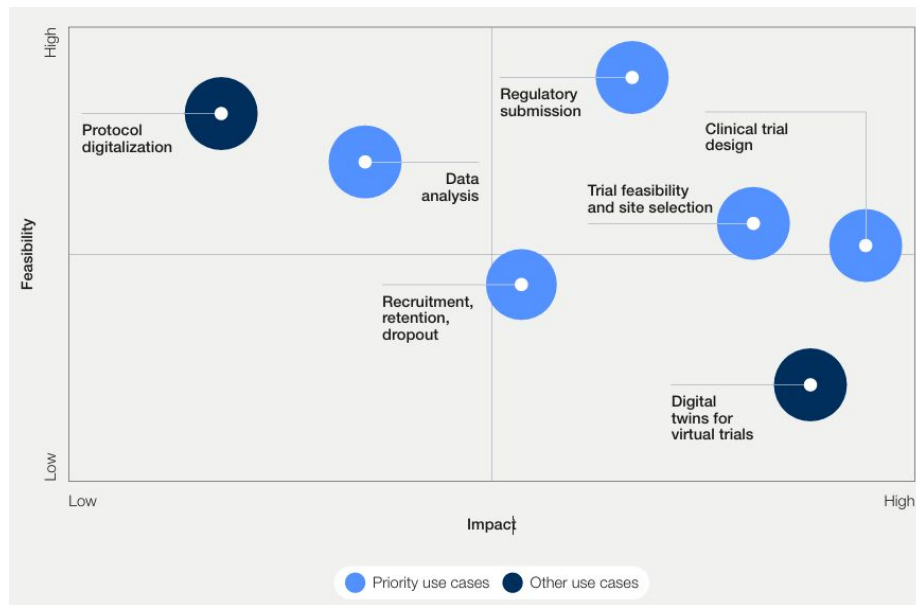
Senior Manager, Statistical Programming, Clinical Data Standards

- Driving Clinical and Operational Data Standards at Medidata.
- Over a decade of experience at Medidata, Seattle Genetics (now Pfizer), Sarepta, and Bioclinica (now Clario).
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- MSc (Medical) Biochemistry, Manipal University
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Evolution of Clinical Trial Conduct



Impact of Protocol Digitization



60% of protocols require at least one amendment

~50% of these amendments are avoidable

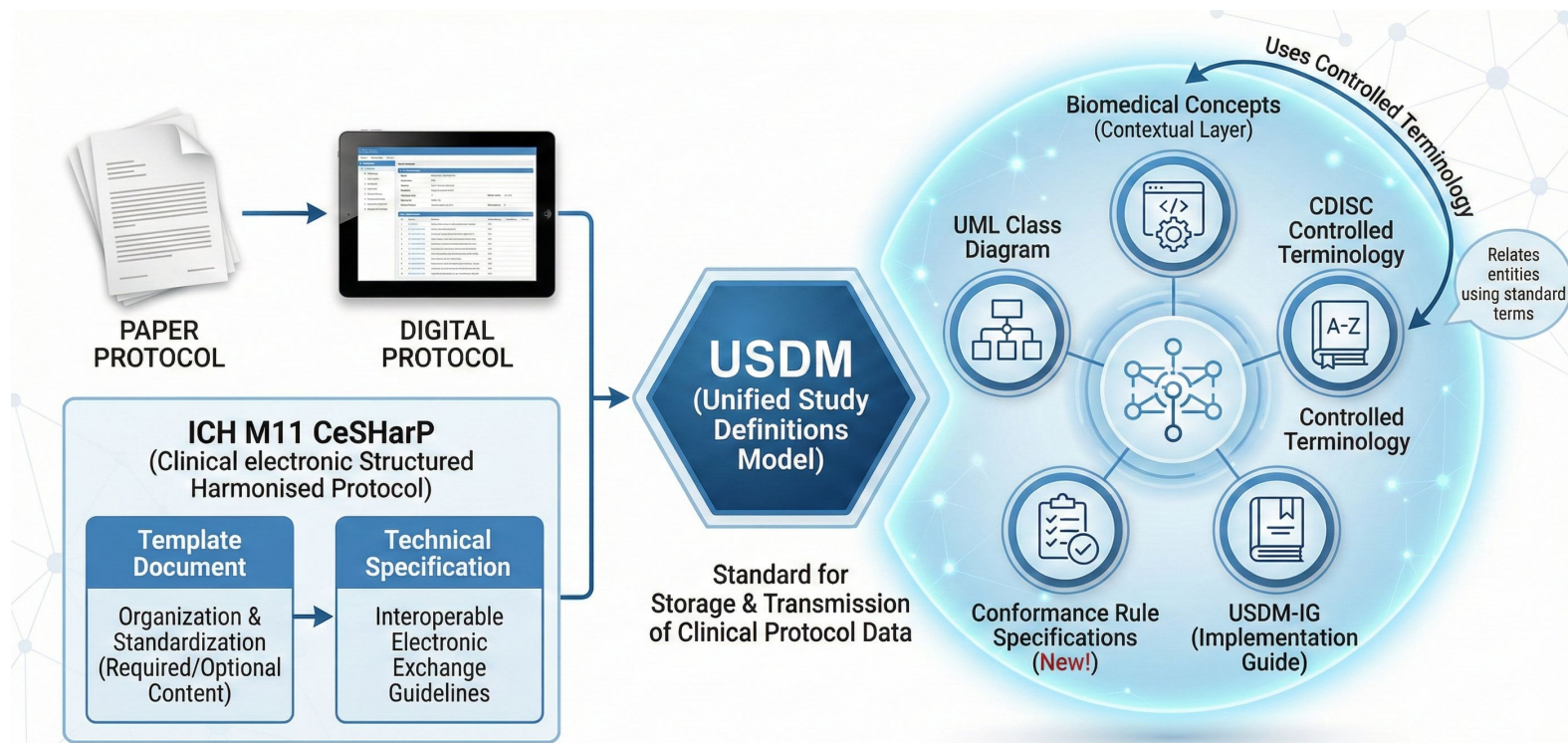
\$2 Billion annual cost incurred from avoidable changes

260 Days added to development timelines per amendment

25% of trial budgets consumed by manual, labor-intensive tasks

World Economic Forum. (2024, December). *Intelligent clinical trials: Using generative AI to fast-track therapeutic innovations*. https://reports.weforum.org/docs/WEF_Intelligent_Clinical_Trials_2024.pdf

Digital Protocol Toolkit



ICH M11 Template Document

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

8	TRIAL ASSESSMENTS AND PROCEDURES	36
8.1	Trial Assessments and Procedures Considerations	36
8.2	Screening/Baseline Assessments and Procedures	36
8.3	Efficacy Assessments and Procedures	37
8.4	Safety Assessments and Procedures	37
8.4.1	{Physical Examination}	37
8.4.2	{Vital Signs}	<Enter Safety Assessments and Procedures>

8.4.1 {Physical Examination}

Include any specific instructions for the collection and interpretation of physical examinations.

{<Enter Physical Examination>}

8.4.2 {Vital Signs}

Include any specific instructions for the collection and interpretation of vital signs.

{<Enter Vital Signs>}



ICH M11 Technical Specification

CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)

<Enter Safety Assessments and Procedures>

8.4.1 {Physical Examination}

Include any specific instructions for the collection and interpretation of physical examinations.

{<Enter Physical Examination>}

8.4.2 {Vital Signs}

Include any specific instructions for the collection and interpretation of vital signs.

{<Enter Vital Signs>}

Term (Variable)	{<Vital Signs>}
Data Type	Text
Data (D), Value (V) or Heading (H)	D
Definition	C154628 For review purpose, see definition of the controlled terminology below The procedures for measurements of the body's basic functions that provide insight into the health status of the person.
User Guidance	Include any specific instructions for the collection and interpretation of vital signs.
Conformance	Conditional: when Vital Signs are required
Cardinality	One to one
Relationship content from ToC representing the protocol hierarchy	8.4.2
Value	Text
Business rules	Value Allowed: Yes Relationship: 8.4.2 Vital Signs Concept: C154628
Repeating and/or Reuse Rules	No



USDM UML

Statistical
analysis

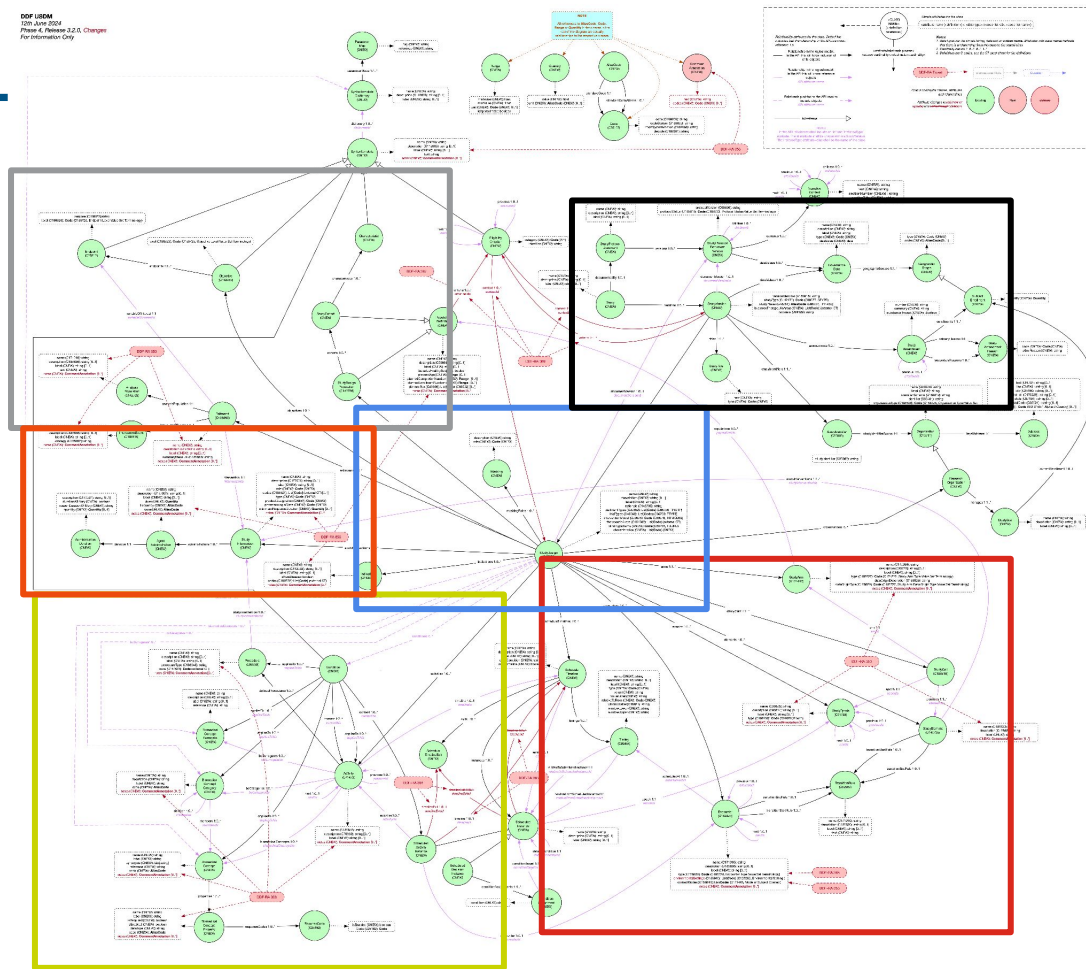
Interventions

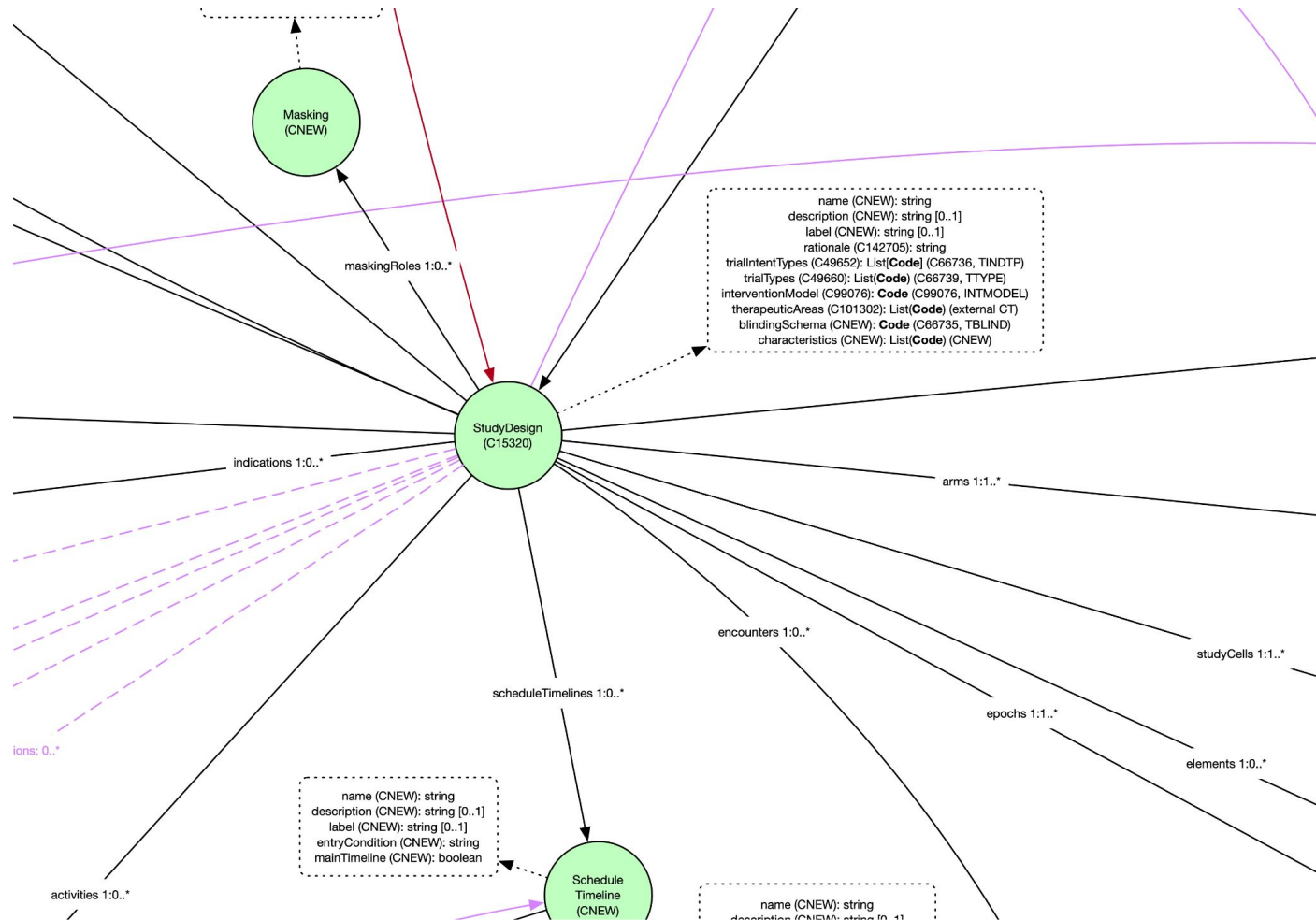
Activities

Revisions and
Documents

Core Concepts

Encounters





Schedule of activities

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

ScheduledActivityInstance

Encounter

Activity

ScheduledDecisionInstance

	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 ≤ 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						
CT Scan (if not within last year and patient passes all other screens)		X						
Concomitant Medications		X		X	X	X	X	X
Laboratory (Chem/Hemat):		X			X	X	X	X
Laboratory (Urinalysis)		X			X			

Schedule of activities

Schedule of activities

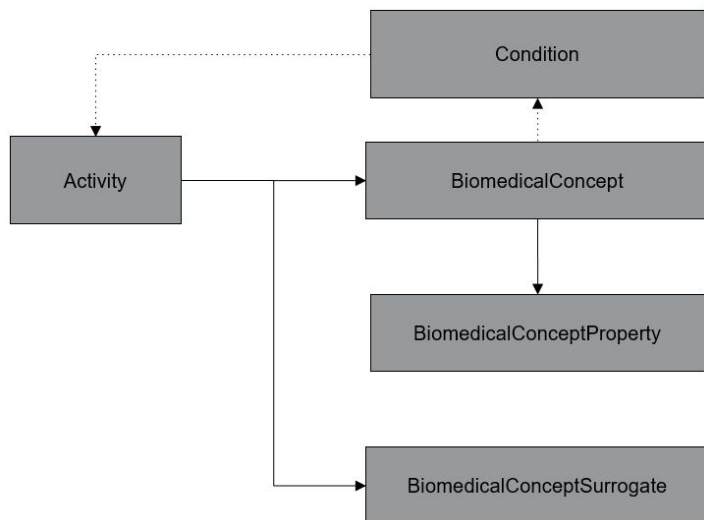
	Screening	Day 1	
Subject related Assessments			
Informed consent	X		
In/Exclusion criteria	X	X	
Demography	X		
Medical history	X		
Randomisation		X	
Efficacy			
Lab efficacy assessments		X	X
PRO questionnaire		X	X
Safety			
Vital signs	X	X	X
ECG	X	X	
Hematology	X	X	
Biochemistry	X	X	
Adverse events	X	X	X
Intervention			
Drug dispensation		X	X
Drug accountability		X	

Corresponding activity class content

label	id	previous	next	children
Subject related Assessments	id_01		id_02	id_02, id_03, id_04, id_05, id_06
Informed consent	id_02	id_01	id_03	
In/Exclusion criteria	id_03	id_02	id_04	
Demography	id_04	id_03	id_05	
Medical history	id_05	id_04	id_06	
Randomisation	id_06	id_05	id_07	
Efficacy	id_07	id_06	id_08	id_08, id_09
Lab efficacy assessments	id_08	id_07	id_09	
PRO questionnaire	id_09	id_08	id_10	
Safety	id_10	id_09	id_11	id_11, id_12, id_13, id_14, id_15
Vital signs	id_11	id_10	id_12	
ECG	id_12	id_11	id_13	
Hematology	id_13	id_12	id_14	
Biochemistry	id_14	id_13	id_15	
Adverse events	id_15	id_14	id_16	
Intervention	id_16	id_15	id_17	id_17, id_18
Drug dispensation	id_17	id_16	id_18	
Drug accountability	id_18	id_17		

Clinical Data Interchange Standards Consortium. *Unified Study Definitions Model Implementation Guide (USDM-IG)*. GitHub, <https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/IG/USDM-IG.pdf>. Accessed 27 Jan. 2026.

Biomedical Concepts



- Conditions are how conditional/dynamic elements are defined in the USDM; eg cycles, footnotes
- Biomedical Concepts are the common representation for reusable domain models, maintained by CDISC/NCI
- Surrogates are used to describe the concepts (if they don't exist as current Biomedical Concepts)

Biomedical Concepts

Biomedical Concepts (BC) are used to define common concepts used in the management of data in research; these are focused on standardisation and reuse.

They are curated by NCI on behalf of CDISC.

Within the context of USDM, BC can be individual 'observations' (like Systolic Blood Pressure) or composites (like Vital Signs).

Structure of BC

```
{
  "links": {
    "parentBiomedicalConcept": {
      "href": "/mdr/bc/biomedicalconcepts/C54706",
      "title": "Blood Pressure",
      "type": "Biomedical Concept"
    },
    "parentPackage": {
      "href": "/mdr/bc/packages/2025-11-18/biomedicalconcepts",
      "title": "Biomedical Concept Package Effective 2025-11-18",
      "type": "Biomedical Concept Package"
    },
    "self": {
      "href": "/mdr/bc/biomedicalconcepts/C25298",
      "title": "Systolic Blood Pressure",
      "type": "Biomedical Concept"
    }
  },
  "conceptId": "C25298",
  "href": "https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C25298",
  "categories": [
    "Vital Signs",
    "Blood Pressure"
  ],
  "shortName": "Systolic Blood Pressure",
  "synonyms": [
    "SYSBP"
  ],
  "resultScales": [
    "Quantitative"
  ],
  "definition": "The maximum pressure exerted into the systemic arterial circulation during the contraction of the left ventricle of the heart.",
  "coding": [
    {
      "code": "8480-6",
      "system": "http://loinc.org/",
      "systemName": "LOINC"
    }
  ]
}
```

Taxonomic organisation of the BCs allows grouping/composition

CDISC release new packages ~ 2-3x annually

Dereferenceable URIs

References to other code systems (where relevant)

Structure of BC - cont

```
"dataElementConcepts": [  
  {  
    "conceptId": "C82535",  
    "href": "https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C82535",  
    "shortName": "Test Method",  
    "dataType": "string",  
    "exampleSet": [  
      "Auscultation automatic",  
      "Auscultation manual",  
      "Cuff-manual palpated",  
      "Doppler",  
      "Oscillometry",  
      "Arterial line",  
      "Venous line",  
      "Continuous noninvasive arterial pressure (CNAP)"  
    ],  
    "ncitCode": "C82535"  
  },  
  {  
    "conceptId": "C62164",  
    "href": "https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C62164",  
    "shortName": "Body Position",  
    "dataType": "string",  
    "exampleSet": [  
      "Decubitus",  
      "Fowlers",  
      "Lateral Decubitus",  
      "Prone",  
      "Reverse Trendelenburg",  
      "Semi-Fowlers",  
      "Semi-Recumbent",  
      "Sitting",  
      "Sitting Legs Dependent",  
      "Sling",  
      "Standing",  
      "Supine",  
      "Trendelenburg",  
      "Unconstrained"  
    ],  
    "ncitCode": "C62164"  
  },  
  {  
    "conceptId": "C70856",  
    "href": "https://evsexplore.semantics.cancer.gov/evsexplore/concept/ncit/C70856",  
    "shortName": "Observation Result",  
    "dataType": "decimal",  
    "ncitCode": "C70856"  
  },  
]
```

List of values (note, not a reference to a CT)

Generic Datatypes

Structure of BC - cont

```
{
  "links": {
    "parentBiomedicalConcept": {
      "href": "/mdr/bc/biomedicalconcepts/C49672",
      "title": "Vital Signs Measurement",
      "type": "Biomedical Concept"
    },
    "parentPackage": {
      "href": "/mdr/bc/packages/2025-11-18/biomedicalconcepts",
      "title": "Biomedical Concept Package Effective 2025-11-18",
      "type": "Biomedical Concept Package"
    }
  },
  "self": {
    "href": "/mdr/bc/biomedicalconcepts/C54706",
    "title": "Blood Pressure",
  },
}
```

```
{
  "_links": {
    "parentPackage": {
      "href": "/mdr/bc/packages/2024-12-16/biomedicalconcepts",
      "title": "Biomedical Concept Package Effective 2024-12-16",
      "type": "Biomedical Concept Package"
    },
    "self": {
      "href": "/mdr/bc/biomedicalconcepts/C49672",
      "title": "Vital Signs Measurement",
      "type": "Biomedical Concept"
    }
  },
}
```

Home

Biomedical Concepts (BCs)

Search by Word

vital signs

BC Categories

BC Short Name

NCIt Code

BC ID

All

NCIt Code

All

Package Date

All

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

Package Date	BC Short Name	BC ID	NCIt Code	Parent BC ID	BC Categories	Synonyms
2024-12-16	Vital Signs Measurement	C49672	C49672		Vital Signs	Vital Signs;VS
2025-11-18	Blood Pressure	C54706	C54706	C49672	Vital Signs;Blood Pressure	BP

```
},
"ncitCode": "C54706"
}
```

ate, respiratory

BCs at the CRF layer

Subject: **Subject**
Page: **Vital Signs**

	OIDs		BCs
Were Vital Signs Collected?	VSSTAT	☐ Yes ☐ No	
Please provide the reason Vital Signs were not collected:	VSREASND		
Date of Measurements:	VSDTC		
Height:	VSORRESHT		HEIGHT (C164634)
Weight:	WEIGHT		WEIGHT (C81328)
BMI (Calculated)	BMI		BMI (C16358)
Blood Pressure:			SYSBP (C25298)
Blood Pressure:			DIABP (C25299)
Systolic Blood Pressure:	SYSBP	mmHg	PULSE (C49676)
Diastolic Blood Pressure:	DIABP	mmHg	TEMP (C174446)
Pulse Rate:	PULSE	BPM	RESP (C49678)
Temperature:	TEMP		
Respiration Rate:	RESP	per minute	

HeartRateMeasurement BC

SDTM
Data Set

Table: VS

bodyPosition

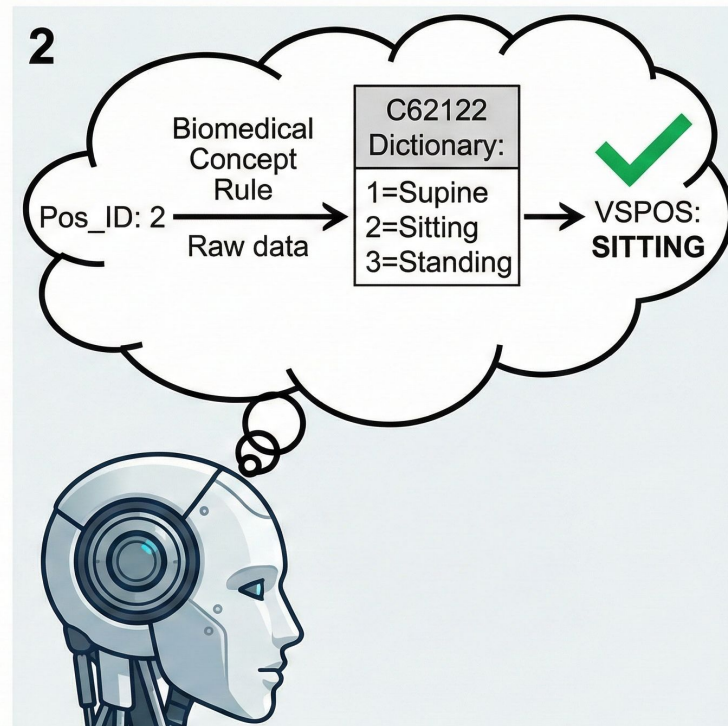
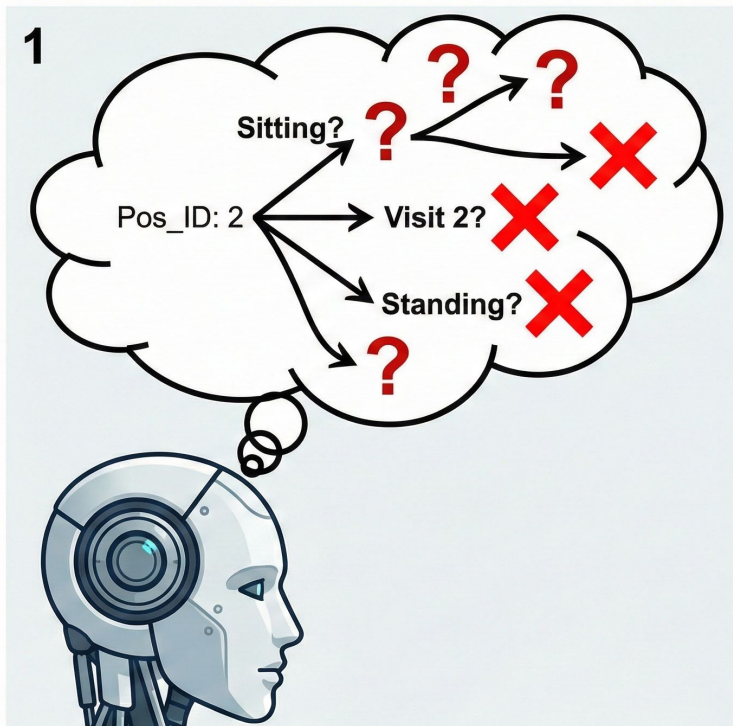
value

unit

assessmentDate

	B	C	D	E	F	G	H	I	J		P	Q	R	S	T	U
	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSTRESU	VISITNUM	VISIT	VISITDY	VSDTC	VSDY	VSTPT
..OT01	VS	01-701-1015	44	PULSE	Pulse Rate	SUPINE	57	BEATS/MIN	57		1	SCREENING 1	-7	2013-12-26	-7	AFTER LYING D
..OT01	VS	01-701-1015	45	PULSE	Pulse Rate	STANDING	62	BEATS/MIN	62		1	SCREENING 1	-7	2013-12-26	-7	AFTER STANDI
..OT01	VS	01-701-1015	46	PULSE	Pulse Rate	STANDING	65	BEATS/MIN	65		1	SCREENING 1	-7	2013-12-26	-7	AFTER STANDI
..OT01	VS	01-701-1015	47	PULSE	Pulse Rate	SUPINE	56	BEATS/MIN	56		2	SCREENING 2	-1	2013-12-31	-2	AFTER LYING D
..OT01	VS	01-701-1015	48	PULSE	Pulse Rate	STANDING	60	BEATS/MIN	60		2	SCREENING 2	-1	2013-12-31	-2	AFTER STANDI
..OT01	VS	01-701-1015	49	PULSE	Pulse Rate	STANDING	57	BEATS/MIN	57		2	SCREENING 2	-1	2013-12-31	-2	AFTER STANDI
..OT01	VS	01-701-1015	50	PULSE	Pulse Rate	SUPINE	56	BEATS/MIN	56		3	BASELINE	1	2014-01-02	1	AFTER LYING D
..OT01	VS	01-701-1015	51	PULSE	Pulse Rate	STANDING	59	BEATS/MIN	59		3	BASELINE	1	2014-01-02	1	AFTER STANDI
..OT01	VS	01-701-1015	52	PULSE	Pulse Rate	STANDING	59	BEATS/MIN	59		3	BASELINE	1	2014-01-02	1	AFTER STANDI
..OT01	VS	01-701-1015	53	PULSE	Pulse Rate	SUPINE	61	BEATS/MIN	61		3.5	AMBUL ECG PL	13	2014-01-14	13	AFTER LYING D
..OT01	VS	01-701-1015	54	PULSE	Pulse Rate	STANDING	65	BEATS/MIN	65		3.5	AMBUL ECG PL	13	2014-01-14	13	AFTER STANDI
..OT01	VS	01-701-1015	55	PULSE	Pulse Rate	STANDING	61	BEATS/MIN	61		3.5	AMBUL ECG PL	13	2014-01-14	13	AFTER STANDI
..OT01	VS	01-701-1015	56	PULSE	Pulse Rate	SUPINE	58	BEATS/MIN	58		4	WEEK 2	14	2014-01-16	15	AFTER LYING D
..OT01	VS	01-701-1015	57	PULSE	Pulse Rate	STANDING	61	BEATS/MIN	61		4	WEEK 2	14	2014-01-16	15	AFTER STANDI
..OT01	VS	01-701-1015	58	PULSE	Pulse Rate	STANDING	62	BEATS/MIN	62		4	WEEK 2	14	2014-01-16	15	AFTER STANDI
..OT01	VS	01-701-1015	59	PULSE	Pulse Rate	SUPINE	59	BEATS/MIN	59		5	WEEK 4	28	2014-01-30	29	AFTER LYING D
..OT01	VS	01-701-1015	60	PULSE	Pulse Rate	STANDING	62	BEATS/MIN	62							
..OT01	VS	01-701-1015	61	PULSE	Pulse Rate	STANDING	59	BEATS/MIN	59							

BC acting as a Guardrail for Transformation



Thanks