Biomedical Concepts (BC) -
## Unified Study Definition Model (USDM)

Agenda

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- Biomedical Concepts (BC)
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  - BC – im Detail
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  - API (Application Programming Interface) Nutzung
- Unified Study Definition Model (USDM)
  - Wer, was, wie, warum
  - Aufbau, BCs im USDMDiskussion
- Referenzen
- Diskussion

Einleitung

BC und USDM

- sind Datenmodelle in Form von Klassen* definiert. Sie beschreiben
  - ✓ die Beziehung von Dingen zueinander
  - ✓ Die Dinge selbst, d.h. definieren Begriffe
- ermöglichen die Entwicklung von Anwendungen, indem einheitliche Strukturen und Schnittstellen definiert werden.
- ermöglichen den Datenaustausch innerhalb und zwischen Anwendungen

Die Datenmodelle werden basierend auf sogenannten Concept Maps erstellt.
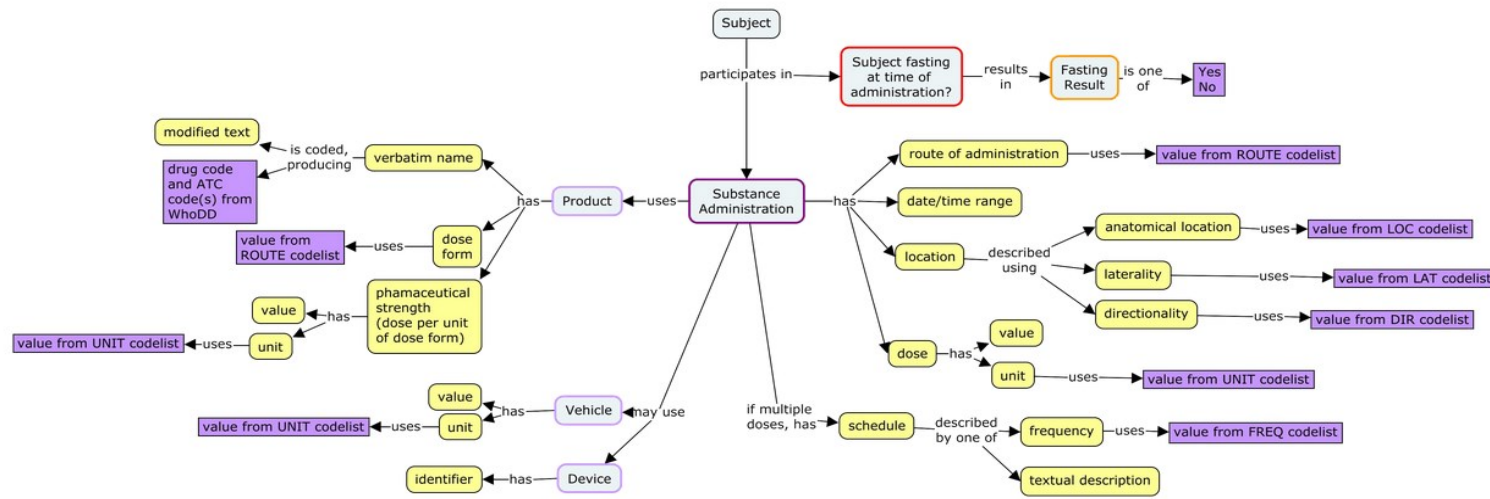
*Klasse ist ein Begriff aus der Objektorientierten Programmierung. Unter Klasse kann man sich ganz grob eine Art Vorlage oder Bauplan vorstellen, um Objekte zu erzeugen. Eine Klasse definiert die Eigenschafte (Attribute bzw. Elemente) und das Verhalten (Methoden) von Objekten, die von der Klasse erzeugt werden.

Biomedical Concepts (BC)
Wer, was ,wie, warum

- **Wer**:

    Conceptual and Operational Standards Metadata Services (COSMoS) ; Projekt Start 2022

- **Was**:

    Verallgemeinerung und Weiterentwicklung der bestehenden Codetable Mapping Dateien

    Stellt Terminologie für biomedizinische Inhalte bereit

    Stellt den Zusammenhang mit den entsprechenden SDTM Variablen her

    Stellt Metadaten zur Generierung von eCRF und define.xml zur Verfügung

- **Wie**:

    Pragmatic, iterative, use-case focused approach

- **Warum**:

    Reduce variability in standards implementations.

    Increase metadata-driven automation.

    Reduce barriers to operational implementation.

Biomedical Concepts (BC)
Datenmodell: conceptual vs. Implementation layer

Das Datenmodell besteht aus zwei Ebenen:
- Biomedical Concepts (Conceptional layer):
  - ✓ Standardisierte Terminologie für biomedizinische Begriffe. Basierend auf NCI EVS (National Cancer Institute Enterprise Vocabulary Services)
  - ✓ Bestehend aus einem oder mehreren DEC (Data Element Concept)
  - ✓ Hierarchisch aufgebaut
  - ✓ Unterstützt die eCRF Erstellung
- SDTM dataset specialization (Implementation layer):
  - ✓ Definiert die SDTM Variablen, die mit einem BC verbunden sind
  - ✓ Definiert die Codelisten der SDTM Variablen
  - ✓ Liefert „Textbausteine" für die Definition von define.xml
  - ✓ Unterstützt die define.xml Erstellung
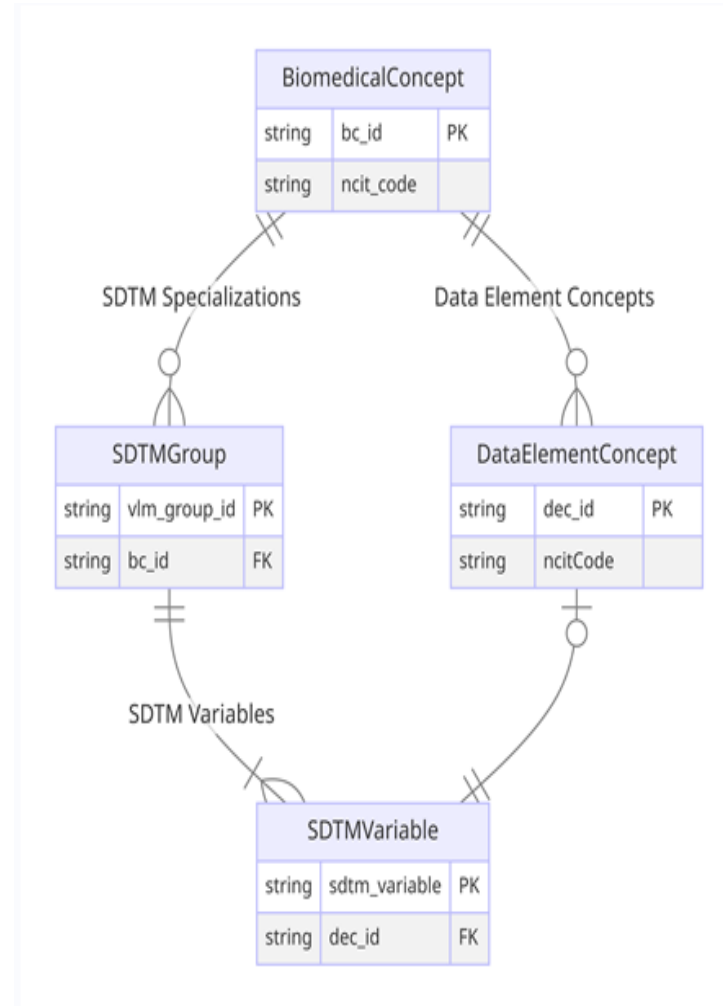
Biomedical Concepts (BC)
BC – im Detail

Group	Column	Description	Class
Biomedical Concept	package_date	Biomedical Concept package release date indicating when the BC package was published to production	BiomedicalConcept
	short_name	NCI Preferred Name for the concept; provisional name will be used if concept is not available in NCIt	
	bc_id	A unique identifier for a Biomedical Concept which will be assigned as the NCIt code if it exists or a placeholder identifier if the concept is not yet available in NCIt	
	ncit_code	NCIt C-code for the Biomedical Concept	
	parent_bc_id	C-code for the parent concept in the NCIt hiearchy; blank if concept is not available in NCIt	
	bc_categories	Biomedical Concept category for the faciliation of API search and extract	
	synonyms	Biomedical Concept synonym equivalent to BC short name for the facilitation of API search and extraction	
	result_scales	Scale of measurement for the Biomedical Concept result	
	definition	NCIt definition for the Biomedical Concept; provisional defintion if concept is not available in NCIt	
	system	Identifies the code system for the synonym concept. The URL of the code system should be used if it exists	Coding
	system_name	Human-readable name for the code system	
	code	Synonym concept for the Biomedical Concept as defined in a code system	
Data Element Concept (DEC)	dec_id	An identifier for a Data Element Concept (DEC) which will be assigned as the NCIt code if it exists or a placeholder identifier if the concept is not yet available in NCIt	DataElementConcept
	ncit_dec_code	NCI C-code for the BC Data Element Concept	
	dec_label	NCI Preferred Name for the concept; provisional name will be used if concept is not available in NCIt	
	data_type	Data Type for the Data Element Concept	
	example_set	Example values for the Data Element Concept	

Momentan nur LOINC

Biomedical Concepts (BC)
SDTM dataset specialization – im Detail

Group	Column	Description	Class
SDTM Group	package_date	Biomedical Concept package release date indicating when the BC package was published to production	SDTMGroup
	bc_id	Biomedical Concept identifier foreign key	
	sdtmig_start_version	The earliest SDTMIG version applicable to the BC dataset specialization	
	sdtmig_end_version	The last SDTMIG version that is applicable to the BC dataset specialization	
	domain	Domain for the SDTM specialization group	
	vlm_source	SDTM VLM Source which categorizes VLM groups by topic variable	
	vlm_group_id	Identifier for SDTM Value Level Metadata group	
	short_name	SDTM group short name which provides a user friendly and intuitive name for the vlm_group_id	
SDTM Variable	sdtm_variable	Variable included in the SDTM dataset specialization	SDTMVariable
	dec_id	Biomedical Concept Data Element Concept idenfifier foreign key	
	nsv_flag	Flag that indicates if the variable is a non-standard variable	
	codelist	C-code for a codelist in NCIt	CodeList
	codelist_submission_value	CDISC submission value for the codelist	
	subset_codelist	Subset codelist short name	SDTMVariable
	value_list	List of SDTM submission values used if subset codelist is not applicable	
	assigned_term	C-code for assigned term in NCIt or left blank when CDISC terminology does not apply	AssignedTerm
	assigned_value	Submission value for assigned term in NCIt if it exists, or an assigned value which will be the default value	
	role	SDTM variable role	SDTMVariable
	subject	Subject in a variable relationship	Relationship
	linking_phrase	Variable relationship descriptive linking phrase	
	predicate_term	Short variable relationship linking phrase for programming purposes	
	object	Object in a variable relationship	
	data_type	Variable data type	SDTMVariable
	length	Variable length	
	format	Variable display format	
	significant_digits	Variable significant_digits	
	mandatory_variable	Indicator that variable must be present within the SDTM group	
	mandatory_value	Indicator that variable must be populated within the SDTM group	
	origin_type	Variable origin type (define-XML v21)	
	origin_source	Variable origin source (define-XML v21)	
	comparator	Comparison operator for SDTM group variables included in VLM	
	vlm_target	Target variable for VLM	

Biomedical Concepts (BC)
BC am Beispiel Blood Pressure (Finding Class)

	Biomedical Concept (BC)										Data Element Concept (DEC)				
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
	package_date	short_name	bc_id	ncit_code	parent_bc_id	bc_categories	synonyms	result_scales	definition	system	system_name	code	dec_id	ncit_dec_code	dec_label	data_type	example_set
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C77140	C77140	Clinical Test Result	decimal	
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C49669	C49669	Unit of Pressure	string	cmHg;mmHG;Pascal
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C13717	C13717	Anatomic Site	string	Arm;Forearm;Thigh;Calf;Artery;Vein
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C25185	C25185	Laterality	string	Left;Right
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C82535	C82535	Test Method	string	Auscultation automatic;Auscaltation manual;Cuff-manual
2023-12-12	Systolic Blood Pressure	C25298	C25298	C54706	Vital Signs	SYSBP	Quantitative	The maximum pressure exerted into the systemic arterial circulation during the contraction	http://loinc.org/	LOINC	8480-6	C62164	C62164	Body Position	string	Decupitus;Fowlers;Lateral Decupitus;Prone;Reverse Trendelenburg;Semi-Fowlers;Semi-
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C77140	C77140	Clinical Test Result	decimal	
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C49669	C49669	Unit of Pressure	string	cmHg;mmHG;Pascal
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C13717	C13717	Anatomic Site	string	Arm;Artery;Calf;Forearm;Thigh;Vein
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C25185	C25185	Laterality	string	Left;Right
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C82535	C82535	Test Method	string	Auscultation automatic;Auscaltation manual;Cuff-manual
2023-12-12	Diastolic Blood Pressure	C25299	C25299	C54706	Vital Signs	DIABP	Quantitative	The minimum pressure exerted into the systemic arterial circulation during cardiac	http://loinc.org/	LOINC	8462-4	C62164	C62164	Body Position	string	Decupitus;Fowlers;Lateral Decupitus;Prone;Reverse Trendelenburg;Semi-Fowlers;Semi-
2023-12-12	Vital Signs Measurement	C49672	C49672		Vital Signs	Vital Signs;VS		The act of assessing an individual's current temperature, heart rate, respiratory rate, pulse oxygenation, and blood pressure.								
2023-12-12	Blood Pressure	C54706	C54706	C49672	Vital Signs	BP		The pressure of the circulating blood against the walls of the blood vessels.	http://loinc.org/	LOINC	55284-4					

https://github.com/cdisc-org/COSMoS/tree/main/export

Biomedical Concepts (BC)
SDTM dataset spezialization am Beispiel Blood Pressure (Finding Class)

Variables für die VLM definiert werden, wenn man die records gemäß Where Clause einschränkt

Where Clause

package_date	bc_id	sdtmig_start_version	sdtmig_end_version	domain	vlm_source	vlm_group_id	short_name	sdtm_variable	vlm_target	dec_id	nsv_flag	codelist	codelist_submission_value	subset_codelist	value_list	assigned_term	assigned_value	comparator
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSTESTCD			N	C66741	VSTESTCD			C25299	DIABP	EQ
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSTEST			N	C67153	VSTEST			C25299	Diastolic Blood Pressure	
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSORRES	Y	C77140	N							
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSORRESU	Y	C49669	N	C66770	VSRESU			C49670	mmHg	
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSSTRESC	Y	C77140	N							
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSSTRESN	Y	C77140	N							
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSSTRESU	Y	C49669	N	C66770	VSRESU			C49670	mmHg	
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSPOS		C62164	N	C71148	POSITION	VSPOS	SITTING;STANDING;SUPINE			IN
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSLOC		C13717	N	C74456	LOC	VSLOC_PULSE	ARTERY;CAROTID ARTERY;DORSALIS PEDIS ARTERY;FEMORAL ARTERY;RADIAL ARTERY			IN
2023-12-12	C25299	3-2		VS	VS.VSTESTCD	DIABP	Diastolic Blood Pressure	VSLAT		C25185	N	C99073	LAT	VSLAT_BP	LEFT;RIGHT			IN
2023-12-12	C25298	3-2		VS	VS.VSTESTCD	SYSBP	Systolic Blood Pressure	VSTESTCD			N	C66741	VSTESTCD			C25298	SYSBP	EQ
2023-12-12	C25298	3-2		VS	VS.VSTESTCD	SYSBP	Systolic Blood Pressure	VSTEST			N	C67153	VSTEST			C25298	Systolic Blood Pressure	
2023-12-12	C25298	3-2		VS	VS.VSTESTCD	SYSBP	Systolic Blood Pressure	VSORRES	Y	C77140	N							
2023-12-12	C25298	3-2		VS	VS.VSTESTCD	SYSBP	Systolic Blood Pressure	VSORRESU	Y	C49669	N	C66770	VSRESU			C49670	mmHg	
2023-12-12	C25298	3-2		VS	VS.VSTESTCD	SYSBP	Systolic Blood Pressure	VSSTRESC	Y	C77140	N							

Biomedical Concepts (BC)
SDTM dataset spezialization am Beispiel Blood Pressure (Finding Class)

SDTM Group				SDTM Variable Part 2													
bc_id	domain	vlm_source	vlm_group_id	sdtm_variable	subject	linking_phrase	predicate_term	object	role	data_type	length	format	significant_digits	mandatory_variable	mandatory_value	origin_type	origin_source
C25299	VS	VS.VSTESTCD	DIABP	VSTESTCD	VSTESTCD	is the code for the value in	IS_DECODED_BY	VSTEST	Topic					Y	N		
C25299	VS	VS.VSTESTCD	DIABP	VSTEST	VSTEST	decodes the value in	DECODES	VSTESTCD	Qualifier					Y	N		
C25299	VS	VS.VSTESTCD	DIABP	VSORRES	VSORRES	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			Y	N	Collected	Investigator
C25299	VS	VS.VSTESTCD	DIABP	VSORRESU	VSORRESU	is the unit for the value in	IS_UNIT_FOR	VSORRES	Qualifier					Y	N		
C25299	VS	VS.VSTESTCD	DIABP	VSSTRESC	VSSTRESC	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			N	N		
C25299	VS	VS.VSTESTCD	DIABP	VSSTRESN	VSSTRESN	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			N	N		
C25299	VS	VS.VSTESTCD	DIABP	VSSTRESU	VSSTRESU	is the unit for the value in	IS_UNIT_FOR	VSSTRESN	Qualifier					N	N		
C25299	VS	VS.VSTESTCD	DIABP	VSPOS	VSPOS	is the subject position during performance of the test in	IS_SUBJECT_STATE_FOR	VSTESTCD	Qualifier					N	N		
C25299	VS	VS.VSTESTCD	DIABP	VSLOC	VSLOC	specifies the anatomical location of the performance of the test in	SPECIFIES	VSTESTCD	Qualifier					N	N		
C25299	VS	VS.VSTESTCD	DIABP	VSLAT	VSLAT	further specifies the anatomical location in	SPECIFIES	VSLOC	Qualifier					N	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSTESTCD	VSTESTCD	is the code for the value in	IS_DECODED_BY	VSTEST	Topic					Y	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSTEST	VSTEST	decodes the value in	DECODES	VSTESTCD	Qualifier					Y	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSORRES	VSORRES	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			Y	N	Collected	Investigator
C25298	VS	VS.VSTESTCD	SYSBP	VSORRESU	VSORRESU	is the unit for the value in	IS_UNIT_FOR	VSORRES	Qualifier					Y	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSSTRESC	VSSTRESC	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			N	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSSTRESN	VSSTRESN	is the result of the test in	IS_RESULT_OF	VSTESTCD	Qualifier	integer	3			N	N		
C25298	VS	VS.VSTESTCD	SYSBP	VSSTRESU	VSSTRESU	is the unit for the value in	IS_UNIT_FOR	VSSTRESN	Qualifier					N	N		
						is the subject position											

Biomedical Concepts (BC)
BC am Beispiel Adverse Event (Event Class)

Auf was bezieht sich das?

Biomedical Concept (BC) related to Adverse Events

package_date	short_name	bc_id	ncit_code	parent_bc_id	bc_categories	synonyms	result_scale	definition
2023-10-03	Anticipated Adverse Event	C156629	C156629	C41331	Events;Reported Events;Adverse Events	Adverse Event;Prespecified Adverse Event	Nominal	An adverse event that is reasonably expected and/or listed in the clinical protocol or other study-related document.
2023-10-03	Solicited Adverse Event	C179175	C179175	C41331	Events;Reported Events;Adverse Events	Adverse Event	Nominal	An adverse event that is reported by a healthcare professional, consumer, or patient through an organized data collection system.
2023-10-03	Unsolicited Adverse Event	C179176	C179176	C41331	Events;Reported Events;Adverse Events	Adverse Event	Nominal	An adverse event that is voluntarily reported by a healthcare professional, consumer, or patient outside of an organized data collection system.
2023-12-12	Adverse Event	C41331	C41331		Subject Disposition;Protocol Disposition Events		Nominal	Any unfavorable or unintended disease, sign, or symptom (including an abnormal laboratory finding) that is temporally associated with the use of a medical treatment or procedure, and that may or may not be considered related to the medical treatment or procedure. Such events can be related to the intervention, dose, route of administration, patient, or caused by an interaction with another drug(s) or procedure(s).

Kein Coding System hinterlegt

Zugehörige DECs

bc_id	dec_id	ncit_dec_code	dec_label	data_type	example_set
C156629	C113380	C113380	Disabling Adverse Event	boolean	Y;N
C156629	C41358	C41358	Adverse Event Attribution to Product or Procedure	string	Not related;Unlikely Related;Possibly Related;Related
C156629	C48275	C48275	Death Related to Adverse Event	boolean	Y;N
C156629	C49489	C49489	Adverse Event Outcome	string	Fatal;Not Recovered/Not Resolved;Recovered/Resolved With Sequelae;Recovered/Resolved;Recovering/Resolving;Unknown
C156629	C53252	C53252	Seriousness of Adverse Event	boolean	Y;N
C156629	C53253	C53253	Severity of Adverse Event	string	Mild;Moderate;Severe
C156629	C78541	C78541	Adverse Event Verbatim Description	string	
C156629	C78605	C78605	Adverse Event Toxicity Grade	string	0;1;2;3;4;5
C156629	C83013	C83013	Adverse Event Action Taken with Study Treatment	string	Drug Withdrawn;Dose Reduced;Dose Increased;Dose Not Changed;Unknown
C156629	C83052	C83052	Adverse Event associated with Hospitalization	boolean	Y;N
C156629	C83053	C83053	Adverse Event Associated with Serious Medical Event	boolean	Y;N
C156629	C83109	C83109	Other Actions taken in Response to Adverse Event	string	Treatment Unblinded;Ptrimary Care Physician Notified
C156629	C83117	C83117	Adverse Event Seriousness Due to Congenital Anomaly	boolean	Y;N
C156629	C83198	C83198	Adverse Event Category	string	
C156629	C83199	C83199	Adverse Event Concomitant Treatment	boolean	Y;N
C156629	C83201	C83201	Adverse Event End Date Time	datetime	
C156629	C83205	C83205	Adverse Event Location	string	
C156629	C83208	C83208	Adverse Event Pattern	string	Intermittent;Continuous;Single Event
C156629	C83210	C83210	Adverse Event Relationship to Non Study Treatment	string	Not related;Unlikely Related;Possibly Related;Related
C156629	C83211	C83211	Adverse Event Involves Cancer	boolean	Y;N
C156629	C83212	C83212	Adverse Event Subcategory	string	
C156629	C83214	C83214	Adverse Event Occurred with Overdose	boolean	Y;N
C156629	C83215	C83215	Adverse Event Start Date Time	datetime	
C156629	C83344	C83344	Adverse Event Dictionary Derived Term	string	
C156629	C84266	C84266	Life Threatening Adverse Event	boolean	Y;N
C156629	C87840	C87840	Adverse Event Pre-specified	boolean	Y;N

Biomedical Concepts (BC)
BC am Beispiel Adverse Event (Event Class)

Zugehörige DECs des Parent BC Adverse Event (C41331)					
bc_id	dec_id	ncit_dec_code	dec_label	data_type	example_set
C41331	C25372	C25372	Category	string	Disposition Event
C41331	C25692	C25692	Subcategory	string	Study Participation;Study Treatment
C41331	C82517	C82517	Observation Start Date Time	datetime	
C41331	C82571	C82571	Reported Event Term	string	
C41331	C82977	C82977	Dictionary-derived Term	string	Adverse Event

Biomedical Concepts (BC)
SDTM dataset spezialization am Beispiel Adverse Event (Event Class)

SDTM Groups						
bc_id	sdtmig_start_version	sdtmig_end_version	domain	vlm_source	vlm_group_id	short_name
C179175	3-4		AE	AE.AETERM	AE	Adverse Event Free Text Format
C179175	3-4		AE	AE.AETERM	AEPRESP	Adverse Event Prespecified
C41331	3-2		DS	DS.DECODE	ADVEVENT	Adverse Event

Zugehörige SDTM Variablen für vlm_group_id=AEPRESP

bc_id	vlm_group_id	sdtm_variable	dec_id	codelist	codelist_submission	subset_codelis	value_list	vlm_target
C179175	AEPRESP	AEACN	C83013	C66767	ACN			
C179175	AEPRESP	AEACNOTH	C83109					
C179175	AEPRESP	AEBDSYCD						
C179175	AEPRESP	AEBODSYS						
C179175	AEPRESP	AECAT	C83198					
C179175	AEPRESP	AECONTRT	C83199	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AEDECOD	C83344					
C179175	AEPRESP	AEENDTC	C83201					
C179175	AEPRESP	AEHLT						
C179175	AEPRESP	AEHLTCD						
C179175	AEPRESP	AELLT						
C179175	AEPRESP	AELLTCD						
C179175	AEPRESP	AELOC	C83205	C74456	LOC			
C179175	AEPRESP	AEOUT	C49489	C66768	OUT			
C179175	AEPRESP	AEPATT	C83208					
C179175	AEPRESP		C87840	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AEPTCD						
C179175	AEPRESP	AEREL	C41358					
C179175	AEPRESP	AERELNST	C83210					
C179175	AEPRESP	AERLDEV						
C179175	AEPRESP	AESCAN	C83211	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESCAT	C83212					
C179175	AEPRESP	AESCONG	C83117	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESDISAB	C113380	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESDTH	C48275	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESER	C53252	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESEV	C53253	C66769	AESEV			
C179175	AEPRESP	AESHOSP	C83052	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESLIFE	C84266	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESMIE	C83053	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESOC						
C179175	AEPRESP	AESOCCD						
C179175	AEPRESP	AESOD	C83214	C66742	NY	NY_NY	N;Y	
C179175	AEPRESP	AESTDTC	C83215					
C179175	AEPRESP	AETERM	C78541					

VLM für AEDECOD?

dec_id= C78605 (Toxicity Grade)?

Biomedical Concepts (BC)
SDTM dataset spezialization am Beispiel Adverse Event (Event Class)

bc_id	vlm_group_id	sdtm_variable	dec_id	codelist	codelist_submission_value	subset_codelist	value_list	vlm_target
					Zugehörige SDTM Variablen für vlm_group_id=ADVEVENT (Parent BC C41331)			
C41331	ADVEVENT	DSCAT	C25372	C74558	DSCAT			
C41331	ADVEVENT	DSDECOD	C82977	C66727	NCOMPLT			
C41331	ADVEVENT	DSSCAT	C25692	C170443	DSSCAT		STUDY PARTICIPATION;STUDY TREATMENT	
C41331	ADVEVENT	DSSTDTC	C82517					
C41331	ADVEVENT	DSTERM	C82571					

Biomedical Concepts (BC)
BC am Beispiel Concomitant Medication (Intervention Class)

Biomedical Concept (BC) related to Concomitant Medication							
package_date	short_name	bc_id	ncit_code	parent_bc_id	bc_categories	synonyms	result_scales	definition
2023-03-31	Intervention or Procedure	C25218	C25218		Procedures;Interventions	Procedure;Intervention		An activity that produces an effect, or that is intended to alter the course of a disease in a patient or population. This is a general term that encompasses the medical, social, behavioral, and environmental acts that can have preventive, therapeutic, or palliative effects.
2023-03-31	Therapeutic Procedure	C49236	C49236	C25218	Procedures;Interventions	Treatment;Therapeutic Intervention		An action or administration of therapeutic agents to produce an effect that is intended to alter or stop a pathologic process.
2023-12-12	Concomitant Therapy	C53630	C53630	C49236	Interventions;Substance Administration;Medication Administration	Concomitant Medication	Nominal	Any pharmaceutical agent, other than the primary therapy, that is administered to or used by the subject prior to or during a specified time period.

Kein Coding System hinterlegt

Zugehörige DECs					
bc_id	dec_id	ncit_dec_code	dec_label	data_type	example_set
C53630	C127786	C127786	Occurrence Indicator	boolean	Y;N
C53630	C171000	C171000	Prespecified Event or Intervention Indicator	boolean	Y;N
C53630	C25372	C25372	Category	string	
C53630	C25692	C25692	Subcategory	string	
C53630	C70902	C70902	Concomitant Agent	string	
C53630	C83025	C83025	Concomitant Medication Daily Dose	string	
C53630	C83034	C83034	Concomitant Medication Dose Unit	string	ng;mg;mg/kg
C53630	C83042	C83042	Concomitant Medication Dose Frequency	string	BID;PRN;QD;QID;TID
C53630	C83085	C83085	Concomitant Medication Use Indication	string	
C53630	C83110	C83110	Concomitant Medication Dose Form	string	Capsule;Injection;Patch;Solution;Suppository;Tablet
C53630	C83120	C83120	Concomitant Medication Route of Administration	string	Intravenous;Oral;Nasogastric;Subcutaneous;Topical
C53630	C83221	C83221	Concomitant Medication Dose	string	
C53630	C83225	C83225	Concomitant Medication Use End Date Time	datetime	
C53630	C83235	C83235	Concomitant Medication Use Start Date Time	datetime	
C53630	C83345	C83345	Concomitant Medication Dictionary Derived Term	string	

Biomedical Concepts (BC)
BC am Beispiel Concomitant Medication (Intervention Class)

Es gibt keine SDTM Group für pre-specified Medications

SDTM Groups

bc_id	sdtmig_start_version	sdtmig_end_version	domain	vlm_source	vlm_group_id	short_name
C53630	3-2		CM	CM.CMTRT	CMFREE	Concomitant Medication Free Text Format

Zugehörige SDTM Variablen

bc_id	vlm_group_id	sdtm_variable	dec_id	codelist	codelist_submission_value	subset_codelist	value_list	vlm_target
C53630	CMFREE	CMCAT	C25372					
C53630	CMFREE	CMCLAS	C83232					
C53630	CMFREE	CMCLASCD	C83232					
C53630	CMFREE	CMDECOD	C83345					
C53630	CMFREE	CMDOSE	C83221					
C53630	CMFREE	CMDOSFRM	C83110	C66726	FRM			
C53630	CMFREE	CMDOSFRQ	C83042	C71113	FREQ			
C53630	CMFREE	CMDOSU	C83034	C71620	UNIT			
C53630	CMFREE	CMENDTC	C83225					
C53630	CMFREE	CMINDC	C83085					
C53630	CMFREE	CMROUTE	C83120	C66729	ROUTE			
C53630	CMFREE	CMSCAT	C25692					
C53630	CMFREE	CMSTDTC	C83235					
C53630	CMFREE	CMTRT	C70902					

Biomedical Concepts (BC)
Inhaltliche Übersicht

- Es gibt derzeit 248 BCs
- Nicht für alle BCs gibt es eine entsprechende SDTM Dataset specialization.
  - BCs die DM zugeordnet werden müssten, haben kein entsprechendes SDTM Dataset specialization
  - Nicht jedes Parent BC hat SDTM dataset specialization (vgl. Beispiel)
- Folgende SDTM domains sind mit BCs hinterlegt
  - Findings: EG, IE, LB, MB, QS, RS, TR, TU , SC, VS
  - Events: AE, BE, DS, MH
  - Interventions: CM, EC, EX, PR, SU
- VLM sind nur für die Result-Variablen von Finding domains definiert

Biomedical Concepts (BC)
API Nutzung

Zugang über den Data Standards Browser: https://library.cdisc.org/browser

Biomedical Concepts (BC)
API (Application Programming Interface) Nutzung

```sas
filename response TEMP;

/*welche Packages gibt es*/
proc http
    url="https://api.library.cdisc.org/api/cosmos/v2/mdr/bc/packages"
    out=response;
    headers
        /* fictitious API key used, real one can be obtained through API Management Developer Portal */
        /* change to "application/xml" for response in XML format */
        "api-key"="xxxxxxxxxxxxxxxxxxxxxxxxxx"
        "Accept"="application/json";
run;

data _null_;
    infile response;
    input;
    put _infile_;
run;
```

```sas
/*alle BCs */
proc http
    url="https://api.library.cdisc.org/api/cosmos/v2/mdr/bc/packages/2023-12-12/biomedicalconcepts"
    out=response;
    headers
        "api-key"="xxxxxxxxxxxxxxxxxxxxxxxxxx"
        "Accept"="application/json";
run;
data _null_;
    infile response;
    input;
    put _infile_;
run;
```

```sas
/*bestimmtes BC + DECs */
proc http
    url="https://api.library.cdisc.org/api/cosmos/v2/mdr/bc/packages/2023-12-12/biomedicalconcepts/C25298"
    out=response;
    headers
        "api-key"="xxxxxxxxxxxxxxxxxxxxxxxxxx"
        "Accept"="application/json";
run;
data _null_;
    infile response;
    input;
    put _infile_;
run;
```

{"_links":{"packages":[{"href":"/mdr/bc/packages/2022-10-26/biomedicalconcepts","title":"Biomedical Concept Package Effective 2022-10-26","type":"Biomedical Concept Package"},{"href":"/mdr/bc/packages/2023-02-13/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-02-13","type":"Biomedical Concept Package"},{"href":"/mdr/bc/packages/2023-03-31/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-03-31","type":"Biomedical Concept Package"},{"href":"/mdr/bc/packages/2023-07-06/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-07-06","type":"Biomedical Concept Package"},{"href":"/mdr/bc/packages/2023-10-03/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-10-03","type":"Biomedical Concept Package"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-12-12","type":"Biomedical Concept Package"}],"self":{"href":"/mdr/bc/packages","title":"Product Group Biomedical Concepts","type":"Biomedical Concept Package List"}}}

12-12/biomedicalconcepts/NEW_L2214","title":"TTS Acceptability Survey - Patch Acceptability","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C122393","title":"Number of Years of Education","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C17468","title":"Socioeconomic Factors","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C17953","title":"Education Level","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C181760","title":"History of Tobacco Use","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C201990","title":"Caffeine Use History","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C81229","title":"Alcohol Use History","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C100948","title":"Waist Circumference","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C16358","title":"Body Mass Index","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C164634","title":"Body Height","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C174446","title":"Body Temperature","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C25298","title":"Systolic Blood Pressure","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C25299","title":"Diastolic Blood Pressure","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C49672","title":"Vital Signs Measurement","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C49676","title":"Pulse Rate","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C49677","title":"Heart Rate","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C49678","title":"Respiratory Rate","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C49680","title":"Body Frame Size","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C54706","title":"Blood Pressure","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C60832","title":"Oxygen Saturation Measurement","type":"Biomedical Concept"},{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C81328","title":"Body Weight","type":"Biomedical Concept"}],"self":{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts","title":"Biomedical Concepts","type":"Biomedical Concept List"}},"name":"Biomedical Concepts 2023-12-12","label":"Biomedical Concept Package Effective 2023-12-12","effectiveDate":"2023-12-12","version":"2023-12-12"}

{"_links":{"parentBiomedicalConcept":{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C54706","title":"Blood Pressure","type":"Biomedical Concept"},"parentPackage":{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts","title":"Biomedical Concept Package Effective 2023-12-12","type":"Biomedical Concept Package"},"self":{"href":"/mdr/bc/packages/2023-12-12/biomedicalconcepts/C25298","title":"Systolic Blood Pressure","type":"Biomedical Concept"}},"conceptId":"C25298","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C25298","categories":["Vital Signs"],"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"}],"dataElementConcepts":[{"conceptId":"C77140","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C77140","shortName":"Clinical Test Result","dataType":"decimal","ncitCode":"C77140"},{"conceptId":"C49669","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C49669","shortName":"Unit of Pressure","dataType":"string","exampleSet":["cmHg","mmHG","Pascal"],"ncitCode":"C49669"},{"conceptId":"C13717","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C13717","shortName":"Anatomic Site","dataType":"string","exampleSet":["Arm","Forearm","Thigh","Calf","Artery","Vein"],"ncitCode":"C13717"},{"conceptId":"C25185","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C25185","shortName":"Laterality","dataType":"string","exampleSet":["Left","Right"],"ncitCode":"C25185"},{"conceptId":"C82535","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C82535","shortName":"Test Method","dataType":"string","exampleSet":["Auscultation automatic","Auscaltation manual","Cuff-manual palpated","Doppler","Oscillometry","Arterial line","Venous line","Continuous noninvasive arterial pressure (CNAP)"],"ncitCode":"C82535"},{"conceptId":"C62164","href":"https://ncithesaurus.nci.nih.gov/ncitbrowser/ConceptReport.jsp?dictionary=NCI_Thesaurus&ns=ncit&code=C62164","shortName":"Body Position","dataType":"string","exampleSet":["Decupitus","Fowlers","Lateral Decupitus","Prone","Reverse Trendelenburg","Semi-Fowlers","Semi-Recumbent","Sitting","Sitting Legs Dependent","Sling","Standing","Supine","Trendelenburg","Unconstrained"],"ncitCode":"C62164"}],"ncitCode":"C25298"}

Unified Study Definition Model (USDM)
Wer, was ,wie, warum

- **Wer**:

  DDF: Digital Data Flow; Kooperation zwischen CDISC und TransCelerate; Projekt Start 2021

- **Was**:

  Beruht auf der ICH Guideline "Clinical electronic structured harmonised protocol" (draft, September 2022). Löst PRM (Protocol Representation Model) eine relativ rudimentäres Modell ab, das sich nicht für einen digitalen Datenfluss über alle Prozesse einer klinischen Studie eignet.

- **Wie**:

  Wurde in drei Phasen entwickelt. Zu jeder Phase gibt es ein CDISC webinar.

- **Warum**:

  DDF: Name ist Programm. Das Projekt soll den digitalen Datenfluss und Austausch innerhalb eines Systems bzw. zwischen verschiedenen Systemen ermöglichen.
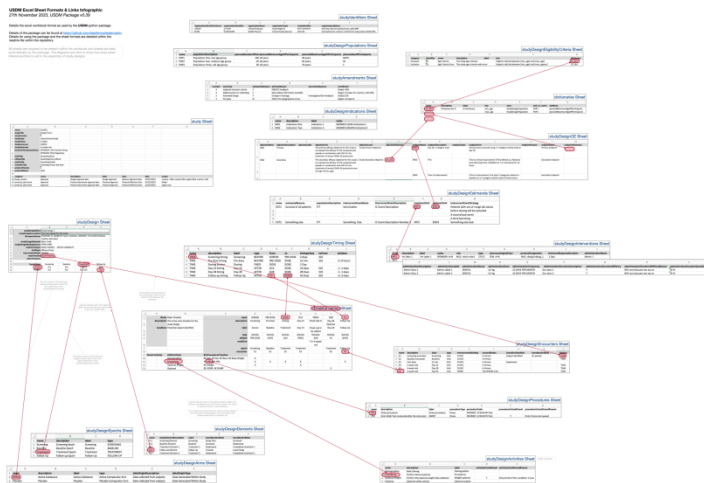
# Unified Study Definition Model (USDM)
Wer, was ,wie, warum

USDM besteht aus 4 Teilen, die offizielle CDISC Standards darstellen:
- Unified Study Definition Modell class diagramm
- API Specification
- CDISC Controlled Terminology (z.B. https://evs.nci.nih.gov/ftp1/CDISC/DDF, https://evs.nci.nih.gov/ftp1/CDISC/Protocol/)
- USDM Implementation guide

USDM Daten Modell

Beispiel, das die einzelnen Klassen in Excel sheets darstellt, die mit Beispieldaten befüllt sind. Hier wird der Zusammenhang zwischen den einzelnen sheets dargestellt
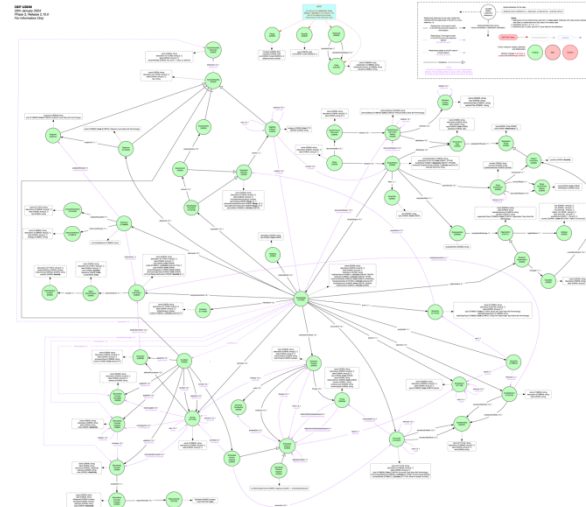
Darstellung der Klassen des USDM und wie diese zusammenhängen

Referenzen

- BC
  - Gesamte Dokumentation: https://github.com/cdisc-org/COSMoS
  - CDISC Biomedical Concepts – Overview training (https://github.com/cdisc-org/COSMoS/blob/main/bc_starter_package/doc/BC%20Overview%20Training.pdf)
  - cdisc_biomedical_concepts_20231212.xlsx, cdisc_sdtm_dataset_specializations_20231212.xlsx (https://github.com/cdisc-org/COSMoS/tree/main/export)
  - Getting Started: Access to CDISC Library API Key Authentication: https://wiki.cdisc.org/display/LIBSUPRT/Getting+Started%3A+Access+to+CDISC+Library+API+using+API+Key+Authentication
- USDM
  - DDF USDM Model Informative.png (https://github.com/cdisc-org/DDF-RA/tree/main/Documents)
  - USDM_xls_sheets.png: (https://github.com/data4knowledge/usdm/blob/main/docs/sheets.png)
  - USDM_CT.xlsx: (https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/CT/)
  - USDM-IG.pdf (https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/IG)
  - USDM Package including Model, API and documentation (https://www.cdisc.org/sites/default/files/2023-06/USDM-RA-v2.0-%20final.zip)
  - Reichlich ein- und weiterführendes Material gibt es hier: https://www.transceleratebiopharmainc.com/assets/digital-data-flow-solutions/
- API
  - CDISC Library try-out: from implementation to evaluation of the API (https://www.lexjansen.com/phuse-us/2020/sd/SD05.pdf)

Diskussion

- Wo liegen die Grenzen der Standardisierung bzw. schränkt die überbordende Standardisierung die Kreativität beim Studiendesign ein

- Wie realistisch ist der End-to-End automation Ansatz

- Wie beeinflussen die neuen Ansätze die Arbeit von DM und Biostatistik in der Zukunft

- Wie kann man bereits jetzt die neuen Datenmodelle nutzen

- Zunehmende Bedeutung der Anwendungsentwicklung im Bereich klinischer Forschung.

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