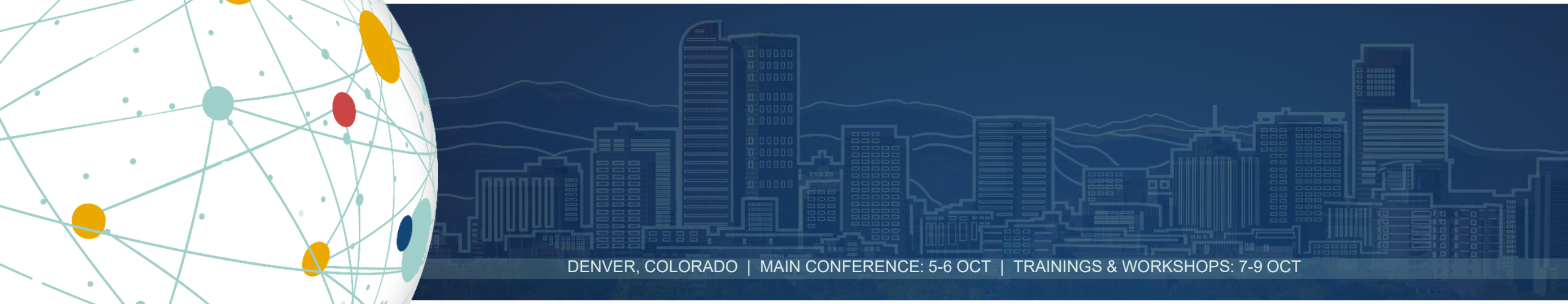


cdisc®

2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Report from SDS: Future Directions

Dave Scocca, Principal Statistical Programmer, Rho, Inc.

Agenda

1. What Comes Next?
2. Digitization
3. Additional Resources

Speakers



I have been a programmer for Rho for 27 years now, and I have worked with CDISC data standards since 2010. As a CDISC volunteer since 2018, I have worked on the SDTM and SDS, including on the SDS subteams for multiple subject instances and Jira issue management. I'm now serving in the Current Lead role on the SDS Leadership Team.

I live in Durham NC.

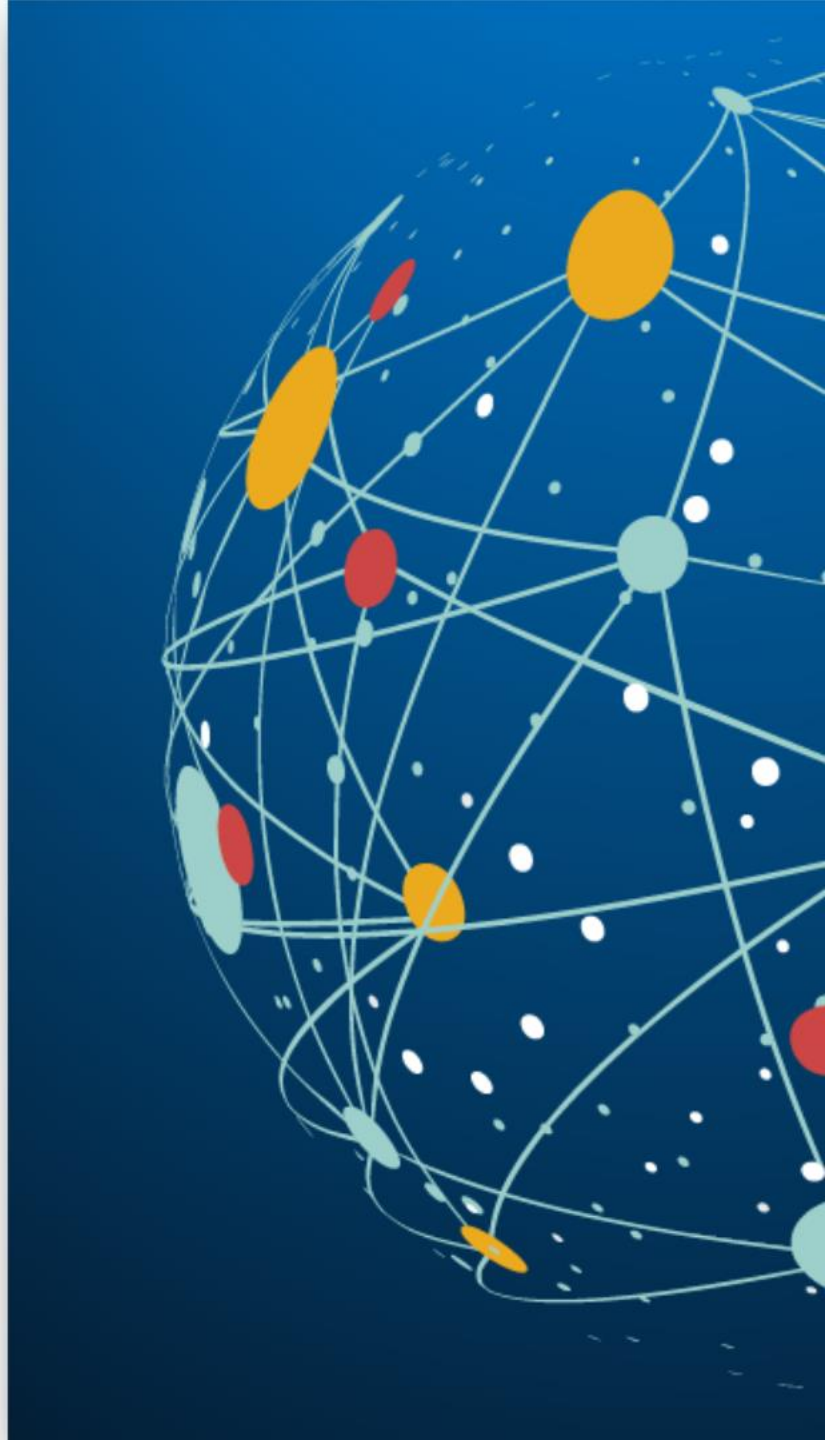
Dave Scocca
Principal Statistical Programmer
Rho, Inc.

What Comes Next?

(following the release of SDTMIG v4.0 and SDTM 3.0)

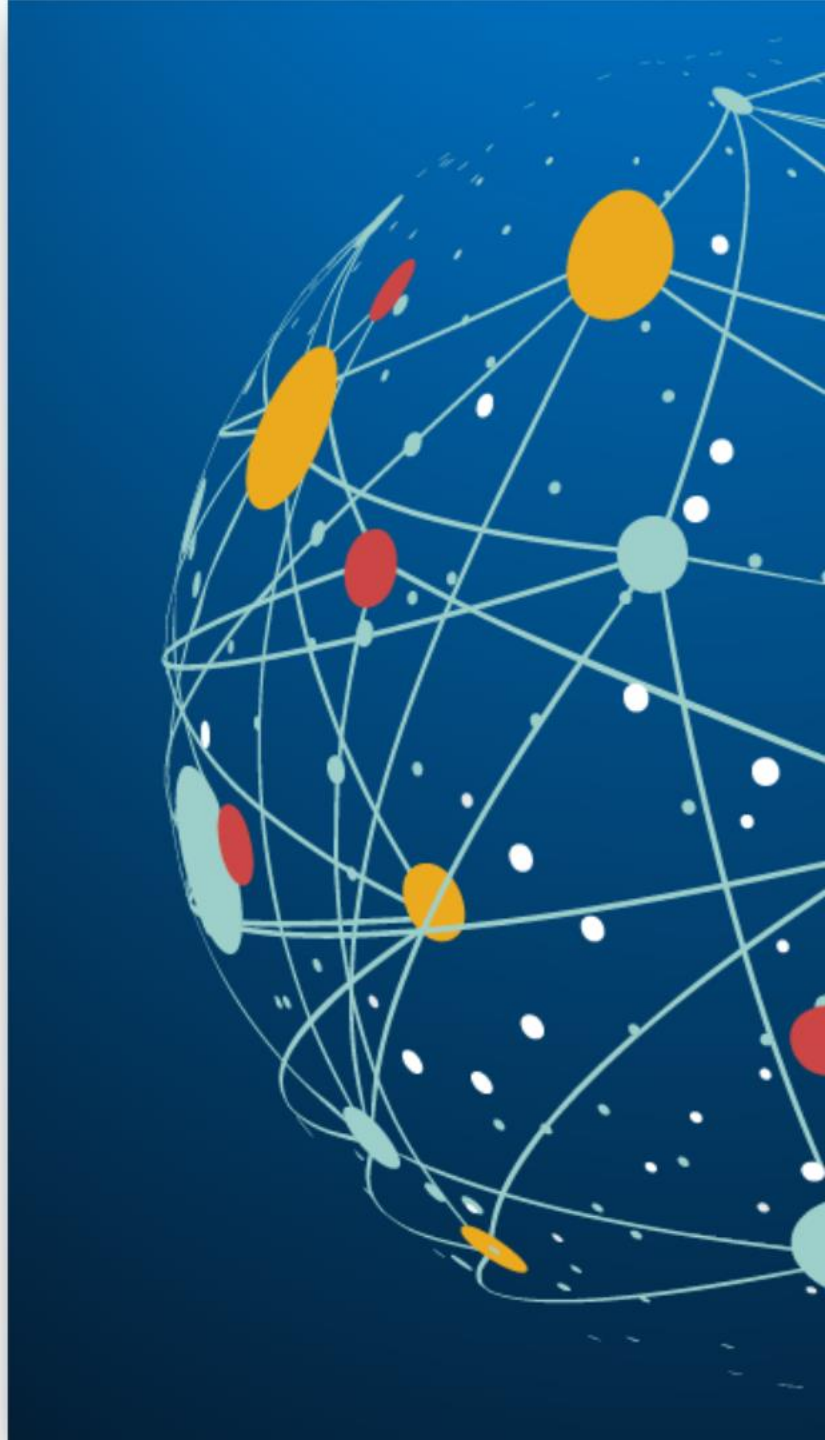
Past Approach

- Gear up for SDTMIG v. N+0.1 (or N+1)
  - Scoping and then development
- That is NOT the plan!



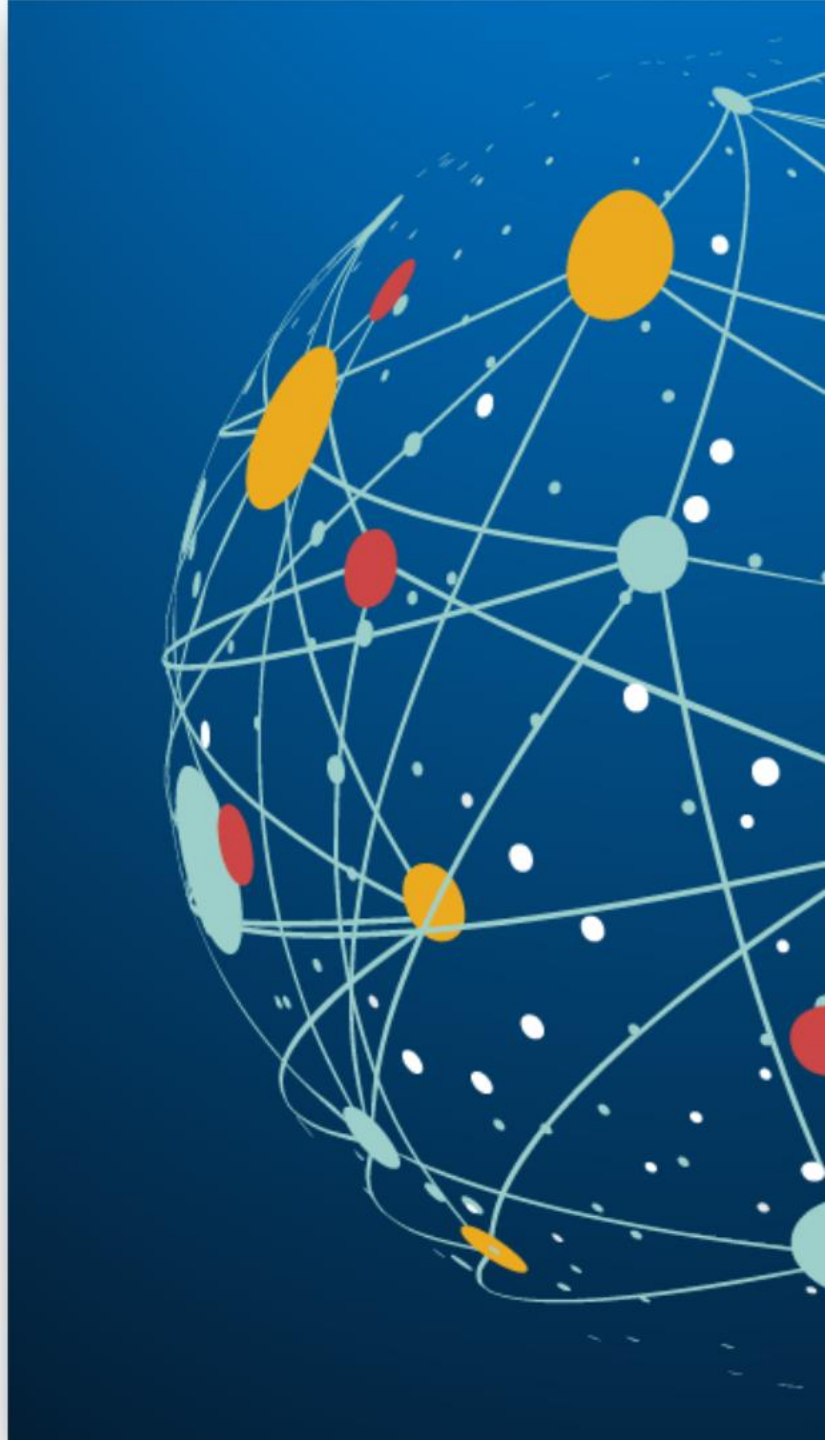
Reasons for Change

- Maturation of the standard
- Concern about update frequency and implementation costs
- Need for fully digitized standards
  - CDISC 360i and CDISC Next-Gen Library
  - Lots of SDTMIG 4.0 labor could have been avoided with more digitization (e.g. variable definitions)



Future Updates?

- No scheduled updates to SDTM & SDTMIG
  - Specific agency requests (DC, LC)
  - Industry consensus on need for an update
    - Conveyed through SDS and CDISC Advisory Council
- Updates to other IGs in progress
  - SDTMIG for Medical Devices v2.0
  - SDTMIG for Associated Persons v2.0
  - Based on SDTM 3.0
  - Will be consistent with SDTMIG 4.0

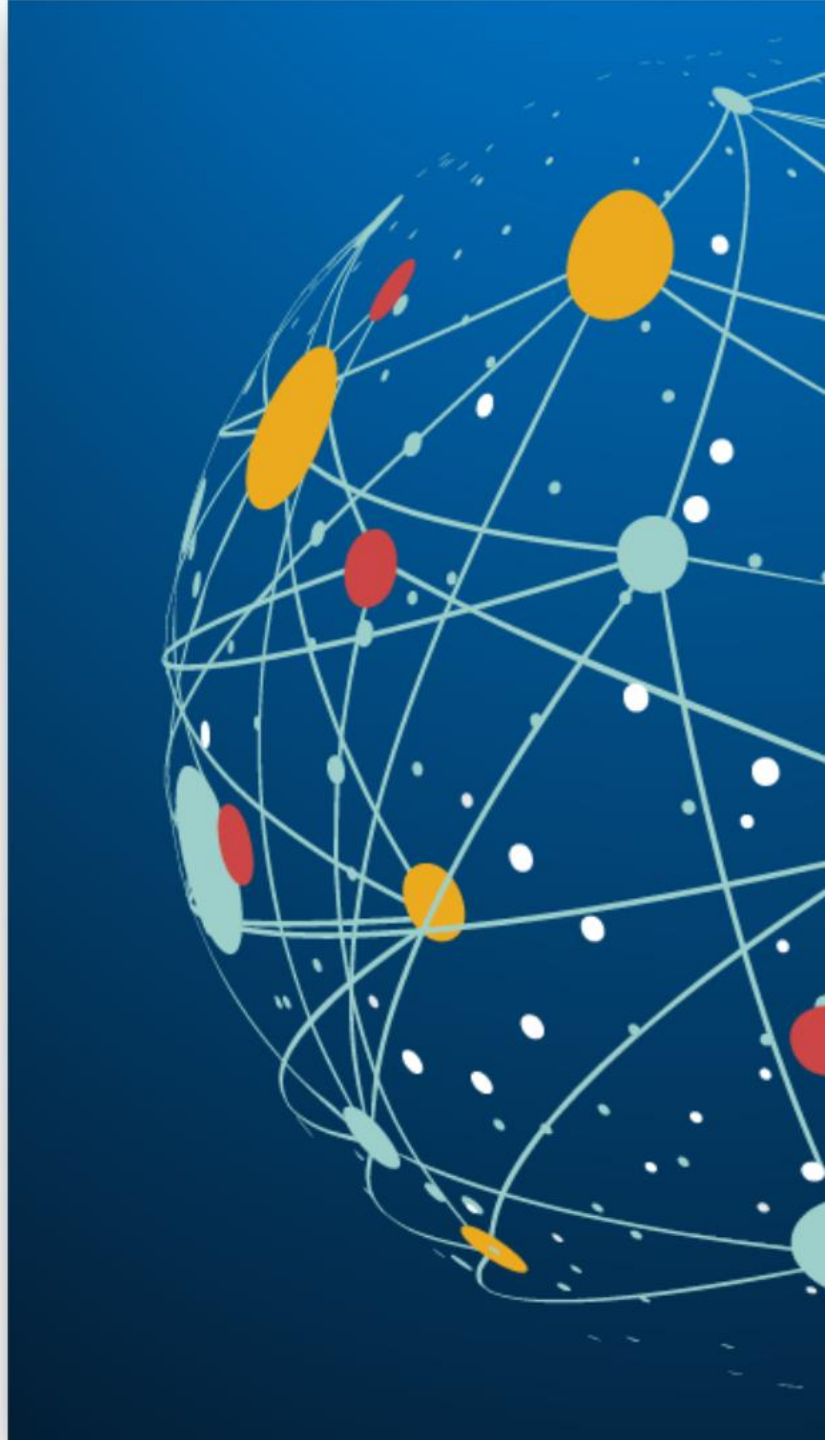


Digitization

CDISC 360i and Biomedical Concepts

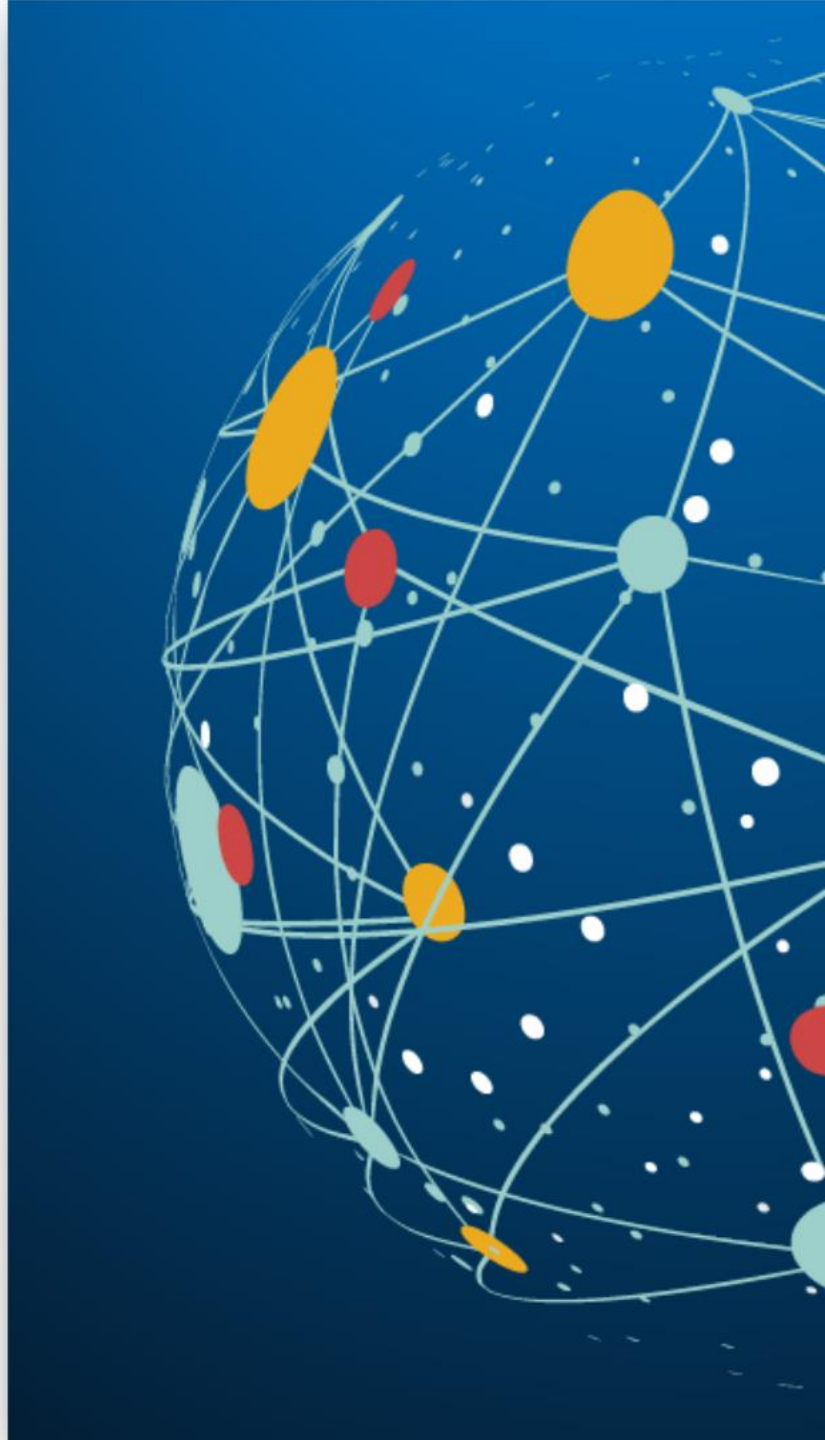
Current Digital Shortcomings

- Model and IG exist as a set of tables
  - No inherent or automatic relationships
- CDISC Library has more linkages, but…
  - Library is created from those tables and does not feed back into the development and maintenance of the standards
- CDISC 360i: End-to-end digitization
  - https://www.cdisc.org/standards/cdisc-360i

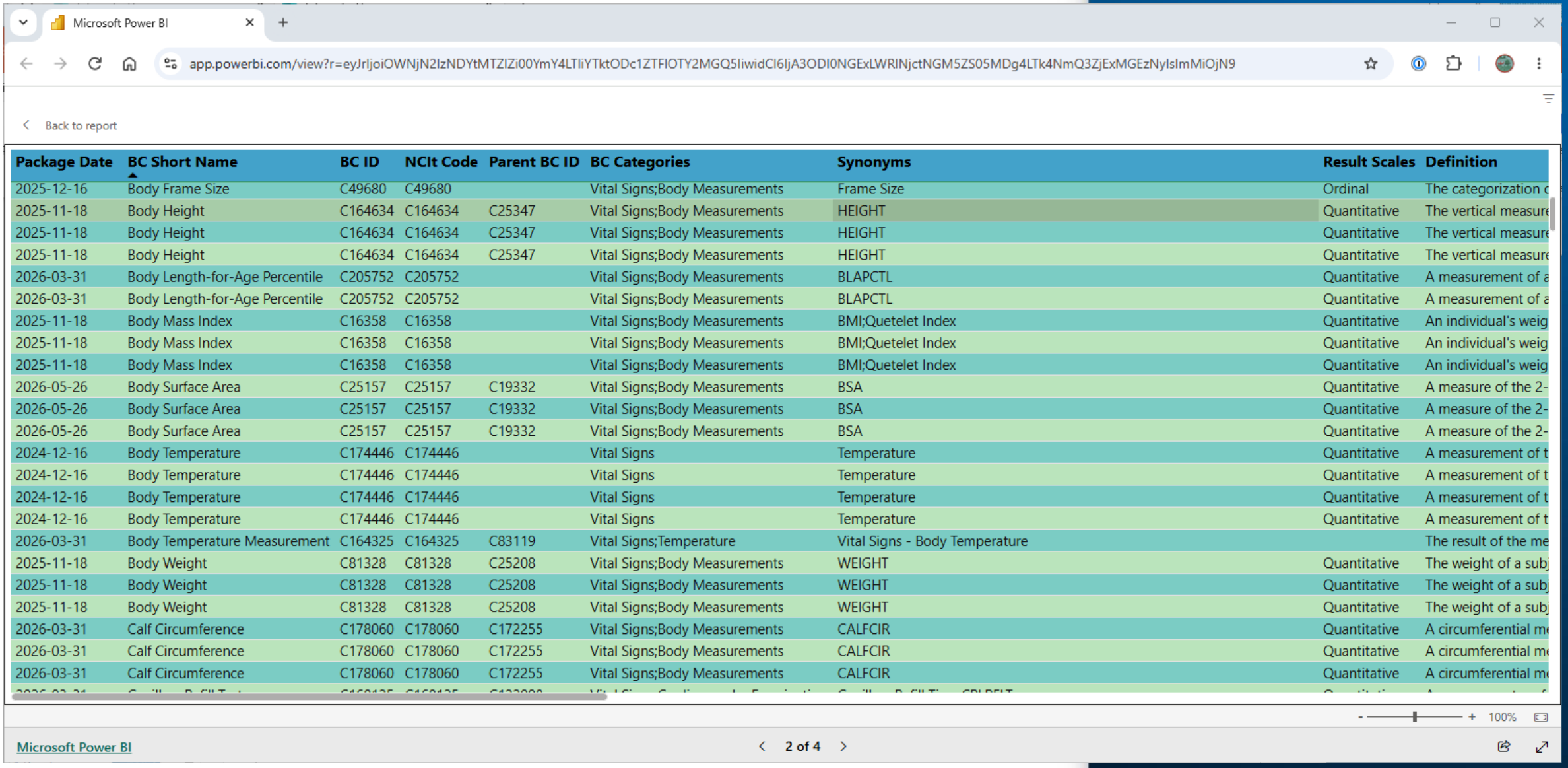


Biomedical Concepts

- https://www.cdisc.org/cdisc-biomedical-concepts
- Conceptual Layer: “Biomedical Concepts”
  - Connected to NCI Thesaurus
- Implementation Layer: “SDTM Specializations”
  - Concrete and tied to standards
  - Value-level metadata for implementations
- Developing and updating biomedical concepts and SDTM specializations



Biomedical Concepts

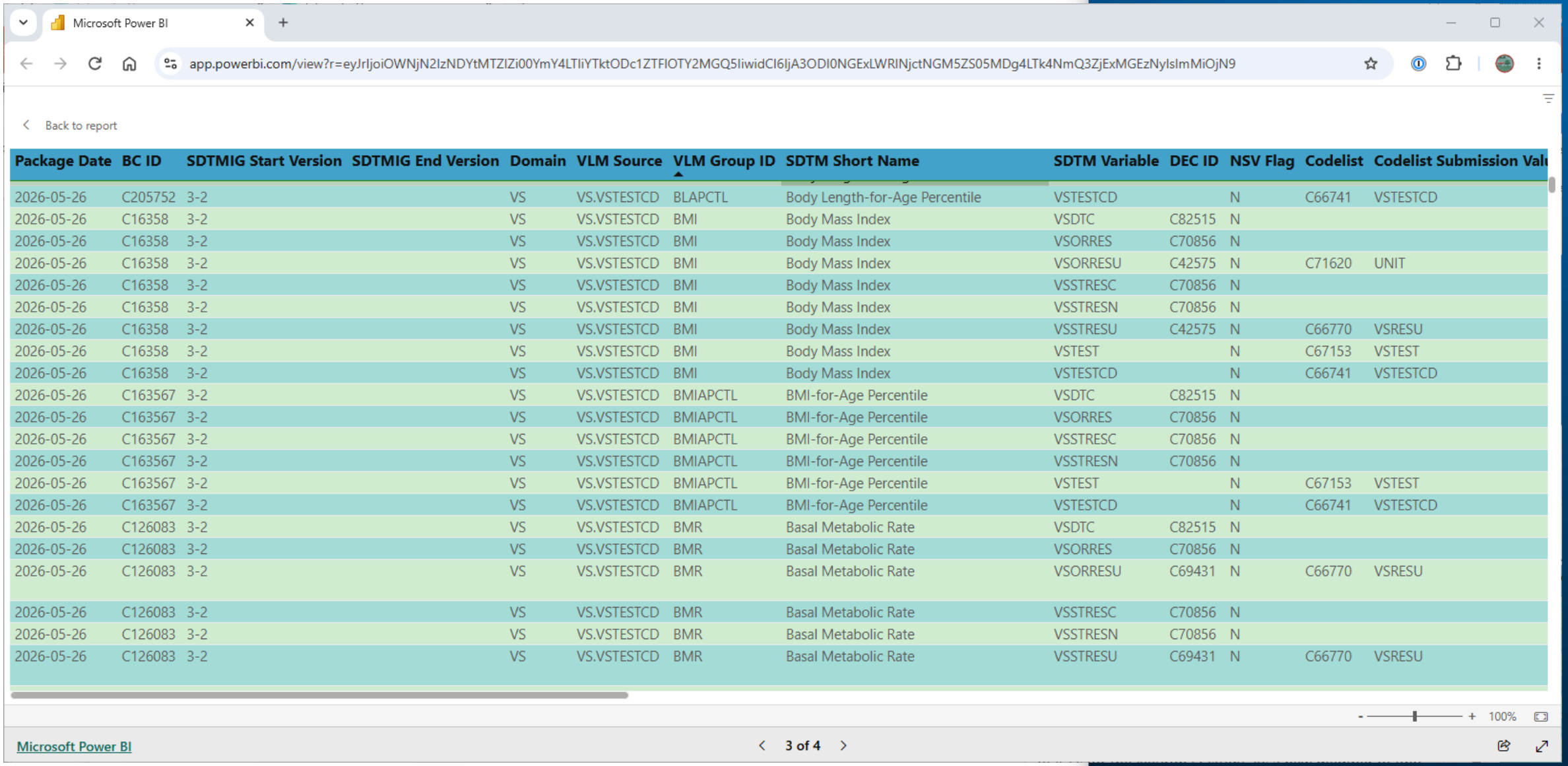


Package Date	BC Short Name	BC ID	NCIt Code	Parent BC ID	BC Categories	Synonyms	Result Scales	Definition
2025-12-16	Body Frame Size	C49680	C49680		Vital Signs;Body Measurements	Frame Size	Ordinal	The categorization c
2025-11-18	Body Height	C164634	C164634	C25347	Vital Signs;Body Measurements	HEIGHT	Quantitative	The vertical measure
2025-11-18	Body Height	C164634	C164634	C25347	Vital Signs;Body Measurements	HEIGHT	Quantitative	The vertical measure
2025-11-18	Body Height	C164634	C164634	C25347	Vital Signs;Body Measurements	HEIGHT	Quantitative	The vertical measure
2026-03-31	Body Length-for-Age Percentile	C205752	C205752		Vital Signs;Body Measurements	BLAPCTL	Quantitative	A measurement of a
2026-03-31	Body Length-for-Age Percentile	C205752	C205752		Vital Signs;Body Measurements	BLAPCTL	Quantitative	A measurement of a
2025-11-18	Body Mass Index	C16358	C16358		Vital Signs;Body Measurements	BMI;Quetelet Index	Quantitative	An individual's weig
2025-11-18	Body Mass Index	C16358	C16358		Vital Signs;Body Measurements	BMI;Quetelet Index	Quantitative	An individual's weig
2025-11-18	Body Mass Index	C16358	C16358		Vital Signs;Body Measurements	BMI;Quetelet Index	Quantitative	An individual's weig
2026-05-26	Body Surface Area	C25157	C25157	C19332	Vital Signs;Body Measurements	BSA	Quantitative	A measure of the 2-
2026-05-26	Body Surface Area	C25157	C25157	C19332	Vital Signs;Body Measurements	BSA	Quantitative	A measure of the 2-
2026-05-26	Body Surface Area	C25157	C25157	C19332	Vital Signs;Body Measurements	BSA	Quantitative	A measure of the 2-
2024-12-16	Body Temperature	C174446	C174446		Vital Signs	Temperature	Quantitative	A measurement of t
2024-12-16	Body Temperature	C174446	C174446		Vital Signs	Temperature	Quantitative	A measurement of t
2024-12-16	Body Temperature	C174446	C174446		Vital Signs	Temperature	Quantitative	A measurement of t
2024-12-16	Body Temperature	C174446	C174446		Vital Signs	Temperature	Quantitative	A measurement of t
2026-03-31	Body Temperature Measurement	C164325	C164325	C83119	Vital Signs;Temperature	Vital Signs - Body Temperature		The result of the me
2025-11-18	Body Weight	C81328	C81328	C25208	Vital Signs;Body Measurements	WEIGHT	Quantitative	The weight of a subj
2025-11-18	Body Weight	C81328	C81328	C25208	Vital Signs;Body Measurements	WEIGHT	Quantitative	The weight of a subj
2025-11-18	Body Weight	C81328	C81328	C25208	Vital Signs;Body Measurements	WEIGHT	Quantitative	The weight of a subj
2026-03-31	Calf Circumference	C178060	C178060	C172255	Vital Signs;Body Measurements	CALFCIR	Quantitative	A circumferential me
2026-03-31	Calf Circumference	C178060	C178060	C172255	Vital Signs;Body Measurements	CALFCIR	Quantitative	A circumferential me
2026-03-31	Calf Circumference	C178060	C178060	C172255	Vital Signs;Body Measurements	CALFCIR	Quantitative	A circumferential me

Biomedical Concepts

Column	Description
BC Categories	Biomedical Concept categories for the faciliation of API search and extract
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
Code	Synonym concept for the Biomedical Concept as defined in a code system
Data Type	Data Type for the Data Element Concept
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
DEC Label	NCI Preferred Name for the concept; provisional name will be used if concept is not available in NCIt
Definition	NCIt definition for the Biomedical Concept; provisional defintion if concept is not available in NCIt
Example Set	Example values for the Data Element Concept
NCIt Code	NCIt C-code for the Biomedical Concept
NCIt DEC Code	NCI C-code for the BC Data Element Concept
Package Date	Biomedical Concept package release date indicating when the BC package was published to production
Parent BC ID	C-code for the parent concept in the NCIt hiearchy; blank if concept is not available in NCIt
Result Scales	Scale of measurement for the Biomedical Concept result
Short Name	NCI Preferred Name for the concept; provisional name will be used if concept is not available in NCIt
Synonyms	Biomedical Concept synonyms equivalent to BC short name for the facilitation of API search and extraction
System	Identifies the code system for the synonym concept. The URL of the code system should be used if it exists
System Name	Human-readable name for the code system

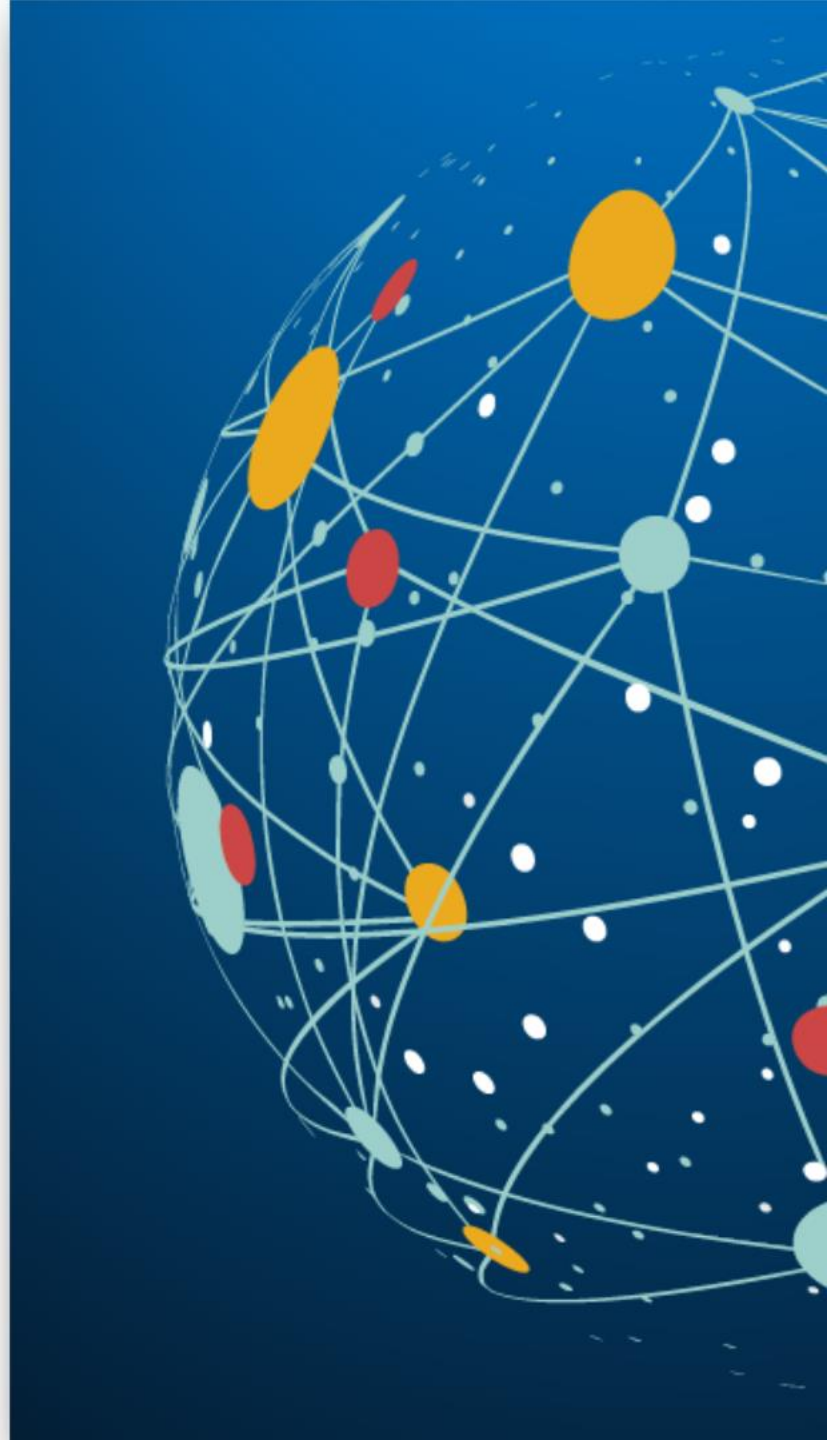
SDTM Specializations



Package Date	BC ID	SDTMIG Start Version	SDTMIG End Version	Domain	VLM Source	VLM Group ID	SDTM Short Name	SDTM Variable	DEC ID	NSV Flag	Codelist	Codelist Submission Valu
2026-05-26	C205752	3-2		VS	VS.VSTESTCD	BLAPCTL	Body Length-for-Age Percentile	VSTESTCD		N	C66741	VSTESTCD
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSDTC	C82515	N		
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSORRES	C70856	N		
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSORRESU	C42575	N	C71620	UNIT
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSSTRESC	C70856	N		
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSSTRESN	C70856	N		
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSSTRESU	C42575	N	C66770	VSRESU
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSTEST		N	C67153	VSTEST
2026-05-26	C16358	3-2		VS	VS.VSTESTCD	BMI	Body Mass Index	VSTESTCD		N	C66741	VSTESTCD
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSDTC	C82515	N		
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSORRES	C70856	N		
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSSTRESC	C70856	N		
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSSTRESN	C70856	N		
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSTEST		N	C67153	VSTEST
2026-05-26	C163567	3-2		VS	VS.VSTESTCD	BMIAPCTL	BMI-for-Age Percentile	VSTESTCD		N	C66741	VSTESTCD
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSDTC	C82515	N		
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSORRES	C70856	N		
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSORRESU	C69431	N	C66770	VSRESU
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSSTRESC	C70856	N		
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSSTRESN	C70856	N		
2026-05-26	C126083	3-2		VS	VS.VSTESTCD	BMR	Basal Metabolic Rate	VSSTRESU	C69431	N	C66770	VSRESU

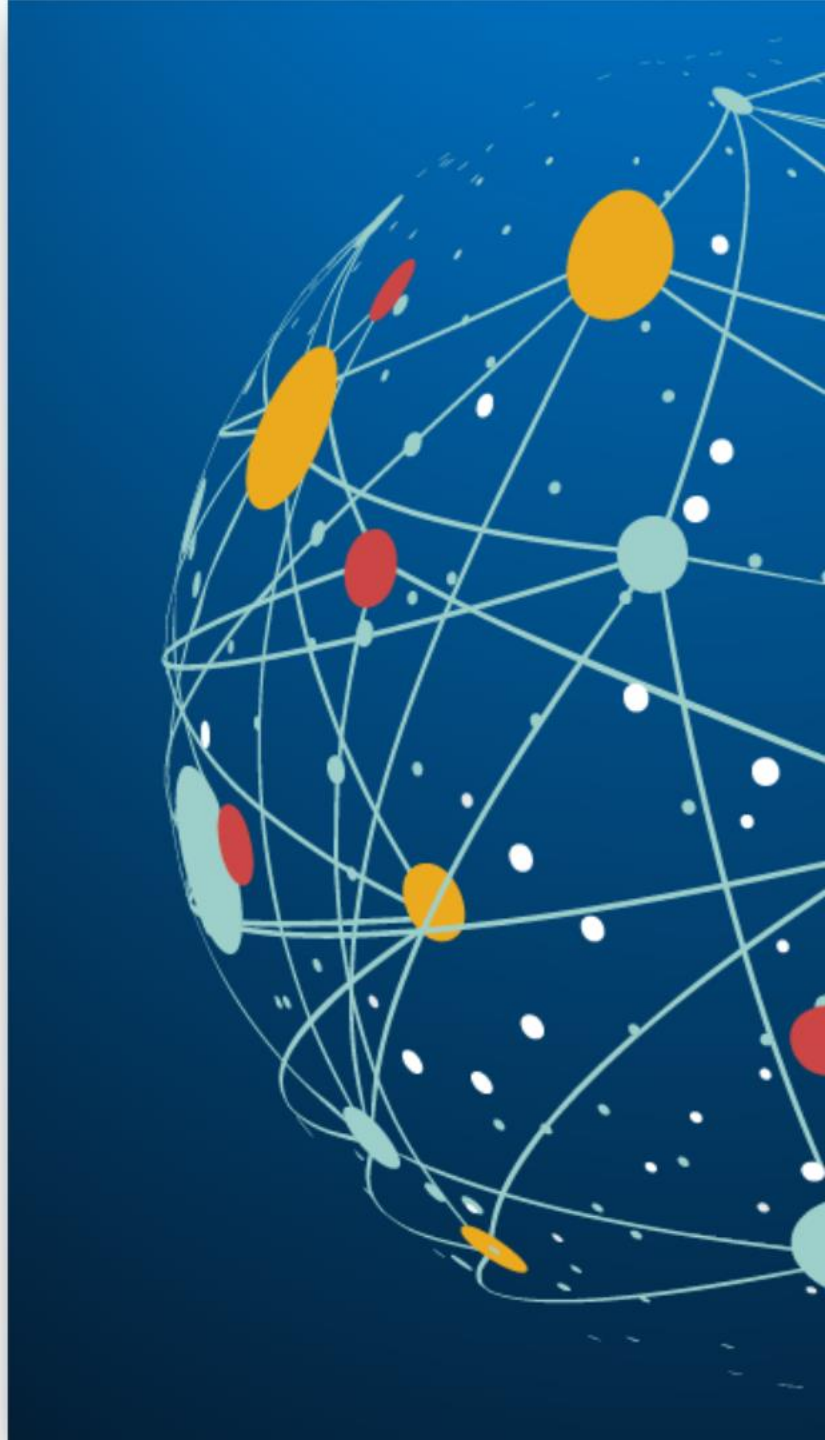
SDTM Specializations

Column	Description
Assigned Term	C-code for assigned term in NCIt or left blank when CDISC terminology does not apply
Assigned Value	Submission value for assigned term in NCIt if it exists, or an assigned value which will be the default value
BC ID	Biomedical Concept identifier foreign key
Codelist	C-code for a codelist in NCIt
Codelist Submission Value	CDISC submission value for the codelist
Comparator	Comparison operator for SDTM group variables included in VLM
Data Type	Variable data type
DEC ID	Biomedical Concept Data Element Concept idenfifier foreign key
Domain	Domain for the SDTM specialization group
Format	Variable display format
Length	Variable length
Linking Phrase	Variable relationship descriptive linking phrase
Mandatory Value	Indicator that variable must be populated within the SDTM group
Mandatory Variable	Indicator that variable must be present within the SDTM group
NSV Flag	Flag that indicates if the variable is a non-standard variable
Object	Object in a variable relationship
Origin Source	Variable origin source (define-XML v21)
Origin Type	Variable origin type (define-XML v21)
Package Date	Biomedical Concept package release date indicating when the BC package was published to production
Predicated Term	Short variable relationship linking phrase for programming purposes
Role	SDTM variable role
SDTM Variable	Variable included in the SDTM dataset specialization
SDTMIG End Version	The last SDTMIG version that is applicable to the BC dataset specialization
SDTMIG Start Version	The earliest SDTMIG version applicable to the BC dataset specialization
Short Name	SDTM group short name which provides a user friendly and intuitive name for the vlm_group_id
Significant Digits	Variable significant_digits
Subject	Subject in a variable relationship
Subset Codelist	Subset codelist short name
Value List	List of SDTM submission values used if subset codelist is not applicable
VLM Group ID	Identifier for SDTM Value Level Metadata group
VLM Source	SDTM VLM Source which categorizes VLM groups by topic variable
VLM Target	Target variable for VLM



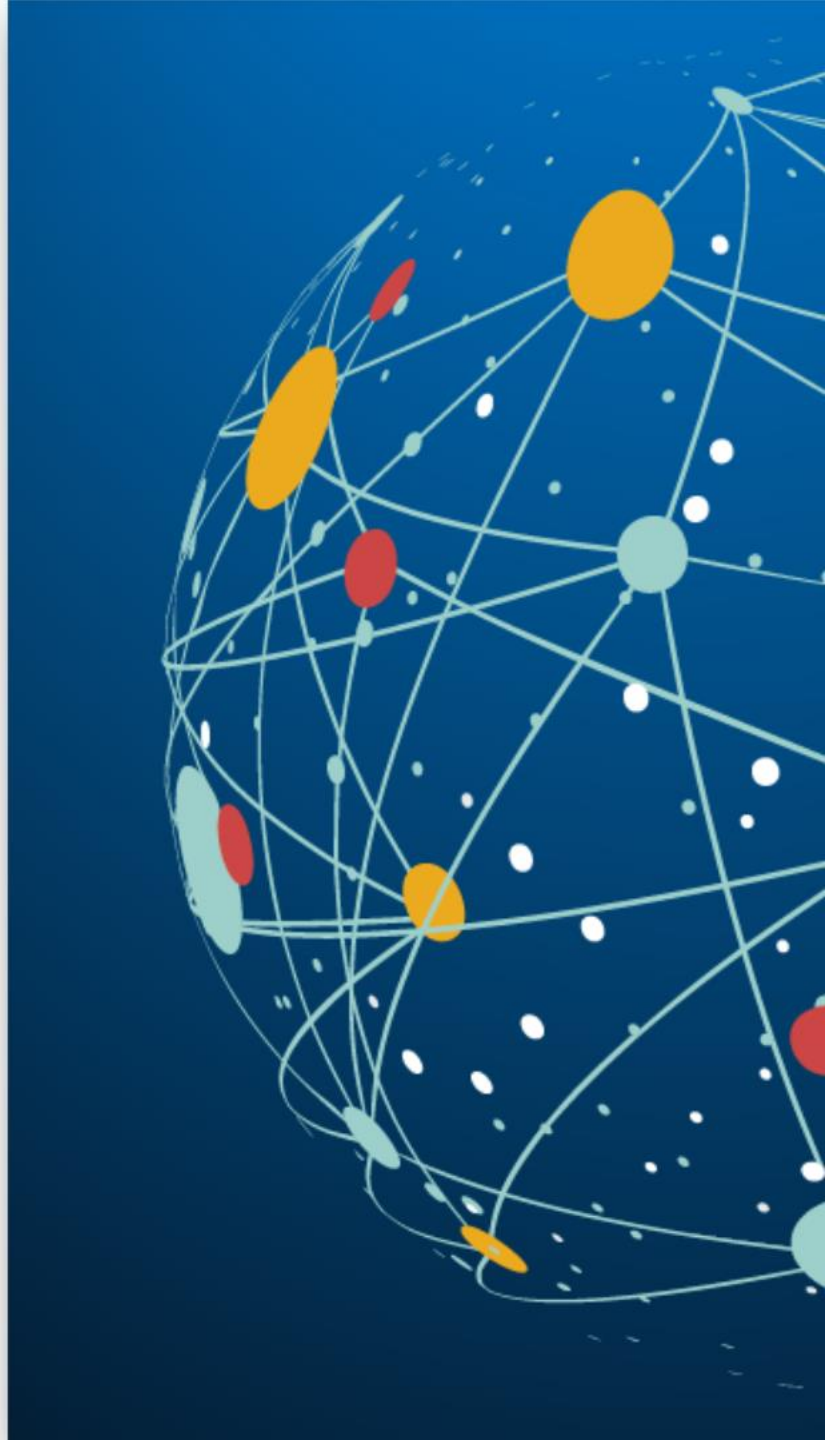
SDS and Biomedical Concepts

- Extend existing library of content
  - Initial push leveraged code tables and terminology
- Goal is to identify gaps and improve completeness



CDISC Library: The Future

- Goal: fully digitized by 2030
- https://www.cdisc.org/cdisc-library
- Evaluating next-generation architecture and infrastructure
  - Changes to Library API will be managed to minimize disruption to existing integrations

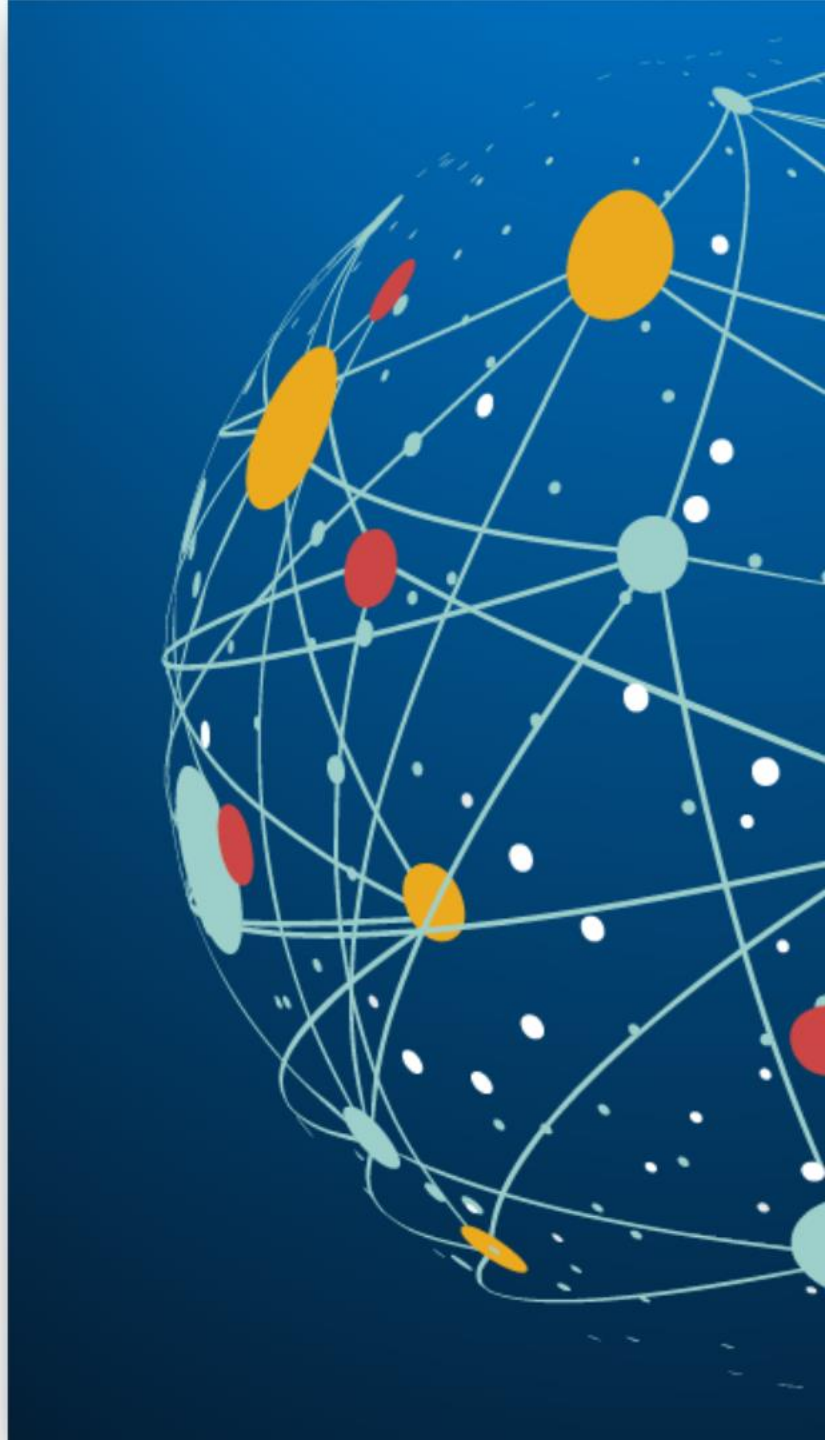


Additional Resources

Support for Implementation

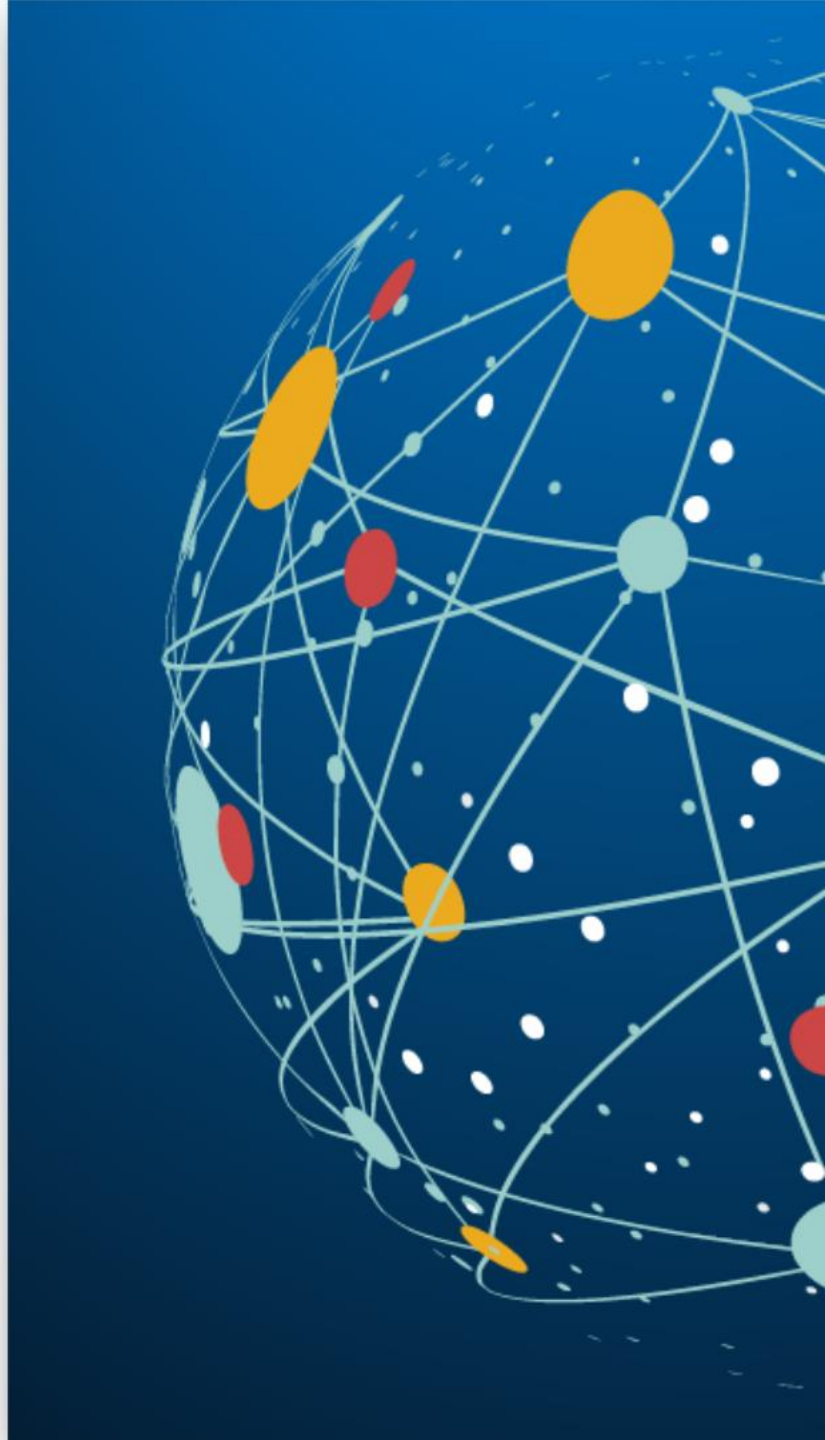
Improving Resources

- Knowledge Base:
  - https://www.cdisc.org/kb
  - General information about using SDTM
- Examples Collection:
  - https://www.cdisc.org/kb/exa
  - “This would really benefit from an example of…”
- Ongoing updates



SDS Activities

- Volunteers welcomed!
  - SDS Home on CDISC Wiki
  - volunteer@cdisc.org
- Work organized by sub-teams
  - Conformance Rules
  - Comment Resolution
  - Controlled Terminology
  - Specific Topics: Labs, QRS, Oncology
  - May adjust structure as needs become clearer



Thank You!



Questions?

