



CDISC Controlled Terminology

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Controlled Terminology P51 Publication and P52 Public Review

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10.04.2022



Question & Answer

1. 'Panelist': Question

OR

1. 'Presentation': Question

Examples:

1) What should be supported by ADaM datasets?

2) Jack: Is there a limit to the number of variables that can be in ADSL?



Content Disclaimer

1. All content in this presentation is for education and information only. References to any specific commercial product, process, service, or corporation are also for information only, and do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.



Agenda

1. Package 51 Publication Release (2022-09-30)
 - Changes post-public review
2. Package 52 Public Review (2022-09-23 to 2022-10-21)
 - New Additions
 - Changes to existing
 - LB/MB/IS Domain changes and effects on CDISC CT
3. Questions



Controlled Terminology Package 51 Publication

2022-09-30

Controlled Terminology Publication Schedule

CDISC Terminology Publication Schedule

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks/30 days)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
47	6/11/2021	6/18/2021	7/16/2021	8/13/2021	9/24/2021	CDASH	Cell Pheno	Define-XML	ECG
47						General	Genomics	Lab	Microbio/Immuno
47						Oncology	PK	Protocol Entities	SDTM Domain
47						SEND	Unit		
48	9/10/2021	9/17/2021	10/15/2021	11/12/2021	12/17/2021	ADaM	Biospecimens	Cell Pheno	ECG
48						General	Glossary	Lab	Microbio/Immuno
48						Oncology	PK	Protocol Entities	SDTM Domain
48						SEND	Unit		
49	12/10/2021	12/17/2021	1/14/2022	2/11/2022	3/25/2022	Biospecimens	Cell Pheno	Genomics	General
49						Microbio/Immuno	Lab	PK	Protocol Entities
49						SEND	Unit		
50	3/11/2022	3/18/2022	4/15/2022	5/13/2022	6/24/2022	Cell Pheno	General	Genomics	Microbio/Immuno
50						Lab	Oncology	Protocol Entities	QRS
50						SEND	Unit		
51	6/10/2022	6/17/2022	7/15/2022	8/19/2022	9/30/2022	Biospec	Cell Pheno	Define-XML	Devices
51						General	Genomics	Lab	Microbio/Immuno
51						Oncology	Protocol Entities	SDTM Domain	SEND
51						Unit			
52	9/16/2022	9/23/2022	10/21/2022	11/18/2022	12/16/2022	Cell Pheno	Define-XML	Define-XML	General
52						Glossary	Lab	Microbio/Immuno	Oncology
52						Protocol Entities	SEND	Unit	
53	12/9/2022	12/16/2022	1/20/2023	2/17/2023	3/31/2023				
53									
53									
54	3/17/2023	3/24/2023	4/21/2023	5/19/2023	6/30/2023				



Controlled Terminology Package 51 Publication Release

- Updates to CDASH, Define-XML, Protocol Entities, SDTM, and SEND Terminology
- ***NEW*** CDISC terminology subset DDF (Digital Data Flow)
- Other Project Support:
 - DRAGON IMI, SDTMIGv3.4



Significant Changes Post-Public Review

- Microbiology/Immunology:
 - ISBDAGT:
 - Proposed submission values for 10 new terms were changed to remove 'MULTIPLE' from the submission value (E.g., BEE MIX VENOM ANTIGENS, MULTIPLE -> BEE MIX VENOM ANTIGENS)
 - Existing term submission value ANIMAL MIX ANTIGENS, MULTIPLE updated to ANIMAL MIX ANTIGENS
 - MICROORG:
 - New MICROORG value ENTAMOEBA DISPAR removed from package as it is already published.
- Lab:
 - LBTEST-CD:
 - New LBTEST-CD values MASTCELE / Mast Cells/Leukocytes removed from package as it is already published.
 - Existing published LBTESTCD=HXDX 18 (C186068) updated to HXDX18 (no spaces in TESTCD values)



Significant Changes Post-Public Review

- General:

- RISKSOC: Proposed new term 'ESSENTIAL WORKER' removed by requester since it was no longer needed for project.

- Biospecimens & Devices:

- ACCPARTY: Proposed new term 'INVESTIGATOR SITE' removed from P51 publication for further discussion in P53.



Significant Changes Post-Public Review

Other, less significant changes* also made in:

- General, Protocol, Microbiology-Immunology, Cell Phenotyping

No post-public review changes made to:

- Define-XML
- Genomics
- Oncology
- SDTM Domain
- SEND
- UNIT

***Please note that changes have been made to the terms proposed in the public review documents (edits to proposed definitions, additions of synonyms, etc.) that were not covered in previous slides. Please refer to published CT as the definitive source for terminology.**

P51 Terminology Products Updates

- Updates on CDISC.org:
 - Updated Codetable mappings:
 - GF, GI, MK, RACE_ETHNIC, RP, SC, TS, and VS
 - **NEW** codetable Mapping
 - IG – Integumentary System domain
 - Unit-UCUM_Codetable
 - Controlled_Terminology_Requests_Denied_P51
 - Paired Codelists product for SDTM and SEND
 - Terminology Publication Schedule
 - LOINC-LB Mapping file
 - Terminology development Rules
 - Update to terminology development Rules for Lab, Unit, and MI
 - Update to QRS Naming and Business Rules ***This document is now being stored exclusively on the QRS page of CDISC.org***



QRS Controlled Terminology Package 51 Publication Release

- 1 new --CAT value
 - Cumulative Illness Rating Scale for Geriatrics Clinical Classification (CIRS-G) (CC)
- 12 new codelists for response terminology
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification ORRES for BPRSA118 TN/TC
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification STRESC for BPRSA118 TN/TC
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification ORRES the Same as BPRSA101 TN/TC
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification STRESC the Same as BPRSA101 TN/TC
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification ORRES the Same as BPRSA103 TN/TC
 - Brief Psychiatric Rating Scale-Anchored Clinical Classification STRESC the Same as BPRSA103 TN/TC



Controlled Terminology Package 52 Public Review

2022-09-23 to 2022-10-21



Terminology Call for Public Review Package P52 - Comments Due by 21 OCT 2022

Created by Dana Booth, last modified by Ann White on Sep 23, 2022

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 52, which consists of the following 18 documents:

- Controlled_Terminology_Requests_Denied
- IS Domain Scope Change – Codetable Mapping and Background (This is a Zip file that contains a background document, which is **for information only**. The Zip file also contains an IS codetable mapping document, which is for Public Review.)
- QRS Naming and Business Rules_2022-09-23
- Rules for Immunogenicity Specimen Tests_2022-09-23
- Rules for MB and MS_2022-09-23
- Rules_for_Lab_Unit_and_MI_2022-09-23
- Rules_for_PK_2022-09-23
- Cell Phenotyping
- Define-XML
- General
- Glossary*
- Laboratory*
- Microbiology-Immunology*
- Oncology*
- Protocol Entities
- QRS*
- SEND
- UNIT

An * indicates that **changes or retirements of existing CDISC Submission Values** are included on the "Changes to Existing" tab in the document. Please review these changes as there may be submission value changes or term deprecations.

Comments due: 21 OCT 2022

Instructions for Reviewers

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P52+-+Comments+Due+by+21+OCT+2022>

<https://www.cdisc.org/public-review/controlled-terminology-package-52>



Controlled Terminology Package 52 Public Review

- ADaM Team
 - No new term or changes to existing to report this quarter.



Controlled Terminology Package 52 Public Review

- Biospecimens Team
 - No new term or changes to existing to report this quarter.



Controlled Terminology Package 52 Public Review

- CDASH Team
 - No new term or changes to existing to report this quarter.



Controlled Terminology Package 52 Public Review

- Cell Phenotyping Team
 - New Terms Added to Existing Codelists:
 - CPTTEST-CD
 - 44 changes to published terms; none significant



Controlled Terminology Package 52 Public Review

- Define-XML Team
 - New Terms Added to Existing Codelists:
 - STDNAM, SDTMIGRS
 - No changes to published term



Controlled Terminology Package 52 Public Review

- Medical Devices Team
 - No new term or changes to existing to report this quarter.



Controlled Terminology Package 52 Public Review

- ECG Terminology Team:
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 52 Public Review

- General Terminology Team:
 - New Terms Added to Existing Codelists:
 - EVAL, LOC, MHEDTTYP, MUSCTS-CD, NCOMPLT, NVTEST-CD, PROCEDUR, ROUTE, RPTEST-CD, SEVRS, VSTEST-CD
 - To support the: Pediatrics TAUG
 - New Terms added to New Codelists
 - AUTEST-CD: Auricular Findings Test Code/Test Name
 - PDFATS-CD: Pediatric Findings About Test Code/Test Name
 - To support the: Pediatrics TAUG
 - Updates to Codetable Mapping Files:
 - DS_Codetable_Mapping
 - MK_Codetable_Mapping
 - RP_Codetable_Mapping
 - VS_Codetable_Mapping
 - 31 changes to published terms; none are significant
 - Less significant changes include definition updates to harmonize definitions across CDISC Glossary and SDTM/Protocol/DDF terminology.



Controlled Terminology Package 52 Public Review

- Genomics Terminology Team:
 - No new term or changes to existing to report this quarter.

Controlled Terminology Package 51 Public Review

- CDISC Glossary Team

- 8 new term glossary terms
- 7 new acronyms, abbreviations, and initials (no changes to existing)
- 8 new references and 1 existing reference update
- 37 changes to published terms; 2 are significant
 - 'objective measurement' being removed – term was citing the SDTMIG but no references to that concept exist in published IG
 - Preferred term update: data collection instrument -> data collection instruments
 - Less significant changes include definition updates to harmonize definitions across CDISC Glossary and SDTM/Protocol/DDF terminology.



Controlled Terminology Package 52 Public Review

- Laboratory Terminology Team
 - New Terms Added to Existing Codelists:
 - LBTEST-CD, LBSTRESC, METHOD, MITS-CD, RESTYPRS
 - To support Pediatrics TAUG
 - 19 changes to published terms; none are significant
 - Update to Rules for Lab, Unit, and MI



Controlled Terminology Package 52 Public Review

- Laboratory Terminology Team (Units of Measure)
 - New Terms Added to Existing Codelists:
 - UNIT
 - 2 changes to published terms; none are significant

Controlled Terminology Package 52 Public Review

- Microbiology-Immunology Terminology Team
 - New Terms Added to Existing Codelists:
 - ISFTDTL, MBTEST-CD, MICROORG
 - 19 Changes to existing term; 16 are significant
 - Updates to Rules documents:
 - Rules for MB and MS
 - ***New*** Rules for Immunogenicity Specimen Tests (IS)
 - ***New*** codetable mapping file for IS domain



Controlled Terminology Package 52 Public Review

- Microbiology-Immunology Terminology Team
 - Significant Changes to Existing Terms
 - ISBDAGT:
 - Submission value change for C187754 - BORDETELLA PERTUSSIS FIMBRIAE ANTIGENS, MULTIPLE to BORDETELLA PERTUSSIS FIMBRIAE ANTIGENS
 - Submission value change for C187772 - HERPES SIMPLEX VIRUSES, MULTIPLE to HERPES SIMPLEX VIRUSES
 - Submission value change for C187773 - HIV VIRUSES, MULTIPLE to HIV VIRUSES
 - Submission value change for C187774 - HTLV VIRUSES, MULTIPLE to HTLV VIRUSES

Controlled Terminology Package 52 Public Review

- Microbiology-Immunology Terminology Team
 - Significant Changes to Existing Terms
 - ISTEST-CD:
 - Remove C132360/EVIGGASC/EBOV Specific IgG AB Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for Ebola virus specific IgG antibody. Refer to IS Example 6 in the SDTMIG 3.4. <https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>
 - Remove C132361/EVIGMASC/EBOV Specific IgM AB Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for Ebola virus specific IgM antibody. Refer to IS Example 6 in the SDTMIG 3.4. <https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>

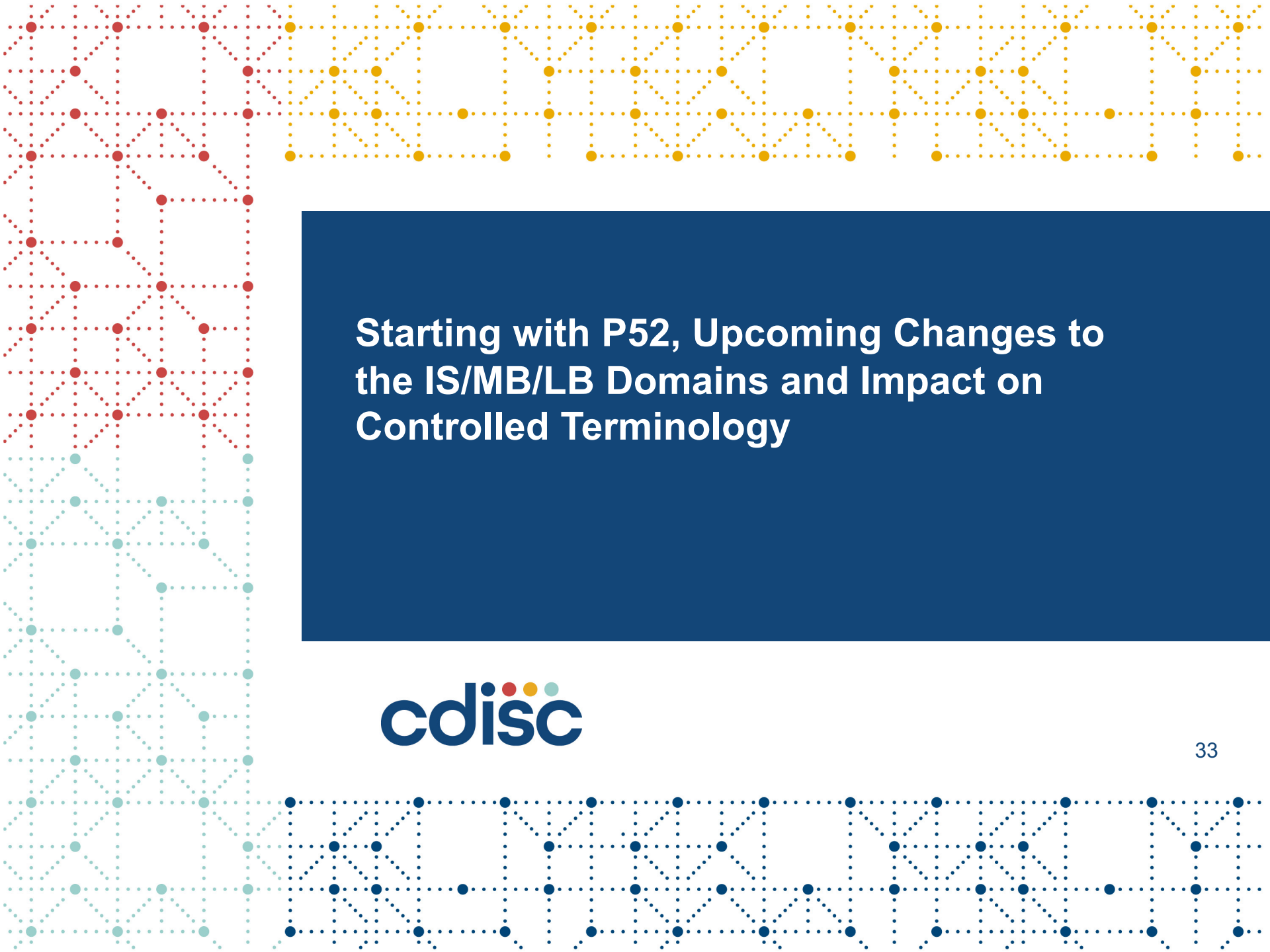


Controlled Terminology Package 52 Public Review

- Microbiology-Immunology Terminology Team
 - Significant Changes to Existing Terms
 - ISTEST-CD:
 - Remove C120622/H1IGGASC/H1 Specific IgG Antibody Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for Influenza H1 specific IgG antibody. Refer to IS Example 6 in the SDTMIG 3.4. <https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>
 - Remove C120623/H3IGGASC/H3 Specific IgG Antibody Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for Influenza H3 specific IgG antibody. Refer to IS Example 6 in the SDTMIG 3.4. <https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>

Controlled Terminology Package 52 Public Review

- Microbiology-Immunology Terminology Team
 - Significant Changes to Existing Terms
 - ISTEST-CD:
 - Remove C132362/IGMABSC/IgM Antibody Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for IgM antibody. Refer to IS Example 6 in the SDTMIG 3.4.
<https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>
 - Remove C120624/TIGGASC/Total IgG Antibody Secreting Cells: Remove from codelist. Per the SDTMIG v3.4, CDISC will no longer develop and control such hyper-specific and pre-coordinated ISTESTs. Map to ISTEST = Antibody-secreting Cells/C181399, and use the variable ISMSCBCE for IgG antibody. Refer to IS Example 6 in the SDTMIG 3.4.
<https://wiki.cdisc.org/display/SDTMIG/IS+Example+6>



Starting with P52, Upcoming Changes to the IS/MB/LB Domains and Impact on Controlled Terminology





Changes to the IS Domain Scope and How It Affects the LB and MB Domains in the SDTMIG v3.4

- The scope of the IS domain has been expanded in the SDTMIG v3.4. The current IS domain in IG v3.4 is designed to house data pertaining to *specimen-based* assessments that measure the “presence, magnitude and scale of the immune response upon an **antigen** stimulation or encounter”.
- This then effectively **expands** the scope of the IS domain from the previous SDTMIG versions (3.2 and 3.3) where the IS domain was limited to “assessments that describe whether a (study) **therapy** provoked/caused/induced an immune response.”
- As a result, most, if not all humoral immune response, antibody tests, should now be represented by the IS Domain only.
- This will result in the deprecation of approximately 400 antibody TEST and TESTCD values from both the Laboratory Test Results (LB) and Microbiology Specimen (MB) domains, and instead, they will be remodeled in the IS domain, using IS domain standard variables including but are not limited to: ITEST-CD, ISBDAGNT (Binding Agent), and ISTSTDTL (Test Detail).



Rationales Behind the IS Domain Scope Update for the SDTMIG v3.4

1. Domain and variable level limitations

- Prior to the SDTMIG v3.4, most specimen-based, antigen-stimulated immune response testing data had been mapped to the MB and LB domains which do not have the sufficient structure and variables to support the meaningful and consistent representation of such data, and as a result, various supplemental qualifiers had been used to map key information in both LB and MB. This also resulted in too much information being mapped and pre-coordinated into the LB/MBTEST-CD variables, thusly overloading the --TEST/CD variables.

2. Multiple different SDTM Findings domains were used to represent specimen-based immune response testing data

- Prior IS domain scope defined by the SDTMIG versions 3.2/3.3 limited its use for collection of “study therapy”-induced immune response testing data, this leads to “baseline” immune response test data *prior to study treatment exposure* being in a different domain. Compounding on this problem, the baseline immune response testing data are mapped to LB or MB, depending on the study type, as well as the SDTMIG version used.

IS Domain Update Knowledge Base Article - Tools and Education Materials in P52

- For more information about the history, the problems that led to, and the rationales behind the IS domain scope update, as well as some IS example modeling, for the SDTMIG v3.4, refer to the Knowledge Base Article on www.cdisc.org, <https://www.cdisc.org/kb/articles/domain-scope-update-sdtmig-v3-4-development-history-and-difficulties-standardizing>.

- This article is also released as reference reading within the P52 CT public review package.



Navigation tabs: New to CDISC, Standards, Education, **Resources**, Events, Membership

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ARTICLES / IS Domain Scope Update for the SDTMIG v3.4: A Development History and the Difficulties of Standardizing Complicated Biological Processes

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IS Domain Scope Update for the SDTMIG v3.4: A Development History and the Difficulties of Standardizing Complicated Biological Processes

Section 1: An expanded scope and new definition for the IS domain in the SDTMIG v3.4

The current Immunogenicity Specimen Assessments (IS) domain in the **SDTMIG v3.4** is designed to represent data pertaining to *specimen-based* assessments that measure the "presence, magnitude and scale of the immune response upon an **antigen** stimulation or encounter." Not only does the new domain definition better align with the scientific definition of "immunogenicity", but it also expands the scope of the IS domain from the previous versions of SDTMIG (i.e., v3.2 and v3.3), where the IS domain was defined to represent data pertaining to "assessments that describe whether a **therapy** provoked/caused/induced an immune response".

The "antigen" (of interest) in the updated IS domain definition is any entity capable of inducing a host immune response, and may be (but is not limited to), drug/test article (i.e., study/non-study therapy), allergen, microorganism (e.g., bacteria, virus, fungi, parasite, etc.), self-antigen (i.e., autoantigen), and others.

The assessments that "detect the presence of, and quantify the magnitude and scale of the immune response upon an antigen stimulation or encounter", and are in scope for inclusion in the IS domain per the SDTMIG v3.4, are the following:

- Activated immune **cells**, specifically and mainly (but are not limited to) those measured via ELISPOT:
 - Cytokine-secreting cells

****This article is informational only and does not require public review.**



Impact on LB/MB/IS Controlled Terminology and Timeline on Upcoming Changes

The change in the IS domain scope will result in the deprecation of approximately 400 antibody TEST and TESTCD values from both the Lab and Microbiology domains, and instead, they will be remodeled in the IS domain, using IS domain standard variables including but are not limited to: ISTEST-CD, ISBDAGNT (Binding Agent), and ISTSTDTL (Test Detail).

Timelines:

1. The MB/IS team will release the 1st batch of LB/MB to IS terms relationship mapping in Package 52, December 2022. This batch includes 344 relationships mapped.
2. The MB/IS team plans to release the 2nd batch of LB/MB to IS terms relationship mapping over Packages 53 and 54 (March and June 2023)
3. The MB/IS team plans to deprecate the LB and MB immune response test terms indicated in this codetable mapping document in P56, December 2023.

Note: there are NO immediate plans to deprecate the affected antibody LBTEST-CD/MBTEST-CD terms at this time. Deprecation will happen in December 2023.

IS Terminology Codetable Mapping File - Tools and Education Materials in P52

The deprecated LB and MB terms will be remapped to IS, and a relationship codetable mapping file is developed and published starting P52, which helps users to:

- Assign the existing terms (which are going to be deprecated) from LB and MB to IS.

- Update dictionary, develop systems and programs in preparation for the SDTMIG v3.4 adaptation, especially with regard to scope changes involving the LB, MB and IS domains.

A	B	C	D	E	F	G	H	I	J	K
C-Code	LBTEST Terms for Deprecation Laboratory Test Name (codelist code = C67154)	C.Code (Concept Code)	When Variable = ISTEEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C129526)	C.Code (Concept Code)	When Variable = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C.Code (Concept Code)	When Variable = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169)	C.Code (Concept Code)	When Variable = ISTSTDIL Immunogenicity Specimen Test Details (ISTSTDIL) (codelist code = C189267)	Additional
C130137	American Cockroach Antigen IgA Antibody	C187776	Allergen-induced IgA Antibody			C189452	AMERICAN COCKROACH ANTIGEN			
C130136	American Cockroach Antigen IgE Antibody	C181398	Allergen-induced IgE Antibody			C189452	AMERICAN COCKROACH ANTIGEN			
C130138	American Cockroach Antigen IgG Antibody	C187777	Allergen-induced IgG Antibody			C189452	AMERICAN COCKROACH ANTIGEN			
C130139	American Cockroach Antigen IgG4 Antibody	C187778	Allergen-induced IgG4 Antibody			C189452	AMERICAN COCKROACH ANTIGEN			
C165933	American Cockroach IgE AB RAST Score	C181398	Allergen-induced IgE Antibody			C189452	AMERICAN COCKROACH ANTIGEN	C189493	RAST Score	
C165918	American Cockroach IgG AB RAST Score	C187777	Allergen-induced IgG Antibody			C189452	AMERICAN COCKROACH ANTIGEN	C189493	RAST Score	
C130112	Animal Mix Antigen IgE Antibody	C181398	Allergen-induced IgE Antibody			C181357	ANIMAL MIX ANTIGENS			
C130113	Animal Mix Antigen IgG Antibody	C187777	Allergen-induced IgG Antibody			C181357	ANIMAL MIX ANTIGENS			
C165927	Animal Mix IgE AB RAST Score	C181398	Allergen-induced IgE Antibody			C181357	ANIMAL MIX ANTIGENS	C189493	RAST Score	
C165908	Animal Mix IgG AB RAST Score	C187777	Allergen-induced IgG Antibody			C181357	ANIMAL MIX ANTIGENS	C189493	RAST Score	

The LB to IS Mapping Tab shows existing LBTESTs to IS domain variables mapping.

P52: Mapped 300+ Existing LBTEST/CD and MBTEST/CD Humoral Immune Response Antibody Tests to ISTEEST/CD, ISBDAGNT and ISTSTDTL

In P52, the MB/IS team released mapped relationships of the following tests:

- Anti-allergen antibody tests are mapped from LB to IS.
- Anti-microbial antibody tests are mapped from MB to IS.

A	B	C	D	E	F	G	H	I	J	K
C.Code	MBTEST Terms for Deprecation Microbiology Test Name (codelist code = C120528)	C.Code (Concept Code)	When Variable = ISTEEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C.Code (Concept Code)	When Variable = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C.Code (Concept Code)	When Variable = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169)	C.Code (Concept Code)	When Variable = ISTSTDTL Immunogenicity Specimen Test Details (ISTSTDTL) (codelist code = C189267)	Addition
C11125	Adenovirus Antibody	C187780	Microbial-induced Antibody	C14179	ADENOVIRIDAE					
C81976	Anti-Saccharomyces cerevisiae Antibody	C187780	Microbial-induced Antibody	C14271	SACCHAROMYCES CEREVISIAE					
C147310	B. burgdorferi IgG and IgM Antibody	C187784	Microbial-induced IgG + IgM Antibody	C76208	BORRELIA BURGDORFERI					
C122098	Borrelia burgdorferi Antibody	C187780	Microbial-induced Antibody	C76208	BORRELIA BURGDORFERI					
C122099	Borrelia burgdorferi IgA Antibody	C187782	Microbial-induced IgA Antibody	C76208	BORRELIA BURGDORFERI					
C122100	Borrelia burgdorferi IgG Antibody	C181394	Microbial-induced IgG Antibody	C76208	BORRELIA BURGDORFERI					
C122101	Borrelia burgdorferi IgM Antibody	C187786	Microbial-induced IgM Antibody	C76208	BORRELIA BURGDORFERI					

The MB to IS Mapping Tab shows existing MBTESTs to IS domain variables mapping.



P52: Mapped 300+ Existing LBTEST/CD and MBTEST/CD Humoral Immune Response Antibody Tests to ISTEEST/CD, ISBDAGNT and ISTSTDTL

1. Again, there are NO immediate plans to deprecate existing LBTESTs and MBTESTs that have been mapped. Deprecation will happen in Dec 2023 publication.
2. The MB/IS team will continue to map **existing** LBTESTs (that will be deprecated) to IS. The mapped relationships will be added to the IS Terminology Codetable Mapping file. Please expect the next batch of mapped relationships from LB to IS, in P53 and P54, which will include humoral immune response antibody tests for autoimmune disease (autoantibodies), and transfusion/transplantation studies (alloantibodies – HLA antibodies).

The MB/IS CT team will maintain and continue to update this codetable mapping file which will be published every quarter...**pls review this file and stay informed of the upcoming changes!**

IS Terminology Codetable Mapping File - New Antibody Terms Mapping in IS

- This codetable mapping file is also used to map new antibody term requests to their respective IS domain variables.
- Pls submit your **new** pre-coordinated antibody tests to the IS/MB team, and we will develop the IS mapping recommendations following rules set by the SDTMIG v3.4.
- Your request can be tracked via the new term request CDISC number (CDISC-#####) in the “New AB Terms Mapping” Tab.

	A	B	C	D	E	F	G	H	I	J
	New Term Request Code	New Term Request	C.Code (Concept Code)	When Variable = ISTEEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C126526)	C.Code (Concept Code)	When Variable = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C.Code (Concept Code)	When Variable = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169)	C.Code (Concept Code)	When Variable = ISTSTDIT Immunogenicity Specimen Test Details (ISTSTDIT) (codelist code = C189267)
1	CDISC-4999	Hazel nut Antigen IgG4 Antibody (f17)	C187778	Allergen-induced IgG4 Antibody			C189480	CORYLUS AVELLANA NUT ANTIGEN		
2	CDISC-4999	Cashew nut Antigen IgG4 Antibody (E202)	C187778	Allergen-induced IgG4 Antibody			C189478	CASHEW NUT ANTIGEN		
3	CDISC-4999	Walnut Antigen IgG4 Antibody (E256)	C187778	Allergen-induced IgG4 Antibody			C189491	WALNUT ANTIGEN		

IS Terminology Codetable Mapping File - Tools and Education Materials in P52

The IS Terminology Codetable Mapping file can also be accessed from the: <https://www.cdisc.org/standards/terminology/controlled-terminology>

- In the **Supplemental Files** section.
- Under the **Codetable Mapping File** tab.

cdisc.org/standards/terminology/controlled-terminology

- Update to the SDTM, SEND, and ADaM paired view files

[Controlled Terminology Release 24 June 2022](#)

Supplemental Files

[NCI FTP Links](#) [Resources](#) [Rules](#) **[Codetable Mapping Files](#)** [Unit-UCUM Mapping File](#) [LOINC to LB Mapping Files](#) [Paired Codelists](#)

Controlled Terminology consists of question (e.g., Variables, TESTs and PARMs) and answer (e.g., response codelists, qualifier variable codelists), which are commonly referred to as codelists and are published alphabetically in the Controlled Terminology publication.

The terms within these codelists may have relationships to other terms within other codelists. For instance, a single TEST in the EGTEST codelist may have a finite set of responses located in the EGSTRESC codelist that constitutes a subset of the EGSTRESC codelist. Another instance, a single VSTEST value may have a constrained set of units of measure that are valid for the numeric responses to that VSTEST. These relationships are not readily apparent in the Controlled Terminology publication files.

To address this issue, the Controlled Terminology Teams have created Codetable Mapping Files based on published Terminology, which show relationships between terms in different Controlled Terminology codelists. These supplemental files provide human and machine-readable linkages between published terms across multiple codelists and may be helpful for data QA/QC, CRF building, and data mapping. These files are for clinical use only.

The Controlled Terminology teams will continue to update these files as new Terminology is published, as well as develop new domain Codetable Mapping Files. If you are interested in seeing specific content developed, please submit the request through the [New Term Request Site](#). CDISC is concurrently working on the development of electronically consumable formats of this content to be published out of [CDISC Library](#).

Note: 2020-09-25: The SEND Leadership Team has decided to remove the SEND codetable mapping files from this page in December 2020, coincident to the CT P44 publication. It is unclear at this time how the files are to be used to support a SEND submission, which is causing some confusion among the user community. These files will no longer be updated beginning with CT Package 43.

[DD Codetable](#)
[DS Codetable](#)
[CV Codetable](#)
[ECG Codetable](#)



Rules for Immunogenicity Testing File - Tools and Education Materials in P52

New standard variables were developed and introduced for the IS domain in the SDTMIG v3.4 to:

- Meet the urgent need for clear and consistent representation of specimen-based, immune response testing data.
- Resolve the long-standing issue of overloading the --TEST/--TESTCD variables.

New variables added to the IS domain, in the SDTMIG v3.4 and SDTM v2.0 are the following:

- MSCBCE (Molecule Secreted by Cells), this variable is restricted to the IS domain.
- BDAGNT (Binding Agent), TSTCND (Test Condition), and CNDAGT (Test Condition Agent) are used in IS, LB and Cell Phenotyping (CP) domains.
- TSTOPO (Test Operational Objective) is used in both the LB and IS domains.

More information, variable definition/scope/usage/rules on the above new IS domain standard variables can be found in the “**Rules for Immunogenicity Test**” document, which also contains IS controlled terminology and CT codelists naming and development rules.

Rules for Immunogenicity Testing File - Tools and Education Materials in P52

- If the MB/IS team gets the same or similar questions more than 5 (give or take) times, it will be added to the **FAQ section** of the IS Rules Doc.
 - Note this also applies to the MB/MS Rule Document.
- This sections contains a lot of “where do I map my data? LB vs IS? MB vs IS?” type of questions and answers, pls make sure to have a look.

GENERAL FAQ

Question 1: Why are antibody tests deprecated from LB and MB and are reassigned to IS, per the SDTMIG v3.4?

Answer:

Antibody tests are considered as humoral immune responses and are in scope for the IS domain per IG3.4. They should be represented by a single IS domain, regardless of study types or pre- vs. post-study therapy exposure.

For more details, refer to the Knowledge Base Article on www.cdisc.org, [IS Domain Scope Update for the SDTMIG v3.4: A Development History and the Difficulties of Standardizing Complicated Biological Processes](#)

Question 2: Where should I map my cytokine and complement protein testing data, such as the Interferon Gamma (IFN- γ) detection/quantification test? They are also considered as immune response related testing. I see complement proteins and IFN- γ as published values in LBTEST-CD, should they be mapped to LB or IS?

Answer:

Our team gets this question very often, as the majority of the tests in IS had once been assigned to, and collected by LB per the SDTMIG 3.2. Generally speaking, a test is mapped to LB, if it is a part of a “**routine urine or blood, standard of care and safety related testing**” - this means one is *only typically* interested in the analyte’s presence/absence, quantity, and whether or not the result is within the normal range (if not within normal range, it may need flagging). **In a grossly simplistic (but true) view, the lab domain is not built to handle anything that requires complicated biological testing, it doesn’t have the standard variables to support such data mapping (this also in part, contributes to the development of newer specimen-based domains, such as CP, GF, MB, MS, IS, etc.).**

Coming back to IS vs. LB, users may find some specimen-based, immune response related tests in **both** LB and IS, below is the general distinction:

- A cytokine (or other similar) test is mapped to the LB domain, if it is a part of a “routine urine or blood, standard of care and safety related testing” – this means one is typically *only* interested in the cytokine’s presence/absence, quantity, and whether

Rules for Immunogenicity Testing File - Tools and Education Materials in P52

The Rules for Immunogenicity Testing file can also be accessed from the: <https://www.cdisc.org/standards/terminology/controlled-terminology>

- In the Supplemental Files section.
- Under the Rules tab.

The screenshot shows the CDISC website page for 'controlled-terminology'. The URL is [cdisc.org/standards/terminology/controlled-terminology](https://www.cdisc.org/standards/terminology/controlled-terminology). The page content includes a notice about updates to terminology files as of 24 June 2022, stating that these files replace all previous Protocol Entities, SEND, CDASH, SDTM, and ADaM Terminology files. It lists approximately 187 new QRS terms and 1045 new terms across Protocol Entities, SEND, CDASH, SDTM, and ADaM Terminology files. A list of updates is provided, including updates to published Codetable Mapping files, QRS Naming and Business Rules, new terminology development rules for Genomics, Unit-UCUM Codetable Mapping, Controlled Terminology Requests Denied, CDISC Terminology Publication Schedule, and SDTM, SEND, and ADaM paired view files. Below this is a 'Supplemental Files' section with a navigation bar containing 'NCI FTP Links', 'Resources', 'Rules' (highlighted with a red box), 'Codetable Mapping Files', 'Unit-UCUM Mapping File', 'LOINC to LB Mapping Files', and 'Paired Codelists'. Under the 'Rules' tab, a list of links is shown: 'Rules for all codelists', 'Rules for ADaM', 'Rules for Genomics', 'Rules for Lab and Unit', 'Rules for Microbiology', 'Rules for Oncology', and 'Rules for PK'.



For Users Who are Implementing/Submitting Under the SDTMIG v3.2/v3.3 – Other Recommendations

Many CDISC users are still using SDTMIG v3.2/v3.3 for whom applications and dictionaries are not yet built or equipped to implement SDTMIG v3.4:

- Per the SDTMIG 3.4, antigen-stimulated immune response testing data should be mapped to the IS domain only. Therefore, the MB/IS CT team will **NO LONGER control, develop or publish** new antibody terms, or other specimen-based immune response testing terminology in the LB and MB domains from this point on.
- Users who are implementing/submitting under the SDTMIG v3.2/v3.3 should consider adding controlled terminology for antibody testing, or other specimen-based, immunogenicity tests as **extensible values** to LBTEST-CD and/or MBTEST-CD codelists, if immune response testing data are still mapped to LB/MB, following the rules set by the SDTMIG v3.2/3.3.

Note: as mentioned earlier, the MB/IS team still encourage users to submit their pre-coordinated **new antibody** term requests to the team, so the MB/IS team can map the term to the IS domain, according to the rules set by the SDTMIG 3.4. The mapping recommendation for the new antibody test can be tracked and will also be published in the [IS Terminology Codetable Mapping File](#) quarterly and will be available to all users.



Controlled Terminology Package 52 Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - TRTEST-CD, TUIDRS, ONCRSCAT, ONCRSR
 - Updates to Codetable Mapping Files:
 - TU_Codetable_Mapping
 - TR_Codetable_Mapping
 - RS_ONC_Codetable_Mapping
 - RS_Lugano
 - 9 change to existing term; 5 are significant

Controlled Terminology Package 52 Public Review

- Oncology Terminology Team:
 - Significant Changes:
 - ONCRSR:
 - Existing term C124427/COMPLETE MRD RESPONSE is being removed from the codelist. Please use published values of CR or sCR instead.
 - Existing term C124428/MRD NEGATIVITY is being removed from the codelist. Please use new term (P52) NEGATIVE instead.
 - Existing term C124429/MRD PERSISTENCE is being removed from the codelist. Please use new term (P52) POSITIVE instead.
 - TRTEST-CD:
 - Existing term C96566/AVMETSUV/Average Metabolic Standard Uptake Value is being removed from the codelist and merged into C181544, which is published in the codelist as SUVMEAN/Standardized Uptake Value Mean. Synonyms being added to C181544 to help with mapping.



Controlled Terminology Package 52 Public Review

- PK Terminology Team
 - Update to PK terminology development rules document
 - Significant update to harmonize structure of information to all other terminology development rules documents.



Controlled Terminology Package 52 Public Review

- Protocol Entities Terminology Team
 - New Terms to Protocol Entities Terminology
 - 1 new Entities: Study Activity
 - 4 attribute for the new entity: Study Activity
 - 14 changes to existing terms; none are significant
 - Less significant changes include definition updates to harmonize definitions across CDISC Glossary and SDTM/Protocol/DDF terminology.

Controlled Terminology Package 52 Public Review

- QRS Terminology Team
 - No New Terms for public review
 - Update to Terminology Development Rules Document
 - QRS Naming and Business Rules
 - 61 changes to existing; 61 are significant
 - The Psoriasis Area and Severity Index (PASI) 2005 is being deprecated from CCCAT codelist and the Psoriasis Area and Severity Index Clinical Classification Test Code/Name codelists are also being deprecated from SDTM publication
 - CDISC recommends using the version of PASI terminology that corresponds with the response values being used. Refer to the new version specific PASI being published with package 52, December 2022 release.



Controlled Terminology Package 52 Public Review

- SDTM Domain Terminology Team
 - No new term or changes to existing to report this quarter.



Controlled Terminology Package 52 Public Review

- SEND Terminology Team
 - New Terms Added to Existing Codelists:
 - SPEC
 - 3 changes to published terms; none are significant.



To the amazing and dedicated CDISC Controlled Terminology Team members and reviewers, YOU are the heart and soul of CDISC terminology!

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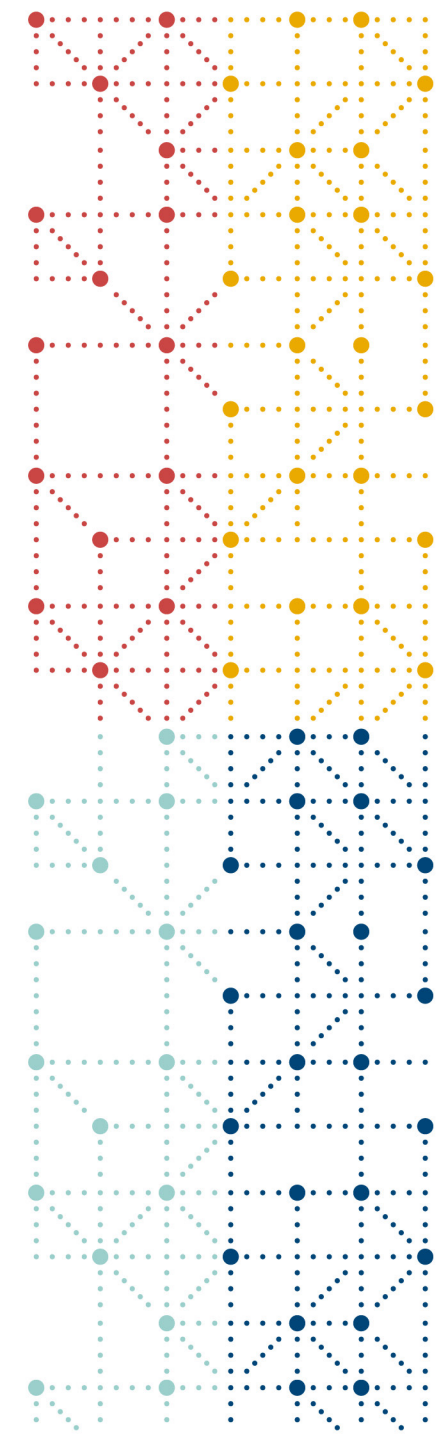


If you are interested in contributing to any of the CDISC Terminology initiatives, please contact us...

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Dana Booth, dbooth@cdisc.org

[CDISC New term request form:](https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc)
<https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>





Q&A



CDISC Education: Upcoming Learning Opportunities

Bernard Klinke



Thank you for your attendance and support of
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