



CDISC Controlled Terminology

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Controlled Terminology P55 Publication and P56 Public Review

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10.03.2023





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 55 Publication Release (2023-09-29)
 - Changes post-public review
 2. Package 56 Public Review (2023-09-22 to 2023-10-20)
 - New Additions
 - Changes to existing
 - Feedback requested – CT publication cadence
1. Questions



Controlled Terminology Package 55 Publication

2023-09-29

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			
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	Biospec	Cell Pheno	General	Lab
53						Microbio/Immuno	Protocol Entities	SEND	Unit
54	3/17/2023	3/24/2023	4/21/2023	5/19/2023	6/30/2023	ADaM	Biospec	Cell Pheno	CV
54						Define-XML	General	Lab	Microbio/Immuno
54						MRCT	Oncology	PK	Protocol Entities
54						SEND	Unit		
55	6/16/2023	6/23/2023	7/21/2023	8/18/2023	9/29/2023	Biospec	Cell Pheno	Devices	ECG
55						General	Genomics	Lab	Microbio/Immuno
55						MRCT	Oncology	PK	Protocol Entities
55						Unit			
56	9/15/2023	9/22/2023	10/20/2023	11/17/2023	12/15/2023	Biospec	Cell Pheno	Define-XML	ECG
56						CDISC Glossary	Lab	General	Genomics
56						Microbio/Immuno	MRCT	Oncology	SDTM Domain
56						SEND	Unit		
57	12/8/2023	12/15/2023	1/12/2024	2/9/2024	3/29/2024				
57									
58	5/31/2024	6/7/2024	7/5/2024	8/2/2024	9/27/2024				
58									
59	12/13/2024	12/20/2024	1/17/2025	2/14/2025	3/28/2025				



9/19/2023

Dates in red are planned and may be adjusted slightly.



Controlled Terminology Package 55 Publication Release

- Updates to DDF, Protocol Entities, SDTM, and SEND Terminology
- Other Project Support:
 - COVID-19 v2.0 TAUG
 - Rare Diseases TAUG
 - DDF USDM (Phase 2)



Significant Changes Post-Public Review

- Cell Phenotyping:
 - CPTTEST/CD: Submission value 'OX40X' updated to 'CD134X' for consistency in naming.
- Laboratory:
 - MITSCD: Submission value 'Adequate Surgical Margin Indicator' updated to 'Adequate Surgical Margins Indicator' for consistency in naming.
- General:
 - PROCEDUR: Removed the double space from the CDISC submission value 'AUTOLOGOUS STEM CELL TRANSPLANT'



Significant Changes Post-Public Review

Other, less significant changes* also made in:

- Microbiology-Immunology

No post-public review changes made to:

- Biospecimens
- CP
- Device
- ECG
- Genomics
- Lab
- Oncology
- PK
- Protocol
- 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.**



P55 Terminology Products Updates

- Updates on CDISC.org:
 - Updated Codetable mappings:
 - DD, EG, IS, RE, RP, SC, and TS
 - Unit-UCUM_Codetable
 - Controlled_Terminology_Requests_Denied_P55
 - Paired Codelists product for SDTM and SEND
 - Terminology Publication Schedule
 - Terminology Development Rules documents:
 - QRS
 - IS
 - MB and MS
 - Lab, Unit, and MI



QRS Controlled Terminology Package 55 Publication Release

- 1 new CAT value
 - FACIT-SEARCHABLE ITEM LIBRARY PEDIATRIC
- 1 new paired TEST/TESTCD codelists
 - QS-FACIT-Searchable Item Library Pediatric (FSLPTN/FSLPTC)



Controlled Terminology Package 56 Public Review

2023-09-22 to 2023-10-23



Terminology Call for Public Review Package P56 - Comments Due by 23 Oct 2023

Created by Alana St. Clair last modified yesterday at 12:38 PM

CDISC invites you to submit comments during the Public Review for Controlled Terminology Package 56, which consists of the following 16 documents:

1. Controlled_Terminology_Requests_Denied_P56 PR Version
2. IS Terminology Mapping Codetable_P56 PR Version
3. Rules for IS
4. Biospecimens
5. Cell Phenotyping*
6. Define-XML
7. ECG
8. General*
9. CDISC Glossary*
10. Lab*
11. Microbiology-Immunology*
12. MRCT
13. Oncology
14. SDTM Domain
15. SEND*
16. 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.

Download the files below for review.

If you have no comments after review:

1. Click 'Like' at the bottom of the page. This will help us determine who has reviewed the documents.

To add comments from within JIRA:

<https://wiki.cdisc.org/display/CT/Terminology+Call+for+Public+Review+Package+P56+-+Comments+Due+by+23+Oct+2023>

Public Review Comment Submission – Process Update!

- Two pieces of information are **CRITICAL** to getting your review comment seen by the CT teams:
 - Component – identifies the name of the specific PR file relevant to the comment.
 - Package (56) – identifies the package number that is relevant to the comment.
- Failure to fill in this information may delay resolution of your comment.

this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any of its members

Create Issue

Select Template | Configure Fields

All fields marked with an asterisk (*) are required

Project* **Controlled Terminology (CT)**

Issue Type* **Improvement**

Summary*

Component/s

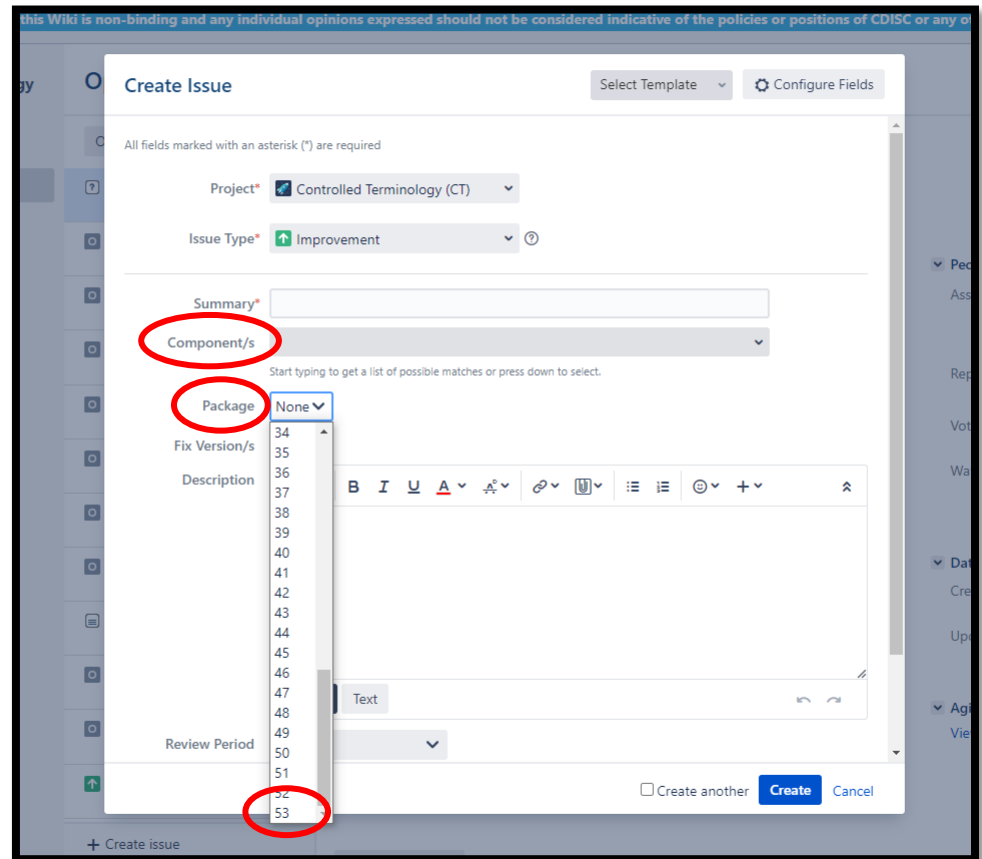
Package **None**

Fix Version/s

Description

Review Period

Create another **Create** Cancel





Controlled Terminology Package 56 Public Review

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



Controlled Terminology Package 56 Public Review

- Biospecimens Team
 - New Terms Added to Existing Codelists:
 - BEDECOD; BSTEST-CD
 - No changes to published terms
 - No denied requests



Controlled Terminology Package 56 Public Review

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

Controlled Terminology Package 56 Public Review

- Cell Phenotyping Team

- No new terms added to existing codelists
- No denied requests
- 10 changes to published terms; 3 are significant
 - CPTTEST-CD
 - C189412 – Update CPTTEST from ‘TLym Cytx Naive Sub/TLymC’ to ‘TLym Cytx Naive Sub/TLym Cytx’
 - C189407 – Update CPTTEST from ‘TLym Cytx Cen Mem Sub/TLymC’ to ‘TLym Cytx Cen Mem Sub/TLym Cytx’
 - C189409 – Update CPTTEST from ‘TLym Cytx Eff Mem Sub/TLymC’ to ‘TLym Cytx Eff Mem Sub/TLym Cytx’

**Changing denominator TLymC to TLym Cytx to make consistent with other cell count terms of this type.



Controlled Terminology Package 56 Public Review

- CV Team
 - No new term or changes to existing to report this quarter.
 - No denied requests.



Controlled Terminology Package 55 Public Review

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



Controlled Terminology Package 56 Public Review

- DDF Team
 - No new term or changes to existing to review this quarter.
 - No denied requests.



Controlled Terminology Package 56 Public Review

- Define-XML Team
 - No new terms this quarter
 - No denied requests.
 - 2 changes to existing; neither are significant (definition updates)



Controlled Terminology Package 56 Public Review

- ECG Terminology Team:
 - New Terms Added to Existing Codelists:
 - HESTRESC
 - Update to ECG Codetable Mapping File
 - No denied requests

Controlled Terminology Package 56 Public Review

- General Terminology Team:
 - New Terms Added to Existing Codelists:
 - DATEST-CD; DIR; FRM; LOC; NCOMPLT; NVTEST-CD; PROCEDUR; PROTMLST; RETEST-CD; ROUTE
 - 18 changes to published terms; 5 are significant
 - See next slide
 - Updates to Codetable Mapping Files:
 - DS_Codetable_Mapping
 - RE_Codetable_Mapping
 - SC_Codetable_Mapping
 - TS_Codetable_Mapping
 - Denied Requests added to Denied Requests spreadsheet

Controlled Terminology Package 56 Public Review

- General Terminology Team:
 - 5 significant changes to existing terms
 - SCTEST-CD:
 - C102713 Source Case Investigation/SRCCSINV is being retired from the codelist
 - This SCTEST was published in error during Ebola v1.0 TAUG development. As per the published Ebola TAUG v1.0, this value is modeled as a --CAT value instead of a SCTEST-CD value.
 - C102625 Contact Investigation/CNTCINV is being retired from the codelist
 - Replace C102625 with a CNEW term in P56; the purpose of this as modeled in the TB TAUG is as an indicator (Y/N) question. The Update NCI C-code, CDISC Submission Value, CDISC Synonyms, CDISC Definition, and NCI Preferred Term.
 - SEX:
 - C45908 submission value UNDIFFERENTIATED is being changed to INTERSEX. 'UNDIFFERENTIATED' is antiquated terminology.



Controlled Terminology Package 56 Public Review

- Genomics Terminology Team:
 - No new term or changes to existing to review this quarter.
 - No denied requests.



Controlled Terminology Package 56 Public Review

- CDISC Glossary Team
 - 9 new terms proposed to be added this quarter:
 - dose-escalation trial
 - screening (period)
 - blood draw
 - eligibility criteria
 - infusion
 - investigational device
 - compendial name
 - active substance
 - protocol title
 - 45 Changes to Existing terms
 - 18 new source additions
 - No denied requests.



Controlled Terminology Package 56 Public Review

- Laboratory Terminology Team
 - New Terms Added to Existing Codelists:
 - LBANMET; LBTEST-CD; METHOD; MITS-CD
 - 35 changes to published terms; 12 are significant
 - Denied Requests added to Denied Requests spreadsheet.

Controlled Terminology Package 56 Public Review

- Laboratory Terminology Team
 - Significant Changes to Existing Terms
 - MITS-CD
 - The team is proposing to remove the following MITS-CD values:
 - C103368/CD20 - Retire from codelist and replace with Membrane Spanning 4-Domains A1/LEU1 (new in P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL
 - C103370/CD56 - Retire from codelist and replace with Neural Cell Adhesion Molecule 1/NCAM1 (new with P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL
 - C103809/CD3 - Retire from codelist and replace with CD3 T-Cell Marker/CD3TCM (new with P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL
 - C103810/CD4 - Retire from codelist and replace with T-Cell Surface Antigen T4/Leu-3 / LEU3 (new with P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL
 - C103811/CD8 - Retire from codelist and replace with T-Cell Surface Glycoprotein CD8/CD8 (new with P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL
 - C156544/CD68 - Retire from codelist and replace with Scavenger Receptor Class D, Member 1/SCARD1 (new with P56). Use published MITSTDTL=POSITIVE CELL COUNT or MITSTDTL=PERCENT POSITIVE CELL



Controlled Terminology Package 56 Public Review

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

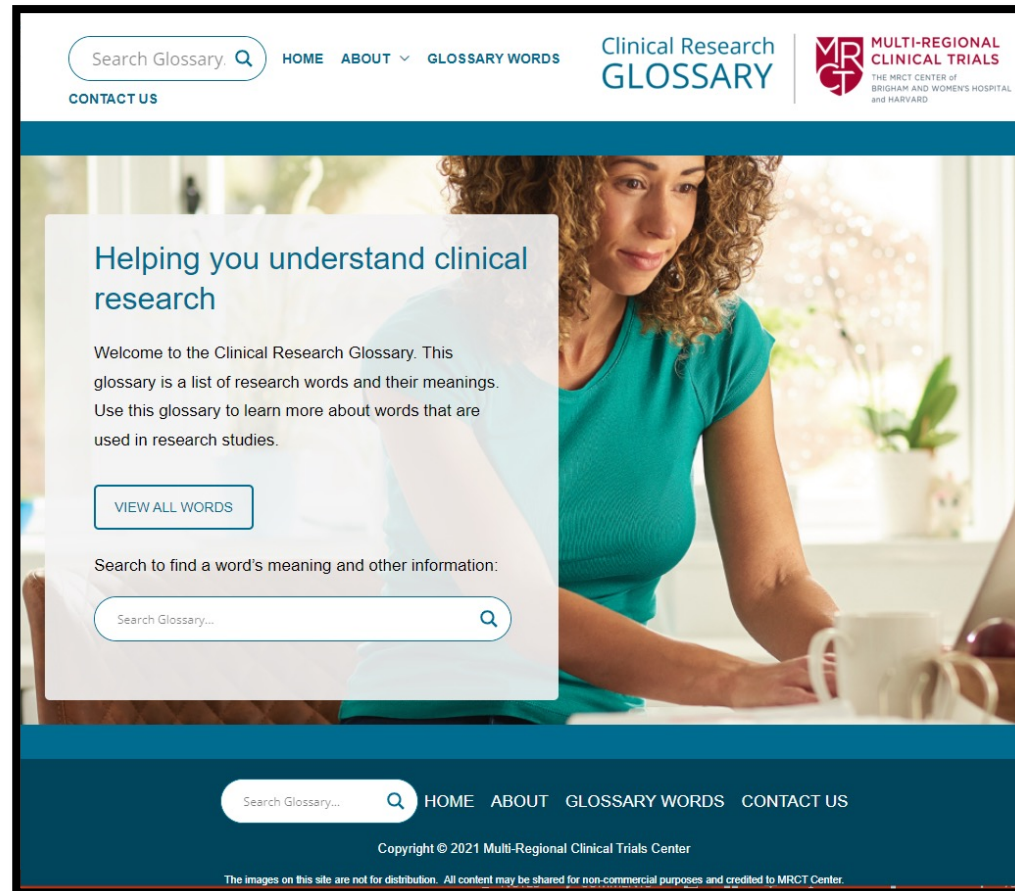


Controlled Terminology Package 56 Public Review

- Microbiology-Immunology Terminology Team
 - New Terms Added to Existing Codelists:
 - ISBDAGT; ISFTSDTL; ISTEEST-CD; MICROORG
 - 377 Changes to existing term; 374 are significant
 - Updates to Codetable Mapping Files:
 - IS Terminology Mapping Codetable
 - Updates to Terminology Team Development Rules Documents:
 - IS
 - Denied Requests added to Denied Requests spreadsheet.

Controlled Terminology Package 56 Public Review

- MRCT Plain Language Glossary
 - 8 new terms



Controlled Terminology Package 56 Public Review

- Oncology Terminology Team:
 - New Terms Added to Existing Codelists:
 - ONCRTS-CD; TUTEST-CD; TRTSET
 - New Codelist
 - DPETSCRS: Response values for TRTEST/CD = FDPL5PS/FDG PET Lymphoma 5PS Score
 - No Changes to existing terms
 - Codetable Mapping File Updates
 - TU_Codetable Mapping
 - TR_Codetable Mapping
 - RS_Onc_Codetable Mapping
 - RS_IWC_HALLEK_CLL_2018
 - Denied Requests added to Denied Requests spreadsheet.



Controlled Terminology Package 56 Public Review

- PK Terminology Team
 - No new terms or changes to existing.
 - Denied Requests added to Denied Requests spreadsheet.



Controlled Terminology Package 56 Public Review

- Protocol Entities Terminology Team
 - No new term or changes to existing to review this quarter.
 - No denied requests.



Controlled Terminology Package 56 Public Review

- QRS Terminology Team
 - No files for public review
 - Denied Requests added to Denied Requests spreadsheet.



Controlled Terminology Package 56 Public Review

- SDTM Domain Terminology Team
 - New Terms Added to Existing Codelists:
 - DOMAIN
 - 1 Change to existing; not significant (definition update)
 - No Denied Requests.

Controlled Terminology Package 56 Public Review

- SEND Terminology Team
 - New Terms Added to Existing Codelists:
 - GVTEST-CD; NONNEO; SBCSND-CD; SPEC
 - 5 Changes to existing terms; 4 are significant
 - NULLFLAV -> The following terms are being proposed to be retired from the Null Flavor codelist due to lack of use in Non-Clinical setting.
 - C42885/DERIVED
 - C150902/UNENCODED
 - C17649/OTHER
 - C50913/INVALID
 - Denied Requests added to Denied Requests spreadsheet.



Scope Change for LB/MB/IS and Impact on Controlled Terminology in P56





The IS Domain Scope Update for the SDTMIG v3.4

- The current IS domain in the SDTMIG v3.4 is designed to collect data pertaining to *specimen-based* assessments that measure the “presence, magnitude and scale of the immune response upon any **antigen** stimulation or encounter”.
- This 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.”
- Per the SDTMIG 3.4, the *antigen of interest* in the above definition may be (but is not limited to), drug/test article (i.e., study/non-study therapy), allergen, microorganism (e.g. bacteria, viruses, fungi, parasites, etc.), self-antigen (autoantigen), and others, that may stimulate a host immune response.
- The current IS domain definition is also more inline with the scientific/medical definition of “immunogenicity assessment” and is well-accepted by the scientific community.
- Both humoral (antibody-mediated) immune response testing + cell-mediated immune response testing are in scope.



1: Domain and variable level structure limitation for LB/MB/IS

Prior to the SDTMIG v3.4, most specimen-based, immune response testing data had been mapped to the MB and LB domains which were not built to collect and model complicated experimental designs and biological processes, which yield complicated data. These domains do NOT have the sufficient structure and standard variables to support the meaningful and consistent representation of such data.

As a result, various supplemental qualifiers had been created and 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-TESTCD variables, and therefore overloading the –TEST and TESTCD variables.



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

The prior IS domain scope defined by the SDTMIG v3.2/v3.3 limited its use to ONLY collection of “study therapy”-induced immune response testing data, this led to “baseline” immune response testing data *prior to study treatment exposure* having to be mapped to a different domain. Compounding on this problem, the same pre-study treatment exposure data would have to be mapped to different domains depending on the version of the SDTMIG used and the study types.



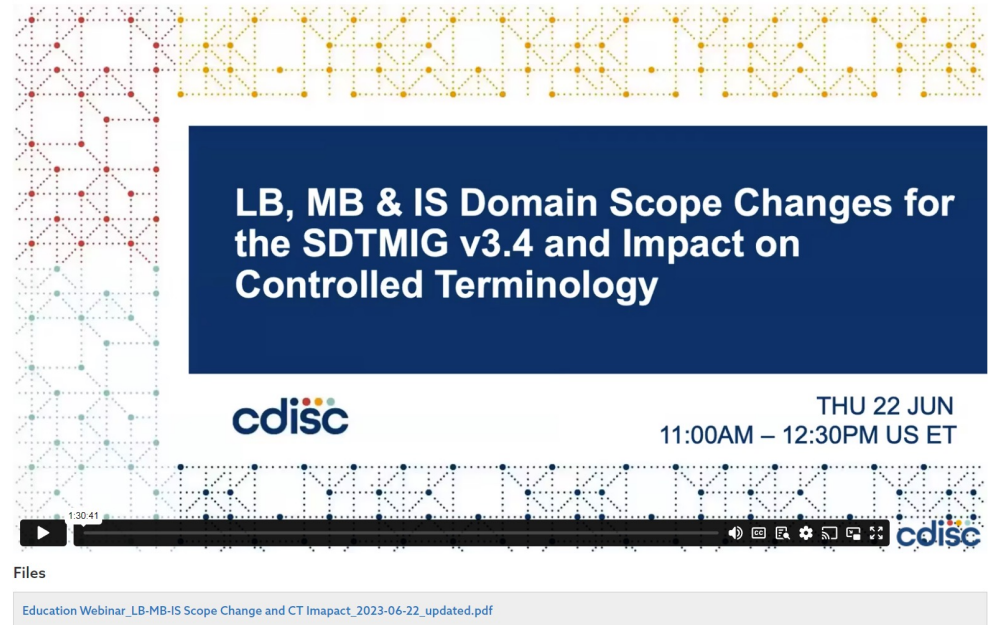
Rationales and the Problems that Led to the IS Domain Update for the SDTMIG v3.4

1. LB/MB/IS in the IGv3.2 and v3.3: significant overlap of domain scope and data mapping between the three domains. Scope definition and demarcation between the three domains were unclear. As a result, multiple different SDTM Findings domains were used to represent specimen-based immune response testing data.
2. Domain and variable level structure limitation for LB/MB/IS.
3. General disagreement and confusion over the prior narrow definition of the IS domain – what's considered as therapy?
4. Multiple SDTM Classes are utilized to model systemic vs. localized immune responses.

For more information and an in-depth analysis on the changes made to LB, MB and IS, refer to this **Knowledge Base Article** on www.cdisc.org:
<https://www.cdisc.org/kb/articles/domain-scope-update-sdtmig-v3-4-development-history-and-difficulties-standardizing>

More Information on IS Domain Representation of Immunogenicity Data in the SDTMIG v3.4

- **Public Webinar:** LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology
- <https://www.cdisc.org/events/webinar/lb-mb-domain-scope-changes-sdtmig-v3-4-and-impact-controlled-terminology>
- Introduction on new IS domain standard variables, MB and IS domain scope changes, new examples, updates to examples in the published TAUGs, and impact on CT, etc.



The image shows a screenshot of a webinar slide and its player interface. The slide has a blue background with a white text box containing the title: "LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology". Below the title is the CDISC logo. To the right of the logo, the date and time are listed: "THU 22 JUN 11:00AM – 12:30PM US ET". The player interface at the bottom shows a progress bar at 1:30:41, a play button, and various control icons. Below the player, a file name is displayed: "Education Webinar_LB-MB-IS Scope Change and CT Impact_2023-06-22_updated.pdf".



Impact on LB/MB/IS Controlled Terminology

The change in the IS domain scope will result in the deprecation of approximately 800+ 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).

This announcement was made since December 2022, and the relevant information has been included in every public review package until P55 (September 2023).

In Package 56 (December 2023), we will:

- Deprecate 374 existing MBTEST-CD terms.
- Deprecate 492 additional existing LBTEST-CD terms.
- There changes to existing terms are now out for public review/comment.



Hedging the Impact of the Changes – CDISC Education and Tools

Tools *already published* on www.cdisc.org to prepare for the transition:

1. A Knowledge Base Article that provides in-depth analysis and explanation on the difficulties and problems that led to the LB/MB/IS domain scope updates and the changes made to these domains in the SDTMIG v3.4.
2. A Codetable Mapping file that shows how **every** deprecated code from the LB/MB domains will be re-modeled and mapped to the IS domain new standard variables.
3. Standards Development and CT Rules documents are published for IS and MB.
 - Contain FAQs for most common and difficult user inquiries on where data should be mapped are published.
4. Webinars for public education:
 - Quarterly CT webinars.
 - Introduction and Office Hours education webinars (June 22, 2023 and Q2-3, 2024).
 - CDISC Interchange presentation.

***Most importantly, these changes had been communicated to the FDA for review and feedback.**

IS Terminology Codetable Mapping File

The deprecated LB and MB terms will be remapped to IS. The mapping can be found in the **IS Terminology Codetable Mapping File**, 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.
- Traceability!!**

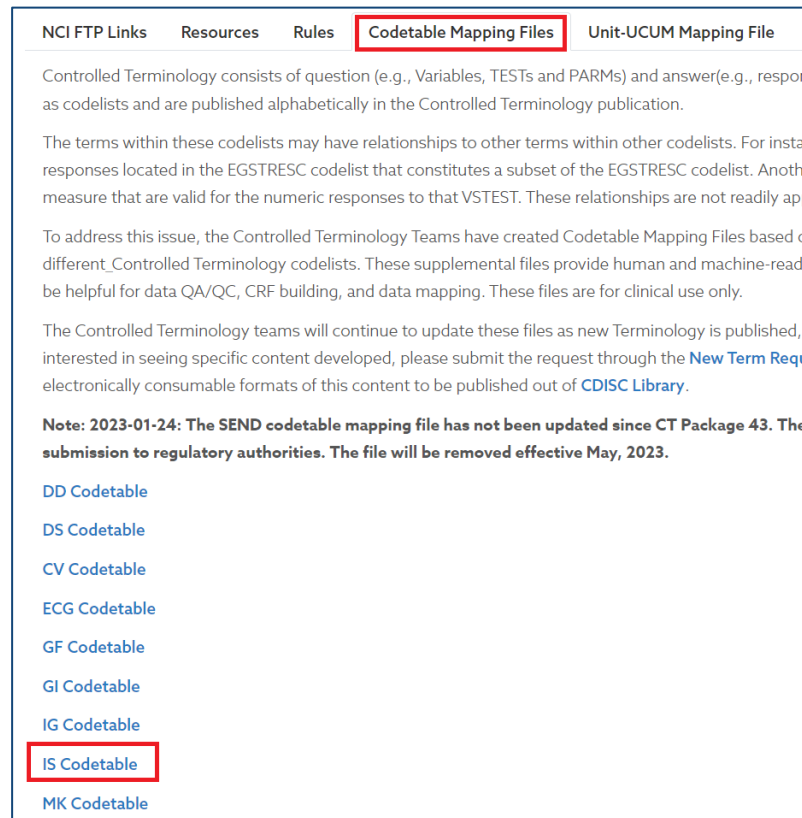
A	B	C	D	E	F	G	H	I	J	K
C-Code	MB TEST Terms for Deprecation Microbiology Test Name (codelist code = C120528)	C-Code (Concept Code)	When Variable = ISTEEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C-Code (Concept Code)	When Variable = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C-Code (Concept Code)	When Variable = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGI) (codelist code = C181169)	C-Code (Concept Code)	When Variable = ISTSTDTL Immunogenicity Specimen Test Details (ISTSTDTL) (codelist code = C189267)	Additional Notes
C130097	Mucor racemosus IgA Antibody	C187776	Allergen-induced IgA Antibody	C187915	MUCOR RACEMOSUS					
C166022	Mucor racemosus IgE AB RAST Score	C181398	Allergen-induced IgE Antibody	C187915	MUCOR RACEMOSUS			C189493	RAST Score	
C130098	Mucor racemosus IgE Antibody	C181398	Allergen-induced IgE Antibody	C187915	MUCOR RACEMOSUS					
C166018	Mucor racemosus IgG AB RAST Score	C187777	Allergen-induced IgG Antibody	C187915	MUCOR RACEMOSUS			C189493	RAST Score	
C130098	Mucor racemosus IgG Antibody	C187777	Allergen-induced IgG Antibody	C187915	MUCOR RACEMOSUS					
C130099	Mucor racemosus IgG4 Antibody	C187778	Allergen-induced IgG4 Antibody	C187915	MUCOR RACEMOSUS					
C139086	HCV Antibody Signal/HCV Antibody Cutoff	C187780	Microbial-induced Antibody	C14312	HEPATITIS C VIRUS			C198277	SIGNAL/CUTOFF RATIO	The modeling for this type of test has changed. SIGNAL/CUTOFF is mapped to ISTSTDTL. The CDISC MBIS team will no longer create antibody target-specific, pre-coordinated signal/cutoff tests.

LB to IS Mapping; MB to IS Mapping
show existing LBTESTs and MBTESTs to IS domain variables mapping.

IS Terminology Codetable Mapping File

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.



NCI FTP Links Resources Rules **Codetable Mapping Files** Unit-UCUM Mapping File

Controlled Terminology consists of question (e.g., Variables, TESTs and PARMs) and answer(e.g., responses) 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, responses located in the EGSTRESC codelist that constitutes a subset of the EGSTRESC codelist. Another measure that are valid for the numeric responses to that VSTEST. These relationships are not readily apparent.

To address this issue, the Controlled Terminology Teams have created Codetable Mapping Files based on different Controlled Terminology codelists. These supplemental files provide human and machine-readable information that are 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, and if you are interested in seeing specific content developed, please submit the request through the [New Term Request](#) in electronically consumable formats of this content to be published out of [CDISC Library](#).

Note: 2023-01-24: The SEND codetable mapping file has not been updated since CT Package 43. The file will be removed effective May, 2023.

- DD Codetable
- DS Codetable
- CV Codetable
- ECG Codetable
- GF Codetable
- GI Codetable
- IG Codetable
- IS Codetable**
- MK Codetable



Rules for Immunogenicity Testing File

CDISC CONTROLLED TERMINOLOGY RULES: Immunogenicity Specimen (IS) Test Code/Name, Binding Agent for Immunogenicity Assessments, and Microorganism Codelists

16 December 2022

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

- If the MB/IS team gets the same or similar questions more than 3 (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:

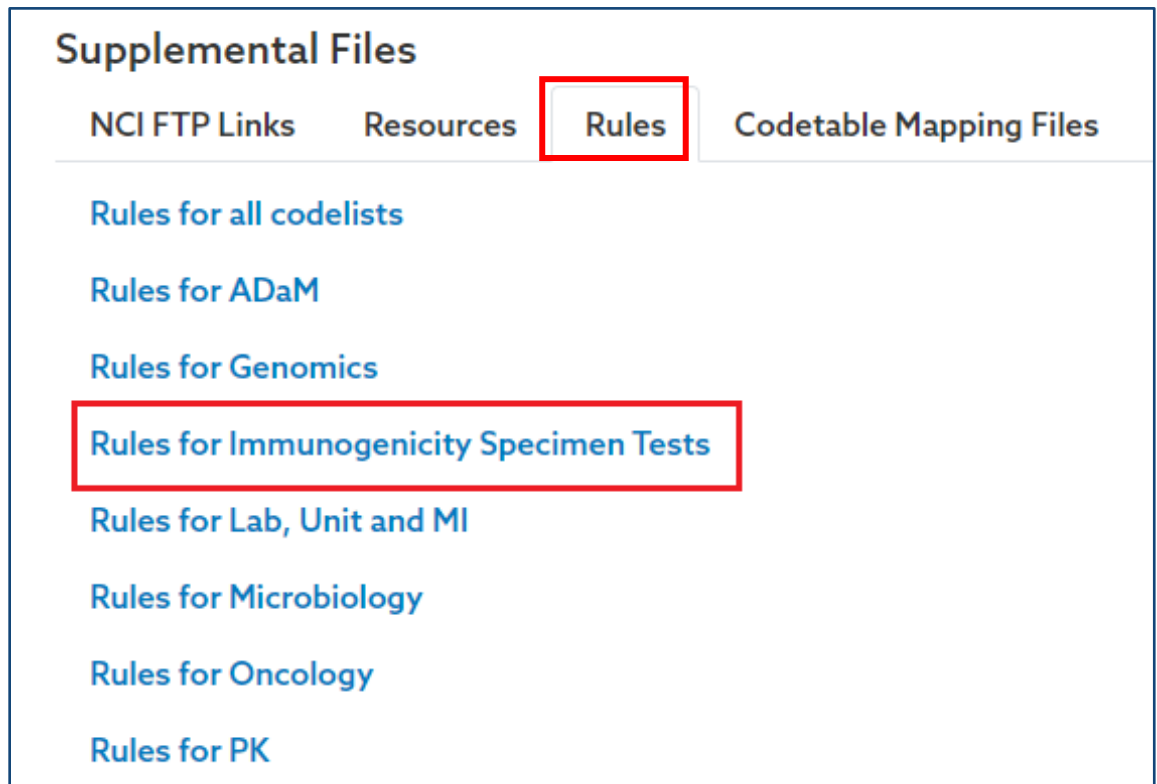
- A cytokine (or other similar) test is mapped to the LB domain, if it is a part of a “routine urine or blood, standard of care and safety related testing” – this means one is typically *only* interested in the cytokine’s presence/absence, quantity, and whether

Rules for Immunogenicity Testing File

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 a web interface for 'Supplemental Files'. At the top, there are four tabs: 'NCI FTP Links', 'Resources', 'Rules', and 'Codetable Mapping Files'. The 'Rules' tab is selected and highlighted with a red border. Below the tabs, a list of rule categories is displayed: 'Rules for all codelists', 'Rules for ADaM', 'Rules for Genomics', 'Rules for Immunogenicity Specimen Tests', 'Rules for Lab, Unit and MI', 'Rules for Microbiology', 'Rules for Oncology', and 'Rules for PK'. The 'Rules for Immunogenicity Specimen Tests' item is highlighted with a red border.

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, cell-mediated 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.

The MB/IS team still encourage users to submit their pre-coordinated **new antibody, or cell-mediated immune testing** 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/cell-mediated tests** can also be tracked and will also be published in the IS Terminology Codetable Mapping File quarterly and will be available to all users.



Announcement: CDISC Terminology Publication Cadence

Currently -> CDISC publishes updates to CDISC terminology on a quarterly schedule: March, June, September, December

To be Implemented -> CDISC leadership is changing the publication cadence for CDISC Controlled Terminology to biannual releases (twice per year): March and September

- CDISC is also considering mechanisms by which draft terminology can be made available to the user community.

***CDISC is currently interested in receiving feedback on this proposal!**

Feedback can be sent to Erin Muhlbradt
(muhlbradtee@mail.nih.gov)



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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Email: membership@cdisc.org





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

Erin Muhlbradt, muhlbradtee@mail.nih.gov

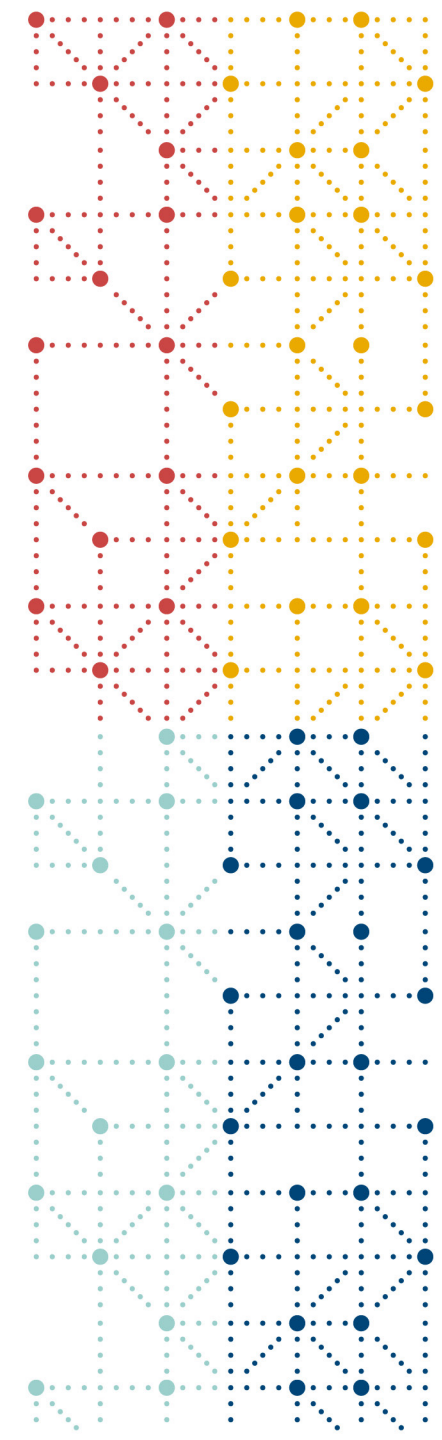
OR

<https://www.cdisc.org/volunteer>

[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
CDISC!