LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology

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Agenda

1. Reasons Behind the Scope Update for the IS Domain for the SDTMIG v3.4
2. What's in Scope for the IS domain? Examples in the SDTMIG v3.4
3. Scope Change for the MB Domain
4. Impact on Controlled Terminology
5. Future Directions
6. Questions.

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

LB/MB/IS Domain Scope Changes Across SDTMIG v3.2 through SDTMIG v3.4

IGv3.2

- **IS** domain scoped for study therapy-induced subject immune response.
- **LB** domain scoped to include non-host microorg tests and other subject immune response assessments.
- **MB** domain scoped to include some non-host microorg tests used for microbial identification purposes only.

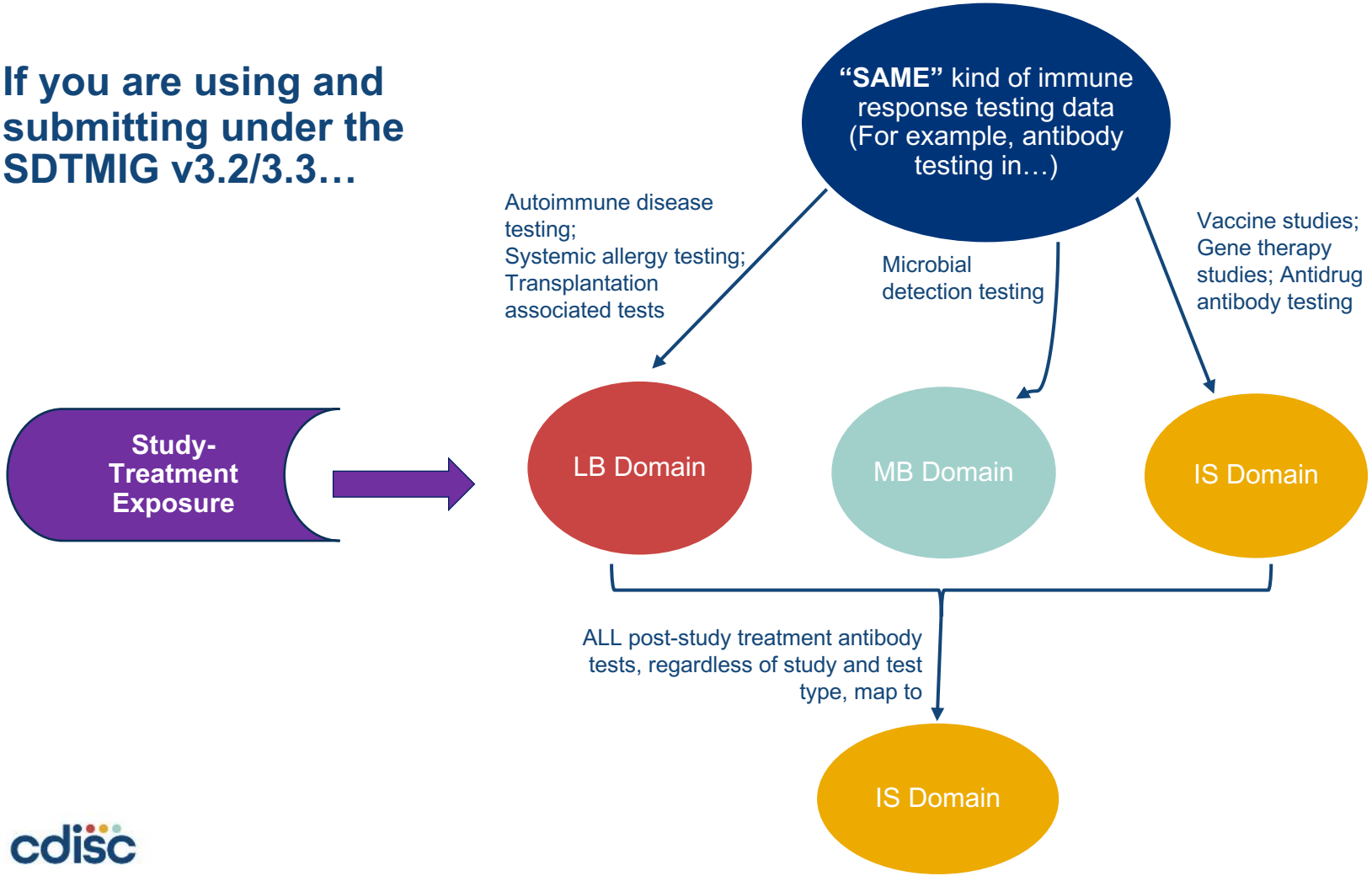
IGv3.3

- **IS** domain scoped for study therapy-induced subject immune response.
- **LB** domain scoped to include other subject immune response assessments, it no longer contains non-host microorg tests.
- **MB** domain scope broadened to include all detection, identification, quantification, and other characteristics assessments of non-host microorg, via direct detection methods and indirect, induced-host/subject immune response.

IGv3.4

- **IS** domain scoped for any antigen-induced subject immune response, not restricted to study therapy.
- **LB** domain no longer contains subject immune response assessments, or any non-host microog tests.
- **MB** domain contains “direct” detection, identification, quantification, and other characteristics assessments of non-host microorg at the time of specimen testing. It no longer contains microorg induced-subject/host immune assessments.

If you are using and submitting under the SDTMIG v3.2/3.3…



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 pervious 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.

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.
2. Domain and variable level structure limitation for LB/MB/IS.
3. Multiple different SDTM Findings domains were used to represent specimen-based immune response testing data.
4. General disagreement and confusion over the prior narrow definition of the IS domain – what's considered as therapy?
5. Multiple SDTM Classes are utilized to model systemic vs. localized immune responses.

For more information, 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

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, and 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.

Ex 1: Specimen-based Allergy Immune Response Testing Data are Mapped to LB and IS, Per SDTMIG v3.2/v3.3

Prior to (Study) Therapy Exposure

Post (Study) Therapy Exposure
*IS domain only reserved for (study) therapy induced immune responses

…	Domain	SEQ	GRPID	--TESTCD	--TEST	--ORRES	--ORRESU	VISIT
	LB (SDTMIG 3.2/3.3)	1	1	C130128	Dog Dander Antigen IgE Antibody	120	kU/L	SCREENING
	LB (SDTMIG 3.2/3.3)	2	1	C165932	Dog Dander IgE AB RAST Score	6		SCREENING
	IS (SDTMIG 3.2/3.3)	3	2	C130128	Dog Dander Antigen IgE Antibody	95	kU/L	VISIT 2
	IS (SDTMIG 3.2/3.3)	4	2	C165932	Dog Dander IgE AB RAST Score	5		VISIT 2
	IS (SDTMIG 3.2/3.3)	5	3	C165932	Dog Dander Antigen IgE Antibody	35	kU/L	VISIT 4
	IS (SDTMIG 3.2/3.3)	6	3	C165932	Dog Dander IgE AB RAST Score	3		VISIT 4

Note the use of the NCI C-code in place of LBTESTCD, and heavily abbreviated LBTEST due to Conformance Rules dictating <8, <40 characters for --TESTCD and --TEST. Also, It is nearly impossible to create and maintain unique and meaningful LBTESTCDs for the large amount and vastly different anti-allergen antibody tests available. The use of NCI c-codes for TESTCD and truncated TEST values renders --TESTCD and --TEST less valuable SDTM mapping assets.

Resolution to Ex 1: Specimen-based Allergy Immune Response Testing Data in IS, Per SDTMIG v3.4

Prior to (Study) Therapy Exposure

Post (Study) Therapy Exposure

* IS domain now is used for all antigen induced immune responses

…	Domain	ISSEQ	ISGRPID	ISTESTCD	ISTEST	ISBDAGNT	ISTSTDTL	ISORRES	ISORRESU	VISIT
	IS	1	1	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN		120	kU/L	SCREENING
	IS	2	1	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN	RAST SCORE	6		SCREENING
	IS	3	2	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN		95	kU/L	VISIT 2
	IS	4	2	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN	RAST SCORE	5		VISIT 2
	IS	5	3	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN		35	kU/L	VISIT 4
	IS	6	3	ARIGEAB	Allergen-induced IgE Antibody	DOG DANDER ANTIGEN	RAST SCORE	3		VISIT 4

1. ALL “antigen”-stimulated immune response tests are in the same domain, no distinction made for prior vs after study therapy exposure.
2. New TEST qualifier variables are introduced in the SDTMIG v3.4 to alleviate TEST/TESTCD overloading issues.
   - LBTESTCD remains human-readable.
   - --TEST, --BDAGNT (binding agent) and --TSTDTL (test detail) clearly and separately represent the “analyte being assessed”, the “binding target of the analyte”, and further testing details of the assessment – note all this INFO was pre-coordinated into the TEST in IGv3.2/v3.3, leading to heavy abbreviation/truncation of the test due to character limit.

Ex 2: Antimicrobial Host Humoral Immune Response Testing Data are mapped to LB, MB and IS, Per SDTMIG v3.2/v3.3

	Domain	SEQ	--TESTCD	--TEST	--ORRES	--ORRESU	VISIT	Supplemental Qualifier Variable
Prior to (Study) Vaccine Exposure	MB (v3.3) or LB (v3.2)	1	NRSVIGG or C-code	MB: Neut. Respirat. Syncytial Virus IgG or LB: Neut. Respirat. Syncytial Virus IgG NT50*	10	titer	Baseline	suppMB: 50% NEUTRALIZATION TITER
Post (Study) Vaccine Exposure	IS (v3.2/3.3)	2	NRSVIGG	IS: Neut. Respirat. Syncytial Virus IgG	60	titer	Visit 1	suppIS: 50% NEUTRALIZATION TITER
	IS (v3.2/3.3)	3	NRSVIGG	IS: Neut. Respirat. Syncytial Virus IgG	90	titer	Visit 2	suppIS: 50% NEUTRALIZATION TITER

*TEST = Neutralizing Respiratory Syncytial Virus IgG Antibody 50% Neutralization Titer

1. Baseline data are triaged into LB if submitting under IGv3.2 and MB if submitting under IGv3.3.
2. MB is used to model non-host microorganism detection, identification and quantification type of data. In this case, the RSV antibody levels at baseline are collected to compare with the RSV vaccine-induced protective antibody levels after study vaccine administration – the baseline measurement is not meant for microbial identification/detection purpose, using MB is a stretch on its domain scope.
3. Baseline data indicates presence of antimicrobial subject antibody response which may be the result of a *previous, non-study* vaccination and/or infection, which is undistinguishable from a scientific perspective - this makes deciding IS vs MB even more difficult, and the use of either domain is incorrect.
4. Again, heavy abbreviation to the TEST due to <40 character limit – rendering the TEST variable a less meaningful SDTM mapping asset.
5. Inconsistent modeling and use of supplemental qualifiers between LB, MB and IS for the exact SAME test. (Row 1 red text is how this test would appear in LB, all values are pre-coordinated into the TEST variable, no suppLB qualifiers used).

Resolution to Ex 2: Antimicrobial Host Humoral Immune Response Testing Data are mapped to IS ONLY, Per SDTMIG v3.4

Prior to (Study) Vaccine Exposure

Post (Study) Vaccine Exposure

…	Domain	ISSEQ	ISTESTCD	ISTEST	ISBDAGNT	ISTSTDTL	ISORRES	ISORRESU	VISIT
	IS (v3.4)	1	MBIGGNAB	Neutralizing Microbial-induced IgG Antibody	Respiratory Syncytial Virus	50% NEUTRALIZATION TITER	10	titer	Baseline
	IS (v3.4)	2	MBIGGNAB	Neutralizing Microbial-induced IgG Antibody	Respiratory Syncytial Virus	50% NEUTRALIZATION TITER	60	titer	Visit 1
	IS (v3.4)	3	MBIGGNAB	Neutralizing Microbial-induced IgG Antibody	Respiratory Syncytial Virus	50% NEUTRALIZATION TITER	90	titer	Visit 2

*ISTSTDTL could also be: NT80, NT90, PRNT50-90, FRNT50-90, IC50-90, etc. (see CT codelist).

1. All antigen-stimulated immune response tests are in the same (IS) domain
   - no distinction made for prior vs after study treatment exposure.
   - no need to decide whether the baseline measurement should be mapped to IS vs MB.
2. Consistent data modeling using the same set of IS standard variables with clear variable scope definitions
3. Controlled terminology codelists supporting ISTEST-CD, ISBDAGNT and ISTSTDTL. This helps to set boundaries on variable scope and shows what values should go into these standard variables.

What's in Scope for the IS domain? Examples in the SDTMIG v3.4

IS domain is used for assessments of “antigen”- induced *humoral (antibody-mediated)* and *cell-mediated* immune response in the subject

- 5 examples on anti-drug antibody (ADA) testing:
  - Examples and controlled terminology developed for the different types of ADAs.
  - Mapping of the “3-tiered testing strategies” for ADAs: Screen, Confirm and/or Quantify steps modeled using the new ISTSTOPO (controlled) variable.
  - Recommendations for Anti-Drug Antibody (ADA) Modeling in SENDIG v3.0 and v3.1: https://phuse.s3.eu-central-1.amazonaws.com/Deliverables/Nonclinical+Topics/Recommendations+for+Anti-Drug+Antibody+Modeling+in+SENDIG+v3.0+and+v3.1.pdf (ADA modeling approaches aligned between clinical and non-clinical standards.)
- 4 examples on study and nonstudy vaccine-related immunogenicity testing:
  - 2 examples on cell-mediated immune response testing using T/B Cell-ELISPOT.
  - 2 examples measuring protective neutralizing and functional antibodies using virus-based neutralization assay and opsonophagocytic killing assay.
- 1 example on systemic, humoral allergy testing.
- 1 example on autoimmune disease humoral response testing.
- New variables introduced to the IS domain: ISBDAGNT (controlled), ISMSCBCE, ISTSTCND (controlled), ISCNDAGT.
- Established variable added: ISTSTDTL (controlled).

Scope Change for the MB Domain in the SDTMIG v3.4

Changes to the MB Domain Scope for the SDTMIG v3.4

- MB is used to model non-host microorganism detection, identification and quantification type of data.
- The MB domain is (typically and mostly) used for the *direct* assessments of the non-host microorganism of interest that indicates a presence (or absence) of the microorganism in the subject's sample.
  - Assays *typically directly* identify, target, detect and/or quantify microbial antigens (i,e. proteins, toxins), genetic material (i.e. DNA, RNA), and metabolic byproducts, etc. Results of such tests are typically reported in presence/absence and concentration.
  - "Complex" genetic findings from assessments of microorganisms in subject samples are in scope for the GF domain (i.e. microbial single nucleotide variation [GF] leading to drug resistance profile [MS])
- The presence of the anti-microbial antibody is the *host's* immune response toward a pathogen, and is a *surrogate* measure for prior or current infection. If a particular anti-microbial antibody is present, it doesn't necessarily signal a current and ongoing infection, nor the presence of the microorganism in the subject's sample, *at the time of specimen testing.*
- Antimicrobial antibody tests were part of the MB domain because they may also be used for microbial identification purposes, but they are passive host immune responses, and do not directly indicate the presence of a Microorg in the subject's specimen. Therefore, they are out of scope for the MB domain definition, and will be removed from MB in the SDTMIG 3.4.

Impact on Controlled Terminology

- Timeline
- Tools & Resources

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

The change in the LB, MB, and IS domain scope will result in the deprecation of approximately 400 antibody and antibody-related 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 not limited to: ISTEST-CD, ISBDAGNT (Binding Agent), and ISTSTDTL (Test Detail).
  - A codetable mapping file is published to help users to establish relationships between every deprecated concept and its mapping to the new post-coordinated elements using the new IS standard variables. This file is updated quarterly.
- CDISC controlled terminology teams will no longer publish humoral immune response antibody tests, as well as other antigen-stimulated cellular immune response tests, in LB and MB. These tests will only be modeled and published in IS.
- Various informational/educational tools have been published on www.cdisc.org to help to guide users through these transitions.
- Actual terminology changes (deprecation) will happen in Dec 2023, P56 CT publication.

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.

Tools and Resources: 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!!**

C-Code	LBTEST Terms for Deprecation Laboratory Test Name (codelist code = C67154)	C-Code (Concept Code)	When Varaible = ISTEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C-Code (Concept Code)	When Varaible = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C-Code (Concept Code)	When Varaible = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169)	C-Code (Concept Code)	When Varaible = ISTSTDTL Immunogenicity Specimen Test Details (ISFTSDTL) (codelist code = C189267)
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
C147276	Arachis hypogaea Antigen IgE Antibody	C181398	Allergen-induced IgE Antibody			C189453	PEANUT ANTIGEN		
C165934	Arachis hypogaea IgE AB RAST Score	C181398	Allergen-induced IgE Antibody			C189453	PEANUT ANTIGEN	C189493	RAST Score
C130116	Bee Mix Antigen IgE Antibody	C181398	Allergen-induced IgE Antibody			C189454	BEE MIX VENOM ANTIGENS		

ReadMe - Overview | ReadMe - Timeline | ReadMe - How to Read this DOC | LB to IS Mapping_2023-03-31 | MB to ...

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

Mapped 400+ Existing LBTEST/CD and MBTEST/CD Humoral Immune Response Antibody Tests to ISTEST/CD, ISBDAGNT and ISTSTDTL

The MB/IS team released mapped relationships of the following tests:

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

C-Code	MBTEST Terms for Deprecation Microbiology Test Name (codelist code = C120528)	C-Code (Concept Code)	When Varaible = ISTEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C-Code (Concept Code)	When Varaible = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C-Code (Concept Code)	When Varaible = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169	C-Code (Concept Code)	When Varaible = ISTSTDTL Immunogenicity Specimen Test Details (ISFTSDTL) (codelist code = C189267)
C100463	DNase-B Antibody	C187780	Microbial-induced Antibody			C187763	DEOXYRIBONUCLEASE-B		
C135410	Ebola Virus IgM Antibody	C187786	Microbial-induced IgM Antibody	C112271	EBOLA VIRUS				
C96600	Epstein-Barr Capsid IgG Antibody	C181394	Microbial-induced IgG Antibody			C187761	EPSTEIN-BARR VIRUS CAPSID ANTIGEN		
C96601	Epstein-Barr Capsid IgM Antibody	C187786	Microbial-induced IgM Antibody			C187761	EPSTEIN-BARR VIRUS CAPSID ANTIGEN		
C96603	Epstein-Barr Nuclear Antibody	C187780	Microbial-induced Antibody			C187760	EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN		
C103403	Helicobacter pylori IgG Antibody	C181394	Microbial-induced IgG Antibody	C14289	HELICOBACTER PYLORI				
C92534	Hepatitis A Virus Antibody	C187780	Microbial-induced Antibody	C14325	HEPATITIS A VIRUS				
C92271	Hepatitis A Virus IgM Antibody	C187786	Microbial-induced IgM Antibody	C14325	HEPATITIS A VIRUS				
C125944	Hepatitis B Virus Antibody	C187780	Microbial-induced Antibody	C14215	HEPATITIS B VIRUS				

ReadMe - How to Read this DOC | LB to IS Mapping_2023-03-31 | MB to IS Mapping_2023-03-31 | ReadMe - New Te ...

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

New Antibody and Other Immune Response Tests Mapping

- The codetable mapping file is also used to map *new* antibody terms and other immune response testing requests to their respective IS domain variables.
- 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.

New Term Request Code	New Term Request	Requester	C-Code (Concept Code)	When Varaible = ISTEST Immunogenicity Specimen Assessments Test Name (ISTEST) (codelist code = C120526)	C-Code (Concept Code)	When Varaible = ISBDAGNT Microorganism (MICROORG) (codelist code = C85491)	C-Code (Concept Code)	When Varaible = ISBDAGNT Binding Agent for Immunogenicity Tests (ISBDAGT) (codelist code = C181169)	C-Code (Concept Code)	When Varaible = ISTSTDTL Immunogenicity Specimen Test Details (ISFTSDTL) (codelist code = C189267)
CDISC-4999	Hazel nut Antigen IgG4 Antibody (f17)	Jenny Jones	C187778	Allergen-induced IgG4 Antibody			C189480	CORYLUS AVELLANA NUT ANTIGEN		
CDISC-4999	Cashew nut Antigen IgG4 Antibody (f202)	Jenny Jones	C187778	Allergen-induced IgG4 Antibody			C189478	CASHEW NUT ANTIGEN		
CDISC-4999	Walnut Antigen IgG4 Antibody (f256)	Jenny Jones	C187778	Allergen-induced IgG4 Antibody			C189491	WALNUT ANTIGEN		
CDISC-3376	Hepatitis C Virus Antibody Signal/Cutoff	Phil Pochon	C187780	Microbial-induced Antibody	C14312	HEPATITIS C VIRUS			C198277	SIGNAL/CUTOFF RATIO
CDISC-5067	Respiratory Syncytial Virus IgM Antibody	Diane Ball	C187786	Microbial-induced IgM Antibody	C14267	HUMAN RESPIRATORY SYNCYTIAL VIRUS				
CDISC-5067	HIV-1 Antibody Signal/Cutoff	Diane Ball	C187780	Microbial-induced Antibody	C14220	HUMAN IMMUNODEFICIENCY VIRUS 1			C198277	SIGNAL/CUTOFF RATIO
CDISC-5067	Bartonella IgG Antibody	Diane Ball	C181394	Microbial-induced IgG Antibody	C86184	BARTONELLA				
CDISC-5067	Coxiella burnetii IgG Antibody	Diane Ball	C181394	Microbial-induced IgG Antibody	C86328	COXIELLA BURNETII				
CDISC-5067	Brucella Antibody	Diane Ball	C187780	Microbial-induced Antibody	C86215	BRUCELLA				
CDISC-5067	Toxocara Antibody	Diane Ball	C187780	Microbial-induced Antibody	C125927	TOXOCARA				
CDISC-5067	Neisseria gonorrhoeae Antibody	Diane Ball	C187780	Microbial-induced Antibody	C86603	NEISSERIA GONORRHOEAE				
CDISC-5360	EBV Antibody Signal/EBV Antibody Cutoff	Diane Ball	C187780	Microbial-induced Antibody	C14204	EPSTEIN-BARR VIRUS			C198277	SIGNAL/CUTOFF RATIO
CDISC-4937	Vaccinia Virus Neutralizing Antibody	Jenny Jones	C181396	Neutralizing Microbial-induced Antibody	C14281	VACCINIA VIRUS				
CDISC-5038	HEV IgM Ab Signal/HEV IgM Ab Cutoff	Diane Ball	C187786	Microbial-induced IgM Antibody	C14295	HEPATITIS E VIRUS			C198277	SIGNAL/CUTOFF RATIO
CDISC-5038	SARS-CoV-2 IgG Antibody Signal/Cutoff	Diane Ball	C181394	Microbial-induced IgG Antibody	C169076	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2			C198277	SIGNAL/CUTOFF RATIO

... | LB to IS Mapping_2023-03-31 | MB to IS Mapping_2023-03-31 | ReadMe - New Term Request | New AB Terms Mapping_2023-06-30

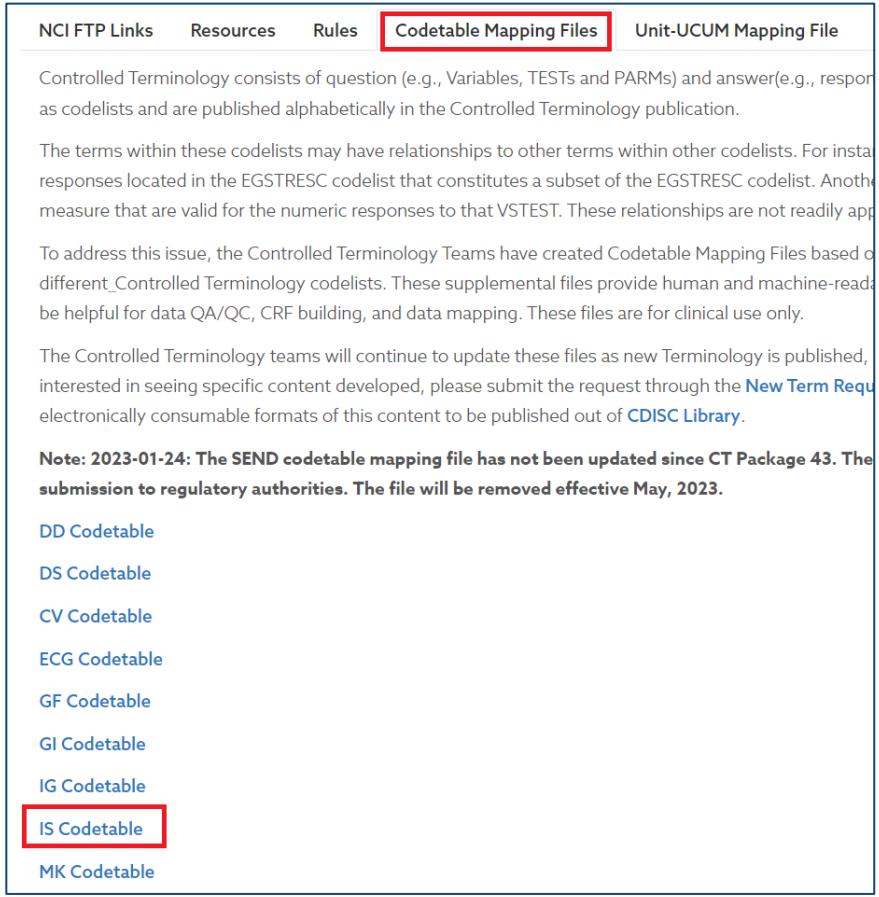
New AB Terms Mapping Tab

Track new requests via the new term request CDISC number (CDISC-12345) and requester name. Traceability between original requested terms to mapping to CDISC standards.

Tools and Resources: 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.



Tools and Resources: 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.

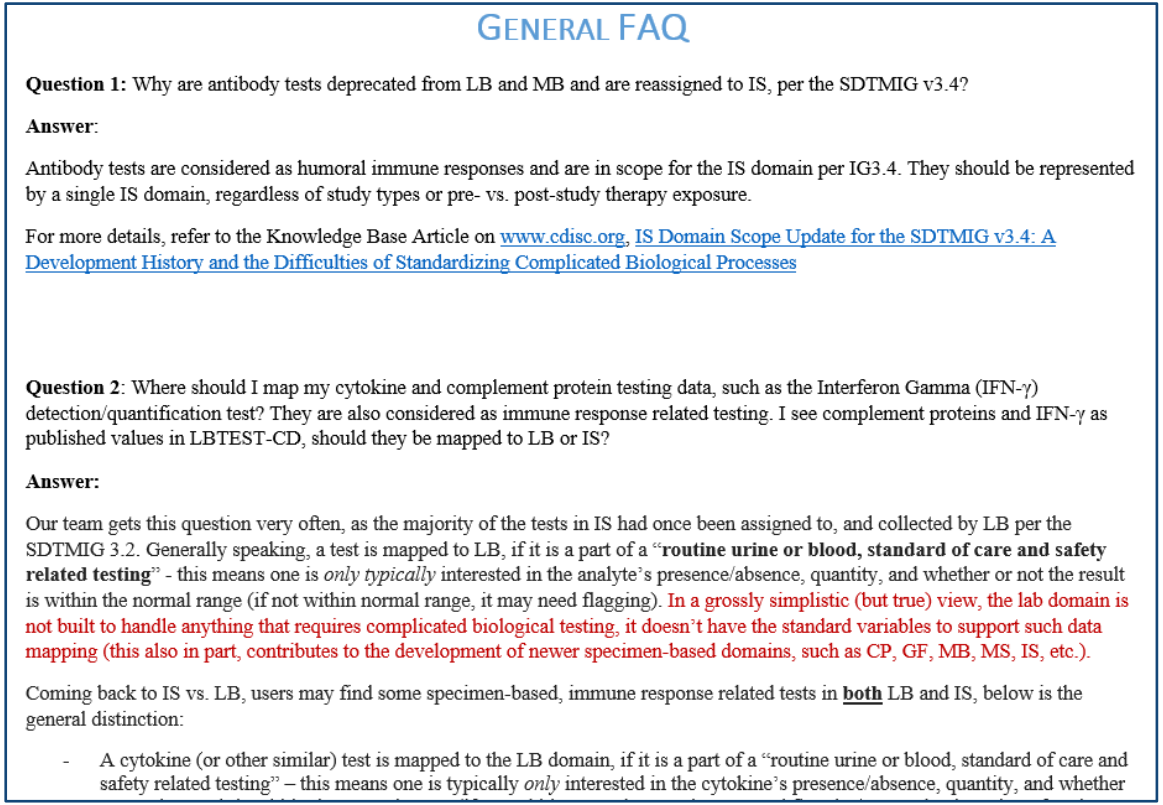
New variables added to the IS domain, in the SDMTIG v3.4 and SDTM v2.0 are the following:

- 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.

Tools and Resources: Rules for Immunogenicity Testing File

- 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.).

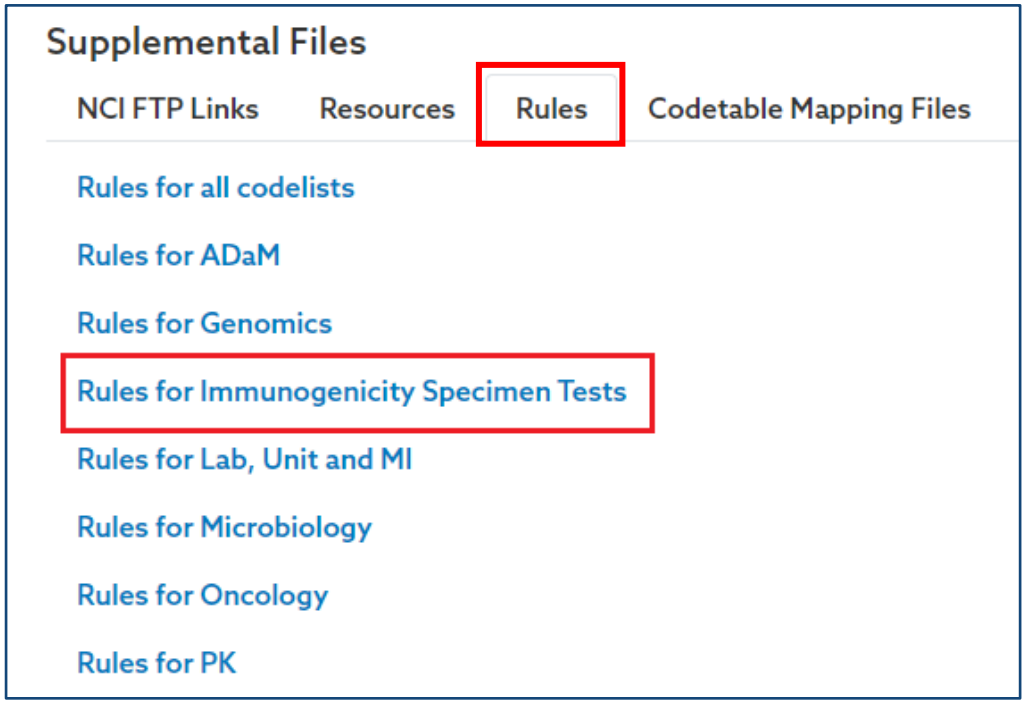
Coming back to IS vs. LB, users may find some specimen-based, immune response related tests in **both** LB and IS, below is the general distinction:

- 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

Tools and Resources: 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.

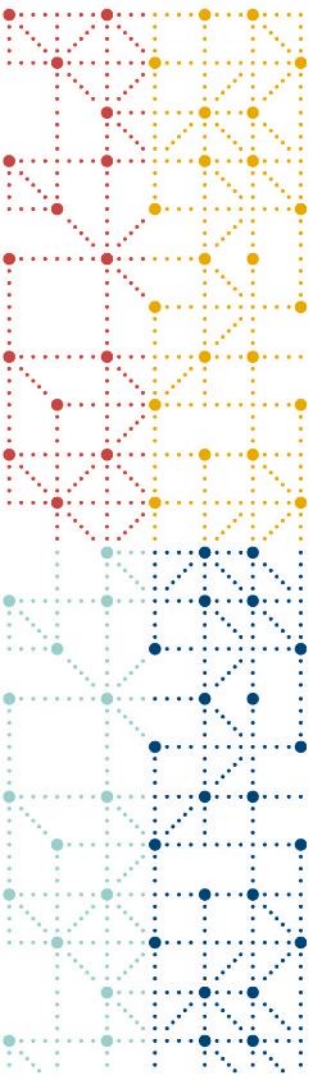


For Users Who are Implementing/Submitting Under the SDTMIG v3.2/v3.3 – Other Recommendations

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.



Future Directions

Today

The CDISC Immunogenicity/Microbiology Subteam goal for 2023 is to:

- Support stakeholder implementation of immunogenicity and microbiology standards through outreach and development/publication of resources and new standards.

To achieve this goal, we are working toward deliverables related to:

- Communication of Standards
- Implementation Support
- Standards Development

In progress for 2023

Communication of Standards

- LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology Webinar
- CDISC US Interchange (October, 2023)
- Training Courses & Office Hours – New Variables, Examples, High-level modeling decisions/principles for OI, IS and MB (Q2, 2024)

Implementation Support/Standards Development

- IS Knowledge Base Article (Published Aug 2022)
- IS Rule Document (Published Dec 2022)
- IS Codetable Mapping File (Published Dec 2022)
- IS and MB Example Collection (estimated mid to late 2023)
  - Update existing immunogenicity examples in LB in published TAUGs – remodel and map to IS
  - New MB examples to add to the SDTMIG v4.0

TAUG-TB v1/v2: Moving Interferon-Gamma Response Assays Data from LB to IS, and Fixes to Original Modeling Errors

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBTSTDTL	LBORRES	LBORRESU	LBSTRESC	LBSTRESN
1	ABC	LB	ABC-01-201	ABC001	1	1	IFNG	Interferon Gamma		1.3	IU/mL	1.3	1.3
2	ABC	LB	ABC-01-201	ABC001	2	1	IFNG	Interferon Gamma		6.2	IU/mL	6.2	6.2
3	ABC	LB	ABC-01-201	ABC001	3	1	IFNG	Interferon Gamma		0.9	IU/mL	0.9	0.9
4	ABC	LB	ABC-01-201	ABC001	4	1	IFNG	Interferon Gamma	Interpretation	POSITIVE		POSITIVE	

Row	LBSTRESU	LBSPEC	LBMETHOD	LBDTC	ASSYAG
1	IU/mL	PLASMA	ELISA	2013-08-26	Nil
2	IU/mL	PLASMA	ELISA	2013-08-26	ESAT-6, CFP-10, TB 7.7
3	IU/mL	PLASMA	ELISA	2013-08-26	Mitogen
4		PLASMA	ELISA	2013-08-26	

LB NSV Metadata

Variable	Label	Type	Role	Origin
ASSYAG	Assay Antigen	text	Non-Standard Record Qualifier	CRF

Modeled in LB in the 2 versions of the TAUG.

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBGRPID	LBTESTCD	LBTEST	LBTSTDTL	LBORRES	LBORRESU	LBSTRESC	LBSTRESN
1	ABC	LB	ABC-01-201	ABC002	1	1	IFNG	Interferon Gamma		1	SFC/10^6 PBMC	1	1
2	ABC	LB	ABC-01-201	ABC002	2	1	IFNG	Interferon Gamma		13	SFC/10^6 PBMC	13	13
3	ABC	LB	ABC-01-201	ABC002	3	1	IFNG	Interferon Gamma		17	SFC/10^6 PBMC	17	17
4	ABC	LB	ABC-01-201	ABC002	4	1	IFNG	Interferon Gamma		30	SFC/10^6 PBMC	30	30
5	ABC	LB	ABC-01-201	ABC002	5	1	IFNG	Interferon Gamma	Interpretation	POSITIVE		POSITIVE	

Row	LBSTRESU	LBSPEC	LBMETHOD	LBDTC	ASSYAG
1 (cont)	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELL	ELISPOT	2013-08-26	Nil
2 (cont)	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELL	ELISPOT	2013-08-26	CFP-10
3 (cont)	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELL	ELISPOT	2013-08-26	ESAT-6
4 (cont)	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELL	ELISPOT	2013-08-26	Mitogen
5 (cont)		PERIPHERAL BLOOD MONONUCLEAR CELL	ELISPOT	2013-08-26	

LB NSV Metadata

Variable	Label	Type	Role	Origin
ASSYAG	Assay Antigen	text	Non-Standard Record Qualifier	CRF

lb.xpt

Row	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBSTRESC
1	ABC	LB	ABC-01-201	1	MYTBGIR	M. tuberculosis IFN Gamma Response	POSITIVE	POSITIVE
2	ABC	LB	ABC-01-202	1	MYTBGIR	M. tuberculosis IFN Gamma Response	INDETERMINATE	INDETERMINATE
3	ABC	LB	ABC-01-203	1	MYTBGIR	M. tuberculosis IFN Gamma Response	NEGATIVE	NEGATIVE

lb.xpt

Row	LBSPEC	LBMETHOD	VISITNUM	VISIT	LBDTC
1 (cont)	BLOOD	ELISPOT	1	VISIT 1	2004-09-18
2 (cont)	BLOOD	ELISA	1	VISIT 1	2004-09-18
3 (cont)	BLOOD	ELISA	1	VISIT 1	2004-09-18

supplb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	ABC	LB	ABC-01-201	LBSEQ	1	COMMTEST	Commercial Test Name	T-SPOT.TB
2	ABC	LB	ABC-01-202	LBSEQ	1	COMMTEST	Commercial Test Name	QuantiFERON-TB Gold In-Tube
3	ABC	LB	ABC-01-203	LBSEQ	1	COMMTEST	Commercial Test Name	QuantiFERON-TB Gold

TAUG-TB v1/v2: Moving Interferon-Gamma Response Assays Data from LB to IS, and Fixes to Original Modeling Errors

Example 1: Measure INF-y using T-Cell ELISPOT

is.xpt

is.xpt

Row	NHOID	STUDYID	DOMAIN	USUBJID	SPDEVID	ISSEQ	ISGRPID	ISLNKID	ISTESTCD	ISTEST	ISMSCBCE	ISTSTCND	ISCNDAGT	ISTSTDTL	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISDTC
1		ABC	IS	ABC-01-201	ABC002	1	1	A	CYKSCCL	Cytokine-secreting Cells	INTERFERON GAMMA	WITHOUT STIMULATING AGENT			1	SFC/10^6 PBMC	1	1	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELLS	ELISPOT	2013-08-26
2	Mycobacterium tuberculosis 13-Cr5_ND_6_A	ABC	IS	ABC-01-201	ABC002	2	1	A	CYKSCCL	Cytokine-secreting Cells	INTERFERON GAMMA	WITH STIMULATING AGENT	CFP-10		13	SFC/10^6 PBMC	13	13	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELLS	ELISPOT	2013-08-26
3	Mycobacterium tuberculosis 13-Cr5_ND_6_A	ABC	IS	ABC-01-201	ABC002	3	1	A	CYKSCCL	Cytokine-secreting Cells	INTERFERON GAMMA	WITH STIMULATING AGENT	ESAT-6		17	SFC/10^6 PBMC	17	17	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELLS	ELISPOT	2013-08-26
4		ABC	IS	ABC-01-201	ABC002	4	1	A	CYKSCCL	Cytokine-secreting Cells	INTERFERON GAMMA	WITH STIMULATING AGENT	Mitogen		30	SFC/10^6 PBMC	30	30	SFC/10^6 PBMC	PERIPHERAL BLOOD MONONUCLEAR CELLS	ELISPOT	2013-08-26
5		ABC	IS	ABC-01-201	ABC002	5	1	A	CYKSCCL	Cytokine-secreting Cells	INTERFERON GAMMA			INTERPRETATION	POSITIVE		POSITIVE				ELISPOT	2013-08-26

Example 2: Measure INF-y using ELISA

Re-modeling in IS

is.xpt

is.xpt

Row	NHOID	STUDYID	DOMAIN	USUBJID	SPDEVID	ISSEQ	ISGRPID	ISLNKID	ISTESTCD	ISTEST	ISTSTCND	ISCNDAGT	ISTSTDTL	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISDTC
1		ABC	IS	ABC-01-203	ABC001	1	1	B	IFNG	Interferon Gamma	WITHOUT STIMULATING AGENT				IU/mL			IU/mL	PLASMA	ELISA	2013-08-26
2	Mycobacterium tuberculosis	ABC	IS	ABC-01-203	ABC001	2	1	B	IFNG	Interferon Gamma	WITH STIMULATING AGENT	TB1 Antigen		6.2	IU/mL	6.2	6.2	IU/mL	PLASMA	ELISA	2013-08-26
3	Mycobacterium tuberculosis	ABC	IS	ABC-01-203	ABC001	2	1	B	IFNG	Interferon Gamma	WITH STIMULATING AGENT	TB2 Antigen		9.8	IU/mL	9.8	9.8	IU/mL	PLASMA	ELISA	2013-08-26
4		ABC	IS	ABC-01-203	ABC001	3	1	B	IFNG	Interferon Gamma	WITH STIMULATING AGENT	Mitogen		0.9	IU/mL	0.9	0.9	IU/mL	PLASMA	ELISA	2013-08-26
5		ABC	IS	ABC-01-203	ABC001	4	1	B	IFNG	Interferon Gamma			INTERPRETATION	POSITIVE		POSITIVE				ELISA	2013-08-26

Example 3: Identification of Mycobacterium tuberculosis

The MB data below are derived records from the IS dataset above, the identification and diagnosis of *Mycobacterium tuberculosis* are interpretations based on the IFNy responses test results above.

Note: there is an existing, pre-coordinated MBTEST = M. tuberculosis IFN Gamma Response/C92241, (also from TB TAUG V1), this test will be deprecated because the modeling is incorrect. The MB/IS team will not publish tests similar to C92241 in the future, and we recommend users to model this type of tests using the below structure. Please be aware that you may also ONLY report the MB records below alone, if you do not care or the lab does not provide you with the actual results and details of the subject's IFN-y levels related changes.

mb.xpt

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	MBSEQ	MBLNKID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBMETHOD	MBDTC	LOINC
1	ABC	MB	ABC-01-201	ABC002	1	A	MTB	Mycobacterium tuberculosis	INTERPRETATION	POSITIVE	POSITIVE	INTERFERON GAMMA RELEASE ASSAY	2013-08-26	71773-6
2	ABC	MB	ABC-01-203	ABC001	1	B	MTB	Mycobacterium tuberculosis	INTERPRETATION	POSITIVE	POSITIVE	INTERFERON GAMMA RELEASE ASSAY	2013-08-26	71773-6

The RELREC dataset below shows the relationship between IS and MB.

relrec.xpt

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC	IS	ABC-01-201	ISLNKID	A	MANY	1
2	ABC	MB	ABC-01-201	MBLNID	A	ONE	1
3	ABC	IS	ABC-01-203	ISLNKID	B	MANY	2
4	ABC	MB	ABC-01-203	MBLNID	B	ONE	2

TAUG-Influenza: Remodel Immunologic responses to Influenza Antigens (section 3.3), in OI and IS domains

is.xpt

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISREFID	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU	ISSTRESC
1	INFL456	IS	INF02-01	1	SAMPBL0201	INFAHIT	Influenza A Hemagglutination Inhibition Antibody Titer	SEROLOGY	1:32	dilution	32
2	INFL456	IS	INF02-02	2	SAMPBL0202	INFAMNT	Influenza A Microneutralization Antibody Titer	SEROLOGY	1:64	dilution	64

Row	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISDTC
1 (cont)	32	titer	SERUM	HEMAGGLUTINATION INHIBITION ASSAY	2011-08-08
2 (cont)	64	titer	SERUM	MICRONEUTRALIZATION ASSAY	2011-08-08

Previous modeling in the Flu TAUG

oi.xpt

oi.xpt

Row	STUDYID	DOMAIN	NHOID	ISSEQ	OIPARMCD	OIPARM	OIVAL
1	INF1230	OI	Influenza B virus (B/Acre/117700/2012)	1	SPCIES	SPECIES	Influenza B virus
2	INF1230	OI	Influenza B virus (B/Acre/117700/2012)	2	TYPE	Type	B
5	INF1230	OI	Influenza B virus (B/Acre/117700/2012)	3	GEOORIG	Geographical Origin	Acre
6	INF1230	OI	Influenza B virus (B/Acre/117700/2012)	4	STRAIN	Strain	117700
7	INF1230	OI	Influenza B virus (B/Acre/117700/2012)	5	YEARCOLL	Year of Collection	2012
9	INF1230	OI	Influenza A/Michigan/45/2015	1	SPCIES	Species	Influenza A virus
10	INF1230	OI	Influenza A/Michigan/45/2015	2	TYPE	Type	A
11	INF1230	OI	Influenza A/Michigan/45/2015	3	GEOORIG	Geographical Origin	Michigan
12	INF1230	OI	Influenza A/Michigan/45/2015	4	STRAIN	Strain	45
13	INF1230	OI	Influenza A/Michigan/45/2015	5	YEARCOLL	Year of Collection	2015

Re-modeling per the SDTMIG 3.4 structure

The IS example below shows how to represent data collected from running the Hemagglutination Inhibition Assay on Influenza A and B viruses. NHOIDs generated from the OI domain above are used in the IS dataset below to show that the following tests are performed against the two specific flu A and B strains. We are assessing whether or not the antibody would prevent influenza-driven Hemagglutination process. Note the **OI dataset** and **NHOID** are used to describe and identify fully the taxonomic classification and information about the two flu strains - so such details do not have to appear elsewhere in the IS dataset.

is.xpt

is.xpt

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISREFID	NHOID	ISTESTCD	ISTEST	ISBDAGNT	ISTSTDTL	ISCAT	ISSCAT	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	VISITNUM	VISIT	ISDTC
1	INF1230	IS	INF1230-011	1	13668	Influenza B virus (B/Acre/117700/2012)	MBAB	Microbial-induced Antibody	Influenza B Virus	Hemagglutination Inhibition Titer	VACCINE-RELATED IMMUNOGENICITY	HUMORAL IMMUNITY	1:40	ratio	40	40	titer	SERUM	HEMAGGLUTINATION INHIBITION ASSAY	1	VISIT 1	2017-05-27
2	INF1230	IS	INF1230-011	2	13668	Influenza A/Michigan/45/2015	MBAB	Microbial-induced Antibody	Influenza A Virus	Hemagglutination Inhibition Titer	VACCINE-RELATED IMMUNOGENICITY	HUMORAL IMMUNITY	1:80	ratio	80	80	titer	SERUM	HEMAGGLUTINATION INHIBITION ASSAY	1	VISIT 1	2017-07-27

New MB Examples - Multi-target Microbial "Detection & Identification" Test

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBGRPID	MBTESTCD	MBTEST	MBTSTDTL	MBCAT	MBORRES	MBSTRESC	MBMETHOD	VISITNUM	VISIT	MBDTC
1	ABC	MB	ABC-001	1	1	HRHPDNM	High-Risk HPV Types DNA, MLTTRG	DETECTION	MICROBIOLOGY	Positive	Positive	POLYMERASE CHAIN REACTION	2	VISIT 1	2018-06-01
2	ABC	MB	ABC-001	2	1	HPV16	HPV Type 16	DETECTION	MICROBIOLOGY	Positive	Positive	POLYMERASE CHAIN REACTION	2	VISIT 1	2018-06-01
3	ABC	MB	ABC-001	3	1	HPV18	HPV Type 18	DETECTION	MICROBIOLOGY	Positive	Positive	POLYMERASE CHAIN REACTION	2	VISIT 1	2018-06-01
4	ABC	MB	ABC-052	1		HRHPMRNM	High-Risk HPV Types mRNA, MLTTRG	DETECTION	MICROBIOLOGY	Positive	Positive	POLYMERASE CHAIN REACTION	2	VISIT 1	2018-06-01

The NSMB dataset below shows the 11 high-risk HPV types, 31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68. Users may wonder why the SDTM "MULTIPLE" convention is not used in the records below, this is because the tests are not "ch *same time* and in a *single* analysis. The outcome of this assessment is a *pooled* positive result (MB dataset above rows 1 and 4), if one or more HPV types are detected in the subject's sample. Therefore, it is inappropriate to use the and MBMAGTRG, and are separated with a semicolon.

nsmb.xpt

nsmb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	MBMOTRG	MBMAGTRG
1	ABC	MB	ABC-001	MBSEQ	1	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 51; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68	
2	ABC	MB	ABC-052	MBSEQ	1	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 45; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68	HPV E6 mRNA; HPV E7 mRNA

Metadata for nsmb.xpt

NSMB Variable Metadata

Variable	Label	Type	Codelist	Role
MBMOTRG	Multi-Microorganism Test Targets	Char		Non-Standard Qualifier
MBMAGTRG	Multi-Antigen Test Targets	Char		Non-Standard Qualifier

mb.xpt

Row	STUDYID	DOMAIN	USUBJID	MBSEQ	MBGRPID	MBTESTCD	MBTEST	MBTSTDTL	MBCAT	MBORRES	MBSTRESC	MBMETHOD	VISITNUM	VISIT	MBDTC
1	ABC	MB	ABC-001	1	1	HRHPDNM	High-Risk HPV Types DNA, MLTTRG	DETECTION	MICROBIOLOGY	Positive	Positive	REVERSE TRANSCRIPTASE PCR	1	SCREEN	2018-06-01
2	ABC	MB	ABC-001	2	1	HRHPDNM	High-Risk HPV Types DNA, MLTTRG	IDENTIFICATION	MICROBIOLOGY	HPV type 31	HPV type 31	REVERSE TRANSCRIPTASE PCR	1	SCREEN	2018-06-01
3	ABC	MB	ABC-001	3	1	HRHPDNM	High-Risk HPV Types DNA, MLTTRG	IDENTIFICATION	MICROBIOLOGY	HPV type 52	HPV type 52	REVERSE TRANSCRIPTASE PCR	1	SCREEN	2018-06-01
4	ABC	MB	ABC-001	4	1	HRHPDNM	High-Risk HPV Types DNA, MLTTRG	IDENTIFICATION	MICROBIOLOGY	HPV type 66	HPV type 66	REVERSE TRANSCRIPTASE PCR	1	SCREEN	2018-06-01

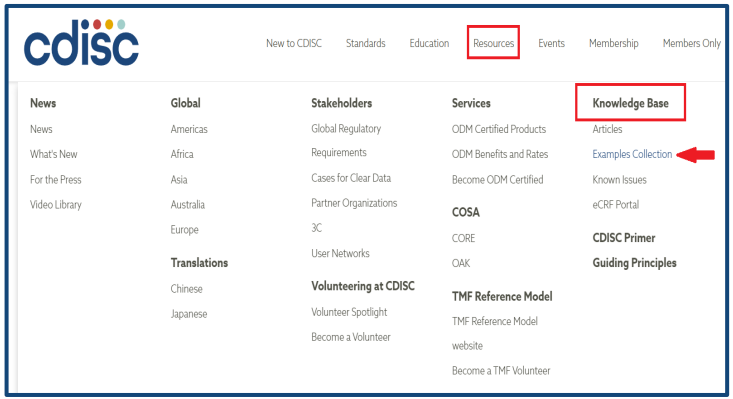
nsmb.xpt

nsmb.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	MBMOTRG
1	ABC	MB	ABC-001	MBSEQ	1	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 51; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68
2	ABC	MB	ABC-001	MBSEQ	2	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 51; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68
3	ABC	MB	ABC-001	MBSEQ	3	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 51; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68
4	ABC	MB	ABC-001	MBSEQ	4	HPV Type 31; HPV Type 33; HPV Type 35; HPV Type 39; HPV Type 51; HPV Type 52; HPV Type 56; HPV Type 58; HPV Type 59; HPV Type 66; HPV Type 68

CDISC Example Collection

These examples will first be published in the **Example Collection** section on CDISC.org: https://www.cdisc.org/kb/examples => Resources => Knowledge Base => Example Collection



The SDTMIGs are updated and published every couple of years. The Example Collection section on CDISC.org allows faster turn-arounds so users have access to “real-life” submission use-cases, modeling guiding decisions and high-level principles, and new variables introduced. The early access to data examples also allows users to submit feedback on whether or not the data are modeled accurately and practically.

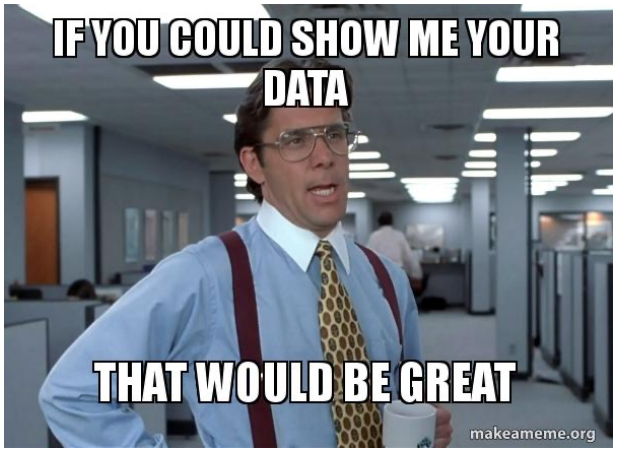
How you can be involved!

Become a CDISC MB/IS subteam volunteer.

- www.cdisc.org/volunteer

Contribute FAQs and use-case examples for modeling:

- Use-case should be real-life, de-identified and submission related.
- We would like to discuss your use-case with you
- Reach out to Jordan Li, IS/MB subteam lead (Jordan.li@nih.gov)



*Send your use-cases to us for evaluation if there are questions on how to map that data, or if you identify gaps in the current structure for MB, MS, IS and OI that need addressing.

The MB/IS Domain-CT Subteam

- Anna Pron-Zwick (team co-lead)
- Patricia Gleason
- Kathleen Hectors
- Jon Neville
- Debra O'Neill
- Phil Pochon
- Daniel Sinnett
- Aileen St. Marie
- Joleen White
- Rachel Zieverink
- Uma Singh
- Jennifer Jessup

Past Member: Ine Wolfs

Thank you!

Questions?