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Getting “under the umbrella” of Specimen-based Findings Domains

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ABSTRACT:

The Study Data Tabulation Model Implementation Guide (SDTM IG) 3.4 has brought together domains that collect observations based on tests or examinations performed on collected biological specimens under one umbrella called “Specimen- based Findings Domains”. They include Biospecimen Findings (BS), Cell Phenotype Findings (CP), Genomics Findings (GF), Immunogenicity Specimen Findings (IS), Laboratory Test Results (LB), Microbiology and Pharmacokinetic domains. Each domain is defined to group measures of a common topic (e.g., microbiology susceptibility, microscopic findings, pharmacokinetic concentrations). This paper presents a comprehensive guide on how to determine the appropriate domain for various specimen-based findings. By examining the specific variables and criteria outlined in SDTM IG 3.4, we offer practical insights and examples to help programmers accurately categorize and report their findings. It also discusses how to use controlled terminology for these domains to ensure clear and consistent data submission.

INTRODUCTION:

In the evolving landscape of Clinical research and data analysis, the Findings Observation Class serves as a critical building block of SDTM submissions. Within the Findings structure, there is a specialized set of domains that are combined under the sub-category of Specimen-based Findings, because they’re all about tests or assessments based on collected specimens. For example, the Genomics Findings (GF) domain captures insights into genetic variations and molecular mechanisms, while the Biospecimen Findings (BS) domain contextualizes observations related to biological samples. The Cell Phenotype Findings (CP) and Microscopic Findings (MI) domains enable detailed analyses of cellular characteristics and microscopic structures, respectively. Additionally, the Immunogenicity Specimen Assessments (IS) domain provides vital data on immune responses, complementing information gleaned from Laboratory Test Results (LB). Microbiological data, categorized under Microbiology Domains (MB and MS), enhance our understanding of pathogenic and commensal microbial interactions. Lastly, the Pharmacokinetics Domains (PC and PP) support drug development and therapeutic monitoring by detailing absorption, distribution, metabolism, and excretion patterns.

A BROAD UNDERSTANDING OF THE FINDINGS CLASS:

Per SDTM, observations derived from planned evaluations provide essential insights into specific tests and measurements, such as Laboratory Tests (LB), Vital Signs (VS), and structured Questionnaires (QS) listed on standardized instruments or scales. These observations are tabulated using a topic variable (that cannot be null) --TESTCD and the synonym qualifier --TEST, (for example: LBTEST and LBTESTCD) that exemplify their application. The variable --TESTCD is restricted to 8 characters and must be annotated on the annotated Case Report Form (aCRF), to reinforce traceability in a clinical submission. While --TEST is restricted to 40 characters, an exception is made for IETEST which is allowed to be 200 characters, because it is not expected to be transformed to column labels.

The Findings observation class encompasses various domains that capture the results of planned test and assessments performed on study subjects. With the release of SDTMIG 3.4, the Findings class now includes several domains, that are classified into four categories: Specimen-based Findings domains, Morphology/Physiology Domains, Tumor/Lesion Domains, and Questionnaires, Ratings, and Scales Domains. Other than these, there are some domains that don’t fall under any specific category.

When the date/time of collection is reported in a findings domain, it should be mapped to the --DTC variable, which records the date and time of acquisition (for e.g., EGDTC for Date/Time of ECG).

When there’s a domain based on a specimen collection, the collection date is likely to be tied to when the source of the finding - i.e. the specimen - was captured, not necessarily when the data were recorded. In order to ensure

that the critical timing information is always represented in the same variable, the --DTC variable is used to represent the time of specimen collection. For example, in LB, the LBDTC variable would be used for all single-point blood collections or spot urine collections. For timed lab collections (e.g., 24-hour interval of urine collections) the LBDTC variable would be used for the start date/time of the collection and LBENDTC for the end date/time of the collection. This approach allows the single-point and interval collections to use the same date/time variables consistently across all datasets for the Findings general observation class.

Please note that, --STDTC should not be used within the Findings general observation class, as it is restricted for use with Events and Interventions domains.

Normalization of Data Structure in Findings Domains:

The Findings domain class follows a vertical structure, ensuring that each observation is recorded as a separate entry. For instance, in the Vital Signs (VS) domain, a sponsor's dataset may include subject records for height, weight, and body surface area - all maintained in a single row. Under the normalized SDTM Findings structure, however, each VS measurement is submitted as one record per observation, meaning a subject could have three distinct records—one for each test or measurement within a single visit or time point. The parameter names are systematically stored within Test Code (--TESTCD) and Test Name (--TEST) variables, while result values are documented in the respective --ORRES and --ORRESU variables for precision in data reporting. Because unique test names may hold different attributes—including origin, role, and definition—it is essential to provide value-level metadata for accurate interpretation and classification. This metadata should be meticulously detailed in the Define-XML document, ensuring transparency and consistency in regulatory submissions. Please see the tabular representation below for this example:

Sponsor Dataset:

USUBJID	DATE	HEIGHT	HEIGHT UNIT	WEIGHT	WEIGHT UNIT	BSA	BSA UNIT
ABC-001-001	12/15/2024	160	cm	100	kg	2.14	m2

Partial SDTM Dataset:

USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSDTC
ABC-001-001	HEIGHT	Height	160	cm	12/15/2024
ABC-001-001	WEIGHT	Weight	100	kg	12/15/2024
ABC-001-001	BSA	Body Surface Area	2.14	m2	12/15/2024

Define-XML representation:

VSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	200		
	VSTESTCD = "HEIGHT" (Height)		float		6		CRF Annotated Case Report Form [3]
	VSTESTCD = "WEIGHT" (Weight)		float		6		CRF Annotated Case Report Form [3] [7]
	VSTESTCD = "BSA"		float		6		Derived Set to VS.VSSTRESN when (VS.VSTESTCD=WEIGHT / [VS.VSSTRESN when VS.VSTESTCD=HEIGHT]^2)/100

Please refer to section 3.1.3 of the SDTM Model v2.0, which outlines the allowable variables in the Findings observation class. Additionally, in SDTMIG v3.4, the assumptions section for each Findings domain provides a detailed list of variables that should typically not be used within that domain, to ensure consistency across standardized SDTM datasets.

3.1.3 The Findings Observation Class

Findings—Topic and Qualifier Variables—One Record per Finding

#	Variable Name	Variable Label	Type	Format	Role	Variable(s) Qualified	Usage Restrictions	Variable C-code	Definition	Notes	Examples
1	--TESTCD	Short Name of Measurement, Test, or Exam	Char		Topic			C82503	The standardized or dictionary-derived short sequence of characters used to	Used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters.	"PLAT", "SYSBP", "RRMIN", "EYEEXAM"

#	Variable Name	Variable Label	Type	Format	Role	Variable(s) Qualified	Usage Restrictions	Variable C-code	Definition	Notes	Examples
									represent the measurement, test, or examination.		
2	--TEST	Name of Measurement, Test, or Exam	Char		Synonym Qualifier	--TESTCD		C82541	The standardized or dictionary-derived name of the measurement, test, or examination.		"Platelets", "Systolic Blood Pressure", "Summary (Min) RR Duration", "Eye Examination"
3	-- SBMRKS	Sublineage Marker String	Char		Variable Qualifier	--TESTCD	CP domain only			Used to further subset the cell population identified in CPTEST based on the use of additional marker(s) that define a sublineage. The value in CPSBMRKS is used in combination with values in CPTEST and CPCELSTA to fully describe the cell population being measured. As such, it is an essential component of the full test name.	Three unnamed sublineages of monocytes have been identified: CCR2+CD16-; CCR2-CD16+; and CCR2+CD16+. Whereas the entire monocyte cell population can be defined as CD14+ cells, the additional CCR2 and CD16 markers are used to differentiate one sublineage from another, none of which has yet been given a name by the scientific community. By combining the CPTEST value of "Monocyte Subset" with the value of "CCR2+CD16-" in CPSBMRKS, the full test is defined to be the CCR2+CD16- monocyte subpopulation.
4	-- CELSTA	Cell State	Char		Variable Qualifier	--TESTCD	CP domain only			A textual description of a subset of the cell population identified in CPTEST based on a particular functional and/or biological state (e.g., primed, activated, proliferating, senescent, G2-arrested). When populated, the values in CPCELSTA and CPSMRKS, in combination with values in CPTEST and CPSBMRKS, fully describe the cell population being measured.	

GENOMICS FINDINGS (GF):

The Genomics Findings (GF) domain provides structured insights into genomic material, specifically DNA and RNA, across both subjects and non-host organisms - the latter referring to organisms that are not the primary focus of a study but whose genomic data is still analyzed. This domain focuses on the structure, function, evolution, mapping, and editing of genomic sequences, helping researchers interpret genetic variations and transcription processes. While the GF domain explores features within DNA and RNA that contribute to predicting protein and amino acid behavior, it does not directly assess proteins or amino acids themselves. Included within this domain are assessments and results related to genetic variation, transcription activities, and derived summary measures, which collectively support advancements in genomics-driven research and precision medicine. In the following section, we will delve deeper into each component, incorporating biological perspectives to better understand the types of data expected in a GF dataset.

This is a fantastic analogy - think of a genome as a cookbook! That makes it much easier to visualize how genetic information is stored and used. Nucleotides act as the letters, forming sequences that create genes, which serve as recipes telling the cell how to assemble proteins or carry out crucial functions. These genes are embedded within DNA, and DNA strands form chromosomes, shaping the genetic blueprint of an organism. Additionally, RNA plays a vital role, helping interpret and execute the instructions encoded in DNA. The Genomics Findings (GF) domain systematically captures and stores this genomic data, enabling researchers to analyze variations, transcription processes, and broader genetic patterns.

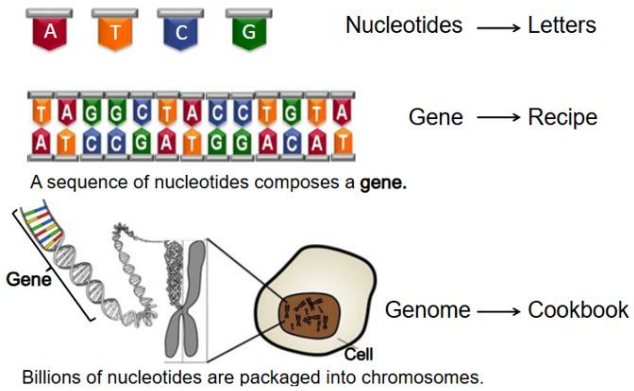


Figure 1. Genomics and Inheritance. Source: SlidePlayer, https://slideplayer.com/slide/7020244/

The Genomics Findings (GF) domain focuses on capturing assessments and results related to transcription, the biological process where DNA instructions are transcribed into RNA, much like copying a recipe onto a new piece of paper. This RNA copy then serves as a messenger, carrying the instructions to the ribosome, which selects the correct amino acids to assemble new proteins. While the GF domain includes data from both DNA and RNA, it does not directly assess proteins or amino acids themselves. However, it may provide predictions on how certain DNA or RNA sequences could influence protein formation.

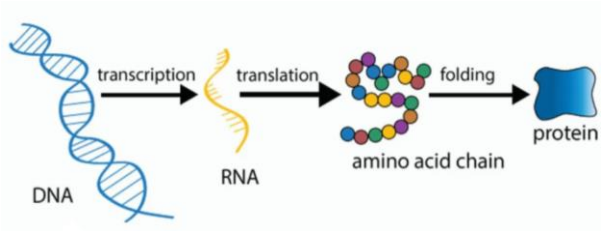


Figure 2. Genomics and Inheritance. Source: SlidePlayer, https://slideplayer.com/slide/7020244/

To summarize, the Genomics Findings (GF) domain captures unique genetic variations, which are specific positions in the genome where individuals have different nucleotides. Because no two genomes are identical, studying these variations provides valuable insights into how genetic differences influence biological functions. The GF domain also includes findings from transcription, the process of converting DNA instructions into RNA, as well as summary measures derived from these assessments.

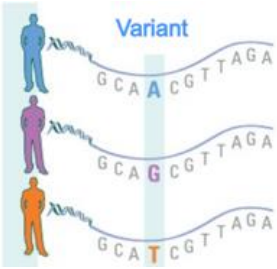


Figure 3. Genomics and Inheritance. Source: SlidePlayer, https://slideplayer.com/slide/7020244/

This structured genomic data helps researchers make predictions about genetic behavior while maintaining a focus on DNA and RNA rather than proteins.

UNDERSTANDING BIOSPECIMEN DOMAINS IN SDTM IG V3.4:

According to the NIH, a biospecimen refers to any biological sample collected from humans, animals, or plants for research or diagnosis—examples include blood, tissue, urine, cells, DNA, RNA, and proteins. The latest SDTM Implementation Guide (SDTMIG v3.4) introduces two new domains:

- **BE (Biospecimen Events)**: Captures actions taken that affect or may influence a specimen, such as collection, freezing, thawing, aliquoting, and transportation.
- **BS (Biospecimen Findings)**: Stores findings related to specimen handling and characteristics, including type, amount, and size, providing essential information about the sample itself.

These domains work together to present a comprehensive view of biospecimen data in a study. The BS domain is not only limited to Pharmacogenomics (PGx) specimens, but it also supports a wide range of biospecimen types. For instance, in a blood sample collection, the BS domain would document key details such as the type of sample (blood) and the quantity collected. Examples of BSTEST values include Specimen Area, Size, Volume, Tumor Tissue Origin, RNA Integrity Number, and Sample Viability Indicator. To view the full list of tests included in this domain, refer to the Biospecimen Test Name codelist (BSTEST) in the SDTM documentation.

Let's look at the BS domain in a little more depth now. The BSSPEC (Specimen Type) variable uses controlled terminology to classify biospecimen types based on their genetic composition. There are two key codelists used for different types of specimens:

- Genetic Material Biospecimens (SDTM) → BSSPEC values come from the Genetic Sample Type (GENSMP) codelist.
- Other Biospecimen Materials (SDTM) → Use the Specimen Type (SPECTYPE) codelist in BSSPEC.

Additionally, for Non-clinical submissions (SEND IG) involving biospecimens of non-genetic material, the Specimen (SPEC) codelist from SEND Controlled Terminology (SEND CT) is used. These classifications ensure standardized representation of biospecimen types across different studies and regulatory submissions.

CELL PHENOTYPE FINDINGS (CP) – UNDERSTANDING MARKER DATA:

The Cell Phenotype Findings (CP) domain, introduced in SDTMIG v3.4, serves as a new specimen-based findings domain designed for reporting marker data. This domain includes but is not limited to genetic and genomic biomarker data and also supports tests used to characterize cell phenotype, lineage, and function based on the expression of specific markers in single-cell or particle suspensions. To accommodate these findings, new variables and concepts have been introduced in SDTMIG v3.4, enhancing the ability to report marker data comprehensively. While a deep dive into domain-specific variables would be out-of-scope for this paper, the SDTMIG v3.4 remains the primary reference for further details.

Cell phenotype relates to what a cell looks like and its functions, while cell lineage describes where the cell originated and its ancestral history. Essentially, this domain enables scientists to capture data on the characteristics, ancestry, and roles of cells by analyzing specific markers present in liquid-based specimens, such as blood or bone marrow samples. Understanding these markers provides valuable insight into how cells behave and interact within the body, contributing to a broader comprehension of cellular functions in both health and disease.

Scope and Purpose of CP:

The Cell Phenotype Findings (CP) domain, is designed for use with disseminated tissue specimens, such as blood, body fluids, and bone marrow aspirates, as well as cell suspensions. It is not currently modeled for evaluations involving solid tissue specimens.

This domain specifically supports tests associated with cell phenotyping using markers, distinguishing it from other findings domains. Tests not linked to marker-based phenotyping are best categorized under other SDTM domains, such as:

- Immunogenicity Specimen Assessments (IS)
- Laboratory Test Results (LB)
- Microscopic Findings (MI)

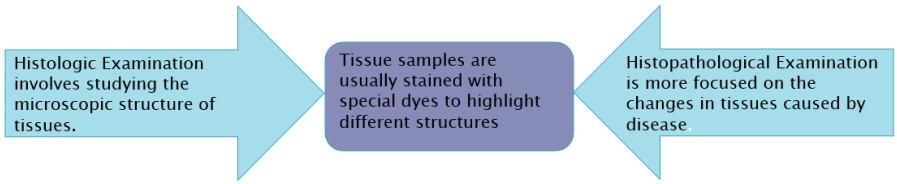
Most importantly, the CP domain does not replace the LB domain for routine lab hematology (e.g., blood cell differentials) or findings obtained through microscopic cell assessments, including immunohistochemical (IHC) techniques. Several new qualifier variables have also been introduced to support the CP domain. For detailed descriptions and appropriate usage, please refer to the SDTM Implementation Guide (SDTM IG).

MICROSCOPIC FINDINGS (MI) – UNDERSTANDING TISSUE ANALYSIS:

The Microscopic Findings (**MI**) domain captures findings derived from microscopic examinations of tissue samples, typically performed on specimens that have been prepared with stains to enhance visualization of structural details. These assessments allow researchers and clinicians to observe cell arrangement, morphology, and abnormalities within tissues.

Some fluid-based cell examinations—such as those involving blood or urine—are considered laboratory tests and should be categorized under the Laboratory Test Results (LB) domain rather than MI. Meanwhile, biomarkers assessed using histologic or histopathological techniques, including cytochemical and immunocytochemical

stains, belong in the MI domain. During histologic and histopathological examinations, special dyes are applied to tissue samples, making cellular structures more visible under a microscope. This process plays a vital role in diagnosing conditions such as cancer, infections, and various diseases by revealing unusual patterns or irregularities in cell arrangements.



When biomarker results are stored in the Microscopic Findings (MI) domain, the variable MITESTCD identifies the biomarker of interest, such as BRCA1, HER2, or TTF1. This ensures a standardized way to represent key molecular markers observed during histologic or histopathological assessments.

Additionally, MITSTDTL serves as a qualifier that provides further descriptive details about the staining results. Examples include:

- H SCORE TOTAL SCORE – A quantitative measure of staining intensity across a sample.
- STAINING INTENSITY – Indicates how strongly the biomarker is expressed in the tissue.
- PERCENT POSITIVE CELL – Represents the proportion of cells exhibiting positive staining for the given biomarker.

By leveraging these variables, the MI domain systematically records biomarker staining data, supporting research and clinical evaluations of cell morphology and molecular expression patterns.

IMMUNOGENICITY SPECIMEN ASSESSMENTS (IS) DOMAIN:

Immunogenicity refers to the ability of a substance—such as a vaccine, pathogen (bacteria, viruses, fungi, or parasites), or drug—to trigger an immune response in the body. This response involves the activation of immune cells and the production of antibodies, helping the body recognize and defend itself against potential threats. Immunogenicity is a key factor in vaccine development and drug safety, ensuring that therapeutic agents stimulate the immune system effectively without causing unintended reactions.

The Immunogenicity Specimen Assessments (IS) domain is specifically designed to document whether a therapy—including biologics, drugs, or vaccines—has provoked an immune response in a subject. This response can be positive (a desired reaction, such as antibody production after vaccination) or negative (an adverse immune reaction). For instance, while a vaccine is expected to induce protective immunity, certain cellular therapies, such as erythropoiesis-stimulating agents, may trigger an undesired immune response, affecting their efficacy and safety.

The **IS** domain plays a crucial role in capturing immune response assessments across various biological contexts. It not only tracks reactions to therapeutic interventions like vaccines and biologics but also evaluates immune responses triggered by allergens, microorganisms, or endogenous molecules.

Examples of key immunogenicity assessments within this domain include:

- **Autoimmune Studies** → Capturing **autoantibody responses** against **self-antigens** to investigate autoimmune conditions.
- **Allergy Trials** → Documenting **antibody production** following exposure to allergens.
- **Microbial Infections** → Recording **immune responses**, specifically **antibody production**, against pathogens such as bacteria, viruses, fungi, and parasites.

Expected outputs in the IS domain can vary and may include:

- Positive or Negative Results – Indicates whether an immune response was detected.

- Presence or Absence of Antibody – Confirms whether the antibody of interest is measurable.
- Antibody Quantification – Provides numerical data on antibody levels in response to a stimulus.

By structuring this information within the IS domain, you would create a standardized dataset to evaluate immune system activity, whether for therapeutic monitoring, allergy sensitivity analysis, or infectious disease research.

The IS domain encompasses data on induced humoral (antibody) immune responses, including antibodies against human leukocyte antigen (HLA) proteins and other immunogenic interactions. This domain systematically records whether an immune response has been triggered in a subject due to biologic therapies, allergens, microorganisms, or endogenous molecules.

Additionally, cytometry techniques play a crucial role in analyzing cellular immune responses by detecting specific antigens using fluorescent-labeled antibodies. While immune responses assessed without flow cytometry techniques are documented in the **IS** domain, immune responses measured via flow cytometry fall under the **CP** domain, due to their specialized approach in cell phenotyping.

Key Takeaway: The IS domain collects structured data on both antibody responses and immune cell responses, regardless of the technique used for measurement. However, flow cytometry-based data is categorized in the CP domain, ensuring precise classification within clinical and immunogenicity studies.

LABORATORY TEST RESULTS (LB) DOMAIN – CAPTURING LAB DATA:

The LB domain is designed to store findings from laboratory tests, including hematology, clinical chemistry, and urinalysis, but does not include microbiology or pharmacokinetic data, as these are captured in separate domains. This domain systematically records laboratory data collected on the Case Report Form (CRF) or received from a central provider or vendor, ensuring consistency across clinical studies.

LB Includes:

- Hematology: Tests related to blood and its components, such as complete blood counts (CBC).
- Clinical Chemistry: Tests that measure chemical substances in the body, like electrolytes, enzymes, and lipids.
- Urinalysis: Tests conducted on urine to detect and measure various substances.

LB Excludes:

- Microbiology Data: Information about microorganisms such as bacteria, viruses, fungi, etc., which are stored separately.
- Pharmacokinetic Data: Information about how a drug is absorbed, distributed, metabolized, and excreted in the body, also stored in a different domain.

FDA Guidance on Laboratory Data Submission:

According to the FDA's 'Study Data Technical Conformance Guide', clinical studies should submit two separate domains for lab results:

- **LB** → Contains SI units, with values recorded in LBSTRESU for SI results, and corresponding values in LBSTRESC and LBSTRESN.
- **LC** (Custom Domain) → Identically structured to **LB**, but stores conventional units, with values recorded in –STRESU for conventional unit results, and corresponding values in --STRESC and --STRESN.

It is ideal if both SI and conventional units come directly from the lab vendor to ensure accuracy. Additionally, all test results obtained on subjects—including results from unscheduled tests or visits and results from local laboratories—should be submitted.

CDISC Considerations:

While CDISC / SDTMIG has not yet provided formal guidance or a provisional domain for LC, information on SI and conventional units is available on the CDISC website: CDISC Standardized Lab Units. Many large central

labs maintain lists of SI and conventional units by parameter and can report results in either or both unit systems. Some labs have even published SI/conventional unit conversion tables on their websites.

MICROBIOLOGY DOMAINS - MB AND MS:

The microbiology domains consist of Microbiology Specimen (**MB**) and Microbiology Susceptibility (**MS**), each serving distinct roles in microbial analysis:

- **MB** → Used for detection, identification, quantification, and characterization of microorganisms in subject samples. However, it does not include drug susceptibility testing.
- **MS** → Specifically captures drug susceptibility testing results for organisms identified in the MB domain.

Together, these domains support standardized microbiological data collection, ensuring researchers can track non-host infectious organisms—including bacteria, viruses, fungi, and parasites—within clinical and research studies.

The Microbiology Specimen (**MB**) domain focuses on the detection, identification, quantification, and characterization of microorganisms within subject samples. However, it does not include drug susceptibility testing, as this is captured in the Microbiology Susceptibility (**MS**) domain.

Key Variables in the MB Domain:

- MBTESTCD / MBTEST → Represents the name of the organism or group of organisms being characterized.
- MBTSTDTL → Describes specific microbiological characteristics, such as "COLONY COUNT" or "VIRAL LOAD".
- MBGRPID → Used to group characteristic records with the identification record of the corresponding organism.

The Microbiology Susceptibility (**MS**) domain is specifically designed to capture data from drug-susceptibility testing on organisms identified in the MB domain. This domain plays a crucial role in evaluating how non-host infectious organisms respond to antimicrobial agents, supporting research on drug resistance and efficacy.

Non-Host Infectious Organisms included in **MS**:

- Bacteria → Used in antibiotic susceptibility testing.
- Viruses → Assesses antiviral resistance profiles.
- Fungi → Evaluates susceptibility to antifungal treatments.
- Parasites → Captures resistance trends in antiparasitic therapies.

By systematically recording drug-susceptibility data, the **MS** domain helps monitor pathogen resistance patterns, guiding effective treatment strategies in infectious disease studies.

PHARMACOKINETICS DOMAINS: PC & PP

The **Pharmacokinetic Concentrations (PC) domain** records **drug or metabolite concentrations** measured in **fluids or tissues** over time. This data plays a crucial role in understanding how a drug is absorbed, distributed, metabolized, and excreted, helping researchers assess its pharmacological behavior. Additionally, the **PC** domain captures key specimen properties, such as volume and pH, alongside drug and metabolite concentration measurements.

Meanwhile, the **Pharmacokinetic Parameters (PP) domain** consists of **derived pharmacokinetic parameters**, which are calculated from the **PC** data. Examples include:

- **AUC (Area Under the Curve)** → Reflects **drug exposure over time**
- **Cmax** → Represents the **maximum drug concentration in the bloodstream**
- **Half-life (t½)** → Measures how long it takes for the drug concentration to **reduce by half**

Since **PP** is a **derived dataset**, it may require **normalization** of the original analysis dataset to align with the SDTM-based **PP** domain structure. These two domains work together to provide a comprehensive view of drug behavior in biological systems, ensuring accurate pharmacokinetic assessments.

PC and PP example:

pc.xpt shows concentration data for drug A and a metabolite of drug A from plasma and from urine samples.

pc.xpt

Row	STUDYID	DOMAIN	USUBJID	PCSEQ	PCGRPID	PCREFID	PCTESTCD	PCTEST	PCCAT	PCSPEC	PCORRES	PCORRESU
1	ABC-123	PC	123-0001	1	Day 1	A554134-10	DRGA_MET	Drug A Metabolite	ANALYTE	PLASMA	<0.1	ng/mL
2	ABC-123	PC	123-0001	2	Day 1	A554134-10	DRGA_PAR	Drug A Parent	ANALYTE	PLASMA	<0.1	ng/mL
3	ABC-123	PC	123-0001	3	Day 1	A554134-11	DRGA_MET	Drug A Metabolite	ANALYTE	URINE	<2	ng/mL
4	ABC-123	PC	123-0001	4	Day 1	A554134-11	DRGA_PAR	Drug A Parent	ANALYTE	URINE	<2	ng/mL
5	ABC-123	PC	123-0001	5	Day 1	A554134-11	VOLUME	Volume	SPECIMEN PROPERTY	URINE	3500	mL

pp.xpt example shows PK parameters calculated from time-concentration profiles for the parent drug and 1 metabolite in plasma and urine for one subject.

pp.xpt

Row	STUDYID	DOMAIN	USUBJID	PPSEQ	PPGRPID	PPTESTCD	PPTEST	PPCAT	PPORRES	PPORRESU
1	ABC-123	PP	ABC-123-0001	1	DAY1_PAR	TMAX	Time of CMAX	DRUG A PARENT	1.87	h
2	ABC-123	PP	ABC-123-0001	2	DAY1_PAR	CMAX	Max Conc	DRUG A PARENT	44.5	ug/L
3	ABC-123	PP	ABC-123-0001	3	DAY1_PAR	AUCALL	AUC All	DRUG A PARENT	294.7	h*mg/L
4	ABC-123	PP	ABC-123-0001	4	DAY1_PAR	LAMZHL	Half-Life Lambda z	DRUG A PARENT	0.75	h
5	ABC-123	PP	ABC-123-0001	5	DAY1_PAR	VZO	Vz Obs	DRUG A PARENT	10.9	L

A **RELREC** can be established between PC and PP using one of these Relationship Type's (RELTYPE):

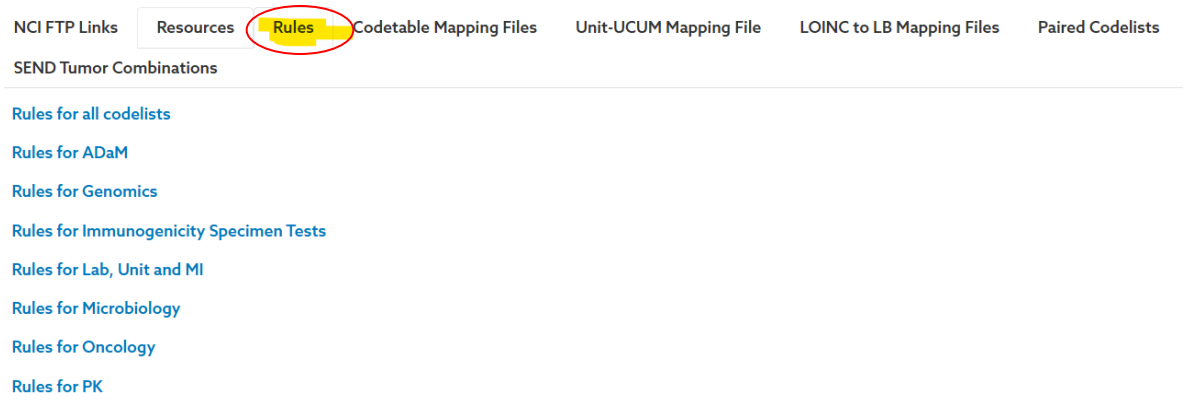
- many to many
- one (PC) to many (PP) **or** many (PC) to one (PP)
- one to one

REFERENCES:

https://www.cdisc.org/standards/terminology/controlled-terminology

Refer to the link above, not only for latest Controlled Terminology but also for Rules, and Codetable mapping files.

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.



ADDITIONAL REFERENCES:

Genomics and Inheritance by Rudolf Hopkins: https://slideplayer.com/slide/7020244/

LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 & Impact on Controlled Terminology by Dr. Jordan Li: https://www.cdisc.org/events/webinar/lb-mb-domain-scope-changes-sdtmig-v3-4-and-impact-controlled-terminology

Study Data Technical Conformance Guide: https://www.fda.gov/media/153632/download

Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.4: https://www.cdisc.org/system/files/members/standard/foundational/SDTMIG%20v3.4-FINAL_2022-07-21.pdf

IMPORTANT NOTES:

Updates in the LB, MB, and IS Domain Scope – SDTM IG v3.4:

As part of the CDISC guidance, when the MB/IS team encounters recurring questions—typically more than five times—they are documented in the FAQ section of the IS Rules Document and the MB/MS Rule Document. These resources offer clarification on mapping decisions, addressing common inquiries such as “LB vs IS?” and “MB vs IS?”. Reviewing these FAQs can provide valuable guidance for data classification within the SDTM framework.

Key Changes from SDTM IG v3.3 to v3.4

The update from SDTM IG v3.3 to SDTM IG v3.4 has led to significant scope changes in the LB, MB, and IS domains, including the deprecation of approximately 400 antibody and antibody-related TEST and TESTCD values from the Lab (LB) and Microbiology (MB) domains. These values have now been remodeled in the IS domain, leveraging standard IS domain variables, including but not limited to:

- ISTESTCD → Represents the antibody or immunogenicity test name.
- ISBDAGNT (Binding Agent) → Specifies the binding agent used in the immunogenicity assay.
- ISTSTDTL (Test Detail) → Captures additional test-specific details related to antibody assessments.

These structural updates ensure better alignment of immunogenicity-related data with its intended scope, facilitating more precise categorization and analysis within the IS domain.

CONTACT INFORMATION:

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