

LPO Webinar Series: CDASH Conformance

Session 1

Using CDASHIG Domains to find the right Rave Form in the GLIB ALS

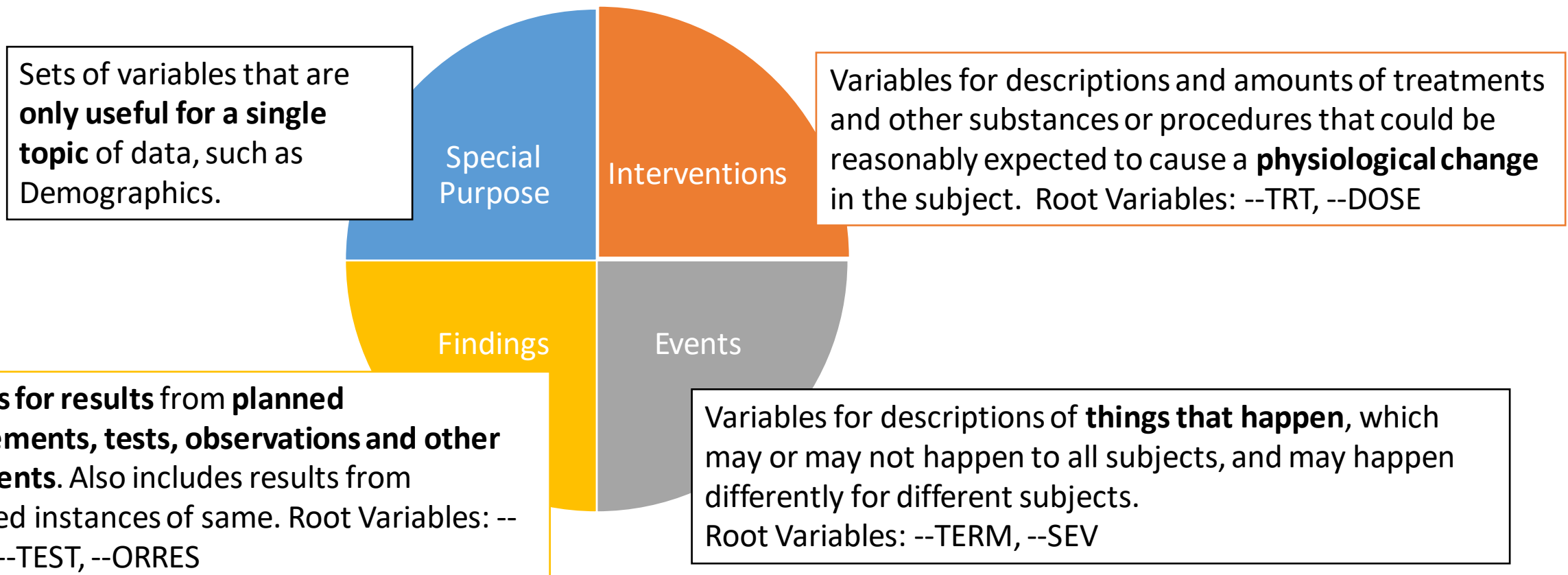
CDASH Conformance Rules Webinar Series

- CDASH Conformance Rules describe how to “conform” to the CDASH standard in such a way that the “harmonization” with SDTM is maintained
- This Webinar Series will cover each conformance rule, with examples of which rules are “built in” to the NCI GLIB ALS and how they have been addressed

Session	Topic Covered
1	Introduction to how CDASH is harmonized with SDTM at the Model and IG level
2	Conformance Rule: Use Variable Naming Conventions that make it easy to create SDTM datasets
3	Conformance Rule: Use the required SDTM controlled terminology to collect data
4	Conformance Rule: Use the published Question Text or Prompt to ask the questions on the CRF
5	Conformance Rule: Follow the Core Designations Conformance Rule: Follow CDASH Best Practices

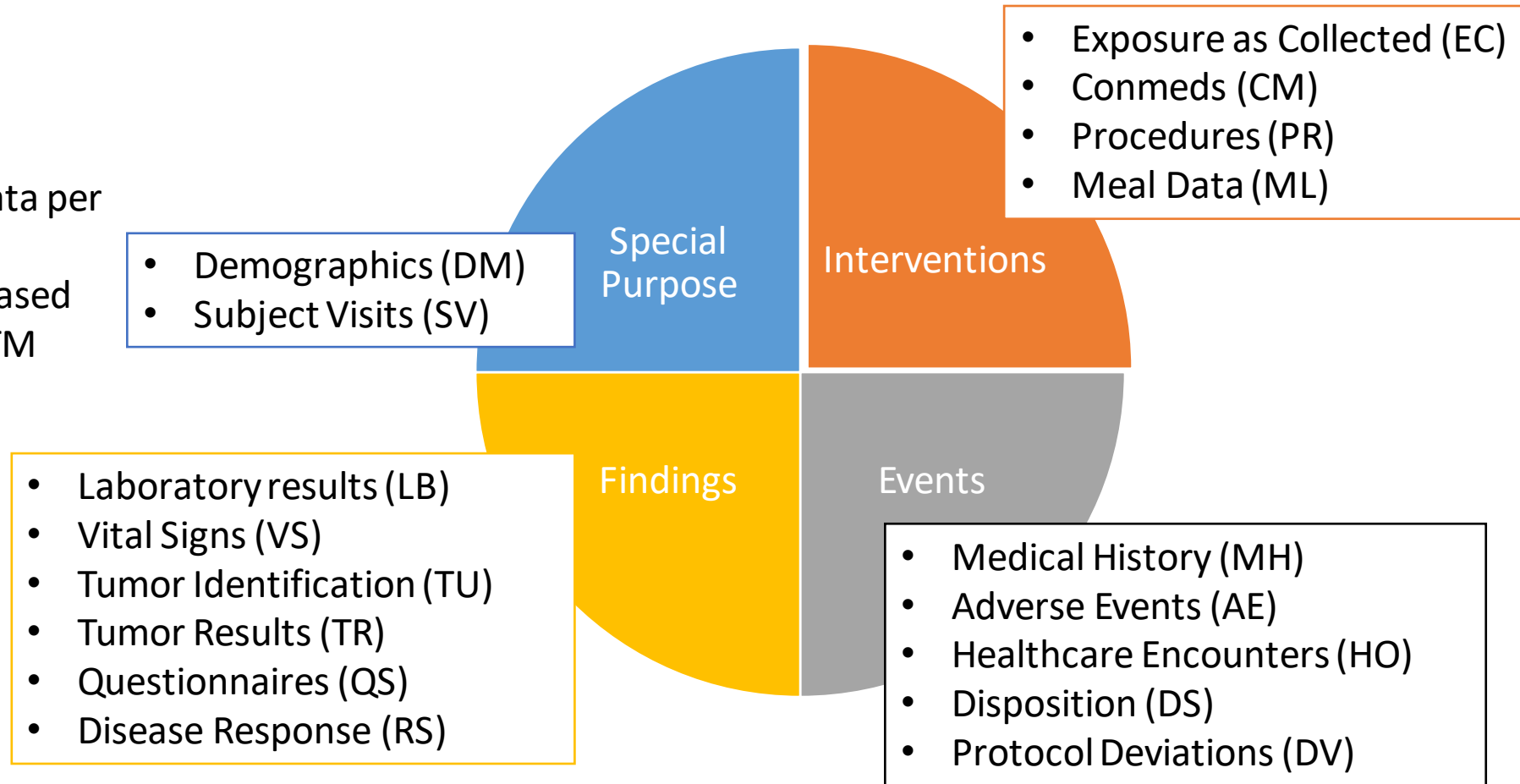
Review SDTM and CDASH General Observation Classes

- SDTM Model - Root Dataset Structures:
 - Observation Class-based sets of variables (with some “Special Purpose” datasets) designed to model all clinical data from a study



Review SDTMIG and CDASHIG Domains

- One topic of data per domain
- Each domain based on a single SDTM (Model) Class

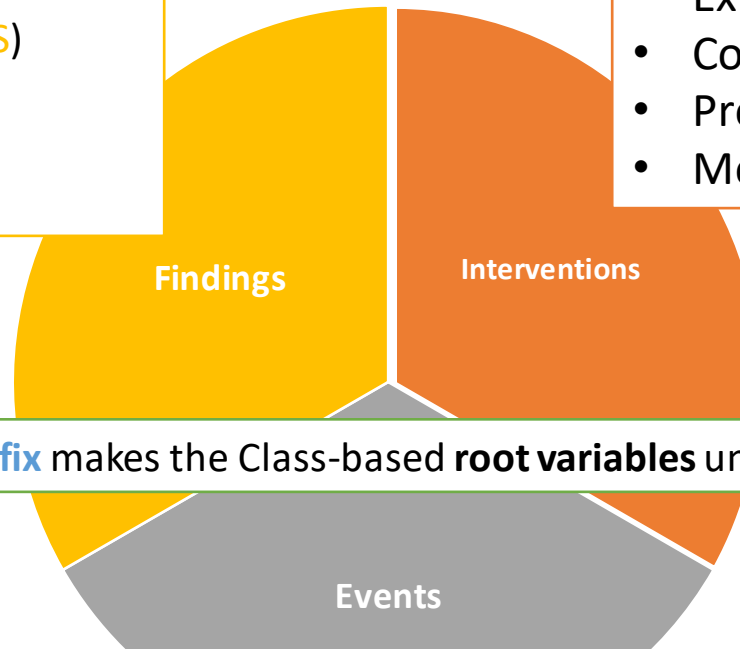


A **2-character** domain code is specified and reserved for each standard topic / domain

Example Class-Based Variables From SDTMIG

- Laboratory results (LBTESTCD, LBTEST, LBORRES)
- Vital Signs (VSTESTCD, VSTEST, VSORRES)
- Tumor Identification (TUTESTCD, TUTEST, TUORRES)
- Tumor Results (TRTESTCD, TRTEST, TRORRES)
- Questionnaires (QSTESTCD, QSTEST, QSORRES)
- Disease Response (RSTESTCD, RSTEST, RSORRES)

- Exposure as Collected (ECTRTRT, ECDOSE)
- Conmeds (CMTTRT, CMDOSE)
- Procedures (PRTTRT, PRDOSE)
- Meal Data (MLTRTRT, MLDOSE)



The **2-character domain code prefix** makes the Class-based **root variables** unique and specific to the domain topic.

- Medical History (MHTERM, MHSEV)
- Adverse Events (AETERM, AEDECOD, AESEV)
- Healthcare Encounters (HOTERM)
- Disposition (DSTERM, DSDECOD)
- Protocol Deviations (DVTERM, DVDECOD)

Where to Find Domain Codes

- Two primary sources where Domain information is published
 - SDTM Controlled Terminology (Domain Abbreviation codelist C66734)
 - SDTMIG Domain Index

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym	Domain Code	Domain Description
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	AG	<p>Procedure Agents</p> <p>An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.</p>
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	CM	<p>Concomitant and Prior Medications</p> <p>An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.</p>
C117755	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	EC and EX	<p><u>Exposure Domains</u></p> <p>Exposure (EX)</p> <p>An interventions domain that contains the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.</p> <p>Exposure as Collected (EC)</p> <p>An interventions domain that contains information about protocol-specified study treatment administrations, as collected.</p>
C111138	C66734		SDTM Domain Abbreviation	BE	Biospecimen Events		
C111138	C66734		SDTM Domain Abbreviation	BS	Biospecimen Findings		
C85441	C66734		SDTM Domain Abbreviation	CE	Clinical Events		
C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medical		
C49569	C66734		SDTM Domain Abbreviation	CO	Comments		
C102605	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Fir		
C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability		
C95087	C66734		SDTM Domain Abbreviation	DD	Death Details; Death Diag Details		
C102618	C66734		SDTM Domain Abbreviation	DE	Device Events		
C102618	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	ML	<p>Meal Data</p> <p>Information regarding the subject's meal consumption, such as fluid intake, amounts, form (solid or liquid state), frequency, etc., typically used for pharmacokinetic analysis.</p>
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	PR	<p>Procedures</p> <p>An interventions domain that contains interventional activity intended to have diagnostic, preventive, therapeutic, or palliative effects.</p>
C102619	C66734		SDTM Domain Abbreviation	DO	Device Properties		
C102620	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationsh		
C49576	C66734		SDTM Domain Abbreviation	DS	Disposition	SU	<p>Substance Use</p> <p>An interventions domain that contains substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use.</p>
C102621	C66734		SDTM Domain Abbreviation	DT	Device Tracking and Dispo		

DOMAIN Controlled Terminology (CT)

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Prefer
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submi Abbreviation Termin
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Doma
C11775	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Do
			SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events
			SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Doma
			SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Doma
			SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medical
			SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
			SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular Syste Domain
			SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability D
C95087	C66734		SDTM Domain Abbreviation	DD	Death Details; Death Diagnosis and Details	A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Do
C10261	C66734		SDTM Domain Abbreviation	DE	Device Events	An events domain that contains data for device-related events.	Device Events Doma
C102618	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Do
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Dom
C102619	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Do
C102620	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Re
C49576	C66734		SDTM Domain Abbreviation	DS	Disposition	An events domain that contains information encompassing and representing data related to subject disposition.	Disposition Domain
C102621	C66734		SDTM Domain Abbreviation	DT	Device Tracking and Disposition	A events domain that contains the logistics and disposition information specific to a given device.	Device Tracking and Domain

Reference the DOMAIN Controlled Terminology (C66734) for a list of all reserved domain codes, domain names and definitions.

Domain Index in SDTMIG

Domain Code	Domain Description
AG	<p>Procedure Agents</p> <p>An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.</p>
CM	<p>Concomitant and Prior Medications</p> <p>An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.</p>
EC and EX	<p><u>Exposure Domains</u></p> <p>Exposure (EX)</p> <p>An interventions domain that contains the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.</p> <p>Exposure as Collected (EC)</p> <p>An interventions domain that contains information about protocol-specified study treatment administrations, as collected.</p>
ML	<p>Meal Data</p> <p>Information regarding the subject's meal consumption, such as fluid intake, amounts, form (solid or liquid state), frequency, etc., typically used for pharmacokinetic analysis.</p>
PR	<p>Procedures</p> <p>An interventions domain that contains interventional activity intended to have diagnostic, preventive, therapeutic, or palliative effects.</p>
SU	<p>Substance Use</p> <p>An interventions domain that contains substance use information that may be used to assess the efficacy and/or safety of therapies that look to mitigate the effects of chronic substance use.</p>

6 DOMAIN MODELS BASED ON THE GENERAL OBSERVATION CLASSES

6.1 Models for Interventions Domains

6.1.1 Procedure Agents

6.1.2 Concomitant and Prior Medications

6.1.3 Exposure Domains

6.1.3.1 Exposure

6.1.3.2 Exposure as Collected

6.1.3.3 Exposure/Exposure as Collected Examples

6.1.4 Meal Data

6.1.5 Procedures

6.1.6 Substance Use

6.2 Models for Events Domains

6.2.1 Adverse Events

6.2.2 Clinical Events

6.2.3 Disposition

6.2.4 Protocol Deviations

6.2.5 Healthcare Encounters

6.2.6 Medical History

6.3 Models for Findings Domains

6.3.1 Drug Accountability

6.3.2 Death Details

6.3.3 ECG Test Results

6.3.4 Inclusion/Exclusion Criteria Not Met

6.3.5 Immunogenicity Specimen Assessments

6.3.6 Laboratory Test Results

6.3.7 Microbiology Domains

Domain Index in SDTMIG

Domain Code	Domain Description
AE	<p>Adverse Events</p> <p>An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.</p>
CE	<p>Clinical Events</p> <p>An events domain that contains clinical events of interest that would not be classified as adverse events.</p>
DS	<p>Disposition</p> <p>An events domain that contains information encompassing and representing data related to subject disposition.</p>
DV	<p>Protocol Deviations</p> <p>An events domain that contains protocol violations and deviations during the course of the study.</p>
HO	<p>Healthcare Encounters</p> <p>An events domain that contains data for inpatient and outpatient healthcare events (e.g., hospitalization, nursing home stay, rehabilitation facility stay, ambulatory surgery).</p>
MH	<p>Medical History</p> <p>The medical history dataset includes the subject's prior history at the start of the trial. Examples of subject medical history information could include general medical history, gynecological history, and primary diagnosis.</p>

6 DOMAIN MODELS BASED ON THE GENERAL OBSERVATION CLASSES

6.1 Models for Interventions Domains

6.1.1 Procedure Agents

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6.1.3.3 Exposure/Exposure as Collected Examples

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6.1.5 Procedures

6.1.6 Substance Use

6.2 Models for Events Domains

6.2.1 Adverse Events

6.2.2 Clinical Events

6.2.3 Disposition

6.2.4 Protocol Deviations

6.2.5 Healthcare Encounters

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6.3 Models for Findings Domains

6.3.1 Drug Accountability

6.3.2 Death Details

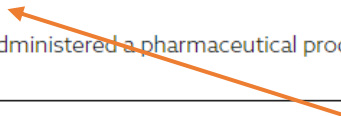
6.3.3 ECG Test Results

6.3.4 Inclusion/Exclusion Criteria Not Met

6.3.5 Immunogenicity Specimen Assessments

6.3.6 Laboratory Test Results

6.3.7 Microbiology Domains



Domain Index in SDTMIG

Domain Code	Domain Description
DA	Drug Accountability A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.
DD	Death Details A findings domain that contains the diagnosis of the cause of death for a subject.
EG	ECG Test Results A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.
IE	Inclusion/Exclusion Criteria Not Met A findings domain that contains those criteria that cause the subject to be in violation of the inclusion/exclusion criteria.
IS	Immunogenicity Specimen Assessments A findings domain for assessments that determine whether a therapy induced an immune response.
LB	Laboratory Test Results A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.
MB and MS	<u>Microbiology Domains</u> Microbiology Specimen (MB) A findings domain that represents non-host organisms identified including bacteria, viruses, parasites, protozoa and fungi. Microbiology Susceptibility (MS) A findings domain that represents drug susceptibility testing results only. This includes phenotypic testing (where drug is added directly to a culture of organisms) and genotypic tests that provide results in terms of susceptible or resistant. Drug susceptibility testing may occur on a wide variety of non-host organisms, including bacteria, viruses, fungi, protozoa and parasites.
MI	Microscopic Findings A findings domain that contains histopathology findings and microscopic evaluations.

6 DOMAIN MODELS BASED ON THE GENERAL OBSERVATION CLASSES

6.1 Models for Interventions Domains

6.1.1 Procedure Agents

6.1.2 Concomitant and Prior Medications

6.1.3 Exposure Domains

6.1.3.1 Exposure

6.1.3.2 Exposure as Collected

6.1.3.3 Exposure/Exposure as Collected Examples

6.1.4 Meal Data

6.1.5 Procedures

6.1.6 Substance Use

6.2 Models for Events Domains

6.2.1 Adverse Events

6.2.2 Clinical Events

6.2.3 Disposition

6.2.4 Protocol Deviations

6.2.5 Healthcare Encounters

6.2.6 Medical History

6.3 Models for Findings Domains

6.3.1 Drug Accountability

6.3.2 Death Details

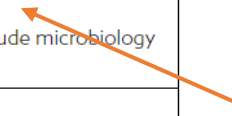
6.3.3 ECG Test Results

6.3.4 Inclusion/Exclusion Criteria Not Met

6.3.5 Immunogenicity Specimen Assessments

6.3.6 Laboratory Test Results

6.3.7 Microbiology Domains



Review CDASH Alignment to SDTM



Same overall structure

- Same general observation classes
- Same special purpose domains

Same domain topics and naming conventions (DM = DM, AE=AE)

- However, CDASH does not put restrictions on how to organize questions
- Multiple domain questions can be on the same data collection form (DM, VS)
- Multiple data collection forms can all be about the same topic (VS at each visit)

Mostly the same variables

Covered in more detail in future sessions

- Same meaning (definitions are important) ensured through QText/Prompt (PreText)
- A few differences to meet data collection needs (DAT/TIM vs DTC, Findings class with multiple TESTs)
- Additional variables (e.g., common non-standard concepts, edit checks)

Same terminology

- Same meaning (definitions)
- Can display synonyms (user friendly) but should store the CDISC Submission Value to avoid transformations
- Use --TESTCD terminology to construct FieldOIDs/ --TEST for PreText

CDASH Conformance

Relevant CDASH conformance considerations:

- Use the available domains for their intended purpose
- Use Model to create new domains

Achieve CDASH conformance at this level (Model and IG) by using the right Forms from the NCI GLIB ALS

- NCI GLIB ALS has SDTMIG/CDASHIG domains “built in”
- To conform to CDASH, use the right Form in the GLIB ALS for the data you need to collect
- Create new (custom) forms that also conform to CDASH

Finding the Right Form in Rave GLIB ALS - **Step 1**

Identify the SDTMIG / CDASHIG Domain Code

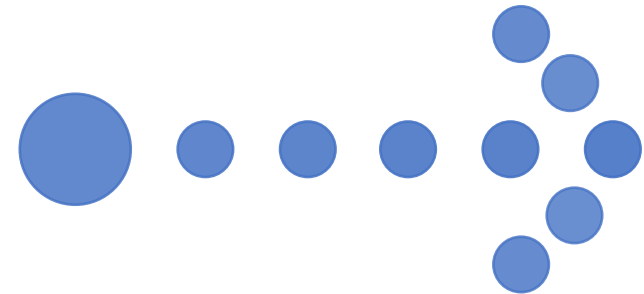
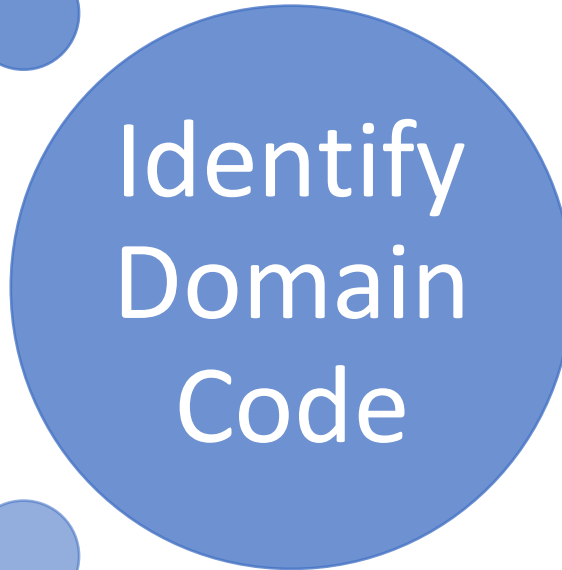
DOMAIN CT



SDTMIG Index



--TESTCD CT



Find the right Form in the GLIB ALS: Step 1- Identify the Correct Domain

In the SDTMIG: Identify the correct domain “topic” of the data you are collecting by reviewing the **Domain Descriptions** in the SDTMIG Index

Hint: *identifying the Observation Class first can help guide you to the right Index.*

Domain Code	Domain Description	Domain Code	Domain Description
AG	Procedure Agents An intervention and therapy agents and their intent.	DA	Drug Accountability A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.
CM	Concomitant and Prior Medications An interventions domain that contains concomitant appropriate medications.	DD	Death Details A findings domain that contains the cause of death for a subject.
EC and EX	Exposure Domain Exposure (EX) An interventions that is prospective Exposure as Collected An interventions	AE	Adverse Events An events domain that includes events and which may not be expected.
ML	Meal Data Information regarding pharmacokinetic	CE	Events An events domain that includes events and which may not be expected.
PR	Procedures An interventions	DS	Disposition An events domain that includes events and which may not be expected.
SU	Substance Use An interventions the effects of ch	DV	Protocol Deviations An events domain that includes events and which may not be expected.
		HO	Healthcare Encounters A events domain that includes events and which may not be expected.
		MH	Medical History The medical history of a subject, including general medical history.
		EG	ECG Test Results A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the ECG including an overall interpretation if collected or derived.
		IE	Inclusion/Exclusion Criteria Not Met A findings domain that contains those criteria that cause the subject to be in violation of the inclusion/exclusion criteria.
		IS	Immunogenicity Specimen Assessments A findings domain for assessments that determine whether a therapy induced an immune response.
		LB	Laboratory Test Results A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.
		MB and MS	<u>Microbiology Domains</u> Microbiology Specimen (MB) A findings domain that represents non-host organisms identified including bacteria, viruses, parasites, protozoa and fungi. Microbiology Susceptibility (MS) A findings domain that represents drug susceptibility testing results only. This includes phenotypic testing (where drug is added directly to a culture of organisms) and genotypic tests that provide results in terms of susceptible or resistant. Drug susceptibility testing may occur on a wide variety of non-host organisms, including bacteria, viruses, fungi, protozoa and parasites.
		MI	Microscopic Findings A findings domain that contains histopathology findings and microscopic evaluations.

Find the right Form in the GLIB ALS: Step 1- Identify the Correct (SDTMIG/CDASHIG) Domain

(or) In SDTM CT: Identify the correct domain “topic” of the data you are collecting by reviewing the DOMAIN terminology codelist names and Definitions

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submission Abbreviation Terminology
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Domain
C117755	C66734		SDTM Domain Abbreviation	PA	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Domain
C111138	C66734		SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events Domain
C11113	C66734		SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Domain
C85441	C66734		SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Domain
C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medication Domain
C49569	C66734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
C102605	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular System Domain
C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability Domain
C95087	C66734		SDTM Domain Abbreviation	DD	Death Details, Death Diagnosis and Cause of Death	A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Domain
C10261	C66734		SDTM Domain Abbreviation	DE	Device Events	An events domain that contains data for device-related events.	Device Events Domain
C102618	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Domain
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Domain
C102619	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Domain
C102620	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Relationships Domain
C49576	C66734		SDTM Domain Abbreviation	DS	Disposition	An events domain that contains information encompassing and representing data related to subject disposition.	Disposition Domain
C102621	C66734		SDTM Domain Abbreviation	DT	Device Tracking and Disposition	A events domain that contains the logistics and disposition information specific to a given device.	Device Tracking and Disposition Domain

Domain 'topic' names

Domain 'topic' definitions

Benefit of using **SDTMIG** to identify the domain: Assumptions and Examples

If you need more information than what the definition / description provides:

- Look at the Assumptions and Examples

Domain Code	Domain Description
AG	Procedure Agents

AG?

AG - Assumptions

1. AG Purpose: Some tests involve administration of substances, and it has been unclear what domain these should be represented in.
 - a. The Concomitant Medications domain seemed particularly inappropriate when the substance was one that would never be given as a medication. Even substances that are medications are not being used as such when they are given as part of a testing procedure.
 - b. The Exposure domain also seemed inappropriate, since although the testing procedure might be part of the study plan, these data would not be used or analyzed in the same way as data about study treatments. The Procedure Agents domain was created to fill this gap.
 - c. The Procedure Agents domain has advantages over the Procedures domain for this purpose. It allows recording of multiple substance administrations for a single testing procedure. It also separates data about substance administrations from data about procedures that do not involve substance administration.
 - d. Information about the conduct of the procedure with which the procedure agent administration was associated, if collected, should be represented in the Procedures (PR) domain.
2. AG Examples and Structure
 - a. Examples of agents administered as part of a procedure include a short-acting bronchodilator administered as part of a reversibility assessment and contrast agents or radio-labeled substances used in imaging studies.
 - b. The structure of the AG domain is one record per agent intervention episode, or pre-specified agent assessment per subject. It is the sponsor's

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGLNKID	AGTRT	AGCAT	AGDOSE	AGDOSU	AGROUTE	AGSTDT
1	ABC123	AG	CD01-101	1	03	IODINATED CONTRAST AGENT	CONTRAST AGENT	100	MBq	INTRAVENOUS	2019-05-22T09:00
2	ABC123	AG	CD01-101	2	03	BARIUM SULFATE SUSPENSION	CONTRAST AGENT	500	mL	ORAL	2019-05-22T08:30
3	ABC123	AG	CD01-102	1	04	GADOLINIUM-BASED SOLUTION	CONTRAST AGENT	170	MBq	INTRAVENOUS	2019-05-22T07:20
4	ABC123	AG	CD01-102	2	04	BARIUM SULFATE SUSPENSION	CONTRAST AGENT	500	mL	ORAL	2019-05-22T07:00
5	ABC123	AG	CD01-103	1	05	POLYETHYLENE GLYCOL	CONTRAST AGENT	500	mL	ORAL	2019-05-22T07:00

Benefit of using **SDTMIG** to identify the domain: Topic Terminology

If you need more information than what the definition / description provides:

- Look at the Assumptions and Examples
- Look at CT for the “**Topic**” variable (or its Synonym Qualifier variable)

6.3.14	Subject Characteristics
6.3.15	Subject Status
6.3.16	Tumor/Lesion Domains
6.3.16.1	Tumor/Lesion Identification
6.3.16.2	Tumor/Lesion Results
6.3.16.3	Tumor Identification/Tumor Results Examples
6.3.17	Vital Signs

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	
Subject Characteristic Test Code	SCTESTCD	Subject Characteristic Test Code	The test code represents
Subject Characteristic Test Code	BRFEDIND	Breast Fed Indicator	An indication as to whether (breast fed) as an infant.
Subject Characteristic Test Code	CTRYDEXP	Country of Potential Disease Exposure	System of classification of countries based on exposure to a disease, regardless of where the subject resides.
Subject Characteristic Test Code	DDDTYPE	Deceased Donor Donation Type	The conditions under which the subject was included in the study, including the condition of the donor.
Subject Characteristic Test Code	EDULEVEL	Level of Education Attained	Highest level of education completed by the subject.
Subject Characteristic Test Code	GENIDENT	Gender Identity	A person's internally felt gender identity, which may or may not correspond to the individual's sex assigned at birth.
Subject Characteristic Test Code	GSTABRTH	Gestational Age at Birth	The gestational age of the subject at birth.
Subject Characteristic Test Code	HANDDOM	Dominant Hand	The preferred hand of the subject for most tasks.
Subject Characteristic Test Code	INCMLVL	Income Level	An indication of the position of the subject in the economic support.
Subject Characteristic Test Code	JOBCLAS	Employee Job Class	A code qualifying the employee's position, time, etc.
Subject Characteristic Test Code	MARISTAT	Marital Status	A demographic parameter indicating the subject's marital status.
Subject Characteristic Test Code	NATORIG	National Origin	System of classification of countries based on the subject's origin, regardless of the nation of birth.
Subject Characteristic Test Code	RISKPOP	Member of High Risk Population	An indication that a subject is part of a population group that has a greater chance of contracting a disease or disorder.

6.3.14 Subject Characteristics

SC - Description/Overview

A findings domain that contains subject-related data

SC - Specification

sc.xpt, Subject Characteristics – Findings, Version 3

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	SC	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
SCSEQ	Sequence Number	Num		Identifier
SCGRPID	Group ID	Char		Identifier
SCSPID	Sponsor-Defined Identifier	Char		Identifier
SCTESTCD	Subject Characteristic Short Name	Char	(SCTESTC D)	Topic
SCTEST	Subject Characteristic	Char	(SCTEST)	Synonym Qualifier

Benefit of using **SDTMIG** to identify the domain: Topic Terminology

If you need more information than what the definition / description provides:

- Look at the Assumptions and Examples
- Look at CT for the “**Topic**” variable

6.3.14	Subject Characteristics
6.3.15	Subject Status
6.3.16	Tumor/Lesion Domains
6.3.16.1	Tumor/Lesion Identification
6.3.16.2	Tumor/Lesion Results
6.3.16.3	Tumor Identification/Tumor Results Examples
6.3.17	Vital Signs

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	
Subject Status Test Code	SSTESTCD	Subject Status Test Code	Terminology evaluated
Subject Status Test Code	SURVSTAT	Survival Status	The state where the

6.3.15 Subject Status

SS – Description/Overview

A findings domain that contains general subject characteristics

SS – Specification

ss.xpt, Subject Status – Findings, Version 3.3. One record

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	SS	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
SSSEQ	Sequence Number	Num		Identifier
SSGRPID	Group ID	Char		Identifier
SSSPID	Sponsor-Defined Identifier	Char		Identifier
SSTESTCD	Status Short Name	Char	(SSTESTCD)	Topic

Benefit of using **SDTMIG** to identify the domain: Topic Terminology

If you need more information than what the definition / description provides:

- Look at the Assumptions and Examples
- Look at CT for the “Topic” variable

- 6.3.14 Subject Characteristics
- 6.3.15 Subject Status
- 6.3.16 Tumor/Lesion Domains
 - 6.3.16.1 Tumor/Lesion Identification
 - 6.3.16.2 Tumor/Lesion Results
 - 6.3.16.3 Tumor Identification/Tumor Results Examples
- 6.3.17 Vital Signs

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
Vital Signs Test Code	VSTESTCD	Vital Signs Test Code	The test code given to the test that analyze including temperature, respiratory rate, hear
Vital Signs Test Code	BMI	Body Mass Index	A general indicator of the body fat an individ ratio of weight to height. (NCI)
Vital Signs Test Code	BMR	Basal Metabolic Rate	The measurement of a subject's energy exp
Vital Signs Test Code	BSA	Body Surface Area	A measure of the 2-dimensional extent of th Body surface area (BSA) can be calculated a chart that relates height to weight. BSA is dosing. (NCI)
Vital Signs Test Code	CHESTCIR	Chest Circumference	The distance around an individual's chest.
Vital Signs Test Code	DIABP	Diastolic Blood Pressure	The minimum blood pressure in the system cardiac cycle.
Vital Signs Test Code	FRMSIZE	Body Frame Size	The categorization of a person's body frame based on the measurement of wrist circumf elbow. (NCI)
Vital Signs Test Code	HDCIRC	Head Circumference	A circumferential measurement of the head
Vital Signs Test Code	HEIGHT	Height	The vertical measurement or distance from t the vertical dimension of extension. (NCI)
Vital Signs Test Code	HR	Heart Rate	The number of heartbeats per unit of time u minute. (NCI)
Vital Signs Test Code	PULSE	Pulse Rate	The rate of the pulse as observed in an ar minute. It can be measured at several anic neck, temple, groin, behind the knees, or o
Vital Signs Test Code	RESP	Respiratory Rate	The rate of breathing (inhalation and exhalation) measured within a unit time, usually expressed as breaths per minute. (NCI)
Vital Signs Test Code	SYSBP	Systolic Blood Pressure	The maximum blood pressure in the systemic arterial circulation during the cardiac cycle.
Vital Signs Test Code	TEMP	Body Temperature; Temperature	A measurement of the temperature of the body.
Vital Signs Test Code	TEMPCB	Core Body Temperature	A measurement of the temperature within the deep tissues of the body.

6.3.17 Vital Signs

VS - Description/Overview

A findings domain that contains measurements includ

VS - Specification

vs.xpt, Vital Signs – Findings, Version 3.3. One recor

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	Role
STUDYID	Study Identifier	Char		Identifier
DOMAIN	Domain Abbreviation	Char	VS	Identifier
USUBJID	Unique Subject Identifier	Char		Identifier
VSSEQ	Sequence Number	Num		Identifier
VSGRPID	Group ID	Char		Identifier
VSSPID	Sponsor-Defined Identifier	Char		Identifier
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTC D)	Topic

Benefit of using **DOMAIN CT** to identify the domain: Comprehensive

ALL domains from ALL published IGs are included in a single list

RECOMMENDATION: Start with DOMAIN CT, then if you need more information about a domain, find it in the SDTMIG and review Assumptions and Examples, or review Topic CT.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submission Domain Abbreviation Terminology
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Domain
C117755	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Domain
C132354	C66734		SDTM Domain Abbreviation	APDM	Associated Persons Demographics	The demographics domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Submission Domain
C147172	C66734		SDTM Domain Abbreviation	APLB	Associated Persons Laboratory Test Results	The laboratory test results domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Results Domain
C147173	C66734		SDTM Domain Abbreviation	APMH	Associated Persons Medical History	The medical history domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Domain
C111138	C66734		SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events Domain
C111138	C66734		SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Findings Domain
C85441	C66734		SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Domain
C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medications Domain
C49569	C66734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
C102605	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular System Findings Domain
C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability Domain
C95087	C66734		SDTM Domain Abbreviation	DD	Death Details; Death Diagnosis and Details	A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Domain
C102618	C66734		SDTM Domain Abbreviation	DE	Device Events	An events domain that contains data for device-related events.	Device Events Domain
C102618	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Domain
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Domain
C102619	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Domain
C102620	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Relationships Domain

SDTMIG

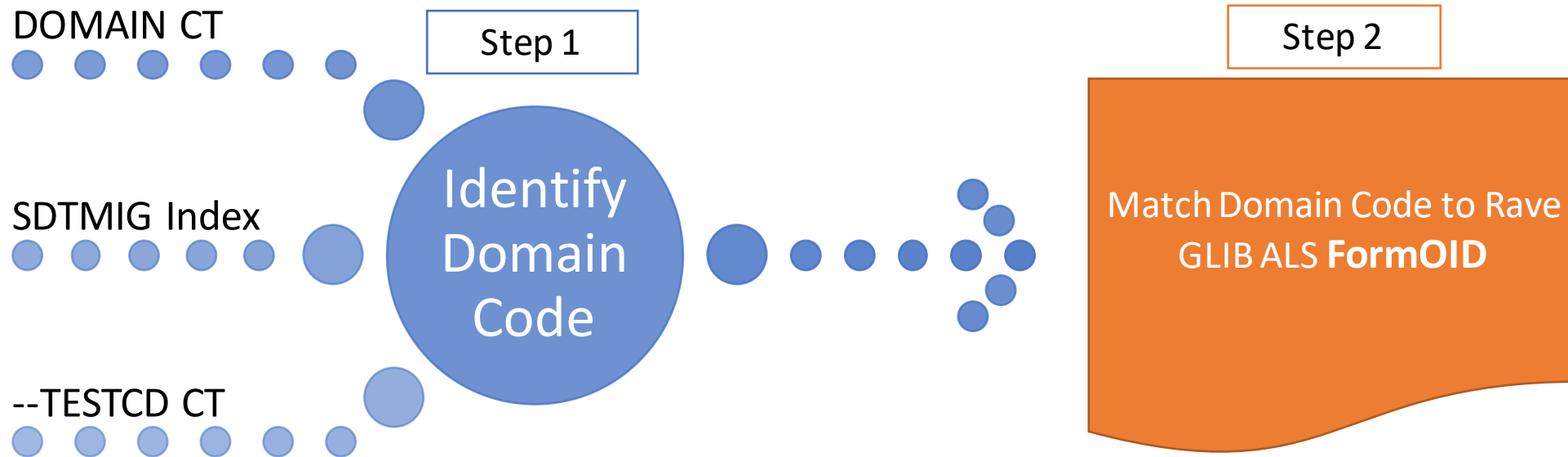
SDTMIG-AP

SDTMIG-PGx

SDTMIG-MD

Finding the Right Form in Rave GLIB ALS - **Step 2**

Find the Rave GLIB ALS FormOID that Matches the Domain Code



Find the right Form in the GLIB ALS: Step 1- Identify the Correct (SDTMIG/CDASHIG) Domain

Either method (SDTMIG Index or DOMAIN CT) will give you the **2-character domain code**

Domain codes

Domain Code	Domain Description	Domain Code	Domain Description						
DA	Drug Accountability	DA	Drug Accountability						
AG	Procedure Agents	AG	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.						
DD	Death Details	DD	A findings domain that contains the diagnosis of the cause of death for a subject.						
EG	ECG Test Results	EG	A findings domain that contains ECG data, including position of the subject, method of evaluation, all cycle measurements and all findings from the						
Domain Code	Domain Description	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred
AE	Adverse Events	C66734	C66734	Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submission Terminology
CE	Clinical Events	C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Domain
AG	Procedure Agents	C11775	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Domain
BE	Biospecimen Events	C11113	C66734		SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events Domain
BS	Biospecimen Findings	C11113	C66734		SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Domain
CE	Clinical Events	C85441	C66734		SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Domain
CM	Concomitant/Prior Medications	C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medication Domain
CO	Comments	C49569	C66734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
CV	Cardiovascular System Findings	C10260	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular System Domain
DA	Drug Accountability	C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability Domain
DD	Death Details; Death Diagnosis and Details	C95087	C66734		SDTM Domain Abbreviation	DD	Death Details; Death Diagnosis and Details	A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Domain
DE	Device Events	C10261	C66734		SDTM Domain Abbreviation	DE	Device Events	An events domain that contains data for device-related events.	Device Events Domain
DI	Device Identifiers	C10261	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Domain
DM	Demographics	C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Domain
DO	Device Properties	C10261	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Domain
DR	Device-Subject Relationships	C10262	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Relationship Domain
DS	Disposition	C49576	C66734		SDTM Domain Abbreviation	DS	Disposition	An events domain that contains information encompassing and representing data related to subject disposition.	Disposition Domain
DT	Device Tracking and Disposition	C10262	C66734		SDTM Domain Abbreviation	DT	Device Tracking and Disposition	A events domain that contains the logistics and disposition information specific to a given device.	Device Tracking and Disposition Domain

Find the right Form in the GLIB ALS: Step 2 - Find the FormOID that matches the Domain code

FormOID=Domain Code

In the GLIB ALS:
Look for the
FormOID that
matches the
Domain Code

FormOID	FieldOID	DataDictionaryName	PreText	F
CM	FORM_OID		FORM_OID	
CM	CM_CMCAT_SPD	LPO_TBD	(Concomitant) [Medication/Treatment/Therapy Category]; NULL	
CM	CM_CMSCAT_SPD	LPO_TBD	(Concomitant) [Medication/Treatment/Therapy subcategory]; NULL	
CM	CM_CMYN	CDISC_SD TM_YES_PID6343337_V1_OF	Were any (concomitant) [medication(s)/treatment(s)/therap(ies)] taken?	
CM	CM_CMSPID		[Line Number/CM Number]	
CM	CM_CMTRT		What was the (concomitant) [medication/treatment/therapy] (name/term)?	
CM	CM_CMOCCUR	CDISC_SD TM_YES_PID6343337_V1_OF	Did the subject take [pre-specified (concomitant) medication/treatment/therapy/dose]?; Has the subject taken [pre-specified (concomitant) medication/treatment/therapy/dose]?	
CM	CM_CMINGRD		What were the active ingredients?	
CM	CM_CMINDC		For what indication, was the (concomitant) [medication/treatment/therapy] taken?	
CM	CM_CMAENO		What was the identifier for the adverse event(s) for which the (concomitant) [medication/treatment/therapy] was taken?	
			What was the identifier for the medical history event(s) for which the (concomitant)	

CRFDraft | Forms | **Fields** | Folders | DataDictionaries | DataDictionaryEntries | UnitDictionaries | UnitDictionaries

Example: Identify the right domain for “prior radiotherapy”

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used to identify a data element in a CDISC submission. The domain abbreviation is used in the dataset submission, i.e. in the dataset name, within the dataset, and as a prefix in the CDISC Glossary.	
C49563	C66734		SDTM Domain Abbreviation	AD	Analysis Dataset	A two-letter prefix used to denote a data element that is used for reporting information about the study. It contains information about the study or subject, but not necessarily about the data element.	
C49562	C66734						
C117755	C66734						
C147168	C66734						
C147169	C66734						
C147170	C66734		SDTM Domain Abbreviation	APDD	Associated Persons Death Details	The death details domain for the particular study subject, or a death details domain for the particular study subject, or a death details domain for the particular study subject.	
C132354	C66734		SDTM Domain Abbreviation	APDM	Associated Persons Demographics	The demographics domain for the particular study subject, or a demographics domain for the particular study subject, or a demographics domain for the particular study subject.	

Review the DOMAIN CT for definitions that include “Therap” (therapy, therapeutic...)

Review definitions for domains that are filtered

Sort A to Z
Sort Z to A
Sort by Color
Sheet View
Clear Filter From "CDISC Definition"
Filter by Color
Text Filters
therap

- (Select All Search Results)
- Add current selection to filter
- A findings domain for assessments that determine whether a therapy induced an immune response.
- A findings domain for the assessment of disease response to therapy, or clinical classification based on response and Clin Classification
- An interventions domain that contains interventional activity intended to have diagnostic, preventive, therapeutic, or palliative effects.
- An interventions domain that contains substance use information that may be used to assess the effects of chronic substances that look to mitigate

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C117755	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.
C112320	C66734		SDTM Domain Abbreviation	IS	Immunogenicity Specimen Assessments	A findings domain for assessments that determine whether a therapy induced an immune response.
C102700	C66734		SDTM Domain Abbreviation	PR	Procedures	An interventions domain that contains interventional activity intended to have diagnostic, preventive, therapeutic, or palliative effects.
C107097	C66734		SDTM Domain Abbreviation	RS	Response and Clin Classification	A findings domain for the assessment of disease response to therapy, or clinical classification based on response and Clin Classification
C49615	C66734		SDTM Domain Abbreviation	SU	Substances Used	An interventions domain that contains substance use information that may be used to assess the effects of chronic substances that look to mitigate

probably “Procedures”

Review definitions

Example: Identify the right domain for “prior radiotherapy”

Confirm by reviewing the Procedures Assumptions and Examples in the SDTMIG.

Domain code is “PR”

pr.xpt

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRDOSE	PRDOSU	PRLOC	PRLAT	PRSTDTC	PRENDTC
1	ABC123	PR	ABC123-1001	1	External beam radiation therapy	70	Gy	BREAST	RIGHT	2011-06-01	2011-06-25
2	ABC123	PR	ABC123-2002	1	Brachytherapy	25	Gy	PROSTATE		2011-07-15	2011-07-15
3	ABC123	PR	ABC123-3003	1	Radiotherapy	300	cGy	BONE		2011-08-19	2011-08-22

5	MODELS FOR	SDTMIG V3.3
5.1	Common	
5.2	Demographics	
5.3	Subject Elements	
5.4	Subject Disease Milestones	
5.5	Subject Visits	
6	DOMAIN MODELS BASED ON THE GENERAL OBSERVATION CLASSES	
6.1	Models for Interventions Domains	
6.1.1	Procedure Agents	
6.1.2	Concomitant and Prior Medications	
6.1.3	Exposure Domains	
6.1.3.1	Exposure	
6.1.3.2	Exposure as Collected	
6.1.3.3	Exposure/Exposure as Collected Examples	
6.1.4	Medications	
6.1.5	Procedures	
6.1.6	Substances	

PR - Assumptions

1. Some example procedures by type include the following:

- Disease screening (e.g., mammogram, pap smear)
- Endoscopic examinations (e.g., arthroscopy, diagnostic colonoscopy, therapeutic colonoscopy, diagnostic laparoscopy, therapeutic laparoscopy)
- Diagnostic tests (e.g., amniocentesis, biopsy, catheterization, cutaneous oximetry, finger stick, fluorophotometry, imaging techniques (e.g., DXA scan, CT scan, MRI), phlebotomy, pulmonary function test, skin test, stress test, tympanometry)
- Therapeutic procedures (e.g., ablation therapy, catheterization, cryotherapy, mechanical ventilation, phototherapy, radiation therapy/radiotherapy, thermotherapy)
- Surgical procedures (e.g., curative surgery, diagnostic surgery, palliative surgery, therapeutic surgery, prophylactic surgery, resection, stenting, hysterectomy, tubal ligation, implantation)

Example: Identify the right domain for “prior radiotherapy”

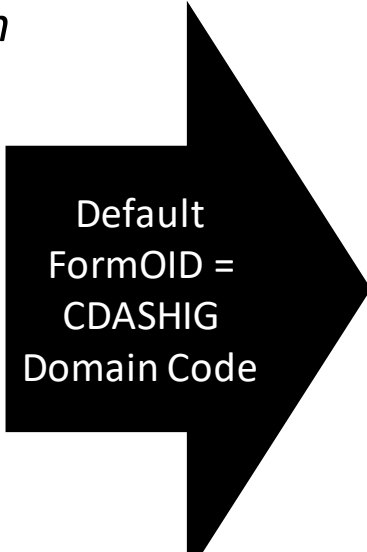
NCI GLIB ALS

FormOID	FieldOID	VariableOID	DataDictionaryName	PreText
PR	FORM_OID	FORM_OID		{FORM_OID
PR	PR_PRYN	PR_PRYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any surgical, therapeutic or diagnostic procedures performed?
PR	PR_PRCAT	PR_PRCAT	LPO_TBD	{[Procedure Category]; NULL
PR	PR_PRSCAT	PR_PRSCAT	LPO_TBD	{[Procedure Subcategory]; NULL
PR	PR_PRSPID	PR_PRSPID		{[Line Number/PR Number]
PR	PR_PRTRT	PR_PRTRT		{What was the procedure name?
PR	PR_PRDECOD	PR_PRDECOD	LPO_TBD	{[Intervention Topic]
PR	PR_PRPRESP	PR_PRPRESP	CDISC_SDTM_YES_PID6343337_V1_0F	{Pre-Specified Procedure
PR	PR_PROCCUR	PR_PROCCUR	CDISC_SDTM_YES_PID6343337_V1_0F	Was [PR_PRTRT] performed?; Has the subject had [PR_PRTRT]?
PR	PR_PRREASOC	PR_PRREASOC		What was the reason that the procedure was not performed?
PR	PR_PRCSTAT	PR_PRCSTAT		Was the procedure data collected?
PR	PR_PRREASND	PR_PRREASND		What was the reason not done?
PR	PR_PRPRIOR	PR_PRPRIOR	CDISC_SDTM_YES_PID6343337_V1_0F	Was the procedure performed prior to study start?
PR	PR_PRSTDAT	PR_PRSTDAT		What was the procedure [start] date?
PR	PR_PRSTTIM	PR_PRSTTIM		What [is/was] the [intended/actual] [intervention] [start/admission] time?
PR	PR_PRONGO	PR_PRONGO	CDISC_SDTM_YES_PID6343337_V1_0F	Was the procedure ongoing?
PR	PR_PREN DAT	PR_PREN DAT		What was the procedure end date?
PR	PR_PREN TIM	PR_PREN TIM		What [is/was] the [intended/actual] [intervention/finding][end/discharge]time?

1. Find the **PR FormOID** in the GLIB ALS.
2. Update PreText to be specific to Radiotherapy (e.g., replace [PR_PRTRT] with Radiotherapy).
3. Remove unnecessary fields.

What to do when you need to combine fields from more than one Form.

- NCI GLIB ALS uses the standard domain codes as the FormOID
- *However, CDASH rules give us the flexibility to use Fields from more than one domain on the same Form*



Default
FormOID =
CDASHIG
Domain Code

FormOID	FieldOID	DataDictionaryName	PreText
TU	TU_TULNKID		[Domain/Observation] Link Identifier
TU	TU_TUTEST	CDISC_SDTM_TUMO_PID6658506_V1_0F	[Measurement/Test/Examination/] (Name) What [is/was] the [result/amount/(subject's characteristic) (of the [measurement/test/examination/question/assessment])?]
TU	TU_TUORRES		What [is/was] the anatomical location (of the [measurement/test/examination]) or What [is/was] the anatomical location where the [measurement/specimen] was taken/collected)?
TU	TU_TULOC	CDISC_SDTM_ANAT_PID6401055_V1_0F	What [is/was] location of the [measurement/test/examination]?
TU	TU_TULAT	CDISC_SDTM_LATE_PID6380040_V1_0F	What was the [measurement/test/examination]?
TU	TU_TUMETHOD	CDISC_SDTM_METH_PID6401601_V1_0F	
TU	VISIT		[Visit]
TU	TU_TUDAT		What [is/ was] the (start) date (of the [Finding])?
TU	TU_TUTIM		What [is/was] the (start) time (of the [Finding])?
TR	TR_TRLNKID		[Domain/Observation] Link Identifier
TR	TR_TRTEST	CDISC_SDTM_TUMO_PID6658345_V1_0F	[Measurement/Test/Examination/] (Name) What [is/was] the [result/amount/(subject's characteristic) (of the [measurement/test/examination/question/assessment])?]
TR	TR_TRORES		What [is/was] the unit (of the [measurement/test/examination/question/assessment])?

Date: (TU_TUDAT)
Target Lesion Location: (TU_TULOC)
Target Lesion Diameter: (TR_TRORES_DIAM)

So, If you want to combine 2 or more domain questions on the same Form, you can update the FormOID (e.g., TU_TR) to reflect multiple target domains.

What to do if you don't find the Domain Code in the GLIB ALS

If you need a domain that is not published in the NCI GLIB ALS, you can create your Rave form based on the same General Observation Class (Interventions, Events or Findings) using the published Domain Code.

This will apply to any domains from SDTMIG-AP, SDTMIG-PGx and SDTMIG-MD and to custom domains.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Prefer
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submi Abbreviation Termin
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Doma
C117755	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Do
C132354	C66734		SDTM Domain Abbreviation	APDM	Associated Persons Demographics	The demographics domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Submission Domain
C147172	C66734		SDTM Domain Abbreviation	APLB	Associated Persons Laboratory Test Results	The laboratory test results domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Results Domain
C147173	C66734		SDTM Domain Abbreviation	APMH	Associated Persons Medical History	The medical history domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Domain
C111138	C66734		SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events
C11113	C66734		SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Domain
C85441	C66734		SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Doma
C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medical
C49569	C66734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
C102605	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular Syste Domain
C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability D
C95087	C66734		SDTM Domain Abbreviation	D		A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Do
C10261	C66734		SDTM Domain Abbreviation	D		An events domain that contains data for device-related events.	Device Events Doma
C102618	C66734		SDTM Domain Abbreviation	D		A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Do
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Dom.
C102619	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Dc
C102620	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Re

Definition will provide the Observation Class

What to do if you don't find the Domain Code in the GLIB ALS

Example:
Biospecimen Events
(to collect genetic
sample shipping)

*First, Identify the
Observation Class of
the Form you need
to add to the ALS
(e.g., Biospecimen
Events is an Events
class domain)*

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Prefer
C66734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)	CDISC SDTM Submi Abbreviation Termin
C49562	C66734		SDTM Domain Abbreviation	AE	Adverse Events	An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.	Adverse Event Doma
C11775 5	C66734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.	Procedure Agents Do
C13235 4	C66734		SDTM Domain Abbreviation	APDM	Associated Persons Demographics	The demographics domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Submission Domain
C14717 2	C66734		SDTM Domain Abbreviation	APLB	Associated Persons Laboratory Test Results	The laboratory test results domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Results Domain
				APMH	Associated Persons Medical History	The medical history domain for those persons associated with the study itself, a particular study subject, or a device used in the study.	Associated Persons Domain
				BE	Biospecimen Events	An events domain that documents biospecimen collection and storage information.	Biospecimen Events
				BS	Biospecimen Findings	A findings domain that documents biospecimen handling information.	Biospecimen Doma
				CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.	Clinical Events Doma
C49568	C66734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.	Concomitant Medical
C49569	C66734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.	Comment Domain
C10260 5	C66734		SDTM Domain Abbreviation	CV	Cardiovascular System Findings	A findings domain that contains physiological and morphological findings related to the cardiovascular system, including the heart, blood vessels and lymphatic vessels.	Cardiovascular Syste Domain
C49578	C66734		SDTM Domain Abbreviation	DA	Drug Accountability	A findings domain that contains the accountability of study drug, such as information on the receipt, dispensing, return, and packaging.	Drug Accountability D
C95087	C66734		SDTM Domain Abbreviation	DD	Death Details; Death Diagnosis and Details	A findings domain that contains the diagnosis of the cause of death for a subject.	Death Diagnosis Do
C10261	C66734		SDTM Domain Abbreviation	DE	Device Events	An events domain that contains data for device-related events.	Device Events Doma
C10261 8	C66734		SDTM Domain Abbreviation	DI	Device Identifiers	A special-purpose domain containing information that identifies a specific device unit.	Device Identifiers Do
C49572	C66734		SDTM Domain Abbreviation	DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.	Demographics Dom
C10261 9	C66734		SDTM Domain Abbreviation	DO	Device Properties	A findings domain that contains the device characteristics that do not vary over the course of the study.	Device Properties Dc
C10262 0	C66734		SDTM Domain Abbreviation	DR	Device-Subject Relationships	A special-purpose domain that contains the linkage of each subject to the device(s) to which they may have been exposed during the study.	Device to Subject Re

Based on "Events"
Observation Class

What to do if you don't find the Domain Code in the GLIB ALS

Example:
Biospecimen Events
(to collect genetic
sample shipping)

*Next, Copy an
existing "Events"
class Form (e.g.,
Medical History)*

FormOID	FieldOID	DraftFieldName	VariableOID	DataDictionaryName	PreText
MH	FORM_OID	PID6446129_V1_0	FORM_OID		FORM_OID
MH	MH_MHYN	Any Medical History Event PID6401576_V1_0	MH_MHYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any medical conditions or events reported?; Has the subject had any medical conditions or events?
MH	MH_MHSCAT	Category for Medical History PID6413031_V1_0	MH_MHSCAT	LPO_TBD	[Medical History Category]; NULL
MH	MH_MHSCAT	Subcategory for Medical History Event PID6413053_V1_0	MH_MHSCAT	LPO_TBD	[Medical History Subcategory]; NULL
MH	MH_MHSCAT	Date of Medical History Collection PID6409588_V1_0	MH_MHSCAT	LPO_TBD	What was the date the medical history was collected?
MH	MH_MHSPID	Medical History Event Sponsor-Defined Identifier PID6421488_V1_0	MH_MHSPID		[Line Number/MH Number]
MH	MH_MHEVDVTP	Medical History Event Date Type PID6421487_V1_0	MH_MHSPID		What was the medical history event date type?
MH	MH_MHTERM	Medical History Event Reported Term PID6421489_V1_0	MH_MHTERM		What is the medical condition or event term?
MH	MH_MHOCCUR	Medical History Event Occurrence PID6401581_V1_0	MH_MHOCCUR	CDISC_SDTM_YES_PID6343337_V1_0F	Did the subject have [pre-specified medical condition/event/group of medical conditions]?
MH	MH_MHPRESP	Medical History Event Pre- Specified PID6401586_V1_0	MH_MHPRESP	CDISC_SDTM_YES_PID6343337_V1_0F	Medical History Event Pre-Specified
MH	MH_MHPRIOR	Prior Medical History Event PID6408638_V1_0	MH_MHPRIOR	CDISC_SDTM_YES_PID6343337_V1_0F	Did the medical condition or event start prior to study start?
MH	MH_MHONGO	Ongoing Medical History Event PID6408640_V1_0	MH_MHONGO	CDISC_SDTM_YES_PID6343337_V1_0F	Is the medical condition or event ongoing?
MH	MH_MHCTRL	Medical History Disease or Symptom Under Control PID6408641_V1_0	MH_MHCTRL	CDISC_SDTM_YES_PID6343337_V1_0F	Is the medical condition or event under control?
MH	MH_MHSTDAT	Medical History Event Start Date PID6409589_V1_0	MH_MHSTDAT		What was the medical condition or event start date?
MH	MH_MHENDAT	Medical History Event End Date PID6409590_V1_0	MH_MHENDAT		What was the medical condition or event end date?
MH	MH_MHLOC	Medical History Event Location PID6408715_V1_0	MH_MHLOC	CDISC_SDTM_ANAT_PID6401055_V1_0F	What was the anatomical location of the medical condition or event?
MH	MH_MHLAT	Medical History Event Laterality PID6408281_V1_0	MH_MHLAT	CDISC_SDTM_LATE_PID6380040_V1_0F	What was the side of the anatomical location of the medical condition or event?
MH	MH_MHDIR	Medical History Directionality PID6407624_V1_0	MH_MHDIR	CDISC_SDTM_DIRE_PID6380044_V1_0F	What was the directionality of the anatomical location of the medical condition or event?
MH	MH_MHDIR	Medical History Event Location Portion or Totality		CDISC_SDTM_PORT_PID6380309_V1_0F	What was the portion or totality of the anatomical location of the of the medical

Copy MH rows

What to do if you don't find the Domain Code in the GLIB ALS

Example:
Biospecimen Events
(to collect genetic
sample shipping)

*Then, Change "MH"
to "BE" on copied
FormOID, FieldOID,
VariableOID*

FormOID	FieldOID	VariableOID	DataDictionaryName	PreText
MH	FORM_OID	FORM_OID		FORM_OID
MH	MH_MHYN	MH_MHYN	CDISC_SDTM_YES_PID6343337_V1_0F	Were any medical conditions or events reported?; Has the subject had any medical conditions or events?
MH	MH_MHCAT	MH_MHCAT	LPO_TBD	[Medical History Category]; NULL
MH	MH_MHSCAT	MH_MHSCAT	LPO_TBD	[Medical History Subcategory]; NULL
MH	MH_MHSTAT	MH_MHSTAT		What was the date the medical history was collected?
MH	MH_MHSPID	MH_MHSPID		[Line Number/MH Number]
MH	MH_MHEVDAT	MH_MHEVDAT		What was the medical history event date type?
MH	MH_MHTERM	MH_MHTERM		What is the medical condition or event term?
MH	MH_MHOCCL	MH_MHOCCL	CDISC_SDTM_YES_PID6343337_V1_0F	Did the subject have [pre-specified medical condition/event/group of medical conditions]?
MH	MH_MHPRESP	MH_MHPRESP	CDISC_SDTM_YES_PID6343337_V1_0F	Medical History Event Pre-Specified
MH	MH_MHPRIOR	MH_MHPRIOR	CDISC_SDTM_YES_PID6343337_V1_0F	Did the medical condition or event start prior to study start?
MH	MH_MHONGO	MH_MHONGO	CDISC_SDTM_YES_PID6343337_V1_0F	Is the medical condition or event ongoing?
MH	MH_MHCTRL	MH_MHCTRL	CDISC_SDTM_YES_PID6343337_V1_0F	Is the medical condition or event under control?
MH	MH_MHSTAT	MH_MHSTAT		What was the medical condition or event start date?
MH	MH_MHENDAT	MH_MHENDAT		What was the medical condition or event end date?
MH	MH_MHLOC	MH_MHLOC	CDISC_SDTM_ANAT_PID6401055_V1_0F	What was the anatomical location of the medical condition or event?
MH	MH_MHLOC	MH_MHLOC	CDISC_SDTM_LATE_PID6380040_V1_0F	What was the side of the anatomical location

Find and Replace

Find what: MH

Replace with: BE

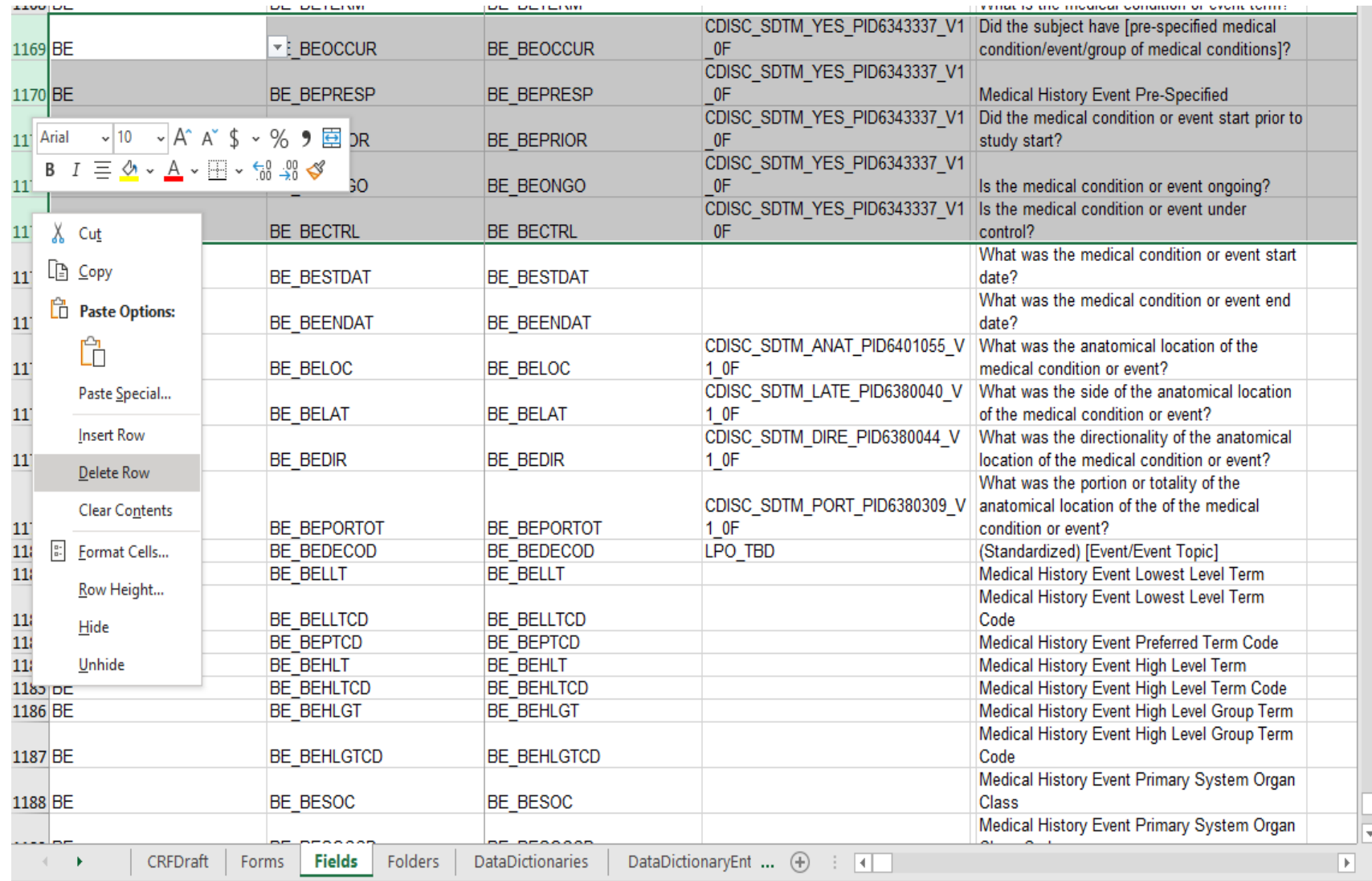
Options >>

Replace All Replace Find All Find Next Close

What to do if you don't find the Domain Code in the GLIB ALS

Example:
Biospecimen Events
(to collect genetic
sample shipping)

*Delete unnecessary
rows*



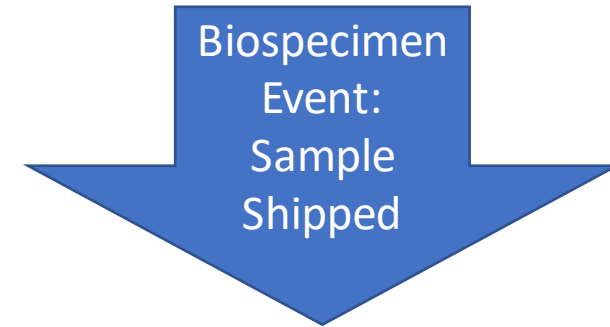
The screenshot shows a spreadsheet with columns for event codes and descriptions. A context menu is open over row 1115, which is highlighted in grey. The menu options include Cut, Copy, Paste Options, Paste Special..., Insert Row, Delete Row (which is selected), Clear Contents, Format Cells..., Row Height..., Hide, and Unhide. The spreadsheet data includes rows 1169 through 1188, with various event codes and descriptions.

Row	Event Code	Description
1169	BE_BEOCCUR	Did the subject have [pre-specified medical condition/event/group of medical conditions]?
1170	BE_BEPRESP	Medical History Event Pre-Specified
1171	BE_BEPRIOR	Did the medical condition or event start prior to study start?
1172	BE_BEONGO	Is the medical condition or event ongoing?
1173	BE_BECTRL	Is the medical condition or event under control?
1174	BE_BESTDAT	What was the medical condition or event start date?
1175	BE_BEENDAT	What was the medical condition or event end date?
1176	BE_BELOC	What was the anatomical location of the medical condition or event?
1177	BE_BELAT	What was the side of the anatomical location of the medical condition or event?
1178	BE_BEDIR	What was the directionality of the anatomical location of the medical condition or event?
1179	BE_BEPORTOT	What was the portion or totality of the anatomical location of the of the medical condition or event?
1180	BE_BEDECOD	(Standardized) [Event/Event Topic]
1181	BE_BELLT	Medical History Event Lowest Level Term
1182	BE_BELLTCD	Medical History Event Lowest Level Term Code
1183	BE_BEPTCD	Medical History Event Preferred Term Code
1184	BE_BEHLT	Medical History Event High Level Term
1185	BE_BEHLTCD	Medical History Event High Level Term Code
1186	BE_BEHLGT	Medical History Event High Level Group Term
1187	BE_BEHLGTC	Medical History Event High Level Group Term Code
1188	BE_BESOC	Medical History Event Primary System Organ Class

What to do if you don't find the Domain Code in the GLIB ALS

Example: Biospecimen Events (to collect genetic sample shipping)

Update the PreText (e.g., Shipping Date)



FormOID	FieldOID	VariableOID	DataDictionaryName	PreText
BE	BE_BETERM	BE_BETERM		Sample Shipped
BE	BE_BESTDAT	BE_BESTDAT		Shipping Date
BE	BE_BESTAT	BE_BESTAT	CDISC_SDTCM_NOT_PID6408948_V1_OF	Sample Not Shipped
BE	BE_BEREASND	BE_BEREASND		Reason Sample Not Shipped

Session 1 Summary

- CDASH and SDTM use the same
 - General Observation Classes (Interventions, Events, Findings)
 - Domains
- Each standardized domain
 - Is based on one General Observation Class
 - Has a standard 2-character domain code
 - Is defined / described in
 - SDTM Controlled Terminology (DOMAIN codelist C66734)
 - SDTMIG Class-based Domain Index
- The NCI GLIB ALS uses the standard domain codes as the FormOID to name the standard forms
 - Find the right form by matching the Domain Code to the FormOID
 - You can update FormOID to reflect more than one target domain (e.g., TU_TR)
- You can create new Forms using the published DOMAIN codes with existing Rave Form metadata from same General Observation Class

Q&A