Immunogenicity Domains Supplement to the Study Data Tabulation Model Implementation Guide

Prepared by the

CDISC Submission Data Standards (SDS) Team

Notes to Readers

- This document provides new SDTM domains that are specific to Immunogenicity data. In particular, Specimen Assessment and Skin Response are being modeled, and guidance is provided regarding their use.
- This document is a supplement to the SDTM Implementation Guide (SDTM-IG), and its contents are targeted for inclusion in the 3.1.4 release. With this in mind, the TOC reflects the Sections of the SDTM-IG in which the new domains are to be inserted.
- Once the publication of the final SDTM-IG v3.1.4 is complete, the domains included in this Supplemental Guide will have become fully active standards.

DRAFT Revision History

Date	SDTM-IG Version	Version	Summary of Changes
2012-07-30	3.1.4	Version 1.0 Draft	Draft for comment.

Note: Please see Appendix A for Representations and Warranties, Limitations of Liability, and Disclaimers.

CDISC Immunogenicity Domain

I. Introduction

The Immunogenicity Specimen Assessments (IS) Findings domain and Skin Response (SR) Findings About domain are used for tests that determine whether a substance provoked/caused/induced an immune response and for recording injection site reactions. For example, a vaccine induces an immune response that is desired. Alternatively, a cellular therapy induces an immune response that is not desired.

Note: The Skin Response (SR) is the first implementation of the Findings About concept that is Findings About an Intervention and uses a different domain code instead of FA.

6 Domain Models Based on the General Observations Classes

6.3 FINDINGS

6.3.13 IMMUNOGENICITY DOMAINS

6.3.13.1 IMMUNOGENICITY SPECIMEN ASSESSMENT — IS

IS.xpt, Immunogenicity Specimen Assessments — Findings, Version 3.1.4. One record per test per visit per subject, Tabulation

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
STUDYID	Study Identifier	DocumentIdentifier.identifier where the document is the StudyProtocolDocumentVersion as part of which the topic test was performed.	Char		Identifier	Unique Identifier for a study.	Req	SDTM 2.2.4
DOMAIN	Domain Abbreviation	Not applicable: A domain is an implementation-specific collection of logically related observations with a common topic.	Char	IS	Identifier	Two-character abbreviation for the domain.	Req	SDTM 2.2.4, SDTMIG 4.1.22
USUBJID	Unique Subject Identifier	SubjectIdentifier.identifier where the subject is the one from whom the specimen tested in the topic test was taken. The subject is a study subject and SubjectIdentifier.typeCode = cross-study.	Char		Identifier	Identifier used to uniquely identify a subject across a submission.	Req	SDTM 2.2.4, SDTMIG 4.1.2.3
ISSEQ	Sequence Number	Not applicable. This is an implementation-specific record identifier.	Char		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req	SDTM 2.2.4
ISGRPID	Group ID	Not applicable. This is an implementation-specific grouping mechanism.	Num		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm	SDTM 2.2.4

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
ISREFID	Reference ID	Specimen.accessionNumberText where the specimen is the one tested in the topic test.	Char		Identifier	Internal or external specimen identifier. Example: 458975-01.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
ISSPID	Sponsor-Defined Identifier	Not applicable. This is an implementation-specific identifier of a type defined by the sponsor.	Char		Identifier	Sponsor-defined reference number.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
ISTESTCD	Immunogenicity Test or Examination Short Name	DefinedObservation.nameCode where the observation is the topic test; this is the code (CD.code) for the topic test.	Char		Identifier	Short name of the measurement, test, or examination described in ISTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in ISTESTCD cannot be longer than 8 characters, nor can it start with a number. ISTESTCD cannot contain characters other than letters, numbers, or underscores.	Req	SDTM 2.2.4
ISTEST	Immunogenicity Test or Examination Name	DefinedObservation.nameCode where the observation is the topic test; this is the decode (CD.displayName) associated with the code for the topic test.	Char		Topic	Verbatim name of the test or examination used to obtain the measurement or finding. The value in SRTEST cannot be longer than 40 characters. (Example: Immunoglobulin E).	Req	SDTM 2.2.3 SDTMIG 4.1.2.1, SDTMIG 4.1.2.7.3
ISCAT	Category for Immunogenicity Test	DefinedObservation.nameCode where the observation is the topic test; this is the decode (CD.displayName) associated with the code for the topic test.	Char		Synonym Qualifier	Used to define a category of Topic-variable values across subjects. Example: SEROLOGY	Perm	SDTM 2.2.3, SDTMIG 4.1.2.1, SDTMIG 4.1.2.4,
ISSCAT	Subcategory for Immunogenicity Test	DefinedActivity.categoryCode	Char	*	Grouping Qualifier	A further categorization of —CAT.	Perm	SDTM 2.2.3, SDTMIG 4.1.2.6

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
ISORRES	Results or Findings in Original Units	PerformedObservationResult.value where the result is that of the topic test as originally recorded; the datatype component depends on the datatype of the result value.	Char	*	Grouping Qualifier	Results of measurement or finding as originally received or collected.	Exp	SDTM 2.2.3, SDTMIG 4.1.2.6
ISORRESU	Original Units	PerformedObservationResult.value where the result is that of the topic test as originally recorded; if the value has a quantitative datatype, this is the unit component of the relevant datatype.	Char		Result Qualifier	Original units in which the data were collected. The unit for ISORRES. Examples: Titer, Index Value, gpELISA unit/mL.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
ISSTRESC	Character Results/Findings in Std. Format	PerformedObservationResult.value where the result is that of the topic test in standardized format; the datatype component depends on the datatype fo the result value.	Char	(_UNIT)	Variable Qualifier	Contains the result value for all findings, copied or derived from ISORRES, in a standard format or in standard units. ISSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in ISSTRESN.	Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
ISSTRESN	Numeric Results/Findings in Std. Units	PerformedObservationResult.value where the result is that of the topic test in standardized format; if the result value has a quantitative datatype, this is the value component of that datatype.	Char		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from ISSTRESC. ISSTRESN should store all numeric test results or findings.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
ISSTRESU	Standard Units	PerformedObservationResult.value where the result is that of the topic test in standardized format; if the value has a quantitative datatype, this is the unit component of that datatype.	Num		Result Qualifier	Standardized units used for ISSTRESC and ISSTRESN. Examples: Titer, Index Value, gpELISA unit/mL.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
ISSTAT	Completion Status	PerformedObservation.negationIndicator where the observation is the topic test; if the negation indicator value is TRUE, then ISSTAT = NOT DONE	Char	(UNIT)	Variable Qualifier	Used to indicate a test was not done. Should be null if a result exists in ISORRES.	Perm	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
ISREASND	Reason Not Done	PerformedObservation.negationReason where the observation is the topic test	Num		Timing	Describes why a measurement or test was not performed. Used in conjunction with ISSTAT when value is NOT DONE.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
ISNAM	Vendor Name	Organization.name where the organization is the one which performed the topic test	Char		Timing	Name or identifier of the vendor that provided the test results.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
ISSPEC	Specimen Type	Biologic.code where the biologic is the material functioning as the specimen which is tested in the topic test; this is the displayName (decode) of the code for the kind of material	Num		Timing	Defines the types of specimen used for a measurement. Example: Serum.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
ISMETHOD	Method of Test or Examination	PerformedObservation.methodCode where the observation is the topic test; this is the decode (CD.displayName) for the code.	Char	ISO 8601	Timing	Method of test or examination. Example: ELISA, ELISPOT.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.2, SDTMIG 4.1.4.8

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
ISBLFL	Baseline Flag	PerformedObservation.baselineIndicator for the topic test; when the indicator value is TRUE, ISBLFL = Y	Num		Timing	Indicator used to identify a baseline value. Should be Y or null (Especially if this is for boosters)	Perm	SDTM 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6
ISLLOQ	Lower Limit of Quantitation	ReferenceResult.value where the reference result is the quantitation range associated with the result of the topic test; this is the value of the lower end of the range.	Num			Indicates the lower limit of quantitation for an assay. Units will be those used for ISSTRESU.	Exp	SDTM 2.2.3
VISITNUM	Visit Number	PlannedSubjectActivityGroup.sequenceNumber, where the subject activity group is the visit of which the topic test is a component	Num			Clinical encounter number. Numeric version of VISIT, used for sorting.	Exp	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISIT	Visit Name	PlannedSubectActivityGroup.name where the subject activity group is the visit of which the topic test is a component.	Char			1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISITDY	Planned Study Day of Visit	PlannedSubectActivityGroup.studyDayRange where the subject activity group is the visit of which the topic test is a component; this is the lower end of the study day range.	Num			Planned study day of the visit based upon RFSTDTC in Demographics.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
TAETORD	Planned Order of Elements within Arm	Indirect BRIDG mapping; the value of this variable depends on the study-specific order of planned elements within the arm to which the study subject was assigned, where the study subject is the one from whom the specimen was taken that is the subject of the topic test and the element is the one in which the topic test occurred in.	Num			Number that gives the planned order of the Element within the Arm.	Exp	SDTM 2.2.5, SDTMIG 5.3.1
EPOCH	Epoch	Epoch.name where the epoch is the one in which the topic test occurred	Char			Epoch associated with the date/time of data collection.	Exp	SDTM 2.2.5, SDTMIG 7.1.2
ISDTC	Date/Time of Collection	PerformedSpecimenCollection.dateRange where the specimen is the subject of the topic test; this is the lower end of the date range	Char			Collection date and time of an observation represented in ISO 8601.	Exp	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.8
ISDY	Study Day of Visit/Collection/Exam	PerformedSpecimenCollection.studyDayRange where the specimen is the subject of the topic test; this is the lower end of the day range	Num			Actual study day of visit/collection/exam expressed in integer days relative to sponsor defined RFSTDTC in Demographics.	Exp	SDTMIG 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

6.3.13.2 ASSUMPTIONS FOR IMMUNOGENICITY SPECIMEN ASSESSMENT (IS) DOMAIN MODEL

1. The Immunogenicity Specimen Assessments (IS) domain model is used for assessments, which determines whether a therapy provoked/caused/induced an immune response. For example, a vaccine is expected to induce an immune response to the therapeutic agent. Alternatively, a cellular therapy such as Erythropoiesis stimulating agents may induce an immune response that is not desired.
2. The following Qualifiers would not generally be used in IS: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --RESCAT, --XFN, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV.

6.3.13.3 EXAMPLES FOR IMMUNOGENICITY SPECIMEN ASSESSMENT (IS) DOMAIN MODEL

Example 1:

In this example, subject was dosed with Hepatitis C vaccine. Information about Hepatitis C Vaccine was recorded in the Exposure domain, which is not shown below

1. Rows 1, 2, 4, and 5 show the measurement of antibody to the vaccine.
2. Rows 3 and 6 show the measurement of viral DNA.

IS.XPT

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU
1	ABC-123	IS	123457	1	HCAB	Hepatitis C Virus Antibody	Serology	3115.016	gpELISA unit/mL
2	ABC-123	IS	123457	3	HCAB	Hepatitis C Virus Antibody	Serology	1772.78	gpELISA unit/mL
3	ABC-123	IS	123457	2	IGDNA	Hepatitis C DNA	Serology	POSITIVE	
4	ABC-123	IS	123460	5	HCAB	Hepatitis C Virus Antibody	Serology	217.218	gpELISA unit/mL
5	ABC-123	IS	123460	6	HCAB	Hepatitis C Virus Antibody	Serology	203.88	gpELISA unit/mL
6	ABC-123	IS	123460	7	IGDNA	Hepatitis C DNA	Serology	NEGATIVE	

Row	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ
1	3115.016	3115.016	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY	Y	100
2	1772.78	1772.78	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY		100
3	POSITIVE			LIVER	POLYMERASE CHAIN REACTION		

Row	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ
4	217.218	217.218	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY	Y	100
5	203.88	203.88	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY		
6	NEGATIVE			LIVER	POLYMERASE CHAIN REACTION		100

Row	VISITNUM	VISIT	TAETORD	EPOCH	ISDY	ISDTC
1	1	VISIT 1	1	PRE-VACCINATION	1	2008-10-10
2	2	VISIT 2	2	POST-VACCINATION	43	2008-11-21
3	4	VISIT 4	2	POST-VACCINATION	343	2009-09-17
4	1	VISIT 1	1	PRE-VACCINATION	1	2008-09-01
5	2	VISIT 2	2	POST-VACCINATION	31	2008-10-02
6	4	VISIT 4	2	POST-VACCINATION	188	2009-03-01

Example 2:

In this example, subject was dosed with the study drug consisting of 0.5mL of varicella vaccine. The immunogenic response of the study drug as well as the pneumococcal vaccine that was given concomitantly was measured to ensure that immunogenicity of both vaccines was sufficient to provide protection.

1. Rows 1 to 4 show the measurement of antibody to the vaccines.

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU
1	GHJ-456	IS	6017	1	PNPSAB14	Pneumococcal Polysacch AB Serotype 14	SEROLOGY	9.715	ug/mL
2	GHJ-456	IS	6017	2	VZVAB	Varicella-Zoster Virus Antibody	SEROLOGY	141.616	gpELISA unit/mL
3	GHJ-456	IS	6017	3	PNPSAB14	Pneumococcal Polysacch AB Serotype 14	SEROLOGY	13.244	ug/mL

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU
4	GHJ-456	IS	6017	4	VZVAB	Varicella-Zoster Virus Antibody	SEROLOGY	870.871	gpELISA unit/mL

Row	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ
1	9.715	9.715	ug/mL	SERUM	ENZYME IMMUNOASSAY	Y	2.5
2	141.616	141.616	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY	Y	2.5
3	13.244	13.244	ug/mL	SERUM	ENZYME IMMUNOASSAY		2.5
4	870.871	870.871	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY		2.5

Row	VISITNUM	VISIT	TAETORD	EPOCH	ISDY	ISDTC
1	1	VISIT 1		PRE-VACCINATION	1	2010-02-06
2	1	VISIT 1		PRE-VACCINATION	1	2010-02-06
3	2	VISIT 2		POST-VACCINATION	31	2010-03-09
4	2	VISIT 2		POST-VACCINATION	31	2010-03-09

Example 3:

In this example, the subject is dosed with multiple study drugs to assess the immunogenic response.

- Rows 1 through 4 are immunogenic responses as assessed by measuring IGE.

.Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT
1	SPI-001	IS	11035	1	JGRASS	Johnson Grass IgE	IMMUNOLOGY
2	SPI-001	IS	11035	2	KBGRASS	Kentucky Blue Grass IgE	IMMUNOLOGY
3	SPI-001	IS	11035	3	OAKTREE	Oak Tree IgE	IMMUNOLOGY
4	SPI-001	IS	11035	4	RYEGRASS	Rye Grass IgE	IMMUNOLOGY

Row	ISORRES	ISORRESU	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	VISITNUM	VISIT	ISDTC
1	5.0000	kIU/L	5.0000	5.0000	IU/mL	SERUM	1	VISIT 1	2011-02-06
2	2.0000	kIU/L	2.0000	2.0000	IU/mL	SERUM	1	VISIT 1	2011-02-06
3	8.0000	kIU/L	8.0000	8.0000	IU/mL	SERUM	1	VISIT 1	2011-02-06
4	4.0000	kIU/L	4.0000	4.0000	IU/mL	SERUM	1	VISIT 1	2011-02-06

6.3.13.4 SKIN RESPONSE — SR

SR.xpt, Skin Response — Findings, Version 3.1.4. One record per test per visit per subject, Tabulation

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
STUDYID	Study Identifier	DocumentIdentifier.identifier where the document is the StudyProtocolDocumentVersion as part of which the topic test was performed.	Char		Identifier	Unique Identifier for a Study.	Req	SDTM2.2.4
DOMAN	Domain Abbreviation	Not applicable: A domain is an implementation-specific collection of logically related observations with a common topic.	Char		Identifier	Two-character abbreviation for the domain.	Req	SDTM 2.2.4, SDTMIG 4.1.22
USUBJID	Unique Subject Identifier	SubjectIdentifier.identifier where the subject is the one from whom the specimen tested in the topic test was taken. The subject is a study subject and SubjectIdentifier.typeCode = cross-study.	Char		Identifier	Identifier used to uniquely identify a subject across submission.	Req	SDTM 2.2.4, SDTMIG 4.1.2.3
SRSEQ	Sequence Number	Not applicable. This is an implementation-specific record identifier.	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req	SDTM 2.2.4
SRGRPID	Group ID	Not applicable. This is an implementation-specific grouping mechanism.	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm	SDTM 2.2.4
SRREFID	Reference ID	tbd	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRSPID	Sponsor-Defined Identifier	Not applicable. This is an implementation-specific identifier of a type defined by the sponsor.	Char		Identifier	Sponsor defined reference number	Perm	SDTM 2.2.4, SDTMIG 4.1.2.6
SRTESTCD	Skin Response Test or Exam Short Name	DefinedObservation.nameCode where the observation is the topic test; this is the code (CD.code) for the topic test.	Char		Topic	Short name of the measurement, test, or examination described in SRTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in SRTESTCD cannot be longer than 8 characters, nor can it start with a number. SRTESTCD cannot contain characters other than letters, numbers, or underscores.	Req	SDTM 2.2.4
SRTEST	Skin Response Test or Examination Name	DefinedObservation.nameCode where the observation is the topic test; this is the decode (CD.displayName) associated with the code for the topic test.	Char		Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in SRTEST cannot be longer than 40 characters. (E.g., Wheal Diameter).	Req	SDTM 2.2.3 SDTMIG 4.1.2.1, SDTMIG 4.1.2.7.3
SROBJ	Object of the Observation	Product.code where the product is the treatment which provoked the response measured by the topic test; this is the decode (CD.displayName) associated with the code.	Char		Record Qualifier	Used to describe the object or focal point of the findings observation that is represented by --TEST. Examples: the dose of the immunogenic material or the allergen associated with the response. (e.g., Johnson Grass IgE 0.15 BAU mL).	Req	SDTM 2.2.3.1

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRCAT	Category for Test	DefinedActivity.categoryCode	Char		Grouping Qualifier	Used to define a category of Topic-variable values across subjects.	Perm	SDTM 2.2.3, SDTMIG 4.1.2.1, SDTMIG 4.1.2.4
SRSCAT	Subcategory for Test	DefinedActivity.subcategoryCode	Char		Grouping Qualifier	A further categorization of --CAT values.	Perm	SDTM 2.2.3, SDTMIG 4.1.2.6
SRORRES	Results or Findings in Original Units	PerformedObservationResult.value where the result is that of the topic test as originally recorded; the datatype component depends on the datatype for the result value.	Char		Result Qualifier	Results of measurement or finding as originally received or collected.	Exp	SDTM 2.2.3, SDTMIG 4.1.2.6
SRORRESU	Original Units	PerformedObservationResult.value where the result is that of the topic test as originally recorded; if the value has a quantitative datatype, this is the unit component of the relevant datatype.	Char	UNIT	Variable Qualifier	Original units in which the data were collected. The unit for SRORRES. Example: mm.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
SRSTRESC	Character Results/Findings in Std. Format	PerformedObservationResult.value where the result is that of the topic test in standardized format; the datatype component depends on the datatype fo the result value.	Char		Result Qualifier	Contains the result value for all findings, copied or derived from SRORRES in a standard format or in standard units. SRSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in SRSTRESN.	Exp	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRSTRESN	Numeric Results/Findings in Std. Units	PerformedObservationResult.value where the result is that of the topic test in standardized format; if the result value has a quantitative datatype, this is the value component of that datatype.	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from SRSTRESC. SRSTRESN should store all numeric test results or findings.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
SRSTRESU	Standard Units	PerformedObservationResult.value where the result is that of the topic test in standardized format; if the value has a quantitative datatype, this is the unit component of that datatype.	Char	UNIT	Variable Qualifier	Standardized units used for SRSTRESC and SRSTRESN, Example: mm.	Exp	SDTM 2.2.3, SDTMIG 4.1.5.1
SRSTAT	Completion Status	PerformedObservation.negationIndicator where the observation is the topic test; if the negation indicator value is TRUE, then ISSTAT = NOT DONE	Char		Record Qualifier	Used to indicate exam not done. Should be null if a result exists in SRORRES.	Perm	SDTM 2.2.3, SDTMIG 4.1.3.2, SDTMIG 4.1.5.1
SRREASND	Reason Not Done	PerformedObservation.negationReason where the observation is the topic test; this is the datatype component value.originalText	Char		Record Qualifier	Describes why a measurement or test was not performed. Used in conjunction with SRSTAT when value is NOT DONE.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
SRNAM	Vendor Name	Organization.name where the organization is the one which performed the topic test.	Char		Record Qualifier	Name or identifier of the vendor that provided the test results.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRSPEC	Specimen Type	Organization.name where the organization is the one which performed the topic test.	Char		Record Qualifier	Defines the types of specimen used for a measurement. E.g., SKIN.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
SRLOC	Location used for Measurement	PerformedObservation.targetAnatomicLocationCode where the observation is the topic test; this is the decode (CD.displayName) associated with the code.	Char		Record Qualifier	Location relevant to the collection of the measurement.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.2, SDTMIG 4.1.4.8
SRMETHOD	Method of Test or Examination	PerformedObservation.methodCode where the observation is the topic test; this is the decode (CD.displayName) for the code.	Char		Record Qualifier	Method of test or examination (ELISA, EIA Microneutralization, PRNT (Plaque Reduction Neutralization Tests)	Perm	SDTM 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6
SREVAL	Evaluator	Performer.typeCode where the performer performing the topic test.	Char		Record Qualifier	Role of person who provided evaluation. Used only for results that are subjective.	Perm	SDTM 2.2.3, SDTMIG 4.1.5.4
VISITNUM	Visit Number	PlannedSubjectActivityGroup.sequenceNumber, where the subject activity group is the visit of which the topic test is a component.	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting	Exp	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
VISIT	Visit Name	PlannedSubectActivityGroup.name where the subject activity group is the visit of which the topic test is a component.	Char		Timing	1. Protocol-defined description of clinical encounter 2. May be used in addition to VISITNUM and/or VISITDY	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
VISITDY	Planned Study Day of Visit	PlannedSubectActivityGroup.studyDayRange where the subject activity group is the one categorized as a visit of which the topic test is a component; this is the lower end of the study day range.	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm	SDTM 2.2.5, SDTMIG 4.1.4.5, SDTMIG 7.4
TAETORD	Planned Order of Elements within Arm	Indirect BRIDG mapping; the value of this variable depends on the study-specific order of planned elements within the arm to which the study subject was assigned, where the study subject is the one from whom the specimen was taken that is the subject of the topic test and the element is the one in which the topic test occurred in.	Num		Timing	Number that gives the planned order of the Element within the Arm.	Exp	SDTM 2.2.5, SDTMIG 5.3.1
EPOCH	Epoch	Epoch.name where the epoch is the one in which the topic test occurred	Char		Timing	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected.	Exp	SDTM 2.2.5, SDTMIG 7.1.2

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRDTC	Date/Time of Collection	PerformedObservation.dateRange where the observation is the topic test; this is the lower end of the date range.	Char		Timing	Collection date and time of an observation represented in ISO 8601	Exp	SDTM 2.2.5, SDTMIG 4.1.4.1, SDTMIG 4.1.4.8
SRTPT	Planned Time Point Name	PlannedSubjectActivityGroup.name, where the activity group is the timepoint of which the topic test is a component.	Char		Timing	1. Text Description of time when measurement should be taken. 2. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See SRTPTNUM and SRTPTREF. Examples: Start, 5 min post.	Perm	SDTM 2.2.5 SDTMIG 4.1.4.10
SRTPTNUM	Planned Time Point Number	PlannedSubjectActivityGroup.sequenceNumber, where the activity group the timepoint of which the topic test is a component.	Num		Timing	Numerical version of SRTPT to aid in sorting.	Perm	SDTM 2.2.5 SDTMIG 4.1.4.10
SRELTM	Planned Elapsed Time from Time Point Ref	PlannedContingentRelationship.pauseQuantity, where the relationship is between the reference timepoint and the topic test	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (SRTPTREF). Not a clock time or a date time variable. Represented as an ISO 8601 duration. Examples: “-PT15M” to represent the period of 15 minutes prior to the reference point indicated by EGTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by SRTPTREF.	Perm	SDTM 2.2.5 SDTMIG4.1.4.3 SDTMIG 4.1.4.10
SRTPTREF	Time Point Reference	DefinedActivity.nameCode where the activity is the one which acts as the reference point for the time point named in TPT; this is displayName (decode) associated with the code.	Char		Timing	Name of the fixed reference point referred to by SRELTM, SRTPTNUM, and SRTPT. Examples: INTRADERMAL INJECTION.	Perm	SDTM 2.2.5 SDTMIG 4.1.4.10

Variable Name	Variable Label	BRIDG Mapping	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	Reference
SRRFTDTC	Date/Time of Reference Time Point	PerformedActivity.dateRange where the activity is the one which acts as the reference point for the timepoint named in TPT; this is the lower end of the date range.	Char	ISO 8601	Timing	Date/time of the reference time point, SRTPTREF.	Perm	SDTM 2.2.5 SDTMIG 4.1.4.10
SRDY	Study Day of Visit/Collection/Exam	PerformedObservation.studyDayRange where the observation is the topic test; this is the lower end of the study day range.	Num		Timing	Actual study day of visit/collection/exam expressed in integer days relative to sponsor defined RFSTDTC in Demographics	Exp	SDTMIG 2.2.5, SDTMIG 4.1.4.4, SDTMIG 4.1.4.6

** Indicates variable may be subject to controlled terminology, (Parenthesis indicates CDISC/NCI codelist code value)*

6.3.13.5 ASSUMPTIONS FOR IMMUNOGENICITY SKIN RESPONSE (SR) DOMAIN MODEL

Definition: This domain model is used for submitting dermal responses to antigens.

1. The SR domain is a Findings About domain used to submit dermal responses to antigens. The method of assessment is typically a skin-prick test.
2. Because a subject is typically exposed to many test materials at the same time. SROBJ is needed to represent the test material for each response record.
3. The following Qualifiers would not generally be used in IS: --POS, --BODSYS, --ORNRLO, --ORNRHI, --STNRLO, --STNRHI, --STRNC, --NRIND, --, --XFN, --LOINC, --SPCCND, --FAST, --TOX, --TOXGR, --SEV.

6.3.13.6 EXAMPLES FOR IMMUNOGENICITY SKIN RESPONSE (SR) DOMAIN MODEL

Example 1 In this example, the subject is dosed with the Study drug at 0.05 BAU/mL of Johnson Grass with increasing concentrations

In the following example,

- Rows 1 through 4 show responses associated with the administration of a Histamine Control.

- Rows 5 to 8 show responses associated with the administration of Johnson Grass IgE. These records describe the dose response to different concentrations of Johnson Blue Grass antigen, as reflected in SROBJ.

SR.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ
1	SPI-001	SR	SPI-001-11035	1	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
2	SPI-001	SR	SPI-001-11035	2	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
3	SPI-001	SR	SPI-001-11035	3	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
4	SPI-001	SR	SPI-001-11035	4	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
5	SPI-001	SR	SPI-001-11035	5	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.05 BAU/mL
6	SPI-001	SR	SPI-001-11035	6	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.10 BAU/mL
7	SPI-001	SR	SPI-001-11035	7	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.15 BAU mL
8	SPI-001	SR	SPI-001-11035	8	WHEALDIA	Wheal Diameter	Johnson Grass IgE 0.20 BAU/mL

Row	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESN	SRLOC	VISITNUM	VISIT
1	5	mm	5	5	mm	BACK QUADRANT1	1	VISIT 1
2	4	mm	4	4	mm	BACK QUADRANT2	1	VISIT 1
3	5	mm	5	5	mm	BACK QUADRANT3	1	VISIT 1
4	5	mm	5	5	mm	BACK QUADRANT4	1	VISIT 1
5	10	mm	10	10	mm	BACK QUADRANT1	1	VISIT 1
6	11	mm	11	11	mm	BACK QUADRANT2	1	VISIT 1
7	20	mm	20	20	mm	BACK QUADRANT3	1	VISIT 1
8	30	mm	30	30	mm	BACK QUADRANT4	1	VISIT 1

Example 2

In this example, the study drug dose is .05 BAU/mL of Dog Epi IgG at increasing concentrations. The size of the wheal is being measured (reaction to Dog Epi IgG) to evaluate the efficacy of the Dog Epi IgG extract versus Negative Control (NC)/Positive Control (PC) in the testing of allergenic extracts.

1. Rows 1 through 6 show the response (description and reaction grade) to the study drug at a series of different dose levels, the latter reflected in SROBJ. The descriptions of SRORRES values are correlated to a grade and the grade values are stored in SRSTRESC.

2. Rows 7 through 12 show the results of wheal diameter measurements in response to the study drug at a series of different dose levels.

3. While SROBJ is populated for all rows, the more detailed information regarding the study drug would be submitted in the EX dataset. The relationship between the SR records and the EX records would be represented using RELREC.

SR.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSPID	SRTESTCD	SRTEST	SROBJ
1	CC-001	SR	CC-001-101	1	RCTGRDE	Reaction Grade	Dog Epi IgG 0 mg
2	CC-001	SR	CC-001-101	2	RCTGRDE	Reaction Grade	Dog Epi IgG 0.1 mg
3	CC-001	SR	CC-001-101	3	RCTGRDE	Reaction Grade	Dog Epi IgG 0.5 mg
4	CC-001	SR	CC-001-101	4	RCTGRDE	Reaction Grade	Dog Epi IgG 1 mg
5	CC-001	SR	CC-001-101	5	RCTGRDE	Reaction Grade	Dog Epi IgG 1.5 mg
6	CC-001	SR	CC-001-101	6	RCTGRDE	Reaction Grade	Dog Epi IgG 2 mg
7	CC-001	SR	CC-001-101	7	WHEALDIA	Wheal Diameter	Dog Epi IgG 0 mg
8	CC-001	SR	CC-001-101	8	WHEALDIA	Wheal Diameter	Dog Epi IgG 0.1 mg
9	CC-001	SR	CC-001-101	9	WHEALDIA	Wheal Diameter	Dog Epi IgG 0.5 mg
10	CC-001	SR	CC-001-101	10	WHEALDIA	Wheal Diameter	Dog Epi IgG 1 mg
11	CC-001	SR	CC-001-101	11	WHEALDIA	Wheal Diameter	Dog Epi IgG 1.5 mg
12	CC-001	SR	CC-001-101	12	WHEALDIA	Wheal Diameter	Dog Epi IgG 2 mg

Row	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESU	SRLOC	VISITNUM	VISIT
1	NEGATIVE		NEGATIVE			FOREARM	1	WEEK 1
2	NEGATIVE		NEGATIVE			FOREARM	1	WEEK 1
3	ERYTHEMA, INFILTRATION, POSSIBLY DISCRETE PAPULES		1+			FOREARM	1	WEEK 1
4	ERYTHEMA, INFILTRATION, PAPULES, VESICLES		2+			FOREARM	1	WEEK 1
5	ERYTHEMA, INFILTRATION, PAPULES, VESICLES		2+			FOREARM	1	WEEK 1
6	ERYTHEMA, INFILTRATION, PAPULES, COALESCING VESICLES		3+			FOREARM	1	WEEK 1
7	5	mm	5	5	mm	FOREARM	1	WEEK 1
8	10	mm	10	10	mm	FOREARM	1	WEEK 1
9	22	mm	22	22	mm	FOREARM	1	WEEK 1
10	100	mm	100	100	mm	FOREARM	1	WEEK 1
11	1	mm	1	1	mm	FOREARM	1	WEEK 1
12	8	mm	8	8	mm	FOREARM	1	WEEK 1

EX.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSPID	EXTRT	EXDOSE	EXDOSEU	EXROUTE	EXLOC
1	CC-001	EX	101	1	Dog Epi IgG	0	mg	CUTANEOUS	FOREARM
2	CC-001	EX	101	2	Dog Epi IgG	0.1	mg	CUTANEOUS	FOREARM
3	CC-001	EX	101	3	Dog Epi IgG	0.5	mg	CUTANEOUS	FOREARM
4	CC-001	EX	101	4	Dog Epi IgG	1	mg	CUTANEOUS	FOREARM
5	CC-001	EX	101	5	Dog Epi IgG	1.5	mg	CUTANEOUS	FOREARM
6	CC-001	EX	101	6	Dog Epi IgG	2	mg	CUTANEOUS	FOREARM

Row 1: Shows the administration Method for administering the dose.

suppex.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
1	CC-001	SR	CC-001-101	EXSEQ	1	EXMETHOD	Administration Method	SKIN PRICK	CRF
2	CC-001	SR	CC-001-101	EXSEQ	2	EXMETHOD	Administration Method	SKIN PRICK	CRF
3	CC-001	SR	CC-001-101	EXSEQ	3	EXMETHOD	Administration Method	SKIN PRICK	CRF

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
4	CC-001	SR	CC-001-101	EXSEQ	4	EXMETHOD	Administration Method	SKIN PRICK	CRF
5	CC-001	SR	CC-001-101	EXSEQ	5	EXMETHOD	Administration Method	SKIN PRICK	CRF
6	CC-001	SR	CC-001-101	EXSEQ	6	EXMETHOD	Administration Method	SKIN PRICK	CRF

RELREC below shows record level relationships.

RELREC

STUDYID	RDOMAIN	USUBJID	SRVAR	SRVARVAL	RELTYPE	RELID
CC-001	SR	101	SRSPID	1		R1
CC-001	SR	101	SRSPID	7		R1
CC-001	EX	101	EXSPID	1		R1
CC-001	SR	101	SRSPID	2		R2
CC-001	SR	101	SRSPID	8		R2
CC-001	EX	101	EXSPID	2		R2
CC-001	SR	101	SRSPID	3		R3
CC-001	SR	101	SRSPID	9		R3
CC-001	EX	101	EXSPID	3		R3
CC-001	SR	101	SRSPID	4		R4
CC-001	SR	101	SRSPID	10		R4
CC-001	EX	101	EXSPID	4		R4
CC-001	SR	101	SRSPID	5		R5
CC-001	SR	101	SRSPID	11		R5
CC-001	EX	101	EXSPID	5		R5
CC-001	SR	101	SRSPID	6		R6
CC-001	SR	101	SRSPID	12		R6
CC-001	EX	101	EXSPID	6		R6

Example 3

This example shows the results from a tuberculin PPD skin tests administered using the Mantoux technique. The subject was given an intradermal injection of standard tuberculin purified protein derivative (PPD-S) in their left forearm at Visit 1 (See Exposure record below). At Visit 2, the induration diameter and presence of blistering were recorded. Because the tuberculin PPD skin test cannot be interpreted using the induration diameter and blistering alone (e.g. risk for being infected with TB must also be considered), the interpretation of the skin test resides in its own row.
Row 1: Shows the diameter in millimeters of the induration after receiving an intradermal injection of 0.1 mL containing 5TU of PPD-S in the left forearm.
Row 2: Shows the presence of blistering at the tuberculin PPD skin test site.
Row 3: Shows the interpretation of the tuberculin PPD skin test. SRGRPID is used to tie together the results to the interpretation.
Row 1-3: Show how to use the timing variables to record that a skin test was given via the Mantoux technique and that the planned time for reading the test was 48 hours later. However, a comparison of datetime values in SRDTC and SRRFTDTC shows that the test was read after the 48 hour planned interval.

sr.xpt

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRGRPID	SRTESTCD	SRTEST	SROBJ	SRORRES	SRORRESU
1	ABC	SR	ABC-001	1	1	INDURDIA	Induration Diameter	Tuberculin PPD-S	16	mm
2	ABC	SR	ABC-001	2	1	BLISTER	Blistering	Tuberculin PPD-S	Y	
3	ABC	SR	ABC-001	3	1	INTP	Interpretation	Tuberculin PPD-S	POSITIVE	

Row	SRSTRESC	SRSTRESN	SRSTRESU	SRLAT	SRLOC	SRMETHOD	VISITNUM	VISIT
1	16	16	mm	LEFT	FOREARM	RULER	2	VISIT 2
2	Y			LEFT	FOREARM		2	VISIT 2
3	POSITIVE						2	VISIT 2

Row	SRDTC	SRTPT	SRELTM	SRTPTREF	SRRFDTC
1	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00
2	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00
3	2011-01-19T14:08:24	48 H	PT48H	MANTOUX ADMINISTRATION	2011-01-17T08:30:00

Row 1: Shows how to record Tuberculin PPD skin test administration technique.

EX.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXDOSE	EXDOSU	EXVAMT	EXVAMTU	VISITNUM	VISIT
1	ABC	EX	ABC-001	1	Tuberculin PPD-S	5	TU	0.1	mL	1	VISIT 1

RELREC below shows record level relationships.

RELREC

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
ABC	SR	ABC-001	SRGRPID	1		R1
ABC	EX	ABC-001	EXSEQ	1		R1

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