

Note: Section 6.3 - NV Domain underwent public review as part of SDTMIG 3.3 Batch 2 toward the end of 2014. The date in the footer of this copy reflects the most recent updates made since then.

6 Domain Models Based on the General Observation Class

6.3 Findings

Nervous System Findings (NV)

NV - Description/Overview for the Nervous System Findings Domain Model

The Nervous System Findings physiology domain represents tests results from neurological examinations or procedures. Information about the examination or procedure may or may not be collected.

NV - Specification for the Nervous System Findings Domain Model

nv.xpt, Nervous System Findings — Findings, Version 3.3. One record per finding per location per time point per visit per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	NV	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
NVSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
NVGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
NVREFID	Reference ID	Char		Identifier	Internal or external procedure identifier.	Perm
NVSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number from the procedure or test page.	Perm
NVLNKID	Link ID	Char		Identifier	Identifier used to link a procedure to the assessment results over the course of the study.	Perm
NVTESTCD	Test or Examination Short Name	Char	(NVTESTCD)	Topic	Short name of the measurement, test, or examination described in NVTEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in NVTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST"). NVTESTCD cannot contain characters other than letters, numbers, or underscores. Example: SUVR, N75LAT, P100LAT, N145LAT, etc.	Req

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
NVTEST	Test or Examination Name	Char	(NVTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in NVTEST cannot be longer than 40 characters. Example: Standard Uptake Value Ratio, N75 Latency, P100 Latency, N145 Latency, etc.	Req
NVCAT	Category for Test	Char	*	Grouping Qualifier	Used to categorize observations across subjects.	Perm
NVSCAT	Subcategory for Test	Char	*	Grouping Qualifier	A further categorization.	Perm
NVORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the procedure measurement or finding as originally received or collected.	Exp
NVORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for NVORRES.	Perm
NVSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from NVORRES in a standard format or standard units. NVSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in NVSTRESN.	Exp
NVSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from NVSTRESC. NVSTRESN should store all numeric test results or findings.	Perm
NVSTRESU	Standard Units	Char	(UNIT)	Variable Qualifier	Standardized unit used for NVSTRESC or NVSTRESN.	Perm
NVSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate a test was not done, or a measurement was not taken. Should be null if a result exists in NVORRES.	Perm
NVREASND	Reason Test Not Performed	Char		Record Qualifier	Describes why a measurement or test was not performed. Examples: BROKEN EQUIPMENT or SUBJECT REFUSED. Used in conjunction with NVSTAT when value is NOT DONE.	Perm
NVLOC	Location Used for Measurement	Char	(LOC)	Record Qualifier	Anatomical location of the subject relevant to the collection of the measurement. Examples: BRAIN, EYE, PRECUNEUS, CINGULATE CORTEX, etc.	Perm
NVLAT	Laterality	Char	(LAT)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing laterality. Examples: RIGHT, LEFT, BILATERAL	Perm
NVDIR	Directionality	Char	(DIR)	Variable Qualifier	Qualifier for anatomical location or specimen further detailing directionality. Examples: ANTERIOR, LOWER, PROXIMAL	Perm
NVMETHOD	Method of Test or Examination	Char	(METHOD)	Record Qualifier	Method of the test or examination. Examples: EEG, PET/CT SCAN , FDGPET, etc.	Perm
NVBLFL	Baseline Flag	Char	(NY)	Record Qualifier	Indicator used to identify a baseline value. The value should be "Y" or null.	Exp
NVDRVFL	Derived Flag	Char	(NY)	Record Qualifier	Used to indicate a derived record (e.g., a record that represents the average of other records such as a computed baseline). Should be Y or null.	Perm

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
NVEVAL	Evaluator	Char	*	Record Qualifier	Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, INDEPENDENT ASSESSOR, RADIOLOGIST.	Perm
VISITNUM	Visit Number	Num		Timing	1. Clinical encounter number. 2. Numeric version of VISIT, used for sorting.	Exp
VISIT	Visit Name	Char		Timing	1. Protocol-defined description of clinical encounter. 2. May be used in addition to VISITNUM and/or VISITDY.	Perm
VISITDY	Planned Study Day of Visit	Num		Timing	Planned study day of the visit based upon RFSTDTC in Demographics.	Perm
NVDTC	Date/Time of Test	Char	ISO 8601	Timing	Date of procedure or test.	Exp
NVDY	Study Day of Test	Num		Timing	1. Study day of the procedure or test, measured as integer days. 2. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC variable in Demographics.	Perm
NVTPT	Planned Time Point Name	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 NVTPTNUM and NVTPTREF. Examples: Start, 5 min post.	Perm
NVTPTNUM	Planned Time Point Number	Num		Timing	Numerical version of NVTPT to aid in sorting.	Perm
NVELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Timing	Planned elapsed time (in ISO 8601) relative to a fixed time point reference (NVTPTREF). 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 NVTPTREF, or “PT8H” to represent the period of 8 hours after the reference point indicated by NVTPTREF.	Perm
NVTPTREF	Time Point Reference	Char		Timing	Name of the fixed reference point referred to by NVELTM, NVTPTNUM, and NVTPT. Examples: PREVIOUS DOSE, PREVIOUS MEAL.	Perm
NVRFDTC	Date/Time of Reference Time Point	Char	ISO 8601	Timing	Date/time of the reference time point, NVTPTREF.	Perm

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

11 NV - Assumptions for the Nervous System Findings Domain Model

- 12 1. Nervous System Physiology Domain Definition: CRF or eDT Findings Data received as a result of tests from a neurological examination or procedure.
13 These are active processes, but information about the examination or a procedure may or may not be collected.
- 14 2. Neurological Examination examples that may have results represented in the NV domain: mental status, cranial nerves, motor system, sensory system,
15 the deep tendon reflexes, coordination and the cerebellum, gait
- 16 3. Neurological Procedures: The following are examples of procedures that could produce NV results: CT, MRI, PET, EEG, EMG, etc.
- 17 4. Additional Findings Qualifiers
- 18 a. Other additional qualifiers from the SDTM Findings Class may be added to this domain
- 19 b. The following qualifiers would not generally be used in NV: --MODIFY, --BODSYS, --LOINC, --TOX, --TOXGR.

20 NV - Examples for the Nervous System Findings Domain Model

21 **Example 1**

22 This PET and PET/CT imaging data example demonstrated the various data, including the PR, AG and NV domains and their relationship in this imaging
23 process.

24
25 The following example demonstrates the SDTM-based modeling of the nervous system information collected and generated (as described above) from separate
26 PET or PET/CT procedures. The TAUG-MS contains the details of the PR and AG domain data.

27
28 Standard Uptake Value Ratio (SUVR) is a measure of nervous system activity. The data below shows measures for standard uptake value ratios taken from three
29 PET scans. SPDEVID shows the scanner used. NVLNKID can be used to link back to the imaging procedure record in the PR domain (PRLNKID), as well as to
30 the tracer administration record in the AG domain (AGLNKID). AGLNKID would be used to determine which tracer uptake is being measured (SUVR), and
31 therefore to which biomarker the findings pertain. NVDTTC corresponds to the date of the PET or PET/CT procedure from which these results were obtained.

32
33 **Rows 1-2:** Show the Standard Uptake Value Ratio (SUVR) findings based on a PET/CT scan for Subject AD01-101.

34 **Rows 3-4:** Show the SUVR findings based on a PET/CT scan for subject AD01-102.

35 **Rows 5-6:** Show the SUVR findings based on an FDG-PET scan for subject AD AD01-103.

36
37 *nv.xpt*

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	NVSEQ	NVREFID	NVLNKID	NVTESTCD	NVTEST	NVORRES	NVORRESU
1	ABC123	NV	AD01-101	22	1	1236	03	SUVR	Standard Uptake Value Ratio	.95	RATIO
2	ABC123	NV	AD01-101	22	2	1236	03	SUVR	Standard Uptake Value Ratio	1.17	RATIO
3	ABC123	NV	AD01-102	22	1	1237	04	SUVR	Standard Uptake Value Ratio	1.21	RATIO
4	ABC123	NV	AD01-102	22	2	1237	04	SUVR	Standard Uptake Value Ratio	1.78	RATIO
5	ABC123	NV	AD01-103	44	1	1238	05	SUVR	Standard Uptake Value Ratio	1.52	RATIO
6	ABC123	NV	AD01-103	44	2	1238	05	SUVR	Standard Uptake Value Ratio	1.63	RATIO

38

Row	NVSTRESC	NVSTRESN	NVSTRESU	NVLOC	NVDIR	NVMETHOD	NVDTTC
1 (cont)	.95	.95	RATIO	PRECUNEUS		PET/CT SCAN	2012-05-22
2 (cont)	1.17	1.17	RATIO	CINGULATE CORTEX	POSTERIOR	PET/CT SCAN	2012-05-22
3 (cont)	1.21	1.21	RATIO	PRECUNEUS		PET/CT SCAN	2012-05-22
4 (cont)	1.78	1.78	RATIO	CINGULATE CORTEX	POSTERIOR	PET/CT SCAN	2012-05-22
5 (cont)	1.52	1.52	RATIO	PRECUNEUS		FDGPET	2012-05-22
6 (cont)	1.63	1.63	RATIO	CINGULATE CORTEX	POSTERIOR	FDGPET	2012-05-22

39
40 A Supplemental Qualifiers dataset is used for additional data elements that are not part of the NV domain.

41
42 **Rows 1-6:** Shows the reference region used for the SUVR tests shown in the NV domain.

43
44 *suppnv.xpt*

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	ABC123	NV	AD01-101	NVSEQ	1	REFREG	Reference Region	CEREBELLUM
2	ABC123	NV	AD01-101	NVSEQ	2	REFREG	Reference Region	CEREBELLUM

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
3	ABC123	NV	AD01-102	NVSEQ	1	REFREG	Reference Region	CEREBELLUM
4	ABC123	NV	AD01-102	NVSEQ	2	REFREG	Reference Region	CEREBELLUM
5	ABC123	NV	AD01-103	NVSEQ	1	REFREG	Reference Region	PONS
6	ABC123	NV	AD01-103	NVSEQ	2	REFREG	Reference Region	PONS

The RELREC table below displays the dataset relationship on how a procedure is linked to multiple Nervous System (NV) domain records and how an individual procedure Agent administration record related to a scan is linked to multiple Nervous System (NV) domain records. For simplicity of review, only examples for USUBJID=AD01-101 are shown. Note that each of the three relationships identified by RELID would need to be implemented for subjects AD01-102 and AD01-103 using unique RELID values for each.

Rows 1-2: Show how to relate records between the procedure and the result. A unique procedure is linked via the PRLINKID value to the same value in the NV domain's NVLNKID variable to obtain the multiple NV results.

Rows 3-4: Link the radiolabeled tracer used to obtain the SUVR results. Multiple SUVR values may result from a single tracer administration, distinguished by brain region (NVLOC). A single AG administration record with the AGLNKID value is linked to the same value in the NVLNKID variable to obtain all of the related NV results.

Rows 5-6: Link the results to the individual scan as defined by the properties/settings of the scanner used. Multiple NVTEST records with the NVREFID value are linked to the same value in the DUREFID variable to obtain all of the related DU results. This relationship is unusual and challenging to manage in a join/merge and only represents the concept of this relationship. To uniquely identify all the DUTEST values related to an individual NVTEST, select an individual NVREFID to join/merge with the DUREFID to revise this to a one-to-many relationship to obtain all related DUTEST results.

relrec.xpt

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
1	ABC123	PR		PRLNKID		ONE	7
2	ABC123	NV		NVLNKID		MANY	7
3	ABC123	AG		AGLNKID		ONE	8
4	ABC123	NV		NVLNKID		MANY	8
5	ABC123	NV		NVREFID		MANY	9
6	ABC123	DU		DUREFID		MANY	9

Example 2

Multiple Sclerosis – Visual Evoked Potential

The following examples show how to represent components of a pattern-reversal visual evoked potential (VEP) test elicited by checkerboard stimuli from a subject with optic neuritis. VEPs are detected via an electroencephalogram (EEG) using leads that are placed on the back of the subject's head. It is important to note that the nature of VEP testing is such that NVMETHOD should be equal to "EEG", and that NVCAT should be equal to "VISUAL EVOKED POTENTIAL". Several latencies from each eye including N75, P100, and N145 as well as the P100 peak-to-peak amplitude (75-100) are collected and should be represented in NVTESTCD/NVTEST. Details about the VEP equipment including the checkerboard size should be represented in the appropriate device domains. To interpret, each VEP component is compared against normative values established by the laboratory using healthy controls. In this example, a VEP component is considered abnormal if it falls outside of three standard deviations from the normative lab mean. These low and high values are stored in

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75 NVORNRLO and NVORNRHI respectively and the interpretation of each VEP component is represented in NVNRIND. In addition to interpreting each VEP
 76 component as normal or abnormal, the overall test for each eye may have an interpretation. In this scenario, NVTESTCD/NVTEST should be equal to
 77 INTP/Interpretation and NVORRES should represent whether the overall test in each eye is normal or abnormal. NVGRPID links the each VEP component to
 78 the overall interpretation.

79
 80 The NV domain should be used to represent the VEP latencies, P100 peak-to-peak amplitude, and their interpretations. SPDEVID allows the results to be related
 81 to both the VEP testing device as well as the checkerboard size.

82
 83 **Rows 1-4:** Show the VEP measurements from the right eye.

84 **Row 5:** Shows that when all the components of right eye VEP are considered together (NVGRPID = 1), the overall test is interpreted as abnormal.

85 **Rows 6-9:** Show the VEP measurements from the left eye.

86 **Row 10:** Shows that when all the components of left eye VEP are considered together (NVGRPID = 2), the overall test is interpreted as abnormal.

87

88 *nv.xpt*

Row	STUDYID	DOMAIN	USUBJID	EXPUNIT	SPDEVID	NVSEQ	NVGRPID	NVTESTCD	NVTEST	NVCAT	NVORRES	NVORRESU
1	MS123	NV	MS01-01	OD	123	1	1	N75LAT	N75 Latency	VISUAL EVOKED POTENTIAL	79.8	ms
2	MS123	NV	MS01-01	OD	123	2	1	P100LAT	P100 Latency	VISUAL EVOKED POTENTIAL	129	ms
3	MS123	NV	MS01-01	OD	123	3	1	N145LAT	N145 Latency	VISUAL EVOKED POTENTIAL	181	ms
4	MS123	NV	MS01-01	OD	123	4	1	P100AMP	P100 Amplitude	VISUAL EVOKED POTENTIAL	5.02	uV
5	MS123	NV	MS01-01	OD	123	5	1	INTP	Interpretation	VISUAL EVOKED POTENTIAL	ABNORMAL	
6	MS123	NV	MS01-01	OS	123	6	2	N75LAT	N75 Latency	VISUAL EVOKED POTENTIAL	83.8	ms
7	MS123	NV	MS01-01	OS	123	7	2	P100LAT	P100 Latency	VISUAL EVOKED POTENTIAL	126	ms
8	MS123	NV	MS01-01	OS	123	8	2	N145LAT	N145 Latency	VISUAL EVOKED POTENTIAL	160	ms
9	MS123	NV	MS01-01	OS	123	9	2	P100AMP	P100 Amplitude	VISUAL EVOKED POTENTIAL	4.37	uV
10	MS123	NV	MS01-01	OS	123	10	2	INTP	Interpretation	VISUAL EVOKED POTENTIAL	ABNORMAL	

89

Row	NVSTRESC	NVSTRESN	NVSTRESU	NVORNRLO	NVORNRHI	NVNRIND	NVLOC	NVLAT	NVMETHOD	NVDTC
1 (cont)	79.8	79.8	ms	54.68	94	NORMAL	EYE	RIGHT	EEG	2013-02-08
2 (cont)	129	129	ms	76.75	113.71	ABNORMAL	EYE	RIGHT	EEG	2013-02-08
3 (cont)	181	181	ms	114.27	156.03	ABNORMAL	EYE	RIGHT	EEG	2013-02-08
4 (cont)	5.02	5.02	uV	5.26	12.64	ABNORMAL	EYE	RIGHT	EEG	2013-02-08
5 (cont)	ABNORMAL						EYE	RIGHT	EEG	2013-02-08
6 (cont)	83.8	83.8	ms	54.42	95.1	NORMAL	EYE	LEFT	EEG	2013-02-08
7 (cont)	126	126	ms	76.9	115.78	ABNORMAL	EYE	LEFT	EEG	2013-02-08
8 (cont)	160	160	ms	115.65	157.65	ABNORMAL	EYE	LEFT	EEG	2013-02-08
9 (cont)	4.37	4.37	uV	4.78	12.7	ABNORMAL	EYE	LEFT	EEG	2013-02-08
10 (cont)	ABNORMAL						EYE	LEFT	EEG	2013-02-08

90

91 Identifying information about the VEP device is represented in the Device Identifiers (DI) domain.

92

93 **Row 1:** Shows how to represent the VEP testing device as a device type. SPDEVID allows the device to be connected to both the testing device properties
 94 as well as the results generated.

95

96 *di.xpt*

Row	STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
1	MS123	DI	123	1	TYPE	Device Type	VEP Testing Device

97
98 Properties of the VEP device that may change between assessments are represented in the Device In-Use (DU) domain.
99

100 **Row 1:** Shows how to represent the checkerboard stimuli size in the DU Domain. SPDEVID allows the checkerboard size to be related to both the VEP
101 testing device as well as the results generated.
102

103 *du.xpt*

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCD	DUTEST	DUORRES
1	MS123	DU	MS01-01	123	1	CHCKSIZE	Checkerboard Size	32X32

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105

