



DS02: Neurological Examination and Procedure Results in SDTM: Challenges and Solution

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NV - Nervous System Findings

- Nervous System Findings

A domain for *morphological and* physiological findings related to the nervous system based on neurological examinations or procedures, involving mental status; skull, spine, and meninges; cranial nerves; motor examination; sensory examination; coordination; reflexes; and gait and station

- Functional impact on:

- Social life and social participation
- Work life
- Relationships and family
- Independence

Challenges in SDTM

- Complex Structure Of Data Collection
- Interrelation Of Data
- Unavailability of Standard Code list for TEST/TESTCD
- Reorganization to simplify Non CRF external Data

Solution: Extensive but Individual level mapping

NVCAT = "GENERAL EXAM"		
Category	NVSCAT	Cranial Nerves ☒
		Coordination/Cerebellar Function ☐
Assessment	NVTESTCD = "EYEMSTAT"	Eye Movements (III, IV, VI) ☒
		Jaw Movement/Facial Sensation (V) ☐
		Facial Motion (VII) ☐
		Swallowing/Pharynx/Larynx (IX, X) ☐
		SCM/Trapezius (XI) ☐
		Tongue (XII) ☐
		Gait ☐

Solution: Extensive but Individual level mapping

^	NVCAT = "MOTOR"	v
Muscle	NVLOC = "SHOULDER"	NVLAT = "RIGHT"
QVAL = "FLEXION" when QNAM = ROM		
QVAL when QNAM = "ORIGLOC" QLABEL = "Original Anatomical Location" in SUPPNV		
		Shoulder Flexion - Right ☒
		Shoulder Flexion - Left ☐
		Elbow Flexion - Right ☐
		Elbow Flexion - Left ☐
		Elbow Extension - Right ☐
		Elbow Extension - Left ☐
		Wrist Extension - Right ☐
		Wrist Extension - Left ☐
		Abduction Thumb (APB) - Right ☐
		Abduction Thumb (APB) - Left ☐
		Abduction 5th Digit (ADM) - Right ☐
		Abduction 5th Digit (ADM) - Left ☐
		Abduction Index Finger (FDI) - Right ☐
		Abduction Index Finger (FDI) - Left ☐
		Hip Flexion - Right ☐
		Hip Flexion - Left ☐
		Knee Extension - Right ☐
		Knee Extension - Left ☐
		Knee Flexion - Right ☐
		Knee Flexion - Left ☐
		Ankle Dorsiflexion - Right ☐

Solution: Extensive but Individual level mapping

NVLOC = "BICEPS"		NVTESTCD = "BCPSSTAT" where 'Biceps'		NVSTAT	
NVSCAT = "UPPER EXTREMITIES"					
Reflex	NVLOC = "BICEPS"	NVTESTCD = "BCPSSTAT" where 'Biceps'	Biceps Right	☒	NVSTAT = "RIGHT"
			Biceps Left	☐	
			Triceps Right	☐	
			Triceps Left	☐	
			Knee Jerk Right	☐	
			Knee Jerk Left	☐	
			Ankle Jerk Right	☐	
			Ankle Jerk Left	☐	
Status	NVORRES		0 (Absent Reflex)	☐	
			1+ (Trace, or seen only with reinforcement)	☐	
			2+ (Normal)	☐	
			3+ (Brisk)	☐	
			4+ (Non-Sustained Clonus)	☐	
			5+ (Sustained Clonus)	☐	
			Not Done	☐	NVSTAT

Solution: Use GRPID to interlink data from same assessment

	NVGRPID = "001"	NVTESTCD = "NSTGSTAT"	Nystagmus ☒
			Tremor ☐
Status	NVORRES/NVSTRESC = 'PRESENT' when 'PRESENT' NVSTRESC = "ABSENT" when 'ABSENT' NVSTAT = "NOT DONE" and NVORRES/NVSTRESC= <null> when 'NOT DONE'		Present ☐
			Absent ☐
			Not Done ☐
If PRESENT, select clinical significance			Clinically significant ☐
	NVTESTCD = "INTP" and NVTEST = "Interpretation"		Not clinically significant ☐
If PRESENT, describe	NVORRES when Status = "PRESENT"	NVGRPID = "001"	

External Data Challenges and Solution

Solution: Analysis of external data to split it on individual data level

SECTION 1: VOLUME MEASUREMENTS

1a. Contusion volume (2 readers)

NVORRES 1a.1 Is contusion volume assessable? ☐ Yes ☐ No contusion ☐ Not assessable: _____

NVMETHOD 1a.2 Imaging modality used: ☐ FLAIR ☐ T2* ☐ NCCT Series ID: _____

1a.3 Volume and location for up to the 3 largest contusions (ordering from 1 to 3 should be based on contusion size)

Contusion #	Location	Volume (mm ³)
1	NVLOC	NVORRES
(2)		
(3)		

1a.4 Total volume (mm³): **NVORRES**

Sample External Data

1a Series ID	Y107	3
1a.1 Is contusion volume assessable?	Y105	Yes
1a.2 Imaging modality used	Y106	NCCT
1a.3 Location Contusion 1	Y109	Left Frontal
1a.3 Location Contusion 2	Y111	Right Frontal
1a.3 Location Contusion 3	Y113	
1a.3 Volume Contusion 1 (mm3)	Y108	2774.42
1a.3 Volume Contusion 2 (mm3)	Y110	2318.00
1a.3 Volume Contusion 3 (mm3)	Y112	0.00
1a.4 Total Contusion Volume (mm3)	Y114	5092.42
1b Series ID	Y117	3
1b.1 Is hemorrhage volume assessable?	Y115	Yes
1b.2 Imaging modality used	Y116	NCCT
1b.3 Hemorrhage Volume Contusion 1 (mm3)	Y118	746.29
1b.3 Hemorrhage Volume Contusion 2 (mm3)	Y120	353.36
1b.3 Hemorrhage Volume Contusion 3 (mm3)	Y122	0.00
1b.3 Presence of contrast extravasation Contusion 1	Y119	No
1b.3 Presence of contrast extravasation Contusion 2	Y121	No
1b.3 Presence of contrast extravasation Contusion 3	Y123	
1b.4 If contrast extravasation is present, indicate method of detection	Y124	
1b.5 Total Hemorrhage Volume (mm3)	Y125	1099.65
1c.3 Edema Volume Contusion 1 (mm3)	Y126	2028.13
1c.3 Edema Volume Contusion 2 (mm3)	Y127	1964.64
1c.3 Edema Volume Contusion 3 (mm3)	Y128	0.00
1c.4 Total Edema Volume (mm3)	Y129	3992.77
1d Series ID	Y132	

Reorganization of external data for easy mapping

NVSPID	NVTESTCD	NVTEST	NVCAT	NVSCAT
	CONTVOLA	Contusion Volume Assessable	VOLUME MEASUREMENTS	CONTUSION
001	CONTVOL	Contusion Volume	VOLUME MEASUREMENTS	CONTUSION
002	CONTVOL	Contusion Volume	VOLUME MEASUREMENTS	CONTUSION
003	CONTVOL	Contusion Volume	VOLUME MEASUREMENTS	CONTUSION
004	CONTVOLT	Total Contusion Volume	VOLUME MEASUREMENTS	CONTUSION
				
	HEMVOLA	Hemorrhage Volume Assessable	VOLUME MEASUREMENTS	HEMORRHAGE
001	HEMVOL	Hemorrhage Volume	VOLUME MEASUREMENTS	HEMORRHAGE
002	HEMVOL	Hemorrhage Volume	VOLUME MEASUREMENTS	HEMORRHAGE
003	HEMVOL	Hemorrhage Volume	VOLUME MEASUREMENTS	HEMORRHAGE
004	HEMTVOL	Total Hemorrhage Volume	VOLUME MEASUREMENTS	HEMORRHAGE

Relation to PR Domain

Some NV evaluations may occur as the results of a procedure. If the information about the procedure is important, it can be represented in the PR domain

SECTION 1: VOLUME MEASUREMENTS

1a. Contusion volume (2 readers)

1a.1 Is contusion volume assessable? ☐ Yes ☐ Not assessable: _____

1a.2 Imaging modality used: ☐ FLAIR ☐ T2* ☐ NCCT

Series ID: _____

PRTRT	PRPRES	PROCCUR	PRINDC	PRLOC	VISITNUM	VISIT	VISITDY	PRSTDTC
FLUID ATTENUATED INVERSION RECOVERY	Y	Y	BRAIN CONTUSION	BRAIN	<Visit number>	<Visit>	<##>	<Date>
T2-STAR	Y	Y	BRAIN CONTUSION	BRAIN	<Visit number>	<Visit>	<##>	<Date>
DIFFUSION WEIGHTED MRI	Y	Y	BRAIN CONTUSION	BRAIN	<Visit number>	<Visit>	<##>	<Date>
CT SCAN WITHOUT CONTRAST	Y	Y	BRAIN CONTUSION	BRAIN	<Visit number>	<Visit>	<##>	<Date>

Conclusion

- NV consist of several types of assessment in different categories. It makes it complex to accommodate in SDTM
- Extensive and individual level mapping is one approach to map NV data to understand it better for analysis
- External data for NV can be tricky to analyze and organize before mapping in SDTM to maintain traceability while maintaining alignment with CRF data

References

- “Implementation of SDTM IG v.3.3 for Neurological Therapeutic Area”, Daryna Khololovych, PHUSE EU Connect 2019, [Link](#)
- “F1106_Neurological_Exam”, [Link](#)
- “08-CDISC UG SDTM IG 2019_CV_MK_NV_Silke Jasky-Gamb”, [Link](#)

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