



## Tips About Data Not Collected in cSDRG for Define.xml v2.0/v2.1

Presented by Sophia Ye  
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# Meet the Speaker

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I got my Master's degree in Statistics from the George Washington University in 2017. Join the industry after graduation, starting from Parexel, and until now. Have more than 6 years experiences in statistical programming, especially in SDTM.



# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

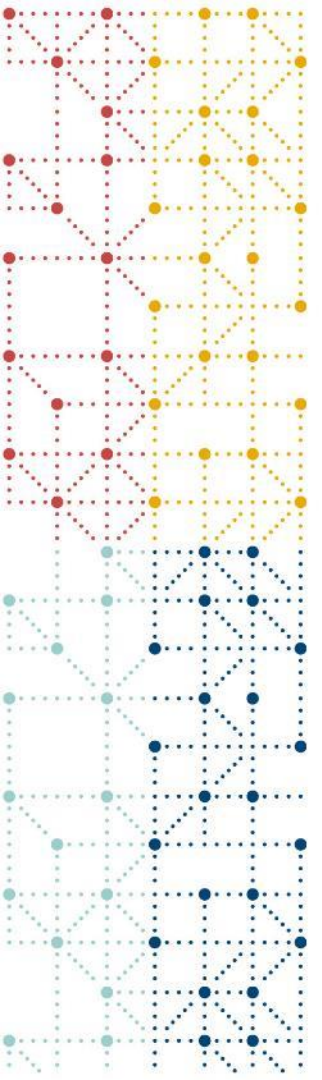


# Agenda

1. Background
2. Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG) (for define.xml 2.1)
3. Examples in cSDRG
4. Examples in define.xml (Note: define 2.1)
5. cSDRG Overview section
6. Summary



**Background**



# Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG) (for define.xml 2.1)



# SDTM-MSG (for define.xml 2.1)

## Under section 3.1 Basic Principles for Annotations:

In the event that intended data were to be collected, but none actually were, the annotated CRF will represent the data that would have been submitted had they been collected. It is not necessary to re-annotate the acrf.pdf to indicate that no data were collected. The fact that no data were collected will be indicated in the Define-XML document using the "HasNoData" attribute for datasets and variables.

- Note
  - Define.xml 2.0, there is no "HasNoData" option.
  - Define.xml 2.0 will delete empty datasets.



**Examples in cSDRG & Define.xml (v2.1)**



# NV, SUPPNV – cSDRG (define.xml 2.1)

- NV – Nervous System Findings
- The criteria specified in the protocol which required an EEG to be performed did not occur, and so NV is not included in the submission. SUPPNV was also planned and is not included. Both are indicated in the Define-XML document with HasNoData attribute set to “Yes”.
- The following variables are represented in the SUPPNV dataset.

QNAM	Description
NVCLSIG	Clinically Significant

# NV, SUPPNV – define.xml (Note: define 2.1)

- Datasets:

<p>NV [STDTMIG 3.3] [No Data]</p>	<p>Nervous System Findings</p>	<p>FINDINGS</p>	<p>One record per finding per visit per subject</p>	<p>Tabulation</p>	<p>STUDYID, USUBJID, NVTESTCD, VISITNUM</p>	<p>Per protocol, electroencephalograms are only performed after such an event were to occur. No subjects within the trial had an occurrence of an electroencephalogram event. Therefore, no data exists for the NV dataset and as such was not submitted.</p>	
<p>SUPPNV [STDTMIG 3.3] [No Data]</p>	<p>Supplemental Qualifiers for NV (Nervous System Findings)</p>	<p>RELATIONSHIP</p>	<p>One record per IDVAR, IDVARVAL, and QNAM value per subject</p>	<p>Tabulation</p>	<p>STUDYID, RDOMAIN, USUBJID, IDVAR, IDVARVAL, QNAM</p>	<p>Per protocol, electroencephalograms are only performed after such an event were to occur. No subjects within the trial had an occurrence of an electroencephalogram event. Therefore, no data exists for the NV dataset and as such SUPPNV was not submitted.</p>	

# NV, SUPPNV – define.xml (Note: define 2.1)

## NV (Nervous System Findings) - [STDTMIG 3.3] **[No Data]**

Related Supplemental Qualifiers Dataset: [SUPPNV](#) (Supplemental Qualifiers for NV)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	Identifier	2	<a href="#">SDTM Domain Abbreviation, subset used for Nervous System Findings</a> <ul style="list-style-type: none"> <li>"NV" = "Nervous System Findings"</li> </ul>	Assigned (Source: Sponsor)

## SUPPNV (Supplemental Qualifiers for NV, Nervous System Findings) - [STDTMIG 3.3] **[No Data]**

Related Parent Dataset: [NV](#) (Nervous System Findings)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
RDOMAIN	Related Domain Abbreviation	text	Identifier	6	<a href="#">SDTM Domain Abbreviation, subset used for Nervous System Findings</a> <ul style="list-style-type: none"> <li>"NV" = "Nervous System Findings"</li> </ul>	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)

# SUPPDM - cSDRG

- DM – Demographics
- The following variables are represented in the SUPPDM dataset. Note: RACE4 and RACE5 were not included in the data as no subject reported more than 3 races.

QNAM	Description
RACE1	Race 1
RACE2	Race 2
RACE3	Race 3
RACE4	Race 4
RACE5	Race 5

# SUPPDM – define.xml (Note: define 2.1)

<p>► QNAM = "RACE4"</p> <p><b>[No Data]</b></p>	Race 4	text	Result Qualifier	41	<p><a href="#">Race</a></p> <ul style="list-style-type: none"> <li>• "AMERICAN INDIAN OR ALASKA NATIVE" = "American Indian Or Alaska Native"</li> <li>• "ASIAN" = "Asian"</li> <li>• "BLACK OR AFRICAN AMERICAN" = "Black Or African American"</li> <li>• "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER" = "Native Hawaiian Or Other Pacific Islander"</li> <li>• "WHITE" = "White"</li> </ul>	<p>Collected (Source: Investigator)</p> <p>Annotated CRF <a href="#">[S]</a></p> <p>Since no subjects had more than 3 Races, RACE4 was not used.</p>
<p>► QNAM = "RACE5"</p> <p><b>[No Data]</b></p>	Race 5	text	Result Qualifier	41	<p><a href="#">Race</a></p> <ul style="list-style-type: none"> <li>• "AMERICAN INDIAN OR ALASKA NATIVE" = "American Indian Or Alaska Native"</li> <li>• "ASIAN" = "Asian"</li> <li>• "BLACK OR AFRICAN AMERICAN" = "Black Or African American"</li> <li>• "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER" = "Native Hawaiian Or Other Pacific Islander"</li> <li>• "WHITE" = "White"</li> </ul>	<p>Collected (Source: Investigator)</p> <p>Annotated CRF <a href="#">[S]</a></p> <p>Since no subjects had more than 3 Races, RACE5 was not used.</p>



# cSDRG

- 3. Subject Data Description

- 3.1 Overview

Were any domains planned, but not submitted because no data were collected?

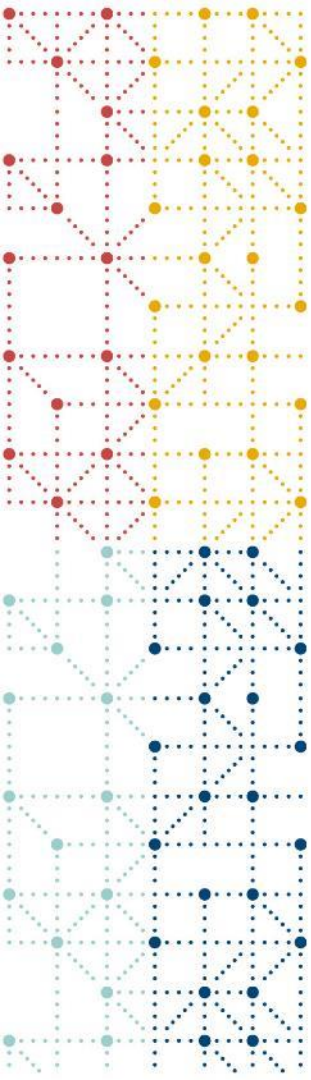
Yes, NV (Nervous System Findings) was not submitted as no EEGs were performed.

Also SUPPOE was planned but no OE findings were considered clinically significant so the SUPQUAL dataset was not created.

# Summary

- This general approach is recommended by MSG.

	Define.xml 2.0	Define.xml 2.1	cSDRG
Datasets	Remove	Keep, with [No Data] shown	Write in section 3.1 overview
SUPP variables	Keep	Keep, with [No Data] shown	Keep, add note



**Thank You!**

