

Please Put Your Data in an Upright Position – Or How to Tackle Verticalisation

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At Clinipace, it's personal.

- ▶ Introduction
- ▶ PROC TRANSPOSE
- ▶ Conclusion



Introduction

- ▶ Focus on SDTM programming
- ▶ SDTM structure: vertical
- ▶ Common challenge: Transform horizontal input data into vertical SDTM domains

- ▶ Assumption: Implementation of SDTM specifications via templates
- ▶ Implementation of SDTM specifications:
 - Definition of SDTM specifications in Excel sheet
 - Excel Sheet is read into SAS
 - Creation of individual SDTM domain templates with information of each variable (name, label, length, type)
 - Realisation of SDTM domains by mapping of templates with study data

Introduction

STUDYID	DOMAIN	USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTAT	VSREASND	VISITNUM	VISIT
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Column Attributes

General | Colors | Fonts

Name:

Label:

Length:

Format: ...

Informat: ...

Type
☒ Character
☐ Numeric



PROC TRANSPOSE

PROC TRANSPOSE

Table 1: Original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	VSND	PULSE	PULSEEND	RESP	RESPND
PHUSE2018	101	101_001	Screening	0	11DEC2017	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	1	.	0	.	0
PHUSE2018	101	102_001	Screening	0	12DEC2017	0	68	0	.	1

PROC TRANSPOSE

```
PROC TRANSPOSE DATA = vs_raw OUT = vs_raw_t (rename=(COL1=vsres _NAME_=testcd));  
  BY studyid siteid subjid visitnum visit vsdt;  
  VAR vsnd pulse resp;  
RUN;
```

PROC TRANSPOSE

Table 2: Transposed original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.

PROC TRANSPOSE

Table 1: Original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	VSND	PULSE	PULSEEND	RESP	RESPND
PHUSE2018	101	101_001	Screening	0	11DEC2017	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	1	.	0	.	0
PHUSE2018	101	102_001	Screening	0	12DEC2017	0	68	0	.	1

PROC TRANSPOSE

Table 2: Transposed original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.

PROC TRANSPOSE

Table 1: original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	VSND	PULSE	PULSEEND	RESP	RESPND
PHUSE2018	101	101_001	Screening	0	11DEC2017	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	1	.	0	.	0
PHUSE2018	101	102_001	Screening	0	12DEC2017	0	68	0	.	1

PROC TRANSPOSE

Table 2: Transposed original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.

PROC TRANSPOSE

```
DATA vs_merged;  
    MERGE vs_raw_t  
        vs_raw;  
    BY studyid siteid subjid visitnum visit vsdt;  
RUN;
```

PROC TRANSPOSE

Table 2: Merged data set of transposed dataset vital signs dataset and original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES	VSND	PULSE	PULSE ND	RESP	RESP ND
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.	1	.	0	.	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.	0	68	0	.	1

PROC TRANSPOSE

Table 3: Merged dataset of data based original vital signs dataset and original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES	VSND	PULSE	PULSE ND	RESP	RESP ND
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.	1	.	0	.	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.	0	68	0	.	1

PROC TRANSPOSE

```
DATA vs_transpose;
SET sdtmtmpl.vs
  vs_merged(RENAME=(studyid=_studyid visit=_visit visitnum=_visitnum));

studyid = _studyid;
visit = _visit;
visitnum = _visitnum;
usubjid = trim(studyid) || "-" || trim(subjid);
domain = "VS";

SELECT (testcd);

  WHEN ("VSND") DO;
    vstestcd = "VSALL";
    vstest = "Vital Signs";
    vsorresu = "";
  END;

  WHEN ("PULSE") DO;
    vstestcd = "PULSE";
    vstest = "Pulse Rate";
    vsorresu = "beats/min";
  END;

  WHEN ("RESP") DO;
    vstestcd = "RESP";
    vstest = "Respiratory Rate";
    vsorresu = "breaths/min";
  END;

  OTHERWISE call missing (vstestcd, vstest, vsorresu);
END;
```

```
vsorres = strip(put(vsres, best.));

SELECT;

  WHEN (testcd = "VSND" and vsnd = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  WHEN (testcd = "PULSE" and pulsnd = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  WHEN (testcd = "RESP" and respnd = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  OTHERWISE call missing (vsstat, vsreasnd);
END;

IF vsnd eq 1 and testcd ne "VSND" THEN DELETE;
IF vsnd ne 1 and testcd eq "VSND" THEN DELETE;

RUN;
```

PROC TRANSPOSE

```
DATA vs_transpose;  
  SET sdtmtmpl.vs  
    vs_merged(RENAME=(studyid=_studyid visit=_visit visitnum=_visitnum));  
  
  studyid = _studyid;  
  visit = _visit;  
  visitnum = _visitnum;  
  usubjid = trim(studyid) || "-" || trim(subjid);  
  domain = "VS";
```

```
SELECT (testcd);  
  
  WHEN ("VSND") DO;  
    vstestcd = "VSALL";  
    vstest = "Vital Signs";  
    vsorresu = " ";  
  END;  
  
  WHEN ("PULSE") DO;  
    vstestcd = "PULSE";  
    vstest = "Pulse Rate";  
    vsorresu = "beats/min";  
  END;  
  
  WHEN ("RESP") DO;  
    vstestcd = "RESP";  
    vstest = "Respiratory Rate";  
    vsorresu = "breaths/min";  
  END;  
  
  OTHERWISE call missing (vstestcd, vstest, vsorresu);  
END;
```


PROC TRANSPOSE

```
vsorres = strip(put(vsres, best.));

SELECT;

  WHEN (testcd = "VSND" and vsnd = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  WHEN (testcd = "PULSE" and pulsend = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  WHEN (testcd = "RESP" and respnd = 1) DO;
    vsstat = "NOT DONE";
    vsreasnd = "REASON NOT COLLECTED";
    call missing (of vsorres:);
  END;

  OTHERWISE call missing (vsstat, vsreasnd);
END;

IF vsnd eq 1 and testcd ne "VSND" THEN DELETE;
IF vsnd ne 1 and testcd eq "VSND" THEN DELETE;
```

RUN;

PROC TRANSPOSE

Table 3: Merged dataset of transposed original vital signs dataset and original vital signs dataset

STUDYID	SITEID	SUBJID	VISIT	VISITNUM	VSDT	TESTCD	_LABEL_	VSRES	VSND	PULSE	PULSE ND	RESP	RESP ND
PHUSE2018	101	101_001	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	PULSE	Pulse Rate	92	0	92	0	12	0
PHUSE2018	101	101_001	Screening	0	11DEC2017	RESP	Respiratory Rate	12	0	92	0	12	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	VSND	Vital Signs Not Done	0	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	PULSE	Pulse Rate	.	0	.	1	16	0
PHUSE2018	101	101_001	Final Visit	99	16APR2018	RESP	Respiratory Rate	16	0	.	1	16	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	VSND	Vital Signs Not Done	0	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	PULSE	Pulse Rate	86	0	86	0	14	0
PHUSE2018	101	101_002	Screening	0	11DEC2017	RESP	Respiratory Rate	14	0	86	0	14	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	VSND	Vital Signs Not Done	1	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	PULSE	Pulse Rate	.	1	.	0	.	0
PHUSE2018	101	101_002	Final Visit	99	23FEB2018	RESP	Respiratory Rate	.	1	.	0	.	0
PHUSE2018	102	102_001	Screening	0	12DEC2017	VSND	Vital Signs Not Done	0	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	PULSE	Pulse Rate	68	0	68	0	.	1
PHUSE2018	102	102_001	Screening	0	12DEC2017	RESP	Respiratory Rate	.	0	68	0	.	1

PROC TRANSPOSE

Table 4: SDTM.VS domain variables

STUDYID	DOMAIN	USUBJID	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTAT	VSREASND	VISITNUM	VISIT
PHUSE2018	VS	PHUSE2018-101_001	PULSE	Pulse Rate	92	beats/min			0	Screening
PHUSE2018	VS	PHUSE2018-101_001	RESP	Respiratory Rate	12	breaths/min			0	Screening
PHUSE2018	VS	PHUSE2018-101_001	PULSE	Pulse Rate			NOT DONE	REASON NOT COLLECTED	99	Final Visit
PHUSE2018	VS	PHUSE2018-101_001	RESP	Respiratory Rate	16	breaths/min			99	Final Visit
PHUSE2018	VS	PHUSE2018-101_002	PULSE	Pulse Rate	86	beats/min			0	Screening
PHUSE2018	VS	PHUSE2018-101_002	RESP	Respiratory Rate	14	breaths/min			0	Screening
PHUSE2018	VS	PHUSE2018-101_002	VSALL	Vital Signs			NOT DONE	REASON NOT COLLECTED	99	Final Visit
PHUSE2018	VS	PHUSE2018-102_001	PULSE	Pulse Rate	68	beats/min			0	Screening
PHUSE2018	VS	PHUSE2018-102_001	RESP	Respiratory Rate			NOT DONE	REASON NOT COLLECTED	0	Screening



Conclusion

- ▶ PROC TRANSPOSE is a reliable way to verticalise data
- ▶ Merging transposed vertical data with pre-transposed horizontal data can be a helpful tool to create and handle “NOT DONE” SDTM observations
- ▶ A mindful selection of variables that are supposed to be transposed is crucial for the „workability“ of the transposed dataset

THANK YOU