

# NSVs (Non-Standard Variables) as Supplemental Qualifiers

## A Review and Primer

# Supplemental Qualifiers

- Supplemental Qualifiers handle data for which there is no existing SDTM qualifier variable.
- Non-Standard Variables (NSVs) are another name for Supplemental Qualifiers
- There can be no “orphan” Supplemental Qualifier records; all must relate back to at least one parent record
- Supplemental Qualifier records do not relate to each other, but only individually back to the parent; If you have a non-standard variable where the response also has an additional qualifier such as a unit, that is an indication that a Findings About (FA) dataset should be used.
- Supplemental Qualifier records share the timing of the parent record; they don't have timing of their own; if the timing is different from that of the parent, mapping to an FA dataset may be called for
- When identifying a data collection (CDASH) variable as a Supplemental Qualifier, it's of paramount importance to be able to identify its parent record
- Supplemental Qualifier records are no less important than the standard qualifiers

# Supplemental Qualifier Examples – EC (1)

LPO	FormOID	FieldOID/Variable	PreText/QT
NRG	CYC_INFO	SUPPEC_QVAL_ITRPYN	Was Treatment Interrupted?
NRG	CYC_INFO	SUPPEC_QVAL_ITRP	If yes, Reason Interrupted
<b>NRG</b>	<b>CYC_DRUG</b>	<b>SUPPEC_QVAL_ECITRPYN</b>	<b>Was Treatment Interrupted?</b>
<b>NRG</b>	<b>CYC_DRUG</b>	<b>SUPPEC_QVAL_ECITRPRS</b>	<b>If yes, Reason Interrupted</b>

Non-Standard Variables

“Operational” dataset

STUDYID	DOMAIN	SUBJID	ECTRT	ECDOSE	ECDOSU	ECSTDAT	ECENDAT	ECITRPYN	ECITRPRS
DEF0001	EC	101	STUDY DRUG	99	mL	15-JAN-2012	15-JAN-2012	Y	Suspected toxicity
DEF0001	EC	102	<b>STUDY DRUG</b>	99	mL	<b>17-JAN-2012</b>	17-JAN-2012	<b>N</b>	

*ec.xpt (blinded)*

STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECDOSE	ECDOSU	ECSTDTC	ECENDTC	ECITRPYN	ECITRPRS
DEF0001	EC	0001-101	1	STUDY DRUG	99	mL	2012-01-15T08:30	2012-01-29T08:30	Y	Suspected Toxicity
DEF0001	EC	0001-102	1	<b>STUDY DRUG</b>	99	mL	2012-01-17T10:30	2012-01-31T10:30	<b>N</b>	

The above depiction of the record in SDTM, often seen in various TAUGs, is for ease of review; when the SUPPEC dataset is created, the two non-standard variables are turned into “vertical” records as shown on the following slide

## Supplemental Qualifier Examples – EC (2)

*suppec.xpt*

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
DEF0001	EC	0001-101	ECSEQ	1	ECITRPYN	Was Treatment Interrupted	Y	CRF
DEF0001	EC	0001-101	ECSEQ	1	ECITRPRS	Reason Interrupted	Suspected Toxicity	CRF
DEF0001	EC	0001-102	ECSEQ	1	ECITRPYN	Was Treatment Interrupted	N	CRF

Relationship Variables (identifying the parent record)

The collected data itself

- Even though these Non-Standard variables may be part of a sponsor’s “operational” dataset, they cannot be added to parent SDTM domains
- These NSV’s are submitted according to the defined Supplemental Qualifier data structure detailed in Section 8 of the SDTMIG; “Expected” column of QEVAL omitted
- To emphasize, SUBJID 101 has 2 SUPPEC records that reference the same “parent” record, one representing the “Was Treatment Interrupted” question and the other to represent the “Reason Interrupted” question.

# Supplemental Qualifiers Example – TU

From our CTEP R6/R7 Content Mapping doc

CDASH FieldOID	CDASH Controlled Terminology	Data Dictionary Name	CDASH QuestionText	CDASH Prompt
SUPPTU_QVAL_PREVIRR	NY	N, NA, U, Y	Was the tumor previously irradiated?	Previously Irradiated?

*tu.xpt*

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC
1	ABC	TU	44444	1		T01	TUMIDENT	Tumor Identification	TARGET	TARGET	LIVER
2	ABC	TU	44444	2		T02	TUMIDENT	Tumor Identification	TARGET	TARGET	KIDNEY
3	ABC	TU	44444	3		T03	TUMIDENT	Tumor Identification	TARGET	TARGET	CERVICAL LYMPH NODE
4	ABC	TU	44444	4		T04	TUMIDENT	Tumor Identification	TARGET	TARGET	SKIN OF THE TRUNK

*supptu.xpt*

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
1	ABC	TU	44444	TULNKID	T01	PREVIR	Previously Irradiated	N
2	ABC	TU	44444	TULNKID	T02	PREVIR	Previously Irradiated	N
3	ABC	TU	44444	TULNKID	T03	PREVIR	Previously Irradiated	Y
4	ABC	TU	44444	TULNKID	T03	PREVIRP	Irradiated then Subsequent Progression	Y
5	ABC	TU	44444	TULNKID	T04	PREVIR	Previously Irradiated	N

# Supplemental Qualifier Example – MB (1)

From our SUPPQ spreadsheet, Theradex captures 2 “supplemental” questions in support of COVID-19 testing, ASYNAM (Assay Name) and ASYDAT (Assay Date)

Non-Standard Variables

“Operational” MB dataset

DOMAIN	SUBJID	MBREFID	MBTEST	MBORRES	MBSPEC	MBLOC	MBMETHOD	MBASYNAM	MBASYDAT	VISIT	MBDAT
MB	0001-101	COV001A	SARSCOV2	POSITIVE	SWABBED MATERIAL	NOSE	PCR	Accula	23-FEB-2022	SCREEN	22-FEB-2022
MB	0001-102	COV002A	SARSCOV2	NEGATIVE	SWABBED MATERIAL	NOSE	PCR	Accula	28-FEB-2022	SCREEN	27-FEB-2022

*mb.xpt*

STUDYID	DOMAIN	USUBJID	MBSEQ	MBTEST	MBORRES	MBSPEC	MBLOC	MBMETHOD	VISIT	MBDTC
DEF0001	MB	0001-101	1	SARSCOV2	POSITIVE	SWABBED MATERIAL	NOSE	PCR	SCREEN	2022-02-22
DEF0001	MB	0001-102	1	SARSCOV2	NEGATIVE	SWABBED MATERIAL	NOSE	PCR	SCREEN	2022-02-27

MBASYNAM	MBASYDAT
Accula	2022-02-23
Accula	2022-02-28

These records represent the “non-standard variables” contained in the operational MB dataset. As we did for the EC example earlier, we’ll now look at how these would be shown in *SUPPMB*.

## Supplemental Qualifier Example – MB (2)

*suppmb.xpt*

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
DEF0001	MB	0001-101	MBSEQ	1	MBASYNAM	Assay Name	Accula	CRF
DEF0001	MB	0001-101	MBSEQ	1	MBASYDAT	Assay Date	2022-02-23	CRF
DEF0001	MB	0001-102	MBSEQ	1	MBASYNAM	Assay Name	Accula	CRF
DEF0001	MB	0001-102	MBSEQ	1	MBASYDAT	Assay Date	2022-02-28	CRF

Relationship Variables (identifying the parent record)

The collected data itself

- Even though these Non-Standard variables may be part of a sponsor’s “operational” dataset, they cannot be added to parent SDTM domains
- These NSV’s are submitted according to the defined Supplemental Qualifier data structure detailed in Section 8 of the SDTMIG; “Expected” column of QEVAL omitted
- To emphasize, both subjects have 2 SUPPMB records that reference the same “parent” record, one representing the “Assay Name” question and the other the “Assay Date” question.

# Supplemental Qualifier Example – Protocol Version (from PBTC) and the CDASH variable RACEOTH (1)

This CRF represents an older, annotated, and fairly simple Demographics page where the subject has identified themselves as both “White” and “Spanish”. The sponsor collected the informed consent date (and protocol version) on this page and then mapped the date to DS as a “Protocol Milestone”. We’ll look at a couple different ways to represent this information.

DEMOGRAPHICS	
Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	<b>SEX</b>
Date of Birth: <u>28/JUN/1971</u> <small>(dd/MON/yyyy)</small>	<b>BIRTHDAT</b>
Age (years): <u>37</u>	<b>AGE</b> <b>AGEU</b>
Race (Check all that apply):	<b>RACE</b>
<input checked="" type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian	
<input type="checkbox"/> Native Hawaiian or <u>other</u> Pacific Islander <input type="checkbox"/> American Indian or Alaska native	
<input type="checkbox"/> Other, specify: <u>Spanish</u>	<b>RACEOTH</b>
Ethnicity	
<input type="checkbox"/> Hispanic or Latino	<b>ETHNIC</b>
<input checked="" type="checkbox"/> Not Hispanic or Latino	
Informed Consent Signed: <u>06/AUG/2008</u> <small>(dd/MON/yyyy)</small>	<b>RFICDAT</b>
Protocol Version <input type="checkbox"/> <u>Version 1</u> <input type="checkbox"/> Version 1.1 <input type="checkbox"/> Version 2.0	<b>PROTVERS</b>



## Supplemental Qualifier Example – Protocol Version (from PBTC) and the CDASH variable RACEOTH (2)

*dm.xpt*

STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFICDTC	SITEID	BRTHDTC	AGE	SEX	RACE	DMDTC
DEF0001	DM	0001-101	1	2008-08-12	2008-09-21	2008-08-06	0001	1971-06-28	37	F	WHITE	2008-08-06

*ds.xpt*

STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSCAT	DSDTC	DSSTDTC
DEF0001	DS	0001-101	1	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	2008-08-06	2008-08-06

The above SDTM Demographics and Disposition datasets, though leaving out a few variables, shows the data from the previous slide. SDTM (or CDASH) doesn't dictate where the "date of informed consent" should be captured. Indeed, the CDASHIG doesn't include RFICDTC in the metadata table though it is talked about under the heading of "Collection of Special Optional Fields". In the SDTM datasets, this date, whether collected on a Demographics page or elsewhere should appear in both the DM and DS datasets. On the following slide, we'll look at a couple options of how the non-standard variables may be shown.

## Supplemental Qualifier Example – Protocol Version (from PBTC) and the CDASH variable RACEOTH (3)

### *suppdm.xpt*

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
DEF0001	DM	0001-101			PROTVERS	Protocol Version	1.1	CRF
DEF0001	DM	0001-101			RACEOTH	Race, other	Spanish	CRF

We notice that in SUPPDM, there's no need to identify an IDVAR or IDVARVAL for the simple reason that in DM, there's only a single record per USUBJID. So the STUDYID, RDOMAIN, and USUBJID are sufficient to identify the parent record.

Below shows how the “protocol version” would be shown as a SUPPDS record. Notice, of course, when using SUPPDS, we do need to more fully identify the parent record by including the IDVAR and associated IDVARVAL. This represents the record that would be created from PBTC's CDASH variable of SUPPDS\_QVAL\_PROTVERS. The “Protocol Version” would be mapped to either SUPPDM or to SUPPDS, but not both.

### *suppds.xpt*

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG
DEF0001	DS	0001-101	DSSEQ	1	PROTVERS	Protocol Version	1.1	CRF

*Questions?*

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