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
NRG	**CYC_DRUG**	**SUPPEC_QVAL_ECITRPYN**	**Was Treatment Interrupted?**
NRG	**CYC_DRUG**	**SUPPEC_QVAL_ECITRPRS**	**If yes, Reason Interrupted**

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	**STUDY DRUG**	99	mL	**17-JAN-2012**	17-JAN-2012	**N**	

ec.xpt (blinded)

STUDYID	DOMAIN	USUBJID	ECSEQ	ECTRT	ECDOSE	ECDOSU	ECSTDTC	ECENDTC
DEF0001	EC	0001-101	1	STUDY DRUG	99	mL	2012-01-15T08:30	2012-01-29T08:30
DEF0001	EC	0001-102	1	**STUDY DRUG**	99	**mL**	2012-01-17T10:30	2012-01-31T10:30

ECITRPYN	ECITRPRS
Y	Suspected Toxicity
N	

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 Question Text	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

Questions?

*NCI**CDISC**Support@nih.gov*