

Considerations and Conventions in the Submission of the SDTM Tumor and Response Domains

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Agenda

- ▶ Review of Tumor domains and representative CRFs
 - TU (Tumor Identification)
 - TR (Tumor Results)
 - RS (Disease Response)
- ▶ Use of Identifiers –LNKID and –LNKGRP as linking variables across the tumor domains
 - ▶ Unique per –LNKID, per “Evaluator”
- ▶ Oncology examples across TU, TR, and RS
 - ▶ Examples from the Prostate Cancer Therapeutic Area User Guide (TAUG)
- ▶ Non–Oncology applications of the “Tumor” domains
 - ▶ Examples from the Cardiovascular TAUG
- ▶ Proposed expansion of the RS domain to include Clinical Classifications

SDTM Oncology Domains

- ▶ Intended to represent data collected in clinical trials where tumors are:
 - Identified
 - Repeatedly measured/assessed
 - Used in an evaluation of therapeutic response
- ▶ Developed primarily with RECIST (Response Criteria in Solid Tumors) in mind
 - Other standardized assessment criteria can also be represented such as Cheson or Hallek
- ▶ Three Domains (TU / TR / RS) have been developed to provide a standardized representation to:
 - Reduce data redundancy
 - Provide a relational approach aligned with SDTM philosophy
 - These domains are not intended to represent all data that might be required is a response assessment. Data may reside in additional domains e.g. LB
 - These domains are currently under evaluation for broader use as we will see

STUDYID 060	Site No. 	Patient No. 	Patient Initials 	BASELINE REGISTRATION
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TU=Tumor Identification

TUMOR ASSESSMENT

TR=Tumor Results

TUTESTCD = TUMIDENT

Up to a maximum of 5 lesions per organ and 10 lesions in total, representative of all involved organs. ALL LESIONS must be followed using the same measurement method and numbering (1, 2, ...) throughout the study. Please measure / follow all lesions identified at Baseline.

TUORRES = TARGET

Are lesions assessed?

☐ Yes, please complete below☐ No

TRTEST = Longest Diameter

TRTESTCD = LDIAAM

Lesion Number	Organ	Date of Assessment TUDTC / TRDTC	Method of Measurement	Measurement*	Do not map
	a: Site (enter the appropriate number) 1 = Lung 2 = Liver 3 = Lymph Node 4 = Skin 5 = Breast 7 = Soft Tissue 8 = Other organ, specify site: b: Subsite (description)		(enter the appropriate number) 1: Physical Examination 2: CT Scan Spiral 3: CT Scan Conventional 4: MRI 99: Other, specify:		
TULNKID TRLNKID	TULOC		TUMETHOD TRMETHOD	TORRES	
M1	a: b:	 day month year		 mm	
M2	a: b:	 day month year		 mm	TORRESU
M3	a: b:	 day month year		 mm	
M4	a: b:	 day month year		 mm	
M5	a: b:	 day month year		 mm	
M6	a: b:	 day month year		 mm	
M7	a: b:	 day month year		 mm	
M8	a: b:	 day month year		 mm	
M9	a: b:	 day month year		 mm	
M10	a: b:	 day month year		 mm	

* Enter result (in millimeters) of the longest diameters for target measurable lesions only

ORIGINAL SITE	YELLOW SITE	CAPSCAPE SITE
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STUDYID 060	Site No. _ _ _ _	Patient No. _ _ _ _	Patient Initials _ _ _ _	Cycle 2, Day 28
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TR=Tumor Results

TUMOR ASSESSMENT

TABLE (M) LESIONS (RECIST CRITERIA)

TRTESTCD = LDIAM

up to a maximum of 5 lesions per organ and 10 lesions in total, representative of all involved organs. ALL LESIONS must be followed using the same measurement method and numbering (1, 2,...) throughout the study. Please measure / follow all lesions identified at Baseline.

TRTEST= Longest Diameter

assessed? ☐ Yes, please complete below ☐ No

Lesion Number	Organ a: Site (enter the appropriate number) 1 = Lung 2 = Liver 3 = Lymph Node 4 = Skin 5 = Breast 7 = Soft Tissue 8 = Other organ, specify site: b: Subsite (description)	Date of Assessment TRDTC _ _ _ _ _ _ _ day month year	Method of Measurement (enter the appropriate number) 1: Physical Examination 2: CT Scan Spiral 3: CT Scan Conventional 4: MRI 99: Other, specify: TRMETHOD	Measurement* TRORRES _ _ _ _ mm	Do not map 0: No 1: Yes, further progression 2: Yes, no further progression TRORRESU
M1	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M2	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M3	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M4	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M5	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M6	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M7	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M8	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M9	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	
M10	a: _ b:	_ _ _ _ _ _ _ day month year		_ _ _ _ mm	

* Enter result (in millimeters) of the longest diameters for target measurable lesions only

ORIGINAL SITE	MEASUREMENT SITE	ASSESSMENT SITE
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CRF - Bone Lesions

This CRF is only an example and is not meant to imply that any particular layout or collection plan is preferable over another. CRF annotated to show mapping. Variables defined in the SDTMIG are in **RED**. If the CDASHIG variable differs from the one defined in the SDTMIG, the CDASHIG variable is in **GREY**. Data collected, but not submitted in SDTM-based datasets, are denoted as **NOT SUBMITTED**. Example CRF Instructions are provided in the first column.

Hide Annotations

	Response Criteria ONCRSCAT Not submitted Pre-specified	<u>PCWG SCHER PROSTATE CANCER 2008</u> <From ONCRSCAT codelist>
	Tumor Type According to Criteria TUTYPN AM TUORRES where TUTESTCD="TUMIDENT", Hidden/pre-specified	<u>BONE LESION</u> <From TUMIDENT codelist>
Record whether or not bone lesions were identified	Were any bone lesions identified? TUY N If yes: Not submitted If no: TUORRES="ABSENT" where TUTESTCD="TRGEXM" and SUPPTU.QVAL="BONE" where QNAM="RESTRG"	- Yes - No <From NY codelist>
Record the date of the scan/image/examination (not the date on which it was read, or the visit date)	Date of Procedure TUDAT TUDTC	___/___/___
Specify the	Method of Evaluation	Scintigraph

method used to identify/evaluate the tumor/lesion.	TUMETHOD	CT Scan <From METHOD codelist>
Indicate who performed the assessment	Evaluator TUEVAL	- Investigator - Independent Assessor <From EVAL codelist>
Identify the evaluator providing this evaluation	Evaluator Identifier TUEVALID	- Radiologist 1 - Radiologist 2 - Radiologist 3 - Oncologist <From MEDEVAL codelist>
	Location TULOC Hidden/pre-specified	<u>BONE</u> <From LOC codelist>
Record the bone lesion ID.	Bone Lesion ID TULNKID	_____
Record the number of bone lesions identified.	Number of Bone Lesions BNLNUM_TORRES TRORRES where TRTESTCD="BNLNUM"	_____

Option: Sponsors can collect: Total number of bone lesions identified by pre-specified locations

Record the number of skull bone lesions identified.	Number of Skull Bone Lesions SKULL_TORRES TRORRES where TRTESTCD="BNLNUM" and TRLOC="SKULL"	_____
Record	Skull Bone Lesion ID	_____

Tumor Identification (TU)

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- Identification of unique tumors for a subject
 - One record per tumor per assessor
 - Classified according to disease assessment criteria – RECIST
 - Target
 - Non-Target
 - New
 - Tumor Location
 - Method of Identification
 - Timing information
 - Controlled Terminology exists for TUTESTCD/TUTEST as well as for Identification Results

A tumor is identified only once in TU and assigned a unique tumor identifier that follows that tumor throughout the study and through all of its measurements and assessments.

TU Example

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Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUTESTCD	TUTEST	TUORRES
1	0606/ABC	TU	013-2486	1	TL01	TUMIDENT	Tumor Identification	TARGET
2	0606/ABC	TU	013-2486	3	NTL01	TUMIDENT	Tumor Identification	NON-TARGET
3	0606/ABC	TU	013-2486	4	R-TL01	TUMIDENT	Tumor Identification	TARGET
4	0606/ABC	TU	013-2486	6	R-NTL01	TUMIDENT	Tumor identification	NON-TARGET
5	0606/ABC	TU	013-2486	7	NEW01	TUMIDENT	Tumor identification	NEW
6	0606/ABC	TU	013-2486	8	R-NEW01	TUMIDENT	Tumor Identification	NEW

Row	TULOC	TUMETHOD	TUEVAL	VISITNUM	VISIT	TUDTC
1 (Cont)	LIVER	SPIRAL CT	INVESTIGATOR	1	BASELINE	2014-11-01
2 (Cont)	BREAST	SPIRAL CT	INVESTIGATOR	1	BASELINE	2014-11-01
3 (Cont)	LIVER	SPIRAL CT	INDEPENDENT ASSESSOR	1	BASELINE	2014-11-01
4 (Cont)	BREAST	SPIRAL CT	INDEPENDENT ASSESSOR	1	BASELINE	2014-11-01
5 (Cont)	COLON	SPIRAL CT	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
6 (Cont)	COLON	SPIRAL CT	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28

TU Example from the PrCA TAUG

STUDYID	DOMAIN	USUBJID	TUSEQ	TUREFID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC
PRCA123	TU	99000	1	IMG-00001		TRGEXM	Targeted Examination	ABSENT	ABSENT
PRCA123	TU	99000	2	IMG-M0001	R-NT01	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET
PRCA123	TU	99000	4	IMG-B0001	R-BT01	TUMIDENT	Tumor Identification	BONE LESION	BONE LESION
PRCA123	TU	99000	5	IMG-B0002	R-BNEW01	TUMIDENT	Tumor Identification	NEW BONE LESION	NEW BONE LESION
TULOC	TUMETHOD	TUEVAL	TUEVALID	VISITNUM	VISIT	EPOCH	TUDTC	TUDY	RESTRG *
	CT SCAN	INDEPENDENT ASSESSOR	RADIOLOGIST	10	SCREEN	BASELINE	2016-01-02	-2	MEASURABLE TUMORS
BRAIN	MRI	INDEPENDENT ASSESSOR	RADIOLOGIST	10	SCREEN	BASELINE	2016-01-02	-2	
BONE	SCINTIGRAPHY	INDEPENDENT ASSESSOR	RADIOLOGIST	10	SCREEN	BASELINE	2016-01-02	-2	
BONE	SCINTIGRAPHY	INDEPENDENT ASSESSOR	RADIOLOGIST	20	WEEK 12	TREATMENT	2016-03-27	84	

*RESTRG – Pre-Specified Result Targeted by Test (SUPPTU record until new variable approved for inclusion SDTM v1.6)

Tumor Results (TR)

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- Qualitative assessments and quantitative measurements of the tumors and/or sites of disease identified in TU
- One record per tumor measurement/assessment, per visit, per assessor
- Unique tumor ID (--LNKID) from TU follows each identified tumor or lesion throughout each subsequent assessment. This --LNKID is unique per identified tumor or lesion, per assessor.
- The identifier TRLNKGRP provides a way to “link” assessment records to support whatever disease response granularity may be required by the protocol
- These periodic assessments and measurements support response evaluations represented in RS
- Certain collected qualifiers that may be represented in TU, such as TULOC are not repeated in TR
- Controlled Terminology exists for TRTESTCD/TRTEST as well as for “Tumor or Lesion Properties Test Results”

TR Example

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRLNKID	TRLNKGRP	TRTESTCD	TORRES
1	0606/ABC	TR	013-2486	1	TL01	V1	LDIAM	6.2
2	0606/ABC	TR	013-2486	2	NTL01	V1	TUMSTATE	PRESENT
3	0606/ABC	TR	013-2486	3	R-TL01	R-V1	LDIAM	6.0
4	0606/ABC	TR	013-2486	4	R-NTL01	R-V1	TUMSTATE	PRESENT
5	0606/ABC	TR	013-2486	5	TL01	V2	LDIAM	5.8
6	0606/ABC	TR	013-2486	6	NTL01	V2	TUMSTATE	PRESENT
7	0606/ABC	TR	013-2486	7	R-TL01	R-V2	LDIAM	5.8
8	0606/ABC	TR	013-2486	8	R-NTL01	R-V2	TUMSTATE	PRESENT
9	0606/ABC	TR	013-2486	9	NEW01	V2	LDIAM	5.2
10	0606/ABC	TR	013-2486	10	R-NEW01	R-V2	LDIAM	5.4

TR Example (Continued)

Row	TRORRESU	TRMETHOD	TREVAL	VISITNUM	VISIT	TRDTC
1 (Cont)	mm	SPIRAL CT	INVESTIGATOR	1	BASELINE	2014-11-01
2 (Cont)		SPIRAL CT	INVESTIGATOR	1	BASELINE	2014-11-01
3 (Cont)	mm	SPIRAL CT	INDEPENDENT ASSESSOR	1	BASELINE	2014-11-01
4 (Cont)		SPIRAL CT	INDEPENDENT ASSESSOR	1	BASELINE	2014-11-01
5 (Cont)	mm	SPIRAL CT	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
6 (Cont)	mm	SPIRAL CT	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
7 (Cont)	mm	SPIRAL CT	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28
8 (Cont)	mm	SPIRAL CT	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28
9 (Cont)	mm	SPIRAL CT	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
10 (Cont)	mm	SPIRAL CT	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28

RS : Response

- ▶ The RS domain represents the response evaluation
 - Determined from the data in TR for RECIST studies
- ▶ A tumor response may be as granular as for a single identified tumor or for a “group” of identified tumors (e.g., “Target” or “Non-Target”)
- ▶ Some cancers require different standardized assessment criteria to better serve as predictors of outcome
 - Hallek as used in CLL includes cell morphology and labs
 - PCWG Scher as shown in the Prostate Cancer TAUG uses both a radiologic response and a tumor marker (PSA) response
- ▶ Multiple response criteria may be used on a single study and the category variables help to distinguish between criteria in such cases
 - E.g. RECIST and Volumetric assessments

Response_20151211.pdf - Adobe Acrobat Pro

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Date Performed _____ Fixed Unit: dd MMM yyyy

RSDTC

Evaluation of Target Lesions

RSTEST when RSTESTCD = "TRGRES" **RSORRES when RSTESTCD = "TRGRES"**

Complete Response ☐

Partial Response ☐

Stable Disease ☐

Progressive Disease ☐

Not Evaluable ☐

NA ☐

RSSTAT when RSTESTCD = "TRGRES"

Evaluation of Non-Target Lesions

RSTEST when RSTESTCD = "NTRGRES" **RSORRES when RSTESTCD = "NTRGRES"**

Complete Response ☐

Non-Complete Response ☐

/Non-Progressive Disease

Progressive Disease ☐

Not Evaluable ☐

NA ☐

RSSTAT when RSTESTCD = "NTRGRES"

Overall Response Evaluation (Target, Non-Target, and New Lesions)

RSTEST when RSTESTCD = "OVLRESP" **RSORRES when RSTESTCD = "OVLRESP"**

Complete Response ☐

Partial Response ☐

Stable Disease ☐

Progressive Disease ☐

Not Evaluable ☐

NA ☐

RSSTAT when RSTESTCD = "OVLRESP"

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RS Example

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Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSCAT
1	0606/ABC	RS	013-2486	1		TRGRESP	RECIST 1.1
2	0606/ABC	RS	013-2486	2		NTRGRESP	RECIST 1.1
3	0606/ABC	RS	013-2486	3	V2	OVRLRESP	RECIST 1.1
4	0606/ABC	RS	013-2486	4		TRGRESP	RECIST 1.1
5	0606/ABC	RS	013-2486	5		NTRGRESP	RECIST 1.1
6	0606/ABC	RS	013-2486	6	R-V2	OVRLRESP	RECIST 1.1

Row	RSORRES	RSEVAL	VISITNUM	VISIT	RSDTC
1 (Cont)	SD	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
2 (Cont)	SD	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
3 (Cont)	SD	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
4 (Cont)	SD	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28
5 (Cont)	SD	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28
6 (Cont)	SD	INDEPENDENT ASSESSOR	4	CYCLE 2 DAY 28	2014-12-28

CRF - Tumor Response

This CRF is only an example and is not meant to imply that any particular layout or collection plan is preferable over another.

CRF annotated to show mapping. Variables defined in the SDTMIG are in **RED**. If the CDASHIG variable differs from the one defined in the SDTMIG, the CDASHIG variable is in **GREY**. Data collected, but not submitted in SDTM-based datasets, are denoted as **NOT SUBMITTED**.

Example CRF Instructions are provided in the first column.

RSCAT must be populated with the criteria and a version number (if appropriate) used in the assessment of response. This CRF may be used to collect response assessments based on PCWG SCHER PROSTATE CANCER 2008 or RECIST 1.1 The sponsor may default the appropriate value for RSCAT in collection or populate the appropriate value when the SDTM-based datasets are created. CDASH variables like <RSTESTCD>_RSCAT (e.g., OVRLRESP_RSCAT) may be created to default the RSCAT associated with each response. The CRF below only illustrates the use of OVRLRESP_RSCAT.

Response Criteria		PCWG SCHER PROSTATE CANCER 2008
OVRLRESP_RSCAT	RSCAT <i>Hidden/pre-specified</i>	
Indicate whether or not response was collected	Was the response assessment performed? RSPERF If no - RSSTAT="NOT DONE" where RSTESTCD="OVRLRESP"	- Yes - No <i><From NY codelist></i>
If the response was not collected, indicate why	Why was the response assessment not performed? RSREASND RSREASND where RSTESTCD="OVRLRESP"	- Not Imaged - Patient Refusal - Site Error - Other
Indicate who performed the	Evaluator RSEVAL	- INDEPENDENT ASSESSOR - INVESTIGATOR <i><From EVAL codelist></i>

assessment		
Identify the evaluator providing this evaluation	What is the evaluator identifier? RSEVALID	- RADIOLOGIST 1 - RADIOLOGIST 2 - ONCOLOGIST 1 - ONCOLOGIST 2 <i><From MEDEVAL codelist></i>
Indicate the response assessment for target lesions	What was the Target Response? TRGRES RSORRES where RSTESTCD="TRGRES"	- Complete Response (CR) - Partial Response (PR) - Stable Disease (SD) - Progressive Disease (PD) - Not Evaluable (NE) - Not All Evaluated
Insert the date of the procedure associated with target response	Date of Procedure for Target Response (e.g., scan date) TRGDAT RSDTC	__ / __ / __
Indicate the response assessment for Non-target lesions	What was the Non-target Response? NTRGRES P RSORRES where RSTESTCD="NTRGRES"	- Complete Response (CR) - Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) - Progressive Disease (PD) - Not Evaluable (NE) - Not All Evaluated
Insert the date of the procedure associated with the	Date of Procedure for Non-target Response (e.g., scan date) NTRGDAT RSDTC	__ / __ / __

Response Assessment in the PrCA TAUG

STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	VISITNUM	VISIT	RSDTC	RSDY
PRC1220	RS	9001	1	RDIORESP	Radiologic Response	PCWG SCHER PrCA	NON-PD	NON-PD	3	VISIT 3	2010-12-03	32
PRC1220	RS	9001	2	TMRESP	Tumor Marker Response	PCWG SCHER PrCA	PD	PD	3	VISIT 3	2010-12-03	32
PRC1220	RS	9002	1	RDIORESP	Radiologic Response	PCWG SCHER PrCA	PD	PD	3	VISIT 3	2010-11-03	29
PRC1220	RS	9002	2	TMRESP	Tumor Marker Response	PCWG SCHER PrCA	NON-PD	NON-PD	3	VISIT 3	2010-11-03	29

RELREC Examples for TU/TR and TR/RS

STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
0606/ABC	TU		TULNKID		ONE	TUTR
0606/ABC	TR		TRLNKID		MANY	TUTR
0606/ABC	RS		RSLNKGRP		ONE	TRRS
0606/ABC	TR		TRLNKGRP		MANY	TRRS

Note this is a dataset-to-dataset RELREC where, for TU/TR for all cases, across all subjects, where TULNKID = TRLNKID, there is a one-to-many relationship.

Similarly, for RS/TR, based on a like value for –LNKGRP, there exists a one-to-many relationship

Non-Oncology Applications

- ▶ As work as proceeded across the Therapeutic Area User Guides, the use of the “Tumor” domains has been expanded to include other types of “Lesions”. The below quote is from the Cardiovascular v1 TAUG:

“A lesion can be almost any abnormal change involving any tissue or organ, usually due to disease or injury. The requirements for identifying lesions other than tumors, such as the arterial lesions involved in CV endpoints, were found to be similar to those for tumors. The CDISC SDS Leadership Team decided to expand the scope of the existing TU and TR domains to include non-tumor lesions, rather than to create new domains for non-oncology data. The TU and TR domain names will be revised in the next version of the SDTMIG to Tumor/Lesion Identification (TU) and Tumor/Lesion Results (TR).”

Examples from the CV TAUG – TU

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTR ESC
1	0606/ABC	TU	013-2486	1	L01	LESIDENT	Lesion Identification	TARGET	TARGET
2	0606/ABC	TU	013-2486	2	L01-1	VESIDENT	Vessel identification	TARGET	TARGET

Row	TULOC	TUMETHOD	VISITNUM	VISIT	TUDTC
1 (Cont)	RIGHT CORONARY ARTERY OSTIUM	CORONARY ANGIOGRAPHY	1.1	UNSCHEDULED	2014-11-01T11:45
2 (Cont)	RIGHT CORONARY ARTERY	CORONARY ANGIOGRAPHY	1.1	UNSCHEDULED	2014-11-01T11:45

Row 1 shows the target lesion identified in the right coronary artery while Row 2 shows the main coronary vessel in which the lesion is located. Thus “lesions” and “vessels” are shown in “pairs”. Note the way in which TULNKID is defined.

Examples from the CV TAUG – TR

Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRLNKID	TRTESTCD	TRTEST	TORRES	TRDTC
1	0606/ABC	TR	013-2486	1	L01	LESSCIND	Lesion Success Indicator	Y	2014-11-01T11:45

The “Identification” records in TU along with this single record in TR shows the outcome of the “Stent Implantation” Intervention as recorded in the PR domain. This “success indicator” record in TR means that the lesion was successfully treated.

Proposed Expansion of RS

Under a proposal currently being evaluated for SDTMIG v3.3, the RS domain will also take on added scope as “Disease response and Clinical Classification”. In this proposal, part of the review for “Batch 3”, there is this “Assumption”:

Clinical Classifications are named measures whose output is an ordinal or categorical score that serves as surrogate for, or ranking of, disease status, symptoms, or other physiological or biological status. Clinical Classifications may be based solely on objective data from clinical records or they may involve a clinical judgement or interpretation....

As we know, it is now permissible for there to be multiple codelists that point to the same SDTM variable, for example, in this case, RSTESTCD. These individual codelists will be unique as per the Clinical Classification noted in RSCAT. The current oncology codelists specific to RS such as ONCRTSCD, ONCRTS, and ONCRSR will retain their oncology specificity.

RS as Clinical Classification Example

Row	STUDYID	DOMAIN	USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT
1	0606/ABC	RS	013-2486	1	ECOG101	ECOG1 – Performance Status	ECOG
2	0606/ABC	RS	013-2486	2	CPS0106	CPS01-Total Score	CHILD-PUGH CLASSIFICATION

Row	RSORRES	RSEVAL	VISITNUM	VISIT	RSDTC
1 (Cont)	1	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28
2 (Cont)	7	INVESTIGATOR	4	CYCLE 2 DAY 28	2014-12-28

At the moment, the RSCAT of ECOG is part of the QSCAT
codelist while the Child-Pugh Classification is part of the
CCCAT (Category of Clinical Classification) codelist

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