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SDTM Oncology Domains: From Patient to Data to Narrative

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Ken Stoltzfus
Clinical Data Strategies
Accenture Accelerated R&D
Life Sciences



consulting | technology | outsourcing

*Cigarettes
smoked*

*Medication
taken*

Birthdate

*Wine
consumed*

Gender

Weight

Temperature

*Blood
pressure*

Patient Centricity

Agenda

- **SDTM Oncology Domains**
 - TU - Tumor Identification
 - TR - Tumor Results
 - RS - Disease Response
- **The Oncology Patient**
- **RECIST Data into SDTM**
- **Patient Narrative**

About Accenture Accelerated R&D Life Sciences

Solutions

Data standards governance activities

CDISC standards-based clinical architecture design/implementation

Data standards content development, implementation and training

Experience

925+ studies converted to SDTM & ADaM (15,000+ domains) supporting 54+ submissions to the FDA

CDISC team leadership and membership: SDS, ADaM, CDASH, SEND, Devices, SHARE, PRG, CT, and CDISC Technical Leadership Committee

FDA-awarded contract for Legacy Data Conversion Services

Agenda

● SDTM Oncology Domains

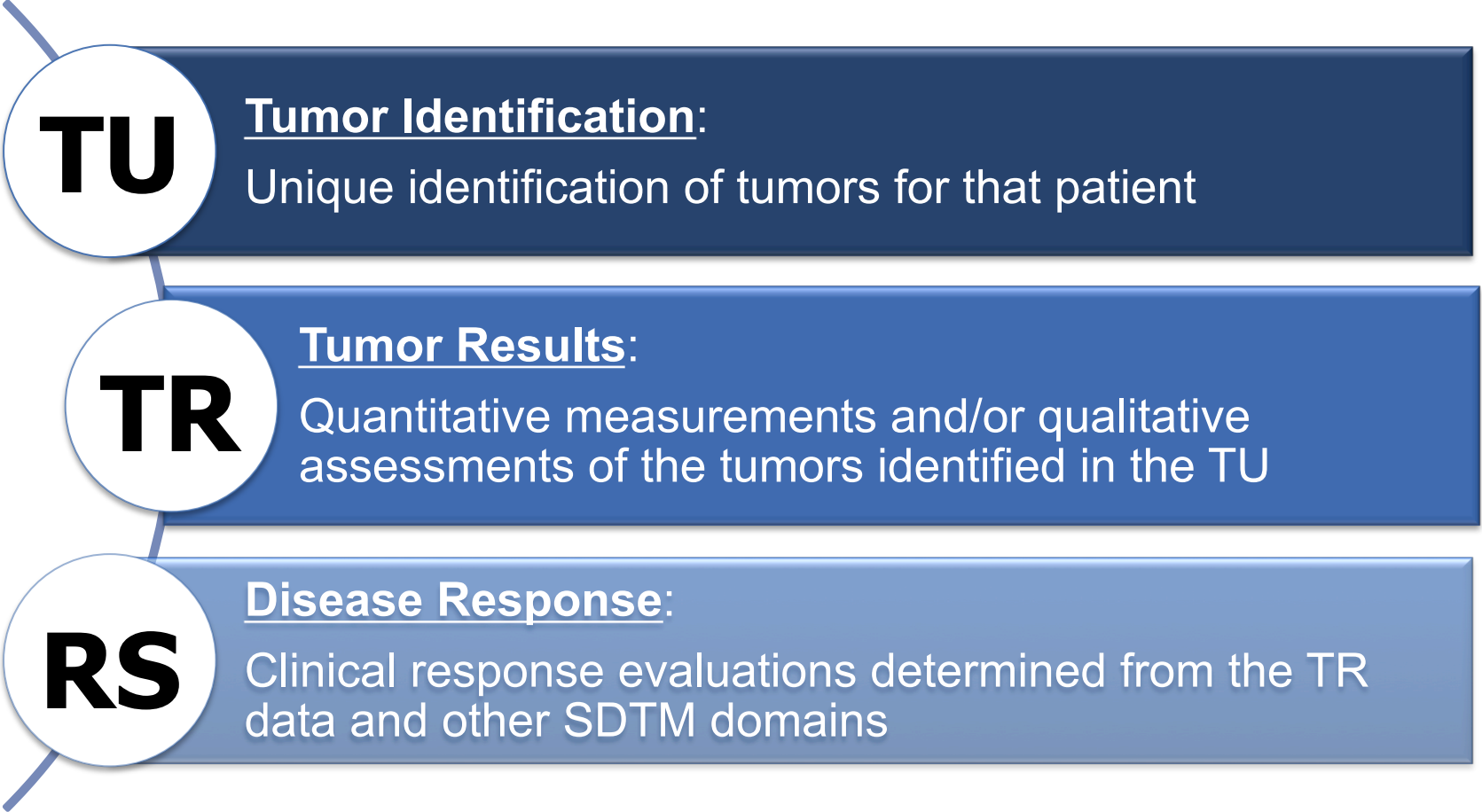
- TU - Tumor Identification
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- RS - Disease Response

● The Oncology Patient

● RECIST Data into SDTM

● Patient Narrative

SDTM Oncology Domains



TU

Tumor Identification:

Unique identification of tumors for that patient

TR

Tumor Results:

Quantitative measurements and/or qualitative assessments of the tumors identified in the TU

RS

Disease Response:

Clinical response evaluations determined from the TR data and other SDTM domains

Source: CDISC Study Data Tabulation Model Implementation Guide (SDTMIG) v3.1.3 - <http://www.cdisc.org/sdtm>

SDTM Oncology Domains



Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req	SDTMIG 2.2.4
DOMAIN	Domain Abbreviation	Char	TU	Identifier	Two-character abbreviation for the domain.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.2 SDTMIG App.C2
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.3
TUSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req	SDTMIG 2.2.4
TUGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain. Can be used to group split or merged tumors which have been identified.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
TUREFID	Reference ID	Char		Identifier	Internal or external identifier. Example: Medical image ID number.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
TUSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
TULNKID	Link ID	Char		Identifier	Identifier used to link identified tumors to the assessment results (in TR domain) over the course of the study.	Exp	
TUTESTCD	Tumor Identification Short Name	Char	(TUTESTCD)	TUMIDENT TUMERGE TUSPLIT	TEST in TUTEST. TUTESTCD cannot be numbers nor can start with a number. Characters other than letters, numbers, hyphens, and underscores. Example: TUMIDENT (Tumor Identification). See Assumption 2.	Req	SDTMIG 2.2.3 SDTMIG 4.1.2.1
TUTEST	Tumor Identification Test Name	Char	(TUTEST)	Synonym Qualifier	Verbatim name of the test for the tumor identification. The value in TUTEST cannot be longer than 40 characters. Example: Tumor Identification. See Assumption 2.	Req	SDTMIG 2.2.3 SDTMIG 4.1.2.1 SDTMIG 4.1.2.4
TUORRES	Tumor Identification Result	Char	TARGET NON-TARGET NEW BENIGN MEASURED NON-MEASURABLE		Tumor identification. The result of tumor identification is a classification of identified tumor. When TUTESTCD=TUMIDENT (Tumor Identification), values of TUORRES might be: TARGET, NON-TARGET, NEW, BENIGN, MEASURED, or BENIGN ABNORMALITY.	Exp	SDTMIG 2.2.3 SDTMIG 4.1.5.1
TUSTRESC	Tumor Identification Result Std. Format	Char			Standard result value for all findings copied from TUTEST.	Exp	SDTMIG 2.2.3 SDTMIG 4.1.5.1
TUNAM	Vendor Name	Char			Identifier of the vendor that performed the tumor identification. This column can be left Null when the vendor provides the complete set of data in the domain.	Perm	SDTM 2.2.3

Source: CDISC Study Data Tabulation Model Implementation Guide (SDTMIG) v3.1.3 - <http://www.cdisc.org/sdtm>

SDTM Oncology Domains



Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core	References
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req	SDTMIG 2.2.4
DOMAIN	Domain Abbreviation	Char	TR	Identifier	Two-character abbreviation for the domain.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.2 SDTMIG App. 2
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.3
TRSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req	SDTMIG 2.2.4
TRGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
TRREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
TRSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm	SDTMIG 2.2.4
TRLNKID	Link ID	Char		Identifier	Identifier used to link the assessment result records to the individual tumor identification record in TU domain.	Exp	
TRLNKGRP	Link Group	Char		Identifier	Used to group and link all of the measurement/assessment records used in the assessment of the response record in the RS domain.	Perm	
TRTESTCD	Tumor Assessment Short Name	Char	(TRTESTCD)	AREA DIAMETER	the TEST in TRTEST. TRTESTCD cannot contain characters other than letters, numbers, or underscores. Example: TSTATE, DIAMETER. See Assumption 2.	Req	SDTMIG 2.2.3 SDTMIG 4.1.2.1
TRTEST	Tumor Assessment Test Name	Char	(TRTEST)	VOLUME RADIODEN SUMAREA	of the test or examination used to obtain the result or finding. The value in TRTEST cannot be more than 40 characters. Examples: Tumor State, Diameter, Radicular diameter, Volume, Area. See Assumption 2.	Req	SDTMIG 2.2.3 SDTMIG 4.1.2.1 SDTMIG 4.1.2.4
TORRES	Result or Finding in Original Units	Char		SUMDIAM SUMLDIAM	tumor measurement/assessment as originally collected.	Exp	SDTMIG 2.2.3 SDTMIG 4.1.5.1
TORRESU	Original Units	Char	(UNIT)	RADIODEN	in which the data were collected. The unit for example: mm	Exp	SDTMIG 2.2.3 SDTMIG 4.1.3.2
							

Source: CDISC Study Data Tabulation Model Implementation Guide (SDTMIG) v3.1.3 - <http://www.cdisc.org/sdtm>

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DOMAIN	Domain Abbreviation	Char	RS	Identifier	Two-character abbreviation for the domain.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.2 SDTMIG App.C2
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req	SDTMIG 2.2.4 SDTMIG 4.1.2.3
RSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness within a dataset for a subject. May be any valid number.	Req	SDTMIG 2.2.4
RSGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
RSREFID	Reference ID	Char		Identifier	Internal or external identifier.	Perm	SDTMIG 2.2.4 SDTMIG 4.1.2.6
RSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier.	Perm	SDTMIG 2.2.4
RSLNKID	Link ID	Char		Identifier	Used to link the response assessment to the appropriate	Perm	
RSLNKGRP	Link Group	Char			BESTRESP	Best Overall Response; Best Response	
					NRADPROG	Non-Radiological Progression	
					NTRGRESP	Non-target Response	
					OVRLRESP	Overall Response	
RSTESTCD	Response Assessment Short Name	Char	(RSTESTCD)		TRGRESP	Target Response	
					NEWLPROG	New Lesion Progression	
RSTEST	Response Assessment Name	Char	(RSTEST)		PR	Partial Response; Partial Remission	
					SD	Stable Disease	
					PD	Progressive Disease	
					CR	Complete Response; Complete Remission	
RSCAT	Category for Response Assessment				NE	Not Evaluable	
RSORRES	Response Assessment Original Result						

Source: CDISC Study Data Tabulation Model Implementation Guide (SDTMIG) v3.1.3 - <http://www.cdisc.org/sdtm>

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Patient Records

Medical History

Headache	2004
Nausea	2010
Vomiting	2011
Alopecia	2011
Bone Pain	2011
Sinus infection	2011
UTI	2012
Skin infection	2012
Broken hip	2012

Prior Medications

Tylenol	2004
Advil	2004
Emetrol	2011
Compazine	2011
Codeine 3	2011
Amoxicillin	2011
Keflex	2012
Corticosteriod	2012
Percocet	2012

Prior Therapies

Colorectal Surgery	2011
Leucovorin	2011
Oxaliplatin	2011
5-FU	2011
Radiotherapy	2011
Radiotherapy	2012
Xeloda	2012
Oxaliplatin	2012

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RECIST CRF

SUBJID

VISIT



Study:
AB-019

Centre: 0001

Subject: 0012

Visit

TARGET LESION SCREENING ASSESSMENTS

TARGET LESION #1			
	Lesion Number	1 TULNKID TRLNKID	
1.	Organ	TULOC	
2.	Lesion location	TULAT TUDIR TUPORTOT	
3.	Was the lesion previously irradiated?	☐ No ☐ Yes Has the lesion been shown to be progressing since it was previously irradiated? ☐ No (Must be recorded as non-target lesion.) ☐ Yes	
4.	Method	TUMETHOD	
5.	Date of Assessment		TUDTC TMDTC
6.	Longest Diameter	TRORRES when TRTESTCD=L	DIAM TRORRESU
7.	Slice Thickness	SLCNTH in SUPPTR	SLCNTHU in SUPPTR

RECIST CRF

SUBJID

VISIT



Study:
AB-019

Centre: 0001

Subject: 0012

Visit

CLINICAL VISIT RESPONSE

RESPONSE SUMMARY		
	Target Lesion Response Assessment	☐ Complete Response ☐ Partial Response ☐ Stable Disease ☐ Progressive Disease ☐ Not Evaluable RSORRES when RSTESTCD=TRGRES
	Non-Target Lesion Response Assessment	☐ Complete Response ☐ Non-CR / Non-PD ☐ Progressive Disease ☐ Not Evaluable ☐ Not Applicable RSORRES when RSTESTCD=NTRGRES
	Were there any new lesions since the last assessment?	☐ No TRORRES ☐ Yes when TRTESTCD=TUMSTATE
	Investigator Overall Response using RECIST 1.0	☐ Complete Response ☐ Partial Response ☐ Stable Disease ☐ Progressive Disease ☐ Not Evaluable RSORRES when RSTESTCD=OVRLRESP

SDTM Oncology Domains: Findings Class

TU

SUBJID	TUSEQ	TUGRPID	TULNKID	TUTESTCD	TUTEST	TUORRES	VISIT
0001/0001	1	TARGET	T01	TUMIDENT	Tumor Identification	TARGET	SCREEN
0001/0001	2	TARGET	T02	TUMIDENT	Tumor Identification	TARGET	SCREEN
0001/0001	3	TARGET	T03	TUMIDENT	Tumor Identification	TARGET	SCREEN
0001/0001	4	TARGET	T04	TUMIDENT	Tumor Identification	TARGET	SCREEN
0001/0001	5	TARGET	T05	TUMIDENT	Tumor Identification	TARGET	SCREEN
0001/0001	6	NON-TARGET	NT01	TUMIDENT	Tumor Identification	NON-TARGET	SCREEN
0001/0001	7	NEW	NEW01	TUMIDENT	Tumor Identification	NEW	WEEK 8
0001/0001	8	TARGET	T04.T05	TUMERGE	Tumor Merged	TARGET	WEEK 16
0001/0001	9	TARGET	T03.1	TUSPLIT	Tumor Split	TARGET	WEEK 24
0001/0001	10	TARGET	T03.2	TUSPLIT	Tumor Split	TARGET	WEEK 24

SDTM Oncology Domains: Findings Class

TR

SUBJID	TRGRPID	TRLNKID	TRLNKGRP	TRTESTCD	TRTEST	TORRES	VISIT
0001/0001	TARGET	T01	R1	LDIAM	Longest Diameter	22	SCREEN
0001/0001	TARGET	T02	R1	LDIAM	Longest Diameter	14	SCREEN
0001/0001	TARGET		R1	SUMLDIAM	Sum of Longest Diameter	36	SCREEN
0001/0001	NON-TARGET	NT01	R1	TUMSTATE	Tumor State	PRESENT	SCREEN
0001/0001	TARGET	T01	R2	LDIAM	Longest Diameter	24	WEEK 8
0001/0001	TARGET	T02	R2	LDIAM	Longest Diameter	14	WEEK 8
0001/0001	TARGET		R2	SUMLDIAM	Sum of Longest Diameter	38	WEEK 8
0001/0001	NON-TARGET	NT01	R2	TUMSTATE	Tumor State	PRESENT	WEEK 8

SDTM Oncology Domains: Findings Class

RS

SUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSTEST	RSORRES	RSCAT	VISIT
0001/0001	1		TRGRESP	Target Response	PD	RECIST 1.0	WEEK 8
0001/0001	2		NTRGRESP	Non-target Response	SD	RECIST 1.0	WEEK 8
0001/0001	3	R1	OVRLRESP	Overall Response	PD	RECIST 1.0	WEEK 8
0001/0001	4		TRGRESP	Target Response	SD	RECIST 1.0	WEEK 16
0001/0001	5		NTRGRESP	Non-target Response	SD	RECIST 1.0	WEEK 16
0001/0001	6	R2	OVRLRESP	Overall Response	SD	RECIST 1.0	WEEK 16
0001/0001	7		TRGRESP	Target Response	SD	RECIST 1.0	WEEK 24
0001/0001	8		NTRGRESP	Non-target Response	PD	RECIST 1.0	WEEK 24
0001/0001	9	R3	OVRLRESP	Overall Response	PD	RECIST 1.0	WEEK 24

RECIST to SDTM

Issues

The collected domains are mostly mis-aligned with TU, TR, and RS in SDTM

CRFs are not designed to identify the lesion once which requires collapsing lesion identifiers

Inconsistent representation of the location of lesion across the duration of the trial

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SDTM Data Flowing Downstream

Patient Narrative

- Regulatory guidance documents call for the submission of subjects' study experience in brief narrative form for those subjects who meet specific criteria, including:
 - Death
 - Serious adverse event
 - Other significant adverse events that are judged to be of special interest because of clinical importance

Patient Narrative

MHDECOD	Subject SUBJID 1001/1234	AGE	RACE	SEX	MHSTDTC RFICDTC RFXSTDTC
EXTRT	Subject 1001/1234 was a 57 year old White female who presented with Stage IIB colorectal carcinoma without spread into other nearby tissues or organs, lymph nodes or distant sites. Her medical history included headache (2007), dizziness (2007), back pain (2007), vomiting (2008), and diarrhea (2008). This subject entered the study on 14SEP2009 and was first exposed to Treatment ABC on 28SEP2009. Medications taken by the subject in the four weeks leading up to study entry include loperamide, bismuth subsalicylate, acetaminophen, ibuprofen, and codeine phosphate. The subject completed the trial on 22FEB2010 as per protocol due to a partial response as determined by a 30% decrease in the sum of the longest diameters of all measurable lesions from baseline.				DSDECOD DSSTDTC
CMDECOD	RSORRES	AESTDTC	VSORRES	TTRORRES/TTRORRESU	when TRTESTCD=
RSTESTCD	=TRGRESP	SYSBP	DIABP		PCHGBL
AETERM	On 04NOV2009 the subject experienced a hypotensive crisis involving a blood pressure reading of 51/35 with accompanying symptoms of nausea, fainting and blurred vision. This was considered a serious adverse event (SAE). At the time of event the subject had taken 2 infusions of a 5-day cycle of Treatment ABC. The SAE occurred on Day 3 after beginning dosing for Cycle 2 with study medication. As a result of the event, trial medication had an action of dose reduced.				AETERM AESER

Acknowledgements

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Contact Information

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Clinical Data Strategies

Accenture Accelerated R&D Life Sciences

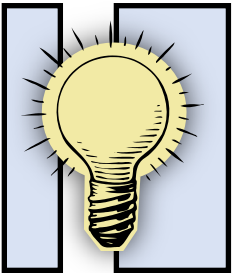
585 East Swedesford Road

Wayne, PA 19087

USA

Tel: 1-610-535-6500 (Ext. 5891)

kenneth.m.stoltzfus@accenture.com



***Feel free to visit the Accenture booth for
more information on Accenture's solutions***

Questions

