WITH STANDARDS – UNLOCK THE POWER OF DATA



Confused about Oncology Response Mappings? We're Here to Help!

Melanie Paules, Kim Musgrave and Erin Muhlbradt



Meet the Speakers

Melanie Paules

Title: Director, Statistical Programming Organization: Takeda

Melanie has worked in pharmaceutical drug development in the areas of statistical programming and clinical data standards. As a CDISC volunteer, she is leading the CDISC Oncology SDS (Submission Data Standards) team in the development and maintenance of the SDTM TU, TR and RS domains and associated terminology, and in the development of CDISC Disease Response Supplements for various oncology disease response criteria.

Erin Muhlbradt

Title: Clinical/Biomedical Information Specialist and CDISC Terminology Program

Organization: US NCI-EVS [c] (MSC Inc., a Guidehouse company)

Dr. Muhlbradt leads the CDISC Controlled Terminology program as well as co-leading the SDS Genomics and SDS Cell Phenotyping teams. She is a terminology representative for CDISC therapeutic area standards development teams and the CDISC Global Governance Group, and is also a CDISC authorized instructor.

Kim Musgrave

Title: Biomedical Data Stewardship, Sr Mgr Organization: Amgen

Kim has participated in the CDISC Oncology SDS team for more than seven years. Kim's focus at Amgen is on the analysis side supporting standard SAP language and table, figure and listing shells. After many years as a statistical programming manager at Berlex and then Amgen, Kim joined the standards organization.



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- The views and opinions expressed in this presentation are those of the author's and do not necessarily reflect the official policy or position of CDISC or for the author's respective organizations.
- {*Please disclose any financial relationship or conflict of interest relevant to this presentation here OR*}
- The author(s) have no real or apparent conflicts of interest to report.



Agenda

- 1. History
- 2. Oncology Terminology Content Developed to Date
- 3. Disease Response Supplement Development
- 4. Future Plans
- 5. Team Recognition

History

- TU, TR and RS modeling examples were attachments to the SDTMIG PDF through v3.1.3
 - Focus on RECIST (Response Evaluation Criteria in Solid Tumor)



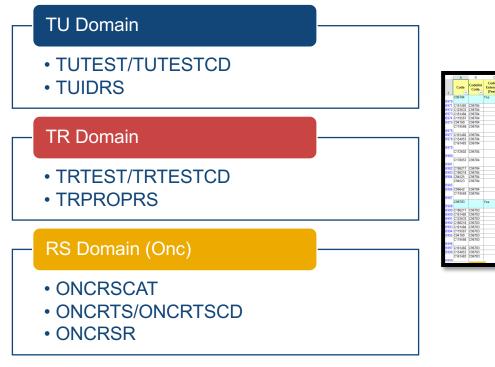
- SDTMIG v3.2 Oncology Domains (TU, TR and RS) and Questionnaire Supplements
- SDTMIG v3.3 RS moved to QRS
- Oncology TAUGs referencing SDTM Examples for Oncology Use Cases
- Additional Oncology examples, terminology and codetable mappings developed for other tumor response criteria based on:
 - Feedback from industry experience with implementation
 - Expert advice/opinion



Oncology Terminology Content Developed to Date

- Oncology CT
- Codetable Mapping Files
- Terminology Development Rules

CDISC Controlled Terminology – Oncology-specific codelists



1		Code	(Yes/No) 🖵	1		· · · · · · ·		
	C96784		Yes	Tumor or Lesion Identification Test Code	TUTESTCD	Tumor or Lesion Identification Test Code	Terminology relevant to the test codes that describe tumor or lesion	CDISC SOTM Tumor Identification Test
5970							assessments for identification purposes.	Code Terminology
5971	C161485	C96784			CVLIND	Cardiovascular Lesion Indicator	An indication as to whether a cardiovascular lesion is present.	Cardiovascular Lesion Indicator
	C123533				DRCRLTLC		A description of the region or relative location for the disease recurrence.	Disease Recurrence Relative Location
		C95784			FIBLIND		An indication as to whether a fibrotic lesion is present.	Fibrotic Lesion Indicator
	C119567				GRUDENT		An indication that a graft with a lesion has been located and characterized.	Graft Lesion Identification
		C95784			LESIDENT		An indication that a lesion has been located and characterized.	Lesion Identification
5976	C119568			Tumor or Lesion Identification Test Code	UMUDENT	Limb Lesion Identification	An indication that a limb containing a lesion has been selected and characterized.	Limb Associated Lesion Identification
	C161482				MEASIND	Measurable Turnor Indicator	An indication as to whether a measurable tumor is present.	Measurable Turnor Indicator
5978	C154853	C96784		Tumor or Lesion Identification Test Code	METIND	Metastatic Tumor Site Indicator	An indication as to whether an anatomical location contains metastases.	Metastatic Tumor Site Indicator
5979	C161483				NTIND	Non-Target Indicator	An indication as to whether a non-target tumor, lesion, or site of disease is present.	Non-Target Indicator
5980	C172602	C96784		Tumor or Lesion Identification Test Code	PTSIND	Primary Turnor Site Indicator	An indication as to whether an anatomical location is the primary tumor site of disease.	Primary Turnor Site Indicator
5981	C178053			Tumor or Lesion Identification Test Code	TIND	-	An indication as to whether a target tumor, lesion, or site of disease is present.	Target Indicator
	C186217				TUBNIND		An indication as to whether bone tumors are present.	Bone Tumors Indicator
		C96784			TUEXMIND	Extramedullary Disease Indicator	An indication as to whether extramedullary disease is present.	Extramedullary Disease Indicator
		C96784			TUMERGE		An indication that multiple tumors have coalesced into one tumor.	Matted Tumor Mass Present
5985		C95784		Tumor or Lesion Identification Test Code	TUMIDENT	Turnor Identification	A classification of malignant disease manifestation as part of the response assessment.	Turnor Identification
5986	C96642	C95784			TUSPLIT		An indication that a single tumor has divided into two or more tumors.	Turnor Fragmentation
5987	C119569	C96784		Tumor or Lesion Identification Test Code	VSLIDENT	Vessel Lesion Identification	An indication that a vessel with a lesion has been located and characterized.	Vessel Lesion Identification
5988	C96783		Yes	Tumor or Lesion Identification Test Name	TUTEST		Terminology relevant to the test names that describe tumor or lesion assessments for identification purposes	CDISC SDTM Tumor Identification Test Name Terminology
5989	C186217	C96783		Tumor or Lesion Identification Test Name	Bone Tumors Indicator	Bone Tumors Indicator	An indication as to whether bone tumors are present.	Bone Tumors Indicator
	C161485			Tumor or Lesion Identification Test Name			An indication as to whether a cardiovascular lesion is present.	Cardiovascular Lesion Indicator
5991	C123633	C96783		Tumor or Lesion Identification Test Name	Disease Recurrence Relative Location	Disease Recurrence Relative Location	A description of the region or relative location for the disease recurrence.	Disease Recurrence Relative Location
	C186218			Tumor or Lesion Identification Test Name		Extramedullary Disease Indicator	An indication as to whether extramedullary disease is present.	Extramedullary Disease Indicator
	C161484			Tumor or Lesion Identification Test Name		Fibrotic Lesion Indicator	An indication as to whether a fibrotic lesion is present.	Fibrotic Lesion Indicator
	C119567			Tumor or Lesion Identification Test Name			An indication that a graft with a lesion has been located and characterized.	Graft Lesion Identification
		C96783		Tumor or Lesion Identification Test Name			An indication that a lesion has been located and characterized.	Lesion Identification
5996	C119568	C96783		Tumor or Lesion Identification Test Name	Limb Lesion Identification		An indication that a limb containing a lesion has been selected and characterized.	Limb Associated Lesion Identification
	C161482				Measurable Tumor Indicator	Measurable Turnor Indicator	An indication as to whether a measurable tumor is present.	Measurable Turnor Indicator
5998	C154863	C96783		Tumor or Lesion Identification Test Name	Metastatic Tumor Site Indicator	Metastatic Tumor Site Indicator	An indication as to whether an anatomical location contains metastases.	Metastatic Tumor Site Indicator
5999	C161483	C96783		Tumor or Lesion Identification Test Name	Non-Target Indicator	Non-Target Indicator	An indication as to whether a non-target tumor, lesion, or site of disease is mexent	Non-Target Indicator

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Oncology Codetable Mapping Files

- Quarterly public review with CDISC CT package; published on CT page on CDISC.org
 - https://www.cdisc.org/standards/terminology/controlledterminology#standard__Codetable_Mapping_Files
- Excel file containing rows and columns that describe relationships between published terms across multiple codelists relevant to a single domain.
- Date on each tab name identifies the CT version date associated with the information.
- Files contain the most up to date information
 - Archive not available...yet

NCI FTP Links	Resources	Rules	Codetable Mapping Files	Unit-UCUM Mapping File	LOINC to LB Mapping Files	Paired Codelists
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different_Control	ed Terminology	codelists.		ide human and machine-readable		ow relationships between terms in rms across multiple codelists and may
interested in seei	ng specific cont	tent develop		ow Terminology is published, as i t through the New Term Request IDISC Library.		
	inclear at this t	time how th	e files are to be used to supp	e SEND codetable mapping file ort a SEND submission, which in		020, coincident to the CT P44 ng the user community. These files
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DS Codetable						
CV Codetable						
ECG Codetable						
GF Codetable						
GI Codetable						
MK Codetable						
Oncology Codet	ible					
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		30 C174367	LESERYSV	Lesion Erythema Severity/I	28 C123619	CLINRESP	Clinical Performance Status Clinical Response	C62222 C123574	NE cCR		
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53 CHISSS VSUDENT ↓ Readb	Tumor Spli	at 39 C119553	LESSCIND	Lesion Success Indicator Lesion Success Indicator	38 C123621	DRCRIND	Disease Recurrence Indicator			C49488	Y
	Vessel Les	tio 41 C119553	LESSCIND	Lesion Success Indicator	39 C123622	HEMARESP	Hematologic Response	C123575	CHR		
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Disease Response Criterion-specific Codetable Mapping Files

- 85 Disease Response Criterion published in ONCRSCAT codelist to date
- 8 Codetable Mapping Files published or in development*
 - RANO Wen PY et al 2010
 - iRANO Okada H et al 2015
 - RECIST 1.0 Therasse P et al 2000
 - RECIST 1.1 E.A. Eisenhauer et al 2009
 - iRECIST Seymour L et al 2017
 - Lugano Cheson BD et al 2014
 - Rajkumar Multiple Myeloma Rajkumar SV et al 2011
 - Kumar IMWG Kumar S et al 2016*



	avail	able at v	www.sciencedirect.co	m							
ELSEVIER	(C	A C-code Concept Code)	B Category of Oncology Response Assessment (ONCRSCAT) (codelist code = C124298)	C	C-code (Concept Code)	E Oncology Response Assessment Test Code (ONCRTSCD) (codelist code = C96782)	F Oncology Response Assessment Test Name (ONCRTS) (codelist code = C96781) V	G	H C-code (Concept Code)	Oncology Response Assessment Result (ONCRSR) (codelist code = C96785)	J Notes
New response eval	2 C12	4415	RECIST 1.1		C94534	TRGRESP	Target Response		C4870	CR	
-	3 C12		RECIST 1.1		C94534	TRGRESP	Target Response		C18058	PR	
Revised RECIST gu	4 C12	4415	RECIST 1.1		C94534	TRGRESP	Target Response			SD	
	-		RECIST 1.1		C94534	TRGRESP	Target Response			PD	
E.A. Eisenhauer ^{a,*} , P. Theras J. Dancey ^g , S. Arbuck ^h , S. G	6		RECIST 1.1		C94534	TRGRESP	Target Response			NE	The category of "non-evalua "NE", represents the condition response cannot be determin confidence. The RECIST part
R. Kaplan ^j , D. Lacombe ^c , J.			RECIST 1.1		C94535	NTRGRESP	Non-target Response			CR	
^a National Cancer Institute of Canada – Cli	-		RECIST 1.1		C94535	NTRGRESP	Non-target Response			NON-CR/NON-PD	
^b GlaxoSmithKline Biologicals, Rixensart, B			RECIST 1.1		C94535	NTRGRESP	Non-target Response			PD	
^c European Organisation for Research and ¹ ^d Memorial Sloan Kettering Cancer Center, ^e Mayo Clinic, Rochester, MN, USA	10		RECIST 1.1		C94535	NTRGRESP	Non-target Response			NE	The category of "non-evalua "NE", represents the condition response cannot be determin confidence. The RECIST page
^f RadPharm, Princeton, NJ, USA	11 C12		RECIST 1.1		C103420	NEWLPROG	New Lesion Progression			EQUIVOCAL	
^g Division of Cancer Treatment and Diagno ^h Schering-Plough, Kenilworth, NJ, USA			RECIST 1.1		C103420	NEWLPROG	New Lesion Progression			UNEQUIVOCAL	
ⁱ East Surrey Hospital, Redhill, Surrey, UK	13 C12		RECIST 1.1		C96613	OVRLRESP	Overall Response			CR	
^j National Cancer Research Network, Leeds,	14 C12	4415	RECIST 1.1		C96613	OVRLRESP	Overall Response			PR	
^k Erasmus University Medical Center, Rotte			RECIST 1.1		C96613	OVRLRESP	Overall Response			SD	
2. admite enterency interest, notice	16 C12		RECIST 1.1		C96613	OVRLRESP	Overall Response			NON-CR/NON-PD	
			RECIST 1.1		C96613	OVRLRESP	Overall Response			PD	
ARTICLE INFO	18 C12		RECIST 1.1		C96613	OVRLRESP	Overall Response			NE	
	19 C12		RECIST 1.1		C96613	OVRLRESP	Overall Response			NED	
Article history:	20 C12		RECIST 1.1		C94536	BESTRESP	Best Overall Response			CR	
Received 17 October 2008			RECIST 1.1		C94536	BESTRESP	Best Overall Response			PR	
Accepted 29 October 2008			RECIST 1.1		C94536	BESTRESP	Best Overall Response			SD	
	23 C12		RECIST 1.1		C94536	BESTRESP	Best Overall Response			NON-CR/NON-PD	
			RECIST 1.1		C94536	BESTRESP	Best Overall Response			PD	
	25 C12	4415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C62222	NE	

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Oncology Terminology Development Rules

NIH NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services	CDISC CONTROLLED TERMINOLOGY RULES:
CDISC, in collaboration with the National Cancer Institute's Enterprise Vocabulary Services (EVS), supports the Controlled Terminology needs of CDISC Foundational an Therapeutic Area Standards.	Oncology Domains TU, TR, and RS
Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required aubmission to FDA and PMDA in CDISC-compliant datasets. Controlled Terminology does not tell you WHAT to collect; it tells you IF you collected a particular data item, should submit it in your electronic dataset.	24 Sept 2021
New requests or changes to existing Terminology can be accessed through the CDISC New Term Request Page.	
Controlled Terminology Release As of 24 Jun 2022 the Protocol Entities, SEND, CDASH, SDTM, and ADaM Controlled Terminology files have been updated on the NCI-EVS Ftp site. The version dates of tiles are 2022-06-24. These terminology files place all previous Protocol Entities, SEND, CDASH, SDTM, and ADaM Terminology files and include terms from Review Pac Additionally there are: • Update to one published Codetable Mapping file: TS • Update to one published Codetable Mapping file: TS • Update to CRS Naming and Business Rules • New terminology Release Tues Controlled Terminology Release Davide Codetable Mapping file: TS • Update to CRS Naming and Business Rules • Update to CRS Naming and Business Rules • New terminology Release Davide Codetable Mapping file: TS • Update to Controlled Terminology Release Denied file • Update to Controlled Terminology Release Denied file • Update to EXTING Requests Denied file • Update to EXTING Requests Denied file • Update to EXTING Requests Denied file • Update to EXTING Requests Denied file • Update to EXTING Request Denied file • Update to EXTING RADA David view files Controlled Terminology Release 24 June 2022 • Update to EXTING Requests Denied file PUPLIENT • Rules Codetable Mapping Files Unit-UCUM Mapping File LOINC to LB Mapping Files Paired Codelists	Please refer to the general rules document that applies to all terminology teams on this webpage: <u>https://www.cdisc.org/standards/terminology.</u> The CDISC submission values and definitions in the TU, TR, and RS codelists have been developed to facilitate re-use by keeping th definitions focused on the meaning of the concept rather than on relating them to a specific published criterion or a particular tumor type. The CDISC submission values and definitions are intended to apply across multiple tumor types, imaging modalities, therapeu agents, and published criterion papers. This means that there may be cases where the appropriate CDISC submission value may not exactly match the term used in the published criterion paper. Within the context of Oncology, the words tumor and lesion are used interchangeably, except in those cases where the word Lesion i qualified by another word. Outside the oncology context however, not all lesions are tumors, therefore we can't consider these terms truly synonymous. For the purposes of CDISC controlled terminology for TU, TR, and RS, the word "Lumor' is used to cover benig or malignant lesions. The word 'Lesion' is used to cover any localized pathological or traumatic structural change, deformit or discontinuity of tissue, organ, or body part, inclusive of tumors. Amy TU, TP, and RS terminology that makes use of the word 'Lesion', instead of 'tumor', is meant to convery a tumor or lesion. In these cases, the team fielt that the concept could be used in oncological as well as mo-oncological cortexts and so suggest the use of 'Lesion' as a more general term that could be re-used acro many contexts. However when the team cited a published standard (e.g., RECIST) definition, the team agreed to use the language from the standard verbatim.
Rules for Ala Rules for ADaM Rules for Genomics Rules for Libb and Unit Rules for Microbiology Rules for PK	 The following terminology rules apply to the Oncology domains TU, TR, and RS: TUINOT OF Lesion Identification Test Code/Name Codelists (TUTEST/TUTESTCD) The TumorLesion Identification of UV will contain the classification of identified tumors/lesions. The classification is typically based on the classification as described in the published criterion. Tumor specific concepts are created and used for the oncology context only. The use of the Lesion terms should be used exclusively for non-oncological contexts. CDISC Submission Values Naming Fragments: IDENT will be used as the suffix fragment in TUTESTCD to denote 'Identification' in the TUTEST value. CDISC Synonyms CDISC Definitions Response Codelist Tumor Jumps (Lumps or Lesion Identification Test Panyle) is the codelist the supplies the scenopse uplues for the



Disease Response Supplement Development

Purpose

Oncology disease response supplements provide a mechanism to represent more extensive examples for each disease response criteria, showing the controlled terminology which will be presented in context for the CDISC user community

- Disease Response Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials
 - Published independently of the CDISC SDTMIG versions
- CDISC QRS Disease Response supplements are new
 - Oncology related ones are developed by CDISC Oncology SDS sub-team
- Creation of a Disease Response supplement requires
 - Detailed SDTM examples
 - Controlled terminology, including codetable mapping files
- SDTM examples within the supplement support various use cases for the disease response criteria of interest
 - SDTMIG TU, TR and RS represent a very small subset of disease response data in oncology studies



Development Process for Disease Response Supplements

- A new QRS Template was created specifically for Disease Response Supplements
- RECIST 1.1 created first since it is used most broadly across industry
- Building Disease Response Supplements
 - Pointing to and not repeating contents from other sources: disease response criteria publication, SDTMIG and controlled terminology documents
 - Build examples: RS, TU, TR, and other applicable domains as needed (PR, GF, CP and MI, etc.) with supporting Controlled Terminology
 - Engage with other SDS teams to align concepts (CP, GF)
 - Create row captions for the examples
 - Develop the supplement section: "General Points on Representation of Data within the Oncology Disease Response Domains"
 - Document the Supplemental Qualifier Name Codes
- Follows the CDISC QRS approval process: initial review by Oncology Team, QRS team review, internal review and public review



Structure of the Disease Response Supplement Response Evaluation Criteria in Solid Tumors 1.1 (RECIST 1.1)

Header

1 Introduction

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers

2 Copyright Status

- 3 The Oncology Disease Response and Supporting Domains Model for RECIST 1.1
 - 3.1 Assumptions for the Oncology Disease Response and Supporting Domains Model
 - 3.2 General Points on Representation of Data within the Oncology Disease Response Domains for RECIST 1.1"
- 4 Examples for the Oncology Disease Response Domains Model for RECIST 1.1

Includes Eleven examples in sections 4.1 to 4.11

5 RELREC

6 Supplemental Qualifier Name Codes



Key RECIST 1.1 Concepts Covered

• Tumors are identified as target tumors, non-target tumors and new tumors

- Target non-lymph node tumors are measured in longest diameter
- Target lymph node tumors are measured in longest perpendicular (short axis)
- Target tumors that split (fragment) and/or merge (coalesce)
- Collected or transferred calculations (e.g., Target lesion sum of diameters)
- Absent, non-pathological lymph nodes, and too small to measure target tumors
- Equivocal and unequivocal new tumors

• Overall response is based on:

- Measurements of target tumors (target response)
- Qualitative assessments of non-target tumors (non-target response)
- Appearance of new tumors

Response related values

- Why RSDTC may be derived in SDTM RS, and general conventions for assigning RSDTC
- Symptomatic deterioration
- Representation of "NE" (Not Evaluable) and "NED" (No evidence of disease)



Key Concepts from SDTMIG

- The preferred SDTM data representation is shown in the examples
 - Note that examples in SDTMIG and this disease response supplement are based on assumptions about the data collection forms

• Linking Between Domains

- Tumor identifier
 - TULNKID in the TU domain links to the TRLNKID in the TR Domain
- Image identifier
 - TUREFID, TRREFID and PRREFID link across the TU, TR and PR Domains
- Link Group
 - RSLNKGRP links the RSTEST='Overall Response' in RS domain with the underlying assessment in TR domain with matching TRLNKGRP
 - Note that some criteria link to data in domains in addition to the TR domain





RECIST 1.1 Examples (1-6)

Response (RS) data and the underlying tumor identification (TU), tumor results (TR), procedure (PR) data and trial disease assessment (TD)

Example #	Topics Covered	Source
1	 Case where lymph nodes are selected as target lesions NE assessment Use of the RSTEST='New Lesion Progression' for equivocal new lesions 	Investigator
2	Preferred representation of split (fragmented) and merged (coalesced) tumors (TULNKID/TRLNKID)	Investigator
3	 How to represent the case were progressive disease due to symptomatic deterioration was determined based on a clinical assessment by the investigator 	Investigator
4	 Use of the acceptance flag to identify records when multiple assessments are performed by independent assessors (Radiologist 1 and Radiologist 2) for the same timepoint 	Independent Assessor
5	Data for a subject that has only Target tumors at screeningThe example includes an unscheduled assessment	Investigator
6	 Shows the investigator tumor identification, tumor results, and response data using RECIST 1.1 along with an independent radiologist's tumor identification, tumor results, and response data using volumetric measurements 	Investigator and Independent Assessor



RECIST 1.1 Examples (7-11)

Response (RS) data and the underlying tumor identification (TU), tumor results (TR), procedure (PR) data and trial disease assessment (TD)

Example #	Topics Covered	Source
7	 Data for a subject with non-target disease only Tumor presentation type supplemental qualifier and the associated controlled terminology (DSPRTY) Procedure data to represent correlative imaging used in addition to the primary method for the RECIST 1.1 evaluation 	Investigator
8	 Data from a breast cancer study in a metastatic setting Tumor state for the non-target in the pleural cavity is an assessment of the pleural effusion "SCINTIGRAPHY" of the "BONE" was not required at every disease assessment per protocol Another different example of procedure data showing how to represent correlative imaging 	Independent Assessor
9	Independent radiologist found no evidence of disease (NED) at baseline	Independent Assessor
10	 Situation where enlargement from nadir of a single non-target does not necessarily mean that the Non-Target Response is PD 	Independent Assessor
11	 Case where lymph nodes are selected as target lesions Shows calculations provided in the data transfer from a review by an independent assessor review 	Independent Assessor



4.1.1 RS Domain Model

The rs.xpt table below shows the terminology used to implement RECIST 1.1 in the RS domain. This example shows the data for one subject collected at the week 6, week 12 and subsequent 8-week follow-up visit

✓ rs.xpt

Rows 1-3: Show the Target Response (RSTESTCD = "TRGRESP") and Non-Target Response (RSTESTCD = "NTRGRESP") tests and corresponding Overall Response (RSTESTCD = "OVRLRESP") at the week 6 assessin RSLNKGRP is used to associate the Overall Response to underlying data in other domains (e.g., TR). Note that "NE" (Not evaluable) is a valid Overall Response value per the RECIST 1.1 criteria which means that

Rows 4-12: Show the week 12, week 20 and week 28 responses.

Rows 13-20: At week 36, the New Lesion Progression test is used to represent an equivocal new lesion (RSTESTCD = "NEWLPROG" and RSORRES = "EQUIVOCAL") and to represent at week 44 that there are une "UNEQUIVOCAL"). There are different methods of collecting data when there is an equivocal new lesion. Some sponsors update the Overall Response when equivocal evidence of a new lesion has been confirm derive (in ADaM) the new progression date as the date when the new lesion was first identified.

Note: Sponsor may include the New Lesion Indicator test (RSTESTCD = "NEWLIND") at every timepoint if the new lesion yes or no question is part of the data collection. rs.xpt

Row	STUDYID	DOMAIN	USUBIID	RSSEO	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC	RSEVAL	EPOCH	VISITNUM	VISIT	RSDTC	RSDY
1	EX11111	RS	90001	1	no crittara	TRGRESP	Target Response	RECIST 1.1	NE	NE	INVESTIGATOR	TREATMENT	40	WEEK 6	2010-02-15	
2	EX11111	RS	90001	2		NTRGRESP	Non-Target Response	RECIST 1.1	NE	NE	INVESTIGATOR	TREATMENT	40	WEEK 6	2010-02-15	46
3	EX11111	RS	90001	3	A2	OVRLRESP	Overall Response	RECIST 1.1	NE	NE	INVESTIGATOR	TREATMENT	40	WEEK 6	2010-02-15	46
4	EX11111	RS	90001	4		TRGRESP	Target Response	RECIST 1.1	SD	SD	INVESTIGATOR	TREATMENT	60	WEEK 12	2010-03-39	88
5	EX11111	RS	90001	5		NTRGRESP	Non-Target Response	RECIST 1.1	NON-CR/NON-PD	NON-CR/NON-PD	INVESTIGATOR	TREATMENT	60	WEEK 12	2010-03-29	88
6	EX11111	RS	90001	6	A3	OVRLRESP	Overall Response	RECIST 1.1	SD	SD	INVESTIGATOR	TREATMENT	60	WEEK 12	2010-03-29	88
7	EX11111	RS	90001	7		TRGRESP	Target Response	RECIST 1.1	PR	PR	INVESTIGATOR	TREATMENT	80	WEEK 20	2010-05-30	147
8	EX11111	RS	90001	8		NTRGRESP	Non-Target Response	RECIST 1.1	NON-CR/NON-PD	NON-CR/NON-PD	INVESTIGATOR	TREATMENT	80	WEEK 20	2010-05-30	147
9	EX11111	RS	90001	9	A4	OVRLRESP	Overall Response	RECIST 1.1	PR	PR	INVESTIGATOR	TREATMENT	80	WEEK 20	2010-05-30	147
10	EX11111	RS	90001	10		TRGRESP	Target Response	RECIST 1.1	PR	PR	INVESTIGATOR	TREATMENT	100	WEEK 28	2010-07-25	204
11	EX11111	RS	90001	11		NTRGRESP	Non-Target Response	RECIST 1.1	NON-CR/NON-PD	NON-CR/NON-PD	INVESTIGATOR	TREATMENT	100	WEEK 28	2010-07-25	204
12	EX11111	RS	90001	12	A5	OVRLRESP	Overall Response	RECIST 1.1	PR	PR	INVESTIGATOR	TREATMENT	100	WEEK 28	2010-07-25	204
13	EX11111	RS	90001	13		TRGRESP	Target Response	RECIST 1.1	CR	CR	INVESTIGATOR	TREATMENT	120	WEEK 36	2010-09-17	257
14	EX11111	RS	90001	14		NTRGRESP	Non-Target Response	RECIST 1.1	CR	CR	INVESTIGATOR	TREATMENT	120	WEEK 36	2010-09-17	257
15	EX11111	RS	90001	15		NEWLPROG	New Lesion Progression	RECIST 1.1	EQUIVOCAL	EQUIVOCAL	INVESTIGATOR	TREATMENT	120	WEEK 36	2010-09-17	257
16	EX11111	RS	90001	16	A6	OVRLRESP	Overall Response	RECIST 1.1	CR	CR	INVESTIGATOR	TREATMENT	120	WEEK 36	2010-09-17	257
17	EX11111	RS	90001	17		TRGRESP	Target Response	RECIST 1.1	PD	PD	INVESTIGATOR	TREATMENT	140	WEEK 44	2010-11-14	313
18	EX11111	RS	90001	18		NTRGRESP	Non-Target Response	RECIST 1.1	CR	CR	INVESTIGATOR	TREATMENT	140	WEEK 44	2010-11-14	313
19	EX11111	RS	90001	19		NEWLPROG	New Lesion Progression	RECIST 1.1	UNEQUIVOCAL	UNEQUIVOCAL	INVESTIGATOR	TREATMENT	140	WEEK 44	2010-11-14	313
20	EX11111	RS	90001	20	A7	OVRLRESP	Overall Response	RECIST 1.1	PD	PD	INVESTIGATOR	TREATMENT	140	WEEK 44	2010-11-14	313

The supprs.xpt table below shows the data on the reason that the response was not evaluable (QNAM = "REASNE") in the case where the reason is collected. > supprs.xpt



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4.1.2 TU Domain Model

The tuxpt table below shows the terminology used to implement RECIST 1.1 in the TU domain. This example shows the data for one subject at screening and at weeks 36 and 44 where new lesions are identified lymph node tumors are measured in the short axis (TRTESTCD = "LPERP" and TRTEST = "Longest Perpendicular") in the TR domain. The image identifier is in TUREFID and matches a PRREFID in the PR Domain.

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Rows 1-6: Show a subject with 4 target lesions with TULNKIDs "T01"-"T04" and 2 non-target lesions with TULNKIDs "NT01" and "NT02" identified at screening. "T01" and "T02" target lesions are lymph nodes. LYMPH NODE") on the right side (TULAT = "RIGHT"). The TULOC contains the location from the anatomical location terminology. Note that some locations in controlled terminology contain laterality and/or (TULOC unless in the controlled terminology, likewise for directionality.

Row 7: Shows at week 36, an equivocal new lesion (TULNKID = "NEW01") was identified in the left lower lobe of the lung (TULOC = "LUNG, LEFT LOWER LOBE"). In this instance, "LUNG, LEFT LOWER LOBE" is a

Row 8-9: Show at week 44, new unequivocal new lesions (TULNKID = "NEW02" and TULNKID = "NEW03") were identified in the cerebellum (TULOC = "CEREBELLUM") and the femoral lymph node (TULOC = ' tu.xpt

Row	STUDYID	DOMAIN	USUBJID	TUSEQ	TUREFID	TULNKID	TUTESTCD	TUTEST	TUORRES	TUSTRESC	TULOC	TULAT	TUDIR	TUMETHOD	TUEVAL	
1	EX11111	TU	90001	1	IMG-00001	T01	TUMIDENT	Tumor Identification	TARGET	TARGET	SUPRACLAVICULAR LYMPH NODE	RIGHT		MRI	INVESTIGATOR	
2	EX11111	TU	90001	2	IMG-00002	T02	TUMIDENT	Tumor Identification	TARGET	TARGET	THORACIC LYMPH NODE			CT SCAN	INVESTIGATOR	
3	EX11111	TU	90001	3	IMG-00001	T03	TUMIDENT	Tumor Identification	TARGET	TARGET	THYROID GLAND	LEFT		MRI	INVESTIGATOR	
4	EX11111	TU	90001	4	IMG-00003	T04	TUMIDENT	Tumor Identification	TARGET	TARGET	SKIN OF THE TRUNK		UPPER	PHOTOGRAPHY	INVESTIGATOR	
5	EX11111	TU	90001	5	IMG-00002	NT01	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	MEDIASTINAL LYMPH NODE	RIGHT		CT SCAN	INVESTIGATOR	
6	EX11111	TU	90001	6	IMG-00001	NT02	TUMIDENT	Tumor Identification	NON-TARGET	NON-TARGET	CEREBELLUM	RIGHT		MRI	INVESTIGATOR	
7	EX11111	TU	90001	7	IMG-00020	NEW01	TUMIDENT	Tumor Identification	NEW	NEW	LUNG, LEFT LOWER LOBE			CT SCAN	INVESTIGATOR	TR
8	EX11111	TU	90001	8	IMG-00019	NEW02	TUMIDENT	Tumor Identification	NEW	NEW	CEREBELLUM	LEFT		MRI	INVESTIGATOR	TR
9	EX11111	TU	90001	9	IMG-00022	NEW03	TUMIDENT	Tumor Identification	NEW	NEW	FEMORAL LYMPH NODE	LEFT		ULTRASOUND	INVESTIGATOR	TR

The supptu.xpt table below shows the data on whether a tumor was previously irradiated (QNAM = "PRVIR") and whether that tumor was shown to be progressing since it was irradiated (QNAM = "PRVIR").

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4.1.3 TR Domain Model

The tr.xpt table below shows the terminology used to implement RECIST 1.1 in the TR domain. This example shows the data for one subject collected at screening, week 6, week 12 and subsequent 8-week follow (measured in the short axis), as well as measurements of other non-lymph node Target tumors, i.e., longest diameter. In this example, when TRTEST = "Lymph Node State" and TRORRES = "NON-PATHOLOGICAL' has reduced below 10mm. The assessment of a lymph node is represented with TRTEST = "Lymph Node State" and TRORRES = "NON-PATHOLOGICAL" when that all target lymph node lesions have short axis les node tumor has short axis greater than or equal to 10mm. The image identifier is in TRREFID and matches a PRREFID in the PR Domain.

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• ••• Rows 1-6: Show the screening identification of the target and non-target lesions. For lymph node target lesions "T01" and "T02" the TRTESTCD used for the assessments are "LPREP" and "LNSTATE". For non-I is "LDIAM".

Rows 7-8: Show the results for the non-targets. "NT01" is a lymph node where the TRTEST used for the assessments is "Lymph Node State" (TRTESTCD = "LNSTATE"). "NT02" is a non-lymph node where the TRTEST used for the assessments is "Lymph Node State" (TRTESTCD = "LNSTATE").

Row 14: Shows a case where the scan was not performed at week 6 (for TRTEST = "Longest Diameter", TRSTAT = "NOT DONE" with TRREASND = "SCAN NOT PERFORMED").

Row 15: Shows a case where the non-target "NT01" was not evaluable (for TRTEST = "Lymph Node State", TRSTAT = "NOT DONE" with TRREASND = "NOT EVALUABLE").

Row 16: Shows a case where the non-target "NT02" was not evaluable (for TRTEST = "Tumor State", TRSTAT = "NOT DONE" with TRREASND = "NOT ASSESSABLE: Image obscured").

Row 30: Shows a target lesion "T04" which is too small to measure. The TRORRES = "TOO SMALL TO MEASURE", and the TRSTRESC and TRSTRESN are standardized to "5" with TRSTRESU as "mm". The standardized to "5" with TRSTRESU as "mm". lesion because it has not disappeared. Providing this The method of standardization of the TRSTRESC and TRSTRESN values is sponsor specific.

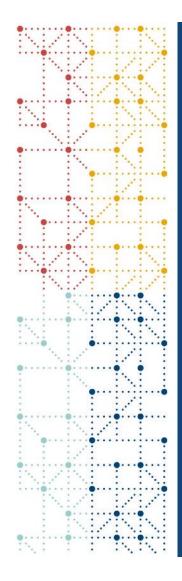
Row 58: Shows a new lesion "NEW01" which has a measurement of 4 mm. Note that this value is less than 5 mm and has not been reported as "TOO SMALL TO MEASURE".

tr.xpt																	
Row	STUDYID	DOMAIN	USUBJID	TRSEQ	TRGRPID	TRREFID	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRSTRESC	TRSTRESN	TRSTRESU	TRSTAT	TRREASND
1	EX11111	TR	90001	1	TARGET	IMG- 00001	A1	T01	LPERP	Longest Perpendicular	17	mm	17	17	mm		
2	EX11111	TR	90001	2	TARGET	IMG- 00001	A1	T01	LNSTATE	Lymph Node State	PATHOLOGICAL		PATHOLOGICAL				
3	EX11111	TR	90001	3	TARGET	IMG- 00002	A1	T02	LPERP	Longest Perpendicular	16	mm	16	16	mm		
4	EX11111	TR	90001	4	TARGET	IMG- 00002	A1	T02	LNSTATE	Lymph Node State	PATHOLOGICAL		PATHOLOGICAL				
5	EX11111	TR	90001	5	TARGET	IMG- 00001	A1	тоз	LDIAM	Longest Diameter	15	mm	15	15	mm		
6	EX11111	TR	90001	6	TARGET	IMG- 00003	A1	T04	LDIAM	Longest Diameter	14	mm	14	14	mm		
7	EX11111	TR	90001	7	NON- TARGET	IMG- 00002	A1	NT01	LNSTATE	Lymph Node State	PATHOLOGICAL		PATHOLOGICAL				
8	EX11111	TR	90001	8	NON- TARGET	IMG- 00001	A1	NT02	TUMSTATE	Tumor State	PRESENT		PRESENT				
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Future Plans

Future Plans: To Do List

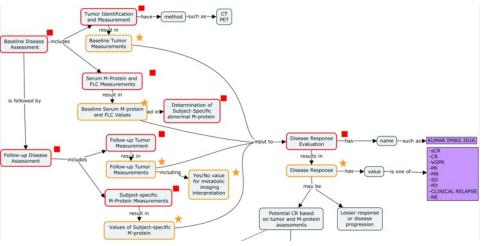
- Additional Oncology Disease Response Supplements
 - Finalize RECIST 1.1
 - Create LUGANO, iRECIST, RANO (2017), IMWG
- IMWG: Multiple Myeloma SDTM Examples and CT development with codetable mappings
- TNM Staging
- Survival FU/Disposition/EOS
- CT Development:
 - Codetable Mapping File for each tumor response criterion.
 - Additions of TU and TR domain linkages into response criterion-specific codetable mapping files.
 - Extensions to existing codelists for TU/TR/RS domains
 - Extensions to existing codelists for other related domains such as GF and CP



Future Plans: End-to-End Mapping

- Concept maps
- Relationships from collection/CDASH to SDTM to ADaM
- Dream of downloading package identifying all domains and variables required for each criterion





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Community Ask

- Please review the disease supplements
- Share examples/use cases for other criteria
 - Join our team
 - Submit through JIRA DRSUPPCOM (Disease Response Supplement Comments)
- Review Quarterly Terminology Releases
- Submit new terms through <u>CDISC Change Request</u> form, including additions/updates to codetable mapping files

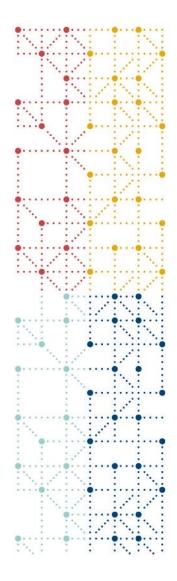




Thanks to our team!

Melanie Paules, Lead Erin Muhlbradt, CT Lead Kim Musgrave, Co-lead Mohtaram Bahmanian, Consultant Prakash Dev, Covance Gregory Goldmacher, Merck Jennifer Gu, Datastand Margarita Harrod, Merck Chris Kaiser, Lilly Catherine Mulvaney, Mint Medical David Neubauer, IQVIA Anh Nguyen-Paulus, Arcus Bio Debra O'Neill, Merck Manjula Reddy, J&J Swarupa Sudini, Pfizer Sharon Weller, Lilly Rachel Zieverink, Medpace





Resources

SDS Oncology (CDISC wiki)

Public Review Disease Response Supplement RECIST 1.1

Oncology Response Criteria SDTM Examples

SDS Oncology To Do List

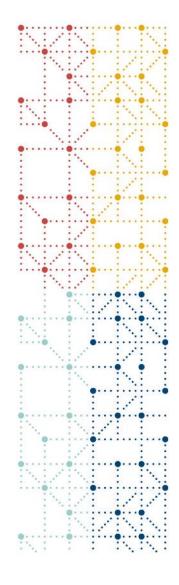
CDISC QRS and CT (CDISC.org)

CDISC Controlled Terminology, Codetable Mapping Files and Oncology Rules <u>CDISC Change Request Form</u> <u>QRS Supplements</u>

General

RECIST 1.1 EORTC Website with Publication and Guidance





Thank You!

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