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)



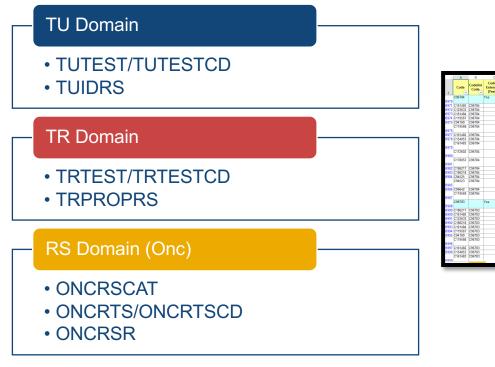
- SDTMIG v3.2 Oncology Domains (TU, TR and RS) and Questionnaire Supplements
- SDTMIG v3.3 RS moved to QRS
- Oncology TAUGs referencing SDTM Examples for Oncology Use Cases
- Additional Oncology examples, terminology and codetable mappings developed for other tumor response criteria based on:
 - Feedback 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 |
|--------------------|-------------------|--------------|---|--|------------------------------------|--|
| | | | (e.g., Variables, TESTs and PA illy in the Controlled Terminol | | codelists, qualifier variable code | alists), which are commonly referred |
| responses locate | d in the EGSTRE | SC codelist | that constitutes a subset of t | thin other codelists. For instance he EGSTRESC codelist. Another is lationships are not readily appare | stance, a single VSTEST value | may have a constrained set of units of |
| 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 |
| DD Codetable | | | | | | |
| DS Codetable | | | | | | |
| CV Codetable | | | | | | |
| ECG Codetable | | | | | | |
| GF Codetable | | | | | | |
| GI Codetable | | | | | | |
| MK Codetable | | | | | | |
| Oncology Codet | ible | | | | | |
| Race Ethnicity Co | detable | | | | | |
| RP Codetable | | | | | | |
| SC Codetable | | | | | | |
| SEND Codetable | | | | | | |
| SR Codetable | | | | | | |
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| | В | C or Lesion Identifi Test Name | D E | F Tumor or Lesion Identification Test Re | G | H I Code No Yes Respon | J ISE Notes | | | | |
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| A C C54948 FEL.ND 10 C19567 GPLLDENT 14 C19567 GPLLDENT 15 further split out into tumor respont C54493 LESIDENT 15 Gr4H6 LESIDENT C54493 LESIDENT 16 C54493 LESIDENT C54493 LESIDENT 17 C19568 LMLDENT C19568 LMLDENT 16 C54493 LESIDENT C19568 LMLDENT 17 C19568 LMLDENT C19568 LMLDENT 18 C19568 LMLDENT C19568 LMLDENT 19 C19568 LMLDENT C19568 LMLDENT 10 C19568 LMLDENT C19568 LMLDENT 13 (2010-05-28) TU (Update); TR (Upc) C19483 TUMERGE 14 (2020-02-12-18) No changes C19482 TUMERGE 142 (2020-03-25) TU (Update); TR (Upc) C194823 TUMERGE 12 C34823 TUMERGE | Fibrotic Le | si Code | (codelist code = C96779) | (codelist code = C | 96778) 🥃 | ✓ Code) (codelis | | C66742) | Code) C71620) - | | |
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| 383 (2019-06-78) TU (Update); IS Onc 393 (2019-06-78) TU (Update); IS Onc 393 (2019-08-77) TU (Update); IS Onc 305 (2019-08-76) TU (Update); IS Onc 305 (2019-08-76) TU (Update); IS Onc 314 (2020-08-76) TU (Update); IS Onc 314 (2020-08-77) TU (Update); IS Onc 314 (2020-08-76) TU (Update); IS Onc 314 (2020-08-77) TU (Update); I | Measurabl | le 10 | ACPPONLP | LPERP Absolute Change From PF | 6 C94536 7 C94536 | BESTRESP | Best Overall Response | C62222 | NE NON-CR/NON-PD | + $-$ | |
| 92 (2019-92-27) TU (Update); TR (Upd 42 (2029-92-27) RS One (Update); 42 (2020-92-27) RS One (Update); 42 (2020-92-27) TU (Update); TR (Upd 43 (2020-92-27) TU (Update); TR (Upd 43 (2020-92-27) TU (Update); TR (Upd 44 (2021-12-18) No changes 45 (2021-92-28) TU (Update); TR (Upd 45 (2021-92-28) TU (Update); TR (Upd 46 (2021-92-28) TU (Update); TR (Upd 47 (2021-92-92) TU (Update); TR (Upd 47 (2021-92-92) TU (Update); TR (Upd 47 (2021-92-92) TU (Update); TR (Upd 48 (2021-92-92) TU (Update); TR (Upd 49 (2022-93-25) TU (Update); TR (Upd 40 (2042-32) TUMDENT 41 (204423) TUMDENT 42 (204423) TUMDENT 43 (204423) TUMDENT 44 (204423) TUMDENT 45 (204423) TUMDENT 46 (204423) TUMDENT 47 (204423) TUMDENT 40 (204423) TUMDENT 40 (204423) TUMDENT 40 (204423) TUMDENT 41 (204423) TUMDENT 42 (204423) TUMDENT 43 (204423) TUMDENT 44 (204423) TUMDENT 45 (204423) TUMDENT 46 (204423) TUMDENT 46 (204423) TUMDENT 47 (204423) TUMDENT 48 (204423) TUMDENT 49 (204423) TUMDENT 40 (20442) TUMDENT 40 (2044 | Metastatio Metastatic | 11 | AREA | LPERP | 8 C94536 | BESTRESP BESTRESP | Best Overall Response Best Overall Response | C96700 C123599 | NON-PD | | |
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| | T Tumor Ider T Tumor Ider | nti 23 C25285 | DIAMETER | Diameter | 20 C132455 21 C132455 | BONERESP | Bone Response Bone Response | C40413 C123599 | NED NON-PD | | |
| | | | FDPL5PS LDIAM | FDG PET Lymphoma 5PS Longest Diameter | 22 C132455 | BONERESP | Bone Response | C35571 | PD | | |
| | | 26 C96684 | LDIAM | Longest Diameter | 23 C132455 24 C135478 | BONERESP | Bone Response Clinical Performance Status | C123607 C125459 | PDu IMPROVED | | |
| | | 27 C174369 | LESELESV | Lesion Elevation Severity/ | 25 C135478 | CPRFSTAT | Clinical Performance Status | C30103 | STABLE | | |
| | T Tumor Ider | 28 C174369 29 C174369 | LESELESV | Lesion Elevation Severity/I Lesion Elevation Severity/I | 26 C135478 27 C135478 | CPRFSTAT CPRFSTAT | Clinical Performance Status | C71686 | WORSENED | | |
| | | 30 C174367 | LESERYSV | Lesion Erythema Severity/I | 28 C123619 | CLINRESP | Clinical Performance Status Clinical Response | C62222 C123574 | NE cCR | | |
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| ReadMe TU_Codetable, * CH622 TUMDENT 40 CH623 TUMDENT C56623 TUMDENT C56623 TUMDENT 50 C56642 TUSPLIT S0 C56642 TUSPLIT 50 C56642 TUSPLIT S0 S1658 TUSEDENT 50 C15658 TUSLENT S0 ReadN | | ati 32 C174367 33 C119551 | LESERYSV LESFLIND | Lesion Erythema Severity/I Lesion Failure Indicator | 30 C123620 31 C123620 | CYTORESP | Cytogenetic Response Cytogenetic Response | C123578 C123579 | CYTOGENETIC CR CYTOGENETIC MINIMAL RESPONSE | | |
| ReadMe TU_Codetable, C4652 TURIDENT C4652 TURIDENT C4652 TURIDENT C56642 TUSPLIT C56642 TUSPLIT S0 C56642 TVSLICENT S0 C56642 TVSLICENT S0 C56642 TVSLICENT S0 C56642 TVSLICENT | T Tumor Ider | nti 34 C119551 | LESFLIND | Lesion Failure Indicator | 32 C123620 | CYTORESP | Cytogenetic Response | C123580 | CYTOGENETIC MINOR RESPONSE | | |
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| S2 CS844 TUBPUT S3 CHIS69 VSUDENT ∢ ► Readh | | 38 C119552 | LESRVIND | Lesion Revascularization In | 36 C123621 37 C123621 | DRCRIND | Disease Recurrence Indicator Disease Recurrence Indicator | | | C49487 C17998 | N |
| 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 | | |
| 4 | dMe TU_Codetab | 42 C174368 | LESSCLSV | Lesion Scaling Severity/Inte Lesion Scaling Severity/Inte | 40 C123622 41 C123622 | HEMARESP HEMARESP | Hematologic Response Hematologic Response | C123585 C123586 | HI-E HI-N | | |
| <u>a.</u> | | 43 C174368 44 C174368 | LESSCLSV | Lesion Scaling Severity/Inte Lesion Scaling Severity/Inte | 42 C123622 | HEMARESP | Hematologic Response | C123587 | HI-P | | |
| | | 45 C119554 | LMBFLIND | Limb Failure Indicator | 43 C123622 44 C123622 | HEMARESP | Hematologic Response Hematologic Response | C123605 C62222 | PD/RELAPSE AFTER HI | | |
| | | 46 C119554 47 C119554 | LMBFLIND | Limb Failure Indicator Limb Failure Indicator | 45 C135479 | LIVRRESP | Liver Response | C4870 | CR | | |
| | | 48 C124446 | LMNDEXAM | Number of Lymph Nodes E | 46 C135479 47 C135479 | LIVRRESP LIVRRESP | Liver Response Liver Response | C18213 C35571 | SD PD | | |
| | | | ReadMe T | U_Codetable_Mapping | 47 C135479 48 C135479 | LIVRRESP | Liver Response | C62222 | NE | | |
| | | | - Reddine | e_coactuble_mapping | 49 C123623 | METBRESP | Metabolic Response | C123407 | CMR PMD | | |
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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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Non-Amgen

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

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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

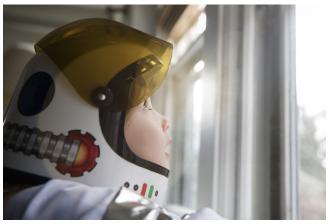
Future Plans: To Do List

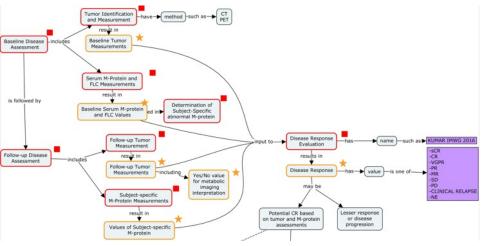
- Additional Oncology Disease Response Supplements
 - Finalize RECIST 1.1
 - Create LUGANO, iRECIST, RANO (2017), IMWG
- IMWG: Multiple Myeloma SDTM Examples and CT development with codetable mappings
- TNM Staging
- Survival FU/Disposition/EOS
- CT Development:
 - Codetable Mapping File for each tumor 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

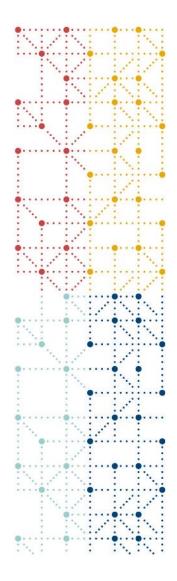




Thanks to our team!

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Resources

SDS Oncology (CDISC wiki)

Public Review Disease Response Supplement RECIST 1.1

Oncology Response Criteria SDTM Examples

SDS Oncology To Do List

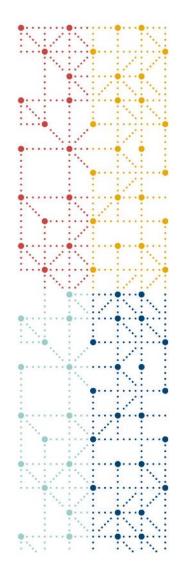
CDISC QRS and CT (CDISC.org)

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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