CDISC Oncology SDS Update:

Disease Response Supplements & Biomedical Concepts Implementations

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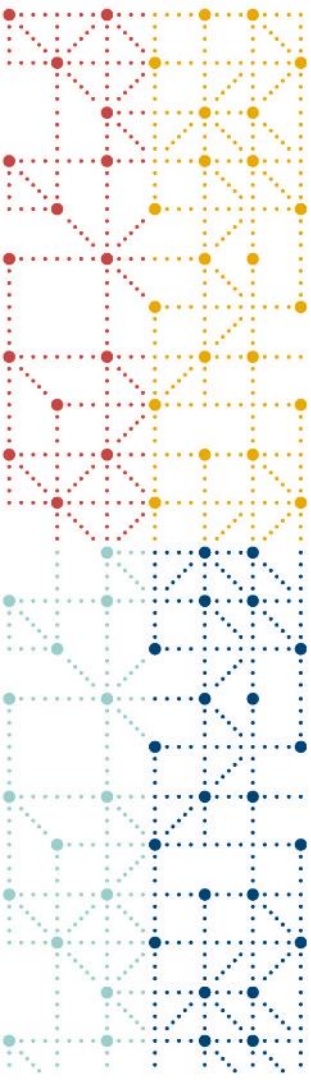
- *The author(s) have no real or apparent conflicts of interest to report.*

Introductions

Name	Role(s)
Ryan Dempsey	Ryan is an Associate Director in the Data Standards Organization at GSK. He is currently eCRF Standards Lead/Product Owner for a cross-functional End-to-End (E2E) Standards Project. He is also a contributing member of the CDISC Oncology SDS Subteam.
Lex Jansen	Lex is a Senior Director, Data Science Development at CDISC. Before CDISC, he was a Principal Solution Consultant and Principal Software Developer at SAS Institute.
Linda Lander	Linda is a Director, Data Science and Biomedical Concepts Product Owner at CDISC. Before CDISC, she was Director Data Standards at GSK.
Erin Muhlbradt	Dr. Muhlbradt is a Clinical/Biomedical Information Specialist & CDISC Terminology Program Lead, US NCI-EVS. Erin leads the CDISC Controlled Terminology program and is a member of the CDISC SDS Oncology Subteam.
Melanie Paules	Melanie is Director, Statistical Programming at Takeda Pharmaceuticals. She leads the CDISC SDS Oncology Subteam.

Agenda

1. Oncology Disease Response Supplement
   - Introduction to CDISC Oncology Standards (Melanie Paules)
   - Oncology Terminology Content (Erin Muhlbradt)
   - Disease Response Supplement (Melanie Paules)
2. CDISC Biomedical Concepts
   - CDISC BC Introduction (Linda Lander)
   - Oncology BC Implementations (Melanie Paules)
3. CDISC Biomedical Concepts Use Cases
   - Study Build (SOA to CDASH) (Ryan Dempsey)
   - Building Blocks for Define.xml (Lex Jansen)
4. Conclusions & Future Plans (Melanie Paules)



Introduction on CDISC Oncology Standards

CDISC SDS Oncology Subteam

- Defines new standards and supports existing CDISC SDTM standards for oncology studies
- Standards include metadata, examples and guidance on implementing CDISC SDTM standards in oncology studies for a variety of use cases
- Included are the following activities:
  - Development of **Disease Response Supplements** to support the implementation of CDISC SDTM standards for various response criteria
  - Support development and **make version updates** to oncology Therapeutic Area User Guides (TAUGs)
  - Build **Biomedical Concepts including Dataset Specializations** for response criteria
  - Oversight of **SDTMIG for TU, TR and RS** Domains
  - Review and approval new controlled terminology requests
- The team is comprised of experts working in oncology research in the pharmaceutical industry, academia research, and a NCI EVS terminology specialist
- Team lead: Melanie Paules, Co-lead: Kim Musgrave, CT Lead: Erin Muhlbradt

History

- SDTMIG v3.1.3 TU, TR and RS first published. Oncology Use Cases SDTM examples were EXCEL attachments to the SDTMIG PDF
- SDTMIG v3.2 Oncology Domains (TU, TR and RS); attachments were dropped. Supplements for questionnaires were introduced.
- Oncology TAUGs developed referencing SDTM Examples for Oncology Use Cases
- SDTMIG v3.3 RS moved to QRS
- Oncology SDS team built of oncology examples, terminology and codetable mappings developed for other tumor response criteria based on:
  - Feedback from industry experience with implementation
  - Expert advice/opinion
- First Oncology Disease Response Supplement Published for RECIST 1.1 (2023)
- First Biomedical Concept and Dataset Specialization Built for RECIST 1.1 (2023)

Oncology Terminology Development

- Oncology CT
- Codetable Mapping Files
- Terminology Development Rules

CDISC Controlled Terminology – Oncology-specific codelists

TU Domain

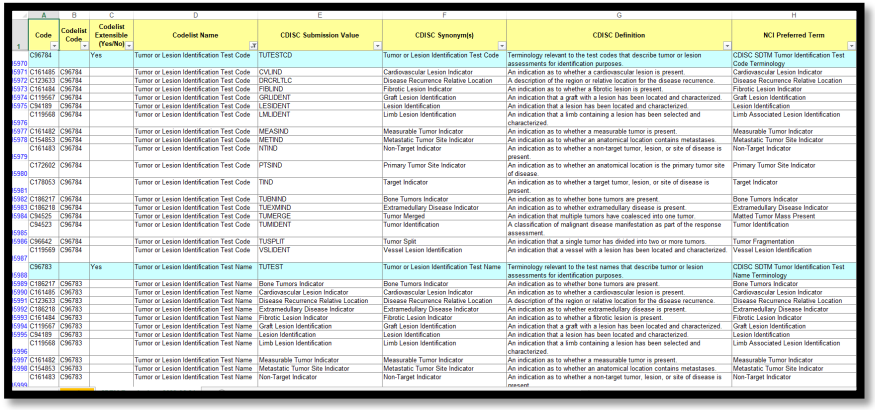
- TUTEST/TUTESTCD
- TUIDRS

TR Domain

- TRTEST/TRTESTCD
- TRPROPRS

RS Domain (Onc)

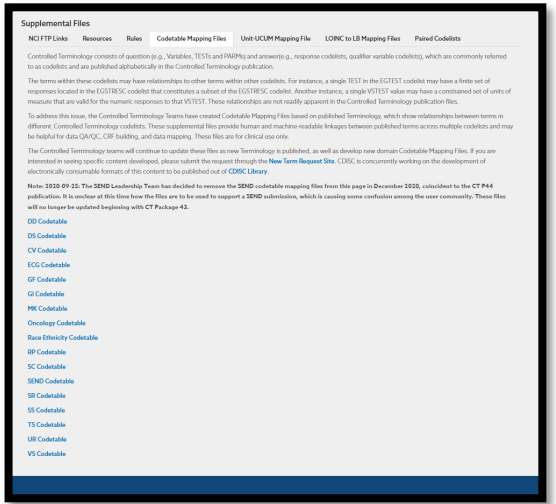
- ONCRSCAT
- ONCRTS/ONCRTSCD
- ONCRSR

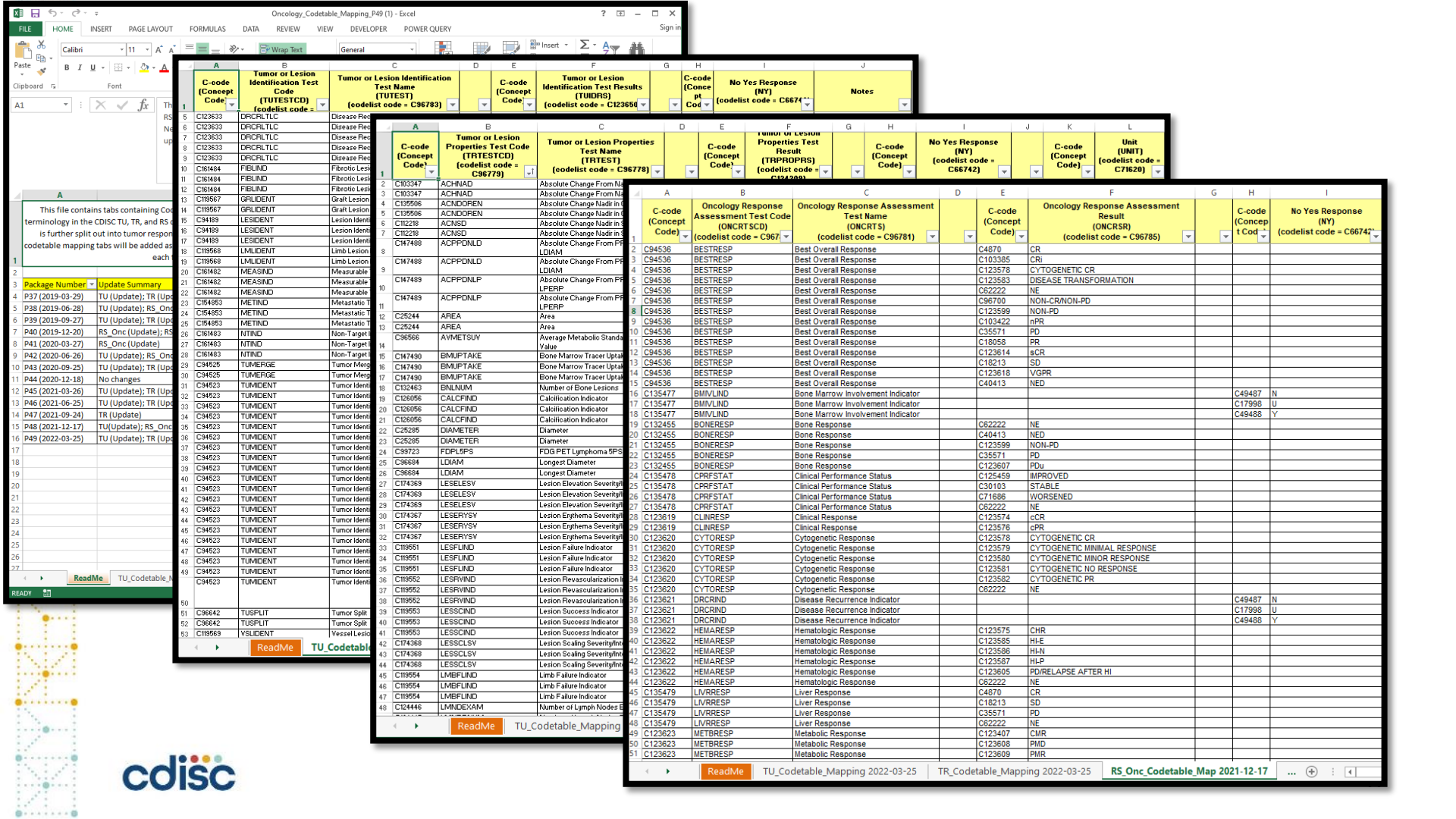


	A	B	C	D	E	F	G	H
4	Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
5970	C96784		Yes	Tumor or Lesion Identification Test Code	TUTESTCD	Tumor or Lesion Identification Test Code	Terminology relevant to the test codes that describe tumor or lesion assessments for identification purposes.	CDISC SDTM Tumor Identification Test Code Terminology
5971	C161485	C96784		Tumor or Lesion Identification Test Code	CVLIND	Cardiovascular Lesion Indicator	An indication as to whether a cardiovascular lesion is present.	Cardiovascular Lesion Indicator
5972	C123633	C96784		Tumor or Lesion Identification Test Code	DRGRLTLC	Disease Recurrence Relative Location	A description of the region or relative location for the disease recurrence.	Disease Recurrence Relative Location
5973	C161484	C96784		Tumor or Lesion Identification Test Code	FIBLIND	Fibrotic Lesion Indicator	An indication as to whether a fibrotic lesion is present.	Fibrotic Lesion Indicator
5974	C119567	C96784		Tumor or Lesion Identification Test Code	GRLIDENT	Graft Lesion Identification	An indication that a graft with a lesion has been located and characterized.	Graft Lesion Identification
5975	C94189	C96784		Tumor or Lesion Identification Test Code	LESIDENT	Lesion Identification	An indication that a lesion has been located and characterized.	Lesion Identification
5976	C119568	C96784		Tumor or Lesion Identification Test Code	LMLIDENT	Limb Lesion Identification	An indication that a limb containing a lesion has been selected and characterized.	Limb Associated Lesion Identification
5977	C161482	C96784		Tumor or Lesion Identification Test Code	MEASIND	Measurable Tumor Indicator	An indication as to whether a measurable tumor is present.	Measurable Tumor 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	C96784		Tumor or Lesion Identification Test Code	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 Tumor Site Indicator	An indication as to whether an anatomical location is the primary tumor site of disease.	Primary Tumor Site Indicator
5981	C178053	C96784		Tumor or Lesion Identification Test Code	TIND	Target Indicator	An indication as to whether a target tumor, lesion, or site of disease is present.	Target Indicator
5982	C186217	C96784		Tumor or Lesion Identification Test Code	TUBNIND	Bone Tumors Indicator	An indication as to whether bone tumors are present.	Bone Tumors Indicator
5983	C186218	C96784		Tumor or Lesion Identification Test Code	TUEMIND	Extramedullary Disease Indicator	An indication as to whether extramedullary disease is present.	Extramedullary Disease Indicator
5984	C94526	C96784		Tumor or Lesion Identification Test Code	TUMERGE	Tumor Merged	An indication that multiple tumors have coalesced into one tumor.	Matted Tumor Mass Present
5985	C94523	C96784		Tumor or Lesion Identification Test Code	TUMIDENT	Tumor Identification	A classification of malignant disease manifestation as part of the response assessment.	Tumor Identification
5986	C96642	C96784		Tumor or Lesion Identification Test Code	TUSPLIT	Tumor Split	An indication that a single tumor has divided into two or more tumors.	Tumor 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	Tumor or Lesion Identification Test Name	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
5990	C161485	C96783		Tumor or Lesion Identification Test Name	Cardiovascular Lesion Indicator	Cardiovascular Lesion Indicator	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
5992	C186218	C96783		Tumor or Lesion Identification Test Name	Extramedullary Disease Indicator	Extramedullary Disease Indicator	An indication as to whether extramedullary disease is present.	Extramedullary Disease Indicator
5993	C161484	C96783		Tumor or Lesion Identification Test Name	Fibrotic Lesion Indicator	Fibrotic Lesion Indicator	An indication as to whether a fibrotic lesion is present.	Fibrotic Lesion Indicator
5994	C119567	C96783		Tumor or Lesion Identification Test Name	Graft Lesion Identification	Graft Lesion Identification	An indication that a graft with a lesion has been located and characterized.	Graft Lesion Identification
5995	C94189	C96783		Tumor or Lesion Identification Test Name	Lesion Identification	Lesion Identification	An indication that a lesion has been located and characterized.	Lesion Identification
5996	C119568	C96783		Tumor or Lesion Identification Test Name	Limb Lesion Identification	Limb Lesion Identification	An indication that a limb containing a lesion has been selected and characterized.	Limb Associated Lesion Identification
5997	C161482	C96783		Tumor or Lesion Identification Test Name	Measurable Tumor Indicator	Measurable Tumor Indicator	An indication as to whether a measurable tumor is present.	Measurable Tumor Indicator
5998	C154853	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 present.	Non-Target Indicator

Oncology Codetable Mapping Files

- Quarterly public review with CDISC CT package; published on CT page on CDISC.org
  - https://www.cdisc.org/standards/terminology/controlled-terminology#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




Oncology_Codetable_Mapping_P49 (1) - Excel
This file contains tabs containing Cod
terminology in the CDISC TU, TR, and RS d
is further split out into tumor respon
codetable mapping tabs will be added as
each
Package Number
Update Summary
P37 (2019-03-29)
P38 (2019-06-28)
P39 (2019-09-27)
P40 (2019-12-20)
P41 (2020-03-27)
P42 (2020-06-26)
P43 (2020-09-25)
P44 (2020-12-18)
P45 (2021-03-26)
P46 (2021-06-25)
P47 (2021-09-24)
P48 (2021-12-17)
P49 (2022-03-25)
No changes
ReadMe
TU_Codetable_Mapping
TR_Codetable_Mapping 2022-03-25
RS_Onc_Codetable_Map 2021-12-17
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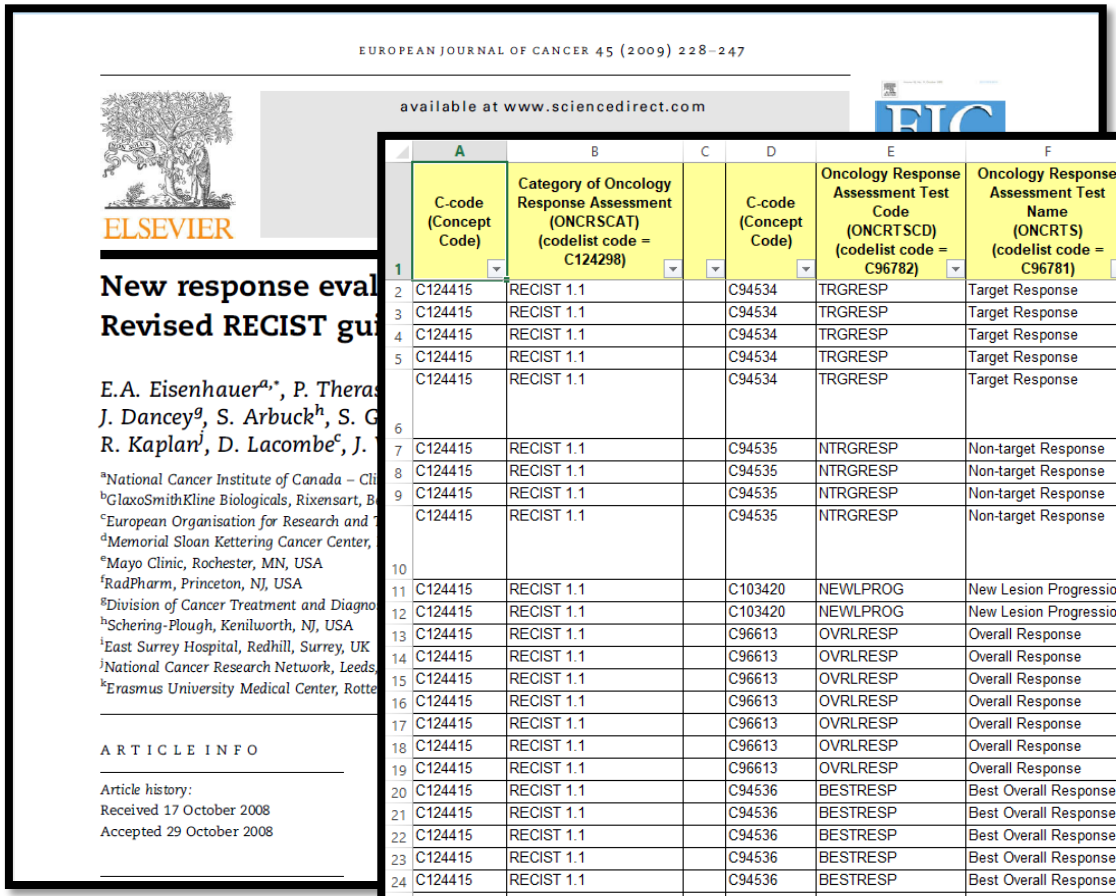
Disease Response Criterion-specific Codetable Mapping Files

- 93 Disease Response Criterion published in ONCRSCAT codelist to date
- 10 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*
  - RANO – *Ellingson et al 2017*
  - RANO-BM – *Lin et al 2015**



EUROPEAN JOURNAL OF CANCER 45 (2009) 228–247

available at www.sciencedirect.com

ELSEVIER

New response eval
Revised RECIST gui

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ARTICLE INFO

Article history:
Received 17 October 2008
Accepted 29 October 2008

	A	B	C	D	E	F	G	H	I	J
1	C-code (Concept Code)	Category of Oncology Response Assessment (ONCRSCAT) (codelist code = C124298)		C-code (Concept Code)	Oncology Response Assessment Test Code (ONCRTSCD) (codelist code = C96782)	Oncology Response Assessment Test Name (ONCRTS) (codelist code = C96781)		C-code (Concept Code)	Oncology Response Assessment Result (ONCRSR) (codelist code = C96785)	Notes
2	C124415	RECIST 1.1		C94534	TRGRESP	Target Response		C4870	CR	
3	C124415	RECIST 1.1		C94534	TRGRESP	Target Response		C18058	PR	
4	C124415	RECIST 1.1		C94534	TRGRESP	Target Response		C18213	SD	
5	C124415	RECIST 1.1		C94534	TRGRESP	Target Response		C35571	PD	
6	C124415	RECIST 1.1		C94534	TRGRESP	Target Response		C62222	NE	The category of "non-evaluable", or "NE", represents the condition where a response cannot be determined with confidence. The RECIST paper uses
7	C124415	RECIST 1.1		C94535	NTRGRESP	Non-target Response		C4870	CR	
8	C124415	RECIST 1.1		C94535	NTRGRESP	Non-target Response		C96700	NON-CR/NON-PD	
9	C124415	RECIST 1.1		C94535	NTRGRESP	Non-target Response		C35571	PD	
10	C124415	RECIST 1.1		C94535	NTRGRESP	Non-target Response		C62222	NE	The category of "non-evaluable", or "NE", represents the condition where a response cannot be determined with confidence. The RECIST paper uses
11	C124415	RECIST 1.1		C103420	NEWLPROG	New Lesion Progression		C86071	EQUIVOCAL	
12	C124415	RECIST 1.1		C103420	NEWLPROG	New Lesion Progression		C123645	UNEQUIVOCAL	
13	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C4870	CR	
14	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C18058	PR	
15	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C18213	SD	
16	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C96700	NON-CR/NON-PD	
17	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C35571	PD	
18	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C62222	NE	
19	C124415	RECIST 1.1		C96613	OVRLRESP	Overall Response		C40413	NED	
20	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C4870	CR	
21	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C18058	PR	
22	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C18213	SD	
23	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C96700	NON-CR/NON-PD	
24	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C35571	PD	
25	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C62222	NE	
26	C124415	RECIST 1.1		C94536	BESTRESP	Best Overall Response		C40413	NED	

RS_RECIST1.1 Mapping 2020-09-25 | RS_iRECIST Mapping 2018-12-21 | RS_LUGANO Mapping 2021-12-17 | RS_RAJKUMARMM_CodMap 2020

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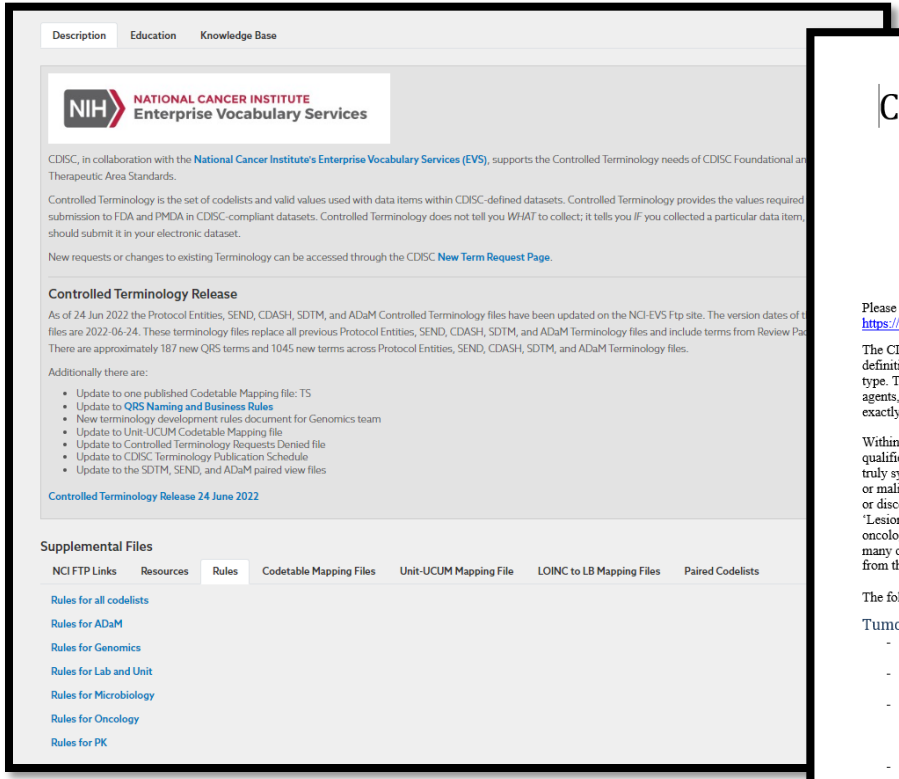
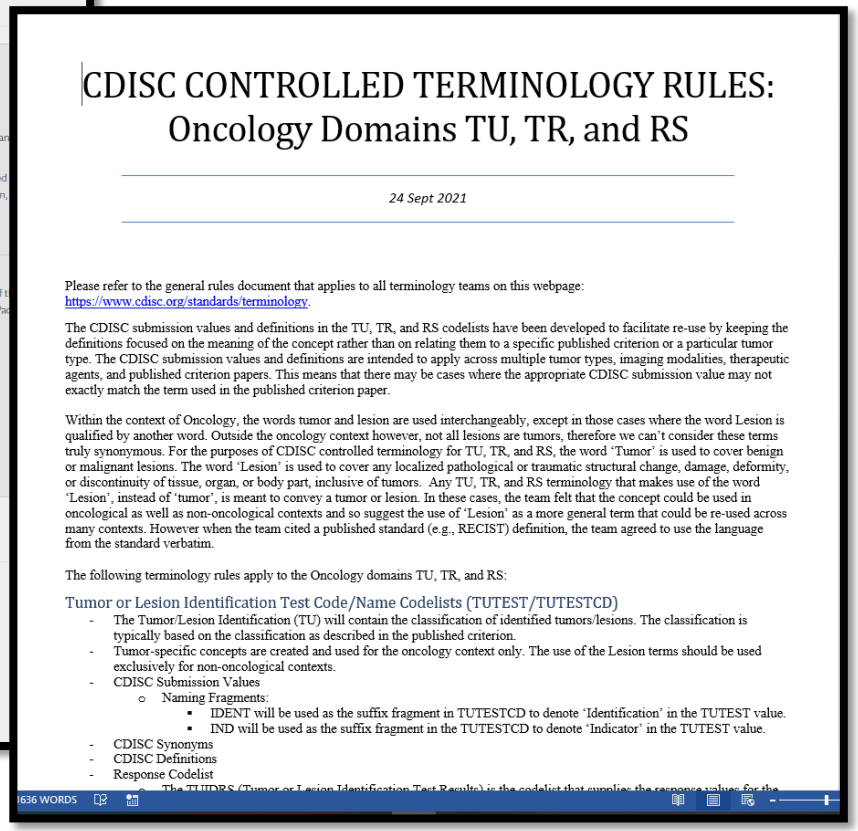
Oncology Terminology Development Rules





CDISC CONTROLLED TERMINOLOGY RULES:
Oncology Domains TU, TR, and RS

24 Sept 2021

Please refer to the general rules document that applies to all terminology teams on this webpage:
https://www.cdisc.org/standards/terminology.

The CDISC submission values and definitions in the TU, TR, and RS codelists have been developed to facilitate re-use by keeping the 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, therapeutic 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 is 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 'Tumor' is used to cover benign or malignant lesions. The word 'Lesion' is used to cover any localized pathological or traumatic structural change, damage, deformity, or discontinuity of tissue, organ, or body part, inclusive of tumors. Any TU, TR, and RS terminology that makes use of the word 'Lesion', instead of 'tumor', is meant to convey a tumor or lesion. In these cases, the team felt that the concept could be used in oncological as well as non-oncological contexts and so suggest the use of 'Lesion' as a more general term that could be re-used across 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.

The following terminology rules apply to the Oncology domains TU, TR, and RS:

Tumor or Lesion Identification Test Code/Name Codelists (TUTEST/TUTESTCD)

- The Tumor/Lesion Identification (TU) 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.
    - IND will be used as the suffix fragment in the TUTESTCD to denote 'Indicator' in the TUTEST value.
- CDISC Synonyms
- CDISC Definitions
- Response Codelist

1636 WORDS

Disease Response Supplement Development

- Purpose
- Development Process
- Structure of the Disease Response Supplement
- Key Concepts

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

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New to CDISC | Standards | Education | Resources | Events | Membership | Members Only

Home / Standards / Foundational / QRS

Where is the RECIST 1.1 Disease Response Supplement?

Description | QRS Supplements | FAQ | QRS Resources | Public Review

How can I access the published supplements?

QRS Supplements

Displaying 1 - 1 of 1

SDTM Domain/ADaM Dataset: SDTM Domain/ADaM Dataset

Permission: Permission

QRS Name Starts With:

QRS Name Contains: RECIST

--CAT Contains:

Apply

QRS Name	Short Name (--CAT)	SDTM Domain/ADaM Dataset	Permission	Version Release Date
Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1)	RECIST	RS	Exempt from Copyright	Version: **1.0** **31 Oct 2023**

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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

Biomedical Concept Overview

- CDISC BC Introduction

Background

Current Problem with Standards Adoption:

- Variation across studies
- Poor quality data from various sources, e.g., venders, CROs, etc.
- Lengthy cycle times to clean and standardize across studies in submissions
- Costly manual efforts
- Insufficient linkages across standards (end-to-end)
- Demand for more standards
- Data re-use challenging

CDISC has evolved:

- CDISC 360 piloted development of linked **Biomedical Concept** metadata to enable end to end automation
- CDISC Library has published data standards as groups of linked metadata

Biomedical Concepts - Benefits to the CDISC Community

Part of the overarching CDISC vision enabling **connected standards**

Facilitates **accurate** and **more consistent implementation** by reducing unnecessary variability

Facilitates **metadata-driven automation**

Increases **quality and efficiency** throughout end-to-end study delivery process

Enables **data reuse**

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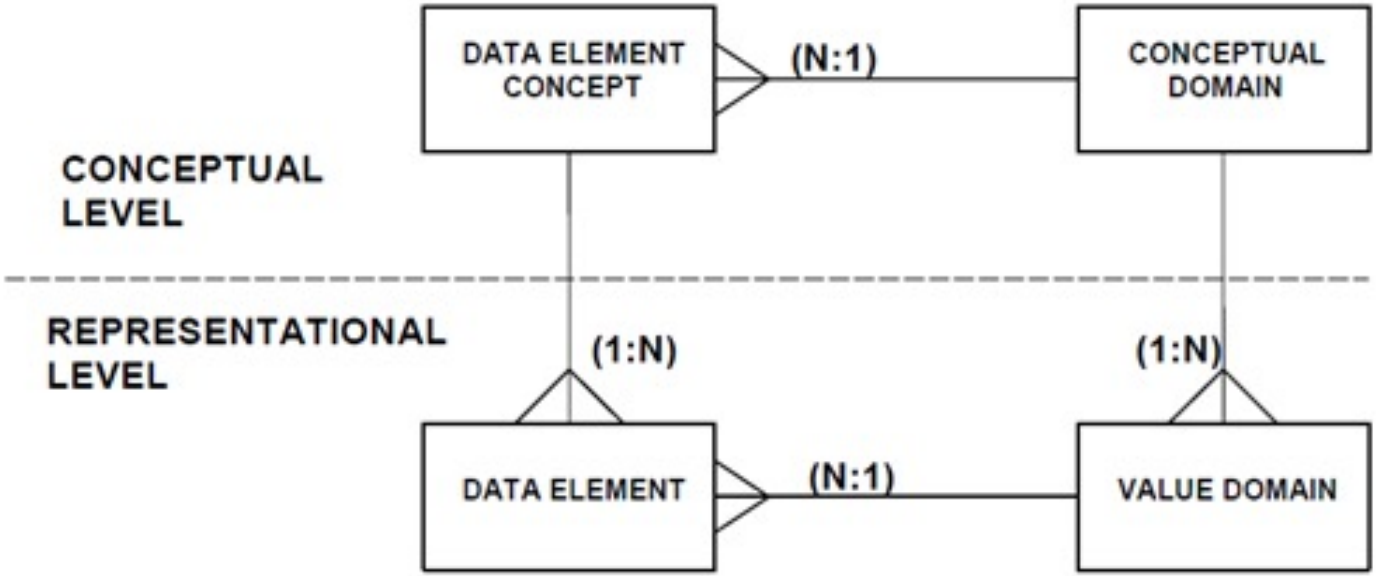
What Is a Biomedical Concept?

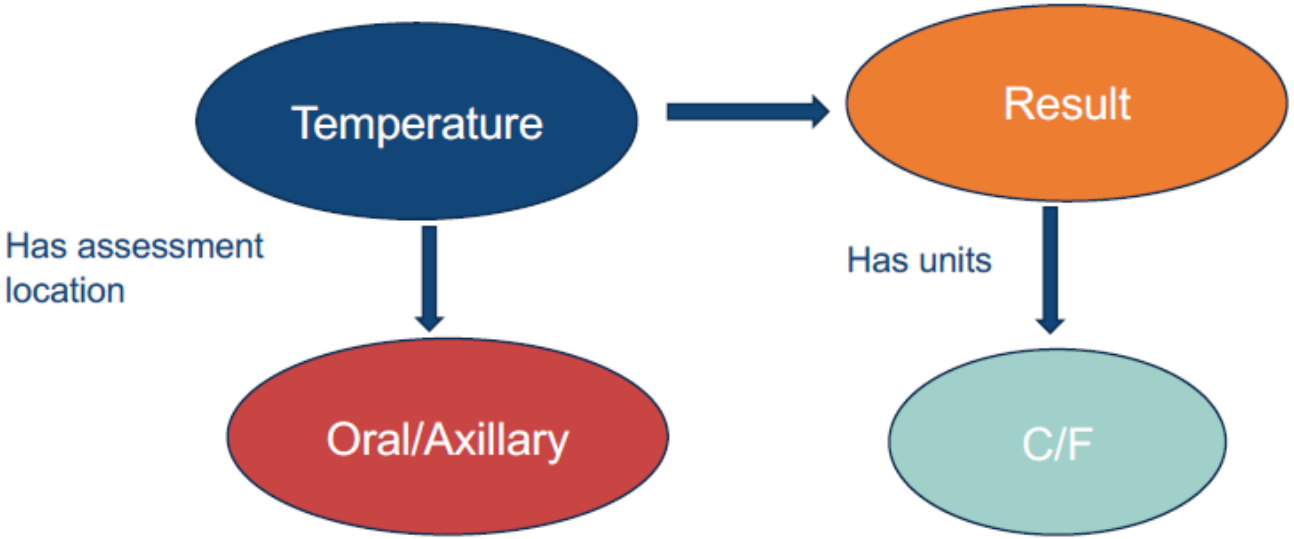
ISO 11179 Definition: A unit of knowledge created by a unique combination of characteristics



What Is a Biomedical Concept?

ISO 11179 Definition: A unit of knowledge created by a unique combination of characteristics

- Independent of study
- Independent of a representation in any standard, but can be tethered to a standard



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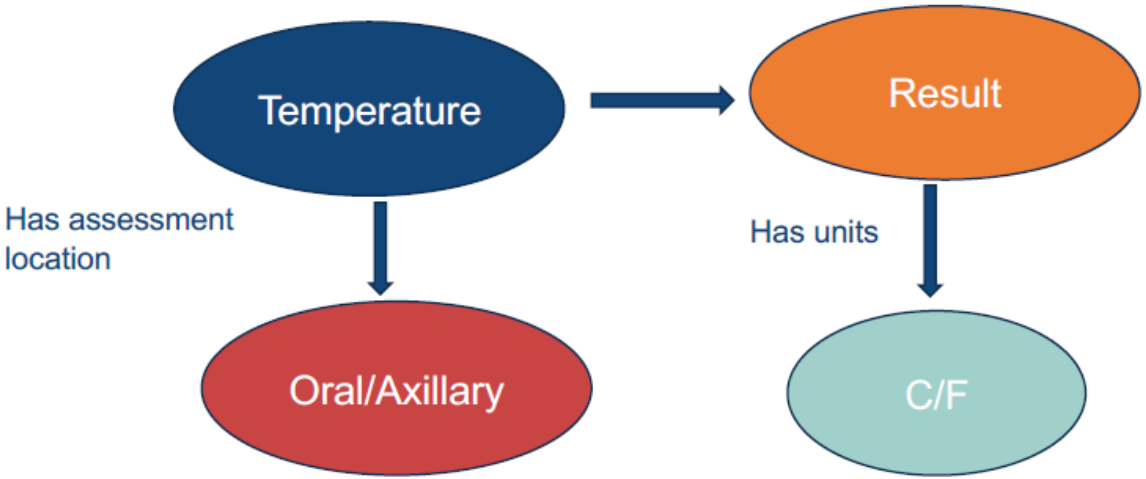
What Is a Biomedical Concept?



Conceptual Layer

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

Implementation Layer

CDISC Biomedical Concepts & SDTM Dataset Specializations

Pragmatic Implementation:

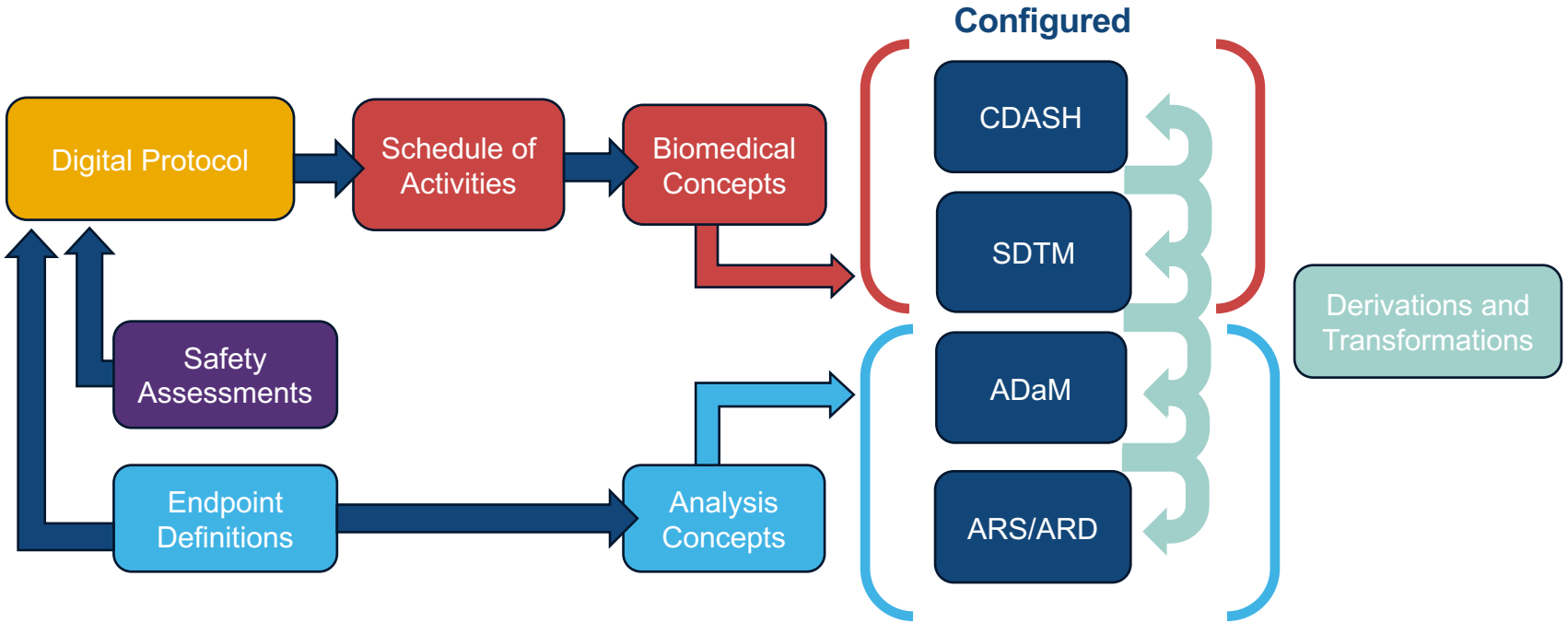
- **Conceptual Layer** – abstract BC's
  - Provides semantics - aligned with NCI terminology
  - Supports study design, Schedule of Activities (SOA)

- **Implementation Layer** - Dataset Specializations with VLM definitions
  - Supports programmers
  - Pre-configured building blocks for Define-XML
  - Tailored to BCs to link with unambiguous semantics & definitions
  - Dataset specializations as an extended dataset structure
  - Extend foundational standards
    - Add explicit relationships between variables
    - Additional operational metadata, e.g., data type, etc.

Foundational Standards vs. Biomedical Concepts

Foundational Standards	Biomedical Concepts
Normative content.	Informative content.
Developed for each individual data lifecycle stage.	Capable of connecting multiple standards.
Multiple data models.	Single framework.
General.	Highly specific & granular. Applied and concise.
Require extensive deliberation and consensus-building, as they are designed to be broadly applicable across various contexts.	Leverage existing foundational standards and utilize metadata and controlled terminology to add specific implementation details, allowing for a more rapid and streamlined curation process.
Provide the foundation for details.	Compatible with study's schedule of activities.
	Value Level Definitions that are curated with implementation details.

CDISC BC Vision



Oncology Biomedical Concept (BC) Implementations

- Oncology BC Conceptual Level
- Oncology BC SDTM Dataset Specializations

Oncology Biomedical Concepts (BCs) for RECIST 1.1

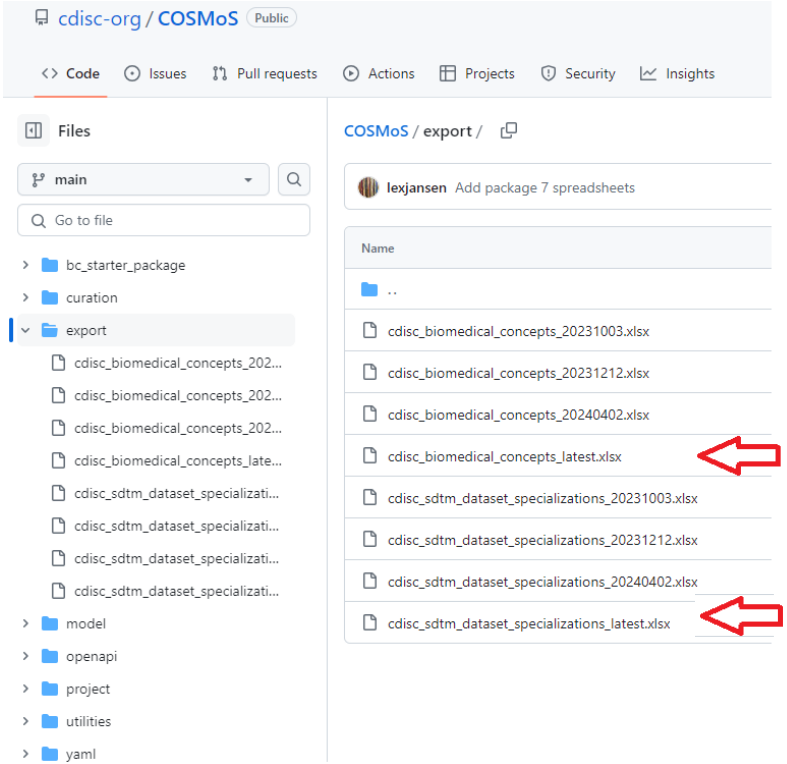
- CDISC Oncology SDS Subteam are early adopters of the CDISC Biomedical Concepts
  - Constructed following the CDISC BC Model
  - Used the SDTMIG for TU, TR and RS, Disease Response Supplement for RECIST 1.1 and Codetable Mapping Files as source reference files
  - Developed both Conceptual BCs and (SDTM) specializations

- RECIST 1.1 is a biomedical concept **category** which encompasses individual biomedical concepts used within the criteria for clinical data

Demonstration

- Filter on bc_categories contains “RECIST 1.1”
- Filter on short_name=Overall Response
- Show links to NCI Thesaurus (nih.gov)

COSMoS/export at main · cdisc-org/COSMoS · GitHub

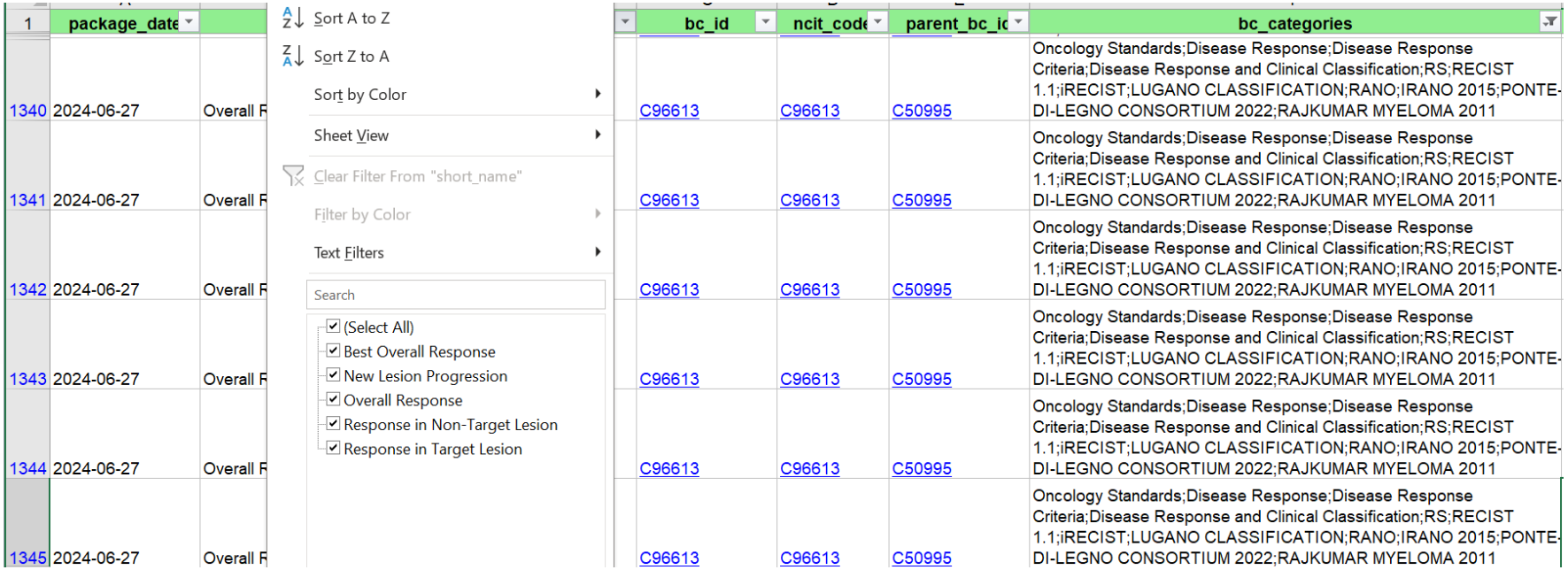


Select the BC “latest” file

Select the specialization “latest” file

Filter on bc_categories=RECIST 1.1

The RECIST 1.1 Biomedical Concepts will be shown.



	package_date		bc_id	ncit_code	parent_bc_id	bc_categories
1340	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011
1341	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011
1342	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011
1343	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011
1344	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011
1345	2024-06-27	Overall R	C96613	C96613	C50995	Oncology Standards;Disease Response;Disease Response Criteria;Disease Response and Clinical Classification;RS;RECIST 1.1;iRECIST;LUGANO CLASSIFICATION;RANO;IRANO 2015;PONTE-DI-LEGNO CONSORTIUM 2022;RAJKUMAR MYELOMA 2011

Filter on short_name=Overall Response
(or vlm_group_id=OVRLRESP)

package_da	bc_id	sdtmig_start version	sdtmig_end version	doma	vlm_source	vlm_group_id	short_name
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)
2024-06-27	C96613	3-2		RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)

sdtm_variable	dec_id	nsv_flag	codelis	codelist_submission value	subset codel	value_list	assigned_term	assigned_value	role
RSLNKGRP	C117394	N							Identifier
RSTESTCD		N	C96782	ONCRTSCD			C96613	OVRLRESP	Topic
RSTEST		N	C96781	ONCRTS			C96613	Overall Response	Qualifier
RSCAT	C25372	N	C124298	ONCRSCAT			C124415	RECIST 1.1	Qualifier
RSORRES	C70856	N	C96785	ONCRSR		CR;NE;PD;PR;SD;NED;NON-CR/NON-PD			Qualifier
RSSTRESC	C70856	N	C96785	ONCRSR		CR;NE;PD;PR;SD;NED;NON-CR/NON-PD			Qualifier
RSEVAL	C51824	N	C78735	EVAL		INVESTIGATOR;INDEPENDENT ASSESSOR			Qualifier
RSEVALID	C117043	N	C96777	MEDEVAL		RADIOLOGIST 1;RADIOLOGIST 2;RADIOLOGIST 3			Qualifier
RSDTC	C82515	N							Timing

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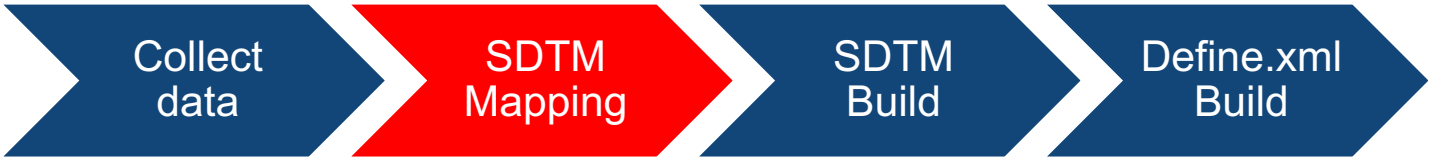
SDTM Mapping – Greatly Reduced for BCs

- Current tasks and flow



- Impact of BC

BC Package for E2E: Use for collection, SDTM, and Define

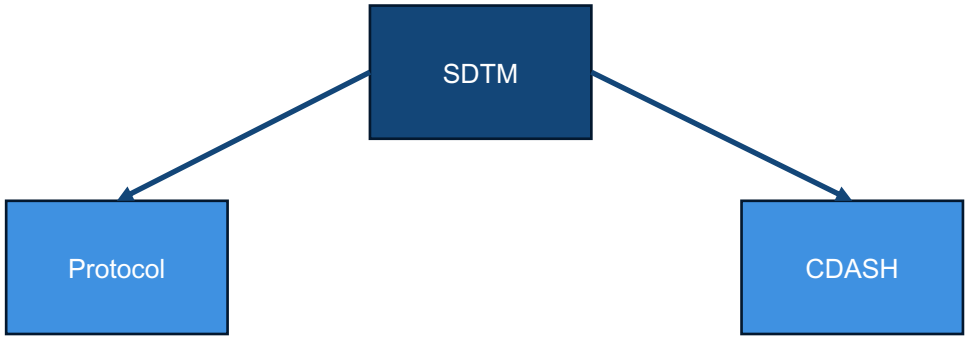
- ❖ Terminology are integral to the BC
- ❖ SDTM Definitions are part of the metadata specialization
- ❖ SDTM Mapping is no longer needed; Targets in SDTM are integral to the BC

Oncology Biomedical Concepts: Use Case 1

- Oncology – Terminology Consistency from Protocol to SDTM

package_date	short_name	bc_id	ncit_code	parent_bc_id	bc_categories	definition	example_set
2023-07-06	Matted Tumor Mass Present	C94525	C94525	C82547	Evaluation Criteria in Solid Tumors Version 1.1;Tumor Identifier Test;Tumor Identification;RECIST 1.1;Merged	A finding indicating that two or more tumors have merged to create a single cancerous mass.	TARGET
2023-07-06	Response in Target Lesion	C94534	C94534	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Target	A qualitative or quantitative measurement of the response of a target lesion(s) to the therapy.	SD;PR;CR;PD
2023-07-06	Response in Non-Target Lesion	C94535	C94535	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Non-Target	A qualitative or quantitative measurement of the response of a non-target lesion(s) to the therapy.	CR; PR; SD; PD; NA; NE; NED
2023-07-06	Overall Response	C96613	C96613	C50995	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Disease Response Assessment Test;Disease Response;RECIST 1.1;Overall	An assessment of the overall response of the disease to the therapy.	CR; PR; SD; PD; NA; NE; NED
2023-07-06	Tumor Fragmentation	C96642	C96642	C82547	Response Evaluation Criteria in Solid Tumors;Response Evaluation Criteria in Solid Tumors Version 1.1;Tumor Identifier Test;Tumor Identification;RECIST 1.1;Split	A finding indicating that a tumor mass has been divided into two or more tumors.	TARGET
2023-07-06	Tumor Status	C96643	C96643	C171082		ndition or state of the tumor at a particular time.	PRESENT;ABSENT;UNEQUIVOCAL;EQUIVOCAL
2023-07-06	Longest Diameter	C96684	C96684	C25285		gest possible length of a straight line passing through the of a circular or spheroid object that connects two points on umference.	12;15;17;TOO SMALL TO MEASURE
2023-07-06	Longest Perpendicular	C96685	C96685			plane through a body or figure given line or plane.	12;15;17

Specializations of BC C96613



Protocol Specialization

bc_id	doma	vlm_source	vlm_group_id	short_name	sdtm_variable	codelis	ion_value	value_list	assigned_tern	assigned_value
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTESTCD	C96782	ONCRTSCD		C96613	OVRLRESP
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTEST	C96781	ONCRTS		C96613	Overall Response
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSCAT	C124298	ONCRSCAT		C124415	RECIST 1.1
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSORRES	C96785	ONCRSR	CR;NE;PD;PR;SD;NED;NON-CR/NON-PD		
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSDTC					

Table 36 presents the overall response at an individual time point for all possible combinations of tumor responses per RECIST 1.1.

Table 36 Evaluation of overall response

Use only the first 8 rows for studies requiring measurable/target lesions at baseline. Use only the last 3 rows for studies without a requirement of evidence of disease at baseline.

TLs	NTLs	New Lesions	Overall Response
CR	CR or NA	No	CR
CR	Non-CR/Non-PD or NE	No	PR
PR	Non-PD or NA or NE	No	PR
SD	Non-PD or NA or NE	No	SD
NE	Non-PD or NA or NE	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD
NA	CR	No	CR
NA	Non-CR/non-PD	No	Non-CR/non-PD[a]
NA	NE	No	NE
NA	Unequivocal PD	Yes or No	PD
NA	Any	Yes	PD
NA	NA	No	NED
NA	NA	NE	NE
NA	NA	Yes	PD

CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NA = not applicable; NE = not evaluable; NED = no evidence of disease; NTL = non-target lesion; TL = target lesion.

CDASH Specialization

bc_id	doma	vlm_source	vlm_group_id	short_name	sdtm_variable	codelis	ion_value	value_list	assigned_tern	assigned_value
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTESTCD	C96782	ONCRTSCD		C96613	OVRLRESP
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSTEST	C96781	ONCRTS		C96613	Overall Response
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSCAT	C124298	ONCRSCAT		C124415	RECIST 1.1
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSORRES	C96785	ONCRSR	CR;NE;PD;PR;SD;NED;NON-CR/NON-PD		
C96613	RS	RS.RSTESTCD	OVRLRESP	Overall Response (RECIST 1.1)	RSDTC					

Forms

OID	Name	Description	Repeating	Aliases	Therapeutic Area	Clinical Stage
RS	Form RS - Disease Response	RS - Disease Response [en]	No			

Section

OID	Name	Repeating	Description	Order No.	Mandatory	Aliases	Condition	IsReferenceData	Repeating Information	SASDatasetName	Domain
CDASH_2-1_IG_33	RS - Disease Response	No	RS - Disease Response [en]	1	Yes						RS

Questions

OID	Name	bc_id	Text	DataType	Order No.	Mandatory	Terminology	Length	Significant Digits	Units	Description
IT.TRGRESP_RSORRES	TRGRESP_RSORRES	C94534	Target Response [en]	text	6	No	Target Response	15			
IT.NTRGRESP_RSORRES	NTRGRESP_RSORRES	C94535	Non-Target Response [en]	text	7	No	Non-Target Response	15			
IT.OVRLRESP_RSORRES	OVRLRESP_RSORRES	C96613	Overall Response [en]	text	8	No	Overall Response	15			

Terminologies

OID	Name	DataType	SASFormatName	Terminology Aliases	Coded Value	Text	Order No.
Overall Response	Overall Response	text			CR	Complete Response (CR)	1
Overall Response	Overall Response	text			PR	Partial Response (PR)	2
Overall Response	Overall Response	text			SD	Stable Disease (SD)	3
Overall Response	Overall Response	text			NON-CR/NON-PD	Non Complete Response/Non Progressive Disease (NON-CR/NON-PD)	4
Overall Response	Overall Response	text			PD	Progressive Disease (PD)	5
Overall Response	Overall Response	text			NE	Not Evaluable (NE)	6
Overall Response	Overall Response	text			NED	No Evidence of Disease (NED)	7

CDASH Specialization

Form RS - Disease Response		
1 RS - Disease Response		
1.8	Overall Response	○ [CR] Complete Response (CR) ○ [PR] Partial Response (PR) ○ [SD] Stable Disease (SD) ○ [NON-CR/NON-PD] Non Complete Response/Non Progressive Disease (NON-CR/NON-PD) ○ [PD] Progressive Disease (PD) ○ [NE] Not Evaluable (NE) ○ [NED] No Evidence of Disease (NED)

OVRLRESP_RSORRES

bc_id = C96613

Summary

- SDTM specializations can be used to develop upstream standards using a metadata driven approach:
  - Protocol
  - CDASH
  - Review models
  - External data
- Incorporating BCs into e2e standards:
  - Ensures consistency
  - Accelerates timelines
  - Reduces conformance errors
  - Allows powerful impact assessments

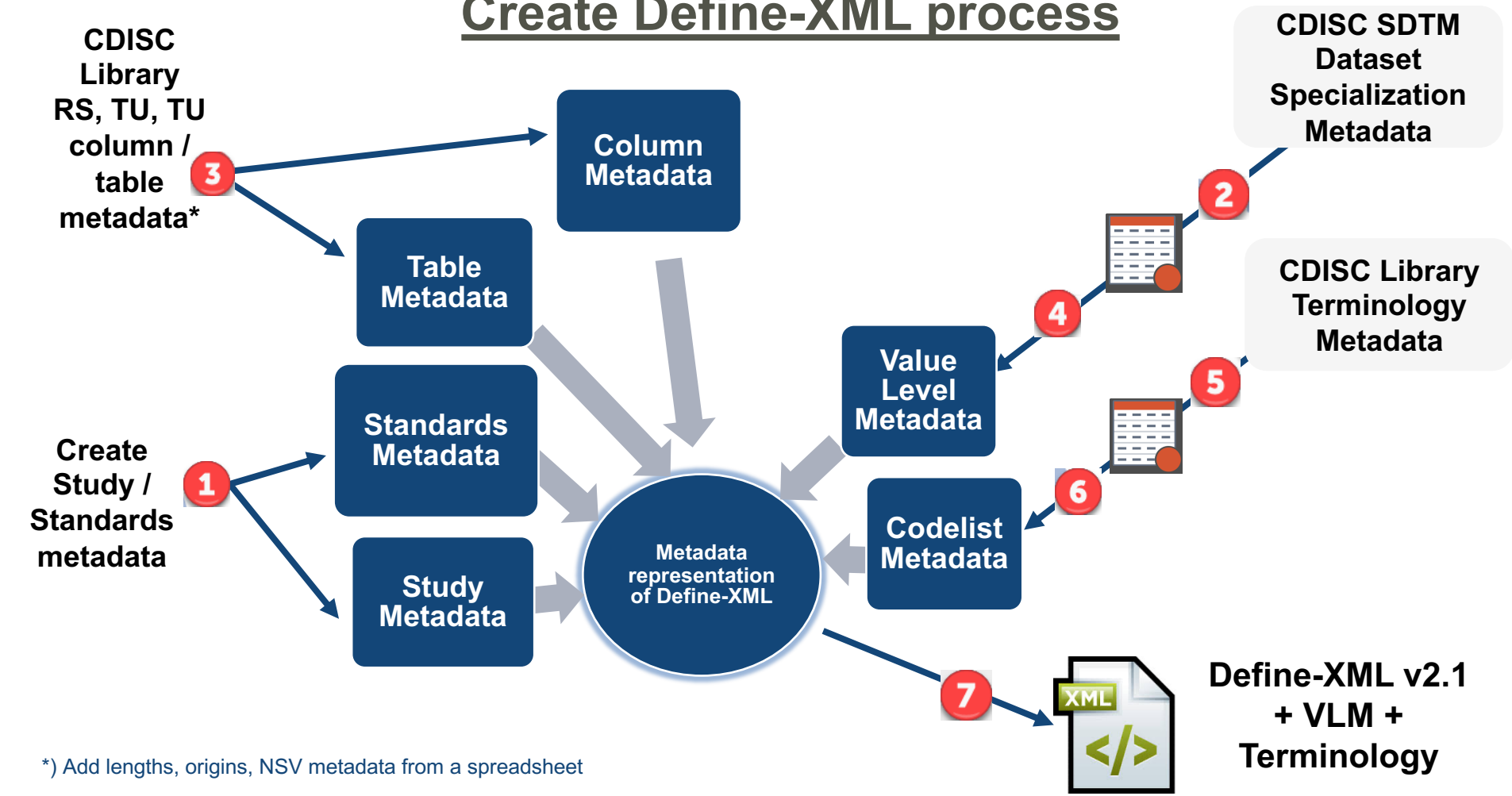
Oncology Biomedical Concepts: Use Case 2

- Define-XML building blocks - RECIST 1.1 from SDTM Dataset Specializations

Define-XML v2.1 document with SDTM Dataset Specializations:
- Value Level Metadata and
- Controlled Terminology metadata for the RS, TR, and TU domains

- SDTM Dataset Specializations are considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- Exercise: present Oncology RECIST 1.1 SDTM Dataset Specializations as Value Level Metadata in Define-XML v2.1
- Oncology Standards as of 2024-06-27:
  - 28 Biomedical Concepts (5 specific for RECIST 1.1)
  - 30 SDTM Specializations (TR, TU, RS (5 specific for RECIST 1.1))
- REST API:
  - GET Biomedical Concepts:
    `/mdr/bc/biomedicalconcepts?category=RECIST 1.1`
  - GET SDTM Specializations:
    `/mdr/specializations/sdtm/datasetspecializations?domain=RS`

Create Define-XML process



*) Add lengths, origins, NSV metadata from a spreadsheet

Expand all VLM

Collapse all VLM

Date/Time of Define-XML document generation: 2024-06-19T15:24:12-04:00
Define-XML version: 2.1.7
Define-XML Context: Submission
Stylesheet version: 2019-02-11

Study Name CDISC01

Study Description CDISC Test Study

Protocol Name CDISC01

Metadata Name Study CDISC01_1, Data Definitions V-1

Metadata Description Data Definitions for CDISC01-01 SDTM datasets

This Define-XML document is based on RS, TR and TU dataset and column metadata extracted from the CDISC Library. Value level metadata (VLM) and codelists were programmatically created by extracting metadata from CDISC SDTM Dataset Specializations and the CDISC Library.

Standards for Study CDISC01

Standard	Type	Status	Documentation
SDTMIG 3.3	IG	Final	
CDISC/NCI SDTM 2024-03-29	CT	Final	
CDISC/NCI DEFINE-XML 2024-03-29	CT	Final	

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
RS [SDTMIG 3.3]	Disease Response and Clin Classification	FINDINGS	One record per response assessment or clinical classification assessment per time point per visit per subject per assessor per medical evaluator	Tabulation	STUDYID, RSDTC, USUBJID, RSTESTCD, RSNAM, RSEVAL, RSEVALID, RSGRPID, VISITNUM		rs.xpt
TR [SDTMIG 3.3]	Tumor/Lesion Results	FINDINGS	One record per tumor measurement/assessment per visit per subject per assessor	Tabulation	STUDYID, VISITNUM, TRDTC, USUBJID, TRTESTCD, TRMETHOD, TRNAM, TREVAL, TREVALID, TRLNKID		tr.xpt
TU [SDTMIG 3.3]	Tumor/Lesion Identification	FINDINGS	One record per identified tumor per subject per assessor	Tabulation	STUDYID, TUEVALID, TULNKID, VISITNUM, TUDTC, USUBJID, TUTESTCD, TULOC, TULAT, TUMETHOD, TUNAM, TUEVAL		tu.xpt

RSTEST		Assessment Name	text	Synonym Qualifier	40	Oncology Response Assessment Test Name, subset • "Best Overall Response" • "New Lesion Progression" • "Non-target Response" • "Overall Response" • "Target Response"	Collected (Source: Investigator)
RSCAT		Category for Assessment	text	Grouping Qualifier	200	Category of Oncology Response Assessment, subset • "RECIST 1.1"	Collected (Source: Investigator)
RSSCAT		Subcategory	text	Grouping Qualifier	200		Collected (Source: Investigator)
RSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	200		
	RSCAT = "RECIST 1.1" and RSEVAL = "INDEPENDENT ASSESSOR" and RSEVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and RSTESTCD = "BESTRESP" (Best Overall Response)	Best Overall Response (RECIST 1.1)	text	Qualifier	200	Oncology Response Assessment Result, subset for Best Overall Response (RECIST 1.1) - Original (Res) • "CR" • "NE" • "NED" • "NON-CR/NON-PD" • "PD" • "PR" • "SD"	Collected (Source: Investigator)
	RSCAT = "RECIST 1.1" and RSEVAL IN ("INDEPENDENT ASSESSOR", "INVESTIGATOR") and RSEVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and RSTESTCD = "NEWLPROG" (New Lesion Progression)	New Lesion Progression (RECIST 1.1)	text	Qualifier	200	Oncology Response Assessment Result, subset for New Lesion Progression (RECIST 1.1) - Original (Res) • "EQUIVOCAL" • "UNEQUIVOCAL"	Collected (Source: Investigator)

TRSTRESC VLM		Character Result/Finding in Std Format	text	Result Qualifier	200	Tumor or Lesion Properties Test Result [22 Terms]	
	TREVAL IN ("INDEPENDENT ASSESSOR", "INVESTIGATOR") and TREVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and TRMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN",	Longest Diameter	text	Qualifier	200		Derived (Source: Sponsor)
	TREVAL IN ("INDEPENDENT ASSESSOR", "INVESTIGATOR") and TREVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and TRMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MAMMOGRAPHY", "MRI", "NUCLEAR RADIOLOGY", "PET SCAN", "PET/CT SCAN", "PET/MRI SCAN", "PHOTOGRAPHY", "SCINTIGRAPHY", "TOTAL BODY RADIOGRAPHY", "ULTRASOUND", "X-RAY") and TRTESTCD = "LNSTATE" (Lymph Node State)	Lymph Node State	text	Qualifier	200	Tumor or Lesion Properties Test Result, subset for Lymph Node State - Standardized (Char Res) • "NON-PATHOLOGICAL" • "PATHOLOGICAL"	Derived (Source: Sponsor)

TUSTRESC VLM		Tumor/Lesion ID Result Std. Format	text	Result Qualifier	200	Tumor or Lesion Identification Test Results [28 Terms]	
	TUEVAL = "INVESTIGATOR" and TUEVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and TUTESTCD = "NTIND" (Non-Target Indicator)	Non-Target Indicator	text	Qualifier	24	No Yes Response, subset for Non-Target Indicator - Standardized (Char Res) • "N" = "No" • "U" = "Unknown" • "Y" = "Yes"	Derived (Source: Sponsor)
	TUEVAL = "INVESTIGATOR" and TUEVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and TUTESTCD = "TIND" (Target Indicator)	Target Indicator	text	Qualifier	24	No Yes Response, subset for Target Indicator - Standardized (Char Res) • "N" = "No" • "U" = "Unknown" • "Y" = "Yes"	Derived (Source: Sponsor)
	TUEVAL IN ("INDEPENDENT ASSESSOR", "INVESTIGATOR") and TUEVALID IN ("RADIOLOGIST 1", "RADIOLOGIST 2", "RADIOLOGIST 3") and TUMETHOD IN ("CALIPER MEASUREMENT METHOD", "CT SCAN", "ENDOSCOPY", "LYMPHANGIOGRAPHY", "MAMMOGRAPHY", "MRI", "NUCLEAR RADIOLOGY", "PET SCAN",	Tumor Merged	text	Qualifier	24	Tumor or Lesion Identification Test Results, subset for Tumor Merged - Standardized (Char Res) • "TARGET"	Derived (Source: Sponsor)

Conclusion

- SDTM Dataset Specializations can be represented as Value Level Metadata definitions in Define-XML v2.1.
- These definitions contain detailed metadata, including Controlled Terminology subsets.
- The SDTM Dataset Specializations can be considered pre-configured building blocks, from which end-users can select and configure to build Define-XML Value Level Metadata
- This provides immediate benefits to SDTM programmers and opens the door to efficient programming and automation

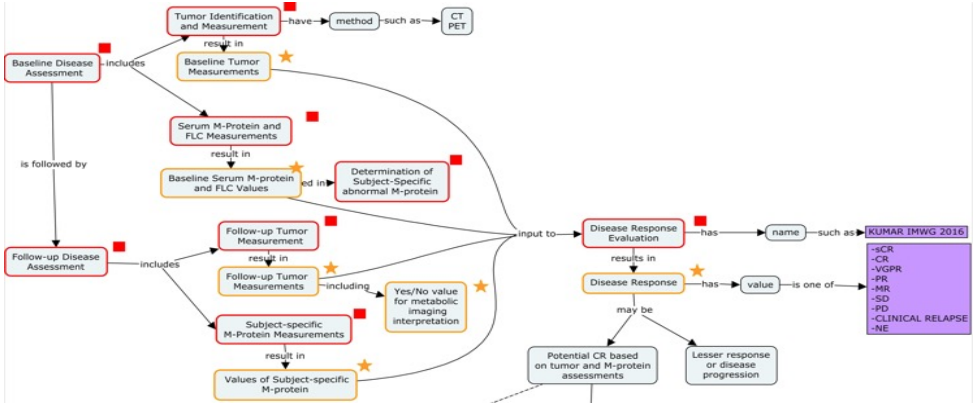
Future Plans

CDISC Oncology SDS Team Future Plans: To Do List

- Additional Oncology Disease Response Supplements with Biomedical Concepts Packages
  - LUGANO is under development
  - iRECIST, RANO (2017), IMWG
- IMWG: Multiple Myeloma SDTM Examples and CT development with GF team
- Oncology TAUGs to be refreshed
  - Breast Cancer TAUG is first and currently under modification
- Survival FU/Disposition (End of Treatment, End of Study, Death)
- CT Development: Extensions and Codetable Mapping File for each tumor response criterion

Vision

- Biomedical Concepts; Concept maps
- Biomedical Concept Metadata Specializations - Relationships from collection/CDASH to SDTM to ADaM and Define.xmls
- Full Package for each criterion



Summary

- Metadata specialization need to expand beyond SDTM
- Goal is to build BCs and Metadata Specializations so they can be associated with all SOA activities
- The strategic vision is for the CDISC user community to shift focus from pulling broad CDISC IG definitions to an approach where specific BCs per study requirements with the linked Metadata Specializations (BC implementations E2E) as the source for programming activities

Community Ask

Building BCs is an iterative approach where we continue to make improvements as we gain more learnings and understanding of the various use cases

- Public review is ongoing until July 16, 2024
- Share your experiences with BCs
- Let us know the gaps in implementation of BCs

Resources

CDISC QRS and CT (CDISC.org)

CDISC Controlled Terminology, Codetable Mapping Files and Oncology Rules

CDISC Change Request Form

QRS Supplements

CDISC Biomedical Concepts

https://www.cdisc.org/cdisc-biomedical-concepts

https://cdisc-org.github.io/COSMoS

Thanks to our teams building the future standards!

- CDISC Oncology SDS Team
- CDISC Biomedical Concepts Team