



## Implementing SDTM and ADaM in Oncology Trials

Presented by DukHyun Kim, Director, Biostatistics, C&R Research



# Meet the Speaker

DukHyun Kim

**Title:** Director

**Organization:** C&R Research

DukHyun Kim is the Biostatistics Director at C&R Research, Korea's CRO. She has been in the industry for more than 16 years including global CRO. She had more than 9 years of experience, involved with statistical review such as ADaM specification, SAP/TFLs shells, ADaM, statistical results, ADRG, ADaM Define.xml and etc. at ICON Clinical Research Korea as biostatistician.

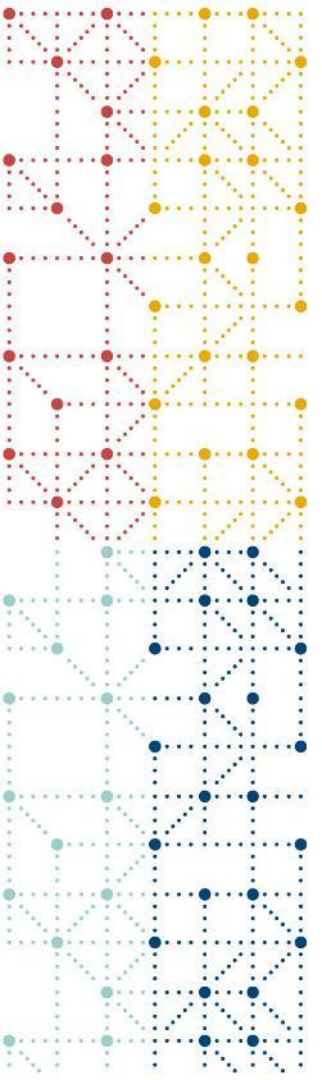
# Disclaimer and Disclosures

- *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.*
- *{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. Oncology Clinical Trials
2. Oncology Specific SDTM Domains
3. Oncology Specific ADaM Domains
4. Conclusion



# Oncology Clinical Trials

# Difficulty in Oncology Clinical Trials

Complexity

Enrollment

Study  
Period



Data  
Collection/  
Handing

Efficacy  
Endpoints

[https://kr.freepik.com/free-vector/writer-s-block-concept-illustration\\_229383793.htm#fromView=keyword&page=1&position=4&uuid=fb9a0c13-114f-46b3-929e-88edd3c0069e](https://kr.freepik.com/free-vector/writer-s-block-concept-illustration_229383793.htm#fromView=keyword&page=1&position=4&uuid=fb9a0c13-114f-46b3-929e-88edd3c0069e)

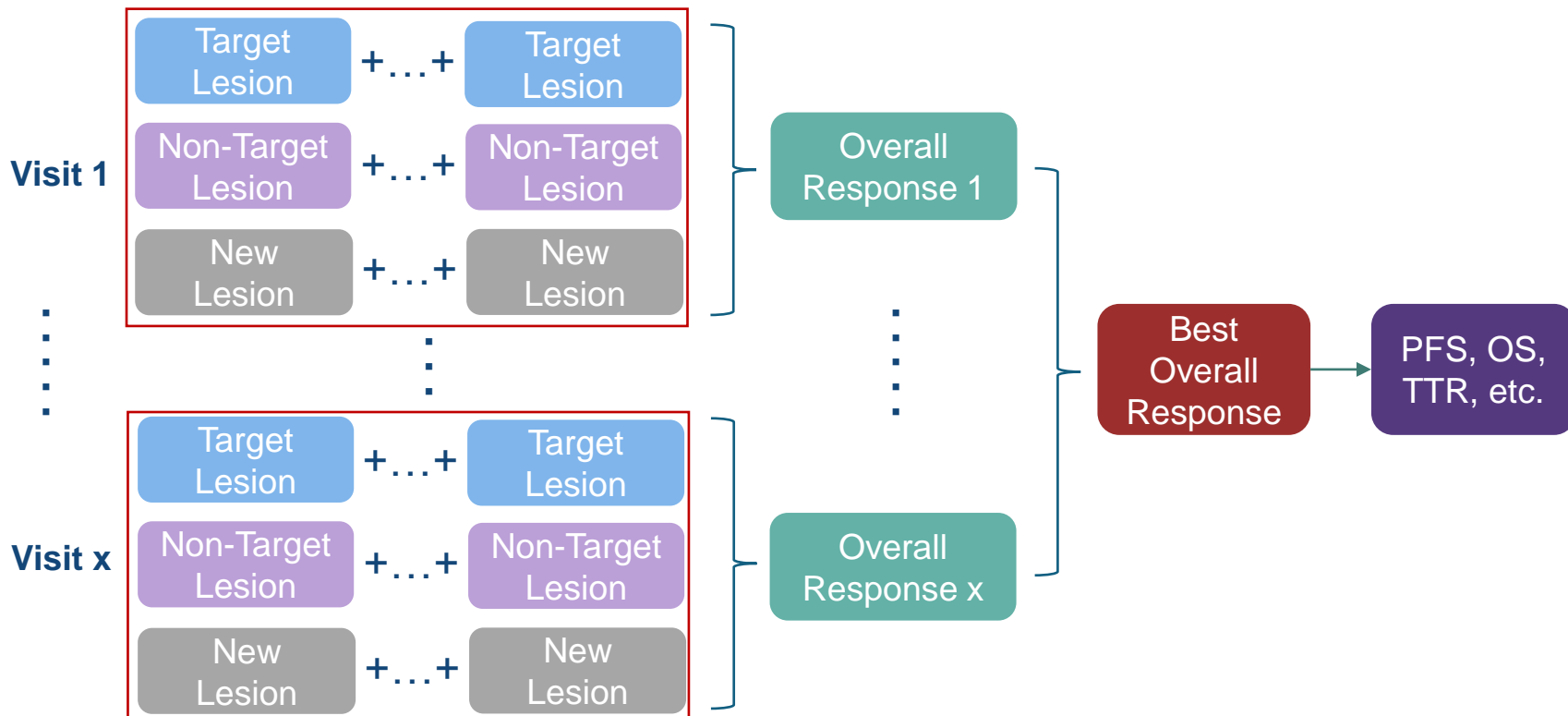
# Efficacy Endpoints in Oncology

- Time to Event
  - Progression-Free Survival (PFS)
  - Overall Survival (OS)
  - Duration of Response (DOR)
  - Time to Response (TTR)
  - Time to Treatment Failure (TTF)
- Response Rate
  - Best of Response (BOR)
  - Objective Response Rate (ORR)
  - Disease Control Rate (DCR)
- Tumor Size
  - Percent Change from Baseline in Sum of Diameter
  - Percent Change from Baseline in Sum of Longest Diameter
  - Percent Change from Nadir

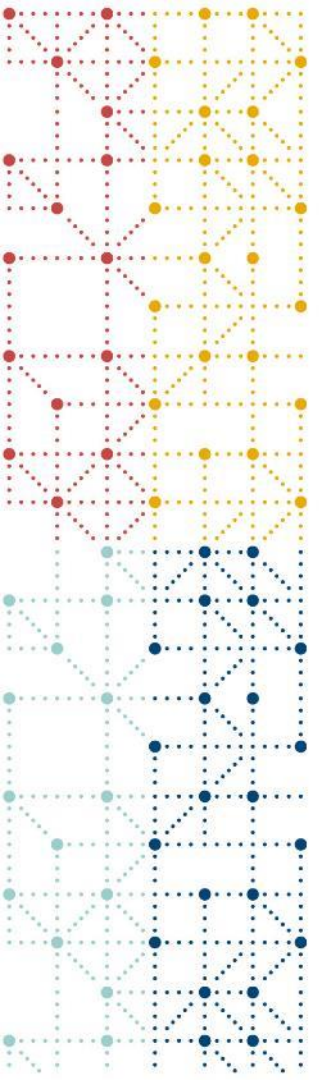


Tumor  
Assessment  
(Image)

# Tumor Assessment for Efficacy Analysis



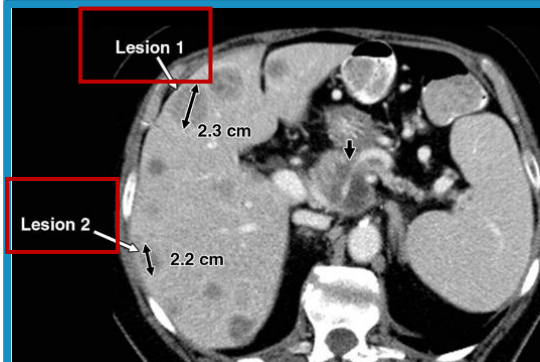




# Oncology Specific SDTM Domains

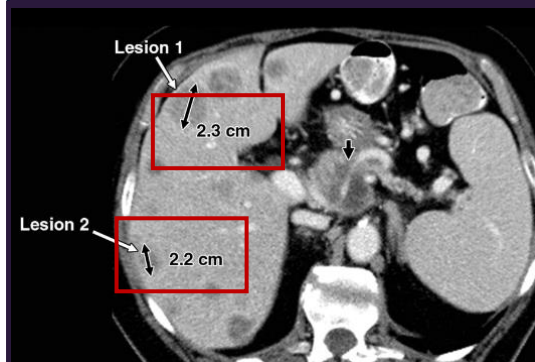
# Oncology Specific Domains from CDISC SDTM

## TU (Tumor/Lesion Identification)



<https://ajronline.org/doi/10.2214/AJR.09.4110>

## TR (Tumor/Lesion Results)



<https://ajronline.org/doi/10.2214/AJR.09.4110>

## RS (Disease Response & Clinical Classification)



[https://www.flaticon.com/kr/free-icon/understanding\\_3240869](https://www.flaticon.com/kr/free-icon/understanding_3240869)

# TU (Tumor/Lesion Identification)

| Form TU/TR - Tumor Identification/Results                            |                             |  |
|--|-----------------------------|--|
| 1 TU/TR - Tumor Identification/Results (RECIST 1.1 - Target Lesions) |                             |  |
| 1.1  | Were any tumors identified? | <input type="radio"/> (N) No <b>TUYN</b><br><input type="radio"/> (Y) Yes  |
| 1.2  | Tumor ID                    | <input type="text"/> <b>TULNKID</b>  |
| 1.3  | Location                    | <input type="radio"/> (BREAST) Breast <b>TULOC</b><br><input type="radio"/> (CHEST) Chest<br><input type="radio"/> (KIDNEY) Kidney<br><input type="radio"/> (LIVER) Liver<br><input type="radio"/> (NECK) Neck                     |
| 1.4  | Laterality                  | <input type="radio"/> (LEFT) Left <b>TULAT</b><br><input type="radio"/> (RIGHT) Right<br><input type="radio"/> (BILATERAL) Bilateral   |
| 1.5  | Directionality              | <input type="radio"/> (DISTAL) Distal <b>TUDIR</b><br><input type="radio"/> (INTERMEDIATE) Intermediate<br><input type="radio"/> (PROXIMAL) Proximal<br><input type="radio"/> (INNER) Inner<br><input type="radio"/> (OUTER) Outer |
| 1.6  | Location Detail             | <input type="text"/> <b>TULOCDTL</b>   |

| Form TU/TR - Tumor Identification/Results                            |                                  |   |
|--|----------------------------------|---|
| 1 TU/TR - Tumor Identification/Results (RECIST 1.1 - Target Lesions) |                                  |   |
| 1.7  | Method of Evaluation             | <input type="radio"/> (CT SCAN) CT Scan <b>TUMETHOD</b><br><input type="radio"/> (DUCTOGRAPHY) Ductography<br><input type="radio"/> (DXA SCAN) DXA Scan<br><input type="radio"/> (ECHOCARDIOGRAPHY) Echocardiography<br><input type="radio"/> (ENDOSCOPY) Endoscopy<br><input type="radio"/> (MAMMOGRAPHY) Mammography<br><input type="radio"/> (MRI) MRI<br><input type="radio"/> (MUGA) MUGA<br><input type="radio"/> (PET SCAN) PET Scan<br><input type="radio"/> (PET/CT SCAN) PET/CT Scan<br><input type="radio"/> (PET/MRI SCAN) PET/MRI Scan<br><input type="radio"/> (ULTRASOUND) Ultrasound<br><input type="radio"/> (X-RAY) X-Ray |
| 1.8  | Date of Evaluation (DD-MMM-YYYY) | <input type="text"/> <b>TUDAT</b>   |
| 1.9  | Evaluator                        | <input type="radio"/> (INDEPENDENT ASSESSOR) Independent Assessor <b>TUEVAL</b><br><input type="radio"/> (INVESTIGATOR) Investigator  |
| 1.10   | Evaluator Identifier             | <input type="radio"/> (RADIOLOGIST 1) Radiologist 1 <b>TUEVALID</b><br><input type="radio"/> (RADIOLOGIST 2) Radiologist 2<br><input type="radio"/> (RADIOLOGIST 3) Radiologist 3   |

<https://www.cdisc.org/kb/ecrf/tumorlesion-identification-results>; TU TR CDISC SDTM IG V3.4

# TR (Tumor/Lesion Results)

| Form TU/TR - Tumor Identification/Results                            |                             |  |
|--|-----------------------------|--|
| 1 TU/TR - Tumor Identification/Results (RECIST 1.1 - Target Lesions) |                             |  |
| 1.1  | Were any tumors identified? | <input type="radio"/> IN No <b>TUYN</b><br><input type="radio"/> M Yes   |
| 1.2  | Tumor ID                    | <input type="text" value=""/> <b>TRLNKID</b> <b>TULNKID</b>  |
| 1.3  | Location                    | <input type="radio"/> (BREAST) Breast <b>TULOC</b><br><input type="radio"/> (CHEST) Chest<br><input type="radio"/> (KIDNEY) Kidney<br><input type="radio"/> (LIVER) Liver<br><input type="radio"/> (NECK) Neck                     |
| 1.4  | Laterality                  | <input type="radio"/> (LEFT) Left <b>TULAT</b><br><input type="radio"/> (RIGHT) Right<br><input type="radio"/> (BILATERAL) Bilateral   |
| 1.5  | Directionality              | <input type="radio"/> (DISTAL) Distal <b>TUDIR</b><br><input type="radio"/> (INTERMEDIATE) Intermediate<br><input type="radio"/> (PROXIMAL) Proximal<br><input type="radio"/> (INNER) Inner<br><input type="radio"/> (OUTER) Outer |
| 1.6  | Location Detail             | <input type="text" value=""/> <b>TULOCDTL</b>  |

| Form TU/TR - Tumor Identification/Results                            |                      |   |
|--|----------------------|---|
| 1 TU/TR - Tumor Identification/Results (RECIST 1.1 - Target Lesions) |                      |   |
| 1.7  | Method of Evaluation | <input type="radio"/> (CT SCAN) CT Scan <b>TUMETHOD</b><br><input type="radio"/> (DUCTOGRAPHY) Ductography<br><input type="radio"/> (DXA SCAN) DXA Scan<br><input type="radio"/> (ECHOCARDIOGRAPHY) Echocardiography<br><b>TRMETHOD</b> |

|      |                                  |   |
|------|----------------------------------|---|
| 1.8  | Date of Evaluation (DD-MMM-YYYY) | <input type="text" value=""/> <b>TRDTC</b> <b>TUDAT</b>   |
| 1.9  | Evaluator                        | <input type="radio"/> (INDEPENDENT ASSESSOR) Independent Assessor <b>TUEVAL</b><br><input type="radio"/> (INVESTIGATOR) Investigator  |
| 1.10 | Evaluator Identifier             | <input type="radio"/> (RADIOLOGIST 1) Radiologist 1 <b>TUEVALID</b><br><input type="radio"/> (RADIOLOGIST 2) Radiologist 2<br><input type="radio"/> (RADIOLOGIST 3) Radiologist 3 <b>TREVALID</b> |

|   |                                 |
|---|---------------------------------|
| What was the longest diameter of the target lesion? | <input type="text" value=""/>   |
| <b>TRORES</b> where TRTESTCD="LDIAM"                |                                 |
| Longest Diameter Unit                               | <input type="text" value="mm"/> |
| <b>TRORESU</b> where TRTESTCD="LDIAM"               |                                 |

<https://www.cdisc.org/kb/ecrf/tumorlesion-identification-results>; TU TR,  
<https://www.cdisc.org/standards/therapeutic-areas/colorectal-cancer/colorectal-cancer-therapeutic-area-user-guide-v10/html>,  
 CDISC SDTM IG V3.4

# RS (Disease Response/Clinical Classification)

| Form RS - Disease Response |   |  |
|----------------------------|---|--|
| 1 RS - Disease Response    |   |  |
| 1.1                        | Disease Response Category   | <input type="text" value="RSCAT"/> <b>RSCAT</b><br>RECIST 1.1  |
| 1.2                        | Was the disease response assessment performed?                              | <input type="radio"/> [N] No <b>RSPERF</b><br><input type="radio"/> [Y] Yes  |
| 1.3                        | Reason Disease Response Assessment Not Performed                            | <input type="text" value=""/> <b>RSREASND</b>  |
| 1.4                        | What was the role of the person performing the disease response assessment? | <input type="radio"/> [INDEPENDENT ASSESSOR] Independent Assessor <b>RSEVAL</b><br><input type="radio"/> [INVESTIGATOR] Investigator   |
| 1.5                        | What is the evaluator identifier?   | <input type="radio"/> [RADIOLOGIST 1] Radiologist 1 <b>RSEVALID</b><br><input type="radio"/> [RADIOLOGIST 2] Radiologist 2<br><input type="radio"/> [RADIOLOGIST 3] Radiologist 3  |
| 1.6                        | Target Response   | <input type="radio"/> [CR] Complete Response (CR) <b>TRGRESP_RSORRES</b><br><input type="radio"/> [PR] Partial Response (PR)<br><input type="radio"/> [SD] Stable Disease (SD)<br><input type="radio"/> [PD] Progressive Disease (PD)<br><input type="radio"/> [NE] Not Evaluable (NE)   |
| 1.7                        | Non-Target Response   | <input type="radio"/> [CR] Complete Response (CR) <b>NTRGRESP_RSORRES</b><br><input type="radio"/> [NON-CR/NON-PD] Non Complete Response/Non Progressive Disease (NON-CR/NON-PD)<br><input type="radio"/> [PD] Progressive Disease (PD)<br><input type="radio"/> [NE] Not Evaluable (NE) |

| Form RS - Disease Response |                       |  |
|----------------------------|-----------------------|--|
| 1 RS - Disease Response    |                       |  |
| 1.8                        | Overall Response      | <input type="radio"/> [CR] Complete Response (CR) <b>OVRLRESP_RSORRES</b><br><input type="radio"/> [PR] Partial Response (PR)<br><input type="radio"/> [SD] Stable Disease (SD)<br><input type="radio"/> [NON-CR/NON-PD] Non Complete Response/Non Progressive Disease (NON-CR/NON-PD)<br><input type="radio"/> [PD] Progressive Disease (PD)<br><input type="radio"/> [NE] Not Evaluable (NE)<br><input type="radio"/> [NED] No Evidence of Disease (NED) |
| 1.9                        | Best Overall Response | <input type="radio"/> [CR] Complete Response (CR) <b>BESTRESP_RSORRES</b><br><input type="radio"/> [PR] Partial Response (PR)<br><input type="radio"/> [SD] Stable Disease (SD)<br><input type="radio"/> [NON-CR/NON-PD] Non Complete Response/Non Progressive Disease (NON-CR/NON-PD)<br><input type="radio"/> [PD] Progressive Disease (PD)<br><input type="radio"/> [NE] Not Evaluable (NE)<br><input type="radio"/> [NED] No Evidence of Disease (NED) |

<https://www.cdisc.org/kb/ecrf/disease-response> ; RS\_eCRF\_Package

# Example 1 – Tumor Identifier

- TU (Tumor/Lesion Identification)

| USUBJID | TUGRPID | TULNKID | TUTESTCD | TUTEST               | TUORRES    | TULOC             | TULAT | TUMETHOD    | TUEVAL       | VISIT  | TUDTC      |
|---------|---------|---------|----------|----------------------|------------|-------------------|-------|-------------|--------------|--------|------------|
| 44444   |         | T01     | TUMIDENT | Tumor Identification | TARGET     | LIVER             |       | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   |         | T02     | TUMIDENT | Tumor Identification | TARGET     | KEDNEY            | RIGHT | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   |         | T03     | TUMIDENT | Tumor Identification | TARGET     | CERVICAL LYMPH    | LEFT  | MRI         | INVESTIGATOR | SCREEN | 2010-01-02 |
| 44444   |         | T04     | TUMIDENT | Tumor Identification | TARGET     | SKIN OF THE TRUNK |       | PHOTOGRAPHY | INVESTIGATOR | SCREEN | 2010-01-03 |
| 44444   |         | NT01    | TUMIDENT | Tumor Identification | NON-TARGET | THYROID GLAND     | RIGHT | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   |         | NT02    | TUMIDENT | Tumor Identification | NON-TARGET | CEREBELLUM        | RIGHT | MRI         | INVESTIGATOR | SCREEN | 2010-01-02 |
| 44444   | T04     | T04.1   | TUSPLIT  | Tumor Split          | TARGET     | SKIN OF THE       |       | PHOTOGRAPHY | INVESTIGATOR | WEEK 6 | 2010-02-20 |
| 44444   | T04     | T04.2   | TUSPLIT  | Tumor Split          | TARGET     | SKIN OF THE       |       | PHOTOGRAPHY | INVESTIGATOR | WEEK 6 | 2010-02-20 |

# Example 1 – Tumor Identifier

- TR (Tumor/Lesion Results)

| USUBJID | TRGRPID    | TRLNKGRP | TRLNKID      | TRTESTCD | TRTEST                                    | TRORES               | TRORESU | TRMETHOD    | TREVAL       | VISIT  | TRDTC      |
|---------|------------|----------|--------------|----------|---|----------------------|---------|-------------|--------------|--------|------------|
| 44444   | TARGET     | A1       | <b>T01</b>   | DIAMETER | Diameter                                  | 17                   | mm      | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   | TARGET     | A1       | <b>T02</b>   | DIAMETER | Diameter                                  | 16                   | mm      | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   | TARGET     | A1       | <b>T03</b>   | DIAMETER | Diameter                                  | 15                   | mm      | MRI         | INVESTIGATOR | SCREEN | 2010-01-02 |
| 44444   | TARGET     | A1       | <b>T04</b>   | DIAMETER | Diameter                                  | 14                   | mm      | PHOTOGRAPHY | INVESTIGATOR | SCREEN | 2010-01-03 |
| 44444   | TARGET     | A1       |              | SUMDIAM  | Sum of Diameter                           | 62                   | mm      |             | INVESTIGATOR | SCREEN |            |
| 44444   | TARGET     | A1       |              | SUMNLNLD | Sum of Diameters of Non Lymph Node Tumors | 47                   | mm      |             | INVESTIGATOR | SCREEN |            |
| 44444   | NON-TARGET | A1       | <b>NT01</b>  | TUMSTATE | Tumor State                               | PRESENT              |         | CT SCAN     | INVESTIGATOR | SCREEN | 2010-01-01 |
| 44444   | NON-TARGET | A1       | <b>NT02</b>  | TUMSTATE | Tumor State                               | PRESENT              |         | MRI         | INVESTIGATOR | SCREEN | 2010-01-02 |
| 44444   | TARGET     | A2       | <b>T01</b>   | DIAMETER | Diameter                                  | 0                    | mm      | CT SCAN     | INVESTIGATOR | WEEK 6 | 2010-02-18 |
| 44444   | TARGET     | A2       | <b>T02</b>   | DIAMETER | Diameter                                  | TOO SMALL TO MEASURE | mm      | CT SCAN     | INVESTIGATOR | WEEK 6 | 2010-02-19 |
| 44444   | TARGET     | A2       | <b>T03</b>   | DIAMETER | Diameter                                  | 12                   | mm      | MRI         | INVESTIGATOR | WEEK 6 | 2010-02-20 |
| 44444   | TARGET     | A2       | <b>T04.1</b> | DIAMETER | Diameter                                  | 6                    | mm      | PHOTOGRAPHY | INVESTIGATOR | WEEK 6 | 2010-02-20 |
| 44444   | TARGET     | A2       | <b>T04.2</b> | DIAMETER | Diameter                                  | 7                    | mm      | PHOTOGRAPHY | INVESTIGATOR | WEEK 6 |            |
| 44444   | TARGET     | A2       |              | SUMDIAM  | Sum of Diameter                           | 30                   | mm      |             | INVESTIGATOR | WEEK 6 |            |

# Example 1 – Tumor Identifier

- RS (Disease Response/Clinical Classification)

| USUBJID | RSLNKGRP  | RSTESTCD | RSTEST                    | RSCAT                              | RSORRES | RSEVAL       | VISIT   | RSDTC      |
|---------|-----------|----------|---------------------------|------------------------------------|---------|--------------|---------|------------|
| 44444   |           | TRGRESP  | Target Response           | RECIST 1.1                         | PR      | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   |           | NTRGRESP | Non-target Response       | RECIST 1.1                         | SD      | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   | <b>A2</b> | OVRLRESP | Overall Response          | RECIST 1.1                         | PR      | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   |           | TRGRESP  | Target Response           | RECIST 1.1                         | NE      | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | NTRGRESP | Non-target Response       | RECIST 1.1                         | NE      | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | SYMPTDTR | Symptomatic Deterioration | PROTOCOL DEFINED RESPONSE CRITERIA | PD      | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   | <b>A3</b> | OVRLRESP | Overall Response          | PROTOCOL DEFINED RESPONSE CRITERIA | PD      | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | BESTRESP | Best Overall Response     | RECIST 1.1                         | PR      | INVESTIGATOR |         | 2010-02-18 |



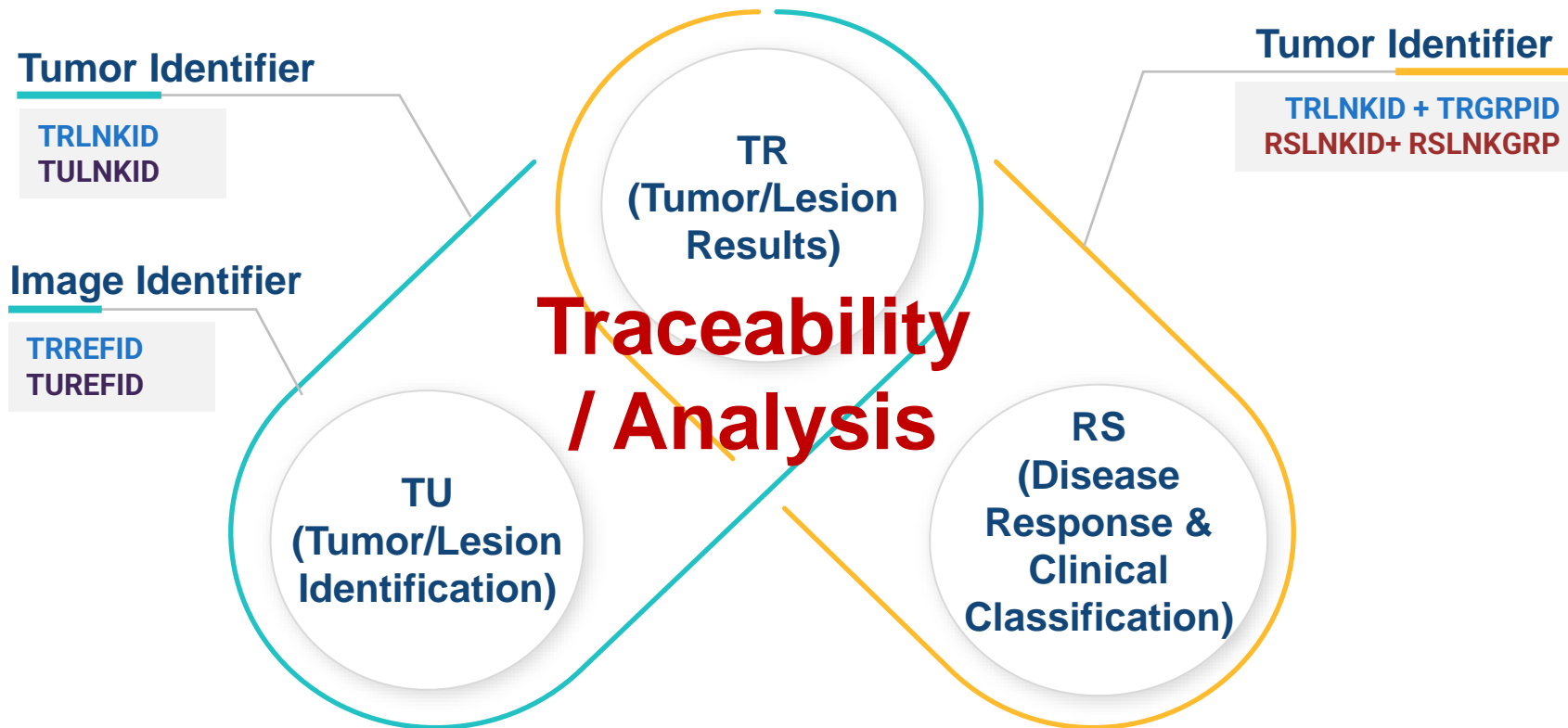
## Example 2 - TU (Tumor/Lesion Identification)

| USUBJID | TUREFID   | TULNKID | TUTESTCD | TUTEST               | TUORRES        | TULOC  | TUMETHOD     | TUEVAL       | VISIT   | TUDTC      |
|---------|-----------|---------|----------|----------------------|----------------|--------|--------------|--------------|---------|------------|
| 11111   | IMG-A0001 | T01     | TUMIDENT | Tumor Identification | TARGET         | LIVER  | CT SCAN      | INVESTIGATOR | SCREEN  | 2010-01-01 |
| 11111   | IMG-A0001 | T02     | TUMIDENT | Tumor Identification | TARGET         | KEDNEY | CT SCAN      | INVESTIGATOR | SCREEN  | 2010-01-01 |
| 11111   | IMG-B0002 | NEWB01  | TUMIDENT | Tumor Identification | NEW BONE TUMOR | BONE   | SCINTIGRAPHY | INVESTIGATOR | WEEK 16 | 2010-03-28 |
| 11111   | IMG-B0003 | NEWB02  | TUMIDENT | Tumor Identification | NEW BONE TUMOR | BONE   | SCINTIGRAPHY | INVESTIGATOR | WEEK 32 | 2010-08-13 |

## TR (Tumor/Lesion Results) – Example 2

| USUBJID | TRGRPID        | TRREFID   | TRLNKGRP | TRLNKID | TRTESTCD | TRTEST               | TORRES | TREVAL       | VISIT   |
|---------|----------------|-----------|----------|---------|----------|----------------------|--------|--------------|---------|
| 11111   | TARGET         | IMG-A0001 | A1       | T01     | DIAMETER | Diameter             | 17     | INVESTIGATOR | SCREEN  |
| 11111   | TARGET         | IMG-A0001 | A1       | T02     | DIAMETER | Diameter             | 16     | INVESTIGATOR | SCREEN  |
| 11111   | TARGET         | IMG-A0001 | A2       | T01     | DIAMETER | Diameter             | 0      | INVESTIGATOR | WEEK 16 |
| 11111   | TARGET         | IMG-A0001 | A2       | T02     | DIAMETER | Diameter             | 10     | INVESTIGATOR | WEEK 16 |
| 11111   | NEW BONE TUMOR | IMG-B0002 | A3       | NEWB01  | NBONECNT | New Bone Tumor Count | 1      | INVESTIGATOR | WEEK 16 |
| 11111   | NEW BONE TUMOR | IMG-B0003 | A4       | NEWB02  | NBONECNT | New Bone Tumor Count | 3      | INVESTIGATOR | WEEK 32 |

# Link between Oncology Specific Domains

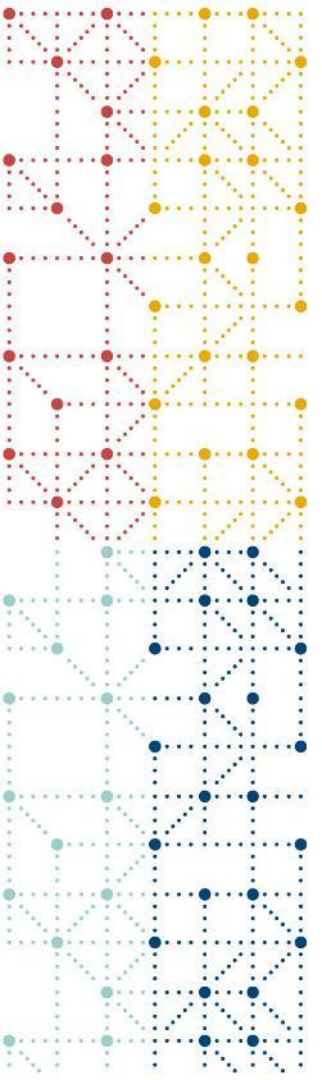




# Mapping Consideration for External Data

Align with SDTM IG and Controlled Terminology such as:

- Date of Image, Not Response Assessment Date
- Assessment Name  
(ex., Sum of Diameter, Overall Response, Best Overall Response, etc.)
- Assessment Name Code: Limited to 8 Characters
- Result of Disease Assessment such as CR, PR, etc.
- Independent Image Evaluator or Reader



# Oncology Specific ADaM Domains

# ADaM Domains for Oncology Efficacy Analysis

## Tumor Results Summary

- Percent Change from Baseline in Sum of Diameter
- Percent Change from Baseline in Sum of Longest Diameter
- Percent Change from Nadir

## Time-to-event

- Progression-Free Survival (PFS)
- Overall Survival (OS)
- Duration of Response (DOR)
- Time to Response (TTR)
- Time to Treatment Failure (TTF)



## Source Data

- ADSL
- TU, TR, RS

## Response Rate

- Best of Response (BOR)
- Objective Response Rate (ORR)
- Disease Control Rate (DCR)

# ADTR for Tumor Results

| USUBJID | TRGRPID    | TRLNKID | TRLNKGRP | AVISIT    | PARAM  | PARAMCD  | ADT        | AVAL  | AVALC   | EVAL                 | EVALID   | TRACPTFL | TRMETHOD |
|---------|------------|---------|----------|-----------|--|----------|------------|-------|---------|----------------------|----------|----------|----------|
| 11111   | TARGET     | T01     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 35.5  | 35.5    | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     | T02     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 18.7  | 18.7    | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     | T03     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 15    | 15      | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     | T01     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 31.2  | 31.2    | INDEPENDENT ASSESSOR | READER 1 | Y        | CT SCAN  |
| 11111   | TARGET     | T02     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 18.7  | 18.7    | INDEPENDENT ASSESSOR | READER 1 | Y        | CT SCAN  |
| 11111   | TARGET     | T03     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 22    | 22      | INDEPENDENT ASSESSOR | READER 1 | Y        | CT SCAN  |
| 11111   | TARGET     | T01     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 31.2  | 31.2    | INDEPENDENT ASSESSOR | READER 2 |          | CT SCAN  |
| 11111   | TARGET     | T02     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 18.8  | 18.8    | INDEPENDENT ASSESSOR | READER 2 |          | CT SCAN  |
| 11111   | TARGET     | T03     | A01      | SCREENING | Longest Diameter (mm)  | LDIAM    | 2017-01-08 | 22.1  | 22.1    | INDEPENDENT ASSESSOR | READER 2 |          | CT SCAN  |
| 11111   | NON-TARGET | NT01    | A01      | SCREENING | Tumor State  | TUMSTATE | 2017-01-08 |       | Present | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | NON-TARGET | NT01    | A01      | SCREENING | Tumor State  | TUMSTATE | 2017-01-08 |       | Present | INDEPENDENT ASSESSOR | READER 1 | Y        | CT SCAN  |
| 11111   | NON-TARGET | NT01    | A01      | SCREENING | Tumor State  | TUMSTATE | 2017-01-08 |       | Present | INDEPENDENT ASSESSOR | READER 2 |          | CT SCAN  |
| 11111   | TARGET     |         | A01      | SCREENING | Sum of Longest Diameter (mm)                                       | SUMDIAM  |            | 69.2  | 69.2    | INVESTIGATOR         |          |          |          |
| 11111   | TARGET     |         | A01      | SCREENING | Sum of Longest Diameter (mm)                                       | SUMDIAM  |            | 71.9  | 71.9    | INDEPENDENT ASSESSOR | READER 1 | Y        |          |
| 11111   | TARGET     |         | A01      | SCREENING | Sum of Longest Diameter (mm)                                       | SUMDIAM  |            | 72.1  | 72.1    | INDEPENDENT ASSESSOR | READER 2 |          |          |
| 11111   | TARGET     | T01     | A02      | WEEK 12   | Longest Diameter (mm)  | LDIAM    | 2017-03-31 | 24    | 24      | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     | T02     | A02      | WEEK 12   | Longest Diameter (mm)  | LDIAM    | 2017-03-31 | 3     | 3       | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     | T03     | A02      | WEEK 12   | Longest Diameter (mm)  | LDIAM    | 2017-03-31 | 7     | 7       | INVESTIGATOR         |          |          | CT SCAN  |
| 11111   | TARGET     |         | A02      | WEEK 12   | Sum of Longest Diameter (mm)                                       | SUMDIAM  |            | 34    | 34      | INVESTIGATOR         |          |          |          |
| 11111   | TARGET     |         | A02      | WEEK 12   | Percent Change from Baseline in Sum of Target Lesion Diameters (%) | PCBSLD   |            | -50.9 | -50.9   | INVESTIGATOR         |          |          |          |

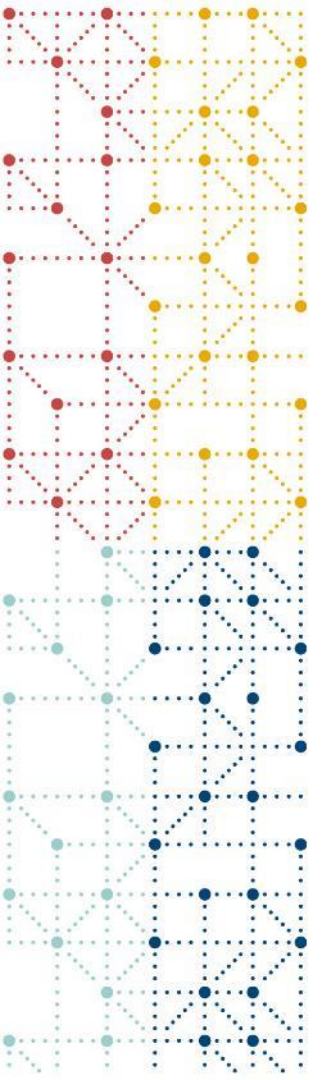
# ADRS for Response Rate

| USUBJID | RSLNKGPR  | PARAMCD  | PARAM                     | RSCAT                              | AVALC    | RSEVAL       | AVISIT  | ADT        |
|---------|-----------|----------|---------------------------|------------------------------------|----------|--------------|---------|------------|
| 44444   |           | TRGRES   | Target Response           | RECIST 1.1                         | PR       | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   |           | NTRGRES  | Non-target Response       | RECIST 1.1                         | SD       | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   | <b>A2</b> | OVRLRESP | Overall Response          | RECIST 1.1                         | PR       | INVESTIGATOR | WEEK 6  | 2010-02-18 |
| 44444   |           | TRGRES   | Target Response           | RECIST 1.1                         | NE       | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | NTRGRES  | Non-target Response       | RECIST 1.1                         | NE       | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | SYMPTDTR | Symptomatic Deterioration | PROTOCOL DEFINED RESPONSE CRITERIA | PD       | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   | <b>A3</b> | OVRLRESP | Overall Response          | PROTOCOL DEFINED RESPONSE CRITERIA | PD       | INVESTIGATOR | WEEK 12 | 2010-04-02 |
| 44444   |           | BESTRESP | Best Overall Response     | RECIST 1.1                         | PR       | INVESTIGATOR |         |            |
| 44444   |           | ORR      | Objective Response        | RECIST 1.1                         | Response | INVESTIGATOR |         |            |



# ADTTE for Time-to-event

| USUBJID | PARAM   | PARAMCD | STARTDT    | ADT        | AVAL | CNSR | EVNTDESC        |
|---------|---|---------|------------|------------|------|------|-----------------|
| 55555   | Overall Survival (days)                         | OS      | 2019-04-05 | 2020-12-31 | 637  | 1    | COMPLETED STUDY |
| 55555   | Progression Free Survival (days) - Investigator | PFSINV  | 2019-04-05 | 2020-11-21 | 597  | 0    | PROGRESSION     |
| 55555   | Progression Free Survival (days) - Independent  | PFSIRC  | 2019-04-05 | 2020-08-21 | 505  | 0    | PROGRESSION     |
| 66666   | Overall Survival (days)                         | OS      | 2019-01-01 | 2019-01-15 | 15   | 0    | DEATH           |
| 66666   | Progression Free Survival (days) - Investigator | PFSINV  | 2019-01-01 | 2019-01-15 | 15   | 0    | DEATH           |
| 66666   | Progression Free Survival (days) - Independent  | PFSIRC  | 2019-01-01 | 2019-01-15 | 15   | 0    | DEATH           |

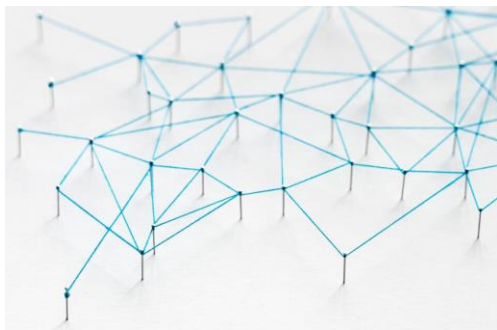


# Conclusion

# Conclusion

## For Oncology Efficacy Analysis

### Data Correlation

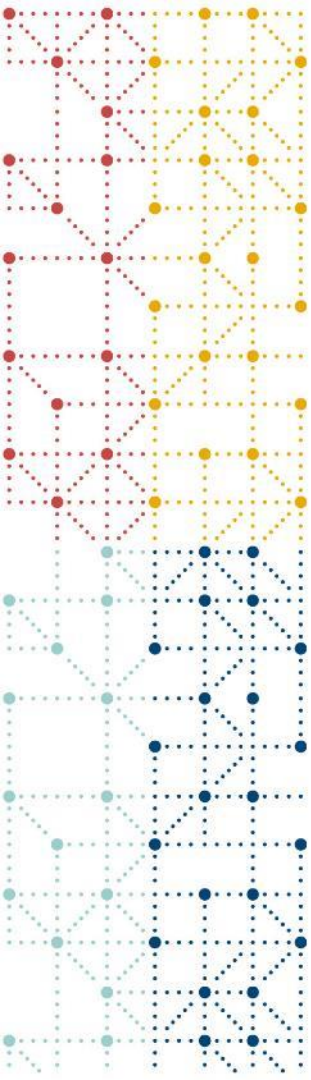


[https://kr.freepik.com/free-photo/geometric-abstract-background-technology-concept-connecting-dots-design\\_21629541.htm#fromView=keyword&page=1&position=6&uuid=10c0531d-bdc4-4642-a486-70ddb33a4ea](https://kr.freepik.com/free-photo/geometric-abstract-background-technology-concept-connecting-dots-design_21629541.htm#fromView=keyword&page=1&position=6&uuid=10c0531d-bdc4-4642-a486-70ddb33a4ea)

### Predefined External Data



[https://www.flaticon.com/kr/free-icon/mapping\\_2471463](https://www.flaticon.com/kr/free-icon/mapping_2471463)



**Thank You!**

