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CDISC-Compliant Clinical Trial Imaging Management System: Focusing on Tumor Response Assessment Data in Clinical Trials

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Meet the Speaker

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Organization: Asan Medical Center, Seoul, Korea

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.*

- *The author has conflicts of interest to report, as follows:*

  - CEO, Trial Informatics

Agenda

1. Background
2. Methods
3. Results
4. Conclusions

Lecture based on our publication

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Original Research

CDISC-compliant clinical trial imaging management system with automatic verification and data Transformation: Focusing on tumor response assessment data in clinical trials

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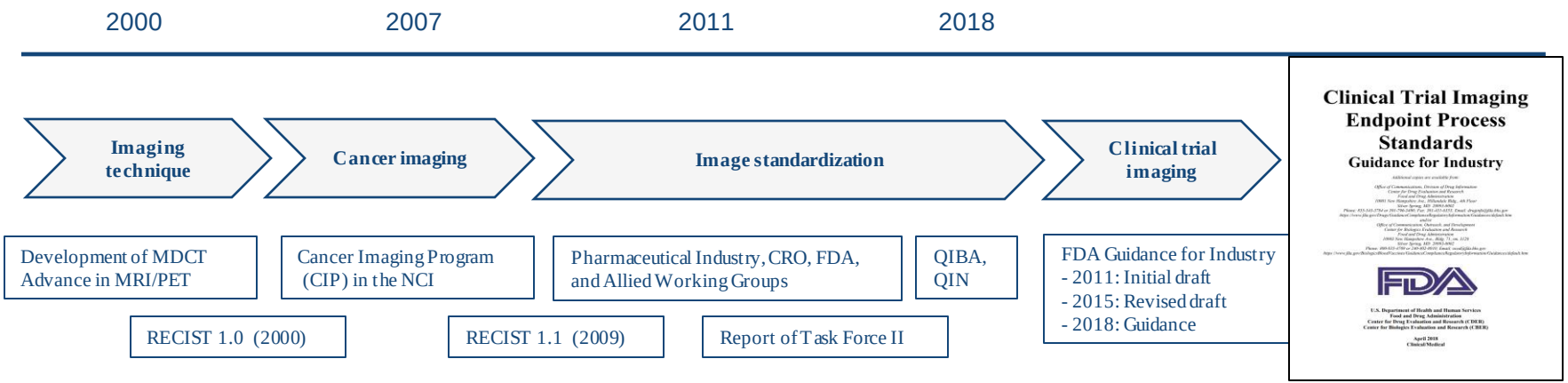
Background

Imaging in Clinical Trials

Increasing use of imaging data in multi-national/center cancer trials

- Imaging biomarkers as primary endpoints in the trial
- RECIST1.1/iRECIST* are most commonly used imaging response criteria



History of clinical trial imaging (M. Nishino (ed.) "Therapy Response Imaging In Oncology" Springer)

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Imaging in Clinical Trials

Issues in data management of RECIST1.1/iRECIST

- Frequent errors of data input in electronic case report form (eCRF)
- Difficulty in transforming eCRF data into Study Data Tabulation Model (SDTM)
  - **Requiring a lot of human resources warranting automation**

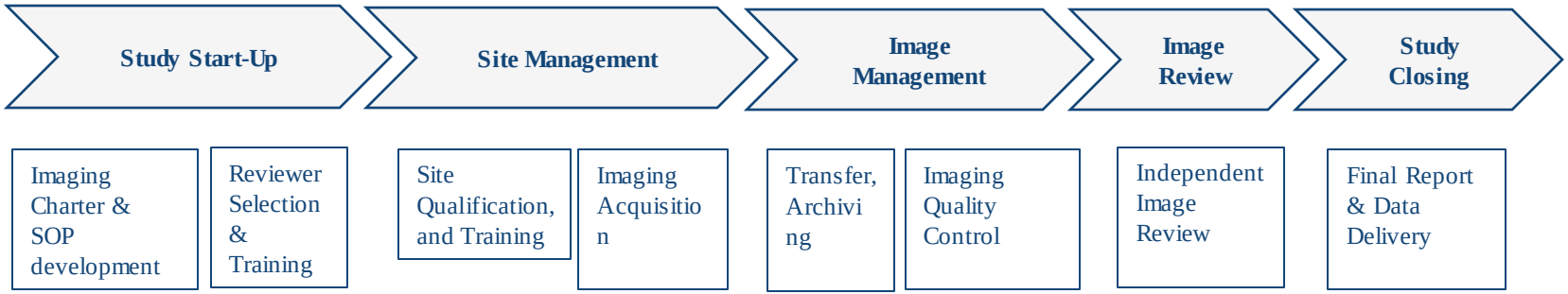
*** Response Evaluation Criteria in Solid Tumors (RECIST 1.1)**
A standard guideline for solid tumor measurement and definitions to provide objective assessment about change in tumor size in both adult and pediatric oncology clinical trials.

*** Immune-Response Evaluation Criteria in Solid Tumors (iRECIST)**
A standard guideline for immune-based therapies/trials.

Central Imaging Core Lab

Specialized institution for imaging endpoints in clinical trials

- Independent imaging service provider for the clinical trial
- Collect medical images, Independent assessment/review
- Increased involvement of imaging core lab

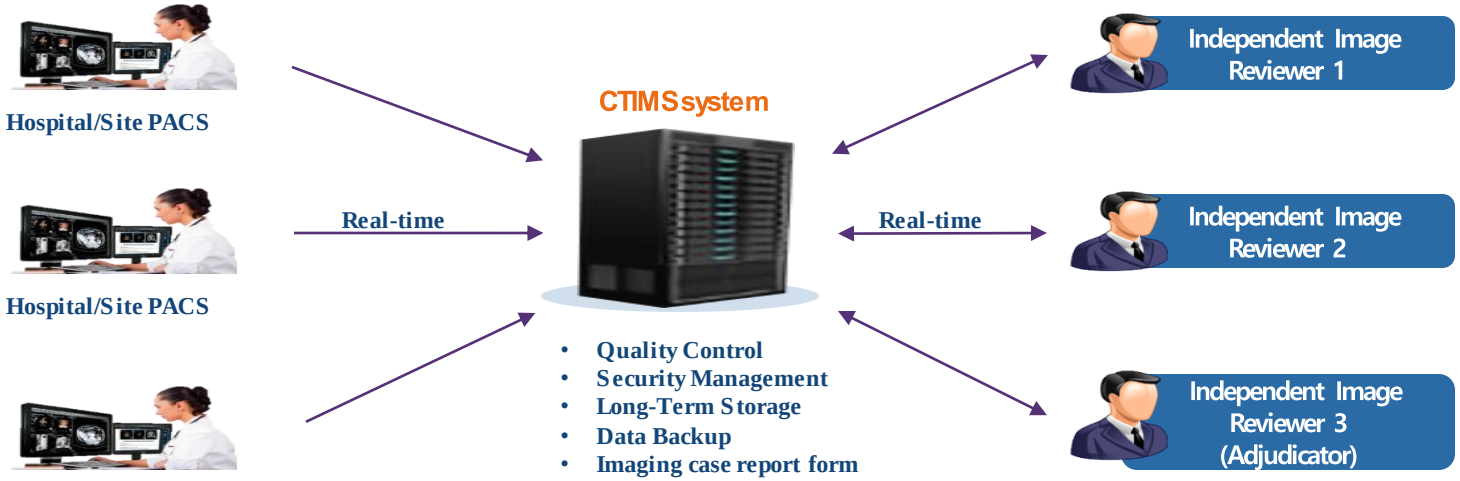


Step-wise operation of clinical trial imaging (M. Nishino (ed.) "Therapy Response Imaging In Oncology" Springer)

Clinical Trial Imaging Management Solution (CTIMS)

Specialized IT solution for imaging management in clinical trials

- In a multi-center clinical trial, the CTIMS enables each hospital/site to anonymize and transfer image data to the central server. CTIMS also enables independent image reviewers to view the images and analyze them. In addition, CTIMS can provide many functions to enhance image data management.



Purpose

To develop automation system for

- Verification of input eCRF data (RECIST 1.1/iRECIST)
- Transformation eCRF data into SDTM dataset

To implement modules in the clinical trial image management system (CTIMS)

- Improve the capability of CTIMS system to provide high quality of service and data

Methods

How SDTM Model of RECIST1.1/iRECIST was implemented into CTIMS

Systematic Review

Study Data Tabulation Model Implementation Guide (SDTMIG v3.3)

- A guideline for standard clinical trial tabulation datasets
- Special Purpose, Findings, Relationships Class
  - Tumor/Lesion Identification (TU), Tumor/Lesion Results (TR), Disease Response (RS)

Case Report Tabulation Data Definition Specification(Define.xml)

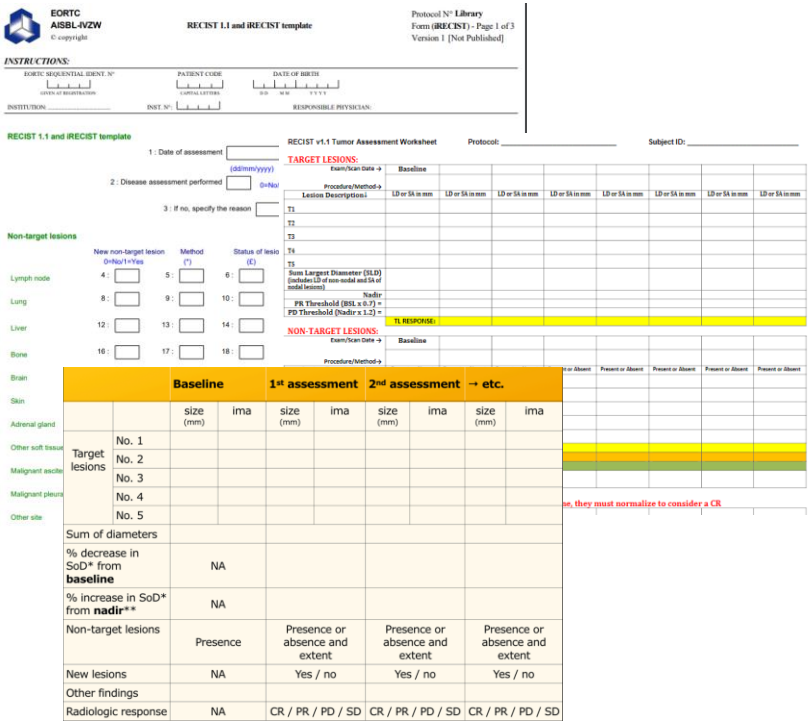
RECIST 1.1 and iRECIST Guidelines and Worksheet(eCRF)

- Reviewed by two radiologists (H.J.P., J.H.S)
- Detailed rules for image analysis and statistical considerations
- Organized common questions from eCRFs or Worksheets

Development of Standard-Compliant eCRF

Question library development for RECIST 1.1/iRECIST

- Based on common standard questions for standard-compliant eCRF
- Use CDISC Controlled Terminology
- Predefined object identifiers (OIDs) for SDTM Domain Mapping



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RECIST 1.1 and iRECIST template

Protocol N° Library
Form (iRECIST) - Page 1 of 3
Version 1 [Not Published]

INSTRUCTIONS:

EORTC SEQUENTIAL IDENT. N° (GIVEN AT REGISTRATION) | PATIENT CODE (CAPITAL LETTERS) | DATE OF BIRTH (DD MM YYYY)

INSTITUTION | INST. N° | RESPONSIBLE PHYSICIAN:

RECIST 1.1 and iRECIST template

1 : Date of assessment (dd/mm/yyyy)

2 : Disease assessment performed (0=No)

3 : If no, specify the reason

RECIST v1.1 Tumor Assessment Worksheet Protocol: Subject ID:

TARGET LESIONS:

Exam/Scan Date →		Baseline							
Procedure/Method→									
Lesion Description↓	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm	LD or SA in mm
T1									
T2									
T3									
T4									
T5									
Sum Largest Diameter (SLD) (includes LD of non-nodal and SA of nodal lesions)									
Nadir									
PR Threshold (BSL x 0.7) =									
PD Threshold (Nadir x 1.2) =									
TL RESPONSE:									

NON-TARGET LESIONS:

Exam/Scan Date →		Baseline							
Procedure/Method→									
Non-target lesions	Present or Absent	Present or Absent	Present or Absent	Present or Absent	Present or Absent	Present or Absent	Present or Absent	Present or Absent	Present or Absent
Lymph node									
Lung									
Liver									
Bone									
Brain									
Skin									
Adrenal gland									
Other soft tissue									
Malignant ascite									
Malignant pleura									
Other site									

Non-target lesions

New non-target lesion 0=No/1=Yes	Method (*)	Status of lesio (£)
4 :	5 :	6 :
8 :	9 :	10 :
12 :	13 :	14 :
16 :	17 :	18 :

		Baseline		1st assessment		2nd assessment		→ etc.	
		size (mm)	ima	size (mm)	ima	size (mm)	ima	size (mm)	ima
Target lesions	No. 1								
	No. 2								
	No. 3								
	No. 4								
	No. 5								
Sum of diameters									
% decrease in SoD* from **baseline**		NA							
% increase in SoD* from **nadir****		NA							
Non-target lesions		Presence		Presence or absence and extent		Presence or absence and extent		Presence or absence and extent	
New lesions		NA		Yes / no		Yes / no		Yes / no	
Other findings									
Radiologic response		NA		CR / PR / PD / SD		CR / PR / PD / SD		CR / PR / PD / SD	

Development of Automatic Verification Module of eCRF Data

Automatic Verification* Module

- Applied RECST/iRECIST rules as conformity check of input eCRF data
- Rules to check errors in calculation values of RECIST/iRECIST
- Check missing values or incorrect values

*** Source data verification of the conformity of the data presented in CRF**

Development of automatic SDTM transformation module

Defined-XML development

- Adapt CDISC SDTMIG Domain, Structure and Organization
- Mapping process to associate with standard variables

Implementation into the CTIMS

- Optimized CTMS system for image in clinical trial
- A web-based system with Java and HTML5 programming languages
- Strict application of regulations for the system (E.g., GAMP, FDA)

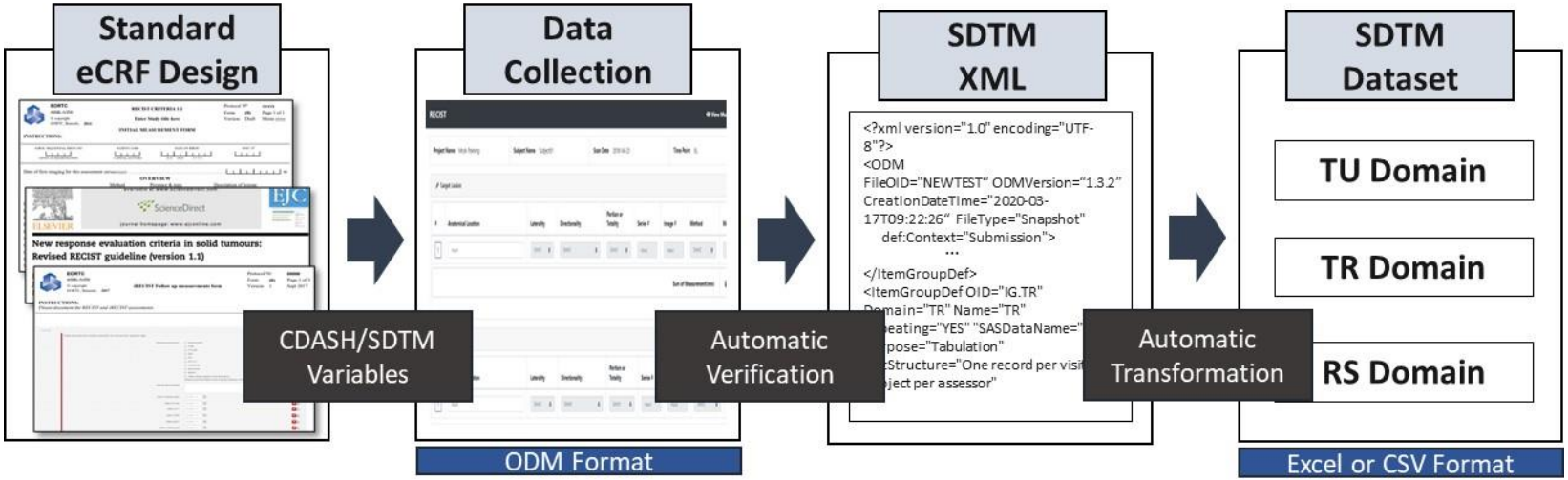
Results

SDTM & RECIST1.1/iRECIST in CTIMS

Overall Process

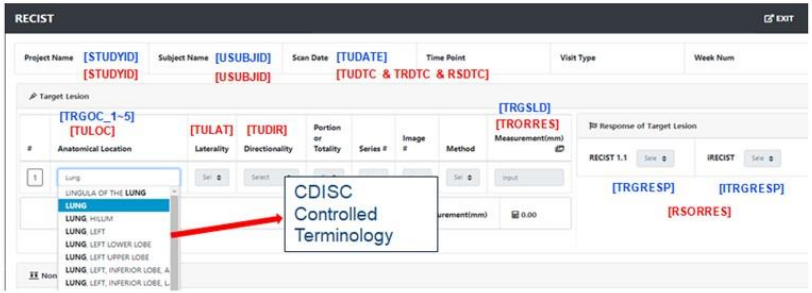
- A web-based CTIMS with Java and HTML5 programming languages

Implementation of the SDTM Model Process



Overall Process

Standard-compliant eCRF



Raw Dataset (Denormalized)

USUBJID	VISIT	READER	TUDATE	TRGOC_1	TRGSLD	TRGRESP	ITRGRESP
1201	WK12_CT	R1	2018-12-11	Lung right upper lobe	16	SD	iSD
1201	WK12_CT	R2	2018-12-11	Lung RUL	19	PD	iUPD

SDTM Dataset (Normalized)

TU Domain

USUBJID	TUSEQ	TULOC	TUMETHOD	TUEVALID	VISIT	TUDTC
1201	1	Lung, Right Upper Lobe	CT	RADIOLOGIST 1	WK12	2018-12-11
1201	2	Lung, Right Upper Lobe	CT	RADIOLOGIST 2	WK12	2018-12-11

TR Domain

USUBJID	TRSEQ	TRTESTCD	TRTEST	TRORRES	TRORRESU
1201	1	LDIAM	Longest Diameter	16	mm
1201	2	LDIAM	Longest Diameter	19	mm

RS Domain

USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES
1201	1	TRGRESP	Target Response	RECIST 1.1	SD
1201	2	TRGRESP	Target Response	iRECIST	iSD
1201	3	TRGRESP	Target Response	RECIST 1.1	PD
1201	4	TRGRESP	Target Response	iRECIST	iUPD

RS Define-XML

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
RS	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, USUBJID, RSTESTCD, VISITNUM, RSEVAL, RSEVALID	[unresolved: COM.COMMENT.RS]	rs.xpt

Go to the top of the Define-XML document

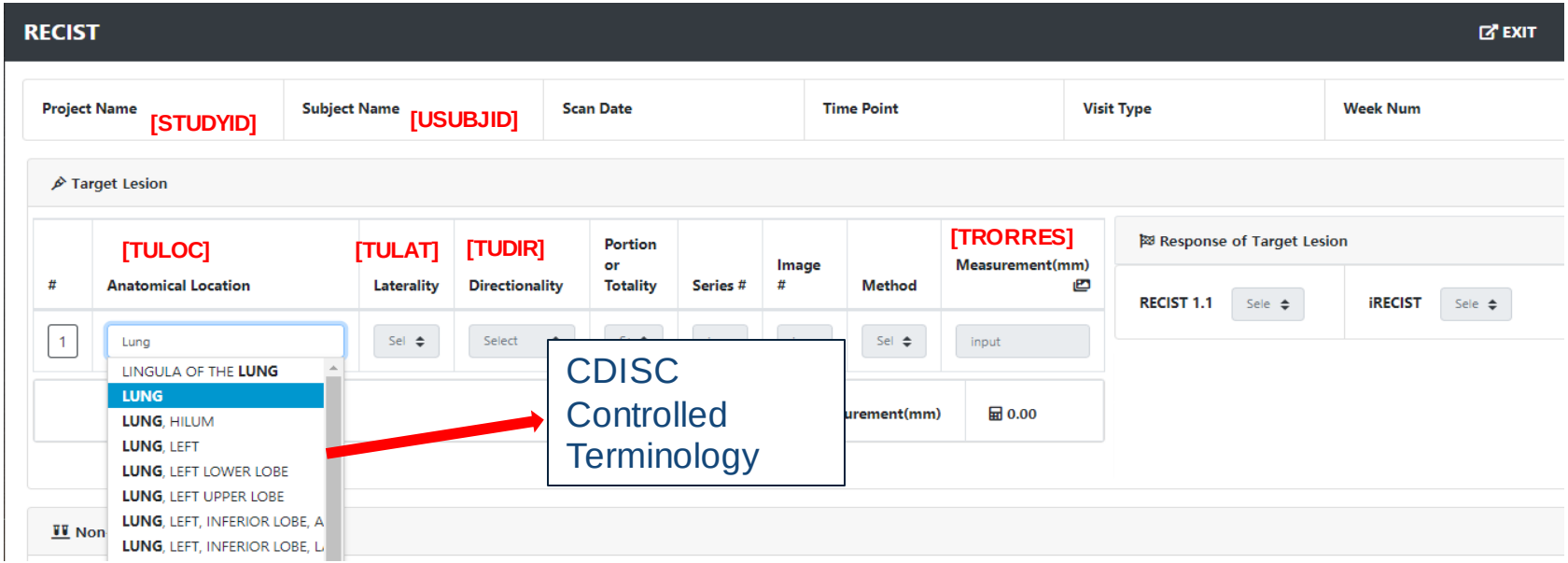
RS (Disease Response and Clin Classification) - FINDINGS

Location: rs.xpt

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	Char	Identifier	20		Protocol
DOMAIN		Domain Abbreviation	Char	Identifier	2		Assigned
USUBJID		Unique Subject Identifier	Char	Identifier	10		Derived Concatenation of STUDYID
RSSEQ		Sequence Number	Num	Identifier	5		Derived Sequential number identifying records within each USUBJID in the domain

The Standard-Compliant eCRF for RECIST1.1/iRECIST

- Question library
- Standard variable annotation & Controlled Terminology



Verification Module

Conformity Checklist of RECIST 1.1/iRECIST→ Verification of input data in eCRF

Conformity Checklist

RECIST / iRECIST 조건식 정리

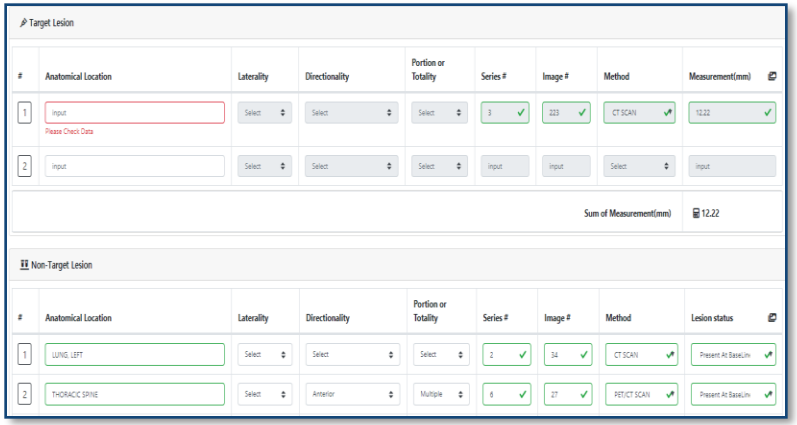
1. Target lesion

RECIST 1.1 / iRECIST Conformity Checklist

1. **Target lesion**
   - Target lesion indication should not be missed.
   - Organ should be defined depending on the response of target lesion indication.
   - Method and Measurement must have values if there is/are a value/values in organ 1 ~ 5.
   - Same values among organ 1 ~ 5 should not be represented.

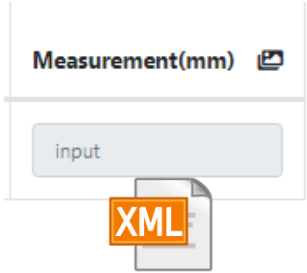
3. New lesion

Verification Result



Question Decomposition by SDTM dataset

Mapping Process by XML



TRTEST (Tumor/Lesion Assessment Test Name)	TRORRES (Measurement Result)	TRORRESU (Original Units)
Longest Diameter	Longest Diameter	mm

Automatic SDTM Transformation Module

SDTM Dataset Example:

USUBJID	VISIT	READER	TUDATE	TRGOC_1	TRGOC_2	TRGOC_3	TRGOC_4	TRGOC_5	TRGSLD	TRGRESP	ITRGRESP
1201	WK12_CT	R1	2018-12-11	Lung RUL					16	SD	iSD
1201	WK12_CT	R2	2018-12-11							NE	NE
1201	WK12_CT	Adjudicator	2018-12-11	Lung right upper lobe					16	SD	iSD

USUBJID	TUSEQ	TU
1201	1	TA
1201	2	TA
1201	3	TA

TU Domain

USUBJID	TRSEQ	TRTE
1201	1	LD
1201	2	LD
1201	3	LD

TR Domain

USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES
1201	1	TRGRESP	Target Response	RECIST 1.1	SD
1201	2	TRGRESP	Target Response	iRECIST	iSD
1201	3	TRGRESP	Target Response	RECIST 1.1	NE

RS Domain

Automatic SDTM Transformation Module

Link Code Adaptation

- Tumor Identification and Tumor Result per subject

TU Domain

USUBJID	TUSEQ	TULINKID	TULOC	TUMETHOD	VISIT	TUDTC
1201	1	R1-T01	Lung, Right Upper Lobe	CT	WK12	2018-12-11
1201	2	R2-T02	Lung, Right Upper Lobe	CT	WK12	2018-12-11

TR Domain

USUBJID	TRSEQ	TRLNKGRP	TRLINKID	TRTESTCD	TRTEST	TRORRES
1201	1	A1	R1-T01	LDIAM	Longest Diameter	16
1201	2	A1	R2-T02	LDIAM	Longest Diameter	19

RS Domain

USUBJID	RSSEQ	RSLNKGRP	RSTEST	RSCAT	RSORRES
1201	1	A1	Target Response	RECIST 1.1	SD
1201	2	A1	Target Response	iRECIST	iSD
1201	3	A1	Target Response	RECIST 1.1	PD
1201	4	A1	Target Response	iRECIST	iUPD

Input data in the eCRF

USUBJID	VISIT	READER	TUDATE	TRGOC_1	TRGSLD	TRGRESP	ITRGRESP
1201	WK12_CT	R1	2018-12-11	Lung right upper lobe	16	SD	iSD
1201	WK12_CT	R2	2018-12-11			NE	NE

SDTM datasets

USUBJID	TUSEQ	TUORRES	TUSTRESC	TULOC
1201	1	TARGET	TARGET	LUNG, RIGHT UPPER LOBE
1201	2	TARGET	TARGET	

TU Domain

USUBJID	TRSEQ	TRTESTCD	TRTEST	TRORRES	TRORRESU
1201	1	LDIAM	Longest Diameter	16	mm
1201	2	LDIAM	Longest Diameter		
1201	3	LDIAM	Longest Diameter	16	mm

TR Domain

USUBJID	RSSEQ	RSTESTCD	RSTEST	RSCAT	RSORRES
1201	1	TRGRESP	Target Response	RECIST 1.1	SD
1201	2	TRGRESP	Target Response	iRECIST	iSD
1201	3	TRGRESP	Target Response	RECIST 1.1	NE

RS Domain

SDTM Dataset Extraction

Previous Actual Dataset

Requirement of Instruction

Subjective Responses

USUBJID	VISIT	READER	TUDATE	TRGIND	TRGOC_1	TRGOC_2	TRGOC_3	TRGOC_4	TRGOC_5	TRGSLD	TRGRESP	iTRGRESP	NTRGOC_1
TEST	SCRN_CT	R2	2019-11-26	Y	Lymph node mediastinal					16			Lymph node perigas
TEST	SCRN_CT	R1	2019-11-26	N									Lymph node mesent
TEST	WK12_CT	R2	2020-01-29	Y	Lymph node mediastinal					16	SD	iSD	Lymph node perigas
TEST	WK12_CT	R1	2020-01-29	N							NE	NE	Lymph node mesent
TEST	SCRN_CT	Adjudicator	2019-10-02	Y	Lymph node paracaval					112			Lymph node multipl
TEST	SCRN_CT	R2	2019-10-02	Y	Lung right					100			Lung right
TEST	SCRN_CT	R1	2019-10-02	Y	Lymph node paracaval					112			Lymph node multipl
TEST	WK12_CT	R2	2019-12-27	Y	Lung right					202	SD	iSD	Lung right
TEST	WK12_CT	R1	2019-12-27	Y	Lymph node paracaval					113	SD	iSD	Lymph node multipl
TEST	WK20_CT	R2	2020-02-19	Y	Lung right					269	SD	iSD	Lung right
TEST	WK20_CT	R1	2020-02-19	Y	Lymph node paracaval					126	SD	iSD	Lymph node multipl
TEST	SCRN_CT	Adjudicator	2019-08-23	Y	Lung right					223			Lymph node paracav
TEST	SCRN_CT	R2	2019-08-23	Y	Lung right								Lymph node paracav
TEST	SCRN_CT	R1	2019-08-23	Y	Lung RML								Lymph node retrope
TEST	WK12_CT	Adjudicator	2019-11-06	Y	Lung right						CR	iCR	Lymph node paracav
TEST	WK12_CT	R2	2019-11-06	Y	Lung right						CR	iCR	Lymph node paracav
TEST	WK12_CT	R1	2019-11-06	Y	Lung RML					10	PR	iPR	Lymph node retrope
TEST	WK20_CT	R1	2020-01-08	Y	Lung RML					0	CR	iCR	Lymph node retrope
TEST	SCRN_CT	Adjudicator	2019-08-30	Y	Lymph node mediastinur					34			
TEST	SCRN_CT	R2	2019-08-30	Y	Lymph node mediastinur					34			
TEST	SCRN_CT	R1	2019-08-30	Y	Lymph node subcarinal					43			
TEST	WK12_CT	Adjudicator	2019-11-11	Y	Lymph node mediastinur					14	PR	iPR	
TEST	WK12_CT	R2	2019-11-11	Y	Lymph node mediastinur					14	PR	iPR	
TEST	WK12_CT	R1	2019-11-11	Y	Lymph node subcarinal					16	PR	iPR	
TEST	WK20_CT	R2	2019-12-09	Y	Lymph node mediastinur					15	PR	iPR	
TEST	WK20_CT	R1	2019-12-09	Y	Lymph node subcarinal					10	CR	iCR	

TEST_RECIST_iRECIST DATASET

SDTM Dataset Extraction

Current SDTM Dataset

STUDYID	DOMAIN	USUBJID	TUSEQ	TULNKID	TUORRES	TUSTRESC	TULOC	TULAT	TUDIR
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
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TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							
TEST	TU	TES							

TU Domain | TR

STUDYID	DOMAIN	USUBJID	TRSEQ	TRLNKGRP	TRLNKID	TRTESTCD	TRTEST	TRORRES	TRORRESU	TRSTAT	TRREASND	TRMETHOD
TEST	TR	TEST01	1									
TEST	TR	TEST01	2									
TEST	TR	TEST01	3									
TEST	TR	TEST01	4									
TEST	TR	TEST01	5									
TEST	TR	TEST01	6									
TEST	TR	TEST01	7									
TEST	TR	TEST01	8									
TEST	TR	TEST01	9									
TEST	TR	TEST01	10									
TEST	TR	TEST01	11									
TEST	TR	TEST01	12									
TEST	TR	TEST01	13									
TEST	TR	TEST01	14									
TEST	TR	TEST01	15									
TEST	TR	TEST01	16									
TEST	TR	TEST01	17									
TEST	TR	TEST01	18									
TEST	TR	TEST01	19									
TEST	TR	TEST01	20									
TEST	TR	TEST01	21									

TU Domain | TR Domain | RS

STUDYID	DOMAIN	USUBJID	RSSEQ	RSLNKGRP	RSTESTCD	RSTEST	RSCAT	RSORRES	RSSTRESC
TEST	RS	TEST01	1	A2	TRGRESP	Target Response	RECIST 1.1	CR	CR
TEST	RS	TEST01	2	A2	TRGRESP	Target Response	IRECIST	iCR	iCR
TEST	RS	TEST01	3	A2	NTRGRESP	Non-target Response	RECIST 1.1	CR	CR
TEST	RS	TEST01	4	A2	NTRGRESP	Non-target Response	IRECIST	iCR	iCR
TEST	RS	TEST01	5	A2	NEWLPROG	New Lesion Progression	RECIST 1.1	NON-PD	NON-PD
TEST	RS	TEST01	6	A2	NTRGRESP	Non-target Response	IRECIST	NON-PD	NON-PD
TEST	RS	TEST01	7	A3	TRGRESP	Target Response	RECIST 1.1	PR	PR
TEST	RS	TEST01	8	A3	TRGRESP	Target Response	IRECIST	iPR	iPR
TEST	RS	TEST01	9	A3	NTRGRESP	Non-target Response	RECIST 1.1	Non-CR/Non-PD	Non-CR/Non-PD
TEST	RS	TEST01	10	A3	NTRGRESP	Non-target Response	IRECIST	Non-iCR/Non-iPD	Non-iCR/Non-iPD
TEST	RS	TEST01	11	A3	NEWLPROG	New Lesion Progression	RECIST 1.1	NON-PD	NON-PD
TEST	RS	TEST01	12	A3	NTRGRESP	Non-target Response	IRECIST	NON-PD	NON-PD
TEST	RS	TEST01	13	A4	TRGRESP	Target Response	RECIST 1.1	PR	PR
TEST	RS	TEST01	14	A4	TRGRESP	Target Response	IRECIST	iPR	iPR
TEST	RS	TEST01	15	A4	NTRGRESP	Non-target Response	RECIST 1.1	Non-CR/Non-PD	Non-CR/Non-PD
TEST	RS	TEST01	16	A4	NTRGRESP	Non-target Response	IRECIST	Non-iCR/Non-iPD	Non-iCR/Non-iPD
TEST	RS	TEST01	17	A4	NEWLPROG	New Lesion Progression	RECIST 1.1	NON-PD	NON-PD
TEST	RS	TEST01	18	A4	NTRGRESP	Non-target Response	IRECIST	NON-PD	NON-PD
TEST	RS	TEST01	19	A5	TRGRESP	Target Response	RECIST 1.1	PR	PR
TEST	RS	TEST01	20	A5	TRGRESP	Target Response	IRECIST	iPR	iPR
TEST	RS	TEST01	21	A5	NTRGRESP	Non-target Response	RECIST 1.1	Non-CR/Non-PD	Non-CR/Non-PD

TU Domain | TR Domain | RS Domain

Validation

Pinnacle 21 Community Software (v 3.0.2)

- Missing one variable ➔ EPOCH (Added)

Mock Test by Two Experienced Radiologists

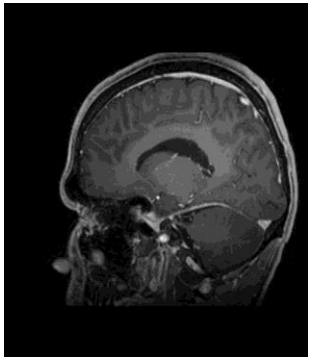
- Previous CTIMS vs. New CTIMS with Automatic Verification
- 176 human errors were filtered in advance

Further Work

Development of the Automatics Pre-screening module

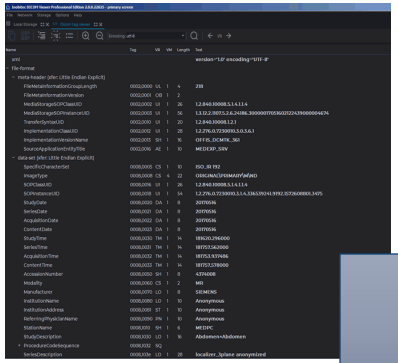
- DICOM Tag Extraction → DICOM Sorting → Pre-Screening by imaging protocol

Image Upload



Ref.radiopaedia.org

DICOM Tags

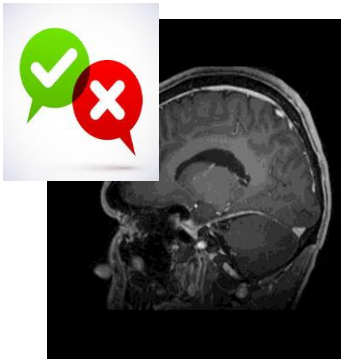


Ref. inobitec.com

DICOM Tags Extraction

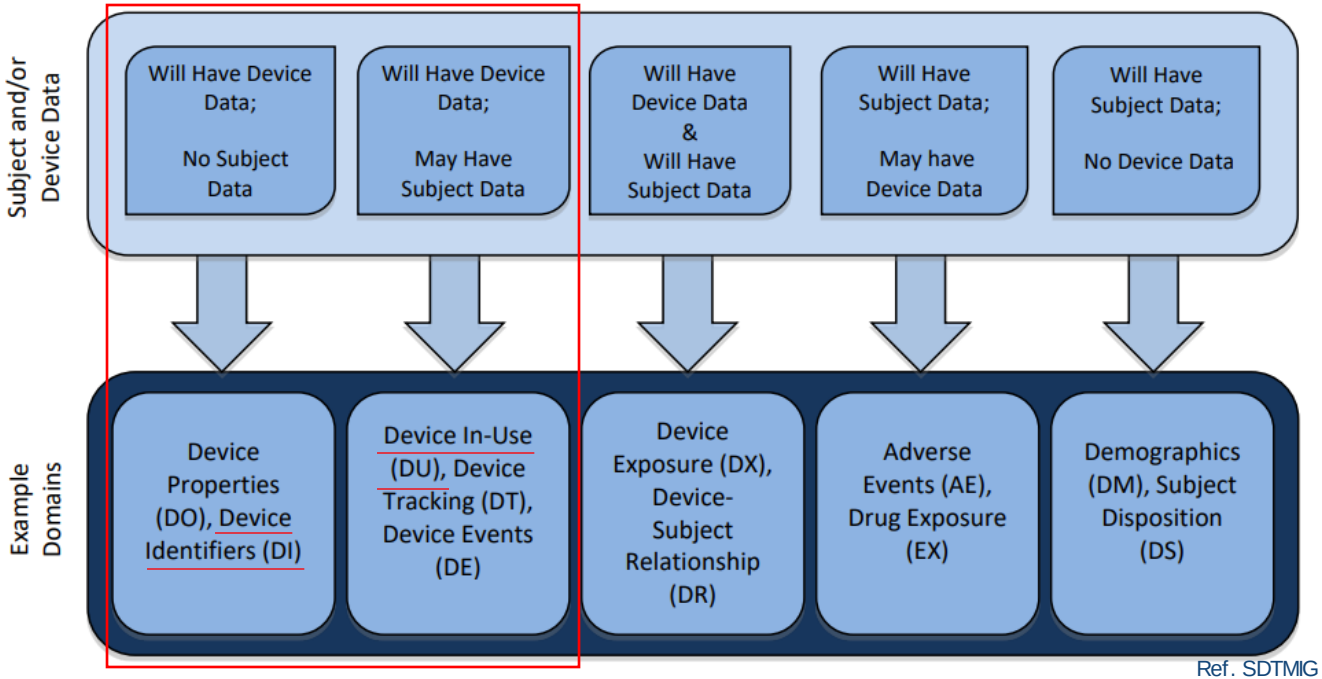
DICOM Sorting

Pre-Screening



DICOM-CDISC conversion

- Designed the table with eCRF questions following CDASH guideline
- Used SDTM-MD variables of two domains (DI, DU) in eCRF



The Automatic Pre-screening Module

- Extracted DICOM Tags → Values
- Matched with pre-defined imaging protocol (Computed Tomography* & Magnetic Resonance**)

Examples of pre-screening related DICOM tags	
DICOM Tag Number	**DICOM Tag Name**
(0008, 0070)	Manufacturer
(0008, 1090)	Manufacturer's Model Name
(0008, 0060)	Modality
(0018, 0050)	Slice Thickness
(0018, 0081)	Echo Time

Examples of CT (Single Acquisition) Protocol				
Scanner	**GE**	**Philips**	**Siemens**	**Hitachi**
Number of Detector	≥16	≥16	≥16	≥16
Detector configuration	≤1.25 mm	≤1.5 mm	≤1.5 mm	≤1.25 mm
Tube voltage	100 – 120 kV	120 kV	120 kV	120 kV
Tube current	260-350 average mA	180 – 200 mAs @ 33 cm Reference	200 – 210 mAs	250 mA
FOV	Large	350-500 mm	350-500 mm	500 mm
Slice thickness	5 mm	5 mm	5 mm	5 mm
Increment	5 mm	5 mm	5 mm	5 mm
AP=Abdomen/Pelvis, C=Chest, CT=Computed Tomography, FOV=Field of View				

The Automatic Pre-screening Module

- Annotated eCRF with SDTM-MD variable & Controlled Terminology

Project [STUDYID]	Demo	Subject	202 [USUBJID]
Visit [VISIT]	Baseline	Time Point	BL
QC Result	PASS		

Scan List

[DUDTC]

2022-05-06 - MRI / MR.Brain (with enhance)(3.0T)

[DUTESTCD, DUTEST]

[DIPARMCD, DIPARM]

[DIVAL]

Manufacturer	Model	Series Number	Series Description	TR[ms]	TE[ms]	TI[ms]	Flip Angle	Mode	NEX	FOV (Column)	FOV (Row)	Slice Thickness	Gap/spacing	QC Result	Exam Comment
GE	SIGNA Architect	700	3D T1 SAG GD	2381	3	1000	8.0	3D	1.0	240	240	3.0	0	Good	
GE	SIGNA Architect	3	Ax T2	5391	118	NA	142.0	2D	2.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	2	Sag T1	2293	23	821	111.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	8	Ax T1_FS GD	450	17	1000	80.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	701	3D T1 AX GD	2381	3	1000	8.0	3D	1.0	230	230	3.0	0	Good	
GE	SIGNA Architect	6	Ax T2* GRE	433	14	2463	20.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	4	Ax T2 FLAIR PROP	9000	102	2463	160.0	2D	2.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	5	Ax T1	2400	22	848	111.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	702	3D T1 COR GD	2381	3	1000	8.0	3D	1.0	230	230	3.0	0	Good	

[DUORRES]

The Automatic Pre-screening Module

- Annotated eCRF with SDTM-MD variable & Controlled Terminology

QC Info

Project [STUDYID]	Demo	Subject	202 [USUBJID]
Visit [VISIT]	Baseline	Time Point	BL
QC Result	PASS		

Scan List

[DUDTC]
2022-05-06 - MRI / MR,Brain (with enhance)(3.0T)
[DUTESTCD, DUTEST]
[DIPARMCD, DIPARM]

Manufacturer	Model	Series Number	Series Description	TR[ms]	TE[ms]	TI[ms]	Flip Angle	Mode	NEX	FOV (Column)	FOV (Row)	Slice Thickness	Gap/spacing	QC Result	Exam Comment
[DIVAL]															
GE	SIGNA Architect	700	3D T1 SAG GD	2381	3	1000	8.0	3D	1.0	240	240	3.0	0	Good	
GE	SIGNA Architect	3	Ax T2	5391	118	NA	142.0	2D	2.0	230	230	5.0	2.0	Good	[DUORRES]
GE	SIGNA Architect	2	Sag T1	2293	23	821	111.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	8	Ax T1_FS GD	450	17	1000	80.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	701	3D T1 AX GD	2381	3	1000	8.0	3D	1.0	230	230	3.0	0	Good	
GE	SIGNA Architect	6	Ax T2* GRE	433	14	2463	20.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	4	Ax T2 FLAIR PROP	9000	102	2463	160.0	2D	2.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	5	Ax T1	2400	22	848	111.0	2D	1.0	230	230	5.0	2.0	Good	
GE	SIGNA Architect	702	3D T1 COR GD	2381	3	1000	8.0	3D	1.0	230	230	3.0	0	Good	

XML

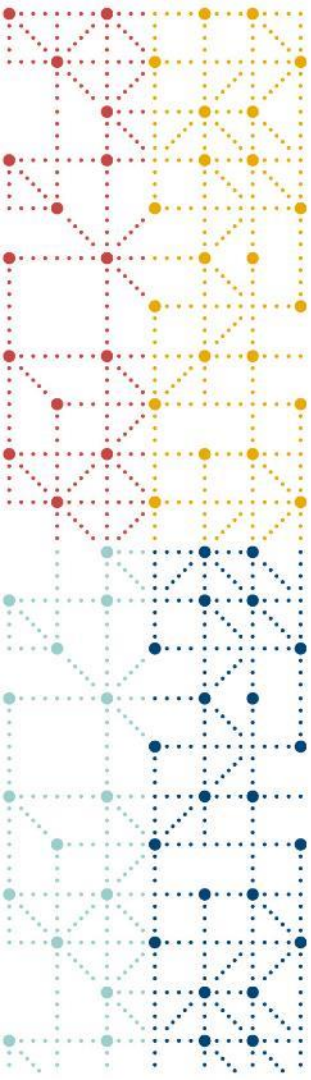
DI Domain

STUDYID	DOMAIN	SPDEVID	DISEQ	DIPARMCD	DIPARM	DIVAL
Demo	DI	0000000850270546	1	DEVTYPE	Device Type	MRI
Demo	DI	0000000850270546	2	MODEL	Model	SIGNA Architect

DU Domain

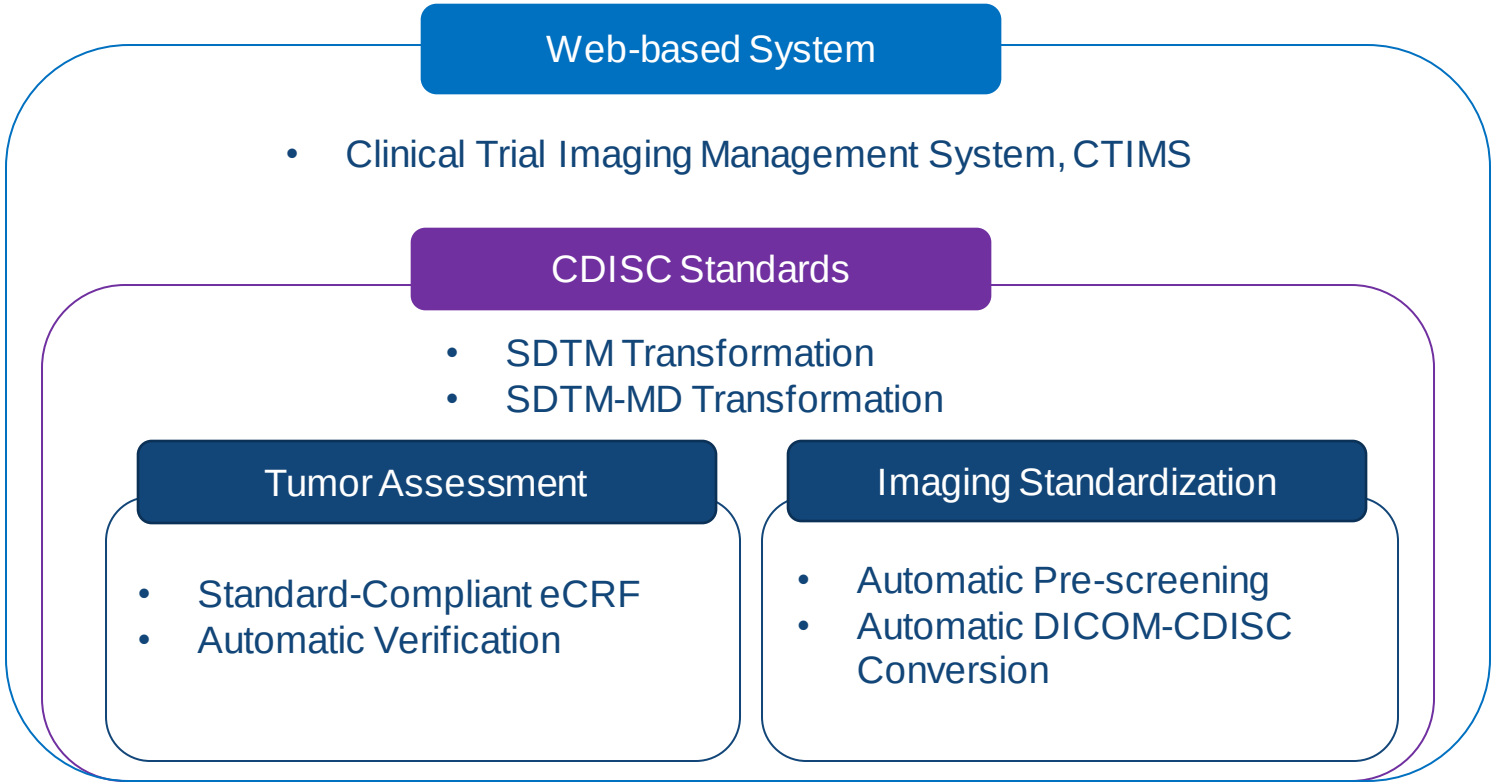
STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUTESTCT	DUTEST	DUORRES
Demo	DU	202	0000000850270546	1	STHICK	Slice Thickness	3.0
Demo	DU	202	0000000850270546	2	FLIPANGL	Flip Angle	8.0
Demo	DU	202	0000000850270546	3	FLDVIEW	Field of View	240

cdisc



Conclusion

CDISC-compliant CTIMS



Benefits of CDISC-compliant CTIMS

1. **Reliable and Reasonable Imaging Data for Quality Check and Tumor Assessment in Clinical Trials**

   Decreased human errors & missing values or typos in eCRF

2. **Ready for submitting to regulatory agencies**

   Unnecessary Detailed Instructions for Data Transfer

   CDISC Standard dataset

3. **Efficient Time-Consuming (Manual Work)**

   Question Library: Modification, Re-Usable

   Pre-screening: Pre-defined protocol

References

- Eisenhauer, Elizabeth A., et al. "New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1)." *European journal of cancer* 45.2 (2009): 228-247.
- Seymour, Lesley, et al. "iRECIST: guidelines for response criteria for use in trials testing immunotherapeutics." *The Lancet Oncology* 18.3 (2017): e143-e152.
- CDISC SDTMIG v3.3, https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3
- RECIST Template https://recist.eortc.org/wp-content/uploads/sites/4/2017/03/RECIST-1.1-iRECIST-template.pdf
- RECIST Tumor Assessment Worksheet https://studylib.net/doc/6971147/recist-tumor-assessment-worksheet
- Radiology Assistant https://radiologyassistant.nl/more/recist-1-1

Thank You!