Topic 4 - You want to use CDISC Submission Values in SDTM for Analysis Results?

CJUG SDTM
LISaS Team
8th February 2012

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If you use **CDISC Submission Values** for **Analysis Results**…

As you know RACE is "BLACK OR AFRICAN AMERICAN" in SDTM, but I prefer proper case "Black or African American" for CRF!

Lab test name should be "Red Blood Cell" instead of "Erythrocytes" for CSR because CDISC terminology is not common in Japan!

Sex="F"? Response="Y"? We should use "Female" and "Yes" for our Listing respectively!!

For Outcome of Event, CDISC value is "RECOVERED/RESOLVED WITH SEQUELAE", but "/" is used for split character in SAS, That's why we should change it to "or"!!

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Many Queries and Requests!!

- From Stakeholders
  - Data Managers
  - Stats
  - Programmers
  - Clinicians or Clinical Study Leaders
  - Medical Writers
  - CRAs

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Help me!

- Do we need…
  - ✓ A lot of data-handling for ADaM creation?
  - ✓ Additional format catalogs?
  - ✓ Training for learning unfamiliar terms?
  - ✓ Being careful about upper-case and lower-case?

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Let's think about it

1. What is the "CDISC Submission Values"?

2. What type of "CDISC Submission Values"?

3. What type of Issues?

4. How should we control Analysis results?

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Study Data Tabulation Model (SDTM)

- SDTM v1.2 Quote;
  - A standard structure for study data tabulations that are to be submitted as part of a product application to a regulatory authority such as the United States Food and Drug Administration (FDA).
- The focus of SDTM is Not on;
  - Data monitoring/cleaning and coding
  - Analysis result

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CDISC Submission Values in SDTM

- Primary users are "Medical Reviewers" in FDA
  - Not Statisticians

Machine-friendly

- Specific "Tools" are used
  - Empirica Study(WebSDM), JReview, JMP Clinical, MAED
  - Formats in outputs depend on the tools, e.g., "F" may be displayed on the inside of the graph to reduce the space, and "Female" in the legend.

RACE	SEX	AEOUT	QSSTRESC
BLACK OR AFRICAN AMERICAN	F	RECOVERED/RESOLVED WITH SEQUELAE	Y

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Reviewer's Desktop JMP Clinical

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Let's think about it

1. What is the "CDISC Submission Values"?
2. **What type of "CDISC Submission Values"?**
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SDTM IG v3.1.2 Quote;

- 4.1.2.1 VARIABLE-NAMING CONVENTIONS
  - *"Variables with names ending in "CD" are "short" versions of associated variables that do not include the "CD" suffix (e.g., --TESTCD is the short version of --TEST)."*
- 4.1.3.4 USE OF CONTROLLED TERMINOLOGY AND ARBITRARY NUMBER CODES
  - *"Controlled terminology or decoded text should be used instead of arbitrary number codes in order to reduce ambiguity for submission reviewers. For example, for concomitant medications, the verbatim term and/or dictionary term should be presented, rather than numeric codes. Separate code values may be submitted as Supplemental Qualifiers and may be necessary in analysis datasets."*

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What dose "code/decode" mean?

Longman Dictionary of Contemporary English

➢ "code"

1. A set of instructions that tell a computer what to do, e.g., source code
2. A set of numbers, letters, or symbols that shows what something is or gives information about it, e.g., zip code

➢ "decode"

1. If a computer decodes data, it receives it and changes it into a form that can be used by the computer or understood by a person [≠ encode]
2. To discover the meaning of a message written in a code (=a set of secret signs or letters) [= decipher]
   #decipher=to change a message written in a code into ordinary language so that you can read it)

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Type of Submission Values

No.1 Value only(or Result)

Example: SEX, AETERM, LBUNIT, Comments

No.2 Code only

Example: LBLOINC, COUNTRY

No.3 Code and Decode

Example: AEPTCD/AEDECOD
Special Case: QSSTRESN/QSORRES
(--STRESN=Code, --ORRES=Decode)

No.4 Short Name and Verbatim Name

Example: LBTESTCD/LBTEST

Note: "SEX" is not categorized as "Short Name" because of no "Verbatim Name" in SDTM.

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Example

SEX	AETERM	LBUNIT	COVAL1
F	headache	mg/L	Subject 123104 died in an automobile accident.

COUNTRY	LBLOINC
JPN	2862-1

Note: Albumin

Code Decode

AEPTCD	AEDECOD	QSSTRESN	QSORRES
10003988	Back pain	4	VERY GOOD

LBTESTCD	LBTEST
EOSLE	Eosinophils/Leukocytes

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Question

- "Code" or "Decode"?

RACE	SEX	COUNTRY	ETHNIC
ASIAN	M	JPN	NOT HISPANIC OR LATINO

Sex="M" gives us enough information to understand! We don't need any additional formats!

I guess RACE="ASIAN" is "decode" but Sex="M" is "code"! We should display "Male" format!

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Let's think about it

1. What is the "CDISC Submission Values"?

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Case1: Capitalization Rule

As you know RACE is "BLACK OR AFRICAN AMERICAN" in SDTM, but I prefer proper case "Black or African American" for CRF!

- Data should be submitted in upper case except;
  - External reference (e.g., MedDRA)
  - Units
  - Comments
  - Values of --TEST in Findings datasets
- For good legibility and readability, Clinicians or Medical writers request us to change CDISC submission values into proper case, which is to use capital letter for the first letter of each word.

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Case2: Unfamiliar Terms

Lab test name should be "Red Blood Cell" instead of "Erythrocytes" for CSR because CDISC terminology is not common in Japan!

- Some CDISC submission values are not common in Japan, US/EU or specific therapeutic area.

Conventional Terms	CDISC Submission Values
Red Blood Cell	LBTEST="Erythrocytes"
White Blood Cell	LBTEST="Leukocytes"
Total Cholesterol	LBTEST="Cholesterol"
O.D. / Oculus Dexter	--LOC="EYE" + --LAT="RIGHT"

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Case3: Abbreviations

Sex="F"? Response="Y"? We should use "Female" and "Yes" for our Listing respectively!!

- Some CDISC submission values are populated for abbreviated (short) word.
  - It can be reduce the file size and output space.
  - Sex="F" / Response="Y" gives us enough information to understand.
- Our colleagues (various stakeholders) request us to change it into "human-readable" format.
  - Sex="Female" / Response="Yes"

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Case4: Specific Characters

For Outcome of Event, CDISC value is "RECOVERED/RESOLVED WITH SEQUELAE", but "/" is used for split character in SAS, That's why we should change it to "or"!!

- Some submission values include the characters.
  - hyphen, slash, comma, parenthesis and quotation
- For technical or special purpose, sometimes these characters are used;
  - Concatenate by "-"
  - Split by "/"
  - Export CSV

Subject	AE Term	Serious/ Action Taken/ Outcome of Event
101	Head ache	Yes/ DOSE REDUCED/ NOT RECOVERED/NOT RESOLVED

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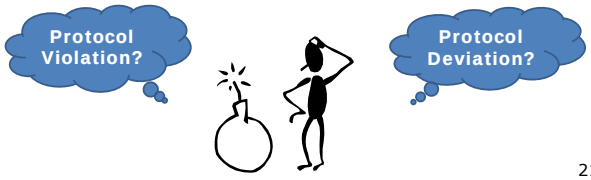
Out of the Scope

- Difference between "CDISC Submission Values" and definitions in your company

CDISC SDTM Controlled Terminology, 2012-08-03
C66727 - NCOMPLT - Completion/Reason for Non-Completion
Codelist extensible: Yes

NCI Code	CDISC Submission Value	CDISC Synonym	CDISC Definition	NCI Preferred Term
C48231	PROTOCOL VIOLATION		An event or decision that stands in contrast to the guidelines set out by the protocol. (NCI)	Protocol Violation



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Customer Satisfaction Survey

- Questions;
  - What do you think about using these CDSIC Controlled Terminology for Analysis results?
- Interview;
  - Stats & Programmers
  - Clinicians or Clinical Study Leaders
  - Medical Writers
  - Native English Speaker or Not

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Example: Summary of Demography

		Placebo (N=30)	Treatment A (N=30)
Sex	F	30 (100%)	30 (100%)
	M	0 (0%)	0 (0%)
Race	AMERICAN INDIAN OR ALASKA NATIVE	0 (0%)	0 (0%)
	ASIAN	15 (50%)	15 (50%)
	BLACK OR AFRICAN AMERICAN	0 (0%)	0 (0%)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0 (0%)	0 (0%)
	WHITE	15 (50%)	15 (50%)
Ethnicity	HISPANIC OR LATINO	30 (100%)	30 (100%)
	NOT HISPANIC OR LATINO	0 (0%)	0 (0%)
Country	CHN	7 (23%)	7 (23%)
	JPN	7 (23%)	7 (23%)
	SGP	8 (27%)	8 (27%)
	USA	8 (27%)	8 (27%)
Pregnant?	Y	3 (10%)	6 (20%)
	N	27 (90%)	24 (80%)

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Example: Listing of Adverse Events

Subject Id	Treatment	Sex	Race	Verbatim term	Preferred term	Start date
123-01-01	Placebo	M	WHITE	Eczema (both arm)	Eczema	2012-01-13
123-01-02	10mg	F	ASIAN	acute myocardial infarction	Acute myocardial infarction	2012-11-23
123-98-92	50mg	M	ASIAN	POUNDING HEADACHE	Headache	2012-02-19

Serious	Severity	Action Taken	Outcome	Location	Laterality
N	MILD	DOSE REDUCED	RECOVERED/RESOLVED	ARM	BILATERAL
Y	SEVERE	DRUG WITHDRAWN	FATAL	HEART, LEFT VENTRICLE	
N	MODERATE	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE	HEAD	

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Example: Summary of Laboratory Results

Visit	Lab test (Unit)		Placebo (N=30)	Treatment A (N=30)
Visit 1	Erythrocyte (10^4/mm^3)	n	30	30
		Mean	440.6	425.3
		SD	62.1	66.3
		Min.	380	378
		Max.	460	445
	Eosinophils/Leukocytes (%)	n	30	30
		Mean	2.23	2.11
		SD	1.72	1.63
		Min.	0.2	0.1
		Max.	7.1	6.8
	Cholesterol (mg/dL)	n	29	30
		Mean	218.0	200.4
		SD	45.5	51.2
		Min.	124	120
		Max.	319	300

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Feel free to talk!

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Let's think about it

1. What is the "SDTM Submission Values"?
2. What type of "SDTM Submission Values"?
3. What type of Issues?
4. **How should we control Analysis results?**

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4. How should we control Analysis results?

4-1: Back ground

4-2: Description in ADaM vs. SDTM

4-3: Consideration about Format catalogue

4-4: Type of Issues
- Capitalization Rule
- Abbreviations
- Unfamiliar Terms

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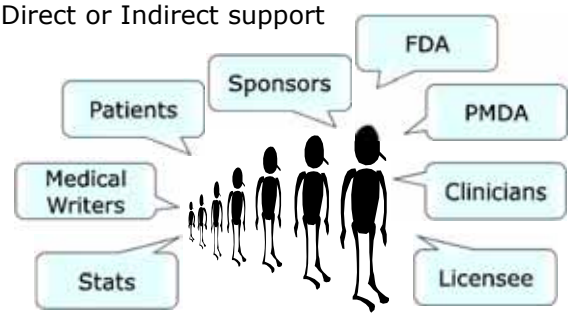
Who is your customer?

- Internal or External use
- Short-term or Long-term benefit
- Direct or Indirect support



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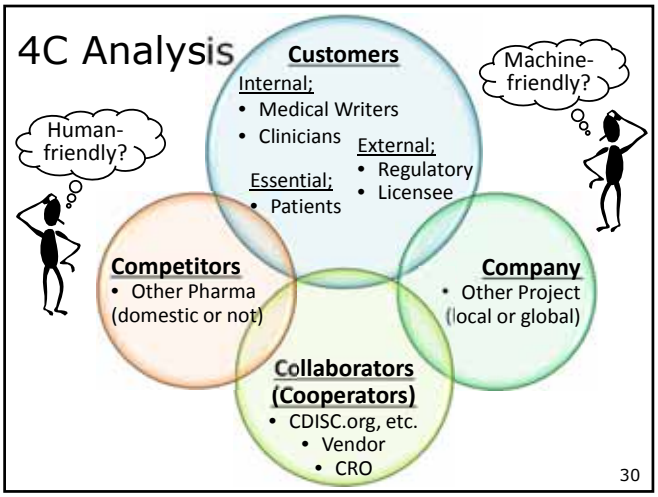
4C Analysis



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If you follow the Simple Analysis Process…

(Raw->SDTM->ADaM->Analysis Results)

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Analysis Data Model (ADaM) v2.1

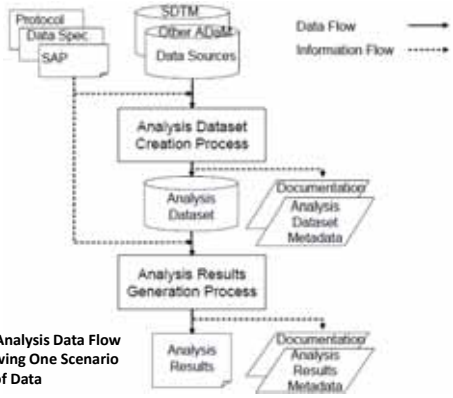

Figure 3.2.1: Analysis Data Flow Diagram Showing One Scenario for the Flow of Data

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4. How should we control Analysis results?

4-1: Back ground

4-2: Description in ADaM vs. SDTM

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SDTM vs. ADaM Traceability

- ADaM IG v1.0 Quote;
  - Any ADaM variable whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values".

SDTM

RACE
ASIAN
WHITE

ADaM

RACEN	RACE	RACE
1	Asian	ASIAN
2	White	WHITE

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ADaM for Adverse Event Analysis v1.0 Quote;

ADAE - Adverse Event Analysis Dataset				
Variable Name	**Variable Label**	**Type**	**Code List / Controlled Terms**	**CDISC Notes**
AESER	Serious Event	Char	(NY)	AE.AESER
AESEV	Severity/Intensity	Char	(AESEV)	AE.AESEV
AESEVN	Severity/Intensity (N)	Num	1, 2, 3	Code AE.AESEV to numeric Low intensity should correspond to low value
ASEV	Analysis Severity/Intensity	Char	*	Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. **May change case of text, such as from all uppercase in AESEV to mixed case in ASEV.**
ASEVN	Analysis Severity/Intensity (N)	Num	1, 2, 3	Code ASEV to numeric Low intensity should correspond to low value

Note: AEREL is described in the same manner as in AESEV.

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Example: ADAE

- ASEV, ASEVN;
  - Apply imputation rules for missing severity of adverse events as specified in the SAP or metadata. May change case of text, such as from all uppercase in AESEV to mixed case in ASEV.

SDTM

AESEV
MILD
MODERATE
SEVERE
(null)

ADaM

AESEV	AESEVN	ASEV	ASEVN
MILD	1	Mild	1
MODERATE	2	Moderate	2
SEVERE	3	Severe	3
(null)	*(null)*	Not Applicable	99

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ADaM Implementation Guide v1.0 Quote;

Table 3.2.4.1Analysis Parameter Variables for BDS Datasets

Variable Name	Variable Label	Type	CDISC Notes
PARAM	Parameter	Char	The description of the analysis parameter. Examples include: "Supine Systolic Blood Pressure (mm Hg)", "Log10 (Weight (kg))", "Time to First Hypertension Event (Days)", "Estimated Tumor Growth Rate", etc. PARAM should be sufficient to describe unambiguously the contents of AVAL and/or AVALC. **PARAM must include test, units (if appropriate), specimen type, location, position, and any other applicable qualifying information needed, any additional information such as transformation function, and indeed any text that is needed.** PARAM may be longer than 40 characters in length. PARAM is often directly usable in Clinical Study Report displays. Note that in the ADaM IG, "parameter" is a synonym of "analysis parameter."

Example: ADLB

- The description in the PARAM column must contain the units, as well as any other information such as location and specimen type that is needed to ensure that **PARAM uniquely describes what is in AVAL**, and differentiates between parameters as needed. **PARAM cannot be the same for different units.**

SDTM

LBCAT	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
URINALYSIS	PROT	Protein	NEGATIVE			
CHEMISTRY	PROT	Protein	100	mg/dL	5.55	mmol/L

ADaM

Note: AVALC can be a character string mapping to AVAL, but if so there must be a one-to-one map between AVAL and AVALC within a given PARAM when AVALC and AVAL are presented. (OpenCDISC v1.3, 29-Mar-2011)

PARAM	PARAMCD	AVAL	AVALC
Urine Protein (qualitative)	UPROT		Negative
Protein (mmol/L)	PROT	5.55	5.55
Protein (mg/dL)	PROTMG	100	100

If you need any conventional/local units

4. How should we control Analysis results?

4-1: Back ground

4-2: Description in ADaM vs. SDTM

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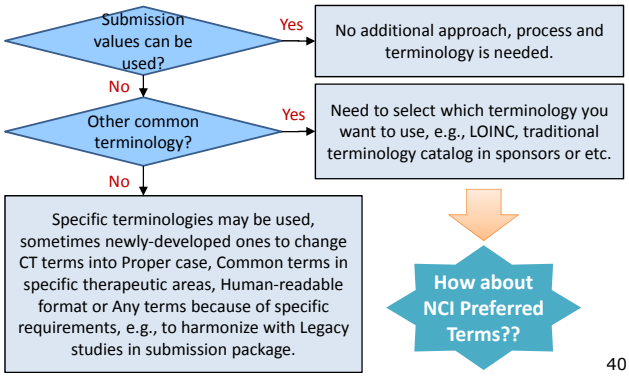
What type of terms are appropriate in Analysis Results?



Using NCI Preferred Terms

- The "NCI Preferred Term" instead of CDISC Submission Values in Analysis results would be preferred as Internal Standards;
  - Because of "Data exchange" and "Transparency"
  - For some sponsors "Death" may be preferable instead of "Death Related to Adverse Event"

Codelist Name	CDISC Submission Value	NCI Preferred Term
Outcome of Event	FATAL	Death Related to Adverse Event
Outcome of Event	NOT RECOVERED/NOT RESOLVED	Not Recovered or Not Resolved
Outcome of Event	RECOVERED/RESOLVED	Recovered or Resolved
Outcome of Event	RECOVERED/RESOLVED WITH SEQUELAE	Recovered or Resolved with Sequelae
Outcome of Event	RECOVERING/RESOLVING	Recovering or Resolving
Outcome of Event	UNKNOWN	Unknown

Traceability ADaM vs. Output

- To keep traceability the "Sort order" and "Decode (Mixed-case)" variables may be added to ADaM.
  - Except ASEV, AREL etc.

RACE	RACEN	RACEC
ASIAN	2	Asian

SEX	SEXN	SEXDECOD
M	1	Male

Note: Some sponsors may remove the SEX and RACE variables from ADaM because of the file size issue or etc.

Analysis Data Model (ADaM) v2.1

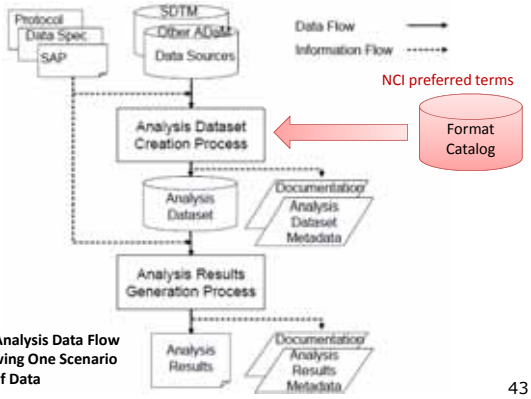


Figure 3.2.1: Analysis Data Flow Diagram Showing One Scenario for the Flow of Data

Should we display all categories which are used on CRF?

StudyDesign: Demographics

Demographics

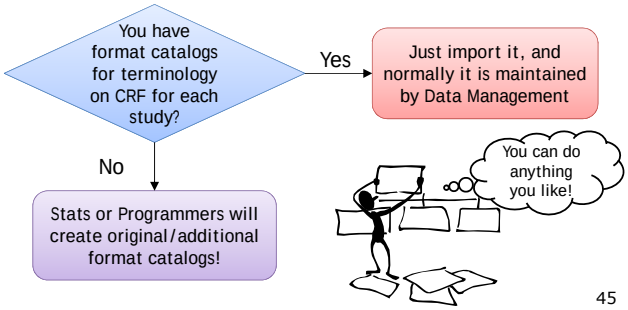
1.*	Sex [Sex]	[SEX] [A:F] Female [A:M] Male

If no Female subjects in a study…

Sex	Placebo (N=30)	Treatment A (N=30)
Female	0 (0%)	0 (0%)
Male	30 (100%)	30 (100%)

If you say "Yes"…

- You must use a format catalog for analysis results in order to display all categories;



Analysis Data Model (ADaM) v2.1

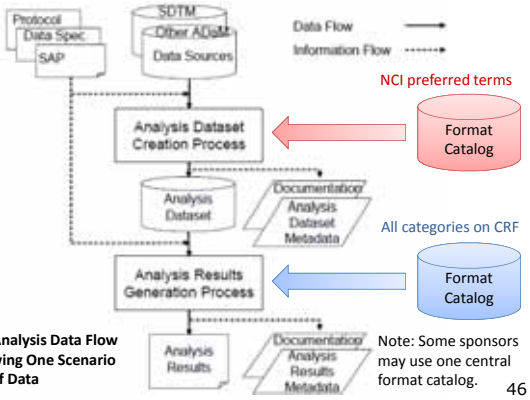


Figure 3.2.1: Analysis Data Flow Diagram Showing One Scenario for the Flow of Data

Note: Some sponsors may use one central format catalog.

4. How should we control Analysis results?

4-1: Back ground

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- Capitalization Rule
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You are Native English Speaker?

Capitalization Rule: Considerations

- 3 Points;
  1. Customers think CDISC Submission Values are "*machine-friendly*"
     - Stats & Programming may make them "*human-friendly*" in analysis data flow
  2. Should be controlled by "Implementer"
     - to avoid conflict between organizations/groups
     - not to cause differences between studies
  3. What do you think about the traceability
     - CRF -> SDTM -> ADaM -> Analysis Results
     - e.g., Different terms may be displayed on CRF

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Capitalization Rule: Solutions

- 5 Options;
  1. Using format catalog for analysis results
     - No sponsor formats should be associated in SDTM and ADaM datasets
  2. Auto-formatting by programming/system
     - No additional format catalog; e.g., Changing the terminology by standard macros
  3. Adding extra variables not defined by IG
     - e.g., RACEC,SEXDECOD in ADSL
  4. Using analysis variables defined by IG
     - e.g., ASEV, AREL in ADAE
  5. Good-bye to "Good legibility and readability"
     - Case-insensitive

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4. How should we control Analysis results?

4-1: Back ground

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About Abbreviations

Type 1;

- A few choices
- May be no-update

Codelist Name	CDISC Submission Value	NCI Preferred Term
Sex	F	Female
	M	Male
	U	Unknown
	UN	Intersex
No Yes Response	N	No
	NA	Not Applicable
	U	Unknown
	Y	Yes

Type 2;

- Many choices
- May be added/updated

Codelist Name	CDISC Submission Value	NCI Preferred Term
Frequency	BID	Twice Daily
	BIS	Twice Weekly
	QM	Monthly
	PRN	As Necessary
	Q10H	Every Ten Hours
	QS	Weekly
	PA	Per Year

(continued)

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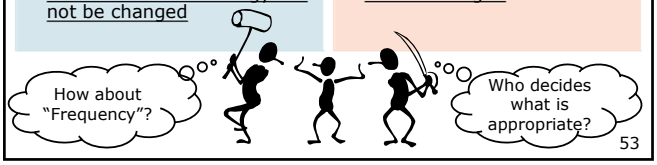
2 opposing points of view

Sex can be "Male" because;	Sex can be "M" because;
• It's easy to modify the terminology because of a few terms	• It's easy to understand because of a few terms
• Once we create a process to modify the terminology, it doesn't need any update because the terminology will not be changed	• Once we have a training to learn the terminology, it doesn't need any update because the terminology will not be changed



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Abbreviations: Considerations

- 2 Points;
  1. Same Situation as "Capitalization Rule"
     - Strongly influenced by the decision about "Capitalization Rule "
  2. "Flag" is not a Topic of discussion
     - Normally "Flag" is not displayed in summary tables (Note: AESER is not a "Flag")
     - e.g., TRTEMFL(Treatment Emergent Flag)="Y", TRTSDTF(Date of First Exposure Impute Flag)="M"

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4. How should we control Analysis results?

4-1: Back ground

4-2: Description in ADaM vs. SDTM

4-3: Consideration about Format catalogue

4-4: Type of Issues

- Capitalization Rule
- Abbreviations
- Unfamiliar Terms

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About Unfamiliar Terms

- Searching on Google.com (not "co.jp")

Red Blood Cell	28,400,000
Erythrocyte	4,250,000

White Blood Cell	30,400,000
Leukocyte	6,290,000

As of Nov 2012

You may never have seen these CDISC terminology regardless of your location!!

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In Some Situations…

- "Global Headquarter" or "Implementer" enforce CDISC terminology
- Not use English Language
- Not use Unfamiliar CDISC Terminology
  - e.g., Erythrocyte
    - RBC or Red Blood Cell?
    - in ADaM Creation Process?
    - in Analysis Results Creation Process?
    - How do we keep traceability

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ADaM: PARAM variable

- Easy to modify
- Difficult to keep the Traceability

SDTM

VSTEST	VSSEQ
Weight	2
Systolic Blood Pressure	6

ADaM

PARAM	PARAMCD	SRC DOM	SRCVAR	SRC SEQ
Weight (kg)	WEIGHT	VS	VSSTRESN	2
Log10 (Weight (kg))	WEIGHTLG			
Systolic Blood Pressure (mmHg)	SYSBP	VS	VSSTRESN	6
Time to First SBP>140 (day)	SYSBPDY	VS	VSDY	6

LBCAT	LBTEST	LBSEQ
URINALYSIS	Protein	1
CHEMISTRY	Protein	23
HEMATOLOGY	Erythrocyte	89

PARAM	PARAM CD	SRC DOM	SRCVAR	SRC SEQ
Urine Protein (qualitative)	UPROT	LB	LBSTRESN	1
Protein (mmol/L)	PROT	LB	LBSTRESN	23
Red Blood Cell (10^4/mm^3)	RBC	LB	LBSTRESN	89

Note: Data Point Traceability Variables = SRCDOM, SRCVAR and SRCSEQ (+ASEQ)
In this case, LBSEQ would be sufficient to provide the needed traceability because of all SRCDOM values are the same throughout the dataset

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Unfamiliar Terms: Considerations

- 2 Points;
  1. Completely different from "Capitalization Rule" and "Abbreviations" for data handling
     - May not be preferable to add any extra format or variables, e.g.;
       - LOC="EYE" & LAT="BILATERAL" > EYELOC="O.U."
     - Difficult to keep Traceability (BDS)
       - If you change the term "Erythrocyte" (LBSTEST) to "Red Blood Cells" (PARAM) then you definitely need "Data Point Traceability Variables"
  2. Typical examples may be useful for customers
     - to reduce queries
     - e.g., Erythrocytes, Leukocytes etc.

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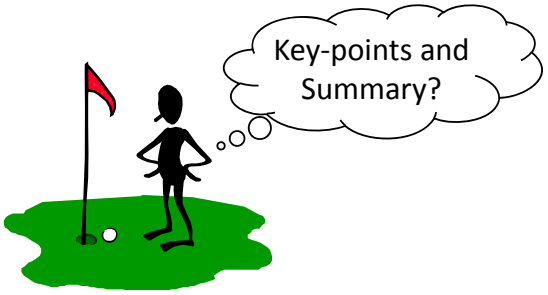
Just a few more slides



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Key-points

- Machine-friendly vs. Human-friendly
- SDTM variables vs. ADaM variables
- Listen to Customer's feedback
- Traceability
- 3 Type of Issues;
  - Capitalization Rule
  - Abbreviations
  - Unfamiliar Terms

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Summary

- Trade-off;
  - "Customer Satisfaction" versus "Cost/Resource"
  - Plus "Traceability"

For example;	Customer Satisfaction	Traceability	Cost/ Resource
All "Decode (Mixed-case)" variables are added to ADaM			
Using format catalog in Analysis results process			
No extra format and Case-insensitive			

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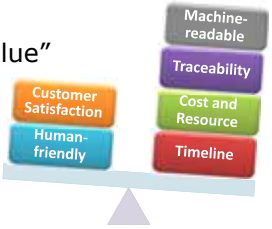
Summary (Cont.)

- If All "Decode" variables are added to ADaM data to satisfy our customer needs + keep traceability, No SDTM variables are displayed in Analysis results
- "CDISC Submission Value" in SDTM is;
  - for submission
  - for traceability



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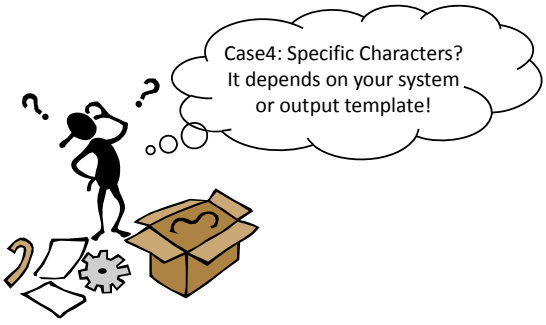
Questions?



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Developing Standardized Clinical Data Terminology

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PDUFA V Reauthorization Performance Goals and Procedures; Fiscal Years 2013 through 2017

- E. Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards development organizations (i.e., the Clinical Data Interchange Standards Consortium (CDISC)) with the goal of completing clinical data terminology and detailed implementation guides by FY 2017.
  - 1. FDA shall develop a project plan for distinct therapeutic indications, prioritizing clinical terminology standards development within and across review divisions. FDA shall publish a proposed project plan for stakeholder review and comment by June 30, 2013. FDA shall update and publish its project plan annually.
- F. Development of terminology standards for data other than clinical data: To address FDA-identified nonclinical data standards needs, FDA will request public input on the use of relevant already-existing data standards and the involvement of existing standards development organizations to develop new standards or refine existing standards. FDA will obtain this input via publication of a Federal Register notice that specifies a 60-day comment period.
- G. FDA shall periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications. In the case of standards for study data, new data standards and terminology shall be applicable prospectively and only required for studies that begin 12 months after issuance of FDA's final guidance on the applicable data standards and terminology.

Reference as of Dec 2012: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm

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References and Key Links

- SDTM v1.3, SDTM IG v3.1.3, ADaM v2.1 and ADaM IG v1.0
- FDA CDER Common Data Standards Issues Document (Ver1.1)
- CDISC eJournal 2012
  http://www.cdisc.org/content3061
  - The Major Impacts of CDISC on Clinical Data Lifecycle - Article by Chengxin Li and Nancy Bauer
    http://www.cdisc.org/stuff/contentmgr/files/0/36b3ee257bd65b5d7f0f279bd45dead4/misc/major_impacts_of_cdisc_on_clinical_data_lifecycle_li__bauer.pdf
- OpenCDISC Rule AD0129 - AD0130, AD0149 - AD0150
  http://www.opencdisc.org/forum/rule-ad0129-ad0130-ad0149-ad0150
- Prescription Drug User Fee Act (PDUFA)
  http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm272170.htm
  - PDUFA V Reauthorization Performance Goals and Procedures; Fiscal Years 2013 through 2017
    http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf
- FDA-WG(Data Validation and Quality Assessment) Group2 - Top 20 validation rule failures
  http://www.phusewiki.org/wiki/index.php?title=Top_20_Validation_Rule_Failures_(CBER)

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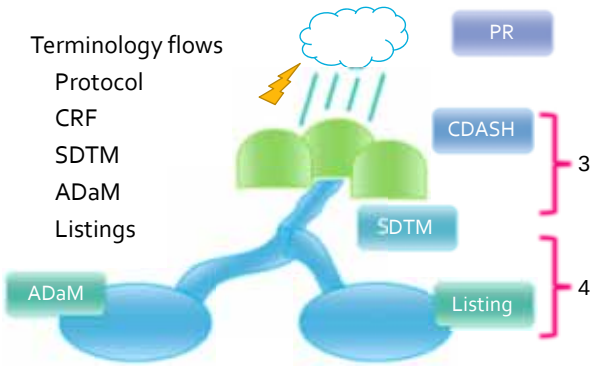
Connection LISaS - Topic 3 & 4



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Topic Discussion Members and Acknowledgments

- Some of the views and opinions expressed in this presentation are those of the individual discussion member and should not be attributed to the organization by which the member is employed.
  - Akira Soma (Tanabe Mitsubishi)
  - Hajime Shimizu (Takeda)
  - Miho Hashio (GSK)
  - Taku Shimizu (AC Medical)
  - Yasutaka Moriguchi (Santen)
  - Takashi Misawa (Acronet)
  - Mamiko Hayashi (Otsuka)

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