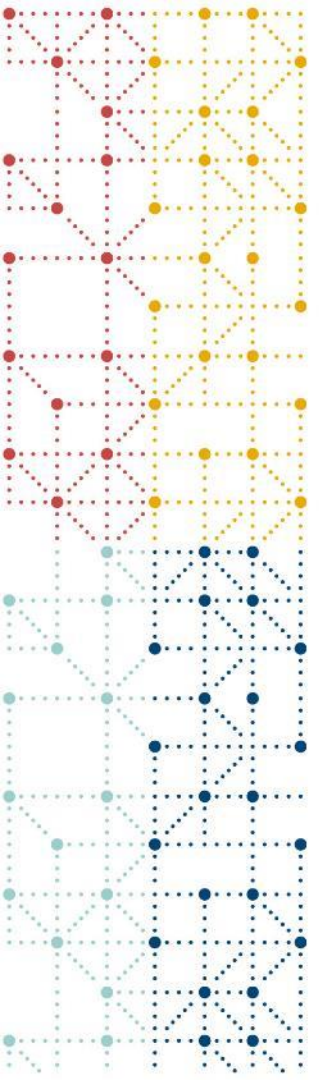# Slashing my first mapping, five years later!

Shizuko Takahara
Kanazawa University

The sub-team "Learn from the ancestors who mapped recklessly" in CJUG SDTM team

Meet the Speaker
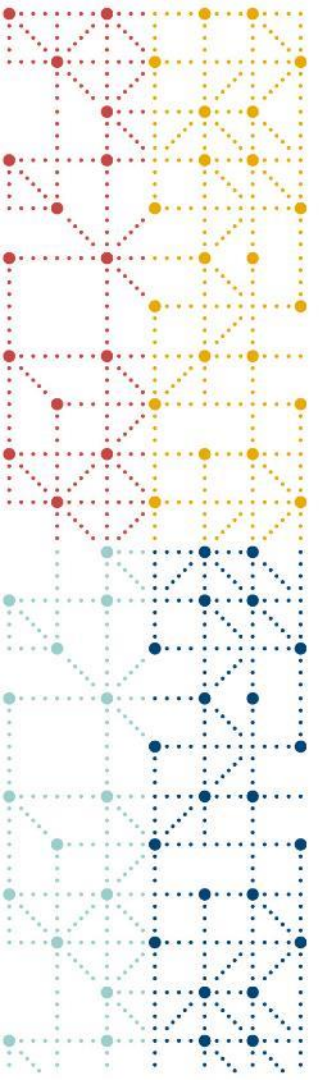
Shizuko Takahara

Title: Data Manager

Organization: Kanazawa University

A data manager for over 20 years in pharmaceutical companies and academia.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*

- *Examples in this presentation are my current solutions, not the official CDISC view.*

- *No COI to disclose*

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Agenda

1. Background / Today's Object

2. Lesson 1 – 4
   - Image of the way of thinking at the time when CDISC mapping was started
   - Lessons learned from those reflections

3. Conclusion

Background / Today's Object

Background

**What I want to say before today's presentation:**

- In 2017, five years ago, I conducted the first CDISC/SDTM mapping of investigator-initiated clinical trial data for lung cancer at Kanazawa University without outsourcing.

- I was the only person in charge of CDISC in my university, and there was no one to instruct me. Also, at that time, there were almost no Japanese materials on SDTM.

- I am a leader of "Learn from your ancestors who mapped recklessly" in CJUG/SDTM team. However, the contents are confidential, so I will present my own case instead.

Today's Object

What I want to say before today's presentation:

- Today's participants are professionals, and I think that only those who do not make such mistakes.

- I hope that it will be useful for your trainee education by knowing examples of how CDISC beginners thought and what mistakes they made.
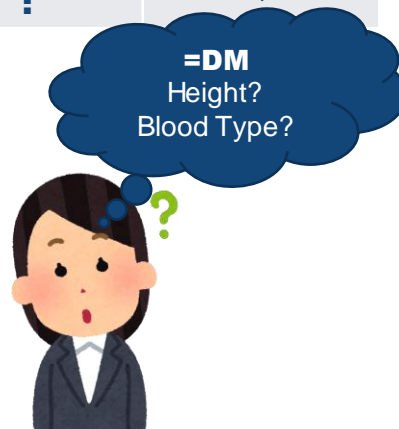
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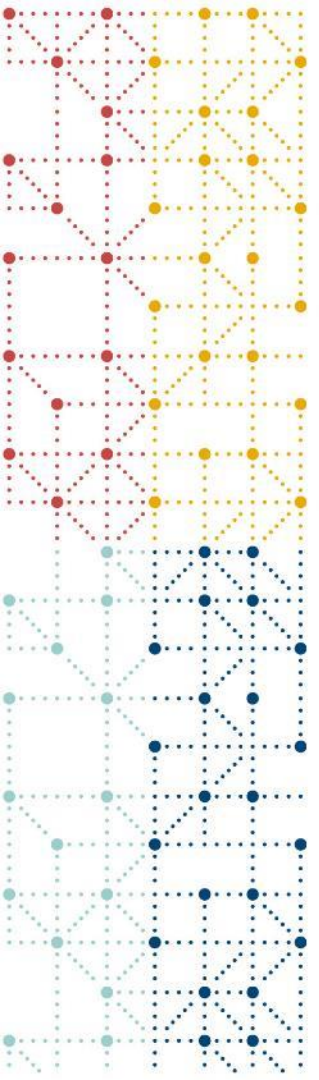
Lesson 1

I just assigned the CRF image to the domain.

I just assigned the CRF image to the domain

Adverse Events	
Event Name	Headache
Start Date	1-Feb-2022
Grade	2
:	:

=AE

Demographics	
Birth Date	18-Jun-1988
Height	156 cm
Blood Type	O
:	.

=DM
Height?
Blood Type?

Disposition
☐ Completed
☐ Adverse Event
☐ Pregnancy
:

=DS

Bad Case 1

Demographics	
Birth Date	18-Jun-1988
Height	156 cm
Blood Type	O
:	.

Demographic =DM

DM Height? Blood Type?

But DM domain does not contain them

If not, they are SUPP?

Bad Case 2

Medical History of the Breast Cancer

Diagnosis Date	22-Aug-2016
TNM at Diagnosis	T2N1M0
HER2 Score	3+
Operation Date	3-Oct-2016
Recurrence Date	22-Feb-2022
Relapsed Organ	Bone, Liver
⋮	

Is there no choice but to create a domain?

Since these are asking the doctor, they are QS in the expanded interpretation?

Asshat!! So, do you assign all CRF items to QS?

I could not find the corresponding **domain** for the **current disease history**.

Do not have an image linking a <u>CRF page</u> to a domain.

You should have an image linking each <u>item</u> to a domain.

Examples for Bad Case 1

Demographics	
Birth Date	*18-Jun-1988*
Height	*156 cm*
Blood Type	*O*
:	

← **DM**

← **VS..."HEIGHT" is in VSTESTCD**

← **LB..."ABO" is in LBTESTCD**

DM
Height?
Blood Type?
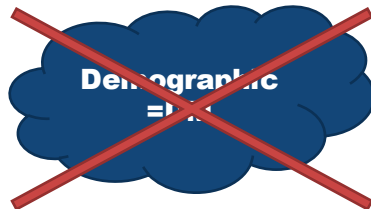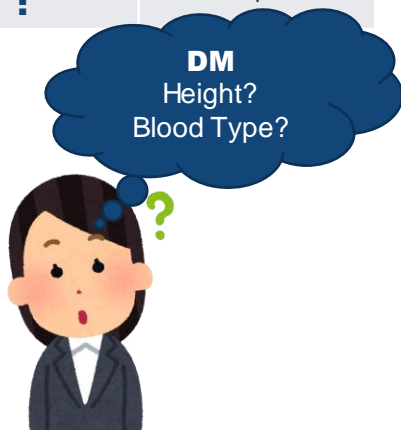
Examples for Bad Case 2

Medical History of the Breast Cancer

Diagnosis Date	22-Aug-2016
TNM at Diagnosis	T2N1M0
HER2 Score	3+
Operation Date	3-Oct-2016
Recurrence Date	22-Feb-2022
Metastatic Organ	Bone, Liver
:	:

MH...MHTERM=Breast Cancer, MHSTDTC=

RS...RSCAT=AJCC V7 RSTESTCD=AJCC101, RSOCCUR=

MI...MITESTCD=HER2, MIOCCUR=

PR...PRTRT=Breast cancer surgery, PRSTDTC=

MH...MHTERM=Breast cancer recurrent, MHSTDTC=

TU...TUTESTCD=DRCRLTLC, TUOCCUR=

Is there no choice but to create a domain?

Since these are asking the doctor, they are QS in the expanded interpretation?
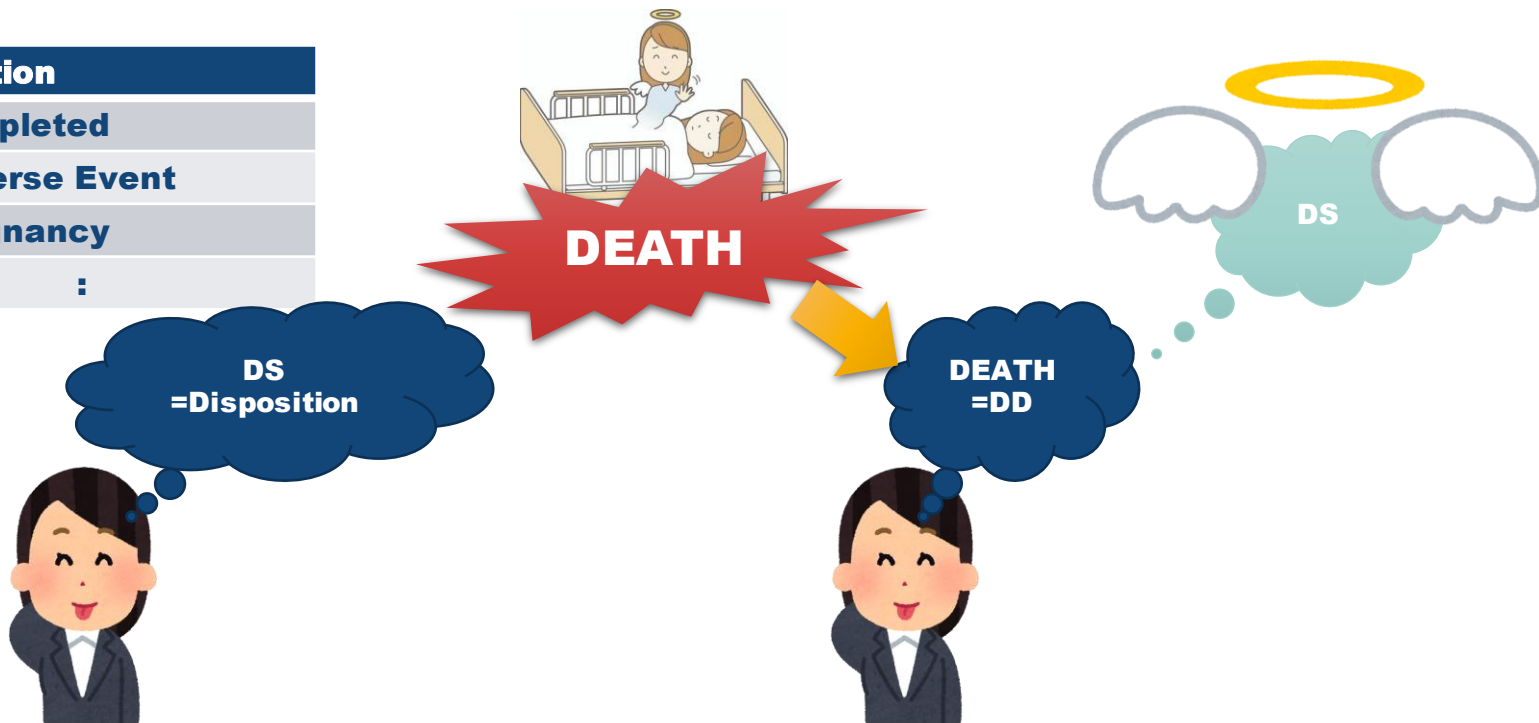
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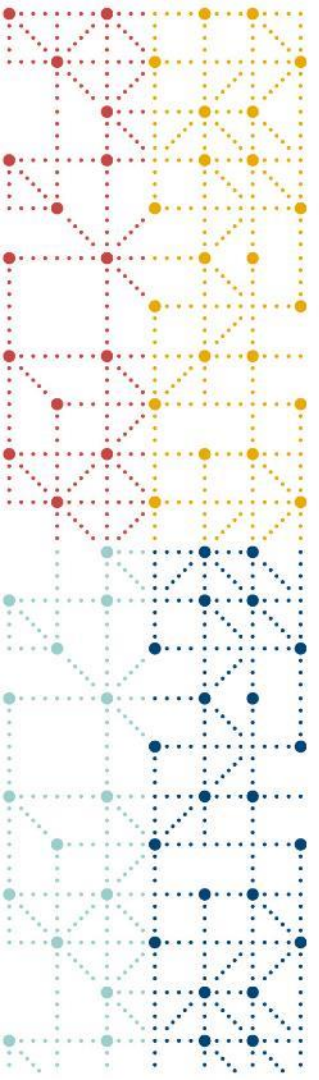
Lesson 2

I was swayed by my image of the domains.

Bad Case 3

Disposition
☐   Completed
☐   Adverse Event
☐   Pregnancy
:

DS =Disposition

DEATH

DEATH =DD

DS

Bad Case 4

RECIST		
Target	Lung R. S7	25mm
	Lung R. S8	7mm
	Liver S4	11mm
	-	-
	-	-
Target Response	PR	
Non-target Response	Non-CR/No-PD	
New Region		

Medical History of the Breast Cancer	
Metastatic Organ	Bone, Liver

TU...TUTESTCD=DRCRLTLC, TUOCCUR=

No!!
It is not
RECIST!

I thought TU, TR, RS
were for RECIST only.

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Bad Case 5

ECG	
Date	8-May-2021
Abnormal findings	N

EG domain is allowed only for each delta time measured by ECG

It is Normal

EG domain

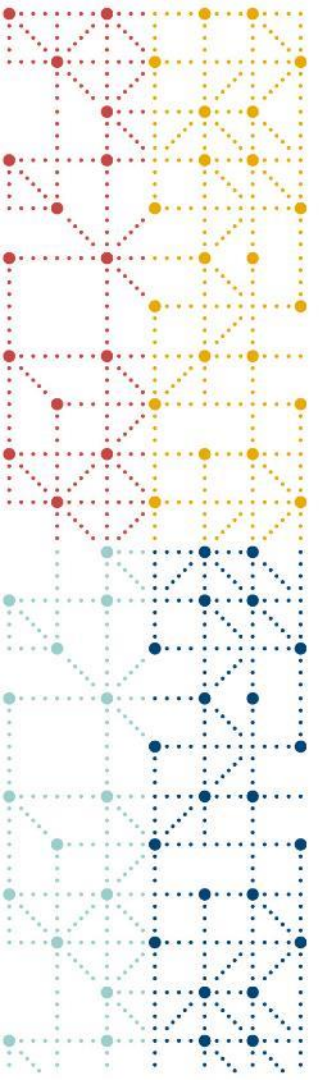QT xx msec
QRS xx msec
ST xx msec
: :
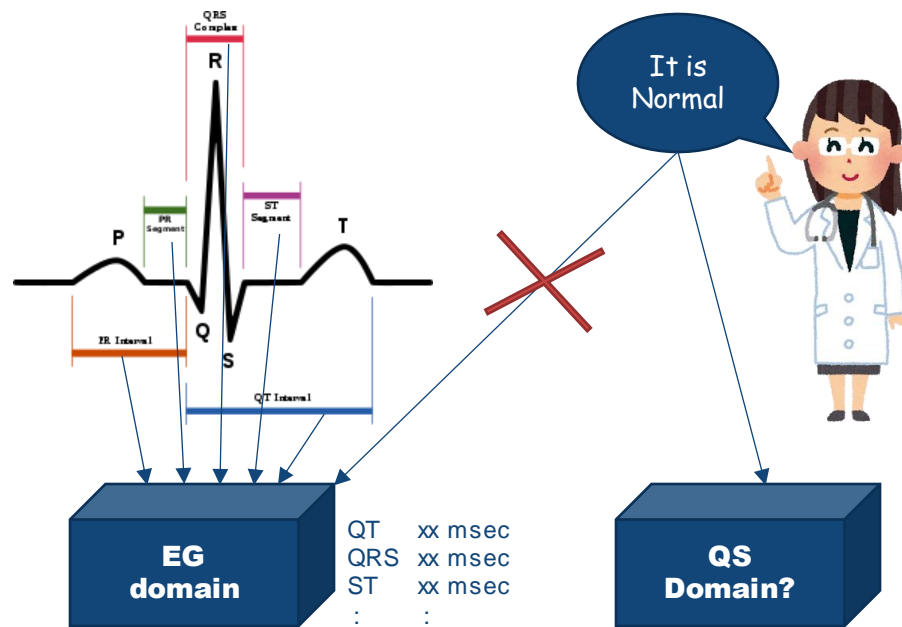
QS Domain?

Do not swayed by your image of the domains.

The worst thing you can do is just look at examples and think you understand.

It is important to grasp
the original image of the domain.

It is necessary to read SDTMIG carefully
and search all over Terminology.

Lesson 3

I thought that if I couldn't find anything in the domain, I should use SUPPQUAL.

Bad Case 1

Demographics	
Birth Date	18-Jun-1988
Height	156 cm
Blood Type	O
:	.

Demographic =DM

But DM domain does not contain them

DM
Height?
Blood Type?

If not, they are SUPP?

Do not use SUPPQUAL easily!

Essentially, do not use SUPPQUAL.

- Any measured items can be represented by one of the "Findings" domains.

- At first, you should look for the appropriate one on the xxTESTCD.

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Bad Case 6

Smoking Usage

- ☐ Never
- ☐ Former
- ☐ Current

SU domain dose not have it

If not, it is SUPP?

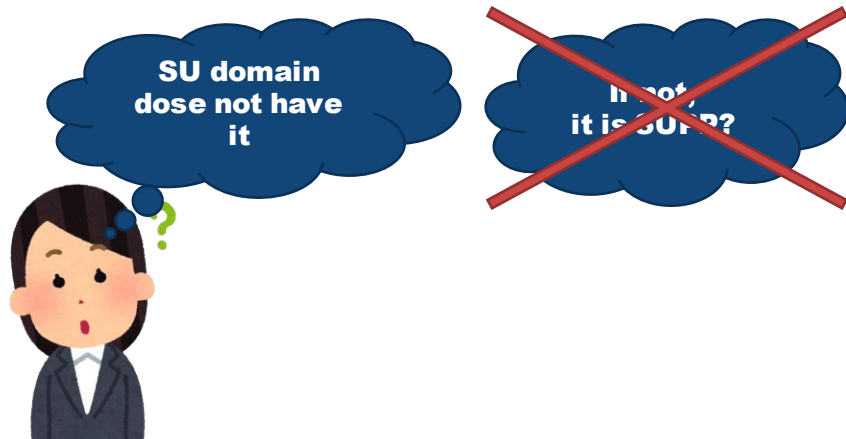Do not use SUPPQUAL easily!

Essentially, do not use SUPPQUAL.

- Not swayed by the item name.
- See the essence of the data.
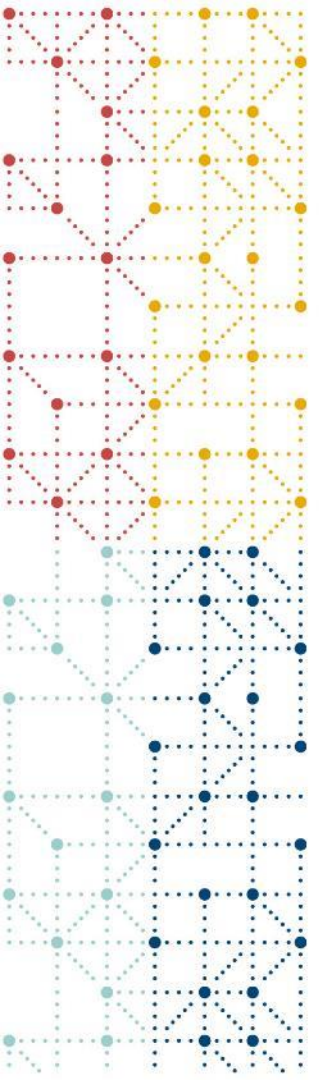- Make every effort before creating a SUPPQUAL.

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Example for Bad Case 6

Smoking Usage
☐ Never
☐ Former
☐ Current

SUPRESP	SUOCCUR	SUSTRF	SUENRF
Y	N		
Y	Y		PRIOR
Y	Y		ONGOING

SU domain dose not have it

If not, it is SUPP?

Lesson 4

I thought they were "QS" because the doctor's judgments were human opinions.

Bad Case 2

Medical History of the Breast Cancer	
Diagnosis Date	22-Aug-2016
TNM at Diagnosis	T2N1M0
HER2 Score	3+
Operation Date	3-Oct-2016
Recurrence Date	22-Feb-2022
Relapsed Organ	Bone, Liver
:	

Is there no choice but to create a domain?

I could not find the corresponding domain for the current disease history.
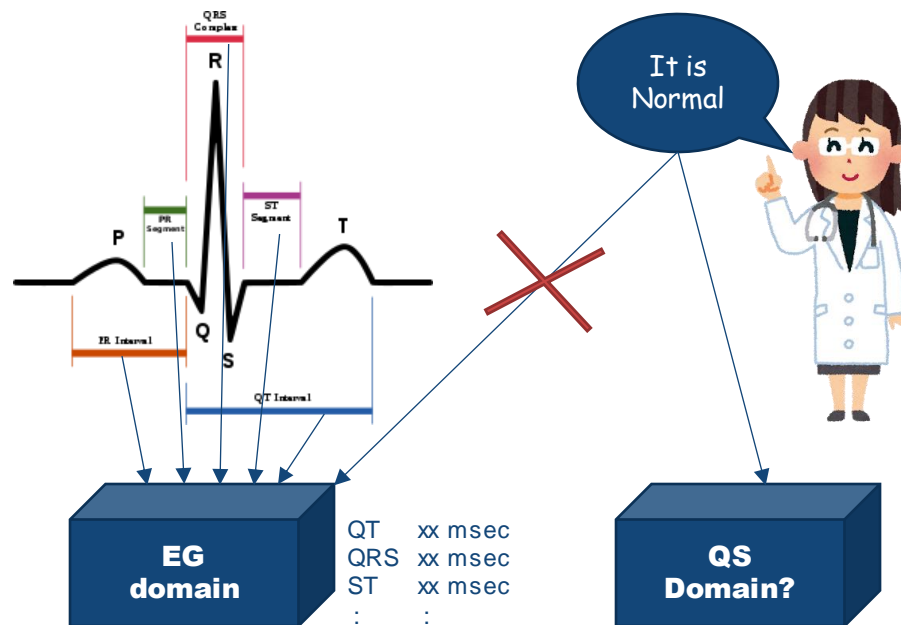
Since these are asking the doctor, they are QS in the expanded interpretation?

Asshat!! So, do you assign all CRF items to QS?

Bad Case 5

ECG	
Date	8-May-2021
Abnormal findings	N

It is Normal

EG domain is allowed only for each delta time measured by ECG

EG domain

QT   xx msec
QRS xx msec
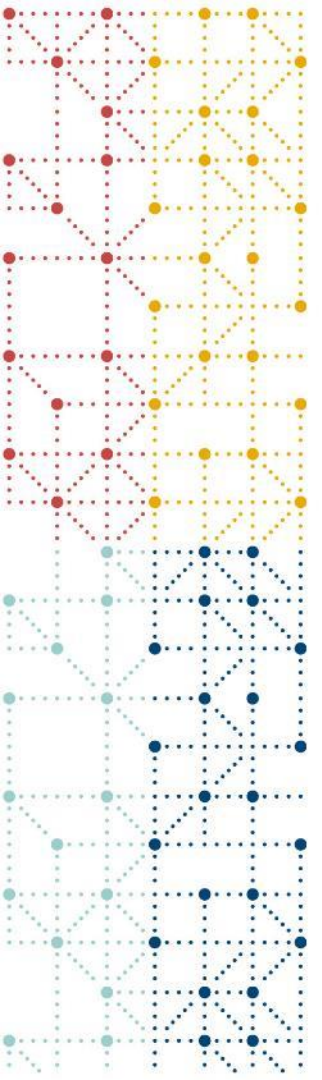ST   xx msec
:   :

QS Domain?

Lesson 4

"QS" is for <u>questionnaires.</u>

A findings domain that contains data for named, stand-alone instruments designed to provide an assessment of a concept.(SDTMIG V3.3)

FACT-G ...

HAMD

SF-36

No specimen
No equipment

QS

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Conclusions

Conclusions(1)

- If you explain the CRF heading and the domain in relation to each other, the image is easy to get excited, but it gets confused when it is divided into multiple domains.

- If only typical examples are described for the domain, the image of the domain will precede it and other uses will be missed.

- It is important to look for what is not there, rather than creating a suppqual if it is not there.

- Beginners may misunderstand the underlying intent of the domain, and you need to correct them with on-the-job training, etc.

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Conclusions(2)

- The most important thing to do in order to create an SDTM, is to read the SDTMIG from end to end, and carefully search for the contents of the Controlled Terminology.

- Do not puff up your domains' image from a few information, for example, brief figures or SDTMIG examples.
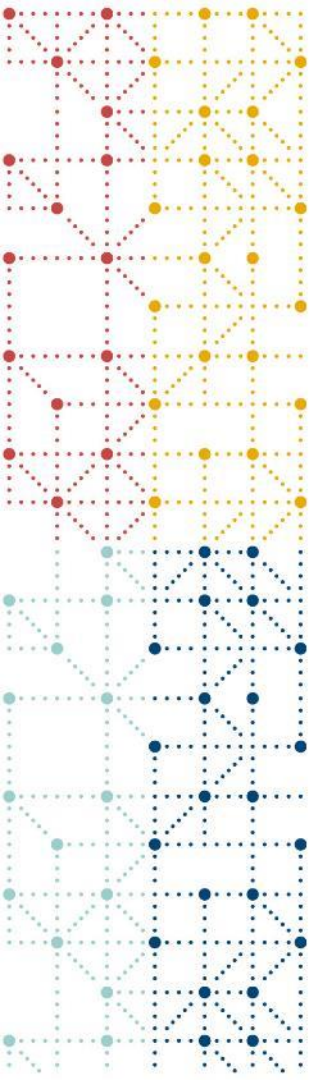
Thank You!

May your trainees have a wonderful CDISC life!