



2024

CDISC JAPAN
INTERCHANGE

TOKYO

12-13 JUNE: CONFERENCE & EXPO | 10-11 JUNE: TRAININGS

Examination of 42 Cases of Blunders in CDISC/SDTM in Physician-led/Industry-led Clinical Trials: Insights from the Field

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Meet the Speaker

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Ph.D. in Medicine, Kanazawa University – Ishikawa, Japan 2022

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"Sub-team learning from past blunders" members

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Mediscience Planning Inc.

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Sanwa Kagaku Kenkyusho Co., Ltd.

Astellas Pharma Inc.



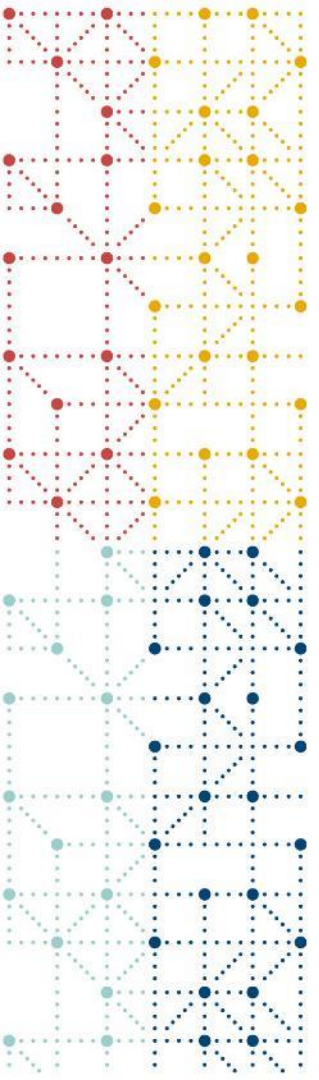
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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *I have no conflicts of interest to report.*



Agenda

1. Background and Objectives
2. Methods
3. Results
4. Discussions
5. Conclusions



Background and Objectives

Formation and purpose of
“Sub-team learning from past blunders”



Background

- This research started in January 2021.
- In Japan, several years have passed since the "Basic Principles on Electronic Submission of Study Data for New Drug Application" was issued in June 2014, the number of staff with experience in using CDISC/SDTM has also increased.
- While there are many cutting-edge presentations by pioneering figures, we thought it would be necessary to extract trends and priority issues that are likely to mistake from "case studies of blunders" by ordinary people, mainly beginners.



Objectives

The aim was to obtain the following effects from an examination of past failures regarding CDISC/SDTM.

- Our primary goal is to prevent staff, especially beginners, from repeating the same mistakes.
- For that purpose, we believe it is effective to investigate the causes of mistakes and use this as an opportunity to take countermeasures.



Methods

What were we doing for 3 years and 4 months?



Methods (1)

- preparation -

1. Discussed case collection rules.
 - Collection to be done anonymously (no inquiries allowed).
 - If the content is unclear, our members involved should make reasonable assumptions.
 - Collection to be done via Google Form.
2. Created a questionnaire form for case collection.
3. Explained our study and requested case collection from CJUG/SDTM team members.

Questionnaire items

1. Please select the category of the failure.
 - A) SDTM mapping
 - B) Define.XML creation
 - C) Reviewer's Guide creation
 - D) Creation of application file (file name, file format, folder, etc.)
 - E) Others... (free text)
2. Please give a simple title to the failure case (Example: I made it SUPP too easily)
3. What kind of data? (To the extent that there is no problem. Example: Smoking history in SU domain)
4. Please explain what you think went wrong.
5. Please explain what you think should have been done (correct answer)
6. Contact email address (optional)



Methods (2)

- Understanding and considering solutions -

4. Interpreted collected cases.
5. Discussed solutions based on lessons learned from collected cases and assigned them to respective domains if related.
6. After completing the above considerations, we reviewed the points for reflection and lessons learned for all cases to make them as uniform as possible.
7. Conducted frequent word analysis for solutions and lessons learned.
 - Unfortunately, frequent word analysis did not reflect any trends, because such as detailed explanations ranking higher.
 - Due to this issue, we decided to add hashtags to the cases and aggregate them.



Methods(3)

- Adoption of hashtags -

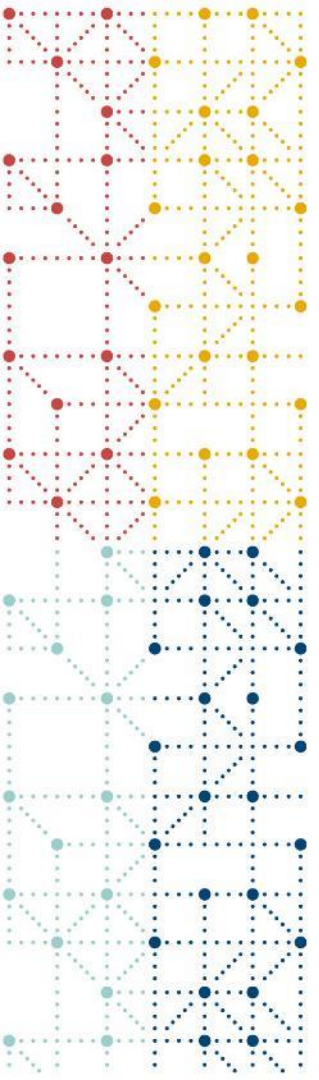
8. Tagged each case with hashtags based on first impressions (initial hashtags).
9. Conducted a preliminary analysis of frequently used words in initial hashtags, revealing the following issues:
 - Significant variation in expressions.
 - Considerable variability among cases.
 - Unclear specifics regarding insufficient checks, as in "insufficient confirmation."
 - Cases marked with general tags like "(lacking) [something]" but only tagged with [something].
10. Reviewed and revised all hashtags (final hashtags):
 - Harmonized expressions for similar content.
 - Added clarity to vague tags like "insufficient confirmation" by specifying what was lacking.
 - Added tags to some cases.
11. Aggregated the final hashtags.

Sample

Items collected through questionnaire

Results of team discussion

#	Domain	Classes	Simple title	What kind of data?	What you think went wrong?	Solutions	Lessons	Hashtags
1	SU	Mapping	I made it SUPP too easily	Smoking history in SU domain (Never / Former / Current)	There was no item that could store smoking history in the SU domain, so I changed it to SUPP.	If you have never smoked, enter SUPRESP=Y and SUOCCUR=N. If you have smoked in the past or are currently smoking, enter SUOCCUR=Y and SUENRF as PRIOR or ONGOING. I chose SUPP because I was swayed by the name of the item "smoking history," but the point is that it only needs to be able to express these three states (never smoked/smoked in the past/currently smokes) >>> Essential meaning all you have to do is grasp it.	Don't be swayed by the item names! Look at the essential meaning! Before you decide to SUPP, think carefully whether you really have no choice but to SUPP.	#Lack of considering domain selection #domain - SUPP #domain - SU



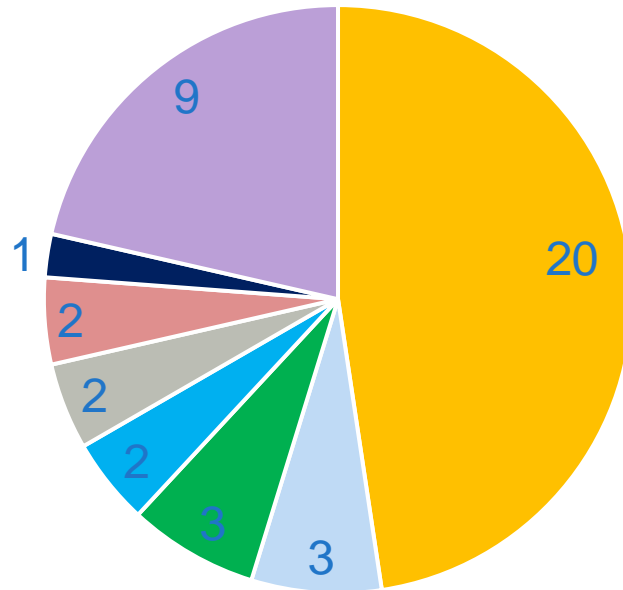
Results

Where do people blunder?



Where do people blunder?

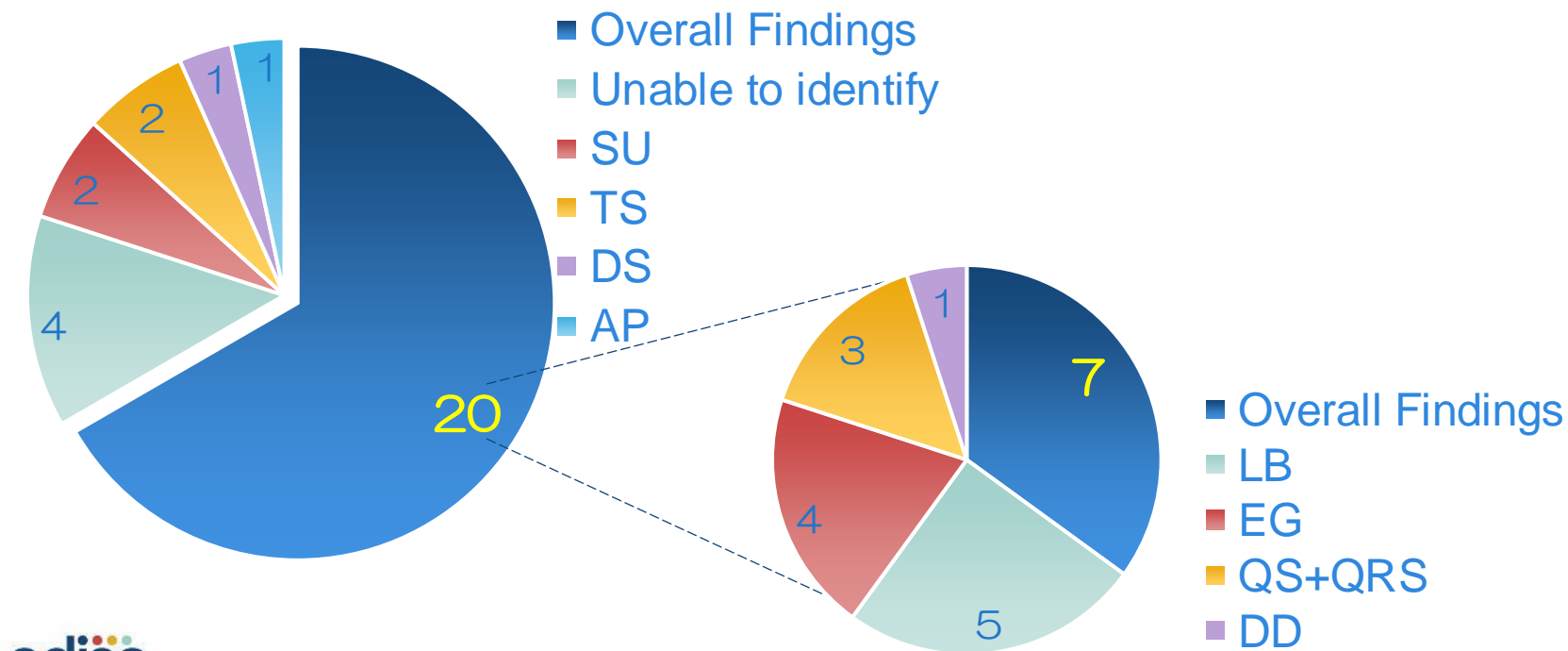
We collected 42 blundered cases.



- Mapping
- Pinnacle21
- Programming
- Define.XML
- TS domain
- Lecture
- Reviewer's Guide
- Others

In which domains do people blunder?

30 out of 42 cases were related to domains.



Frequent hashtags (1) - Lack -

95% (40/42) of cases were caused by some kind of “lack”.

- Communications (colleagues / superiors / statisticians / CROs / vendors) 13
- Confirming the description of SDTMIG 9
- Confirming the specification documents 7
- Confirming the deliverables 5
- Considering domain selection 4
- Confirming the knowledge level of the contractors 4
- Confirming the operating procedures 3
- Education 3

Frequent hashtags (2) - Confirmation -

69% (29/42) of cases were caused by some kind of “Confirmation”.

- Confirming the description of SDTMIG 9
- Confirming the specification documents 7
- Confirming the deliverables 5
- Confirming the knowledge level of the contractors 4
- Confirming the operating procedures 3

Frequent hashtags (3) - Others -

- Not a blunder 9
- Outsourcing vendors 8
- Review system 6
- Pinnacle21 issue - check 5
- Data quality 3
- Imitated SDTM 3
- Do not worry alone 3
- Preconceptions 3



Discussions

What did we learn from this study?





Overall trends

There were many mistakes related to **mapping**, especially in the **Findings type mapping**.

The following factors were considered to be the reasons for the high failure rate:

- There are many types of domains
- The data handled is diverse and the acquisition items **must be created with xxTESTCD**
- Data from external vendors are received
- Mapping **cannot be determined uniquely**



About “Lack”

With the exception of two cases that did not fail, 95% of cases were caused by some kind of deficiency, and in particular, **lack of confirmation** was thought to be a common cause in many cases of failure.

Lack of confirmation was thought to be likely to occur mainly in the following cases.

- 1) There are **problems with the process** (the processes are not defined, confirmation works are missing in the processes, etc.)
- 2) The **checker lacks skills**
- 3) The staff **neglects confirmation**

Lack of knowledge such as lack of SDTMIG confirmation, lack of consideration, and lack of education were also cited as causes.

Discussion of solutions

The following were considered as solutions:

- Insufficient confirmation, insufficient consideration, etc.
 - ☞ Clarification of processes and skill sharing **using check sheets**
- Lack of knowledge, lack of education
 - ☞ Develop self-solving skills by **teaching how to research and think** rather than just teaching answers to questions
- Lack of communication is at the root of the "lack"
 - ☞ Close **communication** not only between superiors and subordinates, but also between other departments and other companies/facilities is necessary to detect and compensate for the "lack" (**Goodies are important items**)





Preconceptions

- Among the cases, there were some that did not fail. It was thought that there was a tendency to think too formally.
- The **importance of communication was reconfirmed**, as it was considered important to consult with those around you rather than worrying alone.



Conclusions

How can you avoid making mistakes in the future?



Conclusions

- Lack of xx, especially lack of confirmation, causes failure.
 - Don't forget to check things such as clarifying processes and using check sheets.
- It is important to develop self-solving skills to overcome lack of knowledge and education.
 - Instead of just teaching the answer, we teach how to research and how to think.
- Communication is the most important thing
 - Communication is important not only between superiors and subordinates, but also between other departments and other companies/facilities.
 - It is important not only to check and educate people, but also not to suffer alone.
 - Goodies are important items♥



Extra

Even behind great success,
people still make mistakes.



Poster presentation at the 15th annual meeting of Japan Society of Clinical Trials and Research



I had pasted the poster in the wrong place and had to reposition it.
What's more, the numbers were wrong too.



Thank You!
Gaow!

Did you make
blunders?

You should
confirm!

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