



JAPAN ACADEMIC WORKSHOP

Friday, 17 November | 1:00pm -5:15pm

Distribution of CDISC Educational Videos for Beginners

Presented by Shizuko Takahara, Lecturer,
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Meet the Speaker

Shizuko Takahara

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

Master of Psychology, Kansai University – Osaka, Japan 2013

Over 25 years of experience in Clinical Data Management in pharmaceutical companies and academia.



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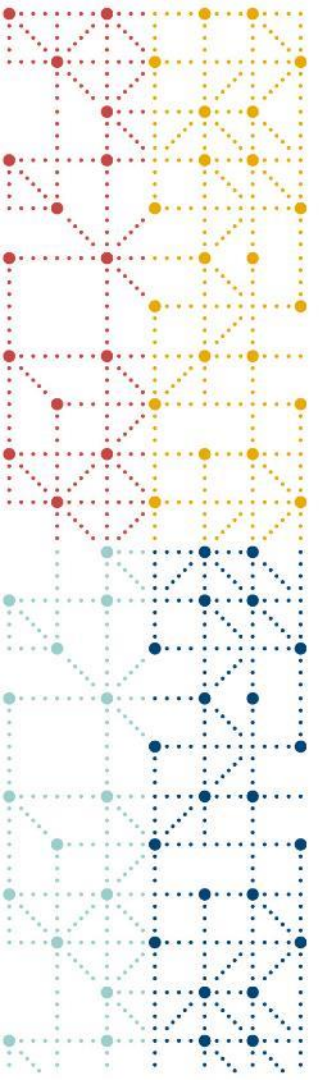
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- *This presentation is the presenter's personal opinion and does not represent the organization.*

- *I have no conflicts of interest to report.*



Agenda

1. CDISC diffusion status in Japanese academia
2. Introduction of CDISC Neko-channel published on YouTube
3. How to Use CDISC Neko-channel
4. Conclusion



CDISC diffusion status in Japanese academia

CDISC diffusion status in Japanese academia

- Results of CDISC Implementation Questionnaire for Japanese AROs (Apr - Jun/2020)^{※1}
 - CDASH, SDTM, or ADaM have not been implemented : 65.9%
 - Number of Data Managers : Median=3, Minimum=0, Maximum=28
 - Obstacles to implementing CDISC standards
 - Human and economic effort required, lack of resources : 85.4%
 - No personnel with knowledge of CDISC:61.0%
- CJUG/SDTM Shin-Ahiru-san Team (launched in Dec 2022)
 - Applications flooded in for "Academia Volunteer Members who want to be CDISC compliant but have been unable to do so".



It's not that ARO staff in Japan aren't interested in CDISC, it's just that they want to implement CDISC but are unable to do so.

^{※1} Nagai K, Ikeda Y, Ohno M, Saito TI, Hinotsu S (2022). Current status and challenges of CDISC standard implementation in Japanese academia. Japanese Pharmacology & Therapeutics, 50, s51-s59

Current Status of ARO in Japan

- Japanese AROs' role is to assist the investigator in clinical research.
 - AROs are attached to hospital organizations, many organizations are staffed co-medicals and do not have computer science specialists.
 - Small size, little funding and staff.
- Even the ARO staff members who participate in Shin-Ahiru-san team only attend about an hour once a month as a web conference, and the rest of the time **they must study on their own.**

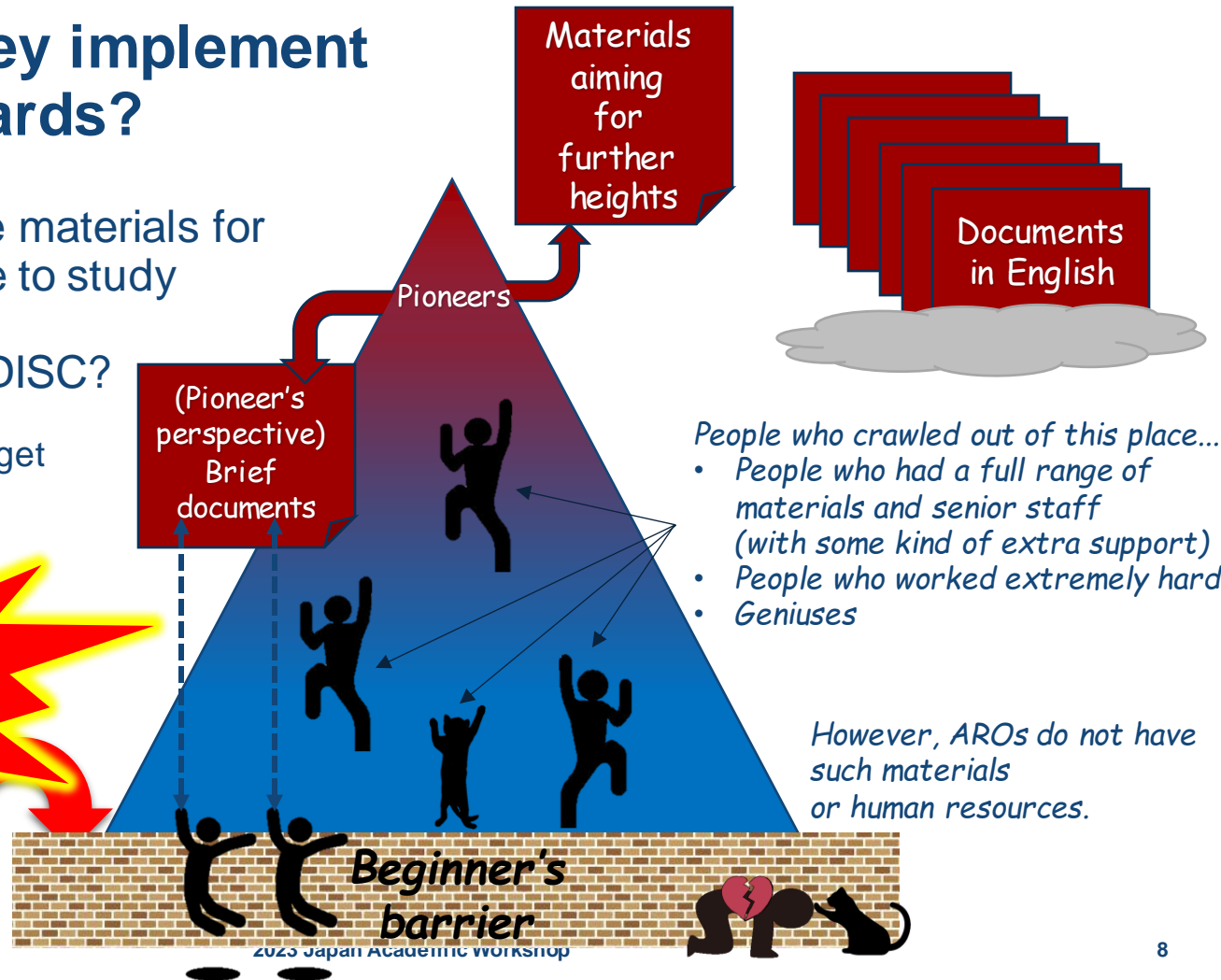


We need materials that enable ARO staff, who are not computer specialists and whose native language is Japanese, to learn CDISC on their own in a fun and enjoyable way **without losing their minds.**

Why can't they implement CDISC standards?

- Lack of Japanese materials for entry level people to study on themselves.
- Polarization of CDISC?
 - Pioneers
 - People who can't get over the barrier

We need materials to overcome this barrier!





Introduction of CDISC Neko-channel published on YouTube



Features of CDISC Neko-channel

The CDISC Neko-channel is a collection of short videos aimed at beginners who have no knowledge of CDISC, as well as beginners who have studied it a little.

- Most of them are short videos of less than 3 minutes.
 - The viewers can watch them in your spare time and never get bored.
- It is provided by Neko-chan personally.
 - Since it is not an organizational operation, there are no meetings or proofreading, and we can provide information quickly and with free ideas.
- Rather than Neko-channel teaching viewers various know-how about CDISC, viewers watch Neko-chan teaching the ignorant girl Zunda-chan.
 - The viewers can easily view them without feeling inferior.
 - It can add humor to the videos.
- There are currently 33 short videos on CDISC Neko-channel.



Example : English Version

I am sorry, but there is no English version of CDISC Neko-channel, and this English version is only 5 pages translation for this presentation.

Even cats can understand

☆CDISC channel☆

What is CDISC?

Person inside: Neko-chan
Voice: ONDOKU-san, Ana and Sara



What is CDISC?



Is CDISC like that thing my mom used to groove to when she was young?



COMPACT
disc
CD-ROM

Nah, that's a different beat, honey. That's a CD. CDISC is the international standard for clinical trial data.



Huh? I'm lost...(>_<)

Don't worry, I'll break it down for you a bit more.



For example, traditional data...

Demographic Data

Patient ID	BIRTHDATE	SEX	...
0001	04-05-06	1	

YY-MM-DD	0	Male	1	Male
MM-DD-YY	1	Female	2	Female
DD-MM-YY	0	Female	1	Female
	1	Male	2	Male

6-May-2004?
5-Apr-2006?
4-May-2006?



Male?
Female?

For instance, even if we receive data like this, we won't understand what it means.



The birthdate order isn't clear, and when it says '1' in the sex column, we can't tell if it's a male or a female.



Getting it is useless, right? 



For example, if there are three studies...

- Study A
 - Demographic (DEMOG)

PATID	BDATE	AGE	SEX	ICDATE
0001	84/12/31	32	0	17/05/01

- Study B
 - Demographic (BG)

IDNO	BIRTHDAY	GENDER	CONCDAY
1	31-12-84	M	01-05-17

- Study C
 - Demographic (BACK)

SUBJECT	INI	BIRTH	IC	GND
04-01	S.T	19841231	20170501	2

different file names

different variable names

different code

different format

different order

It was all jumbled up like this.



This is a mess!
The ones receiving it must be so annoyed.



The CDISC standards were created!

So, you know, they came up with these CDISC standards.
Like, for patient demographics, look!



STUDYID	DOMAIN	USUBJID	...	RFICDTC	...	BRTHDTC	AGE	AGEU	SEX
STUDY-A	DM	0001		2022-10-23		1988-08-08	34	YEARS	M

Like this, they set rules for item names, order, date formats,
and even using 'M' for males and 'F' for females in gender.
Once they established these rules, trials won't be all over
the place, and we won't have a hard time understanding the
data, right?



The people who made it are amazing!



Example : Japanese Orinigo Version

CDISCってなに？



CDISCって、平成の時代に音楽聞いてたあれのこと？



COMPACT
disc
CD-ROM

ちがうよ、あれはCD。CDISCは、臨床試験データの国際標準なの。



ええ～、よくわかんない～
(>_<)

じゃあ、もうちょっとくわしく説明するわね。



たとえば、今までのデータは・・・

• 例：患者背景

被験者番号	生年月日	性別	・・・
0001	04-05-06	1	

YY-MM-DD	0	男	1	男
MM-DD-YY	1	女	2	女
DD-MM-YY	0	女	1	女
	1	男	2	男

2004年5月6日?
2006年4月5日?
2006年5月4日?



男?
女?

例えばこんなデータをもらっても、データの内容がわからないよね。



生年月日は並び順がわからないし、性別1って、男か女かわからないし



もらっても意味ないじゃん (怒)



たとえば、研究が3つあったら・・・

- A研究

- 患者背景(DEMOG)

PATID	BDATE	AGE	SEX	ICDATE
0001	84/12/31	32	0	17/05/01

- B研究

- 患者背景(BG)

IDNO	BIRTHDAY	GENDER	CONCDAY
1	31-12-84	M	01-05-17

- C研究

- 患者背景(BACK)

SUBJECT	INI	BIRTH	IC	GND
04-01	S.T	19841231	20170501	2

ファイル名が違う

項目名が違う

コードが違う

データの形が違う

項目の順序が違う

こんな感じで、バラバラだったのよ。



むちゃくちゃじゃない！これじゃ、もらう側は迷惑だね。



CDISC標準っていうルールができたの

だからね、CDISC標準っていうルールができたの。
例えば患者背景ならね、ほら見て！



STUDYID	DOMAIN	USUBJID	...	RFICDTC	...	BRTHDTC	AGE	AGEU	SEX
STUDY-A	DM	0001		2022-10-23		1988-08-08	34	YEARS	M

こんなふうに、項目の名前も、順番も、日付の表現の仕方も、
性別なら男はMで女はFで表す、など、ルールを決めたら、
試験によってバラバラにならなくて済むし、
データの内容がわからない、なんてこともなくなるでしょ。



作った人、すご〜
い！



How to Use the CDISC Neko-channel

Preferred ways to use the CDISC Neko-channel

The CDISC Neko-Channel is a collection of comical short videos.

Best viewed in the following situations.

- Break time
- On the train or bus
- At home



Usage not recommended

The CDISC Neko-Channel is a collection of comical short videos.

- Not recommended for formal training.
- There are more suitable videos for such occasions.
 - NHO Nagoya Medical Center
 - CDISC Japan User Group



Referenced from CJUG SDTM
Newcomer Education Video 1st
“What is CDISC?”

How to access these videos? (Japanese only)

Those videos can be accessed from “Links” on aCRF.jp.



動画

CDISC | NHO名古屋医療センターARO (随時更新)

NHO名古屋医療センターAROのYoutube

CDISCねこちゃんねるのポータルサイト | ねこちゃん (随時更新)

ねこちゃんのYoutube

CJUG-SDTM (CDISC Japan User Group - SDTM team) | CJUG-SDTM (随時更新)

CJUG-SDTMのYoutube

Or access from the QR code



←Neko Channel

NHO →
Nagoya
Medical
Center



→
CJUG





Conclusion



Conclusion

- Not a few ARO staff are interested in studying CDISC.
- By releasing free CDISC educational content, we have created a system in which even ARO staff can easily study on their own.
- At CDISC Neko-channel, Neko-chan is working hard to ensure that no one falls through the cracks.
- The video creators plan to continue to further enhance the content in the future.



Thank You!

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