



Pioneering Efforts to Expand CDISC Standards in Japanese Academic Research

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Meet the Speaker

Megumi Kitayama

Title: Chief of Data Center

Organization: Wakayama Medical University

I have over 10 years of experience in the Clinical Trials industry, and I have experience as a Clinical Data Manager (CDM) in many academic research developments.

Japan CDISC Coordinating Committee member from 2023
CDISC Japan User Group SDTM sub-team leader from 2022



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.*



Agenda

1. Current situation of implementing CDISC standards in the Japanese Academic Research Organization
2. Establishing a team in the CJUG SDTM team
3. Team Activity Details



Current situation of implementing CDISC in the Japanese Academic Research Organization



**Do you think CDISC standards have been
widely adopted in AROs?**

Implementing CDISC Standards at ARO in Japan

- Questionnaire Survey
- Period: April 27 to June 30, 2020
- Target: 90 AROs
 - CDISC expert liaison committee of the Academic Research Organization (ARO) council
 - TG3(Topic Group 3) of National University Hospital Clinical Research Promotion Initiative (NUH-CRPI)
 - Metropolitan Academic Research Consortium (MARC)

Result	Site Number
No implementation	27 (65.9%)
CDASH	6 (14.6%)
CDASH, SDTM	3 (7.3%)
SDTM	2 (4.9%)
SDTM, ADaM	2 (4.9%)
CDASH, SDTM, ADaM	1 (2.4%)

Nagai et al, Jpn Pharmacol Ther2022 ; 50 suppl 1 : s51-61

Reasons for Obstacles During Implementation

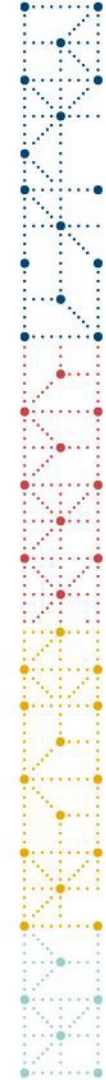
- Shortage of human resources and financial reasons: 85.4%
- Lack of human resources with CDISC knowledge: 61.0%
- Not knowing how to implement the CDISC standards: 31.7%

Nagai et al, Jpn Pharmacol Ther2022 ; 50 suppl 1 : s51-61

ARO is interested in CDISC,
but they need help to implement CDISC.



**Why don't you consider taking
public training?**



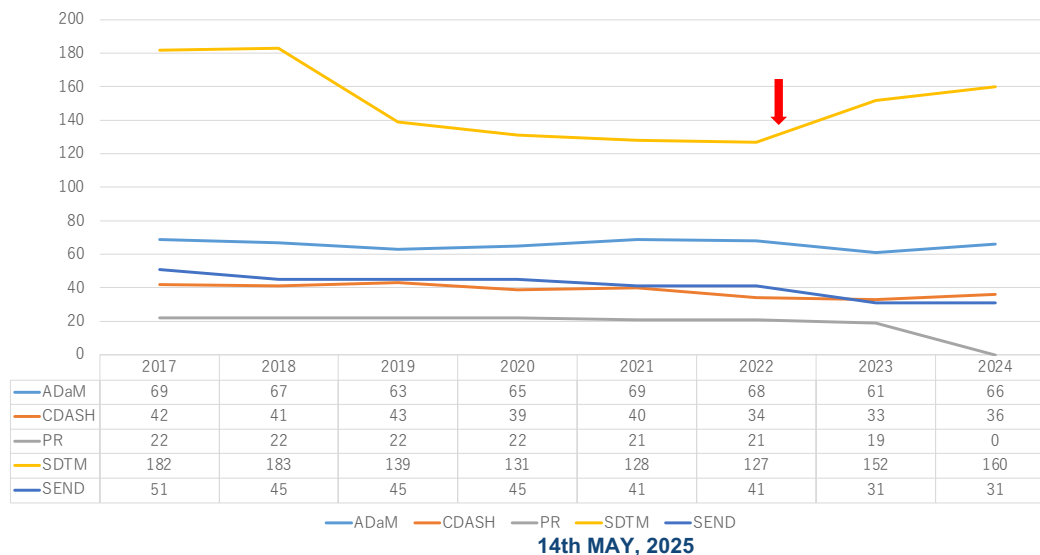
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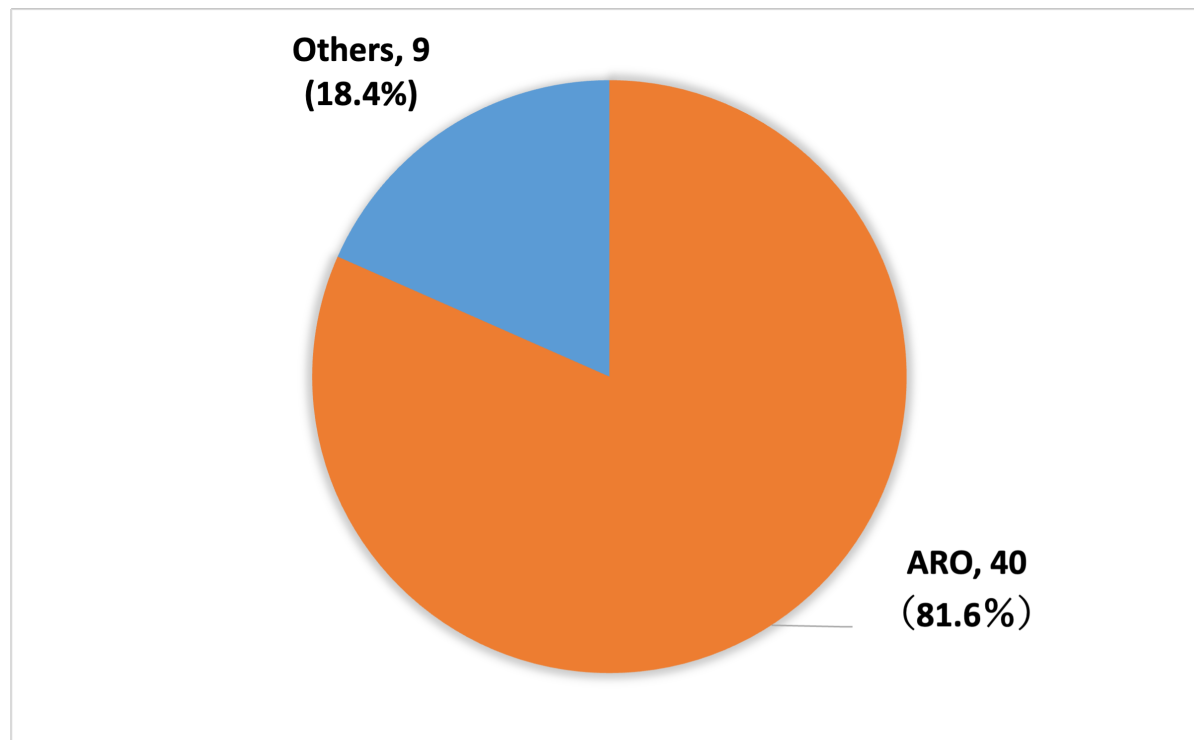
Establishing a specific team in the CJUG SDTM team

Establishing a New Team

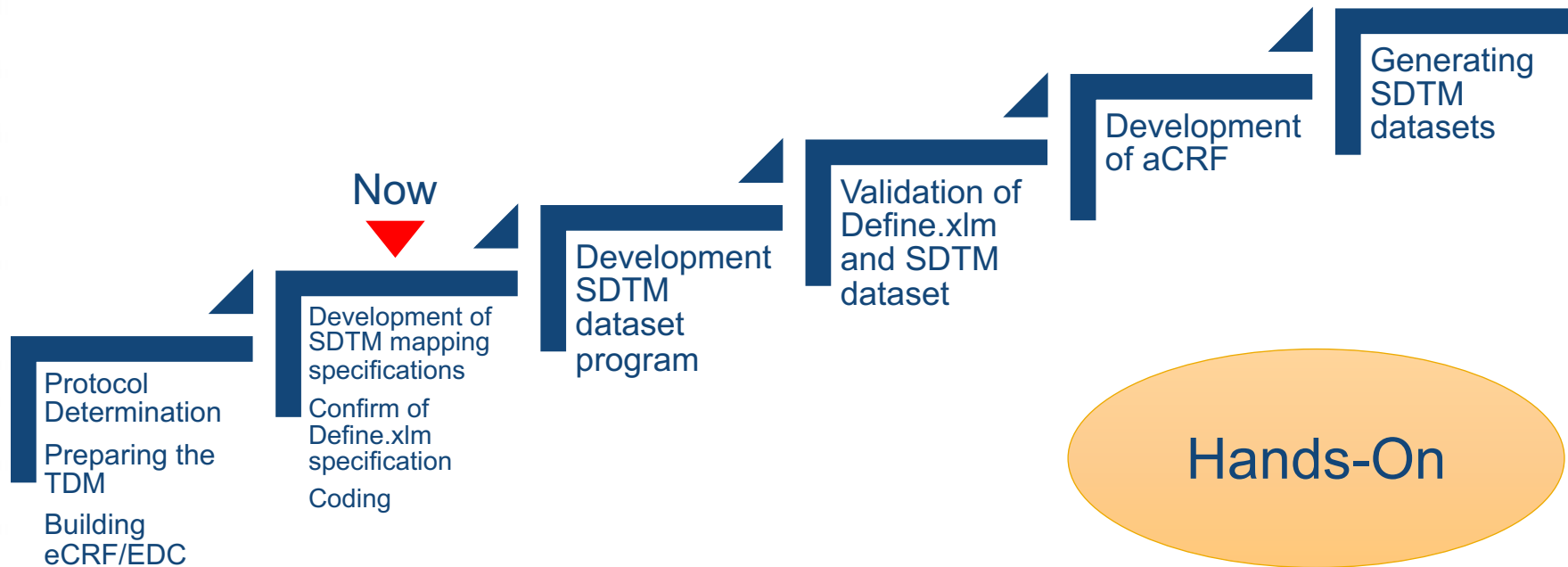
- Send a recruitment eblast on December 1st.
- December 9th, 2022: 45 members join the CJUG SDTM monthly Meeting.



Members status

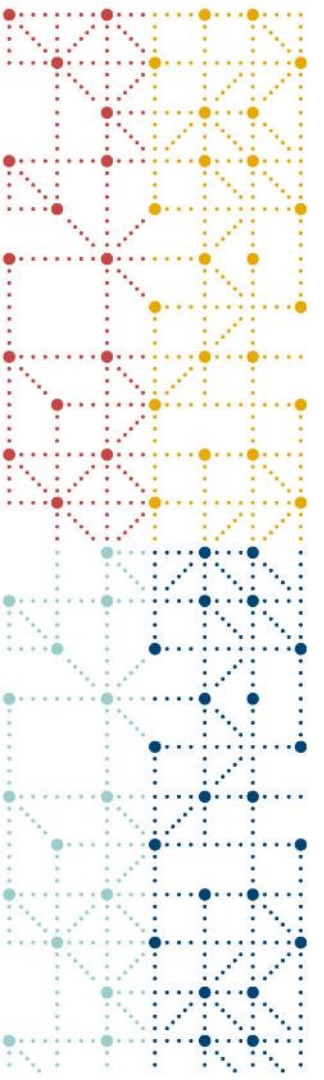


Process of the Team's Activity



Overview of CJUG SDTM Team Activities

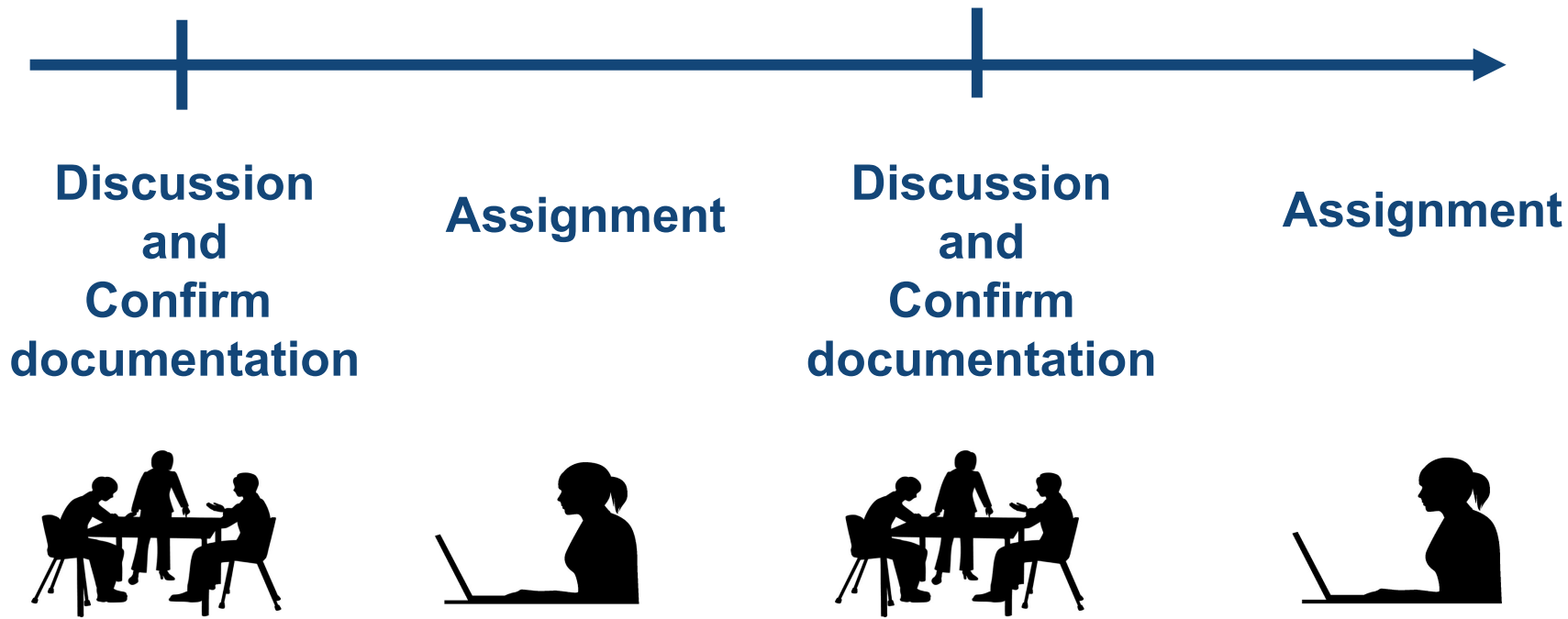
- Monthly meetings take place on the second Friday afternoon.
- Participants can join in a hybrid format — either on-site or online.
- Monthly meeting agenda
 - Internal Presentation
 - Guest Presentation
 - Team activities



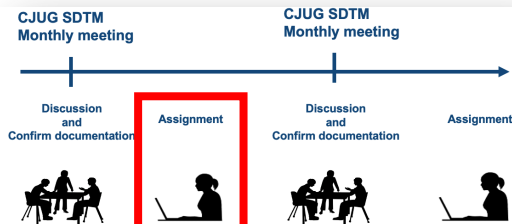
Team Activity Details

CJUG SDTM Monthly meeting

CJUG SDTM Monthly meeting



Example of Our Team's Activities



N	Domain	Keys	Variable Name	Variable Label	Type	length	Controlled Terms, Codelist or Format	Role	Col	Origin	マッピング	項目名	Mapping Definition or Derivation Rule
1	CM	1	STUDYID	Study Identifier	Char	200		Identifier	Req				
2	CM		DOMAIN	Domain Abbreviation	Char	200	CM	Identifier	Req				
3	CM	2	USUBJID	Unique Subject Identifier	Char	200		Identifier	Req				
4	CM		CHSEQ	Sequence Number	Num	8		Identifier	Req				
5	CM		CHGRPID	Group ID	Char	200		Identifier	Perm				
6	CM	3	CHSPID	Sponsor-Defined Identifier	Char	200		Identifier	Perm				
7	CM		CHTRT	Reported Name of Drug, Med, or Therapy	Char	200		Topic	Req				
8	CM		CHMODIFY	Modified Reported Name	Char	200		Synonym Qualifier	Perm				
9	CM		CHDECOD	Standardized Medication Name	Char	200	WHODD	Synonym Qualifier	Perm				
10	CM	4	CHCAT	Category for Medication	Char	200	CHCAT	Grouping Qualifier	Perm				
11	CM		CHSCAT	Subcategory for Medication	Char	200	(TRTSET)	Grouping Qualifier	Perm				
12	CM		CHRESP	CM Pre-Specified	Char	200	(NY)	Variable Qualifier	Perm				
13	CM		CHOCOUR	CM Occurrence	Char	200	(NY)	Record Qualifier	Perm				
14	CM		CHSTAT	Completion Status	Char	200	(ND)	Record Qualifier	Perm				
15	CM		CHREASND	Reason Medication Not Collected	Char	200		Record Qualifier	Perm				
16	CM		CHENDC	Indication	Char	200		Record Qualifier	Perm				
17	CM		CHCLAS	Medication Class	Char	200	WHODD	Record Qualifier	Perm				
18	CM		CHCLASCD	Medication Class Code	Char	200	WHODD	Record Qualifier	Perm				

データの導出元
[Protocol]
プロトコルから設定される値
[CRF]
CRFにて設定、収集された値
[Derived]
導出値 (例: 他受試者からコピーした値、他受試者との計算による派生結果など)
[Assigned]
個別の判断による値 (例: コーディング結果など)
[eODT]
臨床検査施設などから受け取った電子データの値

No.	Domain	Keys	Variable Name	Variable Label	Type	length	Controlled Terms, Codelist or Format	Role	Core	Origin	マッピング	項目名	Mapping Definition or Derivation Rule
1	CM	1	STUDYID	Study Identifier	Char	200		Identifier	Req	Protocol			"Pnewduck"
2	CM		DOMAIN	Domain Abbreviation	Char	200	CM	Identifier	Req	Assigned			"YCH"
3	CM	2	USUBJID	Unique Subject Identifier	Char	200		Identifier	Req	Derived			そのままそのまま
4	CM		CHSEQ	Sequence Number	Num	8		Identifier	Req	Derived			Keyでソートした順に近接順に連番付与
5	CM		CHGRPID	Group ID	Char	200		Identifier	Perm	Assigned			
6	CM	3	CHSPID	Sponsor-Defined Identifier	Char	200		Identifier	Perm	CHP			供用薬/前用薬/供用薬名
7	CM		CHTRT	Reported Name of Drug, Med, or Therapy	Char	200		Topic	Req	CRF			
8	CM		CHMODIFY	Modified Reported Name	Char	200		Synonym Qualifier	Perm	CHP			
9	CM		CHDECOD	Standardized Medication Name	Char	200	WHODD	Synonym Qualifier	Perm	CHP			
10	CM	4	CHCAT	Category for Medication	Char	200	CHCAT	Grouping Qualifier	Perm	CHP			
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No.	Domain	Keys	Variable Name	Variable Label	Type	length	Controlled Terms, Codelist or Format	Role	Core	Origin	マッピング	項目名	Mapping Definition or Derivation Rule
1	CM	1	STUDYID	Study Identifier	Char	200		Identifier	Req	Protocol			"newduck"
2	CM		DOMAIN	Domain Abbreviation	Char	200	CM	Identifier	Req	Assigned			"YCH"
3	CM	2	USUBJID	Unique Subject Identifier	Char	200		Identifier	Req	Derived			そのままそのまま
4	CM		CHSEQ	Sequence Number	Num	8		Identifier	Req	Derived			Keyでソートした順に近接順に連番付与
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9	CM		CHDECOD	Standardized Medication Name	Char	200	WHODD	Synonym Qualifier	Perm	CHP			



14	CM		CMSTAT	Completion Status	Char	200	(ND)	Record Qualifier	Perm	Assigned			
15	CM		CMREASND	Reason Medication Not Collected	Char	200		Record Qualifier	Perm	CRF / Assigned			
16	CM		CMENDC	Indication	Char	200		Record Qualifier	Perm	CRF / Assigned			
17	CM		CMCLAS	Medication Class	Char	200	WHODD	Variable Qualifier	Perm	Assigned		コーディング結果が入る	
18	CM		CMCLASCD	Medication Class Code	Char	200	WHODD	Variable Qualifier	Perm	Assigned		コーディング結果が入る	

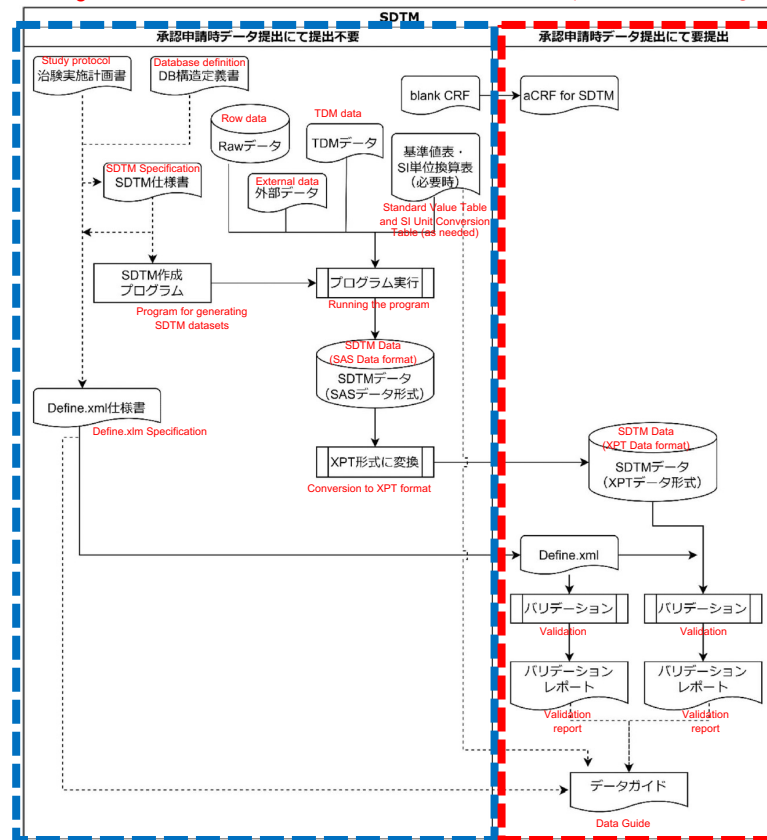
Challenges Faced by CDISC beginners

- **CDISC deliverables are not used in AROs, so many have never seen them.**
- **It's hard to visualize what the final output should look like.**
- **Unclear how to create SDTM datasets.**
- **Don't know the required steps or specific tasks.**

Workflow for Creating SDTM Datasets

Not Required at Marketing Authorization Submission

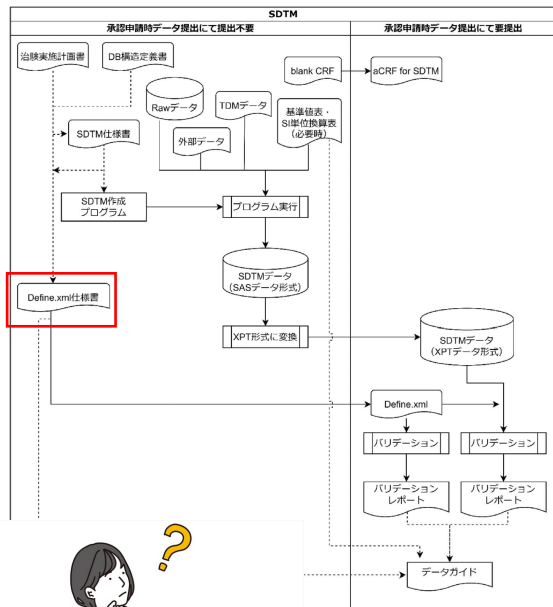
Required at Marketing Authorization Submission



- Not required by the regulatory agency
- Interim outputs

- Required by the regulatory agency
- Final deliverable

It's Still Hard to Understand — Even After Looking It Up



- What is Define.xml?
- Why is it necessary?
- What kind of information does it contain?

Got questions?
Just ask the CJUG SDTM team
- a group of true specialists!



Feel free to ask

— there are many experts in the CJUG SDTM team

9:54



“What is Define.xml in the first place?”

“What kind of document is considered the deliverable?”

“When and where is it used?”

“Why is it necessary?”

Can someone please explain this at the next SDTM team meeting?

Alright! Let's cover the basics of Define.xml in our internal session!

10:24



10:26



It's the specification file for SDTM datasets, and according to CDISC standards, it has to be written in xml.

Making CDISC Standards the New Normal for AROs

- CDISC implementation has not yet been widely adopted in Japanese AROs.
- Key barriers include limited resources and a lack of personnel with CDISC expertise.
- A new CJUG team members gain **hands-on experience** with SDTM processes and tasks through collaborative activities.
- Beginners are supported by experienced CJUG SDTM members, which helps prevent discouragement.
- **Mutual support, not isolation, is essential for successful CDISC implementation.**



Thank You!



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