WITH STANDARDS – UNLOCK THE POWER OF DATA

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2022
JAPAN
INTERCHANGE
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Update on activities of CJUG CDASH sub team

Yuko Tamura, Team Leader, CJUG-CDASH Team
Noriyuki Furuya, Sub-Team Leader, CJUG-CDASH Team

Meet the Speakers

Yuko Tamura

Title: Team Leader

Organization: CJUG-CDASH Team

She has 15 years experience as a clinical trial coordinator, and worked in service planning for an eSource and ePRO service vendor, and has been CJUG CDASH team member since 2017.

Noriyuki Furuya

Title: Sub Team Leader

Organization: CJUG-CDASH Team

He has over 20 years of experience as a data manager working on KISSEI Pharmaceutical, and has been CJUG CDASH team member since 2014.

Disclaimer and Disclosures

- *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.*

- *The author(s) have no real or apparent conflicts of interest to report.*

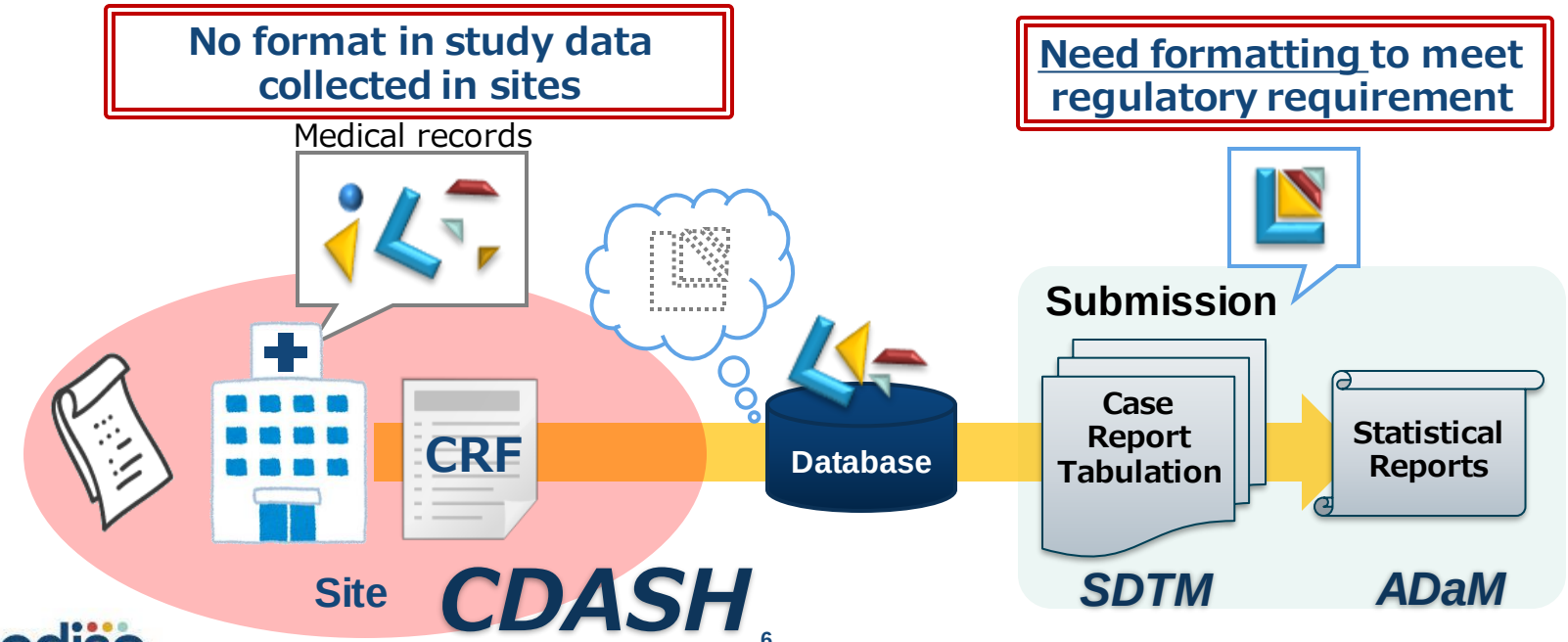
Agenda

1. Introduction of the CDASH Team
2. Introduction of CDASH Sub team 1 : Investigate needs and advantages for using CDASH
3. Introduction of CDASH Sub team 2 : Utilize CDASH standard using eSource
4. Summary

Introduction of the CDASH Team

What is CDASH's value in CDISC?

- ✓Get which data/data format should be collected in clinical trial
- ✓Keep traceability for data to be used in subsequent work and consistency from original data to submission



CJUG-CDASH Sub-Team Activities

CJUG CDASH sub team are discussing about following four topics currently:

1. Investigate needs/advantages for using CDASH
2. Utilize CDASH standard using eSource
3. Create sample of CRF library in conformity with CDASH
4. Create sample of standard CRF completion guide in conformity with CDASH

This session will show some more details for topic of 1 and 2.

Introduction of CDASH Sub team 1

Investigate needs and advantages for using CDASH

Subteam Overview

Topic
Investigate needs/advantages for using CDASH

Team structure		
Proposer	**Team lead**	**Team members**
Yasumitsu Takahashi	**Yasumitsu Takahashi**	**Yuya Ikeda, Noriyuki Furuya and Teruhisa Shiobara**

Objective

- To make position of CJUG-CDASH team's position in the industry more specifically and keep us motivated.
- To promote capability of CDASH and make CDASH more popular.

Simplified data conversion from CDASH/CRF to SDTM by Excel based visualization

LOC, LAT, and DIR variables for controlled terminology. While the overlap exists, ensure that this overlap for these variables is not part of database design.

8.2.2 AE - Adverse Events

Description/Overview for the CDASHIG AE - Adverse Events Domain

The CDASHIG Adverse Events (AE) domain includes clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pha not necessarily have to have a causal relationship with this treatment" (ICH E2A; available at https://www.fda.gov/regulatory-information/). In consultation with regulatory auth the scope of adverse event collection (e.g., collecting pretreatment events related to trial conduct, not collecting events assessed as efficacy endpoints). Events included in the AE protocol requirements. Adverse event terms may be captured either as free text or via a prespecified list of terms. The structure of the SDTMIG AE domain is 1 record per adver responsibility to define an *event*. This definition may vary based on the sponsor's requirements for characterizing and reporting product safety and is usually described in the prot

As with all the data collection variables recommended in CDASH, it is assumed that sponsors will add other data variables as needed to meet protocol-specific and other data col area-specific data elements and others as required per protocol, business practice or operating procedures). Sponsors should define the appropriate collection period for adverse e

Specification for the CDASHIG AE - Adverse Events Domain

Adverse Events Metadata Table

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Data Type	CDASHIG Core	Case Report Form Completion Instructions	SDTMIG Target	Mapping Instructions	Controll Termino Codelist Name
Events	AE	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR	N/A	STUDYID	Maps directly to the SDTMIG variable listed in the SDTMIG Target column.	N/A
Events	AE	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within	What is the site identifier?	Site (identifier)	Char	HR	N/A	DM.SITEID	Maps directly to the SDTMIG	N/A
Events	AE	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A uni within								

Visualize texts and metadata table

Question Text	Prompt	Variable name	Variable Value	CT	Test data	Notes	Variable name	Variable Value	Test data
Were any adverse events experienced?	Any Adverse Events	AEYN	O Yes O No	NY	yes		-	-	-
Adverse Event Category:	Adverse Event Category	AECAT	Sponsor Defined	N/A	ADVERSE EVENTS		AECAT		ADVERSE EVENT
Adverse Event Subcategory:	Adverse Event Subcategory	AESCAT	Sponsor Defined	N/A	GENERAL ADVERSE EVENT CLINICAL COMPLAINTS		AESCAT		GENERAL ADVER CLINICAL COMP
What is the adverse event identifier?	AE Number	AESPID	_____ →Free text	N/A	1 2 3 …		AESPID	_____ →Free text	1 2 3 …
What is the adverse event term?	Adverse Event	AETERM	_____ →Free text	N/A	White blood cell count increased		AETERM	_____ →Free text	White blood cell cou
What is the adverse event start date?	Start Date	AESTDAT	__/___/____	N/A	10-Jan-2020		AESTDTC	YYYY-MM-DD T HH:MM	2020/1/10T10:00
Is the adverse event ongoing?	Ongoing	AEONGO	O Yes O No	NY	No		AEENRF / AEENRTPT AEENTPT	N; Y; NA; U	No
What was the adverse event end date?	End Date	AEENDAT	__/___/____	N/A	20-Jan-2020		AEENDTC	YYYY-MM-DD T HH:MM	2020/1/20T10:00
What is the severity of the adverse event?	Severity	AESEV	O MILD O MODERATE O SEVERE	N/A	MODERATE		AESEV	MILD/MODERATE/SEVERE	MODERATE
Was the adverse event serious?	Serious	AESER	O Yes O No	AESEV	Yes		AESER	Y N	Y
Did the adverse event result in death?	Death	AESDTH	O Yes O No	NY	Yes		AESDTH	Y N	Y
What [is/was] the subject's date of death?	Death Date	DM.DTHDAT	__/___/____	N/A	20-Jan-2020		DS.DSSTDTC DM.DTHDTC	YYYY-MM-DD T HH:MM	2020/1/20
Was the adverse event life threatening?	Life Threatening	AESLIFE	O Yes O No	NY	No		AESLIFE	Y N	N
Did the adverse event result in initial or prolonged hospitalization for the subject?	Hospitalization (initial or prolonged)	AESHOSP	O Yes O No	NY	No		AESHOSP	Y N	N
Did the adverse event result in disability or permanent damage?	Disability or Permanent Damage	AESDISAB	O Yes O No	NY	No		AESDISAB	Y N	N
Was the adverse event associated with a congenital anomaly or birth defect?	Congenital Anomaly or Birth Defect	AESCONG	O Yes O No	NY	No		AESCONG	Y N	N
Did the adverse event require intervention to	Needs Intervention to Prevent Impairment		O Yes						

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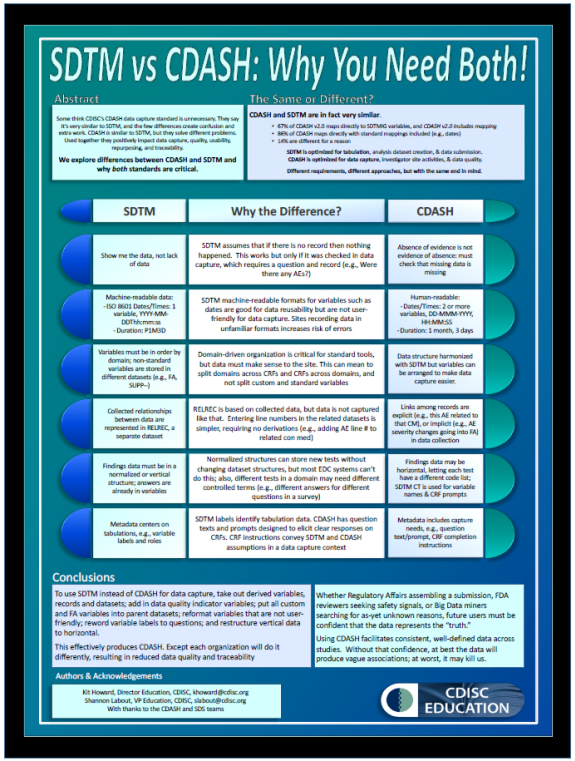
CDASH advantage and status of utilization – data from Questionnaire for Team members



pick up CDASH advantages

CDASH Team questionnaire

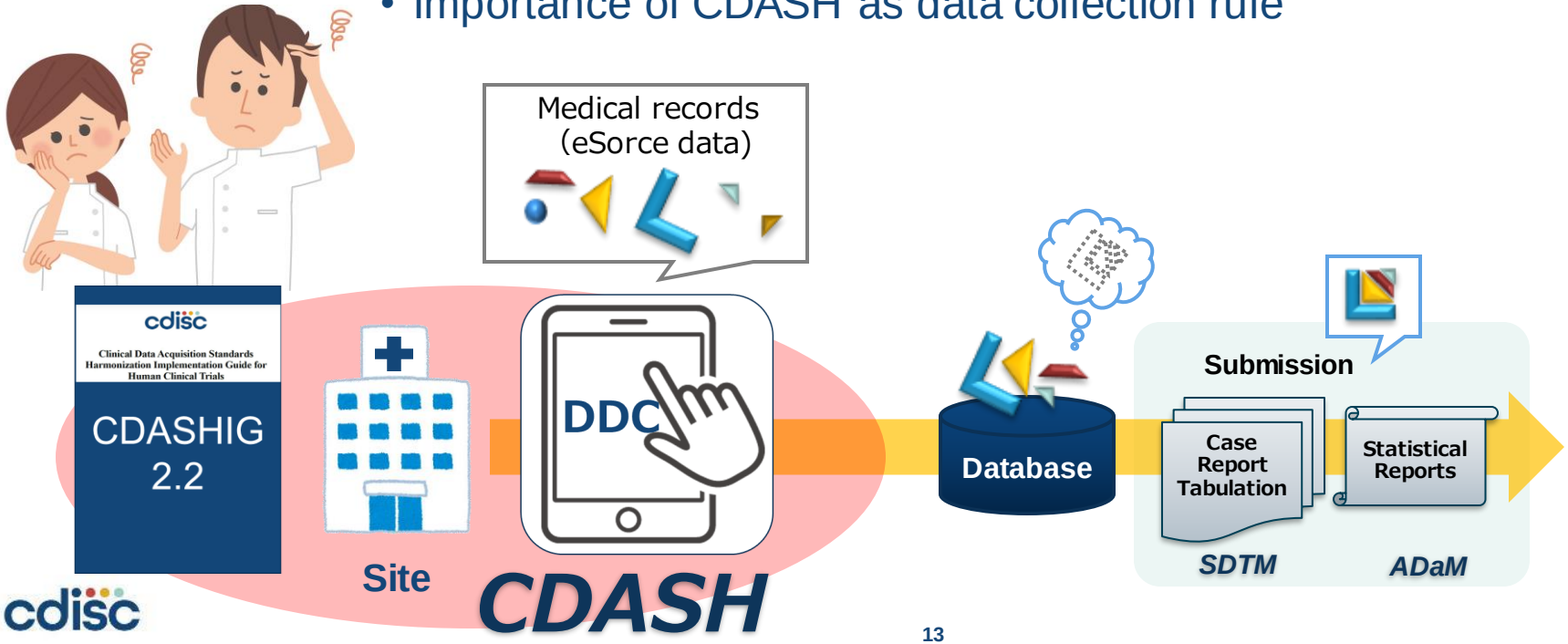
#	Advantage	Status (n=19)
1	Able to specify missing data	19
2	Use familiar format for date/time data considering data entry depending on regions	19
3	Place fields in CRF to ensure easy data collection	17
4	Specify relationship of multiple data by corresponding row #, no need to create additional forms like SDTM RELREC	17
5	Provide not only normalized structure but horizontal expansion, since sometimes normalization is not suitable for CRF Create naming rule of variables	15
6	Create 2 CRF labels as Question text / Prompt to clarity data collection details Prepare CRF data entry guide	13

Introduction of CDASH Sub team 2

Utilize CDASH standard using eSource

Background of this activity

- Increasing # of case studies of eSource, especially DDC
- Increasing opportunity of using CDASH by site staffs/CRCs
- Importance of CDASH as data collection rule



Activity and Objective

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Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials

CDASHIG 2.2

+α

- ✓ Provide additional information for complicated fields to map, and fields not having CDASH variables
- ✓ Consider appropriate variables/mapping to be suitable with SDTM for fields not having CDASH variables

Create
easy material for site staffs/CRC
（Case studies）

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Utilize CDASH standard using eSource

From our current material:

説明文(英語)	項目名	CDASHにある場合は、変数名を追記	事例集への補足説明
Height and Weight	Were height and/or weight collected?	VSPERF	YN自体の情報はEDCでの画面遷移等で必要なだけ、実施していないことを明示したい[NOT DONE]場合はYNではなくPERF/STATなど別の変数が必要 (IGの4.2 データ収集ツールの作成に対するベストプラクティスを参照) 他に重複する項目がある場合HIGH_WEIGHT_VSPERFでもよいが、システムにより文字数制限で使えないこともある
Laboratory Tests (Urine) / Urine Sediment Test	Crystals/Salts (HPF) Result (〇_7)	LBORRES	左記のように1項目で結果を収集する場合は–ORRES変数を利用する。収集された値はSDTMの--ORRESに直接マッピングされる。 所見結果を収集するための質問と、詳細な所見の内容を入力する2項目で結果が収集される場合に、--RES + --DESC が利用される 例: 異常はありましたか？ :--RES変数 どのような異常でしたか？ :--DESC変数 (※詳細はCDASH IG 8.3.1の 9. 参照)
Laboratory Tests (Urine) / Urine Sediment Test / Drug Screen Test / Pregnancy Test	Was the urine sample (Laboratory Tests (Urine)) collected? (〇_8)	LBPERF_URI	同一ページに複数の「実施の有無」が存在するため、以下変数の末尾に追加して区別 ・尿検査: _URIN(URINALYSISを省略) ・尿沈渣検査: _URINSED(URINARY SEDIMENTを省略) ・薬物乱用スクリーニング検査: _DU(DRUG USEを省略) ・妊娠検査: _PREG(PREGNANCYを省略)
Blood Collection (Unscheduled)	Was the blood sample (Hematological Test) collected? (BLD_US)	LBPERF	(IG日本語訳より抜粋)8.3.1 Findings(所見)ドメインに対するCDASHの一般的な前提条件 横型(規格化されていない)の設定で、SDTM 変数に類似した–PERF、--LOC、--STAT は、横型のレコード全体について1 回のみ収集し、その値を当該レコードに関するすべての観察に適用できる。あるいは、CDASH 変数に類似した<--TESTCD>_--PERF を用いて検査毎に収集できる。SDTM申請データセットを作成する際に、横型のレコード全体で収集したすべての変数を縦型の 各レコード(適切な場合) にマッピングしなければならない。
Study Drug Administration ●●	Was study drug administered? (EX)	ECYN	EX_ 投与内容がオープンの場合、EC_ブラインドの場合 YES,NO の選択の場合は、ECYN、 NOを選択して、理由を記載する場合は、ECOCCUR
Study Drug Administration ●●	Was the drug administered in the prescribed manner?	●●YN	CDASHには変数が存在しない。(SDTMへの変換は不要であろう項目) 例として、●●YN ●●は自由につけてよい 規定投与ではない場合には理由を入力:ECREASOC 規定投与量では無い場合: ECDOSADJ(投与量) ECADJ(理由)
Medical History	The points at which this medical history was found	MHSTDAT	MHPRIOR(いつ頃からあった？) または、MHDAT(いつ確認したか？)
Pharmacokinetics ●●	Time of dosing just before specimen collection (〇R)	ECSTTIM_●● or EXSTTIM_●●	ECSTTIM_●● or EXSTTIM_●● ●●に入るのは、3回目であったり、複数の薬剤がある場合 システムによっては、同じ変数を入れられるものもある
Pharmacokinetics ●● / Biomarker Analysis / Laboratory Tests	Time of specimen collection	PCTIM	同じようなフィールドを2つ以上発生する場合の変数命名ルールを決めますか？ →[_+項目名の頭文字]をつけるなどで変数を分ける対応が良いのではないか。繰り返しの項目の場合は数字を付与する対応もあるらしい(2020/04/14議事より)

Our considerations:

- No variables in CDASH but available in SDTM
  - e.g : VS test related : HEIGHT_VSORRES、WEIGHT_VSORRES
- No variables in CDASH and SDTM
  - ✓ Required data. Decide Variable based on CDASH rule
  - ✓ Not required. No need to have Variable

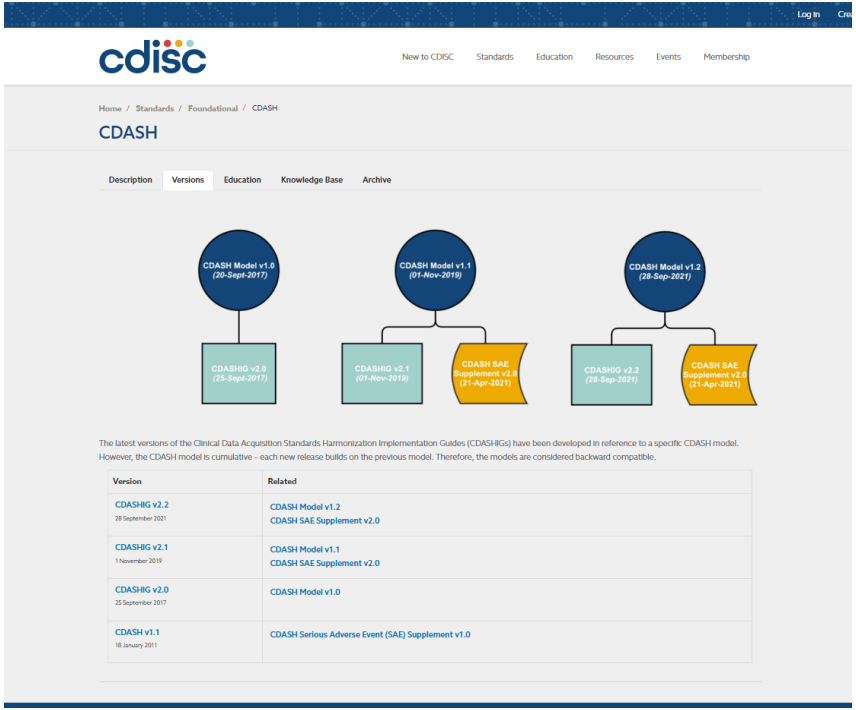

Furuya
Tanaka
Ikeda
Ishikawa
Tomisato
Yamaguchi
Tamura
Kumagai
Kobayashi
Yashima
Takahashi

Summary

Summary

- The latest information about CDASH

https://www.cdisc.org/standards/foundational/cdash



Thank You!

We wish to guide everyone for better understanding of CDASH capability!