CDISC Primer; SDTM and ADaM Implementation FAQ

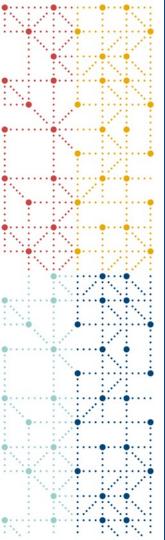
Aatiya Zaidi, Director of Statistical Programming, Gilead Beate Hientzsch, Head of Biostatistics & Statistical Programming, Mainanalytics GmbH Bhavin Busa, VP of Clinical Data Services & Operations, Vita Data Sciences Kit Howard, Sr. Director, Standards Development and Education, CDISC Rebecca Baker, Standards Developer, CDISC



Tuesday, 2020-06-30 11:00 – 12:30 EDT

Today's Agenda

- 1. Housekeeping
- 2. Presenter Introductions
- 3. Feature Presentations
- 4. Question & Answer Session
- 5. Upcoming Learning Opportunities + Resources



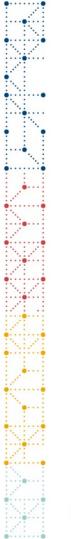
Housekeeping



Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
 - To access make sure that you create a login for the CDISC website if you haven't already
 - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!

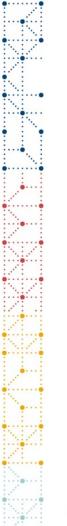




Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.





Our Presenters

- Aatiya Zaidi, Director of Statistical Programming, Gilead
- Beate Hientzsch, Head of Biostatistics & Statistical Programming, Mainanalytics GmbH
- Bhavin Busa, VP of Clinical Data Services & Operations, Vita Data Sciences
- Kit Howard, Sr. Director, Standards Development and Education, CDISC
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CDISC Implementation Primer

A PHUSE – CDISC collaboration project for new implementers



Beate Hientzsch, PHUSE Kit Howard & Rebecca Baker, Standards Development, CDISC

https://www.phuse.eu/phuse-working-groups

Agenda

- Introduction and Background
- Primer Topics
 - How to get started with CDISC
 - Compliance
 - Traceability
- Q&A











Working Groups







- PHUSE heard concerns, CDISC collaborated
- Project launched at PHUSE CSS 2018 in Silver Spring
 - Part of "Optimizing the Use of Data Standards" Working Group
- Over 20 volunteers from many different stakeholders
 - Project Leads: Beate Hientzsch, Y
 Wendy
 Dobson, Bess LeRoy





Project Scope



- Provide starting point implementation guidance to people new to CDISC
 - Data Producers (DM, Prog, Stat, ...)
 - Data Consumers (Stat, Medical, Academia, Writers, ...)
- Identify core topics of interest
- Visual representations, no new documents will be created







Everything freely available







Initial Topics













Achievements

- Intense and productive global teamwork
- Curated material ready for publication













Topic 1: Getting Started with CDISC



Introductions to Standards (Videos)

- What are SDTM and SDTM Concepts
- Intro to the SEND IG
- Intro to the SDTM IG
- Intro to CDASH
- Intro to TAUGs
- Regulatory Requirements
- Intro to ADaM
- Intro to Controlled Terminology

Introduction to CDISC

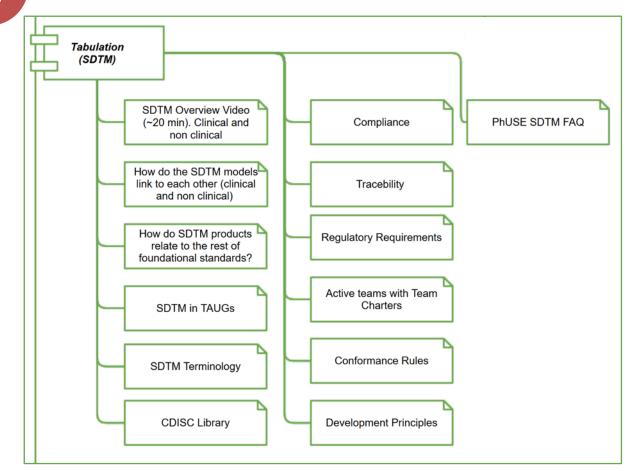
- CDISC for Newcomers
- New to CDISC Roles

Standards Relationships

- Relationships Among IG and Model Versions
- Traceability: SDTM and ADaM



Getting Started with CDISC: SDTM/IG



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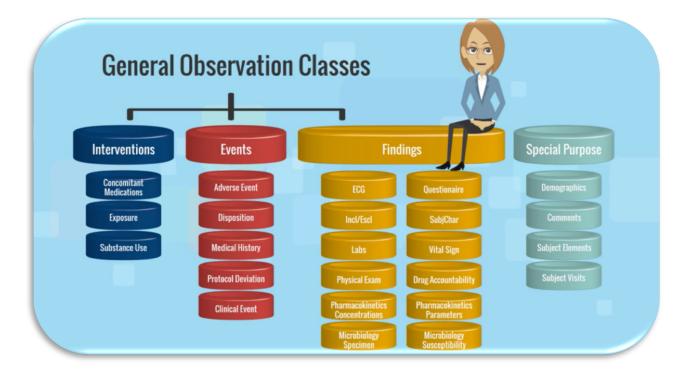


COISC P R I M E R In collaboration with PhUSE



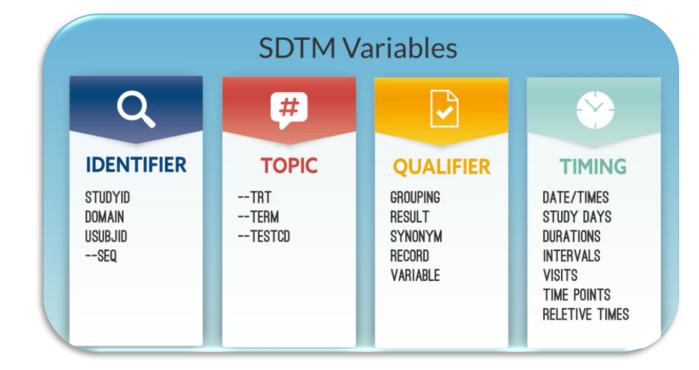


3 Minute Cartoon Videos for Standards





3 Minute Cartoon Videos for Standards





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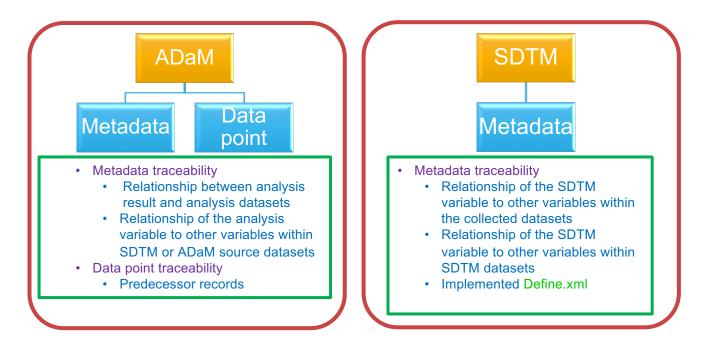
Topic 2: Links Among CDISC Standards Versions

cdisc	New to CDISC	Standards	Education	Resources	Events	Membership
Home / Standards / Foundational / SE	тм					
Description Versions Education	Related			W <u>implen</u> guide		
SDTM v1.7	SENDIG-Animal Rule v1.0 SDTMIG v3.3 SDTMIG for Medical Devices v1.1		<u> </u>	belongs to <u>model versi</u> what stan		
SDTM v1.6 SDTM v1.5 SDTM v1.4	SENDIG-DART v1.1 SENDIG v3.1			whats	sianda	



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Topic 3: Traceability of SDTM/ADaM



Presentation to be recorded and posted









Bonus Topic! CDISC Knowledge Base

Source for Articles, Examples and (soon) Known Issues

cdisc	New to CDISC	Standards	Education	Resources	Events	Membership	Members Only
Home / Knowledge Base							
Welcome to the CDISC Knowledge Base. The K		s a resource for t	<u> </u>	to questions you	may have ab	out implementing Examples	CDISC standards.
Search		Artic	.165			Examples	



¥ * * * *



- Why Not Just Use SNOMED?
- Domain vs. Datasets: What's the Difference
- A Short History of CDISC and SAS Transport Files
- Sex and Gender
- Study Subject vs. Experimental Unit
- Concept Maps for AEs with Increasing Levels of Detail
- Standardized Lab Units
- UCUM and CDISC Codelists
- Changing Event Severity
- LOINC and the SDTM
- SDTM Structure Diagrams

- Domains are Topic-based Except When They're Based on Structure
- Concept Maps for Substance Administration with Increasing Levels of Detail
- Concept Maps for a Finding with Increasing Levels of Detail
- Translating CDASH PRIOR and ONGO to SDTM Relative Timing Variables
- When Did That Happen? A Brief Guide to Representing Timing in SDTM
- Pre-specified Events and Prespecified Findings
- Avoiding SDTM and ADaM Dataset and Variable Name Conflicts
- Assessing Causality



Meal Tolerance Testing aCRF

This example shows data about the last meal before a hypoglycemic event.

Read N	1ore
--------	------

	Standard(s)	Indicate whether or not the meal tolerance testing procedure was performed.	Was the meal tolerance testing procedure performed? MTTYN Not submitted	OYes ONo
	CDASH	Indicate whether or not the meal for meal tolerance testing was administered.	Was the meal for meal tolerance testing administered? AGOCCUR	OYes ONo
			What was the planned time point (numeric) of the meal? Not collected AGTPTNUM	•
		Record the planned time point of meal. Can be pre-printed.	Planned time point of the meal AGTPT	
		Record the meal date using this format (DD- MMM-YYYY).	Meal Date AGSTDAT AGSTDTC	
		Record the meal start time.	Start Time AGSTTIM AGSTDTC LBRFTDTC	
		Record the mean end time.	End Time AGENTIM AGENDTC	
cdiş	20	Record the portion of the meal consumed.	What portion of the meal was consumed? AGDSTXT AGDOSTXT	○ <25% ○≥25% to <50%



Examples: SDTM/IG

Glomerular Filtration Rate 1

This example shows an injection of iohexol administered prior to the GFR test.

Standard(s) SDTMIG, SDTM

✓ ag.xpt

ag.xpt

<

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGSPID	AGTRT	AGDOSE
1	ABC123	AG	ABC123-100-1234	1	1234-1	IOHEXOL	1510

dia

The measured and adjusted GFR results are represented using the Laboratory Test Resul "CALCULATION" would be documented with more detail in the metadata.

Content

In this example, Subject ABC123-1 centrifuged to extract the plasma rate (GFR). The measured GFR wa

The Procedure Agents (AG) doma medications, and therapies admir

In this example, AG shows a recor

> ag.xpt

Read More

The measured and adjusted GFR "CALC**U**LATION" would be docum

> lb.xpt

The relationship between the reco identifying variable (IDVAR) for the dataset relationship was chosen, domains using an identifier uniqu

relrec.xpt

Newcomer's Perspective

Journey

Newcomer

Problem

• First glance of CDISC standards

Solution

• Primer role

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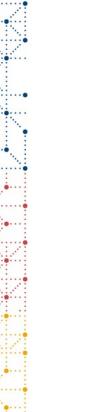
Where to Start?

Q My Account



New to CDISC Standards Education Resources Events Membership Members Only

	Foundational	Data Exchange	Therapeutic Areas	Terminology	In Development	CDISC Library
	BRIDG	CTR-XML	Autoimmune	Glossary	Standards in Development	CDISC Library Archives
	PRM	Dataset-XML	Cardiovascular	Controlled Terminology	CDISC 360	
	SEND	Define-XML	Endocrine			
	CDASH	LAB	Gastrointestinal			
	SDTM	ODM-XML	Infectious			
Non-clinical	SDTMIG	RDF	Mental Health			
Organize	ADaM	SDM-XML	Neurology			
Organize	QRS		Oncology			
	Medical Devices		Other			
	PGx		Rare Diseases			
	Real World Data		Respiratory			
			Treatments			
SEND	PRM		CDASH	SE	ОТМ	
Tabulation for Animal Studies	Model for Planning	Model	for Data Collection		Tabulations of ly Data	А





New to CDISC Standards Education Resources Events Membership Members Only

New to CDISC

CDISC encourages the global adoption of standards by all researchers. Learn more about how CDISC Standards benefit your research.







Video Library



CDISC - Brand

New to CDISC Standards Members Only Education Resources Membership Events



Benefits of Membership and Volunteering



CDISC's Impact in Asia



Impact for Academic Researchers



Whiteboard



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Problem: Where to Start?

Q My Account

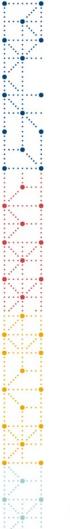


New to CDISC Standards Ed

Education Resources Events Membership

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	PRM	Dataset-XML	Cardiovascular	Controlled Terminology	CDISC 360		
	SEND	Define-XML	Endocrine				
	CDASH	LAB	Gastrointestinal				
	SDTM	ODM-XML	Infectious				ic Area
Non-clinical	SDTMIG	RDF	Mental Health				1 Terminology
	ADaM	SDM-XML	Neurology				A
Organize	QRS		Oncology				Analyze
	Medical Devices		Other				
	PGx		Rare Diseases				
	Real World Data		Respiratory				
			Treatments				
SEND	PRM		CDASH	SI	ОТМ		ADaM
Tabulation for Animal Studies	Model for Planning	Model	for Data Collection	Model for Stu	Tabulations of dy Data	A	nalysis Data Model



Solution: Where to Start!





Primer Team Acknowledgements

Name	Organization	Name	Organization
Alisa Khomyanina	IBM	Lavjot Sandhu	Commonwealth Informatics
Ann White	CDISC	Lou Ann Kramer	CDISC
Ashwini Kawtikwar	Syneos Health	Meenakshi Thakral	JNJ
Changhong Shi	Merck	Matthew Warren	CDISC
Chao Su	Merck	Nate Freimark	The Griesser Group
Charity Quick	RHOWorld	Nick De Donder	BDLS
Eric Crockett	Covance	Parin Shah	Cytel
Hrushi Samant	Syneoshealth	Rebecca Baker	CDISC
John Powell	CDISC	Sabine Erbsloeh	Clinipace
Jon Neville	CDISC	Sanket Sinojia	IQVIA
Julianne Halley	Envigo	Shunbing Zhao	Merck
Kit Howard	CDISC	Soumya Rajesh	Syneos Health
Uday Patil	Syneos health	Sruthi Ragavula	Syneos Health









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Thank you!





The premier community for people working in the biometrics area ☑ @phusetwitta ☞ /phusebook ☑ /phusetube ☞ /company/phuse

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CDISC SDTM/ADaM Implementation FAQ

A PHUSE – CDISC collaboration project for frequently asked implementation questions

Aatiya Zaidi, Gilead Sciences Amy Palmer, CDISC Bhavin Busa, Vita Data Sciences



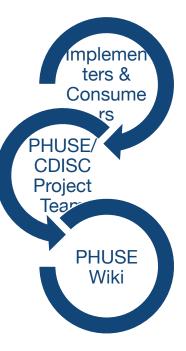
SDTM/ADaM Implementation FAQ

- In the past "Standards Implementation Nuances" sessions at the PHUSE US & EU CSS surfaced various common challenges amongst SDTM and ADaM implementers and consumers
- Industry was in need of a forum and subsequent knowledge base (FAQ) to address these challenges
- This PHUSE forum was chosen by CDISC to be a preferred partner for implementation questions and issues



SDTM/ADaM Implementation FAQ

- A PHUSE project team was formed to collaborate with CDISC, FDA, and industry SMEs
 - Members who participate in developing the standards are helping address implementation questions
- Project team meet and collaborate bi-weekly (Tuesday @ 10:00AM EST)





Collaboration Tool

- Working with PHUSE Wiki (public)
 <u>http://www.phusewiki.org/wiki/index.php?title=SDTM_ADaM_Implementation_FAQ</u>
- Walk through project teamwork site (project team members only)
 <u>https://phuse.teamworkpm.net/projects/157138/overview</u>
- Submitting Questions (public) <u>http://www.phuse.eu/wiki-feedback</u>
- FAQ Database (public) http://www.phusewiki.org/wiki/index.php?title=SDTM_FAQ_Team_Responses



Examples of the Published FAQ (IG Nuances)

How should OTHER be represented for variables bound by non-extensible code lists?

What are best practices for creating CT for/representing questionnaire responses?

What is the general recommendation/approach for generating/submitting custom domains (e.g. non-standard CDISC SDTM domains) to regulatory agencies?

For the Table like 'Summary of Common (>=X%) Adverse Events by Overall Frequency', should the flags for common AEs be created in the ADAE dataset?



Examples of the Published FAQ *(Submission)*

Subject-level Data Listings for FDA CDER's Inspection Process (also called BIMO submission or OSI Pre-NDA

What goes in the "misc" folder with an m5 eCTD folder structure? For example, a lookup file containing SMQ assignment.

How do I make a test submission to the FDA?

Does the Sponsor need to submit SAS Codes? Does it have to be executable? Is there any guidance on that?



Examples of the Published FAQ (Trial Design Domains)

Do you create TA and TE domain for Observation Studies. There is no intervention/medication given to subject in this type of study.

Why are Screen Failures and Not Assigned not represented in TA?

How should a subject that is incorrectly dosed be represented in SE (i.e. a subject is randomized to Drug A, but receives Drug B)? Unplanned element?

How to define an unplanned Element in SE? Example: unexpected washout



Examples of the Current FAQ

units and corresponding converted values in LB in the -STRES variables. However FDA does not require sponsors to submit LB with SI units but may request the results US Conventional units. How do you Dees the FDA accept a submission of split dataset for prepare I. B for a oldbal trial slotted for submission to size? Examples include FA and QS domains. It is mentioned in the submission guideline that the Sponsor should check with their review agency regarding exactly what needs to be included in the submission, i.e. the split datasets or both the split datasets and the un-split datasets. Do you know if it

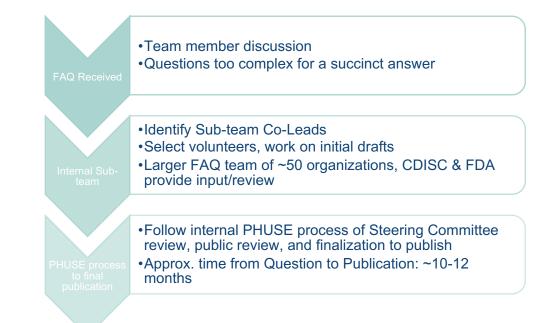


White Papers Developed by FAQ Team

- Best Practices for Submission of Event Adjudication Data
 - <u>https://www.phuse.eu/white-papers</u>
- Integration Strategies in Support of ISS/ISE Submissions
 - To be published soon [completed public review]
- Based on questions received by the user community
 - 1. "There is no guideline for the submission of Event Adjudication Data."
 - 2. "What is the guidance for Integration ISS and ISE submission? Are both integrated SDTM and integrated ADaM databases needed?"



White Papers Developed by FAQ Team





Posters Developed by FAQ Team

Best Practices for Submission of Event Adjudication data



Umpir Jian Dar, Hanna Rud, Matta Landau Brahak Christiansan (Novo Nordisk), Amy Palmar (CDISC). Joanne Zhou (GSK), Jyotuna Garg (DCRI), Poonam Rihel (Novo Nordisk) Elavin Busa (Vita Data Sciences) and Wendy Dobson (PhUSE)

Abstract				M Dataset of Ad	ljudi	cated Data		
 organizations and regulator standards and regulator 	duline for autorisation of awart adjudication data from both star ny agencies, the pharmaceutical industry continues to lease cha r/mr diata collections and regulatory submissions. The PNLEC 0 served a sub-group industry solutions from PAL (2018); CO	langes of lacking	-CAE	iss in the bolow oxample Pint adjudication/Re-adjudic 30: Adjudicator 1/Adjudicato - Adjudicator	silion r 2/Adju	dication committee		
white peper to tackle this is	mus. This postor is prepared based on the white paper.							COMP ANT
Faces			10.010	UV Searce of adapticated event	400	0.007.101.000.0000	INVESTIGATOR REPORTED	
The Phillip Learn reapped	Scope The PHJIE team respective the common precises and challenges for submission of Event adjudication data. The				AC0	REPETAD ADDRESS TRANS	ADJTE MYOCARDAL INSAGOTON	ADJUDICATOR 1
following questions are dis			ADJOUE ADJOUE		100	DIST AD LOCATION	20/241-01	ADJUDICATOR 1
 What level of detailed a should individual adjudt 	Coar the same data structure to percentional across thempsols areas? What load of datalist data should be advised? In Earlief to advise to only data points for the feal outcome or should individual adjudicato's elessionments to submitted in vol?			Turns of Proceeding Information			TYPE I MYCCAREIRL	
 How to present investi- differentiated and east 	gator reported assessments and adjudicator assessments, so the identifiation?	here are clearly	MITTYPE	DV Source of adulticated event		REST AD LODGED THE	INVESTIGATOR REPORTED	
 What should be search 5. Should dete be submit 	Minute should be sended involve of data set to ensure taxoability of events and ease for reviewe? Stread data to submitted both in SDTMACAN/? Is there any conformance, velidation performed on event elsefunction ISDTM data?			adadentin extrem	409	RIGHT AD ALCOLOGY DI	ACUTE MYOCARDIAL INSAGOTION	ADJUDICATOR 2
	Event Adjudication Process			Evaluated oversi cranti data	ACR	RIRET ADJUDICATION	2017-01-01	ADJ/0604008 2
In below discours a serveria	awarnels of the overst adjudication process is depicted, descrit	ing how events are	MITTYPE	Type of exponential infection		RHET ADJUDICATION	INFORMATION	ADJUDICATOR 2
selected and then adjudica	eed against produlined diagnostic citoria.			3 Re-adjutication meson	ACS	READJUDICATION	ADDITIONAL INFORMATION	
i			SO,RAD	UV Sicuros of adjudicated event	ADS	READUIDICATION	INVESTIGATOR REPORTED	
If a subject experiences one of the aminfrond quent types	Event adjudication process		ADJOLE	Adjudication externs	ACR	READ.MORPHIN	UNSTABLE ANGENA	ADJUDICKTOR 1
the investigator under the event for adjudication	identification of events	Special types of events can be shertified by other measures (e.e., bit solves or ECE	ADJDATE	Evaluated over i crant della	ACD	READURATION	2017-01-01	ADJUDIOR/OR 1
	test feet	reading (MITTYPE	Type of exponential infraction	ACS	READJUDICATION	INFARCTION	ADJUDICATOR 1
	investigator Search adjudication Other		READING	3 Re-edutionin mean	A09	READJUDICATION	ADDITIONAL INFORMATION	ADJJDICATOR 2
MedD6A searches in all reported AEs is performed to		When evaluating one type of events the Lemi adjustication	\$0.843	EV Seven of adjusticated event	A09	READUIDINATION	INVESTIGATOR REPORTED	ADJUDICATOR 2
 identify events not sett dentify for adjudication by the 		committee can potentially	ADUDUE	Adudentias extreme	400	URAD ALCOSTON	ADJEE MYCCARDIAL INFARITION	ADJUDICATOR 2
inedges	Site collects information in the form of source documents about the event and an external supplier sends it to the	exercs that should be adjudicated	ADUDATE	Evaluated oversi creets date	ACS	READJUDICATION	2017-01-03	ADJ/08CATOR 2
	event adjudication committee in a blinded manner		MITTARE	Type of excounties interction	100	SEAD LOW ADDRES	TYPE 2 MYOCARDINL INFARCTION	ADJUDIONTOR 2
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	Conferred Not conferred Unable to adjustment		1005	And a	100	STATISTICS.	ADUTE MYCOARDINE.	ADAJORCATION Y
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committee confirms that the event does not fulfit one of the			MITVIE	Type of expression infermion	400	DEAD ALCOCATION	TYPE 2 MYOCARDIN.	ADJUDICATION Y
productional criteria								
		At least two members of the Event adjudication committee	Place Is different	e present investigator repo initialized and exactly identified westigator's reported and ad	alasi as	uncertante and adjud	cator sourcements, so the	we are cheerly
		within the selevant field of operating polyation the ment.			pillor nit	rs asseptioned are supported data. Therefore,	contrast to authoritics, wojust both sets of assessments sh	swich dete door not swid be differentied
	Event adjudication evaluation flow	If they agree on the outcome the adjudication of the ment	and ca	nily identifiable. Ichnical Conformance Guide		The second of all stations	when is considered in standard by	and and a laboration of the
	Agreement after individual							
At least two members of the	evaluation	agree, the adjudication of the event is completed at a consensus meeting	data in	in be interpreted that adjustic captured in other domains o	-g. (AE,	CE, PA) that can be in	I in a standations domain and ked with the adjudication real	uts using the variable -
uthin the intervent field of expertise plus (work	Ym			denoted the schember of schember	~ ~ ~	de wet to ensure trace	which is a second second second	
	aduation commended that the Adjudication CRV header be set up such that it contains the event identifies from the					dentifieds from the		
or vice-chair evaluates the event at a consensus meeting							whooms in the body of the Ad to adjudicated event to the tri	petication CPIP.
	Event adjudication complete							
Event adjustantion samplete II is of antena trapectar for anomane to understand the provise adjustant on Event adjustantion and imported the factors and adjustantion adjustan					boarroves, such as it of the cODPO and			
Bernstehner			ADRIG ab an a	it is incommended to here a appendix to these documents	el densé L	a described in these do	cuments. Adjustication charte	ni cin allo bi induded
Can the same take structs	re be generalized across therapeutic area?		Should	d data be automitted both a refere 2011M state/7	-	ADdN? Is there any a	conformance, validation pe	formed on event
	The therapeutic area should on a general level not affect the structure of the data. Same basic information should be present incorporties of the therapeutic area with the penalitility for adding disease specific dataled assessments.				In general statics overst adjudication data should be submitted in both SDTM & ADaM. However, authorities have			
	What level of tableted data already has well of powership of all on places species decade another term.			previously accupted submitting data only in ADMM that to the processes used did not support generation of SDTM. For ADME only, final assessments would be of interest as opposed to all assessments collected in SDTM. A flag				
There are different approaches observed in the industry for submission of results from the adjudication process; some are submitting only final agreed assessment from the adjudicate and live are submitting individual				should be populated, enabling estimation of only lead assessments as shown in the example. PDA checks that data is in constitution with the processes defined in the charter and it undergoes used validation as				
adjutication associations in	sa agrisid assessment torn till adjudicators and toe are subtrant ten primary adjudication as well	and concern	other f	inding domeins.		and the second sec		
	Declaritier: Patient CDRIC publications that represent adjudication events may be different to this White Paper.				per.			
			-					
							-	- Ristal Netla Services

https://www.phusewiki.org/docs/2019 CSS/Presentations Posters/CSS%20Posters/PP04.pdf



Posters Dovelanad by EAO Team

ISS and ISE Dataset Preparation Best Practices: A PhUSE Whitepaper

PP34 Aatiya Zaidi', Kapile Patel², Bhavin Busa³, Veena Nataraj⁴, Kiran Kumar Kundarapu⁶, Joanne Zhou⁶, Soumya Rajesh², Marguerite Kolb⁷

ntroduction		Adherence to Regulatory A	gency Guidance	
r requirements exist within the industry and from regulatory agenties. The industry of hecks.	DBC complexity and provide data at SDTM only ADMI towil, are no paper in the interact in that calculating and functions to prioring. Investign calculations are interaction in the calculation of the Integrated Barraneay of Sakity (BS) and the Integrated Interaction FAQ issues to address the Integration while gratitories on galactics on how to nome suited at logarity.	Up-versioning of Controlled Terminology (CT) • The FDA TCD ² specifically discuss the use of swederdand and a alaxin controlled terminology • emphasis on using standardard CT at a study- lowi • and thu use of study-specific an sponsor-durined CT an much separate	Harmonization of Coding Dat • FDA and IMDA recommend to alian Media to code advance oversits (A2) and IdMANDA Glassies to addi concensities model/BBMMC • Alian and CMM should be coded to a single version of the respective decisionerse in the and the mean mean second be us the large the advance and the advance and the second of the advance and the advance and the the large that the advance are coded.	
 SSTRF and ADaM Integration 	Scenario 2: SDTM + ADaM Integration	 Recommended to harmonize the CT (most current version available at the time) during integration 	When harmonizing coding dictoraries like ModDRA and WHODrup, the FDA has stro	
Scenario 1: ADaM-only Integration	Sponsor may choose to integrate both the SDTM and the ADAM detabases when: The majority of the studies to be included in the integration have CDISC-compliant.	activities. Note: up-venioning of standardized CT is not required within the individual SDTM or ADM made	events where preferred term or hierarchy	
The majority are all of the ISS and ISE analysiss and manifest publics, (spress and the integration of the ISS and ISE analysis and the ISE and ISE analysis for the ISE and	SDTM and ADaM Statistics in piece: There as a sign state of states as the states and add non-standard study data to be there are to many different states and add non-standard study data to be there are to many different states and add to stress and the states and there are to many different states and add to stress and the states there are to many different states and add to stress and the there are to many different states and the states and the there are an add to and be the states and the states and the Manual the data base to an excessing to states is found to add the states ADAM different and a 1 is necessary to states is found to add the states add the states and a 1 is necessary to states in the states and the states of the states and the states add the states and the states and the states and the states and the states the states and the states and the states and the states and the states add the states and the states and the states and the states and the states add the states and the states and the states and the states and the states add the states and the states and the states and the states and the states add the states and the states add the states and the states and the states and the states and the states add the states and the states and the states and the states and the states add the states and the states add the states and the	Keit direases. 6 Sourgius and CT Internetisation to access the integration lower INNEAR and INNEARCE. THEOR and TREDING. INFORMATING INCOMENTATIONAL INFORMATING THEAN, THEP and THEPP, AVEID and ANDERN, VISIT and VISITINUM, APERICOD and APERICOC.	Nation to Research years and the sec drivent MMMM of the WHODing clean in drivent MMMM of the WHODing clean in Define xml and DRG dense The drivent and DRM will reach be to for the new respond datasets. For some period, these observations in the datasets between the submitted in the datasets	
ADM/ detents and it is necessary to obtain it from the study SOTM detents Stady analysis detents are not CDISC compliant Study SOTM and/or Legacy Data → Integrated ADaM	Study SDTM → Integrated SDTM → Integrated ADaM	Traceability and Complian	table of convented data from one dictions werken to another?.	
		Discourse 1: may reagain the generation of internetiative distances for distances, CT, or searched waves in terretinative. These internetiative distances with not be submitted to PDA or PMDA. Discourse 2: growthes a disk receptore distances and the transmitted Address distances. Similar the next to generate internetiative distances and the transmitted Address distances. Similar the next to generate internetiative distances and the transmitted Address distances a		
Berley	impedia tanany Dapat	 Variables – e.g. xxBEC, ASEC, SRCVAR, SI study level SOTIM VEX Data datasets to dep integrated datasets Sconwen 1: xxBEC can be used to show two > Sconwen 2: XXBEC with integrate to be regeneral provide tracements to study level data 	pict traceability may not be applicable in ceability to stady level data	
Study <u>ADaM</u> → Integrated ADaM	SDTM + Legacy Data → Integrated SDTM → Integrated ADaM 1	 Recommended to run P21 checks, even the for study 5DTM data and study ADaM data Sconsici 2 may generate more compliance integrated SDTM data and another set for in 		
Bad 1 (all and an and a state of the state o		Conclusion	References	
		abusysteed at the second secon	[] Skudy Level Tracebility Considerations End Pr Mond Level Dear Flow? - Published October 201 validate at the University of the end of constraints for dispo- ting the end of the end o	
Bay Hold	was	Acknowledgments We extend our thanks to the all the members of the PhUSE SOTM and ADaM	() CA. Yokay XNA: INCYNER CONTINUE CONTINUES CARACTERISTICS CONTINUES (CONTINUES) (CONT	

https://www.phusewiki.org/docs/2019_CSS/Presentations_Posters/CSS%20Posters/PP34.pdf





Closing Remarks

The forum gives the industry an opportunity to discuss and/or submit CDISC SDTM/ADaM Implementation and Submission related questions which may not directly be addressed by the CDISC, FDA, or other regulatory agencies

Disclaimer:

- 1) not an avenue to obtain consultation and
- 2) ensure regulatory agency feedback is obtained indifferent of recommendations provided by the FAQ team.



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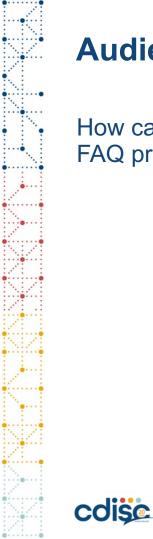
The premier community for people working in the biometrics area ☑ @phusetwitta ☞ /phusebook ☑ /phusetube ☞ /company/phuse

phuse.eu



Are all the videos on the slide "topic 1: Getting started with CDISC" free and available? If so, where?



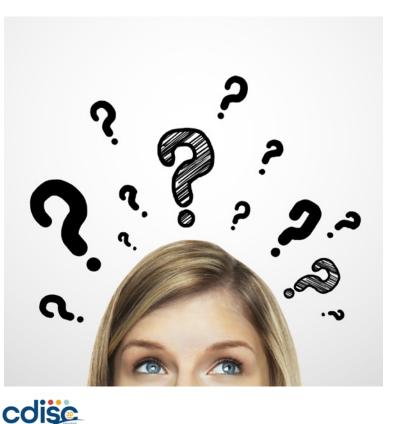


How can I join the implementation FAQ project team?



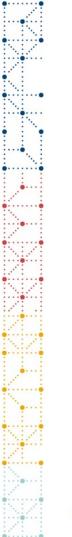






Is the SDTM IG 3.3 now available in PDF format? If not, is there a plan to make this available in the future?

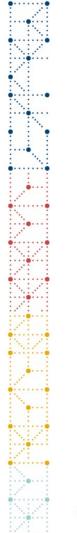
55



Is POOLDEF a relationship dataset domain or a special purpose domain as given in SENDIG 3.0?









Can we shift to CDISC without any SAS exposure or experience?



Additional Resources from PHUSE

- From PHUSE perspective, the CDISC Primer deliverable once final will be housed here https://www.phuse.eu/white-papers
- Link to PHUSE SEND Wiki <u>https://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_Use</u> <u>r_Group</u>

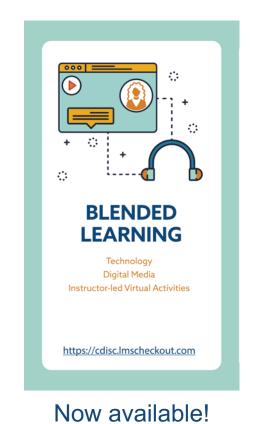




Upcoming Learning Opportunities

NEW Blended Learning from CDISC

- Self-paced online training combined with remote instructorled Q&A
 - Developed by standards experts
 - CDISC authorized instructors
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 - Four global time zones
 - Introductory Offer Additional 25% Off!





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Sessions starting soon!

SDTM Blended Learning*			
	Start Date	Live Q&A	Language
Americas	5 AUG – 9 SEP	Weekly	English
Europe	25 AUG – 29 SEP	Weekly	English
Japan	4 AUG – 8 SEP	Weekly	Japanese
China	3 – 29 SEP	Weekly	Mandarin

*Includes 19 modules & weekly Q&A sessions

CDASH Blended Learning**				
	Start Date	Live Q&A	Language	
Americas	5 – 19 AUG	Weekly	English	
Europe	1 – 15 SEP	Weekly	English	
Japan	4 – 18 AUG	Weekly	Japanese	
China 3 – 17 SEP		Weekly	Mandarin	

**Includes eight modules & weekly Q&A sessions





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2020 Webinars

Date	Webinar Title
7 JUL 2020	Controlled Terminology Updates for Q3
14 JUL 2020	QRS Updates: Logically Skipped Items, EVAL and More
21 JUL 2020	Introducing the CDASH eCRF Project + CDISC Standards for Animal Rule Studies
28 JUL	Leveraging Clinical Research Data Standards in Academia: What's in it for Me?
13 OCT 2020	Controlled Terminology Updates for Q4





Technology Digital Media Great Ideas!

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Visit <u>https://www.cdisc.org/events/education/webinars</u> for information on additional Public Training events.



Join CDISC in July for a free webinar! QRS Updates: Logically Skipped Items, EVAL and More

Get updates on how to handle missing data and evaluator in QRS domains. Specifically, we'll discuss how to represent:

- Missing data which happens due to instrument logic
- Missing data for an unknown reason
- "Check all that apply" responses
- "Other specify" responses
- Administrator/evaluator information when it's collected on a QRS instrument
- We'll also share the latest supplements in progress.

Date and Time:

TUE 14 JUL 2020

11:00 AM - 12:30 PM Eastern US Daylight Time

Presenters:

Dana Booth, SDS QRS Subteam Co-Lead Steve Kopko, SDS QRS Subteam Co-Lead





www.cdisc.org/events/education/webinars

Join CDISC for a Virtual Training: CDISC for Newcomers (Virtual)

New to <u>CDISC Standards</u>? Attend our workshop geared to getting you started with standards to amplify the full potential of data, drive operational efficiencies and expedite the regulatory review process. The workshop goes over examples of the standards, along with how to build them into the process of writing a protocol, collecting and tabulating data, and using the data in analysis. The CDISC <u>Data Exchange</u> <u>standards</u> are reviewed and the <u>CDISC Library</u> is discussed.

The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

Agenda:

- Topic 1: What is CDISC?
- Topic 2: Why Are Standards Needed?
- Topic 3: Overview of Regulatory Requirements
- Topic 4: Overview of CDISC Models
- Topic 5: CDISC Connects Research Globally
- Topic 6: Therapeutic Area User Guides
- Topic 7: Data Exchange Standards
- Topic 8: Implementing CDISC Standards
- Topic 9: CDISC Library
- Topic 10: How Does CDISC Work?

Date and Time:

WED 15 JUL 2020

12:00 - 4:00 PM Eastern US Daylight Time





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Thank You!

Questions, comments, concerns? Email <u>bklinke@cdisc.org</u>

Don't forget to fill out the feedback survey!

