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
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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

Agenda

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

Call to Action

- Implementation is complex
- Large volume of information
- Compliance confusion
- Can be overwhelming for newcomers

Action Taken

- 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, Yv[illegible] 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

Topic 1: How to Get Started with CDISC

Topic 2: Links Among CDISC Standards

Topic 3: Traceability

Topic 4: Compliance

Achievements

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


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PRIMER
In collaboration with PhUSE

Topic 1: Getting Started with CDISC

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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

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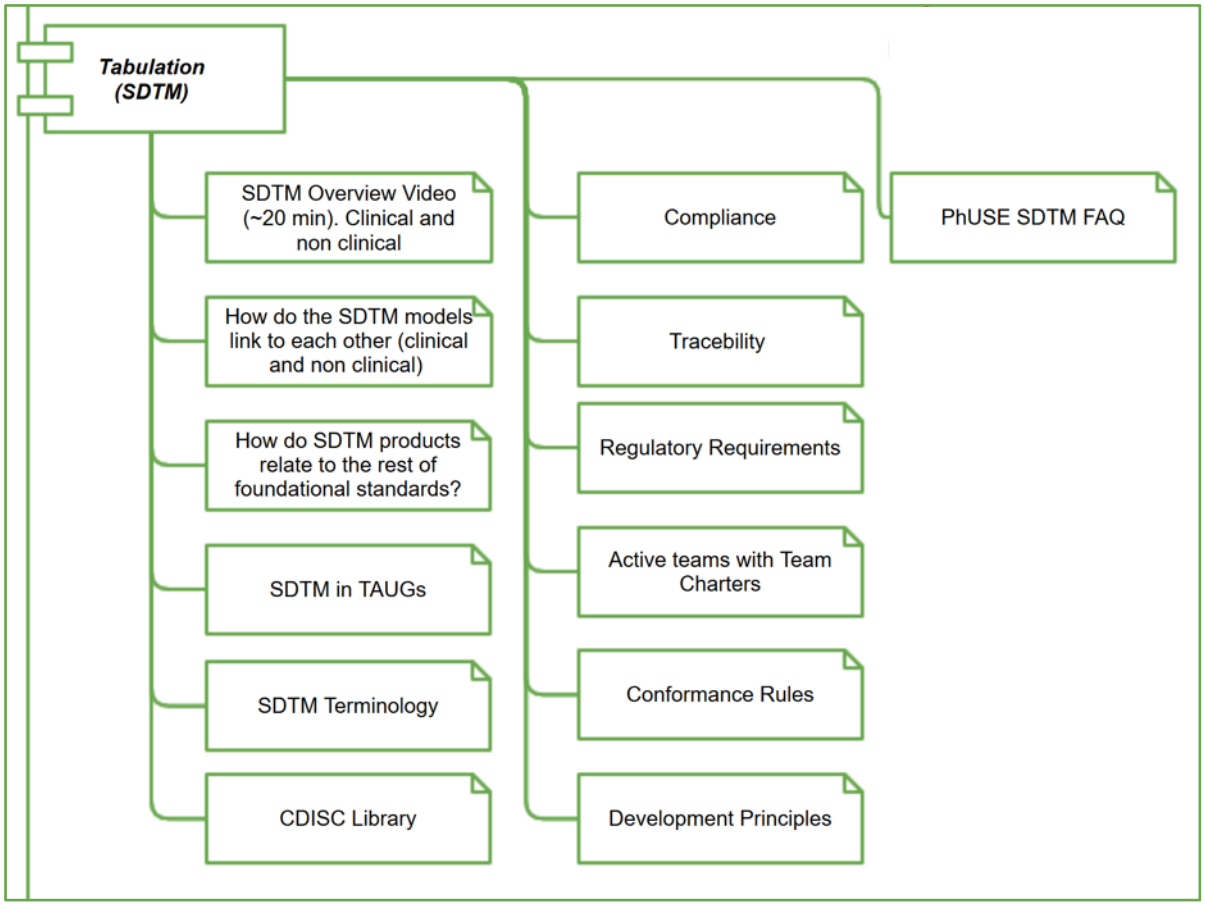
Getting Started with CDISC: SDTM/IG



3 Minute Cartoon Videos for Standards

cdisc PRIMER
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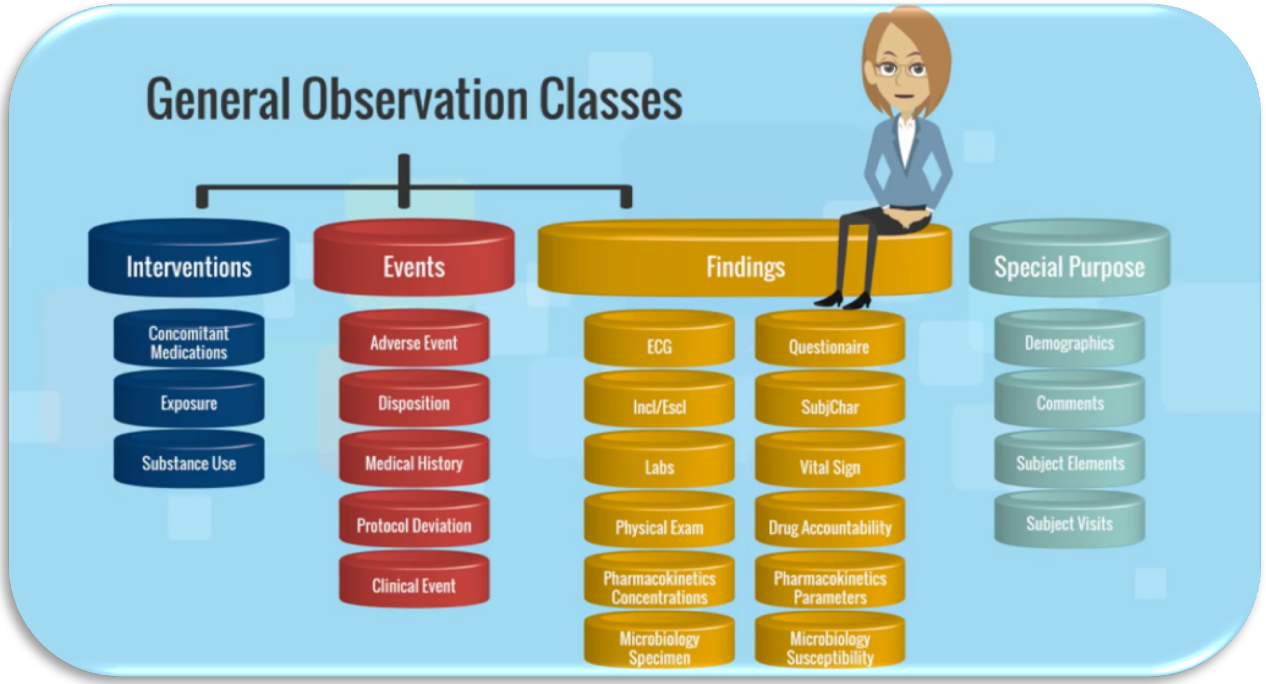
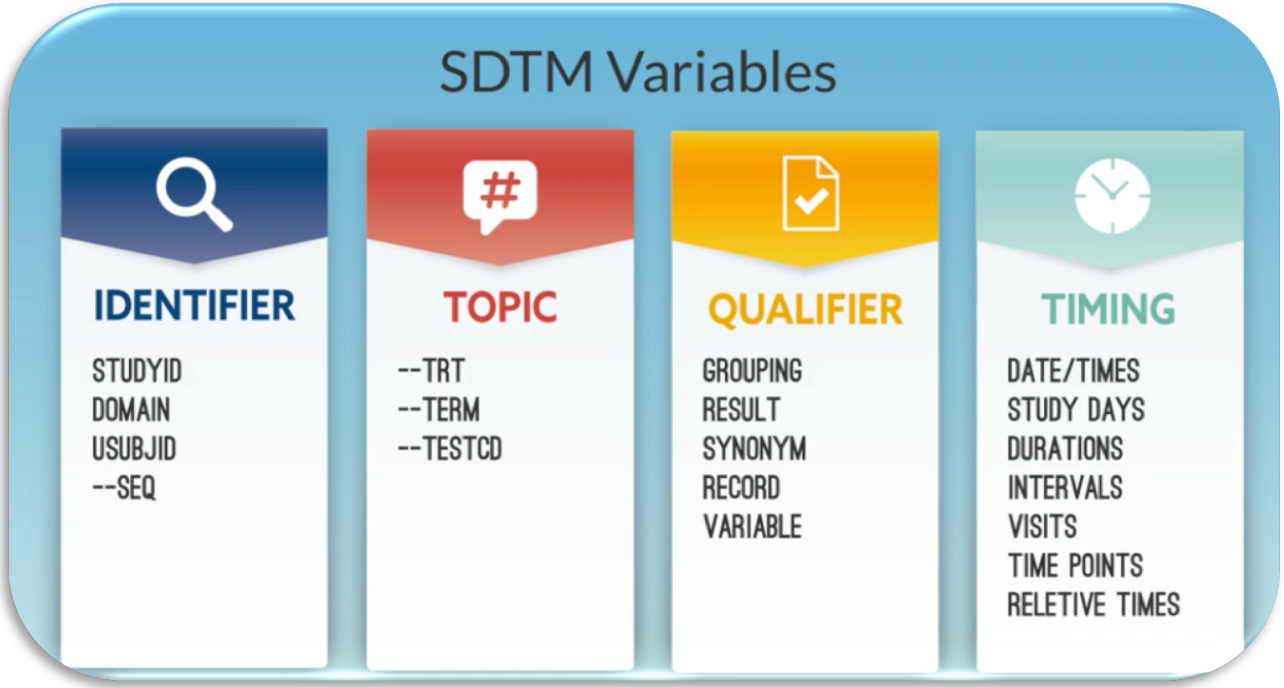
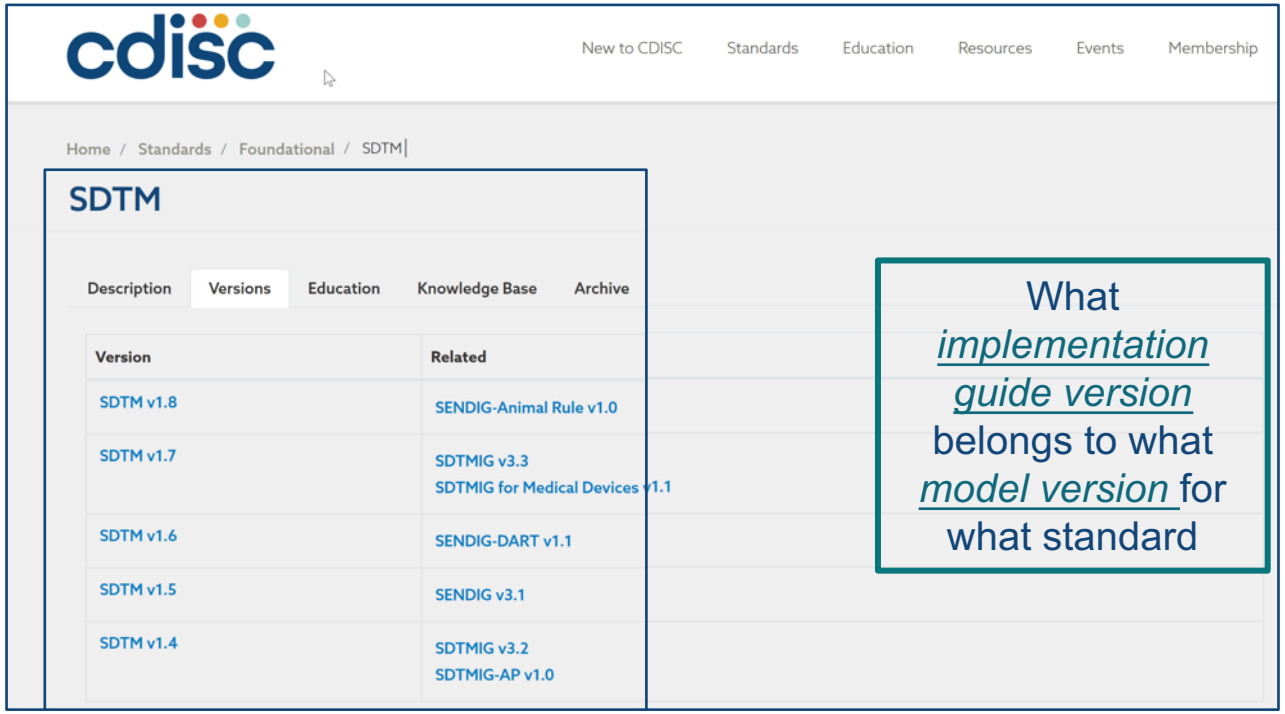
3 Minute Cartoon Videos for Standards



3 Minute Cartoon Videos for Standards



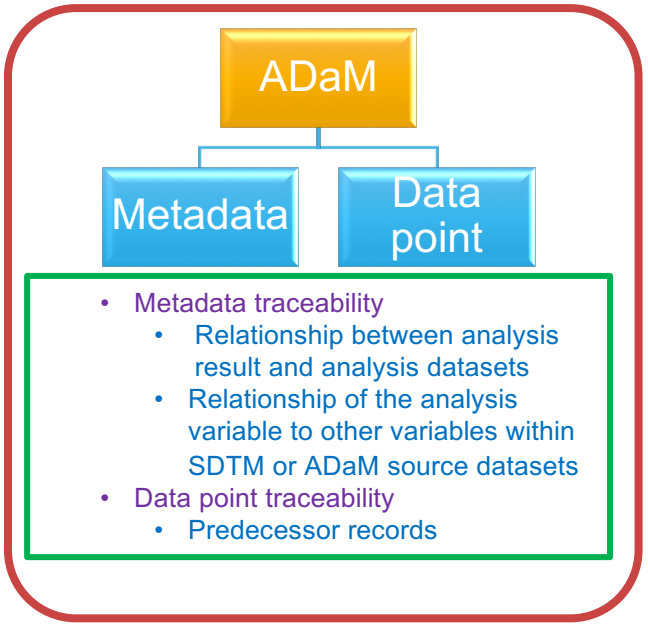
Topic 2: Links Among CDISC Standards Versions

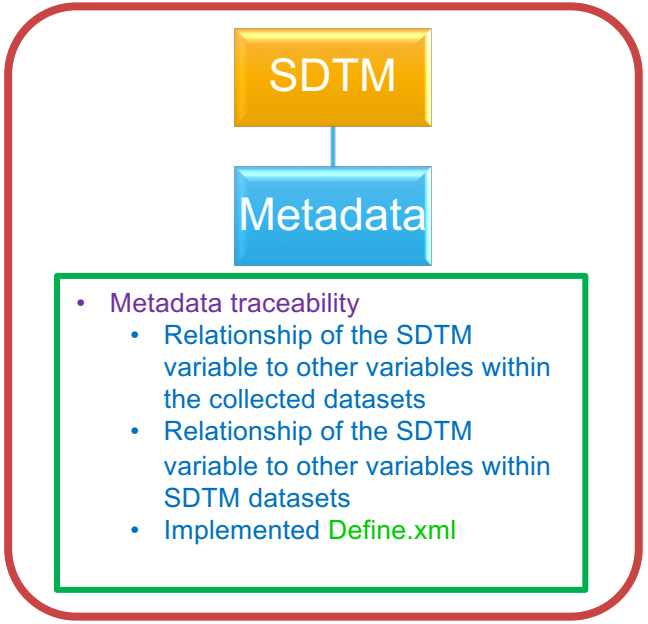


What *implementation guide version* belongs to what *model version* for what standard

On the Newly published CDISC website

Topic 3: Traceability of SDTM/ADaM



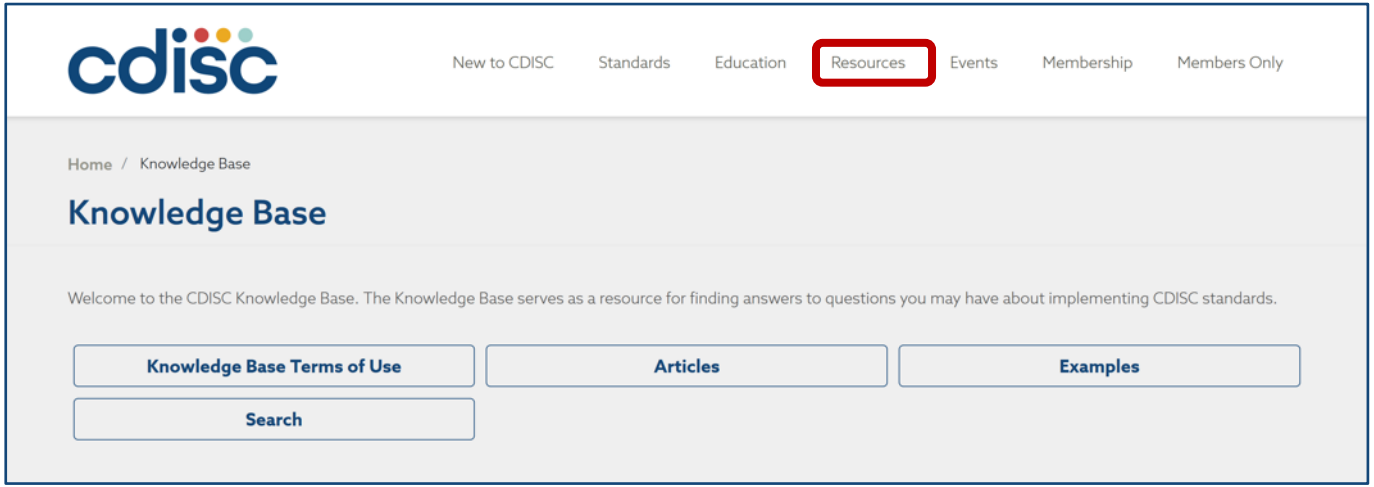


Presentation to be recorded and posted

Topic 4: What Does It Mean to Be CDISC-Compliant?

Bonus Topic! CDISC Knowledge Base

Source for Articles, Examples and (soon) Known Issues



Knowledge Base Article Topics

- 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 Pre-specified Findings
- Avoiding SDTM and ADaM Dataset and Variable Name Conflicts
- Assessing Causality

Examples: CDASH

Meal Tolerance Testing aCRF

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

Read More

Standard(s)

CDASH

Indicate whether or not the meal tolerance testing procedure was performed.	Was the meal tolerance testing procedure performed? MTTYN Not submitted	○Yes ○No
Indicate whether or not the meal for meal tolerance testing was administered.	Was the meal for meal tolerance testing administered? AGOCCUR	○Yes ○No
	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	
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.

Read More

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

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 reco

› ag.xpt

The measured and adjusted GFR
"CALCULATION" would be docum

› lb.xpt

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

› relrec.xpt

Newcomer's Perspective

Journey

- Newcomer

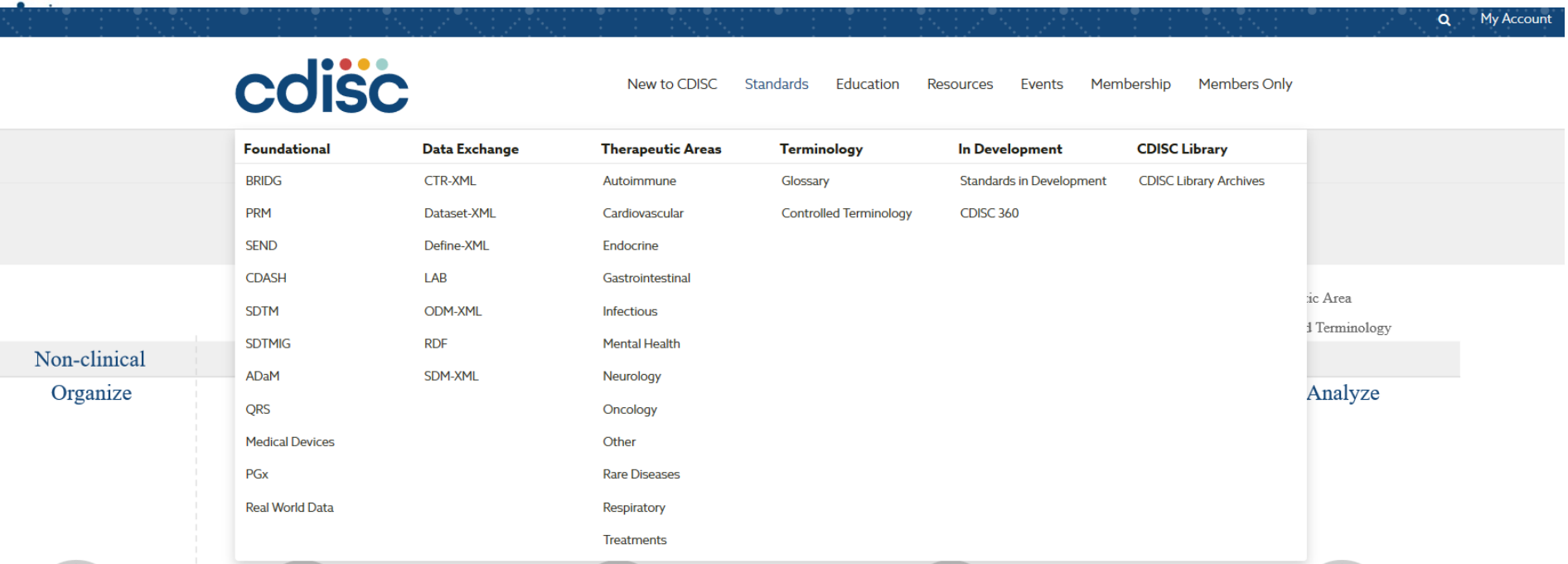
Problem

- First glance of CDISC standards

Solution

- Primer role

Where to Start?

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Education
Resources
Events
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BIOPHARMA
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REGULATORY AGENCY
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Video Library

CDISC - Brand

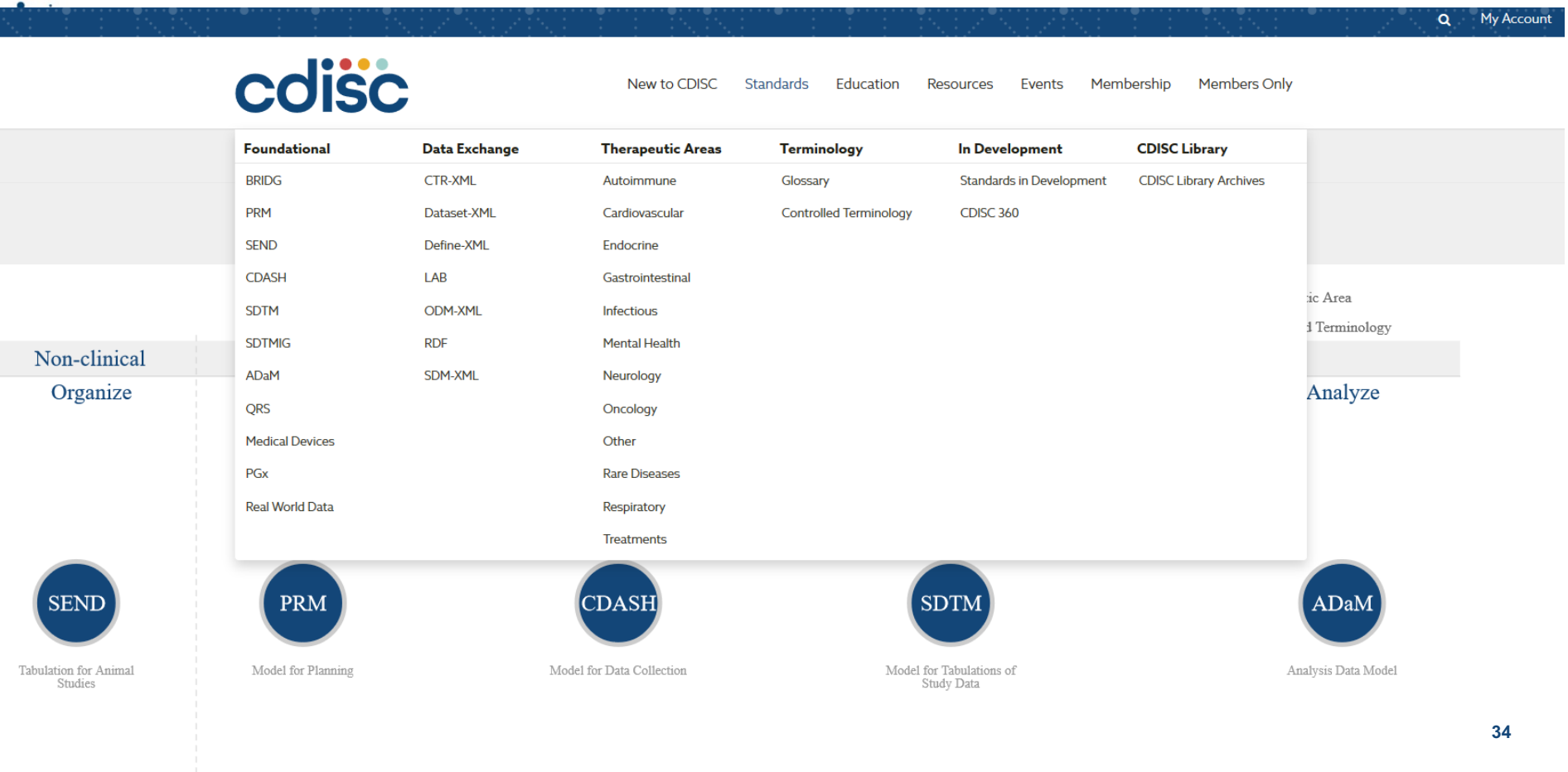
Benefits of Membership and Volunteering

CDISC's Impact in Asia

Impact for Academic Researchers

Whiteboard

Problem: Where to Start?



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

Video Demo: What are SDTM and SDTM Concepts?

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Thank you!

CDISC SDTM/ADaM Implementation FAQ

A PHUSE – CDISC collaboration project for frequently asked implementation questions

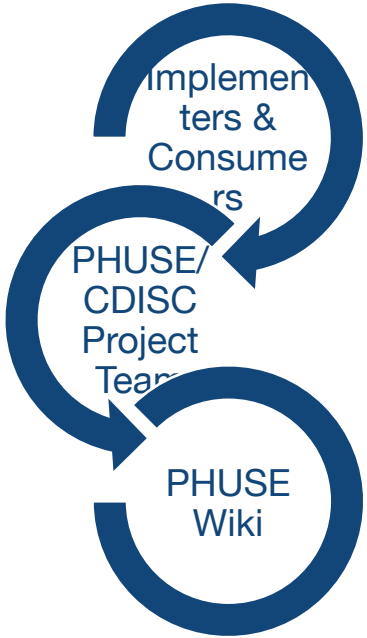
Aatiya Zaidi, Gilead Sciences
Amy Palmer, CDISC
Bhavin Busa, Vita Data Sciences

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)
  http://www.phusewiki.org/wiki/index.php?title=SDTM_ADaM_Implementation_FAQ
- Walk through project teamwork site (project team members only)
  https://phuse.teamworkpm.net/projects/157138/overview
- Submitting Questions (public)
  http://www.phuse.eu/wiki-feedback
- 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)

What is the requirement for Clinical Site Data and Subject-level Data Listings for FDA CDER's Inspection Process (also called BIMO submission or OSI Pre-NDA request)?

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 prepare LB for a global trial slotted for submission to

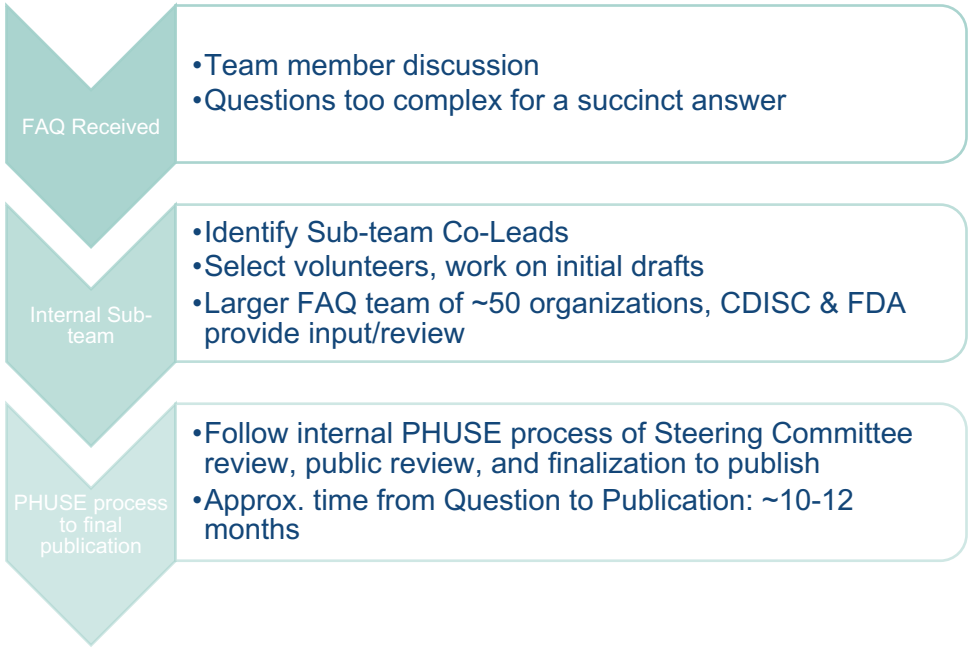
Does the FDA accept a submission of split dataset for illustrative purpose and not necessarily for dataset size? Examples include FA and QS domains. It is mentioned in the submission guideline that the Sponsor should check with their review agency regarding exactly what needs to be included in the submission, 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

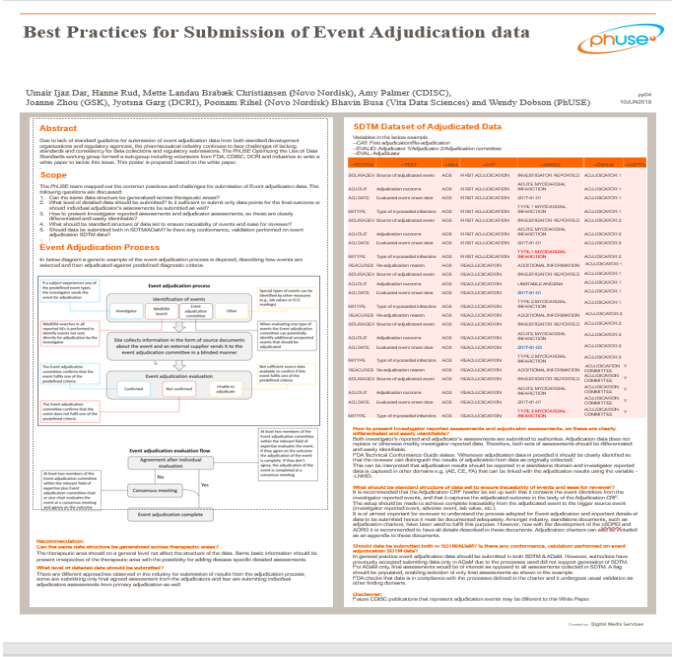
- **Best Practices for Submission of Event Adjudication Data**
  - https://www.phuse.eu/white-papers
- **Integration Strategies in Support of ISS/ISE Submissions**
  - *To be published soon [completed public review]*

- 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

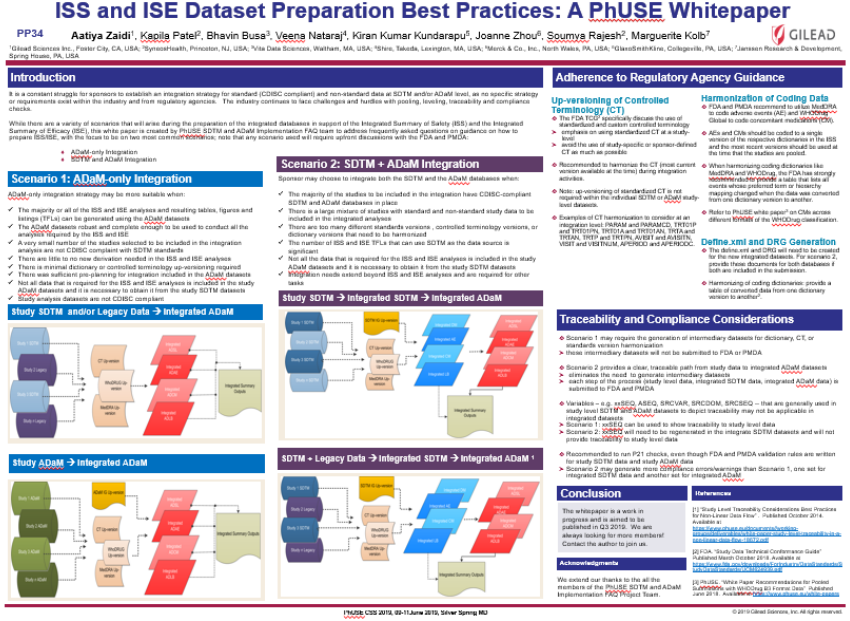


Posters Developed by FAQ Team



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

Posters Developed by FAQ Team



ISS and ISE Dataset Preparation Best Practices: A PhUSE Whitepaper

PP34

Aatiya Zaidi[1], Kapila Patel[2], Bhavin Busa[3], Veena Nataraj[4], Kiran Kumar Kundarapu[5], Joanne Zhou[6], Soumya Rajesh[2], Marguerite Kolb[7]

GILEAD

[1]Gilead Sciences Inc., Foster City, CA, USA; [2]SyneosHealth, Princeton, NJ, USA; [3]Vita Data Sciences, Waltham, MA, USA; [4]Shire, Takeda, Lexington, MA, USA; [5]Merck & Co., Inc., North Wales, PA, USA; [6]GlaxoSmithKline, Collegeville, PA, USA; [7]Janssen Research & Development, Spring House, PA, USA

Introduction

It is a constant struggle for sponsors to establish an integration strategy for standard (CDISC compliant) and non-standard data at SDTM and/or ADaM level, as no specific strategy or requirements exist within the industry and from regulatory agencies. The industry continues to face challenges and hurdles with pooling, leveling, traceability and compliance checks.

While there are a variety of scenarios that will arise during the preparation of the integrated databases in support of the Integrated Summary of Safety (ISS) and the Integrated Summary of Efficacy (ISE), this white paper is created by PhUSE SDTM and ADaM Implementation FAQ team to address frequently asked questions on guidance on how to prepare ISS/ISE, with the focus to be on two most common scenarios; note that any scenario used will require upfront discussions with the FDA and PMDA:

- ADaM-only Integration
- SDTM and ADaM Integration

Scenario 1: ADaM-only Integration

ADaM-only integration strategy may be more suitable when:

- ✓ The majority or all of the ISS and ISE analyses and resulting tables, figures and listings (TFLs) can be generated using the ADaM datasets
- ✓ The ADaM datasets robust and complete enough to be used to conduct all the analyses required by the ISS and ISE
- ✓ A very small number of the studies selected to be included in the integration analysis are not CDISC compliant with SDTM standards
- ✓ There are little to no new derivation needed in the ISS and ISE analyses
- ✓ There is minimal dictionary or controlled terminology up-versioning required
- ✓ There was sufficient pre-planning for integration included in the ADaM datasets
- ✓ Not all data that is required for the ISS and ISE analyses is included in the study ADaM datasets and it is necessary to obtain it from the study SDTM datasets
- ✓ Study analysis datasets are not CDISC compliant

Study SDTM and/or Legacy Data → Integrated ADaM

Study ADaM → Integrated ADaM

Scenario 2: SDTM + ADaM Integration

Sponsor may choose to integrate both the SDTM and the ADaM databases when:

- ✓ The majority of the studies to be included in the integration have CDISC-compliant SDTM and ADaM databases in place
- ✓ There is a large mixture of studies with standard and non-standard study data to be included in the integrated analyses
- ✓ There are too many different standards versions , controlled terminology versions, or dictionary versions that need to be harmonized
- ✓ The number of ISS and ISE TFLs that can use SDTM as the data source is significant
- ✓ Not all the data that is required for the ISS and ISE analyses is included in the study ADaM datasets and it is necessary to obtain it from the study SDTM datasets
- ✓ Integration needs extend beyond ISS and ISE analyses and are required for other tasks

Study SDTM → Integrated SDTM → Integrated ADaM

SDTM + Legacy Data → Integrated SDTM → Integrated ADaM

Adherence to Regulatory Agency Guidance

Up-versioning of Controlled Terminology (CT)

- The FDA TCG[2] specifically discuss the use of standardized and custom controlled terminology emphasis on using standardized CT at a study-level
  - avoid the use of study-specific or sponsor-defined CT as much as possible
- Recommended to harmonize the CT (most current version available at the time) during integration activities.
- Note: up-versioning of standardized CT is not required within the individual SDTM or ADaM study-level datasets.
- Examples of CT harmonization to consider at an integration level: PARAM and PARAMCD, TRTP/P and TRTP/PN, TRT01A and TRT01AN, TRTA and TRTAN, TRTP and TRTPN, AVISIT and AVISITN, VISIT and VISITNUM, APERIOD and APERIODC.

Harmonization of Coding Data

- FDA and PMDA recommend to utilize MedDRA to code adverse events (AE) and WHODrug Global to code concomitant medications (CM).
- AEs and CMs should be coded to a single version of the respective dictionaries in the ISS and the most recent versions should be used at the time that the studies are pooled.
- When harmonizing coding dictionaries like MedDRA and WHODrug, the FDA has strongly recommended to provide a table that lists all events whose preferred term or reason for mapping changed when the data was converted from one dictionary version to another.
- Refer to PhUSE white paper[3] on CMs across different levels of the WHODrug classification.

Define.xml and DRG Generation

- The define.xml and DRG will need to be created for the new integrated datasets. For scenario 2, provide these documents for both databases if both are included in the submission.
- Harmonizing of coding dictionaries: provide a table of converted data from one dictionary version to another.

Traceability and Compliance Considerations

- Scenario 1 may require the generation of intermediary datasets for dictionary, CT, or standards version harmonization
  - those intermediary datasets will not be submitted to FDA or PMDA
- Scenario 2 provides a clear, traceable path from study data to integrated ADaM datasets
  - eliminates the need to generate intermediary datasets
  - each step of the process (study level data, integrated SDTM data, integrated ADaM data) is submitted to FDA and PMDA
- Variables – e.g. ssSEQ, ASEQ, SRCVAR, SRCDOM, SRCSEQ – that are generally used in study level SDTM and ADaM datasets to depict traceability may not be applicable in integrated datasets
  - Scenario 1: ssSEQ can be used to show traceability to study level data
  - Scenario 2: ssSEQ will need to be regenerated in the integrate SDTM datasets and will not provide traceability to study level data
- Recommended to run P21 checks, even though FDA and PMDA validation rules are written for study SDTM data and study ADaM data
- Scenario 2 may generate more compliance errors/warnings than Scenario 1, one set for integrated SDTM data and another set for integrated ADaM

Conclusion

The whitepaper is a work in progress and is aimed to be published in Q3 2019. We are always looking for more members! Contact the author to join us.

References

[1] "Study Level Traceability Considerations Best Practices for Non-Linear Data Flow" . Published October 2014. Available at:

[2] FDA. "Study Data Technical Conformance Guide" . Published March October 2018. Available at:

[3] PhUSE. "White Paper: Recommendations for Pooled Submissions with WHODrug B3 Format Data" . Published June 2018. Available at:

Acknowledgments

We extend our thanks to the all the members of the PhUSE SDTM and ADaM Implementation FAQ Project Team.

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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Amy Palmer – apalmer@cdisc.org

Bhavin Busa – bbusa@vitadatasciences.com

Wendy Dobson – wendy@phuse.eu

Audience Questions

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

Audience Questions

How can I join the implementation FAQ project team?

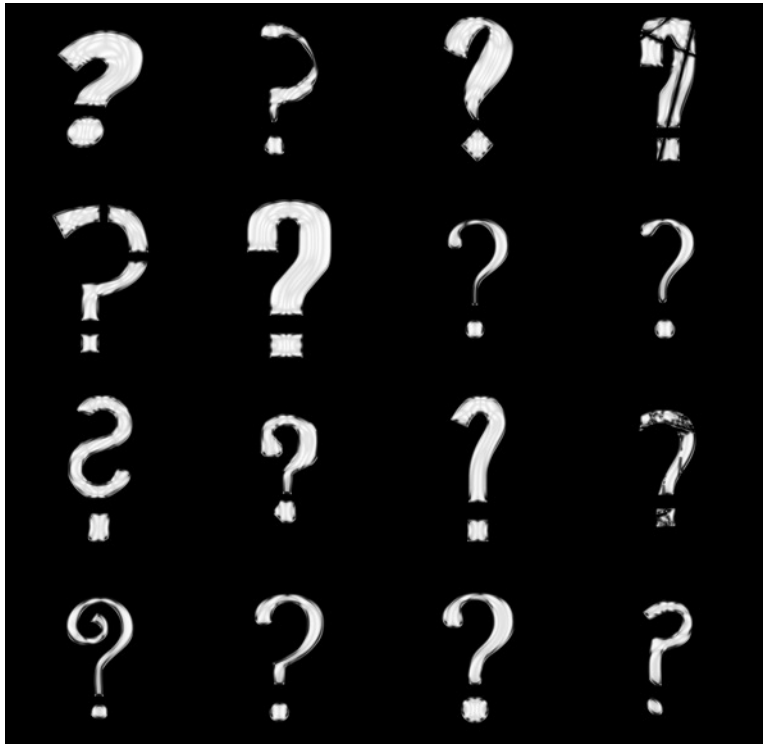
Audience Questions

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

Audience Questions

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

Audience Questions



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

Additional Resources from PHUSE

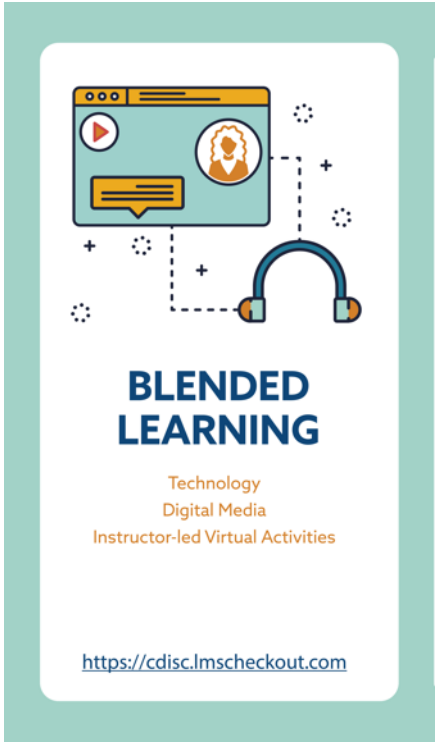
- From PHUSE perspective, the CDISC Primer deliverable once final will be housed here https://www.phuse.eu/white-papers
- Link to PHUSE SEND Wiki https://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_User_Group

(Thanks Wendy!)

Upcoming Learning Opportunities

NEW Blended Learning from CDISC

- Self-paced online training combined with remote instructor-led Q&A
  - Developed by standards experts
  - CDISC authorized instructors
  - Currently in English, Japanese, and Mandarin
  - Four global time zones
  - **Introductory Offer – Additional 25% Off!**



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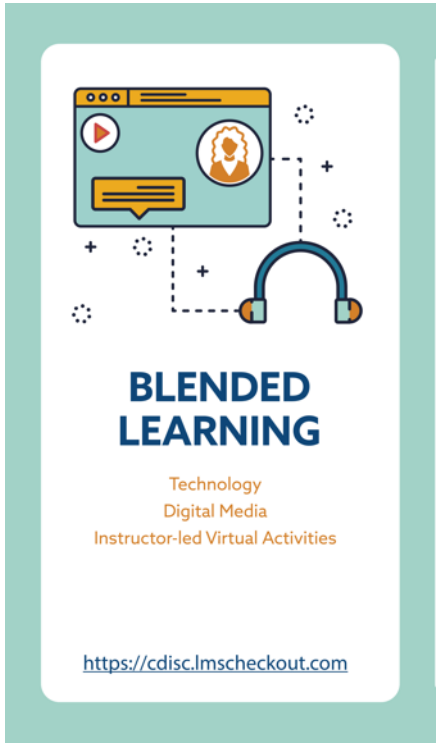
- Sessions starting soon!

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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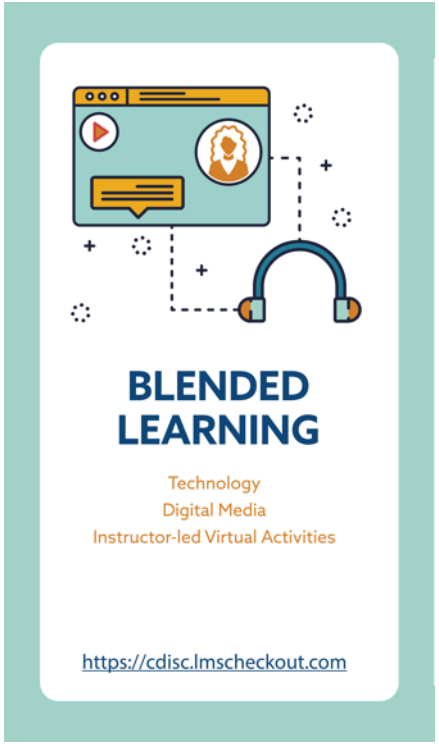

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2020 Webinars

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

Visit https://www.cdisc.org/events/education/webinars 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

Join CDISC for a Virtual Training:

CDISC for Newcomers (Virtual)

New to **CDISC Standards**? 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 **Data Exchange standards** are reviewed and the **CDISC Library** is discussed.

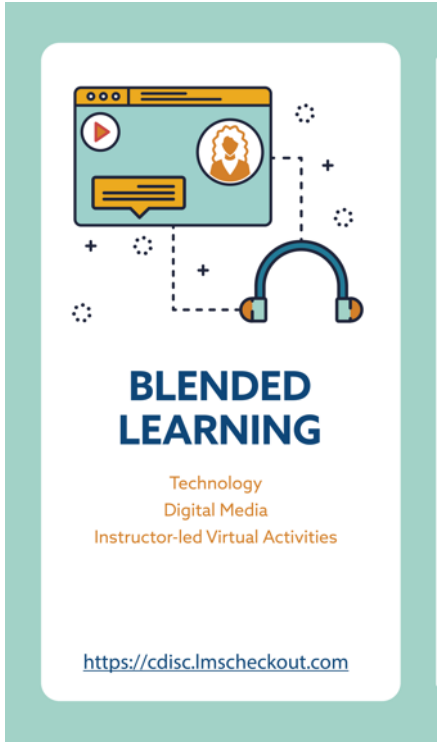
The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

- **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



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!