

SDTM: Let's read outside the Bible

Presented by Sandra Latorre
Data Integration Specialist

PHUSE EU CONNECT 2020 - DS02



AGENDA

1. *Introduction*
2. Usage of CDASH
3. Usage of TAUGs
4. Conclusion



#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #DataGovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

The Holy Bible



SDTMIG v3.2
(Single file)

SDTM v1.4

SDTM Expert



IF ONLY IT COULD BE THAT SIMPLE...

- Conflicts with Regulatory Agencies

SDTM IG v3.2	FDA
ARMCD=«SCRNFAIL»	ARMCD is null

- Regular updates
- Hundreds of pages of pdf non-computable information
- Can't cover everything
→ “how do I map this?”

SOURCES OF INFORMATION

- Controlled Terminology
- CDASH
- TAUG (Therapeutic Area User Guide)
- FDA Technical conformance guide
- ...

AGENDA

1. Introduction
2. *Usage of CDASH*
3. Usage of TAUGs
4. Conclusion



#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #DataGovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

CDASH: CLINICAL DATA ACQUISITION STANDARDS HARMONIZATION

- CDASH= CDISC Standard for data collection?

Were any concomitant medications taken? NOT SUBMITTED CMYN	☐ Yes ☐ No
What was the medication? CMTRT	_____
For what indication was the medication taken? CMINDC	_____
What was the individual dose of medication? CMDOSE	_____

SDTM →

EXAMPLE 1: BEST PRACTICE PHYSICAL EXAMINATION

How would you map this ?

Was the physical examination performed?	☐ Yes ☐ No <i><From NY codelist></i>
Reason Not Performed	
Date	

EXAMPLE 1: BEST PRACTICE PHYSICAL EXAMINATION

How would you map this ?

Was the physical examination performed?	☐ Yes ☐ No <i><From NY codelist></i>
Reason Not Performed?	
Date	

- PE domain ?
- PESTAT ?
- PEREASND ?

EXAMPLE 1: BEST PRACTICE PHYSICAL EXAMINATION

No findings to be collected → not a Findings domain

Was the physical examination performed? PROCCUR PROCCUR where PRTRT = "PHYSICAL EXAMINATION"	☐ Yes ☐ No <From NY codelist>
Reason Not Performed? PRREASOC SUPPPR.QVAL where SUPPPR.QNAM = "PRREASOC" and SUPPPR.QLABEL = "Reason for Occur Value"	
Date PRSTDAT PRSTDTC	

PR domain (procedures)
SUPPPR

→ Source: CDASH IG v2.1

EXAMPLE 2: CONCOMITANT MEDICATION ATC CODES

How would you map this?

		S
		SENSORY ORGANS
		S01
		OPHTHALMOLOGICALS
		S01K
		SURGICAL AIDS
		S01KA
		VISCOELASTIC SUBSTANCES

EXAMPLE 2: CONCOMITANT MEDICATION ATC CODES

QNAM	QLABEL	QVAL
CMATC1	ATC Level 1 Code	S
CMATC1CD	ATC Level 1 Description	SENSORY ORGANS
CMATC2	ATC Level 2 Code	S01
CMATC2CD	ATC Level 2 Description	OPHTHALMOLOGICALS
CMATC3	ATC Level 3 Code	S01K
CMATC3CD	ATC Level 3 Description	SURGICAL AIDS
CMATC4	ATC Level 4 Code	S01KA
CMATC4CD	ATC Level 4 Description	VISCOELASTIC SUBSTANCES

→ *Source: CDASH v2.1*

AGENDA

1. Introduction
2. Usage of CDASH
3. *Usage of TAUGs*
4. Conclusion



#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #DataGovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

TAUG = THERAPEUTIC AREA USER GUIDE

Acute Kidney Injury

Alzheimer's

Asthma

Breast Cancer

Cardiovascular

CDAD

Colorectal Cancer

COPD

COVID-19

Crohn's Disease

Diabetes

Diabetes - Type 1

Diabetic Kidney Disease

Duchenne Muscular Dystrophy

Dyslipidemia

Ebola

Heart Failure

Hepatitis C

HIV

Huntington's Disease

Influenza

Kidney Transplant

Lung Cancer

Major Depressive Disorder

Malaria

Multiple Sclerosis

Nutrition

Pain

Pancreatic Cancer

Parkinson's Disease

Polycystic Kidney Disease

Post Traumatic Stress Disorder

Prostate Cancer

Psoriasis

QT Studies

Rheumatoid Arthritis

Schizophrenia

Traditional Chinese Medicine - Acupuncture

Traditional Chinese Medicine - Coronary

Artery Disease-Angina

Traumatic Brain Injury

Tuberculosis

Vaccines

Virology

EXAMPLE: DIARY DATA

→ *Source: Nutrition TAUG*

Types of diary → high impact on SDTM mapping

- **“Subject recall”**: e.g. over 3 days prior to the visit
- **“End of the day”**: subject completes diary card at the end of each day
- **“Each episode”**: subject completes diary card at each episode

DIARY DATA: SUBJECT RECALL

Over the last 3 days, what was the average number of bowel movements per day?

Over the last 3 days, what was the typical consistency of bowel movements?

- ☐ Watery
- ☐ Loose
- ☐ Soft
- ☐ Formed
- ☐ Hard

CDASH AND SDTM ANNOTATIONS

FA

Over the last 3 days, what was the average number of bowel movements per day?

EVENTFRQ_FAORRES

FAORRES where FATESTCD = "EVENTFRQ"

LB

Over the last 3 days, what was the typical consistency of bowel movements?

CONSIST_LBORRES

LBORRES where LBTESTCD = "CONSIST"

- ☐ Watery
- ☐ Loose
- ☐ Soft
- ☐ Formed
- ☐ Hard

ASSIGNED VALUES

FAOBJ <i>Hidden/pre-populated</i>	BOWEL MOVEMENT
FAEVINTX FAEVINTX and LBEVINTX <i>Hidden/pre-populated</i>	PREVIOUS 3 CALENDAR DAYS
Over the last 3 days, what was the average number of bowel movements per day?	
EVENTFRQ_FAORRES FAORRES where FATESTCD = "EVENTFRQ"	
EVENTFRQ_FATEST FATEST where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	Event Frequency
EVENTFRQ_FAORRESU FAORRESU where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	/day
Over the last 3 days, what was the typical consistency of bowel movements?	☐ Watery
CONSIST_LBORRES LBORRES where LBTESTCD = "CONSIST"	☐ Loose
	☐ Soft
	☐ Formed
	☐ Hard

NON-STANDARD VARIABLES (NSV)

FAOBJ <i>Hidden/pre-populated</i>	BOWEL MOVEMENT
FAEVINTX FAEVINTX and LBEVINTX <i>Hidden/pre-populated</i>	PREVIOUS 3 CALENDAR DAYS
Over the last 3 days, what was the average number of bowel movements per day?	
EVENTFRQ_FAORRES FAORRES where FATESTCD = "EVENTFRQ"	
EVENTFRQ_FASOURCE NSV.FASOURCE where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	RECALL
EVENTFRQ_FACOLSRT NSV.FACOLSRT where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	AVERAGE
EVENTFRQ_FATEST FATEST where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	Event Frequency
EVENTFRQ_FAORRESU FAORRESU where FATESTCD = "EVENTFRQ" <i>Hidden/pre-populated</i>	/day
Over the last 3 days, what was the typical consistency of bowel movements?	☐ Watery ☐ Loose ☐ Soft ☐ Formed ☐ Hard
CONSIST_LBORRES LBORRES where LBTESTCD = "CONSIST"	
CONSIST_LBSOURCE NSV.LBSOURCE where LBTESTCD = "CONSIST" <i>Hidden/pre-populated</i>	RECALL
CONSIST_LBCOLSRT NSV.LBCOLSRT where LBTESTCD = "CONSIST" <i>Hidden/pre-populated</i>	TYPICAL
CONSIST_LBTEST LBTEST where LBTESTCD = "CONSIST" <i>Hidden/pre-populated</i>	Consistency

DATASETS WITH NON-STANDARD VARIABLES

FATESTCD	FATEST	FAOBJ	FAORRES	FAORRESU	FAEVAL	VISITNUM	VISIT	VISITDY	FADTC	FAEVINTX	FACOLSRT	FASOURCE
EVENTFRQ	Event Frequency	BOWEL MOVEMENT	3	/day	STUDY SUBJECT	1	Baseline	-1	2017-01-05	PREVIOUS 3 CALENDAR DAYS	AVERAGE	RECALL

LBTESTCD	LBTEST	LBORRES	LBSTRESC	LBSPEC	LBEVAL	VISITNUM	VISIT	VISITDY	LB DTC	LBEVINTX	LBCOLSRT	LBSOURCE
CONSIST	Consistency	LOOSE	LOOSE	STOOL	STUDY SUBJECT	1	Baseline	-1	2017-01-05	PREVIOUS 3 CALENDAR DAYS	TYPICAL	RECALL

Non-Standard Variables
--> in SUPP--

AGENDA

1. Introduction
2. Usage of CDASH
3. Usage of TAUGs
4. *Conclusion*



#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #DataGovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
#AdvancedAnalytics
#MachineLearning #Digital
#Chatbot #Biometrics #CRO
#ClinicalData
#LifeSciencesExperts
#Whodrug #MedDRA
#Pharmacovigilance
#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

CONCLUSION

- CDASH: not only for collection
- TAUG: not only for the Therapeutic Area
- Hope for the future: smart usage of CDISC Library

CONTACT



Sandra Latorre

Data Integration Specialist

sandra.latorre@businessdecision.be