

A Collaborative Fast Track to Clinical Data Flow Modernisation and Standards Governance Implementation

Paul Vervuren, Danone Research & Innovation
Roger Gagali Angoh, Qualiance

PHUSE Connect Hamburg 2025
Presentation SI07

BRINGING HEALTH THROUGH FOOD TO AS MANY PEOPLE AS POSSIBLE

49%

ESSENTIAL DAIRY
AND PLANT-
BASED

Fresh dairy

Plant-based spoonable

Plant-based beverage

Coffee creamer

High Protein

#1
WORLDWIDE
for fresh dairy products &
plant-based foods and beverages

33%

SPECIALIZED
NUTRITION

Baby Formula

Pediatric medical nutrition

Adult medical nutrition

#2
WORLDWIDE
for early life nutrition

#1
IN EUROPE
for adult medical
nutrition

18%

WATERS

Plain Still

Flavored Still

Sparkling Plain

Sparkling Flavored

Functional

#2
WORLDWIDE
for packaged waters

APPROACHING ADULthood IN DATA STANDARDS AFTER 15Y DEVELOPMENT



CONSTRUCTING A DATA WAREHOUSE FOR NUTRITION CLINICAL STUDIES

Paul Vervuren

PhUSE Barcelona
October 10th, 2016

NUTRICIA RESEARCH | DANONE NUTRICIA RESEARCH

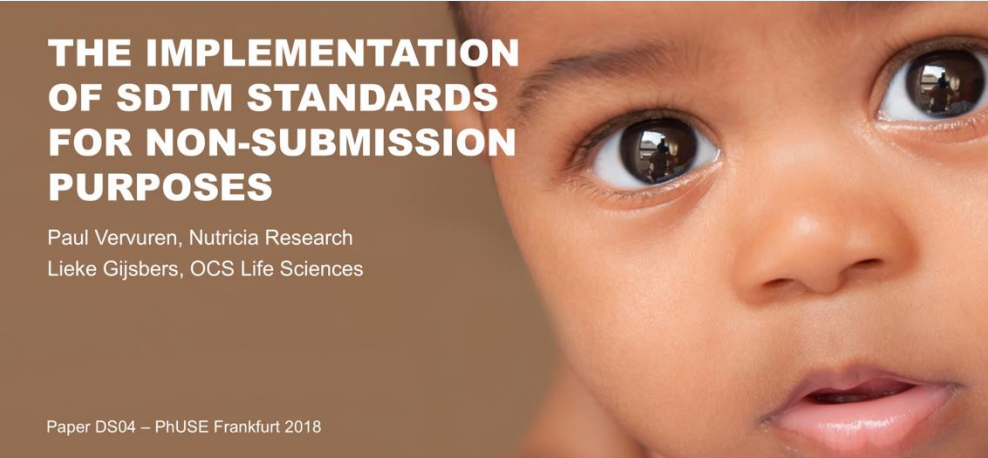


IMPLEMENTING LSAF THE DANONE NUTRICIA JOURNEY

Paul Vervuren
Jean-Marc Ferran

Paper DH04
PHUSE EU Connect 2019

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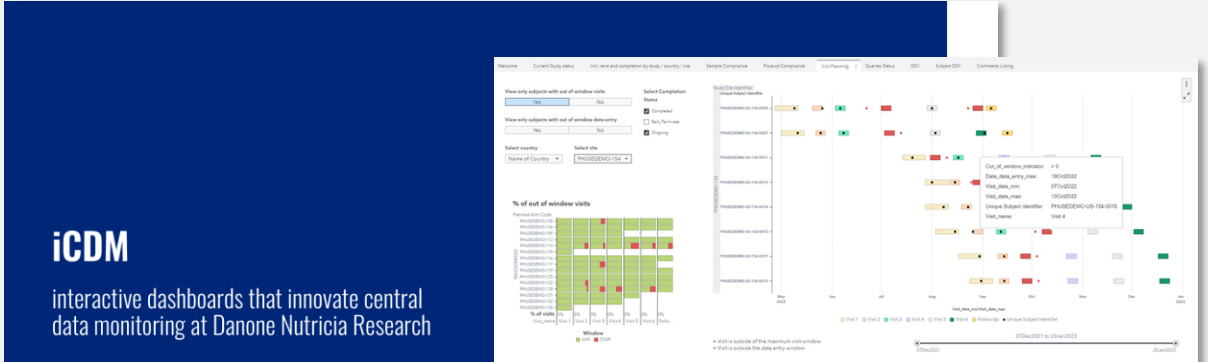


THE IMPLEMENTATION OF SDTM STANDARDS FOR NON-SUBMISSION PURPOSES

Paul Vervuren, Nutricia Research
Lieke Gijsbers, OCS Life Sciences

Paper DS04 – PhUSE Frankfurt 2018

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iCDM

interactive dashboards that innovate central data monitoring at Danone Nutricia Research

Paul Vervuren & Dennis Menkveld
PHUSE EU CONNECT 2022 - AR05

DANONE ONE PLANET. ONE HEALTH | PU

GROWING PAINS ...



How did we map
this in previous
study?

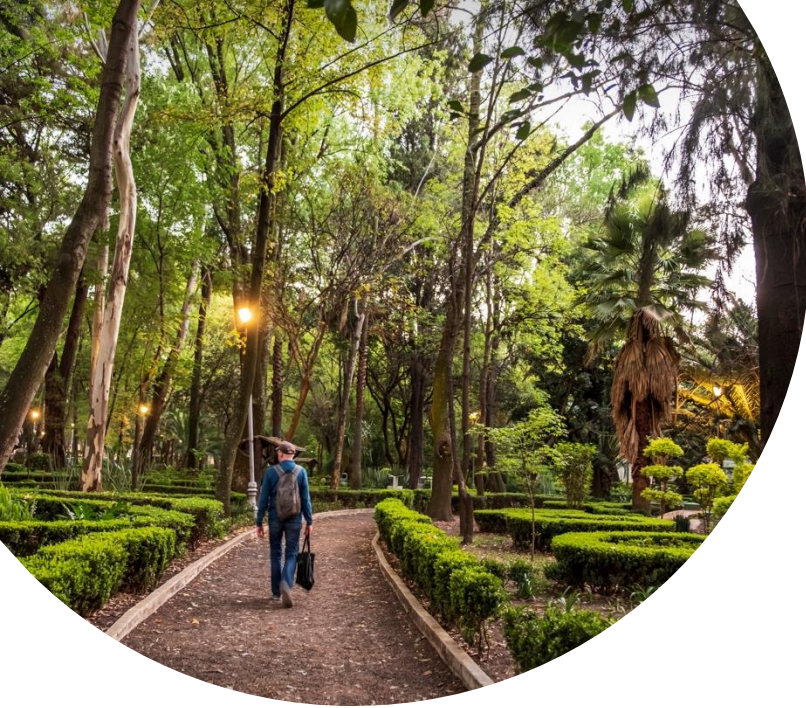
Flavors

What version of
SDTM shall we use?

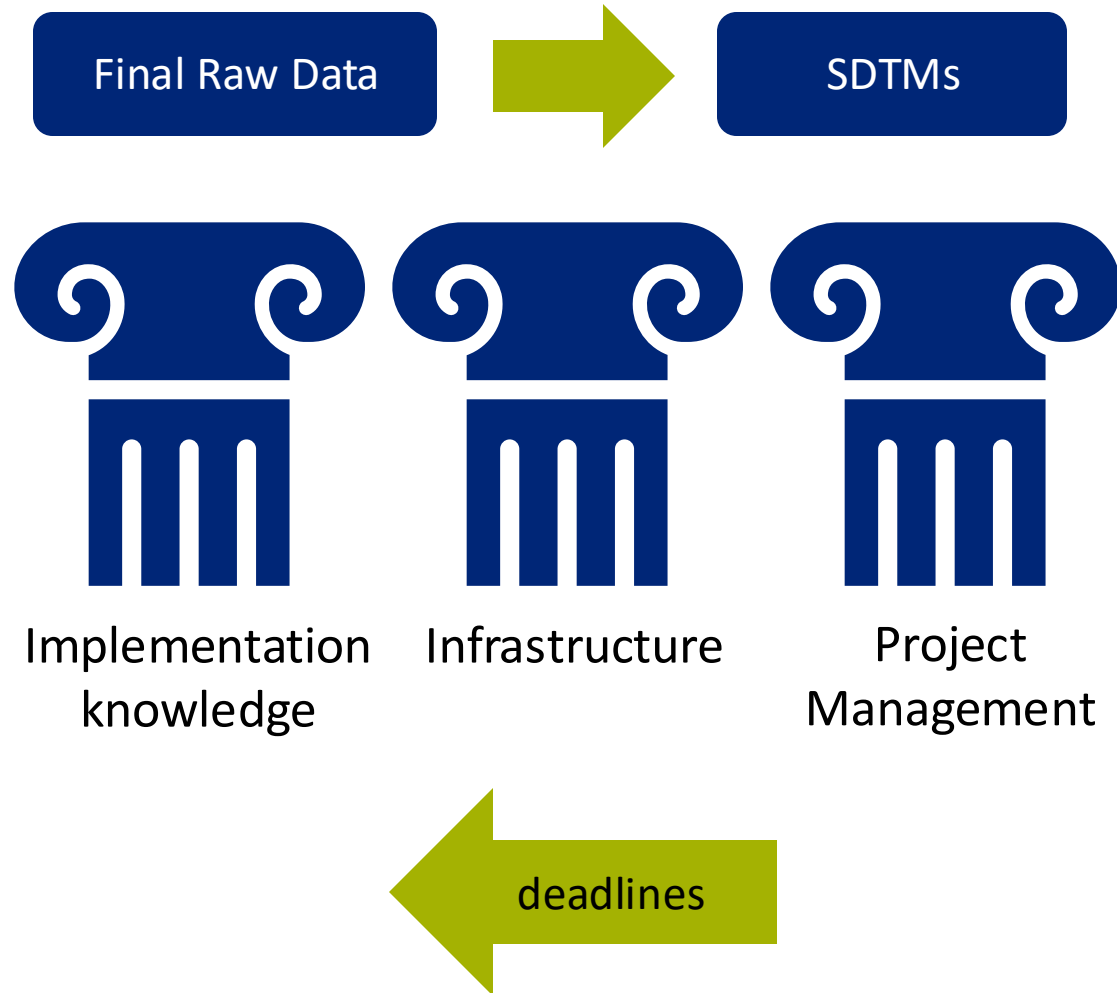
Rework

Does the
programmer create
the SDTMs? Or the
data manager?

Gaps

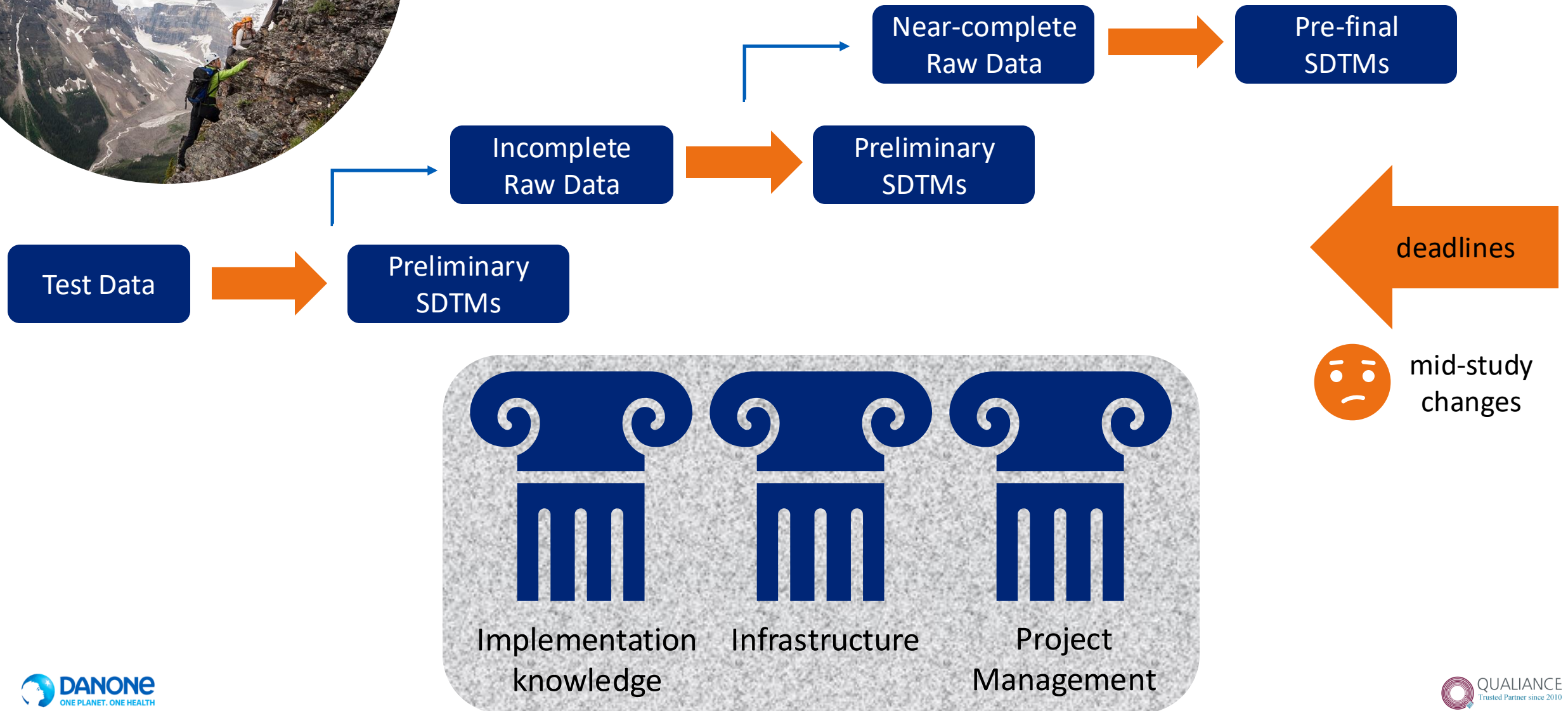


LEGACY DATA CONVERSION: A ONE-SHOT EFFORT

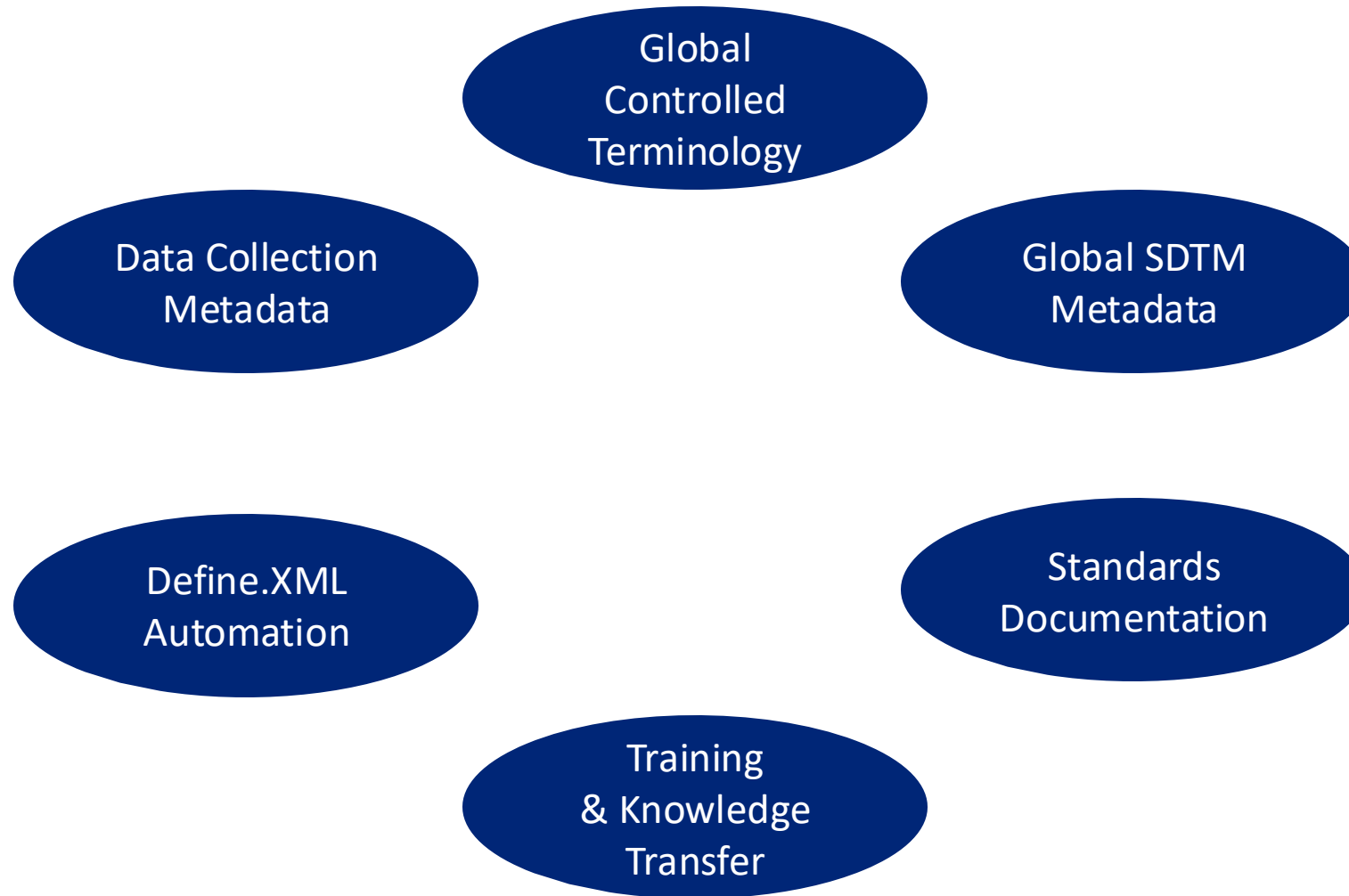




SDTM DATA READY-FOR-USE AT STUDY START REQUIRES A STRONGER FOUNDATION



DATA STANDARDS IMPLEMENTATION OVERVIEW



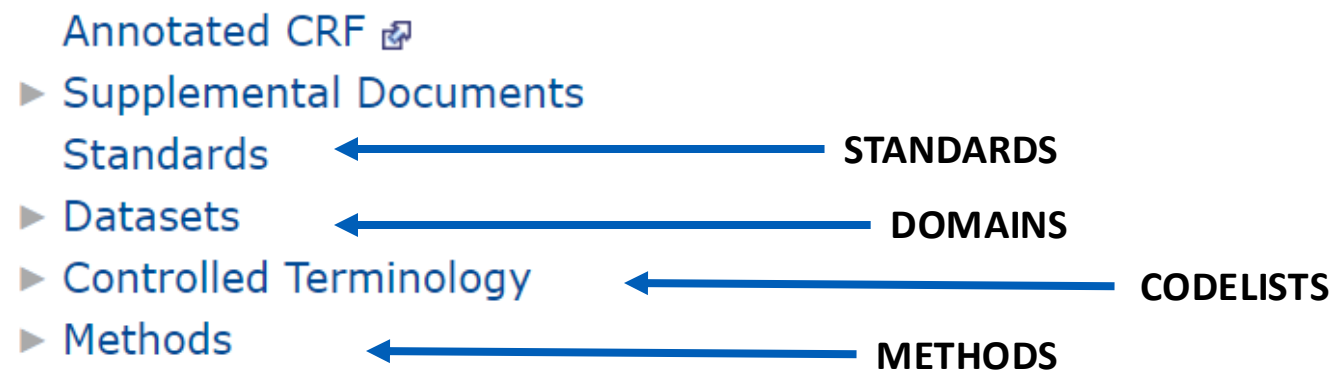
GLOBAL CONTROLLED TERMINOLOGY

CODELIST_NAME	CODELIST_ID	TERM_CODE	SUBMISSION_VALUE	DECODE	IS_EXTENDED
No Yes Response - Yes and No Only	NY_YN	C49487	N	No	
No Yes Response - Yes and No Only	NY_YN	C49488	Y	Yes	
Vital Signs Test Code	VSTESTCD	C16358	BMI	Body Mass Index	
Vital Signs Test Code	VSTESTCD	C178060	CALFCIR	Calf Circumference	
Vital Signs Test Code	VSTESTCD	C25347	HEIGHT	Height	
Vital Signs Test Code	VSTESTCD		VSALL	All Vital Signs Tests	Yes
Vital Signs Test Code	VSTESTCD	C25208	WEIGHT	Weight	

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C66742		No	No Yes Response	NY	No Yes Response
C49487	C66742		No Yes Response	N	No
C48660	C66742		No Yes Response	NA	NA; Not Applicable
C17998	C66742		No Yes Response	U	U; UNK; Unknown
C49488	C66742		No Yes Response	Y	Yes
C66741		Yes	Vital Signs Test Code	VSTESTCD	Vital Signs Test Code
C16358	C66741		Vital Signs Test Code	BMI	Body Mass Index
C178060	C66741		Vital Signs Test Code	CALFCIR	Calf Circumference
C25299	C66741		Vital Signs Test Code	DIABP	Diastolic Blood Pressure

GLOBAL STUDY METADATA DEFINITION

CDISC01_1



DM (Demographics) - [SDTMIG 3.1.2]

Related Supplemental Qualifiers Dataset: [SUPPDM](#) (Supplemental Qualifiers for DM)

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DM) • "DM" = "Demographics"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
SUBJID	Subject Identifier for the Study	text	6		Collected (Source: Investigator) Annotated CRF [3 

← COMMENTS

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STANDARDS DOCUMENTATION

- Danone SDTMIG Implementation – concise 10-page guide
- CRF Annotation Guidelines – linking CRF to SDTM metadata

‘Specify’ Values for Non-Result Qualifier Variables

Indication (disease/condition) #5 id INDICAT ?

- ☐ Medical History
- ☐ Adverse Event
- ☐ Prophylactic
- ☐ Other Indication

CMINDC

Specify "Other Indication" id CMINDSP

CMINDCX

Derived Values from Data Source

Start date id CMSTDAT

CMSTDTC

CMENTPT=END OF STUDY

Ongoing at end of study? #4

id CMONGO

☐ Yes ☐ No

End date id CMENDAT

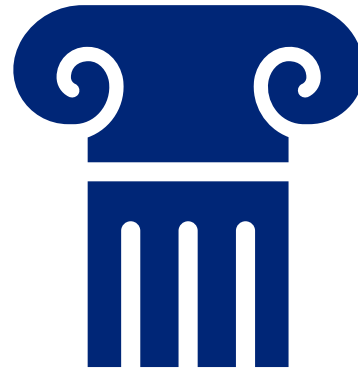
CMENDTC

CMENRTPT=ONGOING

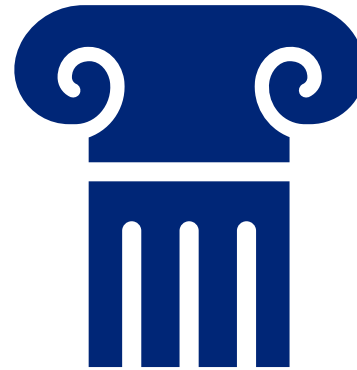
CMENRTPT=BEFORE



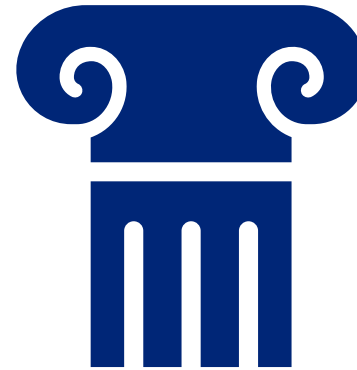
TRAINING & KNOWLEDGE TRANSFER



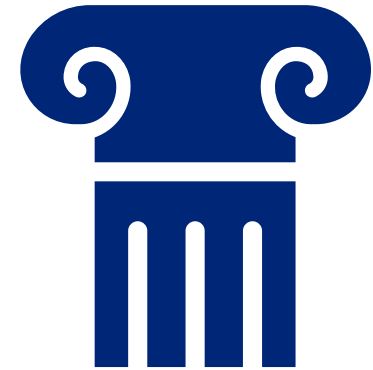
Listen to
the Team



Onboarding &
Progressive
Handover

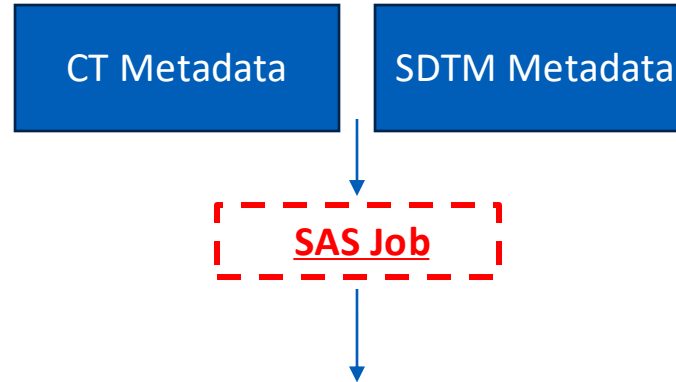


Fit For
Purpose



Continuous
Availability

DEFINE.XML AUTOMATION FROM METADATA



DM (Demographics) - [SDTMIG 3.1.2]

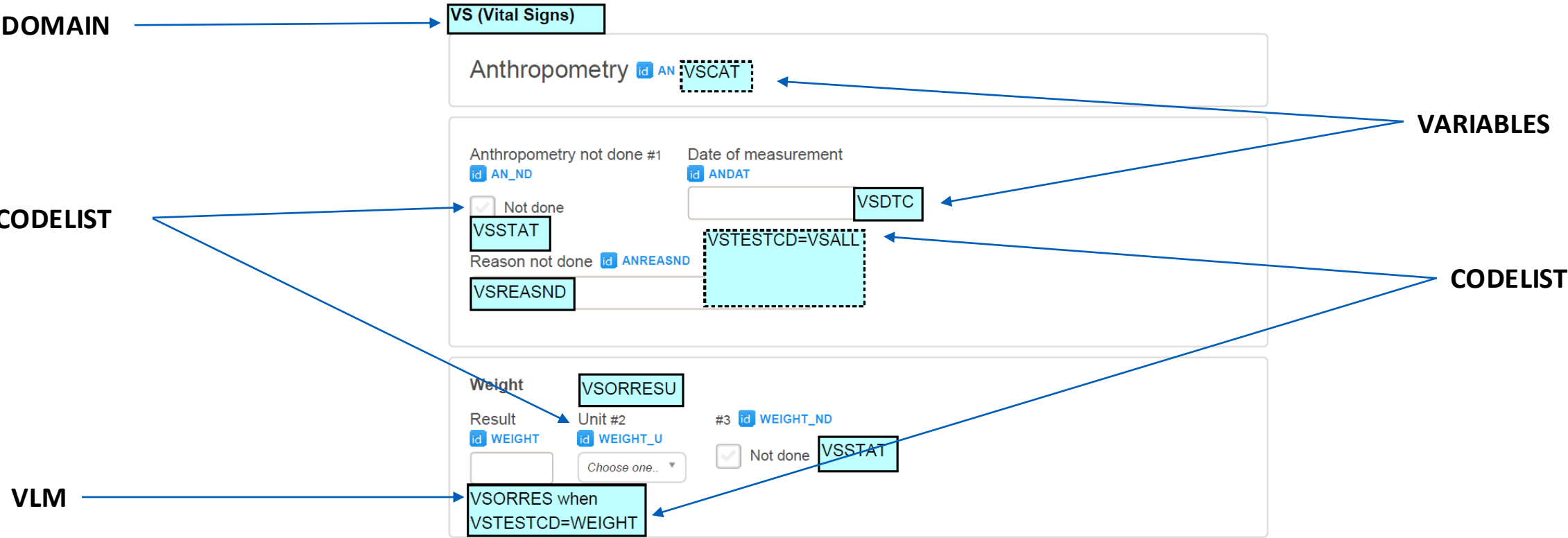
Related Supplemental Qualifiers Dataset: SUPPDM (Supplemental Qualifiers for DM)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
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SUBJID	Subject Identifier for the Study	text	6		Collected (Source: Investigator) Annotated CRF [3] [4]

CDISC01_1

Annotated CRF

- Supplemental Documents Standards
- Datasets
- Controlled Terminology
- Methods

DATA COLLECTION METADATA



FORM_ID	FORM_NAME	EDC_VAR	CDASH_VAR	QUESTION	VISIBLE
AN	Anthropometry	VSCAT	VSCAT		No
AN	Anthropometry	AN_ND	VSSTAT_VSALL	Anthropometry not done	Yes



READY FOR THE NEXT INNOVATION WAVE

Collaboratively created the basis for next innovations

- Increased team knowledge level and autonomy
- Improved consistency and submission readiness
- Reduced project management overhead
- Modernized the data flow end-to-end

On the roadmap for 2026

- Metadata repository
- Biomedical Concepts
- Test data automation
- AI-driven data conversion