

FDA CDER Common Data Standards Issues

Evolution of SDTM Submission
Standards

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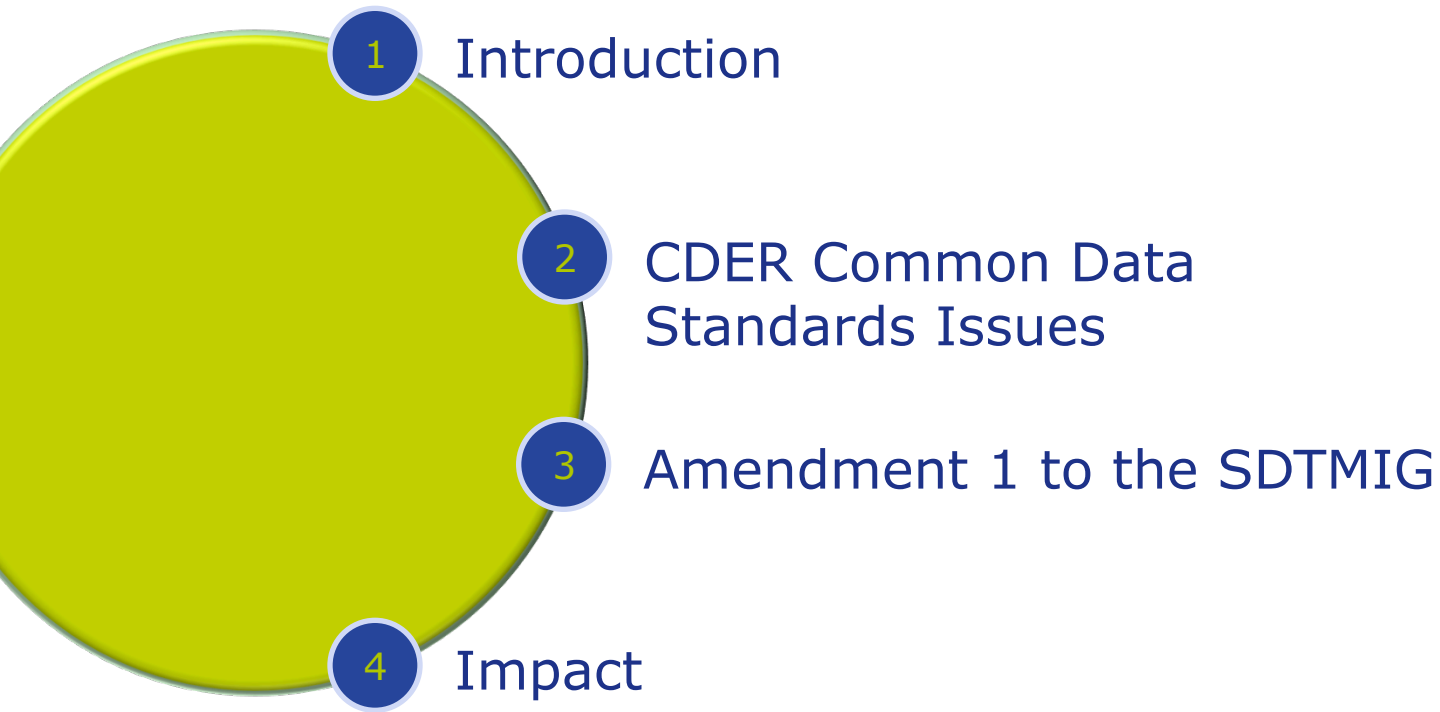
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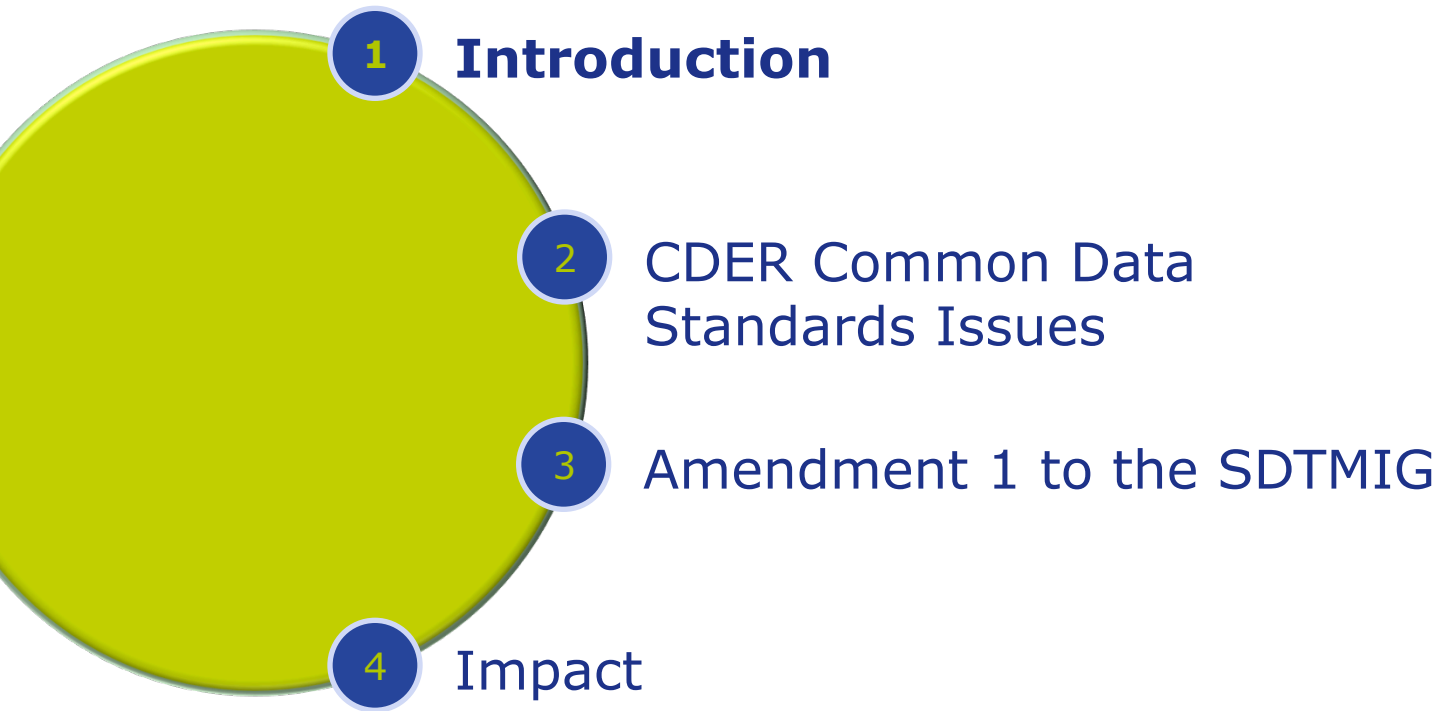
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Introduction

- 06-May-2011: CDER published Common Data Standards Issues Document on the FDA website
 - Document will be updated periodically

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

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Home > Drugs > Development & Approval Process (Drugs) > Forms & Submission Requirements

Development & Approval Process (Drugs)
Forms & Submission Requirements
Electronic Submissions to CDER
CDER Data Standards Program
Electronic Common Technical Document (eCTD)
Electronic Regulatory Review

Study Data Standards for Submission to CDER

These resources are intended to assist submitters in the preparation and submission of standardized study data to CDER.

- CDER Data Standards Common Issues Document (PDF - 115KB)** - The goal of this document is to communicate general CDER preferences and experiences regarding the submission of standardized data to aid sponsors in the creation of standardized datasets. The document is not intended to replace the need for sponsors to communicate with review divisions regarding data standards implementation approaches or issues, but instead, it is designed to compliment and facilitate the interaction between sponsors and divisions.
- Study Data Specifications** - Study specifications for submitting animal and human study datasets in electronic format

Source:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm248635.htm>

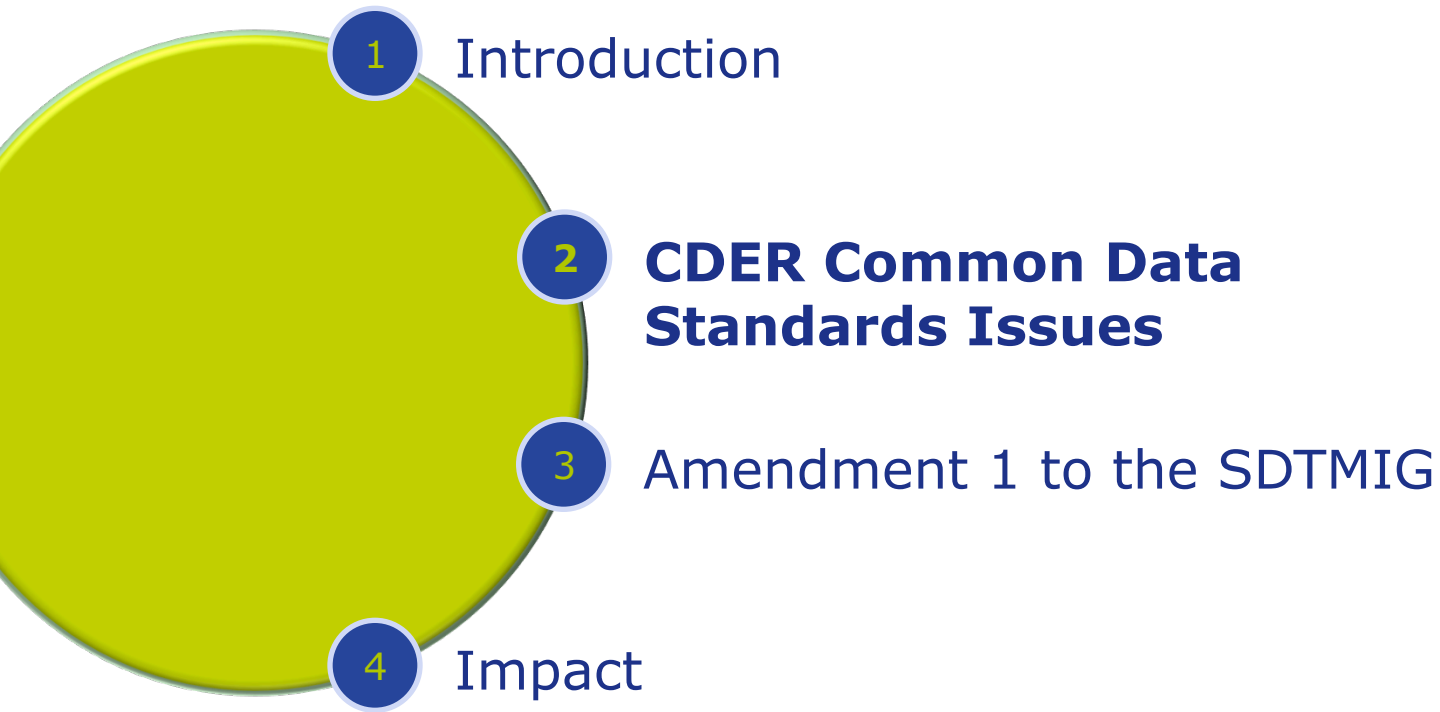
Introduction

- Amendment 1 to the SDTM V1.2 and SDTMIG V3.1.2 has been posted on the CDISC website
 - Public review period ended on 06-June-2011

The screenshot displays the CDISC website with the following elements:

- Header:** CDISC logo with the tagline "Strength Through Collaboration".
- Navigation Bar:** Links for ABOUT, STANDARDS & INNOVATIONS (highlighted), RESOURCES, NEWS, EDUCATION & EVENTS, MEMBERSHIP, and MEMBERS ONLY.
- Left Sidebar (STANDARDS & INNOVATIONS):**
 - ADaM
 - BRIDG Model
 - CDASH
 - Define.XML
 - Healthcare Link Initiative
 - LAB
 - Operational Data Model
 - Protocol
 - SEND
 - CDISC SHARE
- Main Content Area:**
 - Section:** Study Data Tabulation Model
 - Title:** Amendment 1 to the Study Data Tabulation Model (SDTM) v1.2 and the SDTM Implementation Guide: Human Clinical Trials V3.1.2 Open for Public Review
 - Text:** "The Submissions Data Standards Team is pleased to release this amendment for public review."
 - Text:** "This document includes additional variables related to human clinical trials added at the request of FDA CDER and is being posted for comment and for trial use in advance of the next formal release of the SDTM and SDTMIG. Please provide review comments using the spreadsheet provided below by 6 June 2011."
 - Link:** Amendment 1 to SDTM V1.2 and SDTM IG V3.1.2 (doc)
- Right Sidebar:**
 - Section:** Become a CDISC Member (Fee Based)
 - Link:** [Become A Member](#)
 - Section:** Member Log-in
 - Form:** Input fields for "user name" and password (masked with dots), followed by a "Log In" button.
 - Link:** [forgot your password?](#)

Source: <http://www.cdisc.org/sdtm>



General Considerations

- Sponsors should refer to the latest version of SDTMIG
- Sponsors should refer to Amendment 1 to SDTM V1.2
- Sponsors should ensure that every data variable's codelist, origin and derivation is clearly and easily accessible in define file
- Include variables EPOCH, ELEMENT, and ETCD for every subject-level observation
- SDTM should be consistent with submitted analysis datasets

Traceability SDTM and ADaM

- Understanding relationship between the analysis results, the analysis datasets and the SDTM domains
- Establishing the path between an element and its immediate predecessor
- Two levels:
 - Metadata traceability
 - Relationship between an analysis result and analysis dataset(s)
 - Relationship of the analysis variable to its source dataset(s) and variable(s)
 - Data point traceability
 - Predecessor record(s)

Traceability SDTM and ADaM

Table 1 Demographic Data - Per-Protocol

	Treatment 1	Treatment 2
Baseline body mass index (BMI) [kg/m**2]		
N	167	167
Mean	29.06	29.04
SD	4.84	4.80
Min	20.3	16.0
Median	28.69	28.47
Max	40.1	41.2
Baseline BMI (categorical) [N (%)]		
<25 kg/m**2	41 (24.6%)	71 (21.1%)
25-30 kg/m**2	60 (35.9%)	130 (38.7%)
>=30 kg/m**2	66 (39.5%)	135 (40.2%)

• Patient Demographics - Part I

Patient X5 Page 4 (Demo_V1a for Visit 1a) Page 1 of 1.

Visit Date **11-Dec-2007** Blank ☐ Comment

PATIENT DEMOGRAPHICS - Part I **DSCAT = "PROTOCOL MILESTONE"**

Informed consent was obtained on **DSSTDT**

Gender **SEX** ☐ 1 = male, 2 = female

Date of birth **BRTHDTC** Age **AGE** years **AGEU**

(Age is automatically calculated when screen is saved and closed)

Height cm

Weight kg

Waist circumference cm

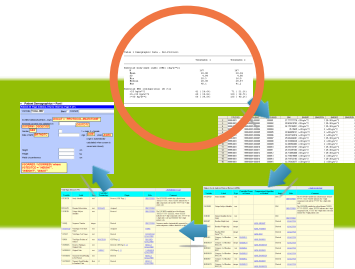
VSORRES / VSORRESU where VSTESTCD = "HEIGHT", "WEIGHT", "WAIST"

	STUDYID	USUBID	SUBID	BMI	BMIGR1	BMIGRIN	BMIGR2	BMIGR2N
2	9999-0001	9999-0001-000001	000001	27.77777778 <30 kg/m**2			1 25-30 kg/m**2	2
3	9999-0001	9999-0001-000002	000002	25.50361502 <30 kg/m**2			1 25-30 kg/m**2	2
4	9999-0001	9999-0001-000003	000003	26.175194521 <30 kg/m**2			1 25-30 kg/m**2	2
5	9999-0001	9999-0001-000004	000004	35.15625 >=30 kg/m**2			2 >=30 kg/m**2	3
6	9999-0001	9999-0001-000005	000005	30.968888131 >=30 kg/m**2			2 >=30 kg/m**2	3
7	9999-0001	9999-0001-000006	000006	39.697163916 >=30 kg/m**2			2 >=30 kg/m**2	3
8	9999-0001	9999-0001-000007	000007	25.82646281 <30 kg/m**2			1 25-30 kg/m**2	2
9	9999-0001	9999-0001-000008	000008	30.103806228 >=30 kg/m**2			2 >=30 kg/m**2	3
10	9999-0001	9999-0001-000009	000009	32.280962683 >=30 kg/m**2			2 >=30 kg/m**2	3
11	9999-0001	9999-0001-000010	000010	28.87613787 <30 kg/m**2			1 25-30 kg/m**2	2
12	9999-0001	9999-0001-000011	000011	29.372387383 <30 kg/m**2			1 25-30 kg/m**2	2
13	9999-0001	9999-0001-000012	000012	26.714852608 <30 kg/m**2			1 25-30 kg/m**2	2
14	9999-0001	9999-0001-000013	000013	32.718619889 >=30 kg/m**2			2 >=30 kg/m**2	3
15	9999-0001	9999-0001-000014	000014	28.719723183 <30 kg/m**2			1 25-30 kg/m**2	2
16	9999-0001	9999-0001-000015	000015	32.270420377 >=30 kg/m**2			2 >=30 kg/m**2	3

Variable	Label	Type	Controlled Terminology	Origin	Role	Comment
STUDYID	Study Identifier	text	Protocol, CRF Page 1		IDENTIFIER	The STUDYID variable has a fixed format: 'XXXX-YYYY', where 'XXXX' indicates the 4-digit compound code and the 'YYYY' the 4-digit study code.
DOMAIN	Domain Abbreviation	text	DOMAIN	Assigned	IDENTIFIER	
USUBID	Unique Subject Identifier	text	Protocol		IDENTIFIER	The USUBID variable has a fixed format: 'XXXX-YYYY-ZZZZZ', where 'XXXX' indicates the 4-digit compound code, 'YYYY' the 4-digit study code and 'ZZZZZ' the 5-digit patient code.
VSEQ	Sequence Number	integer	Derived		IDENTIFIER	Sequence number (automatically generated) to ensure uniqueness within a dataset for a subject
VTESTCD	Vital Signs Test Short Name	text	Assigned		TOPIC	
VTEST	Vital Signs Test Name	text	Derived		SYNONYM QUALIFIER	
VSPDS	Vital Signs Position of Subject	text	POSITION	CRF Page 12	RECORD QUALIFIER	
VSORRES	Result or Finding in Original Units	text	Derived, CRF Page 9, 11		RESULT QUALIFIER	
VSORRESU	Original Units	text	VSRRESU	CRF Page 9, 11	VARIABLE QUALIFIER	
VSTRESC	Character Result Finding in Std Format	text	Derived		RESULT QUALIFIER	
VSTRESN	Numeric Result Finding in Standard Units	float	3.1	Derived	RESULT QUALIFIER	

Variable	Label	Type	Controlled Terminology	Computational Algorithm or Method	Origin	Role	Comment
STUDYID	Study Identifier	text			DM	IDENTIFIER	The STUDYID variable has a fixed format: 'XXXX-YYYY', where 'XXXX' indicates the 4-digit compound code and the 'YYYY' the 4-digit study code.
USUBID	Unique Subject Identifier	text			DM	IDENTIFIER	The USUBID variable has a fixed format: 'XXXX-YYYY-ZZZZZ', where 'XXXX' indicates the 4-digit compound code, 'YYYY' the 4-digit study code and 'ZZZZZ' the 5-digit patient code.
SUBID	Subject Identifier for the Study	text			DM	IDENTIFIER	
HEIGHT	Baseline Height (cm)	integer		ADSL HEIGHT	Derived	ANALYSIS	
WEIGHT	Baseline Weight (kg)	integer		ADSL WEIGHT	Derived	ANALYSIS	
BMI	Baseline BMI (kg/m**2)	integer		ADSL BMI	Derived	ANALYSIS	
BMIGR1	Category 1 of Baseline BMI	text	BMIGR1	ADSL BMIGR1	Derived	ANALYSIS	
BMIGRIN	Category 1 of Baseline BMI (N)	integer	BMIGRIN	ADSL BMIGRIN	Derived	ANALYSIS	
BMIGR2	Category 2 of Baseline BMI	text	BMIGR2	ADSL BMIGR2	Derived	ANALYSIS	
BMIGR2N	Category 2 of Baseline BMI (N)	integer	BMIGR2N	ADSL BMIGR2N	Derived	ANALYSIS	
BMIGR3	Category 3 of Baseline BMI	text	BMIGR3	ADSL BMIGR3	Derived	ANALYSIS	
BMIGR3N	Category 3 of Baseline BMI (N)	integer	BMIGR3N	ADSL BMIGR3N	Derived	ANALYSIS	

Traceability SDTM and ADaM

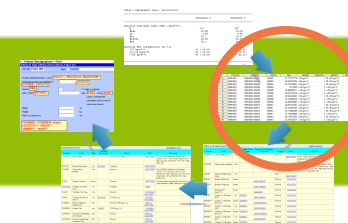


- Analysis Results

Table 1 Demographic Data - Per-Protocol

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Baseline body mass index (BMI) [kg/m**2]		
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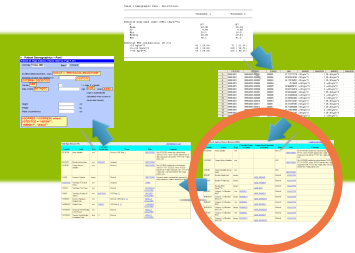
Traceability SDTM and ADaM



- Analysis Dataset

	STUDYID	USUBJID	SUBJID	BMI	BMIGR1	BMIGR1N	BMIGR2	BMIGR2N
2	9999-0001	9999-0001-000001	000001	27.777777778	<30 kg/m**2	1	25-<30 kg/m**2	2
3	9999-0001	9999-0001-000002	000002	25.503615702	<30 kg/m**2	1	25-<30 kg/m**2	2
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Traceability SDTM and ADaM

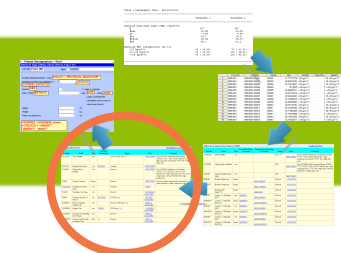


- ADaM define.xml

Computational Algorithms (ADSL.BMI)	
Reference Name	Computation Method
ADSL BMI	Continuous variable, calculated using ADSL.WEIGHT/(ADSL.HEIGHT*0,01)**2 value at visit 3 if visit 3 data not available, the last data collected before randomisation
Computational Algorithms (ADSL.HEIGHT)	
Reference Name	Computation Method
ADSL HEIGHT	equal to VS.VSSTRESN when VS.VSTESTCD="HEIGHT"
Computational Algorithms (ADSL.WEIGHT)	
Reference Name	Computation Method
ADSL WEIGHT	equal to VS.VSSTRESN when VS.VSTESTCD="WEIGHT" and VS.VISITNUM=30 if visit 3 data not available, the last data collected before randomisation

WEIGHT	Baseline Weight (kg)	integer		ADSL.HEIGHT	Derived	ANALYSIS	
				ADSL.WEIGHT			
BMI	Baseline BMI (kg/m**2)	integer		ADSL.BMI	Derived	ANALYSIS	
BMIGR1	Category 1 of Baseline BMI	text	BMIGR1L	ADSL.BMIGR1	Derived	ANALYSIS	
BMIGR1N	Category 1 of Baseline BMI, (N)	integer	BMIGR1N	ADSL.BMIGR1N	Derived	ANALYSIS	
BMIGR2	Category 2 of Baseline BMI	text	BMIGR2L	ADSL.BMIGR2	Derived	ANALYSIS	
BMIGR2N	Category 2 of Baseline BMI, (N)	integer	BMIGR2N	ADSL.BMIGR2N	Derived	ANALYSIS	
BMIGR3	Category 3 of Baseline BMI	text	BMIGR3L	ADSL.BMIGR3	Derived	ANALYSIS	
BMIGR3N	Category 3 of Baseline BMI, (N)	integer	BMIGR3N	ADSL.BMIGR3N	Derived	ANALYSIS	

Traceability SDTM and ADaM



- SDTM define.xml and aCRF

Value Level Metadata (ValueList.VS.VSTESTCD)

Source Variable	Value	Label	Type	Controlled Terminology	Origin	Role	Comment
VSTESTCD	DIABP	DIASTOLIC BLOOD PRESSURE	text		CRF Page 13		
VSTESTCD	HEIGHT	HEIGHT	text		CRF Page 9		
VSTESTCD	PULSE	PULSE RATE	text		CRF Page 13		
VSTESTCD	SYSBP	SYSTOLIC BLOOD PRESSURE	text		CRF Page 13		
VSTESTCD	WAIST	WAIST CIRCUMFERENCE	text		CRF Page 9		
VSTESTCD	WEIGHT	WEIGHT	text		CRF Page 9		

VSSEQ	Sequence Number	patient code
VSTESTCD	Vital Signs Test Short Name	Sequence number (automatically generated) to ensure uniqueness within a dataset for a subject
VSTEST	Vital Signs Test Name	
VSPOS	Vital Signs Position of Subject	
VSORRES	Result or Finding in Original Units	
VSORRESU	Original Units	
VSSSTRESC	Character Result/Finding in Std Format	
VSSSTRESN	Numeric Result/Finding in Standard Units	

• Patient Demographics – Part I
Patient X5 Page 4 (Demo_V1a for Visit 1a) Page 1 of 1.

Visit Date **11-Dec-2007** Blank ☐ Comment

PATIENT DEMOGRAPHICS - Part I **DSCAT = "PROTOCOL MILESTONE"**

Informed consent was obtained on **DSSTDTC**

Gender **SEX** ☐ 1 = male, 2 = female

Date of birth **BRTHDTC** Age **AGE** years **AGEU**
(Age is automatically calculated when screen is saved and closed)

Height cm

Weight kg

Waist circumference cm

VSORRES / VSORRESU where VSTESTCD = "HEIGHT", "WEIGHT", "WAIST"

Controlled Terminology

- Use existing CDISC terminology
- If available CDISC terminology is insufficient, sponsors may propose their own terminology
- Documentation on sponsor-specific terminology should be included in define.xml

The screenshot shows the National Cancer Institute website. At the top, the NCI logo is on the left, and a search bar with the text "Questions About Cancer? 1-800-4-CANCER" is on the right. Below the logo, the text "National Cancer Institute at the National Institutes of Health" is displayed. A navigation bar contains links: NCI Home, Cancer Topics, Clinical Trials, Cancer Statistics, Research & Funding, News, and About NCI. The main content area is titled "Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, CDISC, and NCPDP Terminology". To the right of this title is a small image of a group of people celebrating. Below the title, there is a sidebar on the left with a "Terminology Resources" section containing links to "NCI Dictionaries", "Federal Medication Terminologies", and "FDA Terminology". The main content area below the title is titled "CDISC Terminology" and contains a paragraph about the Clinical Data Interchange Standards Consortium (CDISC), stating it is an international, non-profit organization that develops and supports global data standards for medical research, working with EVS to develop controlled terminology, notably CDISC's Study Data Tabulation Model (SDTM), which is an international standard for clinical research data approved by the FDA.

Questions About Cancer?
1-800-4-CANCER

National Cancer Institute
at the National Institutes of Health

NCI Home Cancer Topics Clinical Trials Cancer Statistics Research & Funding News About NCI

Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, CDISC, and NCPDP Terminology

CDISC Terminology

The [Clinical Data Interchange Standards Consortium \(CDISC\)](#) is an international, non-profit organization that develops and supports global data standards for medical research. CDISC is working actively with EVS to develop and support controlled terminology in several areas, notably CDISC's **Study Data Tabulation Model (SDTM)**. SDTM is an international standard for clinical research data, and is approved by the FDA as a standard electronic submission format.

Source: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

MedDRA and Common Dictionaries

- Sponsors should exactly follow spelling and case
- MedDRA version should be consistent across trials within the submission
- Dictionary name and version should be documented in define.xml

Controlled Terminology (External Dictionaries)	
ADVERSE EVENT DICTIONARY, Reference Name (Codelist.AEDICT_F)	
External Dictionary	Dictionary Version
MedDRA	13.1
DRUG DICTIONARY, Reference Name (Codelist.DRUGDICT_F)	
External Dictionary	Dictionary Version
WHO Drug	WHO-DD 10.SEP
ISO 8601, Reference Name (Codelist.ISO 8601)	
External Dictionary	Dictionary Version
ISO 3166, Reference Name (Codelist.ISO 3166)	
External Dictionary	Dictionary Version

SDTM Datasets

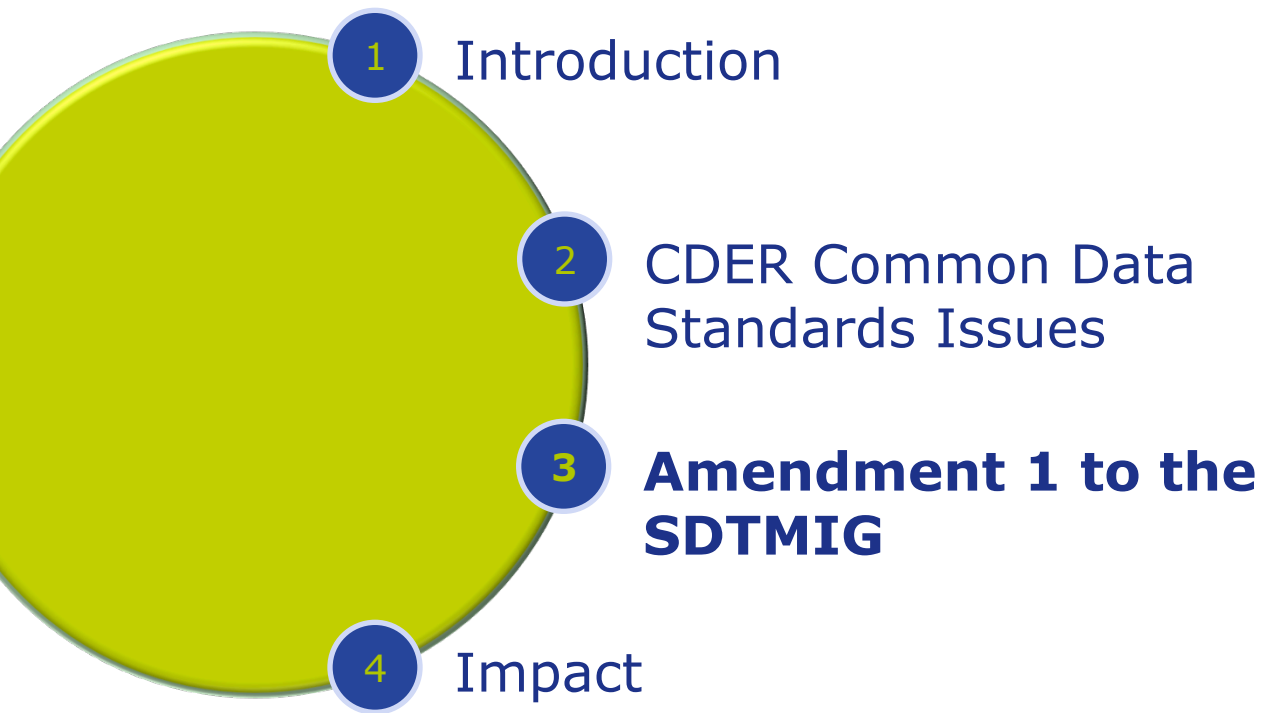
- SUPPQUAL
 - Should not be used as a waste basket
- DM
 - Strongly preferred to use additional variables in [Amendment 1 Section 2.1, Pages 6-7](#)
- DS
 - EPOCH should be used to distinguish between multiple disposition events
 - If DEATH occurs, it should be documented in the last record with the associated EPOCH

SDTM Datasets

- AE
 - Provide variables for MedDRA hierarchy (Amendment 1 Section 2.2, Pages 8-9)
 - Sponsors should include all AEs, not only the one caused by the study treatment
 - AESOC = MedDRA-defined, primary mapped SOC
 - AEBODSYS = SOC used for analysis
- Custom Domains
 - Only to be used for data that does not fit in a published domain
- LB
 - Ideal filesize < 400 megabytes
 - Larger files should be split according to LBCAT, LBSCAT; Non-split dataset should also be included
 - Discuss with your review division

SDTM Variables

- Permissible variables that CDER expects to see
 - --BLFL (LB, VS, EG, Pharmacokinetics, Microbiology)
 - EPOCH
 - --DY and --STDY in SE and Findings
- Dates in ISO 8601
 - Missing dates are missing dates
- USUBJID
 - No leading or trailing spaces allowed
 - should match across all datasets (SDTM, ADaM) on a character basis
- No imputations allowed



Additions to SDTM V1.2/SDTMIG V3.1.2

- New variables in Demographics
- New variables in Events General Observation Class
 - Additional accomodation for MedDRA codings
 - Part of these previously used in SUPPQUAL

Additions to DM

Variable	Label
ACTARMCD	Actual Arm Code
ACTARM	Description of Actual Arm
RFXSTDTC	Date/Time of First Study Drug Exposure
RFXENDTC	Date/Time of Last Study Drug Exposure
RFPSTDTC	Date/Time of First Subject Contact
RFPENDTC	Date/Time of End of Subject Participation
DTHDTC	Date of Death
DTHFL	Subject Died Flag

Additions to DM

- ACTARMCD, ACTARM
 - Actual arm a subject participated in during the trial
 - Randomized subjects that are not treated
 - ACTARMCD/ACTARM= 'NOTTRT' / 'Not Treated'
- RFXSTDTC, RFXENDTC
 - Date/Time of first/last study treatment exposure
 - RFXSTDTC should match SESTDTC for first treatment element
 - RFXENDTC should match SEENDTC for last treatment element
- RFPSTDTC
 - Date/Time of informed consent
 - Should match entry in DS if this is documented as a protocol milestone

Additions to DM

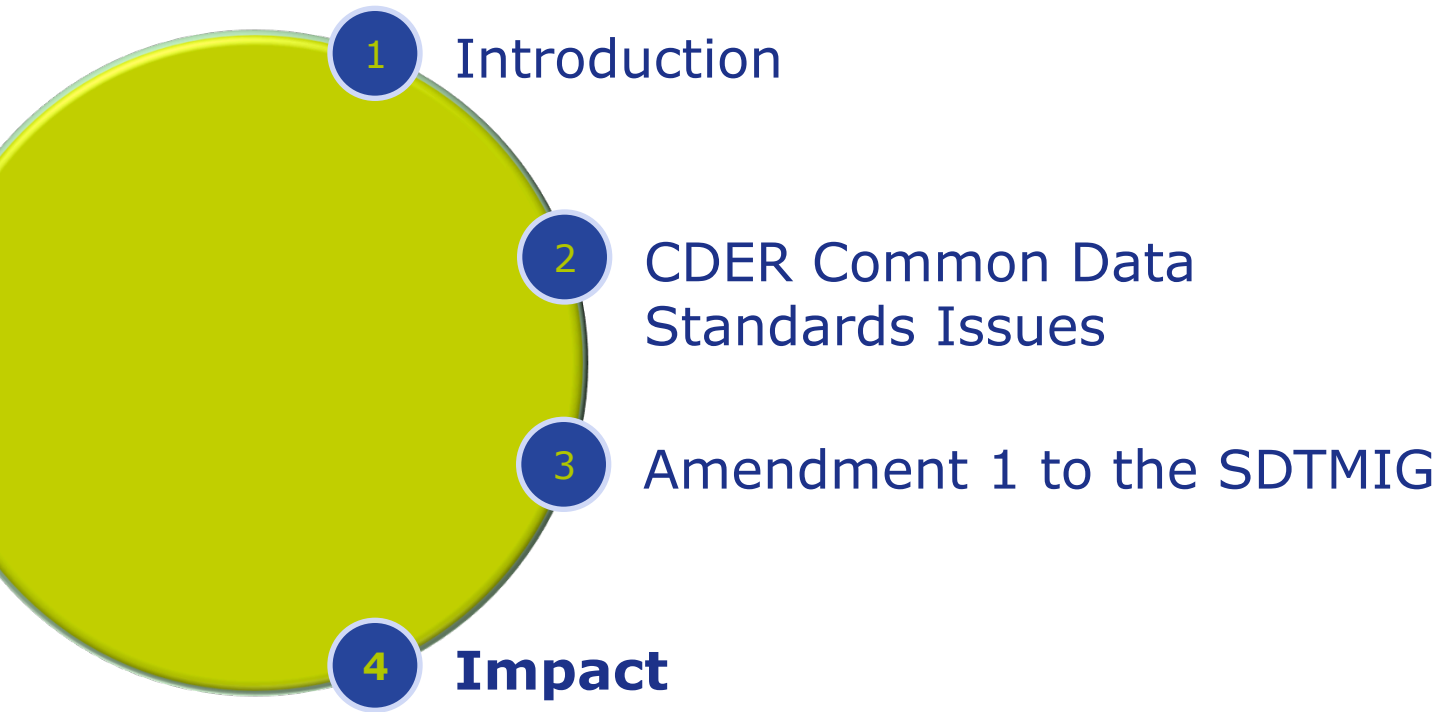
- RFPENDTC
 - Date/Time of end of participation
 - Last known date of participation FOR DATA
 - NOT the last date of participation in study
- DTHDTC, DTHFL
 - Date of death, Subject death flag

Additions to AE

Variable	Label
AETRTEM	Treatment Emergent Flag
AELLT	Lowest Level Term
AELLTCD	Lowest Level Term Code
AEPTCD	Preferred Term Code
AEHLT	High Level Term
AEHLTCD	High Level Term Code
AEHLGT	High Level Group Term
AEHLGTCD	High Level Group Term Code
AESOC	Primary System Organ Class
AESOCCD	System Organ Class Code
AEBDSYCD	System Organ Class Code

Additions to AE

- AETRTEM
 - Treatment emergent flag: 'Y' or null
 - Derivation must be clearly documented in define.xml
- AELLT, AELLTCD, AEPTCD, AEHLT, AEHLTCD, AEHLGT, AEHLGTCD, AESOCCD
 - Promoted from SUPPQUAL ([SDTMIG Appendix C5](#)) into the parent domain
- AESOC
 - Primary system organ class
 - AEBODSYS should contain the SOC used in analysis
- AEBDSYCD
 - Body system code



Impact

- Amendment 1 deals with new FDA expectations
- CDER goes further than Amendment 1
- ETCD, ELEMENT, EPOCH are rarely captured on the CRF
 - SDTM derivation could be complex
- An updated data model together with new/updated check definitions is needed to enable electronic QC



Thank you for your attention

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DRIVE YOUR PERFORMANCE