CDASH 2.0

Berlin

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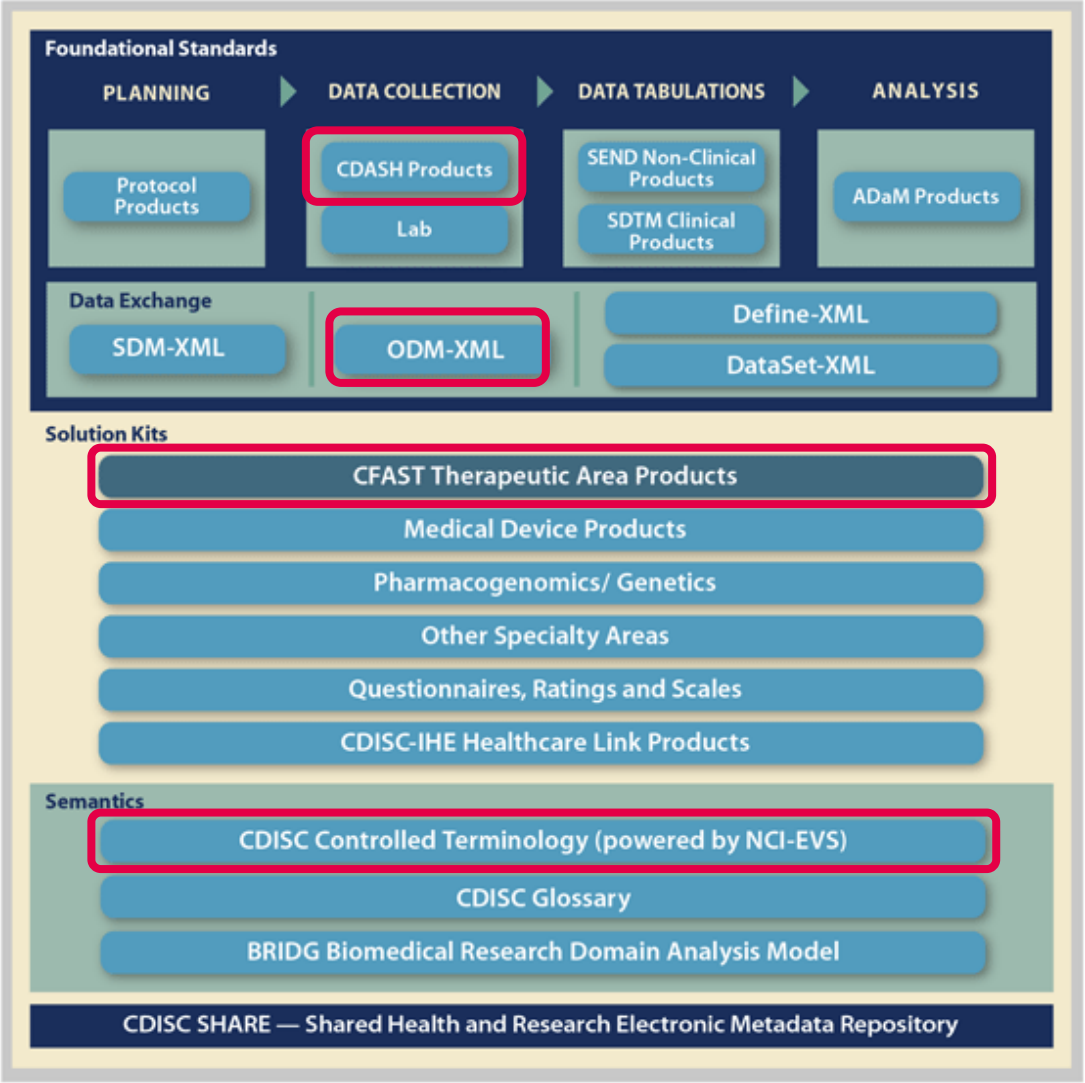
inVentiv Health

Agenda

- CDASH 1.1 & CDASHIG 2.0
- CDASH Concepts
- TAUG Examples
- Current Regulatory Perspective on CDASH
- Questions

CDASH: CDISC End to End



- Clinical Data Acquisition Standards Harmonization (CDASH)
  - is a foundational CDISC standard
  - defines basic standards for the collection of clinical trial data

My CDASH Experience

- 4 CDASH standardization projects since 2008 at various roles
- Worked with Shannon Labout (2008 CDASH Leadership Team)
- Official CDASH Training 2013
- CDASH Team Member 2015
- CDASHIG 2.0 and Data Model 1.0 Contributor
- Ebola and Malaria TAUG CDASH Contributor
- Rheumatoid Arthritis public review
- inVentiv CDASH Trainer

CDASH Documentation Overview

- CDASH V1.1 documentation includes
  - CDASH Standard V1.1 2011-01-18
  - CDASH User Guide V1.0 (for V1.1) 2012-04-12
    - CDASH User Guide V1-1.1 Library of Example CRFs
  - CDASH ODM CRFs And Data Definitions 2011-10-24
  - CDASH Serious Adverse Event (SAE) Supplement V1.0 2013-11-22
- CDASH Implementation Guide V2.0 (Expected release Q42016)
  - CDASHIG V2.0
  - Data Model V1.0
  - Domain Metadata Spreadsheet V1.0
- CDASH Therapeutic Area User Guide (TAUG)
  - Released: Asthma, Breast Cancer, Chronic Hepatitis C, COPD, Diabetes, Dyslipidemia, Traumatic Brain Injury
  - CDASH is available in ~7 of 18 released, ~1 of 5 in review and ~19 of 21 in development as of AUG2016

CDASH Concepts

CDASH 1.1

- CDASH Variables, Questions and Prompts,
- Data Cleaning Prompts
- CDASH Conformance
- CDASH Core
- eCRF Completion Instructions
- SDTM Mapping Instructions
- CDASH Best Practices

CDASHIG 2.0

- CDASH Model and Metadata
- CDASH Variables Label
- Extended SDTM Mapping Instructions
- Same SDTMIG Variable Same CDASHIG Variable
- Ordered by Domain Class (not alphabetical)

http://wiki.cdisc.org/display/CMIG/Changes+from+CDASH+v1.1+to+CDASHIG+v2.0

CDASH Variable, Questions Text and Prompts

- Variable
  - An item of data that is collected in a (e)CRF field
    - AEENDAT
    - EGPOS

ODM	RAVE	InForm	DataLabs
ItemDef OID	Field OID	Item RefName	?

- Question Text
  - provides a full sentence for the collection of data.
    - *What was the adverse event end date?*
  - can contain detailed information
    - *What was the position of the subject during ECG measurement?*
- Prompt
  - can reduce the amount of information on a CRF
    - End Date
  - not as detailed
    - Position

ODM	RAVE	InForm	DataLabs
ItemDef Name	Field Label	Item Default Question	?

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CDASH Questions and Prompts: CDASH V1.1

--TEST

Domain	Question Text	Prompt	SDTM or CDASH Variable Name
EG-Central Processing	What **was** the ECG test name?	<Test name>	EGTEST
LB-Central Processing with CS	What **is** the test name?	<Test Name>	LBTEST
DA	**Is** this the amount dispensed or the amount returned?	Dispensed or Returned	DATEST

--TRT

Domain	Question Text	Prompt	SDTM or CDASH Variable Name
CM	What **was** the **term** for the medication/ therapy taken? Or What **was** the **term** for the medication taken?	Medication Therapy	CMTRT
EX	What **was** the study treatment?	Treatment Name	EXTRT
SU	What **was** the type of substance used?	<Type of Substance>	SUTRT

CDASH Questions and Prompts: CDASHIG 2.0

Question Text	Prompt
What [**is** / **was**] the name (of the [**measurement**/ **test** /**examination**])?	[**Measurement** / **Test** / **Examination**/] (Name)

CDASH Data Cleaning Prompts

- Data cleaning prompt are used by data management and clinical operations to mark data as available or missing. They are generally not submitted in SDTM.

CDASH Standard V1.1

Question Text	Prompt	SDTM /CDASH
Were any medications taken?	**Any meds?**	CMYN
Was the sample collected? or Was the lab performed?	Lab Status	LBPERF
What was the planned dose per administration?	Planned Dose	EXPDOSE
Was the planned dose administered?	Planned dose administered?	EXPOCCUR

CDASHIG 2.0

Question Text	Prompt	CDASH Variable
Were any concomitant medication(s) /therapy(ies) /taken?	Any Concomitant Medications	CMYN
Was the procedure interrupted?	Procedure Interrupted	PRITRPYN
Was the sample collected? ; Or Was the lab performed?	Lab Performed ; or Sample Collected	LBPERF
Were [vital signs/[VSTEST] performed?	Vital Signs Performed ; Or [VSTEST] Performed	[VSTESTCD]_VSPERF

Same SDTMIG Variable Same CDASHIG Variable

CDASH Variable	CDASH Variable Label	Question Text	Prompt
--STAT	Completion Status	Was the [--TEST] not [completed /answered/ done/ assessed/evaluated]?; Or Indicate if the [--TEST] was not [answered/assessed/ done/evaluated/performed].	Not Done
--CSTAT	Collected Completion Status	Indicate if the [--TEST/ topic (specimen/ sample) was not [collected/answered/assessed/ done/evaluated/performed].	Not Collected

- Fields with a direct mapping to an SDTMIG variable (including CT (Controlled Terminology)) should remain the same.
- If there is a difference in the CT a “C” should be put before the variable.
  - E.g.
    --OCCUR Yes, No
    --COCCUR Yes, No, Not Done, Unknown

Normalized and De-Normalized Output Datasets

- In CDASH User Guide V1.0 a number of examples are given for CDASH variables in normalized and de-normalized output datasets. Appendix B gave different approaches for the naming of variables e.g.
  - BpDiabpVSORRES or BP.DIABP.VSORRES
- In CDASHIG 2.0 an underscore is used e.g.
  - [VSTESTCD]_VSORRES or SYSBP_VSORRES

Normalized (Vertical)

SUBJID	VSTESTCD	VSORRES	VSORRESU	VISIT
01001	SYSBP	119		1
01001	DIABP	82		1
01001	HR	68		1
01001	TEMP	37.1	C	1
01001	SYSBP	125		2
01001	DIABP	71		2
01001	HR	73		2
01001	TEMP	37.3	C	2

De-Normalized (Horizontal)

SUBJID	VISIT	SYSBP	DIABP	HR	TEMP	TEMP_U
01001	1	119	82	68	37.1	C
01001	2	125	71	73	37.3	C

De-Normalized CDASHIG 2.0 Variables

- CDASH variables with underscores are unique and can be parsed to create SDTM variables.

Question Text	Prompt	CDASH Variable
What was the result of the [VSTEST] measurement?	[VSTEST] Result	[VSTESTCD]_VSORRES
What was the unit of the [VSTEST] measurement?	[VSTEST] Unit	[VSTESTCD]_VSORRESU
Was the [VSTEST] result clinically significant?	[VSTEST] Clinically Significant	[VSTESTCD]_VSCLSIG
What was the result of the systolic blood pressure measurement?	Systolic Blood Pressure	SYSBP_VSORRES
What was the unit of the systolic blood pressure measurement?	Systolic Blood Pressure Unit	SYSBP_VSORRESU
Was the systolic blood pressure result clinically significant?	Systolic Blood Pressure Clinically Significant	SYSBP_VSCLSIG

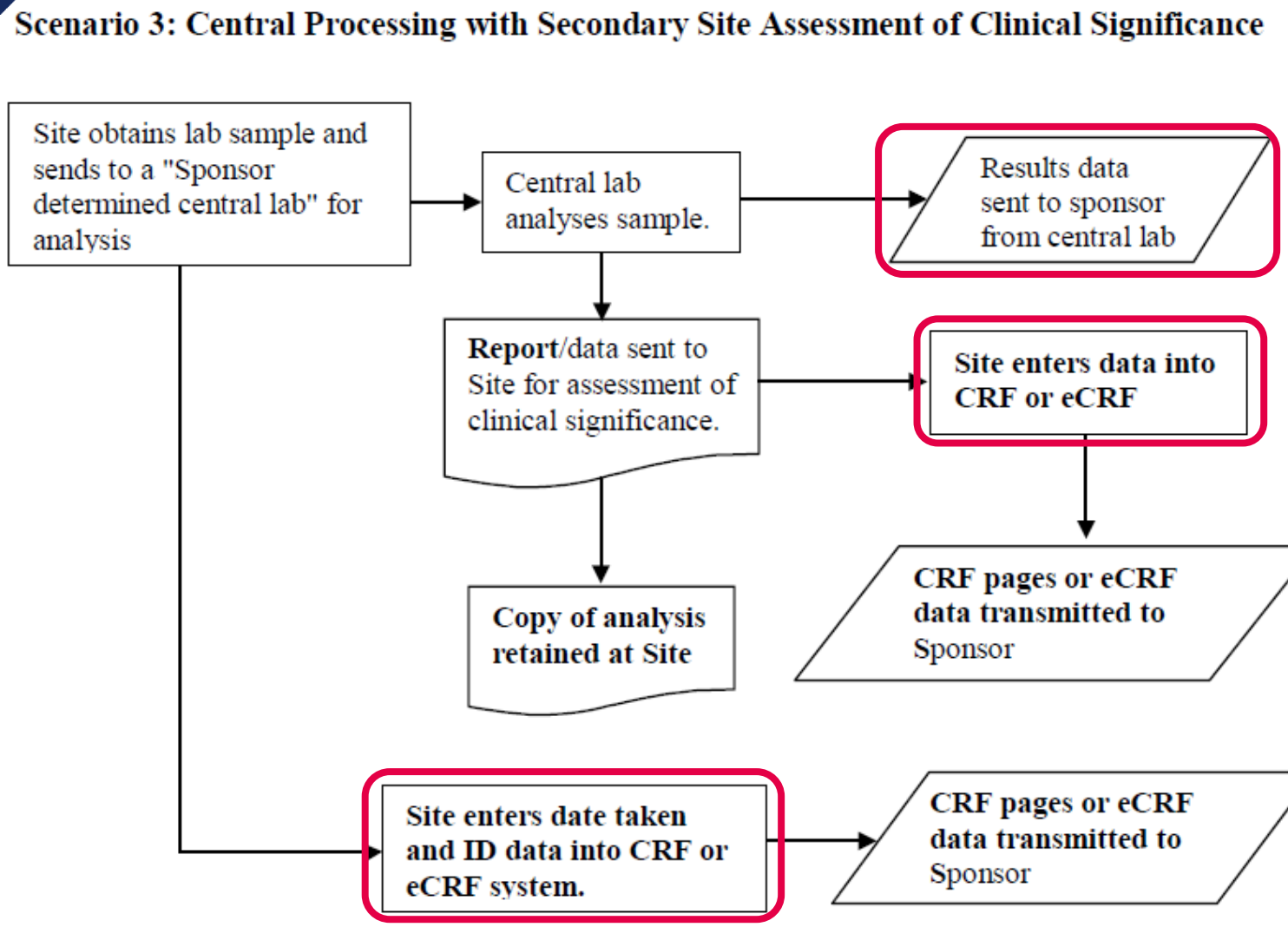
- Multiple SDTM variables can be merged into the one CDASH variable
  - Left Arm, Right Arm
  - EXLOC_LAT

Incorporated CRF Examples

Temperature VSORRES WHERE VSTESTCD = TEMP TEMP_VSORRES	__ __ __.__
Temperature Unit VSORRESU WHERE VSTESTCD = TEMP TEMP_VSORRESU	○ C ○ F
Respiratory Rate VSORRES WHERE VSTESTCD = RESP RESP_VSORRES	__ __ __
Respiratory Rate Unit VSORRESU WHERE VSTESTCD = RESP RESP_VSORRESU	breaths/min
Systolic Blood Pressure VSORRES WHERE VSTESTCD = SYSBP SYSBP_VSORRES	__ __ __
Systolic Blood Pressure Unit VSORRESU WHERE VSTESTCD = SYSBP SYSBP_VSORRESU	mmHg
Diastolic Blood Pressure VSORRES WHERE VSTESTCD = DIABP DIABP_VSORRES	__ __ __
Diastolic Blood Pressure Unit VSORRESU WHERE VSTESTCD = DIABP DIABP_VSORRESU	mmHg

Examples CRFs have been added to CDASHIG 2.0 these were present in CDASH User Guide V1-1.1 Library of Example CRFs

Data Collection Scenarios



Data Collection Scenarios have been incorporated into CDASHIG 2.0 from the CDASH User Guide V1.0 (see section 3.11.1 Lab Scenario Flowcharts (LB))

Scenario 1: Central Processing

Scenario 2: Local Processing

CDASH Best Practices

- CDASH Standard V1.1
  - 10 x Recommended Methodologies for Creating Data Collection Instruments
  - 12 x FAQs on Best Practices for Creating Data Collection Instruments
  - 24
- CDASHIG 2.0
  - 17 x Best Practices for Creating Data Collection Instruments
  - 6 x CRF Design Best Practices
  - 6 x Organizational Best Practices to Support Data Collection
  - 29

CDASH Best Practices

Ref	Best Practice Recommendation	Rationale
4.1.2	The same data should not be collected more than once, unless it is a repeated measure or some other data point that is being evaluated over a period of time.	Collecting the same data more than once creates the opportunity for discrepancies between the entered values. For example, subject's birthdate or age is collected on the demographics page, it is not necessary to collect age on the Lab CRF at every visit.
4.1.8	The data collection instrument/CRF should contain a field that allows the site to record an indication that an assessment was not performed (e.g., VSPERF='N' or TEMP_VSSTAT='NOT DONE')	This will provide a definitive indicator that a data field has missing data and has not been overlooked. This will prevent unnecessary data queries to clarify whether an assessment has been performed.
4.3.1	Collect necessary data only. CRFs should focus on collecting only the data that support protocol objectives and endpoints The protocol should clearly state which data will be collected in the study	Usually, only data that will be used for analysis and to assess safety of the product should be collected on the CRF due to the cost and time associated with collecting data. Data that are collected should generally be reviewed and cleaned. The Protocol (and SAP when it is prepared in conjunction with the Protocol) should be reviewed to ensure that the parameters needed for analysis are collected and can be easily analyzed. The Statistician is responsible for confirming that the CRF collects all of the data necessary to support the analysis

Conformance Tier 1 – CDASH V1.1

- CDASH conformance is separated into two Tiers. Tier 1 is defined in CDASH Standard V1.1 2011-01-18.
  - *All Highly Recommended and applicable Recommended/Conditional Common Identifying and Timing Variables are present in the CRF or available from the operational database.*
  - *All code lists displayed in the CRF use or map to current published CDISC Controlled Terminology when it is available. Subsets of published Controlled Terminology can be used. See Appendix A.*
  - *The implementation of the CRF follows the Best Practice recommendations in Section 3.4 of CDASH v1.1.*
  - *CDASH Question Text or Prompt is used.*

Conformance Tier 2 - User Guide V1.0

- CDASH User Guide V1.0 (for V1.1) 2012-04-12
  - All Level 1 conformances are met.
  - All data collection fields are defined using CDASH naming conventions in the operational database unless an equivalent SDTMIG variable can be used for data collection in a user-friendly manner (e.g., using a recommended input format for data collection)
  - All non-CDASH Variable Names in CRFs follow CDASH recommendations for Creating Fields That Do Not Exist in CDASH (Section 2.4.3).
  - All Best Practice recommendations in Section 3 of CDASH V1.1 are followed.

Conformance CDASHIG 2.0

- 5.1 Conformance Rules
  - Core Designations must be followed
  - CDISC Controlled Terminology must be used
    - (3.8 CDISC Controlled Terminology: either as a CDISC submission value, a synonym or an NCI preferred term)
  - Best Practices must be followed
  - Variable Names
  - Proprietary questionnaires and other validated and/or copyrighted data collection instruments are exceptions to CDASH Conformance rules
  - In order to maintain the validity of a validated instrument, studies that include validated questionnaires, ratings or scales must present the questions and reply choices in the manner in which these were validated. (Reference the QS Domain section).

CDASH Controlled Terminology

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C78418		Yes	Concomitant Medication Dose Form	CMDOSFRM	Concomitant Medication Dose Form
C42887	C78418		Concomitant Medication Dose Form	AEROSOL	aer
C25158	C78418		Concomitant Medication Dose Form	**CAPSULE**	**cap**

CDISC Definition	NCI Preferred Term
A terminology subset of the CDISC SDTM Pharmaceutical Dosage Form codelist created for CDASH Concomitant Medication Dose Form codelist. (NCI)	CDISC CDASH Concomitant Medication Dose Form Terminology
A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).	Aerosol Dosage Form
A solid pharmaceutical dosage form that contains medicinal agent within either a hard or soft soluble container or shell, usually used for the oral administration of medicine. The shells are made of a suitable form of gelatin or other substance. (NCI)	**Capsule Dosage Form**

CDASH Core

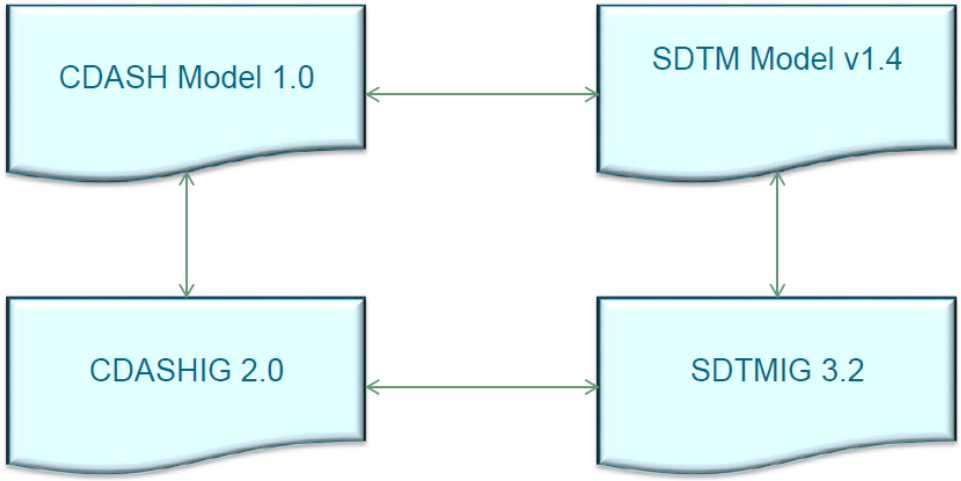
- Highly Recommended (HR): Required, Expected in SDTM, data cleaning prompts.
- Recommended/Conditional (R/C): AETIM if there is something to compare it against.
- Optional (O): All other variables.

  - Creating CRFs in conformance with CDASH can aid in collecting all required and expected variables in SDTM.

Relationship between SDTM and CDASH

Relationships between SDTM and CDASH

- CDASH Model 1.0 aligns with SDTM Model 1.4
- CDASHIG 2.0 aligns with SDTMIG 3.2



CDASH Model 1.0 and CDASHIG 2.0:

An overview prior to Public Review 2016-06-16

http://www.cdisc.org/members-only/members-webinar-archive

- CDISC SHARE links will be added

CDASH to SDTM Mapping Instructions CDASHIG 2.0

Dom	Question Text	Prompt	CDASH Variable	Maps to SDTMIG Variable	Mapping Instructions
SC	What is the subject's marital status?	Marital Status	MARISTAT_ SCORRES	SCORRES ;SCTEST; SCTESTCD	Maps directly to the SDTMIG variable in column K. In addition to the SDTMIG variable SCORRES, create the SDTMIG variable SCTESTCD from the CDASH variable name and determine the value of SCTEST from SCTESTCD. The CDASH prompt may also contain the SCTEST.
LB	Was this lab result clinically significant?	Clinically Significant	LBCLSIG	SUPPLB.QVAL	This field does not map directly to SDTM. This information could be submitted in a SUPPLB dataset as the value of SUPPLB.QVAL when SUPPLB.QNAM = 'LBCLSIG' and SUPPLB.QLABEL='Clinically Significant'.

CDASH to SDTM Mapping Instructions

Dom	Question Text	Prompt	CDASH Variable	CDASH Core	Maps to SDTMIG Variable	SDTM Core
AE	Did the subject have [specific adverse event]?	[Specific Adverse Event]	AEOCCUR	O	FAORRES; CEOCCUR,	Perm; Perm

CRF Completion Instructions	Mapping Instructions	Implementation Notes and Examples for CDASH and SDTM mapping
Indicate if [specific adverse event] has occurred /is occurring by checking Yes or No.	This field does not map directly to an SDTM variable. Since the SDTM AE domain is intended to hold only Adverse Events that actually happen, the values collected in AEOCCUR for pre-specified AEs should be submitted in either a Clinical Events domain, or in a Findings About Adverse Events data set (FAAE).	Example question text - Did the subject have high blood pressure? The CDASH variable AEOCCUR should only be used to report the occurrence of pre-specified adverse events as defined by the protocol. AEOCCUR should not be used for spontaneously reported adverse events. CEOCCUR is used to report the occurrence of pre-specified events not considered to be an adverse event by the sponsor. FAORRES with a FATESTCD of OCCURRENCE is used to report the occurrence of prespecified adverse event.

CDASH TAUG Breast Cancer

Annotated CRF: Tumor Identification/Results Target Lesions

This CRF is only an example and is not meant to imply that any particular layout is preferable over another.

CRF annotated to show mapping. SDTM variables are in Red. If CDASH variable differs from SDTM the CDASH variable is in Blue. * : new variable request submitted. Refer to the corresponding CDASH Metadata table for more information on Sponsor-related Implementation decisions and TA specific usage rules.

Target TUTESTCD=TUMIDENT and TUORRES=TARGET

Response Criteria: RSCAT *Pre-specified*		**RECIST 1.1**	
Were tumors identified? TUYN*	☐ Yes ☐ No	Tumor ID: TULNKID	(A10 or Sponsor-Defined CT)
Location: TULOC	*<Select appropriate values from LOC CT>*	Location Text: TULOCTXT* SUPPTU.LOCTXT	(A200)
Laterality: TULAT	☐ Left ☐ Right ☐ Bilateral *<Select appropriate values from LAT CT>*	Directionality: TUDIR	☐ Distal ☐ Intermediate ☐ Proximal ☐ Inner ☐ Outer *<Select appropriate values from DIR CT>*
Changes to Tumor Identified: TUCHANGE*	Split TUTESTCD=TUSPLIT Merged TUTESTCD=TUMERGE		
Method of Evaluation: TUMETHOD	☐ Clinical Exam ☐ Endoscopy ☐ PET Scan ☐ Physical Examination ☐ CT Scan ☐ Mammography ☐ PET/CT Scan ☐ Scintigraphy ☐ Ductography ☐ MRI ☐ PET/MRI Scan ☐ Ultrasound ☐ DXA Scan ☐ MUGA ☐ Photography ☐ X-Ray ☐ Echocardiogram *<Select appropriate values from METHOD CT>*		
Date of Evaluation: (DD-MMM-YYYY) TUDTC	__/___/____	Diameter: TRTESTCD=DIAMETER TRORRES	
Evaluator TUEVAL	☐ Investigator ☐ Independent Assessor	Diameter Unit: TRORRESU	mm TRDIAMU*
Evaluator Identifier: TUEVALID	☐ Radiologist 1 ☐ Radiologist 3 ☐ Radiologist 2 …	Diameter Too Small to Measure: TRORRES	☐ Yes TRTOOSM*
Tumor Inevaluable? TRINEVAL*	☐ Inevaluable TRTESTCD=TUMSTATE TRSTAT=NOT DONE	Lymph Node State: TRTESTCD=LNSTATE TRLNSTAT* TRORRES	☐ Pathological ☐ Non-Pathological
If Tumor is Inevaluable, Reason Not Done: TRREASND	☐ Cavitation ☐ Necrosis ☐ Insufficient Images/Anatomy ☐ Site Error ☐ Fibrosis ☐ Poor Scan Quality ☐ Inconsistent Modality ☐ Other		

CDASH TAUG Breast Cancer Metadata

Dom	Question Text	Prompt	SDTM Variable Name	SDTM Core
TU	What type of tumors are being identified?	Target / Non-target / New	TUTESTCD	Req
TU	Were <Target; Non-target; New tumors> identified?	Were tumors identified?	N/A	N/A

Description	Case Report Form Completion Instructions
Result of the Tumor identification. The result of tumor identification is a classification of the identified tumor. Examples: When TUTESTCD=TUMIDENT (Tumor Identification), values of TUORRES will be: TARGET, NON-TARGET, or NEW	Indicate the type of tumor being evaluated
Indicates whether or not tumors were identified	Indicate whether or not tumors were identified

Mapping Instructions	Information for Sponsors	Controlled Terminology CodeList Name	Controlled Terminology Value
Maps directly to SDTM (TUTESTCD = TUMIDENT)	Usually pre-printed on the eCRF as the title or form name	(TUMIDENT)	NEW; NON-TARGET; TARGET
N/A	This is intended to be used as a data management tool to verify that missing tumor evaluations are confirmed missing.	(NY)	N; Y

CDASH TAUG Dyslipidemia

Example CRF 1: Anti-dyslipidemic Treatment History

CRF annotated to show mapping. SDTM variables are in **Red**.
If CDASH variable differs from SDTM, the CDASH variable is in **Blue**. ^ New variable under consideration

Has the subject been previously treated for Dyslipidemia? **Not Submitted** **CMINT1YN^**	☐ Yes ☐ No
If subject is Treatment Experienced, please provide the treatment history.	
Category for Medication *Hidden/Pre-specified*	**CMCAT = ANTI-DYSLIPIDEMIC TREATMENT**
Indication: *Hidden/Pre-specified*	**CMINDC = DYSLIPIDEMIA**
Dyslipidemia Treatment:	**CMTRT**
Dose:	**CMDOSE** **CMDSTXT**
Dose Unit:	**CMDOSU**
Dose Form:	**CMDOSFRM**
Frequency:	**CMDOSFRQ**
Route:	**CMROUTE**

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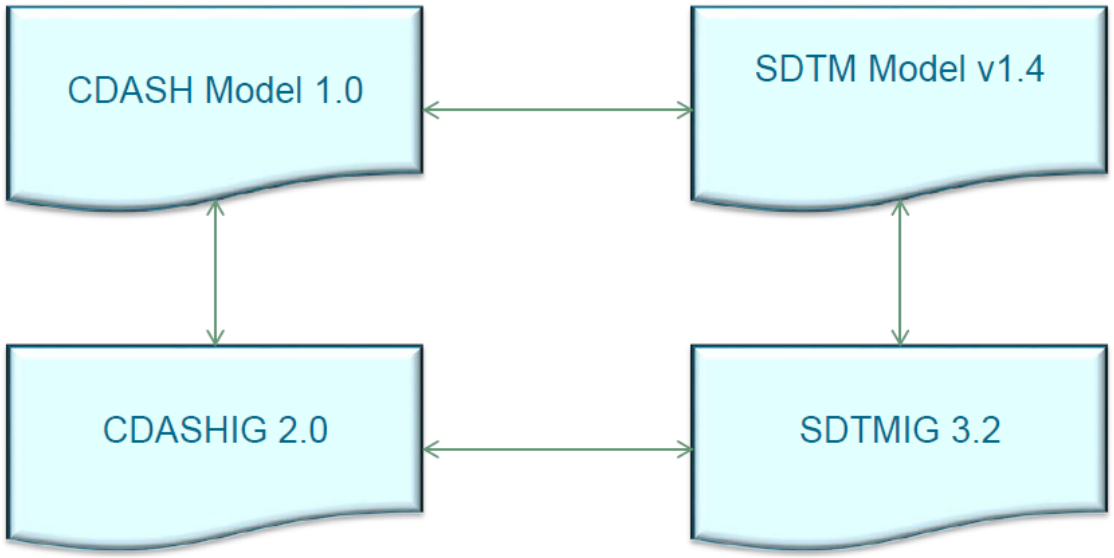

CDASH Model 1.0 and CDASHIG 2.0:

An overview prior to Public Review 2016-06-16

http://www.cdisc.org/members-only/members-webinar-archive

Linking will be available in CDISC Share

CDASH Regulatory Perspectives: FDA

- **FDA Study Data Technical Conformance Guide v3.1**

  4.1.1.2 SDTM General Considerations

  The use of case report forms that incorporate SDTM standard data elements (e.g., Clinical Data Acquisition Standards Harmonization (CDASH)) allows for a simplified process for the creation of SDTM domains.

  8.3.1 Overview

  Traceability can be enhanced when studies are prospectively designed to collect data using a standardized CRF, e.g., CDASH.

CDASH Regulatory Perspectives: PMDA

- **PMDA:** Basic Principles on Electronic Submission of Study Data for New Drug Applications Notification number: 0620-6 2014-06-20

  7. Relationship between electronic data submission and conformity inspection.

  For conformity inspection of application data, ***the CDISC standards such as the Clinical Data Acquisition Standards Harmonization (CDASH) are encouraged*** *to in the future be used from the time of data collection via electronic case report forms.*

- **PMDA:** Technical Conformance Guide on Electronic Study Data Submissions Notification No. 0427001_2015-04-27

  4.1.1.2 SDTM datasets

  The applicant ***may manage the clinical study data using their own unique format that includes SDTM,*** *but even in such cases, the dataset to be submitted must be converted into formats that are in accordance with SDTM and SDTM IG.*

CDASH Regulatory Perspectives: EMA

- The EMA has not released a position on CDISC standards including CDASH. It was expected to be released in *EMA Policy/0070* since it was mentioned in the draft version.
  - *In future, CDISC shall be the required standard, in line with future guidance from the Agency.*
- On the advice of the Clinical Trial Advisory Group on Clinical Trial Data Formats (CTAG2) companies in Europe were not required to use CDISC due to an expected increase in administration.
- This decision may be reversed in the future due to repeated requests being sent to the EMA.

- European Translational Information & Knowledge Management Services (eTRIKS): Standards Starter Pack Standards Guidelines Release 1.0 – 2015-06-25 recommends the use of CDASH.

CDASH's Potential Use within the Industry

- The regulatory agencies do not require collected data to be conformant to CDASH.

  However
  - Data is expected to be traceable from collection to Tables, Listings and Figures (TLF)
  - Data is expected to be Semantically Interoperable
- Information could be imported from Electronic Health Records (EHR) for use in clinical trials.
  - ODM (Operational Data Model) 2.0 is planned to integrate with HL7 FHIR.
  - Standardized collection elements will be needed.
    - CDASH
- The EMA is publishing all Clinical Reports (excluding commercially confidential information)
  - All Individual Patient Data (IPD) will be published in the future after a consultation period

Benefits of CDASH

- CDASH provides the basis for a clinical research wide set of data collection standards.
- CDASH prepares data for SDTM mapping.
- Reduces the need for CROs and external partners to learn internal company standards.
- Supports mergers and acquisitions by enabling groups to communicate in the same language.
- CDASH has SDTM information represented through a CRF format which DM and EDC staff can find more familiar

CDASH Documentation Location

- CDISC CDASH Documentation
  - http://www.cdisc.org/standards/foundational/cdash
- CDISC Wiki (CDASHIG v2.0)
  - http://wiki.cdisc.org/display/CMIG/ReadMe+for+CDASH+v2
  - Public comments closed Tuesday, 16AUG2016.

Any questions?

Thank you

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