



Business & Decision Life Sciences
SEND Webinar
Anne-Sophie Bekx / 15 JUN 2016

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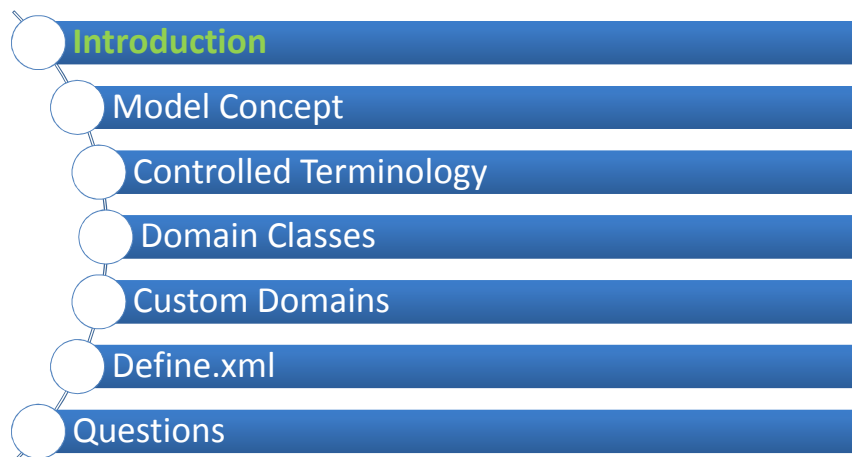
Agenda

- Introduction
- Model Concept
- Controlled Terminology
- Domain Classes
- Custom Domains
- Define.xml
- Questions

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Agenda



SEND

- **Standard for Exchange of Nonclinical Data**
- **CDISC SDTM model v1.2 and SEND Implementation Guide 3.0**
- **AIM :**
 - Define a global standard for study data tabulations
 - Standardize regulatory submissions
- **Focus on study data tabulation content**
- **Will be requested by FDA for all submissions from December 2016**



<http://www.cdisc.org/send>

SDTM versus SEND

Study Data Tabulation Model – “Umbrella Document”

- Developed by the CDISC SDS Team
- Final v1.2 posted 2009-03-26
- 35 Pages

SDTMIG V3.1.2 - Submission Data Standards

- SDTM Implementation Guide: Human Clinical Trials
- Developed by the CDISC SDS Team
- Final v3.1.2 posted 2009-03-26
- 298 pages

SENDIG V3.0 – Standard for Exchange of Nonclinical Data

- SDTM Implementation Guide for Animal Toxicology Studies
- Developed by the CDISC SEND Team
- Final v3.0 posted 2011-05-19
- 256 pages



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SENDIG V3.1 draft

■ Based upon SDTM v1.4

■ To support data from different type of studies

- Single-dose general toxicology
- Repeat-dose general toxicology
- Carcinogenicity studies
- Respiratory and cardiovascular testing done during safety pharmacology studies

■ New domains added:

- Cardiovascular domain (CV)
- Respiratory domain (RE)

■ Expected release: Q2 2016



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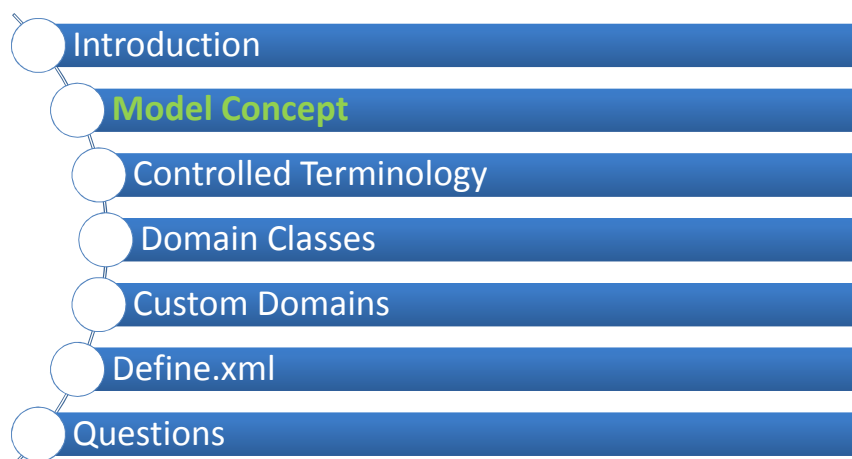
SENDIG-DART V1.0 draft

- **Developmental and Reproductive Toxicology**
- **Based upon SDTM v1.5**
- **Purpose:**
 - Embryo-Fetal Development (EFD) toxicity studies
 - Pre-mated females are treated with protocol specified treatment during fetal organogenesis
 - Study to check for fetal abnormalities
- **Future versions**
 - Fertility studies
 - Postnatal Development
 - Multi-generational studies
- **Expected release: Q2 2016**



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Agenda



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SENDIG Model Concept

Special-Purpose Domains

- Demographics
- Comments
- Subject Elements

Observation Classes

- Interventions
- Events
- Findings

Relationships

- SUPQUAL
- RELREC
- POOLDEF

Trial Design

- Four Tables (TA, TE, TS, TX)

- Within these structures there are fixed variable (column) names and suggested order
- Type of variables:
 - Identifier variables
 - Topic variables
 - Qualifier variables
 - Timing variables
- Variables have defined attributes (e.g., data types)
- Within the variable names, there may be controlled terminology
- Treatment and Demography information is not duplicated on each record



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SEND: Details (1)

SEND: Standard for Exchange of Biomedical Data Implementation Guide (Version 1.0)

2.3 THE SENDIG STANDARD DOMAIN MODELS

The following standard domains with their respective domain codes have been defined or referenced by the SENDIG SEND Team in this document.

Special Purpose Domains (Version 1.0)

- Demographics – Dem
- Comments – Com
- Subject Elements – SE

Interventions: General Observation Class (Version 1.0)

- Experiments – EX

Events: General Observation Class (Version 1.0)

- Dispositions – Dis

Findings: General Observation Class (Version 1.0)

- Body Weights – BW
- Body Weight Gain – BWG
- Clinical Observations – CL
- Death Diagnosis – DD
- Food and Water Consumption – FW
- Laboratory Test Results – LR
- Microscopic Findings – MF
- Necropsy Findings – NF
- Organ Measurements – OM
- Pathologic Images – PI
- Pharmacokinetic Concentrations – PK
- Pharmacokinetic Parameters – PP
- Subject Characteristics – SC
- Tissue Findings – TF
- Toxic Signs – TS
- UIC/Toxic Results – UR

Trial Design Domains (Version 1.0)

- Trial Elements – TE
- Trial Arms – TA
- Trial Sites – TS
- Trial Summary – TSU

Relationship Domains (Version 1.0)

- Supplemental Qualifiers – (SQ) – SQ
- Pooling – POOLDEF

A sponsor should submit only domain elements for which data were actually collected (or directly observed from the laboratory data) for a given study. Domains or table data to collect should be based on the scientific objectives of the study, rather than domains or elements presented in this guide. While some studies will include TA, TX, TS, and a set of domains based on the three general observation classes (especially including BW, BWG, CL, FW, EX, FW, LR, MF, NF, and UR), the actual domains used to represent study data will depend upon the needs of the sponsor.



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SEND: Details (2)

CDISC Standard for Exchange of Biomedical Data Implementation Guide (Version 3.0)

Structure

Published Domains

3.3.3 ORGAN MEASUREMENTS - OM

Weight, Organ Measurement - Findings. One record per test per specimen per subject. Tabular.

Variable Name	Variable Label	Type	Conceptual Terms, Codes, or Format	Role	CDISC Notes	Class
TESTID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DM14LV	Domain Abbreviation	Char	OM	Location	Two-character abbreviation for the domain.	Req
UNIDID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or implementations provided by CDISC.	Req
OMSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
OMTESTCD	Test Short Name	Char	OMTESTCD	Topic	Short name of the measurement, test, or measurement described as OMTEST. It can be used as a column name when covering a column from a related to a horizontal domain. The value in OMTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). OMTESTCD cannot contain characters other than letters, numbers, or underscores.	Req
OMTEST	Test Name	Char	OMTEST	Variable Qualifier	Long name for OMTESTCD. The value in OMTEST cannot be longer than 40 characters.	Req
OMORRES	Result or Findings as Collected	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
OMORRESU	Unit of the Original Result	Char	UNIT	Variable Qualifier	The unit for the original result. The unit of the original result should be mapped to a measurement unit in the <i>Conceptual Terminology</i> . See CDISC Terminology .	Exp
OMORRESX	Standardized Result as Character Format	Char		Result Qualifier	Contains the result value for all findings as observed from OMORRES in a standard format or standard unit. OMORRESX should state all results as findings in character format. If results are numeric, they should also be stated in numeric format in OMORRESX.	Exp
OMORRESN	Standardized Result as Numeric Format	Num		Result Qualifier	Used for results as findings in standard format, contains the numeric form of OMORRESX. OMORRESN should state all numeric test results or findings.	Exp
OMORRESL	Unit of the Standardized Result	Char	UNIT	Variable Qualifier	Standardized unit used for OMORRESN or OMORRESX. Example, if the original unit is mg, the concept, the standard unit might be g for grams.	Exp
OMORRESY	Finding Term	Char	SDY	Result Qualifier	Used to indicate when a test is not done or result is missing. Should be null if a result exists as OMORRESX.	Term
OMORRESZ	Exam Not Done	Char		Result Qualifier	Indicates that OMORRESX is NOT DONE, such as MISSING EQUIPMENT or TESTING LAB OVERSIGHT.	Term
OMORRESA	Specimen Material Type	Char	ORRESA	Result Qualifier	Defines the type of tissue, organ, or fluid specimen used as the object for the finding. Examples: GLAND, ADIPOSAL, KIDNEY, VESICUL, LYMPHNODE.	Req

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SEND: Details (3)

CDISC Standard for Exchange of Biomedical Data Implementation Guide (Version 3.0)

3.3.3.1 ASSUMPTIONS FOR ORGAN MEASUREMENTS (OM) DOMAIN MODEL

- The Organ Measurements (OM) domain contains details of organ weights and relative organ weights.
- Totals and Body Weight will be recorded as the RW domain and this is indicated by the test code (OMTESTCD) of TERMBHW.
- Organ measurement ratios within a single study should either be pure ratios with no units specified or percentages with unit shown as "%". It is strongly recommended that pure ratios and percentages should not be mixed.
- Currently in this model, the sponsor is not expected to attempt to relate the organ weight ratios to their underlying source results used in the calculation through the RELRES or GRPD mechanisms.

3.3.3.2 EXAMPLES FOR ORGAN MEASUREMENTS (OM) DOMAIN MODEL

OM Example 1

The following example shows how a sponsor would supply a domain containing organ weights and relative organ weights.

Row	STUDYID	DOMAIN	OMORRES	OMORRESU	OMORRESX	OMORRESN	OMORRESL	OMORRESY	OMORRESZ	OMORRESA
1	MONK	OM	30.0	g	30.0	30.0				
2	MONK	OM	30.0	g	30.0	30.0				
3	MONK	OM	30.0	g	30.0	30.0				
4	MONK	OM	30.0	g	30.0	30.0				
5	MONK	OM	30.0	g	30.0	30.0				
6	MONK	OM	30.0	g	30.0	30.0				
7	MONK	OM	30.0	g	30.0	30.0				
8	MONK	OM	30.0	g	30.0	30.0				
9	MONK	OM	30.0	g	30.0	30.0				
10	MONK	OM	30.0	g	30.0	30.0				
11	MONK	OM	30.0	g	30.0	30.0				
12	MONK	OM	30.0	g	30.0	30.0				
13	MONK	OM	30.0	g	30.0	30.0				
14	MONK	OM	30.0	g	30.0	30.0				
15	MONK	OM	30.0	g	30.0	30.0				
16	MONK	OM	30.0	g	30.0	30.0				
17	MONK	OM	30.0	g	30.0	30.0				
18	MONK	OM	30.0	g	30.0	30.0				
19	MONK	OM	30.0	g	30.0	30.0				
20	MONK	OM	30.0	g	30.0	30.0				
21	MONK	OM	30.0	g	30.0	30.0				

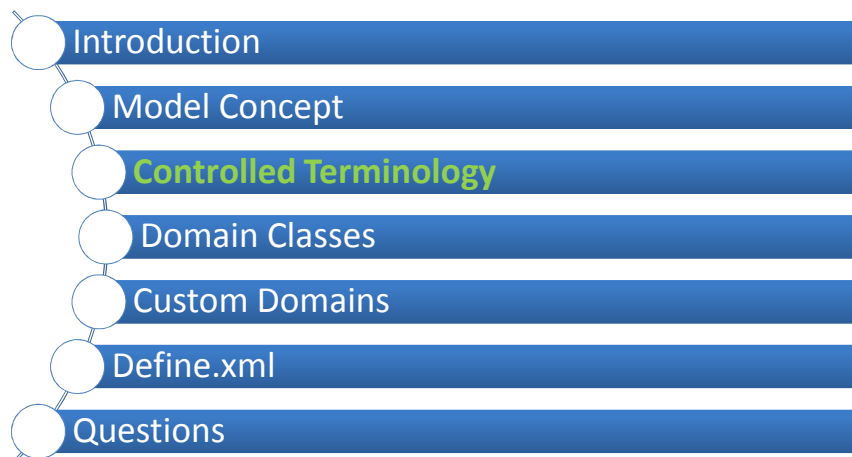
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Agenda



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Formats

- SEND require that all date/time values are submitted in the ISO 8601 format
- YYYY-MM-DDThh:mm:ss
 - 25 Feb 2011 → 2011-02-25
 - 25 Feb 2011, 11:00 am → 2011-02-25T11:00

Variable Name	Variable Label	Type	Controlled Term, Code list, or Format	Role	CDISC Notes
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.
USUBID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies, applications or submissions involving the product.
SUBID	Subject Identifier for the Study	Char		Topic	Subject (i.e., Animal) identifier used within the study.
RFSSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference start date/time for the subject in ISO 8601 character equivalent to date time when subject was first exposed to study day calculation (the --DY variable) in all domains will be base



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Controlled Terminology (1)

CDISC Controlled Terminology (<http://www.cdisc.org/terminology>)

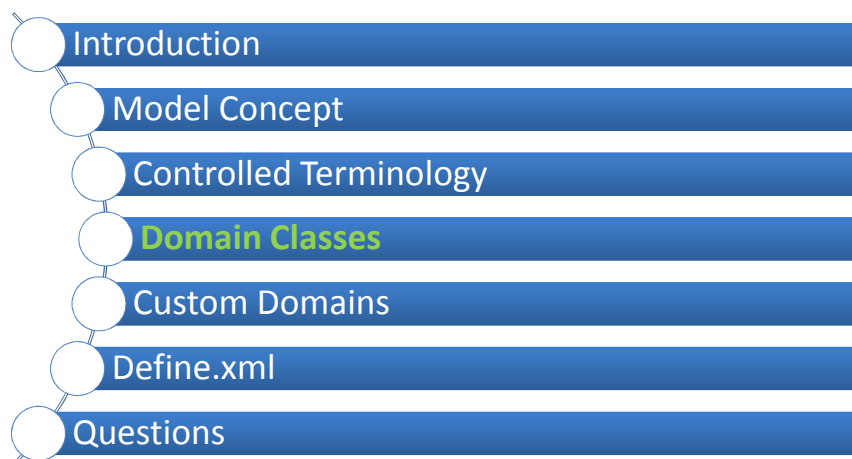
Variable Name	Variable Label	Type	Controlled Term, Codelist, or Format	Role	CDISC Notes
SEX	Sex	Char	(SEX)	Record Qualifier	Nonextensible controlled values are M (Male), F or UN (Undifferentiated, Intersex).
SPECIES	Species	Char	(SPECIES)	Record Qualifier	If this variable is excluded in the TM domain, its present at a higher level (Trial Summary).
STRAIN	Strain/Substrain	Char	(STRAIN)	Record Qualifier	Used to identify the vendor-supplied strain/subst subject (i.e., test system) under study. When app root strain, substrain, and associated genetic and the vendor (e.g., C57BL/6, A/J, B6.129-Prgm-tr FISCHER 344, SPRAGUE-DAWLEY IGS, WIS CYNOMOLGUS, and CHIMPANZEE). The SE

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C66731		No	Sex	SEX	Sex	The assemblage of physical pr is distinguished from female, th male and female, the distinguish (NCI).
C16576	C66731		Sex	F	Female	A person who belongs to the s term is used to indicate biologic gender role distinctions, or both A person who belongs to the s
C20197	C66731		Sex	M	Male	The term is used to indicate bio gender role distinctions, or both
C17998	C66731		Sex	U	U, Unknown	Not known, not observed, not r
C45908	C66731		Sex	UN	Undifferentiated	A person (one of unisexual sp and/or secondary sexual char which combine features of bot

Controlled Terminology (2)

- **Specific SEND Controlled Terminology**
 - Comparable with SDTM but some significant differences
 - Updates on a regular base
- **Sponsor-defined Controlled Terminology**
 - Codelists
 - Coded terms
- **Notes**
 - CDISC Controlled Terminology should always be used when applicable
 - Project consistency

Agenda



Special-Purpose Domains

- **SENDIG**
 - Demographics (DM)
 - Comments (CO)
 - Subject Elements (SE)
- **DM is the central domain in the model**
 - SUBJID refers to a human being in SDTM
 - SUBJID refers to an animal in SEND
 - No RACE and ETHNIC variables but SPECIES and (SB)STRAIN
- **All comments are stored in CO**
- **SE describes the ACTUAL trajectory of a subject during a trial**
- **The concept of VISITS is neglected in SEND**
 - Only planned study day is used: VISITDY

General Observation Classes (1)

■ Interventions

- Investigational treatments, therapeutic treatments, and procedures administered to the subject
- One record per constant dosing interval per treatment per subject or pool
- Topic variable: --TRT

■ SENDIG

- Exposure (EX)



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General Observation Classes (2)

■ Events

- Occurrences, conditions or incidents independent of planned study evaluations occurring during the trial or prior to the trial
- Planned protocol milestones such as randomization
- One record per subject
- Topic variable: --TERM

■ SENDIG

- Disposition (DS)



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General Observation Classes (3)

■ Findings

- Observations resulting from planned evaluations
- One record per finding result or measurement
- Topic variable: --TESTCD

■ SENDIG

- Body Weight (BW)
- Clinical Observations (CL)
- Food and Water Consumption (FW)
- Macroscopic Findings (MA)
- Laboratory Test Results (LB)
- Pharmacokinetics (PP & PC)
- ...

Trial Design Domains

■ Data that is contained in the protocol

■ 'Planned' data

■ SENDIG

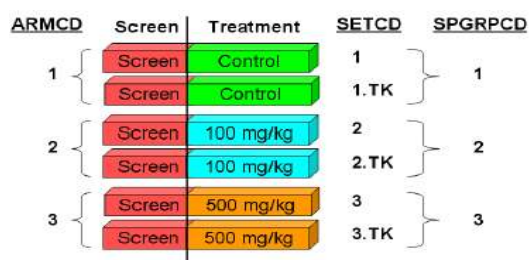
- Trial Arms (TA)
- Trial Elements (TE)
- Trial Summary (TS)
- Trial Sets (TX)

■ Trial Sets = a collection of subjects that have a common path of parameters defined in the protocol

- Arm Code
- Bedding
- Diet
- Housing Humidity
- Light Cycle
- ...

Trial Sets (TX)

Group Number	Group Label	Dose Level	Number of Animals (both sexes combined)	
			Non-Toxicokinetic	Toxicokinetic
1	Group 1, Control	Vehicle Control	14	6
2	Group 2, 100 mg/kg	100 mg/kg/day	14	6
3	Group 3, 500 mg/kg	500 mg/kg/day	14	6



Relationship Datasets

■ RELREC: Related Records

- Used to link data collected in separate domains

■ SUPP--: Supplemental qualifiers

- Addition of sponsor-defined variables is not allowed
- Data that does not belong in an existing standard variable
- Data is linked to the parent domain via a flexible linking mechanism
- Only for General Observation Classes

■ POOLDEF: Pooling

- Only used in SENDIG
- Used when single finding records are captured for a group of subjects: for example cage-based observations
- POOLID and USUBJID are mutually exclusive
- Unique for given set of subjects

Example POOLDEF

- FW (Food and Water Consumption)

Row	STUDYID	DOMAIN	USUBID	POOLID	FWSEQ	FWTESTCD	FWTEST	FWORRES	FWORRESU	FWSTRESC	FWSTRESN
1	13456	FW		C1-101-102	1	FC	Food Consumption	400	g	250	200
2	13456	FW		C1-201-102	2	FC	Food Consumption	420	g	255	210
3	13456	FW		C1-301-102	3	FC	Food Consumption	176	g	265	205
4	13456	FW		C1-302	4	FC	Food Consumption	89	g	120	120

- POOLDEF

Row	STUDYID	POOLID	USUBID
1	13456	C1-101-102	ABC1-101
2	13456	C1-101-102	ABC1-102
3	13456	C1-201-202	ABC1-201
4	13456	C1-201-202	ABC1-202
5	13456	C1-301-302	ABC1-301
6	13456	C1-301-302	ABC1-302
7	13456	C1-302	ABC1-302

Animals 301 and 302

Animal 301 died: new POOLID assigned to animal 302

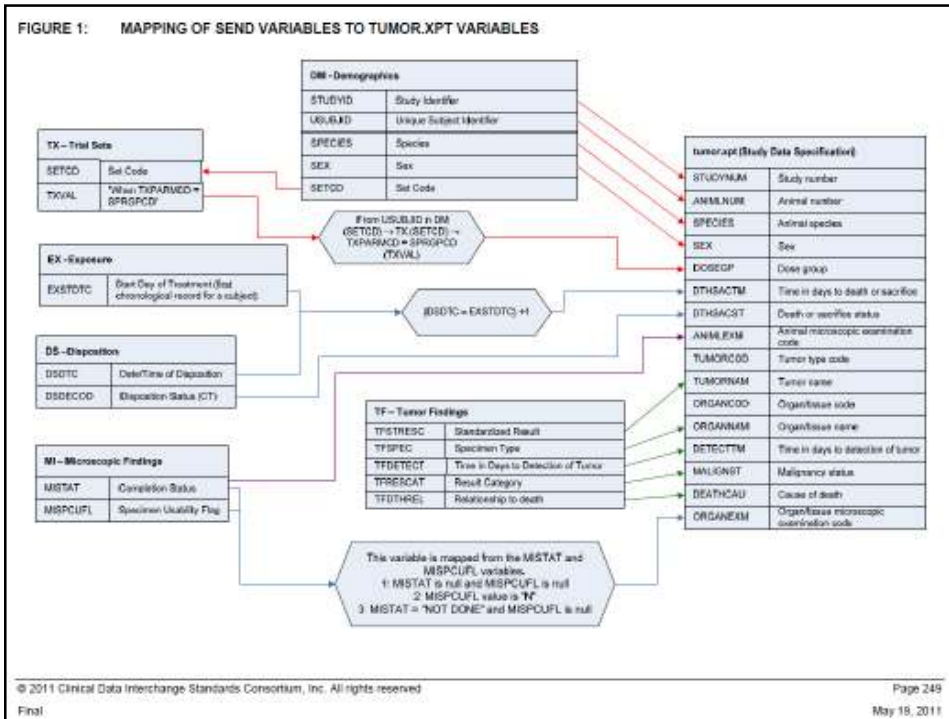
TUMOR.XPT

- Guidelines by FDA for submission of carcinogenicity data

- Domains required for creating tumor.xpt:

- DM (Demographics)
- DS (Disposition)
- EX (Exposure)
- MI (Microscopic Findings)
- TF (Tumor Findings)
- TX (Trial Sets)

- Specific assumptions need to be completed to be in order with FDA



Agenda

- Introduction
- Model Concept
- Controlled Terminology
- Domain Classes
- Custom Domains**
- Define.xml
- Questions

Creation of Custom Domains

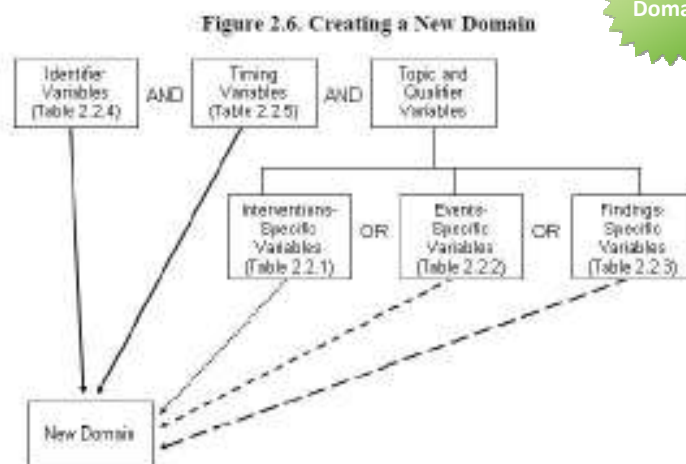
- **When?**
Collected data that does not fit in any of the domains published in SENDIG
- **How?**
 - SDTMIG: well-established procedure
 - SENDIG: ongoing activity of both the SDS and SEND team

“A formal process for the creation of additional domains other than the ones specified in this SENDIG will be developed”

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Procedure



Custom
Domains

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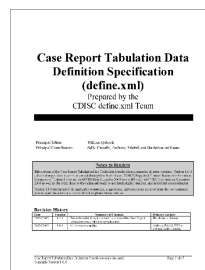
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Agenda

- Introduction
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- Domain Classes
- Custom Domains
- **Define.xml**
- Questions

Define.xml

- Describes the content and structure of the included data in a machine readable format
 - Both SDTM / SEND and ADaM
- XML file structure is based on the CDISC Operational Data Model (ODM)
- Referenced by FDA in the eCTD (electronic submissions) guidance
- Needed for all electronic submissions
- Versions of Define.xml
 - Define v1.0
 - Define v2.0



<http://www.cdisc.org/define-xml>

Define.xml v1.0 content

Table Metadata

Dataset Name
Dataset Label
Class
Structure
Purpose
Keys

Variable Metadata

Variable Name
Variable Label
Type
Controlled Terminology
Origin
Role
Comment

Value Level Metadata

Source Variable
Value
Label
Type
Controlled Terminology
Origin
Role
Comment

Controlled Terminology

Code Value
Code Text

Computational Algorithms

Reference Name
Computational Method



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Origin Metadata: SDTM vs SEND

SDTM

CRF
eDT
Derived
Assigned
Protocol



SEND

Collected
Derived
Other
Not Available



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Origins SEND

- **Collected**
 - Manual or electronic data collected in nonclinical settings
 - Observed or recorded by a person or received from an instrument
- **Derived**
 - Calculated by an algorithm or reproducible rule
 - Not for derived lab test results performed by labs
- **Other**
 - Values from protocol
 - Values defined as part of Trial Design
 - Values for creating dataset: STUDYID, USUBJID, DOMAIN, --SEQ, or --TESTCD.
- **Not Available**
 - Origin of the data is not available
 - Data from another lab without sufficient information



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Define.xml v2.0 example

Table of Contents for Study CDL 001 (CDL01_01_01)

Item	Label	Unit	Frequency	Origin	Test	Unit	Frequency
CDL01_01_01_01	CDL01_01_01_01	mg/L	1	Collected	CDL01_01_01_01	mg/L	1
CDL01_01_01_02	CDL01_01_01_02	mg/L	1	Collected	CDL01_01_01_02	mg/L	1
CDL01_01_01_03	CDL01_01_01_03	mg/L	1	Collected	CDL01_01_01_03	mg/L	1
CDL01_01_01_04	CDL01_01_01_04	mg/L	1	Collected	CDL01_01_01_04	mg/L	1
CDL01_01_01_05	CDL01_01_01_05	mg/L	1	Collected	CDL01_01_01_05	mg/L	1
CDL01_01_01_06	CDL01_01_01_06	mg/L	1	Collected	CDL01_01_01_06	mg/L	1
CDL01_01_01_07	CDL01_01_01_07	mg/L	1	Collected	CDL01_01_01_07	mg/L	1
CDL01_01_01_08	CDL01_01_01_08	mg/L	1	Collected	CDL01_01_01_08	mg/L	1
CDL01_01_01_09	CDL01_01_01_09	mg/L	1	Collected	CDL01_01_01_09	mg/L	1
CDL01_01_01_10	CDL01_01_01_10	mg/L	1	Collected	CDL01_01_01_10	mg/L	1
CDL01_01_01_11	CDL01_01_01_11	mg/L	1	Collected	CDL01_01_01_11	mg/L	1
CDL01_01_01_12	CDL01_01_01_12	mg/L	1	Collected	CDL01_01_01_12	mg/L	1
CDL01_01_01_13	CDL01_01_01_13	mg/L	1	Collected	CDL01_01_01_13	mg/L	1
CDL01_01_01_14	CDL01_01_01_14	mg/L	1	Collected	CDL01_01_01_14	mg/L	1
CDL01_01_01_15	CDL01_01_01_15	mg/L	1	Collected	CDL01_01_01_15	mg/L	1
CDL01_01_01_16	CDL01_01_01_16	mg/L	1	Collected	CDL01_01_01_16	mg/L	1
CDL01_01_01_17	CDL01_01_01_17	mg/L	1	Collected	CDL01_01_01_17	mg/L	1
CDL01_01_01_18	CDL01_01_01_18	mg/L	1	Collected	CDL01_01_01_18	mg/L	1
CDL01_01_01_19	CDL01_01_01_19	mg/L	1	Collected	CDL01_01_01_19	mg/L	1
CDL01_01_01_20	CDL01_01_01_20	mg/L	1	Collected	CDL01_01_01_20	mg/L	1
CDL01_01_01_21	CDL01_01_01_21	mg/L	1	Collected	CDL01_01_01_21	mg/L	1
CDL01_01_01_22	CDL01_01_01_22	mg/L	1	Collected	CDL01_01_01_22	mg/L	1
CDL01_01_01_23	CDL01_01_01_23	mg/L	1	Collected	CDL01_01_01_23	mg/L	1
CDL01_01_01_24	CDL01_01_01_24	mg/L	1	Collected	CDL01_01_01_24	mg/L	1
CDL01_01_01_25	CDL01_01_01_25	mg/L	1	Collected	CDL01_01_01_25	mg/L	1
CDL01_01_01_26	CDL01_01_01_26	mg/L	1	Collected	CDL01_01_01_26	mg/L	1
CDL01_01_01_27	CDL01_01_01_27	mg/L	1	Collected	CDL01_01_01_27	mg/L	1
CDL01_01_01_28	CDL01_01_01_28	mg/L	1	Collected	CDL01_01_01_28	mg/L	1
CDL01_01_01_29	CDL01_01_01_29	mg/L	1	Collected	CDL01_01_01_29	mg/L	1
CDL01_01_01_30	CDL01_01_01_30	mg/L	1	Collected	CDL01_01_01_30	mg/L	1
CDL01_01_01_31	CDL01_01_01_31	mg/L	1	Collected	CDL01_01_01_31	mg/L	1
CDL01_01_01_32	CDL01_01_01_32	mg/L	1	Collected	CDL01_01_01_32	mg/L	1
CDL01_01_01_33	CDL01_01_01_33	mg/L	1	Collected	CDL01_01_01_33	mg/L	1
CDL01_01_01_34	CDL01_01_01_34	mg/L	1	Collected	CDL01_01_01_34	mg/L	1
CDL01_01_01_35	CDL01_01_01_35	mg/L	1	Collected	CDL01_01_01_35	mg/L	1
CDL01_01_01_36	CDL01_01_01_36	mg/L	1	Collected	CDL01_01_01_36	mg/L	1
CDL01_01_01_37	CDL01_01_01_37	mg/L	1	Collected	CDL01_01_01_37	mg/L	1
CDL01_01_01_38	CDL01_01_01_38	mg/L	1	Collected	CDL01_01_01_38	mg/L	1
CDL01_01_01_39	CDL01_01_01_39	mg/L	1	Collected	CDL01_01_01_39	mg/L	1
CDL01_01_01_40	CDL01_01_01_40	mg/L	1	Collected	CDL01_01_01_40	mg/L	1
CDL01_01_01_41	CDL01_01_01_41	mg/L	1	Collected	CDL01_01_01_41	mg/L	1
CDL01_01_01_42	CDL01_01_01_42	mg/L	1	Collected	CDL01_01_01_42	mg/L	1
CDL01_01_01_43	CDL01_01_01_43	mg/L	1	Collected	CDL01_01_01_43	mg/L	1
CDL01_01_01_44	CDL01_01_01_44	mg/L	1	Collected	CDL01_01_01_44	mg/L	1
CDL01_01_01_45	CDL01_01_01_45	mg/L	1	Collected	CDL01_01_01_45	mg/L	1
CDL01_01_01_46	CDL01_01_01_46	mg/L	1	Collected	CDL01_01_01_46	mg/L	1
CDL01_01_01_47	CDL01_01_01_47	mg/L	1	Collected	CDL01_01_01_47	mg/L	1
CDL01_01_01_48	CDL01_01_01_48	mg/L	1	Collected	CDL01_01_01_48	mg/L	1
CDL01_01_01_49	CDL01_01_01_49	mg/L	1	Collected	CDL01_01_01_49	mg/L	1
CDL01_01_01_50	CDL01_01_01_50	mg/L	1	Collected	CDL01_01_01_50	mg/L	1
CDL01_01_01_51	CDL01_01_01_51	mg/L	1	Collected	CDL01_01_01_51	mg/L	1
CDL01_01_01_52	CDL01_01_01_52	mg/L	1	Collected	CDL01_01_01_52	mg/L	1
CDL01_01_01_53	CDL01_01_01_53	mg/L	1	Collected	CDL01_01_01_53	mg/L	1
CDL01_01_01_54	CDL01_01_01_54	mg/L	1	Collected	CDL01_01_01_54	mg/L	1
CDL01_01_01_55	CDL01_01_01_55	mg/L	1	Collected	CDL01_01_01_55	mg/L	1
CDL01_01_01_56	CDL01_01_01_56	mg/L	1	Collected	CDL01_01_01_56	mg/L	1
CDL01_01_01_57	CDL01_01_01_57	mg/L	1	Collected	CDL01_01_01_57	mg/L	1
CDL01_01_01_58	CDL01_01_01_58	mg/L	1	Collected	CDL01_01_01_58	mg/L	1
CDL01_01_01_59	CDL01_01_01_59	mg/L	1	Collected	CDL01_01_01_59	mg/L	1
CDL01_01_01_60	CDL01_01_01_60	mg/L	1	Collected	CDL01_01_01_60	mg/L	1
CDL01_01_01_61	CDL01_01_01_61	mg/L	1	Collected	CDL01_01_01_61	mg/L	1
CDL01_01_01_62	CDL01_01_01_62	mg/L	1	Collected	CDL01_01_01_62	mg/L	1
CDL01_01_01_63	CDL01_01_01_63	mg/L	1	Collected	CDL01_01_01_63	mg/L	1
CDL01_01_01_64	CDL01_01_01_64	mg/L	1	Collected	CDL01_01_01_64	mg/L	1
CDL01_01_01_65	CDL01_01_01_65	mg/L	1	Collected	CDL01_01_01_65	mg/L	1
CDL01_01_01_66	CDL01_01_01_66	mg/L	1	Collected	CDL01_01_01_66	mg/L	1
CDL01_01_01_67	CDL01_01_01_67	mg/L	1	Collected	CDL01_01_01_67	mg/L	1
CDL01_01_01_68	CDL01_01_01_68	mg/L	1	Collected	CDL01_01_01_68	mg/L	1
CDL01_01_01_69	CDL01_01_01_69	mg/L	1	Collected	CDL01_01_01_69	mg/L	1
CDL01_01_01_70	CDL01_01_01_70	mg/L	1	Collected	CDL01_01_01_70	mg/L	1
CDL01_01_01_71	CDL01_01_01_71	mg/L	1	Collected	CDL01_01_01_71	mg/L	1
CDL01_01_01_72	CDL01_01_01_72	mg/L	1	Collected	CDL01_01_01_72	mg/L	1
CDL01_01_01_73	CDL01_01_01_73	mg/L	1	Collected	CDL01_01_01_73	mg/L	1
CDL01_01_01_74	CDL01_01_01_74	mg/L	1	Collected	CDL01_01_01_74	mg/L	1
CDL01_01_01_75	CDL01_01_01_75	mg/L	1	Collected	CDL01_01_01_75	mg/L	1
CDL01_01_01_76	CDL01_01_01_76	mg/L	1	Collected	CDL01_01_01_76	mg/L	1
CDL01_01_01_77	CDL01_01_01_77	mg/L	1	Collected	CDL01_01_01_77	mg/L	1
CDL01_01_01_78	CDL01_01_01_78	mg/L	1	Collected	CDL01_01_01_78	mg/L	1
CDL01_01_01_79	CDL01_01_01_79	mg/L	1	Collected	CDL01_01_01_79	mg/L	1
CDL01_01_01_80	CDL01_01_01_80	mg/L	1	Collected	CDL01_01_01_80	mg/L	1
CDL01_01_01_81	CDL01_01_01_81	mg/L	1	Collected	CDL01_01_01_81	mg/L	1
CDL01_01_01_82	CDL01_01_01_82	mg/L	1	Collected	CDL01_01_01_82	mg/L	1
CDL01_01_01_83	CDL01_01_01_83	mg/L	1	Collected	CDL01_01_01_83	mg/L	1
CDL01_01_01_84	CDL01_01_01_84	mg/L	1	Collected	CDL01_01_01_84	mg/L	1
CDL01_01_01_85	CDL01_01_01_85	mg/L	1	Collected	CDL01_01_01_85	mg/L	1
CDL01_01_01_86	CDL01_01_01_86	mg/L	1	Collected	CDL01_01_01_86	mg/L	1
CDL01_01_01_87	CDL01_01_01_87	mg/L	1	Collected	CDL01_01_01_87	mg/L	1
CDL01_01_01_88	CDL01_01_01_88	mg/L	1	Collected	CDL01_01_01_88	mg/L	1
CDL01_01_01_89	CDL01_01_01_89	mg/L	1	Collected	CDL01_01_01_89	mg/L	1
CDL01_01_01_90	CDL01_01_01_90	mg/L	1	Collected	CDL01_01_01_90	mg/L	1
CDL01_01_01_91	CDL01_01_01_91	mg/L	1	Collected	CDL01_01_01_91	mg/L	1
CDL01_01_01_92	CDL01_01_01_92	mg/L	1	Collected	CDL01_01_01_92	mg/L	1
CDL01_01_01_93	CDL01_01_01_93	mg/L	1	Collected	CDL01_01_01_93	mg/L	1
CDL01_01_01_94	CDL01_01_01_94	mg/L	1	Collected	CDL01_01_01_94	mg/L	1
CDL01_01_01_95	CDL01_01_01_95	mg/L	1	Collected	CDL01_01_01_95	mg/L	1
CDL01_01_01_96	CDL01_01_01_96	mg/L	1	Collected	CDL01_01_01_96	mg/L	1
CDL01_01_01_97	CDL01_01_01_97	mg/L	1	Collected	CDL01_01_01_97	mg/L	1
CDL01_01_01_98	CDL01_01_01_98	mg/L	1	Collected	CDL01_01_01_98	mg/L	1
CDL01_01_01_99	CDL01_01_01_99	mg/L	1	Collected	CDL01_01_01_99	mg/L	1
CDL01_01_01_100	CDL01_01_01_100	mg/L	1	Collected	CDL01_01_01_100	mg/L	1

Variable | Label | Unit | Frequency | Origin | Test | Unit | Frequency

Variable	Label	Unit	Frequency	Origin	Test	Unit	Frequency
STUDYID	Study Identifier		1	Derived			1
DOMAIN	Domain Abbreviation		4	Derived			4
SEQ	Sequence Number		1	Derived			1
TESTCD	Test Code		1	Derived			1
TEST	Test Description		1	Derived			1
VSSTPT	Planned Study Day of Collection	Integer	3	Collected			3
BSSTPT	Study Day Interval Weighted	Integer	10	Derived			10
BSSTPT	Study Day Interval Weighted	Integer	3	Derived			3

Agenda

- Introduction
- Model Concept
- Controlled Terminology
- Domain Classes
- Custom Domains
- Define.xml
- Questions

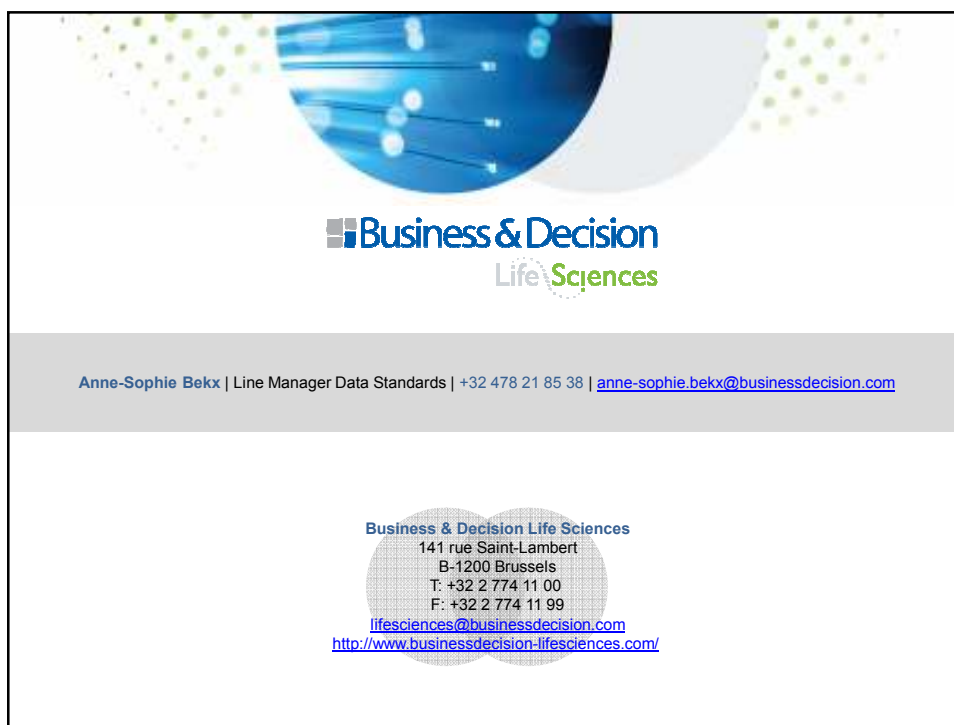




Thank you

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