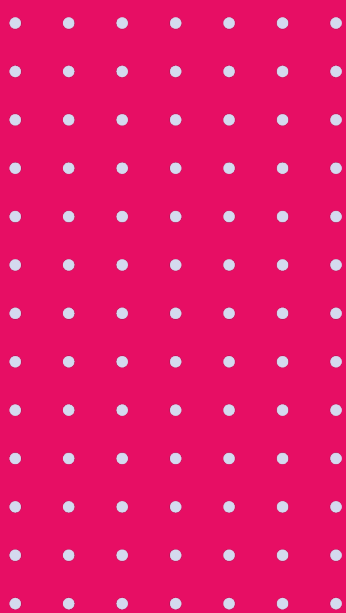




Standards Library: Getting started – A Medical Device Case Study

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“...The Centre for Devices and Radiological Health (CDRH) encourages manufacturers to use data and terminology standards in pre-market submissions and post-market reports for Medical Devices. CDRH currently accept clinical trial data in any format including CDISC standardized formats...”

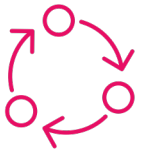
While not yet required – we aim to use CDISC as a data standardization model to provide efficiency gains through standards artifacts reuse, higher quality, and reduced timelines.

CDISC STANDARDS FOR MEDICAL DEVICES > BENEFITS



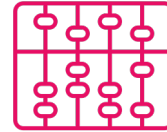
Benefit for CDRH statisticians, instances(*)

- Protocol Deviations
- Data Traceability
- Missing Data
- Trial Data Issue



QCD metrics, examples

- Lead time
- Less rework
- Efficient Multiple standard versioning
- Decreasing number of non standard specs (CRF, SDTM,..)



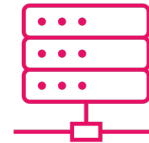
Re-usability and stability, examples

- 90% of the macros to be re-used
- Minimum deviation from standard



Independence of the organization for MD standard implementation, examples

- In house expertise
- Super SMEs
- Less use of CROs



Foundation for future technology enhancement

- CDR
- MDR
- Other project Digital Protocol e.g.CDISC DDF

Foundations for your library

Client CRF library of 218 CRFs

Review of CRFs for most reusable content with the Medical device case study analysis in mind led to populating the standards library with:

Selection of 79 CRFs annotated to SDTM standards

72 SDTM specifications

51 ADaM specifications

16 specifications for MD domains

30 Table shells

22 Table macros

Mapped to CDISC standards while considering Device Specificity including:

- Single Vs Multi use
- Single Patient Vs Multiple patients for same device
- Laterality
- Batch number for identification of components
- Device reported outcomes – specific time points or synced by user
- Device related Deficiencies

Artifact creation starts with a base of a CRF library, CDISC standards, and adding annotations to map to SDTM. ADaM standard mappings can then be created based on the SDTM artifacts. With training on each of the standards the library can continue to evolve as the team become more familiar and map more of their CRF library.

2_company > 1_crf

 COMPANY_CRF_DM001_SDTM-MSG2.0_v1.0.0

DM (Demographics)

Demographics
External ID: DM001
Design Object Name: DM001
Short Label: Demographics
Restricted: No

Demographics (ig_DM001) (External ID: ig_DM001)		
Age		Name: AGE External ID: AGE Required Range 0-115 (3.0)
AGE		
Age Units		Name: AGEU External ID: AGEU Codelist: cl_AGEU_CT Read Only Display Visibility: Include in Data Entry, Include in Extracts
AGEU		
Value calculated by the system		
Sex		Name: SEX External ID: SEX Required Codelist: cl_SEX_CT
SEX	Female (F)	
	Male (M)	
	Unknown (U)	
	Undifferentiated (UNDIFFERENTIATED)	

2_company > 3_sdtm

 COMPANY_SDTM_DM_IG3.3_v1.0.1

	Dataset	Variable		Controlled Terms,			
	Name	Name	Variable Label	Type	Codelist or Format	Core	Role
1							Origin
18	DM	AGE	Age	Num		Exp	Record Qualifier
19	DM	AGEU	Age Units	Char	C66781	Exp	Variable Qualifier
20	DM	SEX	Sex	Char	C66731	Req	Record Qualifier

When using library artifacts with a Medical Device study care should be taken to evaluate relationships between Patients and Devices. SDTMIG MD v1.1 feeds several medical device domains. Your Related Records relationships will vary based on protocol. Below SPDEVID is collected on Device Deficiency form but not related to DI as it is a subset only deficient devices would be recorded.

IN_CDISC_SDTMIG-MD_v1.1

Dataset Name	Variable Name	Variable Label
DI	STUDYID	Study Identifier
DI	DOMAIN	Domain Abbreviation
DI	SPDEVID	Sponsor Device Identifier
DI	DISEQ	Sequence Number
DI	DIPARMCD	Device Identifier Element Short Name
DI	DIPARM	Device Identifier Element Name
DI	DIVAL	Device Identifier Element Value

CO_SDTM_DX_MD1.1_v1.0.1

CO_SDTM_DR_MD1.1_v1.0.1

CO_SDTM_DI_MD1.1_v1.0.2

CO_SDTM_DE_MD1.1_v1.0.1

DE (Device Events)	RELREC (Related Records)
FADE (Findings About)	
Device Deficiency: DECAT = DEVICE DEFICIENCIES	DE.SPDEVID (ONE)=FA.SPDEVID(MANY)
External ID: DE001	FACAT = DEVICE DEFICIENCIES
Design Object Name: DE001	
Short Label: Device Deficiency	
Restricted: No	
Repeats, Max: 999	
Device Deficiency (ig_DE001) (External ID: ig_DE001)	
Unique Tracking Number	Name: SPDEVID
SPDEVID: SPDEVID	External ID: SPDEVID
TRACKNUM in SUPPDE	Required
	Max Length: 50

Study Identifier	Domain Abbreviation	Sponsor Device Identifier	Sequence Number	Device Identifier Element Short Name	Device Identifier Element Name	Device Identifier Element Value
TEST_STUDY	DI	Mod1-S12345	1	DEVTYPE	Device Type	Wearable
TEST_STUDY	DI	Mod1-S12345	2	MANUF	Manufacturer	Veramed
TEST_STUDY	DI	Mod1-S12345	3	MODEL	Model	Mod1
TEST_STUDY	DI	Mod1-S12345	4	SERIAL	Serial Number	S12345
TEST_STUDY	DI	Mod1-S12346	1	DEVTYPE	Device Type	Wearable
TEST_STUDY	DI	Mod1-S12346	2	MANUF	Manufacturer	Veramed
TEST_STUDY	DI	Mod1-S12346	3	MODEL	Model	Mod1
TEST_STUDY	DI	Mod1-S12346	4	SERIAL	Serial Number	S12346

Library Folder Structure

- ▼ standards
 - > development
- ▼ production
 - > 1_industry
 - > 2_company
- ▼ 3_franchise
 - > SX
 - > VC

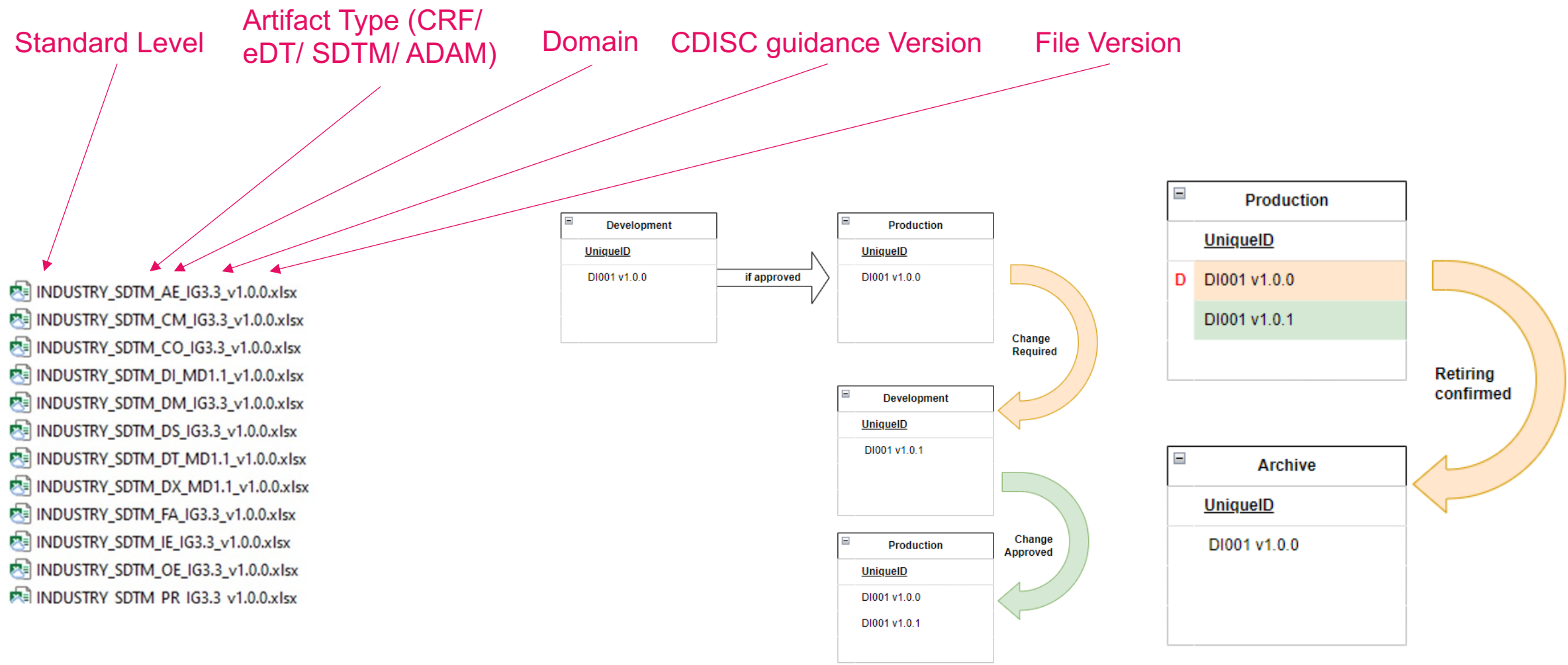
Industry Standards
used for reference.
CDISC, QRS,
MedDRA, etc.

Company standards.
Same across all
Company studies.

Franchise standards.
Same across all
Therapeutic
area/franchise studies.

- ▼ 1_industry
 - > 1_standard
 - 2_sdtm
 - > 3_dictionaries
 - 4_adam
 - 5_tfl
- ▼ 2_company
 - ▼ 1_crf
 - CM099_v1.0.0
 - DM001_v1.0.0
 - DM002_v1.0.0
 - DS001_v1.0.0
 - IE001_v1.0.0
 - ML001_v1.0.0

Traceability is ensured with our file naming structure



CDISC Standards for Medical Devices > Governance



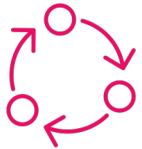
Define your criteria for success

- Tangible measures
- Intangible



Standard Governance board

- Leadership committee for standard implementation
- Process owners or Domain Leads to manage day to day



Business process optimization

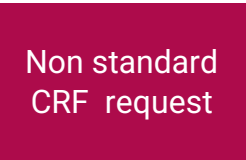
- Deviation management
- Operational Issue management
- CAPA for continuous improvement
- Process flows and SOPs



Continuous knowledge sharing

- Training material
- Training matrix
- Regular refresh / onboarding

Non standard CRF request



Department	Impact (L-M-H)	Role Exp	Contacts	Communication	Vehicle
CDO	High	Sponsor Change Lead champions	See section stakeholders	Project update Project impact	CDO quarterly meeting <u>TownHall</u> email
Stat Programming	High	Sponsor Change Lead champions		Project update Project impact	SP meeting <u>TownHall</u> Email Executive meeting
Clinical Trial	Medium	none		Project update	CDO quarterly meeting

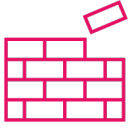
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rtterly		

Training
Slide



Deviation & issues

Conclusion



Progress towards a complete standards implementation can start small.



A Standards Framework allows streamlining for all future studies and has benefits of reusability and quality.



In the case of a Medical device study it allows us to employ early adoption of CDISC standards while also allowing reuse of common metadata for other Therapeutic areas.



Defining the end goals of full adoption of CDISC standards is important before the project starts, both tangible and intangible



The governance team has a continuous role, from the project start up to the consolidation of the organisation, through process flows, decision making process, monitoring and continuous improvement