

Best Practices in Data Standards Governance

Stijn Rogiers

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Data Standards Governance Board



- CDISC Data Standards Subject Matter Experts
- Representatives of Functional Groups
 - Data Managers
 - Statisticians
 - Statistical Programmers
- Management

1. Interpret Data Standards



2. Extend Data Standards



2. Extend Data Standards

PharmaSUG 2018 - Paper DS-10

Designing Flexible Data Standards Models

Melissa R. Martinez, SAS Institute

Data Standard Model

Table ▲	Name	Description	Order ^	Core	Origin Type
AE	STUDYID	Study Identifier	1	Req	Protocol
AE	DOMAIN	Domain Abbreviation	2	Req	Assigned
AE	USUBJID	Unique Subject Identifier	3	Req	Derived
AE	AESEQ	Sequence Number	4	Req	Derived
AE	AESPID	Sponsor-Defined Identifier	5	Perm	CRF
AE	AETERM	Reported Term for the Adverse Event	6	Req	CRF
AE	AEMOD...	Modified Reported Term	7	Perm	Assigned

Data Standard Model

- Attribute: Name
- Order: 1
- Data Type: String
- Length: 255
- Required: Yes
- Must be Unique: Yes
- Required for Define-XML: Yes
- ...

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AE	STUDYID	Study Identifier	1	Req	Protocol
AE	DOMAIN	Domain Abbreviation	2	Req	Assigned
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AE	AEMOD...	Modified Reported Term	7	Perm	Assigned

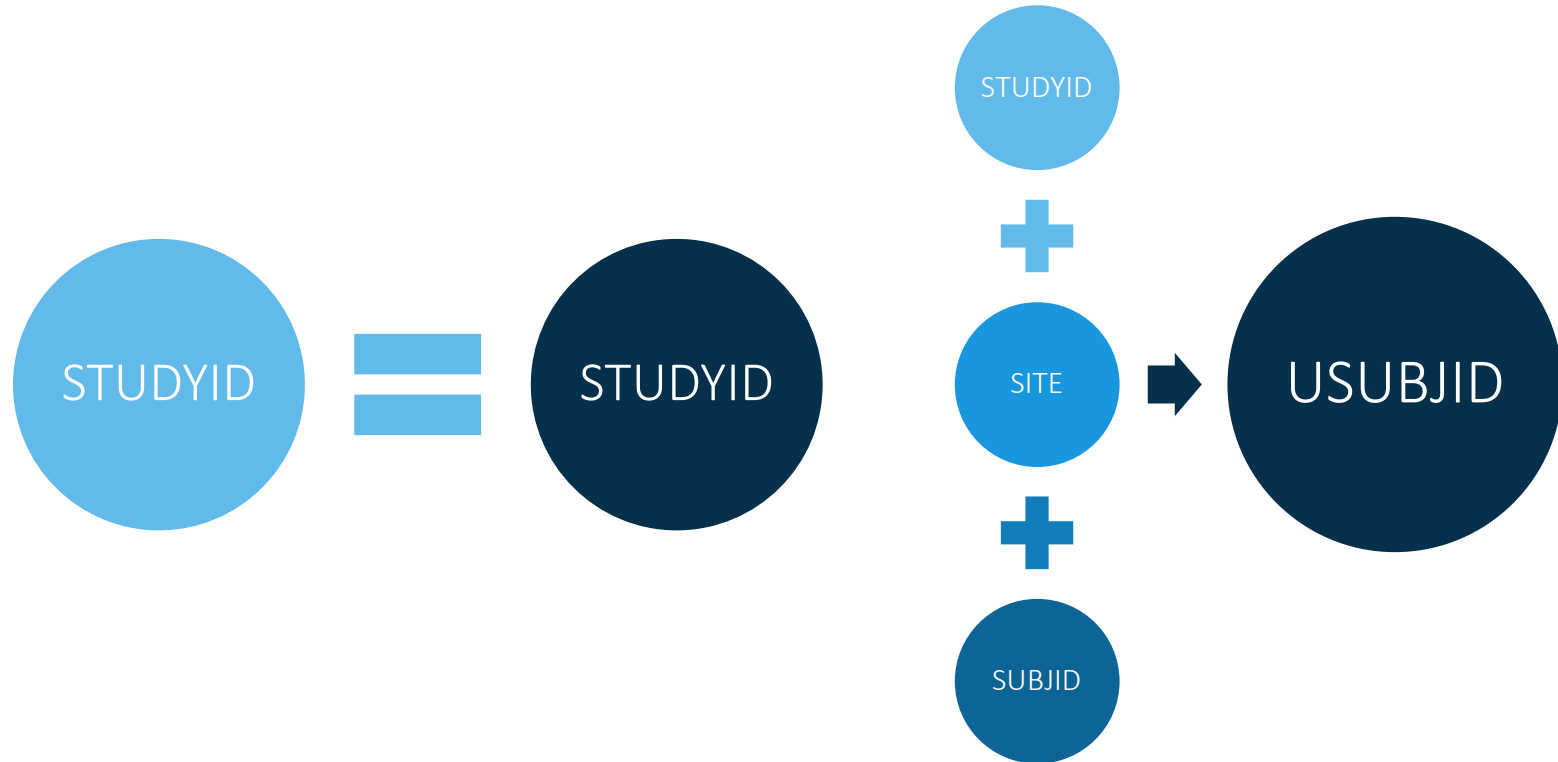
Extending Data Standard Models



- ✓ Additional Information
 - ✓ Related to Data Standard
 - ✓ Should be Standardized
 - ✓ Drive Processes
- ✓ Consolidate Management of Metadata

Example: Data Set Programming

New Attribute: Source Variables



Extend Data Standard Model: Add Attributes

- Attribute: Source Variables
- Order: 25
- Data Type: String
- Length: 255
- Required: No
- Must be Unique: No
- Required for Define-XML: No
- ...

Table ▲	Name	Description	Source Variables	Order ^	Core	Origin Type
AE	STUDYID	Study Identifier		1	Req	Protocol
AE	DOMAIN	Domain Abbreviation		2	Req	Assigned
AE	USUBJID	Unique Subject Identifier		3	Req	Derived
AE	AESEQ	Sequence Number		4	Req	Derived
AE	AESPID	Sponsor-Defined Identifier		5	Perm	CRF
AE	AETERM	Reported Term for the Adverse Event		6	Req	CRF
AE	AEMOD...	Modified Reported Term		7	Perm	Assigned

Example: De-Identification

Go Read!

Jack Shostak

“De-Identification of Clinical
Trials Data Demystified”

(lexjansen.com)

Example: De-Identification

New Attribute: De-Identifying Flag

USUBJID

Reference Start Date

Date Variable

Drop

Example: SDTM-plus

Go Read!

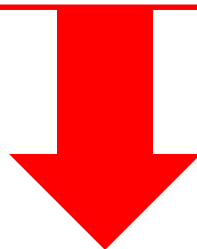
Barry R. Cohen

“SDTM, Plus or Minus”

(lexjansen.com)

Example: SDTM-plus Clinical Interest

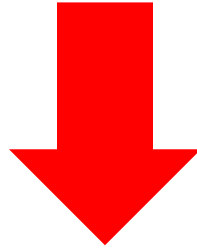
Table	Name	Description	Order	Core	Origin Type
AE	STUDYID	Study Identifier	1	Req	Protocol
AE	DOMAIN	Domain Abbreviation	2	Req	Assigned
AE	USUBJID	Unique Subject Identifier	3	Req	Derived
AE	AESEQ	Sequence Number	4	Req	Derived
AE	AESPID	Sponsor-Defined Identifier	5	Perm	CRF
AE	AETERM	Reported Term for the Adverse Event	6	Req	CRF
	...				
AE	AECLININT	Clinical Interest	24	Perm	CRF





Example: SDTM-plus

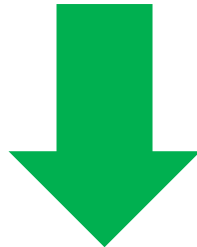
For Submission: SUPPQUAL



STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
ABC123	AE	ABC123-001-001	AESEQ	12	AECLINT	Clinical Interest	N	CRF	Investigator
ABC123	AE	ABC123-001-002	AESEQ	1	AECLINT	Clinical Interest	Y	CRF	Investigator
ABC123	AE	ABC123-001-003	AESEQ	14	AECLINT	Clinical Interest	N	CRF	Investigator
ABC123	AE	ABC123-002-001	AESEQ	8	AECLINT	Clinical Interest	N	CRF	Investigator

Example: SDTM-plus Clinical Interest

Table	Name	Description	Order	Core	Origin Type
AE	STUDYID	Study Identifier	1	Req	Protocol
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AE	AETERM	Reported Term for the Adverse Event	6	Req	CRF
	...				
AE	AECLINT	Clinical Interest	24	Perm	CRF



Example: SDTM-plus Clinical Interest

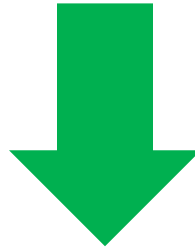
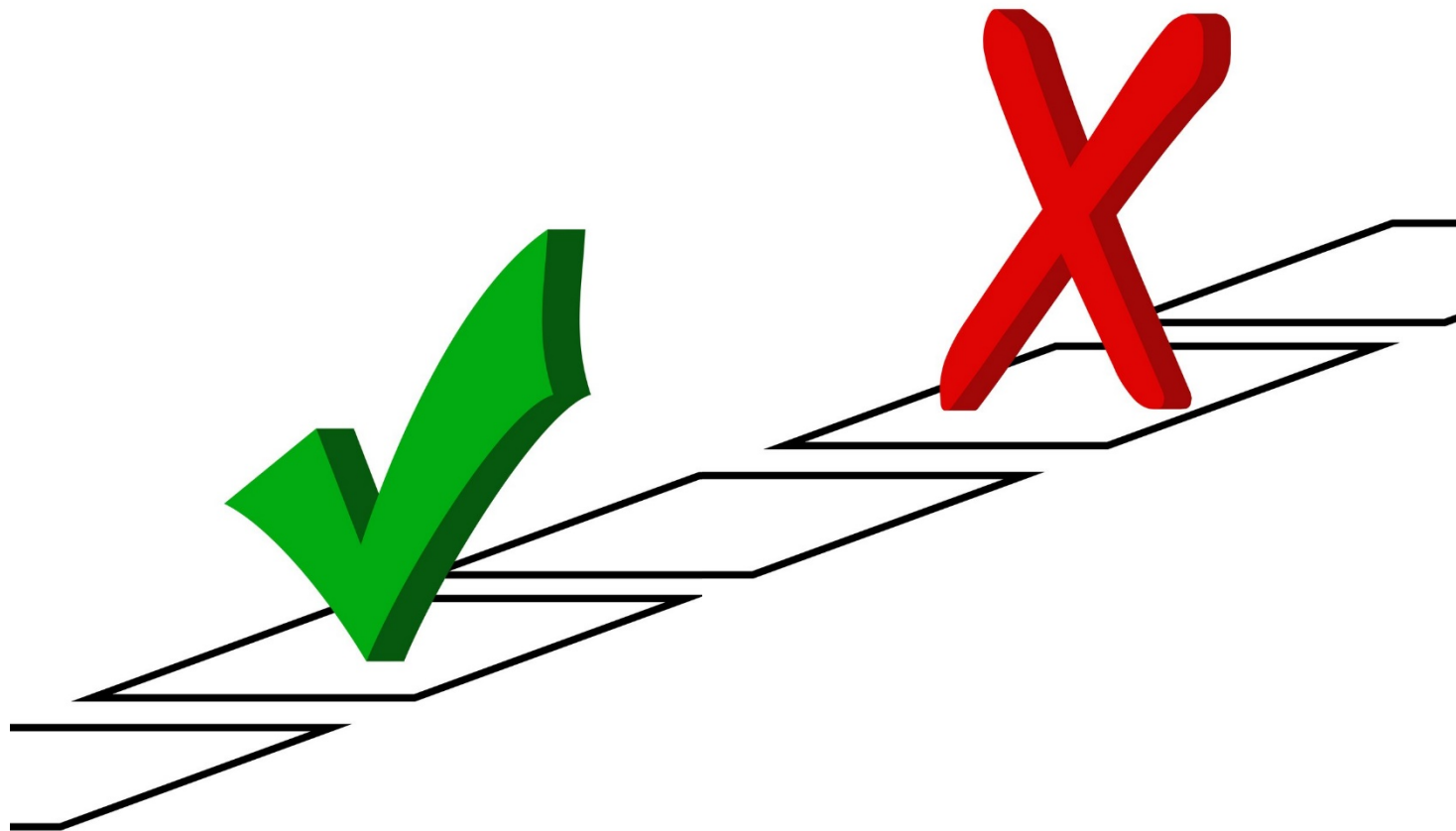


Table	Name	Description	Order	Core	Origin Type	Suppqual Flag	IDVAR	QLABEL
AE	STUDYID	Study Identifier	1	Req	Protocol			
AE	DOMAIN	Domain Abbreviation	2	Req	Assigned			
AE	USUBJID	Unique Subject Identifier	3	Req	Derived			
AE	AESEQ	Sequence Number	4	Req	Derived			
AE	AESPID	Sponsor-Defined Identifier	5	Perm	CRF			
AE	AETERM	Reported Term for the Adverse Event	6	Req	CRF			
	...							
AE	AECLINT	Clinical Interest	24	Perm	CRF	Y	AESEQ	Clinical Interest

3. Enforce Compliance



Metrics!



Verify Consistency



Verify Consistency



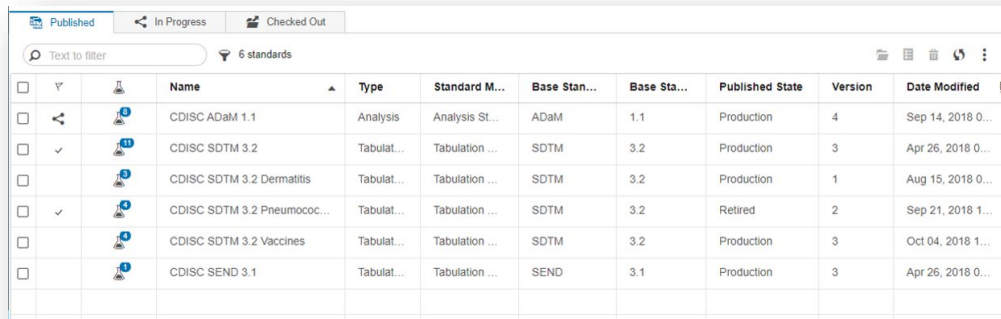
4. Maintain Data Standards



5. Manage Conflict



Tools to Help... Yes we can 😊



Published | In Progress | Checked Out

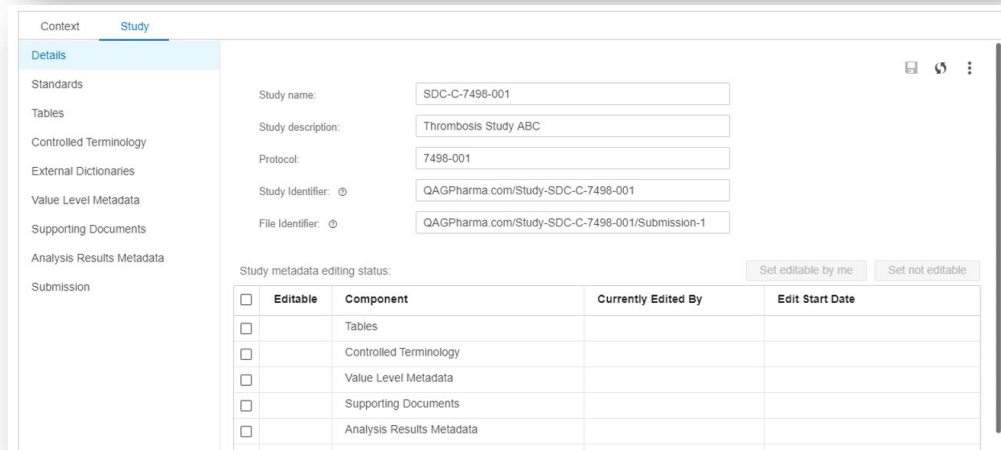
Text to filter | 6 standards

<input type="checkbox"/>	▼		Name	Type	Standard M...	Base Stan...	Base Sta...	Published State	Version	Date Modified
<input type="checkbox"/>	↔		CDISC ADaM 1.1	Analysis	Analysis ST...	ADaM	1.1	Production	4	Sep 14, 2018 0...
<input type="checkbox"/>	✓		CDISC SDTM 3.2	Tabulat...	Tabulation ...	SDTM	3.2	Production	3	Apr 26, 2018 0...
<input type="checkbox"/>	✓		CDISC SDTM 3.2 Dermatitis	Tabulat...	Tabulation ...	SDTM	3.2	Production	1	Aug 15, 2018 0...
<input type="checkbox"/>	✓		CDISC SDTM 3.2 Pneumococ...	Tabulat...	Tabulation ...	SDTM	3.2	Retired	2	Sep 21, 2018 1...
<input type="checkbox"/>	✓		CDISC SDTM 3.2 Vaccines	Tabulat...	Tabulation ...	SDTM	3.2	Production	3	Oct 04, 2018 1...
<input type="checkbox"/>	✓		CDISC SEND 3.1	Tabulat...	Tabulation ...	SEND	3.1	Production	3	Apr 26, 2018 0...

[SAS Life Science Analytics Framework 5.1 \(Oct 2018\)](#)

Standards support ...

- ✓ Clinical metadata management
- ✓ Role-based metadata management
- ✓ Extend metadata models
- ✓ Versioning
- ✓ Reporting
- ✓ Metadata-driven processes
- ✓ Process flow capability



Context | Study

Details

Standards

Tables

Controlled Terminology

External Dictionaries

Value Level Metadata

Supporting Documents

Analysis Results Metadata

Submission

Study name:

Study description:

Protocol:

Study Identifier:

File Identifier:

Study metadata editing status:

<input type="checkbox"/>	Editable	Component	Currently Edited By	Edit Start Date
<input type="checkbox"/>		Tables		
<input type="checkbox"/>		Controlled Terminology		
<input type="checkbox"/>		Value Level Metadata		
<input type="checkbox"/>		Supporting Documents		
<input type="checkbox"/>		Analysis Results Metadata		



Questions?

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