

CDISC Standards: Can the Semantic Web Help?

Dave Iberson-Hurst
PhUSE Single Day Event,
Cambridge, 23rd May 2106

PhUSE CSS Meetings

The 5th PhUSE and FDA Collaboration



Computational Science Symposium 2016
March 13th–15th 2016

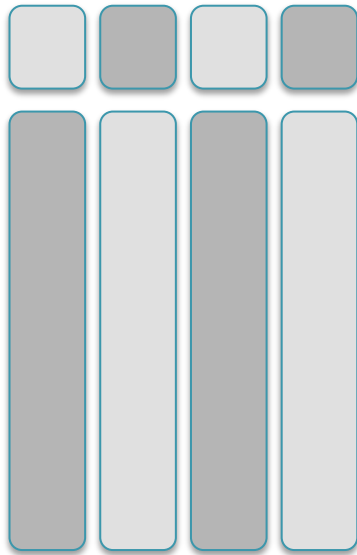
Evaluation Of Alternative Transport Formats

Evaluate and Prototype Alternative Transport Formats for Submission to support both Structure and Content Requirements

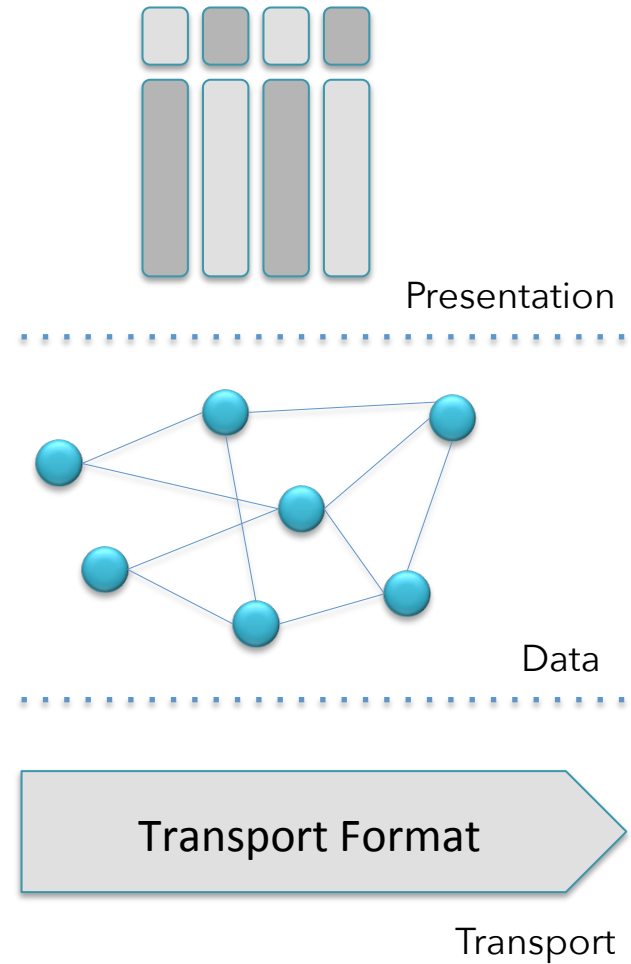
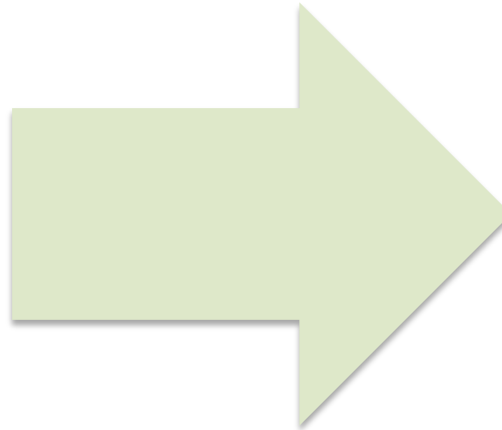
Use Cases for Linked Data

The pharmaceutical, biotechnology, and device development industry has long been constrained by two dimensional, row and column, data structures. These two dimensional data structures support multi-dimensional business processes and multi-dimensional data. The additional dimensions are often defined by non-executable, human business knowledge. Knowledge differences or gaps contribute to inefficient and/or laborous business processes. This project will document use cases for linked data in the clinical trial life-cycle.

So ...



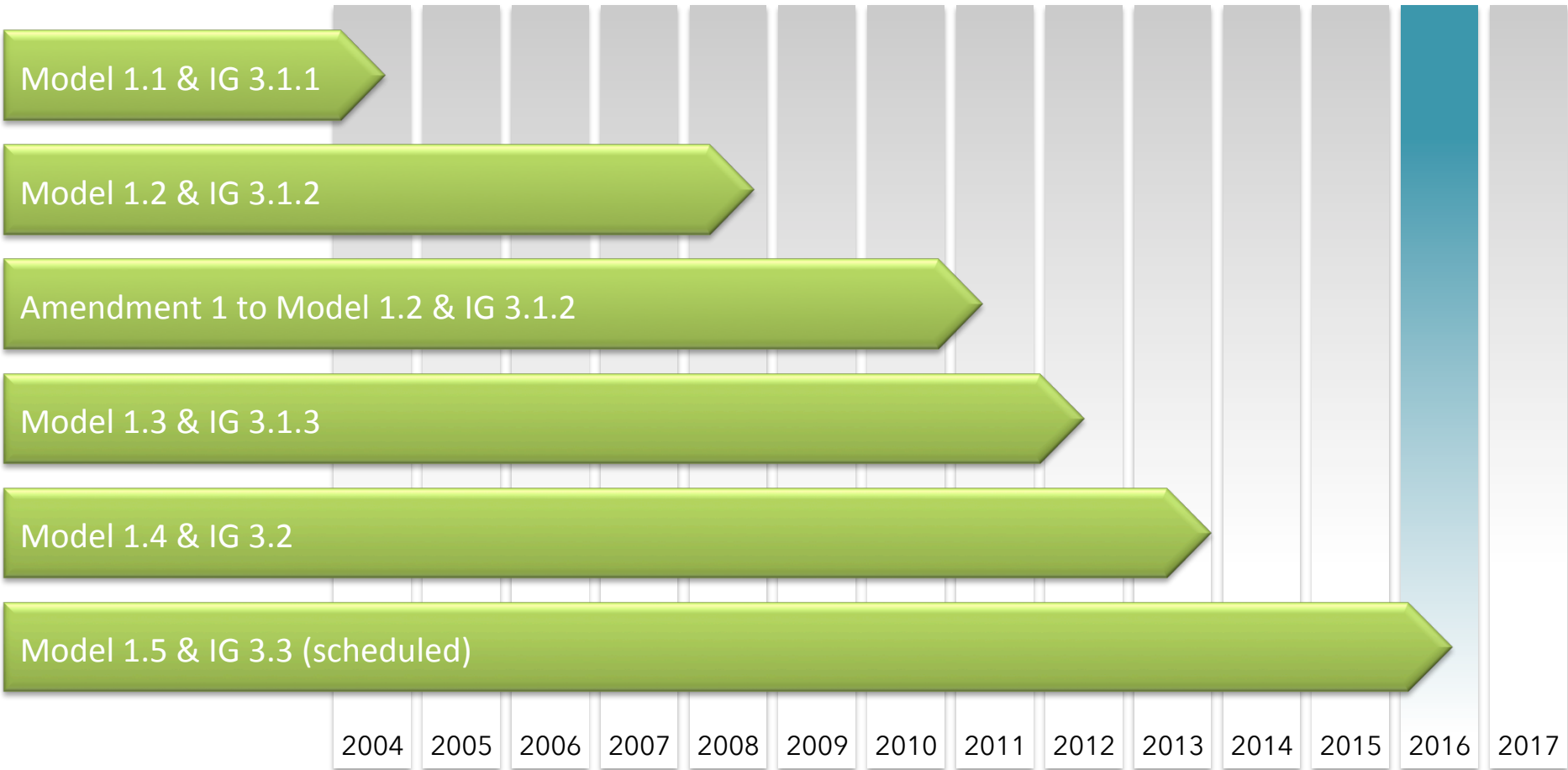
tabular structure
used for
transport, storage
and presentation



Excellent ...
a new IG! 😊



SDTM Versions



- Note: Individual PGx, Devices & QRS Releases not shown

Therapeutic Areas

	Alzheimers	Asthma	CardioV
AE		X	
AG	X	X	
BE	X		
BS	X		
CE			X
CM		X	
DD			X
DI	X	X	
DM			X
DO	X		
DS			X
DU	X	X	
EG			X
EX			
FA		X	X
HO		X	X
IS			
LB	X	X	X
MB			
MH	X	X	X
MI			
ML			



Program Overview – April 2016



Therapeutic Area	Charter Approved	Check of Concepts Completed	Posted for Internal Review	Posted for Public Review	Projected Publication
Breast Cancer v1	Oct 14	Oct 14	Mar 15	Nov 15	Q216
Diabetic Kidney Disease v1	May 15	Aug 15	Jan	May	Q216
Rheumatoid Arthritis v1	Jun 15	Oct 15	Jan	Apr	Q216
CV Imaging v1	May 15	Jul 15	Dec 15	Apr	Q316
Prostate Cancer v1	Nov 15	Apr			Q316
Major Depressive Disorder v1**	Dec 15	Feb	May		Q316
Kidney Transplant v1	Jan	Apr	Apr		Q316
Colorectal Cancer v1	Apr				Q416
Vaccines v1*	Q414	Oct 15	Apr	Q216	Q416
Ebola v1*	Sep 15	Mar	Mar	Q216	Q316
Malaria v1*	Oct 15	May	May		Q416
Nutritional Standards v1*	Mar 15	Q116	Q216	Q316	Q416
Coronary Heart Disease – TCM v1*	Q116	Q216			Q416
Acupuncture – TCM v1*	Q216	Q316			Q117

Key|

Stage completed |

Stage ongoing |

All months reflect when stage is, or is projected to be, completed

*Project duration dependent on volunteer resourcing

**General Anxiety Disorder and Bipolar Disorder pending resource availability

Terminology Changes

Code List	Item	Label	2013-12-20	2014-03-28	2014-06-27	2014-09-24	2014-10-06	2014-12-16	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25
C85491	C86176	Bacteroides splanchnicus		[1]									
C66731	C45908	Intersex		[2]									
C111109	C62954	Medical Device Operational Issue			[3]								
C101859	C17998	Unknown			[4]								
C101841	C100041	Thrombolysis in Myocardial Infarction Flow-1			[5]			[6]					
C101841	C100040	Thrombolysis in Myocardial Infarction Flow-0			[7]			[8]					
C101841	C100043	Thrombolysis in Myocardial Infarction Flow-3			[9]			[10]					

Index	From	To
[1]	BACTEROIDES SPLANCHNICUS	ODORIBACTER SPLANCHNICUS
[2]	UN	UNDIFFERENTIATED
[3]	Device Operational Issue	DEVICE OPERATIONAL ISSUE
[4]	Unknown	UNKNOWN
[5]	TIMI-1	GRADE 1
[6]	GRADE 1	TIMI GRADE 1
[7]	TIMI-0	GRADE 0
[8]	GRADE 0	TIMI GRADE 0
[9]	TIMI-3	GRADE 3
[10]	GRADE 3	TIMI GRADE 3

FDA Feedback

- FDA Feedback
 - PhUSE CS Meeting, March 2016
- Unit code lists for each domain
- CT issues in 62% of applications

This slide is titled "Define File" and is part of a presentation from the U.S. Food and Drug Administration. It lists three main bullet points: 1. Use Define.xml v2.0, with a sub-point that lacking a complete Define file increases reviewer time. 2. Include detailed description of data elements, with sub-points for computational algorithms, code lists, metadata, and sponsor-defined identifiers. 3. Provide separate unit code lists for each domain. At the bottom, there is a blue arrow graphic with the text "Define File" and a small number "8" in the bottom right corner.

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Define File

- Use Define.xml v2.0
 - Lacking a complete Define file greatly increases the amount of time reviewers spend understanding an application
- Include detailed description of data elements:
 - Detailed, reproducible computational algorithms for derived variables
 - Code lists that describe categories, subcategories, reference time-pts
 - Applicable value level metadata & description of SUPQUAL domains
 - Explanations of sponsor-defined identifiers (e.g., -SPID, -GRPID)
- Provide separate unit code lists for each domain

Define File

8

This slide is titled "Items in TCG (continued)" and is part of a presentation from the U.S. Food and Drug Administration. It lists three main bullet points: 1. Use CDISC controlled terminology variables when available (TCG Section 6), with a sub-point in red text stating "Controlled terminology issues in 62% of applications". 2. Include Seriousness Criteria for all serious adverse events (TCG 4.1.1.3), with sub-points in red text stating "Missing (or with inconsistencies) in 50% of applications" and "Important to independently verify that AE was serious". 3. Include study day variable for all observational datasets (TCG 4.1.4.1). At the bottom, there is a blue arrow graphic with the text "Items in TCG" and a small number "10" in the bottom right corner.

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Items in TCG (continued)

- Use CDISC controlled terminology variables when available (TCG Section 6)
 - Controlled terminology issues in 62% of applications
- Include Seriousness Criteria for all serious adverse events (TCG 4.1.1.3)
 - Missing (or with inconsistencies) in 50% of applications
 - Important to independently verify that AE was serious
- Include study day variable for all observational datasets (TCG 4.1.4.1)

Items in TCG

10

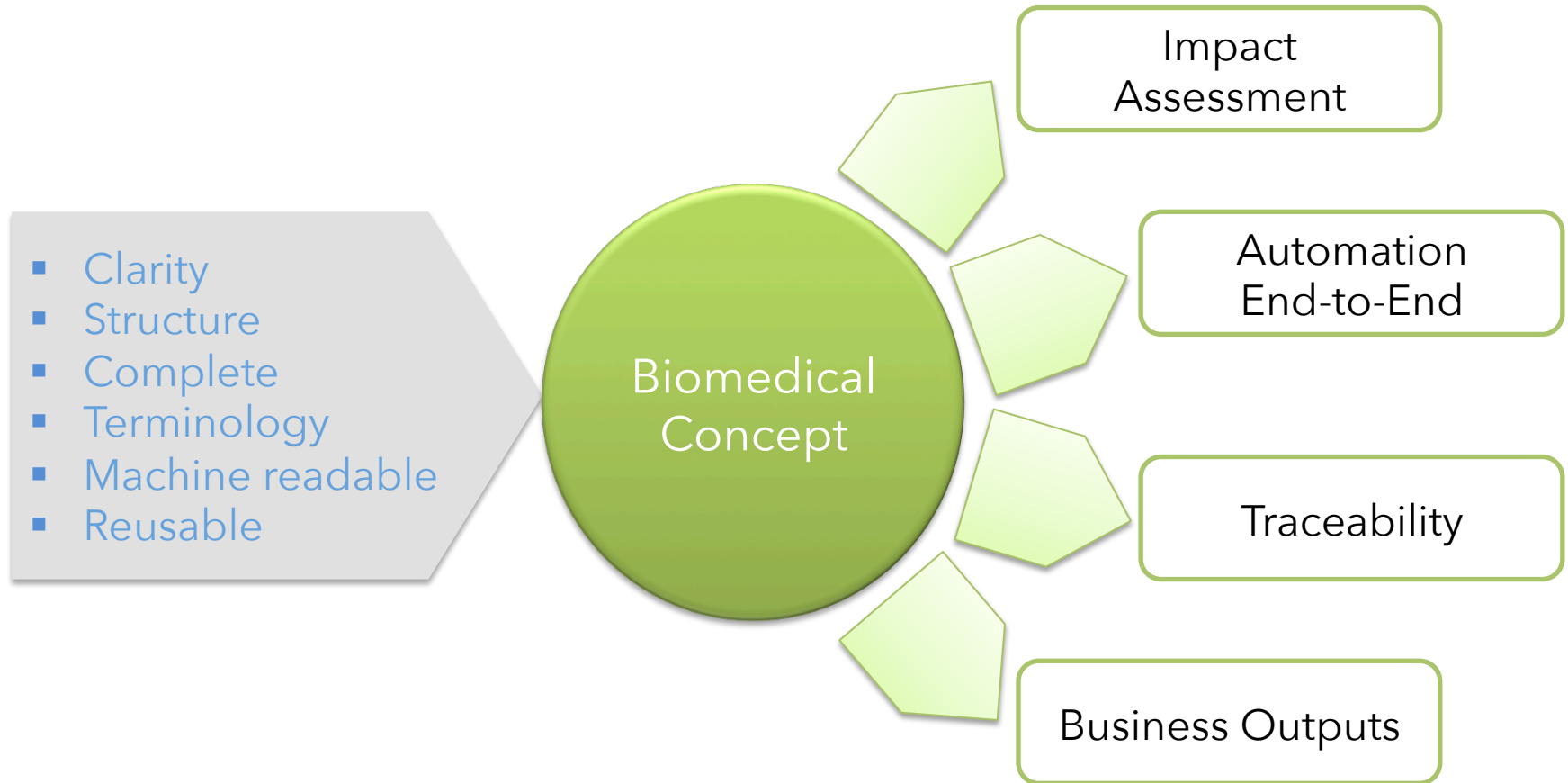
*From a presentation by Mary Doi,
M.D., M.S. (FDA CDER)*

So ...

We need:

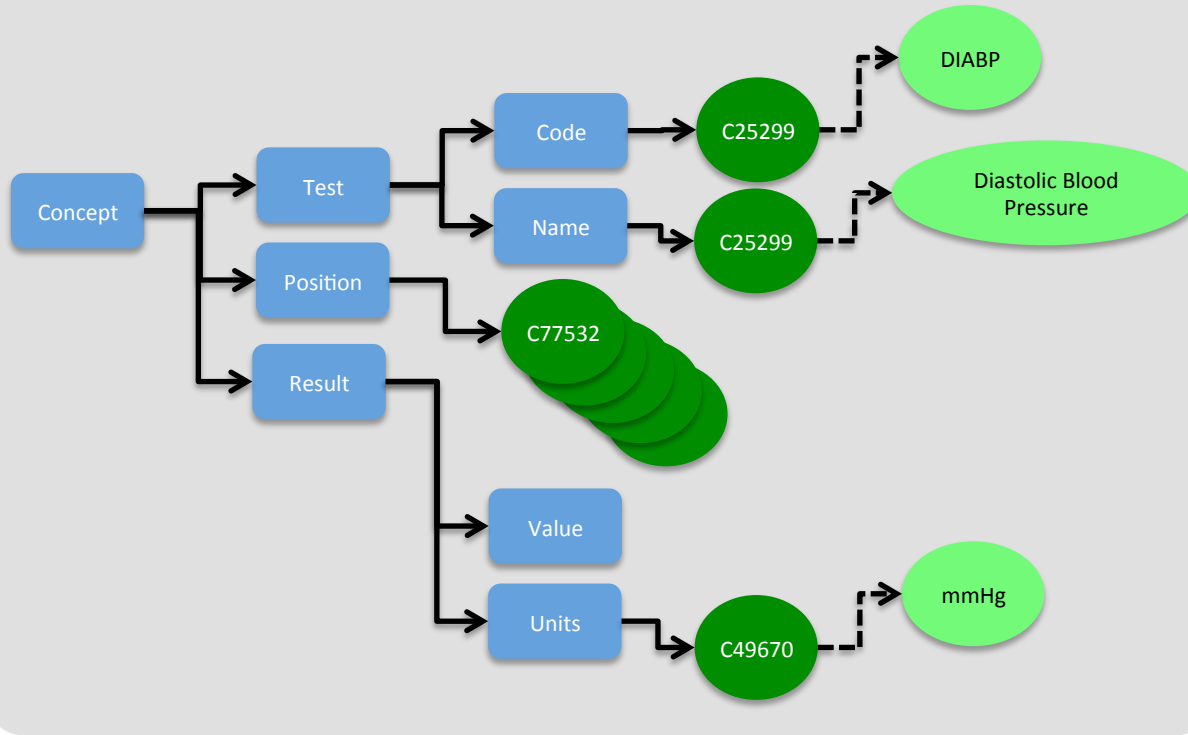
- Control
- Precision
- Visibility
- Ease-of-use

Biomedical Concepts



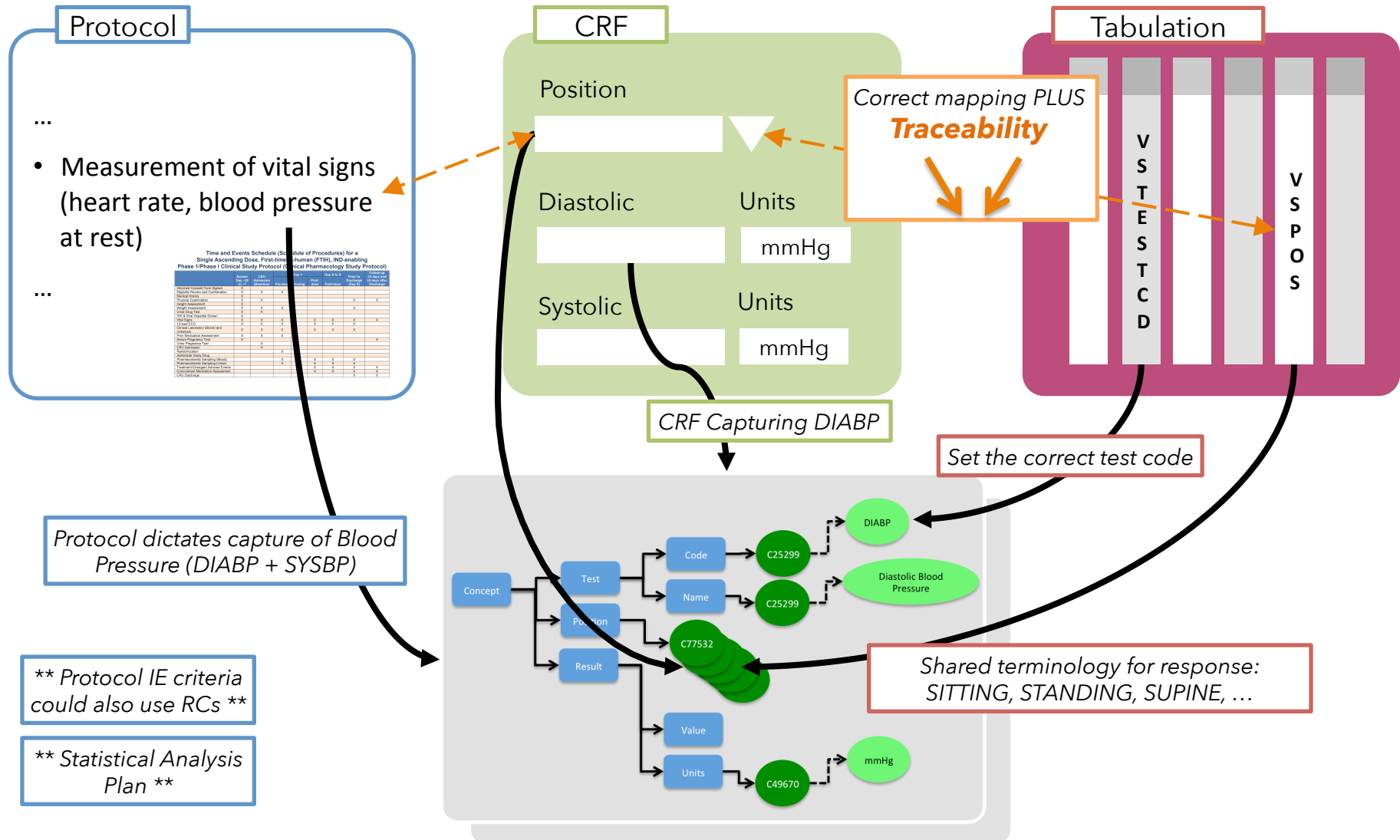
- Detailed information available at
- <http://www.assero.co.uk/wp-content/uploads/2015/10/PhUSESlidesV2.pdf>
- <http://www.assero.co.uk/wp-content/uploads/2015/10/PhUSEPaper.pdf>

Biomedical Concept Example



	C-code (Concept Code)	Vital Signs Test Code (VSTESTCD) (codelist code = C66741)	Vital Signs Test Name (VSTEST) (codelist code = C6715)	C-code (Concept Code)	Units for Vital Signs Results (VSRESU) (codelist code = C66770)	C-code (Concept Code)	Vital Signs Position (POSITION) (codelist code = C71148)
10	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C77532	DECUBITUS
11	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C82173	FOWLERS
12	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C100758	LATERAL DECUBITUS
13	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C82172	LEFT LATERAL DECUBITUS
14	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C82165	PRONE
15	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C82169	REVERSE TRENDLENBURG
				ssure C49670	mmHg	C82171	RIGHT LATERAL DECUBITUS
				ssure C49670	mmHg	C82174	SEMI-FOWLERS
				ssure C49670	mmHg	C111310	SEMI-RECUMBENT
				ssure C49670	mmHg	C82122	SITTING
				ssure C49670	mmHg	C82604	SLING
				ssure C49670	mmHg	C82166	STANDING
				ssure C49670	mmHg	C82167	SUPINE
				ssure C49670	mmHg	C82168	TRENDELENBURG
				ssure C49670	mmHg	C90480	UNCONSTRAINED
				sure C49670	mmHg	C77532	DECUBITUS
				sure C49670	mmHg	C82173	FOWLERS
				sure C49670	mmHg	C100758	LATERAL DECUBITUS
				sure C49670	mmHg	C82172	LEFT LATERAL DECUBITUS
				sure C49670	mmHg	C82165	PRONE
				sure C49670	mmHg	C82169	REVERSE TRENDLENBURG
				sure C49670	mmHg	C82171	RIGHT LATERAL DECUBITUS
				sure C49670	mmHg	C82174	SEMI-FOWLERS
				sure C49670	mmHg	C111310	SEMI-RECUMBENT
				sure C49670	mmHg	C82122	SITTING
				sure C49670	mmHg	C82604	SLING
				sure C49670	mmHg	C82166	STANDING
				sure C49670	mmHg	C82167	SUPINE
				sure C49670	mmHg	C82168	TRENDELENBURG
				sure C49670	mmHg	C90480	UNCONSTRAINED

Define Once, Use Many



Four Steps

STEP 1 MODEL

Create a semantic model that encompasses all the items needed to meet the business need.

STEP 2 SIMPLE

Create a simple MDR and Study Build tool to show the ideas working. The tool will use a simple file-based database to speed progress.

STEP 3 SEMANTIC DATABASE

Take the model from step 1 and build a user interface (UI) on top learning the lessons from step 2.

STEP 4 IMPROVE

Improve the initial implementation from step 3.

Terminology I

History: CDISC Terminology

Show 25 entries

Search:

Label	Identifier	Version	Version Label	Owner					Status		Curr	
CDISC Terminology 2013-12-20	CDISC Terminology	34	2013-12-20	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2014-03-28	CDISC Terminology	35	2014-03-28	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2014-06-27	CDISC Terminology	36	2014-06-27	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2014-09-24	CDISC Terminology	37	2014-09-24	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2014-10-06	CDISC Terminology	38	2014-10-06	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2014-12-16	CDISC Terminology	39	2014-12-16	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2015-03-27	CDISC Terminology	40	2015-03-27	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2015-06-26	CDISC Terminology	41	2015-06-26	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2015-09-25	CDISC Terminology	42	2015-09-25	CDISC	Show	Search			Standard	Status		Triples
CDISC Terminology 2015-12-18	CDISC Terminology	43	2015-12-18	CDISC	Show	Search			Standard	Status	✓	Triples
CDISC Terminology 2016-03-25	CDISC Terminology	44	2016-03-25	CDISC	Show	Search			Standard	Status		Triples

Showing 1 to 11 of 11 entries

Previous 1 Next

Import Changes Submission Load

- All terminology versions since Dec 2013 loaded.
- System loads the Owl files exported from NCIt

Terminology II

Changes: CDISC Terminology CDISC Terminology

Show entries Search:

Code List	Label	2013-12-20	2014-03-28	2014-06-27	2014-09-24	2014-10-06	2014-12-16	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25	
C100129	Questionnaire Category	✓	✎	✎	✎	✓	✎	✎	✎	✎	✎	✎	Changes
C100130	Relationship to Subject	✓	✓	✓	✓	✓	✓	✎	✓	✓	✓	✓	Changes
C100131	Alzheimer's Disease Assessment Scale - Cognitive CDISC Version Test Name	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100132	Alzheimer's Disease Assessment Scale - Cognitive CDISC Version Test Code	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100133	Brief Psychiatric Rating Scale-A Test Name	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100134	Brief Psychiatric Rating Scale-A Test Code	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100135	European Quality of Life Five Dimension Three Level Scale Test Name		✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100136	European Quality of Life Five Dimension Three Level Scale Test Code		✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100137	Hamilton Depression Rating Scale - 17 Item Test Name	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes
C100138	Hamilton Depression Rating Scale - 17 Item Test Code	✓	✓	✎	✓	✓	✓	✓	✓	✓	✎	✎	Changes

Showing 1 to 10 of 504 entries Previous **1** 2 3 4 5 ... 51 Next

[Report](#)

- *Changes to code lists across all versions of the CDISC terminology*

Terminology III

Changes: CDISC SDTM Thrombolysis in Myocardial Infarction Flow Responses Terminology C101841

Code List Changes

Show 25 entries

Search:

Version	Date	Identifier	Submission Value	Preferred Term	Synonym	Extensible	Definition
34	2013-12-20	C101841	TIMIFLOW	CDISC SDTM Thrombolysis in Myocardial Infarction Flow Responses Terminology	TIMI Flow Responses	false	Acceptable values to describe TIMI Flow.
35	2014-03-28						
36	2014-06-27						Acceptable values to describe TIMI Flow. A terminology codelist of acceptable values to describe TIMI Flow.
37	2014-09-24						
38	2014-10-06						
39	2014-12-16		TIMIFLOW TIMIFLRS				
40	2015-03-27						
41	2015-06-26						
42	2015-09-25						
43	2015-12-18						
44	2016-03-25						

Showing 1 to 11 of 11 entries

Previous 1 Next

- Ability to see changes across all versions
- See changes in context
- Shown here are the changes to a selected code list

Terminology IV

Changes: CDISC SDTM Thrombolysis in Myocardial Infarction Flow Responses Terminology C101841

Code List Changes

Show 25 entries

Search:

Version	Date	Identifier	Submission Value
34	2013-12-20	C101841	TIMIFLOW
35	2014-03-28		
36	2014-06-27		
37	2014-09-24		
38	2014-10-06		
39	2014-12-16		TIMIFLOW TIMIFLRS
40	2015-03-27		
41	2015-06-26		
42	2015-09-25		
43	2015-12-18		
44	2016-03-25		

Showing 1 to 11 of 11 entries

Version	Date	Identifier	Submission Value
34	2013-12-20	C101841	TIMIFLOW
35	2014-03-28		
36	2014-06-27		
37	2014-09-24		
38	2014-10-06		
39	2014-12-16		TIMIFLOW TIMIFLRS

- Ability to see changes across all versions
- See changes in context
- Shown here are the changes to a selected code list

Showing 1 to 10 of 11 entries

- One of the code list items with multiple submission value changes

Biomedical Concept I

Edit: Biomedical Concepts

Show 10 entries

Search:

BC	Identifier	Label
1	BC_C100947_TEST	Hip Circumference

Showing 1 to 1 of 1 entries

Previous 1 Next

Properties

Show 10 entries

Search:

BC	Prop	Alias	Question Text	Prompt Text	En	Co	DT	F	Terminology
1	3	Date Time (--DTC)	Date and time?	Date and time	true	false	D+T		
1	5	Test Code (--TESTCD)			true	false	CL		HIPCIR [C100947]
1	6	Test Name (--TEST)			true	false	CL		Hip Circumference [C100947]
1	10	Result Units (--ORRESU)	Result units?	Units	true	true	CL		AU [C73686] in [C48500] mm [C28251]
1	11	Result Value (--ORRES)	Result value?	Value	true	true	F	5.1	
1	1	Baseline (--BLFL)			false	false	BL		
1	2	Body Position (--POS)			false	false	CL		
1	4	Method (--METHOD)			false	false	CL		
1	7	Reason Not Done (--REASND)			false	false	CL		
1	8	Site Of Administration (--LOC)			false	false	CL		

Showing 1 to 10 of 10 entries

Previous 1 2 Next

- Ability to create a BC from a template, adding in extra detail (e.g. units code list)

Biomedical Concept

Biomedical Concept Template:
PQR BC Template

Save

Property Details

Show 5 entries

Item	Submission Value
C28251	mm
C48500	in
C73686	AU

Previous 1 Next

Delete

Notepad

Show 5 entries

Item	Submission Value
C100947	HIPCIR
C100947	Hip Circumference
C28251	mm
C48500	in
C73686	AU

Biomedical Concept II

Search:

Terminology ↑↓

HIPCIR [C100947]
Hip Circumference [C100947]
mm [C28251]
in [C48500]
AU [C73686]

Item	Submission Value
C28251	mm
C48500	in
C73686	AU

Delete

Property Details

Show 5 entries

Item	Submission Value
C28251	mm
C48500	in
C73686	AU

Previous 1 Next

Delete

Search:

Terminology ↑↓

HIPCIR [C100947]
Hip Circumference [C100947]
AU [C73686]
in [C48500]
mm [C28251]

Item	Submission Value
C28251	mm
C48500	in
C73686	AU

Delete

Biomedical Concept

Biomedical Concept Template:
PQR BC Template

Save

Previous 1 Next

Property Details

Show 5 entries

Item	Submission Value
C28251	mm
C48500	in
C73686	AU

Previous 1 Next

Delete

Notepad

Show 5 entries

Item	Submission Value
C100947	HIPCIR
C100947	Hip Circumference
C28251	mm
C48500	in
C73686	AU

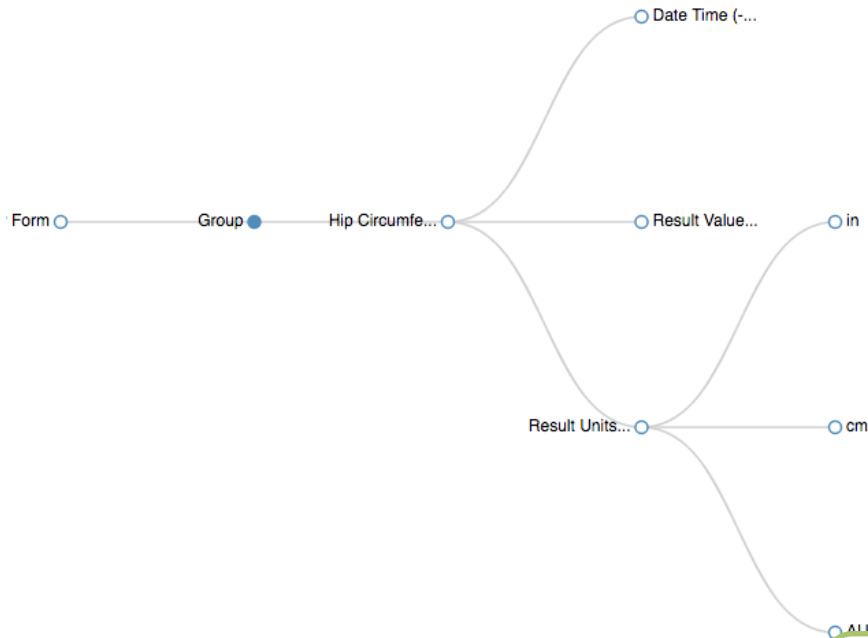
Previous 1 2 Next

1	11	Result Value (--ORRES)	Result value?	Value	true	true	F	5.1	
1	1	Baseline (--BLFL)			false	false	BL		
1	2	Body Position (--POS)			false	false	CL		
1	4	Method (--METHOD)			false	false	CL		
1	7	Reason Not Done (--REASND)			false	false	CL		
1	8	Site Of Administration (--LOC)			false	false	CL		

- Ability to create a BC from a template, adding in extra detail (e.g. units code list)
- Deliberate mistake, add AU !!

Form I

New Form:



Group Details

Label:

Group

☐ Repeating

Update

Delete

Grp+

Common+

BC+

Q+

P'holder+

Biomedical Concept Selection

Show 5 entries

Search:

Identifier	Label
BC_A00002	APGAR Score (BC_A00002)
BC_A00003	Mid Upper Arm Circumference (BC_A00003)
BC_C100947_TEST	Hip Circumference
BC_C111200	Expiratory Reserve Volume (BC_C111200)
BC_C111237	Inspiratory Reserve Volume (BC_C111237)

Showing 1 to 5 of 49 entries

First

Previous

Next

Last

- Build a simple form using the BC definition
- Use of BC allows all the fields to be placed onto the form automatically (including unit code list)

Form II

New Form:

The screenshot displays the 'New Form' interface in Assero. On the left, a concept map shows a central node 'Hip Circumfe...' connected to 'Date Time (-...)', 'Result Value...', and 'Result Units...'. 'Result Value...' is further connected to 'in' and 'cm'. 'Result Units...' is connected to 'cm' and 'AU'. On the right, a 'Group Details' panel is visible, showing a 'Label:' field and a list of 'Biomedical Concept Selection' entries. The list includes 'BC_A00002' (APGAR Score), 'BC_A00003' (Mid Upper Arm Circumference), 'BC_C100947_TEST' (Hip Circumference), 'BC_C111200' (Expiratory Reserve Volume), and 'BC_C111237' (Inspiratory Reserve Volume). The 'Hip Circumference' entry is highlighted. Below the list, it says 'Showing 1 to 5 of 49 entries' with navigation buttons 'First', 'Previous', 'Next', and 'Last'.

Group Details

Label:

Update Delete Grp+ Common+ BC+ Q+ P

Biomedical Concept Selection

Show 5 entries Search:

Identifier	Label
BC_A00002	APGAR Score (BC_A00002)
BC_A00003	Mid Upper Arm Circumference (BC_A00003)
BC_C100947_TEST	Hip Circumference
BC_C111200	Expiratory Reserve Volume (BC_C111200)
BC_C111237	Inspiratory Reserve Volume (BC_C111237)

Showing 1 to 5 of 49 entries

First Previous Next Last

- Build a simple form using the BC definition
- Use of BC allows all the fields to be placed onto the form automatically (including unit code list)

CRF and Annotated CRF

CRF: Demonstration Form No. 1 DEMO 1 (0.1, V1, Incomplete)

Demonstration Form No. 1	
Hip Circumference	
Date and Time?	dd/mm/yyyy --:--
Result value?	.
Result units?	☐ in ☐ cm ☐ AU

Annotated CRF: Demonstration Form No. 1 DEMO 1 (0.1, V1, Incomplete)

Demonstration Form No. 1		Vital Signs	
Hip Circumference			
Date and Time?		dd/mm/yyyy	--:--
Result value?	VSORRES where VSTESTCD=HIPCIR		
Result units?	VSORRESU where VSTESTCD=HIPCIR	☐ in ☐ cm ☐ AU	

- System has enough information in the metadata to auto generate CRF and aCRF views

Domain I

Show: Vital Signs SDTM VS Domain (3.1.2, V1, Standard)

Details

Identifier	Label	Owner	Internal Version	Version
SDTM VS Domain	Vital Signs	ACME	1	3.1.2

Variables

Show 10 entries

Search:

Ordinal	Name	Label	Description	Datatype	Role	
1	STUDYID	Study Identifier	Unique identifier for a study.	Character		Show
2	DOMAIN	Domain Abbreviation	Two-character abbreviation for the domain.	Character		Show
3	USUBJID	Unique Subject Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Character		Show
4	VSSEQ	Sequence Number	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Numeric		Show
5	VSGRPID	Group ID	Used to tie together a block of related records in a single domain for a subject.	Character		Show
6	VSSPID	Sponsor-Defined Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Character		Show

Biomedical Concepts

Show 10 entries

Search:

Identifier	Label	Owner	Version	Version Label
BC_C100947_TEST	Hip Circumference	ACME	1	0.1

Showing 1 to 1 of 1 entries

Previous 1 Next

Add Biomedical Concepts

Remove Biomedical Concepts

Domain II

Show: Vital Signs SDTM VS Domain (3.1.2, V1, Standard)

Details

Identifier	Label	Owner	Internal Version	Version
SDTM VS Domain	Vital Signs	ACME	1	3.1.2

Variables

Show 10 entries

Search:

Ordinal	Name	Label	Description	Datatype	Role
1	STUDYID	Study Identifier	Unique identifier for a study.	Character	
2	DOMAIN	Domain Abbreviation	Two-character abbreviation		
3	USUBJID	Unique Subject Identifier	Identifier used to uniquely		
4	VSSEQ	Sequence Number	Sequence Number given to		
5	VSGRPID	Group ID	Used to tie together a blo		
6	VSSPID	Sponsor-Defined Identifier	Sponsor-defined reference operational database.		

Biomedical Concepts

Show 10 entries

Identifier	Label
BC_C100947_TEST	Hip Circumference

Showing 1 to 1 of 1 entries

Add Biomedical Concepts

Remove Biomedical Concepts

Biomedical Concepts

Show 10 entries

Identifier	Label
BC_C100947_TEST	Hip Circumference

Showing 1 to 1 of 1 entries

Add Biomedical Concepts

Remove Biomedical Concepts

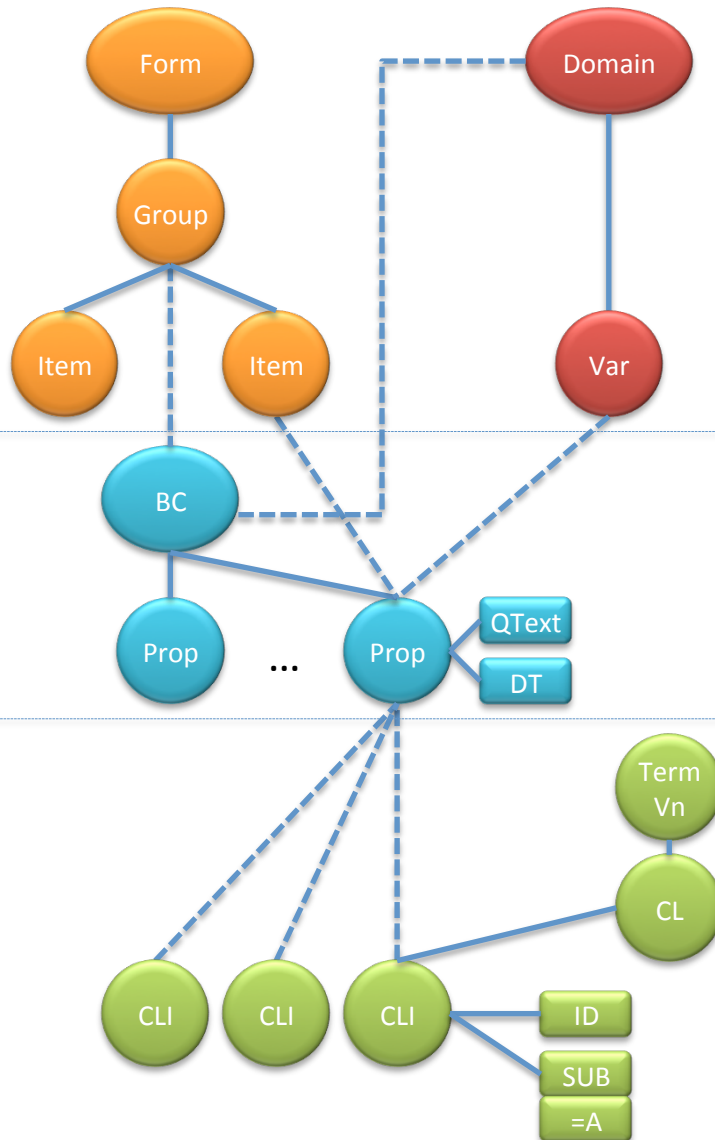
Previous 1 Next

Linked Metadata

Operational

Data

Terminology



- *Much simplified so as to show concepts behind the metadata and the semantic model*

Impact Analysis I

Impact: CDISC Terminology 2016-03-25 versus 2015-12-18 (V44 versus V43)

Show 25 entries

Search:

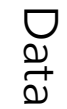
Code List	Item	Old Submission	New Submission	Biomedical Concept	Operational
C67152	C98768	Pharmacological Class of Invest. Therapy	Pharmacologic Class		
C67154	C120652	Rheumatoid Factor Antibody IgA	Rheumatoid Factor IgA Antibody		
C67154	C120654	Rheumatoid Factor Antibody IgM	Rheumatoid Factor IgM Antibody		
C67154	C120653	Rheumatoid Factor Antibody IgG	Rheumatoid Factor IgG Antibody		
C71620	C73686	AU	Absorbance U	Hip Circumference (BC_C100947_TEST) Show	Demonstration Form No. 1 (DEMO 1) View
C71620	C73686	AU	Absorbance U	Hip Circumference Show	Vital Signs (SDTM VS Domain) Show
C71620	C73687	Hip Circumference (BC_C100947_TEST) Show		Demonstration Form No. 1 (DEMO 1) View	
C85491	C86926				
C88025	C114111				
C88025	C3903	Hip Circumference (BC_C100947_TEST) Show		Vital Signs (SDTM VS Domain) Show	
C88025	C8975				
C88025	C3798				

Showing 1 to 12 of 12 entries

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[Report](#)

Operational



Upgrade



Upgrade

Show: Height (BC_C25347) BC_C25347 (0.1, V1, Standard)

Details

Identifier	Label	Owner	Version	Version Label	
BC_C25347	Height (BC_C25347)	ACME	1	0.1	Impact

Items

Show 10 entries

Search:

Alias	Question Text	Prompt Text	Enabled	Collect	Datatype	Format	Terminology
Date and Time (--DTC)	Question text	Prompt text	true	true	D+T		
Result Units (--ORRESU)	Result units?	Units	true	true	CL		ft (C71253) m (C41139) cm (C49668) in (C48500)
Result Value (--ORRES)	Result value?	Result	true	true	F	5.1	
Test Code (--TESTCD)			true	false	CL		HEIGHT (C25347)
Test Name (--TEST)			true	false	CL		Height (C25347)
Baseline (--BLFL)	Question text	Prompt text	false	true	CL		Y (C49488) N (C49487)
Body Position (--POS)	Question text	Prompt text	false	false	CL		
Laterality (--LAT)	Question text	Prompt text	false	true	CL		
Location (--LOC)	Question text	Prompt text	false	true	CL		
Method Code (--METHOD)	Question text	Prompt text	false	true	CL		

Showing 1 to 10 of 10 entries

Previous 1 Next

[Clone](#) [Upgrade](#) [Export JSON](#) [Export Turtle](#)

Terminology References

Show 10 entries

Search:

Identifier	Submission Value	Owner	Identifier	Version Label	Version
C25347	HEIGHT	CDISC	CDISC Terminology	2015-09-25	42
C25347	Height	CDISC	CDISC Terminology	2015-09-25	42
C41139	m	CDISC	CDISC Terminology	2015-09-25	42
C48500	in	CDISC	CDISC Terminology	2015-09-25	42
C49668	cm	CDISC	CDISC Terminology	2015-09-25	42
C71253	ft	CDISC	CDISC Terminology	2015-09-25	42

Showing 1 to 6 of 6 entries

Previous 1 Next

Upgrade

Submission Value	Owner	Identifier	Version Label
HEIGHT	CDISC	CDISC Terminology	2015-09-25
Height	CDISC	CDISC Terminology	2015-09-25
m	CDISC	CDISC Terminology	2015-09-25
in	CDISC	CDISC Terminology	2015-09-25
cm	CDISC	CDISC Terminology	2015-09-25
ft	CDISC	CDISC Terminology	2015-09-25



Submission Value	Owner	Identifier	Version Label
HEIGHT	CDISC	CDISC Terminology	2015-12-18
Height	CDISC	CDISC Terminology	2015-12-18
m	CDISC	CDISC Terminology	2015-12-18
in	CDISC	CDISC Terminology	2015-12-18
cm	CDISC	CDISC Terminology	2015-12-18
ft	CDISC	CDISC Terminology	2015-12-18

And Then ...

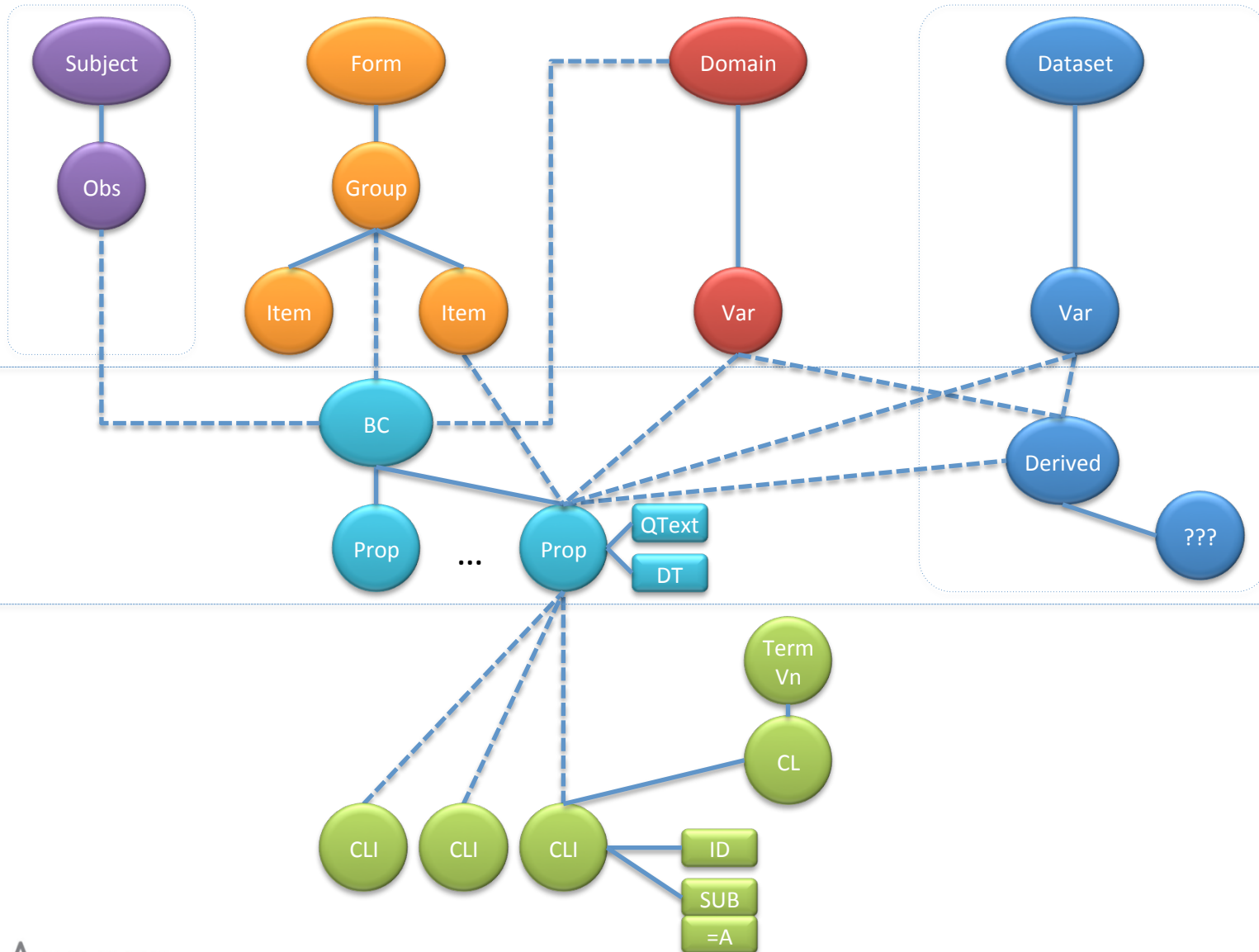
Protocol

Analysis

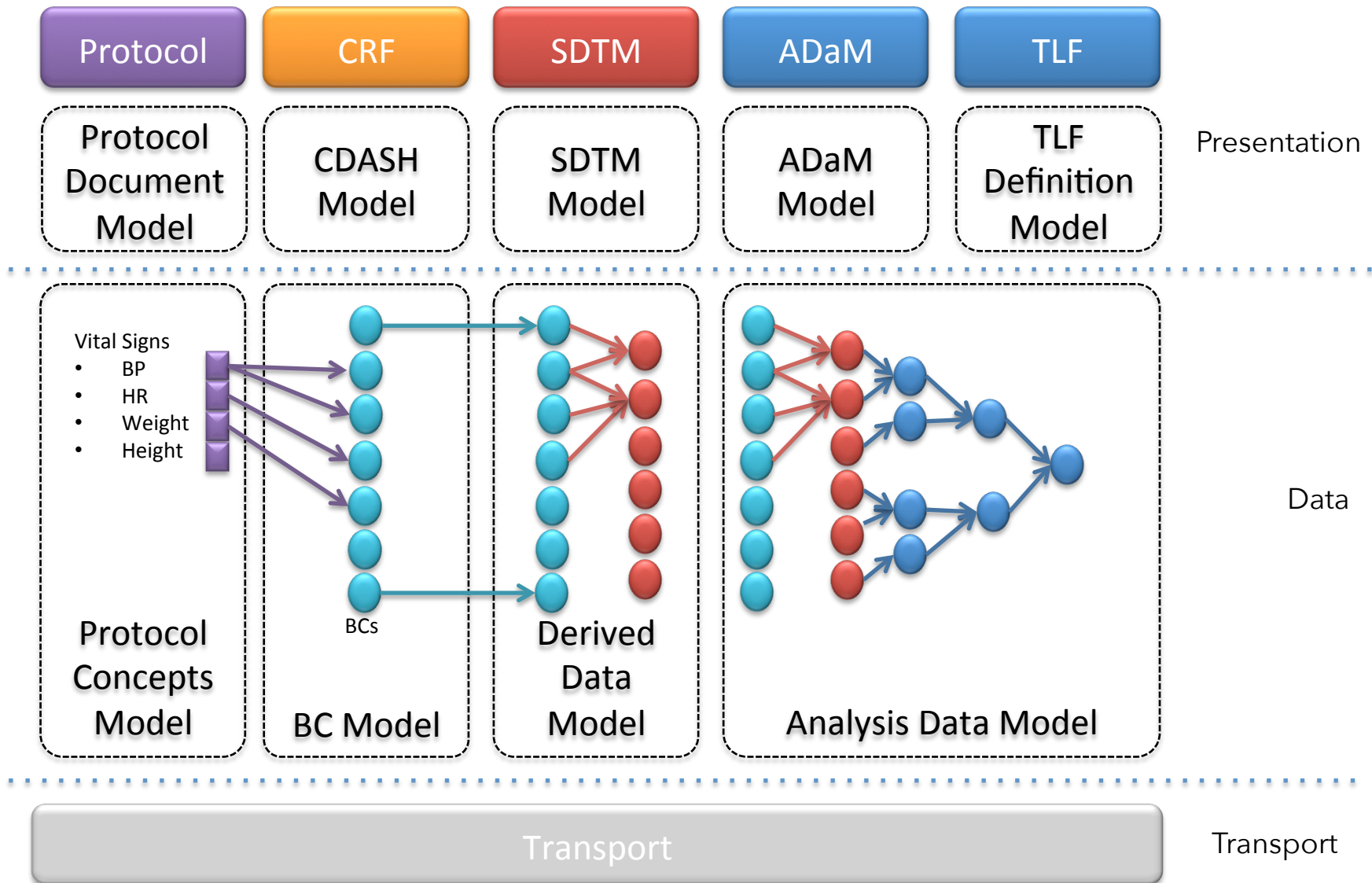
Operational

Data

Terminology



Vision



Summary – Version Management

- Greater need to be aware of versions
 - Understand the data better
- Good version management
 - Provides control
 - Provides precision
 - Provides visibility
- Management of metadata becomes easier

Summary – Linked (Meta)Data

- Tool support to meet these business needs
 - Hard using manual methods
 - Semantic web well suited to support the need
- We need well structured models
- We need to restructure the current CDISC standards into better models

Contact And More Information

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