



CDISC Standards and the Semantic Web

Dave Iberson-Hurst

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Abstract

With the arrival of the FDA guidance on electronic submissions, CDISC SHARE and the notion of Research Concepts the time is ripe to look at improved implementations of the CDISC standards to assist in producing high-quality clinical research data. The presentation/paper, drawing on experience of production work and the CDISC SHARE project, will examine a prototype implementation that is being used to gain insights into the use of Research Concepts combined with Semantic Web technologies as the foundation for implementing the CDISC standards. In particular:

- 1. Review why we want Research Concepts and highlight the principles behind them*
- 2. Look at a prototype semantic web MDR implementation based upon the ISO11179 Metadata Standard, the ISO21090 Healthcare Datatypes Standard, the BRIDG model and RCs taken from the CDISC Therapeutic Area development work.*
- 3. Examine prototype tools to see implementation issues and automation opportunities.*
- 4. Detail the benefits Research Concepts bring to the business and support business artifacts such as annotated CRFs and define.xml.*
- 5. List the existing sources of RC metadata.*



We Need Better

Clarity

- Assumptions section with each SDTM domain contains rules and provisos
- --CAT and --SCAT use. Some better defined than others
- Often see examples quoted as definitive

Complete

- Terminology not defined in all cases
- Variables float, are not related

Easy to Understand

- Should not require 10 years experience before becoming a SDTM guru

Ease of Use

- Electronic
- Indication of changes
- Version managed

Support Business Need

- Data aggregation and re-use of data
 - Sponsor
 - Regulators
 - Data transparency
- Traceability
- Operational efficiency
 - CDISC compliant data to regulators,
 - The end to end clinical trial process

Variable-Based World

VSTESTCD – C66741

C12472	C66741	Vital Signs Test Code	BODYFAT	Adipose Tissue; Body Fat; Fat Tissue
C16358	C66741	Vital Signs Test Code	BMI	Body Mass Index
C25157	C66741	Vital Signs Test Code	BSA	Body Surface Area
C25206	C66741	Vital Signs Test Code	TEMP	temperature
C25208	C66741	Vital Signs Test Code	WEIGHT	Weight
C25298	C66741	Vital Signs Test Code	SYSBP	Systolic Blood Pressure
C25299	C66741	Vital Signs Test Code	DIABP	Diastolic Blood Pressure
C25347	C66741	Vital Signs Test Code	HEIGHT	Height
C49676	C66741	Vital Signs Test Code	PULSE	Pulse Rate
C49677	C66741	Vital Signs Test Code	HR	Heart Rate
C49678	C66741	Vital Signs Test Code	RESP	Respiratory Rate

VSORRESU – C66770

C66770	C66770	true	Units for Vital Signs Results	VSRESU	Units for Vital Signs Results
C25613	C66770		Units for Vital Signs Results	%	Percentage
C28251	C66770		Units for Vital Signs Results	mm	Millimeter
C28252	C66770		Units for Vital Signs Results	kg	Kilogram
C42569	C66770		Units for Vital Signs Results	C	Degree Celsius
C42569	C66770		Units for Vital Signs Results	m2	Square Meter
C44277	C66770		Units for Vital Signs Results	F	Degree Fahrenheit
C48155	C66770		Units for Vital Signs Results	g	Gram
C48500	C66770		Units for Vital Signs Results	in	Inch
C48531	C66770		Units for Vital Signs Results	LB	Pound
C49668	C66770		Units for Vital Signs Results	cm	Centimeter
C49670	C66770		Units for Vital Signs Results	mmHg	Millimeter of Mercury
C49671	C66770		Units for Vital Signs Results	kg/m2	Kilogram per Square Meter
C49673	C66770		Units for Vital Signs Results	BEATS/MIN	Beats per Minute
C49674	C66770		Units for Vital Signs Results	BREATHS/MIN	Breaths per Minute

Variable-Based World

VSTESTCD – C66741

VSORRESU – C66770

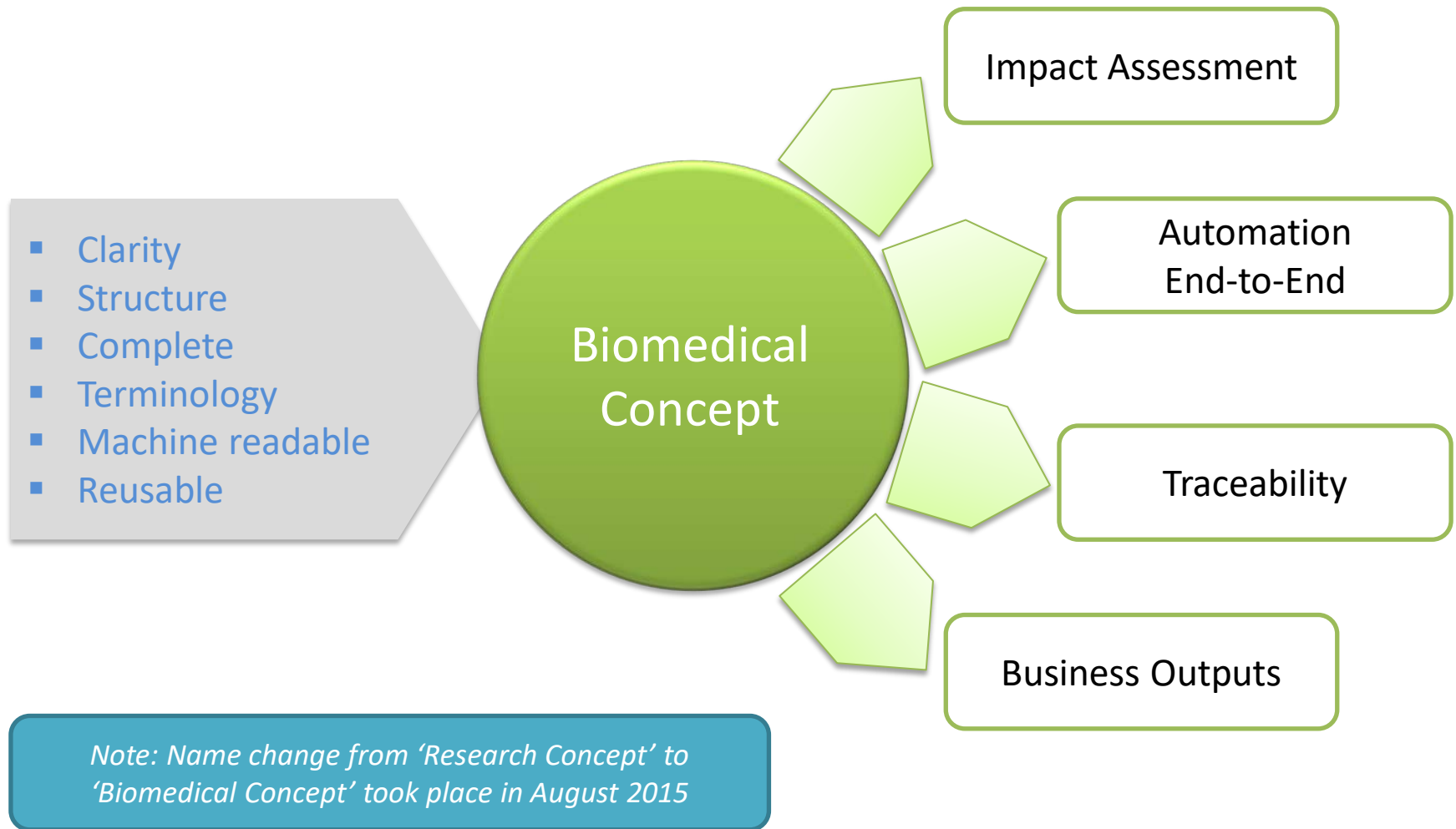
C12472	C66741	Vital Signs Test Code	BODYFAT	Body Tissue; Body Fat; Issue
C16358	C66741	Vital Signs Test Code	BMI	Mass
C25157	C66741	Vital Signs Test Code	BSA	Body Surface
C25206	C66741	Vital Signs Test Code	TEMP	temperature
C25208	C66741	Vital Signs Test Code	WEIGHT	Weight
C25298	C66741	Vital Signs Test Code	SYSBP	Systolic Blood Pressure
C25299	C66741	Vital Signs Test Code	DIABP	Diastolic Blood Pressure
C25347	C66741	Vital Signs Test Code	HEIGHT	Height
C49676	C66741	Vital Signs Test Code	PULSE	Pulse Rate
C49677	C66741	Vital Signs Test Code	HR	Heart Rate
C49678	C66741	Vital Signs Test Code	RESP	Respiratory Rate

VSLOC

VSLAT

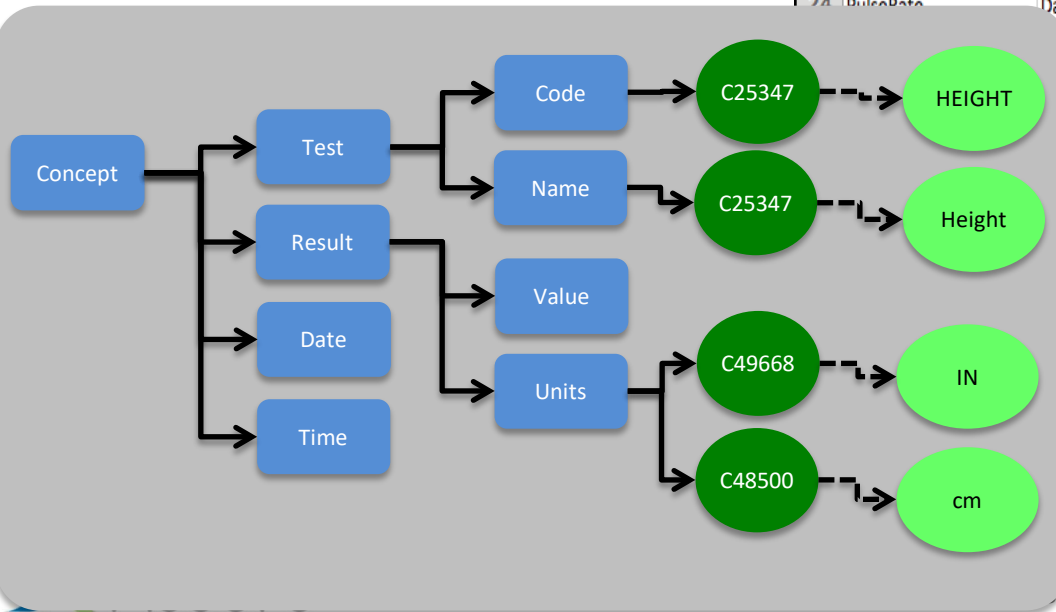
C66770	C66770	true	Units for Vital Signs Results	VSRESU	Units for Vital Signs Results
C66770	C66770		Units for Vital Signs Results	%	Percentage
C28251	C66770		Units for Vital Signs Results	mm	Millimeter
C66770	C66770		Units for Vital Signs Results	kg	Kilogram
C66770	C66770		Units for Vital Signs Results	C	Degree Celsius
C42569	C66770		Units for Vital Signs Results	m2	Square Meter
C44277	C66770		Units for Vital Signs Results	F	Degree Fahrenheit
C48155	C66770		Units for Vital Signs Results	g	Gram
C48500	C66770		Units for Vital Signs Results	in	Inch
C48531	C66770		Units for Vital Signs Results	LB	Pound
C49668	C66770		Units for Vital Signs Results	cm	Centimeter
C49670	C66770		Units for Vital Signs Results	mmHg	Millimeter of Mercury
C49671	C66770		Units for Vital Signs Results	kg/m2	Kilogram per Square Meter
C49673	C66770		Units for Vital Signs Results	BEATS/MIN	Beats per Minute
C49674	C66770		Units for Vital Signs Results	BREATHS/MIN	Breaths per Minute

Biomedical (Research) Concepts



Simple VS Biomedical Concepts

	A	B	C	D	E	F
1	Concept Name	Variable Name	Code List Ref	Code List Item(s)	Type	Format
2	Height	Result.Value			I	3
3	Height	Result.Units	C66770	C49668, C48500	E	
4	Height	Test.Code	C66741	C25347	E	
5	Height	Test.Name	C67153	C25347	E	
6	Height	Date			D	
7	Height	Time			T	
8	Weight	Result.Value			F	6.2
9	Weight	Result.Units	C66770	C28252, C48531	E	
10	Weight	Test.Code	C66741	C25208	E	
11	Weight	Test.Name	C67153	C25208	E	
12	Weight	Date			D	
13	Weight	Time			T	
14	HeartRate	Result.Value			I	3
15	HeartRate	Result.Units	C66770	C49673	E	
16	HeartRate	Position	C71148	C62122, C62166, C62167	E	
17	HeartRate	Date			D	
18	HeartRate	Time			T	
19	HeartRate	Test.Code	C66741	C49677	E	
20	HeartRate	Test.Name	C67153	C49677	E	
21	PulseRate	Result.Value			I	3
22	PulseRate	Result.Units	C66770	C49673	E	
23	PulseRate	Position	C71148	C62122, C62166, C62167	E	
24	PulseRate	Date			D	
					T	
		Test.Code	C66741	C49677	E	
		Test.Name	C67153	C49677	E	
		Result.Value			I	3
		Result.Units	C66770	C49670	E	
		Position	C71148	C62122, C62166, C62167	E	
		Date			D	
		Time			T	
		Test.Code	C66741	C25298	E	
		Test.Name	C67153	C25298	E	
		Result.Value			I	3
		Result.Units	C66770	C49670	E	
		Position	C71148	C62122, C62166, C62167	E	
		Date			D	
		Time			T	
		Test.Code	C66741	C25299	E	
		Test.Name	C67153	C25299	E	



Vital Signs – Additional Information

- CDISC released (2014) additional information for Vital Signs and ECG
- VS Provides units and additional relationships
 - e.g. HEIGHT & WEIGHT just units

	A	B	C	D	E	F	G	H	I
	C-code (Concept Code)	Vital Signs Test Code (VSTESTCD) (codelist code = C66741)	Vital Signs Test Name (VSTEST) (codelist code = C67153)		C-code (Concept Code)	Units for Vital Signs Results (VSRESU) (codelist code = C66770)		C-code (Concept Code)	Vital Signs Position (POSITION) (codelist code = C71148)
1									
46	C25347	HEIGHT	Height		C49668	cm			
47	C25347	HEIGHT	Height		C48500	IN			
48	C25347	HEIGHT	Height		C28251	mm			
121	C25208	WEIGHT	Weight		C28252	kg			
122	C25208	WEIGHT	Weight		C48155	g			
123	C25208	WEIGHT	Weight		C48531	LB			

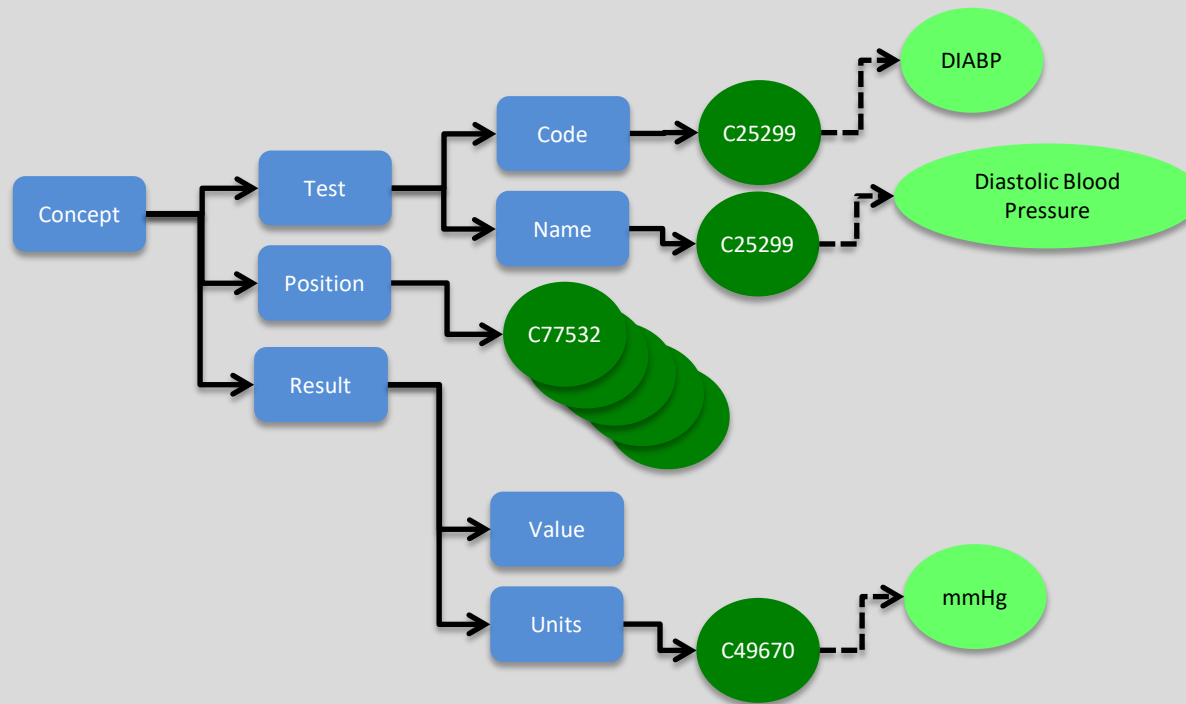
Vital Signs – Additional Information

SYSBP and
DIABP, units
and position

	C-code (Concept Code)	Vital Signs Test Code (VSTESTCD) (codelist code = C66741)	Vital Signs Test Name (VSTEST) (codelist code = C67152)	C-code (Concept Code)	Units for Vital Signs Results (VSRESU) (codelist code = C66770)	C-code (Concept Code)	Vital Signs Position (POSITION) (codelist code = C71148)
1							
10	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C77532	DECUBITUS
11	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62173	FOWLERS
12	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C100758	LATERAL DECUBITUS
13	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62172	LEFT LATERAL DECUBITUS
14	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62165	PRONE
15	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62169	REVERSE TRENDELENBURG
16	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62171	RIGHT LATERAL DECUBITUS
17	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62174	SEMI-FOWLERS
18	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C111310	SEMI-RECUMBENT
19	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62122	SITTING
20	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C92604	SLING
21	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62166	STANDING
22	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62167	SUPINE
23	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62168	TRENDELENBURG
24	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C90480	UNCONSTRAINED
97	C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C77532	DECUBITUS
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62174	SEMI-FOWLERS	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C111310	SEMI-RECUMBENT	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62122	SITTING	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C92604	SLING	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62166	STANDING	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62167	SUPINE	
C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62168	TRENDELENBURG	
108	C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62166	STANDING
109	C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62167	SUPINE
110	C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C62168	TRENDELENBURG
111	C25298	SYSBP	Systolic Blood Pressure	C49670	mmHg	C90480	UNCONSTRAINED

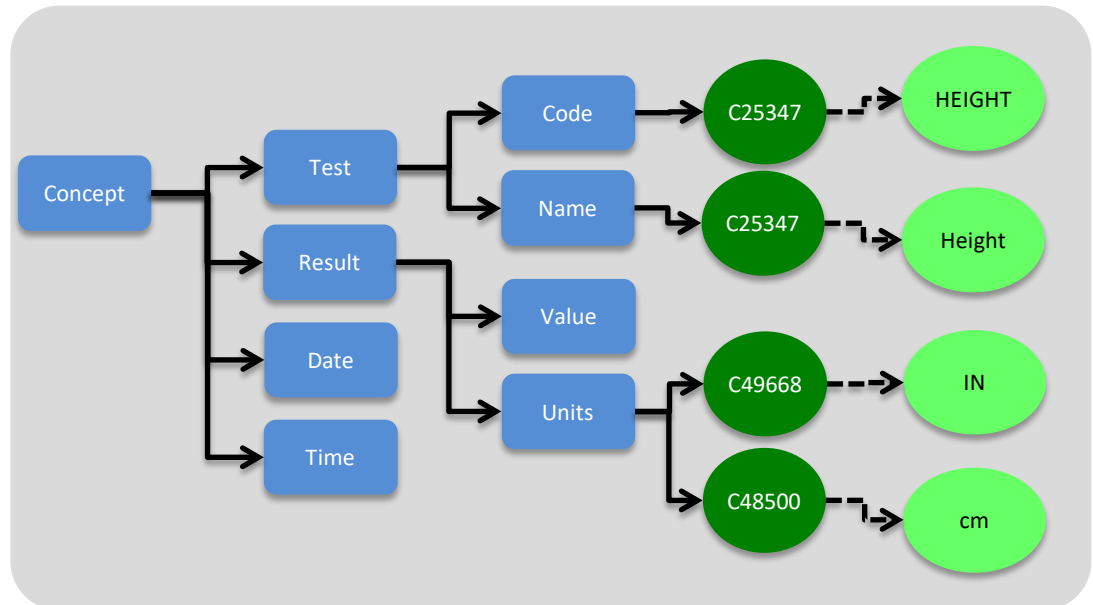
Vital Signs – Additional Information

	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	C62173	FOWLERS
12	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C100758	LATERAL DECUBITUS
13	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62172	LEFT LATERAL DECUBITUS
14	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62165	PRONE
15	C25299	DIABP	Diastolic Blood Pressure	C49670	mmHg	C62169	REVERSE TRENDLENBURG
				ssure C49670	mmHg	C62171	RIGHT LATERAL DECUBITUS
				ssure C49670	mmHg	C62174	SEMI-FOWLERS
				ssure C49670	mmHg	C111310	SEMI-RECUMBENT
				ssure C49670	mmHg	C62122	SITTING
				ssure C49670	mmHg	C82604	SLING
				ssure C49670	mmHg	C62166	STANDING
				ssure C49670	mmHg	C62167	SUPINE
				ssure C49670	mmHg	C62168	TRENDELENBURG
				ssure C49670	mmHg	C80480	UNCONSTRAINED
				sure C49670	mmHg	C77532	DECUBITUS
				sure C49670	mmHg	C62173	FOWLERS
				sure C49670	mmHg	C100758	LATERAL DECUBITUS
				sure C49670	mmHg	C62172	LEFT LATERAL DECUBITUS
				sure C49670	mmHg	C62165	PRONE
				sure C49670	mmHg	C62169	REVERSE TRENDLENBURG
				sure C49670	mmHg	C62171	RIGHT LATERAL DECUBITUS
				sure C49670	mmHg	C62174	SEMI-FOWLERS
				sure C49670	mmHg	C111310	SEMI-RECUMBENT
				sure C49670	mmHg	C62122	SITTING
				sure C49670	mmHg	C82604	SLING
				sure C49670	mmHg	C62166	STANDING
				sure C49670	mmHg	C62167	SUPINE
				sure C49670	mmHg	C62168	TRENDELENBURG
				sure C49670	mmHg	C80480	UNCONSTRAINED

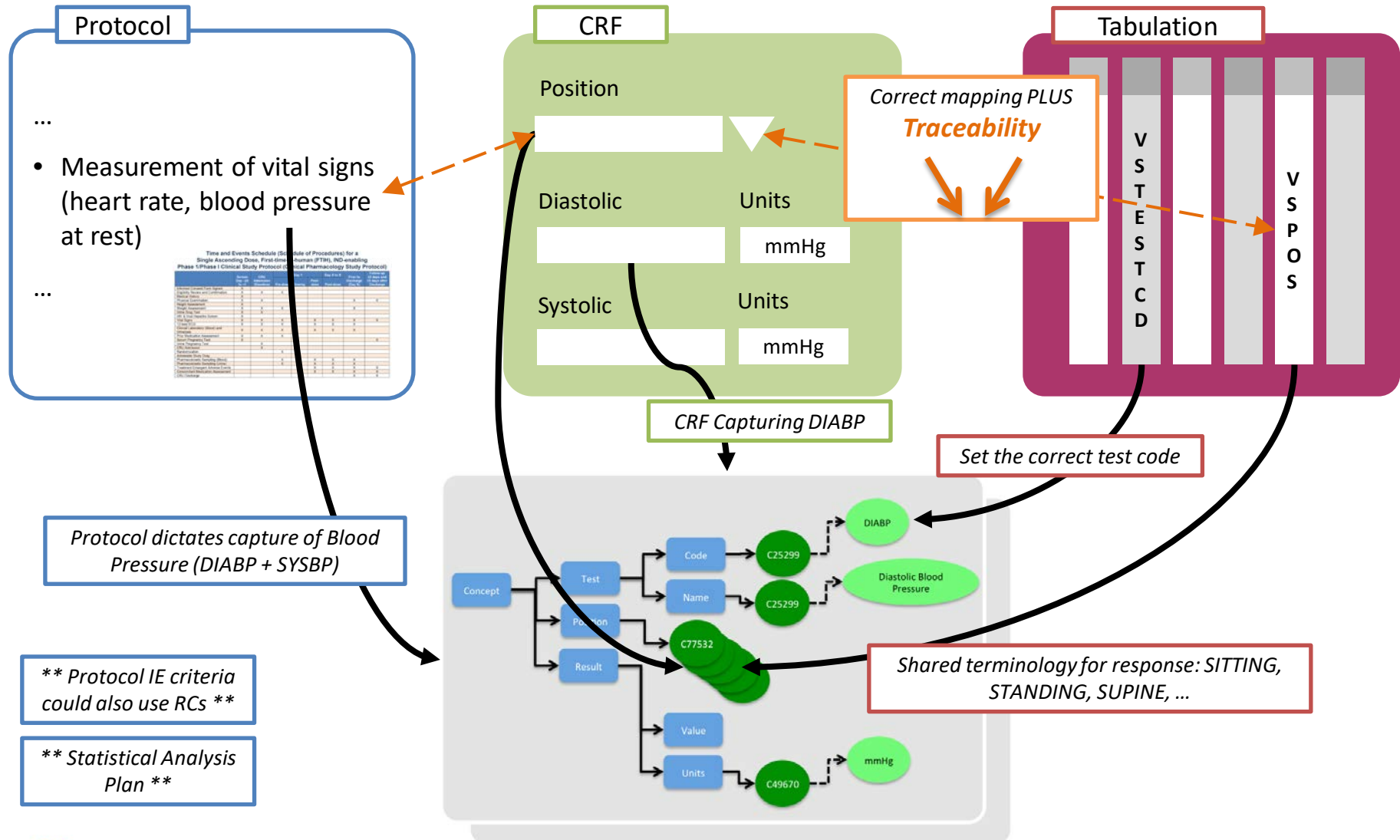


Value Level Metadata

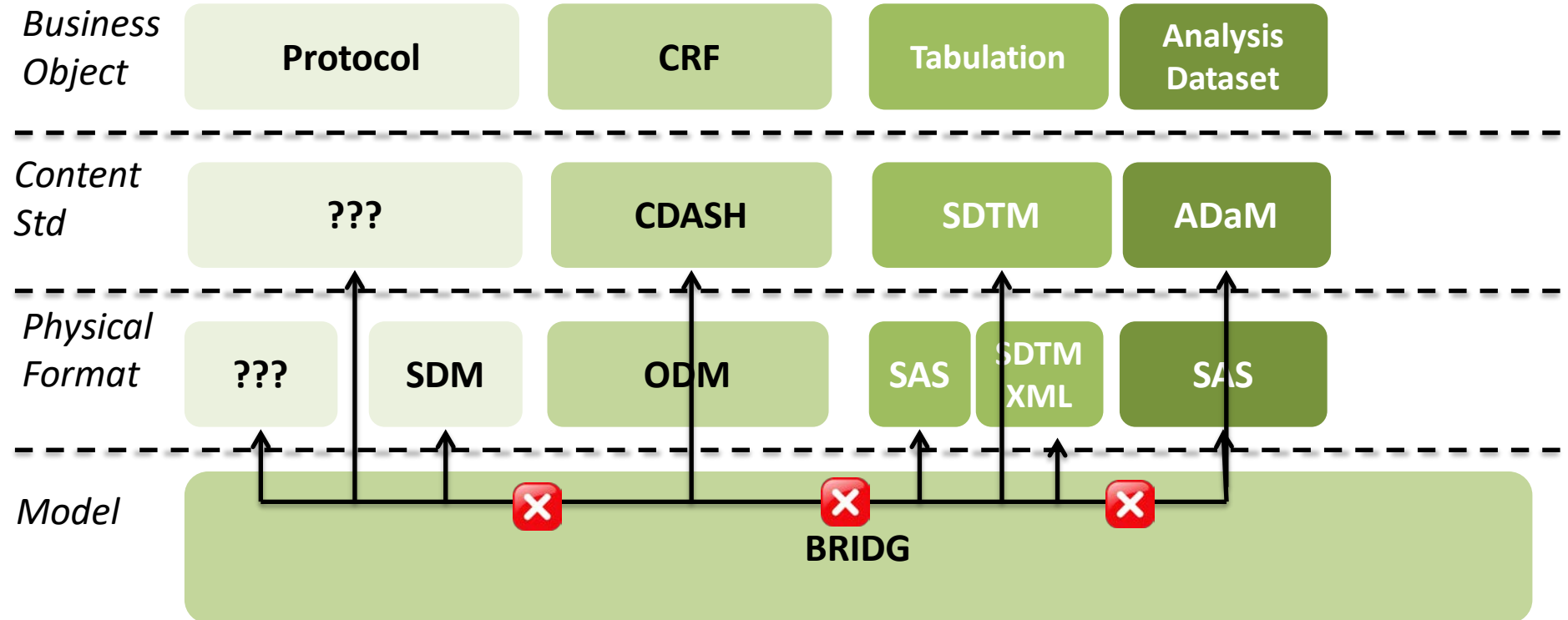
- Contained within the concepts, for example
 - HEIGHT, Integer, ###, “in” & “cm”
 - WEIGHT, Float, ###.##, “lbs” & “kg”
- Also --POS, --LOC, --METHOD, --CAT, --SCAT ... will be handled



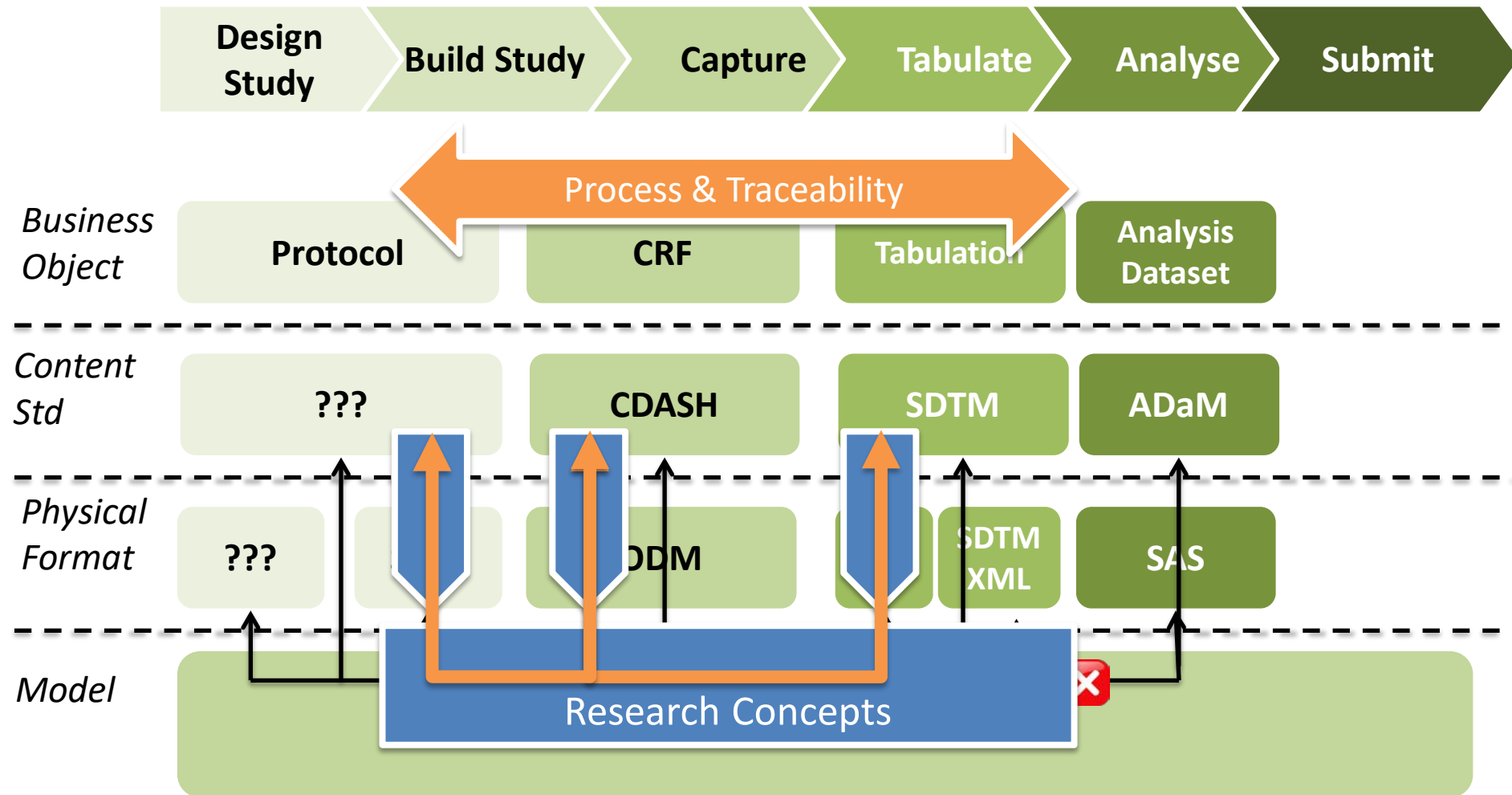
Define Once, Use Many



Silos



Decrease Need for Mapping & Gain Traceability



Increasing Rate of Change

Foundational Products Released in 2014-2015:

- Dataset-XML v1 Final
- *SDTMIG 3.3 Batch 1 (7 draft domains)*
- *SDTMIG 3.3 Batch 2 (Milestones, 2 Domains)*
- **SDTM v1.5**
- **Pharmacogenomics SDTMIG v1**
- **SEND v3.1 Draft B**
- **SEND DART (Reproductive Toxicology)**
- ADaM Results Metadata Spec for Define-XML
- *ADaM IG v1.1 Draft*
- **ADaM Occurrence Data Structure v1**
- **ADaM v1.3 Validation Checks**
- **ADaM Data Structure for Integration (ADSL)**
- **CDISC in RDF** (PhUSE)
- **BRIDG R4**
- Periodic Terminology and QRS Packages
- Updated COP and Process Docs

Upcoming Major New Drafts for Comment:

- *CTReg XML Schema*
- *SDTMIG Batch 3 and Conformance Rules*
- *Define-XML v2.1 and IG*

TAUGs released in 2014-2015:

- Multiple Sclerosis
- Diabetes
- Cardiovascular
- Influenza
- QT Studies
- **Chronic Hep-C**
- **Schizophrenia**
- **Dyslipidemia v1**

Upcoming Provisionals:

- *Virology v2*
- *Diabetes ADaM Supplement*
- *Traumatic Brain Injury*

Upcoming Drafts:

- *Breast Cancer*
- *COPD*

Taken from presentation by
W Kubick, CDISC Intrachange, August
2015

Increasing Rate of Change

 Program Overview – September 2015 						
Therapeutic Area	Organization/PM	Stage 0 Charter Approval	Stage 1 Check of Concepts Completed	Stage 3a Posted for Internal Review	Stage 3b Posted for Public Review	*Stage 3c **Projected Publication
Traumatic Brain Injury v1	CDISC Amy Palmer	Oct 13	Sep 14	Mar	Jul	Q415
Breast Cancer v1	CDISC John Owen	Oct 14	Oct 14	Mar	Oct	Q415
COPD v1	CDISC/Quintiles Sherwood Barbee	Sep 14	Dec 14	Jul	Oct	Q415
ADaM Supplement to Diabetes v1	TCB Rachael Zirkle	NA	NA	Mar	Jul	Q415
Virology v2	C-Path Laura Butte	Mar	Apr	May	Jul	Q315
Diabetic Kidney Disease v1	TCB Rachael Zirkle	May	Aug	Sep	Dec	Q116
Tuberculosis v2	C-Path Laura Butte	Apr	Apr	Sep	Oct	Q116
Rheumatoid Arthritis v1	TCB Trisha Simpson	Jun	Sep	Oct		Q216
CV Imaging v1	CDISC/DCRI Amy Palmer	May	Jul	Oct	Dec	Q216
Prostate Cancer v1	CDISC John Owen	Oct				Q316
Major Depressive Disorder	CDISC Amy Palmer	Oct				Q316
General Anxiety Disorder v1	CDISC Amy Palmer					
Bi-polar Disorder v1	CDISC Amy Palmer					

From: <http://www.cdisc.org/system/files/all/standard/CFAST-TA-Project-Status.pdf>

So ...



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.

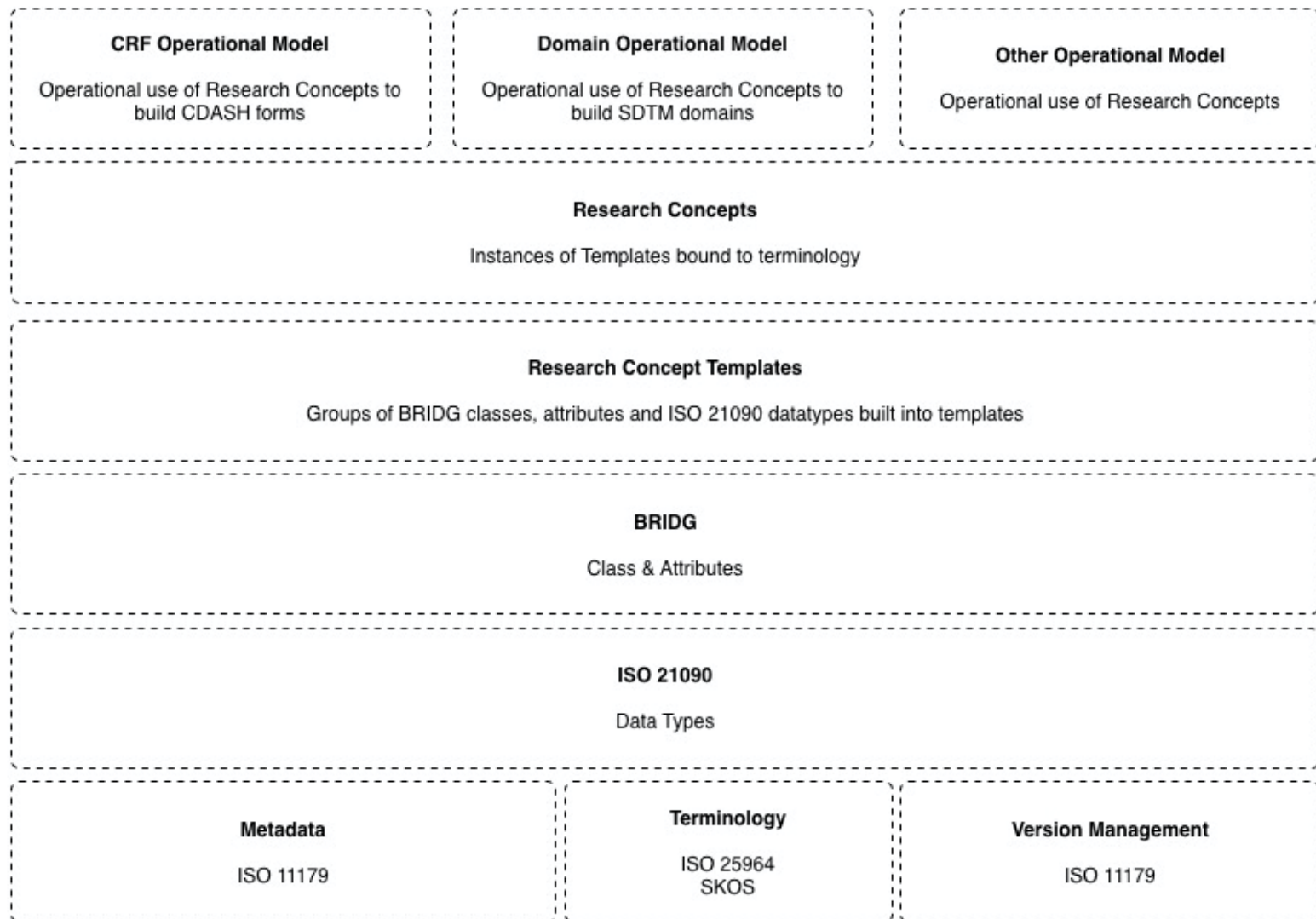
STEP 3 SEMANTIC DATABASE

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

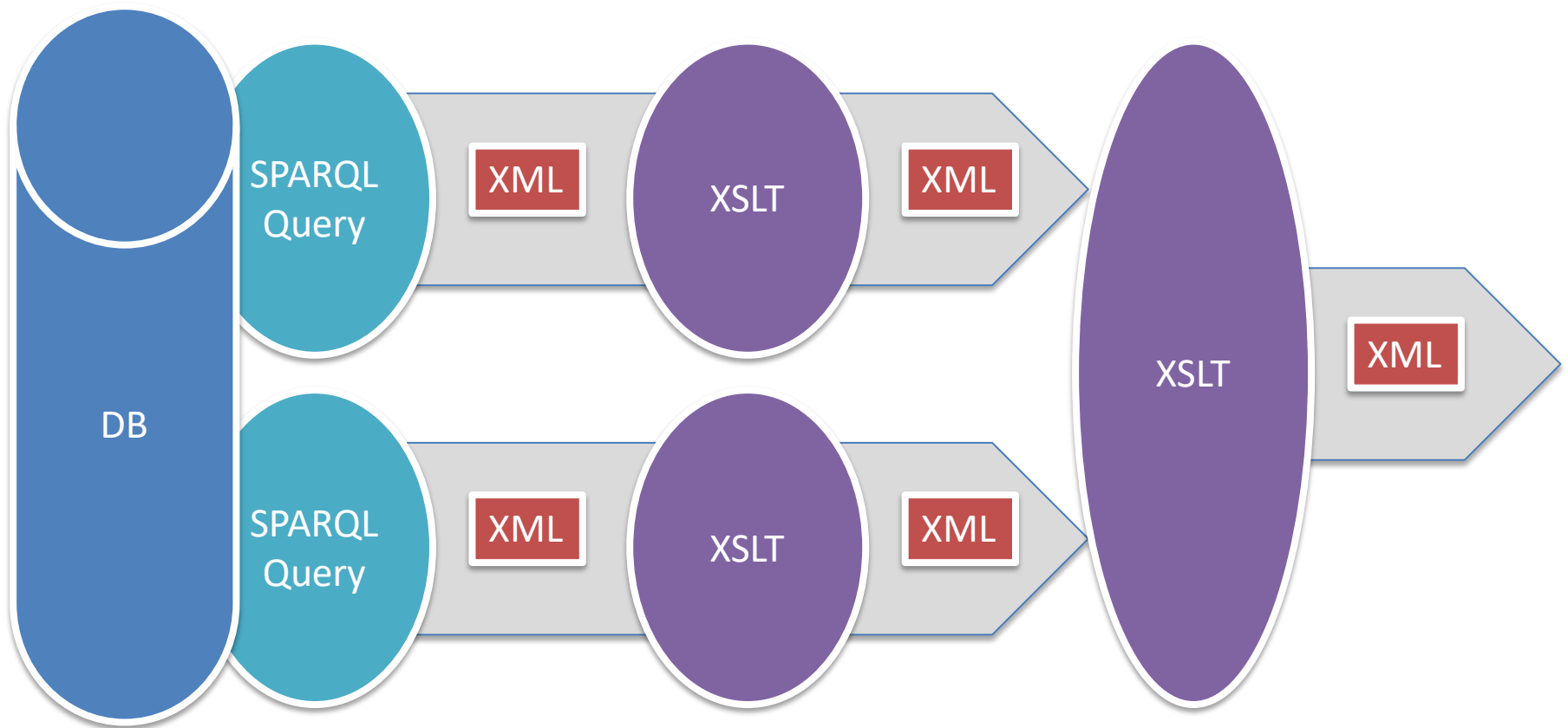
STEP 4 IMPROVE

Improve the initial implementation from step 3.

Step 1: Model



Step 1: Compare Terminology



Step 1: Compare Terminology

Difference between CDISC terminology issued Q4 2014 (SDTM: 15 Dec 2014, QS-FT: 16 Dec 2014) and the preceding version of Q3 2014, 2nd Issue (SDTM: 06 Oct 2014, QS-FT: 24 Sep 2014)

Code	Code List Code	Ext	Name	Submission Value	Synonyms	Definition	Preferred Term	Type
C117995	C100129		Category of Questionnaire	CHART-SF ==> CHART-SF INTERVIEW VERSION	CHSF1	Personality Assessment, 49(1): 71-75). Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF) (Whiteneck GG, Charlifue SW, Gerhart KA, Overholser JD, Richardson GN. Quantifying handicap: a new measure of long-term rehabilitation outcomes. Arch Phys Med Rehabil. 1992;73:519-526). ==> Craig Handicap Assessment and Reporting Technique - Short Form Interview Version (CHART-SF INTERVIEW VERSION) (Whiteneck GG, Charlifue SW, Gerhart KA, Overholser JD, Richardson GN. Quantifying handicap: a new measure of long-term rehabilitation outcomes. Arch Phys Med Rehabil. 1992;73:519-526).	Craig Handicap Assessment and Reporting Technique-Short Form Questionnaire ==> Craig Handicap Assessment and Reporting Technique-Short Form Interview Version Questionnaire	Update
C117996	C100129		Category of Questionnaire	C-SSRS LIFETIME/RECENT VERSION	CSS11	Columbia-Suicidality Severity Rating Scale (C-SSRS) Lifetime/Recent Version 1/14/2009 (Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.; copyright 2008 The Research Foundation for Mental Hygiene, Inc.).	Columbia-Suicide Severity Rating Scale Lifetime/Recent Version Questionnaire	No Change
C117997	C100129		Category of Questionnaire	ESRSA	ESRSA1	Extrapyramidal Symptom Rating Scale-Abbreviated (ESRS-A) (Copyright 2006 Larry Alphas, MD, PhD, Guy Chouinard, MD, All Rights Reserved).	Extrapyramidal Symptom Rating Scale-Abbreviated Questionnaire	No Change
C119092	C100129		Category of Questionnaire	CDLQ	CDLQ1	Children's Dermatology Life Quality Index (CDLQI) (Copyright of M.S. Lewis-Jones, A.Y. Finlay, May 1993, this must not be copied without the permission of the authors).	Children's Dermatology Life Quality Index Questionnaire	New
C119093	C100129		Category of Questionnaire	FLU-IIQ ONCE DAILY	FLUIQ1	Influenza Intensity and Impact Questionnaire (Flu-iiQ) Once Daily (Copyright RH Osborne 2006. No part of the Flu-iiQ may be copied or reproduced in any form without written permission from the author: measuredsolutions@bigpond.com).	Influenza Intensity and Impact Questionnaire Once Daily Version	New

Step 1: Annotated CRF

```
PREFIX sdtm: <http://www.assero.co.uk/CDISCSDTM#>
PREFIX mms: <http://rdf.cdisc.org/mms#>
PREFIX sdtm-1-2: <http://rdf.cdisc.org/std/sdtm-1-2#>
PREFIX cdisc: <http://rdf.cdisc.org/std/schema#>
PREFIX rc: <http://www.assero.co.uk/MDRCDISCRsearchConcepts#>
PREFIX crc: <http://www.assero.co.uk/CDISCRsearchConcept#>
PREFIX term: <http://www.assero.co.uk/MDRThesaurus/CDISC/V39#>
PREFIX iso: <http://www.assero.co.uk/ISO25964#>
PREFIX iso11179: <http://www.assero.co.uk/ISO11179Identification#>
PREFIX co: <http://www.assero.co.uk/CDISCOperational#>
PREFIX cdash: <http://www.assero.co.uk/CDISCCDASH#>
```

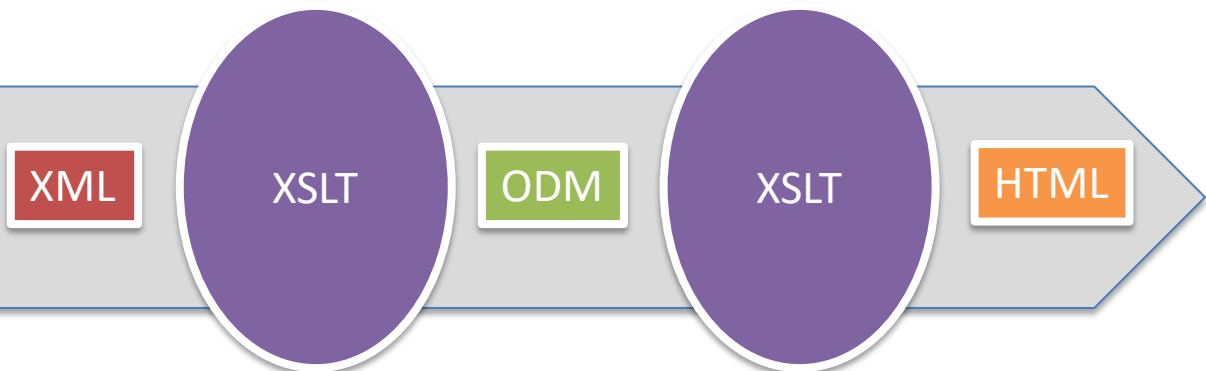
```
SELECT ?form ?fname ?group ?qname ?question ?qtext ?presentation ?rc ?sdtmVarName ?sdtmTopicName ?ref ?value ?code ?rcIdent ?ccode ?termSub
```

```
FROM <http://www.assero.co.uk/MDRCDISCSDTM#>
FROM <http://www.assero.co.uk/MDRCDISCRsearchConcepts#>
FROM <http://www.assero.co.uk/MDRThesaurus/CDISC/V39#>
FROM <http://www.assero.co.uk/ISO25964#>
FROM <http://www.assero.co.uk/ISO11179Identification#>
FROM <http://www.assero.co.uk/CDISCOperational#>
FROM <http://www.assero.co.uk/CDISCCDASH#>
```

```
WHERE {
```

```
{
  ?form rdf:type cdash:Form .
  ?form cdash:partOf ?group .
  ?form co:name ?fname .
  ?group cdash:partOf ?question .
  ?group co:name ?qname .
  ?question co:name ?qname .
  ?question cdash:text ?qtext .
  ?question cdash:presentation ?presentation .
  ?question co:reference ?rc .
  ?variable co:reference ?rc .
  ?variable sdtm:vName ?sdtmVarName .
  ?rc (crc:isPropertyOf | crc:isDatatypeOf | crc:isItemOf)+ ?rcRoot .
  ?rcRoot rdf:type crc:ResearchConceptInstance .
  ?rcRoot iso11179:identifierRelationship ?si .
  ?si iso11179:identifier ?rcIdent .
  OPTIONAL {
    ?rc (crc:hasSimpleDatatype | crc:nextValue)+ ?rcValue .
    ?rcValue rdf:type crc:PropertyValue .
    ?rcValue crc:value ?ccode .
    ?node3 rdf:type iso:ThesaurusConcept .
    ?node3 iso:identifier ?ccode .
    ?node3 iso:notation ?termSub .
  }
}
```

```
SELECT ?form ?fname ?group ?qname ?question ?qtext ?presentation ?rc ?sdtmVarName ?rcIdent ?ccode {
  ?form rdf:type cdash:Form .
  ?form cdash:partOf ?group .
  ?form co:name ?fname .
  ?group cdash:partOf ?question .
  ?group co:name ?qname .
  ?question co:name ?qname .
  ?question cdash:text ?qtext .
  ?question cdash:presentation ?presentation .
  ?question co:reference ?rc .
  ?variable co:reference ?rc .
  ?variable sdtm:vName ?sdtmVarName .
  ?rc (crc:isPropertyOf | crc:isDatatypeOf | crc:isItemOf)+ ?rcRoot .
  ?rcRoot rdf:type crc:ResearchConceptInstance .
  ?rcRoot iso11179:identifierRelationship ?si .
  ?si iso11179:identifier ?rcIdent .
  OPTIONAL {
    ?rc (crc:hasSimpleDatatype | crc:nextValue)+ ?rcValue .
    ?rcValue rdf:type crc:PropertyValue .
    ?rcValue crc:value ?ccode .
    ?node3 rdf:type iso:ThesaurusConcept .
    ?node3 iso:identifier ?ccode .
    ?node3 iso:notation ?termSub .
  }
}
```



Form: Asthma One	
MetaData OID=http://www.assero.co.uk/MDRCDISCCDASH#Form.Asthma_1	
Group: Lilly Percentage Predicted Forced Vital Capacity OID=http://www.assero.co.uk/MDRCDISCCDASH#Horizontal.Asthma_1.LillyPPFVC, Repeating=	
Lilly Percent Predicted FVC VSORRES where VSTESTCD=FVCP Units VSORRESU where VSTESTCD=FVCP	. ☐ % ☐ RATIO
Group: Lilly Forced Vital Capacity OID=http://www.assero.co.uk/MDRCDISCCDASH#Horizontal.Asthma_1.LillyFVC, Repeating=	
Lilly FVC VSORRES where VSTESTCD=FVC Units VSORRESU where VSTESTCD=FVC	. ☐ L ☐ mL

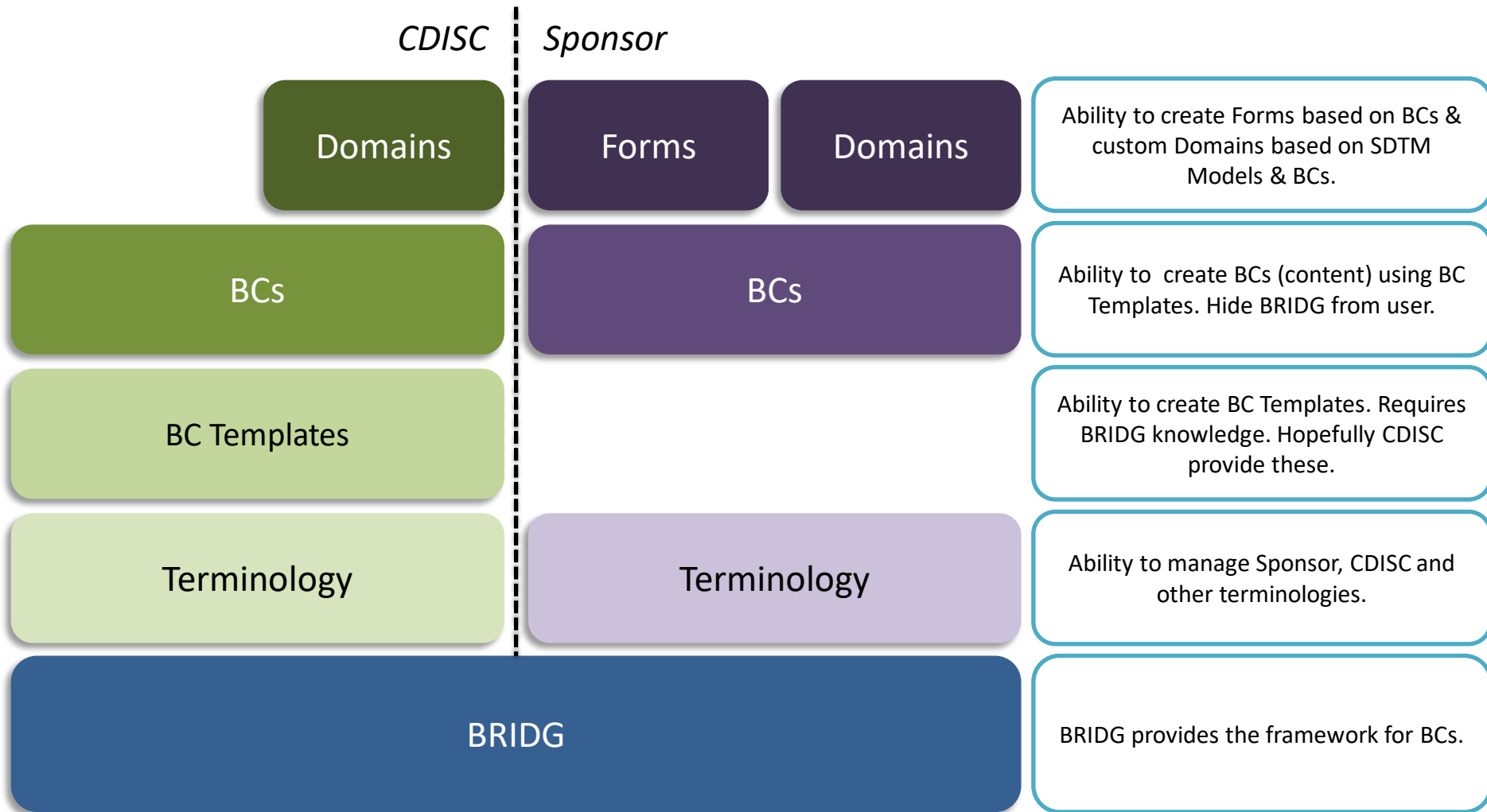
Step 1: Notes

- Used the Topbraid Composer tool to
 - Build the model
 - Be the database
- Lessons
 - BC approach brings benefits
 - Combined SPARQL query & XSLT approach works well

Step 2: Simple Tools

- Desire to 'see it' and focus on user interaction
- Keep it simple for the user

Step 2: Skill Set



Step 2: BC Editing

Navigation

- Home
- Terminology
- RCT and RC Import
- RCT Editor
- RC Editor
- Form Editor
- Domain Editor
- Study Editor
- E2C

Research Concept Editor

Visualisation

Help

Save

Research Concept Info

Reset

Short (File) Name

VS/Height

Long Name

Height

Version

2

Author

Imported

Notes

Initial version

Research Concepts

Research Concept Templates

- BMI (V1)
- BSA (V1)
- BodyTemperature (V1)
- DiastolicBloodPressure (V1)
- HeartRate (V1)
- Height (V1)
- PulseRate (V1)
- SystolicBloodPressure (V1)
- Weight (V1)

Research Concept Editor

Up

Down

Delete

Natural Language Label	Collect	Prompt Text	Question Text	Data Type	Format	Terminology
Test Code (--TESTCD)	☐			CL		HEIGHT (C25347)
Test Name (--TEST)	☐			CL		Height (C25347)
Result Value (--ORRES)	☒	Height	Height	F	5.1	
Result Units (--ORRESU)	☒	Units	Units	CL		cm (C49668)
	☐					in (C48500)
Date Time (--DTC)	☒	Date and Time	Date and Time	D+T		

Research Concept Template

Natural Language Label

SDTM

CDISC Terminology (V40, published 2015-03-27)

Code	Code List Code	Extensible	Name	Submission Value	Synonyms	Definition	Preferred Term
C100129	C100129	true	Category of Questionnaire	QSCAT	Category of Questionnaire	A grouping of observations within the Questionnaire domain.	CDISC Questionnaire Category Terminology
C100759	C100129		Category of Questionnaire	BPI	BPI1	Brief Pain Inventory (BPI) (copyright 1991 Charles S. Cleeland, PhD, Pain Research Group, All Right Reserved).	Brief Pain Inventory Questionnaire
C100760	C100129		Category of Questionnaire	BPI SHORT FORM	BPI2	Brief Pain Inventory Short Form (BPI2) (copyright 1991 Charles S. Cleeland, PhD, Pain Research Group, All Right Reserved).	Brief Pain Inventory Short Form Questionnaire
C100761	C100129		Category of Questionnaire	BPRS-A	BPR01	Brief Psychiatric Rating Scale - Anchored (BPRS-A) (Woerner MB, Mannuzza S, and Kane JM. Anchoring the BPRS: An Aid to Improved Reliability. Psychopharmacology Bulletin 1988; 24(1):112-117).	Brief Psychiatric Rating Scale A Questionnaire
C100762	C100129		Category of	ADAS-COG	ADC	The CDISC version of the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog CDISC Version) containing 15 summary-level tests. This version is based on combining the total pool of ADAS-Cog tests that were observed during a review of multiple case report forms administered in clinical trials of Alzheimer's disease, as well as the CRF administered in the Alzheimer's Disease Neuroimaging Initiative (ADNI) observational study. (Modified from Mohs RC, Rosen WG, Davis KL. The Alzheimer's disease assessment scale: an instrument for assessing treatment efficacy. Psychopharmacol Bull 1983;19(3):448-458).	Alzheimer's Disease Assessment Scale-Cognitive CDISC Version

Step 2: BC Editing

Navigation < Research Concept Editor Visualisation Help

Save

Research Concept Info

Reset

Short (File) Name VS/Height

Long Name Height

Version 2

Author Imported

Notes Initial version

Research Concept Editor

Up Down Delete

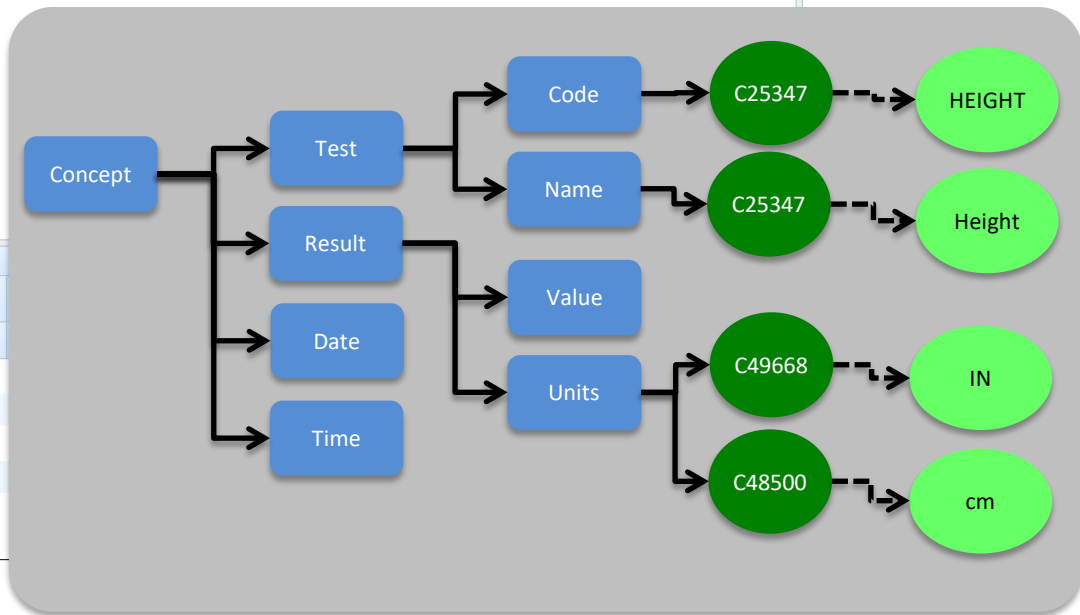
Natural Language Label	Collect	Prompt Text	Question Text
Test Code (--TESTCD)	☐		
Test Name (--TEST)	☐		
Result Value (--ORRES)	☒	Height	Height
Result Units (--ORRESU)	☒	Units	Units
Date Time (--DTC)	☒	Date and Time	Date and Time

Research Concept Template

BC structure 'flattened' using alias to make it understandable to those working in the business today

Menu Structured to reflect the Skill Set

- Terminology
- BC Templates & BCs
- Form & Domains
- Study



Step 2: aCRF

Navigation < Form Editor Visualisation **E2C** Help

E2C Form Visualisation (CRF)

Form: VS Baseline **Domain VS**

BMI **VSTESTCD=BMI (C16358)** **LOINC=39156-5**

Body Mass Index
VSORRES
Units
VSORRESU

Date and Time
VSDTC

BSA **VSTESTCD=BSA (C25157)** **LOINC=8277-6**

Body Surface Area
VSORRES
Units
VSORRESU

Date and Time
VSDTC

Body Temperature **VSTESTCD=TEMP (C25206)** **LOINC=8310-5**

Location
VSLOC

Temperature
VSORRES
Units
VSORRESU

Date and Time
VSDTC

Diastolic Blood Pressure **VSTESTCD=DIABP (C25299)** **LOINC=8462-4**

Position
VSPOS

Location
VSLOC

Automated aCRF generation to show potential of using BCs and investigate issues

Step 2: Notes

- Built using PHP & Javascript
- Database a combination of files
 - ODM for Forms and Studies
 - Define for domains
 - Some bespoke XML for other pieces
 - Terminology XML files from Step 1 exports
- Lessons
 - Can hide the complexity
 - Confirmed the benefits of BCs
 - Can make it easy for the users

Step 3: Semantic Database

- User Interface implemented by Web Site
- Database accessed by SPARQL over HTTP
 - Ontotext
 - S4 Cloud Service
 - Fuseki
 - Apache open source server
- Implements the model developed during stage 1

Step 3 : Terminology

CDISC SDTM Unit for Vital Sign Result Terminology (CDISC, C66770)

Imports owl files issued by CDISC
from Dec 2013 onwards

Code List History

Version	Date	Identifier	Notation	Preferred Term	Synonym	Extensible	Definition
34	2013-12-20	C66770	VSRESU	CDISC SDTM Unit for Vital Sign Result Terminology	Units for Vital Signs Results	true	The unit used to record and describe the result of a test investigating a vital sign. (NCI)
35	2014-03-28						
36	2014-06-27						
37	2014-09-24						
38	2014-10-06						
39	2014-12-16						
40	2015-03-27						
41	2015-06-26						
42	2015-09-25						

Use the power of the query to meet key
business needs. Changes and impact of
changes

Code List Item History

Code List Item	Submission Value	V34	V35	V36	V37	V38	V39	V40	V41	V42	Item History
C25613	%	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C28252	kg	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C42554	ohm	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C42559	C	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C42569	m2	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C44277	F	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C48155	g	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C48500	IN	⊗	⊗	⊗	⊗	⊗	✎	⊗	⊗	⊗	History
C48531	LB	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C49668	cm	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C49670	mmHg	⊗	✎	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C49671	kg/m2	⊗	✎	⊗	⊗	⊗	⊗	⊗	⊗	⊗	History
C49673	BEATS/MIN	⊗	⊗	⊗	⊗	⊗	⊗	⊗	✎	⊗	History
C49674	BREATHS/MIN	⊗	⊗	⊗	⊗	⊗	⊗	⊗	✎	⊗	History
C28251	mm			⊗	⊗	⊗	⊗	⊗	⊗	⊗	History

Step 3: Terminology

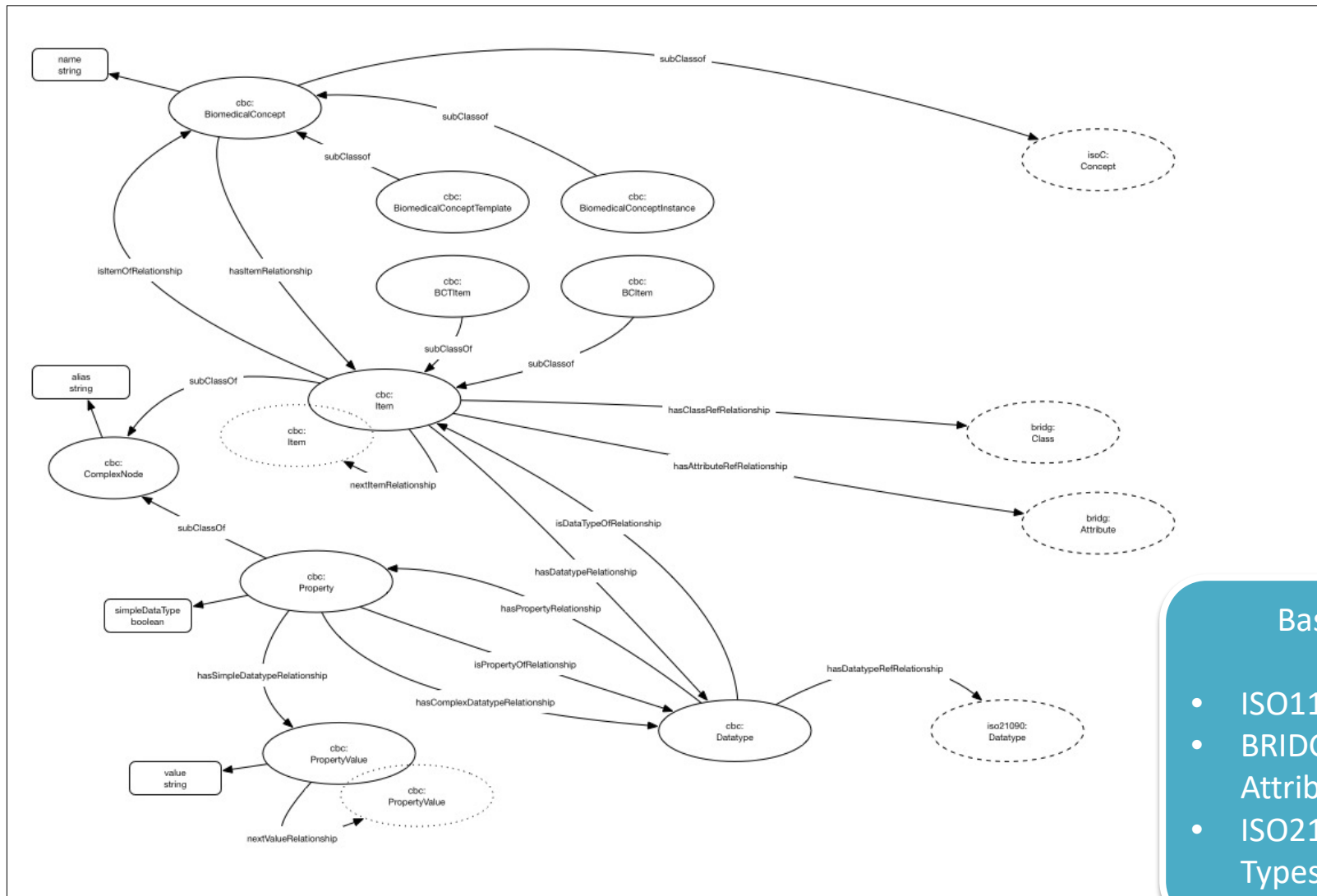
Beats per Minute (CDISC, C49673)

Code List Item Full History

Version	Date	Identifier	Notation	Preferred Term	Synonym	Definition
34	2013-12-20	C49673	BEATS/MIN	Beats per Minute	Beats per Minute	The number of heartbeats measured per minute time. (NCI)
35	2014-03-28					
36	2014-06-27					
37	2014-09-24					
38	2014-10-06					
39	2014-12-16					
40	2015-03-27					
41	2015-06-26		BEATS/MIN beats/min			
42	2015-09-25					

Changes such as submission value changes and when did it change

Step 3: Biomedical Concept



Based on

- ISO1179
- BRIDG Classes & Attributes
- ISO21090 Data Types

Step 3: Tools

```

9 SELECT ?si ?bcName ?bcDtNode ?bcPropertyNode ?bcPropertyValueNode ?datatype ?propertyValue ?propertyAlias WHERE
10 {
11   :BC-C111200 isoI:identifierRelationship ?si .
12   :BC-C111200 cbc:name ?bcName .
13   :BC-C111200 (cbc:hasItemRelationship | cbc:hasDatatypeRelationship)+ ?bcDtNode .
14   OPTIONAL {
15     ?bcDtNode cbc:hasDatatypeRefRelationship ?datatype .
16     ?bcDtNode (cbc:hasPropertyRelationship | cbc:hasComplexDatatypeRelationship)+ ?bcPropertyNode .
17     OPTIONAL {
18       ?bcPropertyNode (cbc:hasSimpleDatatypeRelationship | cbc:nextValueRelationship)+ ?bcPropertyValueNode .
19       ?bcPropertyValueNode rdf:type cbc:PropertyValue .
20       ?bcPropertyValueNode cbc:value ?propertyValue .
21       ?bcPropertyNode cbc:alias ?propertyAlias .
22     }
11

```

SPARQL Query to extract
a specified BC

QUERY RESULTS

Raw Response Table Search: Show 50 entries

	si	bcName	bcDtNode	bcPropertyNode	bcPropertyValueNode	datatype	propertyValue	propertyAlias
1	item:SI- CDISC_BC_C1112 00-1	"Expiratory Reserve Volume"	:BC- C111200_DefinedO bservation_nameC ode					
2	item:SI- CDISC_BC_C1112 00-1	"Expiratory Reserve Volume"	:BC- C111200_DefinedO bservation_nameC ode_CD	:BC- C111200_DefinedO bservation_nameC ode_CD_code	:BC- C111200_DefinedO bservation_nameC ode_CD_code_Valu e1	<http://www.assero .co.uk/MDRISO210 90#DT-CD>	"C111200"	"Test Code (-- TESTCD)"
3	item:SI- CDISC_BC_C1112 00-1	"Expiratory Reserve Volume"	:BC- C111200_DefinedO bservation_nameC ode_CD	:BC- C111200_DefinedO bservation_nameC ode_CD_originalTe xt		<http://www.assero .co.uk/MDRISO210 90#DT-CD>		

Step 3: Biomedical Concept

Biomedical Concept Height (CDISC, C25347, V1)

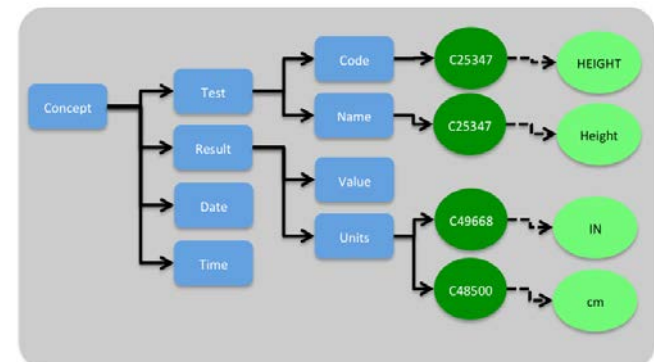
Details

Identifier	Name	Version
C25347	Height	1

Items

Alias	Collect	QuestionText	PromptText	Datatype	Values	Format
Test Code (--TESTCD)	☐	Test Code	Test Code	CL	C25347: Height (CLI-C67153_C25347) HEIGHT (CLI-C66741_C25347)	
Test Name (--TEST)	☐	Test Name	Test Name	CL	C25347: Height (CLI-C67153_C25347) HEIGHT (CLI-C66741_C25347)	
Location (--LOC)	☒	Location	Location	CL		
Method Code (--METHOD)	☒	Method Code	Method Code	CL		
Result Value (--ORRES)	☒	Result Value	Result Value	F		5.1
Result Units (--ORRESU)	☒	Result Units	Result Units	CL	C49668: cm (CLI-C71620_C49668) cm (CLI-C66770_C49668) C48500: in (CLI-C71620_C48500) in (CLI-C66770_C48500)	

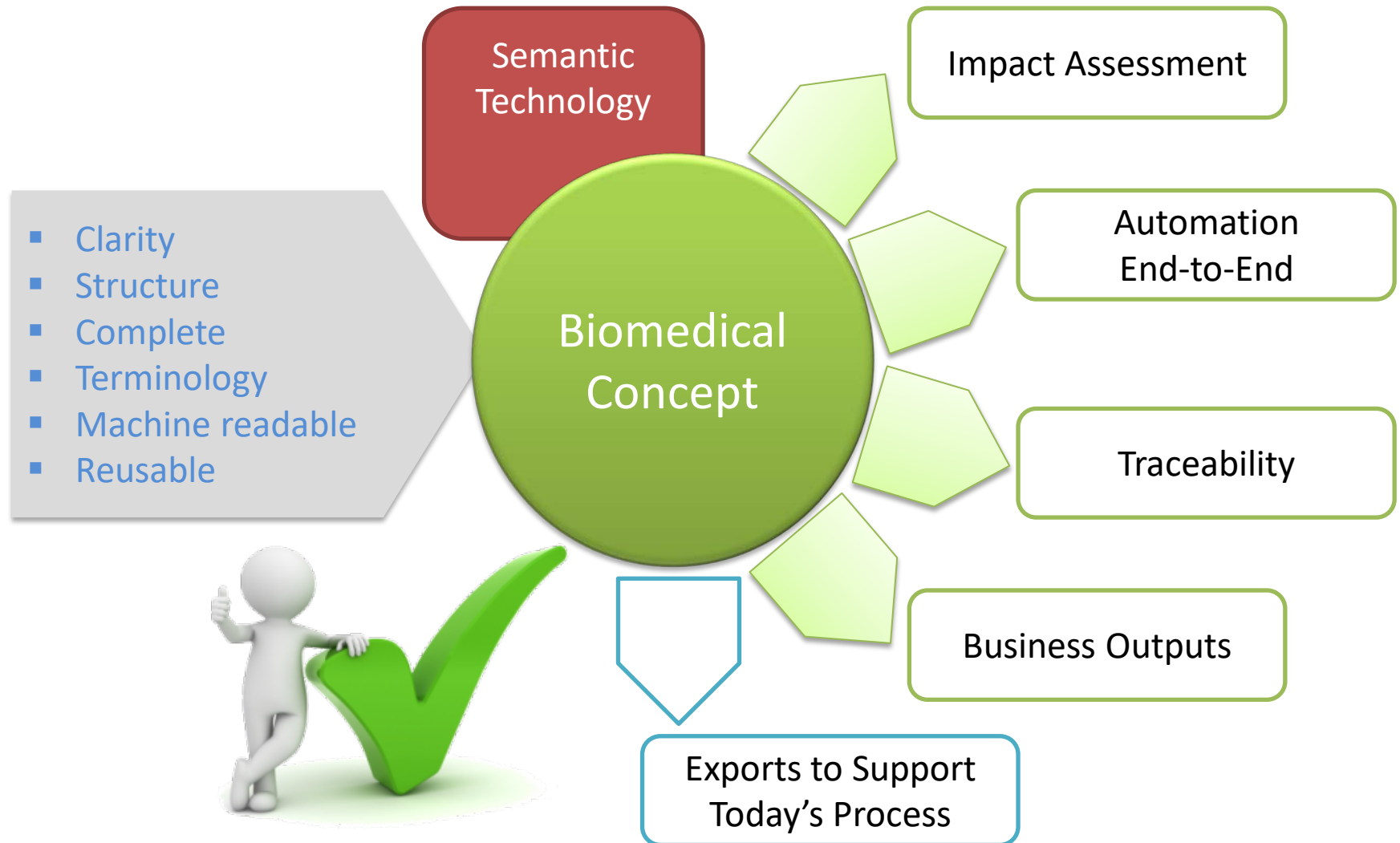
Equivalent BC to that
shown for stage 2



Step 3: Notes

- Version management and namespaces been a tricky area
- Power of SPARQL
- Issues with tools and debugging
- Benefits of BCs and power for impact analysis, great potential
- Forms, Domains and Study Build to be done by end of year
- Blogs will be written!

Summary



Useful Links

Topic	Link
More on Biomedical Concepts	http://www.assero.co.uk/2015/research-concepts-a-what-why-and-how/
ISO25964	http://www.assero.co.uk/2015/terminology-and-iso-25964/
ISO11179	http://www.assero.co.uk/2015/all-things-to-all-men-iso-11179/
Step 2	http://www.assero.co.uk/2015/a-bit-of-a-tangent/
GitHub	https://github.com/daveih/Alba
Paper from Presentation	PhUSE website

Contact And More Information

Email

dave.iberson-hurst@assero.co.uk

Blogs Available At

www.assero.co.uk

