



Into the Fire, Linking CDISC & FHIR

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Abstract

The FDA have announced that “LOINC codes will be required in NDAs, ANDAs, and BLAs for studies that start after March 15, 2020” [1]. Meanwhile talk continues over integrating clinical research with healthcare and interest expressed in Fast Healthcare Interoperability Resources (FHIR), the new Health Level 7's (HL7) standard.

This paper (and the associated presentation) will report on research encompassing:

- Mappings from CDISC terminology to LOINC to aid in the population of SDTM datasets.
- Generate SDTM datasets from data held in a database with that data being extracted from an Electronic Health Record (EHR) via FHIR.
- Can the data extracted from EHRs be driven by research artefacts such as forms based on biomedical concepts?

and include:

- The approach taken, and technology used.
- How to formulate the EHR requests and process the responses
- How the stored EHR data can be used to generate SDTM datasets.
- How mappings from CDISC to LOINC can be automated.
- How UCUM might be used to automate data conversions

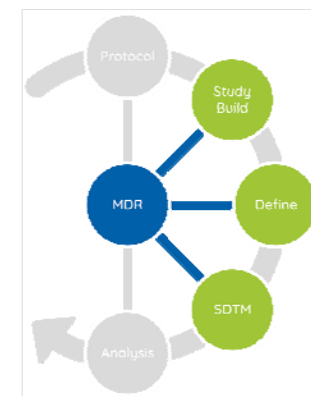
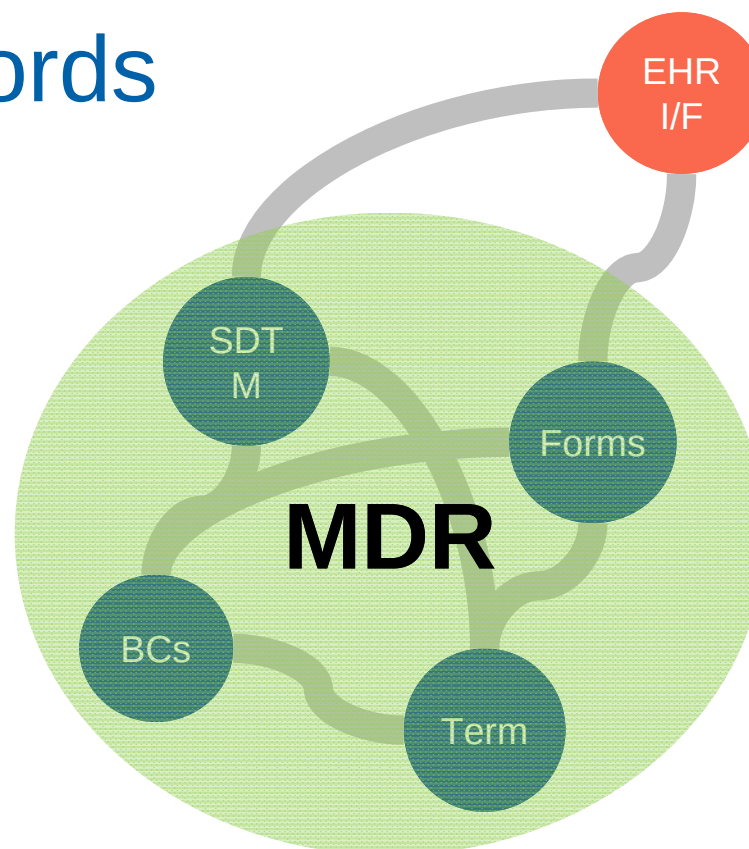
The presentation will conclude with a summary of results, next steps and potential impact.



Electronic Health Records

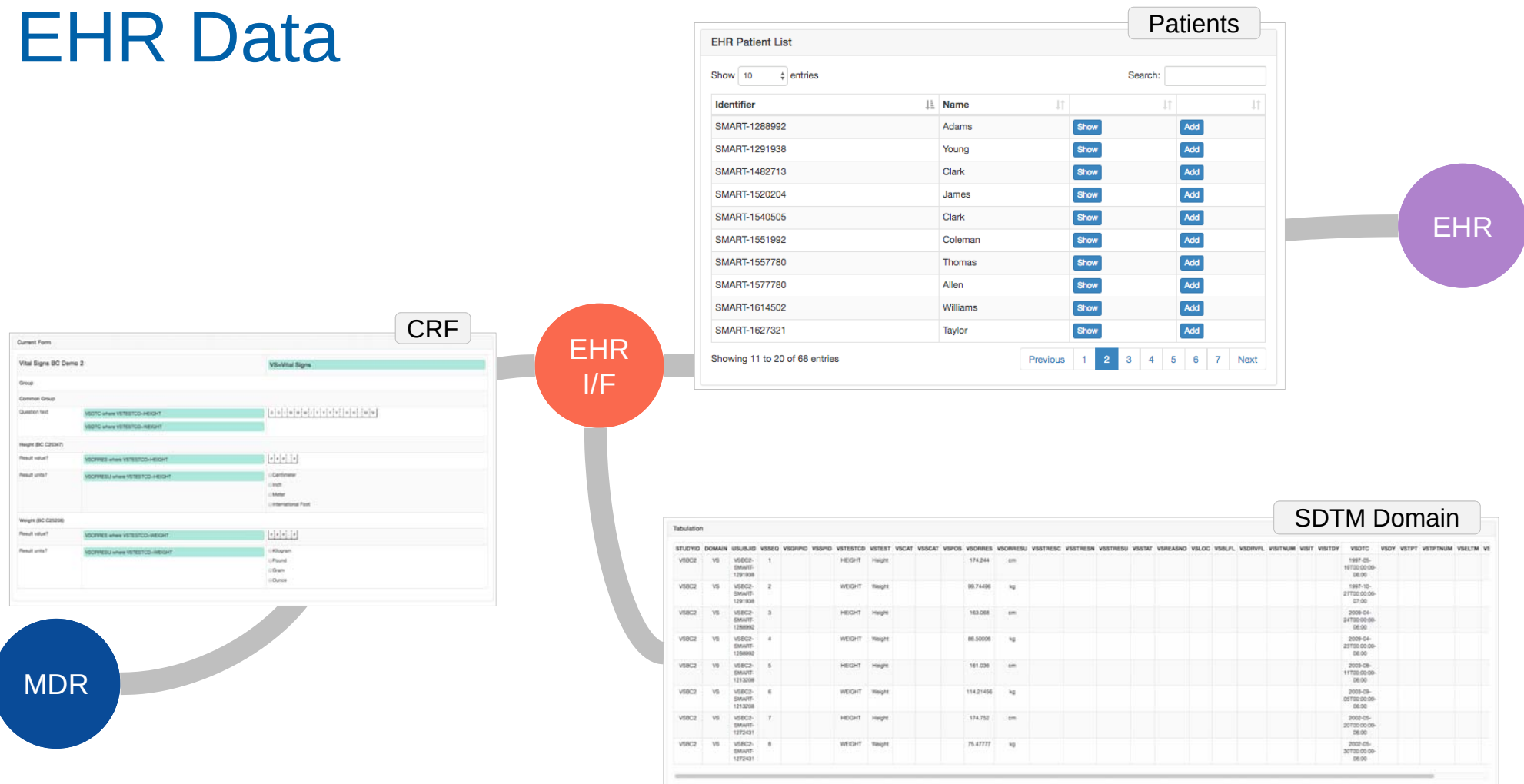
An Experiment

- Application to test and demonstrate some of these ideas. What are the problems? What are the issues?
- Use HL7 FHIR to obtain patient data (using LOINC/UCUM <-> CDISC Terminology mapping).
- Map to form selected from Glandon MDR built using Biomedical Concepts. Can build form on the fly and populate.
- Put into a graph (acting as a simple data warehouse) holding the data for multiple subjects.
- Extract a presentation of the data (SDTM) using domain definitions from the Glandon MDR.
- I want a mechanism that does all the hard work. I think in CDISC terms, the machine does the necessary translations.



EHR Data

Full Description: <https://www.a3informatics.com/graphs-fhir-cdisc/>



EHR Data

EHR Patient List

Patients

Show entries

Search:

Identifier	Name		
SMART-1288992	Adams	Show	Add
SMART-1291938	Young	Show	Add
SMART-1482713	Clark	Show	Add
SMART-1520204	James	Show	Add
SMART-1540505	Clark	Show	Add
SMART-1551992	Coleman	Show	Add
SMART-1557780	Thomas	Show	Add



EHR

So ...

- Select CRF from the MDR
- Add patients/subjects from the EHR. Use the CRF metadata to drive requests to the EHR for the data (and only that data) required by the form
- Create SDTM domains automatically

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Current Form

Vital Signs BC Demo 2

VS-Vital Signs

Group

Common Group

Question text

VS7C where VS7C7D=HEIGHT

VS7C where VS7C7D=HEIGHT

Height (BC C23347)

Result value?

VS0P89 where VS7C7D=HEIGHT

Result units?

VS0P89 where VS7C7D=HEIGHT

Centimeter

Inch

Milli

International Foot

Weight (BC C23336)

Result value?

VS0P89 where VS7C7D=HEIGHT

Result units?

VS0P89 where VS7C7D=HEIGHT

Kilogram

Pound

Gram

Ounce

[illegible]

SDTM Domain

VISIT	VISITDY	VISITC	VSDY	VSTPT	VSTPTNUM	VSELTM	VS
	1987-05-						
	1970:00:00:00						
	00:00						
	1987-10-						
	2770:00:00:00						
	07:00						
	2009-04-						
	2470:00:00:00						
	00:00						
	2009-04-						
	2370:00:00:00						
	00:00						
	2003-08-						
	1170:00:00:00						
	00:00						
	2003-09-						
	0570:00:00:00						
	00:00						
	2002-05-						
	2070:00:00:00						
	00:00						
	2002-05-						
	2070:00:00:00						
	00:00						

LOINC Mapping

- Excellent work done by CDISC Terminology Team
- Loaded Excel Workbook giving me mapping of LOINC codes <-> CDISC Terminology
- NOTE. 1:M nature of the individual rows and repeating LOINC codes

	A	B	C	D	E	F	G	H	I	J	K	L	M
	LOINC Code	Component	Property	Time Aspect	System	Scale	Method	LOINC Short Name	CDISC LBTEST	CDISC TESTDTL	CDISC LBSPEC	CDISC LBMETHOD	
1	2857-1	Prostate specific Ag	MCnc	Pt	Ser/Plas	Qn		PSA SerPl-mCnc	Prostate Specific Antigen		SERUM OR PLASMA	(ANY)	
2	2857-1	Prostate specific Ag	MCnc	Pt	Ser/Plas	Qn		PSA SerPl-mCnc	Prostate Specific Antigen		SERUM	(ANY)	
3	2857-1	Prostate specific Ag	MCnc	Pt	Ser/Plas	Qn		PSA SerPl-mCnc	Prostate Specific Antigen		PLASMA	(ANY)	
4	2571-8	Triglyceride	MCnc	Pt	Ser/Plas	Qn		Trigl SerPl-mCnc	Triglycerides		SERUM OR PLASMA	(ANY)	
5	2571-8	Triglyceride	MCnc	Pt	Ser/Plas	Qn		Trigl SerPl-mCnc	Triglycerides		SERUM	(ANY)	
6	2571-8	Triglyceride	MCnc	Pt	Ser/Plas	Qn		Trigl SerPl-mCnc	Triglycerides		PLASMA	(ANY)	
7													
8													

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	LOINC Code	C	Pr	Ti	Sy	Sc	M	L		CDISC LBTEST	CDISC TESTDTL	CDISC LBSPEC	CDISC LBMETHOD	EXAMPLE CDISC LBSTRESU
1		o	op	m	st	al	et	Ol						
2	2857-1	Pr	M	Pt	Se	Q		P	S	Prostate Specific Antigen		SERUM OR PLASMA	(ANY)	ug/L
3	2857-1	Pr	M	Pt	Se	Q		P	S	Prostate Specific Antigen		SERUM	(ANY)	ug/L
4	2857-1	Pr	M	Pt	Se	Q		P	S	Prostate Specific Antigen		PLASMA	(ANY)	ug/L
5	2571-8	Tri	M	Pt	Se	Q		Tri	gl	Triglycerides		SERUM OR PLASMA	(ANY)	mg/dL
6	2571-8	Tri	M	Pt	Se	Q		Tri	gl	Triglycerides		SERUM	(ANY)	mg/dL
7	2571-8	Tri	M	Pt	Se	Q		Tri	gl	Triglycerides		PLASMA	(ANY)	mg/dL
8		gl	C		r/	n		gl						

LOINC Mapping

- Load of the mappings finds each referenced CDSIC Submission Value and links it to the term in the MDR and links to the LOINC code.
- Example LOINC 2571-8 = CDISC TRIG (C64812) + SERUM OR PLASMA (C105706) + mg/dl (C67015) + ANY Method (which is ignored)
- Note multiple LOINC -> CDISC, SERUM, PLASMA & SERUM OR PLASMA mappings
- Given a set of CDISC C-Codes machine can tell me the LOINC code. Thus a set of variables (BC) -> LOINC

Load Mappings						
Show 10 entries						
LOINC Code	Mappings					
2571-8	Triglycerides (C64812)	TRIG (C64812)	SERUM OR PLASMA (C105706)	(ANY) (Any Permitted, Ignored.)	mg/dL (C67015)	
2571-8	Triglycerides (C64812)	TRIG (C64812)	SERUM (C13325)	(ANY) (Any Permitted, Ignored.)	mg/dL (C67015)	
2571-8	Triglycerides (C64812)	TRIG (C64812)	PLASMA (C13356)	(ANY) (Any Permitted, Ignored.)	mg/dL (C67015)	
2857-1	Prostate Specific Antigen (C17634)	PSA (C17634)	SERUM OR PLASMA (C105706)	(ANY) (Any Permitted, Ignored.)	ug/L (C67306)	ng/mL (C67306)
2857-1	Prostate Specific Antigen (C17634)	PSA (C17634)	SERUM (C13325)	(ANY) (Any Permitted, Ignored.)	ug/L (C67306)	ng/mL (C67306)
2857-1	Prostate Specific Antigen (C17634)	PSA (C17634)	PLASMA (C13356)	(ANY) (Any Permitted, Ignored.)	ug/L (C67306)	ng/mL (C67306)

Showing 1 to 6 of 6 entries

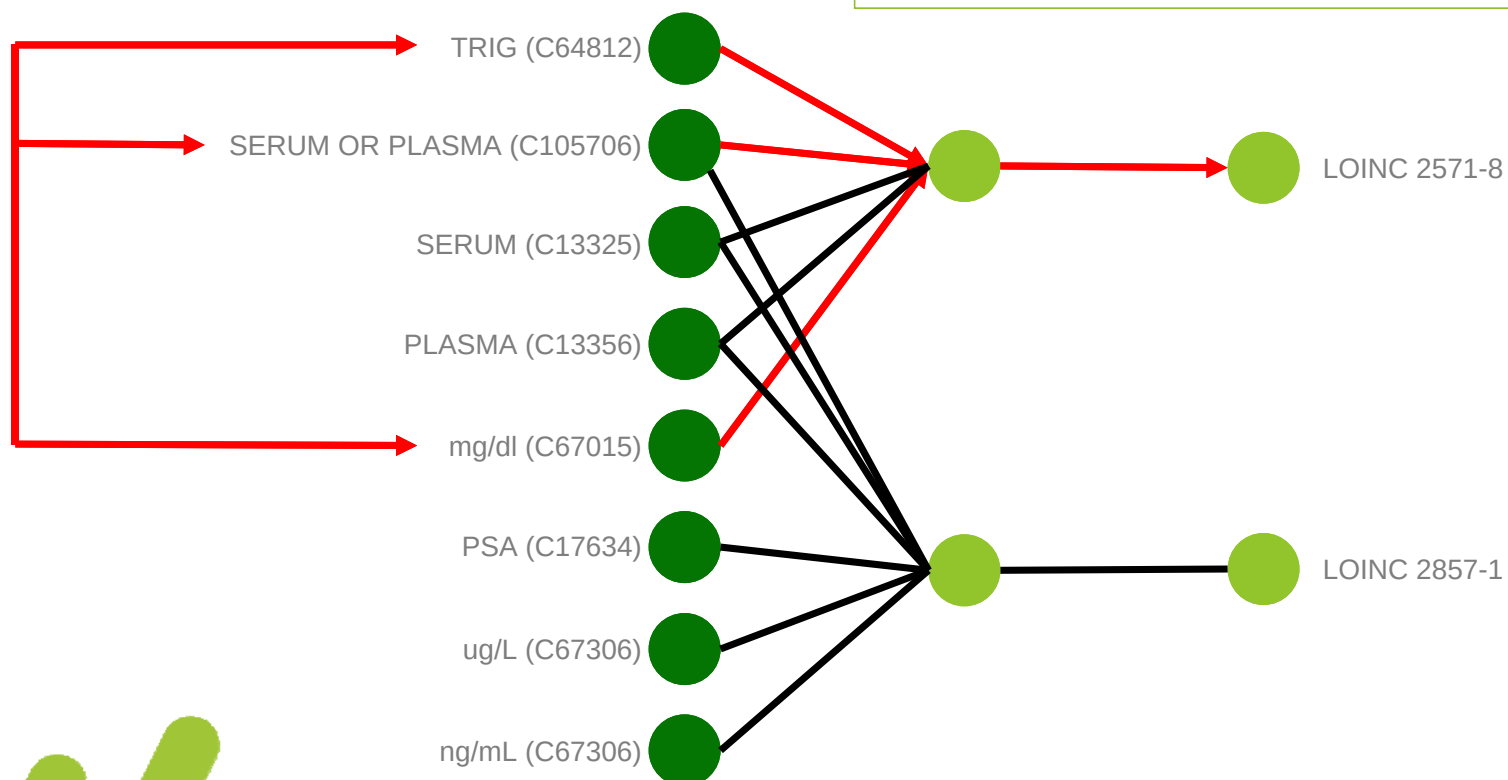
Close

Demonstration



LOINC Mapping

- Small subset of the graph
- Allows for a set of C-Codes to be mapped to a LOINC code
- Additional logic allows for LOINC -> CDISC but note the issue with specimen
- Same mechanism used for UCUM



Summary

So we have

- Driven the EHR requests from the metadata in the BCs used on a 'traditional' CRF:
 - Used the power of the BC and the 'hidden' metadata.
 - The BCs form the backbone, their importance cannot be overstated.
 - Nicely related to FHIR resources. Extracted the data from the FHIR resources.
- Automated mapping from LOINC <-> CDISC
 - 1:1 and 1:M aspects accommodated.
 - In the future the BC could contain the LOINC information rather than map.
- Used queries to extract an SDTM view of the data from the raw EHR data.
 - SDTM is a presentation of the data.



Important

- ```
MATCH (s:Study) -[]-> (su:Subject) -[]-> (bc:BiomedicalConcept) -[*1..5]-> (bcp:`BiomedicalConcept::Propertyx`),(bcp:`BiomedicalConcept::Propertyx`)
 <-[]- (v:`Domain::Variable`) <-[]- (d:Domain)
OPTIONAL MATCH (bcp:`BiomedicalConcept::Propertyx`) -[]-> (bcpv:`BiomedicalConcept::PropertyValue`)
RETURN replace(s.identifier," ","") AS STUDYID,su.identifier AS SUBJID,replace(s.identifier," ","")+ "-" +su.identifier AS USUBJID,
 d.prefix AS DOMAIN,bc.uuid AS uuid,v.name AS name,bcpv.value as value")
```



# Summary

## Next Steps

- Much can be done to create the SDTM derived data automatically, one of our next steps.
- Use UCUM to automate data conversions to create SDTM standard result fields etc.
- Terminology mappings can be automated but we need to think hard about our terminology.
- Integrate LOINC further using the LOINC ontology from BioPortal
- Do a little more work on the spreadsheet loading as it can perform some checks on the work (typographical error etc). Feedback any outcomes to the Terminology Team.



# Questions & Answers

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