



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.



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 (C17834) PSA (C17834) SERUM OR PLASMA (C105706) (ANY) (Any Permitted, Ignored.) ug/L (C67306) ng/mL (C67306)
2857-1	Prostate Specific Antigen (C17834) PSA (C17834) SERUM (C13325) (ANY) (Any Permitted, Ignored.) ug/L (C67306) ng/mL (C67306)
2857-1	Prostate Specific Antigen (C17834) PSA (C17834) PLASMA (C13356) (ANY) (Any Permitted, Ignored.) ug/L (C67306) ng/mL (C67306)

Showing 1 to 6 of 6 entries

Close

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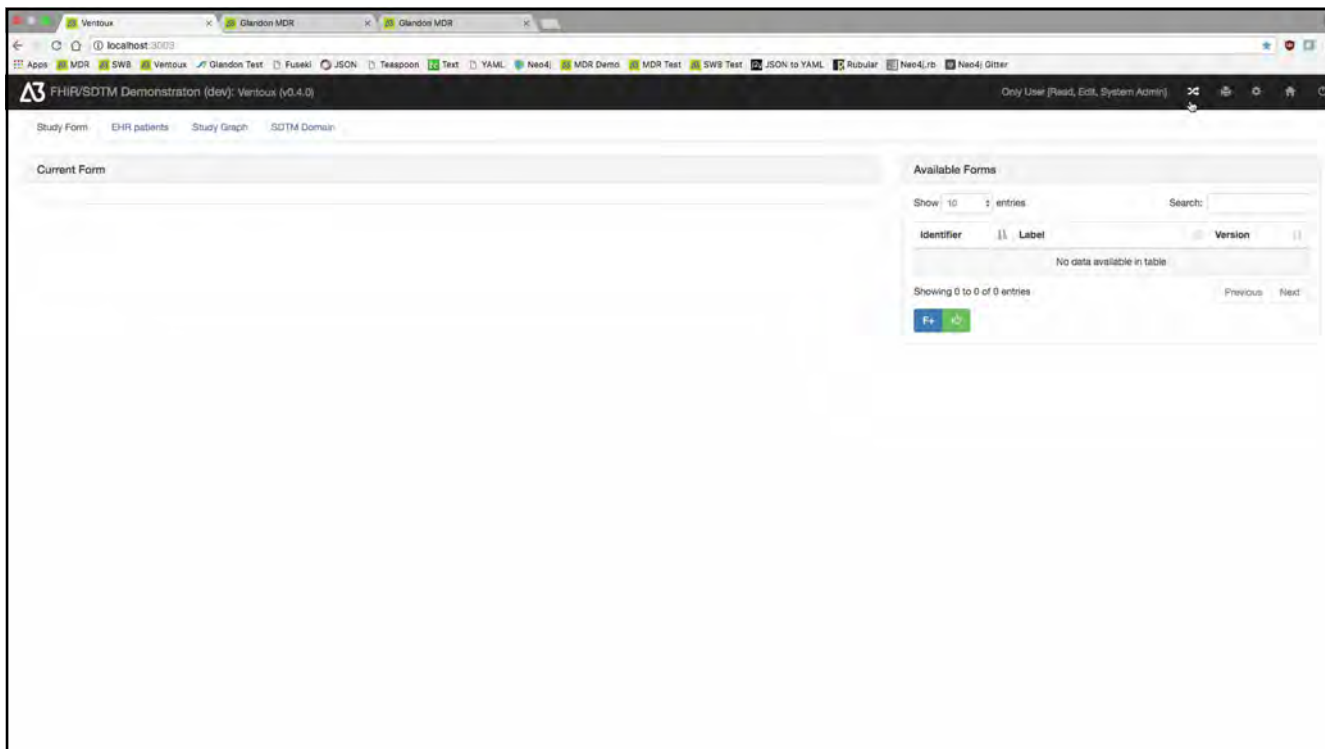
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Demonstration

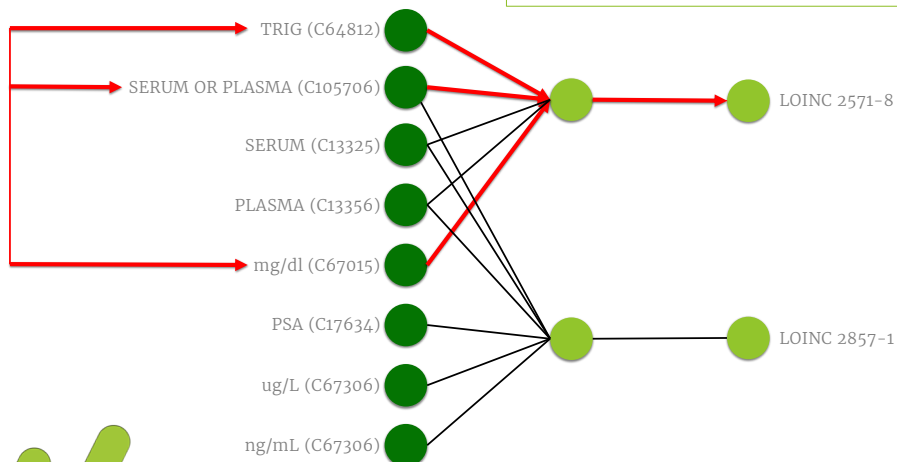


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LOINC Mapping

- 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

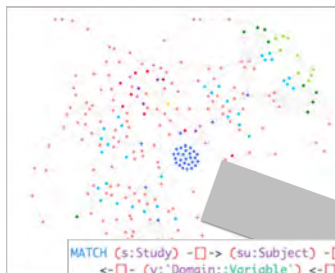
- Driven the EHR requests from the metadata in the BCs used on a 'traditional' CRF:
 - Used the power of the BC and the 'hidden' metadata.
 - The BCs form the backbone, their importance cannot be overstated.
 - Nicely related to FHIR resources. Extracted the data from the FHIR resources.
- Automated 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.

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Data versus Presentation



Important

- The tools focus on the correct data models
- Present the data in the desired user format
- Use query to extract the desired view

```
MATCH (s:Study) -> (su:Subject) -> (bc:BiomedicalConcept) -[*1..5]-> (bcp:"BiomedicalConcept::Property",bcpv:"BiomedicalConcept::PropertyValue")
<-> (v:"Domain::Variable") <-> (d:Domain)
OPTIONAL MATCH (bcp:"BiomedicalConcept::Property") -> (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.uid AS uuid,v.name AS name,bcpv.value as value"
```

STUDYID	SUBJID	USUBJID	DOMAIN	UUID	NAME	VALUE
100001	100001	100001-100001	ADVERSE	100001-100001	ADVERSE	ADVERSE
100001	100001	100001-100001	ADVERSE	100001-100001	ADVERSE	ADVERSE
100001	100001	100001-100001	ADVERSE	100001-100001	ADVERSE	ADVERSE
100001	100001	100001-100001	ADVERSE	100001-100001	ADVERSE	ADVERSE
100001	100001	100001-100001	ADVERSE	100001-100001	ADVERSE	ADVERSE

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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.

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Questions & Answers

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