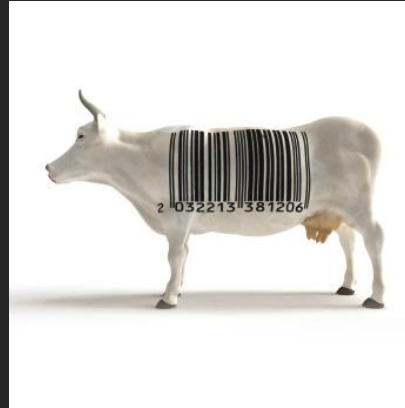


Assessing CDISC Therapeutic Area User Guides in a machine readable format



Johannes Ulander

Standardisation and Harmonisation Specialist

Agenda

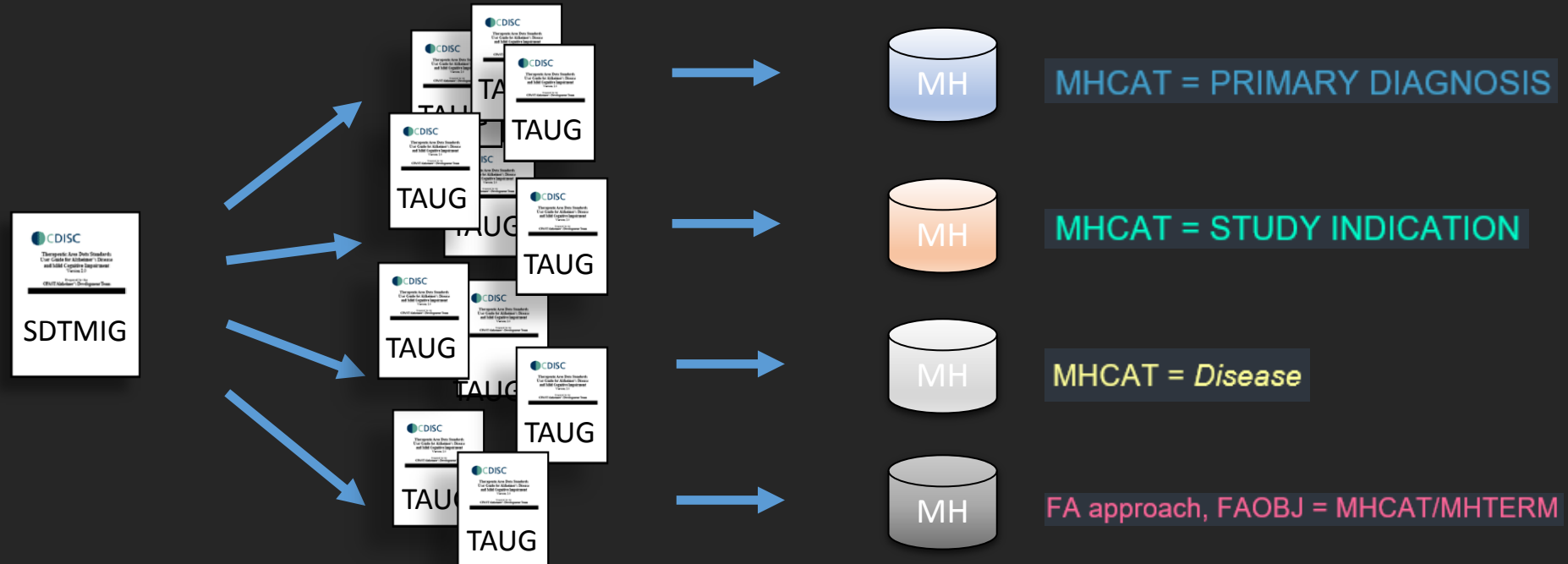
- Background
- A Biomedical Concept for Medical History
- Seeing is believing?
- Impact on standards management
- Conclusions

Background

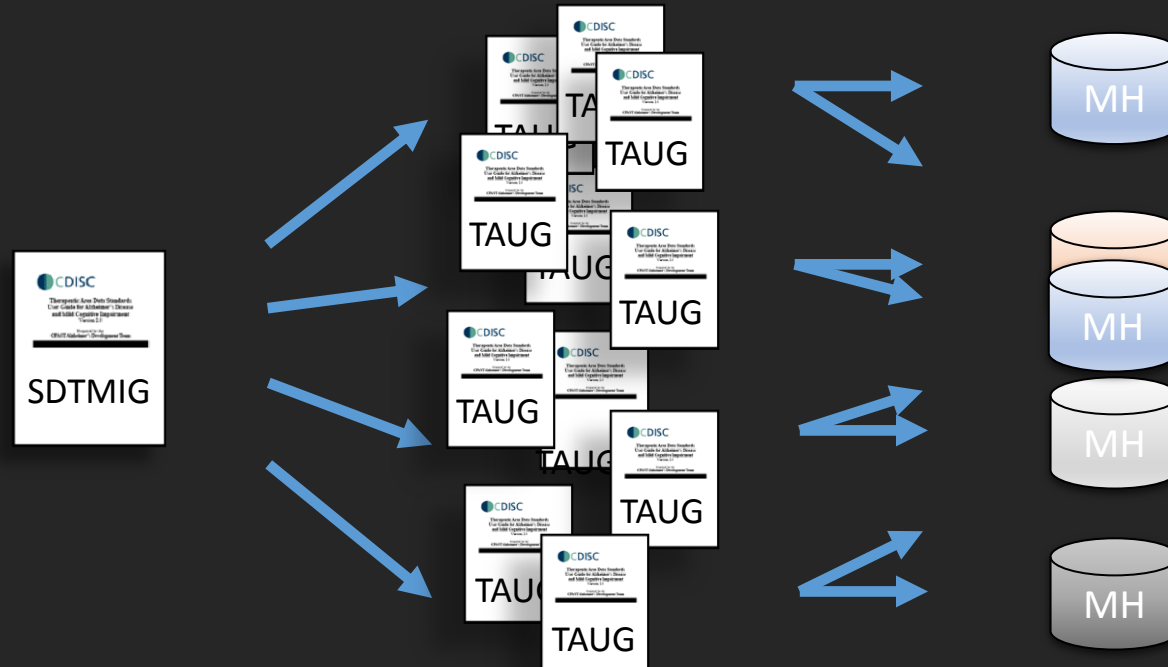
- TAUG Comparison
- Explore
 - CDISC SHARE export
 - Semantic Web
 - Metadata Repository
 - Biomedical Concept
- Impact on standards management
- “There is no such thing as a free lunch”

1. MHCAT = PRIMARY DIAGNOSIS
2. MHCAT = STUDY INDICATION
3. MHCAT = *Disease*
4. FA approach, FAOBJ = MHCAT/MHTERM

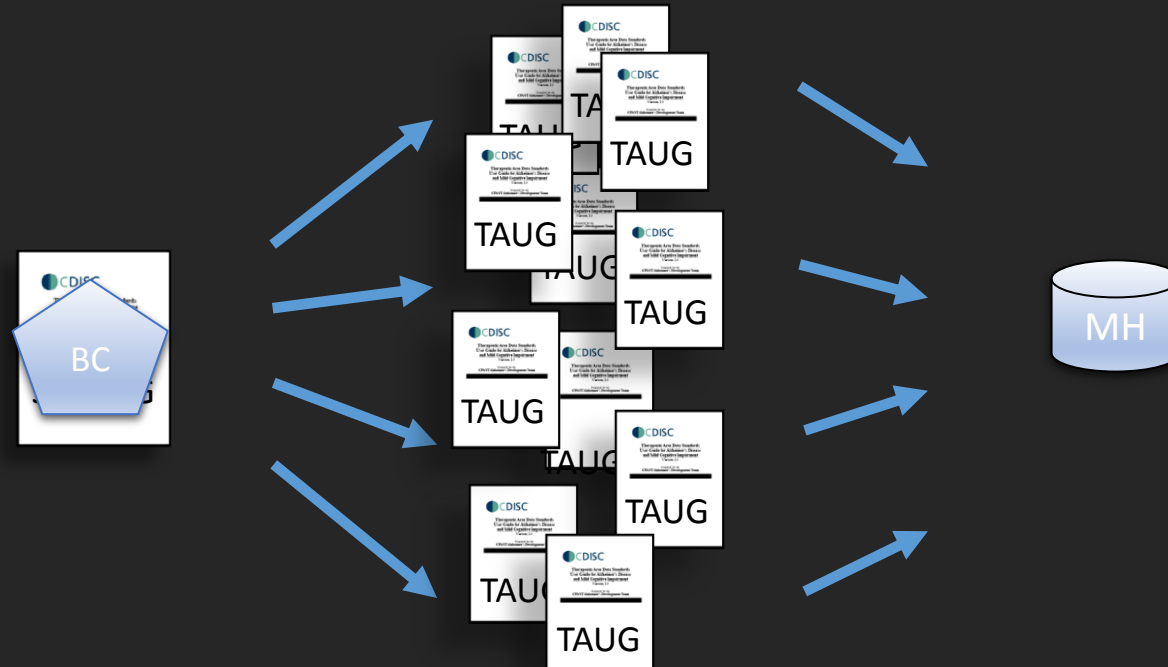
Current setup



Pro presets setup



Proposed setup



One BC to find them

One BC to bind them

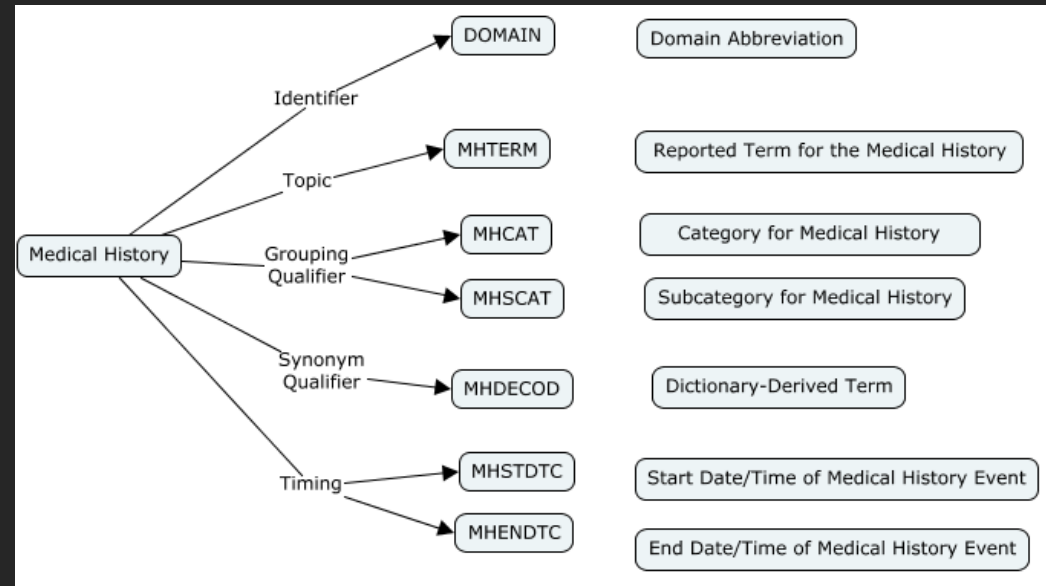
One BC to bring them all, and in ~~the darkness~~ bind them

everlasting happiness = standards



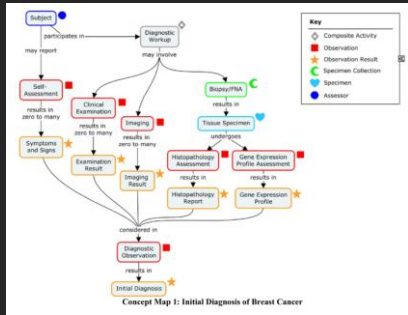
Creating a Biomedical Concept for MH

Symptoms
Diagnosis
Signs
Diagnosis
Date of
Symptom
Sign
Exacerbation
Staging

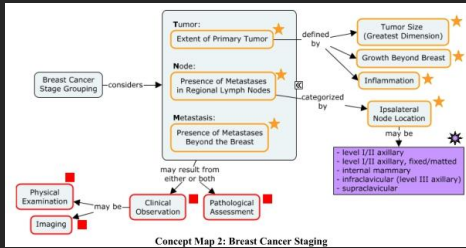


Grandparents
Mother
Father
Gender
Family history
Son
Daughter
Genes
Histopathology
Assessments
Report
Diagnostic procedures
Biopsy
Imaging
Examinations

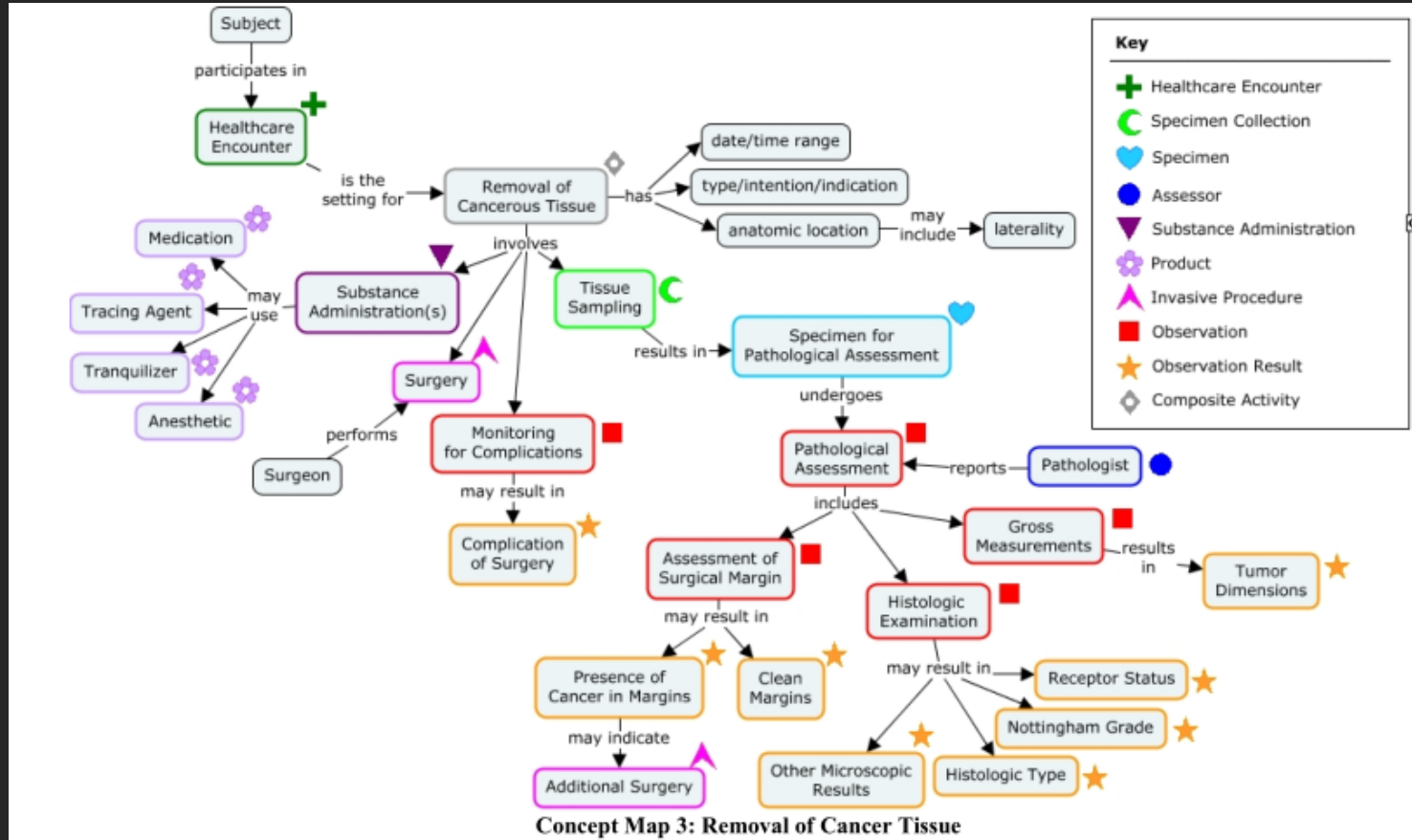
chronic
acute
recurrent
Disease type



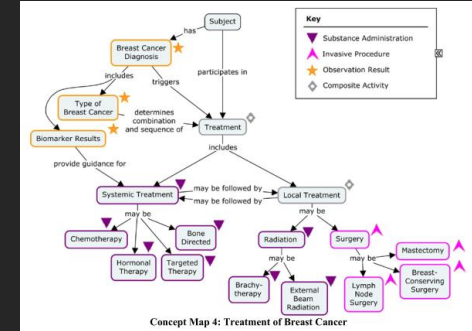
Diagnosis



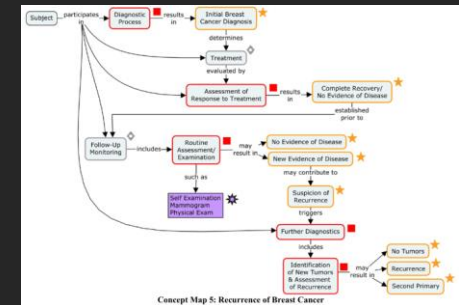
Staging



Concept Map 3: Removal of Cancer Tissue

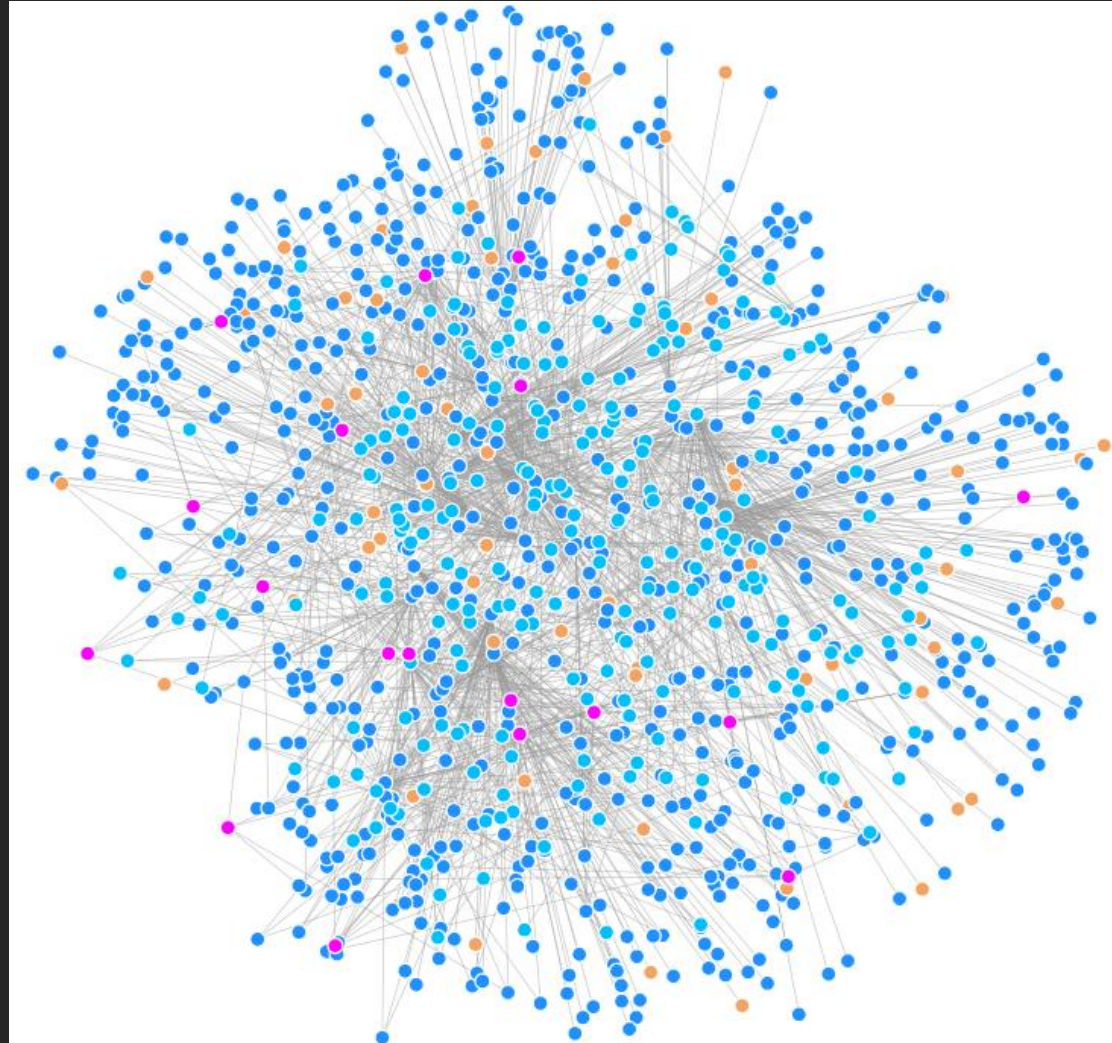


Treatment



Recurrence

Seeing is believing?

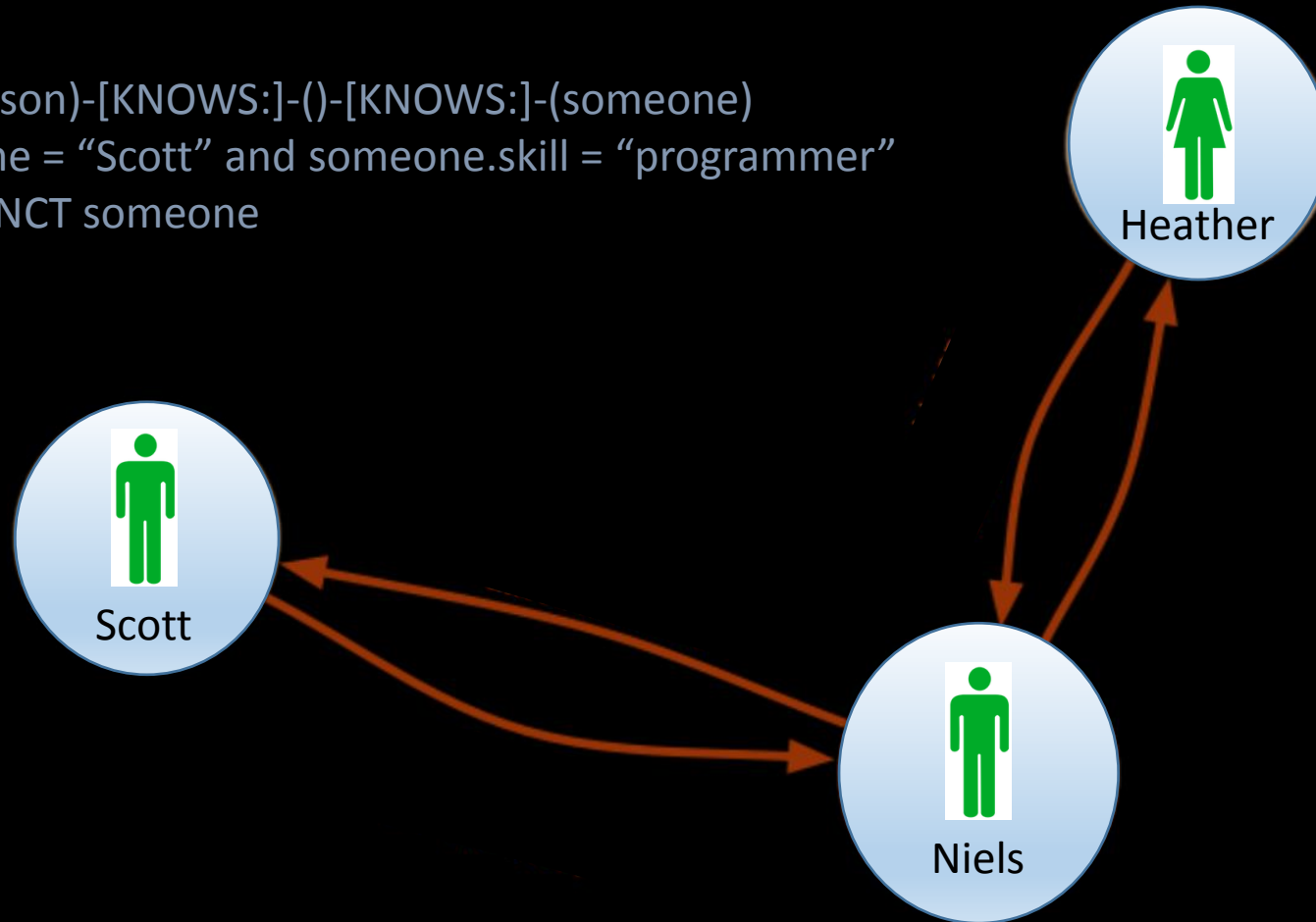


Need some help

- Scott knows Niels
 - Niels knows Heather
 - Heather is a good programmer
-
- Can you help Scott find a good programmer?
 - With a program?

Graphs

```
MATCH (js:Person)-[KNOWS:]-()-[KNOWS:]- (someone)  
WHERE js.name = "Scott" and someone.skill = "programmer"  
RETURN DISTINCT someone
```

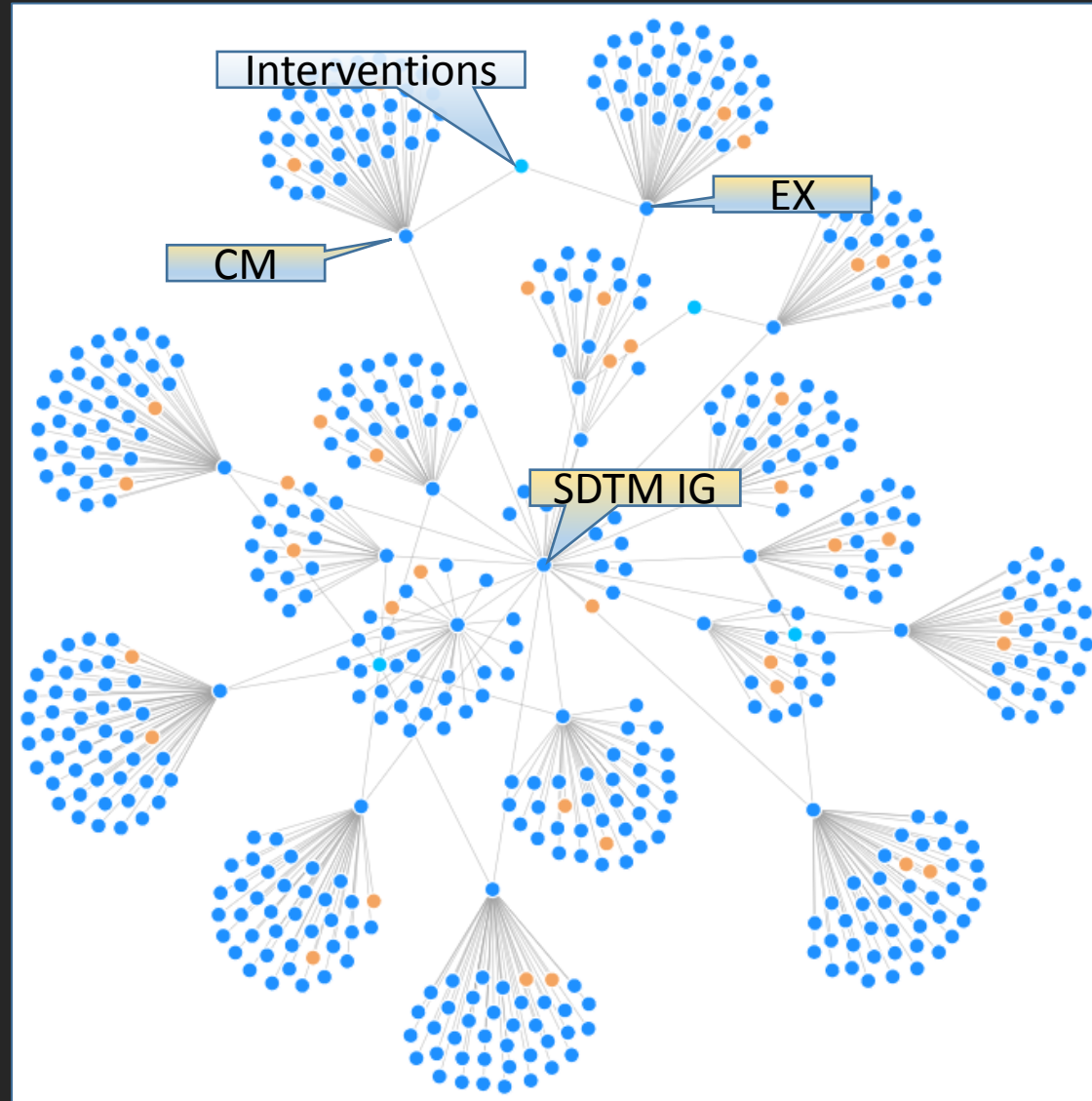


Graph – SDTM IG

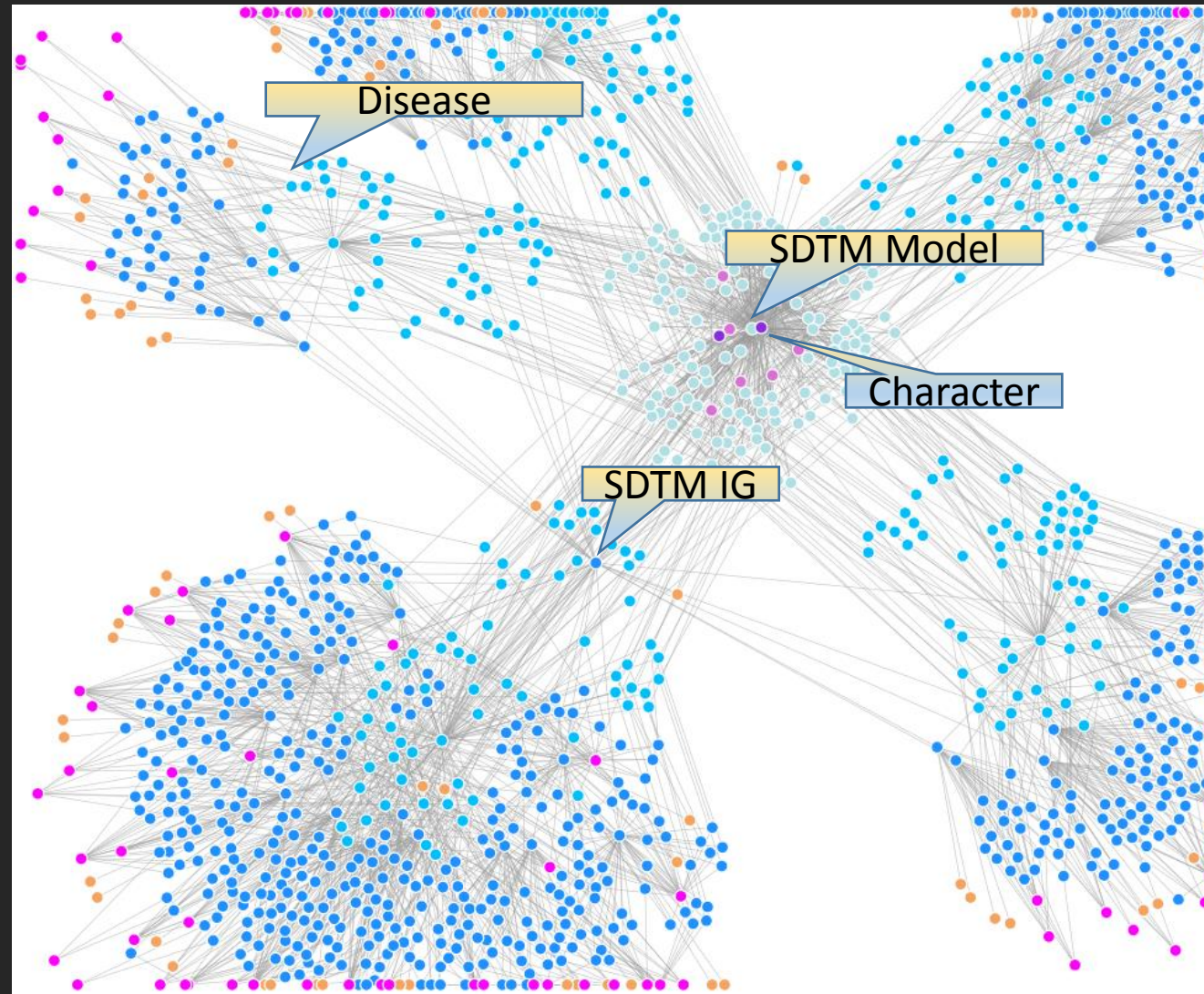
Detailed Metadata Graph:



Graph - SDTM IG



Graph - SDTM IG



Impact analysis

Code List Item Changes

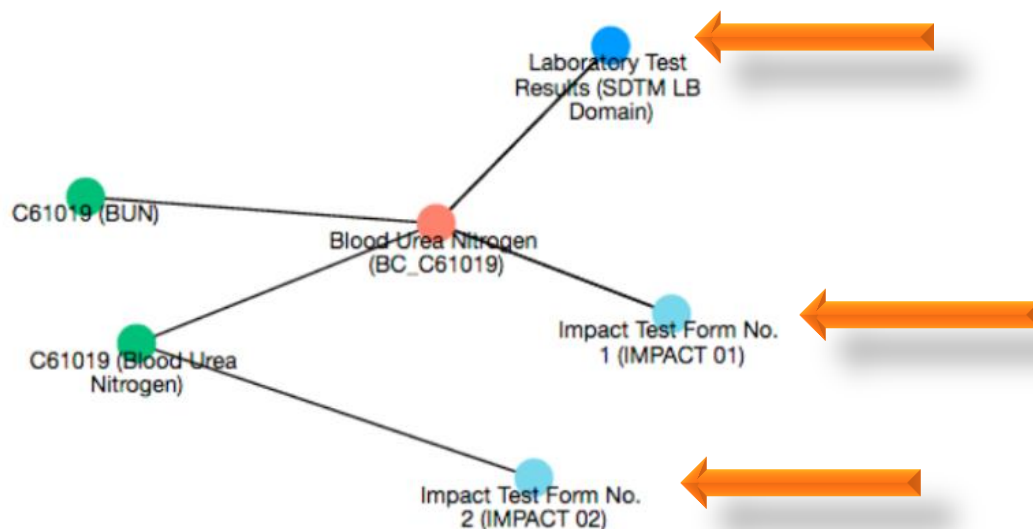
Show 10 entries

Search: urea nitrogen

[illegible]

Impact analysis

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



Code List Item

Code List:	C65047
Identifier:	C61019
Label:	Blood Urea Nitrogen Measurement
Submission Value:	BUN

... and further impact on ADaM and results ...

Conclusions

- SHARE exports in semantic formats can be utilised
- Using Semantic technology in an MDR together with Biomedical Concepts helps standards management
 - Version management
 - Impact analysis
- Tools that we trust are important

Metadata and Traceability



 Thank you for listening

And a special thanks to Dave Iberson-Hurst for letting us try the Glandon MDR