

Knowledge Models as Silver Bullet for Quality Intelligence

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Setting the Scene

- **CDISC** – Clinical Data Interchange Standards Consortium
- **SEND** – Standard for Exchange of Non-clinical Data
- Used as metadata in research and FDA approval processes
- Published quarterly since 2011 as .xls, .txt, .xml and (since 2013) RDXML

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C74456		Yes	Anatomical Location	LOC	Anatomical Location	Terminology codelist used for anatomical location within CDISC.	CDISC SDTM Anatomical Location Terminology
C32042	C74456		Anatomical Location	ACETABULUM	Acetabulum	Two cup shaped areas, one each on the lateral side of the lower pelvis that house the head of the femur to form the ball and socket joint of the hip. (NCI)	Acetabulum
C32043	C74456		Anatomical Location	ACHILLES TENDON		The tendon that, in general, attaches the gastrocnemius muscle to the calcaneous bone in the tarsus.	Achilles Tendon
C32047	C74456		Anatomical Location	ACROMIOCLAVICULAR JOINT	Acromioclavicular Joint	The junction of the upper distal end of the scapula to the distal edge of the collarbone, also known as the acromion and the clavicle. (NCI)	Acromioclavicular Joint
C32048	C74456		Anatomical Location	ACROMION	Acromion	The upper distal process of the scapula. (NCI)	Acromion
C102285	C74456		Anatomical Location	ACUTE MARGINAL ARTERY	ACUTE MARGINAL ARTERY SEGMENT(S); AMARG	The arteries that arise at the junction of the proximal and mid-right coronary artery conduit segments.	Acute Marginal Artery

Challenge

Is the CDISC term „atrial septum“ still valid?

How was „atrial septum“ labeled in 2019?

What is the new term for the outdated term „interatrial septum“?

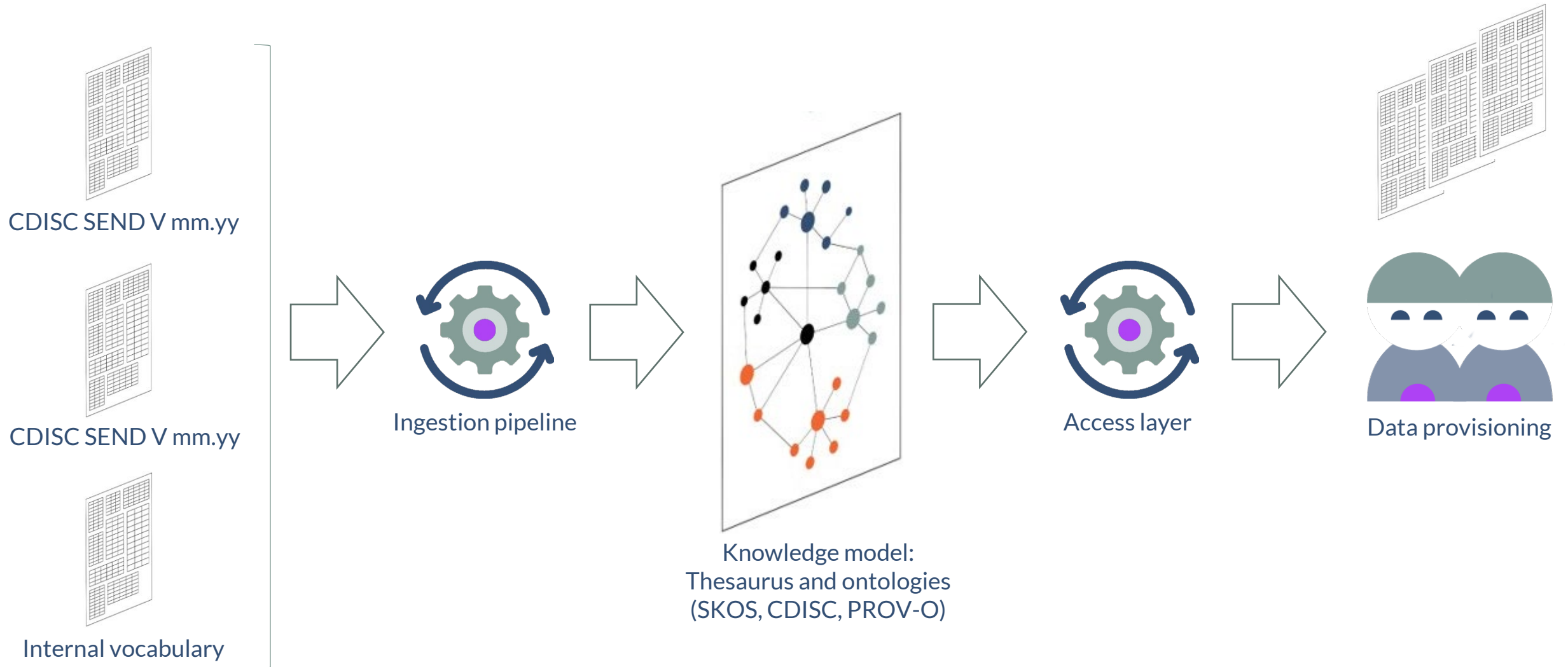
How is a data set classified wrt to a given standard such as CDISC SEND, version 23?

What is the CDISC equivalent to our internal term „heart“?

How can data, classified wrt to different versions of a standard, be compared and analyzed?

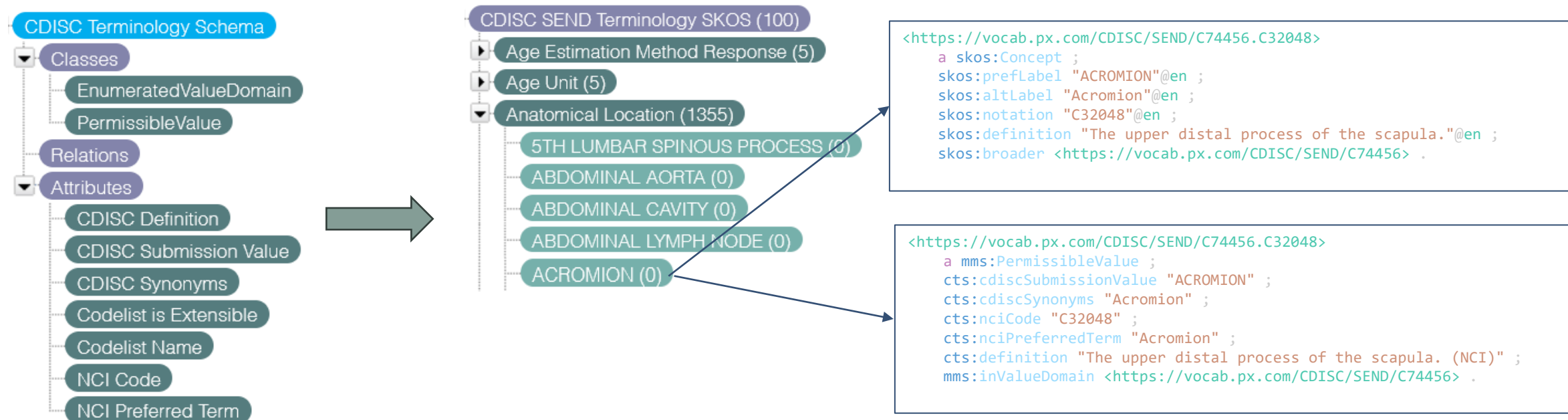


Our Solution: Overview





■ Adding a SKOS layer on top:



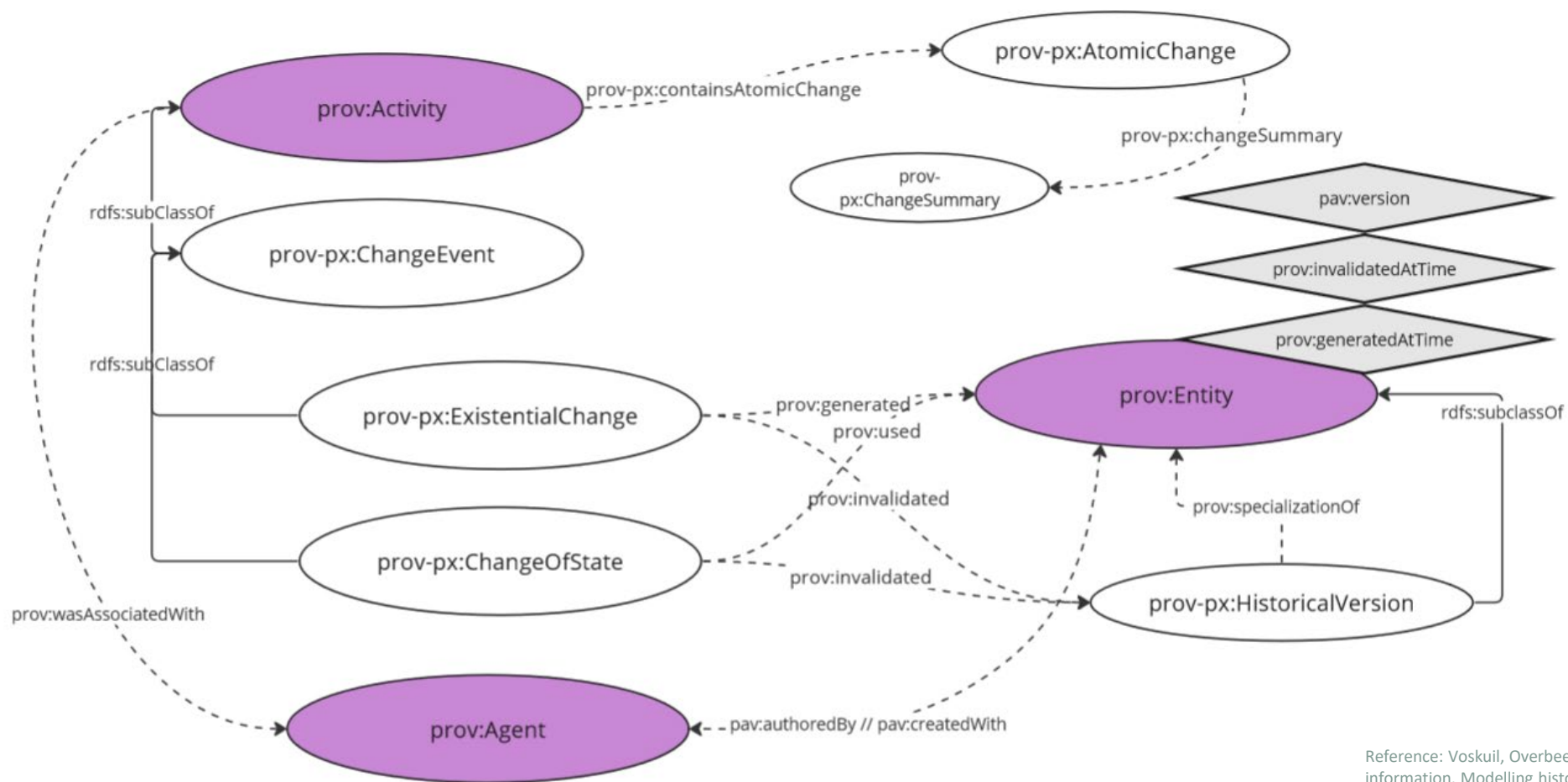
CDISC SEND: Changelog



- 19303 changes over 49 updates since initial release

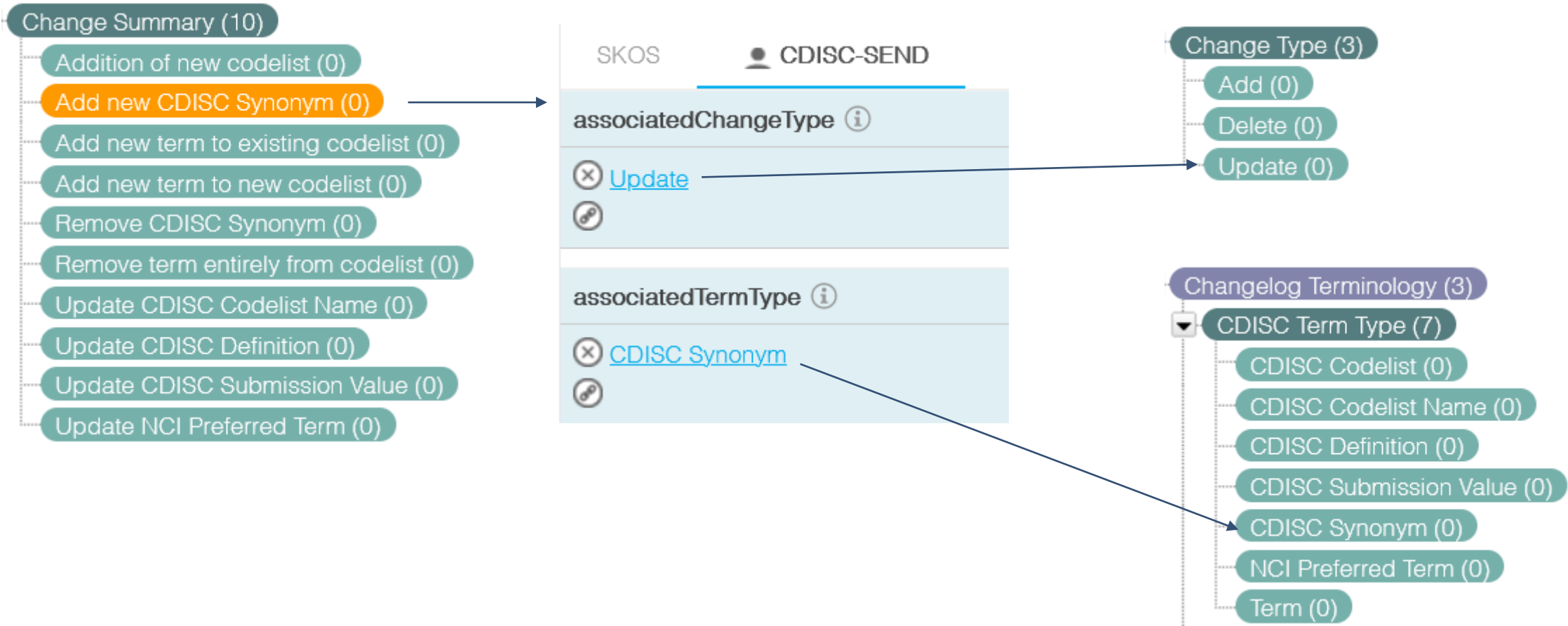
Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2022-06-24	CDISC-5038	Add	C175951	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	---	Magnesium, Ionized	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble CD120b	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNF Receptor 1B	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNFR1B	
2022-06-24	CDISC-5529	Remove	C117844	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Monoclonal Protein Spike	---	C117844 being merged into C92291

Versioning Ontology



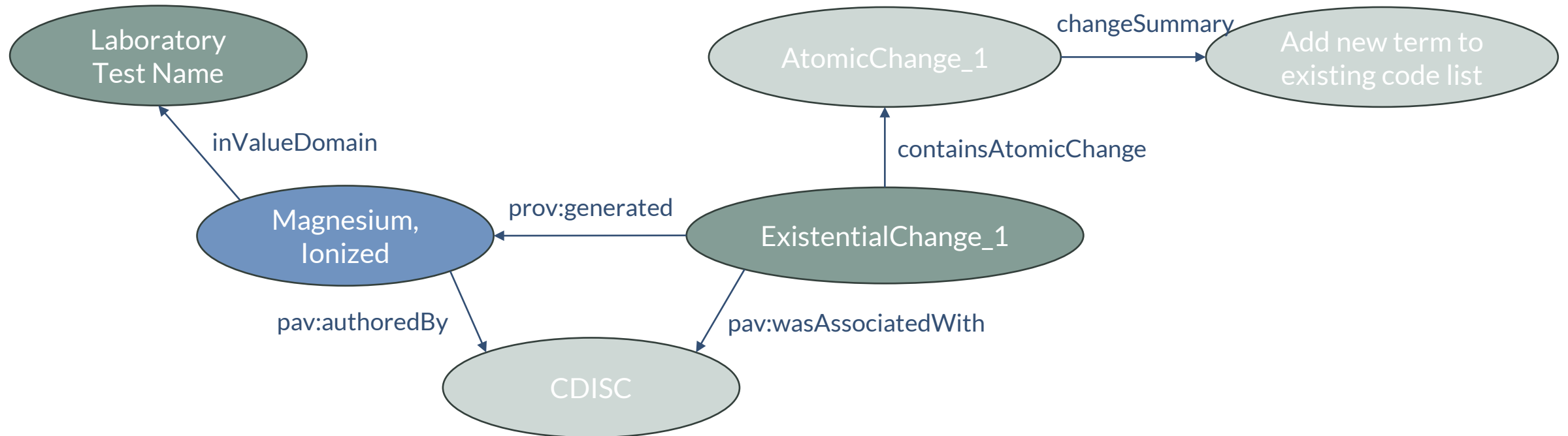
Reference: Voskuil, Overbeek & van Opijnen: A knowledge graph for government information. Modelling history with PROV-O. Semantics 2022.
<https://www.koopoverheid.nl/voor-overheden/rijksoverheid/plooi-platform-open-overheidsinformatie>

Versioning Terminology



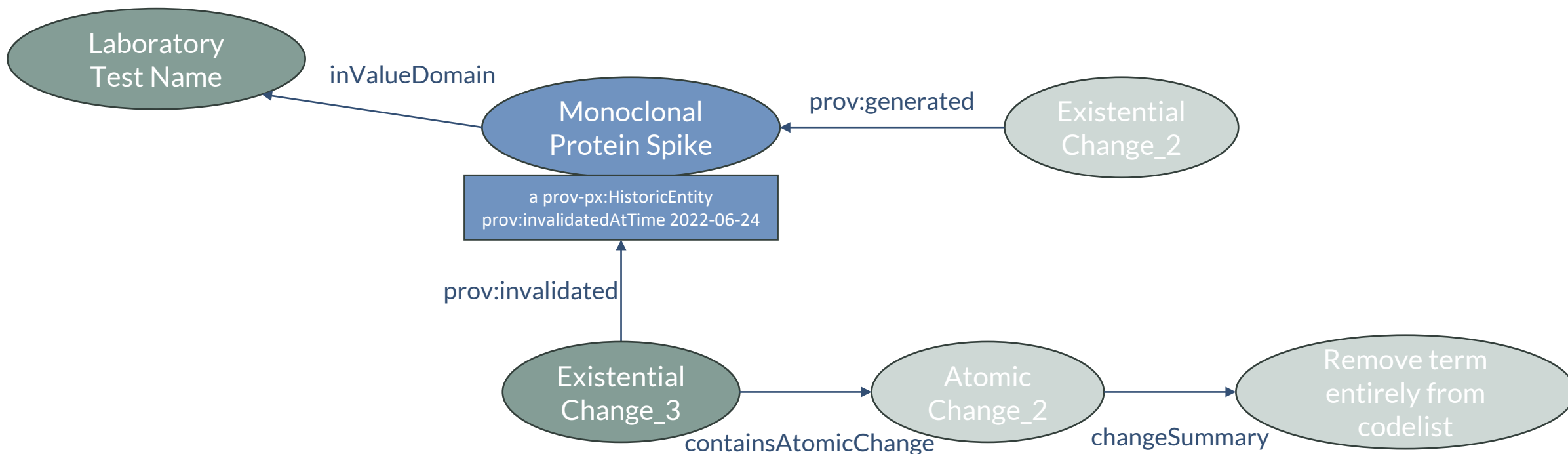
Deep Dive: Create

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
24.06.2022	CDISC-5038	Add	C175951	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Magnesium, Ionized	



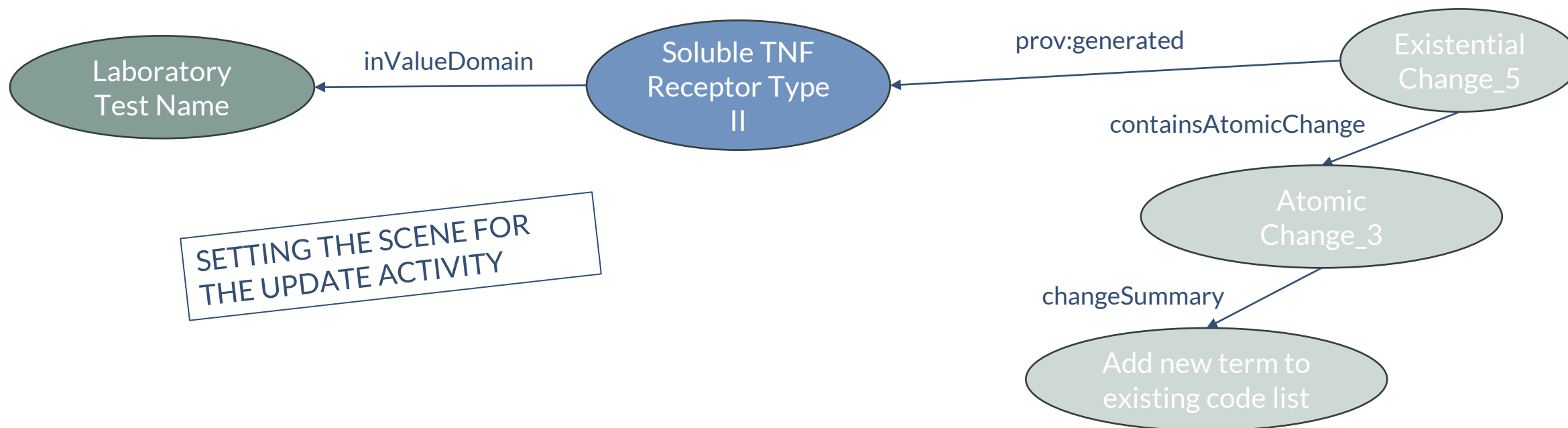
Deep Dive: Delete

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
24.06.2022	CDISC-5529	Remove	C117844	Term	LBTEST	Laboratory Test Name	Remove term entirely from codelist	Monoclonal Protein Spike	---	C117844 being merged into C92291



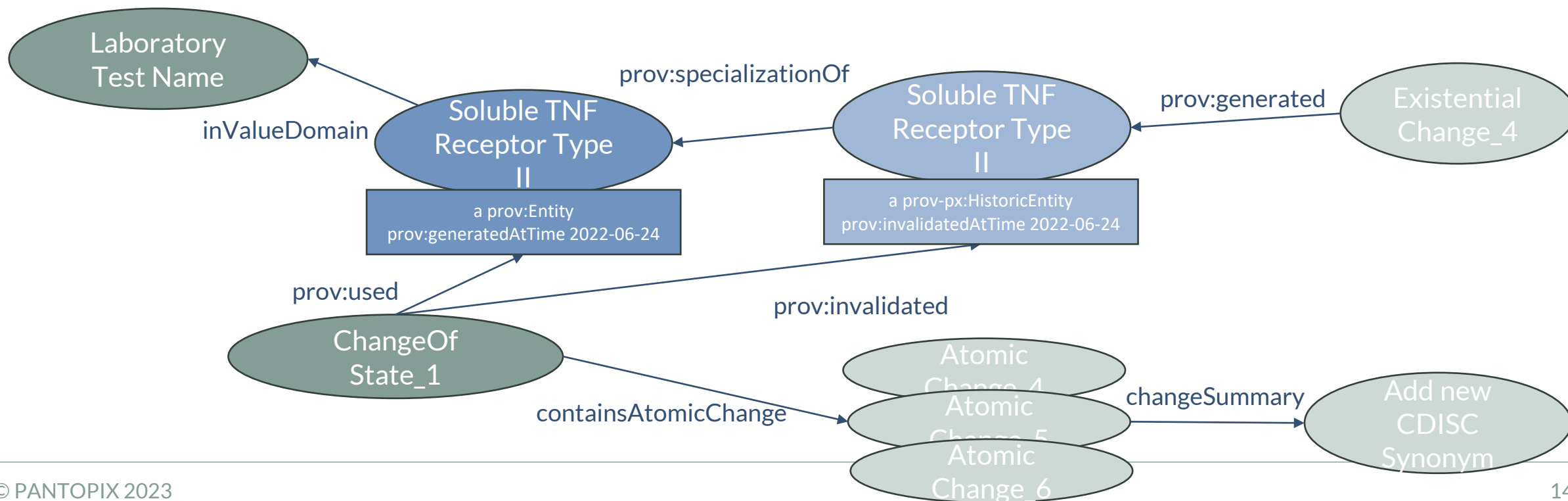
Deep Dive: Update I

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble CD120b	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNF Receptor 1B	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNFR1B	



Deep Dive: Update II

Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New	Change Implementation Instructions
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble CD120b	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNF Receptor 1B	
2022-06-24	CDISC-5064	Update	C117864	CDISC Synonym	LBTEST	Laboratory Test Name	Add new CDISC Synonym	---	Soluble TNFR1B	



Look inside



DEMO CONTROLLED VOCABULARY SEARCH

Enter search term ... **Find** **Save Search**

?

DEMO CONTROLLED VOCABULARY SEARCH

Q Oral **Find** **Save Search**

- Oral (Route of Administration Response)
- Oral Cavity (Anatomical Location)
- Oral Gavage (Route of Administration Response)
- Tablet, Orally Disintegrating (Pharmaceutical Dosage Form)
- Temporal (Directionality)

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DEMO CONTROLLED VOCABULARY SEARCH

Q Oral **Find** **Save Search**

BROWSE BY

- > A - Z
- > Quality Management System

< Back to main page Sort by ...

Search results (list view)

1 - Oral (Route of Administration Response)	view details...
2 - Oral Cavity (Anatomical Location)	view details...
3 - Oral Gavage (Route of Administration Response)	view details...
4 - Tablet, Orally Disintegrating (Pharmaceutical Dosage Form)	view details...

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DEMO CONTROLLED VOCABULARY SEARCH

Q Oral **Find** **Save Search**

BROWSE BY

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 - Archives
 - Aseptic Manufacturing
 - Audits and Inspections
 - ...
 - Knowledge Management
 - ...
 - Technical Transfer

< Back to main page Sort by ...

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DEMO CONTROLLED VOCABULARY SEARCH

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 - ...
 - Knowledge Management
 - ...
 - Technical Transfer

< Back to previous page Sort by ...

Details

Belongs to Codelist: Route of Administration Response	NCI Code C38268
CDISC Submission Value Oral	NCI Preferred Term Oral Route of Administration
CDISC Definition Administration to or by way of the mouth. (FDA)	Synonyms Intraoral Route of Administration PO
Term introduced: 01.01.2011	
Valid until: Today	

Internal Source:
• Source 1
• Source 2

External Source:
• Source 1
• Source 2

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DEMO CONTROLLED VOCABULARY SEARCH

Q Oral Cavity **Find** **Save Search**

BROWSE BY

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< Back to previous page Sort by ...

Details

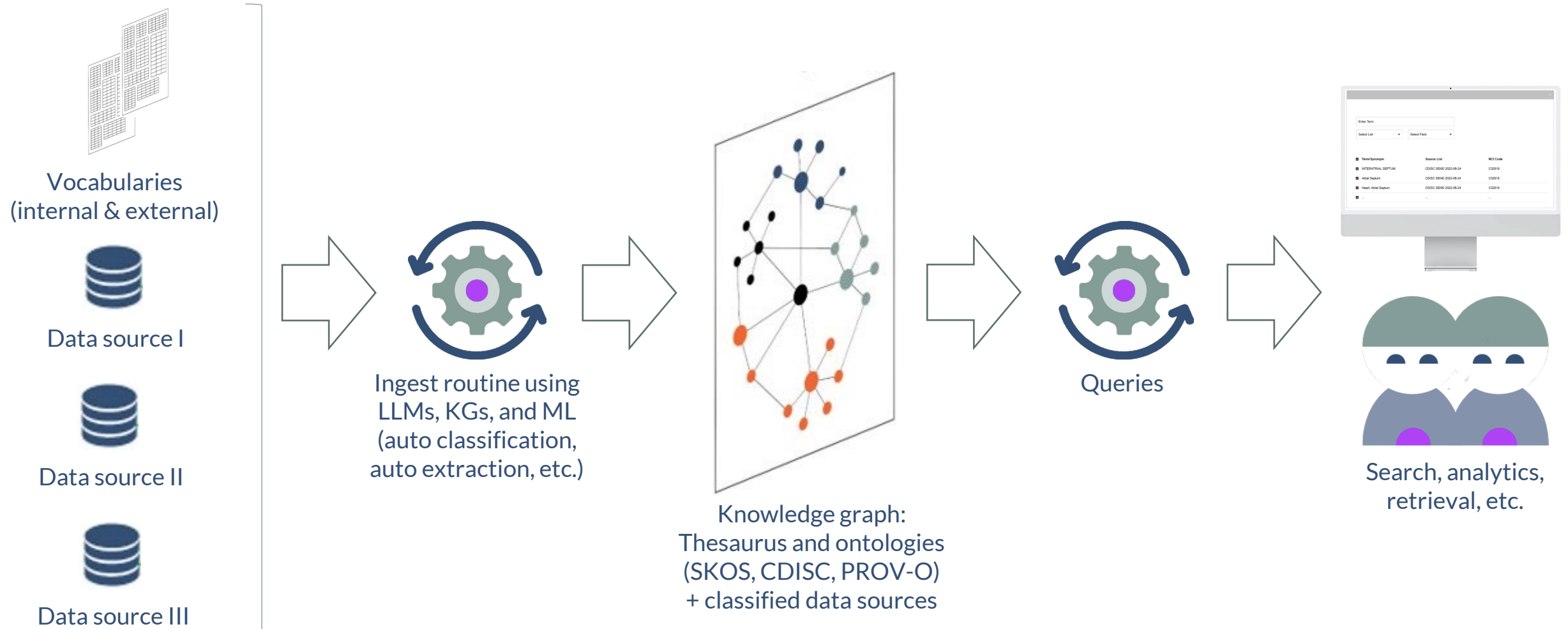
Belongs to Codelist: Anatomical Location	NCI Code C12421
CDISC Submission Value Oral Cavity	NCI Preferred Term Oral Cavity
CDISC Definition The cavity of the mouth.	CDISC Synonyms Buccal cavity Mouth
Term introduced: 01.01.2011	
Valid until: Today	

Internal Source:
• Source 1
• Source 2

External Source:
• Source 1
• Source 2

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Look ahead



Thank you very much!



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