2020/11/20 医療情報学連合大会での発表内容

臨床研究に貢献する統制用語集の管理
- ATHENA standardized vocabularies

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RCT vs RWD

RCT

- 👍 適応交絡を排除するGold standard
- 👍 内的妥当性が高い

- 👎 被験者数が少ない
  併存症、併用療法、高齢者、小児、産婦などの除外ケース多数
- 👎 コスト高・長期間に渡る追跡

RWD

- 👍 外的妥当性が高い
- 👍 被験者数が多い （但し、ビッグデータが手に入る場合のみ）
- 👍 低コスト、実施可能性高い

- 👎 交絡がある状態
- 👎 妥当性低 (Validation研究が必要)
- 👎 **データ品質低・欠損**
- 👎 高信頼性かつ高セキュリティのシステム管理の要求

RWDを用いた臨床研究の課題

従来はRCTがGold Standard. ビッグデータを使った観察研究(Observational Study)は，新たなバイアスを生み出している，新しいエビデンス導出のための手法の開発が必要.

(1)RWDからのETL手法の標準化

(2)異なるDWHの構造

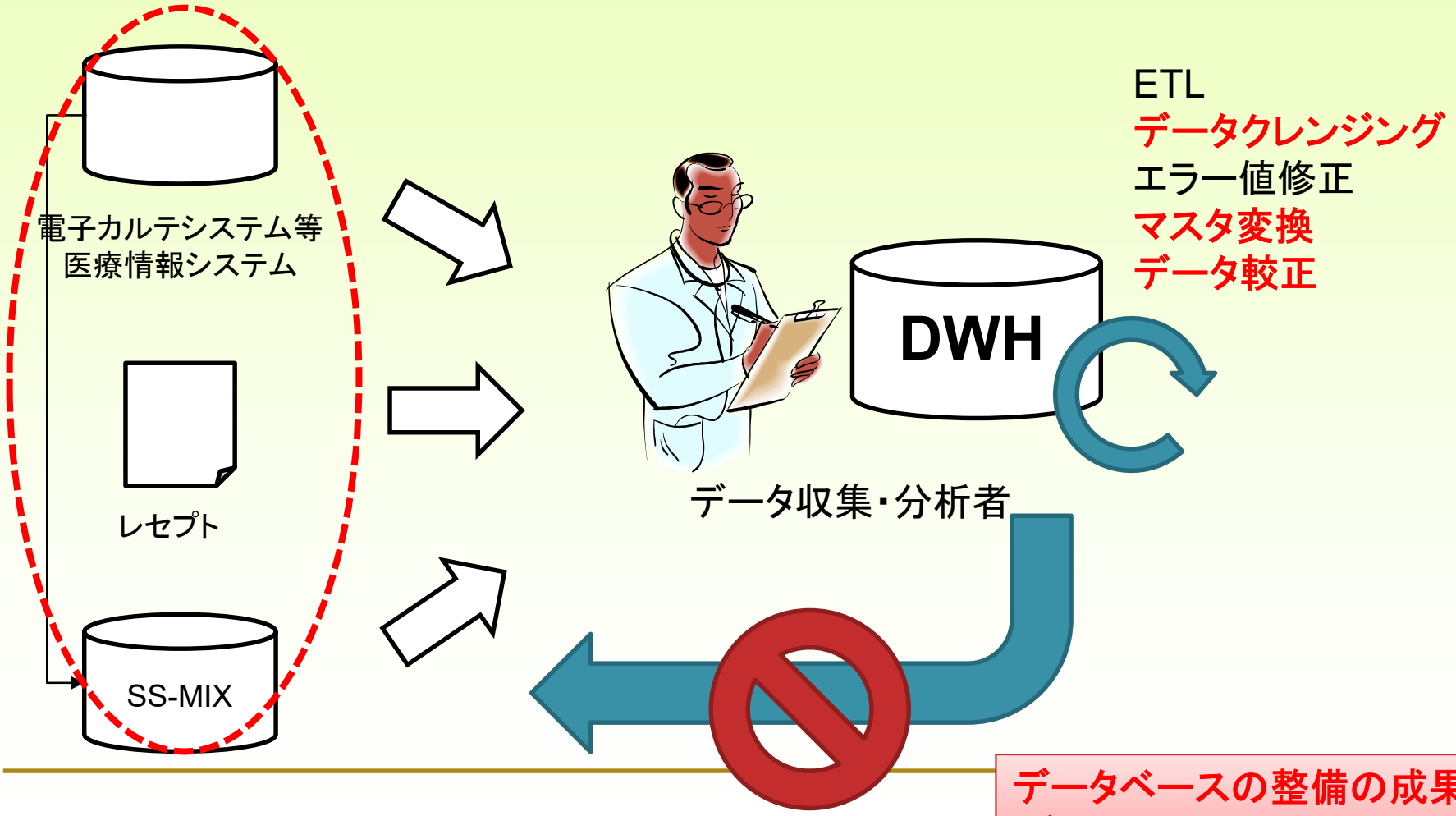
(3)RWDデータの素性の特定と品質改善

(4)RWDの収集対象と時系列上の網羅性

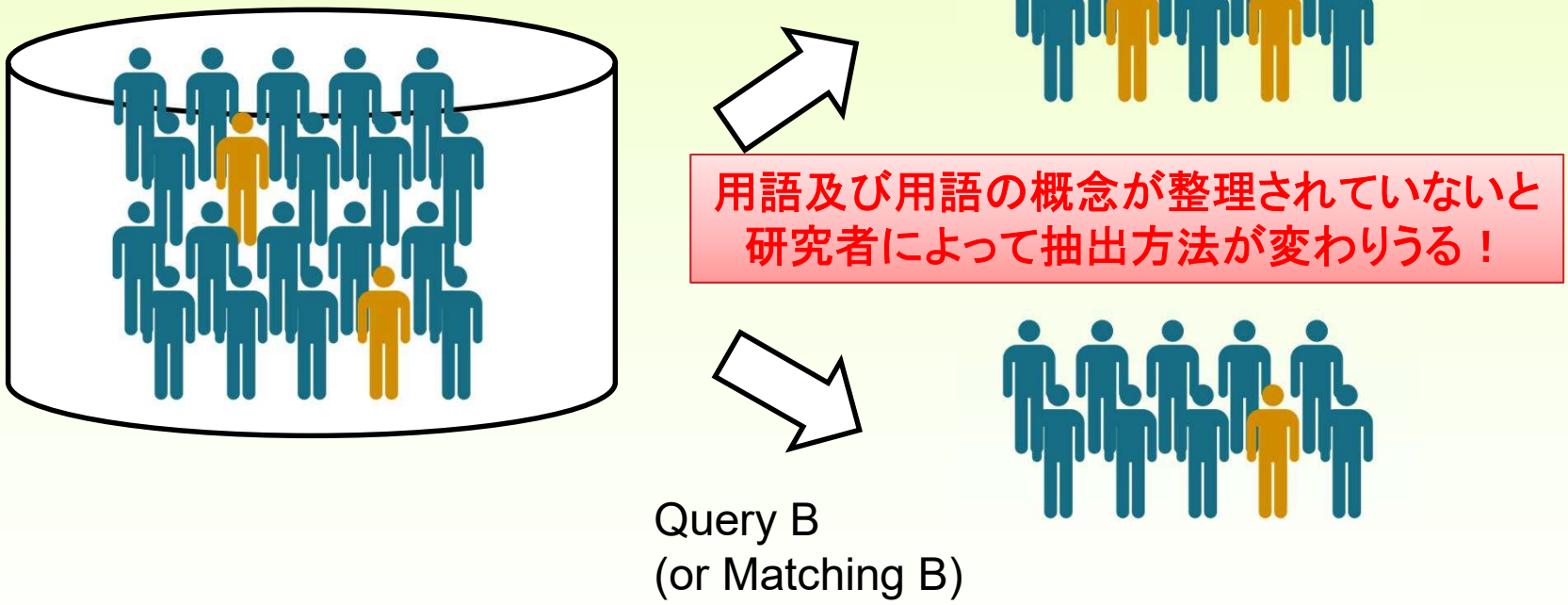
(5)コホートを適切に定義する方法論

※(4)は悉皆的、かつ継続的に取り組まないと困難で、自主参加ベースの臨床DBの弱点ではある。この弱点は統計的手法である程度克服はできるが・・・

RWDデータの素性の特定と品質改善



コホートを適切に定義する方法論



国際的かつオープンな情報規格：OMOP Common Data Model

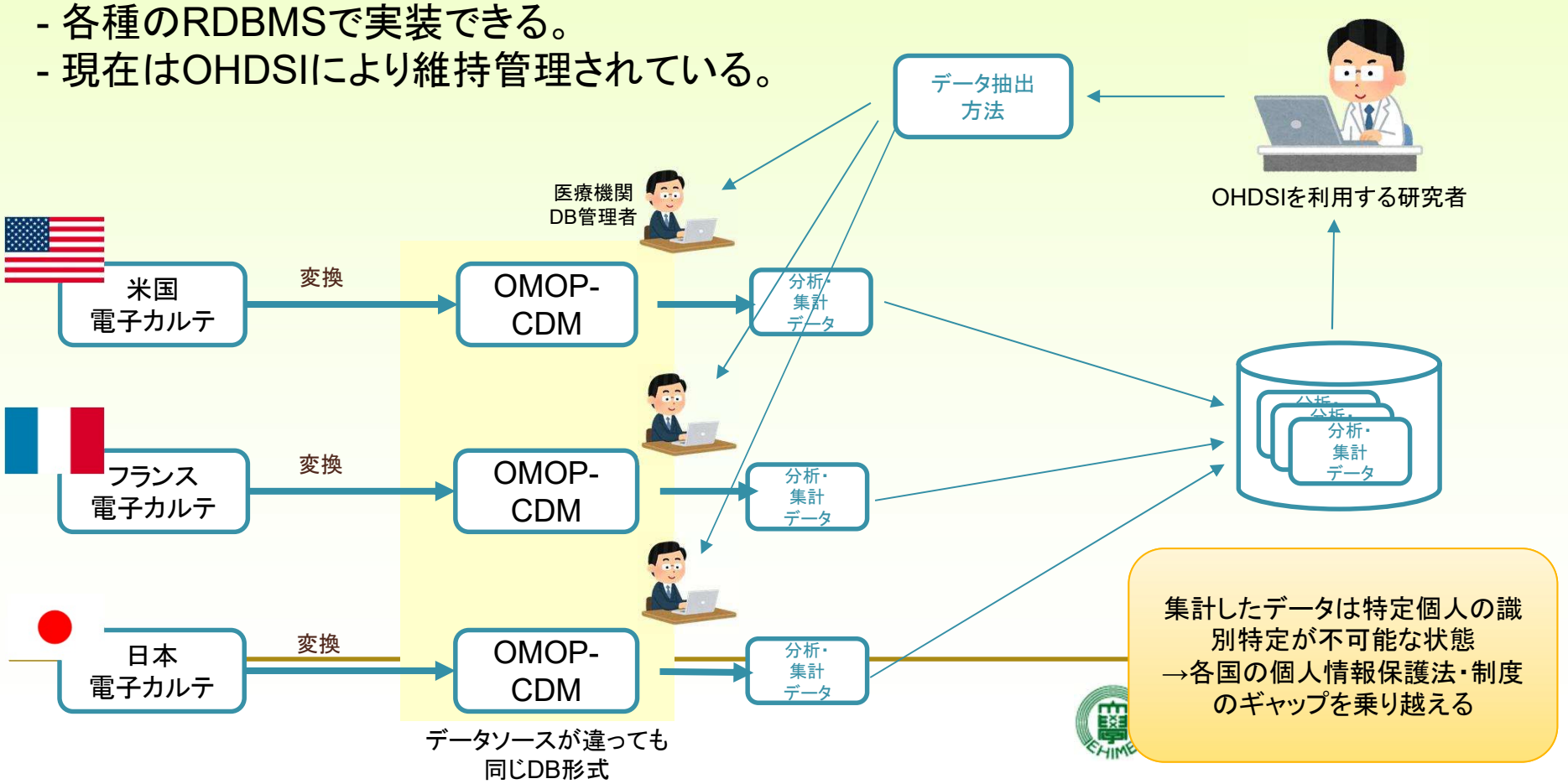
■OMOP-CDM

米団体OMOPが当初開発した、診療情報の分析利用を目的とする、共通の形式・表現をめたパブリックドメインの**Common Data Model**。

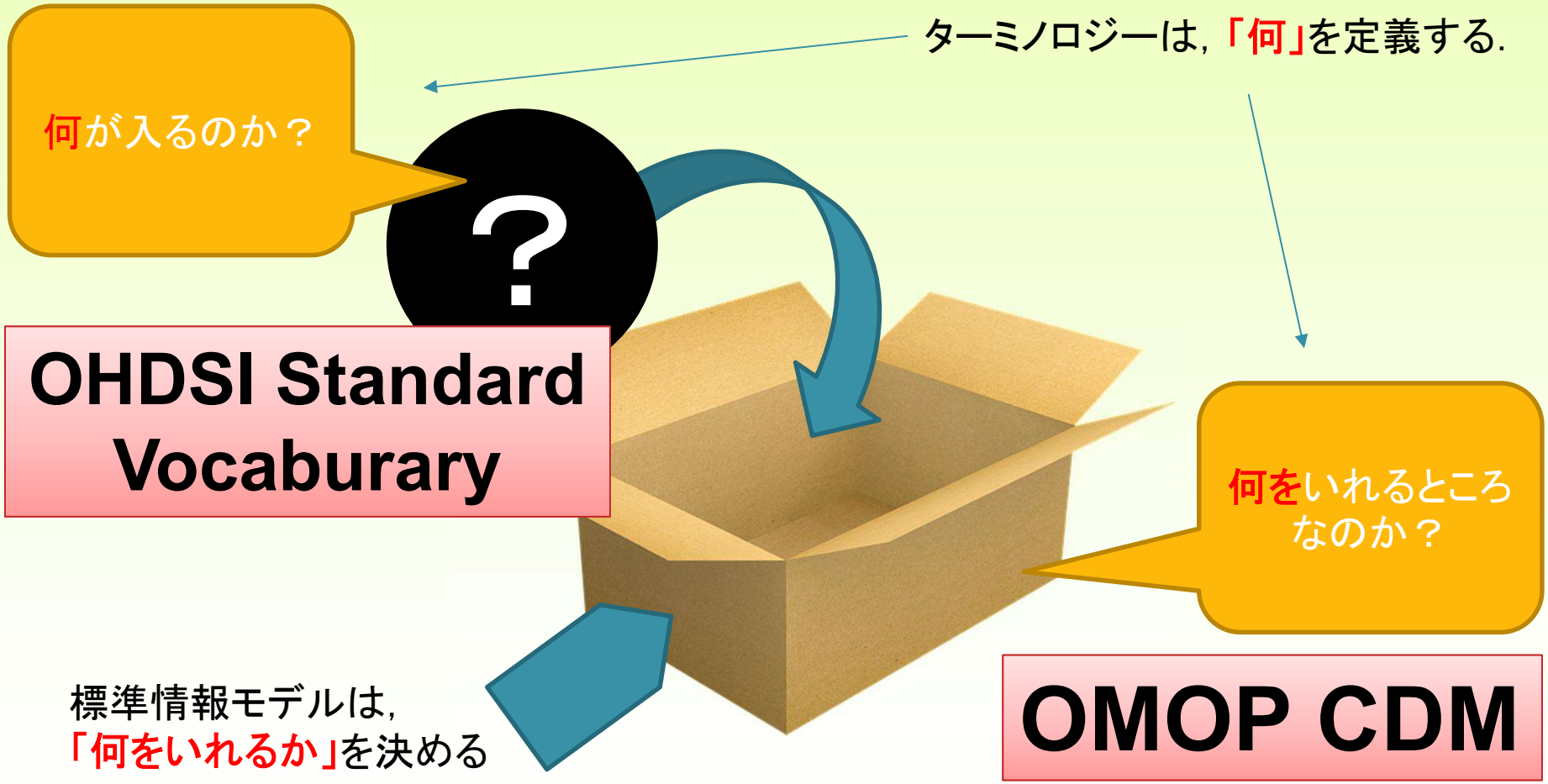
（OMOP: FDAと米製薬企業との過去の共同プロジェクト
“Observational Medical Outcomes Partnership“）

PUBLIC DOMAIN
この作品は著作権法の既知の制約（隣接権や関連する権利を含む）から自由であると特定 されています。この作品は、たとえ営利目的であっても、許可を得ずに複製、改変・翻案、配布、上演・演奏することが出来ます。

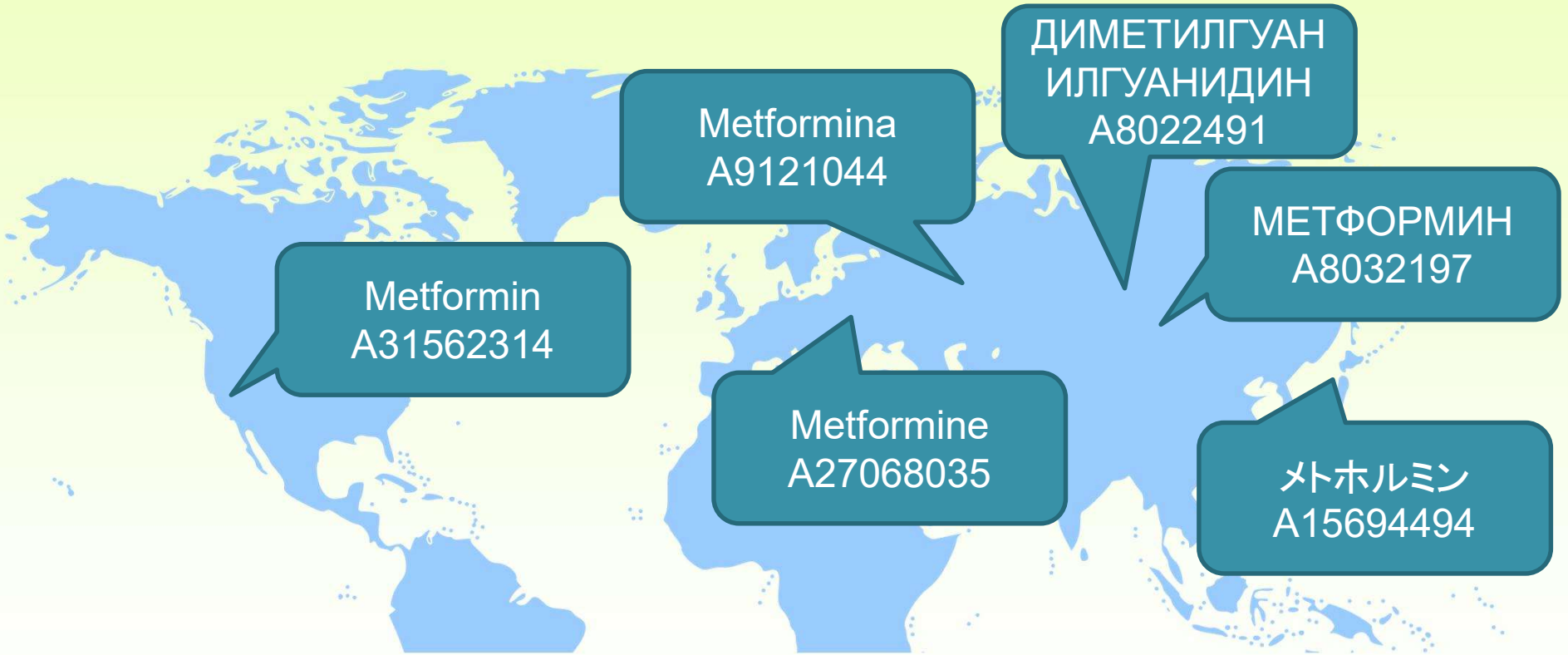
- 各種のRDBMSで実装できる。
- 現在はOHDSIにより維持管理されている。



ターミノロジーと標準情報モデル



国際的研究をするということは
統制用語集間のマッピングも必要



※ Terms with UMLS ATOM code

世界地図 Pixabayからの画像

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OHDSIの統制用語集の管理手法

OMOP standard vocabularies

これらの語彙集に寄せる

Standardised globally

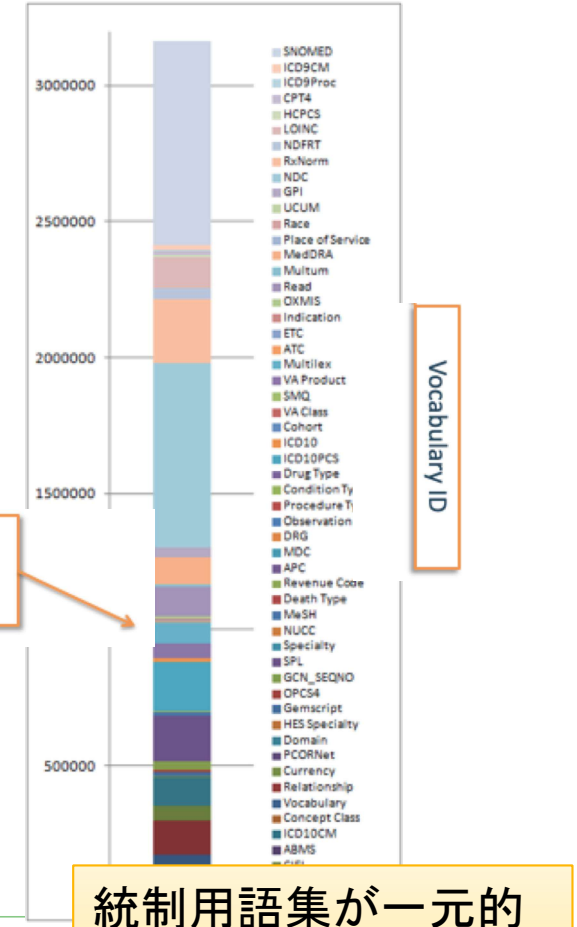
Analytical standards: SNOMED, RxNorm, LOINC

More than 100 'source' vocabularies mapped to the standards

7.4 million concepts

3.0 million standard + 0.5 million classification

Comprehensive hierarchy: ~45 million relationships



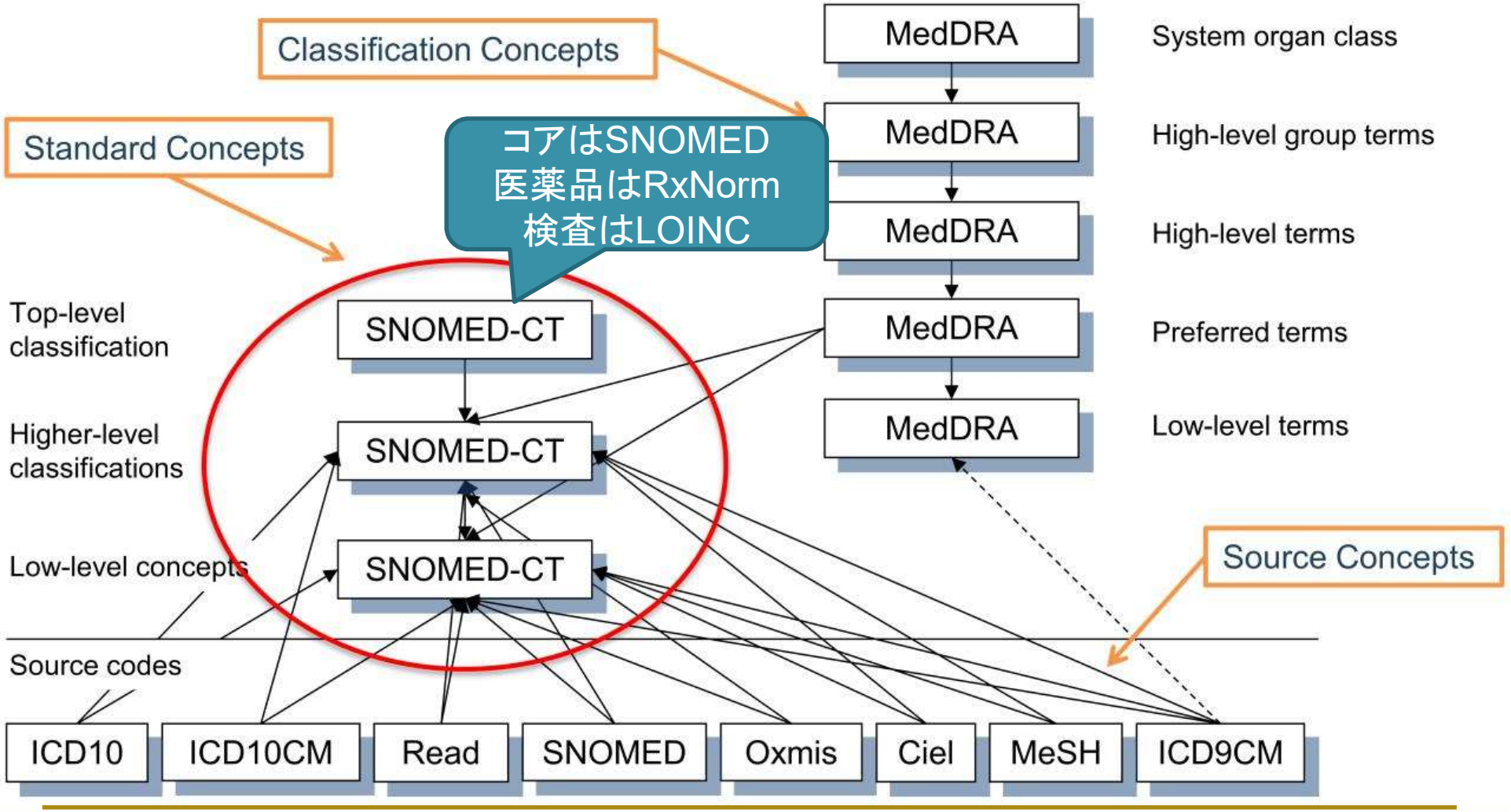
All vocabularies stacked up in one table

統制用語集が一元的に管理されている。Standard Concept / Codeを決めている

Publically available: https://athena.ohdsi.org

Maxim Moinat OHDSI OMOP 12b2 conference
https://www.slideshare.net/MaximMoinat/ohdsi-omop-i2b2-conference-tbingen-2019

OMOP Standard Vocabularyの構成



The Book of OHDSI https://ohdsi.github.io/TheBookOfOhdsi/ExtractTransformLoad.html

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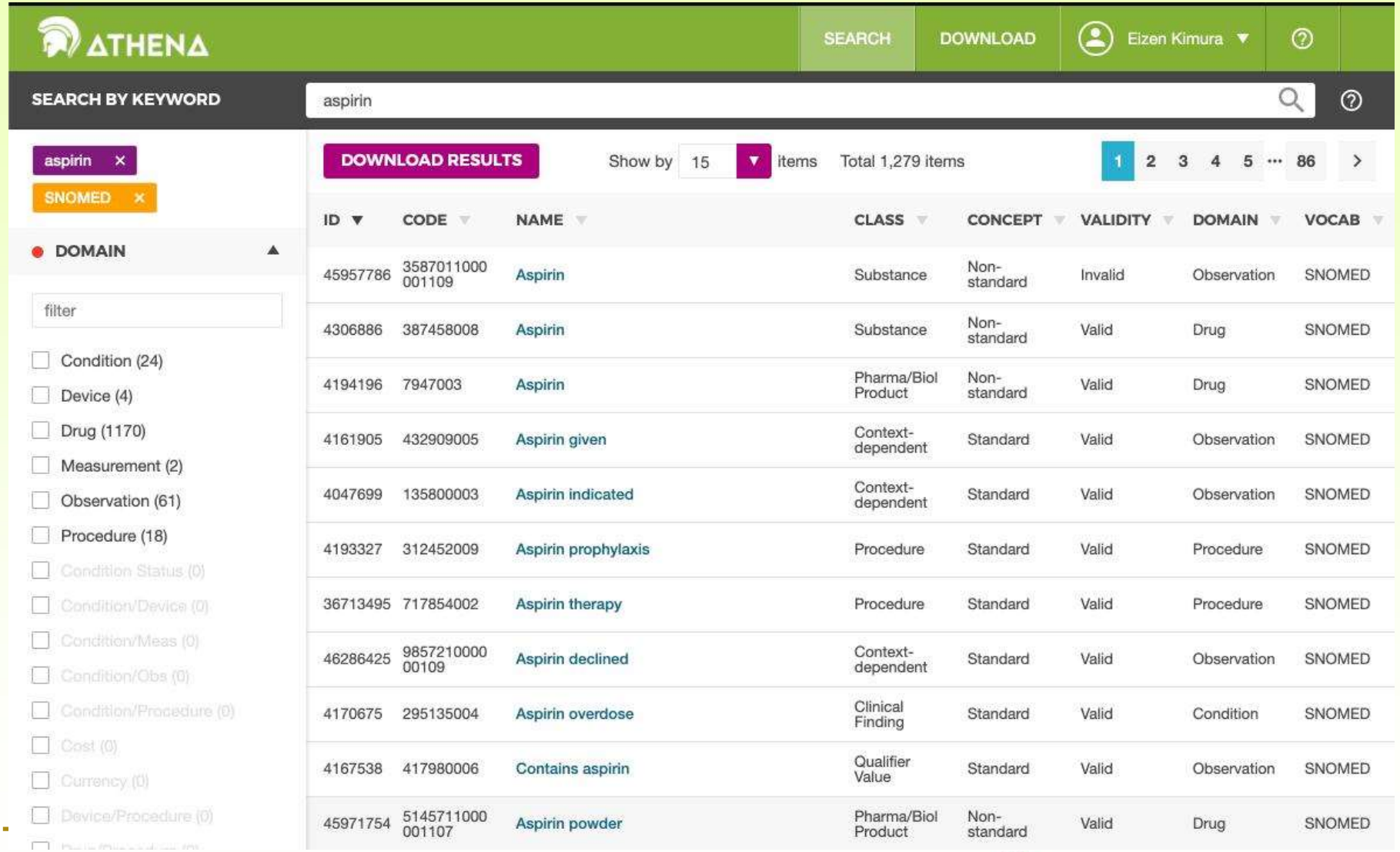
Domains

Condition
Currency
Device
Drug
Ethnicity
Gender
Measurement
Measurement Value
Measurement Value Operator
Metadata
Modifier
Observation
Place of Service
Procedure
Provider Specialty
Race
Relationship
Revenue Code
Route Of Administration
Specimen
Specimen Anatomic Site
Specimen Disease Status
Type Concept
Unit
Visit
Combination Domains

Aspirin とドメイン



ID	CODE	NAME	CLASS	CONCEPT	VALIDITY	DOMAIN	VOCAB
45957786	3587011000001109	Aspirin	Substance	Non-standard	Invalid	Observation	SNOMED
4306886	387458008	Aspirin	Substance	Non-standard	Valid	Drug	SNOMED
4194196	7947003	Aspirin	Pharma/Biol Product	Non-standard	Valid	Drug	SNOMED
4161905	432909005	Aspirin given	Context-dependent	Standard	Valid	Observation	SNOMED
4047699	135800003	Aspirin indicated	Context-dependent	Standard	Valid	Observation	SNOMED
4193327	312452009	Aspirin prophylaxis	Procedure	Standard	Valid	Procedure	SNOMED
36713495	717854002	Aspirin therapy	Procedure	Standard	Valid	Procedure	SNOMED
46286425	9857210000 00109	Aspirin declined	Context-dependent	Standard	Valid	Observation	SNOMED
4170675	295135004	Aspirin overdose	Clinical Finding	Standard	Valid	Condition	SNOMED
4167538	417980006	Contains aspirin	Qualifier Value	Standard	Valid	Observation	SNOMED
45971754	5145711000001107	Aspirin powder	Pharma/Biol Product	Non-standard	Valid	Drug	SNOMED

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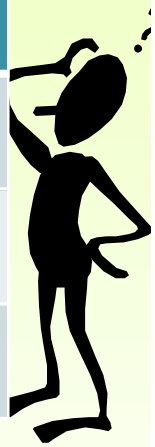
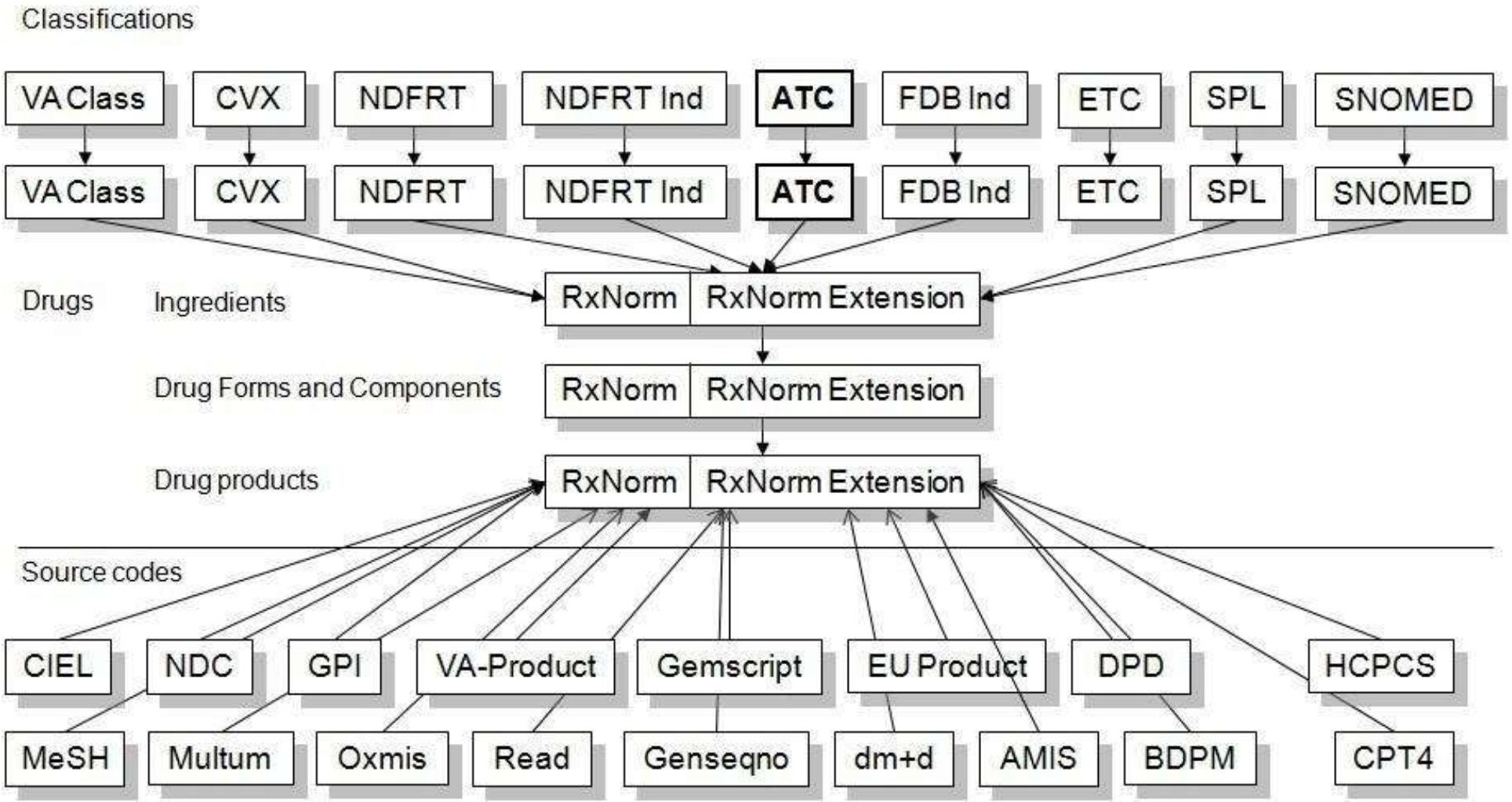
日本がOHDSIに参加するには・・・

Japan	OHDSI Standard Vocaburary
医薬品HOTコードマスター	RxNorm Extension
ICD10対応標準病名マスター	SNOMED-CT
臨床検査マスター	LOINC



- Ontologyに関する基礎的な知識
- OHDSI Standard Vocaburaryで採用されている統制用語集に関する知識
- 臨床的概念を調査・理解できる能力

RxNorm Extension



https://www.ohdsi.org/web/wiki/doku.php?id=documentation:vocabulary:drug

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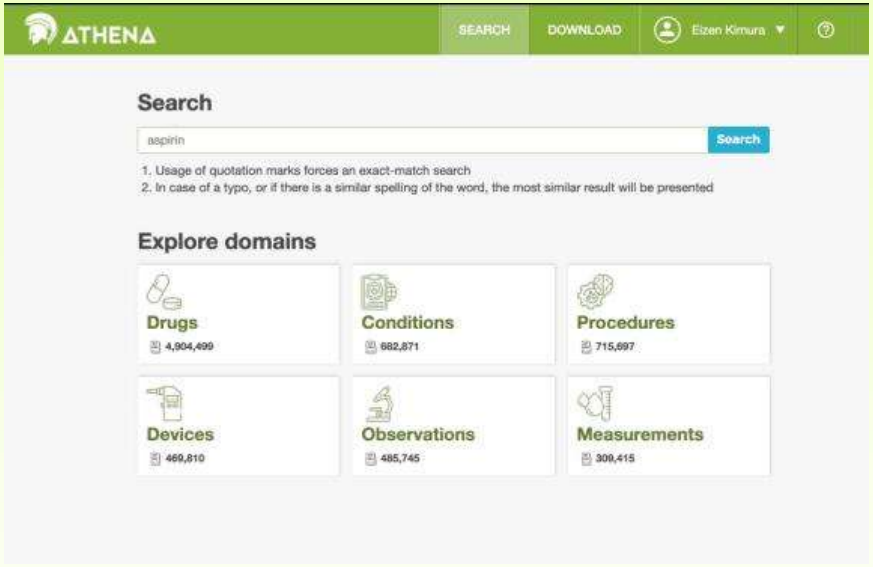
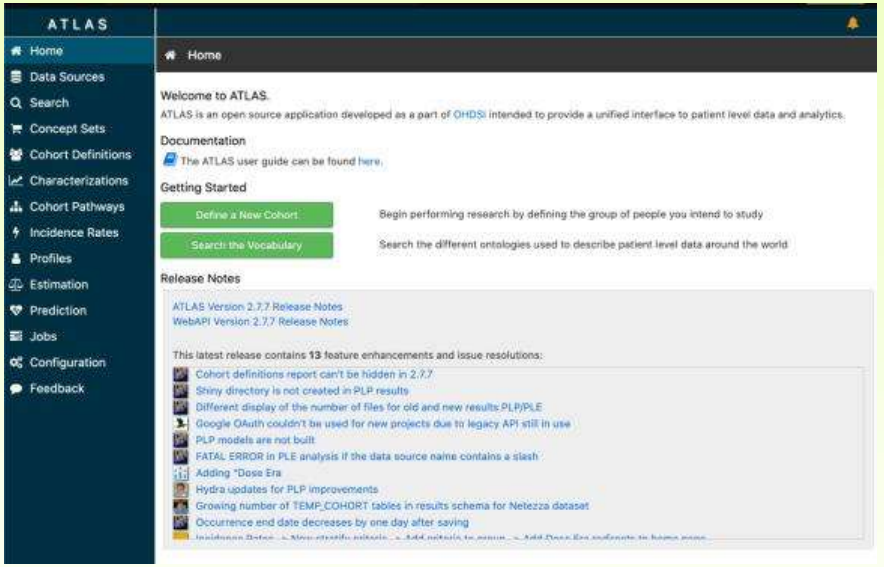
OHDSI Tools

ATHENA



OHDSI Vocaburary Browser

ATLAS



Phenotyping Tool

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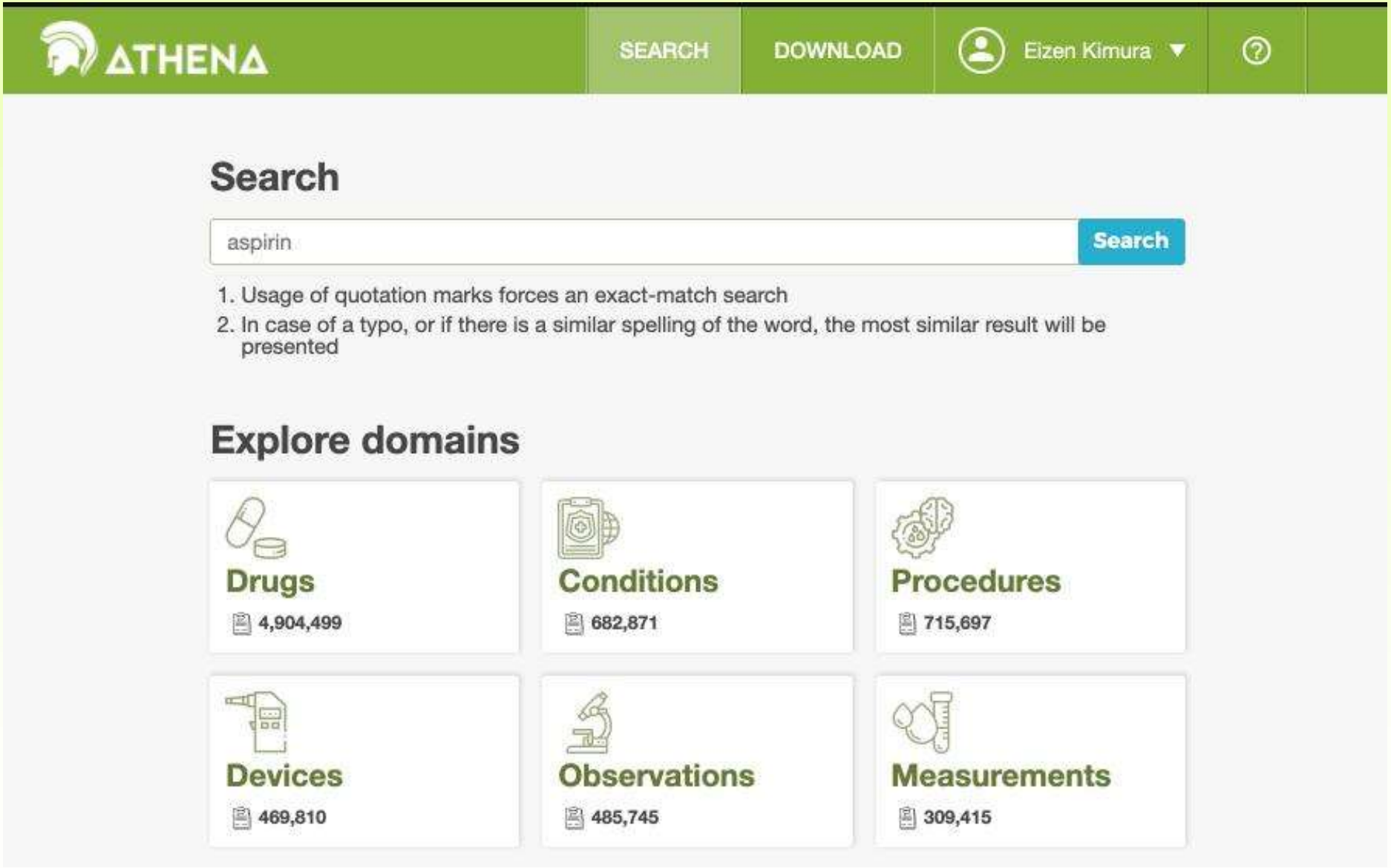
- Question

  「消化管出血」の標準概念IDは何か?

OHDSI Standard Vocabulary の検索サイト ATHENA



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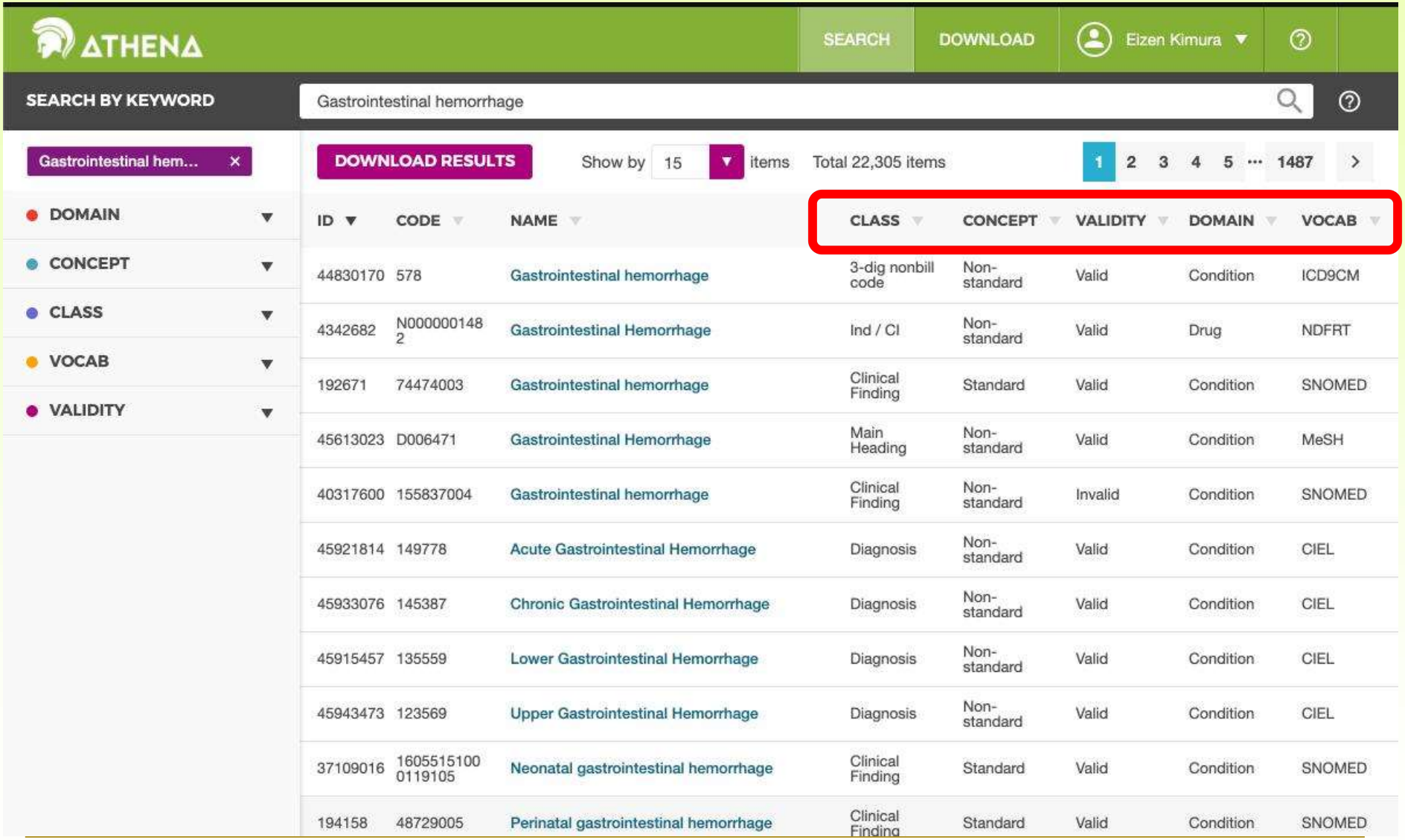
“Gastrointestinal hemorrhage”（消化管出血）の標準IDの検索



ID	CODE	NAME	CLASS	CONCEPT	VALIDITY	DOMAIN	VOCAB
44830170	578	Gastrointestinal hemorrhage	3-dig nonbill code	Non-standard	Valid	Condition	ICD9CM
4342682	N0000001482	Gastrointestinal Hemorrhage	Ind / CI	Non-standard	Valid	Drug	NDFRT
192671	74474003	Gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
45613023	D006471	Gastrointestinal Hemorrhage	Main Heading	Non-standard	Valid	Condition	MeSH
40317600	155837004	Gastrointestinal hemorrhage	Clinical Finding	Non-standard	Invalid	Condition	SNOMED
45921814	149778	Acute Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45933076	145387	Chronic Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45915457	135559	Lower Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45943473	123569	Upper Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
37109016	160551510001191 05	Neonatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
194158	48729005	Perinatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED

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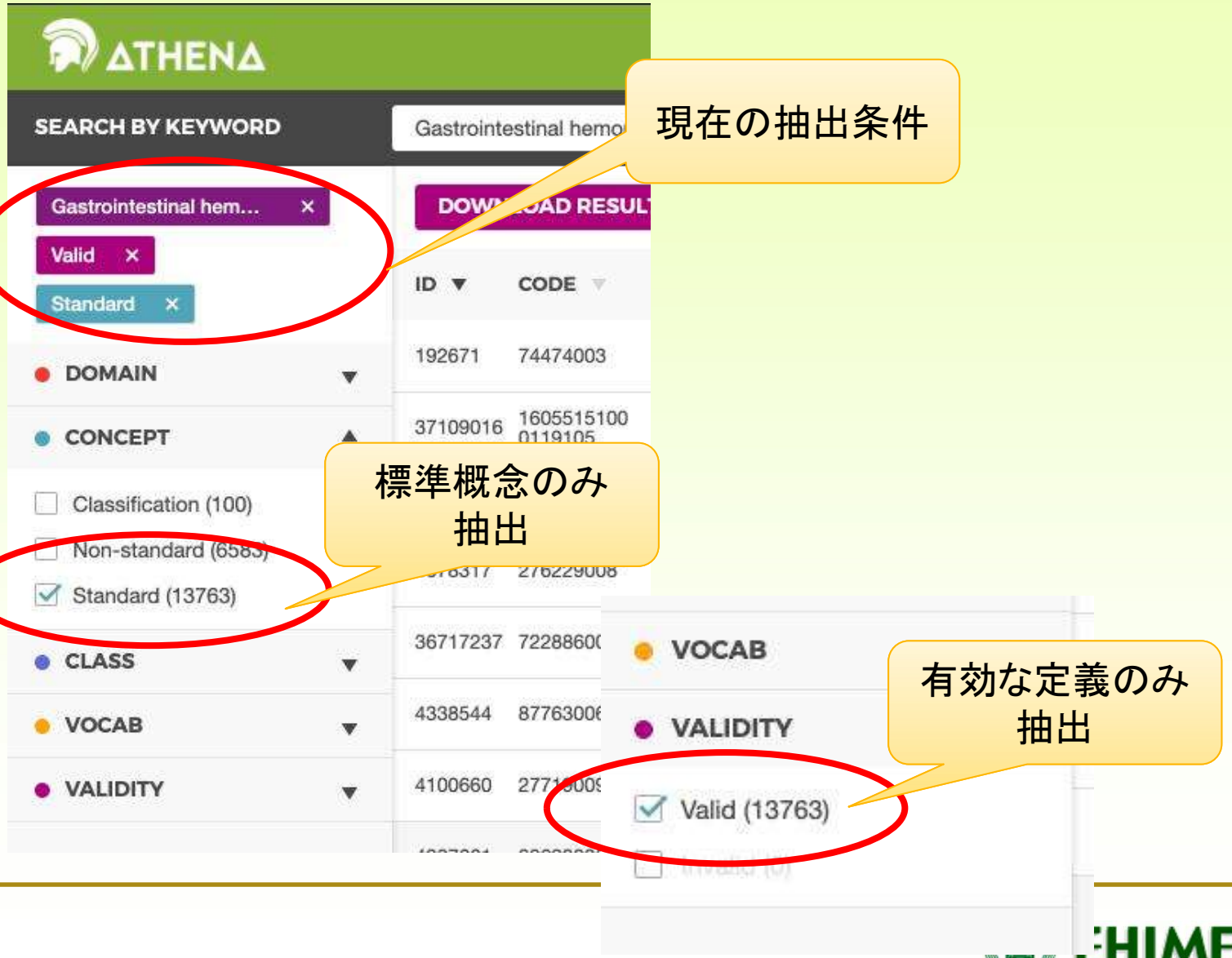
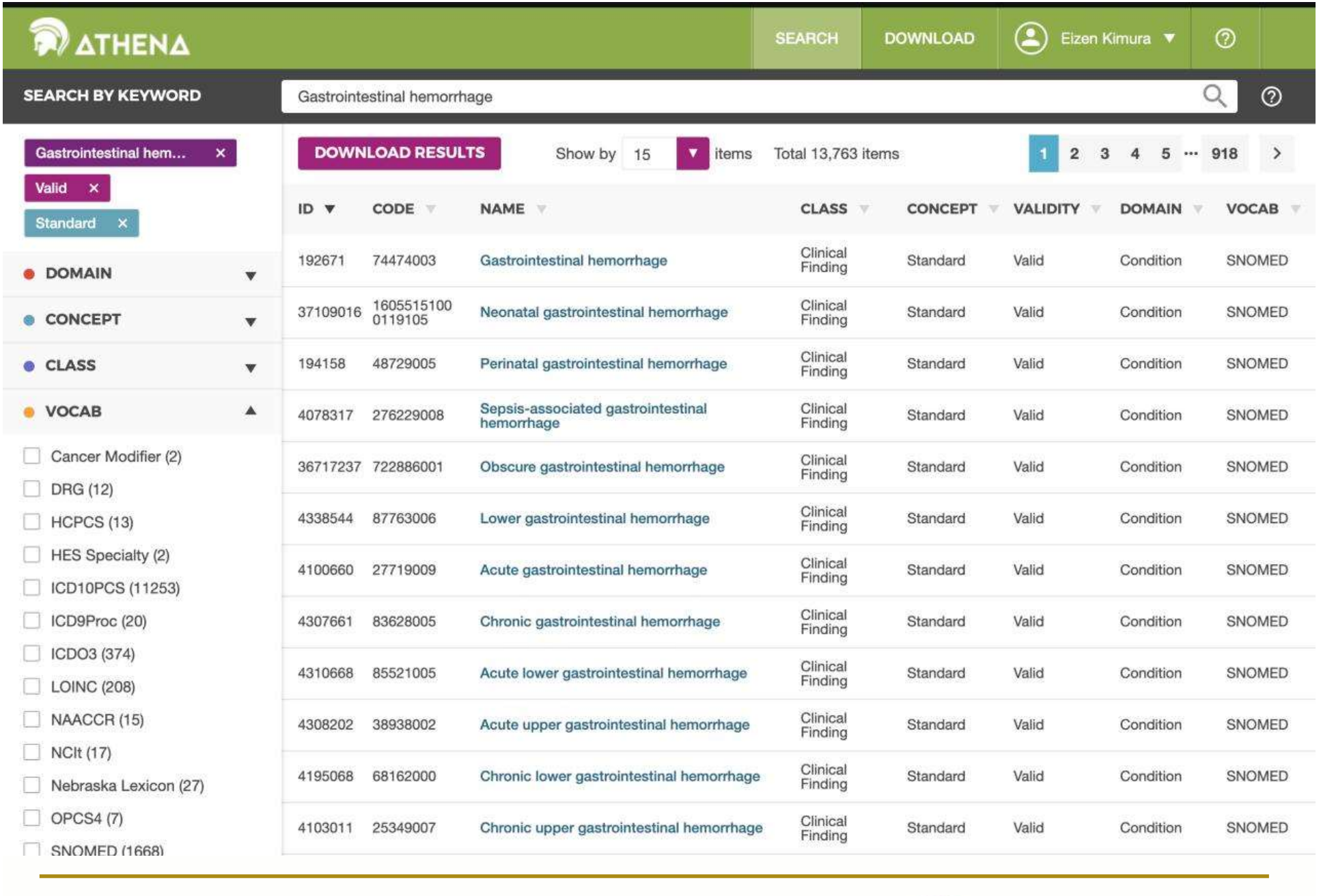
用語の絞り込み


ATHENA
SEARCH BY KEYWORD
Gastrointestinal hemo
Gastrointestinal hem...
Valid
Standard
DOWNLOAD RESULT
ID
CODE
192671
74474003
37109016
DOMAIN
CONCEPT
Classification (100)
Non-standard (6583)
Standard (13763)
CLASS
VOCAB
VALIDITY
36717237
4338544
4100660
VOCAB
VALIDITY
Valid (13763)
現在の抽出条件
標準概念のみ
抽出
有効な定義のみ
抽出



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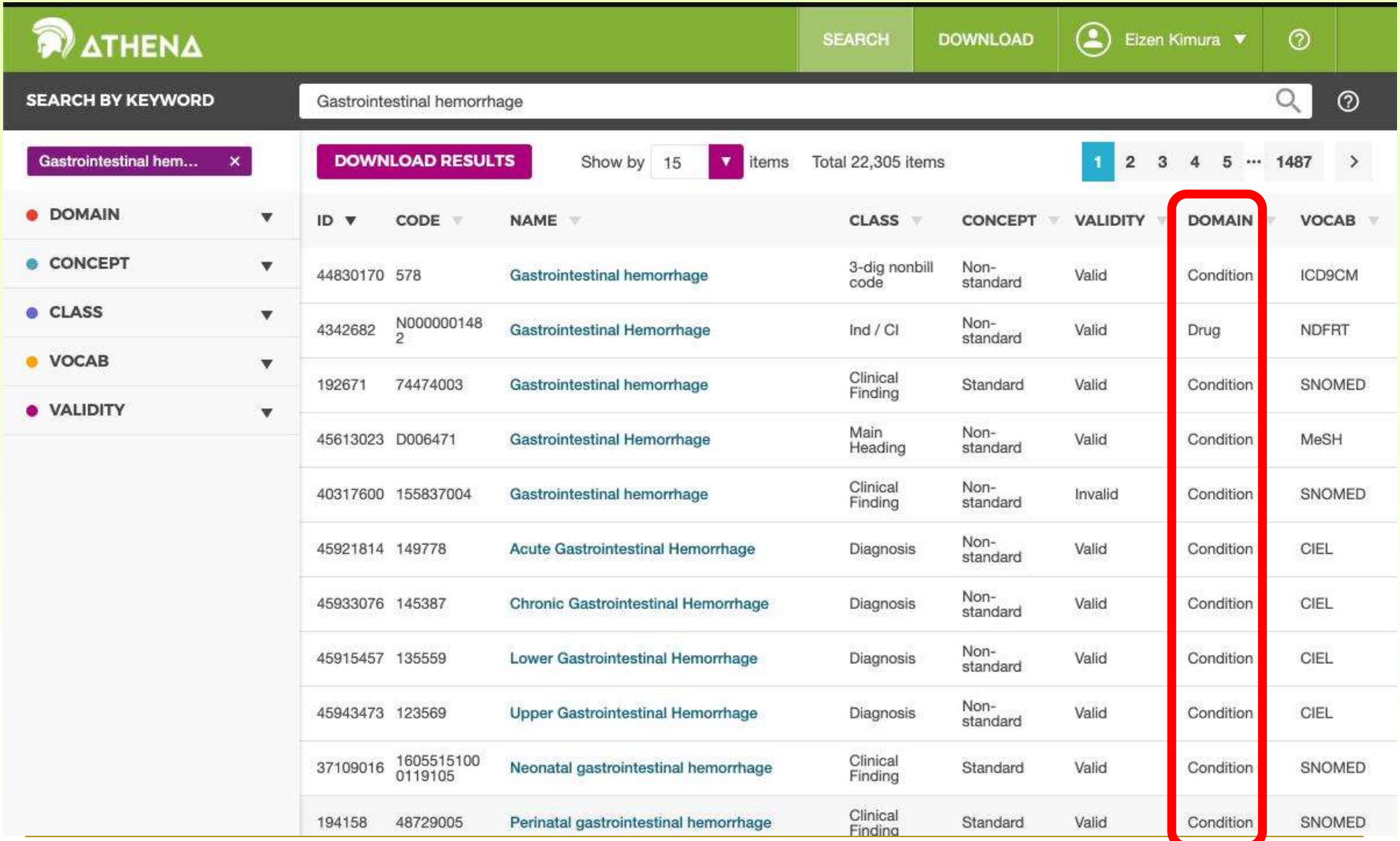
Domainについて意識すること



ID	CODE	NAME	CLASS	CONCEPT	VALIDITY	DOMAIN	VOCAB
44830170	578	Gastrointestinal hemorrhage	3-dig nonbill code	Non-standard	Valid	Condition	ICD9CM
4342682	N0000001482	Gastrointestinal Hemorrhage	Ind / CI	Non-standard	Valid	Drug	NDFRT
192671	74474003	Gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
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40317600	155837004	Gastrointestinal hemorrhage	Clinical Finding	Non-standard	Invalid	Condition	SNOMED
45921814	149778	Acute Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45933076	145387	Chronic Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45915457	135559	Lower Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45943473	123569	Upper Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
37109016	160551510001 19105	Neonatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
194158	48729005	Perinatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED

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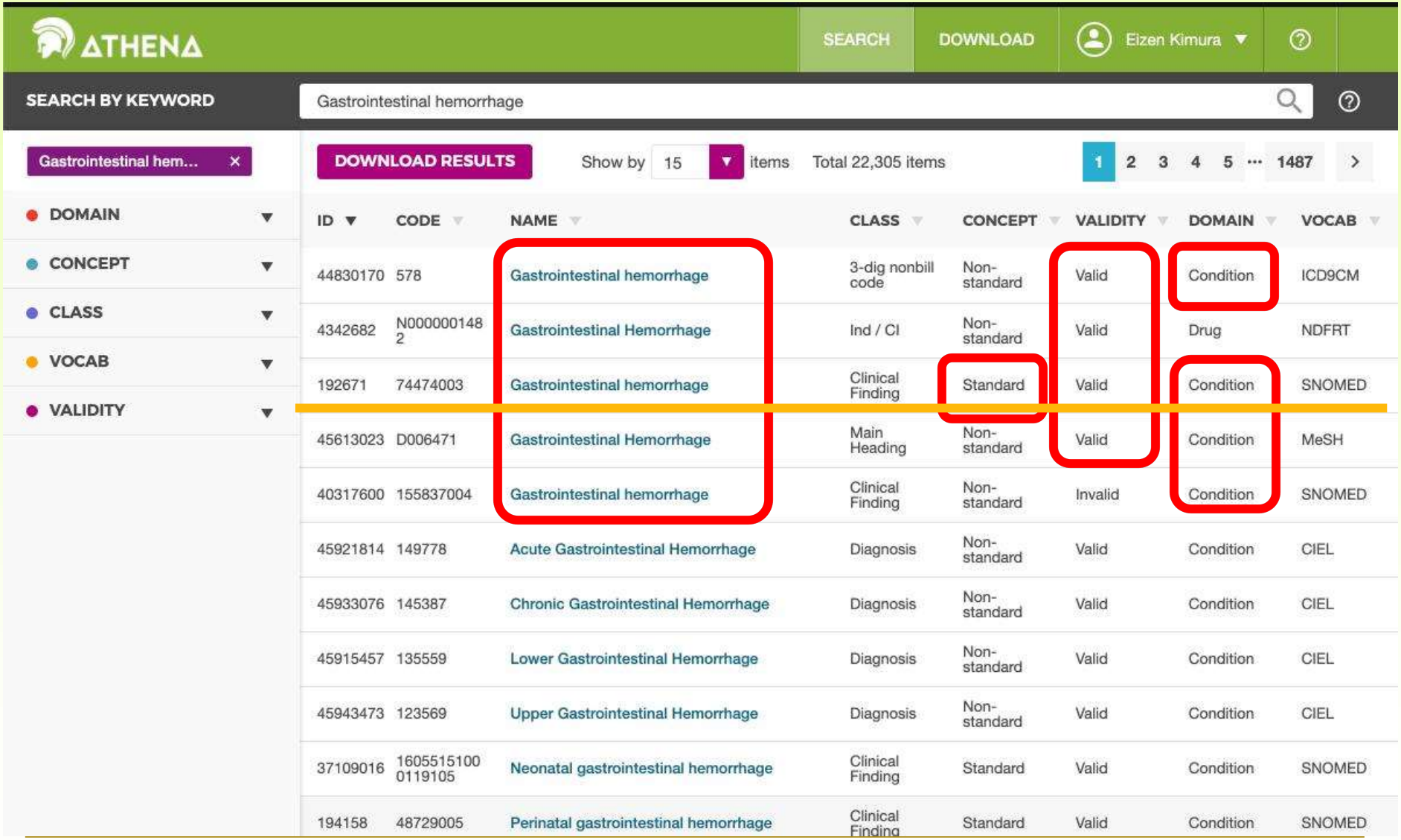
Domainについて意識すること



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37109016	160551510001191 05	Neonatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
194158	48729005	Perinatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED

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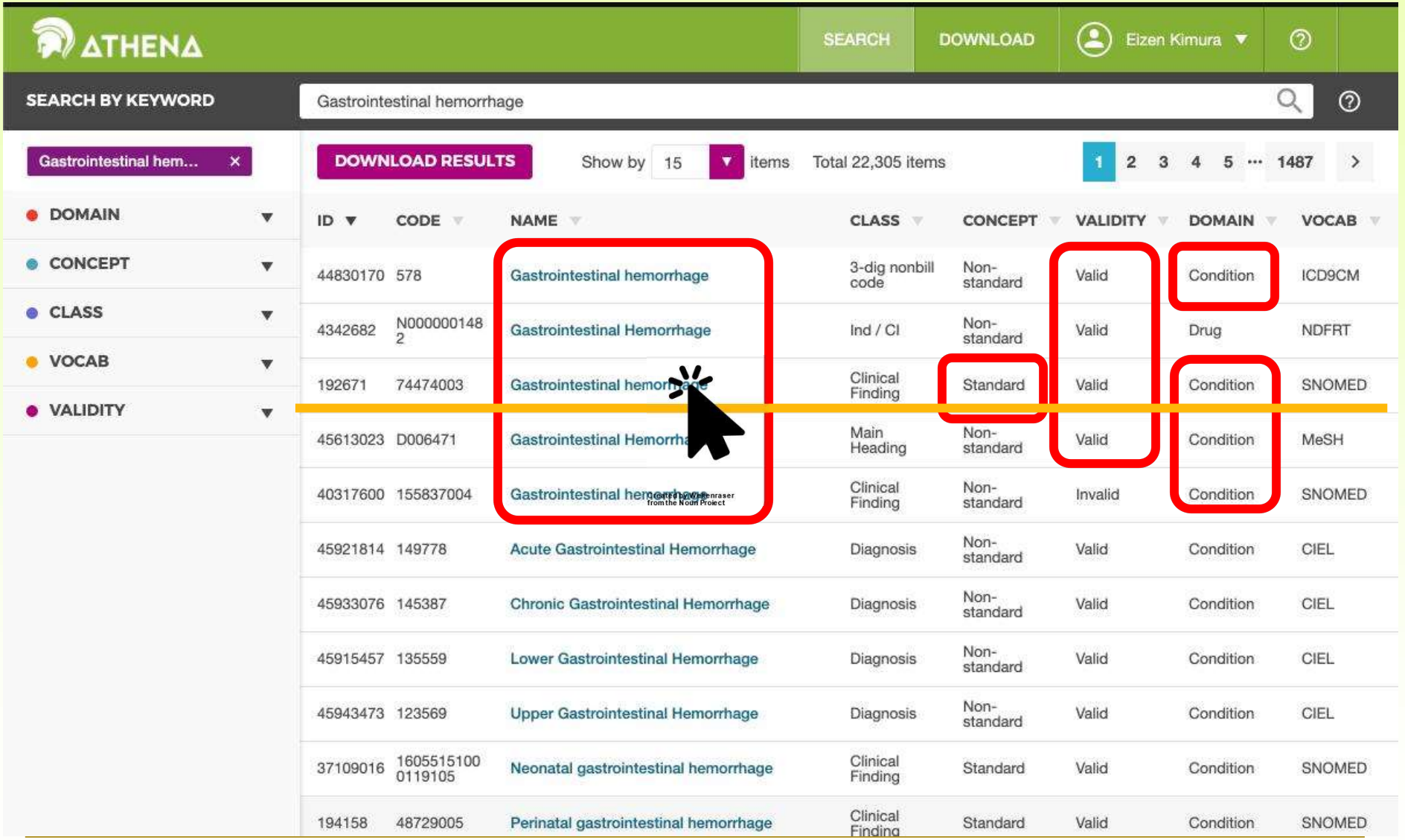
- Question

「消化管出血」の標準概念に対応する ICD10CM コードはどれか？どの ICD9CM コードがこの標準概念に対応するか？

Domainについて意識すること



ID	CODE	NAME	CLASS	CONCEPT	VALIDITY	DOMAIN	VOCAB
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4342682	N0000001482	Gastrointestinal Hemorrhage	Ind / CI	Non-standard	Valid	Drug	NDFRT
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45613023	D006471	Gastrointestinal Hemorrha	Main Heading	Non-standard	Valid	Condition	MeSH
40317600	155837004	Gastrointestinal hemorrhage	Clinical Finding	Non-standard	Invalid	Condition	SNOMED
45921814	149778	Acute Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45933076	145387	Chronic Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45915457	135559	Lower Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
45943473	123569	Upper Gastrointestinal Hemorrhage	Diagnosis	Non-standard	Valid	Condition	CIEL
37109016	1605515100 0119105	Neonatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED
194158	48729005	Perinatal gastrointestinal hemorrhage	Clinical Finding	Standard	Valid	Condition	SNOMED

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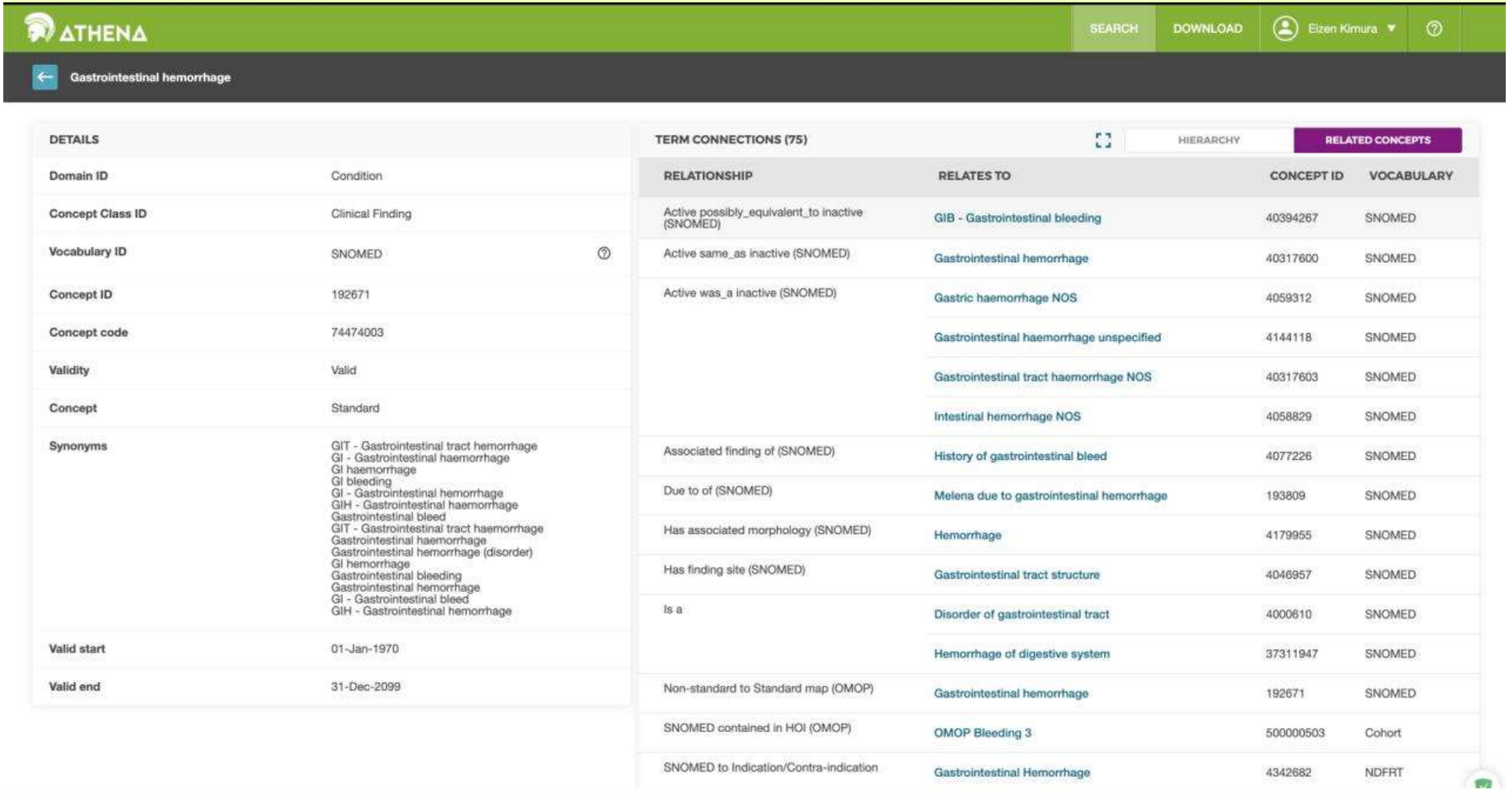
概念と関連する概念群の表示



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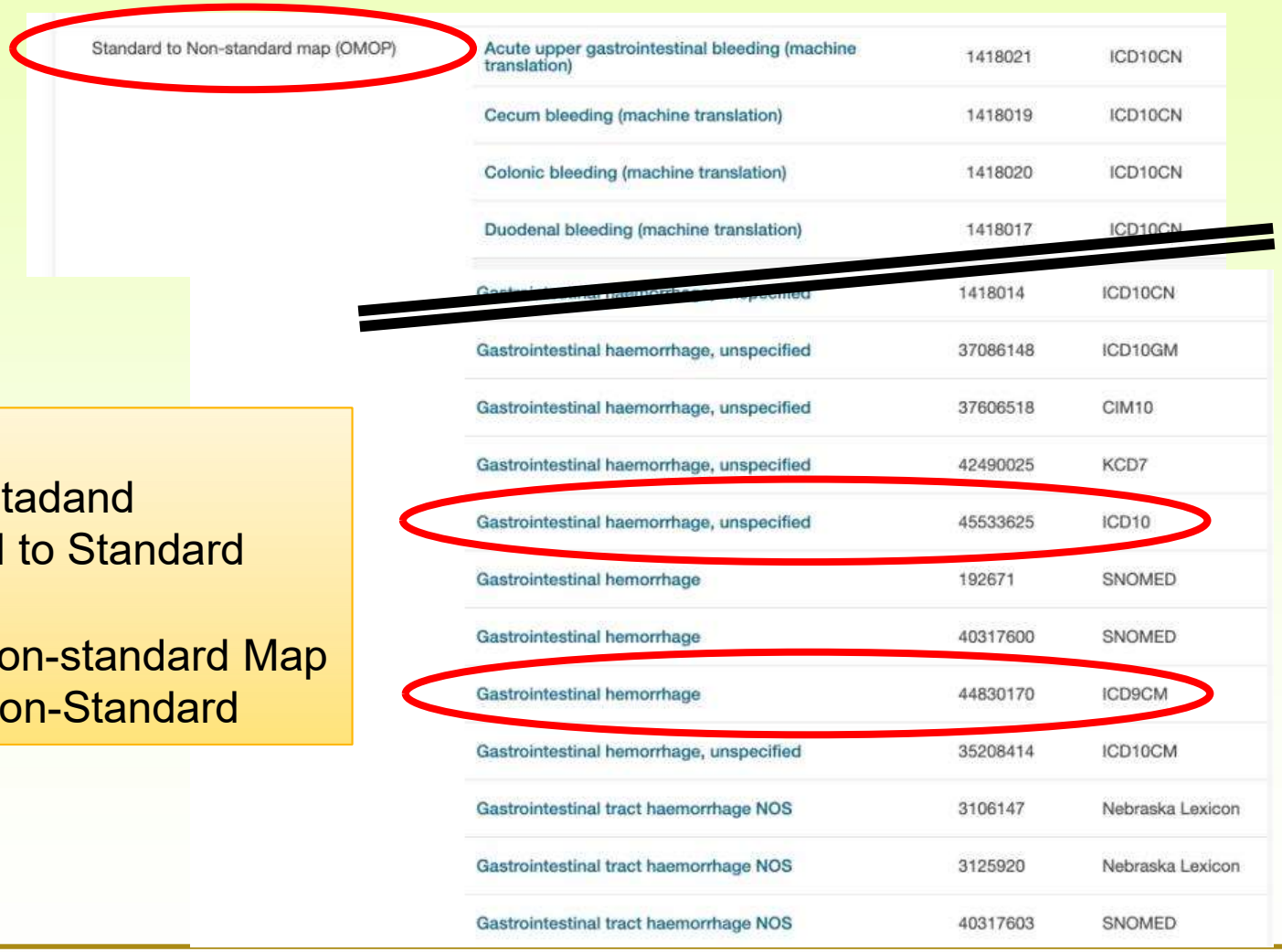
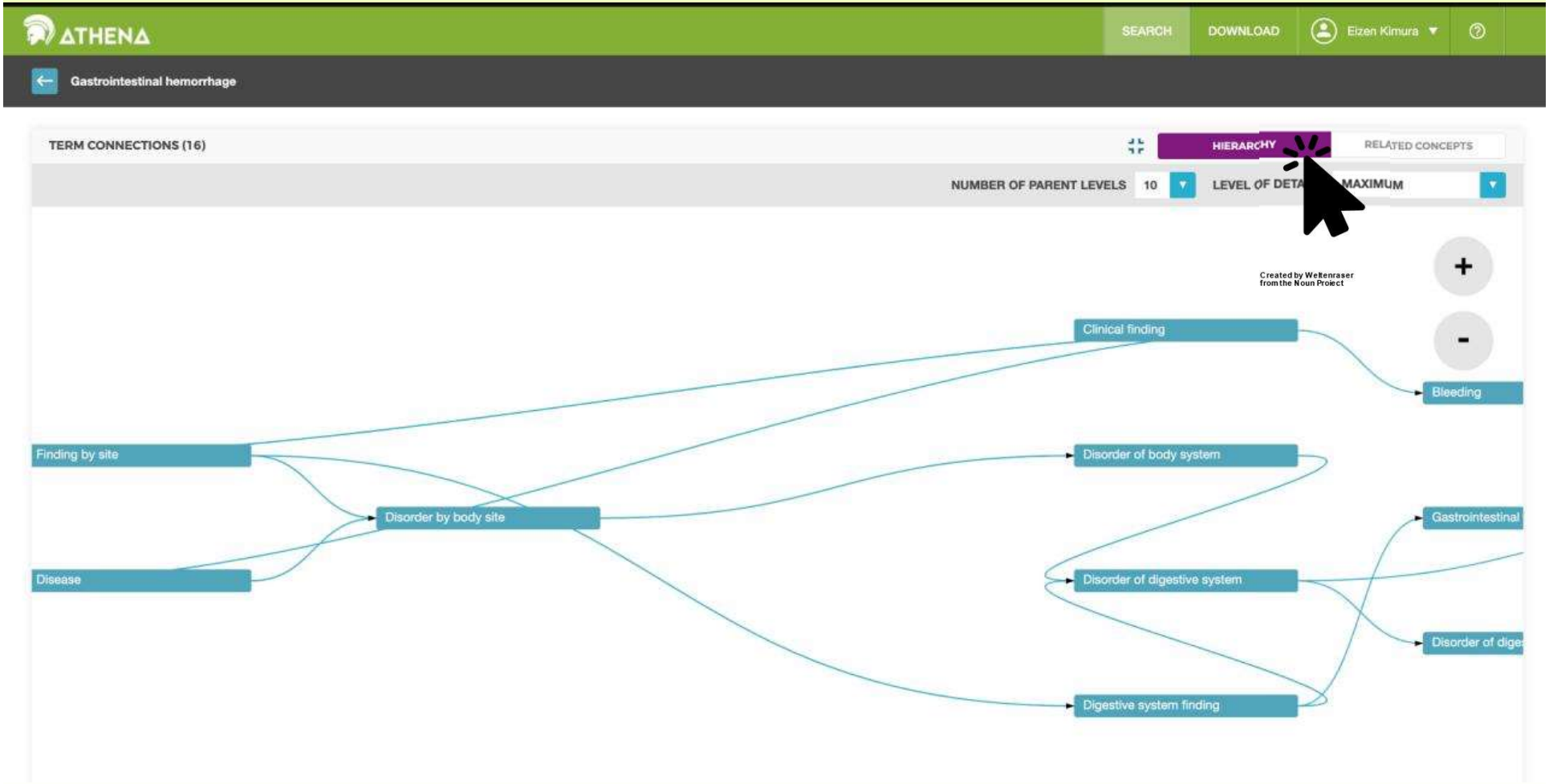
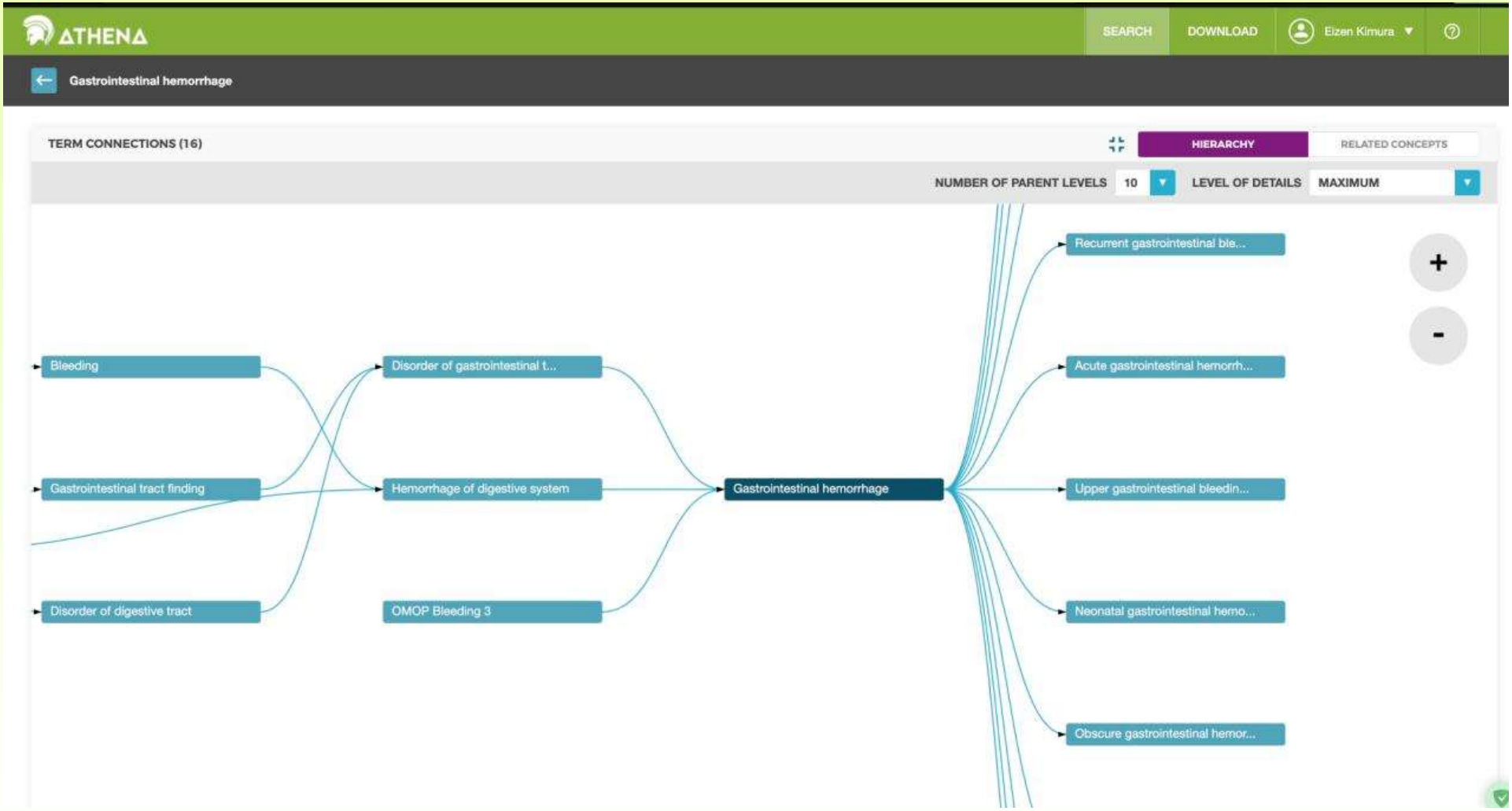


Standard to Non-standard map (OMOP)	Acute upper gastrointestinal bleeding (machine translation)	1418021	ICD10CN
	Cecum bleeding (machine translation)	1418019	ICD10CN
	Colonic bleeding (machine translation)	1418020	ICD10CN
	Duodenal bleeding (machine translation)	1418017	ICD10CN
	[illegible]	1418014	ICD10CN
	Gastrointestinal haemorrhage, unspecified	37086148	ICD10GM
	Gastrointestinal haemorrhage, unspecified	37606518	CIM10
	Gastrointestinal haemorrhage, unspecified	42490025	KCD7
	Gastrointestinal haemorrhage, unspecified	45533625	ICD10
	Gastrointestinal hemorrhage	192671	SNOMED
	Gastrointestinal hemorrhage	40317600	SNOMED
	Gastrointestinal hemorrhage	44830170	ICD9CM
	Gastrointestinal hemorrhage, unspecified	35208414	ICD10CM
	Gastrointestinal tract haemorrhage NOS	3106147	Nebraska Lexicon
	Gastrointestinal tract haemorrhage NOS	3125920	Nebraska Lexicon
	Gastrointestinal tract haemorrhage NOS	40317603	SNOMED

・IS-A関係
Standard to Stadand
Non-Standard to Standard

・Standard to Non-standard Map
Standard to Non-Standard

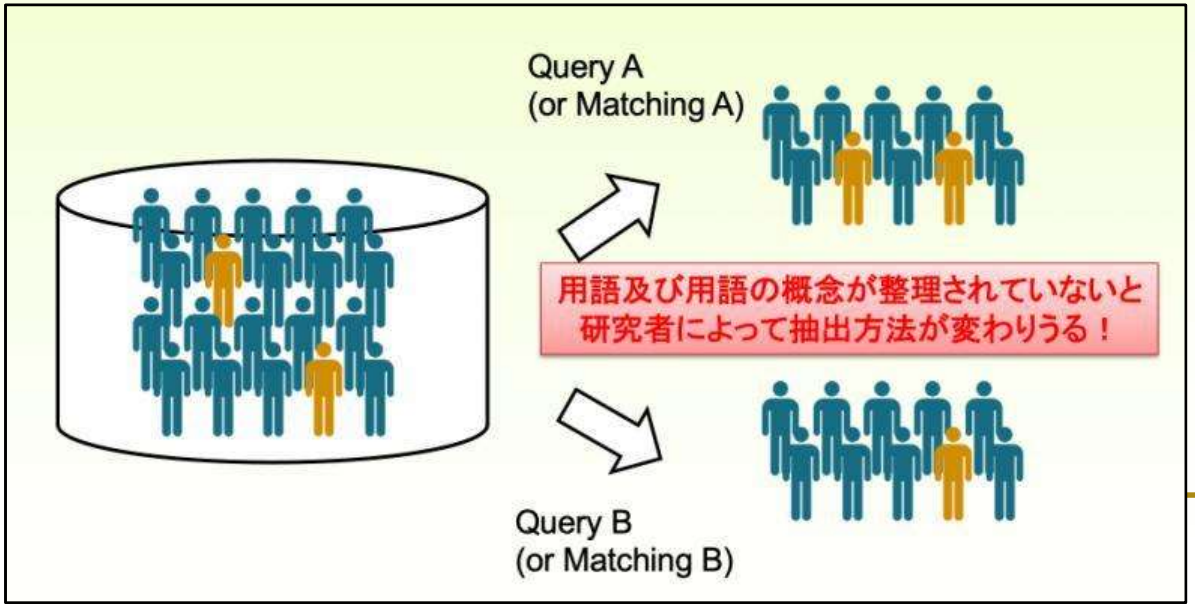

ATHENA
SEARCH
DOWNLOAD
Eizen Kimura
Gastrointestinal hemorrhage
TERM CONNECTIONS (16)
HIERARCHY
RELATED CONCEPTS
NUMBER OF PARENT LEVELS
10
LEVEL OF DETA
MAXIMUM
Created by Weltenraser from the Noun Project
Clinical finding
Bleeding
Finding by site
Disorder of body system
Disorder by body site
Gastrointestinal
Disease
Disorder of digestive system
Disorder of dige
Digestive system finding


ATHENA
SEARCH
DOWNLOAD
Eizen Kimura
Gastrointestinal hemorrhage
TERM CONNECTIONS (16)
HIERARCHY
RELATED CONCEPTS
NUMBER OF PARENT LEVELS
10
LEVEL OF DETAILS
MAXIMUM
Bleeding
Gastrointestinal tract finding
Disorder of digestive tract
Disorder of gastrointestinal t...
Hemorrhage of digestive system
OMOP Bleeding 3
Gastrointestinal hemorrhage
Recurrent gastrointestinal ble...
Acute gastrointestinal hemorrh...
Upper gastrointestinal bleedin...
Neonatal gastrointestinal hemo...
Obscure gastrointestinal hemor...
+
-

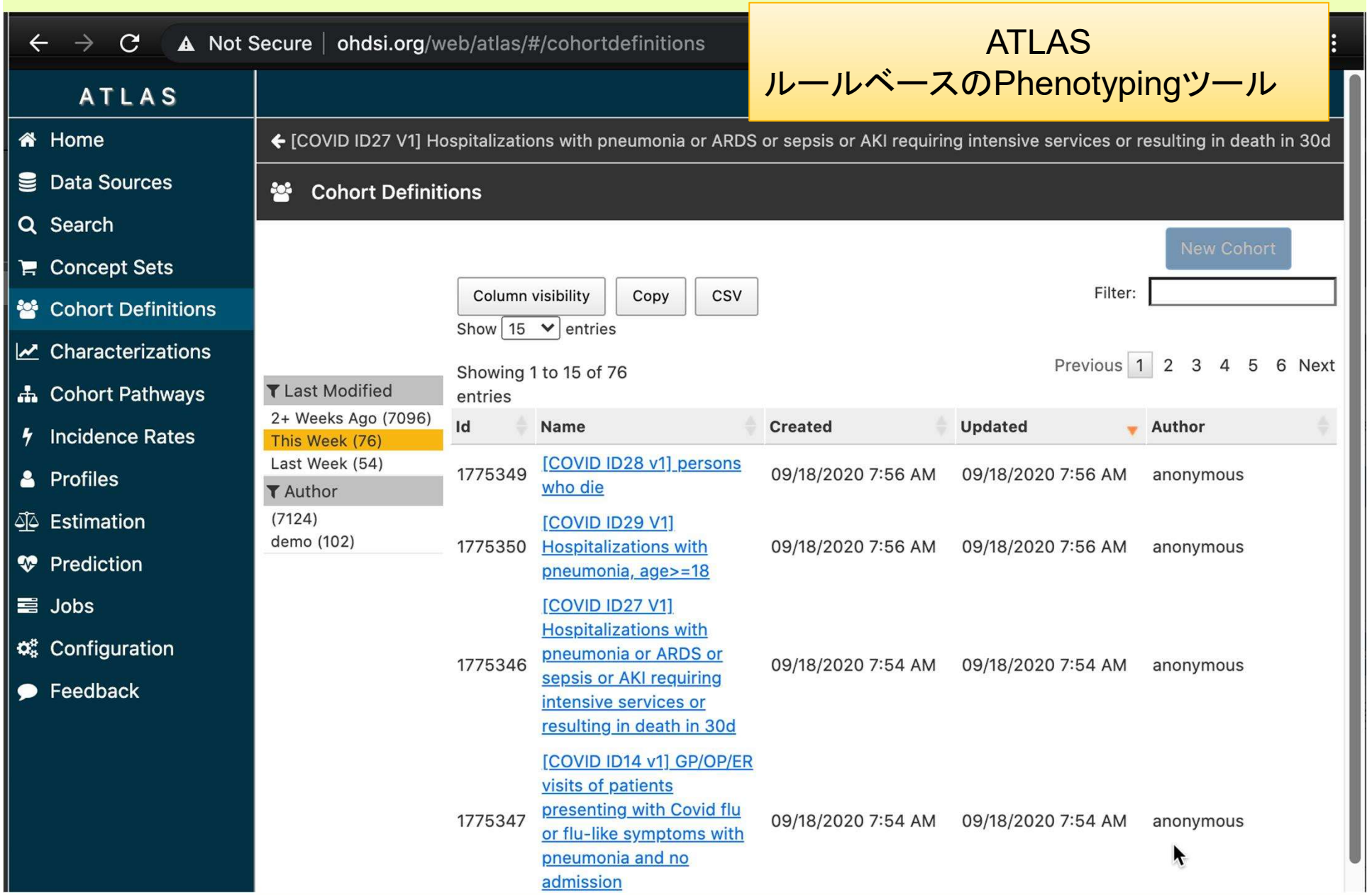
- Question

COVID-19に関して[肺炎、ARDS]を併発して入院した患者の抽出

肺炎、ARDSの定義は？



ATLAS
ルールベースのPhenotypingツール



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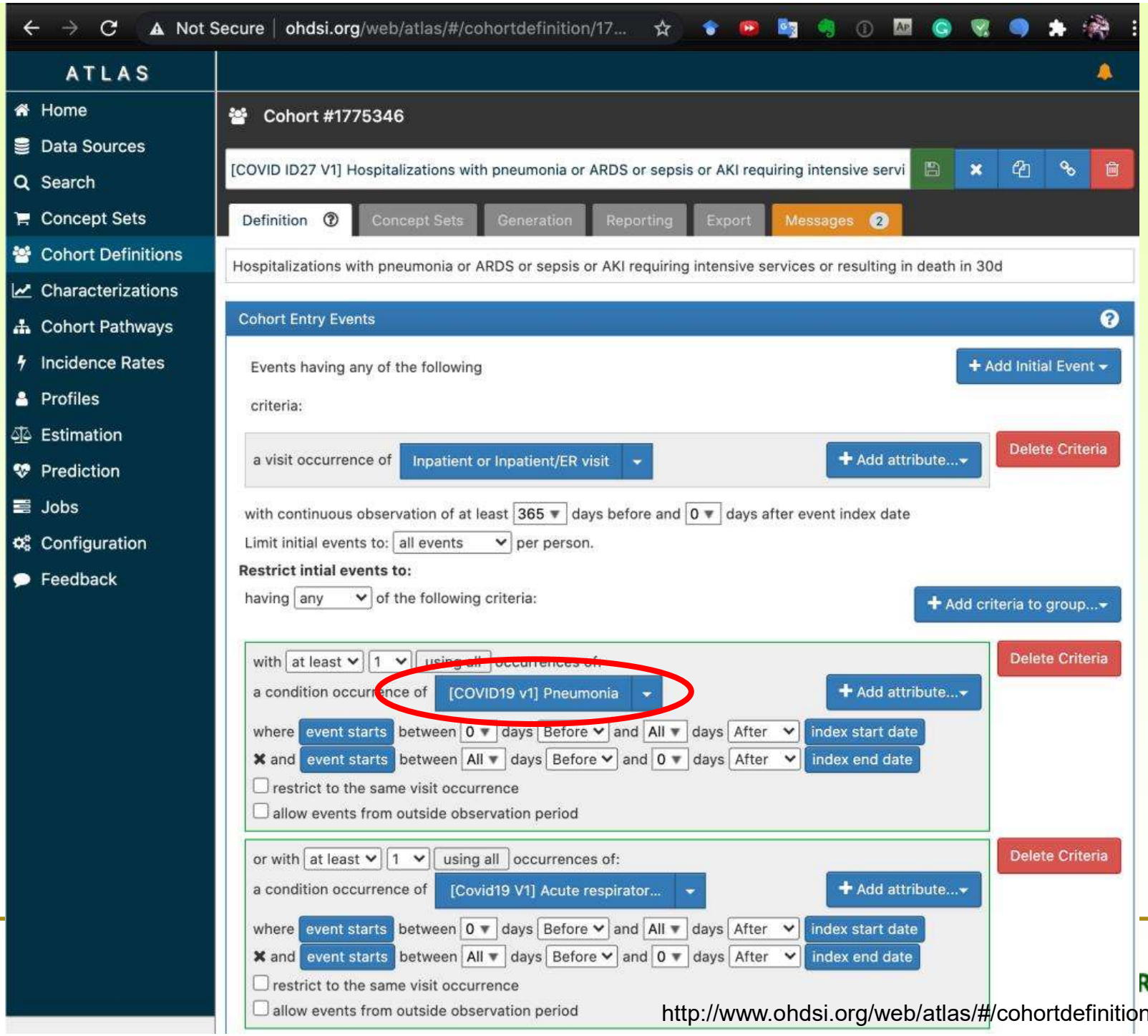
http://www.ohdsi.org/web/atlas/#/cohortdefinition/1775346



RSITY

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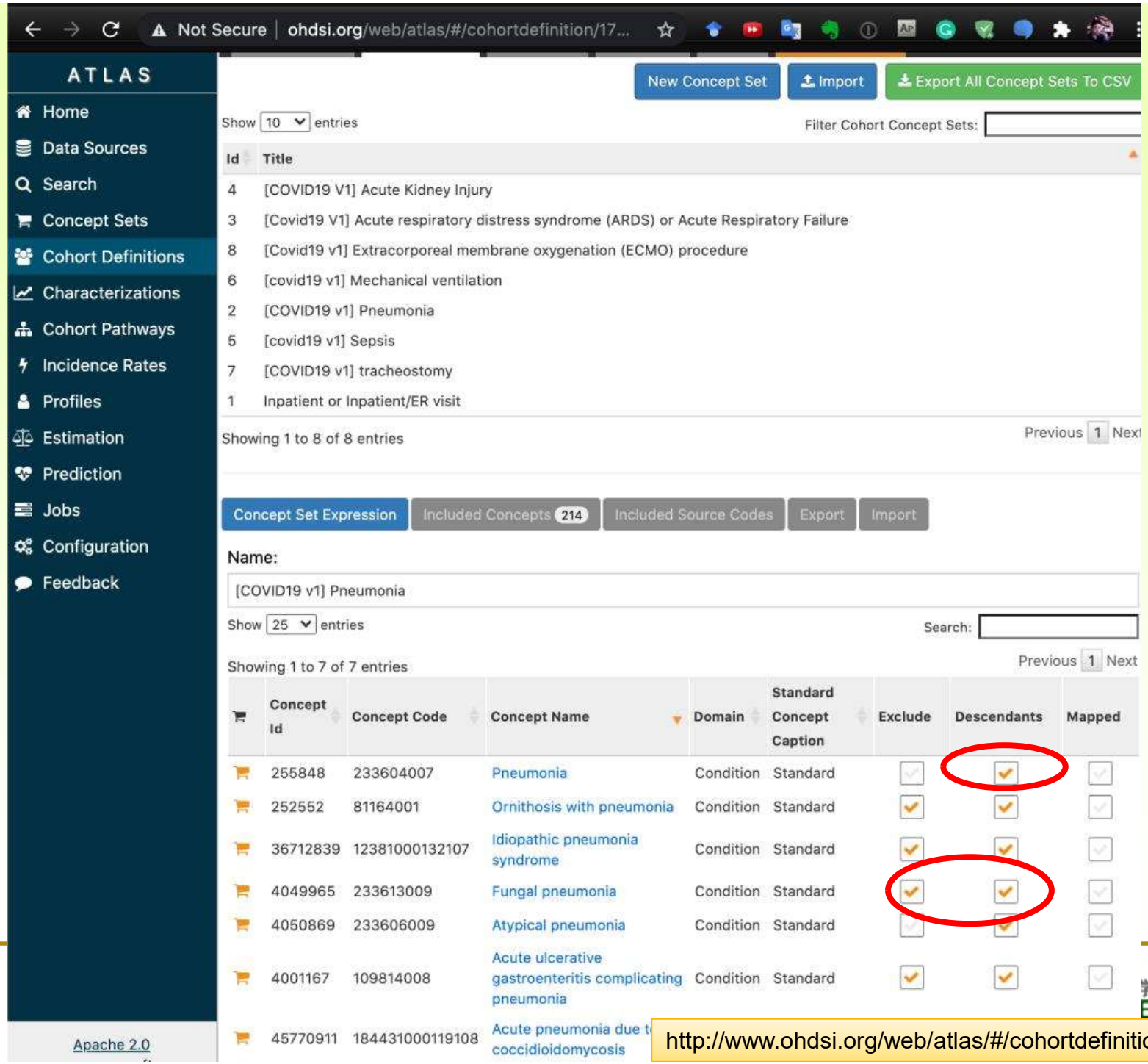

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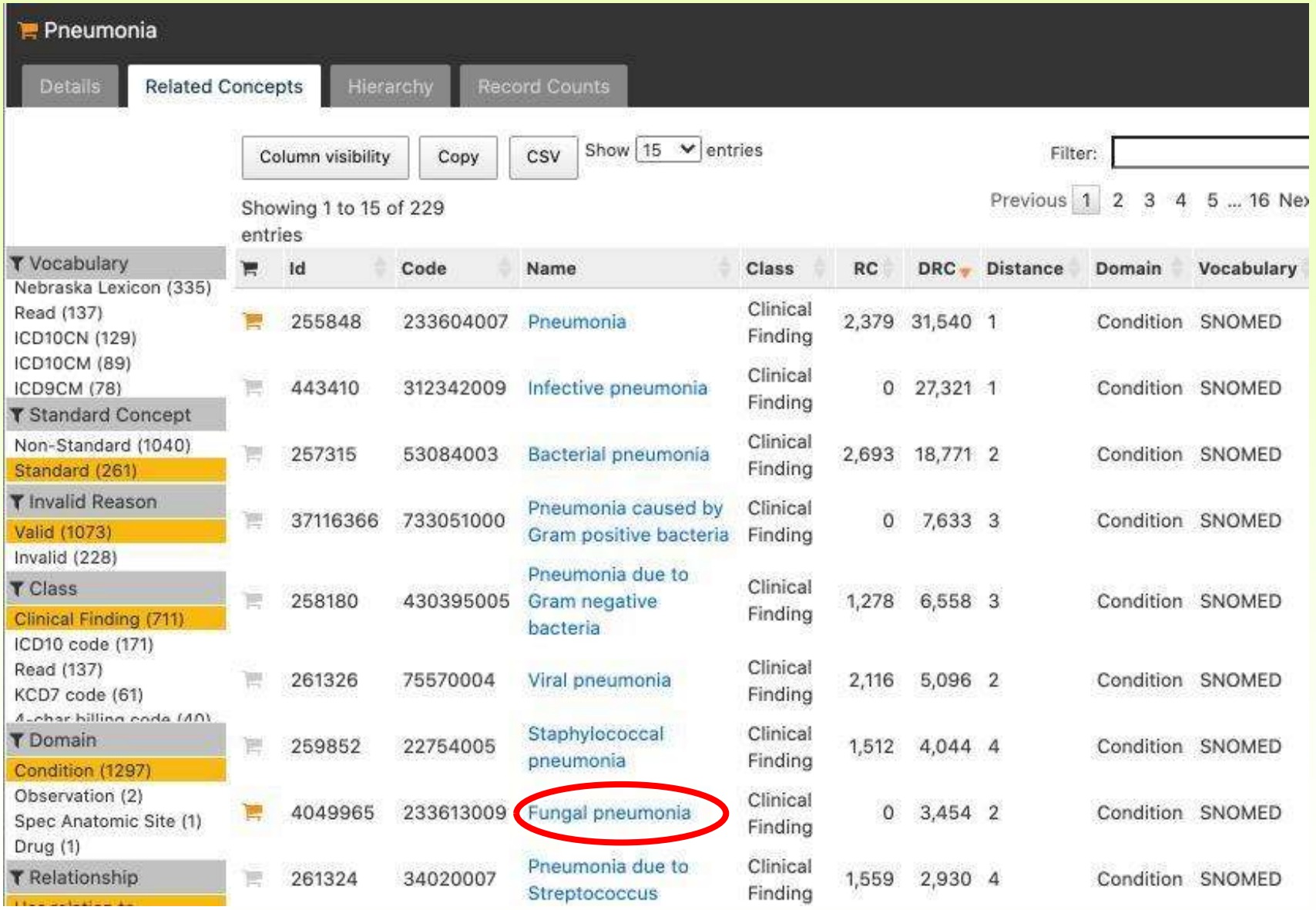

定義外とすべき真菌性肺炎も入っている

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Take home message

- 質の高い国際的なRWD研究をするには、統合された用語集へのマッピングが必要
- 同じ表記でもドメインを意識して使い分ける。
- OHDSI
  - 統制用語集の管理、閲覧 Athena
  - Phenotyping ツール Atlas
- 今後の課題
  - 国内標準マスターからSNOMED、RxNorm、LOINCのマッピング作業が不可避 → 実際の分析に関係するところから着手する
  - FHIR導入も進んでいるので、FHIR Terminologyの整備と両輪で進めたい