OHDSI
Japan Introduction

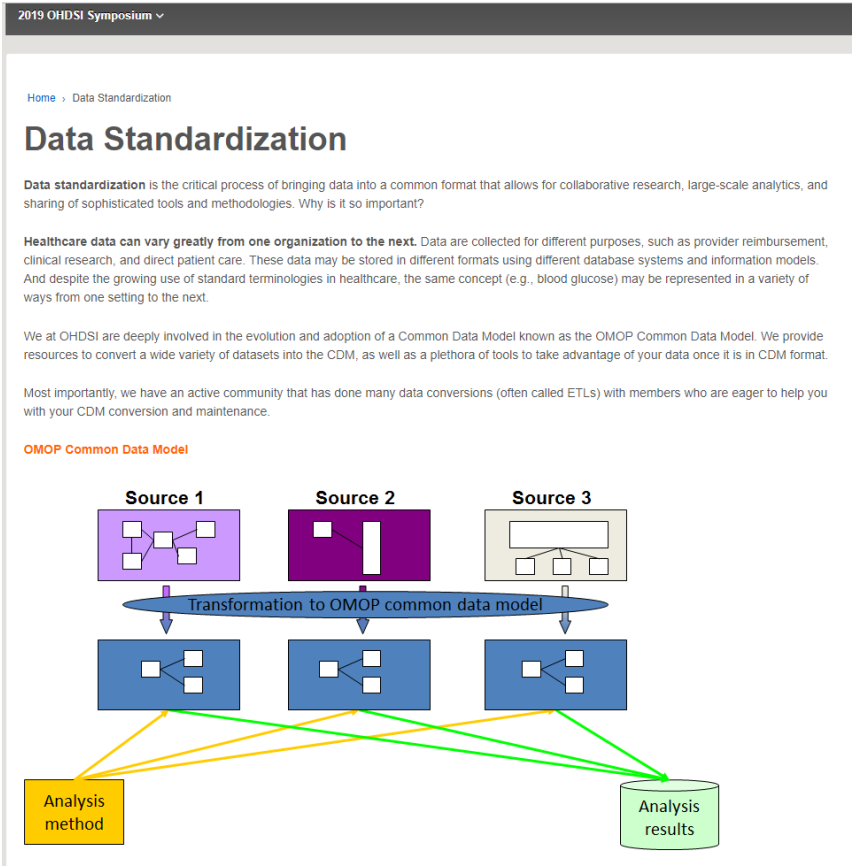
10:00am - 1:00pm [Part 1] Discussion (with some breaks) ＠11階大会議室D
- 10:00-10:10 Opening
- 10:10-10:25 Self-introduction
- 10:30-11:10 The latest situation of OHDSI in Asia, Europe and the United States
- 11:10-11:30 The situation of secondary use of clinical data in Japan
- 11:45-12:15 About Vocabulary / OMOP-JV (with discussion)
- 12:15-12:30 About management of OHDSI Japan

1:00pm-2:30pm　Lunch at Akasaka district
Location: GARB CENTRAL　https://www.garb-central.jp/

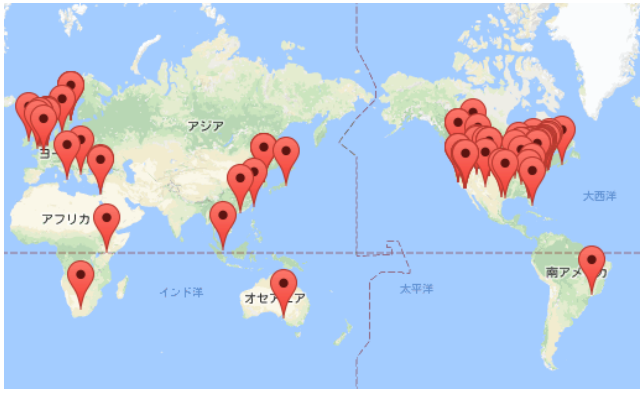
3:00pm-5:00pm [Part 2] OMOP-CDM Mini-Tutorial ＠5階504教室

OHDSI Community

OHDSIは、共通データ形式を使った大規模な観察医療データ分析を推進する、産学官病を問わない学際的なコミュニティ（研究会）です。より良い医療を促進するエビデンスを共同で生みだすことを支援し、観察研究により健康と病気の包括的な理解が得られる世界を目指します。
OHDSIは米国で2015年にスタートし世界中に参加者がいます。

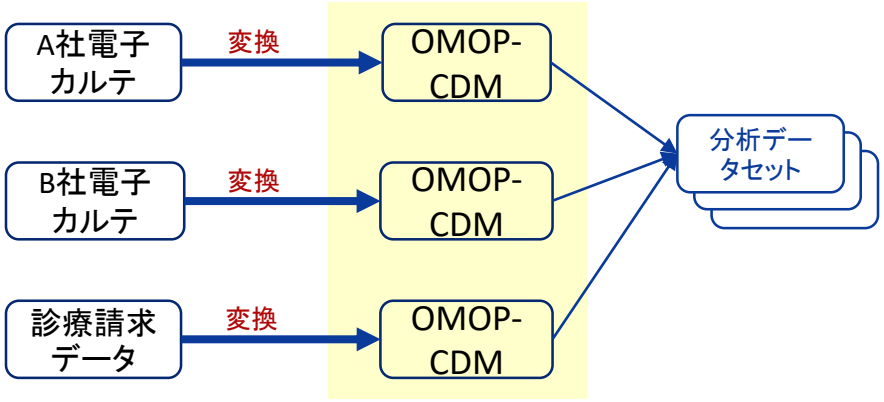


国際的なオープン規格：OMOP Common Data Model



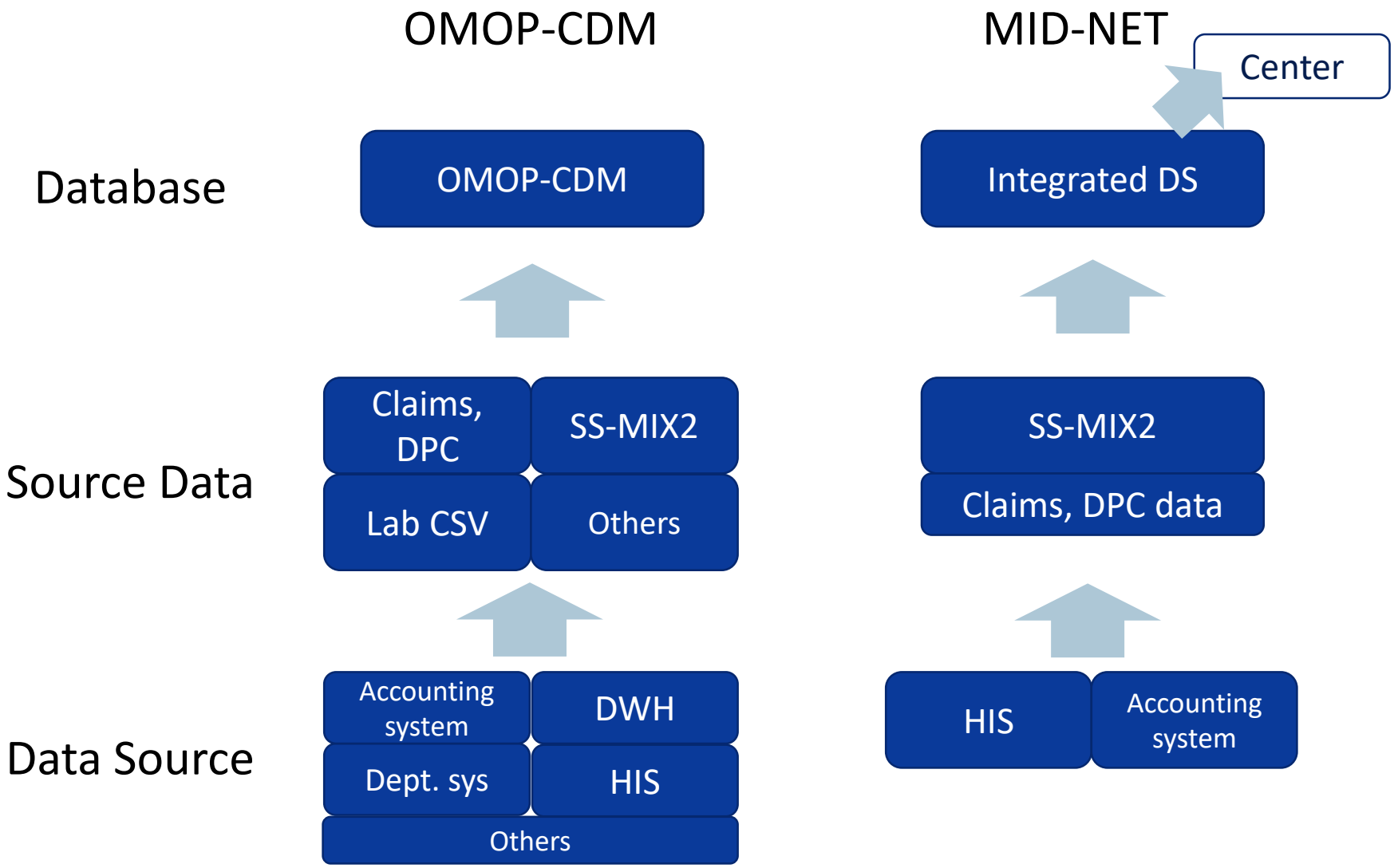
■OMOP-CDM
米団体OMOPが当初開発した、診療情報の分析利用を目的とする、共通の形式・表現の規格。
（OMOP: FDAと米製薬企業との過去の共同プロジェクト
“Observational Medical Outcomes Partnership“）

- 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。
- Public Domainが宣言されている。



データソースが違っても
同じDB形式

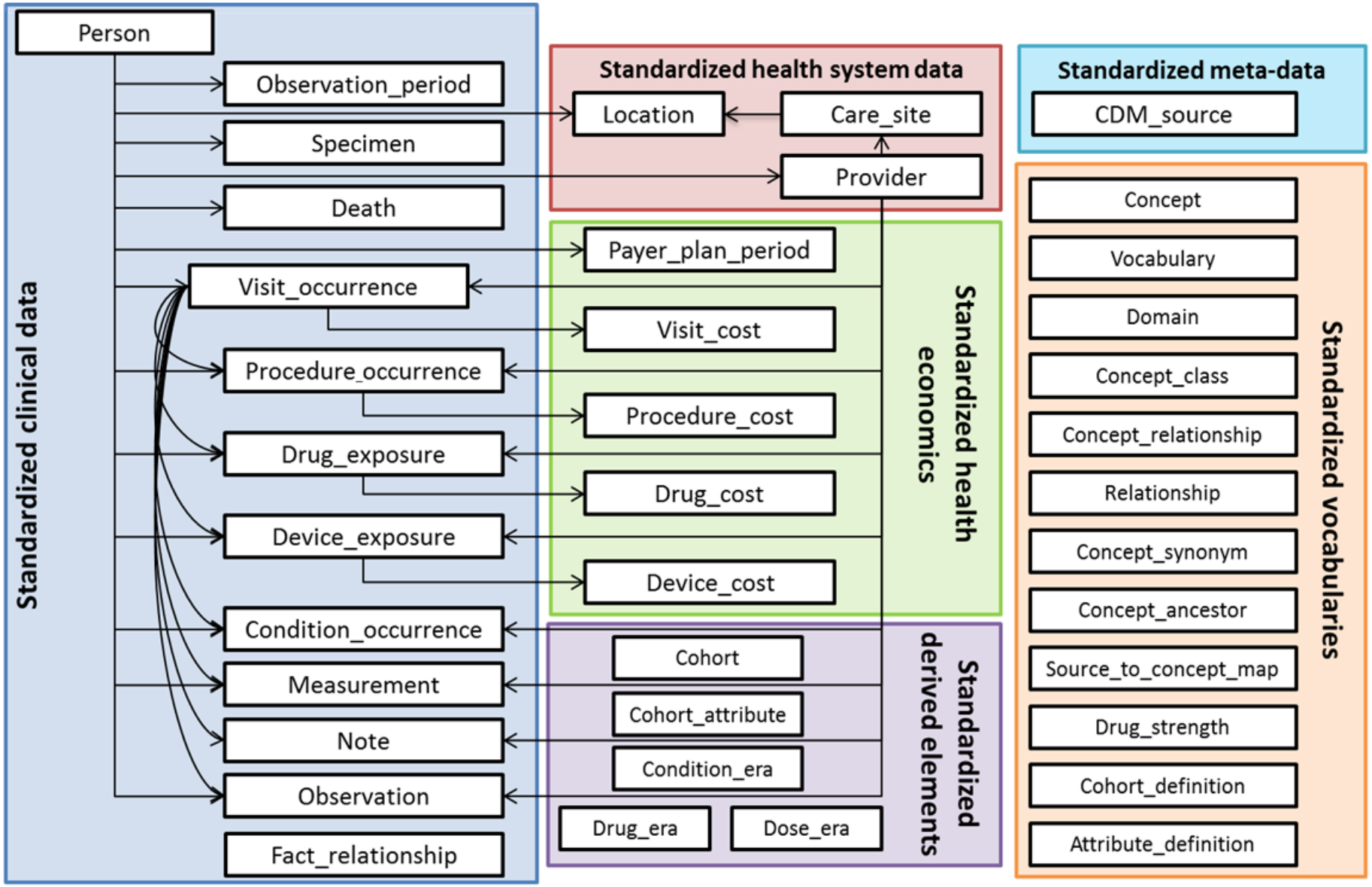
Contrast with MID-NET



MID-NET : PMDA's data infrastructure for drug safety investigation (Japanese Sentinel project)

OMOP-CDMの構成

(図はver5.0)



OMOP-CDM（OHDSI）の利点と欠点

- Strengths
  - Analysis portability
    - Analysis written at one site can possibly be executed by other partners within the consortium
  - Common Data Model, OMOP Vocabularies
  - Tools + R packages
  - Community of researchers, past studies are open source

- Weaknesses
  - ~~Must have recources for data transformation to CDM~~
  - Expertise to install/use OHDSI tools and packages

There is a tool for domestic usage

Medinfo 2017 OHDSI 資料

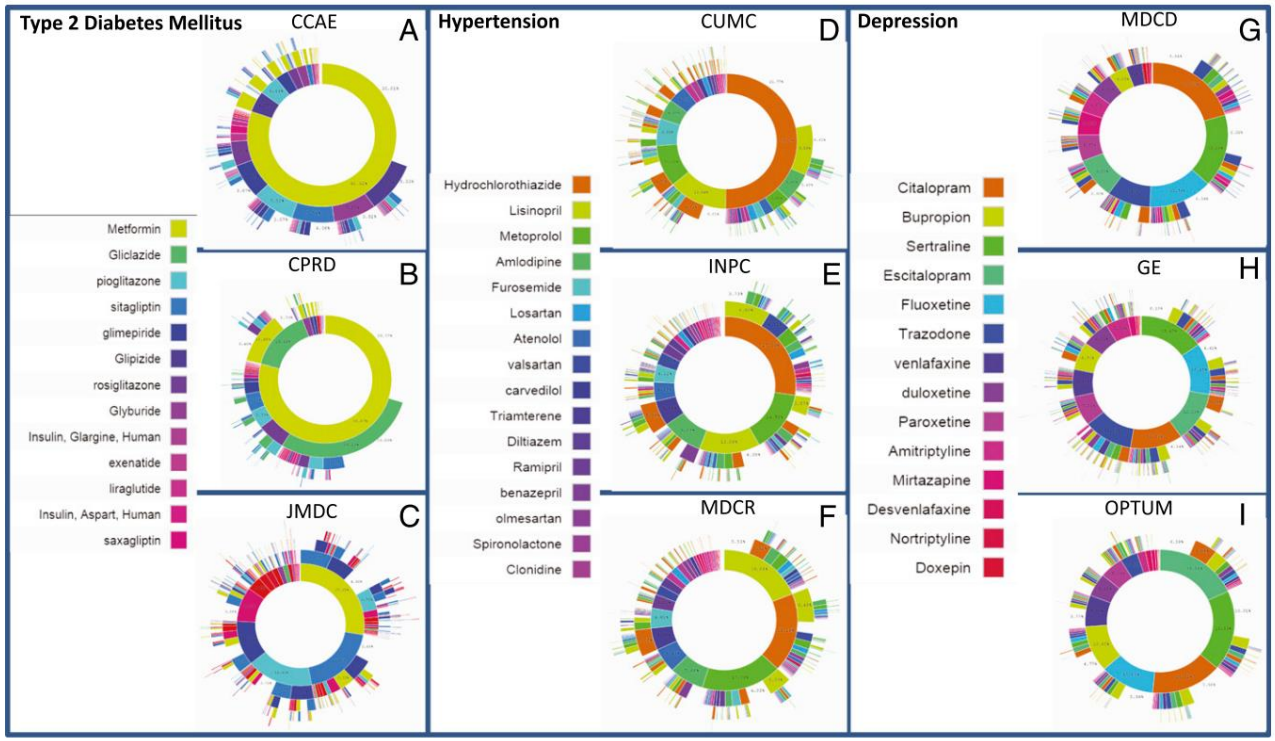
OHDSI/OMOP-CDMによる国際協力研究例

COLLOQUIUM PAPER

Characterizing treatment pathways at scale using the OHDSI network

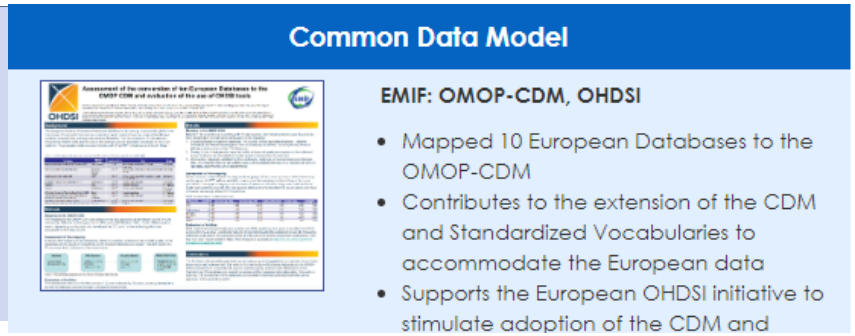
George Hripcsak[a,b,c,1], Patrick B. Ryan[c,d], Jon D. Duke[c,e], Nigam H. Shah[c,f], Rae Woong Park[c,g], Vojtech Huser[c,h], Marc A. Suchard[c,i,j,k], Martijn J. Schuemie[c,d], Frank J. DeFalco[c,d], Adler Perotte[a,c], Juan M. Banda[c,f], Christian G. Reich[c,l], Lisa M. Schilling[c,m], Michael E. Matheny[c,n,o], Daniella Meeker[c,p,q], Nicole Pratt[c,r], and David Madigan[c,s]

4カ国、11データソース、患者数合計2.5億人
T2DM、高血圧、うつ　の治療法推移実態調査



欧州におけるOMOP-CDM利用

OHDSI EUROPE
OBSERVATIONAL HEALTH DATA SCIENCES AND INFORMATICS

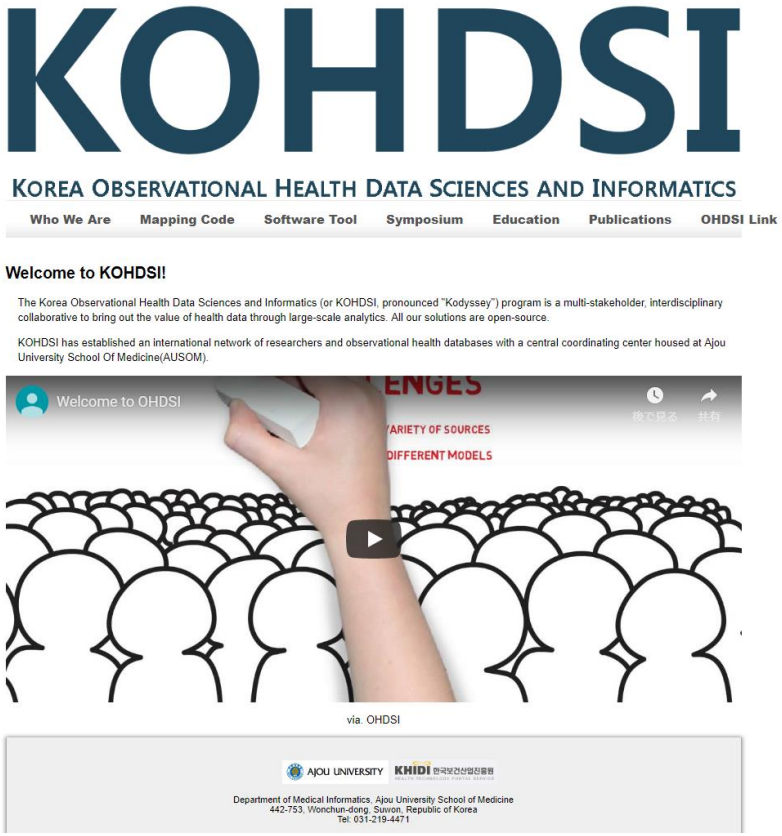


EMIFプロジェクト http://www.emif.eu/

アジアにおけるOMOP-CDM利用

OHDSI 中国于2016年12月成立，总体目标就是，利用数据科学和信息学方法，促进中国的健康医疗数据研究工作。具体来说，我们致力于推动中国健康医疗数据研究方法和应用，包括针对中国临床数据扩展和定制OHDSI的数据科学方法（如各种标准、知识库和软件工具），利用大型观察性健康医疗数据网络对全球性重要健康医疗问题展开调查研究，以及促进生物医学信息学领域的国际合作与教育培训工作。

- OHDSI中国 简介
- OHDSI中国 团队
- OHDSI China Working Group（English）



Self-Introduction

The latest situation of OHDSI in Asia, Europe and the United States

Mui Van Zandt
Director Product Development
IQVIA

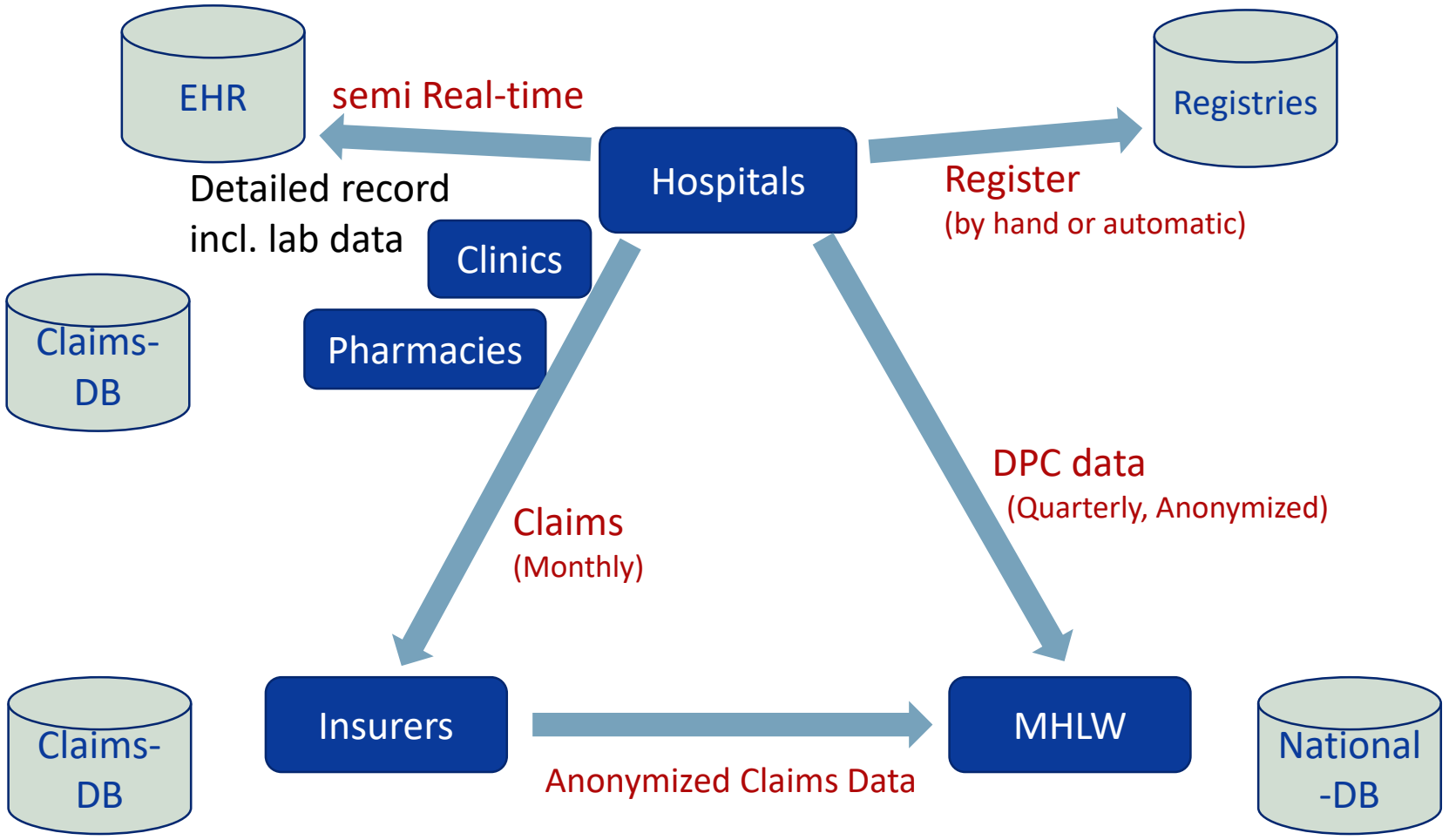
Mui is a Director of Product Development at IQVIA, managing the OMOP Factory. Mui's area of expertise include software development, data conversions, agile process, and project management. The OMOP Factory has been performing OMOP ETL conversions on over 12 different datasets in 6 different countries. Mui has gained extensive knowledge working on large patient databases in the OMOP model and the standard vocabularies that are needed to support these conversions.

Mui is an active contributor to the community through various OHDSI working groups. She is one of the co-leaders of the China OMOP CDM/Vocabulary working group. She leads two of the sub-working groups within the THEMIS working group. She has and continues to perform OMOP tutorial trainings to many different organizations and conference, such as the OHDSI Symposiums, the China Hackathons, and individual universities.

https://www.ohdsi.org/who-we-are/collaborators/mui-van-zandt/

The situation of secondary use of clinical data in Japan

Types of clinical databases in Japan



Major Japanese databases in Japan available for clinical/pharmaco-epidemiology(1)

■Hospital-based

DB name	admin	# uniq ID	Data Source	
MID-NET	PMDA	>4M	SS-MIX2, DPC, Claims	High Quality
EBM Provider	MDV Co.,Ltd.	25M	DPC, Claims, Lab, others	Major in HB
RWD-DB	RWD Co.,Ltd.	20M	DPC, Claims, EMR, Lab	
MIA	NHO	20M	DPC, Claims	1 stop service
JMDC C. DB	JMDC	5.4M	DPC, Claims	
CCT	CCT K.K.	3.6M	DPC, Claims, EMR, Lab	
NCDA	NHO	1.6M	SS-MIX2, Lab, etc.	1 stop service

Reference:
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Major Japanese databases in Japan available for clinical/pharmaco-epidemiology(2)

■Insurance-based

DB name	admin	# uniq ID	Data Source
NDB	MHLW	All Patients	Claims
JMDC C. DB	JMDC	5.6M	Claims
MinaCare	MinaCare	5.6M	Claims, others.
Medi-Scope	Kyowa Kikaku	5.5M	Claims, others
JammNet	JammNet	2.8M	Claims

The Big One, non-profit use only

Major in IB

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Major Japanese databases in Japan available for clinical/pharmaco-epidemiology(3)

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IQVIA NPA	IQVIA Sol. JP	30M	Pha. Claims
JMIRI	JMIRI	11M	Pha. Claims
Medi-Trend	Kyowa Kikaku	3.5M	Pha. Claims
NihonChouzai	a.k.a.Nihon-Chouzai	3.1M	Pha. Claims, others
PFR	CCT K.K.	1.6M	Others

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Personal Information Protection Law in Japan

■ Personal Information Protection Law

Passing PHI to third parties is highly restricted.

- Individual agreement → OK
- Gov's execution under a low → OK (without individual agreement)
- Opt-out permission → banned for PHI
- Usual anonymized data → Virtually impossible
  (Most anonymized data are possible to identify individuals by matching with some additional information)

Instead, "TOKUMEI KAKOU" (anonymous processing) is provided in the PIP low.

- By following specific procedures and rules, anonymized data can be passed.
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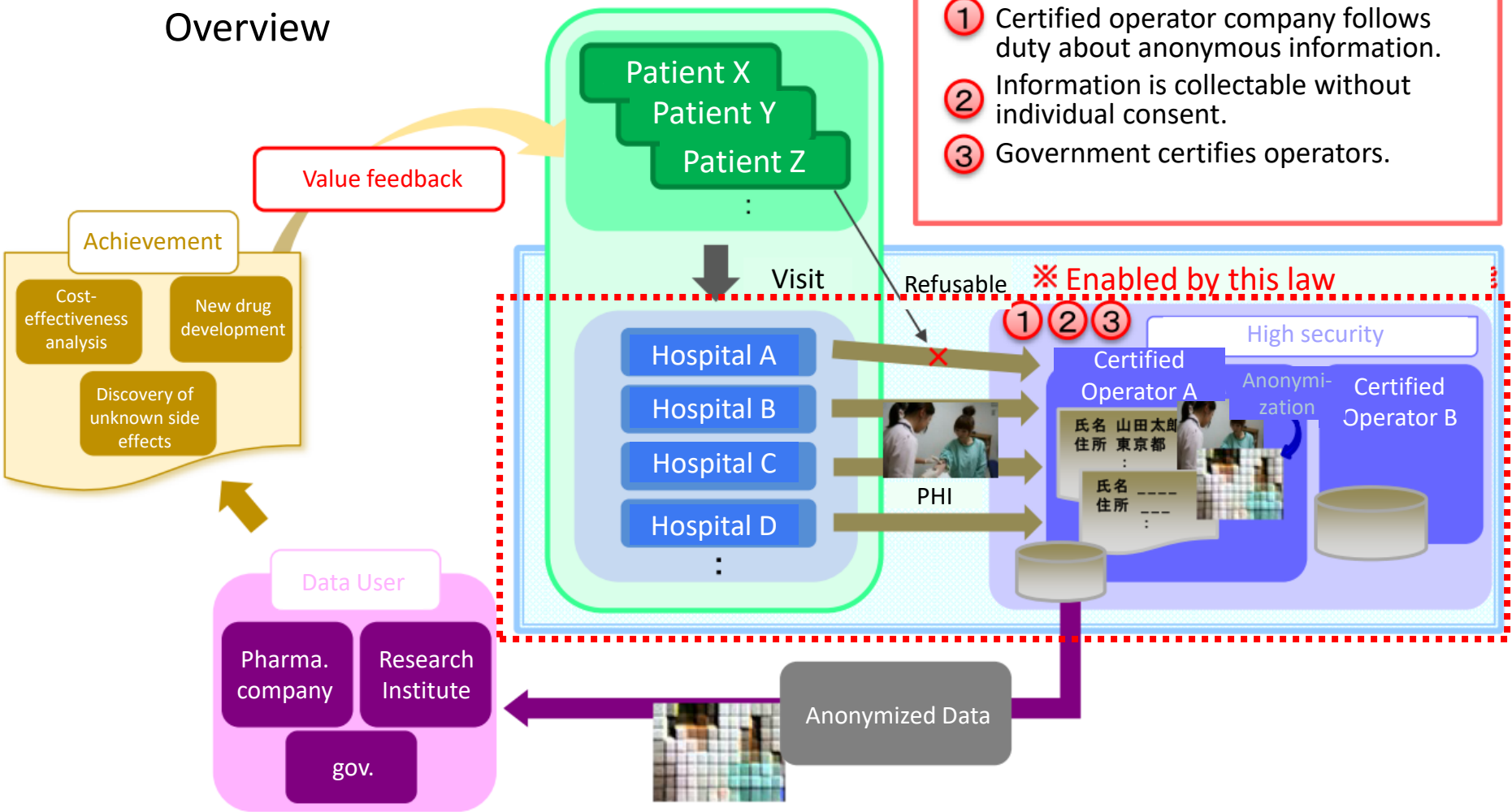
■ Next Generation Medical Infrastructure Law (Medical Big Data Law)

- It partially overwrites the PIP low.
- Certified corporations can collect non-anonymized PHI from hospitals with the "careful opt-out" permission.
- The corporations can merge the data using patient ID and pass the extracted TOKUMEI KAKOU data to third parties.

Next Generation Medical Infrastructure Law (Medical Big Data Law)

Enforced since May 2018

Overview

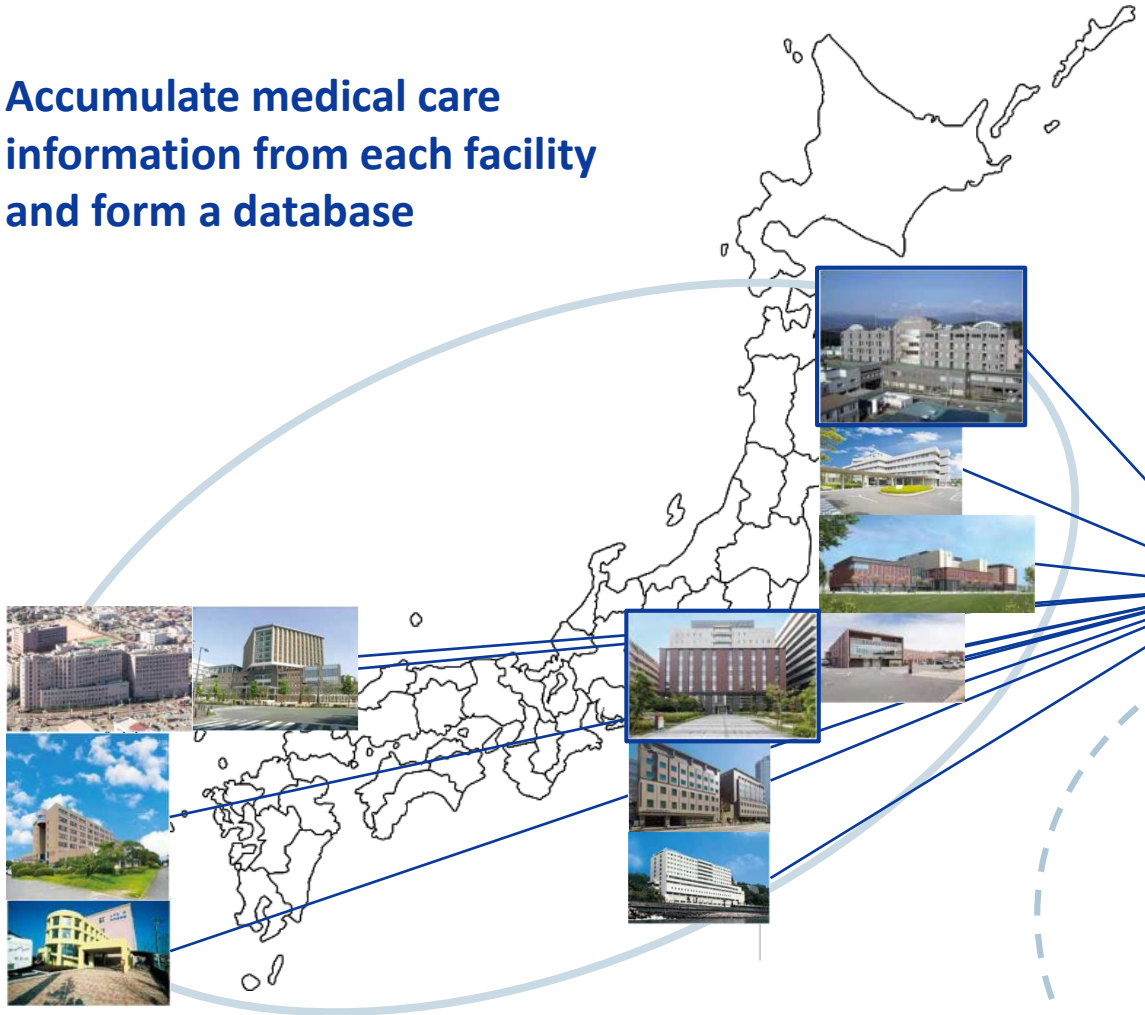


① Certified operator company follows duty about anonymous information.
② Information is collectable without individual consent.
③ Government certifies operators.

Reference: 医療分野の研究開発に資するための匿名加工医療情報に関する法律についてを改変

IHW group's concept of Health and Welfare Clinical Information Database (HWCI-DB)

Accumulate medical care information from each facility and form a database



To become one of Japan's leading data utilization bases with high degree of internationality

Graduate courses:
- Health welfare data science
- Health information analyst

Multi-facility database

International open standards OMOP-CDM

Reserarch

Education

Clinical Support

Hospital management

Cooperation with other DB projects

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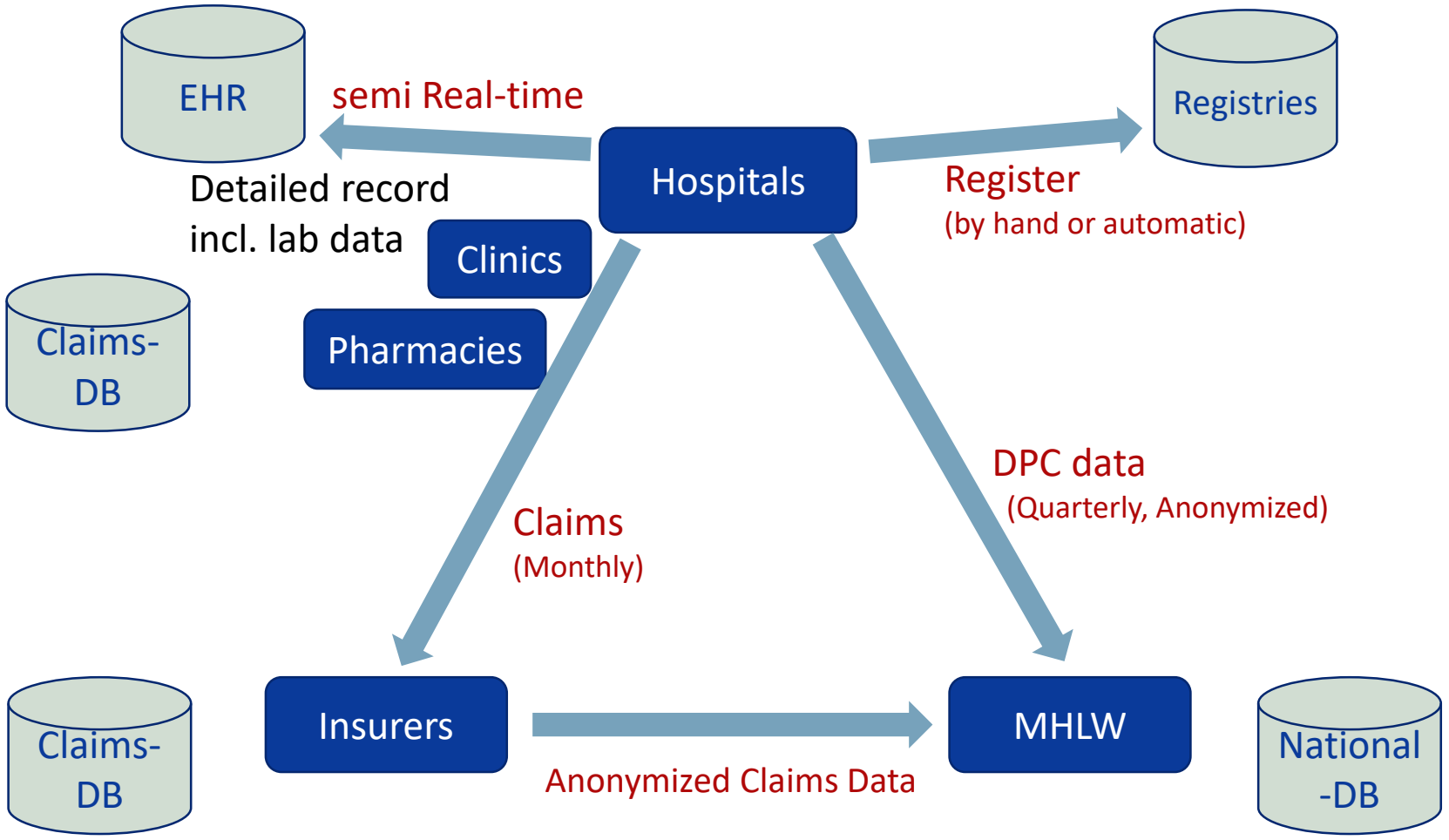

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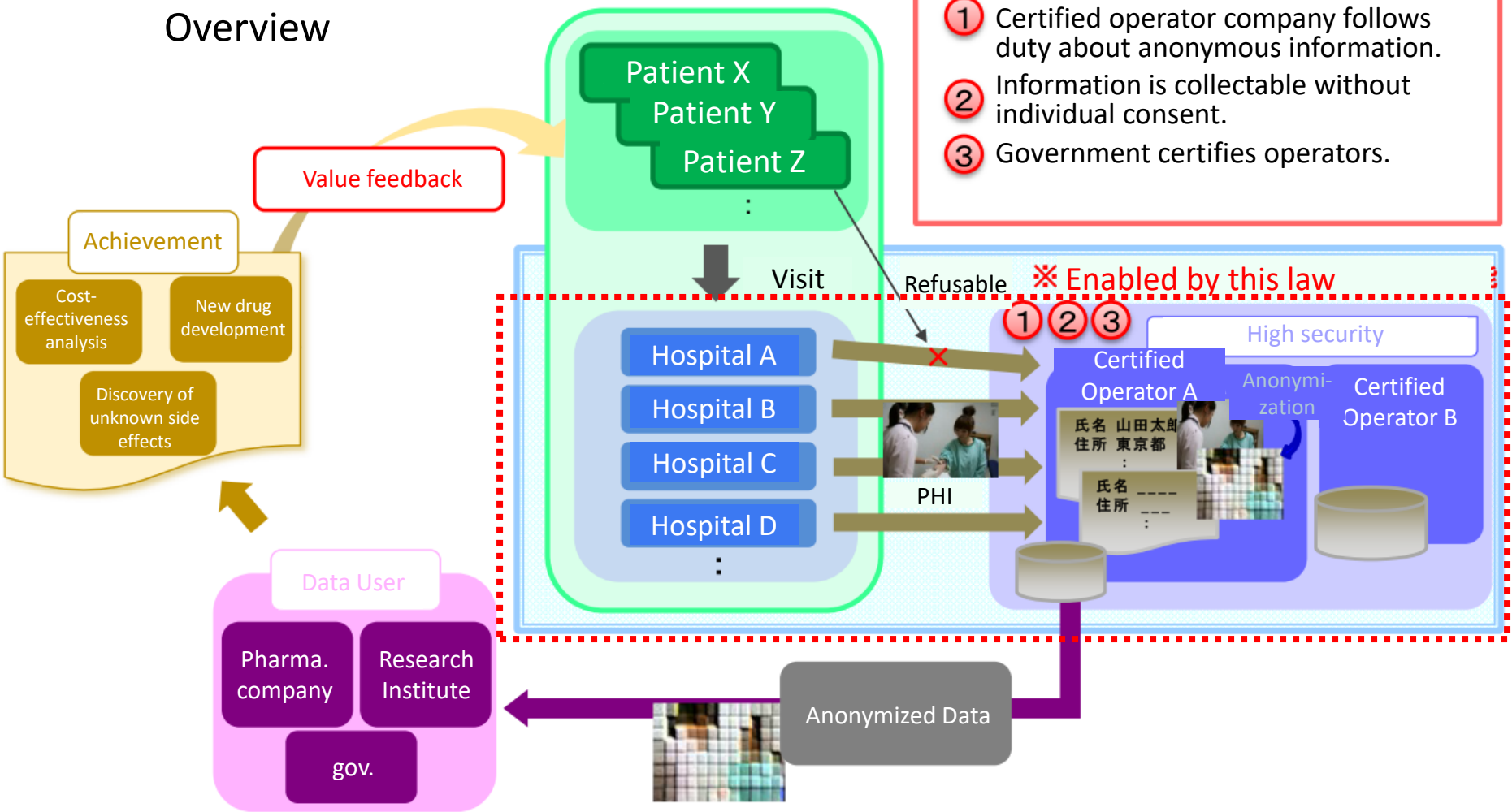

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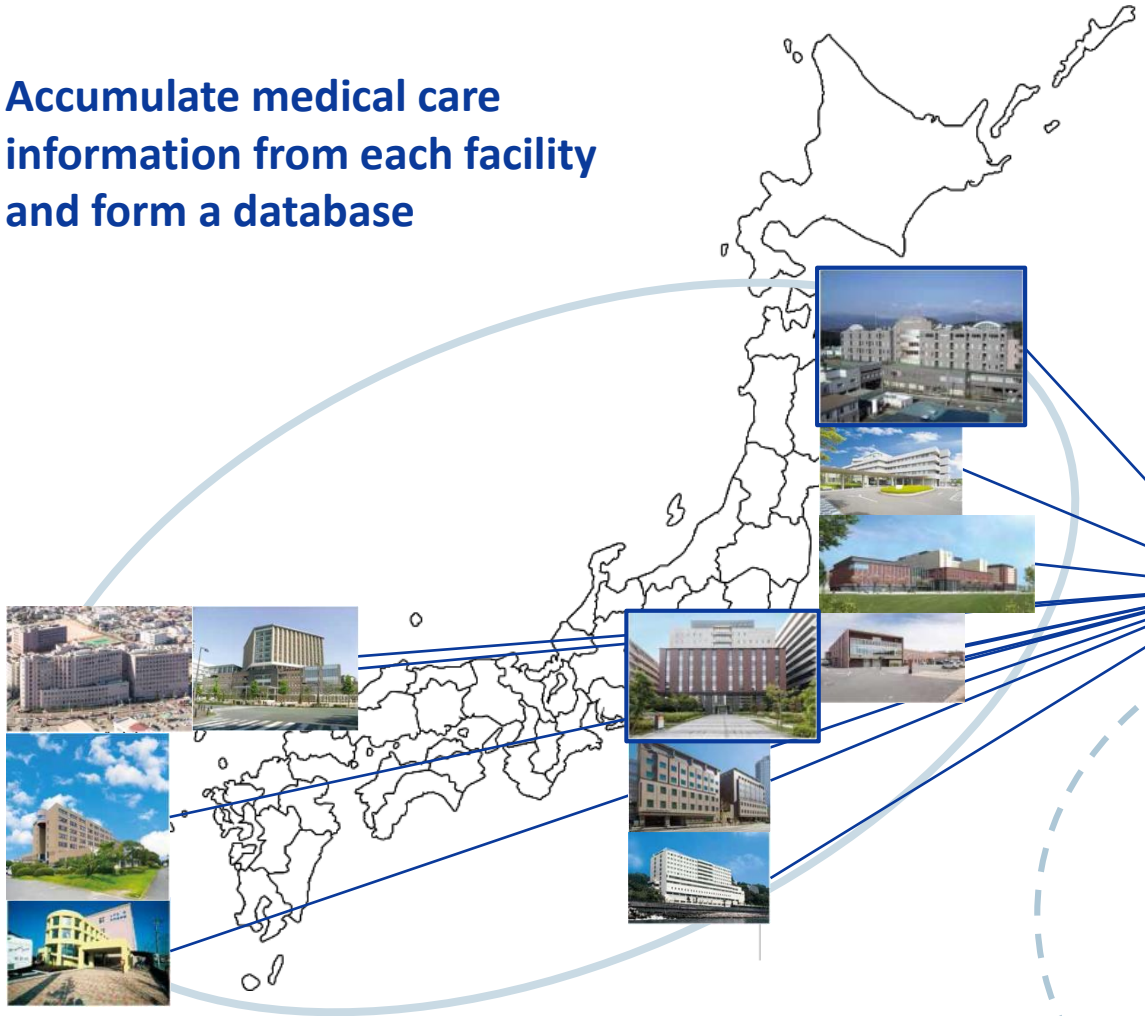

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OMOP-JV

The Intermediate Format
with
Japanese Vocabularies

Difficulty of using OMOP-CDM in Japan

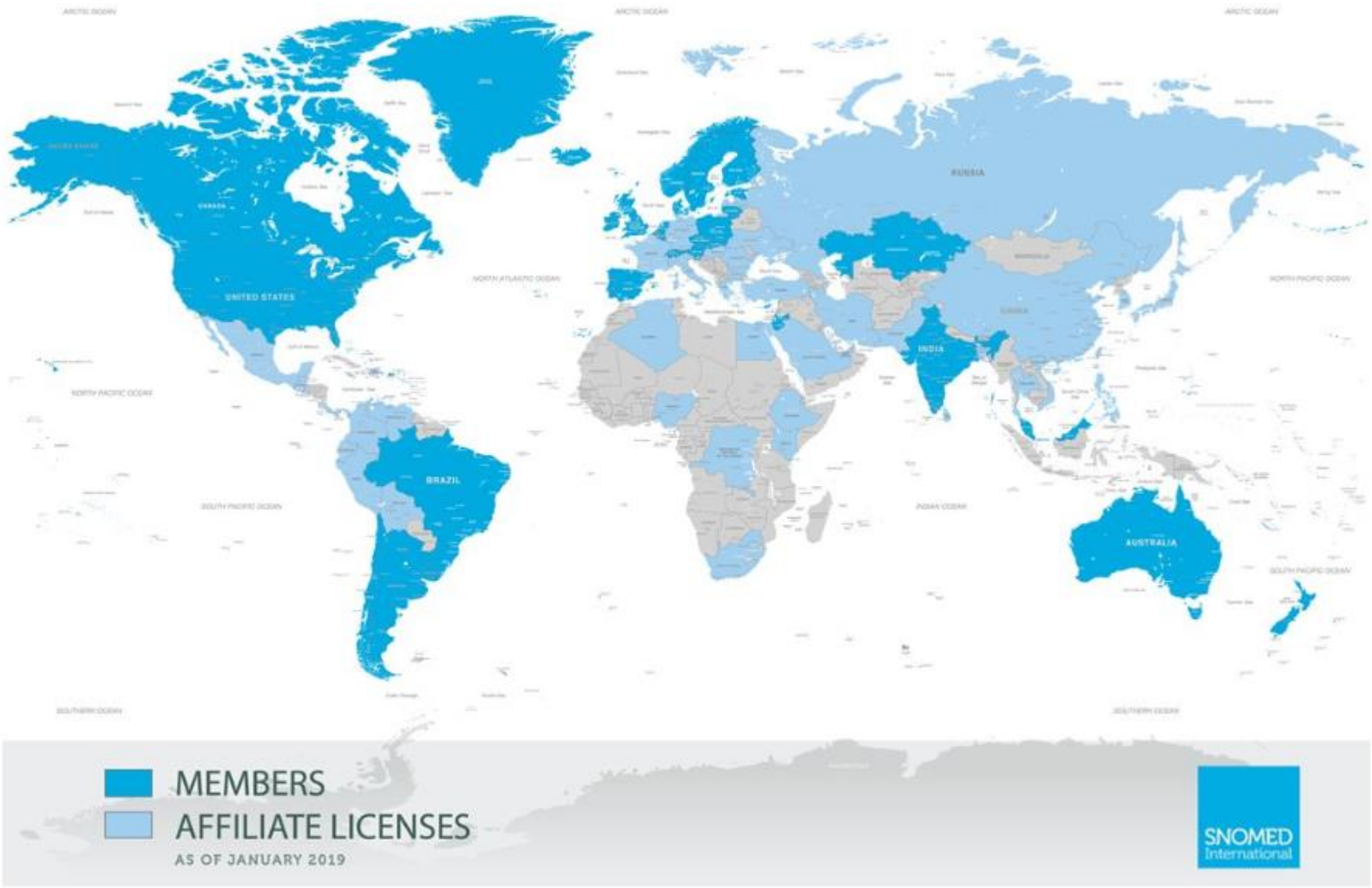
■ OMOP-CDM assumes the use of standard terms mainly used in the United States such as SNOMED-CT, RxNorm, and LOINC.

SNOMED-CT : medicine-clinical terms including disease names.
RxNorm : normalized names for clinical drugs.
LOINC : names and codes for identifying medical laboratory observations.

■ SNOMED-CT is not available in Japan due to license issue. RxNorm is for US pharmaceutical products, and LOINC is not used in Japan. Unification of the LOINC subset to be used is also an issue.

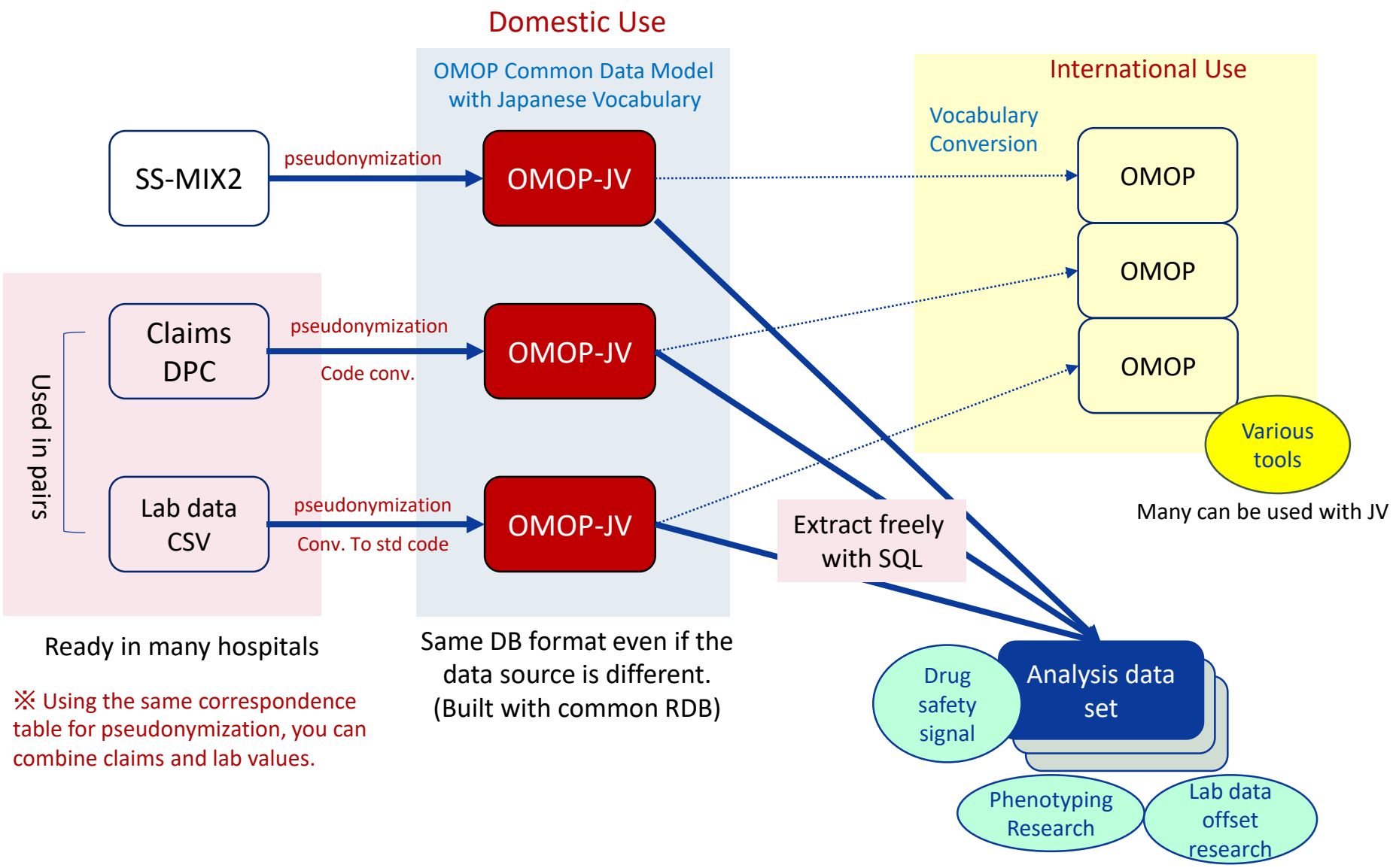
■ For domestic use in Japan, it may be better to use the domestic standard as it is.

SNOMED Members



http://www.snomed.org/our-stakeholders/members

Intermediate Format for Domestic Use



OMOP-JV : OMOP-CDM form in Japan domestic use

■Use Japanese standard terminology

- Disease name: Electronic claims disease name, MEDIS standard disease name, or DPC diagnosis code.
- Drugs: YJ code, electronic claims code, or HOT code.
- Clinical exam: JLAC 10/11

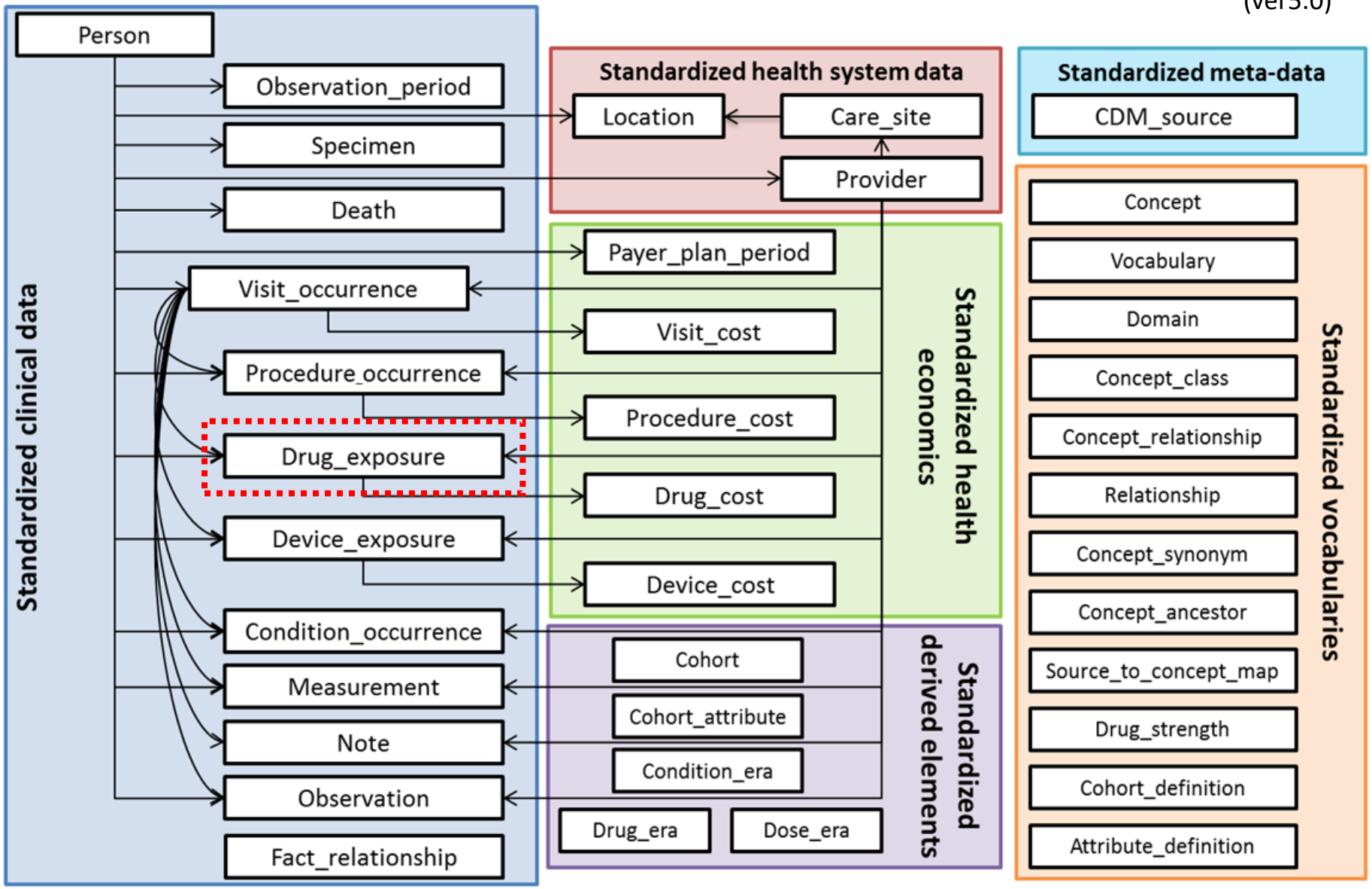
■Add fields for domestic use

- To put Japanese standard terms as they are.
- Multiple standard terminology are also included.
- Data source dependent information is also included.

If you delete the additional fields, OMOP-JV becomes global OMOP-CDM as it is. (except Vocabulary)

OMOP-CDM Constitution

(ver5.0)



OMOP-JV clinica data table (drug)

DRUG_EXPOSURE	drug_exposure_id	システムにより生成される個々の薬剤使用ID(integer) // ユニーク値、親キー
// 医薬品使用情報	person_id	薬剤を使用した患者の患者ID
	drug_concept_id	薬剤に付与された標準薬剤コンセプトのID(integer) // jvではYJを入れる
	drug_exposure_start_date	薬剤を使用開始した日付（処方開始日、調剤日、または治療で薬剤が投与された日）
	drug_exposure_start_datetime	薬剤を使用開始した日時（処方開始日、調剤日、または治療で薬剤が投与された日）
	drug_exposure_end_date	薬剤の使用終了日
	drug_exposure_end_datetime	薬剤の使用終了日時
	verbatim_end_date	元データに記されている終了日(計算ではなく) // 中止日等
	drug_type_concept_id	薬剤使用の情報元を示す事前定義のコンセプトID // 処方オーダ、実施記録、調剤等を示す。(オーダ・実施・調剤)×(処方・注射)
	stop_reason	薬剤中止の理由（例：レジメン終了、変更、廃止など）
	refills	最初の処方以来の補充回数（最初の処方のみなら"0"）
	quantity	記載されたとおりの薬剤の量（浮動小数点数）// jvでは1日量を推奨だが１回量もok.単位をdose_unit_source_valueに記載する
	days_supply	薬剤の提供日数(integer)
	sig	記載されている用法(sig) (例：1 tsp po BID for 10 days) // jvでは服薬タイミング情報(３x食後等）
	route_concept_id	投与経路を示す事前定義のコンセプトID(integer)
	lot_number	薬剤の製造元における口ット番号等
	provider_id	薬剤使用を開始した（処方や投与を行った）医療者ID (PROVIDER table) // 医療者個人だけでなく、jvでは診療科もOK.
	visit_occurrence_id	薬剤使用が開始された受診期間の受診ID (VISIT_OCCURRENCE tableのkeyID) // visit_occurrence_idは下2桁で入外がわかる。
	visit_detail_id	VISIT_DETAIL tableのID // jvではvisit_concept_id(入外区分)をいれる
	drug_source_value	元データに記されている薬剤名(コード/名称） // できるだけ見てわかる略称等とするが、データ量が増える..
	drug_source_concept_id	元データに記されているコード体系（HOTやレセや院内）によるcon (元のOMOPでは標準コードのみ対象）
	route_source_value	元データに記されている投与経路情報
	dose_unit_source_value	元データに記されている用量の単位情報 // jvではquantityの単位情報（Tab、ml、本等）×(/single,/day,/full)
(中間DB)	jv_visit_kind	医薬品情報の一部として得られた入外情報。visit table内の入外等情報とは異なる場合がありえる。
(中間DB)	jv_drug_yjcode	YJ12コード文字列(再マッピング時には上書き、999あり）
(中間DB)	jv_drug_hotcode	HOT9コード文字列(再マッピング時には上書き、99あり）
(中間DB)	jv_drug_rececode	レセ電コード文字列(再マッピング時には上書き）
(中間DB)	jv_drug_miscinfo	この医薬品使用に関わるその他の詳細情報（cgiのQUERY_STRINGと同形式)
(中間DB)	aux_source_pointer	元データ自体の格納場所を示すポインタ情報(暗号化したものをascii文字列化して格納）
(中間DB)	aux_source_infotime	データ元から元データをいつ取得したかを表す日時 //データ元からの抽出日時等
(中間DB)	aux_updatetime	本レコードの最終更新日時

Tentative, may change later.

OMOP-JV clinica data table (measurment)

Measurment table: Lab Test, etc.

measurement_id	個々の測定のID(integer)　// ユニーク値、親キー、BIGINT必要	y	int
person_id	測定が記録された患者の患者ID (PERSON table)	y	int
measurement_concept_id	測定の標準コンセプトID (CONCEPT table) // 標準にマップできない場合は"0". JV標準は現状jlac10	y	int
measurement_date	測定の「日付」	y	date
measurement_datetime	測定の「日時」	n	datetime
measurement_type_concept_id	測定値の出所を示す事前定義のコンセプトID　// 検体検査、細菌検査、薬物血中等	y	int
operator_concept_id	value_as_numberが"以上,未満"等を持つとき (<, ≤, =, ≥, >)の事前定義コンセプトID　// 実値は通常はnull ('='でもOK)	n	int
value_as_number	測定結果が数値のときの結果値 (浮動小数点数) 、NULL可	n	float
value_as_concept_id	測定結果がカテゴリや有無のときの結果値のコンセプトID、NULL可　// 陽性-陰性、低-高など。0は「元データ参照」	n	int
unit_concept_id	結果値単位の標準コンセプトID (CONCEPT table) // 標準コード変換時に単位が(値とともに)変換されることがある点に注意。	n	int
range_low	正常値下限 (浮動小数点数)　// 基準範囲下限。臨床判断値は解釈でありDBに入れるものではない。	n	float
range_high	正常値上限 (浮動小数点数)　// 基準範囲上限。臨床判断値は解釈でありDBに入れるものではない。	n	float
provider_id	測定することに責任のある医療者ID (PROVIDER table)　// 医療者個人だけでなく、jvでは診療科もOK.	n	int
visit_occurrence_id	測定が記録された受診期間の受診ID (VISIT_OCCURRENCE table) // 下2桁 で入外情報がわかる(visit_concept)	n	int
visit_detail_id	VISIT_DETAIL tableのID	n	int
measurement_source_value	元データに記されている測定名 // できるだけ見てわかる略称等とするが、データ量が増える..	n	varchar(50)
measurement_source_concept_id	元データに記されているkeyとなるコード体系 (JLACやレセや院内) によるcon. 院内コードがあれば院内コード	n	int
unit_source_value	元データに記されている測定単位　// 東大コードからテーブルを引いた補充も含む	n	varchar(50)
value_source_value	value_as_numberまたはvalue_as_concept_idの元となる、元データに記されている測定結果文字列	n	varchar(50)
jv_lab_rececode	レセ電コード(再マッピング時には上書き)　// cocept tableに登録はしておくこと	n	varchar(20)
jv_lab_jlac10	JLAC10コード(再マッピング時には上書き)　// cocept tableに登録はしておくこと	n	varchar(20)
jv_lab_jlac11	JLAC11コード(再マッピング時には上書き)　// cocept tableに登録はしておくこと	n	varchar(20)
jv_lab_loinc	LOINCコード(再マッピング時には上書き)　// cocept tableに登録はしておくこと	n	varchar(20)
jv_measurement_miscinfo	この測定に関わるその他の詳細情報 (cgiのQUERY_STRINGと同形式) 検査連携IDもここへ	n	varchar(8000)
aux_source_unit	元データに含まれている通りの単位文字列 (空欄がけっこうある)	n	varchar(20)
aux_source_pointer	元データ自体の格納場所を示すポインタ情報(暗号化したものをascii文字列化して格納)	n	varchar(50)
aux_source_infotime	データ元から元データをいつ取得したかを表す時刻 //データ元からの抽出時刻等	n	datetime
aux_updatetime	レコードの最終更新日時	y	timestamp

Tentative, may change later.

JV Concept Code Allocation (Drug & Measurment)

Structured by decimal digits

■Drug

	JV割当方式	local DWH	claims data	DPC data	ss-mix2
drug_concept_id	00 50Yd dddd	00 500d dddd	00 500d dddd		00 500d dddd
drug_type_concept_id	00 3020 0tnn	00 3020 090n	00 3020 01ab	00 3020 0300	00 3020 040n
drug_source_concept_id	00 61dd dddd	←	1r rrrr rrrr		0(仮)
route_concept_id	00 3021 nnnn		-		00 42cc aabb
dose_unit_concept_id					
jv_drugname_concept_id	00 61dd dddd		-	-	0(仮)

■Measurment

	JV allocation	local DWH	claims data	DPC data	ss-mix2	Lab CSV
measurement_concept_id	00 64dd dddd	←	0	0	00 64dd dddd	00 64dd dddd
measurement_type_concept_id	00 3040 aabb	00 3040 0901	00 3040 0101	00 3040 0301	00 3040 0401	00 3040 0501
operator_concept_id	00 3041 000n	00 3041 000n	-	-	00 3041 000n	00 3041 000n
value_as_concept_id	00 4002 dddd	00 4002 dddd	-	-	00 4002 dddd	00 4002 dddd
unit_concept_id	00 4003 dddd	00 4003 dddd	-	-	00 4003 dddd	00 4003 dddd
measurement_source_concept_id	depends	00 510d dddd	1r rrrr rrrr	1r rrrr rrrr	0	00 510d dddd

Tentative, may change later.

JV Concept Code Rule

■ special concept codes (predefined)
70 Male / 78 Female , 73 Inpatient / 79 Outpatient
(Decimal representation of the initial letters' ASCII code)

■8 digits
00 1 (reserved)
00 2nnn nnnn : predefined (use disease name mnt# as conID)
00 3XXX nnnn : predefined (≤ 4 digits) conID. XXX=class
00 40XX dddd : dynamic (≤ 4 digits) conID (clinical data)
00 41XX dddd : dynamic (≤ 4 digits) conID (health system data)
00 5XXd dddd : dynamic (5 digits) conID e.g. drugs, lab data
00 6Xdd dddd : dynamic (6 digits) conID
00 7 (reserved)
00 8XXX XXXX : omop-jv patient id
00 9 (reserved)

■9 digits
01 (reserved)
..
06 XXdd dddd : dynamic (6 digits) conID expansion
07 Xddd dddd : dynamic (7 digits) conID
08 (reserved)
09 (reserved)

■10 digits
1d dddd dddd : claims data code (receipt code itself) as conID
21 XXXX XXXX : not used

Tentative, may change later.

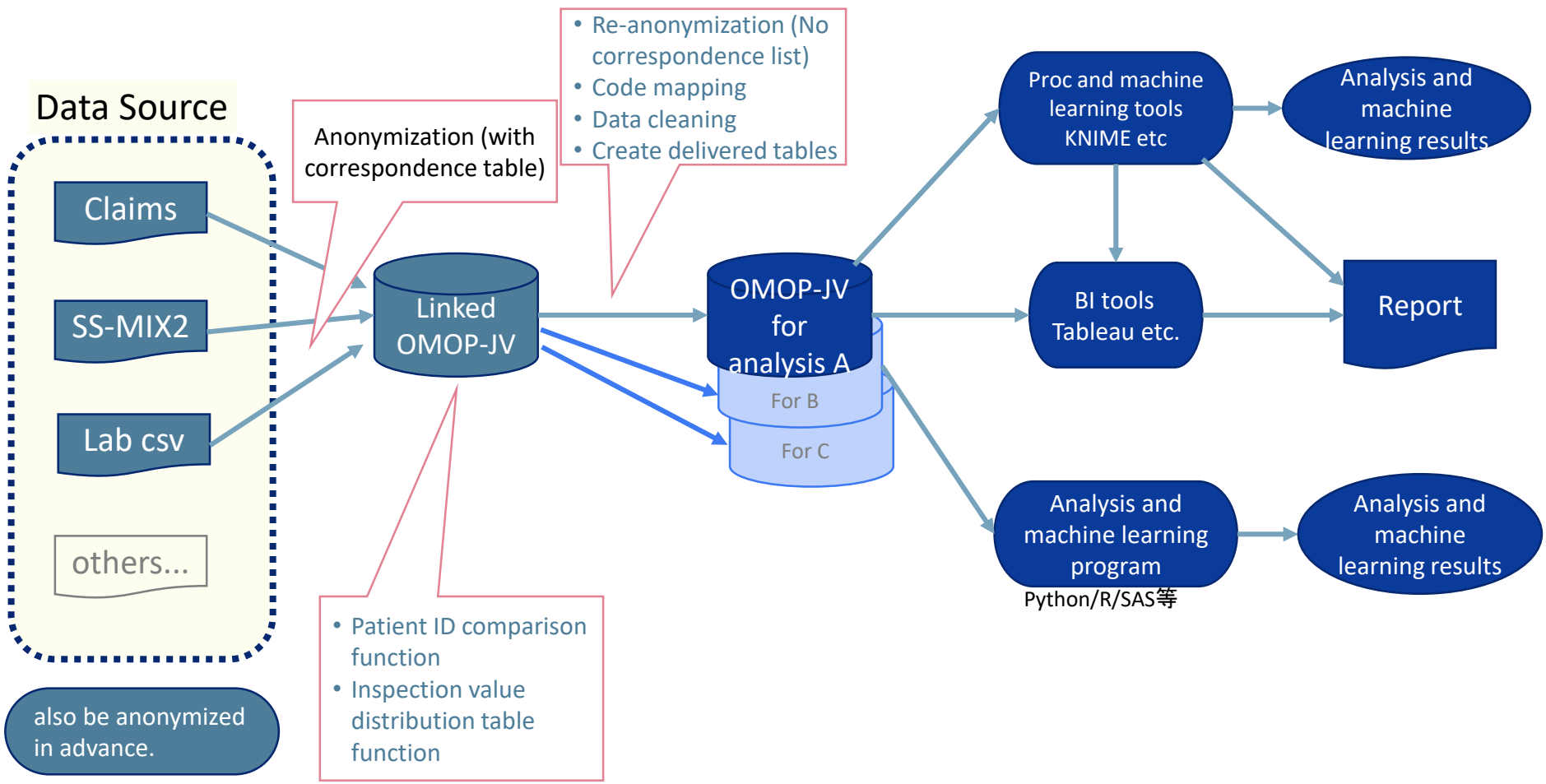
■Useful for domestic use

- You do not have to do unreasonable mapping.
- Analysis can be done with the granularity of standard Japanese terms.

■Common internationalization

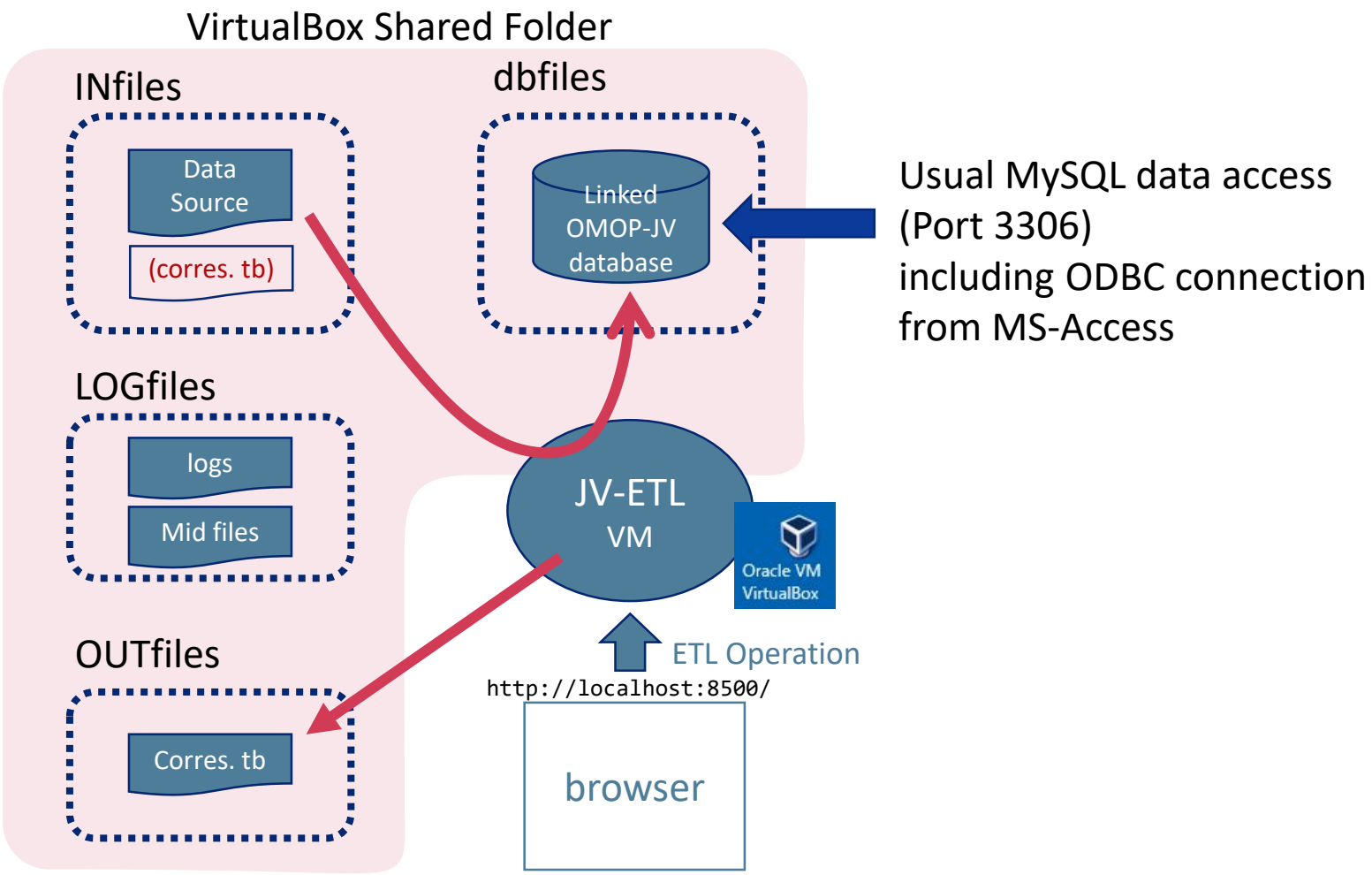
Mapping from Japanese standard terms to standard terms used in global OMOP can be shared throughout Japan, eliminating the need for each person/company to prepare mapping tables.

ETL tool for OMOP-JV (U-Tokyo Version)

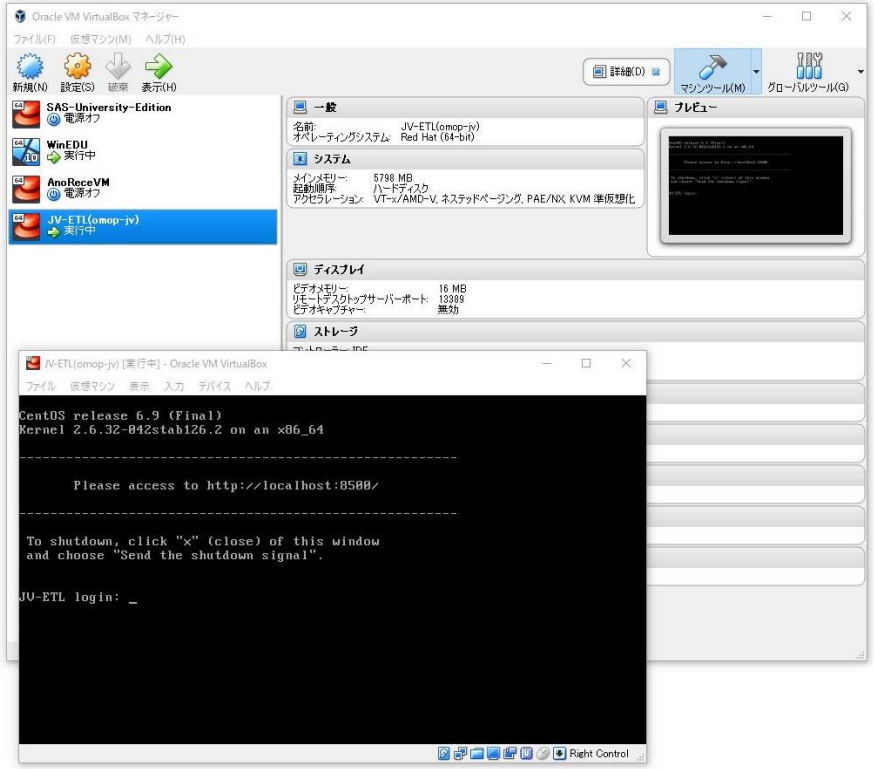


ETL tool for OMOP-JV (U-Tokyo Version)

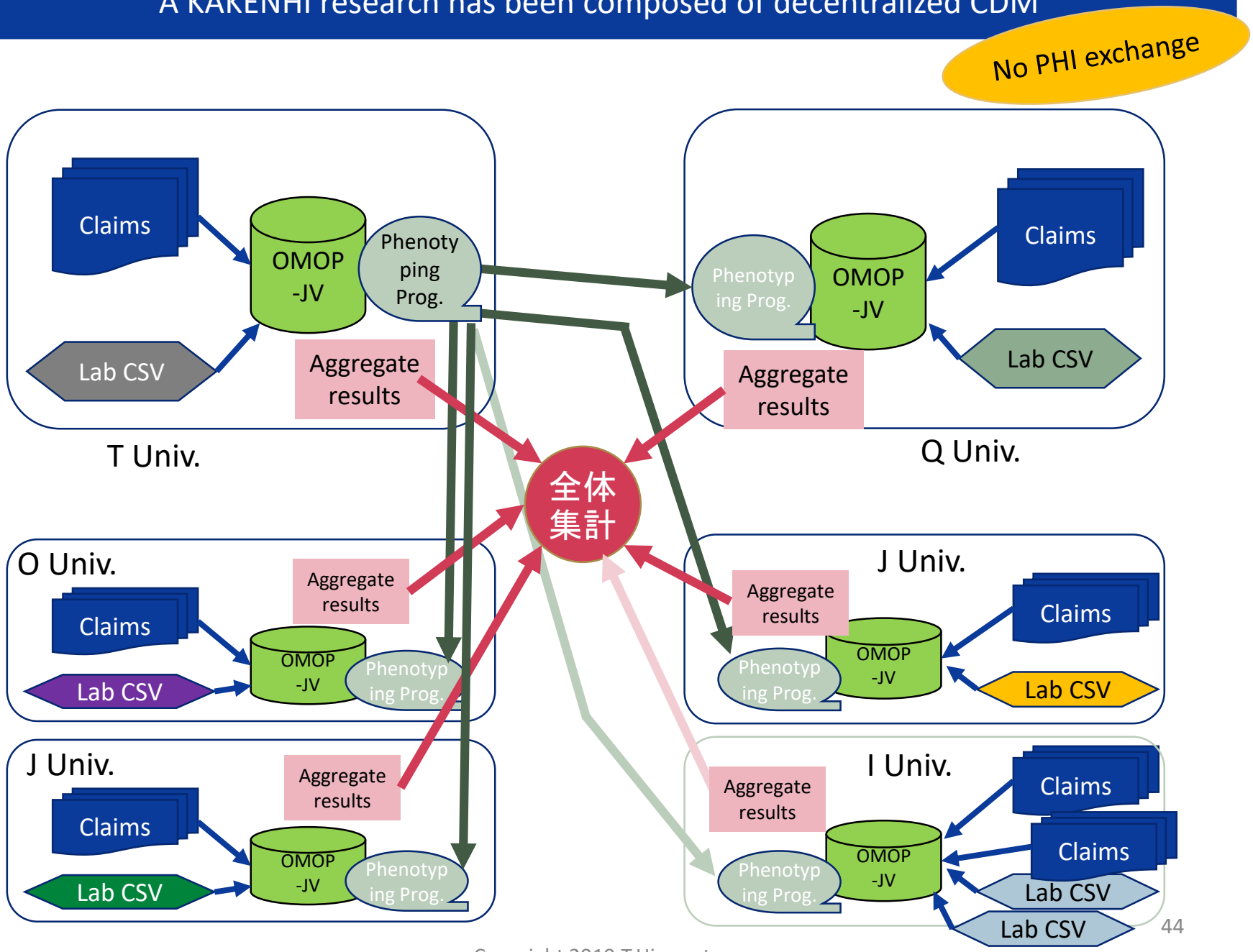
Works on Oracle VirtualBox virtual machine



ETL tool for OMOP-JV (U-Tokyo Version)



A KAKENHI research has been composed of decentralized CDM



Tools are stably supplied by multiple vendors

ETL tools currently have two implementations, which can be selected according to the usage environment.

●U-Tokyo implementation (by Hiramatsu)
- Currently in use at five universities at a KAKENHI research.
- To be provided free of charge to medical facilities etc.
- Support is limited. Need some degree of expert.

●Commercial implementation (major vendor)
- In use at a national university.
- Provided for a fee.
- Supported by major vendors, can be adopted in large-scale business.

The detailed specifications must be the same for the two implementations.
↓
It is necessary to establish a unified specification (OMOP-JV) and to have a neutral "place" to check the compatibility of the implementation.

Setting up OHDSI Japan
and its management
(discussion)

What to do in OHDSI Japan

- A place to establish a unified specification (OMOP-JV) and check the compatibility between implementations.

- OMOP-JV Promotion Activities
  - Free distribution of the U-Tokyo implementation.
  - Holding symposia and seminars (as far as possible).
  - Arrangement and adjustment of OMOP-JV utilization projects.
  - Support for JLAC 10/11 mapping from hospital local code.

- Vocabulary mapping between JV and global OMOP
  - YJ code to RxNorm
  - JLAC10/11 to LOINC
  - Claims disease code to SNOMED-CT

Open Issues

- Individual base? Company/Univ base?
  - In global OMOP?
  - In other countries?
- Corporation? Unincorporated association? Just a community?
- Annual fee from member?
- Supporting member (Sponsor)?