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A case of RWD use in post-marketing study as PV activity in Japan

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Today's agenda

1. Databases available in Japan
2. A case of post-marketing database study
3. Consideration for the future

DBs available for PE researches in Japan

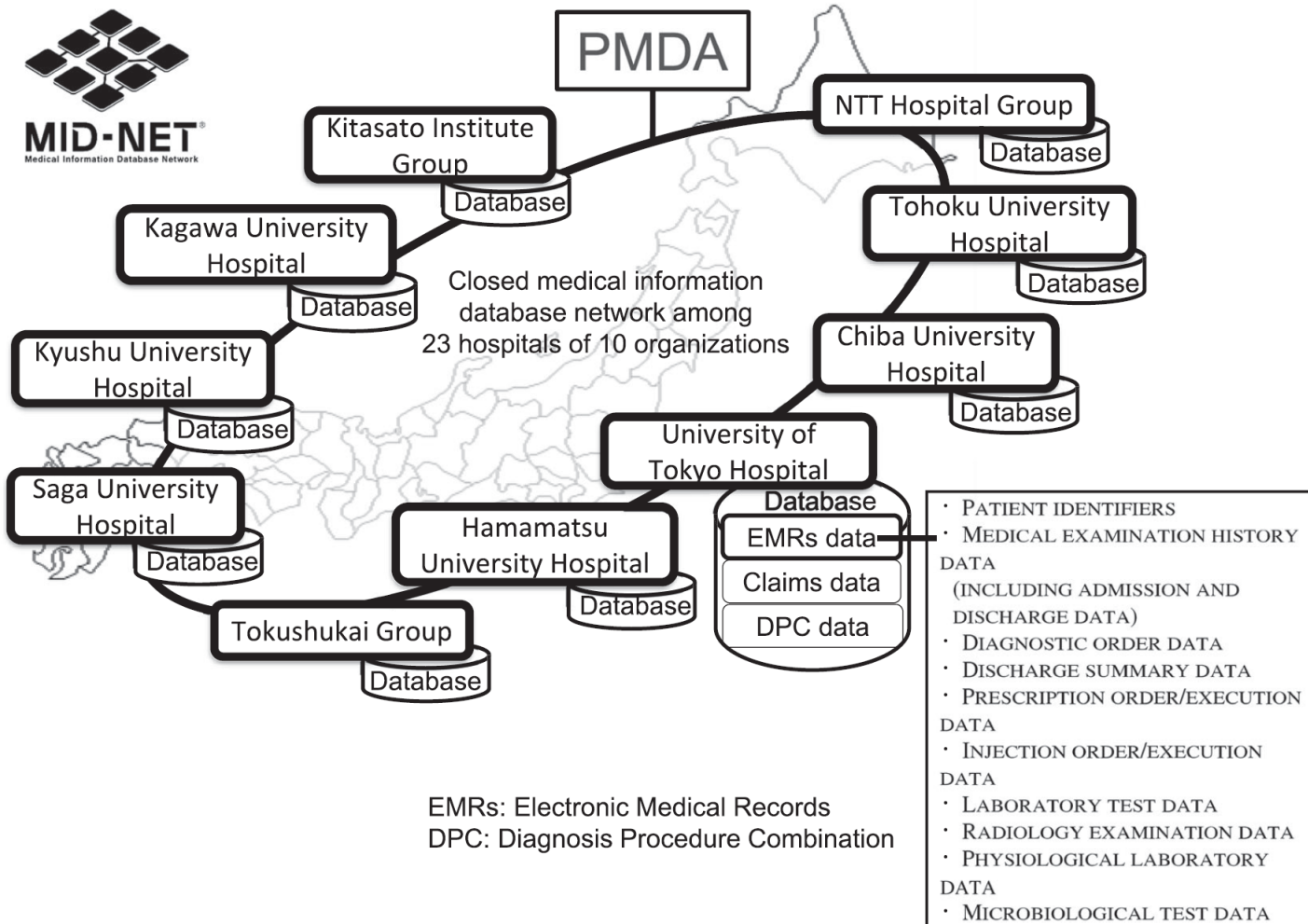
Databases available for pharmacoepidemiology researches in Japan (information obtained from survey answers as of August 2020)

	Hospital-based									NDB	(
	NHO NCDA	NHO MIA	4DIN	HCE/RWD	LDI	MID-NET	MDV (Hospital based)	JMDC (Hospital based)	NCD		
Database organizer	NHO	NHO	4DIN (a.k.a. CCT)	Real World Data, Co., Ltd.	Life Data Initiative	Pharmaceuticals and Medical Devices Agency	Medical Data Vision Co., Ltd.	JMDC Inc.	NCD	Ministry of Health, Labour and Welfare	
Database name	NCDA	MIA	4DIN Research Network	RWD database	Millennium Medical Record	Medical Information Database Network (MID-NET)	EBM Provider®	JMDC hospital database	National Clinical Database	National Database of Health Insurance Claims and Specific Health Checkups of Japan	
Contact information	700-dbpeojct@mail.hosp.go.jp	700-dbproject@mail.hosp.go.jp	info@4din.com	info@rwddata.co.jp	contact@ldi.or.jp	wakaru-midnet@pmda.go.jp	ebm_sales@mdv.co.jp	mdbhelp@jmdc.co.jp	http://www.ncd.or.jp/	suisin@mhlw.go.jp	mdt
Web site URL	https://nho.hosp.go.jp/cnt1-1_000070.html	https://nho.hosp.go.jp/cnt1-1_000070.html	https://4din.com/	https://rwddata.co.jp/	https://www.ldi.or.jp/	https://www.pmda.go.jp/safety/mid-net/0001.html	https://www.mdv.co.jp/	https://www.jmdc.co.jp/	http://www.ncd.or.jp/	https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/ryou/hoken/reseputo/index.html	https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/ryou/hoken/reseputo/index.html
Database Overview											
General description of the database	Clinical database based on 66 NHO hospital information systems	Administrative database for inpatient and outpatient consists of 141 NHO hospitals in Japan.	Network to collect, identify and summarize various data from medical institutions	Integrated database of medical information such as electronic medical record, claims and DPC data.	Database consists of DPC, claims and electric records from university hospitals, cancer hospitals	The medical information Database network system for utilizing in safety assessment managed by PMDA under the Act on the Pharmaceuticals and Medical Devices Agency.	Administrative database for inpatient and outpatient consists of 419 acute (mainly considered as "advanced treatment hospitals") hospitals in Japan	Claims database consists of inpatients and outpatients from multiple acute/non acute hospitals	Multidisciplinary registry platform initially developed by surgery related professional societies in Japan. Currently managing nationwide registries for various surgeries, interventions, pathology, as well as cancer registries. Also collects hospital based DPC / claims data which can be used together with the registry data for research.	Database of health insurance claims and specific health checkups for preparation, implementation and evaluation of medical cost optimization plan	Clear cons subs empl Insur as cr
Data source											
DPC (Format 1)	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	
DPC (EF file)	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	
Medical claim	No	Yes	Limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	
Pharmacy claim	No	No	Limited	No	No	No	No	No	No	Yes	
Electronic medical chart	Yes	No	Limited	Yes	Yes	Yes	No	No	No	No	
Lab test results	Yes	No	Limited	Yes	Yes	Yes	Limited	Yes	No	No	
Ordering	No	No	Limited	Yes	Yes	Yes	No	No	No	No	
Health checkup	No	No	No	Limited	No	No	No	No	No	Yes	
Registry	No	No	Limited	No	No	No	No	No	Yes	No	
Others	No	No	No	No	Yes	Yes	Yes	Yes	No	No	
Data source:				Pathological diagnosis		DPC (F file)	DPC(Dfile)/DPC	H file	N		Eligib

<Reference>

Survey of Japanese databases in Japan available for clinical/pharmaco-epidemiology
 The website of Japanese Society for Pharmacoepidemiology
 URL: https://www.jspe.jp/mt-static/FileUpload/files/JSPE_DB_TF_E.pdf

Outline of MID-NET®



<Reference>

Establishment of the MID-NET® medical information database network as a reliable and valuable database for drug safety assessments in Japan
Pharmacoepidemiol Drug Saf. 2019 Oct;28(10):1395-1404.

◆ Risk management plan of PRALIA®

製造販売後データベース調査（低カルシウム血症）

【安全性検討事項】

低カルシウム血症

【目的】

関節リウマチ罹患患者を対象集団とし、2017年7月3日以降に本剤が初回投与された患者群での低カルシウム血症発現リスクの程度を、本剤非投与患者群と比較して評価する。

【実施計画】

データベース：MID-NET

データ期間：2016年7月～2020年12月

調査のデザイン：コホート研究

調査対象集団：関節リウマチ罹患患者

曝露群：本剤初回投与患者

対照群：本剤非投与患者

想定症例数：曝露群 約1,000例、対照群 約8,000例

アウトカム定義に用いるデータ項目：

低カルシウム血症（血清カルシウム値<8.50mg/dL）

Post-marketing database study
(Important identified risk : Hypocalcemia)

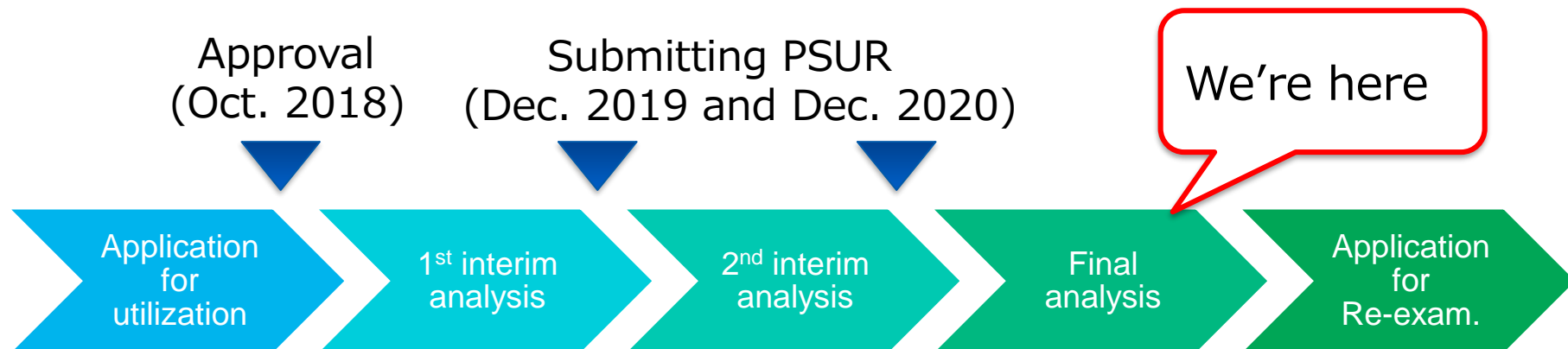
Database to use : MID-NET®

Aim of this DB study

◆ Aim of this DB study using MID-NET®

- ✓ To investigate risk of hypocalcemia in patients administrated PRALIA® compared with control patients
- ✓ To investigate status of implementation of serum Ca test in the real world

<Study timeline>



Study objective / Research question

◆ Study objective

To evaluate the degree of hypocalcemia risk in the patients with rheumatoid arthritis who are treated for the first time with PRALIA[®] in or after July 2017 in comparison with the patients not treated with PRALIA[®].

◆ Research question

Patient	Patients with rheumatoid arthritis
Intervention / Exposure	Treatment with PRALIA [®]
Comparison	Not treatment with PRALIA [®]
Outcome	Hypocalcemia (Serum calcium < 8.50mg/dL)
Timing (Data period)	From July 2016 to December 2020

What is strong point of DB study?

◆ Strong point of DB study

- ✓ It's possible to realize more **timely data collection** than primary data collection.
- ✓ **Lower cost** than primary data collection.

◆ Important point when conducting DB study

- ✓ Reliability of data sources
- ✓ Validity/definition of outcome

We can create meaningful safety-information/evidence for patients and physicians by utilization of RWD appropriately.

◆ The needs for utilizing RWD will increase more in the future.

- ✓ Using various data sources in a study for PV
- ✓ Routine pharmacovigilance activity
(e.g. Safety signal detection/management)
- ✓ KAB(knowledge activity behavior) survey

◆ Expectation

- ✓ Activation of sharing the knowledge and exchanging the opinion regarding RWD use with Asia countries especially China.