

ISPOR 2018, May 19-23, 2018 Baltimore, USA

**Real-world Evidence and Local Evidence Generation
: How Should It be Approached in Asia Pacific ?**

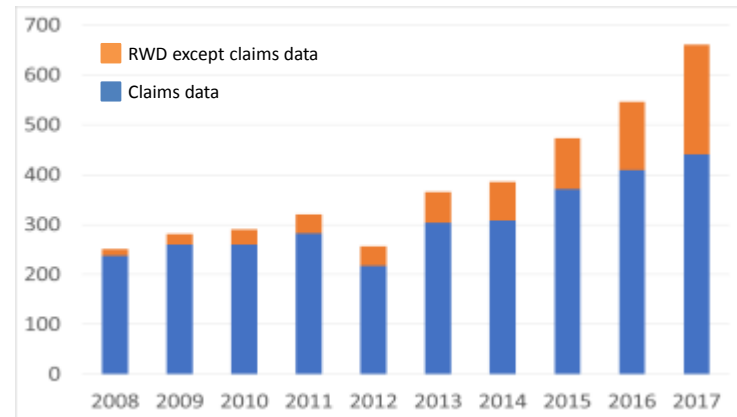
RWD in Japan

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No. of Publication regarding RWD in Japan



Various Real-world Data are Available in Japan

- **Public Databases**

- NDB
- MID-NET
- etc.

- **Registry studies**

- J-DREAM
- SCRUM-Japan
- etc.

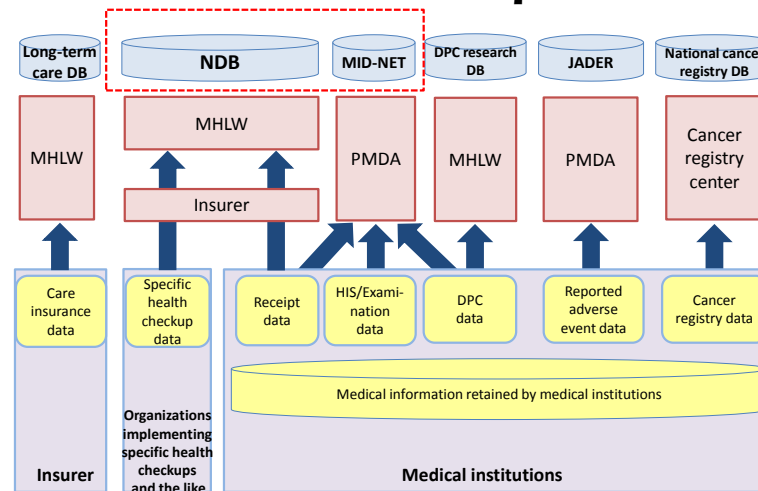
- **Commercial Claims Databases**

- JMDC
- MDV
- etc.

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Public DBs in Japan



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National Database (NDB)

- **In 2008, MHLW started to construct the database of all electronic claims data, specific health checkups, and specific health guidance of Japan**
 - **Specific health checkups are checkups focused on visceral fat obesity and provided to those insured with age above over and including 40 years old and under 75 years old**
 - **Specific health guidance is guidance which is given to those with a checkup result that fulfills a certain criterion**
- **Claims data and specific health check-up data**
 - **Claims data : 13 billion (2009.4~2017.12 (as of 2017.3))**
 - **Special health-check data : 198 million (2008.4~2016.3)**
- **10-year data is accumulated**
- **NDB currently covers approximately 98% of healthcare services provided by health insurance**
- **Only MHLW and academia can assess NDB**

NDB Open Data

- **Many aggregated results (a few hundreds simple statistical tables) from NDB have been published**
- **NDB Open Data is released every year**
 - **1st NDB Open Data**
 - ✓ **October 2016**
 - **2nd NDB Open Data**
 - ✓ **September 2017**
 - **3rd NDB Open Data**
 - ✓ **is coming soon ???**

NDB Open Data

分類名称	診療行為	診療行為	点数	総計	男性	0~4歳	5~9歳	10~14歳	
初診料	11000110	初診	202	258,641,917	13,000,329	15,940,450	6,392,186		
	11010000	初診 (同一日之科目)	141	2,950,072	41,144	34,977	20,904		
	11010010	初診 (他院療養病からの紹介状がない患者)	209	19,367	205	44	432		
	11010020	初診 (同一日之科目・前年度継続患者の増減)	504	3,176	32	41	30		
再診料	12001400	再診	72	1,050,970,707	17,570,050	17,029,106	11,000,100		
	12001000	電話等再診	72	2,284,227	57,197	35,140	19,721		
	12002000	同日再診	72	1,580,571	100,402	94,034	39,037		
	12003000	同日電話等再診	72	253,147	12,501	9,334	4,522		
	12010000	再診料 (同一日之科目)	36	0,289,720	21,535	10,075	11,351		
	12010000	電話等再診 (同一日之科目)	36	309	--	--	--		
	12010010	再診 (累積患者数以下)	53	--	--	--	--		
	12010020	同日再診 (累積患者数以下)	53	11	--	--	--		
	12010030	同日電話等再診 (累積患者数以下)	53	--	--	--	--		
	12011000	再診料 (同一日之科目・前年度継続患者の増減)	26	18	--	--	--		
	外来診療料	21010000	外来診療料	73	171,273,704	2,917,798	2,010,500	1,542,325	
		21011000	同日外来診療料	73	210,217	15,029	6,475	2,719	
21010010		外来診療料 (同一日之科目)	36	7,854,793	43,020	25,515	18,157		
21010020		外来診療料 (他院療養病からの紹介状がない患者)	54	22	--	--	--		
21010030		外来診療料 (同一日之科目・前年度継続患者の増減)	26	9,147	45	40	20		
21011000		外来診療料 (累積患者数以下)	54	--	--	--	--		
21011000	同日外来診療料 (累積患者数以下)	54	--	--	--	--			

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MID-NET

- **MID-NET (Medical Information Database Network)**
 - An integrated real time EMR database
- **Managed by PMDA**
- **Full-scale operation of MID-NET has begun since April 2018**
- **Consists of 23 hospitals in Japan**
- **Population: 4 million patients**
- **4 types data are collected and accumulated:**
 - Claims data
 - Medical charts
 - Laboratory test data
 - Other (e.g. Diagnosis Procedure Combination (DPC) data)
- **Not only MHLW/PMDA and academia, but also companies can use MID-NET**
- **PMDA plan to make extensive use of it in drug safety measures, such as analysis of adverse drug reactions.**
 - In particular, detecting ADR information is expected

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MID-NET

- **Advantages**

- **Various types of data (Claims data, charts data, lab data)**
- **Real time EMR**
- **High quality (GPSP compatible)**

- **Disadvantages**

- **Generalizability**
- **Price ?**

MID-NET

- **User fees**

Post-marketing survey	Other surveys (including analysis dataset)	Other surveys (not including analysis dataset)
JPY 42,123,000 (\$383 K)	JPY 21,061,500 (\$191 K)	JPY 10,820,000 (\$98 K)

\$1=\110

Registry Studies

- **(Medical) Association-initiated Registry studies are increasing year by year....**
 - **NCD**
 - **JROAD(cardiovascular)**
 - **J-IMPACT(cardiovascular)**
 - **J-CKD-DB(chronic kidney disease, CKD)**
 - **J-DREAM (diabetes)**
 - **J-DOME (diabetes)**
 - ⋮
 - ⋮
- **Financial support from MHLW**
- **Common tools to facilitate registry studies**
 - **SS-MIX2 (standard format of data storage)**
 - **MCDRS (Multi-purpose Clinical Data Repository System)**

Registry Studies

- **National-level Registry Studies**
 - **National Cancer Registry (National Cancer Center)**
 - **Started in 2016**
 - **Graphical User Interface to calculate by various categories is provided**
 - **SCRUM-Japan (National Cancer Center)**
 - ✓ **Cancer Genome Screening Project for Individualized Medicine in Japan**
 - **Remudy (National Center of Neurology and Psychiatry)**
 - ✓ **Registry of Muscular Dystrophy**
- **On-going National Project**
 - **Clinical Innovation Network (CIN)**

Clinical Innovation Network (CIN)

- **Clinical Innovation Network (CIN) is a new collaboration scheme with National Medical Research Centers (NCs) and industries, which was proposed by MHLW in 2015.**
- **Purpose of CIN is to facilitate clinical development in Japan by effective utilization of medical information from patient registries.**
 - **In CIN, each NC will make patient registries to search disease related information.**
 - **Pharmaceutical companies will establish a consortium with NC, and will be able to use the information from patient registries through the consortium activities.**
 - ✓ **Patient recruitment to clinical trials**
 - ✓ **Reference data for clinical study protocols**

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Conclusions

- **Although there are some public databases regarding RWD in Japan, access to those databases by industry is quite limited except for MID-NET**
- **Recently, MHLW is very aggressive for utilization of RWD (registry studies, in particular) to facilitate developments of innovative products through the improvement of clinical research environment**
- **Concrete ways to utilize RWD in drug development are still under discussion so we should keep watching**

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EARLY REGISTRATION DEADLINE: 17 JULY 2018



ISPOR 8th Asia-Pacific Conference
8-11 SEPTEMBER 2018, TOKYO, JAPAN



CALL FOR ABSTRACTS ABSTRACT SUBMISSION OPENS: 1 NOVEMBER 2017
ABSTRACT SUBMISSION DEADLINE: 14 MARCH 2018

ABSTRACT & PROPOSAL SUBMISSION INFORMATION

RESEARCH ABSTRACTS

Outcomes research on all health care interventions (including drugs, devices, behavioral modification programs, surgery, disease prevention, gene therapy, screening, diagnostic procedures, and health education) and on all diseases or methodologies are considered. Abstracts are evaluated on the quality of the study (or concept) and the quality of the presentation. Authors of accepted abstracts are required to transfer copyright to ISPOR. Abstracts that have been submitted to another conference and copyright has been transferred to another organization will not be considered. Accepted research is presented as a 15-minute podium presentation or a poster presentation with an author discussion hour. All podium presentations and the top 10% of poster presentations, based on peer review evaluation, are recognized as finalists for an ISPOR Research Presentation Award.

ISSUE PANEL PROPOSALS

Issue panel presentations are designed to show a real debate or discuss multistakeholder perspectives on a new or controversial issue in health economics and outcomes research (HEOR) or its use in health care decision making. Speakers must represent different organizations and present the involved stakeholders' perspectives and distinct/opposing views. Length: 1 hour with time for Q & A.

WORKSHOP PROPOSALS

Workshop presentations discuss new and innovative applications in the conduct and use of HEOR or the latest on real-world data, clinical, economic, or patient-reported outcomes, patient-preferences, and health care policy. Speakers must represent different organizations. Length: 1 hour with time for audience interaction.

For more information on abstract submissions, including instructions, examples, and specific evaluation criteria, please visit www.ispor.org = ISPOR 8th Asia-Pacific Conference.

