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Title: Current Status, Challenges, and Future Perspectives of Real-World Data and Real-World Evidence in Japan

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Short title: Real-World Data and Real-World Evidence in Japan

Supplementary Materials

Supplementary Table 1 Real-world databases available in Japan [1]

Database name	Summary of database	Database administrator	Registered patients (x10,000)	Data Period (year)
<i>Hospital-based</i>				
NHO Clinical Data Archives	Database containing electronic medical record information of 63 NHO hospitals	NHO Headquarters	190	2016~2019
MIA databank	Database containing DPC and receipt information of NHO 141 hospitals	NHO Headquarters	2,000	2010~2019
Convergence CGRN	A network that anonymizes and makes available clinical data in medical institutions	CCT	390	Unknown ~2019
RWD database	Integrated database of medical information such as electronic medical records, DPCs, and receipts	Real World Data, Co., Ltd.	1,900	2003~2019
Medical Information Database Network	A medical information database managed by PMDA that consists of electronic medical records, receipts, and DPC data.	PMDA	470	2009~2019
EBM provider®	Database of inpatient and outpatient care at 385 acute-care institutions nationwide	Medical Data Vision Co., Ltd.	2,844	2008~2019
JMDC Claims Database (hospital-based)	Database of receipts and DPC data from multiple medical institutions	JMDC	880	2014~2019
National Clinical Database	The Registry of Surgery, Interventions, Pathology, and Organ Cancer is operated mainly by the Japan Surgical Society. Can be used in conjunction with DPC and reception databases	NCD	1,200	2011~2019
<i>Insurance-based</i>				
JMDC Claims Database (insurance-based)	Database with multiple health insurance subscribers (total number) as data sources	JMDC	740	2005~2019
JammNet database	Database of receipt data from multiple health insurance societies	JammNet	255	2008~2019
MinaCare Database	Database of health insurance claims and health information from multiple health insurance societies	MinaCare	630	2008~2018
Medi-Scope	Include almost all items of all receipt types (dental)	Kyowa Kikaku Ltd.	666	2010~2019
<i>Pharmacy-based</i>				
Medi-Trend	External prescription database, number of collection pharmacy stores (approx. 880 stores) and prescriptions (approx. 16 million sheets/year)	Kyowa Kikaku Ltd.	647	2009~2019
IQVIA NPA data	Compounding receipt database with data source of about 9,200 dispensing pharmacies (2018 total prescriptions, 151 million)	IQVIA Solutions Japan K.K.	3,200	2015~2019
JMIRI Pharmacy Claims DB	Receipt database with external prescription as data source	JMIRI	3,900	2006~2019
Nihon Chouzai Pharmacy Claims database	Database of prescriptions issued outside the hospital by medical institutions, various surveys on patients, DTC; dispensing at 603 stores	Japan Medical Research Institute (Nihon-Chouzai)	1,623	2001~2019
PFR	Out-of-hospital prescription analysis service; information contained in external prescriptions can be used, information can be provided without time lag	PFR	820	2017~2019
<i>Others</i>				
NHWS	Survey results from >2 million people in 10 major countries; prevalence, diagnosis and treatment rates of >165 diseases, QOL, WPAI, severity and drugs used	SSRI	200	Before 2000~2019

PatientsMap 2019 JP	can be identified Survey results database from >20,000 Japanese doctors; an estimate of consultation rates and patient numbers of ~400 diseases, diseases requiring new drugs, and sales visits from >50 companies	SSRI	16	2011~2018
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CGRN Clinical Trial Global Research Network, *CCT* Convergence CT Inc., *DPC* Diagnosis Procedure Combination, *DTC* direct to consumer, *JMDC* Japan Medical Data Center Inc., *JMIRI* Japan Medical Information Research Institute, *MIA* Medical Information Analysis, *NCD* National Clinical Database, *NHO* National Hospital Organization, *NHWS* National Health and Wellness Survey, *NPA* National Prescription Audit, *PMDA* Pharmaceuticals and Medical Devices Agency, *QOL* quality of life, *SSRI* Social Survey Research Information Co., Ltd., *PFR* product flash report, *WPAI* work productivity and activity impairment

Supplementary Fig. 1. The search strategy

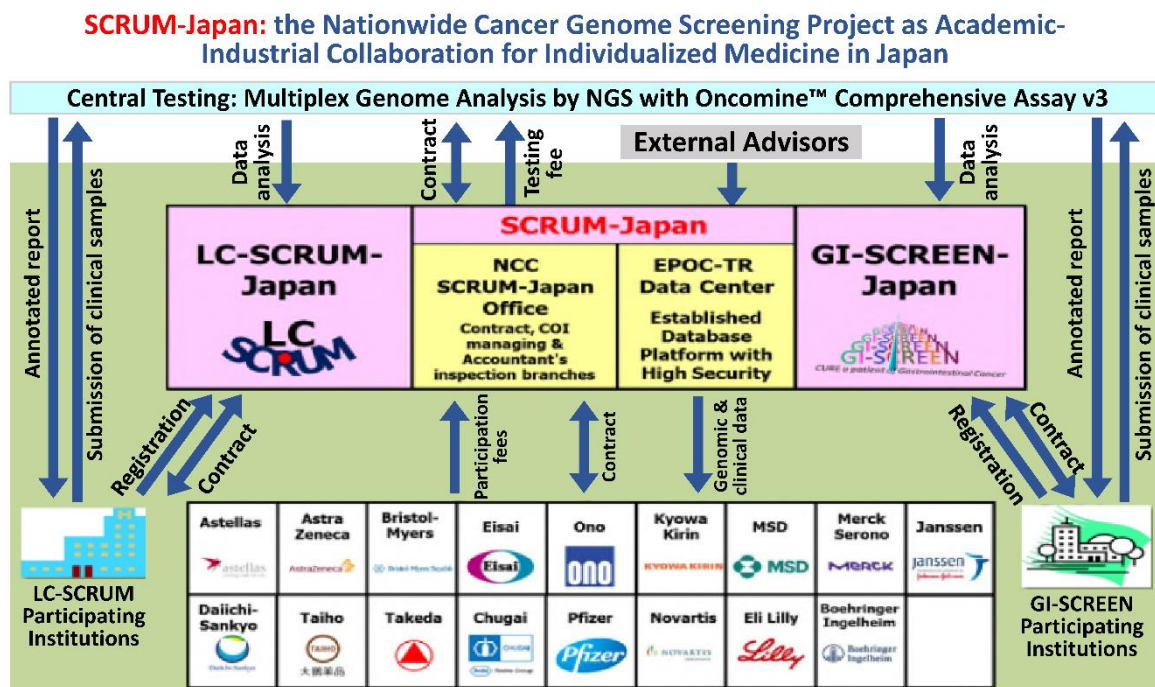
1. PubMed search strategy

(((Perspective[tiab] OR "guideline"[tiab] OR "regulation"[tiab] OR approach[tiab] OR policy*[tiab]) AND ("HTA agency" OR "Regulatory agency" OR industry[tiab] OR "healthcare provider"[tiab] OR "healthcare payer"[tiab] OR stakeholder*[tiab]) AND ("real world data" OR "real world evidence" OR "real world outcome" OR "clinical effectiveness data" OR "hospital data" OR "electronic health records" OR "patient registry" OR "effectiveness"[tiab] OR "alternative study design") AND ("Pragmatic clinical trial" OR "observational design" OR "post-marketing study" OR comparative OR observ*[tiab] OR design*[tiab]) AND ("comparative effectiveness research" OR "outcomes research" OR "relative effectiveness assessment" OR "evidence"[tiab] OR "decision making"[tiab] OR "comparative effectiveness"[tiab]))) AND ("2010/01/01"[PDat] : "2019/12/31"[PDat]))*

2. Ichushi-Web search strategy

("real world data (in Japanese)" OR "real world evidence (in Japanese)") AND ("definition (in Japanese)") AND (from January 1, 2010 to December 31, 2019[year of publication of the listing])

Supplementary Fig. 2. Collaborative research between SCRUM-Japan and pharmaceutical companies [2]. Reproduced with permission from Dr. Ohtsu Atsushi as well as Kagakuhyoronsya Co., Ltd. Copyright© 2018 with “New approaches in SCRUM-Japan Registry”. All rights reserved



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