

Introduce to Real World Data in Japan

2022-12-8

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Agenda

- What is Real world data(RWD)?
 - List of medical databases in Japan
 - How do we select a database?
 - Analysis Environment
 - Example of Visualization
 - Summary
-

What is Real world data (RWD) ?

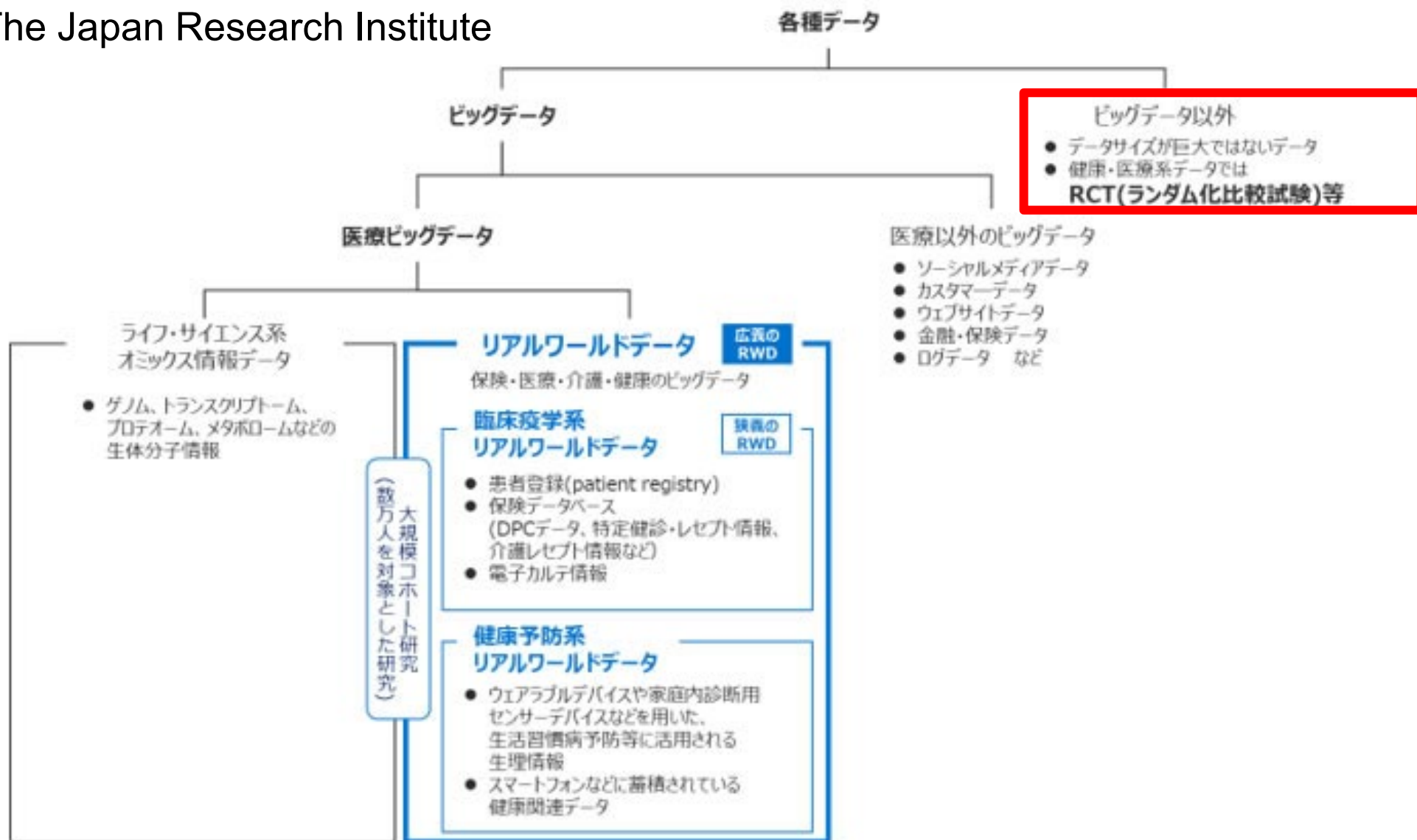
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What is RWD?

- FDA (Food and Drug Administration) (2017)
 - Real-World Data (RWD) are data relating to patient health status and/or the delivery of health care routinely collected **from a variety of sources**.
 - *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
 - EMA (European Medicines Agency) (2019)
 - RWD are defined as “routinely collected data relating to a patient's health status or the delivery of health care from a variety of sources **other than traditional clinical trials**”
 - *Real-World Data for Regulatory Decision Making: Challenges and Possible Solutions for Europe
 - PMDA (Pharmaceuticals and Medical Devices Agency) (2021)
 - These data are called Real World Data (RWD), and they include electronic health record, claims data, patient registry data, etc.
 - RWD still provide valuable information related to the outcomes of using medical products, while **RWD are not obtained in the same manner as well-designed clinical trials** conducted to evaluate medical products.
 - *Utilization of Real World Data - PMDA's approaches -
-

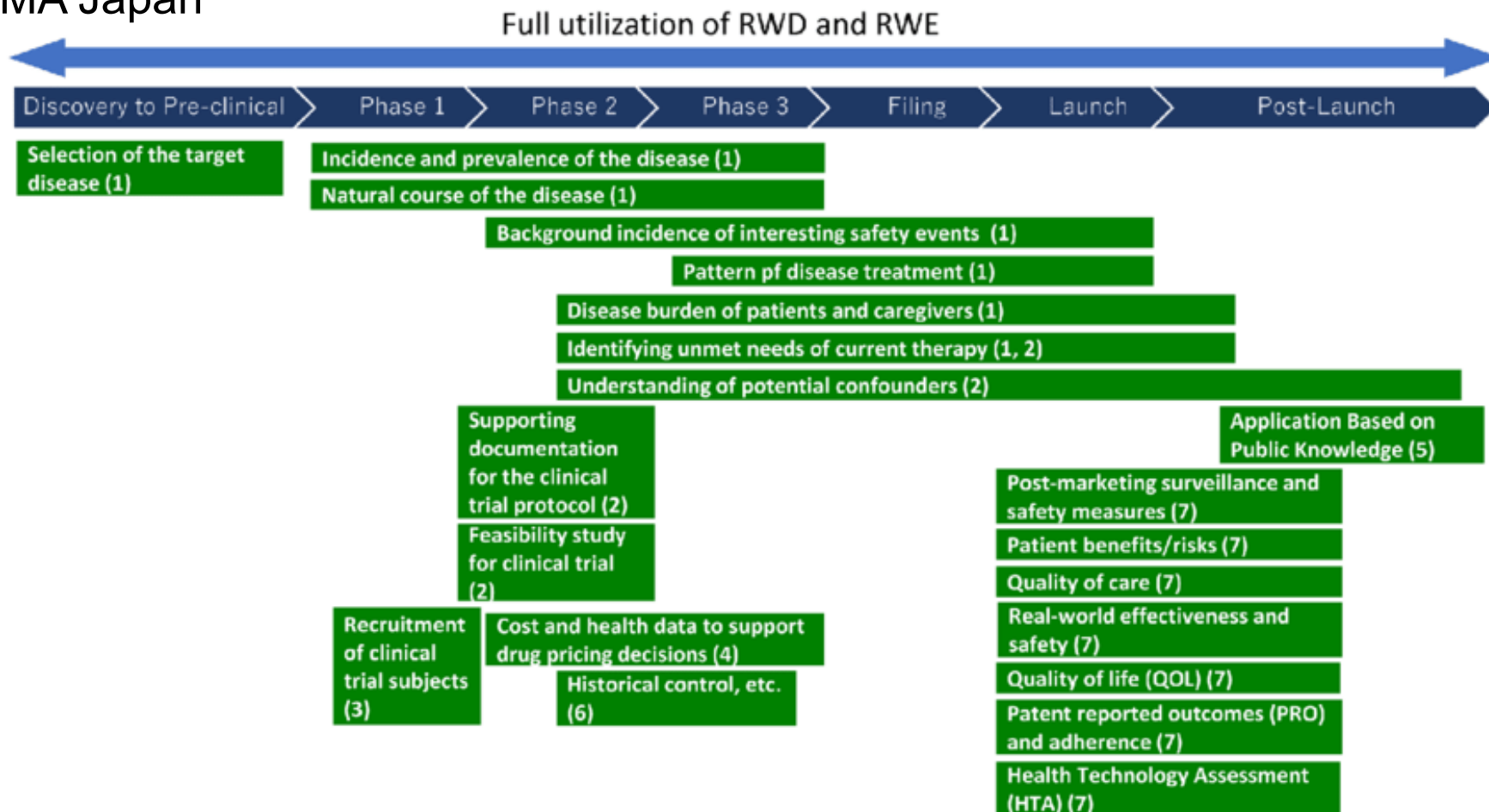
What is RWD?

- The Japan Research Institute



What is RWD?

- PhRMA Japan




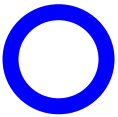
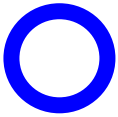
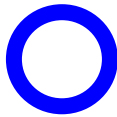

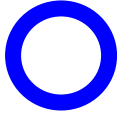



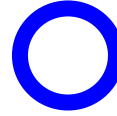



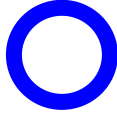

Real-world data and real-world evidence utilization by pharmaceutical companies.

(1) for development strategy; (2) for clinical trial design; (3) for promotion of enrolment of study participants; (4) for drug price calculation; (5) for expansion of indications; (6) for new or additional indications; (7) for identification of unmet medical needs, closing data gaps, and informing clinical practice.

List of medical databases in Japan

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Characteristics of medical databases

	Health insurance societies	Pharmacies	DPC*1	EHR*2	NDB*3
Completeness	 Under 75 age	 All age, Mainly outpatients	 All age, Mainly inpatient	 All age	 All the nations
Traceability		 Unable to trace transfer to other pharmacy	 Unable to trace transfer to other hospital	 Unable to trace transfer to other hospital	
Lab data			 Partially		

*1 DPC: Diagnosis Procedure Combination/Per-Diem Payment System

*2 EHR: Electronic Health Record

*3 NDB: National Data Base

Characteristics of medical databases



General description

Japan's largest epidemiological database consisting of receipts, health checkup results, and subscriber registers from insurers nation wide.

Administrative database for inpatient and outpatient consists of 469 hospitals

Integrated database of medical information such as electronic medical records, DPC data, and receipts

Database of health insurance claims and specific health checkups for preparation, implementation and evaluation of medical cost optimization plan

Data source

Medical Claim
Dental Claim
Pharmacy Claim
Health checkup

DPC(Format 1)
DPC(EF file)
Medical claim
Lab test results(limited)

DPC(Format 1)
DPC(EF file)
Medical claim
Electronic medical chart
Lab test results
Ordering
Health checkup(limited)

Medical claim
Dental claim
Pharmacy claim
Health checkup

Annual number of unique ID (approx. 10K)

870

1167

168

Almost equal to total population in Japan

Age distribution by Insurance type

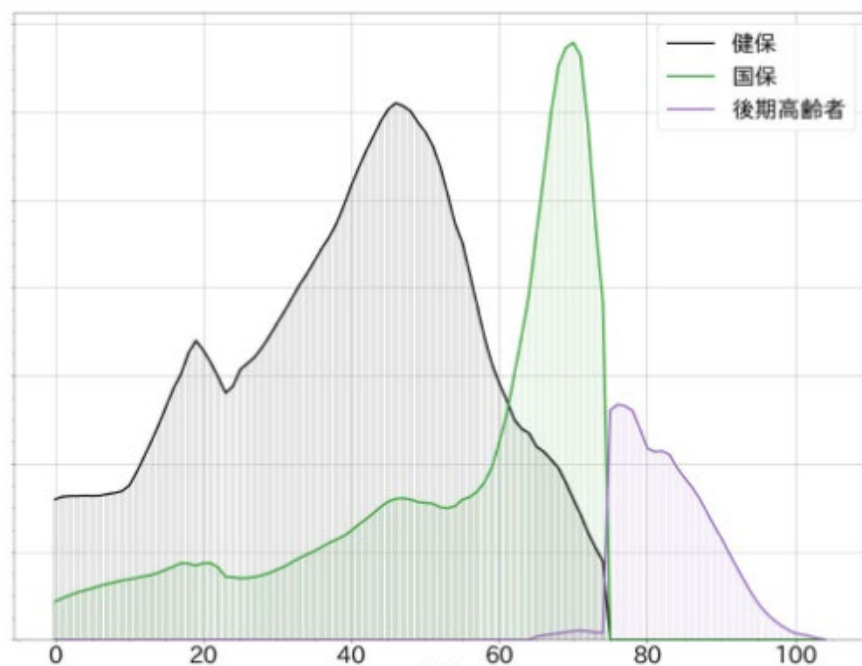
Health insurance societies(健保)



National Health Insurance(国保)



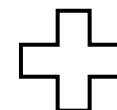
Medical Care System for Older Senior Citizens(後期高齢者)



J M D C



DeSC
Healthcare



2020
Capital and business alliance



Database Industry Trend

2018: "The Next Generation Medical Infrastructure Act" Went into Effect
(The Act on Anonymized Medical Data to Contribute to Research and Development in the Medical Field)

Local public organizations Medical institutes

Schools

Data regarding an individual's medical history from medical institutes,

J M D C

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2022-7
Subsidiary Company

MDV
medical.data.vision

2022-5
Business alliance

DeSC
Healthcare

Data integration and available data are increasing.

Limitations of Claims and DPC

- Insurance name (test disease, off-label use)
- Daily dosage of injections and topical drugs is not known
- Unable to know the relationship between the disease, the medication, and the procedure.
- Limited outcomes and deaths
- Medical treatment at one's own expense is not covered
- Cannot be analyzed in detail if the drug were comprehensive*

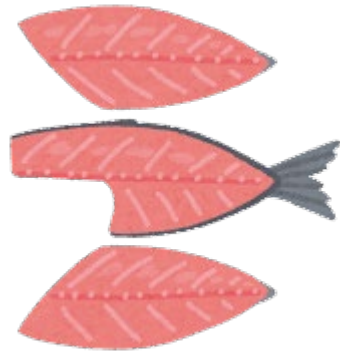
Code	Procedure	detail
J038	artificial kidney1.2	Includes costs for dialysate, anticoagulants, saline, erythropoietin, and darbepoetin

*:“Comprehensive” means that the system adopts a flat-rate remuneration principle instead of the performance-based remuneration system

How do we select a database?

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Clinical Trial



Clinical Trial Data



TLF



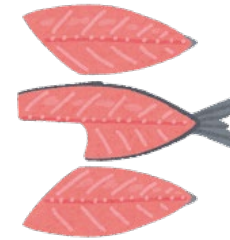
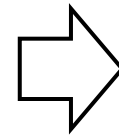
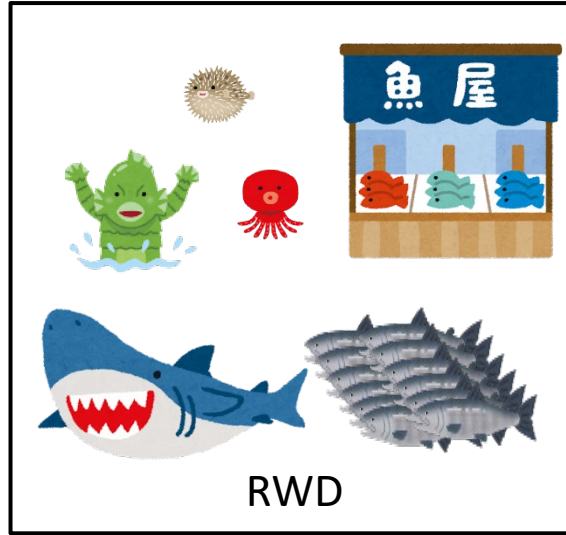
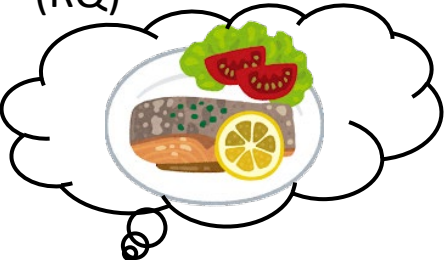
CRA, CRC, DM etc.



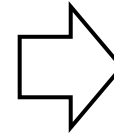
Programmer

RWD

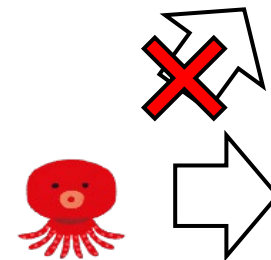
Research question (RQ)



Transformed Data



Results



Programmer

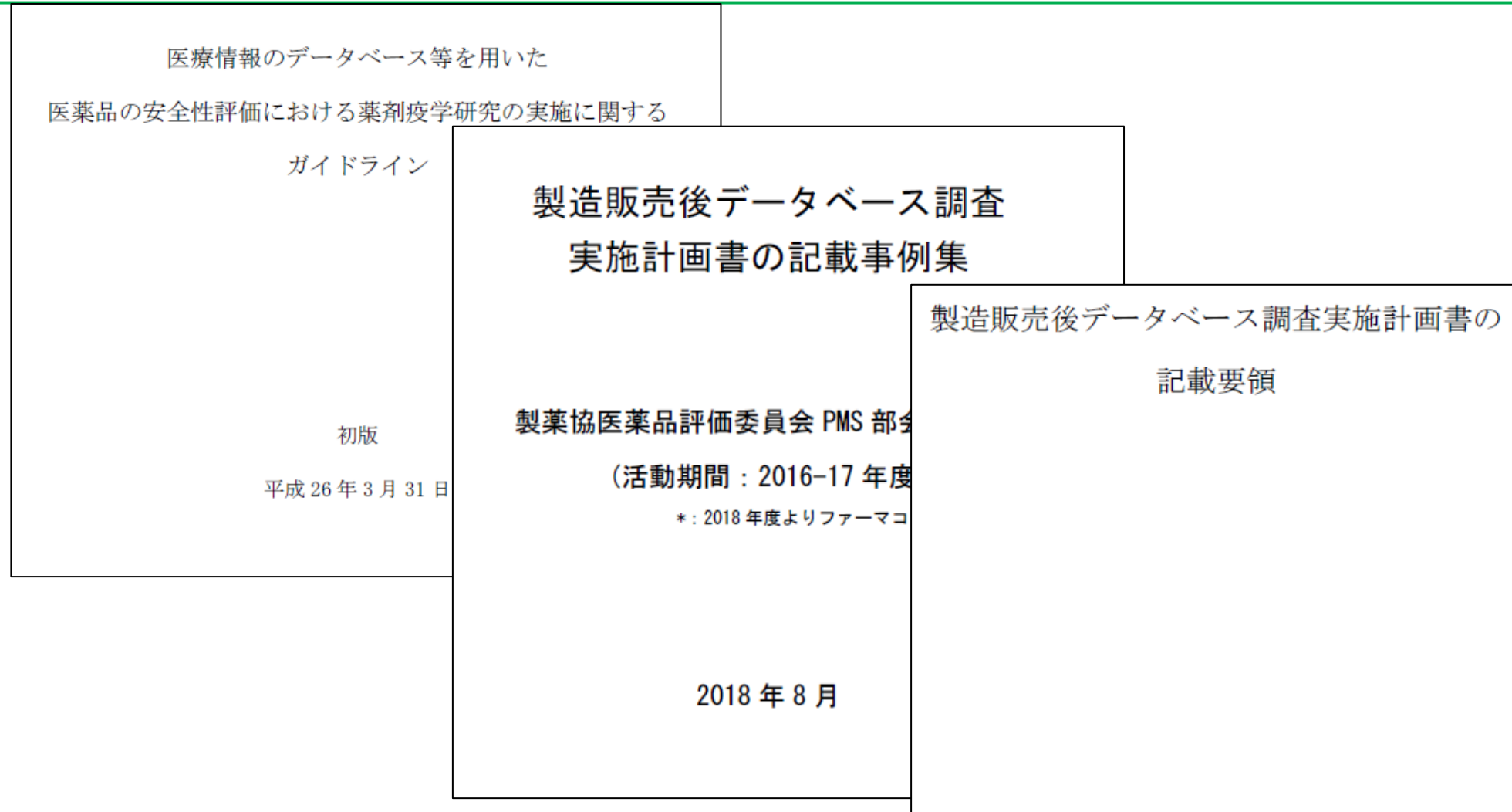
How do we select a database?



If you don't have a RQ or cannot find an appropriate database.

It all depends on Research Question.
You may need to discuss a RQ based on PECO/PICO.
Then you can select an appropriate database.

Reference guidelines for defining RQ

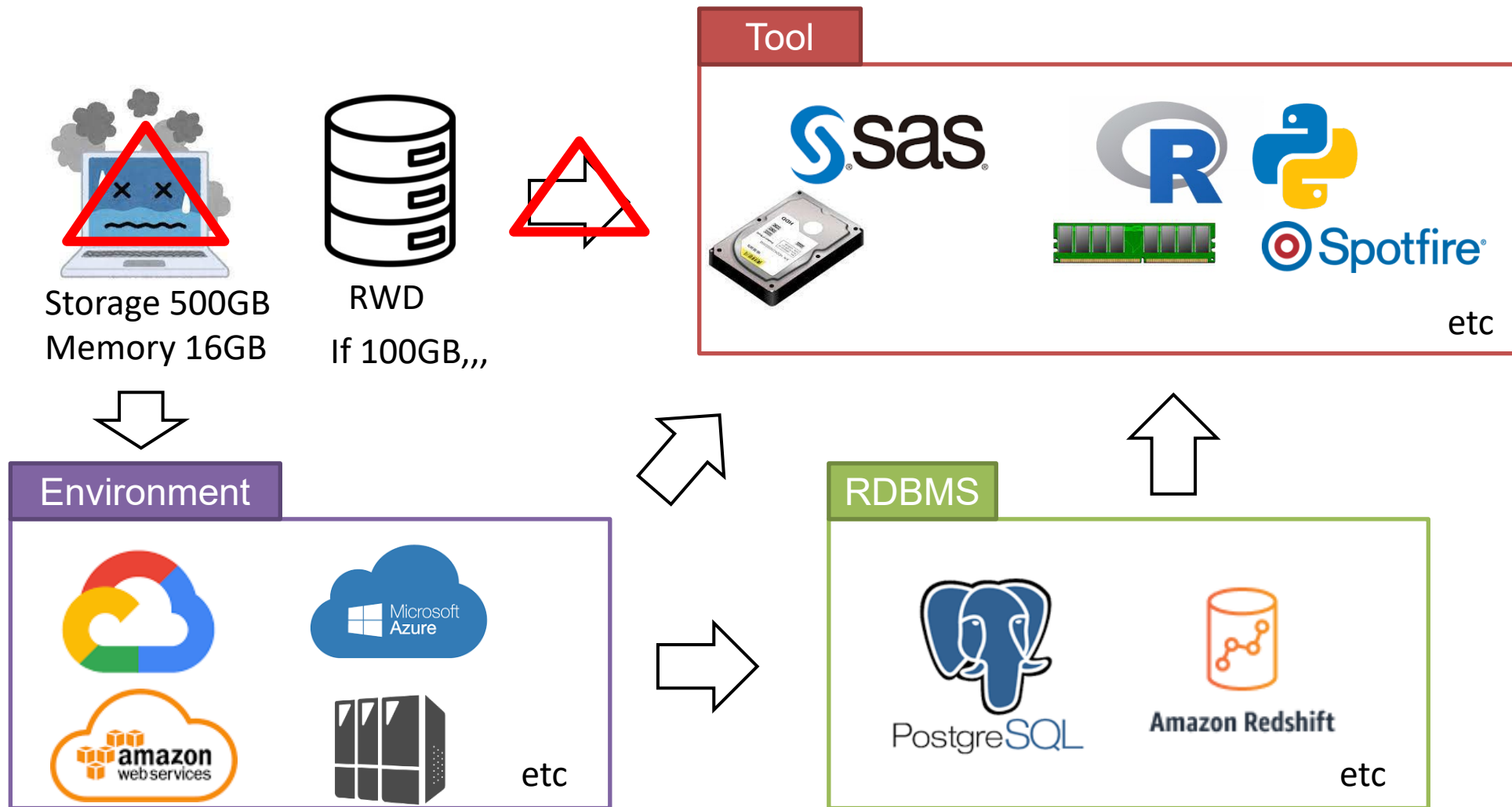


There are specific for post-marketing DB studies,
but it may be useful in setting up research questions.

Analysis Environment

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Analysis Environment



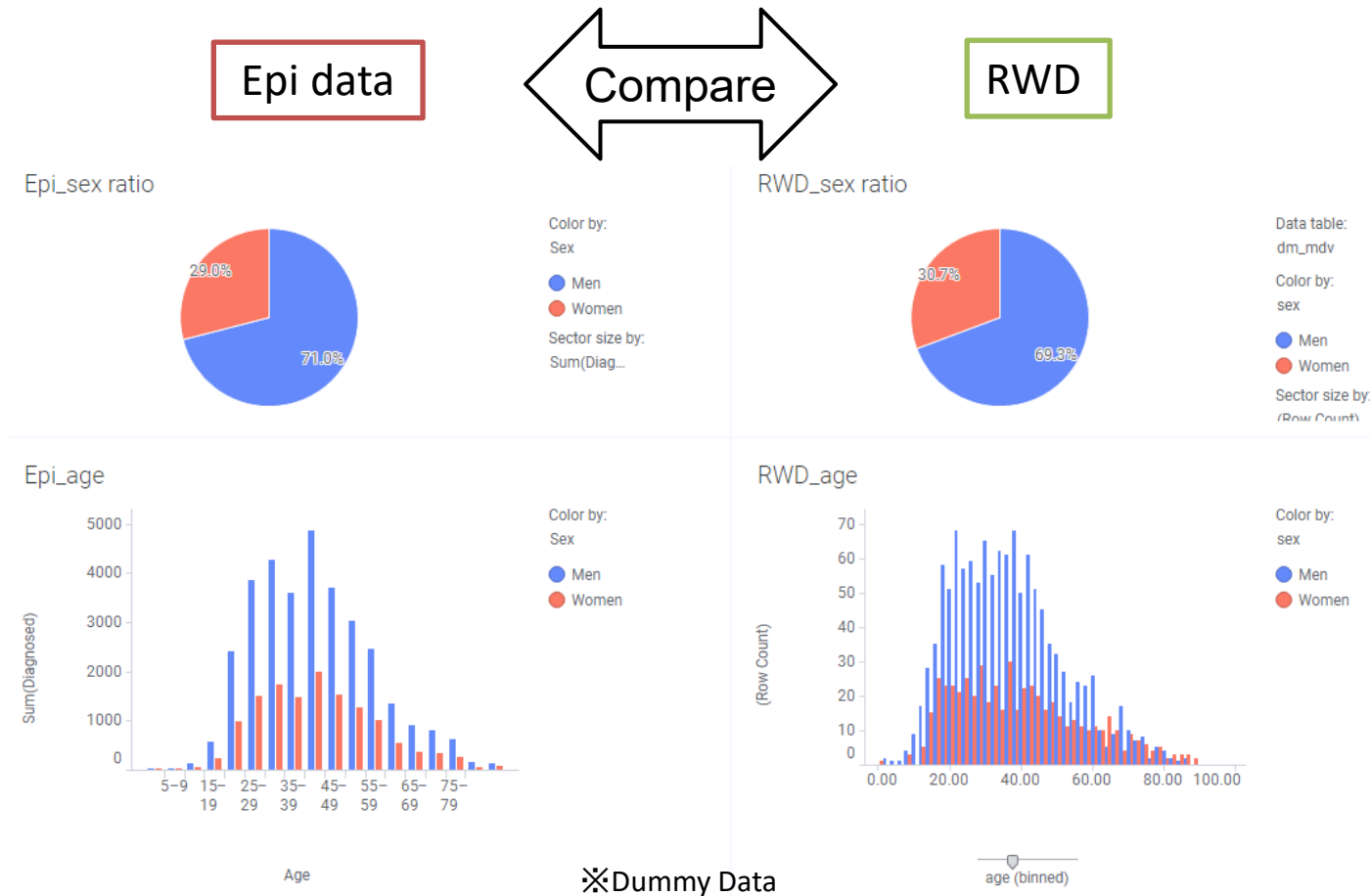
the flexibility to choose the appropriate mix of resources for your databases.

Example of Visualization

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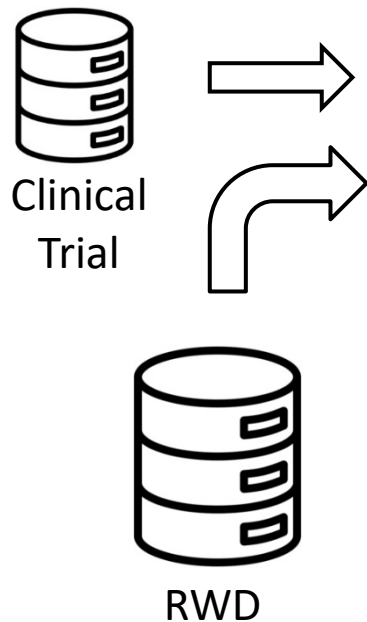
Data Visualization

- Validate the disease definition by comparing age distribution and sex ratio with epidemiological information and clinical trials.



Data Visualization

- Converting RWD to CDISC allows the use of tools such as safety reviews used in traditional clinical trials.



cdisc



<https://brackendata.com/clinical-trial-gov-analytics>

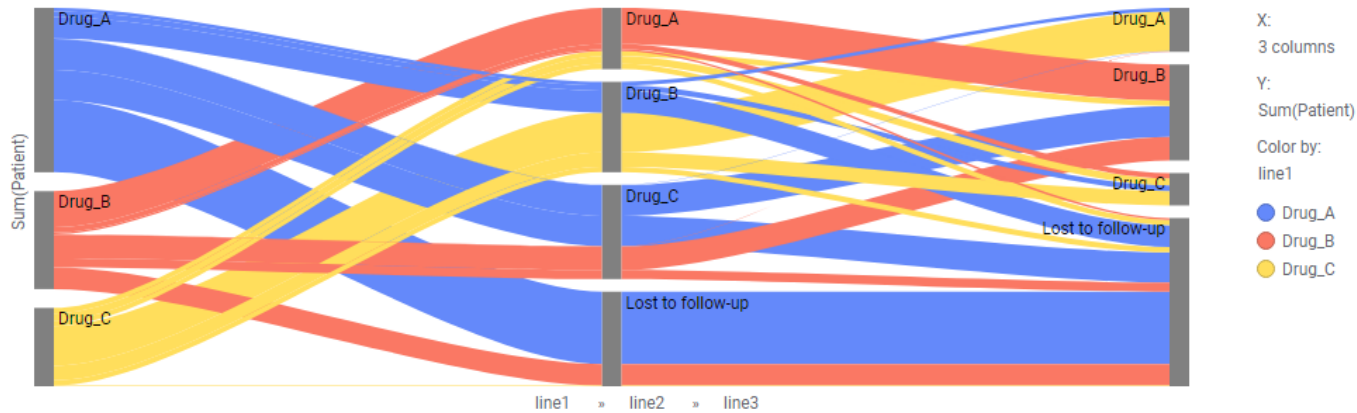
Data Visualization

- Sankey Diagram
 - Treatment Path
 - Severity of adverse events etc.

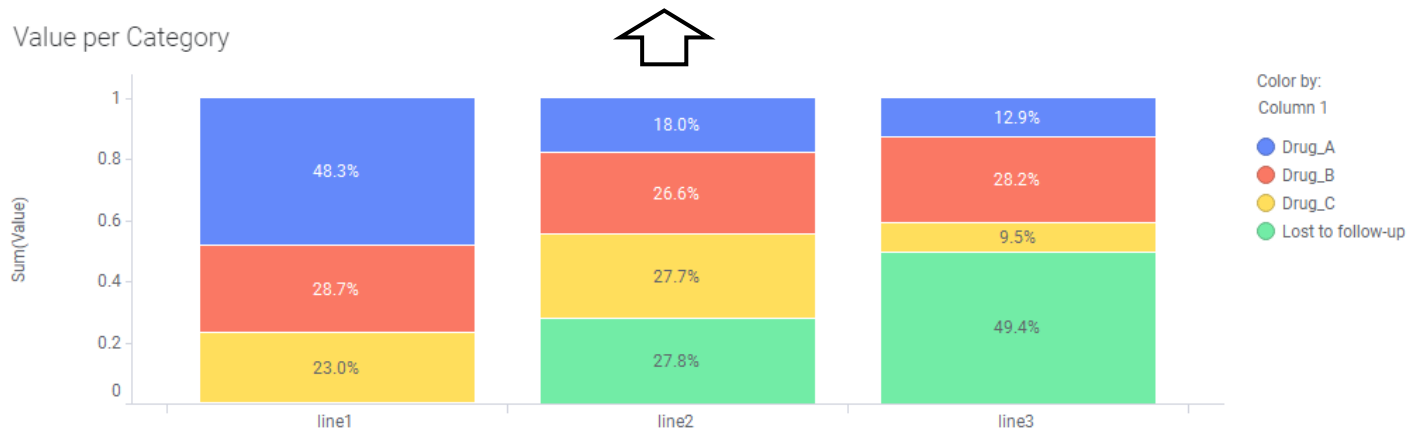
TIBCO Spotfire Mods

<https://www.tibco.com/products/tibco-spotfire/custom-analytics-apps-mods>

Sankey Diagram



Value per Category



Summary

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Summary

- RWD is expected to be used in various ways.
 - However, there is no DB that covers all necessary information.
 - When using RWD, it is important to understand the characteristics of DBs and to select the most appropriate DB.
 - Visualization enables us for understanding the characteristics of DBs and for validating disease definitions and unmet medical needs.
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