Introduce to Real World Data in Japan

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Takashi Misawa
Market Research Team, Clinical Development Dept.
JAPAN TOBACCO INC.

Email: takashi.misawa@jt.com
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)?
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

https://www.jri.co.jp/page.jsp?id=38737
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
Characteristics of medical databases

<table>
<thead>
<tr>
<th>Characteristics of medical databases</th>
<th>Health insurance societies</th>
<th>Pharmacies</th>
<th>DPC*1</th>
<th>EHR*2</th>
<th>NDB*3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness</td>
<td>Under 75 age</td>
<td>All age, Mainly outpatients</td>
<td>All age, Mainly inpatient</td>
<td>All age</td>
<td>All the nations</td>
</tr>
<tr>
<td>Traceability</td>
<td>Unable to trace transfer to other pharmacy</td>
<td>Unable to trace transfer to other hospital</td>
<td>Unable to trace transfer to other hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab data</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Partially</td>
<td>X</td>
</tr>
</tbody>
</table>

*1 DPC: Diagnosis Procedure Combination/Per-Diem Payment System
*2 EHR: Electronic Health Record
*3 NDB: National Data Base

https://kupe.med.kyoto-u.ac.jp/column_vol12.html with some revised.
# Characteristics of medical databases

<table>
<thead>
<tr>
<th>Database</th>
<th>Description</th>
<th>Data Source</th>
<th>Unique ID (approx.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JMDC</td>
<td>General description</td>
<td>Administrative database for inpatient and outpatient consists of 469 hospitals</td>
<td>870</td>
</tr>
<tr>
<td>MDV</td>
<td>Data source</td>
<td>Integrated database of medical information such as electronic medical records, DPC data, and receipts</td>
<td>1167</td>
</tr>
<tr>
<td>HCEI/RWD</td>
<td></td>
<td>Database of health insurance claims and specific health checkups for preparation, implementation and evaluation of medical cost optimization plan</td>
<td>168</td>
</tr>
<tr>
<td>NDB</td>
<td></td>
<td></td>
<td><strong>Almost equal to total population in Japan</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Database</th>
<th>Data Source</th>
<th>Unique ID (approx. 10K)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JMDC</td>
<td>Medical Claim, Dental Claim, Pharmacy Claim, Health checkup</td>
<td>870</td>
</tr>
<tr>
<td>MDV</td>
<td>DPC(Format 1), DPC(EF file), Medical claim, Lab test results(limited)</td>
<td>1167</td>
</tr>
<tr>
<td>HCEI/RWD</td>
<td>DPC(Format 1), DPC(EF file), Medical claim, Electronic medical chart, Lab test results, Ordering, Health checkup(limited)</td>
<td>168</td>
</tr>
<tr>
<td>NDB</td>
<td>Medical claim, Dental claim, Pharmacy claim, Health checkup</td>
<td></td>
</tr>
</tbody>
</table>
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)

https://www.mdv.co.jp/ebm/information/2022/20220624-01.html
Database Industry Trend

Data integration and available data are increasing.

https://www.mdv.co.jp/ebm/information/2022/20220624-01.html
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*

<table>
<thead>
<tr>
<th>Code</th>
<th>Procedure</th>
<th>detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>J038</td>
<td>artificial kidney1.2</td>
<td>Includes costs for dialysate, anticoagulants, saline, erythropoietin, and darbepoetin</td>
</tr>
</tbody>
</table>

*:“Comprehensive” means that the system adopts a flat-rate remuneration principle instead of the performance-based remuneration system
How do we select a database?
Clinical Trial

Clinical Trial Data

TLF

CRA, CRC, DM etc.

Programmer
Research question (RQ)

Hardware/Programming

Programmer

Transformed Data

Results
How do we select a database?

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

Don’t touch RWD !!

It all depends on Research Question. You may need to discuss a RQ based on PECO/PICO. Then you can select an appropriate database.
There are specific guidelines for defining RQ for post-marketing DB studies, but it may be useful in setting up research questions.
Analysis Environment
the flexibility to choose the appropriate mix of resources for your databases.
Example of Visualization
Data Visualization

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

Epi data  Compare  RWD

※Dummy Data
Data Visualization

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

https://brackendata.com/clinical-trial-gov-analytics
Data Visualization

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

[Sankey Diagram Image]

TIBCO Spotfire Mods
Summary
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.