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

RWD in Japan

May 22nd, 2018

Makoto Kobayashi, MEng, PhD
Director and COO
CRECON Medical Assessment Inc.
kobamako@crecon.co.jp

No. of Publication regarding RWD in Japan

Copyright © 2018 CRECON Medical Assessment Inc. All Rights Reserved.
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.
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 ????
MID-NET

- MID-NET (Medical Information Database Network)
  - An integrated real time EMR database
- Managed by PMDA
- Full-scale operation of MID-NET has began 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
MID-NET

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

- **Disadvantages**
  - Generalizability
  - Price ?

**User fees**

<table>
<thead>
<tr>
<th></th>
<th>Post-marketing survey</th>
<th>Other surveys (including analysis dataset)</th>
<th>Other surveys (not including analysis dataset)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JPY 42,123,000</td>
<td>JPY 21,061,500</td>
<td>JPY 10,820,000</td>
<td></td>
</tr>
<tr>
<td>($383 K)</td>
<td>($191 K)</td>
<td>($98 K)</td>
<td></td>
</tr>
</tbody>
</table>

$1=\$110$
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

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
Thank you!