

Pharmaceutical business innovation through utilization of EMR

Abstract

The pharmaceutical industry in Japan is in a transformation phase due to the government's tightening control over healthcare expenditure as a measure against aging society, lower market growth associated with decline in the number of blockbusters and policies to promote generic drug substitution, and dwindling open opportunities to further improve on the standards of care set by existing therapies. To successfully identify and expand into new markets, it is crucial to obtain a robust EMR (Electric Medical Record) database which contains detailed information on disease conditions and treatment. This report discusses opportunities for meaningful use of EMR databases and the key to successful utilization.



Environmental changes in the pharmaceutical industry

The pharmaceutical industry in Japan is in a transformation phase due to the government's tightening control over healthcare expenditure as a measure against aging society, lower market growth associated with decline in the number of blockbusters and policies to promote generic drug substitution, and dwindling open opportunities to further improve on the standards of care set by existing therapies.

Under such circumstances, pharmaceutical companies are shifting their target areas from established primary care areas to diseases with high UMNs, such as oncology and CNS (Central Nervous System). Multiple transformations are required for future success, including development of new drug discovery technologies and strengthening of market assessment capabilities in new target therapeutic areas, provision of value-added promotional activities, and improvement of company-wide cost efficiency.

In addition to traditional commercial information,

detailed information on medical conditions and treatments is essential to identify new markets and generate effective strategies in these markets. Currently, four databases are commonly used in various situations, such as portfolio strategy development, marketability assessment of pipelines, and sales and marketing strategies development (Figure 1).

Characteristics of each database are as follows:

- Sales database
 - Provides drug sales, in terms of sales value and units sold, to hospitals (HP), clinics (GP) and dispensing pharmacies at the national level
 - The data can be broken down by region and/or facility type
- DPC database
 - Provides information on diagnosis, details of medical practices and medications, that are obtained from a limited sample of HPs
 - Data can be used for non-interventional clinical trials

Figure 1: Major existing databases

	Sales database	DPC database	Medical claim database	Dispensing database
Covered facility	HP/GP/Pharmacy	HP	HP/GP/Pharmacy	Pharmacy
Data characteristics	<ul style="list-style-type: none"> • Sales value and units sold at a national level • Data can be divided by region or facility type (w/o specialty) 	<ul style="list-style-type: none"> • Diagnosis, medical practice, prescribed drugs • Can be used for non-interventional clinical trials 	<ul style="list-style-type: none"> • In-hospital & out-of-hospital prescriptions • Coverage varies by age groups 	<ul style="list-style-type: none"> • Out-of-hospital prescriptions • Larger population compared with other databases
# of patients	X	~ 9 millions	Millions	~ 10 millions
Sales	◎	X	X	X
Prescription data	X	◎ (detailed prescription info available)	○ (dates of out-of-hospital presc. is limited / no vaccines)	○ (No vaccines and injections)
Patient data	X	○ (height, weight, age, sex)	△ (age and sex only)	△ (age and sex only)
Indication/Laboratory data	X	○ (lab results unavailable)	△ (diagnosed disease name only)	X
Example analysis	<ul style="list-style-type: none"> ■ Nationwide sales trends ■ Sales by region/facility type 	<ul style="list-style-type: none"> ■ Patient trends by indication ■ Inpatient prescription patterns ■ Share in HP market 	<ul style="list-style-type: none"> ■ Prescription patterns/trends by diagnosis ■ Epidemiology data (prevalence and incidence) 	<ul style="list-style-type: none"> ■ Trends in out-of-hospital prescription.(chronic phase) ■ Out-of-hospital prescription patterns

- Medical claims database
 - Provides in-patient and out-patient prescription data for HPs, GPs and dispensing pharmacies
 - Coverage varies by age group
- Dispensing database
 - Provides out-patient prescription data at dispensing pharmacies
 - Larger samples size compared with DPC and Medical claim databases

and treatment rates. DPC data can be used to obtain such data, but is limited to certain HPs and no GP data is available. Thus, each database has limitations which can create challenges in improving accuracy of strategy building and decision making.

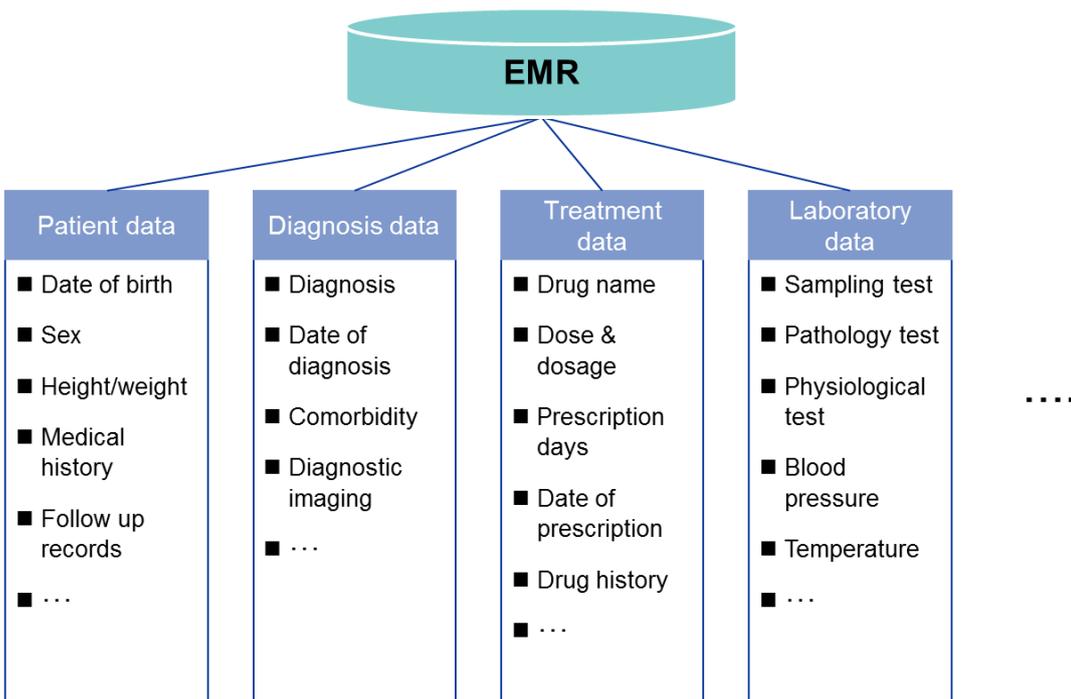
Utilization of EMR is a key to obtain detailed information on the number of patients and actual trends of disease treatment, as it contains patient profile, diagnosis, laboratory results and drug information (Figure 2). Utilization of a robust EMR database will lead to the following benefits:

Improvement from EMR database utilization

Pharmaceutical companies utilize these four databases selecting suitable one(s) for the purpose, as each database has different coverage and data characteristics that could limit usage. For instance, Sales and Medical claim databases can be used for development and evaluation of sales and marketing strategies, but cannot specifically tell the number of patients

- Understand precise of number of treated patients and treatment rates
- Identification of detailed patient segments
- Understand treatment trends in each patient segment

Figure 2: Data items in EMR



EMR database: current infrastructure and utilization

Outside Japan, some pharmaceutical companies have already leveraged EMR. Figure 3 shows the case of Moffitt Cancer Center in the US. M2 Gen, a subsidiary of the Center, built a database of oncology patients and offers the data to pharmaceutical companies for R&D purposes.

Similar efforts have been seen in other institutions, such as the UK's General Practice Research Database, and the Cleveland Clinic's eHealth Services which enables neighboring medical facilities and patients to share medical records. These case studies indicate that access and utilization of EMR by pharmaceutical companies will become more common in the near future.

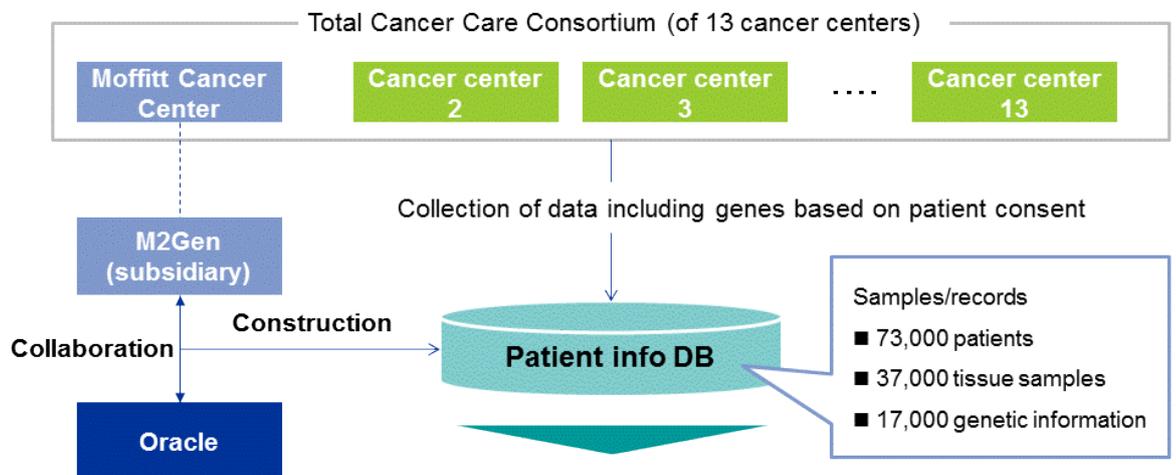
Standardization and utilization of EMR is also evolving in Japan as in the MHLW's Sentinel Project, and the Dolphin Project which is currently undergoing proof-of-concept in Kyoto and Shiga. However, these projects are still in pilot phase and barriers to secondary use of the

data still exist, such as challenges in data standardization and protection of patient privacy.

Currently, the Council for Regulatory Reform led by the Prime Minister's Cabinet is discussing specific measures to promote Information Communication Technology (ICT) utilization in the medical field, which should help overcome challenges posed by data standardization.

As for patient privacy, MHLW has issued the Guideline for Personal Information Protection for Healthcare and Nursing-care Providers which requests to that patient data be anonymized and that consent is obtained from patients when a third party uses personal information. On the other hand, the government promotes deregulation as one of the key initiatives of economic growth strategies and continues to discuss deregulation of personal information protection with ministries. As there is heightened momentum behind use of Big Data in other industries in Japan, achieving an access to EMR is expected as in the other countries.

Figure 3: An example of EMR database utilization



Utilization of data for R&D of oncology drugs / offer as infrastructure to pharmaceutical companies

Opportunities of EMR utilization and keys to success

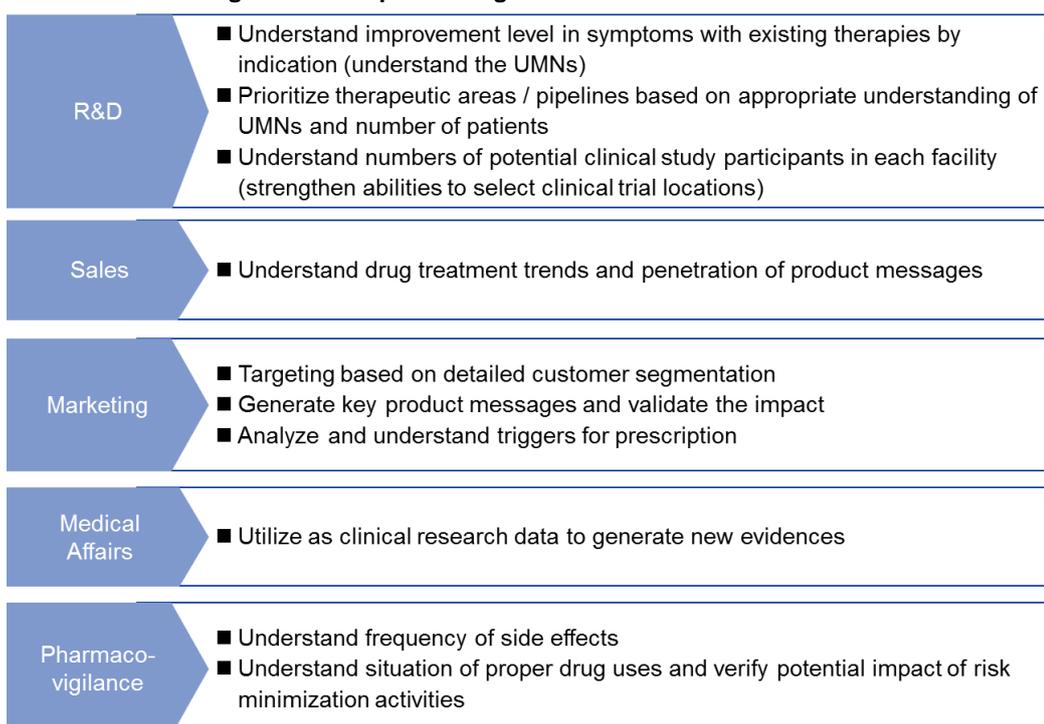
With standardization of EMR format and development of necessary infrastructure, robust EMR databases are expected to become available for commercial use in the near future. EMR enables analysis from various aspects, to properly understand disease-specific treatment trends, construction of detailed patient segmentation, and derivation of number of patients and product shares in each segment. This means that several opportunities will be generated for pharmaceutical companies through proper utilization of an EMR database (Figure 4).

However, pharmaceutical companies will face challenges in fully utilizing EMR databases. To reap the maximum benefit from these databases, it is essential to clarify objectives of database utilization, and make corporate efforts to establish analytical methods, as well as to develop a cross-functional collaboration scheme. Furthermore, it is important to make mid-/long-

term efforts to access a large-sized dataset gathered from multiple medical facilities in a usable format, such as collaboration with medical facilities and/or EMR vendors:

- Clarify objectives of database utilization
 - For effective use of a large-sized EMR database, it is essential to use a hypothesis-based approach in which analysis is made to verify a case-based hypothesis, not an exploratory approach where discussion is made based on the outputs
- Access to large-sized EMR database
 - Currently, it is difficult to simultaneously access EMR of multiple medical facilities in an analyzable format. To make this possible, it is important to collaborate with group hospitals and/or EMR vendors to integrate databases

Figure 4: Examples of large-sized EMR database utilization



- Establish analytical methods that combine EMR with other existing databases
 - To make appropriate analysis of data from EMR combined with other existing databases (i.e. Sales data, Medical claim data and Dispensing data), it is critical to understand and consider the differences in sample data of each dataset
 - Beyond the above databases, physician / patient survey results and/or promotional activity records can also be combined with EMR to perform analysis from various points-of-view
- Organize a dedicated analytic team for database utilization
 - This requires mid-/long-term efforts to establish partnership with external stakeholders, to integrate multiple EMR databases and make appropriate analysis using several databases
 - To promote this initiative steadily, organization reform should be considered, such as establishment of a dedicated analytic team

treatment trends, make detailed patient segmentations, and derive number of patients and product shares in each segment. To reap the maximum benefit from EMR databases, it is essential to establish analytical methods and a dedicated analytic team, as well as to collaborate with external stakeholders, such as medical facilities and/or EMR vendors. Such initiatives will require mid-/long term efforts.

Conclusion

There are limitations in utilization of existing databases, such as difficulties in properly capturing number of patients or product shares, which is essential information to develop and execute strategies in new therapeutic areas. Although the environment for EMR database utilization in Japan is behind the US, a major breakthrough is expected based on initiatives from the relevant healthcare authorities. EMR is expected to overcome the existing limitations and enable analysis from various points-of-view, to properly understand disease-specific



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