A Review of the Challenges and Opportunities for the Use of Real-World Evidence for Medical Devices in Japan

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INTRODUCTION

- New medical devices (hereafter "devices") are often approved based on **limited clinical data** compared to pharmaceuticals. This is due in part to their comparatively **fast-paced development** and **low to moderate risk profiles**. Because of this, data needed to assess their value may be limited.
- The availability of real-world evidence (RWE) may allow for a **deeper review** of the value of new devices.
- However, there may be **unique challenges** when using RWE for assessing devices – some that are unique to each healthcare system.

OBJECTIVE

- To review the challenges and opportunities for the use of RWE for devices in Japan

METHOD

- We conducted a **pragmatic, targeted literature review** to identify literature on the **challenges** and **opportunities** for the use of RWE for devices from 2017, after key guidance was issued in Japan, until December 2024.
- Studies were identified using **PubMed (MEDLINE)** and the Japan-based **CiNii** databases with search terms related to devices, RWE, Japan, and challenges / opportunities.
- Additional studies were also identified by a **grey literature search** of other publicly available sources.

RESULTS

- Table 1 shows the key challenges and opportunities identified for the use of RWE for devices in Japan.
- Japan has a **robust ecosystem for real-world data (RWD)** with many registries and claims databases.
- Moreover, the **regulatory framework has improved** for the use of RWE pre-approval and post-approval.
- However, some challenges remain such as **data quality and accessibility issues**, **resource-intensive data entry**, and **lack of universal device identifiers (UDIs).**
- Lack of UDIs, in particular, makes long-term studies using claims databases challenging.

RESULTS *(continued)*

Table 1. Key challenges and opportunities

Challenges	× Data quality issues (e.g., need for validation, PSM, etc.) × Data accessibility issues × Limited coverage for small hospitals / clinics × Resource-intensive data entry × Lack of UDIs (reliance on functional categories) × Limited data linkage × Privacy concerns × Restriction of "off-label" data collection
Opportunities	✓ Abundance of / increase in data (registries, claims / EHR data, etc.) ✓ Improved regulatory framework ✓ Collaborative ecosystem (e.g., hospitals, societies, MAHs, etc.)

PSM: propensity score matching, EHR: electronic health records
UDI: universal device identifier, MAH: marketing authorization holder

- RWE has been used for a variety of objectives in Japan.
- Table 2 shows examples of the use of RWE for device submissions in Japan.

Table 2. Examples of RWE for devices in Japan

Registry data	✓ Support for an expanded indication for a drug-coated balloon device ✓ Support for a challenge reimbursement application for a novel stent graft system
Claims data	✓ Support for a challenge reimbursement application for a novel screw system ✓ Support for an HTA for a novel pacemaker device
EHR data	✓ Use of post-marketing clinical images for regulatory approval and reimbursement of a SaMD product ✓ Use app log data to support regulatory approval and reimbursement for a SaMD device

HTA: health technology assessment, SaMD: software as a medical device

CONCLUSIONS

- Japan has a robust and growing ecosystem for RWD including registries, claims databases, electronic medical records, and more.
- The regulatory framework for the use of RWE in Japan has also improved.
- However, some challenges remain – some of which are unique to Japan.
- Lack of UDIs, limited coverage for small hospitals and clinics, data accessibility issues, and the resource-intensive aspects of data entry for registries in Japan, for example, are issues that need to be addressed moving forward.

A list of the key publications reviewed

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