RWD7

Utilization of Real-World Data in Post-Marketing Surveillance: Experience from Asia-Pacific

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Background, Objectives and Methods

BACKGROUND

- Real-World Data (RWD) are increasingly being integrated into post-marketing surveillance (PMS) to support the monitoring of product safety and effectiveness.
- However, the extent and characteristics of RWD use in PMS across the Asia-Pacific (APAC) region remain poorly understood.

OBJECTIVE

- To evaluate the extent of RWD integration into PMS across APAC from 2020 to 2025.
- To describe publication trends, methodological approaches, data sources, and outcomes assessed in RWD-based PMS studies.
- To identify opportunities and gaps in the application of RWD for PMS in APAC.

METHODS

- APAC PMS studies utilizing RWD were identified through a literature review.
- Eligible studies were screened using predefined inclusion and exclusion criteria.
- Descriptive analyses were conducted to summarize study characteristics and temporal trends.

1 | Literature Review

- Of 1,318 publications screened, 604 (45.8%) met eligibility criteria, including 452 (74.8%) studies evaluating regulatory-mandated or voluntary PMS using RWD in APAC.

Table 1. Search strategy and eligibility criteria for literature search

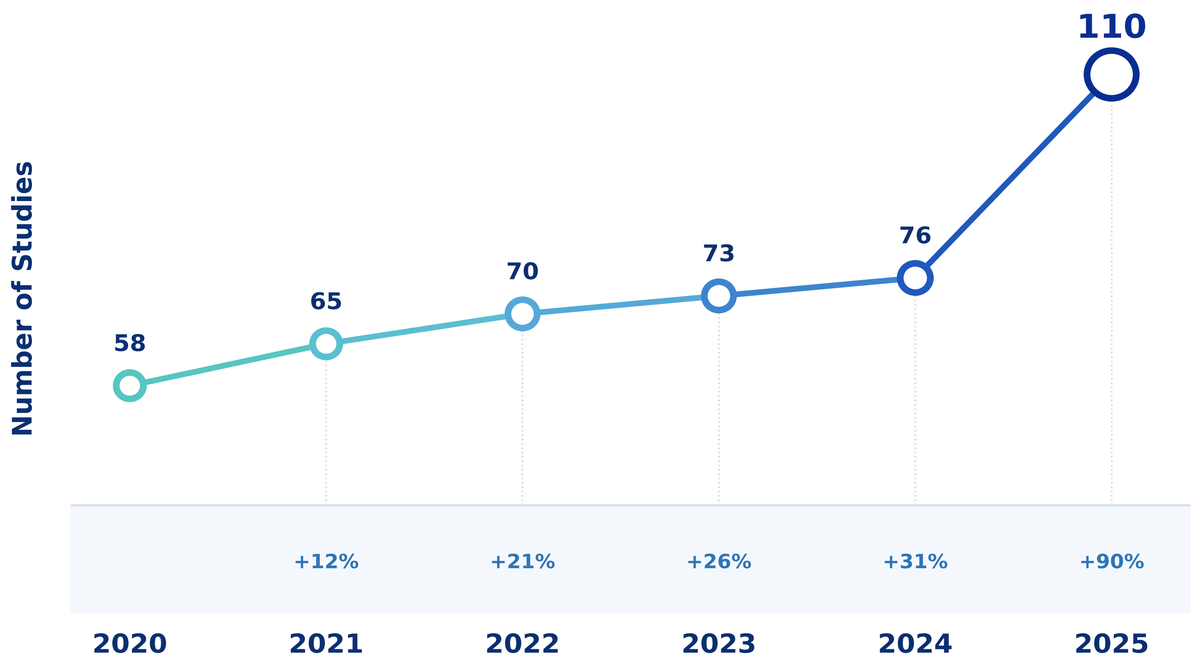
Items	Definitions
Data sources	• PubMed
Search terms	• (((post-marketing surveillance) OR (post marketing surveillance) OR (postmarketing surveillance)) • AND ((Taiwan) OR (Korea) OR (Japan) OR (China) OR (Australia) OR (Singapore))) • NOT ((FDA Adverse Event Reporting System) OR FAERS)
Publication period	• 2020 – 2025
Inclusion criteria	• Studies reporting PMS conducted in APAC countries. : Taiwan, Korea, Japan, China, Australia, Singapore • Original research or observational studies providing real-world safety or effectiveness. • Full-text articles available in English
Exclusion criteria	• Studies derived exclusively from FAERS. • Research conducted outside the APAC region or reporting only global-level analyses. • Publications not containing primary study data, such as reviews, editorials, and commentaries.

2 | Publication Trend

- Publications nearly doubled, increasing from 58 in 2020 to 110 in 2025 (+90%).

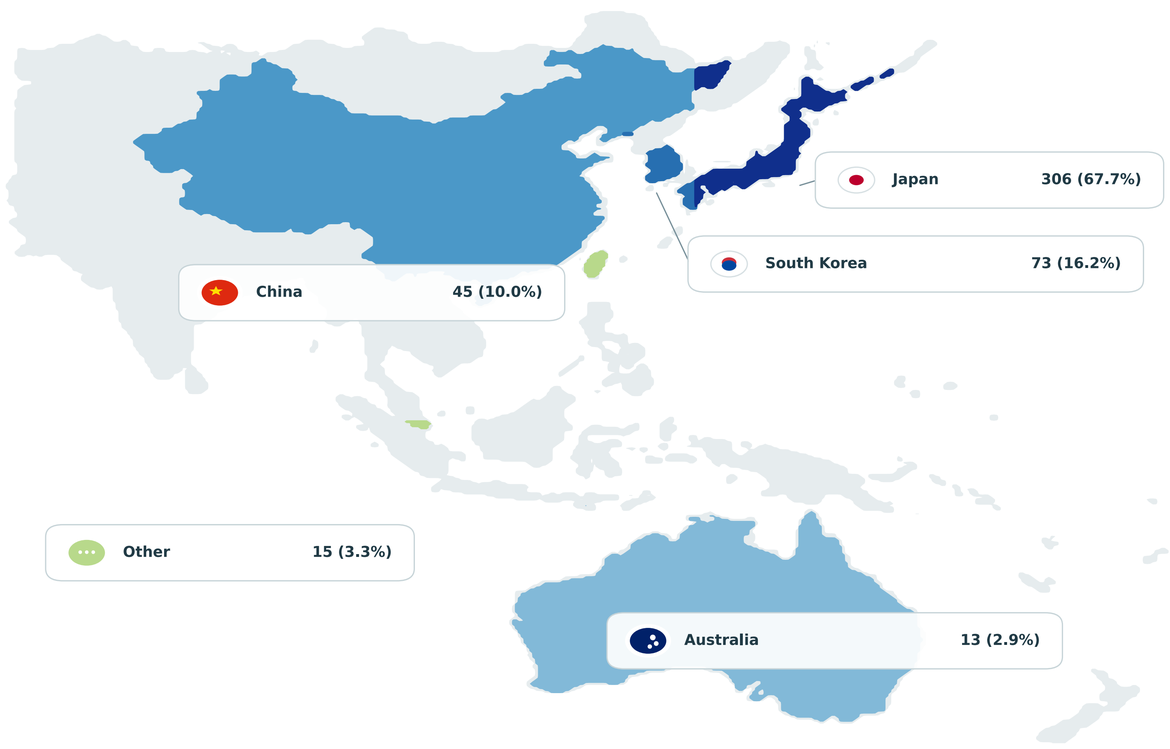
**Counts shown in the figures reflect the final curated dataset after full-text review and data validation*

Figure 1. Publication trends over time



3 | Geographic Distribution

Figure 2. Geographic distribution

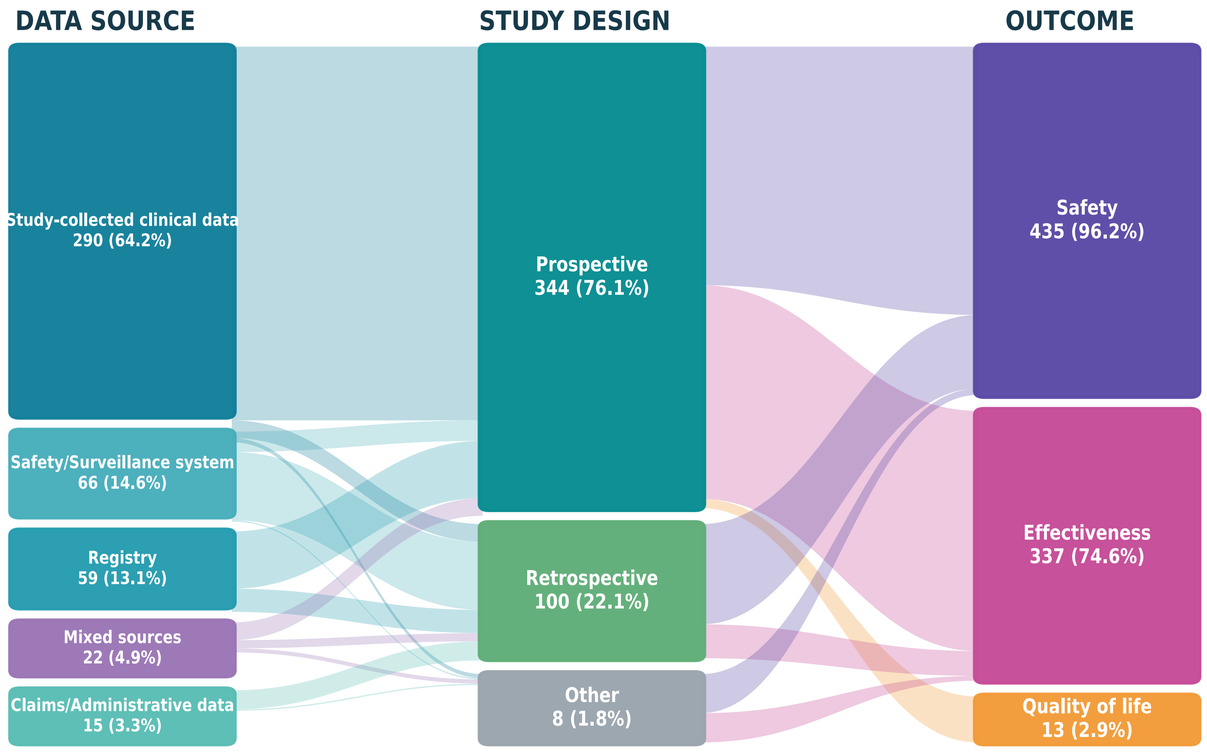


'Other' included Taiwan, Singapore, multinational studies, and other APAC studies.

- Japan accounted for over two-thirds of all included studies (67.7%), followed by Korea (16.2%) and China (10.0%).
- Most studies were prospective (76.1%) and relied on study-collected clinical data (64.2%), indicating a predominance of actively collected post-marketing evidence.
- Safety outcomes were assessed in 96.2% of studies, whereas effectiveness outcomes were reported in 74.6%, highlighting the primary role of RWD in post-marketing safety evaluation.

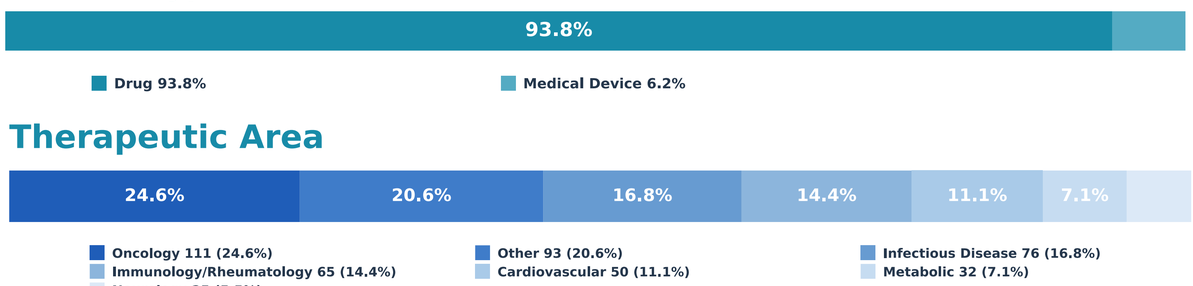
4 | Data Sources, Study Design, and Outcomes

Figure 3. Characteristics of APAC RWD-Based PMS Studies



[1]*Study-collected clinical data included EDC/eCRF, CRFs, PMS datasets, and cohort-based clinical data. Studies using multiple data sources were classified as Mixed sources.*
[2] *Study design: 'Other' included hybrid and mixed-design studies.*

Product Type



Therapeutic Area

'Other' included urology, respiratory diseases, rare diseases, and other less frequently represented therapeutic areas.

5 | Conclusion

- Evidence remained concentrated in Japan; most studies used prospective designs and evaluated pharmaceuticals, with safety assessed in nearly all studies.
- Effectiveness was assessed in approximately three-quarters of studies, whereas QoL outcomes and non-pharmaceutical technologies remained underrepresented.
- Broader geographic coverage and greater diversity in data sources, study designs, patient-centered outcomes, and non-pharmaceutical technologies may strengthen the regulatory value of post-marketing evidence as RWD/RWE frameworks continue to evolve across APAC.

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