

Objectives

- Real World Evidence (RWE) is reshaping healthcare globally, leveraging real world data (RWD) to inform decision-making.
- This study evaluates RWE advancement in multiple countries/markets from different perspectives (e.g., regulatory framework, data accessibility, academic contribution, and patient benefits) with a focus on China.

Methods

- The study combines **comparative policy analysis**, **literature review**, and **case study approaches**.
- By examining **36,601** Chinese publications and **102,825** English publications from **2014 to 2023**, it compares the policy frameworks and developmental trends of RWS across the US, the EU, and China.
- Leveraging insights from literature and cases, we comprehensively evaluates the RWS advancement from **regulatory framework**, **organizations**, **academic outputs**, **data accessibility**, and **RWS application**.

Results

- Regulatory framework:** China’s regulatory framework manifest broad application and communication, while the US and EU is more advanced on detailed framework about RWS-related technical standards, structured data submissions, and lifecycle integration.
- Organization and Initiatives:** China has established strong national-level support for RWS through centralized initiatives and pilot zones.
- Academic outputs:** From 2014 to 2023, global RWE publications increased significantly, with China also demonstrating robust growth but lagging in high-quality studies. Disease area varied for RWE publications, with oncology, cardiovascular disease, and rare diseases being key focus.
- Data accessibility:** While its infrastructure has expanded significantly, challenges remain in database openness, quality standards, and data verification in China
- RWS application:** China’s RWS applications have expanded rapidly across diverse areas but focusing more on pre-approval stages.

