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# **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.

# Organizations HMA - EMA joint Big Data Steering Group DARWIN EU GetReal Institute Organizations CORE-MD **EHDEN** National Evaluation System for health Technology Duke-Margolis Real-World **Evidence Collaborative Projects**

- **American Statistical** Association

# **Projects**

- RCT-DUPLICATE
- OneSource
- Advancing Real-World Evidence Program
- QCARD Initiative

## Regulatory framework

- All regions are aligning toward enhanced data quality, transparency, and standardized regulatory practices.
- China's guidelines emphasize broader application areas like pediatrics and rare diseases, while the US and EU provide more technical and methodological guidance.
- China prioritizes communication frameworks, whereas the US and EU offer detailed specifications for data format and content in regulatory submissions.

- GETREAL Initiative
- Adaptive Licensing pilot project
- Regulatory Science Strategy to 2025
- Big Data for Better Outcomes
- HTx project

Database availability

US and EU currently offer broader, structured

FDA and EMA have clear guidance on database

Limited inter-agency coordination, fragmented

potentially contribute to China's constrained

data ownership, and concerns over data security

quality checks, while China could enhance its

regulatory guideline on formal audit or

access for researchers.

validation mechanisms.

accessibility.

Despite China has abundant RWD resources, the

# **Projects**

- Boao Lecheng International Medical Tourism Pilot Zone
- Methodological Research Project on the Use of Real-World Data for Clinical **Evaluation of Medical Devices**
- Research Project on Evaluation Methods Using Real-World Data to Support Traditional Chinese Medicine, Rare Disease Drugs, Innovative and Clinically Urgent Medical Devices

# Organizations

- Clinical Real-World Data Application Pilot Program
- Hainan Real World Data Research Institute
- NMPA Key Laboratory for Real World Data Research and Evaluation
- China Real World Evidence Alliance (ChinaREAL)

### Conclusion

China's rapid advancement in RWE reflects strong policy support and substantial research potential. However, to match global benchmarks, enhancing data governance, adopting international standards, and promoting database interoperability are crucial. Strategic investments in quality assurance and pilot initiatives can position China as one of the leaders in global RWE, contributing to evidence-based healthcare innovation and improved patient outcomes.