Unlocking the Potential of Real-World Evidence in China

perspective from pharmaceutical Company

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Disclaimer

The views and opinions expressed in the presentation are solely personnel opinions and do not reflect the opinion of company

Agenda

01 Opportunity from the new RWE policy

02 Case study

03 maximize RWE potential

The opportunity with using RWE to support reimbursement decision

The data on product like dosage and duration will be considered addressed in product information (PI)

Although 52% of NRDL submission included RWE, the impact of RWE is not clear

- RWE can be a competitive moat – companies with China RWE ready at launch can negotiate while competitors without RWE wait.
- Use ongoing RWE collection to defend your price during NRDL renewals (every 2 years) and potentially avoid or minimize mandatory price cuts.
- Use Hainan Boao Lecheng pilot zone to generate RWE that serves both regulatory approval and NRDL reimbursement simultaneously – compressing the traditional 3–5 year pathway into 12–24 months.
- In therapeutic areas with multiple comparators, RWE can be the deciding factor for NRDL inclusion when clinical trial data are comparable.
- Use RWE to support new indications, pediatric extensions, or combination therapies for NRDL without running new expensive RCTs

not "using RWE to get listed" – it may have chance to leverage RWE to get listed faster, at a better price, and stay listed longer

Address the payor focused question

What payor Focus

Evidence beyond RCT

Not "does it work?" (RCT already answers that), but "does it work in China or China specific population

Budget impact

Robust data like dosage, adherence ,duration of treatment and hospitalization to answer the question on budget impact

Trust data source

Payor need trust data source to support decision

- ✓ published Hospital registries
- ✓ academic databases
- ✓ Hainan Lecheng
- ✓ 79 dedicated hospital or pilot province

Timing aligned with NRDL calendar

RWE ready 6–12 months before submission deadline

How to ensure the result of RWE could aligned with 2 year renew timeline

China-specific, methodologically sound, answer a payer-relevant question, and ideally from a trusted independent source

The successful cases using prospective study with CRO

3 products have been included in the national basic medical insurance drug list and 1 drug has been included in the category C category*

Manufacturer	Medicine	Therapeutic area	Date of approval	Date of entering NRDL	comment
Sanofi	Belumosufil Mesylater Tablets	Immunology Rare disease	March 2023	March 2024	Prospective RWE in lecheng before approval
Novartis	Inclisiran Sodium Injection	Cardiology	August 2023	March 1, 2024	Prospective RWE in lecheng before approval
Takeda	Teduglutide injection	Gastroenterology Rare disease	March 2024	January 1, 2025	Prospective RWE in lecheng before approval
Simcere	Tralaciclib Hydrochloride Injection	Oncology	July 12, 2022	March 1, 2023	Prospective RWE in lecheng before approval

Develop pipeline-to-payer RWE maps for top therapeutic areas
Starting with a "low-regret" RWE pilot – One hospital, one clear question (e.g., real-world adherence rates).

*Extracted from the presentation in Hainan RWE conference on Dec 27 of 2025 by Deputy director of Hainan provincial healthcare security Bureau

Methodological & Technical Hurdles

The successful cases using regional database

evidence for medical insurance submission

Real world effectiveness of Inclisiran verus the comparator drug in Adult Chinese patient with primary hypercholesterolemia or mixed dyslipidemia *

Key research question

Adherence to Inclisiran or PCSK9 monoclonal antibodies among adult Chinese patients with hypercholesterolemia: a meta analysis based on three database

Sample size

Cohort of Inclisiran: 164

- ✓ Shanghai database 99
- ✓ Chongqing database 39
- ✓ Xiamen database 26

Advantage

RWE AI will accelerate the value system development at “China speed”

Disadvantage

Heterogeneity & Standardization: Fragmented, non-standardized/transparent data across hospital systems.

Data Access & "Silos": Reluctance to share data due to competitive or bureaucratic barriers.

Data Privacy & Security: Strict regulations mandate robust de-identification and security.

* Qiansong, shaoqing lin, lin wang, Adherence to Inclisiran or PCSK9 monoclonal antibodies among adult Chinese patients with hypercholesterolemia: a meta analysis based on three database poster in 9th pharmaeconomic conference 2025

Embrace the opportunity through

Payor demonstrated the direction for using RWE to support decision
No Clear framework and formal NHSA RWE reimbursement guideline
Hesitation to invest
conservative approach

- Multi stakeholder collaboration creats “Win Win ” outcome
- Openness, transparency, mutual trust and policy dialogue
- Aligning early with NHSA – Through academic association to test assumptions
- Multinational companies as enables for cross border evidence use
- Research organization-scientific dialogue on value methodologies and globally accepted standards

Build the capacity and framework together from both side for win-win outcome

Internal preparation in pharmaceutical company

Success requires **long-term investment in RWS infrastructure**, cross-sector collaboration, and agile adaptation to evolving regulations.

Building Internal RWE Capabilities

- Establish a centralized, cross-functional RWE unit (Center of Excellence .COE).
- Develop a corporate RWE strategy aligned with portfolio goals.

Leveraging External Partnerships

- identify the good data source under the quick involving environment

Select the right service providers (CROs, tech-platforms, academic centers).

- Foster academic collaborations to enhance credibility.

Investing in Technology and Infrastructure

- Adopt robust RWE data platforms.
- Embrace AI and analytics tools.
- Ensure compliance by design.

Cultivating a Culture of Evidence-Based Decision Making

- Integrate RWE into early development planning.
- Train the organization and communicate RWE proactively.

Thank You

Thank you for your attention