

# Industry views and practices on RWE in China

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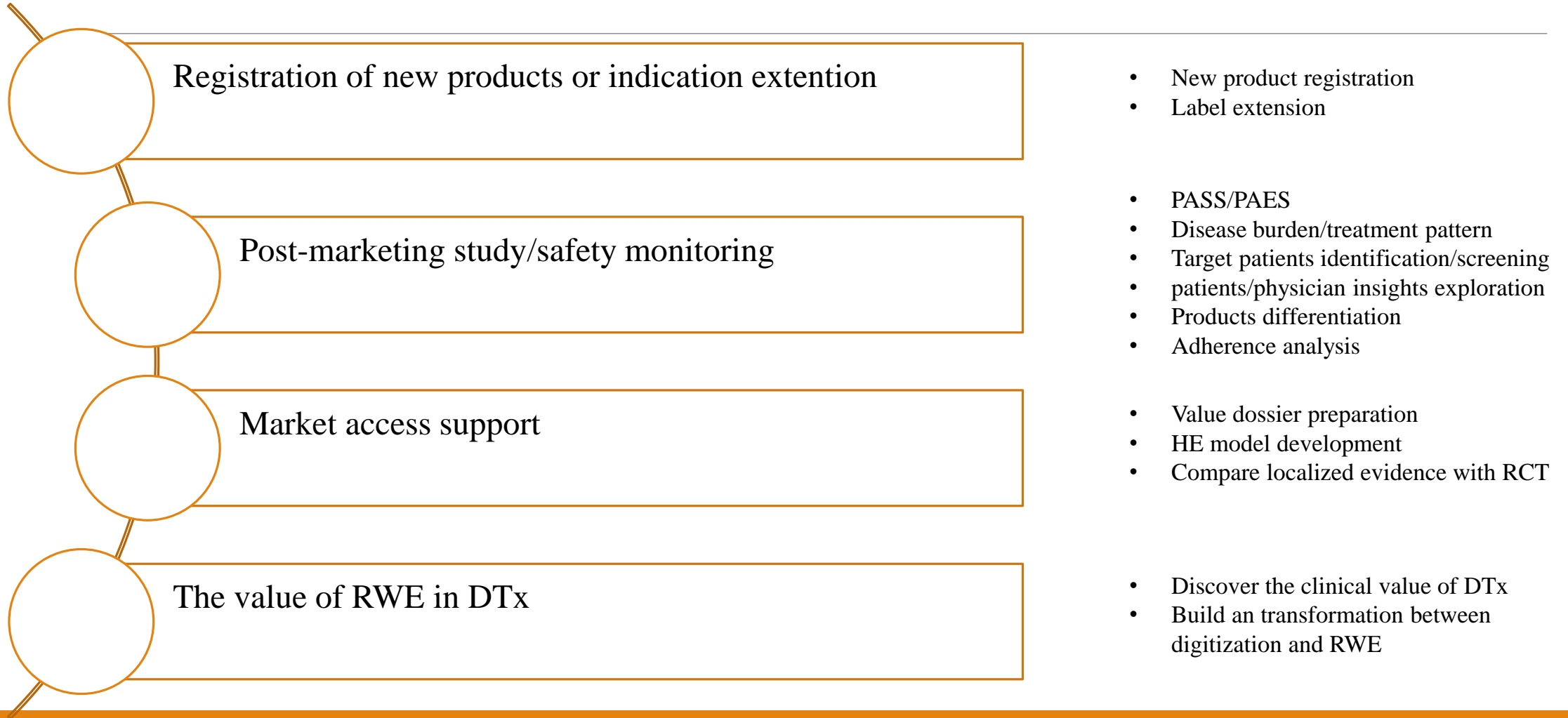


# Industry Views






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- Expectations for RWE's application in China: Based on the active promotion of Chinese regulators and the continuous exploration of academic and industry, we are generally optimistic about the future application of RWE in China in regulatory and other areas.
- Current status of RWD in China: High-quality data and analytics produce valuable RWE. China's RWD foundation is relatively weak, it is needed to not only improve data quality and accessibility, but also to optimize the policy for RWD use and pay attention to patient privacy protection.
- Multi-sectoral collaboration: RWS requires the joint efforts of government, academia, industry, CROs, clinical research experts, clinical institutions, and data companies.
- Impact of new technology advancement: With the development of technology, more and more health data are available, which means that the RWD source, quality and continuity will be greatly improved. How these real-world data can be accessed and utilized is also an area to explore.

# Industry Practices



# Cases Sharing

|              | New product registration  | Label extension  | Post-marketing study  | Market Access   | DTx support  |
|--------------|---|--|---|---|--|
| Company      |  |                        |  |  |   |
| Products     | XEN® Gel Stent  | Bevacizumab  | Praluent  | Tasigna   | TRIO<br>(A diabetes management tool)   |
| Objective    | Registration in China market  | Label expansion: Bevacizumab + platinum-based chemotherapy for part of the first-line treatment of NSSLC | Verify the MACE avoidance in Chinese patients treated with Praluent                 | Evaluate the cost effectiveness compared with Glivec                                | <ul style="list-style-type: none"> <li>Assess the clinical effect of TRIO</li> <li>RWE supporting TRIO product registration and commercialization</li> </ul> |
| Data source  | RWE pilot in Hainan Boao  | Thousands of patients in 3 large cancer hospitals  | Single arm cohort + a regional claims database                                      | One top hospital  | TRIO platform  |
| Study design | Single arm, prospective study   | Retrospective RWS  | Prospective single arm + synthetic arm control                                      | Retrospective data analysis + modelling   | Retrospective analysis+ literature review  |