

Industry views and practices on RWE in China

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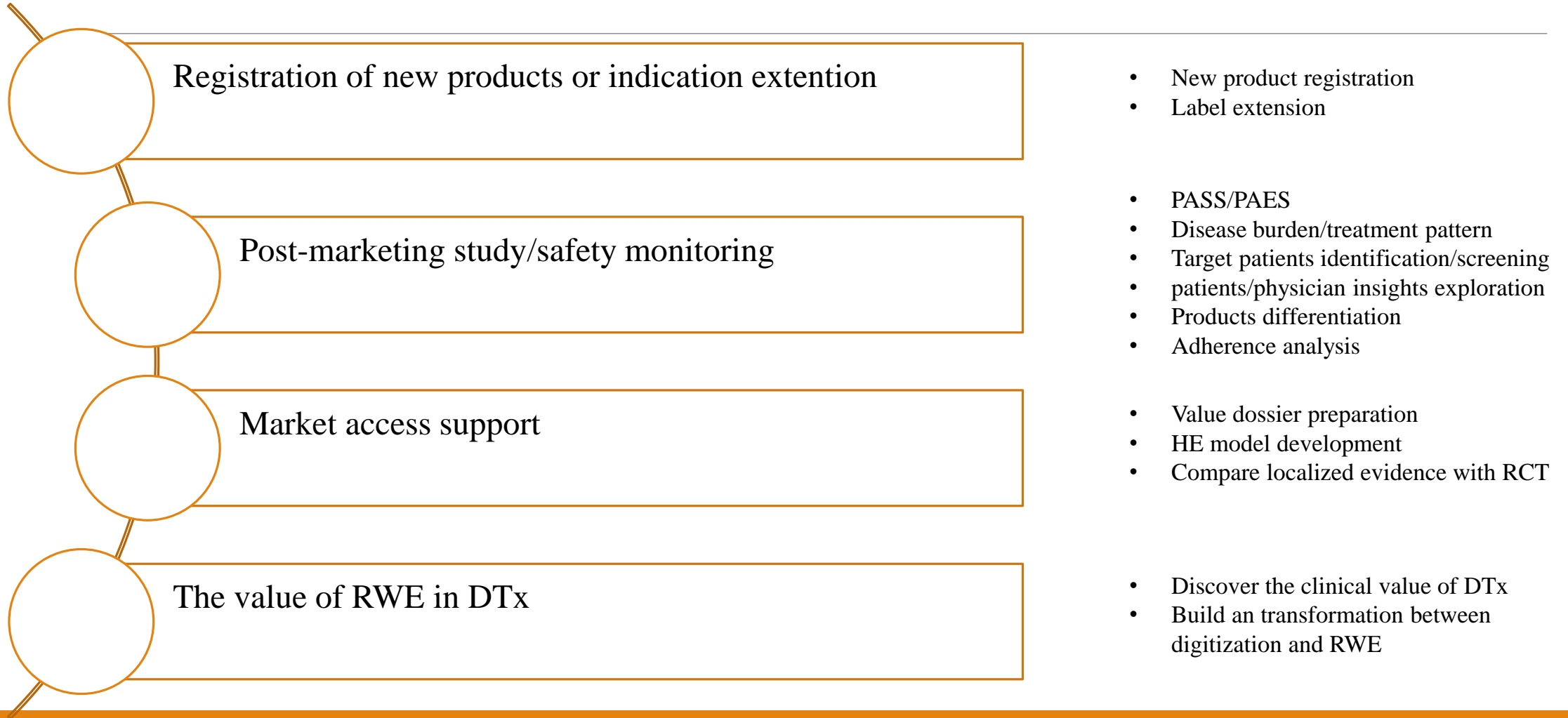
R&D-BASED PHARMACEUTICAL ASSOCIATION COMMITTEE (RDPAC)
CHINA








Industry Views

- 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 (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"> Assess the clinical effect of TRIO RWE supporting TRIO product registration and commercialization
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