

Real-World Evidence Generation Ecosystem in China

An Innovator's perspective

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CHINA: CHANGING LANDSCAPE

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National Reimbursement Drug List (NRDL)

- Volume-based centralized drug procurement policy; updated annually
- Pressure on drug prices cut will remain; **local RWE to support cost effectiveness and budget impact will be key to NRDL negotiations**
- Generic Quality Consistency Evaluation (GQCE) has put pressure on innovator's matured products

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Shorter launch time for innovative and rare disease products/ stronger patent laws

- Accelerated approval pathways and breakthrough therapy designations
- New amendment (4th) to patent laws brings provision for patent term extension and patent linkages
- Legal provision to challenge patent violations

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Increasing regulatory focus on RWE

- Release of relevant guidelines, i.e., Guiding principles of real-world evidence supporting drug development and review (trial)
- Development of networks, platforms and database, i.e., Establishment of Hainan Real World Data Research Institute.
- RWD for Clinical Evaluation of Medical Devices is one of the key projects in the Drug Regulatory Science Action Plan, i.e., market authorization of medical device for surgical management of refractory glaucoma with the submission of clinical RWE of racial differences



EXPERIENCES

- Different practice and understanding on patient privacy and informed consent requirements, i.e., informed consent requirements for chart review
 - Data completeness: separate accessibility to different HIS/EMR modules, i.e., use of technology vendors to work with hospital IT for data access across HIS modules
 - High legal and compliance risks: data ownership and commercial rights concerns multi-center EMR data
 - Data technology vendors working practices and legality
 - Inconsistent data variables with inconsistent vocabulary in different hospitals EMR – difficult data curation and analysis.
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LESSONS LEARNED

- Feasibility assessment and review of data variable early on before conducting an RWE study; data source may include, e.g.,
 - Digital Health China & Linkdoc (National Oncology EMR)
 - National Cancer Center/1 Yong Cloud (National Anti-Tumor Drug Surveillance System)
 - Yidu Cloud (National Multi-disease EMR)
 - Ningbo, Gennlife (Multi EMR & Disease Claims)
 - Tianjin EHR (Regional Database)
 - Use of data vendor/development of technology for a single window access to patient data spread across the HIS/EMR modules
 - Work with site GCP/R&D in drafting a consistent and defined procedures to RWE data access to third parties
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FUTURE DIRECTION

- Stakeholder collaborations and consortium to build RWE infrastructure by shaping RWE standards and sharing best practices
 - Capacity building by investing in RWE education & infrastructure across stakeholders
 - Provision of central Ethics committee to provide a single window clearance to RWE studies
 - Simplify HGRAC regulations and requirements: a clear risk-based approach would be helpful
 - Regulator to optimize the policy for RWD access, use and patient privacy protections, interoperability with overseas data, guidance on the use of new types of data (health mobile data, electronic wearable device data)
 - Uncertainty in government policies: a value-based approach recommend in reimbursement assessments.
 - Improvement in methodology and analytical technology by the CROs/data IT vendors
 - Patient centric approach for a robust and meaningful RWD
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Participation of Chinese patients in global studies for simultaneous development

Digitally and analytical enable environment with healthcare a strategic priority

Rise of domestic biotech R&D: leading chimeric antigen receptor T-cell (CAR-T) therapies

Rising China contribution to global pharma revenue

Changing regulatory landscape

Multinationals are at a crossroads – not just for the sales numbers but strategically it's too hard to miss the opportunity to ride the dragon. With broadening access to newer therapies and increasing evidence, China could lead the wave of an innovation-driven ecosystem.

Data quality

Patent protection mechanism

High attrition rates/talent crunch

Market access constrains and cost driven reimbursement negotiations
