RWD 165

Applying Real-World Evidence to National Healthcare Reimbursement Decision-Making: A Study on Assessment Frameworks Under China's Lecheng Pilot Policy

Shihui Fu, Hailun Wang
Correspondence: Hailun Wang, rws_hs@hainanlecheng.com

Background

The Healthcare Security Administration of Hainan Province, in collaboration with the Boao Lecheng International Medical Tourism Pilot Zone, has initiated a pilot program to examine the application of real-world evidence (RWE) in pharmaceutical pricing and reimbursement decisions. This initiative supports evidence-based policy development for the National Reimbursement Drug List (NRDL), aligning with ongoing developments in China's healthcare policy framework.

Objectives

This study aims to establish an integrated policy implementation framework that provides a standardized and practical approach for utilizing RWE in pharmaceutical reimbursement decision-making in China. The framework comprises two core components: (1) developing technical guidelines to assist pharmaceutical companies in generating high-quality RWE that demonstrates the effectiveness, safety, and economic value of innovative drugs; and (2) creating an assessment framework to enable multidisciplinary expert panels to systematically evaluate the quality, relevance, and reliability of submitted RWE using standardized tools and criteria, thereby providing evidence-based recommendations to support government reimbursement decisions.

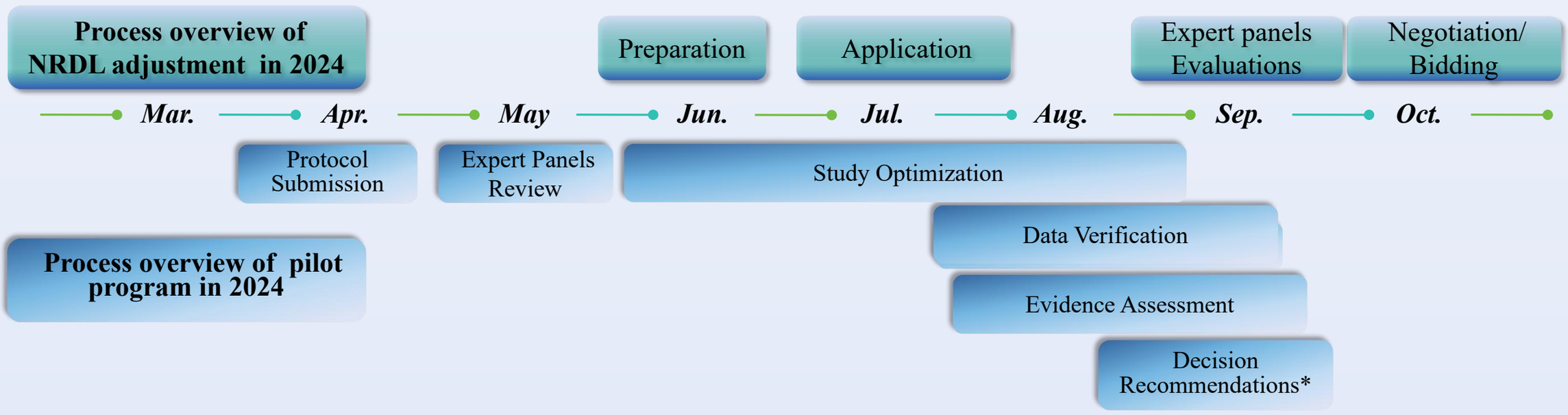
Methods

The development of the framework employed a multi-method approach to ensure comprehensiveness and practical applicability. (1) A comprehensive literature review was conducted, analyzing academic publications, national policy documents, and existing health technology assessment guidelines for RWE application from international agencies (e.g., UK NICE, Canada CADTH). (2) A structured Delphi consensus process was implemented, incorporating six focus group discussions and in-depth interviews with multidisciplinary experts to iteratively refine the framework components according to China's specific healthcare security context and policy requirements. (3) A mixed-methods validation approach was applied, combining quantitative assessment metrics with qualitative evaluation through ten more pharmaceutical case studies to examine the framework's utility in evaluating RWE quality across different therapeutic areas and evidence types.

Results

The study established:
1. A 6-step assessment process:
(1) protocol submission;
(2) expert review;
(3) study optimization;
(4) data verification;
(5) evidence assessment;
(6) decision recommendations.

2. Technical guidelines incorporating:
(1) A standardized RWS report checklist.
(2) A data adequacy self-appraisal worksheet.
(3) A tiered assessment checklist (covering 5 core domains: Protocol Design, Data Reliability, Security&Compliance, Analysis, and Results; 16 secondary criteria; 40 tertiary items).
(4) A qualitative assessment report with structured recommendations across multiple dimensions (clinical effectiveness, safety profile, healthcare resource utilization, and economic value) to support reimbursement decisions.



*Decision recommendations will be submitted to the NHSA before the expert review stage or negotiation/bidding stage, according to the objectives of the RWS.

Conclusions

In conclusion, this pilot program establishes a systematic approach for integrating real-world evidence (RWE) as a complementary evidence source alongside conventional clinical trial data in pharmaceutical reimbursement decision-making. By developing technical guidelines for RWE generation and implementing a standardized assessment framework, the program provides a practical pathway to support more responsive and evidence-based reimbursement decisions.

To date, the program has engaged with over ten innovative drug candidates, with manufacturers submitting real-world studies (RWS) for evaluation. Among these, three RWS were assessed as medium to high quality, providing valuable evidence worthy of consideration in the NRDL decision-making process. This preliminary outcome demonstrates the program's potential to generate credible real-world data that can inform reimbursement policies.

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