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A new path for compliance-driven development: The impact of State Council Order No. 818 on biomedical innovation in China

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In recent years, frontier biomedical technologies such as gene therapy and cell therapy have achieved significant breakthroughs, offering new hope for the diagnosis and treatment of refractory diseases. In oncology, China's cancer research and care landscape is also evolving, with policy reform, precision oncology, multidisciplinary care, and drug development driving clinical innovation.[1] However, these technologies often involve long research and development (R&D) cycles, high costs, technical complexity and uncertain risks. Their ethical and safety challenges have attracted broad attention from the medical community, industry, and the public. To improve the regulatory framework for clinical research and clinical translational application of new biomedical technologies, standardize relevant R&D and application activities, manage potential risks, and promote biomedical innovation, the State Council promulgated the *Regulations on Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies* (State Council Decree No. 818)[2] (hereinafter referred to as the "Regulations").

The Regulations explicitly state their purpose is to "promote innovative development and safeguard medical safety." They adopt a people-centered approach that balances innovation and safety while complementing existing regulatory systems for drugs and medical devices.[3] The Regulations establish a two-stage framework, applying filing-based management to clinical research and approval-based management to clinical translational application. This framework creates a clear boundary between scientific exploration and safety and ethical requirements. Meanwhile, the Regulations further strengthen requirements for institutional qualifications, ethics review, risk control and data integrity.[4] Through this institutional innovation, the state provides clear regulatory guidance for scientific research and technological exploration while supporting innovative application, thereby establishing a legal foundation for the standardized development of frontier technologies such as cell and gene therapies.

TWO-STAGE MANAGEMENT OF CLINICAL RESEARCH AND TRANSLATIONAL APPLICATION

The Regulations establish a two-stage management framework that combines filing and approval for clinical research and clinical translational application of new biomedical technologies.[2] Specifically, clinical research is subject to filing-based management, whereas technologies intended for clinical translational application after completion of clinical research must be approved by the competent health department under the State Council.

In practice (Figure 1), before initiating clinical research, new technologies must complete necessary laboratory and preclinical studies. Research protocols must be reviewed and approved by the institutional academic and ethics committee, and the clinical research institution must submit filing materials to the National Health Commission (NHC) within five working days. After filing, all research activities must strictly follow the approved protocol, with continuous risk monitoring, mitigation measures, and emergency preparedness throughout the study. In cases of safety risks or ethical concerns, institutions shall promptly take measures such as protocol modification, study suspension, or termination, and report to the competent authorities as required.

After completion of clinical research, technologies intended for clinical translational application must meet the relevant requirements of the *Working Specifications for the Approval of Clinical Translational Application of New Biomedical Technologies (for Trial Implementation)*, and applicants must submit an application to the NHC.[5] The technology may enter clinical use only after technical and ethical evaluation and approval. In other words, large-scale clinical application requires administrative approval for clinical translational application. In addition, in the context of major public health emergencies, the Regulations provide an emergency use mechanism allowing eligible new biomedical technologies to be applied within a defined scope and time period after appropriate evaluation.[2] Overall, this two-stage regulatory model provides a clear and lawful pathway for clinical validation of innovative technologies while standardizing procedures and strengthening oversight.

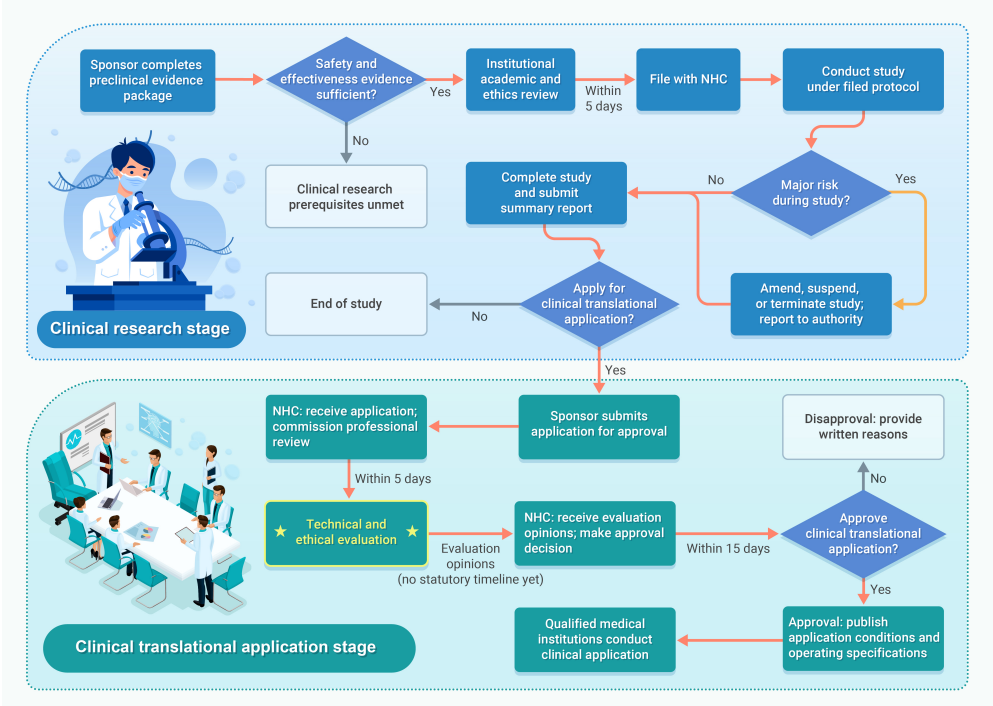

Figure 1. Management pathway for clinical research and clinical translational application of new biomedical technologies under the Regulations Yellow stars denote two special circumstances (priority review and approval; emergency use). NHC, National Health Commission.

INSTITUTIONAL AND ETHICAL COMPLIANCE REQUIREMENTS

In addition to procedural management, the Regulations impose stringent qualification requirements on clinical research sponsors, implementing institutions, and principal investigators. These requirements cover the institutions qualifications, academic and ethics committees, research facilities, qualified personnel, funding support, and comprehensive quality management. These provisions effectively exclude underqualified institutions from conducting such research, leaving

competent Grade III Class A hospitals as the principal sites for technological innovation. The Regulations embody a "patient-centered" principle by providing research participants with safeguards in relation to informed consent, risk management, privacy protection, and insurance coverage.[2,3]

Through high-standard institutional review and strict ethical safeguards, the Regulations institutionalize the protection of research participants' rights and interests while balancing innovation and safety. These requirements are expected to promote more standardized research models and make institutional compliance capacity a key prerequisite for conducting clinical research on new biomedical technologies. Researchers must now focus not only on technology value but also on compliance training, ethics review, data management, adverse event handling, and continuous risk assessment. Consequently, biomedical innovation will increasingly concentrate in high-capability medical institutions, providing more stable protection for research quality and patient safety.

INNOVATION PATHWAYS AND STRATEGIC CHOICES

The Regulations impose stricter compliance requirements on the R&D of new biomedical technologies while providing diversified research pathways for innovative projects at different development stages and with varying technical attributes. Previously, some early exploratory studies were conducted as investigator-initiated trials (IITs) after approval by institutional research management department and ethics committee. Following the implementation of the Regulations, such studies have been incorporated into the NHC regulatory framework. Five major categories and 17 subcategories of new technologies are included in the filing guidance list for clinical research, and only eligible medical institutions that complete the required review and filing procedures may conduct the relevant clinical research. This institutional arrangement renders early exploratory clinical research legally grounded, rule-based and risk-managed.

At the same time, the Regulations do not replace the existing registration pathways for drugs and medical devices. Products meeting the definitions of a drug or medical device may proceed with registration clinical trials in accordance with the relevant laws, regulations, and policies. This "dual-track" arrangement provides multiple pathway options for innovative technologies and facilitates more flexible and efficient early proof-of-concept and exploratory research.

However, not all new biomedical technologies can directly enter the clinical translational application procedure. According to relevant requirements, technologies eligible for clinical translational application are generally highly individualized or intended for rare disease treatment and remain at an early exploratory stage of drug development. Therefore, products developed by technology companies that meet the definition of new biomedical technologies may be flexibly validated through clinical research conducted by eligible medical institutions during the early exploratory stage. As technologies gradually mature, their product attributes become clearer, and registration as a drug or medical device is intended, they should transition to a registration clinical trial pathway for systematic evaluation of safety and efficacy. This institutional arrangement requires R&D stakeholders to consider scientific value, technical attributes, clinical needs, and regulatory pathways at an early stage to avoid delays caused by unclear pathway determination or poor regulatory coordination. The NHC has also emphasized avoiding redundant research and promoting efficient allocation of research resources.[4]

In practice, key challenges involve several decisions. First, sponsors and institutions must determine whether a project should follow the pathway for new biomedical technology, drugs, medical devices, or a hybrid pathway. Second, they need to decide when exploratory clinical research should transition to a registration-oriented trial. Third, regulators and developers need to coordinate expectations for data quality, ethics oversight, adverse-event reporting, and evidence reuse across different regulatory systems. Delayed pathway planning may hinder development progress and reduce the value of early clinical evidence.

CONCLUSION AND POLICY RECOMMENDATIONS

The promulgation and implementation of the Regulations provide institutional support for the R&D and governance of new biomedical technologies in China while establishing clear boundaries for risk control. For rapidly advancing fields such as cell therapy, gene therapy, tissue engineering, and related interdisciplinary technologies, this regulatory framework will help reduce disorderly exploration and repetitive research, improve clinical research quality, and enhance public trust in emerging technologies.

Nevertheless, several challenges remain in implementing the system. First, new biomedical technologies are highly complex and rapidly evolving. Regulators need to continuously improve supporting documents, technical guidelines, and classification lists to enhance the predictability of pathway determination. Second, medical institutions should strengthen academic committees, ethics committees, data management platforms, and adverse event response mechanisms to prevent filing and ethics review from becoming merely procedural. Third, R&D enterprises and research institutions should establish regulatory strategies early and make appropriate choices among IITs, clinical translational application, drug registration, and medical device registration, ensuring that early-stage research data can support subsequent development and translation. Finally, interdepartmental coordination should be strengthened to build integrated synergy across governance frameworks for health administration, drug regulation, science and technology, medical insurance, and ethical oversight.

From a longer-term perspective, the Regulations are not a barrier to innovation but a necessary institutional framework for high-quality innovation. Sustainable medical innovation must be based on scientific evidence, ethical legitimacy, data credibility, and patient safety. Through joint efforts by regulators, medical institutions, research organizations, and enterprises, China is expected to establish a governance system for new biomedical technologies that promotes innovation while maintaining safety, and supports clinical exploration while facilitating standardized translation. Only by continuously improving research quality and translational efficiency within a compliance-based framework can new biomedical technologies better serve the prevention and treatment of major diseases, promote original innovation, and contribute to improving public health.

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AUTHOR CONTRIBUTIONS

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DECLARATION OF INTERESTS

The authors declare no competing interests.