Bridging the translation bottleneck: China's "Catfish Moment" for biomedical advanced technologies

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Received: May 26, 2026; Accepted: July 9, 2026; Published Online: July 10, 2026; https://doi.org/10.59717/j.xinn-med.2026.100236

Citation: Gao J. and Gao C. (2026). Bridging the translation bottleneck: China's "Catfish Moment" for biomedical advanced technologies. *The Innovation Medicine* **4**:100236.

On 1 May 2026, China's *Regulations on Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies* (State Council Decree No. 818, hereafter Order 818) took effect.[1] Widely viewed as China's "Catfish Moment," this landmark regulation is expected to revitalize a stagnant clinical translation system. By clarifying regulatory pathways, it could unlock accumulated results from investigator-initiated trials (IITs) and foster greater collaboration among industry, hospitals, and research institutions in advancing biomedical technologies such as cell and gene therapy.

INNOVATION LANDSCAPE AND TRANSFORMATION PROSPECTS

Over the past decade, clinical trials of innovative pharmaceutical products in China have experienced explosive growth. Its share of interventional trials published in the world's top 100 medical journals rose nearly five-fold, from 3.2% in 2015 to 14.9% in 2024 (overall contribution 7.5%) (Figure 1A). Within this corpus, China's performance in cell and gene therapy (CGT) stands out: it accounted for 11.0% of global CGT trials, well above its average footprint in other pharmaceutical sectors and signaling a clear first-mover advantage in frontier modalities.

Crucially, China's CGT exploration has relied overwhelmingly on IITs, which comprised 94.2% of its high-impact publications — far exceeding contributions from National Medical Products Administration (NMPA) Investigational New Drug (IND) trials or National Health Commission (NHC) stem-cell therapy record-filing pathways. These institution-led studies have played a critical role by generating proof-of-concept data, enhancing regulatory and

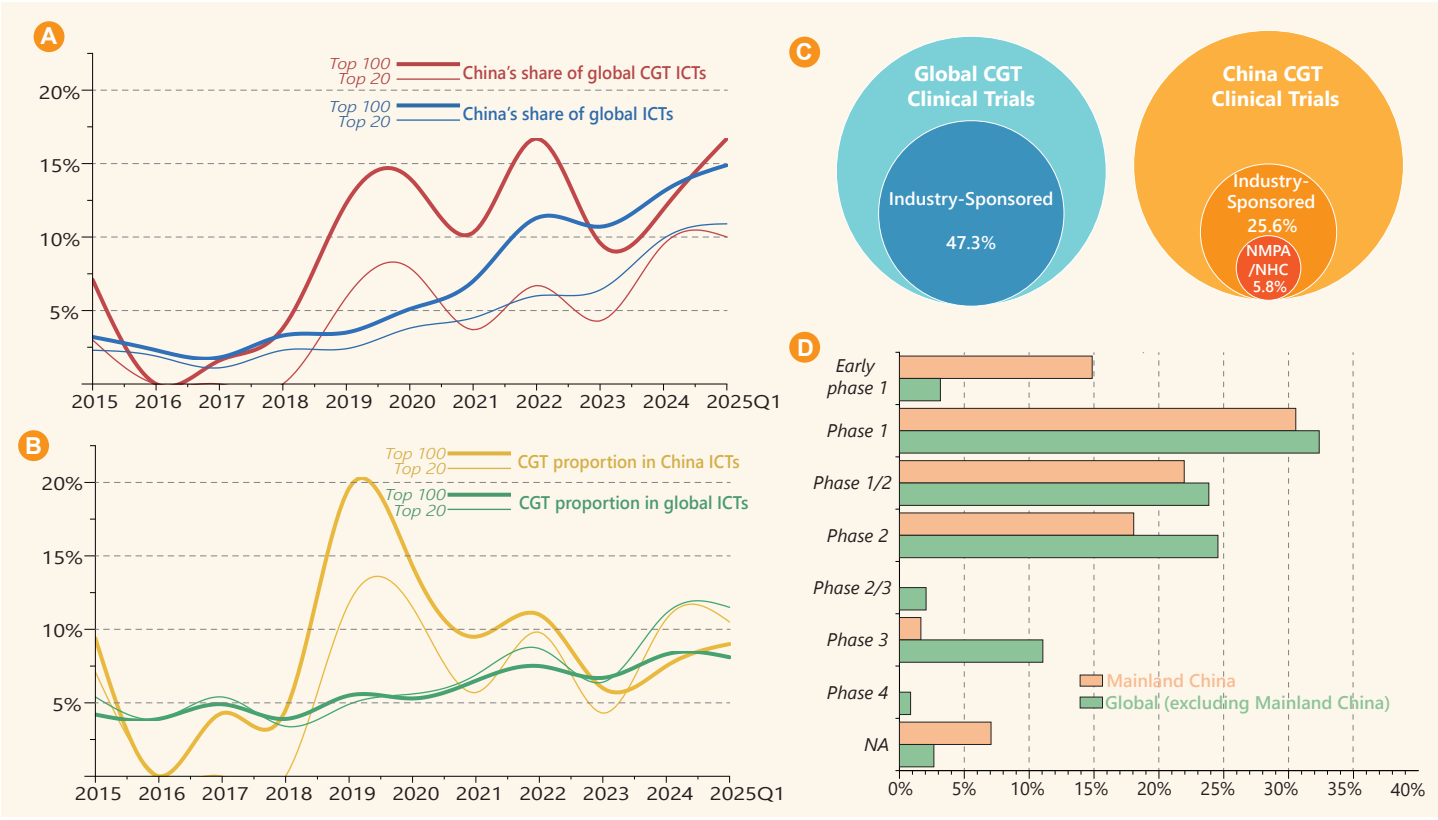

Figure 1. Trends in proportions, sponsorship, and phases of CGT clinical trials globally and in China (A) Temporal changes in China's share of global clinical trials for all therapeutic modalities and for CGT products. (B) Temporal changes in the proportion of CGT trials among all therapeutic modalities globally and in China. (C) Sponsorship and funding sources of CGT trials globally and in China, with the proportion of Chinese trials holding NMPA IND approval or NHC record-filing indicated. (D) Phases of CGT clinical trials globally and in China. Data were derived from interventional clinical trials (ICTs) published in the Top 100 medical journals ranked by Research.com (2025). Temporal analyses were restricted to publications from January 2015 to March 2025.

industry understanding of novel platforms, and building domestic R&D capacity. This IIT-driven momentum enabled China to outpace the global average in CGT output between 2019 and 2022.

Despite rapid growth, China's activity in CGT has moderated in recent years due to structural translation bottlenecks (Figures 1A-B). Industry sponsorship accounts for only 25.6% of Chinese CGT trials—roughly half the global average (Figure 1C)—while heavy reliance on public grants is insufficient to support the long development cycles and high costs of these therapies. More critically, translation pathways remain unclear. IITs have largely been limited to early exploration, leaving promising results stranded due to the absence of clear conversion mechanisms and data standards. Phase distribution is also heavily skewed, with Phase I trials accounting for 14.8% of Chinese studies (versus 3.1% globally), while late-phase trials remain very limited (Figure 1D). Consequently, large volumes of high-quality early data remain stalled, unable to advance from research into commercial development. For example, early IITs on AAV gene therapy for infantile-onset Pompe

disease and hereditary deafness have produced encouraging preliminary findings,[2,3] yet these programs have not progressed into pivotal trials or obtained the necessary regulatory approvals.

In this context, Order 818 serves as the catfish thrown into the pond. It establishes a systematic regulatory framework for the translation of clinical research on biomedical advanced technologies, defined as novel biological methods acting at the cellular or molecular level that have not yet entered clinical use in China. The regulation introduces an NHC record-filing system, allowing qualified institutions, primarily tertiary hospitals, to initiate studies after completing non-clinical safety and efficacy evaluations and obtaining institutional ethics approval. During the research phase, no fees may be charged to subjects, and strict requirements regarding informed consent, non-remuneration, risk prevention, and conflict-of-interest management are enforced. Upon completion, sponsors may apply for "translational application" approval. The NHC prioritizes applications addressing serious life-threatening diseases lacking effective treatments and must render a decision within specified timelines. Approved technologies can then be provided as fee-based medical services at qualified institutions.

Pursuant to the National Health Commission's *Guiding Principles on the Classification of Biomedical Advanced Technologies, Pharmaceuticals, and Medical Devices (Interim)*,[4] this "technology track" forms a distinct regulatory system that complements the NMPA's pharmaceutical and device track. It targets highly innovative and personalized modalities that are difficult to develop through conventional pathways. In the research phase, qualified institutions autonomously classify technologies according to the *Biomedical Advanced Technology Clinical Research Filing Guidance List*.[4] In the translational phase, applications are open for highly personalized technologies lacking comparable mechanisms — especially for rare diseases.

By strengthening institutional review through the NHC filing mechanism, Order 818 improves pre-clinical evaluation, CMC quality control, and risk management, facilitating the transition of high-quality IITs to industrialization. The regulation standardizes clinical research and supports the preservation of China's first-mover advantage in advanced biomedical technologies.

IMPLEMENTATION CHALLENGES, POTENTIAL RISKS, AND KEY EXECUTION PRIORITIES

Although Order 818 charts a clear translation roadmap, its implementation faces multiple challenges arising from the intersection of regulatory science, rapid technological change, and industrial demands.

The foremost challenge lies in adapting regulation to the dual "pharmaceutical–medical technology" attributes of emerging modalities. These technologies simultaneously require rigorous quality control, scalable production, and consistency—characteristics typical of pharmaceuticals—while also involving personalized preparation, living cells, and immediate clinical use, which are features of medical technologies. This hybrid nature creates fundamental classification difficulties. Moreover, the rapid pace of technological iteration and the high degree of supply chain integration make rigid regulatory divisions difficult to sustain, increasing the risk of regulatory blind spots, duplication, and inconsistent application. Frequent changes or uncertainty in regulatory pathways may also trigger adverse effects across the industrial chain, including reduced investment willingness, impaired resource allocation, and elevated compliance costs.

Second, regulators must strike an effective balance between entry requirements and clinical innovation. While Order 818 seeks to both standardize and promote biomedical advanced technologies, overly complex or stringent entry procedures risk further dampening the clinical-research enthusiasm for frontier biomedical technologies. At the same time, effective inter-agency coordination is essential. Clinical data generated under Order 818 should be able to flow smoothly into translational application or NMPA drug-registration pathways. Removing barriers to data sharing between the NHC and NMPA is therefore critical to resolving regulatory uncertainty, maintaining researcher confidence, and supporting continued innovation and industry growth.

Third, the balance between intellectual-property protection intensity and public-health accessibility poses a salient risk. Biomedical advanced technologies differ fundamentally from traditional medical techniques. They rely on standardized manufacturing processes, algorithms, and quality control systems. In contrast to traditional methods, which are difficult to standardize and protect, these technologies possess clear industrial characteristics. However, the current framework under Order 818 does not yet include provisions for data exclusivity comparable to those recently established for pharmaceuticals. In the absence of adequate protection mechanisms, investors may face uncertainty when considering long-term commitments to high-risk innovation. Policymakers therefore need to carefully calibrate the level of protection to encourage original innovation while avoiding excessive restrictions that could limit patient access or hinder broader technological adoption.

To fully unleash the catfish effect and ensure steady, far-reaching implementation, five priority actions require concrete operationalization. First, regulatory capacity building should be accelerated through targeted training programs for institutional review boards and and chemistry, manufacturing, and controls (CMC) assessors specializing in CGT therapies. Second, dynamic equilibrium between regulation and innovation should be maintained through ongoing multi-stakeholder dialogue, permitting measured flexibility in trial design and endpoints while safeguarding participant safety and maintaining an enabling regulatory environment.[5] Third, closer policy coordination between the NHC and NMPA should be pursued to enable the effective utilization and flow of clinical evidence across regulatory pathways, supported by collaborative mechanisms and interoperable data platforms that facilitate integration between the technology track and pharmaceutical registration routes. Fourth, dynamic monitoring mechanisms need to be established with predefined key performance indicators, mandatory public reporting, and iterative feedback loops. Fifth, a humanistic orientation must be upheld by mandating standardized long-term follow-up registries and independent patient representation in translational application reviews.

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FUNDING AND ACKNOWLEDGMENTS

This work was supported by Changping Laboratory (2026G-01-01). All authors are employees of Changping Laboratory.

AUTHOR CONTRIBUTIONS

J Gao conceived the study, conducted data analysis, and wrote the first draft. C Gao supervised the project and revised the manuscript. All authors approved the final version.

DECLARATION OF INTERESTS

The authors declare no competing interests.