Parexel Interview: After Contributing 30% of Global Innovation Assets, What's Next for China's Innovative Drug Industry?

Editor's note:

In 2025, approximately 30% of global innovative drug assets originate from China. License-out deal values continue to reach new highs, the NewCo model has become a new pathway for globalization, and Hong Kong has emerged as one of the largest secondary financing markets for biopharma globally. These figures and concepts together paint an encouraging picture: China's innovative drug industry is making a dramatic leap from "imitation" to "original innovation."

However, behind this picture, another question is emerging: what happens after the molecule is good enough?

Over the past decade, capability building in China's innovative drug industry has mainly focused on the drug discovery stage—identifying good targets, designing strong molecules, and generating solid data. But bringing a molecule from the laboratory to the global market means drug discovery is only halfway. The second half—clinical development—requires a completely different set of capabilities, including the design of global multi-center trials, alignment with different regulatory systems, and the selection and execution of overseas clinical sites.

These capabilities have taken multinational companies (MNCs) decades to build. For example, the China R&D center of Pfizer was established in 2005, and by 2025 it had evolved from a "learner and follower" into a "global contributor." Its trajectory clearly illustrates the long process of building global clinical development capabilities—from initially handling basic tasks such as data entry, to gradually taking on global pharmacovigilance and regulatory submissions, and eventually being able to independently conduct key clinical pharmacology studies and directly support global approvals.

Meanwhile, Chinese biotech companies are entering a phase of systematic capability building in globalization.

The industry has widely recognized that “transaction does not equal globalization.” In 2025, more than 52% of out-licensed assets were still at the preclinical or Phase I stage at the time of licensing. The earlier realization of value reflects a stage-specific choice made when global development capabilities are not yet fully mature.

Chinese innovative drug companies are exploring two paths: BeiGene has chosen to operate globally from the outset, while Innovent Biologics has focused on building a strong domestic foundation before expanding internationally. In addition, embedding governance and legal frameworks, continuously passing clinical and regulatory milestones, and building manufacturing and supply chain systems—all these experiences represent a real “learning process” for Chinese biotech companies.

This also explains why three global executives from Parexel have come together to share their observations.

Charlotte Moser has worked as a physician, researcher and head of commercial clinical development in oncology for over 30 years and currently serves as Chief Medical Officer at Parexel. Chris Learn is Senior Vice President of Global Medical Services and Head of Cell & Gene Therapy, having overseen many clinical trial designs in advanced therapies getting significant moret complex than traditional drug studies. Vera Zheng, Senior Vice President, APAC Strategy and Head of Greater China, moves between China and the U.S., observing wave after wave of Chinese biotech companies pacing at the threshold of globalization.

Taken together, their observations form a picture of the “next stage” of China’s innovative drug industry—not whether the molecule is good enough, but whether clinical development capabilities can keep up.

“Global innovative drug R&D is undergoing a shift from ‘scale-driven’ to ‘precision-driven,’” Charlotte said. “This is not unique to China, but a paradigm shift across the entire industry. If China can learn from global experience and narrow down to the right patient population using biomarkers and selective targets, it can move through this phase more quickly and take place as first in class.”

The three global executives from Parexel, present different functions across drug development, and each dissect this ongoing transformation from different perspectives, as well as the real challenges China’s innovative drug industry faces.

The Shift in Global R&D Paradigm and Objectives

Charlotte Moser has worked in oncology for over 30 years and describes two major cognitive revolutions in the industry.

The first speaks to the current profound understanding of the immune system. In the past, it

was unclear why the immune system could effectively eliminate bacteria and viruses but failed to act against tumors. Today scientists know more about how tumor cells can suppress the immune system to allow unlimited growth. “The knowledge about how cancer manipulates the human immune system has led to a complete new class of therapies and long-lasting disease control—using the body’s own immune system to fight cancer,” Charlotte said. .

The second speaks to the understanding of tumor heterogeneity. Thirty years ago, breast cancer was typically treated as a single disease in clinical trials. Today, scientists recognize that tumors originating from the same organ can consist of multiple subtypes with entirely different disease mechanisms. “Each cancer has different subtypes which differ significantly in pathogenesis and therefor need different treatment approaches.”

These two revolutions have fundamentally changed the underlying logic of drug development.

In the past, a new cancer drug trial could enroll 5,000 patients, treating the disease as a single entity. Now, the strategy has shifted to “precision validation”—using smaller, well-defined patient populations using new histology and other disease biomarkers to determine as early as possible whether a drug works and for whom.

“We emphasize making early judgments with as few subjects as possible, while minimizing patients’ exposure to potential risks,” Charlotte said. This means that early-stage research has become significantly more important and complex. In Phase I trials, we try to validate the best patient population, while testing safety and efficacy. She gave an example: in Phase I studies today, far more questions need to be answered than a decade ago. Where does the drug distribute in the body? Which tissues does it act on? What are the best biomarkers for selection and best read of effect? Is the disease actually controlled? How does the drug affect other organs creating side effects? Has the immune system been successfully activated? If these questions are not clearly answered, moving hastily into large-scale trials almost inevitably leads to failure.

This is not unique to China. Across the U.S., Europe, Japan, and China, the logic of innovative drug R&D is shifting from “doing bigger” to “doing more precise.” However, China has a unique advantage: it does not need to reinvent this methodology—it can and should directly learn from the past three decades of global experience while having access to high quality testing equipment and people to apply this knowledge on new drugs today.

If Charlotte sees a shift in methodology—from “large-scale trials” to “precision validation”—then Chris Learn sees a shift in treatment objectives. “The focus of treatment is moving from controlling symptoms to addressing the root causes of disease and underlying pathophysiology,” he said.

In his view, this distinction determines the fundamental logic of drug development. If the goal is only symptom control, long-term or repeated treatment is often required. But if the root cause can be addressed, patients may achieve long-term remission with a single treatment. “In the past, we were very cautious about using the word ‘cure,’” he said. “But now, there are gene therapies with data showing patients remain disease-free even five years after treatment.”

The shift in methodology and the shift in objectives together constitute a fundamental restructuring of global innovative drug R&D. These newly defined rules present a fresh challenge for both Chinese biotech companies and MNCs alike.

Common Challenges: Failure Rates, CGT, and New Bottlenecks

While the paradigm shift sounds ambitious, in reality it translates into a series of concrete and difficult challenges.

The first challenge: persistently high failure rates.

In 2026, the failure rate of oncology clinical trials remains high. It is widely acknowledged that the success rate of oncology drugs from Phase I to FDA approval remains below 5%. This is no secret, but it is rarely discussed openly.

Charlotte explains that Phase 1 is meant to test and fail, however too often the industry is using “old paradigms to develop new types of drugs.” “At the early stage, we need to answer as many questions as possible—where the drug distributes, what tissues it affects, and whether the disease is truly eliminated,” she said. “It gives us the stage to find the best patient populations who can benefit. If these questions are not adequately addressed early on, moving into large-scale trials will most likely lead to failure.”

The solution points in the same direction: precision—more precise patient selection, endpoints, and early validation. Achieving this requires continuous learning from past projects—not using patients to “trial and error,” but using data to “predict.”

The second challenge: CGT increases complexity by an order of magnitude.

If targeted oncology drug development is like “walking a mapped road,” then cell and gene therapy (CGT) is “trailblazing.”

Chris Learn provided a specific example: the electronic data capture (EDC) content in CGT trials is about 50% more than that of traditional drug studies. “To some extent, these trials resemble academic research rather than industrialized large-scale studies supported by a

mature system," he said.

The root of this complexity lies in the potential long-term or even permanent effects of CGT on the human body. Gene editing, including base editing and promoter modifications, may alter DNA sequences and nucleic acid structures. "Assessing these long-term effects requires more data, deeper research, and more systematic validation," Chris noted.

The third challenge: clinical development is becoming the new bottleneck.

Over the past decade, the bottleneck in innovative drugs was drug discovery—whether good targets and molecules could be found. Now, the bottleneck is shifting toward clinical development-how to test the multiple new assets being discovered.

Both MNCs and biotech companies face the same challenge: how to generate high-quality clinical validation with fewer patients, in less time, and at lower cost. This is not simply a matter of funding, but a comprehensive competition in methodology, experience, and data capabilities.

Charlotte emphasized that early-stage research should focus not on speed, but on precision. "Before moving into larger population studies, we need to gather as much information as possible at the early stage and compare with existing standards of care to understand the potential advantages," she said. For the latter new statistical designs and use of historic data are essential as they can reduce time and useless exposure to patients significantly.

This reflects the evolving role of the global CRO industry—from "trial executor" to "knowledge provider." As Charlotte put it, "We want to help avoid repeated mistakes and not use patients to 'trial and error.'"

Create in & with China

Against the backdrop of this global paradigm shift, China occupies a unique position.

In terms of scale, China already accounts for a significant share of the global pipeline. According to Vera Zheng, about 30% of global innovative drug assets originate from China, with many projects licensed out at preclinical or very early stages. This aligns with industry analyses showing China has become the second-largest source of innovative drugs globally, after the United States.

However, "entry" does not equal "leadership." Vera pointed out that many Chinese assets are licensed out at very early stages. "Some projects are licensed out after only completing clinical trials in China, without fully entering global development," she said. This means their full commercial value has not yet been realized.

The good news is that China has unique advantages.

First, speed. China's drug discovery can be 2–3 times faster than overseas, with 60–70% cost savings. In clinical development, patient recruitment timelines can be shortened by 2–5 times, with costs reduced by up to half. This is not simply due to lower costs, but also higher efficiency in patient recruitment and trial initiation.

Second, the policy environment. China is poised to fully implement the latest ICH GCP standards, and its clinical environment and data quality are now aligned with international standards. Meanwhile, drug review timelines have been significantly shortened, in some cases approaching the efficiency of the FDA.

Third, market growth. According to McKinsey, by 2028 China's innovative drug market is expected to double compared to 2023, with a compound annual growth rate of nearly 17%.

Together, these factors are fundamentally reshaping China's role in the global R&D ecosystem. "China is transforming from a 'market' into an 'innovation engine,'" Vera said. She described this shift more precisely: **from "Made in China" to "Create in China" and "Create with China."**

CRO's New Role: A Two-Way Bridge

In this transformation, the role of CROs is being redefined.

Parexel positions itself as a "two-way bridge." On one hand, it helps MNCs and overseas biotech companies "enter China" and leverage local infrastructure and R&D capabilities. On the other hand, it supports Chinese biotech companies in "going global," advancing multi-regional clinical trials and overseas regulatory approvals.

"We are doing two things," Vera said. "Helping Chinese pharma companies go out, and helping MNCs and overseas biotech come in."

This dual role requires both global vision and local execution.

Charlotte emphasized the importance of on-the-ground experience in clinical trials. "Whether a trial is conducted in Sydney, Shanghai, or Boston can make a big difference. You need teams with global experience who also understand local culture and can communicate in the local language," she said.

Chris highlighted another key factor: **involving experienced experts in day-to-day operations.** "Senior leaders and domain experts are directly involved in trial execution." This "embedded expertise" model is particularly important in emerging fields like CGT, where there are no established templates.

Vera also revealed that Parexel has established a "APAC Knowledge Center," bringing together over 60 experts across the Asia-Pacific region to share real-world project experience globally.

In regulatory strategy, Parexel maintains a global network of highly experienced experts, including former regulators and pharmaceutical professionals, who can provide early-stage guidance in trial design.

This ability to transfer knowledge is becoming one of the most critical differentiators in the CRO industry. As Charlotte noted, “We represent a broad spectrum of expertise across medicine, clinical operations and data-metrics, statistics, real-world-data and regulatory affairs.”

Conclusion

A 30% share of the global pipeline is a milestone for China’s innovative drug industry. But the next milestone may not simply be 40% or 50%.

As Charlotte emphasized, early-stage research should prioritize precision over speed—gaining accurate insights from smaller patient populations. Chris Learn pointed to a shift in objectives—from symptom control to addressing root causes.

China has already demonstrated its capabilities in drug discovery. From me-too to me-better, and now to FIC/BIC, Chinese innovation has reached the global stage at the molecular level. However, clinical development—the shared global bottleneck—will be the true dividing line.

What is needed is not more capital, but deeper methodological expertise, stronger experience systems, and more robust data capabilities.

At the same time, Parexel is signaling a shift: global CRO leaders are redefining China from a “service market” into an “innovation partner.”

For Chinese pharmaceutical companies, a new test has begun. As Vera stated, “Create in China” has already been achieved. The real question is how to realize “Create in China” and “Create with China” in the next stage.