CRO Giant Parexel Advances Patient-Centric Drug Development in China to Better Serve Local Market

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This April, Vicky Hsu was appointed Parexel's Greater China Region Head. In the official announcement, Parexel refers to this appointment as of "critical strategic significance to Parexel's business in the Greater China region and to its commitment to serving patients."

"I'm excited to assume this role, as it allows me to observe the dynamics of the Chinese market from different perspectives," said Vicky.

Parexel, a leading global clinical research organization (CRO), has clinical and operational scale in Greater China dating back over 20 years. In recent years, the acceleration of China's biotech innovation has brought tremendous business opportunities to CRO companies, including Parexel. In addition, local biotech firms are also seeking to pursue a "going global" strategy, which for Parexel, a company with strong global expertise and presence, is another robust growth opportunity to capture.

After six months in her new position, Vicky recently received an exclusive interview with Healthcare Executive where she elaborated on Parexel's approach to expanding its strategic presence in the China market and to consolidating its strategy of patient-centric clinical innovation, which aims to bring more innovative therapies to patients, faster, amid the rapid transformation of the Chinese pharmaceutical industry.

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Healthcare Executive
Dialogue with Vicky Hsu of Parexel:
Focusing on patient demands

Patient-Centric Focus

In July this year, Parexel announced that it would open a new clinical trial supplies depot in China to support timely access to supplies and medications to clinical sites and patients. Once fully operational, the China Depot will become an important part of Parexel's global supply chain network.

Parexel's continued investments in its Clinical Trial Supplies & Logistics offerings will undoubtedly enhance China's competitiveness as a CRO destination market and a key growth driver for Parexel's clinical trial business. The investments also represent an extension of the company's Patients-First focus in ensuring that clinical sites and patients have timely access to the supplies and medications they need and are safely handled at all points in their journey.

In 2017, Parexel commissioned the Economist Intelligence Unit (EIU) to compile an industry report titled *the Innovation Imperative: The Future of Drug Development*. The report found that drugs developed across the industry using patient-centric trial designs had faster study enrollment times and were 19% more likely to be launched.

The question is, how should a CRO company incorporate patient centricity into its clinical trials? For this, Parexel provided a pathway that involves three stages.

"First, before a study begins, we would gather patient feedback and the opinions of healthcare professionals. By listening to their voices, we would be able to understand the potential challenges we may encounter during the execution process. In addition, when conducting trial design, we also need to consider how the trial will impact patients' quality of life," Vicky told the Healthcare Executive reporter.

Vicky Hsu
Senior Vice President,
Greater China Region Head and
Head of Biotech Operations APAC

"Second, during the study stage, we should simplify the patient journey by reducing the time required for visits and testing, with an emphasis on home nursing or direct-to-patient (DTP) drug delivery," Vicky said. "In traditional clinical trials, we usually expect patients to get Investigational Medicinal Products (IMPs) from the trial sites, but for patient-centric trials, we would design a series of different guiding principles, particularly for drug shipment. Meanwhile, we would also develop patient apps to allow them to have closer interactions with the site staff, such as in the case of video dosing or other remote solutions."

Finally, in the commercial development stage, patient-centricity is realized by helping patients understand the study outcome. Many patients mentioned that they received no feedback after the clinical trial was completed. "At Parexel, we are always committed to helping patients obtain a better understanding of the study outcome and updating them on any subsequent progress, while helping them transition to post-study treatment plans," Vicky noted.

"Parexel's patient-centric approach is reflected in its innovations of clinical trial models. To take our patient-centric approach to the next level, we have launched a Patient Innovation Center that can provide sponsors with customized, patient-centric development strategies to enhance patient engagement and reduce their barriers to participation. In addition, we are also the first, among global top-tier CROs, to appoint a Chief Patient Officer (CPO)," Vicky told Healthcare Executive reporter.

In China, Parexel has been implanting its patient-centric strategy since 2018. In 2020, Parexel established its Patient Advisory Council in China to gather insights from diverse patient communities and help shape future trial designs. This year, Parexel has built innovative partnerships with Cancer Hospital Chinese Academy of Medical Sciences (CHCAMS) and Beijing Illness Challenge Foundation (ICF) to obtain direct insights from patients with cancer and rare diseases to improve clinical trial accessibility.

Another important strategic initiative taken by Parexel in China is the implementation of decentralized clinical trials (DCTs). Currently, 80% of Phase II/III trials and all Phase IV trials conducted by Parexel contain a DCT element. "Parexel's DCTs represent an opportunity to rethink the traditional clinical trial model, while keeping the patient at the heart of this emerging paradigm. We are committed to providing all the necessary support needed by patients to improve study access and patient experience."

Parexel has been involved with DCTs since the first trial of its kind in 2011, giving us a wealth of experience to draw upon. Patient Innovation Center staff and Parexel's APAC DCT Taskforce in the region have been making local connections and establishing strategic partnerships with different suppliers to ensure that patients have the opportunity to participate remotely, just as in other parts of the world.

Helping Local Companies Go Global

"Going global" has become a buzzword for China's biopharma industry. Since China joined ICH in 2017, Chinese companies are increasingly planning for international multicenter clinical trials and going abroad. According to NMPA's Center for Drug Evaluation (CDE) statistics, as of July 19, 2021, the number of international, multicenter clinical trials registered in China has reached 1,126, accounting for around 8.31% of all clinical trials conducted in China. For local companies, the first challenge for their overseas development is how to design a good international multicenter clinical trial.

"In recent years, we've attached greater importance to patient needs and technical innovation in our clinical trials. We notice changes are happening in the associated policies and regulations. However, drug development and approval principles remain the same: they must meet clinical needs while their benefits outweigh the risks to patients." Vicky believes that new drug development strategies must be based on a solid understanding of new technologies and tools' scientific, legal, regulatory, and ethical risks and benefits. That is why, in her opinion, multi-regional clinical trials (MRCT)

must comply with local rules and regulations, whether in China or elsewhere, because this can help maximize the benefits to local patients and medical resources.

"An MRCT is a joint research effort that involves more than one clinical center and more than one country to recruit and treat subjects," Vicky said. "Before an MRCT starts, it is necessary to understand the commercial and competitive landscape as well as the regulations in different markets and have a proper regulatory strategy. Moreover, being familiar with the clinical practice of the country/region to be conducted is also a must-have to ensure that the design of an MRCT complies with local requirements," she said.

"Generally speaking, the success of an integrated development requires us to think about how to derive maximum benefits from early interactions with the regulators and HTA; how to choose the right expedited regulatory pathway; how to weed out weaker assets to focus on the winners, and so on. What is more important is to design trials that can truly address the unmet medical needs of patients, and at the same time, attract and retain patients to reduce the incidence of dropout. Finally, articulating a coherent product value story is extremely important, as it is very helpful for both drug development approval and future commercial success," Vicky noted.

Speaking of clinical operations, Vicky pointed out the management of an MRCT is of supreme importance. An international development program that starts with China, for example, will include project human resources, CRA, and data, among other things, and it is important to think about how the operation team can be flexible and communicate effectively across the region.

Over the past five years, Parexel has participated in more than 500 clinical projects in China, with partners including biotech innovation stars and local pharmaceutical leaders such as Junshi Biosciences and CStone Pharmaceuticals. Parexel not only assisted them in pushing ahead with clinical trials in China, but also provided them with a suite of clinical services for their pivotal global studies.

"In our cooperation with our local sponsors, we notice that what really helps is having a highly qualified dedicated team to provide integrated and adaptable services, offer guidance and experience with flexibility, as well as to provide a patient-centric solution," said Vicky.

The internationalization efforts of Chinese biotech companies in the last couple of years have had mixed results. Commenting on this situation, Vicky suggested that companies seeking globalization should not only

understand regulatory strategies, but also how to design scientifically executable clinical trials, and more importantly, how to make scientific evaluation and innovation locally or in a given treatment field, and how to find a professional team to carry out clinical trials, to maximize the chance of launch success.

In Vicky's view, many local pharmaceutical and biotech companies have admirable scientific capacity. Hence, the most critical thing about cooperation with these companies is to achieve complementarity with key strengths, moving ahead with MRCT.

Stay Close to The Chinese Market

On May 29, 2019, the Chinese National Medical Products Administration (NPMA) released *Key Considerations in Using Real-World Evidence to Support Drug Development (Exposure Draft)*, intended to offer regulatory guidelines for implementing real-world studies in China. To further guide and standardize the use of Real-World Evidence (RWE) in drug R&D and review, on January 7, 2020, NMPA released the *Guidelines for Real-World Evidence to Support Drug Development and Review (Interim)*. It is noteworthy that this was the number one announcement issued by NMPA in that year.

From Vicky's perspective, China is at the forefront of exploring how RWE could support regulatory decision-making. A series of guidelines on RWD and RWE have created huge opportunities for biopharma companies to seek ways to use RWE in drug development and applications.

"Today, there are significant opportunities for utilizing RWE in the United States and China and companies need to tailor their approach by locality, drug properties, and actual conditions," said Vicky.

Parexel has been at the forefront of RWE innovation and boasts more than 17 years of experience designing, implementing, and analyzing real-world studies across the globe. "We conducted one of the first synthetic control arm studies and have built novel integrated RWE/RCT platform models. We holistically consider client requirements—bringing together regulators, payers, patients, and physicians to design a custom approach with end goals in mind," said Vicky.

In addition to the emerging real-world studies, Parexel also keeps abreast with changes in the Chinese pharmaceutical market, with a view to expanding and deepening its footprints.

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In July 2021, the CDE released *Guidelines of Clinical-Value-Oriented Clinical Development for Anti-tumor Drugs (Draft for Comments)*, aiming at the problems in clinical research and development of anti-tumor drugs in China. Industry players widely believe that it has raised the bar for the clinical development of anti-tumor drugs in China and set the stage for clinical trials in China to conform to international standards.

Vicky said that this document reflects how, in recent years, Chinese regulators have been working to move the entire drug development industry toward high-quality standards. "It is vital to be patient-centric, to understand patient needs fully, and to develop indications that can fill major clinical gaps quickly."

Parexel has conducted over 1,700 anti-cancer drug development programs globally during the past five years. Vicky believes that in the tumor treatment field in China, the future focus will be on developing innovative therapies with true clinical value and taking drug innovation to the next level.

Vicky also noted that the Guidelines encourage biotech/biopharma companies to expand their pipelines in those fields with unmet needs, such as central nervous system, rare diseases, and cell & gene therapies.

"Parexel has participated in more than 1,000 development programs globally for rare diseases, along with more than 800 immunotherapy development projects. We are experienced to leverage our expertise in different therapeutic areas to shorten the time to market for these innovative therapies." Vicky said, "I am very hopeful that our professional team can provide more flexible and customized services to our customers in China, helping them optimize the processes to make innovative drugs available to patients and healthcare professionals quickly. In the meantime, we are teaming up with many international pharmaceutical companies to introduce advanced therapies into China to address the unmet medical needs of Chinese patients."

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