PINK SHEET
Regulatory News & Insights

Parexel Execs On Trials In War Zones, Biotech 'Green Shoots', China Action And DCT Rework

CITELINE
a norstella company

Parexel Execs On Trials In War Zones, Biotech 'Green Shoots', China Action And DCT Rework

March 9, 2026 By Anju Ghangurde

Parexel's CEO Peyton Howell and India chief Sanjay Vyas talk to the Pink Sheet about clinical trials amid global turmoil, the slowdown in big pharma decision-making and pivot in some cases to the FSP outsourcing model, evolving DCT definitions and India opportunities.

Parexel's CEO Peyton Howell and India country head, Sanjay Vyas (Parexel)

"Parexel has navigated turbulence for more than 40 years," declared CEO Peyton Howell, underlining how the clinical research organization (CRO) has been able to ensure trial continuity amid global tumult, including geopolitical tensions and wars.

Howell, who was in India recently, and Sanjay Vyas, Parexel's country head for India, spoke to the *Pink Sheet* on a gamut of issues, ranging from bringing resilience to clinical trials amid heightened global uncertainties and how some large pharma sponsors were shifting to the functional-service provider (FSP) model, to whether the decentralized trials approach needs more validation.

New opportunities in India were also among the other key talking points (*see box below*).

"We've demonstrated resilience not just this year, but also in past years and through a pandemic, to support clinical trial continuity. It's also a strength because of our global scale, which is differentiated," Howell stated, sharing striking examples of how the CRO is enabling things to stay the course in war zones.

Ukraine for instance, the CEO said, saw a couple of sponsors (a biotech and a big pharma player) start new clinical trials this year, emphasizing the importance of "restoring and preserving" clinical trials. "I think they're trying to be supportive, because for many countries clinical trials support the backbone of the medical system and bring in additional resources to support patient access to new treatments," Howell explained.

Israel was another litmus test for resilience – Parexel had a new clinical trial starting the weekend the war erupted there (not the current war but the previous conflict) and Israel was the first country to have a first patient in.

"It still gives me the chills to think about. Our teams are incredibly proud, because once you open a site in a country for a clinical trial, you want to complete it," Howell stated. From a patient safety perspective, it means continuing to monitor the trials and it "really does make sense to persevere, and we've done that without exception," the CEO added.

On trial placements, Howell indicated that the CRO adjusts the country mix to respond to geopolitical change and has done that. "I think it's an opportunity for India," she stated.

SLOWER BIG PHARMA DECISION-MAKING

Beyond the conflict zone challenges, Parexel's CEO also highlighted a slowdown in decision-making last year by large pharmaceutical companies, essentially driven by policy and regulatory shifts in the US which likely forced them to reassess portfolios and their commercial viability.

"That's in contrast to biotech companies, which really need to proceed with drug development or they have no business. For us, biotech has really been resilient," Howell pointed out.

Citeline's *Annual Clinical Trials Roundup 2025* indicated that overall trial initiations increased from 2023 to 2024 by 5.5%, while industry-sponsored trials, comprising 67% of all trials, were up 3.6% in 2024. Notably though, the number of trial initiations of the top 10 sponsors declined almost 20% from 1,057 trials to 847.

"This represents 12% of all industry-sponsored trials, suggesting that small-medium pharmaceutical and biotech companies initiated the other 88% of trials," the study said.

The wider trend appears to have lifted Parexel's biotech division, which the CEO described as a "strength and a differentiator". "We ended 2025 very strong, record-setting. It was a record for Parexel Biotech, one of our strongest quarters for biotech," she maintained, but added that a quarter does not necessarily make a trend.

Such uptick, though, is being seen as "green shoots" and is certainly "a good indicator" for 2026 overall. "I think that's an exciting indicator," Howell said.

Citeline's *Pharma R&D Annual Review 2025* had indicated that 49.8% of the global pharma pipeline is now considered biotech-based, with "biotech potentially poised to take control next year."

CHINA BIOTECHS WANT TO GO GLOBAL

Adding momentum is the drive by Chinese biotechs in particular, that are supported by an enabling local regulatory environment and looking to expand globally. A record number of China-originated first-in-class drugs were approved domestically in 2025.

"China was negatively impacted during the pandemic, and we felt that. There was really a slowdown in China. Now it's the opposite, where Chinese biotechs that want to go global present an opportunity," Howell stated.

India Opportunities

Parexel appeared enthused by India's Union Budget 2026-27 announcement, which signaled plans to create a network of over 1,000 accredited clinical trial sites in the country as part of wider efforts to bolster the domestic biopharmaceutical sector.

Parexel's CEO Peyton Howell said she was "excited" about the development and that, even prior to the announcement, the CRO had already been focusing on expanding the number of sites, including those under its site alliance umbrella in India.

One of the reasons for her India visit, she stated, was because of the initiative and the opportunity to connect with sites and sponsors, both at the Indian Society for Clinical Research (ISCR) and at the [ET Now] Global Business Summit (GBS), where Howell was a speaker.

"We'll need to partner with sites and the government to share our expertise. One idea raised at the ISCR conference was whether we could support the accreditation process for those 1,000 sites. This could be transformational," Howell said.

Such initiatives, she said, go beyond what was previously seen in China in terms of government-led efforts to support clinical research. "It's very exciting," the CEO reiterated. At the GBS, Howell is reported to have stated, among a string of observations, that as some nations move towards more nationalist regulatory reforms, maintaining a global footprint becomes essential for scientific integrity.

Parexel's own Site Alliance Program features over 300 sites and 16,000 investigators globally, aiming to enhance patient experiences and improve efficiency for sites and clients. The program boasts 40% quicker activation to the key milestone of First Patient First Visit (FPFV) compared to non-alliance sites and offers nearly 20% faster timelines for study start-up completion. It also enables, on average, four times more patient enrolments per site versus non-alliance sites.

Sanjay Vyas, Parexel's India country head said that Parexel has worked regularly with about 800 local sites, but only about 20% of them recruit patients effectively.

"With this announcement, we're hoping that these 1,000 sites will be accredited to build trust. Right now, we're dealing with perception issues among multinational sponsors. We need to build confidence," he added.

Ideas around whether organizations like the Association of Clinical Research Organizations (ACRO) and ISCR could explore some form of accreditation process were apparently placed on the table, though these are still early days.

"If we can create such a framework, it would build confidence among multinational sponsors looking to conduct studies in India. We also hope that these 1,000 sites will support Phase I studies, which we've been discussing for some time," Vyas said.

Howell underlined that the reason why early phase studies are important is that the country and the sites become incumbent on that product. "What we've seen in China is growth in early-phase, Phase I-type studies. That creates and builds momentum for greater patient access to new treatments in a country. So, it is an important point, especially for cancer patients," she explained.

Currently, for new drug substances discovered or developed in countries other than India, Phase I data are required to be submitted along with the application to the regulator. After that, the Indian regulator may grant permission to repeat Phase I trials or to conduct Phase II trials and subsequently a Phase III program concurrently with other global trials for the drug.

Capacity building efforts for early studies though are underway. For instance, the Indian Council of Medical Research (ICMR), under its Network of Phase 1 Clinical Trials, had earlier sealed memoranda of understanding with multiple sponsors including Aurigene Oncology (for its small molecule for multiple myeloma) and ImmunoACT (for a new indication of chronic lymphocytic leukemia).

The network expects to build and enhance India's capacity to conduct early-phase clinical trials, supported by robust infrastructure and dedicated manpower at each trial site, ensuring smooth and effective operations.

Large biopharma firms are also taking strategic China calls, each weighing things differently, with some announcing investments in the country.

"We do have some China-only studies that we are now starting for some large pharma companies. I think that's just part of a careful strategy to be able to keep the data in China, adhere to the regulatory environment, and then launch global studies after you have proof-of-concept. But everyone's take is a little bit different," Howell stated.

Parexel also has a clinical supply chain depot in China. "That's catering to local Chinese domestic clinical trials as well. That gives us a good pivot. We don't have to just rely on the global distribution network," Vyas said, adding that the CRO also has a strong on-ground China regulatory team.

The net results for Parexel are growth and additional jobs in China, a market where it has been for over two decades. "While being in India...I can say it's a good playbook for us to look at, just like Australia is, in terms of how the regulatory environment, with just a little support/clarity and consistency, and some speed, can make a big difference," the CEO asserted.

'BOTH FSP AND FSO ARE CROS'

Parexel's CEO also weighed in on changing outsourcing frameworks where some sponsors have opted for the functional-service provider (FSP) model as against the full-service outsourcing (FSO) approach as they seek to tackle cost and competitive pressures alongside the need to crunch cycle times.

Howell, at the outset, underlined that "both FSP and FSO are CROs" – more generally implying that business isn't necessarily moving out and it's "just a different model."

"The term FSP or even the term insourcing gets used. Insourcing and FSP are still headcounts applied by CROs. For us, it's a business opportunity. There definitely is some confusion. The trend has largely already happened, and it's really just the largest pharma companies (probably top 15)," she asserted.

Howell explained that some of the largest global pharmaceutical companies may have pivoted from a more full-service model to FSP, "but really to hybrid models".

"Each one is a different flavor. There might be one where it's certain site roles versus all FSP roles, or it's data management and certain other skill sets. They're all a little bit different," she explained.

Howell believes that "it's very difficult to go to an all-FSP model" and be cost-effective "because you obviously then have the overhead associated with it, but you also have to ensure full utilization".

"You need a very robust program of work. We were lucky in the past two years. We were part of the largest conversion from a full-service model to an FSP model," she stated.

Elucidating on some of the finer aspects, Vyas pointed out that, starting with the clinical study conduct, it entails many adjacencies including the regulatory, supply chain and the pharmacovigilance aspects. "We have more than 30 customers on the FSP model in the post-approval pharmacovigilance market already. It's the customers' SOPs and processes, but it's our people," he specified, underscoring that the CRO "benefits either way."

Howell further explained that biotech companies generally use the full-service or FSO model and believes that they are rarely going to use FSP models. "If they do, it will be very selective, such as for certain roles or specific needs. That's why, with Parexel Biotech, where we're seeing such significant growth, it's exciting because that's really all in a full-service type business model."

DCT DEFINITION HAS 'EVOLVED'

The executives also shared their views on the seeming toning down of the buzz around the value proposition of decentralized clinical trials (DCTs) as the understanding of the model matures.

Howell indicated that the very definition of DCT had "evolved," not just for Parexel but for the wider industry association as well. "We don't even have a DCT committee anymore, for example. We used to. I think it's evolved because very few trials were ever fully decentralized," she explained.

Instead, the focus is on hybrid models and reducing the patient burden of clinical trials, which can entail a wide range of strategies and tools. She recounted one study where Parexel used Science 37, a clinical research services and technology firm, because "it made sense" and involved mostly adolescents with asthma who were not going to go to a physician site regularly for exacerbations. They reported in an e-diary at home and used technology-based tools.

"That was a great way to get that study done. But I can only think of a handful [of studies] where that was a cost-effective solution. We rarely had fully home nursing type studies," Howell explained. EU regulators had earlier lamented the dearth of trial applications incorporating "critical" decentralized elements.

Some experts have, over the recent past, suggested that biopharma needs "stronger evidence" to demonstrate that DCTs "offer more than a logistical alternative."

Others, though, argued that as adoption matures and organizations move beyond early hype toward more purposeful implementation, it can create the impression that momentum has slowed or that the value proposition of DCTs isn't clear.

"However, such assertions are inaccurate, reflect a narrow definition of DCTs' potential, and misinterpret how innovation adoption unfolds in complex, research-intensive, and highly regulated operating environments," Pamela Tenaerts, chief medical officer, Medable and Kenneth Getz, executive director, Tufts Center for the Study of Drug Development asserted in a recent article.

Parexel's Howell said that using e-diaries, eCOA (Electronic Clinical Outcome Assessment), or telehealth, where appropriate, and looking at the protocol in terms of reducing the patient burden, are perhaps a better way to think about these trial solutions.

"So instead of DCT, we're calling it protocol optimization and relooking at how we review inclusion and exclusion criteria. How can we look at the protocol itself to reduce the number of visits and invasive procedures. Those are the things that cause people to either not want to join a trial or to start and then leave," Parexel's CEO said.

Vyas similarly explained that he advocates adaptive trials and trial optimization. "Do you really require a patient to come in for a blood draw? Now we have devices that we send to patients so they can do the blood draw and ship it out. That's where the hybrid approach comes into play. That's why we've stopped calling them decentralized trials. It's not fully end-to-end," he pointed out, citing other instances as well to drive home his point.

Citeline data showed that in 2023 there were 603 trials initiated with an element of DCT, innovative designs, and AI, while that figure dipped to 594 in 2024.

Alongside underscoring the impact of patient-centered protocol optimization, Howell also referred to moving clinical trials into community settings and "meeting patients where they are," especially in areas like oncology.

"When you think about an oncology or cancer diagnosis, you want to be at home with your family. That's an area we're trying to work on. It's a new model compared to how clinical trials have historically been conducted in most countries," she added.

Expanding clinical research access into countries like India and to rural communities in established markets like the US are trends to watch as well. "Clinical trials are often absent in rural areas of major countries, just as India is underrepresented globally. Those two areas are what I'm most excited and passionate about," Howell said signaling the dichotomy of sorts across markets.