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senior director clinical operations, and general management & business administration Korea of PAREXEL Korea discusses the strengths of Korea's clinical research environment, and how PAREXEL can leverage its technological platform to differentiate itself from the other international CROs conducting global studies in Korea.

Before joining PAREXEL, you had extensive experience of clinical research and development both in the CRO and pharmaceutical industry. How did you leverage this extensive experience in your new role?

Before joining PAREXEL, I spent seven years at ICON. I started as project manager and then progressed to clinical project director and then clinical operations director. At PAREXEL, I am exclusively focused on the Korean market, while at ICON I also managed Taiwan and South East Asia. Moreover, my responsibilities are broader as I manage the Clinical Operations Leader group too. Prior to joining ICON, I worked in the pharmaceutical industry, both for MNCs like Ely Lilly, and local players such as SK Pharmaceuticals.

Korea has gone from an almost non-existent in clinical research to now being ranked 6 th in the world. Moreover, among all cities, Seoul is home to the greatest number of clinical trials. As the 4th largest global CRO with USD 2.4 billion in revenues, how important is Korea to PAREXEL?

Korea manages to combine all the key elements necessary to conduct high-quality global clinical trials and this is why PAREXEL has invested resources into the country. There are three main elements that make the country an attractive place for clinical research.

The first is the ease of patient recruitment. Even though Korea's population pales in comparison to China and India's, the Seoul Metropolitan Area is very densely populated, with 20 million inhabitants out of the 50 million residents of South Korea. Moreover, Seoul is home to large hospitals such as SNU, Severance Hospital and Samsung Medical Centre. A high population density and large hospitals allow CROs to gain access to patients and perform clinical trials on a broad scale. As a matter of comparison, for a global Phase III clinical study, the number of participating sites can be as high as 50 in the USA and China. In small countries like Singapore, it would be only two or three. In Korea, we are in the middle with 8 to 10 sites for the average study. For larger studies, it can reach as high as 30 sites. For a medium-sized country like Korea, this scale is quite impressive. Moreover, this clustering of clinical trials in Seoul increases efficiency. In Korea, 70 percent of studies are conducted in Seoul and satellite cities while the Tokyo Metropolitan Area, a highly densely populated area, accounts for less than 30% of overall trials in Japan. Sites are spread out all over the peninsula which increases inefficiencies because patients and clinical staff need to travel to these sites and coordinate between them.

The second key factor is a short and predictable study start-up timeline. Starting a study requires completing a lot of steps: going through IRB (Institutional Review Board), signing contracts with clinical centres, ethical reviews, and document preparation. Unpredictability means that one study might be able to start in one year, while another will take two or three years to receive approval. Given that conducting clinical trials is extremely demanding in terms of time and financial resources, predictability is key to success. Korea meets that requirement because the government is dedicated to making the country a leader in innovative pharmaceutical research and development. Regulatory review processes are straightforward, and authorities follow their own rules and guidelines. Moreover, the timelines are fast. One of the reasons for this is the government's authorisation for parallel submissions for approval, whereas in other countries it needs to be sequential. In comparison to Korea, countries like India or China benefit from a large patient population, but their study start-up process is long and unpredictable. Moreover, in terms of

legal matters, in order to start a trial, the clinical site, the sponsor and the investigator need to sign a contract. In many countries, this process is complex because sites have their own legal requirements. Conversely, in Korea, it is more streamlined.

Finally, there needs to be a network of efficient clinical centres with highly-qualified staff. Korean hospitals have the necessary infrastructure and are highly consistent in their review processes. For instance, they perform ethical reviews every week, which is not performed in US clinical sites.

Consequently, Korea has all the key elements required to make it a prime destination for global clinical studies.

The other attractive feature of Korea is the maturing biopharmaceutical sector. In the last decade, large companies with extensive R&D capabilities, such as Celltrion and Samsung Bioepis, have emerged and have gone global. Thanks to our global network, we can help them internationalize their operations.

With the blooming of the local biotech sector, local CROs have also emerged. What edge does PAREXEL have other these local players?

Korean CROs mainly take on local projects focused on receiving approval in Korea, whereas international CROs provide the delivery for global studies. Our clients sometimes overlap but the focus is different. Moreover, we focus on Phase I to Phase III. Most local CROs focus on late-phase delivery as well as post-marketing pharmacovigilance studies which are less costly to perform. Apart from cost limitations, the major reason is Big Pharma companies usually prefer to work with a single service provider and sign alliance agreements with one of the global players. Splitting clinical trials between multiple local players in each country would be incredibly inefficient. Instead, we can offer them a turnkey service. Because of this reality, local CROs have not been performing as well as global players and their growth has been lagging behind.

How has your service offering evolved to answer the needs of customers in Korea?

The relationships with our customers have evolved dramatically over the years as the realities of drug development have changed. The fundamental challenge is that it requires a lot more financial investment now to develop a drug compared to 20 years ago. Pharmaceutical firms struggle to keep costs down and manage the risks. In the past, they conducted studies until the end and then

decided whether to continue or give up on the drug. Now their decision process is more strategic. Studies undergo a stringent systematic review process from the start to determine their clinical utility. As a result, they desperately need more agility and flexibility, so it makes sense to hire a CRO who is diversified. If one study stops, we can utilize those resources on another.

Your biggest competitor, IQVIA, collaborated the development of 26 approved drugs in Korea, while PAREXEL only worked on nine. How does PAREXEL differentiate itself in order to increase its market share?

First of all, this number of studies is based on the approval numbers published by the MFDS. But for some studies PAREXEL has collaborated on, the INDs are submitted under the sponsor's name even though we delivered them. As a result, the numbers are not accurate if tracked based on IND applicant's name only.

Overall, top-tier CROs tend to be less differentiated than in the past. 20 years ago, big scale CROs were few and far between. Big players' focus was to increase their global footprint. For instance, there were very few global CROs present in Korea. Now, all of them have a strong presence here. Global footprint is no longer a differentiating factor, and the landscape has become more competitive.

However, PAREXEL has unique advantages compared to competitors. The first is our high-standard technological platform. Our have IMPACT CTMS system is a world-leading informatics software. We also have highly qualified staff because, in the CRO business, people are everything. Our staff includes the regulatory consulting group which is composed of ex-reviewers at the FDA, EMA and Chinese NMPA. It is clearly unrivalled in the industry. Other companies do not have the same level of expertise. Another differentiating factor is that we are flexible. If you are too big, service suffers because each project is not deemed as important. On the other hand, PAREXEL can offer a more specialized, customer-focused service.

What do you think the country should do to further develop clinical research?

In clinical research, Korea has established a strategic position in a short period of time, but things have plateaued. The number of clinical trials is no longer increasing as fast as before. Since 2013, clinical trials have plateaued. That means we have to create new markets. Early-phase is one area where Korea could create value because their proportion in the total is still quite low.

However, in order to deliver early-phase studies, fast and straightforward study start approval is key. As I said, Korea already has that. Authorities have implemented protocols to make early-phase approval simpler. For instance, they allow English protocol to be submitted. Normally every legal document must be translated. Now, only the synopsis has to be translated. The other content can be translated at a later date. I hope regulations can be even more agile in the future in order to further speed up the approval process and shortening review times.

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