

C&R RESEARCH, a leading Korean CRO has been providing regulatory, study development, monitoring, GCP auditing and data management and statistical analysis services since 1997. Established with only a handful of staff by Mr MoonTae Yoon, its CEO & President, today, the company has more than 60 employees and provides the services for the global pharmaceutical companies in Korea. Instead of focusing on the stable and comparably feasible 'post marketing surveillance service', C&R chose more risky route, developing global and regulatory study monitoring capability, because Mr Yoon had foreseen the future growth of global studies in Korea. Based on cumulative

Interview

global study experiences and Korean study experience, especially for cancer, cardiovascular studies, C&R has achieved a growth rate of 20-30 percent in terms of revenue and number of staff, and was also awarded as 'the Korean CRO of the year 2008' by Frost and Sullivan. In an interview, Ms Mi-Yang Kim, Executive Director, C& R Research Korea shared her views about the opportunity and market scenario in Korea.

'All Korean CROs are clinical CROs'



Ms Mi-Yang Kim, *Executive Director,*
C&R Research Korea

Q: *How do you see the opportunity for CROs in Korea?*

The local CRO segment in Korea has grown very fast, especially in the last three years due to the increased number of global trials. Moreover, Japan, US and European pharmaceutical and biotech companies have shown great interest in conducting clinical trials in Korea, as Korea is one of the most recommendable countries in South East Asia due to its clinical trial supportive environment, market size which is ranked 12th in the world, successful records of enrollment rate and speed, well equipped facility, quality data and experienced investigators. Thus, the growth will continue and in fact pick up speed in the coming years. However, the profit ratios of Korean CROs are quite disappointing when compared with the growth in revenue and the number of clinical trials. So, growth, yes, but with skinny fruits – it is an opportunity and risk at the same time.

Q: *What kind of support in terms of environment or infrastructure has been provided to the CROs by the government?*

Firstly, IND approval timeline has been accelerated since Mr MyeongBak Lee became the President of Korea last year. This has added to the supportive environment. Moreover, the government declared their policy for 'deregulation' of unnecessary regulations related to conducting of the global clinical study. The Korean government has also designated 15 sites of 'local clinical trials centers' nationwide since 2004, which are to be provided with upto \$1 million annually for five years from Korean government to build infrastructure.

Q: *What kind of challenges (talent, regulatory, site management) the local CROs are facing? Do you see any kind of competition between local CROs and MNCs?*

In Korea, there is no specialized site management company. So, the CROs generally have to take care of all the site management related activities including CRC trainings and IRB submission. Additionally,



CRAs need to translate and explain in Korean—the written English communication such as urgent questions and data queries from the clinical trial site or to the site. Moreover, the CRC, if they have one-to-two years of experience, most of them want to move out to be a CRA.

Recently, hundreds of CRAs have been recruited by global pharma companies and CROs, there is plenty of opportunity and practically no reason to stay in unstable working contract and environment of CRC positions, which sometimes come without even a room for working and no insurance support in the contract. This scenario can be described as optimistic facilities of the site, but pessimistic working environment for clinical trial staff.

Finally, CRA job in Korea is attractive but considered as one of the toughest among medical jobs that the clinical trial staff and CRA candidate can opt for.

The trend of moving to the global companies is also applicable to the local CROs. Each year almost five to 10 percent of CRAs leave the local CROs and go abroad to study just English. After the English training, they usually choose global CROs or global pharmaceutical company for pursuing their careers as they believe that global company can provide them a stable system for working and sound training with good management, so they can develop themselves while at the same time manage to keep the work-life balance.

In this background, local CROs have been competing with the global CROs for bagging the global study conducted in Korea. However, as just 'a local' CRO, it would be extremely hard to be successful for a long time when we consider the progress of development

and clinical study, which is asking for more global development in business, for example the current change of Japan's regulatory environment to encourage Asian studies. The local CROs need to be comparable with global CROs, not only in cost and personnel capability, but also in the system and structural service standard and quality by certain measures. It would be a survival strategy, and also the way to provide global quality service to Korean companies, which may have not used global CRO services.

Q: What is the current CRO market size in Korea? How many local and multinational CROs are operating in Korea?

The total CRO market size of Korea including pre-clinical CRO, bio-equivalent study and clinical laboratory

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CRO and clinical CRO is estimated as approximately \$50-\$100 million. Within these segments clinical CRO market size is about \$30-\$50 million. As clinical and full service CROs, C&R research was the first such company to be established in Korea and was followed by two other Korean CROs. Additionally, there are several small size monitoring only CROs, EDC service CRO, and so on. Overall, there are seven global CROs in Korea, including one Japanese CRO.

Q: Are there any CRO industry associations to lobby for the members?

There is a Korean CRO Association (KCROA) in existence since 2000. Among members it counts three Korean CROs, one Japanese and two global CROs. The Korean CROs are all clinical CROs, which provide mainly monitoring, study development, and data management and statistical analysis services.

Narayan Kulkarni