LSK Global PS â?? Young-Jack Lee, CEO â?? South Korea

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LSK Global PS CEO Young-Jack Lee discusses the influence of global CROs on the quality of Korean research, and outlines his own strategy for competing in the marketplace and growth outside of Korea.

When we met you in 2008, you were positive about the growth of Korean CROs and LSK Global. Did your expectations live up to reality?

LSK Global has indeed substantially expanded. Today the company employs around 180 people, more than doubling in size since we previously met. Moreover, our source of revenue has substantially changed.

The success of clinical development in Korea has a bright side but also a dark side, the latter of which deals directly with global CROs. Until 2009, the majority of LSK Globalâ??s revenue source came from global studies, which we obtained through global CRO contracts. But now those same CROs have their own affiliates here. Consequently, our sponsor base has substantially changed and these CROs no longer provide us projects. Furthermore, these global companies take our CRAs away from us. LSK Global recruits and trains its own CRAs, and it generally takes at least one year before a fresh CRA can become productive and two years to become independent. At this point, global CROs take our CRAs away, whom they can afford to pay more because they do not have to invest in training. This is tantamount to stealing my people, who should be generating revenue for my company because we invested into training them. Consequently, LSK Global has lost revenue. At one point we had stop taking new projects because we lost so many experienced CRAs to global CROsâ?? local affiliates.

Multinationals work with preferred service providers, and we generally cannot qualify for preferred service providership because our service is limited to Korea. Thus our opportunity to work directly with global companies is extremely limited. Perhaps it is beneficial for global CROs to set up shop

here and increase the number of clinical trials in Korea, but this harms companies like LSK Global. CRAs of global CROs do not complete the life cycle of studies as CRAs hop around from one CRO to next. They spend a couple years at each company and very few see a study from beginning to end. Global CROs do not contribute at all to Korean clinical drug development technology, because all the protocols, data management, statistics and project management are done at these companiesâ?? headquarters. It is nonsensical to believe that because we are active in global clinical trials, Korea will benefit from such activities. Global CROs do not teach us anything. They just use our trained labor, stolen from companies like mine. To them, Korea is like a clinical trial assembly plant country.

How do companies like LSK Global adapt to become more effective without the influence of big CROs?

Our major clients are primarily Korean companies. We still have global projects, but they come through CROs with no affiliate here in Korea. These CROs need support in Korea, so we work with them, providing us with more experience. As far as clinical trial development know-how is concerned, multinational drug companies or CROs do not add anything to Korean infrastructure. Unfortunately the government does not know this. They are happy to see multinationals coming to Korea. But in the small print, they basically usurp Korean companies. Their practice distorts the real picture of drug development, which is quality, not price. For example, a major multinational drug company applies different standards in CRO selections in Korea from the West. In the US, quality comes before price, but in Korea it is vice versa. This sets a bad example for the industry, and many Korean drug companies do the same thing.

But Korea has become very attractive in terms of infrastructure and Korean companies are taking part in much larger studies.

In pre-clinical studies, if a Korean drug companyâ??s research fund is subsidized by the government, as a requirement this company mostly works at the preclinical level in Korea. But there is no such requirement for drug development.

The rapid increase in global clinical study participation ought to be positive for Korea!

It should, but in reality Korea has just become an assembly plant. Protocols and data are entered at global CROsâ?? headquarters. A trial might take place in a Korean hospital, but the brains of the operation take place at the CROâ??s headquarters. Korea is becoming a global assembly plant for clinical trials.

The companies that will become clinical trial powerhouses in Korea are Korean CROs, not local affiliates of global CROs. In the 1960s and 1970s, many global electronic companies were present in Korea, but they were not the ones who established Korea as a leader in electronics engineering; it was Samsung and LG. Korea has historically become a good assembly plant in electronics because Koreans are very disciplined and their work is of high quality. Korea is an excellent clinical trial assembly plant because of its outstanding hospitals and investigators, and its regulatory process is probably the friendliest among developed countries. Our CRAs are very well educated and Korea has the lowest rate of illiteracy and therefore high quality patients. This makes Korea an excellent clinical trial assembly plant.

LSK Global was the first Korean CRO to conduct a global drug development study.

Last week, I am proud to say that Lilly has announced LSK as is its local partner. Our company performed a Phase I first in human oncology study for Lilly CHORUS. This particular study had two sites in Australia and three in Korea, and we did a study in which the protocol was written by them

but LSK Global managed everything. That is an exception rather than a rule. I am negotiating with several more companies for early drug development, usually which involves a couple of countries with limited sites and therefore large drug companies are not bound by a preferred service provider agreement. This is a good opportunity for us, and we are trying to get more services of such nature. While we are currently negotiating with two or three smaller American companies, most of our opportunities come from within. The problem with Korean drug companies is that they only rely on global CROs for their global development. Even the biggest of Korean companies are comparatively small worldwide. $2 billion companies in Japan are considered mid-sized, but no company in Korea makes even over $1 billion. These companies should work with us, not with companies like Quintiles. Sure, maybe we are not as familiar with US regulation, but we can hire somebody who can do that for us. Our opportunity for global studies sponsored by Korean companies has practically shut down. That is very sad and puts my country in a promising position that goes nowhere. The idea that we have realistic opportunities originates from within Korea by Korean drug companies wanting to develop drugs outside. I have to persuade the government to enforce companies to use Korean CROs when the trials are funded by government grants.

What is LSK Globalâ??s current positioning within the current CRO landscape?

In Korea, LSK Global is the only company that offers validated DM services. We can meet the demands of just about any customer. Essentially, LSK Global is the only CRO that can handle data in an accredited manner, which can be submitted to the US or EU regulatory authorities. LSK Global is technically the strongest company in Korea for clinical trials. Our data and statistics are unparalleled, and this is unique in Korea. Furthermore, we have a very strong project management group for both domestic companies and global projects. Unfortunately Korean sponsors do not value our competence, because they do not have expertise to assess CROs. Recently two global drug companies have qualified LSK Global as their vender, and still another global drug company is in the process of qualification assessment of LSK. We now expect some NIV work directly from them. The assessment was quite extensive and we learned a great deal.

If a company like LSK is so strong in its management, how do you promote it to become more internationally attractive?

In the international picture, we are still small. LSK Global can do what Quintiles can do, but we are the only Korean CRO that can. The idea that only American CROs are capable of high quality data management is false; especially considering most of the work ends up being done in China or India. I am fighting very hard to change the mindsets of Korean executives, who often become distressed by global CROs, who do not understand anything. Korean drug companies come to us mainly for domestic portion of their drug development mainly because we are cheap, more accurately they can pressure local CROs to lower pressure.

A few years ago, I submitted a global study budget to a Korean company, a few sites in US and EU and a couple in Korea â?? my price was much cheaper (oncology study). They think my price is cheap because my quality is poor. A middle manager of the sponsor said, â??Oh no, they are no good,â?• â??If nothing else, letâ??s just give LSK Global data management LSK are probably better than US companies.â?• Top executives said no; we want the total package, turnkey. We did not get anything. This middle manager came to me and said, I do not understand this protocol. I find some very serious flaws. I changed it to that. The sponsor paid us a consulting fee, that is it. I spent my time going over the materials in the hope that they would give us some part, but we received nothing. There is a US oncology company that was doing global studies and Quintiles was the global CRO. The company in California gave us QC of Quintiles activity in Korea. Our CRAs and Quaintilse CRAs were trained together for protocol. But my CRAs are basically much better trinaed. We did a number of QC programs for these companies. We keep telling our sponsors, but they do not listen,

their mindset is wrong.

People might overlook your local expertise.

In the US, that is not the problem. Global CROs trust LSK Global more than global drug companies. Global CROs know how to do global drug development in unfamiliar regions, but global drug companies do not. Selling the drug is one thing, but doing clinical trials in unfamiliar regions is something else. I became very close to getting a contract for a couple of studies for middle-tier drug companies in the US. In the end, they could not take the risk of working with small companies. Big companies are tied by preferred service providership, and middle-tier companies have a lack of competence in unfamiliar regions working with unfamiliar CROs.

LSK Global has never cut costs or compromised quality, which hurt us slightly; however, 2014 seems to be turning around. Eventually, people will see that our quality is much higher than others, among the highest in Korea.

What are your expectations in the coming years in terms of expanding your business?

The Korean market is still too small and will stay small. I would like to expand to the West by 2020. I do not know whether we will have the strength or ability, but ideally I would like to acquire a recognized company in the US and send projects there. Also, clinical trial drug development is advancing rapidly in terms of regulatory matters and safety in the US, which we need to absorb here. LSK USA can be our window to learn of global changes and obtain more projects through the added credibility of being established in the US. Only then will Korean drug companies start looking at the value of our service to them, as the leading quality CRO in Korea.

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