# Interview with Sang Goo Shin, President, Korea National Enterprise for Clinical Trials (KoNECT)

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**Korea had a late start, but is now one of the global hot spots for clinical trials. How would you sum up and explain this quick evolution?**

Clinical trials in Korea began in the 1990s, but at that time they were limited to either local studies for domestically developed compounds or registration trials for foreign drugs which were already marketed abroad. Indeed, before 2000 Korea had outdated regulations which were unfavorable to the participation in multinational clinical trials for new global drugs. However by the end of the 1990s and early 2000s, with the global ICH process underway, there was a growing awareness in Korea of the need to change this situation and the IND system was adopted. Since the regulatory changes in 2000, Korea can participate in global trials and the growth has been exponential. One of the key factors in boosting the growth of clinical trials in Korea was the governmentâ??s recognition of their key role in driving the development of the biotech and pharmaceutical industries, as a truly knowledge-based activity. This followed the recommendations of a group of experts from both academia and industry, which insisted on the need to develop centers of excellence in the country, specialized in clinical trials. This included not only the need for new infrastructure, but also for skilled human resources capable of carrying out clinical trials at global standards. So after the year 2004, the Korean government started supporting the development of clinical trials directly, whereas before the focus had been on helping pharmaceutical companies engaged in new drug discovery. A plan was set up by which 14 centers of excellence were to be built by the year 2009 around the country, through a system of central government funding matched by the institutions and the relevant regional authorities. To date, there are 12 such clinical trial centers in operation in Korea. A very large part of the clinical trial activity has been taking place in the Seoul Metropolitan area, but in my view it is important to further develop them in other Korean provinces.

**In this context, what led to the creation of KoNECT in 2007?**

The support to clinical trials was provided directly by the Korean government up until 2007. At that point, they decided that it would be better to create a special body that would be in charge of directing this support, increasing collaboration between the different centers in Korea, and establishing networks on a global level. Therefore, KoNECT was born in December 2007, as a government-funded organization with a budget of about $15 million per year, but operating with a high degree of independence in its decision-making. Although KoNECT is located within the academia, Our committee members also include industry representatives and some government

officials. Our main focus is on selecting the necessary projects in order to support the development of a world-class clinical trials environment in Korea, both in terms of technology and human resources.

**In your view, which are the key driving forces boosting the development of clinical trials in Korea today, and the main obstacles?**

The regulatory changes and proactive KFDA support have been the main initial drivers of clinical trial development over the last several years in Korea, as well as the good level of understanding between the different players in government, industry and academia. Another key success factor has been the high motivation found among hospitals and investigators which were very eager to finally have the opportunity to participate in global trials. In Korea, on top of our advanced healthcare system and cutting-edge technology, we have highly qualified human resources in the medical field. There are a great number of outstanding investigators ready and willing to participate in multinational trials. On the other hand, whereas medical professionals are very eager to conduct clinical trials in Korea the general population still has some apprehensions about taking part in them. This is due to historical reasons, particularly related to human experimentation carried out during the Japanese occupation, but many people still have strong memories about these tragic events. So another key priority for KoNECT and our partners is to work towards overcoming these misconceptions and making people understand the true nature and importance of clinical trials. One of the ways we are doing this is through the development of a clinical trial registry which will serve as a database for patients and the general public in Korea.

**How is Korea seen by multinational pharmaceutical companies in terms of the attractiveness and competitiveness for clinical trials?**

According to the multinational drug companiesâ?? own evaluations, Korea scores very high in terms of infrastructure, speed and quality of clinical trials. Korea is generally well positioned in important aspects such as patient pool and cost-competitiveness as well, but when compared to other huge Asian countries like China and India we are aware that this is clearly not our main edge. In addition, although Koreaâ??s high quality investigators usually have an overseas training in their specialties, and therefore speak a good level of English, this is an area in which more progress needs to be made in the middle levels of organizations. Another concern is the fact that the most famous and largest numbers of university hospitals are located in the Seoul area, making it the only cluster in Korea. In my view, it is imperative to develop at least one more important clinical trials cluster in Korea, in order to be competitive with countries like China and India which have multiple clusters for clinical trials. In this regard, the Southeast region of the Korean peninsula including big cities like Busan and Daegu have the potential to become the second clinical trials cluster we need. Indeed, there are already an important number of medical schools in the region. In 2009 supporting the materialization of this second Korean clinical trials cluster is one of KoNECTâ??s main goals and we are very committed to this vision. There are also many multinational pharmaceutical companies with an interest in seeing this happen and willing to make investments in order to make Koreaâ??s regions more competitive in terms of clinical trials. Asia in general is seeing rapid growth of clinical trials, but at the same time many countries are competing to attract the few pharmaceutical companies that carry them out globally.

**How do you see Koreaâ??s place and progress in this environment?**

Korea first learned about doing clinical trials in the 1990s from Japan, where big pharma was very present and active. This led us to the adoption of the IND system which has allowed Korea to even surpass Japan in term of new trials and made us an example for other countries to follow. However, until recently clinical development in Korea was almost entirely in Phase III. This began changing

significantly in 2007 when the country began seeing more Phase II trials taking place here and now Phase I trials are also starting to increase, thanks to our centers of excellence. In Asia, Singapore is a reference point for Korea as it has succeeded in attracting early phase clinical trials through large-scale investments by key players such as Lilly and Quintiles. We are also benchmarking with Australia, which has a clinical trials density six times greater than Korea. China and India are very low in terms of density, but their populations make the growth potential huge. So each country in Asia has its strong points and though we are competing in many aspects we should also collaborate so that this part of the world reaches a higher participation level of the global trials.

**To what extent is KoNECT directly engaging with foreign players both outside and inside of Korea in support of the countryâ??s clinical trials sector?**

KoNECT is a unique organization, without any true equivalents in other countries. We are representatives of the governmentâ??s will to support clinical trials in Korea, whereas in other countries this is a role often played by the CROs. So in many ways KoNECT is a new paradigm involving government, academia and industry. We listen to the needs of all the players and act as a bridge among them. In terms of international contacts, it is still early days for KoNECT but we have already established an alliance with a network of Phase I trial sites in Japan, for example. We are also collaborating closely with foreign companies like Pfizer, which is making big investments in Korea. In particular, the company has co-sponsored a new high tech education center inaugurated in April 2008, which is linked to 6 university hospitals. We hope to see other multinationals choose Korea for early phase trials and look forward to working with them.

**What is your final message to our readers ?**

Korea will play a crucial role in clinical development in Asia in the future.

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