Deborah Chee – President, KoNECT, South Korea

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Deborah Chee, President of KoNECT (Korea National Enterprise for Clinical Trials), discusses what it takes to build one of the world's leading clinical trials ecosystems and highlights the importance of partnerships and collaborations between different stakeholders in Korea as a key factor in making it such a strategic destination for both global and local sponsors.

What have been the main priorities of KoNECT since we last saw you?

At KoNECT we have three main fields of focus. Our first priority is clinical trial (CT) Capacity Building. There are a number of methods we use to achieve this. Firstly, we are building world-class CT infrastructure and capability (GCE). Moreover, KoNECT is developing data-driven approaches in CT. One of the platforms called KIIS (KoNECT Integrated Clinical Trial Information System) stores relevant data including national health insurance claim data, treatment guidelines/regulatory process and much other information on the clinical trials industry within the country. Furthermore, we provide statistics and strategic analysis on Korea clinical trial enterprises. KoNECT also supports the local clinical development programs of Korean companies and provides consultations and accreditations to local Korean CROs.

Regarding our second priority – increasing strategic collaboration, we coordinate and lead

Nation-wide and global collaborations across governments, academics, hospitals, and industry associations in order to accelerate innovation through the KoNECT Collaboration Center (KCC). With

the support of the Korean government, the KoNECT Collaboration Center for global clinical trials (KCC) was formally opened on September 1, 2015. The collaboration Center for global clinical trials (KCC) was launched to serve as a matrix of collaborative efforts seeking to engage national and international partners in clinical trials. With the innovative concept of space, service, and Information, KCC constitutes an unprecedented systematic clinical trial support system designed to assist sponsors in their clinical trial planning by providing helpful services and information.

Finally, we enhance public awareness of clinical trials, for example by opening the Korea clinical trial information centre (K-CLIC) and public clinical trial awareness campaigns.

KoNECT has existed for 15 years and has ensured the quality and efficiency of clinical trials in Korea. On the way, we were able to build credibility in clinical trial capacity and to help patients. I can say that we have strong basic capabilities in Korea today, and in the last years, my main ambition was to build world-leading capacity. Since 2012, we have developed a strong focus on collaboration with clinical trials centres; 17 leading university hospitals are participating in our program Global Center of Excellence, which strengthens the global competitiveness of the clinical trial industry. With these measures, we reached an increase of early phase clinical trials, including first-in-human trials by global sponsors. We are also pioneering in using data-driven approaches for feasibility, pre-screening and protocol development, not to mention, development of convergence technologies using big data and AI.

Korea is often chosen as a strategic site for global sponsors. We have successfully conducted some multi-ethnic phase I trials in a single centre for a well renowned multinational pharma company. These types of trials are very complex and often lack efficiency, however, the fact we managed to perform them shows our expertise.

In 2013 Korea was ranked 7th in global clinical trial destination ranking, today Korea accounts for 3.5% of all clinical trials registered in the US and is ranked 6th. What factors and trends determined such a positive development for Korea?

The Korean hospitals have a designated infrastructure to support clinical trial quality and a large volume of clinical trials. We do provide high volume patient access as well as medical sophistication and research interests. Global partners do perceive Korea as “technology positive”, as we support molecular testing and scientific innovation.

Korea also has a very high population density, which is an important factor for companies to conduct clinical trials here. It is more cost-efficient and time-saving since less travelling is involved compared to countries like Australia or the USA. Korea maintains a strong focus on quality and efficiency as well as patient protection and data integrity. Recently, we have been specializing in more complicated and sophisticated clinical trials, so this makes us quite unique on a global stage.

While the global number of clinical trials has been declining, we were able to continually increase the number of clinical trials conducted in Korea.

OECD clinical trial forum report mentioned that KoNECT was the first example of the best initiative of its kind. What factors do you think led organization to such success?

One of the key points is our customized and comprehensive learning system for CT workforce from training to certification. The government has made it mandatory for every person involved in clinical trials to take part in a training course. Currently, we offer 50 to 60 training courses per year with over 5000 people benefiting from this program. The professional certification programs are based on a two-level certification to improve the quality of our personnel.

At the end of October 2018, KoNECT and MFDS organized a three-day conference dedicated to “embracing change in clinical development”. What was the outcome of the event, the third of its kind since 2015?

The KoNECT International Conference is the largest event on clinical trials in Asia with recent global topics. This is in line with our new approaches to meet regional medical needs. Until recently, conferences on clinical trials had only been taking place in the USA or Europe. At this year’s event, hosting 1,100 attendees, there were two plenary and 20 breakout sessions, which provided an unparalleled opportunity for our Korean and global participants to listen to global speakers, meet the major players in clinical trials, and form networks and partnerships.

How is this new approach realized in practice?

We have formed an ad hoc network to fulfil unmet medical needs, especially in Asia through top-down and bottom-up proposals to industry. This will bring the benefit of earlier translation and commercialization of new targets and molecules and will also facilitate the collaboration with global

sponsors. We form networks such as the Asia Gastric Cancer Investigator Network, Asia Clinical Pharmacology Network or partnerships with local cooperative study group like KCSG (Korea Cancer Study Group). KCSG is a multicenter cancer study group representing Korea with about 720 members from 110 institutes or hospitals in Korea. The members are primarily clinical oncologists from all oncology disciplines, mainly medical oncology and other cancer-related subspecialties. KCGS is a homogenous, well trained, highly motivated network group with ten disease subcommittees. KoNECT is working together with KCSG in a highly innovative method of collaboration which usually works well with global sponsors and SMEs especially from Europe and the USA in the oncology sector with aspirations of simultaneous global development but limited experience in Asia. As part of this collaboration process, we partner with them, review their pipeline and identify potential collaboration opportunities, helping us to satisfy regional or global unmet medical needs.

KoNECT has been reported to be one of the best government initiatives for clinical trial infrastructure. How can other governments implement this model abroad?

We do in fact have many visitors from other countries to learn from us. Our program is based on an innovative approach responding to the needs of the industry. Our partners are very passionate about working with us and the collaboration with these partners is very tight, which may the reason why other countries may seek to replicate our model. We work with all Korean stakeholders of clinical trials beyond clinical trial sites. As an example, we offer domestic CRO accreditation and consultation services to help domestic SMEs to establish a competitive clinical development plan. We also provide incubation offices and meeting space as well as services like matching and partnering for them. Our support is not limited to domestic partners. These services are available through the KoNECT collaboration centre for international partners as well by providing an information, space, and services. The willingness to work together needs to be there, otherwise, it will be impossible to create such a complex model as you can find it now in Korea.

After many achievements, where do you want to lead KoNECT in the next 5 years?

We are working on a SMART Clinical Trial platform together with the government that will launch in 2019. This will be a nationwide technology convergence driven clinical trials centre network with the goal of improving the efficiency and safety of clinical trials significantly. It will play an integral role by leveraging the IT technologies and data-driven approaches to facilitate faster and safer

delivery of world-leading clinical trials. Through this project, we hope to build the consensus and synergy to address unmet needs in clinical trials. The committee, which I was a part of, has already fully laid out the five-year roadmap for this project. The goal of the project is to transform the Korean healthcare system by providing the positive experience of continuous improvement and innovation in clinical trials through seamless feedback and new knowledge captured from the systems and network. This is a process that will most likely go longer than five years; we are looking for a project runtime of around ten years for this platform.

Any concluding words?

KoNECT is the gateway to Korea for successful conducting of multi-centre clinical trial programs. We are a non-profit organization, so we are here to support any company who wants to conduct clinical trials in Korea or even in Asia. We are willing to help and together with our Asian partners and our experience we do provide excellent value to the drug development industry.

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