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> Korea has been, and will continue to be, contributing to the development of robust regulatory science in alignment and harmonization

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Dr Bae Byuongjun, president of the Korea National Enterprise for Clinical Trials (KoNECT), outlines why Korea stands out in the APAC region as a top clinical trial destination, how clinical trials around COVID-19 treatments are progressing in Korea, the pandemicâ??s effect on trials for medicines in other indications, and how Korea can lead the way for regulatory science in Asia.

Can you begin by giving us an overview of your previous experience?

I graduated from Korea University with a Bachelorâ??s in Social Sciences and earned a Masterâ??s degree in Public Administration from Seoul National University. I also hold a Master of Public Policy from Harvard Kennedy School, and a PhD in Public Health from Cha University.

I passed the national qualification exam for public officer and entered office in 1989. Over the course of 31 years, I have served as Director of the Insurance Policy and Pharmaceutical Policy Division at the Ministry of Health and Welfare, Director of the Seoul Food and Drug Safety, Chief Administrator at the Office of the President, Minister Counsellor of the Korean Embassy in the United Kingdom for the Ministry of Foreign Affairs, Director General of the Bureau of Health Industry Policy, Bureau of Welfare Policy, and Deputy Minister of the Bureau of Social Welfare Policy at the Ministry of Health and Welfare.

You have participated in the industrial policy that has funded KoNECT, can you tell us a few words about it?

In 2015, during my time as director-general of the Bureau of Health Industry Policy at the Ministry of Health and Welfare, I established the â??National Competitiveness Reinforcement Plan for Clinical Trials.â?? As a result, the Clinical Trial Innovation Center (now KoNECT Collaboration Center) was launched.

Based on my experience and knowledge in public health and pharmaceutical policy, food and drug safety regulations, national health and welfare policy, and overseas missions as a civil servant, I was inaugurated as the president of KoNECT to contribute towards the advancement of the environment for clinical trials and new drug development in Korea.

What are your objectives as president of KoNECT?

As the only exclusive clinical trial support organization in Korea, KoNECT has fulfilled numerous roles in the journey towards making Korea a leading country in clinical trials. While drug pipelines increase, the growth of the clinical trial industry is actually slowing down, and so is the growth of global clinical trials in Korea. On top of this, the environment surrounding clinical trials and new drug development is changing in and outside Korea, which is prominent in the rapid rise of clinical trial capability of emerging countries. Given the facts that the competition between countries in the clinical trial industry is getting fiercer, and new technologies are being discovered, we aim to ensure that the environment in Korea allows for efficient clinical trial process and top-notch clinical trial quality.

To this end, first, we will continue to keep up our efforts in broadening patientsâ?? access to innovative new drugs. KoNECT will serve the role of Koreaâ??s national control tower for clinical trials so that the process of clinical trials is safe and efficient.

Second, we will support new drug development by enhancing Koreaâ??s clinical trial competitiveness. To tackle the difficulties working-level researchers find in the clinical trial process of drug development, â??The Committee of National Competitiveness Reinforcement Plan for Clinical Trialsâ?? engaging the industry, academia, and government will be formed to devise the â??The Second National Competitiveness Reinforcement Plan.â?? Furthermore, the training of clinical trial professionals will be expanded to ensure higher clinical trial performance.

Third, we will build a better support system for clinical trials to promote public health clinical research. KoNECT is an affiliated organization to the Korean Ministry of Health and Welfare and was entrusted as a â??National Center for Clinical Research Service (Clinical Trial Coordinating Center)â?? this year. Given such a role, we aim to introduce a support system to promote clinical trials in Korea for public health.

Fourth, we will bring about a reduction in clinical trial costs and times by using clinical trial real world data (RWD) and new clinical trial technologies. Globally, we are welcoming the era of the fourth industrial revolution. In Korea, the national assembly recently passed the so-called *â??three data privacy lawsâ?? [the Personal Information Protection Act (â??PIPAâ??), the Act on the Promotion of Information and Communications Network Utilization and Information Protection (â??Network Actâ??) and the Act on the Use and Protection of Credit Information (â??Credit Information Actâ??) â?? Ed.] and these facts highlight the importance of collecting and utilizing medical and clinical trial

data.

By fully acknowledging such conditions, we plan to discover innovative clinical trial projects based on data acquired by applying fourth industrial revolution technologies with clinical trials. One example would be establishing clinical trial management systems (CTMS) at hospital clinical trial sites by carrying out projects that aim to form smart clinical trial centre platforms. In the end, such efforts will lead to a reduction in clinical trial cost and time.

How would you characterize Koreaâ??s ability to perform Phase I clinical trials? What are Koreaâ??s main advantages compared to other clinical trial hubs in the Asia-Pacific region?

The total number of investigational new drug (IND) approvals by the Korean Ministry of Food and Drug Safety (MFDS) has increased by 5.15 percent from 679 cases in 2018 to 714 cases in 2019. According to data from ClinicalTrials.gov in 2019 analyzed by KoNECT, the number of protocols in Phase I clinical trials has increased by 8.8 percent compared to the year 2018, indicating that Phase I clinical trials led by domestic pharmaceutical companies are becoming more active developing their pipelines.

However, investigator-initiated trials (IITs) are playing a leading role in the development of new drugs worldwide. In this regard, KoNECT intends to support clinical trials in areas with high public unmet medical needs such as the development of vaccines and therapeutics for COVID-19 and rare diseases.

Key opportunities for Korea in early phase trials include the fact that over the last 20 years, major sites and investigators in Korea have accumulated clinical research experiences, global-level excellencies, and capabilities through participating in various global clinical studies as well as taking key R&D partner roles with global & local pharma companies.

Moreover, right now, Korea has specialized Phase I units in 20 hospital-based clinical trial centres. According to the 2016 Top Global CRO report, four Korean sites made it into the list of the worldâ??s top ten clinical trial sites in oncology.

Recently, more and more key investigators are engaging as advisory board members and principal investigators (PIs) in global clinical studies. In particular, they have a strong influence over the study planning, design, data and results analysis of the Phase I oncology studies sponsored by global pharma companies.

Behind that, there is a strong motivation and joint collaboration between government, industries and academia to promote Korea as a global leader in developing new drugs with a patient-centric approach.

MFDSâ??s plan for the next five years is to expand early access and opportunities to new treatment through expedited review.

The clinical trial application (CTA) or IND procedure, which takes only 30 working days in Korea, allows for simultaneous application submissions to institutional review boards (IRBs), Ethics Committees (ECs) and the MFDS. This has greatly reduced the average time taken to obtain clinical trial approvals in Korea. Also, Korea boasts highly competitive study start-up timelines (112 days) in comparison to other countries.

With the COVID-19 pandemic ongoing around the world, what lessons are there to be learnt about how clinical trials are conducted?

As we speak, more than 760 clinical trials are being conducted worldwide to find potential treatments and vaccines for COVID-19. Including seven IITs and five sponsor-initiated trials (SITs), a total of twelve clinical trials on COVID-19 treatments are being conducted in Korea. Vaccine-related studies have not been carried out yet, but DNA vaccine clinical trials are expected to begin as early as June.

Through the Central Clinical Committee for Emerging Disease Control, the Korean government has expanded its participation and taken a new level of response to facilitate the systematic operation of the central-regional administrative management system while promoting the involvement of all national medical institutions, the role sharing of primary, secondary, and tertiary medical institutions, and establishing public-private partnerships for prevention of epidemics in addition to the treatment of confirmed patients.

The government is also actively taking the lead in the development of vaccines and treatment while operating a quarantine system.

With the COVID-19 situation, we became aware that two-thirds of clinical trials for the development of vaccines and treatments related to COVID-19 were initiated by researchers.

In the case of urgent or rare diseases such as infectious diseases or public health crises, the IIT is the starting point for the development of treatment methods.

The Korean government is providing medical care expenses for IITs through the revision of the Health Insurance Act (â??18.5). Partial medical care expenses are also provided for SITs with a large public interest, such as response to the public health crisis and research on rare incurable diseases. While most developed countries such as the US, UK, and Japan are in the process of assembling and operating the government-led support organizations dedicated to clinical trial planning to completion in addition to providing the cost, Korea still lacks an all-phase research support system. In that regard, KoNECT intends to build and operate an organization that is fully dedicated to supporting clinical trials carried out for unmet public medical needs.

As clinical development and global trials are becoming more and more expensive, what role will data play in cost reduction? How can the quality of Korean patient data facilitate better performance?

The Korean government recently announced an â??Innovation Strategyâ?? to strategically foster the bio-health industry (2019). It is expected that research using medical big data will become more active in the future as it includes the plan for the use of medical big data in research and greater openness to the private sector.

The â??three data privacy lawsâ??, which enables personal information to be used for research after a de-identification process, is planned to pass (Jan 2020) and be enforced (Aug 2020). The clinical trial data will be more accessible after the designation of data-centred hospitals, according to published data usage guidelines.

How is KoNECT incorporating the possibilities of real world evidence (RWE) into its studies?

KoNECT expects South Koreaâ??s new initiative in clinical trials, the Smart Clinical Trial Center Platform Project (2019 to 2022), to foster a stronger national clinical trial network. In line with the governmentâ??s initiative for the new drug development industry, KoNECT has strived to lay the foundation for high-quality medical research for new drug developments and expects the Smart Clinical Trial Center to be a trigger for building a world-leading healthcare system based on RWD and RWE. The Smart Clinical Trial Center platforms will enable South Korea to conduct more efficient and speedy trials with better safety monitoring and management system for clinical trial participants, using a data-driven approach in study designing and planning.

The Smart Clinical Trial Center Platform project involves seven major hospitals in Korea and is expected to achieve higher efficiency for clinical trials. The comprehensive aggregation of electronic health records (EHRs) and advanced technologies will bring digital innovation in clinical trials. A National Clinical Trial Management System (CTMS) will replace the current system with a single control system, and standardized clinical trial data will enable the utilization of variations of the care process, a smart recruitment system, and a smart patient safety system. This will also provide more patient-centred management by using a data-driven approach and decision making. A nationwide network will bring the synergy to address unmet needs in clinical trials in Korea.

What potential is there for alignment in regulatory science across the key Asia-Pacific markets? Is there an opportunity to play a greater regional role thanks to its clinical trial infrastructure and experience?

The Korean MFDS has made continuous updates in line with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and has been a major participant in the council over the years. Korea was appointed as a full ICH member in 2016 (the sixth country globally) and was selected to sit on the ICH Management Committee.

Korea has been, and will continue to be, contributing to the development of robust regulatory science in alignment and harmonization. In addition to the ICH activity, the Korean government has made continuous regional efforts with Japan and China for harmonization in regulatory science. Korea has been working as part of the APEC Regulatory Harmonization Steering Committee (RHSC) and was selected as an APEC Center of Excellence for Regulatory Science in the area of â??Multi-Regional Clinical Trialsâ?? (MRCTs) & good clinical practice (GCP) Inspection.

What does Asia do best within global life sciences? What is your vision for the role of Korea within international regulatory science and new drug development?

Koreaâ??s drug development history goes back a long way. The first-ever locally developed new drug was approved in 1999. Since then, local companies in Korea has never ceased developing new drugs. As a result, at least one or two new drugs developed by local pharma companies are approved annually. Thanks to this commitment to new drug development, we are seeing first approval on a couple of biosimilar products in the global market developed by Korean pharma companies.

Another recent successful drug development by a Korean pharma company is SK Pharmâ??s epilepsy treatment XCOPRIÂ®, which recently gained US FDA approval. The success story continues with a couple more local pharma companies closing a global deal on product licenses with global pharma companies.

Recently, we have also seen more and more start-up/bio venture companies enter the industry. Their key focus is on developing new drugs that will be approved globally. We already see that the nationâ??s clinical industry is accumulating more and more global study experience as local pharma companies continuously hone their new drug development efforts and capabilities. The Korean government is also providing strong support to that end.

We are confident that Korean pharma companies/sites/investigators will play a major role in the development of new drugs in the future, especially regarding innovative new drugs that will address unmet medical needs. This is evident in the fact that the Korean MFDS is leading the evolution of ICH guidelines.

How would you like clinical trial sponsors to view Korea?

Over the last 20 years, Koreaâ??s clinical trial field has shown remarkable growth. As major sites and investigators in Korea accumulate clinical research experiences and capabilities, Korea as a nation reported stellar performance in the conduct of clinical studies.

These facts are evident in the growth figures in the clinicatrials.gov registry and the results of the inspections carried out by multiple health authorities. I strongly believe that sponsors will be rewarded for placing their trust in Korea, the strong clinical research partner for you.

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