Last year was a milestone for Korea’s pharmaceutical industry. Hanmi Pharmaceutical, one of the most prominent pharmaceutical companies in Korea, concluded an out-licensing deal worth KRW 8 trillion (USD 6.8 billion). In terms of the nation as a whole, 30 large-scale deals worth more than KRW 9 trillion (USD 7.6 billion) were closed for technology export and drug development. Domestically-developed biomedicine was also approved by the FDA to enter the global market.

In 2015, the size of the global pharmaceutical market was USD 1 trillion. As the demand for medicine is increasing due to a surge of chronic diseases and the advancement of treatment technologies, the figure is expected to increase up to USD 1.4 trillion by 2020, according to IMS Health. That is an average growth rate of 4 to 7 percent every year. In the same year, the Korean market was approximately KRW 19 trillion (USD 16.1 billion). Korean pharmaceutical companies and the government spent approximately KRW 1.7 trillion (USD 1.4 billion) on drug development, 60 percent of which was on clinical trials*. As such, the pharmaceutical market is growing fast both domestically and globally, and major players are keen on clinical trials as a means of enhancing their drug development capabilities.

**Korea’s clinical trials in the global market**

Korea’s clinical trials are making noticeable achievements. In contrast to the declining number of clinical trial sites around the world (CAGR: -2.85 percent, 2011-2015), the global market share of Korea’s clinical trial sites has constantly increased over the same period (CAGR: +9.34 percent). In terms of global clinical trial protocols, Korea has maintained 7th place since 2013, while being Asia’s most attractive clinical trial market.

When it comes to multinational clinical trial protocols, Korea never lost its no.1 spot since 2011, proving its strong competitiveness. These are encouraging signs when we consider the fact that countries around the world are engaged in fierce competition to attract clinical trials in their home country from the global pharmaceutical market, thereby providing patients with greater access to quality medical treatment.

**NIH Clinicaltrials.gov based Industry Sponsored Trials: Korea’s Site Share Trend**

Despite the global financial crisis and the resultant erosion of R&D productivity, Korea’s clinical trial market has shown solid growth. Since 2004, the number of Korea’s Investigative New Drugs (IND) approvals has increased 15.7 percent annually. In addition, the estimated value of total study budget for

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*Source: KISTEP, Korea Financial Supervisory Service, and PhRMA*
clinical trials received by Korea's clinical trial centers (Regional Clinical Trials Center and etc.) has increased more than 15 percent a year. The Contract Research Organization (CRO) market has also shown a rapid average growth rate of over 20 percent a year. The vibrant growth of the clinical trial market is expanding the market, not to mention enhancing the competitiveness of, relevant industries while bringing in qualified human resources.

Number of IND Approvals by Ministry of Food and Drug Safety (2004-2015)

According to Thomson Reuters, Korea is likely to drive the "next wave" of growth in the global clinical trial market. Many academic papers repeatedly quote Korea's success stories, encouraging others to follow the country's footsteps.

**KoNECT program boosting clinical trials**

Behind such phenomenal growth was the steadfast support from the government as well as strong collaboration among the government, industry, and academia working tirelessly for the development of the nation's clinical trial industry.

First of all, the government initiated three kinds of programs to support clinical trial infrastructure: the Regional Clinical Trials Center (RCTC), Global Center of Excellence in Clinical Trials (GCE), and the Korea National Enterprise for Clinical Trials (KoNECT). After establishing the Institutional Review Board (IRB) in 2002, Korea first built its RCTCs in 2004 and GCE in 2012. A total of 15 RCTCs and five GCEs were established afterwards. In 2008, KoNECT initiated a training program for clinical trial human resources (1st class: 2008-2013, 2nd class: 2014 to date) to support clinical trial infrastructure in a more systemic and reliable manner. Now, KoNECT is serving as a control tower for nationwide decision making, while RCTCs disseminate global standards and procedures to nearby hospitals and other institutions. As a result, Korea's clinical trial industry has become more competitive, and thus experienced an exponential growth during the past 10 years.

Second, the government provided easy access to clinical trial information so that a higher number of productive and effective clinical trials can be conducted in Korea. Among such means are KoNECT Collaboration Center and KoNECT Integrated Clinical Trial Information System (KIIS). Their main objective is to resolve grievances of foreign researchers by providing clinical trial information to them.

Last but not least, the government, industry and academia are continuously working to improve the quality of clinical trials as well as to establish the network of clinical trial researchers. In terms of quality improvement, education on patient protection was made mandatory among clinical trial researchers since 2016. The government and the private sector are making various efforts to strengthen the capability of CROs, i.e. by establishing a certification system. In terms of research network, a network of researchers for diseases such as cancer is being established.

Korea ready for high-quality clinical trials

One notable phenomenon in the recent global market is that the weight, which was once put on Africa and Asia, has been shifted to the traditional markets of North America and Europe. Meanwhile, countries around the world are vying to attract clinical trials to their domestic market and improve R&D productivity. Utilizing nation-wide information on clinical trials and networking researchers have become a critical task.

Under such circumstances, despite a mere 20-year history in clinical trials, Korea has gained ground as a competitive global clinical trial market, especially in Asia. The government's strong will to boost clinical trials, transparent regulations, patient-centered research activities, a nation-wide information system, a training program for clinical trial professionals and strong government-industry-academia collaboration are the factors that make the future of Korean clinical trial market much brighter.

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