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START **KOREA**









Ministry of Health and Welfare





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Why Choose Korea: The Clinical Trials Industry at a Glance



Did you know that Korea is one of the global top 10 countries for conducting clinical trials?

More industry-sponsored drug studies have been conducted in Korea than any other Asian country for the past 5 years. Korea has consistently ranked in the top 10 countries for clinical trials since 2011 and the country's capital, Seoul remains the world's top city for the total number of industry-sponsored drug trials conducted.



Korea Good Clinical Practice (KGCP) was legislated in 1995, with an amendment in 2001 in order to adopt ICH-GCP. Following the introduction of a new Clinical Trial Authorization (CTA) process in 2002, the number of multinational trials began to increase rapidly. Strategic government investments were made to promote nationwide clinical trial capabilities and human resources development through regional clinical trial centers, as well as the establishment of the Korea National Enterprise for Clinical Trials (KONECT) to promote and support the industry.



The accelerating growth of clinical trial activity over the past decade initially centered on late-phase clinical development. However, there has been an emerging new trend for early phase research driven by a surge in new drug development by domestic companies, as well as notable increases in Phase I oncology trials by multinational companies looking to capitalize on the renowned expertise of Korean investigators.







KOREA, THE BEST PLACE FOR CLINICAL TRIALS





With a robust consumer market and R&D ecosystem, Korea has well and truly entered the global pharmaceutical market as one of the few countries capable of full-spectrum drug development.



Pharmaceutical Market

Korea is the 11th largest pharmaceutical market in the world. The Korean pharmaceutical market is estimated to exceed US\$18~22B value annually by 2025. Growth is projected to continue at an annual rate of 4.5%~7.5% at the domestic level, being close to the world average of 7~10%. (IQVIA Market Prognosis, Sep 2019; IQVIA Institute, Dec 2019)

National Healthcare System

South Korea has a compulsory National Health Insurance (NHI) system with universal coverage, covering 97.2% of the country. The system provides high quality care to the majority of the population with high efficiency, ensuring access to outstanding medical institutions and medical care. With a rapidly aging population and a demand for the most innovative therapies, medical needs are expected to increase.

Korea's Healthcare and **R&D Ecosystem**



The Korean pharmaceutical industry has been accelerating its investments in open innovation with a focus on R&D for entry into overseas markets. Such efforts have diversified in recent years to encompass not only innovative new medicines, but also platform technologies, medical devices, healthcare IT solutions, and incrementally modified drugs and advanced therapy medicinal products (ATMPs)

In 2016, the Korean Ministry of Food and Drug Safety became the sixth member of the ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), which aims to establish a shared international standard across all stages of the pharmaceuticals regulation process. As a full ICH member, Korea is proud to be an active contributor to the development of robust global pharmaceutical regulations.

Korea's all-encompassing protection of intellectual property rights is another factor that invigorates the R&Dintensive pharmaceutical market.



Where is **R&D** actually occurring?

The nation's drug development pipeline shows a thriving R&D ecosystem thanks to efforts at the national level to further enhance clinical trial capabilities for global development.

According to a report published by Citeline in 2022, the above figure counted all drugs in development by pharmaceutical companies from those at the preclinical stage, through the various stages of clinical testing and regulatory approval, and up to and including launch.

Among the 20,109 drugs in the pipeline, the US comes in with 53.4% of all drugs in R&D being in development and Korea is the fourth biggest individual country, covering 13.1% of all drugs R&D worldwide, which means that an increasing number of clinical trials are destined for start-up in Korea.

Korea's Ministry of Food and Drug Safety has approved 34 new domestically-developed drugs, as well as the world's first monoclonal antibody biosimilars.



Easy access to target patient pools has been one of the major attractive highlights of Korea's clinical trial industry.

High density with an aging population: With a total population of over 50 million and half of it living in the capital, Seoul, Korea is one of the most densely populated countries in the world. It has an average density of 527 people per square kilometer, or 1,366 people per square mile. The country tops out at more than fifteen times the average population density of the United States. Korea is also one of the most rapidly aging societies in the world with a life expectancy at birth of 83.5 years.

Due to high standards of living and clinical expertise, disease patterns and medical unmet needs in Korea are similar to those in Western countries. Three leading causes of death were cancer, heart diseases, and pneumonia and these three causes of death occupied 45.9% of the total deaths.



Leading causes of death in Korea, 2020

The national 99% literacy rate means that patients are more likely to have a high level of education and can make informed decisions about clinical trial participation. Korea's secondary education system is one of the strongest in the OECD.

A Readily-Accessible Patient Population



Easier access for patients to comprehensive clinical trial information improves participation levels

The Ministry of Food and Drug Safety routinely publishes updated clinical trial information on its website (nedrug.mfds.go.kr). Patients and guardians can conveniently access clinical trial information by searching for diseases, hospital contacts, participation criteria, and status.

The MFDS has noted that the sharing of such information will not only help patients wanting to participate in trials but also researchers and companies as they develop their trial plans. The Ministry has pledged to continue providing useful information to support the socially vulnerable including patients with rare and intractable diseases.

Affiliated with the Ministry of Heatlh and Welfare, KoNECT has been giving patients faster access to clinical trials through our website (findtrial.or.kr), which provides the general public with the information on clinical trials enrollment. The website is designed to be user-friendly and patient-focused, while also providing information for professionals in academia and industry.



Investigators Networks for patient referral/recruitment

Several investigators networks are currently working on ways to improve patient recruitment and collaborative research in clinical trials. As the singular government funded organization mandated with covering all clinical trial activity in Korea, KoNECT works together with these networks to promote collaboration. KoNECT routinely links sponsors with investigators and patients, providing this service.

Streamlined CTA Process



The Clinical Trial Authorization (CTA) process allows for applications to be submitted in parallel to the Ministry of Food and Drug Safety (MFDS) and institutional review boards (IRBs)/Ethics Committees (ECs).

- After submission, the MFDS issues either a response for trial approval or a request for supplementary information to the applicant within 30 working days.
- After submission, IRB/EC reviews are undertaken via review meetings that occur at least monthly at the site level, taking on average 3 weeks for approval with expedited review meetings held when necessary. Recently, mutual recognition of central IRB/EC approval across sites participating in the same study has been introduced, expediting the review timeline.

The entire review timeline for both MFDS and IRB/EC takes between 4 to 8 weeks on average.

Continuous improvements for the CTA Process

In Aug 2019, the MFDS issued its 'Comprehensive 5-Year Plan to Advance Clinical Trials', aiming for Korea to become the global leading country in developing new drugs with patient-centric approaches. As part of the 'Comprehensive 5-Year Plan to Advance Clinical Trials', the following strategies will be implemented to improve the CTA process:



Streamlined CTA Process



Continuous implementation of ICH guidelines by Korea's MFDS through strong ICH participation over the years

As a full ICH member, Korea has been actively contributing to the development of robust global pharmaceutical regulations.



World-Class Medical Research Infrastructure with State-of-the-Art Facilities



Cutting-edge digital systems and advanced medical infrastructure are the critical contributors to the quality of healthcare in South Korea, which is now ranked as being among the world's best.

In Seoul and other major cities in Korea, most hospitals are fully equipped with modern systems and facilities ready for your clinical trials.

Visitors are frequently impressed when they see the size of the facilities, the number of beds and state-ofthe-art electronic medical record (EMR) systems. Major hospitals are also home to highly specialized phase 1 units with dedicated clinical study resources.

EMR System for efficient records and data tracking

Cutting-edge medical software is essential to ensure clinical trial efficiency and quality. Most Korean hospitals have adopted electronic medical records (EMRs) and use picture-archiving-and-communication systems (PACS), with many of the nation's clinical trial sites using EMR and/or electronic health records (EHR) systems for clinical trial feasibility assessment and data capture. In parallel with the increasing usage of EMR for site feasibility, hospitals in Korea are developing clinical data retrieval systems (CDRS) that enable queries of anonymous biomarker data and assessments of pool sizes for eligible patients meeting inclusion/exclusion criteria. As an example, one of the leading hospitals maintains medical records for 6.8M patients, derived from 52M patient visits one year.

Top 7 sites (based on CTA Approval #) fact sheet, 2020

	Seoul National University Hospital	Yonsei University Severance Hospital	Samsung Medical Center	Asan Medical Center	The Catholic Univ. of Korea Seoul St.Mary's Hospital	Gachon University Gil Medical Center	Korea University Anam Hospital	
Beds	1,761	2,615	2,160	2,715	1,453	1,600	1,120	
Outpatient /Day	8,700	10,000	8,603	13,631	6,719	4,173	3,665	

*Figures subject to change



World-Class Medical Research Infrastructure with State-of-the-Art Facilities



Data-driven approaches by trial sites provide more value for industry collaboration

EMR systems are commonly used in most hospitals in Korea and "Real World Data" has become a meaningful resource for researchers to analyze clinical data to develop new therapeutic solutions. To access hospital clinical data in a more effective way, some major institutions have developed new convergence technologies for big data analysis. Here are is an example of approaches from sites to support systems using hi-tech collaboration with biopharmaceutical companies in the healthcare industry.

CASE STUDY : Big data-based feasibility and pre-screening

A big data platform called ABLE (Asan Biomedical research Environment) system has been developed to support feasibility and pre-screening while protecting patients' privacy by removing identifiable information. Researchers can easily design research hypotheses, review clinical data and extract necessary data.

ABLE is an integrated database of patient clinical information suitable for research purposes because it anonymizes all subject-identifiable information

Data Extraction & Cleaning Anonymization





What's coming next

National R&D Project

Next Generation Smart Clinical Trials (since 2019)

"Smart Clinical Trial Platform Infrastructure Development Project" by Ministry of Health and Welfare

This project has been launched to improve clinical trial technology through the use of ICT(Information and communications technology) approaches to increase the success rate of new drug development in Korea. Government investment in the project is approximately KRW 9.8 billion (USD 8.4 million) with eight research hospitals/organizations participating.





NGS instruments Image courtesy of Severance Hospital



Particle therapy system (launching in 2022) Image courtesy of Severance Hospital



Clinical sample storage Image courtesy of ASAN Medical Center



GE FASTIab Duo (automated radiopharmaceutical synthesis) Image courtesy of Asan Medical Center



Biobank Image courtesy of Samsung Medical Center



Patient blood analysis Image courtesy of Samsung Medical Center

Clinical Trial Sites Designated by the Korean Government



Based on the Federal Regulation for the Designation of Clinical Trial Sites, there are 205 medical institutions designated by the government as fully-certified clinical trial centers (as of March 2022)



Exceptional Clinical Investigators

Korea is home to hundreds of highly-qualified investigators with global research experience who are keen to engage in new studies with their patients.

With the availability of internationally-renowned investigators, global and regional suppliers, an enthusiastic patient pool and transparent regulatory practices, South Korea is a highly attractive early phase destination.

Korea boasts extensive resources and is home to more than 93,000 practicing clinicians, 3,600 hospitals with 43 teaching hospitals, and approximately 60,000 clinics across the nation. There are 2.2 physicians per 1,000 people, comparable to the U.S. doctor-to-patient ratio. Hospitals are equipped with advanced facilities and cutting-edge technology. The level of care is monitored continuously by the government through hospital accreditation and evaluation programs aimed at ensuring the quality of both hospital practices and patient management.

Korea applies top-tier medical care and world-class treatment know-how for cancer treatment. For some major types of cancer, 5-year relative survival rates rank among the highest in the world.

More and more Korean investigators are becoming actively involved in IITs (Investigator-Initiated Trials) which are increasing throughout the country in number and quality. With the support of global pharma companies, Korean investigators are playing significant roles as global PIs and advisory board members.

Every site personnel involved in each clinical trial is required to complete a minimum number of annual training hours for GCP training, as mandated by the MFDS.

Expanding presence of Korean researchers in the global clinical research field





Looking for specific information about globally renowned clinical investigators in Korea for specific therapeutic areas of significant unmet medical needs?

Find out more information on the top disease areas(Cancer, Immunology, Neurology, Infectious diseases) for clinical trials in Korea on the KoNECT website: www.konect.or.kr/en/index.do

World-Class Sustainable Quality & Performance



World-Class Sustainable Quality & Performance



Faster Study Start-up

The study start-up (SSU) process is frequently noted as one of the most cumbersome and costly bottlenecks present in clinical research. Major milestones in the process include site selection and initiation, contract and budget execution, and other activities occurring prior to enrollment of the first patient. Korea boasts highly competitive SSU timelines in comparison to other countries.





Fast and predictable enrollment

Korean sites have shown superior performance in patient recruitment, ensuring greater confidence for sponsors, as well as excellent patient enrollment numbers in comparison to other top tier countries. Across diverse data points for clinical trial performance, including average number of patients per site, total number of trials and study start up times, Korea remains a highly competitive destination for global clinical trials.



Source: TrialTrove® | Informa, September 2019

The average Pts/Site/Mo for a country represents the mean trial-level Pts/Site/Mo of all trials conducted in that country. Only Actual Pts/Site/Mo values are used to calculate the mean (and not Anticipated or Predicted values). Where a trial is conducted in multiple countries, the same trial-level Pts/Site/Mo is assigned to all participating countries.

Site Quality



Clinical research sites in Korea are routinely inspected by the MFDS after a clinical trial is completed, and have proven track records for audits by foreign regulatory authorities including the US FDA, EMA, and PMDA

Between 1 October 2008 to 9 October 2019, 39 US FDA inspections were undertaken by CDER in Korea. For all 39 cases, there were no Official Actions Indicated(OAI).

IRBs/ECs at major sites throughout the country have been accredited by international organizations including FERCAP and AAHRPP and have their own human research protection oversight. Korean sites have repeatedly demonstrated outstanding performance in patient recruitment, ensuring greater confidence for sponsors.

* FERCAP : Forum for Ethical Review Committees in the Asian and Western Pacific Region

* AAHRPP : The Association for the Accreditation of Human Research Protection Programs, Inc



FDA Inspection Classification(2008-2019) Bioresearch Monitoring Cases among the Leading Countries in Clinical trials

IN; India, CA; Canada, DE; Germany, FR; France, IT; Italy, GB; United Kingdom, ES, Spain, KR; Korea, CN; China, JP; Japan, BE; Belgium, NL; Netherlands, AU; Australia, TW; Taiwan

NAI: No Action Indicated, VAI: Voluntary Action Indicated, OAI: Official Action Indicated, CDER: Center for Drug Evaluation and Research

Inspection Classification from 10/1/2008 through 10/9/2019 (Report Date - October 2019). Not all countries include data for 2019.

Source: FDA

Committed to the Continuing Evolution of Clinical Research Excellence



Committed to the Continuing Evolution of Clinical Research Excellence

The bio-health industry has been selected as one of the government's three new priority target growth engines for the future national economy. Pan-government support will drive strong bio-health industry growth through its 'Innovative Strategy on the Bio-health Industry' (2019 ~ 2030).

In addition to pan-government support, the MFDS as the main government division for clinical trials will continue to advance the clinical trial environment through its comprehensive 5-year plan (2019 ~ 2023), aiming for Korea to become the global leading country in new drug development involving patient-centric approaches. With this nationwide approach, the next generation of smart clinical trials will be unveiled using ICT technology for faster and safer trials in Korea. The strategic initiatives being launched by academia, government and industry, will ensure the continuing evolution of the nation's clinical research excellence.

Pan-Government



National R&D Project Next Generation Smart Clinical Trials (Since 2019)



MERCK

"Reflecting on my 20 years of experience with Korea's clinical trial industry"



Andy Lee SVP, Head of Global Clinical Trial Operations

It has been about 20 years since my first visit to Korea to explore the prospect of conducting a clinical trial in this country. At that time the infrastructure was embryonic and no Western clinical trials had been conducted in Korea. I am proud that my protocol was the first Western study done in Korea. Since that time we have seen amazing growth in many sectors in the country. Many brands have become household names and carry with them a reputation for high quality. As I reflect on my most recent visit to the KoNECT International

Congress (KIC), I am amazed at the progress and high-standard of work done in this country. Before departing, I got up early and climbed to the top of the Namsan Tower to see the sunrise. I arrived at exactly 6.00 a.m. at what is described by the signpost as the "geographic center of Seoul". For me it is rather spiritual in that it provides a 360 degree view of the city and beyond. All sorts of people visit this landmark and it is a central place from which one can look at the city and country. The tower itself is an iconic reminder of the innovative culture in Korea, the people are warm and friendly, especially the older men and women who meet at the pinnacle of the tower for daily exercise. How far has Korea come in 20 years since I first visited? Well it started with my study being the first Western study approved, to Seoul becoming the number 1 city in the world for clinical trials. It is not important how you start the race, it is more important how you finish. Seoul is number 1. This is absolutely amazing!! It has happened because of the dedicated work of many people, but particularly the collaboration between, KoNECT, MOHW, MFDS, multinational sponsors, local companies and above all the many people in hospitals, suppliers, companies and support jobs. I feel proud to be a very small part of this success. Thank you all for a great experience and best wishes for continued success.



AstraZeneca

"Korea has become the 'go-to' country."

AstraZeneca's purpose is to push the boundaries of science to deliver life-changing medicines. In 2015, AstraZeneca invested 23% of our total revenue in core R&D activity; critical to success is decisions regarding where to place such investment.

Delivering life changing medicines is only possible with strong partnership and collaboration with world-leading medical and clinical scientists, researchers and institutions, enabling timely access to cutting edge technologies, operating within a strongly supportive regulatory and governance framework, conducive to conducting best in class clinical research activities. Korea is at the forefront of high quality and accelerated delivery – achieved through strong partnerships with world leading physicians and researchers.

Over recent years, AstraZeneca has partnered with Korea across all phases of research and multiple therapeutic areas. In Asia, AstraZeneca has seen an increase in clinical trial activity of 74% over the last 4 years, with close to 25% of all studies conducted in Korea. The passion, discipline, winning spirit, and performance of Korea is exemplary. Currently, there are over 3500 patients participating in our Global Medicines Development programs in Korea.

Korea has become the "go-to" country for many areas of research, including very complex immune-oncology and oncology programs, from first in man to late phase research. A recent example of quality delivery excellence was Korea's participation in a key oncology program – the journey for this FDA breakthrough designated compound began in Korea with the first patient dosed, and in recent later phase trials, Korea continued the journey, contributing the fastest and highest volume of patients. The direct impact was key scientific questions were answered three times faster with Korea's participation and leadership – enabling patient lives to be transformed.



"Well-defined regulatory review processes, focus on quality and significant medical expertise."

Sanofi is committed to a more open and productive research & development model, focused on patient needs and based on biotechnology. This model significantly accelerates the pace and enhances the productivity of research, driving the development of more effective health solutions in major therapeutic areas. In light of this, South Korea is one of the countries where we can work with ideal partners in developing our pipeline.

Leading hospitals in South Korea provide state-of-the-art facilities for clinical research and are dedicated to advancing medical science in collaboration with biopharmaceutical partners. Over the past several years, Sanofi has established a comprehensive network with a number of excellent research centers. The objective of the network collaboration is to improve efficiency in clinical research. Sanofi's collaborations with the institutions have successfully demonstrated the value of such partnership across the multi-therapeutic portfolio and in all phases of research. Through the embodiment of efficient site level clinical operations, patient recruitment and access to well curated and followed-up patient biobanks, both Sanofi and the South Korean medical community have been able to work together on achieving significant advancements for patients.

Its well-defined regulatory review processes, focus on quality and significant medical expertise are additional advantages to conduct clinical research in South Korea.



ESTIMONIALS

"Swift site activations and very speedy patient enrollments with huge patient pools in many therapeutic areas."

Astellas is an R&D-driven global pharmaceutical company headquartered in Tokyo, Japan. The company was formed by the merger of Yamanouchi and Fujisawa on April 1st, 2005. "Contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products" is the Raison d'être of Astellas. Our vision is "On the forefront of healthcare change to turn innovative science into value for patients".

Our communication slogan, "Changing tomorrow," is a phrase that expresses our pledge to develop new medicines that are vital to patients worldwide. At the same time, this means that Astellas hopes to share in the bravery, hope and desires of patients.

In Korea, the Korean GCP revision to comply with ICH GCP became effective in 2001 and the separation of IND and NDA was enforced in 2002. Promptly after the implementations, we started ICH GCP-compliant clinical trials in Korea by phase 3 programs first. Since then, secure and prompt improvements in the performance of clinical trials have been successfully achieved by the extraordinary efforts of the government, academia and industry in the nation. For example, the initiation of the Regional Clinical Trial Center program in 2004, the establishment of KoNECT in 2008, and the introduction of the Global Center of Excellence initiative in 2012 contributed a lot to the evolution of clinical trial environments in Korea. Now, Korea is the second most popular Asian country following Japan for our multiregional clinical trials (MRCTs). Korea's participation in MRCTs of phase 1, 2, and 3 stages is currently our common solution.

We think swift site activations and very speedy patient enrollments with huge patient pools in many therapeutic areas are big advantages of Korean clinical trial sites. We are confident that they keep up with globally-advanced regulatory science and succeed at a world-class level in clinical trial quality also. We surely expect further and sustained growth of the clinical trial environment in Korea.



APPENDICES Related Agencies & Associations

Ministry of Health and Welfare

The vision of the Ministry of Health and Welfare (MOHW) of Korea is to "Build a Happy Society and Happiness for All." The ministry aims to achieve this goal via three core objectives: building social safety nets for a better tomorrow, taking a whole-life perspective approach to healthy living, and ensuring stability after retirement. The MOHW operates 4 departments responsible for the active implementation of the Ministry's vision, as well as 6 bureaus responsible for operational needs on a day-to-day basis. Of the 6 bureaus under the MOHW, the Bureau of Health Industry has several specific initiatives to facilitate the speedy growth of the clinical trial industry. The bureau is in charge of the establishment and coordination of the Health Industry Policy Program, which is regularly renewed. The MOHW is responsible for oversight of the health and healthcare industries, which includes all businesses involved in the provision of medical services, beauty cosmetics, pharmaceutical products and medical devices. The ministry works to foster, support and improve infrastructure for the industry through the maintenance of affiliated organizations including Korea Health Industry Development Institute (KHIDI), the governance of research and development programs, and the determination of principles for bioethics policy.

http://www.mohw.go.kr/

Ministry of Food and Drug Safety

Under the vision of "Safe Food and Medicine, Healthy Citizens, and Well-Being in Society", the Korean Ministry of Food and Drug Safety (MFDS) is making every effort to protect and improve public health through safety oversight and guidance for food, pharmaceuticals, cosmetics, herbal medicines and medical devices that are available throughout the country. The MFDS believes that only thorough regulatory provisions for all foods and medicines can truly ensure quality of life and provide a strong foundation for growth in the healthcare industry. One of the core strategies of the MFDS is a priority focus on the provision of services that are the most practical and most needed in the healthcare sector. The Ministry aims to support the bio-pharmaceutical industry as a new engine for growth in Korea, and promotes the development of cutting-edge convergent technology in medical devices with integrative support across all cycles, as well as the development of new overseas markets for Korean companies. The organization has 1 office of the director general and 7 bureaus, with the Pharmaceutical Safety Bureau and Medical Devices Safety Bureau being heavily involved in clinical trial regulations. The Clinical Trials Management Division under the Pharmaceutical Safety Bureau provides guidance and interpretations of Korean Good Clinical Practice and is responsible for authorizing all clinical trials throughout the country. Both bureaus have divisions focused on the evaluation of safety for pharmaceutical products and medical devices.

http://www.mfds.go.kr/

Korea Health Industry Development Institute

Korea Health Industry Development Institute (KHIDI) is a government-affiliated institution that provides professional and systematic support for the development of the domestic health industry and enhancement of healthcare services. Since its establishment in 1999, KHIDI has led the expansion of healthcare R&D investment and consistently promoted the competitiveness of Korea's healthcare industry in regards to its health services, pharmaceuticals, medical devices, cosmetics/nutraceuticals and food products. KHIDI has earned an outstanding reputation through its years of efforts for international expansion and outreach in this sector, and has witnessed the rapid growth of the global healthcare sector within Korea. KHIDI has been proud to play a major role in the pharmaceutical industry's development as the nation's only organization fully dedicated to fostering growth in the health industry. The institute has striven to produce more successful research outcomes via greater investments in Health Technology (HT) R&D. Furthermore, initiatives have been taken to improve competitiveness in specific areas of the health industry. For those interested in starting clinical research in Korea, KHIDI's Industry Promotion Center is available for help. The center provides comprehensive information on research-oriented hospitals, as well as Korea's pharmaceutical and medical devices industry.

https://www.khidi.or.kr/eps

Korea Drug Development Fund

Established in September 2011, the Korea Drug Development Fund (KDDF) is a government-affiliated program providing financial support for R&D efforts. With a budget of 1 billion US dollars to enhance national competitiveness in the global arena the program aims to transform Korea into a global leader in new drug development. KDDF is now backed by three health-related Korean ministries: the Ministry of Science, ICT, and Future Planning, the Ministry of Trade, Industry, and Energy, and the Ministry of Health and Welfare. In the first phase of its business strategy, KDDF opened up its own platform to invest in global drug development. It has created an outstanding screening system to evaluate research and development (R&D) projects, coupled with a successful milestone-based output management system. This platform further aims to establish channels between academia, research institutes, government organizations and industry, to ultimately create an extensive human resources pool of healthcare professionals for continued success in drug development. Currently, a number of tools have been developed and/or are in use, including: mutual recognition systems for IRB review processes, common IRB review application forms, and eCRFs which enable auto-migration of data in electronic health records.

http://www.kddf.org/

Korea Pharmaceutical and Bio-Pharma Manufacturers Association

Since its foundation in 1945, the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) has worked to strengthen collaboration between new companies and mature companies that have experience with product launches in overseas markets. The KPBMA envisions the achievement of this goal through timely manufacturing plans and adequate provision of high-quality medicines. In particular, the KPBMA aims to enhance the global competitiveness of Korea's pharmaceutical industry by increasing R&D investments, and lay the groundwork for fair competition in the industry by establishing solid partnerships with external stakeholders. With approximately 190 member companies, KPBMA has witnessed expanded R&D investments since the implementation of the Drug Substance Patent Law in 1987, which helped place Korea as one of the world's top 10 countries for the commercialization of new molecular entities in 2003. Over 2 trillion won was collectively invested by 65 companies to upgrade manufacturing plants in compliance with c-GMP standards. In addition to increased credibility and fair competition in the international pharmaceutical market, the Fair Competition Committee and the Hotline Reporting Center for code compliance complaints were established. KPBMA is also collaborating with the Korean Research-based Pharmaceutical Industry Association to hold the annual Korea Pharma Associations Conference. Rapid growth in the Korean pharmaceutical market can be attributed to continuous investments in R&D and GMP accreditation aligned with KPBMA's efforts.

http://www.kpbma.or.kr/

Korean Research-based Pharmaceutical Industry Association

The Korean Research-based Pharmaceutical Industry Association (KRPIA) was established in March 1999 with 24 pharmaceutical companies sharing a research orientation toward the generation of scientific and clinical evidence for both newly developed and already marketed drugs. The KRPIA and its member companies strive to build the policy environment needed to expedite R&D for innovative new drugs, and sustain amicable cooperative relationships between stakeholders in the industry. The Association has made numerous significant contributions to Korean society, including the development and supply of pharmaceutical products with a heavy therapeutic focus on serious diseases. It promotes mutual growth through collaborative partnerships to enter overseas markets and foster open innovation. KRPIA partners with the Korea Pharmaceutical Manufacturers Association each year to hold the annual meeting of the Korea Pharma Associations Conference. The KRPIA will continue to attract the interest of global pharmaceutical companies to Korea's local R&D efforts and strengthen its competitiveness in the global market. KRPIA also seeks to promote transparency in Korea's pharmaceutical industry through ethical management and improved drug pricing systems.

http://www.krpia.or.kr/

Korean Association of Institutional Review Boards

The Korean Association of Institutional Review Boards (KAIRB) was founded on March 18, 2002, with a mandate to ensure the highest globally-recognized standards of bioethics and safety in the area of clinical research. It seeks to promote ethical oversight for scientific and socially-responsible clinical research, with adherence to Korean Good Clinical Practice (KGCP) and ICH guidelines. A number of initiatives and workshops focusing on the development and improvement of ethics reviews for clinical trials have been organized by KAIRB since its foundation. As a result, overall awareness in Korea for the importance of research ethics has been improving not just among professionals in the biomedical research community, but also among the general public. KAIRB will continue to play an important role in advancing research ethics and research review capacities throughout the country. The organization continually reviews global standards in research ethics to disseminate the most updated guidances among Korea's institutional review boards to their advance research ethics and review capacities. It also focuses on improving coordination for faster responses and better economic efficiency in reviews. To achieve these goals, KAIRB holds regular meetings and training programs for healthcare professionals aimed at enhancing their understanding of research ethics.

KoNECT, the Gateway to Clinical Trials in Korea

KoNECT (Korea National Enterprise for Clinical Trials) was established in 2007 as a non-profit organization funded by the Korean Ministry of Health and Welfare to support multinational clinical development and to promote Korea's clinical trial capabilities. Since then, KoNECT has been committed to the development of clinical trial standards and infrastructure in Korea

The organization is dedicated to building stronger relationships between academia, government and industry to enhance the capabilities of clinical trial stakeholders in Korea, and for international collaboration in clinical trials.

KoNECT provides one-stop service for smooth planning and faster initiation of clinical development in Asia.

In 2014, KoNECT opened the KoNECT Collaboration Center to support local and international sponsors planning to conduct clinical trials in Korea, KoNECT provides information through the KoNECT website and serves as a one-stop shop for clinical trial planning in Korea. The center offers a wealth of information and other related services.

https://www.konect.or.kr/en/index.do

For further information about KoNECT and its services, please contact: kcc@konect.or.kr





What can KoNECT do for your clinical trial?

 The KoNECT International Conference, supported by the Ministry of Health and Welfare annually brings together more than 1,000 attendees from across government, academia and industry to share up-to-date topics on clinical trials and development. The program focuses on key issues, challenges and opportunities in the clinical research arena including regulatory sciences, real world studies, data-driven clinical development, continuously evolving ethical issues, and patient-centric approaches. More information is available at: www.konectintconference.org



2. Investigator Networks

To fulfil unmet medical needs in cancer patients especially in Asia, KoNECT works with Asia/Korea collaborative study groups and pro motes earlier translation and achievement of POC for new targets and molecules.



3. STUDY feasibility based on EMR data

For a stakeholder to enter into Korea for clinical development, it is paramount to identify site feasibility in Korea. To support study feasibility in Korea, KoNECT provides study feasibility service by cooperating with major hospitals, and major hospitals identify the patient population with target indication based on Electronic Medical Record (EMR) system.



Currently, 8 major hospitals are participating in study feasibility service as follows. Ask us, or find out more at: www.konect.or.kr/en/index.do

















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