The Right Place For Clinical Trials In Asia

START WITH KOREA

Ministry of Health and Welfare

KONECT
Korea National Enterprise for Clinical Trials

DISCLAIMER

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KoNECT, the Gateway to Clinical Trials in Korea

The Ministry of Health and Welfare (MOHW) originally established the Korea National Enterprise for Clinical Trials (KoNECT) to build clinical trial capacity and capabilities in 2007. 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 a one-stop service and space for new sponsors to Korea for smooth planning and faster initiation of their clinical trials.

In 2014, KoNECT opened KoNECT Collaboration Center (KCC) to support global and other sponsors who are planning clinical trial in Korea. KoNECT provides information through KoNECT Integrated Clinical Trial Information System (KIIS) and also a one-stop-shop service for clinical trial planning in Korea. We also provide incubator office with administrative support, clinical trial interactive gallery, and others from KCC. It is a mixture of information, service, and work space. (http://kcc.konect.or.kr/)

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

KCC

One-Stop Shop
for your clinical trial planning, accelerating the smooth and efficient conduct of clinical trials in Korea

An Open Community
for networking and business partnering between different parties involved in the field of clinical research

A Flagship Store
experiencing capabilities of the Korean clinical trial industry

INTRODUCTION

For study sponsors, the success of a development program can depend upon choosing the right country to conduct clinical trials. A comprehensive understanding of the quality, reliability and benefits that are intrinsic to each location is therefore critical for the decision-making process. Korea's clinical development landscape is characterized by rich experience, cutting-edge infrastructure and an exceptionally supportive government that together provide a highly favorable ecosystem for clinical development.

Korea is rapidly becoming recognized as a global leader in clinical research, standing as a Top 10 location worldwide in terms of the number of studies conducted annually. International sponsors cite numerous advantages within the country that consistently ensure speed and quality for the conduct of their clinical trials. In addition to a high population density, the Korean healthcare system provides universal coverage and is characterized by clusters of high-capacity hospitals concentrated in large cities like Seoul. Optimized recruitment practices combined with the large volumes of daily patient traffic that these institutions receive allow for rapid recruitment and accelerated study start-up times.

Korea has one of the world's most efficient clinical trial approvals (30 working days), and its medical institutions and practices meet the highest international standards. Korea's research-intensive ecosystem of collaborative innovation along with the rapid growth of R&D expenditure has increased the diversity of global talent found within the country, complemented by some of the most advanced IT infrastructure and training. With a highly educated and motivated workforce, Korean sites have proven track records in quality and efficiency in clinical trials.

Another significant advantage is the extensive support provided by the Korean government for the pharmaceutical R&D industry and clinical trials, including the establishment of the Korea National Enterprise for Clinical Trials (KoNECT) and designation and support of Research-driven Hospitals, Regional Clinical Trial Centers and Global Clinical trial centers of Excellence. The data generated by Korean sites are accepted for Japanese registration, which allows for a flexible regulatory strategy for Asian development, facilitating regional research networks and ultimately reducing the drug lag in this region.

For those seeking a strategic edge in clinical trials, start with Korea.

OVERVIEW OF CLINICAL TRIALS IN KOREA

COUNTRY PROFILE

Population

50 million, with 25% concentrated in Seoul Metropolitan Area

Land Area

100,000 km^2

Main Cities

Seoul, Busan, Incheon, Daegu, Daejeon and Gwangju. Each of these cities has a population of more than 1 million and the Seoul Metropolitan area has more than 10 million.

Location

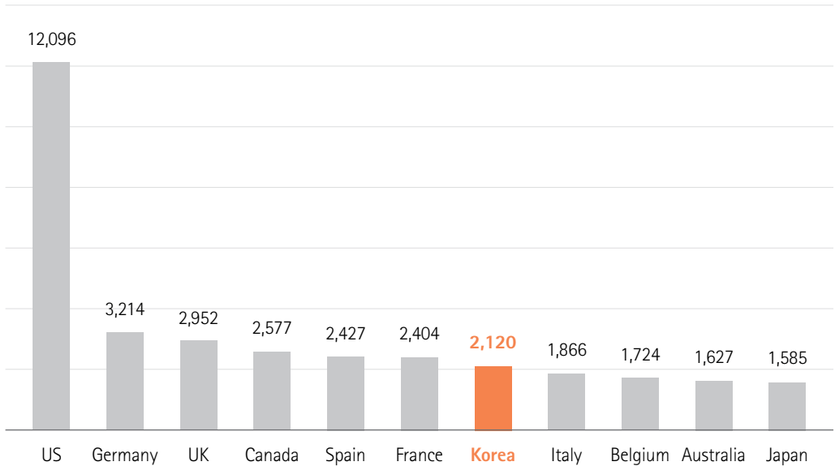
The southern portion of the Korean Peninsula is flanked by the Yellow Sea to the west, and the East Sea to the east. It is only two hour flight from major cities in China and Japan

Healthcare system

Centralized healthcare system through universal National Health Insurance that covers 98% of the population comprising very large and modern hospitals with world-class quality of care and 66 hospitals per million population, the second highest among OECD members.

Korea Occupies the Natural Connecting Route between the Japanese Archipelago and China

Korea has conducted more industry-sponsored drug studies than any other Asian countries for past 5 years. Korea has been ranked the top 10 country since 2011 and the country's capital of Seoul has remained the world's top city for the number of industry sponsored drug trials.[1]

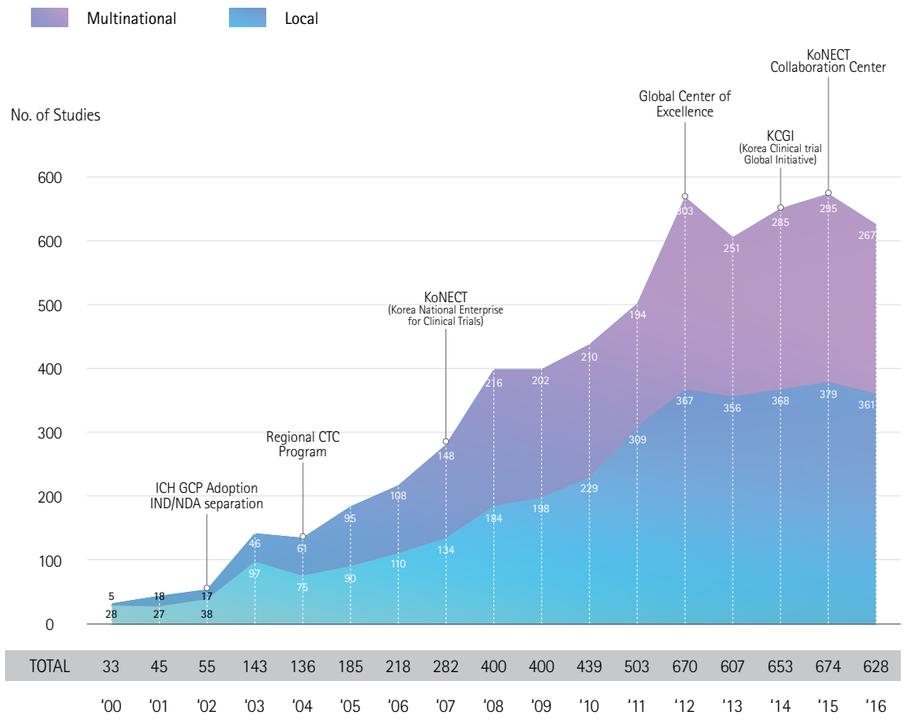


Number of Industry-Sponsored Interventional Drug Trials in Top10 Countries, 2011-2016

Source: KoNECT's analysis of ClinicalTrials.gov data

Korea Overview

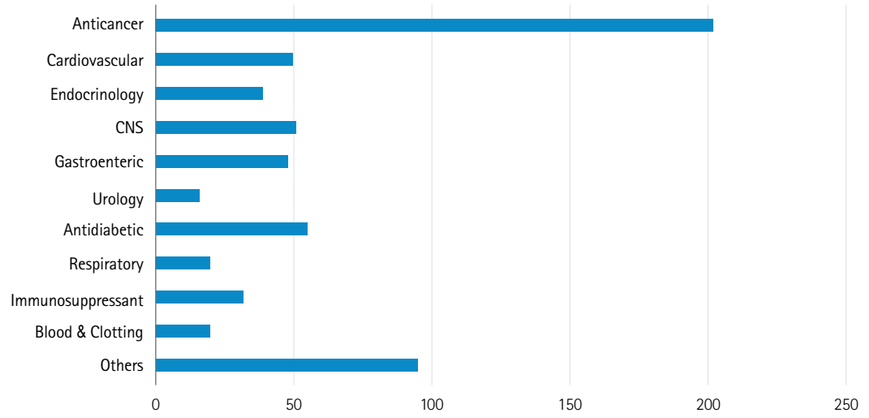
Korea Good Clinical Practice (KGCP) was legislated in 1995, with an amendment in 2001 in order to adopt ICH-GCP. Following the introduction of a new Clinical Trial Authorization (CTA) process in 2002, the number of multinational trials began to increase rapidly. Strategic government investments were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



Growth of Korea's CTA Approvals and Government Initiatives

Source: Ministry of Food and Drug Safety (MFDS)

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



The number of CTA Approval by Therapeutic Area [N=628], 2016

Source : Ministry of Food and Drug Safety [MFDS]

The vast majority of international pharmaceutical companies and CROs have a presence in Korea as trial sponsors or operators. Korean local CROs are also growing rapidly with accumulated expertise from participation in local and multinational trials, and provide the full range services needed for trial planning and execution.

Top 10 Multinational CTA Holders in Korea, 2014-2016

Rank	2014 (N=652)		2015 (N=675)		2016 (N=628)	
	Sponsor	Number of CTAs	Sponsor	Number of CTAs	Sponsor	Number of CTAs
1	Quintiles	31	Quintiles	35	Quintiles	42
2	Novartis	26	Novartis	18	Eli Lilly	16
3	MSD	18	Janssen	18	PPD	15
4	GlaxoSmithKline	15	MSD	17	Janssen	14
5	PPD	15	PPD	17	MSD	13
6	PRA	15	AstraZeneca	15	Novartis	12
7	Pfizer	14	PRA	13	Parexel	22
8	Boehringer Ingelheim	13	inVentiv Health	11	Covance	10
9	AstraZeneca	13	Covance	11	INC Research, Beohringer Ingelheim, GSK	9
10	Bayer	11	BMS, Bayer, Alvogen, Roche, Eli Lilly	10	Abbvie	8

Source: Ministry of Food and Drug Safety (MFDS)

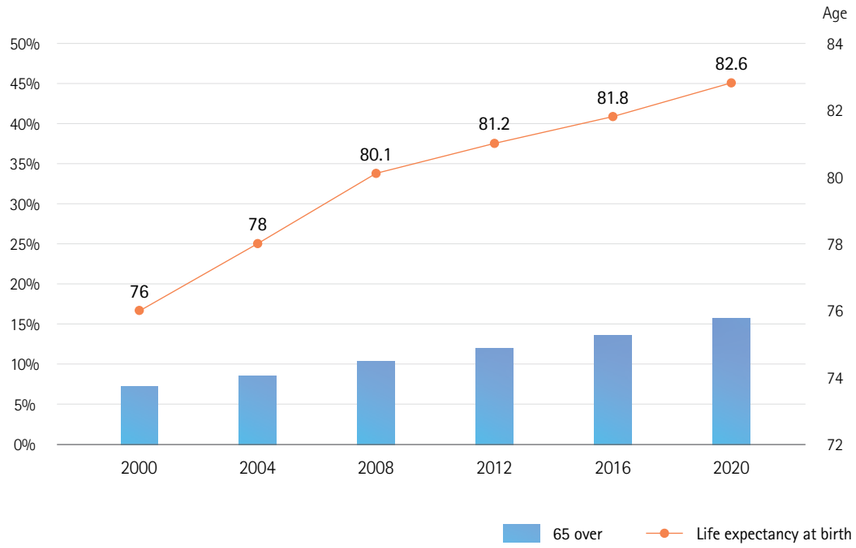
KOREA: A COMPETITIVE EDGE IN CLINICAL TRIALS

Favorable Demographics

- High Population Density with Aging Population

Korea is one of the world's most densely populated countries, with a total population of over 50 million (approximately double that of the Canadian and Taiwanese populations). The country tops out at more than fifteen times the average population density of the United States.[2]

Korea is also one of the most rapidly aging societies in the world with a life expectancy at birth of 81 years.[3]

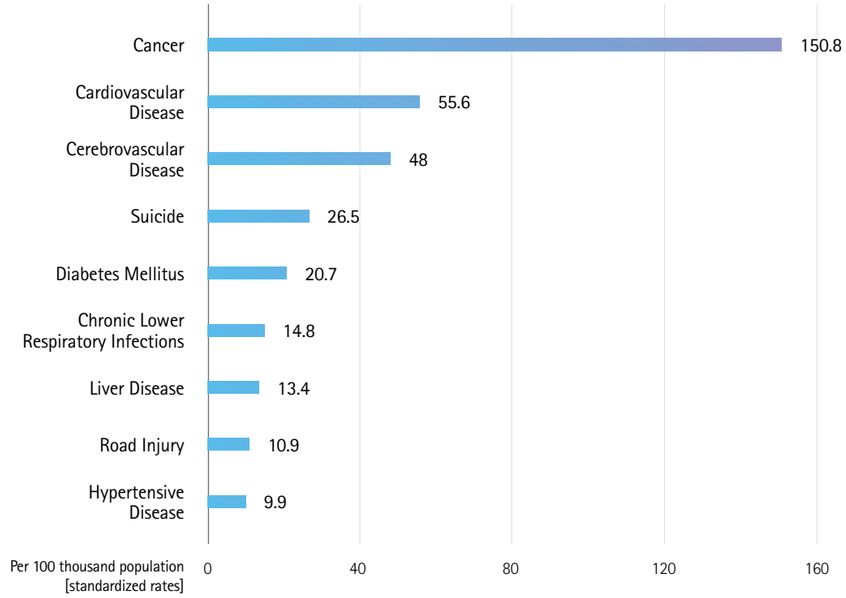


Current and Projected Demographics for Korea, Showing a Rapidly Aging Population, 2000-2020

Source: Statistics Korea

- Workforce with Higher Education

Korea's secondary education system is one of the strongest in the OECD, as measured by average student scores in literacy, math and science. Throughout the country, 82% of adults aged 25-64 have further pursued upper secondary education, which is significantly higher than the OECD average of 76%.[4] The clinical trial sector in particular places a heavy emphasis by mandating continuing education, with ongoing workshops and certification programs held throughout the year.



Major Causes of Death in Korea, 2015

Source: Statistics Korea

- Westernized Disease Pattern and Clinical Practice

Due to high standards of living and clinical practice, disease patterns in Korea are similar to those in Western countries and Korea patients have similar unmet medical needs that Western countries have. Cancer was the leading cause of death in the country in 2015, accounting for 27.9 percent of all deaths reported, followed by cardiovascular diseases, which accounted for 10.3 percent of all deaths. Together with the aging of the population and an easily accessible healthcare system, the high incidence of these chronic diseases ensures large and relevant patient populations.

World-Class Infrastructure & Medical Care

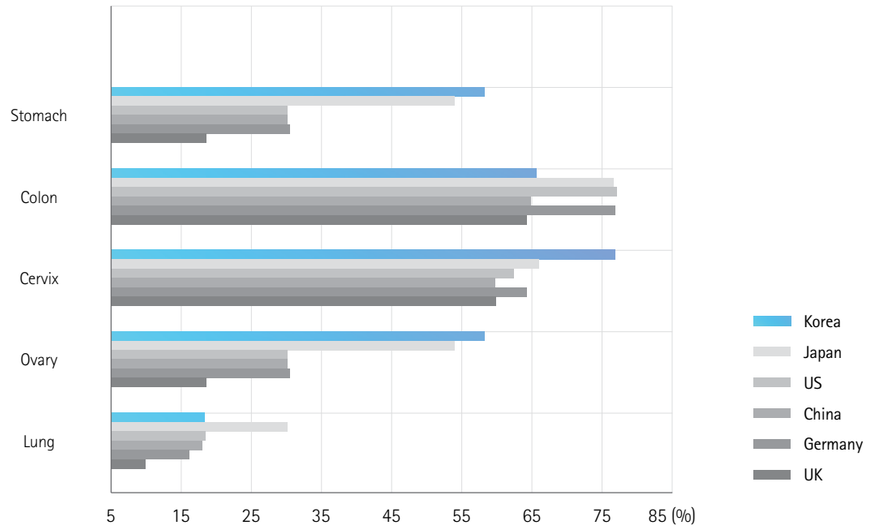
- An Outstanding National Healthcare System

A centralized healthcare system supported by near-universal National Health Insurance covers 98% of the Korean population. All citizens are covered under the system for preventative care, treatments and medication for both outpatient and inpatient needs. In 2015, the system handled 906 million outpatient visits and 16.4 million hospitalizations.[5]

For the provision of healthcare services, 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.

Healthcare services are primarily provided by hospitals with advanced facilities and cutting-edge technology, with the level of care monitored continuously by the government through hospital accreditation and evaluation programs aimed at ensuring the quality of both hospital practices and patient management.

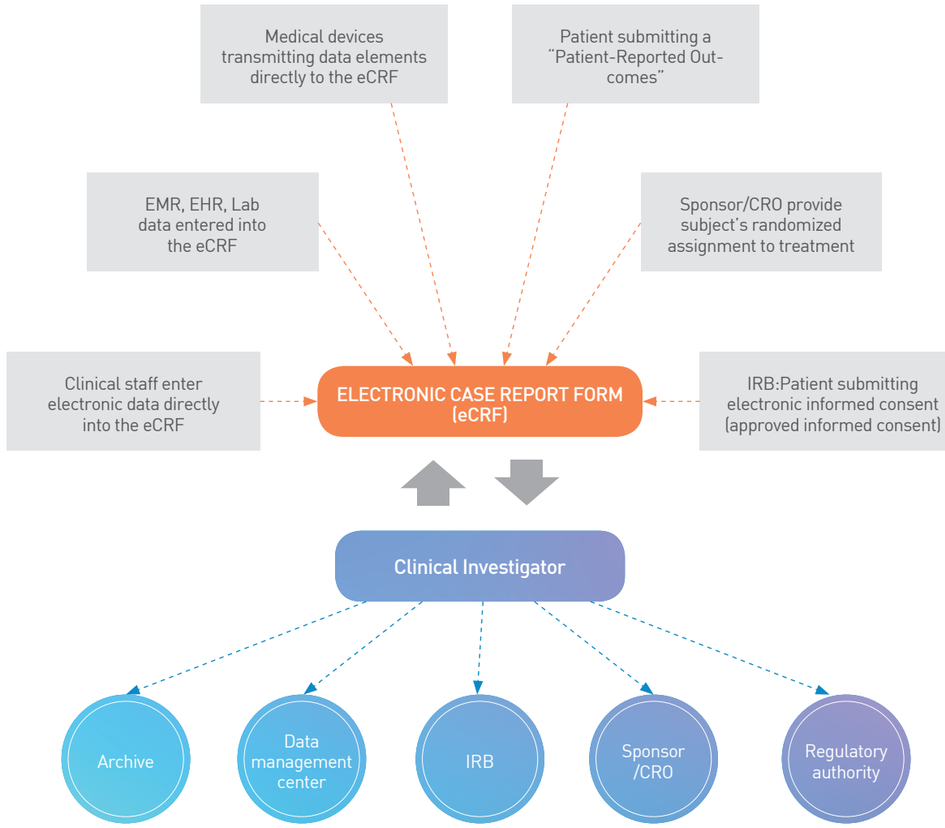
Korea provides top-tier medical care for cancer treatment. For some major types of cancer, the 5-year relative survival rates rank among the highest in the world.



5-Year Cancer Survival Rates [Age Standardized]
Source: Allemani et al., Lancet 2015

- EMR System for Efficient Clinical Research

Modern medical software is also used extensively to enhance clinical trial efficiency and quality. Most Korean hospitals have adopted electronic medical records (EMRs) and use picture-archiving-and-communication systems (PACS). Many clinical trial sites utilize EMR and/or electronic health records (EHR) systems for clinical trial feasibility assessment and data capture. Concurrent with the increasing usage of EMR for site feasibility, hospitals in Korea are developing clinical data retrieval systems (CDRS) that enable queries of anonymous EHR data and assessments of pool sizes of eligible patients meeting inclusion/exclusion criteria.



Electronic Data Capture Made Easy Using A Standardized eCRF in Major Centers

Streamlined Regulatory Process & Faster Study Start Up

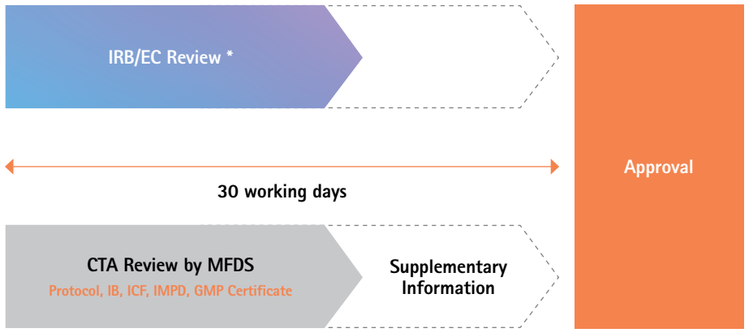
- Clinical Trial Authorization (CTA) Process

The CTA process was introduced by the Korean government in 2002, which has continuously sought to improve the nation's regulatory environment through careful analysis of the industry and global trends.

After a submission, the Ministry of Food and Drug Safety (MFDS) issues either a response for trial approval or a request for supplementary information to the applicant within 30 working days.

The CTA procedure in Korea allows for applications to be submitted in parallel to institutional review boards (IRBs)/Ethics Committees (ECs) and the MFDS. This has greatly reduced the time taken until clinical trial approval. In general, the entire process from submission of application until clinical trial approval takes between 6 to 10 weeks.

Most sites regularly meet for IRB reviews at least monthly and hold expedited review meetings as necessary.



CTA : Clinical Trial Application
IB : Investigator's Brochure
ICF : Informed Consent Form
IMPD : Investigational Medicinal Product Dossier

* Individual Site's IRB/EC requirments are available at http://kiis.konect.or.kr/

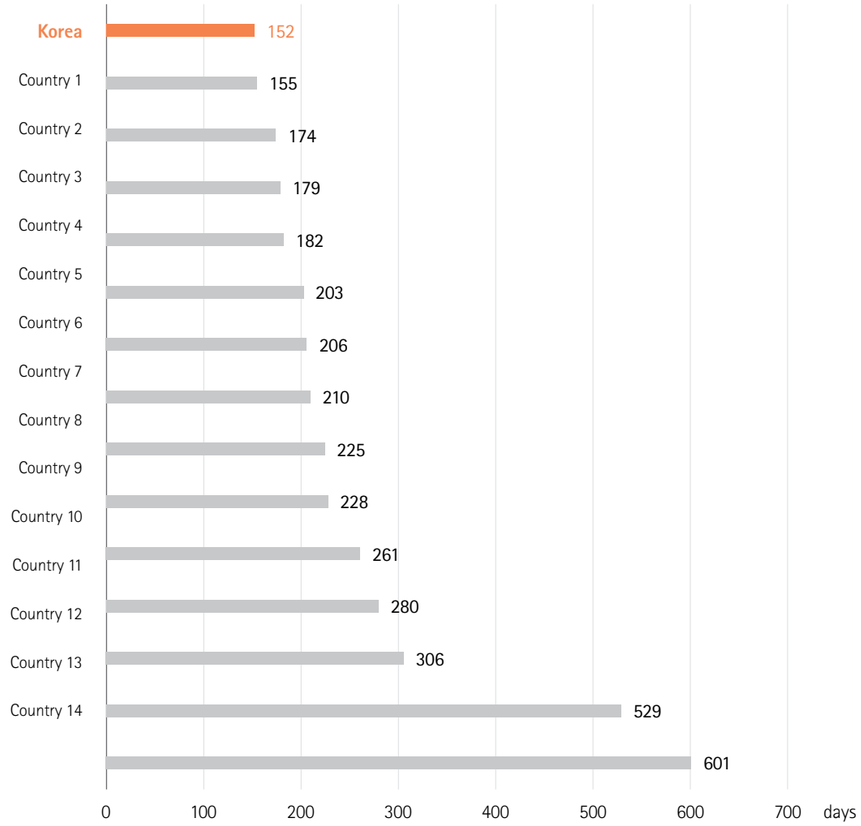
Clinical Trial Authorization Process

Source: KoNECT

- 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 has shown more competitive SSU timelines than other countries.



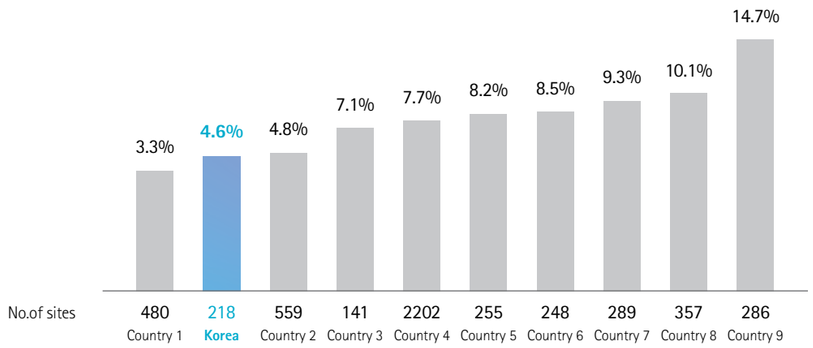
Protocol to Study Start-Up in Countries† for Top 10 R&D Pharma. Companies

†Top 15 countries based on number of study sites

Source: KoNECT

Site Excellence & Study Quality

Korean sites have shown better performance in patient recruitment, ensuring greater confidence for sponsors in involving Korean sites.



Proportion of Non-Recruiting Sites in Countries† for Top 10 R&D Pharma. Companies

†Top 10 countries based on number of study sites

Source: KoNECT

In order to ensure greater levels of integrity, the Regulation for the Designation of Clinical Trial Institutions states that only institutions designated by the Korean regulatory authorities (MFDS) are permitted to engage in clinical trials. Currently there are 184 institutions that are designated clinical trial sites, with every site under continual government oversight. Assurances for quality and ethical standards are provided by the Korean government through annual evaluations, with full public disclosure of the evaluation results made available online.

The site personnel involved in clinical trials are required to complete a minimum number of annual training hours for GCP training, as mandated by the MFDS.

Clinical research sites in Korea are supposed to be 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.

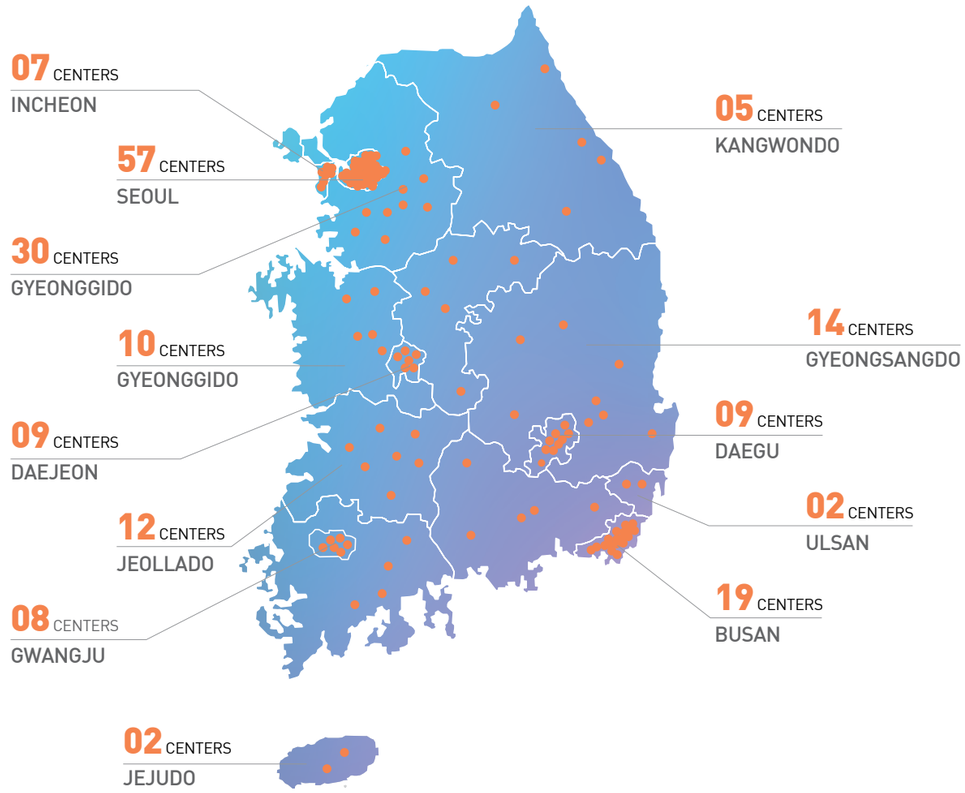
For example, between 1 October 2008 to 30 September 2015, 37 US FDA inspections were undertaken by CDER and CBER in Korea. For all 37 cases, there were no Official Actions Indicated (OAI).[6]

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.

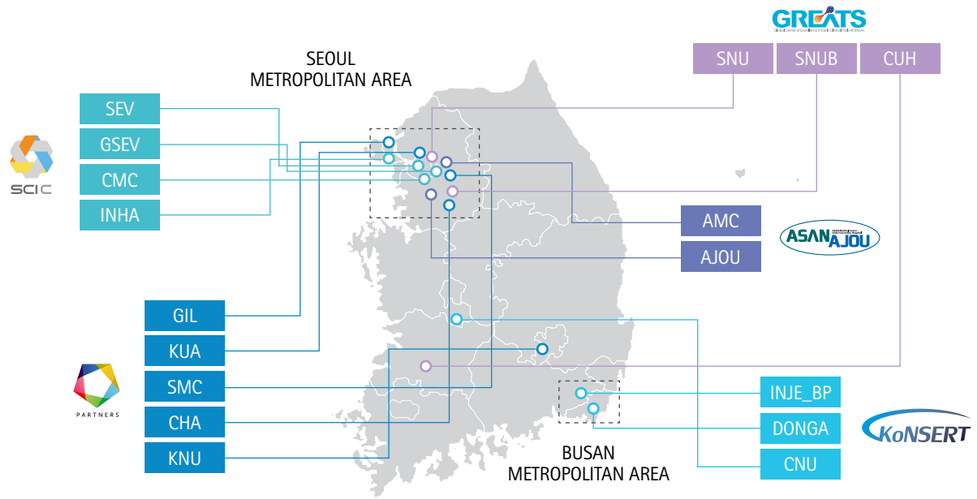
Korean sites have repeatedly demonstrated their better performance in patient recruitment, ensuring greater confidence for sponsors when involving Korean sites.

Clinical Trial Sites Designation by Government

Based on 'Regulation on Designation of Clinical Trial Sites', 184 medical institutions are designated by the government as qualified clinical trial sites. (as of December 2016)



KCGI and Global Centers of Excellence in Clinical Trials



SEV	Severance Hospital	SNU	Seoul National University Hospital
GSEV	Gangnam Serverance Hospital	SNUB	Seoul National University Bundang Hospital
CMC	The Catholic Univ. Korea Seoul St. Mary's Hospital	CUH	Chonbuk University Hospital
INHA	Inha University Hospital		
		AMC	Asan Medical Center
GIL	Gachon University Gil Medical Center	AJOU	Ajou University Hospital
KUA	Korea University Anam Hospital		
SMC	Samsung Medical Center	INJE_BP	Inje University Busan Paik Hospital
CHA	Cha University Bundang Cha Hospital	DONGA	Donga University Hospital
KNU	Kyungpook National University	CNU	Chungnam University Hospital

The Global Centers of Excellence Program by Korea Clinical Trials Global Initiative, funded by an R&D grant from the Ministry of Health and Welfare, supports 5 consortia (different colored boxes) located around the nation

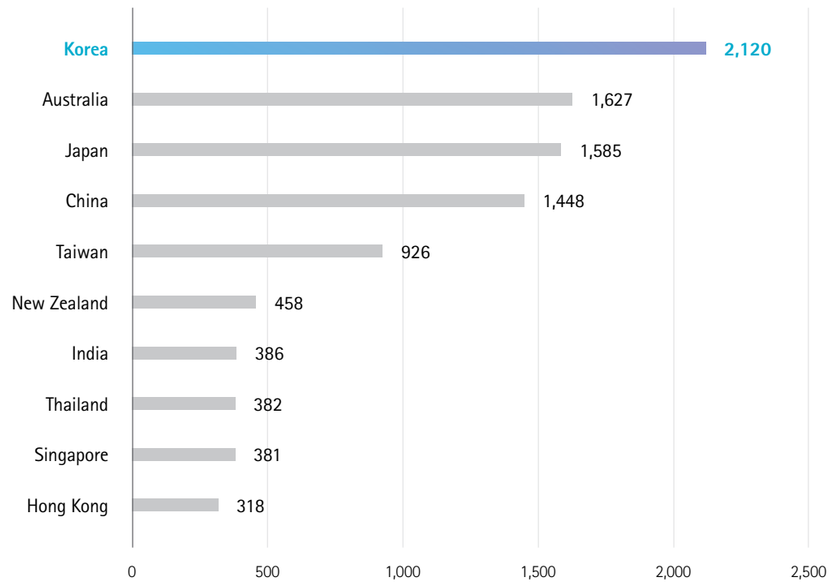
Korea Clinical Trials Global Initiative (KCGI) is one of the major initiatives placed by the Ministry of Health and Welfare (MOHW) through KoNECT to promote clinical and translational research through reforming and renovating research infrastructure at the leading university hospitals as core investigative sites. KCGI's Global Centers of Excellence (GCE) program provides grants to the top 5 university hospitals' consortia to set up and upgrade their clinical trials centers (CTCs) for early phase clinical development, focusing on specialized therapeutic areas or unmet R&D needs.

Accumulated Experience in Drug Clinical Trials

Korea has collectively accumulated extensive experience in clinical trials in diverse therapeutic areas and ranks as the top country for clinical trial conduct in Asia. The government has laid out a credible roadmap to ensure growing participation in local, regional, and global drug development.

Trial data generated in Korea have frequently been accepted for drug registration in Japan. With acceptance of data from regional clinical trials, countries in Asia, including Korea, Japan, China and Taiwan, can collaborate closely to build up regional research networks and reduce drug approval timelines within the region.

Efforts continue at the national level to further enhance clinical trial capabilities for global development, and focus on the consolidation of existing research activities and scientific expertise, optimization of critical clinical trial resources, and the creation of international platforms for collaboration.



Number of Industry-sponsored Drug Trials in Asia Pacific, 2011-2016

Source: KoNECT's analysis of ClinicalTrials.gov

WHY KOREA

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 conduct 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.

AstraZeneca

Image and Text Provided Through AstraZeneca's Courtesy

Sanofi

"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.

SANOFI

Image and Text Provided Through Sanofi's Courtesy

Astellas

"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.

astellas
Leading Light for Life

Image and Text Provided Through Astellas' Courtesy

INC Research

"A broad range of scientific talent and medical infrastructure"

The pharma and biotech customers that INC Research (a global CRO) supports, have a significant focus on innovative and targeted therapies to treat cancers often requiring at present sophisticated screening for tumor molecular abnormalities prior to matching "the right patient to the right trial".

As such, we support a collective interest in accessing South Korea's broad range of scientific talent and medical infrastructure to support development of novel medicines. We have conducted over 28 studies in Oncology at 31 medical institutions in South Korea since 2012, and we currently represent 14 biotech/pharma companies in 18 active trials with over 50 clinical lead-investigators.

The trial sponsoring companies we support reflect a range of US and European biotechnology groups, multinational pharmaceutical companies, and international cooperative oncology groups. Typically about 40-50% of these trials are first-in-patient trials with targeted oncology therapies (notably lung and GI cancers at present), with the balance being multi-country international Phase II/III trials.

South Korea is an important medical study location, and INC Research is pleased to collaborate with institutes and investigators to advance leading-edge biotechnology research for the benefit of cancer patients. We therefore maintain a dedicated office and clinical trial support staff in Seoul, S. Korea to support our customers' needs to place research studies into the dynamic and innovative medical and clinical trial environment we see in this country's major medical centers.

inc Research

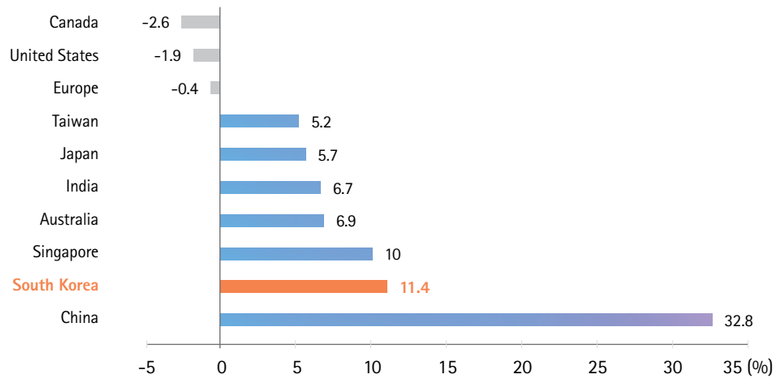
Image and Text Provided Through INC Research's Courtesy

KOREA'S PHARMACEUTICAL MARKET LANDSCAPE

The Korean pharmaceutical market is estimated to be worth more than USD $19 billion annually, according to data published by the Korea Health Industry Development Institute (KHIDI). In terms of production, it presently contributes 1.9% of the global pharmaceutical market. Growth is projected to continue at an annual rate of 10% at the domestic level, surpassing the world average of 6-7%.

The Korean pharmaceutical industry has been accelerating 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.

The Korean Ministry of Food and Drug Safety has approved 26 new domestically-developed drugs, as well as the world's first monoclonal antibody biosimilars.[7]



5-Year Cancer Survival Rates [Age Standardized]

Source: Allemani et al., Lancet 2015

Innovative New Drug Developed in Korea Since 1999

NO	Product	Company	Indication	Approved date
1	Sunpla injection	SK Chemical	Stomach Cancer	Jul. 1999
2	EGF topical solution	Daewoong Pharm. Co., Ltd.	Skin Ulceration	May. 2001
3	Milican	DongWha Pharm	Liver Cancer	Jul. 2001
4	Q-roxin Tablet	Choongwae Pharma Corporation	UTI	Dec. 2001
5	Factive Tablet	LG Life Science Ltd	Antibiotic	Dec. 2002
6	Apitoxin	GuJu Pharm. Co., Ltd.	Osteoarthritis	May. 2003
7	Psedovaxin injection	CJ	Antibiotic	May. 2003
8	Camtobell injection	ChongKunDang Pharm. Corp.	Anticancer	Oct. 2003
9	Revanex Tablet	Yuhan Corporation	Peptic Ulcer	Sep. 2005
10	Zydena Tablet	Dong-A Pharm. Co., Ltd.	Erectile Dysfunction	Nov. 2005
11	Levovir Capsule	Bukwang Pharm. Co., Ltd.	Hepatitis B	Nov. 2006
12	Pelubi Tablet	Daewon Pharm. Co., Ltd.	Osteoarthritis	Apr. 2007
13	Mvix Tablet	SK Chemical	Erectile Dysfunction	Jul. 2007
14	Noltec Tablet	Ilyang. Co., Ltd	Peptic Ulcer	Oct. 2008
15	Kanarb Tablet	Boryung Pharm. Co., Ltd.	Hypertension	Sep. 2010
16	Pyramax Tablet	Shinpoong Co., Ltd.	Malaria	Aug. 2011
17	Zepeed Tablet	Choongwae Pharma Corporation	Erectile Dysfunction	Aug. 2011
18	Supect Capsule	Ilyang. Co., Ltd	Anticancer	Jan. 2012
19	Zemiglo Tablet	LG Life Science Ltd.	Type II Diabetes	Jun. 2012
20	Duvie Tablet	ChongKunDang Pharm. Corp.	Type II Diabetes	Jul. 2013
21	Riavax injection	Gemvax & Kael Co., Ltd.	Anticancer	Sep. 2014
22	Acelex	Crystal Genomics	Osteoarthritis	Feb. 2015
23	Zabolante	DongWha Pharm	Antibiotic	Mar. 2015
24	Sivextro Tablet	Dong-A ST	Antibiotic	Apr. 2015
25	Sivextro Injection	Dong-A ST	Antibiotic	Apr. 2015
26	Suganon Tablet	Dong-A ST	Type II Diabetes	Oct. 2015
27	Olita Tablet	Hanmi Pharm,Co.,Ltd.	Interstitial Lung Disease	May 2016
28	Besivo Tablet	Ildong Pharmaceutical, Co.,Ltd	Hepatitis B	May 2017

Source : Ministry of Food and Drug Safety (MFDS)

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/neutraceuticals 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.

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

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.

https://www.kairb.org/

GREATS
Global Center of Excellence in Early Clinical Trials @ SNUH

Become Great Through GREATS

SEOUL NAT'L UNIV HOSPITAL

ABOUT GREATS CONSORTIUM

SNU BUNDANG HOSPITAL

CHONBUK NAT'L UNIV HOSPITAL

WHAT WE DO

- **SNUH**-Global Center of Excellence in Early (General & Rare Disease) Clinical Trials
- **SNU Bundang**-Global Center of Excellence in Geriatric Early Clinical Trials
- **CUH**-Global Center of Excellence in Natural Medicines

HOW WE DO

Core Values

Guiding
GREATS guides you through the maze of successful clinical trial projects

Respectful
GREATS is respectful of your unique clinical trial needs

Ethical
GREATS is ethical in every conduct of its clinical trial business : it always puts human rights first

Adept
GREATS works skillfully to get the job done

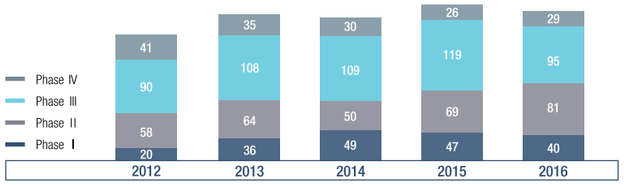
Trustworthy
GREATS is reliable, responsible, and can be trusted completely

Sustainable
GREATS provides you with a sustainable clinical trials infrastructure

ASAN Medical Center
AJOU University Hospital

ASAN Medical Center

Clinical Trials in Asan Medical Center



Efficient & Speedy Operation of Clinical Trials

AMC IRB accepts English version protocols for phase 1studies in healthy volunteers & patients
First in Korea

IRB review & contract negotiation proceed in parallel

Shorter turnaround time
AMC provides at least one month in advance of your timeline

Accurate feasibility and pre-screening by
clinical research data warehouse & electronic management

High volume center
the highest patient volume in Korea

2,714 Beds

1,671 Doctors

11,380 Out-patients
(on Daily Average)

2,499 Admissions
(on Daily Average)

1,100 Clinical Trial
(on going)

9 Per Month,
IRB Regular Review

39 Research Beds with Dedicated Study Team

Ajou University Medical Center

Excellence in Clinical Trial

- Phase Ⅰ to Ⅳ clinical trials & IIT supporting
- Optimal research environment
- Dedicated Phase Ⅰ research unit

Reliable Partner in Investigator Sponsored Trial

- Academic Research Organization Full Service
- ANYCAP system development

Innovative coaching of Pharmaceutical Industry

- Clinical development Accelerated center (CDAC)
- Clinical Translational research services

We are always there for you

We are committed to caring for you and your family

SCI-Consortium of Clinical Trials Centers at University Hospitals

ABOUT SCI-CONSORTIUM

The SCI Consortium (hereafter SCI-C), consists of clinical trials centers (CTCs) of excellence from the four leading university hospitals in Korea.

KEY FIGURES

- More than 7.4 Million In-and Out-patients per years (5,909 Beds)
- 1,545 Clinical Investigators
- 177 Dedicated Beds for Clinical Pharmacology Study
- 1,100 Sponsored Contracts per years
- 30,000 Active Patients Enrolled in Clinical Studies
- The Most Advanced IT-based Clinical Trial Supporting System
- Recognized as Center of Excellence by Major Global Pharmas and CROs

Global Reputation

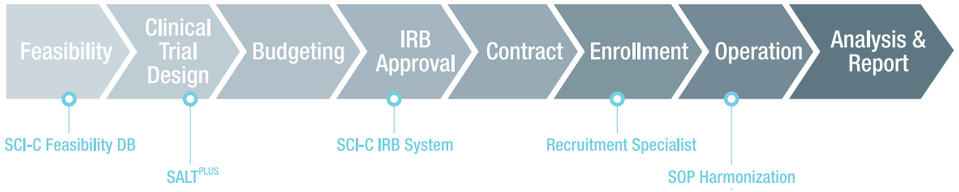
Recognized by Frost & Sullivan White Paper Titled 'Asia: Preferred Destination for Clinical Trials' as Specialized Clinical Trial Centers

FROST & SULLIVAN

DRIVE YOUR CLINICAL TRIALS THROUGH THE OPTIMIZED PATHWAY TO SUCCESS

MAIN SERVICES

One Project Management System



SCI-C Feasibility DB
Enhancing study feasibility assessment via IT-driven database

Recruitment Specialist
Effective enrollment to the patients oriented early phase trials through the pre-screening call center

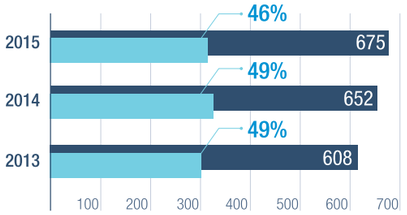
SALT PLUS (Strategic Advisory Leadership Team)
Multidisciplinary Consulting Service for Successful New Drug Development

SCI-C IRB System
The first mutual recognition system for IRB approval in Korea

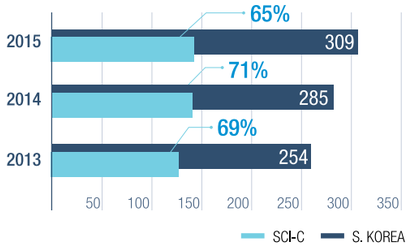
SCI-C Operation
Optimized resources for patients-oriented early phase clinical trials

PERFORMANCE IN CLINICAL TRIALS

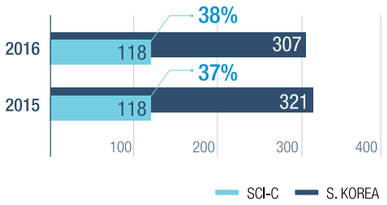
Excellence in National Performance



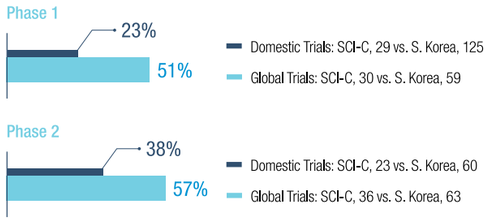
Competency in Global Clinical Trials



Early Phase Clinical Trials in Nation (Ph1 & Ph2)



More Exposure to Early Phase Global Trials in 2016



KoNSERT

COST EFFECTIVE, TIME EFFICIENT, WELL-ORCHESTRATED, AND FULLY COMPLIANT CLINICAL TRIALS

Clinical and Non-Clinical Services

Conventional Phase 1 Trials

- First-in-human
- Bioavailability / Bioequivalence
- Drug-drug(food-drug) interaction
- Special population
- Thorough QT

Technology Driven Clinical Trials

- Microdosing & human mass balance
- Cocktail studies for drug inter action potential
- Biomarker driven clinical studies (pharmacogenomics/metabolomics/imaging)
- ePOC translational research
- Phase 1 studies in target patient populations
- POC trial in treatment naive patients (KoNSERT ; Korean Network for South East Regional Network)
- Platform for combining 'Bottom-Up' PBPK and 'Top-down' PopPK data analysis

Bioanalytical / Genomics analytical Core Lab Services

- Advanced bioanalytical method development
- Protein binding assay
- In vitro metabolism, in vitro permeability and transporters
- Metabolite identification
- Genotype method development
- Haplotype and LD analysis
- Functional analysis of SNPs and copy number variation
- Gene expression profiling

Clinical Trial Core Infrastructures

QA/EDUCATION(HRPC)
· SOP Development & management
· Internal Audit-protocol specific & systems
· Internal & External Education management

CLINICAL TRIAL PHARMACY
· Storage, Dispensing
· Preparation : IV solution, suspension, encapsulation
· GMP compliant

CORE LABS(CENTRAL)
· Drug Analytical Core lab.
· Pharmacogenomics Core lab.
· Other biomarkers

DATA MANAGEMENT&BIOSTATISTICS
· Biostatistics
· Data management
· IT/DBA

COMMUNICATION/BD
· Communication
  - International/domestic
· Business developmant
· Ext. Site Managemant
  - Site coordinator

PROJECT MANAGEMENT
· Project Director
· Project Manager
  - Functional unit
  - Contract/Budget/Payment
  - Protocol/CSR medical writer

SUBJECT RECRUITMENT
· Subject registry, feasibility reply
· Call center for subject recruit
· Healthy, Patients, Special Population, Foreign residence
· Regional subject recruitment center

Clinical Trial Operation

EARLY PHASE TRIAL
· Trial in Healthy Subjects
· Trial in Patients
· Phase 0, I, IIa study conduction
· PK/PD study Design
· Specimen collection/Strorage
· Modeling/Simulation
· Clinical Pharmacologists, Physician investigators/CRCs
· Project management

LATE PHASE TRIAL
· Phase II, III, PMS conduction
· Clinical Investigators/CRCs
· OPD

IJUBP CTC

Regional Trial Infrastructure

Regional IRB
· Joint IRB/Regional IRB establish
· e-IRB set up
· Certification, Education/Training
· International certificaton [FERCAP/AAHRPP]

REGIONAL EDUCATION TRAINING CENTER
· Development and maintain education Training programs
· DB for education system
· Global education program development of material
· 1000 candidate trining

REGIONAL CENTER FOR CLINICAL TRIAL PROMOTION
· Management of KoNSERT (Korean Network of South East Regional Clinical Trial Organization) office and regional collaboration
· Clinical trial forum, event for citizens, advertise
· Strong network with domestic/global trials

C-KoNSERT

'SEE' KONSERT

Communication
Collaboration
Cooperation
Contract
Corporation
Commercial

INJE UNIVERSITY BUSAN PAIK HOSPITAL
CLINICAL TRIAL CENTER

LATE PHASE

CORE LAB./DBMS
- PK/PD
- BA/BE
- DDI
- FIH
- PGx

- Early phase in patients
- Ethnic bridging
- Healthy elderly
- Human metabolism
- PK/PD, ePOC clinical trials in healthy
- E-IND(microdosing)
- tQT

- Cardiovascular
- Arthritis
- Diabetes
- Psychiatric condition
- Renal Dysfunction
- Hepatic Dysfunction
- Osteoporosis
- Asthma
- COPD
- Parkinson
- HCV
- Hematologic malignancy
- Alzheimer

- Subject Database
- Investigator Network
- Regional Collaboration Capacity

- Providing qualified experiences on full range of clinical trials
- Supporting Business Development
- Offering infra-structured system

Dong-A University Hospital Clinical Trials Center
ETC 동아대학교병원 지역임상시험센터

Cadiovascular / Neurological Disease

PK/PD
BA/BE
DDI

- Cardiology
- Neurology
- Gastroenterology
- Hemato-Oncology
- Rheumatology
- Endocrinology

LATE PHASE - Multi Center Trial

CNU HOSPITAL CHUNGNAM NATIONAL UNIVERSITY HOSPITAL 임상시험센터 Clinical Trials Center

Rheumatic Disease

BIO DRUG
FIH
PK/PD
BA/BE

- Drug-Drug interaction
- Vaccine trials
- Drug-Food Interaction
- New Formulation
- Evaluation
- ODF, Controlled release Combined

PARTNERS

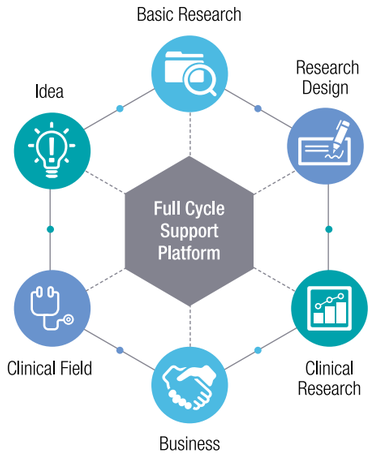
WE ARE STRIVING FOR PARTNERS TO BE A PARTNER!

Personalized & precision clinical trial based on
Advanced **R**esearch **T**ools,
Network in the biomedical **E**cosystem and
Robust **S**upport system

SMC Full-Cycle Clinical Trial Support Platform

Virtuous Cycle Clinical Trial Support Platform

Shifted from the stage of drug development to the idea development, translational research, design, clinical entry, and initial development stage



- **3,500 practicing clinicians** with experience across all therapeutic areas and **330 specialists** including clinical pharmacologist, CRC, CRA
- Diverse patient population with **5 million outpatients** and **250,000 inpatients** per year for disease-specific subject populations
- Completed **140 phase 1** and **373 phase 2** clinical trials for the last 5 years with full range of services including consulting, regulatory affairs and education
- Global infrastructure composed of 5 hospitals total of **158 beds** for early and late phase clinical trials

SAMSUNG MEDICAL CENTER

KOREA UNIVERSITY ANAM HOSPITAL

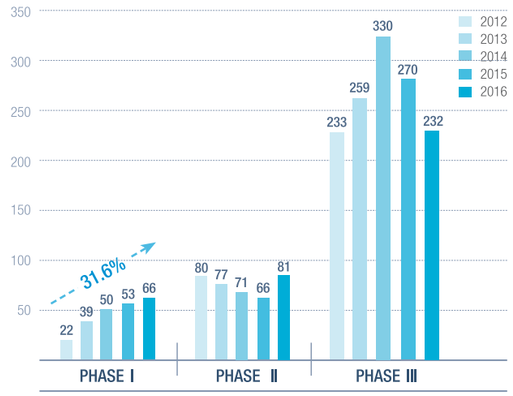
Gachon University Gil Medical Center

KYUNGPOOK NATIONAL UNIVERSITY HOSPITAL

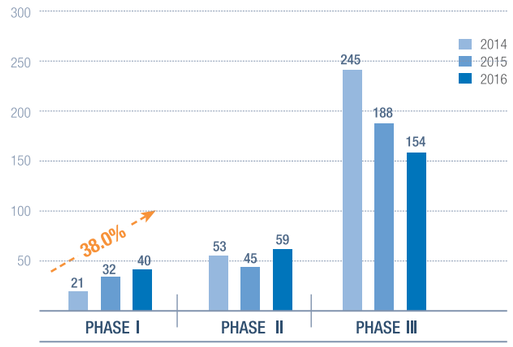
CHA Bundang Medical Center, CHA University

PARTNERS Globalization in Clinical Trials (Unit : Case)

Local Pharma Clinical Trials conducted for the past 5 years



Global Pharma Clinical Trials conducted in the past 3 years



※ KFDA Clinical Trial to Approval Subject (IRB Approval Date Standard), Apply CAGR

Excellence in Clinical Trial Site

tgen Integrated platform for early realization of precision medicine

Pfizer	CORE Research Site
BMS	Oncology Center of Excellence
Sanofi	Premier Research Site
AstraZeneca	Onco Alliance Center
INC Research	Catalyst Site

Global Center of Excellence in Clinical Trials

References

1. ClinicalTrials.gov.
2. The World Bank.
3. Statistics Korea. Population Projections for Korea.
4. OECD. Education at a Glance 2014.
5. Health Industry Representatives Association.
6. US FDA. Inspection Classification Database Search.
7. The Ministry of Food and Drug Safety, Korea.

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Email: KoNECT: kcc@konect.or.kr KCGI: info@kcgi.or.kr

The Right Place For Clinical Trials In Asia

START WITH KOREA

KONECT
Korea National Enterprise for Clinical Trials

15F, KPX B/D, 137 Mapodae-ro, Mapo-gu, Seoul, 04143, Republic of Korea
http://kcc.konect.or.kr/ Tel. +82-2-398-5040~5044 E-mail. kcc@konect.or.kr