The Right Place For Clinical Trials In Asia

START WITH KOREA
DISCLAIMER

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TABLE OF CONTENTS

5 Introduction

6 Overview of Clinical Trials in Korea

7 Korea: A Competitive Edge in Clinical Trials

10 Favorable Demographics

12 World-Class Infrastructure & Medical Care

14 Streamlined Regulatory Process & Faster Study Start Up

16 Site Excellence & Study Quality

17 Clinical Trial Sites Designation by Government

18 KCGI and Global Centers of Excellence in Clinical Trials

19 Accumulated Experience in Drug Clinical Trials

20 Why Korea

24 Korea’s Pharmaceutical Market Landscape

Appendices

26 Related Agencies & Associations

28 Clinical Trial Center Consortia under Korea Clinical Trials Global Initiative [KCGI]
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 km²

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 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 Intervventional Drug Trials in Top10 Countries, 2011-2016
Source: KoNECT’s analysis of ClinicalTrials.gov data

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

KoreaOverview
Korea Overview
Korea Clinical Trial Environment
Why Korea
Korea Pharmaceutical Market
Appendices

START WITH KOREA
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).

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.

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

<table>
<thead>
<tr>
<th>Rank</th>
<th>Sponsor</th>
<th>Number of CTAs 2014</th>
<th>Number of CTAs 2015</th>
<th>Number of CTAs 2016</th>
</tr>
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<tr>
<td>1</td>
<td>Quintiles</td>
<td>31</td>
<td>35</td>
<td>42</td>
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<tr>
<td>2</td>
<td>Novartis</td>
<td>26</td>
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<td>19</td>
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<td>3</td>
<td>MSD</td>
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<td>14</td>
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<td>4</td>
<td>GlaxoSmithKline</td>
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<td>5</td>
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<tr>
<td>6</td>
<td>PRA</td>
<td>15</td>
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<td>22</td>
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<td>7</td>
<td>Boehringer Ingelheim</td>
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<td>11</td>
<td>10</td>
</tr>
<tr>
<td>9</td>
<td>AstraZeneca</td>
<td>13</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td>Bayer</td>
<td>11</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>

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.\(^3\)

- **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.

- **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.

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

Major Causes of Death in Korea, 2015
Source: Statistics Korea
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](image)

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](image)
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.

- 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.
Site Excellence & Study Quality

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

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

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
AstraZeneca

“AstraZeneca 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.

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.
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.

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.
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.

### 5-Year Cancer Survival Rates [Age Standardized]

<table>
<thead>
<tr>
<th>Country</th>
<th>(% of 5-Year Cancer Survival Rates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>-2.0</td>
</tr>
<tr>
<td>United States</td>
<td>-1.9</td>
</tr>
<tr>
<td>Europe</td>
<td>0.0</td>
</tr>
<tr>
<td>Taiwan</td>
<td>5.2</td>
</tr>
<tr>
<td>Japan</td>
<td>5.7</td>
</tr>
<tr>
<td>India</td>
<td>6.7</td>
</tr>
<tr>
<td>Australia</td>
<td>6.9</td>
</tr>
<tr>
<td>Singapore</td>
<td>10.0</td>
</tr>
<tr>
<td>South Korea</td>
<td>11.4</td>
</tr>
<tr>
<td>China</td>
<td>32.8</td>
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</table>

Source: Allemani et al., Lancet 2015

### Innovative New Drug Developed in Korea Since 1999

<table>
<thead>
<tr>
<th>NO</th>
<th>Product</th>
<th>Company</th>
<th>Indication</th>
<th>Approved date</th>
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<tbody>
<tr>
<td>1</td>
<td>Sunplia injection</td>
<td>SK Chemical</td>
<td>Stomach Cancer</td>
<td>Jul. 1999</td>
</tr>
<tr>
<td>2</td>
<td>EGF topical solution</td>
<td>Daewoong Pharm. Co., Ltd.</td>
<td>Skin Ulceration</td>
<td>May. 2001</td>
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<td>3</td>
<td>Milican</td>
<td>DongWha Pharm</td>
<td>Liver Cancer</td>
<td>Jul. 2001</td>
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<td>4</td>
<td>Q-roxin Tablet</td>
<td>Choongwae Pharma Corporation</td>
<td>UTI</td>
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<tr>
<td>5</td>
<td>Factive Tablet</td>
<td>LG Life Science Ltd</td>
<td>Antibiotic</td>
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<td>7</td>
<td>Pseudovaxin injection</td>
<td>CJ</td>
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<td>May. 2003</td>
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<td>9</td>
<td>Revanex Tablet</td>
<td>Yuhan Corporation</td>
<td>Peptic Ulcer</td>
<td>Sep. 2005</td>
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<td>10</td>
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<td>Dong-A Pharm. Co., Ltd.</td>
<td>Erectile Dysfunction</td>
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<tr>
<td>11</td>
<td>Levoir Capsule</td>
<td>Bukwang Pharm. Co., Ltd.</td>
<td>Hepatitis B</td>
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<td>SK Chemical</td>
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<td>Hypertension</td>
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<td>Pyramax Tablet</td>
<td>Shinpoong Co., Ltd.</td>
<td>Malaria</td>
<td>Aug. 2011</td>
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<td>Zepeed Tablet</td>
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<td>Acelex</td>
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<td>Osteoarthritis</td>
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<td>DongWha Pharm</td>
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<td>28</td>
<td>Besivo Tablet</td>
<td>Idong Pharmaceutical, Co.,Ltd.</td>
<td>Hepatitis B</td>
<td>May 2017</td>
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</table>

Source: Ministry of Food and Drug Safety (MFDS)
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.

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 1997, 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 cGMP 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 Korea 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.

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 drugs and sustain amicable cooperative relationships between stakeholders within 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.

Korean Association of Institutional Review Boards

The Korean Association of Institutional Review Boards (KARI) was established in 1999 with the aim of improving 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 KARI 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. KAIB 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 guidelines among Korea’s institutional review boards to their advance research ethics and research capacities. It also focuses on improving coordination for faster responses and better economic efficiency in reviews. To achieve these goals, KAIB holds regular meetings and training programs for healthcare professionals aimed at enhancing their understanding of research ethics.

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 industry. 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 been working to promote the competitiveness of Korea’s healthcare industry in regards to its health services, pharmaceuticals, medical devices, cosmetics 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 responsible for fostering growth in the health industry. The institute has striven to produce more successful research outcomes via greater 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, KHIDI has witnessed expanded R&D investments since the implementation of the Drug Substance Patent Law in 1997, 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 cGMP 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. KHIDI has also collaborated 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 KHIDI’s efforts.

http://www.khidi.org/

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

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http://www.krpi.or.kr/
Clinical Trial Center Consortia under Korea Clinical Trials Global Initiative (KCGI)

**WHAT WE DO**
- SNUH-Global Center of Excellence in Early (General & Rare Disease) Clinical Trials
- SNU Bundang-Global Center of Excellence in Generic Early Clinical Trials
- CHUH-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
- Adaptable
  - 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

**BECOME GREAT THROUGH GREATS**
Clinical Trial Center Consortia under Korea Clinical Trials Global Initiative (KCGI)

### Clinical Trials in Asan Medical Center

<table>
<thead>
<tr>
<th>Phase</th>
<th>2013</th>
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<td>13</td>
<td>12</td>
<td>16</td>
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</tbody>
</table>

High volume center: highest patient volume in Korea

2,714 beds

1,871 doctors

11,380 outpatient (daily average)

2,496 admissions (daily average)

1,100 Clinical trial on going

9 per month with expedited review

39 Research tools with dedicated study team

### Efficient & Speedy Operation of Clinical Trials

AMC EMR accepts English version protocols for phase I studies in healthy volunteers & patients

First in Korea

DB review & contract negotiation proceed in parallel

### Shorter Turnaround Time

AMC provides 2 days for review of applications for your studies

**EMR**

**OCIS**

**PACS**

**ERP**

**Clinical Research Data Warehouse & Electronic management**

Fast & Accurate Feasibility

Highly Efficient Screening

### Ajou University Medical Center

**Excellence in Clinical Trial**

- Phase I to clinical trials & IT 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 (ETAC)
- Clinical translational research services

**We are always there for you**

We are committed to caring for you and your family
ABOUT SCI-CONSORTIUM
The SCI Consortium (hereafter SCI-C), consists of clinical trial centers (CTCs) of excellence from the four leading university hospitals in Korea.

KEY FIGURES
- More than 7.4 Million in and Out-patients per year (5,909 Beds)
- 1,545 Clinical Investigators
- 177 Dedicated Beds for Clinical Pharmacology Studies
- 1,703 Sponsored Contracts per year
- 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 as Frost & Sullivan White Paper Titled ‘Asia Preferred Destination for Clinical Trials’ as Specialized Clinical Trial Centers

START WITH KOREA
32

SCI-Consortium of Clinical Trials Centers at University Hospitals

DRIVE YOUR CLINICAL TRIALS THROUGH THE OPTIMIZED PATHWAY TO SUCCESS

MAIN SERVICES
One Project Management System

Feasibility Clinical Design Budgeting IRB Approval Contract Enrollment Operation Analysis & Report

SCI-C Feasibility DB Enhancing study feasibility assessment in an IT-driven database
Recruitment Specialist Effective enrollment to the patients entered early phase trials through the pre-qualifying roll-out center

SALC™ (Strategic Advisory Leadership Team) Multidisciplinary Consulting Service for Successful Clinical Drug Development

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

SCI-C Operation Optimized provision of patient-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

2015 2014 2013

2015 2014 2013

150 100 50 0

150 100 50 0

150 100 50 0

150 100 50 0

150 100 50 0

150 100 50 0

150 100 50 0

150 100 50 0

SCI-C % KOREA

Phase 1 23% Domestic Trials: 524, 29 in, 5, Korea, 125
Global Trials: 10, 6 vs, 5, Korea, 59

Phase 2 36% Domestic Trials: 524, 29 in, 5, Korea, 60
Global Trials: 10, 6 vs, 5, Korea, 43
Personalized & precision clinical trial based on
Advanced Research Tools
Network in the biomedical Ecosystem and
Robust Support system

SMC Full-Cycle Clinical Trial Support Platform
Efficient cycle Clinical Trial Support Platform
Facilitates the flow of drug development to the site 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, CDA
Diverse patient population with 5 million outpatients and 250,000 inpatients per year for disease-specific subject populations
Complete 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

Clinical Trial Center Consortia under Korea Clinical Trials Global Initiative (KCGI)
References
1. ClinicalTrials.gov.
2. The World Bank.
6. US FDA. Inspection Classification Database Search.
7. The Ministry of Food and Drug Safety, Korea.
The Right Place For Clinical Trials In Asia

START WITH KOREA