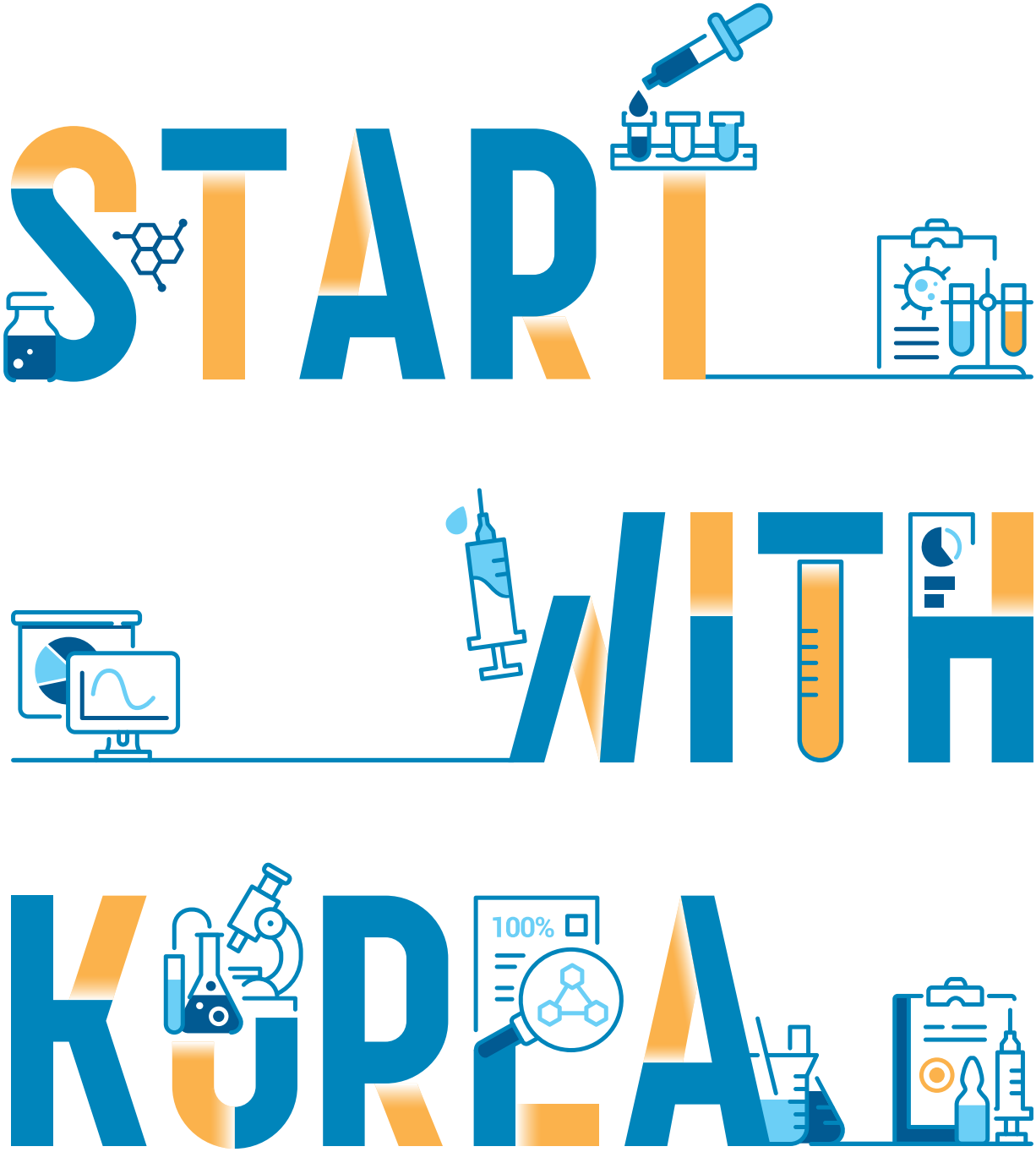
START WITH KOREA



KONECT
Korea National Enterprise for Clinical Trials

Ministry of Health and Welfare

Disclaimer

This publication is intended solely to inform sponsors and stakeholders about the clinical trial environment, capabilities, and infrastructure in Korea. It is not intended for any other use. Certain company-specific information has been provided voluntarily and may have been anonymized where appropriate. The data and details included may not be exhaustive or up to date, and are subject to change over time.

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Publication date: May 2025

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(Source : KoNECT's analysis of ClinicalTrials.gov data, 2025)

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(Source : KoNECT's analysis of ClinicalTrials.gov data, 2025)

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(Source : KoNECT's analysis of ClinicalTrials.gov data, 2025)

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13th Biggest Country in the Global Pharma Market

(Source : KHIDI, 2024)

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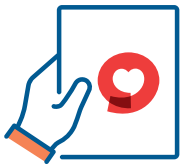
Global Rank #3: Korea for Number of R&D Pipelines

(Source: Citeline, 2024)

99.6%



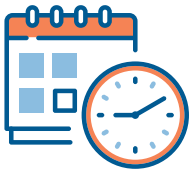
Virtually the Entire Population (99.6%) is Covered by the NHI

200+

200+ Medical Institutions Designated by the MFDS as Major Clinical Trial Sites

(Source : MFDS, 2024)

30 Days



30 Working Days from MFDS-IND Application to Approval

3 Weeks

3 Weeks from IRB Submission to Approval (on average)

0 zero

Zero OAIs from FDA Inspection (2009-2024)

(Source : FDA, 2025)

* Bioresearch Monitoring Cases

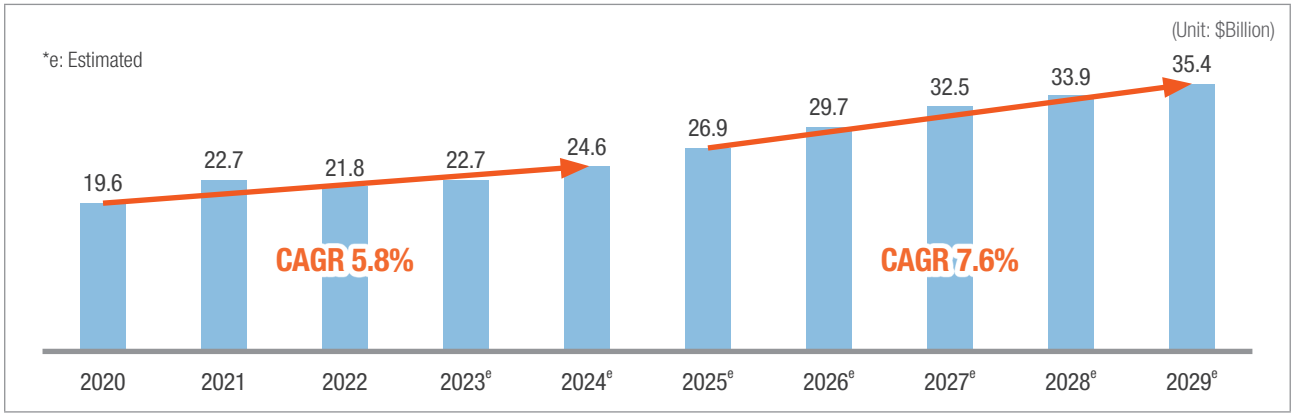
※ KHIDI: Korea Health Industry Development Institute
NHI: National Health Insurance
MFDS: the Ministry of Food and Drug Safety

(1) Overview of the Korean Pharmaceutical Market

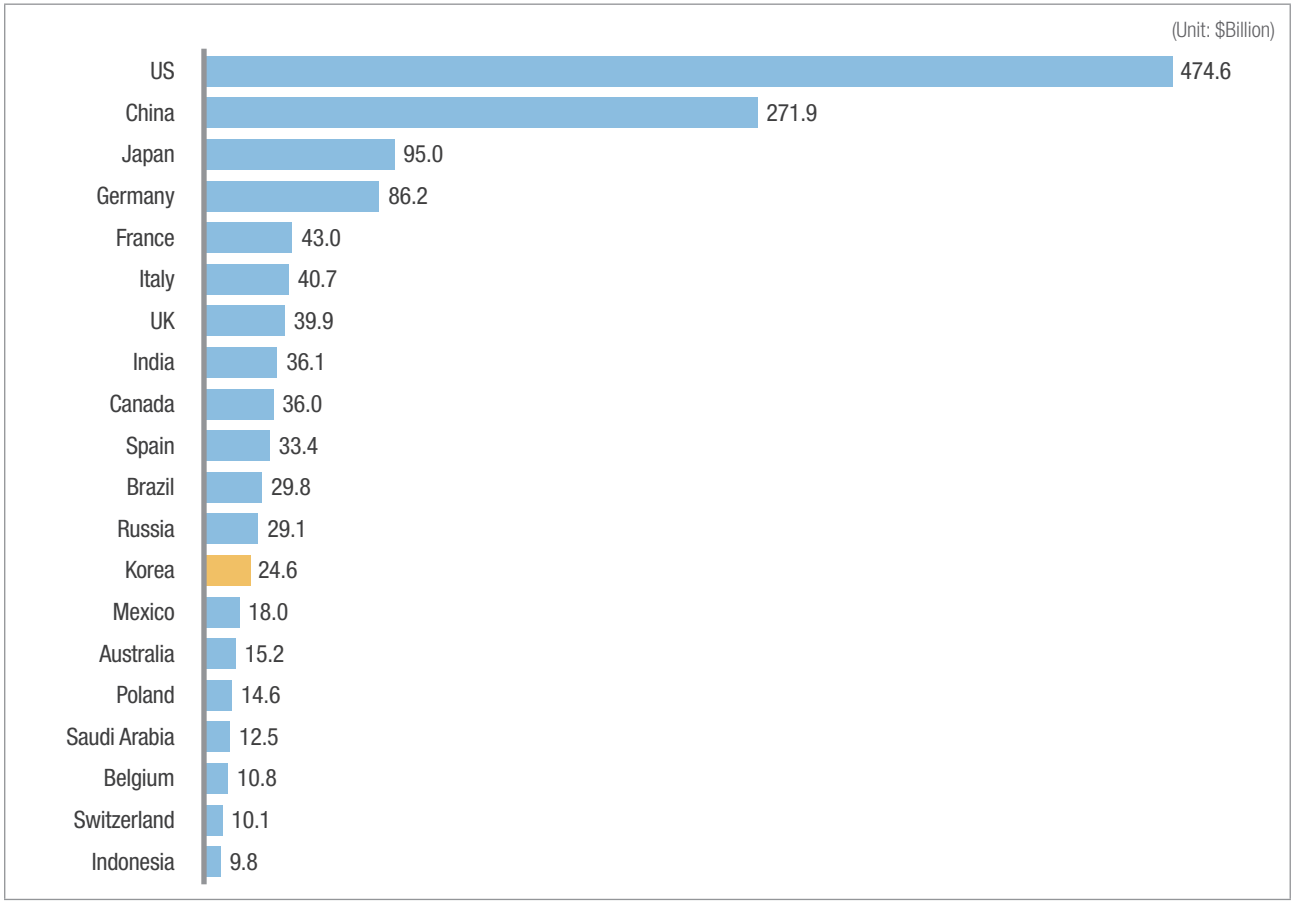
Korea's pharmaceutical industry continues to grow steadily, driven by sustained R&D investment, strong government support, and cutting-edge technology.

As of 2024, the global pharmaceutical market is valued at USD 1,571.2 billion, with Korea ranking 13th worldwide at USD 24.6 billion. Korea's domestic market is expected to grow at an annual rate of 7.6% from 2024 to 2029, outpacing the global average of 5.1%.

Pharma Market Size and Compound Annual Growth Rate of Korea's Pharmaceutical Industry



Pharma Market Size, 2024(Estimated)

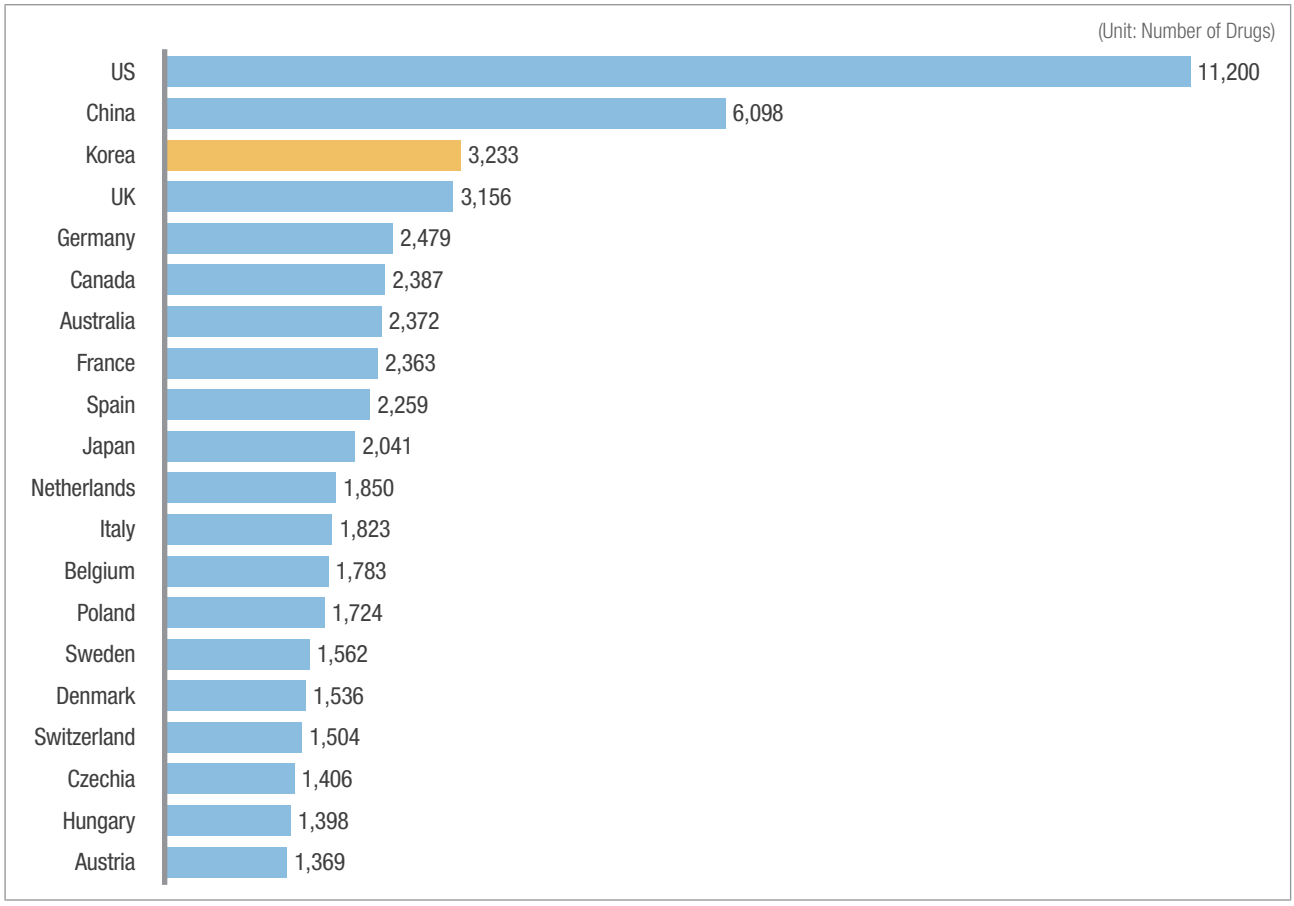


(Source: 2024 Global Healthcare Market Outlook, KHIDI, analyzed by KoNECT)

Global pharmaceutical companies present in Korea are steadily expanding their R&D investments. This continued growth has enabled Korea to secure the third-highest number of drug development pipelines globally—with 3,233 active candidates, according to the 2024 Citeline report.

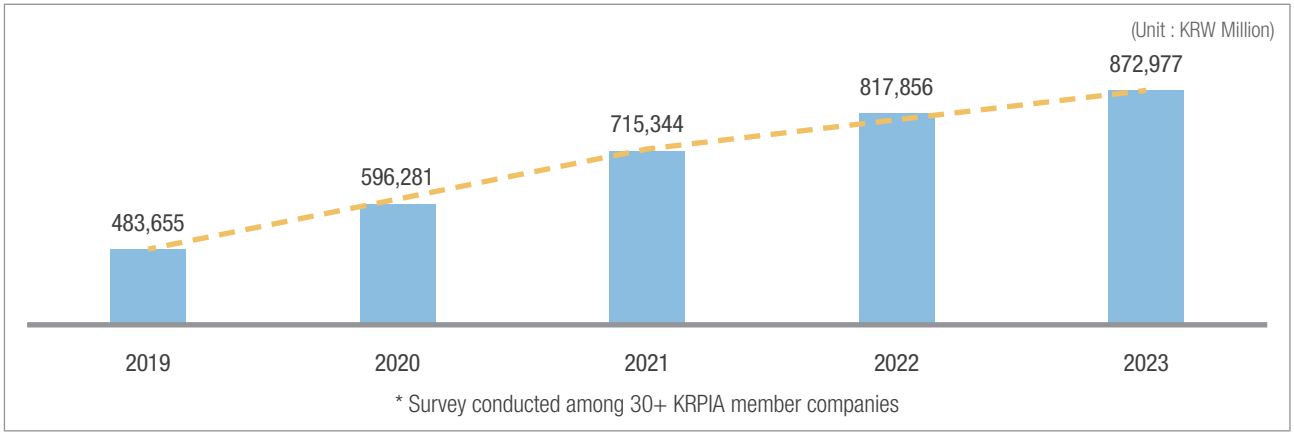
In parallel, R&D investment by global pharmaceutical companies in Korea has shown consistent growth over the past five years, rising from KRW 483.6 billion in 2019 to KRW 872.9 billion in 2023. This sustained investment reflects Korea's increasing importance as an R&D hub and a strategic location for clinical development in Asia.

Where is R&D actually occurring?



(Source: Pharma R&D annual review 2024, Citeline, Apr 2024)

R&D Investment by Global Pharmaceutical Companies in Korea



(Source: 2024 KRPIA R&D Survey Report, KRPIA, November 2024)

(2) Global Leader in Clinical Trials

Korea's Global Standing in Clinical Trials

Korea has consistently ranked among the world's top 10 countries for clinical trials. In 2024, Korea ranked 6th globally for industry-sponsored clinical trials. At the city level, Seoul placed 2nd worldwide as one of the most active cities for industry-sponsored clinical trials. Korea also ranks as the 2nd most active country in Asia for multinational clinical trials.

Industry-Sponsored Trials in 2024 (Total Protocol)

Country	US	China	Australia	Spain	Germany	Korea	UK	Canada	Japan	Italy	France
Protocol Share (%)	21.15	14.59	4.24	3.81	3.61	3.46	3.39	3.27	2.96	2.88	2.85

Industry-Sponsored Trials in 2024 (Multinational Protocol)

Country	US	Spain	Australia	Canada	UK	Italy	Germany	France	Poland	Japan	Korea
Protocol Share (%)	10.42	5.68	4.68	4.53	4.40	4.38	4.38	3.96	3.91	3.70	3.13

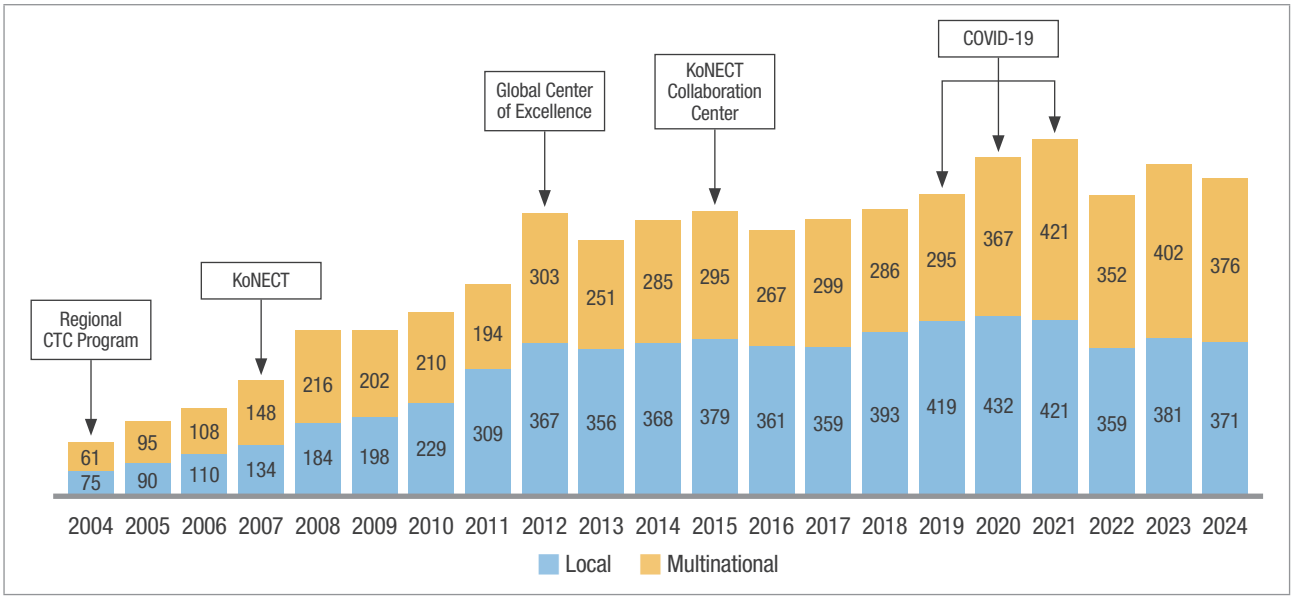
(Source: KoNECT's analysis of ClinicalTrials.gov data, 2025)

Growth of Korea's Clinical Trials with KoNECT

Since the introduction of the IND process in 2002, Korea's clinical trial industry has shown consistent growth. Strategic government investments have strengthened clinical trial infrastructure and cultivated human resources, beginning with the launch of the Regional Clinical Trial Center (CTC) Program in 2004. The establishment of KoNECT further advanced the industry. In 2012, the Global Center of Excellence was established to support domestic companies in conducting global clinical trials. This was followed in 2015 by the launch of the KoNECT Collaboration Center, aimed at attracting global pharmaceutical companies and fostering co-development within Korea's clinical trial ecosystem. To accelerate future growth, the Korean government continues to drive initiatives aimed at positioning Korea as a leading global hub for clinical trials, reflecting a strong commitment to innovation and global competitiveness.

Growth of Korea's Clinical Trials 2004-2024

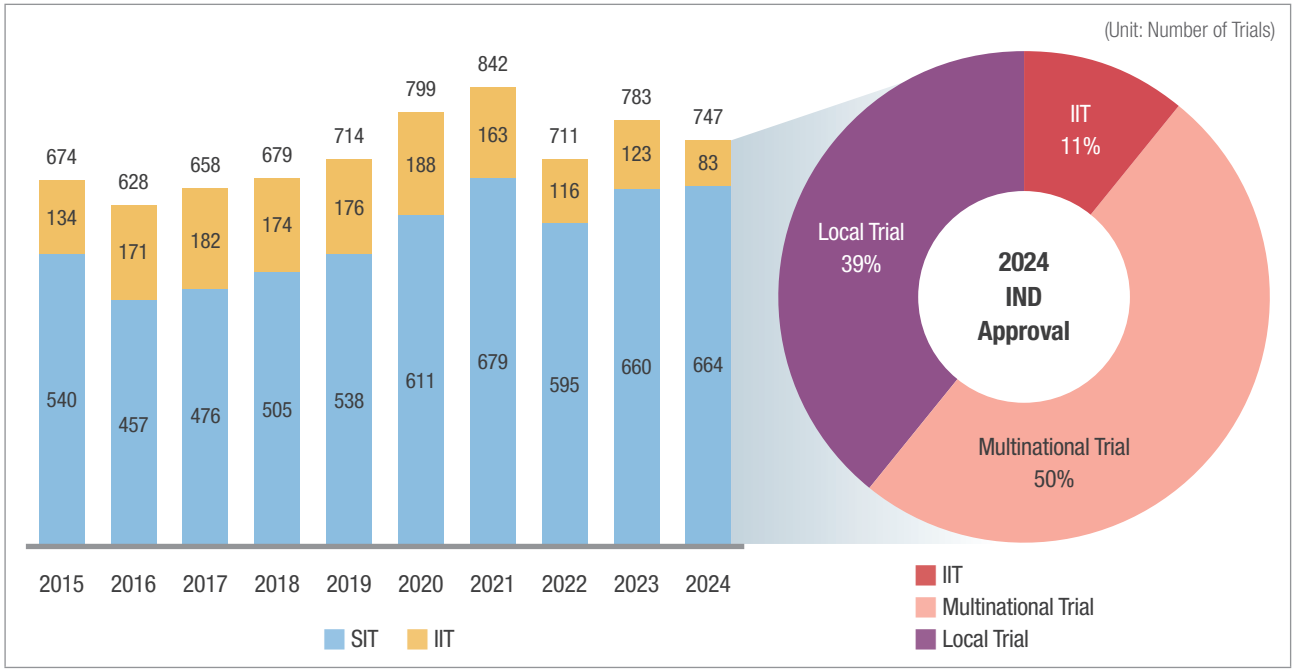
Ministry of Food and Drug Safety (MFDS) IND Approval Status



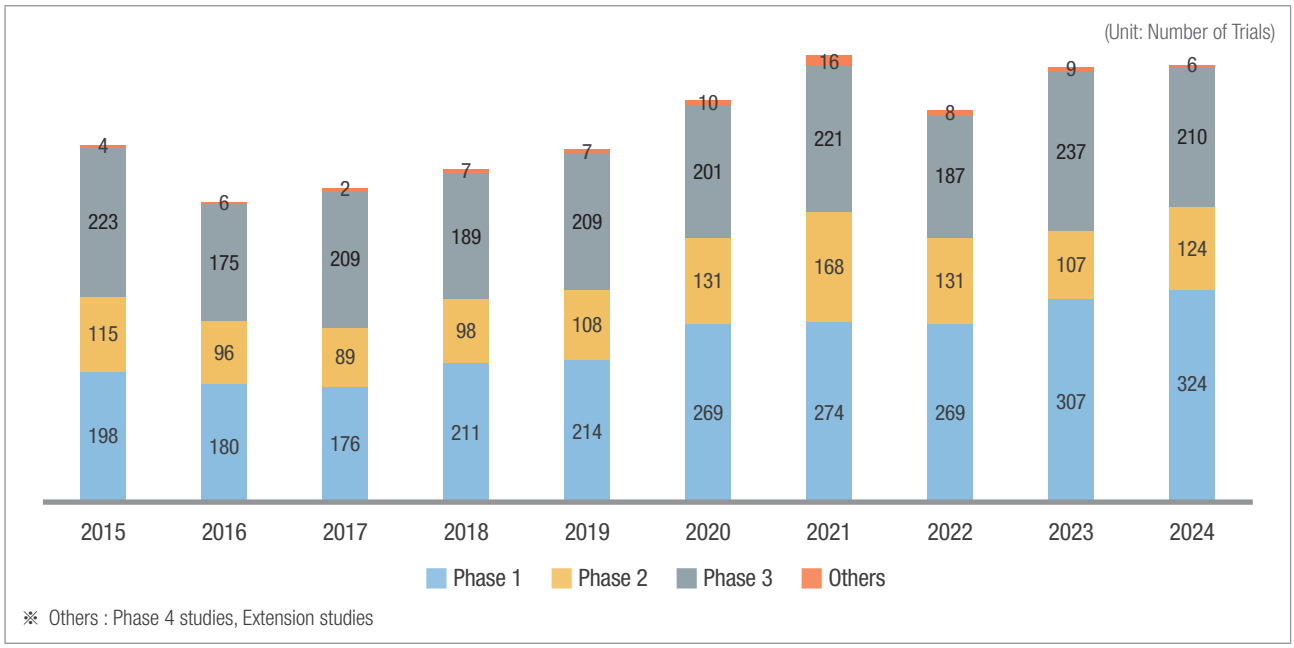
(Source: Ministry of Food and Drug Safety (MFDS), analyzed by KoNECT, 2025)

Over the past decade, the number of clinical trial approvals in Korea has steadily increased, primarily driven by the growth of sponsor-initiated trials (SITs). In particular, the share of early-phase trials has steadily increased, driven by the expansion of domestic drug development pipelines and growing interest from global pharmaceutical companies looking to tap into Korea's world-class researchers and cutting-edge research infrastructure.

IND Approval Status for SIT & IIT in Korea



IND Approval Status for SIT by phase



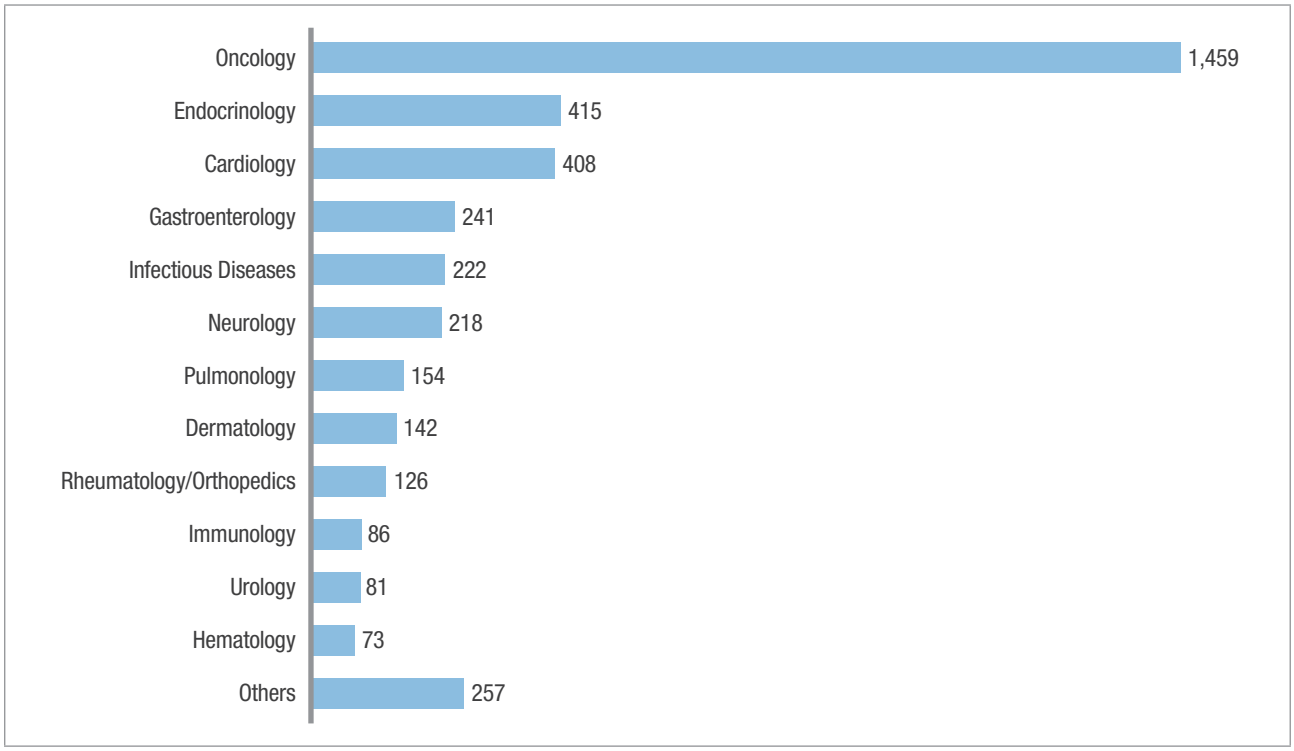
※ Others : Phase 4 studies, Extension studies

(Source: Ministry of Food and Drug Safety (MFDS), analyzed by KoNECT, 2025)

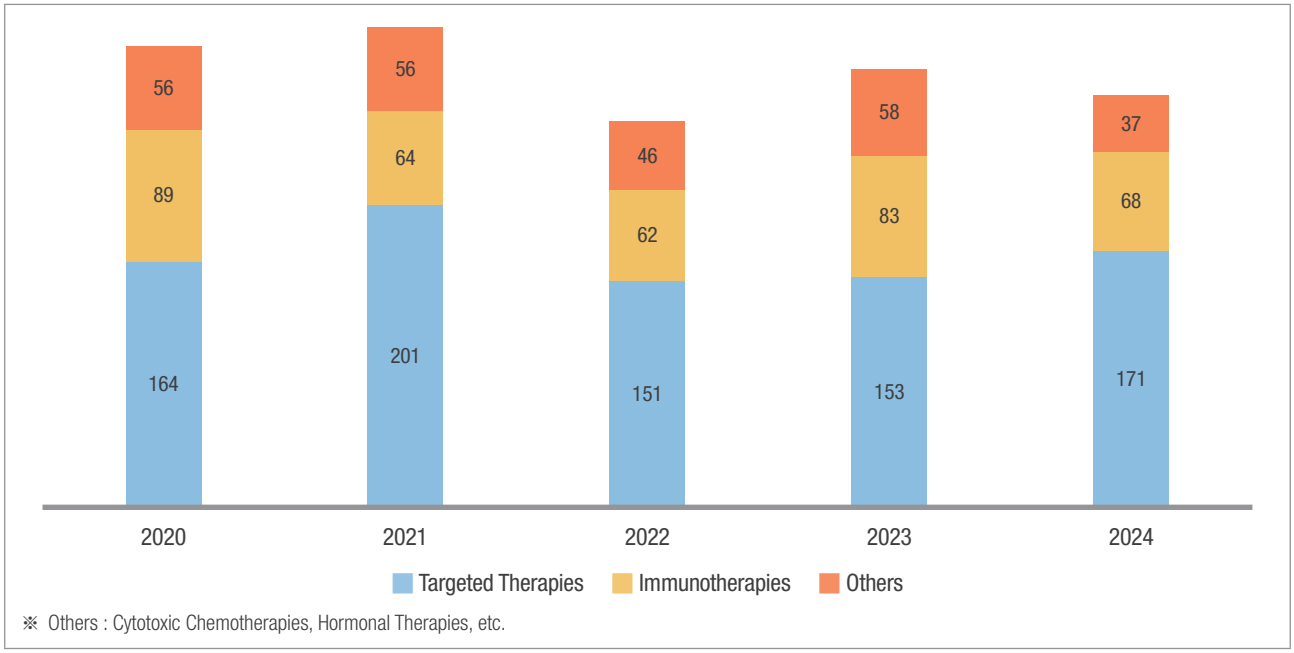
Clinical Trial Landscape in Korea

Korea has long demonstrated strong capabilities in oncology research, which remains the leading therapeutic area in clinical trials. A diverse range of oncology studies—including targeted therapies, immunotherapies, and other advanced treatment modalities—are actively being conducted, accelerating the development of innovative cancer treatments. In addition to oncology, Korea continues to expand its clinical trial landscape across other therapeutic areas such as endocrinology, cardiology, and neurology.

Number of IND Approvals by Therapeutic Area (2020-2024)



Number of IND Approvals by Type of Oncology Drugs (2020-2024)

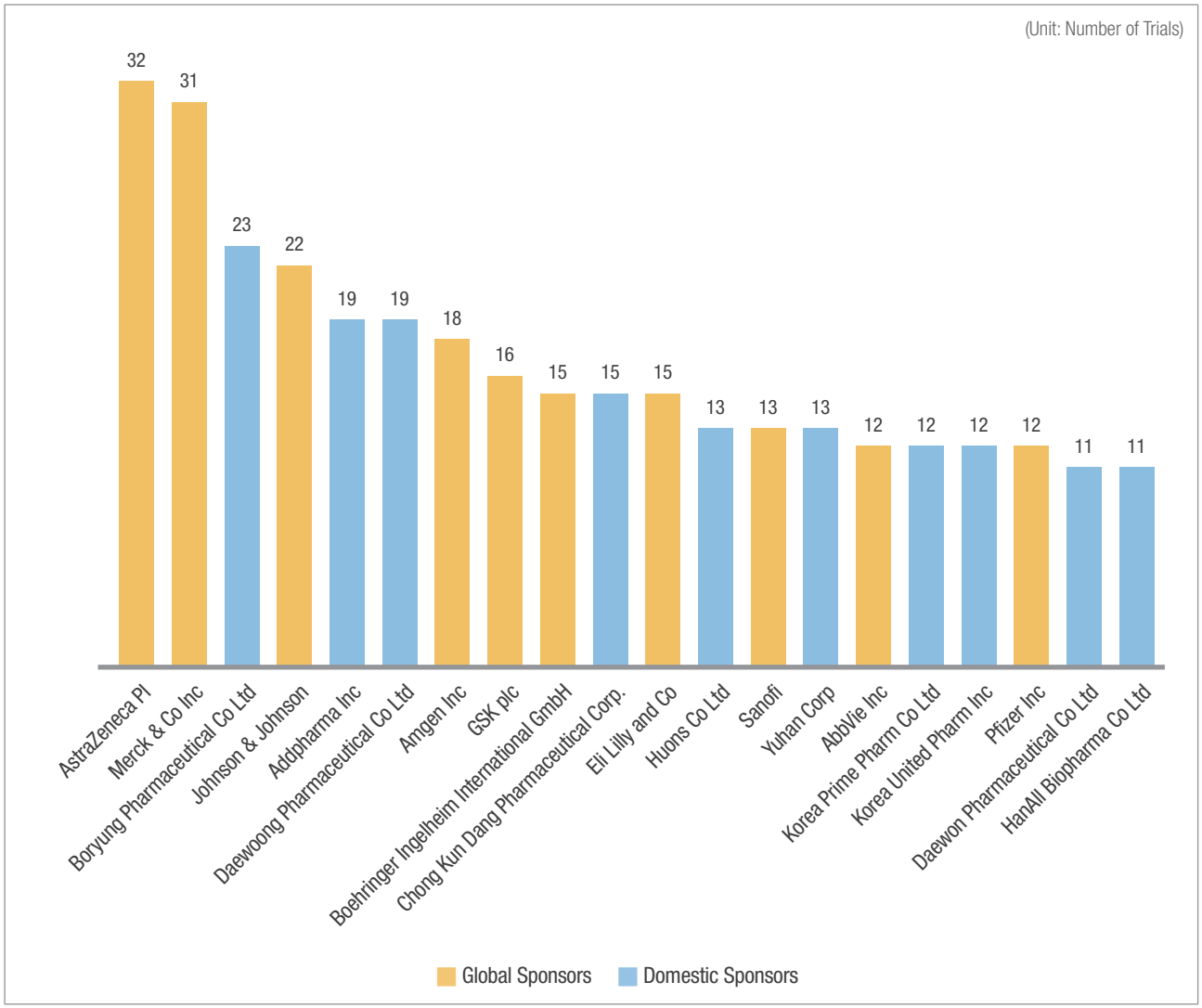


(Source: Ministry of Food and Drug Safety (MFDS), analyzed by KoNECT, 2025).

With strong support from government initiatives, Korean pharmaceutical and biotech companies are actively advancing new drug development. At the same time, global pharmaceutical companies continue to expand their presence in Korea's clinical trial landscape. According to GlobalData Trial Analytics (2024), the top clinical trial sponsors in Korea represent a balanced mix of domestic and multinational sponsors, highlighting Korea's growing role as a global hub for clinical research and collaboration.

20 Top Sponsors in Korea

(Trial Start Date: 01 JAN 2024 - 31 DEC 2024)



(Source: Global Data Trial Analytics)

※ Other leading global sponsors are also actively conducting clinical trials in Korea.

Key Advantages of Conducting Clinical Trials in Korea

Key Advantages of Conducting Clinical Trials in Korea

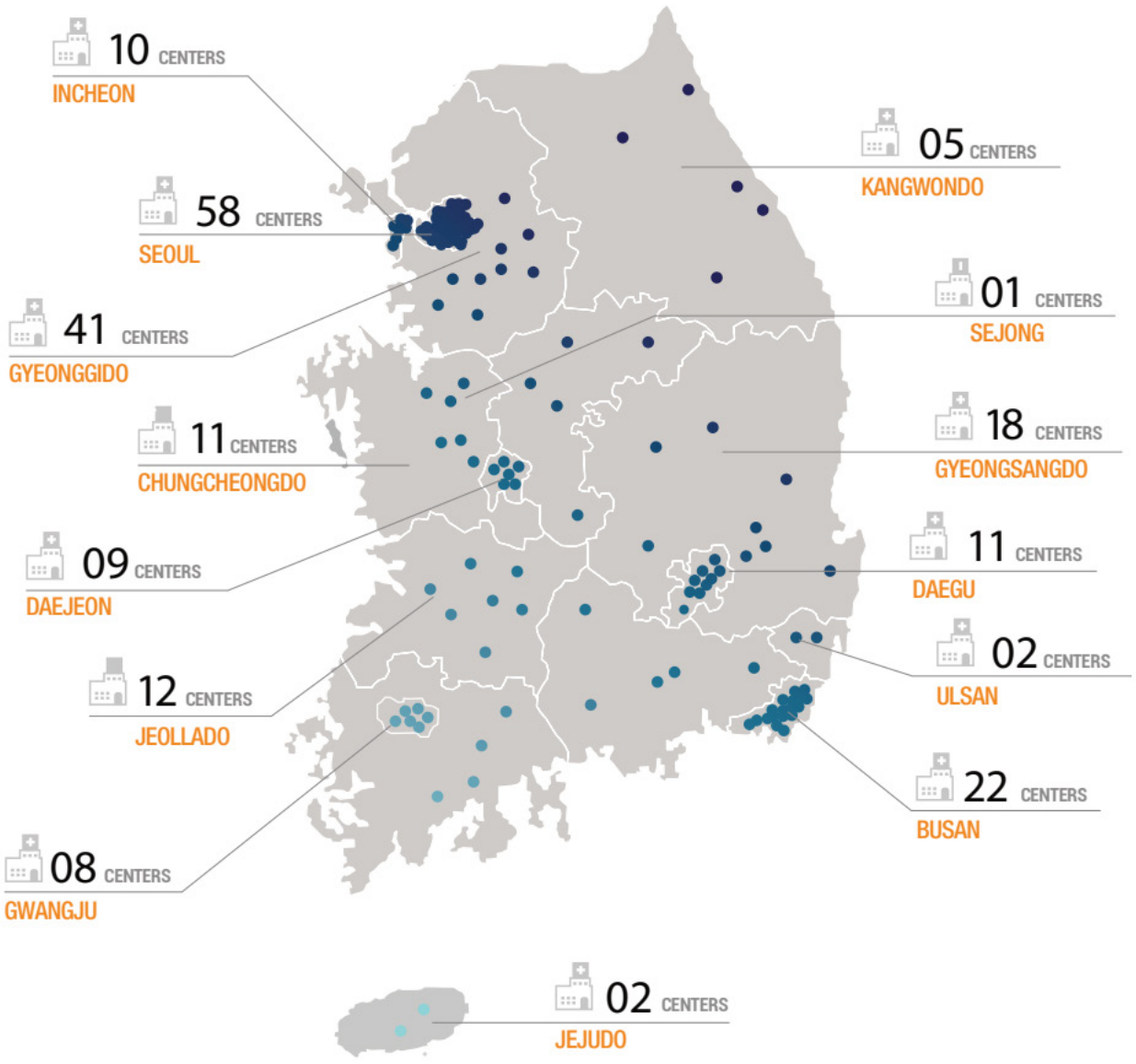
(1) World-Class Research Infrastructure Aligned with Global Standards

As of December 2024, a total of 210 medical institutions in Korea have been designated as major clinical trial centers. Many regional hospitals also participate in clinical research under the oversight of these accredited institutions. Most of these centers are general and tertiary hospitals that meet global clinical trial standards and are staffed by highly qualified medical professionals actively involved in trial operations.

Notably, in Newsweek's 2024 ranking of the <World's Best Hospitals>, 17 Korean hospitals were listed among the top 250 globally, including four within the top 50—underscoring Korea's strength in advanced medical infrastructure and global excellence.

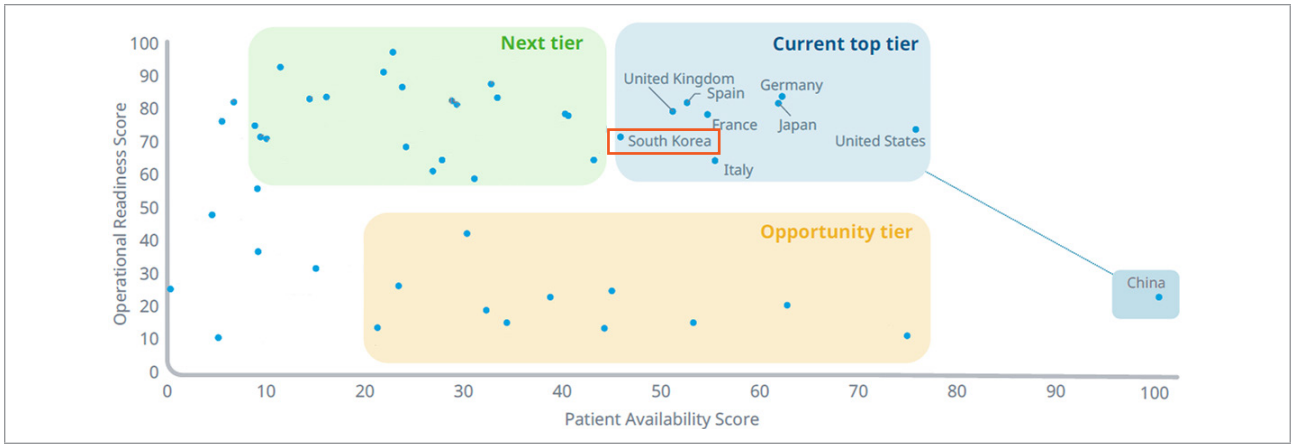
Moreover, Institutional Review Boards (IRBs) at major clinical trial centers in Korea have been accredited by international organizations such as FERCAP and AAHRPP, and have their own human research protection oversight. Korean sites have consistently demonstrated excellence in patient recruitment, which further enhances their reliability and appeal to global sponsors.

※ FERCAP : Forum for Ethical Review Committees in the Asian and Western Pacific Region
※ AAHRPP : The Association for the Accreditation of Human Research Protection Programs, Inc



Operational Readiness & Patient Availability

Korea ranks among the top nine countries globally in both operational readiness and patient availability—two key factors that contribute to high clinical trial success rates and strong patient retention. This reflects the country's robust infrastructure, highly qualified investigators, and streamlined regulatory environment.



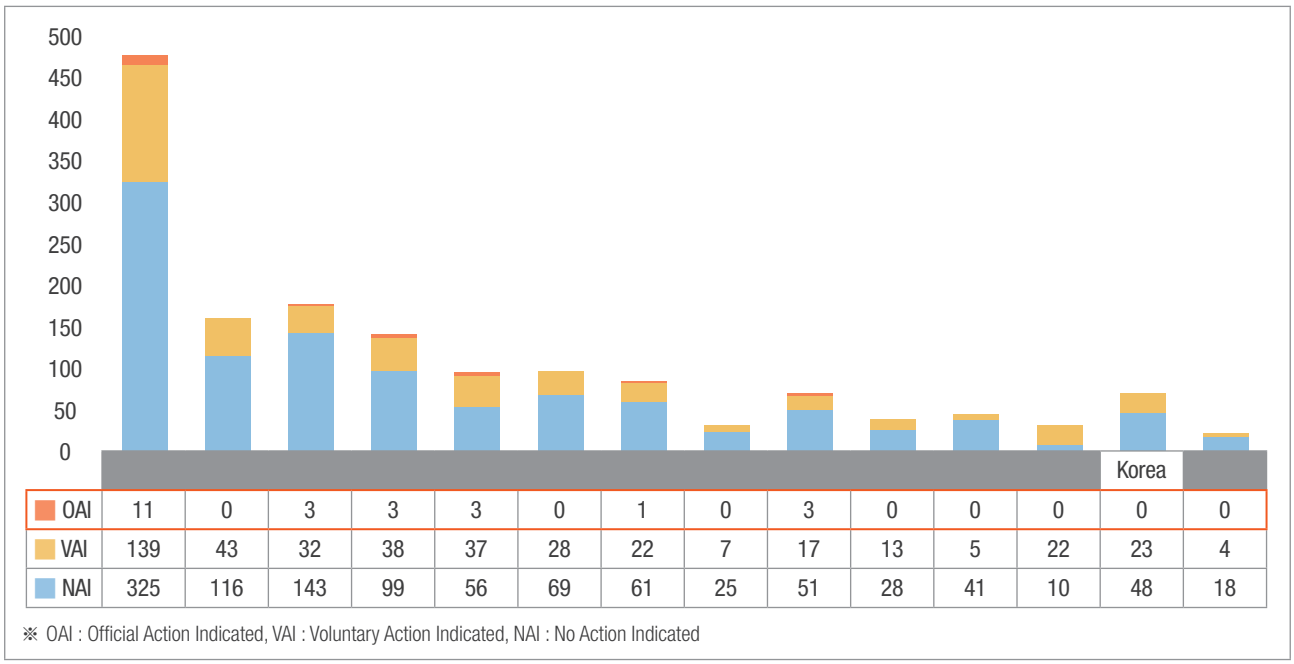
(Source : Rethinking Clinical Trial Country Prioritization, IQVIA, 2024)

Global Compliance

Clinical trial sites in Korea are regularly inspected by the Ministry of Food and Drug Safety (MFDS) and have also performed well in inspections by major global regulatory authorities—such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). From 2009 to 2024, the U.S. FDA's Center for Drug Evaluation and Research (CDER) conducted 71 Bioresearch Monitoring inspections in Korea, with no Official Action Indicated (OAI) issued.

FDA Inspection Classification(2009-2024)

Bioresearch Monitoring Cases among the Leading Countries in Clinical Trials



OAI	11	0	3	3	3	0	1	0	3	0	0	0	0	0
VAI	139	43	32	38	37	28	22	7	17	13	5	22	23	4
NAI	325	116	143	99	56	69	61	25	51	28	41	10	48	18

※ OAI : Official Action Indicated, VAI : Voluntary Action Indicated, NAI : No Action Indicated

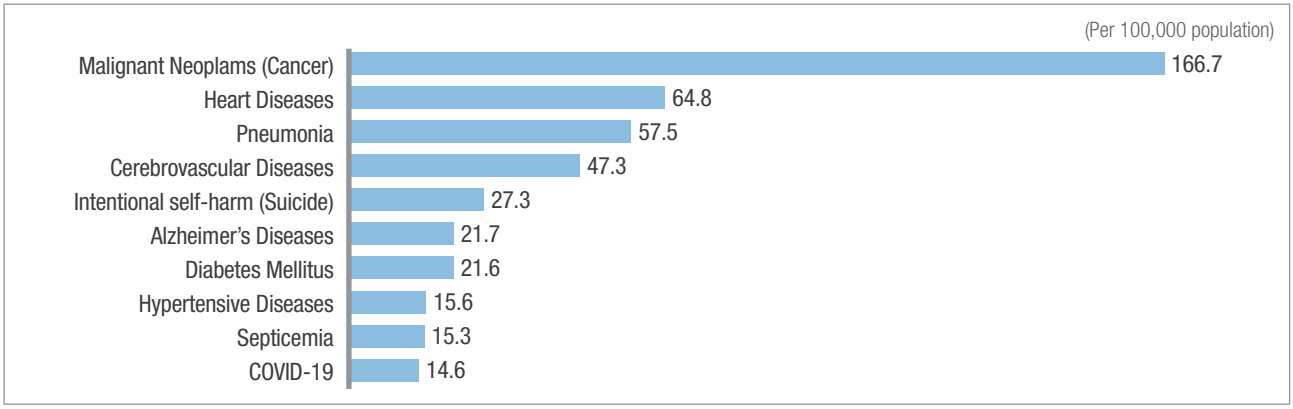
(Source : the U.S. Food and Drug Administration (FDA))

(2) Enabling Efficient and Engaged Trial Participation

Aging Population & Westernized Disease Patterns

With a life expectancy of 83.5 years for those born in 2023, Korea is rapidly becoming an aging society—driving increased demand for new drugs and innovative therapies, while providing a large, diverse patient pool for clinical trials. Korea's disease patterns are well aligned with those of Western countries. In 2023, cancer alone accounted for 41.9% of total deaths among the top 10 causes, highlighting the need for continued innovation in oncology drug development.

Leading Causes of Death in Korea, 2023



(Source: Statistics Korea, 2024)

High Accessibility to Medical Services

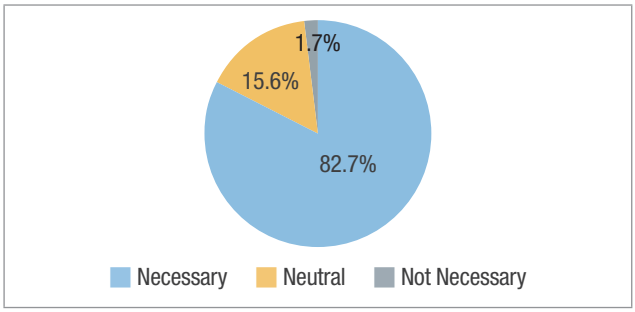
Korea offers one of the most accessible healthcare systems among OECD countries, with 12.8 hospital beds per 1,000 people—nearly three times the OECD average—and an average of 17.5 doctor visits per person annually, surpassing the OECD average of 6.3. Virtually the entire population is covered by National Health Insurance (NHI), and most major hospitals use electronic medical records (EMRs), enabling systematic management of trial participants' data by disease. Leveraging this infrastructure, KoNECT provides feasibility services to help global pharmaceutical and biotech companies conduct clinical trials in Korea. Furthermore, individuals interested in participating in clinical trials can easily access relevant information through the Ministry of Food and Drug Safety (MFDS) website (https://nedrug.mfds.go.kr/searchClinic) or KoNECT's Clinical Trial Participation Portal(see #3 on page 18 for details.)

(Source: OECD Health Statistics Report, Ministry of Health and Welfare, 2024)

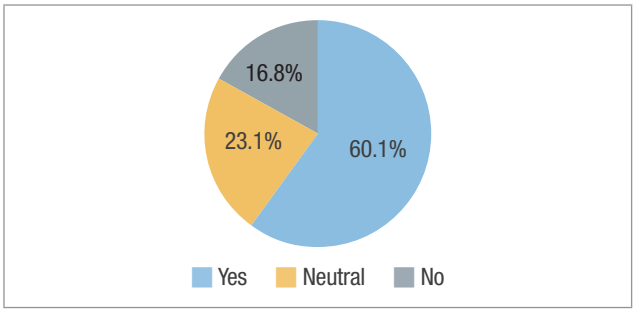
Positive Public Attitude Toward Clinical Trials

The Korean public maintains a generally positive perception of clinical trials. According to surveys conducted by KoNECT, over 80% of respondents acknowledge the necessity of clinical trials, and more than 60% express a willingness to participate. These findings highlight a strong public understanding of the value of clinical research and a supportive environment.

Necessity of Clinical Trials



Willingness to participate in clinical trials

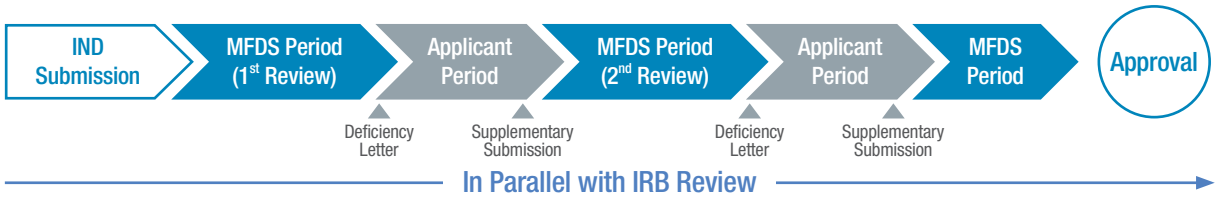


(Source: KoNECT Survey on Public Awareness of Clinical Trials, 2023)

(3) Streamlined Regulatory Processes with Cost and Time Efficiency

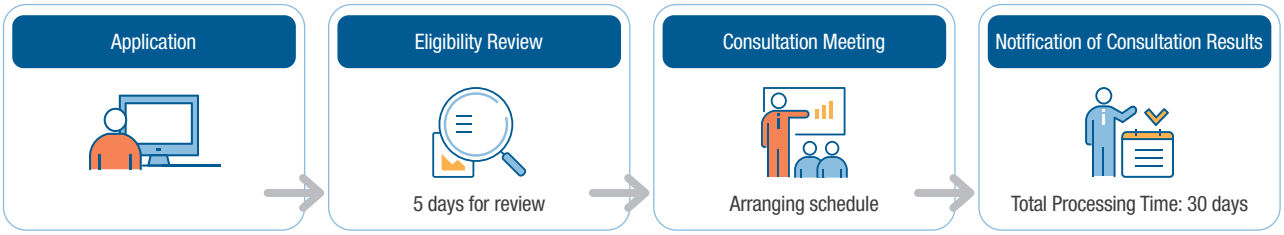
CTA Process in Parallel with IRB Review

Clinical trials in Korea require approval from both the Ministry of Food and Drug Safety (MFDS) for the Investigational New Drug (IND) application and the Institutional Review Board (IRB) at the trial site. IND reviews typically take 30 working days, while IRB approval takes about 3 weeks. However, for drugs intended to treat serious public health threats—such as infectious diseases—the MFDS may designate them as "Preliminary Crisis Response Medical Products," allowing for expedited IND review. Moreover, since IRB and IND reviews can proceed in parallel, this concurrent system shortens timelines and accelerates trial initiation.



Pre-Consultation and "Navigator" Program for Innovative Products

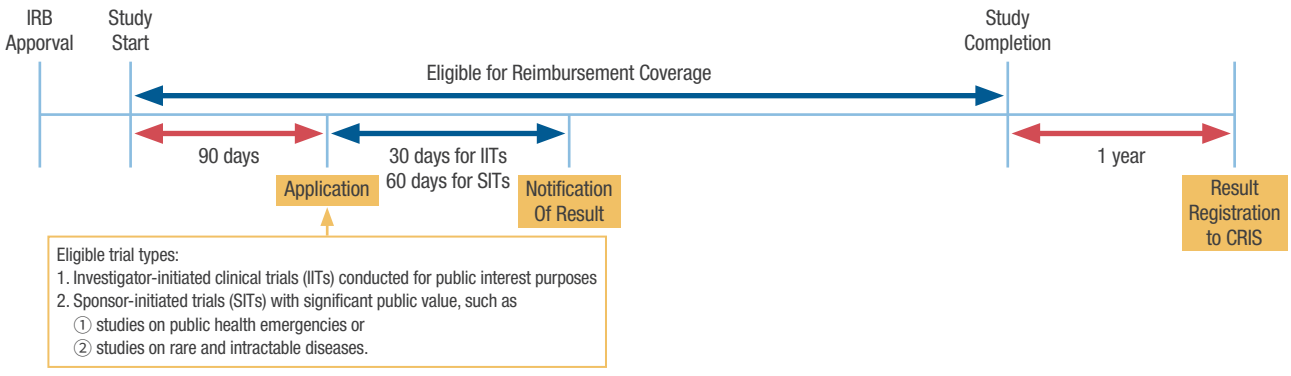
The Ministry of Food and Drug Safety (MFDS) offers pre-submission consultations for companies developing innovative products—such as treatments for life-threatening or serious diseases, orphan drugs, preventive or therapeutic agents for public health emergencies, new drugs, and advanced biopharmaceuticals. These consultations allow companies to request a review of the adequacy of their data before submitting an Investigational New Drug (IND) application or a New Drug Application (NDA).



Beginning in June 2025, the MFDS will launch the "Navigator" Program, selecting 20 innovative products—including breakthrough drugs, cell and gene therapies, and advanced medical devices for priority support. Each product will be assigned a dedicated case manager to provide customized, end-to-end regulatory guidance throughout the development and approval process.

Application of Health Insurance Benefits to Clinical Research

The National Health Insurance Service (NHIS) of Korea provides coverage for standard medical care costs incurred during clinical trials under certain conditions. Applications must be submitted within 90 days of the study start date, and results must be registered in the Clinical Research Information Service (CRIS) within one year of study completion. By sharing costs that were previously borne entirely by sponsors, this policy helps reduce the overall financial burden of conducting clinical trials.



(4) Integration of Advanced Technologies and Smart Clinical Infrastructure

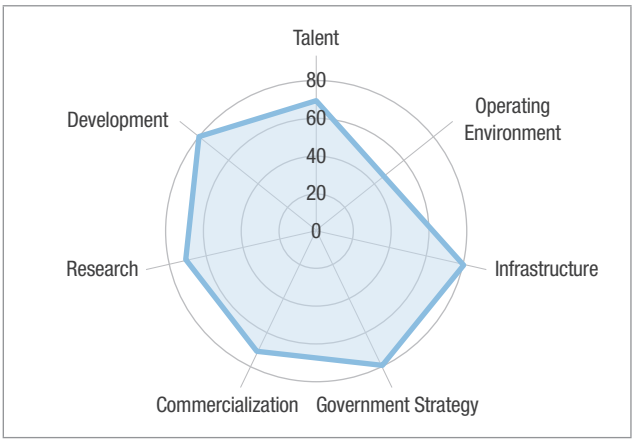
Korea's Leadership in Smart Clinical Innovation

Artificial intelligence (AI) is reshaping drug development—reducing costs and timelines, accelerating candidate discovery, and increasing clinical trial success rates. To lead this transformation, Korea's Ministry of Health and Welfare (MOHW) launched the "Medical AI R&D Roadmap (2024–2028)," promoting AI integration across the entire drug development lifecycle. According to Tortoise Media's 2024 Global AI Index, Korea ranks 6th globally, with outstanding performance in key categories such as development, government strategy, and infrastructure. The chart below highlights Korea's balanced strengths across research, infrastructure, and commercialization, reinforcing its position as a global leader in AI-driven clinical innovation.

Global AI Index Rankings (Top 10 by Year)

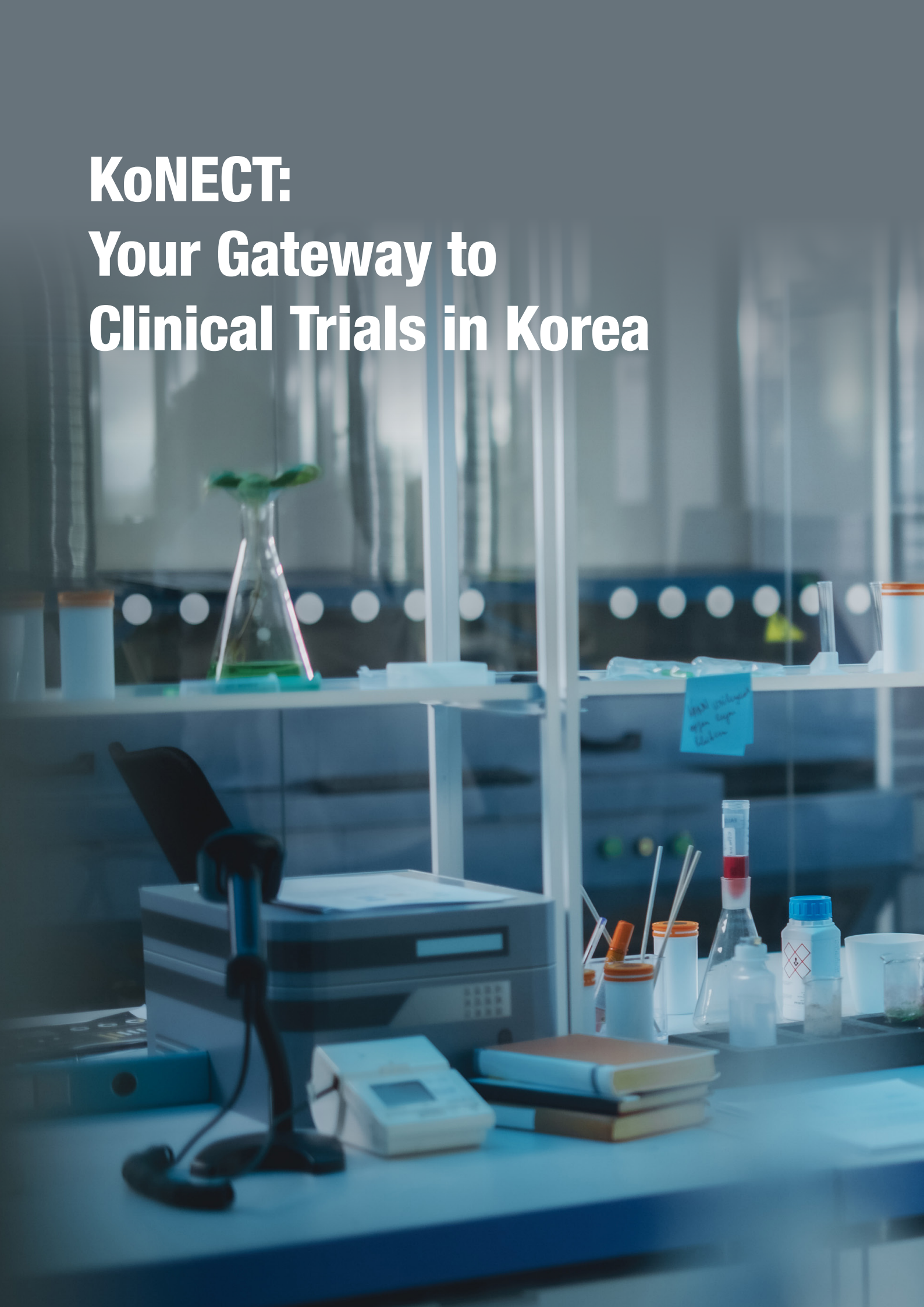
Rank	2021	2023	2024
1	US	US	US
2	China	China	China
3	UK	Singapore	Singapore
4	Canada	UK	UK
5	Israel	Canada	France
6	Singapore	Korea	Korea
7	Korea	Israel	Germany
8	Netherlands	Germany	Canada
9	Germany	Switzerland	Israel
10	France	Finland	India

Korea's AI Strengths by category



(Source: The Global Artificial Intelligence Index 2024, Tortoise Media)

KoNECT:
Your Gateway to Clinical Trials in Korea



KoNECT: Your Gateway to Clinical Trials in Korea

KoNECT (Korea National Enterprise for Clinical Trials) was established in 2007 as a non-profit organization with funding from the Ministry of Health and Welfare (MOHW) to advance Korea's clinical trial capabilities and infrastructure.

KoNECT (Korea National Enterprise for Clinical Trials) was approved as a foundation under the Ministry of Health and Welfare (March 25, 2014) with the goal of strengthening the global competitiveness of domestic clinical trials and supporting new drug development. In accordance with the 「Special Act on Fostering and Support of Pharmaceutical Industry (Act No. 15908, promulgated on December 11, 2018)」, KoNECT was designated as:

- An Institution Specializing in the Management of Information on the Research and Development of New Drugs (July 9, 2014)
- The National Center for Clinical Research Service (March 2, 2020)

KoNECT supports domestic and multinational clinical trials by strengthening research infrastructure, conducting policy studies, and providing expert training and certification. It also manages the collection and dissemination of clinical trial data to enhance trial quality and efficiency in Korea.

For more information about KoNECT, please visit the KoNECT website.
https://www.konect.or.kr/en/index.do

KoNECT: Your Gateway to Clinical Trials in Korea

KoNECT advances Korea's clinical trial environment by strengthening national infrastructure, supporting domestic companies and investigators, and enabling global sponsors to efficiently conduct clinical trials in Korea.

1. Feasibility Service for Accelerated Clinical Development in Korea

KoNECT partners with the Health Insurance Review and Assessment Service (HIRA), 40 major hospitals, and 13 cancer-specialized institutions to provide insights on patient populations and top investigators by disease area. This service supports global sponsors in evaluating patient pool availability and identifying investigators—enabling faster, more informed decisions for initiating clinical trials in Korea. Between 2022 and 2024, KoNECT provided 144 data reports. According to the 2023 Feasibility Service Performance Survey, 48% of service requests resulted in decisions to conduct clinical trials in Korea. Most data reports are delivered within 10 working days of application.

National Patient Data from Health Insurance Review and Assessment Service (HIRA)	- Patient volume over the past three years, including breakdowns by gender, age group, healthcare institution, inpatient/outpatient status, clinical department, region, comorbidities, and medical expenses
Site-Level Patient and Investigator Data from Major Hospitals	- Number of patients by disease(based on eligibility criteria) - Recommended investigators - Rising investigators with expertise by disease area
Epidemiological Data	- Comprehensive insights for 130 major diseases, including incidence and prevalence rates, mortality rates, age of onset, disease prognosis, diagnostic characteristics, and associated risk factors and genetic profiles

For more information and application details, please visit the official website.
https://www.konect.or.kr/en/contents/EMRData/view.do

2. Ensuring Quality and Competitiveness of Korean CROs

KoNECT operates a voluntary CRO registration platform to enhance the efficiency of clinical trial operations and promote collaboration within Korea's clinical research ecosystem. The platform offers timely, accurate information on the overall Korean CRO landscape, as well as insights into the strengths of individual companies. In particular, KoNECT operates the K-ACRO (KoNECT Accreditation of CROs) program to identify and highlight high-performing CROs with proven expertise and competitiveness. By connecting qualified Korean CROs with global sponsors as strategic partners, KoNECT supports the successful conduct of clinical trials in Korea. A list of registered CROs is available on pages 23–24. For more information, please contact KoNECT by email(kcro@konect.or.kr).

3. Clinical Trials Enrollment Support

KoNECT operates the Korean Clinical Trials Participation Portal—a public platform that enhances accessibility and transparency for both potential participants and sponsors, facilitating broader engagement in clinical research.

	General Services	Specialized Service
For Participants	- User-friendly educational content, including explanations of clinical trial terminology - Online clinical trial participation application - General inquiry and consultation service	- Comprehensive information on clinical trials and investigational products - Online application for trial participation - Mobile alert notifications for trial updates - Personalized consultation services
For Sponsors	- Participant enrollment support through an online platform	- Patient recruitment support through a dedicated webpage and consultation service

For more information, please visit the official website.
https://www.koreaclinicaltrials.org

4. Comprehensive Training Program for Clinical Trial Professionals

Since its designation in 2016 as Korea's first officially authorized clinical trial education institution, KoNECT has provided extensive training programs—offering 80 courses to 16,326 participants in 2024 alone. Notably, since 2012, KoNECT has certified professionals in four key clinical trial roles. This certification program transitioned into a formal licensure system in 2023, issuing Korea's first official qualifications for clinical trial professionals.

Training Program (80 courses in 2024)	Clinical Research Coordinator (CRC), Clinical Research Associate (CRA), Quality Assurance (QA), Regulatory Affairs (RA), Data Management (DM), Medical Writing (MW), Statistics, etc.
Certification Program (4 key clinical trial roles)	Principal Investigator (PI), Clinical Research Coordinator (CRC), Clinical Research Associate (CRA), Clinical Research Pharmacist (CRP)

For more information, please visit the official website.
https://lms.konect.or.kr/web/en/index.do

5. Asia's Leading Clinical Trials Conference: KoNECT International Conference

The KoNECT International Conference (KIC) has been held annually since 2014, in collaboration with the Ministry of Health and Welfare (MOHW) and the Ministry of Food and Drug Safety (MFDS). Each year, the conference brings together approximately 1,500 global experts to address key issues in drug development and clinical trials. It also serves as a leading platform for business partnering, with over 70% of participants representing the industry.

For more information and registration details, please visit the official website.
https://www.konectintconference.org/web/index.do

6. Clinical Trials Intelligence: Domestic & Global Data

As the government-designated agency for information management in new drug development, KoNECT conducts research and analysis on domestic and global clinical trials. Each year, KoNECT publishes trend reports based on data from the Ministry of Food and Drug Safety (MFDS) and ClinicalTrials.gov, along with the <KoNECT Brief> and the <KoNECT Clinical Trials White Paper>. Other publications include national industry surveys and statistical reports.

For more information, please visit the official website.
https://www.konect.or.kr/en/board/NoticeAndMedia/boardList.do

7. SmartTech Clinical Research & Innovation

From 2023 to 2027, the Ministry of Health and Welfare (MOHW) is investing approximately USD 17 million over five years to establish a next-generation clinical trial environment by developing innovative technologies and to enhance the overall efficiency of clinical trials. As the project lead, KoNECT is coordinating a national consortium for smart clinical trial technology development, comprising 35 institutions and focusing on four strategic areas.

Project 1	Project 2	Project 3	Project 4
Decentralized Clinical Trials (DCTs) Technologies	Digital Therapeutics	Advanced Regenerative Medicine and Advanced Biological Products	Data Standardization and Implementation

For more information, please visit the official website.
https://www.scrc.kr/main/main

Appendices

Appendix 1. Key Agencies & Industry Associations

Ministry of Health and Welfare (MOHW)

The vision of the Ministry of Health and Welfare (MOHW) of Korea is "Building a Happy Society for All." The MOHW aims to achieve this goal through three missions: building social safety nets for a better tomorrow, taking a life-course approach to healthy life, and supporting a stable life after retirement. The Ministry of Health and Welfare (MOHW) coordinates and oversees health and welfare related affairs and policies. Its mission is to establish an inclusive welfare state that ensures happy and healthy lives for all citizens. The ministry consists of four offices and 20 bureaus with approximately 3,000 employees. Of the 20 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 establishing and coordinating the Health Industry Policy Program, which is regularly updated. The MOHW is responsible for oversight of the health and healthcare industries, including all businesses involved in the provision of medical services, cosmetics, pharmaceutical products, and medical devices. The ministry works to foster, support and improve the industry's infrastructure through affiliated organizations including Korea Health Industry Development Institute (KHIDI). It also overseas the national R&D programs and establishes principles for bioethics policy.

https://www.mohw.go.kr/eng/

Ministry of Food and Drug Safety (MFDS)

Under the vision of "Your Safety is our standard", 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, alongside the National Institute of Food and Drug Safety Evaluation (NIFDS) and six Regional Offices. The Pharmaceutical Safety Bureau and Medical Devices Safety Bureau oversees clinical trial regulations, with specialized divisions ensuring the safety and efficacy of new medical products in compliance with international standards.

https://www.mfds.go.kr/eng/index.do

National Institute of Food and Drug Safety Evaluation (NIFDS)

National Institute of Food and Drug Safety Evaluation (NIFDS) is a specialized institute that performs science-based risk assessment, testing/analysis and review/evaluation of food and drug products, medical devices, cosmetics, etc. and has been playing a key role for regulatory science in the food and drug safety area. NIFDS will be committed to enhance its expertise in future-oriented researches in response to the 4th Industrial Revolution, and review/evaluation of medical products with new concepts. As NIFDS give its highest priority to the people with the vision of 'inclusive nation', it will also strive to protect every one in the country in terms of food and drug safety.

https://www.mohw.go.kr/eng/

Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA)

The Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) is an organization representing the Korean pharmaceutical industry, established in 1945 with the mission of 'improving national healthcare through the sustainable development of the pharmaceutical industry'. To achieve the purpose, KPBMA plays a variety of roles, including policy support activities, educational programs, and supporting for its member companies. Membership extends beyond Korean pharmaceutical companies to encompass biotech firms specializing in digital therapeutics and artificial intelligence, as well as multinational pharmaceutical corporations.

https://www.kpbma.or.kr/eng/

Appendix 1. Key Agencies & Industry Associations

Korea Drug Development Fund (KDDF)

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 has been backed by three Korean ministries: the Ministry of Science and ICT (MSIT), the Ministry of Trade, Industry, and Energy (MOTIE), and the Ministry of Health and Welfare (MOHW). 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. With a mission to advance Korea's biomedicine technologies and meet global standards, KDDF aims to fund 1,234 drug development projects, achieve 4 FDA or EMA approvals for new drugs, and deliver 1 blockbuster drug by 2030.

https://kddf.org//en

Korean Research-based Pharmaceutical Industry Association (KRPIA)

Korean Research-based Pharmaceutical Industry Association (KRPIA) represents all its member pharmaceutical companies that produce innovative new drugs through continuous R&D activities to enhance patients' health and to enrich the quality of their lives. KRPIA is striving to create an environment where local and global research-oriented pharmaceutical companies actively invest in developing new drugs and contribute to enhancing the health of all humankind. KRPIA was established in March 1999 and gained official approval for an incorporated association by the Ministry of Health and Welfare (MOHW) in June 2000 and by the Ministry of Food and Drug Safety (MFDS) in 2014. As of 2023, its membership includes a total 48 research-oriented pharmaceutical companies.

https://www.krpia.or.kr/eng/

Korean Association of Institutional Review Boards (KAIRB)

The Korean Association of Institutional Review Boards (KAIRB) was founded in March 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 as well as training programs to enhance the capabilities of IRB members have been organized by KAIRB since its foundation. As a result, overall awareness in Korea for the importance of research ethics has been mainly among professionals in the biomedical research community, especially in emerging areas such as AI-based clinical trials and real-world data studies. 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 and enhancing the reliability and efficiency of 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/

Korea Health Industry Development Institute (KHIDI)

Korea Health Industry Development Institute (KHIDI) is a government-affiliated institution that provides professional and systematic support for the development of the domestic health industry and enhancement of healthcare services. Since its establishment in 1999, KHIDI has led the expansion of healthcare R&D investment and consistently promoted the competitiveness of Korea's healthcare industry in regards to its health services, pharmaceuticals, medical devices, cosmetics/nutraceuticals, digital healthcare, and AI-driven healthcare technologies. KHIDI has earned an outstanding reputation through its years of efforts in supporting the globalization of Korea's healthcare industry 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 provides not only comprehensive information on research-oriented hospitals, pharmaceutical and medical devices industries, but also offers tailored support and infrastructure matching services through specialized divisions.

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

Appendix 2. Directory of Korean Clinical Research Organization

To enhance the capabilities and credibility of domestic CROs, KoNECT operates a voluntary registration platform. To date, over 70 domestic organizations, including CROs and laboratories, are registered under the program. Further details are available on the official website.

https://www.konect.or.kr/kr/pages/cro/croAllList.do

1. Clinical Research Organization

Updated Date: 29 March 2024

* KoNECT Accredited CROs

Specialty								Company Information			
Clinical Operation	Consulting	Data Management	Medical Writing	Pharmacovigilance	Quality Assurance / Quality Control	Regulatory Affairs	Statistics	Name	URL	Email	Tel
■		■						C&R Research Inc.*	www.cnrres.com/en	BD@cnrres.com	(+82)-2-6251-1500
■			■					CLIPS Bnc CO.,LTD *	www.clipsbnc.com	clips@clipsbnc.com	(+82)-2-70-5001-3800
		■					■	D2S*	www.d2s.co	manager@d2s.co	(+82)-70-8670-1702
■								Novotech Asia Korea	novotech-cro.com	jai.kim@novotech-cro.com	(+82)-2-0794-0600
■		■						Hyundai ADM Bio	hdadmbio.com/eng	hdadmbio@hdadmbio.com	(+82)-2-730-1457
■							■	LSK Global Pharma Services Co.,Ltd	www.lskglobal.com/en	bd_dept@lskglobal.com	(+82)-2-546-1008
■						■		UMT	www.e-umt.com	ncshin@e-umt.com	(+82)-70-4818-8500
■								RNDmotiv	www.rndmotiv.com	rndmotiv1@rndmotiv.com	(+82)-2-734-8434
■			■					SEOULCRO CO.LTD	www.seoulcro.com	yb.seong@seoulcro.co.kr	(+82)-2-3447-0181
■						■		DreamCIS	www.dreamcis.com/eng	krbd@tigermedgrp.com	(+82)-2-2010-4500
■	■							Neo Nutra Co.,Ltd.	www.neonutra.com	help@neonutra.com	(+82)-2-2277-3935
■			■					KH MEDICARE CO.,Ltd	blog.naver.com/khmedicare	khmediceo@khmedi.kr	(+82)-10-9464-6031
■								Korea Medicine Research Institute Inc.	www.kmri.co.kr	novakim@kmri.co.kr	(+82)-31-750-0880
■			■					Dt&CRO	www.dtncro.com/en/main	info@dtncro.co.kr	(+82)-31-322-2400
■						■		EPS International Korea Ltd.	www.epsik.co.kr	epsik@epsik.co.kr	(+82)-2-6385-3300
■						■		WIKICRO	www.wikicro.com	wikicro.com@wikicro.com	(+82)-31-712-8520
■			■					Mediplexus Co., Ltd	www.mediplexus.net	suwan.son@mediplexus.net	(+82)-70-4099-1344
■							■	CC&I research	www.ccnires.com	info@ccnires.com	(+82)-2-6927-6980
■		■						Pharmaron US Clinical Services Inc.	www.pharmaronclinicalservices.com	dujin.lee@pharmaron.com	(+82)-10-9336-3767
■		■						BX PLANT Co.,Ltd	www.bxplant.co.kr	info@bxplant.co.kr	(+82)-2-6259-7371
■						■		Synex Consulting Ltd.	www.synex.co.kr/index_ES.asp	HRM@synex.co.kr	(+82)-2-6202-3300
■			■					Symyoo Co., Ltd	www.symyoo.co.kr	info@symyoo.com	(+82)-2-584-2007
■							■	Research Mentor	www.researchmentor.co.kr	info@researchmentor.co.kr	(+82)-2-463-7821
■		■						Korean Cancer Study Group	www.kcsg.org/en/index.do	kcsg@kcsg.org	(+82)-2-797-4437
■			■					Promedis	promedis.co.kr/en	info@promedis.co.kr	(+82)-2-2135-5979
■								CalebMultilab Inc.	www.calebml.co.kr	calebml@calebml.co.kr	(+82)-2-6202-1300
■								MBIO	www.m-bio.co.kr	kjh@m-bio.co.kr	(+82)-31-778-6694
■	■							MIRACULUS	www.miraculus.co.kr	jacob.kim@miraculus.co.kr	(+82)-10-6432-8772
■		■						ariBnC		bellacharm@aribnc.com	(+82)-70-7462-9404
	■				■			CiKLux Inc	www.ciklux.com	hyunsang.cho@ciklux.com	(+82)-10-8288-7771
	■	■						SNUBITS		snubits.gjk@gmail.com	(+82)-31-712-9000
	■					■		Meditip	meditip.co.kr/?theme=en	bd@meditip.co.kr	(+82)-2-2088-3170
	■						■	EvidNet,Inc.	evidnet.com/en	contact@evidnet.com	(+82)-2-6091-5331
	■				■			Consulting BARO Inc.	blog.naver.com/consultingbaro	seryun.kim@baro-cqa.com	(+82)-10-8278-0185
		■					■	Helptrial Inc.	www.helptrial.com	admin@helptrial.com	(+82)-10-3478-5462
		■					■	BETHESDASOFT	www.bethesdasoft.co.kr	mytrial@bethesdasoft.co.kr	(+82)-70-4607-3283
		■						SAFESOFT	safesoft.co.kr/default/	safesoft@safesoft.co.kr	(+82)-31-8023-9700
			■			■		Linical Korea Co.,Ltd	www.linical.com	hana.kim.b@linical.com	(+82)-2-2038-8700
				■	■			SELTASQUARE	www.seltaglobal.com	sales@seltasquare.com	(+82)-2-6951-2102

Appendix 2. Directory of Korean Clinical Research Organization

2. Laboratory Service & Others

Specialty							Company Information			
Method Development	Project Management	Quality Assurance / Quality Control	Sample Analysis	IT Solution	Logistics	Investigational Product	Name	URL	Email	Tel
■			■				SCL Healthcare	www.sclhealthcare.co.kr	central_lab@scllab.co.kr	(+82)-31-280-6232
■			■				GCCL	eng.gccl.co.kr	gccl@gccorp.com	(+82)-31-270-1381
■			■				EONE LIFE SCIENCE INSTITUTE	www.eonels.com	leens@eonels.com	(+82)-32-210-2374
■			■				HuScience Co.,Ltd	huscience.net/en/main/index.php	huscience@huscience.net	(+82)-2-898-4998
■	■						Geneon biotech	www.geneon.kr	gene@geneon.kr	(+82)-70-4712-9090
	■	■					ODIN Bio&Science Co.,Ltd	odinbionsci.com/	leehiw76@gmail.com	(+82)-10-3812-5009
	■						Novotech Asia Korea	novotech-cro.com/	jai.kim@novotech-cro.com	(+82)-2-794-0600
	■		■				SML Meditree co.,Ltd.	www.medi-tree.com	meditree@medi-tree.com	(+82)-2-575-3395
			■				CalebMultilab Inc.	www.calebml.co.kr	calebml@calebml.co.kr	(+82)-2-6202-1300
			■				MBIO	www.m-bio.co.kr	kjh@m-bio.co.kr	(+82)-31-778-6694
			■				Korea Medicine Research Institute.Inc.	www.kmri.co.kr	novakim@kmri.co.kr	(+82)-31-750-0880
				■			SAFESOFT	safesoft.co.kr/default	safesoft@safesoft.co.kr	(+82)-31-8023-9700
					■	■	Clinigen Korea LLC	www.clinigengroup.com	juhyun.park@clinigen.co.kr	(+82)-2-2088-1153

3. Medical Device

Specialty							Company Information			
Clinical Operation	Consulting	Data Management	Medical Writing	Pharmacovigilance	Quality Assurance / Quality Control	Regulatory Affairs	Statistics	Name	URL	Email	Tel
■						■		Evertri Inc.	www.evertri.com	sunny@evertri.com	(+82)-10-6201-7040
■		■						The Way Healthcare	www.theway-hc.co.kr/default	theway@theway-hc.co.kr	(+82)-10-9246-3036
	■						■	GRK Partners CO.,LTD	www.grkcon.com	ceo@grkcon.com	(+82)-10-6594-0622
	■						■	GIVITAInc.	gi-vita.io	info@gi-vita.io	(+82)-2-6083-8403
		■						oncoMASTER	www.onco-master.com	contact@oncomaster.co.kr	(+82)-2-2286-1560
			■			■		Medical Research,Co.Ltd.	www.jungnp.com/eng/main	jnpconsulting@gmail.com	(+82)-2-866-2182

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