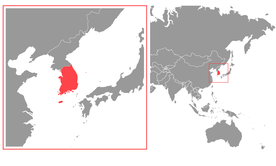
# Clinical Trials in South Korea

H1 2021 Research report

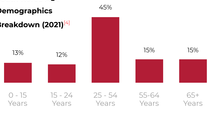


## Location Data

The Clinical Trials industry in South Korea has demonstrated unprecedented growth over the past two decades in terms of both the quality and quantity of clinical trials conducted. The country's blend of clinical research experience, advanced healthcare infrastructure, high population density, and a highly supportive, investment minded, government has boosted the country into one of the top locations worldwide for conducting clinical trials



**South Korea Age Demographics Breakdown (2021)**[4]




The country' population is 51,32 million people,[1] 96% of which are of Korean ethnicity.[2]

South Koreans have access to a universal healthcare safety net, although a significant portion of healthcare is privately funded. In 2015, South Korea ranked first in the OECD for healthcare access. Satisfaction of healthcare has been consistently among the highest in the world – South Korea was rated as the second most efficient healthcare system by Bloomberg.[3]

The Ministry of Food and Drug Safety (MFDS), is a South Korea government agency responsible for promoting the public health by ensuring the safety and efficiency of foods, pharmaceuticals, medical devices and cosmetics as well as supporting the development of the food and pharmaceutical industries.[5]
The main goal is to offer people safe foods and drugs.

Clinical Trials Regulations may be found on the MFDS website at: https://www.mfds.go.kr/eng/brd/m_18/list.do

식품의약품안전처

## South Korea - Clinical Trial Overview

There are a multitude of factors that make South Korea stand out as an excellent destination for the conduct of clinical trials. Those include but are not limited to:

- The excellence of Korean investigators
- Regulatory reform and harmonization in the early 2000s
- The establishment of the "Clinical Trial Centers (CTCs)" many with world-class facilities including phase 1 units and well-trained clinical trial personnel
- The Human Research Protection Program (HRPP)
- Efficient and experienced IRBs at major university hospitals

These factors and more, have contributed significantly to South Korea's success in attracting global development studies.

184 medical institutions were designated by the Korean government as qualified clinical trial sites, 57 of which are within the Seoul agglomeration.[6]

Four Korean sites are included in top-10 global clinical investigator sites: Seoul National University, Asan Medical Center, Samsung Medical Center, and Yonsei University Severance.[7]

Korea also has one of the world-wide lowest percentages of nonrecruiting sites at just 4.6%.[7]

The key disease patterns in Korea are similar to those in Western countries. Korean patients also have similar unmet medical needs as patients in Western countries.[7]

## Regulatory & Ethics Approval Process

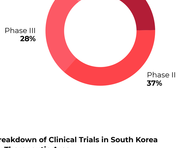
- The Korean Ministry of Food and Drug Safety (MFDS) is the main regulatory body for drugs, medical devices, food, and cosmetic products.[8]
- The sponsor should obtain Institutional Review Board (IRB) approval for a new clinical study.
- All of the documents in the clinical trial application should be translated into Korean language.
- The IRB approval process can take 1-2 months.
- After the completion of IRB approval process the clinical study should be registered in CRIS (Clinical Research Information Services).[9]
- Korea's drug clinical trial approval forms can now be submitted through the e-registration system. Applicants and CROs can self-register their products after receiving both IRB and MFDS approval.
- To obtain approval of a clinical trial protocol in South Korea, a foreign company without an established presence in Korea must delegate all rights and responsibilities for the execution of the clinical trial through an agreement with a contract research organization established in Korea.

## Trial Data

Based on data extracted from ClinicalTrials.gov, there were 387 clinical trials initiated in South Korea (including local and bioequivalence studies) during the first half of 2021. This translates to a 28% increase in the number of clinical trials initiated in comparison with the first half of the previous year when only 302 studies were initiated.

However, if one excludes bioequivalence studies and studies without a defined "Phase", there were only 226 clinical trials initiated during H1 2021 compared to 163 studies initiated in H1 2020, representing a 38% jump.

**Breakdown of Clinical Trials in South Korea by Phase (H1 2021)**

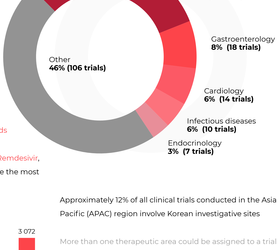

The majority of clinical trials conducted in South Korea were interventional studies representing 84% of all studies conducted.

The most frequent phase of clinical trials conducted across the South Korean sites by total number of studies was Phase II.

**Breakdown of Clinical Trials in South Korea by Therapeutic Area**

The largest number of clinical trials initiated in South Korea during the first half of 2021 by therapy area were Oncology (71 study), Gastroenterology (18 studies), Cardiology (14 studies), Infectious diseases (10 studies) and Endocrinology (7 studies).

Also, during the same period there were 10 interventional studies initiated with the aim of evaluating different COVID-19 treatment methods with 3,376 subjects to be enrolled.
In accordance with these studies' descriptions, Remdesivir, Fluvoxamine, Clevudine and Sotrovimab became the most promising medications in this area.




Approximately 12% of all clinical trials conducted in the Asia Pacific (APAC) region involve Korean investigative sites

**Number of Clinical Trials conducted in South Korea vs. APAC Region**


More than one therapeutic area could be assigned to a trial. Observational Clinical trials and Clinical trials without FDA-defined phases (from I to IV) were not included in this chart. APAC is defined as macro-region including East Asia, South Asia, Southeast Asia and Oceania.

## Sponsor Data

By country / region of origin Europe accounted for the largest number of foreign pharmaceutical sponsored clinical trials initiated in the first half of 2021 in South Korea.

The headquarters of foreign sponsor companies conducting clinical trials in the first half of 2021 in South Korea were split between Europe (4 companies), the U.S. (3 companies) and Japan (1 company).

At the same time there were two domestic innovative South Korean companies – Chong Kun Dang Pharm. and Daewoong Pharmaceutical, conducting clinical studies in South Korea and which appear in the TOP-10 ranking table.

Observational clinical trials and clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking.

**Top-10 clinical trial Sponsors in South Korea in H1 2021**

| № | Company Name | Studies | Subjects |
|---|---|---|---|
| 1 | Hoffmann-La Roche | 19 | 11 247 |
| 2 | Chong Kun Dang Pharmaceutical | 19 | 1 671 |
| 3 | Merck | 14 | 8 842 |
| 4 | AstraZeneca | 12 | 5 247 |
| 5 | Janssen | 6 | 19 931 |
| 6 | Daewoong Pharmaceutical | 6 | 1 617 |
| 7 | Daiichi Sankyo | 5 | 1 944 |
| 8 | Novo Nordisk | 4 | 5 400 |
| 9 | Bristol-Myers Squibb | 4 | 1 018 |
| 10 | AbbVie | 4 | 660 |
| | **Combined share** | **41%** | **62%** |

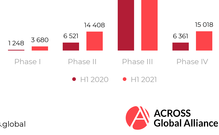
More than one Sponsor company may be involved in a clinical trial.

## Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in South Korea during the first half of 2021 (including multi-center international studies) significantly increased in comparison with the same period in 2020.

The total number of subjects raised from 67,173 subjects in the first half of 2020 to 92,787 subjects in the first half of 2021 representing a growth rate of 38%.

**Breakdown of Number of Subjects Enrolled in South Korea by Phase (H1 2021)**




* Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

# Clinical Trials in South Korea

H1 2021 Research report

## Data Search and Analysis Approach

All of stats data used in this document were downloaded from the ClinicalTrials.gov website as a .CSV file with the download options listed in the table below.

.CSV file export was completed with the following options:
Number of studies [to download]: all studies.
Select table columns: All available columns.
Select file format: Comma-separated values.

| № | Item Name | Fields in Pivot Table | Details |
|---|---|---|---|
| 1 | Number of H1 2021 Trials conducted in South Korea vs. APAC Region | NCT | |
| 2 | Breakdown of Clinical Trials initiated in South Korea by Phase | NCT, Phases | Exclude "Not Applicable" and empty values in "Phase" field |
| 3 | Percentage Breakdown of Clinical Trials initiated in South Korea by Phase | NCT, Phases | Exclude "Not Applicable" and empty values in "Phase" field |
| 4 | Breakdown of Clinical Trials in South Korea by Therapeutic Area | NCT, Conditions, Phases | See below * |
| 5 | Breakdown of Interventional vs. Observational Trials in South Korea | NCT, Study Type | |
| 6 | Sponsors Ranked By Number of Studies and Number of Subjects | NCT, Enrollment, Phases, Sponsor | See below ** |
| 7 | Breakdown of Number of Subjects Enrolled in South Korea by Phase | NCT, Phases, Enrollment | See below *** |

* Use "Phases" filed as a filter. Exclude "Not Applicable" and empty values in "Phase" field. Use a simple Dictionary of Nosologies (see below) to count the number of studies for each nosology.

** Use "Phases" filed as a filter. Exclude "Not Applicable" and empty values in "Phase" field. Use "Number of values" by "NCT Number" field. Use "Sum" by "Enrollment" field. Use decreasing sorting of the table by "NCT Number" field.

*** Exclude "Not Applicable" and empty values in "Phase" field. Use "Number of values" by "NCT Number" field. Use "Sum" by "Enrollment" field.

If you want to use the same source .CSV file used in this report – just let us know via info@across.global and we'll send it to you.

**Dictionary of Nosologies used for Breakdown by Therapeutic Area**

| № | Therapeutic Area | Filter String |
|---|---|---|
| 1 | Gastroenterology | *gastr + colon + liver + cron + nash + pancrea* |
| 2 | Hematology | *hema + blood* |
| 3 | Dermatology | *derm + skin* |
| 4 | Urology | *urolog + nephr* |
| 5 | Immunology | *immun* |
| 6 | Infectious diseases | *infect + virus* |
| 7 | Cardiology | *cardi + heart + stroke* |
| 8 | Neurology | *neuro + cognitive* |
| 9 | Oncology | *cancer + phoma + noma + tumor + sarcoma* |
| 10 | Ophthalmology | *eye + ophtalm* |
| 11 | Rheumatology | *rheum + arthr* |
| 12 | Endocrinology | *endocrin + insulin + diabete* |
| 13 | Mental health | *mental + psych + depress + anxiety* |
| 14 | Surgery | *surger + transplant* |
| 15 | Geriatrics | *alzh + parkins* |

## About The White Paper

The White Paper is a free publication produced by ACROSS Global (CRO) Alliance for decision makers in the pharmaceutical industry. The document pulls together data from numerous public sources into a single brief document to aid decision makers planning to conduct clinical trials.

All of the data contained in this document are actual as of 12-JULY-2021.
For more information or if you would like to review a .CSV file of the data extracted from ClinicalTrials.gov (used in this White Paper) please write to: info@across.global.

## About ACROSS Global

ACROSS Global is a global alliance of local contract research organizations successfully operating in 98 countries and covering more than 25 therapy areas.

High recruitment rates combined with innovative technology allows ACROSS partner companies to offer our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

All clinical studies conducted by ACROSS Partners conform to Good Clinical Practice (GCP) as well as local and international regulations ensuring the highest level of quality of the final study data.

We apply continuous improvement methodology to our working practices and IT infrastructure – and replace outdated R&D strategies by novel, more efficient approaches to clinical research.