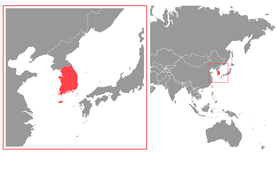
Clinical Trials in South Korea

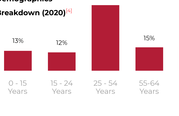
January - June 2020 Research report

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 (2020) [1]



The country' population is 51.27 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

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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

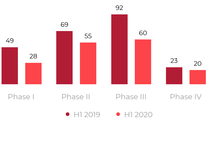
- The Korean Ministry of Food and Drug Safety (MFDS) is the main regulatory body for drugs, medical devices, food, and cosmetic products.[8]
- The sponsor should obtain Institutional Review Board (IRB) approval for a new clinical study.
- All of the documents in the clinical trial application should 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.

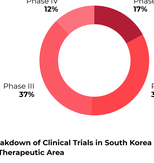
Trial Data

Based on data extracted from ClinicalTrials.gov, there were 302 clinical trials initiated in South Korea (including local and bioequivalence studies) during the first half of 2020. This translates to a 30% decline in the number of clinical trials initiated in comparison with the first half of the previous year when a total of 428 studies were initiated.

However, if one excludes bioequivalence studies and studies without a defined "Phase" there were only 163 clinical trials initiated during the first half of 2020 compared to 233 studies initiated in previous year, representing a 30% decline.

Breakdown of Clinical Trials in South Korea by Phase (January - June 2020)

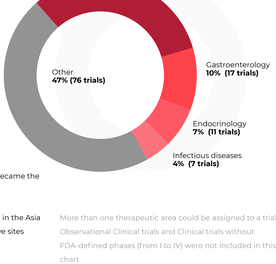




The majority of clinical trials conducted in South Korea were interventional studies representing 85% of all studies conducted.

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

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 2020 by therapy area were Oncology (52 studies), Gastroenterology (17 studies), Endocrinology (11 studies) and Infectious diseases (7 studies).

Also, during the same period there were 7 interventional studies initiated with the aim of evaluating different COVID-19 treatment methods with 8,285 subjects to be enrolled. In accordance with these studies' descriptions, Remdesivir, Clevudine and Lopinavir-Ritonavir became the most promising medications in this area.

Approximately 13% 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 2020 in South Korea.

The headquarters of foreign sponsor companies conducting clinical trials in the first half of 2020 in South Korea were split between Europe (4 companies) and the U.S. (3 companies).

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

Top-10 clinical trial Sponsors in South Korea in H1 2020

№	Company Name	Studis	Subjects
1	Merck Sharp & Dohme	15	13 013
2	Chong Kun Dang Pharmaceutical	9	643
3	AstraZeneca	6	2 281
4	Eli Lilly	5	14 108
5	Hoffmann-La Roche	5	1 633
6	Novartis	4	1 631
7	Janssen	4	947
8	AbbVie	4	880
9	Daewoong Pharmaceutical	4	471
10	HK inno.N Corporation	4	207
	Combined share	**37%**	**53%**

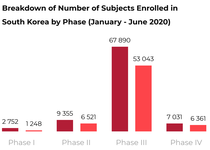
Observational clinical trials and clinical trials without FDA-defined phases (from I to IV) were not counted in this ranking.

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 2020 (including multi-center international studies) saw a steep decline when compared to the same period in 2019. The total number of subjects fell from 87,028 subjects in the first half of 2019 to 67,173 subjects in the first half of 2020 representing a decline rate of 23%. The most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

Breakdown of Number of Subjects Enrolled in South Korea by Phase (January - June 2020)



* 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.

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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 2020 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*

№	Therapeutic Area	Filter String
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 11-AUG-2020.
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 99 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.