Clinical Trials in APAC

H1 2021 Research report

Location Data

The Asia Pacific (APAC) Region is defined as macro-region including East Asia (China, Hong Kong, Japan, Mongolia, South Korea and Taiwan), South Asia (Bangladesh, India, Nepal and Pakistan), Southeast Asia (Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam) and Oceania (Australia and New Zealand) countries.

During the past two decades the Asia-Pacific region has emerged as a very promising region for conducting clinical trials, accounting for over 18% of total number of studies conducted Worldwide in the first half of 2021[1].

The APAC region offers a genetically diverse population of 4.3 billion people (i.e. 60% of worldwide population)[2], and in countries such as India and China, many of these people may be treatment-naïve. This mega-population includes also a large affluent sub-population that manifests lifestyle-related health conditions similar to those in Western countries.

In some cases — such as cardiovascular diseases, infectious diseases and hepatitis — the incidences of disease may even be significantly higher than in Western countries, especially for older populations[3].

Intellectual property protection in Singapore and Japan are amongst the strongest in the world, and other APAC countries are also increasingly focusing on protecting innovator's rights[4]. Singapore as an example, has a sophisticated transportation and communication infrastructure, regulatory framework, and educated workforce, which supports both clinical operations and supply chain whilst and there are other countries across the APAC region that aspire to achieving such standards.

In APAC countries approvals, including Institutional Review Board (IRB), regulatory requirements, import licensing, and contract negotiations can often be undertaken simultaneously. Governments in Asia-Pacific continue to implement measures to improve the regulatory environment for clinical trials in their countries[4].

APAC countries are rapidly becoming more competitive by building appropriate site experience, technological expertise, infrastructure, and scale to manage large clinical trials – as well as study compliance levels equivalent to Europe and North America, as indicated by analysis of the outcomes of the U.S. FDA inspections by region[4].

The average clinical trial cost in Asia is about 30%–40% lower than the USA and the EU, with the combined cost for each patient per visit in China, India, and Thailand nearly equivalent to per patient per visit cost in the USA alone[4].

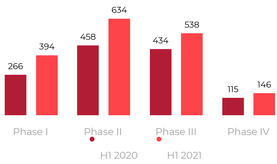
Trial Data

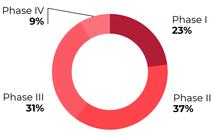
During the first half of 2021 there were 3,072 clinical trials initiated in the APAC region including local and bioequivalence studies. This represents a 26% increase in comparison with the previous year when a total of 2,436 studies were initiated.

However, if one excludes bioequivalence studies and studies without FDA-defined Phase 1,712 clinical trials were initiated during the first half of 2021 compared to 1,273 studies initiated in previous year with year on year growth rate of 34%.

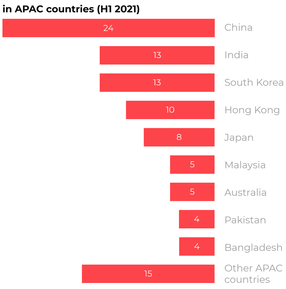
The largest number of clinical trials initiated in the APAC region during the first half of 2021 were related to Oncology, Infectious Diseases, Cardiology, Endocrinology and Gastroenterology. Other prominent therapy areas included Dermatology, Rheumatology and Geriatrics.

Breakdown of Clinical Trials in APAC Countries by Phase (H1 2021)





Clinical Trials COVID19-related Nosologies in APAC countries (H1 2021)



The majority of clinical trials conducted in the APAC region were interventional studies with an 84% market share.

The most frequent phase of clinical trials conducted across the APAC region by number of studies was Phase II.

The most active countries involved in various COVID-19 treatment methods were China (24 studies), India (13 studies) and South Korea (13 studies). The total number of COVID-19 trials represent 3% of the total number of clinical studies initiated in the APAC region during H1 2021.

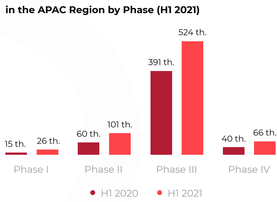
"Other APAC countries" includes Thailand, Singapore, Nepal Philippines, Vietnam, Taiwan, and New Zealand.

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in the APAC region during H1 2021 (including multi-center international studies) rose from 505,238 subjects in the previous year to 717,950 subjects in H1 2021 with a year on year growth rate of 42%. Within the APAC region, the most prevalent Phase of clinical trials by total number of participating subjects was Phase III.

* 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.

Breakdown of Number of Subjects Enrolled in the APAC Region by Phase (H1 2021)



Sponsor Data

During the first half of 2021 there were more than 200 Pharmaceutical companies worldwide which sponsored clinical studies with FDA-defined Phase I – IV in APAC region.

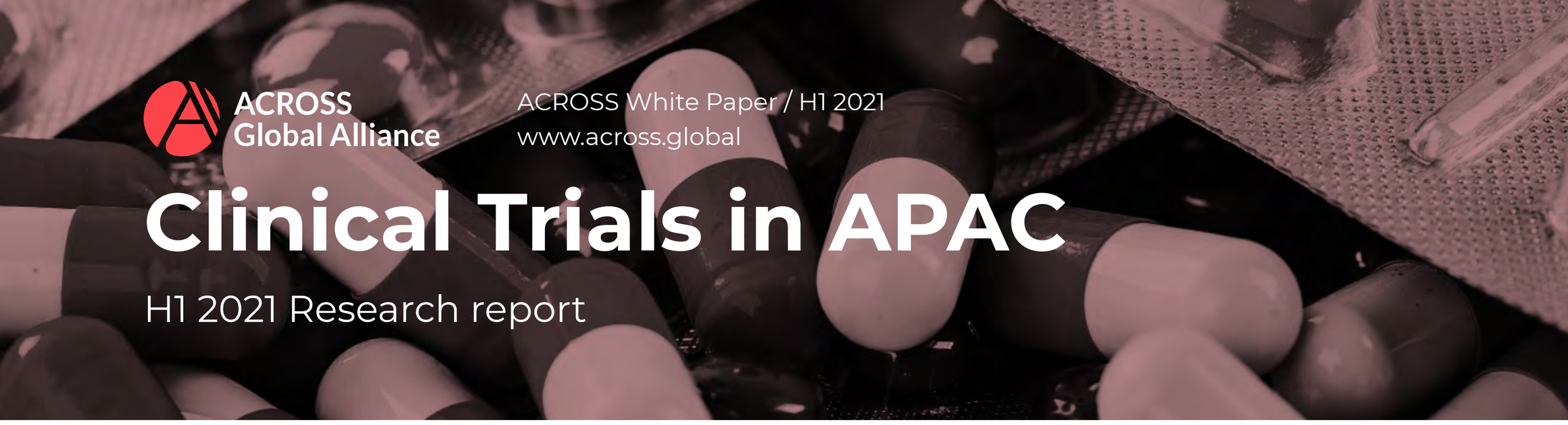
The leading companies are the global international corporations – AstraZeneca, Merck, Pfizer, Novartis, Janssen, Bristol-Myers Squibb, Eli Lilly, Hoffmann-La Roche, AbbVie, Boehringer Ingelheim, Celgene and GlaxoSmithKline – which usually conduct large multi-international clinical trials with many countries involved.

These companies dominate local markets of many countries across the world – but the local pharmaceutical companies are striving to change this 'global domination'.

In East Asia the most active local Sponsors of clinical trials were Chinese companies – Chia Tai Tianqing Pharmaceutical Group, Jiangsu HengRui Medicine, BeiGene, and Innovent Biologics; South Korean companies – Chong Kun Dang Pharmaceutical, Daewoong Pharmaceutical, HK inno.N Corporation, and Dong-A ST; and Japanese companies – Otsuka, Takeda, Eisai, Daiichi Sankyo, and Kyowa Kirin.

In South-East Asia one of the most prominent local players was a Malaysian company Hovid Berhad.

In Oceania there were several promising domestic market players – Opthea, Telix, and Atridia. But the prevalent market share in this region is still held by the large international "Big Pharma" players.



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Data Search and Analysis Approach

All of stats data used in this document were downloaded from 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	Breakdown of Clinical Trials in APAC Countries by Phase	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
2	Percentage Breakdown of Clinical Trials in APAC Countries by Phase	NCT, Phases	Exclude “Not Applicable” and empty values in “Phase” field
3	Percentage Breakdown of Interventional vs. Observational Trials	NCT, Study Type	
4	Clinical Trials with COVID19-related Nosologies in APAC Countries in H1 2021	NCT, Conditions	Use “COVID” keyword in “Conditions” field
5	Breakdown of Number of Subjects Enrolled in the APAC Region by Phase	NCT, Phases, Enrollment	See below *

* 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.

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.

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.