

Evolution of Clinical Trials in the Asia Pacific Region Compared to the US and the EU5

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Section 1: Summary

Over the last five years, the global clinical trial landscape has changed significantly. During the analysis period between 2017-2021, over 70,000 new clinical trials were registered in the APAC region, the US, and the EU5. The APAC region was the largest contributor, with more than 50% of the trials followed by the US (29%) and the EU5 (17%). During this period, the highest growth was witnessed in the APAC region (CAGR of 14%), while the US grew marginally, and negative growth was observed in the EU5. The APAC region has become the preferred destination for conducting clinical trials due to its large patient population, ease of regulatory compliance, low cost of conducting studies, high-quality standards and the presence of top clinical institutions acting as sites. Notably, China's regulatory reforms have accelerated drug approval by reducing the overall review and process.

China recorded the largest number of new trials during the assessed period, followed by the US and India; China and India together accounted for ~40% of the total trials recorded among the countries of interest.

In China, the number of new trials doubled during 2017-2021. However, the US remained steady primarily from 2017-2020 with a slight increase in 2021. This indicates that the onset of the COVID-19 pandemic did not significantly impact China's research activity. The growth in the US in 2021 was amid increased research due to the pandemic.

- The changes in the clinical landscape in China was attributed to many factors including^{2,3}:
 - o An aging population with an estimated 2.2 billion hospital visits each year
 - o New drug innovation model and many foreign companies are entering to China market
 - o China's focus on fast approval of innovative therapies since joining the International Council for Harmonization (ICH) in June 2017
 - o 29,140 hospitals and over 1 million independent outpatient clinics, along with a large and growing network of qualified hospitals to conduct clinical trials

In China, high growth was observed across all trial phases compared to other countries of interest. Across all regions, China registered the highest growth in early-stage (Phase 0 and Phase I) and late-stage trials (Phase III) over the last five years. China registered the highest growth for ongoing trials compared to other countries.

Across all regions, oncology was the leading therapy area for clinical trials, followed by central nervous system (CNS) diseases and infectious diseases during 2017-2021. All top five therapy areas in the APAC region registered significantly higher growth than the US and the EU5; infectious diseases witnessed the highest growth due to increased research activity due to COVID-19. In China, oncology trials registered the highest growth compared to other countries.

In the APAC region, post-operative pain was the leading indication for clinical trials, followed by non-small cell lung cancer (NSCLC) and COVID-19. Breast cancer and NSCLC trials dominated in the US, while in the EU5, COVID-19 trials were highest. The APAC region accounted for the highest number of trials for all top 5 indications (post-operative pain, NSCLC, COVID-19, type 2 diabetes, and breast cancer) compared to the US and the EU5 during 2017-2021.

The APAC region accounted for the highest number of industry-sponsored trials followed by the US and the EU5. In addition, the APAC region registered the highest growth both for industry-sponsored trials and non-industry-sponsored trials compared to the US and the EU5.

In the APAC region, Jiangsu Hengrui Medicine Co Ltd was the leading sponsor for clinical trials, followed by Merck & Co Inc and Novartis AG, while Merck & Co Inc accounted for the highest number of trials in the US and EU5 followed by Novartis AG.

The Chinese government launched the "Made in China 2025" industrial strategy in 2015, under which biotechnology was listed as one of the ten key sectors for development. Since then, investment has increased, and large Chinese biopharma companies are spending more on research and development (R&D) and specifically looking to innovative areas. China's biopharma industry has transformed from solely generic to innovative drugs

and technologies; many generic players are also becoming more innovative. Over the last five years, the number of Chinese biopharma companies with innovative pipelines has risen steadily from 48 companies in 2017 to 249 companies in 2021.

In China, foreign pharma companies have been very active for decades, with several players increasing their investments and setting up regional headquarters in China. In 2020, 271 licensing partnerships were signed between foreign companies, including Roche, Bayer, AbbVie, and Pfizer, and Chinese pharma companies¹⁷. Foreign biopharma company-sponsored clinical trials grew at a CAGR of 18% from 2017-2021.

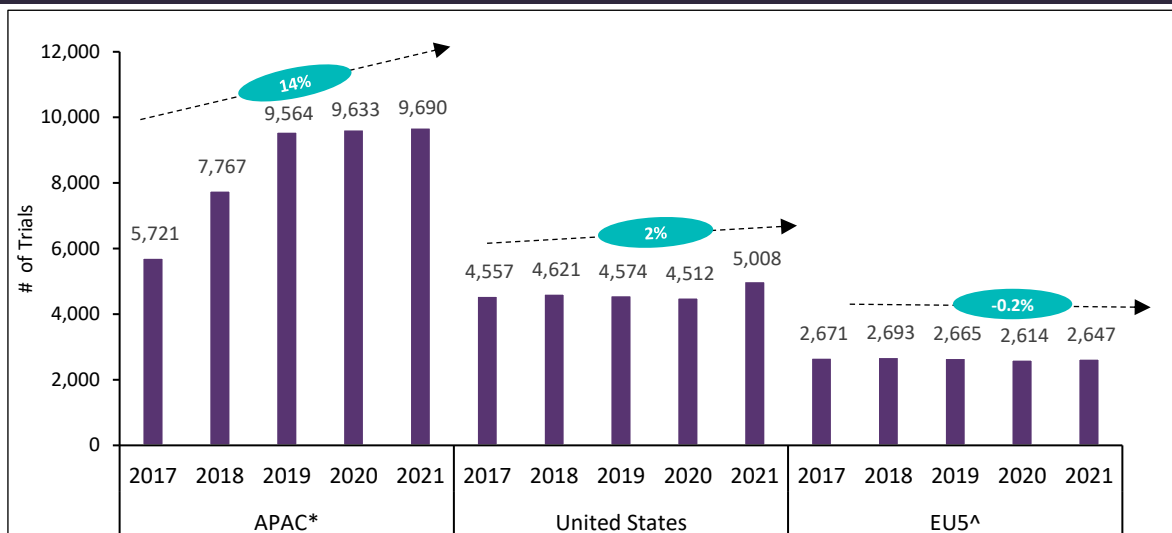
With changing global clinical trials landscape, APAC is emerging as the hot spot for conducting clinical trials, especially in China. China has created a new regulatory environment for trials and new drug approvals, which has helped China become a front runner in conducting clinical trials. Moreover, foreign pharma companies see China as an attractive market.

Section 2: The Evolution of Clinical Trials in the APAC Region Compared to the US and the EU5

This section provides an analysis of number of clinical trials registered during 2017-2021 and evaluated trends in trial phases, trial status, therapy areas, indications and sponsors in the APAC region, the US and EU5.

2.A: From 2017 -2021 Asia Pacific accounted for over 50% of clinical trial activity across the regions of interest

Figure 1: Number of Trials by Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and United Kingdom; CAGR: Compound annual growth rate; #: Number

In the period between 2017-2021, over 71,496 new clinical trials were recorded. The APAC region was the largest contributor with more than 50% of the trials followed by the US (29%) and the EU5 (17%). During this period, highest growth was witnessed in the APAC region (CAGR of 14%) while the US grew marginally (CAGR of 2%) and negative growth was observed in the EU5.

- In the APAC region, the number of new trials increased gradually, and a fluctuating trend was observed in the US
- The high growth in the APAC region was attributed to growing patient population, low cost of conducting clinical trials, and ease of regulatory compliance along with availability of top clinical institutions as sites. For example, China’s regulatory reforms has accelerated the drug approval by reducing the overall review and approval process¹

“First of all, the Asia Pacific region has become the hot spot for conducting of clinical trials in general, and there are different reasons due to ease of regulatory compliance. For example, low costs of conducting studies, growing patient population, and presence of a few top clinical institutions acting in these countries. For example, regulatory agencies in China are working towards an enhanced clinical trial process by reducing the overall revenue.”

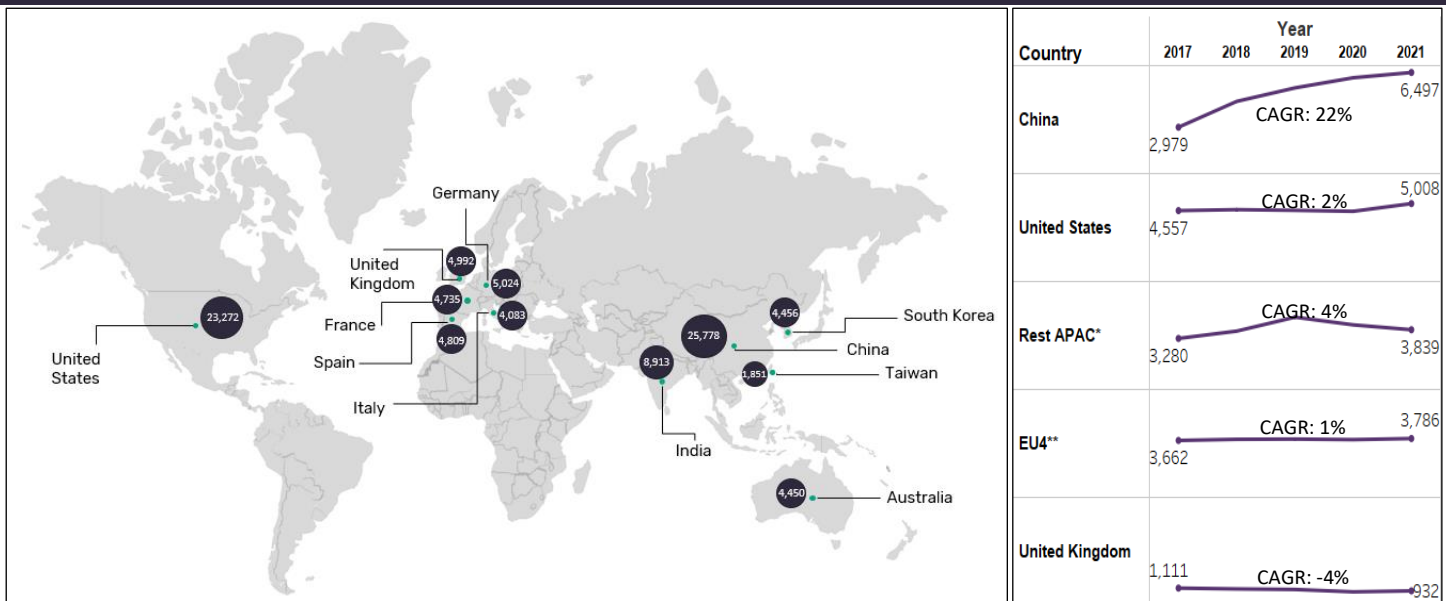
- Medical Alliances Operations Leader,
EU Pharma Company

“Taiwan, South Korea, India you see a lot of increased activity. Clinical trial activity also in India more recently because of the change in government regulations. So that is one reason for increased activity in APAC. Even though these are very small geographies right by populations, but you still see increased activity.”

- Clinical Development Medical Director,
US Pharma Company

2.B: In the 5 year period, 2017 -2021 , the number of clinical trials in China increased two-fold making it a preferred destination for trial sponsors

Figure 2: Number of Trials by Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; **EU4: France, Germany, Italy, Spain and United Kingdom; CAGR: Compound annual growth rate; #: Number

China recorded the largest number of new trials during the assessed period, followed by the US and India; China and India accounted for ~40% of the total trials recorded among the countries of interest.

- In China, the number of new trials doubled during 2017-2021 while the US remained mostly steady from 2017-2020 with a slight increase of 2% in 2021. This clearly indicates that the onset of COVID-19 pandemic did not significantly impact China’s research activity. The growth of trials in the US in 2021 was amid increased research due to the pandemic.
- In China, the changes in clinical landscape were attributed to many factors^{2,3}:
 - o An aging population with an estimated 2.2 billion hospital visits each year
 - o Implementation of a new drug innovation model, and many foreign companies are increasing their focus on China market
 - o Since joining International Council for Harmonization (ICH) as a full regulatory member in June 2017, China has been focusing on fast approval of innovative therapies
 - o 29,140 hospitals and over 1 million independent outpatient clinics along with large and growing network of qualified hospitals to conduct clinical trials
 - o US regulators are willing to accept clinical development data from China if it meets global quality standards

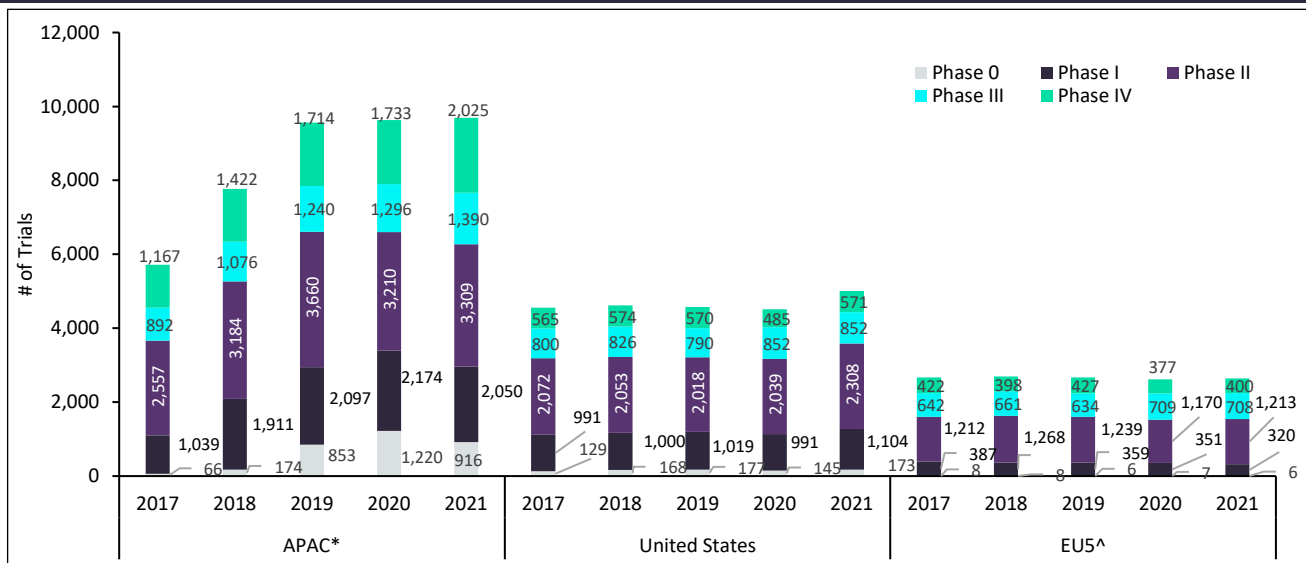
During 2017-2021, China registered highest growth (CAGR of 22%) followed by the rest APAC, the US and the EU4, while growth declined in the UK.

In the APAC region, China accounted for 57% of all trials recorded during 2017-2021, Australia and India grew at a CAGR of 8% and 5% respectively, while Taiwan and South Korea witnessed negligible growth.

“The FTE rates for clinical research in China is much less comparable to European countries and United States, this makes the cost per patient across all therapeutic areas and phases much lower in Asian countries.” - Medical Alliances Operations Leader, EU Pharma Company

2.C: Significant growth was observed across all stages of clinical development in the APAC region

Figure 3: Number of Trials by Phase and Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and United Kingdom; #: Number

CAGR by Phase and Region (2017-2021)					
Region	Phase 0	Phase I	Phase II	Phase III	Phase IV
APAC	93%	19%	7%	12%	15%
US	8%	3%	3%	2%	0%
EU5	-7%	-5%	0%	2%	-1%

Notably, in all regions, the proportion of Phase II trials was high among all trial phases; the proportion of Phase II trials in the US and the EU5 was greater than in the APAC region (45% vs 46% vs 38%). Phase II trials registered highest growth (CAGR of 7%) in the APAC region compared to the US where it grew at 3% and no growth was noted in the EU5.

- In the APAC region, the proportion of Phase I trials was 22% followed by Phase IV (19%), Phase III (14%) and Phase 0 (8%)
- In the US, the proportion of Phase I trials was 22% followed by Phase III (18%), Phase IV (12%) and Phase 0 (3%)
- In the EU5, the proportion of Phase III trials was 25% followed by Phase IV (15%), Phase I (13%) and Phase 0 (0.3%)

All phases of clinical trials in the APAC region registered higher growth, compared to the US and the EU5. In the US, Phase I trials grew at a CAGR of 3% while declined growth reported for Phase 0, Phase I and Phase IV trials in the EU5.

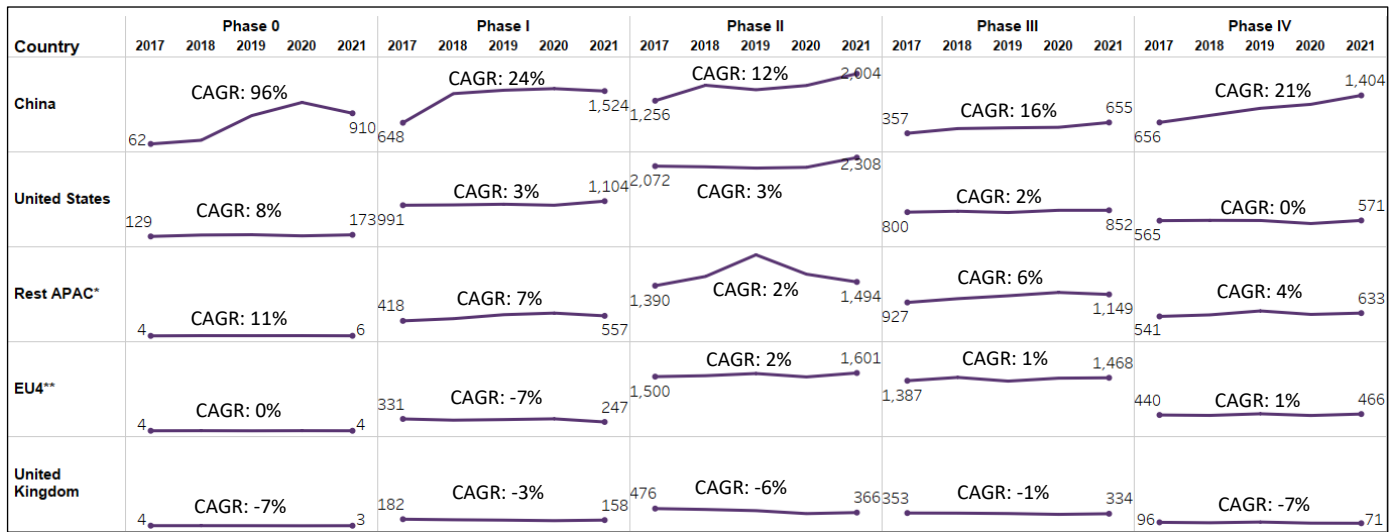
Growth of Phase 0 trials (CAGR of 93%) outnumbered other phase trials in the APAC region as well as the US and the EU5.

Early-stage trials (Phase 0 and Phase I) registered highest growth (CAGR of 28%) in the APAC region compared to the US, while growth declined in the EU5.

In the APAC region, late-stage trials (Phase III) registered highest growth (CAGR of 12%) followed by the US and the EU5 (CAGR of 2% each).

2.D: Across all regions, China registered the highest growth in early-stage and late-stage trials over the last five years

Figure 4: Number of Trials by Phase and Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Rest APAC: India, South Korea, Australia and Taiwan; **EU4: France, Germany, Italy and Spain; #: Number

In China, highest growth was observed across all trial phases compared to other countries of interest; growth of Phase 0 trials (CAGR of 96%) outnumbered trials in other phases in China as well other countries.

Notably, across all countries, the proportion of Phase II trials was highest among all phases; the proportion of Phase II trials in the US, the rest APAC, the EU4 and the UK greater than China.

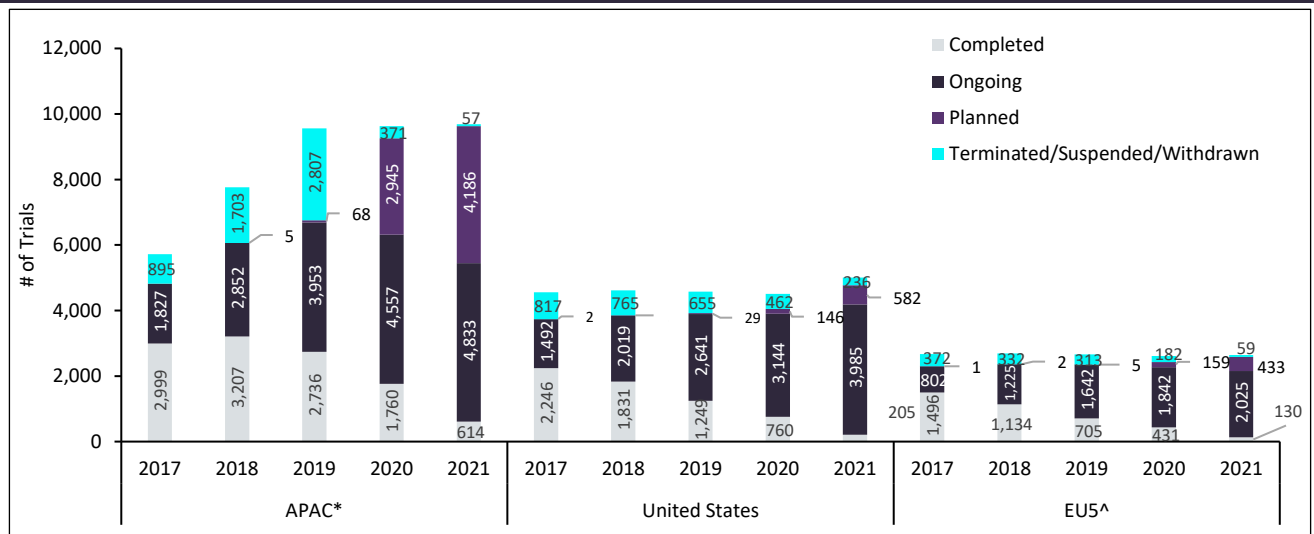
Among all countries, early-stage trials (Phase 0 and Phase I) registered the highest growth in China (CAGR of 36%) followed by the rest APAC (CAGR of 7%) and the US (CAGR of 3%)

- In the EU4 and the UK, declined growth was observed

China registered highest growth (CAGR of 16%) in late-stage trials (Phase III) followed by the rest APAC, the US and the EU4 while declined growth was observed in the UK.

2.E: The number of planned trials in the APAC region was significantly higher than the US and the EU5

Figure 5: Number of Trials by Trial Status by Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and United Kingdom; #: Number

Across all regions, ongoing trials contributed to the highest proportion among all trials during 2017-2021; the proportion of ongoing trials in the US and the EU5 was greater than APAC region (57% vs 57 vs 43%). All regions showed a gradual increase in the number of ongoing clinical trials with the APAC and the US registered equal growth (CAGR of 28% each) while EU5 grew at 26%.

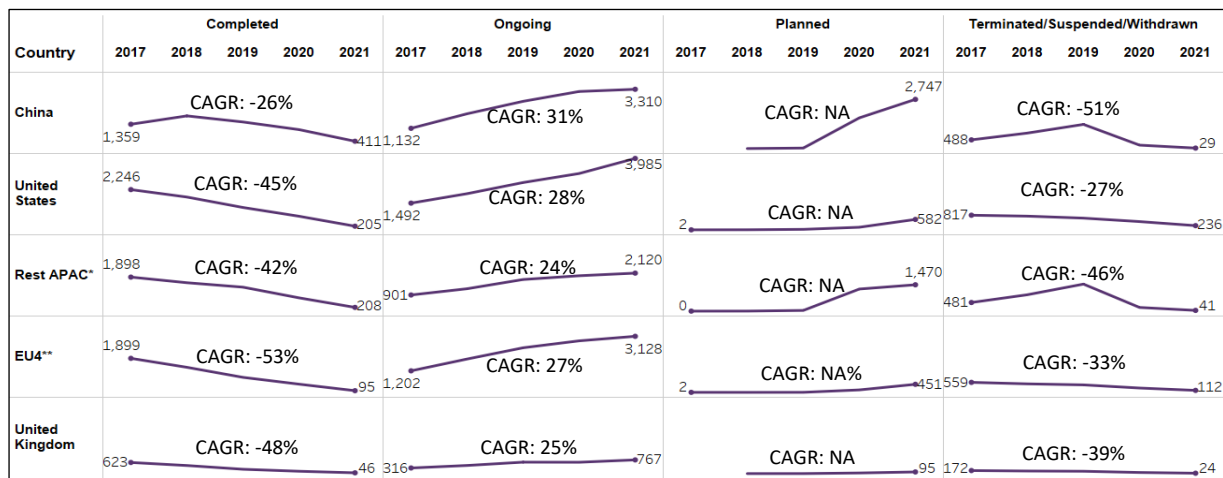
The proportion of completed trials in the APAC and the US was equal (27% each) while in the EU5, it was slightly high (29%); growth declined in all regions during 2017-2021.

The number of planned trials in the APAC region was 9x and 12x more than in the US and the EU5 respectively. Across all regions, the proportion of planned trials witnessed a sharp growth in 2020 and 2021.

The proportion of terminated/suspended/withdrawn trials was almost equal in the APAC and the US (~14%) while in the EU5, it was 9%; growth declined in all three regions during 2017-2021.

2.F: Ongoing clinical trials registered the highest growth in China compared to other countries and regions of interest

Figure 6: Number of Trials by Trial Status by Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Rest APAC: India, South Korea, Australia and Taiwan; **EU4: France, Germany, Italy and Spain; #: Number

Across all countries, ongoing trials contributed to the highest proportion among all trials during 2017-2021; the proportion of ongoing trials was highest in the EU4 followed by the UK, the US, China and the rest APAC. In addition, all countries showed a gradual increase in the number of ongoing clinical trials, with China registered highest growth (CAGR of 31%) followed by the US, the EU4 (CAGR of ~28% each) and the UK and the rest APAC (CAGR of ~25% each).

The proportion of completed trials was the largest in the UK and rest APAC followed by the US, EU4, and China; growth declined in all countries during 2017-2021.

The proportion of planned trials was largest in China, followed by the rest APAC, the US, the EU4 and the UK.

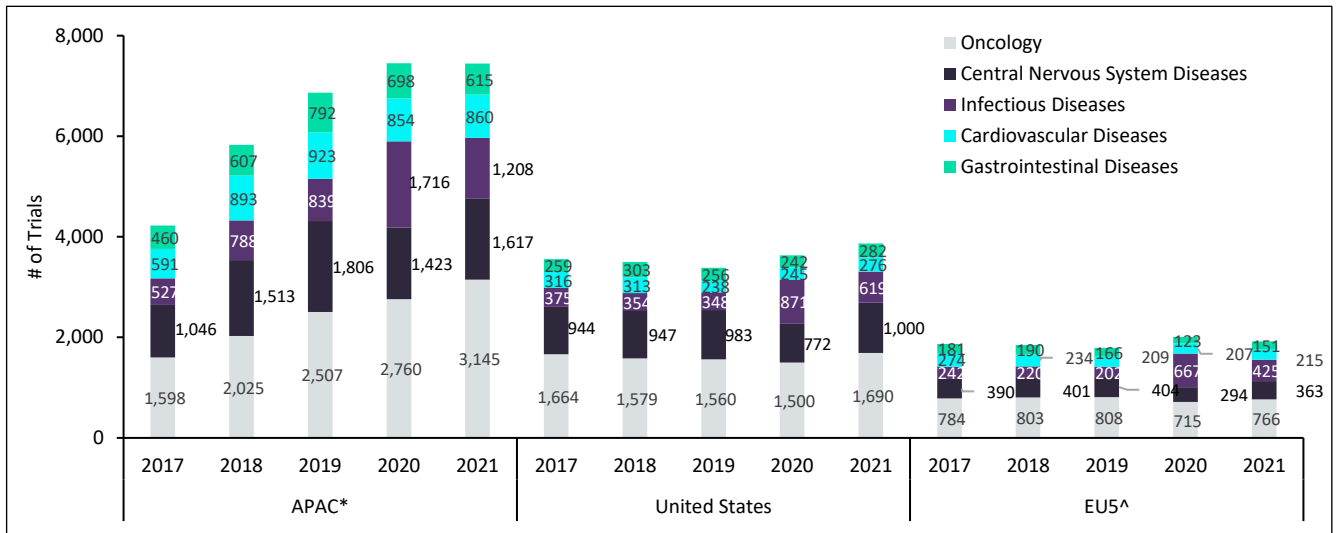
- Planned trials in China and India were 6x and 3x more than the US, respectively

China and the rest APAC witnessed a sharp growth of planned trials in 2020 and 2021 compared to other countries.

The proportion of terminated/suspended/withdrawn trials was largest in rest APAC followed by the US, China, the UK and the EU4; growth declined in all countries during 2017-2021.

2.G: Oncology trials dominant the clinical development across all regions with APAC growth outperforming the both EU and the US from 2017 - 2021

Figure 7: Number of Trials by Top 5 Therapy Areas and Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and United Kingdom; #: Number

CAGR by Therapy Areas and Region (2017-2021)

Region	Oncology	Central Nervous System Diseases	Infectious diseases	Cardiovascular diseases	Gastrointestinal diseases
APAC	18%	12%	23%	10%	8%
US	0%	1%	13%	-3%	2%
EU5	-1%	-2%	15%	-6%	-4%

Across all regions, oncology was the leading therapy area for clinical trials, followed by CNS diseases and infectious diseases during 2017-2021. All top five therapy areas in the APAC region registered significantly higher growth than in the US and the EU5; infectious diseases witnessed the highest growth due to increased research activity due to COVID-19. In the APAC region, the proportion of oncology trials doubled during 2017-2021. However, it remained steady primarily in the US and the EU5 during the same period; APAC growth was higher (CAGR of 18%) than the US and EU5. The high growth of oncology trials in the APAC region was attributed to^{4,5}:

- The ease of site access, particularly for oncology trials compared to the US and Europe
- Low operating costs on clinical trials (industry-sponsored trials costs in Asia were less compared to the US and Western Europe)
- The pharmacogenomic profile of the Asian population is an important factor that requires Phase I data in local populations
- For adoptive cell transfer (ACT) studies, China is the key country and ACT represents an increasingly attractive treatment for patients with cancer because of the potential for significant anti-tumor efficacy, minimal toxicity and long-term immunoprotection

In the APAC region, infectious diseases witnessed the highest growth (CAGR of 23%) followed by oncology, CNS diseases, cardiovascular diseases, and gastrointestinal diseases.

- Highest growth in clinical trials for infectious diseases was due to increasing research for new and effective therapies:
 - o Increasing disease prevalence due to high population density, poor prevention education, low healthcare spending, various environmental factors and others^{6,7,8}

In the US, clinical trials for gastrointestinal diseases and CNS diseases grew at ≤2% while oncology remained constant and declining growth noted for clinical trials for cardiovascular diseases (CAGR of -3%).

In the EU5, except for infectious diseases, clinical trials in other therapy areas (oncology, CNS diseases, cardiovascular diseases, and gastrointestinal diseases) showed declining growth.

2.H: The growth of oncology trials in China outpaced key regions and countries, whereas infectious diseases trials had the highest growth in India

Figure 8: Number of Trials by Top 5 Therapy Areas and Country

Country	Oncology					Central Nervous System Diseases					Infectious Diseases					Cardiovascular Diseases					Gastrointestinal Diseases				
	2017	2018	2019	2020	2021	2017	2018	2019	2020	2021	2017	2018	2019	2020	2021	2017	2018	2019	2020	2021	2017	2018	2019	2020	2021
China	1,040				2,564	452				992	279				616	370				633	230				372
	CAGR: 25%					CAGR: 22%					CAGR: 22%					CAGR: 14%					CAGR: 13%				
United States	1,664				1,690	944				1,000	375				619	316				276	259				282
	CAGR: 0%					CAGR: 1%					CAGR: 13%					CAGR: -3%					CAGR: 2%				
Rest APAC*	836				898	624				667	280				637	259				267	284				283
	CAGR: 2%					CAGR: 2%					CAGR: 23%					CAGR: 1%					CAGR: 0%				
EU4**	1,378				1,295	453				446	264				462	334				263	274				241
	CAGR: -2%					CAGR: 0%					CAGR: 15%					CAGR: -6%					CAGR: -3%				
United Kingdom	334				256	159				123	104				130	100				76	91				60
	CAGR: -6%					CAGR: -6%					CAGR: 6%					CAGR: -7%					CAGR: -10%				

Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Rest APAC: India, South Korea, Australia and Taiwan; **EU4: France, Germany, Italy and Spain; #: Number

Among all countries, oncology was the leading therapy area for clinical trials, followed by CNS diseases and infectious diseases except

- In India, CNS diseases ranked 1st followed by infectious diseases and oncology
- In South Korea, cardiovascular ranked 3rd

All top five therapy areas registered the highest growth for clinical trials in China compared to other countries of interest except for infectious diseases, where India witnessed the largest growth (CAGR of 33%). Clinical trials Infectious diseases witnessed the highest growth in all countries except China, where oncology registered the highest growth.

- Highest growth in clinical trials of infectious diseases was due to an increase in the research activity of the COVID-19 pandemic
- In India, under “Infectious Disease Biology Program” more focus was given to conduct clinical research toward the development of new and improved diagnostics, drugs, and vaccines for infectious diseases^{7,11,12}

Growth of oncology trials (CAGR of 25%) in China outpaced other countries; the rest APAC grew at a CAGR of 2% while growth remained steady in the US and declining growth noted for EU4 and the UK.

- In China, the growth in oncology trials were associated with a significant increase in cancer incidence, development of innovative products by domestic companies, focus on immuno-oncology, and leadership in cell therapy^{9,10}

Among the EU4 countries, except for infectious disease, clinical trials in the other four therapy areas showed declining growth and similar trends were observed in the UK.

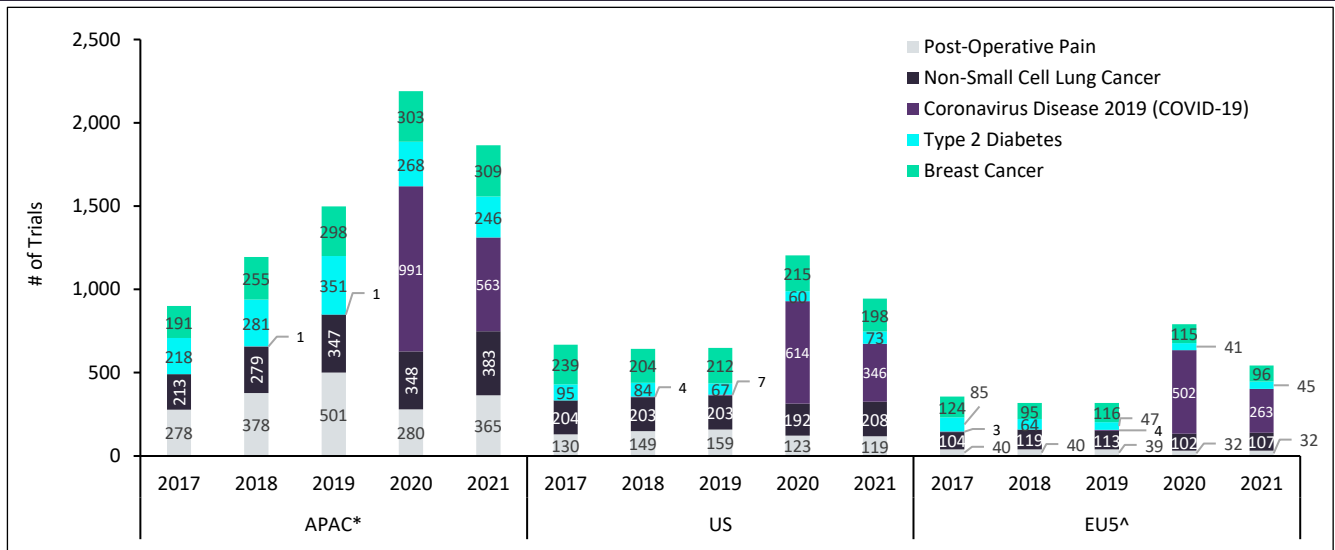
- In France, clinical trials in CNS diseases and cardiovascular diseases grew at a CAGR of 5% and 3%, respectively, while oncology and gastrointestinal disease had negligible growth.

“I think in China, just in terms of numbers who are in great need of new therapies and the government has in the last few years, you know kind of elevated the need for new therapies in China, and so as a result of that, there's been a greater awareness of the need for participants in these trials.”

- Chief Medical Officer,
US Pharma Company

2.1: As expected, a sharp growth was observed for COVID-19 trials in 2020, which declined in 2021.

Figure 9: Number of Trials by Top 5 Indications and Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and United Kingdom; #: Number

The APAC region accounted for the highest number of trials for all top 5 indications compared to the US and the EU5 during 2017-2021.

In the APAC region, post-operative pain was the leading indication, followed by non-small cell lung cancer (NSCLC) and COVID-19. Breast cancer and NSCLC trials dominated in the US, while in the EU5, COVID-19 trials were highest.

The top four indications (post-operative pain, NSCLC, type 2 diabetes and breast cancer), except for COVID-19, registered the highest growth in the APAC compared to the US and the EU5. In all the regions, a sharp growth was observed for COVID-19 trials in 2020, which declined in 2021.

Except for COVID-19, the highest growth was noted for NSCLC (CAGR of 16%) in the APAC region, followed by breast cancer, post-operative pain, and type 2 diabetes.

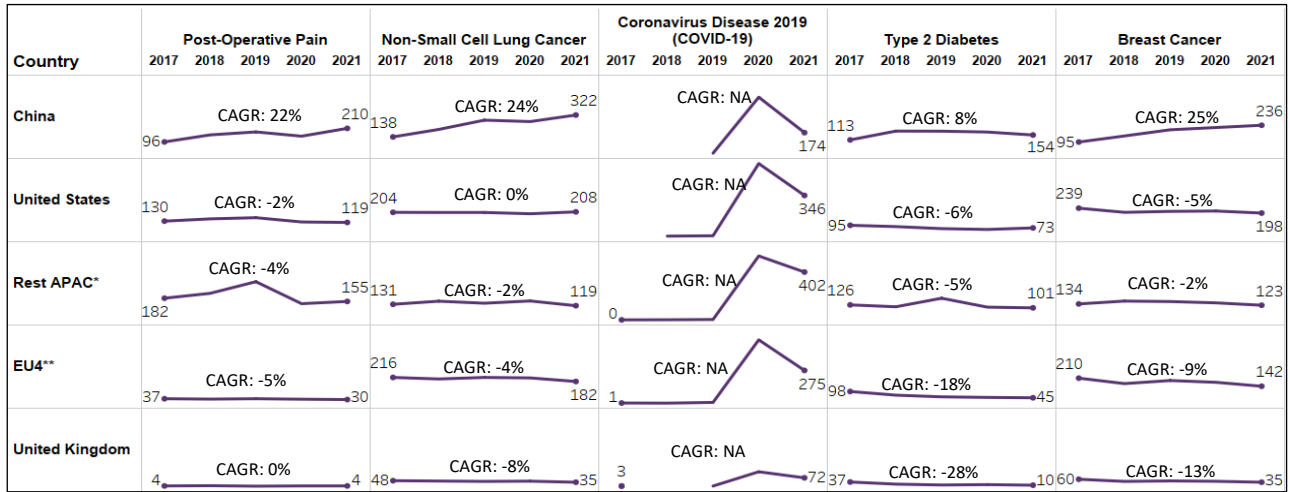
Post-operative pain trials grew at a CAGR of 7% in the APAC region while declined growth noted in the US and the EU5.

NSCLC trials grew at a CAGR of 16% in the APAC region, while marginal growth noted in the US and the EU5 with a CAGR of 0.5% and 1% respectively.

Breast cancer and type 2 diabetes trials in the APAC region grew at a CAGR of 13% and 3%, respectively, while growth declined in the US and the EU5.

2.J: The top four indications in China registered significantly higher growth compared to other countries; in all countries, a sharp growth was observed for COVID-19 trials in 2020, which declined in 2021

Figure 10: Number of Trials by Top 5 Indications and Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Rest APAC: India, Australia, South Korea and Taiwan; **EU4: France, Germany, Italy and Spain

China accounted for the highest number of trials for NSCLC, type 2 diabetes and post-operative pain compared to other countries during 2017-2021. On the other hand, breast cancer, post-operative pain and NSCLC were the leading indications in the US, the rest APAC and the EU4, respectively.

In China, except for COVID-19, the top four indications (post-operative pain, NSCLC, type 2 diabetes and breast cancer) registered significantly higher growth compared to other countries; growth mainly declined in other countries.

In China, except for COVID-19, the highest growth was noted for breast cancer (CAGR of 26%) followed by NSCLC at 24%, post-operative pain at 22% and type 2 diabetes at 8%.

Breast cancer trials growth was attributed to¹³:

- Testing of new drugs and investigation of newer drug targets in breast cancer
- The emergence of local biopharmaceuticals as key players in the domestic market focusing more on breast cancer R&D
- Reforms by the Chinese government in conducting clinical trials and the trial approval process

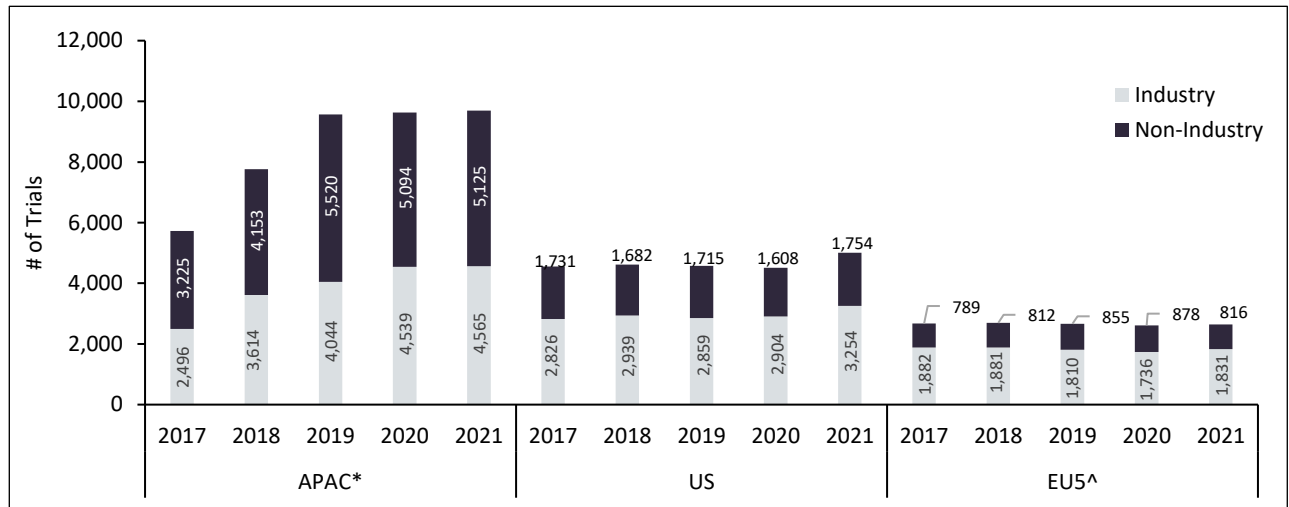
NSCLC trials growth was attributed to¹⁴:

- Biopharmaceutical R&D and the rapid development of anti-lung cancer drug clinical trials
- NSCLC treatment paradigm was evolving, which was primarily driven by the development of anti-angiogenic therapy, targeted therapy and immunotherapy

In all countries, a sharp growth was observed in COVID-19 trials in 2020, which declined in 2021.

2.K: In the APAC region, significant growth was observed both for industry-sponsored trials and non-industry-sponsored trials

Figure 11: Number of Trials by Sponsors Type and Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and UK

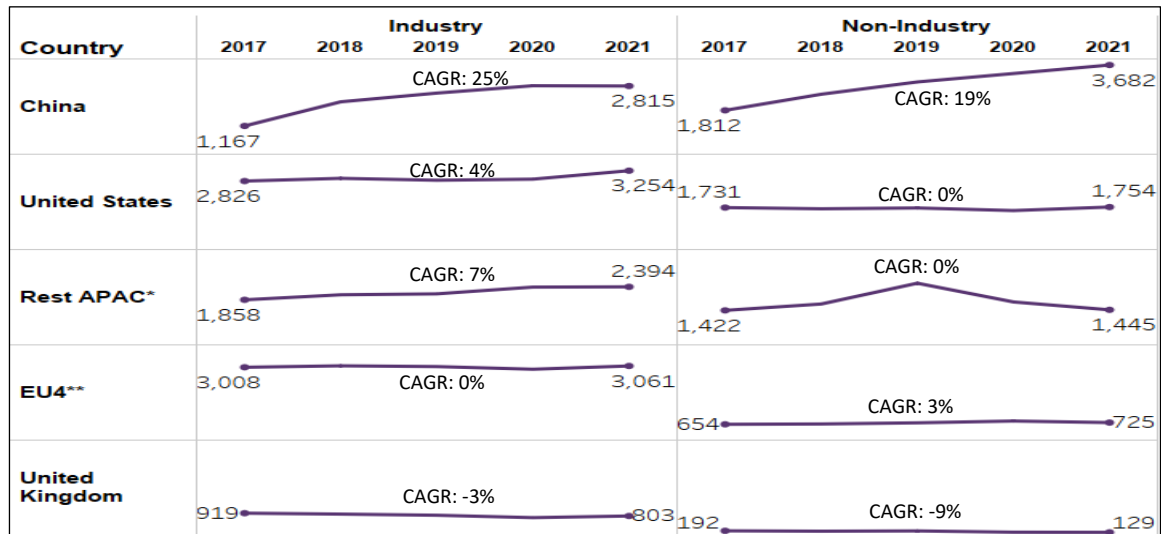
The APAC region accounted for the highest number of industry-sponsored trials, followed by the US and the EU5.

Both industry-sponsored trials (CAGR of 16%) and non-industry-sponsored trials (CAGR of 12%) registered the highest growth in the APAC region compared to the US and the EU5.

- In the US, industry-sponsored trials grew at a CAGR of 4%, while no growth noted for non-industry sponsored trials
- In the EU5, non-industry sponsored trials grew at a CAGR of 1%, while declined growth noted for industry-sponsored trials

2.L: In China, both industry-sponsored trials and non-industry-sponsored trials registered the highest growth compared to other key countries and regions

Figure 12: Number of Trials by Sponsors Type and Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Rest APAC: India, Australia, South Korea and Taiwan; **EU4: France, Germany, Italy and Spain

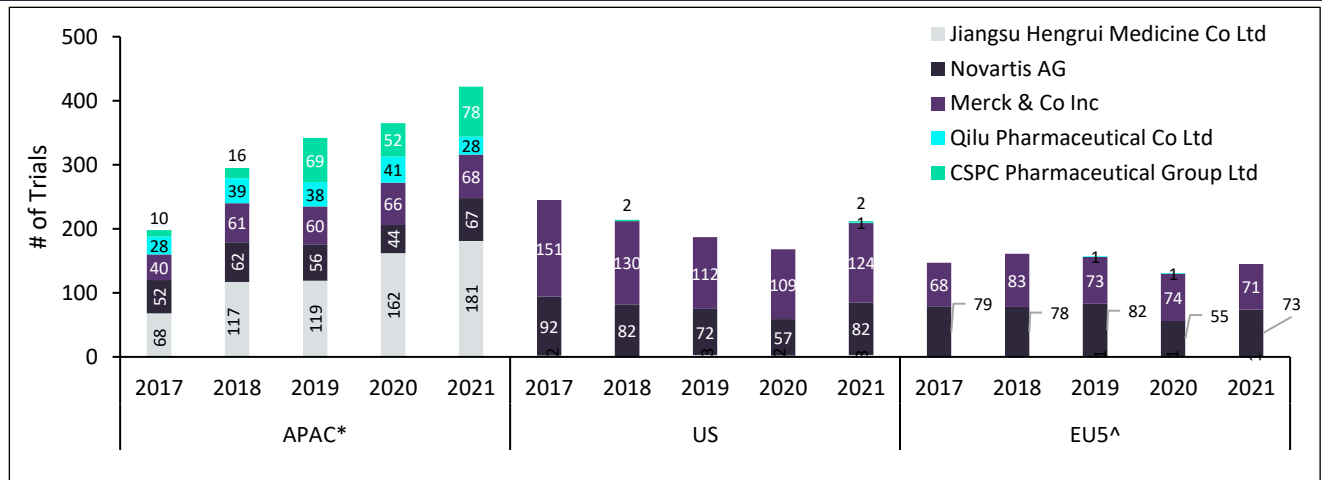
The proportion of industry-sponsored trials was higher than non-industry-sponsored trials in all countries except China and India.

In China, both industry-sponsored trials (CAGR of 25%) and non-industry-sponsored trials (CAGR of 19%) registered the highest growth compared to other countries.

- In the US, industry-sponsored trials grew at a CAGR of 4%, while no growth noted for non-industry sponsored trials
- In the rest APAC, industry-sponsored trials grew at a CAGR of 7%, while no growth noted for non-industry sponsored trials
- In the EU4, non-industry sponsored trials grew at a CAGR of 3%, while no growth noted for non-industry sponsored trials
- In the UK, a decline growth was observed for both industry-sponsored trials and non-industry sponsored trials

2.M: All top five sponsors registered the highest growth in the APAC region compared to the US and the EU5

Figure 13: Number of Trials for Top 5 Industry Sponsors by Region



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

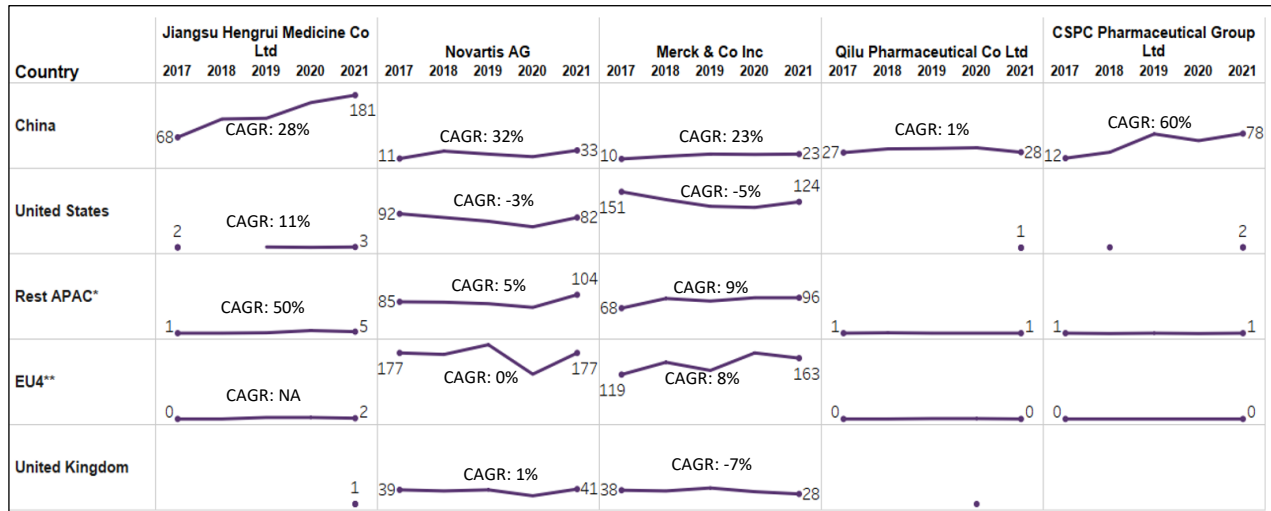
*APAC: China, India, Australia, South Korea and Taiwan; ^EU5: France, Germany, Italy, Spain and UK

In the APAC region, Jiangsu Hengrui Medicine Co Ltd was the leading sponsor, followed by Merck & Co Inc and Novartis AG. In contrast, Merck & Co Inc accounted for the highest number of trials in the US and EU5 followed by Novartis AG. All top five sponsors registered the highest growth in the APAC region compared to the US and the EU5.

- In the APAC region, the highest growth was noted for CSPC Pharmaceutical Group Ltd, followed by Jiangsu Hengrui Medicine Co Ltd, Merck & Co Inc and Novartis AG
- Jiangsu Hengrui Medicine Co Ltd registered the highest growth in the APAC region followed by the US, while in the EU5, only one trial registered each year from 2019-2021
- Novartis AG grew at a CAGR of 7% in the APAC region, while declined growth noted in the US and the EU5
- Merck & Co Inc grew at a CAGR of 14% and 1% the APAC region and the EU5, respectively, while growth declined in the US
- Qilu Pharmaceutical Co Ltd and CSPC Pharmaceutical Group Ltd registered very few trials in the US and EU5

2.N: All top five sponsors registered the highest growth in China compared to other countries of interest

Figure 14: Number of Trials for Top 5 Industry Sponsors by Country



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*APAC: China, India, Australia, South Korea and Taiwan; **EU5: France, Germany, Italy, Spain and UK

In China, Jiangsu Hengrui Medicine Co Ltd was the leading sponsor, followed by CSPC Pharmaceutical Group Ltd and Qilu Pharmaceutical Co Ltd, while Merck & Co Inc and Novartis AG were the leading sponsors in other countries. All top five sponsors registered the highest growth in China compared to other countries of interest.

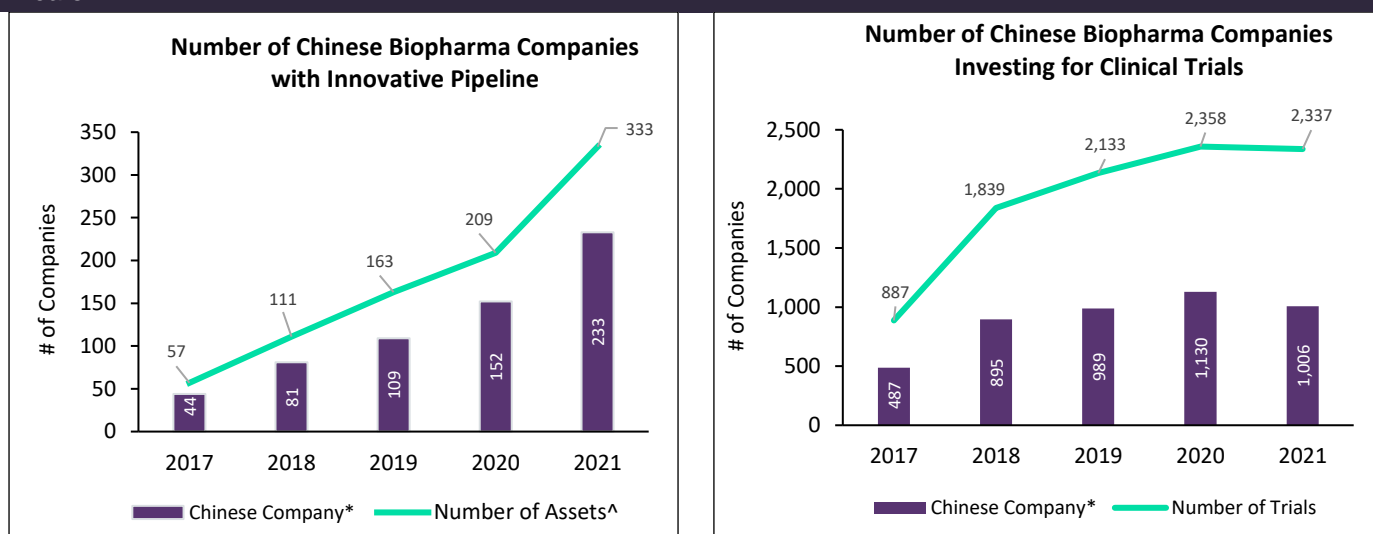
- Jiangsu Hengrui Medicine Co Ltd recorded a few trials in other countries
- Novartis registered the second-highest growth in the rest APAC followed by the UK, while growth declined in the US and no growth was noted in the EU4
- Merck & Co Inc registered the second-highest growth in the rest APAC followed by the EU4, while growth declined in the US and the UK
- Qilu Pharmaceutical Co Ltd and CSPC Pharmaceutical Group Ltd registered very few trials in the US, the rest APAC, the EU4 and the UK

Section 3: Growth in Number of Biopharma Companies and Investment in Clinical Development in China from 2017 - 2021

This section provides an analysis of investments made by Chinese biopharma companies and foreign biopharma companies in China in the last five years. Biopharma companies' investment was measured in terms of innovative pipeline and clinical trials.

3.A: Over the last 5 years, the number of Chinese biopharma companies with innovative therapies have grown steadily

Figure 15: Number of Chinese Biopharma Companies with Innovative Pipeline and Clinical Trials in the Last 5 Years



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*Companies headquartered in China; ^include assets from discovery to pre-registration, which is being developed in China for each respective year by a specific company for a specific indication; Note: Chinese companies conducting trials in China: These are companies headquartered in China conducting clinical trials in China or involved in a multi-national trial with Chinese arm (China as one/multiple locations); The number of companies conducting clinical trials were higher than the number of companies in the pipeline as it includes companies where the interventions in the trials might not be an asset in the active pipeline.

The Chinese healthcare market is growing at a fast rate and is expected to become the world's largest healthcare market in the future, from innovative drugs to vaccine development and biotechnology – Chinese biopharma companies are registering significant growth.

Even though China is the second-largest pharma market globally, the biotech industry is in the early stage of development compared to the US and some European countries (biotech-driven treatments accounted for only 12% of the China's total drug market¹⁸). Companies in this space are also far behind their global counterparts both in terms of revenue and R&D investments.

- In 2019, the sales of top biotech drugs (biologics) globally were in the range of USD 6-20 billion, while Chinese biologic sales were in the range of USD 0.46-0.77 billion¹⁸

It was estimated that China's biotech market would be USD 96 billion by 2023 (from USD 40 billion in 2018) due to growth drivers^{18,19} listed below:

"Now China is seen as an emerging economy with a centralized healthcare system where you can directly negotiate with one HTA, right? Which is the Chinese Government authority and that reimbursement happens through the entire country, so that is one reason. The other reason also is that there is a keenness from the Chinese themselves, to be abreast of new age technologies and modern medicine."
- Clinical Development Medical Director,
US Pharma Company

China's Biotech Industry - Growth Drivers	
Accessibility	<ul style="list-style-type: none"> As of April 2019, the National Medical Products Administration (NMPA), licensed 33 antibody/fusion protein-based therapies (21 imported and 12 domestic drugs). This is considered as a notable improvement compared to 21 approvals in May 2018.
Streamlining of regulatory standards	<ul style="list-style-type: none"> Since the National Healthcare Security Administration (NHSA) establishment in 2018, more branded drugs were added to the list of those that qualify for patient reimbursement, including drugs from foreign companies. Specifically, anticancer "PD-1" drugs have been included into drug list, which is a key focus area for biotech players. The National Medical Products Administration (NMPA), has been employing a clearer and more efficient drug-approval system based on global standards. This transformation was expected to shift the healthcare industry's focus from generic to innovative drug development.
New drugs price reduction	<ul style="list-style-type: none"> Since 2018, there have been five rounds of National Reimbursement Drug List (NRDL) price negotiations for reducing price of new drugs. Consequently, generic drug makers in China were pushed for innovation to make up for this margin correction. Large Chinese pharma companies are now spending more on R&D and specifically looking to innovative areas such as oncology. At the same time, biotech companies in China are also emerging with more concentrated product pipeline.
Improving access to capital	<p>Key recent developments include:</p> <ul style="list-style-type: none"> Changes to the Stock Exchange of Hong Kong's listing rules for pre-revenue biotech companies and the China Securities Regulatory Commission's new fast-track approval for the listing of high-tech 'unicorns,' Growing private equity and venture capital investment in biotech.

The Chinese government launched the "Made in China 2025" industrial strategy in 2015, under which biotechnology was listed as one of the ten key sectors for development. Since then, investment has increased, and large Chinese biopharma companies are spending more on R&D and explicitly looking to innovative areas. China's talent pool is rapidly expanding as local talent continues to evolve and western-trained scientists are coming back home. The returnees have been the key driver behind the formation of innovation companies in China over the past ten years.

China's biopharma industry has transformed from solely generic focus to innovative drugs and technologies focus; many generic players are also working towards enhancing their innovation focus. Many companies have more than 50% of their pipeline targeting innovative biologics or are tapping into novel modalities, such as cell therapies. Over the last five years, the number of Chinese biopharma companies with innovative pipelines has risen steadily from 48 in 2017 to 249 in 2021.

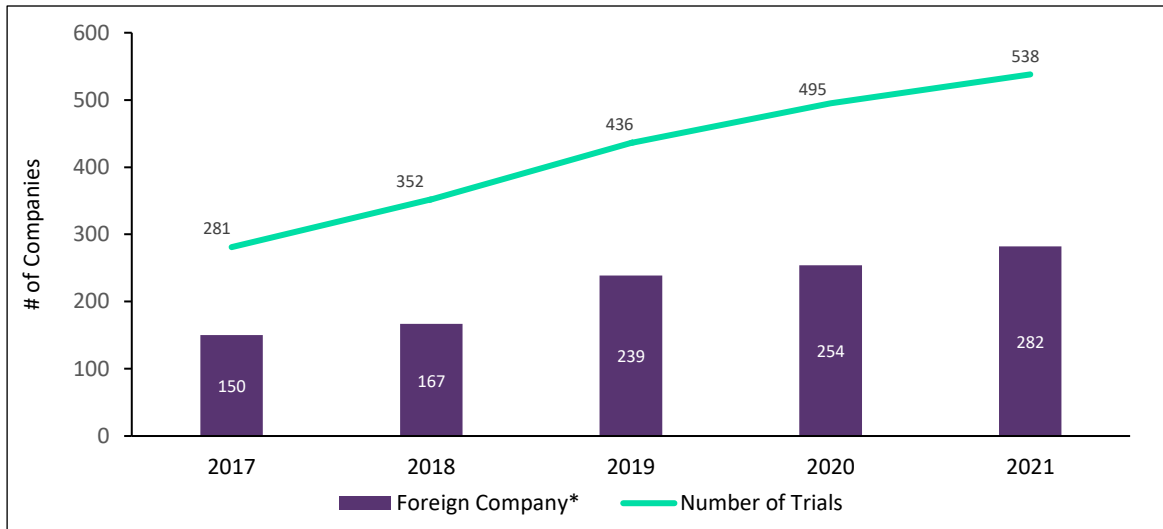
In future, China's biotech market has the potential to go global, either by out-licensing to overseas partners or by developing assets in the major markets such as the US and the EU. Chinese biotech firms currently compete heavily with foreign companies to capture domestic market share. However, many companies have already stepped forward and are looking to tap the vast global market.

- In 2019, BeiGene's lymphoma treatment was approved by the US FDA - the first China-discovered innovative cancer drug to secure such an approval¹⁵
- In January 2021, BeiGene signed a \$2.2 billion deal with Novartis to license their PD-1 drug in major markets outside of the country¹⁶

Other biotech companies also entered into licensing agreements with global multinational corporations (MNCs) to obtain approval for their new biological drugs.

3.B: China’s regulatory reforms have attracted more foreign biopharma companies in the last five years

Figure 16: Number of Foreign Biopharma Companies Investing for Clinical Trials in China in the Last 5 Years



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/02/2022]

*These are the foreign companies (headquartered other than China) conducting clinical trials in China or involved in multi-national trials with the Chinese arm (China as one/multiple locations)

In China, foreign biopharma companies have been very active for decades, with several players increasing their investments and setting up regional headquarters in China. In 2020, 271 licensing partnerships were signed between multinational companies, including Roche, Bayer, AbbVie and Pfizer and Chinese pharma companies¹⁷.

Below are a few examples of development and commercialisation¹⁷

- In September 2020, Pfizer agreed a US\$480 million deal with CStone Pharmaceuticals, which has a focus on immuno-oncology. This gave Pfizer a 9.9 % stake in the Hong Kong-listed company and an exclusive license to commercialise CStone’s cancer drug in China.
- In September 2020, AbbVie agreed to pay mainland biotech company I-Mab up to US\$2 billion for access to its experimental cancer drug.
- In May 2020, Eli Lilly entered into a US\$255 million deal with Junshi Biosciences, a Shanghai-listed biotechnology company, to work together on an antibody treatment for COVID-19
- In November 2019, AstraZeneca announced that it was setting up a one billion USD fund in China to accelerate work in the life sciences

“So clearly one is the commercial benefit because traditionally these markets are lucrative, the US market in particular and your access and reimbursement can actually be segmented and based on negotiations with several authorities as there is no central HTA. Staying on top of technology and staying at the cusp of advances in medicine is also in their interest. Third would be tapping and having access to talent which exists in these geographies and they don't have that quality of talent and expertise in China.”

*- Clinical Development Medical Director,
US Pharma Company*

“Those global pharma also see them as a market right. So it's like a win for both at least for now, global pharma launched their innovative molecules in one of the largest markets. I mean by population, which is rapidly increasing economic power.”

*- Clinical Development Medical Director,
US Pharma Company*

“When I say costs, I mean all type of costs, CAPEX, OPEX and TOTEX everything and for sure this is a big advantage and also a lot of space for a creation of new entities for creation of new facilities because from my point of view, Chinese market is less covered by available infrastructure and this segment comparable to European and American markets.”

*- Medical Alliances Operations Leader,
EU Pharma Company*

Section 4: Methodology

This analysis is focused on the changing dynamics of clinical trials distribution in the Asia-Pacific (APAC) region (China, India, Australia, South Korea and Taiwan), the US and the EU5 (France, Germany, Italy, Spain and United Kingdom) during 2017-2021. It also looked into the growth of clinical trial activity in these regions, regulatory change and the impact the COVID-19 pandemic. Note: For regional analysis, the EU5 was considered, while the EU4 and the UK were considered at the country-level analysis. Similarly, the APAC was considered for regional level analysis while China and the rest APAC were considered at the country level.

Insights have also been gathered through primary research interviews and inputs from key personnel from industry experts including clinical development and regulatory heads from western biotech/pharma companies.

Clinical trials data were extracted from GlobalData's (GD) proprietary *Pharma Intelligence Center: Clinical Trials Database* on February 08, 2022, with the following scope:

- Period of Analysis: The study period between January 2017 - December 2021
- Trial Phases: Phase 0 – IV
- Trial Status: All trial status (planned, ongoing, completed, terminated, suspended, withdrawn)
- Therapy Areas: All
- Location: the APAC (Australia, China, India, South Korea, Taiwan), the US, the EU5 (France, Germany, Italy, Spain and the UK)

Inclusion Criteria: This study provides a comprehensive analysis of the clinical trial landscape in the APAC, the US and the EU5, considering new pharma trials registered during the years 2017-2021.

- New trials: All trials registered in each of the respective calendar years were counted in for the analysis

Classification of Pharma Trials Phases: For this project, pharma trials phases were classified as follows:

- Phase 0
- Phase I/II to Phase II
- Phase II/III to Phase III
- Phase III/IV to Phase IV

Trial Count in Multi-center Trials: The sum of total trials in all countries will be greater than the total number of unique trials in the APAC, the US and the EU5 regions because one trial could occur in multiple countries

- Example: Location 1 US + Location 2 China + Location 3 Germany: This trial will be counted once in each respective country

Top 5 Therapy Areas: Top 5 therapy areas have been considered based on the highest number of trials in the APAC region and then number of trials in each TA was analyzed versus the US and the EU5.

Top 5 Indications: Top 5 indications have been considered based on the highest number of trials in the APAC region and then number of trials in each indication was analyzed versus the US and the EU5.

Top 5 Industry Sponsors: Top 5 industry sponsors have been considered based on the highest number of trials in the APAC region and then number of trials by each sponsor was analyzed versus the US and the EU5.

Trials Status: GD has considered all trial status (planned, ongoing, completed, terminated, withdrawn, and suspended)

Pharma/Biotech Companies:

- Companies that develop pharmaceutical interventions for therapeutic purposes and Biological structures for therapeutic or diagnostic purposes (i.e., viral vectors + plasmids, etc.). Pharma and biotech Companies (e.g., AstraZeneca, Novartis, J&J etc.)/ Biotech companies (e.g., Bavarian Nordic etc.)
- For the purpose of this analysis, GD team considered biopharma companies with innovative drugs
 - The GD team considered the number of innovative drugs in development by China-based biopharma companies since 2017: Analysis includes unique companies with innovative pipeline on a yearly basis for the period – 2017-2021

- The GD team also considered the number of clinical trials being run by Chinese and foreign biopharma companies since 2017 (the analysis includes unique companies involved in clinical trials on a yearly basis for the period between 2017-2021)

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Section 6: Abbreviations

APAC: Asia-Pacific

CAGR: Compound Annual Growth Rate

CNS: Central Nervous System

COVID-19: Coronavirus Disease 2019

ICH: International Council for Harmonization

MNC: Multinational Corporation

NHSA: The National Healthcare Security Administration

NMPA: The National Medical Products Administration

NRDL: The National Reimbursement Drug List

NSCLC: Non-Small Cell Lung Cancer

PD-1: Programmed Cell Death Protein 1

R&D: Research and Development

USFDA: The United States Food and Drug Administration

Section 7: About US

7.B: About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts.

With an unmatched team of analysts, epidemiologists, and consultants, we provide high-quality, accurate, and transparent insight that can help you achieve growth and increase business value. Our analysis is supported by a 24/7 client support team, and our analyst teams are available to further address client-specific issues or information needs on an inquiry or proprietary consulting basis.

GlobalData has offices in New York, San Francisco, Boston, London, India, Korea, Japan, Singapore, and Australia.

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