# State of the Global Biotech Landscape: Where the Opportunities Lie

Published by: GlobalData Healthcare Consulting

Published: November , 2022

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# Section 1: Summary

Over the last five years, the global biotech and pharmaceutical landscape has witnessed continued growth. The analysis period (2017-2022) encompasses a unique timeframe including the global COVID-19 pandemic, which introduced a wide variety of challenges and opportunities to the clinical development industry. Almost 27,000 clinical trials were initiated in 2021 across the world. Nearly half of these trials (12,900) had locations in APAC, followed by Europe (5,000) and the US (4,900). This represented growth of 5.3% per annum globally since 2017. While growth in clinical trials was seen universally, growth rates between regions were highly variable. In the US and RoW, growth was less than 2%, while EU growth was just under 3%. Growth in APAC, however, was almost 10%, contributing massively to the global scene.

Geographic distribution of early clinical trials has remained uneven over the analysis period. Phases I and II were dominated by APAC, which served as a trial location in 57% and 49% of trials, respectively. US and EU geographic shares remained stable at approximately 20% at phases I through III, while RoW representation is low in phases I and II but on par with the US and EU in phase III.

Internationalization of trials follows a similar pattern. Of all phase III trials run in the US in 2021, 66% had additional trial sites outside the country. Likewise in the EU, 58% of trials were international. In APAC and RoW, on the other hand, the proportion was reversed. Domestic trials dominated both regions, accounting for over 70% of phase III's in 2021.

Reaching full strength in 2020, the COVID-19 pandemic generated a forceful push for modernization in the clinical trial space. Development firms seeking to boost capabilities via innovative web-enabled solutions, called decentralized trials (DCTs) or virtual trials (VT), were able to recruit and retain subjects that were previously inaccessible, especially in such circumstances. DCTs grew 10-20% over the analysis period, indicating an industry interest in the advancing technology. APAC DCT phase I trials grew particularly strongly at 60% over the analysis period, although small 2017 initial utilization is at least partially responsible.

COVID-19 also stimulated a surge in investment in the biotech industry. In the US IPO deals jumped from 49 worth $5.6Bn in 2019 to 75, worth over $18Bn the next year. In APAC, the number of biotech IPOs doubled and the value nearly tripled to 55 deals worth $9.4Bn over the same range. While the gravity of COVID-19 catalysed this financial enthusiasm, the return to normative growth seen pre-2020 in APAC demonstrates the sustained opportunity within this region.

Outside of the direct causal range of COVID-19, macroeconomic cycles are another relevant force on the biotech clinical landscape. In fact, the possibility of an impending recession may counteract much of the investment experienced in the last few years. A loss to the scale of the 2008 financial crisis would be worth $100B in global equity offerings if replicated today. However, the value of biotech companies may be somewhat insulated from the brunt of the economic downturn, as seen by the returns of the S&P Biotech ETF remaining strong compared to the S&P 500 in the wake of 2008.

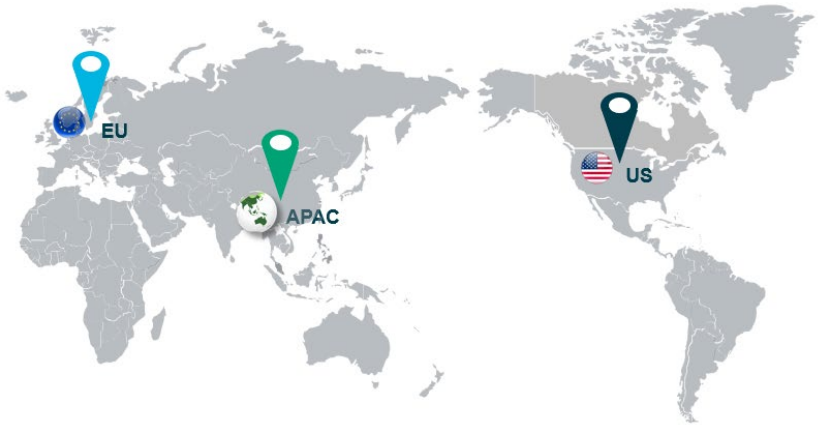
Upstream effects of patient-level legislation also have the ability to effect clinical development. In August of 2022, with the passing of the Inflation Reduction Act, the US Medicare system was drastically reshaped. Certain components of the bill, namely drug coverage and drug price negotiation, among others, may serve to remove the incentive of pharmaceutical developers to innovate. Researchers from the University of Chicago estimate that the net effect of this legislation will be the loss of 331.5 million years of life, 31 times greater than the impact of COVID-19.

Even with the uncertainty produced by recent economic and political phenomena, sustained growth in the biotech and pharmaceutical development industries is almost certain. While regions like the US and Europe have historically been anchors for clinical programs, burgeoning trials metrics and accessibility to huge pools of potential subjects in APAC present a desirable destination for developers across the world.

# Section 2: State of Global Clinical Trials Landscape

*Over the last 5 years the number of Clinical Trials being conducted has grown steadily at a CAGR of 5.3%*

Figure 1: Global Dynamics in Clinical Development




| | No. Trials (2021) | Trial Growth[1] | No. Sites |
|---|---|---|---|
| APAC | 12.9K | 9.8% | 6.8K |
| US | 4.9K | 1.5% | 8.1K |
| EU | 5.0K | 2.9% | 7.5K |
| ROW | 4.1K | 1.8% | 3.2K |
| Global | 26.9K | 5.3% | 25.5K |

Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
1. CAGR: 2017-2021; Note: EU = all European countries

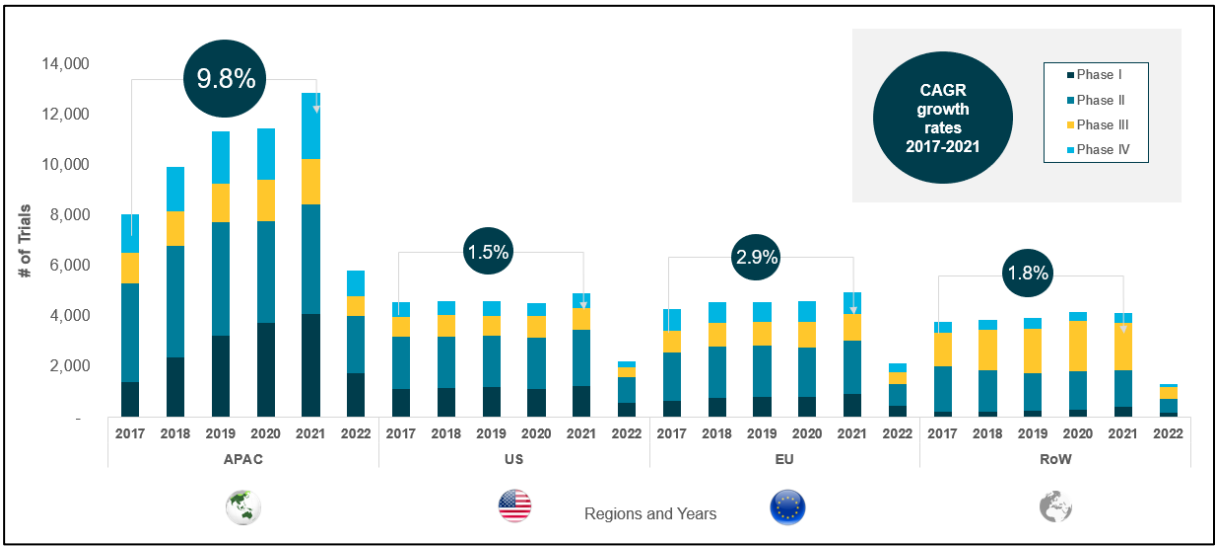
In 2021, almost 27,000 trials were initiated across the world, representing a CAGR of 5.3% since 2017. Among the three major regions (APAC, US, and EU), APAC has established itself as a central hub of trial activity both in terms of actual number of trials and growth trajectory, with almost half of all trials run in 2021 (almost 13,000). Over the same time period (2017-2021), APAC trials experienced substantial year-on-year growth witnessing a CAGR of 9.8%.

Since 2017 Europe has been the second fastest growing region, with a YoY growth rate just one third that of APAC (2.9% with a total of 5,000 trials in 2021). Meanwhile the US has had the least number of trials in 2021 (4,900) and slowest growth of just 1.5% year-on-year 2017-2021.

Interestingly, despite having greater numbers of trial sites, both the US and EU have experienced a decline (-2.5% and -1.2%, respectively) since 2017; a stark contrast to the number of trial sites in APAC which over the same period has grown with a CAGR of 6.9%.

*The growth trajectory in APAC over the last 5 years is unprecedented and surging, showing that the region is increasingly considered a preferred destination for trial sponsors*

Figure 2: Number of Trials and Growth Rate, 2017-H2 2022




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

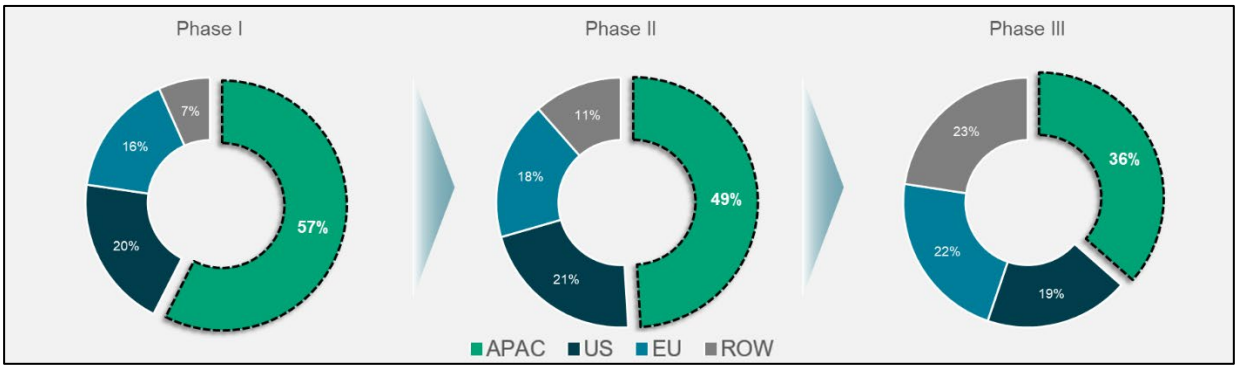
Note: EU = all European countries

While the COVID pandemic was a volatile force on the clinical trial landscape, looking at the distribution of trials over this five-year period provides insight into prior trends. All regions, including RoW (including South & Central America and Middle East & Africa), have shown growth from 2017-2021. However, looking at the pre-pandemic period of 2017-2019, the US had a growth rate of 0.4%, Europe grew by 2.0%, and RoW grew by 1.3%, while APAC grew by 12.1%.

Phase II accounts for the majority of trials run in APAC, the US, and EU over the analysis period. This trend has been stable over the 5 years, with the exception of the growing number of phase I trials which alters this distribution within APAC. In RoW, phase III trials tend to dominate the pipeline.

*APAC continues to dominate early-stage development, a trend which has been consistent over the last 5 years*

Figure 3: Geographic Distribution Among Trial Phases, H1 2022

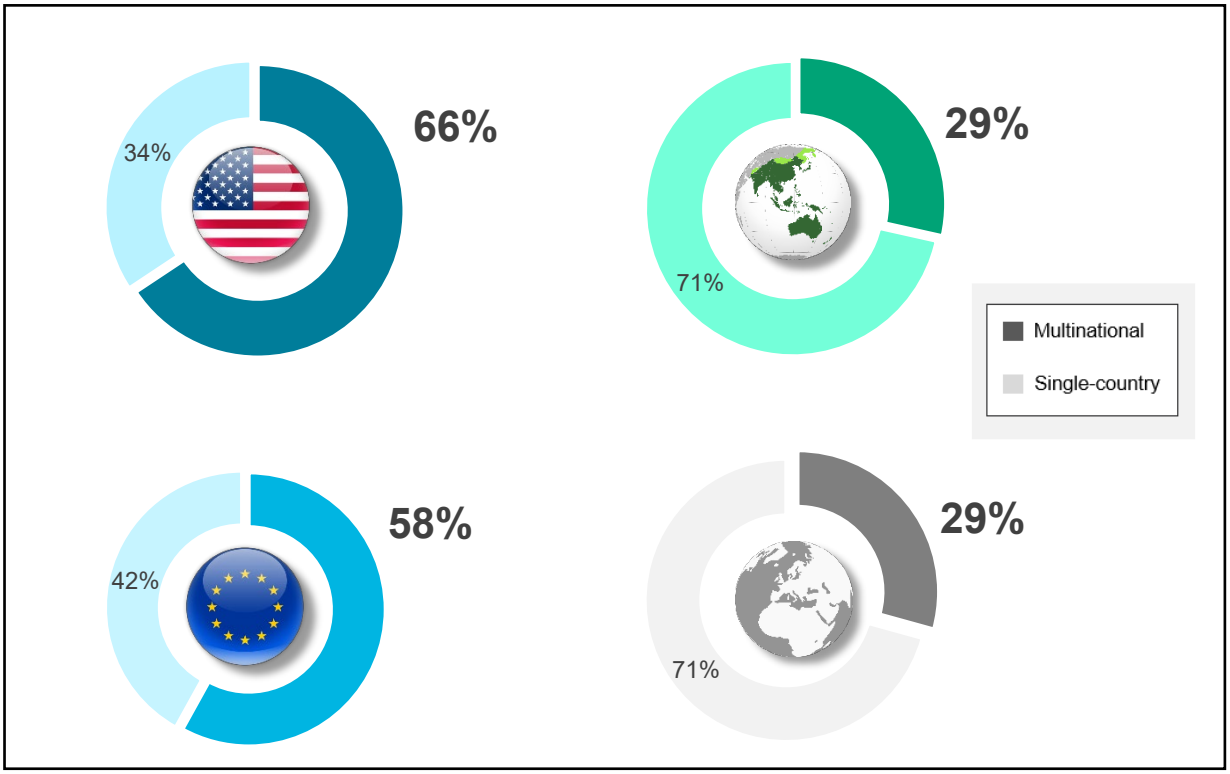



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries

Concentrating on trials initiated in H1 2022, APAC accounts for the greatest proportion of early phase development with almost 60% of phase I trials being conducted in this region. For phase II trials, 50% are run in APAC, while US and EU retain roughly 18% and 20% of trials, respectively. By phase III, international distribution becomes more uniform, however APAC continues to contribute the largest proportion of trials with 36%. It should be noted that these phase-level trends are not unique to 2022 and have been consistent over the 5-year analysis period.

*The vast majority of Phase III trials run in the Western markets are multinational trials*

Figure 4: Single vs Multinational Phase III Trials, 2021




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries

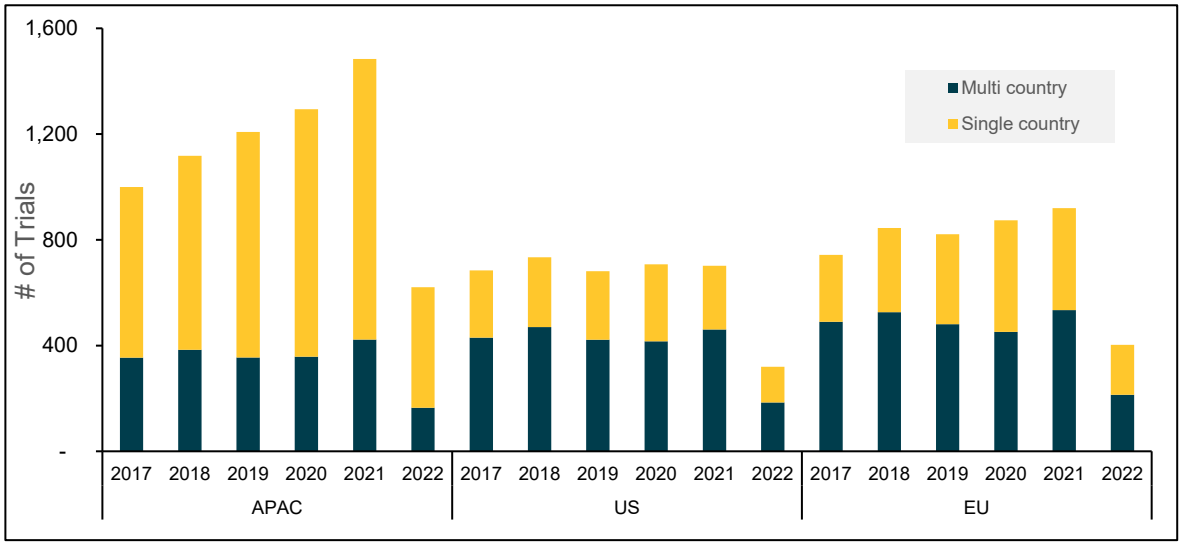
Figure 4 illustrates the phase III trials conducted in 2021 within each region, and the proportional split of trials which are domestic single-country or part of a multi-country trial program. Although the geographic sponsor representation is fairly even between the regions, it is evident that the extent of internationality is quite disparate.

The US and Europe have a significant majority of internationalization among their 2021 phase III trials. In the US, 66% of trials were multinational, and in Europe that number was 58%. On the other hand, only 29% of 2021 phase III trials in APAC and RoW were multinational.

The APAC region, with significant trial numbers and considerable trial sites, has highly domestically skewed trial reach, meaning its underutilized capacity could be a potential opportunity for growth in multinational trials in this region.

*Proportions of single country versus multinational Phase III trial ratios have generally remained constant Globally since 2017, with the exception of APAC*

Figure 5: Single vs Multinational Trials, 2017-H2 2022



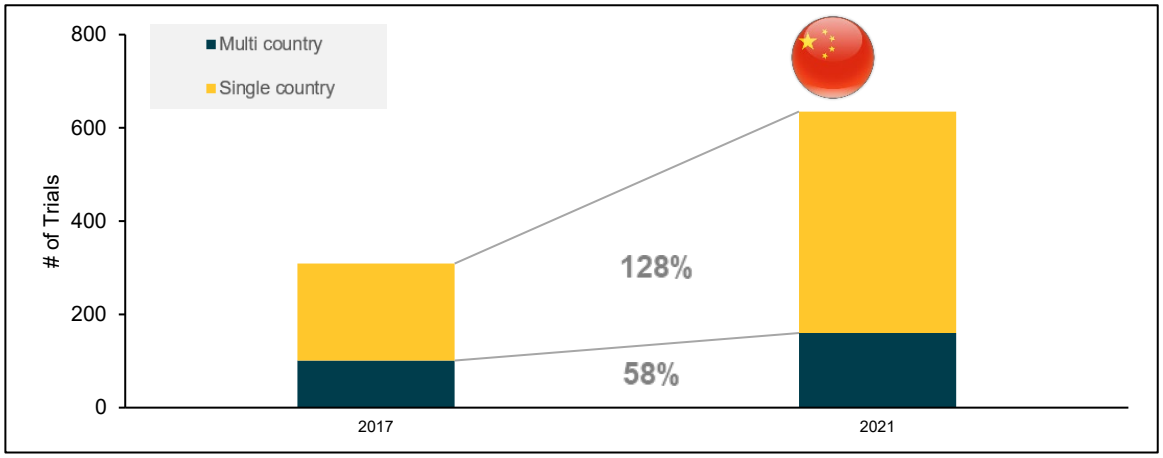

Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries

APAC is positioned as a high-growth area and the internal clinical trial trends are rather unique. Within the region, multi-country trials are growing modestly, whereas single-country trials are surging.

This dynamic appears to be driven primarily by Chinese domestic trials. From 2017-2021, Chinese sponsored multi-country trials have grown by 68%, while single-country trials have grown by 128%.

*The significant upswing in single-country Phase III trials in China is a driving force of growth within this APAC trend*

Figure 6: Single vs Multinational Trials in China, 2017-2021

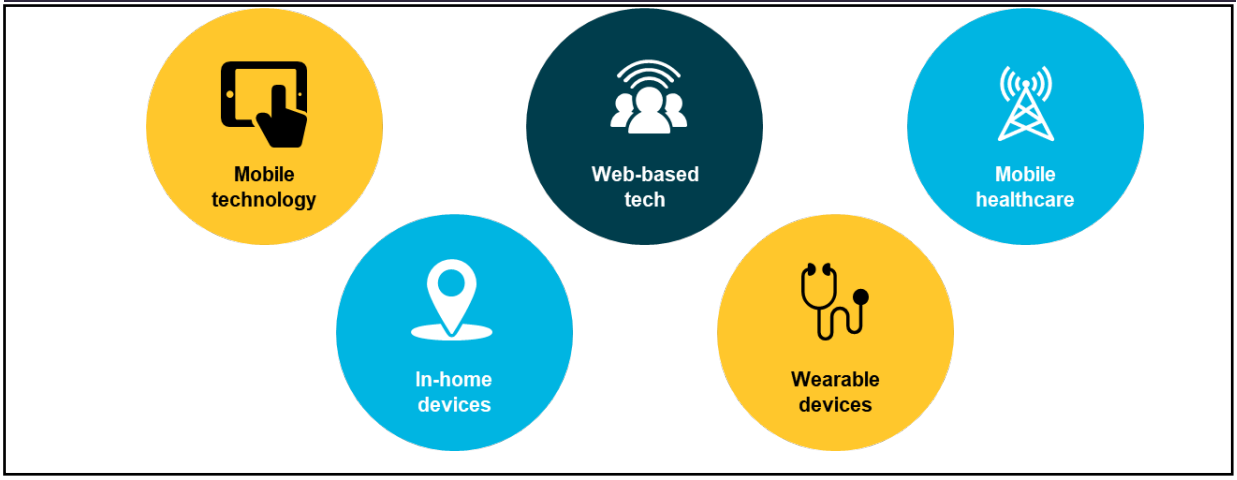



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

## Section 3: Lasting COVID Impact

*Pre-existing enthusiasm for innovative clinical trial techniques has intensified over the last few years*

Figure 7: Decentralized or Virtual Trial Qualification (Non-exhaustive)




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

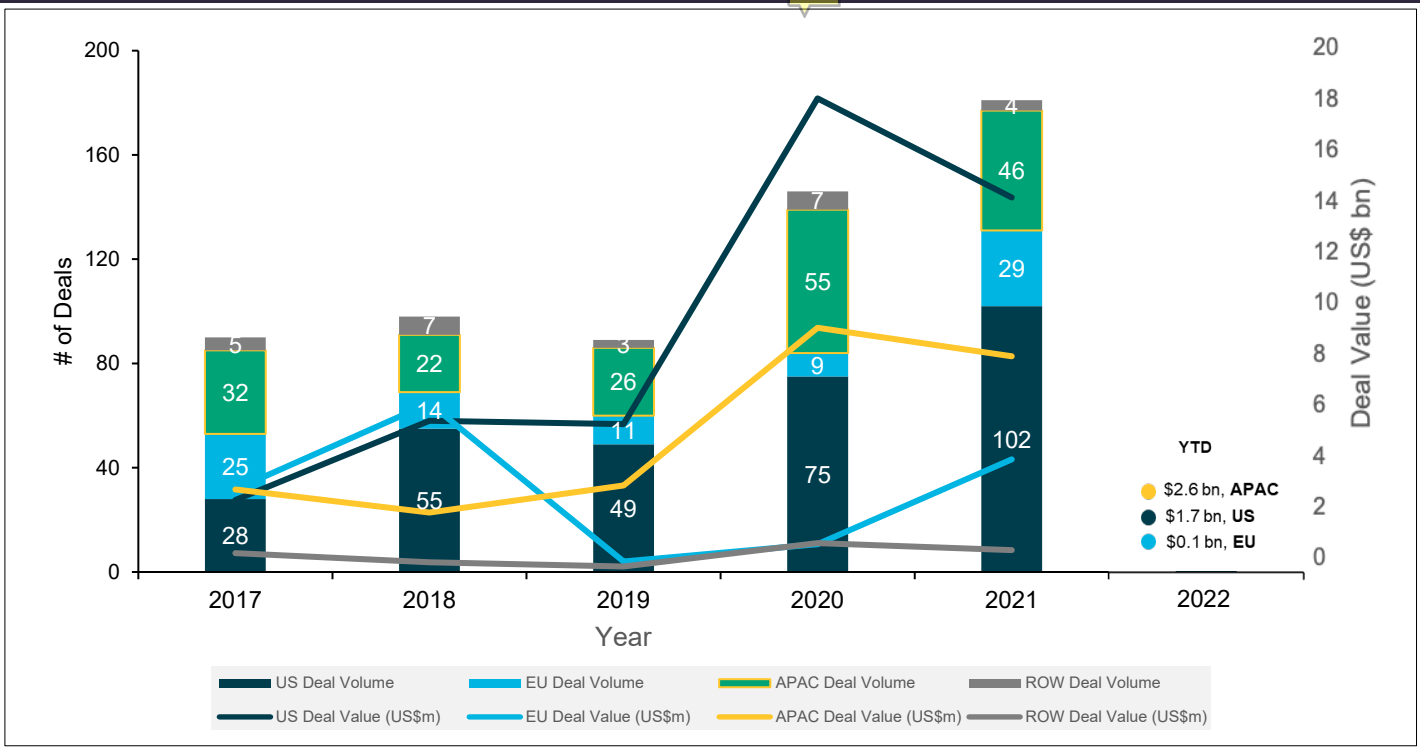
Clinical trial optimization has been a source of innovation within the biotech industry for years. These efforts were propelled recently by the COVID-19 pandemic, as organizations were forced to adapt to new and complex logistical and administrative challenges associated with the outbreak. This dynamic combined with the resources invested in advancing clinical development since late 2019 accelerated the progress of the already cutting-edge industry.

Decentralized or virtual trials are ways clinical development firms have optimized the clinical trial process. DCTs involve web- and mobile device-enabled participation in clinical trials, among other accessibility-enhancing modern features that increase trial participation, retention, and data collection, particularly during challenging times. These DCTs have grown across the board over the analysis period between roughly 10-20%. Phase I trials in APAC, however, serve as an outlier, witnessing almost 60% growth over the same time span.

## Section 4: Biotech Economic Landscape

*As we enter the post-pandemic era, biotech investment remains high internationally*

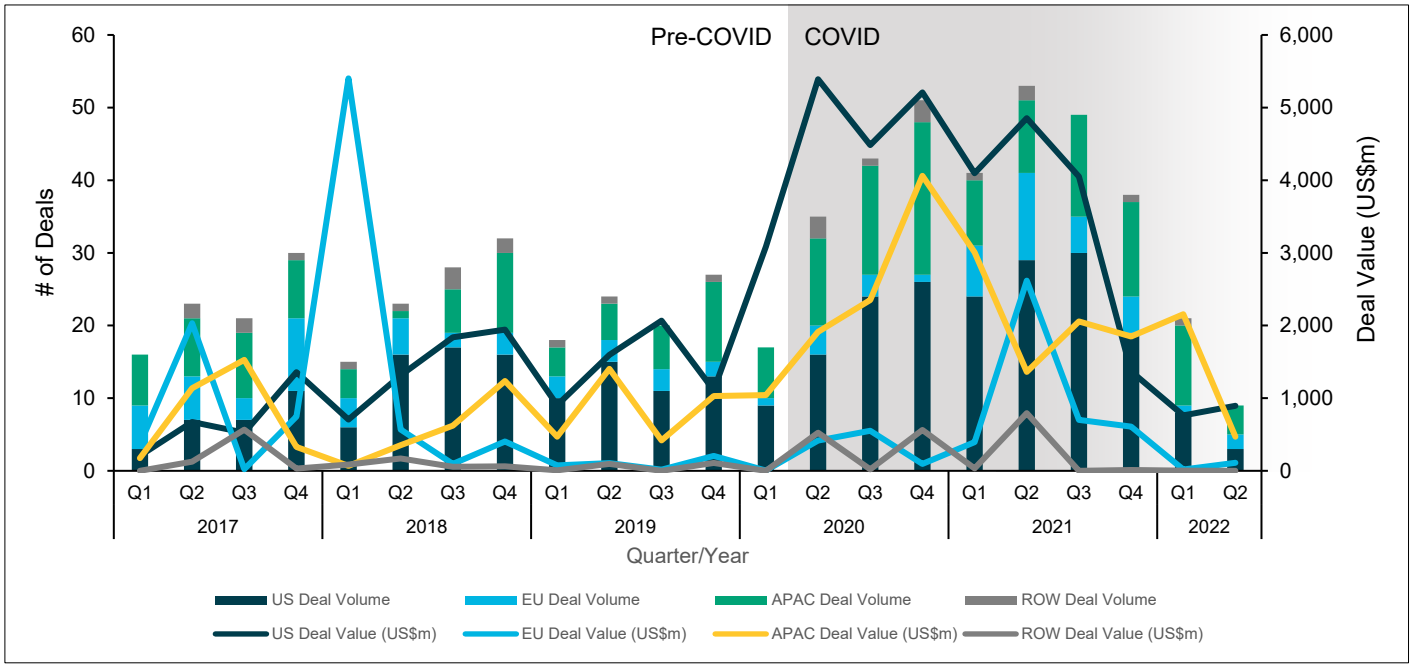
Figure 8: IPO Deal Volume and Value by Deal Geography – 2017-2022




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries; YTD = July 2022

2020 saw a huge swell in biotech investment, fueled largely by COVID and the ensuing clinical research initiatives. In the US in 2020, 75 deals valuing over $18Bn in total were completed, up from 49 valuing $5.6Bn the year before. A similar but more extreme trend occurred in APAC, with 26 deals valued at $3.2Bn in 2019 up to 55 valued at $9.4Bn in 2020. Deals in Europe also grew in 2020, though 2019 deal volume was particularly low in the region.

Figure 9: Deal Volume and Value by Deal Geography - Q1 2017-Q2 2022



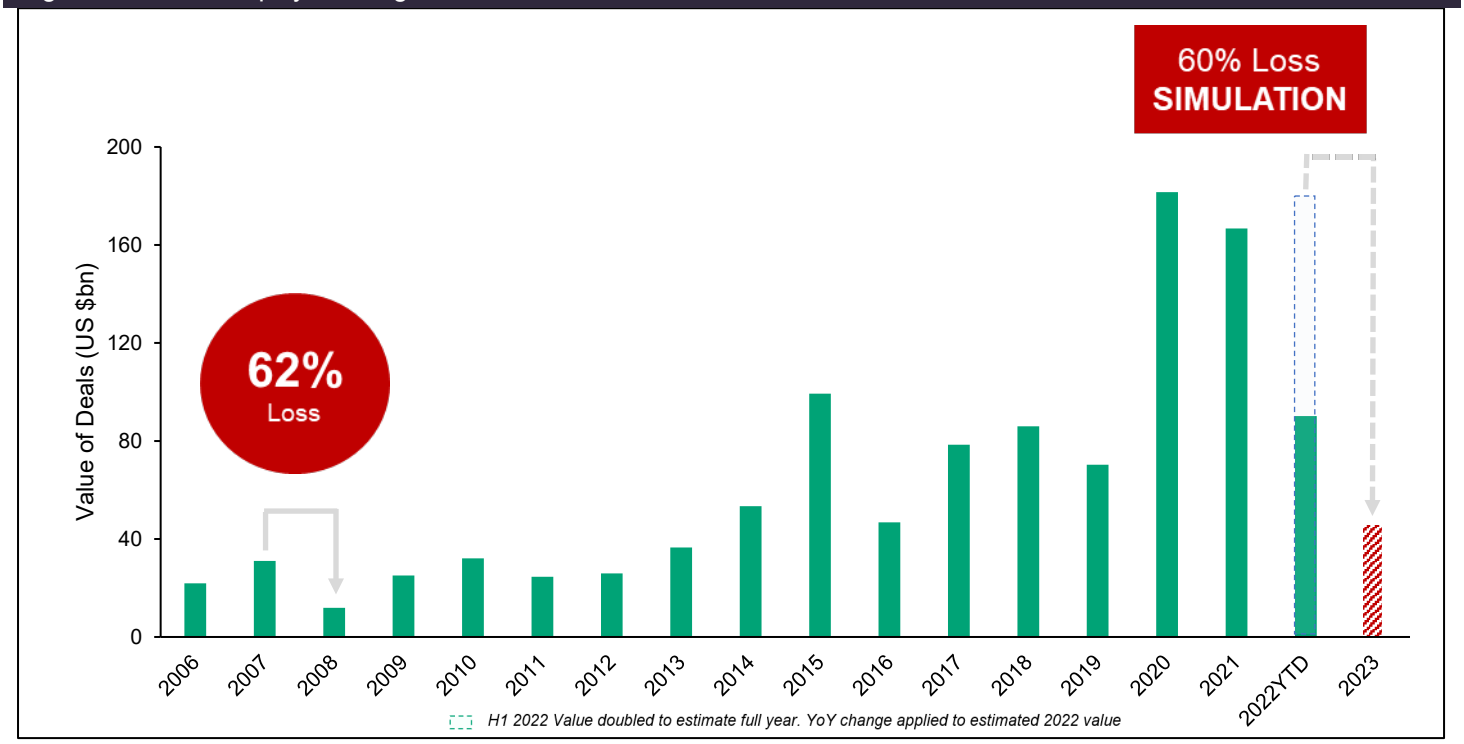

Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

Note: EU = all European countries

The COVID economic impact is particularly noticeable when considering the deal volume and value on a quarterly basis. Both APAC and US had a substantial peak in 2020, though the US follows suit of the other regions and tapers off by the end of 2021. On the other hand, APAC returns to a sustainable level by the first half of 2021 and maintains higher deal values compared to the pre-pandemic period through Q1 2022.

*Equity losses similar to those of previous recessions could constrict biotech investment opportunities*

Figure 10: Global Equity Offerings – 2008 Financial Crisis

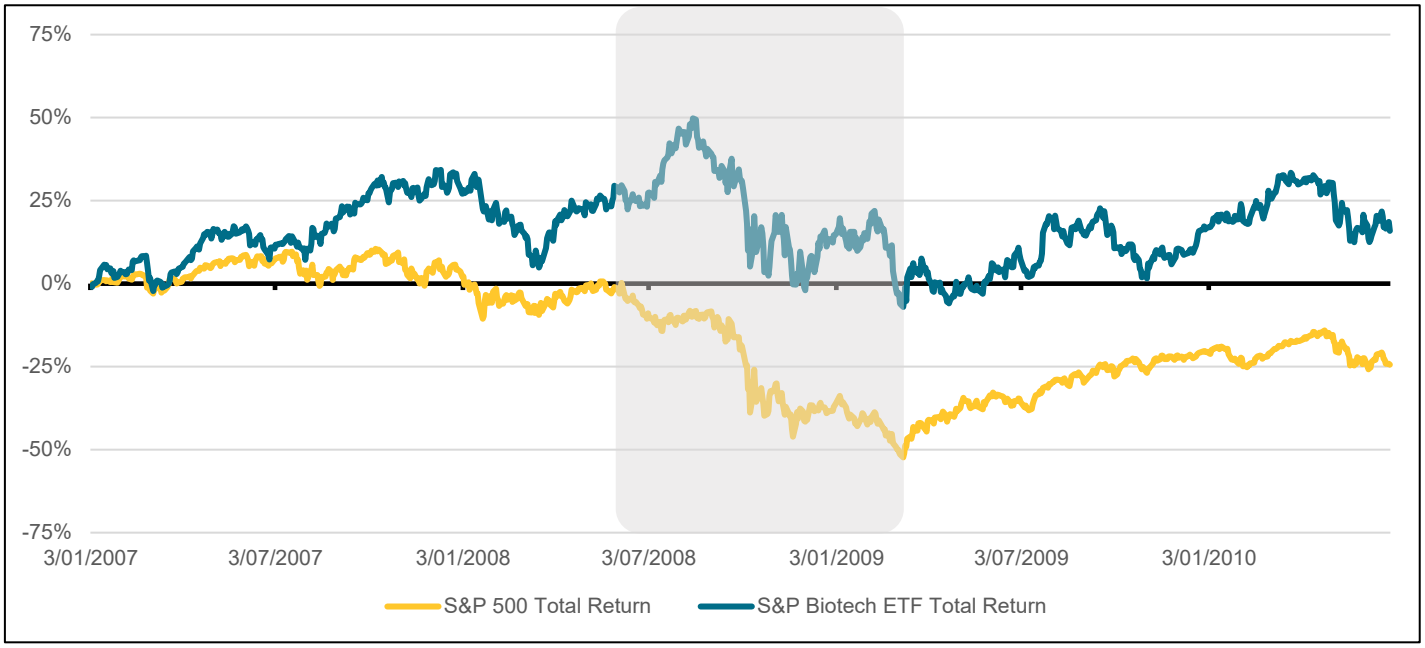



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

Although the biotech industry is in the midst of a revolution, there are macroeconomic cycles that impose constraints on the access to certain sources of capital. During the financial crisis of 2008, the value of equity offerings within the biotech industry contracted by 62% the following year, a difference of nearly $20Bn. Doubling the value of equity offerings from first half of 2022 gives a full year estimate of roughly $180Bn. An equivalent and conservative 60% loss in 2022 terms would equate to over $100Bn in lost equity offering in 2023.

*Biotech has performed better than other industries in past economic crises raising the question: could past performance be a good predictor of future performance?*

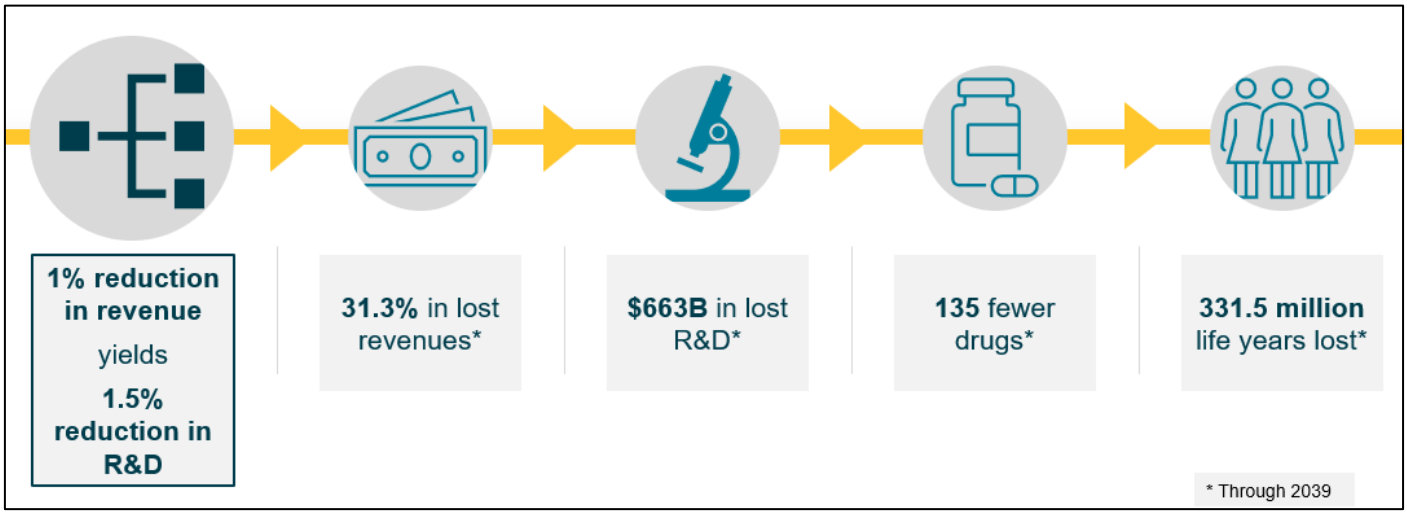
Figure 11: Total Returns: Market Index vs Biotech Index




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]

While some sources of biotech funding may dry up due to inflationary market behavior, there is also evidence that the industry as a whole may be insulated from the majority of the potential economic recession. A comparison of the S&P 500 index versus the S&P Biotech ETF during and after the 2008 crisis demonstrates the shielding of the industry, barely dipping into negative returns while the market index approached and exceeded 50% losses.

Figure 12: Potential R&D Effects of Inflation Reduction Act[1]



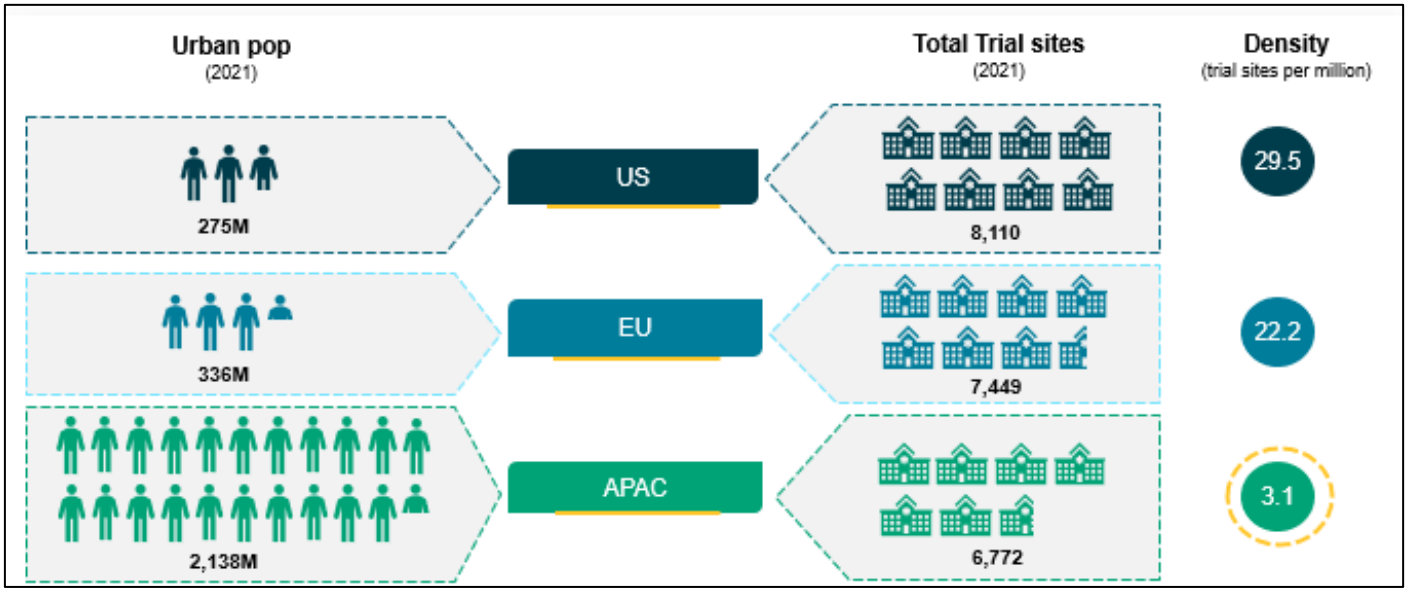

Source: GlobalData; The University of Chicago Brief: The Impact Of HR 5376 On Biopharmaceutical Innovation And Patient Health, Published 29 Nov 2021
Note: EU = all European countries

Legislation among large countries can apply forces on clinical development through funding and incentivization structures both directly on companies and indirectly at the market level. In August of 2022, the US passed the Inflation Reduction Act, which includes Medicare drug coverage restructuring and gives the government the ability to negotiate certain drug prices. These price controls may feed back into the clinical research field, disincentivizing innovation and stifling R&D. A Brief published by researchers at the University of Chicago has provided estimates of the effect of this particlar piece of legislation, basing much of the analysis on an estimation of R&D elasticity calculated as an average of sources among the academic literature. A forecasted 18.5% reduction in R&D spending as a consequence of foregone revenues is predicted to have significant opportunity costs, such as 135 fewer drugs reaching market and an equivalent of 331.5m life years lost. Ultimately the modelled effects at the patient level (life years lost) are expected to be 31 times greater than the COVID impact has been to date[1].

# Section 5: APAC as a Focus for Clinical Development

*International trial site saturation presents opportunities for development in APAC*

Figure 13: Clinical Trial Site Density and Capacity

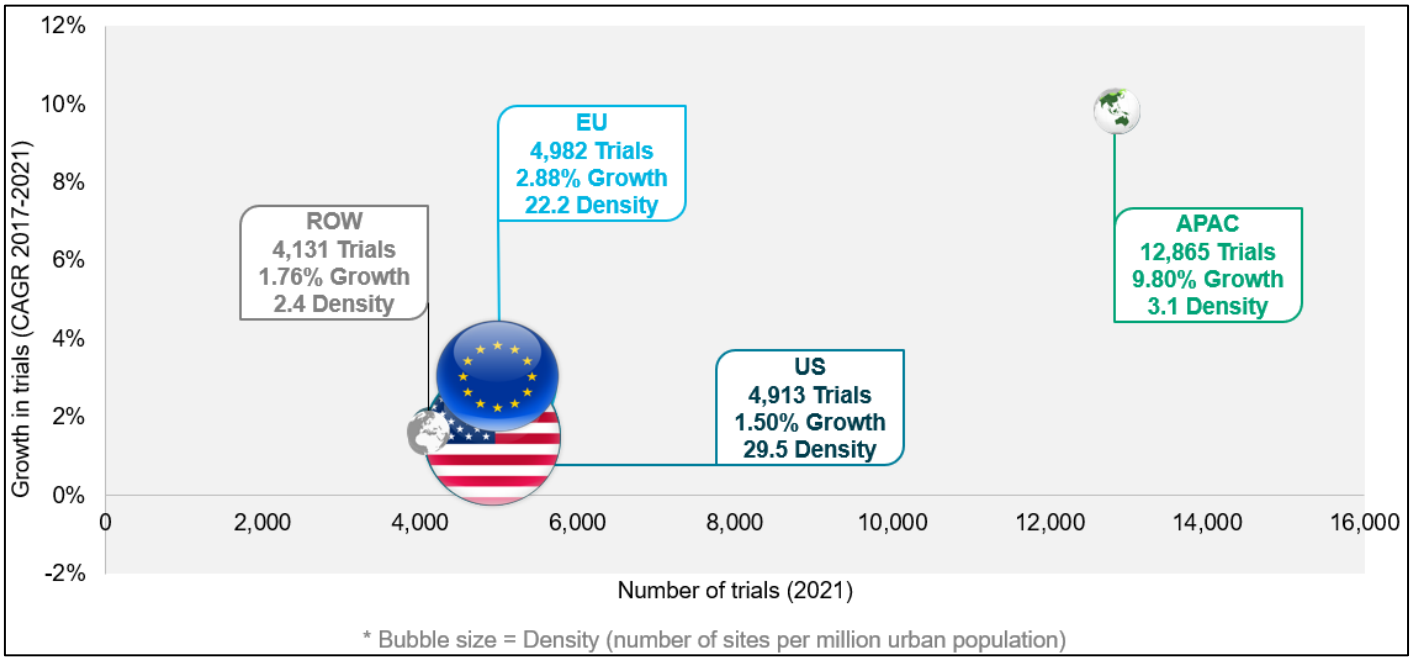



Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries

For clinical developers, trial site density is hugely important in determining receptivity of regional clinical programs. A region with a large number of trial sites and relatively small patient population has a high density. For example, the US has the highest density with 29.5 trial sites per million urban population, while Europe has a density of 22.2. APAC, on the other hand has nearly as many trial sites, but an urban population several times larger than the US or Europe, yielding a density of 3.1 trial sites per million urbanized population. Although APAC has fewer trial sites, the overwhelming urbanized population qualifies the region as massively unsaturated, with enormous growth capacity as a site for clinical trials.

*APAC is uniquely positioned as a prime location for clinical investment*

Figure 14: Clinical Trial Capacity and Activity Regional Matrix




Source: GlobalData; Pharma Intelligence Center Clinical Trial Database [Accessed on 08/25/2022]
Note: EU = all European countries

Connecting many of the metrics discussed so far, a clear clustering effect presents itself. The US, EU, and RoW regions all group around 4,000-5,000 trials in 2021 and 1%-2% growth since 2017, with a discrepancy emerging between the saturation of the US and EU compared to RoW. The striking outlier, however, is APAC. With just short of 13,000 trials in 2021, nearly double digit 5-year trial growth, and a largely untapped, treatment naive urbanized population, the region is positioned as an ideal region for continued clinical trial growth.

Moreover, many countries within this region have historically been welcoming to biotech R&D, such as the innovation rebates and incentive schemes in Australia and the continued investment of the Chinese government in biotech clinical development. From trial activity and capacity to integration of next-generation clinical techniques and broad institutional welcoming, APAC is brimming with features to make it the primary trial hub of the future.

## Section 6: References

1. The Impact Of HR 5376 On Biopharmaceutical Innovation And Patient Health
2. Pharma Intelligence Center: Clinical Trials Database
3. Clinical Trial.gov



GlobalData PLC, John Carpenter House, 7 Carmelite Street, London EC4Y 0AN +44207 936 6400
Registered Office: John Carpenter House, John Carpenter Street, London EC4Y 0AN
Registered in England No. 03925319

## Section 7: Abbreviations

APAC: Asia-Pacific
EU: Europe
CAGR: Compound Annual Growth Rate
RoW: Rest of World
DCT: Decentralized Trial
VT: Virtual Trial

# Section 8: About US

## 8.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.

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### 8.B1 : Contact Us

If you have any queries about this report or would like further information, please contact GlobalData at the telephone numbers or email address provided below.

North America: +1 646 395 5460

Europe: +44 (0) 207 406 6789

+44 1204 543 523

Asia Pacific: +91 40 6616 6800

Email: info@globaldata.com

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