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Pandemic Perspectives: The Lost Trials Of 2020

Clinical Study Starts Fell 8% Amid COVID-19

by Daniel Chancellor

New development programs fell sharply in the early part of the year as COVID-19 spread around the world, but activity picked up in the second half. Oncology trials rebounded strongly and infectious disease trials ballooned, but autoimmune and CNS studies took a hit.

Disruption to clinical trials was a well-documented side effect of the COVID-19 pandemic, with trial sponsors and clinical sites dramatically scaling back activities in line with increased hospital burden, lockdown measures, and reduced patient mobility.

As the Western world battles with second and third waves of infection, thankfully the clinical trial ecosystem has been largely insulated from additional mitigation measures. At a global level, study sponsors have mostly returned to normal clinical trial activity despite soaring pandemic case numbers, although this belies important trends within key therapy areas and geographies.

Pandemic Perspectives

One year on from the World Health Organization declaring COVID-19 a global pandemic on 11 March 2020, editors across Informa Pharma Intelligence publications are taking a [closer look](#) at its impact and possible lasting implications for the biopharma and medtech industry.

Even with a full recovery by the end of 2021, many drug developers will still be counting the cost of the lost trials of 2020.

This analysis looks at clinical trials initiated by the biopharmaceutical industry with a confirmed

start date of between January 2019 and December 2020.

While not a complete representation of total clinical trial disruption caused by the pandemic – COVID-19-related updates to trials already in progress are not readily reported by sponsors – it casts light on how well (or not) the industry has been able to restore normal clinical trial activity.

By and large, the picture is a healthy one, with 2020's total of 5,276 trials coming in only 8% lower than the 5,706 trials reported by Trialstrove in 2019, despite this once-in-a-century global event. On a month-by-month basis, this peaked at 37% fewer trials in February and March, recovering firmly by June and then staying close to prior year levels throughout the second half of 2020. This creates important momentum for 2021 as vaccination programs begin, confidence returns to society, and repairs can begin in earnest.

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Explosion In Infectious Disease Research Offsets Declines In Other Therapy Areas

The fact that the overall slump in clinical trial activity was not steeper is primarily due to an incredible surge in infectious disease research, led by trials of drugs for COVID-19 infection, prevention, and complications. As Exhibit 2 shows, surging case numbers were accompanied by rapid deployment of clinical trials, initially led by academic and government groups, and later by industry sponsors. This analysis is purely looking at the biopharmaceutical industry, which had doubled its usual rate of infectious disease research by April, and maintained this intense activity throughout the entire year.

While no other pocket of clinical research witnessed a comparable boost through the pandemic, certain therapy areas were more insulated from disruption. Oncology was one of these, which is counterintuitive considering that many cancer patients receive immunosuppressive therapy and were at greater risk of severe COVID-19, but perhaps unsurprising considering the weight and urgency of investment in the area. Clearly, drug developers were prioritizing the momentum of these programs, as 4% more oncology trials were initiated in H2 2020 compared with the prior year. Metabolic (and endocrinology), despite having the largest drop of the top five therapy areas in H1 2020 (-41%), rebounded strongly with just a 3% dip in the second half of the year. Autoimmune and CNS research remained firmly below par for the entirety of 2020.

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Clinical Trials Bounce Back Strongly In North And South America

Segmenting new clinical trials in 2020 along the lines of geography is equally revealing (Exhibit 3), as a disconnect emerges between the degree of disruption and COVID-19 caseload. It might be expected that the Americas and Europe, which have shouldered the greatest burden of infection and mortality, would also have the most lost clinical trials in 2020. This holds true for Europe, which reported a 12% annual decline despite normal activity resuming by H2 2020. However, North America is completely flat for the year and, remarkably, South America saw 15% more clinical trials in 2020 compared to 2019. Oceania, largely spared from the pandemic owing to strict government measures, saw a 2% decline in trials overall, while Asia declined by 10%. Within Asian countries there were strongly diverging performances in terms of pandemic response and cases, although it is notable that clinical trial activity in China, where the virus is heavily suppressed, only reached 90% of the 2019 total.

While the degree of disruption to new clinical trials over the entire year seems hard to correlate, the temporal distribution of when each region reached peak disruption is more logical. Trial activity was lowest in Asia in February, with a 54% reduction from baseline, while Europe and North America both bottomed out at -46% in the bleak month of April. By and large, those regions that experienced the first wave of infection sooner were able to recover sooner, although the magnitude of overall recovery is variable. As for the strong performance in South America, this perhaps represents an enduring legacy of the pandemic with new clinical trial infrastructure.

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Note: trials that span continents are counted for every region in which there is an associated study location.

Later Stages Of Research Return Ahead Of Phase I Trials

As clinical trial capacity has returned, drug companies have prioritized making up for lost time with their existing assets, rather than advancing new drugs into first-in-human Phase I trials. This is shown in Exhibit 4, as new Phase II and Phase III trials bounced back to usual levels of activity both quicker and more strongly. In total, there was no net cost to mid- and late-stage trials, which achieved 95% and 105% of their expected activity in 2020, respectively. Rather, Phase I activity was down 11% overall, equivalent to the loss of 321 clinical trials. This delay in early-stage research will trickle down to subsequent larger trials over time.

The evolution of Phase IV studies followed its own unique trajectory, with the biopharmaceutical

industry failing to reach the average 2019 mark in 11 out of the 12 months during 2020. Discretionary Phase IV trials have certainly been deprioritized, while regulators may have afforded drug companies with a degree of flexibility in terms of post-marketing commitments while the immediate focus was on COVID-19 therapies.

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Note: trials that span phases, such as a Phase I/II study, are counted at the lower level of development.