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Examining The Clinical Trials Landscape

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In a post-pandemic world, the evolving landscape of clinical trials just got more complex. The year 2022 was one of many adjustments given the incidence of lower trial initiations. The health care industry endured the impacts of geopolitical conflicts, curbed growth in China and stagflation in major markets.

Citeline's latest Clinical Trials Roundup provides an overview of the Phase I-III clinical trials initiated in the prior calendar year (2022) across all therapeutic areas comprehensively covered by Trialrove, as well as in-depth analyses into the key diseases and geographies.

As of 26 June 2023, Trialrove curated 9,104 Phase I-III clinical trials (*see Exhibit 1*) investigating at least one drug and with a disclosed start date within the calendar year of 2022. This marks a decline of 12.5%, breaking the upward trend of clinical trial counts for the first time since 2016.

The clinical trial landscape slightly changes when taking a closer look at industry-sponsored trials, which may better represent the current health of the pharmaceutical industry. In 2022, industry-sponsored trials (*see Exhibit 2*) decreased by 7% overall, but if we exclude COVID-19 trials, this reduces to a 4% decline, reflecting the industry's survival mode since 2021.

Exhibit 1

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Exhibit 2

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Exhibit 2 also supports a trending departure of COVID-19 trials research by industry sponsors in 2021 (619 trials) and 2022 (344 trials). Companies such as Roche and Novartis have shifted their focus away from COVID-19 over the last two years, while Pfizer held on like a long-distance

champion in this arena. The exclusion of COVID-19 trial count is a way to minimize the COVID effect on the trials landscape, providing a surrogate health check on clinical research. The decrease in trial numbers in 2022 demonstrated a more restrained and cautious environment for clinical research, guided by a complex myriad of factors: the global economy, legislation and overall political climate.

Clinical Trial Activity By Therapeutic Area

The ranking of therapeutic areas by trial initiations in 2022 remained the same as in prior years, albeit most therapeutic areas (TAs) saw a modest decrease in trial counts (*see Exhibit 3*).

Infectious disease had a dramatic rise to second place when its trial initiations rose from 760 trials in 2019 to 3,053 trials in 2020, largely contributed by COVID-19 trials. While the pandemic persisted through 2021, the number of ID trial initiations dropped to 2,771 trials, and further decreased to 1,711 (-38%) in 2022, closing the gap of its lead over central nervous system (CNS) trials.

Oncology continued to be the top-ranking TA with a clear lead, even though its trial initiations were down by 10%. The cardiovascular TA experienced a 15% decrease of trial initiations in 2022, while other TAs such as metabolic/endocrinology, autoimmune/inflammation, ophthalmology and CNS held on to their 2021 rebound and saw a smaller reduction ranging between 1% and 3%. Genitourinary is the only TA with growth, posting a 4% rise in 2022.

Exhibit 3

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Top Diseases

Each year Citeline analyzes the top 10 diseases for clinical trial activities to get a glimpse of where research efforts are taking place. After a two-year reign, COVID-19 finally gave up its number one spot back to an oncology disease (unspecified solid tumor, 566 trials), though it continues to exert its presence in a close second place (563 trials). Clearly, the pandemic disruptions to clinical trials have subsided. The makeup of the top 10 diseases has been consistent for several years, with some slight ranking shifts.

Cancer makes up half of the top 10 chart and four out of five diseases within the top five: unspecified solid tumor, non-small cell lung cancer (NSCLC), breast cancer, and non-Hodgkin's lymphoma (NHL). The COVID-19 trials clearly had a major cut from 1,333 (13%) in 2021 to 563 (6%) in 2022. However, the phase distribution of COVID-19 trials in 2022 is more evenly distributed between Phases I, II and III, as opposed to the inflated Phase II trial numbers seen in prior years.

Respiratory vaccines and respiratory infections were the other two indications that rode the wave with the COVID-19 trials, but their numbers also took a dive and moved down the ranks in 2022.

Head and neck cancer dropped off the top 10, making way for pain (nociceptive) to rejoin the fold as number 10. Most of the other top diseases had a modest reduction of trial initiations, though their proportion with respect to total trials barely changed. Type 2 diabetes is the disease within the top 10 that had the highest increase in trial initiations, exhibiting rising activity in early-phase development.

The steady upward trend of rare disease R&D also suffered a setback in 2022, with 13% fewer trial initiations than the previous year, wiping away the post-pandemic rebound observed in 2021.

The receding trial initiations in 2022 no doubt impact rare disease trials. The nature of rare disease research inherently faces tougher challenges, as most conditions are debilitating or fatal, particularly in pediatrics. Due to a limited patient pool for rare diseases, clinical trials often had to expand recruitment to multiple countries for suitable patients, resulting in longer trial timelines and higher expenditure. The depressed economic climate for biopharma in 2022 also accentuated the challenges further.

Historically, oncology indications have dominated the rare disease landscape, and 2022 is no different. NHL continues to be the most studied rare disease, while other indications experienced minor decreases in trial counts. Only head and neck and liver cancer experienced notably fewer trial starts in 2022. Outside oncology, the top three rare indications in 2022 were the same as in the previous year: amyotrophic lateral sclerosis (35 trials), tuberculosis (33 trials), and sickle cell disease (28 trials).

Geographic Survey Of Trial Activity

China retained its lead in trial initiations with 3,405 trials (vs. 3,795 trials in 2021), with the US in a close second at 2,876 trials (vs. 3,310 trials in 2021). In 2022, we observed a downward trend in trial starts across all regions, with the sharpest decline in Asia (-12%). We have not yet seen the impact of pain points with the new EU Clinical Trials Information System (CTIS) on trial initiations, as that was only made mandatory by the European Medicines Agency (EMA) Clinical Trials Regulation on 31 January 2023. Although frustrations were heard loud and clear as sponsors struggled with CTIS earlier this year, it would be premature to project how this episode might interfere with trial activities in 2023 and the implications this may have on regional differences.

All countries had fewer trials in 2022, reflecting a shared trend of lower trial volume all around. Ukraine suffered the biggest loss of trial initiations (-154%) due to displacements of trial subjects, and clinical trials in Russia also plunged by 86% compared to 2021. The lack of stability caused by the war extended to Poland and Hungary, where clinical trials went down by 35% and 34%, respectively. Both Poland and Ukraine were considered as up-and-coming locations for clinical trials in recent years. One can expect the low numbers of clinical trials in these regions to continue in 2023 as there has been no sign of armistice.