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What Pandemic? Clinical Trials Shake The COVID-19 Dust Off Their Feet

by Alex Shimmings

Industry-sponsored clinical trial activity has returned to pre-pandemic trends now that the turmoil of COVID-19 has abated, finds a new report from Citeline.

Citeline's annual analysis of completed clinical trials for 2023 reveals a clear break from the COVID-19 pandemic-driven fluctuations seen since 2020. The industry has finally got back where it was at the end of the last decade now that the focus on infectious diseases and vaccines has tapered off and disruptions to other trials have come to an end.

Citeline's TrialTrove database recorded 4,295 industry-sponsored trials from Phase I to Phase III/IV that either reached completed status or reported primary endpoints during 2023. This figure was 10.7% higher than the 3,881 completed trials in 2022 and represents a return to growth. "Since 2020, the completed trials counts have alternated between annual decreases, in 2020 and 2022, and increased trial completions, in 2021 and 2023," found Citeline's *Annual Completed Clinical Trials* report. But now it appears that "pandemic-related disruptions and

Key Takeaways

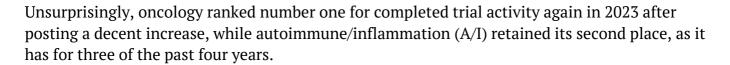
- Nearly 11% more clinical trials completed in 2023 than in 2022.
- Fluctuations caused by the COVID-19 pandemic have come to an end.
- Success rates for clinical trials also rose last year.



infectious disease-related activity come to an end after three years of oscillations."

Growth in clinical trial completions in 2023 was seen across all therapeutic areas, although the rates across different therapy areas were not uniform (see Table 1). With coronavirus in the rearview mirror, infectious diseases growth was negligible compared with other therapy areas, while central nervous system (CNS) returned to third place for the first time since 2020. The CNS area saw relatively small annual changes to the number of trial completions during the pandemic years (2020–22), but its position has been buffeted around the rankings over the past four years by the surge of infectious disease activity.

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The increasingly busy metabolic/endocrinology therapy area returned to fourth place, narrowly edging out infectious diseases into fifth place, as the latter returned to its 2020 early pandemic period position (albeit with far higher counts: 648 vs. 485).

Unlike the shuffling seen in the upper orders since 2020 the four smallest therapy areas have retained their placings in the rankings since at least 2016, even while their numbers of completed trials grew last year. Cardiovascular was notable for reversing its trend of decreasing trial completions between 2020 and 2022, reflecting a renewal of industry interest in this area. Vaccines trial completions have nearly doubled since 2020, while ophthalmology and genitourinary also managed modest rises in 2023.

The distribution of clinical trial completions by therapy area and phase again highlights the importance of oncology, which continues to run a relatively high proportion of Phase I/II trials, at 14% (see Figure 1). Also coming in higher than the average (7%) were vaccines and ophthalmology: all three are areas where efficacy endpoints are more commonly evaluated at Phase I.

Annual growth driven by increased Phase I activity was most pronounced in cardiovascular and infectious diseases, "presumably from new candidates in clinical development," the report said. "Phase I activity in A/I, CNS, and oncology changed, year-on-year, by only an average of 1.7%, which suggests growth in these therapy areas was mainly due to increased activity in later-stage trials as successful clinical stage drugs move forward."

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Diseases

Looking more granularly at the top five diseases for trial completions in 2023, despite a dip in numbers, coronavirus came top of the list in what is likely to prove its last hurrah. COVID-19 has topped the disease list since 2021 and trials here are also included in the respiratory vaccine group and so contribute to the broader disease classification's inclusion in the top five for the first time. "COVID-19 counts remain high compared to 2020, but a substantial annual decrease is reported as this pandemic transitions to the endemic chapter," the report said.

Of the two cancer indications included, breast cancer counts dropped to their lowest levels since 2016, ranking in fifth place.

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Success Rates

Not only were more trials completed last year than in 2022, their success rates rose too. This, the report said, was "another reflection of how the challenges of the pandemic years are no longer driving trends in 2023."

13 different diseases reported at least 25 trials that hit their primary endpoint, and the average success rate for these top diseases increased from 31.6% to 33.3% from 2022 to 2023 (see Table 3). Again, coronavirus topped the disease charts, although its total of 79 was a decrease on 2022's 94, and in terms of rank based on percentage of trial attaining primary outcome per disease, it fell to 11th place. Type 2 diabetes, on the other hand, had nearly double the number of positive trials in 2023 than the year before, and ranked eighth.

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Companies

Although clinical trials activity last year was naturally dominated by the top 20 pharma companies (by sales), when taken as a whole, all other pharma firms increased their shared of completed trials, with those based in China playing an increasingly important role. Average success rates across the most active sponsors increased from 24.7% to 31.3%.

The top five sponsors by overall completed trial counts in 2023 were headed up once again by <u>Pfizer Inc.</u>, while <u>AstraZeneca PLC</u> has held on to second place for the past three years. <u>Merck & Co., Inc.</u> and <u>Roche Holding AG</u> reported their highest completed trials counts in five years, attaining third and fourth ranks, respectively. <u>Bristol Myers Squibb Company</u> replaced <u>Novartis AG</u>, which has completed fewer trials annually for most of the past five years, in the top five (see Table 4)



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However, when looking just at the successfully completed trials, AstraZeneca easily took the top spot; its successfully completed trials included 17 Phase III studies as its increasing R&D spend paid dividends (see Table 5).

In fact, AstraZeneca reported near or greater than two-fold higher positive trial counts (64) than the last four sponsors on the list, including *Eli Lilly and Company* (33), *Sanofi* (29), Novartis, and *AbbVie Inc.* (28 each). Overall, it enjoyed a 37.6% success rate, though on this measure Chinese firm *Jiangsu Hengrui Medicine Co., Ltd.* outstripped it at 51.4%.

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See *Citeline's <u>Annual Completed Clinical Trials Report</u>* for more analysis, including an in-depth look at the top three therapeutic areas.