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# PHESI GLOBAL DATA ANALYSIS

MOST STUDIED DISEASE AREAS:

**JANUARY-JUNE 2023** 

GEN LI, PRESIDENT AND FOUNDER, PHESI

### OVERVIEW

As part of our patient-centric data-led approach to clinical development, Phesi has conducted a global analysis of all clinical trials conducted in the first six months of 2023, using our Trial Accelerator™ platform driven by the world's largest trials database.

This mid-year report highlights the top five most studied disease areas to date in 2023 and is based on 13,490 recruiting clinical trials. It also shows Phase II terminations continue to rise amidst an overall decline in clinical trial productivity.



## **KEY FINDINGS**

### DEPRESSION NOW ONE OF THE TOP FIVE MOST STUDIED DISEASE AREAS IN CLINICAL DEVELOPMENT

Our analysis reveals that Covid-19 is no longer one of the top five most studied disease areas as seen in 2022, and activity for depression has increased – becoming the fourth most studied disease globally in the first six months of this year.

Three of the top five most-studied diseases fall within oncology, with solid tumours currently the most studied disease indication, and breast cancer falling to the second-most studied disease, stroke third, and prostate cancer fifth (Figure 1).



Figure 1. The top five most studied disease indications in the first six months of 2023





#### Figure 2. The top five most studied disease indications in 2022

Awareness of the global mental health crisis has been growing in the wake of the Covid-19 pandemic. An estimated <u>5% of adults</u> are affected by depression globally. With SSRIs (the last major class of antidepressants) launched over forty years ago, new therapies to tackle this disease are desperately needed.

As clinical development investment into Covid-19 continues to wane – a trend we saw begin to emerge at the end of 2022 – the industry is allocating resources to other disease areas. Increased investment into depression therapies is likely due to greater awareness, improved understanding of the underlying causes of the disease, and growing investment in new avenues such as psychedelics. There will be particular challenges in clinical trials in this area, so companies will need to design protocols carefully to ensure treatments reach patients as soon as possible.



## 2023 DATA SHOWS PHASE II TERMINATIONS CONTINUE TO RISE

This latest analysis also shows that the rise in Phase II attrition identified in our end-ofyear 2022 analysis has increased further (Figure 3). So far in 2023, almost a third (31%) of trials at Phase II have been cancelled – this is a 55% increase on pre-Covid levels. High levels of cancellations at Phase II increase the overall costs of clinical development considerably. More worryingly, such delays will have a knock-on effect on the rate at which new therapies reach market, and may even prevent viable new therapies from ever reaching patients.

The clinical development industry is still feeling the effects of disruption caused by the pandemic. The fallout is likely to continue for some time longer and could result in two more years of high levels of Phase II attrition. The strain of these trial cancellations on the global drug development pipeline will be severe, and to ease the pain, productivity and trial efficiency need to improve.

Unnecessary protocol amendments and trial cancellations are a symptom of inadequate protocol design. In order to improve the successful outcome of clinical studies, the industry must go back to the fundamentals and use data to improve the design of clinical trial protocols. By applying predictive analytics in protocol design, the industry can overcome enrollment difficulties, accelerate clinical trials and avoid amendments, overall improving productivity.





#### Figure 3: Phase II attrition rate from 2017 to first six months of 2023

Age-related trial amendments highlight need to improve protocol design and clinical trial productivity

In our six month analysis of global data we have used age-related trial amendments as an example to illustrate that a better understanding of protocol amendments is required to improve the efficiency and productivity of clinical trials.



From 13,490 currently recruiting Phase II and Phase III trials, we identified 872 trials as having one or more patient age-related amendments. Unsurprisingly, some indications such as Crohn's Disease, Sickle Cell Disease and Amyotrophic Lateral Sclerosis are more prone to age-related amendments than the others (Figure 4)



Figure 4: Trends in age-related trial amendments from the current year



As clinical trials progress, the probability of having one or more age-related protocol amendments increases (Figure 5). Amendment related data such as this example, can help the industry proactively optimize trial design and improve clinical development productivity.



Figure 5. Percentage of trial amendments tracked from year clinical trial started



## CONCLUSION

In the first six months of this year, there have been significant changes to last year's top five studied disease areas. While COVID-19 related clinical trials have moved out of the top five, the affects of the pandemic will be continue to be felt for at least the next few years despite the industry having more tools to mitigate its impact. Depression has become the number four studied disease with solid tumors now occupying the number one position which encouragingly indicates a renewed focus around innovation in oncology.

With rising levels of trial terminations, our industry must follow a more data-led, patient-centric approach to optimize protocol design, minimize protocol amendments, accelerate trials and improve productivity. Using indication-specific digital patient profiles to simulate trials will ultimately ensure that patients get the treatments they need faster.



## ABOUT PHESI

#### PATIENT-CENTRIC DATA ANALYTICS TO SIMULATE CLINICAL DEVELOPMENT

Powered by the world's largest clinical trials database, Phesi's AI-driven solutions enable life sciences companies to accelerate drug development and commercialization. Turn real-world data into insights and answers with our Trial Accelerator™ platform generating Digital Patient Profiles, optimizing protocol design, creating Digital Twins and Digital Trial Arms.



FIND OUT MORE ABOUT <u>PHESI</u> AND <u>THE TRIAL</u> <u>ACCELERATOR™</u> PLATFORM.





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