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PHESI GLOBAL ANALYSIS:

TOP FIVE STUDIED DISEASE AREAS IN 2024

DR GEN LI, FOUNDER
AND CEO OF PHESI

SUMMARY

Our annual global clinical development analysis leverages real-world contextualized data from 132 million patients using Phesi's Trial Accelerator™ platform. This year's analysis of 67,469 recruiting clinical trials shows that in 2024, breast cancer was the world's most studied disease for the fourth year we have been running our ranking – followed by solid tumors, stroke, prostate cancer and non-small cell lung cancer. The data reveals that one in three clinical trials were terminated during Phase II, a 50% increase from before the COVID-19 pandemic. This represents an increase of tens of millions of dollars wasted on trials that ultimately fail that could be prevented by using data science, AI and clinical data analytics to deliver greater precision in trial design and execution.

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SECTION 1: TOP FIVE STUDIED DISEASE AREAS

Our 2024 analysis of 67,469 recruiting clinical trials using Phesi Trial Accelerator™ reveals that breast cancer is the world's most studied disease for the fourth consecutive year. This is followed by solid tumor, stroke, prostate cancer and non-small cell lung cancer. Once again this year's analysis shows that four of the top five most studied diseases are within oncology (fig. 1).

It is not surprising to see breast cancer trials staying at the top of the list, given breast cancer is the top killer among women with cancer. In 2023, COVID-19 dropped from second to fourth position (fig. 2), and in 2024 it has finally fallen out of the top five as studies for COVID-19 therapies continue their downwards trend. COVID-19 has been replaced by non-small cell lung cancer, re-entering our ranking of the top 5 most studied diseases for the first time since 2021 (fig. 4).

There are two main forces driving treatment innovation: the unmet needs of patients suffering from disease and the industry's improved understanding of disease. The latter is the case for intensified efforts in non-small cell lung cancer, where the data shows an increase in the number of biomarker-specific trials.

Our analysis reveals that more than half (51%) of all non-small cell lung cancer trials are now biomarker-specific. More biomarker-led studies lead to more targeted treatments with higher precision resulting in a higher success rate which is good news for patients and good news for the industry as improved ROI becomes an increasingly important requirement.

The industry has already seen two waves of biomarker-specific non-small cell lung cancer treatment – EGFR and PD1/PD-L1. While a significant portion of trials still target EGFR (23%) and PD1/PDL1 (11%), trials targeting KRAS (6%) and ALK (5%) are increasingly gathering momentum. Other biomarkers currently of interest to researchers include MET and ROS1.

Solid tumor trials are the foundation for innovative cancer treatments and it's encouraging to see that they continue to be the second most studied disease globally for the second year running. Continued investment in this area remains a promising sign for patients in need. Stroke retains its position in 2024's analysis as the third most studied disease, having first entered the top five ranking in 2022 (fig. 3).

FIGURE 1. TOP FIVE MOST STUDIED DISEASE INDICATIONS IN 2024

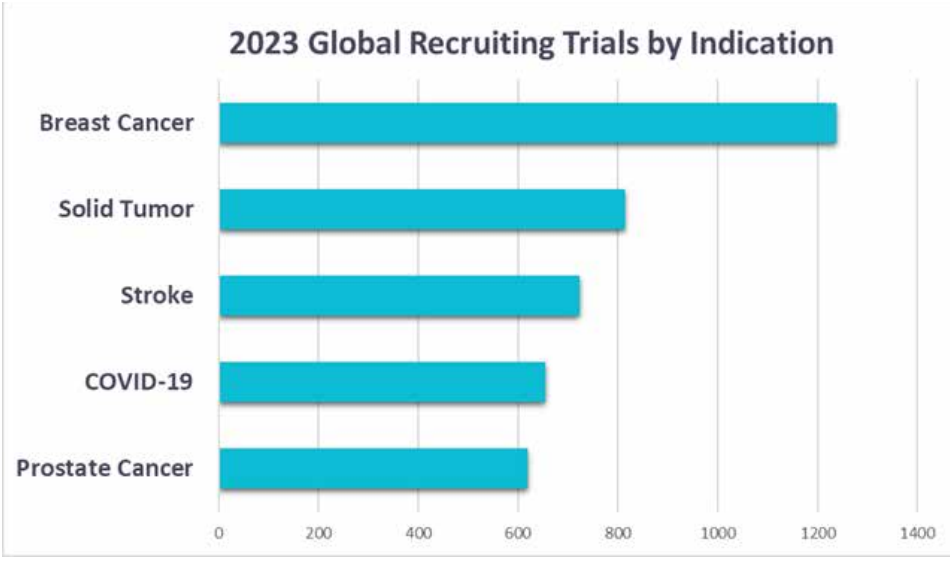

FIGURE 2. TOP FIVE MOST STUDIED DISEASE INDICATIONS IN 2023

FIGURE 3. TOP FIVE MOST STUDIED DISEASE INDICATIONS IN 2022

FIGURE 4. TOP FIVE MOST STUDIED DISEASE INDICATIONS IN 2021

SECTION 2: TRIAL ATTRITION RATES

Phesi's annual global analysis is one of the few studies dedicated to tracking Phase II attrition rates. This important metric can highlight a slowing down of the rate at which new therapies reach market and the rising development costs for industry.

Phesi's 2022 global analysis data revealed a significant increase in attrition rate at Phase II and disappointingly, this finding has persisted with the Phase II clinical trial attrition rate in 2024 remaining high (fig. 5). 2024 data shows that one in three (31%) clinical trials were terminated during Phase II – rising from 29% in 2023 and representing a 50% increase from an average of 20% before the COVID-19 pandemic. This indicates an increased loss of tens of millions of dollars on trials that ultimately fail.

While it is clear that the COVID-19 pandemic had a negative impact on Phase II clinical trial success, with the pandemic now behind us, we had hoped this would lead to a reduction in the Phase II attrition rate. This will inevitably have a knock-on effect on Phase III trials and a significant negative impact on ROI across the biopharmaceutical industry.

FIGURE 5. PHASE II ATTRITION RATE (2017–2024)

SECTION 3: IMPLICATIONS FOR TRIAL DESIGN AND EXECUTION

Encouragingly, oncology research continues to be a major priority for the clinical development industry, however with increasing trial cancellations the industry is at risk of increasingly wasting valuable resources at a time when clinical development pipelines and financial models are under greater scrutiny. The industry's ability to successfully leverage emerging technologies and to digitally transform will be key to improving productivity and performance.

It is clearer than ever that sponsors need to focus on utilizing patient-centric data science, AI and analytics for greater precision in clinical trials – ensuring every aspect of trial design is optimized including the most suitable investigator sites to deliver smarter trials and faster cures.

2025 must see a greater focus for clinical trials on understanding the patient and who is treating them. This means patient-centered design to eliminate unnecessary and costly protocol amendments and patient-centered investigator site selection to ensure access to the right specialists and to improve enrollment and reduce patient burden.

In collaboration with partners using our AI-driven Trial Accelerator™ platform, Phesi is helping the industry to improve the precision and certainty of clinical trials and is transforming drug development using digital patient profiles to model disease, digital twins to predict safety and efficacy outcomes and external control arms to reduce the number of patients undergoing testing in trials. This disruptive innovation will ultimately get therapies to patients faster. Trial Accelerator has consistently been proven to minimize amendments and shorten cycle times and has helped companies deliver many lifesaving medicines to patients,

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