PHESI
Smarter trials. Faster cures.

PHESI.COM

PHESI 2024 ANALYSIS

OF ONCOLOGY CLINICAL TRIAL INVESTIGATOR SITES

MAY 2024

OVERVIEW

Oncology is the most widely studied therapeutic area. Phesi's annual global analysis shows that three of the five most studied diseases in 2023 were in oncology. Breast cancer was the most studied disease for the third year running, followed by solid tumors and prostate cancer ranked in fifth place.

This Executive Briefing examines the growth of recruiting oncology sites globally using data from Phesi's Trial Accelerator™ platform. 11,755 Phase I, II and III oncology clinical trial sites, open for recruitment since 2019, were analyzed to determine what impact the growth of investment in oncology trials is having on investigator sites globally.

KEY FINDINGS

Our analysis shows that recruiting oncology clinical trial investigator sites have increased by 49% in the past five years. However, poor investigator site selection is leading to trial failures.

While the US still dominates oncology research, China has become a significant driving force behind the increase, with a 374% jump in recruiting oncology investigator sites over the past five years. The smallest growth in investigator sites was seen in the UK and Canada, both increasing by 20%. Of the top five highest growth countries after the US, three are in Asia – China (374%), Korea (83%), Taiwan (69%). The remaining two are in Brazil (158%) and Spain (87%).

Country	Percentage increase in recruiting sites since 2019
China	374%
Brazil	158%
Spain	87%
Republic of Korea	83%
Taiwan	69%
Australia	59%
Poland	56%
France	49%
Italy	42%
Japan	38%
Germany	28%
United States	21%
United Kingdom	20%
Canada	20%

"Cancer remains an area of high investment in the pharmaceutical industry, which is reassuring news for patients. But it also means investigator sites are under increasing pressure. Many sponsors are exploring the potential of countries outside of the US to conduct trials where competition for patients and investigators is so high," said Dr Gen Li, President, Phesi. "The clinical development industry has shown rapid progress in precision medicine, but the same level of precision is not yet given to investigator site selection and country allocation. The saturation of cancer investigator sites in certain areas causes a higher percentage of non-performing and poor performing sites, resulting in trial failures."

FAILURE TO SELECT THE RIGHT SITES

A previous analysis **of enrollment data from cancer clinical trials conducted by Phesi in 2023 showed that nearly one in five sites enrolled just a single patient, delaying lifesaving medicines reaching patients. The impact of poorly performing sites on cost is substantial. Phesi data shows that a single-patient site has an average cost-per-patient that is ten times higher than a high performing site.**

Further analysis of NSCLC clinical trials, performed using Trial Accelerator data, reveals the impact of failing to precisely select investigator sites as well as the most experienced investigators. The 471 recruiting Phase I NSCLC trials that Phesi analyzed targeted more than 20 specific genetic markers. 20% of the investigators working on these 471 NSCLC trials had no history of strong recruitment in lung cancer studies and were shown to specialize in different areas

of oncology. The analysis also found that the top 100 lung cancer investigator sites in the US each recruit for 39 trials on average. A single investigator cannot meaningfully recruit patients for 39 trials and for this reason, overly burdened investigator sites will predictably have a detrimental impact on oncology clinical development.

SOLVING THE CHALLENGE WITH DATA

Digital analytics is driving transformational change across the clinical development landscape with data holding the key to designing and executing smarter trials to deliver faster cures.

"Sponsors need to be truly data-driven in their design and operations approaches and select the most relevant, high enrolling investigators to relieve pressure on oncology investigator sites and increase the success rate of oncology trials. To achieve this, sponsors must use real-world data, such as data from previous and ongoing clinical trials and Digital Patient Profiles, to gain a deep understanding of the target patient population. With a comprehensive patient view from the outset, sponsors can optimize trial design, reduce patient burden and select investigator sites and countries with far higher precision. Using patient-centric data to inform and optimize trial protocol design will lay the groundwork to successfully deploy digital twins and external control arms, minimizing the burden on patients and investigator sites even further,"
said Dr Gen Li, President, Phesi.

HOW CAN PHESI HELP?

Phesi is at the forefront of the industry in helping sponsors make data-led decisions to optimize protocol design and improve investigator site selection. Our AI-driven Trial Accelerator™ platform leverages the world's largest contextualized clinical trial database, putting the patient at the heart of clinical development. Trial Accelerator™ powers a number of our key services:

DIGITAL PATIENT PROFILES

Leveraging global data from more than 108 million patients and almost 500,000 clinical studies, Trial Accelerator™ generates a detailed statistical view of the patient attributes (demographics, comorbidities, concomitant medications, outcome and so on) for any indication. This ensures that the program and protocol design align precisely with the characteristics of the target patient group and the unmet medical need. The second edition of our Digital Patient Profile Catalog covering 34 indications can be accessed here. The Digital Patient Profile is the precursor to the generation of the Digital Twin used as an enhancement to the regulatory submission.

PATIENT ACCESS SCORE

Derived from the Digital Patient Profile, our Patient Access Score is a unique performance measure to help sponsors select the best enrolling investigator sites in 195 countries, eliminating non-active, non-enrolling investigator sites and zeroing avoidable protocol amendments.

PATIENT BURDEN SCORE

Our Patient Burden Score enables sponsors to optimize protocol and study design by predicting how many times a trial participant may need to visit an investigator site, what procedures will be conducted, and what data needs to be collected and recorded during each visit. It can reduce patient burden and simplify trial design to improve investigator site performance, shorten enrollment cycle times and significantly reduce costs.

DIVERSITY EQUITY & INCLUSION PLANNING

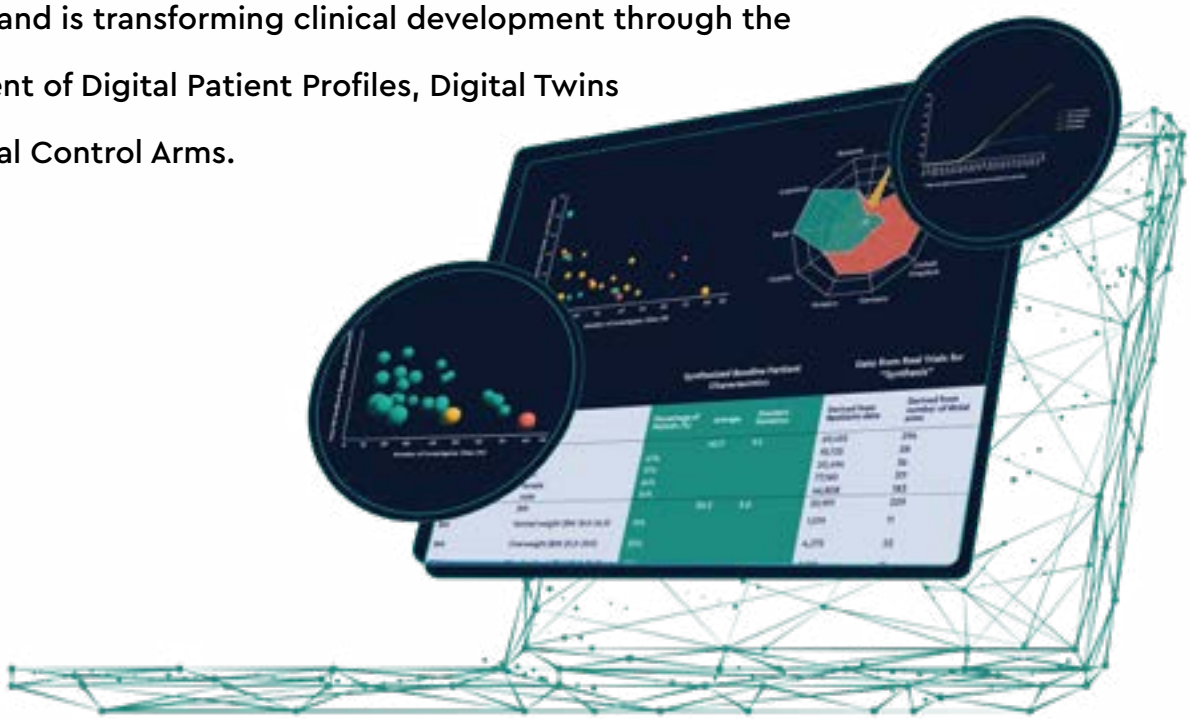
Phesi helps clients to accurately define DE&I targets, write the plan and identify the lead enrolling investigator sites by indication to meet those enrolment objectives ensuring compliance with the FDA regulations.

TRIAL RESCUE & HEALTH CHECK

Phesi can evaluate a client's protocol (synopsis, final protocol or amendments), country and investigator site (including CRO nominated sites) list, and enrollment cycle time targets to determine whether it's possible to achieve a better outcome.

ABOUT PHESI

Phesi's patient-centric integrated data analytics solution delivers smarter trials and faster cures. We use our AI-driven Trial Accelerator™ platform with global data from 108 million patients and 195 countries to create Digital Patient Profiles and our unique Patient Access Score to assess investigator site potential. We deliver actionable insights with unrivalled precision to enable sponsors to optimize protocol design, improve enrollment and reduce patient burden and enrollment cycle times. Trial Accelerator has been proven to deliver innovative medicines and is transforming clinical development through the development of Digital Patient Profiles, Digital Twins and External Control Arms.



FIND OUT MORE ABOUT PHESI AND THE TRIAL ACCELERATOR™ PLATFORM.

PHESI
Smarter trials. Faster cures.

PHESI
Smarter trials. Faster cures.

PHESI.COM

PHESI 2024 ANALYSIS

OF ONCOLOGY CLINICAL TRIAL INVESTIGATOR SITES

MAY 2024