FROST & SULLIVAN

# 2024 ENABLING TECHNOLOGY LEADER

*IN THE GLOBAL AI-ENABLED CLINICAL TRIAL DESIGN INDUSTRY*

PHESI
Smarter trials. Faster cures.

FROST & SULLIVAN

2024 BEST PRACTICES AWARD

## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Phesi excels in many of the criteria in the AI-enabled clinical trial design space.


### *Transforming Clinical Trials: Harnessing AI for Success in Healthcare Research*

> *"Phesi emphasizes the vital role of empowering industry users by equipping them with advanced tools, fostering innovation, and improving efficiency in trial design and execution."*
>
> ***- Aarti Chitale***
> ***Healthcare Senior Industry Analyst***

Clinical trials play a pivotal role in the healthcare industry, serving as the cornerstone for evaluating the safety and efficacy of drugs and devices. The success of clinical trials is paramount for advancing medical knowledge, developing new therapies, treatments, and ultimately improving patient outcomes. Successful clinical trials contribute to the approval of new drugs and treatments, leading to advancements in disease management and potential cures for various health conditions.

However, clinical trials often encounter numerous challenges that impede their success. These challenges include difficulty recruiting patients, inadequate participant demographic diversity, complex trial designs, inefficient trial management processes, regulatory hurdles, and high costs and resource constraints. These challenges result in delays in trial timelines, increased costs, and trial failures, leading to setbacks in medical research and development efforts.

Artificial intelligence (AI) presents a promising solution to many of these challenges in clinical trials. The technology can optimize various aspects of trial design, execution, and management by leveraging vast data to enhance decision-making processes. These advanced powered tools can improve patient recruitment by efficiently identifying suitable candidates, analyzing complex datasets to streamline trial designs, predicting patient responses to treatments, and enhancing trial monitoring and management through real-time data analysis.

Moreover, AI can aid in personalized medicine research by analyzing patient data to identify subpopulations that may respond differently to treatments, leading to more targeted and effective cohort selections and participant recruitment. Additionally, AI-driven predictive analytics help identify potential safety issues early in the trial process, minimizing risks and improving trial outcomes overall.

### *Phesi: Navigating Challenges in Clinical Trial Execution*

Established in 2007 in East Lyme, Connecticut, United States, Phesi specializes in delivering comprehensive clinical development analytical products and services to biopharmaceutical firms worldwide. Employing cutting-edge technologies and profound expertise, the company offers an unparalleled clinical trial database alongside predictive analytics tools. The approach involves aggregating data and developing integrated algorithms to meticulously analyze patient data, trial designs, and execution strategies. Rather than solely relying on big data, the emphasis is placed on precision analytics to accurately understand patient diseases, efficiently identify eligible candidates for trials, and optimize trial designs for streamlined processes and improved outcomes. This technology empowers trial sponsors to make informed decisions swiftly, expediting drug development timelines while upholding the highest standards of data integrity and patient-centricity.

Throughout the execution phase of clinical trials, numerous obstacles may surface. Phesi excels in providing support when trials encounter hurdles in meeting enrollment milestones or other crucial objectives. Navigating clinical trials involves overcoming obstacles such as variations in patient demographics and selecting suitable trial sites across various countries, requiring strategic planning and adaptability. Frequent clinical trial challenges include patient demographic discrepancies and trial site and country location factors. These disparities often lead to protocol modifications and hinder the progress of trials, causing delays in research timelines. The trial rescue process undertaken by Phesi involves a comprehensive analysis of various factors, spanning patient profiles, trial designs, and site performance. Leveraging its extensive database and advanced algorithms, Phesi accurately and efficiently diagnoses underlying issues.

### *Driving Global Clinical Trial Excellence with Phesi's Technology*

Phesi’s groundbreaking health check and trial rescue service tackles the critical challenges inherent in the clinical trials landscape. This comprehensive Software-as-a-Service (SaaS) solution equips clinical development teams with the tools to utilize study and control arm data efficiently, streamlining the product development process. Built upon Phesi’s esteemed AI-driven Trial Accelerator platform, the company’s service meticulously evaluates trial protocols from various perspectives, including those of patients, countries, study sites, and investigators. With a strong focus on precision in data analysis and

decision-making, the company's trial rescue service identifies and resolves issues swiftly to ensure the seamless progression of clinical trials, thereby contributing to advancing effective medical treatments.

Phesi's approach distinguishes between reactionary projects aimed at addressing ongoing trial issues and proactive initiatives focused on optimizing trial design and execution preemptively. Powered by advanced algorithms and significant computing and data capabilities, the platform analyzes large volumes of relevant data to identify patterns and trends, informing inclusion and exclusion criteria, outcome measures, and trial design decisions.

Phesi's SaaS platform represents a remarkable milestone, consolidating digitalized patient data from a vast pool of over 100 million individuals globally. This expansive dataset spans over 4,000 indications, furnishing sponsors with invaluable insights to strategically plan and seamlessly execute clinical trials. Once a protocol is submitted, the company offers insights on crucial design elements (e.g., inclusion and exclusion criteria) to address persistent clinical trial challenges. Given that phase 3 trial protocols typically undergo an average of 3.3 significant amendments, incurring costs of up to $1.5 million per trial for sponsors, Phesi's innovative approach offers a cost-effective solution for optimizing trial efficiency and success.[1]

For over two decades, Phesi has methodically gathered and organized data from various sources, encompassing product and disease registries, electronic health records, medical claims, and continuously updated robust resources. This meticulous approach ensures that sponsors have access to rich, structured datasets, thereby enhancing their ability to refine their offerings and drive innovation.

Key features of its platform, include the Phesi Patient Access Score, Diversity, Equity, and Inclusion Data Service, and the Digital Patient Profile (DPP).[2] The recently launched second edition of the DPP enriches protocol design by offering a statistical overview of patient attributes across various conditions, enabling sponsors to develop digital twins and digital trial arms to enhance clinical development strategies.

From Frost & Sullivan's observation, the company underscores the importance of enhancing the diversity of patient populations in trials, utilizing existing data to inform enrollment strategies effectively. Phesi's unique position in the industry and its capabilities in providing digital twins, synthetic control arms, and external control arms set it apart, with its precise and comprehensive datasets distinguishing it from competitors.

### *Collaborative Approach to Trial Optimization*

Phesi emphasizes the vital role of empowering industry users by equipping them with advanced tools, fostering innovation, and improving efficiency in trial design and execution. Phesi primarily serves pharmaceutical and biotech firms, engaging closely with key stakeholders such as heads of development, clinical operations, and therapeutic areas. Notably, oncology constitutes about 50% of Phesi's focus, specifically addressing complex diseases and tackling rare or ultra-rare conditions.

[1] https://www.phesi.com/news/trial-accelerator-launches/
[2] https://pharmatimes.com/news/phesis-ai-driven-trial-accelerator-platform-contains-over-100-million-patients/

Within client organizations, Phesi collaborates with diverse professionals, including protocol writers, clinicians, program heads, study managers, and heads of innovation, data sciences, and digital analytics. The company orients itself toward client-side advisory, driven by a core mission to optimize trial design and execution from a patient-centric perspective. The system encompasses four core module views: patient profile, trial performance, country performance, and investigator site performance. Phesi's Trial Accelerator platform aims to enhance the focus on patients throughout the entire clinical trial process, an aspect often overlooked. Through innovations like digital twins, digital control arms, and digital patient profiles, Phesi's AI platform strives to drive innovation while easing the burden on patients and trial sites.

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***- Norazah Bachok***
***Best Practices Research Analyst***

Phesi spearheads initiatives to innovate trial design and reduce patient burden, highlighting the importance of diversity in clinical trials, particularly in placebo-controlled trials. The partnership models adopted by the company foster a collaborative, risk-sharing approach, incentivizing it to deliver tangible value to clients. Collaborations with numerous consulting organizations enable Phesi to provide strategic advice and integrated analytical offerings, solidifying its role as a trusted client-side advisor.

The global reach of Phesi's data, spanning 195 countries, underscores the significance of understanding global disease epidemiology, patient profiles, standards of care, and socioeconomic factors. Despite its strong digital presence in the United States, the company underscores its capability to access relevant patient profiles globally, tailoring its approach to meet the specific attributes of patients under study.

### *Patient-Centric Approach to Data-Driven Innovation*

Phesi prioritizes data utilization to refine study design, ensuring patients undergo only necessary tests and procedures, while upholding scientific integrity. The company minimizes discomfort and unnecessary practices through a patient-centric lens, advancing medical knowledge and facilitating innovative treatment development. Moreover, Phesi's adaptability shines in addressing both commonly studied and rare diseases across diverse regions, ensuring comprehensive coverage without overlooking any indication or population of interest. Emphasizing precision in data analysis, especially in selecting clinicians for specific trial contexts, the company offers broader country coverage and dynamic data feeds, empowering clients to make well-informed trial locations and patient populations decisions.

Furthermore, Phesi's technology seeks to revolutionize clinical trials by digitizing patient data. Acknowledging the critical importance of balancing technological advancement with human insight, the company underscores the necessity of integrating AI and machine learning with human judgment. While these technologies offer substantial potential, Phesi emphasizes their synergy with human expertise, especially in healthcare's nuanced landscape. By melding these tools into decision-making processes, researchers can streamline data analysis. Through a holistic approach that blends advanced technology

with human intuition seamlessly, the company aims to propel healthcare research forward, fostering the development of more effective treatments and interventions.

Collaborating closely with clients, Phesi's dedicated team delves into data analysis, addresses inquiries, and provides solutions that benefit study sponsors, investigators, and patients alike. From initial clinical development planning to trial implementation, the company optimizes protocol designs, selects optimal investigator sites, streamlines enrollment cycles, and oversees clinical research organizations. Phesi's end-to-end solution offers unparalleled insights and support for clinical research and trial decision-making. Insights from Frost & Sullivan underscore Phesi's dedication to precision, contextualization, and global coverage in the clinical research landscape.

## Conclusion

Phesi stands at the forefront of patient-centric data analytics services, epitomized by its groundbreaking Trial Accelerator platform. Through a unique fusion of human expertise and advanced artificial intelligence (AI) tools, the company pioneers a transformative approach to clinical research, ensuring nuanced decision-making in medical contexts. By prioritizing patient well-being and advancing medical understanding, Phesi advocates for trial designs that reduce the patient's burden while accelerating the development of life-saving treatments. This patient-centric ethos is bolstered by the company's expansive global database, offering invaluable insights into disease epidemiology and patient demographics, empowering researchers to make informed decisions grounded in real-world evidence.

Furthermore, Phesi's innovative partnership models and proactive optimization strategies underscore its commitment to driving tangible value for clients and fostering collaborative relationships within the industry. Embracing risk-sharing approaches and strategic alliances, the company demonstrates confidence in its data-derived insights and ensures mutual success and innovation. Positioned as a trusted advisor, Phesi guides clients towards more innovative trials and faster cures, solidifying its status as a trailblazer in AI-enabled patient-centric data software services, poised to shape the future of healthcare through data-driven innovation and compassionate, patient-centered care.

With its strong overall performance, Phesi earns Frost & Sullivan's 2024 Global Enabling Technology Leadership Award in the AI-enabled clinical trial design.

# What You Need to Know about the Enabling Technology Leadership Recognition

Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

## Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

### *Technology Leverage*

**Commitment to Innovation**: Continuous emerging technology adoption and creation enables new product development and enhances product performance

**Commitment to Creativity**: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

**Stage Gate Efficiency**: Technology adoption enhances the stage gate process for launching new products and solutions

**Commercialization Success**: Company displays a proven track record of taking new technologies to market with a high success rate

**Application Diversity**: Company develops and/or integrates technology that serves multiple applications and multiple environments

### *Customer Impact*

**Price/Performance Value**: Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience**: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience**: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience**: Customer service is accessible, fast, stress-free, and high quality

**Brand Equity**: Customers perceive the brand positively and exhibit high brand loyalty

## About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at http://www.frost.com.

### The Growth Pipeline Engine™

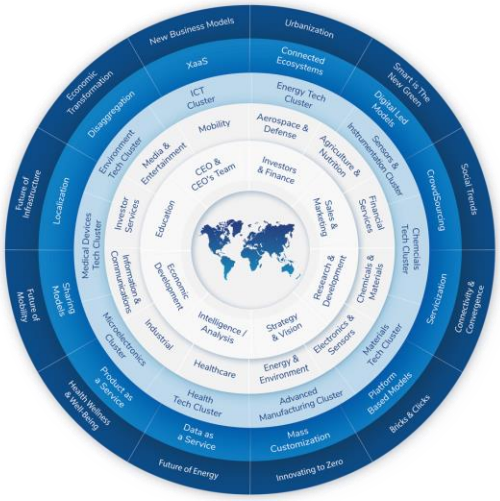
Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
Learn more.


***Key Impacts***:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

### The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.




***Analytical Perspectives:***

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)