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TRANSFORMATIONAL GROWTH LEADERSHIP

Reimagining Clinical Development: How Phesi Is Advancing Data-driven Drug Development with Clinical Data Science

An Exclusive Conversation Featuring

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The pharmaceutical industry continues to confront recurring challenges in clinical development, ranging from pipeline pressures and regulatory complexity to patient recruitment difficulties and trial design inefficiencies. As new therapies become increasingly complex and personalized, traditional clinical development approaches are often insufficient to address these evolving demands.

In this Transformational Growth Leadership discussion, Dr. Gen Li, Founder and President of Phesi, shares how clinical data science, digital patient profiles, and advanced analytics are enabling a more precise and transparent approach to clinical trial design and execution. Drawing on examples from oncology and metabolic disease research, he explains how the integration of large-scale clinical data and analytics is transforming how pharmaceutical companies understand patient populations, design trials, and accelerate innovation.

> “Artificial intelligence is a powerful tool, but it should never be the center stage. The real power comes from how we use it to solve problems.”
>
> — Dr. Gen Li, Founder and President, Phesi

Addressing the Pharmaceutical Pipeline Challenge

Nitin Naik: *The pharmaceutical industry frequently speaks about the challenge of maintaining a strong pipeline. From your perspective, what transformative trends have shaped your vision for Phesi?*

Dr. Gen Li: The concept of pipeline challenges has always been part of the pharmaceutical industry. In fact, the name "**Phesi**" originates from the phrase **Pharmaceutical Pipeline Enhancement Strategies,** which was suggested by one of my mentors who was a senior executive in Bristol-Myers Squibb. That idea of improving and sustaining the pipeline has been central to our thinking since the company was created.

From my personal perspective, the industry does not necessarily need to face pipeline crises as frequently as it does. When a company launches a product, it typically has about ten years of exclusivity. That period provides significant time to build additional innovations on top of the infrastructure already developed for that product.

In reality, of course, managing a pharmaceutical company involves far more complexity than that simplified view. However, there are many opportunities to improve the way pipelines are developed and maintained. That is where clinical data science and a deeper understanding of patient populations can make a significant difference.

Frost & Sullivan's **Transformational Growth Leadership Program** aims to honor visionary business leaders who possess the foresight and leadership acumen to drive positive change within their organizations. The leaders we celebrate hail from diverse sectors and company sizes, yet they all share an unwavering commitment to innovation and excellence.

Understanding Patient Populations Through Digital Patient Profiles

Nitin Naik: *Could you share examples where your platform has helped pharmaceutical companies address complex challenges in clinical trials?*

Dr. Gen Li: One example comes from our work with **KRAS mutations in non-small cell lung cancer**, which historically have been difficult to target therapeutically. With recent breakthroughs in subsets such as G12C mutations, researchers are now exploring additional mutations in the same family. In working with a client, we constructed a digital patient profile based on the trial design to better understand the patient population associated with these mutations. When we assembled that population, we discovered that KRAS mutations were significantly more prevalent among Caucasian patients than other populations. That insight has important implications for trial design, including site selection and geographic strategy.

Another example involves **metabolic dysfunction-associated steatohepatitis (MASH)**, previously known as NASH (nonalcoholic steatohepatitis). Using our platform, we developed digital patient profiles for MASH patient populations in both the United States and China. The differences between these populations were substantial. For instance, the average age of patients in the United States was about 49.5 years compared with roughly 53 years in China, and body mass index levels were also significantly different. Variations in comorbidities and disease severity further highlighted how patient populations can differ across regions. Insights like these allow sponsors to design clinical trials and global strategies that better reflect the realities of the patient populations they aim to treat.

From Digital Patient Profiles to Digital Twins

Nitin Naik: *How does your system actually generate these insights and support clinical trial planning?*

Dr. Gen Li: The process usually begins with a guiding document provided by the client. This document might be a draft protocol, a finalized protocol, or even just a preliminary description of a proposed study.

Using that document, we recruit a digital patient population from our global patient data ecosystem based on the inclusion and exclusion criteria defined in the protocol. This process closely resembles a real clinical trial, except that the recruitment occurs in cyberspace rather than hospitals.

Once the digital patient population is assembled, we compare it with the assumptions built into the trial design. In most cases, discrepancies appear between the theoretical patient population and the actual population that exists in reality.

By identifying these differences early, sponsors can refine the trial design before initiating the study. When the alignment between the design and the real-world patient population becomes strong, the digital patient profile evolves into a **digital twin** of the population that would eventually be recruited in an actual clinical trial.

This capability is extremely powerful because it allows researchers to effectively "meet" their patients before the trial begins. It provides a realistic view of the patient population and enables more informed decision-making about protocol design, investigator site selection, and operational planning.

Enhancing Site Selection and Trial Execution

Nitin Naik: *How does this approach influence operational aspects such as investigator site selection?*

Dr. Gen Li: Our patient data are contextualized not only by disease characteristics but also by information about the physicians treating those patients. This enables us to identify which investigators, and clinical sites have direct access to relevant patient populations.

Improving the precision of investigator site selection is essential for modern clinical development, especially in the era of precision medicine. If the clinical development infrastructure does not evolve alongside medical innovation, it becomes difficult to fully realize the benefits of new therapies.

When sponsors first see these insights, their reaction is often one of surprise. They realize that long-standing challenges can be addressed from a different perspective using clinical data science.

Expanding the Role of Clinical Data Science in Drug Development

Aarti Chitale: *Looking ahead, how do you see the Phesi platform evolving over the next several years?*

Dr. Gen Li: Our journey has always been guided by the needs of our clients. In the early years, we were primarily a benchmarking company, but over time our capabilities expanded as clients asked us to address increasingly complex challenges in clinical development.

Looking ahead, we expect to move further upstream in the clinical development process. Today, we are often engaged when a clinical trial encounters difficulties and requires rescue support. While that work will continue, we increasingly want to contribute earlier, during trial planning and development strategy.

For example, when sponsors consider external control arms, they need to engage regulatory authorities much earlier in the development process. That thinking must be integrated into the overall development plan rather than introduced late in the trial lifecycle.

As we move upstream, our insights will also extend to areas such as regulatory engagement and marketing strategy. Ultimately, our goal is to bring greater objectivity and transparency to decision-making in clinical development, replacing intuition with evidence derived from clinical data science.

The Role of Artificial Intelligence in Clinical Data Science

Nitin Naik: *Artificial intelligence is becoming central to many discussions in healthcare and drug development. How do you see AI contributing to your work?*

Dr. Gen Li: There are three major trends shaping the transformation of the pharmaceutical industry.

The first is **artificial intelligence**, which has become a dominant topic across industries. The second is **precision medicine**, driven by advances in our understanding of disease at the molecular and cellular levels. The third is the development of **clinical data science**, which is our primary focus at Phesi.

Clinical data science is supported by technologies such as AI, machine learning, and big data. However, it is important to recognize that AI itself is only a tool. It should not become the center of attention.

The effectiveness of AI depends on how it is applied to solve real problems. Artificial intelligence does not automatically generate knowledge if the underlying knowledge does not exist.

For example, if we lack a fundamental understanding of how specific investigator sites perform in recruiting patients, AI cannot simply create that knowledge. Similarly, AI cannot improve clinical trial design unless we understand the principles behind trial design.

Rethinking Clinical Trial Rescue Strategies

Aarti Chitale: *Could you elaborate on how your platform supports trial rescue situations?*

Dr. Gen Li: Many clinical trials require rescue because patient recruitment falls behind schedule. When this happens, the typical response is to expand the number of countries and investigator sites involved in the trial. For example, a study running in 20 countries may expand to 40 or increase the number of sites from 1,000 to 2,000 in an attempt to accelerate recruitment.

However, this linear approach often fails because clinical development is not a linear process. Simply adding more sites does not guarantee faster enrolment.

When we engage in trial rescue, we begin by diagnosing the root cause of the problem. Frequently, the issue is a misalignment between the trial design and the actual patient population. Using digital patient profiles, we analyze whether the trial is being conducted in the right countries and whether investigators have access to the appropriate patients.

In one case, we recommended shutting down about 30% of the sites because they had little potential to recruit patients. By focusing on the most productive sites, the sponsor was able to bring the trial back on track within four weeks. Because this approach is grounded in clinical data science, it is repeatable across different trials and therapeutic areas.

The Importance of Partnerships in the Clinical Ecosystem

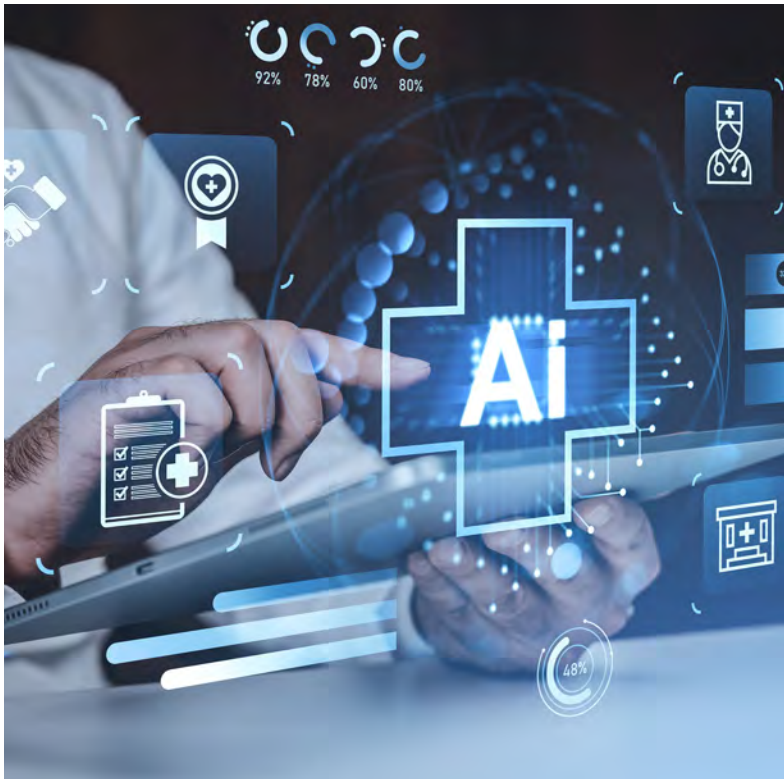
Nitin Naik: *How do partnerships contribute to your growth strategy?*

Dr. Gen Li: Partnerships are fundamental to the pharmaceutical industry. Drug development involves many participants, including contract research organizations, service providers, and consulting firms.

Phesi represents one component within this broader ecosystem. Because we focus on clinical data science, we naturally collaborate with other organizations that bring complementary expertise.

In many ways, our relationships with clients are also partnerships. We work together to solve complex problems and advance clinical development strategies.

Given the complexity of drug development, collaboration across the ecosystem is essential for both survival and growth.



Driving Innovation for Rare Diseases

Nitin Naik: ***What excites you most about the future of your work?***

Dr. Gen Li: What excites me most is the potential impact on patients, particularly those with rare and ultra-rare diseases.

Even the largest pharmaceutical companies often have limited data for many diseases. For example, a company that leads the market in type 2 diabetes may still only possess a small fraction of the available global data related to that condition.

Rare diseases present an even greater challenge. Over the years, we have worked on nearly 2,000 rare and ultra-rare diseases. Clinical data science enables us to generate insights that can accelerate the development of treatments for these conditions.

As regulatory authorities become more open to leveraging clinical data science, we believe it will become possible to bring life-saving therapies to patients faster and more efficiently.

Closing Reflection: Embracing the Momentum of Innovation

As the pharmaceutical industry evolves, innovation in clinical development is becoming both necessary and inevitable. Advances in AI, precision medicine, and clinical data science are reshaping how researchers understand diseases, design trials, and develop treatments.

For Dr. Gen Li, the message to the industry is clear: innovation may be challenging, but it is no longer optional. The momentum of technological and scientific progress continues to accelerate, and organizations must adapt to remain competitive.

Those who embrace these changes will unlock new possibilities for drug development and ultimately improve outcomes for patients worldwide.

Dr. Gen Li | Founder and President, Phesi

Dr. Gen Li is the **Founder and President of Phesi**, a clinical data science company focused on improving drug development through patient-centric analytics and clinical data insights. With more than two decades of experience in pharmaceutical research and development, he has been a pioneer in applying data-driven approaches to clinical trial design and development strategy. Prior to founding Phesi in 2007, Dr. Li served as Head of Productivity for Pfizer Worldwide Clinical Development following the acquisition of Pharmacia. Earlier in his career, he also contributed to developing the first computer-automated resource management system at Bristol-Myers Squibb. Dr. Li holds a PhD in Biochemistry from Beijing University and an MBA from the Johnson Graduate School of Management at Cornell University.

Nitin Naik | Associate Partner, Frost & Sullivan

Nitin Naik is an accomplished leader with 25+ years driving transformational growth for Fortune 500 pharmaceutical, biotechnology, and medical device companies. As an Associate Partner at Frost & Sullivan, Nitin leads the Healthcare and Life Sciences practice, directing analyst and consulting teams that unlock growth opportunities through advanced analytics and commercial intelligence. Nitin brings deep expertise at the intersection of disruptive technologies, and new business models and recognized for implementing executable strategies across New Product Planning, Business Development & Licensing, M&A, and Go-to-market initiatives. Prior to joining Frost & Sullivan, he has served in leadership positions with A*STAR Singapore and other healthcare organisations.

Aarti Chitale | Industry Principal, Frost & Sullivan

Aarti Chitale brings 15+ years of expertise in pharmaceutical contract research and technology enabled drug development. She leads the Contract Research Services program, guiding strategy across tech vendors, eClinical providers, and central lab ecosystems. As a trusted growth expert, she supports global stakeholders in navigating disruption and identifying high impact opportunities.

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Annexure: Advancing Data-driven Clinical Development

As clinical research grows more complex, pharmaceutical companies are increasingly adopting data-driven approaches that integrate clinical data science, real-world evidence, and advanced analytics to improve trial design and patient recruitment. These capabilities are enabling more precise, patient-centric clinical development strategies aligned with the rise of precision medicine.

To support organizations navigating this transformation, Frost & Sullivan provides forward-looking intelligence across clinical research innovation and data-enabled drug development, including:

- Frost Radar™: Artificial Intelligence-enabled Clinical Trials, 2026
- Pharmaceutical Clinical Contract Peripheral Services, Global

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