FROST & SULLIVAN

2024 ENTREPRENEURIAL COMPANY OF THE YEAR

IN THE GLOBAL AI-ENABLED CLINICAL TRIAL DESIGN INDUSTRY

QUANTHEALTH

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. QuantHealth excels in many of the criteria in the AI-enabled clinical trial design industry space.

Artificial Intelligence-enabled Clinical Trial Design Market Overview

The artificial intelligence (AI)-enabled clinical trial design market is undergoing significant transformation, driven by a critical assessment of data utilization and a recognition of the prevailing challenges within the industry. There is a substantial gap between available data and its practical application, leading to a proliferation of AI solutions to address this discrepancy. However, despite the burgeoning interest in AI, there remains a notable concentration of efforts either in early-stage drug discovery or late-stage patient enrollment, leaving a significant void in clinical trial design and optimization.

The industry's primary challenge lies in failing to meet trial endpoints, with a staggering 90% of trials falling short of demonstrating experimental therapies' anticipated efficacy and safety profiles.[1] This failure underscores current knowledge's inadequacy regarding drugs and patients, leading to flawed assumptions that jeopardize trial outcomes.

Consequently, there is a pressing need to enhance protocol optimization to ensure trial designs are more effective, minimizing the risk of endpoint failure and improving overall trial success rates. Moreover, regulatory hurdles pose a significant barrier to integrating AI solutions into clinical trial processes.

[1] Duxin Sun, "90% of Drugs Fail Clinical Trials," American Society for Biochemistry and Molecular Biology, March 12, 2022, https://www.asbmb.org/asbmb-today/opinions/031222/90-of-drugs-fail-clinical-trials#:~:text=It%20takes%2010%20to%2015,candidates%20in%20clinical%20trials%20fail.

While organizations such as the United States (US) Food and Drug Administration recognize the potential benefits of AI, they remain cautious, adhering to rigorous validation procedures and a careful approach to implementation. The overwhelming volume of investigational new drug (IND) and pre-IND applications compounds the regulatory burden, resulting in prolonged approval timelines and exacerbating the complexity of the trial process.

While the AI-enabled clinical trial design market faces significant obstacles, the convergence of technological innovation and industry collaboration promises to overcome these challenges, ushering in a new era of more efficient, effective, and patient-centric drug development processes.

Driving Efficiency in Clinical Trial Design: QuantHealth's AI Innovations

Recent advancements in data analytics and AI technology offer a promising solution to the industry's woes. Companies like QuantHealth are spearheading efforts in bio-simulation, in-silico trials, and synthetic evidence generation, collaborating closely with stakeholders across the pharmaceutical (pharma) industry, academia, and regulatory bodies.

Founded in 2020 and headquartered in Tel Aviv, Israel, QuantHealth is a clinical informatics company. By leveraging AI-driven solutions, the company significantly enhances the probability of trial success, ultimately reducing trial duration, costs, and inefficiencies while ensuring patients receive the treatments they need in a timely manner.

QuantHealth's Clinical Trial Simulator: Synthetic Evidence Generation Platform

The Clinical Trial Simulator offers a revolutionary approach, leveraging AI technology to enable clinical development and clinical operations teams to conduct comprehensive trial simulations rapidly and efficiently. QuantHealth developed the simulator utilizing data from 350 million patients, over 700,000 therapeutics, 100,000 molecules, and 180,000 clinical trials. This simulator generates synthetic trial data capable of providing predictive insights with an accuracy rate of nearly 86%.[2] Users can explore thousands of trial variations within minutes, meticulously assessing each parameter's impact on endpoint success, commercial viability, and protocol feasibility. By providing a holistic view of trial outcomes under diverse scenarios, the simulator empowers stakeholders to make informed decisions throughout the trial lifecycle, ultimately enhancing efficiency and efficacy in drug development.

QuantHealth's Synthetic Evidence Generation Platform complements its simulator. The platform is a powerful tool that forecasts therapy performance across all clinical phases. It synthesizes evidence in the in-silico realm as soon as it understands a therapy's mechanism and establishes preclinical data. The platform predicts biological drug responses and real-world patient outcomes by integrating various datasets, including real-world data and knowledge graphs mapping human biology and drug pharmacology. This projection enables the creation of individual patient outcome models, allowing for precise predictions of how patients will respond to novel therapies. The platform facilitates the simulation of thousands of protocol variations through deep patient predictions and sophisticated AI techniques, encompassing changes in drug delivery, combination therapies, endpoints, and patient cohorts.

[2] QuantHealth, "Qh - Home," QuantHealth, accessed April 18, 2024, https://quanthealth.ai/.

Innovations and Application Diversity Set the Company Apart

QuantHealth's innovations set it apart from competitors, particularly its validation approach and real-world simulations for novel therapies. The company has embarked on a rigorous validation journey, having authenticated simulation technology on over 80 clinical trials across various indications and therapeutic areas, including oncology, respiratory disease, autoimmune disease, and cardio-metabolic conditions. Its robustness distinguishes QuantHealth's validation approach, with a model for each clinical trial taking about one to two months to build.

> *"Frost & Sullivan is impressed by QuantHealth's pioneering technologies: the Clinical Trial Simulator and Synthetic Evidence Generation Platform. The company's rigorous validation ensures solution reliability, while its diverse applications across therapy areas highlight its leadership in delivering tailored solutions to medical challenges."*
>
> ***- Ojaswi Rana***
> ***Best Practices Research Analyst***

The process begins with data validation, ensuring that the datasets used for training the model represent the population accurately and capture all relevant clinical characteristics. The next step involves logical validation to ensure the model behaves as expected, followed by mathematical validation to optimize numerical accuracy. Finally, the model undergoes extensive simulation, including retrospective and prospective comparisons to actual trials, further enhancing its reliability and effectiveness.

Moreover, QuantHealth's real-world simulations for novel therapies represent a new approach in the industry. While other companies may focus on early development or control arm analysis, QuantHealth's simulations encompass the entire spectrum of novel therapies, bridging a crucial gap in the market and defining a new category of capabilities.

Further, the company conducts simulations across many therapies, encompassing various medical disciplines. QuantHealth leverages diverse datasets to address multiple questions pertinent to various therapeutic domains. This approach underscores its commitment to versatility and innovation, allowing it to tackle challenges across different fields of medicine.

However, despite the broad range of indications covered by QuantHealth's simulations, the company maintains a focused approach to what it does and solves. While its real-world evidence modeling and evaluation tool offers a comprehensive view of multiple therapeutic areas, QuantHealth's expertise lies in the precision and depth of its solutions rather than attempting to address every conceivable problem across the healthcare landscape. This strategic balance between breadth of coverage and depth of expertise ensures that the company is positioned at the forefront of innovation while delivering impactful solutions tailored to specific challenges within each therapy area.

Frost & Sullivan is impressed by QuantHealth's pioneering technologies: the Clinical Trial Simulator and Synthetic Evidence Generation Platform. The company's rigorous validation ensures solution reliability, while its diverse applications across therapy areas highlight its leadership in delivering tailored solutions to medical challenges.

Tailored Engagements: Elevating Clinical Simulation You Can Trust

QuantHealth prioritizes customer satisfaction through a tailored engagement approach. The process often begins with a pilot phase, where the company conducts proof of technology exercises in collaboration with customers, enhancing trust and confidence in its methodologies and technologies. This initial phase also includes proof of value demonstrations, showcasing how QuantHealth's solutions can effectively support clinical programs and trials.

Following successful pilots, satisfied customers typically transition into partnership or continued engagement models. These ongoing relationships allow QuantHealth to provide sustained support across various clinical phases for specific programs or entire portfolios. The company remains flexible in its licensing model, prioritizing customer needs and ensuring rapid assistance in drug development.

QuantHealth's engagement approach combines software access with hands-on support and services, ensuring that customers receive comprehensive assistance in building and customizing models to meet their specific requirements. This hybrid method facilitates seamless collaboration between QuantHealth and its customers, optimizing the use of its platform while providing personalized support.

The company's commitment to customer satisfaction is evident in its high retention rate, with six out of seven customers continuing their engagements with QuantHealth.[3] The average pilot duration ranges from three to six months, followed by subscription-based partnership models typically spanning one year or longer.[4] This customer-centric approach underscores QuantHealth's dedication to accelerating drug development and delivering impactful solutions to its clientele.

The company's customer base includes small biotechnology (biotech) companies and large pharma corporations. In its initial years, QuantHealth primarily collaborated with small biotech companies, leveraging these partnerships to refine its technology. However, as it expanded, it served diverse clients, including big pharma companies like Sanofi and IQVIA. Additionally, it continues to maintain partnerships with numerous smaller biotech firms.

Case Study

QuantHealth performed a Phase IIB trial for an immune-modulating asset in acute respiratory distress syndrome (ARDS) for a sponsor. Using its AI engine, the company conducted simulations on the initial protocol draft provided by the sponsor. QuantHealth used a model trained on relevant immune modulating pathways and respiratory patient data from real-world datasets and made baseline predictions for the primary endpoint and overall survival for placebo and experimental arms. The more than 1,000 protocol variations tested revealed potential improvements.

[3] Frost & Sullivan Interview with QuantHealth, (March 28, 2024).

[4] Ibid.

Simulations suggested expanding the target population to include bacterially induced ARDS, narrowing to more advanced cases post-intubation, and focusing on the initial 90 days for clinical effects. These adjustments allowed for a 4.5 times larger population, 16.5% greater efficacy on the primary endpoint, 11 months shorter trial duration, and reduced 251 participants while maintaining statistical significance.[5] Overall, the simulation recommendations considerably enhanced the trial's scope and efficiency.

Frost & Sullivan praises QuantHealth for its customer-centric approach, emphasizing tailored solutions. The company builds trust in its methodologies through proof of technology exercises in the pilot phase, often leading to long-term partnerships. The company's hybrid engagement model combines software access with hands-on support, ensuring seamless collaboration. With a high retention rate and flexible licensing, QuantHealth accelerates drug development, serving diverse clients.

QuantHealth: Setting the Standard for Innovation and Excellence in Clinical Development

QuantHealth actively maintains its brand equity through strategic communication and visibility efforts. The company engages with industry professionals and stakeholders through various channels such as conferences, webinars, podcasts, interviews, and newsletters. Additionally, QuantHealth sponsors events focused on AI for clinical development, further solidifying its presence and expertise in the field.

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Best Practices Research Analyst

The response to QuantHealth's initiatives has been overwhelmingly positive. Organizations, including big pharma and contract research organizations (CRO), recognize the novelty and complexity of QuantHealth's work, considering it to be at the forefront of the industry. Despite being a Series A company, QuantHealth is acknowledged as the most advanced in its space, having dedicated significant resources and expertise to address complex challenges in clinical development.

Partnerships with industry giants like IQVIA and investments from Pitango, Millenia Partners, Shoni Health Ventures, and Nina Capital validate QuantHealth's achievements. The quality and rigor demonstrated by QuantHealth over the years have earned it respect and admiration from advanced analytics teams within pharma, further solidifying its position as a leader in the field.

QuantHealth has experienced remarkable commercial success and expects continuous growth this year. With a strategic plan in place, the company aims to collaborate with ten out of the top 20 big pharma companies over the next two years, focusing on sustained partnerships rather than pilot projects.

[5] Trial Design Case Study, (QuantHealth).

Additionally, QuantHealth plans to expand its product offerings beyond clinical development into regulatory and clinical operations, broadening its scope within the pharma industry. In June, the company expanded its presence from the European, Middle Eastern, and African markets into the US, increasing its global footprint.

To further accelerate its growth trajectory, QuantHealth secured a strategic investment from Accenture Ventures in January 2024, augmenting its Series A round to $17 million.[6] This investment, along with contributions from other investors and a CRO, underscores confidence in QuantHealth's innovative approach to utilizing AI-powered clinical trial simulations for cost-effective drug development. The additional funding supports the advancement of QuantHealth's platform, enabling cloud-based simulation of clinical trials and facilitating the rapid growth of patient treatments.

Frost & Sullivan applauds QuantHealth for its proactive efforts to maintain brand equity and industry leadership. The company has established itself as a prominent player in AI-driven clinical development through strategic communication initiatives such as conferences, webinars, and sponsored events. The overwhelmingly positive response from industry stakeholders, including big pharma and CROs, underscores the company's pioneering position and the complexity of its work.

Conclusion

Effective technology integration is paramount to success in the artificial intelligence (AI)-enabled clinical trial design industry. However, stakeholders must discern and adopt the most suitable technology solutions to maximize their market impact amidst numerous options. With its Clinical Trial Simulator and Synthetic Evidence Generation Platform, QuantHealth delivers unparalleled benefits to the pharmaceutical industry.

The Clinical Trial Simulator enables rapid and comprehensive trial simulations, allowing clinical development teams to explore numerous trial variations quickly and efficiently. This capability enhances trial efficiency by significantly reducing the time and resources needed for trial planning and design. Similarly, the Synthetic Evidence Generation Platform provides valuable insights into endpoint success, commercial viability, and protocol feasibility. QuantHealth empowers stakeholders to make informed decisions throughout the trial lifecycle by synthesizing evidence and predicting patient outcomes. These technologies streamline the drug development process and increase the likelihood of trial success and the development of effective therapies, ultimately contributing to advancements in patient care and treatment outcomes.

The company pairs its technology focus with customer-centric values, ensuring its cutting-edge solutions are tailored to meet unique client needs. This approach has earned QuantHealth a solid reputation in the AI-enabled clinical trial design market, with clients recognizing its commitment to delivering innovative and impactful solutions.

QuantHealth earns Frost & Sullivan's 2024 Global Entrepreneurial Company of the Year Award for its strong overall performance in the AI-enabled clinical trial design industry.

[6] Archana Rani, "QuantHealth Receives Funding to Expedite Clinical Trial Simulations Use," Clinical Trials Arena, January 9, 2024, https://www.clinicaltrialsarena.com/news/quanthealth-funding-trial-simulations/.

What You Need to Know about the Entrepreneurial Company of the Year Recognition

Frost & Sullivan's Entrepreneurial Company of the Year Award recognizes the best up-and-coming, potentially disruptive market participant.

Best Practices Award Analysis

For the Entrepreneurial Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Entrepreneurial Innovation

Market Disruption: Innovative new solutions have a genuine potential to disrupt the market, render current solutions obsolete, and shake up competition

Competitive Differentiation: Strong competitive market differentiators created through a deep understanding of current and emerging competition

Market Gaps: Solution satisfies the needs and opportunities that exist between customers' desired outcomes and their current market solutions

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

Passionate Persistence: Tenacity enables the pursuit and achievement of seemingly insurmountable industry obstacles

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

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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™.
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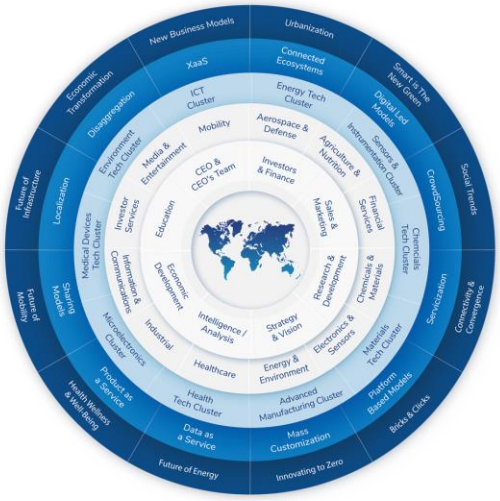
Key Impacts:

- **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)