

AI-POWERED CLINICAL TRIAL SIMULATION

The End of Guesswork: How AI and Machine Learning Are Redefining Success in Clinical Development

QuantHealth has pioneered a new category of AI capability – clinical trial simulation – built on the industry's first pharmaco-clinical foundation model and a proprietary data asset of over 350 million patient lives.

1. AI and Machine Learning: A Primer for the Life Sciences Leader

At its core, Artificial Intelligence (AI) is a broad field of computer science focused on creating machines that can perform tasks that typically require human intelligence, such as learning, problem-solving, and decision-making. Machine Learning (ML) is a subset of AI where algorithms are “trained” on large datasets to recognize patterns and make predictions without being explicitly programmed for that task.

In drug development, this means an ML model can learn from data on millions of patients and thousands of past clinical trials to learn the complex, multi-dimensional relationships between a drug, a disease, a patient's biology, and the ultimate clinical outcome.

2. The Spectrum of AI in Clinical Development

AI and ML are being applied across the clinical development lifecycle, with varying levels of sophistication and impact. Understanding this spectrum is key to appreciating the leap forward that clinical trial simulation represents.

Stage	Application of AI/ML	Key Benefit
Early Stage: Data Mining & Pattern Recognition	Identifying potential drug targets from genomic data; analyzing electronic health records (EHRs) to find eligible patients for a trial.	Efficiency: Accelerating tasks that would be manually intensive and time-consuming.
Intermediate Stage: Predictive Analytics	Building models to predict patient enrollment rates; identifying patients at high risk of adverse events.	Optimization: Improving the operational aspects of trial conduct.
Advanced Stage: Clinical Trial Simulation	Creating a virtual, in-silico model of an entire clinical trial to predict its outcome before it even begins.	De-risking: Providing a data-driven Probability of Technical Success (PTS) to guide strategic investment and design decisions.

While early and intermediate applications of AI provide valuable efficiencies, they only solve part of the problem. They can make a trial run faster or find patients more easily, but they cannot answer the most fundamental question: **Will this trial succeed?** To answer that, a new class of technology is required.

3. Defining the Category: AI-Powered Clinical Trial Simulation

Clinical trial simulation is the pinnacle of AI/ML in drug development. It represents a categorical shift from using AI to optimize the *process* of a trial to using AI to predict the *outcome* of the trial itself. This is the difference between having a faster car and having a GPS that tells you the best route to your destination and your probability of arriving on time.

A true clinical trial simulation platform must have three core components:

- 1. A Massive, Longitudinal Data Asset:** The ability to learn from the real-world experiences of millions of patients over many years.
- 2. A Sophisticated Biological Knowledge Graph:** The ability to understand the complex interplay between a drug's mechanism of action, the disease pathway, and patient biology.
- 3. A Powerful Predictive Engine:** The ability to integrate these components to run thousands of virtual trials and generate a robust, accurate prediction of the primary endpoint.

Many companies claim to use AI, but very few have the integrated capabilities required to perform true clinical trial simulation. This is the category that QuantHealth has pioneered and continues to lead.

4. The QuantHealth Approach: Leadership Through Unmatched Capability

QuantHealth has established itself as the leader in clinical trial simulation by building a platform that is unmatched in its data, its biological depth, and its predictive power. Our approach is not an incremental improvement on existing methods; it is a fundamental re-imagining of how clinical trials are designed and de-risked.

The Industry's First Pharmaco-Clinical Foundation Model

At the heart of our solutions are the foundation models, a new class of AI, trained on massive, diverse datasets, that can be adapted to a wide range of downstream tasks. The LRDM is trained on:

- **350+ million patient lives:** providing an unparalleled view of disease progression and treatment effects in the real world.
- **A proprietary knowledge graph:** that maps the full biological cascade, from a therapeutic entity to its target, pathway, cell, and ultimately, the disease itself.

- **Data from tens of thousands of clinical trials:** allowing the model to learn the nuances of trial design and their impact on outcomes.

This “digital-drug and digital-twin in-one” platform allows us to create a virtual replica of any Phase 2 or 3 trial and predict its outcome with **85-90% accuracy**, a level of performance that has been prospectively validated across more than 350 trials.

The Power of Prospective Prediction

The ultimate test of any predictive model is its ability to predict the future, not just explain the past. QuantHealth is the only company in the field that has publicly demonstrated the ability to **prospectively predict the outcome of Phase 2 and 3 trials before the results are announced.**

This is our core differentiator and the foundation of our category leadership. It is the difference between a weather forecast and a history book. While other companies may be able to retrospectively analyze why a trial failed, we provide our partners with the foresight to know whether it will succeed in the first place and make smarter optimizations before a patient is enrolled or capital is deployed.

5. The Impact: From Prediction to Value

Building brand authority is not just about having the best technology; it's about delivering tangible value. The QuantHealth platform translates its predictive accuracy into concrete benefits for its pharmaceutical customers:

- **Massive Cost Savings:** In one engagement with a top-10 pharma company, our platform delivered \$31.4 million in savings by informing a trial protocol redesign.
- **Accelerated Timelines:** Our simulation platform has been shown to help reduce enrollment times by up to 15 months by identifying more precise patient cohorts.
- **Increased Probability of Success:** By identifying the optimal trial design, our platform has achieved a 2.8x increase in the predicted probability of success for a key asset.

6. Conclusion: Setting the Standard for a New Era

Artificial intelligence and machine learning are not a trend; they are the foundation of modern drug development. As the industry moves up the spectrum of AI maturity, the ability to accurately simulate clinical trial outcomes will become the new standard for strategic decision-making.

QuantHealth has defined this new category. With our industry-leading foundation model, our massive real-world data asset, and our proven track record of prospective validation, we are not just a vendor; we are the partner of choice for pharmaceutical companies who want to lead in this new era. We provide the technology and the validated evidence to turn the uncertainty of clinical development into a predictable path to success.

The era of guesswork is over. The era of simulation has begun.

References

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