IN SILICO TRIALS AND THE LIVING HEART PROJECT

How Virtual Modeling and AI Are Enabling MedTech In Silico Clinical Trials

Key Takeaways

In silico trials utilize computational modeling and simulation to emulate human system dynamics, offering a sophisticated and ethical alternative to traditional testing methods.

Regulatory agencies, such as the FDA, are increasingly recognizing the potential of In silico trials, as evidenced by recent guidance aimed at supporting their utilization in medical device submissions.

These trials can expedite trial timelines, increase patient safety, and are cost-effective, making them invaluable tools in drug and medical device development.

THE LANDSCAPE

In silico trials represent a groundbreaking approach in medical research, leveraging modeling and simulation to enhance insights, refine methodologies, and potentially replace animal and human testing. Central to this approach is the development of patient-specific models that form the foundation for complete virtual cohorts. These models are used to assess the safety and efficacy of new drugs and medical devices. Such methods are increasingly being recognized as valuable tools to complement and enrich traditional clinical trials, potentially reducing the number of required patients, improving statistical significance, and accelerating regulatory approval timelines. The implications of this novel approach are significant for the development of drugs and medical devices, as well as regulatory assessment. In silico trials use computational modeling to emulate human system dynamics, offering a sophisticated and more ethical alternative to conventional in vivo and in vitro testing. This approach can not only dramatically expedite trial timelines and increase patient safety, but it is also cost-effective.

Regulatory agencies are acknowledging the potential of In silico trials, leading to a shift towards their increased acceptance in the life sciences sector. This is evident from the actions of the FDA, which, on November 16, 2023, issued the final guidance titled "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions." This guidance provides a comprehensive framework to support regulatory submissions, aiming to bolster confidence in the utilization of computational evidence in these submissions, thus marking a significant advancement in the field.

THE CHALLENGE

The challenge lies in transforming the traditional approach to medical research and regulatory assessment. Embracing In silico trials requires a shift in mindset and practices within the life sciences sector. Current practices rely on animal and human testing which is a taxing and time consuming process. Additionally, ensuring the credibility and acceptance of computational evidence in regulatory submissions poses a significant challenge.

THE SOLUTION

Dassault Systèmes stands as the driving force in pioneering In silico trials, a position solidified by the foundational role it played a decade ago with the initiation of the first collaboration for the Living Heart Project. As the originator of this innovative endeavor, Dassault Systèmes has been pivotal in propelling the evolution of virtual twin modeling. The Living Heart Project, celebrated for its innovative and collaborative nature, utilizes Dassault Systèmes' advanced software capabilities and has evolved into an extensive global research collaboration. This initiative includes crucial partners such as the FDA, leading cardiovascular researchers, clinicians, and industry experts globally, all collaborating to create an exceptionally precise digital model of the human heart. This model not only acts as a guide for regulatory processes but also seeks to expedite the development of new treatments, thereby broadening healthcare possibilities and tailoring medical care to individual needs.

Recently, Tata Consultancy Services (TCS) and Dassault Systèmes collaborated to develop the first digital heart model for an athlete. In this initiative, TCS worked with Des Linden, an acclaimed Olympian and Boston Marathon winner, marking a significant step in personalized healthcare and athletic performance.

Furthermore, the integration of Dassault Systèmes' technology with Medidata's clinical trial expertise creates a powerful synergy. In a groundbreaking demonstration of its potential, their teams have used Dassault Systèmes 3DEXPERIENCE platform to combine state-of-the-art modeling of human pathophysiology with Medidata's generative AI simulants capabilities to create virtual twin patient populations suitable for use as synthetic control or even treatment arms. This innovative approach is crucial in enhancing the effectiveness and efficiency of In silico trials, a field increasingly vital in advancing medical research and developing new treatment methods.

If we look beyond simply boosting the acceptance of In silico trials, the combination of these innovative technologies provides healthcare providers with a remarkable opportunity to re-think their patient relationships. It allows them to test procedures on accurate virtual replicas, simulating outcomes and possible complications before actually performing it on the patient. One day, the twin will serve as the virtual patient monitoring system, truly enabling location free healthcare that works for all.