How In Silico Medicine Can Accelerate Innovation in Medical Devices

Virtual human simulation models benefit the development of next-generation medical devices.

From Physical to Virtual Humans

Modern medical devices are becoming ever more complex with better functionality, which provides patient benefit but also increases the risk of design errors. Therefore, it is important that new medical devices are tested for safety and efficacy several times throughout the development cycle. The validation and clinical evaluation of medical devices can be performed *in vivo* using living animals or humans, but this is expensive, time-consuming, and sometimes even risky to the test subjects. Alternatively, testing can be conducted with tissue-mimicking phantoms or *in vitro*, which can reduce time and costs but does not accurately reflect a real human.

The question then arises: is it possible to eliminate the drawbacks of time, cost, and possible safety risks while maintaining the advantages of *in vivo* evaluation? One way to do this could be *in silico medicine,* which refers to the use of virtual human models to replace their physical counterparts in testing of new medical devices. The aim of these virtual humans is to replicate human anatomy and physiology so accurately that they can be used as the testbench in computational simulations when developing medical devices. For example, medical devices incorporating physiological closed-loop control (PCLC) technology, such as

a pacemaker, could be validated using a realistic electrophysiological heart model to ensure its safety and efficacy. Similarly, an insulin pump with glucose monitoring could be validated using a virtual patient model with varying glucose levels.

The Medical Devices Industry Is Starting to Embrace Modeling and Simulation

The automotive and aerospace industries have used computational models and simulations for their design processes ever since they became widely available. The benefits of working with simulation models in R&D are obvious in large-scale projects such as designing a new airplane, where using real-world prototypes is very expensive and not always practical nor feasible. Therefore, companies in these industries have seen the value of using computer simulations with plant models as the method to validate designs early in the development process before starting real-world testing.

The adoption of modeling and simulation in the medical device industry, however, has been relatively slow, especially when it comes to validation and clinical evaluation. So why aren't medical device companies fully adopting modeling and simulation despite the obvious benefits? To gain some insights, the Medical Device Innovation Consortium (MDIC) conducted a survey among their members to find out what is holding the industry back from fully embracing computational modeling and simulation. The majority of respondents (61%) indicated that regulatory uncertainty was the main reason while the lack of expertise (49%), expenses (32%), and scientific maturity (32%) were also mentioned as barriers. At least some uncertainty might stem from the newness of the regulatory process. Furthermore, there might be an overall lack of experience in the industry with establishing the scientific creditability of computational models.

Despite all these challenges, many leading medical technology companies have already seen the benefits of modeling and simulation in their R&D work. For example, Cambridge Consultants created a new ventilator design in just 47 days using simulation techniques. Medtronic used in silico methods in the development of their next-generation artificial pancreas system for automated insulin therapy. Tandem Diabetes Care deployed cloud-based in silico clinical trials with virtual patient populations to accelerate continuous glucose monitoring device development. However, these types of applications are just the beginning of the possibilities that virtual humans can offer for the medical devices industry in the future.

In Silico Clinical Trials Are the Future

In silico clinical trials involve the use of patient-specific models to form virtual cohorts in the clinical evaluation of new medical devices. There are several advantages to these virtual trials compared with physical clinical studies. In silico trials allow thousands of different simulation scenarios and virtual patients and thus enable larger scale clinical studies. In addition to ensuring medical device safety in different clinical situations, the patient-specific performance evaluation can also identify the patient types that have the best response to the treatment. Moreover, companies would see reduced time and costs for conducting clinical studies while also benefiting from an accelerated pathway for new products from preclinical studies through clinical trials to the market.

The regulators are also supportive of using digital evidence from virtual patient populations for new device approvals. For instance, the FDA issued guidance for assessing the credibility

of in silico models in medical device submissions to provide clarity about the regulatory expectations. Furthermore, they have also published in silico case studies from across nearly all FDA centers. The European Parliament adopted amendments that mention in silico clinical trials and digital twin technologies. Furthermore, consortiums such as MDIC and European Virtual Human Twins (VHT) bring together various healthcare stakeholders to increase adoption of in silico medicine and develop standards and best practices.

Overall, in silico trials will decrease the need for in vivo testing and allow organizations to conduct physical clinical trials with fewer patients and better planning. Whether in silico trials can completely replace humans in clinical studies in the future is yet to be seen, but the benefits of accelerating product innovation and the introduction of life-saving technology to the market faster are clear to everyone.

The Time for In Silico Transformation Is Right Now

In today's rapidly changing healthcare market, the medical device industry is forced to evolve and look for new ways to shorten the time-to-market for next-generation products without compromising quality and patient safety. If companies want to remain competitive, they need to fully leverage the capabilities of computational modeling and simulation in their R&D processes. This approach will help them reduce the duration and cost of the product development cycle and, at the same time, improve the quality, performance, and safety of their products.

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In Silico Medicine: Medical Device R&D with MATLAB and Simulink

About the Author

Dr. Visa Suomi is the medical devices industry manager at MathWorks. He has over 15 years of international experience in the medical devices and healthcare sector, with an interdisciplinary background from the medical technology industry, academia, and clinical research. He holds a doctoral degree (DPhil in Healthcare Innovation) from the University of Oxford, UK, with a focus on translating academic and clinical research into commercial applications.