How In Silico Medicine Can Accelerate Innovation in Medical Devices

Dr. Visa Suomi, Medical Devices Industry Manager at MathWorks, explains how virtual human simulation models can 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 using living animals or humans, but this is expensive, time-consuming, and sometimes even risky to the test subjects. Alternatively, the 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, costs, 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, a ventilator design could be validated ***using a realistic lung model of a virtual patient*** to ensure its safety and performance. 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 Modelling 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 environment models as the method to validate designs early in the development process before starting real-world testing.

The adoption of modelling and simulation in the medical devices industry, however, has been relatively slow, especially when it comes to validation and clinical evaluation. So why aren't medical devices companies fully adopting modelling and simulation despite the obvious benefits? The Medical Device Innovation Consortium (MDIC) ***has conducted a survey on their members*** to find out what is holding back the industry from fully embracing computational modelling and simulation. The majority of respondents (75%) indicated that regulatory uncertainty was the main reason; the lack of expertise (42%), cost (34%), and scientific maturity (32%) were also mentioned. 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 medical technology companies have already seen the benefits of modelling and simulation in their R&D work. For example, ***Cambridge Consultants*** managed to create a new ventilator design in just 47 days using simulation. Innovative startups have also lowered the barriers of expertise and cost to medical device manufacturers by offering device design and validation tools as a software service. Services such as ***v-Patients*** offer a selection of different virtual humans that companies can use in a simulation environment to validate their medical devices. However, these types of applications are just the beginning of the possibilities that virtual humans can offer for the healthcare industry in the future.

In Silico Clinical Trials Are the Future

In silico clinical trials refer to the use of patient-specific models to form virtual cohorts in the clinical evaluation of new medical devices. There are several advantages in these virtual trials compared with physical clinical studies. In silico trials allow thousands of different simulation scenarios and virtual patients and thus enable clinical studies to be conducted on a much larger scale. Apart from ensuring the 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. FDA ***has addressed*** and ***provided a strategic policy roadmap*** for in silico trials in the regulatory evaluation of new medical products and devices. The European Parliament has also recently adopted amendments ***specifically mentioning in silico clinical trials***. Furthermore, consortiums such as ***Avicenna Alliance*** and ***In Silico World*** have been formed to bring together different healthcare stakeholders with the aim of growing the adoption of in silico medicine and developing standards for Good Simulation Practice (GSP).

Overall, in silico trials will decrease the need for in vivo testing and allow physical clinical trials to be conducted with fewer patients and better planning. Whether in silico trials can completely replace real 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 are clear to everyone.

The Time for Virtual Transformation Is Right Now

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

Learn more: ***MATLAB and Simulink for Medical Devices***

About the Author

Dr. Visa Suomi is the Medical Devices Industry Manager at MathWorks. He has over 10 years of international experience in the life sciences 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 the focus on translating academic and clinical research into commercial applications.