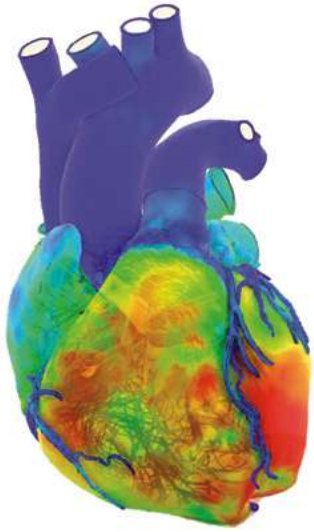
ACCOLADES FOR LIVING HEART ON-CLOUD UNDERSCORE GROWING AWARENESS OF PROJECT COMMUNITY AND VALUE OF MODELING AND SIMULATION FOR LIFE SCIENCES

Moves from FDA highlight importance of virtualization for innovation, quality, and cost control in healthcare

Three years ago, the Huffington Post wrote this about the Living Heart Project: "This is thought leadership at the leading edge of innovation in medical research and innovative in several ways. First, in the application of advanced simulation and 3D visualization technology in the biomedical arena, and second in its crowdsourcing approach."[1] At that time, the vision may have been profound but the technology was nascent. Fast forward to today and we find the Dassault Systèmes' Living Heart—the flexible and robust 3D multiphysics model of a lifelike, beating, human organ—available to all on the cloud as a commercial-grade business tool. More importantly, leaders across the medical device industry are now embracing the project vision and putting plans in place to act on it.

Yet the project team is not standing still. The first-of-a-kind applications of disease modeling, personalization and device design optimization emerging from the community are receiving increasing attention these days from private industry, medical professionals and regulators. When this new capability is combined with the power and universal access provided by the cloud, the broader benefits of simulation for the future of healthcare are becoming ever more apparent.



To explore this potential, the Dassault Systèmes team worked with members of the Living Matter Lab at Stanford University led by Professor Ellen Kuhl (and supported by Hewlett Packard Enterprise (HPE), Advania and Uber Cloud) to create a highly detailed version of the Living Heart FEA model that could exploit this power. The model contained sufficient detail as to predict the electrical conductivity through the ion channels in each of the cells of the heart. These cells were assembled into the Living Heart electrical model and began to communicate and function as a real heart would, confirmed by placing the heart model into a human torso and computing the ECG trace. The model was then subject to the molecular level interactions of drugs known to have varying side effects. The model correctly predicted the electrical signal of a healthy heart and also the known disruptions to the natural rhythm when exposed to a drug, even spontaneously inducing a life-threatening arrhythmia. With over 250 million independent variables to be solved, it is a truly multiscale and multiphysics breakthrough to predict from cell-to-organ, enabled by the power of the cloud and ushering in a new horizon for biomedical simulation.

SIGNIFICANCE NOTED

The significance of this work was not ignored. At the recent 2017 Supercomputing conference in Denver, Colorado, the team received three separate awards: the Editor's Choice Award for "Best Use of HPC on the Cloud" from HPC Magazine; the "Best Paper Award" from Intel (at their developer co-event); and the "Innovation Excellence Award" from Hyperion/IDC. The judging panels represented a broad range of HPC and other subject-matter experts—who overwhelmingly voted for the Living Heart from among more than 110 submissions, in the case of the Hyperion/IDC award.

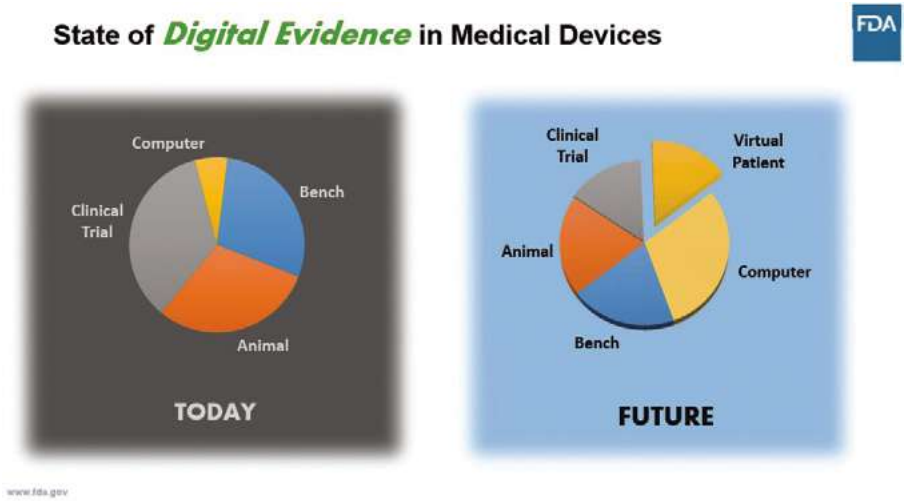
As important as these technical breakthroughs are, the Living Heart Project is unique in its emphasis on rapidly translating technology into practical, real-world applications. For healthcare, this means bridging the cultural and technical boundaries between researchers and medical professionals. We are now seeing signs that this is happening. As evidence, this fall, in honor of the 6th International World Heart Day, Dr. Nikki Stamp, an Australian cardiologist, featured the Living Heart in a network TV special on the future of cardiovascular medicine. In Germany, Dr.Christian Schlensak, a cardiothoracic surgeon from University Hospital Tübingen, gave a public-television demonstration of how the Living Heart could improve pre-surgical planning of a complex congenital heart-defect repair.

Such validation from both IT and medical sources reflects the important advancements the project members have made and reveals the potential of simulation to address some of the toughest technical and business challenges in healthcare. The continued growth worldwide of the project also reflects the second point from the Huffington Post, the significant input—in the form of innovation, sharing of real-world data and clinical experience—from a vast team of academic researchers, physicians, industry and regulatory agencies committed to

[1]Simon, Phil. "Crowdsourcing Healthcare" Huffington Post, 12 November 2014, https://www.huffingtonpost.com/phil-simon/crowdsourcing-healthcare_b_6149028.html

a better future and the principle that a rising tide lifts all boats. Together this collaboration is advancing heart modeling to become more powerful, flexible and accurate over time and showing no signs of slowing down.

Of course, in between the innovations of the researchers and practice of the clinicians lie the regulatory bodies. The U.S. Food and Drug Administration (FDA) clearly sees the bigger-picture message behind the success of the LHP: validated virtual human and animal models will deliver huge time and cost savings while enabling innovation throughout the healthcare industry to the benefit of all patients. In line with their mission to protect health and safety, and promote public health awareness, the agency has been a supporter of the LHP from its earliest days, advising the expanding LHP community on their growing interest in simulation for regulatory purposes for years.



Source: Dr. Tina Morrison, U.S. Food and Drug Administration - Access 17 Nov 1, 2017

Dassault Systèmes has reciprocated by sharing its expertise and experience in related industries with the agency. Dassault Systèmes is a founding member of the Medical Device Innovation Consortium and serves on the FDA's policy committee to establish verification and validation standards for drug and device modeling (V&V 40). For its part, the FDA has already begun exploring virtual clinical trials and accepting simulation data to support regulatory submissions to the Center for Devices and Radiological Health (CDRH).

When FDA Commissioner Scott Gottlieb announced the agency's new Innovation Institute this year, he made a point of saying that "in silico" tools will improve drug development and make device regulation more efficient. The director of the CDRH, Jeffrey Shuren, publicly cited simulation as a possible source for regulatory approval in a recent article in the New England Journal of Medicine.

NEW WAY TO CONDUCT RESEARCH

With the release of the Living Heart on the cloud, the industry has a new way to conduct medical research—virtual organs-on-the-cloud. Just three years ago, simulation of a clinical use of a medical device for improved design, selection or training was out of reach for all but the most advanced organizations. Today, companies of all sizes can immediately access a complete, on-demand HPC environment in which they can scale up virtual testing securely and collaboratively without having to build and manage an in-house, physical infrastructure of computing resources.

Most importantly, the underlying technology, methods and platform that power the Living Heart are also immediately available for companies outside of the cardiovascular arena. For example, the Abaqus Knee Simulator, a highly advanced application that offers virtual knee-implant wear testing to replace lengthy bench tests, is being refined in the latter stages of the FDA's Medical Device Diagnostic Tool (MDDT) program. Other virtual organs—such as brain, spine, foot, colon and eye—are being used to design and test implants and replacements, surgical tools, syringes, catheters and more.

Is this evolution or revolution? Real-world testing in living humans remains the endpoint for FDA approval, but with the barriers to innovation and the skyrocketing costs of the current systems, it is simply not sustainable. With the ability to incorporate real-word evidence, optimize designs faster, and get advance notice when proposed drugs or devices will have unexpected side effects, in-silico methods on the cloud are poised to take their rightful place in medical research and practice.

Once in place, customized devices and treatments become a logical and practical reality. For their part, the FDA projects that evidence sources could move to almost 50% digital and virtual patients. The industry is already gathering valuable insights from simulation that help to produce more effective and reliable devices. Yet those insights are lost and rarely applied to directly lower the costs or increase the speed of regulatory approval. The FDA seeks to change that and the members of the Living Heart Project have doubled down on their effort to help them with the goal that no device will ever be put into a real patient before first being tested in a virtual one. We all will benefit if they are successful.

And so the beat goes on! Medicine today is in many ways a less predictable industry than others, and the digital age is bringing with it a huge transformation in healthcare practices. The power of simulation, in combination with high-performance computing on the cloud, is key for this transformation to be fully realized, and to add predictability for the benefit of patients and innovators everywhere.

For More Information

www.3ds.com/heart