BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Dassault SystÃ¨mes extends collaboration with FDA

25 July 2019 | News

To spur medical device innovation by enabling innovative, new product designs



Dassault Systèmes has announced the five-year extension of its collaboration with the U.S. Food and Drug Administration. The 3DEXPERIENCE platform will be used to develop a new digital tool to enable more efficient regulatory review of cardiovascular and medical devices.

Researchers hope the first-of-its-kind process will increase industry innovation and pave the way for an efficient path for patients to access safe, effective new treatments for the world's leading cause of death – heart disease.

This second phase of their ongoing collaboration supports the 21st Century Cures Act, using virtual patients based on computational modeling and simulation to improve efficiency of clinical trials for new device designs.

A groundbreaking project with the Living Heart simulated 3D heart model will examine the use of heart simulation as a source of digital evidence for new cardiovascular device approvals. This includes an in silico clinical trial aimed to reduce animal testing or the number of patients required while still ensuring safety and efficacy of the device is demonstrated.

The new digital process is intended to be more efficient and less expensive than current ones – whose delays and costs can impede patient access to novel treatments – without losing rigor or confidence in a device's safety and efficacy.

The FDA has publicly recognized the public health benefits offered by modeling and simulation, and the potential for in silico clinical trials to safely advance medical products more efficiently, from preclinical studies through clinical trials to market.