MODELING AND SIMULATION

Industry Perspective

- Computational modeling is being used by U.S. manufacturers to improve the design of nearly every physical product or process by providing the opportunity to perform virtual experiments on the computer prior to building a single physical prototype.
- Modeling and simulation can support or, in some cases, replace time consuming testing and traditional clinical trials to bring higher quality data much earlier.
- Validated models can transform the way projects do their testing in the lab and let us confidently interpret smaller clinical data sets to get new therapies to more patients in less time.
- To stay competitive, the healthcare industry is now adopting computer modeling to address the complex challenges of treating an aging population, reducing healthcare costs, and ensuring the reliability of each treatment for all patients.
- When bringing new devices forward, it is critical that we can predict the safety and efficacy for the entire patient population we expect.
- The next challenge is the development and refinement of in-silico trials frameworks, which are computer models of therapies applied to virtual patient populations. This approach will provide critical information about the safety and efficacy of a treatment therapy with no patient harm.
- We need to support access to clinical data for model development & validation, and a regulatory approach to encourage these applications by U.S. companies for new device therapies.

FDA Perspective

- FDA recognizes the public health benefits offered by modeling and simulation, including those in the area of in-silico clinical trials (using individualized computer simulation in development and/or regulatory evaluation of medical products).
- Modeling and simulation play a critical role in, among other areas, organizing diverse data sets, exploring alternate study design strategies, and predicting performance, so that safe and effective new therapeutics can advance more efficiently from pre-clinical studies through clinical trials to market.
- FDA routinely advises industry on using modeling and simulation to, for example:
  1) predict clinical outcomes
  2) inform clinical trial designs
  3) support evidence of effectiveness
  4) identify the most relevant patients to study
  5) predict product safety
- In some cases, in-silico clinical trials are used to replace human clinical trials, especially those that are intended to evaluate the risk of drug interactions.

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SETTING THE STANDARD

Clinical Perspective

- Optimal repair of complex congenital heart disease cannot always be predicted by expert opinion.
- Patient-specific flow modeling of surgical approaches before the surgery can help predict the best treatment and guide the operative approach.
- Patient-specific 3D models of anatomy and planned reconstructions improves pre-operative planning and intra-operative guidance.
- A dedicated modeling team of engineers, surgeons, and cardiologists are required to work together to create, analyze, and refine the models to guide clinical decision making.

ASME V&V40 Standard

- This Standard assesses the credibility of computational modeling, with application to medical devices, by providing a framework for assessing the relevance and adequacy of completed V&V activities that establish credibility. The credibility should be commensurate with the degree to which the model is relied on as evidence of device performance, functional characteristic, and/or safety to support a decision, and the consequences of that decision being incorrect.
- Traditionally, the development of medical devices has involved physical testing in labs (bench tests, or in-vitro testing) and in humans or animals (in-vivo testing).
- These tests provide valuable insights, but the use of computational models and simulation provides another, more efficient avenue for looking at medical devices.
- Companies can build models of devices and the body's systems and run simulations of how the device will perform when deployed.
- They can quickly adjust variables to model different scenarios, making it possible to run through a large number of possibilities in a relatively short time and find the optimal result.