Model of Success

Industry leaders are increasingly turning to numerical simulation and modelling to reduce costs, lessen risks, foster innovation, and augment diagnostics and trials to create better products. CD-adapco's Kristian Debus sat down with Dawn Bardot from the MDIC to better understand their vision

What exactly is the role of the MDIC?

The Medical Device Innovation Consortium (MDIC), formed in late 2012, is a US public-private partnership between industry, government – including the FDA, Centers of Medicare and Medicaid, and National Institute of Health – and other interested parties, software companies and medical device manufacturers. Our vision is to create an opportunity for all stakeholders to come together and collaborate on regulatory science. If we are to meet 21st century demands and technologies, we have to find new ways of validating device safety and cost effectiveness.

At MDIC, we have three projects that identify new methods and tools for demonstrating medical devices. The Patient Centered Benefit Risk (PCBR) assessment project is looking to bring the patient's voice and needs into medical device assessment. The Clinical Trial Innovation and Reform (CTIR) initiative focuses on bringing US products to market faster, as well as ways to conduct more simple trials based on electronic medical records and collected data. The last is the Computational Modelling and Simulation (CM&S) project, which aims to facilitate the use and acceptance of simulation tools in the regulatory review process.

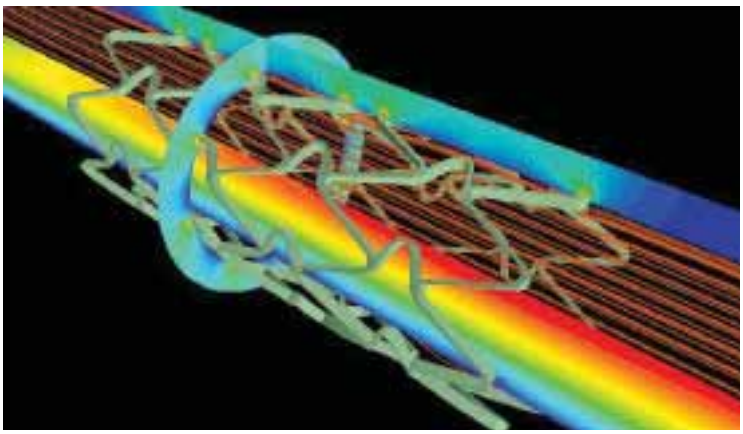

Figure 1: Cardiovascular simulation showing streamlines and velocity through a stent

How close are the other two projects working alongside the CM&S group? There seem to be mutual benefits here.

It is absolutely right that all three project groups should overlap. For instance, the CM&S working group recently had a presentation at a workshop hosted by the CTIR project. The presentation showed that by using virtual patients from CM&S, the number of real patients necessary in a clinical trial can be reduced. In addition to demonstrating the device in a safe, effective and faster manner, CM&S can also augment trials where recruiting real patients is difficult.

The PCBR project, meanwhile, recently released its framework document. A major focus was on demonstration projects for evaluating a patient's preference, or a population of patients' preferences or risk tolerance for medical devices. Here, the willingness of participants to use devices that have been demonstrated through virtual patients can also be used as evidence to support bringing new devices to market.

Where can CM&S tools help the most in the regulatory review process?

We now have the ability to rely on CM&S for business decisions and root cause analyses.

Keywords

Public-private partnership
Computational modelling and simulation
Multiphysics
Cooperation model

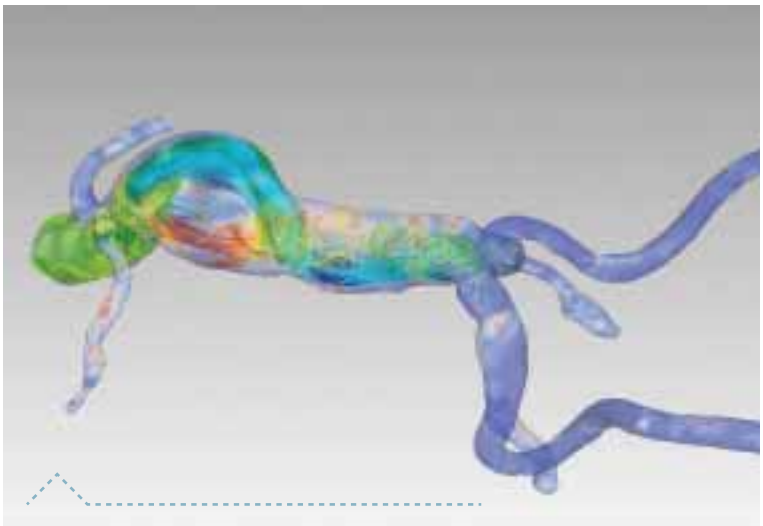

Figure 2: Abdominal aorta aneurysm rupture risk investigation with STAR-CCM+ software. Predicting aneurysm rupture status is one of the areas where the simulation community is working together to establish best practices and validations

However, it is not prevalent in areas where medical device companies face major expenditures: clinical trials and reimbursement. Clinical trials account for 50% of the cost required to bring a product to market, but numerical simulation – which can keep these costs down – is not being used. The other biggest opportunity is at the reimbursement stage, where these models can be used to answer questions for reimbursement agencies.

So the MDIC wants to foster the cooperation and communication necessary to achieve these goals for CM&S?

Yes – there is no other place where all the stakeholders can collaborate and talk about how to overcome these barriers. There are other professional trade bodies, but the MDIC is particularly focused on collaboration and remains a non-profit organisation.

In which areas is CM&S being applied right now?

The majority of use has been in analysing blood flows and in respiratory analysis, where there is the biophysics component – devices that are either interacting with or implanted in the human. Outside, there are external components of the medical device process that are of interest, like dialysis machines. In the qualification of devices, modelling the manufacturing process and understanding the risk and liability is becoming important. In the total product development cycle, CM&S can be informative in multiple aspects.

Do you see applications in diagnostics and patient monitoring as well?

Definitely. Increasingly, there will be opportunities for CM&S to help inform scientists, whether in the context of medical devices or health apps. For example, asthmatic systems are trying to recognise triggers and the need for an inhaler. Environmental conditions are crucial here. Based on big data, these systems can predict triggers, but they can also rely on atmospheric condition models to monitor environmental changes. The predictive understanding from CM&S and the empirical observations from big data can come together to work for health apps and medical devices. It will be interesting to see where the discussion goes around diagnostics using CM&S. Modelling can play a supporting role in treatment planning, interventional organisation and device positioning, and can help in the medical training realm.

At CD-adapco, our current focus is on multidisciplinary, multiphysics simulations in STAR-CCM+®. How important is this in regulatory science?

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I think it is really important for code manufacturers to consider multiphysics. Medical devices are natively multiphysics-oriented with the interaction between the biological and engineering components.

What are the biggest challenges for current tools to be accepted in regulatory decision-making?

Last year, the MDIC asked members about the chief hurdles in using CM&S at the regulatory stage. Return on investment and the specialisation needed to use the tools were among the popular answers, but the majority found regulatory uncertainty to be the largest obstacle. We can get around this by having examples where CM&S is leveraged at the regulatory stage and by making this information public. Also, demonstration projects to showcase the utility and credibility of CM&S in the regulatory phase are needed to overcome any uncertainty.

So it is a 'chicken and egg' problem. The regulatory body wants to see more modelling and examples from industry, while pharma will only start going in this direction if the FDA requires it.

It is less about CM&S being required by the FDA and more about vendors wanting to understand the expectations of regulatory agencies. More examples from vendors will help the FDA explore framework and validity, and offer feedback on CM&S tools. Currently, such collaboration occurs one-on-one between a sponsor/vendor and the agency. What we need is a purpose that can bring together academics, industry and regulators; something similar to the moon race or genomic project. I think the community would rise to that opportunity. We need to identify what the 'moonshot' challenge for this community is.

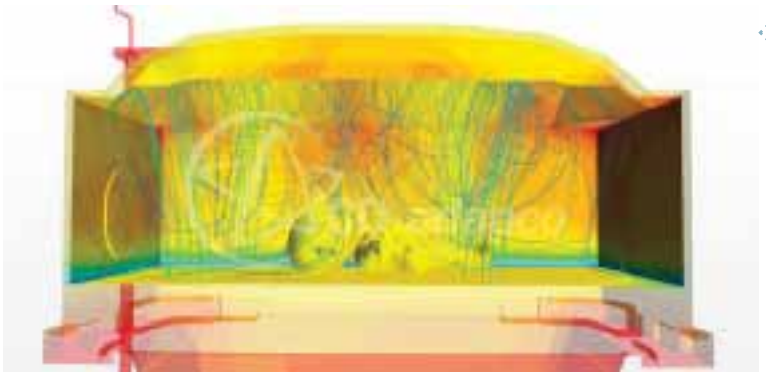

Figure 3: Thermal and flow analysis inside an infant incubator – devices like incubators can get regulatory approval using simulation as evidence

What about the conflict of interest for commercial vendors in collaborating?

We have to recognise that, in this complex space, none of us have all the tools and knowledge to go it alone. We have to explore a cooperation model to fiercely compete, but also collaborate when the information is shareable.

Do you think technology developed by vendors is ready to tackle these hurdles now?

Absolutely. CM&S has been used in regulatory submission for decades. In angioplasty, there was a device approved for market based solely on simulation. The technology from code manufacturers is ready; the people using these technologies are ready; and the MDIC wants stakeholders to know that modelling is also ready to use. Our goal is to find a grand challenge for the community so we can establish verification and validation benchmarks, as well as foster cooperation.

What is your advice for end-users and vendors?

Start using CM&S throughout the entire product development cycle more frequently. You can enrich and validate the models at every step, and document this to start developing processes. We have seen surprising openness from code manufacturers to collaborate and work together. Most end-users are single-user or smaller teams, and code vendors can help them through established processes, automated scripts, cloud-sourced high-performance computing nodes, code verification suites and so on. Vendors can support both end-users and regulators in this journey.

Dawn Bardot is Senior Program Manager, Modelling & Simulation at MDIC. She has more than 15 years of experience in computational model validation and uncertainty quantification, and over the course of her career has worked with start-up companies, government organisations and academia. Dawn holds a number of patents and pending applications, has been published in a number of journals, and is called upon regularly to address conferences and seminars.