LIFE SCIENCES

TRANSFORMING THE VALUE CHAIN

Creating Opportunity in the Life Sciences Industry with Modeling and Simulation

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

SUMMARY

S DASSAUL

INTRODUCTION

The Healthcare environment and the broader Life Sciences ecosystem are changing rapidly. Increasing costs, emerging technologies, time-to-market pressures and stringent regulatory requirements are just some of the drivers forcing a rethink of virtually every aspect of the industry, including business operations, research and development processes and value-based pricing options.

In order to overcome these challenges, Life Sciences organizations are embracing innovative new approaches, such as using modeling and simulation across the entire value chain in order to improve collaborative decision making, save time and money, achieve better patient outcomes and remain competitive.

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

SUMMARY

TRANSFORMATION DRIVERS

COST: Medical research and development is growing more costly as devices and treatments become more complex, regulatory burdens intensify, and the demand for effective and highly personalized care rises. To remain economically sustainable, organizations are embracing a range of digital technologies to help reduce costs while providing safer and higher-quality value-based solutions.

According to PricewaterhouseCoopers, the Healthcare industry will be #1 in R&D spending, topping an estimated \$180 Billion by 2020^{*}.

SERVICE: Cultural and cost pressures have created a new focus upon patient empowerment: Patients are increasingly active participants in their own diagnosis and care, as well as in the routine management of their medical treatment. Additionally, new services are being offered across the value chain to evaluate the efficacy of medical devices and procedures in order to deliver personalized treatments and improve patient outcomes.

INNOVATION: Innovation is the key to staying competitive and flexible in a world where knowledge and sophisticated technologies are growing exponentially. Implicit in this effort is the need to explore multiple options and optimize speed, accuracy, efficiency and cost-effectiveness at every stage while maximizing the value of outsourced resources and knowledge of all participants.

TRANSFORMATION THROUGH MODELING AND SIMULATION

The extremely complex nature of physical human systems—their biological interactions with devices and drugs and the requirement for exacting precision—have posed considerable challenges to those who wished to leverage the power of simulation in life sciences applications. However, today's advanced modeling and simulation applications are proving their considerable worth in a wide range of life sciences applications, including medical device performance, bone modeling and bio-mechanics, as well as human organ interaction with devices and drugs. These advancements are enabling life sciences organizations to take advantage of outsourced services, accelerate the development of innovative medical devices, provide precision personalized treatments and ultimately increase outcome value to the patient.

By using modeling and simulation applications within an integrated, digitally managed and collaborative computing environment such as Dassault Systèmes' **3DEXPERIENCE**[®] platform, organizations are able to create lifelike simulation models for exploration, discovery, development, testing, and commercialization. When R&D activities take place within this data-driven, model-based environment, all stakeholders can leverage a single source of truth. Every modification to the digital model and related information is propagated automatically and every change and decision is associated with the right model. Distributed teams are able to continually test and validate their designs at each stage, thereby reducing the time and costs associated with trial-and-error physical testing.



BENEFITS OF USING A COLLABORATIVE, DATA-DRIVEN, MODEL-BASED PLATFORM:

- Reduce the number of labor-intensive tasks and introduce automation
- Foster collaboration and knowledge sharing throughout the value chain
- Expand networks of collaboration/cooperation beyond the enterprise
- Accelerate innovation and regulatory approval processes
- Minimize cost and increase value to the patient

DASSAULT SYSTÈMES AND THE FDA EXTEND COLLABORATION

Dassault Systèmes has announced a 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.

66 Modeling and simulation can help to inform clinical trial designs, support evidence of effectiveness, identify the most relevant patients to study, and assess product safety. In some cases, in silico clinical trials have already been shown to produce similar results as human clinical trials.

- Tina Morrison, Ph.D., Deputy Director in the Division of Applied Mechanics, Office of Science and Engineering Labs, Center for Devices and Radiological Health, FDA.

Read the Press Release here.

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

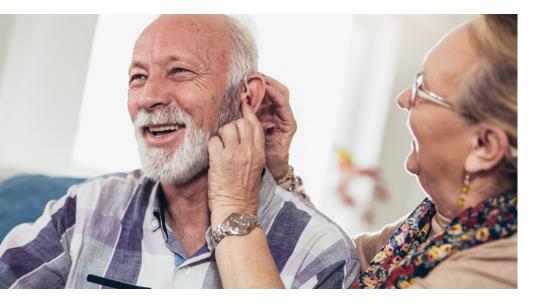
(4)

LEADING THE WAY

GN RESOUND: PERSONALIZING HEARING AIDS WITH VIRTUAL TESTING

The World Health Organization reports that an estimated 900 million people will have disabling hearing loss by the year 2050. Unaddressed hearing loss poses an annual global cost of 750 billion US dollars. Some 18% of adults experience some hearing loss in the speech-frequency range, with the percentage rising to nearly 50% in adults over the age of 75. This means many people miss out during quiet conversations. Intervention to address hearing loss can bring great benefit to individuals and society.

As one of the world's largest providers of hearing instruments, GN ReSound strives to provide customers with effective, technologically advanced assistance devices which balance efficacy, durability, comfort, and aesthetic appeal.



Since no two patients are identical, hearing aids must be configured to the needs of specific individuals relative to physical fit, the degree of amplification required, operability, and sound quality. To meet their aggressive development objectives, GN ReSound uses multiphsylcs simulation software from the SIMULIA brand of Dassault Systemes-during the earliest stages in the design

process-to rapidly assess and improve performance. Extensive physical prototyping has been eclipsed by realistic simulation of sound, vibration, and impact damage.

Since a hearing aid's receiver component (the loudspeaker) is particularly sensitive to damage from physical shock and impact, extensive physical testing has traditionally been used to assess the product's ability to withstand accidental drops. SIMULIA's Abagus FEA software empowers GN ReSound engineers to simulate structural reliability with virtual drop tests. This virtual testing process enables engineers to guickly evaluate alternative designs and make design improvements without building and breaking multiple physical prototypes. Similarly, the ability to test the receiver's physical and acoustic isolation from the microphones helps developers to optimize acoustic gain while preventing unpleasant, and potentially damaging, feedback.

Assessing performance during simulated drop testing, virtual vibration tests, and sound pressure tests-in combination

> Rubber suspension round receiver botto

physical prototyping—allows with the company to evaluate and understand the design and engineer an optimized solution. This enables GN ReSound to bring new, innovative products to market sooner, with the goal of improving a patient's quality of life and helping people rediscover the sounds they have been missing.

Read the Case Study here.

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound **Digital Orthopaedics** University of Sheffield

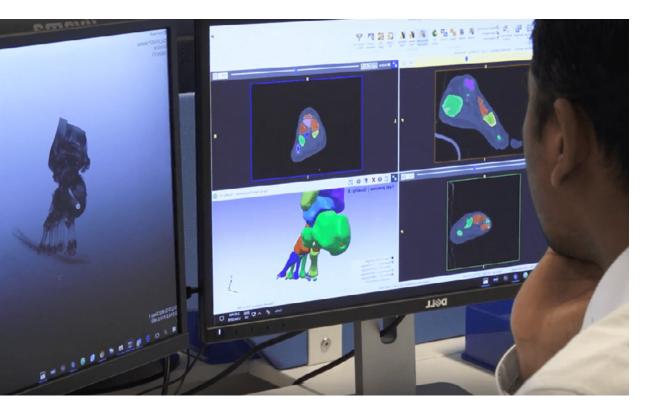
(5)

LEADING THE WAY

DIGITAL ORTHOPAEDICS: PRE-OP DECISION-MAKING SERVICE IMPROVES PATIENT OUTCOMES

Twenty-eight bones, 30 joints and more than 100 tendons, muscles and ligaments are in the average human foot—and from one person to the next, no two of them fit or function exactly the same. That fact underscores the complexity of formulating and executing effective orthopaedic diagnoses and treatments.

The Belgian-based firm, Digital Orthopaedics, is leveraging Dassault Systèmes' cloudbased **3DEXPERIENCE** platform and its 3D modeling and simulation applications to make truly personalized treatments and surgeries possible—thereby increasing treatment success and improving patient outcomes. The company is also developing its own applications, so surgeons can utilize an individual patient's anatomical and syndrome data to craft fully individualized treatment plans and even simulate surgical procedures in advance.



The system lets physicians use patient imaging to generate individualized digital models depicting the patient's precise physiology—often incorporating the specific details of the injury or abnormality creating the need for treatment. These models and simulation results are used not only to precisely plan procedures and treatments, but to also predict likely outcomes. Surgeons can compare potential outcomes arising from alternative approaches and select the best option for the individual patient with a high degree of confidence—before any procedures take place. The success of corrective surgeries, placement of implants, and the fitting of prosthetic ankles all stand to benefit from this process.

Initiatives such as those developed by Digital Orthopaedics are transforming the standard "one treatment type suits all" thinking towards individualized therapeutic approaches.

By using the **3DEXPERIENCE** platform applications on the cloud, the company is looking beyond in-situ standalone systems towards a cloud-centric system which connects with hospital imaging systems and patient information to make simulation-based clinical decision-making services available worldwide. This will facilitate collaboration and knowledge-sharing between geographically dispersed teams and specialists. The Cloud-based system offers the potential to diminish time and resources required to formulate an accurate diagnosis and an effective treatment plan—all while improving the prospects for treatment success, and meaningfully improving the patient experience. The company's founders already envision applying the technology to plan treatments for the spine, shoulders, and knees.

Click <u>here</u> to read the full story.

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

UNIVERSITY OF SHEFFIELD: EDUCATING FUTURE RESEARCHERS AND CLINICIANS

Although its adoption is not yet uniform nor widespread, computational modeling and simulation has already taken root within the life sciences academic and research communities. The technology is favorably impacting the way research is conducted, products are developed, treatments are applied, and patient outcomes improved. For modeling and simulation to achieve its full potential, greater numbers of would-be innovators, researchers and clinicians need to be informed and educated about its infinite possibilities.

The University of Sheffield's Insigneo Institute is a collaborative initiative with the Sheffield Teaching Hospitals NHS Foundation and the UK's largest academic group dedicated to the implementation of personalized, predictive 'in silico medicine'. With more than 150 members including clinicians as well as academics, the Institute focuses on developing sophisticated models of health and disease that are tailored to each individual patient's anatomy, physiology and particular circumstances, aimed at aiding diagnosis and reducing patient risk in any actual clinical intervention. Central to the Institute's methodology is the use of Dassault Systemes' **3DEXPERIENCE** platform and Abaqus FEA software. Proven commercial software, such as Abaqus, provides high quality simulation results, which is critical in achieving acceptance of modeling and simulation by medical equipment manufacturers and government regulators.

G Dassault Systèmes digital healthcare solutions show that SIMULIA's simulation capabilities are now available to a much broader audience and span the entire innovation cycle. CIMdata believes Dassault Systèmes is a leader in providing simulation to the digital healthcare industry. With the **3D**EXPERIENCE Twin,

Dassault Systèmes makes another step forward in applying simulation technology to our daily life. CIMdata believes that SIMULIA has the major multiphysics and multiscale simulation capabilities to enable the digital twin.



Each year, the University's intensive four-day collaborative event, known as the MultiSim Modelathon, draws doctoral and postdoctoral researchers from around the world to explore the power and potential of modeling and simulation within the life sciences field. In 2018, the event focused on the use of research in multi-scale modelling of arthrosic joints to improve patient outcomes. Attendees were placed on teams and were challenged to develop a model of a human femur and simulate the effects of gait, loading and wear on a replacement hip for an osteoarthritic patient. The participants gained valuable insight into building and evaluating finite element and kinematic models from personalized clinical data.

For Enrico Dall'Ara, an Associate Professor in the Department of Oncology and Metabolism at the University of Sheffield, "The people at this event are the future of multi-scale modeling in the area of Biomechanical Engineering. Bringing them together now not only helps in sharing knowledge and expertise, but also in creating the next-generation professionals who will drive our industry and research forward in the future."

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

LEVERAGING MODELING AND SIMULATION ACROSS THE VALUE CHAIN

The economic, cultural, and technological factors driving change across the life sciences industry are seemingly inexorable. For researchers, clinicians, and companies the big question is how they will adapt and apply new ways of doing business to overcome their industry's challenges.

By using proven modeling and simulation applications, connected with the collaboration, intelligence and data management capabilities of the **3D**EXPERIENCE platform, stakeholders from different disciplines are able to leverage a single-source of knowledge for research, development, testing and certification.

The platform provides full digital continuity and traceability across disciplines, including requirements, design, simulation, and project planning. Organizations are able to collaborate on the evaluation and development of innovative medical devices, therapies and patient care, before committing to physical testing, which is critical in the face of rising costs and time-to-market pressures.

Ultimately, the use of modeling and simulation on the **3DEXPERIENCE** platform enables Life Sciences organizations to optimize their long-term enterprise sustainability and meet their objectives in terms of cost, innovation and services.

Our **3D**EXPERIENCE[®] platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE**[®] Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 250,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

3DEXPERIENCE



Europe/Middle East/Africa Dassault Systèmes 10, rue Marcel Dassault CS 40501 78946 Vélizy-Villacoublay Cedex France Asia-Pacific Dassault Systèmes K.K. ThinkPark Tower 2-1-1 Osaki, Shinagawa-ku, Tokyo 141-6020 Japan

Americas Dassault Systèmes 175 Wyman Street Waltham, Massachusetts 02451-1223 USA

INTRODUCTION

Transformation Drivers

Transformation through Modeling and Simulation

LEADING THE WAY

GN Resound Digital Orthopaedics University of Sheffield

