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WHITE PAPER

Disruption in Healthcare Is Here: Are You Ready?

In silico medicine — the adoption of predictive computer models — promises to drastically accelerate and amplify medical device and pharmaceutical innovation while simultaneously taming the unsustainable rise in healthcare costs.

Are you ready for innovation through simulation?

Engineering simulation, or the use of computer models to assess the behavior of a device or treatment in its working environment, is now used by 85% of the top 50 healthcare companies as part of their product and process development.

Simulating the performance of drugs, devices and therapies in a low-risk, cost-effective virtual environment can develop (disruptive) innovations much faster and at lower cost. Healthcare pioneers have repeatedly reported returns on investment of greater than 500%.

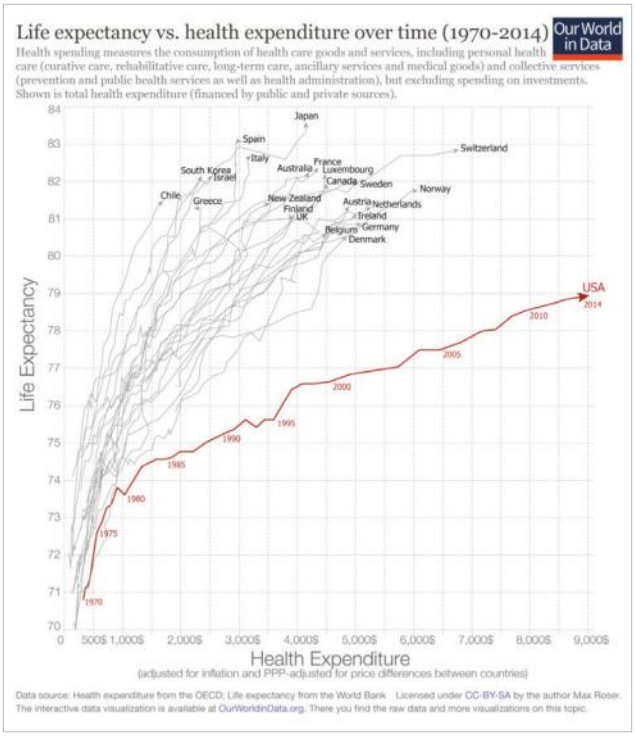
Ansys is fully embracing the in silico approach by creating the necessary software and enabling access to computational power to make simulation pervasive from startups to large global companies, from concept to in-patient performance.

/ Disruptive Trends: Threats or Opportunities?

Access to good healthcare should be an elementary right for any human being. However, establishing and maintaining this right is proving to be a significant challenge for some economies. Today, healthcare represents 12% of European GDP and 17.9% of US GDP [1.d., 1.e], or $3.3 trillion, a rapidly increasing percentage of an already large proportion of the wealth of these countries. At the same time, citizens are becoming less satisfied with the quality and access to care provided. As healthcare advances, increased life expectancy leads to new pathologies and chronic diseases requiring new, more costly care.

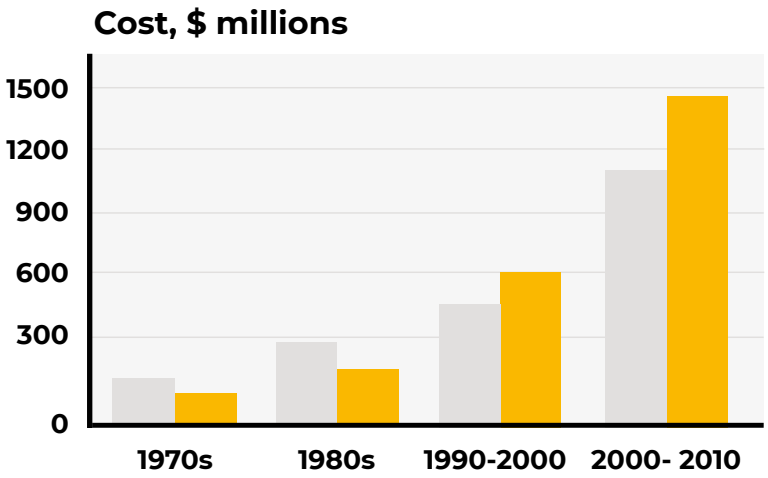
The U.S. spends 30% more of its GDP on healthcare than other industrialized countries, yet has a lower (healthy) life expectancy. Among other factors, it can safely be postulated that billions of dollars are wasted each year on treatments that have no significant impact on the patient and in some cases are detrimental. Predicting the impact of a given treatment on a patient is key to mitigating these costs through outcome -based healthcare.

Maximizing patient safety in the face of more complex devices and sophisticated treatments means that regulatory agencies like the FDA are requesting more extensive clinical trials. Agencies often ask more questions to better understand how the new therapies interact with the pathologies and the body despite the large human variability. As a result, in the last 50 years, the cost of bringing a new drug to the market has increased to more than $2 billion for some drugs today, even when accounting for inflation — a 10x cost multiple. This high barrier to entry causes many pharmaceutical and medical device companies to hesitate before pursuing radically new treatments.



In summary, as populations age, as new complex treatments and devices require more extensive testing and the outcomes of many treatments are not as desired, the cost of healthcare is spiraling upwards at an unsustainable rate. Some see these trends as a threat to bringing innovative solutions to market; others believe that they make the industry ripe for disruption.

Whether perceived as threats or opportunities, leaders from all constituents in the industry, including the regulators, agree that there will be no solution to improving global health while simultaneously controlling costs without a radical, disruptive shift in technology.

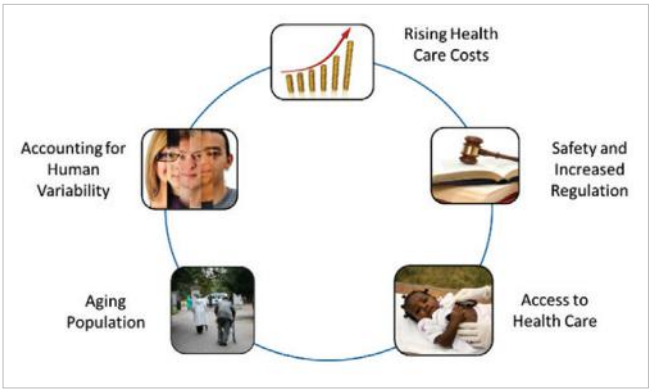


The cost of developing a new drug has skyrocketed since the 1970s. Source: Tufts Center for the Study of Drug Development. (https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html).

/ Taking the Initiative: Barriers to Capturing Disruptive Opportunities

To capture the opportunity through disruptive approaches, innovators in the healthcare industry must overcome a number of barriers at the policy, regulatory, technology and workforce education/skills level.

Policy makers and regulators need to accelerate legislation and approaches that facilitate the adoption of innovation best practices commonly used in other industries such as automotive and aerospace — both of which deliver highly complex solutions in a highly regulated environment. In turn, educators need to ensure that the next generation of scientists, researchers and engineers are skilled in the most current tools and techniques, particularly those underpinning the digitalization of almost every other industry. These initiatives will take several years to bear fruit, yet action is needed now.



The healthcare industry experiences major trends pushing for a short term (r)evolution.

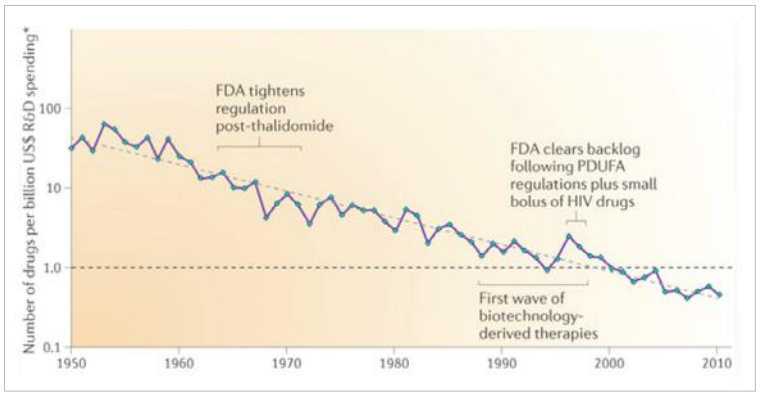
At the technological level, industry pioneers are moving to address three key barriers to controlling the spiraling cost of healthcare:

- The requirement for more extensive and complex clinical trials.
- The ability to predict the impact of a treatment on a patient.
- The need to tailor a treatment to a specific patient.

/ Innovation through Simulation

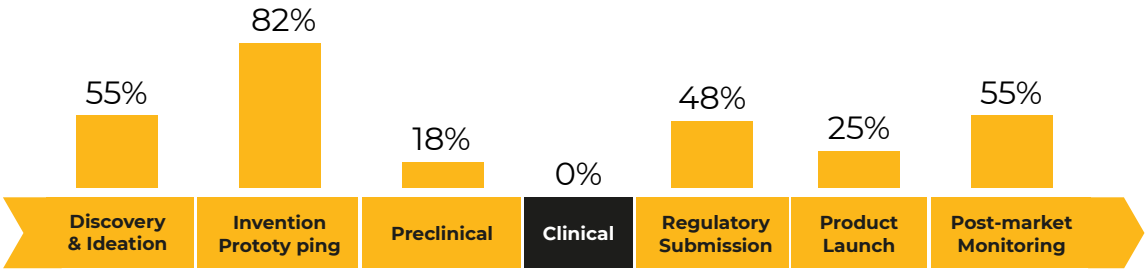
The Avicenna Alliance [1.c], a European consortium of leading companies such as Medtronic, Johnson & Johnson, Cipla and Boston Scientific, among others, is championing the cause of the “in silico clinical trial.” In this approach, treatment processes are tested using virtual patients in the early stages of the treatment or device development process in advance of, and to complement, clinical trials.

This advocacy is occurring because these leading companies are realizing significant return on investment (ROI). Research has found that the typical ROI of this simulation-based approach exceeds 500% [5g, 5.i],and this is expected to grow even more if computer models could be used beyond product design and prototyping and extended to systematic use for regulatory approval purposes.



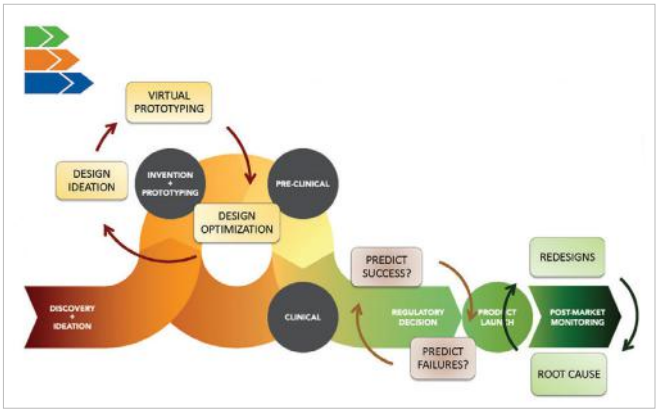
https://sciencebasedmedicine.org/what-does-a-new-drug-cost-part-ii-the-productivity-problem/productivity/

Outside of healthcare, the simulation approach is not new and in many cases is standard practice. However, while the healthcare industry is lagging behind other industries such as aerospace, automotive and high-tech for the large-scale adoption of simulation based techniques, several best practices are emerging:



Percentage of respondents using some form of computational modeling and simulation (CM&S) during various phases of the life cycle (MDIC Survey).

- **Virtual Human Laboratory (VHL):** By modeling the behavior of a medical device or a drug in its working environment, the human body, the designer has access to a Virtual Human Laboratory to assess the impact of any innovation and modification on the patient. The simulations are physics-based to ensure accuracy. Parametric studies offer a systematic method to modify and optimize a design in a realistic yet zero-risk, low-cost environment. Combining this approach with advances in large-scale computing, such as the cloud, enables large design spaces to be rapidly assessed.



- **In Silico Testing:** Optimizing a treatment for a given patient using practices such as the VHL is not enough for regulatory purposes, however. Any innovation will likely be used by a large population of different people. Virtually testing the same prototype on large libraries of patient specific data in silico delivers the confidence that the product will succeed by significantly adding to the body of evidence. In silico testing also reduces the risk of failure in later-stage physical clinical trials.

- **Simulation-driven FDA Approval:** By leveraging the VHL and in silico testing, simulation results, when properly reported and following the regulatory templates, can be used to reduce the size of the required clinical trial and accelerate the time-to-use by the patient.

As industry pioneers adopt these practices, the common thread in the solutions they are developing is a simulation-based approach. Combined with the advent of big data, simulation opens the possibility of personalized medicine and treatments tailored to the individual. This approach can detect diseases before they emerge and customize treatment to maximize the chances of success while minimizing the cost of care.

- **Virtually Certified Body Area Network (BAN):** As the number of wearable and implantable devices increases, the effect of the electromagnetic field on the body cannot be ignored. Assessing the specific absorption rate (SAR) is challenging, expensive and time-consuming using physical testing alone. The virtually certified BAN provides a means to determine SAR and assess the potential risks of excessive energy absorption by the body in a zero-risk, low-cost computational environment.

Why Are Companies Adopting Simulation?

9X	Reduction in a company's development time
4X	Reduction in overall product cost
26%	More likely to meet product cost targets
22%	More likely to hit product launch date
16%	More likely to hit product quality target

/ Simulation Is Pervasive through All Healthcare Sectors

As the following quotations from interviews across the industry testify, simulation based approaches are making a quantifiable impact.

- **Medical Devices:** "A leading medical device company reported that engineering simulation enabled them to address a portion of the FDA's questions, thereby reducing the size of the clinical trial; this resulted in releasing the product two years earlier, during which thousands of patients were helped and the cost of bringing the product to market was significantly reduced."

- **Pharmaceutical:** "Computational fluid dynamics (CFD) simulation saved hundreds of thousands of dollars, providing characterizations that apply to the overall scalability of ASI's products and significantly reducing the need for building and testing prototypes." — Rudolf Pavlik, Director, Product Development, ASI, Millersburg, U.S.A. [5.G].

- **Wearables:** Mariya Lazebnik, Ph.D., senior scientist at Medtronic, points out, “Right now, patients with implantable devices cannot have an MRI scan because of the harmful interaction between the device and the scanner.” During an MRI scan, body temperature rises, which affects the implanted device. “This is a complex problem: the size and shape of the patient will influence the magnitude of that interaction.” Medtronic uses coupled physics — electromagnetic and thermal — in Ansys to simulate these scenarios. [2.C].

- **Cardiovascular:** “Cardiatis has invested significantly in the latest simulation and analysis tools such as Ansys and Mimics®. These tools allow virtual simulation so clinicians may evaluate the effect of the implanted multilayer flow moderator (MFM®) on blood flow, velocity, wall shear stress (WSS) and peak WSS.” — Noureddine FRID, CEO, Cardiatis [5.e].

- **Audiology:** Claus Wuerfer, head of hearing instrument hardware design at Oticon, suggested that, ”Today, hearing aid devices are a lot more than an acoustic equipment. This is a convenience instrument that helps people to be free in their daily environment. Nowadays, the complexity of the equipment doesn’t allow us to test it with trial and error. With simulation you can see inside the device and understand its behavior interacting with the patient-specific head.” [2.b].

/ Industry Leaders Partner with Ansys

Eighty percent of the top 50 healthcare companies are using Ansys software to design, test and deploy their medical device, pharmaceutical or biotech solutions. Common reasons for choosing Ansys include:

- **Quality and Reliability.** Ansys solutions are recognized for accuracy that is built on a foundation of 45 years of simulation industry leadership. Ansys’ longstanding presence in the healthcare industry gives confidence that they are a solution partner, not a product vendor.

- **Enterprise Deployment of Technology Across Disciplines from the Desktop to the Cloud.** Engineering organizations typically contain tens and sometimes hundreds of computational tools with high levels of redundancy. The breadth of Ansys solutions across multiple physics, embedded software, systems and functional safety integrated in a single platform enables organizations to deploy a common solution across the enterprise on a range of hardware configurations. This integrated solution method substantially increases engineering productivity, reduces IT and training spending, and streamlines the QA process.

- **Implementation Risk Management.** Deployment of simulation technology capable of modeling the complexity of the human body, complex medical devices or pharmaceutical processes requires not just the tools themselves but also a partnership for implementation. This includes technical support and experts in the industry, as well as a service organization capable of customizing tools and workflows, and improving the skills of the user workforce, so they can be seamlessly integrated into a customer workflow. Ansys has an acknowledged best-in-class customer excellence organization.

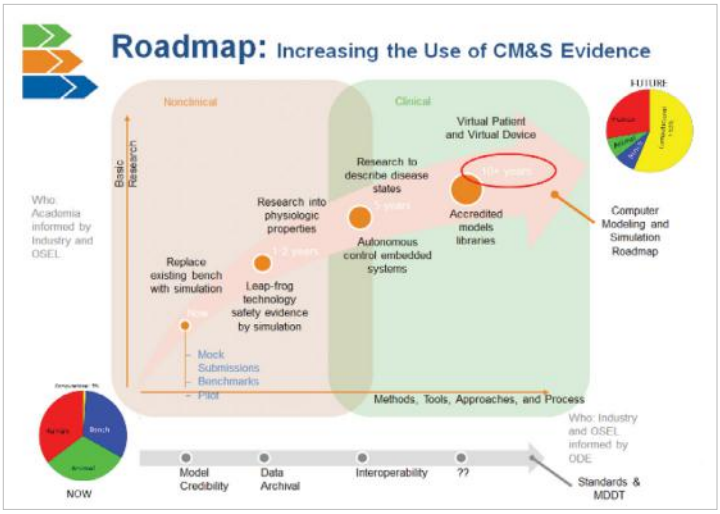
- **Integrated Ecosystem.** Complex product development typically involves a broad range of solution partners. Ansys’ partner ecosystem of industrial, academic, regulatory and policy experts is extensive and open to adapt to the needs of a customer’s end-to-end design process.

/ Conclusion

Just like the in vivo and in vitro revolutions that shaped medicine as we know it today, the in silico technology shift is further accelerating and amplifying the pace of medical innovation without compromising patient safety. Inspired and led by industrial pioneers, regulatory authorities and policy makers are wholeheartedly embracing the movement to encourage and regulate the adoption of engineering simulation for healthcare. The in silico revolution promises to tame unsustainable cost escalation and provide quality healthcare for all.

Several barriers remain for simulation to become as mainstream and standard practice as it is in industries like aerospace, automotive and high-tech. However, as the return on investment continues to be quantified across all sectors of the industry, the in silico disruption, when combined with very low cost and almost limitless compute power, is inevitable.

The question is, are you ready?



/ Learn More

Learn more about how Ansys is enabling customer success in healthcare.

1. Visit **Ansys.com/healthcare.**
2. Join our regular **healthcare webinar series** or watch archived meetings.
3. Contact us: **Contacts and Locations.**

/ References

1. Market data

a. Deloitte Infographic, “2018 Global Health Care Outlook”

b. Frost & Sullivan: **Critical Trends for Healthcare Transformation** (website reached on Feb. 19, 2018)

c. Avicenna Alliance: avicenna-alliance.com

d. **Data World Bank** (accessed March 7, 2018)

e. **Healthcare System Tracker** (Accessed March 7, 2018)

2. Videos

a. **Medtronic: Neuromodulator**

Modeling the untestable behavior of recharging wearables

b. **Starkey Laboratory: Hearing Aid Devices**

Starkey Hearing Technologies uses simulation to speed hearing aid device development and provide a quality product.

c. **Medtronic: Pacemaker**

Medtronic uses simulation to ensure the safety of implantable devices in conjunction with MRI scanners.

d. **Oticon Hearing Device**

Digital Exploration benefits helps Oticon innovative cutting edge designs

f. **Sheffeld Hallam Hospital: Mending a Broken Heart**

Dr Paul Morris, Cardiology Doctor uses CFD to avoid unnecessary invasive measures which are more expensive

f. **Avicenna Alliance: The Future of Si**mulation in Medicine

Adriano Henney, Avicenna Alliance discusses the strategic role of simulation for regulatory approval

g. **In Silico Trials.com**

Luca Emili, CEO In Silico Trials, discusses the importance of simulation to accelerate the FDA approval process

h. **MDIC**

Medical Device Innovation Consortium (MDIC) and FDA develops methods and approaches to facilitate quick approval of new devices.

i. **RPP**

James Kennedy, Director of Healthcare RPP discusses the growing interest of policymakers for Personalized Healthcare

j. **Fluidda**

FluidDA uses simulation to help pharmaceutical companies determine the effectiveness of drugs early in the development process.

3. Webinars

a. **www.Ansys.com/healthcare-webinar**

20+ recordings of webinars where users discuss their adoption of simulation

4. White Papers

a. **Digital System Prototyping for Medical Devices**

Modeling the entire medical device system, including embedded software, accelerates and amplifies innovation

b. **Engineering Simulation: A Promising Tool for Securing**

Regulatory authorities and policy maker encourages the adoption of in silico approach: concrete steps to benefi t from it.

c. **Leveraging Engineering Simulation to Fast-Track Personalized Healthcare**

Simulation is used to design wearable and exploit big data towards personalized healthcare.

/ Case studies

a. **Pharma**

- ASI: The Right Mix
- FluidDA: Taming the Cost of Respiratory Drug Development

b. **Wearables / Diagnosis**

- Medtronic: Charged Up
- Synapse: Wearing a wire
- Starkey: I hear you

c. **Cardiovascular**

- Cardiatis: Innovative at heart
- Shanghai
- Heart to Heart

d. **Orthopedic**

- Cut to the bone
- Boning Up

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