



# Avicenna Alliance

## Association for Predictive Medicine

### Avicenna Alliance Newsletter

#### MARCH – APRIL 2025

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#### Digitalising non-clinical evaluation

By Thierry Marchal

President and Secretary General, Avicenna Alliance

Since the publication of the Medical Device Regulation approved on April 6, 2017 (MDR 2017) and its application on May 25, 2021, we know that results of computational modeling and simulation (CM&S) can be taken into account during regulatory approval in the European Union. The 2017 MDR states in Chapter II Section 10.1.e

- *'Particular attention shall be paid to [...] where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand'*

And later on in Annex VII section 4.5.4.a

- *'The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address [...] the planning, conduct, assessment, reporting and, where appropriate, updating of the pre-clinical evaluation, in particular of [...] the pre-clinical testing, for example laboratory testing, simulated use testing, computer modelling, the use of animal models,'*



However, the applicability of these encouraging statements has not entirely met our expectations:

- The process to validate *in silico* data and models was unclear;
- The data to be reported and the format for reporting this data were not defined in detail in any guideline;
- Finally, Notified Bodies (NBs), which review and approve medical device submissions for the European Union, often lack the knowledgeable resource and expertise to review *in silico* evidence.

As a result, there is very little public information and publication regarding the number, or even existence, of submissions containing *in silico* evidence accepted by European NBs. In the meantime, several medical device manufacturers have mentioned the inclusion of Finite Element Method (FEM) and Computational Fluid Dynamics (CFD) results in submissions. In parallel, leading NBs confirmed having *in silico* expertise within their staff as well as the occasional appearance of digital evidence in submissions.

In a letter sent to the Avicenna Alliance in March 2025 on behalf of the EU Commissioner for Health and Animal Welfare, the European authorities reminded us that: “Data from computer modelling and simulated use testing, including software-based models, are already now recognised as useful sources of pre-clinical data (see guidance [MDCG 2024-10 Clinical evaluation of orphan medical devices](#)).”

Follow up discussions with at least two Notified Bodies confirmed that not only do they have the experienced resources to review *in silico* evidence, there are internal recommendations regarding the information and format required to accept *in silico* evidence in a regulatory submission. Referring to international publications and standards, they explained that it was possible to assess the quality of a CM&S model.

Nothing now prevents medical device manufacturers from starting the conversation with the aim of submitting *in silico* evidence to selected Notified Bodies. Surprisingly, some Notified Bodies have expressed an apparent lack of demand from medical device manufacturers to submit *in silico* evidence; such a clear demand would encourage NBs to invest more for handling this new evidence in the future. More submissions and public comment would now be crucial to ensure that this becomes a routine activity.

Although there is no formal evolution in an already existing regulation, its applicability to non-clinical testing with a view to its partial digitalisation is a major step forward.

Thierry



## Spotlight on the Clinical Deployment Task Force

By Erica Beaucage-Gauvreau & René Bombien  
Task Force Leader & Task Force Co-Chair

[The Clinical Deployment Task Force](#) is gearing up for an ambitious year in 2025, with a clear mission: to expand the network of professionals interested in the clinical application of *in silico* methods and pave the way for their broader adoption in healthcare. As computational modelling and simulation gain traction in medical research and practice, the task force aims to harness this momentum to foster collaboration, gather evidence, and explore pathways for integration and reimbursement.



### Building a Network of Experts

A key priority for the task force is to grow a robust network of professionals with expertise in applying *in silico* methodologies in clinical settings. To achieve this, the team will actively engage with the *in silico* health community, leveraging platforms like LinkedIn to conduct polls and spark conversations. This outreach will not only increase the task force's visibility but also help identify key players who can contribute to advancing these technologies.

### Cataloging Case Studies

Another cornerstone of the 2025 agenda is the development of a comprehensive inventory of *in silico* applications that have already been successfully integrated into clinical practice or are nearing implementation. Through targeted interviews with stakeholders, guided by a structured questionnaire, the task force will gather valuable insights into the challenges and successes faced during the clinical adoption process. These case studies will serve as a resource for identifying best practices and areas for improvement, helping to streamline future deployments.

### Exploring Reimbursement Pathways

*In silico* methods hold immense promise for enhancing patient care and reducing costs, but their adoption hinges on demonstrating value to investors, Health Technology Assessment (HTA) bodies, and payers. To this end, the task force will investigate reimbursement processes for *in silico* approaches, seeking to showcase their economic and clinical benefits. This exploration will provide critical insights into how these methods can secure financial support, ultimately helping to drive broader acceptance and implementation.

As the Clinical Deployment Task Force embarks on these initiatives, the overarching goal remains clear: to bridge the gap between innovation and clinical practice by creating a supportive ecosystem for *in silico* methods. With a strong network, a growing body of evidence, and a focus on sustainability, the task force is poised to make meaningful strides in 2025. Stay tuned for updates as we continue this exciting journey toward transforming healthcare through *in silico* innovation.

### [Poll on Computer Modelling & Simulation](#)

The Avicenna [Clinical Deployment Task Force](#) is engaged to grow a network of professionals with expertise in clinical applications of *in silico* methodologies, to foster collaboration and knowledge exchange.

We kindly ask your collaboration and answer to a 3 questions poll on the use of Computational Modelling & Simulation.



If you are you interested in joining us for a more detailed questionnaire to understand your needs and your questions, please send an email to [manager@avicenna-alliance.com](mailto:manager@avicenna-alliance.com).

[CLICK HERE TO ANSWER THE POLL](#)

## Spotlight on our member Hemolens Diagnostics: Pioneering Innovation in Cardiovascular and *In Silico* Diagnostics

By Ziemowit Ostrowski  
Director CFD

Based in the United Kingdom, the Netherlands, and Poland, [Hemolens Diagnostics®](#) is a forward-thinking MedTech startup at the forefront of cardiovascular diagnostics and *in silico* technologies.

Committed to redefining how heart disease is detected and managed, Hemolens® leverages cutting-edge tools such as **artificial intelligence (AI)**, **biomedical engineering (BME)**, and **computational fluid dynamics (CFD)** to deliver precise, non-invasive diagnostic solutions.

A standout example of Hemolens® innovation is its flagship product, **Cardiolens FFR-CT Pro®**. This advanced diagnostic tool reconstructs the coronary artery lumen from CT scans and, using *in silico* methods, assesses noninvasively the risk of ischemia, decreasing unnecessary invasive procedures. It is a core component of the Cardiolens® Platform—a complementary solution designed to support cardiologists and radiologists in the early detection and personalized management of coronary artery disease (CAD). By enabling earlier diagnosis the Cardiolens® Platform may help optimize clinical decision-making, streamline patient pathways, and improve health outcomes.



Hemolens® technological leadership in cardiac innovations has not gone unnoticed. In 2024, the company was ranked among the top 10 Polish entities (including universities) for patent filings by the European Patent Office, reflecting its strong commitment to research, innovation, and IP development.

Its work is grounded in a multidisciplinary approach that blends clinical expertise, data science, and scalable design, making its solutions suitable for both high-tech hospitals and underserved settings.

As healthcare increasingly shifts toward personalized, data-driven care, Hemolens Diagnostics® is positioning itself as a key player in the global MedTech landscape. With its focus on non-invasive, AI-powered diagnostics, Hemolens® may not only enhance the accuracy and speed of disease detection but also shape the future of preventive cardiology and digital health.



## Why becoming an AA Partner?

By Thierry Marchal  
President & Secretary General  
Avicenna Alliance

Successfully advocating for the adoption and regulation of *in silico* medicine is a major challenge that the Avicenna Alliance has tackled over the last 10 years. We are acutely aware that we cannot succeed alone! Of course, the Avicenna Alliance can rely on its large network of industry members and Avicenna Fellows. We can also count on the crucial support from the academic community through the Virtual Physiological Human Institute, which represents 50% of the Alliance. But that is not enough,



because stakeholders who are willing to improve health care, cover a much wider range of organizations.

With the well-being, and sometimes the lives, of patients at stake, time and efficiency are crucial: we cannot work in parallel, but we absolutely must join forces in a soft but effective way.

The Avicenna Alliance brings a lot of value to this collaboration-, including:

- A team of recognized thought leaders and technical experts
  - Experience of interacting with regulators and policy makers;
  - Access to industry and academic executives;
  - Access to large teams to define and execute roadmap and plans.
- Support from other leading healthcare companies and world-famous academic leaders
- Extensive network across the *in silico* community: industry, academic, clinicians, regulators, some policy makers, some patient organizations
- A wealth of knowledge about *in silico* methods
  - In silico case studies;
  - Most advanced models and technologies;
  - Industry impact and metrics.
- Large library of collaterals (videos, case studies, publications, policy communications, deck, etc.)

In return, we expect our partners to share their vision and guide us on this important journey. We value mutual partnership and participation in our events and their events so that we can continuously expand this community.

Please contact Thierry Marchal ([secgen@avicenna-alliance.com](mailto:secgen@avicenna-alliance.com)) if you would like to become a partner and find out the very simple process (just send in a partner application form) for joining us.



# AVICENNA ALLIANCE PARTNERS



## Avicenna's Webinars Series

by Roberta Maggi  
Office Manager, Avicenna Alliance

Every month, The Avicenna Alliance gives the opportunity to one of its members to present their world-class research. These webinars, alternating academic and industrial speakers, are open to both the Avicenna members and non-members.

This is a unique opportunity to stay up to speed with the fast-progressing *in silico* research and development. These webinars, offering a deep dive into the amazing work by our members, may nicely complement the ongoing research that you are leading and therefore lead to new collaborations to fast-track your work.

Do not hesitate to ask for information if you are interested in contributing as speakers and, if you are not an Avicenna member yet, we will be happy to give you all the information you need to become a member and enjoy all the privileges reserved for our members, including the opportunity to present one of these webinars and gain visibility for your organization and research/project!



All 58 recordings are available in the [members only area](#) of the [Avicenna website](#). Last webinar, held on May 13<sup>th</sup>, is also available in the [public area](#).

For further information, please contact Roberta Maggi [manager@avicenna-alliance.com](mailto:manager@avicenna-alliance.com).

### Our future webinars

- June 10<sup>th</sup>, 2025: **"iSi Health: bringing in silico technologies from bench-to-bedside"** by Erica Beaucage-Gavreau from KU Leuven – [Click here to register](#)
- July 8<sup>th</sup>, 2025: **"Biomechanical digital twins in cardiovascular medicine"** by David Perrin from Predisurge – [Click here to register](#)

### Our most recent webinars

- May 13<sup>th</sup>, 2025: **"Revolutionizing Drug Discovery and Development with AI-Powered *in silico* Solutions"** by Luca Emili from InSilico Trials – [Watch the recording](#)

*This webinar will demonstrate how InSilicoTrial's technology delivers a more efficient and cost-effective drug development pathway, significantly reducing the need for early-stage human trials and enhancing decision-making.*

- April 8<sup>th</sup>, 2025: **"ERAMET – building a transparent ecosystem for orphan and paediatric drug developmen"** by Prof Ine Skottheim Rusten from Systems Resource Lab AS (SRLAB) – [Watch the recording](#)

*In this talk, five use-cases, including paediatric extrapolation and characterisation of drug benefit/risk in selected groups of rare diseases, will be presented. Each of the use-cases is planned to lead to the submission and regulatory approval. Training will be offered in order to familiarise regulatory assessors, drug developers and clinical researchers with these new approaches.*

- March 11<sup>th</sup>, 2025: **"How to design, manufacture, and optimise drugs and regenerative medicine using in silico methods?"** by Himanshu Kaul from University of Leicester – [Watch the recording](#)

*The use of in silico approaches to design, manufacture, and optimise therapies (both drugs or cell-based) is a potentially powerful approach to addressing this challenge. However, a lack of multiscale methods that can couple gene regulatory network activity to higher level cellular activity and spatial*



*gradients is a critical barrier to this. In this talk, I will elucidate ways in which various in silico modalities are being successfully coupled to predictively engineer patient-specific therapies.*

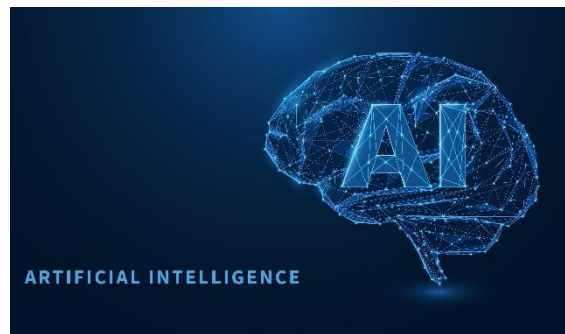
**58** recording are available online. Learn more about what other members are doing.

[Watch the recording](#)

## EU Policy and Regulatory updates

### Researchers and innovators invited to shape Europe's AI Strategy in Science

The European Strategy for Artificial Intelligence (AI) in Science is set to accelerate the responsible integration of AI across research disciplines. This initiative will support scientists throughout the EU in adopting AI technologies, driving advances in critical fields such as health, climate, and clean technologies. The European Commission has launched two consultations - a call for evidence and a targeted questionnaire - encouraging researchers and innovators to contribute.



A key element of the strategy is the creation of the European AI Research Council, known as RAISE (Resource for AI Science in Europe), which will consolidate resources and foster AI development and application across scientific domains.

AI is already transforming areas like medical diagnostics, drug discovery, climate modelling, and materials science. The strategy aims to build on these achievements by enhancing access to AI tools, computing infrastructure, and by attracting talent and investments, strengthening EU innovation and competitiveness.

Additionally, the European Research Area Forum has released an updated version of its 'Living Guidelines on the responsible use of Generative AI in research,' offering timely guidance to help the research community responsibly navigate AI's rapid evolution.

Link to updated edition of the European Research Area Forum '[Living Guidelines on the responsible use of Generative AI in research](#)'

[Link to Call for evidence](#)

[Link to targeted questionnaire](#)

Both consultations remain open until 5 June 2025.

### EMA qualifies first artificial intelligence tool to diagnose inflammatory liver disease (MASH) in biopsy samples



On 20 March 2025, the European Medicines Agency (EMA) issued its first **Qualification Opinion (QO)** on an artificial intelligence (AI)-powered tool designed to assist pathologists in diagnosing and grading metabolic dysfunction-associated steatohepatitis (MASH) during clinical trials. This milestone marks the EMA's Committee for Medicinal Products for Human Use (CHMP)'s first endorsement of an AI-based development methodology, confirming that evidence generated using the tool can be considered scientifically robust in future submissions for

MASH therapies.

MASH is a progressive liver condition characterized by fat accumulation, inflammation, and fibrosis, unrelated to alcohol use. It is often associated with metabolic conditions like obesity, type 2 diabetes, and hypertension and, if left untreated, may progress to severe liver disease.

The **AIM-NASH tool**, validated through a clinical study comparing its performance to human pathologists, demonstrated improved reproducibility and consistency in assessing disease activity. By reducing variability in clinical trials, the tool could accelerate the development and approval of new treatments for MASH.

**Full information** can be found [here](#)

### MEPs blueprint to boost Europe's research and innovation

On 11 March 2025, Members of the European Parliament (MEPs) put forward a report urging stronger research and innovation capacities in view of the upcoming 10th Research Framework Programme (FP10). They advocate for FP10 to become an independent EU programme with a significantly increased budget, supporting the goal of investing 3% of GDP in R&D and funding at least 75% of excellent proposals.



Recognising the administrative hurdles faced by participants, MEPs stress the urgent need to radically simplify both application and management processes. Drawing on stakeholder input, they suggest FP10 should pursue three key objectives:

- Fostering a European competition of ideas, ensuring smoother transition from basic research to innovation scale-up;
- Supporting strategic research initiatives requiring large-scale, cross-border collaboration;
- Deepening the European Research Area.

They further call for enhanced budgets and autonomy for the European Innovation Council (EIC) and the European Research Council (ERC), vital to drive disruptive innovation and high-risk research addressing societal challenges.

Additionally, MEPs champion mission-driven programmes, promoting bottom-up research and interdisciplinary collaboration, while highlighting the need to maintain international cooperation and uphold academic freedom throughout the EU and its partner countries.

**Full information** can be found [here](#)

### Commission adopts proposal for the next European Research Area Policy Agenda 2025-2027

On 28 February 2025, the European Commission presented its proposal for a Council Recommendation on the European Research Area (ERA) Policy Agenda 2025-2027. This proposal reflects extensive collaboration among the Commission, EU Member States, Horizon Europe Associated Countries, and stakeholders, who together shaped the agenda within the ERA Forum.



Building on the first ERA Policy Agenda 2022-2024, the new agenda serves as a strategic roadmap for the next three years, focusing on key areas such as open science, research assessment reform, and fostering research careers. It aims to translate the priorities set in the Pact for Research and Innovation into concrete actions, supporting the EU's long-term vision for research cooperation.

The proposed agenda is structured around three pillars:

1. A policy narrative framing the ambitions, achievements, and lessons learned.
2. ERA structural policies and targeted actions addressing emerging challenges like AI in science, research security, and science-for-policy collaboration. Expected deliverables include a roadmap for AI in science, reinforced cooperation on research security, and the establishment of a science-for-policy observatory.
3. An annex presenting concise workplans for each policy area and action, based on ERA Forum co-created documents.

The Council is expected to adopt the ERA Policy Agenda 2025-2027 in May 2025, during the Polish Presidency.

**Full information** can be found [here](#)

## Recent news

### [The Avicenna Alliance Publishes its Fourth Edition of the In Silico Medicine Glossary](#)



in the “*in silico*” landscape.

The Avicenna Alliance is pleased to announce the release of its Fourth Edition of the Avicenna Alliance Glossary, an essential resource aimed at defining and clarifying key concepts in the field of *in silico* medicine.

In the scientific literature, occasional confusion and diverging opinions can lead to misunderstandings regarding certain *in silico* concepts. To address this, a dedicated team of academic and industry members of the Avicenna Alliance has worked together to develop clear, consensus-based definitions of terms regularly used

This latest edition features an expanded list of definitions, reflecting the ongoing evolution of the field. We recognize that different interpretations / definitions may exist and we welcome your feedback, as the glossary is intended to grow and adapt over time.

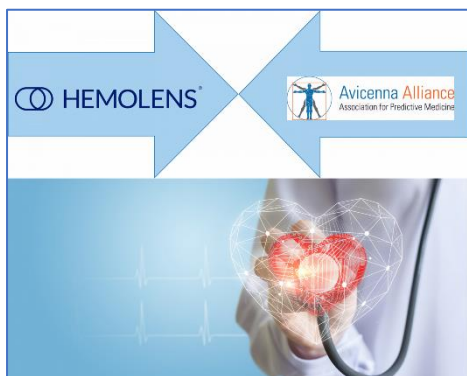
Future editions will continue to refine existing definitions and introduce new concepts to further support clarity and consistency.

We invite you to explore the updated glossary and share your comments or suggestions with Roberta Maggi at [manager@avicenna-alliance.com](mailto:manager@avicenna-alliance.com).

Special thanks and recognition go to the contributors — among other Avicenna Members — who revised the glossary during this and previous editions.

[Click here to explore the Glossary](#)

### [Welcome on Board, Hemolens Diagnostics!](#)



We are delighted to welcome Hemolens Diagnostics as a new member of the Avicenna Alliance!

Based in Poland, Hemolens is an innovative MedTech startup at the forefront of cardiovascular diagnostics and *in silico* technologies.

Hemolens was recently ranked among the top 10 Polish entities for patent filings in 2024 by the European Patent Office—a testament to their commitment to innovation.

Their flagship product, **Cardiolens FFR-CT Pro**, exemplifies **Hemolens'** advanced capabilities: a non-invasive diagnostic tool that reconstructs coronary arteries from CT scans, using **AI, BME, and CFD** to assess the risk of ischemia. It is part of the **Cardiolens Platform** – an integrated suite developed to support cardiologists and radiologists in accurate, early detection and management of coronary artery disease.



The technology enables earlier diagnosis and risk assessment, helping to optimize patient pathways and improve outcomes.

We're thrilled to have **Hemolens'** expertise onboard and look forward to collaborating with them in shaping the future of predictive medicine.

[Learn more about Hemolens Diagnostics](#)

### [Poll on Computer Modelling & Simulation](#)



The Avicenna [Clinical Deployment Task Force](#), led by Co-Chairs Erica Beaucage-Gauvreau & René Bombien, is engaged to grow a network of professionals with expertise in clinical applications of in silico methodologies, to foster collaboration and knowledge exchange.

We kindly ask your collaboration and answer to a 3 questions poll on the use of Computational Modelling & Simulation.

If you are you interested in joining us for a more detailed questionnaire to understand your needs and your questions, please send an email to [manager@avicenna-alliance.com](mailto:manager@avicenna-alliance.com).

[CLICK HERE TO ANSWER THE POLL](#)

### [April 8th - Avicenna Webinar on ERAMET: Advancing Orphan & Paediatric Drug Development](#)



Join Next Avicenna Webinar on ERAMET: Advancing Orphan & Paediatric Drug Development! The EU-funded ERAMET project is transforming how orphan and paediatric medicines are developed. By integrating advanced Computational Modelling & Simulation (CM&S) techniques with real-world data, ERAMET is building a transparent ecosystem to support both medicine developers and regulators.

**Date: April 8, 2025**

**Time: 5:00 PM CET**

This ecosystem is built on three pillars

- A repository connecting key drug development questions, data & methods
- High-quality standards for data and analytical validation
- A knowledge-enhanced AI system to streamline CM&S credibility assessment

Applied to five use cases—including paediatric extrapolation and rare diseases like ataxia and bronchopulmonary dysplasia — ERAMET aims to accelerate regulatory approval and bring life-changing medicines to vulnerable patients faster.

With expert Dr [Ine B Skottheim Rusten](#) leading the discussion, this Avicenna Alliance webinar is a must-attend for anyone in drug development, regulatory science, and healthcare innovation.

### [Avicenna Alliance at the IMDRF meeting in Japan – 10/14 March 2025](#)



This year's International Medical Device Regulators Forum (IMDRF) was organized by the PMDA, taking place in Tokyo.

As an observer to IMDRF, the Avicenna Alliance was invited to attend the open sessions, which provided the opportunity to network with global Regulatory Authorities, the WHO, Trade Organizations, and industry representatives. The Alliance was represented by Marc Horner (Ansys), who leads the [International Affairs Working Group](#) for the Alliance. Marc connected with many active and affiliate members to discuss the growing importance of *in silico* methods and the need for global

harmonisation to maximise the utilisation/benefits of *in silico*.

One exciting observation was the result of a recent member survey, where *in silico* was a common topic highlighted by members as needing regulation. It is one of many topics however, so the question now is how to support the prioritization of *in silico* for immediate guidance development. The Avicenna Alliance welcomes your ideas on how to accomplish this goal.

The date of the Fall meeting has not yet been announced. Please follow this page so to receive the latest updates on global harmonisation, IMDRF, and other *in silico* news.

### [Avicenna Alliance Submits MDR Revision Proposals to the European Commission](#)



The Avicenna Alliance is pleased to announce that, in a letter sent to the European Commissioner for Health and Animal Welfare, Olivér Várhelyi, we have formally submitted our proposals for the revision of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) to the European Commission.

Our recommendations align with the European Parliament's recent resolution, calling for urgent action to address regulatory bottlenecks, improve efficiency, and support innovation in the European medical device sector. A key focus of our proposals is the acceptance of digital evidence from *in silico* methods for pre-clinical AND clinical investigation, including *in silico* clinical trials (ISCT), to accelerate market access while ensuring patient safety.

We will continue to work closely with EU policymakers and stakeholders to ensure that the regulatory framework remains predictable, efficient, and innovation-friendly.

[Read more about our proposals here](#)

## Members Corner

### Events

#### Orthopaedic Surgical Manufacturers Association (OSMA) Spring Meeting



Among others, our members [Mathieu Rimaud](#) from TwinSight, [Marc Horner](#) from Ansys, and [Luca Emili](#) from InSilicoTrials attended the [Orthopaedic Surgical Manufacturers Association \(OSMA\)](#) Spring Meeting, which focused on cutting-edge topics such as AI/ML, cybersecurity, SaMD, PMS opportunities, smart implants, *in silico* evidence, EU regulations, digitalization in documentation, and patient-specific implants.

#### "In Silico for Cardiovascular Devices: Progress & Real-World Use"

Online free webinar (Zoom), organized by [Bio2Device Group](#)  
June 10 - 6:15 pm - 8:30 pm PT

Find out how far *in silico* methods have really come: [Kristian Debus](#), Virtonomy's CCO, will talk about recent progress across regulatory, industry, and software landscapes, while [John Wesley Benjamin](#), Virtonomy's Simulation Team Lead, will share real-world examples of how simulation is used throughout the device lifecycle from design to clinical phases.

This is a great opportunity to hear from experts and get a practical view of where this exciting field is headed.

A promotional graphic for a webinar. On the left, there are two headshots: Kristian Debus, PhD, CCO US, and John Benjamin, Simulation Team Lead. Below them is the text "[FREE WEBINAR]" and "IN SILICO FOR CARDIOVASCULAR DEVICES: PROGRESS &amp; REAL-WORLD USE". A purple box contains the date and time: "June 10 | 6:15 pm - 8:30 pm PT". A paragraph of text describes the webinar content. On the right, there is a 3D medical illustration of a human pelvis and lower torso, showing a blue and purple vascular or structural model.

[More info](#)

[Link to participate](#)

## Publications

### Team NB published a Position Paper on European Artificial Intelligence Regulation



On 14 April 2025, Team-NB published an updated Position Paper on the EU Artificial Intelligence Act, highlighting key implementation challenges. The paper stresses the urgency of designating Notified Bodies (NBs) for high-risk AI systems, warns of bottlenecks in the designation process, and calls for leveraging existing MDR/IVDR frameworks. It also raises concerns about resource gaps and the need for specialized expertise. Team-NB urges early engagement between manufacturers and NBs to ensure timely compliance and market access.

[Read the full document](#)

### Team NB published a position paper outlining "guidance for preparing technical documentation" for medical device submissions

On 9 April 2025, the Association of Notified Bodies adopted the updated 3rd version of its Best Practice Guidance on technical documentation submission under MDR (EU) 2017/745. The paper offers a harmonized framework to support manufacturers in structuring technical documentation for medical devices, clarifying key requirements of Annexes II and III. It includes good practices, examples, and tips to improve dossier clarity, traceability, and alignment with notified bodies' expectations, ultimately streamlining the conformity assessment process.



[Read the full document](#)

### Code & Cure - Episode 9: Beating childhood cancers with *in silico* medicine

Child cancer is one of the most feared diseases worldwide, as the stakes are high for the patients, as well as doctors and families alike. In the 9th video of the Code and Cure series, we will explore how computer models can simulate how a tumour will respond to chemotherapy to help doctors refine their chemotherapy schemes for fragile patients.



[Click here for the podcast](#)

## Code & Cure - Episode 8: Digital hearts - The future of cardiovascular medicine

Heart diseases are the leading cause of death worldwide, with conditions like arrhythmia and atrial fibrillation often requiring implanted devices such as pacemakers and occluders. Discover how *in silico* medicine enables clinicians to virtually test these devices, optimising selection and improving surgical precision.



[Click here for the podcast](#)



## Other News and interesting links

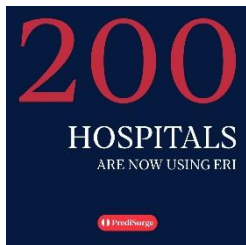
### Advancing Digital Drug Development for Prostate Cancer



InSilicoTrials and COSBI have expanded their collaboration by integrating two advanced **prostate cancer models** into the InSilicoTrials platform. These models help accelerate safer, more effective therapies by supporting immunotherapy strategies and optimized protocols for CRPC, reinforcing our commitment to advancing accessible, impactful simulation technologies in drug development.

[Read the press release](#)

### ERI in 200 hospitals



Great news for the progress of *in silico* methods!

Our member Predisurge celebrates an important milestone: the Endoleak Risk Index (ERI) is now supporting clinical decisions in 200 hospitals across several countries. A special thank you to all clinicians and partners for their continued trust in *in silico* technology to enhance data-driven endovascular care.



Interested by this content and being an actor of the *In silico* evolution?

[Contact us](#)

**Join the Avicenna Alliance!**

