Avicenna Alliance
Association for Predictive Medicine

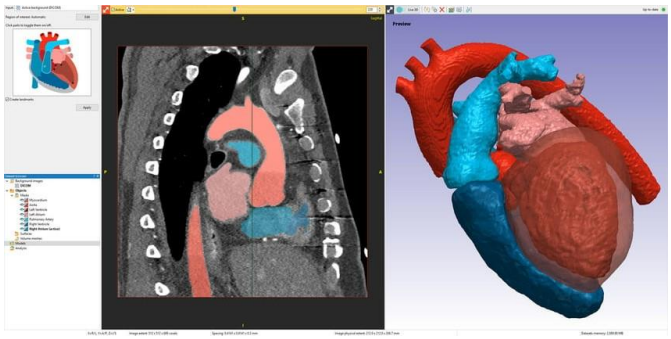
Avicenna Alliance Newsletter
JULY – AUGUST 2025

In this Newsletter

Towards Personalized Healthcare

By Thierry Marchal
President and Secretary General, Avicenna Alliance

The remarkable progress made by segmentation tools such as Simpleware, Mimics, Amira, etc., which are increasingly leveraging AI in smart ways, as well as the integration of AI technology into medical imaging equipment, greatly simplify the process of moving from the patient, in fact from medical imaging, to 3D or 4D patient specific model of any of us.



This technology is very important for feeding future *in silico* clinical trials with virtual patients. Thanks to statistical shape modelling technology (SSM), it is also possible to create an unlimited number of patient realistic models while avoiding any patient privacy issues: a major step towards the systematic adoption of *in silico* clinical trials.

As we rapidly move in this direction, it is urgent to think about the next logical step: personalised healthcare. Indeed, if it is possible to easily, quickly and reliably move from your body to a 3D or 4D model of your organ(s), it becomes easier to PREDICT the progression of a potential pathology in your own body. It would be even more important to PREVENT the negative, and

sometimes fatal, evolution of this pathology by testing different treatments and selecting the most effective and efficient one. This is clearly a dream come true for humanity.

Personalised healthcare will have multiple benefits. Indeed, although 'one size fits all' treatments have been very useful, it does not take into account the wide variability of human beings or the different stages of progression of a disease. The ability to move from a given patient at a given time to their digital twin would allow different treatments to be tested quickly, providing additional information to the doctor or the clinician for her/him selecting the best solution, taking into account recovery time, inconvenience during treatment, durability, cost, etc.

By browsing through the numerous webinars recorded by the Avicenna Alliance or the presentations given during the Avicenna Days, you will find numerous examples of emerging or well establish personalized healthcare applications. This includes the many pediatric patients treated by Prof David Hoganson, the creation of digital twin of cancerous tumours by Prof Maria Angeles Perez, start-ups such as Predisurge or Twinsight for cardiovascular and orthopedic pathologies respectively, not to mention the INSIGNEO's work recently presented by Enrico Dall'Ara and Prof Yu Feng in-depth studies on respiratory pathologies, to name a few.

"We are not there yet", is what I hear regularly. I disagree with this statement. There are now many applications of personalised medicine commonly available to patients. With the rapid advances in *in silico* medicine, personalised healthcare will become more common every year. Of course, we are not yet able to accurately predict how any human body will evolve in all circumstances. But our goal is to humbly to provide assistance to the medical staff for improving patient comfort and saving as many lives as possible. And we can start today.

Thank you for your continued commitment to *in silico* medicine to better care for patients.

Spotlight on the Public & Patient Involvement (PPI) Task Force

By Cyrille Thinnes
Task Force Leader

Putting patients at the centre: how the Avicenna Public & Patient Involvement (PPI) task force is shaping the future of *in silico* medicine

The Avicenna Alliance's Public & Patient Involvement (PPI) Task Force is on a mission: to ensure that the development of *in silico* medicine is deeply rooted in addressing patient needs, priorities, and perspectives. By connecting innovation with lived experience, the Task Force is striving to make digital healthcare solutions more accessible, trustworthy, and impactful.

From dialogue to partnership

The Task Force believes that patients shall be integral partners in advancing *in silico* medicine. Recent meetings have focused on building capacities for structured engagement with patient organisations, ensuring their voices are heard early in the innovation process. Plans are underway to invite representatives from umbrella organisations and networks to selected meetings, offering them an active role in shaping discussions, co-authoring publications, and contributing case studies and testimonials.

These exchanges will go beyond information sharing, creating a genuine two-way dialogue where patients and experts learn from each other. The aim is simple but powerful: embed the patient voice into every step of *in silico* medicine's journey, from research and regulation to real-world application.

Clearer language, wider reach

One of the challenges in patient engagement is enabling access to a field which tends to be riddled with technical jargon. Insights from patient workshops show that while some technical terms, like *in silico*, need explanation, others such as "digital twin" are instantly relatable and build trust.

To bridge communication gaps, the task force has published its glossary and all publications on its website and will translate key resources into multiple languages. Native speakers will review these translations to ensure clarity and cultural relevance, helping to reach patients across borders.

Case studies that inspire

Real-world examples are essential for showing how *in silico* methods can make a difference. The task force is currently gathering case studies, with a focus on rare diseases and children's health. The aim is to compile a portfolio of use cases, to showcase the positive societal impacts of *in silico* medicine and spark discussion and collaboration among diverse stakeholders.

Addressing concerns, building trust

A recent patient organisation survey revealed promising awareness levels—75% recognised the potential of *in silico* methods—but also identified key challenges. Privacy, over-reliance on technology, and mistrust of industry remain concerns for some groups. The Task Force is committed to addressing these openly through transparent communication and clear safeguards, ensuring patient trust is earned and maintained.

Looking ahead

The months ahead will see the Task Force deepening collaborations, developing training materials to foster best practices in effective PPI, publishing a position paper, and gathering new examples of how patient involvement can drive *in silico* medicine progress. By combining strategic outreach, accessible communication, and compelling storytelling, the PPI task force is ensuring that innovation in *in silico* medicine is guided by the very people it strives to benefit.

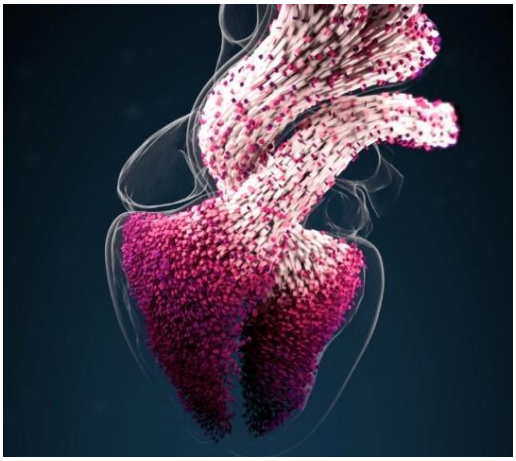
Spotlight on our member ELEM Biotech

By Christopher Morton, Business Executive and CEO and Mariano Vazquez, CTO / CSO

ELEM Biotech: V.HEART, Virtual Humans for Cardiac Safety

Promising drugs have reached patients only to be withdrawn after unexpected cardiac side effects. Each withdrawal is more than an industry setback—it disrupts lives, ends treatments, and erodes trust.

ELEM Biotech tackles this challenge with **V.HEART**, a high-performance platform for cardiac Virtual Humans or digital twins of the human heart. In a recent collaboration with a major pharmaceutical company, V.HEART simulated the effects of candidate compounds on cardiac rhythm, with a focus on QT interval prolongation—a key marker of proarrhythmic risk.



V.HEART's predictions aligned with clinical trial results and, importantly, leaned on the side of caution—ensuring safety signals were not underestimated. By modelling diverse virtual populations, including sex-specific differences, it delivered insights that animal models cannot provide—the outcome: earlier risk detection, fewer late-stage failures, and faster development decisions.

The FDA and EMA's commitment to **New Approach Methodologies (NAMs)** is creating real opportunities to strengthen drug safety for patients while reducing reliance on animal testing. Published V.HEART cases, mindful of the latest ICH E14/S7B guidance, also show how NAMs are transitioning from regulatory vision to real-world practice.

With over 5,000 virtual human cases, ELEM illustrates that *in silico* trials are a practical tool for safer and more efficient drug development, reducing the time and cost to bring life-saving medications to patients.

These achievements not only advance the Avicenna Alliance's mission but also reflect ELEM's roots as a *spin-off* of the Barcelona Supercomputing Center—where scientific excellence meets healthcare innovation.

Spotlight on our Partner iSi Health

By Erica Beaucage-Gauvreau
Insitute Manager, iSi Health

Breaking Boundaries in *In Silico* Health: Reflections from the KU Leuven iSi Health Symposium

On Friday, 12 September 2025, the historic city of Leuven became the stage for an exciting exchange of ideas at the **iSi Health KU Leuven Institute Symposium**. Among the highlights of the day was the panel *"Q&A with Industry: Discipline Borders"* moderated by Avicenna Alliance President and Secretary General **Thierry Marchal**.
The room was alive with curiosity and anticipation as a distinguished panel – **Ilse Sienaert, Anne-Gaelle Dosne, Charles Taylor, and Roger Assaker** – took the stage. Their mission? To confront some of the toughest questions standing in the way of healthcare innovation.
The conversation moved quickly to the heart of the matter:

- How can we **build confidence in *in silico* methods** so that patients, clinicians, and regulators alike can trust digital simulations to guide healthcare decisions?
- What can be done to **overcome regulatory inertia in Europe**, where groundbreaking technologies often move faster than the frameworks meant to govern them?
- And how do we **foster entrepreneurship in healthcare**, ensuring that visionary ideas don't remain in labs but reach the patients who need them most?

The insights shared were both inspiring and sobering. Each speaker drew not only on their successes but also on the lessons learned through challenges and setbacks. The result was a rich and honest discussion – one that underscored the importance of collaboration, resilience, and vision in shaping the healthcare of tomorrow.
Together, we took an important step forward, pushing the boundaries of science and innovation to improve patient well-being.

iSi Health: Where Physics Meets Medicine

Behind this symposium stands the driving force of **iSi Health** – the **KU Leuven Institute of Physics-based Modelling for *In Silico* Health**. Established to unite expertise across KU Leuven and UZ Leuven, the institute is pioneering a future where **digital twins** and ***in silico* trials** are not the exception, but the norm.
The work of iSi Health spans many fronts. Researchers develop **physics-based simulations** that replicate biological processes at every scale – from molecules and cells to organs and the human body as a whole. These models hold the potential to transform medicine, allowing clinicians to test therapies in a virtual space before applying them to real patients.

But science alone is not enough. iSi Health is also addressing the essential questions of **credibility, ethics, regulation, and economics**. By promoting rigorous standards of validation and fostering dialogue between

engineers, clinicians, regulators, and entrepreneurs, the institute ensures that *in silico* medicine doesn't remain a visionary concept but becomes a trusted reality in clinical practice.
Through **education and training**, iSi Health is shaping the next generation of innovators, equipping young scientists and healthcare professionals with the skills to thrive at the intersection of physics, computation, and medicine. And by acting as a hub for **collaboration and networking**, the institute brings together diverse disciplines to solve shared challenges.

A Vision for the Future

The story of iSi Health is one of ambition and transformation. Its vision is clear: a healthcare system that is **safer, more personalized, and more efficient**. A system where *in silico* clinical trials reduce costs and risks, where digital twins help doctors make better decisions, and where patients benefit from treatments tailored precisely to their needs.
As the symposium in Leuven reminded us, achieving this vision requires courage, dialogue, and perseverance. And thanks to initiatives like iSi Health, supported by passionate leaders and forward-thinking entrepreneurs, the future of healthcare is already being written – one simulation at a time.

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 62 recordings are available in the members only area of the Avicenna website. Last webinar, held on 9 September 2025 is available in the public area too.

For further information, please contact Roberta Maggi manager@avicenna-alliance.com.

Our future webinars

- 7th October 2025: **"Stratification of patients with spine metastases at high risk of fracture: from biomechanical analyses in the laboratory to an *in silico* clinical tool"** by Enrico Dall'Ara from University of Sheffield – Click here to register
- 11 November 2025: **"Real-Time Medical Digital Twins: Geometry, Simulation, and Immersive Interaction"** by Marco E. Biancolini from RBF Morph – Click here to register

Our most recent webinars

- 9 September 2025: **"Credibility Assessment of the FDA's MDDT-qualified 'Endpoint - numaScrew Virtual Pullout Test' model"** by David Benoit and Julien Clin from Numalogics – Watch the recording

  This webinar will outline the end-to-end process of achieving formal qualification of a computational model and simulation (CM&S) tool through the FDA's Medical Device Development Tools (MDDT) program. Specifically, it will detail the methodology used to establish the credibility of 'Endpoint – numaScrew Virtual Pullout Test' model, which is designed to replicate screw pullout behavior in synthetic bone foam, consistent with ASTM F543-A3..

- 26 August 2025: **"*In silico* medicine and digital twins through the foundational paradigm of *in silico* oncology: historical landmarks and current evolutionary status"** by Georgios Stamatakos from NTUA – Watch the recording

  This webinar will present a brief, yet comprehensive, overview of the formal emergence of in silico medicine through its foundational paradigm of in silico radiation oncology in 2002 and the current evolutionary status of in silico oncology, including cancer digital (virtual) twins, in conjunction with expected future accomplishments, will be sketched.

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

EU Policy and Regulatory updates

Questionnaire from the EU Commission

The EU Commission wants to draw up guidelines and a code of practice for the transparency of AI systems in accordance with Article 50 of the AI Act.
The consultation consists of a questionnaire that providers and operators of corresponding AI systems can answer from now until **October 2, 2025.**

- Press release on the consultation
- Questionnaire of the consultation

In addition, the Commission offers stakeholders the opportunity to participate in the preparation of the Code of Practice. You can also contact the Commission **until 2 October 2025** :

- Communication from the Commission on the Code of Practice
- FAQ on the Code of Practice and the Guideline on Transparency

The transparency obligations for providers and operators of corresponding AI systems will apply from 2 August 2026.
BvMed Trade association recommend that affected companies participate in the consultation individually.

European Commission's Call for Evidence (future oriented) for the targeted revision of the MDR and IVDR.

This is an opportunity for Avicenna's members to contribute individually and talking about acceptance of digital evidence.

The revision aims to streamline and future-proof the regulatory framework of MDR and IVDR by reducing administrative burden, enhancing predictability and cost-efficiency, while safeguarding patient safety.

Other key aspects:
- Targeted consultations are foreseen (with focus on SMEs)
- No public consultation, no impact assessment
- Call for Evidence is open until 6 October on the 'Have Your Say' platform

Link to Call

Civil Protection Mechanism Update

On 17 July 2025 a proposal was made to update the EU Civil Protection Mechanism, integrating health emergency preparedness and response. The new regulation proposes around €11 billion in funding to enhance the EU's capacity to detect, monitor, and combat cross-border health threats, including pandemics and non-communicable diseases.
Read more

Programme of the 2025 Danish Presidency of the Council of the European Union

From 1 July to 31 December 2025, Denmark will hold the Presidency of the Council of the European Union.
Recognising rising global competition, the Danish Presidency emphasises that the green transition and life sciences must be tightly interwoven with competitiveness policy. Reforms will boost sustainable growth, with climate, energy, and **health driving EU competitiveness**.

The Presidency's top priority is securing agreement on the **pharmaceutical package** to improve patient access, stimulate innovation, and streamline regulation. It will also advance the critical medicines proposal to strengthen supply chains and reduce dependency on non-EU sources.

Explore the full programme here.

Study on AI in Healthcare

On 8 August the Commission published a study on the deployment of artificial intelligence in healthcare. The study provides insights into the current state of AI applications in healthcare settings and discusses challenges and opportunities for their integration.
Read More

Cybersecurity Action Plan for Healthcare Providers

On 8 August a comprehensive action plan was launched to improve the cybersecurity of hospitals and healthcare providers across the EU. The plan focuses on prevention, detection, response, and deterrence to strengthen the security of health systems against cyber threats.
Read more

EU4Health Programme Developments:

Targeted Consultation for 2026 Work Programme (August 7): The Commission launched a consultation inviting stakeholders to share their views on future priorities for the EU4Health programme. This consultation aims to inform the 2026 Annual Work Programme and shape the EU's strategic direction on public health.
Read more

Call for Tenders on Substances of Human Origin (August 4): The European Health and Digital Executive Agency (HaDEA) published a call for tenders to support joint work among EU countries in the field of Substances of Human Origin (SoHO). The objective is to ensure the safety and quality of SoHO therapies and improve patient access to these treatments.
Read more

Medical Countermeasures Strategy

On 9 July 2025 **t**he Commission launched a new strategy to enhance the EU's response to health emergencies. It focuses on developing next-generation flu vaccines, new antibiotics to combat antimicrobial resistance, antivirals for insect-borne diseases, and dual-use countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats. This initiative aims to bolster the EU's health security and support innovation in the biotech sector. Read more

Commission facilitates data access for researchers under the Digital Services Act

Through an initiative under the Digital Services Act (DSA), the European Commission helps qualified researchers access internal data of very large online platforms (VLOPs) and search engines (VLOSEs) in the European Union.

These rules will enable independent research into the systemic risks and mitigation measures of VLOPs and VLOSEs.
Through a delegated act, the Commission is clarifying how VLOPs and VLOSEs should share data with qualified researchers, detailing the legal and technical requirements for data access. It also establishes a new online DSA data access portal for researchers to find information and communicat e with VLOPs, VLOSEs, national authorities, and the Digital Services Coordinators (DSCs).

Researchers must be vetted by a DSC to access internal data. On June 27, the Board of Digital Services Coordinators endorsed an intention for further cooperation among all DSCs to uniformly implement the vetting and data access procedures.
The European Parliament and Council now have three months to review the delegated act, which will enter into force at the end of this period, upon publication in the Official Journal. At that time, the first researchers can submit their application to access platforms' internal data.
This regulation complements the existing DSA obligation for VLOPs and VLOSEs to provide access to researchers to data publicly available on their interfaces.

Read more information about the adoption of the delegated act.

High-level multistakeholder workshop AI Compute Stack

On 7 July 2025 in Brussels, th e European Commission hosted a high-level workshop on the AI Compute Stack.
The amendment sets out EU support to the establishment of ultra-scale AI Gigafactories - world-class compute infrastructure designed to develop, train and run the next generation of v ery large AI models, supporting the objectives of the AI Continent Action Plan.

The proposal also introduces a dedicated Quantum Pillar, as a first action of the Quantum Europe Strategy published on 2 July 2025.

Next steps

The proposal will now undergo the legislative consultation procedure in the Council, with the European Parliament providing its opinion.

More information will be available soon on the EuroHPC webpage

Recent news

[iSi Health Symposium: Virtual Twin Driving Healthcare 2.0, 11–12 September 2025 in Leuven]

Join the iSi Health Celebrations – 600 Years of KU Leuven! Be part of the future of healthcare at the iSi Health Symposium: Virtual Twin Driving Healthcare 2.0, taking place on 11–12 September 2025 in Leuven, Belgium.

Two days packed with inspiration:

- World-class **keynotes**
- Clinician and patient perspectives
- Legal & regulatory insights
- Industry sessions & interactive Q&As
- Exhibition of cutting-edge virtual human twin projects

This will be a fantastic opportunity not only to contribute to the discussions and explore the many perspectives of virtual twins driving healthcare—from clinicians, to patients & the public, to industry, to regulators—but also to connect in person with members of the **InSilicoHealth network** and beyond.

Don't miss this unique chance to shape the next era of *in silico* health and celebrate six centuries of innovation at KU Leuven!

Save the date and join the iSi Health Celebration in Leuven.

Programme

Registration

[Avicenna Alliance at the first Strategic Day and General Assembly of the SILICA Alliance in Paris]

In 2023, the Avicenna Alliance was proud to have contributed to the creation of SILICA, whose mission is to promote, organise and facilitate scientific, educational and research activities related to artificial health data.
On 8 July 2025, Thierry Marchal, President and Secretary General of the Avicenna Alliance, participated in the first Strategic Day and General Assembly of the SILICA Alliance held in the office of UniCancer in Paris. With its focus on artificial data and its use to accelerate clinical trials, SILICA is an interesting and powerful complement to the Avicenna Alliance.

It was a fantastic experience to be able to exchange ideas with people who have similar, albeit slightly different, objectives. Divided into two working groups, Methodology and Access to Authorities, the members developed a concrete action plan with deliverables and timing. For the Avicenna Alliance, a better understanding of each stakeholder's objectives facilitates fruitful and effective activities.

Our mutual collaboration allows the two organisations to work closely together, minimising overlap in order to maximise rapid impact for patients.

2nd European Summit on *In Silico* Pharmaceutical Summit

On 27 June, during the 2nd European Summit on *In Silico* Pharmaceutical Summit organized by Ansys, our President and Secretary General, Thierry Marchal, moderated the round table discussion on regulation.
Panelists included Andrea Manfrin (MHRA), Gavin Quigley (BSI), Ine Skottheim Rusten (formerly EMA and CEO of SRLAB) and Professor Alex Frangi from the University of Manchester and head of the UK's CEiRSI initiative in the field of health.

All participants emphasized the importance of *in silico* evidence and their organizations' readiness to accept the results of computational modeling and simulation as part of the regulatory approval process. Of course, they reminded the audience that the credibility of this *in silico* evidence must be demonstrated, as with any other evidence. Panelists explained that *in silico* data was more common in the regulatory approval process for pharmaceuticals than for medical devices, but both concluded that there was a clear trend towards *in silico* evidence.

This roundtable concluded that it was essential to communicate and collaborate more closely in the future; regulators encouraged the public to engage with them early and often.

The audience was pleasantly surprised by the regulatory authorities' open-mindedness towards *in silico* evidence. The ball is in our court to embrace this evolution!

Members Corner

Events

Avicenna Alliance Webinar "Reflections on the history of *in silico* medicine and where it could (should?) head" by Prof. Peter Hunter from University of Auckland.

2 October 2025 – 5 pm CET

Abstract:
The Physiome Project, the European VPH initiative and the US IMAG program have helped facilitate the use of physics and engineering approaches to physiology and medicine. In this talk I will discuss these initiatives but argue that we should now bring much more of the biochemistry underpinning human physiology into our modelling frameworks.

Click here to register

VHGS II

Virtual Human Global Summit II: From New York to Barcelona

23–24 October 2025, Barcelona

The second **Virtual Human Global Summit (VHG)**, co-organised by ELEM Biotech, take place this year in Barcelona. The event will bring together more than 100 leaders from all over the globe to discuss the adoption of Virtual Human Twins to improve human health.

Discussions will focus on aligning research with clinical and industry needs, shaping policy and shared infrastructure, addressing ethical and societal issues, and fostering international cooperation for real-world impact.

The inaugural summit in New York (2023) showcased progress in cancer, cardiology, sepsis, and diabetes. Yet, participants recognised that broader adoption requires tackling challenges such as data access, regulatory clarity, cultural trust, and sustainable infrastructure.

Over the past two years, the momentum has accelerated rapidly. International initiatives such as the EU's EDITH project and multiple collaborations, including those in the US and Spain, have brought virtual human

models closer to clinical reality. The themes that emerged in New York—**data, collaboration, and trust**—remain fundamental, with the focus now shifting toward real-world adoption.

"*We are at a decisive crossroads in healthcare: embracing or not the Virtual Human concept. Fortunately, it seems that we have made the proper choice. Now it is just a matter of speeding things up,*" says Mariano Vázquez, co-organiser of the Barcelona meeting, and CTO/CSO of ELEM Biotech and researcher of the Barcelona Supercomputing Center.

Critically, patient access and trust will underpin these discussions, ensuring that virtual human twins evolve not only as a technical achievement but also as a means for safer, more accessible, and personalised healthcare worldwide.

Unique online event hosted by Avicenna Alliance member Hemolens Diagnostics®.

"What Your Cardiac CT Images Aren't Telling You (Yet)."

Wednesday, October 8, 2025, at 17:00 (CEST)

Participation is free and open to all interested parties, particularly cardiologists, primary care physicians, and medical teams eager to integrate advanced cardiac CT angiography (CCTA) into their workflows. **The webinar is also intended for experts, guideline authors, opinion leaders, and those involved in the clinical implementation of digital diagnostic tools.**

Hemolens® technology employs multiple innovative methods, including **Computational Fluid Dynamics (CFD)** and **artificial intelligence (AI)**, to support non-invasive diagnosis and enhanced functional assessment in coronary artery disease.

Register for the event

Why Attend?
This webinar is designed for cardiologists, physicians, radiologists, residents, and fellows seeking to leverage non-invasive cardiac imaging in their daily clinical decision-making.
Participants will not only explore how high-quality cardiac CT complements invasive techniques and enhances patient care but also gain insight into how AI and **CFD** technologies are transforming CCTA into a powerful functional assessment tool.

Agenda and Takeaways

During the webinar, you will:

- Learn how to ensure optimal CCTA image quality for reliable interpretation.
- Gain insights into risk stratification, calcium scoring, and plaque characterization.
- Discover referral strategies—knowing exactly when CT is the right choice.
- See how AI-powered monitoring supports plaque progression/regression tracking.
- Experience practical case demonstrations with Cardiolens Viewer® – a web-based platform to analyze CCTA scans. It features AI-powered coronary segmentation, enabling faster and more precise assessments.
- Join a live Q&A session with experts.

Presenters

- Prof. Cezary Kępka, MD, PhD, DSc – Interventional cardiologist, expert in coronary imaging and patient-tailored therapeutic strategies.
- Prof. Mariusz Kruk, MD, PhD, DSc – Internationally recognized authority in cardiac CT and risk assessment, contributor to European guidelines.

Register Today!
Don't miss this chance to stay up to date with the latest in digital cardiac diagnostics and see how innovative tools like Cardiolens Viewer® can improve patient pathways and the decision-making process.

Click here to register

MDIC CM&S In-person Symposium 2025 Nov 4-6 in Washington DC metro region

The MDIC Symposium on Computational Modeling and Simulation is a gathering of industry experts, regulatory professionals, and innovators in computational modeling and simulation (CM&S). Attendees get the opportunity to explore cutting-edge insights into model credibility assessment and effective presentation of computational evidence for regulatory submissions. The Symposium features dynamic panel discussions, in-depth real-world case studies, and expert-led sessions that provide attendees with invaluable strategies for advancing regulatory-grade evidence and fostering device innovation.

Symposium Website: https://mdic.org/ModSim

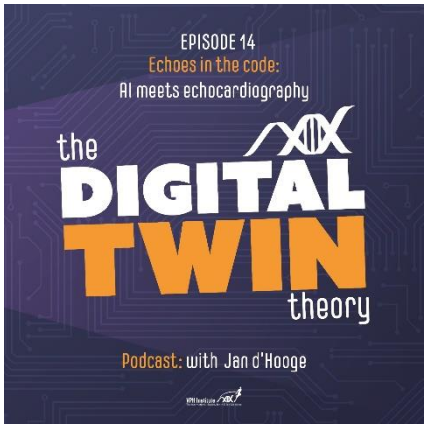
As like most MDIC efforts, the symposium will have significant amount of FDA, device manufacturers (MDMs)- mid-senior executives in attendance. MDIC is co-locating 4 events (MedXR, CM&S, Quality and RWD/RWE) at the venue offering significant opportunities for networking and engagements for the attendees and exhibitors/sponsors. For FDA, CDRH director, Dr. Michelle Tarver will be there along with folks from various topic areas.
These are the links to the events.

MedXR: https://mdic.org/forum-event/mdic-medical-extended-reality-summit/
Modeling &Simulation: https://mdic.org/forum-event/mdic-symposium-on-computational-modeling-and-simulation/
Medical Device Quality Summit: : https://mdic.org/forum-event/2025-mdic-excellence-in-quality-summit/
RWD/RWE: https://mdic.org/forum-event/2025-mdic-real-world-evidence-summit/

Contact Jithesh Veetil jveetil@mdic.org about participation, including opportunities to sponsor, exhibit or support the Symposium.

Publications

Echoes in the code: AI meets echocardiography



Davide Montesarchio, heads to Leuven, Belgium, where he sits down with Prof. Jan d'Hooge—Vice-Rector for Research Policy at KU Leuven and leader of the Cardiovascular Imaging & Dynamics group.

D'Hooge's lab is turning everyday echocardiography into a predictive, precision tool. Together, Davide and Jan explore how computer modelling, simulations, and AI are redefining what a simple "echo" can reveal—and what that means for patients, clinicians, and the future of in silico medicine. Tune in for a journey where math meets muscle and pixels predict prognosis

Watch the video

InSilicoTrials' SimCardioTest featured in the 24th edition of The Project Repository Journal (PRj), a publication dedicated to celebrating Europe's boldest research initiatives under Horizon Europe, LIFE, and ERC.

The article highlights the groundbreaking conclusions of the SimCardioTest EU project eHealth_EU.
IST's Senior R&I Project Manager, Vincenzo Carbone, PhD, together with Irene Balelli, Yves Coudière, Oscar Camara, Beatriz Trenor Gomis, Michèle Barbier, and Maxime Sermesant, showcase how *in silico* medicine is reshaping cardiovascular treatments.

By easily integrating advanced cardiac simulations into an easy-to-use *in silico* trials platform, SimCardioTest makes powerful modelling tools accessible to researchers, clinicians, and industry, without the need for specialised hardware or software. This cloud-based approach accelerates the development of new devices and drugs, while ensuring safety, scalability, and regulatory compliance.

It's a clear demonstration of how *in silico* medicine can cut costs, speed up innovation, and improve patient outcomes.

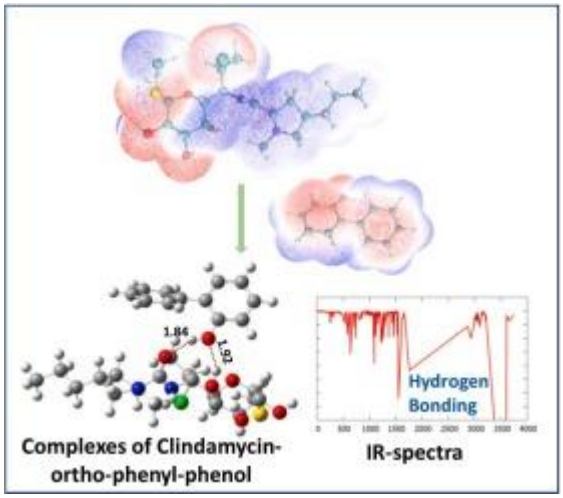
Read the full feature in the latest PRj issue

InSilicoMinds published the article **"DFT Studies for Searching of Anti-Microbial Excipients for the Novel Formulation of Clindamycin"** in the Journal of Computational and Theoretical Chemistry

Key highlights:
- Binding energy and electrostatic interaction analysis
- MESP mapping and IR spectral simulation
- Identification of the most stable excipient-drug complex for optimal formulation performance

InSilicoMinds' work exemplifies how *in silico* modelling can accelerate excipient selection and formulation design in drug development.

[Read the article on ScienceDirect]



Other News and interesting links

Major milestone at our member **Twinsight**: FDA clearance of their first product, SurgiTwin 3D

SurgiTwin 3D is a SaaS platform for semi-automatic planning of total knee arthroplasty (TKA). By combining medical imaging with machine learning, it helps surgeons streamline preoperative planning and tailor procedures to each patient's anatomy.

This clearance is more than a regulatory milestone. It's the foundation for Twinsight broader vision: transforming orthopedics with cutting-edge digital twin technology.

A huge shoutout to the incredible TwinTeam 👏, who achieved this clearance in under 7 months!

InSilicoTrials Secures Top 5 in FDA's Generative AI Challenge

InSilicoTrials has been recognized as a Top 5 performer in the **FDA**'s **precisionFDA Generative AI Challenge** (**Low Code Tier**), for designing AI that can extract accurate, context-aware insights from dense regulatory documents.

Our FDA-recognized approach focused on building a **solid benchmarking framework for retrieval-augmented generation** (**RAG**) **systems**, showing that even without fine-tuning or heavy coding, it is possible to meaningfully advance how AI supports regulatory knowledge and decision-making.

The challenge highlighted how **novel AI-driven solutions**, **rigorous evaluation metrics**, **and real-**

world application scenarios can drive progress in document retrieval, question answering, and chatbot development. Submissions were assessed not only on accuracy, but also on **usability and efficiency**, qualities that are essential if AI is to become a trusted tool in regulatory science.

For InSilicoTrials, this recognition confirms that **in silico innovation has a role beyond clinical trials**. The same approaches that help accelerate drug development can also transform regulatory workflows, paving the way for safer, faster, and more reliable access to life-saving products.

Learn more

Participate to InSilicoMinds' one-question survey

InSilicoMinds, is pioneering *in silico* modelling & simulation solutions empowering pharmaceutical and life sciences organizations to accelerate R&D, optimize regulatory submissions, and enhance patient outcomes.

Answer the one-question survey

Patents with a Pulse: Hemolens Diagnostics® Leading the Way in MedTech IP

Our member Hemolens Diagnostics® has secured its place among the country's TOP 10 most innovative private sector entities and universities in the 2024 European Patent Office (EPO) Patent Index. With seven European patent applications filed last year—all focused on cutting-edge non-invasive cardiovascular diagnostics—Hemolens continues to shape the future of digital medicine and MedTech innovation.
"We are truly honored to be recognized alongside such esteemed organizations. For us, IP—including patents, copyrights, trademarks, and know-how—is a strategic asset safeguarding innovation and competitive advantage, especially in the face of growing cyber threats and IP infringements. Behind these assets is the company's core strength: its R&D team," explains **Barbara Łania-Pietrzak, Intellectual Property Manager at Hemolens Diagnostics®.**

Protecting Innovation in Digital Cardiology

Company is developing a portfolio of patent applications to protect its non-invasive cardiovascular diagnostic tools, including poromechanical modeling and **CFD** simulations for assessing myocardial perfusion based on CCTA images and clinical data, a method for reconstructing central aortic pressure waves from peripheral measurements for precise assessment of coronary flow, and an innovative approach to training AI for estimating of hemodynamic parameters solely from vessel geometry, enabling the creation of advanced next-generation diagnostic tools.
These patents protect not static products but evolving systems. Without robust protection, such innovations risk unauthorized use or imitation, which can threaten their long-term value.

Patent protection starts with strategy. As **Dr. Marek Bury, European Patent Attorney at Bury & Bury Patent Law Firm**, says:

“Planning patent protection requires careful consideration of market strategy. A patent alone does not generate revenue—its purpose is to protect future cashflows originating from using inventions from overtaking by competition and imitators.”
Expert patent attorneys with technical literacy are at the heart of successful innovation. For Hemolens, close collaboration between inventors and IP specialists—especially those versed in European law—is eighty percent of success in patent proceedings. Attorneys proactively supervise the patent process, from early assessment and drafting to representation in disputes—striking a balance between broad protection and enforceability.

Integrated IP Management in MedTech

At Hemolens Diagnostics®, integrated IP management supports every department within the organization, including R&D, marketing, commerce, quality, HR, and the management board. This holistic approach factors patent strategy into business and risk management, ensuring rapid market response and endurance in the highly volatile MedTech environment.
Successful innovation in MedTech requires proactive, company-wide IP management. Hemolens Diagnostics® demonstrates this with its sustainable strategies and collaborative approach, helping secure inventions and drive value in global healthcare.

If you want to read more about patenting, sign up for Hemolens Newsletter: Join The Hemolens Journal: Your Monthly Cardio Brief - Hemolens

Join the Avicenna Alliance!