Avicenna Alliance
Association for Predictive Medicine

# Avicenna Alliance Newsletter
# NOVEMBER – DECEMBER 2025

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## 1000 & 10th Anniversaries

By Thierry Marchal
President and Secretary General, Avicenna Alliance

Happy New Year to the *in silico* community!

As we close out a wonderful 2025, which has demonstrated the growing interest of authorities around the world in *in silico* solutions (particularly AI and computational modeling and simulation (CM&S)), we are entering a very promising 2026. Allow me to mention four figures.

2025

2025 was an excellent year for the Avicenna Alliance, which welcomed new members and partners. This year also saw growing interest in *in silico* technologies from all players in the healthcare sector. We saw patients expressing keen interest, clinicians leveraging CM&S to confirm and often optimize their decisions, regulators and policymakers engaging in more discussions about the need and sometimes urgency to adopt and regulate *in silico* methods and AI – as illustrated by various activities at IMDRF events – academics

amplifying and deepening their research, and industries accelerating medical innovation through wider adoption of computational modeling and simulation.

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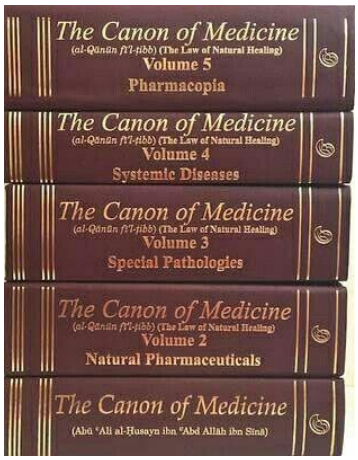


2025 was a very special year, as we celebrated the millennium of the publication of Avicenna's Canon of Medicine, the definitive reference work for centuries. This famous scientist and physician was the first one to define and recommend clinical trials to test and validate new treatments. The Avicenna Alliance fits perfectly with this philosophy, suggesting the addition of modern technologies, such as computational modeling and simulation, to accelerate the process.
Surprisingly, during the Christmas holidays, I enjoyed rereading Ken Follett's book 'World Without End'; I was surprised and somewhat proud to see two explicit references to Avicenna's work in this modern and popular bestseller.

2026

We do not believe that 2026 will mark a pause in this enthusiasm for *in silico* methods. On the contrary, we anticipate an acceleration in their adoption, deployment and constructive regulation. Of course, we cannot expect a rapid transition to the integration of AI and CM&S without continuous and passionate promotion of this technology in order to inform and convince, but also to be guided by all stakeholders towards better, safer and more affordable healthcare.

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The year 2026 will mark the 10th anniversary of the Avicenna Alliance, created in April 2016 at the suggestion of the European Commission. Much progress has been made since its inception. At the time, we dreamed of an exciting future where *in silico* methods would be ubiquitous. The road travelled so far has been long, punctuated by successes and frustrations. We have not yet achieved our goals. But we are no longer dreaming because we know that *in silico* medicine is within reach; we just need to push a little further. Let's celebrate this important anniversary at the Avicenna Days in April 2026.

Okay, I understand that these are just numbers! Many of us are engineers and we love numbers. But we all understand that behind these numbers are many people: patients, clinicians, researchers, drug and medical device manufacturers and policy makers. They are all driven by a single goal: to make healthcare safer, more affordable, more effective – in fact, better. That's what lies behind these numbers.

Let's fully embrace 2026: we've got a lot to do!

## Spotlight on the APAC Task Force

By Hemant Punekar
APAC Task Force Leader

**"Fostering Collaboration in APAC for *In Silico* Methods"**

The U.S. FDA followed by a few agencies around the world are progressively accepting evidence based on computer modeling and simulation (CM&S), Digital Twin and AI, also known as *in silico* methods, in regulatory submissions for many years. Over the past decade, these methods have been formally integrated into FDA guidance MDCG documents in EU and review practices in various regions.

Many Asia-Pacific (APAC) countries export pharmaceuticals and medical devices to the rest of the world and have begun exploring CM&S-based evidence for streamlining regulatory submissions. However, local adoption of these practices remains in its early stages. It is noteworthy that the International Medical Device Regulators Forum (IMDRF) held its 27th Management Committee (MC) meeting in Tokyo, Japan (March 2025), followed by the 28th MC meeting in Sapporo, Japan (September 2025). The next two IMDRF MC meetings is scheduled for Singapore in March and September 2026. This clearly shows the importance and focus on the APAC region for the adoption of *in silico* methods.

Avicenna Alliance has established a dedicated APAC Task Force with the mission to foster collaboration among regulators, industry, and academia in the region. The goal is to advance *in silico* methods, best practices, and policies for regulatory science and innovation. Avicenna Alliance members have actively participated in IMDRF meetings, advocating for the acceptance of *in silico* methods.

On the Avicenna Alliance website, under the **Resources** tab, two key documents are available:

- **The Avicenna Flyer** – *"In silico medicine and the Avicenna Alliance"* outlines the need and potential of *in silico* methods, along with the Alliance's origins, mission, activities, and partners.
- **One-Pager** – *"Enabling the acceptance of in silico methods in the medical device development lifecycle"* begins with the problem statement: *"The lack of harmonized regulatory guidance for digital evidence generated by in silico methods is hampering access to safe and effective medical devices."* It explains how these methods optimize device development and emphasizes the importance of global harmonization for accepting digital evidence.

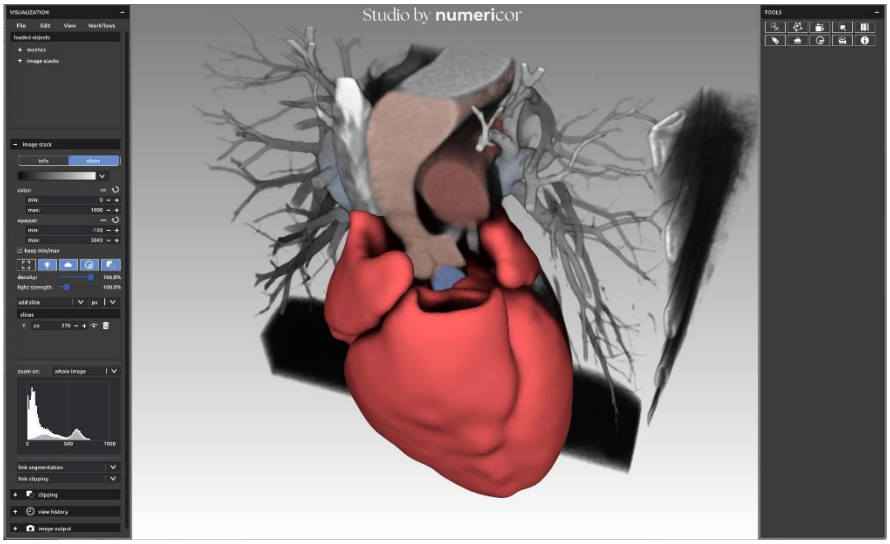
While these resources are valuable, language remains a challenge in some APAC regions, where regulators, industry, and academia primarily operate in local languages. To address this, Avicenna Alliance has made these documents available in Japanese, Korean, and Chinese, under the **Multilingual Focus Docs** section. Spanish and Portuguese versions are also provided.

These documents are freely accessible to anyone working toward global harmonization of *in silico* methods. They serve as an excellent starting point for local-language discussions. Members of Avicenna Alliance have already used these documents for such discussions and seen the benefits. For further information on this topic, Avicenna Alliance at **manager@avicenna-alliance.com** can be contacted.

# Spotlight on our member NumeriCor

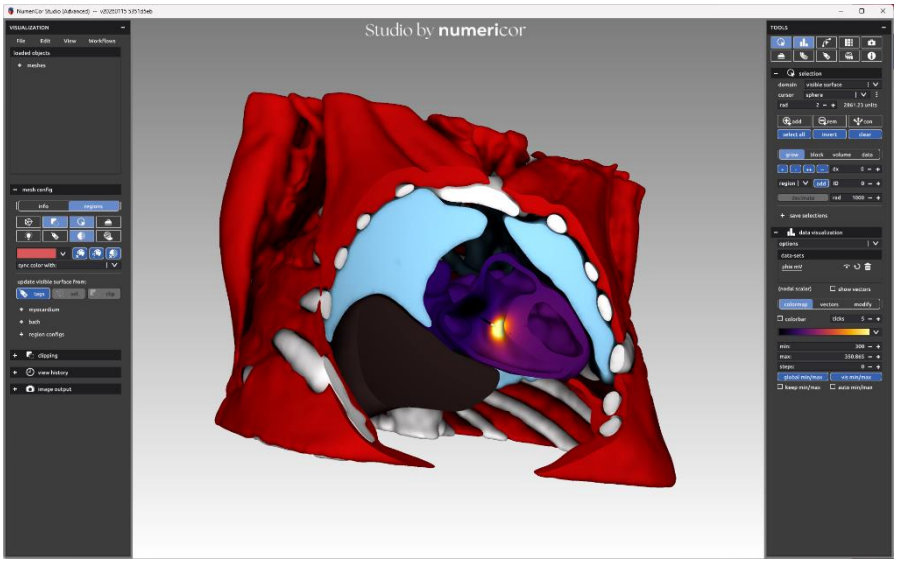
By Aurel Neic, CEO

**NumeriCor GmbH: Pioneering Cardiac Digital Twins and *In Silico* Innovation**




NumeriCor GmbH is at the forefront of computational cardiology, delivering advanced simulation solutions that transform how heart function is modelled and understood. Specialising in end-to-end cardiac electrophysiological and electromechanical simulation technologies, the company bridges decades of academic excellence with industrial-grade tools designed for research, clinical translation, and medical device development.

Founded by leaders in computational cardiology — including co-founder and CSO Professor **Gernot Plank** of the Medical University of Graz, and CEO/CTO **Aurel Neic**, a specialist in high-performance simulation and mesh generation — NumeriCor embodies a deep integration of research and application. Senior R&D engineer and Product Manager **Luca Azzolin,** very active in the Avicenna Alliance activities, contributes expertise in atrial modelling and digital twinning technologies, supporting the company's mission to deliver precise and robust simulation workflows.




At its core, NumeriCor provides a suite of products that enable realistic, high-fidelity cardiac simulations and digital twin creation.
NumeriCor **Studio** offers a graphical front-end tailored for cardiac simulations, integrating everything from image segmentation and mesh generation to simulation execution and results analysis — all within a single environment. **CARP-EP/EM**, the company's high-performance simulation engine, powers multi-scale electrophysiology and electromechanical modelling and builds on widely validated research code used in hundreds of peer-reviewed studies. Complementing these is **CardioTwin**, an automated pipeline that transforms clinical MRI or CT scans into detailed, simulation-ready heart models in minutes, facilitating rapid cohort generation or patient-specific virtual twin creation.

These tools enable researchers and developers to conduct ***in silico* experiments** that would otherwise be costly, time-consuming, or impractical in the lab. For the medical device industry, NumeriCor's simulations support the design and optimization of therapies such as anti-tachycardia pacing, conduction system

pacing, and implantable cardioverter-defibrillators (ICDs). By replicating electrograms and incorporating detailed device geometries, the software can predict device performance metrics — including impedance and capture thresholds — with high precision.

NumeriCor's approach also accelerates innovation through advanced digital twinning workflows, where simulated models are closely calibrated to physical measurements and even individual patient data. For both academic users and industry partners, this accelerates R&D cycles, supports hypothesis testing, and enables virtual clinical trial scenarios in a safe, reproducible environment.

As the field evolves, NumeriCor advocates for broader collaboration among experts to address shared challenges in **policy, certification, and liability frameworks** — emphasising that simulation-based tools will be key to safely innovating next-generation cardiovascular therapies.

## Spotlight on our Partner ISO

By Martin Golebiewski HITS gGmbH, Heidelberg (Germany)

**Emerging standards for *in silico* and personalized medicine**

Many different types of human data are used to set up computational models and Virtual Human Twins (VHTs) for simulations and predictions, e.g. for *in silico* clinical trials, disease prognosis, treatment predictions or patient stratification. These data need to be interoperable to integrate them into the models or use them for model validation. To achieve this, standards are crucial for structuring, describing, and associating models and data, as well as their respective parts, graphical visualization, and applied methods[1]. Such standards also assist with describing how components interact together, or are linked, and how they are embedded in their context.

Standards are defined by the scientific communities, e.g. the COMBINE network (SBML, SBGN, CellML, SED-ML, etc.), and by Standard Defining Organizations (SDOs) such as the International Organization for Standardization (ISO). The Heidelberg Institute for Theoretical Studies (HITS) in Germany is involved in these efforts and leads the drafting of international standards in the domain through the ISO committee ISO/TC 276/WG 5 Data Processing and Integration chaired by HITSter Martin Golebiewski:

ISO 20691, published in 2022, provides a framework for the development and application of domain-specific and interoperable (meta-) data standards in the whole life sciences. It defines requirements and rules for the application of standards for formatting, description, and documentation of data, as well as for the design of interoperable data formats and terminologies for semantic annotation. There is also an interactive annex available online.

ISO 9491 “Recommendations and requirements for predictive computational models in personalized medicine research” provides guidelines for modelling in the field of personalised medicine. It has two parts, the first ISO 9491-1 "Guidelines for constructing, verifying, and validating models" was published in 2023 as ISO technical specification and currently is transformed into an ISO international standard. It gives recommendations and requirements for data preparation and for integrating data into computational models. Furthermore, it describes model formatting, validation, simulation, storing, sharing and their application in clinical trials and research as well as ethical requirements for modelling. The annex lists specific standards and modelling approaches for personalised medicine. This ISO standard was already included as requirement for applicants in funding calls of the European Commission on Virtual Human Twin projects. The second part ISO TS 9491-2 "Guidelines for implementing computational models in clinical integrated decision support systems" contains recommendations for computational models and their application in the clinical research context. It is currently under publication.

The ISO 23494 series “Provenance information model for biological material and data” describes how to document the provenance information for biological data and specimen information to trace it back to their original sources, even after several data processing steps.

[1] https://doi.org/10.5281/zenodo.10492795

To complement these activities, a new joint working group is currently formed between ISO and the International Electrotechnical Commission committee for medical equipment, software, and systems (IEC/TC 62) to address the standardisation of the credibility of computational modelling in the field of medical devices through verification, validation, and uncertainty quantification. This work will build on the national US standard ASME V&V 40:2018 for assessing the quality and model credibility of medical devices and extend it to an international standard. Also in this emerging standardisation committee, HITS plays a leading role and is founding member.

## 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!

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All 66 recordings are available in the members only area of the Avicenna website. Last webinar, held on 13 January 2026 is available in the public area too.

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

### Our future webinars

- 10 February 2026: **"Is stroke being treated as a heart-brain axis disease?"** by Oscar Camara from UPV – Click here to register
- 10 March 2026: **"The role of standards toward *in silico* medicine"** by Fredric Constantino from ASME – Click here to register

### Our most recent webinars

- 13 January 2026: **" Arm in arm: CM&S and AI support coronary artery disease diagnostics"** by Ziemowit Ostrowski and Andrzej Kosior from Hemolens Diagnostics – Watch the recording

  *This webinar will present how RBF Morph enables the creation of real-time medical Digital Twins, seamlessly accessible across platforms ranging from laptop and web dashboards to specialized medical software, embedded imaging systems, and fully immersive virtual reality environments. Powered by proprietary ROM technology, these applications run wirelessly on Meta Quest 3 and Apple Vision Pro, providing mobility and intuitive interaction.*

- 11 November 2025: **"Real-Time Medical Digital Twins: Geometry, Simulation, and Immersive Interaction"** by Marco E. Biancolini from RBF Morph – Watch the recording

  *This webinar will present how RBF Morph enables the creation of real-time medical Digital Twins, seamlessly accessible across platforms ranging from laptop and web dashboards to specialized medical software, embedded imaging systems, and fully immersive virtual reality environments. Powered by proprietary ROM technology, these applications run wirelessly on Meta Quest 3 and Apple Vision Pro, providing mobility and intuitive interaction.*

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

# EU Policy and Regulatory updates

Over the past months, the European Union has advanced several major regulatory initiatives in the fields of medicines, medical devices, digital health, and artificial intelligence. These developments aim to strengthen patient safety, improve access to innovative therapies, and adapt regulatory frameworks to rapidly evolving technologies.

Across medicines, devices, digital regulation, and AI governance, the EU is entering a period of **significant regulatory consolidation and modernization**. The most recent initiatives focus on:

- improving patient safety and transparency
- stimulating innovation in areas of unmet need
- increasing resilience of supply chains
- enabling responsible use of data and artificial intelligence

Stakeholders in regulatory affairs, R&D, compliance, digital health, and market access should closely monitor upcoming implementation timelines throughout 2026 and beyond.

### Targeted Revision of MDR and IVDR

On 16 December 2025, the European Commission proposed a **targeted revision of the Medical Devices Regulation (MDR)** and the **In Vitro Diagnostic Regulation (IVDR)**. These proposals do not replace existing legislation but aim to make it **more workable in practice** while maintaining high standards of safety.

The revision primarily focuses on:

- simplifying certain conformity assessment procedures
- improving availability of **orphan and breakthrough devices**
- addressing persistent shortages of critical medical technologies
- ensuring proportional requirements, especially for SMEs and niche manufacturers

For innovators, the revision creates clearer pathways for **novel high-risk technologies**, encouraging research and development in areas where unmet medical needs persist. For regulators and notified bodies, it seeks to rebalance workload and streamline processes that have proven burdensome since MDR/IVDR implementation.

This initiative responds directly to concerns expressed by industry, healthcare professionals, and patient groups about delays in device certification and market availability.

The **Medical Device Regulation (MDR)** became fully applicable on 26 May 2021, replacing the former Medical Device Directive. It introduced one of the most comprehensive overhauls of medical device regulation in the EU.

The MDR:

- strengthened clinical evidence and post-market surveillance obligations
- expanded responsibilities across the supply chain
- introduced **UDI traceability systems**
- reinforced requirements for notified bodies

Manufacturers must now continuously monitor safety and performance throughout the entire device lifecycle, not only up to market entry. Distributors and importers were formally recognised as economic operators for the first time and assigned explicit obligations.

Although transformative, MDR implementation has also presented challenges, including certification bottlenecks—hence the **targeted revisions proposed in 2025**.

## Landmark Reform of EU Pharmaceutical Legislation

On 11 December 2025, EU legislators reached a **provisional political agreement** on a comprehensive reform of the EU pharmaceutical framework—the most significant revision in over two decades.

The reform package aims to:

- accelerate access to safe, effective medicines
- strengthen **supply chain resilience and shortage monitoring**
- stimulate innovation, particularly for unmet medical needs
- simplify regulatory procedures without compromising safety

Key elements include:

- **shorter regulatory timelines** for both innovative and generic medicines
- creation of **regulatory sandboxes** to test novel technologies under supervision
- incentives for development of **rare disease treatments**
- clearer application of the **Bolar exemption** to support earlier generic entry
- establishment of a **list of critical medicines** with vulnerability assessments

The agreement still requires formal adoption by the European Parliament and Council, but it sets the direction for a more flexible and innovation-friendly pharmaceutical environment over the coming years.

## EMA Scientific and Operational Updates

In December 2025, the European Medicines Agency (EMA) recorded several important milestones.

Scientifically, the Committee for Medicinal Products for Human Use (CHMP):

- recommended **seven new medicines for approval**
- endorsed **twelve extensions of indication**
- advanced therapies such as the **first gene therapy for Wiskott–Aldrich syndrome**
- supported a **first-in-class treatment intended to delay the onset of Type 1 diabetes**

Operationally, EMA implemented:

- new **eCTD validation criteria (v8.2)**
- updated **EU eCTD M1 specifications (v3.1.1)**

These became mandatory on 1 December 2025, signalling EMA's ongoing transition toward fully digital regulatory workflows.

Finally, EMA adopted its **2026 work programme**, prioritizing:

- implementation of new pharmaceutical legislation
- enhanced use of digital tools and AI
- strengthened crisis preparedness and medicine availability monitoring

## Progress on EUDAMED Implementation

On 27 November 2025, the European Commission declared the functional readiness of four core modules of the **European Database on Medical Devices (EUDAMED)**:

- Actor registration
- UDI/Device registration
- Certificates
- Market surveillance

This declaration triggers a six-month transition period, after which the listed modules will become **mandatory from 28 May 2026**.
Once fully operational, EUDAMED will significantly improve:

- traceability of devices through UDI
- transparency for patients, clinicians, and regulators
- coordination between authorities across Member States

It represents a cornerstone of MDR implementation and a major step toward a more robust device safety system in the EU.

### Launch of AI Act Whistleblower Tool

On 24 November 2025, the European Commission introduced a **secure whistleblower mechanism** dedicated to reporting suspected breaches of the AI Act.
The tool enables individuals to report:

- risks to fundamental rights
- safety concerns
- violations involving AI applications in healthcare and beyond

It provides encrypted communication channels and allows anonymous follow-up, enabling regulators to investigate without compromising reporter identity. This mechanism will be particularly relevant for **high-risk AI systems in medical devices, diagnostics, and decision-support tools**, reinforcing trust in AI adoption in healthcare settings.

### Digital Omnibus Package

The **Digital Omnibus Package**, published in November 2025, introduces technical adjustments to a range of digital regulations, including the **GDPR** and the **ePrivacy Directive**.
Its goals include:

- harmonising rules across Member States
- reducing overlapping obligations
- clarifying how health data may be processed in research and innovation
- easing compliance obligations particularly for SMEs in health and life sciences

The package complements broader initiatives such as the **European Health Data Space** and supports a more agile digital regulatory environment.

# Recent news

## Happy Holidays and Merry Christmas

Dear Avicenna Alliance Members, As 2025 comes to a close, we want to take a moment to celebrate all that we've achieved together this year. It's been a remarkable journey of collaboration, innovation, and progress—and none of it would have been possible without your dedication and enthusiasm.
The festive season is a tim e to pause, enjoy the company of loved ones, and recharge for the year ahead. We hope you find moments of joy, laughter, and well-deserved rest over the holidays.

Looking ahead to 2026, we are excited to continue our shared mission of advancing *in silico* methods and shaping the future of medical innovation. With your continued support and passion, the possibilities are endless!

Wishing you a joyful Christmas, wonderful holidays, and a New Year filled with health, happiness, and success. May it be bright, inspiring, and full of achievements we can celebrate together!

Warmest wishes,
The Avicenna Alliance Board

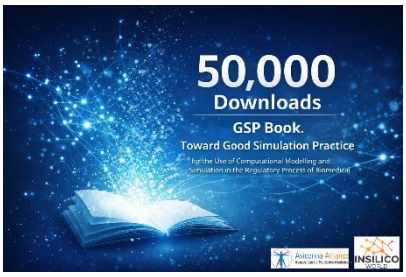
## Welcome to Our New AI Task Force Co-Chair: Tomáš Kulhánek

The Avicenna Alliance is pleased to welcome Tomáš Kulhánek as the new Co-Chair of the AI Task Force, joining Nirnith Devireddy in leading our work at the intersection of artificial intelligence and *in silico* medicine.
Tomáš is a lecturer at the First Faculty of Medicine, Charles University, Prague. His background spans computational physiology, structural bioinformatics, and software development and architecture. With experience across academia, industry, and entrepreneurship, he has contributed to advanced digital simulators of human physiology, AI-driven health modelling, and medical software systems.

We welcome Tomáš, his expertise and vision to the Task Force as we continue strengthening our leadership in AI for healthcare innovation.

Read more about the Avicenna Artificial Intelligence (AI) Task Force

## A Major Milestone for Good Simulation Practice!




We're proud to announce that the Avicenna GSP Task Force book, "Toward Good Simulation Practice – Best Practices for the Use of Computational Modelling and Simulation in the Regulatory Process of Biomedical Products", has officially surpassed 50,000 downloads!
This open-access Springer publication is the result of a truly community-driven effort, bringing together experts from industry, academia, regulators, and clinical practice to build a common foundation for credible, transparent, and impactful computational modelling and simulation.

The book has become a global reference for anyone working in *In Silico* Trials and for those integrating modelling & simulation into the regulatory lifecycle of biomedical products.

A huge thank you to everyone who contributed and to the growing community driving the adoption of Good Simulation Practice across the world.

Access the book Read more on the Avicenna website

## Avicenna at MDIC Real-World Evidence Summit

Several Avicenna Alliance Members and Partners attended the MDIC Computational Modelling & Simulation (CM&S) Symposium in College Park, MD.
Among them were our Research & Technology Working Group Leader, Prof. Liesbet Geris (VPH Institute), our *In Silico* Application (ISA) Working Group Leader, Dr. Cécile Rousseau (Voisin Consulting Life Sciences (VCLS)), the Avicenna UK *In Silico* Regulatory Innovation Task Force co-Chair, Prof. Alex Frangi (University of Manchester), the Avicenna Nonclinical Application Task Force co-Chair, Dr. Julien Clin (Numalogics), and the newly appointed co-chair of the Global Harmonization Task Force, Dr. Tina Morrison (EQTY Labs).

A big thank you to Dr. Pras Pathmanathan (FDA), Dr. Cheryl Liu (Stryker) and the MDIC team for organizing this fantastic symposium bringing together great speakers, regulators, industry leaders, and innovators to explore the latest advancements and challenges in CM&S —an increasingly indispensable tool for accelerating medical device evaluation and transforming regulatory science.

The presence of representatives from FDA, MHRA, and PMDA highlighted the global commitment to integrating CM&S into regulatory frameworks, signalising a shared vision for harmonized approaches and standards that foster innovation while ensuring patient safety.

We are proud to see our members and partners actively shaping these discussions, reinforcing the Avicenna Alliance's mission to position *in silico* medicine and advanced modelling as key enablers for evidence generation, regulatory convergence, and patient-centric healthcare innovation worldwide.

Looking ahead, the Avicenna Alliance will continue to work closely with global stakeholders to develop standards, best practices, and collaborative initiatives that accelerate the adoption of *in silico* methods (CM&S and AI) and pave the way for international regulatory harmonization.

## Welcome to Our New Partner: iSi Health!

The Avicenna Alliance is delighted to welcome iSi Health KU Leuven Institute – the KU Leuven Institute for *in silico* health – as our newest Partner.

iSi Health brings exceptional multidisciplinary expertise at the intersection of medicine, computational modelling, and simulation. As a central hub uniting the existing *in silico* expertise at KU Leuven and UZ Leuven, the institute plays a key role in fostering collaboration across academia, clinical practice, and industry.

Through pioneering work spanning method development, clinical translation, education, and the socio-economic and legal integration of *in silico* technologies, iSi Health is shaping the future of healthcare and accelerating the bench-to-bedside adoption of *in silico* methods.

We are delighted to join forces and advance our shared mission of driving innovative, safe, and impactful *in silico* solutions for patients worldwide.

“We are excited that iSi Health has become a Priority Member of the Avicenna Alliance. This partnership strengthens our common commitment to accelerating the clinical implementation of computational modelling for health to benefit patients, industry, and regulators alike. Together, we are working towards shaping the future of healthcare” said Prof.Ilse Jonkers, Director of iSi Health.

“iSi Health is a key organization that connects academic, clinical and industrial research, accelerating the adoption of *in silico* technology for patients. It plays a vital role in communication, information and education. We have been working with iSi Health since its creation but this formal partnership will help us better serve patients with Computational Modelling and Simulation” added Thierry Marchal, President and Secretary General of the Avicenna Alliance.

## AA at the Belgian Cleanroom Workshop in Antwerp

The Belgian Cleanroom Workshop held an insightful event with a strong focus on the clean rooms for the pharmaceutical and medical device industry, in Antwerp, Belgium on 21 October.

Our President and Secretary General, Thierry Marchal presented the topic: “Using ISO 14644 to Optimize Contamination Control Strategy: limitations of traditional approaches, complementarity of CFD and promises of Clean Room Digital Twin” at the Belgian Cleanroom Workshop held in Antwerp on 21 October.

We often hope that ISO standards will explicitly refer to engineering simulation. The ISO 14644 is a great example: this standard states that “Computational fluid dynamics (CFD) is a suitable tool for varying this factor while predicting the effectiveness of different cleanroom designs.” and it continues “… the amount of air required for a particular cleanroom is not dependent on the volume of the room, but rather on the nature of the activities within the room and the design of the air distribution system …”, an observation easier to demonstrated through simulation.

Other presentations highlighted the importance of good regulations or illustrated that employees movements in clean rooms could further disperse unwanted particles if people move at speeds greater than 0.5 m/s. Thanks to advanced *in silico* technologies, CFD models involving moving objects and people, we are able to easily assess the actual risk of contamination. *In silico* technologies can quickly investigate various

alternatives before building the cleanroom and guarantee excellent working conditions for drug manufacturing or operating rooms in hospitals.

As usual, collaboration between different technologies and solutions will accelerate affordable medical innovation for patients.

## Avicenna Alliance Launches Its Artificial Intelligence Podcast Series

The Avicenna Alliance is proud to announce the launch of its Artificial Intelligence Podcast Series, exploring how AI is transforming healthcare, life sciences, and *in silico* medicine.
The first episode, "AI in Healthcare: The Future of Medicine," is now available on Spotify: **Listen on Spotify**

Hosted by Nirnith Devireddy (Co-Chair of the Avicenna Alliance AI Task Force; CEO & Founder of InSilicoMinds) and moderated by Mounica Gunapati (AI Lead at Elevance Health), Episode 001 breaks down artificial intelligence in plain language — what it is, why it matters, and how it's redefining the future of medicine.

In this episode, we explore:

- What exactly is AI?
- How does it benefit patients, clinicians, and the healthcare industry?
- How does AI complement *in silico* modelling and simulation?
- What defines "good data" for trustworthy AI?
- What trends are shaping the near- and long-term future of AI in healthcare?

By bridging science, policy, and patient needs, the Avicenna Alliance continues to advance the responsible adoption of digital technologies — ensuring that AI and *in silico* methods accelerate safer, faster, and more transparent innovation in medicine.

**Avicenna Alliance Podcast series page**

# Members Corner

## Events

**EURAICA 2026 – European Conference on AI for Clinical Applications (Brussels, 11–12 March 2026)**

The Avicenna Alliance is pleased to co-organise **EURAICA 2026**, a new European conference dedicated to how **AI, modelling & simulation, synthetic/artificial data, and real-world evidence (RWE/RWD)** are reshaping **clinical development and evidence generation**.

Randomised clinical trials remain the cornerstone for demonstrating causal efficacy and safety. Yet increasing protocol complexity, recruitment challenges, limited representativeness, and difficulties in translating results to real-life practice are slowing patient access to innovation. EURAICA's ambition is to move beyond both unrealistic expectations and unjustified resistance by building a **rigorous, shared framework** to assess where AI-enabled approaches genuinely add value—and under which methodological and regulatory conditions.

The programme brings together **regulators and HTA experts (including EMA and HAS, with additional agencies invited)**, senior leaders from pharma/biotech, innovative CROs, AI technology providers, and academic and clinical experts. With attendance deliberately capped at **150 participants**, EURAICA is designed for high-quality, in-depth discussions and privileged networking.

**Avicenna members benefit from a dedicated member rate (-30%)**. Seats are limited and early registration is strongly recommended.

**Register here:** https://euraica2026.forms-wizard.biz/users/new

**Member code: AVICENNA30%**

**VPH 2026 — the Virtual Physiological Human Conference**

Connect with leading researchers, clinicians, and decision-makers driving innovation in healthcare. Showcase your cutting-edge solutions, explore real-world applications of predictive models and digital twins, and engage with experts shaping the future of diagnosis, treatment, and personalized medicine. Position your organization at the forefront of impactful scientific and clinical collaboration.

You will be able to do this *and more* at **VPH 2026 — the Virtual Physiological Human Conference**.

Alongside scientists and industry leaders, you'll even meet **regulators and policymakers** shaping the future landscape of digital health.

📍 **Milan, Politecnico**
📅 **1–4 September 2026**

**Exhibition and Sponsorship packages** are now open for industry partners!
**https://vph-conference.org/industry/**

The scientific programme is in development, but here's a sneak peek at what's coming:

- Computational & AI-driven drug delivery and design
- Multi-omics data integration
- Neuroinformatics & brain–computer interfaces
- Decision support systems for clinical applications Industrial applications of digital twins
- *In silico* oncology & organ-on-a-chip trials
- Credibility, verification & validation of digital twins
- Regulatory science for digital twins
- Trusted AI in health and care
- … and many more cutting-edge topics shaping the next decade of healthcare.

👉 **Join us in Milan and be part of the community building the future of virtual medicine. https://vph-conference.org/**

**Exclusive Member Briefing Sessions on *In Silico* Methods in Emerging European Health Policy and Regulation**

On 21 and 27 of January 2026, the VPH Society is organising two exclusive online briefing sessions to present the latest updates in the policy and regulatory context and how this is effecting the *in silico* medicine field.

The sustained efforts of the *in silico* medicine community, including by the VPH Society and its industrial partners of the Avicenna Alliance, across meetings, collaborative projects, conferences, and scientific publications, are now translating into policy impact that surpasses expectations. In a series of legal text proposals released in December 2025 by the European Commission, *in silico* approaches – well beyond AI alone – are explicitly positioned as essential tools across the full life cycle of medical therapies.

These developments span multiple strategic initiatives, including breakthrough pathways under the current Medical Device Regulation, the proposed MDR revision, the Biotech Act, and the European Cardiovascular Plan. Together, they signal a decisive shift in how *in silico* medicine and digital technologies are recognised within Europe's regulatory and innovation frameworks.

To analyse these changes in depth, the VPH Society is organising **two exclusive online briefing sessions**, open only to VPH Society members and industry members of the Avicenna Alliance.
These briefings are intended as strategic moments for a community that has helped shape the current policy landscape – and whose continued engagement will be critical in determining its final outcome.

These briefing sessions will:

- Examine the *fine print* of the newly released policy and regulatory proposals;
- Provide a clear overview of the most important changes and their potential implications;
- Reflect on the collective journey that led to this moment;
- Outline the actions still required, particularly during the parliamentary phase, to ensure that positive elements are retained;
- Discuss how members can actively contribute going forward.

The two meetings are complementary in scope:

- **21 January** – 14 /15.30 CET: **Emergence of *In Silico* in Health Policy & Regulatory Science – Register now**
- **27 January** – 14 / 15.30 CET: ***In Silico* as Regulatory Evidence in EU – Register now**

All registration requests will be reviewed and **access will be granted exclusively to VPH Society members and industry members of the Avicenna Alliance**.

## Publications

**AI in Healthcare: The Future of Medicine - Ep.001**

Everybody is talking about AI. But have you ever wondered:

- What exactly is AI in simple terms?
- How does it benefit patients and the healthcare industry?
- What is the difference between AI *in silico*, computational modelling and simulation?
- What makes good data for AI?
- What trends can we expect in the near and long-term future?

In this first episode of the Avicenna Alliance AI Podcast Series, host Nirnith Devireddy (Co-Chair of the Avicenna Alliance **AI Task Force**; CEO & Founder of InSilicoMinds) and moderator Mounica Gunapati (AI Lead at Elevance Health) discuss in simple and provocative terms how artificial intelligence is shaping the future of healthcare.

**What If We Could Test Drugs on a Digital You? – By SANO**

What if doctors could test a risky procedure on a virtual version of you before performing it in real life?
This video introduces the concept of **digital twins** and their growing relevance for medicine and healthcare. Drawing on the historical example of the Apollo 13 mission, it illustrates how virtual replicas—originally used to test procedures and manage risk in aerospace—can be applied to complex, high-stakes environments. A digital twin combines computational models, continuous data inputs, and simulation capabilities to predict system behaviour under different conditions.
While digital twins are already widely used in industry to optimise machine performance, their application in healthcare opens new possibilities, from hospital workflow optimisation to personalised medicine. By modelling organs and physiological systems using principles from mathematics and physics, it becomes possible to simulate surgical procedures or drug responses *in silico*, reducing reliance on animal or human testing.
The video also highlights key challenges, including data access, security, validation, and regulation. Finally, it presents the role of initiatives such as the **VPH Institute** and the **Avicenna Alliance** in building the scientific, regulatory, and collaborative ecosystem needed to translate digital twin technologies into real-world healthcare decision-making.

**WATCH THE VIDEO**

## Other News and interesting links

Congratulations to the HEMOLENS DIAGNOSTICS team on being awarded the prestigious Prix Galien | Galien Forum CEE!
Cardiolens® being recognized as a breakthrough innovation in non-invasive cardiac diagnostics and digital health is an outstanding achievement. Competing alongside such remarkable startups highlights the strength and international relevance of Polish MedTech. Kudos to the entire team and presenters for this success, and congratulations to all nominees and laureates for helping shape the future of healthcare!

More information here

## JOB OPPORTUNITIES

**Virtonomy**

**Sales Development Representative (m/f/d)** for our Munich office

**(Application only accepted by email)**

**Key Responsibilities:**

- Proactively identify, prospect, and develop new customer opportunities.
- Consistently expand and qualify leads to build a strong and high-quality sales funnel.
- Consultative selling, understanding customer needs, pain points, and tailoring solutions to deliver value.
- Manage the entire sales process, from prospecting and first outreach, through quotation preparation (in collaboration with our technical team), to negotiations, and closing deals.
- Prepare for customer calls and interaction with technical research, engaging presentations, and more.
- Build and nurture strong long-term relationships with key decision-makers and stakeholders.
- Work closely with senior leadership, technical teams, and marketing to develop compelling proposals and presentations.
- Good experience in account management.
- Research target accounts, monitor and analyse market trends, competitors, and new regulatory changes (FDA, MDR, etc.).
- Represent Virtonomy at industry events, trade shows, and conferences to showcase our solutions and build networks.

**What You Bring:**

- University degree in Medical Engineering, or Business with a medical specialty, or similar
- 3-4 years of experience in pre-sales, business development, or relevant industry exposure, ideally in healthcare, medtech, or related industries
- A hunter sales mindset with a proven ability to generate leads, build relationships, and close deals.
- Passionate about the medical industry and motivated to contribute to the success of a growing scale-up.
- Solid understanding of sales cycles, prospecting, negotiation, and closing techniques.
- Excellent presentation and communication, with the ability to engage stakeholders at all levels.
- Ability to work independently, take initiative, thrive in a dynamic environment, and bring new ideas to the table.
- Multitasking abilities to handle various tasks efficiently and prioritize responsibilities.
- Experience in using CRM software, preferably HubSpot, and sales enablement tools.
- Eager to learn, develop, and grow within a fast-paced, international scale-up.
- You enjoy working in an international environment and speak fluent English.

**What we offer**

- An international and very motivated team with high performance and a cooperative mindset
- A high degree of responsibility and extensive creative opportunities from day one, with short decision-making processes
- A future-oriented business with high impact in the medical domain
- With us, there are many career paths and development opportunities for you; what you can't do yet, you can learn with us!
- Flexible working hours & home office possible

You have what it takes, and are you motivated to change an industry? **Send us your application documents by email,** stating why you are the one, the possible starting date, and a salary expectation, **to: careers@virtonomy.io (Application only accepted by email)**

**MDsim**

**Product Manager (PM)**

We are building SPINEsim — an AI-driven SaMD platform designed to bring unprecedented precision to spinal surgery. But to bridge the gap between "cutting-edge Computer Modeling & AI" and "clinical reality," we need a, exceptional Product Manager (PM).
This isn't your typical PM role. You'll be at the intersection of computer modeling, AI, biomechanics, and the operating room.

**What will you be doing?**

- Lead the product vision from "Design Controls" to "Commercial Launch."
- Translate complex AI outputs into intuitive clinical insights for surgeons.
- Partner with our C-suite to shape the strategic roadmap.
- Empower our Sales & Marketing teams to tell the story of how we're saving lives.

**Who you are?**

You know your way around ISO 13485 and IEC 62304. You can talk "model drift" with engineers and "pedicle screw trajectory" with surgeons. You are a builder, a strategist, and a champion for patient safety.

To Apply, email: **Roger.assaker@mdsim.health**

**SANO**

We're now looking for an **experienced and visionary Leader of the "Medical Imaging and Robotics" Research Group** to join our team in Kraków.

If you're dedicated to innovation and eager to shape the future of healthcare through AI, robotics, and computational medicine, this is a unique opportunity to support your own research group within an international environment where investigators, engineers, and scientists collaborate to create real-world impact.

At Sano, you'll find freedom, strong institutional support, and an inclusive and diverse, vibrant community committed to advancing digital health and computational research across borders.

More details and application instructions can be found here: Leader of the Research Team "Medical Imaging and Robotics" - Centre for Computational Personalized Medicine

# Join the Avicenna Alliance!