Avicenna Alliance
Association for Predictive Medicine

Avicenna Alliance Newsletter
MAY – JUNE 2025

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The digitalization of clinical trials: we are all moving in the same direction

By Thierry Marchal
President and Secretary General, Avicenna Alliance

First conceived by the innovative physician Avicenna and mentioned in his Book of Healing, published just over a millennium ago, in 1025, clinical trials are now an essential cornerstone of medical innovation. This stage is crucial for demonstrating the novelty and, more importantly, the safety for patients of any new treatment.

Unfortunately, clinical trials and the regulatory approval process, while essential, significantly slow down medical innovation. The entire regulatory approval process can take between 5 and 10 years for medical devices and sometimes more than 15 years for a new drug. The approval of a new treatment can cost up to €0.5 billion for medical devices and sometimes more than €2.5 billion for a new drug. Even more critical is the uncertainty associated with this lengthy process:

only 1 in 20 drugs and 1 in 5 medical devices initially submitted for regulatory approval will be approved for use by patients.

The digitalization of clinical trials is seen by many in academia and industry as the most promising way to accelerate medical innovation without compromising patient safety. Many authorities have now confirmed their interest in the digitalization of clinical trials.

- For several years now, the US FDA has been accepting *in silico* evidence as part of its regulatory approval procedures.
- At the recent LifeScience 4EU conference held in Krakow in May 2025, Emer Cooke, Executive Director of the European Agency, presented slides explicitly mentioning the need for "transforming clinical trials" and "driving digital transformation"; she also discussed the role of 'modelling and simulation'.
- At the 2nd European Summit on *In Silico* Pharmaceuticals in London on June 26, Andrea Manfrin (MHRA) and Gavin Quigley (BSI) shared their views during the regulatory roundtable, highlighting the value of *in silico* evidence (once its credibility has been demonstrated) for regulatory authorization.
- In a recent conversation, René Bombien and Surash Surash, TüV SüD, repeatedly confirmed their interest and willingness to accept *in silico* evidence.

Regulatory Round Table discussion at UCL, London, 26 June 2025

We have never been closer to the deployment of *in silico* (clinical) trials. But there still seems to be a lack of communication to confirm the enormous interest of each stakeholder. It will be crucial to communicate about the successful use of *in silico* evidence for regulatory approval in order to further accelerate medical innovation for the benefit of patients.

Spotlight on the Cancer and *In Silico* Oncology Task Force

By Georgios Stamatakos
Task Force Leader

Advancing Cancer Digital Twins: The Work of the Avicenna Alliance's Cancer and *In Silico* Oncology Task Force

The Cancer and *In Silico* Oncology Task Force of the **Avicenna Alliance** is actively leading international efforts to integrate digital twin technologies into cancer care, with the goal of transforming oncology through personalized, simulation-driven medicine.

One of the Task Force's recent major achievements has been the successful completion of a **special topic collection** in the journal *Frontiers in Physiology* (Section: Computational Physiology and Medicine), titled: *Multiscale cancer modeling, in silico oncology, and digital (virtual) twins in the cancer domain*
This collection includes **6 articles** authored by **33 contributors** from Europe and the United States, with **over 11,000 views**, **2,655 downloads**, and **14 citations** to date. It represents a powerful transatlantic collaboration involving academic institutions, industry leaders, and regulatory stakeholders.

In the **editorial article**, special attention was given to the role of the **Avicenna Alliance Cancer and *In Silico* Oncology Task Force,** the **VPH Institute**, **EDITH**, and **EMA**, alongside relevant U.S.-based initiatives and organizations such as the **National Academies** and **ASME**. These efforts highlight a growing international commitment to integrating digital twins into clinical oncology practice.

Digital or virtual cancer twins simulate disease progression and treatment response using patient-specific data, with the potential to vastly improve decision-making, personalize therapies, and enhance clinical outcomes. While other areas of *in silico* medicine have made faster progress, oncology still faces complexity at the molecular and systems levels. However, the momentum is building—particularly through projects using **prostate cancer** as a model—and this special issue lays the groundwork for future clinical translation.

Notably, companies such as **Philips** and **Varian** have shown significant interest, particularly in the field of radiation oncology, and Partnerships are also expanding, including ongoing collaboration with **Dr. Ravi Radhakrishnan** at the **University of Pennsylvania**. These developments suggest a growing opportunity to engage not only with medical device manufacturers but also with the pharmaceutical industry, which will be critical in broadening the scope of digital twin applications.

Next Steps for 2025:

- Creation of a **library of related publications**
- Engagement with **external reviewers** to formalize a **position on usability** of cancer digital twins
- **Dialogue with Health Authorities**
- **Informing and educating Avicenna members** about the clinical potential and regulatory pathways of *in silico* oncology

As noted by Prof. **Georgios Stamatakos**, "The above-mentioned collection of papers can serve as a solid foundation for the next fundamental steps toward the clinical translation of *in silico* oncology. By joining forces across continents and disciplines, we can accelerate the realization of digital twins in everyday cancer care."

Spotlight on our member MCR – Mediolanum Cardio Research: Advancing Cardiovascular Innovation

By Maria Cristina Jori, Consultant and former Medical Director, and Sara Paina, Project Leader

Mediolanum Cardio Research (MCR) is a leading Italian Contract Research Organization (CRO) specializing in cardiovascular medicine.
Founded in 2002 and headquartered in Milan, MCR has earned a strong reputation for its scientific expertise and commitment to excellence in clinical research. The organization provides end-to-end services for the design, management, and execution of clinical trials, with a particular focus on cardiology, internal medicine, and related therapeutic areas.

MCR's strength lies in its integrated, science-driven approach, combining rigorous methodology with deep therapeutic insight. With over two decades of experience, MCR supports pharmaceutical companies, biotech firms, and medical device manufacturers as well as not for profit research organizations in bringing innovative therapies to patients. Its services range from project management, regulatory consulting and clinical trial management to data analysis and medical writing, ensuring high-quality outcomes at every phase of product development.

As a member of the Avicenna Alliance, MCR plays an active role in supporting the advancement of *in silico* medicine and regulatory science. The organization's involvement underscores its commitment to innovation and its forward-looking vision of integrating computational modelling and simulation into the development of cardiovascular therapies.

MCR's dedication to scientific integrity, patient safety, and innovation makes it a valuable partner within the Avicenna community and the wider biomedical ecosystem. By combining clinical excellence with technological advancement, MCR continues to contribute meaningfully to the evolution of precision medicine and evidence-based healthcare solutions.

Spotlight on our Partner Sano – Centre for Computational Medicine

By Maciej Malawski, Director

Sano, the Centre for Computational Personalised Medicine based in Kraków, Poland, is a European Centre of Excellence dedicated to transforming healthcare through advanced computational technologies. Established in 2019, Sano combines expertise in computer science, artificial intelligence, and biomedical engineering to support innovation in disease prevention, diagnosis, and treatment.

Sano is structured around six interdisciplinary research and development teams, with around 25 PhD students, postdocs, and scientific programmers. Areas of focus include computational neuroscience, medical imaging and AI, extreme-scale data computing, structural genomics, robotics, and software development. Notable projects include high-fidelity simulators for fetoscopic surgeries using generative AI, EEG-based diagnostics for dementia and stroke, and cardiovascular simulations from 0D to 3D modelling. Their tools increasingly integrate AI and virtual reality for real-time clinical decision support.

Flexible in its collaboration model, Sano engages in partnerships ranging from small-scale pilots to fee-for-service contracts and large co-funded research initiatives, such as Horizon Europe. Its strategic partners include the University of Sheffield and local institutions like AGH University and the Life Science Krakow Cluster.

Sano has recently joined the Avicenna Alliance as a Partner, reinforcing its commitment to advancing *in silico* medicine and contributing to the development of virtual human twins and regulatory-grade digital health solutions. This membership marks a new chapter of collaboration with stakeholders across Europe dedicated to the future of personalized, data-driven medicine.

By bridging cutting-edge research and real-world healthcare needs, Sano is playing a leading role in shaping the future of computational medicine in Europe and beyond.

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 60 recordings are available in the members only area of the Avicenna website. Last webinar, held on 8th of July is available in the public area too.

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

Our future webinars

- 26th 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 – Click here to register
- 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

Our most recent webinars

- 8th July 2025: **"Biomechanical digital twins in cardiovascular medicine"** by David Perrin from Predisurge – Watch the recording

  In this presentation, we will outline the technical development of our products, from modelling to algorithm integration and validation, and demonstrate their deployment in clinical workflows through real-world use cases.

- 10th June 2025: **"iSi Health: bringing *in silico* technologies from bench-to-bedside"** by Erica Beaucage-Gauvreau from KU Leuven – Watch the recording

  In this presentation, we will discuss the activities and future initiatives of iSi Health that will help to support the clinical implementation of in silico technologies.

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

Watch the recording

EU Policy and Regulatory updates

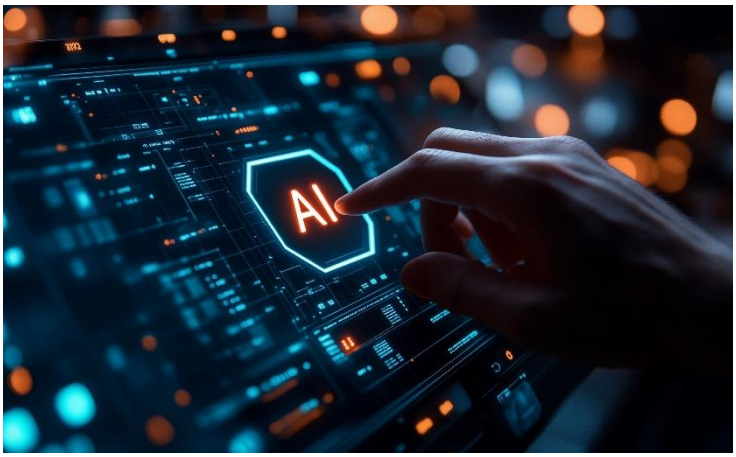
Commission simplifies instructions for use of medical devices to further digitalise healthcare systems

Healthcare professionals will be able to receive instructions for use of medical devices in electronic format, rather than solely on paper, following a regulation of the European Commission presented today. The regulation applies to all medical devices used by healthcare professionals within the EU. Professionals can still request paper versions if preferred. The adoption of electronic instructions for use is a part of the Commission's broader initiative to modernise healthcare, support environmental sustainability, and alleviate financial and administrative pressures on device manufacturers. The measure was broadly supported in recent consultations of the European Commission with professionals and industry representatives.

This announcement is part of the Commission's ongoing work to streamline and improve the EU's rules for medical devices. In the coming days, the Commission will adopt a decision to establish an expert panel to provide scientific and clinical advice concerning devices intended for small patient populations, such as children or patients with a rare disease.

The Commission is furthermore carrying out an evaluation of the regulatory framework, with a view to a revision of the legislation for Medical Devices and In Vitro Diagnostics, to reduce unnecessary burden and make the requirements more cost-efficient and proportionate. This will ensure a secure supply of safe devices for EU patients, while supporting innovation and boosting the competitiveness of the EU's medical devices sector.
This evaluation and its follow up actions will be presented in December, when Commissioner **Várhelyi** will host a conference on medical devices in Brussels.

News from the Medical Device Coordination Group



On 19 June 2025 the MDCG released a comprehensive FAQ on the interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act This publication aims to address common inquiries concerning the integration and application of the AI Act alongside existing medical device regulations within the European Union. The document serves as a guide for stakeholders to navigate the regulatory landscape and ensure compliance with the evolving legislative framework.

Key takeaways include:

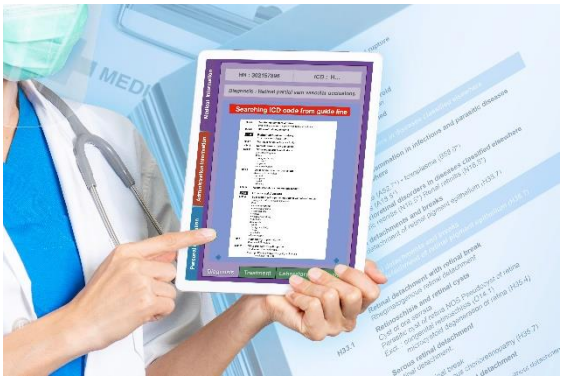
- **High-risk classification**: Under AIA Article 6(1), an AI system is classed as high-risk if it's a safety component or a medical device subject to conformity assessment under MDR/IVDR—but this doesn't change the device's risk class under MDR/IVDR.

- **Terminology alignment**: “Manufacturer” in MDR/IVDR equates to “provider” in AIA, while “deployer” in AIA is not the same as “user” under MDR/IVDR.
- **Quality management & risk lifecycle**: It encourages integrating AIA-specific data governance, transparency, human oversight, and lifecycle surveillance into existing MDR/IVDR QMS.
- **Technical documentation & post-market monitoring**: A single coherent technical file is recommended that satisfies both MDR/IVDR and AIA requirements, including AI-specific oversight and ecosystem interaction risks.

This “living document” will evolve with more FAQs as new regulatory challenges emerge.
Download the full document.

MDCG 2025-4: Key Guidance for Medical Device Software on Online Platforms

Published in June 2025, this document clarifies the regulatory obligations for all parties involved in bringing Medical Device Software (MDSW) apps to the EU market, with a particular emphasis on online platform providers.



Released by the European Commission's Medical Device Coordination Group (MDCG), this document is of great importance for stakeholders involved in the implementation of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.

Key features of the guidance include:

- Analytical vs Clinical Performance Studies: it provides a precise differentiation between these types of studies, facilitating appropriate methodological approaches.
- Sponsor Responsibilities: it clarifies the obligations of sponsors based on study type, including provisions related to academic research, ensuring comprehensive compliance and oversight.
- Regulatory Criteria: it establishes clear criteria for the necessity of applications or notifications to competent authorities, specifically concerning Articles 58(1), 58(2), and 70 of the IVDR.
- Companion Diagnostics and Left-over Samples: it offers specific guidance regarding the utilisation of companion diagnostics and the ethical use of left-over samples in research.
- Substantial Modifications Management: it delivers strategies for handling substantial modifications per Article 71 of the IVDR, supporting adaptability in evolving research initiatives.

For full details, access the official document here

European Virtual Human Twins (VHT) Initiative: Accelerating innovation and making personalised medicine a reality through virtual human twins

The European Commission is organising a high-level event to discuss the strategic vision for the European Virtual Human Twins (VHT) Initiative – a major step towards driving AI innovation and making personalised medicine a reality, on 21st October 2025 in Brussels. Launched in December 2023, the **European Virtual Human Twins Initiative** supports the emergence and adoption of the next generation of VHTs in health and care.

It showcases the EU’s commitment to advancing health data infrastructures, supercomputing capacity, and artificial intelligence, in alignment with core Commission priorities, including the AI Continent Action Plan, and the **Apply AI** and **Life Sciences Strategies**.

Since the Initiative's launch, more than 90 organisations from industry, academia and research have signed the **European Virtual Human Twins Manifesto** – a Statement of Intent on the collaborative development of VHTs and their increased adoption across the EU.

The event will build on this momentum, bringing together leading stakeholders from across Europe – including researchers, healthcare professionals, industry innovators, policymakers, and Member State authorities – to further shape the **strategic vision of the Initiative**. A central focus will be on **accelerating innovation** and bringing VHT technologies into **clinical practice**.

Key discussion topics

- The role of the VHT Initiative in addressing the gaps identified in the **VHT Roadmap** developed by the **EDITH** Coordination and Support Action
- How the forthcoming advanced platform for virtual human twins can reap the benefits of, and be integrated into, the **European Health Data Space** and other health data infrastructures (e.g. cancer imaging, genomics)
- Key aspects for VHT solutions uptake, in particular **regulatory aspects**
- Challenges and opportunities for VHT foundational **research**

The event is targeting the following audience:

- Representatives of Health Ministries and/or Research and innovation and/or Digital Ministries of EU Member States; Member states representatives from Permanent representations to the EU
- Representatives of European and national health professional societies and patient associations
- Academia and research institutes working on VHTs
- Industry and SMEs working on VHTs

The European Commission is setting up a scientific panel of independent experts to support the implementation and enforcement of the AI Act.

The panel will focus on general-purpose AI (GPAI) models and systems, advising the EU AI Office and national authorities on systemic risks, model classification, evaluation methodologies, and cross-border market surveillance. It will also alert the AI Office of emerging risks.

The Commission is looking for 60 members for a renewable 24-month term.

Candidates should have expertise in GPAI models and systems, AI impacts, or related fields, such as model evaluation, risk assessment and mitigations, cybersecurity, emerging systemic risks, and compute measurements and thresholds. Experts must have a PhD or equivalent experience and remain independent of any AI provider.

The selection process will ensure gender balance and representation across EU Member States and EEA/EFTA countries. While EU citizenship is not a requirement, 80% of the experts must be from the EU or EFTA Member States.

Applications are open until 14 September.

EU Pharma Package: A Major Reform to Modernise Medicines in Europe

The EU is undergoing its biggest pharmaceutical reform since 2004. On 4 June 2025, the Council agreed on its position for the **Pharma Package**, a set of new rules aiming to make medicines **more accessible, innovative, and sustainable** across the EU.

Proposed by the European Commission in April 2023, the Pharma Package updates outdated legislation to better meet today's healthcare challenges while keeping the EU pharmaceutical industry globally competitive.

Key Objectives

- Ensure timely and equal access to safe, affordable medicines
- Tackle drug shortages with stronger supply chain measures
- Reward innovation in antibiotics, rare diseases, and children's medicines
- Accelerate drug approval with a more efficient EMA process
- Promote environmental responsibility in pharmaceutical production

What's New?

- New **incentives**: Extended data and market exclusivity for innovative medicines
- Support for **orphan drugs** and **antimicrobials**, including a voucher system
- Improved **shortage response** and monitoring of critical medicines
- Required **environmental risk assessments** for all new products

Access to medicines still varies across Europe. This reform aims to close those gaps, support cutting-edge research, and future-proof EU healthcare—while protecting both **public health** and the **environment**.
The Council and European Parliament will now negotiate the final text.

AI in Health: Navigating the Future of European Healthcare

On 14 May 2025, the European Policy Centre hosted a 2-hour session title 'AI in Health: Navigating the Future of European Healthcare' in Brussels.

The event brought together a diverse panel of experts representing key sectors - regulatory, policy, industry, academia. The discussions touched on both the opportunities and the challenges related to the rapidly changing digital health landscape. Central to the discussions were the need for trust, data governance, strategic alignment, and interdisciplinary collaboration. All considered as pillars of the EU's vision for responsible and strong, competitive healthcare innovation, the event relates closely to the ongoing discussions in the field of *in silico* medicine.

Two key legislative initiatives underpinned the discussions: the **AI Act** and the **European Health Data Space (EHDS).** Both frameworks were not only presented as regulatory necessities but also as foundational tools for building trust, addressing data bias, and enabling equitable innovation across the EU, highlighting the social implications that were addressed.

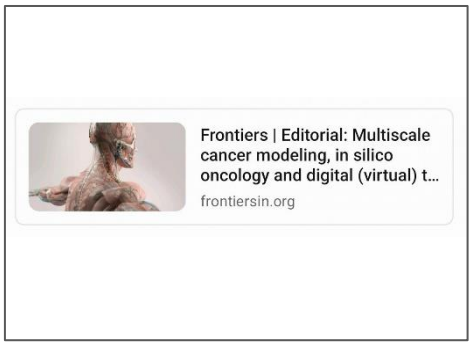
The discussions resonated directly with the ambitions in the field of *in silico* medicine and the vision for the Virtual Human Twin, which was also addressed by one of the speakers. The call to action is clear: there is a

need to build coherent and navigable frameworks, strengthen **AI literacy** among healthcare professionals, and foster more **trust** by investing in transparency, stakeholder inclusion, and societal alignment.
As one speaker aptly put it to conclude: *"The future is ours to shape."* Now is the time to ensure that vision includes **trustworthy *in silico* infrastructures** that serve both science and society. Yet, for this future to materialize, Europe must lead **ethically, responsibly**, and **strategically**, aligning regulation with innovation and embedding health AI in its broader industrial and competitiveness strategies.

More information on the event can be found here.

Recent news

New open-access, peer-reviewed paper collection



A new open-access, peer-reviewed paper collection titled "Multiscale Cancer Modeling, *In Silico* Oncology and Digital (Virtual) Twins in the Cancer Domain" has been published in Frontiers in Physiology – Computational Physiology and Medicine. Edited by the Avicenna Cancer and *In Silico* Oncology Task Force Leader, Prof. Georgios S. Stamatakos, together with Prof. Maria Angeles Perez, and Prof. Ravi Radhakrishnan, the collection highlights recent advances in *in silico* oncology and cancer digital twins.

The editorial introduces *in silico* oncology as a rapidly evolving discipline supporting cancer prevention, diagnosis, prognosis, and treatment optimization through computer-based modelling.

These models—mechanistic or AI-based—must undergo strict clinical validation to be applied in real-world settings.

Cancer digital twins simulate disease progression and treatment outcomes, enabling personalized care. Their transformative potential is recognized in major initiatives across the EU (EDITH, EMA, Avicenna Alliance) and the US (National Academies, ASME).

Explore the collection here and the editorial here

Digital Twins at work: when real life meets virtual intelligence – Milan, 29th of May 2025

On May 29th, 2025, our President and Secretary General, Thierry Marchal, and Office Manager, Roberta Maggi, took part in the workshop "Digital Twins at Work: When Real Life Meets Virtual Intelligence" held at the Cascina Triulza Auditorium near Milan and organized by Alessandro Maiocchi from Bracco.

As part of this exciting initiative led by the Federated Innovation ecosystem, Thierry delivered a keynote titled "Healthcare Digital Twin: The New Reality for a Safer, Faster and More Affordable Healthcare in Industry and Hospitals". His presentation explored the transformative role of digital twins in revolutionizing the healthcare sector.

The event also featured our Research & Technology Working Group Leader, Prof. Liesbet Geris (VPH Institute), who gave a compelling overview of the EDITH project. She was joined by a diverse line-up of esteemed speakers from academia, industry, research centres, foundations, and startups — all united by a shared vision for advancing digital innovation.

The workshop blended expert talks with interactive discussions, inviting participants to exchange insights and shape the future of Digital Twin applications.

One key takeaway from the discussion was that Digital twins in healthcare are no longer a distant concept — they are already being used to support patient care today. While ongoing research and model refinement are crucial to expand their application and improve their reliability, collaborative initiatives like the Avicenna

Alliance are helping drive this progress. We must act now, as this technology is already capable of saving lives.

Equally important is building trust among key stakeholders — industry, academia, regulators, clinicians, and patients. Open dialogue is essential to understand each other's perspectives and challenges. This Italian workshop on digital twins stands as a strong example of the kind of productive collaboration we need.

LifeScience 4EU event in Krakow

As part of the Polish Presidency of the European Council, Klaster LifeScience Krakow led by Kazimierz Murzyn organized the LifeScience 4EU event. This two-day conference brought together decision-makers and opinion leaders from the healthcare sector to brainstorm on the future of healthcare in Europe. Thierry Marchal, Secretary General & President of the Avicenna Alliance, and Liesbet Geris, Executive Director of the VPH Institute, responsible for the Research and Technology working group, were invited to take part in various panels.

They explained the importance of engineering solutions, including the virtual human twin, to better help the medical community and they painted an exciting future harnessing AI for healthcare, including personalized healthcare, while keeping in mind the limitations of this technology. Many discussions illustrated the evolution of traditional clinical trials away from Europe. This calls for a rapid adoption of *in silico* clinical trials that would streamline the regulatory approval process while amplifying patient safety.

The final report and recommendations from this prestigious event will help guide Europe towards better and more affordable healthcare for its citizens, but also inspire the world and facilitate closer collaborations between regions.

Click here for video

Welcome to our new Partner: Sano!

We are delighted to welcome Sano – Centre for Computational Personalised Medicine as a new Partner of the Avicenna Alliance!

Based in Kraków, Poland, Sano is a leading non-profit research institute dedicated to advancing computational medicine.

Through the development of sophisticated computer models and AI-driven tools, Sano transforms complex medical data into actionable insights for disease prevention, diagnosis, and treatment.

With strong collaborations across Europe and a mission to bridge research and clinical practice, Sano brings valuable expertise to our growing community:

"The addition of Sano, a leading centre for computational medicine, as a new partner will raise the profile of the Avicenna Alliance and enable our members to join forces for closer collaboration between industry, academia and hospitals" said Thierry Marchal, President & Secretary General, Avicenna Alliance.

“At Sano, we work on a new generation of digital twin solutions. So, industry partnerships through Avicenna Alliance are vital for ensuring that these technologies move beyond research into practical, real-world deployment”, said Maciej Malawski, Director of Sano.

We look forward to working together to shape the future of *in silico* medicine!

Learn more about Sano Science…

Members Corner

Events

iSi Health 2025

Join the iSi Health celebrations for the 600 years of KU Leuven!
Virtual Twin Driving Healthcare 2.0
September 11th & 12th 2025 I Leuven, Belgium

Register here
Programme

VPHi Summer School

Missed the VPH Summer School? Now you can catch up!

The 8th VPH Summer School brought together brilliant minds in biomedical modelling, simulation, and integrative medicine — and now, all sessions are freely available to watch on YouTube!

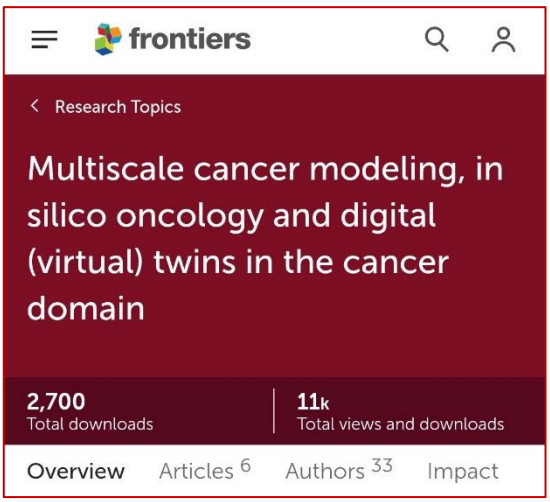
From cutting-edge lectures to insightful Q&As, explore the full experience and dive into the latest advancements in *in silico* medicine.

Watch now

Publications

New open-access, peer-reviewed paper collection: "Multiscale cancer modeling, *in silico* oncology and digital (virtual) twins in the cancer domain".
Frontiers in Physiology – Section Computational Physiology and Medicine.

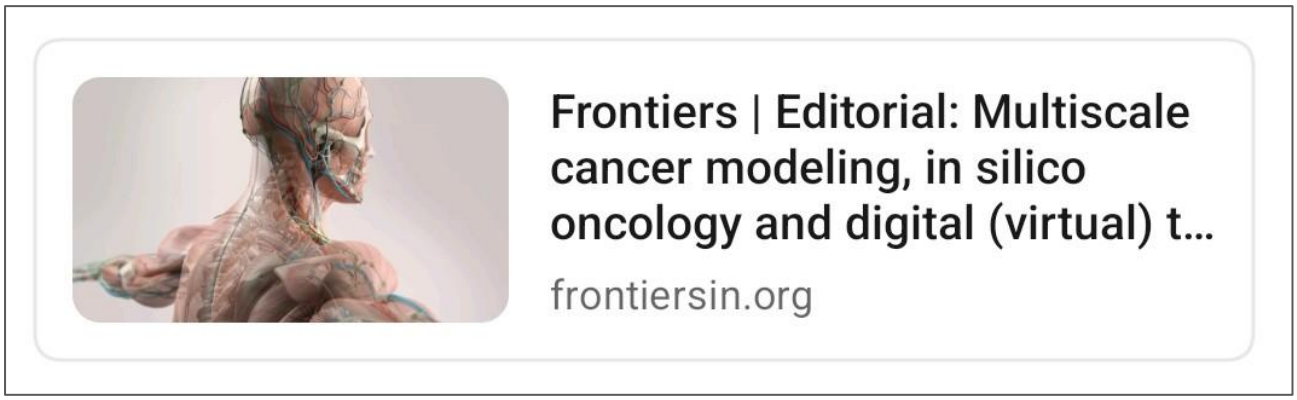
Some of the latest developments in multiscale cancer modeling, *in silico* medicine in the cancer domain (*in silico* oncology) and cancer digital twins are freely accessible through the paper collection of Frontiers in Physiology dedicated to these very hot topics.



The "topic" has been edited by Research Prof Georgios S. Stamatakos, *National Technical University of Athens, Greece, and Co-Chair, Avicenna Alliance Cancer and In Silico Oncology Task Force*, Prof Maria Angeles Perez, *University of Zaragoza, Spain*, and Prof Ravi Radhakrishnan, *University of Pennsylvania, USA*.

The editorial of the topic is accessible here.

"*In silico* oncology, a pivotal branch of the fast evolving *in silico* medicine, is a scientific, technological, and progressively clinical discipline that aims to support cancer prevention, diagnosis, prognosis, monitoring and patient-specific optimization of clinical interventions or simulating clinical studies by conducting *in silico* experiments, i.e., experiments on a computer. *In silico* experiments utilize models or technologically integrated digital (virtual) twins of parts of - or the entirety of–the human body, and eventually its environment, as well as these models' biological behavior and/or interactions with eventual intervention(s). The models utilized can be based on mechanistic multiscale modeling and simulation and/or artificial intelligence (AI) modeling including machine learning. Each model must undergo a strict clinical validation and certification before being exploited in a real clinical setting."



"In summary, digital or virtual twins are becoming pivotal in oncology. Cancer digital twins facilitate personalized cancer care by simulating disease progression and treatment responses, enhancing decision-making and therapeutic outcomes. The transformative potential of digital twins in healthcare has been emphasized both in the European Union (EDITH, EMA, Avicenna Alliance - Cancer and *In Silico* Oncology Task Force) and the United States (National Academies, ASME). Collectively, these endeavors highlight a global commitment to integrating digital or virtual twins into medicine and especially oncology. By fostering collaboration between engineering, medical, and regulatory communities, these *in silico* initiatives are expected to strengthen personalized medicine and accelerate the development of effective cancer therapies."

Code & Cure Understanding *In Silico* Medicine

After over a year of dedicated work, the completion of VPHi's animated video series is now available. Composed by 10 episodes, the series is crafted to make the world of *in silico* medicine accessible to everyone, from students and professionals to curious minds.

Watch the full series

Predisurge featured in Maestria Magazine

The article highlights Predisurge journey in transforming cardiovascular surgery through cutting-edge simulation technologies and personalized planning tools. It's an honour to be recognized among innovators shaping the future of healthcare.

A big thank you to *Maestria* for showcasing our vision and to all who support our mission to bring precision and safety to the operating room.

Read the full article on Page 12

Other News and interesting links

Sawbones® and Numalogics Achieve First-Ever FDA Qualification of an Orthopedic Device Mechanical Test Under MDDT Program

Last month in May, Sawbones and Numalogics, Inc. announced that their jointly developed Finite Element Analysis (FEA) model for orthopaedic screw pullout testing has received formal qualification from the United States Food and Drug Administration (FDA) through its Medical Device Development Tools (MDDT) program[1]. This achievement marks the first-ever FDA qualification of a mechanical test for an orthopaedic device, setting a new precedent for virtual testing in regulatory science.
The qualified tool simulates screw pullout behaviour in accordance with ASTM F543[2], a widely accepted standard for evaluating the mechanical performance of orthopaedic screws. Built on Sawbones' industry-standard synthetic bone materials and powered by Numalogics' advanced FEA modelling technology, the model enables accurate, reproducible virtual testing, reducing reliance on time-consuming and costly physical bench tests. This validated virtual method allows orthopaedic device manufacturers to replace or supplement physical testing for both product design optimization and regulatory submissions.

Interested users can access the tool directly through the Sawbones' ENDPOINT™ platform, a suite of virtual orthopaedic implant test tools, at: https://www.sawbones.com/endpoint-virtual-orthopedic-mechanical-implant-tests-fea

[1] **Medical Device Development Tools (MDDT) Program** – An FDA initiative that qualifies tools (such as models, clinical trial simulations, or biomarker tests) for use in medical device development and regulatory review, ensuring they meet standards for scientific validity and reliability in a specific context of use.

Learn more

Dr. Tina Morrison has joined Virtonomy's Scientific & Regulatory Advisory Board

Virtonomy is thrilled to announce that Dr. Tina Morrison has joined **Virtonomy's Scientific & Regulatory Advisory Board**!

A pioneer in regulatory science and *in silico* medicine, Dr. Morrison brings nearly 20 years of leadership at the **U.S. FDA**, where she championed the adoption of simulation and digital evidence in medical product evaluation.

Her vision perfectly aligns with Virtonomy's mission to advance **digital twin technologies** and ***in silico* clinical trials**.

Read the full Linkedin post

New funding opportunities for the *in silico* medicine community!

The European Commission has announced the Health and Research Infrastructures 2025 Work Programmes. These programmes contain several opportunities in the *in silico* medicine domain.

Calls of relevance for the community that have recently been published:

Work Programme 4. Health (deadline 16/9/2025)

- HORIZON-HLTH-2025-01-CARE-01: End user-driven application of Generative Artificial Intelligence models in healthcare (GenAI4EU)
- HORIZON-HLTH-2025-01-TOOL-03: Leveraging multimodal data to advance Generative Artificial Intelligence applicability in biomedical research (GenAI4EU)

Link: 2025 Horizon Europe 'Health' calls for proposals - European Commission

Work Programme 3. Research Infrastructures (deadline 18/9/2025)

- HORIZON-INFRA-2025-01-EOSC-05: Using Generative AI (GenAI4EU) for Scientific Research via EOSC
- HORIZON-INFRA-2025-01-TECH-04: AI-generated digital twins for science

Link: wp-3-research-infrastructures_horizon-2025_en.pdf

Explore all calls

InSilicoTrials named one of the fastest-growing startups by Sifted

InSilicoTrials has been featured in the **Sifted 100** – France & Southern Europe 2025, a list that highlights the most promising and fastest-growing startups, based on key growth metrics including fundraising, headcount expansion, and revenue growth.

See the full list
Read the Linkedin post

New Release from NumeriCor

Two highly detailed cardiac models now publicly available and generated in just a couple of minutes using latest NumeriCor product **CardoTwin**.

These models were built **entirely from open-access raw CT images**, showcasing the **speed**, **automation, and accuracy** of CardioTwin's fully integrated pipeline. No manual segmentation, no tedious processing—just fast, high-quality results.

This marks a major step forward in giving researchers, clinicians, and engineers access to enabling technology that builds **patient-specific heart models directly from their own imaging data**.

Whether you're developing cardiac devices, running simulations, or building digital twins, **CardioTwin** accelerates your workflow dramatically.

Link to download

A **video tutorial** has been created to walk you through the process step-by-step:
- How to download a core version of **Studio**
- How to access the **models** from NumeriCor website
- How to visualize them directly in **Studio**

Whether you're a researcher, clinician, or engineer, this guide will get you up and running in no time.

Link to video tutorial

Time to stop improvising 3D leg alignment analysis?

While 3D imaging has revolutionized orthopaedics, many alignment methods are still stuck in 2D. The result: inconsistent practices and incomparable studies.
A new **international consensus**, endorsed by 35 global experts, provides a unified framework for 3D analysis of lower limb alignment—standardizing joint centres, coordinate systems, and alignment metrics.
This major step forward empowers surgeons to better personalize bone corrections, improve surgical reproducibility, and prepare for the 4D era.

According to Twinsight, the adoption of this consensus will help make surgical practices more reproducible.
A 3D morphometric approach is essential for accurate planning and better personalization.

It is precisely with these standards in mind that Twinsight is developing its **SurgiTwin** solution for total knee arthroplasty planning.

Read the full Linkedin post

JOB OPPORTUNITIES

Medical Data Processing Analyst

About Hemolens Diagnostics®:
We're a multidisciplinary team of bioengineers, cardiologists, and IT professionals developing cutting-edge, non-invasive diagnostic tools that aim to revolutionize cardiology and reduce risks associated with invasive procedures.

Location: Wrocław, ul. Legnicka 48 G | Hybrid work: 4 days onsite, 1 day remote

Your Role:
- Process, evaluate, and correct medical data
- Collaborate with AI, CFD, and Web Development teams
- Work with 3D medical data analysis software

Skills:
- Eagerness to learn — no prior extensive experience needed; we'll teach you!
- Passion for data analysis and working with medical data
- Degree in biomedical engineering, medicine, physiotherapy, or related fields
- Knowledge of electrophysiology, radiology, cardiology, especially coronary vessel imaging (angiography, FFR, IVUS, OCT, CT)

Apply now

National Sales Network Conference and Career Fair

Meet Edwards at the National Sales Network Conference and Career Fair, August 7th & 8th in Las Vegas.

Edwards Lifesciences is excited to be part of NSN 2025 and is actively seeking passionate, driven Sales professionals who are ready to make a meaningful impact. At Edwards Lifesciences, we believe in building strong, lasting partnerships with healthcare providers and industry leaders—and it all starts with exceptional people like you.

If you're ready to take the next step in your career, we'd love to learn more about you. Please complete the form so we can explore how your talents align with the exciting opportunities we have to offer.

We're looking forward to meeting National Sales Network members and sharing more about Edwards Lifesciences career opportunities across our US sales organization.

If you're ready to take the next step in your career, we'd love to learn more about you. Start your pre-conference journey by registering with us now: Edwards Lifesciences @ NSN 2025

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

Contact us

Join the Avicenna Alliance!