



Avicenna Alliance

Association for Predictive Medicine

Avicenna Alliance Newsletter NOVEMBER – DECEMBER 2024

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Another fantastic year with amazing achievements

By Thierry Marchal
President & Secretary General

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I can't believe we're already reached the end of the year 2024 and have enjoyed a well-deserved and, I hope, relaxing break. It's the perfect time to stop for a few minutes and review some of the highlights of the year.

- **Global Pharmaceutical Legislation:** the new Global Pharmaceutical Legislation (GPL) was passed by the European Parliament on 10 April with 488 votes in favour, 67 against and 34 abstentions. It explicitly states that “Regulatory decision-making on the development, authorization and supervision of medicinal products may be supported by access and analysis of health data, including real world data, [...] and/or data generated via *in silico* methods, such as **computational modelling and simulation**, digital molecular representation and **mechanistic modelling, digital twin** and artificial intelligence (AI)”
- **IMDRF:** the International Medical Device Regulators Forum meetings were hosted by the FDA in Washington ([March](#)) and Seattle ([September](#)). Our delegates met with many people from different agencies and the WHO organization to propose the creation of a discussion and working group related to *in silico* technologies. The concept was well received and will be discussed at future meetings.
- **Publication of the book “Toward Good Simulation Practice”:** after 3 years of intensive work coordinated by InSilicoWorld, Marco Viceconti and Luca Emili, following a thorough review by the FDA and a nice foresight by Pras Pathmanathan, the book ‘Toward Good Simulation Practice’ was published in open

access in February; it was also presented at an online event in May. The book has been downloaded more than 35,000 times.

- **Meeting at the EU Parliament with MEP Stelios Kypouropoulos**: On February 21st, Member of the European Parliament (MEP) Stelios Kypouropoulos hosted a session dedicated to *in silico* medicine at the initiative of the Avicenna Alliance to inform Members of Parliament of the importance of *in silico* methods and *in silico* oncology for the Europeans citizens. The session included some very interesting contributions from MEP Kypouropoulos, Professor Geris, Professor Stamatakos and Thierry Marchal.
- **Proposition of numerous amendments to the revised Medical Device Regulation (MDR)**: at the suggestion of several MEPs, the Avicenna Alliance has carefully examined the current version of the MDR, which is open to revision, and has submitted numerous amendments for the adoption and regulation of *in silico* methods for preclinical and clinical applications.
- **Life Sciences Open Space in Krakow**: The Avicenna Alliance was invited to give a keynote speech at the Life Sciences Open Space conference in Krakow, Poland. This speech gave rise to numerous discussions aimed at amplifying the role of SANO, the Centre for Computational Personalized Medicine, and paved the way for engaging with the Polish authorities in preparation of their Presidency of the EU.
- **Engagement with the regulatory authorities around the world (Brazil, Japan, Korea, India, Australia)**: While Europe is a priority for the Alliance, it is essential to develop our relationships with other regions. Our reputation has facilitated various engagements, confirming the global interest and commitment to *in silico* methods. It also facilitates our discussions with Europe, which wants to remain at the forefront of digital transformation.
- **Improved communication** through our [website](#), social media ([LinkedIn](#) and brand-new [Instagram profile](#)) and [webinar series](#): great achievements will have no impact without a solid communications strategy. In 2024, we stepped up our communication through regular news, social media, popular monthly webinars and publications, all of which can be accessed from our updated website.
- **Avicenna Day and VPH 2024 Conference**: while remote communication is effective, there's no substitute for face-to-face meetings and the great opportunity to engage with you, including at Avicenna Alliance Day and the VPH 2024 events in Stuttgart.
- **Welcoming New Members and partners**: as every year, we were delighted to welcome many new members and partners who brought their own perspective, enthusiasm, time and ecosystem. Among them, we are proud to mention [Adsilico](#), [ToxByDesign](#), [InSilicoMinds](#), [Abimed](#), [Bioreme](#), ISO.

It's hard to sum up all the major achievements of the Avicenna Alliance, and its members, in just a few lines. But we can genuinely say that we have made amazing progress towards one of our ultimate goals: to have *in silico* evidence, including computational modelling and simulation, and digital twins, accepted for regulatory approval in Europe, and beyond.

Merry Christmas and a Happy and Successful New Year 2025.



Spotlight on the Notified Bodies and Standardization Task Force

By Bernard Staumont & Simon Sonntag
Task Force Leaders

The Notified Bodies (NB) and Standardization Task Force, co-led by Simon Sonntag and Bernard Staumont, continues its efforts to drive the acceptance of ***in silico* methods and evidence** by regulatory authorities and conformity assessment bodies, including Notified Bodies (NBs).

In response to the lack of guidance identified by NBs, the Task Force launched a standardization initiative, which remains a central focus.

The **2024 objectives** included:

- **Promoting acceptance of *in silico* evidence:** Engaging with key stakeholders and improving guidance documents.
- **Expanding networks:** Mapping key actors, building connections, and enriching contact lists of NBs and standards organizations.
- **Advancing ISO standards:** improving ISO documents in terms of inclusion of *in silico* methods.



Activities in 2024

Several significant activities have marked the year:

- **Strengthened standardization initiative:** Monthly meetings with growing participation from academia, industry, standards organizations, and ISO Committee leaders
- **Active engagement with ISO Committees:** Regular liaison with ISO/TC 276/WG 5 ("Data processing and integration") to gather feedback and contribute to standards development.
- **Key contact list development:** Establishing a comprehensive list of stakeholders in Notified Bodies and standardization organizations.
- **Dissemination of the GSP Book:** Following its publication, the book was shared with notified bodies, and experts in standardization, sparking discussions on future applications.
- **Key Events and Resources:**

Task Force members actively participated in prominent events, including:

- InnovaHeart event (February 6-7, Leuven)
- FDA/MDIC Symposium on Computational Modeling and Simulation (April 16-17, Washington)
- VPH Conference (September 4-6, Stuttgart)
- EDITH Roadmap and Standards Implementation Guide (Virtual Human Twin initiative)

These initiatives demonstrate the Task Force's strong commitment to advancing regulatory acceptance of computational modelling and simulation methods.

Spotlight on our member InSilicoTrials

by Luca Emili
CEO

InSilicoTrials is an innovative Italian company, at the forefront of revolutionizing healthcare through the power of *in silico* medicine. Founded with a mission to accelerate drug development and medical device innovation, the company leverages advanced computational modelling and simulation (CM&S) technologies to provide cutting-edge solutions for the pharmaceutical and medical device industries.



The company's unique platform enables researchers, developers, and regulators to harness the potential of **digital evidence**, reducing the time, cost, and risks associated with traditional clinical trials. By integrating **Good Simulation Practices (GSP)** and adhering to **regulatory standards**, InSilicoTrials offers validated tools that meet the rigorous requirements of global health authorities, including the FDA and EMA.

One of the company's standout features is its **user-friendly interface**, which democratizes access to sophisticated simulation tools. These tools empower small and large organizations alike to implement CM&S in their workflows without the need for extensive computational expertise. This approach ensures that **innovative therapies and medical devices** reach the market faster and more efficiently, benefiting patients worldwide.

InSilicoTrials is also a vocal advocate for **in silico medicine standards**. The company collaborates with regulatory bodies, industry stakeholders, and academic institutions to shape the future of healthcare.

Through active participation in initiatives of the **Avicenna Alliance**, InSilicoTrials is helping to establish credibility and global acceptance of CM&S as a pivotal component of modern medicine.

Luca Emili serves as the Avicenna Alliance GSP Task Force Leader, playing a pivotal role in driving the group's initiatives. He has significantly contributed to key projects, including the development of the GSP Task Force Book.

With its groundbreaking solutions and unwavering commitment to innovation, InSilicoTrials is driving the transformation of healthcare into a more **efficient, precise, and patient-centric industry**.

Public Review Open for VVUQ 40.1 Technical Report

Your Feedback Matters!

The VVUQ 40.1 Technical Report, titled "Assessing Computational Model Credibility Using the ASME V&V 40 Risk-Based Framework: Tibial Tray Component Worst-Case Size Identification for Fatigue Testing, is now open for public review".

This technical report provides critical insights into computational model credibility and offers guidance for risk-based decision-making in medical device evaluation. Ensuring its accuracy and applicability is vital for advancing in silico methods in regulatory and industrial practices.

To achieve this, your feedback is essential. The input from experts across disciplines will ensure the report is comprehensive, robust, and meets the needs of the community.

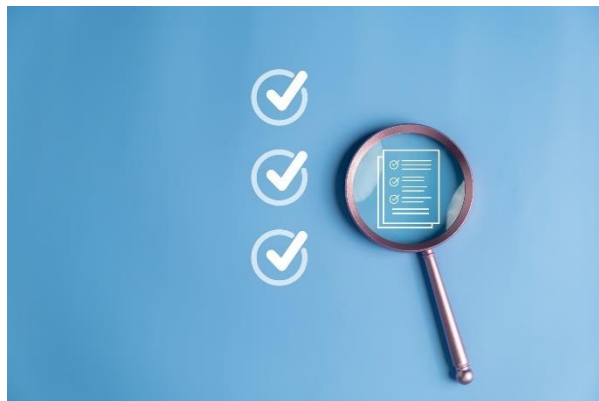
Key Information:

- Deadline for comments: 09 January 2025, 11:59 PM (local time).
- How to participate: Review the draft report and provide comments.
- Share widely: Feel free to distribute the draft and comment form to colleagues or other stakeholders who may be interested.

The draft report and contact people for more information are available for download in the ASME page at the following link: [C&S Connect > Public Review Page](#).

Your contribution to this review process will help strengthen the foundation for computational model credibility, supporting innovation and trust in in silico methodologies. Let's make this a collective effort!

Submit your feedback before 2025, January 9th – every perspective counts!



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 53 recordings are available in the [members only area](#) of the [Avicenna website](#). Latest 2 webinars, held on November 12th and December 10th, are also available in the [public area](#).

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

Our future webinars

- January 14, 2025: "***In Silico* Medicine: The Story So Far**" by Prof Marco Viceconti from University of Bologna – [Click here to register](#)
- February 18, 2025: "**From Innovation to Market: lessons and challenges from *in silico* CM&S disruption in Biotech and Pharma's *in silico* predictive toxicology**" by Matthieu Chareyre from Tox By Design – [Click here to register](#)

Our latest webinars

- December 10th, 2024: "**PyAnsys – Heart: A Python framework for LS-DYNA based heart simulations**" by Wenfeng Ye, Michel Rochette, Karim El Houari & Martijn Hoeijmakers from ANSYS Inc – [Watch the recording](#)

In this talk, the speakers present PyAnsys-Heart, a free, open-source, python-based high-level interface to Ansys LS-DYNA dedicated to heart modelling. They introduce the relevant heart modelling features available in Ansys LS-DYNA and describe how PyAnsys-Heart leverages them through automatic geometry preprocessing, boundary conditions setting, customizable complexity and results postprocessing.

- November 12th, 2024: "**Superior Spine Care with a Patient-Specific Biomechanical Digital Twin of the Spine**" by Roger Assaker and Richard Assaker from MDsim – [Watch the recording](#)

The presentation will introduce SPINesim, a SaMD developed by MDsim to generate a patient-specific biomechanical digital twin of the spine that can be used by spine surgeons to plan the optimal spine surgery that respects geometric alignment and predict the mechanical balance of the construct.

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

[Watch the recording](#)

EU Policy and Regulatory updates by the RPP team

By the RPP Team

06.11.2024, 20.11.2024 Várhelyi is confirmed for Health and Animal Welfare Commissioner after Facing Second Round of Questions

On November 6, 2024, Olivér Várhelyi, the Commissioner-Designate for Health and Animal Welfare, presented his strategic objectives during his Commission [hearing](#). **His main priorities include enhancing Europe's health resilience, ensuring the availability of critical medicines, and boosting the competitiveness of the EU pharmaceutical sector.** Várhelyi also aimed to address health crisis preparedness, tackle non-communicable diseases, support animal health and welfare, and promote sustainable agricultural practices.

President Ursula von der Leyen underscored these priorities, aligning them with broader EU goals. Várhelyi's proposals **included the Critical Medicines Act, a revision of the Medical Devices Regulation, and a new health plan focused on diseases like cardiovascular conditions, diabetes, and obesity.** Várhelyi's responses, however, generated mixed reactions. As he faced a second round of questions before his confirmation, he did not commit to updating the Cross-border Healthcare Directive but promised to improve its implementation and support universal access to sexual and reproductive healthcare. **On vaccines, he defended Hungary's national emergency authorisations but emphasised the potential for faster EU-wide approvals during future crises through EU pharma legislation and pledged to address vaccine misinformation.**

Later, on 20 November 2024, the European Parliament approved Olivér Várhelyi as a Commissioner for the von der Leyen Commission, though his portfolio has undergone significant adjustments. **Notably, the responsibilities for the Health Emergency Preparedness and Response Authority (HERA) and matters related to sexual and reproductive health and rights have been removed from his mandate.**



Olivér Várhelyi during the confirmation hearing 2024 © European Union, 2024 - Source: EP

12.11. 24 Public Health Subcommittee (SANT) to Become Full Legislative Committee

The EPP, Renew, and S&D Groups have agreed to upgrade the Subcommittee on Public Health (SANT) to a full legislative committee. This move, aimed at strengthening the EU's health response, follows extensive negotiations, with the S&D agreeing after securing assurances on food safety and pesticide regulation remaining under ENVI's control. Starting in January 2025, the newly empowered SANT will focus on public health issues such as pharmaceutical regulation, health crisis preparedness, mental health, and relations with the WHO, while ENVI will shift its focus to climate policy and environmental protection. **The decision is**

expected to be confirmed by the [Conference of Presidents](#) in the latest European Parliament Plenary of the year.

12.11.24 "GPL: Key Updates on General Pharmaceutical Legislation (GPL) before the end of the Hungarian Presidency"

The EU Council's recent discussions on the **General Pharmaceutical Legislation (GPL) focused on key proposals addressing medicine shortages, regulatory data protection (RDP), and transferable exclusivity vouchers (TEVs)**. New measures include shortage prevention plans for critical medicines, with Member States identifying the medicines and companies required to notify authorities of shortages at least three months in advance. RDP is set to a seven-year baseline, with a potential additional year for products addressing unmet medical needs. The market access timeline for authorisation holders is shortened to four years, with no interference in national pricing or procurement. Finally, TEVs are restricted to priority antimicrobials, with a cap on sales to prevent high costs from blockbuster drugs.

21.11.24 European Parliament Approves All European Commission Nominees

For the first time in 25 years, the European Parliament has approved all nominees for the European Commission. Despite intense negotiations, portfolio adjustments, and cross-vetoes, the Commission was confirmed and is set to begin its work on December 1, after the final European Parliament plenary vote on November 27.

26.11.24 UK Consultation on Medical Device Regulations and Market Access

The UK is currently holding a [consultation on medical device regulations](#), focusing on post-market surveillance (PMS) requirements, market access pathways, and in vitro diagnostic (IVD) devices. The proposed changes aim to enhance PMS for medical devices, responding to the Independent Medicines and Medical Devices Safety Review, which called for stronger safety measures. **The consultation outlines four key themes: introducing an international reliance scheme to expedite market access for globally approved devices, revising UK CA marking requirements for improved traceability, categorising IVD devices based on risk, and retaining assimilated EU law until the transition to updated regulations.**

The consultation also highlights challenges raised by the Association for British HealthTech Industries (ABHI), including potential delays and higher costs due to conformity assessments by Approved Bodies. The Labour Party has expressed a commitment to aligning UK regulations more closely with EU standards. **The consultation closes on January 5, 2025, and is crucial for stakeholders in the UK MedTech industry.**

03.12.24 EPSCO Council Advances Key Health Initiatives

On 3 December, EU Member States gathered for a formal [EPSCO](#) meeting to advance several critical health initiatives. The Council adopted [conclusions](#) on **Cardiovascular Health**, emphasising prevention, early detection, and treatment, alongside promoting healthier lifestyles and health literacy. **Organ Donation and Transplantation** also saw renewed political commitment with the adoption of [Council Conclusions](#), with calls to update the EU action plan.

A new [recommendation](#) focused on **Smoke- and Aerosol-Free Environments**, extending protections against second-hand smoke and aerosols to outdoor areas, including playgrounds and terraces, and covering e-cigarettes and heated tobacco products. This supports the goal of a tobacco-free generation by 2040 under Europe's Beating Cancer Plan. Ministers also discussed the [European Health Union](#), with a focus on the Draghi report's recommendations and their impact on national healthcare systems. Other topics included a **Pharmaceutical Package [progress report](#)**, MDR & IVDR framework revisions, and negotiations on pandemic preparedness and joint procurement.

03.12.24 HTACG Meeting Highlights and Next Steps

On December 3, 2024, the Member State Coordination Group on Health Technology Assessment (HTACG) published its [2025 Work Programme](#), emphasising the implementation of the **Health Technology Assessment Regulation (HTAR) through joint clinical assessments (JCAs) and joint scientific consultations (JSCs)**. The programme focuses on assessing new active substances, particularly cancer treatments and advanced therapy medicinal products, with robust guidance. The work also highlights collaboration across subgroups, stakeholder engagement, and the gradual introduction of medical device assessments.

The HTACG's strategic direction prioritises JCAs, JSCs, and emerging health technologies, with plans to initiate **5-7 joint scientific consultations for medicinal products and 1-3 for medical devices, scheduled for February–March and June 2025**. Stakeholder engagement will include collaboration with the Health Technology Assessment Stakeholder Network, outreach events, and awareness promotion for HTAR. **Input from emerging health technologies and stakeholders will shape the 2026 Work Programme, set for approval in November 2025.**

11.12.24 Polish Council Presidency Programme: Key Priorities for 2025

The Polish Council Presidency's [Programme](#) for January to July 2025 focuses on a range of strategic priorities across health, agriculture, competitiveness, and sustainability. **Key areas include mental health, digital healthcare infrastructure, and a forward-looking approach to employment challenges, with an emphasis on addressing skills shortages and improving digital skills.** Poland will also focus on ensuring a competitive and resilient agricultural sector, promoting food security, high-quality standards, and environmental sustainability, while navigating EU enlargement issues.

The programme highlights Poland's shift from pandemic recovery, focusing on long-term strategies for the Single Market, industrial development, and trade policy. Poland aims to strengthen EU economic security, enhance competitiveness, and maximise trade agreements, continuing the legacy of Hungary's focus on global competitiveness and strategic autonomy.

12.12.24 European Commission Launches Public Consultation on MDR and IVDR Evaluation

The European Commission has opened a [public consultation](#) and call for evidence on the targeted evaluation of the [Medical Devices Regulation \(MDR\)](#) and [In Vitro Diagnostics Regulation \(IVDR\)](#). This initiative seeks to assess the effectiveness, efficiency, and relevance of the current regulatory framework to ensure it aligns with emerging needs and EU priorities. It follows the European Parliament's resolution and a joint proposal from nine Member States advocating for an MDR revision, marking the first steps in the Commission's revision process.

The consultation, open from **12 December 2024 to 21 March 2025**, aims to gather feedback on the regulations' effectiveness in ensuring safe, effective devices, fostering sector competitiveness, and supporting innovation. The final adoption of the evaluation is scheduled for **Q4 2025**, with stakeholder feedback shaping the future of compliance, innovation, and market access in the medical device sector.

Relevant Dates:

- [High-Level Conference on the functioning of the public healthcare systems](#): Warsaw, January 16th
- [The European way of growth: A growth policy for a secure, resilient and globally competitive European Union](#), 30 - 31 January, The ICE Kraków Congress Centre.
- High-Level Conference on CMA (Critical Medicines Act): Brussels, February 19th
- [Ministerial conference on the ministry's presidency priority "Future of labour in a digital Europe](#), 20-21 February, Gdańsk, Poland.
- [Competitiveness Council](#) (Internal market and industry), 6 March, Brussels, Belgium.
- [High Performance Computing Summit: Krakow, March 17-20](#)

Recent news

[Merry Christmas or Happy Holidays](#)



Dear Avicenna Alliance Members, As we approach the close of 2024, it's time to pause and reflect on another remarkable year of collaboration and progress. Soon, many of us will take a deserved break to celebrate and recharge with our loved ones.

On behalf of the entire Avicenna Board, I want to express our heartfelt gratitude for your unwavering dedication throughout 2024. Your hard work and commitment have been instrumental in advancing the adoption and regulation of *in silico* methods, driving

forward meaningful achievements and shared success.

Now, let's take this time to rest, reconnect, and rejuvenate. Together, we'll embark on 2025 with renewed energy and enthusiasm, continuing our ambitious mission to make *in silico* methods an integral part of biomedical innovation.

Wishing you Happy Holidays, a joyful Christmas and a successful New Year filled with happiness, health, and even greater accomplishments!

The Avicenna Alliance Board

[Webinar "In Silico Medicine: The Story So Far" by Prof Marco Viceconti](#)

New Avicenna Monthly Webinar
"In Silico Medicine: The Story So Far"



Marco Viceconti
Full Professor
University of Bologna

Join an exceptional Avicenna Alliance Webinar by Prof Marco Viceconti: January 14th, 2025

Discover the Evolution of *In Silico* Medicine

Explore the fascinating journey of *in silico* medicine, from its early beginnings in the 1960s to its current role as a transformative force in biomedical innovation. World famous expert Prof. Marco Viceconti will guide us through the origins of computer modelling and simulation in medical product development and their evolution into "*In Silico (Clinical)* Trials."

This webinar will:

- Remind us of key milestones, including the Physiome Project and the founding of the VPH Institute and Avicenna Alliance.
- Examine how *in silico* medicine has grown into a thriving research area and emerging industrial sector.
- Present insights from a recent SWOT analysis on the adoption of *In Silico* Trials by biomedical industries, conducted by the InSilicoWorld consortium.

About the Speaker

Prof. Marco Viceconti, a leader in industrial bioengineering and a pioneer of *in silico* medicine, has made significant contributions through his work at the University of Bologna, as the founder of the Insigneo Institute and the VPH Institute, driving to the creation of the Avicenna Alliance. With over 400 published

papers and numerous accolades, including the Huiskes Medal for Biomechanics, Prof. Viceconti brings unparalleled expertise to this webinar.

Before the progressive retirement of one of the founders of *in silico* healthcare, don't miss this opportunity to deepen your understanding of *in silico* medicine's journey and future!

[REGISTER NOW!](#)

[Highlights from the NAFEM France Biomedical Session](#)



Our President and Secretary General Thierry Marchal alongside Daniel Fougères (Micado) had the honour to co-chair a series of six presentations during the NAFEM France Biomedical Session. The session brought together exceptional speakers from academia ([Badr Kaoui](#), [Tévy Julie Pigeon](#), Kenza Oussalah), industry ([Philippe Favre](#), [Julien Sigüenza](#)), and a regulatory expert ([Jean-Matthieu Prot](#)).

Professor [Irene Vignon-Clementel](#) opened the event with an outstanding keynote, emphasising the growing role of *in silico* methods, not only in industry but also in clinical applications. She nicely describes the central role of the EDITH CSA project.

A lively panel discussion followed, featuring [Jean-Matthieu Prot](#), [Philippe Favre](#), [Yanneck Suchier](#), and [Julien Sigüenza](#). Key insights highlighted a strong appetite for wider adoption of simulation technologies, tempered by ongoing trust challenges. To bridge this gap, participants suggested increased sharing of regulatory submissions involving modelling and simulation, the development of additional standards, and enhanced dialogue among stakeholders.

These discussions are set to continue through [Biomed In Silico France](#).

A big thank you to the organisers for an outstanding event: Jean-Marc Crepel, [Didier Large](#), [François Large](#), and [Tim Morris](#)!

[Avicenna Alliance is Now on Instagram!](#)

Avicenna Alliance is now on Instagram!



Avicenna Alliance
Association for Predictive Medicine



Here's something new! The Avicenna Alliance has joined Instagram to bring you the latest updates, insights, and highlights from the world of *in silico* medicine.

Follow us to stay connected with our activities, events, and achievements. Let's expand our community and raise awareness about the potential of *in silico* solutions.

We invite you to follow our page and share this news with your network - let's grow together!

See you on Instagram!

Follow us here: <https://www.instagram.com/avicennaalliance/>

[Avicenna Day \(AAD\) 2024 Recordings Now Available](#)



Did you enjoy AAD 2024 and want to rewatch presentations from world-class thought leaders? Or did you miss the event? This news is for you!

Following the successful AAD 2024 on September 3 in Stuttgart, we're pleased to announce that a selection of session recordings is now publicly available on the Avicenna website. Full recordings are also accessible for members in the members' only area.

AAD 2024 brought together 75 in silico specialists, executives, clinicians, standards organizations, and regulators. The event showcased the Alliance's role as a central communication platform, driving collaboration to accelerate safer and more effective patient solutions.

Don't miss your chance to watch or rewatch these key moments.

[Click here to watch the recordings](#)

Members Corner

Events

“Join the iSi Health celebrations for the 600 years of KU Leuven!”

iSi Health is organising several events for the 600 years of KU Leuven in 2025.

Discover how innovation meets centuries of academic excellence. Be part of inspiring discussions, groundbreaking advancements, and the vibrant history of one of the world's oldest universities. Event details available [here](#).

Let's honour this incredible milestone together!

Join the iSi Health celebrations for the 600 years of KU Leuven!

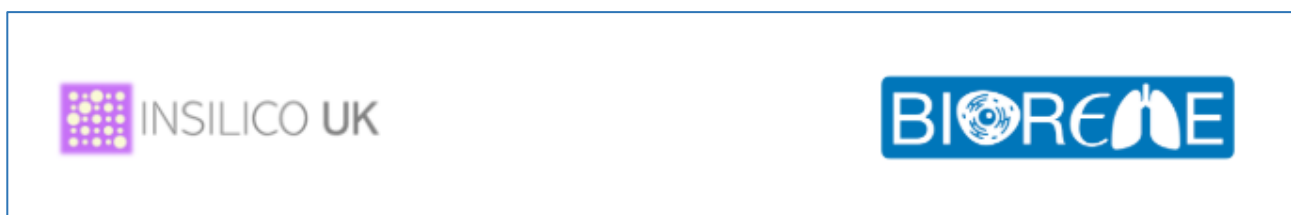
The graphic features three event cards connected by a blue line. Each card has a central icon and several surrounding circles with text.

- MODELING CHALLENGE**
Digital Twin Builder for Health Incubator
January-September 2025
Icons: A person on a screen, a gear, a lightbulb, and a 360-degree view icon.
Surrounding text: PhD & Postdoc, Modeling clinical needs, 360° view of clinical needs.
- SYMPOSIUM**
Virtual Twin Driving Healthcare 2.0
September 11-12, 2025
Icons: Three people, a gear, and a lightbulb.
Surrounding text: Pioneer Keynote Speakers, Thematic Interactive sessions, Virtual Twin ecosystem.
- SUMMER SCHOOL**
Innovation Bootcamp for Virtual Twin for Health
September 8-10, 2025
Icons: A graduation cap, a lightbulb, and a microscope.
Surrounding text: PhD & Postdoc, Multi-disciplinary program, Hands on approach.

Logos at the bottom: KU LEUVEN, iSi HEALTH KU LEUVEN INSTITUTE, bcs Knowledge knows no end.

Advancing In Silico Respiratory Medicine: An Introduction

2025, February 7th 12:00–13:00 GMT,
Online



Join us for this 1-hour webinar introducing a groundbreaking collaboration between InSilicoUK and BIOREME. Explore the latest progress in in silico medicine and its applications in respiratory health. The session will outline collaboration goals, including advancing computational models for clinical practice and reviewing promising technologies.

Attendees will have the opportunity to contribute during the webinar discussion or through a follow-up survey.

Follow-On Workshop on March 14th at University of Manchester.

This in-person event will delve deeper into webinar themes, focusing on identifying exemplar case studies to drive innovation in respiratory medicine.

Don't miss this chance to shape the future of in silico medicine!

[For more details, visit the landing page](#)

Workshop "Mathematics for our Health" – Politecnico of Milan



**POLITECNICO
MILANO 1863**

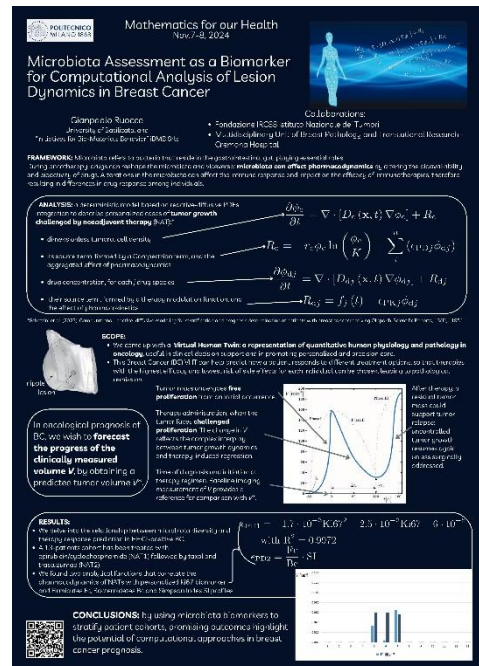
On November 7th – 8th 2024 Politecnico of Milan hosted the workshop "Mathematics for our Health". Among the distinguished keynote speakers, two famous researchers in the field of computational oncology were offering their seminal views:

- Prof. L. Preziosi, from Politecnico Torino, with a talk entitled "Modelling cell migration to understand cancer invasion"
- Prof. T. Yankeelov, from University of Texas at Austin, with a talk entitled "How mechanism-based digital twins can realize clinical trials for patients who are not average"

The prestigious University had the opportunity to showcase their last research effort on Virtual Oncological Twin: a representation of quantitative human physiology and pathology in oncology, useful in clinical decision support and in promoting personalized and precision care.

In particular, they showed how their Virtual Twin was nicely able to scrutinize the effect of personalized microbiota on pharmacodynamics when simulating breast cancer proliferation and related neoadjuvant therapy.

[Click here for Poster](#)



Publications

Why 'digital twins' could speed up drug discovery

BBC article

2024, December 13th



AI-powered digital twins are revolutionizing medical research and device testing. Companies like **Adsilico** create computer-generated models of human hearts to test cardiovascular devices, such as stents and prosthetic valves, in a virtual environment. These synthetic hearts replicate diverse attributes, including age, gender, and health conditions, enabling trials across underrepresented populations.

Adsilico's AI-driven simulations not only enhance device safety but also offer detailed insights by replicating thousands of scenarios. This approach significantly reduces reliance on costly and limited human and animal trials. Adsilico CEO Sheena Macpherson highlights the potential to minimize errors and save lives through rigorous virtual testing.

Meanwhile, drug manufacturers like Sanofi are leveraging AI to create simulated patients and streamline clinical trials, cutting costs and improving success rates. While challenges like biased data remain, advancements in AI-driven digital twins promise a more inclusive, efficient, and humane future for medical research.

adsilico

[Read the full article](#)

Women's Health in Drug Development: A Critical Focus



InSilicoTrials published a white paper highlighting critical gaps in women's health research and how *in silico* methods can help address them. While some progress has been made, significant disparities remain in understanding how medications affect women differently than men. These gaps arise from physiological differences and historical biases within research. To address these challenges, our white paper emphasizes the crucial role of *in silico* methodologies like PBPK and QSP modelling.

These approaches simulate drug interactions within women's unique physiological contexts, including during pregnancy and lactation.

InSilicoTrials, a leader in this field, leverages these technologies to optimize treatments for women and ensure their inclusion in virtual trials. By incorporating *in silico* approaches, researchers can bridge knowledge gaps and develop safer, more effective treatments for women, ultimately improving health outcomes for this underserved population.

[Download the white paper here.](#)

Other News and interesting links

Official Podcast of the InSilicoUK Pro Innovation Regulations Network



In Silico Trials, Real Impacts

Join the official Podcast of the InSilicoUK Pro Innovation Regulations Network. We're uniting visionaries to craft a national strategy that fast-tracks virtual clinical trials, propelling the UK to the forefront of healthcare innovation. We explore how computational modelling is reshaping patient care, boosting the economy, and accelerating medical breakthroughs. Tune in for insights on creating the UK's optimal ecosystem for in silico evidence in medicine. The future of healthcare is here – be part of the revolution.

[Join the podcast](#)

Episode 7: In silico medicine- Revolutionising musculoskeletal care

Many health conditions affecting bones and muscles are connected to illnesses or simple ageing. In this video, we dive into some of the most advanced in silico medicine solutions that are revolutionising how we diagnose, prevent, and treat musculoskeletal disorders.



[Watch the video](#)

InSilicoTrials is Now Part of the NVIDIA Inception Program to Revolutionize Healthcare

InSilicoTrials has recently been accepted into the [NVIDIA](#) Inception Program, now gaining significant advantages. As part of the program, we



will receive access to cutting-edge NVIDIA technologies like GPUs and software, crucial for AI development. This will undoubtedly boost our R&D capabilities to help us accelerate drug discovery efforts. The program also fosters valuable connections with investors, industry experts, and other startups within the NVIDIA ecosystem, creating a supportive environment for continued growth and innovation.



InSilicoTrials Finalist of 2024 Fierce Diversity, Equity & Inclusion Awards

InSilicoTrials was a finalist for the [Fierce Healthcare](#) DEI Awards, a prestigious program recognizing outstanding achievements in Diversity, Equity, and Inclusion (DEI) within healthcare. With numerous submissions across nine categories, a distinguished panel of judges evaluated entries based on criteria such as innovation, impact, measurable outcomes, sustainability, scalability, and ethical considerations.



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