



Avicenna Alliance

Association for Predictive Medicine

Avicenna Alliance Newsletter SEPTEMBER – OCTOBER 2025

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From Animal Testing to Animal Caring

By Thierry Marchal
President and Secretary General, Avicenna Alliance

Animal testing is a costly and time-consuming stage in the regulatory approval process. Until now, it has been considered an essential step in testing new drugs and medical devices as it provides crucial information to maximize the safety of future patients. Of course, animals are only a distant model of a person, but they nevertheless provide valuable information, just like any bench test, clinical trial, or computational model.

To quote the renowned Professor Marco Viceconti, who compared the different models, “Should I feel closer to a mouse than to a patient-specific computer model simply because it is a living being?” Similarly, in September 2018, Tina Morrison, then Deputy Director at the U.S. Food and Drug Administration (FDA), presented a slide at the European Parliament suggesting that computer

What is a model?

Model: a representation of a system, entity, phenomena, or process.

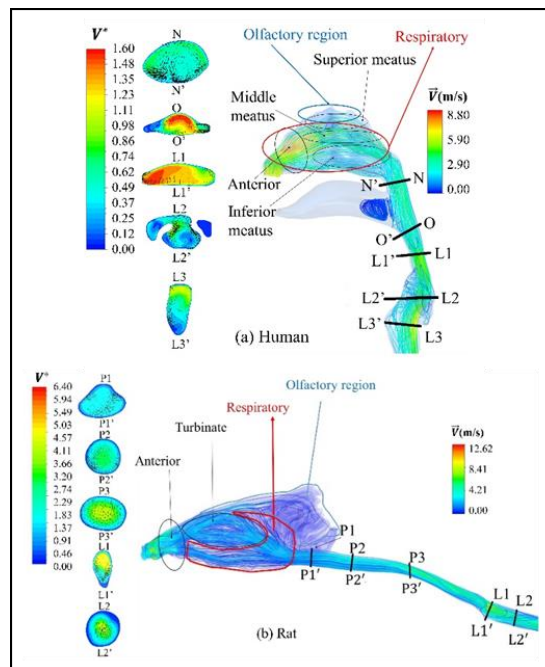
In vitro (laboratory) In vivo (animals/humans) In silico (computer)

http://medicalimplanttestinglab.com/news.html www.wakehealth.edu

simulations can be used for models just like bench or animal testing.

Do We Still Need Animal Testing?

With the development of accurate, patient-specific computer models of the human anatomy, increased computational power, and the continuous refinement of physiological models, one may wonder whether we still need the costly and time-consuming step of animal testing, which some may criticize as unethical. Many organizations, including the FDA and Australian authorities, are considering phasing out animal testing. In fact, we must be driven by patients and their safety: any step that slows down the medical innovation or reduces the affordability of treatments should be eliminated unless removing them would compromise patient safety (during clinical trial or during treatment).



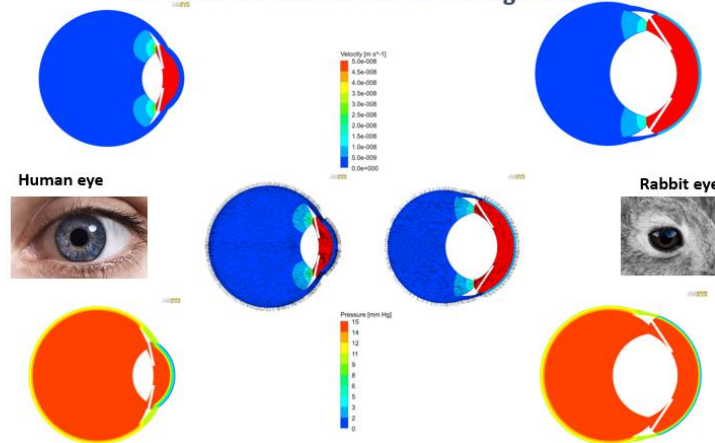
Respiratory drug delivery, comparison between human and rat. Courtesy of Oklahoma State University

Several colleagues at the Avicenna Alliance, such as Professor Enrico D'all Ara, University of Sheffield, for foundational research, or Simon Sonntag, CEO of Virtonomy, for regulatory approval, recently told me that despite the fantastic progresses made in *in silico* methods and the obvious need to move away from testing drugs and devices on animals, it will still take more than a decade to massively reduce animal testing; but we can expect a significant reduction of the number of animals involved every year. D'all Ara even suggested creating digital twins of mice to accelerate research and innovation. Others, such as Fluidica or Oklahoma State University, have developed advanced animal models to gather more information, streamline the translation to human modelling, and contribute to faster validation of those models.

Are *in silico* Models a Waste of Time in the Interim?

With a growing number of people believing that animal testing could be partially or completely replaced by patient-specific computer models, one might wonder whether it is necessary to continue developing computer models of various animals. In the short term, these models will amplify existing research and actually increase the safety of living beings during testing. Subsequently, they will reduce the number of animals needed before moving on to clinical trials. *In silico* models of mice, rats, or guinea pigs are an important component of reducing animal testing in the short term.

Understanding the difference and similarities between human and animal testing is essential



As computer models of animals are perfected and their need for regulatory approval is reduced, computer models of rabbits, cats, dogs, monkeys, etc. could be increasingly used to improve treatments for the animals themselves. On the one hand, there is an ethical question of investing in *in silico* models to treat our pets when so many people in various parts of the world do not have access to adequate healthcare. On the other hand, computer models of animals are now accelerating medical innovation for human patients today. So, why not make them available to our veterinary friends, as this *in silico* medicine for pets can also build more trust in *in silico* medicine for humans? Furthermore, we are not just talking about pets in industrialized regions, but also providing better care to farm animals, which would benefit everyone.

In summary, in the short term, *in silico* animal models accelerate affordable medical innovation for human beings. They will reduce the need for animal testing without compromising patient safety. In the long term, as animal testing is phased out, these computer animal models will be repurposed to take care of our beloved pets and livestock. Both will reduce suffering while accelerating medical innovation and making it more affordable for patients, both two- and four-legged!

Thierry

Spotlight on the Good Simulation Practice (GSP) Task Force

By Luca Emili

Task Force Leader

“Establishing Trust in *In Silico* Medicine: The Avicenna Alliance Good Simulation Practice Task Force”

In the rapidly evolving landscape of biomedical innovation, computational modelling and simulation (CM&S) offer unprecedented opportunities to accelerate development, enhance safety, and reduce reliance on traditional testing.

To turn this potential into regulatory-ready, patient-safe applications, the Avicenna Alliance’s [Good Simulation Practice \(GSP\) Task Force](#) is developing a benchmark framework—akin to Good Clinical Practice—that aims to make *in silico* methods credible, reproducible, and globally accepted.

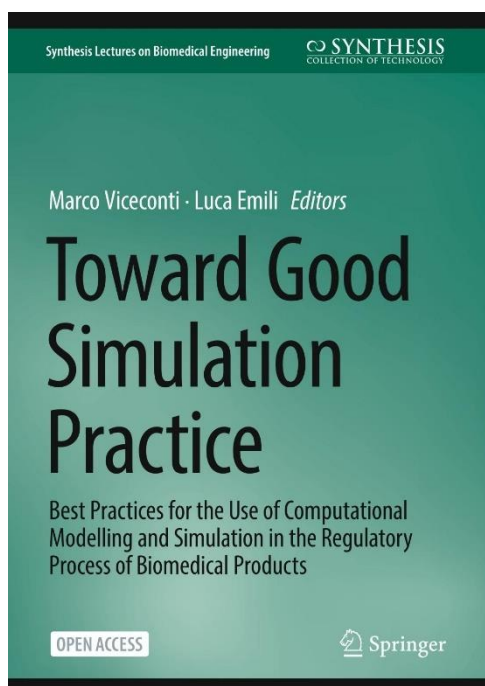
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The Avicenna Alliance is a multi-stakeholder association that brings together academia, industry, regulators, and policy makers committed to advancing *in silico* medicine. Within this ecosystem, the GSP Task Force plays a central role in establishing good practice for CM&S in the biomedical domain.

As *in silico* approaches gain prominence in drug and device development, the need for a widely accepted framework of best practices has become increasingly urgent. The GSP Task Force addresses this by working toward a shared foundation that supports model credibility, regulatory readiness, and stakeholder trust. Its mission “to draft a Good Simulation Practice document widely recognised and accepted, similar to Good Clinical Practice”, captures this ambition.

Within the Avicenna Alliance’s structure, the Task Force operates under the [Policy Development Working Group](#), aligning its activities with the Alliance’s broader goal: translating the Roadmap for *in silico* medicine into policy and practice and fostering a regulated, harmonised *in silico* market in Europe and beyond.

Key priorities of the GSP Task Force include engaging with regulators such as EMA and FDA to build recognition of the GSP framework, producing guidance documents for both regulators and industry, and promoting consensus across the *in silico* community through outreach initiatives such as the InSilicoWorld Community of Practice. The Task Force also contributes to reference works, including the open-access book [“Toward Good Simulation Practice – Best Practices for the Use of Computational Modelling and Simulation in the Regulatory Process of Biomedical Products”](#) (February 2024), and maintains the “context of use” taxonomy that underpins regulatory dialogue.



Achievements and Milestones

To date, the Task Force has mobilised 144 experts from academia, industry, and regulatory bodies—including contributors from the FDA—in the creation of its publications. It has produced a widely circulated position paper capturing best practices, expanded outreach through public channels to gather community input, and helped embed the GSP concept across the broader *in silico* ecosystem.

For the biomedical sector, the GSP Task Force is highly significant. While modelling and simulation are increasingly used across pharmaceuticals, medical devices, and combination products, common standards are still developing. The GSP framework helps address this gap by reducing development risk, shortening

timelines, and improving the predictability of outcomes—objectives central to the Avicenna Alliance. It also lays the foundation for broader regulatory acceptance of *in silico* evidence, enabling tighter integration of CM&S into product development and regulatory submissions. Just as importantly, the initiative unites industry, academia, regulators, and patients, building the multi-stakeholder alignment essential for trust and adoption.

Next Steps and Outlook

Looking ahead, the GSP Task Force will continue refining its guidance documents, incorporating international feedback and working toward formal standardisation through recognised bodies. Strengthening regulatory engagement and promoting global harmonisation will remain key priorities to ensure the GSP framework gains traction across jurisdictions. The Task Force will also broaden its educational efforts through webinars, workshops, and targeted dissemination. Ultimately, its objective is to embed GSP principles into everyday *in silico* practice—across industry, research environments, and regulatory dossiers—ensuring modelling and simulation remain technically robust, patient-centred, and aligned with regulatory expectations.

Why This Matters for You

For members of the Avicenna Alliance, this work has direct impact. The GSP initiative is defining the standards to which model-based evidence will increasingly be held, and close involvement places you and your organisation at the forefront of regulatory-ready *in silico* practice. In interactions with notified bodies or regulatory authorities, GSP-aligned models can streamline discussions and improve acceptance. The book and the broader GSP initiative also offer strong, ready-to-use material for presentations and communications. For audiences across industry, regulatory, and clinical environments, the GSP framework provides a clear and compelling rationale for investing in, standardising, and integrating *in silico* methods within modern biomedical development.

Are you interested in joining the Task Force? Please contact Roberta (manager@avicenna-alliance.com).

Your involvement in the GSP Task Force will help broaden the collective expertise of our community and participating in the GSP Task Force offers members a unique opportunity to influence emerging best practices, strengthen regulatory alignment and position their organisation at the forefront of *in silico* innovation.

Spotlight on our member Twinsight

By Mathieu Rimaud, CEO
Avicenna Alliance Treasurer

Twinsight: Pioneering Digital Twin Technology with FDA-Cleared Surgical Innovation

Twinsight is a trailblazing company at the forefront of digital twin technology, revolutionizing industries such as healthcare, manufacturing, and organizational psychology. Their innovative solutions harness the power of virtual replicas to enhance decision-making, optimize operations, and improve outcomes across various sectors.



A major milestone in the company's journey has been the FDA 510(k) clearance for its flagship product, SurgiTwin 3D. This web-based Software as a Medical Device (SaMD) is designed to support pre-operative planning for total knee replacement surgeries. By harnessing patient-specific imaging data, SurgiTwin 3D generates detailed two- and three-dimensional models, allowing surgeons to simulate procedures with remarkable precision. The platform integrates a comprehensive database of surgical materials, making it possible to tailor plans to individual patients. While SurgiTwin 3D does not provide diagnoses or surgical recommendations, it serves as a powerful decision-support tool, enhancing the planning process and enabling surgeons to optimize implant placement through interactive simulations. According to CEO Mathieu Rimaud, who also serves as Treasurer and an active member of the Avicenna Alliance, the FDA clearance represents a major step forward for Twinsight, opening the door to commercialization in the U.S. market and marking the company as a leading innovator in digital health.



Twinsight's innovations have garnered both national and international recognition. The company was a finalist in the 2024 Trophées Bref Eco de l'Innovation in the "Jeunes pousses" category, while Rimaud received the Startup Prize at the 2023 Innотrophées hosted by the Grenoble Chamber of Commerce. Earlier, in 2022, Twinsight was highlighted for early-stage innovation with the Talents de l'Entrepreneuriat award. Adding to its growing list of accolades, Twinsight has also been nominated for the MedTech Malta Awards 2025, underscoring its expanding international presence.

Beyond healthcare, Twinsight's digital twin technology is making an impact across other sectors. In manufacturing, it helps optimize production processes, reduce downtime, and increase overall efficiency. In organizational psychology, particularly in Australia, Twinsight combines AI-driven insights with psychological expertise to enhance employee well-being, improve performance, and foster safer, more productive work environments. These applications demonstrate the versatility of Twinsight's technology and its potential to transform both human and operational outcomes.

With a growing footprint spanning Singapore, Malaysia, Thailand, India, the Philippines, the USA, and Canada, Twinsight is committed to connecting, consolidating, and managing complex projects and assets efficiently. Its global vision emphasizes sustainability, operational excellence, and smarter resource management, reflecting the company's mission to make industries more intelligent and responsive through digital twin solutions.

Rimaud is also a prominent advocate for the broader adoption of digital twin technology in medicine. He emphasizes its role in personalized, simulation-driven surgical planning and actively promotes the concept that each patient's life trajectory is unique, requiring tailored interventions to achieve optimal outcomes. Through this thought leadership, Twinsight is shaping the future of AI-assisted surgery and setting new standards for clinical innovation worldwide.

From its FDA-cleared surgical solutions to industry-wide applications, Twinsight exemplifies the transformative potential of digital twin technology. By delivering tools that enhance decision-making, operational efficiency, and patient care, Twinsight is paving the way for smarter, safer, and more sustainable industries around the globe.

Spotlight on our Partner TÜV SÜD

By Surash Surash
Clinical Reviewer

TÜV SÜD: Global Expertise at the Forefront of Medical Device Innovation

With over 150 years of experience, TÜV SÜD has grown into a global leader in testing, inspection, certification, and training, operating across more than 1,000 locations with a workforce exceeding 30,000. Their reputation as a trusted partner spans multiple regulatory territories — from the EU and UK to the U.S. and Asia — making them a cornerstone of medical device regulation worldwide.

Navigating Complex Regulatory Landscapes

As a Notified Body under the European Medical Device Regulation (MDR), TÜV SÜD plays a critical role in ensuring that medical devices meet the highest standards of safety and efficacy. Their expertise spans conventional devices, Software as a Medical Device (SaMD), orphan and rare disease products, and breakthrough technologies. TÜV SÜD's global reach allows them to provide consistent guidance and certification across diverse regulatory environments, helping manufacturers navigate evolving frameworks efficiently.



Embracing the Next Frontier: AI and In Silico Methods

TÜV SÜD has positioned itself at the forefront of innovation in regulatory science. Their work with Artificial Intelligence, advanced digital health applications, and SaMD demonstrates a commitment to integrating emerging technologies safely into healthcare. In silico methods — computational modelling and simulation — are increasingly central to their approach, enabling more efficient testing and predictive evaluation of medical devices. These methods bring together industry, healthcare, academia, and regulators to accelerate device development while maintaining patient safety.

Driving Innovation through Expertise and Collaboration

Beyond certification, TÜV SÜD invests heavily in training and knowledge-sharing. They provide specialized courses on AI in medical devices and MDR compliance, helping stakeholders stay ahead of regulatory changes. Their labs and technical teams uphold rigorous standards, offering ISO 17025-accredited testing and certification services globally.

Through these initiatives, TÜV SÜD not only supports compliance but also fosters innovation, helping developers bring safe, effective, and groundbreaking devices to market more efficiently. By bridging traditional regulatory frameworks with cutting-edge technologies, they are shaping the future of medical device regulation.

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 65 recordings are available in the [members only area](#) of the [Avicenna website](#). Last webinar, held on 11 November 2025 is available in the [public area](#) too.

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

Our future 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 – [Click here to register](#)
- 10 February 2026: "**Is stroke being treated as a heart-brain axis disease?**" by Oscar Camara from UPV – [Click here to register](#)

Our most recent webinars

- 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.

- 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 – [Watch the recording](#)

*In this webinar the speaker will present the development of an *in silico* clinical tool designed to identify patients with spinal metastases at high risk of fracture. The session will trace the translational pathway from biomechanical analyses conducted in the laboratory to the creation of a clinically deployable, patient-specific simulation platform. The presentation will explore the computational modelling techniques, the integration of clinical data, and the validation process needed to ensure reliability and clinical relevance.*

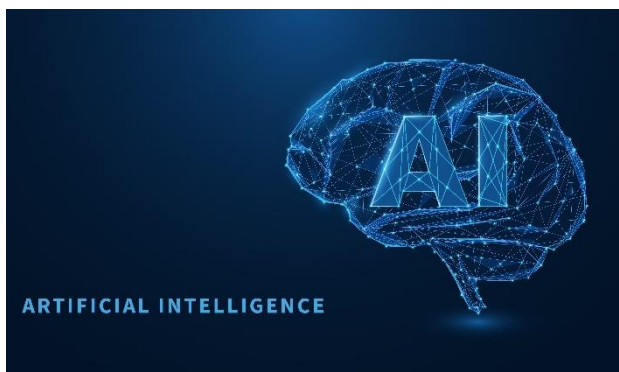
65 recording are available online. Learn more about what other members are doing.

EU Policy and Regulatory updates

AI in Healthcare

The European Commission launched a flagship initiative in October 2025 to increase the use of AI in healthcare, building on a study from August 2025. This is part of a broader "Apply AI Strategy" to integrate AI across key sectors, with a focus on improving diagnostics and public services.

Supporting the diffusion of digital health technologies in Europe can deliver a "triple win": improved healthcare outcomes for citizens, more sustainable healthcare systems, and a stronger, more competitive economy. Recognising healthcare as a strategic sector, the European Commission highlights it in the Competitiveness Compass and the AI Continent Action Plan, reflecting priorities outlined by President von der Leyen and recent Letta and Draghi reports.



To secure European leadership in trustworthy AI and advanced medical technologies, the EU is investing across the entire AI value chain. Key initiatives include:

Supercomputing: The EuroHPC Joint Undertaking launched 13 AI Factories, including 10 focused on healthcare, providing start-ups and SMEs access to advanced AI resources. The EU will also develop AI Gigafactories to train complex AI models.

Chips: A review of the Chips Act aims to strengthen Europe's autonomy in designing and producing AI semiconductors, critical for AI-powered wearables, implantable sensors, connected devices, diagnostics tools, and medical robots.

Cloud: A proposed Cloud and AI Development Act will boost private investment in cloud infrastructure, supporting AI-driven diagnosis, decision-making systems, patient-centred care models, preventive health, and other disruptive healthcare technologies.

These measures collectively aim to position Europe at the forefront of AI-enabled digital health innovation.

[More information](#)

Public Consultation TEHDAS2 (Second Joint Action Towards the European Health Data Space)

TEHDAS2 has just launched a [Public Consultation](#) on 11 draft guidelines and technical specifications linked to the implementation of the EHDS.

The consultation is open to all stakeholders — citizens, health professionals, authorities and regulators — to ensure the outputs are relevant, balanced and practical.

Public Consultation on the EU Biotech Act

The European Commission held a public consultation on the proposed EU Biotech Act, which was open until November 10, 2025. The consultation, launched in August 2025, gathered input from the public and various stakeholders to help shape future legislation intended to strengthen Europe's biotechnology sector. Key areas of focus included simplifying regulations, improving



access to funding, and addressing skills gaps to accelerate the time-to-market for biotech products.

Goals of the consultation

- To identify challenges and barriers in the current biotechnology and biomanufacturing sector.
- To gather evidence and views from all relevant sectors, including medical, agricultural, industrial, and environmental.
- To shape policy actions that could simplify and harmonize regulations, support startups, and address issues like skills gaps and data governance.

Consultation topics

- General views on biotechnology
- The current regulatory environment in the EU
- Access to capital for biotech companies
- Biotechnology clusters and organizations
- Biotechnology manufacturing processes
- Workforce availability, upskilling, and reskilling
- Data and artificial intelligence integration
- Biosecurity and defense applications.

[More](#)

New EU4Health Calls for Proposals

HaDEA published new calls for proposals under the 2025 EU4Health Work Programme, focusing on implementing cancer screening, leveraging AI for cardiovascular health, promoting lifelong prevention, and supporting a medicine pricing tracker.

[More Information](#)

EU-WHO Partnership Renewal

The World Health Organization (WHO) and the European Union (EU) have renewed their collaboration to advance universal health coverage (UHC) with Phase V (2025–2028) of the UHC Partnership, WHO's largest platform for strengthening health systems and primary health care. Supported by EUR 40 million from the EU, with further contributions expected in 2027, this phase focuses on building resilient, equitable, and people-centred health systems aligned with the health-related Sustainable Development Goals.



Since its launch in 2011, the UHC Partnership has helped over 115 countries implement health reforms, improving governance, service delivery, health financing, and emergency response, reaching more than 3 billion people worldwide. Phase V prioritizes strengthening health financing and governance, evidence-informed planning, and integrated, high-quality service delivery, including sexual and reproductive health, noncommunicable diseases, and mental health. It also emphasizes equity, gender equality, climate resilience, and domestic

resource mobilization.

EU Commissioner Jozef Síkela highlighted that strong health systems underpin sustainable development and global stability, while WHO Director-General Dr Tedros Adhanom Ghebreyesus stressed that partnership is key to translating global commitments into national action. Phase V comes at a crucial time, as countries face

climate change, economic instability, and reduced development assistance. Together, the EU and WHO aim to strengthen resilient, sustainable, and inclusive health systems worldwide through a primary health care approach.

[More information](#)

Council Calls for EU Clinical Trials Leadership

In September 2025, the EU Council called for urgent action to address the decline in EU clinical trials and urged the Commission to improve the ecosystem through updated regulations and an investment plan.



The Council approved conclusions on life sciences for the Union's competitiveness. The Council welcomes the ambition of making the EU the world's most attractive place for life sciences by 2030, as outlined in the Commission's recent strategy, and provides guidance to unlock the Union's full potential for competitiveness. The Council encourages support throughout the whole value chain from fundamental research and uptake to stronger research in advanced therapy medicinal products (ATMPs), a leading EU role in clinical trials and a broad approach to biotechnology. It also calls for the use of

advanced technologies — such as artificial intelligence and quantum computing — in life sciences, while stressing the importance of developing skills, and attracting and retaining talent. At the same time, it underlines the importance of a business-friendly regulatory framework, that reduces administrative burden and supports innovative SMEs and sustainable manufacturing capacities. Finally, in the conclusions is highlighted the need for a coordinated governance framework on life sciences and for swift implementation of the proposed actions.

The Council stresses the urgent need to address the EU's declining share and reduced global impact in clinical trials. It calls on the Commission to improve the ecosystem for multi-country and multi-centre clinical trials, including by updating the regulatory framework and establishing an investment plan for clinical research. It also underlines the challenges of using health data for research and innovation, insisting on the need to overcome remaining hurdles to strengthen disease prevention and deliver high-quality healthcare. Measures include better coordination among existing clinical trial projects, further digitalisation of health systems, and using artificial intelligence.

the Council calls for an ecosystem that boosts R&I, strengthens support for innovative SMEs, and preserves Europe's manufacturing capacity. A business-friendly regulatory framework that reduces administrative burdens and fosters innovation will be key. The Council looks forward to forthcoming Commission proposals — including the Innovation Act and the Biotech Act — to cut fragmentation, simplify rules, improve transparency, and shorten the time needed for research-intensive biotech innovations to reach the market. The announced R&I Agenda for Food Systems and the Bioeconomy Strategy are also expected to play an important role in agriculture, food, and environmental systems, ensuring food security, safeguarding human and animal health, and protecting the environment.

[Read more](#)

European Commission Work Programme 2026

On 21 October 2025, the European Commission unveiled its Work Programme for 2026, outlining the major policy priorities, strategic initiatives and legislative proposals that will steer EU action in the year ahead.



The new programme defines the Union's economic, social and geopolitical ambitions for 2026 through 47 planned legislative initiatives. The emphasis is on cutting red tape, improving competitiveness and bolstering security, while also advancing progress in innovation, energy policy, defence, employment and environmental sustainability. The overarching goal is clear: to build a more agile, resilient and future-ready European Union.

As part of its better-regulation agenda, the Commission also plans 20 evaluations of existing laws to assess their effectiveness, streamline overlapping rules, reduce administrative complexity and lower compliance costs. Key expected developments include the Biotech Act, scheduled for adoption in the third quarter of 2026, and continued progress on the Medical Devices Regulation, which is due to be finalised before the end of 2025—underscoring the EU's sustained attention to healthcare and patient safety.

The most substantial section of the programme falls under the heading *A new plan for Europe's sustainable prosperity and competitiveness*. This cluster brings together initiatives designed to strengthen the EU's industrial foundation, reinforce its innovation leadership and accelerate its green and digital transitions.

Among the headline initiatives are:

- The European Innovation Act, which aims to integrate and strengthen Europe's research and innovation landscape.
- The Advanced Materials Act, supporting the development and deployment of next-generation strategic materials.
- The Cloud and Artificial Intelligence Act and a renewed Chips Act, both geared toward enhancing Europe's technological autonomy.
- The European Critical Raw Materials Centre, created to secure reliable access to essential resources for industry.

Together, these measures outline a broad and interconnected policy framework that promotes scientific excellence, sustainable technological development and Europe's long-term competitiveness in global health and industry.

Full document [here](#)

Recent news

[Avicenna Alliance at the IMDRF Meeting in Sapporo – September 2025](#)



The Avicenna Alliance had the honour to attend the International Medical Device Regulators Forum (IMDRF) meeting in Sapporo, hosted by the PMDA. As an observer to IMDRF, the Alliance joined the open sessions to engage with global Regulatory Authorities, the WHO, Trade Organizations, and industry representatives.

Representing the Alliance, **Mark Palmer (Ansys, part of Synopsys)** and **Alex Frangi (University of Manchester)**, Co-Chair of the **UK *In Silico* Regulatory Innovation Task Force**, highlighted the growing momentum behind ***in silico* methods** and their potential to transform regulatory science.

For the first time, Alex Frangi, representing the Avicenna Alliance and UK CEIRSI, presented a lecture entitled "DIGITAL EVIDENCE FOR THE DIGITAL ERA Evidence-based on *In Silico* Technologies; Computational Modelling and Simulations Model-Informed Evidence: Why to Harmonise, and Why to do it Now?" on Day 3, during the closed-door session.

Conversations with regulators — FDA, MHRA and TGA — and stakeholders such as Colvin Heather (Johnson & Johnson) provided valuable guidance before the presentation as well as inspiring suggestions for follow up activities. These discussions further illustrated the growing importance of ***in silico* methods** and the need for **global harmonisation** and confirmed the interest from regulators and stakeholders in prioritising *in silico* within future IMDRF guidance.

The Alliance looks forward to building on these outcomes and advancing the role of **digital evidence worldwide**.

[The Avicenna Alliance attends the EMA workshop in Amsterdam](#)



On 8 October, Martha de Cunha, Policy Development Working Group Leader, and Thierry Marchal, President and Secretary General of the Avicenna Alliance, participated in the EMA Workshop on mechanistic models organised by Flora Musuamba and Peter Arlett of the European Medicines Agency (EMA).

This workshop was a particularly informative meeting bringing together members of regulatory authorities — the EMA, of course, but also the MHRA and the FDA, as well as several national regulatory agencies—academic leaders such as Francesco Pappalardo and representatives of the Virtual Physiological Institute, as well as representatives of the pharmaceutical industry and software developers.

Numerous presentations described the methods used to develop, verify and validate models following well-established methods for defining "Questions of Interest", "Context of Use", "Risk Assessment", etc. Although PBPK, PKPD and other methods were discussed at length, other solutions involving various mechanistic models, including 3D models, were also addressed, illustrating the rapid progress made in Europe in terms of the acceptance of *In Silico* Evidence (ISE) for the regulatory approval process.

We still have a long way to go. But we are delighted that important milestones have been reached, among

others thanks to the contribution of the Avicenna Alliance and its partners, who are determined to accelerate medical innovation for the patients.

[Avicenna Alliance at RAPS meeting in Pittsburgh](#)



On October 8th, various key members of the Avicenna Alliance including Marc Horner, International Affairs WG leader, Martha de Cuhna, Policy Development WG Leader, and our new partner Surash Surash from the leading Notified Body TÜV SÜD, spoke at the Regulatory Affairs Professional Society (RAPS) meeting in Pittsburgh to highlight the essential and increasing role of *in silico* methods throughout the total product life cycle of medical devices.

The session titled "Modelling the Future: Regulatory Perspectives on *In Silico* Tools for Medical Devices" was also included Samhitha Mohan, Sr. Manager, RA from Becton Dickinson. The session

included insights about how *in silico* generated data can contribute to medical device development and areas where *in silico* can benefit traditional testing. Regulatory frameworks that support *in silico* adoption in different territories across the world were also presented. The audience appreciated the update on the widespread deployment of computational modelling & simulation and the potential impact of harmonized regulatory approval processes globally.

The Alliance looks forward to continuing to promote the global harmonization of *in silico* technologies to benefit patients.

[Avicenna Alliance Welcomes the Notified Body TÜV SÜD as a New Partner](#)



The Avicenna Alliance is delighted to welcome TÜV SÜD as its newest Partner. TÜV SÜD is a leading Notified Body operating across multiple regulatory territories, including the EU, the United States, the UK, and Asia. With more than 150 years of experience, a presence in 1,000 locations worldwide, and over 30,000 employees, TÜV SÜD is a trusted global partner in testing, inspection, certification, and training solutions.

At the forefront of medical device regulatory affairs, TÜV SÜD actively engages with Artificial Intelligence, Software as a Medical Device (SaMD), Orphan Devices, and breakthrough technologies. The organization recognizes *in silico* medicine as a critical

milestone in regulatory development—an area where collaboration between industry, healthcare, academia, and regulators is essential to ensure computational modelling becomes an integral part of the medical device sector.

"It is an honour for TÜV SÜD to now be part of the global alliance that Avicenna represents and to work with stakeholders from around the world to bring *in silico* and computational modelling into the medical device regulatory lexicon", said Surash Surash, Clinical Reviewer at TÜV SÜD.

"The Avicenna Alliance is delighted to welcome TÜV SÜD as an important partner. Together we will work to increase the presence of *in silico* evidence (ISE) in the regulatory approval process in Europe", added Thierry Marchal, President and Secretary General of the Avicenna Alliance.

The Avicenna Alliance looks forward to working with TÜV SÜD in advancing the adoption of *in silico* methods and shaping future regulatory frameworks that will accelerate innovation and patient access to safe and effective medical technologies.

[The Alliance at the iSi Health Symposium](#)



On 11 and 12 September 2025, our partner iSi Health, Erica Beaucage-Gauvreau and Rocio Castro Vinuelas, organised an excellent symposium in Leuven to bring together key players in the *in silico* community and promote networking, brainstorming and exchanges.

Liesbet Geris, our Research and Technology Working Group Leader gave an excellent keynote describing the progress of regulatory science and the acceptability of *in silico* evidence in Europe. Our President and Secretary General Thierry Marchal had the privilege of moderating the panel “**Navigating the Valley of Death: from bench to bedside**”.

With an outstanding panel of experts – **Ilse Sienaert, Anne-Gaelle Dosne, Charles Taylor, and Roger Assaker** – we explored the key challenges and opportunities for shaping the future of healthcare innovation, while inspiring the new generation to embark in this difficult but exciting journey.

The discussion touched on:

- Building confidence in ***in silico* methods**
- Addressing **regulatory inertia in Europe**
- Fostering **entrepreneurship in healthcare**

The insights shared by these visionary entrepreneurs were both inspiring and thought-provoking, highlighting not only their successes but also the lessons learned along the way.

Together, we took an important step in pushing the boundaries of science and innovation to improve patient well-being.

[Avicenna Alliance to Attend IMDRF Meeting in Japan – September 2025](#)



The Avicenna Alliance is honoured to be invited once again as an Observer to the upcoming International Medical Device Regulators Forum (IMDRF) meeting, which will be hosted by PMDA Japan in Sapporo from September 15–19, 2025. This high-level global event will bring together regulatory authorities, trade organisations, and industry representatives from around the world to address pressing topics in medical device regulation.

As an observer, the Avicenna Alliance will participate in the **open sessions** and engage in **side discussions** to highlight the importance of ***in silico* medicine** and its growing relevance for regulatory science.

Dr. Mark Palmer (Ansys, part of Synopsys), and **Prof. Alex Frangi (University of Manchester)**, Co-Chair of the **UK *In Silico* Regulatory Innovation Task Force** will represent the Avicenna Alliance. Prof. Frangi will deliver a talk entitled “***In Silico* Trials for Medical Devices: International Initiatives and Regulatory Harmonisation**”; this presentation which will explore the transformative potential

of *in silico* approaches to address current challenges in **evidence generation, patient safety, and innovation acceleration**. The talk will also highlight **key international initiatives** driving the adoption of *in silico*.

Recent discussions among IMDRF participants have shown increasing recognition of *in silico* methods, yet the challenge remains to **prioritize this topic** amid other regulatory initiatives. The Avicenna Alliance will use this opportunity to gather insights and explore collaborative strategies to support the **development of specific guidance** for *in silico* evidence.

Stay tuned for updates following the meeting, and follow the Avicenna Alliance for the latest on ***in silico* regulation, digital evidence, and global harmonization**.

Members Corner

Events

Insigneo / Sano Modelathon

13–16 January 2026

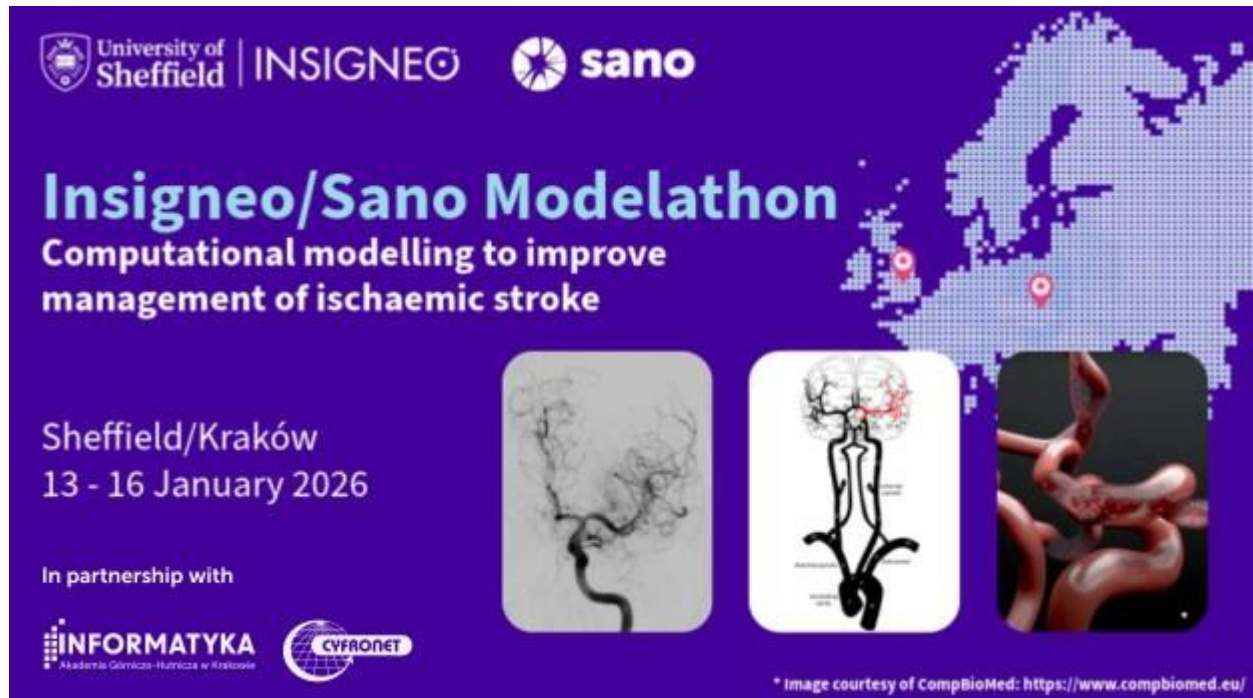
Hybrid (University of Sheffield ↔ Sano Centre for Computational Medicine, Kraków)

Are you passionate about modelling, computational science, or exploring the future of personalised medicine? The Insigneo Institute and Sano Centre for Computational Medicine invite you to join Modelathon 2026 — a unique international challenge on Computational Modelling to Improve Management of Ischaemic Stroke.

This four-day, team-based sprint brings together scientists, engineers, clinicians, and innovators from across Europe to co-create prototype solutions using 0D, 1D, and 3D multiscale models. Whether your background is physics, biomedical engineering, computer science, medicine — or even genetic engineering — this is your chance to see how modelling can transform healthcare.

Participation is free — with mentoring, HPC access, and meals provided for on-site participants. Interdisciplinary teams will compete to design the most impactful computational approach to support stroke diagnosis and treatment.

[Info and registration](#)



The poster features a dark blue background with a light blue dotted map of Europe on the right side. At the top left, it displays the logos for the University of Sheffield, INSIGNEO, and sano. The main title 'Insigneo/Sano Modelathon' is in large white font, followed by the subtitle 'Computational modelling to improve management of ischaemic stroke' in a smaller white font. Below this, the location 'Sheffield/Kraków' and dates '13 - 16 January 2026' are listed. Three images are arranged horizontally: a grayscale angiogram of a brain vessel, a schematic diagram of a brain with a highlighted stroke area, and a 3D anatomical model of a brain vessel. At the bottom left, it says 'In partnership with' followed by the logos for INFORMATYKA and CYFRONET. A small note at the bottom right states '* Image courtesy of CompBioMed: https://www.compbioMed.eu/'

[REGISTER NOW: IN SILICO MEDICINE & BEYOND - A new VPH Chapter](#)

On 19 Nov 2025 we will bring together thought leaders who are shaping the future of healthcare to explore how *in silico* medicine is transforming research, regulation, and clinical practice. Do not miss it!

***In silico* medicine & beyond: a new VPH chapter**

Wed, Nov 19, 2025 3:00 PM - 4:00 PM CET



What will *in silico* medicine look like ten years from now—and what will it take to get there?

Join the high-level on line event on **19 Nov 2025**: "[In silico medicine & beyond - A new VPH chapter](#)".

Featuring an exceptional line-up of speakers who will bring a unique perspective on how digital twins, AI, and simulations are reshaping healthcare:

- [Prof. Liesbet Geris \(VPH Director\)](#) – presenting a forward-looking vision for VPH and in silico medicine over the next decade;
- [Dr Eric Vibert \(Paris Saclay University /INSERM\)](#) – on Digital Twins in liver surgery and how technology is transforming the operating room;
- [Tina Morrison \(EQTY Labs\)](#) – on regulatory innovation and trust as enablers of responsible adoption;
- [Steven Bourke \(PersonalPulse\)](#) – on the value of mutual creation with patients.

Together, they'll explore how science, policy, and clinical practice can align to bring *in silico* medicine from research to real-world impact.

And at the end of the program, we'll unveil something special: a new route designed to reflect our growth, our multidisciplinary community, and our vision for the future.

Join this Wednesday from 15 to 16 CET.

[Registration](#)

[EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures](#)

24-25 Nov 2025, Amsterdam, NL and Online Free online event

The workshop is focusing on discussing the current regulatory frameworks for the approval of medical countermeasures against these threats based on non-clinical data (usually animal models) as key evidence for the demonstration of efficacy in humans.



[More info and registration](#)

Publications

Virtonomy and NVIDIA Advance the Future of *In Silico* Medical Innovation

Virtonomy has published a new article in collaboration with NVIDIA, highlighting how their joint work is reshaping the future of *in silico* medical innovation. By integrating **digital patient twins**, **AI-driven modelling**, and **GPU-accelerated simulation**, the partnership is enabling a new generation of scalable, high-fidelity workflows for medical device development.

Powered by NVIDIA's AI infrastructure, Virtonomy is building anatomically accurate, data-driven digital twins that represent diverse patient populations. These advanced models allow engineers and clinicians to:

- Simulate complex device–patient interactions under realistic physiological conditions
- Conduct large-scale virtual trials with statistically significant cohorts
- Accelerate development cycles and improve clinical outcomes
- Strengthen regulatory submissions with robust in-silico evidence

This collaboration represents a significant step toward unifying AI, simulation, and cloud computing into a single ecosystem — driving safer, faster, and more cost-effective healthcare innovation.

[Read the full article here](#)



ELEM Biotech's Virtual Hearts Featured in National Geographic

ELEM Biotech's **Virtual Hearts** have been featured in the latest issue of *National Geographic*, in the edition titled "*Corazón Invencible – Bioimpresión, polipíldora, genómica, IA: la ciencia descubre cómo tratarlo para vivir más años.*"

The article includes a dedicated section on ELEM Biotech's pioneering cardiac simulations, along with insights from **CTO Mariano Vázquez**, who explains how advanced computational modelling is transforming cardiovascular medicine.

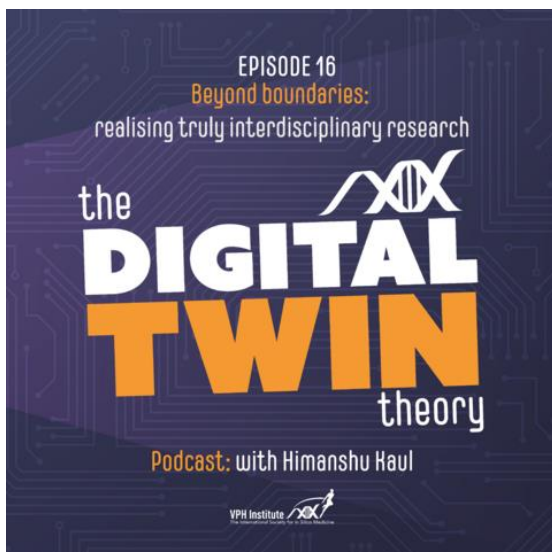
The full animated heart simulation showcased in the feature can also be seen at the **Science Museum's Engineers Gallery** in London. The model was developed by ELEM Biotech, based on research from the **Barcelona Supercomputing Centre**, and visualised by its Data Visualisation Group as part of the *Virtual Heart* installation.



[THE DIGITAL TWIN THEORY PODCAST - Episode 16: We don't need better models, we need smarter systems.](#)

Collaborating across disciplines is easier said than done, and interdisciplinarity is at the heart of *in silico* medicine. In this episode of The Digital Twin Theory podcast, we welcome back Himanshu Kaul (University of Leicester) to discuss the real challenges and the practical strategies for interdisciplinary collaborations.

[Listen here](#)



Other News and interesting links

Twinsight Shortlisted for MedTech Malta Awards 2025

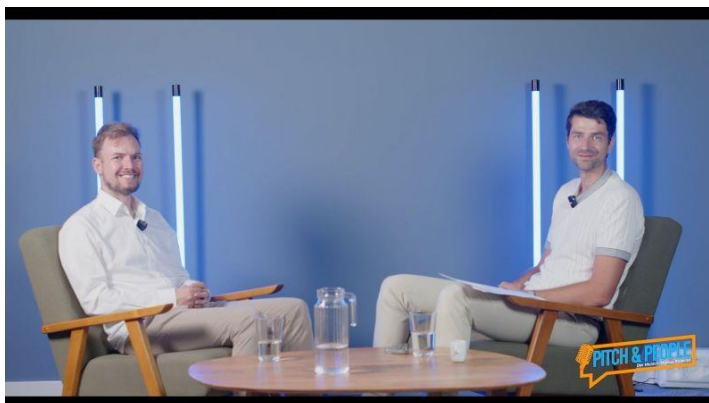
Twinsight has been officially nominated for the **MedTech Malta Awards 2025**, recognising the company's innovative contributions to healthcare. The team expressed gratitude for the honour, noting how proud they are to see the work of the **#TwinTeam** featured alongside other inspiring leaders shaping the future of medical technology.

Winners will be announced during the **MedTech Malta Gala Awards** on **14 November**.



Virtonomy Uses Patient Digital Twins to Save Lives

How can virtual simulations revolutionize medical technology and help save lives? In the latest episode of the *Pitch & People* video podcast, **Simon Sonntag**, Founder and CEO of **Virtonomy.io**, explains how the Munich-based MedTech startup is accelerating the development of medical devices—making the process faster, safer, and more ethical through the use of **patient-specific digital twins**.



“We tested an implant virtually and were then able to give a patient the treatment that saved their life,” Simon shares in the interview.

From pediatric cardiac surgery to the approval of new implants, Virtonomy showcases the real-world impact that technology can achieve when applied responsibly.

[Watch the full episode](#) of *Pitch & People* featuring Simon Sonntag of Virtonomy:

MDsim and University of Luxembourg Launch Industry–Academia Doctoral Fellowship



MDsim announces a new collaboration with the **University of Luxembourg** through an industry–academia doctoral fellowship supported by the **National Research Fund Luxembourg (FNR)**.

The PhD project aims to advance the modelling of muscular structures within the **patient-specific biomechanical digital twin** that powers **SPINesim**. The

research will be jointly supervised by **Laurent Adam** from MDsim and **Prof. Stéphane P.A. Bordas (FLSW)** from the University of Luxembourg.

This fellowship marks an important step toward deepening scientific innovation in digital biomechanics and improving next-generation in-silico spine simulation technologies.

[Read the full announcement here](#)

Hemolens Diagnostics® has been nominated for the [Prix Galien Polska / Galien Forum CEE](#) in the category 'Best Innovative Startup' for our **Cardiolens®** Platform.

The Prix Galien is often referred to as the 'Nobel Prize of Innovation in Medicine.' It's one of the most prestigious international distinctions recognizing groundbreaking technologies that have the potential to transform healthcare.

This year's Polish edition brings together leaders from science, healthcare, government, and industry — including representatives of the Ministry of Health, the Medical Research Agency, and top universities. Being part of this elite group of innovators is both an honor and a strong validation of our mission to revolutionize non-invasive cardiac diagnostics.

For Hemolens, this nomination is more than recognition — it's an opportunity to gain visibility among decision-makers shaping the future of healthcare in Poland and beyond, strengthen collaborations with clinical partners, and continue scaling Cardiolens® internationally.

[Learn more](#)



JOB OPPORTUNITIES



MDsim

If you're passionate about turning cutting-edge medical technology into real-world impact, this is your chance to join us.

We're hiring full-time across several roles:

- [Cloud & DevOps Engineer](#)
- [UX/UI Designer](#)
- [Marketing Manager](#) – to help position MDsim as the next gold standard in spine care innovation.

Don't see a perfect fit but still want to contribute to our mission?

Reach out through our [website](#)

At MDsim, our purpose is clear: make high-tech innovation accessible and impactful — improving outcomes for patients, empowering caregivers, reducing costs for payors, and benefiting society as a whole.

Apply now

Hemolens Diagnostics



We are looking for a **Senior Finance Specialist** to join our team.

What is the role all about?

- Month-end closing
- Reporting
- Capitalization analysis
- Optimization of cloud resource costs

What do you need to be successful in the role?

- Higher education in finance, accounting, economics, or a related field
- 5–7 years of experience in finance and controlling
- Experience in month-end closing
- Proactivity and responsibility

If you want to participate in a unique project and its commercialization, join us!

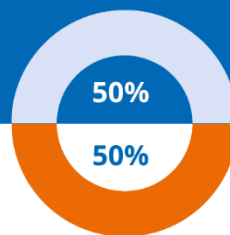
[Apply here](#)

Join the Avicenna Alliance!

The Avicenna Alliance Membership



Representation of VPH Institute



Industry Representation

