Avicenna Alliance
Association for Predictive Medicine

Avicenna Alliance Newsletter
JANUARY – FEBRUARY 2025

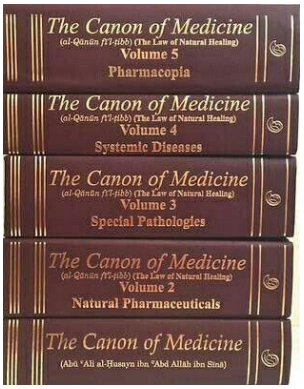
In this Newsletter

A 2025 Millennium Year with a great start

By Thierry Marchal
President and Secretary General, Avicenna Alliance

Exactly a thousand years ago, an eminent Persian physician and scientist named Ibn Sīnā (980 - 1037 AD), or Avicenna in the Latinized version of his name, completed The Canon of Medicine, a veritable encyclopaedia of medicine compiling all the medical knowledge of his day.

This amazing publication is divided into five books:



1. Essays on basic medical and physiological principles, anatomy, diet and general therapeutic procedures,
2. List of medical substances following an essay on their general properties,
3. Diagnosis and treatment of diseases specific to one part of the body,
4. Diagnosis and treatment of conditions covering multiple body parts or the entire body,
5. Formulary of compound remedies.

Among these publications, Avicenna postulated that all diseases (even rare ones) have a cause. He also recommended conducting trials with a control group and a treatment group: the concept of clinical trials was born. This publication remained the medical reference for several centuries. Today, many people and organisations still refer to his visionary approach by perpetuating his name, such as the AVICENNA Alliance.

Fast forward a thousand years on, the clinical trial is now a cornerstone of our approach to health safety. It is so important that approval of a new medical device can take up to 10 years and cost €0.5 billion, or 15 years and up to €2.5 billion for a new drug, among other things to carry out in-depth clinical trials. These timescales and huge costs are unaffordable for many companies and unacceptable for patients, considerably slowing down medical innovation around the world. As we all know, the solution lies in rigorous, properly validated *in silico* clinical trials that precede, refine and reduce clinical trials. The US administration and the FDA have shown us the way over the last 15 years.

In 2025, in many regions of the world, health authorities are moving towards formal acceptance of *in silico* clinical trials.

- This week, I sent a letter to Olivér Várhelyi, European Union Commissioner for Animal Health and Welfare, suggesting various amendments to the European Medical Device Regulation (MDR). I shared the in-depth review of the current MDR carried out by a large group of Avicenna members under the leadership of Martha De Cunha, head of the Policy Development Working Group.
- This week, Marc Horner, Head of the International Affairs Working Group who is representing the Avicenna Alliance at the International Medical Device Regulators Forum (IMDRF) in Tokyo, told us that, at the opening session, the IMDRF hosts cited *in silico* clinical trials and Modelling & Simulation (M&S) as areas requiring guidance.
- This week, Matthieu Chareyre, a key member of the Alliance and CEO of ToxBy Design, shared with us the growing interest of the EU - Japan collaboration to learn more about *in silico* technologies and good simulation practice.

When we created the Avicenna Alliance in 2016, we knew it would take time to get the attention of global authorities (hopefully less than another thousand years!). Thanks to our perseverance and the active support of our academic and industry members, partners and leaders, we are now making more and more concrete advances in both medical device regulation and pharmaceutical legislation. There is no doubt that the next few years will be crucial in accelerating medical innovation to make medicines faster, safer and more affordable for both patients and industry through a larger adoption of *in silico* technologies and *in silico* clinical trials.

Thank you for your continued valuable support.

Spotlight on the Artificial Intelligence (AI) Task Force

By Nirnith Devireddy
Task Force Leader

Mission

The Avicenna Alliance's AI Task Force is dedicated to driving the education, promotion, and responsible adoption of artificial intelligence (AI) in pharmaceutical development, medical device innovation, and in-silico medicine. By leveraging the combined expertise of our members, we aim to establish the Avicenna Alliance as an ideal partner for the European Commission, FDA, and other key stakeholders in this rapidly evolving field.

Key Objectives

1. Establish the AA as a Leader in AI for Healthcare: Leverage the Avicenna Alliance's unique combination of application-specific knowledge and technical expertise to position the organization as a trusted advisor and collaborative partner for policymakers and regulators.

2. Identify Impactful AI Use Cases: Collect and showcase success stories demonstrating the real-world impact of AI-powered solutions in areas such as drug discovery, clinical trial optimization, medical device development, and patient-centric care.

3. Inform AI Policy and Standards: Provide expert input on AI-related policy questions to support the responsible and effective use of these technologies. Collaborate with relevant consortia to contribute to the development of standards and guidelines.

4. Promote AI Adoption: Raise awareness of the benefits of AI-driven in-silico models and digital twins, highlighting how these innovative tools can accelerate medical advancements, improve patient outcomes, and foster more efficient, effective, and equitable healthcare policies.

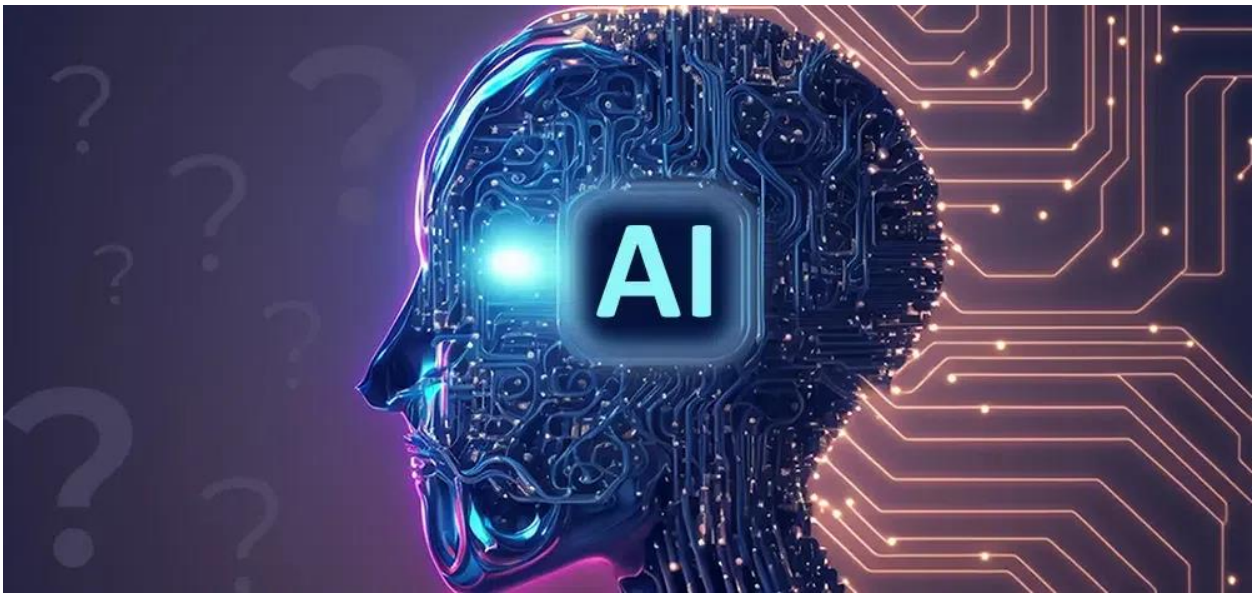
Timely Initiatives

- The AI Task Force is closely monitoring the FDA's recently released draft guidance on "Fostering the Development of Safe and Effective Medical AI/ML-Based Software" and the *"Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products"* We are actively engaging with policymakers and regulators to ensure the Avicenna Alliance's perspective is represented as this important guidance evolves.
- The AI Task Force is launching a new podcast series focused on educating stakeholders on the uses and success stories of AI in pharmaceutical development, medical device innovation, and in-silico medicine. Through this platform, we will showcase real-world examples of how AI is transforming healthcare and driving better patient outcomes.

  The podcast will feature interviews with industry experts, policymakers, and Avicenna Alliance members, delving into topics such as:
  - Leveraging AI to accelerate drug discovery and repurposing
  - Applying machine learning to optimize clinical trial design and patient recruitment
  - Utilizing digital twins and in-silico models to predict patient responses and inform personalized treatment strategies
  - Addressing regulatory and ethical considerations in the deployment of AI-powered healthcare solutions

- Nirnith Devireddy, the AI Task Force Co Chair, is a member of the AI/ML Task Force at the Indian Society of Clinical Research (ISCR) and will be presenting a position paper titled, *"USE OF ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING (ML) IN DRUG DISCOVERY, RESEARCH AND DEVELOPMENT"* at the 2025 ISCR Conference in Mumbai, India on January 31st. ISCR advocates for ethical AI/ML adoption and alignment with global standards. This position paper emphasizes the need for responsible AI/ML integration to enhance efficiency, reduce costs, and improve outcomes across the drug development lifecycle, while ensuring patient safety and advancing healthcare innovation in India and globally.

Through these collaborative efforts, the Avicenna Alliance AI Task Force is committed to advancing the responsible adoption of AI in healthcare, ultimately leading to safer, more effective, and more accessible medical solutions for all.



Spotlight on our member Tox By Design: Revolutionizing Toxicology Through Computational Innovation

By Matthieu Chareyre
Founder, Qualified Person and President

Tox By Design is at the forefront of transforming toxicology by leveraging cutting-edge computational and *in silico* methods. This innovative approach aims to improve the safety assessment of chemicals and pharmaceuticals while significantly reducing the reliance on traditional animal testing.

Founded on the principles of precision and sustainability, Tox By Design integrates advanced modelling techniques, artificial intelligence (AI), and machine learning to predict toxicological outcomes with remarkable accuracy. These computational tools simulate biological systems, enabling researchers to assess the safety of substances across various populations and conditions. This not only accelerates the development process but also provides a more ethical and cost-effective alternative to conventional methods.

The organization collaborates with regulatory bodies, academic institutions, and industry leaders to align its technologies with global standards. By doing so, Tox By Design ensures that its innovations meet the stringent requirements for safety evaluations in diverse sectors, from pharmaceuticals to consumer products.

At its core, Tox By Design envisions a future where toxicology is more predictive, inclusive, and sustainable.

By pushing the boundaries of computational science, the company is paving the way for safer products and a healthier world while championing the ethical imperative to reduce animal testing in research.

In Silico Medicine: A New Scientific Discipline Emerges in Greece

By Georgios Stamatakos
Research Professor, National Technical University of Athens (NTUA)
Cancer & In Silico Oncology Task Force Leader

On December 21, 2024, the historic city of Sparta, Greece, hosted a remarkable event shedding light on the evolution of *in silico* medicine. Research Professor Georgios S. Stamatakos, a pioneer in the field, delivered a comprehensive lecture at sparta.komvos, exploring the origins, development, and future prospects of this groundbreaking approach to modern healthcare.

Unveiling *In Silico* Medicine

In silico medicine, which emerged in Greece in 2002, harnesses computational models and simulations to study biological systems and improve medical practices. The lecture, available here, navigated through the discipline's initial shaping steps, the current landscape—including *in silico* trials—and its vast clinical potential. Special emphasis was placed on *in silico* oncology, exemplifying its transformative impact.

Key Institutions and Global Impact

Prof. Stamatakos highlighted the pivotal roles played by the Virtual Physiological Human Institute (VPHi) and the Avicenna Alliance in advancing *in silico* medicine. These organizations have been instrumental in driving regulatory frameworks, clinical

validation, and international collaboration, paving the way for broader clinical adoption.

A Multidisciplinary Dialogue

The event, organized by sparta.komvos in cooperation with the Brussels-based Foundation for Global Governance and Sustainability (FOGGS), concluded with a multifaceted discussion moderated by Dr. Georgios Kostakos, Director of sparta.komvos and Executive Director of FOGGS. Beyond the scientific discourse, the discussion delved into the renaissance ideal of the "homo/femina universalis," underscoring the importance of multidisciplinary knowledge in tackling today's complex scientific challenges.

Access to Supportive Materials

For those eager to explore further, several resources are readily accessible:

- A brief abstract providing an overview and definition of *in silico* medicine.
- A collection of thirteen related documents and videos, available in both Greek and English.

As the birthplace of classical medicine, Greece once again stands at the forefront of medical innovation, embracing the digital age with *in silico* medicine. Prof. Stamatakos' lecture not only celebrated this progress but also inspired a vision of a future where computational science and medicine converge to revolutionize healthcare.

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 56 recordings are available in the members only area of the Avicenna website. Last webinar, held on March 11th, is also available in the public area.

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

Our future webinars

- April 8th, 2025: **"ERAMET – building a transparent ecosystem for orphan and paediatric drug developmen"** by Prof Ine Skottheim Rusten from Systems Resource Lab AS (SRLAB) – Click here to register
- May 13th, 2025: **"AI Predictive Modelling for Drug Development"** by Luca Emili from InSilico Trials – Link to register available soon here.

Our latest webinars

- March 11th, 2025: **"How to design, manufacture, and optimise drugs and regenerative medicine using in silico methods?"** by Prof Himanshu Kaul from the University of Leicester – Watch the recording

  Over 90% of drugs fail after pre-clinical animal testing, leading to massive economic costs, time loss, and missed opportunities for promising drugs. In silico approaches offer a powerful solution by designing and optimizing therapies, but the lack of multiscale methods linking gene activity to cellular behaviour remains a barrier. This talk explores how different in silico modalities are being combined to engineer patient-specific therapies.

- February 18th, 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 – Watch the recording

  Computational Modelling and Simulation (CM&S) is set to revolutionize drug and medical device development, with mature technologies showing promising in silico successes and initial regulatory acceptance. For long-term impact, CM&S must address real-world biotech and medtech challenges, withstand financial pressures, and meet strict regulatory standards. Early success came from in silico predictive toxicology through (Q)SAR models, driven by regulatory needs. Market potential grew only after regulatory acceptance, highlighting its importance. Establishing new standards for prediction accuracy will be key to supporting compliance and driving future CM&S advancements.

- January 14th, 2025: **"*In Silico* Medicine: The Story So Far"** by Prof Marco Viceconti from University of Bologna – Watch the recording

  In this webinar, Prof Marco Viceconti reviews the story of in silico medicine, and in particular of the use of computer modelling and simulation in the development and derisking of medical products, what is sometimes referred to as "In Silico Trials".

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

Watch the recording

Recent news

Advancing In Silico Medicine: Strengthening Dialogue with EU Policymakers

On February 17, our President & Secretary General Thierry Marchal, alongside Nayara Maldonado Solís from RPP, had the opportunity to meet with the team of MEP Kulja, MD, to discuss the creation of an MEP In Silico Coalition. This initiative would establish a regular dialogue between in silico experts from the Avicenna Alliance and the VPH Institute, and MEPs committed to new technologies in healthcare.
It was encouraging to see that ***in silico*** **medicine, computational modelling & simulation, and AI for Health** are now widely recognized concepts in these discussions—a significant leap forward from our early engagements with EU policymakers.

However, important challenges remain. Despite progress in EU regulations and the growing openness of the MDR towards in silico methods, key questions still need answers:

- How should in silico data be reported for regulatory approval?
- How can computational models producing this evidence be validated?
- How do we equip regulators with in silico-savvy engineers capable of assessing this evidence?

We are pleased to see growing alignment on these issues and look forward to contributing to the next steps that will help make healthcare safer, faster, and more affordable — in Europe and beyond.

Welcome to René Bombien, New Co-Chair of the Clinical Deployment Task Force

The Avicenna Alliance is pleased to welcome René Bombien as the new Co-Chair of the Clinical Deployment Task Force.

René Bombien brings a wealth of experience in both clinical practice and regulatory affairs. A board-certified **cardiac surgeon**, he has over a decade of experience in cardiovascular surgery, having trained at **Johann Wolfgang von Goethe University, Christian Albrechts University, and Ludwig Maximilian University Hospital**. His expertise extends to **cardiovascular research**, including work at the **Cedars Sinai Medical Centre** in Los Angeles.

In the regulatory field, René has been active since 2011. From 2013, he has been with the **Clinical Centre of Excellence at TÜV SÜD**, served as **Chief Medical Officer at TÜV SÜD Denmark MHS** (NB CE2443) from 2021 to 2024 and is now **Clinical Director at** qtec-group. His deep knowledge of clinical evaluation and regulatory requirements will be invaluable in driving the Task Force's mission forward.

We look forward to his leadership, together with Erica Beaucage-Gauvreau, in advancing in silico clinical deployment and strengthening the dialogue between clinicians, regulators, and industry.

Welcome, René!

In Silico Medicine: A New Scientific Discipline Emerges in Greece

On December 21, 2024, Research Professor Georgios S. Stamatakos, a great pioneer of in silico oncology, delivered a lecture in Sparta, Greece, exploring the emergence, evolution, and clinical potential of in silico medicine.
Held at sparta.komvos and organized in collaboration with the Foundation for Global Governance and Sustainability (FOGGS), the event highlighted groundbreaking advancements in *in silico* oncology and trials.

Professor Stamatakos emphasized the pivotal roles of the Virtual Physiological Human Institute (VPHi) and the Avicenna Alliance in advancing predictive medicine globally. A discussion moderated by Dr. Georgios Kostakos followed, emphasizing the need for interdisciplinary approaches to address complex scientific challenges.

Click here to watch the video

Click here for the abstract of the lecture, including a definition of *in silico* medicine

Click here for further documentation

Introducing the plain language *in silico* medicine glossary

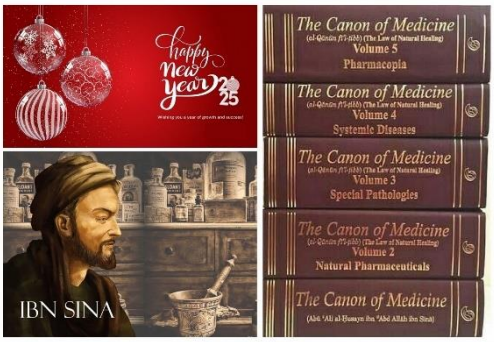
As *in silico* medicine continues to advance, new concepts and terms emerge rapidly—often before widespread consensus is established. To make this transformative field more accessible to all the stakeholders including the patients, we are pleased to present the "Plain language *in silico* medicine glossary", now published on Zenodo.

This glossary translates complex, technical language into terms understandable by non-experts, aiming to empower patients and the public with a clearer understanding of *in silico* medicine and its potential impact on healthcare.

Explore the glossary here

We recognize that language evolves, and we welcome your feedback to help us refine and expand this dynamic resource. Together, let's make *in silico* medicine more accessible for everyone!

Happy New Year, 2025, the Millennium Year



Dear Avicenna Alliance members, as we welcome the new year, we hope you had a joyful holiday season filled with moments of relaxation and happiness with your loved ones.
Looking back on 2024, we are deeply grateful for your dedication and efforts to advance *in silico* methods and their integration into regulatory frameworks. Your commitment has been instrumental in achieving significant milestones and driving meaningful progress throughout the year.

2025 is an important year as it marks the millennium since the publication by the Persian physician-philosopher Avicenna of the Canon of Medicine, a five-book encyclopaedia of medicine, among the most influential works of its time, and in which he described, among other things, the importance of clinical trials.

Inspired by Avicenna, let us continue this journey with renewed energy and determination. Together, we can build on our successes and bring the *in silico* approach closer to becoming a standard practice in healthcare innovation.

Wishing you all a Happy New Year filled with health, happiness, and success in both your personal and professional endeavours!

Warmest regards,

The Avicenna Alliance Board

Members Corner

Events

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

Symposium: "Virtual Twin Driving Healthcare 2.0"
The iSi Health Institute is pleased to invite you to participate in the symposium Virtual Twin Driving Healthcare 2.0, taking place in Leuven on September 11–12, 2025, as part of KU Leuven's 600th anniversary celebrations. This event will bring together the entire *in silico* health ecosystem, featuring inspiring keynotes from leading experts, clinicians, industry leaders, regulators, and patient advocates, followed by interactive panel discussions. Whether you are in academia, industry, healthcare, or a patient advocate, this is a unique opportunity to connect, collaborate, and shape the future of *in silico* medicine.

More information and registration

Summer School: Innovation Bootcamp for Virtual Twin for Health
We are excited to invite PhD students and postdoctoral researchers to apply for the iSi Health Summer School, taking place from September 8–10, 2025, in Leuven, Belgium, as part of KU Leuven's 600th anniversary celebrations.
This Summer School offers a unique opportunity to explore the exciting field of Virtual Twins for Health. You will have the opportunity to refine your computational skills, broaden your professional network by engaging with peers, industry experts, and leaders in in silico health technologies, deepen your understanding of the ethical and legal dimensions of in silico health, and gain valuable hands-on experience.

Application deadline: March 31, 2025 (23:59 CEST)

More details and application submission

Publications

Human relevant frontiers in drug safety and efficacy
Paper on the meeting report with the Indian Regulators
2025, January 14th
ALTEX – Alternatives to Animal Experimentation

India is steadily embracing alternatives to traditional animal-based testing, expanding from cosmetics and agrochemicals to drug development. In July 2024, the Centre for Predictive Human Model Systems (CPHMS), the Central Drugs Standard Control Organization (CDSCO), and the Indian Council of Medical Research (ICMR) hosted a workshop to explore emerging trends in complex in vitro models and computational modelling. The event highlighted the need for regulators, funding agencies, academia, start-ups, and industry to collaborate in advancing these innovative non-clinical approaches.

Read the full document

THE DIGITAL TWIN THEORY PODCAST - Episode 9: "Bones, Joints and Bytes" with Prof Marco Viceconti

Musculoskeletal applications are among the most advanced frontiers of *in silico* medicine. In our first episode of 2025, we sit down with a true pioneer in the field: Prof. Marco Viceconti.

Join us as we explore the evolution of *in silico* medicine through the insights of one of its most influential figures.

Click here for the podcast

Other News and interesting links

Special Issue on Challenges in Evaluation and Identification of Tissue Biomechanical Properties and Parameters – CALL from ASME

ASME is calling for contributions to a special issue focused on the challenges of evaluating tissue biomechanical properties. Researchers are invited to submit original studies or reviews addressing key hurdles in experimental and modelling approaches, particularly inverse modelling. Submissions should highlight how the research tackles these challenges and offer insights into future directions.

Info and submission

ROMed2VR: Revolutionizing Pre-Surgical Planning with CFD, reduced order modelling and VR

The groundbreaking **ROMed2VR project** has launched with the mission of transforming pre-surgical planning for Congenital Heart Diseases (CHDs). By combining **Computational Fluid Dynamics (CFD)** and **Virtual Reality (VR)**, this innovative initiative aims to provide surgeons with advanced tools to enhance decision-making and patient outcomes.

Leading contributors to the project include **RBF Morph**, **InSilicoTrials**, **ENGYS**, and **Fondazione Toscana Gabriele Monasterio (FTGM)**. Together, they are pushing the boundaries of medical technology to develop a streamlined, patient-specific system for planning and optimizing **Modified Blalock-Taussig Shunt (mBTS)** procedures.

The ROMed2VR project combines **CFD simulations** and **Radial Basis Functions (RBF) mesh morphing into a VR-enabled platform.** This will allow clinicians to visualize and interact with patient-specific models in real time, facilitating more precise and effective surgical planning.

RBF Morph is leading activities related to the VR environment. By ensuring seamless integration of VR technology into the ROMed2VR platform, RBF Morph enables surgeons to interact intuitively with patient-specific models during the pre-surgical planning phase. This innovative approach enhances understanding of complex physiological conditions and supports better decision-making.

InSilicoTrials will focus on the evaluation of the VR navigation system and its eventual **commercialization through their proprietary web platform**. By leveraging their expertise in regulatory-compliant software solutions, InSilicoTrials ensures that the ROMed2VR pl
atform meets industry standards and is ready for broader adoption, thus enhancing accessibility to cutting-edge medical tools worldwide.

With its expertise in **open-source CFD solutions**, **ENGYS will contribute to the development of high-fidelity simulations that underpin the ROMed2VR platform.** These simulations provide the foundation for accurate and patient-specific fluid dynamics modelling, enabling the precise analysis of critical factors such as blood flow and pressure.

As a public research hospital within Tuscany's healthcare system, **Fondazione Toscana Gabriele Monasterio (FTGM)** specializes in cardiology and cardiac surgery, with a focus on congenital heart defects. Leveraging its extensive clinical expertise, FTGM will act as an external research organization (OdR) on behalf of ENGYS, contributing invaluable insights to ensure the project's clinical relevance and efficacy.
The ROMed2VR project was officially launched on **25 November 2024** in Trieste, Italy, where partners convened to establish objectives and strategies for the year-long initiative. With a total budget of €426,644.42 and funding of €319,010.23, the project is poised to deliver transformative advancements in CHDs treatment by October 2025.

Together, the ROMed2VR consortium is advancing the future of CHDs care, setting a new standard in surgical planning through innovation and collaboration.

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

[Contact us]

Join the Avicenna Alliance!