Avicenna Alliance
Association for Predictive Medicine

Avicenna Alliance Newsletter
MARCH – APRIL 2023

In this Newsletter

Engaging with authorities

By Thierry Marchal
Secretary General, The Avicenna Alliance

Most of us recognize the value of *in silico* methods and are using Computational Modelling and Simulation extensively for research, ideation or product development. But if you truly believe this technology has the potential to dramatically change healthcare, to make it more efficient, safer and more affordable, it is not enough to limit discussions to just engineers and experts. It is essential to involve the patients and the public in our conversation, as our PPI Task Force is doing it extensively. Other key stakeholders such as Policy Makers and Regulators are also an important part of the audience who we must educate and influence.

During the European Parliament's plenary session that took place in the second week of March, The Avicenna Alliance had the unique opportunity to visit the European Parliament in Strasbourg, France, to meet with policymakers, Members of the European Parliament (MEPs) and organise discussion about *in silico* medicine. The Strasbourg Parliament provides a great platform for policy advocacy, given that meetings with MEPs take place during an opportune moment within their policymaking process, namely the plenary votes. Avicenna

managed to secure meetings with four MEPs featuring three different political groups, the Socialists & Democrats, the European People's Party Group and the European Conservatives and Reformists Group, who all expressed support of moving *in silico* medicine forward on the EU's policy agenda as a priority for new initiatives in healthcare. Additional meetings took place in Brussels, while more follow-up discussions are now planned in April and May. The Avicenna Secretariat is currently in the process of following up with the MEPs, to steer several activities, among which are proposing amendments on relevant upcoming files, submitting parliamentary questions, organising a presentation about *in silico* given by Avicenna during an event in the EP, and laying the foundations for a MEP Coalition on predictive medicine!

In addition, on March 27 & 28, The Avicenna Alliance had the privilege to be invited as an Observer to the International Medical Device Regulators Forum (IMDRF) meeting held in Brussels. This was a unique opportunity to learn, inform, network and share the central role of modelling and simulation (*in silico* methods) for regulatory approval. Digital Evidence was not yet a key topic for most of the presentations that we attended; but many side conversations with Regulators, industry leaders and Non-Governmental Organizations revealed great interest and support for *in silico* methods and most see the necessity to investigate, regulate, and deploy *in silico* outputs. Digital Evidence is now perceived as a promising solution for complementing traditional evidence and improving the regulatory approval process while further increasing patient safety. We are delighted to have been invited to pursue these important discussions during the next IMDRF conference in Berlin in September!

While these engagements are wonderful opportunities to discuss *in silico* methods with numerous decision makers, they will be useless if we do not nurture these new contacts towards the delivery of safe and affordable *in silico* predictive medicine. Therefore, I am asking each of you to regularly challenge us and our Policy Development Working Group led by Martha De Cunha, in achieving concrete progress in this matter.

Policy Development Working Group ("PDWG")

by Martha De Cunha Maluf-Burgman
Working Group Leader, Avicenna Alliance

In silico technologies continue to gain relevance in the development of medicines and medical devices. The digital evidence generated from *in silico* models is also becoming an important element in clinical trials and during regulatory submission processes.

The Avicenna's Policy Development Working Group **("PDWG")**, led by Martha De Cunha Maluf-Burgman, MBA (Edwards Lifesciences), works towards:

- A forward-looking policy framework to facilitate the **large-scale deployment of *in silico* technologies** and their acceptance by health authorities.
- To significantly reduce the time and cost for **approval and reimbursement** of health care technologies through *in silico*.
- To foster medical innovation, including for those with unmet medical needs such as **rare diseases and pediatric applications**.

PDWG members represent a broad group of stakeholders, including academia, research organisations, medtech and the pharmaceutical industry. The working group's members are working to collaborate with the European Medicines Agency (EMA), patient associations, notified bodies and other stakeholders to promote the adoption of *in silico* evidence in the regulatory pathway. This includes proposing an *in silico* pathway and the associated good simulation practices (GSP), and then informing and educating the different stakeholders. Group activities also include organising workshops, creating white papers, meeting with international health authorities, and much more.

We therefore invite you to participate in some or all the activities from our PDWG. Please email Roberta Maggi (manager@avicenna-alliance.com) to receive an invitation to our different task forces meetings.

Looking forward to collaborating with you to enable a future where *in silico* technologies are a norm and not an exception.

Martha 😊

Spotlight on the Global Harmonization Task Force

by Marc Horner
Task Force Leader, Avicenna Alliance

Computational modelling has the potential to significantly accelerate medical innovations, ensuring safe, effective, and affordable healthcare. However, the US Food and Drug Administration is currently the only agency with an established and consistent framework for including computer modelling and simulation results to support regulatory evaluation.

This limits the use of modelling by device manufacturers since companies will tend to pursue the development of tools and techniques that support regulatory activities across the broadest number of geographies. Therefore, global harmonization of regulatory frameworks is one of the leading barriers to broader adoption of digital evidence.

The Global Harmonization Task Force (GHTF) is working globally to converge towards a common framework that could eventually harmonize the different regulations. This includes developing position papers that outline best practices based on existing frameworks. These documents are available in multiple languages to ensure the correct comprehension of these practices. GHTF members participate in conferences, workshops, and the like to socialize these practices with stakeholders in engineering, quality, and regulatory affairs professionals.

The GHTF is also engaging directly with global competent authorities to socialize and educate stakeholders regarding the benefits of digital evidence to the healthcare industry, and patients.

Introducing the Tissue Characterization Task Force

by Nele Famaey
Task Force Leader, Avicenna Alliance

There is a strong, industry-driven need for a quality label for computer simulations in *in silico* medicine. Various agencies have formulated guidelines regarding model credibility, including rigorous verification and validation processes. However, clear guidelines on how to assess the quality of model input parameters are still lacking. Indeed, material properties of the involved tissues are often essential input parameters, but it is extremely difficult for numerical analysts to find appropriate and reliable values for their simulations. The scientific literature abounds with articles experimentally characterizing biological tissues, but widely recognized testing standards for these tissues are absent. This shortcoming leads to significant variability and hence (epistemic) uncertainty of test results, on top of the already high inherent variability exhibited by biological tissues.

To minimize the degree of uncertainty and error that propagates into computer simulations, the Tissue Characterization Task Force is driving efforts to:

1. Identify the extent of variability in currently present in biological tissue characterization methods. The task force has launched the C^4Bio initiative (Community Challenge towards Consensus on Biological Tissue Characterization), in which research groups from all over the world are invited to test the same tissue type using the same test method, each using their tried and tested methodology. A pilot study on uniaxial tensile testing of aortic tissue revealed a disconcerting amount of variability between groups, with coefficients of variation in the order of 100%, proving the urgent need for this kind of study.

2. Reach community consensus on testing protocols. Again, under the C^4Bio initiative, the task force brings the testing community together to find consensus protocols and quantify to what extent the use of these optimized protocols can reduce inter-research group variability. A consensus protocol for uniaxial tensile testing of aortic tissue is currently being formalized.

3. Enable wide adoption of the obtained consensus. The task force connects stakeholders in the entire chain of tissue characterization and modeling, from test bench manufacturers, over experimentalists to medical device simulators and regulatory bodies.

4. Ultimately, create a universal tissue properties database. The pinnacle of the task force's efforts is to enable the creation of a tissue property database with regulatory grade material properties of various relevant biological tissues.

Nele Famaey

Introducing Mimesis

by Giulia Russo and Francesco Pappalardo
Co-founders, Mimesis

Mimesis is an innovative start-up, founded in 2020 as a spinoff of the University of Catania, which offers to the biomedical industry and pharmaceutical companies the first generation of *in silico* solutions.

Our solution consists in computational models that replicate the behaviour of the human immune system, and simulate its responses both in the presence of viruses, bacteria, tumours and auto-immune diseases, including in the presence of pharmacological therapies. This approach considerably reduces the time and costs of research and drug development.

The Universal Immune System Simulator (UISS) is the main product produced by Mimesis: thanks to the use of virtual patients, the framework simulates the effects of a given therapy on the immune system, thus reducing the risk of possible side effects and predicting its effectiveness even before its implementation.

As part of the *In Silico* World project (HORIZON 2020), Mimesis is committed to reducing regulatory barriers in the adoption of *in silico* models. Furthermore, the company cares about ethics: the solutions adopted do not require the use of any humans, leading to a reduction in the number of patients participating in in vivo clinical trials.

Mimesis is the result of more than twenty years of research by its partners. The founding partners, Prof. Francesco Pappalardo and Dr. Giulia Russo, together with the other members, tirelessly carry on the research work, making Mimesis one of the most important start-up in the health sector.

Joining Avicenna is another step forward for Mimesis and we hope to be able to contribute to carrying on the goals set by this great Alliance.

Giulia and Francesco

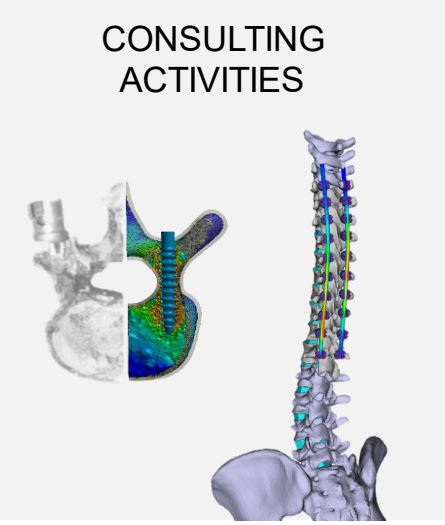
Introducing Numalogics

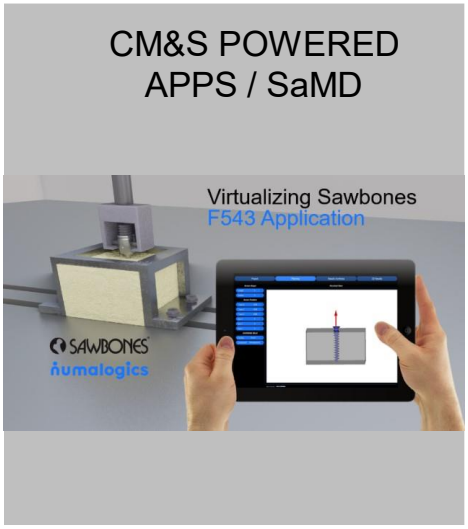
By Julien Clin, Director of Biomechanical Simulation R&D, and Dustin Arless, Business Development Manager.

Numalogics Inc. a privately held firm, based in Montréal (Canada) was founded in 2010 by 3 recognized key opinion leaders orthopedic spinal surgeons (Stefan Parent, Jean-Marc Mac-Thiong, Hubert Labelle).
Our mission is to democratize computational modeling & simulation (CM&S) for the medical device community. Since 2017, we have been active contributors to the ASME V&V40 committee.

Historically, our main focus has been modeling and simulating spine surgery.

We have developed an advanced spine model, called NumaSpine, that allows us to perform virtual spinal surgeries, test different kinds of spinal implants to gain insight into their biomechanics, perform *in silico* clinical studies, and help surgeons to plan their surgeries.





Our business is divided into two main branches that feed each other: consulting activities and the development of value-added software solutions (apps and software as medical devices embedding CM&S).

Our consulting activities leverage our high-end models, notably the NumaSpine model, to support the product development of our customers through their entire life cycle, notably by bringing insight into their biomechanical interactions with the human body.

Through our second business model, we aim to democratize the use of CM&S by non-specialists. We have two main audiences:

- Non-simulation engineers: whom we aim to reach by virtualizing ASTM or ISO standard tests and embedding these virtualized tests into easy-to-use apps.
- Surgeons: whom we aim to reach by embedding CM&S predictive tools into software as medical devices, pre-operative planning software for instance.

We strongly believe a concerted effort is needed for the large-scale adoption of *in silico* modeling across the entire healthcare ecosystem. We intend to contribute to that effort through the Avicenna Alliance. Working together, we will help overcome the challenges that our community is facing.

Avicenna Alliance Pharmaceutical Strategy TF white paper

This position paper titled "T**he potential of *in silico* approaches to streamline drug development"** highlights the potential of *in silico* medicine, using computational modelling and simulation to aid drug discovery, development, and delivery. The goal is to encourage making *in silico* medicine to be a standard to complement *in vivo* and *in vitro* approaches in healthcare through a collaborative ecosystem of stakeholders, including industry, academia, regulatory agencies, standard organisations, patients, clinicians, policy makers, and payers. In the current context, drug development and testing has proved to be unsustainable, costing $2 to 2.5 billion and taking 10 to 15 years.

In silico or CM&S allows for the simulation of complex biological systems and the prediction of drug efficacy, toxicity and other critical parameters, reducing the need for animal testing and costly clinical trials. The *in silico* approach could be a potential accelerator for regulatory reviews and approval processes, a strategy to reduce costs and environmental footprint, and ultimately improve patient outcomes. However, the impact of *in silico* methods during regulatory processes, post-market surveillance, and investigation of adverse events is still limited. The absence of a clear process for the large-scale adoption of *in silico* results for regulatory purposes remains a barrier. It is important to extensively define the context of use of i*n silico* methods and demonstrate their validity for specific questions of interest.

Overall, *in silico* medicine has the potential to overcome socio-economic and technological barriers to medical innovation and improve patient safety. One of the main objectives of this paper is to outline the potential of *in silico* approaches in drug development and recommend their use prior to animal testing or clinical trials to refine results, identify relevant animal models and populations, reduce in vivo testing, optimise drug dosing, and better inform testing on real patients.

Link to white paper

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 only available to the Avicenna 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 attending these webinars and watching previous ones!

All 34 recordings are available in the members only area of the Avicenna website.

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

Our future webinars

- May 9 2023 "**Outsmarting cancer with liquid biopsy**" by Aline Cerf from SmartCatch. Register now
- June 6 2023 "**Life is Motion - An integrated view on the neuromuscular system**" by Oliver Röhrle from University of Stuttgart. Register now

Our latest webinars (For members only)

- April 4 2023 "***In silico* models of coronary artery pathophysiology for clinical decision support**" by Frans van de Vosse from Eindhoven University of Technology. Watch the recording

  In this webinar an overview of the development of the in-silico models and use for clinical decision making is given. In addition the possible use for future in-silico clinical trials to optimize procedures and medical devices has been discussed in the context of the generated synthetic data collections using hybrid (mechanistic-data driven) models.

- March 7 2023 "***In silico* trial simulation platform Jinkō**" by Shiny Martis & Claudio Monteiro from Novadiscovery. Watch the recording

  During this webinar Dr Shiny Martis B explained how jinkō can be used to extract, classify and qualify pieces of knowledge in a systematic, transparent and traceable manner, and use these in research reports and literature reviews. Dr Claudio Monteiro showcased how this knowledge is then leveraged directly within jinkō to help lower the cost and ethical constraints as well as achieve greater trial efficiency through the design and simulation of in silico trials. Two practical use cases using nova's non small cell lung cancer (NSCLC) disease model of epidermal growth factor receptor (EGFR) mutated lung adenocarcinoma (LUAD) are illustrated.

More than **30** recording are available online. Learn more about what other members are doing.

Watch the recording

EU Policy and Regulatory updates by the RPP team

Commission's Proposal for a revision of the general pharmaceutical legislation gets further postponed

According to a spokesperson for the European Commission, **the date of publication of the draft proposal has been once again postponed to April 26th.** Chances that the negotiations will be finalized by the end of the current mandate are increasingly slim. Policymakers have already expressed their dissent and urged the Commission to publish the document. During last week's European Council meeting EU leaders expressed the urgency of this new pharmaceutical legislation and called on the Commission to "step up efforts at national and EU level to reduce barriers to cross-border business and take work forward on access to medicines across Member States while also strengthening incentives for investments in innovation".

In the meantime, the NAT Commission of the European Committee of the Regions is discussing a proposal for renunciation. The NAT secretariat recommended not issuing an opinion on the Revision of the General Pharmaceutical Legislation, giving the explanation that the file is "very technical" and regions and local authorities have "limited competence" on the subject**.**

Commission launches implementation of European Regional Innovation Valleys

The **Commission launched a call for expression of interest for Regional Innovation Valleys (RIVs)** which will remain open until 18 September 2023 and aims at identifying local challenges and needs in various innovation domains. The main goal of RIVs, a flagship initiative of the New European Innovation Agenda, is **to identify up to 100 regions committed to enhancing the coordination and direction of their research and innovation projects** through understanding the local challenges and needs.

This call for expression of interest will **enable regions to express their interest to become regional innovation valleys and identify specific local challenges and needs**. Regions are also invited to **indicate in which innovation domain** (**including healthcare system,** food security, renewable energy, circular economy, etc) **they would like to strengthen their R&I investments**.

Spain: New Minister of Health appointed

José Manuel Miñones, has been appointed as new Minister of Health in Spain on 28 March. The new Minister is expected to hold the position during the Spanish Presidency of the Council of the EU. Most of the legislative and political priorities in the area of health had already been informally communicated by the previous Minister on different occasions**. More specifically, three legislative priorities were put forward, namely the EHDS, the modification of EMA fees and the SoHo regulation**. **Three political priorities** were furthermore announced: 1) combating childhood obesity, 2) fighting against HIV and its stigma and, finally, 3) mental health.

Despite this, some of the statements had been so far contradictory or not comprehensive. **Therefore, the new Minister could have a final say and influence on such priorities before the start of the Presidency.**

New Subcommittee on Public Health elects its Chair and Vice-Chairs

The Subcommittee on Public Health (SANT) held its constitutive meeting on 23 March and appointed its Chair and Vice-Chairs. **The chairs of the SANT subcommittee will play a leading role in shaping the future of European public health policy, among which is the EU's new pharmaceutical strategy.**
Earlier in March, , the European People's Party (EPP) announced that MEP Tomislav Sokol (EPP, Croatia) will serve as EPP's Coordinator within SANT.
The newly created subcommittee is mandated to address issues in the field of **public health, pharmaceutical and cosmetic products, health aspects of bioterrorism, the European Medicines Agency (EMA), and the European Centre for Disease Prevention and Control (ECDC)**. However, the ENVI committee will remain responsible for examining and voting on legislative proposals.
The complete list of 30 SANT members can be found here.
The first ordinary meeting of the subcommittee will take place on **20 April in Strasbourg.**

European Commission adopts Digital Europe Work Programme for 2023/2024

The European Commission has adopted its Digital Europe Work Programme for 2023/2024.
The areas covered under the 2023/2024 WP and its budget are:

- Health Data Space which is focusing on Federated European Infrastructure for Intensive Care Units (ICUs) and Genome of Europe.
- Under Artificial Intelligence, the focus is on testing and experimentation facilities for the use of AI and on the Virtual Human Twins Models.

It should be noted that the funding opportunities for the year 2024 do not include an indicative budget yet and that this will be specified with an amendment to the WP in the coming months.

ENVI/LIBE Draft Report on EHDS under discussion

Work is currently ongoing in EP Committees ENVI and LIBE on a joint report on the **European Health Data Space. The complete list of negotiators can be found here.**
A draft report was published on 15 February. The deadline for amendments was 23 March. Consideration of amendments is set to start on 13 April.
Recent discussions on the EHDS file in the European Parliament has been mainly focused on allowing patients to decide whether to share their data or not for secondary use. This has caused a heated debate among political groups, with EPP and Renew supporting an opt-out in opposition to an opt-in approach endorsed by the Greens and some representatives of the S&D.
Should more policymakers join the call for the inclusion of an opt-in option, the negotiations in the Parliament might risk coming to an impasse.

We hope you find these updates useful! Should you have any questions or thoughts, please don't hesitate to reach out to Mehi from the RPP team via m.holler@rpp-group.com

Recent news

We are delighted to welcome France Biotech as a new Avicenna Partner

Founded in 1997, France Biotech is an independent association, uniting the country's leading innovative health companies and their expert partners and works in close cooperation with public authorities in France and across Europe.

www.france-biotech.fr

The potential of *in silico* approaches to streamline drug development

The Avicenna Pharmaceutical Strategy TF position paper is out!
It calls for adaptation of *in silico* technology to be a standard practice to complement *in vivo* and *in vitro* approaches in healthcare.

READ THE FULL DOCUMENT

DON'T LOOSE THE AVICENNA DAYS 2023!!!

An exhaustive update on recent progress and achievements related to the adoption and deployment of *in silico* methods.

REGISTER TODAY!!!

Avicenna Alliance Observer at IMDRF meeting in Brussels

The Avicenna Alliance received the honor to be invited as an Observer to the International Medical Device Regulators Forum (IMDRF) meeting in Brussels on March 27 & 28 .

Avicenna Alliance meets with MEPs in Strasbourg

During the European Parliament's plenary session in the second week of March, Avicenna had the unique opportunity to visit the European Parliament in Strasbourg to meet with policymakers and organise discussion about *in silico* medicine.

Welcome RBF Morph!

Welcome to our new member RBF Morph!

Based in Monte Compatri, Rome, RBF is a pioneer and leader in mesh morphing, a key technology used in engineering simulation.

Mimesis is a new Avicenna member!

We are truly delighted to welcome Mimesis as a new Avicenna member!

Mimesis is an innovative start-up, founded in 2020 as a spinoff of the University of Catania, which offers to the biomedical industry and pharmaceutical companies the first generation of *in Silico* solutions.

Shiny Martis is the new Pharmaceutical Strategy TF Co-Chair

We are delighted to welcome Shiny Martis as the new Pharmaceutical Strategy TF Co-Chair.

Shiny is Academic Partnership and Customer Success Scientist at Nova Discovery and is taking the lead of the TF together with Cécile De Coster.

Members Corner

Recent publications

"The UK Life Sciences Council advocates for ten recommendations"
December 2022

In November 2022, the UK Life Sciences Council acknowledged that the development of new sovereign arrangements for the regulation of medical devices presented a golden opportunity to drive innovation and growth in the UK whilst ensuring patient safety remains at the heart of the UK's regulatory approach to. Following the publication of a Joint Statement in December 2022, the Advisory Group was formed to provide initial proposals to the UK Government in three priority areas: international recognition, routes for innovation; and system capacity.

The Group has taken a patient-centred approach, with patient safety and maintaining access to existing and novel products at the core of its discussions.

Aligned Proposals

To help create a system-wide UK integrated pathway for HealthTech, MHRA to become a more responsive regulator with supportive innovation pathways:

1. Consider expanding the role of the MHRA in the direct regulation of HealthTech, focusing initially on innovation.
2. The MHRA and other health system partners must access a robust international horizon scanning capability to seek innovation proactively. Work should be done in partnership with health system partners, academia and industry to identify relevant horizon-scanning capabilities.
3. Develop a model for expanded bespoke pre-market regulatory advice for novel/innovative products.
4. Expand the use of Real-World Data to transform clinical investigations and performance studies by enabling earlier access when planned with proportionate post-market surveillance.
5. Develop performance metrics for support and uptake of HealthTech Innovation in the UK.

Ensure the supply of safe medical devices to UK patients is maintained through expanded recognition (e.g. to US approvals) and removing burden where possible:

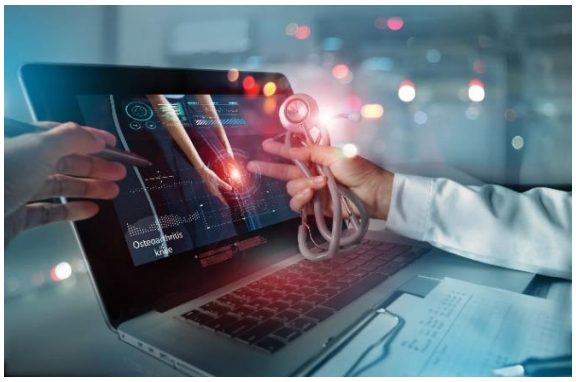
6. Building on current product recognition routes from the EU, rapidly explore building a UK product regulation equivalence route for the approvals of medical devices to include other trusted jurisdictions such as the US for a greater proportion of products.
7. Explore greater flexibility over the requirements for physical UKCA markings on parts, instructions and labels before products can be marketed in the UK. Make greater use of registration and traceability mechanisms to ensure patient safety.
8. The MHRA has already announced its intention to expand recognition for medicines, and create a new recognition framework by the end of 2023. Aim to align changes to the Medical Devices Legislation to the Medicines legislative timeline if possible.

Ensure the future system is enabled, and avoids current challenges, through the development of a UK regulatory skill programme:

9. Explore delivering a UK HealthTech Regulatory skills programme.
10. Investigate investing in the delivery of a UK network of Centres of Excellence in Regulatory Science and Innovation (CERSIs).

Link to publication: https://www.gov.uk/government/news/advisory-group-reform-proposals

"The potential contribution of *in silico* studies to improved treatment of osteoarthritis"
March 22nd, 2023
Nature Reviews Rheumatology (The potential contribution of *in silico* studies to improved treatment of osteoarthritis | Nature Reviews Rheumatology).



This article, based on the work of iSi Health member Ali Elahi, "Contribution of collagen degradation and proteoglycan depletion to cartilage degeneration in primary and secondary osteoarthritis: an *in silico* study", addresses the topic of Osteoarthritis, its many appearances and how it can stabilize or progress aggressively.

The most important question addressed is whether *in silico* approaches, despite difficulties in validation, can help with the identification of experimentally challenging subtypes. And if they can, if will these approaches translate to clinical benefits.

Link to publication

"APC 2023 Engaged Research bursary recipients announced"
March 13th, 2023
Press release for the Engaged Research Bursary by APC Microbiome Ireland

Avicenna Public & Patient Involvement (PPI) Task Force Leader, Cyrille Thinnes' application has been awarded 2,800 EUR to support the development of a PPI Toolkit in Digital Health with the Avicenna Alliance PPI TF, to enable applications also in the gut health area.

Engaged Research places the citizen at the centre of the research project and involves collaborating with non-specialist stakeholders and the wider community throughout the research life cycle.
APC Microbiome Ireland funds up to five projects annually – allowing researchers the opportunity to embed aspects of engaged research into their research activity and build their professional capacity as engaged researchers.

Link to publication

Events

ELEM Biotech to attend ESC Congress 2023 in Amsterdam

ELEM Biotech is proud to announce that it attends ESC Congress 2023 which takes place on 25th-28th August in Amsterdam. This event is a significant gathering of experts and professionals in cardiology and cardiovascular health, and ELEM Biotech is excited to be part of it.

By introducing its technology at the ESC Congress, ELEM, that **will also carry the flag for the Avicenna Alliance** during these 3 days, aims to impact and significantly enhance the **recognition of *in silico* computational modelling** in the field of cardiology. Simulation diseases and treatments in human hearts can significantly contribute to efficiencies for surgeons and improving patient outcomes.

In particular, the most important European Society of Cardiology event in Europe provides ELEM an ideal platform to showcase its innovative solution in *in silico* clinical trials and how it benefits pharmaceutical and medical device companies.

"*Our attendance at the ESC congress is a great opportunity to network with some of the world's best experts in the medical space and to **highlight the importance of in-silico** towards modern cardiology. By generating new evidence on an unprecedented scale, we hope to contribute to the future of medicine - one that is more precise, inclusive, and **focused on improving patients' quality of life***", said Christopher Morton, ELEM's CEO.

Link to the event webpage

Nova Discovery is organizing an event dedicated to *in silico* clinical trials in Lausanne, Switzerland

This one-day event will take place in Lausanne on Thursday the 25th of May, where 3 main sessions will be held followed by a networking session.

- Session 1: Dose finding & optimization
- Session 2: Synthetic control arms
- Session 3: Precision medicine: Best responders & Biomarkers identification

Final programme available soon.

Link to registration

CompBioMed Conference 2023 – 12/14 September 2023, Science Congress Center Munich, Garching, Germany

CompBioMed Conference 2023 will address all aspects of the rapidly burgeoning domain of computational biomedicine, from genome through organ to whole human and population levels, embracing data driven, mechanistic modelling and simulation, machine learning and combinations thereof.

Contributions from academic, clinical and industrial participants are equally welcome.

- 4 confirmed plenary speakers
- 13 symposia
- International Organising Committee of renowned experts.

Registration and abstract submission for thid third iteration of the CompBioMed Conference, CBMC23, is open.

Register before 31st July 2023 for the early bird discount.

The deadline for abstract submission is 31st May 2023.

Social event on the evening of 13 September 2023 at the oldest brewery in the world, the Bräustüberl Weihenstephan, including a guided tour of the brewery, beer tasting, and a conference dinner.

Link to the event

Other News and interesting links

MDIC seeks industry input for a human body Computational Modeling & Simulation (CM&S) Needs Assessment

What is the purpose of this Needs Assessment?

Computational modeling and simulation (CM&S) of the human body has the potential to accelerate product development and enhance efficacy and safety of the devices – especially given the ability of CM&S to predict device in vivo performance. Industry adoption of CM&S, however, has been slow due to the lack of resources, expertise, and clinically relevant data. With funding provided by the National Institutes of Health (NIH) and other public funding sources, many academic researchers have made great strides in advancing the science and technology in CM&S. The models developed through these funded projects are not always discoverable, accessible, and applicable for industry context of use. Moreover, the potential of these models receiving approval as FDA qualified Medical Device Development Tools (MDDT) needs t o be realized.

To bridge this gap, the Medical Device Innovation Consortium (MDIC) is leveraging its Public-Private partnership to bring together stakeholders from industry, NIH, and FDA to create a publicly available resource of publicly funded human body computational and simulation models, which will be prioritized according to industry needs. MDIC aspires to promote credible practices for computational modeling and simulation while providing access to trusted models along with all associated metadata for future MDDT submissions.

As part of the vital input collection for this project, the MDIC CM&S steering committee requests information regarding your human body CM&S needs. Your input to this needs assessment along with those from other industry members will be aggregated and prioritized for this effort.

Who should take the Needs Assessment?

Individuals in the industry that are currently using or hoping to use CM&S for medical devices or diagnostics at any stage of the total product life cycle. Please set aside 10-15 minutes to fill this questionnaire.

If you have any questions on this industry needs assessment or MDIC programs, please contact us at cms@mdic.org.

The MDIC CM&S Needs Assessment will remain open March 30 – April 30, 2023.

Link to survey

Link to project landing page

Disclaimer: The Industry Needs Assessment can be taken anonymously. MDIC won't share or sell contact the information provided with any third party external to the process.

Job opportunities

1. MDsim (4 open positions)

AI/ML engineer

Software as a Medical Device

Your mission is to be part of the team of PhDs, Engineers and Software Developers dedicated to the development of a Software as a Medical Device (SaMD) platform aimed at helping Surgeons & Designers of Medical Devices to design, certify and use innovative devices in optimally planned and executed surgeries.

You will work within a highly competent and motivated team with the purpose to improve the quality of life of millions of patients around the globe by merging the latest and greatest of engineering technologies and medical sciences.

Responsibilities

- Develop proof-of-concepts (POCs) of the application of AI/ML methods for image analysis, surrogate modeling and reduce order modeling, including model selection, training, and validation.
- Mature and industrialize the POCs working with the software development team.
- Participate to the deployment of the AI models within the SPINEsim platform.
- Work with other team members like bio-mechanical modeling engineers and medical images experts to develop the best integrated technical solution.
- Perform tech-watch and stay up-to-date with novel AI/ML methods.
- Propose new ideas or product functionalities supported by artificial intelligence.
- Overall, own the AI/ML dimension of the company's solutions.

Requirements and skills

- PhD in computer science or applied mathematics or similar, specialized in AI, ML, Deep Learning, or any other related fields.
- Proven experience as Artificial Intelligence/Machine Learning engineer or similar role with excellent knowledge of deep learning algorithms.
- Ideally:
    - Experience in developing and applying CNN (ideally U-net or similar) to perform image segmentation and landmarking.
    - Experience in developing and applying surrogate modeling or reduce order modeling techniques.
- Good knowledge of Python. Other programming languages is a plus.
- Knowledge of some key AI/ML/DL frameworks like TensorFlow, pyTorch, Keras, … is mandatory.
- Basic knowledge of numerical methods like the finite element, finite difference, finite volume, … methods to solve differential equation is a plus.
- Excellent communication and teamwork skills.
- Great attention to details, organizational skills, and an analytical mind.
- Highly motivated with a "can do" attitude.

Your work will be rewarded with a competitive salary, a complete benefit package, the ability to participate to the start-up's stock options plan, a good work/life balance and the sense of purpose with a direct positive impact on millions of lives.

If you are interested please send your CV to: Laurent.ADAM@MDsim.health or roger.assaker@mdsim.health

Data Scientist – Medical Imaging

Software as a Medical Device

Your mission is to be part of the team of PhDs, Engineers and Software Developers dedicated to the development of a Software as a Medical Device (SaMD) platform aimed at helping Surgeons & Designers of Medical Devices to design, certify and use innovative devices in optimally planned and executed surgeries.

You will work within a highly competent and motivated team with the purpose to improve the quality of life of millions of patients around the globe by merging the latest and greatest of engineering technologies and medical sciences.

Responsibilities

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- Overall, own the AI/ML dimension of the company's solutions.

Requirements and skills

- PhD in computer science or applied mathematics or similar, specialized in AI, ML, Deep Learning, or any other related fields.
- Proven experience as Artificial Intelligence/Machine Learning engineer or similar role with excellent knowledge of deep learning algorithms.
- Ideally experience in developing and applying CNN (ideally U-net or similar) to perform image segmentation and landmarking.
- Good knowledge of Python. Other programming languages is a plus.
- Good knowledge of medical imaging systems and associated file formats.
- Knowledge of some key AI/ML/DL frameworks like TensorFlow, pyTorch, Keras, … is mandatory.
- Excellent communication and teamwork skills.
- Great attention to details, organizational skills, and an analytical mind.
- Highly motivated with a "can do" attitude.

Your work will be rewarded with a competitive salary, a complete benefit package, the ability to participate to the start-up's stock options plan, a good work/life balance and the sense of purpose with a direct positive impact on millions of lives.

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Full Stack Software Developer

Software as a Medical Device

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You will work within a highly competent and motivated team with the purpose to improve the quality of life of millions of patients around the globe by merging the latest and greatest of engineering technologies and medical sciences.

Responsibilities

- Work with development team and product manager to ideate software solutions.
- Contribute to client-side and server-side architecture-
- Build the back-end architecture made of different services aiming at supporting the computational pipeline.
- Build the front-end with appealing visual design optimized for effectiveness and efficiency (front end to be available as a web and mobile app, and enabling AR/VR).
- Work with bio-mechanical and modeling engineers, as well as data scientists to develop the back-ends components/services.
- Create security and data protection settings to comply with regulations for cybersecurity & GDPR.
- Develop with a strict procedure to ensure the highest quality and safety for all stakeholders.
- Develop and maintain an efficient build pipeline targeting multiple environments.
- Develop unit tests to be integrated in the build pipeline.
- Troubleshoot, debug and upgrade software.
- Write technical documentation and participate to quality and regulatory submission and audits.

Requirements and skills

- Proven experience as a Full Stack Developer or similar role.
- Proven experience developing web-application. Experience in mobile app development and AR/VR applications is a plus.
- Experience with Azure platform (Azure Git/Pipelines/VM/Insight...).
- Knowledge of front-end languages and libraries/frameworks (e.g. HTML/ CSS, JavaScript, TypeScript, XML, jQuery, React, Angular).
- Knowledge of back-end languages (e.g. C#, Java, Python) and frameworks (e.g. .NET, Spring, Node.js,..)
- Experience with containerization using Docker.
- Familiarity with databases (e.g. MySQL, MongoDB), web servers (e.g. Apache) and UI/UX design.
- Excellent communication and teamwork skills.
- Great attention to details, organizational skills and an analytical mind.
- Highly motivated with a “can do” attitude.
- Degree in Computer Science or relevant field.

Your work will be rewarded with a competitive salary, a complete benefit package, the ability to participate to the start-up’s stock options plan, a good work/life balance and the sense of purpose with a direct positive impact on millions of lives.

If you are interested please send your CV to: Laurent.ADAM@MDsim.health or roger.assaker@mdsim.health

Computer Modeling & Simulation (FEA/AI) Engineer

Software as a Medical Device

Your mission is to be part of the team of PhDs, Engineers and Software Developers dedicated to the development of a Software as a Medical Device (SaMD) platform aimed at helping Surgeons & Designers of Medical Devices to design, certify and use innovative devices in optimally planned and executed surgeries.

You will focus on building a high-fidelity digital twin of the human body with the ambition to improve the quality of life of millions of patients around the globe by merging the latest and greatest of engineering technologies and medical sciences.

Responsibilities

- Develop a high-fidelity bio-mechanical model of the human body using finite element technology.
- Optimize the model for accuracy and performance.
- Verify & validate the model on a large number of patients.
- Work with the Software Development team to use the model within a SaMD.
- Participate to the clinical validation of the model and to quality and regulatory submissions.

Required Skilles

- Strong experience in nonlinear finite element analysis with the ability to use and develop a large variety of FE Solvers.
- Strong experience in biomechanics and in-silico medicine.
- Advanced knowledge of AI technologies.
- PhD or a MS in bio-mechanical engineering with a focus on modeling and simulation.
- Excellent verbal and written communication skills.
- Problem solver with a rigorous mind.
- Highly motivated with a “can do” attitude!.

Your work will be rewarded with a competitive salary, a complete benefit package, the ability to participate to the start-up’s stock options plan, a good work/life balance and the sense of purpose with a direct positive impact on millions of lives.

If you are interested please send your CV to: Laurent.ADAM@MDsim.health or roger.assaker@mdsim.health

2. Mediolanum Cardio Research (MCR)

Data Manager (DM)

MCR is looking for a Data Manager (DM) to be hired in our Data Management & Statistics team.

The candidate would be in change of the following tasks:

- Ensure management of clinical trials data through review of clinical data and data bases in compliance with standard operating procedures, client guidelines and applicable regulations/guidelines;
- Assist the senior DM in the development and implementation of strategy for data cleaning;
- Develop the data management plan for the assigned projects;
- Ensure clinical trial data quality and accuracy through review of case report forms for completeness and consistency;
- Perform centralized monitoring activities, supporting the Project Leader and CRAs;
- Perform data coding with MedDRA and WHOCC_ATC dictionaries
- Supporting the senior DM in the creation, updating, maintenance, and validation of e-CRFs and clinical databases, and in the development of related documentation.

Requisites:

- Previous experience in the role for at least two years
- Knowledge of GCP, applicable regulations, SAS system
- Good knowledge of English.

The position is full-time
If you are interested please send your CV to: jori@mcr-med.com

3. Quibim

Data Scientists

We are looking for **Data Scientists** to join our R&D Department.

As part of the Advanced Development and Clinical AI team or the Strategic Projects and Frontiers of AI team, you will be part of the innovation that will change the medical imaging market, transforming imaging data into actionable predictions.

Your main task will be:

- Design and develop medical imaging analysis algorithms.
- Research activities in the framework of internal and external projects.
- Participate in planning and executing activities focused on publishing Quibim's scientific research.
- Customer interaction to improve the product and to see the use of the developments at the customer's premises.
- Documentation and regulatory-related tasks.

You will be our ideal candidate if you have:

- Excellent development skills in Python.
- Computer vision knowledge.
- Experience working with AI Frameworks (Tensorflow and PyTorch).
- ML and DL knowledge.
- Advanced level of English
- Integrity and proactivity.

Other skills that would be nice to have are:

- HPC cluster knowledge.
- Cloud computing knowledge.
- Docker and CI/CD technologies.
- Medical imaging knowledge (Image preprocessing, MRI is a plus).

JOIN OUR TEAM!

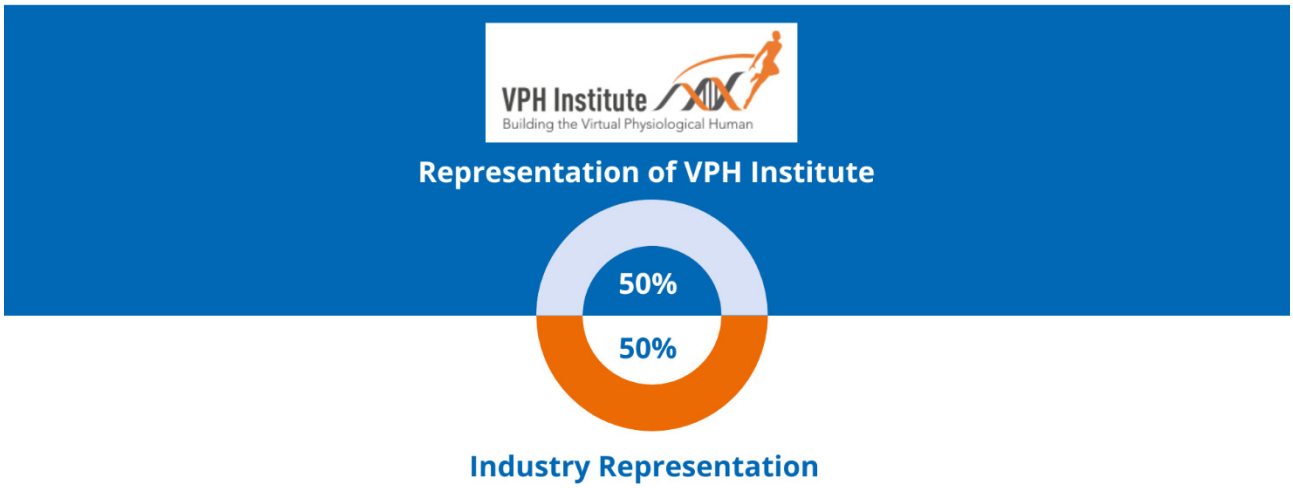
If you are interested please send your CV to: corinastefanescu@quibim.com

About Quibim

We design and create pioneering tools that unlock imaging data to maximize drug programs and improve patient outcomes. By following an AI-first approach to help detect pathologies and predict outcomes in oncology/immunotherapy, rheumatology and neurology. The company is specialized in tissue profiling at every body part and imaging modality, Quibim develops novel quantitative imaging biomarkers to deeply analyze disease mechanisms, advancing in drug discovery and monitoring treatment progress.

Quibim is proud in its commitment to creating a diverse workforce and providing equal employment opportunities to all employees and applicants for employment without regard to race, religion or belief, sex, sexual orientation, gender identity, gender expression, parental status, national origin, age, disability, marital status or any other characteristic. Quibim culture ensures a fair treatment and opportunity for all.

The Avicenna Alliance Membership



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Contact us

Join the Avicenna Alliance!