Avicenna Alliance

Association for Predictive Medicine

Making Medicine Modern

In silico medicine and the Avicenna Alliance

AVICENNA IN ONE YEAR

avicenna-alliance.com

Upcoming Activities
Key Dates

AVICENNA to form part of EU delegation to US Senate;

WEBINAR 1*
Avicenna Alliance/European Forum for Good Clinical Practice (EFGCP) on "Defining Appropriate of in silico medicine"

WEBINAR 2*
Avicenna Alliance/European Forum for Good Clinical Practice (EFGCP) on "

*participation only by invitation

Webinar 2

Webinar 1

3rd Meeting of International Working Group

2nd Meeting of Research Working Group

2nd Meeting of Policy Development Working Group

Signing of FDA-Avicenna Memorandum of Understanding

U.S. FOOD & DRUG ADMINISTRATION

Avicenna presentation at BMES conference

Avicenna workshop with EU Joint Research Centre (JRC)

JRC EUROPEAN COMMISSION

1st Meeting of International Working Group

1st Meeting of Research Working Group

1st Meeting of Policy Development Working Group

Avicenna 1st event in European Parliament

European Parliament

Advocacy on European Medicines Agency Regulation (Avicenna text suggestions accepted)

Advocacy on Medical Devices Regulation (Avicenna text suggestions accepted)

Avicenna Project concluded

Avicenna Alliance
Association for Predictive Medicine

EC calls on Avicenna Project Members to develop pre-competitive Alliance

Avicenna Alliance
Association for Predictive Medicine

Avicenna Project concluded

Avicenna Alliance
Association for Predictive Medicine

VPH Institute under FP7

VPH Institute
Building the Virtual Physiological Human

FDA singles out Avicenna Alliance to form part of EU delegation

U.S. FOOD & DRUG ADMINISTRATION

Adriano M. Henney, Ph.D.
Secretary General
Avicenna Alliance for Predictive Medicine

April 18, 2017

Dear Dr. Henney,

On behalf of the FDA's Modeling and Simulation working group, I would like to invite you to participate in a delegation from the European Union that will visit the U.S. Food and Drug Administration in Maryland on May 15, 2017 to discuss the advancement of *in silico* medicine. We greatly value the E.U.-U.S. cooperation that the Avicenna Alliance facilitated last fall together with MEPs Sean Kelly and Nicola Caputo to begin discussions on the regulatory needs regarding *in silico* medicine.

With the recently adopted Medical Devices Regulation and the ongoing EMA Regulation, both containing references to the use of modelling and simulation, we are eager to promote cross-regulatory dialogue on this topic. Continuous exchange of ideas, best practices and harmonization wherever possible should be a key goal at these new cross-roads of medicine.

As representatives of industries and academia in the field of *in silico* medicine, and an important international interlocutor, we would look to the Avicenna Alliance to represent the commercial and research sector in this rapidly emerging field and hope that you will be available to participate and help continue to drive this partnership.

We hope that this event will further regulatory and policy thinking in this field and look forward to your response.

Sincerely,

Tina Morrison

Tina Morrison, Ph.D.
Chair, FDA's Modeling and Simulation Working Group

Deputy Director, Division of Applied Mechanics
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

By the 15 May 2017, the Avicenna Alliance will have visited the FDA for high level talks on the future of regulation of in silico medicine. The full invitation letter can be found below. Avicenna Alliance welcomes this collaboration with the FDA and looks forward to the next steps towards effective regulation of the in silico market.

Avicenna Alliance to meet with Senior US Senator to discuss EU-US Cooperation on *in silico* medicine

On 17 May 2017, Members of the Avicenna Alliance, together with a select number of EU officials will meet with the Office of Senior Republic Senator for Mississippi Thad Cochran, to discuss closer EU-US cooperation in the field of in silico medicine.

Senator Cochran has been a leading figure in promoting the need to modernize existing policy frameworks to take into account the advent of in silico medicine and to ensure its potential for healthcare is realized.

A core goal of the Alliance International Working Group is to encourage cross-border Regulatory cooperation on in silico medicine. With a great deal of regulatory work in the pipeline at EU level on modelling and simulation and significant progress already made in the US, the time is now to ensure harmonization and exchange of best practices.

The meeting will focus on an exchange of information and lessons learned at EU and US level on taking the first steps in regulating in silico medicine and how best we can cooperate in the future.

Avicenna Alliance members will have the opportunity to put forward their views to high level regulators and policy makers and to provide input on the next steps.

Quibim joins Avicenna Alliance as Member

A participant at the Avicenna launch event in the European Parliament in October last year, Modelling and Simulation Company, Quibim has opted to join the Avicenna Alliance as a paid member.

Based in Valencia, QUIBIM applies advanced computational models to radiological images to objectively measure changes produced by a lesion or by a pharmacological treatment, offering additional quantitative information to the qualitative approach of radiology.

The company provides state of the art solutions for early diagnosis, lesion grading-phenotyping-staging, treatment selection/follow-up, in addition to the validation against clinical endpoints.

Promeditec joins Avicenna Alliance as Member

promeditec

Adding to the expanding list of Members, the Avicenna Alliance welcomes Promeditec into the Alliance.

Promeditec is a company that is developing the project InSilicoTrials.com. InSilicoTrials.com is a web-based platform that provides healthcare companies and researchers with an easy-to-use tool to perform computational testing on medical devices (in orthopaedics, and cardiovascular) during the development and validation process.

Key MEP to visit Nova Discovery Site

MEP Françoise Grossetête (EPP, France) is to visit the new site of Avicenna Member, NovaDiscovery in Lyon in May 2017.

Françoise Grossetête is arguably one of the most important leading figures in health in the European Parliament. As the lead MEP in charge of the Cross-Border Healthcare Directive, Orphan Medicinal Products Regulation, Clinical Trials Regulation and a driver of various cancer initiatives, her voice carries significant weight in Parliament.

Through Avicenna, the case was made to her office of an SME in her constituency, expanding to create new jobs in her area, in one of the most high text and revolutionary fields of healthcare today.

The visit by Mrs. Grossetête to the expanded NovaDiscovery facility, will mark a recognition of not just the influence of a company in her constituency at EU level, but a recognition of how even the most time-constrained and influential MEPs can see the potential of in silico medicine and the impact of Avicenna Members.

EMA reaches out to Avicenna

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Political advocacy normally revolves around the art of reaching out to politicians with the best messages. It is not often that the politicians arrive unprompted on your doorstep looking for your input. Such has been the case however with the European Medicines Agency (EMA) modelling and simulation working group.

Over the first opening months of 2017, Avicenna & VPH have been contacted by the Head of the EMA's modelling and simulation working party to discuss the possibility of collaboration in 2017.

With workshop webinar's already part of the Avicenna strategy to develop concrete recommendations for policy makers, the EMA would like to take this one step further.

Further links have also been created with our colleagues in DG Connect and now it seems a joint Avicenna/European Commission/EMA meeting or webinar is on the cards.

Avicenna presents to JRC in ISPRA

On 07 March 2017, representatives of Avicenna and VPH at the invitation of the European Commission's Joint Research Centre (JRC). The 2000 strong staff at ISPRA represent a wholly different level of policy making than Avicenna normally engages with.

From technical annexes, chemical classification, exposure and animal testing alternatives, the JRC is responsible for providing the Commission with the most up to date technical advice. Very importantly, they also develop the kinds of technical documentation & procedures adhered to by for example, pharmaceutical and medical devices companies when submitting applications for market authorisations.

Avicenna and the JRC broke major ground, agreeing on immediate next steps and the potential for in silico to expand significantly if given the right incentive or push from regulators.

That an optional means of submitting modelling and simulation data was essential was agreed and that the first step towards that would be to develop a common submission form. With a wealth of regulatory precedent to draw upon, experts at the JRC were convinced that this simple step would give industries the confidence they need to explore the potential of in silico as a means of better promoting the safety and efficacy of products.

The JRC is eager to maintain links with Avicenna and has agreed that they would like to receive an invitation to join as an Observer Member in the Alliance thus expanding the Avicenna Regulatory Membership further.

1st VPH-Avicenna Work Placement given green light

Building on the Avicenna Alliance launch event in October 2016 with MEP Sean Kelly where the suggestion was made to include Ireland in the VPH-Avicenna work placement programme, steps are now underway to put this into practice.

Avicenna Member Medtronic has been making contact with its national offices and plans are being created to take 2-3 students at the Medtronic Galway facility in Ireland.

MEP Mairead McGuinness, EPP lead for the Medical Devices Regulation and Vice-President of the European Parliament, is on board with the notion of a site visit and seeking press coverage to mark the student's first day at work.

The Secretariat will be following the theme of EU policy makers bringing Europe home, creating jobs on the ground by engaging with a European organization, Avicenna.

Plans are also in development to extend these to VPH members in Belgium with Avicenna Member Ansys also set to put the programme in place and engage with Belgian policy makers.

Moderating EU eHealth Week in Malta

Over the last few years eHealth week has become more and more of a key event for healthcare industries with key officials from the Council and Commission present to put forward the latest in policies and to hear the latest technological developments at the 3 day conference.

In 2017, the Avicenna Alliance made its first appearance to eHealth week at the invitation of the Commission to act as moderator of the session "In Silico Trials: Fostering Safety and Effectiveness by Digitising Trials" on 12 May.

Avicenna Alliance Secretary General Adriano Henney led the discussion on how best we can realise the full potential of in silico medicine for research and proof of product efficacy while ensuring robust safety standards.

The take away from this meeting is that after 1 year of the Alliance up and running, in silico medicine makes its first appearance as a topic on the eHealth Week Agenda. This demonstrates the rising industry and political importance of this issue and the perceived potential by health stakeholders.

In Silico – turning Big Data into Personalized Medicine, European Parliament

On 11 October 2016, MEPs Nicola Caputo (S&D, Italy) and Seán Kelly (EPP, Ireland) hosted the launch event of the Avicenna Alliance in the European Parliament in Brussels entitled "In silico – turning big data in to personalized medicine".

The event saw full attendance with no seat unfilled and representation from key groups such as HOPE, CPME, EFN, CAAT and others. Featuring presentations from major industry and research players and a keynote presentation by Dr. Tina Morrison from the US Food and Drug Administration, the event focused on examples of how computer modelling and simulation can help us overcome the major health challenges we face today.

Our biggest challenge today is the same as it has been for quite some time – complexity. We simply have not been able to deliver on fully personalized medicine because there are too many factors, too many variables and no tools to make sense of them. This is why in silico medicine is representative of the new era of healthcare. By using computer modelling and simulation tools we can begin to understand these variables, these complexities – we can turn big data into personalized medicine.

Achieving this presents a host of regulatory challenges. Dr. Tina Morrison from the FDA outlined how US regulatory authorities are looking at key issues such as how to validate the effectiveness and usefulness of models that are submitted as evidence of the benefits of products.

In the EU, we need to do the same. Our current legal and policy frameworks are already groaning under the weight of new technologies that are constantly calling into question the suitability of our current frameworks. At this event we have taken the first steps to doing so. Our next step in the Avicenna Alliance in 2017 is to bring all the actors together to get to work on developing these policy solutions and to continue our dialogue with the Commission, FDA and Parliament to see how we can put harmonized policies in place to enable the uptake of in silico.

Avicenna presents at Materialise World Summit

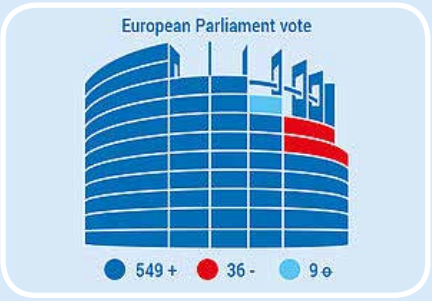
On the 20 and 21 April 2017 the Avicenna Alliance presented at the Materialise World Summit a two-day event which brings together stakeholders from various businesses and industries to discuss the progress of technology in the area of healthcare, industrial and technological businesses.

Since the goal of the Materialise Summit is to address the challenges and opportunities that open up in this new digital era for different industries, this conference will also be an ideal platform for the Alliance's Secretary General to present the Avicenna Alliance and its plans to bring these communities together to address these major challenges.

Further details about the Materialise World Summit can be found here.

www.worldsummit.materialise.com

EMA Regulation Vote Result – Major Gains for *In silico*



On 10 March 2016 the European Parliament through an overwhelming majority, voted in favour of requiring the EMA to take into account alternative models in clinical trials.

The Avicenna Alliance has been working with supportive Members of the European Parliament to modernize elements of the 2004 EMA Regulation to enable the in silico market and provide certainty for investors and researchers in the in silico community.

The following text was adopted by the European Parliament:

4b. ''The Agency shall develop a framework for the regulatory acceptance of alternative models and shall take into consideration the opportunities presented by these new concepts which aim at providing for more predictive medicines. These concepts may be based on human relevant computer or cellular models, pathways of toxicity, or adverse outcome pathways.''

Nearly all amendments to this Regulation were voted through in one single bloc. Only two were deemed in need of separate votes – this was one of them.

It will take the pharmaceutical industry some time to come to terms with what has just happened. This was meant to be a non-controversial dossier, a simple matter of separating how we regulate veterinary medicines from human medicines. The Avicenna Alliance had other plans however and over the next few months the pharmaceutical industry will start to see just how big a change this amendment could bring and alter how they look at clinical trials.

Under this European Parliament backed-text, the EMA will now need to build a policy framework for alternatives such as modelling and simulation. The Avicenna Alliance will be there to inform how this framework can be built to drastically reduce costs to industry and make clinical trials far more predictive.

VPH Institute joins European Commission eHealth Stakeholder Group

The European Commission has appointed the Virtual Physiological Human Institute (VPHi) to its eHealth Stakeholder Group. With VPHi representing 50% of the membership of Avicenna, this provides the Alliance access to a key influential group in Brussels.

The eHealth Stakeholder Group was set up in 2012 to "platform for stakeholders to contribute to the development of legislation or policy related to eHealth; for example by providing reports, opinions and relevant data."

Membership of this group is recognition of the growing influence of VPH in EU policy and of the work that has been done so far. The European Parliament Resolution on the eHealth Action Plan in 2014 specifically called on the European Commission and EU Member States to support the work of VPHi and recognized it as a successful eHealth initiative. Since then VPHi has successfully advocated for the inclusion of in silico medicine in Horizon 2020 and has made major gains for modelling and simulation in medical devices and medicinal product legislation.

In this new group, VPHi will work on the next steps towards a policy framework for in silico medicine, continued support for researchers employing modelling and simulation in their work and ensure the modernisation of medicine through in silico.

Medical Devices Regulation – adopted version takes into account modelling and simulation.

On 05 April 2017, the Medical Devices and In-Vitro Diagnostic Medical Devices were adopted, setting out the rules by which medical devices are put on the EU market. In the midst of the shouting over the powers of notified bodies, changes from Class IIb to Class III and a balance between regulation and innovation, a small change was suggested to an Annex which found its way into the final text.

From the time of entry into force, Notified bodies must now take into account "the pre-clinical testing, for example laboratory testing, simulated use testing, computer modelling, the use of animal models". The same also applies to manufacture design.

The impact of this change will not be felt by the industry at large for some time but the policy change is momentous and should not be underestimated. That notified bodies will need to take into account what modelling and simulation has been done has the potential to significantly impact on companies that have invested in in silico approaches, augmenting their marketing authorization application.

Avicenna will be working to guide this process to ensure new policies in this field take into account the needs of Avicenna Members.

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As the Secretariat of the Avicenna Alliance, Rohde Public Policy brings expert policy guidance to this revolutionary new field.

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