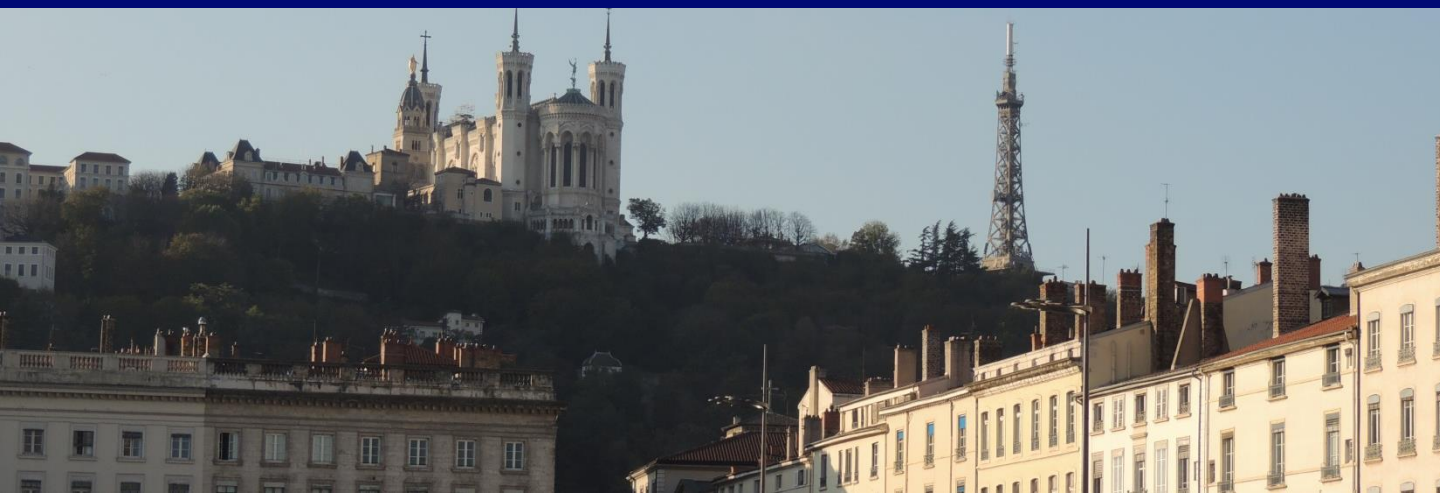
AVICENNA
A Strategy for *in silico* Clinical Trials

Avicenna Newsletter
November 2014



Third Avicenna Project Meeting in Sunny Lyon

The Avicenna Project met for their third event on 31st October 2014 in Lyon, France. The group of 50 expert stakeholders, from industry, regulatory affairs and patient representatives, came together to discuss the research challenges of modelling and simulation technologies, in the development of pharmaceutical products and medical devices.

The one day event, the third in a series of five, is aimed at designing a pathway towards the successful modernisation of the clinical trials process. The goal is to make clinical trials leaner, quicker, more efficient and less expensive.

The day began with presentations from six experts on the research challenges related to *in silico* clinical trials in pharma and devices. Professor Amin Rostami, from Manchester University, presented on the challenges of forming and maintaining consortia. Professor Marco Viceconti, from Sheffield University, presented on *in silico* methods, specifically related to hip replacements. Alfonso Bueno-Orovio, from the University of Oxford, addressed the subject of systems approaches to pharmacology and toxicology. Following a coffee break, Horst Hahn, from the Karlsruhe Institute of Technology, presented on the simulation and modelling of liver perfusion. David Mitton, from the University of Lyon, discussed the research challenges of developing meshes for hernia repair. Finally, Professor Gabriele Dubini, from the Politecnico di Milano, addressed the topic of modelling vascular devices and fatigue behaviour of peripheral stents.

Following lunch, there were a series of brainstorming sessions, in which the attendees were asked to identify the research priorities related to their specific areas of expertise. Their conclusions will be used to form recommendations to the EC and other research funding agencies with the goal of increasing the capability and usefulness of computer modelling and simulation in the development and assessment of biomedical products. The aim is to define a research agenda that is driven by the needs of producers, regulators, medical professionals and patients.

At the close of the event, delegates were asked to sign up to help edit and/or author the Avicenna Roadmap. This policy document will form the basis for a strategy for *in silico* clinical trials. It will be published at the project's conclusion in September 2015.

The Event was partially funded by non-binding research grants from Ansys Inc. and Covidien plc

The University Of Sheffield. | VPH Institute Building the Virtual Physiological Human | OBSIDIAN BIOMEDICAL CONSULTING LTD. | LYNKEUS | INSIGNEO Institute for *in silico* Medicine

In silico Clinical Trials - Explained!

Easy to understand video demystifies the clinical trials process

Want to know more about *in silico* clinical trials? Struggling to explain the concept to non-experts in the field? The Swiss-based healthcare company Roche have produced a three minute animated video which explains, in a clear and easy to understand way, the benefits of clinical trial simulation.

Eschewing jargon for plain English and using simple, cartoon graphics, the video explains how clinical trial simulation can be used to address the difficulty of correctly predicting the success or failure of clinical trials.

It outlines how *in silico* clinical trials can be used as a risk management tool to explore how different trial designs will perform, to detect the drug effects they hope to see.

It also explains that simulated trials can be used to assess the impact of differences in dosing regime, patient profile, sample size, trial duration and choice of comparators.

The video is one in a series of three, which explain the benefits of using pharmacokinetic and pharmacodynamic modelling, and the benefits of using modelling and simulation in drug development, respectively.

The video can be viewed here:

www.youtube.com/watch?v=dW4fek6plP4&list=UUH_ZBgtt6-8-VA52pao0SSA