



Avicenna Alliance
Association for Predictive Medicine

Minister Karen Andrews MP
Suite M1.48
Parliament House
Canberra ACT 2600
Australia

31 October 2019

Dear Minister Andrews,

On behalf of the Avicenna Alliance, I am writing to put forward a request not often heard from industries – “regulate our sector” – meaningful and modern regulation is needed.

The Avicenna Alliance represents industries and researchers that have a commercial or research interest in the uptake of computer modelling and simulation (CM&S) in healthcare. Modern CM&S has the capacity to make sense of previously unapproachable complexity can raise the bar for safety in paediatric trials, can widen our knowledge of rare diseases and in general ensure only the safest and most effective treatments are funded.

Today a lack of regulation of our sector holds back the uptake of CM&S solutions. While some progress has been made, there are a host of questions in need of collective answers - How should computer models be validated? Who will be reviewing and assessing the simulation results following which approval process? What standard requirements should industries meet when submitting CM&S data to support a market authorization or when seeking reimbursement?

In previous decades guidance has been provided for Good Manufacturing Practices and Good Distribution Practices. Today, we are in need of “Good Simulation Practices”.

Too often in the regulation of medical devices we develop our own rules across different regulatory systems and expend a great deal of effort seeking common ground afterwards - overcoming regulatory barriers of our own creation. With CM&S, we are at the beginning and have the opportunity to be aligned from the beginning.

This warrants the specific attention of the International Medical Devices Regulators Forum (IMDRF).

Will you lend your support to raising this issue at international level so that Good Simulation Practices can help enable the healthcare sector, save taxpayer money and improve patient safety?

Thank you for your time and we look forward to hearing from you.

Kind regards,

Thierry Marchal

Secretary General
Avicenna Alliance