Commissioner Stella Kyriakides

Date: 09 June 2021

Directorate-General for Health and Food Safety
European Commission
1049 Bruxelles/Brussel
Belgium

Dear Commissioner Kyriakides,

We are writing to ask you to place computer modelling and simulation (CM&S) in healthcare as part of your policy agenda from 2021 onwards.

The advent of CM&S forever altered engineering, aircraft design, automotive science, finance, weather prediction and a range of other sectors redefining the world in which we live. These same advances in science now stand to redefine what we consider to be modern medicine.

The computational 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 ensure only the safest and most effective treatments are funded.

This scientific sophistication however is not mirrored by the policy frameworks which govern their application as illustrated by 2 examples:

1. Today we have the technical capacity to drastically increase the safety standards in paediatrics through the use of CM&S. We are poised to transition from “exploratory trials” in humans to “confirmatory trials” where we seek to confirm what has been predicted in virtual studies. The Paediatrics Regulation provides no means of realising this scientifically possible and ethically essential leap in safety standards.

2. That there are so few patients suffering from rare disease is at once a blessing and a curse as we lack the numbers necessary to conduct comprehensive trials and ensure effective treatments. CM&S has the capacity to enable trials to be conducted virtually, drastically expanding our ability to understand these rare conditions. Despite the myriad of incentives for industries to develop orphan drugs, no incentives for the use of CM&S solutions are provided for in the Orphan Medicinal Products Regulation.

Many of these barriers are shared by different regulatory agencies across the world but so too are the potential benefits to healthcare if we take policy action. Certainty in the form of clear guidelines and rules must be developed for industries and researchers in the field of modelling and simulation so that patients can benefit from these new approaches. Common “Good Simulation Practice” guidelines must be created now and together, so that in future years we are not burdened with overcoming differing regulatory barriers of our own creation.

The policy barriers holding back CM&S in healthcare are multifaceted and so too must be the solutions.

As such, we call on the Commission to:

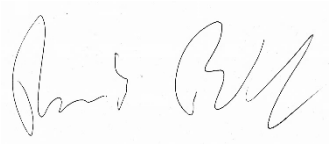
1. Launch an open consultation on the use of CM&S in healthcare;
2. Include the use of CM&S in any revision of the Paediatrics Regulation to ensure the highest safety standards for children.
3. Encourage the use of "*in silico* trials" in any revision of the Orphan Medicinal Products Regulation to improve our understanding of rare diseases;
4. Work with the US FDA and other regulatory agencies to develop "Good Simulation Practices" internationally to avoid the creation of unnecessarily differing standards that restrict the growth of this field.

Will you and your team work with us to ensure that innovation in healthcare is never held back by a lack of innovation in policy and provide the means to ensure only the safest and most effective treatments are developed for EU citizens?

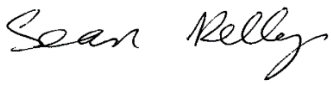
We look forward to your response and would very much welcome the opportunity to meet with you and your teams to discuss these priorities.

Yours sincerely,

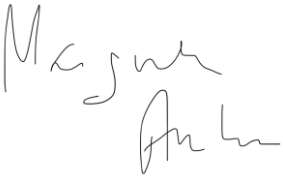
Frédérique Ries
(Renew Europe, Belgium)



Brando Benifei
(S&D, Italy)



Sean Kelly
(EPP, Ireland)



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