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e-Seminar Series

e-Seminar #31
Assessing the Credibility of Computational Models: Application of the FDA-Endorsed ASME VV-40

26 July 2023 2pm CEST / 1pm BST (1h duration)

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Computational models in the medical field are more and more stepping out the door of the laboratories they were developed in to find practical applications in the clinical or regulatory practice, for instance. In fact, terms such as digital twin in healthcare or in silico trials sound now very familiar to the scientific community. Still, a lot is about trust, and before a model is adopted by a clinician, a manufacturer, a regulator, its credibility must be demonstrated. In 2018 ASME issued the V&V-40 technical standard, which provides a Context of Use and Risk-oriented framework to establish the credibility of computational models. We will give an overview of this framework highlighting its key steps and provide our experience about its application.

This is the 31st in a series of online e-Seminars organised by CompBioMed.
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Alessandra Aldieri is currently assistant Professor with time contract at Politecnico di Torino, Italy. She got the PhD in Bioengineering and medical-surgical sciences from Politecnico di Torino in 2020. Later, she worked as a post-doctoral fellow at University of Bologna. She mainly works in the field of computational biomechanics and particularly on bone mechanical behaviour investigation through computational models. She has recently worked on the credibility assessment of an in silico methodology to predict proximal femur fracture, which was the object of a qualification advice request to the European Medicine Agency (EMA) for its use in clinical trials on treatments against osteoporosis.

Cristina Curreli is a research fellow at University of Bologna and at the Rizzoli Orthopedic Institute (Italy). She received a PhD in Biomechanics at the University of Pisa (Italy). Her research activities mainly focus on the development and validation of patient-specific models to support clinical decisions (Digital Twins in Healthcare) and of computer modelling & simulations that can be used to complement real world clinical trials and generate additional information to assess the safety and/or the effectiveness of new medical product (In Silico Trials). She is currently working on the definition of specific techniques to assess the credibility of computational models and on the regulatory activities needed for the qualification of these novel digital methodologies to be used in clinical practice.

Moderated by Tim Weaving, **UCL**

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