

IEEE BHI - BSN 2021

July 27th, 2021 – Online 15:40 – 18:15 CEST

WORKSHOP ON ASSESSING CREDIBILITY OF IN SILICO TRIALS FOR REGULATORY PURPOSES

Workshop description

The use of modelling and simulation to evaluate the safety and efficacy of new medical products, usually referred to as *In Silico* Trials, is moving from the research labs to a concrete industrial reality. Probably the biggest barrier in this translation from research to innovation is the lack of a specific regulatory science to evaluate the credibility of this predictive model when used to assess medical products such as drugs or medical devices. This workshop provides an update on the latest developments in the field, by some of the leading experts.

Organisers:

Marco Viceconti, University of Bologna



Liesbet Geris, University of Liege



Program

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| 15:40 – 16:05 | Credibility of In Silico Trials for orthopaedic devices following ASME VV-40 – Jeff Bischoff, Zimmer Biomet |
| 16:05 – 16:30 | Verification, validation, uncertainty quantification and applicability: a theoretical framing – Marco Viceconti, University of Bologna |
| 16:30 – 16:55 | Verification of mechanistic Agent-Based Models – Francesco Pappalardo, University of Catania |
| 16:55 – 17:00 | Break |
| 17:00 – 17:25 | Credibility of In Silico Trials for assessing tissue engineering constructs – Liesbet Geris, University of Liege |
| 17:25 – 17:50 | A taxonomy of possible contexts of use for In Silico Trials – Luca Emili, In Silico Trials Technologies |
| 17:50 – 18:15 | Credibility of In Silico Trials: a regulatory perspective - Pras Pathmanathan, FDA |