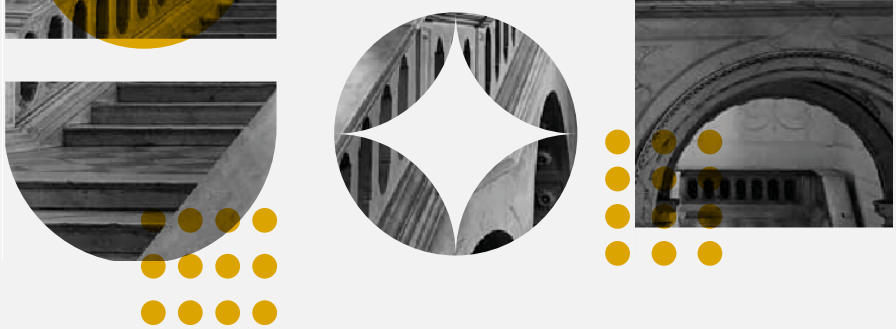

INSILICO WORLD

14TH MARCH 2024 | h 14:00–18:40

# WORKSHOP: THE REGULATORY BARRIERS TO IN SILICO TRIALS

h 14:00–15:50

## PRESENT

**14:00**

**Opening remarks**

Francesco Pappalardo (Host and WP4 leader -In Silico World consortium)

**14:10**

**Review of current regulatory pathways in Europe and the USA to certify DTHs and MDDT/DDT**

Cristina Curreli (In Silico World consortium)

**14:30**

**Principles and regulatory application of credibility assessment with ASME V&V 40-2018**

Jeff Bischoff (Zimmer-Biomet; chair of the ASME V&V40 committee)

**14:50**

**Bringing ASME VV-40 to the international level: the new IEC/ISO work group**

Regina Geierhofer (Siemens Healthineers; Secretary of the IEC TC62)

**15:10**

**Toward Good Simulation Practice: from position report to future technical standards**

Vincenzo Carbone and Klaus Zeier (In Silico World consortium)

**15:30**

**EMA Qualification advice on BoneStrength and on UISS-TB**

Alessandra Aldieri and Giulia Russo (In Silico World consortium)

**15:50**

**Coffee break**

h 16:00–18:40

## FUTURE

**16.10**

**Credibility of Computational Models Program: new guidance from FDA-CDRH**

Prasanna Pathmanathan(FDA-CDRH)

**16.40**

**Devices vs. Drugs: statistical inference approaches at the root of an epistemological divide.**

Marco Viceconti (In Silico World consortium)

**Presentation and open discussion on the In Silico World Report on regulatory barriers to in silico methodologies.**

**17.40**

**Presentation and roundtable - Assessing the credibility of data-driven and hybrid models. Is a general credibility framework possible?**

Marco Viceconti, Saverio Ranciani, Jeff Bischoff, Regina Geierhofer, Prasanna Pathmanathan

**18:40**

**end of workshop**

Monastero dei Benedettini, Catania (Italy) info@insilico.world

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