


# Workshop



## In Silico Clinical Trials Concepts and Adoption (drugs, devices, the industry and Regulatory)

March 5th, 14:00 – 20:00 CET

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**Webex Meeting link** <https://medlab.webex.com/medlab/j.php?MTID=m5010d60ae86fe2177fc80d12758be801>

### Agenda March 5<sup>th</sup>, 2021, 14:00 – 20:00 CET

14.00-14.10	<b>Introduction</b>	<b>Dimitrios Fotiadis</b> InSilc project Coordinator Professor of Biomedical Engineering, University of Ioannina / FORTH Head of the Unit of Medical Technology and Intelligent Information Systems Editor in Chief IEEE Journal of Biomedical and Health Informatics	<b>Rapporteur</b> Lorenza Petrini Associate Professor at the Department of Civil and Environmental Engineering, Laboratory of Biological Structure Mechanics (LaBS) at Politecnico di Milano
<b>Session 1: In silico clinical trials projects</b>		<b>Chair</b> <b>Georgia Karanasiou</b> Senior Researcher InSilc Coordination team	
<b>14.10-14.15 Introduction of Speakers</b>			
14.15-14.30	<b>Presentation 1:</b> InSilc- an In Silico platform for drug-eluting BVS design,	<b>Georgia Karanasiou</b> Senior Researcher InSilc Coordination team	

	development and evaluation	
14.30-14.45	<b>Presentation 2:</b> INSIST:- In Silico Clinical Trials for treatment of acute Ischemic Stroke	<b>Alfons Hoekstra</b> Full Professor Computational Science and Engineering, University of Amsterdam
14.45-15.00	<b>Presentation 3:</b> In Silico Trials within StriTuVad project	<b>Francesco Pappalardo</b> Associate Professor at the University of Catania
15.00-15.15	<b>Presentation 4:</b> SILICOFCM: In Silico Trials for drug tracing the effects of sarcomeric protein mutations leading to familial cardiomyopathy	<b>Nenad Filipović</b> SILICOFCM project Coordinator Professor and the Head of Centre for Bioengineering at the Faculty of Engineering, University of Kragujevac
15.15-15.30	<b>Presentation 5:</b> Adoption of In Silico Trials: barriers and future perspectives	<b>Marco Viceconti</b> Professor of Computational Biomechanics, Department of Industrial Engineering Alma Mater Studiorum – University of Bologna Director of the Medical Technology Lab of the Rizzoli Orthopaedic Institute
15.30-16.00	<b>Panel Discussion</b>	
<b>Session 2: Standardization and Regulatory framework</b>		<b>Chair</b>
		<b>Cristina Jori</b> Medical Director Mediolanum Cardio Research S.r.l.
<b>16.00-16.05 Introduction of Speakers</b>		
<b>In silico medicine</b>		
16.05-16.20	<b>Presentation 1:</b> The evolution/ revolution of In Silico medicine	<b>Elazer Edelman</b> Director, Institute for Medical Engineering and Science, MIT Edward J. Poitras Professor in Medical Engineering and Science, Massachusetts Institute of Technology Professor of Medicine, Harvard Medical School Senior Attending Physician, Brigham and Women's Hospital
<b>In silico companies perspective</b>		
16.20-16.35	<b>Presentation 1:</b> InSilicoTrials - the crowdsourcing platform for modeling and simulation in Life sciences	<b>Luca Emili</b> CEO at InSilicoTrials
16.35-16.50	<b>Presentation 2:</b> In Silico Clinical Trials to support drug	<b>François-Henri Boissel</b> CEO at Novadiscovery

	development: why, how and what	
<b>Clinical/Research perspective</b>		
<b>16.50-17.05</b>	<b>Presentation 1:</b> Towards the adoption of In Silico medicine: the researcher point of view	<b>Liesbet Geris</b> Executive Director, VPH Institute University of Liège & KU Leuven Chair Research & Technology WG, Avicenna Alliance
<b>17.05-17.20</b>	<b>Presentation 2:</b> Towards the adoption of In Silico medicine: the clinical researcher point of view	<b>Robert Byrne</b> Director of Cardiology at the Mater Private Hospital, Dublin Chair of Cardiovascular Research at the Royal College of Surgeons
<b>17.20-17.30</b>	<b>Coffee break</b>	
<b>Industrial perspective</b>		
<b>17.30-17.45</b>	<b>Presentation 1:</b> Benefits and challenges for using CM&S for medical device development and clinical trials	<b>David Flynn</b> Research Fellow Global Technology Services CM&S Center of Excellence Boston Scientific
<b>17.45-18.00</b>	<b>Presentation 2:</b> Adoption of In Silico medicine: use and barriers of M&S in a Medical Technology Company	<b>Markus Reiterer</b> Dist. Scientist of Medtronic
<b>18.00-18.15</b>	<b>Presentation 3:</b> Adoption of In Silico Design Verification/Validation Testing in the Medical Device Industry	<b>Dejan Krsmanovic</b> Founder & President of CardioMed Technology
<b>Regulatory perspective</b>		
<b>18.15-18.30</b>	<b>Presentation 1:</b> Towards the adoption of In Silico medicine: challenges and opportunities for regulatory assessment	<b>Flora Musuamba</b> Vice Chair person at EMA MSWP Member of the EMA SAWP Expert in Pharmacometrics and Pharmacovigilance at the FAMHP Professor of Clinical Pharmacology at Universities of Lubumbashi and Namur
<b>18.30-18.45</b>	<b>Presentation 2:</b> Using Modeling and Simulation to Advance Regulatory Science in Medical Device Development and Research	<b>Ali Kiapour</b> Director of Biomechanics Research at the Department of Neurosurgery, Massachusetts General Hospital, Harvard Medical School Member of ASME V&V40 committee on computational modeling of medical devices
<b>18.45-19.00</b>	<b>Presentation 3:</b> Standards on In Silico methods for medical	<b>Klaus Zeier</b> Team Manager Health at DIN German Institute for Standardization

	devices - The devil really is in the details	Project Manager in the field of International European and German Standardization of Medical Devices
<b>19.00-19.15</b>	<b>Presentation 4:</b> Widespread In Silico medicine: pure fantasy or reality just around the corner?	<b>Thierry Marchal</b> Secretary General, Avicenna Alliance Program Director for Healthcare Solutions, ANSYS Member of eHealth stakeholder group to EU Commission
<b>19.15-19.45</b>	<b>Panel Discussion</b>	
<b>19.45-20.00</b>	<b>Conclusions</b>	