Bilkent EEE Distinguished Seminar Series

Bilkent University - Department of Electrical and Electronics Engineering

On Trials and Tribulations: In Silico Regulatory Science for the Digital Era

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Novel medical technologies are being introduced at unprecedented rates, demanding scientific evidence of their safety and efficacy at pace to ensure patient safety and benefit. With success in both in-vitro/in-vivo studies, products are tested on clinical trials assessing use in humans. Predicting low-frequency side effects has been difficult because such side effects may not become apparent until many patients adopt the treatment. When medical devices fail at later stages, financial losses can be catastrophic. Testing on many people is costly, lengthy, and sometimes implausible (e.g., paediatric patients, rare diseases, and underrepresented or hard-to-reach ethnic groups).

Computational Medicine underpins In-silico trials (IST), i.e., computer-based trials of medical products performed on populations of digital twins (aka virtual patients). Computer models/simulations are used to conceive, develop, and assess devices with the intended clinical outcome explicitly optimised from the outset (a-priori) instead of tested on humans (a-posteriori). This will include testing for potential risks to patients (side effects) and exhaustively exploring medical device failure modes before being tested in human clinical trials. In-silico evidence is still consolidating but is poised to transform how health and life sciences R&D and regulations are conducted. UK can take a leadership position in in-silico trials, which would cement its position as a global leader in health and life sciences, help drive the UK economy and provide UK citizens with early access to innovative health products.

In this talk, I will introduce the attendees to this world of new possibilities and summarise progress made in this new paradigm among academia, industry, regulators, and policymakers. A recent landscape report would be a helpful companion to this talk: *Frangi, AF et al. Unlocking the Power of Computational Modelling and Simulation Across the Product Lifecycle in Life Sciences: A UK Landscape Report. InSilicoUK Pro-Innovation Regulations Network, 2023, doi:10.5281/zenodo.8325274.*

Bio: **Professor Alejandro F Frangi** FREng FIEEE FSPIE FMICCAI is the Bicentennial Turing Chair in Computational Medicine at the University of Manchester, Manchester, UK, with joint appointments at the Computer Science and Health Sciences Schools. He is the Director of the Christabel Pankhurst Institute on health technologies research and innovation. He is also the Royal Academy of Engineering Chair in Emerging Technologies, with a focus on Precision Computational Medicine for in silico trials of medical devices. He is an Alan Turing Institute Fellow. His research vision was recently awarded an ERC Advanced Grant from the European Research Council under the Computer Science and Informatics (PE6) panel. He also leads the InSilicoUK Pro-Innovation Regulations Network. Professor Frangi's primary research interests lie at the crossroads of medical image analysis and modelling, emphasising machine learning (phenomenological models) and computational physiology (mechanistic models). He is particularly interested in statistical methods applied to population imaging and in silico clinical trials. His highly interdisciplinary work has been translated into cardiovascular, musculoskeletal and neurosciences.