Mark Palmer, Position Statement for International Affairs Lead

Background

From my early childhood watching the television program "The 6 Million Dollar Man" and throughout my training and professional career, my imagination has been captured by the idea of the interface between engineering and medicine restoring health and extending life. This passion led me to pursue a combined engineering and pre-medical program at Princeton University followed by the combined MD/PhD program at the University of Michigan. My research in large deformation computational mechanics applied to the human body resulted in my development of a standalone, strongly coupled, multiscale, finite element solver. This code was pivotal in the visualization and evaluation of the mechanics of training induced injury from large deformations in skeletal muscle spanning the protein level to the organ level.

At the end of my clinical training, I made the difficult decision that I was more of an engineering scientist than a clinician. This led me down the path of launching a startup company based on the code from my thesis work while serving on the board of the Western Michigan Science and Technology Initiative, a regional incubator for the state of Michigan. I then transitioned to academia as a tenure track faculty member at the University of Michigan with dual appointments in Kinesiology and Biomedical Engineering. There, I established my own computational modeling laboratory collaborating with the Chair of Orthopedic Surgery while developing classes on the finite element method, musculoskeletal imaging, and image-based modeling.

I was recruited to Medtronic in 2014 by the Corporate Strategic Scientific Operations organization where I lead a team that collaborates across the Medtronic Enterprise on new applications of modeling and simulation with a special emphasis on device-tissue interactions. My team also collaborates with academia and simulation suppliers to de-risk new modeling capabilities for application in our applied engineering processes. In recognition of my contributions to Medtronic, I have been promoted 3 times over the last 6 years now holding the position of Director of Research and inducted to the Medtronic Technical Fellows. My experience in modeling and reputation in the industry has led to more than 40 peer reviewed publications and refereed conference papers, over 30 keynote or invited lectures, and over 30 internal symposia presentations.

Computer Modeling Applied to Medical Devices

In 2015, I was selected as the chair for the Enterprise Modeling and Simulation Working Group at Medtronic to develop a strategy for a holistic infrastructure, accelerate the application of CM&S towards safe & effective therapies, and to drive business value creation. Through this work, I am connected across the 20 Operational Units at Medtronic as well as a diversity of Functions and geographies. The positioning of my team within the Enterprise as well as my leadership of the Working Group provide connections to the more than 70 chronic medical conditions we treat, the diversity of products in our portfolio, and participation in our R&D Council, Clinical Evidence Council, and Global Policy and Advocacy Council where I can draw on their experience and expertise in support of strategies for advancing *in silico* methods. I also regularly report to the Medtronic Board of Directors and Executive Committees on the strategy and achievements of the modeling community across the Enterprise.

Work for the *in silico* Community and the Avicenna Alliance

Since the development of the Avicenna Roadmap through 2021, I have supported the activities of the Alliance through Markus Reiterer who served as the Medtronic representative and as a member of the Avicenna Board. In 2021, Markus stepped down from the Alliance and I have endeavored to fill his role and continue his vision as well as the vision of the Alliance particularly for global harmonization. While I have filled this role, the International Working Group has launched the UK Task Force and is working to launch the APAC Task Force. We have also continued our work through the Global Harmonization Task Force and RPP to coordinate meetings with Regulators from 5 geographies with more in the planning stages. The Working Group has also been refining our strategy for engagement with the IMDRF as we continue towards the goal of an IMDRF Work Item for CM&S. We were also able to partner with ASME towards further awareness and adoption of the V&V40 standard. Outside of the Alliance, I serve as co-editor for Frontiers in Physiology Journal, Industry Advisor for the FDA ENRICHMENT in Silico Clinical Trials Project, Advisory Board for ASME, ASME Biomedical Technical Advisory Panel, Standards Committee for ASME VV40 (CM&S) and VV70 (AI/ML), NAFEMS Business Impact Working Group, NAFEMS Americas Steering Committee, the Advisory Board for CompBioMed, and the M&S Steering Committee for MDIC.

Plan for advancing the goals of the Avicenna Alliance

To advance the international goals of the Avicenna Alliance, I will work with the members of the Alliance on the following areas:

- Establish and support the new leadership team for APAC Task Force: leverage the CM&S network in the region to solidify the leadership team for the Task Force with particular emphasis on connections to academia to provide technical support to the regulatory community. I will also work with the leadership team to facilitate the development and execution of a strategy for the APAC region with an initial focus to Japan, China and Korea while other countries might be approached in a more opportunistic way.
- Strengthen the collaboration among in silico stakeholders: Extramural participation in advisory boards and standards committees for in silico methods has brought me in contact with thought leaders, leaders from across industries, and initiatives for advancing computational methods across industries. I have and will continue to bring the lessons learned, experiences, and insights from these interactions back to the Alliance and the Medical Device community to inform and accelerate our efforts.
- Focus on Global Harmonization: Through the International Working Group, the constituent task forces, and RPP, I will continue our initiative to establish connections with Regulatory authorities that are members of the IMDRF Committee with the goal of advocacy for a work item for CM&S and in silico methods. We will also pursue IMDRF Observer Organization status for the Alliance for calendar year 2023. I will collaborate with the Medtronic Global Advocacy Council to prioritize CM&S as an area for global harmonization with WHO and trade organizations that also influence IMDRF priorities.
- I will work actively with other Working Group Leaders and Task Force Leaders to ensure a close collaboration with the International Working Group activities. Close collaboration with the Notified Bodies TF in its engagement with Standard Organizations, the

Pharma Strategy TF to ensure a global focus on in silico pharma, the PPI TF to facilitate attention to Patients around the world and of course to expand the visibility of the GSP TF outputs will be key collaborations with the Policy Development working group. On the other hand, the dissemination of the progress of the Tissue Characterization and the AI Task forces outside Europe will be essential as well as identifying possible avenues for non EU funding will drive our close collaboration with the Research and Technology Working Group.

- I will bring my experience acquired in a large medtech company to provide advice and guidance to the Avicenna Alliance Board towards an efficient and effective activity to better advocate for the regulation and deployment of in silico methods.
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