## **Guidelines for Credible Practice of Modeling and Simulation in Healthcare**

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The role of computational modeling and simulation (M&S) in healthcare research and practice continues to expand [1-2]. However, the full potential of M&S for facilitating scientific discovery and clinical care can only be realized when M&S workflows and end-products are credible. Nevertheless, there is a lack of broadly accepted standards and guidelines to promote credible practice of M&S among academia, industry, clinics and regulatory bodies [3-5]. To help fill this critical gap, the Committee on Credible Practice of Modeling & Simulation in Healthcare (the Committee) was established under the Interagency Modeling and Analysis Group (IMAG) and the Multiscale Modeling (MSM) Consortium [6]. Specifically, the Committee is charged with (1) developing and adapting guidelines and procedures for credible practice of M&S in healthcare, (2) cultivating consistent terminology, (3) demonstrating workflows for credible practice, and (4) promoting credible practice. This informational poster focuses primarily on the Committee's work to develop and adopt *Guidelines for Credible Practice of Modeling and Simulation in Healthcare*, accompanied by practical pointers for the MSM research community on implementing this guidance to establish M&S credibility.

Since its establishment in 2013, the Committee has drafted its perspectives regarding the essential elements of credible practice of M&S in healthcare; formally known as "The Ten Simple Rules of Credible Practice of M&S in Healthcare" (Table 1) [7]. After reaching a consensus within the Committee, we surveyed the

Rule 1 Define context clearly	Rule 6 Document adequately
Rule 2 Use appropriate data	Rule 7 Disseminate broadly
Rule 3 Evaluate within context	Rule 8 Get independent reviews
Rule 4 List limitations explicitly	Rule 9 Test competing implementations
Rule 5 Use version control	Rule 10 Conform to standards
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**Table 1:** The Committee's "Ten Simple Rules of Credible Practice of M&S in Healthcare" [7-9].

broader research community to ensure our approach for establishing *Guidelines for Credible Practice of Modeling and Simulation in Healthcare* took into account a balanced representation of the interests and perspectives of global stakeholders in simulation-based medicine. Although preliminary results suggest noticeable differences between the perspectives of the Committee and the global research community, both groups agree that the four rules highlighted in Table 1 are necessary for credible practice of M&S in healthcare [8-9]. Finally, the Committee's work has had an early impact in the field by informing the IMAG U01 funding program [10]. Looking to the future, it is likely that guidance provided by the Committee will evolve with the further penetration of M&S into healthcare. In doing so, the Committee is dedicated to work with the IMAG/MSM community to develop consistent terminology, illustrative workflows, and resources for promoting credible practice of modeling and simulation in healthcare.

## **References:**

- [1] Grace C. Peng, "Editorial: What biomedical engineers can do to impact multiscale modeling". *IEEE Trans. Biomed. Eng.*, 58:3440-2, 2011.
- [2] U.S. Food and Drug Administration, Advancing Regulatory Science at FDA, A Strategic Plan, August 2011.
- [3] J.A. Kopec et al., "Validation of population-based disease simulation models: a review of concepts and methods," *BMC Public Health*, Vol. 10, Issue 710, November 2010.
- [4] D. Waltemath et al., "Reproducible computational biology experiments with SED-ML The Simulation Experiment Description Markup Language," *BMC Syst. Biol.*, Vol. 5, Issue 198, December 2011.
- [5] Erdemir, A et al., "Considerations for Reporting Finite Element Analysis Studies in Biomechanics," J. Biomech., Vol. 45, pp. 625-33, 2012.
- [6] L. Mulugeta and A. Erdemir, "Committee on credible practice of modeling & simulation in healthcare", ASME 2013 Frontiers in Medical Devices, Washington, DC, 2013, 10.1115/FMD2013-16080.
- [7] A. Erdemir, et al., "Ten 'not so simple' rules of credible practice of modeling and simulation in healthcare: A multidisciplinary committee perspective", 2015 Frontiers in Medical Devices, Washington, DC, 2015.
- [8] L. Mulugeta et al., Developing Credible Practice Guidelines for Modeling and Simulation in Healthcare: A Multifaceted Approach, 38<sup>th</sup> Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 16-20 August 2016, Orlando, FL.
- [9] T.M. Morrison, et al., "Credible Practice of Modeling and Simulation in Healthcare", Virtual Physiological Human Conference 2016, 26-28 September 2016, Amsterdam, Netherlands.
- [10] Predictive Multiscale Models for Biomedical, Biological, Behavioral, Environmental and Clinical Research, PAR-15-085 (NIH U01), <u>http://grants.nih.gov/grants/guide/pa-files/PAR-15-085.html</u>, May 22, 2016

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