The Potential Impact of Physiological Computer Models in Medicine: Considerations for Ensuring Patient Safety
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Computational modeling has the potential to accelerate the ongoing revolution in healthcare underway attributable to personalized medicine and information technology. Many potentially clinically useful computer models are based on the underlying mechanisms of human physiology, such models have unique benefits but also present unique challenges. The impact of these benefits are numerous and span the entire medical product life-cycle from design to clinical outcomes as well as regulatory evaluation. The challenges are also numerous and include establishing trust, obtaining useful data, incorporating patient variability (if necessary) as well as ensuring models are validated and their use doesn’t endanger patients. The field of verification, validation, and uncertainty quantification (VVUQ) has been enormously successful in the physics and engineering communities and is starting to be applied to mechanistic models and successes and challenges have been recently identified for complex cardiac electrophysiological models. Unique challenges exist for clinical applications and will be discussed along with ongoing efforts to address these challenges for specific applications including considering the associated risks to patients.

Richard Gray, PhD:

Richard A. Gray, PhD is one of the world’s leading experts on the mechanisms of cardiac fibrillation and defibrillation. Along with Dr. Jalife, he pioneered the technique of whole heart optical mapping which catalyzed the study of cardiac arrhythmias. Dr. Gray published the first optimal mapping studies on atrial fibrillation, ventricular fibrillation, atrial defibrillation, and ventricular defibrillation. In addition, Dr. Gray introduced “cardiac phase mapping” that has revolutionized the study and analysis of reentry and fibrillation, and is now entering clinical practice in cardiac electrophysiology labs in hospitals around the world. After an illustrious academic career, including serving as Director of the Biomedical Engineering Graduate Program at the University of Alabama at Birmingham (UAB), he joined the Food and Drug Administration (FDA) in 2008 where he currently leads the Computer Modeling Lab in the Office of Science and Engineering Laboratories in the Center for Devices and Radiological Health. His current research efforts include studying the mechanisms of cardiac electrophysiological medical devices and pioneering methods for verification, validation, and uncertainty quantification for complex computer physiological models with Dr. Pathmanathan (FDA). His full curriculum vitae includes over 150 peer-reviewed publications, 35 invited presentations, Principal Investigator on 7 Grants (including 2 NIH, and 2 NSF), as well as numerous awards, positions and significant intra- and extramural service.