**Connected Health** is realized by integrating technology to support and provide healthcare remotely, and our Connected Health Environment is rapidly changing and complex. The industry is challenged to become more connected, effective, and accessible, and always to maximize healthcare resources.

The Internet of Things, Healthcare Internet of Things, Internet of Medical Things and the like are expanding rapidly, only to be eclipsed by the volume of information generated, and potential barriers of security, interoperability, and scalability are at the forefront. Regardless of the platform design and technology used, e.g., mobile apps, wireless communication, wearable personal health/medical devices, the cloud, or big data analytics, health enterprises, leaders, and consumers want and expect to implement strategies, products, systems, and tools that support clinical decisions and the healthcare delivery systems. Patients and consumers alike need to be well-informed. They want to be involved and empowered in their own healthcare.

Can we help create an environment in which clinicians, EHR/EMR systems, and devices can seamlessly send and receive accurate, secure information while maintaining privacy? Can health data be shared with minimal extra effort and worry, and will 2016 be a turning point?

The goal of this workshop is to bring together professionals to discuss their perspectives on gaps and barriers to the adoption and diffusion of this rapidly changing Connected Health landscape, and the role of standards for solutions in facilitating health information interoperability and portability.

**Location and Time**

<table>
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<tr>
<th><strong>Hyatt Arlington</strong></th>
<th><strong>Date:</strong> Wednesday June 29, 2016</th>
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<tbody>
<tr>
<td>1325 Wilson Blvd</td>
<td><strong>Time:</strong> 1:30 – 3:00 pm</td>
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<tr>
<td>Arlington, VA 22209</td>
<td><strong>Room:</strong> TBD</td>
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</tbody>
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Session Chair

Carole Carey is IEEE EMBS (Engineering in Medicine and Biology Society) Liaison to IEEE-SA, EMB Standards Committee Chair and the Life Sciences Technical Community Standards Committee. She is also a member of the EMB Technical Committee on Translational Engineering on Healthcare Innovation, and IEEE Future Directions: the Big Data Initiative, the Brain Initiative and the Digital Senses Initiative. She has over 23 years of regulatory science experience as a former Scientific Reviewer in the Office of Device Evaluation Division of Cardiovascular Devices, and as International Advisor and Director of International Staff at U.S. FDA Center for Devices and Radiological Health.

Carole C. Carey

In her role as Center liaison, she participated in standards development at the national and international levels. She earned her B.S.EE/M.Eng from Johns Hopkins University and Loyola University of Maryland respectively, served as a Mansfield Fellow in the Government of Japan’s Ministry of Health, Labour and Welfare (MHLW) and Japan’s Pharmaceutical and Medical Devices Agency (PMDA), and is currently a senior regulatory consultant.

Session Co-Chair

CAPT Hung Trinh, UHPHS, is currently serving as the Chief Engineer for the DoD/VA Interagency Program Office (IPO) and previously DoD technical lead for the Electronic Health Records data sharing effort at the James A. Lovell Federal Health Care Center in North Chicago. While at the Department of Health and Human Services (HHS), he worked in the Office of the Assistance Secretary for Preparedness and Response (ASPR), where he was responsible for standing up the biomedical program in support of the Emergency Support Function (ESF) #8 response. He was also the acting Program Manager for the Healthcare and Public Health Critical Infrastructure Protection (CIP) Program; his role has included the coordination and collaboration between public and private stakeholders in the healthcare and public health arena to enhance resiliency of the sector. CAPT Trinh also served in the Food and Drug Administration (FDA) Commissioners’ Office and at the Center for Devices and Radiological Health.
Panelists and Presentations

William Riley, Ph.D., currently serves as the National Institutes of Health’s Director of the Office of Behavioral and Social Sciences Research (OBSSR). Before his current NIH appointment, he served as a Health Scientist Administrator and Deputy Director in the Division of AIDS and Health Behavior Research at the National Institute of Mental Health (NIMH), a Program Director at the National Heart, Lung, and Blood Institute (NHLBI), and Chief of the Science of Research and Technology Branch (SRTB) in the Division of Cancer Control and Population Sciences (DCCPS) at the National Cancer Institute (NCI). He also serves as a Professorial Lecturer in the School of Public Health at George Washington University. Dr. Riley completed his Bachelor of Science degree in Psychology and Sociology from James Madison University and his Master of Science and Doctorate in Clinical Psychology from Florida State University.

Paolo Bonato, Ph.D., serves as Director of the Motion Analysis Laboratory at Spaulding Rehabilitation Hospital, Boston MA. He is an Associate Professor in the Department of Physical Medicine and Rehabilitation, Harvard Medical School, and an Adjunct Professor of Biomedical Engineering at the MGH Institute of Health Professions, Harvard Medical School. Dr. Bonato is a Member of the Advisory Board for the IEEE Journal of Biomedical and Health Informatics and Associate Editor of the IEEE Journal of Translational Engineering in Health and Medicine. He was the Founding Editor-in-Chief of the Journal of NeuroEngineering and Rehabilitation and currently serves as IEEE Engineering in Medicine and Biology Society (EMBS) Vice-President for Publications since 2013. He received an M.S. degree in electrical engineering from Politecnico di Torino, Turin, Italy in 1989 and a Ph.D. degree in biomedical engineering from Universita’ di Roma “La Sapienza” in 1995.
Kathy Grise is IEEE Staff as Senior Program Director, Future Directions, IEEE Technical Activities. She works directly with IEEE volunteers and consultants in support of new initiatives such as IEEE Cloud Computing Initiative, Big Data Initiative, Green ICT Initiative, and the IEEE Technology Navigator. She previously served as Engineering Development Manager and Technical Resource Program Manager for the IBM Corporation’s Systems and Technology Group, where she set strategy and direction for key initiatives to promote the vitality of the technical community. In addition to business group level coverage, she provided detailed coverage to all organizations under several senior executives, and served as co-lead of worldwide team.

John Zaleski, Ph.D., CAP, CPHIMS is Chief Informatics Officer for Bernoulli Enterprise, a leader in real-time data integration and enterprise patient safety surveillance. He has seven awarded US Patents and has published three books on medical device integration and analytics: Integrating Device Data into the Electronic Medical Record, Medical Device Data and Modeling for Clinical Decision Making, and Connected Medical Devices: Integrating Patient Care Data in Healthcare Systems. He is a contributing author to the Dictionary of Computer Science, Engineering and Technology by CRC Press, and has authored over 50 published journal articles, conference symposia presentations and continuing medical education training sessions. John has 30 years of professional experience, has led IRB-approved clinical trials and the development of three clinical product lines, achieving Class II FDA approval. Dr. Zaleski is a certified analytics professional and is President of the Philadelphia Chapter of INFORMS, is a Senior Member of IEEE, and a member of AMIA and of HIMSS. He received his Doctorate in Systems Engineering from University of Pennsylvania and BS, MS, Aerospace Engineering from Boston University.
Karson Mahler is Senior Policy Advisor for the Office of the National Coordinator for Health Information Technology, where he advises the National Coordinator on legal, regulatory, and economic issues involving technology, healthcare, and advancements in digital health. He also leads the development and coordination of federal policy and regulatory initiatives in areas including competition, consumer protection, and safety and oversight of health IT. Previously, Mr. Mahler served as an attorney in the Health Care Division of the Federal Trade Commission (FTC), where he investigated and litigated a variety of healthcare antitrust matters, analyzed healthcare mergers and collaborations, and conducted research and advocacy on competition issues in the healthcare and health IT industries. Mr. Mahler is an active member of the State Bar of Georgia and the American Health Lawyers Association. He received his J.D. from Emory University School of Law and holds a B.S. in Mathematics from the University of Georgia.

Bakul Patel is Associate Director for Digital Health at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software. Mr. Patel is also the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) “software as a medical device” working group, a global harmonization effort. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.